Comprehensive Healthcare Simulation
Series Editors: Adam I. Levine · Samuel DeMaria Jr.

Dimitrios Stefanidis
James R. Korndorffer Jr.
Robert Sweet *Editors*

Comprehensive Healthcare Simulation: Surgery and Surgical Subspecialties

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To our wives Evie, Melanie, and Ania for all their support throughout our careers and patience while editing this book.

Foreword

It has now been over 25 years ago since, as a young program director, I was approached by the Chief of Urology who complained that his residents were receiving poor basic surgical skills training during their general surgery internship under my direction. This encounter, along with other observations, convinced me that surgical training needed a fresh new approach to instruction in basic surgical skills. Few resources were available at that time to guide a young program director. Now 25 years later, a clerkship director, program director, or other leader in surgical education can find a wealth of outstanding information and guidance in this Surgery and Surgical Subspecialties Edition of *Comprehensive Healthcare Simulation*. The editors, Drs. Stefanidis, Korndorffer, and Sweet, are acknowledged leaders in the field of healthcare simulation and have accumulated a Who's Who list of authors that provide the best expertise available in their respective fields. This edition includes guidance for every step in the process of designing a new surgical skills program or reorganizing a long-standing program, including valuable information in the increasingly important area of simulation for nontechnical skills. Cross-fertilization and peer learning are certain to develop as a result of the comprehensive review of the current state of simulation for the subspecialties of surgery. This textbook should find a home in the library of every surgical educator.

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Preface

The application of simulation in surgery has seen tremendous growth in the past couple of decades. Our field has transitioned from the stage of justification for the use of simulation in surgery to broad implementation of simulators and skills curricula in many aspects of surgical training and education. Today, most educators and administrators recognize the value of using simulation-based curricula to prepare learners for the demanding environment of the clinic, wards, and operating room. Simulation-based training and assessment have become a part of our training culture. In addition, surgical applications of simulation have disseminated broadly across the surgical disciplines and levels of learners.

Still, several questions exist on how to optimally use simulation-based curricula to maximize the benefit to learners and the institutions they serve across the lifelong learning continuum that defines a surgical career.

We, therefore, present to you this book: *Comprehensive Healthcare Simulation: Surgery and Surgical Subspecialties.*

The book is part of *The Comprehensive Textbook of Healthcare Simulation* series and targets those who are involved in the training or assessment of surgeons and their teams using simulators and simulations. It aims to provide the reader with the best available evidence and methods for effective training and assessment using simulators in surgery. Our goal was to generate pragmatic chapters that will provide readers with information easy to adopt and replicate and/or tailor for their respective environment.

We are proud to present to you an international author list comprised of well-known experts and scholars offering their insight and guidance of best simulation practices in their discipline. Unique to this book is its focus on each surgical subspecialty where simulation is used.

Our book is comprised of five parts: Part I, Introduction to Surgical Simulation; Part II, Procedural Simulation; Part III, Simulation for Nontechnical Skills; Part IV, Subspecialties of Surgery: State of the Art; and Part V, Conclusion. In the first part, we start with a historical perspective (Chap. 1) and overview of simulation use in surgery (Chap. 2). We then propose a taxonomy for surgical simulation that aims to clarify some terms that cause confusion in the field (Chap. 3) and discuss principles of validity (Chap. 4). The latter chapter, written by one of the editors, provides the most up-to-date definitions around simulator validity and validation, a much needed reference for this often misunderstood concept in surgical simulation. Chapters 5 and 6 explore the necessary resources and funding models for effectively running your surgical simulation center.

Part II addresses important constructs around procedural simulation, the most common type of simulation used in surgery. The first chapter (Chap. 7) in this part addresses the role of simulation for outcome-based training exploring the concepts of competency/proficiency/mastery training. Best practices for skill maintenance, remediation, and reentry, performance assessment, and optimization are addressed in Chaps. 8, 9, and 10, respectively. This part concludes with the use of simulation for purposes of certification and high-stakes assessments (Chap. 11).

Part III addresses the application of simulation for nontechnical skills training in surgery. It provides best practices for debriefing (Chap. 12), team training in the operating room (Chap. 13), and applications of human factors in surgery (Chap. 14).

Part IV comprises the largest component of this book and addresses the use of simulation in multiple surgical subspecialties, including general surgery, laparoscopic surgery, robotic surgery, surgical endoscopy, surgical oncology and HPB surgery, bariatric surgery, critical care, cardiothoracic surgery, otolaryngology, urology, ophthalmology, vascular surgery, transplant surgery, plastic surgery, orthopedic surgery, and obstetrics and gynecology (Chaps. 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, and 30). These chapters present the state of the art of simulation in each subspecialty and provide best practices and future directions.

Finally, the last part that concludes this book is written by simulation visionary Dr. Richard Satava (Chap. 31) who provides the reader with his thoughts on the future of surgical simulation.

We believe that those who utilize and reference this book will obtain a great overview of how simulation is applied across surgical subspecialties and identify best practices in each discipline. Importantly, our hope is that this book will lead to cross-pollination of best practices among subspecialties, ultimately benefiting the learners and the patients they serve.

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The editors wish to thank Dr. Adam I. Levine, editor of the original book *The Comprehensive Textbook of Healthcare Simulation*, who contacted and encouraged us to create this book and introduced us to the publisher. We also want to thank Victoria Dodge who assisted with the editing of this book and Maureen Alexander, the Developmental Editor of Springer, who effectively guided us throughout the development of the book you have in your hands.

Contents

Part I Introduction to Surgical Simulation

Part II Procedural Simulation

Part III Simulation for Non-technical Skills

Part IV Subspecialties of Surgery – State of the Art

Part V Conclusion

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Part I

Introduction to Surgical Simulation

Historical Perspective

David Marko Hananel

Preamble

Although for some of us looking back at the last few decades of surgical simulation is a sentimental journey, we must review it as a basis of what is to come. If we look at surgical simulation as an emerging new industry, we can now identify the significance of key technologies and events that have shaped this industry to date.

Although ancient texts, such as the *Sushruta Samhita* from India, written in Sanskrit around 500 CE (origin date unknown but thought to go back to 1000 BCE), mention the use of various models to practice surgical skills for speed and accuracy, we will focus on the recent history of medical simulation and shifts in surgical education [1]. Surgical residency as we know it today in the USA began in the early 1900s at Johns Hopkins under the guidance of William Halsted. During those formative years, we have evidence that dog labs were used to teach both procedural and team-based skills. The animals were used in a similar manner to how patient simulators are used today.

If we consider an integrative model of surgical education and training, focused on patient management we need to consider at least technical skills simulators and human patient simulators. From a historic perspective, how they eventually met to result in a comprehensive model of simulation is just as interesting as how each came to be and evolved over the last 20 plus years.

To those of us who were present at the inception of this industry, this summary may seem like a trip down memory lane, but what is important for the next generation of clinical educators and developers is to be aware of the work that preceded them and build upon it, rather than start over. While researching this chapter, it became evident that it is increasingly more difficult to find pictures, descriptions, and references to work that this industry is built upon.

This chapter is structured to look at technologies that were enablers and then key events and players that followed and cleared the path to arrive at today.

Building Blocks: Virtual Reality

Like any complex product, the birth of healthcare simulation had to wait for many enabling technologies to evolve until they met a creative spark or transformational event to come to life. Although the medical simulation community is relatively small, it has evolved to a cast of thousands made up of practitioners, educators, technologists, and funders, which can be validated by looking at the growth of communities like American College of Surgeons-Accredited Education Institutes (ACS-AEI) and the Society for Simulation in Healthcare (SSH).

Simulation as a tool to acquire skills has been used in many other industries where the same basic training challenges in the real world exist:

- The cost of experimentation is too high.
- The consequences of experimentation are not acceptable.
- The complexity of what we are studying requires multiple trials and varied approaches.

Thus, we have seen simulation as a core component in training for the nuclear industry, aviation, and of course the military. Medicine presents several challenges that needed to be overcome:

- What we interact with is not a cockpit, dashboard, or control panel designed by us and is well characterized but a patient; thus we need to have an accurate representation of a patient.

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- Unlike machinery which we design and understand by design, we have an infinite number of variations of what a patient is, and our understanding of the human body keeps evolving rapidly.
- We have almost as many different interventions that can be performed on a given patient, with yet many more devices that can be used during those interventions.

The early attempts at simulation based training simplified things by using either animal models or cadavers as the platform to practice on before advancing to patient care, forgoing the challenge of creating an adequate representation of a living patient. Eventually, a set of emerging technologies matured enough around the same time to create the notion of a virtual patient. What initially sparked the imagination of surgical educators was the potential to objectively assess the performance of the surgeon in a simulated environment, which favored virtual reality. As the simulation would take place in the digital domain, supported by mathematical models based on physics, we could track, measure, and quantify everything that would take place in the simulation. It brought together multiple core technologies:

- Real-time interactive graphic simulation, based on finite element modeling concepts, rendering and texturing using powerful graphic processing units (GPU)
- Improved computer displays with higher resolution and color
- Haptic devices to touch objects (collision detection) that exist only as digital representations and eventually manipulate and reshape them (deformation and cutting)

Let’s consider each one of these technologies: The early GPUs were not single processors or cards but a computing system with a series of boards and large amounts of memory in cabinets the size of refrigerators, such as those designed, built and sold by Evans & Sutherland in the early 1970s, based on work done at the University of Utah. The early computer screens used for simulation were monochrome vector graphic displays, basically displaying a flickering green line drawing of the objects of interest (Fig. 1).

These early image generators were driven by minicomputers that could fill a room and had to run the mathematical models or what we would consider state engines today that then the image generators could render on a screen (Fig. 2).

It took another 20 years for Silicon Graphics Inc. (SGI) (https://en.wikipedia.org/wiki/Silicon_Graphics) to combine those capabilities into smaller packages, based on technology developed at Stanford, and commercialize the technology. Their products dominated the world of computer graphics, animations, and simulation for most of the 1980s and early 1990s. Many of us remember the small refrigerator-sized purple boxes.

Fig. 1 Evans & Sutherland graphics displays. (Image courtesy of Evans & Sutherland, Salt Lake City, UT. All rights reserved. Used by permission)

Fig. 2 Early simulation platform. (Image courtesy of Evans & Sutherland, Salt Lake City, UT. All rights reserved. Used by permission)

Rapid evolution of computing technologies created another major shift, and in 1993 Nvidia (https://en.

wikipedia.org/wiki/Nvidia) created one of the first graphics card, building a complete graphics engine on a single board and then eventually on a chip to bring graphic simulation to off-the-shelf personal computers, completing the journey as we know it today in roughly 20 years and seeing the demise of two generations of graphics computing software and hardware.

Returning to the history of surgical simulation, some early designs were built upon the SGI platform but saw no commercial acceptance until they could be ported to the PC architecture. They were complex to maintain, expensive to acquire, and not very reliable.

The second challenge was the development of better ways to visualize the virtual environment. The earliest surgical simulators still used CRTs (cathode ray tubes) which were bulky and heavy and difficult to place correctly to recreate the proper relationship between the patient, instruments, and surgeon. Going back to the days of Evans & Sutherland (https://en.wikipedia.org/wiki/Evans_%26_Sutherland), they started with monochrome vector graphics monitors that needed at least two people to carry them. Over a few years, they evolved to support multiple colors for the lines representing the objects of interest at a significant premium. Today's LCD panels and 4k displays provide us with acceptable images and based on the targeted application, developers can now consider affordable head-mounted displays and other novel technologies to render the surgical field.

The third challenge that needed to be addressed was the interaction with the patient. The path of least resistance was the emerging field of minimally invasive or laparoscopic surgery: it made the interaction with the patient much more controlled (only 6 degrees of freedom to track per hand) than approaching open surgery with many more degrees of freedom of tracking two hands and ten fingers with almost no limitations.

Two competing approaches framed the initial field. One emerged from work done at MIT in the 1990s by industry pioneers Thomas Massie and Dr. Kenneth Salisbury, to become Sensable, now owned by 3D Systems (https://www.3dsystems.com/scanners-haptics#haptics-devices).

The second approach came out of research done in the 1990s at Stanford by Louis Rosenberg, who founded Immersion Corporation (https://en.wikipedia.org/wiki/Immersion_Corporation), to commercialize his ideas. Both groups used similar components but different kinematic models to accomplish their goal of allowing us to feel and interact with virtual objects. Since then several more competing technologies were created, with varying approaches to the volume we can work in, degrees of freedom, accuracy, and obtrusiveness of the haptic mechanism.

These early technologies enabled several interesting surgical simulators to be directly built upon them: a sinus surgery simulator (Fig. 3) developed jointly between the military (Madigan), academia (UW), and industry (Lockheed Martin) with funding from TATRC [2–4], a vascular anastomosis simulator (Fig. 4) [5, 6] developed by Boston Dynamics with support from DARPA, and an arthroscopy simulator for shoulder procedures (Fig. 5) [7, 8] developed by Prosolvia and University Hospital in Linköping, Sweden, with support from the Swedish government.

What these three examples have in common is that they each demonstrate the challenges of developing an advanced VR surgical simulator, complex hardware for haptic feedback, powerful computers, and graphics cards to keep up with the model calculations and image rendering, yet the end users were not satisfied that the use of these systems could improve surgical performance significantly. The numerous studies performed around these systems, however, pointed the way for future developers and commercial offerings.

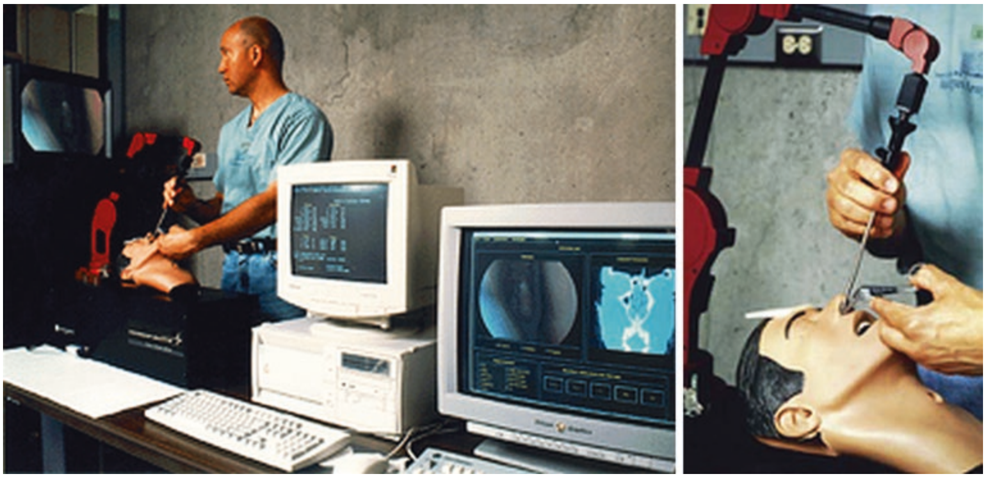

Fig. 3 Sinus surgery simulator ca. 1995 University of Washington. (Courtesy of Mika N. Sinanan, MD)

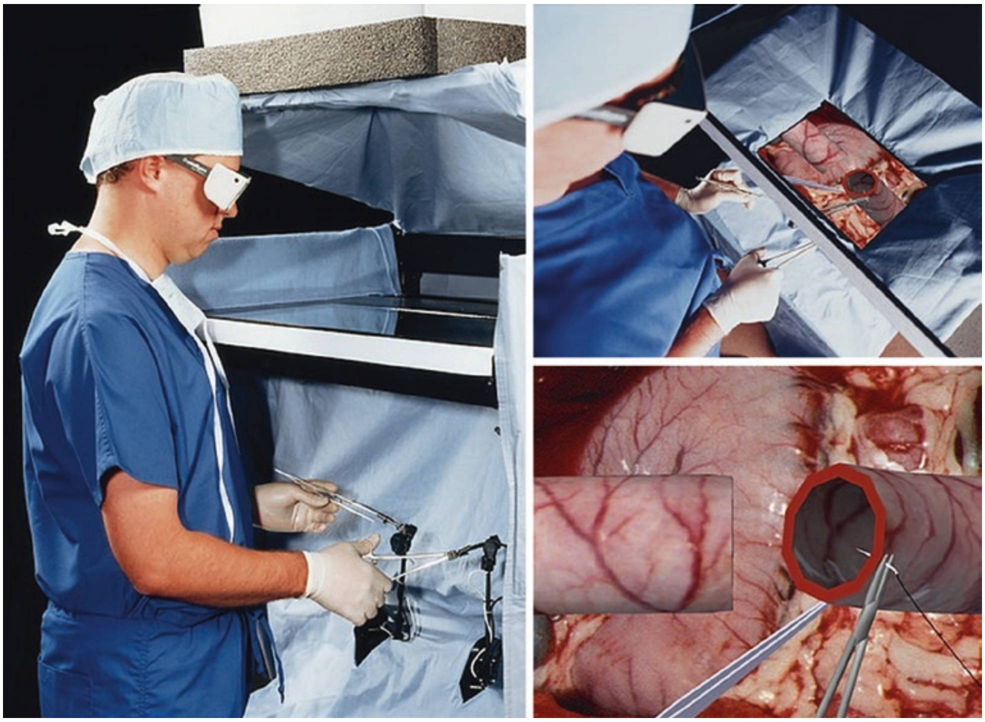

Fig. 4 Anastomosis simulator ca. 1998 Boston Dynamics. (Used with permission of Boston Dynamics)

Fig. 5 Shoulder arthroscopy simulator ca. 1997 Prosolvia

Building Blocks: Human Patient Simulation

Many of us that were focused on surgical education stayed focused on technical skills acquisition, first basic skills then targeting full procedures. In parallel the field of anesthesia was working on developing their own simulation platforms: full patient mannequins with a physiology engine behind them to teach both physiology and patient management. Although some early work resulted in Harvey that included select aspects of physiology, almost in parallel the University of Florida in Gainesville under Samsun Lampotang, PhD, and Dr. Michael Good [9, 10] and Stanford in California under Dr. David Gaba [11] developed their own versions of a full patient simulator.

Both eventually were commercialized and were used by many healthcare educators before newer generations were developed. Figures 6 and 7 show the CASE 0.5 or the comprehensive anesthesia simulation environment from Dr. Gaba and Stanford. This was the first (used once only – in May of 1986) pre-prototype proof of concept simulator which was put together from some existing devices (e.g., a commercially available noninvasive blood pressure simulator), some components adapted from existing items and some purposely built. Of note in Fig. 6 a COMPAQ portable computer can be seen to the right of Dr. Gaba, a precursor to todays laptops for those that remember the sewing machine sized “portable” computers.

For the patient simulators to become reality, the key enablers were the creation of mathematical models of human physiology (added by the Gaba team in 1991 to CASE 2.0) and the interaction of drugs. Based on those models, one can mathematically solve a complex set of interconnected equations to approximately predict patient progression [10, 12, 13]. Lessons learned from both commercial implementations were invaluable and carry forward to today’s products, specifically the University of Florida design continues to live in the line of patient simulators offered by CAE of Montreal, Canada.

In addition, the fields of cognitive psychology, human factors, and education had to develop models for team-based performance, decision-making under stress, and assessing

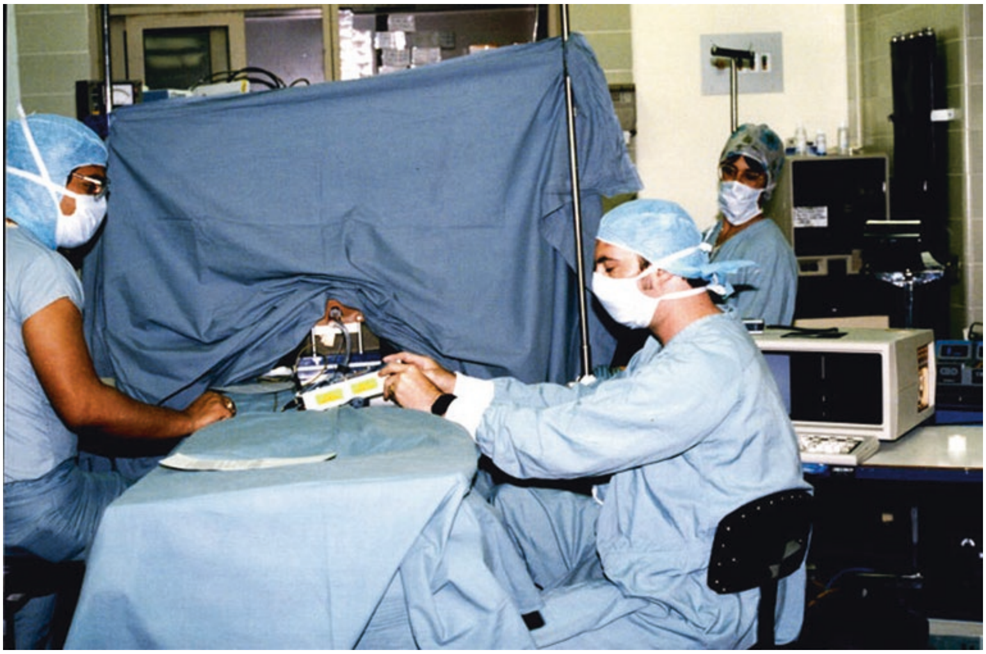

Fig. 6 CASE 0.5 or the comprehensive anesthesia simulation environment. (Photo credit: David Gaba)

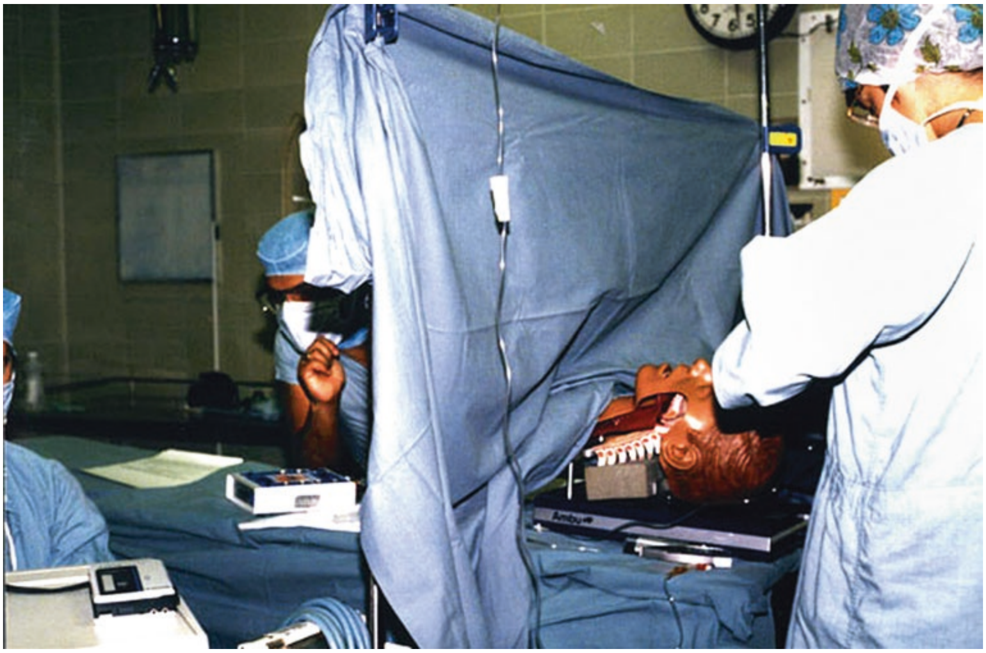

Fig. 7 CASE 0.5 or the comprehensive anesthesia simulation environment. (Photo credit: David Gaba)

human performance under these conditions to enable team-based training exercises [14].

Connecting the Dots

A few thought leaders had started to bring the surgical and anesthesia sides together in some of the earliest attempts at team-based training, Penn State University in Hershey under Drs. Thomas Krummel and Bosseau Murray as well as at the University of New Mexico under Dr. David Wilks in Albuquerque being among them. It is important to note that from the very beginning, both these programs worked with the medical school, nursing programs, and the hospital looking for an integrated model to training. However, it took many years for the patient simulators to receive a hearing within the world of surgery.

The first formal appearance of a patient simulator in the world of surgery was at the SAGES Annual Meeting on April 27, 2006, supported by grant W81XWH-06-1-0529 from the US Army Medical Research and Materiel Command (USAMRMC) led by Drs. Satava and Haluck and presented/

demonstrated by Dr. Wilks using a METI Human Patient Simulator or HPS. The patient simulation discussion was triggered looking for a hands-on approach to teach basic anesthesia considerations to surgical residents as covered in a chapter of the *SAGES Manual Basic Laparoscopy and Endoscopy*. A few years later, in the Spring of 2009, Dr. Seymour took a METI Human Patient Simulator to the ABS in Philadelphia with Drs. Lewis, Bell, and Buyske in attendance to demonstrate the concept of a physiology-driven patient simulator and discuss what a surgical version of it would have to be able to do.

Clearly by this time, the concept of simulation in support of improved surgical training had started to gain acceptance as could be seen by the growing number of research articles with the professional journals. The time had come to establish the scientific and professional underpinnings for this new domain.

First Meeting of the Elders

Dr. Satava had almost single handedly jump-started the notion of using Virtual Reality (VR) based surgical technical skills training [15, 16], and over a few years had moved the needle from let's build it and they will come to let's obtain validity evidence and they will come. He organized a meeting on July 9–10, 2001, named the "Metrics for Objective Assessment of Surgical Skills Workshop" with subject matter experts in objective assessment of surgical technical skills and representatives of relevant official bodies involved in surgical education, evaluation, and certification to create a consensus around appropriate metrics that all could use [17].

The workshop identified the challenges and demonstrated the need to move toward standards in performance metrics so that training effectiveness could be compared across competing design and technologies for the same skill sets [18]. The results of that workshop were published and shared with both industry and academia and were funded by USAMRMC under award DAMD17–02–1-0207.

Second Meeting of the Elders

Almost concurrently, Dr. Carlos Pellegrini, a pioneer in laparoscopic surgery [19, 20], was questioning the prevalent model of surgical education in light of the rapidly evolving new surgical technologies and interventions and looking for ways to adapt to the changing landscape.

Not even a year later, in June of 2002, the American Surgical Association (ASA) Council in partnership with the American College of Surgeons (ACS), the American Board of Surgery (ABS), and the Residency Review Committee for Surgery (RRC-S) established a Blue Ribbon Committee on Surgical Education based on the ASA Presidential Address by Dr. Debas earlier that year [21]. Their principal concerns were lower numbers of applicants into surgical residency programs and challenges of acquiring laparoscopic surgical skills (interview with Dr. Pellegrini, May 9, 2017). They were charged "with examining the multitude of forces impacting health care and making recommendations regarding the changes needed in surgical education to enhance the training of surgeons to serve all the surgical needs of the nation, and to keep training and research in surgery at the cutting edge in the 21st Century."

Their analysis, resulting report, and recommendations that were published in 2005 have led to many observable changes in surgical education [22]. Among them was the creation of the Surgical Council on Resident Education (SCORE), "a nonprofit consortium formed in 2006 by the principal organizations involved in U.S. surgical education. SCORE's mission is to improve the education of residents in general surgery and related specialties through the development of a national curriculum."

At the same time, with the arrival of Dr. Pellegrini as a regent at the ACS and Dr. Ajit Sachdeva's leadership of the Education Division, the path was laid in 2005 to launch the ACS Accredited Education Institutes (ACS-AEI) to "educate and train practicing surgeons, surgical residents, medical students, and members of the surgical team using simulation-based education." This partnership laid the groundwork to truly bring together the principles of adult education and educational design with the rapidly changing requirements of lifelong learning for our surgeons.

Slow Growth

Despite the enthusiasm of medical educators, gradual acceptance by the professional societies, publication of many hundred peer-reviewed journal articles, and over a hundred of industry participants with commercial simulators at all price points, the adoption of simulation-based surgical education has been a slow process. Ten or so years ago, we could look at a technology adoption curve, survey programs that had invested in simulators, and clearly recognize the early adopters and the followers and relate that back to individuals. Today that is not possible as almost every residency program has some type of simulation-based training activity that they participate in. In fact simulation is an integral part of the ACGME surgical residency program requirements.

The last few decades have seen surgical educators and simulation technologists with an interest in surgical simulation move from the Medicine Meets Virtual Reality (MMVR) conference, first held in 1992 and driven by futurist, visionaries, innovators, and early adopters to the Society for Simulation in Healthcare (SSH) established in 2004 with membership from physicians, nurses, allied health and paramedical personnel, researchers, educators, and developers from around the globe to finally the ACS-AEI that launched in 2005 with the now (2017) aptly named Annual ACS Surgical Simulation Conference. That clearly demonstrates the readiness of this community to broadly embrace simulation.

At this point we can only hypothesize why growth has been this slow. With so many companies active in this field, from small to large, to subsidiaries of industrial giants, both market size and profitability have been only a fraction of the early forecasts. We have been predicting the inflection point as far back as we can remember, citing various key events, such as those mentioned earlier. We first looked for validation studies and then better technology to lower cost and improved fidelity, as well as acceptance by the professional societies.

There are some aspects that are clear: on the surgical simulation side, although VR simulation has been quite successful from the beginning to train basic skills [23–25], it has not reached the level of sophistication required to train complex surgical procedures, except in some special cases, such as endoscopy, endovascular procedures [26, 27], TURP [28], and laser-based prostate procedures [29]. What these have in common is they are being performed in narrow, tubular structures with minimal, controlled deformations and simple images to render. VR simulators are also quite expensive and time-consuming to develop.

In response, we have seen a return to physical trainers, but now bringing the promise of objective assessments from the VR world by adding sensors and markers of many types into the physical models. Furthermore, long-term research projects underway are collecting tissue properties data to develop more realistic synthetic tissues for such models.

The Catalyst

Viewed from an economics perspective, any industry that lacks standards is not mature and would not attract large investments as both direction and timing are unknown. Although the years since the second meeting of the elders have seen the introduction of many new products and some companies becoming profitable, in many ways the expectations outpaced development.

Several years back during a discussion with Dr. Richard Reznick in Toronto, he articulated a vision for a full-patient simulator sophisticated enough so that residents theoretically could be able to train their first 2 years without having to treat real patients. His description of needs was very similar to those articulated during the demonstration of the human patient simulator at the ABS. While the technology to get there was probably available, the effort to develop such a platform would require a government agency with vision and a long-term budget of hundreds of million dollars.

The last few years have seen a group of forward thinkers within the DoD developing a long-term vision and funding strategy to change that. This group that cuts across many agencies brings together the healthcare providers, the educators, and scientists. They brought two key elements together: a road map based on experience and a deep understanding of the educational process together with funding opportunities attached to open source, standards based tools, and no associated royalties to create the fundamental building blocks that all simulators could share and thereby also exchange information with each other. The funding opportunities stipulate that the results should not only address the need of the military but also of the civilian side. It seems that our community has now been given this opportunity and of course the associated challenges and is looking at the future of medical education.

It is a vision for distributed, interoperable part-task trainers developed and sold by many different companies that can be combined into a full body patient simulator that brings together decision-making, technical skills, and team-based performance training. It allows for objective assessment and focuses on patient management so that the learners can expand from technical skills to managing a complete medical episode from first encounter with a caregiver until they can return to normal life. The Advanced Modular Manikin™ (AMM™) project (DOD Award # W81XWH-14-C-0101) now in its second phase and being led by the CREST team (Center for Research in Education and Simulation Technologies at the University of Washington) at its core is developing a unified platform to bring researchers, developers, and industry together with guidance from the professional societies and diverse user groups to accelerate the path forward and reduce the initial investment required to create new surgical simulators.

Having a common platform with open standards will allow developers to target specific interventions, training scenarios, or diseases and create specific models without having to build out the complete infrastructure required each time. The common, core building blocks will be published and made available to all interested parties. Having the common platform will allow many individual trainers to connect and exchange data. To accomplish that, the project will also define what it means to be AMM Compliant™ and the process for that claim to be verified. The funders are already looking for means to support the maintenance and growth of the standards and a certification process to assure interoperability. As part of the AMM project, CREST has created a website to disseminate information on the draft standards, reference systems, and developer guides (https://www.advancedmodularmanikin.com).

A second core project is the development of a modular, open-source physiology engine that started somewhat earlier and is now available online. As stated on their website, “BioGears is an open source, comprehensive, extensible human physiology engine released under the Apache 2.0 license that will drive medical education, research, and training technologies. BioGears enables accurate and consistent physiology simulation across the medical community. The engine can be used as a standalone application or integrated with simulators, sensor interfaces, and models of all fidelities.” This program was also funded under the auspices of the DOD contract number: W81XWH-13-2-0068 and can be accessed through a web site (https://www.biogearsengine.com).

The Future

As we consider the many challenges presented by the development of an integrated training platform for surgery, it is interesting to see that the fields of surgical device development, surgical education, and new paradigms in patient care are moving closer together. This is happening at the level of identifying requirements in each of these domains, in the data models that need to be created and the development workflows themselves.

The first step in any robust simulator development program is the execution of a detailed cognitive task analysis (CTA) [30, 31] that details the critical steps, decisions, and skills required to perform the intervention to be learned. This same CTA can and should be also used in considering new tools and technologies to perform the intervention itself as it clearly identifies the most challenging parts of the intervention that could benefit from better tools.

The data models and standards we need to create, such as to document patient cases, assess performance, and evaluate outcomes, are the same ones that are being considered for electronic medical records (EMR), board exams, credentialing, predictive models of drug interactions, different population studies to understand societal costs of caring for patients, etc. We are still at a stage where different institutions, societies, and agencies have created similar but different, in many cases competing, constructs that make it very difficult to compare results, perform large-scale studies, and easily exchange findings. It is imperative that in the world of healthcare simulation, we move toward universal standards, such that educational content can be shared by all and performance metrics become comparable between sites. Also performance data of learners we collect during simulations need to converge with performance data that is collected in the patient care environment.

Thus, a core effort of developing the AMM platform is to define and vet the initial data models used to create simulated patients, to define findings and trigger events, to build a common model for learner performance assessment, and to document in the language of educators and providers. The next level is to create the data models that will be used for all modules to communicate at the technical level and support interoperability. Finally, the hierarchy of modules and the standard interfaces between them will be designed, tested, and made public.

A major task in creating these standards and the development platform is to share, vet, and update the various designs, make them available to all, and provide the documentation and training required to encourage broad-based adoption.

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Overview of Simulation in Surgery

Don J. Selzer

Simulation has long played a role in the acquisition of skills in healthcare [1]. Various modalities have been used to prepare the surgeon for the operating theater. Not surprisingly, some of the first simulation occurred with cadavers. However, preservation proved challenging. As a result, carved figures resembling human anatomy were used. Procedures were carried out in a manner similar to that performed in the operating theater of the day. As time passed, interest in realism exceeded that of the carved figures. More complex simulators were developed to recreate actual physiology. However, these rudimentary moveable models did not always appear outwardly consistent with human anatomy. For example, one of the earliest functional devices was an obstetric simulator that consisted of a glass uterus situated in a wooden pelvis with a flexible fetus [1]. Although over the years, multiple simulators were developed for multiple anatomic structures and medical disciplines, Abraham Flexner specifically singled out the importance of obstetric simulation in his landmark report in 1910 [2]. Over the years, detractors of the benefits of simulation have remained. William Osler is famously attributed to say that there is no better place to learn medicine than at the bedside.

The importance of simulation became more evident when the military and airline industry demonstrated the benefit of training pilots prior to actual flight [3]. Anesthesiology and surgical investigators began to evaluate the potential role of structured simulation and its impact on skill acquisition. As the research began to support the importance of simulation, options for training began to multiply. Further, as research began to support the importance of a protected environment in which a medical student or surgical resident can practice his or her skills, regulatory bodies began to expect these venues in medical schools and training programs (Fig. 1) [4]. The Association of American Medical Colleges has stressed the importance of simulation-based education and has invested in confirming its use within current curricula and ongoing curricular reform. Within surgery, there remains concern by some that simulation, although helpful, has yet to demonstrate a clear benefit [5]. However, the direction and standard are clear as suggested by Dietl and Russell who demonstrated that "simulation effectively reduces the surgeon's learning curve, improves communication, and reduces errors while increasing patient safety" [6–8]. Educators now see simulation as an integral part of training. Moreover, the public understands that through the use of simulation, basic skills can be honed prior to a trainee ever touching an actual patient [9, 10].

The use of simulation in surgical education can be divided into two main areas: technical skill/procedural and nontechnical skill/scenario-based. A review of the benefits and drawbacks of each type of simulation will demonstrate that the building blocks for a robust curriculum and eventual assessment of performance are available. The keys to a successful program that maximizes education outcomes based upon the investment of time and money are less clear [11]. Ultimately, there are endless combinations of training options that offer the opportunity to educate, assess, and practice in the lower stake confines of a simulated environment.

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Fig. 1 Department of Surgery Skills Laboratory at Indiana University School of Medicine

Validation, Fidelity, and Reliability

Before reviewing the types of simulation, one must consider the goals of simulation and the ways in which one can describe how each form of simulation meets those goals. Ultimately, simulation aims to recreate a scenario that a trainee will encounter in the treatment of actual patients. A measurement of the comparison of these simulated scenarios in reality and their proximity to reality is an assessment of their validity [12]. In other words, a scenario is valid if it approximates real life. Validity can be further defined. For example, an overall assessment of the simulation and how it compares to reality is considered face validity. A comparison of how the simulated environment allows the participant to complete tasks to an accurate level of his or her abilities is construct validity. Finally, it is important to know how performance on a simulator will predict a trainee's performance in reality. This is referred to as criterion-related validity.

Fidelity measures the degree to which a simulated environment more closely provides a picture of reality. As an analogy, compare a low-resolution image to a high-resolution image. Upon evaluation of the low-resolution image closely, one sees rough borders of the items within the image with blocklike configuration. The high-resolution image provides smoother boundaries and a more lifelike appearance. Within simulation, an example may be the difference between using a box trainer with reusable laparoscopic instruments to perform laparoscopic suturing versus a computer-based simulator with a virtual reality (VR) environment in which computer-projected instruments are used to sew computer-generated items together. While the two may allow one to complete the task and therefore are valid, the VR is clearly more complex and with the aid of complex computer software approaches a more realistic picture of what is seen in the operating room. Therefore, this VR simulator is considered high fidelity. Frequently, as in this scenario, higher fidelity generally means higher cost. Controversy remains over the benefits of high-fidelity simulator versus the clear financial implications. Many feel, when used appropriately, low-fidelity simulators provide as effective teaching as high-fidelity devices [13].

Reliability represents the ability of the simulation to be repeated consistently by different users at different times but yield similar results for similar performances [12]. For example, if the simulation is attempting to measure aptitude, an individual observing the simulation must consistently come to the same conclusion regarding a trainee's performance at completion of the simulation. This is referred to as test-retest reliability. Moreover, when two trainees perform the simulation in a similar fashion, the observer should come to the same conclusion with each trainee. This is referred to as internal-consistency reliability. And, two observers watching a similar performance of the simulation should come to the same conclusion regarding the assessment of that performance if completed by the same trainee or by different trainees. This is referred to as inter-rater reliability.

Types of Simulation

Technical Skill/Procedural Simulation

In surgical education, the timely acquisition of technical skills remains the focus. Simulation in technical skills training has included both biologic and synthetic models. Some of the first models used for training were biologic in nature. Although initially used to study anatomy, cadavers were then used to prepare for performing the actual procedure. The lack of consistent preservation techniques initially limited the usefulness of cadavers. However, a cadaver naturally provides the most realistic anatomic model, and they remain a consistent component of surgical training [14–17].

Cadavers have generally been used in either a "fresh frozen" format or an "embalmed/preserved" format. The benefits of frozen cadavers are clear. Once adequately thawed, the tissues and the anatomic layers including tissue planes remain lifelike [18]. Unfortunately, natural processes do lead to deterioration of the tissue and a short window of usefulness exists. While the preservation process negatively affects tissue realism, it does significantly increase the timeline for use thereby allowing the cadaver to be used over repeated sessions. Recent trends have provided hybrid preparation techniques that attempt, somewhat successfully, to maximize the realism of fresh cadavers with the usefulness of a preserved one [14, 19]. In addition, some educators have created "live cadavers" connecting the blood vessels of cadaveric specimen to pumps, simulating circulation, and providing an even more realistic educational experience [19–21].

Although the benefits of using cadavers in simulation are clear, the drawbacks may be less obvious. Perhaps more obvious, a lack of flexibility prevents placement in the lithotomy position and limits the use of a cadaver in some procedures (e.g., proctectomy). Although this may be overcome by removal of the legs, some institutions, including the author's, do not support sectioning of cadavers. In addition to inherent issues with a cadaver, there are less obvious environmental issues to address. The use of cadavers requires adequate ventilation and a method of collecting fluids that are commonly associated with the use of cadavers (i.e., intestines remain unprepped). This limits the locations in which cadavers can be used. At some institutions, this requires competing with undergraduate gross anatomy courses for lab space presenting yet another challenge to creating a robust curriculum.

In addition, as the number of medical schools continues to increase, the demand for cadavers has dramatically risen. Fortunately, there remains a continued understanding by the public that donation of one's body to science is a very effective method of providing beneficence to society even after one has passed. Still, the cost of obtaining a cadaver may range from $1500 to more than $3000 depending on the venue and the source. In addition, if one elects to use frozen cadavers, infectious diseases may be transmitted postmortem (e.g., HIV or hepatitis C). So, each frozen cadaver requires these tests and increases costs by more than $500 per cadaver. In the end, the cost to obtain "safe" cadavers in an environment conducive to surgical training may be prohibitive for routine use in a skills curriculum in most programs.

Nevertheless, appropriate simulators for a number of surgical procedures (e.g., open inguinal hernia) are still not available requiring a cadaveric model to provide the best training experience [22]. The limited supply of cadavers and the cost associated with using cadavers have led to some programs using cadaver parts. The use of parts provides a potentially more efficient manner of using this limited resource. However, an interest in returning a collection of cremated ashes to the family members of individuals donating their bodies makes it challenging to offer cadaver parts. The parts must be tracked and returned for cremation. As a result, this option is generally offered at limited sites.

A beating heart and circulating blood with the potential for hemorrhage are helpful in creating a lifelike scenario that creates buy-in by the participant. Naturally, one of the biggest drawbacks for cadavers is the lack of bleeding and movement associated with a living being. Although some centers have overcome these obstacles with circulating pumps attached to sectioned cadaver parts as described above, the expense and regulatory challenges of obtaining cadavers remain major barriers to their use [16, 19]. Therefore, animal models have been identified as another biologic simulated environment for some common surgical procedures. Some of these models were initially identified as efforts to research the surgical treatment of diseases which demonstrated similarities to the human model. For example, canine stomachs have proved very similar to humans while bovine or porcine hearts share a significant resemblance to our own [23]. Animate models do provide actual bleeding, not simulated bleeding, with a beating heart and breathing lungs. This actual living environment clearly sells the benefits of the model. For example, Advanced Trauma Operative Management (ATOM) developed at the University of Connecticut and later adopted by the American College of Surgeons Committee on Trauma has demonstrated the role of the swine model in teaching the skill set necessary to manage traumatic injury [24].

There are also several challenges, however, working with animate models. Acquiring animals for educational sessions is largely dependent on the access to these animals. For the most part, comparative anatomy has helped to identify similarities between human organ systems and several other mammals. Animal size and availability, ease of administering anesthetic, and cost are also determining factors in this decision on which model to use. However, for primarily social reasons, the swine model is most commonly chosen.

In fact, the revolution of laparoscopy was significantly facilitated by the ability for practicing surgeons to practice laparoscopic cholecystectomy with the swine model [25].

Access to an animal holding facility necessary to receive and temporarily house these animals limits this option for some institutions. In addition, for some locations in large metropolitan areas, access to pig farms is quite limited. Therefore, while, in some areas, there is ample access to porcine models for training that are even less expensive than some lifelike synthetic inanimate models currently available for purchase, in some other settings, obtaining pigs can prove even more expensive than considering cadaver models. Over the years, ethical treatment of animals has raised concern regarding the use of animals for educational sessions. For example, bowel preparatory techniques are not used. Limiting the use of live animals in education is considered so important by some that the European Union has pushed to reduce, refine, and replace the use of animals in educational sessions [26]. In fact, the UK has eliminated the use of live animals for surgical training, but some trainees (e.g., military medical trainees) travel outside the UK to neighboring countries like Denmark to participate in trauma surgical training courses [27]. Still, access to pig farms likely offers access to food processing facilities where organs commonly disposed at the completion of processing can be used for training purposes. For example, an ex vivo pig liver has been used in comparison to virtual reality simulators and in the laparoscopic cholecystectomy verification of proficiencies developed at Southern Illinois University [28, 29].

Fig. 2 Example of a low-fidelity “box trainer” with camera, ports, and instruments used to practice basic laparoscopic surgical tasks or procedures

The limited availability of cadavers and the ethical dilemma of using animals have led to a rise in the availability of inanimate synthetic alternatives that range in complexity from a piece of foam to a computer-simulated environment. The prior is an example of a low-fidelity model, while the latter is considered high fidelity. Controversy continues regarding the benefits and drawbacks of low-fidelity versus high-fidelity models. Innovative educators have generated numerous low-fidelity models that commonly represent bedside procedures, simple surgical tasks, or a single component of a much more complex procedure [5, 30]. Moreover, these low-fidelity models have demonstrated success in recreating these tasks or procedures in a low-stress environment during which feedback can be provided without risk to the patient. Examination of the benefit of these low-fidelity models has suggested that skills learned here transfer effectively to the operating room and are even preferred by instructors and learners to other forms of simulation including cadavers and animals [5]. These models are present throughout surgical education. For example, in thoracic and abdominal surgery, basic surgical techniques used in minimally invasive procedures can be practiced in what are commonly called “pelvic trainers” or box trainers (Fig. 2). These trainers are omnipresent and relatively inexpensive with an external hard plastic housing with several holes cut in the top surface that are covered by small thin diaphragms, or some trainers have a rigid plastic endoskeleton that is covered by a sheet of thin pliable material on top. The cut holes or the pliable sheet located on the top surface allows introduction of minimally invasive instrumentation while watched by a small posable camera that sends an image to a contained LCD screen or sends the image to a connected monitor or laptop computer. With availability of electronic materials in most major cities, one can construct a model like this at home [30]. These models have proven very effective, and one is used in the Fundamentals of Laparoscopic Surgery (FLS). FLS is an assessment program developed by the Society of American Endoscopic and Gastrointestinal Surgeons (SAGES) to demonstrate proficiency in basic laparoscopic surgery. It has two components: an assessment of knowledge through a multiple-choice examination and a technical assessment using five basic laparoscopic tasks with efficiency and accuracy benchmarks. In addition to the laparoscopic trainers, similar low-fidelity environments are used to recreate an endoluminal environment used to practice endoscopic procedures [31–33]. Even more rudimentary models are used to simulate tasks including basic suturing and knot tying.

Almost every medical student has benefited from using a piece of thread wrapped around some relatively immobile object [34]. From this basic model, the student has been able to practice knot tying. These rudimentary models have been embellished as well. For example, a box with pieces of cloth is fashioned to recreate an abdominal wall and can be used to practice laparotomy. In orthopedic surgery, the sawhorse has effectively provided an inanimate model from which many boney procedures can be practiced [35]. Despite the simplicity of materials used in creating these models, many learners ultimately do confirm similarity to patient care activities. For example, a model using ventilator tubing and a thick neoprene-type cloth can recreate a lifelike cricothyroidotomy. Residents trained with the model at the author's institution have made anecdotal comments that the model effectively recreates the anatomy of the region and offers a realistic comparison to human anatomy.

Unfortunately, to the untrained observer, the low-fidelity simulators do not measure up. The initial impression for most is that the high-fidelity models provide greater benefit. These high-fidelity models generally involve the use of audiovisual equipment and computers [36]. Still others use extremely high-tech computers modeling force feedback referred to as haptics. Simulators that provide haptic feedback add an additional element of realism with physical feedback representing instrumentation encountering or engaging tissue.

High-fidelity simulators may also use lifelike physical components to represent organs being manipulated during a procedure. For example, materials created by industry may mimic the abdominal right upper quadrant with a realistic liver and gallbladder generated from synthetic material that has come from exhaustive material science research. Using actual laparoscopic equipment with hardware mounted on a rolling tower, the trainee is able to initiate and perform an entire laparoscopic cholecystectomy with lifelike materials configured in realistic anatomical structures without using any biologic material. Similarly, some devices use segments of intestine either donated from a cadaver or retrieved from an animal during preparation for delivery to market. These are then mounted on a fixed stricture to represent the anatomically correct configuration of the human colon allowing an endoscope to be introduced and perform a screening colonoscopy or even a diagnostic procedure with interventions including biopsy or snare removal of polyps. Similarly, bones taken from cadavers or animals mounted to a fixed structure can be used to perform orthopedic surgical procedures [35]. Entire mannequins are available to offer the ability to perform multiple procedures on one device and during one scenario. The mannequin provides a lifelike configuration to a patient creating an element of realism of the trainee. Some simulators provide video recording that may be evaluated by computer software to measure outcomes including overall time, accuracy of movement, efficiency of movement, and potential untoward effects of errant movements. Although all of these lifelike models that simulate real scenarios represent high-fidelity simulators, the most commonly considered devices in this category are used to train technical skills and utilize virtual reality (VR).

VR simulators have limitations based upon the capabilities of computer programming and hardware to generate a lifelike environment. Although there are VR simulators for simplistic tasks like intravenous line insertion, the most common VR simulators cover laparoscopic and endoscopic tasks. Although under development, the ability to introduce one's hands into a box and simulate open surgery in a VR environment exists currently for orthopedic surgical procedures (Sim-Ortho, OSSimTech™) [37]. The greatest benefits of VR simulators are the ability to reproduce identical tasks for all trainees and generate measurements from which metrics are determined to demonstrate overall improvement in trainee movements and the acquisition of surgical skill [36]. In fact, at the author's institution, an attending surgeon commonly performs the tasks on the VR simulation to set a benchmark for trainees to exceed as they train toward proficiency.

The greatest drawback of high-fidelity simulators is their cost. Although these simulators also can occupy significant space, especially the mannequin-based devices, the cost of many of these simulators can reach and exceed $100,000 per device. Additionally, contracts to maintain the devices with complex computer hardware and software, as well as surgical instrumentation that interfaces with the hardware, can cost more than $20,000 per year. High costs generally place these simulators out of reach for smaller training programs, may require the cooperation of several programs at one institution, could necessitate the involvement of clinical entities or healthcare organizations, or demand the identification of a benefactor who can support the mission with philanthropic efforts. Packaging of VR simulators and the images provided on the screen do immediately engender interest from trainees and potential benefactors which draws trainees to the training center and helps encourage philanthropy. Furthermore, they provide an image of futuristic training where surgeons-in-training demonstrate proficiency prior to touching a patient, similar to the flight simulators used in pilot training today. Ultimately, there exist roles for both low- and high-fidelity simulators. A review of the literature suggests a consensus of surgical educators is that low-fidelity simulators remain effective in training basic tasks (e.g., basic suturing), while high-fidelity options are effective in the training of complex tasks including surgical procedures (e.g., total gastrectomy) [38].

Nontechnical and Scenario Simulation

Simulated scenarios like a clinic visit have been used in physician training for decades. Placing an individual who partakes in the role of a patient in an exam room can quickly create a lifelike scenario for someone in any level of training from medical student to surgical fellow. Creating a script and structured method of introducing the learner to the simulated scenario along with an assessment checklist for the actor to use provides an opportunity to demonstrate the acquisition of skills and even improvement from prior events. This objective structured clinical examination (OSCE) using a simulated and standardized patient has played a role in assessment of clinical skills since the 1980s [39]. As time has passed, these training environments have generally moved from an actual clinic to an area dedicated to simulation within the medical school of healthcare organization. These simulation centers can consist of rudimentary rooms with limited materials including an exam table, microphone, and video camera. However, in other locations, rooms are staged to represent an operating theater (Fig. 3), ambulance bay, emergency department, or even an entire hospital ward or intensive care unit [40]. Each room contains at least one audiovisual recording device, but sometimes there are several viewpoints captured for review. Not only do these simulated environments contain physical structures including gurneys, beds, beside tables, IV poles with IV pumps, and bedside chairs for actors to sit, but they also commonly contain VR mannequins that simulate movements of a real patient with eyes that open, speakers that provide breath sounds, abdominal and thoracic movements to simulate a beating heart or breath movements, and simulated telemetry tracings on a bedside monitor which provides vital signs and data just like that seen in the actual hospital room. All of these aids have provided an ability to insert the trainee into as lifelike of a scenario as possible [41, 42]. When an event takes place in one of these simulated venues, the trainees commonly remark on how they were made to feel the same level of stress as that of the actual hospital environment. In addition, these simulated environments provide an opportunity for not only an individual to partake in the training process but for groups of individuals from multiple disciplines or specialties to work together [43]. At the author's institution, simulated events involving medical and nursing students are part of the curriculum for both schools, while coordinated sessions involving surgical and anesthesiology residents in a simulated operating room have proven beneficial to train for stressful events during a simulated laparoscopic crisis.

Naturally, with the ability to record comes the ability to watch and listen to the recording. It has been shown that there is not only benefit of reviewing the checklist with the learner after the completion of an activity, but providing an audio and video recording of the learner and simulated patient partaking in the interaction is very beneficial for the learner [40]. Watching the video after the completion of the session provides an opportunity for review or debrief. In fact, this activity is now considered as important to assessment and improvement as the actual simulated interaction. It provides an opportunity to show specific areas for improvement and clearly shows the learner actions that he or she may not even recognize were performed.

Fig. 3 Simulated operating room arranged for an emergent Caesarean section session at the Indiana University Health Simulation Center

Incorporating Simulation into the Curriculum

The application of simulation in surgery has mainly focused on training and assessment. Dr. K. Anders Ericsson has suggested that mastery of any complex skill requires approximately 10,000 hours of deliberate practice. Although his initial discussions and evaluations revolved around playing the piano, the analogy has been drawn to surgery and the completion of surgical tasks [44, 45]. Almost immediately after this connection was drawn, many in surgical training broke down the average hours a week a surgical resident participated in clinical experience and multiplied that over the 5-year clinical residency. Ultimately, this seemed to justify the long hours and the overall time a young doctor dedicates to surgical training. However, there are at least four competing forces that have shaped the amount of time a resident is allotted for formative skills training under the time-honored Halsted training model of graduated responsibility in the operating room: work-hour restrictions, medicolegal environment, dwindling financial margins in the healthcare industry, and billing guidelines. When one adds that the public has come to expect that training happens prior to actual patient care, the need for a controlled and consistent environment in which education can occur without risk to human life was needed. Although simulation was clearly used prior to the quadripartite wallop to operating room training, it provided an opportunity to effectively expand the time residents train and ultimately worked to meet the standard set by Ericsson's theory [46, 47].

Although using simulation for education has demonstrated clear advantages for years, there are best practices by which simulation has provided different outcomes and arguably can be used in a more effective manner [5, 11]. Specifically, effective use of simulation requires performance review, mandatory participation, and a delicate balance of timing and repetition. First, simulation requires a timely review of the performance. An effective teaching strategy previously introduced is referred to as the BID technique: brief, intraoperative teaching, and debrief [48]. In this strategy, prior to the surgical procedure, the attending surgeon and resident discuss the expectations of the procedure. This may include which portions of the procedure the resident will perform or if the resident will perform all portions of the operation. It should also include a discussion of which portions the resident hopes to focus improving his or her performance. Then, during the procedure, the surgical attending provides immediate feedback regarding resident performance. Although immediate feedback comes in many forms, the expectations here are formative feedback that helps the trainee understand immediately what he or she is doing well and where he or she must improve. Finally, during the debriefing, the resident and faculty member discuss what went well and what can improve, and a comparison is drawn to prior performances. In this regard and to utilize the BID model in simulation, prior to the session, preparation must take place. This should include aligning a resident's reading with his or her simulation experience. At the author's institution, a module from the Surgical Council on Resident Education (SCORE) web-based materials is developed for each simulation session. The module provides not only a book chapter or article to review, but there are also procedure descriptions and when available even a video. It is expected that the trainee arrives to the simulation having completed this preparation. At the beginning of the simulation session, a very brief review of the task or event is performed. Then, the simulation commences. Depending on the session, use of immediate feedback should be consistent with the overall goals. Feedback may be offered, or trainee performance without direction can be assessed to determine a level of autonomy. Finally, upon completion of the session, a review of what went well, areas where the trainee struggled, and an assessment of the end result should occur. This debrief can be added with the benefit of video recording if available.

Second, simulation training must be mandatory. The draw to the clinical environment is strong. The end result is that a trainee will consistently choose to continue clinical duties rather than retreating to the simulated environment for an educational experience. If voluntary participation is encouraged, in general, and not surprisingly, trainees will engage in the simulation infrequently, if at all [49]. If trainees attend simulation sessions infrequently, faculty participation will naturally trail as well, creating a spiral of nonparticipation. Trainees won't participate as a lack of faculty presence suggests a lack of importance, while the lack of trainee participation will suggest a lack of importance of the sessions to the faculty.

At the author's institution, since the development of a comprehensive skills lab curriculum, the sessions are considered mandatory. This requires that the schedule is available well in advance. Moreover, it requires that the trainees prepare in advance and arrange coverage for clinical responsibilities by other trainees or advanced practice providers. Despite the preponderance of electronic scheduling tools with alarms and reminders, trainees still sometimes miss their simulation sessions. Creating a successful skills lab curriculum remains an uphill climb and is dependent on department leadership support.

Finally, effective scheduling of simulation sessions is a delicate balance of timing and repetition. Effective timing would suggest that a teaching session occurs immediately before the skill is required in clinical practice. For example, teaching tube thoracostomy immediately before a resident takes trauma call would provide the best opportunity for the trainee to remember the key components of performing the skill before application of the skill. However, arranging this type of timing creates an element of complexity that is likely not obtainable or sustainable in most training programs. For example, it would require that every rotation for every resident at every level has a simulation-based training program. Even if rotations at a program are 2 months long, that would require 30 simulation programs covering multiple disciplines. In general, this level of complexity requires a bandwidth and financial investment that few, if any, program possesses. However, there are variations on this theme that provide some proximity of skills practice prior to application. A curriculum that calculates the most common procedures performed by trainees per year allows the simulation curriculum to focus on those procedures during the preceding 6–12 months. For example, if laparoscopic cholecystectomy is most commonly performed on rotations during the second year of residency, it would be reasonable to introduce that procedure in the simulated environment during the completion of the first year of residency or the very beginning of the second year [8, 11]. An even closer link between simulation and clinical use could be established by initiating simulation training of laparoscopic cholecystectomy at the beginning of the rotation or immediately prior. This technique, referred to as "just in time" training, has proven effective for simple tasks including endotracheal intubation and lumbar puncture [50, 51].

In addition to timing simulation sessions to maximize skill retention, it is important to identify a time when attendance is maximized. Each residency training program has accommodated the changes in work hours differently. Night float, midweek days off, and staggered vacations have had an impact on all facets of training including didactic and simulation sessions. Choosing a day of the week and a time of day that allows the most trainees to attend is key.

Although the focus of most simulation activities is surgical residents and medical students, simulated surgery remains a major component of training practicing surgeons in new procedures. Hands-on courses that draw practicing surgeons from afar have long incorporated cadavers and live animal sessions. Choosing the best timing for these courses must consider common times for family vacations and surgical meetings. Although industry has commonly sponsored such courses, interest has waned over the years. In addition, willingness of practicing surgeons to travel from home for work purposes has diminished. Moreover, recruiting faculty for these courses can be a challenge if the course is timed poorly. Finally, conflict of interest policies have been introduced by most medical schools and healthcare organizations making travel to industry-sponsored courses untenable. In fact, although eventually repealed, Massachusetts passed a law that prevented physicians from participating in such events. Ultimately, whether one is training medical students, residents, or practicing surgeons, event timing is key to ensuring participation and allowing for participants to focus on the event.

In addition to the intricacies of timing events, establishing the role of repetition within a simulation curriculum is important. As proposed by Ericsson, repetition is a core component of deliberate practice and key to the current goal of proficiency-based training [45]. However, as mentioned, the time that a medical school or surgical residency can devote to simulation events is limited. Therefore, incorporating deliberate and repetitive practice into the curriculum may be challenging and costly. Besides the significant initial capital investment needed for high-fidelity simulators, cadaver sessions are frequently associated with the highest cost per session and, therefore, are infrequently used in most programs. In contrast, inanimate simulations with low-fidelity simulators or even sessions that incorporate computer-based VR simulators can be repeated frequently with limited per use supply costs. As a consequence, high-fidelity simulators that recreate human anatomy have come to replace cadavers and animate models in many facilities. Although material science has allowed these anatomical models to effectively recreate human tissue, these developments have not come without a cost. For example, mannequins commonly used in team-based scenarios commonly have neck, chest, and abdominal skin inserts that may be used more than once but generally not more than three times. The use of these materials can quickly add up and may call into question the role of low fidelity or even animate models which may be available in some environments at comparatively lower costs.

As many work to create the best educational opportunities and utilize the mandated simulation environments in their own facilities, the secret to success of medical student and resident simulation training is not having the best simulators or the most robust curriculum but the unconditional support of the institution and department leadership. Published literature has demonstrated the educational value of cadavers [22], animate models [13, 23, 24], and low- and high-cost simulators [5, 11]. Nevertheless, it is the enthusiasm that the teaching faculty bring to each session and the importance leaders have placed on student, resident, and faculty member presence at each session that mark the key ingredients for a successful program.

In addition to education, simulated scenarios have come to play a role in assessing both technical and nontechnical skills. Likely the most common simulated setting that has been used to assess and certify an individual skill set has been the cardiac resuscitation in Basic Life Support and Advanced Cardiac Life Support programs. Advanced Trauma Life Support was added to these as required certification for individuals entering surgical residency. More recently, Fundamentals of Laparoscopic Surgery (FLS) and Fundamentals of Endoscopic Surgery (FES) have proven effective in demonstrating proficiency in basic laparoscopic and endoscopic skills and completion of these certificates are now necessary components to sit for the

American Board of Surgery Qualifying Examination [52]. Besides providing evidence of technical proficiency in technical skills, FLS certification has also been used for reduction in professional liability insurance premiums. The newly developed FES curriculum has been shown to improve proficiency and quality of diagnostic and therapeutic endoscopy and has the potential to be used also for privileging [53].

Similar high-stakes assessments in a simulated environment have been created for nontechnical skills. The OSCE has proven to be an extremely effective method to assess patient interaction skills. In fact, the US Medical Licensing Examination Step 2 Clinical Skills assessment relies heavily on this tool. Several additional assessment tools have been developed and validated for the assessment of nontechnical skills such as NOTECHS and NOTSS [54]. As curricular change has swept medical schools and milestones have come to replace competencies in postgraduate training, it is likely that simulation will play a bigger role in assessing skill competency.

Finally, in addition to education and assessment, simulation has been adapted directly into clinical practice as a method of preparing not for a general event but a very specific event and procedure. For example, computer software is currently available to gather all radiologic imaging data to create three-dimensional image of a patient's anatomy. This allows for a practicing surgeon or even teams of surgeons in many specialties to prepare for the delicate and coordinated efforts needed in challenging cases [55–59]. For example, hepatobiliary surgery has embraced this concept in approaching liver tumors [60]. With the increasing availability of 3-D printers, not only will virtual images be available, but physical models will be an option for surgeons to practice and prepare for these challenging scenarios [61].

Conclusion

As simulation curricula have demonstrated success in educating and assessing trainees, the number of simulation centers and skills labs has risen dramatically. Each institution uses these valuable resources differently. Literature demonstrates the benefits of simulation for both technical and nontechnical skills. The logistics of putting together simulation sessions including determining their ideal timing and duration will vary based on the needs of the individual program. Financial investment is important to the success of simulation programs as each of these resources has a capital investment and an ongoing replacement expense. However, support by institutional and department leadership and enthusiastic faculty is key to the overall success of a simulation program.

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A Taxonomy Guide for Surgical Simulation

Aimee Gardner, James N. Lau, and Sara Kim

Term	Definition	Reference
Accreditation	A formal review of programs, such as medical schools, simulation centers, or hospitals, based on established standards. Typically, formal bodies, such as the Liaison Committee on Medical Education (LCME), Accreditation Council for Graduate Medical Education (ACGME), Society of Simulation in Healthcare (SSH), the American College of Surgeons (ACS), and the Joint Commission, review various programmatic aspects, such as quality of personnel, organizational structure, training content, delivery of programs or curricula, and rigor of evaluation data collection and monitoring	Joint Commission [1] Nasca et al. [2]
Adaptive training	Technique in which all aspects of the teaching method are varied according to the performance of the trainee. The specific objective and the task are adjusted to the level and actual skill level of the trainee	Kelly [3]
Andragogy	Teaching methods particularly developed for adult learners. Principles of adult learning are based on what is known about how adults learn, such as their need to know why they are learning something and how the learning materials are relevant to their work	Knowles [4] Knowles et al. [5]
Angoff standard setting procedure	A formal standard setting method to determine passing scores in exams. The method involves a panel of judges or experts whose assessment of each test item based on a probability that a minimally competent individual would answer correctly. The sum of their judgment informs the passing cutoff score	Hurtz and Hertz [6] Kaufman et al. [7]
Assessment	Use of metrics to improve the process of teaching and learning that is process-oriented (i.e., how learning is going) and diagnostic (i.e., what can be improved)	Angelo and Cross [8]
Augmented reality	A type of technology that inserts virtual objects, such as sound, video, or graphics, into the normal field of view to offer a new means of visualization for a learner	Vera et al. [9] Botden et al. [10] Barsom et al. [11]
Avatar	A graphical representation of a trainee in a virtual simulation *See also* virtual reality simulation, computer-based simulation	Patel et al. [12]
Basic assumption	An explicit statement coined by the Center for Medical Simulation (CMS, Boston) intended to create a safe learning environment by acknowledging trainees' basic aptitudes, training, and ambition to succeed *See also* psychological safety	Rudolph et al. [13]

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Term	Definition	Reference
Bias	Sources of confounding factors that create an unfair assessment processes and outcomes for test takers. These factors may include the test takers' age, gender, sexual orientation, ethnic background, cultural exposure, socioeconomic status, and other demographic characteristics. Bias is introduced by a number of factors, including how test items are constructed, what assumptions are made about test takers' preexisting knowledge, how a pool of context experts is formed, how a scoring system is devised, how test items were piloted, and what judgment is made about individuals' academic achievements or employment. Judgment and statistically based quantitative techniques are applied to detect possible biases in test items	Scheuneman [14]
Bloom's taxonomy	A framework for organizing expertise into knowledge (recall), comprehension (interpret), application (generalize knowledge to specific situations), analysis (chunk knowledge into parts and establish relations among the parts), synthesis (conceptualize new knowledge), and evaluation (make judgment based on evidence). It is commonly used to develop educational objectives and constructing test items	Bloom [15]
Boot camp	A training program intended to provide uniform competency among new trainees. Boot camps typically take place in the fourth year of medical school to prepare students for a particular specialty or occur when a new cohort of trainees, such as interns, join a residency program	Antonoff et al. [16]
Certification (or Maintenance of Certification)	Assures that healthcare professionals, such as surgeons, possess, at the time of credentialing and on an ongoing basis, the highest standards of medical knowledge, clinical acumen, improvement of medical practice, lifelong learning, and professionalism as established by a certifying body, such as the American Board of Surgery. Certification or Maintenance of Certification serves a critically important function of accountability to the public and society. Each certifying body specifies the cycle of certification, for example, requirements for every 3 years or every 10 years	Malangoni [17]
Checklist	A set of measurable, explicit, and observable performance-related behaviors associated with task completion. The Objective Structured Assessment of Technical Skill (OSATS) is an example of an assessment modality in surgical technical competence that includes a list of items for observers to notate the completion or omission of specified behaviors demonstrated by trainees during task completion	Martin et al. [18] Faulkner et al. [19]
Coaching	Observation of performance with overall and explicit detailed real-time feedback from an educator with content expertise and educational training	Bonrath et al. [20] Stefanidis et al. [21]
Cognitive load theory	Human's working memory has limited capacity to process multiple tasks simultaneously. Therefore, learning is dependent on instructional design modalities that take into account a learner's ability to assimilate existing knowledge and accommodate new knowledge. In general, three types of cognitive load exist. The intrinsic load refers to inherent difficulty in tasks. The extrinsic load refers to manners in which information presented (e.g., voice-over PowerPoint slides) and extraneous factors may interfere with information process (e.g., animations that do not match learning goals). Lastly, the germane load is related to a mental schema constructed during new learning that is stored in long-term memory	Sweller [22] Sweller et al. [23] Sweller [24]

Term	Definition	Reference
Cognitive task analysis	A process to give meaning to behavior. Coordinated cognitive processes involved in performing complex actions	Crandall [25]
Confidentiality	An agreement made between learner and a simulation entity to keep simulation activities (simulated clinical scenarios, standardized patient scenarios, participant performance, debriefings, discussions, etc.) confidential	
CONSORT diagram	Also referred to as a study flow diagram, CONSORT stands for Consolidated Standards of Reporting Trials, shows. It illustrates the flow of study subjects from screening, recruitment, attrition, randomization, and completion of study trials	Andrade [26] CONSORT [27]
Competency	A set of knowledge, skills, attitudes, and behaviors expected in a learner to demonstrate as evidence that the learner meets the threshold of performance that has been formally established by an entity, such as the Accreditation Council for Graduate Medical Education (ACGME). ACGME endorses six general competency areas: (1) patient care, (2) medical knowledge, (3) professionalism, (4) systems-based practice, (5) practice-based learning and improvement, and (6) interpersonal and communication skills. Competencies are determined based on measurable outcomes within the target learning and professional domains	Englander et al. [28] Frank et al. [29] Higgins et al. [30]
Computer-based simulation	The use of a computer program or activity to simulate clinical scenarios and activities *See also* avatar	Lin et al. [31]
Credentialing	A set of standards applied to an organization or individuals for assessing compliance with requirements that are specified by a formal body, such as the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Credentialing guidelines typically specify training, certification courses, staffing, and infrastructure. As an example, providers must be credentialed for procedures that have been newly introduced to hospitals. Therefore, a provider may be certified in a specialty, such as surgery or pediatrics, but also must be credentialed to perform selected procedures based on the available institutional or specialty board or society guidelines	Cassel and Holmboe [32] Kaplan and Shaw [33]
Crisis resource management	A training program adopted from aviation that emphasizes the role of human factors and nontechnical skills required for effective teamwork in high risk, high stress situations. *Also referred to as* crew resource management	France et al. [34] Hughes et al. [35] Salas et al. [36]
Debriefing	Facilitated reflection of an event or activity and subsequent analysis	Fanning and Gaba [37]
Deliberate practice	A highly structured activity with the specific goal of improving performance requiring learner motivation, feedback, repetition, and goals. Deliberate practice is based on the premise that expertise is developed not by innate qualities in individuals or their extensive experiences but by practice activities that are designed to maximize performance. For example, surgical competence in technical skills is a result of a series of practices of selected tasks for maximizing performance	Ericsson et al. [38] Crochet et al. [39]
Distributed practice	The technique of scheduling a time break between serial teaching or mentored practice sessions for skills acquisition	Kwon et al. [40]
Embedded simulation person	Participants in a learning environment or simulation that contributes to or is the point of the clinical encounter with its specific learning objectives *Also referred to as* standardized patient, confederate, and actor	

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Term	Definition	Reference
Engagement	Learner's abilities through behaviors and experiences that optimally result in cognitive learning. The facets that contribute to learner engagement encompass the physical, behavioral, emotional, and cognitive domains: *Physical*: To the extent at which the learner is tactile in the involvement of the educational activity *Behavioral*: Learner's involvement at which there is a high degree of attention effort and contribution to the educational activity *Emotional*: Affective reactions that tied to the learner's attitudes, interests, and values toward the activity *Cognitive*: Motivated acquisition of attitudes, interest, and values in the comprehension and mastery of skill	Choi et al. [41]
Experiential learning theory	A process through which experiences outside of traditional classrooms are transformed into learning and knowledge. At the core of the learning process lies reflections on experiences	Kolb and Kolb [42] Kolb [43]
Expert	Facile or practiced in the learning objective	
Evaluation	Use of metrics to determine the quality of teaching and learning that is product oriented (i.e., what has been learned) and involves judgment (i.e., what is the final status)	Angelo and Cross [8]
Feedback	Input provided to the learner based on observations of performance and focuses on gaps in performance in comparison with standards and learning outcomes	Burns [44] Voyer [45]
Fidelity/realism	The degree to which the simulation or teaching experience is to the actual situation, problem, environment, and concept around the specific educational objective(s). The three dimensions that contribute to the fidelity of a teaching experience are physical, emotional, and conceptual. The fidelity of the simulation directly relates to learner engagement: *Physical*: Where the tactile, visual, auditory, and olfactory elements of the simulation are genuinely felt as nearing or at reality *Conceptual*: Plausible simulation *Emotional*/experiential: Where the simulation generated similar feelings in learners to those one could expect from a real situation *High*/low: The extent at which the overall or facets of the realism of the simulation is similar. High denoting most real and low fidelity (usually compromised due to a logistical concern but sacrificed to preserve another desired aspect of the simulation) being less real	
Formative assessment	Judgment made about the gap between a learner's performance and a standard or criterion in order to target feedback to learners for performance improvement. Information generated from formative assessment can be used to improve the quality of the learning process, including adjustment of quantity of learning content, teaching methods, instructional design of content, etc. Suggested strategies for formative assessment include eliciting prior knowledge, providing timely and specific feedback, teaching for transfer of knowledge, and encouraging trainee self-assessment	Taras [46] Shepard [47] Boston [48]

Term	Definition	Reference
Gamification	Application of game design elements to non-game contexts primarily to motivate behaviors. The concept of competition such as Sim Wars or keeping a leaderboard during simulation training such as the laparoscopic virtual reality trainer are examples of gamification in simulation-based education	Deterding [49] Kerfoot and Kissane [50]
Frame of reference (FOR) training	A method for calibrating raters who assess performance using rating scales or checklists. Rating training based on the FOR approaches involves the following: (a) description of what constitutes performance, (b) highlighting behaviors that differentiate low vs. high performance, (c) practice of ratings typically based on video clips of recorded performances, and (d) providing feedback to raters particularly where their assessment did not meet the standards established by experts in the field *See also* rater training	Dierdorff et al. [51] Gardner et al. [52]
Haptics	The use of devices to recreate the sense of touch during a simulation by applying forces, vibrations, or motions to the trainee	Okamura [53] Panait et al. [54]
High-stake assessment	A form of testing of an individual's competence for the purpose of licensing or certification where failed performance has serious consequences for an individual's professional advancement or credentialing, such as the USMLE (US Licensing Medical Examination) Step 1 and Step 2 exams or specialty board certifying exams. Standardized patients used during the USMLE Step 2 clinical skills exam is an example of high-stake simulation	Epstein [55] Norcini and McKinley [56]
Human patient simulator	A humanlike mannequin that is under the control of a simulation specialist and is able to exhibit realistic presentations (e.g., vitals, heartbeat, lung sounds, vitals, eye blinking, seizures, bleeding) to provide learners with realistic simulation scenarios and situations	
Informed consent	A required protocol for researchers to complete with study subjects to aid the participant's decision-making prior to formally enrolling in a study. A typical informed consent includes the following components: explanation of study purposes, risks and benefits involved in participating in studies, alternative procedures or courses of treatment plans, incentives, the voluntary nature of study participation, and contact information. During the informed consent discussion, subjects are encouraged to ask questions for clarifications	Pizzi and Goldfarb [57] APA [58]
In situ simulation	Simulation activities carried out in real clinical environments	Gardner et al. [59] Steinemann et al. [60] Patterson et al. [61]
IRB (institutional review board)	The IRB is a committee that conducts ethical reviews and approvals of research protocols to ensure the rights and well-being of research subjects. Investigators conducting research studies with human subjects are required to submit an IRB application for approval prior to initiating the studies. The risk level determines the application status: exempt, expedited, or full board review	Stryjewski et al. [62]
Just-in-time training	An educational episode that occurs directly prior to application of skills in a clinical environment	Kamdar et al. [63]
Needs assessment	A formal framework for the identification of the problem that needs to be addressed. The identified gap would be between the current state and the desired state	Kern et al. [64]
Orientation	An introduction to a simulation environment that takes place prior to a learning episode to prepare participants for the learning experience and clarify course objectives, environment, roles, and expectations *Also referred to as* prebriefing, briefing	
Human factors	Environmental, organizational, and individual characteristics which influence the way in which individuals work and behave. These factors affect the health and safety of the providers as well as the patients	

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Term	Definition	Reference
Interprofessional education	A learning episode that occurs when learners from two or more professions learn about, from, and with each other to enable effective collaboration and enhance the quality of care	WHO [65]
Interprofessional learning	Learning that occurs as a result of interaction between individuals from two or more professions that can occur formally as a result of interprofessional education or informally through proximity	
Judgment	The ability to make considered decisions or come to rational conclusions *Also referred to as* decision-making	Anderson [66] Pugh et al. [67] Madani et al. [68]
Kirkpatrick's evaluation of training	Delineating evaluation of training into four levels: reaction (i.e., learner's satisfaction with teaching methods), learning (i.e., knowledge test), behavior (i.e., application of knowledge to real-world situations), and results (i.e., measurable impact of training on organization). It provides a useful framework for designing a comprehensive approach to evaluation beyond reaction as the sole evidence for demonstrating effectiveness of training	Kirkpatrick [69] Bates [70]
Learning objectives	Knowledge, skills, and attitudes that are the result of an educational strategy that can be measured.	
MedEdPORTAL	Association of American Medical Colleges (AAMC) sponsored online peer-reviewed medical education curricular repository free to all to download and utilize	MedEDPortal [71]
Metacognition	Commonly defined as "thinking about thinking," refers to the mental process that regulates and monitors one's own learning. Examples include planning how to approach learning activities, monitoring comprehension while engaging in activities, checking the outcome of activities, or evaluating progress toward task completion. A surgeon's decision to convert to an open procedure from an endoscopic approach involves metacognition: monitoring one's thoughts and actions regarding potential risks to the patient as well as judgment to proceed with an open procedure	Livingston [72] Dominguez [73]
Novice	Beginner or new to the particular learning objective	
Observer	Trained individual in assessing the performance of a task or series of tasks	
Participant	Individual that is one of the targeted learners in simulation or teaching environment	
Pervasive learning	Learning in an as-needed basis through formal and informal methods. The environment and social context can be utilized to contribute to effective pervasive learning	Pontefract [74]
Procedural simulation	A form of simulation that represents the detail steps and sequential process of a medical procedure to be learned	
Proficiency and mastery	Proficiency is a marker of reaching established performance standards or criteria that allow a learner to progress to the next level of task complexity. For example, in video-assisted thoracoscopic lobectomy, time and case load may be used to determine the learning curve for setting proficiency levels. Mastery refers to a performance standard involving knowledge and skills that must be achieved regardless of the duration of time	Dong et al. [75] Li et al. [76] Wayne et al. [77]
Psychological safety	Refers to individuals' perceptions of the consequences of taking interpersonal risks, particularly in team settings. These perceptions arise from individuals' personalities and leaders setting an explicit tone and expectations for team members to group processes by sharing information and speaking up concerns	Edmondson [78]
Qualitative research	The purpose is to build a theory of a phenomenon or human behaviors. Data constitute information collected via observations, interviews with structured questions, focus groups with a small sample of subjects, or journal logs from convenience or purposeful sampling of subjects. Predominant themes that reach a point of saturation are reported based on content analyses of collected information. Qualitative research may involve a case study of a subject or ethnography which involves a nonintrusive, nondirected observations of subjects in their own environment, such as operating rooms, classrooms, etc.	Krueger [79] Merriam [80]

Term	Definition	Reference
Quantitative research	The purpose is to test hypotheses based on measurable and quantifiable data collected via tests, surveys/questionnaires, checklists, or other data collection modes. Data analyses may include simple descriptive statistics such as frequencies to more complex inferential statistics such as correlations, regressions, and other analytical methods. Randomized controlled trials or pre- and post-test study design are examples of quantitative research approaches	Krueger [79]
Rapid cycle deliberate practice	A technique of serial simulations with interspersed debriefs to allow for learners to build upon their skills systematically and in a safe learning environment	Hunt [81]
Rater training	Training intended to standardize rater ability to appropriately follow instructions for completing rating scales, observation tools, or scoring of items in order to minimize variability across multiple raters	West et al. [82]
Remediation	Strategies to bridge a learner's performance and established standards or criteria. A system of remediation is recommended as follows: (1) assessment of skills and knowledge, (2) identification of deficiencies based on performance outcomes, (3) deliberate practice in domains of tasks with timely and specific feedback, and (4) reassessment	Gas et al. [83] Hauer et al. [84]
Root cause analysis	A process or collection of processes utilized to analyze the cause of a serious poor patient care outcome or situation	AHRQ [85]
Scaffolding	Tools to aid learners' thinking, meaning making, and task engagement processes, such as stories, analogies, outline of content, concept maps, hints, cues, worked out examples, illustrations, etc., as a learner develops expertise, the need for scaffolding during learning processes fades	Cannon-Bowers et al. [86]
Scenario	The scene for the simulation. This would be comprehensibly presented as a curriculum, requiring an overall goal, specific objectives, an overall script, descriptions of what participants should be doing, timeline, assessment tool(s), and possibly a debriefing guide	
Serious gaming	A computer application that aims to combine aspects of teaching and learning with video game technology to teach, train, educate, and heal. Serious gaming technology is used in education, vocational training, health, defense, advertising, and business	Mouaheb et al. [87]
Self-motivated benchmarks	Trainee initiated accomplishment of a specific set of learning objectives. Usually associated with task trainers or virtual reality simulators	
Shared mental models	Members of a team have a shared mental picture or sketch of the relevant facts and relationships that define a task, event, situation, or problem. When a team has a shared mental model, everyone is on the same page regarding what to expect and how to interact with one another. Shared mental models enable the team to anticipate and predict each other's needs; identify changes in the team, tasks, and resources; and adjust the course of action or strategies as needed. Huddles or briefing are examples of establishing shared mental models in teams	TeamSTEPPS [88]
Situational monitoring	Team members' awareness of what is going on around them. This enables the members to adapt to changes in the situation and create opportunities to support other team members. New and emerging information is communicated among team members to develop and maintain a shared mental model. Team leadership that establishes a culture of speaking up and mutual support is critical to maintaining situational monitoring	TeamSTEPPS [88]
Spaced practice	The technique of interspersing time or another task between the serial repetitious performance of skills acquisition.	Perruchet [89]
Summative assessment	Judgment made about a learner's performance or competence based on cumulative evidence, such as weekly quizzes, midterm, final exam, or class participation	Taras [46]
Task trainer	A model or device that is utilized by the trainee in mentored practice for a particular skill or sets of skills	

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Term	Definition	Reference
Team	An identifiable group of two or more individuals working independently toward a shared goal that requires the coordination of effort and resources to achieve mutually desired outcomes	Salas et al. [90]
Team-based learning	An active learning and small group instructional strategy that provides learners with opportunities to apply conceptual knowledge through a sequence of activities that include individual work, teamwork, and immediate feedback	Parmelee et al. [91] Burgess et al. [92]
TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety)	A program developed by the US Department of Defense in collaboration with the Agency for Healthcare Research and Quality (AHRQ) that provides a framework for organizations to implement structured processes designed to promote effective teamwork among healthcare workers and improve patient safety	Mayer et al. [93] Meier et al. [94]
Teamwork	A description of the cognitions, behaviors, and attitudes that make interdependent performance possible	Salas et al. [95]
Team effectiveness	The evaluative judgments regarding the results of performance relevant to set criteria. These can be subjective (e.g., self-report assessments, observer opinion) or objective (e.g., time to intubate, adverse events) *Also referred to as* team performance	
Team training	Learning episodes that occur with two or more individuals to teach or assess teamwork behaviors and/or clinical performance. Team training can be true interprofessional education sessions with members from different specialties, can include one individual working with a confederate team who are intended to represent other specialties, or can consist of members from the same specialty working together in a simulated environment	Gardner and Hull [96]
Transfer	Refers to whether skills and knowledge acquired in one context (e.g., simulation settings) generalize to another context (e.g., operating rooms). For transfer to take place, the fidelity and approximation of the real world in training format, content, and settings become highly relevant. Furthermore, determining the minimum requirements for fidelity (i.e., low vs. high fidelity) for facilitating transfer is critical in terms of selections of tasks, steps required by learners to complete within tasks, and environment in which tasks are completed, such as the look and feel of materials (e.g., texture of synthetic human skin), models (e.g., anatomic model), care settings (e.g., outpatient, trauma bay), and clinicians vs. non-clinician confederates as team members. The nature and complexity of target skills, such as simple suturing vs. complex procedural tasks, may determine the degree of fidelity that is appropriate for transfer	McGaghie et al. [97] Norman et al. [98] Perkins and Salomon [99]
Virtual reality simulation	The use of computer technology to create immersive and engaging learning environments. This modality also commonly incorporates physical aspects, such as surgical instrumentation, to fully capture requirements of the task	Aggarwal et al. [100] Gallagher et al. [101] Grantcharov et al. [102]
Virtual patient	Target of a clinical encounter in an interactive simulation or virtual reality environment	
Validity	The degree to which evidence and theory support the interpretation of metrics entailed by proposed uses of tests and measures	AERA [103]
Zone of proximal development	The distance between the actual developmental level as determined by independent problem-solving and the level of potential development as determined through problem-solving under guidance or in collaboration with more capable peers. The goal of instruction is to identify where a learner's needs lie within this zone in order to provide the necessary scaffolding for the learner's developmental trajectory	Vygotsky [104] Kneebone et al. [105]

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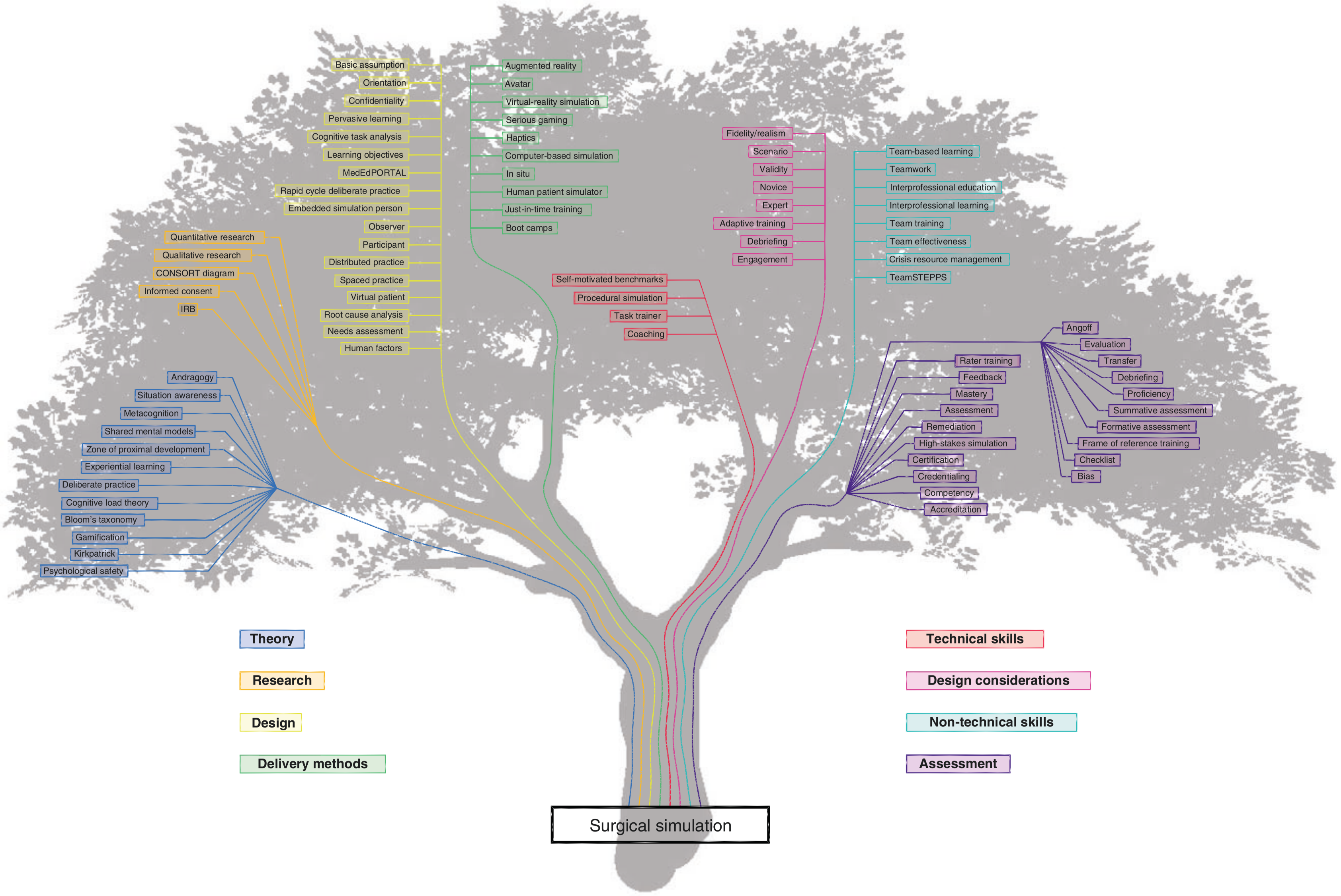

Fig. 1 Taxonomy tree of terms used within surgical simulation, categorized into branches of theory, research, design, delivery methods, technical skills, design considerations, nontechnical skills, and assessment

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Principles of Validity

James R. Korndorffer Jr.

Background

Over the past 15 years, the use of simulation and simulators in medical training and assessment has seen an exponential growth. In part to justify their use, educators using simulation have attempted to evaluate the utility of simulation. Part of this justification focused on "validation efforts." Unfortunately, these efforts have been mostly misguided. The original concepts of a validated test were developed early in the twentieth century when test or skill assessments were used to predict successful job performance. Later, validation was applied to education testing. It was during this period that the concepts of types of validity, construct, content, and criterion were widely utilized. Additionally, during this period, it was the test or tool that was considered valid, not the results obtained from using the tool. These concepts were last supported by the Joint Committee on Standards for Educational and Psychological Testing, comprised of the American Educational Research Association, the American Psychological Association, and the National Council on Measurement in Education in the 1974 "Standards" [1]. However, since the 1974 Standards, the concepts of validity and validation have changed significantly. Unfortunately, in the simulation literature, most investigators have clung to the 1974 concepts instead of those put forth in 1985 [2] and have persisted in the 1999 [3] and 2014 [4] Standards, namely, the unitary concept of validity. There are no "types of validity," but rather all of validity is focused on evaluating if there is validity evidence to support the proposed use of the results.

Unitary Concept of Validity

There are several essential themes vital to the understanding of the unitary concept of validity [5, 6]. First and foremost, the assessments (or simulators) are not valid or invalid. It is the results that are evaluated for validity evidence. The accumulated evidence should support the intended use of the results. As an example, consider a stopwatch that requires winding. If wound appropriately, the time (results) would compare to time on a digital stopwatch. There would be evidence the results are valid. However, if not wound sufficiently, the results would not be the same as a digital stopwatch. There would be evidence the results are not valid. So, the same "tool" or simulator can give results that have evidence for validity or have a lack of evidence. Therefore, it is critical to demonstrate that the results of the use of a tool or simulator have validity evidence not the tool or simulator themselves.

The second key concept is that validation is a hypothesis-driven process. The hypothesis of validity is proven or disproven by the accumulation of evidence. A single study showing the results obtained have some validity evidence is similar to a single clinical trial showing promise of a new cancer treatment. Would you change to the new drug based on a single study? With such evidence, continued investigation would occur; after all, there still is a probability the hypothesis is wrong.

The third key concept is that the validation process requires multiple sources of evidence to be evaluated for a result interpretation to be supported. One of the most

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common pieces of evidence used to evaluate validity of simulation in the medical field is identifying differences between novices and experts. Such evidence is a minimum level of evidence for validity of the results even if the only goal of the assessment was to distinguish between these two groups. However, other factors also need to be evaluated. Was the difference because of familiarity with the device? Was handedness the reason for the differences in results? The initial premise in validation studies, like in other studies, is whether the null hypothesis is true (there is no validity to the results). The goal is to obtain as much evidence as possible to be able to reject the null hypothesis and thus show evidence for validity of the results.

Types of Validity Evidence

There are five key sources of validity evidence. These are evidences based on (1) test content, (2) response process, (3) internal structure, (4) relations to other variables, and (5) consequences of testing. [4] These may, by themselves, seem similar to the old types of validity, but none can stand alone to purport validity of an assessment result; they are simply considered another piece of evidence supporting the intended use of the results.

Evidence for test content in simulation is often based on expert opinion that the simulation content is representative of the desired domain being evaluated. In written tests, this is more easily understood as the test blueprint. Using that as a conceptual framework, how this relates to simulation can be understood easier. If it is determined that to perform laparoscopy, certain skills are required (blueprint for success) such as overcoming the fulcrum effect, functioning in a two-dimensional environment, and performing with decreased degrees of freedom, then these should be the content of what is measured. Other contents outside of the domain, despite a potential ease of ability to measure, would not contribute to the validity evidence.

Evidence based on response processes is often obtained from evaluating the cognitive processes used by the trainee to perform the task. A trainee may be able to "game the system" in a virtual reality simulator if it does not require an appropriate response process. An example was one of the early attempts at virtual knot tying. The trainees were required to laparoscopically create two throws to create square knots. However, the system was set up such that while the trainee thought she/he was performing what they believed was an appropriate process, in fact the same maneuvers outside of the system would tie and then untie a single knot throw. While the "result" was correct, the process to obtain the result was wrong. The response process also includes the evaluator. If the evaluator is scoring an aspect of a performance, it is important that she/he is not influenced by other factors, not related to the criteria. For example, if the criteria to be judged are the result, then the method or time it takes the trainee to achieve the result should not affect the evaluator's scoring.

Evidence based on internal structure focuses on the interrelationship of the components of the assessment and how that interrelationship aids in the measurement of the construct of interest. This is perhaps easiest to understand in written assessments. Items meant to evaluate a certain body of knowledge should perform similarly for a particular group of learners. If not, then the structure creates variability in the results, not the construct of subject knowledge. In simulation, if an assessment of communication skill uses several standardized patient scenarios, then there should be evidence that the variability in the results comes from variability in participant skill, rather than variability of the scenarios.

Evidence based on relations to other variables is the evidence most familiar to educators using simulation. This evidence is what many incorrectly describe as "construct validity." However, all the evidence gathered is used to determine if interpretations of the results truly assess the construct of interest not just how the results relate to another single variable. Most commonly, this evidence is obtained by identifying a correlation between the results and a variable believed to be a surrogate. For example, individuals that perform better technically in the operating room might be expected to have better results on a simulator. While finding convergent evidence as in this example is often where the investigation into evidence based on relations to other variables typically ends, a more complete appreciation of this concept also includes the understanding of the importance of discriminant evidence. Discriminant evidence is obtained when there is a lack of correlation between the results and a construct dissimilar to the construct of interest. For example, if simulation results do correlate to "real-world" experience, convergent evidence is present; but if the simulation results do not correlate to age, gender, or handedness, discriminant evidence is also shown. This adds to the evidence for validity.

Evidence based on consequences of testing is one of the more challenging concepts of validity evidence. This is where the evidence needs to be based on the intended use of the results. Perhaps more importantly, care must be taken to avoid using the results in an unintended manner. If a simulation is developed to identify individuals that can perform safely in the operating room and those with better scores do have improved performance in the operating room, then there is evidence for such use, and the consequences are theoretically improved patient safety. If, however, the primary goal of the simulation is identifying those that need more training, the scores were used so that only high-scoring trainees were allowed in the operating room; such use may lack validity evidence as the consequences would be that those who need the training, the low-scoring trainees, would be prevented from receiving that training through time in the operating room.

Summary

Validity is defined as the "degree to which evidence and theory support the interpretations of test scores for the proposed use of tests" [4]. The evidence needed varies in type and amount based on the intended use of the results. If the intended use is simply training, then little evidence other than proof of correct learning is needed. However, if the intended use of the results is for credentialing, evidence of varying types is needed before such inferences can be made. For educators, using simulation adherence to the hypothesis-driven unitary theory of validity is therefore recommended, as incorrect and potentially inappropriate assumptions of trainee knowledge and skill can be avoided.

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Equipping and Staffing a Surgical Simulation Center

Dawn Swiderski and Ashley Yurco

Abbreviations

ACP	Advanced Care Provider
AV	Audiovisual
CHSE	Certified Healthcare Simulation Educator
CHSE-A	Certified Healthcare Simulation Educator – Advanced
CHSOS	Certified Healthcare Simulation Operations Specialist
CVAT	Central Venous Adjunct Trainer
IP	Intellectual property
IPE	Interprofessional education
SOP	Standard operating procedure
SP	Simulated participants
SSH	Society for Simulation in Healthcare
VR	Virtual reality

Types of Surgical Simulation Centers

Surgical simulation center can mean many different things. Centers vary in size and utilization. The first question to ask when deciding how to staff and equip a surgical simulation center is "what will this center be used for?". Deciding what types of education a center plans to conduct will assist in deciding which type of center will be most helpful. Surgical simulation centers may include wet labs, dry labs, patient simulation labs, or any combination thereof. Key resources required by all these types of labs include personnel, equipment, and learners.

Wet Lab

The term "wet lab" is used when referring to a place where cadaveric or animal models are used for training purposes. Cadaveric training has been used in medical education for many years [1]. For surgical simulation, cadavers can be used for anatomy review or to learn and practice procedures. Full or partial cadavers may be used depending on the educational objectives and budget. The same cadaver may also be used by multiple specialties to practice different procedures, reducing the cost to one department [1]. Learners are able to come into the wet lab and practice performing new procedures on real human tissue.

Wet labs may also provide education utilizing in vivo or ex vivo animal models [2]. In vivo animal models are an excellent way to practice procedures that require blood flow and are often used for research purposes. Ex vivo animals or explanted animal organs can also be used for anatomy review when cadavers are not available or for training on certain procedures that medical professionals may need to practice.

Preliminary studies have shown that while less expensive low-fidelity models are an efficient training method for novice learners, more experienced learners achieved greater improvement with the use of animal or cadaveric models [3]. In vivo animal models are an excellent resource to mimic complications and produce live blood flow but can be expensive, have different anatomy than humans, and cause ethical concerns. While using human cadavers provides the human anatomy that should be studied, they are even more costly than the animal models and typically cannot replicate live blood flow. However, recent studies have shown the possibility of modifying fresh human cadavers to simulate perfusion making these an ideal simulation modality [4, 5].

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Dry Lab

The second type of surgical simulation center is a dry lab. This is where learners can practice procedures on task trainers, discussed in detail later in this chapter. Procedural training is an excellent modality to build cognitive knowledge, practice or rehearse, and assess or evaluate a learner's skill level [6]. Deliberate, repetitive practice has been shown to increase learner retention [7], and in a field as dynamic as healthcare with ever-changing and ever-evolving procedures, this repetitive practice is extremely important. This type of practice can be used for a variety of tasks from suturing to performing surgery on bench models or task trainers.

Patient Simulation Lab

Patient, or high-fidelity, simulation provides a highly realistic and interactive experience for the learner and is a growing resource used by surgical simulation centers to train a variety of healthcare providers [8]. This type of education utilizes mannequins and/or simulated participants (SP) who can interface with medical equipment used throughout the hospital or clinical setting. Patient simulation affords learners the opportunity to practice a wide range of clinical skills emphasizing decision-making and a variety of nontechnical skills including team training. Clinical scenarios and/or procedures that are high risk or infrequently encountered in the clinical environment can be effectively practiced in a low-stakes environment.

Combination

Most surgical simulation centers offer a combination of some or all of these labs. Each of the labs discussed in this chapter is better suited for different kinds of educational offerings. With this in mind, to produce the most effective educational experience, a combination must be used.

Commonly, these labs are combined using procedural task trainers and mannequin-based education. Combining these two modalities increases the capabilities of what learners can practice and offers cost savings. Learners can perform a full physical assessment on a patient and obtain a real-time history before transferring to a task trainer to complete the necessary procedure. This allows learners to treat a patient from start to finish and prevents them from performing invasive procedures on an expensive patient simulator which often has costly replacement parts.

Wet and dry labs are also commonly combined when it comes to surgical training. Laparoscopic surgeons typically begin practicing their skills and techniques on a task trainer in a dry lab to obtain an understanding of how to complete a three-dimensional task while looking at a two-dimensional screen. Once learners have grasped the understanding of how to utilize the instruments and camera in the dry lab, they can transfer this skill to the wet lab to practice performing actual laparoscopic procedures on an in vivo animal model.

Personnel

One of the primary factors to consider when starting a surgical simulation center is what sort of personnel will be needed. Regardless of the position a surgical simulation center is looking for, there are common characteristics and skills which should be present in a candidate. Medical knowledge can be very helpful with any position in the center. People who are assisting with an educational opportunity for learners should have at least basic knowledge of educational content so they can provide appropriate feedback to both learners and facilitators. As simulation can be technologically heavy, it is also important a candidate be comfortable with equipment and troubleshooting problems.

An undergraduate or graduate degree and pertinent certifications or licensures are also important qualities to consider when hiring personnel. This demonstrates an understanding of education and experience which may decrease the time needed for orientation or onboarding of a new teammate. The ideal candidate for a surgical simulation center will also have experience in multitasking, time management, and teamwork. Working with multiple user groups can be very demanding at times and may be stressful; having these skills will allow a teammate to keep things organized and be able to navigate the many elements of the simulation center.

It is not only extremely time-consuming to find new teammates who have the necessary skills, knowledge, and flexibility, but it can also be very expensive. One simulation center alleviated this financial strain by bringing in recent nurse graduates as interns to support some of the simulation sessions by assisting with setup and breakdown, technical running of scenarios, and acting as SPs [9]. Another center used medical students, with proper training, as assistants in a dry lab to extend operating hours through evenings and weekends to allow for a more flexible schedule to accommodate the needs of learners [10]. Doing this not only helped the simulation center save money but also provided these assistants a valuable clinical experience to add to their resume.

Some additional positions a center may consider include volunteers, work-study students, and research interns. These positions are generally unpaid or have a lower hourly wage. People in these positions may be used to assist with setting up or breaking down courses and helping with tasks such as literature reviews or filing.

Orientation and Training

Before a surgical simulation center begins hiring, an appropriate orientation process must be in place. Even if a teammate goes through an orientation with the organization or hospital system the center is affiliated with, a separate orientation should be given to the surgical simulation center itself. This orientation process can be dependent on the person's position and experience level. At a minimum, this process should orient a new teammate to the equipment and labs available for use at their particular center.

Training for surgical simulation center personnel will depend on the teammate's background. There are few simulation training programs, and those that do exist focus on training faculty and clinicians working in the healthcare field, making it difficult for personnel with a strong technology background but no healthcare experience to receive adequate training [11]. A center may choose to do on-the-job training to allow for new personnel to become familiar with equipment at their own pace and by example. There are five different domains that a new teammate should be familiar with: information technology, audiovisual (AV) technology, theater and drama, academia, and healthcare [11]. Depending on the background of the person hired for the job, orientation and training should focus on these topics.

Professional Development

Professional development is also a very large part of hiring someone for a surgical simulation center. The simulation community is growing every day, and, in turn, more continuing education opportunities are becoming available. To promote professional development, teammates may attend small local conferences or large international conferences. Continuing education conferences also offer an opportunity for teammates to present their experiences to the rest of the simulation community. Simulation continuing education conferences are also an excellent way to introduce new teammates to the field of simulation. Many times sessions are available to help those who are new to simulation but have a background in healthcare or technology to assist in bridging the knowledge gap [11].

Certifications are also available to teammates participating in continued education. The Society for Simulation in Healthcare (SSH) offers three different simulation certifications: Certified Healthcare Simulation Educator (CHSE), Certified Healthcare Simulation Operations Specialist (CHSOS), and Certified Healthcare Simulation Educator – Advanced (CHSE-A) [12]. Obtaining any or all of these certifications will validate a teammate's simulation expertise and enhance the education provided to learners by the center. Preparation courses and study materials are available for these certifications.

Positions

Depending on the education a surgical simulation center provides, the positions that it will need to hire for may vary. As a center continues to grow, it may also be necessary to incorporate new positions or have multiple teammates in the same position. Some of the basic positions a simulation center may have include a manager/administrator, faculty, veterinarian/veterinary technician, simulation technologist/specialist, and SPs.

Manager/Administrator

The first position needed for a surgical simulation center is a manager or administrator. Although it is not necessary, this person being a medical professional such as a paramedic, nurse, or surgical technologist is helpful because of his or her familiarity with equipment, instruments, and medical terminology. This position will be responsible for the general operations of the center as well as communicating with learners, facilitators, and other customers.

A manager or administrator may be responsible for the setup, maintenance, and warranties of the equipment and supplies at the surgical simulation center as well as scheduling educational opportunities. These duties require a manager or administrator to be familiar with all aspects of the surgical simulation center to ensure that it operates efficiently. This person will need to be aware of the capabilities of the simulation resources available at the lab so they can best pair the equipment with the needed education, training, and objectives.

Faculty

Each educational experience at a surgical simulation center will need faculty, or someone to provide the education. There may be one faculty member for all courses at the center depending on expertise or different faculty who are subject matter experts for each course. Faculty are typically clinicians but can also be simulation experts.

Faculty should be well versed in the procedure being taught as well as have extensive knowledge of curriculum development and adult learning to ensure objectives are being reached through the session. It is also important faculty be familiar with the supplies being used to ensure equipment and supplies are utilized appropriately.

If participating in patient simulation scenarios, faculty will also need to be well versed in the art of debriefing to ensure all learners understand what went well in the scenario and could be improved. This debriefing gives the learners and faculty time to discuss the objectives of the scenario and its effectiveness; in the proper setting, debriefing is where the majority of the learning occurs [13]. It is also important faculty be cognizant of the psychological safety of participants to ensure that if something goes awry in a case, learners feel they have a safe place to discuss what happened.

When onboarding new faculty members or growing a simulation center, it is suggested that a faculty development curriculum be in place and implemented to standardize education and debriefing styles [6, 14].

Veterinarian/Veterinary Technician

If a surgical simulation center will be using in vivo animals, a veterinarian and a veterinary technician will also be necessary. A veterinarian will oversee animal care, and a technician will be responsible for maintaining the health and well-being of the animal while in holding, during surgery, and postoperatively [15]. Teammates working with animals should be encouraged to obtain certification from the American Association for Laboratory Animal Science to ensure the animals are cared for with the utmost respect and that all regulations are being followed [16].

Simulation Technologist/Specialist

Since many types of simulation are very technology heavy, it may be necessary to have a simulation technician or technologist on staff. This person will be responsible for ensuring the equipment is working properly and maintained. A simulation technologist will also be responsible for programming case scenarios on the computer to run a simulator and ensuring the cases work properly before a user group arrives. Simulation technologists may be asked to assist faculty or other teammates when deciding which technology or mannequin is best suited for an educational course.

Even when high-fidelity mannequins or other technology-based simulations are not occurring in a surgical simulation center, a simulation specialist may be necessary. While faculty members are the experts in the content matter being presented, a simulation specialist would be the expert on the simulation modalities used to present the information. Simulation specialists should be knowledgeable about the equipment located in the center. They may also develop creative and innovative uses for current resources or create new ones.

Depending on the size of the simulation center and the budgeted amount of money for personnel, this could be one joint position or two separate positions with very different roles and responsibilities. If this is two positions, it will be imperative that the teammates work together to best assist faculty members and managers/administrators to offer high-quality education.

Simulated Participants

Simulated participants are people who play the role of a patient, family member, or another healthcare provider [8]. Using an SP is a great way to assess a learner's communication and physical assessment skills. Learners can interact with SPs who are acting as patients to perform full physical assessments, allowing them an opportunity to become comfortable with how to ask the right questions to arrive at a diagnosis and provide patient education.

Family member SPs are a great addition to a scenario to allow learners to practice coping with different family dynamics that may be present in the clinical setting. These SPs can play parents to a child admitted to the hospital, significant others of a battered patient, or family members to whom a provider may need to break bad news. These experiences encourage learners to practice communicating with family members in a respectful and meaningful way that can be interpreted by those outside the medical community.

Healthcare confederates are typically licensed providers who are incorporated into scenarios to enhance realism and add the layer of interprofessional communication and collaboration to a case. Simulated participants can also assume this role if trained appropriately. They can play nurses, first responders, or consulting physicians. Learners will need to not only focus on providing excellent patient care but also appropriately collaborating and communicating with the other providers involved. Should SPs be used in this capacity, they will need to be trained to become familiar with how to respond to cues from learners and facilitators [6].

It is important SPs have proper and adequate training to ensure their involvement is meeting educational objectives. Simulated participants should be familiar with the case they are participating in and feel confident in portraying assigned roles [6]. The surgical simulation center should receive feedback from their learners and faculty members about the SPs used for their scenario to pass along for personal and professional growth. Simulated participants will also need to receive training on any evaluation tool they may be completing for learner assessment.

Fig. 1 Wet lab setup for cadaveric training lab. (Courtesy of Carolinas Simulation Center)

Equipment

All surgical simulation centers will need equipment to implement educational sessions. The type of lab and learners to whom a center will provide education to will guide the equipment needed. Some of the categories of equipment include surgical equipment, specimen, task trainers, simulation mannequins, AV equipment, room layout, and moulage. In addition to procuring equipment, a simulation center will need to research equipment maintenance and repair, warrantees, supply cost, and the innovation options available.

Operating room equipment will also be necessary in a wet lab (Fig. 1). Tables and overhead lights are a few of the basic pieces of equipment that will be needed. Additional equipment will be dependent on the procedures that will be performed. Some other supplies that may be needed for specific courses are power drills, radiology equipment, and laparoscopic and arthroscopic towers. Using in vivo animals will likely require anesthesia machines. Whether a wet lab has cadavers, animals, or both, safety for learners must be a priority. Safety equipment and personal protective equipment will be needed for all learners.

Surgical Equipment

As a surgical simulation center, the most obvious equipment that will be needed are surgical instruments. The types of surgical instruments will be dependent on the types of educational courses that will take place at a lab. Surgical instruments can be very costly to purchase. If budget is a concern for a center, there are a few companies that sell instruments that are made to look and feel like surgical instruments but are not made of the same material, making them more affordable [17]. If a surgical simulation center is affiliated with a hospital, the most cost-effective approach is to establish a relationship with the operating room to obtain instruments that are no longer used in surgery; this approach is discussed in detail later in the chapter.

Specimen

It is also fundamental for a surgical simulation center with a wet lab to procure appropriate specimens. It is very important to use reputable, accredited vendors when ordering and disposing of cadaveric or animal specimen to ensure ethical and legal standards are met. For cadaveric specimens, faculty may choose to order a whole cadaver or only the anatomical part necessary for the specific procedure (e.g., femoral head to toe tip for knee arthroplasty). Vendors should be accredited by the American Association of Tissue Banks demonstrating that they abide by all standards and regulations set by this organization [18]. Paper work with a negative serology report from a Clinical Laboratory Improvement Amendments certified laboratory and demographic information for cadavers must accompany a specimen that arrives at the lab to establish that it is safe to use [19]. Live animal models may be used for acute or chronic procedures. If an acute procedure is being performed, euthanasia and disposal will be necessary; for a chronic procedure, a lab will need an appropriate living space for the animal [20, 21].

Task Trainers

If a surgical simulation lab includes a dry lab, it will need to have task trainers to practice procedures on (Fig. 2). Task trainers are devices used to practice a specific procedure and generally represent a human body part [8]. There is significant variability in task trainers. Many are specific to a procedure and specialty, while others transcend disciplines; their choice depends on local training needs. Task training simulation can allow for a theoretical preparation, introduction to a procedure, self-training, and final practical examination [22].

Virtual reality (VR) task trainers are the most high-tech and, in turn, often the most expensive. There are commercially available VR task trainers for procedures including arthroscopy (Fig. 3a), endoscopy, ultrasound (Fig. 3b), and laparoscopic and robotic surgery (Fig. 3c). The platform of these trainers varies depending on the company that produces them. Many not only let a learner see what it would be like to perform a procedure, but also provide haptic feedback allowing them to experience how the live procedure would feel.

There are also many low-fidelity task trainers commercially available [8]. These range from CPR mannequins or airway heads that can be used for airway management training to central line placement trainers which have the ability to simulate blood flow and are ultrasound compatible. Depending on the features of these low-fidelity task trainers, they can also be very costly.

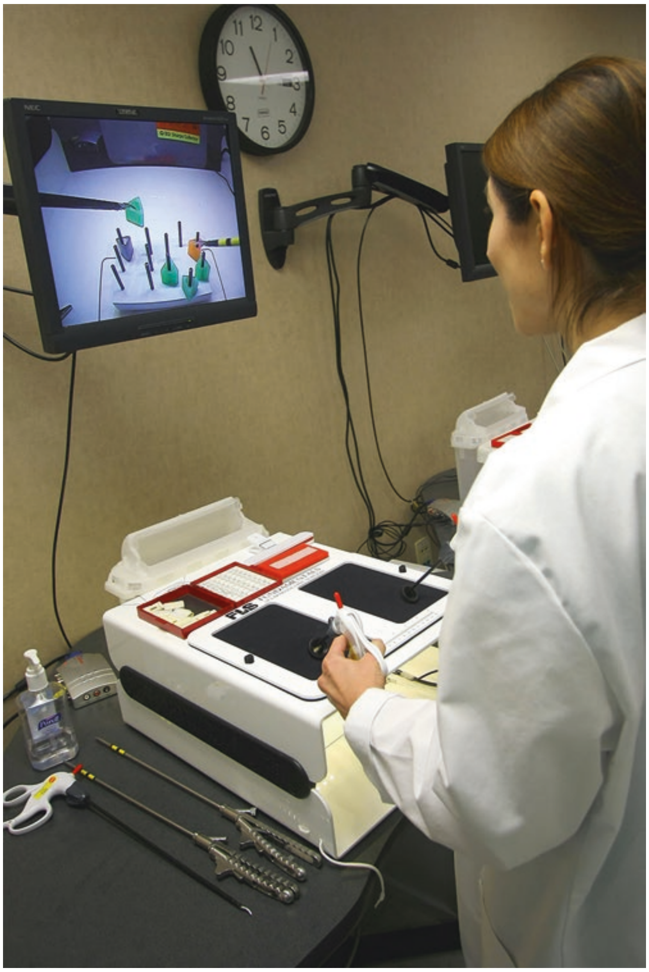

Fig. 2 Using Limbs & Things Fundamentals of Laparoscopic Surgery™ (FLS) task trainer to practice laparoscopic surgery skills. (Courtesy of Carolinas Simulation Center)

Simulation Mannequins

High-fidelity mannequins are generally full-body and can mimic human body functions [8]. The top-of-the-line mannequin is able to have different heart, lung, and bowel sounds depending on the scenario and can have physiological responses such as sweating, urinating, and pupillary responses when appropriate. Many mannequins come with preprogramed responses to questions, and some have medication recognition software which allows them to have an immediate appropriate physiological response to medications. High-fidelity mannequins come in all different shapes, sizes, and colors (Fig. 4a–e). There are premature infants, children, adults, women that give birth, and trauma mannequins that can all be used for different kinds of simulation experiences. There are also multiple companies that make high-fidelity mannequins. Many surgical simulation centers that offer high-fidelity simulation will have multiple mannequins used for a variety of scenarios. Although having multiple high-fidelity mannequins can greatly enhance the simulation experience of learners, it can be cost prohibitive as some mannequins have associated equipment costing upward of $250,000 [23]. This makes it extremely important to conduct a product evaluation, discussed later in this chapter when making the decision to purchase a high-fidelity mannequin. This ensures a lab purchases a mannequin that meets all of their learners' needs. Some key factors to keep in mind when deciding which high-fidelity mannequin to purchase are educational objectives of the program, personnel to run and support mannequins, additional accessories needed, the type of software, and overall cost, including maintenance fees [6].

Fig. 3 Virtual reality trainers including (**a**) Touch of Life Technologies (ToLTech) ArthroSim™ arthroscopic surgery simulator, (**b**) CAE Healthcare's Vimedix™ ultrasound simulator, and (**c**) Intuitive Surgical's ® da Vinci® Skills Simulator. (Courtesy of Carolinas Simulation Center)

High-fidelity mannequins cannot run without a computer or monitoring system. Generally, the system used is dependent on the brand of mannequin that is purchased. Although they share several similarities, different systems have different nuances all surgical simulation center teammates need to be familiar with. These computer systems allow a technologist to control the workings of the mannequin and how it responds to learner interventions.

Not all patient simulators are high-fidelity. There are many medium- and low-fidelity options that can be used depending on the training taking place at the lab. These simulators can have some or none of the capabilities of the high-fidelity simulators. Examples of these are static mannequins that have no interactivity and mannequins that have heart and lung sounds but do not have physiological responses.

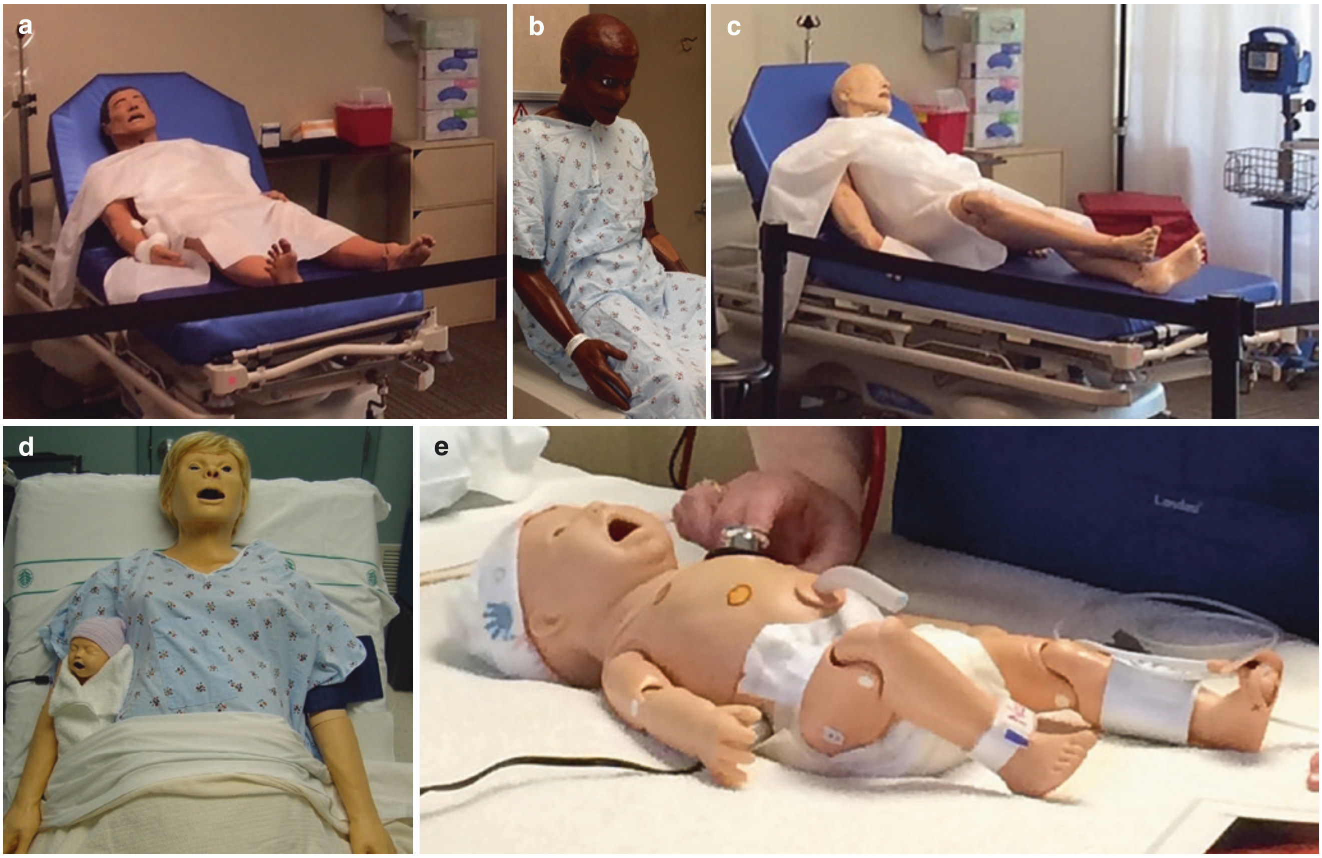

Fig. 4 Full-body mannequins including Laerdal's Nursing Kelly in (**a**) tan, (**b**) brown, and (**c**) light, (**d**) Gaumard's ® Noelle® S550 Maternal and Neonatal Birthing Simulator, and (**e**) Gaumard's® Newborn HAL® S3010 Neonate. (Courtesy of Carolinas Simulation Center)

Audiovisual Equipment

Most surgical simulation centers will also need an AV system to equip their lab (Fig. 5). This will allow for faculty or technologists to communicate with the learners through the mannequin. Doing this adds a layer of realism that cannot be achieved from only using the canned responses that come standard on most mannequins. An AV system can also be used to allow for live streaming of learner performance to a classroom for others to view. With larger learner groups, this is an excellent way for learners to participate in all scenarios even if they are not physically in the room. Live streaming of cases allows for participants who watched the case to give feedback to their peers as to what they saw went well and opportunities for future growth. The difference between the active learning that goes on in the simulation rooms and the passive learning that is occurring from watching the live streaming of the simulations is a great topic of discussion and should be used in the debriefing of the simulation scenario. Many AV systems will also have the ability to record and play back scenarios allowing for assessment and research to be done on specific cases. If performance is being recorded and retained by the lab for purposes such as assessment or research, it is important to inform learners of this fact and assure their videos will not be shared. A surgical simulation center should have a policy or procedure specifying how long they will retain videos, but for research purposes, federal regulations require that all research record be retained for at least 3 years [24].

Room Layout

When setting up a patient simulation lab, it is best to create an environment that mimics an actual patient or operating room utilizing the same medical equipment used in the real patient care environment. This may include patient beds, medication or code carts, and live defibrillators or other medical equipment (Fig. 6). This creates a realistic environment and gives learners the opportunity to practice with the equipment used in the clinical setting. If a surgical simulation center is affiliated with a hospital system, it may be possible for the patient lab to obtain some of the outdated equipment to assist in cost savings. While creating a realistic clinical environment for simulations to take place, it is still important to remember that the primary objective of simulation is education; therefore, a balance between a clinical, educational, and theatrical environment must be achieved [25].

Fig. 5 Facilitators using Laerdal SimView™ computer software and AV system for high-fidelity mannequin-based simulation. (Courtesy of Carolinas Simulation Center)

Fig. 6 Simulated inpatient hospital room with Laerdal SimMan® 3G. (Courtesy of Carolinas Simulation Center)

Moulage

To add realism to a scenario when using patient simulators or SPs, a surgical simulation center may choose to use moulage. This is the art creating artificial bruises, lacerations, or other injuries using makeup, latex, or other supplies. Moulage can be added to the mannequin or SP to demonstrate, for example, the severity of a trauma or to guide learners toward a proper diagnosis (Fig. 7).

Equipment Maintenance and Repair

With high-tech equipment comes maintenance and repairs. Having experienced simulation technicians can make completing these tasks much easier as they are able to be done in house. Most patient simulators come with the option to have a yearly preventative maintenance package. If heavy repairs or maintenance must be done to a piece of equipment, the surgical simulation center may need to send it

Fig. 7 Laerdal SimMan® 3G moulaged as a motor vehicle accident victim for a high-fidelity scenario. (Courtesy of Carolinas Simulation Center)

back to the manufacturer to be fixed. If a piece of equipment needs to be sent back to the manufacturer, the lab may try to negotiate a loaner model as to not disrupt the education offerings that may be planned.

Warrantees Versus Do It Yourself

Warrantees are a great way to ensure that equipment works properly and is kept up to date, but they can be extremely costly and are only available for a limited amount of time after the purchase is made. Some surgical simulation centers may choose to take care of their mannequins on their own to avoid some of these costly arrangements. Before deciding to not purchase a warranty for a piece of equipment, it is important to ensure the teammates at the center are well versed in the maintenance and repair procedure for the mannequin, including how to check functionality and replace parts [6].

Supply Cost

Depending on the type of lab a surgical simulation center has, supplies can be extremely costly, especially when it comes to patient simulators and task trainers. Tracking new tissue sets or replacement costs assists in creating budgets and costing structures for user groups. One way that a center can reduce its supply cost is if they are affiliated with a hospital system, procuring expired supplies that can no longer be used in the patient care setting. This model has advantages for both parties involved; the hospital system does not have to dispose of expensive medical supplies that are no longer in use and the surgical simulation center does not have to make a separate purchase of these supplies. Having this relationship with a hospital also ensures that learners are practicing with the same equipment and supplies that they will use in a clinical setting. Practicing with the same supplies will allow learners to be more comfortable with the kits or items needed to perform procedures on patients. If this is not an option, there are practice supplies available through a variety of different vendors. These practice supplies are made to look and feel like the medical supplies but are less expensive [17].

Innovation

An innovative mind in a surgical simulation center enhances the education a center is able to provide exponentially. As discussed, much of the equipment or supplies used to provide education are very expensive. Innovation is one way to cut back on some of these costs. Teammates are able to create their own simulation models that can be used to produce high-quality education and are less expensive and sometimes more user-friendly. If a center has teammates who are innovators, it is important to establish intellectual property (IP) guidelines ahead of time to ensure all parties are covered legally.

Homegrown Models

One option to alleviate some of the financial burden of having to acquire multiple task trainers is to create homemade models (Fig. 5.8). Cost-effective supplies such as Knox® gelatin can be used to create models that are ultrasound compatible [26], and butcher products are an inexpensive alternative to providing suture practice. The Internet has many "cookbooks" or guidelines to making some of these inexpensive yet realistic task trainers [27–29].

Equipment does not always have to be flashy and new to achieve educational objectives. Simulation teammates can

Fig. 8 Carolinas Simulation Center teammates created a patented adjunct trainer to reduce cost associated with central venous line placement training (Courtesy of Carolinas Simulation Center)

collaborate with clinicians to find gaps in what is commercially available and fill them with their own creations (Fig. 5.9a, b) such as the Central Venous Adjunct Trainer (CVAT) which was created at Carolinas Simulation Center in Charlotte, North Carolina. This adjunct trainer allows learners to place the guidewire in the commercial task trainer and then move to the CVAT to nick and dilate the skin, place the catheter, and aspirate and flush each port preventing unnecessary damage to the expensive tissue sets in the commercial models. Homegrown models also give faculty an opportunity to customize the task trainers to fit the objectives and goals of the course being held. Innovation can also be used to make modifications to current simulation models to enhance the experience for learners.

Intellectual Property

Most companies have rules in place about IP and how it is handled with their employees. If a surgical simulation center is going to create innovations, all teammates involved should be familiar with the IP policy of the center or overarching system. It is important to follow guidelines and to make sure all parties involved are on the same page before moving forward with anything. To protect the IP of the design team, a patent should be applied for early in the process and a log of contributions made by each team member to ensure credit is given to all of those involved in the process [11].

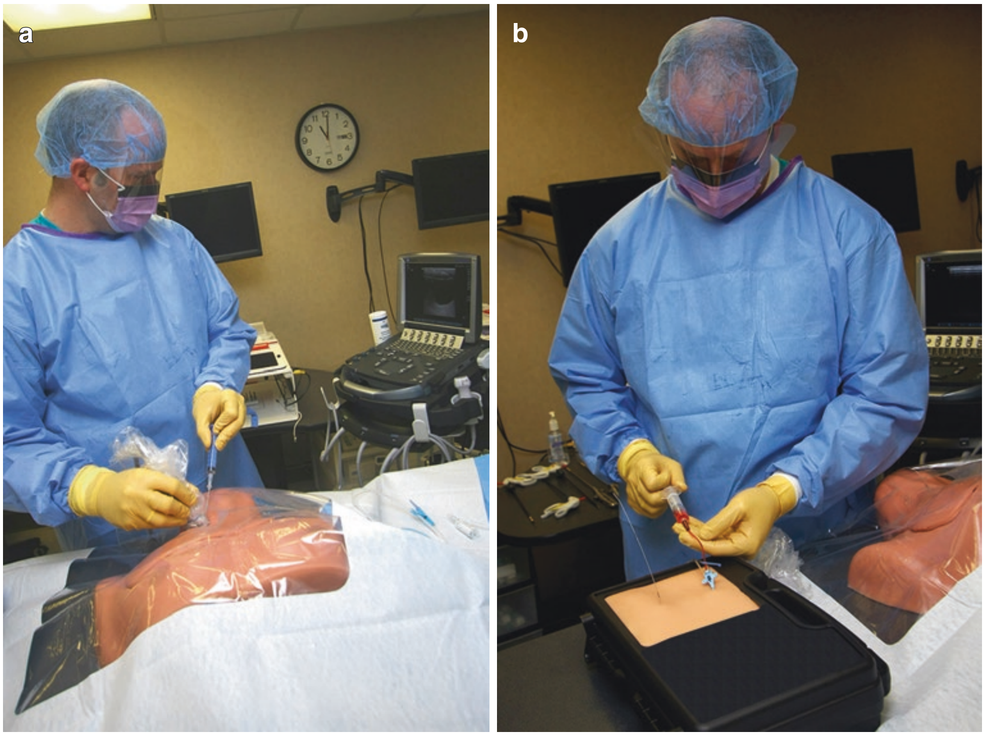

Fig. 9 (**a**) Placing guidewire on SimuLab's CentralLineMan using ultrasound guidance and then (**b**) flushing and aspirating line on the CVAT (Courtesy of Carolinas Simulation Center)

Learners

User groups of a surgical simulation center span across all healthcare providers. Physicians, Advanced Care Providers (ACP), nurses, allied health professionals, and technicians can all benefit from practicing patient care skills in a simulated environment before working with live patients. In addition to healthcare providers participating in educational courses at a center, there may also be research conducted. To ensure that space and resources are being used to the fullest potential, a center will need to track learner usage regardless of what types of learners it serves.

Healthcare Providers

Physicians from medical school through residency, fellowship, and continued education will likely participate in simulation in all previously discussed types of labs. Novice surgeons or those in residency can practice their skills on cadavers to achieve a better visual and haptic understanding of how a procedure should progress. Participants are also able to learn new ways to perform procedures or test new products on cadavers before using them in the operating room.

Physicians and ACPs can use surgical simulation to practice high-risk procedures not commonly done in the clinical setting. Surgical simulation can also be used for certification or credentialing purposes including central line placement [30, 31]. Physicians and ACPs who are new to the clinical setting and practicing providers are all able to use these task trainers to enhance their skills and provide safe patient care.

Several other healthcare providers such as nurses and first responders are also able to utilize task trainers. Basic procedures such as IV placement and airway management can be practiced on commercially available or homemade trainers. Many programs require the learners to demonstrate proficiency of a task using a simulator before being able to complete the task in the clinical setting. This ensures patients are getting high-quality care from new providers. It has been shown that simulation in dry labs not only increases student confidence with repeated practice but also can reduce the risk of harm to patients [32].

Patient simulators afford healthcare providers of all levels the opportunity to hone their decision-making and nontechnical skills and to experience cases not commonly seen in the clinical setting. Further, patient simulators enable faculty to create scenarios around any medical problem to address learning objectives, including code scenarios.

One of the greatest benefits of patient simulation is the ability to hold team training sessions, allowing providers from different disciplines to practice working together as a team in a low-stakes environment. Such sessions enhance communication skills and allow for better understanding of each other's role.

Patient simulation can also be used for interviewing or onboarding new teammates for clinical positions [33]. Departments can use simulation scenarios as a competency during the interview process for new healthcare teammates. Once a new teammate is hired, patient simulation can also be used to orient teammates to equipment, assess performance gaps, and identify and address high-risk situations that may warrant further education [34].

Research

Another focus of wet and dry labs is research. Studies are conducted using both animals and cadavers to expand medical knowledge and test new processes or procedures. Many medical device companies will use a wet lab with cadavers when developing new products to test them and educate the providers who will be using them. Companies may have their own dedicated lab space or work with simulation centers to rent the wet lab. When working with medical device companies, it is important that a lab consult with their legal department to ensure all rules and regulations, such as the Sunshine Act, are being followed [35, 36].

Learner Hours

It is very important to track learner hours to compare the usage of different programs at a surgical simulation center. Tracking these hours allows a center to charge groups appropriately and anticipate future usage and growth. When new or existing customers request to use the center, it can be helpful to look back at previous years' data to anticipate the usage of the center. Tracking learner hours is also a great way to show the impact a surgical simulation center has on healthcare providers within the system, which may be linked to patient care and outcomes. This tracking is also a requirement for a center to become accredited.

A surgical simulation center must choose how it will track learner hours and make sure all teammates are using the same method for documentation and recording. Some centers may choose to only track number of learners and number of hours, while other centers may want to include supplies used, number of rooms, and number of faculty members as well. A surgical simulation center may want to consider accreditation criteria for governing bodies and build usage metrics accordingly. Regardless of how a center decides to track learner hours, continuity and consistency are key.

Resource Management

Once a surgical simulation center has been built, it is important to understand the resource management of how to run a center. Resources that should be considered are utilization and data management such as space and usage statistics; product evaluation and selection including industry contacts, systems integration, standardization, and reciprocity of equipment; and standard operating procedures (SOP).

Utilization and Data Management

Once a surgical simulation center is up and running, it must be decided how to best utilize the space and track data metrics. Although education is very rarely revenue generating, it is still very important to keep track of how the center is used and how the education impacts the learners who participate. Learner hours in the simulation space must be tracked to establish appropriate costing models. Tracking must also be done for equipment maintenance and repairs or warranties that go along with certain pieces of equipment. It is very important to put a good deal of thought into the data utilization and management that will occur at a surgical simulation center from the beginning. Having a coherent plan will ensure that the center can collect data accurately from the beginning and not have to go back and fix things later.

Space

Surgical simulation centers come in a variety of sizes, but space is many times a determining factor of the types of activities which can be performed. Some accrediting bodies have a square footage requirement for physical space. With more and more programs and types of healthcare teammates wanting to participate in surgical simulation, the need for space is often an issue. User groups often must request simulation space months or even a year in advance to secure time for their learners.

When planning the space for a simulation center, one must also consider the storage needs. Adequate storage will be required to house all supplies and equipment when not in use. Not having enough storage can impede on space that could be used for active simulations.

One way to alleviate some of the problems that arise from a need for space is to have the capability to run mobile or in situ simulations. This can range from having a large mobile hospital unit that can be taken anywhere to loading a mannequin in the back of a vehicle to take to the interested learners. One advantage to the in situ model of simulation is that the education takes place where the healthcare teammates will be seeing patients. Learners can use their own equipment and supplies on a mannequin to practice procedures or test new equipment, policies, processes, or codes. Participating in in situ simulations also gives participants an opportunity to practice working with the team members that they work with every day. In situ simulation can be used in any clinical setting to identify latent safety threats and knowledge gaps, improve communication and safety, reinforce teamwork, and assess systems competencies [34].

Usage Statistics

All the information discussed in this section is very important to show the value of a surgical simulation center and to ensure that operations run as smoothly as possible. The problem, however, arises when asked how to best track these metrics. There are many options for how to track utilization or data ranging from very low-tech and homegrown to all-inclusive learning management systems [37–40]. Many centers that are just starting out can use an Excel or Access document to track usage, but as they grow, a more advanced system will need to be put into place.

Product Evaluation and Selection

As discussed earlier in this chapter, there are multiple companies from which a surgical simulation center can obtain equipment or supplies. Performing product evaluations is a great way to try out equipment before purchasing and to build industry contacts. Further, it can prevent unnecessary cost to the healthcare system by not allowing weak products to be used clinically. Conducting these product evaluation or selection meetings can encourage systems integration and continuity if the center is part of a larger institution.

Reciprocity is another important aspect to consider when discussing product evaluation and selection. The simulation center can test new supplies or equipment, and the company receives feedback from the simulation and healthcare teammates. This may also be a way for centers to receive free or discounted products.

Industry Contacts

Industry contacts are the experts on the products they represent. Companies typically have local or regional representatives who are happy to bring their equipment to a surgical simulation center for a demonstration. Having the representative come to the center allows for all teammates to participate in the demonstration and interact with the piece of equipment. This is also a perfect time to ask questions about the equipment. Having a close relationship with industry contacts can be helpful even if a center is not in the market for new equipment. They are often knowledgeable in equipment repair and may have extra demonstration models that could be used as backup or additional equipment for large courses.

Systems Integration

Simulation can be used to integrate a new product or process into a larger hospital system. A surgical simulation center with mobile capabilities can take a product that is being introduced into the system and provide demonstrations and training for providers in a low-stakes environment. This ensures providers are comfortable with new products and all providers are receiving adequate and consistent education. Simulation can also be used to design, test, and enhance system processes to decrease human error and increase patient safety [6].

Standardization

Having standardization of products is one of the greatest outcomes of a product evaluation or selection. Performing a well-thought-out product evaluation at a surgical simulation center will allow for healthcare teammates from different disciplines and specialties to test the products before a decision is made regarding purchases. Getting input from a wide range of healthcare teammates is important, especially when making decisions to purchase new equipment or supplies for standardization across a large system. Having this continuity ensures that patients will receive similar care regardless of what location they go to within a system. Standardization of products also assists with providers who float between locations, ensuring no matter the facility, they know how to properly use the equipment.

Standard Operating Procedures

To ensure that the education being provided at a surgical simulation center is of the greatest quality, an SOP manual should be in place [41–46]. This document will lay out the policies and procedures of the center for teammates, learners, and administration. An SOP should be a fluid document that is updated as needed and reviewed on a regular basis. All teammates should be familiar with the SOP to ensure continuity with learners. The SOP for the surgical simulation center will typically be in conjunction with the SOP or policy and procedure manual of the larger institution that the center falls under; it is advised to clear the center SOPs with the institution's legal department to ensure that the document will be enforceable [6].

Required Documentation for Accreditation

Accrediting bodies require a written SOP manual with a formal approval process for each policy or procedure. The document should also be cohesive and easily accessible either in a written or electronic format. It should be organized, indexed, complete, and coherent. If a surgical simulation center is affiliated with a larger institution or hospital system, it is acceptable to reference the parent institution's policies or procedures, but this should be explained in a separate document. Accrediting bodies look for a manual that is detailed enough that a reader with no knowledge of the center could understand what is expected of the faculty, staff, learners, and the organization as a whole.

Required sections of this manual by accrediting bodies include quality improvement process, confidentiality procedures, mechanisms to protect and address physical and psychological safety of individuals involved in simulation, appropriate separation of simulation and actual patient care materials, and storage and maintenance of equipment and supplies. Other things that are expected to be included by centers applying for accreditation are information on curriculum design, the learning environment and activities, and ongoing curriculum feedback and improvement. These topics ensure that learners are receiving the highest quality of education possible.

Other Topics to Include

Although a good place to start, the requirements of an SOP manual are by no means an all-inclusive guide of what this document will need to include. The first thing to include in this manual is the mission and vision of the surgical simulation center; this will set the stage for what the rest of the document should support. An administrative overview should also be included. This may speak to leadership, organization, and budget process for a center. It is important to include operational procedures regarding scheduling, new learners, and team member orientation and professional development as a general overview to all who are interested in conducting simulation at a center.

Larger SOP manuals may include a separate section for faculty, learners, and teammates. This is also a good place to house procedures related to equipment and supplies within a center including how these items are procured, who is responsible for them, and where they are stored.

One of the overarching goals of the SOP manual will be to ensure that policies or procedures are in place to protect the psychological and physical safety of the learners at the surgical simulation center. Topics to include are video retention and storage, resolving customer complaints, and information about live equipment being used, if applicable.

The most important thing to remember when it comes to creating an SOP manual is that it must be followed. If a center is not able to follow the policies and procedures that are set out, they must be reviewed and edited or removed. This ensures the integrity of the center.

Budget and Cost

In order to equip and staff a surgical simulation center, financial support is required. Whether starting a brand-new center or creating an annual budget for an existing center, a keen understanding of the cost associated with a surgical simulation center is imperative. This budget should reflect the sustainability of a center including the expenses and revenue. A fee structure or costing model should be established and reviewed on a regular basis to support the center's budget.

Budget

The budget for a surgical simulation center is extremely variable. Building or upgrading a center can cost millions of dollars [6]. The amount will depend on the types of labs and simulation modalities a center will include, types of education provided, and number of teammates employed.

A capital budget will need to be created for high-cost items that will depreciate over time. Classification of what is part of the capital budget will be up to the governing body of the center or the institution under which it falls. This budget will typically include simulators, medical equipment, and center renovations [6].

An operating budget should include the revenue and expenses expected for the surgical simulation center, typically in a 5-year plan. This budget should include any revenue generated, personnel costs including benefits, services and supplies purchased, and any required maintenance fees. A monthly financial report should be closely monitored to ensure the center is operating at or under the approved budget to ensure sustainability.

Sustainability

Once a surgical simulation center is up and running, it must continue to be sustained. The support of simulation champions and key stakeholders will be extremely important in providing this sustainability. These are individuals who not only use the simulation center but also promote and help it grow. Champions and stakeholders may sit on boards or steering committees for the center and will spread the word about simulation-based education throughout the healthcare community.

If the surgical simulation center is part of a larger organization, it will be imperative to have the organization's support especially for funding and buy-in. Funding and the budget for the surgical simulation center may funnel up through another department within the larger organization such as medical education. Having budgetary support and approval of this department will increase the sustainability of the center as well. Having this organizational support is one way to guarantee that there will always be users of the surgical simulation center to sustain it. A hospital-based center may encourage teammates to utilize the resources available to enhance patient care.

Expenses

When establishing a new surgical simulation center, start-up costs can be extensive. The initial purchase of space, equipment, and supplies will likely be in excess of the annual operating budget. Some things that will continue to be included on the annual operating budget will be payroll, equipment maintenance, and disposable supplies. If a center is planning on being accredited or sponsoring teammates to get simulation certifications, these fees should also be included in the annual budget.

Revenue

Many centers receive some if not all of their funding from the institution they belong to such as a medical school or hospital system. Having this source of funding allows for better financial stability but not a lot of revenue generation. The expense of operating simulation sessions for the education of learners falls primarily on the parent institution in this model, as external funding can be rare.

If a surgical simulation center is not fully funded by an institution or is solely department based, there is the possibility to receive funding from multiple sources. Some centers may be able to partner with local institutions or departments that may be interested in using the center for education and training purposes.

Grants

Grants can come from the local, state, or federal government. Government grant funding is typically applied for or requested by a surgical simulation center to cover the cost of a specific project or initiative. Receiving government grants can bring a lot of positive value and attention to the simulation center but can also be very time-consuming and competitive.

Grants can also be received from corporations or foundations. Qualifications for these types of grants are more focused and are typically for specific pieces of equipment [6].

Philanthropy

Philanthropic support can come to a surgical simulation center from private donors in the form of restricted or unrestricted donations. Restricted donations must be used for a specific purpose, and unrestricted donations can be used for anything the center may need at that point. This type of funding is especially useful for start-up and expansion of a center.

Creating a Fee Structure

To generate revenue or to show the educational value to a larger institution, a surgical simulation center must have a fee structure in place. Creating a sustainable fee structure can be broken down into five phases: evaluation of programs, understanding of broader implications, developing a strategic approach, generating the fee structure, and final analysis and decision-making [6].

The first step to evaluating a program interested in the space is to identify what exactly the requestor is interested in and what resources will be needed, including teammates, physical space, and equipment. Established centers may also find it useful to evaluate a program's past utilization and expected growth to adjust pricing as necessary.

When creating a fee structure, a surgical simulation center must also have a good understanding of broader implications and the expectations of the larger institution or governing board. Depending on whether the center is expected to be a mission-supporting cost center or a revenue-generating department makes a difference in how the fee structure will be created [6].

The way a center develops its strategic approach to a fee structure can vary. This can include flat fee, hourly, or per participant pricing. Some centers may decide to choose one of these pricing models and then add additional fees for resource- or time-intensive courses. Decisions on which type of fee structure to implement should be discussed with the key stakeholders of the surgical simulation center and be accompanied by a fair market analysis.

To create the actual fee structure, a center must calculate the per hour cost of a simulation [47]. After finding this, the cost per course or per student can be calculated. From this leadership of the center can adjust costs of programs with markups or discounts as they see fit. Once these steps are done and the fee structure is finalized and approved by leadership and stakeholders, it can be implemented.

Tips and Tricks

Starting a new surgical simulation center or undergoing a large expansion of a current center can be extremely stressful. One of the best ways to learn how to do this is from someone who has been successful in the past. Reaching out to other simulation centers and asking them how they did it can be a great way to get ideas. There are also message boards, blogs, or alliance groups available through different simulation accrediting bodies [48–51]. Across the simulation community, there have been many lessons learned and some helpful tips and tricks for dealing with things such as technology, learner response, scenarios, debriefing, and faculty development.

Technology

To offer the highest quality of surgical simulation, a center will inevitably have some degree of technology. When working with technology, there is always the potential of the technology failing. Therefore, teammates should always have a backup plan. If the technology suddenly stops working, the teammate should be able to do some basic troubleshooting to try to get it back up and running. If this does not work, there should be a plan to continue the scenario or education using different equipment or other options that are not reliant on technology.

Learner Response

Although simulation has been around for quite some time, it is still a new modality of training for many facilitators and learners. To ensure that everyone has a positive experience at a surgical simulation center, buy-in is extremely important. Engaging learners in the education provided is the best way to receive a positive learner response, but this is not always the case. At times, faculty may need to tailor the education to specific learners to increase their buy-in of the simulation environment. It is very important to not let one learner's response negatively affect the education provided to the rest of the user group.

Scenario

It can sometimes be difficult to create appropriate scenarios for patient simulation. Although reusing scenarios is one way to save time, they frequently need to be adjusted or customized depending on the user group. Making sure the objectives are being met and the scenario is within the scope of the healthcare teammates participating is a necessity. Reviewing scenarios and going through a dry run before a user group arrives will assist in ensuring everything runs as smooth as possible. Prepackaged scenarios can also be purchased or even found online [52–55].

Facilitators and technologists must also decide if it will be more efficient to run the scenario "on the fly" or use a preprogrammed scenario. Running a scenario "on the fly" allows for changes to be made in the moment based on how the facilitator thinks the learners are progressing and allows quick adjustments in response to unexpected learner actions. On the other hand, there is more room for error when using this option. For example, a facilitator could change some vital signs but forget to change other associated vitals taking away from the realism of the scenario. Preprogrammed scenarios are great for many situations but can be more difficult to alter if things do not progress as expected [6], a challenge not uncommon when dealing with a variety of learners from different disciplines.

Debrief

There are many styles of debriefing simulation, but no matter which a center or faculty uses, they are all an art. The debriefing is many times where the participants learn the most. They get to hear from the faculty and their peers as to what went well and what opportunities for growth were present. A surgical simulation center should have some sort of debriefing training for new faculty or facilitators, and teammates should encourage seasoned faculty to grow their debriefing skills to properly facilitate the discussion. Teammates should also feel comfortable enough to step in and assist with debriefing or facilitate conversations (please also refer to Chap. 11).

Faculty Development

As a surgical simulation center grows, so will the amount of faculty required to facilitate the education offered. Having a faculty development plan or modules can assist with ensuring all learners are receiving the best education possible. Faculty development may be in person or rely on online training, including assigned readings and discussion boards, videos, and observation opportunities.

Faculty members should not only be well versed on the topic that they are teaching but also on simulation and adult learning theory. A thorough orientation to all equipment and supplies should also be included in faculty development to ensure faculty familiarity and equipment functionality. Having simulation champions available to act as mentors to new faculty members can be helpful throughout the orientation or development process.

Future of Simulation

As with other aspects of the healthcare field, simulation education is ever evolving. As simulation grows and more research is done on the topic, the amount of programs using this modality of education increases. Some of the expected growth opportunities for simulation are an increase in hybrid simulation used for interprofessional education (IPE), augmented reality, and telesimulation.

In its simplest form, hybrid simulation is any experience that incorporates two or more modalities of simulation [8]. This could be achieved in many different ways, including using a task trainer or VR in conjunction with an SP or high-fidelity mannequin. Hybrid simulation can be used for all learner groups but may be the most beneficial for IPE situations. Interprofessional education brings learners from two or more professions together to learn about, from, and with each other [8]. Incorporating hybrid simulation into IPE may make it easier for healthcare professionals to collaborate on one patient's care together [56]. For example, a physician could be placing a chest tube, and a respiratory therapist could be intubating on separate task trainers, while a nurse performs a physical assessment. Recently, hybrid simulation has been used to create more realistic IPE for a trauma team by combining a surgical cut suit with a high-fidelity mannequin to allow participants to practice invasive procedures that would typically have to be completed on a separate task trainer [57].

One form of hybrid simulation is augmented reality. Augmented reality is a type of simulation that incorporates VR into the real-world physical environment [8]. Augmented reality is one cutting-edge way to bring an increased sense of realism to simulation-based education. This type of medical simulation could potentially be used for learners across the spectrum of healthcare professionals and assist in creating a more realistic environment to increase buy-in from learners and facilitators. One study investigated the incorporation of Google Glass™ into high-fidelity simulation and found 80% of the students recommended continuing with this modality [58]. Unfortunately, as found in an integrative review paper, there is a lack of published material regarding the learning theories or strategies used in augmented reality simulation [59].

The definition of telesimulation proposed to the SSH is "a process by which telecommunication and simulation resources are utilized to provide education, training, and/or assessment to learners at an off-site location" [60]. This cutting-edge simulation technique allows for learners and facilitators to participate in simulation-based training sessions from anywhere around the world, increasing the potential for collaboration and growth of simulation in rural communities. Telesimulation has even been used in a cross-cultural simulation setting allowing participants from different countries to participate in simulations and debriefings together [61].

Conclusion/Summary

This chapter has provided a basic overview of how to equip and staff a surgical simulation center. By having a better understanding of the different types of labs and the personnel, equipment, and learners for each, readers should be better prepared to effectively create or improve the operations of their own center. While not all-inclusive, this introduction to resource management along with some helpful tips and tricks should assist in establishing or enhancing surgical simulation in a healthcare setting.

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Funding Models for a Surgical Simulation Center

Jennifer A. Calzada and Farrah Leland

Introduction and Background

The current trend in simulation center development is to build a center with funded infrastructure and initial capital. The funding methods to support ongoing operations are more variable and can be a struggle unless the center is one of the rare centers that have sustainable financial resources. That puts significant upgrades or expansions nearly out of reach for many centers.

The source of funding for its continuing operations is often overlooked but an important consideration when establishing a simulation center. As with any business, a plan should be developed based on the needs of the program and the resources of the institution. In order to develop a comprehensive business plan to sustain the center, it involves understanding your current partners and potential partners and navigating a complex system to bring these partners together.

General Themes for Funding

Fee for Service, or Cost Center One commonly used funding model is the fee for service model, also sometimes called a cost center or recharge model. A cost center is a part of a company or organization considered as a unit so that the cost relating to it can be calculated separately for the company's accounts [1]. Since fee for service is also commonly used for physician payment in delivering healthcare, we will use the term cost center in this chapter. A cost center model usually has an internal fee and external fee.

Internal – An internal fee for service model requires that all users within the system or organization be charged the same internal rate. The internal rate is usually set annually by dividing the annual costs to provide the service by the estimated total annual usage. The methodology for determining the costs and usage varies from center to center. Your institution may have a specific methodology for calculating internal costs, which sometimes may be limited to passing on hard costs only, often called recharges. Some examples of costs that should be considered are salaries (with benefits cost) for key personnel to run the center, depreciation of equipment, travel, and supplies. Usually, a center would have several different rates depending on the type of service or activity being provided. For example, you might have a rate for those that just want to use a certain piece of equipment and don't require a simulation technician to run it and a rate for users that want to use your entire center, staff, and multiple pieces of equipment/simulators. The users in the example would get different rates because the resources needed are different. When calculating usage, break out your activities and services, and determine the unit base (e.g., hour) and how many of those units your project will "sell" during the year. An example of the usage calculation for a high-resource simulation might be:

				Units sold
Rate #	Name	Short description	Unit base*	Proposal estimate
1	*High-fidelity simulation*	High-tech models with instruction	Hour	780

*Rate #1 unit estimate based on usage of five times per week, 3 h per session

Some limitations of having a cost center or recharge model are that you must charge that fee for users that use the center, regardless of a department's ability to pay. You

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cannot just charge those departments that have grant funding to pay for it; you must charge all departments or divisions that utilize the same resources. For this reason, many centers opt out of this model as it may discourage some usage due to lack of funds. Some institutions also may not allow a simulation center to be an internal cost center for the same lack of funding reason but instead may consider the center's expenses a *cost of education* to the overall institution. Before exploring your rates for a cost center, you should confirm your ability to use this model with your administration.

External – An external fee for service model has more flexibility in the way it is structured. Non-federal external user rates do not have to be cost-based like internal user rates. Or in other words, you can set a rate to recover at least the cost of providing the service and apply additional charges like overhead rate, surcharges, sales tax, and in some cases a built-in profit rate. Market demand will help set your external fee structure. The only real limitation with external fee for service is that depending on the structure of your organization, you may still need to consider potential compliance issues around whether your rate is at fair market value. In addition, if a center charges external users, your institution could be subject to additional taxes based on unrelated business income tax (UBIT). UBIT can be a concern for nonprofit educational institutions; therefore, you should again verify with your administration the availability of this type of charge.

With both the examples above, your options will be the most limited and prescriptive if you are part of a federal or state institution. Private, nonprofit institutions of higher education will have less restrictions, except with regard to the overall institution maintaining nonprofit status. For-profit, private institutions will have virtually no restrictions, other than what the market will bear.

Certifications (CME, CEU, ATLS, MOCA, BLS, ACLS, and More) Another variation of fee for service is running certification courses at your simulation center. This variation differs slightly in that you are most likely charging (or internally recharging) learners on an individual basis. The rate planning should be the same, considering your expenses for supplies, personnel, equipment, and space usage and any additional expenses to provide the certification. Again, your institution will likely determine if you are able to include any built-in profit rate. Table 1 shows just a brief overview of potential certifications.

Where do you start if you want to offer certification courses? A good place to start is with any certification courses already offered for your own internal learners. Do you offer CPR classes for your healthcare professionals, residents, or medical or nursing students? Opening these up to external audiences is an easy start.

Next consider what subject matter experts you have at your institution. If you are a medical college only, starting with those aimed at physicians and residents is key. Same for a nursing college, start with nursing certifications. If you are comprehensive health sciences center, then numerous options exist for physicians, nurses, and allied health professionals.

The key considerations to offering certification courses are:

- Ensure you have the access to the required subject matter experts, either on staff or paid independent contractors.
- Determine required resources from the authorizing authority.

Table 1 Overview of certifications

Certification	Demand	Availability	Complexity to offer	Audience
Various AHA CPR classes (BLS, ACLS, PALS)	High	High	Medium	All healthcare providers with patient care roles
ATLS (Advanced Trauma Life Support)	Medium	Low	High	Surgeons, EM physicians, physician extenders
PHTLS (Prehospital Trauma Life Support)	High	Medium	High	Prehospital
NRP (Neonatal Resuscitation Program)	Low	Low	High	Those working with neonates
ALSO (Advanced Life Support for Obstetrics)	Low	Low	High	Those working in obstetrics
ATCN (Advanced Trauma Care for Nurses)	Medium	Low	Medium	Nurses working in critical care
TNCC (Trauma Nursing Core Course)	Medium	Low	Medium	Nurses working in trauma care
TCCC (Tactical Combat Casualty Care)	Medium	Medium	High	Military, prehospital
FES (Fundamentals of Endoscopic Surgery)	Medium	Low	High	Required for all graduating general surgery residents as of 2018
FLS (Fundamentals of Laparoscopic Surgery)	Medium	Low	High	Required for all graduating surgery residents
FRS (Fundamentals of Robotic Surgery)	Low	Low	High	Not currently required
MOCA (Maintenance of Certification in Anesthesiology)	Low	Low	High	No longer required, but optional to maintain certification
CME (Continuing Medical Education)	High	High	Varies	With support from an accredited CME provider, almost any educational opportunity can offer credits
CEU (Continuing Education Units)	High	High	Varies	Same as CME, but offered for nurses and allied health

- Determine start-up process, costs, and timeline.
- Determine *allowed learner costs* or check the *average market costs*.
- Plan a sample course budget based on learner charges and course expenses.
- Compare any start-up costs to any per-course profit to determine how many courses and how much time it will take to recoup those costs.

Based on your budget, you may determine a specific certification is not a viable option for your center. This process should also be repeated on an annual basis to ensure that total revenue has not slipped or expenses increased that make a course no longer profitable. It is easy for these numbers to slip unnoticed unless you regularly review course-by-course budgets.

Philanthropy Supported Philanthropy support is funding through a donation of money by an individual, trust, foundation, or company. Philanthropy support might be the most sought-after way to fund a simulation center. When a donor gives the gift of cash and they do not place limitations on the way it can be used, it opens many doors for a simulation center. Those centers that are funded solely on philanthropy may not feel the same pressure of justifying the need for their existence every year during budgeting time. Philanthropists are usually looking for a *great cause* or something that really pulls at the heartstrings (like curing a disease), while the education and training that a simulation center provides are perceived to be something that should already be supported by the institution. Likely for this reason, philanthropy funding is difficult to secure.

Unrestricted Versus Restricted Gifts An unrestricted gift is a gift that may be used for any purpose because the donor did not specify a specific use or place any restrictions on the use of the funds. Unrestricted gifts allow flexibility on how to use the funds and are preferred because they do not put limitations on how the center can use the money. Restricted gifts are those where the donor specifies a specific purpose or type of use of the gift. All gifts are a welcome addition to your budget, but if the restricted gifts can be directed toward the purpose of supporting operations of the simulation center, then you have some flexibility in the way you spend it.

Endowment Endowments are gifts that are invested, and any income generated from that principal investment can be used to fund the program identified by the endowment. The principal or endowment amount is never spent and continues to grow over time and generate a steady source of income. Many donors choose to name endowments to honor their family or create a personal legacy. Since you are limited to spending only the generated income, many organizations have minimum amounts to establish an endowment. Your institution will also set the percent of the endowment principal that your center is allowed to budget for annual spending. Current endowment spend rates are generally 5%, meaning a $250,000 endowment gift will give you $12,500 in annual funding.

Hospital/Health System Funded Simulation centers that are funded by hospitals or a health system usually include operations costs in the funding model. However, the amount of funding varies greatly, and the variances could be dependent on whether the trainees are hospital/health system employees, types of courses, and funding availability. Some of the funding allocated may be in-kind such as capital infrastructure or sharing personnel. As with any of the other models, scrutinizing costs and showing value will be important to the continuation of funding. Health systems want to see a return on investment (ROI) which is difficult for simulation centers. Simulation is expensive and it is challenging to show a direct relation to ROI for all programs.

Health systems can be large and are often geographically spread over a city or cities which can also create challenges. If your simulation center serves a health system and you only have one physical site, it will be imperative to determine your funders' expectations for training across sites. This complexity creates a justification for additional funding from your health system.

School of Medicine Funded Most school of medicine-based simulation centers receive some level of funding support for ongoing operations, sometimes to cover the costs of medical student and resident education as a cost of education. However, these same centers may still feel pressure from administration to control costs.

Centers may be allowed to pass on *recharges* to other departments to help offset some or all costs of providing simulation training for that department's courses, residents, or faculty. However, this determination is almost always a senior administration decision as to whether it's even allowed.

Another possible, although rarely used, avenue to recoup ongoing operational costs from simulation education can be a *fee* (similar to a lab fee) added to each medical student's tuition costs. There are some considerations for instituting these fees. First, private medical colleges with high tuition rates may feel it will be a detriment to recruiting high-quality medical students. Second, students themselves may already feel a simulation center should be an institutional cost, same as classrooms or libraries. Lastly, this would not cover any costs for residents and fellows, which can be higher per person costs due to more complexity in training.

Grant Funded Grant funding is especially desirable in academic settings as it is often a measure of scholarly achievement. Grants are non-repayable funds disbursed from one party to another. Grants usually require an application and identify deliverables and scope of work for the project being funded. The type and category of a grant such as federal, non-federal, or internal depends on the source of the granting agency.

Federal – A federal grant is disbursed from a federal agency to a recipient to carry out a public purpose of support or stimulation authorized by a law of the United States. Common federal sources for simulation centers include Agency for Healthcare Research and Quality (AHRQ), Department of Defense (DOD), National Institutes of Health (NIH), or National Science Foundation (NSF), to name a few. The current funding climate makes federal grants highly competitive, with success rates on applications often around 10–15%, and the application process is often highly complex and resource intensive to complete.

Non-federal – There are a large number of nonprofit organizations and for-profit businesses that provide grants. Foundation support is a common source of this type of funding. Foundations that are known to support simulation projects include both the Robert Wood Johnson Foundation and the Macy Foundation. It is important to determine a foundation's primary funding areas, as most often have specific areas of interest. Competition for funding from large national foundations can be just as steep as federal grants. Consider looking at local and statewide foundations in your area as well; the funding may not be as high, but neither will the competition.

Internal – Many institutions have internal funding opportunities. The benefit of an internally funded grant is there may be limited competition due to the nature of the type of grant. That said, internal grants are also usually for smaller funding amounts than the larger federal and non-federal sources.

State Funded Many states also offer grants or state government funding available to support or supplement education, social welfare, work force development, science, or other programs.

Hybrid Funding Model The majority of simulation centers currently have multiple sources or hybrid funding models. Hybrid funding offers the same critical diversity in funding that you want in your investment portfolio. Reliance on only one source of funds, even your own institution, puts a center at future risk when funds are less available or priorities shift to other programs or projects.

While a hybrid model diversifies your funding, it also creates challenges. For example, if a center is funded by both the health system and a school of medicine, which learners have priority? If your center relies on some external fees and internal users do not pay a fee, do external users take priority over internal users? As centers have increased utilization and space is limited, determining your prioritization for use of the center is an important consideration. Your center may also be asked to produce data on who, what, and how long the different types of learners are using your center. Depending on the funding portfolio of the center, ensuring that the funding received is equitable in relation to the funding source by collecting data to be able to show your funding source may be necessary in a hybrid model.

Cost Savings

Simulation centers are expensive, not only at start-up for infrastructure and capital purchases but also for ongoing operations. Due to the intense amount of resources needed to keep centers running, they are always looking for ways to reduce, or at least control, costs. While increasing funding is always preferred, reducing required costs can equally help balance a budget to a desired margin or breakeven.

The key term is reducing *required costs*. If you budgeted for an expense, for example, $5000 per year for central line kits, then reducing that cost by any amount is a savings. However, what can often happen is simulation centers are offered a *great opportunity* for retired equipment or expired supplies that were not planned for or budgeted. These examples may not be actual cost savings and could cost you additional unbudgeted money to maintain and operate.

Expired Supplies Donations of expired supplies are a great way to save on costs. If you are affiliated with a hospital or clinic, talk to materials management department or supply warehouse as to whether you can get first pick of any supplies that have expired, been opened and not used, or just no longer are going to be stocked. Many supply companies will also donate expired supplies and materials. It will be important to follow all compliance issues around the use of the supplies for education, for example, appropriately marking expired suture with "Not For Human Use" and ensuring that realistic bottles of drugs are also marked, emptied, and replaced with sterile water.

Expired supplies can be one of the single largest and easiest to maintain cost savings for a simulation center. Nearly all hospitals or clinics will have supplies that regularly expire or become unsterile for their use. If you provide any training for these institutions, you will have the added benefit of having the same brand. However, as stated above, be cautious that the expired supplies are actually budgeted for supplies and are actual cost savings. Be certain that they don't cost you additional unbudgeted money to make them functional or that the manpower involved in salvaging or sifting through them ends up costing you the same as if you purchased them directly.

A word of caution on expired supplies. It can be easy for the flow of supplies to overwhelm your staff in the frequency and volume of donations. You will need to balance controlling this flow with ensuring that you are not missing specific, critical supplies you use frequently. Depending on the size and volume of your healthcare partners, you may want to either establish a list of supplies you will take or just *take it all* and sort out what you need.

Become a Hospital Cost Center Depending on your institutions' relationship and hospital policies, you may be able to have your simulation center established as a cost center within the hospital's inventory system. You would become just another department, same as Anesthesiology. This may allow you to take advantage of your partner hospital's volume pricing for those supplies that rarely expire. The one drawback is you would be limited to those supplies that the hospital regularly orders.

Retired Equipment Just as you do for supplies, you may sometimes have the opportunity to acquire equipment that is being retired or replaced. This can be a large, capital savings, as long as it is a piece of equipment that you already intended to purchase. Common examples are operating room tables, stretchers, defibrillators, ultrasound machines, video laryngoscopes, laparoscopic towers and cameras, endoscopic cameras and scopes, and even the rare robotic surgery machines. The drawback is this equipment will often be heavily used, not the most current version, may require servicing, or may even be so dated the manufacturer will no longer support with service. All these criteria should be considered before accepting retired equipment.

Advanced Funding Opportunities

Larger and more established simulation centers will often be in a position to take advantage of the more advanced funding opportunities. Some of these will also require other institutional resources outside of the simulation center, but they can be some of the most consistent sources of funding.

Patents, Licensing Research and work done by faculty and staff at your institution, within your simulation center, may sometimes rise to the level of being considered for a patent or license. Your institution will have very specific policies and processes regarding these options, which may fall under an Office of Research, an Office of Technology Transfer, or even just your General Counsel. Engaging the appropriate authority on these at the *earliest stage* possible is often critical to success.

How do I know if I have a work that has the potential for a patent? If you think it could or are even asking this question, it is always better to get appropriate institution expertise involved or at least aware as early as possible. What type of simulation work might qualify? Homegrown simulators or equipment are key opportunities.

Is it worth patenting my idea? Patents are expensive and can be a long process. The benefit of having a patent is that it allows you to grant a patent license to others. A patent allows the person holding the patent to stop others from making his invention. A patent holder may license his invention to allow others to do something such as use or build his invention. Typically, the licensor receives royalties from the licensee for such use. In order to grant a license, a licensor must have a patent on the invention. It is important to do your due diligence on the market and cost of a patent to understand whether this is the appropriate direction for you. Many organizations have intellectual property specialists that can help and supply information to help you decide on whether you want to pursue a patent on a specific invention.

Contracts Depending on your institutional policies, you may be able to establish one-time or ongoing contracts with other institutions to provide education, training, services, or simply access to your center for a contracted fee. Looking for contract opportunities outside the simulation community is a great way to supplement funding to support a center. For example, you could give access to your center for a contracted fee for the production of a commercial that requires a healthcare setting.

Contracts with other regional healthcare institutions for specific training purposes or even just providing the simulation setting for their own trainings can be a valuable ongoing source of funding. Pitching these ideas and securing contracts can be an extensive process, but once secured, the funding can be a consistent stream. As your simulation center reaches ***max*** capacity due to the increased utilization, the ***ability*** to execute contracts may be limited.

Conclusion/Summary

Regardless of your funding strategy, there are limitations and advantages to all of them. The more you can diversify to maintain viability if one funding source is depleted or removed, the more stable your simulation center will be going forward. However, with diversifying comes the challenge of prioritization of users. The best, most desirable type of funding would be an endowment that is large enough to generate enough income to pay for annual operations costs. Whatever your funding model is, limiting your costs and creating close partnerships with your funders will better position your simulation center to sustain itself through the financially constrained times that everyone is facing.

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Part II

Procedural Simulation

Outcome-Based Training and the Role of Simulation

Ronit Patnaik and Dimitrios Stefanidis

Introduction

Surgical skills have traditionally been acquired by trainees through the apprenticeship model, which was established by William Halsted, MD, FACS. Trainees observe senior surgeons and then perform under their direct supervision until a sufficient level of mastery is achieved. Indeed, this “see one, do one, teach one” paradigm was the sole standard for surgical training for more than a century and has served surgical education well. These principles have guided the field for the past century; however, technological, educational advancements and limits placed on resident training in the modern era have reduced the utility of apprenticeship education.

Problems with the traditional apprenticeship model of clinical education have been clearly documented [1]. Of particular concern is the consistent finding that clinical experience alone yields biased and uneven caseloads among surgery residents. While common operations may be performed routinely, many procedures are done rarely, if at all [2, 3]. This led Bell et al. to observe, “Methods will have to be developed to allow surgeons to reach a basic level of competence in procedures which they are likely to experience only rarely during residency.” Even for commonly performed procedures, the numbers of repetitions are not very robust, stressing the need to determine objectively whether residents are actually achieving basic competency in these operations.

The implementation of work-hour restrictions on resident physicians, beginning in 2003, limited the time trainees can spend on direct patient care, the cornerstone of the Halstedian approach. The scope of surgical knowledge and practice continues to expand with scientific advances. The introduction of laparoscopic and minimally invasive surgical techniques, however, has presented new challenges to the traditional Halstedian training model. The adoption of laparoscopic techniques occurred with such rapidity that practicing surgeons barely had time to acquire these challenging skills. Hence, trainees must acquire a growing volume of knowledge and become adept at an expanding arsenal of surgical skills despite limitations on time spent at the hospital. A report from the American Board of Surgery in 2009 demonstrated that current training methods may result in suboptimal experiences. In the report, the authors found that for 121 “must-know” operations, an average general surgery trainee only had more than 10 experiences in just 18 operations, less than 5 experiences in 83 operations, and less than 1 experience in 31 operations [3]. Thus, traditional surgical clinical education is likely inefficient. Surgical educators must utilize new approaches that complement the apprenticeship model to produce the next generation of surgeons.

Given this need the use of simulation in graduate medical education has gained significant traction as a way to provide trainees with exposure to various techniques and procedures before clinical application to patients. A conference hosted by Harvard Medical School involving educational leaders from eight other US medical schools concluded “investigation of the efficacy of simulation in enhancing the performance of medical school graduates received the highest [priority] score” [4]. Hence, they suggest that enhancement of the traditional time-based clinical education model with practices like simulation-based medical education should be a high priority for medical education policy and research.

Simulation – defined as a situation in which a particular set of conditions is created artificially to experience something that could exist in reality – has been gaining popularity in surgery since the early 1990s. One of the first virtual human abdomen simulators was described by Richard Satava in 1993 [5]. In the late 1990s, Richard Reznick and colleagues developed the Objective Structured Assessment

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of Technical Skill benchtop exam, which introduced simulation to skills assessment [6].

Simulation-based medical education engages learners in lifelike experiences with varying fidelity designed to mimic real-life encounters. McGaghie and colleagues argue that simulation-based medical education with deliberate practice is superior to traditional, time-based, education strategies in achieving specific clinical skill acquisition goals [7]. Simulation has long been viewed as an attractive option for surgical resident education because it gives learners an opportunity to practice clinical skills in a low-stakes setting before operating room (OR) experience. Advocates of simulation in surgical education point out the benefits of providing a practice environment where learners can master fundamental surgical skills such as knot tying, basic laparoscopy, and skin closure rather than learning these skills in the high-cost OR [8].

Given the wide implementation of simulation for skills training in surgery, the goal of this chapter is to explore the factors that impact skill acquisition and provide recommendations for optimal skills curriculum design and implementation. We will analyze the rationale for outcome-based training, the prevailing paradigm in surgical simulation, and review the supportive evidence and discuss the challenges with its implementation and its limitations.

Issues with Existing Training Paradigm (Time-Based Learning)

In most countries surgical training is time-based and time-limited; in the US general surgery residents, for example, start training typically on July 1 and graduate 5 years later. The same paradigm is followed by all surgical subspecialties. This time-based training model typically requires completion of an arbitrary number of procedural repetitions over a set period of time. This paradigm assumes that once a trainee has completed the required number of procedures and training duration, they have obtained the knowledge and skills necessary for safe independent practice. This approach, however, does not take into account individual trainee differences in baseline skill and skill acquisition rate that typically vary widely among learners [9]. Trainees come from a variety of backgrounds that lead to variability in prior knowledge and educational experiences and have variable innate abilities, personal motivations, and individual biases. Skills curricula in which practice performance is based solely on reaching a number of task or procedure repetitions set up learners for failure to develop an adequate skill set, leaving some individuals insufficiently trained. This method can also be inefficient as some learners will achieve the desired level of performance with fewer task repetitions and spend unnecessarily additional time training (Fig. 1). A more desirable outcome would be for all trained individuals to achieve a uniform, adequate level of performance that is necessary to perform safe surgery.

Evidence that the current time-based paradigm is not achieving this desired training outcome is provided by a study by Mattar et al. [10]; it identified that of the fellowship program directors interviewed, 21% felt that their new fellows (recently graduated residents) arrived unprepared for the operating room. This study also showed that the program directors felt that 38% of fellows demonstrated lack of patient ownership, 30% could not independently perform a laparoscopic cholecystectomy, and 66% were deemed unable to operate for 30 unsupervised minutes of a major operation. According to the fellowship program directors in the study, 30% could not atraumatically manipulate tissue, 26% could not recognize anatomical planes, and 56% could not suture. On a similar note, Birkmeyer et al. showed a wide variation in technical skill even among fully trained, practicing bariatric surgeons [11]. Their findings additionally suggested that surgical skill is a strong predictor of clinical outcomes; patients treated by surgeons with low skill ratings were at least twice as likely to die, undergo reoperation, or have complications and be readmitted after hospital discharge as compared with patients treated by surgeons with high skill ratings.

Similarly, Barsuk et al. showcased that simulated central venous catheter insertion performance was uneven among experienced attending physicians. Only a small minority met or exceeded the minimum passing scores, and attending physicians performed significantly worse than residents who completed a central venous catheter simulation-based mastery learning curriculum [12].

Additional evidence suggests that the number of procedures a trainee has performed does not correlate with procedural skill. Barsuk et al. demonstrated that a residents' clinical experience or the number of procedures performed was not a proxy for skill level. Though the study revealed that experience and year of training were positively associated with procedure performance, overall performance was poor even in the most experienced residents [13]. Hence, clinical experience (equivalent to time-based learning or number of procedures performed during residency or years in practice) is not meaningfully associated with the ability to meet or exceed the minimum passing score for a clinical procedure in a controlled setting. The same authors demonstrated that if a standard number of practice hours or practice repetitions are prescribed among a group of trainees to learn a task, at the end of training, individuals will achieve different levels of performance [13]. Similarly, Brunner et al. concluded that neither a predetermined training duration nor an arbitrary number of repetitions are adequate to ensure laparoscopic proficiency following simulator training. They suggested that standards which define performance-based endpoints should be established [14].

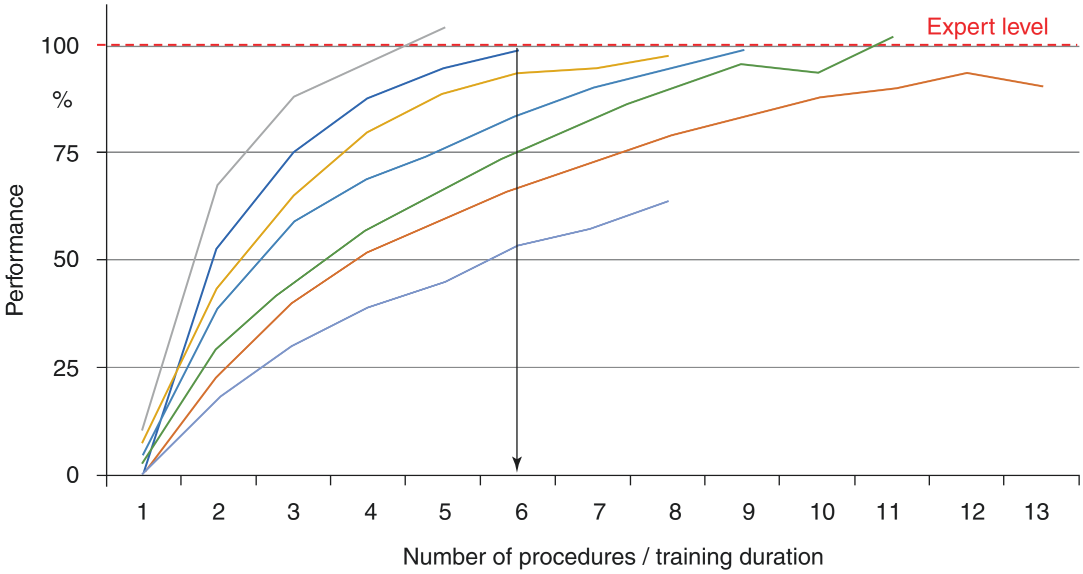

Fig. 1 The figure depicts the typical learning curves of different individuals during training. Each trainee (colored lines) achieves the expert performance level at different points during training and after a variable number of task/procedure repetitions (some may never get there). When the training duration or number of repetitions to perform a procedure during training is chosen arbitrarily (solid black line with arrow), some trainees will not have achieved the desired performance level at the end of training, while others will have trained unnecessarily long. Therefore, time- or procedure number-based training is ineffective and inefficient at promoting robust and uniform skill acquisition of learners

The presented evidence makes it clear that the goal of surgical training programs to produce competent surgeons who have the skills to confidently and safely perform procedures is not and cannot be consistently achieved using time-based training paradigms. Thus, it is imperative that new, more effective training approaches be developed to ensure adequate and uniform skill acquisition of trainees by the end of training. To achieve this outcome, non-time-based training paradigms have therefore been proposed and are being gradually implemented into the residency curriculum [15–18]. Examples include the introduction of competencies, milestones, and entrustable professional activities (EPAs) by the Accreditation Council for Graduate Medical Education (ACGME). In 1999, the ACGME developed a set of six core competencies that define key professional qualities that every physician should acquire to function effectively as an independent practitioner. Each of the competencies has been broken down into discrete units, milestones, for use as progress metrics toward achievement of each core competency [19]. These milestones are competency-based developmental outcomes, such as knowledge, skills, attitudes, and performance, which can be demonstrated progressively by residents from the beginning of their education to the time when they can practice independently. Simulation offers a unique opportunity for the development of such programs as it provides the test bed where different outcome-based approaches can be tried and optimized. In the next section, we will therefore explore how skill is typically acquired and outcome-based approaches are currently used for optimal skill acquisition on simulators.

Dreyfus and Dreyfus Model of Skill Acquisition

Commissioned by the US Air Force to describe the development of the knowledge and skill of a pilot, Stuart Dreyfus and Hubert Dreyfus developed a model of professional expertise that plots an individual's progress in performance through a series of five levels: novice, advanced beginner, competent, proficient, and expert [21] (Fig. 2). They later identified a similar process of development in the chess player, the adult learning a second language, the adult learning to drive an automobile, and many others [22]. This is known as the Dreyfus model of skill acquisition and knowledge development.

When applied directly to medicine, these levels of professional expertise can be described as follows [22] (see Table 1):

1. In the novice stage, the freshman medical student begins to learn the process of taking a history and memorizes the elements, chief complaint, history of the present illness, review of systems, and family and social history.
2. In the advanced beginner stage, the junior medical student begins to see aspects of common situations, such as those facing hospitalized patients (admission, rounds, and discharge) that cannot be defined objectively apart from concrete situations and can only be learned through experience. Maxims emerge from that experience to guide the learner.

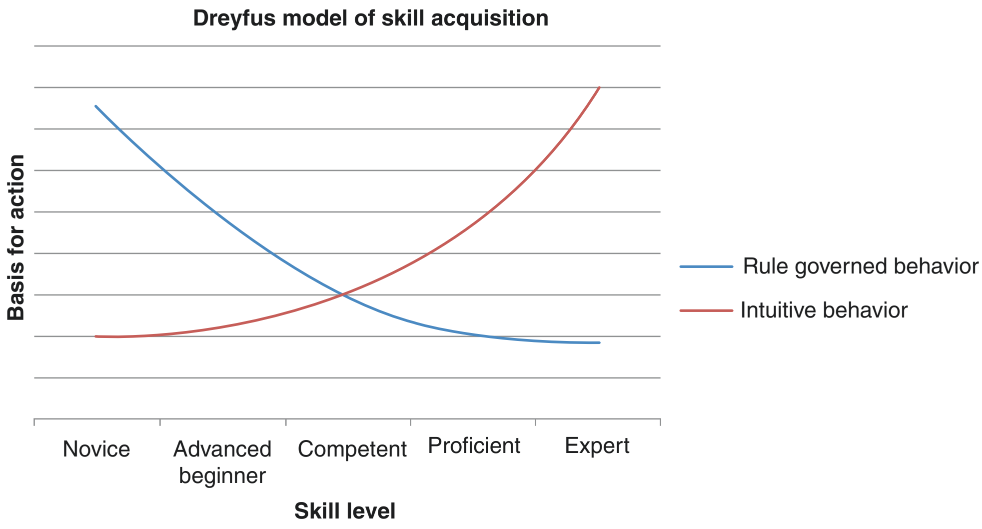

Fig. 2 Dreyfus and Dreyfus model of skill acquisition

Table 1 Principles of the Dreyfus and Dreyfus model of skill development applied to the development of a physician's competence [23]

Novice
Is rule driven
Uses analytic reasoning and rules to link cause and effect
Has little ability to filter or prioritize information, so synthesis is difficult at best, and the big picture is elusive
Advanced beginner
Is able to sort through rules and information to decide what is relevant on the basis of past experience
Uses both analytic reasoning and pattern recognition to solve problems
Is able to abstract from concrete and specific information to more general aspects of a problem
Competent
Emotional buy-in allows the learner to feel an appropriate level of responsibility
More expansive experience tips the balance in clinical reasoning from methodical and analytic to more readily identifiable pattern recognition of common clinical problem presentations
Sees the big picture
Complex or uncommon problems still require the reliance on analytic reasoning
Proficient
Breadth of past experience allows one to rely on pattern recognition of illness presentation such that clinical problem solving seems intuitive
Still needs to fall back to methodical and analytic reasoning for managing problems because exhaustive number of permutations and responses to management have provided less experience in this regard than in illness recognition
Is comfortable with evolving situations; able to extrapolate from a known situation to an unknown situation (capable)
Can live with ambiguity
Expert
Thought, feeling, and action align into intuitive problem recognition and intuitive situational responses and management
Is open to notice the unexpected
Is clever
Is perceptive in discriminating features that do not fit a recognizable pattern
Master
Exercises practical wisdom
Goes beyond the big picture and see a bigger picture of the culture and context of each situation
Has a deep level of commitment to the work
Has great concern for right and wrong decisions; this fosters emotional engagement
Is intensely motivated by emotional engagement to pursue ongoing learning and improvement
Reflects in, on, and for action

3. In the competent stage, the resident physician learns to plan the approach to each patient's situation. Risks are involved, but supervisory practices are put in place to protect the patient. Because the resident has planned the care, the consequences of the plan are knowable to the resident and offer the resident an opportunity to learn.
4. In the proficient stage, the specialist physician early in practice struggles with developing routines that can streamline the approach to the patient. Managing the multiple distracting stimuli in a thoughtful way is intellectually and emotionally absorbing.
5. In the expert stage, the mid-career physician has learned to recognize patterns of discrete clues and to move quickly, using what he or she might call "intuition" to do the work. The physician is attuned to distortions in patterns or to slow down when things "don't fit" the expected pattern.

Outcome-Based Training Paradigms Using Simulators

Understanding the Dreyfus model may help clarify some of the confusion that exists in the literature around outcome-based curricula. The terms competency-based education, proficiency-based training, and mastery learning are often used interchangeably and generate confusion; while all refer to outcome-based goal-oriented training, there are distinct differences and common characteristics among them. The *Oxford English Dictionary*, second edition, defines competence as "sufficiency of qualification; capacity to deal adequately with a subject." On the other hand, proficient is defined as "advanced in the acquirement of some kind of skill: skilled, adept, expert." Hence, the term proficiency is more appropriately applied to the acquisition of a particular technical skill, while competency carries with it a much broader connotation as to the ability to deal with all aspects of a subject [24]. As postulated by the Dreyfus and Dreyfus model, competence develops after having considerable experience, while proficiency is the next level of performance. According to Dreyfus, "Proficiency is shown in individuals who use intuition in decision making and develop their own rules to formulate plans." Accordingly, proficiency is followed by expertise and mastery (Fig. 2).

Proficiency-based training is the most commonly used term and paradigm in surgical simulation. It uses expert-derived performance goals as training endpoints and tailors the educational experience of trainees to their own individual needs independent of how many practice repetitions they may need to achieve a required level of performance. Thus, a proficiency-based curriculum emphasizes deliberate practice to a certain level of performance rather than an arbitrary number of repetitions and incorporates appropriate feedback on performance ensuring optimal and uniform skill development among trainees. Task-specific proficiency criteria should be derived from a representative sample of the expert population. If the proficiency criteria are too stringent, too few trainees will achieve proficiency. If too lax, trainees may develop inferior skills. The goal of this type of training is not only to improve performance but also to make it more consistent [24]. Studies have shown that even medical students can achieve outstanding success at tasks normally reserved for practice by advanced surgical residents through proficiency-based training paradigms [25]. Proficiency-based training is most beneficial when it incorporates increasing difficulty tasks during skill acquisition. Thus, learners train in multiple tasks to reach proficiency and progress from the simpler ones to the more complex ones as they achieve proficiency in each.

Another popular term used in the literature for goal-oriented training is "mastery learning" as defined by McGaghie et al. in 1978. Mastery-based learning is a "stringent form of competency-based education that requires trainees to acquire clinical skill measured against a fixed achievement standard without regard to the time needed to reach the outcome" [26]. It is founded on the principle of "excellence for all." Hence, all motivated learners can reach a predefined "mastery" standard, provided they are given time and resources to achieve the standard. This is a departure from the traditional apprenticeship model in which some learners fail any given task, learning time is fixed, and educational outcomes are variable. Mastery indicates a much higher level of performance than competence alone, and evidence shows that mastery-based learning leads to longer skill maintenance without significant decay. Educational outcomes are uniform in mastery learning with little or no variation, whereas educational time varies among trainees.

In mastery learning, learners are required to meet or exceed a minimum passing score before completing training and performing a procedure or skill on actual patients. This strategy ensures that clinicians working with patients are competent despite variation in the number of procedures performed in the past. In 2009, McGaghie et al. described the following seven core principles of the mastery-learning bundle [27]:

1. Baseline or diagnostic testing
2. Clear learning objectives, sequenced as units usually in increasing difficulty
3. Engagement in educational activities (e.g., skills practice, data interpretation, and reading) focused on reaching the objectives
4. A set of minimum passing standard (e.g., test score) for each educational unit
5. Formative testing to gauge unit completion at the preset minimum passing standard for mastery
6. Advancement to the next educational unit given measured achievement at or above the mastery standard
7. Continued practice or study on an educational unit until the mastery standard is reached

Both mastery learning and proficiency-based progression rely on deliberate practice (DP). Deliberate practice describes the process, whereby mastery can be attained by any motivated learner through a process of intensive, goal-directed practice with immediate feedback [28]. Deliberate practice has at least nine elements:

1. Highly motivated learners with good concentration
2. Well-defined learning objectives that address knowledge or skills that matter clinically

3. Appropriate level of difficulty for the medical learners
4. Focused, repetitive practice of the knowledge or skills
5. Rigorous measurements that yield reliable data
6. Informative feedback from educational sources (e.g., teachers, simulators)
7. Monitoring, error correction, and more deliberate practice
8. Performance evaluation toward reaching a mastery standard
9. Advancement toward the next clinical task or unit

The goal of deliberate practice is constant skill improvement. Research shows that deliberate practice is a much more powerful predictor of professional accomplishment than experience or academic aptitude [29].

It is clear from the aforementioned descriptions that proficiency-based training progression and mastery learning are two sides of the same coin. Their main components include goal-oriented training (with one difference perhaps being how the training goal is being defined), provide quality feedback to learners, promote deliberate practice, and use frequent performance assessments to inform training progress. In this chapter, we, therefore, refer to these training paradigms as outcome-based training.

Evidence of Effectiveness of Outcome-Based Training Paradigms

Numerous studies have demonstrated the effectiveness of both proficiency-based and mastery trainings. The first prospective, randomized, double-blind clinical trial of simulation-based training for the operating room was conducted by Seymour et al. in 2002 [30]. It showed with statistical significance that surgical residents trained to a "proficiency benchmark" on a virtual reality simulator made fewer intraoperative errors when compared to the control group, which was trained using conventional time-based methods. In this study, the intervention group trained to a "proficiency benchmark" was 29% faster, nine times less likely to fail to make progress, and five times less likely to injure the gallbladder or burn nontarget tissue. Ahlberg et al. showcased that training on a VR simulator to a level of proficiency significantly improved intraoperative performance during a resident's first ten laparoscopic cholecystectomies. Similarly, Sroka et al. demonstrated that skills learned in a laparoscopic simulator resulted in improved performance in the operating room, particularly with laparoscopic cholecystectomy or its component steps in humans [31]. Proficiency-based simulator training has also been shown to result in durable improvement in operative skill of trainees even in the absence of practice for several months [32]. Three systematic reviews and one meta-analysis have confirmed that the addition of simulation to conventional surgical training resulted in improved objective performance in the operating room, decreased operating times, increased ability to complete surgical procedures, and decreased intraoperative error rates [33].

Simulation-based mastery learning (SBML) has been shown to improve skills in diverse clinical areas, including end-of-life discussions [34], advanced cardiac life support [35], and management of pediatric status epilepticus, cardiac auscultation [36], and central line placement [30]. It has also been shown to reduce patient complications, decrease length of hospital stay, and reduce hospital costs [37, 38]. For example, mastery learning was associated with reduced catheter-related bloodstream infections [18, 39]. Moreover, central line-associated bloodstream infection (CLABSI) rates in the medical intensive care unit were noted to be significantly less than those in the surgical intensive care unit located in the same university-affiliated academic medical center, where residents performing central venous catheter (CVC) insertions had not been exposed to the curriculum [40, 41]. This SBML curriculum was implemented at a local community hospital and again showed a significant decrease in that hospital's CLABSI rate after eligible residents completed the SBML curriculum [40]. Finally, investigators also quantified the cost savings associated with the reduction in CLABSI rates as compared with the cost of implementing the SBML curriculum and demonstrated a 7:1 return [37].

Madan and colleagues demonstrated that goal-directed laparoscopic training leads to better laparoscopic skill acquisition compared to repetition-based training [42]. Importantly, evidence also exists for the effectiveness of this approach when implemented in the resident clinical curriculum. In 2013, Ferguson et al. demonstrated that despite there being no difference between groups of residents at the start of training, competency-based curriculum residents who participated in their surgical boot camp showcased a significant improvement in technical skill performance compared to residents in the control group, which did not participate in the competency-based curriculum. They also demonstrated that, after several months of clinical training, competency-based curriculum residents did not demonstrate any reduction in their technical abilities, and these abilities remained superior to those of their resident colleagues in the control group. The authors also demonstrated that junior-level competency-based curriculum residents had technical skills comparable with those of PGY-5 residents in the control group [15].

The largest body of evidence for the use of simulation in surgical education comes from literature on the development and validation of the fundamentals of laparoscopic surgery (FLS) curriculum. FLS is an example of a program that allows proficiency-based training and provides a competency-based assessment tool. The FLS curriculum has been endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the American College of Surgeons once proficiency criteria were set [43], and currently all general surgery trainees must successfully complete the FLS curriculum before sitting for their American Board of Surgery examinations.

The gold standard would be to show a link between goal-oriented training (enhanced with simulation) and improved patient outcomes. Such a study will require a large number of participants to detect a measurable difference in morbidity and mortality, which would require a multi-institutional trial. A group at the Mayo Clinic conducted a randomized controlled trial that showcased that a simulation-based mastery learning curriculum decreased operative time, improved trainee performance, and decreased intraoperative and postoperative complications and overnight stays after laparoscopic total extra-peritoneal inguinal hernia repair [44].

Laparoscopic common bile duct exploration (LCBDE) is another example of the implementation of mastery-based training for an operation rarely encountered by surgical residents. The Northwestern University group developed a new low-cost LCBDE simulator, a rating scale for use with the simulator [45], and designed and implemented an educational curriculum aimed at training surgical residents the essential steps for performing both a transcystic and transcholedochal LCBDE [46]. A mastery standard was established with a minimum passing score as determined by two surgeons with previous experience performing LCBDE. None of the ten residents who participated in the original study achieved the mastery standard during the initial pretest. However, all residents achieved the mastery standard after a period of deliberate practice on the LCBDE simulator and demonstrated a significant improvement in their perceived ability to perform an LCBDE independently. Importantly, the introduction of the SBML curriculum leads to increased clinical utilization of LCBDE in the operating room [47]. Implementation of the LCBDE curriculum resulted in a favorable return on investment for the hospital; it resulted in short duration of stay for patients and lower hospital costs compared to patients who received LCBDE + laparoscopic cholecystectomy (LC) compared to patients who received endoscopic retrograde cholangiopancreatography (ERCP) + LC.

Recently, the division of orthopedic surgery at the University of Toronto shared their 8-year outcomes of a competency-based surgical residency training program [17]. In order to establish their program, they used curriculum maps, entrustable professional activity assessments, intensive use of skills labs, and summative and formative feedback sessions. In designing the orthopedic learning modules, the curricular design committee consulted with a number of content experts in surgical training, motor skills development, and curriculum development [30]. The committees wanted to take the lessons learned from the literature on skill acquisition and apply them to this curriculum from the outset. These included findings that surgical skill acquisition and retention improve via focused educational design:

1. Deliberate practice with frequent feedback
2. Technical skill rehearsal in a nonoperating room setting
3. Personal constructive summative and formative feedback
4. Small student-to-teacher ratio learning
5. Targeted teaching
6. An appropriate assessment process

Based on the experience with the pilot, the Division of Orthopedic Surgery fully transitioned to the competency-based curriculum (CBC) in the 2013–2014 academic year. That year, the Royal College of Physicians and Surgeons of Canada (RCPSC) announced a Competence by Design (CBD) initiative, which mandated that all postgraduate specialty programs in Canada were to adopt a competency-based framework by the year 2022. This was a landmark decision because for the first time in North America, a country's main regulatory body for medical education had approved a new paradigm in postgraduate education – a competency-based program – that was not time-based.

Of the 14 residents that were part of the CBC pilot, eight graduated in 4 years of training, as opposed to the conventional 5-year time frame. Five of the remaining six graduated in the usual 5 years. One resident took time out of the clinical program to pursue a master's degree and was anticipated to complete the CBC curriculum in 4 years. This trend was replicated in the following years. All graduates of the CBC curriculum successfully passed the licensing examination for orthopedic surgery from the RCPSC in their first attempt. In addition, each trainee has successfully completed a clinical fellowship after residency training. In essence, efficiencies gained through the program resulted in a shortened time to completion for some learners. The benefit of this to the program and the postgraduate medical education office was that 1 less year of funding was necessary for a resident salary, assessment, and feedback.

A curriculum that follows the above principles is likely to spark trainee interest, ensure participation and satisfaction, and lead to an effective and efficient way of acquiring new skills.

Table 2 lists the published studies that have demonstrated the effectiveness of goal-oriented training. Table 3 lists studies comparing the goal-oriented training model with the traditional time-based training model.

Table 2 Evidence for simulation-based goal-oriented training

Author	Title
Ahlberg et al. (2007)	Proficiency-based virtual reality training significantly reduces the error rate for residents during their first ten laparoscopic cholecystectomies
Barsuk et al. (2009)	Use of simulation-based mastery learning to improve the quality of central venous catheter placement in a medical intensive care unit
Barsuk et al. (2009)	Simulation-based mastery learning reduces complications during central venous catheter insertion in a medical intensive care unit
Barsuk et al. (2012)	Simulation-based education with mastery learning improves paracentesis skills
Barsuk et al. (2012)	Simulation-based education with mastery learning improves residents' lumbar puncture skills
Barsuk et al. (2014)	Dissemination of a simulation-based mastery learning intervention reduces central line-associated bloodstream infections
Barsuk et al. (2016)	The effect of simulation-based mastery learning on thoracentesis referral patterns
Nousiainen, et al. (2016)	Simulation for teaching orthopedic residents in a competency-based curriculum: do the benefits justify the increased costs?
Nousiainen, et al. (2018)	Eight-year outcomes of a competency-based residency training program in orthopedic surgery
Korndorffer (2005)	Simulator training for laparoscopic suturing using performance goals translates to the operating room
Santos et al. (2012)	Development and evaluation of a laparoscopic common bile duct exploration simulator and procedural rating scale
Schwab et al. (2017)	Single-stage laparoscopic management of choledocholithiasis: an analysis after implementation of a mastery learning resident curriculum
Seymour et al. (2002)	Virtual reality training improves operating room performance: results of a randomized, double-blinded study
Stefanidis et al. (2008)	Proficiency-based laparoscopic simulator training leads to improved operating room skill that is resistant to decay
Wayne et al. (2006)	Mastery learning of advanced cardiac life support skills by internal medicine residents using simulation technology and deliberate practice
Wayne et al. (2008)	Simulation-based education improves quality of care during cardiac arrest team responses at an academic teaching hospital: a case-control study
Zevin et al. (2014)	Surgical simulation in 2013: why is it still not the standard in surgical training?

Table 3 Studies comparing goal-oriented training vs time-based (traditional) training

Author	Title
Barsuk (2017)	Residents' procedural experience does not ensure competence: a research synthesis
Madan (2008)	Goal-directed laparoscopic training leads to better laparoscopic skill acquisition
McGaghie (2011)	Does simulation-based medical education with deliberate practice yield better results than traditional clinical education? A meta-analytic comparative review of the evidence

Implementation Challenges

Stefanidis and Acker et al. [48] discussed the challenges they faced during the implementation of a proficiency-based laparoscopic skills curriculum in a general surgery residency program. They suggested that such a skills curriculum can be implemented effectively in a surgical training program only when dedicated personnel and protected training time are ensured by the program. They also suggest that – to maintain trainee motivation – the curriculum must challenge the residents and nurture a healthy competitive environment supported by an award system. A continuous monitoring system must be in place to assess individual resident training progress as well. Furthermore, the overall effectiveness and efficiency of the curriculum should be assessed periodically. Changes should be implemented early as needed to optimize the curriculum over time. Overall, the curriculum should be fluid and open to change.

A major challenge for implementation is cost, both in terms of financial investment and potential demands on faculty and trainee time, especially for trainees who may even require more practice than that provided for by the traditional time-based curricula [16]. Nousiainen et al. showed that, although the financial investment and the time required in running a simulation program are substantial, they lead to improved trainee and trainer satisfaction and improved learning outcomes. Their study also suggested that sufficient financial support is required for the infrastructure and time investment by faculty needed for a well-developed proficiency-based learning program. Unfortunately, cost data are extremely limited in the literature; Zendejas et al. pointed out in a systematic review that only 1.6% of studies provide any cost comparison when examining simulation-based training compared to other instructional methods in medical education [49].

Importantly, when such curricula are implemented in a residency program, the variability of skill acquisition by residents and different times they achieve required training goals create a significant logistical challenge to training programs. Instead of administering a curriculum with predefined start and end, the new curricula require either flexibility in training duration or significant efforts to remediate those trainees who are behind in skill acquisition so they can complete all training goals in time. This challenge can clearly be perceived as being insurmountable by program directors, and additional evidence is needed as to how best to implement the new curricula with minimal disruption to ongoing training and administrative structure. The Toronto experience can clearly serve as a guide.

Limitations of Outcome-Based Paradigms

As mentioned in the previous sections of this chapter, outcome-based training has numerous advantages compared to time-based training paradigms, but some limitations also exist. There are a number of unanswered questions that need to be addressed to optimize its effectiveness: Who is the appropriate expert from whom to derive performance goals? How many experts are needed to create reliable goals? How many times should trainees perform the task at the expert level to be considered proficient? Should we even use expert performance as a training goal, or are there other more suitable methods? Are the available metrics the most appropriate for performance assessment and sensitive enough to distinguish subtle performance differences? [20] Indeed, while numerous studies have demonstrated transfer of simulator-acquired skill to the operating room, this transfer is typically incomplete. Despite trainees achieving expert-derived performance goals on simulators, their performance in the clinical environment and the operating room lags behind that of experts [50–52]. Some authors have speculated this may be due to incomplete acquisition of skill during training, which is then unmasked in the demanding environment of the operating room. Other possible reasons include differences in fidelity between the simulated and clinical environment, performer anxiety and increased stress level in the more demanding operating room environment, and insensitive metrics of performance that do not enable the accurate detection of when skill acquisition is maximal and complete [50–52]. Some authors have therefore explored additional ways of improving skill acquisition on simulators and transfer to the clinical environment. Strategies such as mental skills training to manage stress and performance anxiety have been proposed and have been shown to lead to improved skill transfer [53–55]. Further, the implementation of overtraining, i.e., ongoing training beyond initial acquisition of proficiency, has also been proposed [9, 56]. In addition, refined assessment methods have been proposed such as the use of motion metrics [57] and secondary task measures for performance assessment [58]. The latter are based on an important expert characteristic (“automaticity”) that distinguishes them from novices which is their ability to engage in extraneous activities without requiring significant attentional resources. Using such metrics for performance assessment has been previously shown to lead to improve skill transfer to the operating room compared to typical proficiency-based training [58].

Conclusion

The available evidence suggests that outcome-based training paradigms (proficiency-based training/mastery learning) are superior to traditional time-based training and lead to superior skill acquisition that is uniform among learners. Simulation provides a unique opportunity to implement and study such novel training paradigms to help maximize trainee skill outside the clinical environment. The lessons learned from the application of outcome-based training on simulators can be used to inform clinical training and identify implementation strategies of this administratively demanding training paradigm in the residency curriculum.

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Skill Maintenance, Remediation, and Reentry

Marlin Wayne Causey and Robert M. Rush Jr.

Introduction

Initial acquisition of surgical skills is well studied due to the drive to create the most highly skilled surgeons in the world. Progression of surgical skills training and development builds upon existing knowledge and is benchmarked based on case requirements, the six domains of physician competency, and milestones during residency [1–3]. Disruptions in this process, either by planned or unplanned absences, have the potential to negatively impact surgical skill development, maintenance, and progression to mastery. During formal residency training programs, surgical experience is based on a defined case type and volume with minimum requirements needed prior to graduation. Implementation of the 80-hour workweek and the widening variety of surgical training and skills mastery required in open, laparoscopic, endovascular, and robotic surgery has deepened the breadth of operative exposure leading to a greater variability in case volume experience [4]. This variability has trended toward a reduction in the required operative minimums in some subspecialty surgeries (such as vascular and cardiac surgery) while concomitantly decreasing exposure to some more traditional basic skills (such as vaginal, forceps, vacuum deliveries, and open appendectomy) [4–6]. This, combined with the drive to perform the most cutting-edge types of operations, such as robotic and advanced laparoscopic/endoscopic surgery, has shifted the training experience toward more specific and highly technical procedures and surgical subspecialties. Often more experienced senior surgeons need to update skills in newer technologies and procedures that newly graduating residents learn while in training (Figs. 1 and 2). The formal operative training experience will vary even among individuals in the same training program due to differences in clinical encounters, program requirements, changes based on available faculty and rotations, and the unpredictability of certain services such as transplant surgery, trauma, and open vascular surgery [4, 7].

As our profession continues the journey toward higher-quality outcomes and patient safety, we are learning or reverifying that there may be a price for both over and under "production" – numbers or cases seen or performed. This discussion focuses not only on how simulation is and can be used to maintain surgical skills once acquired but also on the potential uses for simulation in surgeon/proceduralist refreshment, reentry, and remediation after absences from a standard practice.

Developing, Maintaining, and Acquiring Surgical Skills

The broad variability in surgical trainee experience has required a shift to standardize training programs and to teach basic operative skills outside of the operating room. Measures to accomplish this has, in some cases, translated to clinical success [8, 9]. A large part of this emphasis now focuses on surgical simulation and teaching fundamental skills outside of an operating room, with skills that are directly transferable to operating room care. This is especially important as demonstrated by the requirement for all general surgery residents (and also those of select other specialties) to obtain

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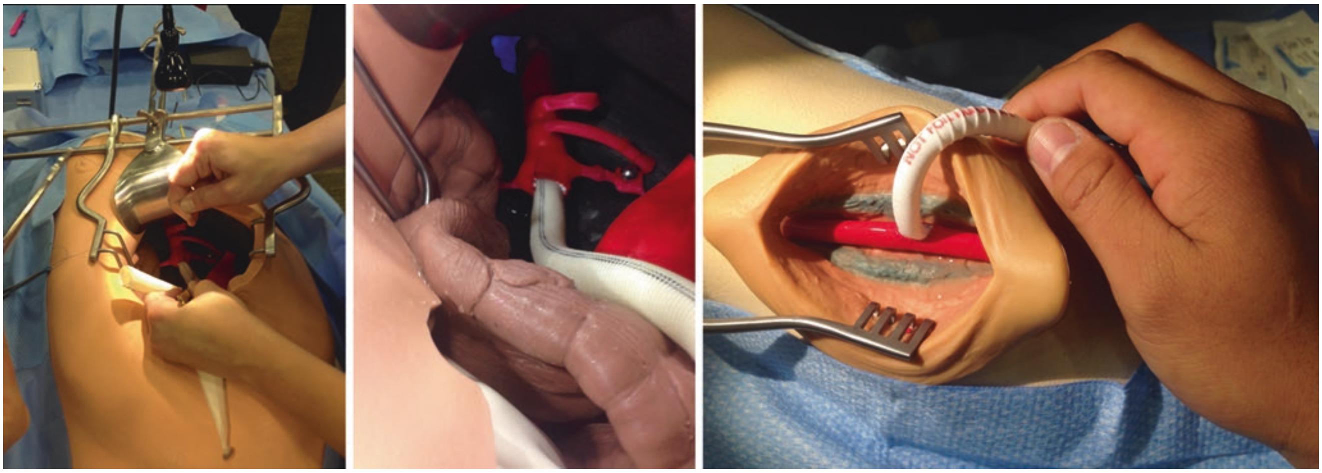

Fig. 1 Open vascular simulator designed to train residents for open vascular surgical cases. This is especially important because certain tasks should not be trained intraoperatively the first time, such as a proximal aortic anastomosis (left and middle). Other tasks are helpful to facilitate technical skills acquisition and familiarity, such as a peripheral anastomosis (right). These simulators may also be successfully used in reentry and reintegration of surgeons following surgical hiatus

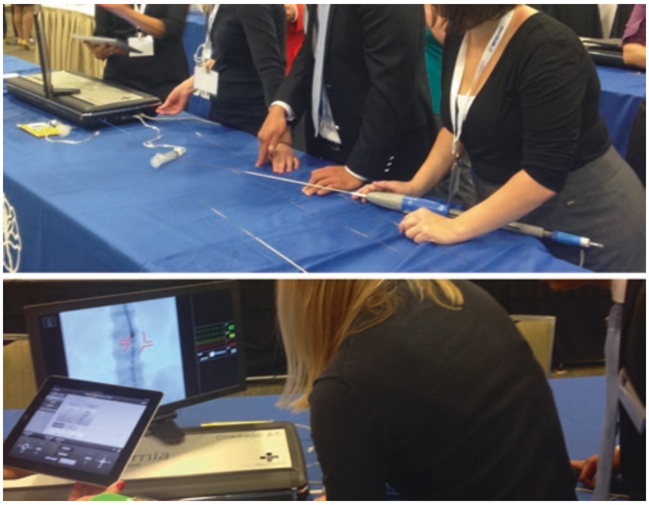

Fig. 2 Endovascular abdominal aortic aneurysm simulation trainer. This trainer is beneficial to help trainees develop endovascular skills and facilitates procedural familiarity in multistep complex procedures. This type of simulation is also beneficial in training surgeons on new procedures and helping to solidify the cognitive to technical skills interface

certification in *Fundamentals of Laparoscopic Surgery*, *Advanced Trauma Life Support*, and *Advanced Cardiovascular Life Support* prior to graduation [10, 11]. These training platforms help to formalize essential basic surgical tasks as an augmentation to the case minimum requirements, as changes in operative exposure may not be enough for proficiency [10, 12]. This process of residency training relies largely on having a structured and planned curriculum exposing differing case experiences in an organized, repetitive manner. Curriculum planning involves organizing experiences that expose residents to the operative experience and clinical practice of differing surgeons and surgeons with differing types of training which should be augmented with simulation training to teach basic skills, defined technical deficiencies, and critical complex skills [7, 13]. Residency training also largely relies on the hope for case exposure and through the national certifying boards, and the Accreditation Council for Graduate Medical Education establishes minimum case-type numbers [14]. These processes in surgical training are highly important in the establishment of fundamental skills. In addition, they also serve to teach adult trainees a model for developing, refining, and maintaining their own surgical skills. Available hybrid courses and certifications are shown in Table 1.

Junior practicing surgeons face similar challenges to trainees as their early post-residency years serve as a pinnacle of the graduated training experience of formal surgical residency and fellowship. During the initial stages of being a newly credentialed surgeon, they are moving from "competency" to "proficiency and expertise" as referenced by the Dreyfus and Dreyfus model of skills acquisition [15]. In addition, they are developing processes and habits for continued personal surgical skill maintenance and improvement. This is a critical phase for newly minted surgeons as they have had a large breadth of surgical exposure and they begin to develop their clinical practice and the type of surgical procedures that they incorporate into their new practice. This is likely the most vulnerable time to have clinical interruptions as this could stall acquisition and solidification of the cognitive to technical skill interface [16]. This interface is very important because during this early timeframe, the junior surgeon first understands the importance of the small nuances to operative surgery, uses past experiences to assimilate present clinical judgment, and utilizes recommendations from more senior surgeons in an independent

Table 1 Some of the myriad of courses available to surgeons and simulation/education centers to assist in acquisition, maintenance, refreshment, refinement, and remediation of surgeon technical and cognitive skills

Platform or program	Skills addressed	Fidelity	Validation level	Includes assessment tool	Includes didactic	Includes simulation	Includes team scenarios	High-stakes exam
FLS	Basic laparoscopic skills	Medium	High	Yes	Yes	Yes	No	Yes – needed for graduation from GS residency
FES	Basic flexible endoscopy skills	High	High	Yes	Yes	Yes	No	Yes – needed for graduation from GS residency
ATLS	Advanced trauma skills for providers	Low	High	Yes	Yes	Yes	No	Yes – some hospitals require for credentialing
ACLS	Advanced non-trauma life support skills	Medium	High	Yes	Yes	Yes	Yes	Yes – most hospitals require surgeons to be certified
FUSE	Fundamental use of surgical energy	N/A	No validation studies to date	Yes	Yes	Yes (optional)	No	Yes – but certification not required by any governing bodies at this point
FRS	Basic robotic skills	High	Validation study in progress	Yes	Yes	Yes	Yes	Yes – (under development)
TeamSTEPPS	Basics of team training and communication among caregivers	Low to medium (but variable – high-fidelity simulators can be used)	Yes	No	Yes	Yes	Yes	No – but the training is required in many hospitals for all staff
ATOM	Advanced Trauma Operative Management for surgeons	High	Moderate	Standard procedures with direct instructor feedback	Yes	Yes (Live tissue model)	Yes – need to work with OR team	No
ASSET	Advanced Surgical Skills for Exposure in Trauma	High	Ongoing	No	Yes	Yes (cadaveric model)	No	No

manner. The junior surgeon also formalizes the leadership lessons learned during training, develops their own style of leadership and teambuilding, and applies this experiential cognitive knowledge to patient care and leading the operative team [17]. As the junior surgeon gains experience, the application of cognitive knowledge and judgment is better applied in the treatment of surgical disease, and the surgeon understands the importance of continual self-improvement, continuing medical education, and hopefully recognition of their own limitations [18]. Any break in clinical practice in these early stages may significantly hinder surgeon development in this critical stage of their surgical maturation.

Once a surgeon transitions from junior surgeon to a more seasoned and experienced surgeon, they develop a clinical practice and surgical practice patterns that reflect their training, the formalization of the cognitive to technical skill interface, and their understanding of their own surgical skills. These more seasoned surgeons have many challenges in that they need to further refine their clinical practice, often serve to mentor more junior surgical colleagues, and serve to help administratively develop the delivery of medical and surgical care to patients. As surgeons become more senior, they often have much more control over their patient population and flexibility in their operative schedule as their administrative and practice development responsibilities become more demanding. With this shift toward a less operative practice develops, the need for continued surgery and self-improvement lessens, but the necessary minimums to maintain proficiency are unknown and unstudied and may be important for certain complex procedures (pancreatectomy, carotid endarterectomy, and coronary artery bypass grafting) [19]. A survey of 995 surgeons at the American College of Surgeon’s Clinical Congress demonstrated that increasing age is associated with decreases in clinical caseload and complexity and that their decision to retire will be based on skill level as opposed to age [20].

When assessing the skill level of senior surgeons, it has been demonstrated that expert surgeons are able to master new tasks faster than novice surgeons [21]. Studies have also demonstrated that practicing senior surgeons perform cognitive tasks at or near the level of their younger colleagues. This is perhaps an area that may be well served and augmented by simulation since this serves to allow operative experience and skills retraining without many of the necessary other duties required with clinical operative care (notes, orders, pages, and follow-up). Certainly, simulation is important in teaching new surgical techniques to senior surgeons that are decades removed from formal training [22, 23] (Fig. 2). Senior surgeons also benefit in the simulation experience as part of their own training but are also necessary in providing invaluable feedback for the simulation planning and learning curriculum [24, 25]. It is also during this period that breaks in clinical practice likely have the least impact in regard to regression of surgical skills due to the solidification of the cognitive to technical interface, established practice patterns, and a foundation of clinical experience. This concept is partially supported by a study that demonstrated that increased repetition count for a laparoscopic surgical skill improved skills and that time lapses between trainings had no impact [26].

Remediation of Surgical Skills

There are many situations that lead to breaks in clinical practice, predicating the need for surgical skill remediation. One of the most highly studied populations, which has significant absences from traditional surgical practice, is military surgeons. This is especially the case for general, orthopedic, and their subspecialty derived surgeons [27]. Military surgeons face significant issues both during times of combat and upon redeployment from combat environments. The significant changes in operational combat tempo and the variability in surgeon deployment location may alter the amount of operative experience, often among surgeons who are only short distances from one another or who were in the same location only months apart. Battlefield trauma is almost impossible to predict. Inexperienced, deployed surgeons represent an opportunity to assess surgical maturation secondary to the long-standing Middle Eastern conflicts. In addition, this “break from clinical practice” is viewed as a positive career development time – in comparison to disciplinary action or illness which often is kept more secret [28].

Military surgeons, upon successfully completing a deployment, face several different hurdles to reestablish their preexisting practice. The first major hurdle is termed reintegration. This is the process that all soldiers undergo that transitions them from a combat surgeon to a garrison surgeon in the United States. In addition, the process involves being reunited and reestablishing relationships with family and friends. This process is variable and may require varying amounts of time depending on the combat stressors and the length of the deployment. Though not specifically studied, military surgeons likely have an easier time compared with other soldiers with this reintegration phase because the nature of their military occupation, surgery, is similar to their civilian/garrison job (though the patient population, facilities, and disease treatment are different). The arguably more challenging transition for military surgeons is the process of successfully and proficiently providing clinical surgical care upon reentry.

This transition is critical not only for surgeon psyche and confidence but also for patient safety. While surgeons in the military are often very highly trained, deployments with little operative experience will decrease their current skills, particularly as the garrison skill set involves more specialized surgery than is being performed on or near the battlefield (typically open surgery except in larger centers). Also, surgeons who practice subspecialty surgery in a busy clinical practice may find that their subspecialty skills may decline despite a more rigorous trauma surgical experience [27]. It is in this group that simulation is important not only upon reentry but also while the surgeons are deployed in combat zones. Surgeons and surgical teams often rehearse simulated scenarios, but the resource limitations and austere environments allow only for open surgical rehearsal. Current efforts have allowed for the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) fundamental courses and certification to be available in deployed settings, such as the Fundamental Use of Surgical Energy (FUSE) and the Fundamentals of Laparoscopic Surgery (FLS) (Fig. 3).

Outside of the military, surgical remediation training has demonstrated benefit in training surgeons. One interesting study by Tausch and authors has demonstrated that recent technological advances have allowed off-the-shelf instrument tracking capabilities. These tracking capabilities have demonstrated that expert surgeons acquire skills quicker and this could easily be integrated into remediation training for surgeons who require absences from clinical surgical practice [29]. Remediation of surgical skills should follow a pathway of ensuring surgical skills validation with the use of simulators in a planned curriculum, as opposed to “simulator time” [30]. Studies have demonstrated technical assessment tools for differing technical surgical skill sets, such as vascular, laparoscopic, and robotic surgery [1, 24, 29, 31]. Furthermore, focused evaluations of a surgeon’s technical skills can be assessed through crowdsourcing their surgical videos both during laparoscopic/arthroscopic/endoscopic cases and open in both simulated and live patient settings. This allows for a surgeon to (1) receive timely feedback (usually within 48 h of completing a real or simulated case/scenario) and (2) focus on exact areas to improve on, such as

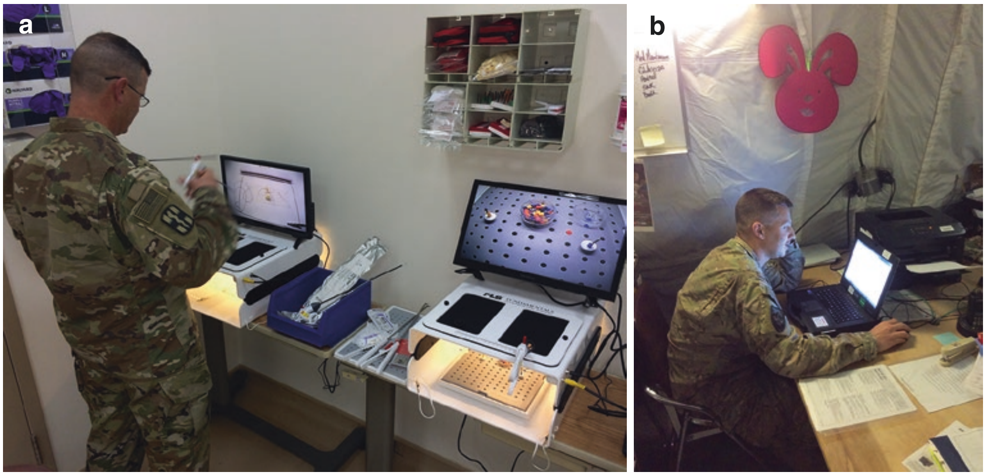

Fig. 3 (**a**) OR technologist practicing with the Fundamentals of Laparoscopic Surgery (FLS) simulators to improve skills and awareness during laparoscopy at the US Military Hospital – Kuwait. (**b**) A surgeon in Iraq taking the FUSE exam online through an international traveling test center

a laparoscopic bowel anastomosis or robotic urethral anastomosis, in which he or she can then use a specific simulation platform to address the deficiency [32, 33].

One major attempt at creating an objective assessment tool by which clinical surgical care is continuously evaluated is through a process mandated by The Joint Commission in 2008 – the Ongoing Professional Practice Evaluation (OPPE) [34–36]. Through the OPPE process, local medical staff are required to monitor the performance of all practitioners who are either granted new credentials or who maintain existing privileges. The OPPE is a screening tool that objectively assesses practitioners in an attempt to identify those who might be delivering an unacceptable quality of care [35]. If this screening process identifies a practitioner who may meet this threshold, the Focused Professional Practice Evaluation (FPPE) process seeks to validate or refute the delivery of substandard care [34, 36]. Given the requirement for hospitals to perform this continual competency assessment and the design to have it be an objective assessment, strides have been made in the medical specialties to accomplish this task. A psychiatric study looked at computer-based clinical assessments in the OPPE process. This study assessed 410 psychiatrists, at the same institution, around their competency for credentialing through a computer-based simulation program that evaluated their actions during a clinical encounter (Measure 1) and their integration of information from open-ended questions based on the simulated scenarios (Measure 2). Physicians who failed either part of these two measures (18%) were referred to the FPPE process [37]. Other nonsurgical specialty organizations have attempted to objectify this process through recommended concepts, activities, and metrics [38–40]. These studies demonstrated that simulation training may provide a method in the objective quantification of surgical skills for those surgeons reentering the workforce, obtaining new credentials, and credentialing renewal process.

Programmed Absence

Military deployments, in regard to the clinical practice break, are very similar to other scenarios that may face surgeons during their career. These scenarios include sabbaticals, significant illness, maternity leave after pregnancy, or the death of a significant family member. These may be viewed as a more programmed absence (like military deployments), in that the time is usually a shorter, fixed amount of time varying from 2 to 9 months. Programmed absences that are of shorter duration are usually accompanied by an initial time of reduced clinical activity, often in a supervised role, or with no clinical reentry process. This is often because the duration of clinical break is short, not perceived to be significant, and the surgeon and partners are anxious to complete the reentry process. When studied among military surgeons to determine the self-perceived detriment in clinical skills following deployment, it was felt that 1–6 months was needed to return to their pre-deployment surgical skill level. In addition, the time required for military surgeons to return to their pre-deployment baseline was higher for surgical specialists. Surgeons determined that 6 months was the most time they could deploy without a significant decrement in skills [27]. While there is a role for simulation in the maintenance and reentry process in shorter programmed absences, very few programs use it. Remediation currently is mostly done with direct clinical surgical supervision on patients. "Ad hoc" methods of practicing technical skills and teamwork through simulation have been described for maintenance of skills which can be part of the tool kit for programmed absences. A forward surgical team working in an austere environment in a time of low casualty load demonstrated this option during a 5-month deployment (Fig. 4). This technique can also enhance technologist and nurse skills and improve team communication. It functions as a low-threat, safe environment prior to real scenarios where expeditious and expert care is needed to save a casualty's life as well as their own.

Fig. 4 (**a**, **b**) First-generation vascular injury simulator used for surgeon/tech skills sustainment and team training at a forward base in Afghanistan; (**c**–**e**) upgraded simulator at the same location using expired medical supplies to include an aorto-bifemoral ribbed arterial graft that was triply perfused, plaster abdominal sidewalls, moleskin anterior abdominal wall, and chain of water-filled condoms strung together for bowel; (**f**) patient arrived and taken to OR where initial laparotomy performed; (**g**) repaired iliac artery injury; (**h**) temporary abdominal closure; (**i**) view of vascular conduit used for simulator

The need for surgical simulation during programmed absence is especially important following longer clinical breaks, which may occur after an illness to the surgeon or a family member who needs extended care. These programmed (often unplanned) absences may often take 6 months or longer for resolution or stabilization. When using the information from military surgeons, it is notable that these clinical breaks clearly lead to a decrement in clinical skills. Addressing this concern is currently left to the local hospital through the credentialing and renewal process [27]. In these circumstances, simulation is highly important to the reentry process as surgical skills will have depreciated from their level prior to the absence. In addition to surgical supervision, the use of simulation-based curricula focused on that surgeon's clinical practice and specialty is important. The time required for simulation and supervision reentry will vary based on the surgeon's experience, with more experienced surgeons requiring less time than junior surgeons.

Especially important will be the reentry process of junior surgeons who have yet to establish their cognitive to technical skill interface.

The final, largely unstudied group that will require a very structured reentry process are those surgeons who have a programmed absence secondary to disciplinary action. The time away from clinical practice will certainly be variable but often will require a time greater than 6 months. In addition to the break from clinical practice, these surgeons may also have other reasons to require remediation. Certainly, the time away from practice will require simulation training and supervision, but also incorporated into this process will need to be specifically defined remediation, which often is currently performed by state licensing boards and local hospitals. A combination of disciplinary action-specific remediation, supervised reentry, and a simulation curriculum focused on assessing surgical skills through validated tools will optimize the transition back into surgical practice. A group out of Mount Sinai used focused 2-day to 6-week hybrid courses that integrated SBT (simulation-based training) with supervised clinical practice in the operating room for the evaluation of individual providers for competency while simultaneously providing refresher training that was approved by the state licensing body of New York [41].

Reentering the Surgical Workforce

As outlined previously, differing factors may lead to absences in surgical practice during a surgeon's career. The timing of the absence, whether during formal training or junior surgical or senior surgical years, greatly impacts the type, amount, and supervision required for successful reentry. Another factor that is a potential barrier is the reentry reintegration of the surgeon into the operative team. Because of the absence, the team may have changed, the absence may be combined with a move, or in the case of the military surgeons, the assigned personnel may have changed. This adds a layer of complexity to the reentry process, and this process is not uncommon to deploying surgical teams that go to combat zones [42]. A team-based simulation training program in these military units demonstrated an improvement in the cohesion of the team members and benefit to team dynamics. In addition it has led to improved trauma resuscitative capabilities in decreased resuscitation time (mean of 24.4–13.5 min, $P < 0.01$) and reduced critical events missed (5.15–1.00; $P < 0.01$) [43]. These programs are also delivered on a mobile platform to different hospitals and surgical teams as they are taken into combat zones and have utilized for training in rural communities [44, 45]. The development of the surgeon as a team leader is critically essential in optimizing patient care by enhancing team communication, building surgeon-staff relational trust, and continual surgical care improvement.

Mental Skills Curriculum

The solidification of the cognitive to technical skill interface, refinement of technical surgical skills, and linking surgical technical and nontechnical skills are critical in developing and perfecting surgical practice. Perhaps the greatest challenge of simulation training currently is to develop models that so closely replicate human models that the learner participant can directly translate and apply the skills to clinical practice. Additionally, because human medicine is variable and constantly changing, these simulation exercises need to accommodate patient variability, adapt to different user skill levels and learning environments, and stay current with improvements in surgical techniques and technology. A mental skills curriculum is designed to help surgeons develop and enhance coping skills for transference of clinically (cognitive) trained and simulation (technical)-trained skills to the operating room during stressful situations. A study looking at personality differences among junior surgeons demonstrated that as a surgeon progresses, they have a greater appreciation of their personality and enhanced professional insight which is critical in stressful situations [46]. This again highlights the aforementioned vulnerability junior surgeons may have to significant clinical absences early in their career and the importance of developing mental skills. A study looking at orthopedic surgeons during their preoperative preparation for complex trauma operations demonstrated that this process involved interaction with other surgeons and operative materials. This study concluded that this preoperative process created mental imagery, which in turn led to development of an operative strategy and enhanced discussion with junior assisting surgeons [47].

As surgical training progresses and graduated responsibility increases, surgeons develop coping skills for stressful situations, both in the preoperative planning process and in the operating room. For example, during their formal training, general surgeons are trained under stressful and continuously dynamic situations particularly in trauma and acute care surgery and in the surgical intensive care unit. In these environments, stakes can be high, and poor decisions can lead to immediate patient demise. These experiences, when appropriately supervised and coached, are beneficial in developing mental skills in coping with stressful situations and allow the surgeon to best utilize their technical skills in performing surgical tasks. One interesting study utilizing coping techniques found that technical skills were increased following mental skills training. There was an improvement in laparoscopic surgical skills performance by 22%, and participants had a higher satisfaction rate in task performance [48]. This study and others support a positive benefit to the mental preparation process for simulation, which is likely transferable to the operating room [49–53]. This mental preparation can be as easy as discussing a surgical case or patient presentation with a colleague prior to the actual surgery.

These same coping skills are certainly beneficial to surgeons following leaves of absence and may even be required if the surgeon's external environment produces stress. These programs for reentry surgeons likely should replicate the skills learned by trainees using simulators and simulated surgery on animals. By performing surgeries in a low-stress environment during a reentry program, surgeons will be able to perform surgery in a lower-stress environment and determine the impact of their absence and external stressors on their individual reentry process. One study has suggested that perhaps physiologic measurements may also be employed to determine surgeon focus during simulation during surgical cases [54]. While these types of studies are in their infancy and simulation may not evoke the same physiologic response, this is perhaps a future tool for assessing surgeon reentry into clinical practice.

Conclusion

Simulation and its role in the reentry process has gained traction over the past half-decade. Studies have demonstrated that surgical skills do depreciate over time and that surgeons do understand this phenomenon. Absences from surgical practice and the method for reentry are based on several factors – the individual's duration of absence, the stage of their career, and the circumstances (external stressors) related to the absence. Studies performed on military surgeons, who have more frequent programmed absences, demonstrated that 6 months is a break point in self-perceived skills detriment. Structured reentry programs are clearly needed for surgical absences that occur longer. Surgeons may also be significantly impacted based on the stage of their career development with junior surgeons likely sustaining the most profound impact due to the lack of experience, the disruption of the cognitive to technical interface, and a need for surgical skills refinement. Successful reentry of a surgeon into clinical practice should focus on programs that incorporate simulation and mental skills curriculum. This is necessary to bring the surgeon's technical skills back to the baseline level prior to the absence while also developing coping skills and determining the impact of potential external stressors – as reentry is a stressor as well. Programs designed for reentering the surgical workforce should seek to solidify the cognitive to technical skill interface and refine technical skills learned during formal training or experiential practice. Through a well-thought-out reentry plan, surgeons may successfully return to clinical practice, in an initially supervised manner, and safely deliver surgical care. Substituting simulation for volume is not intuitive to our culture. Programmed simulation incorporated into a surgical practice while learning a skill with focused maintenance of that skill and incorporating new techniques, order of the steps of the procedure, and for surgeons refreshing, reentering, or remediating their skills is the way forward. Showing continued learning is intuitive to most surgeons but will still take personal time, self-reflection, and insight.

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Performance Assessment

Timothy M. Kowalewski and Thomas S. Lendvay

Introduction

Traditional surgical education has suffered from some long-standing challenges. These include a lack of objectivity or quantitative rigor in performance evaluation and a growing training gap due to tightening resource constraints and concomitant increase in number and diversity of skills requiring mastery. These are compounded by the constant influx of new technologies in the operating room [1], which further challenge the historically arduous, prolonged learning curves associated with surgical skill acquisition (5–7 years) [2]. In the past two decades, technology has augmented surgical education with a variety of simulators and robotic platforms. While these bring new training and learning challenges, they also promise a heightened level of scientific rigor for performance evaluation [3]. This offers further promise of semiautomated mentoring in skills training which can decrease the time, risk, and resource cost of training for students and faculty alike. The need for objective metrics remains pressing, and quantitative rigor is becoming increasingly available [4–6].

Need for Objective Measurements of Skill

Shifting healthcare reimbursement to performance-based compensation, increasing public awareness of variable healthcare quality, rapid adoption of new technologies, and a general trend toward continuous process improvement are all drivers of the need for increasing objectivity in surgical performance assessment.

The Training Need

Among novice surgeons in training, the ACGME and RRCs provide the direction for tracking individual's performance and maintaining standards for advancement. Despite standard core competencies against which all trainees in residencies are compared, a major challenge in this system has been that advancement – hinged to these core competencies – is still dictated by individual faculty within the program of the trainees [7]. This leads to variability of feedback to the trainees and to subjective biases based on personalities and leaves room for graduates not actually having all the necessary proficiencies to practice safe and effective healthcare.

In the most recent publication distributed by the ACGME regarding the core competency progression of residents from 1 year to the next, the trends were to be expected – residents achieved "graduation" benchmarks across the board for all milestones [8] (Fig. 1).

Using such grading systems alone can make it difficult to hold a trainee back from advancement as most faculty provide higher-"level" scores as the trainees ascend by the program year. In general, faculties are not experts on deciding whether a trainee is a 3 or a 4 out of 5 for interpersonal communication skills. This allows for a high degree of variable feedback scores and the benchmarks against which faculty grade the trainees are ill defined and left up to the Residency Program Directors of the residencies to instruct the faculty how to ideally score. This process is quite different than say a management consulting firm that applies psychological testing and customer feedback as metrics of success and advancement.

Whereas a trainee's advancement relies on faculty-only feedback, once a clinician is in practice, the primary feedback to the practicing clinician comes from self-selected peers usually within the practicing clinician's hospital network or community. Credentialing organizations around the country are struggling to standardize privileging and credentialing guidelines [9]. To date, there is no national standard. The concern is that with a growing number of high profile

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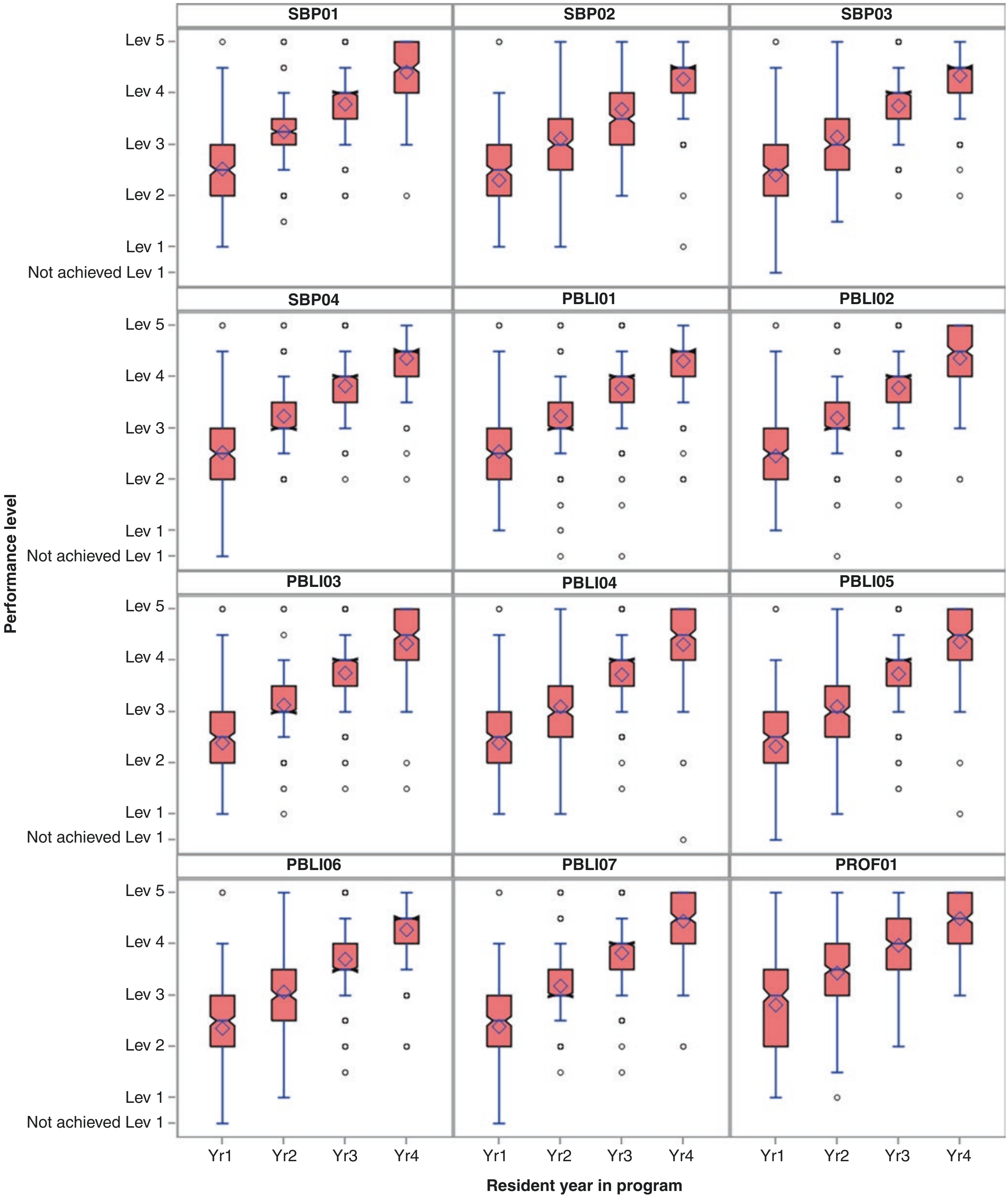

Fig. 1 Nationwide urology resident progression among the core competencies of systems-based practice, problem-based learning, and professionalism over the course of 1 year. (Reproduced with permission of ACGME)

and extremely costly malpractice suits [10] as well as the changing process by which payers reimburse hospitals are taking notice that these practice-granting processes need an infusion of objective methods. Furthermore, physician reimbursement is now being tied to patient satisfaction scores [11]. In order to ensure optimization of physician-patient communication, it will be imperative to utilize nontechnical skills or communication skills assessment methods so that administrators overseeing the satisfaction scores can hone in on deficits and provide targeted remediation to these clinicians.

Need for Periodic Recertification of Existing Skills: Skill Decay and Use

Another growing concern among healthcare leaders and providers is the MOC process. Each surgical Board decides how to recertify their members and has a duty to the public to ensure safe and effective providers. In the beginning years of the American Board of Surgery (ABS), if a surgeon wanted to receive board certification, the Board would send a delegate to that surgeon's parent hospital and watch the clinician practice their craft in the operating room and on the wards [12]. After 2 years, this practice was abandoned. It was unscalable and unsustainable, yet the ABS knew that the practice of the clinician was a critical piece to ensuring the quality of the surgeon. The result was what most Boards do today which is administer 5- or 10-year written recertification exams as a means of quality control. These exams are based solely on cognitive skills and not on any technical skills appraisal. The only surrogate for technical skills is through case log submissions and complication reports which are put together by the clinicians themselves and not extracted from an independent data registry. The recertifying surgeon also needs to demonstrate that s/he is acquiring CME credit through regional and national conferences or hands-on course participation. These are passive learning processes and are not held to rigorous standards. Thus, the quality of the clinician recertifying can only be objectively ascertained through a single cognitive test – a sliding scale score based on clinical knowledge of the specialty.

This lack of technical skills appraisal provides evidence of the lag Boards demonstrate in their tracking methods behind the current reimbursement and regulatory environment that the parent hospitals are experiencing. In addition, there is significant variation in practices such that surgeons may have been granted certification or privileging at the beginning of their practices when fresh out of training, but as their practices change, the same recertification processes that were used upon initial certification remain identical. This has impacts on surgeons who sub-specialize, on surgeons who leave practice for a period of time (military deployment, leave of absence for personal reasons, infirmities, increasing administrative or teaching roles), and on the aging surgeon. The one size fits all recertification processes cannot objectively appraise the resultant variability from the above matters.

Technical skills decay as surgeons age [13] and as surgeons redistribute their clinical practices among other competing endeavors [14]. Evidence-based research provides insight into the skills decay phenomenon. No different than a professional athlete or a theatrical arts professional needs to warm up before performances or demonstrates a diminution of skill after long periods of rest, surgeons, too, experience such decays [15, 16]. Despite evidence supporting this reality, because we do not have systems in place to objectively quantify skills in practice, we cannot identify clinicians who may be experiencing skills degradation. And surgical Boards do not have the means to identify surgeons in need. It remains up to the surgeon himself/herself to recognize a skill deficit and either cease practicing that skill or seek remediation avenues.

Definition and Decomposition of Surgical Skills

In order to establish objective assessment of clinicians, a common language must be agreed upon for metrics. This section addresses how surgical skills are decomposed into constituent parts. Researchers have stratified surgical skills with varying degrees of resolution, incorporating insights form a variety of fields spanning education to aircraft pilot training. This has resulted in a nomenclature that can sometimes overlap but nonetheless help clarify the type and role of various skill components in surgery. This vocabulary can also help provide structured guidance to curriculum developers, hospital administrators, trainees, or researchers to focus resources where they may be most impactful.

Outcomes Versus Skills

We define surgical skill as the ability of a surgeon to consistently bring about a desired surgical outcome for a patient independent of patient-specific aspects. The importance of skills to surgery is irrefutable. But patient outcomes are the primary criterion for evaluating surgical success. Measures of skill – even a subset of overall skill like technical skill demonstrated in a single procedure as an indicator of overall practice – have shown to correlate directly to patient outcomes [17]. But "correlate" does not mean "equate." Skill is necessary but not sufficient for positive patient outcomes. There is more to surgery than surgical skill alone. Even a surgical master can make mistakes, and even procedures that are completed without error have unavoidable risks or complications. Having excellent surgical skills will thus maximize but not guarantee successful outcomes. With this in mind, the ultimate importance of different skills or their constituent parts is determined by the degree to which they positively impact patient outcomes.

Cognitive Versus Psychomotor, Technical, and Nontechnical

Perhaps the most fundamental decomposition of surgical skill is into cognitive and psychomotor skills. Miller's pyramid reproduced in Fig. 2 spans this distinction and stratifies skill from the perspective of an instructor or evaluator [18].

Miller's four-layer pyramid implies that certain skills are foundational; they must be developed before others can be addressed. Typically, a finer degree of granularity is used in the surgical literature in reference to skill acquisition, particularly in simulation. The literature often distinguishes between cognitive and technical skills [19]. According to Miller's pyramid, this would place cognitive skills at the bottom two levels: "knows" and "knows how." Technical skills would belong to the top two layers, "shows how" and "does," with simulation typically falling into the "shows how" layer.

Many of these finer distinctions of technical skill arise due to a change in focus. Whereas Miller's pyramid was constructed primarily from the point of view of the evaluating clinician, the simulation literature moved toward stratifying skills from the perspective of the trainee and his perception. Technical skills are often further stratified into visuospatial and psychomotor skills [20, 21]. Visuospatial skills consist of being able to accurately reconstruct and navigate a 3D environment based on one's depth perception of 2D video that is typically displayed along a different axis than that of the tool interaction. In his comprehensive decomposition of skill categories, Satava further distinguishes psychomotor, visuospatial, perception, and haptic skills [3]. Haptics refers to a subject's ability to perceive haptic (tactile sensory) cues such that resolution of more subtle haptic cues implies stronger haptic abilities.

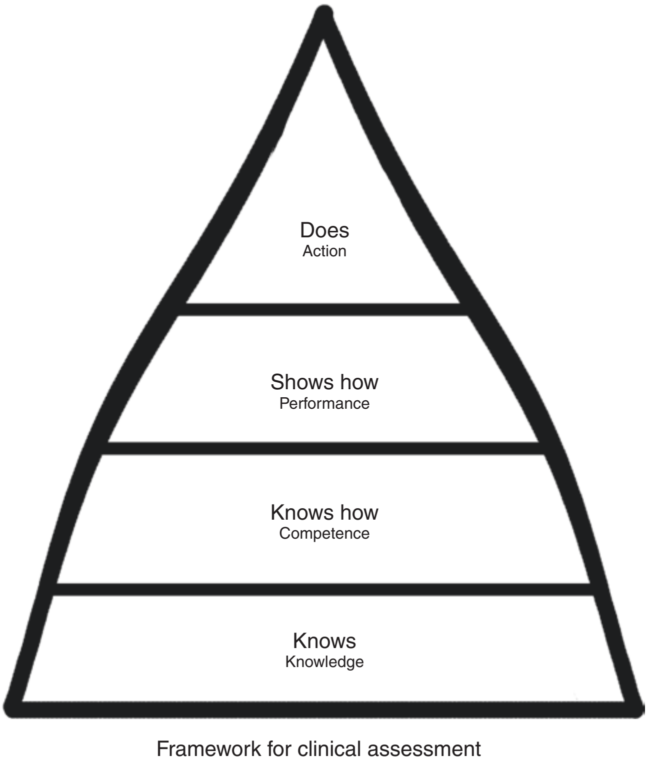

Fig. 2 Miller's pyramid: a "framework for clinical assessment" [18]

Gallagher et al. proposed a hypothetical map of attentional resources across different training levels, reproduced in Fig. 3 [22]. In this map, Gallagher et al. suggest that an individual surgeon has a fixed attentional capacity threshold. A novice surgeon must consciously attend to at least five items: psychomotor performance, depth and spatial judgments, operative judgment and decision-making, comprehending instruction, and gaining additional knowledge. For a typical novice surgeon, the simultaneous combination of these demands is beyond their attentional capacity. As a result, their ability to learn in at least some of these categories is significantly diluted. Gallagher et al. suggest that simulation-based pre-training of novice surgeons can refine technical skills like psychomotor performance and depth and spatial judgments such that most or all of the categories receive sufficient attention. This reasonably supposes that once trained, technical aspects will demand less attention, thus freeing attentional resources for the acquisition of other important skills or knowledge.

Gallagher et al. did not rigorously analyze the process of and neurophysiological elements involved in the relationships between attention, skill categories, and skill acquisition. But the hypothetical attentional resource map finds both conceptual and empirical support in the motor learning literature ("motor" in this field is synonymous with "muscle"). For example, the single channel theory of attention and its supporting evidence reveal that attention demand is usually estimated indirectly by the extent to which the tasks interfere with each other. Processing sensory stimuli (or performing other processes early in the sequence) can apparently be done in parallel, with little interference from other tasks. But processes associated with response selection or with response programming and initiation interfere greatly with other activities [23, p., 121].

Since early stages of surgical training deal heavily with response selection and programming, this supports Gallagher's notion of attentional resource strain. Moreover, "some evidence suggests that directing one's attention to movement or environmental cues may differ according to one's skill level" [23, p., 121]. Also of interest is that "other evidence, based on secondary task techniques, suggests that attention demands are highest at both the initiation and termination stages of movement" [23, p., 121]. Such

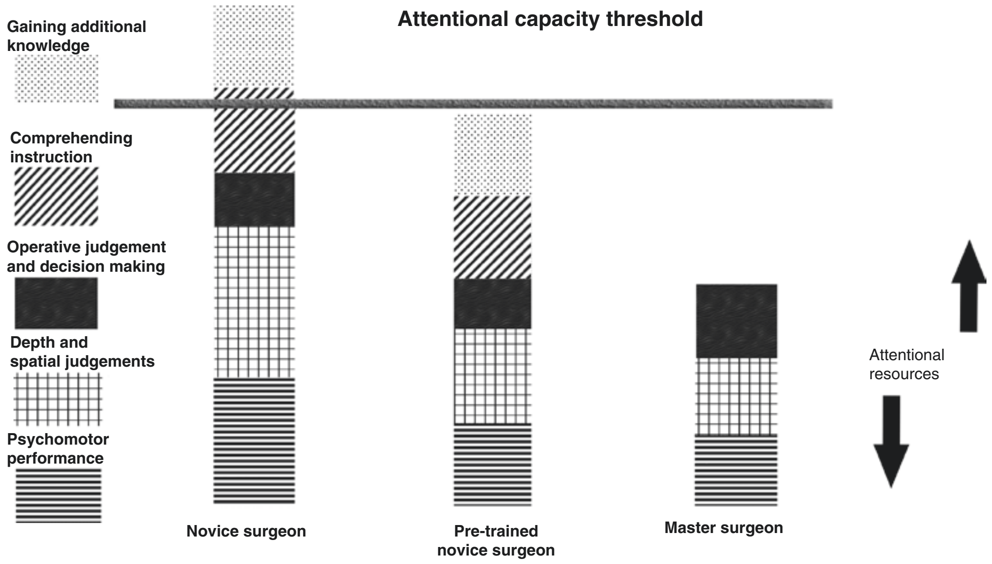

Fig. 3 Gallagher's hypothetical attention resource map indicates the benefits of simulation training. (Reproduced with permission [22])

observations suggest strategies for developing relevant dynamic metrics. However, Schmidt and Lee conclude that "even though attention has had a long history of thinking in psychology, we are still unclear about its nature and the principles of its operation—indeed, even its definition." The motor learning literature recognizes that "learners appear to pass through various stages phases when acquiring skill:

1. The *cognitive phase*, in which emphasis is on discovering what to do, e.g., observing the target motor skill. Trainees are most responsive to verbal instruction or feedback in this stage.
2. The *associative phase*, in which the concern is with perfecting the movement patterns.
3. The *autonomous phase*, in which attentional requirements of the movement appear to be reduced or even eliminated [23, p., 429]."

Human physiology employs numerous senses. Of these, however, the surgeon is essentially limited to three: sight, touch, and somesthesis (i.e., bodily perception). While balance, hearing, and possibly other senses are employed in surgery, the essential three senses identified in Table 1 – sight-related skills like visuospatial localization and depth perception – have often been the object of study in the surgical literature. However, no work exists investigating the role of proprioception in surgical skill acquisition and surgical performance. Yet their importance to technical skill can be elucidated.

Proprioception is crucial to the practice and acquisition of manual motor skills. This is vividly illustrated by the well-documented cases of Ms. G. L. and Mr. Ian Waterman (summarized in [24], original sources [25–28]). These individuals suffered from complete, permanent loss of somesthesis. They could not use proprioceptive senses to localize their body or limbs, only vision could provide this information. However, their efferent neural pathways – those sending control signals *to* muscles – were unaffected. Thus they could exert voluntary muscle control. The following symptoms and phenomena ensued in sequential order:

Table 1 Human senses and the subset of senses available to surgeons

Sense categories	Human senses	Senses used in surgery
Exteroceptive senses	Sight	Sight
	Taste	
	Smell	
	Touch (tactile, heat, forces)	Touch
	Hearing	[a]
	Balance (vestibular sense)	[a]
Interoceptive senses	Pain	
	Movement of organs	
Proprioception	Somesthesis (body/limb localization)	Somesthesis

[a] While balance is critical for standing or sitting during surgery and providing orientation, beyond this, it does not contribute to dynamic surgical activity. Hearing is of utility in surgery, but not crucial to its performance

- Could not walk or stand upright.
- Could move limbs, but could not control them in a precise way.
- When not looking at limbs, did not know their location or if they were moving. Arms (particularly fingers) moved uncontrollably. Sometimes arms would unwittingly hit own self.
- Using constant visual tracking, could eventually learn some control over muscles, but learning was very slow, difficult, and demanded inordinate attention.
- Relearning to sit up took 2 months.
- Relearning to stand took 1.5 years longer.

- Relearning to walk took several additional months. However, he could only walk with slow, somewhat awkward steps and only while looking at his feet.
- When visual information was suddenly removed, immediately fell to the floor (e.g., lights unexpectedly switched off).
- Decades later, still relies exclusively on vision for control. Controlled limb motions are still slow and ponderous, and hands are primarily restricted to only three fingers.
- Typically uses excessive force when holding objects, especially if not looking at them.
- Eventually learned to avoid falling to the floor due to sudden removal of visual information by exerting incredible, conscious effort to tense many muscles. Attempting this for a few minutes resulted in complete mental and physical exhaustion, requiring several days of rest and recovery.
- Tasks involving simultaneous cognitive load and fine motor control nearly exceeded the limits of his attentional capacity (e.g., could not write during dictation, had to constantly switch between listening and attempting to write).

The ramifications of these phenomena for surgical skill are profound. Clearly, proprioception is essential to surgical skill proficiency. This alone implies proprioception in surgery should be actively studied. The inordinate attention required in the above cases is empirical evidence that strongly corroborates Gallagher's hypothetical attentional resource hypothesis. Also, it is evident that somatosensory activity is a key component to surgical skill learning and performance. This strongly suggests that proprioception may yield a universal (cross-procedure, cross-modality) dynamic metric for surgical skill. Thus, proprioception should be better understood.

Proprioceptive somesthesis consists of several sensor groups and multiple neurological centers to which they relay data ([23], Chap. 5). These sensors include:

- Vestibular system: senses internal acceleration or rotation of the head (this sense infers the exteroceptive direction of gravity since gravity registers as an acceleration).
- Muscle receptors: muscle spindles innervate the fleshy part of the muscle and sense stretching position and velocity; Golgi tendon organs innervate the tendons, sense contraction, and have been shown to respond to forces less than 0.1 g.
- Joint receptors: are suspected to sense specific joint positions, joint extremes, continuous joint position, and/or joint velocity. However, there is much uncertainty about whether or how this comes to pass.
- Cutaneous receptors: sense deep or superficial pressure in the skin which often correlates to muscle or limb information as well as touch. Additionally, this group includes temperature, pain, and chemical stimuli. However, it has been shown that primary somesthesis in not affected by these later pathways.

The neurological centers where the sensors send their information to and along what pathway include *(listed reaction times are round trip)*:

- Spinal cord (via spindles): myotatic reflexes, effect individual muscles *(30–50 ms)*
- Cerebellum and cortex (via spindles): long loop reflexes, effect individual muscles *(50–80 ms)*
- Higher centers (via receptors): triggered reactions, effect associated musculature *(80–120 ms)*; reaction time, effect any musculature *(120–180 ms)*

Vision, on the other hand, is a much slower process. Motor control pathways that include vision feedback have reaction times ranging from *200 ms to 3 s*, depending on the type of visual stimulus and type of motion involved. These data apply to natural vision tasks. However, vision in MIS is significantly limited since it comes from a 2D image, typically viewed well off-axis from the original 3D task space. Of the typical visual cues for depth perception, only parallax, depth from motion, perspective, relative size, occlusion, texture gradient, and lighting/shading are available to the surgeon. Cues like familiar size, accommodation, foveal distortion, and inferred overhead lighting are not available. This, compounded with the typically imperfect lighting and picture quality in MIS video, implies that the data available to visual sense and perception is atypically limited and that visuospatial localization from depth perception requires more time, attention, and learning, especially for MIS trainees. This suggests that in MIS the *minimum* reaction time for the visual feedback loop is in fact longer than 200 ms. Moreover, in the case of novice surgeons, visual feedback loop times would be significantly longer, and the information may not be completely reliable as evidenced by common depth perception errors in early training.

MIS tools and the related fulcrum effect effectively alter the kinematic chain of the human limb and end effector. For a first time user, the immediate result is that proprioceptive perception and control must adapt to the novel kinematics. If a novice would not have somesthetic perception and somatomotor control well refined, he would depend exclusively on vision to track both tool and target – as was born out in the study. This would fall into the classic closed-loop motor learning theory reviewed in the motor learning literature, characterized by its precision and slow speeds. As the proprioception and related control adapt to the new kinematics and somesthetic tracking becomes more reliable, the subject needs to confirm tool tracking via vision less and less. At the expert level, target gaze is dominant, and proprioception allows both faster overall tracking and faster, more accurate motor control. However, it is very unlikely this process would continue until a schema or open-loop control strategy is acquired. Unlike fast, precise schemas that have taken years to develop for virtuoso piano playing or high-speed professional sports activity – both are cases where high precision and high-speed performance are only possible via schemas – surgery requires a higher level of precision in more degrees of freedom, moves at a slower pace, and exhibits much greater variability. This essentially precludes the notion of surgical schemas.

The result of the above discussion implies a hierarchical control structure is chiefly active in surgical training, especially in MIS. The neurophysiological analysis and relevant evidence reviewed above allows us to construct a relatively accurate system diagram. The multiple feedback blocks and their respective reaction times suggest a major loop/minor loop control strategy exists [29]. This method is a classic, well-documented way of effectively combining dynamic systems of disparate reaction times. The inner, minor loop traditionally operates at much faster dynamics than the outer, major one (e.g., the stabilizers on supersonic jets require very fast dynamics to suppress vibration and turbulent disturbances, while the pilot's commands have a much smaller bandwidth). The inner one is tuned in such a way that the outer loop's optimal tuning is easy to realize. This can be implemented recursively, as illustrated in the system block diagram below (Fig. 4). Note the feedback loop response times are indicated.

Thus learning a surgical task first relies on vision-based feedback control. Progress involves learning to make sense of proprioceptive information and training somatomotor centers to use this information during motion. Eventually, dependency on visual tracking is reduced, as evidenced in the eye-tracking study. This enables target gaze, where eyes fix strictly on a target, while proprioceptive feedback motor control drives a tool to target. This affords at least two benefits. First, the eyes do not need to switch back and forth between target and tool to realize tracking. Since visual feedback takes (at least) twice as long to incorporate than somesthesis, this would seriously compound the delay time involved in task tracking. Second, the proprioceptive feedback can directly drive somatomotor control centers. Because this loop is 2–10 times as fast as the visual feedback loop, psychomotor performance can be significantly faster. Thus, proprioception is critical in surgical performance and skill acquisition. In fact, the degree to which a surgeon exploits internalized proprioception in favor of visual processing alone is a measure of psychomotor skill.

Typical Use Cases of Skill Metrics: Ideal Requirements

New Technology Certification

Since the introduction of laparoscopy in the mid-1980s, surgery has seen a rapid rate of new surgical technologies being employed, sometimes outpacing adequate training. In 1999, the FDA approved the use of the da Vinci surgical robot that has since transformed whole areas of surgical disciplines. Laparoscopy and robotic surgery never passed through a rigorous training and efficacy testing process. Surgeons who were early adopters decided to do their next cases using these technologies after fairly minimal training or proctoring. Despite high-profile malpractice cases and surgical complications related to the inadequate training of surgeons using these technologies and approaches, there are no standard pathways in place for surgeons to adopt new technologies. Each hospital decides which surgical approaches and technologies warrant special credentialing processes, and each hospital is different. Furthermore, the processes in place for new technology credentialing typically involves sign-off from peers in the institution with whom the surgeon is befriended, thus eliminating objectivity in the process of proficiency assessment.

Objective skills appraisal provides a common ground against which all surgeons adopting new technologies in the operating room can be compared. In an ideal professional situation, surgeons would need to show competency and proficiency in the use of a new technology before using it in a human patient. The reality is that access to physician expertise, available time and resources for the training, and the

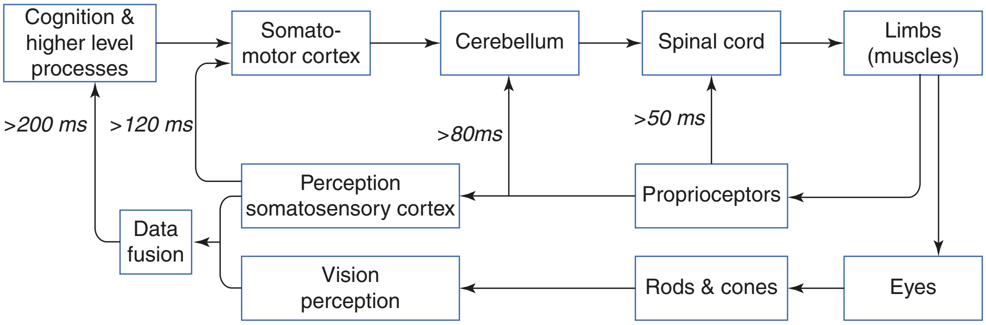

Fig. 4 System block diagram of human motor tracking

surgeon's overestimation of their own capabilities lead to new technology utilization before adequate skill is achieved. This may place patients at risk of harm. The FDA is working to establish guidelines for medical device companies to demonstrate that their new technology is not only safe and effective but also that it is usable by the surgeons. The FDA is calling out to professional leaders and key opinion leaders to encourage their hospitals to embrace [30].

Identifying Best Targets for Effective Remediation

The best targets for remediation are those skills that are universally required for competent performance and can be objectively assessed with validated tools and where clear feedback can yield change. The most basic and fundamental metric is task time. Although extremely easy to track and undisputable across any skill, speed of practice does not always confer safe surgery. Furthermore, giving feedback to a trainee that they are too slow may incentivize poor technique in exchange for improved task time. Other metrics such as bimanual dexterity represent a hard skill that can be objectively measured; directly influences task time, efficiency, and safety; and can be improved with training [3]. When watching a performance, it is immediately evident whether both hands are being used to complete a task. Also, poor bimanual dexterity has been validated a metric that can confer expertise – the higher the degree of bimanual dexterity, the higher the expertise. Bimanual dexterity can also be assessed in an automated way through tool motion or hand motion tracking; thus immediate feedback can be given to the learner about their performance in this skills domain. When deficits are observed, there are multiple low and high fidelity drills that exercise bimanual dexterity for minimally invasive and open approaches. Other areas of skill that meet the criteria of best targets for effective remediation include:

- Depth perception
- Control of instrumentation (laparoscopic, robotic, open)
- Force sensitivity or tissue handling (although this one requires human observation)

Summative Versus Formative Feedback

Assuming that the various components of skill can be measured accurately and readily, how will such information be presented to trainees, established surgeons, or risk assessment department to best improve patient outcomes? The amount of time elapsed from the completion of a procedure can govern this. Gallagher's hypothetical map (see Fig. 3) [22] was suggested primarily as a means to motivate pretraining of surgical trainees via simulation, that is, to hone their technical skills like tool handling and cognition of the procedural flow before joining their attending surgeon in the operating room. But this implies that implementing validated, objective metrics for technical skills can be used to evaluate whether surgeon trainees are ready for higher-level instruction or learning based on their available attentional resources. This would suggest proving skill evaluation information preemptively, *before* an operation ever takes place.

Another approach is to maintain records or data logs of surgical procedures (e.g., recorded videos, compiled ratings, simulator databases) and periodically process this data to provide a summative feedback to a trainee, practicing surgeon, or risk assessment department. This has the potential to link performance to outcomes but only retrospectively. This may occur with varying levels of delay: annually, monthly, or even shortly after the end of a procedure. Conversely, formative feedback would provide meaningful input on skill or performance more proximally – perhaps immediately upon the completion of a procedure or, even better, during a given procedure. This would have the benefit of making the skill evaluation data most relevant and actionable to a consumer. Individuals could learn more immediately from their mistakes or successes or even while they are occurring.

This leads to the ideal case for formative feedback of zero time delay, that is, virtually real-time measurement and structured feedback on skill, that is, "what is the skill rating at any moment within a surgical task?" and "what can one change in this instant and context to improve?" and not just summary (more summative) information such as total time upon completion of a task or procedure. This could ultimately accelerate or mitigate the prolonged, arduous learning curves associated with surgical skill acquisition.

Aggregation Versus Individuation of Skill and Context and Skill Decay

The impact of surgical skills to patient outcomes is a function of both context and time. For example, technical mastery of suturing can be targeted as a particularly critical skill. The manual dexterity required to master suturing in manual laparoscopy can ensure some dexterity in simpler technical tasks: if one masters suturing, he or she must implicitly be at least passable in other aspects like basic tissue manipulation. But while the success of some procedures hinges on suturing mastery, others may be able to completely avoid it or complete such procedures with comparable outcomes using tools like the Autosuture^{TM} (Covidian Corp. Dublin, Ireland) that obviate the need for traditional suturing. The resulting impact that mastery of suturing has on ultimate patient outcomes is thereby also function of the specific procedure in question. While this relative importance of a specific skill like suturing mastery to the patient outcome depends on the wider procedural context, the understanding of the skill in and of itself is also context dependent. For example, skill changes with time: a trainee's mastery of suturing increases with practice, but a master surgeon's level of technical proficiency can also decay with lack of use.

The level of granularity between aggregation and individuation can apply to an individual surgeon (e.g., their entire practice), a specific class of procedures (e.g., all of the appendectomies they have ever performed), a specific procedure on a particular date, specific steps or minutes within that procedure, and across the various components of skill (e.g., cognitive vs. psychomotor vs. visuospatial). In practice, aggregation (combining of performance evaluations from multiple dates or for a given performance from multiple raters using a method like averaging or median) provides more reliable, statistically stable results as it avoids the prevalence of outliers since spurious events like occasionally erroneous ratings or unusually extreme performances can cancel out. However, this introduces a necessary drawback: the more aggregation occurs over time intervals, the less formative (immediate) the feedback can be, somewhat hampering its possible utility. This delay can also overlook issues like identifying decayed skills that need a quick warm up. Feedback averaged over an entire practice may not provide the most up-to-date assessment of a surgeon's skill. Conversely, the evaluation of a single segment from a single procedure may not accurately reflect that surgeon's entire practice or aptitude in other procedural contexts. Independent of the level of aggregation, the principle of extremes can still apply. For example, a risk assessment department can look at a histogram of all surgical technical skills evaluated for a given procedure and identify the extremes: e.g., the top and bottom quartiles. This can identify individuals most and least deserving of additional resources for training and improvement. Then for a particular individual, a more individuated assessment, say, for the riskiest steps of a given procedure, can assess which of their component skills are weakest, e.g., "respect for tissue," and target very specific resources to improve them.

Methods of Surgical Skill Measurement

Determining methods to reliably, objectively, and quantitatively measure surgical skill remains an active area of research. While numerous approaches have been proposed over more than two decades, few have yet established widespread use. This is particularly true for more technology-dependent computational approaches that promise most quantitative rigor. However, with the increasing popularity of robotics and continual incursion of advanced technologies into the operating room, it is reasonable to expect that such methods will penetrate into practice.

Subjective Versus Objective Metrics

Barring technology and automation, earlier methods such as the objective structured assessment of technical skill (OSATS) employed manual, subjective evaluation of performance via expert review of video-recorded procedures [31, 32]. Objectivity was argued based on a consistent checklist and preset Likert scale evaluations with categories such as "respect for tissue," "time and motion," "instrument handling," "respect of instruments," etc. Such methods are equally applicable in both simulation and real surgical environments and scale well across the different tasks or modalities (e.g., robotics, laparoscopy, endoscopy, open surgery, etc.). However, they require a human proctor to manually evaluate each individual's tasks which is expensive and does not scale well to large numbers or concurrent trials. Multiple variants of OSATS have become practical de facto standards for skill assessment; the core concept of anonymized video review with structured survey instruments employing Likert scales remains the same, but some Likert domains may be slightly altered for specific surgical procedures or specialties. Examples include the global operative assessment of laparoscopic skills (GOALS) instrument for laparoscopy [33] and the global evaluative assessment of robotic surgery for robotic surgery [34]. Such approaches also invariably suffer from the subjectivity of the evaluator's judgment and imperfect inter- and intra-rater agreements. On the other hand, they are more objective than traditional in person "over the shoulder" subjective evaluations. This is due to blinding raters to the identity of surgeons whose performances they evaluate through videos, the aggregation of multiple ratings, and consistent textual descriptors used to anchor provided ratings. However, such tools are not as objective as rigorous quantitative algorithms. For example, the same panel of OSATS raters may provide slightly different scores to the same video at different times, whereas a quantitative method would provide the same deterministic score for each performance.

Methods to overcome barriers of scale for objective assessment of large groups of surgeons have been developed employing crowdsourcing to assess surgeon skill. Chen et al. first described posting a single robotic suturing video to a large group of distributed, independent, anonymous crowdworkers to rate the performance using a validated robotic skills assessment tool. When compared to a panel of expert robotic surgeons reviewing the same video, the crowd of presumably nonmedically trained crowdworkers agreed with the expert ratings. Furthermore, instead of the 3 weeks it took the experts to do the survey, it took the crowd of almost 500 people less than 24 h to complete the survey [35]. This methodology for objective skills assessment has since been validated for open, laparoscopic, and robotic animate, human, and dry lab surgery skills [36–44]. The enabling capability of crowdsourcing is evidenced by the consistently inexpensive and rapid results that mirror expert reviews.

Proficiency Benchmarks

Proficiency methods are based on the repetition of tasks or procedures until predetermined performance criteria have been met. To set the performance criteria on some criterion tasks like suturing, a pool of "expert surgeons" completes multiple repetitions, and their resulting scores are averaged. A trainee must score within 1 standard deviation of their average score at least two consecutive times to achieve proficiency. This approach deals well with the large amount of variability inherent within and among subjects, and applications of proficiency-based methods have spread beyond VR since their introduction to surgery. It is from within the corpus of VR surgical simulation studies that proficiency-based evaluation and training arose [22]. However, this approach suffers from some problems as well. The proficiency benchmarks tend to be highly task specific: two different tasks intended to evaluate suturing skills (e.g., a virtual reality simulation and a reality-based Fundamentals of Laparoscopic Surgery (FLS) suturing task) will provide different "task-specific" scores. This means that proficiency criteria must be established for each task. Furthermore, the choice of the "expert subjects" and their resulting performance can vary significantly as no universal criteria are established or espoused in selecting them: two groups of experts from different geographic locations may yield different proficiency criteria perhaps because they teach different suturing techniques, e.g., how to tie knots or hold the suture and needle. Ideally, skill evaluation metrics would move beyond tallying task-specific events to seeing the "skill" exhibited in the task – something that structured survey tools like OSATS can better cope with.

Technical Skills (Psychomotor, Visuospatial)

The act of surgery invokes numerous human physiological systems during its execution by a surgeon. Of those specifically identified in the surgical literature (e.g., Miller's pyramid, Gallagher's attentional resource chart), technical skills are most easily amenable to traditional scientific measurement and observation. Cognitive skills can, for the most part, be directly assessed with traditional examinations. While cognitive skills, knowledge, and sensory perception are important in surgery, their inaccessibility via direct observation precludes them from convenient scientific investigation. As a result, technical skills have received the most research effort to date.

In Simulation

Virtual reality (VR) was introduced into surgical simulation in 1993 [45] and continues to be adopted, evaluated, and improved as a tool for training and measuring surgical skill with varying degrees of granularity from its outset [6, 46–50]. In simulation, the benefits of VR include the ability to deploy the same environment between subjects and tasks and so offer a consistent training platform for trainees, low cost of long-term use, ease in data collection, and ease of tracking the virtual environment. Drawbacks include high initial cost, steep cost increases for better realism in visual representation, internal modeling or haptic rendering, and the inability to extract similar data from real cases. The bulk of the surgical literature in the VR simulation area has focused primarily on validation. That is, in establishing that skills acquired during simulation trials ultimately transfer to operating room (OR) performance. These validation studies rely almost exclusively on summary metrics like task time, path length, and economy of motion (path length divided by task time or similar efficiency measure) and provide typically positive but sometimes mixed results about the validity of simulators to train OR-transferable surgical skills [51].

In terms of metrics, VR natively supports automation and objectivity in recording metrics, more so than in reality-based procedures or simulations. Time to task is automatically computed along with more novel tool path metrics such as path length, economy of motion, smoothness, etc. Recording complete tool trajectories is trivial. Such information can provide a rich source for dynamic analysis, though this source of data and its subsequent, potential dynamic analysis are basically ignored. Because VR systems synthesize their environments, tracking of virtual tissue and objects and how they are interacted with is also trivial. Thus, once the expense of creating the environment is incurred, it is inexpensive to automate the accurate detection of both procedural and cognitive errors in VR. This is a major benefit of VR.

Reality-based (RB) simulators consist of physical objects that either mimic anatomy with varying degrees of realism or simply provide inexpensive, nonanatomical objects as a means for basic manipulation. These simulators employ real surgical tools used in the OR or slightly modified versions. Perhaps the most notable of these is the McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS). It originally consisted of seven laparoscopic tasks (peg transfers, pattern cutting, clip and divide, endolooping, mesh placement and fixation, suturing with intracorporeal or extracorporeal knots) executed on inexpensive materials like gauze, rubber grommets, latex gloves, tubing, and foam. The original purpose of MISTELS was to develop a series of structured tasks to objectively measure laparoscopic skills [20, 21]; these tasks were not necessarily developed to systematically accelerate or optimize the learning curves for skill acquisition. The chief metrics used in MISTELS are task time and an error penalty. These metrics are combined into a single score based on the following formula (Table 2):

$$\text{Score} = \text{preset constant} - \text{completion time} - \text{penalty}$$

Table 2 Equations used to compute FLS scores per Task with t for task time and E for task-specific error counts; derived from [20, 52, 53]

FLS task	FLS score
Peg transfer	$\mathrm{FLS}_{\mathrm{Peg}} = (300 - t - 17E_{\mathrm{dr}})/237$
Cutting	$\mathrm{FLS}_{\mathrm{Cut}} = (300 - t - 2E_{\mathrm{a}})/280$
Suturing	$\mathrm{FLS}_{\mathrm{Sut}} = (600 - t - E_{\mathrm{pd}} - E_{\mathrm{g}} - E_{\mathrm{q}})/520$

Both the preset constant (cutoff time) and penalty are unique to each of the seven tasks. MISTELS was successfully validated with varying degrees of granularity [54–59]. Eventually, the Fundamentals of Laparoscopic Skills (FLS) committee, mandated in the late 1990s by the Society of American Gastrointestinal and Endoscopic Surgery (SAGES), adopted the MISTELS program with the exception of two tasks (clipping tubular structure and securing a mesh were found to lack utility) [19]. Since this adoption, a number of studies ensued to reinforce the validation of the MISTELS/FLS paradigm [52, 60–65]. Most notably, given proficiency-based training, translation of skills to the OR was established [66, 67] along with positive evidence for its utility in skill retention and maintenance [53, 68].

FLS and similar RB simulators are less expensive than VR simulators because they require less technology and do not need to invest resources to accomplish realism in accurate models or visual and haptic rendering. As such, validation only considers the metrics used for skill scoring and does not need to address the quality of realism in simulation since the subject is already interacting with real-world objects. However, the acquisition of metrics typically requires manual oversight for timing and particularly with evaluating errors for task-specific penalty scores. FLS trainers, like most RB methods, do not utilize tool path analysis, neither for summary metrics like path length and economy of motion nor for dynamic metrics or force information.

Robotics provides a platform in which dry lab simulations and OR procedures can both be logged in an identical manner and yield consistent, automatically generated metrics. This would be ideal for validation studies of dry lab or realistic VR training skills transferred to the operating theater. However, Intuitive Surgical, Inc. (Sunnyvale, CA), the company that currently deploys the vast majority of surgical robotic platforms, does not have universal open access to the data streams internally collected during operation. Some work is underway for creating VR tasks intended to train or evaluate robotic skills which resemble FLS constructs, but these are not as developed or validated as the FLS program and remain an active area of research at this time [69–71]. If dynamic metrics are successfully created based on tool trajectories from VR or RB simulation, they would be naturally well-suited to extend into surgical robotics.

Computational Metrics

Computational metrics obviate the need for human raters. They operate on quantitative data actively streaming or previously recorded from the operating room. This can include continuous video and a variety of tool tracking variables like tool tip and handle positions, orientations, and forces. Such data are generated either via customized sensors as in early work [72] but more commonly through existing computerized systems to which such data are already inherent; the increasingly ubiquitous da Vinci surgical robot (Intuitive Surgical, Inc.) is an example. This area of research has been highly active and continues to make significant progress [73, 74].

The basic approach employs methods from machine learning. This includes constructing a sophisticated mathematical model and “training” it with data captured from surgery that is labeled according to skill ranked level (e.g., novice, expert, intermediate). Then the ability of the model to quantify skill is evaluated by testing it with entries that were not part of the training set to emulate what a real-world situation would be like: the model must analyze data it has never seen before. This process is called cross-validation. The resulting models are typically said to classify skill level when referring to discrete predetermined skill levels such as novice or expert. Alternatively, they are said to quantify or score skill level when they provide a score that can take on a continuum of values instead of discrete categories. In this literature, the word metric and measure take on very specific, narrow mathematical meanings that are not compatible with the wider sense of the words in the surgical literature. This area of research is primarily hampered by a dearth of rich datasets that capture the massive variability of surgical practice, skills, and regionally varying techniques. To date, no computational methods have shown to predict patient outcomes. However, some techniques have recently been applied that effectively automate OSATS – a technique shown to correlate to patient outcomes – directly on raw video (from dry lab procedures) with surprising accuracy [75].

Among the most mature accomplishments in this area to date is the study by Ahmidi and colleagues [76] which summarizes the problems of automatically segmenting a surgical task into constituent sub-parts and atomic surgical gestures called “gestemes.” More importantly, it also establishes a formal standard for validating the success of computational metrics, leave-surgeon-out cross-validation (also called leave-one-user-out or LOUO), and provides an open dataset captured from the da Vinci robot. This is particularly important given the scarcity of such data and the fact that surgeons vary so widely in their captured data.

Typical metrics such as procedural errors, task time, accuracy, blood loss, fluid use, etc. are specific not only to a particular task or procedure (e.g., FLS peg transfer or cutting, etc.) but are also specifically fixed to a certain modality. For example, the amount of blood loss may be cheaply computed in VR but may be difficult or impossible within RB, robotics, or traditional manual MIS.

Since the 1970s, hidden Markov models (HMMs) have enjoyed considerable success in computer speech recognition and voice identification [77]. They also showed promising results when applied to robotics problems such as human task segmentation or task identification [78–82]. Hannaford and Rosen successfully applied Markov modeling techniques to surgical skill/performance evaluation [83–86] in part by developing the Blue-DRAGON [87–89] data capture device and a subsequent, smaller version known as the Red-DRAGON [90] (see Fig. 5). The Blue-DRAGON employed a novel spherical mechanism and was used to record a large database of surgeon-tool interactions for common laparoscopic procedures executed in live porcine models. This exposed surgery to modern signal processing and led to validating the Markov modeling approach for surgical skill recognition [91]. Both the Red-DRAGON and the use of HMMs for surgical skill evaluation were eventually licensed and commercialized as the Electronic Data Generation for Evaluation (EDGE) machine by Simulab Corp (Seattle, WA).

The EDGE platform (Fig. 6) was used to collect data from hundreds of FLS task recordings across more than ten geographically diverse training hospitals in the United States. The motion data is ten-dimensional (tooltip position in x,y,z, tool rotation and grasp angle for both hands) and sampled at 30 Hz. Tool path plots of a peg transfer task for disparate skill levels reveal characteristic distinctions in refined vs. crude motion (see Fig. 7). Similar interesting nuances can be seen in the grasping force plots (Fig. 8).

The use of HMMs for surgical performance measurement and processing has gained considerable momentum since its inception at the Biorobotics Lab. This was primarily at Johns Hopkins University [92–94], but development has spread internationally [95, 96]. The strong reception of surgical Markov modeling in academia has spurred research activity in this field. While this academic success lends credibility to this method, it also may introduce alternative models which could potentially outmode classical HMMs by offering better performance in surgical applications [97].

Some earlier robotics studies from the University of Nebraska proposed some more intuitive metrics [98–100].

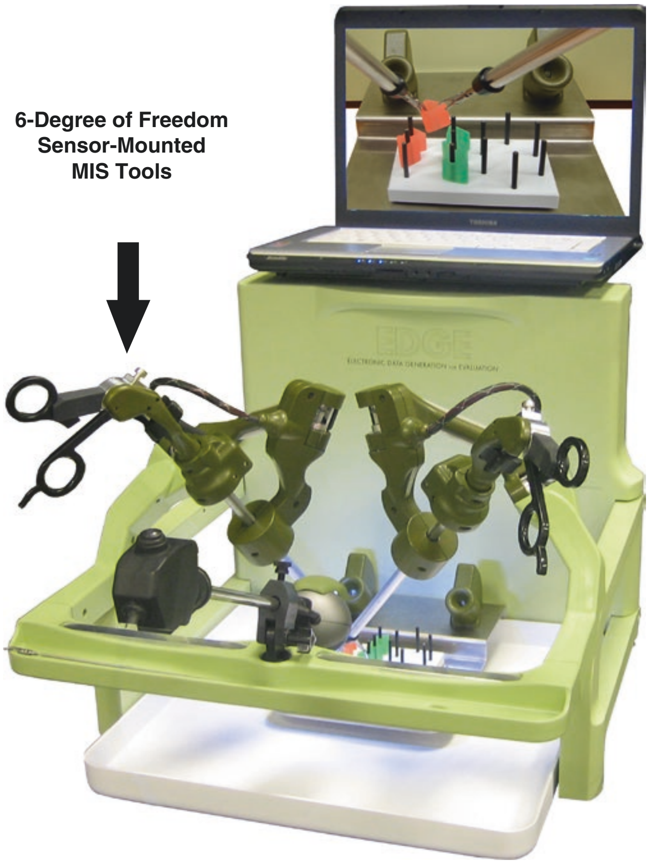

Fig. 6 Simulab's award-wining EDGE platform, a commercialized version of the Red-DRAGON. (Used with permission of Simulab Corporation)

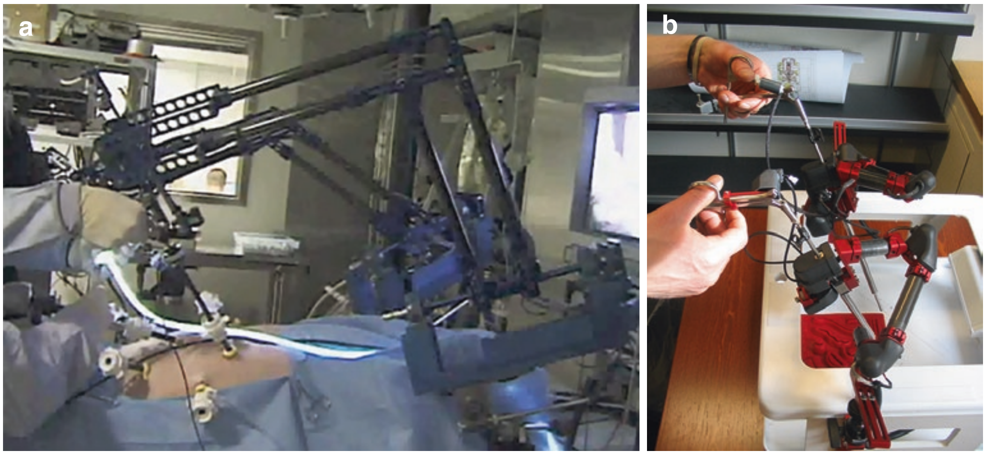

Fig. 5 The Blue-DRAGON collecting data during surgical training in live pigs (**a**) and the subsequent, smaller Red-DRAGON [90] (**b**) in use on an artificial tissue model. (**a**) Used with permission of Jacob Rosen; (**b**) used with permission of Scott Gunther

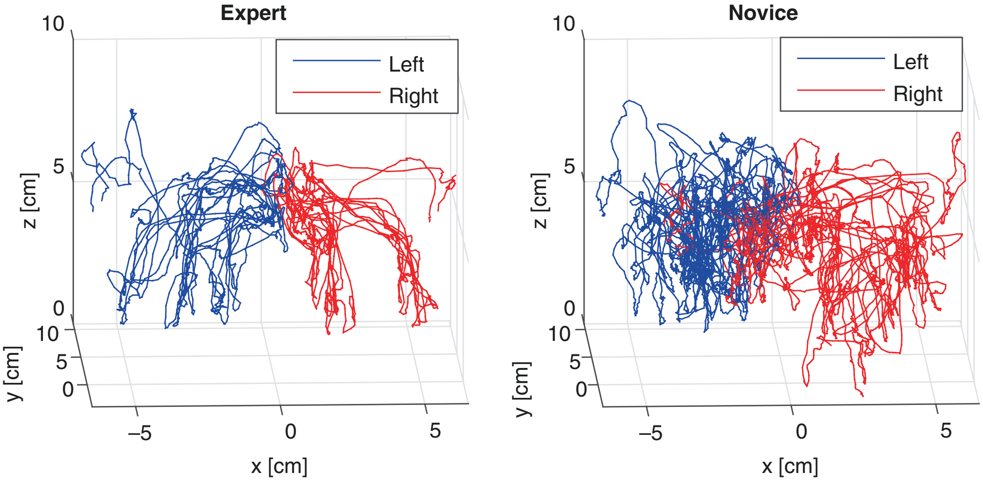

Fig. 7 3D plots of tool path in Cartesian space. The expert data (left) indicates refined, deliberate motion, ambidexterity, and economy of motion. The novice data (right) reveals the right hand (red line) dominates and consistently crosses into the left hand region to compensate

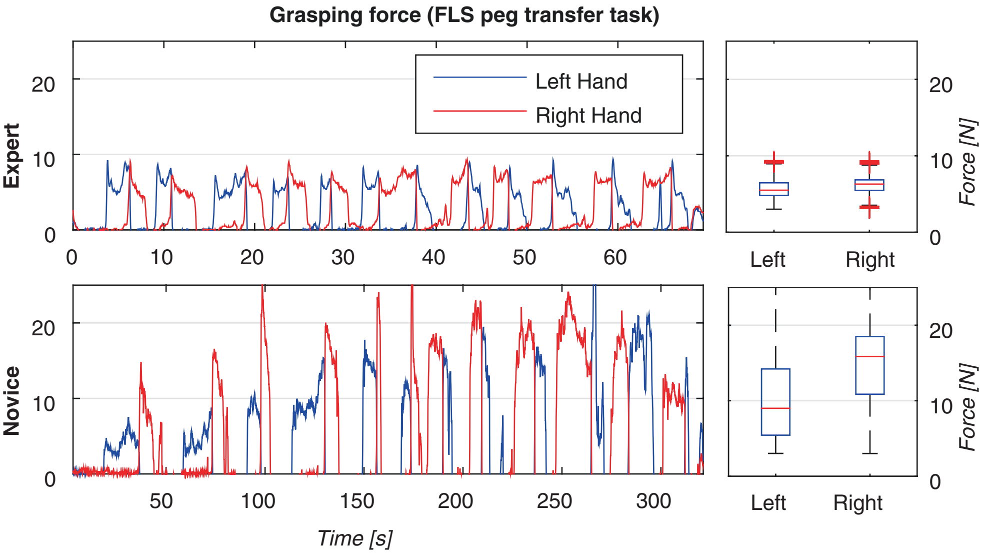

Fig. 8 Plots of left and right hand grasping force in FLS peg transfer tasks recorded with EDGE. Boxplots shown for left and right hands separately for all grasping forces recorded above 3 N to segment grasp events

Movement time intervals (e.g., time spent reaching for an object, time spent holding, etc.) and the coefficient of their variation allowed for finer granularity in temporal analysis. Another metric is the radius of curvature of the trajectory computed from the three-dimensional trajectory of a point and its time derivatives. Phase portraits of position vs. displacement were suggested for bimodal analysis. From the phase portrait, the suggested mean absolute relative phase (MARP) value, which measures the extent to which tools are out of phase (moving in opposite directions), was found to be significant (in phase registers with lower MARP, out of phase induces higher MARP). Moreover, electromyogram (EMG) signals were evaluated and also indicated a correlation to skill level. Historically, static metrics were predominant in the literature, with task time being the most prevalent. Any of the listed platforms that compute economy of motion (EoM) and/or tool path implicitly acquire and potentially log time-dependent tool path data. However, such metrics were potentially found to have little or no value over task time [101].

Another interesting branch of inquiry comes from eye tracking [102]. For example, five novices and five experts were presented with a VR laparoscopic targeting task where a target appeared in a laparoscopic simulation and they were to touch the target in minimal time with a laparoscopic tool. To see if the performance differences between groups were accompanied with eye movement differences, researchers looked at the amount of eye gaze on the tool and then characterized their eye behavior through eye and tool movement profiles. In terms of eye gaze behavior, novices tended to gaze at the tool longer than experts. Several eye gaze behaviors identified in this study, including target gaze, switching, and tool following, are similar to previous findings. The target gaze behavior was the preferred strategy for experts, and novices tended to follow the tool more frequently than experts [102]. Figure 9 and Table 3 demonstrate these phenomena.

There are several ramifications of this study in light of the surgical and motor learning literature reviewed above. First,

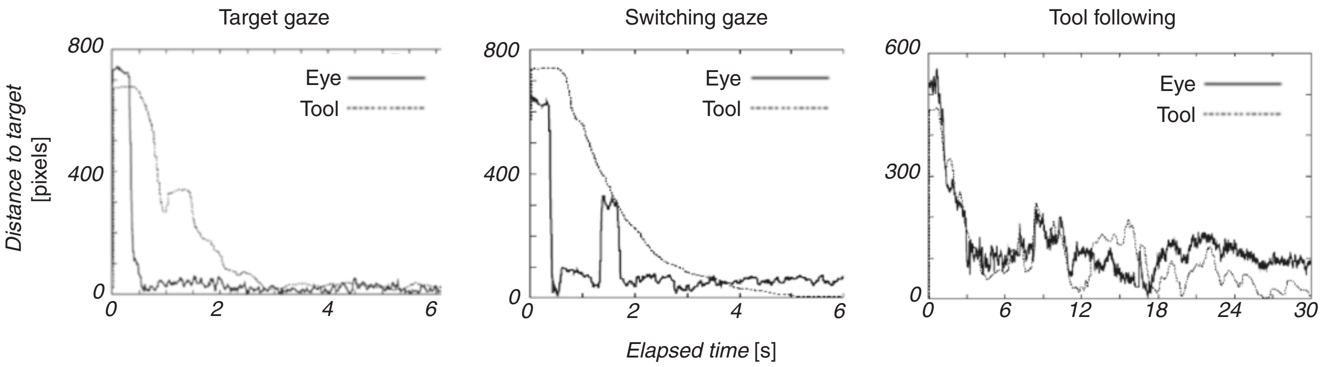

Fig. 9 Eye vs. tool movement profiles typifying different types of gaze patterns taken from [102]. (Reproduced with permission). Eyes gaze at (1) the target, left; (2) eyes switch between target and tool, center; and (3) eyes follow tool during motion, right

Table 3 Eye movement behavior distributions for expert and novices over all trials found in [102]

Group	Target gaze	Switching gaze	Tool following	Loss
Expert	73.3%	13.3%	8.9%	4.4%
Novice	53.3%	17.8%	26.7%	2.2%

the differences in the movement profiles and their associated task times corroborate the notion of Gallagher's attentional resources; the tool following profile of a novice indicates active attentional focus on the tool, while the target gaze of the expert suggests a level of autonomy in the manipulation task. Second, the difference in gaze and targeting patterns across skill levels, as suggested in the motor learning literature reviewed, is reproduced here in a VR laparoscopic setting. And third, this presents strong evidence of open-loop control in the expert (and hence faster performance) vs. closed-loop control in the novices, at least in the sense of a visual feedback loop.

This same study also makes the following two important observations [102]:

- Laparoscopic tool movement is unlike direct hand movement because proprioceptive feedback from hand position does not map directly to the tool tips necessitating additional visuomotor and spatial transformations [103].
- Tactile feedback from tool movement is minimal because of friction between the tool and the cannula (a tunnel-like structure surrounding the tool at the patient entry point), and thus, the surgeon has a greater reliance on the indirect visual information [104, 105].

Exploiting eye tracking in establishing metrics of surgical skill remains an active area of research and recently includes more rigorous methodologies for computational extraction [106].

Nontechnical Skills (NOTSs)

We have focused on technical skills which represent skills centered on a surgeon's kinematic signatures or hand/tool motions, yet surgical success also involves effective communication and human-human interaction – commonly referred to as nontechnical skills. Recent literature has started to address how to distinguish nontechnical surgical skills (NOTSs) such as effective communication, leadership, cooperation, read-backs, and team choreography [107]. These elements can be assessed through objective scoring tools validated in the literature. Clinical areas such as catastrophe or code environments, anesthesia team management, and urgent complex clinical care scenarios have been the initial benefactors of such assessment [108]. These types of scenarios tend to be practiced in simulation centers, yet some have advocated for in situ training scenarios so that any equipment or resource deficits existing on the wards/in the ORs can be unmasked during the simulated team training.

Operationalizing the assessment can be challenging, however, as video and audio from multiple vantage points may need to be obtained to capture the whole room, extensive time is required for coaches/instructors to debrief the teams, and the scenarios themselves can create quite stressful environments which subjects need to reconcile. In addition, in situ training involving patients introduces the concerns around maintaining patient privacy and HIPAA compliance. Thus most in situ scenarios still involve standardized patients or mannequins.

It is clear that effective communication leads to improved team dynamics. And the link to patient outcomes has been indirectly confirmed through malpractice evidence whereby a number of claims in surgery have been related to poor communication; whether between clinician and patient or provider-provider [16]. Operative choreography will become a metric for entire teams [109]. Systems-based training will parallel military training experience that has benefited from decades of evidence to support its value.

Currently there is a dearth of computational or quantitative tools to automatically process NOTSs. While such "soft skills" were traditionally only perceptible or analyzable to humans, this is slowly changing. For example, automatic speech recognition was historically perceived in the same way. But it is now a mature field of research with increasingly dependable algorithms that have become inexpensive and ubiquitous (e.g., Apple's Siri voice assistant). Key aspects of NOTSs are not just what is being said but how it is being said. This includes not only the efficiency of communication or correctness of language but also tone or emotional content – aspects that were historically incomputable. However, new branches of computer science and engineering are actively gaining momentum such as affective computing that can computationally grapple with such aspects [110, 111]. In the interim, however, crowdsourcing methods which have already found considerable success in evaluating surgical technical skills are immediately suitable for providing such evaluations more automatically and objectively than expert human raters [112].

Conclusions

The technology and knowledge exist to elevate the objectivity in a clinician's skill, both technical and nontechnical. And we know that the skill of the surgeon influences patient outcomes. Yet, the utilization of objective performance assessment has lagged awareness. There are many barriers to standard assessment including cost, time, and expertise. The onus is on thought leaders in the field of objective skills assessment to enlighten practicing surgeons and organizations tasked with establishing certification, credentialing, and privileging with a unified method for skills appraisal. Until there is agreement on cost-effective, universally agreed upon standards to capture surgeon performances and provide objective, iterative feedback that helps surgeons improve their skills, resistance will exist. Furthermore, we as surgeons should proactively figure out standard feedback methods before regulatory bodies comprised of non-clinicians decide for us how we are to be assessed.

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Performance Optimization

Nicholas E. Anton and Eric Bean

Abbreviations

ACEP	Army Center for Enhanced Performance
AHRQ	Agency for Healthcare Research and Quality
CEP	Center for Enhanced Performance
CSF2	Comprehensive Soldier and Family Fitness program
LC	Laparoscopic cholecystectomy
MI	Mental imagery
MSC	Mental skills curriculum
OSATS	Objective structured assessment of technical skills
SMART	Stress-management and resilience training
STAI	State-Trait Anxiety Inventory
TeamSTEPPS	Team Strategies and Tools to Enhance Performance and Patient Safety
USMA	US Military Academy
VR	Virtual reality

Introduction

High-level surgical performance is characterized by a mastery of extensive and ever-evolving knowledge, skills, and abilities to accurately diagnose illness and disorders in the body and offer direct treatment interventions [1]. Inherent components of successful surgical performance include executing intricate technical details flawlessly, maintaining concentration on relevant information amidst environmental distractions, communicating effectively with the surgical team, balancing attention, and sustaining sound clinical judgment. Surgeons must execute exceedingly difficult surgical procedures safely under challenging clinical situations that can impair cognitive and physical function in less proficient performers [2–4]. Thus, it is apparent that there can be significant differences in individual and intraprofessional surgical performance dependent upon proficiency at executing the aforementioned factors, experience, and management of the psychophysiological demands of surgery. In an effort to reduce the variability in surgeons' performance, we will provide an operational definition of performance optimization, briefly discuss the process of skill mastery, outline programs designed to optimize performance in other high-stakes domains, identify how cognitive performance-enhancing strategies have been implemented in surgery, and consider the future of performance optimization in surgical education.

Performance Optimization

Individual Performance

Our definition of performance optimization is having the clarity and knowledge of what comprises expert performance and skill mastery in a specific domain and utilizing techniques and competencies to work toward consistently executing performance at that standard. Expert performance in any domain is context-specific, but it can generally be considered as consistently exceptional or extremely good performance that is in the uppermost range of a normalized performance distribution (see Fig. 1) [5].

Salthouse (1991) contends that aside from the obvious knowledge gaps between experts and novices, experts are free from information processing constraints, as they are able to use past experiences to manage expectations for performance, focus attention on relevant information, and

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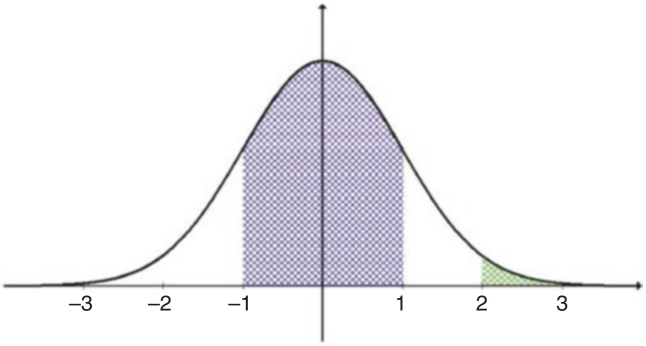

Fig. 1 Visualizing expertise through normalized performance distribution

develop a deeply structured understanding of how knowledge is interrelated, allowing for easy assimilation into performance [5]. Moreover, experts are able to consistently execute exceptional performance regardless of internal or external conditions. In order to masterfully execute skills in variable conditions, experts have likely developed techniques and competencies to reliably perform their best. Accordingly, the goal of interventions to facilitate individual performance optimization should focus on reducing the learning curve to attain the trainable elements of expertise and to consistently enable high-level performance irrespective of situational barriers.

Performance of the Team

Due to the inherent integration of most occupations, effective participation in groups and teams is a fundamental element of many performance contexts. Groups, defined by a common purpose, are comprised of individuals that influence each other and the ultimate performance of the group profoundly [6]. Group cohesion is the fundamental property of team performance that can ultimately impact interpersonal dynamics, communication, and individuals' commitment to the group's goals.

Cohesiveness is essentially the tendency of a group to remain unified in the quest for completion of its objectives, and it is impacted by situation factors (e.g., proximity), personal factors (e.g., individual satisfaction within the group), leadership factors (e.g., interrelationship of the leader with other members of the group), and team factors (e.g., clearly defined roles) [6]. Effective teams share a common mental model of knowledge about relevant environmental factors that represents their ability to share understanding about a situation and engage in intentional and coordinated efforts to accomplish their common goal [7]. In order to optimize the performance of the team, it is critical to enhance these factors, as they will ultimately impact the effective pursuit of the team's goal.

Surgery-Specific Performance Optimization

In 1999, the Institute of Medicine released a report estimating between 44,000 and 98,000 deaths occur annually in hospitals in the United States directly resulting from medical errors [8]. Additionally, the Joint Commission reported in 2006, more than 60% of sentinel events in healthcare are caused by poor communication [9]. In a recent survey of 72 surgeons (i.e., residents and attendings) at an academic medical institution, 40% of respondents reported they had witnessed an intraoperative complication directly resulting from the primary surgeon's stress level [10]. These numbers are alarming, as the errors are largely preventable. As previously outlined, surgery is an incredibly cognitively demanding profession, and those cognitive demands can exceed one's ability to manage them which ultimately leads to stress [2–4]. In a study of the effects of stress on surgical performance, Wetzel et al. (2006) found that stress can impact surgeons' manual dexterity, emotional control, decision-making ability, and communication with the surgical team [4]. However, in their review of the impact of stress on surgical performance, Arora et al. (2010) found that surgeons who utilized stress-coping skills were able to mitigate the negative effects of stress better than surgeons who did not utilize these skills [2]. Similarly, communication breakdowns throughout the continuum of surgical care have been identified as significant barriers to favorable patient outcomes and can directly lead to patient harm [11]. Still, communication breakdowns can also be averted through interventions such as medical team training [12]. Another barrier to surgical performance being more closely examined is surgeon burnout. Burnout, a psychological condition characterized by depersonalization, emotional exhaustion, and low perceived personal accomplishment, is strongly correlated with major medical errors committed by surgeons [13]. Similar to acute stress and communication breakdowns though, it is possible to facilitate skills to counteract burnout by enhancing physician resilience and psychological well-being [14].

It is clear that within healthcare, a domain with such high-stakes situations, performance lapses can directly reduce patient safety and ultimately lead to heightened mortality. It is also evident there are skills surgeons can develop at the individual and team level to prevent lapses in performance. Thus, it is incredibly important to identify methods of optimizing these skills, and subsequently, surgical performance at the individual and team level, as this can reduce the potential for errors and increase patient safety.

Skill Mastery

Defining Expert Surgical Performance

Abernethy et al. (2008) explain that expert surgical performance is defined by mastery of self-monitoring perceptual, motor, attentional, and cognitive attributes of performance [15]. The authors point out that through extensive experience, deliberate practice, and study, expert surgeons develop high-level sensitivity to cognitive and technical errors and formulate schemas to correct these errors quickly. Likewise, experts develop highly attuned pattern-recall and perceptual discrimination (i.e., between normal/safe and abnormal/unsafe situations) which contributes to their anticipation of imminent situations with limited information.

Expert surgeons also display the ability to make more efficient, economical motor movements (i.e., subtle, smooth movements, exerting force only when required) during surgery than less experienced surgeons, which allows them to resist operative fatigue more effectively [15]. Further, experts display an ability to automate actions, which allows them to balance attention between multiple relevant sources of information. Expert surgeons also have more comprehensive declarative and procedural knowledge to intervene and solve problems than non-experts. This is characterized by forward-thinking reasoning (i.e., highly structured progressive inferences to facilitate diagnostic solutions based on pattern-recognition and high-level clinical reasoning). In addition to these elements of surgical expertise, several cognitive factors have been cited as important characteristics for performance excellence in surgery [16].

McDonald et al. (1995) interviewed 33 highly proficient surgeons; and participants reported that mental readiness for surgery was a greater determinant of successful performance than technical or physical readiness [16]. Furthermore, participants explained that several mental factors are imperative for surgical success. These include self-belief and confidence, positive mental imagery, full focus, distraction control, commitment and motivation, and constructive self-evaluation.

The goal of surgical education is to help trainees develop high-level proficiency in all of the aforementioned nontechnical skills. However, due to the extensive amount of experience necessary to execute these knowledge, abilities, and skills expertly, there is an apparent need to identify techniques and competencies to optimize trainees' performance in order to expedite the learning curve of mastering surgical proficiencies. Surgical simulation training, consisting of deliberate practice and effective feedback, could be a strategy to reduce the learning curve to attain surgical expertise and maintain expertise through continued training.

Deliberate Practice

Skill mastery exists on a continuum from cognitive, to associative, to autonomous phase. The cognitive phase is the initial phase of learning a skill, characterized by a high-level of instruction and conscious effort to think through procedural steps by learners. The associative phase is the intermediate level of learning, defined by skill refinement, and less cognitive effort during performance. The autonomous phase is the advanced phase of learning highly automatic skill execution, with very little conscious thought on procedure steps, and freedom to direct attention to other relevant information for performance (see Fig. 2) [17]. Expertise and skill mastery, the highest performance standard in any domain, cannot be simplified as the result of innate ability or experience alone [18]. While natural aptitude for a particular skill set or extensively acquired experience are certainly contributing factors to expertise, Ericsson et al. (1993) argue that the process of attaining the maximal possible level of performance in a given domain, even for highly experienced performers, can result from deliberate efforts to practice skills and improve.

The process of deliberate practice consists of motivation by learners to exert effort to improve skills, immediate and informative performance feedback from an external source, and awareness of their performance results [18]. Upon attaining basic competency at a skill, learners should be given the opportunity to learn individualized problem-solving and critical-thinking methods to correct performance deficits on their own through additional practice. This process has been shown to increase speed, accuracy, and performance of motor, cognitive, and perceptual tasks, which are all hallmarks of expert surgical performance [15]. Simulation-based

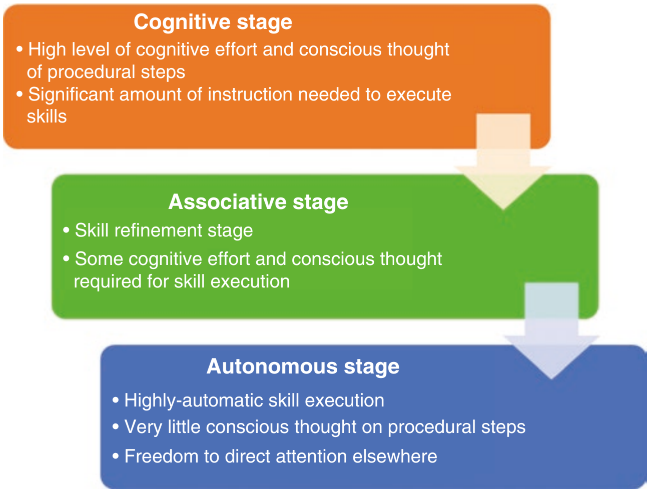

Fig. 2 Summary of Fitts and Posner's (1967) three-stage theory of motor skill acquisition

medical education may offer learners at all levels of experience an opportunity for deliberate practice to learn and acquire surgical skills or optimize their proficiency of already-learned surgical skills.

Indeed, a meta-analytic review of the effectiveness of simulation-based medical education featuring deliberate practice found that simulation training with deliberate practice is superior to standard clinical training programs in the acquisition of a variety of skills, including laparoscopic surgery [19]. Even for expert surgeons, deliberate practice through simulation training may offer an opportunity to prevent arrested development or decline of skills and to continue to develop and improve as a function of continual refinement of advanced cognitive processes attaining greater control during performance [20]. However, individual practice alone may be insufficient to aid a performer in attaining expertise in a particular domain. Rather, this process can be enhanced further at any level of skill mastery through objective feedback and performance coaching.

Value of Objective Feedback and Coaching

Feedback is a critical method of performance optimization for performers at any level, as it offers insight into the deficient mechanics of a particular skill that require improvement or highlights positive areas of performance that should be replicated in future performances. There are two sources of feedback: intrinsically based, which involves self-assessment of skill relative to the intended goal of the task, and augmented feedback, which consists of information provided by an external source that supplements intrinsic feedback [21]. The information gained from feedback can serve to motivate a performer to maintain effort in practice, reinforce desirable behavior or punish undesirable behavior, and can identify errors, then methods to correct, performance.

Coaching, the act of empowering performers to achieve improved performance through personal growth and self-directed learning, involves a collaborative relationship between a learner and a mentor where the mentor provides augmented feedback to optimize the learner's performance [22]. Effective augmented feedback consists of information that is relevant, immediate, factual, confidential, respectful, helpful, tailored, and encouraging [23]. In the scope of skill mastery and developing expertise, augmented feedback is most impactful to enhance learning of new skills during the cognitive phase of skill mastery, whereas expert performers in the autonomous phase of skill mastery learn to develop highly effective self-monitoring systems to gather intrinsic feedback to fine tune performance as needed [19], which is one of several important characteristics of expert surgical performance [15].

Nonetheless, attaining and maintaining expertise is an arduous process as outlined throughout this section. The literature suggests that less experienced surgeons may be susceptible to experience drastically deteriorated performance due to heightened stress and an inability to adaptively cope with the demands of those difficult situations due to their lack of expertise [2]. Also, even expert surgeons may experience performance declines due to complacency and lack of skill maintenance [18], which may be further exacerbated by challenging clinical situations. This potential deficiency in the performance of less experienced and expert surgeons alike highlights the additional need to offer methods to enhance surgical performance that can be practiced deliberately, during surgical simulation training. Cognitive skills, often implemented by elite performers in other domains, may offer surgeons at all levels of expertise reliable techniques to optimize their performance.

Performance Optimization Training

In order to perform a successful surgery, surgeons must utilize both technical and nontechnical skills. While technical skills represent the execution of physical actions required for surgical performance, nontechnical skills are considered to be the social skills (e.g., communication, leadership), personal resource factors (e.g., stress-coping skills), and cognitive skills (e.g., situational awareness, decision-making) which supplement technical skills to aid in efficient and successful surgical performance [24]. For our purposes, and for the sake of simplicity, the term "cognitive skills" will refer to trainable psychological abilities that underpin successful learning and performance, which encompasses stress-coping strategies, techniques to develop and maintain awareness, and effective decision-making, among other proficiencies [25]. Importantly, cognitive skills consist of psychological strategies and competencies designed to help performers consistently achieve their ideal cognitive state for performance [26] and have been implemented extensively in high-stress domains outside of medicine to address the cognitive, behavioral, emotional, and psychophysiological barriers to excellent performance [27]. The effectiveness of these skills in other domains may offer important insights into methods of optimizing the performance of surgeons.

Military

It is widely known that tactical operators (e.g., Army Soldiers, Special Forces, etc.) within the military face some of the most arduous, stressful, and mentally demanding work environments relative to the norm. They are tasked to perform at an extremely high standard, as they must make split second decisions that can mean the difference between life and death. As is the case with expert surgeons, expert military professionals have acquired both technical and nontechnical abilities that lead to consistently high performance. Recognizing the need to provide operators with the cognitive skills to effectively cope with and manage the physical and psychological demands, many various military organizations deliberately train tactical operators in this capacity.

In 1993, the United States Military Academy (USMA) established the Center for Enhanced Performance (CEP) that focused on training mental skills to cadets in order to enhance their performance in the classroom, in athletics, and in their military training. As these graduates assumed leadership positions in the Army, they noticed that little was being done throughout the force to teach soldiers these cognitive skills. As the need grew and the value was recognized, the Army established the Army Center for Enhanced Performance (ACEP) in 2006. ACEP (now the Comprehensive Soldier and Family Fitness program, CSF2), through expert practitioners, teaches cognitive skills and competencies (e.g., goal setting, mental imagery, attention control, optimism, confidence, energy control, etc.) to soldiers in order to enhance their mental toughness and resiliency, thereby enhancing their performance on and off the battlefield [28, 29]. Various research studies have demonstrated positive effects in terms of performance as compared to control groups, knowledge of and use of mental skills, and resilience [28, 30, 31].

The Special Operations Command of the US Military also recognized the need for systematic training and development of cognitive skills to enhance performance, resilience, and overall well-being [32]. In 2014, the preservation of the CSF2 program was developed to help special operators and their families maintain and improve readiness, effectiveness in the battlefield, and long-term well-being. The program takes a holistic approach through training special operators in four domains of physical, spiritual, mental, and social well-being. The approach involves an interdisciplinary team comprised of strength and conditioning coaches, athletic trainers, physical therapists, dieticians, sport psychologists, and licensed clinical social workers.

In general, the military takes a developmental approach to training tactical operators. A common phrase outlining their approach is "crawl, walk, run," which aligns nicely with the theory of deliberate practice. In the "crawl" stage, learners are given a description and purpose of the task or skill, description of performance standards, visual demonstration of the skill, and any necessary information required to execute the skill. In the "walk" stage, learners practice the skill in a slow, step-by-step pace, receive feedback throughout, and practice the skill until they can complete it entirely without feedback or coaching (i.e., akin to the cognitive and associative phases of deliberate practice). In the "run" stage, learners execute the skill at full speed under realistic battlefield conditions (akin to the autonomous stage of deliberate practice). In this stage, the military often relies on various forms of simulation to generate battlefield conditions without battlefield risk [33]. As the learner moves through the stages, the levels of challenge, stress, and pressure increase in order to test their ability under conditions they might face in the battlefield, which can be incredibly challenging and stressful [34]. Importantly, when learners reach the stage of learning where they participate in more advanced tactical simulations, they are less cognitively focused on the execution of the skill and able to apply those mental resources elsewhere (e.g., critical thinking and problem-solving).

Elite Athletics

Historically, performers' use of cognitive skills has received the most attention in elite athletics. Dating back to Coleman Griffith's (1928) work to study the psychology of sport and his application of psychological principles to enhance the performance of athletes [35], cognitive skills have been acknowledged as crucial elements of performance excellence in sport [26]. The US Olympic Committee first established a sport psychology program in 1983 [36], and since that time, cognitive skills training has been a prominent part of the training regimen for champion athletes.

Gould et al. (2002) interviewed ten Olympic champion athletes (representing nine disciplines) to determine what psychological factors had influenced their athletic performance [37]. The authors determined that cognitive skills such as mental imagery and rehearsal (i.e., mentally rehearsing a performance), arousal regulation (i.e., relaxation and activation skills to allow to optimize arousal levels), goal setting (i.e., setting effective goals for performance), attention management (i.e., maintaining focus and concentration), and well-developed action plans for competition (i.e., to directing thoughts and behaviors) are being used regularly by Olympic champions. Importantly, while these champion athletes reported they had learned some of these skills serendipitously through self-development, direct cognitive skills training from coaches and sport psychology consultants were important factors in their performance excellence. Cognitive skills training to optimize athletic performance has also been conducted effectively with professional athletes [38], collegiate athletes [39], and junior athletes [40], which highlights the applicability of this type of training across levels of experience.

Aviation

Similar to the expectations for surgeons and healthcare providers, pilots and cockpit crews are expected to consistently perform without errors, as the stakes for potential errors are extremely high [41]. The similarities of these fields extend to the benefit of deliberate practice through simulation training for skill mastery, as simulator-based decision-making training has been shown to enhance pilots' skills at all levels (i.e., depending on the fidelity of the simulation) and decision-making [42, 43]. However, unlike the culture of healthcare where the acknowledgement of performance errors and the factors that contribute to it (e.g., stress, fatigue, interpersonal and team-related issues) has traditionally been discouraged, the aviation industry has created a culture where errors are acknowledged and dealt with effectively [41]. Furthermore, cognitive skills training programs to optimize performance, manage stress effectively, and maintain situational awareness (i.e., attention management), as well as team-based training to enhance teamwork and communication (i.e., based in human factors training), and manage crisis situations, effectively have been implemented with regularity.

Situational awareness has been identified as a significant component of effective decision-making in pilots, as it allows individuals to balance attention between the various relevant environmental elements, comprehend situational factors based on individual elements, and project the future status of a situation based on these factors [44]. Endsley and Robertson (2000) explain that one component of enhancing aviation teams' situational awareness is to train individuals in cognitive and team-based skills in attention and thought management to reduce the impact of distractions, to develop action plans for contingencies, attention sharing and communication with others, and information seeking/filtering [45]. The authors developed a team-based situational awareness program that focused, in part, on implementing these skills to help individuals manage distractions, improve their situational awareness, and enhance teams' communication and vigilance. The large majority of participants (89%) rated the skills as "very useful" or "extremely useful," and at least 50% of participants reported a moderate behavioral change in their use of the skills taught through the program. There have also been attempts to implement cognitive skills to optimize the performance of military pilot trainees.

Military pilots are routinely confronted with challenging and stressful performance situations that require them to manage stress and thought processes effectively to optimize performance [46]. Fornette et al. (2012) implemented a cognitive-adaptation program with military pilot trainees in a randomized controlled study design, which implemented mindfulness and cognitive restructuring techniques. Mindfulness techniques are essentially strategies designed to increase awareness by maintaining open attention in the present moment and reserve judgment or visceral reactivity, whereas cognitive restructuring techniques aim to reprogram how we perceive or think about a particular situation which can lead to more positive and adaptive thoughts during stressful situations [46]. The authors found that trainees who had below-median performance prior to the intervention significantly improved their in-flight performance after cognitive-adaptation training, and 70% of all intervention-group trainees reported they were able to lower their in-flight stress more effectively after training. McCrory et al. (2013) introduced a cognitive skills training program consisting of goal setting, imagery, and attention management during cognitive skills coaching sessions with military pilot trainees to enhance their confidence to operate the aviation equipment and manage stress [47]. At the conclusion of the study, participants displayed significantly increased confidence, reduced anxiety, and increased self-regulatory behavior (flight planning, remembering flight brief information, contingency planning, etc.).

Lessons Learned for Surgical Education

There are several important factors related to effective cognitive and team-based skills training that can be extracted from high-pressure domains and applied to surgical education. For example, team-based skills training has consisted of teaching learners methods to communicate effectively and sharing mental models and information to enhance teams' collective situational awareness [45]. Cognitive skills training has aimed to teach learners skills and competencies such as methods of developing effective goals and action plans for performance, mental imagery/rehearsal, attentional and thought control, situational awareness, optimism, methods to build confidence, energy management, mental toughness, and resilience [31, 37, 46, 47].

These skills are often implemented during simulation training where deliberate practice can be applied to facilitate the integration of these techniques as habits for performance as learners transition through the stages of learning. The development of these skills as performance habits frees up cognitive processing for problem-solving and decision-making in more advanced training scenarios [32, 47]. Furthermore, research with soldiers and Olympic athletes suggests that cognitive skills coaching from trained coaches and sport psychologists is an important source to help these performers learn how to use cognitive skills effectively [32, 37, 47]. These factors are important considerations when determining best practices of applying team-based and cognitive skills with surgeons. It is important, though, to identify how these skills have already been implemented in surgical education. This will help determine potential areas of improvement for nontechnical skills training.

Current State of Team-Based and Cognitive Skills Training in Surgery

Optimizing Team Performance

Effective teamwork is an incredibly important factor contributing to surgical success and ultimately patient outcomes [48–50]. There are several salient elements of effective surgical team performance, which have been discussed previously in this chapter but include leadership and understanding of roles, mutual performance monitoring, shared mental models and anticipation of needs, adaptability, common purpose (i.e., and placing that purpose above individual goals), and closed-loop communication [51]. Traditionally, surgical training has focused on enabling surgical trainees to improve their individual technical skills, but relatively little work has been done to enhance these interpersonal, team-based skills that are critical to the optimal performance of the entire surgical team [7]. One of the most significant advances in team training within healthcare has been the development of the Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS) [51].

TeamSTEPPS is a didactic-based curriculum that can assist healthcare systems to develop effective clinical teams and is available nationally through the Agency for Healthcare Research and Quality (AHRQ) [51]. The curriculum is delivered via five educational modules which help learners identify and understand the benefits of team training and teach them skills and competencies to enhance their leadership, communication, situational awareness and monitoring, and mutual support. In a randomized controlled study of this program's effectiveness on multiple levels of healthcare provider performance (i.e., perception about ability to implement teamwork concepts in performance, learning of teamwork concepts, observed teamwork behaviors, and self-reported use of teamwork behaviors), the TeamSTEPPS-trained providers significantly enhanced their perceptions of their ability to perform teamwork behaviors, enhanced their performance on a written test of optimal teamwork behaviors (i.e., learning), increased their quality and quantity of preoperative case briefings and the quality of teamwork behaviors, and demonstrated positive changes in the culture of patient safety [52]. Gardner and Scott (2015) explain that simulation training may further optimize the effectiveness of team-based training, as surgical teams can be aided in the deliberate practice and mastery of these important interpersonal factors through contextually accurate environments and didactic reflection on best practices of team dynamics [7].

Leadership has also been recognized as an important factor in the performance of surgical teams [53]. Poor leadership from the primary surgeon, characterized by vague and ineffective communication, expression of frustration, poor situational awareness, and poor planning, is highly correlated with avoidable surgical errors [54]. Conversely, effective leadership consists of emphasizing the team's collective goal, displaying motivation and enthusiasm, creating learning opportunities for teammates, forming bonds with teammates, engaging teammates to gather additional perspectives, and considering individual abilities and needs [53, 55]. Formal leadership training for experienced surgeons has been effective, as the majority of 21 surgeons who participated in a leadership training program felt that the program was effective and encouraged self-reflection to improve deficient intraoperative behaviors [56].

Surgical residents could greatly benefit from leadership training incorporated during simulation training, due to the limited opportunities for trainees to practice these skills in the clinical environment [57]. Bearman et al. (2012) implemented a 2-day nontechnical skills training course with 12 surgical residents which featured practice of intraoperative communication (e.g., identifying challenges and benefits, briefing, debriefing, task-focused communication, graded assertiveness) and role delegation (i.e., important elements of surgical leadership), during advanced cardiac life support simulation exercises. The authors found that all participants reported that all of the leadership skills taught and the simulation scenarios were valuable educational tools to enhance their nontechnical skills.

The findings of the few studies implementing teamwork and leadership skills during surgical simulation training have found promising results. However, based on the relatively limited research of the impact of these nontechnical skills on surgical performance, it is clear that much more work needs to be done to implement these skills in randomized controlled studies.

Optimizing Individual Performance

While teamwork and leadership skill development largely occur outside of the simulation lab, cognitive skills, like those psychological tools and strategies implemented in the military, in aviation, and in elite athletics, have begun to be implemented during surgical simulation training to optimize the individual performance of surgeons. While research on the effects of cognitive skills in surgical education is in its infancy, the literature is indicative that cognitive skills training may be an effective supplement to technical skills training [58–68].

In spite of the recognized importance of multiple psychological factors in successful surgical performance [16], surgical education researchers have primarily focused on implementing only one cognitive skill with learners, mental imagery (MI). Synonymous with mental rehearsal and mental practice, MI is the process of creating quasi-sensory imagined experiences, which exist in the mind in the absence of those physical stimulus conditions, which can produce genuine sensory and perceptual experiences [67, 68].

For surgical novices, Arora et al. (2011) demonstrated that a group who received MI training in addition to physical practice during simulated laparoscopic cholecystectomy (LC) training significantly outperformed controls that received physical practice alone and had a shorter learning curve of the procedure [58]. Arora et al. (2011) discovered participants reported significantly lower stress compared to a control group (measured subjectively with the State-Trait Anxiety Inventory (STAI) and objectively displayed lower stress (measured with heart rate and cortisol levels) [59]. In regard to optimizing the technical and nontechnical performance of surgical trainees, Komesu et al. (2009) found that obstetrics and gynecology residents who received MI training on the procedural steps of a cystoscopy significantly outperformed controls based on objective measures of surgical performance and considered MI to be a more useful pre-performance preparation strategy than reading a standard textbook [60]. MI may also be an effective tool to enhance trainee's teamwork, as emergency, anesthesia, and surgery residents who received MI training significantly enhanced their teamwork during a simulated trauma resuscitation scenario compared to controls who only received technical training [61].

MI may also be an effective tool for continuing education of experienced surgeons. Immenroth et al. (2007) conducted a randomized controlled study with 98 experienced surgeons undergoing laparoscopic training and assigned participants to a MI group, an additional technical training group, and a control group [62]. Results indicated that LC performance on a physical simulator was significantly higher at posttest for the MI group, who reported that MI was a valuable tool in their education. Patel et al. (2012) found that vascular surgeons who received MI training had significantly less intraoperative errors during critical stages of arterial procedures [63].

Results from the research implementing MI with surgical novices, slightly more experienced trainees, and experienced surgeons have largely indicated that MI is an effective training tool [58–63]. In addition to the implementation of MI, there have been some, albeit significantly less, attempts to incorporate more comprehensive cognitive skills training in surgical education.

Maher et al. (2013) implemented a stress management program with first- and third-year surgical residents who were asked to perform a high-stress patient care simulation module [3]. The stress management group received training in energy and attention management techniques and MI. While differences in technical performance were not statistically significant, there was a trend toward enhanced performance (i.e., measured with OSATS) for the experimental group, and the stress management training program was rated as valuable by 91% of participants. In a randomized controlled study that implemented a stress management intervention with experienced surgeons, the experimental group displayed significantly increased observed teamwork (i.e., measured with the Observational Teamwork Assessment for Surgery), increased stress-coping skills (i.e., measured with the Surgical Coping Questionnaire), and reduced stress (i.e., measured with heart rate variability) compared to controls [4]. Experimental group participants also displayed improved technical skills, confidence, and decision-making after this training.

Recently, a novel and comprehensive mental skills curriculum (MSC) has been developed to reduce surgical trainees' stress and enhance their performance [64–66]. A multidisciplinary team consisting of a surgeon educator with extensive experience in simulation-based research, a performance psychologist with extensive experience in mental skills training, and an education psychologist with expertise in instructional design collaborated to develop the curriculum based on David Kern's (2009) model [64, 69]. Following a needs assessment, identification of goals and educational objectives, and development of instructional methods, the curriculum was formulated. Consisting of eight video-education modules, a workbook to allow for immediate practice of learned mental skills, and applied practice of skills during laparoscopic simulator training, this MSC teaches surgical trainees cognitive skills such as goal setting, energy management (i.e., relaxation and "psyching-up"), attention and thought management, mental imagery, refocusing strategies, and performance routines. Further information on this MSC is described in detail elsewhere [64].

In a study of the efficacy of this novel MSC to enhance surgical novices' laparoscopic intracorporeal suturing performance and use of performance-enhancing mental skills, results indicated that MSC-trained novices significantly enhanced their laparoscopic performance and increased their use of mental skills from baseline to posttest [64]. Additionally, the majority of participants expressed that the MSC was effective in optimizing their laparoscopic performance. In another study to determine the effectiveness of the curriculum to reduce novices' stress during two validated stress tests (i.e., the Trier Social Stress Test and the O'Connor Tweezer Dexterity Test), the MSC was effective at reducing novices' perceived stress and workload during both stress tests [65]. This finding indicates that this MSC may be effective at reducing novices' stress in a variety of situations. In a subsequent randomized controlled trial of the effectiveness of the MSC to enhance surgical novices' laparoscopic suturing performance compared to controls, MSC group participants displayed significantly enhanced mental skill use from baseline to posttest and significantly higher laparoscopic skill retention over a period without technical skills training compared to controls [66]. These findings indicate that a comprehensive MSC can offer several significant benefits to surgical novices, including significantly enhanced surgical skills [64], use of mental skills [64], reduced stress and workload during validated stress tests [65], and surgical skill retention [66]. It is evident, then, that a comprehensive MSC may offer incremental benefits to surgical performance beyond those of single-skill cognitive skill interventions.

Burnout, as described previously, is a detrimental psychological condition that can lead surgeons to commit significant medical errors [13]. Unlike acute disruptions to performance, like stress or loss of focus, burnout is a chronic syndrome that results from situational job demands (e.g., workload is too high, time pressures, lack of control, lack of feedback, etc.) that lead one to feel overloaded, which can contribute to diminished psychological well-being and ultimately, reduced quality of patient care [13, 70]. However, research has shown that psychological resilience and grit can enhance physicians' psychological well-being and attenuate the negative effects of burnout on performance [14, 71, 72]. Resilience is considered to be one's ability to respond and cope with stress in a positive and adaptive manner, "bounce back" when faced with challenges and grow stronger through this process [14]. Similarly, grit is a psychological trait characterized by passion and perseverance to pursue long-term goals [71]. Resilience and grit may moderate the relationship between burnout and performance, and interventions designed to enhance physicians' resilience and grit could be effective at preventing or managing burnout and optimizing performance. Presently, there are no known attempts to implement resilience-enhancing interventions with surgeons. However, there have been attempts to implement such interventions with other healthcare providers, and these studies may provide insight into how skills to enhance resilience can be implemented effectively with surgeons. Sood et al. (2011) implemented a 90-min stress management and resilience training (SMART) intervention with department of medicine faculty that focused on teaching these physicians how to manage attention, nonjudgmentally, in the present moment and maintain a flexible psychological disposition to adapt to situations as opposed to maintaining fixed prejudices [73]. Also, participants were instructed on how to execute a paced breathing meditation for relaxation. In this randomized controlled study, the authors found that this resilience intervention led to significant improvements in resilience, perceived stress, and quality of life at 8 weeks post-intervention compared to controls. Essentially, this intervention focused on teaching similar principles to mindfulness, which has been described previously in this chapter and has been identified as a cognitive skill that can potentially reduce physicians' burnout [46, 74, 75].

In a study of the effectiveness of a mindfulness-based intervention that taught physicians how to engage in mindful meditation exercises to develop self-awareness for cognitions and physiological states and awareness for how they communicate with others, Krasner et al. (2009) found that this intervention was effective at reducing participants' burnout and total mood disturbances and increasing their empathy, conscientiousness, and emotional stability [74]. Similarly, a mindfulness-based stress reduction intervention that focused on teaching meditative exercises to increase relaxation was incorporated with healthcare providers in a randomized controlled study [75]. The authors found that this intervention was effective at reducing the providers' perceived stress, burnout, and distress compared to controls. Based on this evidence with other healthcare providers, it is possible that cognitive skills interventions designed to increase psychological well-being and reduce burnout through mindfulness and psychological resilience techniques may be effective if applied with surgeons, but research must be performed in this area to determine the efficacy of these skills to reduce surgeons' burnout and optimize performance.

Performance Coaching

The use of feedback to enhance clinical performance has long been incorporated in surgical education through the apprenticeship model [76]. Surgical faculty have traditionally provided knowledge to trainees on the execution of technical skills based on personal professional experience and advice [77]. Trainees are expected to absorb technical and nontechnical skills in the operating room directly through repetition or by observing modeled behavior paired with knowledge by surgical faculty. Surgical skills coaching takes this process a step further, as a coach can collaborate with trainees during deliberate practice of technical and nontechnical surgical skills during simulation training to achieve self-determined goals through objective assessment and feedback, structured debriefing, guided self-reflection, and behavior modeling [78, 79].

In a systematic review of the literature, Min et al. (2015) found that surgical skills coaching can be effectively incorporated in simulation training because this setting allows for a safe practice environment and by viewing videotapes of learners' intraoperative performance, which allows for enhanced self-reflection of technical skills and delivery of individually tailored feedback [79]. Coaching interventions, which commonly consist of an informative lecture, augmented concurrent feedback, and debriefing, can significantly enhance technical performance. Importantly, coaching interventions were shown to reduce intraoperative error rates.

In regard to nontechnical skills coaching, these interventions focused primarily on enhancing learners' team-based skills (e.g., communication) and leadership [78]. The majority of reviewed studies found that coaching significantly enhanced learners' nontechnical skills. However, the results from these studies should be taken with some caution, as some of the studies did not use control groups, the majority of observers assessing intraoperative nontechnical skills were not blinded, and there were no longitudinal assessments of nontechnical skills.

The literature on the impact of surgical skills coaching to optimize surgeons' technical and nontechnical skills performance is indicative that this is a highly effective training paradigm. For trainees, who are frequently performing surgical procedures in the operating room but lack accurate self-assessment and may not regularly reflect analytically on methods to optimize their performance, coaching during deliberate practice of skills may offer additional opportunities for experiential learning and growth [78]. It is unclear, though, how well-received coaching for continuing education would be for experienced surgeons. A recent study by Mutabdzic et al. (2015) indicated that some surgeons reported a lack of interest to participate in coaching to improve their technical skills because they did not feel that practicing technical skills further would enhance patient outcomes. There was concern that coaching would be perceived as being related to incompetence by peers and trainees, and there was concern that coaching would remove elements of control over self-directed learning [80]. However, Ericsson (1993, 2004) contends that even experienced surgeons may experience arrested skill development or surgical skill decay in the absence of continued deliberate practice of skills [18, 20]. Through deliberate practice that allows experienced performers to seek out training situations that challenge their current level of performance, these individuals are able to develop cognitive mechanisms to monitor and control performance in similar performance situations. A surgical skills coach could identify areas for experienced surgeons' to improve their skills and appropriate tasks to challenge their current skill level, which could lead to further skill mastery and the attainment of expertise. Indeed, Stefanidis et al. (2016) recently conducted a study in which they reviewed intraoperative videos of practicing surgeons to identify areas for improvement, developed a coaching curriculum accordingly, and implemented the coaching curriculum with the participating surgeons in group and one-on-one sessions [81]. The authors found that blinded group sessions allowed practicing surgeons to participate in peer review of intraoperative technical skills, which afforded them the opportunity to learn from each others' successful performances and areas for improvement. The authors also posit that the ideal surgical coach for technical skills is a well-respected peer, with contextually specific knowledge of the learner's surgical subspecialty, whereas nontechnical skills coaching may be best served by a human factors specialist or similar domain-specific expert who can provide insightful performance feedback. These considerations emphasize the need to incorporate surgical skill coaching with trainees and experienced surgeons alike.

Future Directions for Performance Optimization in Surgery

The research strongly suggests that nontechnical techniques such as cognitive skills training, leadership and team-based skills training, and coaching are effective at optimizing surgical performance when implemented during surgical simulation training. However, the research on implementing nontechnical skills training in surgical education is still emerging, and researchers could benefit greatly from considering how these skills have been implemented in other high-stakes domains. For instance, mental imagery is the cognitive skill that has been used most frequently to enhance the surgical performance of surgical novices [58, 59], trainees [60, 61], and experienced surgeons [62, 63]. However, compared to the much more extensive cognitive skills training programs in the military [28–30, 32] and elite athletics [36–40] that have included multiple effective skills with performers, there is room to expand the application of cognitive skills training in surgical education to include several more strategies and competencies to optimize performance. Some skills, such as resilience and mindfulness, have been taught to healthcare providers outside of surgery, and the results of these studies indicate that these skills can reduce provider burnout and enhance empathy and quality of life [74, 75].

Indeed, there are few studies that have incorporated multiple cognitive and team-based skills into a comprehensive training curriculum that facilitates learners' deliberate practice of these skills with the guidance of a coach during surgical simulation training. Research has clearly demonstrated that individual cognitive factors (e.g., confidence, positive MI, concentration, distraction control, commitment and motivation, and constructive self-evaluation) [16] and team dynamics (e.g., leadership and understanding of roles, mutual performance monitoring, shared mental models and anticipated needs, common purpose, adaptability, and closed-loop communication) [51] significantly impact surgical performance and are important elements of surgical expertise. The literature suggests that there is an extensive learning curve to become an expert surgeon [15], which illustrates the importance of developing strategies to supplement the experiential learning process and reduce the learning curve for surgical trainees and practicing surgeons to approach and achieve skill mastery.

Within medicine and other high-stress domains, deliberate practice through simulation training has offered learners a modality to practice skills in a safe environment [19]. This may be the ideal setting for learners to learn and train to use nontechnical skills to optimize their performance, as training during simulated exercises has proven to be an effective training paradigm to teach learners these skills [7]. In spite of a seemingly intuitive conclusion, that a comprehensive nontechnical skills curriculum which teaches multiple individual cognitive skills and team-based skills should be developed and implemented widely to offer surgical trainees the strategic flexibility to manage dynamic intraoperative challenges effectively, little work is being done to this end. TeamSTEPPS is one exception, as this national team-training curriculum is being implemented widely through the AHRQ to facilitate enhanced clinical team performance [51]. TeamSTEPPS has been largely accepted and implemented throughout several healthcare systems [52], and while it is effective at enhancing clinical team performance, it does not aim to enhance individual providers' performance. Conversely, a recently developed comprehensive MSC has been successful at enhancing surgical novices' laparoscopic suturing performance, use of mental skills [64], and surgical skill retention [66] and reducing their stress and workload during two validated stress tests [65].

If surgical educators are aiming to optimize surgical performance of trainees or practicing surgeons, they should develop a robust and comprehensive cognitive and team-based skills training curriculum, modeled after TeamSTEPPS and this novel MSC, which features skills training to enhance learners' communication, leadership, stress-coping awareness and decision-making, attention management, and resilience (see Fig. 3). Furthermore, a comprehensive performance optimization curriculum should feature deliberate practice and objective feedback with performance coaching to offer learners an opportunity to master newly learned technical and nontechnical skills. Also, similar to the "crawl, walk, run" approach of the US military, educators should gradually increase the difficulty of training to coincide with the stages of learning, which will force trainees to develop increasingly complex cognitive processes to execute skills and optimize their performance under variable and challenging clinical situations. In conclusion, when training the next generation of surgeons, surgical educators should develop comprehensive curricula along these lines to teach and optimize technical and nontechnical skills concurrently.

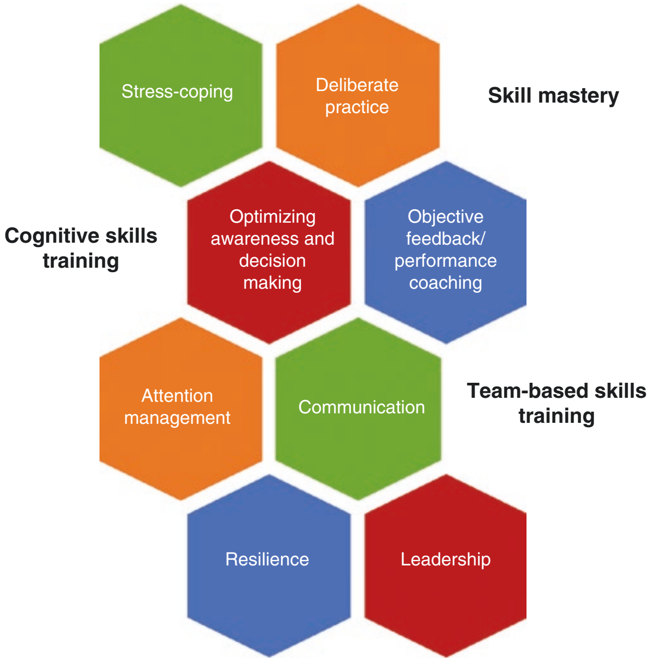

Fig. 3 The necessary components of a comprehensive performance optimization curriculum in surgery

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Use of Simulation in High-Stakes Summative Assessments in Surgery

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Key Issues Relating to the Use of Simulation in High-Stakes Summative Assessments in Surgery

Simulation is being used widely in surgery for teaching, training, and formative assessments and to provide feedback to improve performance. The use in high-stakes summative assessments is now beginning to receive greater attention. The latter trend has been fueled by the recent emphasis on advancing competency-based education and training, focus on improving processes of credentialing and privileging using objective data, and evolving requirements for Maintenance of Certification. Considerable progress has recently been made in developing and validating new simulation-based assessment methods to address a range of clinical, technical, and nontechnical skills. These experiences serve as a foundation for additional advances that need to be made in this domain. Thus, processes of certification, licensure, credentialing, and privileging could be enhanced, which should benefit patients.

The main goal of certification is to ensure that a candidate is competent in essential elements required of his or her specialty. The certification process specifically helps to affirm that a candidate has achieved the requisite level of knowledge, skills, and judgment as defined by the profession [1]. The overarching aim of the certification process is to support delivery of safe and effective patient care [2]. Presently, board certification in surgery in North America includes evaluation of several domains of competence; however, technical skills, which are the hallmark of surgery, are not directly assessed at the time of certification. Board certification in general surgery in the United States includes two formal examinations. The qualifying examination is a multiple-choice examination that is used to assess surgical knowledge and its application to surgical practice [3], and the certifying examination is an oral examination that focuses on assessment of diagnostic and management skills, along with problem-solving and judgment [4]. Although questions posed during the written and oral examinations may focus on certain elements of an operation, technical skills are not formally or directly assessed during the certification process. Technical skills are observed and assessed throughout residency training by the faculty and program director, and the surgical experience of a resident is confirmed through review of his or her surgical case log. This approach has limitations and provides indirect confirmation of technical capabilities of a resident [5, 6]. Measures of knowledge and judgment as surrogates for assessment of technical skills are inadequate, and it has been shown that results of reliable and valid measures of knowledge (e.g., the American Board of Surgery In-Training Exam, or ABSITE) do not correlate well with technical skill or operative performance [7]. This gap in assessment at the time of certification has been recognized by professional surgical societies and surgical boards, and efforts to develop objective assessments of technical skill for the purpose of certification and licensure are underway [8–10]. Given the importance of technical competence in the care of surgical patients and evidence that suggests better technical skill leads to improved outcomes, [11] objective documentation of technical skills at the time of certification needs to be explored.

Recommendations to improve the processes of credentialing and privileging in surgery have included focus on objective assessment of technical skills at the completion of specific skills training and retraining courses [12, 13]. Professional surgical societies have pursued development of models for summative assessment of technical skills following participation in skills training courses. One such model developed by the American College of Surgeons (ACS)

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Division of Education involves five levels, including verification of knowledge and skills, verification of preceptorial experience, and verification of outcomes at the higher levels [12, 14]. Data from valid high-stakes summative assessments may be used in the processes of credentialing and privileging and to address requirements of the joint commission for Focused Performance Practice Evaluations (FPPE) [15].

Validity Evidence for High-Stakes Summative Assessments

Validity refers to the degree to which evidence supports the interpretation of test scores [16]. Wide adoption of contemporary validity theory within the context of development and evaluation of surgical assessment tools has not occurred [17–19]. Surgical educators need to stay up-to-date with the current theories of validity and apply them to simulation-based high-stakes summative assessment methods. This is of utmost importance within the context of summative assessments, because decisions based on inferences from test scores result in significant impact on both the individual and society at large. A high level of validity evidence is required for high-stakes assessments [20], aiming to minimize the risk of both false positives (passing a candidate who is incompetent and should fail the exam) and false negatives (failing a candidate who is competent and should pass the exam). Messick [21] and Kane [22] have developed contemporary validity frameworks that can guide validation studies in order to build evidence of validity for the interpretation of test scores.

Messick describes a framework of validity in which five distinct sources of validity evidence are sought in order to build a validity argument [21]. A validity hypothesis is tested by examining the evidence to refute or support the interpretation of test scores. The amount of validity evidence required again depends on the goal and purpose of the evaluation, with validation studies aiming to gather evidence from various sources. Messick's five sources of validity evidence are (1) content, (2) response process, (3) internal structure, (4) relationship to other variables, and (5) consequences [21].

Kane's validity model uses an argument-based approach to validation to address the inferences made from test scores [23]. The first step in Kane's model is to outline the intended use of the assessment scores and then to evaluate the plausibility of this evidence based on four validity inferences. The four inferences in Kane's validity argument are (1) scoring, (2) generalization, (3) extrapolation, and (4) implications/decisions [22].

These theories can help guide the objectives for validation studies when developing a high-stakes assessment model; they outline the multiple sources of validity evidence that can be investigated in order to build a robust, credible high-stakes examination. It is important to understand that the higher the stakes associated with the exam, the higher the level of validity evidence required.

Defining Competence for High-Stakes Decisions

The use of the word "competence" within the domain of surgery has been inconsistent, with the terms technical competence, surgical competence, and operative competence being referenced in the literature. The definition of competence used for a high-stakes assessment is critical as it must be fair to both the examinee who has invested time and effort into their training and to the public in order to protect their safety. Satava et al. have defined competence in technical skill as an individual who is able to address all of the requirements, be suitable, fit, and adequate [24]. When considering Dreyfus and Dreyfus' model of skill acquisition, the definition of competence reflects an individual who possesses skill beyond an advanced beginner but who has not yet reached proficiency or expertise [25]. A more recent systematic review has suggested that the term technical competence has most often been applied to individuals who possess a minimum standard of performance to provide safe and independent surgical care [26]. Thus, the present definition of competence most widely used in the literature does not describe an expert, rather it describes an individual who is safe to enter independent practice. One must also recognize that competence is a fluid phenomenon, with individuals having the opportunity to progress to proficient or expert or even regress in their skill.

When considering a high-stakes exam, this definition of competence must be translated into a test score in order to differentiate between candidates who meet a defined standard and those who do not.

Setting Passing Scores for Simulation-Based Examinations

A passing score is a cut point along the exam's score scale that reflects the level of competence deemed necessary to reach established standards [27]. Standard-setting methodologies are processes that are used to set the passing score for an assessment method; the passing score reflects the minimum level of competence deemed necessary [27]. While standard-setting methodologies have a long history of use within the domain of medicine for written examinations, their use in performance-based assessments, especially surgical skill assessments, has been limited. Furthermore, standard setting addresses the "consequences" domain of Messick's validity framework and thus helps to build validity evidence.

Several standard-setting methods have been described in the literature for performance-based assessments. Common among all methods is the need to rely on the value judgments of experts in setting a passing score, resulting in a somewhat arbitrary decision [28]. However, despite being arbitrary, a standard must still be credible. Norcini and Guille have described the criteria needed for a standard to be credible: (1) it must be set by an appropriate number and type of judges, (2) it must use an appropriate methodology, and (3) it must produce reasonable outcomes [29].

A recent study applied and compared different criterion-based standard-setting methodologies to the world's largest Objective Structured Assessment of Technical Skills (OSATS) database. Criterion-based approaches require that individuals meet a specified standard of achievement rather than comparing performance to other members in the group (normative based) [20, 30]. The contrasting groups, borderline group, and borderline regression criterion-based methods were applied to performance data from 513 first year surgical residents. The results demonstrated stable passing scores and consistency in the OSATS pass/fail decision across the three methodologies [31]. This was the first large-scale study to apply and compare these methodologies for performance-based technical skill assessment; it outlined the process of standard setting, which is an essential step in certification exam development.

Current Simulation-Based Assessments Used in High-Stakes Settings

Several high-stakes simulation-based performance assessments have been developed and implemented within the broader domain of medicine as a component of certification or licensure. Examples outside the domain of surgery include the Israeli Board of Anesthesia examination and the objective structured clinical examination (OSCE) of the Medical Council of Canada. Within the domain of surgery, examples include the Fundamentals of Laparoscopic Surgery (FLS) examination, the European Board of Vascular Surgery technical skill examination, and the Colorectal Objective Structured Assessment of Technical Skill (COSATS).

The Israeli Board of Anesthesia Examination

Anesthesiologists are expected to possess skills necessary to manage a wide range of acute intraoperative anesthetic events, many of which require technical skills relating to various types of procedures. Requisite technical skills for this specialty include, for example, endotracheal intubation, insertion of an arterial line, insertion of central lines, and management of a difficult airway.

In the early 2000s, the Israeli Board of Anesthesiology recognized the lack of performance evaluation at the time of board certification and the lack of performance assessments during the training process. At that time the testing committee of the board decided to develop, evaluate, and subsequently implement an OSCE as a component of the Israeli Board of Anesthesia certification process [32, 33].

The development of the examination involved several steps. First, the content of the examination was defined through expert opinion, which identified the clinical skills residents would be expected to possess at the completion of training. A Delphi methodology was used to identify tasks that would represent those skills, and scenarios were created to assess those tasks. Simulation models were then developed to assess the chosen tasks. The models were piloted by junior attending staff prior to implementation. The tasks included management of a trauma casualty, hypertension after induction of a general anesthetic, regional anesthesia landmarking on a standardized patient, management of convulsions, and adjustment of ventilator setting in response to arterial blood gas results.

A passing score based on checklist scores was set at 70%. An overall holistic assessment scale was also used. In 2006, Berkenstadt et al. published results of the first 114 trainees who had taken the examination over the 2-year pilot study [34]. Interstation reliability was 0.35–0.45 and acknowledged to be low. This was felt to be due to the limited number of stations (case specificity) and the limited number of candidates ($n = 17$ per year). The results demonstrated a weak correlation with the written and oral examination, suggesting that they are most likely measuring different constructs. The examination became a mandatory component of the Israeli Board of Anesthesia exam and continues to be a component of the certification process.

The Medical Council of Canada (MCC) Objective Structured Clinical Examination (OSCE)

The Medical Council of Canada (MCC) has a legislated national mandate to ensure that Canadian medical doctors meet the same demanding and consistent standards across the country [35]. In the late 1980s, MCC recognized that many competencies expected of licensed candidates (e.g., history taking, physical examination, communication skills) were not being assessed through the existing examination process [36]. To address this gap, MCC requires that individuals complete two examinations, one of which is a simulation-based multi-station OSCE required for medical licensure in Canada prior to entry into independent clinical practice [37]. MCC conducted several pilot studies to evaluate the OSCE and the logistics of incorporating this performance-based examination into high-stakes, large-scale testing for the purpose of licensure. Several studies investigated the psychometric properties of the exam and large-scale feasibility [36, 38]. Following these studies, the OSCE became a mandatory component of Canadian medical licensure process in 1994.

The Fundamentals of Laparoscopic Surgery (FLS) Program

The technical skill component of the Fundamentals of Laparoscopic Surgery (FLS) program [39] includes assessment of basic laparoscopic skills, including peg transfer, cutting, placement of a ligating loop, and intra- and extracorporeal knot tying. The FLS program has been extensively studied, and validity evidence demonstrates its ability to discriminate between expert and novice laparoscopic surgeons [40]. A passing score has been set for FLS using a methodologically sound approach allowing for pass/fail decisions. In 2009, FLS became a mandatory prerequisite for all candidates seeking certification by the American Board of Surgery [41]. The limitation of the FLS examination is that it only assesses basic laparoscopic skills.

The European Board of Vascular Surgery Examination

In the early 2000s, the European Board of Vascular Surgery (EBVS) recognized the lack of formal assessment of technical skill at the time of completion of training, and the board decided to develop a technical skill exam for certification of vascular trainees. A technical skill examination consisting of three vascular surgery tasks on simulated benchtop models was developed and evaluated. The first pilot demonstrated evidence of construct validity, inter-rater reliability, and good internal consistency of the exam. Since 2004, this technical skill examination has been incorporated into the board certification process. One of the limitations of this examination is lack of rigorous methodology for standard setting [10].

The Colorectal Objective Structured Assessment of Technical Skill (COSATS) Examination

The lack of objective assessment of technical skill at the time of surgical certification was recognized by the American Society of Colon and Rectal Surgeons (ASCRS) and the American Board of Colon and Rectal Surgery (ABCRS). Recognizing this gap in assessment, the ASCRS has developed a test for objective assessment of technical skill for the purpose of board certification of colorectal residents. This Colorectal Objective Structured Assessment of Technical Skill (COSATS) is a multiple station examination conducted in a skills lab. Candidates rotate through eight stations and are asked to perform technical tasks specific to the practice of colon and rectal surgery on simulation models.

In 2014, after two initial pilot studies [8], COSATS was offered at the time of the oral ABCRS examination, although the results of COSATS were not considered during certification by the board. The results demonstrated a very high reliability of pass/fail decisions ($p_0 > 0.80$). Furthermore, when the pass/fail status of COSATS was compared to the pass/fail status of the ABCRS oral and written examination, the results demonstrate that all of the candidates who failed COSATS passed the oral and written examinations, suggesting that the COSATS helps to identify technical deficiencies in individuals who would otherwise go on to be certified through the current ABCRS certification process [9].

Discussions are currently underway between ASCRS and ACS to define the tenets of a collaboration that will result in COSATS being offered to all colorectal surgery residents, possibly during the period of training formally assess skills and allow for remediation prior to graduation from the training program. Opportunities to offer COSATS to general surgery trainees and practicing surgeons will also be explored.

Advantages Relating to the Use of Simulation for Certification and Licensure

Miller's pyramid of assessment serves as a useful taxonomy for understanding assessment within surgical education, with each level of the pyramid representing graduated assessment techniques. Assessment of performance in real-world settings involving patients is considered the most authentic and uncued assessment approach. Within Miller's theory of assessment, this type of real-world assessment reaches the highest level of assessment, representing the peak of the pyramid and is called the "does" level of assessment [42]. An example of assessment at this "does" level would be the observation and evaluation of a resident's performance during a real surgical case. Intuitively, it would make sense to consider this approach ideal for high-stakes summative assessment. However, despite the advantages of assessment in real settings, there are many complexities that need to be addressed to yield valid assessments and to ensure patient safety. Also, patient variables can impact the assessment results.

The "shows how" level of assessment is the second highest level in Miller's pyramid of assessment. This level aims to assess the ability of learners to demonstrate or "show" what they "know how" to do [42]. This level of assessment typically involves performance-based assessments using simulation. While it can be argued that these assessments may be somewhat artificial, they elevate the assessment beyond just the focus on knowledge and possess several advantages regarding their use in high-stakes summative examinations. Simulation allows assessments in safe settings where patient care is not compromised. It allows room for error, allowing test takers to complete a task incorrectly, and the consequences of an error can be fully played out. This is important, because it allows examinees to realize the consequences of error and permits evaluators to witness and document problems with performance which can then be remediated [43]. Assessments can also be standardized, which makes them fair across all candidates. Also, simulators can be used repeatedly, and reproducible platforms for formal testing can be developed. Lastly, simulations and simulators are available at any time and can also be used to assess procedures that are less commonly performed [44].

Disadvantages Relating to the Use of Simulation for High-Stakes Summative Assessments

A number of disadvantages relating to the use of simulation for high-stakes summative assessments must be considered, and barriers need to be addressed. These include feasibility and costs, dealing with the failing examinees, examination security, and training to the test.

Feasibility and Costs

No matter how reliable or "valid" an assessment is deemed to be, a major obstacle to implementation is feasibility. Two main feasibility issues are (1) cost of simulated technical skill examinations and (2) large-scale administration of simulated technical skill examinations. Simulated technical skill examinations are extremely labor-intensive in terms of model development, examination administration, examiner time commitment, the cost of exam setup, models, and lab rental. The feasibility issues and high costs relating to simulated examinations present major obstacles. The first question that needs to be addressed by the surgical community at large is the value of testing and documenting the achievement of technical competence of surgeons. There must be strong buy-in from a variety of different stakeholders.

While a formal cost analysis had not been carried out on the COSATS exam, it has been estimated that the cost would be approximately $1000 per candidate. When compared to the current cost of the Canadian General Surgery Board exam (which is well over $1000) [45] and the ABCRS certification exam (which is $700 for the written examination and $800 for the oral examination) [46], the cost of a technical skill exam does not seem unreasonable.

The second major feasibility issue is the size of the examination. For example, when considering a technical skill examination for general surgery residents in the United States, the number of general surgery residents who would need to be tested is significant. There are over 200 accredited general surgery programs in the United States, with over 1000 general surgery residents graduating each year [47]. A simulated technical skill exam to accommodate this number of residents annually would pose logistical challenges.

One way to address issues of exam size and feasibility is to develop a robust examination infrastructure. This would help to offer the examination across the country with the appropriate standardization in administration. A good option would be to use the consortium of ACS-accredited Education Institutes (ACS-AEIs) [48].

Dealing with the Failing Examinees

An important question that relates to the outcomes of a high-stakes exam is what to do with examinees who fail the exam. How will these individuals be remediated? Will these individuals require retesting? How many opportunities will they be offered to retest before they are required to retrain? Developing and evaluating strategies for remediation will need to be pursued, and a pathway for dealing with a failing examinee will need to be defined.

Examination Security

While examination security is important, literature regarding the impact of knowledge of the examination content on examinee performance is interesting. The OSCE literature suggests that prior knowledge of content may not provide an advantage to candidates as one might expect [49]; furthermore, it has been shown that prior knowledge of exam content can actually disadvantage a candidate. Swartz et al. conducted a study that was meant to deliberately violate test security by having the first group taking an OSCE exam provide detailed information to a second group who subsequently took the same OSCE exam. Despite this deliberate assault on test security, the authors found that having access to information on exam content had little effect on exam performance [50]. When we consider technical skill assessment, such a result is likely because if the examinee does not know how to perform a specific procedure, it is unlikely that knowledge of that procedure being on the examination would improve performance.

Training to the Test

Training to the test is another element to consider when designing high-stakes summative simulated technical skill assessments for residents. Surgery training programs may start to train residents to the content of the examination. However, if the examination represents the broad range of technical skill required of that specialty, then placing additional effort into training technical skills reflected in the examination would likely improve the learning experience of residents. Furthermore, over time a large bank of procedures could be developed with a sample of tasks being chosen for any specific examination administration. Since examination content would change over time and since the content would reflect a broad range of different procedures, exposing residents to these cases would only help to improve clinical training.

Furthermore, regulatory bodies have specific requirements for training that residents will still need to achieve [41, 51]. Thus, even if institutions train to test, they must still ensure that candidates are familiar with and have completed a full and complete range of surgical procedures during their training.

Future Directions

Surgeons in practice progress through various phases during their careers. The skill set of surgeons following completion of residency training is fairly broad, and this gets more focused in later years. If surgeons want to perform procedures they have not performed in a while, retraining becomes necessary. Such retraining should involve high-stakes summative assessments, and the use of simulation can be very helpful in this process. Following participation in a retraining program, observations by a preceptor or proctor can help to confirm achievement of specific levels of performance. Patient care outcomes should then be evaluated for a period of time. Data from these assessments could then be used in the processes of credentialing and privileging and for FPPE. A similar assessment process would be useful during the reentry process if an individual has been out of clinical practice for a period of time [52]. In addition, such assessments could be useful in processes of remediation if gaps in performance are found. Senior experienced surgeons who are winding down their practices prior to retirement or have recently retired may be recruited to serve as assessors for high-stakes summative assessments in simulated settings. They could also serve as consultants and provide valuable feedback to surgeons in practice based on results of high-stakes summative assessments. The recruitment of senior surgeons who are becoming less clinically active or have recently retired could help in addressing issues relating to feasibility of implementation of such high-stakes summative examinations.

The use of simulation-based high-stakes summative assessments should be supportive of professional efforts of individuals to provide optimal care to surgery patients. If these examinations are considered punitive or are unduly complex or expensive, they will not be widely embraced by the surgical community. Sharing of experiences across the surgical specialties should help in advancing the goals of the professional surgical organizations and the profession as a whole, which will serve the best interests of patients.

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Part III

Simulation for Non-technical Skills

Making It Stick: Keys to Effective Feedback and Debriefing in Surgical Education

John T. Paige

Introduction

Surgery often relies on the “art of healing,” since its practitioners draw frequently on intuition, experience, and “feel” to treat patients under their care. Likewise, effectively passing onto the next generation the knowledge and skills required to practice surgery involves the “art of teaching.” If done properly, such teaching can produce the cherished “*eureka!*” moment in the learner in which the knowledge or skill is embedded into his/her memory. This epiphany typically occurs during a moment of feedback or debriefing following an educational endeavor.

Whether consciously or unconsciously, surgical educators engage in some form of feedback and/or debriefing every day they interact with students/trainees. The informal discussion reviewing technical points of a just completed operative procedure and the structured review after a simulation-based exercise are but two examples of these educational opportunities involving teacher and learner. Unfortunately, surgical educators often receive little or no training or instruction regarding the most effective manner in which to give feedback or debrief. Much like surgical students are expected to know knot tying and suturing without much instruction, surgical educators are assumed to have mastered the skills of providing effective feedback and debriefing. The result is the neglect of these important skills in surgical education courses and training. Surgical education’s transition from the apprenticed-based model of Halsted [1–3] to a more objectives-based curricular model [4] has compounded this deficiency. Combined with fewer clinical opportunities to learn due to work-hour restrictions [5, 6] and patient safety and financial concerns [7, 8], each educational experience must be optimized to get the most learning from it. Thus, learning how to provide effective feedback and debriefing provides some of the biggest “bang for the buck” in surgical education.

The use of simulation-based training (SBT) has been at the forefront of the transformation of surgical education into the objective-driven curricular structure in the twenty-first century. SBT’s benefits are manifold in surgical education, ranging from improved technical performance in the OR [9, 10] to more safe and effective teamwork [11–13]. In addition, the high technology component of SBT, with its virtual reality machines and computer-based manikins, lends a certain *caché* to the field, drawing attention from surgical educators to incorporate these components into training. Consequently, work in the development of SBT in surgical courses and residencies has concentrated disproportionately on simulators, scenarios, and curricular development rather than providing effective feedback and debriefing. This fact persists even though feedback and debriefing have been identified as key elements in SBT’s utility [14, 15]. This chapter will try to address this deficiency by elucidating key practices and principles related to giving effective feedback and debriefing in surgical education. First, it will provide definitions for both terms and provide a theoretical framework related to their use. Next, it will attempt to identify key best practices for optimizing trainee/student learning using either technique. Finally, it will delineate several concrete examples of their use in current health educations training.

Feedback and Debriefing in Context

Defining Feedback and Debriefing

Although they are often used synonymously by educators and surgeons alike, the terms *feedback* and *debriefing* describe different concepts and have different origins in the English language. The word *feedback* first arose in 1920 in electronics to describe “the return of an output signal to the

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input of an earlier stage" [16]. From this origin, it was expanded in 1955 to include "information about the results of a process" [16]. Among its contemporary uses, the definition most germane to this chapter would be the following: "the transmission of evaluative or corrective information about an action, event, or process to the original or controlling source…" [17]. Thus, *feedback* in surgical education involves the instructor/teacher providing information back to the learner related to his/her knowledge, skills, or attitudes (KSAs) related to a performance, event, exam, rotation, or the like.

Debriefing, on the other hand, is the gerundive of the verb *debrief*, which was coined in 1945 to describe the process of "obtain[ing] information (from someone) at the end of a mission" [18]. Such an etymology belies its military origins during World War II when post-mission accounts began to be used for both operational and educational benefit [19]. In current usage, "to interrogate (as a pilot) usually upon return (as from a mission) in order to obtain useful information" is still the most common definition for debrief [20]. For this chapter, the definition "to carefully review upon completion" is more apropos [20]. *Debriefing* in general, therefore, involves a more comprehensive process than just providing *feedback*, even though giving feedback is clearly an important subset of this process. Thus, feedback and debriefing are part of a continuum of providing information to a learner. Feedback is more unidirectional and specific, whereas debriefing is bidirectional and reflective. Nonetheless, each format can cross over into the other, since their theoretical underpinnings follow similar cycles of cognition (Fig. 1).

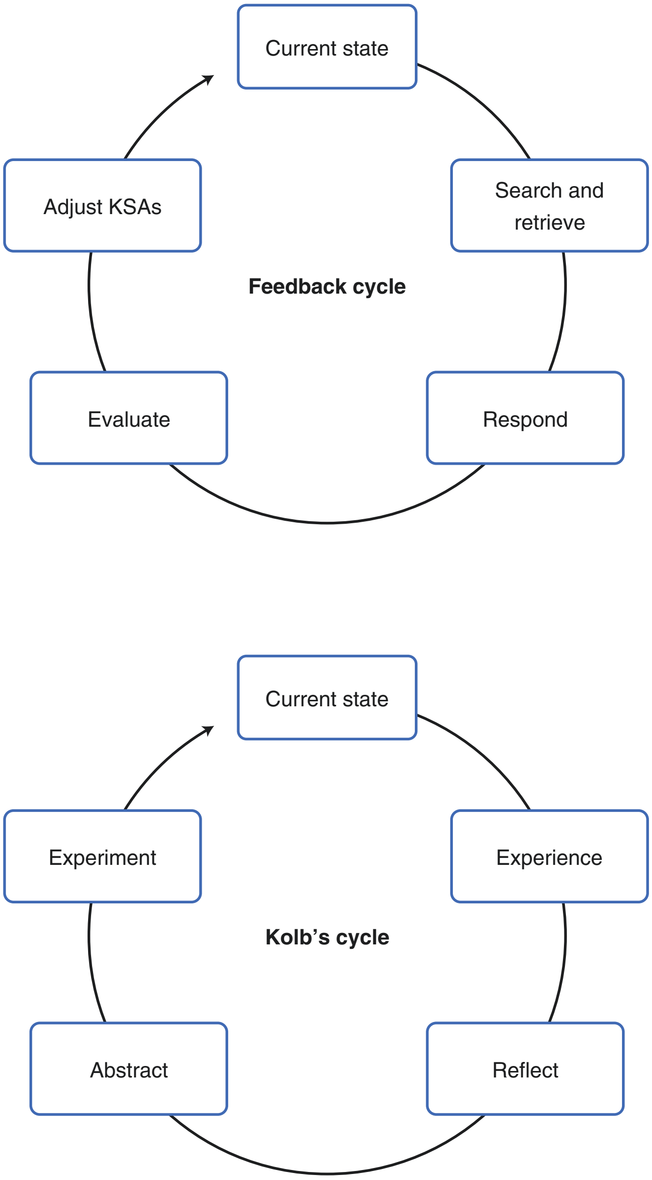

Fig. 1 Feedback and experiential learning cycles

Feedback and Types of Assessment: Formative Versus Summative

Feedback in the context of an educational activity is often based on an instructor's assessment of the learner related to the knowledge, skill, or attitude being demonstrated. It is thus crucial to understand the types of assessment that can be undertaken and how they might inform how the feedback is delivered. Assessment provided during an educational encounter can impact the learner in a wide variety of ways, depending on the context of when it is given and its purpose [21]. *Formative* assessment [21–23] is more focused on providing specific, data-based information to the learner regarding his/her progress toward a particular or overall learning objective or expected level of achievement. In this setting, an instructor's feedback may highlight weaknesses in performance and suggest tasks and objectives to help improve them or to reach predetermined benchmarks. Such formative assessment typically occurs during a practice session or established educational activity, is informal in nature, does not involve grades, involves low-inference measurements, and is low stakes. *Summative* assessment, on the other hand, is a more formal, graded activity that typically occurs outside of an educational event. It is based on high-inference measurements and is high stakes in nature (e.g., determining advancement to a higher level) [21–23].

Although feedback might be given in conjunction with summative assessment, the lion's share of feedback in SBT in surgical education is given in relation to formative assessment. Providing it in an effective manner, therefore, is essential in order to optimize learner progress in surgery, especially since its intent is to change the learner's behavior in order to achieve a learning goal [24]. Key to having such ability is to understand how feedback works in a contextual framework.

Feedback Frameworks

Several frameworks have been developed to contextualize how feedback works. Bangert-Drowns et al. [25] proposed a useful five-stage cyclical feedback process similar to Kolb's learning cycle [26] in which the learner starts at a current state, is prompted to undergo search and retrieval strategies through questioning by the instructor, provides a response, evaluates the response based on instructor feedback, adjusts KSAs based on the evaluation, and thus enters a new current state (Fig. 1 [25, 26]). Through this iterative process, the learner is guided toward the educational objective (i.e., the clear, specific goal) of the feedback episode.

Three learner conditions are needed for feedback to be effective: *motive*, *opportunity*, and *means*. *Motive* reflects the fact that the learner recognizes the need for the feedback. *Opportunity* emphasizes that the feedback needs to be timely in order for the learner to act upon it. Finally, *means* indicates that the learner must be willing and able to use the feedback to improve [24].

Thus, in order to be effective, the learner must understand the feedback, accept it, and be willing to act upon it [27]. Additionally, Kulhavy and Stock [28] have emphasized that effective feedback contains two important elements: verification and elaboration. Verification involves the act of confirming to the learner whether an answer is correct or incorrect. This verification can be explicit in nature (i.e., a positive check mark) or implicit in character (i.e., a poor outcome in an SBT scenario based on incorrect decisions). Elaboration describes the manner in which information is conveyed to the learner in order to provide cues to guide the learner to the correct answer. It can be directive or facilitative in quality.

Narciss and Huth [29] developed a framework for designing feedback based on instructional context, learner characteristics, and elements of the feedback. Instructional features such as objectives, tasks, and obstacles combine with learner goals and objectives, prior KSAs, and motivation to exert an influence on the feedback based on its content, function, and presentation. They have shown that such systematic design for feedback has positive effects on learners' accomplishments and motivation. Thus, by targeting key instructional and learner features, feedback can be tailored to enhance its effectiveness.

Theoretical and Structural Elements of Debriefing

Unlike *feedback*, which focuses on verification and elaboration of information to a learner in an often one-way direction to help improve learning and performance, *debriefing* is an interactive process of bidirectional reflective analysis [30]. In essence, it is a process to facilitate learners' analysis, interpretation, and assimilation of events during an educational encounter in order to move them from simply *experiencing* these events to *making sense* of what has occurred [19]. In this manner, the learner is prompted by a facilitator to engage in self-reflective practice to identify and resolve gaps in KSAs or performance. This interactive process, if done correctly, can produce powerful, positive responses in learners, leading to enhanced adoption of KSAs and improvements in clinical performance.

The educational effectiveness of debriefing can be found in its theoretical underpinnings, especially when it is employed during SBT. At its essence, the process of debriefing is embedded into Kolb's theory of experiential learning (Fig. 1 [25, 26]) [19, 26]. This cyclical process of learning begins when a learner undergoes a concrete experience (i.e., a simulation-based scenario). This experience leads to reflection and observation which in turn prompts abstract conceptualization of new rules and principles. These new rules and principles are then tested through active experimentation by the learner, leading to new concrete experiences. In this cycle, the debriefing process corresponds to the reflection on events and the formation of new principles. Such *reflection on action* is an important component of Schön's concepts regarding reflective practice [31]. This type of reflection occurs after an event such as a SBT experience and can be combined with or replaced by *reflection in action* in which learners "think aloud" during an SBT episode. The key to learning is thus the self-reflection and conceptualization, highlighting the fact that a scenario or SBT serves as a catalyst for the actual learning that occurs during a debriefing.

As described by Lederman [32], any debriefing contains seven common structural elements: the debriefer, participants, learning scenario or experience itself, impact of the scenario, recollection, report, and time. These structural components can further be categorized into three overarching elements related to (1) people involved in the debriefing (i.e., the facilitator and the learners, which could be one and the same if the debriefing is self-directed), (2) events related to the debriefing (i.e., the scenario/learning encounter and its impact on the learner), and (3) experience of debriefing itself (i.e., recollection, report, and time). These structures are the scaffolding upon which the debriefing process is constructed, promoting the self-reflective learning that is such a powerful educational tool. Paragi et al. [33] divide this process into three major components: (1) an introduction, (2) the debriefing itself, and (3) a closure. The second component is further subdivided into four aspects: (1) engagement of the learner, (2) focus on the events, (3) reflection and critique, and (4) application to everyday practice. It is within this construction that the learners pass through the various phases of the debriefing process.

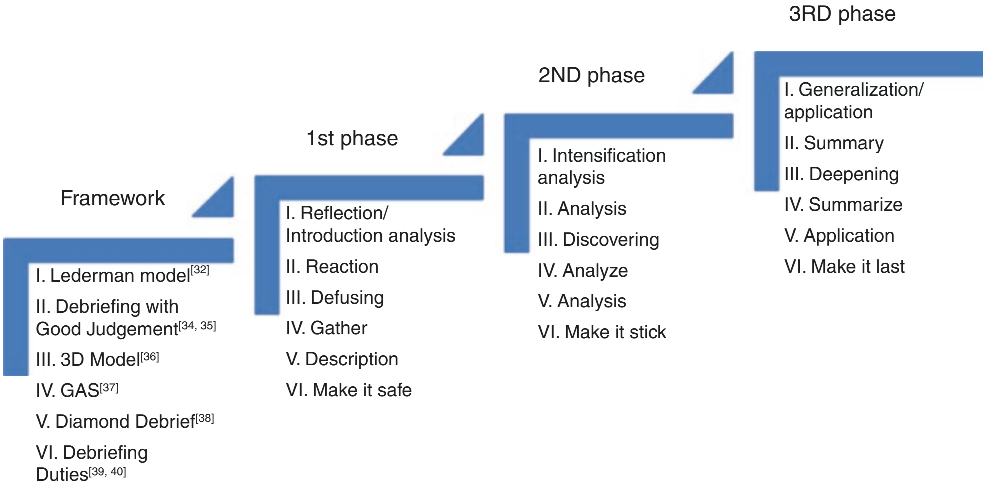

Fig. 2 Three-phase models of debriefing

Phases of the Debriefing Process

The educational power of debriefing rests in the structured process by which the learners respond to, interpret, and apply experiences to gain KSAs and improve performance. In healthcare and beyond, multiple models have been proposed to describe this learning process. A large number of these frameworks consist of three distinct phases which more or less align with one another (Fig. 2 [19, 30, 32, 34–40]). Several multiple phase frameworks have also been proposed [19, 30], but they too can often be aligned into three main groupings. For example, the Healthcare Simulation After Action Review's (AAR's) [41] seven phases can be clustered as follows: (1) define rule, explain learning objectives, benchmark performance, (2) review expected actions, identify what happened, examine why things happened the way they did. and (3) formalize learning. Likewise, Petranek's seven "Es" [42] can be clumped into three: (1) events, emotions, empathy; (2) explanations and analysis, everyday applicability; and (3) employment of information, evaluation.

Rudolph et al.'s [34, 35] three-step model, debriefing with good judgment, is one of the most concise and useful in delineating the necessary phases through which a learner proceeds during a debriefing. First, he/she must react to the experience by discussing emotional responses. Next, he/she proceeds to analyze the experience, identifying gaps in performance and formulating solutions. Finally, he/she undergoes a summary of what happened, formulating lessons learned for application in practice. Thus, through this reaction, analysis, and summary process, the learner is able to make sense of what happened and how it can be applied.

The debriefing duties model [39, 40] is another framework that has utility, especially for those beginning in debriefing. This model delineates three key duties that a facilitator should undertake to lead learners through a debriefing process. Each duty corresponds to key components of the debriefing process. The first duty is for the facilitator to *make it safe.* This step involves creating a learning environment in which learners feel psychologically safe to speak up without retribution [19, 30]. In general, the facilitator can help create such an environment by demonstrating respect to learners and focusing on the *debriefing process* itself rather than people [43, 44]. The second duty of the facilitator is to *make it stick.* This step entails engaging the learners in Schön's reflection on action to analyze and synthesize their experience in relation to the learning objectives of the training session [40, 43, 45]. The final duty for the debriefer is to *make it last* by eliciting a commitment from each learner to a change in behavior based on their analysis and synthesis [33, 40].

Best Practices for Feedback and Debriefing

Giving Effective Feedback

Although seemingly straightforward to do, giving effective feedback can be a difficult undertaking, especially for a surgical educator who has not had any formal training in the process. Fortunately, research into how to give effective feedback has revealed best, and worst, practices (Table 1) [24, 27, 46]. Keys to enhancing learning include providing feedback that is unbiased, objectives-based, clear, actionable, based on understandable measurements, consistent with other feedback, manageable, and timely. The timing of feedback should be based on the nature of the task and the complexity of what is being taught. Immediate feedback is most useful for difficult tasks, motor skills/procedural learning, and conceptual knowledge. Delayed feedback works for simple tasks, and it seems to promote transfer of learning [24].

Table 1 Best practices related to giving effective formative feedback [24–26]

Best practices (What should be included)	Worst practices (What should be avoided)
Related to *clear goal*	Having *no goal* or related to *vague* goal
Tangible and transparent results	*Extensive error analyses, diagnosis*
Actionable objectives	*Normative comparisons, progressive hints*
User-friendly delivery, *unbiased* in character	*Loaded terms*, *biased* delivery
Timely	*Interrupting* learner, *poor timing*
Ongoing in nature	*Threats to self-esteem*
Consistent in character	*Discouraging* learner
Elaborated information in *manageable units*	*Praising* learner
Focus on task	*Focus on person*

Nicol and Macfarlane-Dick [47] have emphasized that giving effective feedback is instrumental in helping to promote self-regulated learning by learners. They have delineated seven practices for giving good feedback. These principles include making sure to clarify good performance, facilitate self-reflection, provide high-quality information regarding learning, encourage dialogue around learning, encourage positive self-esteem, provide opportunities to close performance gaps, and provide information to help shape teaching. By following these best practices, they argue that learning will be enhanced, since self-regulated learners have been shown to be higher achievers due to persistence, resourcefulness, and higher confidence levels.

Learner characteristics have also been found to influence how to give the most effective feedback. For high-achieving learners, facilitative feedback given in a delayed fashion seems to be effective. On the other hand, low-achieving learners require immediate feedback that is directive, employs elaboration, and employs scaffolding of information. Finally, specific and goal-directed feedback should be given to learners with low-learning orientations (i.e., trying to achieve learning goal) and/or high-performance orientations (i.e., aiming to please others) [24].

In the surgical educational literature, Jensen et al. [48] demonstrated that providing feedback is valued by both surgeons and residents. Unfortunately, a true disconnect exists between them in that surgeons believe that they provide enough in the operative setting, whereas residents crave more. This perceived gap in the amount of feedback provided extends as well to the timeliness and quality of the feedback provided. Interestingly, Kannappan et al. [49] have shown that medical students perceive that both positive and negative feedback related to technical skills acquisition can be potent motivators. Additionally, Cortes et al. [50] have demonstrated the superiority of verbal feedback from experts over computer-generated feedback on motion efficiency for third year medical students learning technical surgical skills. Boyle et al. [51] illustrated the benefit of combining standardized, timely (i.e., proximate) feedback with SBT. Such feedback improved the learning curve and reduced the error rates of surgical residents undergoing a virtual reality hand-assisted colectomy. Soucisse et al. [52] reached similar improvements in technical ability after providing video-based feedback. Surgical residents who received such one-on-one feedback had better technical scores when performing an intestinal anastomosis compared to those who did not. Providing quality feedback has also shown benefits beyond technical skill acquisition. Garner et al. [53] showed that immediate feedback improved faculty-student dialogue on surgical clerkships. Finally, Yule et al. [54] have extended the benefit of feedback to the acquisition of nontechnical skills when it is combined in a coaching framework.

Evidence Base for Effective Debriefing

As with feedback, best practices have been identified for providing effective debriefing. For example, in a recent critical review on debriefing in healthcare, Sawyer et al. [30] identified seven process elements of a debrief that they viewed as essential for making it effective. Three of these elements help set up the debriefing process and, hence, typically occur at the beginning of the learning intervention/debriefing itself. They include establishing an environment of psychological safety, an assumption that all learners are trying to do their best and want to improve, and delineating the basic set of rules related to the debriefing. The remaining four elements involve the debriefing process itself. They relate to establishing a shared understanding of the events that took place, addressing key learning objectives, asking open-ended question, and using periods of silence to elicit learner reflection and response.

Within the surgical education literature, Ahmed et al. [55] identified best practice guidelines for debriefing in surgery by conducting semi-structured interviews of surgical educators and residents in the United States, Britain, and Australia. Arora et al. [56] then combined this work with an extensive literature review to develop an evidence-based, end-user-informed assessment tool for debriefing, the Objective Structured Assessment of Debriefing (OSAD) instrument, which incorporated eight key features of effective debriefing and behavior-based anchors using a Likert scale (Table 2 [55–57]). As a result, the OSAD can serve as a debriefing guide/script for a facilitator, self-assessment tool for improvement, or observer-based instrument for giving feedback. The eight elements of the OSAD can be grouped into clusters based on Paragi et al.'s [33] structure and the duties of debriefing framework [39, 40] to show when each particular component of the debrief should be particularly emphasized (Fig. 3 [33, 39, 40, 55–57]).

Other debriefing assessment tools that have been published in the healthcare literature include the Debriefing Assessment for Simulation in Healthcare (DASH) [58] tool and the Peer-Assessment Debriefing Instrument (PADI) [59–61]. Each of these instruments emphasizes particular components of effective debriefing that a facilitator should strive to include. Brett-Fleeger et al. developed the DASH through theory elaboration. In this iterative process, they combined a review of existing debriefing assessment tools, two from fields outside healthcare and three from within healthcare (including the OSAD), with semi-structured interviews with debriefing facilitators in the United States, Europe, and Australia to create a seven-point Likert-type scale with six domains of best practice. These domains were behaviorally anchored activities of an effective debriefer: (1) establishes an engaging learning environment, (2) maintains an engaging learning environment, (3) structures debriefing in an organized way, (4) provokes engaging discussions, (5) identifies and explores performance gaps, and (6) helps trainees achieve or sustain good future performance. Saylor et al. drew on prior tools such as the OSAD and DASH to help develop the PADI using a Delphi technique in order to identify eight key areas of effective debriefing for their four-point peer assessment instrument. These domains included the following: (1) structure and organization of the debriefing, (2) verbal and nonverbal communication, (3) setting the stage and ground rules for the debriefing session, (4) talking about defusing (dealing with the emotional aspects of the simulation), (5) recapping the simulation experience, (6) reflecting on action (facilitating learner's self-reflection), (7) facilitating learner's connection of simulation experience to clinical practice, and (8) summarizing, providing key takeaway points for the learner. As with the OSAD, each of these instruments can be used as a guide for conducting an effective debrief and as a tool for feedback. In addition, most of the domains can be clustered around the components of a debriefing structure to demonstrate where they should be emphasized. In this manner, novice facilitators can not only know the key elements of an effective debrief, but they can understand when to focus on each one.

In addition to the above-mentioned elements of effective debriefings, research has also focused on adjuncts and techniques to optimize learning during a debriefing. Useful adjuncts to assist with teaching during a debriefing include involving a co-debriefer to provide another viewpoint and

Table 2 Objective Structured Assessment of Debriefing (OSAD) instrument

Approach	Manner in which the facilitator conducts the debriefing session, their level of enthusiasm and positivity when appropriate, showing interest in the learners by establishing, and maintaining rapport and finishing the session on an upbeat note
Establishes learning environment	Introduction of the simulation/learning session to the learner(s) by clarifying what is expected of them during the debrief, emphasizing ground rules of confidentiality and respect for others, and encouraging the learners to identify their own learning objectives
Engagement of learners	Active involvement of all learners in the debriefing discussions, by asking open questions to explore their thinking and using silence to encourage their input, without the facilitator talking for most of the debriefing, to ensure deep rather than surface learning occurs
Reaction	Establishing how the simulation/learning session impacted emotionally on the learners
Reflection	Self-reflection of events that occurred during the simulation/learning session in a step by step factual manner, clarifying any technical clinical issues at the start, to allow ongoing reflection from all learners throughout the analysis and application processes, linking to previous experiences
Analysis	Eliciting the thought processes that drove a learner's actions, using specific examples of observable behaviors, to allow the learner to make sense of the simulation/learning session events
Diagnosis	Enabling the learner to identify their performance gaps and strategies for improvement, targeting only behaviors that can be changed, and thus providing structured and objective feedback on the simulation/learning session
Application	Summary of learning points and strategies for improvement that have been identified by the learner(s) during the debrief and how these could be applied to change their future clinical practice

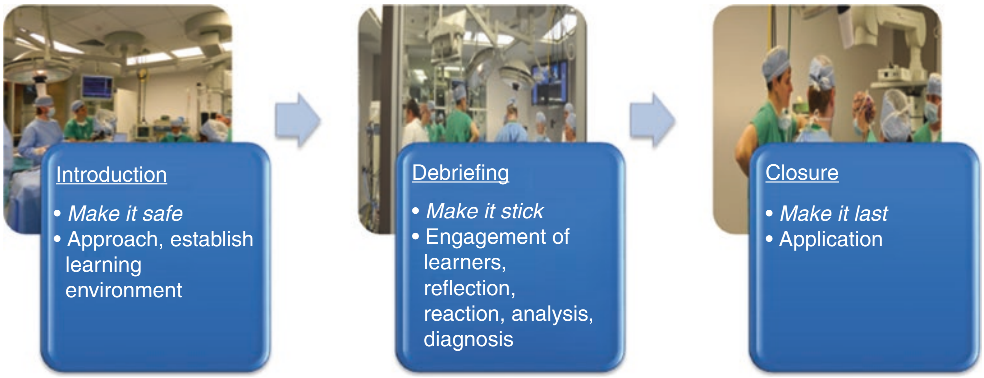

Fig. 3 OSAD within the debriefing structure

help manage learner needs, following a debriefing script to guide the facilitation, and employing video review to highlight key performance issues [30]. Although still somewhat controversial, recent evidence suggests that video review does not convey any advantage compared to debriefing without it [62, 63]. Certain techniques related to a facilitator's conversational approach during a debriefing have demonstrated effectiveness in enhancing learner acquisition of KSAs (Table 3 [19, 21–23, 30, 34, 35, 44, 64, 65]).

Debriefing adjuncts and conversational approaches provide facilitators with tools to help overcome the inevitable obstacles and challenges that may arise during a debriefing. According to Kolbe et al. [66], these barriers can exist at the individual, team, or organizational level. Individual-based obstacles include cognitive biases, errors of attribution, lack of familiarity with the debriefing process, lack of knowledge on the subject (e.g., human factors, teamwork), and a focus on people and actions rather than meaning. Team-based barriers include group think (i.e., sharing only information that is consistent with existing views), lack of psychological safety among certain members, avoiding new information or undiscussable topics, and a reluctance to communicate explicitly among team members. Finally, organizational obstacles include lack of support, lack of follow-up, lack of confidentiality, and avoidance of undiscussable topics (i.e., the proverbial elephant in the room about which no one will speak). Any of these situations can impede the effectiveness of a debriefing, and, as a result, they should be avoided.

Finally, the timing and style of a debriefing can impact effectiveness, given the situation and skill being taught. For post-event debriefing, facilitator- and self-guided reflections can be undertaken. In a review of facilitator- versus learner-guided debriefing formats, Cheng et al. [67] emphasized that each has its advantages in certain contexts. For example, facilitator-led debriefings are particularly useful in time-pressed situations in which learners have little relevant background or clinical experience or in cultural situations where deference to superiors is strong. Learner-led debriefings, on the other hand, are more suited for situations in which time is not an issue, and learners have a high degree of relevant background or clinical expertise or cultural backgrounds in which subordinates have limited dependence on superiors. Either way, both types of leading a debrief have demonstrated effectiveness in behavioral skills training [68, 69]. Within-event debriefing involves a facilitator-led "stop and go" process in which the action is stopped, a debriefing is undertaken, and then the action is resumed. This style of debriefing is less effective for surgical skills acquisition compared to traditional post-event debriefing [70].

Table 3 Conversational approaches to enhance learning during a debriefing

Conversational approach	Examples	Technique
Learner self-assessment	Plus/delta (+/Δ) [19, 30]	Asking open-ended questions regarding what went well (i.e., plus) and what could be changed (i.e., delta) related to the learning activity
Directive feedback	Formative feedback [21–23]	Providing specific, data-based information to the learner regarding his/her progress toward a particular or overall learning objective or expected level of achievement
Focused facilitation	Advocacy inquiry [30, 34, 35]	Advocating debriefer's observation of an action and then inquiring about the learner's frame of mind about the particular action
	Guided team self-correction [30, 64]	Learners are asked to compare their performance during the learning activity to against a prespecified model of performance and are then guided to self-correct their actions
	Circular questions [30, 65]	Asking a third learner in a learning activity to comment on the relationship between two other learners who also participated in the learning activity in order to "circle back" and comment from an outside perspective on an activity in which they participated

Examples of Feedback and Debriefing in Surgery and Simulation

Tools Used in Surgery

As mentioned at the beginning of this chapter, feedback and debriefing are often used synonymously, although they have different meanings and origins. Nonetheless, they form a continuum of providing information to a learner. Hence, certain tools/structures for one could potentially have utility for the other. For example, the difference between directed feedback and performing a micro-debriefing during a learning activity may be simply due to the degree to which the learner's perspective is explored [71]. This case is certainly true in surgical education for two scripts that can be used for either giving feedback or to facilitate a more reflective debriefing.

The first of these tools, developed by Ahmed et al. [72], is denoted by the acronym *SHARP*. It is a five-step process for providing feedback or conducting a debriefing after a surgical educational experience. It begins before the encounter when the instructor and learner mutually *set learning objectives* for the activity at hand. After the learning event, it then proceeds to an assessment by the learner regarding the question "How did it go?" Next, the instructor and learner *address concerns* raised by the learner, and, then, they *review learning points*. Finally, they *plan ahead* by identifying actions that can be taken to improve future performance. Developed from the OSAD elements for effective debriefing, the

SHARP has been shown to improve both the frequency and quality of debriefing in the operating room setting [57, 72]. Its concise, compact nature makes it an attractive instrument for conducting both feedback and debriefing in surgical education.

The second of these scaffolds for giving effective feedback and debriefing is the laparoscopic colectomy (Lapco) train the trainer (TT) format for teaching in surgery. Created by Mackenzie et al. [73] in order to improve the quality of teaching in the English national laparoscopic colorectal training program, it consists of a three-part process known as set, dialogue, and closure. The set occurs before the learning event and involves the instructor and learner "aligning agendas" by agreeing upon learning objectives for the activity. In addition, the instructor works to remove any potential mental or ergonomic situations that would serve to distract the learner. The dialogue is the structured manner in which feedback is given during the learning event and is denoted by the acronym *SIX STEPS*. The instructor first halts all activity by saying "*stop*." Next he/she *inquires* about what the learner is thinking regarding his/her activity. Following the response, the instructor *explains* what he/she sees as the issue and then proceeds to provide *structure teaching* related to it. Then, the instructor *elicits* a check from the learner by having him/her repeat back what was taught. Finally, the instructor allows the learner to *proceed if safe* to do so. In essence, the dialogue represents a process of Schön's reflection on action, and it could be classified as what Eppich et al. have termed a micro-debriefing [71]. This blending of feedback and debriefing demonstrates their similarities. The closure is a post-procedure/training debriefing in which the instructor encourages the learner to reflect on what went well, what could be improved, and guides him/her to an overall "take home" message delineating what to work on related to the training. By using this framework, instruction for the training exercise is consistent, predictable, and standardized. It has even been successfully adapted for use in a cadaveric hands-on course held at the annual meeting of a national surgical society [74].

Formats Used in Simulation in Healthcare

A large number of debriefing formats have been developed for use in simulation in healthcare. They typically follow a three-phase model in which the reflection moves from emotional response through analytical understanding to commitment to change (Fig. 1). In addition, multiphase models such as TeamGAINS [62], Promoting Excellence and Reflective Learning in Simulation (PEARLS) [75], and Healthcare Simulation AAR [34] are also available. Each one is designed to promote the reflective practice by the learner that will lead to identification of performance gaps and the formulation of action plans to address them. Some formats have been designed for a particular setting. For example, TeamGAINS focuses on providing a structure for SBT of healthcare teams [62]. Other formats, like Healthcare Simulation AAR, have been adapted from other industries [34]. All of them serve as a scaffold on which the facilitator can construct an effective debriefing session in order to optimize learning. Thus, a facilitator can choose that format most conducive to the SBT session being taught. In addition, he/she can enhance a format's effectiveness by adopting debriefing adjuncts and conversational approaches that will elicit the greatest learner response for the particular group and SBT event.

Faculty Development

Both feedback [76] and debriefing [14, 15] have been recognized as essential components for the utility of SBT. Yet, determining the type and method of feedback/debriefing that is most effective for improving performance has been, and still remains, a top research need in surgical education [77, 78]. Additionally, the various formats of debriefing available have led to questions of whether "one size fits all" for SBT activities for advocates of a particular framework [79]. Combined with the fact that many faculty are lacking in formal or even informal training in how to give effective debriefing, the need for adequate and effective faculty development in this important area of surgical education is evident. Facilitator training has been recognized as an essential ingredient for successful educational outcomes [43]. In fact, it is commonly performed in other high-risk industries in order to ensure effective debriefing [80].

To date, educators in healthcare and surgery have attempted to address this need for faculty development in effective feedback and debriefing in various manners. Offerings can range from formal multiday courses [81] to online modules [82]. Another more innovative example is the development of so-called Debriefing Olympics [83]. In surgical education, faculty time is limited, and their availability is constrained by clinical responsibilities. Thus, they typically do not have time to be gone for extended periods of time. A potential solution to this problem which has had some success has been the development of workshops dedicated to teaching debriefing techniques and concepts at national surgical educator meetings [40, 84].

Each of the above faculty development formats has its advantages and disadvantages in terms of time requirement, cost, availability of expert faculty, and effectiveness. What, then, is the best way to go about developing faculty in feedback and debriefing? In a review of the current status of faculty development in debriefing for SBT, Cheng et al. [79] delineated five key components of an ideal program in training faculty in effective debriefing: (1) a course to teach various methods of debriefing together with opportunity for deliberate practice, feedback, and actual debriefing; (2) summative assessment of debriefing performance using established debriefing assessment tools; (3) formative assessment of debriefing performance with expert feedback; (4) peer feedback of debriefing performance; and (5) opportunity for self-assessment of debriefing performance with structured group feedback. Following one or more of these five suggestions when developing a curriculum in debriefing would surely enhance its effectiveness.

Conclusion

Feedback and debriefing are recognized as essential components for successful surgical educational outcomes. Although often used as synonyms, feedback and debriefing are better understood as points on the continuum of providing useful information to learners in order for them to achieve learning objects and goals. Feedback is most commonly used in everyday teaching and consists of specific, data-measured information related to a particular goal or objective that is timely, actionable, clear, and manageable. Debriefing involves a bidirectional reflective learning process that is part of the Kolb's experiential learning cycle. Its structure consists of an introduction, the debriefing itself, and a closure. Its process has typically been described as a three-phase model in which the learner first reacts emotionally to the learning experience, proceeds through understanding the meaning of the experience, and finishes by devising a strategy by which to improve performance in the future. Effective debriefings are characterized by eight key elements: approach, establishment of a learning environment, engagement of learners, reaction, reflection, analysis, diagnosis, and application. These elements can be grouped into three debriefer duties: making it safe, making it stick, and making it last. In surgical education, the SHARP tool and the Lapco TT teaching format can be used for giving directed feedback as well as debriefings. In SBT, many debriefing formats are available as well as conversational approaches and debriefing adjuncts. The best format to choose often depends on the nature and context of the SBT experience, and melding them often can enhance learning. Faculty development in giving effective feedback and debriefing is needed to give more surgical educators the KSAs necessary to optimize learning in today's challenging healthcare environment.

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The Science and Training of Expert Operating Room Teams

Aimee Gardner and Louise Hull

Introduction

It is critical that surgeons not only possess the relevant technical ability and knowledge required to perform a case in the operating room but also that they are able to demonstrate appropriate leadership, communication, and other team-related skills. Although previously it was thought that these nontechnical skills developed and refined naturally over time, this is no longer considered the case. Simulation has been offered as an approach to catalyze their development and refinement. Accordingly, the use of simulation-based team training (SBTT) has received increased interest among surgical educators and leaders.

This chapter provides a comprehensive overview of aspects related to SBTT for operating room (OR) teams. First we provide a foundation for understanding OR team training by providing a succinct summary of the conceptual underpinnings related to team training. We then discuss methodical issues related to team training strategies and measurement, followed by research on its effectiveness. Finally, we conclude the chapter with a discussion of implementation issues and areas for future research.

Conceptual Underpinnings

There are a number of theoretical underpinnings to support the use of SBTT for healthcare and OR teams. Although training surgical teams together in a simulated setting can have a number of goals (e.g., identify latent safety threats [1], test readiness of new workspace [2], enhance familiarity with a checklist [3], measuring speaking up behaviors [4], etc.), one of the primary aims is to enhance team-based competencies among teams. In other words, the goal is to improve, polish, and perfect teamwork. Teamwork is the means by which individual task expertise is translated, magnified, and synergistically combined to yield superior performance outcomes [5]. According to team scientists, there is a "big five" of teamwork – five characteristics that delineate high-performing teams from lower-performing teams [6]. These include (1) *team leadership*, having a clearly designated leader to help direct action, delegate responsibilities, problem solve, and manage resources; (2) *adaptability*, the team's ability to change behaviors and processes in response to dynamic cues from the environment; (3) *mutual performance monitoring*, the ability to keep track of each other's performance to ensure adherence to ideal practice; (4) *backup behavior*, providing support to other team members when task overload or assistance is needed; and (5) *team orientation*, coordinating activities toward overall team goals and progress. When each of these are learned and honed by team members, teams should have enhanced performance outcomes.

These five core components of teamwork are made possible by the specific attitudinal, behavioral, and cognitive processes of teams. As noted by others [7–8], expert teams are systematically different in the way they think, feel, and act. Expert surgical teams have shared knowledge structures (i.e., *team mental models*) [9–10], know where knowledge exists among the team (i.e., *transactive memory systems*) [11–14], and are able to scan their environments to anticipate environmental activities (i.e., *situation awareness*) [15–17]. Furthermore, highly effective team members feel differently toward one another. Specifically, they have a shared perception that other team members will perform their job (*mutual trust*) [18] and also believe that each other is capable of performing their tasks (*collective efficacy*) [19–21]. Finally, they engage in behavioral activities that lead to the big five

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noted above. They integrate their collective set of interdependent tasks (*coordination*) [22] and also actively and promptly speak out to one another to clarify goals, provide updates on progress, and voice concerns (*communication*) [23]. Training programs intended to enhance teamwork among OR teams should make concerted effort to ensure that the simulated environment allows for each of these aspects to be triggered, measured, and explored and discussed in the debriefing process.

Methodologies

After simulation has been chosen as the method for enhancing team development and effectiveness, there are a number of issues related to operationalizing the team training that must be considered. Like any educational endeavor, the training should be based upon a thorough needs assessment [24]. There are a number of team-based curricula that exist relevant to OR teams. For example, Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS™) is a systematic approach originally developed by the Department of Defense and the Agency for Healthcare Research and Quality (AHRQ) designed to introduce tools and strategies to improve team performance in healthcare. Research has shown that the TeamSTEPPS training program results in enhanced teamwork behaviors for OR teams [25]. Additionally, the American College of Surgeons (ACS) and the Association of Program Directors in Surgery (APDS) have developed a national skills curriculum for fostering team-based skills in the OR [26].

Other more granular issues exist for implementing team training as well. One of these involves team composition. For example, the use of true interprofessional teams (individuals from two or more professionals), including only one individual (e.g., a surgery resident) working with a confederate team, who are intended to represent other specialties and combining members from the same specialty to work together are all examples of team training. However, for true interprofessional education to occur, that in which learners from two or more professions learn about, from, and with each other to enable effective collaboration and enhance the quality of care, simulation should involve diverse members of the OR team [27].

Finally, the location for a simulation training program is an important factor in the delivery process. Simulation can occur in a controlled environment, such as a mock or virtual operating room. In these environments, SBTT may be easier and more efficient to implement, as learners are physically removed from patient areas and may be more focused on educational goals in the private and psychologically safe setting. Additionally, simulation educators are able to remove/add real or fake/faulty equipment to the operating room in order to manipulate the environment and stimulate desired behaviors. Similarly, mock OR environments can be optimally designed for the use of technology for video recording and other data performance capture systems that may be more difficult to put in place in other settings.

In situ simulation, on the other hand, occurs in the actual environment where patient care happens. This approach has a number of advantages over center-based simulation, including the opportunity to learn about the actual operating environment, increased realism of the physical environment, enhanced ability to get busy OR personnel to the simulation activities, and the use of less costly equipment and space [28]. However, as noted by Raemer [29], in situ simulation has a number of disadvantages and complexities as well. For example, participants may be easily distracted by clinical duties when in close proximity to the clinical environment. Additionally, the environment may lack necessary privacy that may impact performance, simulation quality, and confidentiality during debriefings. The physical setting may offer a number of limitations, such as the ability to insert certain features designed to increase realism (e.g., screaming, smoke generator, etc.) and elaborate setting up and taking down of scenario-specific structures and the wear and tear of using real equipment.

In sum, surgeon educators face a number of logistical and operational concerns when designing and implementing SBTT programs for OR personnel. Regardless of strategy chosen, educators should stay attuned to best practices in training program development, which include conducting a needs assessment, developing learning objectives, selecting and designing the training program, implementing the training, evaluating the effect of the training program, and providing feedback to the trainees, where junior or senior, and system [30].

Measurement Issues

Lack of Standardization

Over the past 15 years, a number of behavioral marker systems have been developed to capture the nontechnical and teamwork skills that contribute to safety and efficiency in the OR. Tools now exist to evaluate the nontechnical skills of individual OR team members including Nontechnical Skills for Surgeons (NOTSS) [31], Scrub Practitioners' Lists of Intraoperative Nontechnical Skills (SPLINTS) [32], and Anesthetists Nontechnical Skills (ANTS) [33], as well as the OR team as a whole (e.g., Observational Teamwork Assessment for Surgery (OTAS)) tool [34]. Despite their focus, there is large overlap in the skills captured (e.g., leadership, situational awareness, and communication). Many of these tools have been tested and have been found to be acceptable and feasible for use in the OR and simulation-based environments. A recently published systematic review identified seven behavioral marker systems for use in surgery [35]; the fact that several assessment tool exist has resulted in no single assessment tool being consistently selected and used to evaluate the quality of OR teamwork. This has led to a lack of standardization, an issue that has been raised repeatedly but remains unresolved to date [36–37]. Lack of standardization makes it difficult at best to compare the effectiveness of different SBTT programs. Unfortunately, until this issue is resolved, our ability to identify the most effective training method(s) will be hampered.

Selecting a Teamwork Assessment Tool

With a number of tools available, surgical educators and simulation instructors are faced with the dilemma of deciding which tool to utilize. What is the "best" and most appropriate assessment tool to use in SBTT? While there is no straightforward answer, a number of factors should be considered to guide selection and implementation, such as the psychometric properties of the tool, measuring individuals versus teams, rater training, and acknowledgment of teamwork versus team effectiveness.

Psychometric Properties

It is critical to carefully scrutinize the psychometric quality of the tool when selecting an assessment tool to evaluate OR teamwork. Assessment tools should yield valid results (measure what they purport to measure) and be reliable (consistent measure). (For a comprehensive overview of the reliability and validity evidence for OR teamwork assessment tools, see Dietz et al. [35].) While it may appear obvious to select a preexisting teamwork assessment tool that has been subjected to reliability and validity testing, there is evidence in the surgical literature of developing and utilizing tools from "scratch" with little evidence of validity or reliability [38].

Individual- Versus Team-Level Evaluation

Another question centers on the unit of measurement. For example, should we be evaluating the individual contribution of OR team members to teamwork or should we be evaluating the overall teamwork performance of OR teams? The simple answer is both; it is important to be able to discriminate between individual-level and team-level teamwork performance. While team-level teamwork performance evaluation provides teams with a "snapshot" of overall teamwork performance, such assessments are not overly useful in identifying individual performance areas that should be targeted for improvement and should be the focus of feedback. Furthermore, due to the complexities and dynamic nature of teamwork, individual team member is unlikely to contribute equally to team-level teamwork performance. For these reasons, it is critical that individual contributions to teamwork are captured. This is not to say that individual assessments need to be conducted for all OR team members; rather information, for example, qualitatively, should be gathered to determine the individual contributions of OR team member to team-level teamwork performance.

In addition to the above, the SBTT approach used has implications in relation to the most appropriate assessment tool to select. For example, if confederate-based training program is developed (i.e., not IPE training, as previously described) intuitively, it makes little sense to use a teamwork assessment tool such as OTAS that captures the collective contribution of OR team members; rather in this case, using an assessment tool such as NOTSS and ANTS that captures the individual contribution of OR team members would be better suited.

Rater Training

Another important, but frequently overlooked, issue in assessing the quality of OR teamwork is the fact that assessing teamwork skills is a skill in itself and thus requires training. Regardless of the psychometric robustness of an assessment tool, assessments are likely to vary considerably between raters (i.e., unreliable) without adequate training. For example, one team found that implementing frame of reference training for instructors evaluating intraoperative communication increased interrater reliability from 0.32 to 0.91 [39]. In short, it is critical that simulation instructors are trained to proficiency in evaluating teamwork skills. Evidence-based guidelines on program requirements to training faculty in OR nontechnical and teamwork skill assessment have been developed to guide the development of faculty training programs [40]. These guidelines stipulate seven essential training program content elements including training in the recognition of nontechnical and teamwork skills, practice in rating nontechnical skills, and training in providing feedback/debriefing following a nontechnical skills assessment.

Teamwork vs. Team Effectiveness

While "teamwork" and "team effectiveness" are interrelated, these constructs are conceptually distinct, and this difference must be acknowledged when selecting assessment tools.

Teamwork performance is one aspect of performance that contributes team effectiveness. Triangulation of teamwork, technical skills, and other processes and outcomes related to effective teamwork and team performance provides a more complete picture of how well a team is functioning and the interrelationships between these different aspects of performance.

Finally, Krokos et al. [41] proposed a number of guiding principles for effective measurement of team performance and team performance measurement variables, summarized in Tables 1 and 2, which should be considered in addition to the measurement issues described above.

Effectiveness of Team Training

Evaluating the effectiveness of team training is essential in order to determine whether the desired goals have been achieved. Within healthcare, there have been multiple reviews, some systematic, on the effectiveness of team training. For example, a systematic review exploring the effectiveness of interventions to improve teamwork and communication among healthcare staff concluded that although some studies demonstrated evidence for improved attitudes, better teamwork, improved technical performance, and improved efficiency or reduced errors, overall study quality was poor and evidence for technical or clinical benefit from teamwork training in medicine is weak and better quality research is needed [42].

Table 1 Guiding principles for effective measurement of team performance

Principles	Description
1. Capture the multiple contributors to teamwork effectiveness	Consider both individual and collective contributions Collect data on both moment-to-moment interactions and outcomes Measure observable behaviors, cognitions, and attitudes
2. Measure specific facets of performance	Measure specific processes and outcomes related to effective teamwork or team effectiveness, rather than one overall rating
3. Clearly define performance criteria	Clearly describe performance criteria so raters can be consistent in their assessments
4. Train raters to a common frame of reference to maximize rater reliability	Train raters using frame of reference and behavioral observation training When possible, use automated data collection methods to reduce cognitive load of raters and enhance objectivity of ratings
5. Select measurement format based on performance criteria	Ensure format of rating tool allows for appropriate understanding of team performance (i.e., quality may be better assessed with a numeric scale than a checklist) When possible, several measurement formats (e.g., checklists, rating scales) should be used in conjunction with one another to provide the most comprehensive measurement
6. Consider measurement purpose and practicality	Ensure your measurement strategy allows attainment of overarching goals (e.g., educators will want to collect information that allows for assessment, diagnosis, and remediation of skill deficiency) Consider the burden placed on participants, raters, and the organization

Adapted from Krokos et al. [41]

Table 2 Summary of team performance measurement variables

Components of team performance	Individual procedural taskwork
	Individual nonprocedural taskwork
	Teamwork
	Team leadership
	Mutual performance monitoring
	Backup behaviors
	Adaptability
	Team orientation
Performance targets (what to measure)	Individual or team processes
	Individual or team outcomes
Measurement instrument formats	Checklist
	Frequency scale
	Distance and discrepancy scale
	Rating scale

Adapted from Krokos et al. [41]

Effectiveness of OR Team Training

One of the largest studies exploring the effectiveness of OR team training is that reported by the Veterans Health Administration [43–44]. Based on crew resource management principles, the training involved a mixture of lectures, group work, and video presentations to training surgical teams to work as a team; question one another when safety risks arise; carry out checklist-guided preoperative briefings and postoperative debriefings; and implement other communication strategies (e.g., recognizing red flags, stepping back to reassess a situation). Over a three 3-year period, over 100,000 surgical procedures were sampled, and after controlling for baseline differences in risk-adjusted mortality rates, the hospitals ($n = 74$) that completed the training experienced a significant reduction of 18% in mortality rates ($P = 0.01$) compared to a reduction of 7% ($P = 0.59$) in the hospitals that had not completed the team training program. In addition, after adjusting for surgical risk, a decrease of 15% in morbidity rate for hospitals that had completed the training was observed, compared to a decrease of 10% for hospitals that had not completed the program (decline was 20% steeper in the "trained" group ($P = 0.001$)).

Effectiveness of Simulation-Based OR Team Training

Despite the increasing popularity of OR SBTT, little research has been designed and conducted to enable the "how effective is it?" question to be fully answered. To highlight why this debate continues to exist, we have applied Kirkpatrick's hierarchical model of training evaluation to the findings of a systematic review conducted by Cumin et al. [37], exploring the effectiveness of multidisciplinary OR SBTT (Table 3). It is clear that efforts need to be directed to exploring and determining whether the skills learnt in SBTT transfer to the clinical environment and whether SBTT has an impact at an organizational level (e.g., patient outcomes). This conclusion is in line and similar to that drawn by a critical review of the literature on simulation-based team training in healthcare: "much work is needed to establish a robust and defensible evidence base for SBTT" [45].

Table 3 Kirkpatrick's level in relation to Cumin et al. [37]

Kirkpatrick level	Definition applied to SBTT	Evidence of effectiveness
Level 1: Reaction	The degree to which participants react favorably to simulation-based team training	Participants' reactions to the SBTT training were positive in all studies Evidence that SBTT is perceived to be useful for learning, scenarios perceived as realistic and appropriately challenging
Level 2: Learning	The degree to which participants acquire the team knowledge, skills, and attitudes based on their participation in simulation-based team training	Mixed findings Technical skills improved post-training Conflicting results regarding improvement in teamwork performance No improvement in teamwork climate or safety climate item
Level 3: Behavior	The degree to which participants apply the teamwork skills learnt in the simulated environment to the clinical environment	None of the studies objectively demonstrate that skills acquired from simulation are transferred to the OR Conflicting results as to whether the simulations would result in a change to practice (self-report)
Level 4: Impact	The degree to which simulation-based team training has an impact at an organizational level	None of the studies objectively demonstrated benefits in patient outcomes Policy and equipment changes were made as a result of reflective learning from training

Implementing Simulation-Based Team Training

> "Future work should focus on how best to overcome the barriers to implementation of [simulation-based] team training interventions for full OR teams" [37].

Although OR SBTT is widely regarded as a valuable education and training tool, widespread adoption and implementation remain patchy. Why are we not widely implementing an intervention that is widely accepted and has been found to be a promising intervention in improving teamwork and team performance? This is not a dilemma that is unique to OR SBTT nor is it a dilemma unique to the surgical community; the World Health Organization has described the evidence to translation gap as one of the greatest challenges facing the healthcare community. It is has become apparent that greater attention needs to be paid to identifying and understanding how best to overcoming the barriers to implementation.

Barriers to Implementing SBTT

A number of barriers have been identified that hinder the implementation of SBT and SBTT. How best to overcome these barriers is critical to increasing adoption and ensuring the sustainability of OR SBTT. A recently published survey study exploring the implementation of the American College of Surgeons/Association of Program Directors in Surgery simulation-based national skills curriculum, that includes team skills training, found a number of obstacles to implementation [46]. Identified barriers included costs, limited personnel, lack of faculty incentives, resident work-hour restrictions, lack of faculty protected time, lack of trained faculty, lack of administrative buy-in, lack of resident protected time, complexity of curriculum, and limited resident motivation and lack of space. In addition, Cumin et al. [37] identified the following barriers to implementing simulation-based multidisciplinary team training in the OR: problems recruiting participant (especially senior OR staff), lack of fidelity of surgical models, and financial costs involved. In addition to pinpointing the barriers to implementation, it is equally important to identify the factors that facilitate SBTT, to leverage implementation. Cumin et al. [37] identified the following factors affecting implementation success: prescenario familiarization to appreciate limitations of the models and environment, clarification of the training objectives, allowing adequate time for participants to learn, ensuring the environment was psychologically safe, and allowing nurses and physicians to feel a sense of equality.

Many of the aforementioned barriers may not be overly surprising to those that have attempted to implement simulation-based team training. However, these studies reveal two important findings. First, it is clear that there is unlikely to be a “quick fix” to overcoming barriers to implementation and a multifaceted approach is required (i.e., the provision of incentives for simulation faculty, in isolation, is unlikely to increase adoption). Second, barriers to simulation-based team training differ between settings, and as such the strategies to overcome barriers will need to be tailored (i.e., it would be futile to provide incentives for faculty if this has not been found to be a barrier to SBTT in a particular setting). How should those wishing to increase SBTT select appropriate implementation strategies? Although there is no magic answer, guidance can be provided from the rapidly expanding and emerging field of implementation science. Implementation success has been conceptualized as a function of the effectiveness of the intervention being implemented (in this case SBTT) and implementation factors (i.e., the factors that either hinder or facilitate implementation) [47].

Deliberating this conceptualization of implementation success, it is clear that efforts to date have focused on exploring the effectiveness of simulation-based team training, and not nearly as much attention has been directed toward the factors that influence implementation and implementation success. The importance of identifying strategies to optimize implementation has recently been highlighted: a review of the surgical simulation literature concluded “to enable the more widespread incorporation of best practices and existing simulation curricula in surgery, effective implementation strategies need to be developed” [48].

What Are Implementation Strategies?

Implementation strategies are methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice [47]. More than 70 discrete implementation strategies have been identified and documented in the implementation literature; these have been categorized into nine groups: use evaluative and iterative strategies (e.g., audit and provide feedback), provide interactive assistance (e.g., provide local technical assistance), adapt and tailor to context (e.g., promote adaptability), develop stakeholder interrelationships (e.g., identify and prepare champions), train and educate stakeholders (e.g., distribute educational materials), support clinicians (e.g., revise professional roles), engage consumers (e.g., increase demand), utilize financial strategies (e.g., alter incentive/allowance structures), and change infrastructure (e.g., change accreditation or membership requirements) [49].

With more than 70 implementation strategies to select, those involved in the delivery of SBTT have a wide range of strategies to enhance the adoption, implementation, and sustainability of simulation-based OR team training. Although it is unclear exactly what strategies are most appropriate to increase uptake of SBTT, it is clear that the selection and tailoring of implementation strategies should match the barriers to implementation. Powell et al. proposed four methods, including concept mapping, conjoint analysis, group model building, and intervention mapping to match implementation strategies to factors likely to affect implementation success [50].

Future Work

Despite the plethora of work that has already been done to investigate the impact of OR team training, there are a number of areas that warrant further exploration. Traditionally, work within surgical team training has taken a prescriptive approach, focused on developing practical knowledge on how individual efforts can be directed toward the collective goals. However, the complex interplay and function of teams leave a number of questions for those interested in studying and using simulation training to enhance OR team functioning. Below is an overview of a few areas in which future work can continue to expand the way we consider and develop surgical teams.

Team Composition

One challenge facing the day-to-day performance of OR teams is the heterogeneity of team members. OR teams are often composed of members who are constantly changing, possess unique training, and have multiple functionalities. As such, the complexity of creating coherence within OR teams is far greater than teams that are composed of individuals with similar backgrounds and who work together on a consistent basis. Dynamic teams pose a particular challenge for simulation educators. For example, if each operative episode contains a new team, is it enough that individuals are trained with representative members of other specialties to develop and enhance critical teamwork processes, or must all possible combinations of teams be trained together? Do the competencies learned transfer to new team dynamics, or must they be built up and polished again if one or more team member departs and/or is replaced? Additionally, the role of personal team member characteristics needs to be considered. Operating room teams are made up of individuals, and as such, individual idiosyncrasies impact the team. Factors such as background, specialty, previous experience, personality, and attitudes impact team processes and performance. Thus, future work should continue to consider how individual characteristics impact team training endeavors.

Team Size

When delivering simulation-based training for OR teams, the number of individuals comprising a team needs to be considered. Of course, as team size increases, there are a greater number of coordination challenges. Teams that are too small, however, may not have the cognitive and/or behavioral resources necessary to complete a task effectively. Thus, it is likely that there is an ideal range of team members needed to adequately perform OR team training. Future work should consider the size of OR teams and how it may serve as a critical contingency for critical coordinating mechanisms.

Teams and Time

The role of time in training OR teams plays a critical, but often overlooked, role in simulation research and practice. Teams are thought to go through four developmental stages: forming, norming, storming, and performing [51]. As such, the effectiveness of team training, and teams in general, relies on processes that develop over time and operate on different time scales. Simulation methodologies and evaluation must consider how team attitudes, behaviors, and cognitions change, not only as a result of a one-time simulation interventions, but also as a thoughtful consideration of how teams move from initial formation to desired outcomes. Focusing on when behaviors arise as well as how quickly they occur and in what cycles would help us understand the role that time plays in simulation-based team training. According to Mohammed et al. [52], incorporating temporal considerations into the team training process can be done in a number of ways. First, it could entail measuring constructs or variables of interest at multiple points of time. For example, educators may want to examine the impact of a new simulation-based new trauma team curriculum on trauma team performance throughout the year. A longitudinal approach may follow those teams into the clinical arena and measure their effectiveness during a code at three different points of time to better understand how desired competencies develop and/or diminish over time. Additionally, simulation team training may be further understood by examining time-oriented variables, such as how much time groups decide to dedicate to certain tasks, when teams decide to coordinate action, and how teams respond to time urgency situations. Adopting a temporal perspective in this way will likely enrich our understanding of other concepts often studied within OR teams, like team mental models, psychological safety, speaking up, coordination, and team leadership. A third way to incorporate time into consideration of simulation team training is a combination of the first two areas and requires consideration of both temporal variables and longitudinal aspects. Topics such as team member socialization, team learning, and group familiarity are topics critical to better and more accurately understanding the impact of team training endeavors. Finally, time can be considered as a part of the general context in simulation-based training for OR teams. Factors such as time pressure, perceptions of decreasing time to complete tasks, and external deadlines are all realistic aspects of OR team functioning and should be included in simulation design, evaluation, and transfer studies.

Adaptive Teams

Team adaptation is described as the “process by which team members use the available resources to functionally change current cognitive or behavioral goal-directed action or structures to meet expected or unexpected demands” (Burke et al. [53] p. 1192). As OR teams must be ready to face any unexpected turbulence during a case, it is critical that simulation training endeavors equip team members with adaptive capabilities. Teams that are unable to adapt not only face potential decline or dissolution but are likely to put patient safety at risk. Thus, simulation training for OR teams must encourage the development of coordinate, adaptive, and cohesive behavior during moments of uncertainty. For example, simulation activities may encourage team leaders to constantly scan the environment, obtain information and resources, anticipate potential threats, explore alternative means to accomplish tasks, and identify ways to respond to new challenges. Future work should explore methods by which training programs can equip OR teams with the necessary skills to identify and adapt to changing circumstances and to examine their effectiveness.

In sum, there are a number of areas for future work to fully understand OR team training. One way for surgical educators to do this is by building bridges across disciplines. Studying teams is a social science and as such lends itself to cross-disciplinary research. Collaborations with those outside of surgery can be valuable for surgical educators to help stimulate development of new ideas, offer opportunities for methodological triangulation, help us from “reinventing the wheel,” and make apparent how a theory, construct, or phenomenon can change across settings. Scientists from numerous industries and disciplines study group phenomenon, such as power, cohesion, cooperation, decision making, team composition, and psychological safety. As surgical education scientists, it would be beneficial to soften the boundaries that exist between different industries, gain access to research from other disciplines and specialties, and understand how that work may align/diverge from our own.

Conclusion

Now more than ever, it is clear that the effectiveness of a surgeon is dependent upon not only his or her technical skills but also on the nontechnical and teamwork skills that allow for efficient and effective interactions in the operating room. This chapter has highlighted a number of issues that educators implementing simulation training to improve the quality of operating room teams must consider. By relying on the theoretical and practical concepts discussed here, surgeon educators can continue to adopt and implement strategies that will be most effective in achieving these aims.

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Human Factors Psychology in Surgery

Brittany L. Anderson-Montoya and Mark W. Scerbo

Introduction

Human factors is a discipline concerned with designing devices, equipment, and systems based on an understanding of human capacities and limitations. Human factors specialists focus on improving the work environment to increase productivity, efficiency, safety, human-system reliability, comfort, and job satisfaction. Human factors addresses both physical and psychological concerns. On the physical side, human factors includes ergonomics which focuses on human physical and biomechanical capabilities. Information about human anatomy, anthropometry, physiology, and movement science is applied to the design of equipment, controls, and workspace layouts. Although ergonomics is an important area of human factors, this chapter focuses on the psychological side.

Human factors sits at the intersection of psychology and engineering. Information about human cognition, motivation, physiology, personality, sensory perception, and social interaction are applied within areas of engineering including computer hardware, software, systems, modeling, and simulation. From this hybrid of psychology and engineering, several topics have emerged that are of primary interest to human factors psychologists including cognitive engineering, error prevention, complex system and process control, safety, situation awareness, and workload.

Human factors psychologists are often interested in improving human performance. In general, there are four ways to improve human performance on the job: (1) select the best workers for the job, (2) motivate the workers to perform better, (3) train people to do the job better, or (4) modify the tasks to make it easier for people to perform the job. Although human factors psychologists work with all four of these methods, they are primarily focused on the last two. They are heavily involved with developing and evaluating training programs and systems or designing the work environment, tools, and equipment either by extending human capabilities or removing impediments. The other two methods fall more within the area of industrial and organizational (I/O) psychology which emphasizes selection, appraisal, motivation, and training. Human factors and I/O psychology also differ in their unit of study. Human factors psychologists typically focus on individual performance, while I/O psychologists focus more on organizations. However, both types of psychologists study performance at the team level.

Lastly, human factors is a very broad and diverse discipline including specialists who work with automated systems, command and control systems, communications, computers, consumer products, displays and controls, internet systems, military systems, simulation, transportation (aerospace, surface, subsurface, unmanned vehicles), tools/equipment, training systems, virtual environments, and warning systems. There are a growing number of specialists who work in healthcare and design and evaluate alarm and warning systems, electronic health record systems, medical devices, robotic systems, and simulator-based training systems [1].

Historical Perspective

The origins of human factors are often traced to Frank and Lillian Gilbreth, who were pioneers in "management science." The Gilbreths studied work processes and showed how to increase efficiency by redesigning the tasks workers performed. For example, they showed how to increase the efficiency of brick layers by eliminating unnecessary motions [2]. They also studied surgery and determined it would be more efficient for the instruments to be organized and for a "caddy" to bring the instruments to the surgeon instead of the

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surgeon repeatedly interrupting the procedure to select his own instruments [3]. Although it took some time for these recommendations to be adopted, these modifications to the surgical process are still used today with the role fulfilled by the scrub technician or a nurse.

Although the Gilbreths were quite successful in their efforts to increase worker productivity, the discipline of human factors did not emerge until after World War II when it became clear that selecting and training the best individuals could not overcome the safety challenges faced by military personnel when operating their equipment. In Great Britain, Norman Mackworth [4] conducted an experiment using a simulated radar display to determine why well-trained and highly motivated radar operators often missed critical signals on their screens. He discovered operators failed to detect more and more signals over the course of a 2-hour session. This decline in monitoring performance is called the *vigilance decrement* and is one of the most replicated findings in human factors research and real-world work environments plagued by poorly designed displays [5].

In the United States, Alphonse Chapanis, a researcher at the Aeromedical Laboratory and one of the founders of modern human factors, was asked to investigate a series of crashes involving the B-17 airplane. Chapanis suggested that the shape of the flaps and landing gear controls be made unique so that they could be distinguished by touch. This simple modification has all but eliminated B-17 crashes involving these two controls. Later, Safren and Chapanis [6] provided one of the first human factors analyses in healthcare. They studied incident reports of medication errors in a hospital and identified seven types of errors, immediate causes of those errors, and offered four recommendations for reducing errors by standardizing pharmacological terminology, adding safety checks to the medication procedures, redesigning the work space for nurses, and providing targeted training.

Human Factors and Surgery

There are many areas where human factors can improve surgery, and simulation offers an ideal environment for applying human factors concepts to surgical training and assessment. The three major areas are shown in Fig. 1. Human factors researchers have contributed to the design and evaluation of surgical instruments, equipment, the layout of operating rooms, training systems, and virtual reality systems [1, 7, 8]. In addition to how surgeons interact with their instruments and equipment, many human factors researchers are concerned with improving surgical performance. This includes understanding and managing errors, the antecedents to error (e.g., workload, stress, and fatigue), and minimizing error through training and better-designed systems that reflect cognitive skills [9–11]. Lastly, surgeons do not work in isolation. Thus, human factors concerns regarding equipment and individual performance must be understood within the context of the surgical team because working in teams moderates individual performance [12]. Behaviors that may be optimal for an individual may be detrimental to a team. Further, teams introduce their own unique concerns such as communication, coordination, cooperation, and leadership and may require team-level coaching and management. Discussion of all of these areas is beyond the scope of this chapter; thus, we will concentrate on several topics that affect performance at an individual level (in bold-faced type) because they are foundational to understanding performance with equipment or within teams.

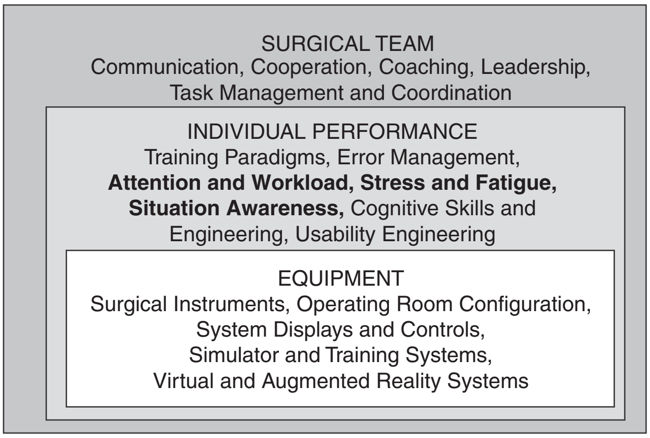

Fig. 1 Application areas for human factors in surgery

Attention and Mental Workload

Few would argue that performing surgery is a critical activity that requires the surgeon to focus attention on the task at hand. However, each case differs due to variations in patient characteristics, individual ORs, surgical teams, and the surgeon’s state of mind. Combinations of these factors can make a case more or less challenging and can fluctuate within a case, increasing or decreasing task difficulty as the surgery progresses. Most surgeons can adapt to changes in task difficulty bringing additional attention to the task as needed. However, even the best surgeons can find themselves in a situation where the task demands exceed the ability to attend effectively, creating the opportunity for error.

The relationship between attention and task demands has been studied extensively in the human factors domain and is referred to as *mental workload* [13]. In general, as the difficulty of a task increases, it demands more attention, and individuals must allocate more attentional “resources” to meet the increased demand [14]. However, the ability to meet the increased demand is limited by the amount of attentional resources available at any given time and the difficulty of the task. For tasks where enough attentional resources are available to meet the demand, the mental workload is low. On the other hand, mental workload is considered high when a task demands all available attentional resources (or more resources than can be allocated).

Two qualitatively different types of tasks have been described that have different implications for attention [15]. Many simple tasks for which mental workload is low can be described as *data limited*. For these tasks, when performance reaches its peak, investing any additional attentional resources in the task will have no effect on performance. For example, adding two digits together cannot be performed better by focusing more attention on the task. By contrast, difficult tasks are said to be *resource limited*. Performance on these tasks improves as more attention is devoted to the task. For resource-limited tasks, increasing task difficulty is accompanied by increased mental workload. However, a task that requires all of an individual's attentional resources may result in optimal, but not necessarily perfect performance. For example, novices who are first learning intracorporeal knot tying may focus all of their attention on the task, but not be able to perform according to expected criteria. Tasks that have high mental workload may demand more attentional resources that are available. Performance on these tasks is erratic and is suboptimal.

Another characteristic of tasks with high mental workload is that it is difficult to focus attention on anything other than the task at hand. Wickens [16, 17] reviewed the research on tasks that could or could not be performed together well and argued that attentional resources could be divided along different dimensions, each comprised of its own limited resources. According to his multiple resource theory (MRT) of attention, there are three orthogonal dimensions of attention (see Fig. 2). The first dimension is characterized by the stage of information processing in which attentional resources are distinguished by the perceptual/cognitive processes used for organizing information and response processes used for executing actions. The second dimension is differentiated by the processing code used for either spatial distance/location judgments or verbal/language activities. The third dimension addresses processing modality and is separated into auditory and visual resources. Further, the visual resources are separated into focal and ambient processes. Focal visual processing is driven by the foveal/parvocellular system and handles acuity and pattern recognition. Ambient visual processing is driven by the peripheral/magnocellular system and is largely responsible for motion detection. Based on this model, individuals can perform two tasks simultaneously without much difficulty if they require attentional resources from distinct dimensions or codes. On the other hand, it is much more difficult to perform two tasks that demand attentional resources from the same combination of dimensions/codes. Thus, a surgeon can more easily perform a visually intensive task like laparoscopic surgery (visual/spatial task) while holding a conversation (auditory/verbal task) than simultaneously searching for anatomical anomalies (visual/spatial task).

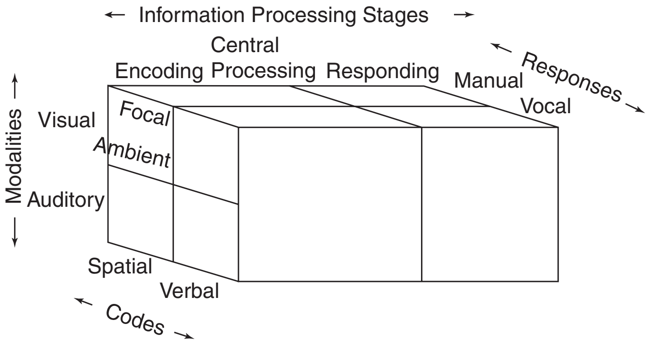

Fig. 2 Three dimensions of multiple resources of attention with the visual subdivision. (Adapted from Wickens 2002)

Workload Assessment Methodology There are a variety of methods that can be used to measure workload, and each should be selected based on several criteria [18]. The first criterion is sensitivity and refers to the ability of a measure to distinguish between variations in workload imposed by tasks, that is, resource-limited tasks. The second characteristic is diagnosticity or the degree to which a measure reflects the demands imposed on a particular resource. Some measures are more sensitive to specific types of resources (e.g., visual-spatial processing versus auditory processing). Thus, if a task places high demands on a particular resource or set of resources, the measure should be sensitive to these dimensions alone. The third dimension concerns intrusiveness, which refers to how the measure interferes with the primary task of interest. Although each of these criteria is important, the level of each should be determined by the domain or task under investigation. For instance, laparoscopic surgery places heavy demands on visual and spatial resources and the psychomotor response modality [19, 20]. Thus, an ideal workload measure for laparoscopy would be the one with a high sensitivity and diagnosticity in the visual, spatial, and motor dimensions. Additionally, it should have a low level of intrusion so as not to interfere with the primary surgical task.

Methods for measuring mental workload fall into three categories: subjective, physiological, and performance. Each has its advantages and disadvantages attributable to sensitivity, diagnosticity, and intrusiveness. Further, not all methods are feasible during live surgery; thus, simulation offers a viable, safe alternative to measure mental workload associated with surgical tasks.

Subjective Measures Individuals can be asked to provide ratings of their subjective impressions of mental workload typically through a survey or rating scales [18]. Subjective reports can be used to identify the specific resources contributing to mental workload, reveal workload differences between individuals who may have comparable performance scores, and corroborate measures of performance. Subjective measures are advantageous because they are inexpensive, efficient, and nonintrusive and can generalize across different tasks. However, the ability of an operator to assess their own level of workload is not completely reliable, and data are typically collected after the fact, leading to potential decay of memory during periods of high workload [21].

Numerous instruments have been developed to assess subjective mental workload [22]. One of the most widely used instruments is the National Aeronautics and Space Administration-Task Load Index [23] (NASA-TLX). The NASA-TLX provides an overall index of mental workload as well as the relative contributions of six workload subscales: mental, physical, and temporal task demands and effort, frustration, and perceived performance. The psychometric characteristics of the NASA-TLX are well documented [24].

The NASA-TLX has been shown to be sensitive to mental workload differences in laparoscopic surgery [25]. Yurko, Scerbo, Prabhu, Acker, and Stefanidis [26] reported the results of several simulation-based studies using the NASA-TLX to examine workload in a complex laparoscopic task (intracorporeal suturing and knot tying). Their participants were novices who trained on the *Fundamentals of Laparoscopic Surgery* (FLS) curriculum and were tested on a porcine model. Subjective mental workload was measured at baseline, during training, and after performance proficiency levels had been reached. Their results showed NASA-TLX scores declined with increasing suturing proficiency during the training interval. More importantly, the workload scores increased with increasing task difficulty (during transfer from the simulator to the operating room) and were also positively related to the errors in the OR procedures.

Physiological Measures Physiological indices provide an alternative measure of workload reflecting an individual's autonomic activity in response to changes in task demands. There are far more measures that can be discussed here, but several of the more reliable indices include pupillary activity, cardiac functioning, and brain activity as measured by electroencephalogram (EEG) and event-related potential [18] (ERP).

There is evidence that pupil diameter reflects changes in workload [27]. Specifically, there is a positive correlation between increases in pupil diameter and mental demand. Recently, researchers have examined whether pupil diameter can provide an effective index of mental workload for surgical tasks. For example, Zheng, Jiang, and Atkins [28] measured surgeons' pupil response across several simulated surgical tasks that differed in difficulty. They found that when task difficulty increased, pupil size increased along with task completion times.

Cardiac activity is frequently used as a workload measure. Although heart rate is fairly easy to acquire, it is not a very reliable index of mental workload. On the other hand, heart rate variability has been shown to be a more sensitive index of mental workload. Specifically, heart rate variability decreases with increases in mental workload [29], and some frequencies appear to be particularly sensitive [30] (e.g., 0.1 Hz) to changes in task demand.

Measuring an individual's EEG with electrodes attached to the scalp has also been used to assess mental workload. The EEG signal is typically categorized into four fundamental bandwidths based on frequency: delta, 0.5–3 Hz; theta, 4–7 Hz; alpha, 8–12 Hz; and beta, 13–30 Hz. However, these bandwidths can also be examined in more narrow ranges. For instance, some studies have shown a decrease in the alpha bandwidth with higher task difficulty [31]. Other researchers have found that ratios of the EEG power in bandwidths provide a reasonable index of task engagement. For example, an engagement index based on the ratio of beta/alpha + theta was shown to distinguish between high and low levels of workload [32].

Another brain-based measure is the ERP which is derived from averaging EEG records which are time locked to a stimulus presentation. The resulting waveform is a sequence of separate components, which reflect neuronal activity tied to sensory and cognitive processing. The components are characterized by their polarity and order of occurrence latency in milliseconds from the onset of the stimulus event [33] (e.g., P1, positive 100 ms, N2, negative 200 ms, P3, positive 300 ms, etc.). Studies have shown that ERP components can vary as a function of an individual's attention, expectancies, and decisions together with changes in task parameters [34]. Most importantly, research shows that the ERP can be a reliable and diagnostic measure of mental workload [33]. More specifically, the P3 component is attenuated with increases in primary task demand [35–37].

Collectively, physiological techniques are minimally intrusive to the primary task. Investment in equipment, however, can be costly. Also, most systems require users to be physically connected/wired to the recording devices which can limit their use in genuine working environments, making simulation an ideal environment to apply these techniques. Lastly, these measures do vary in their reliability; therefore, they are often used as complementary indices in concert with other measures of mental workload [18].

Performance-Based Measures The last method for assessing workload includes performance-based measures which fall into two categories. The first are primary task measures which reflect an individual's performance on the task of interest. Two fundamental metrics of primary-task performance are speed and accuracy. In general, performance is expected to decline as task demands exceed the available resources necessary for unimpaired performance [18]. However, if the primary task is too easy (e.g., data limited), the operator may have ample resources to perform the primary task, and it will not be sensitive to changes in workload. By contrast, if an individual is overloaded by the task demands, it will result in poor performance. Although there may be some sensitivity issues with primary measures of task performance, they provide the foundation for other corroborating measures.

The other category of performance-based measures is the secondary task. An individual can be asked to perform a secondary task simultaneously with the primary task. Typically, the operator is asked to focus attention on the primary task and perform the secondary task only if they have the spare attentional resources to do so [18]. Thus, the secondary task method provides a measure of reserve attentional capacity not used on the primary task. The residual resources are available to be allocated to other activities, enabling the operator to multitask.

As noted above, Wickens' [16, 17] theory of multiple resources makes clear predictions regarding how combinations of different tasks will affect overall performance. Specifically, two tasks that use different attentional resources can be time-shared reasonably well. By contrast, when two tasks draw upon the same combination of resources, performance on one or both tasks will suffer.

The choice of a good secondary task depends primarily on two key characteristics. A secondary task must be sensitive to the primary task, meaning it must reflect the resource demands of the primary task [18]. Further, a secondary task should be resource limited; that is, it should require attentional resources to be performed well. In addition, a secondary task should be diagnostic and compete for the same resources used by the primary task. A secondary task that draws from a different pool of resources than those used by the primary task can be time-shared more effectively and therefore will be less sensitive to the demands of the primary task.

Assessing Laparoscopic Skills with a Secondary Task To date, there have been several attempts to use a secondary task to assess the mental workload associated with laparoscopic skills, and much of this research relies heavily on simulation. Hsu, Man, Gizicki, Feldman, and Fried [38] examined differences between novices and experts with the FLS peg transfer task. They asked their participants to perform two-digit addition problems as the secondary task and found that although both groups of participants performed similarly on the peg task, the novices completed fewer math problems. Grant, Carswell, Lio, Seales, and Clarke [39] used a time estimation/production secondary task and found that the variability of the estimated intervals was sensitive to workload differences.

Stefanidis, Scerbo, Korndorffer, and Scott [40] used a secondary task based on Wickens' MRT [16]. They argued that a secondary task requiring visual-spatial resources should compete for the spatial resources needed for laparoscopy. Their secondary task required participants to monitor a nearby display for the brief appearance of squares presented at random on either the left or right side. Participants pressed a foot pedal whenever they detected a sequence of three squares on the same side of the display. They had four groups with different levels of surgical and simulator experience performing a laparoscopic suturing task along with the spatial secondary task and found that the more experienced participants had higher scores on both the suturing and secondary tasks. However, differences between experts and residents with extensive experience on the laparoscopic trainer only emerged on the secondary task.

In a second study, Stefanidis, Scerbo, Sechrist, Mostafavi, and Heniford [41] used the secondary task method to examine skill acquisition. They had novices practice laparoscopic suturing in weekly 1-hour sessions over a period of 4 months. In addition, these individuals performed the suturing task simultaneously with the secondary square detection task for 10 min during each training session. The results showed that suturing skill and secondary-task performance improved for all participants. Most trainees achieved the predetermined proficiency levels of speed and accuracy on the suturing task; however, the results also showed that none of the trainees achieved secondary-task proficiency. Higher secondary task scores were correlated, however, with longer training times suggesting that extended practice resulted in an improved ability to multitask.

Stefanidis, Scerbo, Smith, Acker, and Montero [42] conducted another study using the secondary square task to determine how novice surgeons would perform if given enough practice for their skills to become automatic, that is, so that the task can be performed with few demands on attention. The researchers had a group of trainees practice laparoscopic suturing on an FLS simulator until they achieved expert-level criteria for completion time and accuracy and were tested on a live porcine model. After this test, the trainees continued practicing on the FLS simulator until they reached expert-derived performance levels on the combined suturing and secondary task and were then tested a second time on the porcine model. This group of trainees was compared to a control group that did not practice on the simulator but were assessed in all testing sessions.

The results for the suturing task showed that on average, the trainees needed 54 repetitions on the simulator to reach the suturing proficiency criteria. Also, the combined task condition was challenging – only 41% of the trainees achieved the secondary task criterion while performing the primary suturing task simultaneously. On average, these trainees needed an additional 109 repetitions of the suturing task. Regarding the secondary task, performance levels did not differ from baseline by the time participants met the initial suturing proficiency criterion (nearly 0% correct). However, by the end of the training regimen, the secondary task scores were significantly higher (near 35% correct).

The most important finding, however, came from the test sessions in the OR. The suturing scores of those in the automaticity training group were significantly higher during the first OR test compared to their baseline scores and also significantly higher on the second OR test (after extended training) compared to the first OR test. On the other hand, the performance levels of those in the control group did not change significantly between baseline and the OR tests for any of the recorded parameters. Thus, the extended training coupled with the secondary task resulted in significantly better performance and transfer of skills to the OR condition.

Recently, Scerbo [43, 44] and his colleagues developed a new secondary task designed specifically for laparoscopic procedures. This task requires the same visual-spatial processing resources needed for laparoscopic surgery, that is, monitoring the position of objects in space. Participants are shown brief presentations of a two-dimensional simulated tunnel comprised of white dots (see Fig. 3). Four colored balls appear at the 12, 3, 6, and 9 o'clock positions within the tunnel, at the same simulated distance from the observer. On about half of the presentations, one ball appears to move closer or farther away. Participants respond to the change in ball position using a foot pedal. In addition, the new task is superimposed at 50% transparency directly onto the laparoscopic display resulting in a combined video image of both tasks. This technique improves upon the square task used by Stefanidis et al. [40] because it places the secondary task into the same visual focal region as the primary task and therefore draws upon the same visual resources used by the primary task as required by MRT.

Fig. 3 Spatial secondary task superimposed on the primary suturing task

Scerbo et al. [44] conducted the first of several experiments aimed at evaluating the efficacy of the new spatial secondary task by examining differences in laparoscopic experience. They had novices and experienced surgeons perform the FLS peg transfer task on a laparoscopic simulator along with the secondary task. Their results showed that the novices performed more poorly than the surgeons on the primary peg task and had lower secondary task scores. These results suggest that the primary task was more difficult for the novices leaving fewer attentional resources for the secondary task.

More recently, Scerbo [45] and his colleagues had a group of trainees practice intracorporeal suturing and knot tying until they reached FLS proficiency and were assessed on this task using the ball and tunnel secondary task. They then reassessed performance after a 1- or 5-month interval during which their participants refrained from practicing any FLS laparoscopic tasks. Upon their return, they were assessed immediately on suturing and knot tying with the secondary task. The results showed that skills deteriorated slightly during the interval when trainees could not practice. Suturing performance times increased by 35%, and secondary task scores declined by 30%. The trainees were then given 40 min to practice suturing and knot tying and were reassessed with the secondary task. The investigators showed that the skill deficits were nearly erased after a single refresher session.

Britt et al. [46] used the same spatial secondary task to measure mental workload when transferring suturing skills from a box simulator to more realistic surgical conditions using a fresh cadaver. They found that mental workload increased dramatically when participants transferred from the FLS platform to human tissue under more realistic suturing conditions as indexed by both an increase in suturing times and a decrease in secondary task scores.

Collectively, these studies show that measuring laparoscopic performance with a secondary task can provide a complementary measure of mental workload that corroborates traditional measures of primary-task performance. This method may also offer a better means for determining when simulator training is complete and maximize transfer of skill to the clinical environment. Further, the secondary task used by Scerbo and his colleagues may provide a standard index of mental workload allowing investigators to assess the relative differences among a variety of laparoscopic tasks with a common metric.

Situation Awareness

Mental workload and corresponding available attentional resources can directly impact an individual's situation awareness (SA). Situation awareness is a multidimensional construct that refers to an individual's ability to interpret and understand their current environment [47, 48]. While multiple models and definitions of SA exist (e.g., see definitions offered by Chiappe et al. [49] and Klein et al. [50]), three theoretical models have been identified as the most predominant [51, 52]. Researchers suggest the primary point of contention among the models resides around whether the models define the concept of SA as the process of acquiring SA or as a product acquired through having SA [51–53]. Smith and Hancock [54] proposed a cyclical perceptual-based model consisting of an individual externally directing consciousness to assess a situation, and the resulting knowledge acquired then modifies behavior. Their model contends SA is both a process and a product. Bedny and Meister [55] proposed an alternative model of SA based on activity theory positing that SA cannot be assessed as a single construct but rather must be considered as one dimension of cognitive activity that is intricately connected to other behavioral constructs. Like Smith and Hancock [54], their model also considers SA as a process and a product.

The third model proposed by Endsley [47, 48], which considers SA as a product, is founded on information processing and is the most popular, widely accepted, and researched model to date [51, 56, 57]. Per Endsley's [47, 48] model, situation awareness is comprised of three levels: perception, comprehension, and projection. Perception consists of information gathering through sensory channels. The gathered information is then translated into awareness for one's surrounding environment. Perception can be affected, however, by an individual's level of workload and subsequent amount of spare attentional resources available. Reduced attentional resources can inhibit information gathering which can result in decreased SA. For example, a surgeon who has decreased spare attentional capacity, such as a novice surgeon, will have fewer resources available to perceive incoming stimuli and may miss novel information, thus losing situation awareness. Further, perception of incoming information does not necessarily result in correct interpretation of the stimuli. This is addressed in Level 2, which is comprehension, or the synthesizing of the information gathered during perception into meaningful forms. Accurate comprehension is partly dependent on the individual having an accurate mental model. For example, a surgeon may be confronted with a novel situation and may not correctly comprehend the meaning of the situation, thus resulting in loss of SA. The third level of SA is projection or the ability to predict future states of systems or environments. The surgeon who cannot accurately predict what may occur is again liable to lose SA.

Situation awareness can also transcend from the individual to the team, a component that can be critical during surgery. If a surgeon possesses SA for a scenario but does not communicate with the operative team to ensure shared comprehension, there can be poor outcomes. However, not all information needs to be communicated to all team members. Team situation awareness consists of each team member possessing accurate SA at all levels for their role. Only critical information that needs to be communicated across multiple team members should be conveyed to achieve shared SA. However, achieving and researching shared SA is a complex process [58]. Heretofore, research on SA has been primarily focused on the individual [57], and the remaining discussion will subsequently focus on individual SA.

Situation Awareness Assessment Methodology Measuring SA can be a challenging endeavor, and contention exists regarding which approach and tool are most appropriate [59]. Much of the challenge lies in the disagreement regarding how to define SA and which model best explains it [51, 52]. As such, an appropriate measure of SA is partially contingent upon which theoretical model is adopted. However, as Endsley's three-level information processing model is the most universally accepted, many assessment techniques have been developed in alignment with this model and will be the focus for this discussion. Measures of SA fall into two broad classifications: indirect and direct [60, 61]. Indirect measures are often subjective assessments made either by the participants or by external observers. Direct measures generally consist of probing techniques. Measures can further be divided into several subcategories: freeze-probe techniques, real-time probe techniques, self-rating techniques, observer-rating techniques, performance measures, and process indices/physiological techniques [51, 56, 62]. Like measures of mental workload, each approach has advantages and disadvantages, and it has been suggested a multipronged approach may be the most appropriate method to capture reliable assessments of SA [51, 56].

Freeze-Probe Technique A direct measure of SA, the freeze-probe technique, involves using simulation and pausing the simulated scenario to administer a series of questions related to the individual's current perceptions [51, 52, 62]. The advantage of this approach is that it is an immediate and direct measure of SA and removes the burden from the participant having to rely on memory associated with a post-analysis technique. Criticisms of this approach are that the freezes can interfere with task performance and this technique can only be used during simulated scenarios.

The most popular freeze-probe technique is the Situation-Awareness Global Assessment Technique (SAGAT) developed by Endsley [51, 56, 62, 63]. While SAGAT has primarily been used to assess SA in aviation, it has the potential to be applied to surgical simulation, and this technique lends well to assessing SA in surgery during simulated scenarios. Recently, Gardner, Kosemund, and Martinez [64] examined the feasibility of using SAGAT to assess surgical medical trainees' SA for two postoperative simulated scenarios. They found it was possible to measure a team's SA during simulated scenarios using SAGAT, and the breaks in the scenario were not disruptive to the overall simulation.

Real-Time Probe Techniques Resembling freeze-probe techniques, real-time probe techniques are also used to assess SA during a scenario rather than after [51, 52, 62]. However, real-time probes do not pause a scenario to query participants about SA but rather administer the questions, while the scenario continues to unfold. Subject-matter experts (SME) develop a set of questions to be administered at predetermined time points during a scenario, and the participant's SA is subsequently assessed based upon their answers and their response time replying to the enquiries. The primary advantage to real-time probe techniques is the less-intrusive nature of administering the measure. Further, there is the potential to use real-time probe techniques during actual performance. However, administration of this technique can still be intrusive, and there is the potential for bias in the response if the query directs one's attention to something in the display which previously had not been attended to. Additionally, if the participant is experiencing high workload levels, they may find it difficult to respond, even if they have accurate SA, and if they do respond, it may interfere with their primary-task performance.

The Situation Present Assessment Method [65] (SPAM) was developed as a real-time probe technique and has been used to assess SA for air traffic controllers; however, there has been little application of this type of approach to measuring SA in surgery. While it can be used during actual performance, there remains the concern that administration of SPAM can interfere with primary-task performance [59]. Indeed, Pierce [66] found that novices' task performance on a simulated air-traffic control task was negatively affected when SPAM was administered. Therefore, if used to assess SA during surgery, it may be safer to use real-time probe techniques in conjunction with simulation to avoid possible detrimental effects to patient safety.

Self-Rating Techniques Another approach to assess SA is to directly query participants about their perceived SA through subjective assessment techniques [51, 52, 62]. Self-ratings are typically administered upon scenario completion and represent an indirect measure of SA [60]. Advantages to self-rating techniques include their nonintrusive nature and ease of administration. However, they have many disadvantages. A primary limitation to self-rating techniques suggested by Endsley [62] is that they are more representative of how confident an individual is in their level of SA as opposed to a true assessment measure of their SA. Another limitation is the need for participants to rely on memory. There are also concerns regarding the sensitivity of self-ratings. Finally, Endsley [62] points out that post-assessment of SA may be affected by the outcome of the scenario.

Multiple self-rating techniques for SA have been developed [51, 62]. The Situation Awareness Rating Technique [67] (SART) is a well-used subjective measure of SA [56, 68]. Currently, most self-rating techniques are geared toward aviation and military applications with very little application in surgery. Self-rating techniques could be used in conjunction with other more objective measures of SA to assess if surgeons' perceived SA are an accurate reflection of SA.

Observer-Rating Techniques Another indirect measure of SA is observer-rating techniques [51, 52, 62]. This measure of SA consists of SMEs observing and rating an individual's SA as a scenario unfolds. Advantages associated with observer-rating techniques are they are nonintrusive and can be used in real time and for real-world applications. However, similar to self-rating techniques, there is the question as to how accurately an external observer can truly assess SA. Another potential limitation of observer-rating techniques is the need to find qualified individuals with enough expertise to assess the scenario.

Multiple surgeon and operating team assessment tools have been developed that assess nontechnical skills including SA. All of these tools represent observer-rating techniques and may represent the most widely used technique for assessing SA in surgery. The Oxford Nontechnical Skills (NOTECHS) assessment tool was modified from an aviation version of NOTECHS and requires SMEs to assess an operating team's SA on three dimensions that adhere to Endsley's [47] model of situation awareness: notice, understand, and think ahead [69]. Each dimension of SA is assessed on a four-point scale ranging from below standard to excellent. The Oxford NOTECHS was designed to assess an overall score for the whole team and scores for each subteam (surgeons, nurses, anesthetists). Overall, Mishra and colleagues [69] found inter-rater reliability was high for SA except for the anesthesia team. Sevdalis and colleagues [70] also modified the aviation NOTECHS to create a revised NOTECHS to assess surgeons' nontechnical skills. Their version of NOTECHS concurrently measures situation awareness and vigilance on three subscales and also requires SMEs to assess performance. Unlike the Oxford NOTECHS which broadly measures SA, NOTECHS is more specific in its subscales which consist of monitoring patient parameters, being aware of anesthesia, and communicating with the anesthesia team in the event of a crisis. Further, the NOTECHS scale developed by Sevdalis et al. [70] uses a six-point rating scale ranging from not done to done very well. The overall internal consistency for the SA subscale was acceptable apart from ratings for the operating department practitioner, who is a technician assisting the anesthetist.

Another assessment tool for surgeon's nontechnical skills is the Nontechnical Skills for Surgeons [71, 72] (NOTSS). Like the Oxford NOTECHS [69], NOTSS [71, 72] uses a four-point assessment scale ranging from poor to good and assesses SA on three subscales that mimic Endsley's [47] model. The three subscales consist of gathering information, understanding the information, and projecting to future states [71, 72]. While Yule and colleagues used SMEs as raters, they also assessed the viability of using novice raters who had received a 2.5-hour training session on the NOTSS assessment tool. They found that expertise affected ratings and novices would require longer training, perhaps 2 days, to be more accurate in their assessments. Further, they found that inter-rater reliability on the SA subscales was quite low.

The Observational Teamwork Assessment for Surgery (OTAS) was developed as a team assessment tool [73]. Unlike the other observer-rating techniques, OTAS does not have subscales for measuring SA and only provides one global score for monitoring/situational awareness. However, OTAS is intended to be used for each surgical subteam (surgeons, nurses, anesthetist) and during the three phases of surgery: pre-, intra-, and postoperative. OTAS uses a seven-point assessment scale ranging from problematic behavior to exemplary behavior. Overall inter-rater reliability for SA was moderate during tool validation and refinement.

Performance Measures Another indirect measure of SA is performance measures, which are considered nonintrusive and are relatively simple to measure [51, 52, 62]. However, there is significant concern over the ability to truly discern an individual's level of SA based on performance assessment. Endsley [62] further describes three forms of performance measures for SA: global measures, external task measures, and imbedded task measures.

Process Indices/Physiological Techniques A final technique used to assess SA is process indices which include physiological techniques. Endsley [62] acknowledged that while P300 and other electroencephalographic methods were useful for assessing if information was cognitively registered, she cautioned about their use for truly measuring SA. A commonly used physiologic technique for assessing SA is eye tracking, which has been applied to surgery. Indeed, Tien, Atkins, Zheng, and Swindells [74] assessed expert and novice surgeon's SA using eye tracking during a simulated laparoscopic gallbladder removal. They found that experts were more likely to glance periodically at the patient's vitals, suggesting they had higher levels of SA compared to novices. Tien et al. [74] acknowledged that looking at a display does not necessarily equate to perceiving and understanding the display, but one of their participants did recount important information from the display suggesting a higher level of SA.

While the majority of SA measures for surgery are external observations, the other approaches can be adapted and used as corroborating measures of SA. Although a number of these techniques cannot be performed during actual surgery, simulation offers a pragmatic, feasible method of assessing surgeons' SA safely. Further, simulation can offer a viable method for training SA [75]. Recently Chang and colleagues [76] compared a traditional lecture-based approach to a simulation-based training approach for training critical care fellows on SA. They found the simulation-based approach resulted in moderately better SA scores using SAGAT, indicating that simulation may indeed offer a good approach for training SA in surgery as well.

Stress

The constructs we have discussed, namely, mental workload, attention, and situation awareness, are all susceptible to the effects of stress. Few would deny that surgery is an inherently stressful occupation, yet the effects of stress in relation to the surgeon are not well acknowledged, and little training and few interventions are available for stress mitigation [77–82]. The effects of stress, however, can be deleterious to a surgeon's performance, and there is evidence that younger surgeons and female surgeons may be more susceptible to stress and report higher levels of burnout [83]. Therefore, studying the effects of stress and developing mitigation techniques are paramount for optimal patient care and to avoid physician burnout.

Stress can be experienced both physically (e.g., strain, sprain) and cognitively. While physical stress is important and relevant to the surgeon, especially with the development of laparoscopic surgical techniques (e.g., see research by Aitchison et al. [84]; Miller et al. [85]; and Shepherd et al. [86]), the focus for this chapter will be the psychological components of stress. Psychological stress can be difficult to define, making it challenging to study and quantify. Since Hans Selye first offered a definition of stress [87], there have been multiple attempts to define stress [88]. Salas and colleagues [88] built upon the definition first introduced by Lazarus and Folkman [89] describing stress as an appraisal process and offered the following definition of stress: "a process by which certain environmental demands (i.e., performing in front of others, taking an examination, industrial noises) evoke an appraisal process in which perceived demand exceeds resources and results in undesirable physiological, psychological, behavioral, or social outcomes" [88]. Therefore, a stressor that one person appraises as stressful may not be perceived as stressful by another person, making the stress appraisal process highly subjective and the subsequent mitigation of stress even more challenging.

Stressors can be endogenous, or internal (e.g., fatigue, physical strain, worry), or exogenous, or external (e.g., noise, time pressure, interruptions) [90]. There is a plethora of stressors surgeons are exposed to, including long work hours, complex procedures, making difficult decisions, time pressure, and equipment issues, including the introduction of new equipment and technology [83, 91, 92]. Stress has been found to affect a surgeon's nontechnical skills such as communication and decision-making and even psychomotor skills [80]. Simulation offers a safe method to examine how different stressors impact a surgeon's technical and nontechnical skills in the operating room. Further, new technologies and surgical techniques can be trialed and practiced in a simulated setting, allowing surgeons to become comfortable with these new techniques prior to operating on a live patient.

Stress Assessment Methodology Similar to situation awareness, stress can be challenging to assess as it is difficult to measure directly [79]. Further, measurements can be inconsistent, and many variables can impact an individual's appraisal of stressors [90]. Therefore, stress is assessed through its effects which fall into two categories: subjective measures and objective measures.

Subjective Measures Subjective measures of stress rely on participants self-reporting their perceived level of stress [79]. The subjective measures of stress have the same advantages and disadvantages as subjective measures of workload. In addition, Matthews and colleagues [93] highlight some specific limitations of subjective stress assessment measures. First, they acknowledge that subjective stress measures may not be suitable for assessing stress changes during short periods of time and suggest physiological measures would be more suitable to capture these finite changes. Matthews et al. [94] also recognize that subjective assessments are not appropriate for capturing a person's unconscious stress state. Despite these limitations, multiple validated assessment tools are available to assess subjective stress; however, in a review of the literature, Arora and colleagues [79] found that many studies assessing the impact of stress on surgical performance did not use these validated assessment tools, with a few exceptions.

The Dundee Stress State Questionnaire [93, 94] (DSSQ) is one subjective assessment tool that has been used to assess stress associated with surgical performance. Matthews and colleagues [93, 94] recognized subjective stress is a complex construct which likely cannot be narrowed down to one single dimension; therefore, they sought to identify the possible dimensions of subjective stress. Through a series of studies, they developed and validated the DSSQ [93, 94], a 90-item assessment of stress containing 11 subscales (energetic arousal, task interest, success motivation, concentration, tension, hedonic tone, confidence control, self-focus, self-esteem, task-relevant cognitive interference, task-irrelevant cognitive interference) and 3 domain categories: distress, engagement, and worry.

The DSSQ has successfully been used to assess perceived stress for surgical environments and tasks [92, 95, 96]. Klein and colleagues [92] initially used the DSSQ to assess if distortions in a simulated endoscopic surgical task affected novices' stress and performance. They found visual disruptions resulted in reduced performance and increased ratings of stress on the DSSQ compared to participants who did not experience a disruption. Klein et al. [95] conducted another study comparing a laparoscopic and robotic interface and found participants reported lower levels of stress on the DSSQ with the robotic interface. However, a limitation of both these studies was the use of undergraduate university students who had no formal medical training. In a more recent study, Klein and colleagues [96] sought to extend the research examining the robotic and laparoscopic interfaces with first-year residents and expert surgeons. The results were similar to those obtained with the undergraduates; for both groups, performance was better for the robotic interface, and participants reported lower levels of stress on the DSSQ for the robotic interface.

While the DSSQ [93, 94] is a reliable measure of stress, its biggest limitation is its length of 90 items. Often the questionnaire is administered at baseline prior to a task and upon completion of the task resulting in participants responding to 180 items. For surgeons with limited time, completing the DSSQ may not be feasible. Recognizing the length as a limitation of the DSSQ, Helton [97] developed the Short Stress State Questionnaire (SSSQ, Helton, 2004), which may be a more appropriate assessment tool for surgeons. The SSSQ contains the same three dimensions of stress as the DSSQ: distress, engagement, and worry. However, it is more concise with only 24 items (48 total if administered pre- and post-task). Although some of the subscales of the DSSQ were not represented or loaded onto a different dimension on the SSSQ, Helton has found the overall SSSQ score to be similar to the DSSQ [97, 98]. Therefore, the use of the SSSQ could be advantageous for assessing subjective states of stress related to surgical performance.

Another well-validated stress assessment tool is the State-Trait Anxiety Inventory (STAI), a 40-item questionnaire that measures a person's general anxiety and anxiety for the present moment [99]. Similar to the DSSQ, a limitation of the STAI is its length; therefore, Marteau and Bekker [100] developed the STAI-6, a six-item version of the longer STAI. Marteau and Bekker [100] found the abbreviated version maintained results comparable to the original STAI. Further, they noted the short length should result in less missing data and obtaining maximum response rates.

The STAI and STAI-6 have been successfully used to assess stress associated with performing surgical tasks [81, 91, 101, 102]. For example, Wheelock et al. [101] examined how distractions during actual surgical procedures impacted surgical staff's perceived stress. The researchers administered the STAI after a surgical procedure to the surgeon, scrub nurse, and anesthetist and found that overall surgeons reported higher levels of stress compared to the other surgical staff. Further, Wheelock et al. [101] found nurses reported higher levels of stress associated with equipment disruptions and acoustic distractions were perceived as more stressful by the surgeons. Simulation offers a method to further assess how distractions are perceived and how staff can be trained to mitigate stress and distractions.

Objective Measures The complete physiologic response to stress is a complex process and is beyond the scope of this chapter. In basic terms, when an event is appraised as stressful, two biological systems are activated: the autonomic nervous system and the HPA axis (the hypothalamus, pituitary gland, and adrenal cortex) [103]. In turn, the activation of these subsystems results in measurable physiologic arousal changes [90]. Arora et al. [79] found five forms of physiological assessment have been used to assess stress in relation to surgery: heart rate, heart rate variability, skin conductance, eye blinks, and salivary cortisol measures. A comprehensive overview of each of these techniques and the studies employing these techniques in relation to stress assessment associated with surgical procedures is provided in their review article and therefore will not be repeated here.

Of note, Arora et al. [79] found heart rate and heart rate variability were the most commonly used physiologic measures of stress. They noted a normal response to an event that is perceived as stressful is increased heart rate. On the other hand, heart rate variability has been used as an indirect measure of stress and manifests as interval changes between consecutive heart beats [79, 104]. However, if using heart rate as a measure of stress, it is important to consider possible confounding factors that may affect the results. For example, Everly and Lating [105] note that certain individual factors, such as chronic blood pressure, can confound the measurement of heart rate. Further, factors such as recent caffeine consumption or physical exertion should also be measured or controlled prior to assessing stress.

Combined Arora et al. [79] noted that not only can stress be difficult to measure, but there is not one tool available to capture a direct measure of stress. In the attempt to close this gap, Arora and colleagues [80] developed the Imperial Stress Assessment Tool (ISAT) to concurrently measure objective indicators of stress and subjective perceptions of stress. Further, they recognized that oftentimes only one objective measure is used to assess stress, which can make it difficult to establish validity of that measure. They also noted that an individual's subjective perception of stress may have more of an effect on performance; therefore, Arora and colleagues [80] developed a multipronged approach for assessing stress in surgery by combining two objective assessment measures (heart rate, cortisol) and a subjective assessment measure using the STAI-6. They trialed the resulting ISAT with 11 practicing surgeons and found that for 70% of the procedures, there was a high correlation of increased heart rate, cortisol, and subjective stress assessments on the STAI-6.

Arora and colleagues [106] further validated the ISAT with novice surgeons. They assessed whether stress had any effects on psychomotor performance for novice surgeons. They found self-reported stress correlated with physical measures of stress. Further, increased stress was correlated with poorer psychomotor performance, indicating that stress may indeed have negative consequences for patient safety.

Stress-Coping Techniques One area where simulation can serve a vital role is developing and testing stress-coping techniques for surgeons and associated staff, an area where research is lacking [82, 107]. However, it must be considered that a potential reason for the slow implementation of research and subsequent development of training and coping techniques for surgeons may be traced to the developed culture that surgeons should operate as autonomous individuals and not show signs of weakness [78]. Indeed, Arora et al. [78] queried surgeons regarding their perceptions of stress and found that most reported stress was a difficult concept to acknowledge in the surgical community. Despite this, most welcomed the concept of formal training in stress mitigation techniques. Arora and colleagues [78] surmised that simulation-based training may afford the best approach for assessing stress and offering coping and mitigation training for stress.

Efforts are currently underway to understand how to mitigate the effects of stress for surgeons. For example, Engelmann et al. [108] recognized that occasional breaks are often offered to workers in demanding occupations. Despite the potential for long hours and high cognitive and physical demand associated with performing surgical procedures, surgeons are not generally afforded the opportunity to take microbreaks while operating. Therefore, Engelemann and colleagues [108] examined how implementing intraoperative breaks during laparoscopic surgery affected surgeons' stress, through measuring stress hormones via saliva and operative workflow and time. They found that the breaks did not increase operative time, and psychological stress was reduced compared to surgeons who were not offered the opportunity to take breaks.

Recently, Anton and colleagues [11, 109–114] have assessed the need for stress training for surgeons and have conducted a series of studies assessing if mental skills training can be beneficial for surgeons to reduce stress. An eight-module mental skills curriculum was developed and trialed with a small population of surgical novices [11]. Initial results indicated that while heart rate increases were observed in a transfer task, participants did not report an increase in perceived stress on the STAI-6, suggesting the mental skills curriculum may have mitigated their perceived stress levels. In a larger randomized, controlled study, Stefanidis et al. [114] trained novices to proficiency on the *Fundamentals of Laparoscopic Surgery* before assessing skill transfer after training and assessing retention 2 months post-training on a live porcine model. Half of the participants also received the mental skills curriculum. Participants' stress was measured using heart rate assessments and the STAI-6. Stefanidis and colleagues found that while there were no differences in heart rate assessment during the transfer task, participants with the mental skills training did have higher heart rates on the retention task. However, these same participants reported lower levels of perceived stress on the STAI-6 for both the transfer and retention task. Further, the mental skills curriculum group had a greater overall increase in improved performance compared to the control group. These results lend support to the suggestion by Arora and colleagues [80] that an individual's perception of stress may have a larger impact on their performance compared to objective measures.

Ultimately, the goal of using simulation-based assessment and training for stress would be to transfer to novel settings and the real world. Indeed, Andreatta and colleagues [115] questioned whether training in stress-free simulated environments would transfer to the operating room. Therefore, they sought to determine if they could introduce sources of stress during simulation-based training. Medical students performed four different exercises of varying difficulty on a laparoscopic simulator. For the first two and final exercise, they were alone; however, for the third exercise, the researcher watched them while making neutral sounds or offering cautionary advice. Andreatta et al. [115] reported they could induce a stress response in the simulated setting and found the combination of performing a difficult task coupled with having the researcher watching elicited stronger stress behaviors.

It is not possible, however, to replicate all stressful scenarios that may be present in the operating room; therefore, it would also be prudent to explore whether training on a few stressors generalizes to novel tasks. Using a computer-based task, Driskell and colleagues [116] explored this concept and found that stress training on one stressor did transfer to a unique stressor. However, they did not evaluate whether the training then transferred to a real environment. Recently, Baker and colleagues [117] explored whether anesthetic trainees exhibited similar levels of stress in a simulated environment as in the real world for performing a rapid sequence induction. While they found no significant difference in subjective stress, measured using the STAI-6, they did find heart rate variability was significantly greater in the real environment, indicating that simulation may not produce the same levels of stress as the real operating environment. However, as previously noted, subjective assessments of stress may be a more important indicator of how performance may be impacted, and more research will be needed to truly determine how stress training in a simulated environment translates to the real world. Another important consideration LeBlanc [118] raised is that different factors can affect stress and used the example that during a simulated scenario, a trainee may experience stress from being observed by a supervising faculty member as opposed from experiencing stress from the scenario itself. In this example, unlike the purposeful stress manipulation by Andreatta et al. [115], the goal would be for the different simulated scenarios to elicit stress as opposed to the observer. LeBlanc [118] suggested for the simulated scenario and training to be effective, the scenario itself needs to elicit the stress response. When designing simulated surgical procedures to study stress, this will be an important concept to consider and control for.

Conclusions

Surgeons can benefit from applying human factors concepts to their training. This chapter highlighted only a fraction of the human factors approaches that are available, focusing on concepts affecting performance at an individual level. Future work should also incorporate other concepts and focus on new and emerging ideas and techniques, embracing simulation as a method of assessment and training.

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Part IV

Subspecialties of Surgery – State of the Art

Simulation in General Surgery

Mark W. Bowyer and Ryan B. Fransman

Introduction

The training of surgeons and surgical specialists has undergone significant changes in the last 20 years. Medical and technical progress has led to increasing specialization and practice focused to narrow skill sets. The introduction of work-hour restrictions in the United States and the European Union has led to dramatically decreased opportunities for exposure to clinical material [1–7].

Open operative experience has been adversely affected by substantial advances in technology that have resulted in the increased use of minimally invasive, endoscopic, and endovascular approaches to the treatment of surgical disease [8–11]. A recent study estimated that over the past 14 years, the number of percutaneous and endovascular interventions increased by 200–1000%, while the number of open gastrointestinal and vascular operations decreased by 30–70% [12]. The increasingly non-operative management of trauma has also resulted in a significant decrease in exposure by trainees to open surgical experience with trauma [13, 14]. In a 10-year review of patients admitted to a Level 1 trauma center, Jennings et al. noted a decrease from 100% to 19% and 93% to 28%, respectively, in the operative management of patients with spleen and liver injuries [15].

Despite the advantages of minimally invasive surgery (MIS) and newer technologies, there will always be a role for open surgical intervention. Open surgical procedures can guide and assist in training surgeons in MIS techniques, as surgeons competent in open techniques have a greater appreciation of the anatomical relationships necessary for MIS procedures. Although proficiency in MIS is important for a graduating chief resident in general surgery, the ability to perform open surgical procedures may be more important as it is the backup for MIS procedures. General surgeons who are not comfortable with open surgical procedures may be reluctant to convert MIS procedures to open procedures when necessary or, even worse, may not acknowledge the need to perform an open procedure when the conditions are not appropriate for an MIS approach, thus potentially putting patients at risk [16].

Based on data from the Accreditation Council on Graduate Medical Education case logs of residents graduating in July 2005, Bell [17] identified that many essential operations in both common and uncommon categories were being done infrequently. They noted that there were few operations that were done ten or more times on average during residency and raised concerns about the volume and breadth of operative experience reported by graduating residents. This has led to an increasing disquietude about the ability of surgery residents to practice independently following completion of their training [18–20].

Post-residency fellowship directors and surgeons in practice have expressed strong opinions that operative experience and perioperative decision-making skills of graduating residents are lacking [21]. Malangoni et al. published a review of general surgery resident case logs in 2013 representing numbers from chiefs graduating in 2010–2011 [20]. The case logs report numbers for 67 "common-essential" and 66 "uncommon-essential" procedures over the entirety of a surgical residency. In the Malangoni review, 23 common-essential operations performed a median of 1 to 4 times, and 4 had a median frequency of 0. No uncommon-essential operations were done a median of 5 or more times, whereas 37 had a median between 1 and 4, and 29 had a median of 0 [20].

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These authors also found a decline in the number of open cavitary operations done as minimally invasive approaches have increased, with significant decreases in the frequency of open cholecystectomy, appendectomy, inguinal/femoral hernia repair, and partial colectomy. They concluded that some common-essential operations continue to be performed infrequently and that education in the operating room must improve, and alternate methods for teaching infrequently performed procedures are needed with the statement that "Simulation may prove valuable in exposing residents to a variety of scenarios that they may not encounter otherwise" [20].

State of Simulation for Open Surgery

Simulation technology, with the potential to foster the development of technical skills in a safe, nonclinical environment, has been suggested by many as a way to remedy the problem described above [20, 22]. In the last two decades, there have been significant advances in the development of simulators and simulation technologies that can be used to teach surgical skills. To date, the bulk of this effort has been focused on the development of simulators to teach laparoscopic and endoscopic procedures with great success as outlined in other chapters in this book.

An ideal procedural simulator is one which enables the user to "suspend disbelief" and use actual instruments in a fashion that approximates that of an actual patient procedure. The laparoscopic surgeon performs procedures using long instruments while focusing on a two-dimensional display screen, and the endoscopist likewise views a two-dimensional screen while manipulating the controls of a scope. These procedures are well suited to the development of simulators with a high degree of face and content validity. However, open surgical procedures require the manipulation of the tissue using one's hands as well as a number of shorter instruments in three dimensions. The ability to replicate human tissue qualities with tissues that can be cut, bled, and sutured or stapled in a realistic fashion in a cost-effective fashion has proved challenging, and the state of the art for simulation of open surgical procedures has lagged far behind that for laparoscopic and endoscopic procedures. The majority of simulators that have been developed are comprised of silicon or latex which bears little resemblance to human tissue. While there have been several advances in creating models with tissues that are more realistic and "human" in nature (see examples described later in chapter), there has not yet been a demand significant enough from the surgical community to put these models into the hands of trainees in a cost-effective fashion.

When looking at the available literature on simulation for open surgical skills, there is a paucity of results. Though many comprehensive reviews of the laparoscopic simulation literature have been performed, including a Cochrane Database review, until recently there had been no comprehensive literature review of the advances and pitfalls in the use of simulation technology in the training of open surgical skills. In a recent (2013) self-described "comprehensive review" of the literature, Fonseca et al. identified only 31 studies which reported an experience with simulation-based training of "open surgical" skills [22]. This search included all studies purported to train or evaluate skills in open surgery and included basic surgical skills, such as suturing and knot tying as well as more advanced skills specific to multiple surgical domains. In this review, synthetic models were used in 18 studies, animal models in 15, and cadaveric models in 4 [22]. "Open" gastrointestinal surgery was the focus of only six of these studies, and two of these were done with an anesthetized porcine model to teach surgical residents an open Billroth II gastric resection [23] and an open segmental colectomy [24]. Of the remaining four, one [25] utilized a simulated abdominal wall with synthetic bowel (Simulab, Seattle Washington) to train residents to open an abdomen and perform a hand-sewn bowel anastomosis, while the other three utilized explanted fixed porcine bowel on the bench top [26] or in the Berlin Operation Trainer (BOPT). The BOPT is a "box" trainer in which a plastic abdominal cavity containing a removable board with painted organs and affixed porcine bowel was attached to train bowel anastomosis [27, 28]. In a separate review article published in 2013, Davies et al. set about to "summarize the current standard of available open surgical simulators" [29]. These authors found that the then current literature contained a total of 18 studies investigating the efficacy of open surgical simulation using live animal, bench, and cadaveric models in many surgical specialties including general, cardiac, trauma, vascular, urologic, and gynecologic surgery [29]. These authors note that "studies concerned with the benefit of open surgical simulation are few and far between," "making it difficult to draw conclusions regarding the benefits" [29]. It is also important to note that Davies et al. found no studies investigating the efficacy of virtual reality-based or software-based simulators for open surgery. They highlight the BOPT (described above) as an example of an open surgical simulator and describe a haptic-enabled virtual reality simulator under development in their lab to teach open inguinal hernia repair (VREST Virtual Lichtenstein Trainer), which is yet to be completed. The authors further conclude that "high fidelity virtual reality models that accurately simulate surgical procedure and surgical anatomy have the potential to become a fundamental part of surgical training" [29]. Unfortunately, the current state of the art in virtual reality for open surgical skills falls well short of these lofty goals, and further development and refinement will be required. Thus far, insufficient attention has been directed toward the development of high-fidelity simulation models for resident training in complex open procedures.

Live Tissue and Cadavers

Historically, live animal or cadaveric human or animal specimens have been used as "simulators" to teach open surgical procedures. Live tissue is a very close approximation of human tissue allowing for the practice of open procedures with excellent tissue tool interaction and tissue that bleeds when cut and can be sutured and stapled using the instruments actually used in the operating room. Live tissue allows for realistic training of tissue hemostasis, ligation of blood vessels, and dissection in natural surgical planes. The limitation of live tissue is that for many procedures, there are notable differences between the anatomy of the animal model and human anatomy. Additionally, the use of animals is an emotionally charged topic with significant social pressure being brought to bear with resultant limits or, in many countries, outright bans on their use for surgical training. Given the significant societal pressures, it is not farfetched to predict that there will eventually be a significant limitation, if not an outright ban, on the use of live animals for surgical training in the future. As such, it is essential that the medical simulation community work proactively to develop acceptable alternatives.

Cadavers provide realistic human anatomy, but cadaveric tissues do not bleed, and the texture of organs and the tissue planes are altered by the lack of blood flow and/or any preservation method used to prepare the specimen. Perfusion of cadaveric specimens has been proposed to overcome some of the perceived limitations of this model. Garrett lamented the shortcomings of simulated models of the arterial tree and set about to create a human cadaveric circulation model and published a report on his experience with perfusion of more than 20 cadavers and their subsequent use for teaching a variety of endovascular techniques in 2001 [30]. Aboud et al. reported on the use of perfused cadavers to train neurosurgeons to deal with cerebral aneurysms [31]. This model, which has been referred to in the popular press as the "living cadaver," has also been successfully trialed for use in training trauma skills [32].

Reihsen et al. recently described a fresh-perfused cadaveric model with high anatomic and tissue fidelity that is developed to assess performance of hemorrhage and airway management skills during a simulated polytrauma scenario [33]. Using fresh human cadavers obtained within 96 h of death, hemorrhage from a right traumatic amputation and left inguinal wound was simulated using cannulation of the right popliteal and left femoral artery, respectively. The thoracic aorta (thoracotomy method) or external iliac arteries (Pfannenstiel method) was used for catheter access points. Lung ventilation to simulate chest rise and fall was achieved using bilateral chest tubes connected to a bag valve mask. The cost for acquisition and preparation of donors was estimated at $3611 to $9399 per specimen [33]. Working out of the Cadaver lab at the University of Southern California (USC), Carey et al. have published a series of reports using a perfused cadaver model in which the femoral vessels were cannulated and perfused using a vortex centrifugal pump and a novel perfusate. A mean arterial pressure of 80 mm Hg and venous pressure of 15 mm Hg were established, resulting in dermal and microvascular perfusion. The trachea was intubated and mechanically ventilated with successful pulmonary ventilation. This model, which is reported to cost $1262.55, has been used for a wide variety of open surgical skills in multiple disciplines [34, 35].

Depelch et al. have recently published the development of a "pulsated revascularized and reventilated cadaver for surgical education" [36]. This model/process which has been named "SimLife" requires extensive preparation of a fresh cadaver with cutdown and cannulation of both arteries and veins in all four extremities, with removal of all native blood and thrombi by flushing with 12 liters of warmed saline (the first two with heparin), and intubation/tracheostomy. The specimens can then be used soon thereafter or frozen with the cannulas left in place for subsequent usage (after defrosting for 3 days). The specimen is connected to hydraulic and pneumatic pumps that allow for perfusion with warmed pulsatile-colored water to simulate blood flow and air to simulate ventilation. This has been coupled with a computer-driven software (under ongoing development) allowing for modulation of "vitals" in response to actions by the learners. The authors have used this model in a limited number of trainees with reported success satisfaction and relate that the cost of this preparation should be comparable to the price of a modern advanced patient simulator (estimated at €2000 euros per learner for a surgical day). The authors further note that while cost is important, the major barrier to widespread use will be the availability of human cadavers and the extensive time (and skill set) required to prepare and maintain the specimens both before and during a course [36].

While the use of cadaver specimens either fixed, frozen, or perfused seems like an excellent solution to the need for "simulated" training, the availability, acceptability, and costs limit universal use for this purpose. One of the authors of this chapter (MB) is one of the principal architects of the Advanced Surgical Skills for Exposure in Trauma (ASSET) course, which teaches vascular exposures for trauma during a 1-day course using fresh human cadavers [37, 38]. The ASSET course has been promulgated to over 95 sites in 11 countries in the last 6 years, and this experience has highlighted the challenges with obtaining cadaveric specimens for surgical training. The availability, quality, and costs of cadavers are highly variable around the world and even within the United States. The cost of cadaveric specimens used in the United States for the ASSET course has ranged from free (one site) to as much as $8000 per cadaver with the norm being around $2000, and the quality of the specimens obtained is highly variable. There are currently very few sites in the United States that have the availability to routinely procure and prepare the fresh specimens required for the previously described perfused cadaver model. Additionally, there are many places in the world where human cadaver use is either prohibited or prohibitively expensive.

Virtual Reality

There has been substantial interest in creating virtual reality (VR) simulators to be used to teach open surgical procedures. The yet to be fully realized potential of VR computer-based training is that the parameters required to achieve tasks can be set. This could include time limits, correct planes, intentional versus unintentional tissue injury, instrument placement and handling, and finally realistic tissue reaction to intervention to name a few which can be constantly monitored with staged data gathering to holistically evaluate the trainee on a proficiency level. VR simulation is renewable and allows reuse and therefore promotes retraining, repetition, and consistency. An additional feature of VR simulation is the potential ability to provide multiple variations of anatomy and pathology for training and ultimately surgical rehearsal on a simulation of an actual patient's anatomy prior to performing the procedure. The multiple promises of VR as detailed above have not come to fruition for open surgical procedures as the technology required to do this is still in its infancy, and there are currently no such simulators being routinely used to train surgeons for open surgical procedures.

Some nascent progress in this field is being made with an example being a VR-based open surgical trainer for orthopedics developed by OSSimTech (Montreal, Canada; ossimtech.com). This company specializes in the design, research, and development of virtual reality-based open surgery training simulators and has plans to release a virtual reality training simulator to teach and train orthopedic open surgery in 2017. The simulator uses haptic feedback (applied force and resistance) allowing for the handling and manipulation of multiple orthopedic tools in a highly realistic 3D environment with detailed imaging. OSSimTech has developed proprietary software that provides sensory feedback on visual, audio, and touch levels depending on the selected surgical procedure. OSSimTech simulators combine in one device the visual display of surgical sites in open surgeries and the use of haptic force feedback actuators that can be mounted on instruments for open surgery (screwdrivers, drills, saws, etc.). They believe that this unique and innovative training solution will be able to substitute for animal and cadaveric models (http://ossimtech.com/en-us/).

Physical Models

There is a growing and mostly unmet need for simulators which can allow for training of open surgical procedures in a realistic and cost-effective fashion. A potential solution is the use of physical (and perhaps ultimately virtual reality) models with surgically correct human anatomy allowing for the training of emergent and elective open intrathoracic, intra-abdominal, and extremity surgical procedures. Ideally, such models would be composed of human tissue characteristics, with anatomically correct (surgical, not textbook) tissues and tissue planes that bleed in a realistic fashion when dissected using actual surgical instruments. Such models should also reflect a variety of pathologies and be cost-effective. Studies have demonstrated that high-fidelity models result in improved skill acquisition [39]. To date, insufficient attention has been directed toward the development of high-fidelity simulation models for resident training in complex open procedures. There are currently a few simulation companies who have developed sophisticated high-fidelity physical models that have the potential to be adapted and/or expanded to teach complex open surgical skills. The remainder of this chapter will provide an overview of some of these models which represent the current "state of the art" for physical simulators.

Models from Operative Experience, Inc. (OEI)

Operative Experience, Inc. (North East, MD; www.operativeexperience.com) was founded by an experienced trauma surgeon, Dr. Robert Buckman, with the mission to "revolutionize surgical and medical team training" using physical simulators upon which "major surgical hands-in-the-body operations can be performed using standard surgical instruments" [40]. Dr. Buckman has sought to develop models that had realistic human tissue properties that can be incised, retracted, and sutured representing what he has termed "Biofidelic Emulation™" [40]. Using a variety of proprietary viscoelastic materials, Dr. Buckman has created prototype models of the entire body with an emphasis on teaching trauma and emergency obstetrical skills. The commercialization of these models has been largely influenced by market demands and research and development dollars available. Currently, OEI market products for teaching medics tactical combat casualty care with full-body manikins configured with five different sets of wounds, upon which medics can practice a variety of hands-on life- and limb-saving skills. Other well-developed (and commercially available) products are simulators for teaching lower extremity fasciotomy; above and below the knee amputations; damage-control craniotomy (Fig. 1a, b); emergency thoracotomy (Fig. 2) allowing for decompression of tamponade, repair of cardiac wounds on a beating heart, cross clamping of the aorta, and control of hemorrhage from the lungs and great vessels; emergency obstetrical surgery to include cesarean section (emergent and non-emergent) and emergency hysterectomy (Fig. 3); and control of postpartum hemorrhage.

Though not yet commercially available, Dr. Buckman has also produced prototypes of full-body simulators with intra-abdominal contents allowing for the training of management of traumatic injuries and performance of general surgical procedures (Fig. 4). The materials and technologies used to make these models have the potential to replicate virtually any organ or tissue in the body with both normal and abnormal anatomies and pathologies. The materials used by OEI require no special handling, and one of the clear strengths of the models produced is that the maker faithfully replicates surgical anatomy and surgical planes, as only one with decades of surgical experience could do.

Models from SynDaver™ Labs

SynDaver™ Labs (Tampa, FL; www.syndaver.com) was founded in 2004 by Christopher Sakezles, PhD, who holds a Doctorate in Polymer Science to commercialize a system of sophisticated synthetic human tissues and body parts. Significant attention has been paid by this company to develop tissues that exhibit "chemical and physical properties (water, fiber, and salt content, strength or modulus in shear, coefficient of static or dynamic friction, surface energy, dielectric properties, heat capacity, porosity, etc.)

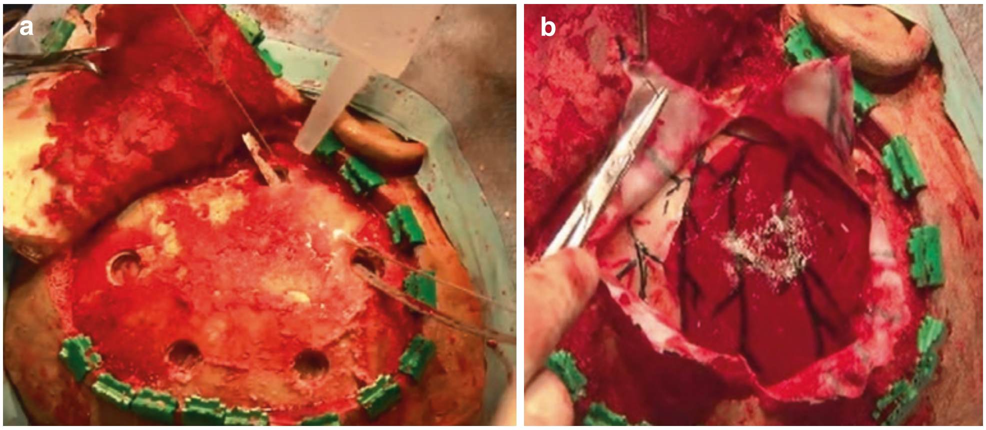


Fig. 1 Damage-control craniotomy simulator (Operative Experience, Inc.; North East, MD) with realistic anatomical features to include the skin, soft tissue, muscle, and a two-table skull that can be opened with standard instruments as seen on the left (**a**), dura, and representation of pathology in the form of a simulated subdural hematoma as depicted on the right (**b**). (Images with permission and courtesy of Operative Experience, Inc.)

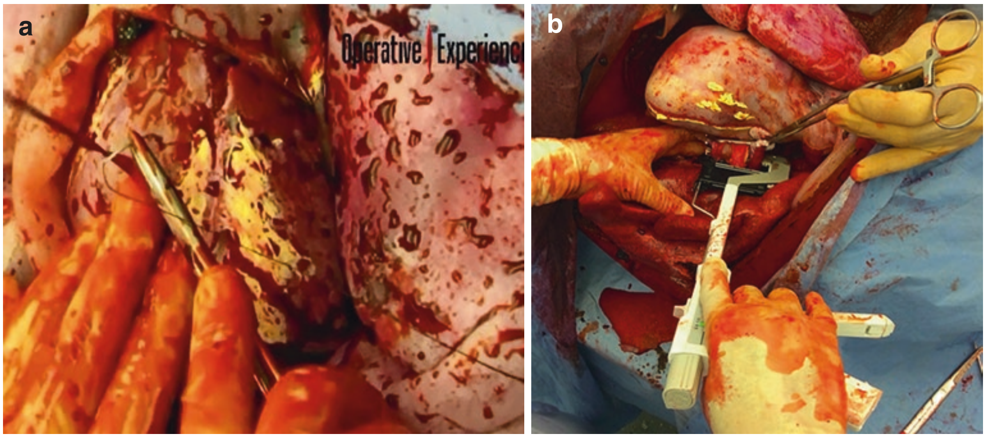


Fig. 2 Emergency department (resuscitative) thoracotomy model/simulator (Operative Experience, Inc.; North East, MD) with realistic anatomical features designed to train for unilateral and bilateral thoracotomies, pericardiotomy; cardiac injury hemorrhage control on a beating heart as seen on the left (**a**); aortic cross clamping; clamping of the left subclavian artery; exposure of the innominate artery; control of the pulmonary hilum as depicted on the right (**b**); open-chest cardiac massage; and internal cardiac defibrillation. (Images with permission and courtesy of Operative Experience, Inc.)

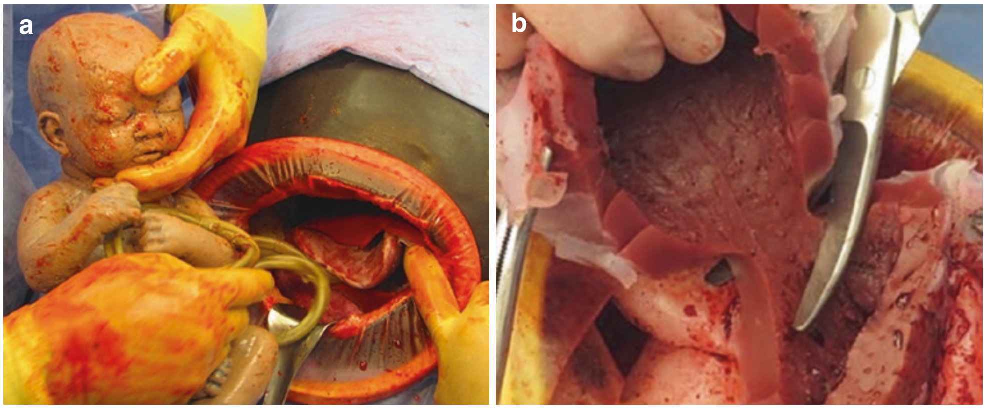


Fig. 3 Emergency obstetrics model/simulator (Operative Experience, Inc.; North East, MD) with realistic anatomical features designed to train for emergent and non-emergent cesarean section seen on the left (**a**), emergency hysterectomy as depicted on the right (**b**); and control of postpartum hemorrhage. (Images with permission and courtesy of Operative Experience, Inc.)

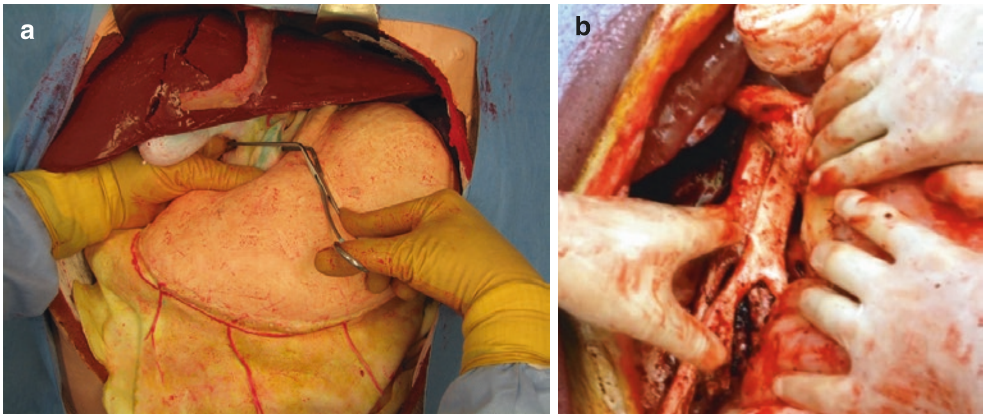


Fig. 4 Abdominal trauma model/simulator (Operative Experience, Inc.; North East, MD) with realistic anatomical intra-abdominal features in which a variety of emergent and elective surgical procedures might be practiced. The pringle maneuver is demonstrated in the picture on the left (**a**) and the right to left visceromedial rotation (Cattell-Braasch) with exposure of the aorta and an injury of the inferior vena cava depicted in the picture on the right (**b**). (Images with permission and courtesy of Operative Experience, Inc.)

Fig. 5 SynDaver anatomy model comprised of realistic synthetic representations of bones, muscle, vessels, nerves, organs, and other tissues used to teach human anatomy. (Image with permission and courtesy of SynDaver™ Labs)

that mimic the properties of the target tissue" [41]. The tissues are compatible with all known imaging techniques and surgical devices such as lasers, bipolar, monopolar, and harmonic devices [41].

The company states that they have currently created human tissues (SynTissue™) designed to mimic more than 100 soft tissues. These tissues have been assembled into very sophisticated full-body models "featuring complete and functional musculoskeletal, cardiovascular, respiratory, gastrointestinal, endocrine and nervous systems based on CT, MRI and ultrasound images of actual patients" [41]. The company offers a suite of synthetic humans to include a SynDaver Anatomy Model (Fig. 5), a mortuary training model, a musculoskeletal model, a surgical model (Fig. 6), and the SynDaver patient (Fig. 7). The SynDaver Surgical Model (Fig. 6) is a perfused, ventilated model with a realistic and complete representation of intrathoracic and intra-abdominal anatomical features. Per the company, this model has been used in a wide variety of procedures including laparoscopic surgery with insufflation, coronary stent placement with fluoroscopy, chest tube placement, cricothyroidotomy, central line placement with ultrasound, septal defect repair, bowel resection, ECMO, tracheotomy, infusion port placement, appendectomy, carotid endarterectomy, embolectomy, craniotomy, angioplasty, femoral cutdown with closure device, and many more [41]. SynDaver states that any or all of the components are replaceable and that the model can be customized to replicate a variety of "pathologies and injuries" and that the "client may select the gender and skin tone" [41]. The company offers a number of part-task surgical trainers as well to include anastomosis skills, airway training, a wearable chest tube trainer, and craniotomy as well as organs such as the liver and large bowel. In spite of this wide variety of products that have the potential to teach advanced surgical skills, a brief search of the medical literature turns up only two published reports of these products, one using SynDaver synthetic skin for testing negative-pressure wound therapy [42] and the newborn airway trainer in a comparative study of such trainers [43]. The SynDaver patient (Fig. 7) is the perfused, ventilated synthetic human described above, connected to an open-source physiology engine with an "autonomic nervous system controlling respiration rate, tidal volume, end-tidal CO2, heart rate, heart waveform, arrhythmia, systemic vasoconstriction, system-wide blood volume, body temperature, blink rate, and pupil dilation" [41]. This model is essentially a high-fidelity human patient simulator made of realistic synthetic human tissues and organs, which, per the company, will allow for the ability to "operate on any part of the body" in a realistic fashion.

Fig. 6 SynDaver surgical model provides the addition of perfusion and ventilation to the anatomy model seen in Fig. 5. This model has the potential to train a multitude of surgical procedures on perfused ("bleeding") human realistic tissues and organs. (Image with permission and courtesy of SynDaver™ Labs)

The technology and models offered by SynDaver Labs are certainly impressive, and this or similar technology may well be suited for training open surgical procedures in the near future. The potential of being able to customize the models with different pathologies is attractive. Also of interest is that the company claims they can also add living human cell layers to the luminal components of their systems [41]. The relative system cost (estimated at $85,000 for the SynPatient) and the cost of replacing individual organs ($400 for a liver and $450 for a colon) (Fig. 8) may limit the wide-

Fig. 7 SynDaver patient model is an animated full body with the skin and realistic synthetic representations of bones, muscle, vessels, nerves, organs, and other tissues that has a computer-driven physiology engine allowing for representation of physiology in addition to anatomy. (Image with permission and courtesy of SynDaver™ Labs)

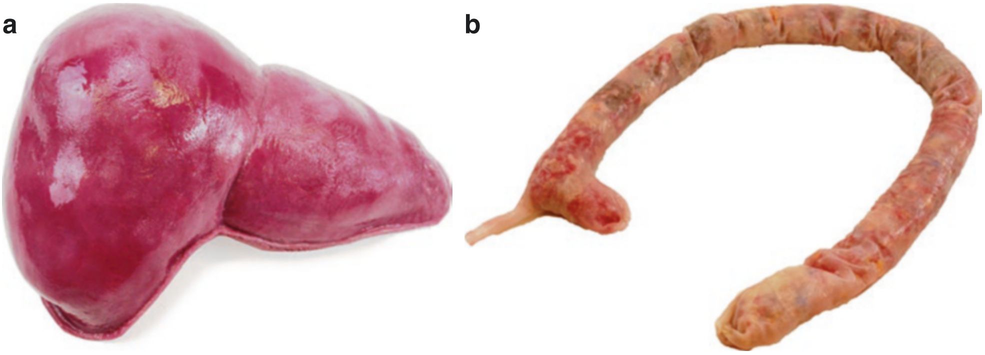


Fig. 8 SynDaver organs to be used with SynDaver synthetic human models or ex vivo for training with a synthetic liver seen on the left (**a**) and large bowel pictured on the right (**b**) pictured. (Images with permission and courtesy of SynDaver™ Labs)

spread use for routine training. Additionally, the materials used to construct these synthetic humans require special handling and storage when not in use to prevent drying out and the growth of algae.

Models from Simulab

Simulab Corporation (Seattle, WA; www.simulab.com) is a medical technology company founded in 1994 and promotes itself as "dedicated to replicating human anatomy, and turning it into realistic, easy-to-use training tools that help save lives" [44]. Simulab is probably best known for the TraumaMan© manikin that was originally developed more than 15 years ago to teach the surgical skills (cricothyroidotomy, pericardiocentesis, chest tube thoracostomy, and diagnostic peritoneal lavage) for the Advanced Trauma Life Support (ATLS©) course run by the American College of Surgery. This simulator which has replaceable synthetic (latex free) tissues has largely replaced the use of animals and cadavers for teaching ATLS© skills around the world and is currently being used to teach over 35,000 students in more than 40 countries each year [44]. Simulab has since expanded its product line to include more than 20 product families for multiple specialties to include (but not limited to) trainers for arthrocentesis, central lines, lumbar punctures, nerve blocks, paracentesis, PICC lines, suturing, laparoscopic skills, additional trauma skills, ultrasound, and venipuncture. The TraumaMan© system has been expanded to include a Surgical Abdomen Platform (Fig. 9) allowing the transformation of the abdominal area into an abdominal surgical site that can "accommodate a wide array of surgical scenarios" [44]. This platform includes an "anatomically correct" vertebral column, kidneys, large and small intestines, renal artery, and the aorta with a large replaceable abdominal tissue pad that can be reused for multiple scenarios (Fig. 10). This includes a "catastrophic event team training" module with a nicked aorta, nicked renal artery, and lacerated kidney scenarios. As with the previously detailed open surgical simulators, there has yet to be a published study detailing the use of this model for training.

Models from Strategic Operations, Inc.

Strategic Operations (STOPS), Inc. (San Diego, CA; www.strategic-operations.com) was established in 2002 to provide "Hyper-Realistic™" training services and products for military and law enforcement personnel [45]. Located in what was once one of the largest independent TV/movie studios in America, STOPS uses Hollywood-style special effects to create immersive training environments. As part of this effort, they have created a human-worn surgical simulator known as the "cut suit" to assist with training of medical teams and individual providers. The cut suit was initially developed as a trainer for tactical combat casualty care training (Fig. 11a) to train the performance of surgical airway, needle thoracentesis, tube thoracostomy, and control of hemorrhage on a live standardized patient actor wearing the suit. The surgical cut suit (Fig. 11b) is an expanded version which contains realistic though smaller than real-life organs in the chest and abdomen enabling thoracotomy and laparotomy for the control of simulated traumatic injuries. The surgical cut suit has been utilized with some success to train military healthcare providers to provide team-based damage control interventions in fairly realistic simulation-based combat trauma scenarios (Fig. 12a, b), [46–48].

Models from the Chamberlain Group

The Chamberlain Group (Great Barrington, MA; www.thecgroup.com) was established in 1999 to design and build "mimetic organs for surgical and interventional training" [49]. With roots in special effects and modeling, the Chamberlain Group has collaborated with numerous surgical leaders to develop a number of realistic trainers. One of the earliest and most successful products has been a beating heart model (Fig. 13a). More recently, Dr. Marc DeMoya from the Massachusetts General Hospital has used this model to develop a prototype for trauma thoracotomy (Fig. 13b). The Chamberlain Group offers a number of other products for virtually all of the surgical disciplines and more recently has developed an Advanced Abdominal Surgical

Fig. 9 The expanded TraumaMan© System (Simulab Corporation, Seattle, WA) which adds an articulating head and Surgical Abdomen Platform to the original TraumaMan© manikin. (Image with permission and courtesy of Simulab Corporation)

Fig. 10 The TraumaMan© System Surgical Abdomen Platform (Simulab Corporation, Seattle, WA) being set up in a picture on the left (**a**) and utilized as depicted on the right (**b**) in a recent resident training exercise at the North Pacific Surgical Society Meeting. (Images courtesy of Major Leo Daab, MD, Madigan Army Medical Center)

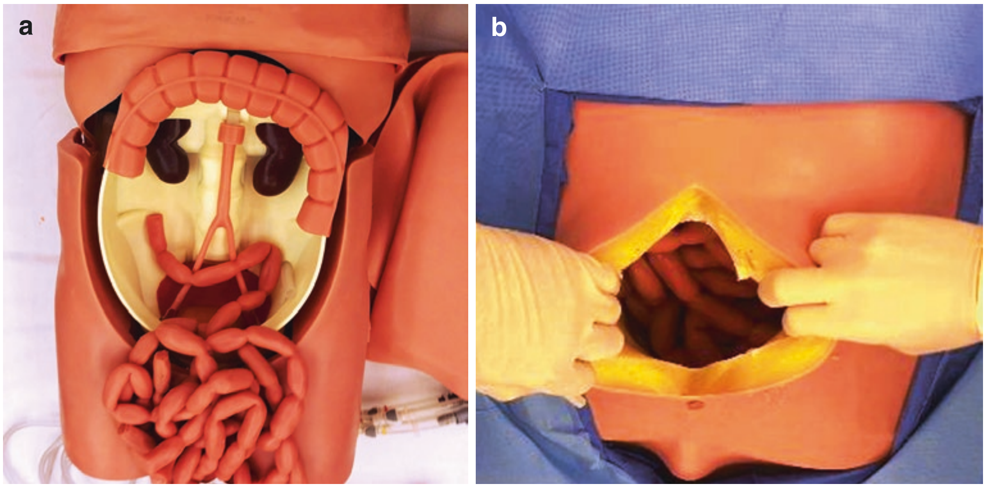
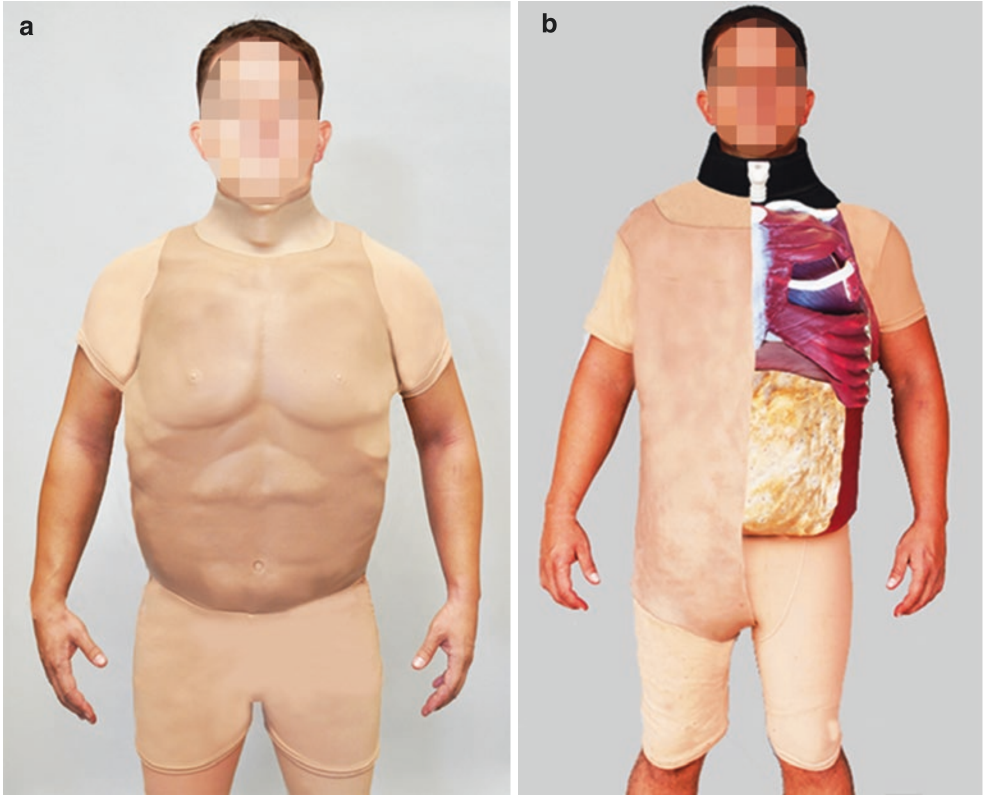


Fig. 11 The human-worn surgical simulator (Strategic Operations, Inc.; San Diego CA) is worn by a standardized patient actor and allows for tactical combat casualty care training with the basic model on the left (**a**) and for open surgical management of injuries in the chest and abdomen with the expanded model seen on the right (**b**). (Images with permission and courtesy of Strategic Operations, Inc.)



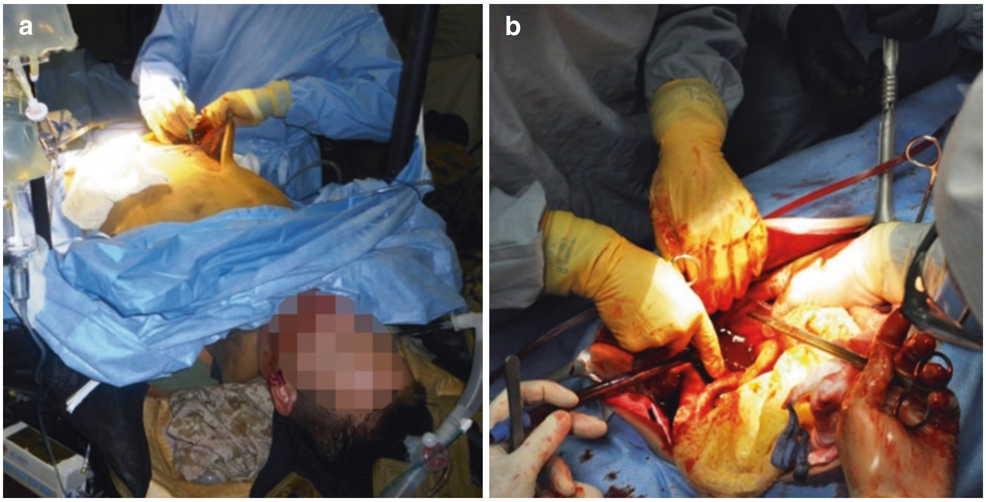


Fig. 12 The human-worn surgical simulator (Strategic Operations, Inc.; San Diego CA) worn by a standardized patient actor being used to train damage-control surgical intervention in the abdomen in a simulated trauma patient with the abdominal entry seen on the left (**a**) and control of bleeding seen on the right (**b**). (Images with permission and courtesy of Strategic Operations, Inc.)

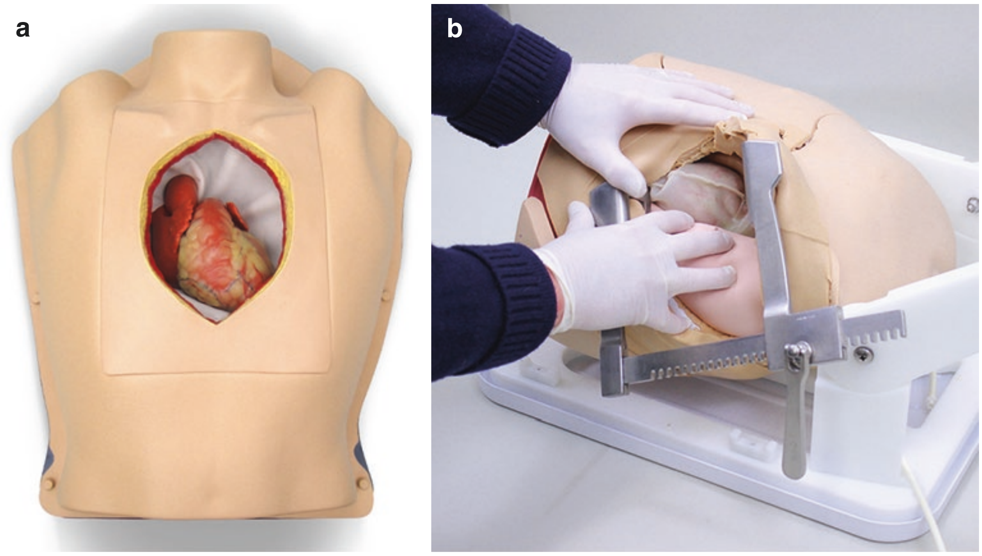


Fig. 13 The Chamberlain Groups' (Great Barrington, MA) beating heart in the thorax model seen on the left (**a**) and a recent emergent thoracotomy prototype developed in conjunction with Dr. Marc DeMoya pictured on the right (**b**) allows for training of open surgical procedures in the chest. (Images with permission and courtesy of The Chamberlain Group)

Trainer (Fig. 14) which, by their report, can be used to teach open and laparoscopic hemicolectomies, bariatric procedures, appendectomy, ventral hernia repair, and low anterior resection [49]. Additionally, in collaboration with the Boston Children's Hospital, the Chamberlain Group has developed a pediatric surgical simulator named "Surgical Sam" (Fig. 15a, b) which is billed as "the world's first beating heart, breathing, bleeding, high fidelity team trainer for pediatric surgery" [49]. Surgical Sam is a modular system representing a 14-month-old infant which can be perfused and intubated and configured to allow for training of pediatric cardiothoracic (Fig. 15a) and general surgery modules (Fig. 15b), as well as emergent resternotomy and redo-laparotomy scenarios that can be used for both individual and team trainings [49]. "The thorax and abdomen of the General Surgery Module present an intubate-able trachea, ventilatable lungs, liver and gallbladder, esophagus, stomach and attached mesentery membrane, small bowel with rooted mesentery, colon,

Fig. 14 The Chamberlain Groups' (Great Barrington, MA) Advanced Abdominal Surgical Trainer composed of a simulated abdominal wall and intra-abdominal organs allowing training for a variety of laparoscopic and open surgical procedures. (Images with permission and courtesy of The Chamberlain Group)

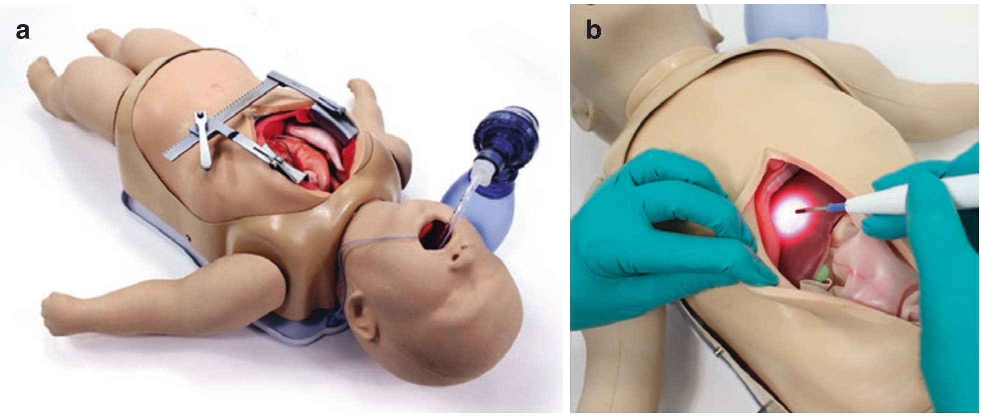


Fig. 15 The Chamberlain Groups' (Great Barrington, MA) Surgical Sam Pediatric Surgical Trainer, co-developed with the Boston Children's Hospital, enables training of open surgical skills in the chest as depicted on the left (**a**) and the abdomen as seen on the right (**b**). (Images with permission and courtesy of the Chamberlain Group)

and inferior vena cava. Bowels can be filled with succus entericus simulant and are suturable for active repair. There are separate liver and IVC blood flows and a diffuse surgical bleed, all within a fluid-tight abdominal cavity. Bleeder sites on the abdominal IVC are obscured by the small bowel and colon" [49]. As with the other modules described above, there has yet to be reported validity or efficacy of training with these particular models.

Assessment Tools for Open Surgical Skills

Moorthy et al. describe the current assessment of technical skills as being unreliable and in most cases subjective in nature [50]. Countless intervention models directly correlate improvement and skill solidification with objective feedback. With the ever evolving advancements we are seeing in medical simulation and the growth of virtual reality simulation, there most certainly is an ability to give immediate feedback, yet further investigation is required prior to comprehensive evaluation of surgeons [50].

When assessing a surgeon's manual skill, written examinations lack reliability; however, checklists, dexterity analysis, and global rating scales remain valid methods [51]. As with any successful training model, there is a need for continuous assessment and constructive feedback with "expert" instruction. This is especially true when teaching residents on appropriate handling of the tissue, fluidity of motion, instrument handling, and intraoperative communication. It is also imporant to set performance standards against which trainee skills can be compared to allowing for more objective and consistent assessments. Reznick et al. argue that when comparing multiple simulation models, there is a need for investigating and demonstrating their differential reliability [52]. This is where virtual reality may be of benefit as immediate assessment can be obtained according to software adjustments. Furthermore, inter-rater reliability should always have a part when approving these simulation models for the training of the current and future surgeon [53].

Assessment techniques that are currently utilized when evaluating the reliability of simulations include case-specific checklists that, while subjective, allow for accurate evaluation of performance in any surroundings, be it military or civilian. This chapter in particular is evaluating simulation products and technique concurrently ascertaining the need for and effectiveness of simulation assessment. Data analysis has one mutual outcome with regard to mechanical simulation versus cadaveric/live human operative training, and that is the lack of variability of mechanical models allowing comparative assessment between students. This is often times difficult to achieve on human models as anatomy is most times inconsistent. The current framework consists of cognition, clinical skill, technical ability, and social interactive skills [54].

Simulators are desired methods of evaluating medical procedures. Yet as with any new intervention, there are always some institutions that maintain the "old school" approach of the apprenticeship model of surgical residency training. This model has led the surgical training world for generations where the resident learns directly from an expert surgeon on actual patients. This method is successful on many levels; it forces the student to pre-read and identify pertinent steps in the progression of the procedure, basic technical skills, and active learning with the infamous intraoperative "pimping." One issue of acquiring the basic surgical skill in this setting is limited by finding a mentor that its goal is to teach as much and if not more than the student desires to learn, ensuring multiple "basic" procedures to master repetitively in order for the student to advance. The ACGME (Accreditation Council for Graduate Medical Education) has invested in residency training that examines technical skills and assesses acquired skills by utilizing these traditions yet simultaneously incorporating the advances in simulation medicine to give the learner the best holistic approach to their training.

The desired training simulation model is one that is reliable, practical, affordable, reproducible, and realistic. Simulation allows for identification of resident skill set in a controlled environment which permits mistakes without directly affecting a patient's health. With the current simulators currently available, residency programs can customize training sessions according to their desired curriculum.

Summary and Conclusions

Changes in surgical practice coupled with training work-hour restrictions have resulted in surgeons who, upon finishing training, may not be fully prepared to independently perform a number of open surgical procedures, which have historically been managed by the "general surgeon." As it is unlikely that the current work-hour restrictions will be lifted, surgical educators must take it upon themselves to train residents in open surgical skills using novel, efficient, and cost-effective ways. A large part of the solution to this problem may very well be the expanded use of simulation technologies. As we look to the future, it is most likely that live tissue models will play less of a role and that cadavers (perfused and unperfused) will not be able to fully meet the demand. As such, simulation should and will take on an increasing role in the training of surgeons to perform open surgical procedures. It is entirely possible that virtual reality/computer-based simulators will be able to fill some of this currently unmet need, but in spite of significant advances in technology, there are no models available currently that provide realistic replication of open surgery for training. There are still a number of currently available human tissue and physical models which realistically replicate human anatomy enable training on a number of open surgical skills, required of a well-rounded general surgeon. Nevertheless, insufficient attention has been directed toward the development and application of high-fidelity simulation models for resident training in complex open procedures. The cost of these technologies is a significant barrier, and there is no current mandate to utilize these technologies. It is likely that the quality of tissues used in these physical models will continue to improve and that the nascent 3D printing industry will develop materials that can be used in collaboration with medical simulation experts to create realistic models that can be used to teach open surgical skills in a cost-effective fashion.

There is a clear need for simulation training of open skills. This will require the continued development of clinically relevant open simulation models. Furthermore, the effectiveness of such models for skill acquisition, the transfer of skills to the operating room, and the retention of such skills over time will have to be demonstrated before wide spread use.

With proper focus and expansion of this exciting technology, one can envision a future in which surgical trainees are able to practice to proficiency essential open surgical operations on models that are near replicas of living human anatomy and physiology. Such models would have the potential of having multiple pathologies and common anatomical anomalies as well as replication of a specific patient's pathology to allow practice just prior to operating on that patient. Dedicated effort and investment of resources toward this problem will likely pay long-term dividends in terms of improved patient outcomes.

Disclaimer The views expressed herein are those of the authors and are not to be construed as official or reflecting the views of the Department of Defense, the Uniformed Services University, or the US government. The authors have nothing to disclose.

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Simulation in Laparoscopic Surgery

Anjali A. Gresens and Rebecca C. Britt

How Simulation Is Currently Used in Laparoscopic Surgery (Technical and Nontechnical)?

Halsted's apprenticeship model of surgical training is no longer the norm. Time constraints on trainees, costs, and concerns about patient safety have forced educators to rethink the traditional paradigm [1–5]. Stunt and colleagues summarize the four reasons to incorporate simulators into surgical training: improved educational experience, patient safety, cost-efficiency, and ability to assess performance and progress [6]. As a result, simulation has become an adjunct to the apprentice-type model in surgery and skills testing on a simulator is required for board certification. In the setting of reduced work hours, simulators are integral in residency training for laparoscopic surgery. Several studies focusing on laparoscopic surgery have shown that simulation shortens the learning curve from novice to expert and improves operative performance [4, 5, 7, 8]. Simulation can benefit a surgeon in any stage of training, as uncommon scenarios and complex skills can be practiced in a safe environment without impacting patient safety.

In current surgical education, trainees are expected to have basic laparoscopic skills prior to participating in a laparoscopic surgery. Operating room time is simply too valuable to spend on rudimentary skill acquisition, and it poses an unnecessary risk to patient safety [1, 9]. These skills are not innate and must be learned. While students can practice knot-tying and suturing anywhere and at any time, laparoscopic skills require dedicated time, simulators, and trainers, and a substantial learning curve [10]. Unlike open surgery, laparoscopy encompasses the special challenges of impaired depth perception, altered tactile feedback, and fixed instruments on a fulcrum [9, 10]. Learners must master hand-eye coordination, spatial orientation, and tissue handling as they pertain to laparoscopy. To accomplish these tasks, programs are developing simulation labs for resident training outside of the operating room, and an increasing number of programs are providing trainers for home use.

Laparoscopic surgery is uniquely suited to simulation, as it requires cameras, computer monitors, and specialized instruments on which learners must be trained. Surgical educators across the country partnered with the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) to develop the Fundamentals of Laparoscopic Surgery (FLS) curriculum. FLS combines technical skills with cognitive and decision-making abilities to assure all learners have the basic core competencies needed to perform laparoscopy [11]. Nationally, the American Board of Surgery (ABS) has seen the value of simulation training in laparoscopy and has mandated that all surgeons seeking certification must successfully pass the FLS curriculum.

What Is the State of the Art?

Several simulators currently exist on the market for laparoscopic surgery. Many researchers have sought to identify the best laparoscopic simulator available, and no single device has been named. In general, the requirements for a laparoscopic simulator include cost-effectiveness, accessibility, construct validity, translation to the operating room and across procedures, and the ability to differentiate novice from expert [12]. Simulators are created to teach laparoscopic competency. These attributes include accuracy, precision, tissue handling, hand-eye dissociation, fixed entry point, and altered tactile sensation [10]. Various modalities are presently used, all with advantages and disadvantages.

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Box Trainers

The most basic laparoscopic skills can be learned and practiced on a box trainer. Both commercial and home-assembled models are currently being used, ranging in cost from $5 to over $100 [10]. These simulators consist of a box to mimic a patient's abdomen, a simple stationary camera and monitor, and two ports for instrument use. At-home models often incorporate the use of a laptop computer for the camera and monitor aspect. The laparoscopic ports and instruments are the same or similar to those used in the operating room. The most basic box trainers teach rudimentary laparoscopic skills to neophytes in the form of spatial orientation and hand-eye coordination. These skills are learned with picking up and moving objects from one place to another and coordinating movements between instruments. Once accomplished, the learner can move on to further their dexterity and tissue handling abilities with tasks such as cutting a circle out of gauze or suturing. Metrics for assessing performance include speed, accuracy, and precision. The FLS program is well suited to the box trainer, as the goal is to teach critical principles and skills.

These box trainer simulators are simple and low-fidelity, but teach perhaps the most essential laparoscopic skills. A trainee's initial exposure to laparoscopy is often on one of these trainers. They are inexpensive to assemble and maintain and provide a structured, low-risk environment for the learners. Most importantly, box trainers provide real-world haptic feedback that can be lacking in other simulator modalities. While one box trainer is not superior to another, there are standardized FLS box trainers used across the country for testing purposes. Box trainers have repeatedly been shown to improve technical skills of trainees when compared to trainees without prior laparoscopic experience [13, 14].

Laparoscopic Towers

More sophisticated than the box trainer is the laparoscopic tower, which is technically a more advanced type of box trainer. These towers are often composed of the same equipment as used in the operating room. Components include: a box to mimic a patient's abdomen, a laparoscopic light source, a laparoscopic camera and monitor, and three or more ports (one dedicated to camera use). Trainees are taught how to assemble and troubleshoot the components of the light source and camera. They are also taught the more advanced concepts of spatial orientation with angled lenses. These tower trainers will require an assistant to hold the camera or, alternatively, a camera-holding apparatus that the trainee can manipulate that holds the camera steady while the trainee operates. These trainers are for the more developed laparoscopists and teach the learner how to maneuver around the abdomen, working in multiple quadrants. However, they may also be used to teach the same basic skills as the simple box trainer. In addition, these laparoscopic tower trainers can be utilized to teach appropriate port placement.

As expected, the tower trainers are more costly than the simple box trainers. Not only is the equipment expensive and with multiple components, but it also must be maintained. While tasks could be limited to peg transfer and suturing, more advanced skills could be practiced with the use of animal organs or plastic organ models. Learners can easily practice cholecystectomy or colon resection on these trainers if the materials are made available. Due to the high costs of equipment and materials, these trainers are generally stationary and kept in a secure place, decreasing accessibility.

Virtual Reality Simulators

Virtual reality (VR) simulators also have a place in the laparoscopic simulation training. Ideally, these VR trainers are designed for the learners most advanced in laparoscopy. VR computer simulators fail to adequately provide tactile feedback, and as such are ineffective simulators for novice learners when teaching respect for tissue and tissue handling [12]. However, while the box trainers and towers can provide more realistic skills training, they are generally not procedure-specific [15, 16]. The computer-based models are well matched to this procedure-based simulation. For example, the trainee may practice the principles of laparoscopic cholecystectomy and simulate a procedure before actually seeing one in the operating room. Vast numbers of procedures can be included on one computer trainer, encompassing General Surgery, Colorectal Surgery, Gynecology, Urology, and other specialties. Advanced laparoscopists also benefit by simulating a rare procedure prior to performing it in the operating room, such as laparoscopic adrenalectomy. With the advances in virtual reality, these computer-based simulators may even be able to simulate a specific patient based on reconstructions from a CT scan.

Current VR simulators include Simbionix Lap Mentor, ProMIS by Haptica, Immersion Medical Lap VR, and iSurgical's i-Sim. All are costly and as such may be inaccessible to many learners for routine use. These high-fidelity models are often only found in a simulation center. The trade-off, however, is that these VR simulators can provide an unlimited number of realistic operating room scenarios in a low-risk setting that does not impact patient safety. In addition, they can provide standardized computer evaluation, document metrics, and provide performance logs, which cannot be done with box trainers. Skills acquired on VR models have shown to be translatable to the operating room and improve overall surgical skills [15].

Animal and Cadaveric Models

Less common in laparoscopic simulation is the use of animal and cadaveric models. When available, these models provide the most realistic simulation outside of a real operating room. All levels of learners can gain something from access to these simulators. Novices can practice port placement, camera skills, and hand-eye coordination, while advanced learners can perform real procedures in an environment that protects patient safety. Learners may also practice the management of complications in real time, which is ideally suited to this setting. The downside of animal and cadaver simulation remains availability and costs associated with their usage.

Generally, animal and cadaver labs are only used in an arena where multiple types of learners can have exposure, as to not waste any educational experiences. For example, a laparoscopic cholecystectomy may be performed by General Surgery, followed by a laparoscopic hysterectomy performed by Gynecology, followed by a laparoscopic nephrectomy performed by Urology. For cadaver models, specific embalming techniques must be employed to maintain flexibility and allow for insufflation. In live animal models, veterinary assistance and anesthesia are required. Therefore, only specialized centers have the capabilities to provide access to this type of simulator.

Comprehensive Simulation Centers

Researchers have attempted to determine which type of simulator is the ideal for laparoscopic surgery education. Zendejas et al. suggested that box trainer simulators had somewhat superior learner satisfaction and improved task times compared to VR simulators [7]. However, the overwhelming conclusion is that no single simulator has been determined as the gold standard and that the various simulators are complementary [16, 17]. Thus, state of the art in laparoscopic simulation is a comprehensive simulation center that includes a variety of simulators to benefit all skill levels and specialties, from novice to expert surgeon. Box trainers, laparoscopic towers, VR simulators, and animal models all have a place in laparoscopic surgery curricula.

A successful center must include dedicated staff for support and upkeep, easy and convenient access for learners, and equipment that is translatable to the operating room setting [18]. The American College of Surgeons Accredited Education Institutes have helped to create and develop guidelines for simulation centers across the country [19]. Dedicated educators and funds must be provided from the facility and dedicated to a simulation center. Studies have shown that simulation is cost-effective in reducing operative time and decreasing waste [3].

In addition, a comprehensive simulation center should include a cross-specialty training program for laparoscopy [17]. Experienced surgeons from all specialties should be included in teaching their trainees in the simulation center. This “buy-in” of faculty allows attending surgeons to evaluate the trainees prior to working with them in the operating room. Specific specialty-based skills can also be taught in this setting. Faculty oversight may avoid trainees from developing bad habits, which are more difficult to correct once learned. Trainees may even find a mentor through this experience, benefitting both parties. In addition, the other benefit to a cross-specialty center is the reduction of material costs and the increase of time the facility is used, thereby making it more cost-effective [17].

What Curricula Exist at a National Level?

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) launched the Fundamentals of Laparoscopic Surgery program in October 2004. Prior to the development of this program, there were no curricula present at the national level to teach or standardize the practice of laparoscopic surgery. At that time, surgeons attended courses and took their knowledge back to their communities to become credentialed in laparoscopic surgery. The late 1990s was the advent of laparoscopic surgery. As it became more popular and grew in communities internationally, there became a need for teaching basic laparoscopic skills and standardizing training programs. The vision was to create a curriculum that would encompass manual skills, technical knowledge, and surgical decision-making. A box trainer was developed that was inexpensive and accessible. Once the cognitive aspect of the program was developed and the basic laparoscopic skills were identified, SAGES began beta testing the program in several sites across the country. A high-stakes exam was also developed to give the program more credibility. SAGES partnered with the American College of Surgeons (ACS) in 2005 to increase visibility of the FLS program and bring it to a national stage. Ultimately, the American Board of Surgery mandated that the FLS program be included in the requirements for board certification starting in 2009 [11, 20].

The FLS program has become the benchmark of curricular surgical training for residency education in America. As of 2014, 10 years after the rollout of the FLS program, over 9000 surgical residents, fellows, and participating physicians have completed the program. There are more than 150 different testing locations across the United States and Canada, and it is gaining popularity around the globe. Overall FLS certification pass rates were 88% when examined in 2009, with 93% pass rate on the cognitive portion and 92% pass rate on the technical skills aspect. Within the past few years, SAGES and the ACS have recommended that all surgeons who perform laparoscopy should have successfully completed the FLS program [11, 20].

How Is This Field Uniquely Applying Simulation for Training that Others Should Learn from?

Laparoscopy is uniquely suited to simulation, as it has evolved rapidly alongside technology, especially with developments in the gaming and movie industries. High-definition devices and virtual reality simulators have become mainstream and are now available to the general public. In fact, many of these devices are even portable and handheld. As a result, laparoscopic simulation has developed into in-home simulators that are easily accessible. The techniques and skills are translatable across procedures and specialties. Open operations that used to be the "bread and butter" of surgery are being replaced by laparoscopic surgeries. As such, the demand for simulation in the field of laparoscopic surgery is growing exponentially. Many centers have even created virtual operating rooms that incorporate laparoscopic trainers and virtual reality to simulate patient scenarios, which may be used for a single-learner or team training.

Stated previously, the Fundamentals of Laparoscopic Surgery program is distinctive to the field of simulation. It was the first education program with validity evidence to show that skills learned outside of the operating room could be directly translated into surgical skills inside the operating room. The American Board of Surgery has included FLS as a core competency for General Surgery education. Successfully completing the course is now required for their board certification. Healthcare stakeholders have also taken an interest in standardized testing, resulting in some hospitals requiring FLS before granting laparoscopic privileges.

While General Surgery has embraced laparoscopic simulation training through the FLS program, other specialties should and will likely follow suit. FLS training would be beneficial for other specialties and subspecialties such as Gynecology and Urology. In addition, the FLS curriculum paves the way for additional simulation programs to be developed in other arenas. SAGES has started to roll out similar programs for endoscopic surgery and surgical energy, which will soon also be required for ABS certification. The main purpose is to provide a standardized and measured metric for surgical education where trainees may gain skills in a structured, safe, and low-risk environment that does not affect patient safety. The field of robotic surgery is also following suit and is beyond the scope of this chapter.

The American College of Surgeons Accredited Education Institutes (ACS-AEI) program was created in 2005. Since its inception, the consortium has worked to set the standards for surgical education and training. In response, several programs have developed comprehensive simulation centers [19]. While these centers are not limited to laparoscopic simulation, all centers include training boxes for FLS programs and incorporate other simulators to further the laparoscopic skills of their trainees. As the field of minimally invasive surgery (MIS) and advanced laparoscopic surgery grows and evolves, further simulators for innovative laparoscopic techniques will be necessary. Currently, there are over 150 MIS fellowship programs across the country, an increase of 87.5% in the past 10 years [21].

What Are Next Steps that Are Needed in This Field?

Simulation in laparoscopic surgery is still in its infancy. Further research and development is needed in several areas: access to simulators, procedure-based simulators, and resident time investment [18]. As work hour restrictions have begun to limit the time residents spend in the operating room, the laparoscopic community must address all of these above challenges. Residents will need access to simulators either in their home or in a 24-h simulation center. It is vital that they practice their skills with the same equipment, sutures, and instruments as in the operating room. At the very least, the equipment and box trainers must be translatable to the operating room so that proper technique and skills acquisition can be fostered.

Programs will continue to adapt to the changing work hour environment and impress the importance of simulation training to their learners. Investment of time on a simulator will be vital to the development of their skills in the operating theater. There is even discussion regarding a competency-based curriculum rather than a traditional time-based 5-year curriculum. Competency-based programs in Canada have piloted this type of training and have shown some promising results. While costs of simulation and faculty are higher, training and skill acquisition may be expedited [22, 23]. Cost-benefit analyses must be done before this educational model becomes mainstream, but it represents the paradigm shift in current surgical training. Simulation is imperative for learning in this setting and may pave the way for procedure-based simulators. Even in the traditional arena, procedure-based simulators are becoming important as certain operations are becoming regionalized or less common.

As of 2012, the ABS requires faculty assessment of resident intraoperative performance, but this metric is not yet standardized nor based on patient outcomes. Further research must be done to evaluate clinical outcomes once trainees reach competency to operate on patients, looking at decreased operating room time, cost savings, and patient safety [13]. The future of MIS will go beyond simulators and validation studies and lie with the development of evidence-based comprehensive surgical skills curricula, to the benefit of surgical trainees and their patients [9].

The Fundamentals of Laparoscopic Surgery program has room to grow and develop. Currently, it is only a mandated curriculum for General Surgery. However, laparoscopic surgery has expanded greatly in the fields of Gynecology, Urology, and other surgical subspecialties, and they would also benefit from this FLS training. Moreover, efforts are underway to make the FLS curriculum accessible and available to surgeons worldwide. Global outreach is already underway in translating the didactic online curriculum into Spanish and other languages. Finally, the FLS program is just the first step in effective laparoscopic simulation training. It opens the door for the creation of new programs to teach advanced laparoscopic skills, or even procedure-specific skills, in a measured and standardized approach [9, 11, 20].

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Simulation in Robotic Surgery

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History of Robotic Virtual Simulation

Virtual reality (VR) simulation for robotic-assisted surgery begins with Rick Satava, MD, FACS, who presented Mimic Technologies Inc. with an ideal project in 2002 after years of advocating for growth. Mimic was still a relatively new company at the time, having only incorporated in March of the previous year. Up to this point, they had developed a TURP (transurethral resection of the prostate) simulator in conjunction with what was at the time Simbionix (now 3D Systems) and were looking for new avenues of development. Mimic and Satava applied for and received funding from the Defense Advanced Research Projects Agency (DARPA) to create VR simulation for Computer Motion's ZEUS robot.

Yulun Wang, PhD, started Computer Motion in 1993 with DARPA funding as well. He was able to build a robotic arm to hold a laparoscopic camera, the Automated Endoscopic System for Optimal Positioning (AESOP). Computer Motion continued development, eventually funded through the commercial sector, to create ZEUS – an integrated and wristed laparoscopic robot.

By the time Mimic's funding was received in 2003, Computer Motion had merged with Intuitive, and the ZEUS was phased out of production. Intuitive allowed Mimic to begin developing simulation for their da Vinci Surgical System instead and provided assistance with instrument models and prospective cannula placement.

The first version of Mimic's simulator consisted of a computer rigged to display VR software through the da Vinci's stereoscope, taking in data through the master controllers and foot pedals of the surgeon console. Mimic's initial software presented some issues in the complexity of their first simulation – the anastomosis portion of a robotic-assisted prostatectomy. This first attempt was not well received, as it tested the culmination of years of experience when for many users of the new technology, the fundamentals had yet to be mastered. It was clear that revision was necessary, and from then Mimic's focus shifted to the rudiments of robotic handling.

Starting with the first prototype in 2007, Mimic spent 4 years setting benchmarks and beta testing the device. After validation as a training tool in 2008, the first VR simulator, dV-Trainer, became commercially available in 2010 (Fig. 1) [1]. Instead of piggybacking off of the da Vinci's surgeon console, the dV-Trainer is a stand-alone unit that sits on an adjustable table top with a board of foot pedals below. In the ensuing years, Mimic has released updated graphics and over 300 exercises. The hardware has changed very little, other than improving integrity of the simulated master controller gimbals. The robotic community has since realized the shortage of procedure-specific training that Mimic initially attempted to supply [2, 3]. As a result, Mimic returned to developing procedural simulation by utilizing three-dimensional recordings of successful surgeries. The video was overlaid with augmented reality simulation for full-length procedures with choice-driven outcomes and is now available as Maestro AR. Interactive technology such as this reinforces knowledge and helps surgeons with skills such as retraction, suturing, and dissection, among others.

Though Mimic was on the frontlines of robotic VR simulation, they are not the only producer. The Robotic Surgery Simulator (RoSS) came out of the Center for Robotic Surgery at Roswell Park Cancer Institute in alliance with the University of Buffalo's School of Engineering and Applied Sciences in early 2010 and commercialized into Simulated

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Fig. 1 Early version of the dV-Trainer. (With permission of Mimic Technologies)

Surgical Systems LLC. RoSS' creation is due to Thenkurussi Kesavadas, PhD, and Khurshid Guru, MD, who made RoSS with the goal of being a long-overdue "flight simulator" for robotic surgeons [4]. RoSS is unique from the dV-T in its design of simulated linkage-based master controllers, and in that it is built as a single unit with integrated foot pedals and processing PC.

In December of 2010, Intuitive released the da Vinci Skills Simulator (dVSS, commonly referred to as the "backpack" since the simulator simply hooks on to the back of the surgeon console) in conjunction with the new da Vinci Si model. One of the many new features of the Si was the dual console capacity. The two surgeon consoles can be used simultaneously with the same slave patient-side cart, with one surgeon handing off tools to the other. Two consoles may not be necessary to complete a successful surgery, but offer unique teaching abilities for residents to play an active role in the case. Institutions could also choose to keep one console in the operating room (OR) for surgery and wheel the other out for simulation with the dVSS attached.

In early 2014 Intuitive released the da Vinci Xi and new Skills Simulator, complete with updated graphics and more advanced software. The Xi dVSS also has additional training modules from 3D Systems, formerly Simbionix, including full-length procedures and tutorials for new instrumentation, such as the EndoWrist Stapler and Vessel Sealer. There is also some customization available using Intuitive's Simulation Marketplace [5].

To further develop intraoperative skills, Mimic released the Xperience Team Trainer (XPT-Trainer) in 2014, a haptic-enabled laparoscopic platform that can also be used as first assistant training in robotic-assisted surgery. Communication with the surgeon, for tasks such as needle handoffs, retraction, energy application, and instrument exchange, is one of the most critical features that the XPT-Trainer can simulate. It also aids in training with accurate port placement, especially considering difficulties originating from the sheer bulk of the da Vinci [6].

The RobotiX Mentor from 3D Systems is the newest player to the field of robotic VR simulators. Released in 2014, it is a promising option for the Simbionix's LAP Mentor. The LAP Mentor can easily be connected with the RobotiX Mentor for team training, with a first assistant.

Comparison of Virtual Reality Simulators: What's Currently on the Market

This section provides comparative data on the functionality of the four commercially available robotic simulators shown in Fig. 2:

- da Vinci Skills Simulator (Intuitive Surgical Inc., Sunnyvale, CA)
- dV-Trainer (Mimic Technologies Inc., Seattle, WA)
- Robotic Surgery Simulator (Simulated Surgical Skills LLC, Williamsville, NY)
- RobotiX Mentor (3D Systems, Littleton, CO)

Each of these possesses unique traits which make them valuable solutions for different types of users and learning environments.

Features and Capabilities (Table 1)

da Vinci Skills Simulator (Intuitive Surgical Inc.)

The da Vinci Skills Simulator (dVSS) consists of a customized computer package that attaches to the back of the surgeon console of an actual da Vinci Si robot via a single fiber optic networking cable identical to that used to connect the components of the actual robotic surgical system.

Attached simulators of this type are usually referred to as "embedded trainers" because they take advantage of the equipment that has already been constructed, purchased, and installed for use of the real system. These kinds of simulators

Fig. 2 Robotic VR simulators: da Vinci Skills Simulator, dV-Trainer, RoSS, and RobotiX Mentor. (With permission of Intuitive Surgical Inc., Mimic Technologies, Simulated Surgical Systems, and 3D Systems, formerly Simbionix [5, 7–9])

are especially common in military facilities which face limited space and weight constraints. They can significantly reduce the hardware that must be purchased solely for simulation purposes. The US Navy uses these kinds of simulators aboard ships to reduce weight and space requirements, enabling them to train while the ship is at sea.

Another significant advantage of an attached simulator is that it allows the trainee to use the actual controls from the real system to drive the simulator. This insures that the training experience is almost identical in feel to the real system, which can contribute to higher transfer of skills from the training sessions to the real system. Additionally, this minimizes the amount of time spent learning the unique functionalities of the simulator device and allows the trainee to focus the majority of his/her learning experience on skills acquisition and proficiency development. Finally, there is the cost advantage for the simulator device itself. Because much of the hardware and software expenses are already embedded in

Table 1 Robotic simulator feature comparison

Features	dVSS	dV-Trainer	RoSS	RobotiX Mentor
System manufacturer	Intuitive Surgical Inc.	Mimic Technologies Inc.	Simulated Surgical Systems LLC	3D Systems (of Simbionix USA Corporation)
Specifications (simulator only)	Depth 7″ Height 25″ Width 23″ 120 or 240 V power	Depth 36″ Height 26″ Width 44″ 120 or 240 V power	Depth 44″ Height 77″ Width 45″ 120 or 240 V power	Depth 29″ Height 55″ Width 36″ 120 or 240 V power
Specifications (complete system as shown in Fig. 2)	Depth 41″ Height 65″ Width 40″ 120 or 240 V power	Depth 36″ Height 59″ Width 54″ 120 or 240 V power	Depth 44″ Height 77″ Width 45″ 120 or 240 V power	Depth 30″ Height 55″ Width 62″ 120 or 240 V power
Visual resolution	VGA 10124 × 768	VGA 1024 × 768	VGA 1024 × 768	HDMI 1920 × 1080
Components	Customized computer attached to da Vinci surgical console	Standard computer, visual system with hand controls, foot pedals	Single integrated custom simulation device	Self-contained works are unit, computer monitor, PC simulation processor
Support equipment	da Vinci surgical console, custom data cable	Adjustable table, touch screen monitor, keyboard, mouse, protective cover, custom shipping container	USB adapter, keyboard, mouse	Keyboard, mouse, power cable
Exercises	56 simulation exercises	70+ simulation exercises (for each robotic version)	52 simulation exercises	67 simulation exercises
Full-length procedures available	No	Yes	Yes	Yes
Optional software	PC-based simulation management	Mshare curriculum sharing web site	Video and haptics-based procedure exercises (HoST)	MentorLearn web management system
Optional team-training hardware	None	Xperience Team Trainer	None	LAP Mentor
Scoring method	Scaled 0–100% with passing thresholds in multiple skill areas	Proficiency-based point system with passing thresholds in multiple skill areas	Point system with passing thresholds in multiple skill areas	Proficiency-based point system with passing thresholds in multiple skill areas
Student data management	Custom control application for external PC. Export via USB memory stick	Export student data to delimited data file	Export student data to delimited data file	Export student data to delimited data file
Curriculum customization	None	Select any combination of exercises, set passing thresholds and conditions	Select specifically grouped exercises, set passing thresholds	Select any combination of exercises, set passing thresholds and conditions
Administrator functions	Create student accounts on external PC. Import via USB memory stick	Create student accounts. Customize curricula	Create student accounts. Customize curriculum	Create student accounts, customize curricula
System setup	None	Calibrate controls	Calibrate controls	None
System security	Student account ID and password	PC password, administrator password, student account ID and password	PC password, administrator password, student account ID and password	Student account ID and password

the real system, the simulator can be very economical to purchase.

Attached simulators like the dVSS also come with inherent disadvantages to balance their positive traits. The largest drawback is the availability and accessibility of a simulator which requires the real robotic system. An attached dVSS simulator cannot be used without access to an actual surgeon console and therefore is only available for use when the robotic system is not in use. This implies that the trainee would only be able to use the simulator outside of normal operating room working hours and would need logistical access to the robot and the simulator. da Vinci robots are expensive devices, costing upward of 2 million USD, which hospitals typically attempt to maximize use of it in order to recoup their investment. In a very active surgical hospital, it can be difficult to obtain access to a surgeon console to support training with this simulator.

The dVSS is designed to connect to the surgeon console using the same networking cable that connects the major robotic components. This makes the attachment and setup process very easy for clinicians to master. However, it also means that the dVSS can only be used with the model of surgeon console for which it was specifically designed. The previous models, including the S, use a different set of cables which are not compatible with the simulator, and the Xi has its own simulator that cannot be interchanged with the Si simulator.

Similar to the military's experience with embedded and attached simulators, heavy usage of the dVSS comes with a corresponding heavy use of the surgeon console. The Army and Navy have discovered that these types of simulators put more usage hours on real equipment controls which lead to more maintenance costs for those devices. Given the possibility of regular and continuous simulation training with such a device, in addition to actual surgical usage, the real equipment may experience usage rates that are many times higher than normal for the equipment. Since the da Vinci systems operate under a maintenance contract that covers most service costs, the additional costs of maintenance are not borne by the hospital owner but by the equipment vendor. The primary impact to the owner would only be in availability for both real surgeries and training events due to increased maintenance.

dV-Trainer (Mimic Technologies Inc.)

The dV-Trainer is a separate, stand-alone simulator of the da Vinci robot. The surgeon console, controls, and vision cart are mimicked in hardware, while a 3D software model replicates the functions of the robotic arms and the surgical space.

As Mimic also developed the core simulator software for the dVSS and used the same package in version 1.0 of their own dV-Trainer, this resulted in nearly identical exercises in the dVSS and version 1.0 of the dV-Trainer. The current version 3.0 of the dV-Trainer has a number of new exercises, which are not found in the dVSS, and the graphics have been upgraded, so the visual presentation is no longer identical. The differences in visual presentation can be seen in Figs. 3, 4 and 5.

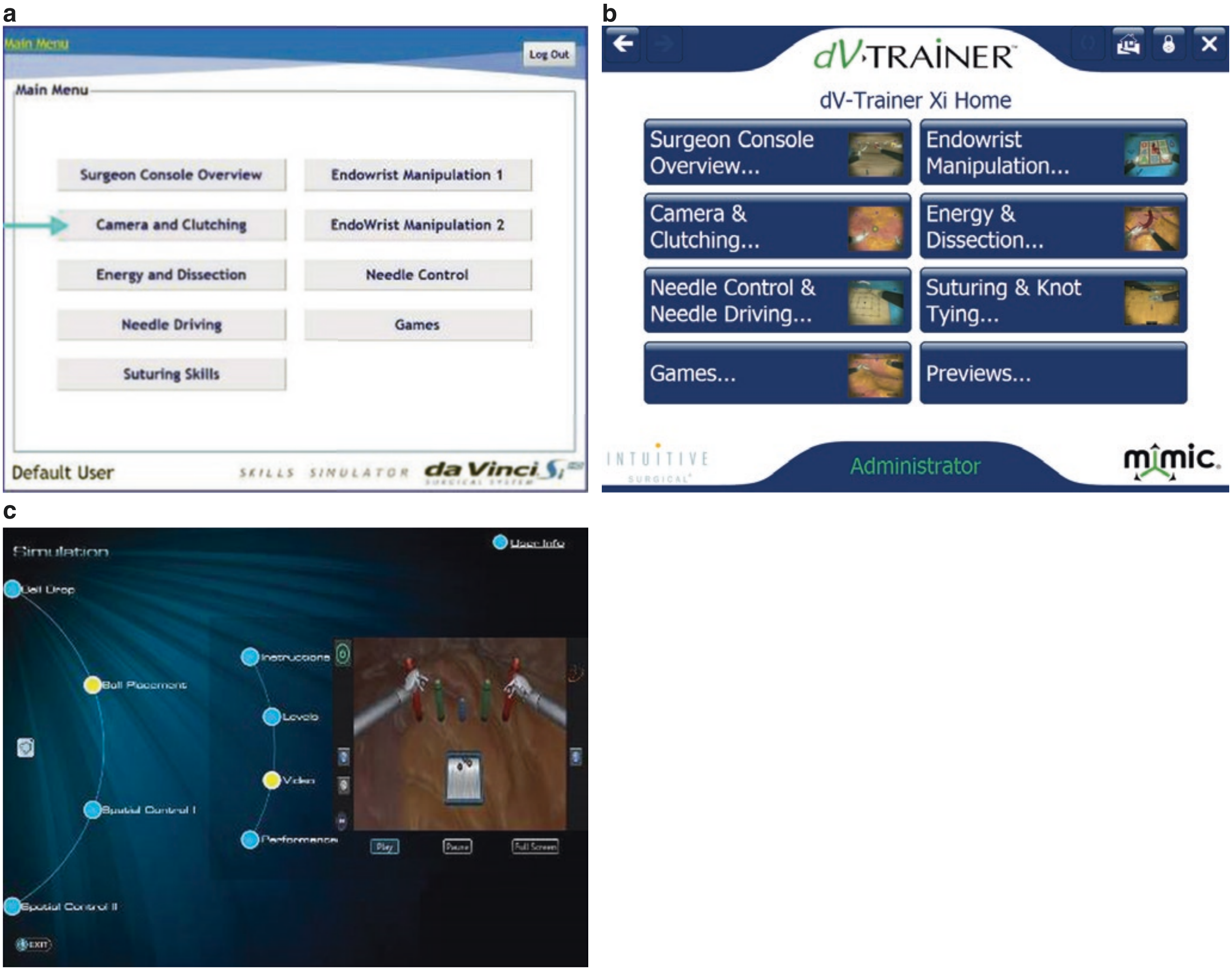
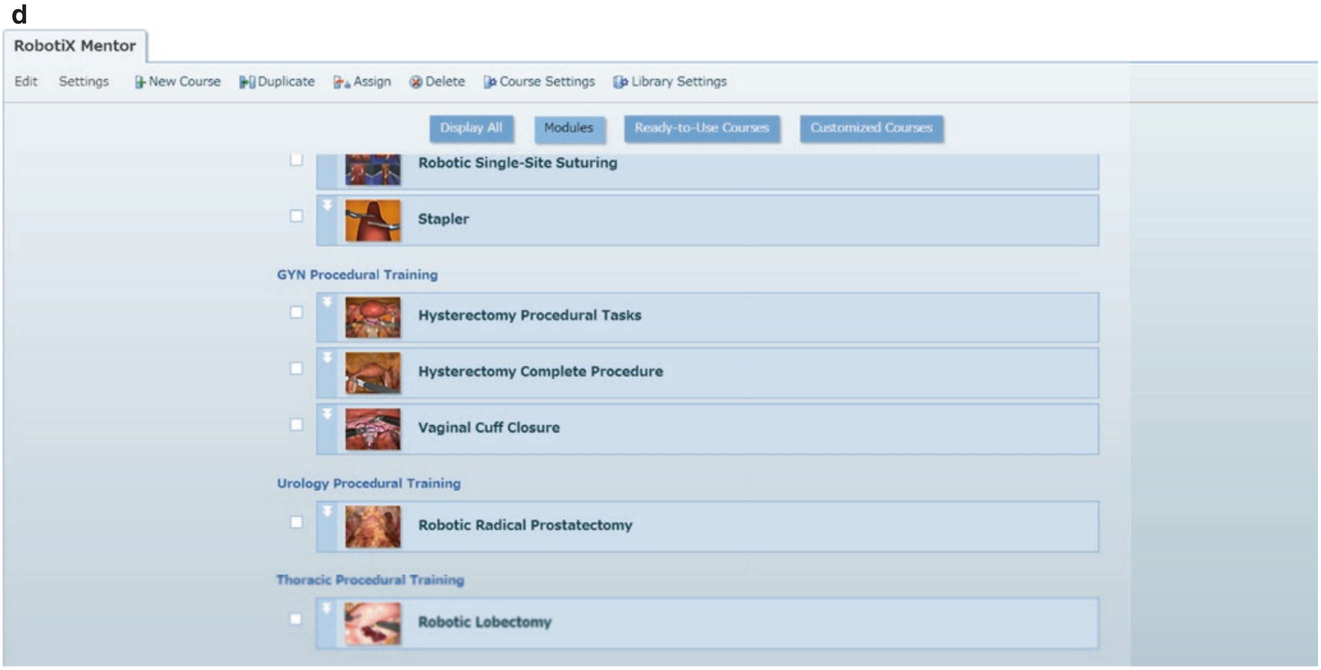


Fig. 3 Comparative simulator exercise menus. (With permission of Intuitive Surgical Inc., Mimic Technologies, Simulated Surgical Systems, and 3D Systems, formerly Simbionix [5, 7–9])



☐ Robotic Single-Site Suturing

☐ Stapler

GYN Procedural Training

☐ Hysterectomy Procedural Tasks

☐ Hysterectomy Complete Procedure

☐ Vaginal Cuff Closure

Urology Procedural Training

☐ Robotic Radical Prostatectomy

Thoracic Procedural Training

☐ Robotic Lobectomy

Fig. 3 (continued)

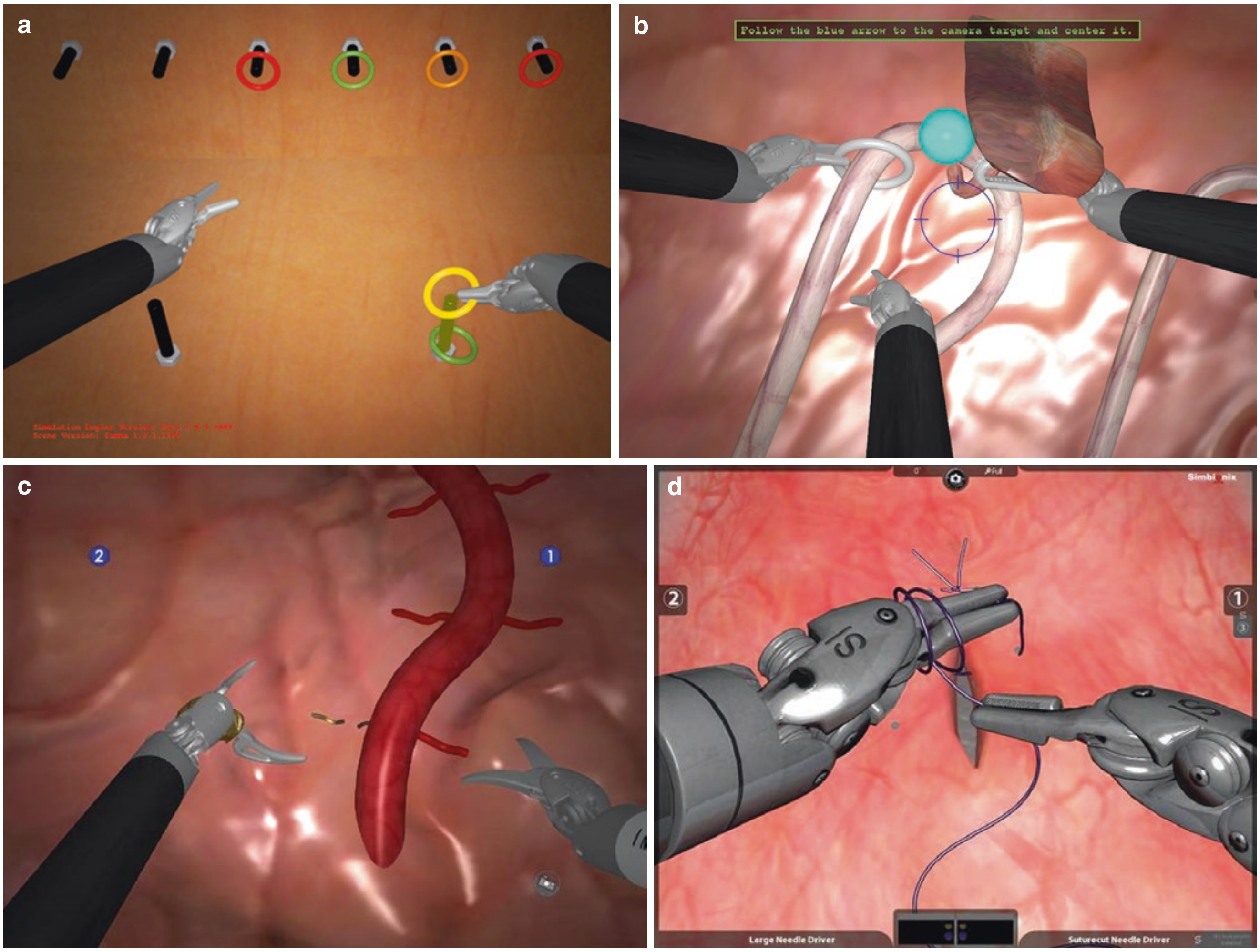


Fig. 4 Selected dVSS exercise images. (Source: Intuitive Surgical Inc. [5])

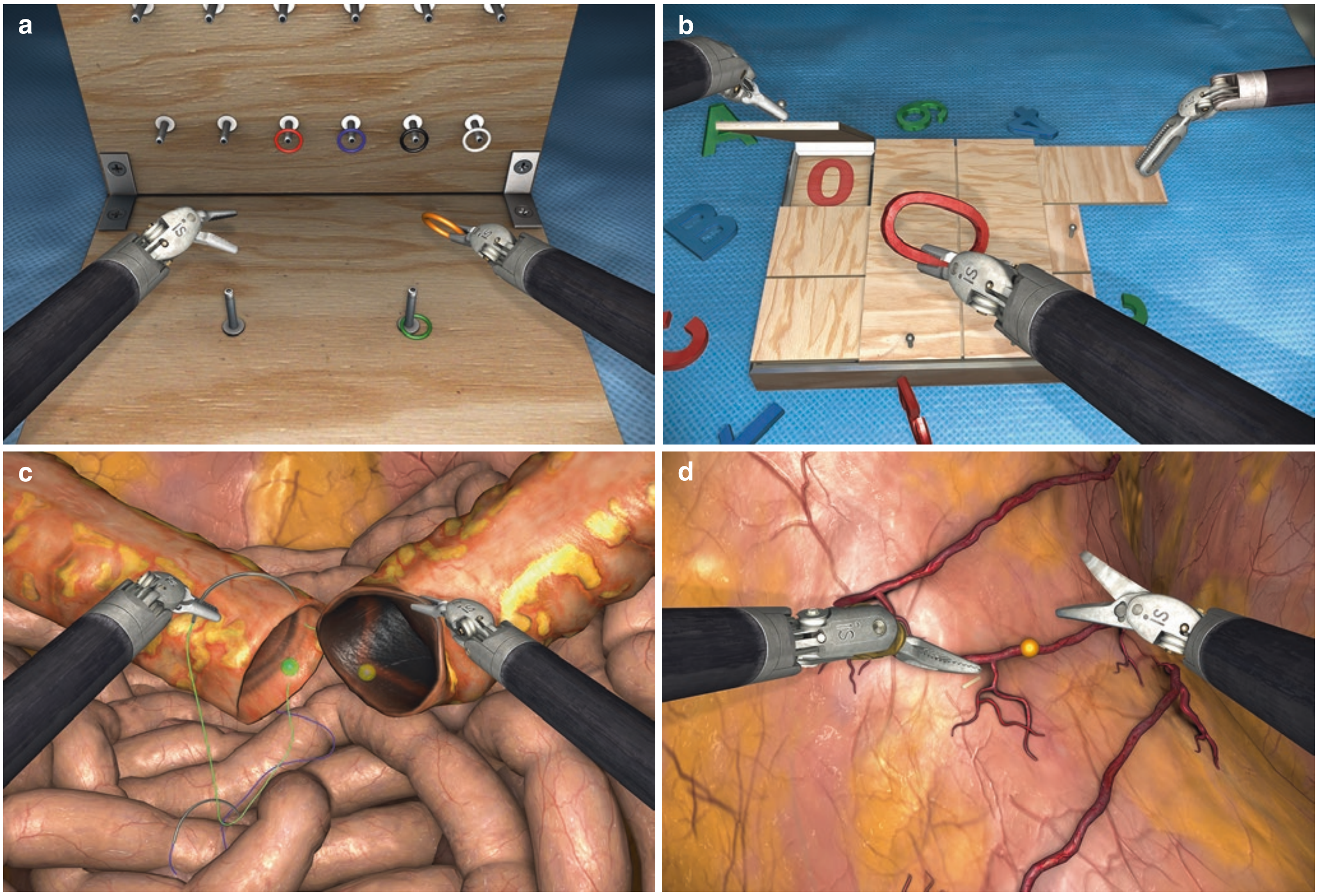


Fig. 5 Selected dV-Trainer exercise images. (With permission of Mimic Technologies [7])

The dV-Trainer consists of three major pieces of equipment and a number of smaller support pieces. The largest pieces are the "Phantom" hood which replicates the vision and hand controls of the da Vinci surgeon console, the foot pedals of the surgeon console, and a high-performance desktop computer which generates the 3D images and calculates the interactions with the surgeon's controls. Smaller support equipment includes a touch screen monitor, keyboard, and mouse to enable an instructor to guide the student through exercises and allow an administrator to manage the data that is collected.

Because the dV-Trainer replicates both the hardware and software of the da Vinci robot, it is a much larger system than the dVSS alone, though smaller than a real surgeon console with the dVSS attached. It has the advantage of providing a training system that is completely independent of the need for any piece of the real surgical robot. The simulator can be configured to imitate the S, Si, or Xi model of the da Vinci robot.

The disadvantage of this kind of system is that the simulated hardware is different from the real equipment and does not exactly replicate the feel of the real robotic equipment. The dV-Trainer uses its own unique hand controls which are connected to three cables for measuring movement, rather than the more precise arms that are used in the da Vinci robot. The dV-Trainer foot pedals look and function almost identically to the robotic foot pedals.

Robotic Surgical System (Simulated Surgical Systems LLC)

The Robotic Surgical System (RoSS) is also a complete, stand-alone simulator of the da Vinci robot. This device is designed as a single piece of hardware that has a similar appearance to the surgeon console of the robot. The hardware device includes a single 3D computer monitor, hand controls that are modified commercial force feedback devices, pedals that replicate either the S or the Si model of the da Vinci robot, and an external monitor for the instructor. The simulator can be configured to imitate either the S or the Si model of the da Vinci robot.

The hand controls are modified SensAble Omni Phantom™, force feedback, 3D space controllers (3D Systems Inc., Rock Hill, SC). These devices have a much smaller range of motion than the controllers on the da Vinci robot and so require more frequent clutching than the actual robot. The 3D image is generated by a single computer monitor with polarized glasses, which generates a visual scene with less depth of field than the actual robot.

The company has developed a set of 3D virtual exercises that are unique from those found in both of the other simulators. They also provide optional video-based surgical exercises, called HoST modules, in which the user is guided through the movements necessary to complete an actual surgical procedure. At this writing, these modules are available for radical prostatectomy, hysterectomy, and cystectomy. These guided videos take advantage of the force feedback capabilities of the hand controllers to push and pull the student's hands to follow the simulated instruments on the screen. They require the student to perform specific movements accurately during the video before the operation will proceed.

RobotiX Mentor (3D Systems, Cleveland, OH)

The RobotiX Mentor is a stand-alone simulator as is RoSS and the dV-Trainer, but takes a novel approach to simulating the physical surgeon console. Whereas the dV-Trainer uses a system of cable-driven master controllers and RoSS uses a robotic arm, the RobotiX Mentor does away with any motion hindering system whatsoever. The master controllers are free floating, with only tensionless cables connecting them to the console unit. Issues with jamming cables or too much tension are eliminated. The fully adjustable stereo viewer and foot pedals function similarly to the da Vinci's.

There are two main components: a self-contained workspace unit that functions as a simulated surgeon console and a tower with computer monitor, PC and simulator processor, keyboard, and mouse. From the tower, groups can view ongoing simulation; administrators can load and evaluate specific metrics and monitor curriculum completion status. The tower can be a shared resource between the RobotiX Mentor and LAP Mentor simulators if a facility has both pieces of technology available.

Some of the exercises found on the RobotiX Mentor are the same as those on the dVSS, as Simbionix contributed to the suturing skills available. The majority of those available however are novel to the device, the most exciting of which are full-length, as well as segmented and guided, procedures. Here, novice surgeons can practice anatomy recognition and learn how to perform advanced skills, while more advanced surgeons can prepare for clinical cases.

Exercise Modules

Each simulator allows an administrator or instructor to manage and organize student performance according to unique login credentials for the student. Alternatively, they all have a universal "guest" account to make the system accessible to anyone, but without the ability to uniquely identify and track the performance of a specific student.

Once logged into each system, the instructor or the student navigates the instructional materials using the menu systems illustrated in Fig. 3. Since the Intuitive Skills Simulator (dVSS) and the Mimic dV-Trainer provide very similar exercises and organizations, the navigation through the exercises is similar in form, though different in visual appearance. The RobotiX Mentor has a similarly tabbed and indexed exercise library. The RoSS simulator uses a very unique arced orbital menu for progressing through exercises.

Each simulator provides on-system instructions for every exercise in the form of textual documents and video demonstrations with spoken audible instructions.

dVSS

The dVSS contains 45 exercises organized into 9 categories (Table 2). These begin with introductory video and audio instructions on how to use the robotic equipment and move through progressively more difficult skills.

To prepare the student for success in each exercise, the simulator offers written instructions on the objective of each exercise prior to performance. There is also a narrated video of an instructor performing the exercise while explaining the necessary steps. Upon completion of each exercise, the system automatically proceeds to a scoreboard showing the student's performance on the exercise. Details on the scoring systems of each simulator are discussed later on.

Figure 4 presents screenshots of some of the key exercises in the simulator. These include the Ringboard, Ring Walk, Energy Dissection, and Interrupted Suturing exercises. The suturing exercises on this simulator were developed by Simbionix USA Inc. (Cleveland, OH, now 3D Systems) for integration into the dVSS. This expansion of the system demonstrates the ability of the simulator platform to blend together exercises and scoring systems created by multiple independent vendors.

Table 2 dVSS exercise categories

Surgeon console overview	An introduction to the controls of the da Vinci robot
EndoWrist manipulation 1	Basic hand movements and usage of the wristed instruments
Camera and clutching	Basic foot clutching for both the camera and the third arm
EndoWrist manipulation 2	Intermediate use of the hands and wristed instruments
Energy and dissection	Use of the energy pedals and associated instruments
Needle control	Focused exercises for dexterous manipulation of a curved surgical needle
Needle driving	Repetitive exercises for needle driving
Games	Challenging and entertaining game environments to apply the skills learned
Suturing skills	Suturing exercises with needle, following suture, knot tying, and tissue closure

dV-Trainer

Most of the simulation software for Intuitive's initial dVSS was developed by Mimic Technologies. Therefore, version 1.0 of the dVSS and the dV-Trainer contained nearly identical exercises, closely matching menu systems, and identical scoring mechanisms. However, over time the two sets of software have diverged and the current versions of the simulators differ in functionality and appearance. The current version of the dV-Trainer (v 3.0) contains over 70 exercises organized into 9 categories.

The dV-Trainer is also the only system compatible for the S, Si, and Xi versions of the da Vinci robot. To compensate for the different foot pedals between the S and Si, Mimic produces exchangeable pedal boards. There are over 70 exercises for each version, meaning that for all 3 systems, there are upward of 300 including full-length procedures and guided procedural training modules.

Though many of the exercises are identical between the dVSS and the dV-Trainer, the graphics resolution and details have been improved in version 3.0 of the dV-Trainer software. Since this system is driven by a commercial PC which can be upgraded easily, it is possible for the hardware and software to evolve as newer computer technologies are available (Table 3).

Just as with the dVSS, the dV-Trainer simulator offers written instructions on the objective of each exercise prior to performance. There is also a narrated video of an instructor performing the exercise while explaining the necessary steps. Upon completion of each exercise, the system automatically proceeds to a scoreboard showing the student's performance on the exercise.

Figure 5 presents screenshots of some of the key exercises in the dV-Trainer simulator. These include the Ringboard, Matchboard, Tubal Anastomosis, and Energy Switching exercises.

RoSS

The RoSS simulator contains 52 unique exercises, organized into 5 categories and arranged from introductory to more advanced (Table 4), just as in the other 2 simulators. The RoSS system of exercises is unique in that they list fewer exercises, but provide three different difficulty levels for most of them where each level is actually a unique exercise.

Table 3 dV-Trainer exercise categories

Surgeon console overview	An introduction to the controls of the da Vinci robot
EndoWrist manipulation	Basic and intermediate use of the hand controllers and wristed instruments
Camera and clutching	Basic foot clutching for both the camera and the third arm
Energy and dissection	Use of the energy pedals and associated instruments
Needle control and needle driving	Focused exercises for dexterous manipulation of a curved surgical needle, with repetitive exercises for needle driving
Games	Challenging and entertaining game environments to apply the skills learned
Suturing and knot tying	Suturing exercises with needle, following suture, knot tying, and tissue closure

Table 4 RoSS exercise categories

Orientation module	Introduction to the surgeon controls of the da Vinci robot
Motor skills	Development of precise controls of the instruments, including spatial awareness
Basic surgical skills	Instruction on handling a needle, using electrocautery pedals and instruments, and the use of scissors on the robot
Intermediate surgical skills	Control of the fourth arm, blunt tissue dissection, and vessel dissection
Hands-on surgical training	Video and haptic-guided instruction through specific surgical procedures

Similar to the other simulators, the RoSS includes a narrated video showing an instructor performing the exercise. Upon completion of an exercise, the simulator automatically proceeds to the scoreboard for the exercise.

The RoSS contains a unique capability that is not found in either of the other simulators called "Hands-on Surgical Training" or "HoST." This is an integration of surgical skills exercises with a video of an actual surgery. Videos of actual surgical procedures play in the surgeon's visual space, overlaid with animated icons which instruct the student to perform specific actions during the progression of the surgery video. The necessary actions are prompted with audio instructions. For the HoST exercise to progress, the student must perform the specific actions at specific times. The simulator will pause the video and allow the student to repeat the action until it is performed as required by the instructions.

The hand controllers of the RoSS simulator are modified versions of a commercially available 3D haptic input device called the Omni Phantom™. This product uses internal motors and gears to apply haptic feedback to the hand movements of the user. For the HoST exercises, the simulator uses this capability to move the student's hands in sync with the movements of the surgeon's instruments in the master video.

Figure 6 provides screenshots of the Motor Skills Ball Placement, Intermediate Vessel Dissection, 4th Arm Tissue Retraction, and HoST Radical Prostatectomy.

RobotiX Mentor

Software for the RobotiX Mentor is developed by 3D Systems, who also developed suturing tasks for Intuitive's dVSS, but the scoring system has changed significantly. There are 35 basic tasks and 32 procedural tasks, with 3 full-length procedures (hysterectomy, prostatectomy, and lobectomy) (Table 5).

Similar to the above-discussed simulators, RobotiX Mentor has written instruction on how to complete each task, as well as listed objectives. Completing the task launches the scoreboard. The RobotiX Mentor also has on screen guid-

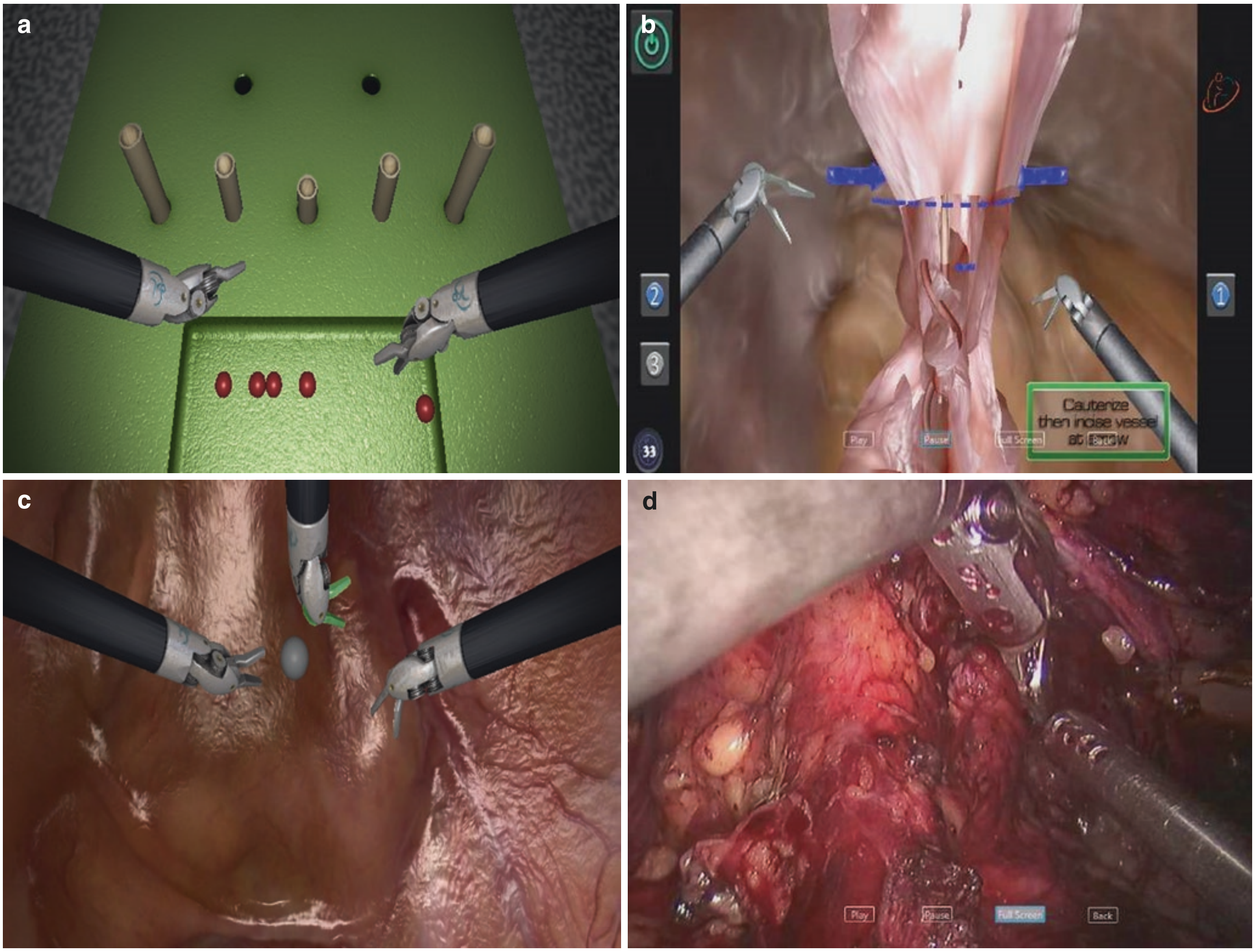


Fig. 6 Selected RoSS exercise images. (With permission of Simulated Surgical Systems [8])

Table 5 RobotiX Mentor exercise categories

Fundamentals of Robotic Surgery (FRS)	Replicates tasks on FRS physical dome, same as on dVSS
Robotic basic skills	Non-anatomic fundamentals, organized with incremental difficulty increase
Robotic essential skills	Non-anatomic fundamentals based on RTN and FLS, with optional connection for team training
Robotic suturing	Knot tying, continuous and interrupted suturing tasks
Robotic single-site suturing	Knot tying and suturing tasks specific for single-site instrumentation
Stapler	EndoWrist Stapler orientation of manipulation and firing

ance available in the form of step-by-step coaching, as written instruction, warning signs, and other visual displays.

Figure 7 illustrates several exercises available: FRS Fourth Arm Cutting, Vertical Defect Suturing, Camera Targeting task from Basic Skills Module, and Prostatectomy Bladder Neck Dissection Team Training.

Proficiency Scoring System

Each of the four simulators provides a different scoring method. All four use the host computer to collect data on the performance of the student at the controls in multiple performance areas. With this data, they provide a score for specific performance traits, as well as combining all of these into a single composite score of performance for the entire exercise. The algorithm used to create this composite score is described in the user's manuals of each of the simulators. Examples of each of these scoreboards are shown in Fig. 8.

In addition to the objective metrics that can be collected by the computer, the developers of each simulator have been challenged to provide thresholds which indicate whether the student's score is considered a "passing" or "failing" performance. All four have identified threshold scores which would indicate acceptable and warning scoring levels. These are commonly interpreted as "passing" (above acceptable threshold) and "failing" (below warning threshold), with a "warning" area between the two thresholds. These thresholds create

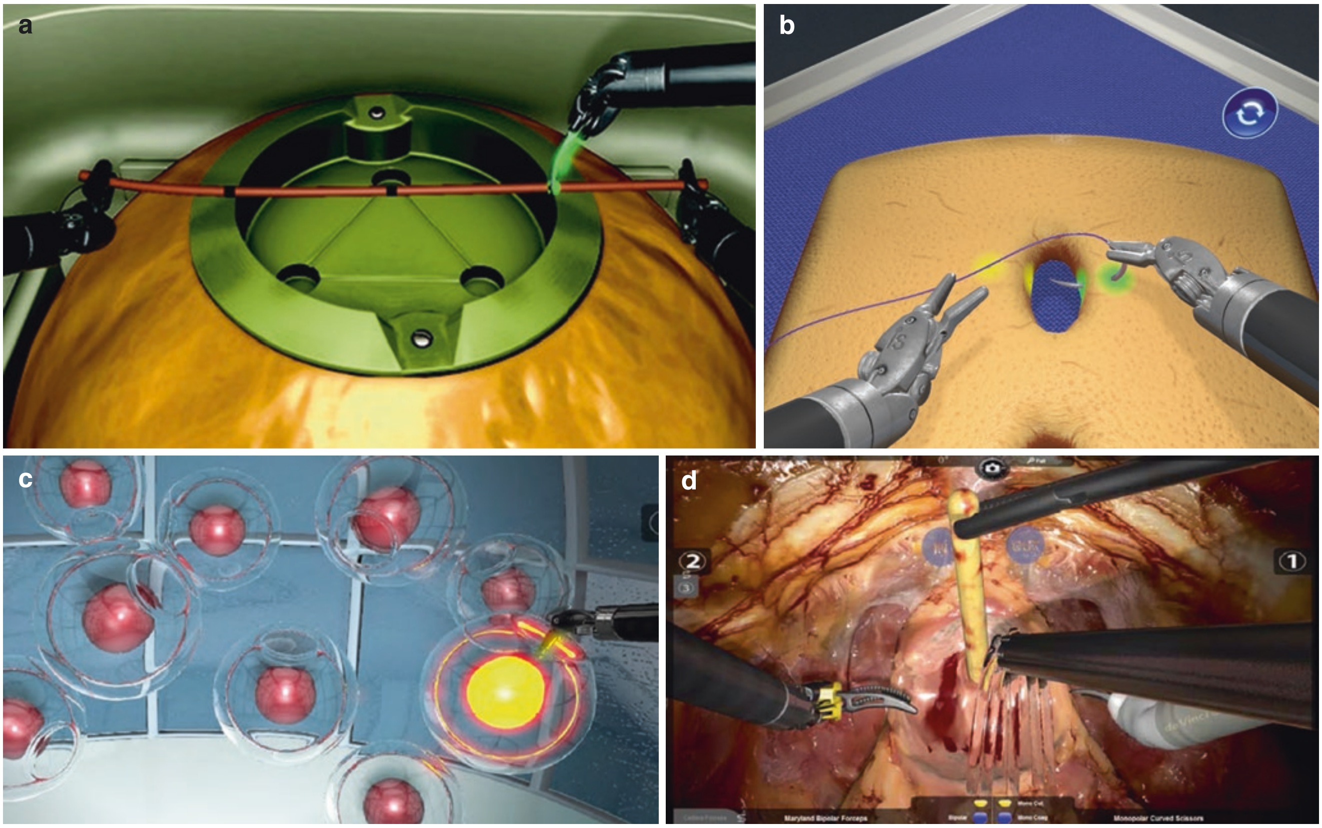


Fig. 7 Select RobotiX Mentor exercises. (With permission of 3D Systems, formerly Simbionix [9])

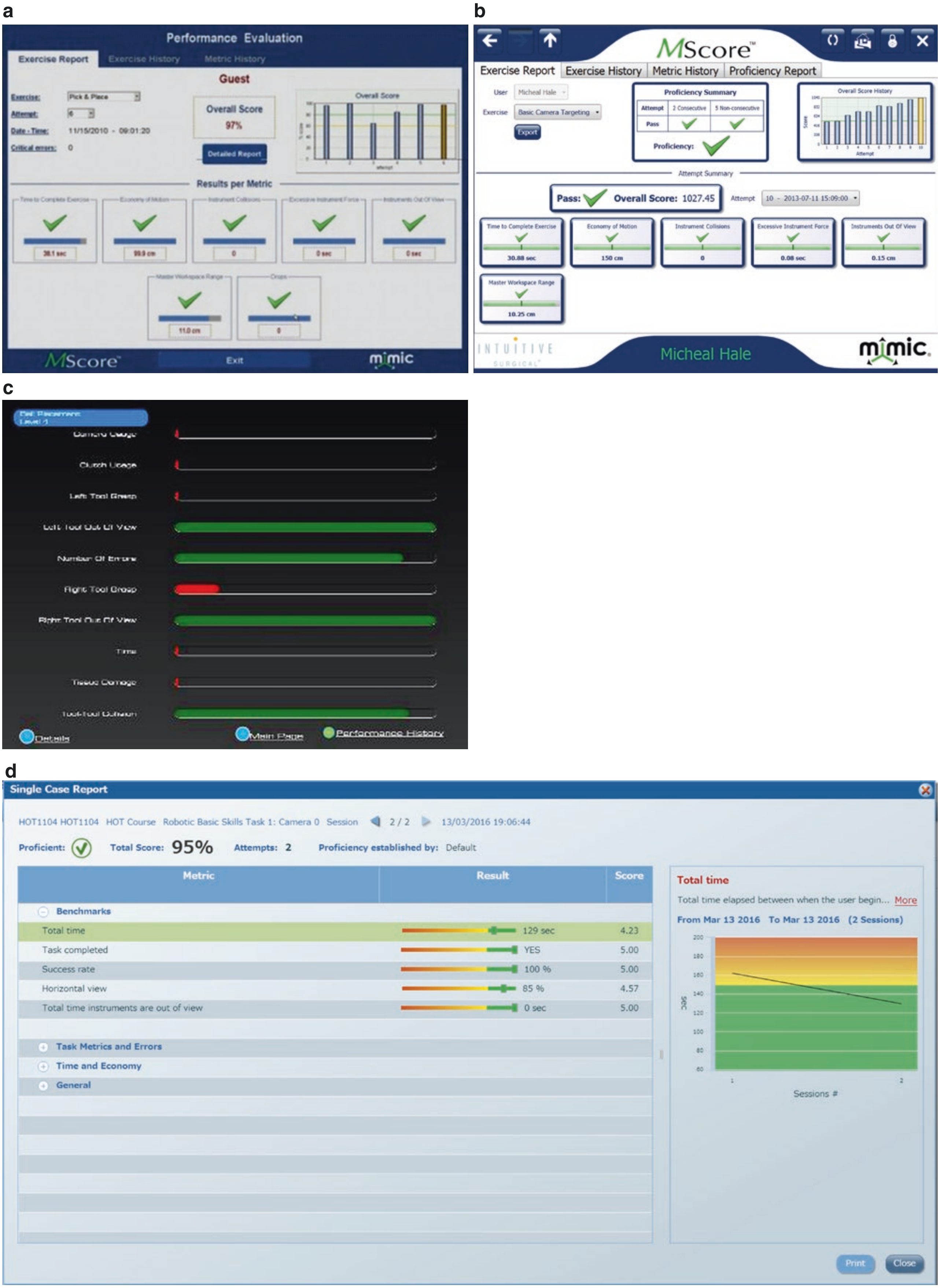
green, yellow, and red performance areas, which can be used to visually communicate the quality of the student's performance in each area of measurement. Each simulator system arrives at these thresholds through similar, but slightly unique, methods. For example, the Mimic dV-Trainer thresholds were derived from data on performance from 100 surgeons who had performed at least 75 robotic cases each. Each surgeon performed the exercises multiple times, ranging from 10 to over 130, to create a data set which was large enough to identify performance levels that are characteristic of qualified and experienced surgeons. The exact method is described more fully in the system's user guide [7]. Additional details on scoring thresholds appear in some of the validation studies for each simulator listed later in the chapter.

Each of the simulators gives the student a single overall score for performance on an exercise. To achieve this, an algorithm was needed to combine very different types of metrics. For example, the number of seconds to complete an exercise needs to be combined with liters of blood loss, centimeters of instrument movement, number of instrument collisions, and other similarly varied metrics. As in most educational environments, this is achieved by converting each metric into a score which falls between some defined minimum and maximum value. Most people understand this concept from their academic experience in which all assignments were graded in the range from 0% to 100% or between 0 points and the maximum total points for all assignments. These normalizations make it possible to create a single composite score of the student's performance across multiple assignments. This same approach has been used in the simulators, where the resulting composite metric may be a total point score or a percentage.

The simulator manufacturers all work with experienced robotic surgeons to assist in establishing the relative values of each measure used in the composite score, just as they did for the threshold levels described earlier. Because these evaluations are the opinions of the specific people who have collaborated with the company on the development of the system, the dV-Trainer, RoSS, and the RobotiX Mentor provide the ability for a system administrator to adjust these levels to meet the needs of unique curriculum, courses, and students being evaluated.

dVSS

The dVSS performance scoring method has a number of metrics, which are applied to every exercise and others which are only used for exercises in which they are relevant. Table 6 presents the metrics, which are applicable to all but the suturing exercises. As the suturing exercises were created by Simbionix, not Mimic, they have an entirely different format (Fig. 9). For details on the more specialized metrics, the reader may consult the user's manual for the simulator [5].



Exercise: Pick & Place

Attempt: 6

Date - Time: 11/15/2010 - 09:01:20

Critical errors: 0

Overall Score 97%

Time to Complete Exercise	Economy of Motion	Instrument Collisions	Excessive Instrument Force	Instruments Out Of View	Master Workspace Range	Drops
38.1 sec	99.9 cm	0	0 sec	0 sec	11.0 cm	0

User Micheal Hale

Exercise Basic Camera Targeting

Proficiency Summary

Attempt	2 Consecutive	5 Non-consecutive
Pass	✓	✓

Proficiency: ✓

Pass: ✓ Overall Score: 1027.45

Attempt 10 - 2013-07-11 15:09:00

Time to Complete Exercise	Economy of Motion	Instrument Collisions	Excessive Instrument Force	Instruments Out Of View	Master Workspace Range
30.88 sec	150 cm	0	0.08 sec	0.15 cm	10.25 cm

Micheal Hale

HOT1104 HOT1104 HOT Course Robotic Basic Skills Task 1: Camera 0 Session 2 / 2 13/03/2016 19:06:44

Proficient: ✓ Total Score: 95% Attempts: 2 Proficiency established by: Default

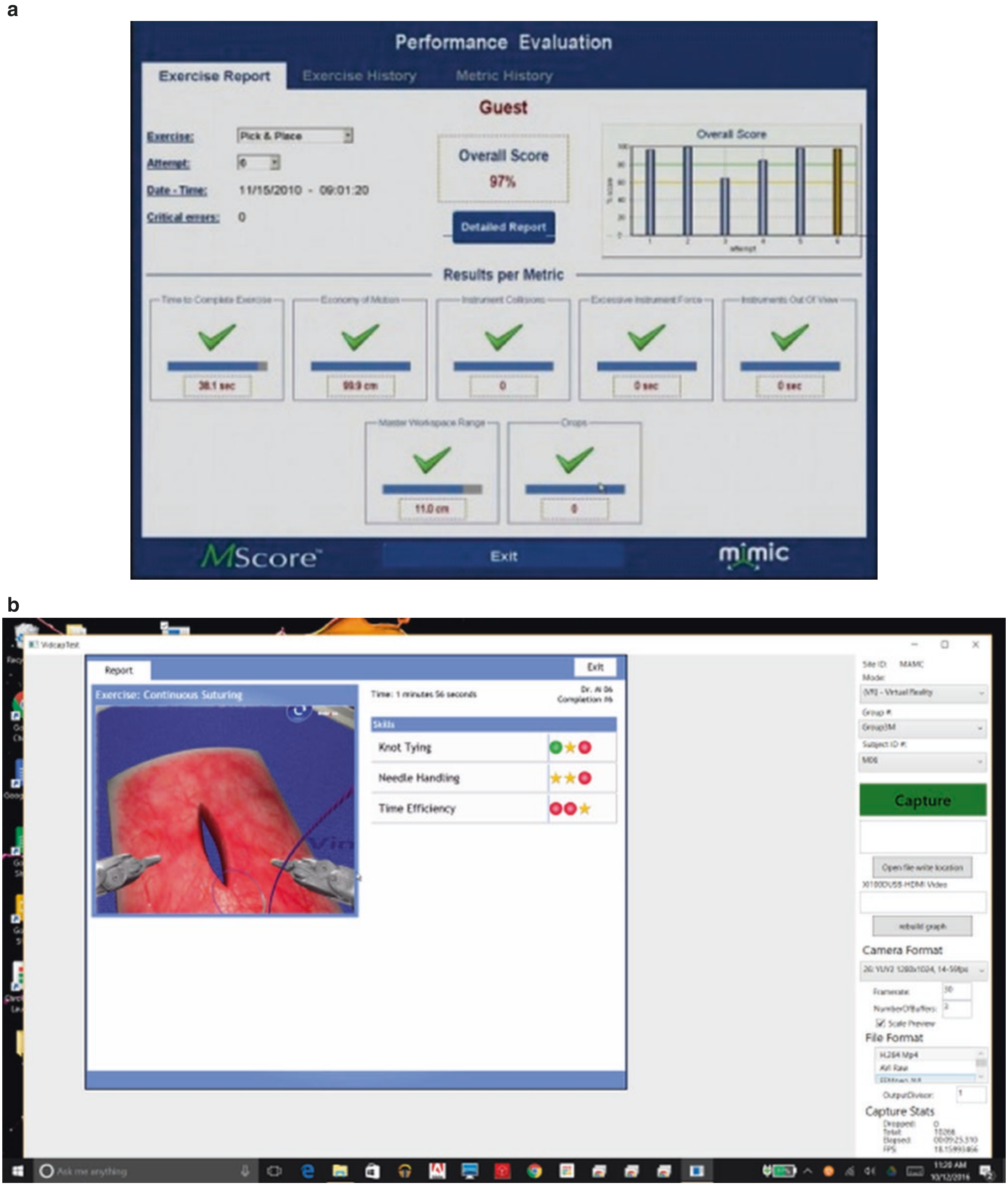
Metric	Result	Score
Benchmarks		
Total time	129 sec	4.23
Task completed	YES	5.00
Success rate	100 %	5.00
Horizontal view	85 %	4.57
Total time instruments are out of view	0 sec	5.00
Task Metrics and Errors		
Time and Economy		
General		

Total time

Total time elapsed between when the user begin... More

From Mar 13 2016 To Mar 13 2016 (2 Sessions)

Fig. 8 Examples of scoring pages from each simulator. (With permission of Intuitive Surgical Inc., Mimic Technologies, Simulated Surgical Systems, and 3D Systems, formerly Simbionix [5, 7–9])



Guest

Exercise: Pick & Place
Attempt: 6
Date - Time: 11/15/2010 - 09:01:20
Critical errors: 0

Overall Score 97%

Time to Complete Exercise	Economy of Motion	Instrument Collisions	Excessive Instrument Force	Instruments Out Of View	Master Workspace Range	Drops
✓ 38.1 sec	✓ 99.9 cm	✓ 0	✓ 0 sec	✓ 0 sec	✓ 11.0 cm	✓ 0

Exercise: Continuous Suturing

Time: 1 minutes 56 seconds

Dr. Al 06
Completion /6

Skills	
Knot Tying	● ★ ●
Needle Handling	★ ★ ●
Time Efficiency	● ● ★

Fig. 9 Comparison of Mimic and Simbionix score sheets. (With permission of 3D Systems, formerly Simbionix [9])

Because the dVSS is a closed, turn-key system with an ease of use similar to the actual surgical robot, most of the data displays and threshold adjustments found in the other simulators are not available in this device. Simulator settings are determined by the manufacturer and cannot be changed by the user.

dV-Trainer

Originally, the dVSS and the dV-Trainer shared the same scoring method, but more recent versions of the dV-Trainer offer both this original "version 1.0" scoring method and a new "version 2.0 and 3.0" method based on the proficiency measured from experienced surgeons. The skills measured are the same (Table 6), but the interpretation of those into a score is different. The instructor can select the preferred scoring method for each curriculum that is constructed in the dV-Trainer. The newer scoring method uses total points earned rather than percentages. The passing and warning thresholds can be adjusted by the administrator.

RoSS

The principles behind the scoring system on the RoSS are the same as those for the dVSS and the dV-Trainer. However, most of the metrics collected are different. The standard measurements are shown in Table 7.

Like each of the other simulators, there are multiple displays of the performance data for a student. The initial display presented at the completion of an exercise shows a horizontal bar which is colored green, yellow, or red to indicate passing or failing. The magnitude of the bar is a rough measure of the quality of performance (Fig. 8). Additional displays show the numeric score and its relative position to a passing threshold.

Table 6 dVSS and dV-Trainer scoring method

Overall score	Composite evaluation of the exercise performance
Time to complete	Number of seconds to complete the exercise
Economy of motion	Number of centimeters of instrument tip movement
Instrument collisions	Number of times that the instruments touched each other
Excessive instrument force	Number of seconds that excessive robotic force was applied against objects in the environment
Instrument out of view	Number of centimeters that an instrument tip moved outside of the viewing area
Master workspace range	Radius in centimeters that contains the movement of the instrument tips
Drops	Number of objects dropped from the grasp of the instruments

Table 7 RoSS scoring method

Overall score	Composite evaluation of the exercise performance
Camera usage	Optimal movement of camera
Left tool grasp	Optimal number of tool grasps with left-hand tool
Left tool out of view	Distance left-hand tool is out of view
Number of errors	Number of collision or drop errors in an exercise
Right tool grasp	Optimal number of tool grasps with right-hand tool
Right tool out of view	Distance right-hand tool is out of view
Time	Time to complete the exercise
Tissue damage	Number of times that instruments damaged tissue with excessive force or unnecessary touches
Tool-tool collision	Number of times tools touched each other

Table 8 RobotiX Mentor scoring method

Total time	Time to complete the exercise
Number of movements (left instrument)	Number of times left instrument moved
Number of movements (right instrument)	Number of times right instrument moved
Path length (left instrument)	Distance in millimeters that left instrument traveled
Path length (right instrument)	Distance in millimeters that right instrument traveled
Distance by camera	Optimal movement of camera
Instrument collision	Number of times tools touched each other
Total path of instruments traveled out of view	Number of millimeters that an instrument tip moved outside of the viewing area
Number of times instruments are out of view	Number of times each instrument is out of the camera view
Total time instruments are out of view	Time in seconds that an instrument tip moved outside of the viewing area
Clutch usage	Number of times finger or foot petal clutch was used

RobotiX Mentor

Similar to the other simulators, the metrics graded include both those evaluating errors and efficiency. All metrics are listed in Table 8.

All metrics for the RobotiX Mentor are graded on a color-coordinated scale from one to five, but the numbers of occurrences for applicable errors are also shown. The administrator can set benchmark scores for each individual metric, and the trainee's score is evaluated against this. The main score sheet also displays the number of attempts, the number of proficient attempts, and the number of attempts that were consecutively proficient. Where the dVSS and dV-Trainer show previous attempts as a bar graph, the RobotiX Mentor displays them as a curve.

System Administration

All of the simulators contain system configuration and student management functions which require a special administrator account to access and modify. These allow instructors to create curriculum and scoring methods which are unique to the lessons they are offering. They also allow an instructor or administrator to create new student accounts and export student scores for evaluation and analysis outside of the simulator device. Some course instructors use this capability to create custom performance reports for students who attend the courses.

dVSS

For the dVSS, most of the administrator functionality is fixed within the delivered system. The administrator can create specific user profiles for the simulator using a dedicated program on a separate external PC. This program, the “da Vinci Skills Simulator Manger,” allows the administrator to create a profile for the user. The profile can then be loaded onto a USB memory stick and inserted into the USB port on the dVSS. The simulator will automatically read this data in and display the user names at the login screen.

Similarly, the USB memory stick can be inserted into the dVSS, and the performance data collected from exercises performed by each user will be automatically loaded onto the USB stick. This stick can then be inserted in the PC, and the data will be loaded into the management software on the external PC and exported to a delimited file for formatting and analysis in a spreadsheet program.

The entire transfer process is automated such that the contents of the USB stick are completely erased and reloaded each time it is inserted into the PC or the dVSS. The stick cannot safely be used for any purpose other than as the transfer mechanism between the two devices. This method is meant to create an ease of use similar to the real robot.

New users can also be created under the “Administrator” login on the dVSS. This profile can also manage passwords and be used for exporting data. Users that were created with the external software cannot be changed by the administrator and vice versa.

dV-Trainer

The administrator on a dV-Trainer has the ability to create new user accounts; specify S, Si, or Xi representation; create new curriculum; set passing thresholds; and export user data for analysis.

The simulator contains over 70 exercises, any combination of which can be organized into a curriculum for a specific course. The administrator creates the new curriculum name and then adds each exercise that should be part of the curriculum. This set of exercises can be organized into phases or folders to match the course that is being taught. For example, an instructor may have a curriculum that consists of a warm-up with easy exercises, pre-course evaluations, and post-course evaluations. These would appear as three separate sections within the curriculum.

The administrator can export data from the simulator according to multiple criteria. The export may include all of the data on the machine or subsets defined by the unique user ID, date range, completion status, or a specific exercise.

The capabilities provided for an administrator of the dV-Trainer are significantly more robust than those available on the other two simulators.

RoSS

The RoSS administrator account is used to create student accounts. Each user can then be assigned a specific subset of the entire simulator curriculum.

For the RoSS system, the administrator can assign portions of the curriculum hierarchy which are applicable to a specific user. The curriculum is organized such that customization consists of selective subsets of the hierarchy of exercises, rather than the ability to select specific exercises in unique combinations.

The administrator can also edit the passing thresholds for each exercise. This allows a site to create curriculum which is considered passing for practitioners at different levels, such as medical students, residents, attendings, and specialists.

The scores can be exported as individual delimited data files for each student account. These can then be removed from the system for analysis and recording.

RobotiX Mentor

Through MentorLearn, administrative tasks can easily be completed and transferred to the RobotiX Mentor system over the web. MentorLearn includes a library of exercises, software to create new exercises, online didactics, performance review, and performance assessment. MentorLearn is available for all 3D Systems simulators, and user data will sync across when in the online mode.

MentorLearn opens when the RobotiX Mentor is first powered on and must be logged into to proceed to the VR exercises. Using administrative functions on MentorLearn, one can create new curricula, modify old, and organize other exercises. Any of the 67 exercises can be grouped together to form a new curriculum.

There are several levels of administrator for MentorLearn. The client administrator has complete access and will create other user types. Course directors can create and group users, modify and add curricula, and monitor and export data. Proctors can create and assign curricula but have more limited access. Learners can access the simulation, while guests cannot.

Evidence for Validity

Validation studies serve to determine whether a simulator can actually teach or assess what it is intended to teach or assess. In medical simulation, there are generally accepted validity classifications, which include face, content, construct, concurrent, and predictive validity [10]. All validation studies of robotic surgery simulators have been conducted using the method defined by the American Psychological Association (APA) and American Educational Research Association (AERA) in 1985 and as interpreted and popularized by McDougall for surgical simulation [10, 11]. More recently, the APA and AERA have published and supported a new "unitary model" of validation [12]. However, literature reviews indicate that this new method has never been applied to surgical simulators, so no examples of its use in this field are available [13]. All of the validation studies conducted on the robotic surgery simulators described in this chapter have been conducted with the McDougall model [10], hence the structure and content of the table and text.

Table 9 provides a summary of the published validity evidence for these simulators. Several publications have explored the face, content, construct, and concurrent validity of robotic simulators. While these publications have approach validity using outdated methodologies, they still provide some evidence for the validity of these simulators. There is only one published study addressing the predictive validity of the dVSS [31]. Recent presentations also explore the validity of the RoSS curriculum and the RoSS' HoST procedural modules [14, 36]. The RobotiX Mentor has the least number of published studies documenting validity, but it is also the most recently introduced to the market.

Table 9 Validation of robotic surgical simulators

Validity evidence	dVSS	dV-Trainer	RoSS	RobotiX Mentor
Face *Subjective realism of the simulator*	[14–18]	[1, 16, 18–23]	[18, 24, 25]	[16, 18, 26]
Content *Judgment of appropriateness as a teaching modality*	[14–18]	[16, 18–21, 23]	[18, 27, 28]	[16, 18, 26]
Construct *Ability to distinguish experienced from inexperienced surgeons*	[14, 15, 17, 18, 29]	[18, 19, 21–23]	[18, 30]	[26]
Concurrent *Extent to which simulator correlates with "gold standard"*	[31]	[21, 23, 32, 33]	[34]	–
Predictive *Extent to which simulator predicts future performance*	[31, 35]	–	–	–

Virtual reality simulation covers a broad scope and has the unique capability of training surgeons from basic skills all the way through full-length procedures. However, it is important to keep in mind that VR isn't the only way train. Improvement may be limited using only VR simulation, as surgeon performance after 6–7 weeks has been shown to plateau, at least while using the dVSS [31]. There is also a soundly based fear that VR simulation training will improve a surgeon's performance on the simulator but that this may not correlate with better outcomes for the patient. VR simulation has been criticized as being an all-inclusive means of education that neglects case experience [37]. Essentially, VR simulation is clearly beneficial, but should not be the last word on robotic training. Even with the possible detriments, VR simulation has proven to increase surgical skills and introduce new technology to prospective surgeons [38].

Team Training

OR Staged Simulation

Catastrophic life-threatening events are always a possibility, even with minimally invasive surgery. Dr. Anna-Sophia Huser and her team out of Essen, Germany, recruited six full surgical teams to study the effect of simulating emergencies in the OR that necessitated resuscitation [39]. Using a life-sized mannequin adapted to hold five trocars and connected to the da Vinci patient cart, Huser et al. timed the first call for response, undocking and removal of the robot, beginning of chest compressions, initiation of chest compressions, and start of defibrillation after the simulated patient exhibited ventricular fibrillation. In total, the time to start chest compressions averaged 70 ± 30 s, while second rehearsal 7 weeks out from the initial averaged 25 ± 6 s between the six teams [39]. Between the first and second simulations, a debriefing to discuss the difficulties with resuscitation during robotic procedures occurred, and a flowchart was added to the OR wall explaining the procedure for emergencies during robotic-assisted surgery [39].

The surgical teams found numerous difficulties during the simulation. Removing the da Vinci from the patient's side took much longer than expected; however removing the arms while leaving the robot in place saved time [39]. The components of the da Vinci alone consume an impressive amount of floor space, which hinders the surgical team's mobility extensively. Working around the robotic arms is not possible.

Hospitals are increasingly dealing with lawsuits with regard to the da Vinci robot used unnecessarily, or poorly, during surgery [40]. During a time where public outcry is a viable mode of communication, it is obvious that curriculum instatement and enforcement is necessary to negate liability of damages. Failure to resuscitate in a timely manner is only one way to cause harm to the patient during robotic-assisted surgery. Overall, errors in manual technique account for up to 56% of malpractice claims [41]. In order to avoid them, preparation through simulation is critical.

Dry Lab

Virtual reality is an excellent option for training both novice and experienced surgeons, but it is far from being the only method available. Dry lab or "box trainers" are also a practical option. Box trainers span from low to high fidelity, but are generally considered to be lower fidelity than VR simulators. Many come with the benefits of being affordable and allow use of the actual robot without a simulated surgeon console.

Rocking Pegboard

Development of the rocking pegboard module originated from a study by Kahol et al., who was looking into how fatigue can affect psychomotor and cognitive skills during laparoscopic VR simulation [42]. The ring transfer task validated by FLS and ProMIS was modified to slowly move the entire pegboard using OpenGL programming API from SensAble Technologies and then played through the SensAble haptic joystick. The trainee then had to maintain awareness of how the pegboard was oriented as well as how they managed their own tools [42].

Dr. Thomas Lendvay and his team furthered development of the rocking pegboard task into a physical model, consisting of panels of vertical and horizontal pegs mounted to a Labnet GyroTwister lab shaker to evaluate preoperative warm-up simulation specifically for robotic surgery [1].

Looking at the number of gauges in the model at Madigan Army Medical Center, it should be clear that completion is more difficult than it may initially appear. Hand-eye coordination is clearly tested, but a surgeon's sense of timing and patience are also critical to success. The rocking pegboard module was simulated in virtual reality by Mimic and can be found on the dV-Trainer.

MLabs

Mimic has also developed physical representations of some of their most popular VR modules. Three different tasks are featured on a rotating carousel: pick and place, matchboard, and pegboard. All can be found under the EndoWrist manipulation tabs on the dVSS and dV-Trainer. The carousel sits in a plastic shell, with each module's pieces placed in specifically marked areas and niches to replicate the VR tasks (Fig. 10).

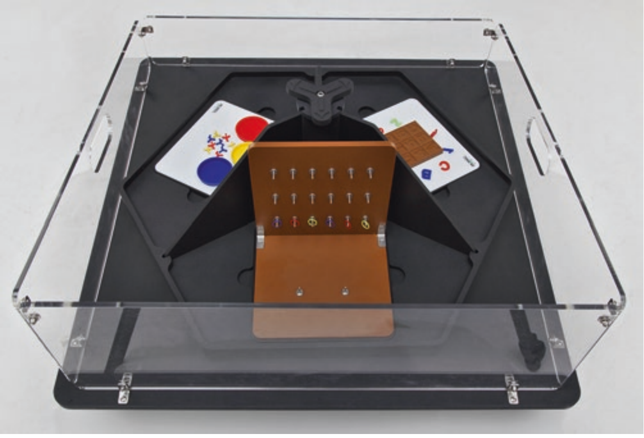


Fig. 10 MLabs dry lab. (With permission of Mimic Technologies [7])

Mimetic Tissue

Artificial tissues, or mimetic tissue, can closely simulate the skin, muscle, adipose tissue, bone, and vasculature. For robotic surgery, the majority of mimetic tissues in use are just models designed for laparoscopic simulation. The Chamberlain Group, a primary supplier of mimetics, produces high-grade models for robotic, laparoscopic, and open surgery simulation. They also have a shelf life that greatly exceeds that of live tissues, which can degrade after only a number of hours. An additional argument in favor of mimetic tissue is that biological differences still exist between human and other animal tissues, such as a porcine model, whereas mimetic tissue has been specifically designed to replicate human tissues. Mimetic tissue also comes without any of the ethical concerns of animal labs.

The FRS dome is an example of mimetic tissue designed specifically for robotic surgery, as well as a few models created by the Chamberlain Group with Intuitive Surgical for robotic targeted procedures as far back as 2000, such as the Sea Spikes Pod, used for training 3D awareness and dexterity (Fig. 11).

Wet Lab

There is a significant jump between the basic skills provided by box trainers (or "dry lab") and the procedural skills offered in tissue models ("wet lab"). Prior research studies have demonstrated that skills acquired using robotic VR simulation transfer to cadaver training and from box trainers to VR [44, 45]. More evidence is needed to draw a definitive conclusion, but it is encouraging to see overall skill development that can grow from multiple sources in order for surgeons to develop a well-rounded education.

Fig. 11 The Chamberlain Group insufflated abdomen with ports, laparoscopic radical prostatectomy trainer, and Sea Spikes Pod. (With permission of the Chamberlain Group [43])

Human cadavers are the gold standard for practicing medical techniques, but there are numerous drawbacks. Many facilities are not able to facilitate cadaver use due to their high cost. Due to medicine's dark history with obtaining deceased through resurrectionists for rehearsing procedures, there are strict regulations in handling human tissues. This is true not only in the United States but internationally as well. Only since 2004 have surgeons in the United Kingdom had access to cadavers for surgical simulation [46]. Cadavers may be the most realistic representation of surgical cases, but do not have many of the characteristics of animate tissue, such as tonus muscle or skin elasticity. There is also somewhat variable evidence as to their benefit [46]. Next to human cadavers, animate tissues from pig or goats are the best option for high-fidelity training [38]. Animal models allow for surgeons to progress past the basic skills training offered in VR simulators to learning procedures. This does require that equipment is available for animal use and that the facility is equipped to handle the animals. High cost alone can be prohibitive; one porcine robotic lab costs over $1000 (or up to $500/h) and must be repeated for every trainee, but ethical concerns also arise [21, 47]. Animal labs also require a dedicated robot (to avoid any possible contamination), which only a handful of institutions are equipped to do, as well as the facilities and staff to care for them. This relegates animal labs to only specific, training-based locations that a surgeon must travel to, making them a relatively inaccessible resource.

Differences in anatomy from humans are always present. Goats can be detrimental due to the large change in digestive organs as they are ruminants. Some procedures can be performed analogously, but special awareness, control of bleeding, and tissue handling can all be rehearsed in a non-critical environment [48].

Wet lab simulation offers higher fidelity simulation than dry lab, but has the additional challenges of tissue deterioration and possible contamination. Dry lab still has some of the same detriments as wet lab. Using the entire da Vinci for simulation requires that an OR is dedicated for simulation for a given period or transported to a different location, which has increased risks of damage from mishandling. Allowing novice surgeons to practice at the console also allows for damage to the device from inadvertent arm collisions or other errors [49]. Dry and wet labs also require dedicated instruments for simulation. Though they have more uses allotted before expiration than the standard instruments, robotic training instruments still only have a limited number of procedures. The same camera scopes can be used for clinical settings as well as simulation, but must go through sterilization before reentering the OR, adding further room for equipment damage and additional expense.

VR simulation not only required less effort to set up and maintain, but was found to be the preferred means of practicing suturing skills by a group of residents and medical students at John's Hopkins in comparison to a dry lab model [50]. The study confirmed that both simulators could improve novice surgeon's efforts, but nearly twice as many participants claimed to prefer the dVSS simulator over a mimetic tissue model.

The one national requirement for da Vinci certification is completion of a porcine lab and two proctored surgical cases. The appropriateness of this approach is questionable, as expert surgeons have documented that it can take a novice up to 250 cases to gain proficiency with the da Vinci [51]. The da Vinci does have a sizeable learning curve, which can be complicated by external factors, so practice is crucial to the development of robotic skills.

Both dry and wet labs necessitate reflective assessment by the trainee or subjective assessment from an expert trainer, which is often not precise [52]. VR simulators have the added benefit of integrated objective grading with instant feedback. The accuracy or importance of this feedback is sometimes questionable, but it is at the very least consistent. There is some concern that too much VR training might not be beneficial, as trainees could become excellent VR surgeons, but may lack the real-life skills for actual surgery [50].

Means of Assessment

VR trainers have the bonus of automatically scoring each attempt. When it comes to wet or dry lab simulation, other means must be utilized to create an accurate and quantitative representation of each task. The goal with assessment is to remain objective.

Global Ratings Scales

GEARS

The Global Evaluative Assessment of Robotic Skills (GEARS) tool (Table 10) is a global ratings scale developed by Goh et al. [53] GEARS consists of a six-domain and five-point Likert scale, anchored at 1, 3, and 5. Global ratings scales have been shown to be more effective than checklists and can be used for multiple procedures [54]. Domains include depth perception, bimanual dexterity, efficiency, force sensitivity, autonomy, and robotic control. The final score is the result of the sum of all six domains.

Table 10 GEARS tool [53]

Depth perception				
1 Constantly overshoots target, wide swings, slow to correct	2	3 Some overshooting or missing of target, but quick to correct	4	5 Accurately directs instruments in the correct plane to target
Bimanual dexterity				
1 Uses only one hand, ignores nondominant hand, poor coordination	2	3 Uses both hands, but does not optimize interaction between hands	4	5 Expertly uses both hands in a complementary way to provide best exposure
Efficiency				
1 Inefficient efforts; many uncertain movements; constantly changing focus or persisting without progress	2	3 Slow, but planned movements are reasonably organized	4	5 Confident, efficient, and safe conduct, maintains focus on task, fluid progression
Force sensitivity				
1 Rough moves, tears tissue, injures nearby structures, poor control, frequent suture breakage	2	3 Handles tissues reasonably well, minor trauma to adjacent tissue, rare suture breakage	4	5 Applies appropriate tension, negligible injury to adjacent structures, no suture breakage
Autonomy				
1 Unable to complete entire task, even with verbal guidance	2	3 Able to complete task safely with moderate guidance	4	5 Able to complete task independently without prompting
Robotic control				
1 Consistently does not optimize view, hand position, or repeated collisions even with guidance	2	3 View is sometimes not optimal. Occasionally needs to relocate arms. Occasional collisions and obstruction of assistant	4	5 Controls camera and hand position optimally and independently. Minimal collisions or obstruction of assistant

Initial validation of gears proceeded with 29 participants after IRB approval, all performing robotic-assisted laparoscopic prostatectomy, with evaluation occurring during the vesicle dissection portion. Scores were assigned four trained observers. While difficulty of the case was not a scored metric, observers took this into consideration when completing GEARS. GEARS earned construct validity and high levels of interobserver consistency [53]. GEARS was externally tested for construct validity by Aghazadeh et al. and was displayed between both experts and novices as well as experts and intermediate surgeons during in vivo porcine tasks [55]. External validation also confirmed interobserver reliability [55].

GEARS is still a relatively new tool, and as such validation evidence is somewhat limited. However there are some interesting implications of the two studies cited above. Aghazadeh found poor correlation between participant self-scoring and that of the experts, which is unsurprising.

Interobserver consistency was likely achieved in both cases because of specific training before evaluation occurred. Multisite or indeed universal, interobserver consistency will be far more difficult to achieve especially while maintaining objectivity. There are also only a limited number of expert robotic surgeons in the world, who may or may not be available for providing feedback via GEARS. As a result of some of these constraints, researchers began to question if the layman could accurately perform objective analysis and assessment of highly advanced surgical skills.

C-SATS

The Crowd-Sourced Assessment of Technical Skills (C-SATS) was able to prove just that, using Amazon.com's Mechanical Turks. C-SATS has been validated for robotic surgery using GEARS and an abbreviated version with only three of the original domains (depth perception, bimanual dexterity, and efficiency). Crowd workers (often just called Turks) have shown a high aptitude for such assessment, demonstrating interobserver reliability between expert robotic surgeons [56, 57].

C-SATS has the attribute of inherent blindness in the scores, avoiding bias in student-teacher relationships [58]. Another benefit, and one that will prove to be useful as validation studies continue, is the efficiency of crowd workers compared to expert surgeons. In one study, it took 4 h and 48 min to receive 487 valid scores from the crowd workers, while it took 7 expert surgeons 14 days to review the same 12 videos [57]. Crowd workers are also available for relatively little pay. Each video review costs from $0.25 to about $1.00 and takes generally 30–50 responses from crowd workers to reach agreement with the expert assessment [56]. One study determined an individual's performance assessment to cost only $16.50 using crowd workers, compared to the man-hours required of an expert robotic surgeon costing at least three to six times more [59].

C-SATS is not proposed to replace traditional mentoring relationships, but as an additional means of assessment. It presents as a way to evaluate without bias, particularly for situations where remediation is being initiated or already in progress. C-SATS could theoretically be integrated into VR simulators or with human surgery, each with the potential for real-time appraisal [56].

Vector Analysis

The da Vinci collects data for each motion as a surgeon manipulates the master controllers and foot pedals on the surgeon console and how these translate to operation of the patient-side cart arms, totaling 334 different dimensions of data collection. However this data is not freely available; researchers must enter a binding agreement with Intuitive to access the data through their application programming interface (API). To reach an agreement with Intuitive, research must illustrate long-term goals, previous experience with research, and clinical use of the da Vinci, as well as a history of successful communication [60].

At the time of collection, API data is transferred synchronously between 10 and 100 Hz to an external computer for further analysis. Included data consist of but is not limited to master controller positions, angles, and velocities; patient cart arm positions, angles, and velocities; and any pedal or head sensor activations. This information can then be used to calculate a surgeon's efficiency of time and space, use of workspace, and mastery of robotic instrumentation [61].

Curriculum Development

The Fundamentals of Laparoscopic Surgery (FLS) course has been demonstrated to be effective for teaching laparoscopic skills, but does not apply well to robotic-assisted surgery [62]. FLS proved to be too simple in its two-dimensional format to be used for the three-dimensional stereoscopic view with robotic surgery and lacked advanced grading metrics [62]. The Fundamentals of Robotic Surgery curriculum, currently undergoing validation, aims to parallel the evaluative goals of FLS [63].

Fundamentals of Robotic Surgery Background

The revolution in healthcare of evidence-based medicine requires evidence-based education in its entirety. The introduction of simulation for surgical (and all procedural) training furnishes quantitative assessment of skills performance, providing evidence of skills proficiency. The use of full life cycle curriculum development utilizing proficiency-based progression (PBP) has become the new standard for technical skills training and assessment [64].

The Fundamentals of Robotic Surgery (FRS) is a multispecialty, PBP curriculum of basic cognitive, psychomotor (technical), and team training and communication skills to train and assess surgeons to safely and efficiently perform robotic-assisted surgery. The curriculum was developed using a full life cycle development process that begins with the outcomes and metrics [65]. All stakeholders, including the accrediting bodies, should be involved in the curriculum development process from the very beginning to ensure the final curriculum and assessment methods will meet the rigorous requirements of determining proficiency, meeting standards, and possibly even fulfilling certification criteria. A graphical description of the process is provided below (Fig. 12) and will be described in more detail in this section.

To create a full life cycle curriculum, the FRS committee convened over 90 national/international robotic surgery

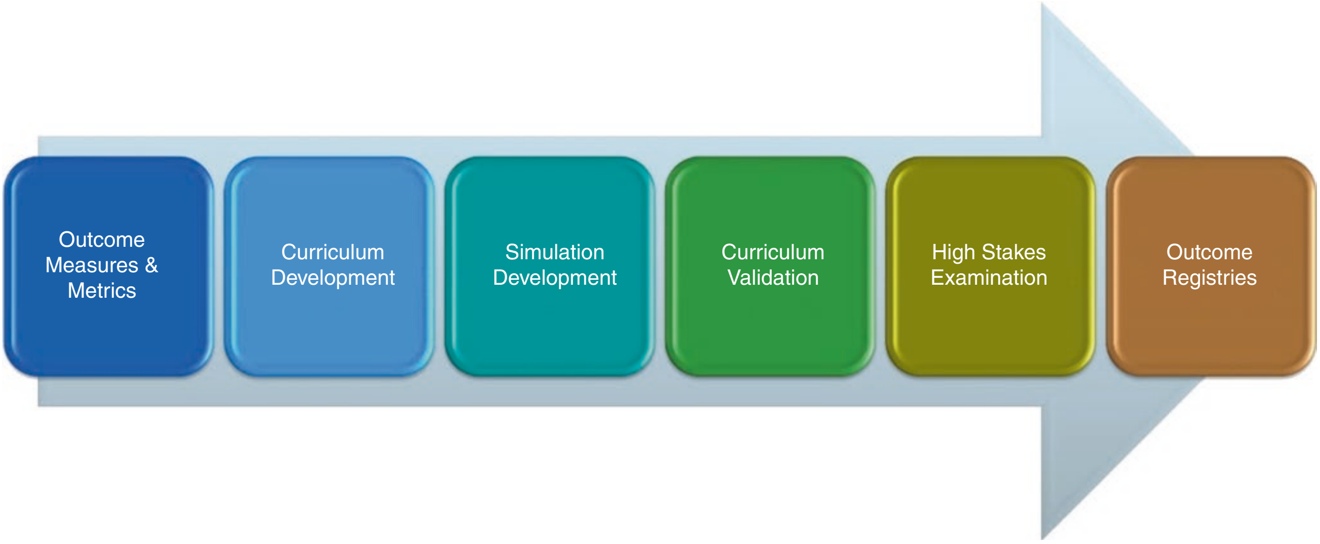


Fig. 12 Life cycle development model. (With permission of Jeff Levy)

experts, behavioral psychologists, medical educators, statisticians, and psychometricians. Represented in the clinical subject matter experts (SME) were all of the major surgical specialties in the United States that currently perform robotic-assisted surgical procedures, as well as the US Department of Defense (DoD) and Veteran Affairs (VA). These leaders in robotic surgery participated in four consensus conferences described below:

1. Outcomes measures (December 2011) – In this consensus conference, the skills necessary to begin the process of creating a robotic surgery curriculum were identified and defined. A prioritized matrix of 25 specific robotic surgery skills, outcome measures, and metrics was produced (see below). Consensus was achieved through expert discussions and use of Delphi and modified Delphi methods. This same technique was employed in the subsequent consensus conferences as well. This matrix served as the core material for the development and design of the FRS curriculum (Table 11).
2. Curriculum planning (April 2012) – Prior to the Curriculum Planning Consensus Conference, Drs. Jeffrey Levy and Richard Satava cofounded the Alliance for Surgical Simulation in Education and Training (ASSET), a coalition of senior leadership from a diverse cross section of US and international surgical societies, accrediting organizations, US military, and government. This organization drove consensus on how to best utilize simulation to have the greatest impact on surgical education, training, and evaluation. ASSET members developed a curriculum template for teaching surgical education with the aid of simulation. The consensus-based framework was published in 2012 [66].

Table 11 Prioritized robotic surgery skills

Pre-op	Intra-op	Post-op
1. System settings 2. Ergonomic positioning 3. Docking 4. Robotic trocars 5. Operating room setup 6. Situation awareness 7. Closed-loop communications 8. Response to system errors	9. Energy sources 10. Camera control 11. Clutching 12. Instrument exchange 13. Foreign body management 14. Multi-arm control 15. Eye-hand instrument coordination 16. Wrist articulation 17. Atraumatic tissue handling 18. Dissection – fine and blunt 19. Cutting 20. Needle driving 21. Suture handling 22. Knot tying 23. Safety of operative field	24. Transition to bedside assistant 25. Undocking

The ASSET curriculum template was critically reviewed by FRS Curriculum Planning Consensus Conference participants, and it was decided to use the template for FRS curriculum development. A curriculum outline was developed for FRS based on the ASSET template and agreed upon by all participants.

3. Curriculum development (August 2012) – The curriculum outline developed in the Curriculum Planning Consensus Conference was reviewed and curriculum development continued. The expert participants were split into development workgroups for the four modules

in the curriculum: (1) Introduction to Robotic Surgical Systems, (2) Didactic Instructions for Robotic Surgical Systems, (3) Psychomotor Skills Curriculum, and (4) Team Training and Communication Skills (Fig. 13). The final curriculum was reviewed by all of the participating societies and launched in March 2014.

The 25 FRS outcome measures developed in the first consensus conference were then distilled into 7 tasks that would assess proficiency of trainees' psychomotor robotic surgery skills, including (1) docking and instrument insertion, (2) ring tower transfer, (3) knot tying, (4) railroad track, (5) utilization and switching of the fourth arm, (6) pattern dissection, and (7) vessel energy and dissection. A physical model was then developed that contained the seven tasks depicted in Fig. 14.

In the Curriculum Development Consensus Conference, it was discussed that simulation provides a safe environment for trainees to overcome the initial learning curve of psychomotor tasks and procedures. In the training environment, high-fidelity VR simulators provide immediate (formative), objective, and automated feedback. In the testing environment, simulators provide the advantages of objective assessments of performance metrics resulting in a more accurate and consistent reporting process. In addition, simulation is not as labor intensive for the faculty/expert preceptors who are supervising novices learning new surgical skills or serving as proctors in a testing environment.

Based on these qualities of simulation, computer-assisted design (CAD) diagrams and specifications for the physical model were provided to robotic simulation companies so that the physical model would be accurately replicated and the newly developed simulations would have the same measurements, dimensions, and task specifications (Fig. 15).

VR simulation models were developed for the same FRS psychomotor tasks. An example comparison of the physical and simulation models for the ring tower transfer task is shown in Fig. 16. The two models are essentially identical in appearance.

4. Validation study design (November 2012) – Design of the FRS validation study was discussed by clinicians, psychologists, researchers, and psychometricians, who agreed it needed to meet the most rigorous evaluation that would satisfy criteria for high-stakes testing and evaluation. The goal of the trial was to conduct a formal valida-

The surgeon sits in in control at the console and sends information to the team (verbal commands), or data to the instrument(s) by moving the manipulator handles. Because all the data must go through the computer, the robotic system can amplify this information (data) to enhance the surgeon's psychomotor skills/performance beyond normal human physical limitations. Examples include:

- The video image can be increased in size to give the surgeon magnified vision
- The use of "false coloring" (infra-red, ultraviolet, etc.) to "see" structures, properties (e.g. heat) and functions (e.g. blood flow) not visible to the human eye
- Hand motion scaling and tremor elimination that provides the surgeon with a precision of less than 100 microns facilitating the performance of minimally invasive surgery by helping overcome some of the inherent limitations of laparoscopic surgery

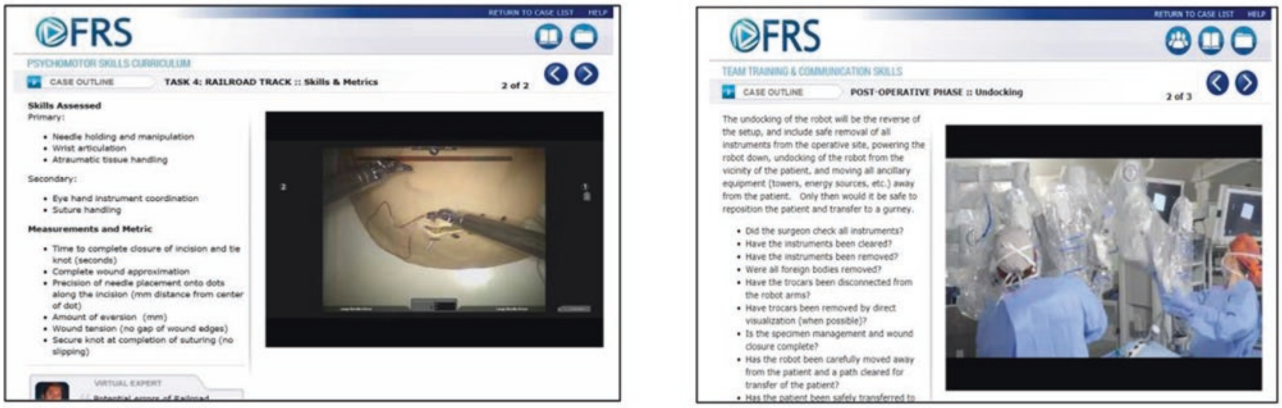
Module 1: Introduction to Robotic Surgery

Setting up the robotic system involves configuring components so that they will have the workspace required for the operation and anticipate an accurate, safe and optimal positioning of the robot relative to the patient. Operational requirements are dependent on the particular case, surgeon, discipline and preferences.

The set up specifically requires:

- Proper positioning of the robotic manipulators relative to the patient (or patient surrogate, such as animal, cadaver, phantom or skills station).
- Calibration of the camera, patient side manipulators and the master manipulators.
- Configuration of patient arms according to the requirements of the procedure.
- Selection of other surgeon preferences on the surgeon's console.

Module 2: Didactic Instructions



Skills Assessed

Primary:

- Needle holding and manipulation
- Wrist articulation
- Atraumatic tissue handling

Secondary:

- Eye hand instrument coordination
- Suture handling

Measurements and Metric

- Time to complete closure of incision and tie knot (seconds)
- Complete wound approximation
- Precision of needle placement onto dots along the incision (mm distance from center of dot)
- Amount of eversion (mm)
- Wound tension (no gap of wound edges)
- Secure knot at completion of suturing (no slipping)

Potential errors of Railroad

Module 3: Psychomotor Skills Curriculum

The undocking of the robot will be the reverse of the setup, and include safe removal of all instruments from the operative site, powering the robot down, undocking of the robot from the vicinity of the patient, and moving all ancillary equipment (towers, energy sources, etc.) away from the patient. Only then would it be safe to reposition the patient and transfer to a gurney.

- Did the surgeon check all instruments?
- Have the instruments been cleared?
- Have the instruments been removed?
- Were all foreign bodies removed?
- Have the trocars been disconnected from the robot arms?
- Have trocars been removed by direct visualization (when possible)?
- Is the specimen management and wound closure complete?
- Has the robot been carefully moved away from the patient and a path cleared for transfer of the patient?
- Has the patient been safely transferred to

Module 4: Team Training and Communication Skills

Fig. 13 FRS online didactics. (With permission of CaseNetwork and Jeff Levy)

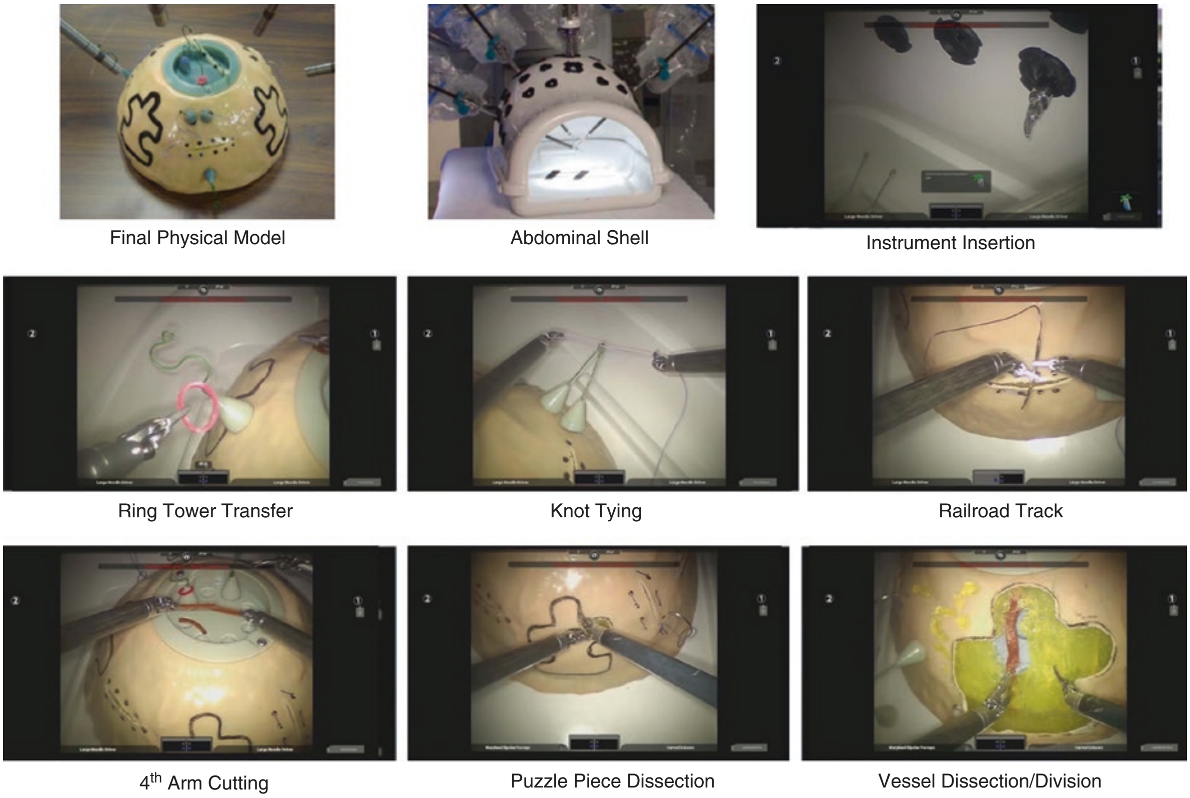


Fig. 14 FRS training exercises. (With permission of Jeff Levy)

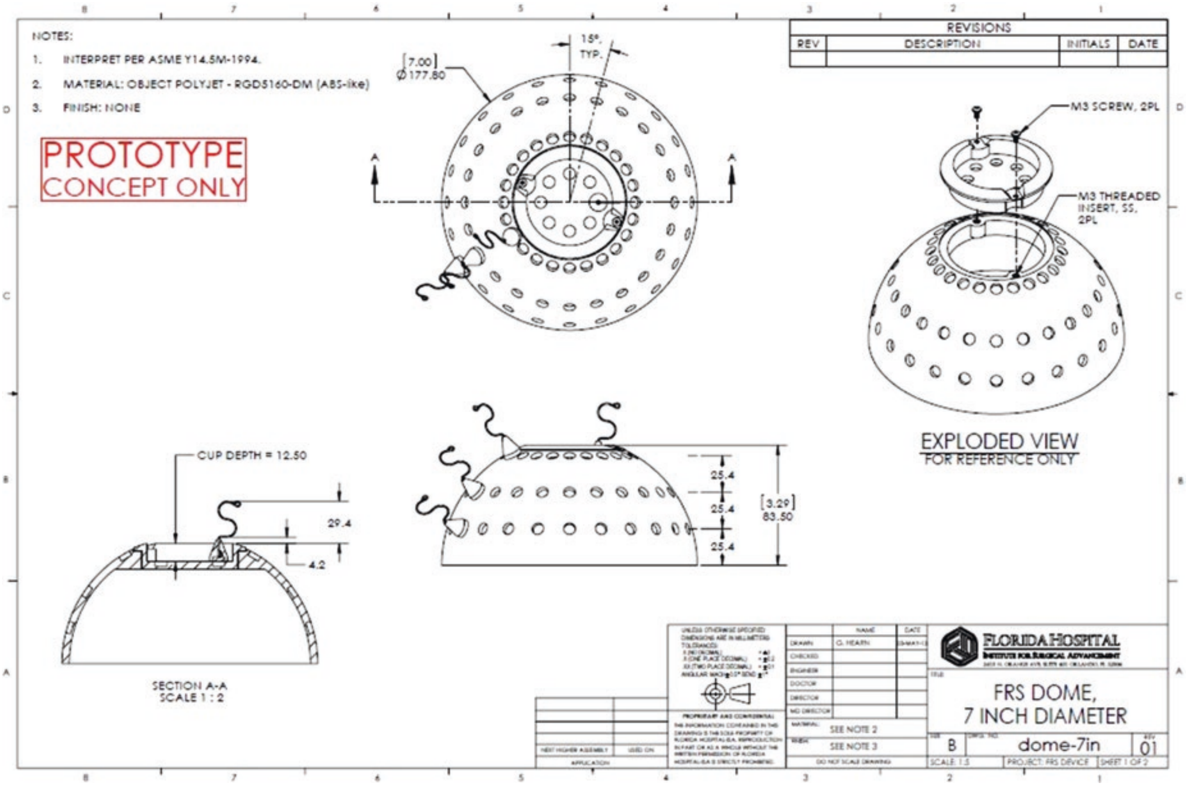


Fig. 15 Prototype FRS dome. (With permission of Jeff Levy)

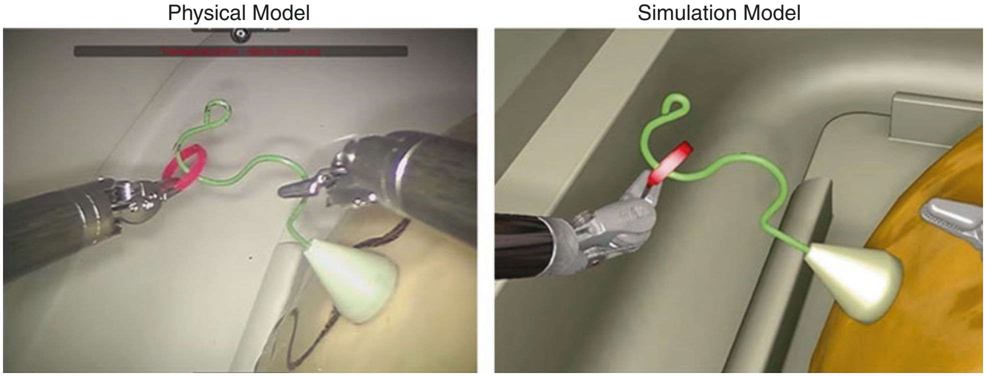


Fig. 16 Comparison of ring tower transfer between physical and virtual reality. (With permission of Jeff Levy)

tion of the didactic online FRS curriculum, psychomotor (technical) skills, and team training and communication skills components and to demonstrate that FRS is an effective education, training, and assessment tool.

During the Validation Study Consensus Conference, the research questions and hypotheses were developed and the validity measures established. The criteria for experts, novices, and participating institutions were defined. The process to conduct a PBP model of training and testing was also determined.

Following the consensus conference, 12 international institutions that excelled in robotic training and were already American College of Surgeons Accredited Educational Institutes (ACS-AEI) were selected through a formal proposal process. Expert benchmarks were set by calculating the mean of expert results for each of the seven tasks. Novices were then randomized to either the control group or one of three experimental groups including the FRS physical model, the dVSS, or the dV-Trainer simulator. Following PBP training, novices would have to reach the expert benchmarks on two consecutive trials to be proficient in each task. Pre- and posttests were performed on an avian tissue model to determine the impact of training, in the form of pelvic turkey limbs (drumsticks). The same seven tasks were recreated using the skin, musculature, and vasculature of the model. There is of course anatomical variation in the tissues between different specimens, but care was taken to clearly mark outlines on the epidermis with surgical markers and to present clear vasculature for dissection. When no vessels were isolatable, small tendons were used instead.

A chart depicting the validation trial design and randomized subject flow is shown in Fig. 17. The final results of this work are being prepared for publication as multiple journal articles covering various aspects of the project.

Robotic Training Network

In parallel to the development of FRS, the Robotic Training Network (RTN) was formed by nine obstetrics and gynecology programs with a mission to develop a standardized curriculum and approach to teach basic robotic surgical skills in a stepwise fashion to residents and fellows in graduate medical education training programs.

A structured curriculum was developed for residents and fellows, which contained three components or phases:

1. Phase I covered the bedside assistance didactics, hands-on training, and assessment.
2. Phase II covered the surgeon console didactics, hands-on training, and assessment.
3. Phase III is for ongoing maintenance of skills and is in development.

Five robotic exercises/drills were tested and validated among various institutions in the RTN and found to demonstrate reliability and construct validity for basic robotic skills (Fig. 18).

The exercises were developed with a physical model and with simulation and include:

1. Tower transfer (left image depicted below in simulator)
2. Roller coaster (right image depicted below in simulator)
3. Big dipper
4. Railroad tracks
5. Suturing

Specialty-Specific Robotic Curricula

The FRS and RTN curricula serve as basic curricula that all specialties engaging in robotic surgery must complete and will serve as a prerequisite to participation in a specialty-specific curriculum. Specialty-specific curricula will also be built to reinforce content within the FRS and RTN and emphasize the unique information/skills that must be taught for surgeons to become proficient in robotic procedures in their specialty. See the graphic of the "Sweet Tree" Model of Robotic Curriculum Development from a Common Template* in Fig. 19.

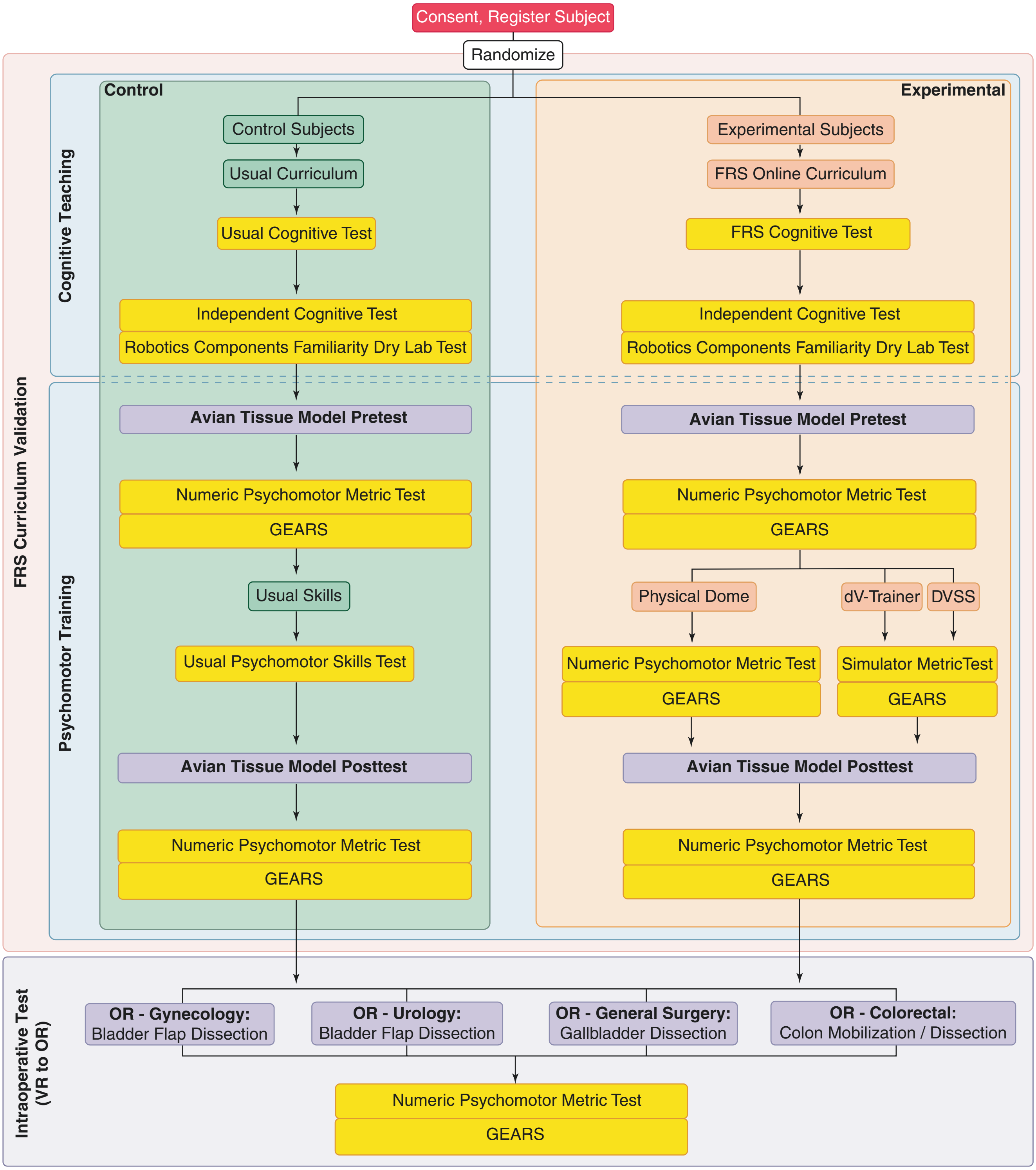


Fig. 17 FRS validation study flow. (With permission of CaseNetwork and Jeff Levy)

Fig. 18 Example modules from RTN. (With permission of Mimic Technologies)

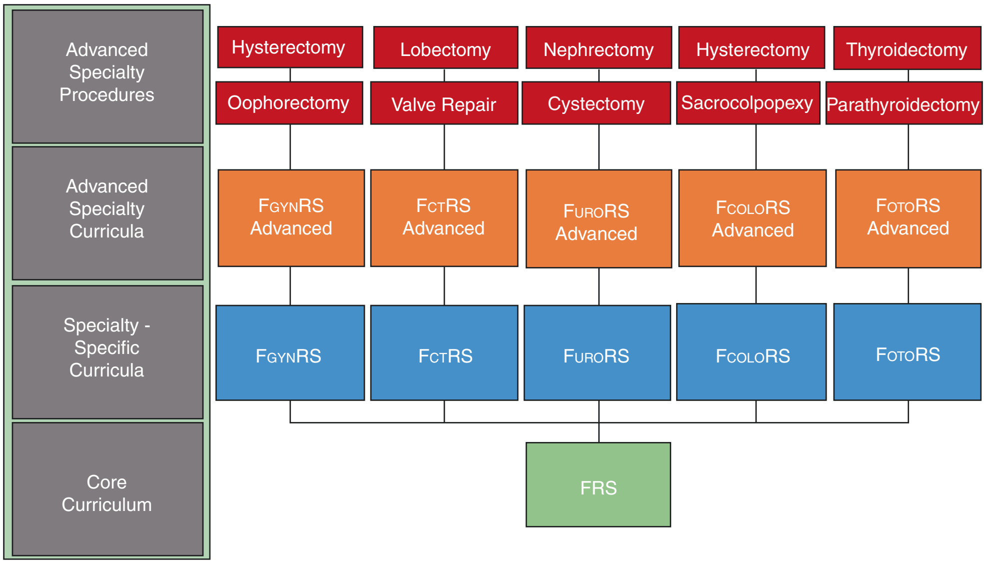


Fig. 19 FRS specialty curricula. (*Adapted from original development by Robert Sweet, MD, With permission of Jeff Levy)

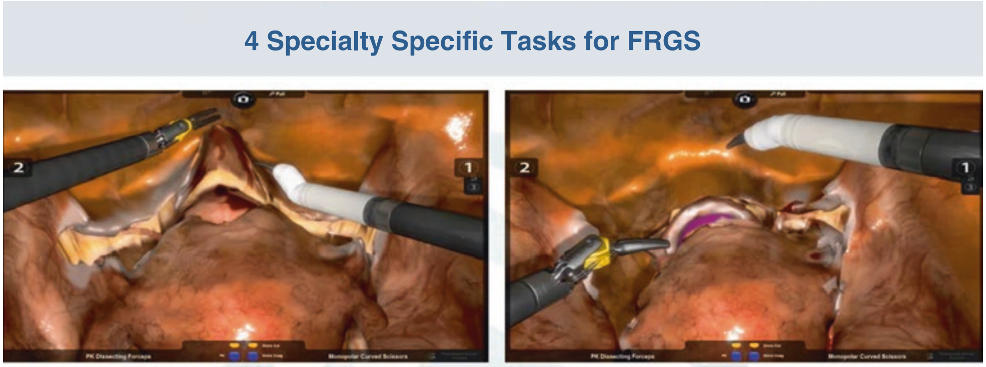
The Fundamentals of Robotic Gynecologic Surgery (FRGS) was the first specialty-specific curriculum to be developed. Leadership from FRS, RTN, Ob/Gyn societies, and academic institutions worked in partnership to conduct a single consensus conference and build upon previous work and experiences. All of the major Ob/Gyn societies in the United States, the American Board of Obstetrics and Gynecology (ABOG), the American Medical Association (AMA), and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) were represented at the meeting. During the meeting best practices in curriculum development and design principles for gynecologic-specific robotic psychomotor skills for the beside assistant and console surgeon were discussed.

The resulting curriculum incorporated didactics, psychomotor skills, and team training that established a standardized robotic surgical curriculum specific to gynecologic surgeons for the development and maintenance of robotic surgical skills. Four new gynecologic procedure-related tasks were designed and then developed into high-fidelity VR simulations. See the VR images below (Fig. 20) representing the development of a bladder flap, colpotomy incisions, the closure of the vaginal cuff, and the dissection of the ureter.

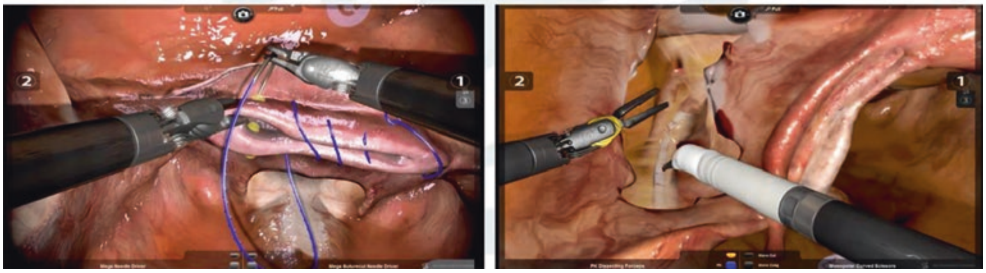
Robotic Registry Consensus Conference

The new era of information science has resulted in immediate availability, analysis, and sharing of real-world data (RWD) that is available at the time of the occurrence – at the pace of innovation and change. However, the potential benefit of emerging technologies and innovations is slowed by the continued use of prospective clinical trials, peer-reviewed evaluations, and the submission of research publications, which require rigorous and careful evaluation and prolonged completion time.

One solution that has emerged is the development of "registries" or databases that are created in near real time and reflect data that is available at the time of occurrence, as opposed to the traditional practice of stored data that is awaiting review and possible publication. By implementing this solution, healthcare professional communities of individual physicians, hospitals, governing bodies and societies, industry, and federal agencies can work together using infor-



Bladder Flap Colpotomy



Vaginal Cuff Ureter Dissection

Fig. 20 FRGS specialty tasks. (With permission of 3D Systems, formerly Simbionix)

mation before it has become obsolete, allowing for real-time analysis and decisions that reflect the current status in the process of dynamic change.

One example of rapid innovation and transformation is robotic-assisted surgical devices. A RWD robotic surgery registry would allow:

- Physicians to evaluate their operative performance for self-improvement
- Educators to develop standardized training programs and certification processes for ongoing education, remediation, and privileging
- Hospitals to develop quality measures, effectiveness, and risk assessment to trend patient care for quality improvement
- Industry to assess the performance of their devices to promote more rapid iterations toward improved functionality and safety
- Government to maintain minimal safety and effectiveness standards and stay informed of new developments that could influence policies

In September 2016, the Institute for Surgical Excellence (ISE) convened a landmark consensus conference that brought together the FDA, 40 robotic surgery experts, and registry experts including MDEpiNet, surgical society representatives, and representatives of all of the robotic device makers to determine the necessary metrics and structure to create a national robotic registry. This meeting was the first step in forming a public-private partnership to design, develop, and successfully implement a RWD robotic surgery data registry that systematically collects near real-time device-related and process-related data, is interoperable with clinical databases, and utilizes those data to improve device safety, surgeon/team performance, and public health.

Future of Robotic Surgery

Tissue Realism

One significant problem in all medical simulations is the lack of a “physics engine” for the human body. Within the military and entertainment simulation communities, there are multiple physics engines, software libraries which contain the computational equations for accurately representing the behavior of objects in the virtual world. These products provide much of the realistic behavior for all of the dynamic actions that are visible in a simulation or game – e.g., humans walking, water flowing, objects blown by wind, object breaking, explosions, and objects falling downstairs. Unfortunately, these engines are specialized for hard objects like airplanes, tanks, and buildings or continuous environmental objects which contain significant random motions, like the wind blowing cloth and hair or waves on a body of water. They do not include models which are accurate for modeling the pliability of human tissue, nerve response within the tissue, the quiver of circulation driven by a beating heart, perfusion of blood in tissue, or blood escaping through an incision. Most of the features that are required to represent tissue in a model and on a graphics screen have not been captured in algorithms which can run in real time within a surgical simulator [67].

The physics models for solid objects and environments have been developed with hundreds of millions of dollars of investments by both the military services and the entertainment gaming companies. Both of these communities serve tens of thousands or millions of customers, respectively, providing the motivation and the funding to make such large investments. Modeling human tissue with a similar accuracy can leverage the work that has been done in these other fields, but we should expect that achieving a comparable level of realism will require an investment in the hundreds of millions of dollars. Given the current market size for surgical simulators and the revenues of the companies that serve it, it is unrealistic to expect this investment to come from the private sector. Only if accurate tissue modeling is tied to some metric of national security, stimulating government investment, can we expect to see significant progress on human tissue modeling.

Patient-Specific Simulation

As we have explored the very early edges of realistic tissue modeling, our community has wondered about the possibility of creating a patient-specific simulation model based on data and images collected prior to a surgery. Would it be possible to convert this data into a model which is accurate both in appearance and behavior within a simulator? Would it be possible to rehearse a surgery on a simulator using a model like this? Such a capability would allow a surgeon to practice a particularly risky case multiple times in a simulator before attempting it on the human patient. The library of these cases would also provide an outstanding learning environment for residents and fellows before they assist with a real case.

We have also seen the initial efforts to create 3D printed models of patient-specific organs by transferring the CT or MRI scan data of a patient through a modeling software program and then sending to a 3D printer for rendering using rigid and pliable resins. These initial explorations have been used to demonstrate capability and to create physical models which can be used to educate the physician, patient, and residents on the details of the case. If it is possible to create a solid physical model of the anatomy, could this be extended to a dynamic virtual model?

The physical model is usually not pliable and realistic to the touch. It does not bleed. It cannot be cut or operated upon in any way. It has no ability to measure the success of actions taken on it. So a realistic simulation model is significantly more complex to create than the 3D printed physical model. However, the first step toward such a model may be similar in that the digital scan (X-ray, CT, MRI) is transferred to a 3D modeling software package (SolidWorks, Maya, 3ds Max, etc.). Within such a program, the details of the image and model can be manipulated. Color and texture can be added to the external surface. Internal geometries can be edited and added. Properties of flexibility, pliability, and sheer strength can be specified. These steps create a model which appears more realistic, but the dynamics of behavior and reaction to surgical intervention require the creation of software code within a specific simulation. This software is the same as that described in realistic tissue modeling above.

Patient-specific tissue modeling is an exciting and challenging goal, which our community will be pursuing for year or decades to come.

Patients are becoming more and more educated about their diseases, treatment options, and selecting surgeons. A common question during consults now is "how many of these have you done?" Numbers, however, are not synonymous of skill. A newly accredited surgeon could be exceptional while an expert's skills begin to deteriorate. Simulation offers a risk-free way to certify and recertify surgeons in a way that is easily understandable to patients [35]. They have a right to know how many hours have been spent practicing for a procedure or how often their surgeon's tremors cause unnecessary tissue damage – and this can all be measured without any added harm to a patient or cost to an institution. As medical science moves forward with awareness and transparency, so must robotic surgery progress along with it [68].

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Simulation in Surgical Endoscopy

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Background

Historically, surgical skills have been taught and learned by practicing on real patients under the tutelage of a more experienced surgeon. This apprenticeship model of training surgeons dates back to the Halstedian era. Surgical endoscopy, like other surgical skills, has been taught under this same framework for many years [1]. Trying to learn procedures on actual patients can be problematic for many reasons. The complexity and variability of patient anatomy can be difficult for learners trying to acquire basic fundamental skills. Reliable and repetitive practice that is helpful and often necessary to acquire basic skills is not always possible relying only on real patients in clinical practice. The cognitive load of learners who are trying to acquire basic skills in the clinical environment may detract from a learners' ability to focus on the more complex decision-making or procedural aspects of the case [2, 3]. Additionally, there are ethical concerns with perceived *practice* occurring on real patients. Studies have shown that endoscopic procedures performed by novice trainees may result in not only longer procedures but also increased patient discomfort and risk [4, 5]. These patient safety and ethical concerns, along with the desire for surgical educators to teach residents and students in an efficient manner in the era of the 80-h workweek, have allowed simulation to become a mainstay for many surgical skills including flexible endoscopy [6].

Endoscopic simulation experience is highly variable among residency programs, and while there is an Accreditation Council for Graduate Medical Education (ACGME) requirement for residency programs to have "meaningful simulation experiences," there is no provision specific to simulation in flexible endoscopy for surgical residents [6, 7]. Surveys have shown that flexible endoscopy is one of the most common procedures performed by practicing general surgeons, especially in rural settings, so there is a growing agreement that the need to ensure adequate training and competence in flexible endoscopy for graduating residents is paramount [8, 9]. Case volume has historically been used as a surrogate for competence in endoscopy, but there is no clear consensus on the number of scopes required to achieve competence [10–13].

Out of the need for a more objective assessment of competence, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) created the Fundamentals of Endoscopic Surgery (FES) program to ensure practitioners can demonstrate core competency in both the cognitive and technical aspects of endoscopy [14–16]. Similar to the Fundamentals of Laparoscopic Surgery (FLS) program, the technical skills portion of the FES exam takes place in a simulation environment, and passing the FES exam will now be required for all general surgery residents graduating in 2018 and beyond in order to become eligible to sit for the American Board of Surgery Qualifying Exam [7].

There is currently no standardized simulator or curriculum to help trainees develop competency in surgical endoscopy, and there are numerous upper and lower endoscopy simulation platforms that can be purchased or have been described for building one's own simulation lab. Each simulator has its own inherent strengths and weakness that may lend better or worse for training a specific skill set (basic skills vs. complex skills, diagnostic vs. therapeutic procedures, upper vs. lower endoscopy, etc.). This chapter will give an overview of the available endoscopy simulators and outline the best practices in education for establishing meaningful surgical endoscopy simulation curricula for trainees.

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Types of GI Simulators

There are four broad categories of endoscopy simulators—mechanical or physical models, computerized or virtual reality (VR) models, composite animal models, and live animal models. A recent meta-analysis showed that compared with no simulation training, all types of simulators significantly improve endoscopic skill. This improvement is seen not only in simulation-based metrics but translates to improved skill in the clinical environment with regard to procedural time, process behaviors, and risk of procedural and major complications [17]. However, there have been few studies that compare different simulation modalities to one another, making it important to consider the desired curricular learning objectives in the context of the strengths and weaknesses of each individual platform when choosing a simulator.

Mechanical or Physical Models

The first endoscopy simulators were physical models developed in the late 1960s and early 1970s [18, 19]. Physical or mechanical simulators are inanimate models that are most often made of plastic and rubber material and are configured with various degrees of realism to mimic human upper or lower gastrointestinal anatomy. Because of the inexpensive materials, physical simulators are relatively low cost, do not require extensive setup, and can be used reliably for repetitive practice. They utilize a standard endoscope and tower, allowing learners to familiarize themselves with the same equipment used in clinical practice.

Physical models, however, can lack realism because the synthetic materials do not feel or respond as normal human tissue would. Many physical simulators also lack clinical variation because they are designed to have a fixed configuration. Additionally, most physical models do not have built-in feedback metrics for learners, so they require the presence of a mentor or proctor for performance feedback and to ensure learners are performing skills appropriately. They have a limited clinical variety, reliable setup, and low cost, making them ideal for training basic, fundamental skills. Multiple studies demonstrate improvement in clinical skills using physical simulators, especially early in the learning curve for surgical endoscopy training [20–23].

There are several physical simulators that are commercially available, as well as published descriptions of "homemade" physical models that can be built in one's own simulation center (Table 1). The most widely available commercial, lower endoscopy physical models are the Kyoto Kagaku Colonoscope Training Model and the Koken Colonoscopy Simulator Type II (formerly IB) [24, 25]. These models are similar in design with a plastic torso and a silicone

Table 1 Physical simulators

Simulator	Design features	Target skills
Kyoto Kagaku Colonoscope Training Model	Plastic mannequin torso Silicone rubber colon Anal sphincter manipulated by hand pump allowing for suction and insufflation Can be positioned supine, left lateral, or right lateral Soft abdominal wall allowing for manual pressure Different setup configurations of the colon allowing for varying difficulty No simulated cecum	Colonoscopy Basic scope navigation Loop management
Koken Colonoscopy Simulator Type II	Plastic torso Silicone rubber colon	Colonoscopy Basic scope navigation "Add-on" modules Polypectomy Hemostasis with clipping Balloon enteroscopy
Koken EGD Simulator	Plastic head Silicone rubber esophagus and stomach Trans-oral and trans-nasal scope insertion	Upper endoscopy Basic scope navigation Cannulation of papilla for ERCP Ulcer identification "Add-on" modules Polypectomy Clipping for hemostasis
Endoscopy Training System (ETS, aka SCOPE)	Plastic mannequin torso Silicone rubber colon Also includes non-anatomic unit for fundamental skills Can be used as procedure simulator or part-task trainer Basic electrocircuitry that provides feedback to the learner	Basic skills required of both upper and lower endoscopy Scope navigation Loop reduction Mucosal inspection Tool targeting Retroflexed tool targeting

Table 1 (continued)

Simulator	Design features	Target skills
Thompson Endoscopic Skills Trainer (TEST)	Five part-task training modules included within a single training box	Basic endoscopy skills Knob control Retroflexion Torque Polypectomy Navigation with loop reduction
Trus UGI model	Part-task trainer Made of foam, cardboard box, plastic table cloth, and stickers Proficiency metrics established Ability to build at home	Basic upper endoscopy skills Scope traversal Tip deflection Torque Retroflexion
MITIE Flexible Endoscopy Targeting model	Part-task trainer Proficiency metrics established Made using pool hose, plastic pegboard, Hasbro game operation, and hot biopsy forceps	Basic lower endoscopy skills Scope traversal Tip deflection Torque Tool targeting
McGill low-cost simulator	Part-task trainer made from off-the-shelf materials Wooden box lined with fabric Hollow plastic tube with metal targets, wired to electrocircuitry Slinky lined with material secured to cardboard box	Targets basic FES skills Retroflexion Targeting Navigation and loop reduction Mucosal inspection

rubber colon. The Kyoto Kagaku model has different colonic configurations that allow for varying difficulty, while the Koken lower GI model can be used not only for basic navigation skills but has additional modules available for polyp resection, hemorrhage control, and balloon enteroscopy. Koken also manufactures an esophagogastroduodenoscopy (EGD) simulator that can be used for training basic upper endoscopy skills including ulcer detection, polyp resection, and cannulation of the papilla for ERCP [26]. While there is no current validity evidence for the use of either of the Koken simulators for skills assessment, the Kyoto model has been studied more extensively for skills assessment and has shown some validity evidence relating to procedural completion rate, completion time, and peak force exerted throughout the procedure [27].

The Simulated Colonoscopy Objective Performance Evaluation (SCOPE) model is another physical simulator commercially available under the name Endoscopy Training System (ETS). This model is based on the Kyoto Kagaku colonoscopy body model but adds a second, non-anatomic unit for additional fundamental skills. These have been used together to assess fundamental skills of scope manipulation, basic tool targeting, loop reduction, and mucosal inspection in a realistic configuration to human anatomy with a high level of validity evidence [28–30]. The ETS adds a retroflexion task to the SCOPE platform to more fully represent the skills domain for gastrointestinal endoscopy. The Thompson Endoscopic Skills Trainer (TEST) (EndoSim LLC, Hudson, MA) is a part-task training simulator that has demonstrated validity evidence for skills assessment with modules mimicking retroflexion, knob control, torque, polypectomy, and navigation with loop reduction [31, 32]. The effectiveness of training using both the ETS and TEST is currently being evaluated.

There are several homemade task trainers that have also been described. The Surgical Training for Endoscopic Proficiency (STEP) is a partnership between SAGES and Olympus America Inc. to provide training equipment and curricula for surgical endoscopy [33]. This partnership developed two novel low-cost physical simulators with limited content validity evidence, as well as suggested performance metrics to indicate training proficiency. The Trus upper GI model is made of foam, a cardboard box, a plastic tablecloth, and stickers to teach scope traversal, tip deflection, torque, and retroflexion at a total cost of less than 5 dollars. The MITIE Flexible Endoscopy Targeting model is designed using a pool hose, a plastic pegboard, the Hasbro game operation, and a hot biopsy forceps wired to the game to train users in scope traversal, tip deflection, torque, and tool targeting. Not associated with the STEP program, a research group from McGill University recently reported the development of a low-cost, self-assembled simulator for training and evaluation of flexible endoscopic skills [34]. The tasks are based on the SAGES FES program and include retroflexion, targeting, navigation and loop reduction, and mucosal evaluation. The model costs an estimated $65 in supplies to make. The initial report shows limited validity evidence with respect to the assessment of expert and novice endoscopists. The effectiveness of this new model for training is currently being evaluated.

The X-Vision ERCP training system is created in a mechanical workshop from aluminum and plastic materials. It requires an “organic papilla” and can be used for sphincterotomy and stent placement. This platform has demonstrated some limited validity evidence when used for assessment; however, it is not commercially available, and its setup is extensive [35–37]. The effect on training for ERCP is unknown.

The major strengths of physical simulators are their reliability, relatively low cost, and easy setup that allows learners to practice basic fundamental skills in a reproducible and repetitive manner. While physical simulators may not always have as much realism as other models, such as the composite animal models, they mitigate many of the challenges and costs associated with more elaborate simulation platforms.

Virtual Reality (VR) Models

Virtual reality models were first developed in the 1980s and utilize computer technology for simulated flexible endoscopy [38, 39]. VR simulators have simple modules to practice basic skills but also cater to advanced learners by offering more complex tasks with a wide range of clinical variability. VR models require essentially no setup time after initial installation, and because of the computerized nature of the modules, they can be easily reset and used for repetitive practice.

There are three commercially available VR platforms—the BRONCH/GI Mentor II (Simbionix, Cleveland, OH), the GI Mentor Express (Simbionix, Cleveland, OH), and the AccuTouch/EndoVR (CAE Healthcare, Quebec, Montreal, Canada) [40, 41]. These simulators have basic modules for upper and lower endoscopy, as well as more advanced modules for ERCP, polypectomy, biopsy, and interventions for hemostasis (Table 2). The scopes that are part of the VR platforms have a similar feel to endoscopes used in clinical practice and allow users to suction, irrigate, insufflate, and navigate as one would in an actual clinical procedure. The VR simulators provide built-in feedback metrics and a “virtual attending” that can assist in guiding the learner through the simulated case. The programming on these simulators also allows instructors to establish customized training for individual learners to meet their learning needs.

Cost, limited portability, and lack of realistic haptic feedback are the major drawbacks of VR endoscopy simulation. The initial cost can be well over $60,000, with additional modules for clinical variety resulting in a greater expense [42–45]. These costs are often prohibitive for training programs or simulation centers and essentially preclude their use beyond such programs or centers. While some of the VR systems use robotic technology to provide haptic feedback during procedures, in our experience this is not similar to real haptic feedback during clinical endoscopy. Technical failures of VR equipment also require expertise, time, and potential cost to fix. Simbionix has attempted to address the limited portability of the GI Mentor II by the creation of the GI Mentor Express [40, 46]. While this model is more portable and considerably cheaper than the BRONCH/GI Mentor II, it is still significantly less portable and more expensive than many of the physical or composite training models [46].

Table 2 Commercially available VR simulators

		BRONCH/GI Mentor II	GI Mentor Express	AccuTouch/EndoVR
Features	Screen	Single 24″ monitor	Laptop screen	Two 24″ monitors
	Portability	Limited	Desktop platform	Limited
	Adjustable simulator height		X	X
	Virtual patient cases	X	X	X
	Curricular management system	X	X	X
	Initial cost estimate	$64,500 (for basic gastroscopy and colonoscopy modules)	3–4x less than GI Mentor II	$46,750 (basic upper GI modules) $74,750 (basic lower GI modules)
Feedback	3-D map	X	X	X
	Pain indicator	X	X	X
	Virtual instructor	X	X	X
	Basic task and fundamental skills modules	X	X	X
Modules	Virtual delivery of medication during procedures			X
	Basic upper GI endoscopy	X	X	X
	Basic lower GI endoscopy	X	X	X
	ERCP	X	X	X
	Emergency bleeding/hemostasis techniques	X	X	X
	EUS			X
	Bronchoscopy	X	X	X
	Advanced bronchoscopy procedures			X

The benefits of training and skills assessment on both the GI Mentor and EndoVR simulators have been studied extensively. With regard to lower endoscopy, several studies demonstrate validity evidence for several of the tasks and metrics on these platforms [47–54]. Skills in lower endoscopy gained on VR platforms also translate to improvement in the clinical environment with regard to shorter procedure times, more complete exams, higher subjective and objective assessment scores, higher cecal intubation rates, and reduced patient discomfort [55–59]. There is also validity evidence for VR simulators in upper endoscopy [60–62]. Similar to lower endoscopy, upper endoscopy skills gained on VR simulators translate to improvement in skills in the clinical environment [55]. Despite this validity evidence for fundamental endoscopy, studies suggest that VR simulators may oversimplify complex tasks for other skills such as laparoscopy, which may make VR not the best modality for training in therapeutic or interventional endoscopy [63, 64].

SAGES chose the GI Mentor II and GI Mentor Express as the simulation platforms for the FES technical skills exam. One likely reason for this choice is the need for a model that has reliable standardization when delivering a high-stakes exam; however, the cost associated with a VR simulator, the lack of realistic haptic feedback, and possibility of technical failures may make training on VR simulators challenging for some programs. Additionally, unlike SAGES' sister program FLS, the FES tasks on the GI Mentor platforms cannot be used for training. VR-based training modules designed to help trainees prepare for the FES exam are currently under development and evaluation.

Composite Models

Composite models use a physical structure or frame (often a plastic mold) to mount ex vivo animal organs that are adapted and altered to mimic the desired anatomy and pathology. Using animal organs allows composite models to have more realistic feeling tissue while eliminating some of the infrastructure, cost, and ethical concerns of using whole live animals for simulation. The endoscopic appearance and haptic feedback of composite models are more similar to clinical endoscopy in humans, and these models utilize the typical GI endoscopy tower and scope during performance of the simulated procedures. Composite models are often adapted to have polyps or active hemorrhage to practice therapeutic endoscopy in a controlled environment; however, the shelf life, setup, and preparation of the ex vivo organs to mimic human anatomy with pulsatile bleeding capabilities can be lengthy and often result in onetime use.

The composite models are summarized in Table 3. The most well-known composite model is the Erlangen active simulator for interventional endoscopy (EASIE). This model was developed in the 1990s for therapeutic endoscopy training [65, 66]. The model was then modified to the compactEASIE [67–69]. Both of these models have plastic heads and torsos with porcine organs that are tailored to practice over 30 upper GI skills including hemostasis techniques, ERCP, PEG insertion, EUS, and double-balloon enteroscopy. To practice hemostasis techniques in a controlled environment, plastic cannula connected to a pulsatile perfusion system can be placed through perforations in the organ wall to simulate bleeding. Similarly, the EndoX and Welsh Institute for Minimal Access Therapy (WIMAT) suitcase model are lower endoscopy composite models [70–72]. The EndoX uses ex vivo bovine colon that is attached to a platform arranged to mimic human lower GI anatomy. This simulator has demonstrated some limited validity evidence when combined with observational assessment and is used for training basic scope navigation to various landmarks [70]. The WIMAT model uses ex vivo porcine colon to train in the resection of sessile, non-bleeding pedunculated, and bleeding pedunculated polyps. This model has also demonstrated some validity evidence in the assessment of these skills using observational rating scales [71, 72].

Table 3 Composite simulators

Simulator	Design features	Target skills
compactEASIE	Plastic head and torso Porcine ex vivo organs Pulsatile infusion system to simulate bleeding	Over 30 upper endoscopy skills including: Polypectomy Hemostasis techniques ERCP PEG insertion EUS Double-balloon enteroscopy
WIMAT suitcase model	Ex vivo porcine colon mounted in "suitcase" structure Ability to simulate bleeding	Lower endoscopy polyp resection Sessile polyps Non-bleeding pedunculated polyps Bleeding pedunculated polyps
EndoX	Ex vivo bovine colon attached to platform designed to simulate human LGI anatomy	Basic lower endoscopy skills Scope navigation

When compared with VR simulators, composite models have superior validity evidence; however, they are considered the most difficult to incorporate into training [73]. The time associated with altering composite models to mimic human anatomy may not make sense for helping learners acquire basic fundamental skills, which typically requires repeated, deliberate practice. The higher fidelity of animal tissue compared with physical or VR models and the ability to simulate gastrointestinal hemorrhage make composite models attractive simulators for practicing complex, interventional tasks.

Live Animal Models

In the past, live animal models have been used to practice endoscopy. A 35-kg pig was found to be the animal model of choice. Live animals do not, however, have the same anatomy as humans, and the infrastructure required for an animal lab, the cost associated with this infrastructure, the ethical concerns, and the more widespread availability of other types of simulators have virtually eliminated the need to use live animals for endoscopic simulation [74].

Realism of GI Simulators

There are at least 27 studies that have evaluated the validity evidence of endoscopic simulators, and many suggest that realism is an important component of highly effective colonoscopy simulators [75]. One of the studies that evaluated the transfer of skills to the clinical environment compared the Kyoto Kagaku physical platform to the GI Mentor VR platform [76]. This study showed that training with the VR platform or the VR platform and physical platform for 3 weeks resulted in better clinical performance than training on the physical platform alone. The Kyoto Kagaku physical model was rated as more realistic than the GI Mentor in this study but was preferred less by learners, likely due to setup time. Hill et al. performed another comprehensive comparison of the realism of the Kyoto Kagaku, Koken, EndoVR, and GI Mentor simulators [77]. They created a novel colonoscopy simulator realism questionnaire (CSRQ) and found that experts consistently rated the GI Mentor less realistic than the other three simulators. The VR platforms outperformed physical platforms with regard to visual realism and mimicking patient discomfort, but visual response, haptic feedback, and insufflation and deflation were most realistic on the physical platforms. From this study there was no single preferred simulation platform with regard to realism.

Overview of Advanced Endoscopy Simulators

The increasing complexity of novel endoscopic procedures continues to push the standard of care and has created a need for a more advanced simulation experience. The limited clinical exposure for common procedures like endoscopic ultrasound (EUS) or ERCP is only minimally being met by simulation-based practice. Their complexity is difficult to mimic which is evidenced by the limited number of platforms available for practice. Despite the paucity of available avenues for advanced endoscopic training, simulators exist that accurately mimic clinical experience and can serve as valuable tools for trainees.

A large amount of advanced endoscopic simulation experience has been gained using live tissue and hybrid platforms. These simulators have the advantage of being reminiscent to real-life clinical experience in appearance and tissue handling. As stated above, the organs are costly, are difficult to store and assemble, and have a shelf life on the order of days. Because of these factors, implementation into a training program using an effective curriculum is difficult resulting in abandonment except for unique training situations. This is supported by a study which showed live animal and hybrid models to be the most difficult to incorporate into training programs [73]. A lengthy discussion surrounding the use of live tissue and hybrid models is beyond the scope of this chapter, and the following will focus on simulation models that can be better implemented into a training environment.

ERCP

The Koken EGD Simulator is the only physical simulator available for papilla cannulation [26]. Previous Koken models included a specific ERCP training model, but this was discontinued in 2013 and replaced with the EGD simulator, which yields similar cannulation abilities. The effectiveness as a training tool is unknown due to a lack of published data but serves as an option for training and deliberate practice.

Both the GI Mentor and EndoVR simulators have ERCP training capabilities [40, 41]. As 2 add-on modules, the GI Mentor has 18 virtual patient cases allowing trainees to use a duodenoscope to practice cannulation, sphincterotomy, stone extraction, and stent placement using a split screen for simultaneous endoscopic and fluoroscopic viewing [40]. The GI Mentor has demonstrated both construct and face validity with users believing it should be incorporated into a training program [78]. The EndoVR simulator has similar add-on modules that allow individuals to practice ERCP interventions; however, there is no formal validity evidence for these modules.

Endoscopic Ultrasound (EUS)

There are both physical and VR models available for EUS training. EUS phantoms are physical models developed by Olympus, which attempt to simulate various endoscopic lesions identified via ultrasonography. The phantom casing houses a silicon block that serves as the medium EUS. Within the silicon, there are various shapes that mimic cystic masses, tumors, and lymph nodes at various depths. These models have the advantage of being cheap and reusable but do a poor job at simulating human anatomy and procedural conditions [79, 80].

The GI Mentor has an add-on module called EUS Mentor [40]. Contrasted to the phantoms, this platform is better at simulating human anatomy, scope maneuvering, and landmark identification. A drawback of the GI Mentor includes the lack of resistance when inserting tools into the working channels [80]. The last available simulator is the 3-D computerized EUS Meets Voxel-Man (EMVM). This computer program can be accessed from anywhere and uses cadaveric anatomy to teach trainees basic endoscopic anatomy using real-life pictures. EMVM is strictly a cognitive simulation tool and should be used as an adjunct to other forms of hands-on training [80].

Percutaneous Endoscopic Gastrostomy (PEG)

PEG tube placement is a very common procedure for enteral feeding access with over 200,000 procedures performed annually. There are currently no VR simulators for training and only two reports of homemade physical simulators. Lujber et al. described using a pumpkin as the medium for PEG placement. This technique obviously lacks anatomic accuracy but may assist with learning procedural steps [81]. The second physical simulator involves creation of a foam gastrointestinal tract that requires multiple hand-sewn anastomoses. The setup time for this simulator is approximately 30 min and requires replacement of components every 3–4 repetitions [82]. Both simulators have drawbacks and are not commercially available, making their utility within a training program suboptimal. Further development is required for the creation of a novel platform for PEG simulation training.

Endoscopic Submucosal Dissection (ESD)/Endoscopic Mucosal Resection (EMR)

There are no published reports of physical or virtual reality simulators used for ESD or EMR. Training currently relies on both in vivo and ex vivo tissue-based simulators. The latter is more often used due to their greater availability and decreased cost. There are no commercially available physical simulators, and it is unknown whether virtual reality modules are being developed. Although difficult to implement into training programs, tissue-based models are the current standard for simulation-based ESD/EMR training [83].

Dilation/Stenting

There continues to be increasing utility for endoscopic intervention of esophageal and colorectal strictures/stenoses. Similar to above, there are no available computerized or VR simulators for stricturoplasty or stenting. There is one report of a homemade model using a paper cylinder and foam filler that simulates an esophageal stricture. This model has some content validity evidence and is relatively simple and easy to employ in a training setting [84]. Its long-term utility is currently unknown. This represents the first and only simulator available for endoscopic stricture/stenosis intervention.

Training Principles

Mastery Learning and Deliberate Practice

While the decision of which simulation model to choose is important, the training curriculum is equally, if not more, critical for optimal training outcomes. Some simulators have built-in curricula that incorporate visual and auditory tutorials followed by trainee practice. These curricula are usually based on assigning modules to learners for them to complete, without requiring any particular performance benchmark to be reached. This leads to suboptimal outcomes as trainees are left with an unstructured framework and haphazard curricula, leading to a great amount of variability in the trainee performance upon completion of the curriculum. This is in contrast to training outcomes when mastery learning principles are used for curriculum development.

Mastery learning theory requires learners to achieve a predefined learning goal before they are able to progress to higher levels and more complex tasks [88, 89]. This methodology is attractive for surgical and procedural endeavors because it allows learners to confirm the acquisition of fundamental skills as they progress forward in a curriculum. Knowing that learners start with varying levels of skill, the amount of time required to achieve proficiency hinges on their ability to reach a preset standard and not just completing a module or a particular number of repetitions. Ideally, deliberate, distributed practice lasting for no more than 60–90 min per training session should be employed which gives the trainee freedom and flexibility for longitudinal practice [90].

Simulation-based mastery learning has been employed in multiple different settings and has resulted in remarkable outcomes [85–87, 91–95]. The ability to develop a mastery learning curriculum is technically feasible for all endoscopy simulators, but execution can be lacking due to inherent limitations of the simulator itself. For example, the cost of training and availability of supplies can be prohibitive using mastery learning for live tissue and hybrid models. Physical simulators may be cost-effective for mastery learning-based deliberate practice if there are limited consumables associated with the simulated tasks. In contrast, VR models are typically a onetime cost for programs, which makes them ideal for deliberate practice. Furthermore, the majority of these simulators have multiple different modules ranging from fundamental skills to complex, advanced endoscopic techniques. The ability to develop a curriculum using these modules results in high levels of customization and gives programs a greater control of learned material. Currently, there is only one publication where mastery learning concepts were applied to training for endoscopy [56]. This study compared training to an expert-derived performance standard on the AccuTouch colonoscopy simulator to non-simulation-based traditional training. Subjects in the simulation training group had cecal intubation rates 2.5 times higher than the control group, with significantly less pain reported by patients and faster procedure completion times. These findings are promising for future studies incorporating a simulation-based mastery learning approach.

Feedback

Effective feedback is a hallmark of learning and has been linked to improved trainee outcomes when properly employed in simulation-based training [96]; however, there are different types and methods of approaching feedback during endoscopic training. In the clinical setting, feedback is typically immediate due to concerns for patient safety. Simulation offers the ability to customize how feedback is administered to the learner.

There is evidence to show that the timing of feedback is an important factor during endoscopic simulation training. Specifically, trainees that are given feedback *after* completion of a simulated endoscopic task have better transfer of skill to new and different tasks [97]. One explanation for this finding is that concurrent feedback may inadvertently increase cognitive load in a prohibitive manner resulting in loss of "learning in action" for the trainee. Additionally, simply relying on the simulator to supply feedback is less effective when compared to early, constructive feedback from a trained expert [98]. This means that the "virtual attendings" used by VR simulators may best be replaced with a trained proctor for optimal outcomes. This methodology is based upon Vygotsky's scaffolding principle, which states that novice learners require maximal support by an expert early in learning. Lastly, feedback should be given before trainees embark on self-paced deliberate practice. Trainees who received delayed feedback performed worse, which may be a result of reinforcement of suboptimal behaviors prior to feedback [99]. Extinction of these behaviors prolongs training, detracts from learning new skills, and further frustrates the learner.

Assessment and Metrics

Many of the different endoscopic simulators have built-in metrics that can be used to assess trainees throughout practice sessions. The utility of these metrics is often limited, and metrics are frequently chosen based on how easy they are to measure instead of how well they fit the construct being assessed. Regardless of the simulator chosen to train students, determining how they will be assessed is important to gage outcomes and the efficacy of a simulator and/or curriculum.

Currently, FES is the only endoscopic assessment tool that is used for professional certification [7]. FES uses the VR Simbionix GI Mentor platforms and is composed of five separate tasks that encompass basic endoscopic skills required for safe endoscopy [16]. An ideal training simulator would both promote passing the FES skills exam and improve clinical performance. It has been previously shown that relying on clinical experience alone to prepare residents to pass FES can lead to high first-time failure rates, and there is a paucity of training curricula designed to prepare students [100].

Ideally, using a mastery learning curriculum that targets the tasks tested on the FES skills exam would likely yield results similar to those seen in FLS [86]. Unfortunately, these tasks are proprietary and unavailable for training purposes on the GI Mentor platform. Many of the simulators described above lack the ability to practice basic endoscopic skills, and using them may perpetuate high first-time failure rates. In order to promote success on FES, the simulator chosen needs to be matched with a curriculum that practices fundamental endoscopic tasks.

There are multiple other assessment tools that can longitudinally track the performance of trainees throughout the training. Examples include the Global Assessment of Gastrointestinal Endoscopic Skills (GAGES), Mayo Colonoscopy Skills Assessment Tool (MCSAT), and Rotterdam Assessment Form for colonoscopy (RAF-c) [101–103]. Each is unique and measures variables including cognitive, technical, and interpersonal skills. These assessment tools are designed for clinical endoscopy, and their utility in simulation-based assessment is currently unknown. Although designed for clinical use, any of these assessment tools could likely be modified and applied in a simulation setting, but further validity evidence for the use of these tools in a nonclinical setting would be needed. Furthermore, simulated endoscopy training typically occurs in concert with patient practice, and these tools can be used during clinical endoscopy to track the effectiveness of simulation training. For example, differences in pre- and post-simulation training scores using one of the assessments above can help determine the effectiveness of a particular simulation-based training curriculum. As these different endoscopic simulation curricula are developed, application of these assessment tools in their raw or modified form can be investigated as a way to judge trainee proficiency outside of the clinical setting.

Conclusions

It is imperative that surgeons learn flexible endoscopy in a manner that is both safe and ethical for patients and efficient and effective for learners. In order to achieve this, one must have specific learning objectives and choose a simulator that is best equipped to meet those objectives. Physical and VR simulators are best for implementing curricula that revolve around repetitive, deliberate practice and are focused on basic skill acquisition, whereas composite models allow learners to practice therapeutic procedures in a controlled environment with tissue that responds realistically. There are also a wide variety of simulators for more experienced learners to practice advanced procedures, but currently few of these simulators are well studied or lend themselves easily to deliberate practice. Considering how feedback will be delivered to learners and what assessments will be used to track learners' progress are also keys to success. There is still no uniformly agreed-upon measure of proficiency; however, the FES test is becoming the early standard for surgical endoscopists. More work is needed to develop standardized, cost-effective, and reliable simulation-based curricula that allow for the acquisition of endoscopic skills while ensuring patient safety.

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Simulation in Surgical Oncology and Hepato-Pancreato-Biliary Surgery

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Introduction

Surgical oncology includes a spectrum of procedures with varying levels of technical and cognitive complexity. Hepato-pancreato-biliary (HPB) surgery, due to the complexity and relative infrequency of procedures, is an ideal domain to benefit from simulation-based training. Foundational technical and cognitive skills acquisitions are most often facilitated by task trainers, while advanced procedural skills, including minimally invasive approaches to operations that practicing surgeons may be already doing in an open approach, tend to require the higher anatomic and tissue fidelity of a cadaver or live animal model. Simulation offers the potential to serve as refresher or warm-up practice for infrequently performed procedures in HPB surgery. Significant needs in the field include data connecting performance in the simulation lab to operative performance or patient outcomes, as well as robust assessment tools with validity evidence for a trainee's competence to participate in clinical cases or to operate autonomously.

The Role of Simulation in Hepato-Pancreato-Biliary Surgery

HPB surgery comprises procedures with high technical demands, including minimally invasive and open liver resections, pancreatic resections, and biliary resections/reconstructions. Studies examining the learning curve for HPB procedures estimate that 30–60 clinical cases are required to achieve mastery [1–4]. Studies of learning curves often come from surgeons at high-volume centers with substantial domain knowledge, who then pioneered the new approaches. This is a fundamentally different context than a trainee learning from an expert faculty in an environment in which the procedures are already being performed. It is reasonable to conclude that for a resident or fellow, some of the learning curve of a new procedure will occur during training, with the remainder occurring during independent practice. For a practicing surgeon, the experience of being taught a procedure that has already been standardized likely moves the surgeon through the "pioneering" phase of the learning curve and may result in a learning curve that is less than the published figures of 30–60 cases [5]. However, the relative contributions of prior experience, case volume, context of learning, and simulation-based training have not been precisely defined.

Exposure to these procedures during the course of general surgery residency has increased over the last decade, based on ACGME case log review and surveys of program directors [6–8]. However, these case log numbers are well below those advocated by the International Hepato-Pancreato-Biliary Association for trainees intending to perform HPB cases as part of their practice [9] and must also be taken in the context of overall concerns that graduating residents are not prepared for the level of autonomy expected of fellowships and senior practice partners [10]. Taken together, these data suggest that exposure to these cases may not mean the residents are participating in a meaningful way or achieving competency.

Simulation offers clear benefits in initial skills acquisition, which for HPB surgery may potentially allow residents to more fully participate in clinical cases with a higher level of autonomy than they would without prior simulation-based training. Simulation also allows practice of critical portions of HPB procedures, such as hepatico-jejunostomy, which can augment the clinical exposure and accelerate achieving competence. The Americas Hepato-Pancreato-Biliary Association (AHPBA) has recognized the value of this application of simulation, offering a structured training course for HPB fellows yearly including dedicated simulation-based training. In addition, simulation can be used as an assess-

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ment tool in a competency based or mastery-training framework, to evaluate readiness to participate in clinical cases or determine competence for autonomy. Assessment tools with robust validity evidence are required to capitalize on this use of simulation and remain the subject of ongoing work.

Practicing surgeons adopting new approaches such as minimally invasive liver resection or procedures such as image-guided irreversible electroporation into their practice may also use simulation, often in the form of cadaver or live animal laboratory teaching and practice. In HPB surgery, this is typically in the context of an industry-sponsored workshop, although instructors are most commonly other practicing HPB surgeons. Formal assessment components are lacking in this application as well.

Outcomes for complex HPB procedures have been linked to surgeon volume [11–13], which, coupled with evidence that simulation can be used as a warm-up to improve operative performance in other contexts [14–16], suggests a role for simulation in improving a low-volume surgeon's technical performance. This may not translate into improvements in overall patient outcomes, as there are dimensions of high performance observed in high-volume centers that relate to nontechnical skills such as teamwork skills and early recognition of and intervention to minimize the impact of postoperative complications. The role of simulation in training and assessing teamwork skills is discussed elsewhere in this book and is not specifically unique to HPB surgery.

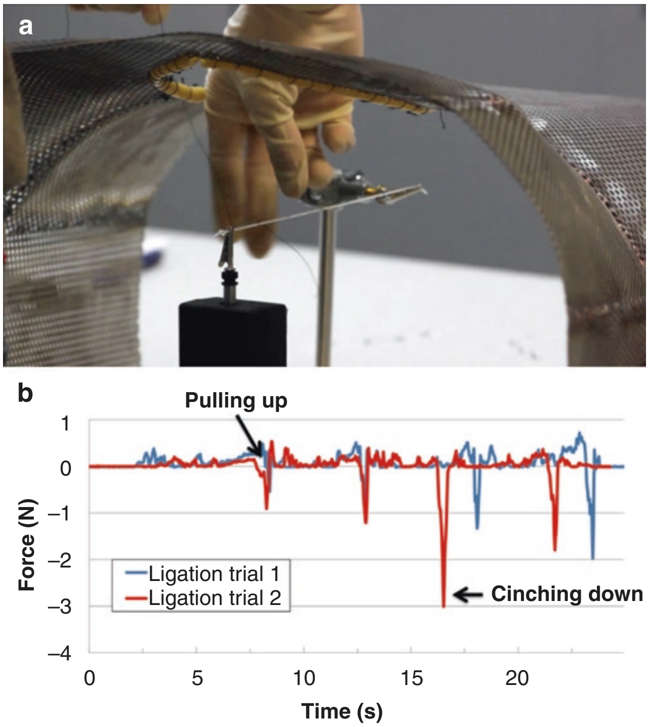

Fig. 1 (**a**) Photograph of force feedback simulator used to teach delicate knot tying, demonstrating force sensor attached to simulated blood vessel, encased in an apparatus to create the physical constraints of a deep abdominal or retroperitoneal task. (**b**) Example of output from force sensor, which displays the magnitude and direction of force applied, providing real-time feedback to inform deliberate practice

Simulation Modalities and Curricula Used in HPB Surgery

Foundational Technical Skills

As with most open surgical procedures, foundation technical skills in HPB surgery include suturing, knot-tying, and opening and closing a laparotomy incision. Models and curricula for these skills are some of the earliest described and integrated into graduate medical education [17–20]. In the current era, opportunities to practice tying secure knots deep in the abdomen and retroperitoneum without disrupting the delicate tissues or vessels have been supplanted in many contexts by surgical energy devices. Simulation provides an ideal deliberate practice platform for this critical skill [21, 22]. In one published curriculum, trainees tie knots in a simulator that provides physical limitations similar to an open surgical case, and a force sensor provides real-time feedback of the amount of positive (pulling up) or negative (synching down) force exerted by trainees during knot tying (Fig. 1). The curriculum takes into account final-product analysis by measuring the diameter of the knot with digital calipers, which was shown to correlate with air knots and incomplete ligation of the vessel. Through deliberate practice, trainees can achieve force metrics equivalent to experienced surgeons. However, performance of this skill in the simulation lab has not been correlated to performance in the operating room.

Hepato-pancreato-biliary surgeons employ hepaticojejunostomy, choledochojejunostomy, and pancreaticojejunostomy in many procedures. The relative infrequency of these anastomoses within surgical training, coupled with the high-stake nature of the procedure – specifically the potential for severe complications if a leak occurs – makes these procedures ideal for simulation-based training [23]. Pugh and colleagues describe one example of using simulation to teach pancreaticojejunostomy, with a focus on combining the technical skills with cognitive training on decision-making associated with performing the skill [24]. In the course of interacting with the simulated pancreas and jejunum, the trainee is challenged to engage in critical thinking around four aspects of intraoperative decision-making: (1) surgical planning by setting up the pancreas and bowel for ideal placement of the back wall sutures, (2) error recognition by identifying inadequate mobilization of the pancreas, (3) error prevention by recognizing friable tissue and adjusting suture placement and tension, and (4) error rescue by managing the anastomosis after a stitch pulls through the pancreas. Incorporating decision-making and technical skills is an ideal application of simulation in not only acquiring foundational skills but accelerating the learning curve by providing a standardized experience in a more compressed format. By allowing trainees to experience the consequences of their decisions, adult learning principles are maximally applied, creating a highly effective learning environment.

Another technical and cognitive skill that is relatively unique to HPB surgery is ultrasonography. In addition to identifying pathology and providing anatomic planning and guidance during surgical procedures, ultrasound is integral to performing image-guided tumor ablations in the liver or pancreas. There are numerous commercially available curricula and simulators to teach the fundamentals of ultrasound [25, 26]. Image-guided thermal ablation may involve a radiofrequency energy-based probe or microwave energy-based probe and can be delivered in the course of a laparoscopic or open procedure. Irreversible electroporation is an ablation technique that uses electrical fields to create permanent pores in cell membranes, inducing apoptotic cell death, and has been applied to liver and pancreatic tumors [27, 28].

Several models have been described to facilitate training and practice of the complex visual-spatial task of positioning a needle in a liver tumor under ultrasound guidance. Tumor mimics visible as hyperechoic structures with ultrasound can be created and implanted in an in vivo or ex vivo liver model, allowing for instruction and deliberate practice of laparoscopic or open ablation [29, 30]. One example of an ex vivo model is represented in Fig. 2. Using the conceptual framework of measuring expert performance and establishing target performance metrics from expert data, trainees perform ablations of a tumor mimic placed in standard configurations in an ex vivo bovine liver. Feedback data include the time required to place the needle, the number of passes, number of readjustments, and the percent of tumor ablated. Training

Fig. 2 Model for training and assessing performance of ultrasound-guided liver tumor ablation. (**a**) Physical setup of simulator, ultrasound, and ablation machine during training, (**b**) tumor mimics created ex vivo and implanted into bovine liver, (**c**) ultrasound appearance of tumor mimics during ablation, and (**d**) appearance of liver after ablation

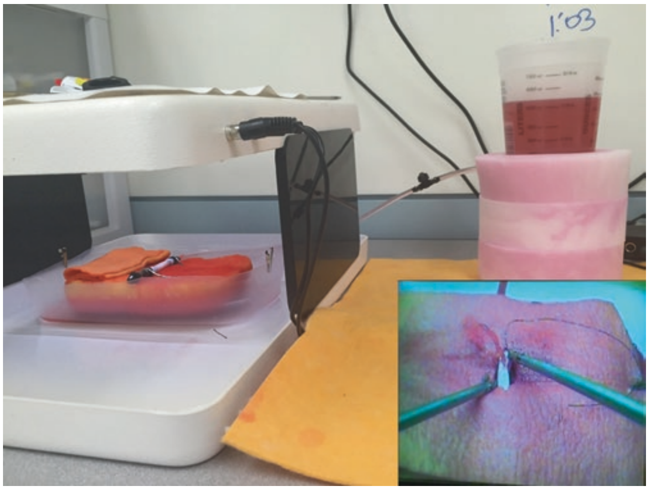

Fig. 3 Setup for model used to train and assess suture repair of a bleeding vessel. Inset shows a screenshot of participant suturing vessel analog, while it is bleeding

on these models has not been shown to correlate with improved performance in the operating room, and as mentioned above, this connection remains one of the "holy grails" of simulation in surgical education.

Another example of simulation-based training for a specific skill employed in the course of an HPB operation is the management of unexpected bleeding during a laparoscopic hepatectomy. In this context, the bleeding may result from an injury, avulsion, or partial transection of a vessel that is intended for preservation, such as the middle hepatic vein. Taking the concept of the *Fundamentals of Laparoscopic Surgery* manual task 5 – laparoscopic suturing – to a higher level of complexity, the task trainer developed by McClintic et al. allows for instruction, practice, and assessment of a surgeon's performance of laparoscopic suturing a bleeding vessel (Fig. 3). Performance metrics include time, amount of blood loss, and vessel patency. This represents another application of simulation-based training for an infrequent but high-stake skill.

Complex Procedural Skills

Simulation-based training has enormous potential for procedural learning in HPB surgery, across the spectrum of minimally invasive to maximally invasive operations. For example, the Advanced Surgical Skills for Exposure in Trauma (ASSET) course was developed for both surgical trainees and practicing surgeons who need to learn or refresh on the operative skills required in managing complex traumatic injuries. In this course, a standardized curriculum and fresh cadavers are employed to teach a variety of exposures including liver mobilization and exposure of the inferior vena cava [31, 32]. Another innovative use of simulation in training is the "Cut Suit" Human Worn Partial Task Surgical Simulator (Strategic Operations, San Diego, CA), which has a perfused peritoneal cavity that allows for performance of a variety of abdominal procedures, primarily focused on trauma. Using this model, military medical technicians can undergo training as a first responder to a battlefield injury, performing a laparotomy and hemorrhage control in the case of liver injury [33].

Laparoscopy presents unique technical and cognitive skills challenges, and the training and mastery of fundamental skills in laparoscopic surgery is discussed elsewhere in this book. Dimensions of laparoscopic surgery unique to HPB surgery and amenable to simulation-based training include image-guided ablation, discussed above, liver and pancreas resections, choledochal cyst resection/reconstruction, and common bile duct explorations. Simulation-based training in laparoscopic liver resections is most frequently taught in the context of either a cadaver or live animal course and is almost exclusively targeted to practicing surgeons with high volumes of open cases who are looking to adapt this newer approach [34, 35]. The advantage of cadaver-based training is the anatomic fidelity; the disadvantages include cost, poor tissue quality in formalin-preserved cadavers, and limited window of use in fresh cadavers (see Table 1). A relatively new method of preparing cadavers using hypertonic saline instead of formalin, termed a Thiel prep, offers improved tissue handling and longer duration of use and is well-regarded by users [36].

In contrast, live animal training provides the fidelity of bleeding tissues, an attribute most valuable to practicing surgeons or advanced trainees. Teh and colleagues describe the rationale for using a sheep model for liver surgery based on anatomic similarities to humans not found in the porcine liver [37], although the porcine model is often used in laparoscopic liver resection courses. Specific courses that include laparoscopic liver resection using live animal models have been designed for advanced trainees such as fellows in Transplant, Hepatobiliary, or Surgical Oncology programs and are intended to augment and accelerate their clinical learning. A perfused human cadaver that offers a combination of the benefits of anatomic fidelity and bleeding tissues, and which has shown promise in areas outside of HPB surgical simulation, could also be employed as part of a simulation-based training curriculum for liver or pancreas surgery [38–40]. Other investigators have developed synthetic abdominal models that could be used for HPB surgery training [41].

Laparoscopic common bile duct exploration (LCBDE) is an infrequently performed procedure, for a variety of reasons including high technical demands and concerns over competition with gastroenterologists who perform endoscopic retrograde cholangiopancreatography (ERCP). However, training programs may wish to include this expe-

Table 1 Simulation-based training

Simulator/ modality	Ideal training context	HPB tasks or procedures	Advantages	Disadvantages	Selected references(s)
Live animal	Initial skills acquisition for advanced trainee; practicing surgeon adopting new approach	Lap or robotic liver or pancreas resection; trauma	Bleeding model increases fidelity; tissue characteristics, ability to do complete procedure	Anatomic differences; high cost, need to travel, limited throughout, and opportunities to practice	[42]
Cadaver	Initial skills acquisition for advanced trainee; practicing surgeon adopting new approach	Lap liver or pancreas resection; trauma	Anatomic fidelity; perfused cadaver has bleeding fidelity	High cost, need to travel, limited throughout, and opportunities to practice; variable quality of anatomy	[31, 32, 34, 39]
Ex vivo tissue or organ models	Initial skills acquisition for trainee	Image-guided liver tumor ablation	Relatively inexpensive, allows opportunities to practice to performance metrics	Not well suited to simulating dissection, not ideal for simulating an entire procedure; lower anatomic fidelity	[29]
Task-specific models or simulators	Initial skills acquisition for trainee, refresher, or warm-up for trainee or practicing surgeon	LCBDE; pancreaticojejunostomy, hepatico-jejunostomy; choledochal cyst excision	Can be low-cost; do not require special animal facilities; more portable	Not well suited to simulating dissection, not ideal for simulating an entire procedure; can have expenses related to replacement components	[17, 18, 19, 20, 21, 22, 23, 24]
Virtual reality	Initial laparoscopic or robotic technical skills acquisition for trainee or practicing surgeon; refresher or warm-up	Foundational skills – suturing, knot tying, anastomoses	Many curricula, clear performance metrics, able to practice as much as needed to reach metrics	High cost; limited throughput and procedure-specific training	[47, 48]

rience for residents or fellows, and health systems looking to streamline care pathways and reduce costs associated with additional length of stay and unnecessary procedures may wish to ensure that this skillset is available at a given institution. Thus, simulation-based training curricula in LCBDE represent an opportunity to augment initial skills acquisition and maintain competency at an infrequently performed procedure. There are multiple curricula and models described, including a porcine model [42, 43] and synthetic task trainers [44, 45]. In both models, surgeons are able to work with the actual equipment used in clinical cases, allowing for practice in the nuances of efficiently maneuvering catheters or a flexible scope into the cystic or common duct in a reproducible configuration with presumed high transfer to the clinical environment. A mastery learning deliberate practice curriculum demonstrates that training on the constructed model results in resident achievement of performance metrics in both trans-cystic and trans-choledochal procedures [45].

One concern in selecting a simulation-based training curriculum is the cost of the model or equipment. For example, the costs of constructing a LCBDE model using supplies easily available at a hardware or craft store will differ exponentially from using a live animal model. Commercially available models are often hundreds or thousands of dollars and may have replaceable components such as the bile duct and gallbladder in a LCBDE model, which create substantial variable costs for training additional surgeons or residents or for allowing the necessary deliberate practice to achieve mastery. An innovative alternative is the use of 3D printing to create a portion of a homegrown simulator, with low-cost supplies used for the replaceable portions. This is demonstrated in the creation of a model using 3D printing to simulate a pediatric choledochal cyst for use in laparoscopic choledochal cyst excision and reconstruction [46]. Delegates at a national pediatric training event found this model useful, reproducible at local centers, and possessing reasonable tactile feedback compared to the actual clinical context.

Robotic-assisted HPB surgery is performed in a relatively small number of higher-volume, specialized tertiary referral centers worldwide [5]. As discussed in the chapter devoted to robotic surgery, there are robust virtual reality (VR) platforms that provide adequate training on the mechanics of operating the robot controls to perform the tasks associated with most surgical procedures, including HPB surgery. These training programs provide the fundamentals for both the novice trainee and the experienced surgeon seeking to adopt a robotic approach to procedures he/she currently performs in an open or laparoscopic fashion. After proficiency-based training using VR simulators, the next step is participating in cases as an assistant or attending a live animal training course, depending on the availability of expertise at one's center. A resident or fellow working with a practicing surgeon will participate in clinical cases with a graduated level of autonomy that will depend on the trainee's skill, the volume of cases available, and the faculty's ability and willingness to mentor a trainee through graduated autonomy in robotic HPB surgery. A practicing surgeon will perform a prescribed number of cases under proctored supervision, which varies significantly depending on the institution, and is often not based on demonstration of proficiency, but rather on fulfilling a preset number of cases.

The process of privileging a surgeon to perform robotic HPB surgery varies by institution and may take into account an attestation by a resident or fellowship program director or a review of outcomes from prior or current experience. There remain, as in other aspects of simulation-based training discussed, significant knowledge gaps as to what metrics achieved in the simulation environment correlate with safe, competency surgery in clinical environment [47, 48]. Learning curves of at least 60 cases are described, but a careful review of cases and outcomes should be undertaken as surgeons begin a robotic experience and as individuals will all have unique learning curves based on prior experience, inherent talent, and case volume [3].

Summary and Conclusions

HPB surgery training begins with the foundational skills required for many if not all surgical disciplines, and the ideal delivery of this training is in the context of mastery-based learning curricula integrated into a general surgery residency. While the case numbers logged by many graduates of general surgery training programs exceed the ACGME requirements, they are consistently below the recommended exposure for surgeons intending to make HPB surgery a regular focus of their practice. In addition, both the Society of Surgical Oncology and the AHPBA have incorporated structured cognitive curricula into their fellowships. The nuances of patient selection, coordinated multidisciplinary care, and perioperative decision-making are at least as important as the technical skills in achieving excellent patient outcomes, and fellowship training is encouraged for any surgeon seeking to specialize in HPB surgery.

Simulation can play a role in the initial technical skills acquisition around tasks and procedures encountered in HPB surgery. As health systems continue to pursue value-based care, simulation-based training to proficiency may be a strategy to ensure that clinical cases are used only for the training that cannot be achieved in the simulation lab. Simulation holds great promise to serve as an assessment tool for readiness to participate in operative cases and to determine appropriate degree of autonomy at the trainee and practicing surgeon levels. There is a critical need for robust assessments with validity evidence for use in these contexts.

For the practicing surgeon, simulation can serve as a means to accelerate the adoption of a new technique or approach to a procedure already performed in a different fashion. In addition, there is reasonable evidence that simulation as a warm-up improves operative performance; however, there has yet to be a connection established between a warm-up and improved patient outcomes. Further study developing clear associations between simulation-based training and patient outcomes is the highest priority in research involving simulation and education.

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Simulation in Bariatric Surgery

Boris Zevin

Current Use of Simulation in Bariatric Surgery

Obesity is a global epidemic. In 2014, the World Health Organization estimated that more than 1.9 billion adults over the age of 18 were overweight (BMI: 25.0–29.9 kg/m^2) and that over 600 million adults were obese (BMI ≥30 kg/m^2) [1]. Obesity increases the risk of developing multiple obesity-related comorbidities including metabolic syndrome, sleep apnea, obesity hyperventilation syndrome, dyslipidemia, osteoarthritis, and others. The worldwide prevalence of obesity has more than doubled between 1980 and 2014; and at least 2.8 million people die each year worldwide from obesity-related comorbidities [1].

Bariatric and metabolic surgery is the most effective strategy for weight loss and for resolution of obesity-related comorbidities in individuals with BMI ≥35 kg/m^2. Surgical management of morbid obesity results in a greater than 60% excess weight loss [2]. Diabetes resolution or improvement is noted in greater than 86% of patients, hyperlipidemia improvement in greater than 70%, hypertension resolution or improvement in greater than 78%, and obstructive sleep apnea resolution or improvement in great than 83% of patients [2]. Laparoscopic (minimally invasive) approach to bariatric and metabolic surgery has been shown to result in equivalent rates of resolution of obesity-related medical comorbidities and significantly less postoperative morbidity (postoperative pain, surgical site infection, hernia formation) as compared to the open (laparotomy) approach [3]. Presently, over 90% of bariatric and metabolic surgery operations are performed using a minimally invasive approach in North America [4].

Contemporary bariatric and metabolic operations include laparoscopic Roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy, laparoscopic adjustable gastric banding, and laparoscopic biliopancreatic diversion with a duodenal switch. The usual path to a career in bariatric and metabolic surgery requires successful completion of a general surgery residency program followed by 1 or more years of a minimally invasive bariatric surgery clinical fellowship. The requirement for minimally invasive bariatric surgery fellowship training prior to the establishment of independent practice is in agreement with the results of a recent survey of practicing surgeons in the United States [5]. Accordingly, 41% of senior surgeons felt that graduating surgery residents do not have adequate training for independent practice, and 47% felt that graduating surgery residents do not have adequate preparation for transition to an attending role [5]. To address these issues, the American Society for Metabolic and Bariatric Surgery (ASMBS) certificate of fellowship completion has specific requirements for cognitive, clinical, and technical training in bariatric and metabolic surgery [6]. The cognitive requirements include attendance of relevant didactic educational sessions, patient management conferences, multidisciplinary conferences, and completion of a formal research project. The clinical requirements include management and evaluation of 50 morbidly obese patients preoperatively, 100 patients in a postoperative inpatient setting, and 100 patients in a postoperative outpatient setting [6]. The technical requirements include performance of 50 intestinal bypass procedures, 10 restrictive procedures, and 5 revisional bariatric procedures.

Simulation is currently a formal part of surgery residency training. Graduating surgery residents in the United States are required to pass the Fundamental of Laparoscopic Surgery curriculum and soon also the Fundamental of Endoscopic Surgery curriculum prior to sitting for the American Board of Surgery exams. The role of simulation for training and assessment in bariatric and metabolic surgery is currently much less extensive. Herein I discuss the current use of simulation in the training of technical and non-technical skills in bariatric and metabolic surgery, as well as

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future directions for simulation-based research including the development of a national comprehensive simulation-based curriculum for training in bariatric and metabolic surgery, the use of simulation for high-stakes assessment and certification, and the evidence for cost-effectiveness of simulation-based training.

Technical Skills Training

Laparoscopic Roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy, and laparoscopic adjustable gastric banding are the most commonly performed bariatric and metabolic operations in North America [7]. Simulation-based training can be used for technical skill acquisition in these advanced minimally invasive operations.

Laparoscopic Roux-en-Y Gastric Bypass

Laparoscopic Roux-en-Y gastric bypass (LRYGB) is one of the most technically demanding bariatric operations with an estimated learning curve of 50–100 cases [8]. The LRYGB operation has been broken down into the following individual tasks using hierarchical task analysis by Zevin and colleagues [9]:

1. Patient positioning
2. Abdominal access and port insertion
3. Placement of liver retractor
4. Creation of Roux limb
5. Creation of jejunojejunal anastomosis
6. Dissection of phrenoesophageal ligament
7. Creation of gastric pouch
8. Positioning of Roux limb
9. Creation of gastrojejunal anastomosis
10. Closure of potential hernia sites
11. Testing of gastrojejunal anastomosis
12. Removal of ports and closure of port sites

A number of these tasks can be successfully learned using virtual reality and benchtop trainers.

Jejunojejunostomy

Zevin et al. developed and provided validity evidence for a comprehensive simulation-enhanced training curriculum for the creation of the Roux limb and the jejunojejunal anastomosis [10]. This curriculum was developed for intermediate-level (PGY 3 and 4) surgery residents and includes a cognitive module, a technical skills module, and a nontechnical skills module. The cognitive module includes self-directed reading materials on the topic of bariatric and metabolic surgery, as well as a 2-h faculty-led lecture on the technical aspects of LRYGB, laparoscopic sleeve gastrectomy, and laparoscopic adjustable gastric banding. The technical skills module includes proficiency-based training for the task of Roux limb and jejunojejunal anastomosis creation using laparoscopic box trainer and cadaveric porcine small bowel. A distributed practice schedule of 90 min maximum per session is followed with specific feedback during each practice session. The task of Roux limb creation and jejunojejunostomy is broken down into individual steps including:

1. Measurement of small bowel
2. Division of small bowel
3. Placement of stay suture
4. Creation of enterotomies
5. Creation of stapled jejunojejunal anastomosis
6. Closure of common enterotomy with intracorporeal suturing

Technical proficiency is assessed using the Bariatric Objective Structured Assessment of Technical Skill (BOSATS) scale [9]. Successful completion of this technical skill module requires demonstration of proficiency – defined as BOSATS score ≥ 80%. The nontechnical skills module of this comprehensive curriculum will be discussed in section "Nontechnical Skills Training."

The evidence of validity for the comprehensive simulation-enhanced training curriculum for the creation of Roux limb and jejunojejunal anastomosis was provided in a randomized controlled trial, which compared intermediate-level surgery residents allocated to the simulation-enhanced curriculum (SET) group and intermediate-level surgery residents allocated to the conventional training group [10]. The SET group completed the simulation-enhanced training curriculum, while the conventional training group continued with conventional surgery training. Technical skills of the study participants were assessed by performing a laparoscopic Roux limb and jejunojejunal anastomosis in a live anesthetized porcine model. Intermediate-level residents in the SET curriculum group outperformed residents in the conventional training group (BOSATS: 56(47–62) vs. 44(38–53), $P < 0.05$). Intermediate-level residents in the SET curriculum group then went on to perform a laparoscopic Roux limb and jejunojejunal anastomosis in a human patient in the operating room (OR). Objective assessment of operative performance in the OR demonstrated transfer of acquired technical skills from the laboratory to the OR [10]. Furthermore, operative performance of an intermediate-level resident who completed the SET curriculum was equivalent to that of a graduating chief surgery resident. The authors hypothesized that completion of the SET curriculum may shorten the learning curve for an advanced minimally invasive procedure in the OR, which in turn may transition some of the advanced minimally invasive surgery training from fellowship into residency.

An advanced simulation training program for the performance of a laparoscopic jejunojejunostomy by junior surgery residents (PGY 1) was developed by Boza, Varas, and colleagues [11]. Completion of a validated basic laparoscopic training curriculum and the Fundamentals of Laparoscopic Surgery course was a prerequisite for participation in this training program. The objective of the program was to provide junior surgery residents with the skills necessary to perform a complete two-layer laparoscopic handsewn jejunojejunostomy. The proposed advanced simulation training program consisted of 14 training sessions in a laparoscopic box trainer on bovine small bowel (Fig. 1). A step-by-step video content was delivered to each resident before the first training session, explaining how to perform each step of a laparoscopic two-layer handsewn jejunojejunostomy. During each training session, residents learned a specific task, repeated it, and received effective feedback to achieve proficiency (global OSATS ≥84% and modified OSATS ≥90%). A new task was then added, obligating the resident to continue repeating the first task as he/she learned the newly added task, reinforcing and consolidating previously acquired skills. Each training session was supervised by an experienced laparoscopic surgeon who measured trainee's performance using objective metrics (global OSATS scale, modified OSATS scale, and time to task completion). Each training session was limited to 60 min.

Upon the completion of training, nine junior residents were asked to perform a laparoscopic jejunojejunostomy on a live porcine model. Their operative performance was compared to a control group of 11 general surgeons, who graduated from traditional surgery residency programs without simulation training, and 6 certified bariatric surgeons. Junior residents demonstrated superior operative performance as compared to the control group of general surgeons (global OSATS scale: 21(20.5–21) vs. 12(8–14), $p < 0.01$; the modified OSATS scale: 18(17–18) vs. 9(8–11), $p < 0.01$; operative time: 18(16–21) min vs. 23(20–28) min, $p < 0.05$; and total path length: 112(90–129) m vs. 548(373–625) m, $p < 0.01$). Even more compelling was the finding that junior residents were able to achieve the same operative performance as certified bariatric surgeons (modified OSATS score: 18(17–18) vs. 19(17–19), $p = 0.365$; and total path length: 112(90–129) m vs. 63(54–137) m, $p = 0.299$). In a follow-up study, technical skills acquired in a simulation laboratory were shown to transfer into the OR [12]. Operative performance of 10 junior residents, who completed the advanced laparoscopic training program described above, was compared to 12 general surgeons without simulation training and 5 certified bariatric surgeons. All junior residents were able to complete the entire laparoscopic jejunojejunostomy without any takeovers, whereas 6(50%) general surgeons needed takeover by a certified bariatric surgeon. Junior residents demonstrated superior operative performance on the laparoscopic jejunojejunostomy as compared to general surgeons without previous simulation training; however, junior residents demonstrated inferior operative performance as compared to the certified bariatric surgeons. These results suggest that completion of a formal simulation-based training curriculum can overcome the early part of the learning curve in the OR; however, ongoing training and practice in the OR on human patients will be required to achieve expertise in laparoscopic bariatric and metabolic surgery.

Laparoscopic jejunojejunostomy can also be learned using a virtual reality (VR) platform. Lewis et al. assessed whether VR simulation is an effective adjunct for training and assessment of technical skills in laparoscopic bariatric surgery [13]. Twenty surgeons were recruited into the study – 5 experienced (performed >100 LRYGB), 5 intermediate (performed >75 basic and >50 intermediate laparoscopic cases), and 10 novice surgeons (performed >75 basic laparoscopic cases). Each surgeon was asked to perform one laparoscopic jejunojejunostomy, in a laparoscopic box trainer using cadaveric

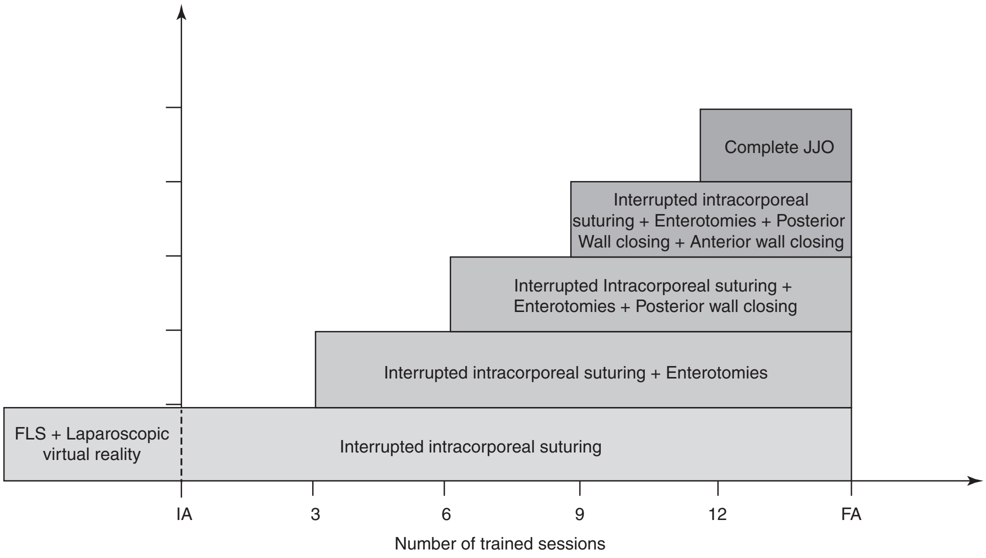


Fig. 1 Structure of a laparoscopic jejunojejunostomy training program. *IA* initial assessment, *FA* final assessment, *FLS* fundamentals of laparoscopic surgery, *JJO* jejunojejunostomy. (obtained from Varas et al. [11])

porcine small bowel, and one laparoscopic jejunojejunostomy in the LapMentor VR simulator (Simbionix, Chicago, IL) using the bariatric surgery module. This module required a surgeon to choose their preferred position for the bowel, to complete an enterotomy using an energy device, to position and to engage a stapling device, and to review the results. This module did not require a laparoscopic stay suture placement or closure of the common enterotomy. Operative performance on the cadaveric porcine small bowel and on the VR simulator was recorded using a video camera. Videos were assessed by blinded expert assessors using the OSATS global rating scale and the modified OSATS scale. The results of the study demonstrated construct validity for the VR simulator; however, concurrent validity was not demonstrated as there was no correlation between surgeon's performance in the VR simulator and in the laparoscopic box trainer [13]. The authors of this study concluded that the bariatric surgery module on the VR simulator can be used to train a surgeon how to perform a laparoscopic jejunojejunostomy; however, the laparoscopic box trainer with cadaveric porcine small bowel should be used for assessment of advanced laparoscopic skills.

Gastric Pouch and Gastrojejunostomy

VR platforms can also be used to simulate creation of the gastric pouch and the gastrojejunostomy as part of the LRYGB [14]. Giannotti et al. demonstrated construct validity for the tasks of gastric pouch creation and gastrojejunostomy in the gastric bypass module for the LapMentor VR platform [14]. Twenty surgeons were recruited into this validation study: 10 general surgeons (performed 75–100 non-bariatric laparoscopic cases) and 10 bariatric surgeons (performed 50–100 laparoscopic bariatric cases). Each surgeon was asked to create the gastric pouch and the gastrojejunostomy on the VR simulator. The VR simulator recorded the following parameters for the task of gastric pouch creation: total time to complete the procedure; volume of the gastric pouch (cm^3); percentage of fundus included in the pouch; percentage of unsafe dissection; time in which coagulation was unsafely used; number of serious complications, bleeding incidents, and noncauterized bleeding; distance of the first stomach dissection from GE junction; number of times the linear cutter was fired; whether dissection was performed at the angle of His when at least 50% of the fat was resected at the left crural area of the diaphragm; and whether the gastric pouch was totally separated from the stomach. The VR simulator recorded the following parameters for the task of gastrojejunostomy creation: total time needed to complete the task, number of injuries resulting from jejunal overstretch, number of punctures larger than 1 cm, number of punctures not used for the gastrojejunal anastomosis, and distance of the puncture created on the jejunum from the end of the cut limb.

There were significant differences in performance metrics between bariatric and general surgeons for gastric pouch creation including volume of the gastric pouch (median 22.1 vs. 48.3 cm^3; $p < 0.01$), percentage of fundus included in the pouch (median 8.4 vs. 29.4%; $p < 0.01$), and distance of the starting point of stomach dissection from the gastroesophageal junction (median 47.5 vs. 26.6 mm; $p = 0.03$). Dissection at the angle of His was performed by all bariatric surgeons compared to only three dissections performed by the general surgeons ($p < 0.01$). When the safety parameters were considered, the time in which coagulation was unsafely used was significantly lower for the bariatric surgeons as compared to general surgeons (median 3.5 vs. 26.5 s; $p < 0.01$), as was the number of bleeding incidents (median 0 vs. 5.5; $p < 0.01$) and the number of noncauterized bleeding incidents (median 0 vs. 1; $p < 0.01$). There were also significant differences in performance metrics between bariatric and general surgeons for gastrojejunostomy creation: the number of punctures larger than 1 cm (median 0 vs. 1; $p = 0.03$) and the distance of the puncture created on the jejunum from the end of the cut limb (median 53.3 vs. 65.8 mm; $p < 0.01$).

A large number of LRYGB operations in the United States are performed using a robotic platform. A training curriculum for the robotic RYGB, using the dV-Trainer robotic training platform, was proposed by Fantola et al. [15]. The authors' institution required surgeons and residents to complete this curriculum with a score ≥90% prior to participation in robotic RYGB cases. Fantola et al. divided the robotic RYGB into five steps:

1. Creation of the gastric pouch
2. Seromuscular suture approximating jejunal loop and the gastric pouch
3. Full-thickness handsewn gastrojejunal anastomosis
4. Measurement of biliopancreatic and alimentary limbs
5. Creation of jejunojejunostomy

Each of these steps was represented within the training curriculum by one or more basic modules on the dV-Trainer. Creation of gastric pouch was represented by the "camera targeting" and "energy switching" modules. Seromuscular suturing was represented by the "tube anastomosis horizontal" module. Full-thickness handsewn gastrojejunal anastomosis was represented by the "tube closure horizontal" and "knot the ring 2" modules. Measurement of biliopancreatic and alimentary limbs was represented by the "rope walk" module. Creation of jejunojejunostomy was represented by the "tube closure vertical" and "interrupted suture" modules. The training curriculum was described in detail in the manuscript; however, the authors did not provide any data to support the validity of this training curriculum [15].

In summary, multiple training platforms including laparoscopic box trainers with cadaveric tissues, VR simulators and robotic trainers can be used for procedural training in LRYGB. A number of simulation-based training curricula for technical skills acquisition have been proposed, and some have been extensively validated. Technical skills relevant to bariatric surgery that have been acquired on a simulator have been shown to transfer to the OR.

Laparoscopic Sleeve Gastrectomy

Laparoscopic sleeve gastrectomy is currently the most common bariatric and metabolic procedure performed in the United States [16]. Despite the popularity of this procedure among bariatric and metabolic surgeons, there is currently no simulation-based curriculum addressing simulation-based training; a literature search failed to identify any published studies on this topic. This is clearly an area for ongoing research given the widespread utilization of laparoscopic sleeve gastrectomy as the preferred bariatric and metabolic procedure.

Most of the technical skills required to perform a laparoscopic sleeve gastrectomy are currently acquired during residency or bariatric surgery fellowship. Practicing surgeons, who are interested in learning the technical aspects of laparoscopic sleeve gastrectomy, often choose to attend an industry-sponsored weekend course, which usually includes practice sessions on a live anesthetized animal model. The VR module can be developed for simulation-based training in the critical steps required to perform a laparoscopic sleeve gastrectomy: division of the gastrocolic ligament and the short gastric vessels, identification of the left crus of the diaphragm, and division of the stomach along an appropriately sized bougie using laparoscopic stapling devices. Once a VR module is available, it must undergo rigorous testing to provide evidence in support of validity. With sufficient evidence supporting the validity of such a module, it should be incorporated into a formal simulation-based training curriculum, which addresses the cognitive knowledge, technical skills, and nontechnical skills required to perform a safe laparoscopic sleeve gastrectomy. Once such a curriculum is created, it should undergo testing to provide evidence supporting its validity prior to implementation.

Laparoscopic Adjustable Gastric Banding

Laparoscopic adjustable gastric banding (LAGB) was a very common minimally invasive procedure performed for morbid obesity in the 1990s and 2000s. Its initial popularity, however, started to dwindle more recently, in part due to the unpredictability of weight loss and a higher than expected reoperation rate, with the procedure accounting for approximately 6% of primary bariatric procedures in 2013 [17]. Given the initial popularity of LAGB, researchers from Rensselaer Polytechnic Institute and Harvard Medical School developed a virtual reality LAGB simulator and conducted a study to test its validity [18]. Figure 2 depicts the VR interface of the simulator. The steps of the LAGB programed into the VR trainer

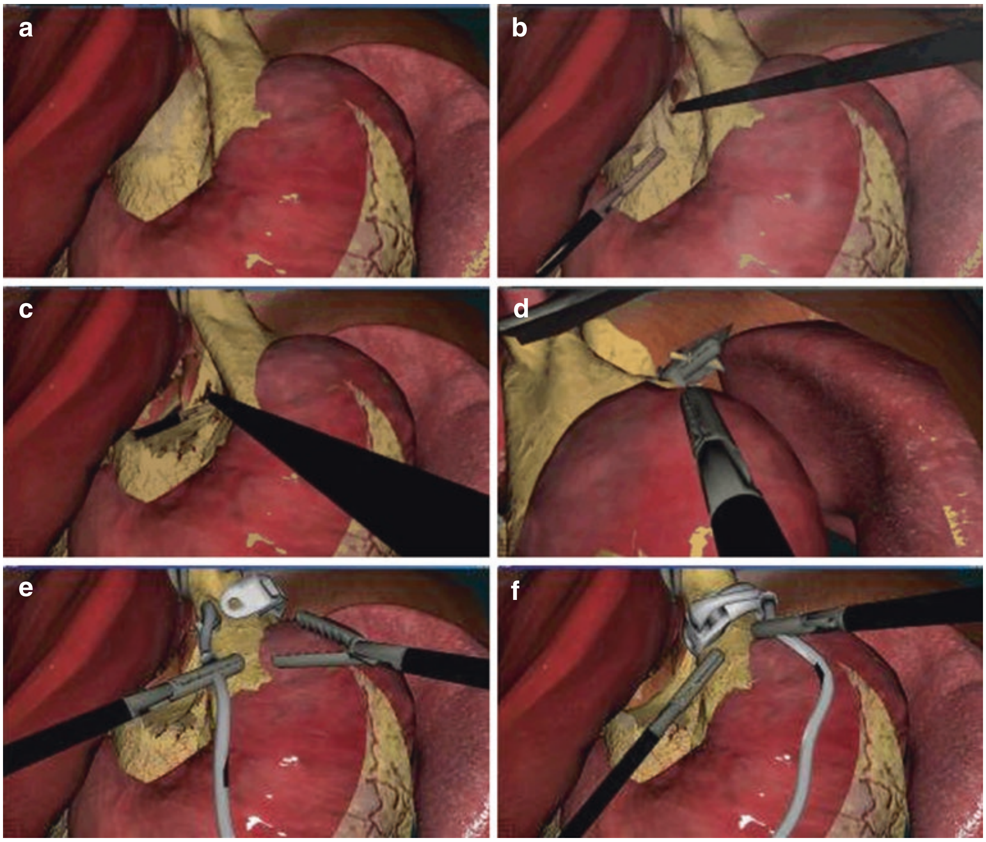


Fig. 2 Virtual reality interface for the laparoscopic adjustable gastric band simulator. (**a**) Undissected scene, (**b**) dissection of pars flaccida, (**c**) dissection of the peritoneal layer medial to right crus, (**d**) grasping of the band on top of the fundus through retrogastric channel, (**e**) placement of the band around the stomach, and (**f**) locking the band in place. (obtained from Sankaranarayanan et al. [18])

included dissection of pars flaccida, dissection of peritoneum medial to the right crus, creation of the retrogastric channel, grasping of band and pulling it through the retrogastric channel, and placement and locking of the band in place. A validation study was carried out using 28 surgeons – 13 experienced surgeons (greater than 4 years of laparoscopic experience) and 15 novice surgeons (4th year medical students, junior, and intermediate-level residents). Study participants felt that the realism of the equipment and laparoscopic instruments was high, whereas the realism for the stomach and fat behavior was moderate; the overall realism of the simulator compared to the actual procedure was moderate. In addition, study participants reported that the VR simulator was a realistic trainer for the LAGB procedure and that the VR simulator can be a useful trainer for residents and surgeons before their OR experience. Evidence for construct validity was provided with experienced surgeons receiving higher scores than novice surgeons for the task of band placement and electrocautery. Extensive search of the literature failed to identify any additional studies describing LAGB simulators.

Nontechnical Skills Training

The importance of nontechnical skills in surgery cannot be overstated. Nontechnical skills, such as communication, teamwork, situation awareness, and leadership, can have a profound impact on the safety and workflow in the operating room. Failures in nontechnical skills have been shown to lead to an increased number of errors in surgery [19]. Thirty-six percent of communication errors in the operating room were shown to result in inefficiency, team tension, waste of resources, patient inconvenience, and procedural error [20]. A systematic review of the impact of nontechnical skills on technical performance in surgery concluded that failures in nontechnical skills were associated with a greater rate of technical errors in the operating room [21].

Simulation centers provide an excellent environment to teach and evaluate nontechnical skills in surgery [22]. Unlike technical skills, nontechnical skills are not procedure-specific and are likely transferable from one procedure to another [23]. Dedy et al. conducted a randomized controlled trial of 22 junior surgery residents to demonstrate that nontechnical skills can be learned in a simulation laboratory. In their study, Dedy and colleagues randomized junior residents to conventional surgery training vs. conventional surgery training with an addition of a 2-month nontechnical skills training curriculum [22]. Residents who completed the nontechnical skills training curriculum demonstrated greater knowledge of and improved attitudes toward nontechnical skills as compared to conventionally trained residents [22]. The authors also reported a significant within-group improvement in nontechnical skills for curriculum-trained residents vs. no within-group improvement in nontechnical skills for conventionally trained residents despite ongoing residency training [22].

Zevin et al. designed a comprehensive SET curriculum for an advanced minimally invasive procedure (previously described in Jejunojejunostomy), which included a nontechnical skills module addressing communication, teamwork, situation awareness, and leadership skills [10]. This module was comprised of a 1-h interactive expert-led seminar demonstrating video examples of nontechnical skills in the OR and in aviation, as well as a 15-min scripted simulated intraoperative crisis scenario followed by a 15-min structured debriefing session. The debriefing session was structured around major concepts of nontechnical skills in the OR. Anaphylactic shock following antibiotic administration in a patient undergoing LRYGB procedure was selected as the intraoperative crisis scenario. The educational effectiveness of this nontechnical skills module was evaluated in a randomized controlled trial of 20 intermediate-level surgery residents randomized to the SET curriculum vs. conventional residency training [10]. Post-intervention assessment of nontechnical skills was conducted using a simulated intraoperative crisis scenario (tension pneumothorax in a bariatric patient following placement of a subclavian central venous catheter) using previously validated Non-Technical Skills for Surgeons (NOTSS) scoring system [24]. SET curriculum-trained residents significantly outperformed conventionally trained residents in all measured nontechnical skills including situation awareness, decision-making, leadership, communication, and teamwork [10].

Based on the results of the randomized controlled trials presented above, as well as the recommendation from the Accreditation Council for Graduate Medical Education (ACGME) in the United States for surgery trainees to demonstrate mastery of teamwork-related competencies, a nontechnical skills training module should be incorporated into any future simulation-based training curricula for bariatric and metabolic surgery [25, 26].

Future Directions for Simulation Research in Bariatric Surgery

A substantial amount of work has already been done in the domains of cognitive, technical, and nontechnical skills training in bariatric and metabolic surgery. It is time for investigators in the bariatric community to start moving toward novel research ideas including (1) development, validation, and implementation of a national simulation-based training curriculum for bariatric and metabolic surgery, (2) development of a high-stakes examination for certification in bariatric and metabolic surgery, and (3) demonstration of the cost-effectiveness of simulation-based training in bariatric and metabolic surgery.

National Simulation-Based Training Curriculum

Presently, there are 125 accredited bariatric surgery fellowship programs in North America with 1–3 fellows per program (https://fellowshipcouncil.org). The knowledge and operative skills of incoming bariatric surgery fellows are quite variable at the beginning of fellowship training. This variability in knowledge and operative skills can result in some fellows not being given the primary surgeon role in the first 3 months of the fellowship [27]. In an online survey of 286 current fellows, past fellows, and fellowship program directors administered via the Fellowship Council, the most commonly reported reasons for fellows not being given the primary surgeon role were "unfamiliarity with the bariatric procedure," "inability to complete a laparoscopic anastomosis," and "poor tissue handling"(Fig. 3) [27]. The same survey also reported that only half of the responding bariatric fellows felt that they had adequate advanced laparoscopic training during their residency and very little of their training took place in the form of simulation-based practice. Seventy-two percent of respondents to this survey felt that an advanced laparoscopic skills curriculum would be of value [27]. The responses of the survey participants regarding the proposed content of the advanced laparoscopic surgery curriculum are depicted in Fig. 4.

The framework for the design, validation, and implementation of simulation-based training curricula in surgery was

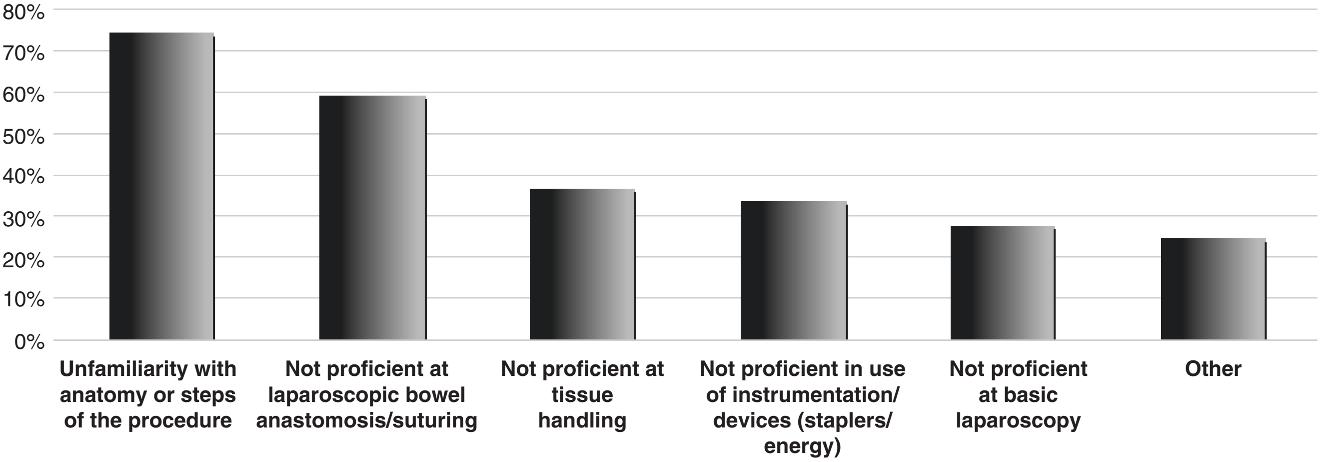


Fig. 3 Reasons why bariatric fellows are not given the role of the primary surgeon within 3 months of the start of the fellowship program. (obtained from Nepomnayshy et al. [27])

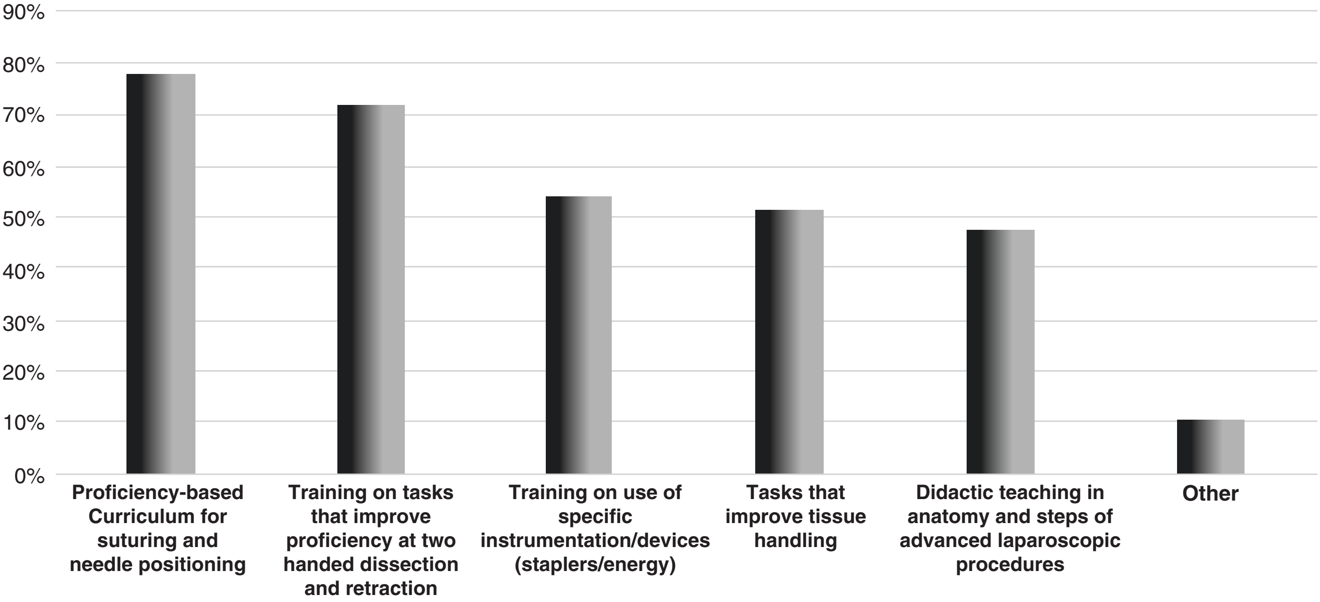
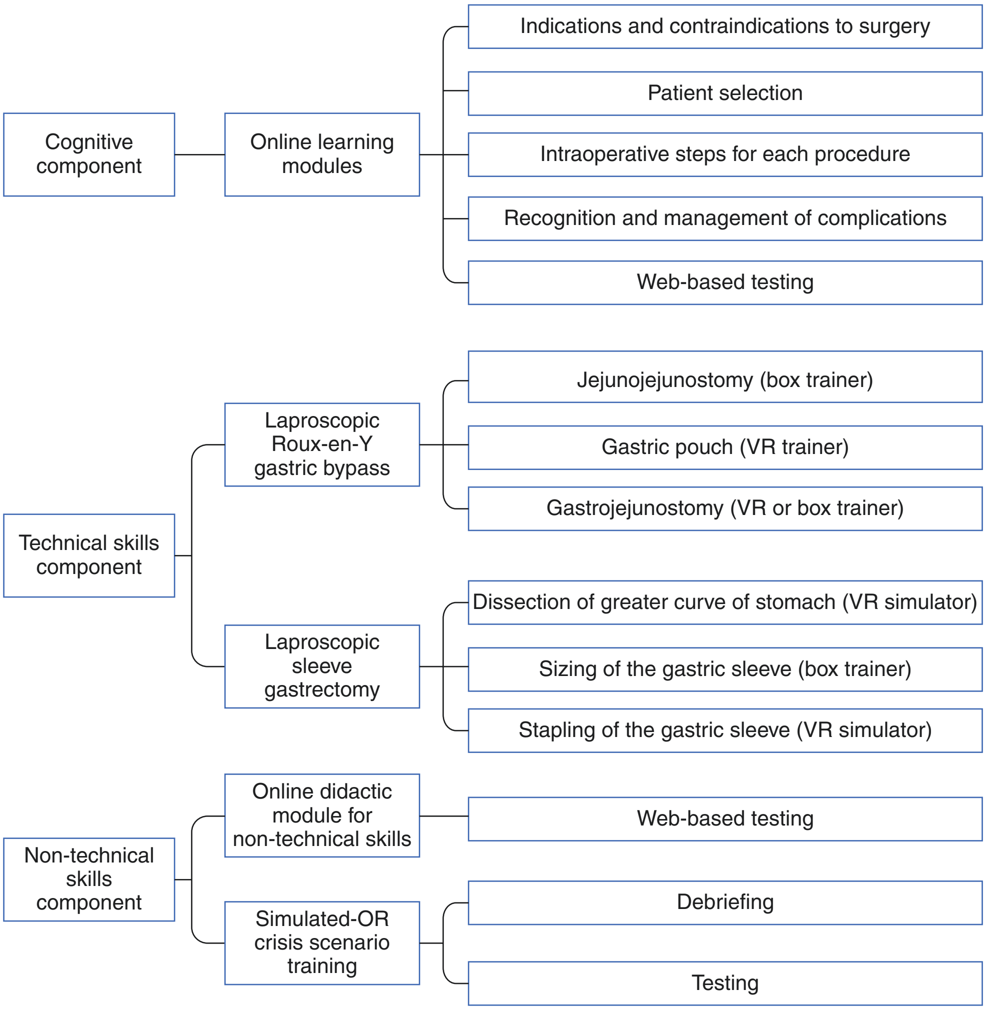


Fig. 4 Proposed content of an advanced laparoscopic surgery curriculum. (obtained from Nepomnaysky et al. [27])

previously developed by Zevin et al. using the Delphi methodology [28]. This framework can be used to develop a national simulation-based training curriculum for bariatric and metabolic surgery, which can be administered at the beginning of advanced upper GI and bariatric surgery fellowship. The proposed content for the national simulation-based training curriculum is presented in Fig. 5. Most of the components of this curriculum have already been developed and validated (please refer to section "Current use of simulation in bariatric surgery" in this chapter); however, additional research is still required to create the laparoscopic sleeve gastrectomy module. This proposed curriculum can utilize a combination of online learning modules, synthetic models and cadaveric tissues, box trainers and VR simulators, as well as hybrid simulations for nontechnical and technical skills training. This curriculum must adhere to the educational principles of proficiency-based training, deliberate practice, distributed practice schedule, as well as timely and constructive feedback. Completion of such a national simulation-based curriculum in bariatric and metabolic surgery at the beginning of fellowship training may standardize the knowledge and technical and nontechnical skills of incoming fellows. This, in turn, may allow fellows to take on the role of the primary surgeon earlier on in their training, to engage in higher-level learning in the operating room, and to participate in a greater number of complex laparoscopic bariatric operations including revision and conversion operations.

Once a national simulation-based training curriculum in bariatric and metabolic surgery has been developed, evidence for its validity should be sought via a multicenter randomized controlled trial prior to widespread implementation. In this trial, incoming advanced upper GI and bariatric surgery fellows can be randomized to the intervention group (completion of the national curriculum) or the control group (conventional fellowship training). Post-intervention assessment can be carried out after a predefined duration of training (e.g., 1 month) at which time every participant within the intervention group would be expected to have reached predefined proficiency. Post-intervention assessment can include the objective assessment of knowledge of bariatric surgery, technical skills assessment in the OR during LRYGB, and nontechnical skills assessment. A number of reliable and

Fig. 5 Proposed content for the national simulation-based training curriculum for bariatric and metabolic surgery



valid assessment scales for technical and nontechnical skills are available [9, 29]. By securing support for this randomized controlled trial from the American College of Surgeons consortium of Accredited Education Institutes (ACS-AEI) and the Fellowship Council, additional data on the learning curves of curriculum-trained and conventionally trained fellows can be collected during fellowship training. By linking the educational outcomes and learning curves from the randomized controlled trial with patient outcomes from the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database, we may be able to answer the ultimate question of whether simulation-based training leads to improved patient outcomes. A recent study by Aminian et al. reported that fellow participation in LRYGB was independently associated with higher rates of overall complications, serious complications, surgical complications, and reoperation [30]. Mandatory completion by incoming fellows of a national comprehensive simulation-based training curriculum may decrease these complications.

Use of Simulation for Certification

Simulators provide an excellent platform for high-stakes assessment in bariatric and metabolic surgery. High-stakes assessment for certification prior to independent practice in bariatric surgery may become a requirement in the future given the inverse relationship between operative skill and patient complications and mortality [31]. John D. Birkmeyer and colleagues conducted an elegant study of 20 practicing bariatric surgeons in the State of Michigan who participated in a statewide collaborative quality improvement program [31]. Each surgeon was required to submit a single representative videotape of himself or herself performing a LRYGB. Each videotape was rated in various domains of technical skills (on a scale from 1 to 5) by at least 10 peer surgeons who were unaware of the identity of the operating surgeons. The authors then assessed the relationship between technical skill ratings and risk-adjusted complication rates using data from a prospective, externally audited, clinical-outcomes registry. The bottom quartile of surgical skill, as compared with the top quartile, was associated with higher complication rates (14.5% vs. 5.2%, $p < 0.001$) and higher mortality (0.26% vs. 0.05%, $p = 0.01$). The lowest quartile of skill was also associated with longer operations (137 min vs. 98 min, $p < 0.001$), higher rates of reoperation (3.4% vs. 1.6%, $p = 0.01$), and readmission (6.3% vs. 2.7%; $p < 0.001$). Given these findings, introduction of a high-stakes simulation-based examination at the end of bariatric fellowship training may help ensure a minimum acceptable level of technical proficiency of graduating fellows prior to the start of independent practice.

A contemporary example of using simulation for high-stakes assessment and credentialing can be found in colorectal surgery. In 2014, the American Board of Colon and Rectal Surgery (ABCRS) introduced a high-stakes examination for the assessment of technical skill at the same time as the oral ABCRS examination. This examination – the colorectal objective structured assessment of technical skill (COSATS) – was originally developed in 2012 by de Montbrun and colleagues as a technical skill examination to assess competence in colorectal technical skill at the time of certification [32]. At the time of ABCRS COSATS examination, candidates rotated through eight 12-min technical skill stations (rectal prolapse, pelvic bleed, ileal pouch anal anastomosis, coloanal anastomosis, laparoscopic ileorectal anastomosis, colonoscopy, handsewn anastomosis, and laparoscopic sigmoidectomy) [33]. The candidate's technical skills were evaluated at each station by a board-certified colorectal surgeon using a task-specific checklist, a global rating scale, and an overall performance score. Evidence of validity for this high-stakes examination was sought by examining the inter-rater reliability and the reliability of the passing score; the relationship between the COSATS scores and ABCRS oral examination results; and by setting a credible passing score for the pass/fail rate. De Montbrun et al. reported a passing rate for the technical skill component of the examination of 85.7–90%. The inter-rater reliability was high, as was the reliability of the pass/fail decision. Interestingly, there was a low correlation between the COSATS scores and the oral ABCRS scores suggesting that these examinations measured different constructs of surgical competency. This hypothesis was supported by the finding that all individuals that failed the COSATS component passed the ABCRS oral examination.

Developing a similar technical skills examination tailored to the specific surgical competencies required to perform bariatric and metabolic surgery should be one of the directions for future simulation research. In fact, the technical skills component of the proposed national comprehensive simulation-based training curriculum for bariatric surgery (Fig. 4) may be adopted for use in high-stakes assessment and certification; however, additional research on the reliability, validity, and feasibility of this curriculum as a testing platform is required.

Cost-Effectiveness of Simulation

Despite strong evidence confirming educational effectiveness of simulation-based training for bariatric and metabolic surgery, the implementation of simulation-based training curricula remains a challenge. The paucity of cost-effectiveness studies is one plausible factor that is contributing to the lack of widespread implementation of simulation-based training curricula. In a systematic review of 967 comparative studies on simulation-based training, only 59 studies (6.1%) reported some cost elements, and only 15 (1.6%) provided information on costs compared with another instructional approach [34].

There is no question that simulation-based training in surgery can be expensive; however, conventional surgery training is also not cheap. Bridges and Diamond calculated the cost of training one surgery resident for 4 years in the operating room at $47,970 [35]. Harrington and colleagues reported a figure of $45,061 per year as the cost of training 15 senior residents to perform two laparoscopic enteroenterostomies [36]. Simulation-based training can also result in substantial cost savings as was demonstrated by Cohen et al. [37]. In their study, Cohen et al. estimated the hospital cost savings related to a reduction in catheter-related bloodstream infections (CRBSI) after simulation-based training for residents. Residents were required to complete a simulation-based mastery learning program in central venous catheter insertion. Hospital-reported CRBSI rates were assessed before and after simulation training. Annual savings from reduced CRBSIs were compared with the annual cost of simulation training. The results of this study showed that approximately 9.95 CRBSIs were prevented among intensive care unit patients with central venous catheters in the year after simulation-based training. Incremental costs attributed to each CRBSI were approximately $82,000. The annual cost of the simulation-based education was approximately $112,000. Net annual savings after simulation-based training were greater than $700,000, a 7 to 1 rate of return on the simulation training intervention [37].

To date, there are no published cost-effectiveness studies for simulation-based education in bariatric and metabolic surgery. Such studies are of great importance as administrators and hospitals try to balance the need for simulation-based training against the costs associated with this type of training. As I have already discussed, there is good quality evidence confirming the educational effectiveness of simulation-based training in bariatric and metabolic surgery; however, administrators and hospitals have to decide not only whether an educational intervention is effective but also whether the associated change in the outcome of interest (duration of training, patient outcomes, etc.) is significant enough to justify the difference in costs [38]. Implementation of a national simulation-based training curriculum in bariatric and metabolic surgery across fellowship programs will require robust cost-effectiveness studies to support the additional investment in capital and in human resources. Tolsgaard et al. have proposed a general four-step model – Program Effectiveness and Cost Generalization (PRECOG) model – to conduct cost-effectiveness studies in health profession education [38]. The schema of the PRECOG model is depicted in Fig. 6.

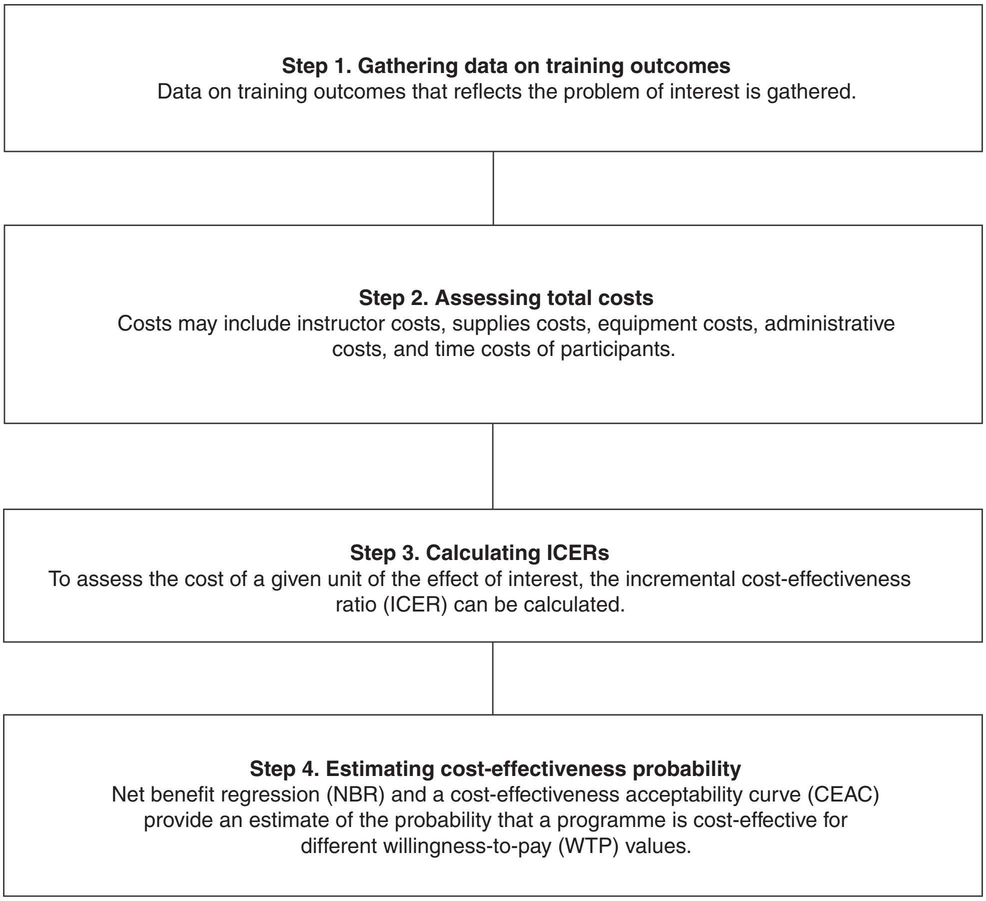


Fig. 6 Program Effectiveness and Cost Generalization (PRECOG) model for cost-effectiveness studies in medical education. (obtained from Tolsgaard et al [38])

Step 1. Gathering data on training outcomes
Data on training outcomes that reflects the problem of interest is gathered.

Step 2. Assessing total costs
Costs may include instructor costs, supplies costs, equipment costs, administrative costs, and time costs of participants.

Step 3. Calculating ICERs
To assess the cost of a given unit of the effect of interest, the incremental cost-effectiveness ratio (ICER) can be calculated.

Step 4. Estimating cost-effectiveness probability
Net benefit regression (NBR) and a cost-effectiveness acceptability curve (CEAC) provide an estimate of the probability that a programme is cost-effective for different willingness-to-pay (WTP) values.

Step 1 involves gathering data on the training outcomes of interest. The purpose of this step is to estimate the effect of different training programs. Using the example of the proposed randomized controlled trial for a national simulation-based training curriculum in bariatric and metabolic surgery (section "The Visioning Simulation Conference"), Step 1 would examine operative performance of curriculum-trained and conventionally trained fellows, their operative efficiency, technical errors, as well as patients' outcomes and complications. Resource utilization in the operating room will also be compared between the two groups.

Step 2 involves the assessment of total costs. Using the example above, the total costs for the national simulation-based curriculum and for the conventional training would be calculated. Such costs would include personnel, equipment, and time. The costs for patients' complications will also be collected.

Step 3 involves the determination of the incremental cost-effectiveness ratio (ICER), defined as the cost of one additional unit of the outcome of interest. ICER is the difference in training costs between different training programs (DC) divided by the difference in their effectiveness (EC) (ICER = DC/DE). Using our example, DC is the difference in the cost of a national curriculum vs. conventional fellowship training, whereas EC is the difference in time required to complete LRYGB in the OR.

Lastly, Step 4 involves the estimation of the cost-effectiveness probability. The authors of the PRECOG model [38] describe the concept of "willingness to pay" (WTP), which is defined as the maximum amount that an administrator is prepared to pay to achieve a certain outcome. Using health economic theory for the estimations of uncertainty at Step 1, Step 2, and Step 3, the authors propose a method for calculating the cost-effectiveness of an intervention for different WTP values. The results of these calculations can inform administrators and educators and can allow for concrete recommendations to be made. Collaborations with health economists in cost-effectiveness studies are recommended to ensure the highest-quality methodology and results. High-quality cost-effectiveness studies with appropriate methodological rigor are required to support the continued investment into simulation-based training and education in bariatric and metabolic surgery.

Emerging Technologies and Simulation

A number of emerging technologies and procedures in bariatric and metabolic surgery have recently arrived on the market including intragastric balloons, single anastomosis duodeno-ileostomy (SADI), stomach intestinal pylorus sparing surgery (SIPS), endoscopic sleeve gastroplasty, and a gastric emptying system. Intragastric balloons (ReShape Integrated Dual Balloon System, ORBERA Intragastric Balloon System) and gastric emptying system (AspireAssist) have been FDA approved for use in class I and II obesity in conjunction with continuous medical monitoring and lifestyle therapy [39]. A systematic review and meta-analysis of randomized controlled trials of intragastric balloons for weight loss reported an 11.16% of excess weight loss at greater than 3 months, a 4.77 kg 3-month weight loss, and 4.09% of weight loss at greater than 3 months [40].

Single anastomosis duodeno-ileostomy and stomach intestinal pylorus sparing surgery are a relatively new procedure for North America; however, early reports of safety and efficacy are quite promising [41]. Early reported postoperative complications include an anastomotic leak rate of less than 2% and bleeding rate of less than 2% [41]. Estimated excess weight loss is reported at 50–95% with a 6–60-month follow-up [41]. As surgery trainees and experienced surgeons start to introduce these emerging technologies into their practice, simulation can play an important role in both education and assessment of competency prior to exposure to patient care. High- and low-fidelity simulators can be developed to teach critical components of each procedure in the safety of a simulation laboratory. Deliberate practice on simulators can be combined with an objective assessment of relevant knowledge and technical proficiency to ensure that an acceptable level of competency has been achieved prior to attempting that procedure on a real patient. Following simulation-based training in a laboratory, telementoring and telecoaching in the operating room can provide surgeons with the necessary guidance early on in their experience with these novel procedures, thereby ensuring the highest standard for patient safety.

Conclusion

Simulation can be used for acquisition of technical and nontechnical skills in laparoscopic bariatric and metabolic surgery. Future research efforts should focus on the development of a national simulation-based training curriculum for laparoscopic bariatric and metabolic surgery, on the use of simulation for certification, and on the use of simulation for the introduction of emerging technologies in bariatric and metabolic surgery into the operating room. In addition, high-quality cost-effectiveness studies with appropriate methodological rigor are required to support the investment into simulation-based training and education in bariatric and metabolic surgery.

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Simulation in Critical Care

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Introduction

Simulation can help improve education in critical care where there is a shortage in critical care-trained providers and an increase in population at risk for critical illness. In addition, the skills and procedures performed are often high-risk and in a high stress situation, not generally an optimal training environment. This chapter will focus on ways simulation can be used to train and refine skills frequently utilized in the intensive care unit such as airway management, including orotracheal and surgical intubation, cardiopulmonary resuscitation, thoracentesis and paracentesis, ultrasound, and ventilator management.

Simulation in Advanced Cardiac Life Support

One of the first commonly used medical simulators is the Resusci-Annie cardiopulmonary resuscitation (CPR) simulator. In the 1950s, James Elam and Peter Safar collaborated in the concept of rescue breathing for victims of respiratory arrest. They published videos and other instructional materials at the time and then recruited Norwegian toymaker Asmund Laerdal to build a practice model. Laerdal had saved his own son Tore from near drowning in 1955 by pulling him out of the water and clearing his airways, making him receptive to the concept of CPR [1].

Simulation continued as an integral part of CPR and in basic and advanced cardiac life support (ACLS) as highlighted in a 1981 Lancet study that demonstrated that only 29% of house officers were able to properly perform CPR [2]. Adding high-fidelity mannequin simulation to ACLS-certified residents for 6 months improved adherence to American Heart Association ACLS guidelines during cardiac arrest codes from 44% to 68% of the ACLS events [3]. However, no significant difference in event survival or discharge rate was observed in patients treated by the two groups.

DeVita et al. [4] introduced medical emergency team (MET) simulation. The study evaluated MET responses to five scenarios (three arrhythmias, compromised airway, and stroke) and subsequent interventions, using a high-fidelity mannequin. They reported improvement in survival from 0 to 89% and task completion rate plateaued after three simulations. The study did not address the validity of the simulation model or curriculum.

Hoadley [5] found that high-fidelity simulation increased comfort level of ACLS participants in performing CPR compared to low-fidelity simulation. Rogers et al. [6] corroborated these results and found statistically significant higher scores in the high-fidelity simulation group. Interestingly, the authors found that basic psychomotor skills such as airway management and defibrillation were improved equally in both high- and low-fidelity simulations. However, knowledge in cardiac arrest management and observed confidence were significantly improved in the high-fidelity group.

In contrast, Adams et al. [7] posed the question of novice learners and the simulation fidelity level. Following cognitive load theory, the authors postulated that novice learners are less likely to benefit from high-fidelity simulators and are more susceptible to excess and irrelevant stimuli that are potentially detrimental to learning. They found that medical students equally benefited from video- or simulation-based ACLS instructions compared to didactics only.

Likewise, there doesn't seem to be any benefit to high-fidelity simulation training in the long-term retention of ACLS skills compared to traditional teaching. High-fidelity simulation scores were improved immediately after instructions, but the 1-year scores declined to levels similar to those of traditional teaching. The authors concluded that high-fidelity simulation led to better immediate performance and satisfaction with instructions; however, it did not improve the

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retention at 1 year [8]. Yoo et al. [9] found similar results with improved immediate post-instruction test scores in the simulation group but loss of retention of skills and knowledge at 1 month. Weidman et al. [10] examined actual patient outcomes and quality measures of CPR performance in two groups of residents. They were taught with either high-fidelity immersive simulation (14 residents) or traditional instructions (16 residents). The authors studied 98 resuscitation events over a 12-month period and found no significant difference between the groups. They questioned the benefit of immersive simulation on patient outcomes. Similarly, Han et al. [11] evaluated 103 medical residents over a period of 9 months. The residents were randomized to control ACLS instructions and simulation-based curriculum. The residents were then followed as they performed 21 mock codes and 147 actual codes. There were no differences in CPR quality measures or mortality.

While the fidelity of the simulation model may not affect medium- to long-term ACLS performance, other adjuncts to the simulation scenario may improve results. DeMaria et al. [12] studied the effect of adding a situational stressor on high-fidelity simulation ACLS scenarios. They found that adding psychological stressors (family member and staff members) during the ACLS instructions to medical students (code leaders) increased 6-month retention of the acquired skills.

Simulation training in CPR and ACLS appears to improve immediate performance, knowledge, and comfort levels. It does appear to have a benefit in improving the performance of high stress ad hoc interdisciplinary teams such as MET teams. Investing in simulation training should be considered in this setting. However, it doesn't appear to affect long-term retention of information or performance. Retention of skill and knowledge can be improved by making the scenarios as true-to-life as possible, incorporating situational stressors such as family members into the scenario.

Simulation in Airway Management

Endotracheal Intubation

Models to demonstrate and simulate orotracheal intubation were in existence long before the contemporary enthusiasm for simulation training. Despite some anatomic and functional limitations, high-fidelity simulation is an acceptable and realistic model for airway simulation with some limitations. SimMan®, a commercially available product, for example, offered highly realistic endotracheal intubation simulation; however, the distance from the teeth to vallecula was judged too short, and it is difficult to achieve a face bag-valve-mask seal and ventilation [13]. This is thought to confuse the novice learners and lead to more invasive airway maneuvers. Mannequin-based simulation has been used as a 30-min, multidisciplinary, "just-in-time" education for pediatric and emergency medicine residents prior to taking call for the pediatric intensive care unit (PICU). No improvement in first attempt nor overall intubation success was observed after the training compared to control [14]. Similarly, Tofil et al. [15] showed that their high-fidelity mannequin-based simulation curriculum for residents rotating through the PICU failed to improve clinical performance (intubation and intraosseous line); however, it did increase the trainees' level of confidence.

The question of whether improvements in simulated intubation translated into clinical practice competency was studied in 13 postgraduate year-1 (PGY1) pediatric residents at the beginning of an 8-week clinical rotation. After a 2-h instruction lesson, significant improvement in performance was observed; however, performance deteriorated over the period of clinical rotation, concluding that the simulation was not transferrable to real-life clinical scenarios [16].

Garcia et al. [17] shifted focus to finding variables that delineated experts from novices in a mannequin intubation simulation model. They examined time to intubation, intubation success, hand position, and force applied during intubation. Only force applied correlated with experience level.

Mosier et al. [18] showed that a comprehensive 11-month-long simulation-based curriculum for 16 pulmonary and critical care fellows improved first-time intubation success and lowered desaturation rate significantly. Clinical improvement was noted in the first 6 months of simulation training, compared to historical controls 2 years prior to curriculum implementation. The training sessions were held twice monthly with hands-on simulation on high-fidelity simulators and emphasized difficult intubation management. Norman et al. [19] subsequently reviewed 24 studies comparing low- and high-fidelity simulators and no intervention. They concluded that while all types of simulation showed consistent improvement in skills acquisition, expensive high-fidelity simulators portended minimal if any advantage over low-fidelity counterparts.

Recently, Schebesta et al. [20] questioned the fidelity and validity of the two high-fidelity human simulators (HAL® and SimMan®). They compared anesthesia residents' ability to manage different airway scenarios in actual patients versus the high-fidelity simulators and assessed the duration, difficulty, realism, and success rates. They concluded that there was adequate validity for endotracheal intubation simulation; however both validity and fidelity were low for laryngeal mask intubation and mask ventilation. Finally, Prottengeier et al. [21] studied dual-tasking, the effect of combining a cognitive burden with the technical aspects of securing an airway. Volunteers were asked to secure an airway while performing the Paced Auditory Serial Addition Test (PASAT) [22]. PASAT added the value of simulating divided attention during lifesaving interventions of acute care medicine, thereby mimicking real-life emergency scenarios. Significant effects on performance were seen with divided attention, demonstrating the validity of the model. The paramedics reported feeling this mimicked their real working conditions.

Overall, studies suggest that simulation training for orotracheal intubation is effective, particularly for early learners. The advantage of high-fidelity simulators over low-fidelity models, however, appears limited.

Cricothyroidotomy

Cricothyroidotomy is a lifesaving procedure in a cannot intubate/cannot ventilate scenario. Because it is rarely performed and therefore experience is limited, simulation training has been proposed to be a valuable method to provide some degree of experience.

Different training models have been studied. McCarthy et al. [23] studied canine placement of cricothyroidotomy in a canine model vs human cadavers and found a large portion of misplaced cricothyroidotomies in the canine model. The results of this study suggest low validity of the canine model. Several studies have compared the effectiveness of cricothyroidotomy training using low-fidelity models versus high-fidelity simulators and assessed skill transfer on cadavers. No advantage was observed in one model over the other [24, 25].

Wong et al. [26] studied the number of simulated cricothyroidotomies on a low-fidelity mannequins to achieve a <40-s successful simulated procedure completion. They found that time and success rate plateaued after the fourth and fifth attempt, respectively.

Siu et al. [27] studied the effect of physician age and number of years since graduating residency on the proficiency of cricothyroidotomy using a global rating scale, procedural time, and checklist scores for assessment. They found that the younger outperformed the older anesthesiologists. This was true before and after a 1-h high-fidelity mannequin-based simulation. The group subsequently studied the retention rate of cricothyroidotomy procedural skills at 1 year after a single high-fidelity simulation training session. They found that the global rating scale, procedural time, and checklist scores were retained at 1 year [28].

Park et al. [29] highlighted the cognitive biases toward performing cricothyroidotomy as opposed to supraglottic airway, when it was introduced to anesthesia residents. The investigators found that residents were more likely to initiate whatever procedure they were taught first.

Howes et al. [30] used low-fidelity simulators to train attending anesthesiologist on morbidly obese and burnt obese models. They found success rate at 60% and 77%, respectively, as opposed to 100% in slim unmodified mannequins. The authors suggested that modifying the mannequins provided a more difficult clinical scenario and better prepared the subjects for real-life scenarios, although this was not measured in the study.

While cricothyroidotomy is a crucial lifesaving procedure that must be performed in minutes, it is also extremely rare and most intensivists have not performed the procedure, so it is a procedure where simulation in education is critical. There is no role for animal models. Cadaver models produce equal results when compared to low-fidelity models, so their increased cost is not justified. Simulation for cricothyroidotomy is best performed in a low-fidelity model to competence, which could be achieved on average in four or five repetitions per learner.

Tracheostomy

Percutaneous tracheostomy has emerged as a safe and cost-effective method of accomplishing long-term airway control in critically ill patients with one experienced group suggesting that it should be considered the “gold standard” [31]. One study reported a learning curve of 20 percutaneous dilatational tracheostomies (PDT) before the rate of complications plateaued [32]. Simulation may be an adjunct for training, but the data are limited, and no model, animate or inanimate, has been shown to be more effective beyond the trainees’ positive reaction to the experience [33, 34].

Simulation in Paracentesis and Thoracentesis

Draining ascites and pleural fluid are common lifesaving procedures in the ICU, but complications of these procedures can be life threatening, including pneumothorax, hemorrhage, or bowel perforation. Moreover, few graduating medical students have any experience with these procedures. Sixty-six percent of the students have never performed paracentesis, and only 11% would attempt it alone or are confident in performing paracentesis [35]. Training via simulation may help fill this void [36, 37].

Low-fidelity simulation in paracentesis improved the posttest performance scores by 50% in internal medicine residents [38]. Another study showed that paracentesis simulation increased post-instruction procedural skill score to 92.7% compared to the pre-instruction score of 33% [39]. This simulation even led to improved patient outcomes. Specifically, internal medicine resident performance of paracentesis was more cost-effective than those performed by interventional radiology and required less blood product transfusions [40].

Similar to paracentesis, experience with thoracentesis is inconsistent in training. Ninety-two percent of students report never having performed one, and only 1% would attempt it alone [35]. Here again, simulation may fill the experiential void. Wayne et al. [41] showed that after controlling for baseline variables, a low-fidelity thoracentesis simulation-based curriculum improved performance of PGY3 internal medicine residents post-instruction score from 51.7% to 88.3%. Likewise, Duncan et al. [42] studied the effect of a zero-risk simulation environment on the iatrogenic complications in patients undergoing thoracentesis in the outpatient setting. The interventions included a dedicated group of instructors, use of ultrasound guidance, and simulation-based instructions on anatomic and cadaveric models. Prospectively recorded 363 thoracentesis procedures over 2 years following interventions showed significant decline in the rate of iatrogenic pneumothorax and chest thoracostomy placement. Subsequently, the authors mandated this simulation-based training models to all physicians-in-training in their institution. Common to both of these studies is a formal curriculum in addition to the simulation exercises.

Simulation as part of training may improve outcomes. Similarly, Lenchus [38] reported an immediate 33% improvement in thoracentesis performance in internal medicine residents after simulation-based curriculum. Barsuk et al. [43] showed that simulation-based training in thoracentesis improved performance skill level in internal medicine residents from 57.6% to 96.2% and boosted their confidence in performing the procedure. This led to fewer referrals to interventional radiology or pulmonary specialists when compared to those receiving traditional instruction and house staff hospitalists.

Jiang et al. [44] examined the retention of skills acquired following a simulation-based curriculum and skill transfer to the clinical setting. They enrolled 52 medical students and calculated the learning curve of thoracentesis in a low-fidelity simulator. They found that time, performance, and confidence scores plateaued after four attempts. They retested the students at 6 months and found no significant decline in those scores, indicating retention of skills. At 1 year after instruction, the students' performance was compared to first year residents (whom never practiced on a simulator before) on real patients. Students outperformed the residents in all categories, indicating transference of learned simulation skills to real-life clinical application.

Paracentesis and thoracentesis are common ICU procedures that have measurable complications. As a result, the effects of education interventions utilizing simulation translate directly to reduced patient morbidity. These education interventions can be performed on low-fidelity simulators, with minimal repetitions, and achieve durable results.

Ventilator Management

As previously mentioned, rescue breathing, intubation, and respiratory resuscitation were some of the very earliest uses of medical simulation. Simulators for the respiratory system vary from a simple balloon to complicated simulators that mimic changes in lung compliance with the onset of lung injury. Advanced simulators also exhibit the differential lung pressures (between two lungs) seen in unilateral pathology such as pulmonary contusion or pneumothorax.

One effective use of simulation is as an adjunct to didactics in a classroom setting. Hardman et al. [45, 46] and Takeuchi et al. [47] published their work on virtual ventilator simulation. Those modules represented the early stages of clinical simulation to allow prediction of patient outcome and provide learners with a module to understand the physiology of different ventilation strategies and modes. Kuebler et al. [48] proposed a mechanical single lung model and examined its effect on the understanding of respiratory mechanics and physiology. They tested 232 medical students whom received traditional theoretical teaching on lung pressure-volume curves and respiratory pressures before and after simulation training. They reported significant improvement in self-assessments of physiology understanding after simulation training.

Keegan et al. [49] compared simulated ventilator with live animal ventilation. They designed a crossover study where students were enrolled in the live animal ($n = 52$) or simulation ($n = 57$) groups after receiving theoretical instructions a week prior. The groups were then crossed over a week later. The students received a 15-question quiz after each session, and the results showed a lower initial score in the live animal group, which improved significantly after undergoing simulation. Conversely, the simulation group quiz results did not improve significantly with equivalent scores in both groups at the conclusion. The authors conclude that simulation enhanced the ability of students to provide mechanical ventilation in live animals.

Clinical ventilator management has also been addressed with simulation, particularly as intensive "boot camp" orientation has become more prominent in graduate medical education. Wayne et al. [36] showed that a medical student simulation-based boot camp training on several bedside procedures including mechanical ventilation significantly improved the post-training test scores compared with historical PGY1 controls. A similar study was performed with the more experienced PGY1 residents, in which Cohen et al. [37] reported that internal medicine interns who trained using high-fidelity simulators in ventilator management and readiness for spontaneous breathing trials outperformed historical controls significantly.

Schroedl et al. [50] studied 60 first year medical residents and their bedside intensive care unit (ICU) skills (ventilator management and circulatory issues). They randomized the residents to receive traditional teaching with or without the addition of a simulation-based curriculum. Residents were tested after completing their ICU rotation on their bedside assessment skills. Simulation-trained residents scored significantly higher compared to their traditionally trained counterparts. The authors concluded that simulation has an added benefit to traditional instruction of ICU skills. Singer et al. [51] compared 40 PGY1 internal medicine residents who received a 4-h simulation-based curriculum in respiratory failure and circulatory shock to 27 PGY3 traditionally trained residents. Both groups were evaluated with a bedside clinical assessment quiz that focused on ventilator management and liberation. PGY1 residents significantly outperformed their senior counterparts. The authors postulated that simulation-based education is becoming an increasingly important and powerful tool to novice learners in the era of resident-hour restrictions. Jansson et al. [52, 53] performed a prospective clinical trial to gauge the effect of introducing a simulation-based ventilator management bundle to critical care nurses. They randomized 30 nurses to intervention (single session with a high-fidelity human simulator) and control (traditional didactic teaching session without simulation). Baseline knowledge and ventilator-care skill scores were measured and compared to those at 6 and 24 months as performed on real patients. They found that knowledge scores did not differ throughout the study; however, the skill scores were significantly improved only at 6 months, and both groups' scores improved at 24 months.

Yee et al. [54] evaluated their 3-day 12-h intern mechanical ventilation boot camp. They enrolled 17 PGY1 to undergo training including a high-fidelity human simulator connected to breathing simulator module. The residents were evaluated before and after receiving instruction. Scores increased by a median of 25% and were significantly improved in the management of acute respiratory distress syndrome (ARDS) and mucus plug cases. Also, the self-reported confidence scores increased significantly. Managing severe respiratory failure requiring mechanical ventilation can be intimidating and confusing. Utilizing simulation when educating about mechanical ventilation allows the learner to experiment with various settings and observe physiologic changes without risk of patient harm. The evidence suggests that using simulation for ventilator management training enhances and solidifies the skill and knowledge of learners from a variety of backgrounds.

Simulation in Vascular Access

After securing the airway, one of the most critical steps in rescuing and stabilizing a critically ill or arresting patient is establishing vascular access. This fine motor skill is virtually never done under direct visualization and therefore requires an intersection of anatomic knowledge and technical skill in a high-pressure environment. One study showed inexperienced practitioners had more than twice the mechanical complications of experienced practitioners [55, 56]. Given the high-stake nature of these procedures, training programs and hospitals around the country have turned to simulation-based curricula for these procedures. Simulators for vascular access range from low-fidelity, low-cost rubber tubes embedded in gels to complicated ultrasound compatible anatomic mannequins.

Intraosseous Access (IO)

Establishing IO access is one of the easiest and fastest methods to begin resuscitation, especially in cases where providers have little experience or when access may be technically challenging, such as obese patients or infants. Gable et al. [57] designed a low-fidelity simulation course for paramedics responding to obese patient. The trainees received a 3-h didactic and simulation course on the bariatric knowledge, transport, airway, and vascular and IO access. Paramedics were assessed with a cognitive and confidence pre- and posttests. There were observed significant improvements in all categories. Ballistic gel was added to IO mannequin to simulate an obese extremity. Tofil et al. [15] used a chicken leg IO insertion model to train PGY2 residents before and during a pediatric ICU rotation. Skill index scores and confidence level improved significantly after simulation; however, it did not differ significantly from their PGY3 traditionally trained residents. Oriot et al. [58] published a 20-point scale evaluation model that was validated by training and testing 31 emergency physicians. They suggest using this scale to train novice learners and found that scoring >15 out of 20 correlated with successful IO access.

Central Venous Catheterization (CVC)

While CVC access is often needed for hemodynamic monitoring, lifesaving therapeutics, and advanced technologies, rapidly establishing this access is often critical. However, complications of CVC insertion such as pneumothorax, central vein laceration, air embolism, and central line-associated bloodstream infections (CLABSI) among others can be life threatening. Simulation-based curricula have targeted this need to establish access rapidly and safely.

While simulation curricula are generally a product of resident training programs, national patient safety initiatives have resulted in some hospital-based curricula for CVC placement. Shieh et al. [59] reported their hospital wide effort to standardize CVC placement and decrease associated complications. They employed a multifaceted approach including proper documentation, cognitive and simulation training, and use of ultrasounds guidance. They report long-term reduction in CVC-associated pneumothorax at 85% and CVC-associated bloodstream infection at 62% when comparing data from year 2006 to the period of 2008–2014. Barsuk et al. [60] demonstrated a 74% reduction in CLABSI after a simulation based training was instated for residents rotating in the medical intensive care unit.

Werner et al. [61] developed a simulation-based teaching module and a validated checklist for 28 pediatric emergency medicine attendings. Participants were assessed using a femoral CVC placement mannequin before interventions and received a 20-min lecture on the procedure and checklist, followed by hands-on training until all participants achieved all critical steps of the checklist. They were tested at 2- and 12-month intervals. Competency increased from 32% before intervention to 93% at 2 months. The skills were retained at 12 months with a competency score of 85%. The authors postulate that simulation-based training increased competency and long-term retention of learned skills.

In an effort to identify factors leading to unsuccessful subclavian CVC placement, Nathawani et al. [62] recruited 46 junior surgical residents to perform the procedure on a low-fidelity simulation model. Technical skills were assessed using a checklist. The cognitive assessment consisted of presenting a picture of an obese patient, in which the residents were asked to provide anticipated difficulties and propose solutions for CVC placement. The authors found significant correlation between poor cognitive assessment scores and the number of errors made. The authors postulated that the lack of good decision-making is a significant factor that leads to technical difficulty and failure. In the same venue, Gardner et al. [63] found that incorporating erroneous technique into simulation improved the retention of learned CVC placement skills by surgical interns at 1 month, in comparison to interns who only practiced how to perform the skills correctly.

Varas et al. [64] sought to validate a different grading scale for CVC placement. They studied total path length by tracking hand motion, stratified levels of expertise, and compared it to the validated global rating scale method. The authors found that both assessment tools agreed and believed that total path length method added construct validity to the rating process. This was also independently validated by Clinkard et al. [65].

McGraw et al. [66] assessed a simulation-based curriculum for ultrasound-guided femoral and internal jugular CVC placement. They enrolled ten PGY2 residents (anesthesia and emergency medicine), who were required to prepare in advance by completing an online reading module and a pretest. Subsequently, they had four hands-on training sessions and were assessed based on hand motion analysis and completion times. Nine of the residents met expert benchmarks in hand motion, and six achieved faster procedure times than the expert mean at the conclusion of the curriculum. The authors concluded that deliberate simulation training improved technical proficiency.

A MedEdPORTAL search in March 2017 of the terms "central venous" and further narrowed to simulation yielded nine peer-reviewed published curricula for central access. The targeted learner ranged from medical students to senior residents and fellows. Of note, Diederich et al. [67] showed that both low- and high-fidelity models were equally effective in achieving learning outcomes. That being said, performing CVC access under ultrasound guidance is currently the standard of care. Incorporating a simulation-based curriculum that affords the learner the opportunity to include ultrasound is imperative.

Moureau et al. [68] published an evidence-based consensus statement and recommendations for simulation-based training. Use of anatomical models and ultrasound simulations were grade A and B recommendations, respectively. The authors also recommended the following minimal requirements to achieve proficiency in ultrasound-guided CVC cannulation: (a) 6–8 h of didactic sessions and (b) 4 h of practical simulation on anatomical models, then followed by (c) 6 h of ultrasound training on human volunteers to detect normal anatomy.

Establishing central venous access is one of the most common procedures in the intensive care units, emergency departments, and operating rooms.

Future of Simulation in Critical Care

In the future, undergraduate medical education will continue to develop the use of virtual patients in all facets of education including critical care. There is an efficiency gained by handling a virtual patient. The learner can select or be assigned patients in their area of educational need. They can be "seen" at a time of convenience to the learner, and the interactions are more easily scored. This efficiency will allow the learner to review many more cases than would be possible with live interactions, and the case selection is not limited to available patients in a particular clinic, but rather can be assigned to represent a desired spectrum of patient wellness and pathophysiology. This will result in a more efficient acquisition of knowledge and experience, with the limitation of losing human interactions. Even those human responses will be simulated and the simulations will steadily improve over time.

To date critical care simulation has centered on discreet tasks within the practice of critical care. Future simulation in critical care will bring the discreet tasks together into the integrated management of a critically ill patient. A learner will be presented with a critically ill simulated patient and then be required to manage the discreet tasks above including intubation, central venous access, ventilator management, and so on while also managing the cognitive load of the differential diagnosis and resuscitation and discuss therapeutic options and initiate treatment plans. Once mastered, these actions can then be undertaken as part of interprofessional education including the full multidisciplinary ICU rounding team. Taken even further, we envision junior learners rounding on a handful of simulated patients in a simulated ICU ward, including admissions, transfers, decompensating patients, etc. In addition, we envision ongoing routine in situ training of the ad hoc multidisciplinary team rounding in the ICU on a simulated patient handling a rare case or high-risk case as it unfolds over time.

We presented a fraction of the myriad studies that have shown benefit to patients from simulation in training and assessment. As a result, we anticipate simulation will become an increasingly large part of ongoing hospital privileging, verification of competence, maintenance of certification, and other forms of certifications. This continues the precedent set with advanced cardiac life support (ACLS) and maintained with an ever-increasing number of similar programs such as Advanced Trauma Life Support (ATLS), Focused Assessment Transthoracic Echocardiography (FATE), and so on. While the curricula and assessments are useful, the regulatory burden is increasing to a perhaps unsustainable point. We advocate strongly for restraint in national regulation and the unfunded mandates to hospitals and training programs that those regulations represent.

Conclusion

The rescue and stabilization of critically ill patients occurs in a fast-paced, high-pressure environment where there is very little margin for error. Data regarding the confidence of the learner has typically been discounted as an educational outcome measure since technical skill is clearly more important. But in these ICU procedures, where time is of the essence, practitioner confidence in their knowledge and skill may carry more weight than confidence would in other technical skills. Errors, either as a result of poor technique or hesitation and delay, can have a devastating outcome for a patient and shatter a career. A robust simulation-based curriculum with ample opportunity for deliberate practice to competence in the knowledge and skills for practice in critical care is essential for any provider practicing in this area.

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Simulation in Cardiothoracic Surgery

Hadley K. Wilson and Richard H. Feins

Background

Cardiothoracic surgery is a dynamic and innovative field that is tailoring its training to the changing landscape of today's medicine. The inherently high-risk nature of cardiothoracic procedures, along with work hour restrictions and increasing administrative and clerical responsibilities, has created a challenging environment to develop trainees who possess the necessary skills to thrive in independent practice. Many training centers are starting integrated 6-year cardiothoracic surgery training programs and are looking for ways to train their residents more efficiently. In an effort to improve patient care and further develop the skills of resident and attending cardiothoracic surgeons, simulation has emerged as an attractive adjunct to the traditional apprenticeship model of training in cardiothoracic surgery. In addition, simulation in cardiothoracic surgery has been reported by Tesche [1] as a useful recruiting tool for attracting students to the field of cardiothoracic surgery. Simulation is also an ideal training method for attending physicians to broaden their skill set as new technology and techniques emerge.

The goals of simulation-based training in cardiothoracic surgery are to develop an affordable, realistic, and widely available program that can teach a learner particular tasks in a risk-free environment. This will give the trainee ample opportunity to gain experience with as many repetitions as necessary to proficiently and safely perform the task in the operating room. To this goal, simulators must demonstrate sufficient reliability, validity, and competency in order to be effective [2]. That is to say that training devices must predictably reproduce consistent results, accurately simulate the task for which they were designed, and translate those skills to improvement in the operating room. Furthermore, without experienced instructors to guide training surgeons and defined curricula to follow, these simulators will never reach their potential and desired outcome. Cardiothoracic surgery has been in the forefront of developing surgeons to be competent simulation-based trainers and in developing detailed training paradigms with standardized assessments tools. A comprehensive list of cardiothoracic surgery simulators that are now available is shown in Table 1.

Current Simulators

Simulation-based training simulators in cardiothoracic surgery can be broken down into essentially three types of trainers: those constructed of non-tissue-based materials, those

Table 1 Procedures for which simulators exist for training in cardiothoracic surgery

Cardiopulmonary bypass
Coronary artery bypass grafting
Heart valve surgery
Percutaneous heart valve surgery
Heart transplantation
Ventricular assist device placement
Cardiac surgery adverse events of massive air embolism, acute intraoperative aortic dissection, and sudden postoperative loss of cardiac function
Transvenous pacemaker placement
Open, thoracoscopic, and robotic lobectomy
Antireflux surgery
Esophageal myotomy
Bronchoscopy (rigid and flexible) including foreign body removal and stent placement
Navigational bronchoscopy
Endobronchial ultrasound
Esophagoscopy (rigid and flexible) including foreign body removal and stent placement
Minimally invasive esophagectomy
Chest wall resection and reconstruction
Removal of mediastinal masses
Mediastinoscopy
Chest tube insertion
Tracheostomy
Thymectomy

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constructed of tissue-based materials, and those aided by computers, virtual reality, or some combination of all three. While they differ in construction, each is useful and complimentary for developing certain skill sets of the surgeons training with them while minimizing the risk of training in the operating room under the traditional apprenticeship model. Each category has its own unique benefits and challenges that will be explored in this section.

Non-tissue Component Task Trainers

Non-tissue component task trainers emerged early as an affordable alternative to tissue and computer-based models. These simulators are designed to take one portion of an operation and give the learner the opportunity to practice that particular component repetitively until proficiency has been obtained (Fig. 1). Those skills can ultimately be transitioned into the operating room.

Fann and colleagues [3] describe a coronary anastomosis simulator in 2008 that gives residents in cardiothoracic surgery the opportunity to practice end-to-side anastomosis with a portable task station. Coronary anastomosis is perhaps the most well-studied cardiothoracic surgery procedure and consequently a logical starting point for simulation-based training. Residents of all experience levels participated and were supplied with a task station complete with 3 mm silicone target vessels, silicone vein grafts, appropriate instruments, and suture. The residents were first trained on the setup of the task station by an attending cardiothoracic surgeon and watched a brief instructional video. Residents performed two timed end-to-side anastomoses as a baseline skills assessment and were instructed to practice with the task trainer on their own, returning in 1 week for a follow-up assessment. The anastomoses were evaluated by attending cardiothoracic surgeons for patency. Resident performance was rated using performance scores modified from the Objective Structured Assessment of Technical Skills (OSATS) as described by Reznick [4]. Additionally, residents completed an exit questionnaire rating the realism and practicality of this simulator. Times to complete the anastomosis decreased by 20% after a week of practice. Furthermore, residents' technical skills assessment improved after training with the simulator as well. The majority of residents found the simulator both helpful and realistic, while all residents felt more confident performing a coronary anastomosis after using the task station.

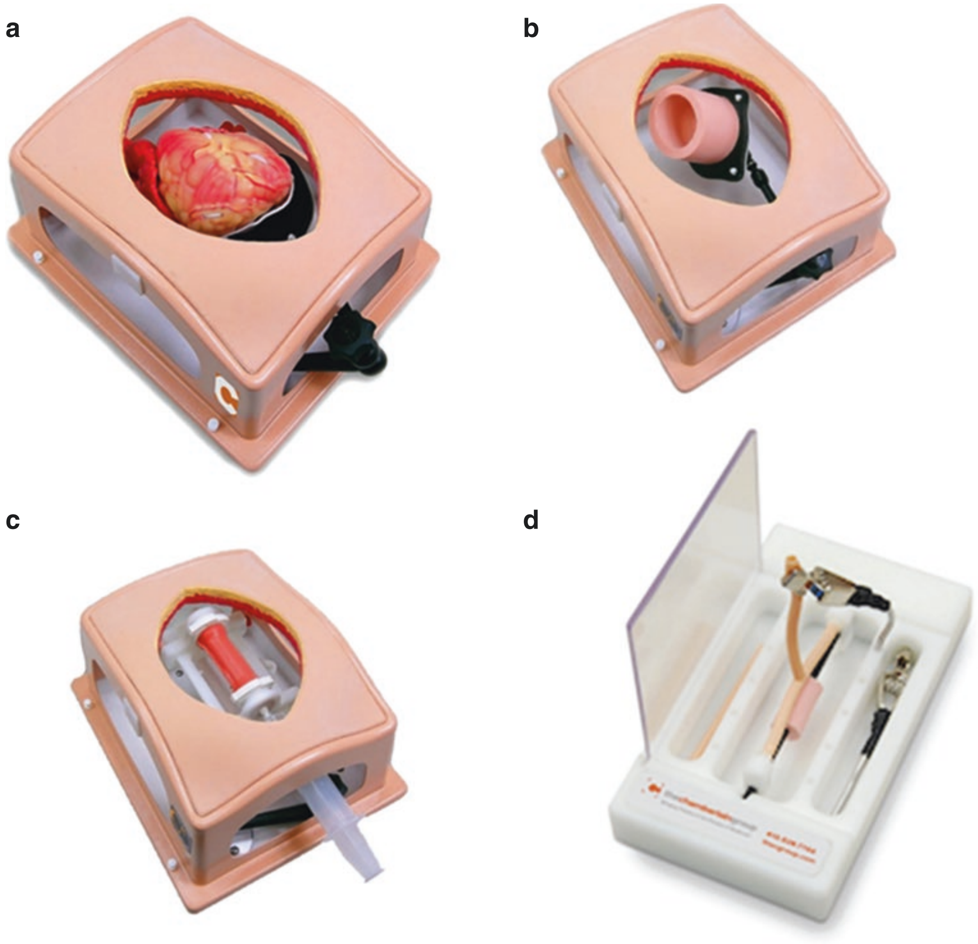


Fig. 1 Non-tissue simulators. (**a**) Chamberlain Group Heart Case with beating heart. (**b**) Chamberlain Group Heart Case with aortic valve. (**c**) Chamberlain Group Heart Case with aortic segment. (**d**) Chamberlain Group Pocket Vessel Anastomosis Trainer. (Used with permission of The Chamberlain Group, Great Barrington, MA)

A group from the Mayo Clinic used an aortic anastomosis task trainer to study medical student and resident improvement of skills after deliberate practice. Trainees first performed an aortic anastomosis on a porcine heart for a pretest baseline skills assessment. The trainees were then given a task station constructed of a wood block with synthetic aortic conduit secured in place, a scoring rubric, necessary surgical instruments, and suture to practice on their own and keep a log of practice attempts. At the end of 5 weeks, the participants completed a posttest evaluation performing an aortic anastomosis on a porcine heart. Performance was graded based on criteria funded by the Agency for Healthcare Research and Quality including bite, spacing, use of instruments, and knot tying. Residents also completed a posttest questionnaire for this simulator. Mean posttest scores improved significantly after training with the simulator with medical students improving the most. Additionally, the participants agreed that the models were both effective and realistic. Overall cost was just $22.50 per participant [5].

Hossien [6] reported an intermediate-fidelity mitral valve surgery simulator that was inexpensive, easily reproducible, and effective. Given the complexity of mitral valve surgery, this model offers an affordable model to gain operative repetitions of a procedure that traditionally requires years of experience to gain proficiency. A synthetic mitral valve and two papillary muscles were created using silicone and set within a cylindrical canister to simulate the typical exposure of the mitral valve during mitral valve repair or replacement. Triangular and quadrangular resection of the mitral valve was performed in addition to sliding plasty and augmentation of posterior leaflet. This model supported suturing and tissue manipulation while remaining easily reparable by adding more silicone. The simulated mitral valve can be constructed to represent a number of different pathologies and is suitable for both annuloplasty and mitral valve repair. This study, however, did not utilize resident participation and consequently the true effectiveness of the model remains to be determined.

Joyce et al. [7] described a mitral annuloplasty simulator constructed of a silicone-based cylinder similar to Hossien's model and studied resident performance before and after training with the simulator. As in the previously mentioned studies, a pretest evaluation was administered prior to training with the simulator. Each participant first watched an instructional video on how to perform mitral valve annuloplasty with a porcine model and plastic mitral model. The residents then performed a mitral valve annuloplasty on a porcine heart for their pretest assessment. Formative feedback was given, superimposed over the video of their initial annuloplasty on the porcine heart, and participants were then given 2 weeks to practice the exercise on the silicone mitral valve trainer. At the end of 2 weeks of practice with the silicone mitral valve model, the residents performed a second mitral valve annuloplasty on a porcine heart. The Objective Structured Assessment of Technical Skills was used as the scoring rubric for this simulation. Mean time to completion of the procedure improved significantly after training with the silicone model as did improvement in technical skills.

These non-tissue-based models have excellent reliability and competency; however, their realism is inferior to that which can be achieved on tissue models. Residents do, however, have the opportunity to develop basic skills using these models that may translate to skills improvement in the operating room. Simulators of this nature are excellent models for home practice offering significant opportunity to gain repetitions prior to performing high-risk procedures in the operating room.

Tissue-Based Simulation

In an effort to increase the realism of simulators, many centers are experimenting with animal and cadaver models to improve their surgical training curricula. These simulators bring a realism that has not yet been realized in non-tissue-based models. Porcine models have largely been the most available and popular tissue models for training cardiothoracic surgery residents given the similar anatomy, affordable cost, and abundant supply. Cadaver models afford the trainee real human anatomy and tissue but can be in short supply, variable in their condition, and often costly to acquire and maintain.

At the Cardiothoracic Surgery Boot Camp experience held annually at the University of North Carolina at Chapel Hill, first-year cardiothoracic surgery fellows train in many different simulator platforms. For coronary artery anastomosis, residents train using both the coronary artery task station discussed above and anastomosis on porcine hearts that will be addressed in this section. For this simulator an explanted porcine heart was situated to reflect normal exposure after median sternotomy (Fig. 2). Residents were allowed 2.5× loupe magnification for the simulation. This model allowed residents the opportunity to expose the left anterior descending artery, make an arteriotomy, and create an end-to-side anastomosis using cryopreserved saphenous vein. Residents were supervised by attending physicians from across the country and evaluated on tissue manipulation, needle angles, use of instruments, and graft orientation using a 3-point global scale (1 good, 2 average, 3, poor). Significant improvement was noted in all parameters. Residents also completed an exit questionnaire in which they agreed that the porcine hearts were good training tools [8].

Greene and colleagues [9] report a pressurized cadaver model for cardiothoracic surgery simulation. The goal of this trainer was to train residents in redo sternotomy and internal

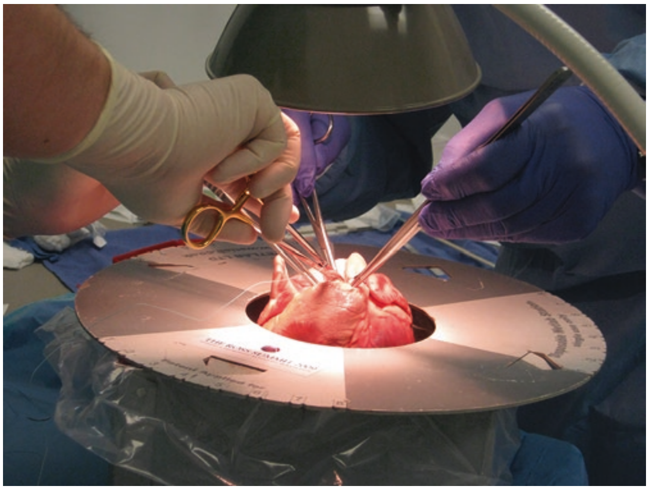


Fig. 2 A pig heart suspended in a simple cardboard box being used to train

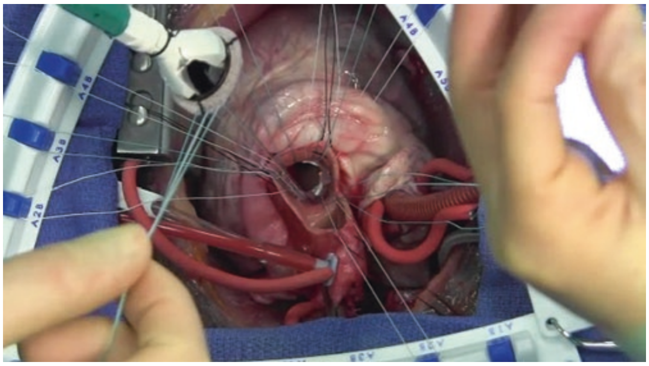


Fig. 3 The Cardiac Surgery Simulator (Ramphal) for training in most all cardiac surgery procedures. Here seen doing an aortic valve replacement

mammary artery harvest. Unfixed cadavers were used for training, and pressurization was obtained by accessing the common femoral artery and introducing a cannula. The cadavers were massaged to allow perfusion of small capillaries and removal of clot. Tap water with red dye was used as the perfusate, and then median sternotomy was undertaken using standard or redo sternotomy saw. Retractors were placed to facilitate dissection of the internal mammary artery, and the simulation was carried out. This model allows high-fidelity simulation of living tissues; however, it is unable to be reused. The ability to provide a resource for deliberate practice for training cardiothoracic surgeons is therefore limited.

Carter and Marshall [10] describe a bovine open lobectomy simulator for teaching thoracic surgical skills. The simulator consists of a human torso model with posterolateral thoracotomy incision. Bovine lungs were used and a single lung placed within the torso to simulate a deflated lung. Medical student volunteers without prior surgical experience participated in the study and were given instruction on the use of the simulator and surgical instruments via electronic dissemination. Students then practiced open lobectomy on the model over the course of 4 weeks and were evaluated using the Objective Structured Assessment of Technical Skills. Students' scores improved significantly from the first to fourth weeks of practice, and average time needed to complete the procedure was significantly reduced from first to fourth weeks as well. This study shows individuals without any surgical experience can improve their performance with deliberate practice using simulation-based training.

The mainstays of tissue-based cardiothoracic surgery simulators are the preserved animal tissue models, reanimated to simulate live organs and placed in a humanoid environment. The breakthrough in this technology was the Cardiac Surgery Simulator developed by Dr. Paul Ramphal and colleagues in the Department of Surgery at the University of the West Indies-Mona in 2004 [11] (Fig. 3). Ramphal sought to broaden the availability of surgical experience to both surgery residents and OR staff. The simulator consists of an explanted porcine heart which is prepared with balloons in each ventricle and a perfusion line connected to the aorta. The balloons are driven by a computer-driven device that compresses an air bladder in such a fashion to simulate the heart beating in various rhythms. Perfusion of the heart is by a hydraulic system connected outside the field of view to the aorta. A computer interface is controlled by an instructor or other person at the head of the bed to simulate appropriate hemodynamic responses including changes in heart rhythm, heart rate, and blood pressure. The model can be used for simulating cannulation for bypass, going on bypass, coming off bypass, proximal and distal coronary anastomosis, valve surgery, aortic valve replacement, off-pump coronary bypass, ventricular assist device placement, heart transplantation, and other procedures that are still in development. This simulator is currently as close as one can come to a real heart operation without actually performing the procedure on a human. The learner can perform multiple cannulations in one simulation session or multiple proximal and distal anastomoses before the heart will need to be replaced. Additionally, critical events such as air embolism can be simulated and repeated multiple times until the learner develops the desired level of comfort. This simulator is already employed by several university centers and is a mainstay for the Thoracic Surgery Directors Association (TSDA) Boot Camp program.

A further application of the preserved, animated tissue model is the Thoracic Surgery Simulator developed at the University of North Carolina at Chapel Hill (Fig. 4). This simulator uses a tissue block consisting of the trachea, esophagus, left lung, and heart. The heart is made to beat in a fashion similar to that used in the Ramphal cardiac simulator, and the pulmonary vessels are perfused with a bloodlike fluid. This simulator has been used for open, thoracoscopic,

Fig. 4 Thoracic Surgery Simulator for open, thoracoscopic, and robotic surgery. (Photo courtesy of KindHeart, Inc., Chapel Hill, NC)

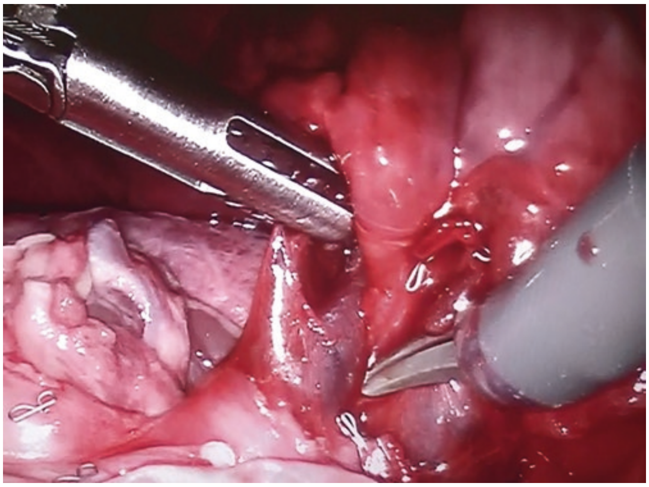


Fig. 5 Robotic dissection of the left superior pulmonary vein using the Thoracic Surgery Simulator. (Photo courtesy of KindHeart, Inc.)

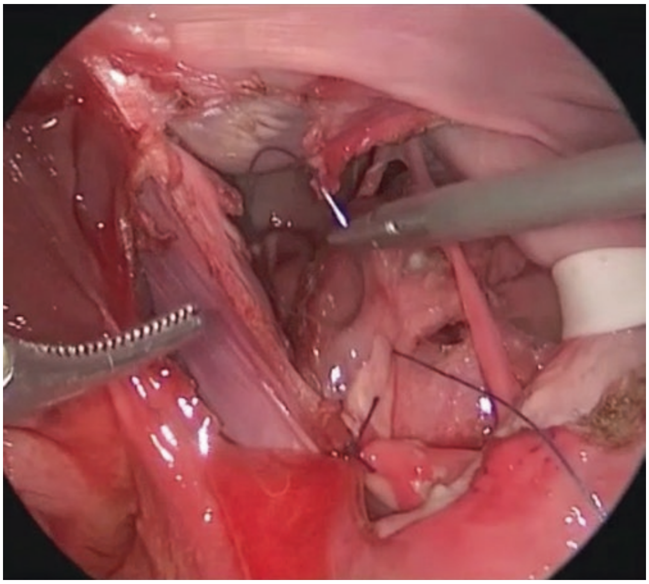


Fig. 6 Closure of the esophageal hiatus using the hybrid foregut simulator. (Photo courtesy of KindHeart, Inc.)

and robotic lobectomy training (Fig. 5). A full curriculum for robotic lobectomy using this simulator is under development.

Similarly, a hybrid tissue simulator that uses the anatomic features of animal organs and the real-life feel of tissue is being developed for foregut surgery. With this model, esophageal myotomy, repair of paraesophageal hernias, antireflux procedures, and minimally invasive esophagectomy can be performed by open, laparoscopic, and robotic technique (Fig. 6). A formal curriculum in these techniques is under development for robotic procedures.

The real tissue feel of the preserved animal tissue, its relative low cost compared to live animals and cadavers, and the ability to tailor the model for a wide variety of operations make this model extremely attractive for both traditional training and training for adverse events. Other procedures such as foregut surgery, thoracic esophageal surgery, and mediastinal surgery are under development at UNC.

Computer-Aided Simulation

With rapidly advancing technology, computer-aided simulation has emerged as a versatile platform for training cardiothoracic surgery residents. While animal tissue models are quite prevalent in simulation training today due to their accessibility, low cost, versatility, and haptic feedback, there remains a place for computer-aided simulation, particularly in the introductory phase of training. Computer-aided, virtual reality simulation requires no replacement of tissues and less supervision. Two areas where computer-based simulation has been very helpful are in training for catheter-based skills endovascular stenting (TEVAR) and transarterial valve replacement (TAVAR) and in the training for bronchoscopy, endobronchial ultrasound, upper GI endoscopy, and trans-esophageal ultrasound (TEE) (Fig. 7). As modeling and haptic technology improve, it's not unreasonable to think that computer-aided models will assume an even greater role in cardiothoracic training.

Solomon et al. [12] described a virtual reality simulator of video-assisted thoracoscopic surgery right upper lobe resection that incorporates common anatomical variants and haptics. The system is driven by a laptop and a model of the human torso that simulates exposure in a typical VATS right upper lobe resection. Instruments are coupled to a haptic device that provides tactile feedback to the user while they view their operation on a computer screen. This simulator provides both teaching and testing modes depending on whether the learner is exploring the anatomy or performing the operation. This allows the trainee to familiarize himself with the platform and anatomy prior to training in the operation. First the user selects the area to insert the thoracoscope port, and then other ports may be inserted. More ports may be added as needed, and an endo-dissector and stapler are included in the instruments available. At any time, the user can relocate the thoracoscope port to adjust their view. Trainees were evaluated using the Objective Structured Assessment of Technical Skills. In this study repetitive training on the simulator resulted in improved resident scores; however, improvement in the operating room was not studied. Additional research into the haptics required to generate the necessary degree of realism, and decreasing the costs will be important in future of models like this one.

Simulation has been used in cardiothoracic surgery for the development and testing of new devices. At Stanford University, the division of cardiothoracic surgery is experimenting with a simulator that incorporates both non-tissue-based task stations and computer-aided devices. In cardiothoracic surgery, it is often difficult for both attending surgeon and resident to see the same structures at the same time from their position at the operating table. This makes it challenging for the attending surgeon and trainee to accurately communicate during the procedure. Brewer et al. [13] hypothesized that by providing the attending surgeon and trainee with simultaneous visualization of the surgical field, they could improve trainee performance in the operating room. In this study they employed a "wearable surgical visualization system" composed of a Google glass device that can both stream video and, fitted with a laser pointer, can precisely designate structures. A non-tissue-based task station that was fully visible to the learner and partially obscured to the trainer was used. For a baseline performance, the trainers were instructed to read a script describing where the learner should place needles. This was done first on the portion of the trainer that both instructor and trainee could see, and the instructor was allowed to point and designate where

Fig. 7 Computerized virtual reality for bronchoscopy, esophagoscopy, and endobronchial ultrasound (CAE Healthcare, Sarasota, FL)

to place needles. For the portion obscured to the instructor, they were required to read only the script without any additional alteration in instruction. This was then repeated using the wearable surgical visualization system so that both trainee and instructor could maintain simultaneous visualization of the entire surgical field. Residents were judged both on time to completion and accuracy of needle placement. While the time to completion was unchanged after institution of the wearable surgical visualization system, resident accuracy improved significantly for the areas obscured to the instructor. There was no difference in accuracy of needle placement in the portion of the trainer that was readily visible to both instructor and learner suggesting no learning effect. This model of training is a clever and exciting tool that could greatly aid training in the operating room by providing continuous simultaneous visualization of the surgical field for both the attending surgeon and resident.

National Efforts in Simulation-Based Training in Cardiothoracic Surgery

Simulation-based training has garnered much attention in recent years given the changing paradigm of graduate medical education. The high-risk nature of cardiothoracic surgery, work hour restrictions, and push for quality improvement has generated discussion regarding the safest, most effective, and ethically sound way to train residents in cardiothoracic surgery. Simulation-based training is a popular and necessary tool in today's training environment and has been the subject of research at a national level. Program directors and leaders in the field from across the country have come together to pioneer the implementation of simulation in training cardiothoracic surgery residents. The Visioning Simulation Conference addressed the need for simulation and sought to determine future training needs. National organizations such as the Thoracic Surgery Directors Association, Society of Thoracic Surgeons, and Thoracic Surgery Foundation for Research and Education have developed training programs and events such as TSDA "Boot Camp," Top Gun, and The Senior Tour to bring awareness and encourage participation in simulation-based training. These have been driving forces in the pursuit of improving our training programs in cardiothoracic surgery.

The Visioning Simulation Conference

Simulation-based training in cardiothoracic surgery really got its start with the Visioning Simulation Conference sponsored by the then Thoracic Surgery Foundation for Research and Education and hosted by the Center for Medical Simulation in Cambridge, Massachusetts, in 2007. The meeting addressed the use of simulation as a training tool to meet the continually changing needs in thoracic surgery. The conference brought together pioneers of simulation in other fields, simulation developers, and government and industry funding sources.

As reported by Carpenter et al. [14], the meeting not only covered simulation-based training for the most basic skills but also its use for less obvious skills such as communicating with a team, conveying bad news to patients and families, and for adverse event training. Simulation as an ideal avenue for continued education for fully trained surgeons was also demonstrated. Not surprisingly, they found that simulation at nearly every level should be both possible and beneficial.

The meeting proposed a number of pathways to the specialty. For adult cardiac surgery, a mainstay of simulation should be uncommon complications that may be experienced in the operating room. These are infrequent occurrences in practice and provide little opportunity for real-life training. By using simulation-based training, a resident may gain experience dealing with catastrophic events that might otherwise require a lifetime of experience in which to become comfortable. Infrequently encountered procedures should also be simulated to increase the case volume for training surgeons beyond what is available in the operating room. Furthermore, common high-risk procedures such as redo sternotomy could be simulated to better prepare residents for their operative experience.

In congenital cardiac surgery, the extensive variation in anatomy makes it nearly impossible for a trainee to experience every type of congenital defect. A repository of images and variants could be constructed to increase the knowledge base and assist surgeons in operative planning for patients that have similar pathology.

General thoracic surgery was felt to be amenable to simulation given the common use of endoscopy and video-assisted thoracoscopic surgery. Simulation is an attractive tool for training in these techniques to better develop resident proficiency and also broaden attending physician skill set.

Lessons from other fields such as aviation were a crucial part of this meeting and greatly improved the understanding of how to apply simulation in the field of cardiothoracic surgery. It is absolutely paramount that the simulation accurately simulates reality. If the simulator does not simulate what it was designed to simulate, then bad habits will be developed, and proficiency will not be achieved.

The final and possibly most important goal of the meeting was to determine what activities should be simulated and where to locate the simulators. Basic skills simulators should be available to all institutions at the local level. Techniques such as suturing, chest tube placement, central lines, and anastomosis can be accomplished with relatively inexpensive and low-fidelity simulators. More complex simulators should be distributed at a regional or mobile center as these can be quite expensive and difficult to maintain. Such simulation activities would include congenital heart surgery, device implantation, robotics, and endovascular techniques. Regional simulation centers could provide access to trainees in that area that may not otherwise have access to training in these techniques [14].

The TSDA Boot Camp

In 2008, the Thoracic Surgery Directors Association created the TSDA Resident Boot Camp where cardiothoracic surgery residents from across the country came to train on simulators to develop crucial skills early in their training. This was likely the first national resident educational program in simulation for any specialty ever developed in the United States. The idea for the Boot Camp was created by Drs. Richard Feins, George L. Hicks, Jr., and James Fann and was funded by TSDA initially and then by the Joint Council for Thoracic Surgical Education. The 4-day Boot Camp has been held annually at the University of North Carolina at Chapel Hill and focuses on teaching residents the cornerstones of cardiothoracic surgery including cardiopulmonary bypass, troubleshooting bypass, mediastinoscopy, video-assisted thoracoscopic surgery, and open lobectomy. Each year between 32 and 40 residents attend the program rotating through stations complete with state-of-the-art simulators using porcine organs and non-tissue-based task stations under guidance of attending cardiothoracic surgeons from around the country. The five modules include cardiopulmonary bypass, vessel anastomosis, thoracic endoscopy, hilar dissection, and valve repair and replacement. The TSDA Boot Camp has become a mainstay of resident education in cardiothoracic surgery. All participants surveyed have found it to be extremely helpful and would recommend it to other residents. Boot Camp has also become a model for other surgical specialties and has been instrumental in the acceptance of simulation-based training in cardiothoracic surgery [15].

Funding for Boot Camp is presently provided by participant fees, industry support, and the Society of Thoracic Surgeons.

Senior Tour

The Senior Tour is a concept created to help meet the need for trained instructors for training cardiothoracic surgery residents on simulators using the skills of retired or soon to be retired cardiothoracic surgeons. Senior Tour training drew retired attending cardiothoracic surgeons from across the country to train in the use of six cardiac or six thoracic simulators at a two-and-one-half-day meeting in Chapel Hill. Senior Tour members are now participating in simulation training at the local level and as faculty for Boot Camp each year. The Senior Tour has been found to be an effective way to utilize the knowledge and experience of this generation of surgeons to build the skills foundation of new generations of cardiothoracic surgery residents [16].

Top Gun

As simulation becomes more popular among training institutions, a friendly competition has arisen as a way to attract cardiothoracic surgery residents to participate in simulation-based training to improve their skills. The Top Gun competition uses low-fidelity simulators to create a technical competition among cardiothoracic surgery residents at a national level. The low-fidelity coronary anastomosis simulators were distributed annually to first-year cardiothoracic surgery residents. An instructional video and scoring rubric were included. Cardiothoracic surgery residents voluntarily participated by submitting a baseline video of themselves completing the anastomosis, and these were judged by three evaluators in a blinded fashion. The residents were coached by a mentor, and a final video was submitted and judged by the same evaluators. The top five residents were then asked to participate live at the AATS annual meeting to determine which one would win the Top Gun designation. This innovative strategy exposes cardiothoracic surgery residents to simulation and improves their baseline skill set. The competitive and national nature of the Top Gun challenge normalizes simulation as a mainstay for cardiothoracic education and fuels residents' desire to participate in a simulation curriculum [17].

STS University

At its annual meeting in 2005, the Society of Thoracic Surgeons created a hands-on experience with simulation for participants wanting to learn new skills. Given the name STS University, the program provides 2 h courses in a wide range of cardiothoracic surgical procedure such as thoracoscopic lobectomy, the MAZE procedure, aortic homografts, ventricular assist devices, and TEVAR and debranching procedures. STS University has been extremely popular with meeting attendees as an introduction to new procedures and new training methods.

The Cardiac Surgery Simulation Study

The Ramphal simulator was recently employed in a multicenter study by Feins and colleagues [18] sponsored by the Agency for Healthcare Research and Quality and published in 2017. This is likely the largest study ever done in surgical simulation. The group studied first-year traditional cardiothoracic surgery fellows or fourth-year integrated cardiothoracic surgery resident's improvement in skill after deliberate practice first using component task simulators [8] and later performing full operations on the Ramphal simulator. Eight institutions participated and used deliberate practice to hone skills of commonly performed cardiac operations such as cardiopulmonary bypass (CPB), coronary artery bypass grafting (CABG), and aortic valve replacement (AVR). One of the most important benefits of the simulation program is that residents were also trained on catastrophic events using the Ramphal simulator including massive air embolism (MAE), acute intraoperative aortic dissection (AIAD), and sudden deterioration in cardiac function (SDCF). Residents first practiced operations broken into components such as aortic cannulation until proficient and then moved to more advanced procedures ending with full operations. Using 19 OSATS/Likert-based assessment tools developed by the group, the study collected over 19,000 data points in over 3000 combined hours of simulation-based training and found a clear relationship between number of repetitions and improvement in operative skills. An example of a component task assessment tool used in this study is shown in Fig. 8. An example of a complete procedure assessment tool is shown in Fig. 9. All participants achieved perfect or near perfect scores on all modules with the training method. The study was guided by a detailed 39 session syllabus that outlined the goals and objectives, simulation setup and use, and specific assessment tools. The syllabus/curriculum was felt to be an essential component of the simulation-based training and now has been given to the Thoracic Surgery Directors Association for widespread dissemination. It is expected to become a mainstay for cardiothoracic surgery. Importantly, this study also formulated a new method for training in adverse event management. Unlike most simulation-based training in adverse event management, training this study first identified the component parts of handling an adverse event, developed modules and simulators for component task training, and then applied that training to handling the total adverse event as part of a routine cardiac surgery operation.

Costs of Simulation in Cardiothoracic Surgery

The cost of providing simulation training in cardiothoracic surgery is primarily defined, as in most simulation, by the availability of trained simulation-based faculty. Component task simulators such as a length of pressurized pig aorta used for practicing aortic cannulation (Fig. 10), the static pig heart used for practicing coronary artery bypass, and even models for tracheostomy/tracheal resection and chest tube insertion are relatively inexpensive and readily built or obtained. Practice on aortic valve replacement can be readily achieved by a heart secured in a box at relatively little cost [2]. The expense is greater for synthetic simulators with products such as the Heart Case from the Chamberlain Group (Fig. 1). The Heart Case retails for about $1300 with an additional $1125 for the synthetic heart. The anatomical model for aortic valve replacement sells for $155 and can be used for several sessions. Virtual reality computer simulators usually cost about $100,000 and are specific to a particular procedure (Fig. 6). They have the advantage of being a one-time cost, but maintenance costs and upgrades need to also be factored in. Tissue-based simulators for both cardiac and thoracic procedures such as the Cardiac Surgery Simulator (CSS, Ramphal) (Fig. 3) and the Thoracic Surgery Simulator (TSS) (Fig. 4) have different financial models for acquiring. The Cardiac Surgery Simulator purchase price is approximately $150,000, but special pricing is available to academic institutions. Initial purchase includes tissue blocks. The Thoracic Surgery Simulator is supplied free of charge, the only cost being for the tissue blocks. The CSS, TSS, and Abdominal Surgery Simulator are available from KindHeart, Inc.

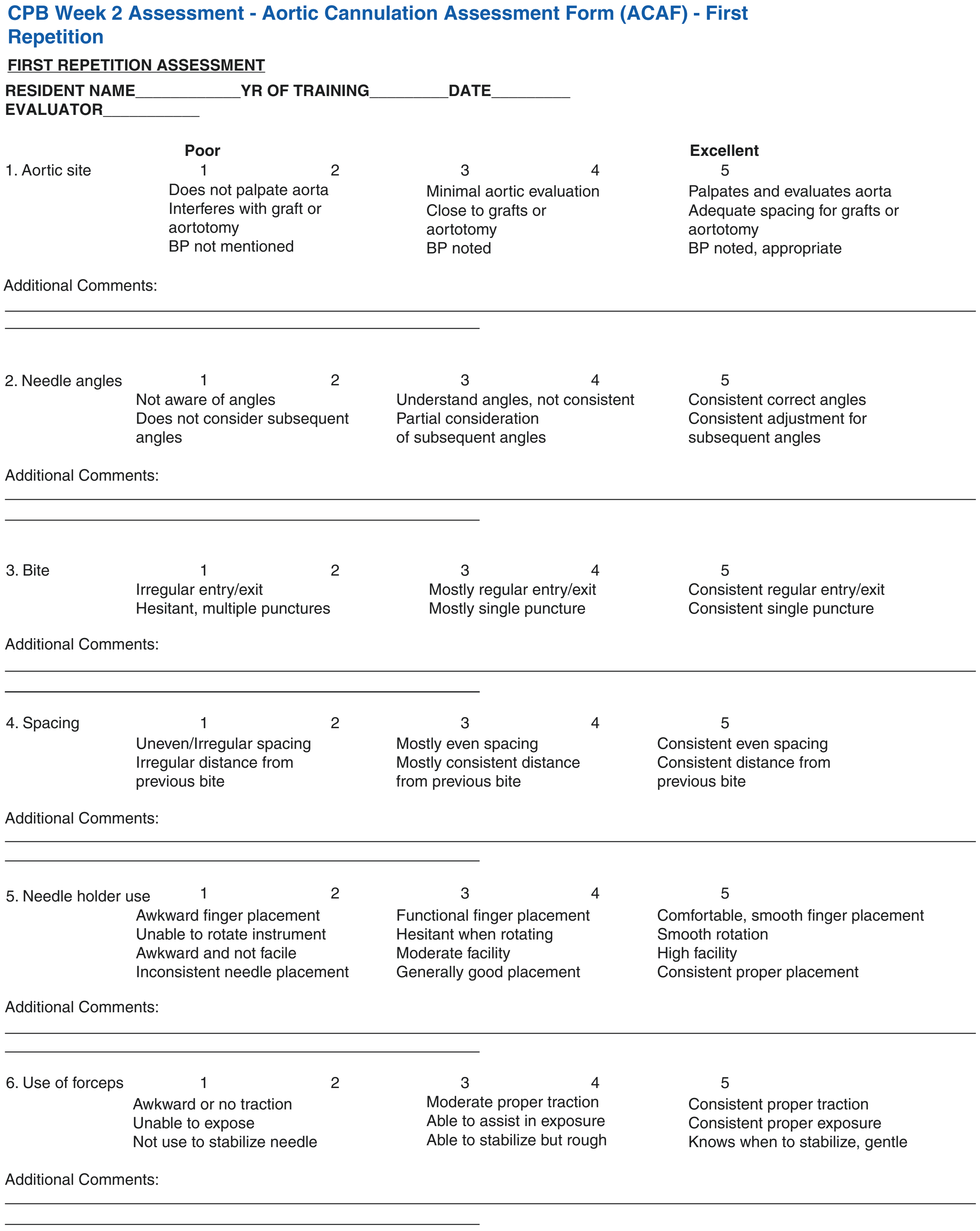
Future Directions

It's clear that simulation-based training is becoming a mainstay for graduate medical education in cardiothoracic surgery. The benefit of providing a nearly risk-free scenario for deliberate practice is a huge addition to the traditional apprenticeship model that has been used in surgical fields for years. Increasing quality improvement measures, work hour restrictions, and ethical concerns have been the driving force for innovation in surgical education.

In the future it is likely that we will see that competency in simulation must be achieved prior to performance in the clinical setting and for advancement in residency. Future research, however, will be required to determine how to meaningfully measure simulation proficiency as it translates to real-life practice in the operating room. The creation of a standard simulation-based curriculum in cardiac surgery by the participants in the Cardiac Surgery Simulation Study is a major step in expanding adoption.

As new technology continues to be developed, simulation-based training for the practicing surgeon will become increasingly the standard for shortening patient exposure during the learning curve in the clinical setting. This is already the case for robotic lobectomy where a tissue-based simulator is being widely used. Simulators also have a role to play in product development and human factors research for new devices.

The use of simulation-based performance is being considered for certification and maintenance of certification but will require a very high degree of validity and reproducibility before it can be widely employed in such a high-stakes role.



CPB Week 2 Assessment - Aortic Cannulation Assessment Form (ACAF) - First Repetition

FIRST REPETITION ASSESSMENT

RESIDENT NAME____________YR OF TRAINING_________DATE_________
EVALUATOR___________

	Poor				**Excellent**
1. Aortic site	1	2	3	4	5
	Does not palpate aorta Interferes with graft or aortotomy BP not mentioned		Minimal aortic evaluation Close to grafts or aortotomy BP noted		Palpates and evaluates aorta Adequate spacing for grafts or aortotomy BP noted, appropriate

Additional Comments:

2. Needle angles	1	2	3	4	5
	Not aware of angles Does not consider subsequent angles		Understand angles, not consistent Partial consideration of subsequent angles		Consistent correct angles Consistent adjustment for subsequent angles

Additional Comments:

3. Bite	1	2	3	4	5
	Irregular entry/exit Hesitant, multiple punctures		Mostly regular entry/exit Mostly single puncture		Consistent regular entry/exit Consistent single puncture

Additional Comments:

4. Spacing	1	2	3	4	5
	Uneven/Irregular spacing Irregular distance from previous bite		Mostly even spacing Mostly consistent distance from previous bite		Consistent even spacing Consistent distance from previous bite

Additional Comments:

5. Needle holder use	1	2	3	4	5
	Awkward finger placement Unable to rotate instrument Awkward and not facile Inconsistent needle placement		Functional finger placement Hesitant when rotating Moderate facility Generally good placement		Comfortable, smooth finger placement Smooth rotation High facility Consistent proper placement

Additional Comments:

6. Use of forceps	1	2	3	4	5
	Awkward or no traction Unable to expose Not use to stabilize needle		Moderate proper traction Able to assist in exposure Able to stabilize but rough		Consistent proper traction Consistent proper exposure Knows when to stabilize, gentle

Additional Comments:

Fig. 8 Example of component task simulator for training in aortic cannulation as part of the cardiopulmonary bypass compete procedure

CPB Weeks 5-7 Assessment - Complete cardiopulmonary bypass - Week 5 First Repetition

WEEK 5 FIRST REPETITION ASSESSMENT

RESIDENT NAME____________YR OF TRAINING_________DATE_________
EVALUATOR___________

	Poor				**Excellent**
1. Briefing	1 No briefing	2	3 Incomplete briefing	4	5 Complete briefing

Additional Comments:

____

____

2. Communication	1 No communication Timid, quiet	2	3 Sometimes communicates Some communication, incomplete	4	5 Good communication throughout Confident, appropriately audible

Additional Comments:

____

____

3. Aortic cannulation	1 Awkward Hematoma, bleeding Air in line No testing of line No heparin	2	3 Moderate facility Reasonable, some ooze Bubbles stuck to tubing Partial testing, BP or flow	4	5 High facility, smooth No hematoma or leakage Line de-aired Line tested for BP and flow Heparin given

Additional Comments:

____

____

4. Venous cannulation	1 Awkward RCA injured Leaking	2	3 Moderate facility Too close to RCA Reasonable, some ooze	4	5 High facility, smooth Appropriate position No leakage

Additional Comments:

____

____

5. Initiating CPB	1 No ACT checked No communication No confirmation of circuit function	2	3 ACT checked, unsure Partial communication Some acknowledgement of circuit function	4	5 ACT checked, appropriate for CBP Communicates “on bypass” Confirms circuit is functioning properly

Additional Comments:

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6. Cross clamp, CPG	1 Clamp placed, no communication No CPG given LV not assessed	2	3 Clamp placed, no flow down CPG given, no dose Questions LV distention	4	5 Clamp placed, flow down CPG given, dose appropriate Questions LV distention, palpates LV

Additional Comments:

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Fig. 9 Example of the assessment tool used in the Cardiac Surgery Simulation Study for assessing the performance of the complete procedure of cardiopulmonary bypass. Notice that the component task of aortic cannulation is only a single evaluation point in the complete procedure assessment tool

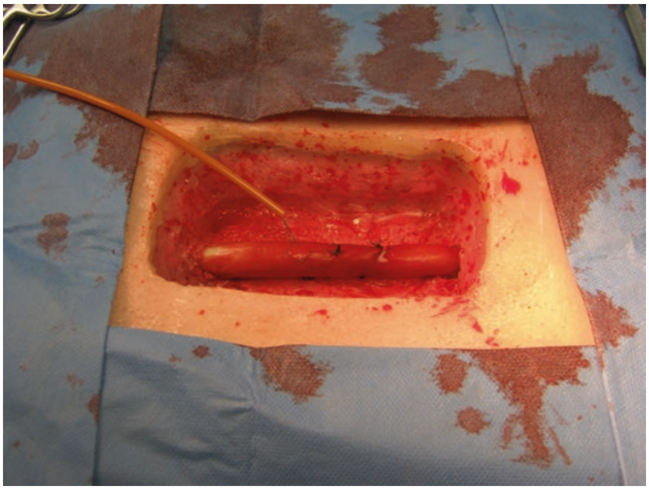

Fig. 10 Segment of pressurized pig aorta used for aortic cannulation component task training

Certainly the sophistication of simulators themselves will continue to improve. Computer-aided simulation will continue to evolve, and the costly one-time investment may soon be outweighed by the reusability and versatility of these programs. As the technology advances, virtual reality simulators may also lead to more realistic systems with advanced haptics providing the learner with a totally immersive experience where reliability, validity, and competency are all maximized. Reanimated tissue-based simulators along with detailed curricula continue to be developed for a variety of procedures in cardiothoracic surgery. Training in adverse events, a virtual impossibility in the clinical setting, will become an increasingly important part of risk reduction.

While live practice in the operating room will always be a necessary part of mastering procedures to some extent, simulation-based training will increasingly be employed to more safely and efficiently prepare residents and practicing surgeons for doing cardiothoracic surgery procedures on patients.

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Simulation in Otolaryngology

Luv Javia, Maya G. Sardesai, and Ellen S. Deutsch

Introduction

Otolaryngologists have been at the forefront of creatively using simulation to enhance education, research, and systems processes and are now at the forefront of developing simulators and expanding the field of simulation. Simulation is not new to otolaryngologists; we have a long and proud history of developing creative ways to teach and to provide experiential learning opportunities. For example, using models almost 100 years ago that might today be called simulators, Dr. Chevalier Jackson developed bronchoesophagology techniques and principles that are still important. Dr. Jackson is said to have collaborated with George Pilling, who made medical equipment, so that custom endoscopy equipment could be created as needed based on the specific structure of the aspirated or ingested foreign body that Dr. Jackson was called upon to remove. Dr. Jackson established the bronchoesophagology course, which allowed surgeons to practice endoscopic techniques on animal models. A movie from 1925, entitled "Chevalier Jackson Demonstrating Proper Tracheotomy Technique," features Dr. Jackson performing a tracheotomy on a rag doll in the back of his limousine [1]. In a movie entitled "Chevalier Jackson 1945 Endoscopy," Dr. Jackson demonstrates the proper technique to remove an open ingested safety pin without perforating the esophagus [2]. Both movies can be viewed on the American Broncho-Esophagological Association website (http://www.abea.net).

In other historic examples of simulation, the House Ear Institute, established in 1946, embraced practicing otologic surgical procedures on cadaveric temporal bones [3]; temporal bone laboratories remain important in otolaryngology education. Dr. Ted A Cook's classic text entitled "Basic Soft Tissue Surgery," published in 1982, uses a pig's foot model as the medium for practicing the construction of rotation flaps, Z-plasties, and other local soft tissue flaps [4]. New technologies, such as lasers and Hopkins rod telescopes, have enabled both more aggressive and less invasive surgical techniques, and even experienced surgeons value the opportunity to learn new techniques or hone existing skills using simulators.

Now, firmly in the twenty-first century, the use of simulators in otolaryngology has blossomed. There is a growing body of evidence specific to otolaryngology demonstrating the effectiveness of simulation as a learning modality [5, 6], and specific skills relevant to otolaryngology have been demonstrated to be transferrable from simulation to procedures on actual patients ("in vivo") [6]. In addition to using simulation to improve the capabilities of individuals and teams, patient care is not delivered in a vacuum, and simulators have also been integrated into otolaryngologic simulations designed to improve the systems we work within [7].

This chapter will explore the wide array of simulators that are currently available to otolaryngologists, whether purchased or adapted or constructed locally, as well as simulators which are being developed by creative otolaryngologists collaborating with engineers, educators, and others.

Otology

There is an abundance of simulators for otologic procedures. This discipline in otolaryngology is perhaps one of the most developed and active in terms of producing a variety of simulators for a wide range of procedures. Otology simulators range from simple physical models to complex,

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technologically sophisticated virtual reality devices. Physical models are often easily constructed from parts which are readily available and inexpensive. While some simulators achieve utility despite their simplicity and low cost, some provide engaging virtual reality experiences, including complex electronic assessment and feedback processes, based on high-level technology.

One of the most basic training necessities for medical students and otolaryngology residents is learning proper otoscopy including how to properly identify normal versus pathologic findings on exam. The OtoSim™ (OtoSim, Inc., Toronto, Ontario, Canada) is a commercially available otoscopy simulator that uses a realistic model ear, otoscope and high-fidelity images of tympanic membranes, and varied middle ear pathologies. One version incorporates insufflation, to simulate pneumatic otoscopy. In a study of medical students, 93% of respondents reported increased confidence in otoscopy after using OtoSim [8].

Myringotomy and ear tube insertion are often a trainee's initial experience with microscopic surgery. Simulators for this procedure allow preliminary exposure and practice with eye-microscope-hand coordination as well as experience manipulating small instruments in small spaces prior to working with real patients. There are a number of physical models that have been described for myringotomy with ear tube insertion [9–11]. Many are constructed with syringes simulating the external auditory canal and stretched plastic from a glove or other source for the tympanic membrane. These are easily constructed and can be loaded repeatedly for multiple myringotomy attempts. Volsky et al. describe a model which consists of a three-part simulator. Although this allows for greater fidelity of the auricle and external auditory canal, a consideration is that this model would require purchase of basic pieces for repeated use. It is unclear whether this is commercially available for purchase [10]. Clark, Westerberg, and Mitchell describe a low-cost microsurgery ear trainer that allows removal of ear canal foreign body, myringotomy tube placement, tympanomeatal flap elevation, myringoplasty, and middle ear tasks [12].

At our institution, our 2nd-year otolaryngology residents practice with a low-tech model, constructed from scraps of wood and a couple of hinges prior to operating on real pediatric patients. Despite the simplicity of construction, the model provides realistic challenges as instruments are manipulated in tight spatial confines with only indirect visualization of the patient's anatomy and the surgeon's hands and instruments (Fig. 1).

Others have described virtual reality simulators for myringotomy [13], with some incorporating haptic feedback [14, 15]. These require special computer programing and hardware and are not as easily available. Optimizing the quality of haptic feedback has been challenging. Monfared has developed a middle ear simulator which is high fidelity and inexpensive to produce. The middle ear ossicles are 3-D printed and loaded in a cartridge which includes other adjacent structures such as tendons, nerves, and ligaments [16]. This platform has the potential to support the performance of various middle ear surgeries.

Fig. 1 Ear simulator designed to develop skills in myringotomy in both normal and narrow ear canals. A piece of plastic inserted between the layers creates the tympanic membrane. (Courtesy of Steve Handler)

Endoscopic ear surgery is a relatively new surgical approach in otology which is gaining acceptance with surgeons. This requires surgeons to shift how they perform ear surgery, as they have only one hand available for dissection, in contrast to the availability of two hands when using a microscope. Surgeons can benefit from training with simulators to get more experience with endoscopic ear surgery. The transcanal endoscopic ear surgery (TEES) simulator is a reusable 3-D-printed task trainer. Trainees use endoscopic equipment through a simulated ear canal to move rings between posts in a simulated middle ear chamber [17]. In an ovine model, endoscopic equipment is used to perform canalplasty, middle ear dissection, myringoplasty, and ossiculoplasty [18].

For more experienced otolaryngologists, there are several temporal bone simulators that have been developed to teach the central skill of an otologic surgeon: temporal bone drilling. The conventional method of learning by drilling cadaveric temporal bones was not always called “simulation” but is consistent with the educational principles and advantages of simulation. The traditional resource of cadaveric temporal bones has been augmented by synthetic physical temporal bones that can be drilled, similarly accompanied by irrigation and suction. Some are synthetic temporal bones that can be purchased [19]. Because they are primarily bony structures, rather than soft tissue, temporal bones may be particularly suitable for 3-D printing, and several authors have described 3-D-printed temporal bones that can be drilled [20–24]. The 3-D-printed bones allow customization to support training based on different pathologies. There are also a multitude of virtual reality temporal bone simulators including the VOXEL-MAN, Visible Ear Simulator, Mediseus temporal bone simulator, Ohio State University Simulator, and Stanford temporal bone surgical simulator, which typically combine a virtual image of the temporal bone with a physical interface shaped and held like a drill [25–29]. With advances in virtual reality technology, these simulators get better and better. Most provide haptic feedback and 3-D visual interfaces to enhance their realism. For example, the Ohio State University Simulator allows an immersive experience with audible drill sounds, haptic feedback, varied pathologies, and even training modules that evaluate and provide feedback for the trainee (Fig. 2). The VOXEL-MAN (Voxel-Man, Hamburg, Germany), Ohio State University Simulator, and Mediseus (Medic Vision, Melbourne, Australia) virtual temporal bone simulators are probably the three most studied [26, 27, 29]. Virtual temporal bone simulators can be expensive, although the software for the Visible Ear Simulator (Alexandra Institute, Aarhus, Denmark) is available for free, and only the hardware must be purchased [25]. Many virtual temporal bone simulators are not available for purchase and remain prototypes.

The future is bright with the probability of a greater variety of 3-D-printed temporal bones with more realistic coloration and enhanced feel during drilling. The potential to custom print different bones with a variety of pathologies will be helpful both for training purposes and presurgical planning. One area that is ripe for advances is the further development and availability of middle ear simulators for training residents in ossiculoplasty. Moreover, no one thus far has developed a cholesteatoma simulator – a difficult surgical entity that would likely benefit trainees.

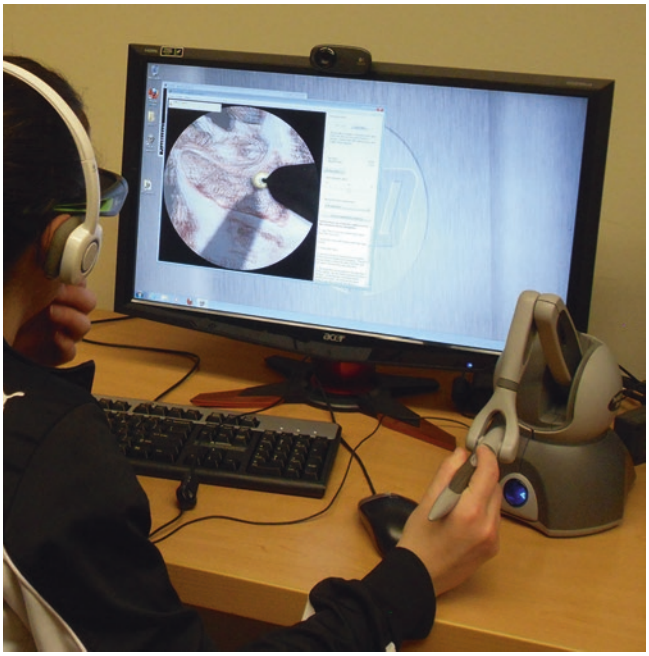

Fig. 2 Ohio State Virtual Temporal Bone Simulator, which provides 3-D visualization, as well as haptic and audible feedback

Sinus and Rhinology

Simulation for sinus and skull base procedures is especially valuable because sinus and skull base procedures have the potential to be particularly high acuity and can carry significant risk of ophthalmologic, neurologic, and intracranial complications. In addition, rhinology is the most litigated field of otolaryngology with endoscopic sinus surgery (ESS) being the most commonly litigated rhinology procedure and two-thirds of cases in a 10-year review resulting in high payouts [30]. Minor complication rates have been noted to be higher and major complication rates lower in settings with residents [31], which highlights the impact of training and experience. ESS involves keyhole surgery with advanced instrumentation, and thus there is limited opportunity for simultaneous participation of trainers and trainees. Traditional sinus surgery education, employing human and animal cadavers and live animal models [32, 33], has been shown to improve performance in an ex vivo setting and continues to be used as a primary training modality [33] However, cadaveric and animal models can be costly and complex to manage.

Fortunately, sinus and skull base surgery are particularly amenable to simulation applications since sinus tissues are more rigid and less vulnerable to deformation than many other anatomical sites. This reduces the computational requirements of electronic and virtual reality models [34]. In addition, sinus procedures rely heavily on instrumentation which can serve as devices for capturing motion data for analysis and feedback.

At the most fundamental level, simulation has been used for sino-nasal and skull base anatomical education, providing an interactive three-dimensional vantage; newer simulators can demonstrate patient-specific characteristics [35]. Medical students also reported a positive attitude toward use of the simulator as a training tool in general [36], and sinus simulation has been shown to improve test scores and time to test completion compared with controls [37].

For procedural training, several virtual-reality-based simulators for sinus surgery have been developed. The nasal endoscopy simulator (NES), among the earliest to be described, used a graphics workstation, a tracking system for measuring the position of the endoscope and surgical instruments in space, a head model, and image data sets of the nasal cavity and paranasal sinus area [38]. The lack of haptic feedback in its initial release posed a limitation; subsequent models have incorporated haptic feedback [39, 40] but have limited validation data [41].

The endoscopic sinus surgery simulator (ES3) developed through Lockheed Martin [34] has amassed the most validity evidence of any sinus simulator currently in existence. This procedural simulator trains and assesses the performance of tasks such as sinus injection which require navigation, ambidexterity, and accuracy [42]. The hardware includes four components: (1) an SGI Octane workstation simulation platform (Silicon Graphics Inc., Mountain View, CA); (2) a personal computer-based haptic controller, providing control and coordination between a universal physical instrument handle and a set of virtual surgical instruments; (3) a personal computer-based voice-recognition-enabled instructor, which operates the simulator by responding to spoken commands; and (4) an electromechanical platform, which serves as the human interaction interface, with a replica of an endoscope, a surgical tool handle, and a rubber-headed manniquin. This simulator collects performance data throughout trainee use. Performance errors measured by this simulator were defined using a rigorous modified Delphi method with participation from experts in otolaryngology, surgical education, statistical analysis, behavioral science, and simulator development. A list of error categories was generated, and each category was discussed item by item until consensus was reached on each error attribute, classification, measurement, and reporting standard. The simulator analyzes performance data to provide formative feedback in real time regarding performance errors. It also archives data for summative result analysis and reporting [43].

Performance on the ES3 has been shown to correlate strongly with scores on the pictorial surface orientation (PicSOr), a simulator involving visuospatial perception tasks [44]. The PicSOr provides an objective test of perceptual skill that requires the respondent to orient an arrow perpendicular to a cube using cursor keys and has been shown to predict laparoscopic technical skill in three initial studies of laparoscopic performance [45]. Additional validity evidence has been shown for the ES3 in multi-institutional testing of participants ranging from novices to experts [42, 46]. Individual subjects demonstrate improvement across repeated trials and moderate term (average 35 days) skill retention [47]. The ES3 is also one of the few simulators to shown improved time, reduced errors, and greater instrument manipulation dexterity on tasks such as scope navigation, mucosal injection, middle turbinate medialization, uncinectomy, and maxillary antrostomy [6]. Despite extensive validity evidence, commercial production of the ES3 and other sino-nasal and skull base simulators has been limited by a small market, and new models are currently not available for off-the-shelf purchase.

This financial limitation has prompted exploration of lower-cost alternatives. Malekzadeh et al. described an easily reproducible sinus task trainer using a stainless steel bread pan, unflavored gelatin, eggs, suture, plastic beads, and silicone cardiopulmonary resuscitation (CPR) manniquin mask (Laerdal, Wappinger Falls, NY) [48]. The total cost was less than US$5, and it provided trainees' exposure to tasks including probing sinus recesses, targeted injections, removal of tissue (represented by suture and beads), and creating an endoscopic antrostomy into the maxillary sinus. The model was shown to have some validity evidence and has potential as a tool to evaluate endoscopic sinus skills [49]. One limitation of this model was the incorporation of biological materials, such as eggs, that decompose over time.

Subsequent sinus surgery models, such as the Seattle Sinus Simulator, have incorporated nonbiological alternatives such as silicone, molded using modeling dough, Styrofoam, and a silicone manniquin mask [50]. Combining this task trainer with a knowledge-based curriculum has shown some validity evidence. Specific tasks which can be performed include endoscopic visualization using a 0° nasal endoscope, suctioning the nasal cavity and nasopharynx, sinus injection, removing a nasopharyngeal pin using Takahashi forceps, "uncinectomy" involving removing a pin from the uncinate region with a backbiter, suctioning the maxillary sinus, using a 30° endoscope to remove a vertically oriented pin in the middle meatus, and using 45° forceps to remove a pin from inside the maxillary sinus. The overall cost was less than US$15. This model, similar to the other low-cost models described, also requires model construction time which is another required resource. In addition, though components are reusable, the silicone rubber rendering of the sinus anatomy will ultimately become worn and will need to be replaced.

Despite the limitations of the various simulators that have been developed, ESS remains a critical area within otolaryngology that benefits from simulation education given the technical and anatomical complexity, surgical risks, and keyhole nature of these procedures. With each iteration, the sophistication and complexity of sinus task trainers and curricula improve.

Airway

Laryngeal and airway simulators are well established in otolaryngology. Surgeons have been using airway simulators for a long time to teach airway skills such as intubation, microlaryngoscopy, and bronchoscopy. This has developed into using simulators to teach retrieval of airway foreign bodies and running evolving simulation scenarios that teach residents how to manage patients with difficult airway situations. For example, at our institution, collaboration with the animal care facility allows trainees to practice bronchoscopy and retrieval of a variety of airway foreign bodies from anesthetized pigs [51]. Additionally, at a 1-day, intensive simulation-based boot camp for mid-level otolaryngology residents, simulation sessions use high-fidelity manniquin to simulate a variety of scenarios with attending surgeons acting in the role of confederates as residents manage the mannequin's deteriorating medical conditions. Sample scenarios include a tracheostomy false passage leading to a tension pneumothorax requiring quick assessment and intervention with needle decompression and management of a manniquin with a simulated post-tonsillectomy hemorrhage that requires bronchoscopic evaluation and aspiration of simulated clot from the manniquin's lower airways.

Simulation difficulty can run the gamut from accomplishing discrete psychomotor tasks using low-technology physical simulators to complex scenarios requiring high-technology manniquins and attending physician participation as confederates. The important role of simulation in airway management cannot be overstated. Practice managing airway scenarios that require quick evaluation and intervention, increasing familiarity with surgical equipment such as bronchoscopes and their attachments, and simulating rare situations such as emergent "slash" tracheotomy or needle decompression of a pneumothorax can potentially mean the difference between life and death in a real patient situation. The unpredictability and rarity of these events make them difficult to study, but testimonials demonstrate the value of preparing by using simulation [52]. The field of laryngology has also spawned new, ingenious simulators that can be used to teach microlaryngeal surgery and the safe and effective application of lasers to laryngeal surgery.

Intubation training with manniquin simulators has been described for at least 40 years using a variety of models ranging from neonatal to pediatric to adult simulators [53–56]. Some simulators are full body and include high-fidelity technologic elements that allow for realism in simulation. Capabilities include chest wall motion (e.g., unilateral chest movement to represent right main stem intubation or foreign body occlusion of one bronchus), eye blinking, ability for a confederate to supply "voice" remotely, vital signs that can change in response to medical interventions, laryngospasm and variable tongue volume, and pharyngeal obstruction. Manniquin anatomy allows participants to adjust the head and neck position and intubate and ventilate using a variety of airway devices. Several vendors make full-body electronic manniquins suitable for complex airway scenarios, and many vendors make low-technology manniquins which can be used for preliminary airway skill training (e.g., mask ventilation, intubation) or in combination with either high-technology manniquins or standardized patients to create hybrid simulations. Figure 3 shows a low-technology simulator used in a hybrid simulation based on controlling intraoral hemorrhage and then removing endobronchial clots using rigid bronchoscopy. Simulators can be used in simulating scenarios that are limited only by one's imagination. The full-body simulators can be modified to allow for more realism or to suit training needs; for example, rice cereal was placed in a bag under the skin of the SimMan (Laerdal, Wappinger Falls, NY) to simulate crepitus during simulation of a pneumothorax.

Fig. 3 Low-technology manniquin prepared to allow rigid airway endoscopy and removal of simulated clot positioned at the manniquin's carina

Besides simulators for basic airway management and intubation, there has been a flourish of development in the field of laryngology. Earlier simulators included human, porcine, or sheep larynges used for procedures such as vocal fold biopsy, vocal fold medialization with injectable materials, or submucosal vocal fold flap elevation [32, 57, 58]. The use of real biological tissue provides incredible realism; however access to these tissues or a tissue lab can be prohibitive and expensive, and organizers should be aware of local regulations. This has led to the development of nonbiological laryngeal simulators for training a variety of laryngologic surgeries. Sophisticated laryngology simulators include industry-produced custom vocal cord replicas [59], 3-D-printed models with an electromagnetic tracking system [60], 3-D-printed laryngotracheal frameworks [61], and fabricated laryngeal models with replaceable vocal cords [62]. As in other fields, 3-D printing is being used more and more to construct custom anatomy and pathology. Ainsworth et al. describe a 3-D-printed high-fidelity laryngeal framework used with molded arytenoid cartilages and intrinsic laryngeal musculature [61]. The thyroarytenoid muscle was constructed with conductive silicone such that there is real-time feedback of successful needle placement during transcervical vocal fold injection. 3-D printing will likely be an area of growth in the future as it becomes more readily accessible by academic institutions and training programs. Ross et al. describe a 3-D-printed airway with embedded LEDs that is used to train endoscopic psychomotor skills [60].

While some of the models rely on custom manufactured systems, there are a few ingenious low-technology, low-cost models that are more readily constructed. Specifically, the Georgetown Laryngeal Model uses modular laryngeal cartridges made from rubber bands surrounded by plastic wrap within a PVC pipe [63]; the ingenious design can be used to practice a wide variety of laryngeal surgical procedures [63]. The model can be used to practice grasping and cutting sutures from the vocal cords, as well as resection of papillomas and epithelial and subepithelial lesions. The simplicity yet modularity of this simulator makes it a favorite at a regional simulation-based boot camp for mid-level otolaryngology residents. Cabrera-Muffly and colleagues describe a laryngeal injection simulator constructed from toilet paper tubes, zip ties, thin balloons, and other easily found objects [64].

Dr. James Burns has also shared a useful simulator for laser laryngeal surgery at a regional boot camp, based on his work using chick chorioallantoic membranes as a model for simulating human vocal fold microcirculation within the superficial lamina propria [65]. Residents were able to practice ablating vessels in the chorioallantoic membrane with lasers in the simulation laboratory.

Virtual reality bronchoscopic simulators replicate flexible bronchoscopy with accurate distal airway anatomy; some can give haptic feedback [51, 66–70]. There is also a bronchoscopy simulator website that provides the opportunity to explore virtual bronchoscopy using real-time video [71].

Additional Types of Simulators

There are many additional simulators to address the diversity of otolaryngology procedures, which are valuable additions to the training armamentarium. Epistaxis control is a common consultation request that junior residents often field. A high-fidelity task trainer can be constructed with a cadaveric head and IV tubing with fake blood going through the posterior cribriform plate and nasal cavity simulating a sphenopalatine artery bleed [72]. To simulate epistaxis from an anterior vascular source, a non-electronic CPR trainer can be modified in a similar manner, with the IV tubing and blood flow emerging near the nare [73].

One of the most common surgical procedures in otolaryngology and arguably one of the first for trainees to learn is the tonsillectomy. Surprisingly, there are not a lot of published reports of simulators for doing a tonsillectomy [74]; however there are several for ligation of bleeding vessels as may be encountered during tonsillectomy [74–77]. There is a virtual reality simulator of a subtotal or intracapsular tonsillectomy, with haptic feedback [78].

Interestingly, there are a myriad of peritonsillar abscess drainage simulators [72, 79–81]. Each can be constructed fairly easily using water balloons in gelatin, latex gloves filled with vanilla pudding, or even cod liver oil capsules embedded in silicone tonsil molds. All of these simulated tonsils with abscesses are inserted into the oral cavity or pharynx of a cadaveric head or task trainer.

With the expansion of robotic surgery into otolaryngology, it is important that residents get appropriate training in this novel modality. Basic maneuvering and operation of the da Vinci robot can be taught with the da Vinci Skills Simulator (Intuitive Surgical, Delaware) [82–84]. Instead of actual surgical procedures, this simulator involves the use of the da Vinci controls to navigate in a virtual reality world to complete nonanatomic tasks such as camera targeting, placing objects on a match board, placing rings on pegs, needle targeting, and energy dissection. Others have described using cadaveric heads and using the robot in a curriculum with residents to learn how to perform radical tonsillectomy, supraglottic partial laryngectomy, and base of tongue resection [85].

Simulation provides benefit in practicing techniques in facial plastics and complex wound closures. In our boot camp, we routinely use one of the most widely used simulators – a pig's foot – upon which various skin defects are created and then reconstructed using a variety of local rotation and advancement flaps. Others have described the use of open-cell foam and elastic foam tape, readily available in a hospital setting, to practice interrupted suturing maneuvers and to construct and execute local flaps [86]. Some have used a polystyrene head with molded, pigmented latex on top that can then be used to create facial defects with flap reconstruction [87]. A low-cost gelatin prosthetic facial skin simulator can be used to perform Z-plasties and bilobed, rhomboid, and paramedian forehead flaps [80].

A recent report discusses the use of ovine head and neck tissue as a simulator for performing blepharoplasty, ptosis repair, orbital floor exploration, mandibular plating, facial nerve dissection and repair, tracheotomy, laryngofissure, tracheal resection, and laryngectomy [33]. The authors found this model to be anatomically compatible, affordable, and useful for a variety of procedures.

A fine needle aspiration biopsy virtual reality simulator, which includes haptic feedback, has been described for thyroid nodules [88]. Microvascular anastomosis skills can be practiced using chicken thigh vasculature or commercially available synthetic materials ranging from Penrose drains to small caliber tubes. IV tubing and fake blood can be used to simulate bleeding or to test for anastomotic leaks. The inverting Connell stitch commonly used in total laryngectomies can be practiced on simulated bowel.

Griffin et al. describe the first published neck dissection simulator in which they use a Blue Phantom Central Line Placement Training Model (CAE Healthcare, Montreal, Quebec, Canada) and modify it such that a selective neck dissection could be performed with real surgical instruments, complete with vascular and neural structures commonly encountered during a neck dissection [89].

Rigid esophagoscopy is an important skill to learn which can result in significant morbidity or even mortality if not performed carefully. Recently a group constructed an esophagoscopy model with force sensors under the maxillary incisor and at the tip of the esophagoscope [90].

Skills for Teams

The skills for individuals which were described in the preceding paragraphs are essential, but may not be sufficient, as almost all healthcare is delivered by teams. Otolaryngologists work with a large variety of teams because our patient care settings include the operating room, hospital inpatient and intensive care units, emergency departments, testing and rehabilitation units, and outpatient clinics. Whether an episode of patient care is routine, such as scheduled, elective surgery, or emergent, like responding to a patient in the emergency department with airway obstruction who cannot be ventilated and cannot be intubated, teams must somehow distribute responsibilities and integrate the varied capabilities of the team members. Some teams are relatively stable, such as office or operating room teams, for elective cases. Others teams are spontaneous, such as the providers who may participate in an unscheduled, emergent procedure in the operating room in the middle of the night. In either case, responsibilities are distributed by participant roles. In larger organizations, there may be several people capable of fulfilling specific roles (e.g., lead physician, medication nurse, respiratory therapist), so the exact combination of people who are available to participate in a single event may have many possible permutations.

Insufficient or ineffective communication among team members is often cited as a contributing factor when patient outcomes fall short of desires or expectations [91], but this assessment may provide a veneer of analysis with only minimal exploration of team function. Concepts related to creating and optimizing a shared mental model have been extensively explored in the human factors literature. Salas and colleagues propose a model for five key dimensions of effective teams: team leadership, mutual performance monitoring, backup behavior, adaptability, and a team orientation [92]. Weller, Boyd, and Cumin describe shared mental models, mutual respect and trust, and closed-loop communication as requirements for effective teams [93]. Endsley's classic work describes three increasingly insightful levels of situational awareness in dynamic decision-making: Level 1, perception of elements in the environment; Level 2, comprehension of the current situation; and Level 3, projection of future status [94].

Simulation, including debriefing, can be used to practice communication, improve situational awareness, and increase interdisciplinary understanding [93]. Geis et al. simulated the care of a patient with a post-tonsillectomy hemorrhage during in situ evaluations of new patient care areas before they were opened for actual patient care, with the goal of improving the capabilities of both the teams and the facilities [95].

Dr. James Kearney, Dr. Kelly Malloy, and Maria Magro developed simulations involving otolaryngology residents and student registered nurse anesthetists as learners managing a high-technology manniquin with a simulated airway fire during tracheotomy and, separately, a simulated airway fire during tonsillectomy. The simulations took place in a simulated operating room, with typical layout and equipment (e.g., monopolar electrosurgery device), and otolaryngology attendings, certified registered nurse anesthetists (CRNAs), and surgical nurses participated as "confederates" to complete the typical staffing of an operating room team. The "fire" was simulated using a commercial fog machine. Debriefing includes discussion about the information communicated between team members and the roles and responsibilities of the participants.

Volk et al. developed a simulation course involving teams of otolaryngology residents and fellows, anesthesiology residents and fellows, CRNAs, and operating room nurses as learners [96]. Providing the simulations in situ (in actual patient care locations) allowed integration of the course into regular working hours; the elimination of travel time (e.g., to a simulation center) facilitated residents' ability to spend the morning accomplishing patient care, participate in the simulation for several hours, and then participate in afternoon rounds. The authors report that the interprofessional structure improved the realism and the interpersonal and team dynamics. During debriefing, participants recognized that perceptions of the patient's diagnosis and management goals differed between team members, helping participants understand the value of good communication skills and a shared mental model.

Our teams also include the patients and their families who learn to care for themselves or for family members who have tracheotomies or other medical devices or technologies. Patients and families may improve both their skills and their comfort by practicing tracheotomy changes on commercially available manniquins prior to having a family member with a tracheotomy discharged from the hospital. Finally, otolaryngologists also collaborate with members of teams who may not be quite as obvious. Simulation has been used to help providers learn how to use new modules in electronic health records [97] and can be used to develop and test software improvements for electronic health records.

Systems Improvements

The use of simulation for systems evaluation, process implementation, and process improvement has been well-described in other areas of medicine [98] and is a budding field in otolaryngology. Low-frequency, high-acuity events such as intraoperative emergencies (e.g., airway fire) and surgical airway codes lend themselves to multidisciplinary complex scenario simulation that can evaluate and enhance interprofessional communication and teamwork skills along with identifying systems issues.

Development of the Difficult Airway Response Team (DART) at the Johns Hopkins Hospital in Baltimore, Maryland, provides an example of the use of simulation for interdisciplinary process improvement on a large scale in otolaryngology [99]. Review of prior adverse airway events in their institution suggested that most events occurred outside the operating room, involved multiple clinical disciplines, and had ineffective communication, an outdated paging system, unreliable access to equipment and staff, and unclear provider roles as contributing factors. The authors used their findings to develop the DART, which included mechanisms to identify and label patients with at-risk airways, establishment of specialized teams and tools, and formulation of appropriate management algorithms. The program was then implemented, tested, and refined using in situ simulation in five different clinical areas of the hospital including the surgical intensive care unit, labor and delivery unit, and inpatient floor. Initial trials were used to identify barriers to mobilization in various settings and ideal locations for the airway carts. Iterative simulations enabled improvement of the DART cart design, including replacement of non-safety sharps, relocation of fiber-optic scopes to optimize infection control, standardization of light boxes, protection of the cart with a locked cover, labeling of light source connectors to decrease confusion, and routine maintenance to ensure equipment integrity. Simulation was also used for training, and helped clarify provider roles and choice of airway algorithms, and established the importance of onsite post-event debriefings which then became a standard component of the DART program.

Similarly, Johnson et al. used simulation to identify and implement process improvements in the management of pediatric airway obstruction in an emergency department resuscitation setting [7]. The evaluation phase involved six simulations based on a complex scenario with a manniquin representing a 4-year-old boy who had aspirated a grape and needed management by an ED team with otolaryngologists and anesthesiologists available for consultation. Among the safety threats identified was lack of availability of appropriately specialized airway equipment in the ED. Following the evaluation phase, an airway cart with specialized equipment, a written procedural algorithm, and a designated airway team with a team-specific paging system was developed and implemented. The subsequent six simulations were used to assess this novel system, based on objective measures such as consultant time to arrival, as well as qualitative measures, such as participant opinion about institutional preparedness.

Both examples demonstrate how simulation can be used for evaluation of systems in addition to training. This is particularly valuable in otolaryngology where many conditions occur rarely but can be imminently life-threatening and can occur in varied settings (e.g., ED, operating room, postoperative care unit, intensive care unit, inpatient floor, outpatient clinic, and home).

Simulation can be an effective tool in otolaryngology patient education. Patient education during transitions of care has been shown to reduce readmissions in surgical patients in at least three randomized controlled trials [100]. Home care that requires technical skills, such as tracheotomy care, benefits from simulation training for both patients and caregivers in both pediatric populations and in adults. With the Affordable Care Act, the Centers for Medicare and Medicaid Services (CMS) dedicated US$1 billion over 3 years to test care models to reduce hospital-acquired conditions and improve transitions of care [101]. Strategies that enhance patient and caregiver participation through education about medical conditions, appropriate care, and monitoring promise to enhance patient experience and adverse outcomes. Simulation is likely to play a significant role when advanced technical skills are needed by patients and their caregivers.

Integration into a Comprehensive Curriculum

Despite simulation's attractiveness and proven value, integrating simulation into the curriculum of our residents and fellows has been challenging. An ethical imperative to practice on simulators [102] may conflict with production pressures, but otolaryngologists have come up with creative solutions such as taking advantage of weekly lecture or conference educational time that is already protected. Successful examples include 1-h sessions in which residents or fellows practice removing "aspirated" foreign bodies from high-technology manniquins while recognizing and managing oxygen desaturation, laryngospasm, and other relevant responses [103] or 1-h sessions in which residents or fellows practice designing and completing local flaps on pigs' feet [4].

Contemporary circumstances make it difficult to provide 1- or 2-week simulation-based courses in the style of visionaries like Chevalier Jackson and his bronchoesophagology course from the early twentieth century or the house group and their otology courses beginning in the mid-twentieth century [3], but a number of brief but intensive boot camps have been developed. Boot camps are often designed for novices but have also been provided for experienced faculty seeking to refresh skills that may be infrequently used. Typically, boot camps last for 1 day and address a range of technical and nontechnical skills. Because of their short duration, they are often designed to provide exposure, rather than expertise, and stimulate anticipatory thinking. Some boot camps are intended for local participants, who are learning how to access local resources. Other boot camps can accommodate up to 30 or 40 residents, require 15–20 faculty members (plus simulation staff), and provide opportunities for both learners and faculty to try out and discuss a wide variety of procedures, techniques, and philosophies.

The "ORL Emergencies Boot Camp" follows a classic educational structure, with novice otolaryngology residents learning simpler technical skills during the morning and more complex technical skills mid-day and then applying these skills while participating in teams to manage a high-technology full-sized human simulator with a medical crisis as the finale in the afternoon [104–106]. Feedback and debriefing occur during or immediately following each simulation activity. Both learners and faculty find the boot camps exhausting but satisfying and valuable [107].

Similar simulation-based boot camps have been implemented across the USA and in Canada, and many faculty attend more than one boot camp, sharing ideas and techniques. The similarities between boot camps offer opportunities to standardize specific aspects of their curricula, which could enable more rigorous evaluation of their educational impact. The differences between boot camps allow faculty to develop new simulators and new simulations, which enrich the range of available teaching options.

The Accreditation Council for Graduate Medical Education (ACGME) program requirements for graduate medical education in otolaryngology specifically mentions the option to use "surgical simulator labs" as a method to allow residents to demonstrate knowledge of anatomy through procedural skills, as a component of the core competencies [108]. Although not specifically endorsed by the ACGME, it makes sense that simulation could be used to learn or demonstrate components of each of the core competencies. For example, professionalism could be incorporated in simulations that address obtaining informed consent or delivering bad news. Systems-based practice skills could be developed by designing or participating in simulations designed to improve system-level aspects of otolaryngology healthcare delivery, like the airway emergency projects mentioned earlier in this chapter.

Simulation also has relevance for many of the ACGME otolaryngology milestones, including some level 4 and level 5 ratings. For this discussion, from a simulation perspective, the milestones [109] can be distilled into three broad domains. One domain is technical skills, such as identifying specific otolaryngologic anatomic structures, and performing procedures such as otoscopy, myringotomy, tympanostomy tube placement, mastoidectomy, and endoscopic sinus surgery; each of these skills can be demonstrated or performed on simulators [5, 6, 11]. However, the number and variety of simulators which represent aspects of the broad range of normal and abnormal otolaryngic conditions at a level of physical fidelity that would be engaging for experts are limited [110].

The second domain is cognitive knowledge. Learning and demonstrating cognitive knowledge – like discussing therapeutic options, formulating treatment plans, and interpreting diagnostic studies – can be accomplished or demonstrated in an abstract manner (e.g., by asking theoretical questions), but embedding cognitive tasks into simulations can make the tasks less abstract and more engaging and can enhance their situational and psychological fidelity.

The third domain includes patient safety, resource utilization, lifelong learning, and professionalism. In this domain, simulation can be used to develop or evaluate the capabilities of residents and fellows, and, if trainees choose to develop simulation skills themselves, simulation provides techniques that can be added to their own leadership portfolios. Simulation can be used to evaluate and improve resource utilization, to help develop cost effective care practices, or to identify and mitigate potential patient safety hazards. Trainees can demonstrate skills in systems-based practices by using simulation to analyze morbidity and mortality ("M&M") findings and then provide feedback to improve patient safety. Simulation can be used as a tool to help residents and fellows practice leadership and communication skills, and trainees may also develop simulation skills that allow them to coach and educate others to improve their own communication skills. Debriefing is an essential component of simulation, based on principles that are also relevant and can be used to understand and improve actual patient care experiences. Finally, simulation, including nonjudgmental debriefing, provides affective experiences that can foster engagement in lifelong learning.

Summary

The field of otolaryngology is both exciting and demanding because of the unique importance of the anatomic structures encompassed and the diverse nature of medical conditions which must be understood and managed. Simulation will undoubtedly expand our patient care capabilities, but the validation process is challenging because of the small numbers of residents and relatively small numbers of faculty members in each otolaryngology program and the difficulty in demonstrating direct improvement in patient outcomes from educational interventions. For both individuals and teams, simulation with facilitated debriefing can provide formative and summative feedback and may ultimately serve as a valuable tool for evaluation and certification. In response, the SimTube project, sponsored by the American Academy of Otolaryngology–Head and Neck Surgery, is designed to develop a platform to support multi-institutional evaluations of educational interventions. Commercial simulator availability is similarly challenging because otolaryngology is a specialized market. Despite these obstacles, simulation promises to deliver significant benefits for cognitive and procedural training in otolaryngology, for reentry education, for expanding our expertise as new technologies arise, and for improving the systems that we work within, and many otolaryngologists are developing simulators and designing simulations that can benefit both trainees and experienced otolaryngologists and, ultimately, our patients.

Simulation has a long history in otolaryngology, with evidence of the use of task training over 90 years ago. The subspecialty of otology has well-developed and specialized task trainers which range from low-tech, low-cost models to high-fidelity virtual reality models that can provide quantitative formative and summative feedback. These simulators can provide training that addresses basic examination skills, intermediate skills like myringotomy and tube insertion, and highly specific skills like temporal bone and skull base surgery. Rhinosinology also has robust simulator technology including several low-cost models as well as high-fidelity trainers with strong evidence for validity. Simulation applications in laryngology are broad, and include airway management, which is often a multidisciplinary activity; airway simulations that incorporate team skills, communication, and resource management are particularly valuable. Salient examples include integrated courses such as otolaryngology emergency boot camps and airway management courses that couple task training with complex scenarios and provide andragological learning with an emphasis on self-reflection and feedback.

The technical complexity of combining very specific anatomy with the varying textures and tensile properties of head and neck tissues in close juxtaposition is a significant barrier to simulator development in otolaryngology. Additionally, otolaryngology involves focused and specific applications that are relevant to a smaller audience, limiting the commercial market, and thus reducing corporate investment. Once trainers and programs are developed, this small audience also poses challenges to achieving rapid and robust validity evidence, as sample sizes are necessarily limited and trainee populations are varied.

Despite these challenges, otolaryngologists, engineers, and educators have developed several robust models, and the scholarly work around these models, and around novel educational strategies, is expanding exponentially. This trend promises to continue with the advent of 3D printing, which will undoubtedly have a prominent role in future otolaryngology simulation, and brings the opportunity to incorporate patient-specific anatomy. With increasing emphasis on quality metrics, the budding application of simulation to process improvement, including evaluation, testing, and implementation of new programs in otolaryngology, promises to flourish.

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Simulation in Urology

Wesley Baas and Bradley Schwartz

Introduction

Since the dawn of medicine, physicians have relied upon their patients to be the instruments of their education. This became more apparent since the implementation of Halsted's apprenticeship model centered around the mantra: "see one, do one, teach one" [1]. Under this model trainees are required to learn quickly, often through their mistakes, by practicing their craft on their patients. Although this objective was intended to function with proper oversight and controls, this method of learning has been the subject of increasing debate about the safety and ethicality of training on patients [2]. Because of this, finding ways to bypass this learning, or accelerate the early learning curve, has become very appealing. Simulation is a relatively new and emerging field with the aim to allow trainees to practice techniques and procedures in a controlled environment that does not jeopardize patient health [3].

Simulation is particularly enticing in urology, a field that has been pushing the boundaries of new technologies from the early 1900s. With new technology and techniques come significant learning curves. As such, even urologists who have been in practice for many years are finding that they are having to learn new procedures outside of their traditional training. This has also brought about the challenge for attending physicians to teach residents procedures that they themselves are relatively inexperienced with.

The Accreditation Council for Graduate Medical Education (ACGME), the governing body of American medical residencies, has been tasked with assuring residents are properly trained before independent practice. In their most recent release of requirements for urology residencies, the ACGME states that residencies are responsible for "developing the skills, knowledge, and attitudes leading to proficiency in all the domains of clinical competency requires the resident physician to assume personal responsibility for the care of individual patients" (http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/CPRs_07012015.pdf).The way in which residencies need to reach this goal is never explicitly stated, but simulation has become an increasingly popular option. Despite no requirements from the ACGME at the time of this writing, residencies are increasingly using simulation and skills laboratories to help residents master a number of surgical skills (Fig. 1). In the following chapter, the currently available simulation options in urology will be discussed including endoscopy, laparoscopy, robotics, and open surgery. Please note that terminology of validation has recently shifted in urology to update the vernacular [5]. A chapter elsewhere in this textbook can be read for further reference.

Endoscopy

Since Antonin Desormeaux excised a urethral papilloma using an endoscope with lighting from a kerosene lamp in the 1850s, endoscopy has come a long way [6]. Endoscopy is now performed routinely by urologists through a number of instruments, namely, cystoscopes and ureteroscopes, which are made both rigid and flexible, and in a number of sizes. Because endoscopy is used for a number of procedures both diagnostic and therapeutic in nature, a strong foundation of endoscopic skills is needed for all training urologists. As such, a number of simulators for endoscopic procedures have been developed and will be discussed below.

Bladder/Urethra

Cystourethroscopy

Cystourethroscopy represents one of the most commonly performed procedures by urologists, occurring both in the

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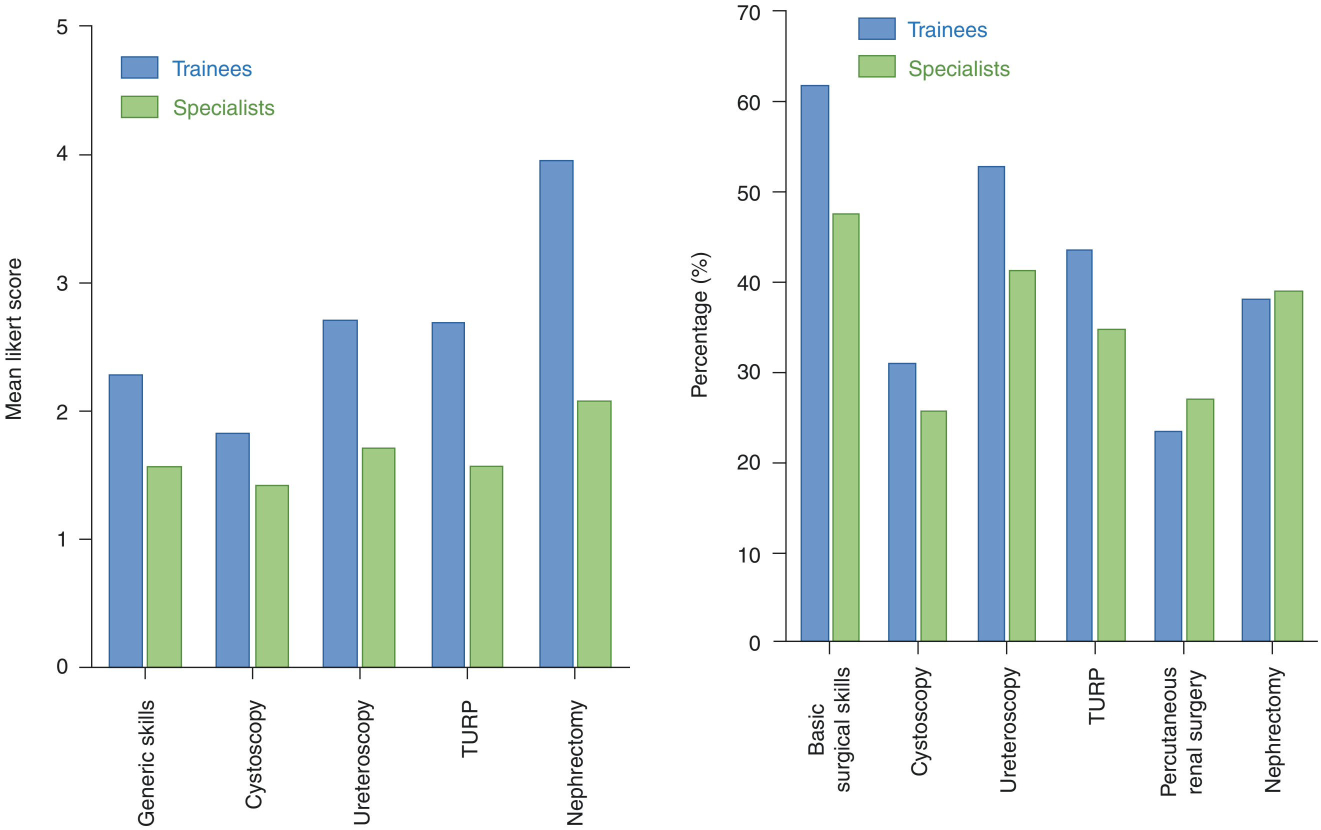

Fig. 1 Results of survey of 263 urological trainees and specialists comparing perception of need for additional training and whether or not simulation had been used for training. (From Ref. [4], with permission)

office and in the operating room. For diagnostic purposes, either a rigid or flexible cystoscope is typically used to thoroughly examine the bladder and urethra in both males and females. There are currently a number of options for simulation of cystourethroscopy including both bench models and virtual reality (VR) simulators. The URO Mentor™ (Simbionix Corp, Cleveland, OH, USA) can be used for both flexible and rigid cystoscopy and ureteroscopy. By utilizing a sophisticated visual engine, the URO Mentor is able to offer high-fidelity simulation with a number of features, including two- and three-dimensional rendering, collision detection, texture mapping, X-ray rendering, and special effects such as blood, smoke, and stone fragments [7]. In a study by Schout et al., the URO Mentor system was used in training of flexible cystoscopy by both novice and expert endoscopists. The study demonstrated validity evidence and found that simulation with the URO Mentor system resulted in large improvements in novice performance in terms of time, trauma caused, areas inspected, and global rating scale score [8]. This was followed by another study from the same group, in which study participants who received training on the URO Mentor virtual reality system performed significantly better doing cystourethroscopy on real patients than those who did not receive VR training [9].

With the advent of high-fidelity trainers and simulators has also come significant cost, with simulators often costing tens of thousands of dollars. Some have questioned if low-fidelity models could allow for the same learning experience for novices, particularly with more simple tasks such as instrument handling. Matusmoto et al. demonstrated that a low-fidelity model consisting of a Penrose drain representing the urethra, an inverted Styrofoam cup representing the bladder, and drinking straws inserted into the cup as ureters was just as effective for skill improvement in a group of 40 medical students when compared to a $3700 high-fidelity model [10]. Similarly, the same authors presented that a low-fidelity model of Styrofoam tubing (urethra) leading into a bell pepper (bladder) with 18-gauge angiocaths puncturing the bell pepper (ureters) allows for trainees to practice cystoscopy and cannulation of ureters with various types of wires. The advantage of this system is its low cost and the ability of trainees to use the same equipment they would use in the operating room, including cystoscopes and guidewires.

There is currently little literature available about the utility of human cadavers in cystourethroscopy simulation, but this may represent a viable option in the future. In one study from the OB/GYN literature, Bowling et al. used fresh frozen cadavers to assess cystoscopy skills in 29 OB/GYN residents. The authors placed abnormalities such as a vaginal mesh eroding into the urethra to create clinical scenarios. The residents were divided into a study group who received training via a didactic session with bench model versus a control group. The residents did cystoscopy on the cadavers and were scored in a number of ways. The authors found that residents who underwent didactic training had significant decreases in scope assembly time and increases in task-specific checklists (92.9% vs 52.5%, $p < 0.001$) and global rating scores (87.8% vs 57.6%, $p < 0.001$) versus that of the controls [11]. Cadavers, however, remain expensive and can be scarce in certain areas of the world.

Transurethral Resection of Bladder Tumor (TURBT)

In 2013, there were 72,570 new cases of bladder cancer diagnosed in the United States, and with an ever increasing incidence of bladder cancers, transurethral resection of bladder tumors (TURBT) is a procedure very commonly performed by urologists [12]. TURBT represents a potentially fruitful target for simulation, as there is a steep learning curve with inexperienced endoscopists being prone to inadequate inspection of the bladder, incomplete tumor resection, inadvertent bladder perforation, and/or increased bleeding. In addition to its technical difficulties, patient outcomes have been shown to be tied to experience, as inexperience with TURBT has been found to be a predictor of higher readmission rates and higher recurrence rates after TURBT for Ta and T1 tumors [13]. Currently, there is one major TURBT simulator described in the literature, the Uro-Trainer® (Karl Storz GmbH, Tuttlingen, Germany) [14]. The Uro-Trainer is a VR simulator with both visual perception and haptic feedback, enabling users to resect papillary bladder tumors as well as carcinoma in situ (CIS) [14, 15]. The commercially available Uro-Trainer features a customary resectoscope and two flat screens. Users are able to use multiple different instrumentations with varied resection loops as well as laser instruments [15]. The Uro-Trainer was first presented by Reich et al. and was shown to be a valuable teaching tool for both medical students and urology residents [16]. In a subsequent study, Kruck et al. demonstrated increased area of inspection (36.8–54.3%, $p < 0.05$) and improvements in resection rates (26–52.0%, $p < 0.05$) among novice endoscopists [15]. In the Kruck study, the Uro-Trainer was also used to teach new techniques to experienced urologists. They found that experienced urologists have significant improvement in both bladder inspection (52.2% vs 62.7%, $p = 0.003$) and resection rates (43.8% vs 57.1%, $p = 0.002$) with integrated photodynamic diagnostics (a type of fluorescence cystoscopy) versus standard white light cystoscopy [15].

Recently, there has been a second TURBT simulator validated in the medical literature. The Simbla TURBT simulator (SAMED GmbH, Dresden, Germany) is a high-fidelity simulator which consists of a resectable bladder with anatomical structures and embedded tumors [17]. This model allows for the use of standard OR instruments, with connected monopolar or bipolar diathermy, and can be connected to irrigation for continuous flow throughout the system. de Vries et al. identified 21 procedural steps and 17 pitfalls associated with TURBT, and the Simbla simulator was found to cover 13 steps and 8 pitfalls. Although not perfect, this simulator was found to have validity evidence [17]. One advantage of this model over its VR counterparts is the ability to use real instruments and irrigation.

Intravesical Botulinum Toxin Injection (Botox)

In 2011 the FDA approved the use of intra-detrusor injection of Botox® (botulinum toxin) for the overactive bladder, and with that approval came a new procedure to be learned by many urologists. Typically, this procedure is done cystoscopically under local or general anesthesia. The goal is to deliver an even distribution of botulinum toxin to the detrusor muscle, usually via 20–30, 1 cc injections [18]. Currently, there is one VR trainer described in the literature, developed at the University of Minnesota. Their system allows for virtual bladder models of multiple sizes and bladder wall thicknesses. This allows learning of injection patterns, with optimum penetration depth, and dose control [18]. This simulator is currently not commercially available and is yet to have been verified, but it presents a potential source of simulation of an increasingly popular procedure.

Prostate

Transurethral Resection of the Prostate (TURP)

Transurethral resection of the prostate (TURP) represents a classic procedure for the treatment of medically refractory lower urinary tract symptoms secondary to BPH. However, as pointed out by Wignall et al., TURP training is difficult for a number of reasons. TURP requires the user to work in a small three-dimensional space, represented on a two-dimensional monitor, requiring significant visual-spatial coordination [19]. This can become even more difficult as the endoscopist frequently encounters visual impairment from tissue and blood. Furthermore, this procedure can result in serious adverse events including urinary incontinence, erectile dysfunction, profuse bleeding, hyponatremia, and injury to a number of structures including the urethra, ureter, or rectum [19]. Although once a popular procedure performed during residency, there has been a halving in the number of TURPs done by graduating urology residents over the last 15–20 years [19, 20]. Because of these issues, there has been a push for the use of simulation as a tool to augment training for this procedure.

TURP simulators can be broadly divided into virtual versus physical models, each of which has their own advantages and disadvantages. Physical simulators often rely upon standard TURP equipment that is used on surrogates for prostatic tissue such as chicken breast, vegetable matter, or pig liver. At the authors' home institution, trainees use the standard TURP resectoscope with associated electrocautery capabilities in an OR-like environment with irrigation fluid and a standard endoscopy tower to resect portions of porcine liver. This model is particularly useful for more inexperienced trainees who can experience with assembling the resectoscope and using equipment likely identical to that used in the OR. The main disadvantage of this model is the lack of bleeding when resecting the tissue [21].

The Bristol TURP Trainer (Limbs and Things, UK) represents another option in terms of physical model TURP trainers (Fig. 2). This is a disposable bench model with a synthetic prostate within a latex bladder on a plastic base [22]. Trainees use a real resectoscope with attached monopolar or bipolar diathermy to resect the prostate model. The model is complete with irrigation fluid and life-like anatomy including ureteral orifices and verumontanum and is made of a synthetic material that can be cut with the resectoscope diathermy loop. This is one of few physical models that have validity evidence [23]. Advantages of this model are that trainees get to manipulate real instruments, identify pertinent anatomy, manage fluids, and handle resected prostatic chips. As with other physical models, the Bristol TURP trainer does not allow for bleeding or other potential complications of TURPs.

Fig. 2 Bristol TURP simulator. (From Ref. [22] with permission)

Since the introduction of the first VR TURP trainer in 1990 by Lardennois et al., the use of virtual reality for TURP simulation has grown significantly [19, 24]. Early virtual reality models were plagued with limitations including lack of haptics, inaccurate deformation of tissues, and lack of bleeding [19]. Significant advancement came in 2000 with the production of the University of Washington virtual reality TURP simulator in partnership with the Gyrus ACMI (Reading, Berkshire, United Kingdom). Oppenheimer et al. recognized hemostasis as a critical learning point in successful TURP training and, as such, developed simulated bleeding through the creation of a bleeding movie texture map library [25]. From this spawned the University of Washington VR TURP trainer (UWTURP), which has collected the most validity evidence as a TURP trainer to date [23, 26]. The UWTURP consisted of a physical model of the penis and pelvis with digital recreations of urothelium and resection bed being based off of digital footage from actual TURP procedures. The simulator can track both motion and force data, allowing for objective measures of operative errors, blood loss, grams resected, irrigant volume, and amount of electrocautery use. In its numerous validation studies, the UWTURP has been found to successfully distinguish novices from experts. In a study by Sweet et al., none of the TURP experts had an operative error on a 5-min resection task, whereas novices resected the sphincter 50% of the time and 16% had to stop the operation because of blood loss making vision impossible [26]. As is the goal of simulation, ideally the novices will learn from these mistakes in a simulated setting rather than harming patients during the early learning curve. Unfortunately, this simulator is no longer commercially available.

Another VR TURP simulator is the PelvicVision TURP simulator. The PelvicVision consists of a modified resectoscope attached to a robotic arm, foot pedals, and a standard desktop computer [27]. The simulator allows for haptic feedback as well as real-time tracking of variables such as resectoscope movements, blood loss, resection volumes, flow of irrigation, and errors (bladder perforation, resection of the sphincter, perforation of prostatic capsule). In a small study by Källström et al., the PelvicVision demonstrated validity evidence with students demonstrating a positive learning curve and improving self-assessments in which they found the procedure to be easier with increasing numbers of simulations [27].

Finally, VirtaMed also has a commercially available VR TURP simulator called UroSim/TURPSim™ [28]. This simulator allows users to perform entire TURP procedures with both resection and coagulation or focus on particular areas of interest. Validity evidence was gathered in two separate studies [29, 30]. Bright et al. demonstrated that experts (200+ TURPS) when compared to novices (no TURP experience) resected significantly more prostate per minute and had significantly less diathermy time that was not touching tissue. They also demonstrated that novices got significantly better by repetitive training on the simulator [29].

Photoselective Vaporization of the Prostate (PVP)

Since its introduction in 1998, the GreenLight™ (American Medical Systems, Inc. Minnetonka, MN) laser photoselective vaporization of the prostate (PVP) has been shown to be an effective treatment of bladder outlet obstruction secondary to BPH and is significantly less morbid than traditional TURPs [31–33]. The basis of GreenLight PVP in the treatment of BPH is the use of a potassium-titanyl-phosphate (KTP) crystal, through which a laser beam fires, at a wavelength selectively absorbed by hemoglobin. By doing this, hemoglobin-containing tissue is preferentially vaporized, with nearly instantaneous hemostasis [34]. Because of a growing number of these procedures being done, a GreenLight Simulator (GL-SIM) was created by Sweet et al. at the University of Minnesota and has been shown to have validity evidence [35]. It has been used as part of the required hands-on training pathway for new users by AMS (now Boston Scientific) since 2012. The GL-SIM consists of a camera, scope, and fiber which are all pre-attached to a module, to which a foot pedal is also attached. The simulator uses a standard laptop to run its VR software and display the video output. The system comes pre-loaded with five task training modules (anatomy identification, sweep speed, tissue-fiber distance, power settings, and bleeding coagulation) as well as six full operative cases (with increasingly larger prostates). The GL-SIM has been shown to have additional validity evidence in a study by Herlemann et al., which was later confirmed by Aydin et al. [36] Evidence of validity was demonstrated in two of the five training modules, as well as in operative time, errors made, and instrument cost [35]. Interestingly, Herlemann et al. found that the ability to play a musical instrument was associated with improved outcomes on the simulator [36].

Holmium Laser Enucleation of the Prostate (HoLEP)

Just as is the case with PVP, holmium laser enucleation of the prostate (HoLEP) represents an emerging alternative to the standard, more morbid, TURP. HoLEP uses a holmium: yttrium-aluminum-garnet (Ho:YAG) laser to enucleate the entire lobes of the prostate via emission of pulsed 2140 nm energy [37]. Some have suggested that HoLEP has become the new "gold standard" for surgical management of BPH, and as such, it is becoming increasingly popular [38]. Because it involves a technique significantly different than TURP, HoLEP has been shown to have a steep learning curve, longer than that of a standard TURP [39]. This has been viewed as a major disadvantage of HoLEP and a reason that some in the urological community have not adopted the technique [40].

To help with the steep learning curve of HoLEP, a benchtop model was created for simulation training. The benchtop model is referred to as the Kansai Medical University HoLEP bench model developed by Kinoshita et al. [28]. The model consists of a model of prostatic hyperplasia, which can be installed into a box simulator, and standard cystoscopic equipment and holmium lasers are used to enucleate the model. In addition, trainees are responsible for real-time fluid management to complete the procedure. The Kansai Medical University HoLEP bench model demonstrated validity evidence in a study of 36 participants by Aydin et al. [41]. Interestingly, 97% of participants in the study felt that the model should be implemented into training programs.

A virtual reality platform for HoLEP, called the UroSim HoLEP simulator (VirtaMed, Zurich, Switzerland), has subsequently been developed. The UroSim HoLEP simulator uses a cystoscope module connected to a computer system to simulate the procedure (Fig. 3). The system is equipped with haptic feedback and six different operative cases with varying anatomical variations and degrees of prostatic hyperplasia. In a study of 53 participants, Kuronen-Stewart et al. divided participants into three groups (novices, intermediate,

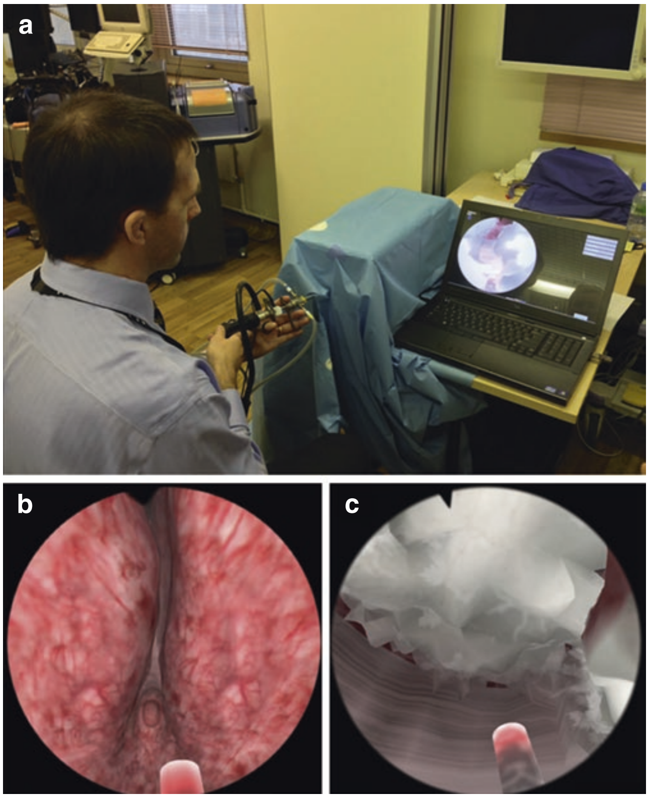

Fig. 3 (**a**) The UroSim simulator with resectoscope and display in use, (**b**) view of simulated prostatic anatomy, (**c**) mid-procedure view notable for circular fibers seen at the bladder neck. (From Ref. [42])

and experts). The study ultimately demonstrated validity evidence with significant differences in the enucleation efficiency (grams enucleated per hour) between each group and a realism score of 5.6 out of 10 among experts [42].

Transrectal Ultrasound (TRUS) Prostate Biopsy

The TRUS-guided prostate biopsy represents the gold standard to histologically diagnose prostate cancer and likely will remain that way for the foreseeable future. However, this relatively simple procedure is not without risk, with 0.69% of men requiring hospitalization to treat complications and reported mortality rates of 1.3% at 120 days [43, 44]. Because of the current apprenticeship model used to learn prostate biopsies, there has been a push to develop simulators that may bypass the early learning curve and help avoid errors made in human patients. Given the emergence of targeted therapies for prostate cancer, there also is importance in accurate sampling of the prostate to avoid areas of untreated cancer.

The first prostate biopsy simulator was developed by Chalasani et al. at the University of Western Ontario [45]. 3D TRUS images were collected from 50 patients at the time of live biopsy and used to create a TRUS image bank to be used as the TRUS images seen during simulation. These images were incorporated into a mock pelvis which allowed for multiple simulated biopsies to be done with either a standard endfire or sidefire TRUS probe. The mock pelvis is a rectangular box made using polyoxymethylene plastic complete with dense elastic foam imbedded in the pelvis to simulate the rectal wall, as well as a tight elastic port of entry representative of the anus. The pelvis can be manipulated to allow the biopsies to be performed in the left lateral decubitus or lithotomy positions. Movement of the probe is tracked by an embedded magnetic sensor, and biopsies are fired with a foot pedal. In a small study of 26 physicians, Chalasani et al. demonstrated that promising results with face validity evidence did not reach statistical significance, likely because of the small sample size.

A second prostate biopsy simulator has recently been introduced by Fiard et al. [46]. The simulator (unnamed, Grenoble University Hospital, Grenoble, France) consists of a laptop computer attached to a Phantom Omni haptic device, which has a stylus representing the ultrasound probe. Moving the stylus allows the user to explore the virtual prostate, of which the images were obtained from actual human biopsy procedures. The software comes equipped with an evaluation system that scores users on their ability to accurately sample 12 sectors of the prostate. In their small study of 21 participants (7 experts and 14 novices), Fiard et al. demonstrated validity evidence. Impressively, the median rating of realism was 9/10 by novices and 8.2/10 by experts. Construct validity did not reach statistical significance despite a 12% difference in scoring between novices and experts, likely the result of the small pool of participants.

Kidney/Ureter

Ureteroscopy

Ureteroscopy (URS), or upper tract endoscopy, represents a broad topic of multiple instruments used for a number of purposes. As technology has improved, there have been increasingly more indications for the usage of upper tract endoscopy including management of upper tract urolithiasis, ureteral strictures, UPJ obstruction, ureterocele incision/excision, upper tract biopsies, and ablation/excision of upper tract tumors. Broadly speaking, ureteroscopy is accomplished by the use of either semirigid or flexible ureteroscopes, of which there are many options depending upon manufacturer and the indicated procedure. The use of URS has been increasing in time, particularly with the increasing incidence of urolithiasis in the United States, and urologists often use ureteroscopy as first-line treatment in stones <2 cm [47, 48].

Studies of the ureteroscopic learning curve have used varying endpoints to deem competence, as there is no established outcome currently for expertise of URS. Operating room time, fluoroscopy time, stone-free rates, complication rates, instrument damage, and cost have all been used as surrogate outcomes in the measurement of a URS learning curve [49]. Although there is no clearly delineated learning curve, there is a very established improvement in complication and success rates of URS with surgeon experience [49]. Tasked with the job of determining residents are well trained upon graduation from residency, the ACGME has placed the minimum number of ureteroscopy cases for graduating residents to be 60, but they also note "the minimum requirement for procedures does not supplant the requirement that, upon a resident's completion of the program, the program director must verify that he or she has demonstrated sufficient competence to enter practice without direct supervision" (http://www.acgme.org/portals/0/pfassets/programresources/480-urology-case-log-info_.pdf). Accordingly, there has been a recent push to be able to objectively measure teaching programs and assess the skills attained by trainees. The Objective Structured Assessment of Technical Skills (OSATS) is one such tool. Based on a 14-point curriculum, the OSATS was designed to assess the necessary cognitive and psychomotor skills and has been shown to correlate ureteroscopic performance with experience [50].

As discussed in other sections, there has been a push to augment training programs and potentially bypass the early error-prone learning curve of procedures with simulation. URS in particular has seen significant advances in simulation options over the last decade. Currently available training tools are broadly categorized into virtual reality, bench, animal, and human models (Fig. 4).

Aside from simplistic bench models, such as the University of Toronto model consisting of a Styrofoam cup

Fig. 4 Currently available commercial ureteroscopy simulators. (**a**) Uro-Scopic trainer. (**b**) URO Mentor. (**c**) Scope Trainer. (From Ref. [51], with permission)

advocated by Matsumoto et al. (discussed in cystoscopy section of chapter), there are three main validated bench models currently available. The first of which is the URO-Scopic™ trainer from Limbs & Things (Bristol, United Kingdom). The URO-Scopic™ trainer is a high-fidelity physical model through which standard semirigid and flexible ureteroscopes can be passed. The model simulates a male pelvis with an attached urethra, a bladder, bilateral ureters, and collecting systems [51]. There have been three studies done to analyze the URO-Scopic™ trainer. In the first study, Matsumoto et al. demonstrated validity evidence of the model in a study of 17 urology residents. The URO-Scopic™ trainer was shown to significantly improve the performance of the residents, as evidenced by OSATS, pass rating, and time of procedure [52]. The URO-Scopic™ trainer was further studied by Mishra et al. in an evaluation of the URO-Scopic™ trainer versus a VR simulator (URO Mentor™, to be discussed later). In their study of 21 urologists with no experience in ureteroscopy, the trainees gave the URO-Scopic™ trainer a realism score of 6.74/10, and users were found to improve performance of URS via a global rating score system with each attempt at URS [53]. Similar validation evidence has also been compiled for the CREST KUB model (University of Minnesota, now University of Washington). The CREST KUB model is a 3D-printed model of the urethra, bladder, and bilateral upper tracts and has been used for the hands-on AUA courses since 2014. This was the first application of 3D printing for urologic education [54].

The second available bench model is the Scope Trainer (Mediskills Ltd., United Kingdom). The model is high-fidelity and is comprised of a distensible bladder and a single collecting system. The Scope Trainer boasts some interesting features including a transparent dome that allows visualization of instruments within the model, reproduction of lumbar lordosis to enhance realism, a collecting system containing both stones and papillary tumors, as well as a “percutaneous” access tract for antegrade passage of a scope. There are currently two studies available studying the Scope Trainer, both of which were done by Brehmer and colleagues. In their first study, 14 urologists were observed and scored using a task-specific checklist when performing rigid ureteroscopy on both patients and the Scope Trainer model. All study participants claimed the model was similar to surgery, and to further back this up, participants scored identically between human and model cases [55]. As may be expected, the study participants who had subspecialized in endourology scored significantly higher than their counterparts on both human and model surgery (18.2 vs 16.8, $p = 0.0084$). In the second study, 26 urology residents used the Scope Trainer for semirigid ureteroscopy. They had initial baseline scores taken, they then trained on the model under supervision, and then a post-training procedure was done. Baseline and post-training procedures were scored on a task-specific checklist and a global score (maximum = 19). The urology residents were found to significantly improve their skills from an average baseline score of 7.7 to a post-training score of 17.2 [56]. In this regard, the Scope Trainer showed promise as a tool for improving ureteroscopic skills particularly, as commented by the authors, in manual dexterity. Indication of validity was also demonstrated in this study, with experienced residents scoring an average total score of 17.6 versus an average score of 7.7 by inexperienced residents.

The third validated bench URS model is the “adult ureteroscopy trainer” (Ideal Anatomic Modeling, Holt, Michigan). Quite interestingly, White et al. used CT images of the upper tract of a patient who had difficulty spontaneously passing renal calculi to make their model. Rapid prototyping involves the creation of thin, virtual, horizontal cross sections from animation modeling software to transform those virtual cross sections into physical form one after the other to create a physical model. In doing so, they exactly replicated that patient’s collecting system into a durable silicon mold. Results from their initial study of 46 participants (ranging from urology attendings to medical students) were rather impressive, with 100% of participants rating the model as realistic, 98% thought it would serve as a good training format, and 96% recommended it for urology training [57]. Validity was demonstrated with expert and novice endoscopists removing a lower pole calculus and being scored by a global rating scale and ureteral checklist (modified for the absence of the bladder and urethra). Expert endoscopists were found to score significantly better than their novice counterparts (33.1 vs 15.0, $p < 0.0001$) and performed the task in less time (141.2 vs 447.2 s, $p = 0.01$). The authors touted that the model cost of $485, in comparison to other models which can range from $3700 to $60,000. However, one notable limitation of this model is the lack of the bladder and urethra, which eliminates the essential step of guidewire manipulation and cannulation of the ureteral orifice.

A recent publication has demonstrated a new, unvalidated, flexible ureteroscopy model called the K-Box® (Porgès-Coloplast, France) [58]. The K-Box® consists of four independent boxes made of polyurethane and has a number of interesting features that have not been seen in previous models. There are a number of trays that can be swapped in and out of each box, allowing for multiple challenging configurations for the user to navigate. The model uses a standard ureteroscope and instruments such as wires and baskets, as do other physical models. If the user becomes confused as to their location within the model, the lid can be removed, and the scope’s location can be seen, acting as a surrogate for fluoroscopy. Guidewires, access sheaths, and ureteroscopic baskets can be used within the model to accomplish tasks including stone removal in the model. Trainees also have the capability to use water in the model, which allows for the use of laser to fragment stones. The K-Box® appears to be a viable model which needs further study to establish validity.

In addition to physical bench models, there has been the emergence of virtual reality (VR) simulators which, in contrast to bench models, use computer-based systems to simulate particular procedures. The feasibility of a URS simulator was first demonstrated by Preminger et al. in 1995, and since that time the field has seen significant advances, particularly with the advance of available technologies [59]. The most studied VR ureteroscopy simulator is the URO Mentor (Simbionix, Israel). The URO Mentor consists of a male pelvic mannequin incorporated with a Windows-based computer interface. The simulator allows for the usage of both flexible and semirigid ureteroscopes which are passed through the interface device, which looks like a penis, into the mannequin. Once inside the mannequin, the system converts movements, tracked by a sensor on the tip of the endoscope and three sensors within the workstation, into realistic images on the monitor. The system also allows for realistic 2D fluoroscopic imaging during simulations as well. There are a number of virtual working instruments available to users when using the URO Mentor including guidewires, baskets, forceps, stents, dilators, and a number of lithotripsy probes (laser, lithoclast, and electrohydrolic) [7].

The URO Mentor was first described by Michel et al. in 2002, and since that time there have been a number of validation studies done [7, 51]. In their study, Michel et al. set to demonstrate face validity, stating that both trainees and endourological instructors felt the URO Mentor displayed a high degree of realism, but they never disclosed how many participants were in the study nor how it was done [7]. There have been many studies demonstrating validity evidence for the URO Mentor simulator. Watterson et al. and Wilhelm et al. did similar studies in 2002, both of which demonstrated evidence of validity. In their studies they used 20 and 21 medical students, respectively, and randomized them to teaching on the URO Mentor system versus control groups. Both found that the trained participants did significantly better than the control groups (Watterson, global rating score 23.6 vs 14.7, Wilcoxon <0.001; Wilhelm, 21.3 vs 16.1, $p < 0.001$) [60, 61]. Jacomides et al. studied the time to completion of training modules on the URO Mentor for 16 medical students and 16 urology residents. They found that the students significantly decreased the time to completion of the module after training on the URO Mentor for 5 h, decreasing their times from 17.4 to 8.7 min ($p < 0.05$). They found no significant difference in times among the residents, but interestingly, they found the medical students were able to complete the task in similar times to first-year residents (who had a median 14 clinical ureteroscopies) after training [62]. This suggests that medical students may be able to bypass the early learning curve and catch up to residents, in terms of operating times, by using the VR simulator. Matsumoto et al. further demonstrated validity evidence by assessing 16 urology residents via a number of parameters in the task of basketing a distal ureteral stone on the URO Mentor. In their study they found that senior residents were scored significantly better than junior residents in terms of global rating scores (29.4 vs 20.8, $p = 0.005$), examiner checklist assessment (19.1 vs 15.2, $p = 0.02$), pass/fail rating, time to complete task (352.9 vs 576.8 s, $p = 0.02$), and incidence of scope trauma (0.6 vs 4, $p = 0.02$) [63]. In a study of 89 participants, consisting of both urologists and urology residents, Dolmans et al. found that URO Mentor scored a mean global realism score of 3.14 (1–5-point Likert scale) for URS and 82% of participants rated it ≥3.5 on a scale of 1–5 in terms of usefulness as an educational tool. In this study the overall rating for the URO Mentor on a 10-point scale (1 = poor, 10 = excellent) was 7.3 [64].

The URO Mentor has also been evaluated in multiple studies. Validity is particularly important because it helps answer the ultimate question if a simulator can effectively translate to improved clinical performance. Ogan et al. studied 16 medical students and 16 urology residents with the URO Mentor. Participants underwent a baseline evaluation on the URO Mentor, and the medical students then underwent 5 h of supervised training on the simulator. After the medical students received training, all participants then underwent a second evaluation on the URO Mentor, as well as an assessment done of a similar task on a fresh frozen cadaver. The study found that the medical students significantly improved performance from their baseline assessment to their second simulated task but still underperformed against the residents in the cadaveric ureteroscopy in multiple subjective and objective measurements. In terms of validity, the student performance on the post-training simulation strongly correlated with performance on the cadaver in areas of time ($r^2 = 0.320$), global rating score anatomy ($r^2 = 0.402$), and overall scores ($r^2 = 0.384$). These correlations did not hold for urology residents, suggesting that the URO Mentor may be helpful in predicting the performance of inexperienced endoscopists but likely does a poor job predicting performance for those with more experience [65]. Knoll et al. studied 20 urologists of varying experience (21–153 total flexible URS) in their performance in treating a lower calyceal stone. They found that those that had performed less than 40 URS scored significantly worse than those who had greater than 80 cases. They also suggested validity by comparing five inexperienced urology residents versus five inexperienced urology residents trained on the URO Mentor. In their comparison, they found that the simulator-trained group performed significantly better on their first four ureteroscopy cases on humans, as assessed by operative times between the groups [66].

The use of live animals for surgical training remains controversial, and as such, ex vivo animal models have been advocated by a number of authors. By using organs obtained from pigs already being slaughtered for food, legal and ethical issues have been essentially erased [67]. Strohmaier and Giese first described the usage of an ex vivo porcine model, as they were looking for something with a more realistic feel than the plastic models that were available at the time [68]. The authors used an en bloc resection of all retroperitoneal organs (kidneys with ureters, bladder, urethra, aorta, vena cava, intestine, rectum, and anus) from freshly slaughtered adult pigs, with subsequent isolation of the urinary tract. The authors found that ureteroscopes (7.5–9 F) could be successfully navigated through the porcine GU system and gave a more accurate "tissue feeling" than physical models. Since their publication, there have been subsequent authors describing similar porcine ex vivo setups [21, 69, 70]. Soria et al. did a validation study that was divided into three levels. During the level 2 portion of the study, an ex vivo porcine renoureteral unit was used for training of laser lithotripsy of a mid-ureteral stone. The model in a study of 40 participants has a global realism score of 4.25 ± 0.13 on a 5-point Likert scale (1 = the worst, 5 = the best) [71]. Further validation and data regarding educational value for ex vivo models are still lacking at this point in time.

Percutaneous Access/Lithalopaxy

Since first described by Fernström and Johansson in 1976, percutaneous nephrolithotomy (PCNL) has represented a viable and increasingly popular way to manage complex renal calculi [72]. With further advances in technique since its inception, PCNL has largely supplanted the need for open surgery in the removal of renal calculi [73]. Despite its utility, there is a quite high incidence of complications associated with PCNL, with an overall complication rate of up to 83% [74]. Possible complications including hemorrhage requiring transfusion (11.2–17.5%) and colonic (0.2–0.8%) or pleural (0.0–3.1%) injuries are particularly associated with access portion of the procedure. In addition to its inherent risks, PCNL is also known for its steep learning curve, making training particularly difficult. Current literature suggests that 36–45 cases are needed to become competent and 105–115 cases are needed to achieve proficiency for

PCNL [75, 76]. In addition, as little as 11% of urologists obtain percutaneous access without the help of a radiologist, suggesting that many trainees may not have exposure to percutaneous renal access [77]. Given all of these factors, simulation in PCNL has become increasingly popular.

There are currently four bench models of PCNL described in the literature, three of which utilize ex vivo porcine renoureteral units. The first was described by Hammond et al. in which the authors placed pebbles within a porcine kidney/ureter, which was then placed inside a chicken carcass [78]. Urology residents were then taught needle access, guidewire placement, tract dilation, retrograde and antegrade pyelograms, renal access sheath insertion, and rigid and flexible nephroscopy with the assistance of fluoroscopy. This model has never been validated, but evaluation via anonymous surveys suggested that the residents were satisfied with the model, and it allowed them to become more comfortable with the equipment and technique of renal access.

A second bench model proposed by Strohmaier and Giese also used ex vivo porcine kidneys and ureters, but in a considerably different way [79]. The cadaveric porcine renoureteral units had calculi placed within them via opening the collecting system, followed by a watertight closure with a running suture. The ureters were then cannulated with ureteral catheters, through which saline could be instilled to induce hydronephrosis. They were then placed on a rectangular silicone mold, and then the entire setup is covered with a liquid silicone. The liquid silicone takes approximately 3 h to solidify and lasts about 1 week. Once set, trainees can use ultrasound or fluoroscopic guidance to accomplish needle access to the collecting system and perform the usual steps to achieve nephrolithotomy. The authors also suggest that endopyelotomy, incision of calyceal neck stenosis, antegrade stent placement, and inserting percutaneous drainage catheters can be trained as well.

In 2008 Zhang et al. published the creation of a unique ex vivo porcine model that was created wrapping a porcine kidney in a full-thickness skin flap complete with fascia and muscle and found this system to be rather successful (Fig. 5) [80]. However, the authors noted that the 12th rib is an important anatomical landmark for percutaneous renal access and thus modified their model to incorporate a portion of porcine thoracic or abdominal wall that contained at least two ribs [81]. As with the previous bench models, this model allowed for both ultrasound- and fluoroscopy-guided renal access and subsequent nephrolithotomy. In their study, 126 urologists tried this model, of which 90.5% rated the model as "helpful" or "very helpful" for simulation of PCNL.

Currently there is one PCNL bench model with some validity evidence, first described by Zhang et al. [82]. Designed at the Peking University Shougang Hospital, this model is 36 × 32 × 12 cm and composed of three components made of mixed silicon materials (Fig. 6). The model consists of a kidney with a dilated collecting system with an attached ureteral stump. This is then encased in simulated perirenal tissue of approximate 4 cm thickness. The model was designed to simulate the texture of the human body as much as possible. Trainees can use both fluoroscopy and ultrasound to obtain renal access. One major advantage of this model was that it was shown to be able to be punctured multiple times and used by multiple trainees, although the cost-effectiveness of this versus ex vivo animal models has never been studied. In their study, Zhang et al. demonstrated validity evidence for the model. Nine experts (>60 cases) and thirty novices were enrolled in the study and performed fluoroscopy-guided percutaneous renal access on the model. Experts gave the model an overall appraisal of 4 out of 5

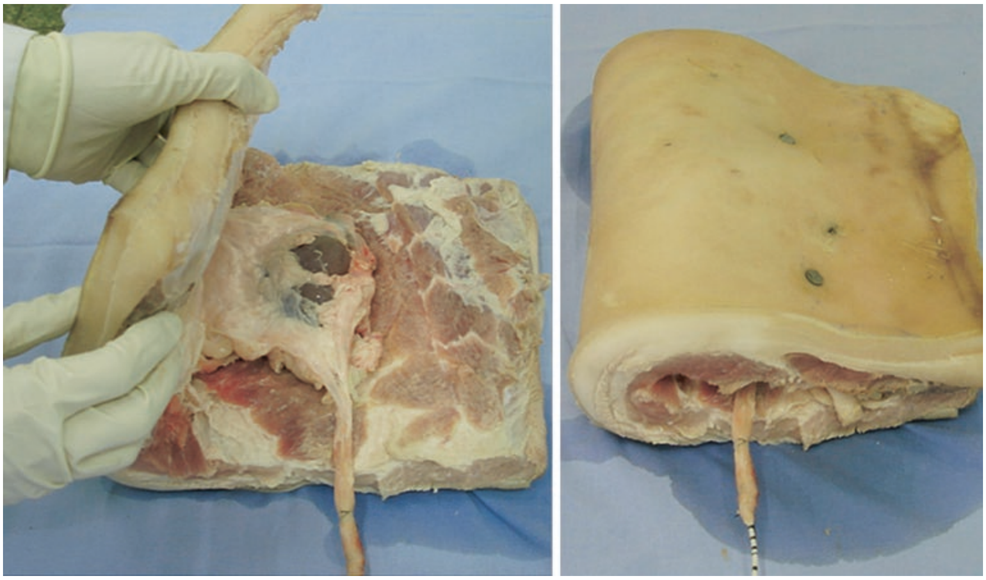

Fig. 5 Ex vivo porcine kidney wrapped in full-thickness skin flap. (From Ref. [80])

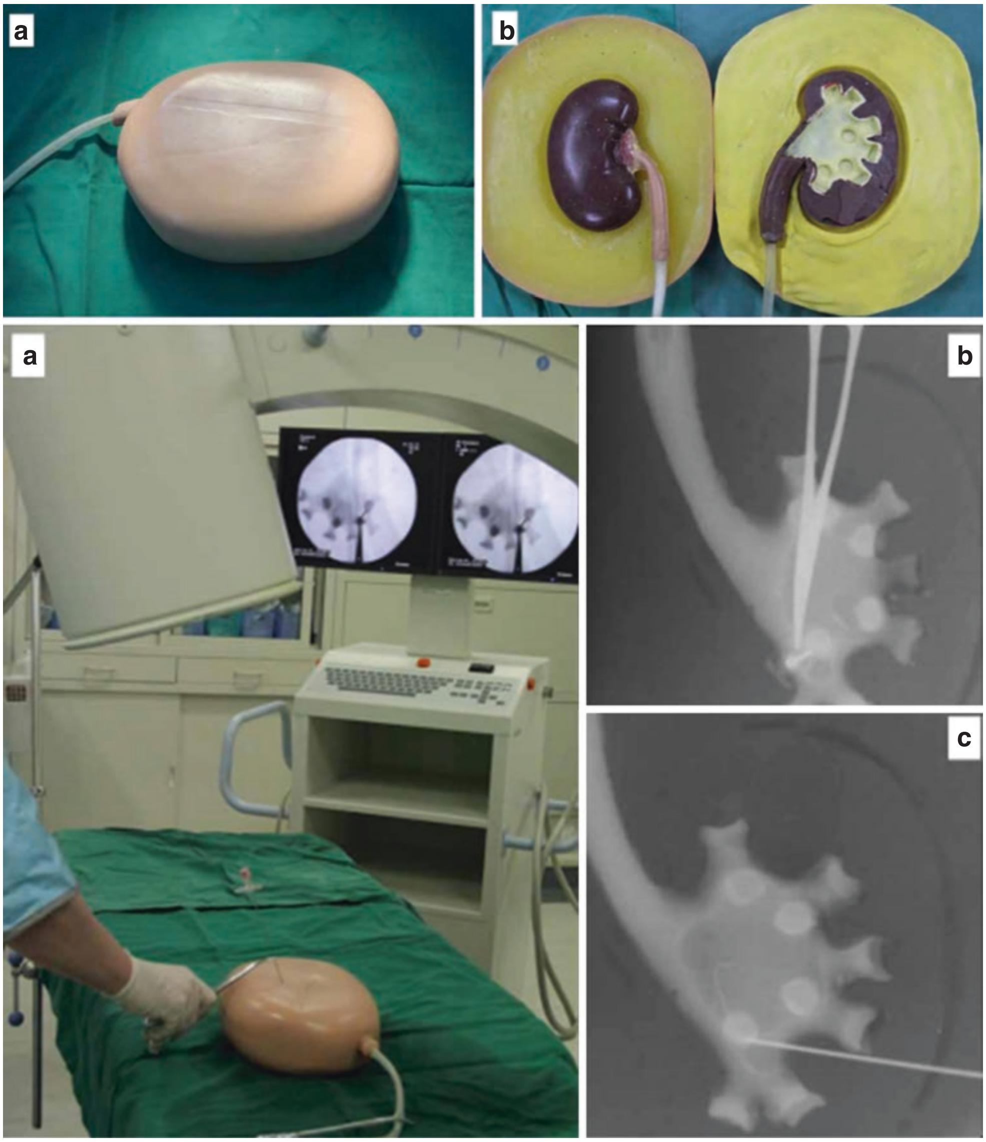

Fig. 6 Validated PCNL model compatible with both fluoroscopy and ultrasound. (**a**) Practice of fluoroscopy-guided PRA. (**b**) Puncture C-arm at 20°. (**c**) Guidewire placement, C-arm upright. (From Ref. [82])

points on a 1–5-point Likert scale and scores of 5 and 4 for utility of this as a training tool and an assessment tool, respectively. Significant differences were found between experts and novices, with experts taking less total time (183.11 vs 278.00 s, $p < 0.001$), shorter fluoroscopy time (109.22 vs 183 s, $p < 0.001$), and fewer attempts (1.28 vs 2.35, $p < 0.001$). After two 1-hour skills sessions on the models, novices significantly improved their total time (278.00 vs 189.93 s, $p < 0.001$), fluoroscopy time (183.13 vs 121.97, $p < 0.001$), and number of attempts (2.35 vs 1.43, $p < 0.001$). After training, there was no significant difference in performance of the novices versus the experts in the aforementioned categories.

As with other procedures, percutaneous renal access has seen the development and validation of a virtual reality simulator. The PERC Mentor™ (Simbionix, Israel) is one such simulator, which has a number of interesting features for training in percutaneous renal puncture. The PERC Mentor™ uses a torso mannequin (which can actually be added onto the previously discussed URO Mentor system) linked to a computer-based simulation system. The mannequin is considered a high-fidelity flank model, designed to provide haptics of skin, muscle, connective tissue, and ribs as one would experience in a human. The simulator comes with a virtual C-arm and mock angiographic instruments allowing users to make percutaneous access under simulated fluoroscopic guidance, which is controlled by a foot pedal. A metal needle containing a spatial sensor is placed through the simulated torso into a digitally projected renal collecting system. Contrast medium can be delivered through a ureteral catheter, and placement can be confirmed in real time with aspiration of “urine” from the collecting system. Among its many features is the displacement of organs with respirations, something that has not been able to be simulated with bench models. There are a number of tasks and case scenarios able to be performed, with difficulty ranging on a scale of 1–10. During tasks and case scenarios, a number of endpoints are measured, including operative time, number of puncture attempts, fluoroscopy time, rib collisions, collecting system perforations, and vascular injuries [83].

The PERC Mentor™ was initially validated by Knudsen et al., in which 63 novices (medical students and inexperienced residents) used the PERC Mentor™ to learn percutaneous renal access [84]. Study participants underwent baseline testing on the simulator, in which the goal was to make percutaneous access into the kidney and pass a wire into the collecting system. Users were then randomly divided into two groups. The first group underwent two 30-min training sessions on the simulator, while the second group received no training. They then returned for another attempted percutaneous renal access in a different case scenario and were assessed using a global rating scale, as well as a number of parameters collected by the simulator. The study found that the two groups were not significantly different at baseline, but after training, the intervention group improved their performance on 11 of the 14 measured outcomes, whereas the untrained group made no improvements. Additionally, the trained group performed significantly better than the untrained group on the posttest in all but two parameters (number of rib collisions and amount of contrast on antegrade nephrostogram). The authors contended that validity evidence was demonstrated because the high-fidelity flank model, fluoroscopy foot pedal, and realistic needle allowed all participants to successfully achieve percutaneous renal access. The authors also asserted that validity evidence was demonstrated because the simulator was developed with the input of a number of experts in the field, who ultimately help create the case scenarios, anatomy experienced, and imaging data. Finally, this study demonstrated validity evidence for the PERC Mentor™ by correlating the subjective global rating score with objective measures with Spearman rank correlations. This was further backed up by a study from Park et al., in which 9 experts (5 urologists and 4 interventional radiologists) were compared against 63 novice medial students and residents on a case scenario using the PERC Mentor™ [85]. Evidence of validity was demonstrated with the experts significantly outperforming the novices as assessed by the global rating score (24 vs 12 out of 25). Experts also rated the PERC Mentor™ highly on 5 of 6 domains (mean 8.1 on 10-point scale).

Obtaining skills that can be translated to better performance in the operating room is the ultimate goal of any simulator. In a follow-up study to the initial PERC Mentor™ validation study, Margulis et al. attempted to see if users trained on the PERC Mentor™ performed better in the OR [86]. Using the same 63 novices from the initial study, the authors evaluated the trained and untrained groups in their ability to achieve percutaneous renal access in anesthetized pigs. The study found that the trained group performed significantly better than their control counterparts in terms of the number of punctures (1.9 vs 2.7, $p = 0.005$), number of infundibular punctures (0.3 vs 1.1, $p = 0.002$), and number of collecting system perforations (0.4 vs 0.8, $p = 0.003$) and scored higher on the global rating score (3.8 vs 2.7, $p < 0.001$). The authors then did a crossover study in which the control group underwent training on the PERC Mentor™, and they were subsequently found to perform at a level with no statistical difference of the initially trained group. While surgery on an anesthetized pig may not truly represent translation of skill to humans, it provides promising evidence that the simulator improves performance without putting humans in undue danger.

In addition to the PERC Mentor™, there has recently been described a hybrid simulator called the SimPORTAL (University of Minnesota). The SimPORTAL is a fluro-less “C-arm” trainer that was paired with a transparent silicon flank bench model for its initial study [87]. The unit consists of two webcams mounted onto a small C-arm (device sits on a standard desk) which was produced with a 3D printer. The C can be tilted (−30°/+30°) and rainbowed (−15°/+15°). The cameras are attached to a MacBook Pro™, and through a video processing technique, the camera images are fused, overlaid, and processed to achieve a simulated X-ray image which can be seen on a screen by the user. In their initial trial study with 14 participants, Veneziano et al. found that 92.8% of participants found it to be of at least equal value to currently available simulators (PERC Mentor™), and as such it warrants further validation studies [87]. This model has been used for the AUA hands-on PCNL courses since 2015.

Laparoscopy

Laparoscopy represents a growing field of urology, as urologists continue to push the boundaries of what is possible within the realm of laparoscopic surgery. Laparoscopic surgery was first introduced in the 1970s with a few gynecologists trying laparoscopy for ovarectomies, adnectomies, and myomectomies, but did not really gain traction until expansion into general surgery with laparoscopic cholecystectomies and appendectomies [88]. Over the past 25 years, in particular, minimally invasive surgery (MIS) has seen a staggering growth in the field of urology, with an increasing number of indications for MIS. Laparoscopy has been found to have a steep learning curve that requires unique skills, which do not translate well from skills learned in other modalities, such as open surgery [89]. Trainees are required to navigate a three-dimensional space on a two-dimensional monitor using instruments that are unique to laparoscopy and often have limited degrees of freedom of movement [90]. Given this information, the ACGME has placed the current requirement on graduating urology residents to be 50 cases, although it is unknown if this is enough to be truly proficient at laparoscopy (http://www.acgme.org/portals/0/pfassets/programresources/480-urology-case-log-info_.pdf). As is the case in the previously mentioned surgical modalities, there have been a number of laparoscopy-specific simulators created to help bypass the steep learning curve seen with laparoscopic surgery.

Basic Laparoscopic Skills

There are a number of skills required for laparoscopic surgery that are unique. Many of the fundamental skills cross over between urology, general surgery, and gynecology. Please refer to the general surgery and gynecology chapters for specific applications in those fields. Laparoscopic surgery is known for its requirement of hand-eye coordination to accomplish accurate movements while watching a monitor which is producing a two-dimensional image of a three-dimensional space. Manual dexterity is also especially important given the amplification of small movements by the length of the instruments, as well as the fulcrum effect of the body causing movements of the hands to mirror that of the instrument. Because these are basic skills that must be mastered to be proficient at laparoscopy, regardless of the operation being performed, there has been the creation of simple bench models that aim to help trainees master the basic skills of laparoscopy. Interestingly, in addition to acquiring skills, there has also been evidence to suggest that practicing on a simulator prior to real surgery improves surgical performance [91].

The field of bench (also termed “box trainers” or “video trainers”) for laparoscopy is huge, with a number of variations of the basic premise of having a box through which instruments can be passed to perform a variety of tasks while using a camera to project the images onto a monitor. In their 2014 Cochrane review on the topic of laparoscopic surgical box trainers (limited to those with no prior laparoscopic experience), Nagendran et al. found an astounding 770 publications requiring screening, of which 32 were ultimately included on the topic [92].

Within the confines of a standard box trainer, a number of tasks can be performed depending on the desired skill to be practiced. The Fundamentals of Laparoscopic Surgery (FLS) simulator represents one such box trainer that is considered by many to be the gold standard for the development of laparoscopic skills [93]. Based on the McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS), the FLS consists of five tasks: peg transfer, pattern cutting, ligating loop, extracorporeal suturing, and intracorporeal suturing. The complete program also has an online didactic portion. The FLS has been extensively studied, with all five tasks being validated, and proficiency on the FLS has been shown to improve operative performance [94–97]. In fact, in 2009, the FLS was added by the American Board of Surgery as a requirement before being able to sit for board examinations in general surgery [98].

Munz et al. have put forth a number of suggested box trainer tasks that can easily be done at any institution [99]. To practice instrument navigation, Munz et al. had trainees conduct preset calculations on a calculator inside the box by using a pair of graspers. Coordination was practiced by placing a 30 cm piece of twine marked at 1 cm intervals with blue lines inside the box. Users then “walked” their way down the twine by only grasping at the lines. To practice grasping, a simple setup of two dishes can be placed inside the box, and objects can be transferred back and forth between dishes (chickpeas or small bolts are common objects to grasp). Cutting can be accomplished with a number of setups including grasping twine as above and cutting every centimeter on a marked line or cutting out along the lines of a circle drawn on a piece of cloth or examination glove. An added element of difficulty can be added to any of these tasks by timing the exercises and working on improving efficiency to improve times to accomplish tasks.

Given the number of tasks that can be practiced on box simulators and the relative simplicity of their creation, there have recently been publications on making a “homemade” lap simulator [100]. Using only a translucent storage box, an LED light source, and a webcam hooked to a monitor, Aslam et al. created a relatively simple and cost-effective box trainer. In their study of 34 trainees, 96.9% found the homemade box trainer to be satisfactory, and there was no significant difference in the completion of a variety tasks on the homemade box trainer versus a commercially available model.

As was demonstrated in a recent Cochrane review, box model training appears to improve technical skills of trainees, particularly in those with no prior laparoscopic experience [92]. The authors found in their meta-analysis that when comparing box model training to no training, those who used box trainers took significantly less time to complete tasks (0.54 standard deviations (SD) lower), they made less errors (0.69 SD lower), they had better accuracy scores (0.67 SD higher), and they had overall higher composite scores (0.49 SD higher). The authors also noted that there appears to be no significant difference when comparing the skills obtained on any one box trainer versus another [92].

Despite its availability, training of basic laparoscopic skills is not limited to box trainers. As has been the case with other surgical modalities, virtual reality has become an increasing popular option for skill acquisition and surgical simulation. Of the available VR simulators, the MIST-VR

(Minimally Invasive Surgical Trainer, Virtual Reality; Virtual Medical Presence, UK) is likely the best studied. First described in 1997, the MIST-VR is a computer-based system that consists of a frame holding two laparoscopic instruments whose movements are tracked and translated into virtual reality movements displayed on a standard monitor [101]. A foot pedal is also present to control simulated diathermy. The MIST-VR allows users to work through a series of laparoscopic surgical tasks of increasing complexity, with an emphasis on developing the psychomotor skills necessary to perform laparoscopic surgery. The MIST-VR has been validated in a number of studies and, as such, has been integrated into many training programs around the globe [102]. The MIST-VR has been shown to demonstrate both validity evidence in a number of studies [103–109].

A slight modification to the MIST-VR is the EndoTower (Verefi Technologies, Inc., Elizabethtown, PA). The EndoTower is an additional software which is downloaded onto the MIST-VR computer system and also requires a slightly different handpiece. The EndoTower specifically focuses on the use of the angled laparoscopic camera, which has been known to create problems with novice laparoscopists because of its off-axis viewing. The EndoTower creates a virtual tower which serves as an obstacle course for users to navigate and find hidden objects [107]. In a study by Ganai et al., training on the EndoTower was found to significantly improve the performance of third year medical students on a porcine navigational assessment with better object visualization and scope orientation scores than controls ($p < 0.05$) [110].

Released in 2002, the LS500 (Xitact, Switzerland) was a groundbreaking virtual reality simulator that combined haptics with high-fidelity simulation software. The LS500 focused on laparoscopic cholecystectomy and was validated in a number of studies [111–113]. It was from the LS500 platform that the LAP Mentor™ (Simbionix, Cleveland, OH) was launched in 2003. Now on its third edition, the LAP Mentor is a validated VR laparoscopic simulator that has expanded from a number of laparoscopic-specific tasks to include modules on a number of operations [114]. In terms of basic laparoscopic skills, the LAP Mentor allows for translocation of objects, camera manipulation, clip applying, clipping and grasping, cutting, and a variety of two-handed maneuvers. There are a number of skills necessary for suturing that can be learned as well on the LAP Mentor including needle loading, knot tying, interrupted suturing, continuous suturing, and more advanced techniques such as "backhand" technique and anastomosis suturing. Because the FLS is considered the gold standard for laparoscopic training, the Simbionix set to match the FLS with the introduction of the "essential tasks module." The module includes peg transfer, pattern cutting, and placement of ligating loop, as is seen in the FLS program. In a study by Pitzul et al., the LAP Mentor essential tasks module demonstrated validity evidence with the FLS [93].

While both box trainers and VR simulators have both merits on their own, it becomes natural to question if one modality is better than the other. Gurusamy et al. did a meta-analysis of all studies that directly compared VR training versus box trainers. The authors found two studies that attempted to answer this question [115]. They found that in the first trial, operative time was significantly shorter for the VR group compared to the box trainer group, but there were no reported numerical values ($p < 0.004$). In the second study, the VR group was found to have a 36% improvement in terms of operative performance versus 17% for the box trainer group ($p < 0.05$) [116]. Given the small numbers in these studies, they likely do not truly answer the question of superiority, and the question becomes more complex when considering cost-effectiveness. This will ultimately require further studies.

Adrenal/Kidney

Since the first laparoscopic nephrectomy was performed in 1990 by Clayman and coworkers, laparoscopy has found its way to nearly every indication for renal surgery. In contrast to open surgery, laparoscopic renal surgery has been found to decrease hospital stays and postoperative pain and improve cosmesis without sacrificing surgical outcomes [117–120]. Arguably, the majority of renal procedures done today, including radical nephrectomy, partial nephrectomy, and pyeloplasty, should be performed with laparoscopy or robotics.

Radical/Partial Nephrectomy

Currently there are a number of simulation options specific to radical and partial nephrectomy, many of which have been validated in a number of studies. The simplest of which is a bench model out of the University of Western Ontario. Using a commercially available polyvinyl alcohol (PVA) powder (Air Products and Chemicals, Inc; Allentown, PA), researchers were able to create a PVA liquid that could be poured into a custom mold and freeze-thawed into a renal model. Once the model was made, tumors could be suspended within the mold using a custom tumor mold [121]. Initially created for a model used in renal ablative therapy simulation, the model has now been expanded to use for partial nephrectomy. The unique feature of this model is its echogenic properties when scanned with an ultrasound probe, allowing for trainees to use ultrasound to define tumor borders before the simulated laparoscopic partial nephrectomy (LPN). Fernandez et al. studied the model's utility in LPN by having the model placed within a standard laparoscopic box trainer and having five MIS fellows do ten LPNs each. The study found that participants successfully identified 98% of tumors in a mean time of 1.12 min using a 7.5 MHz laparoscopic ultrasound probe. The researchers found that positive surgical margins increased steadily over the first three cases of each fellow but steeply declined until no fellows had positive margins on their ninth and tenth cases. Four of the five fellows recommended the model for training of LPN [122]. This model was further expanded upon by Abdelshehid et al., when they created an entire case scenario surrounding LPN, with a simulated OR environment with other team members including anesthesia, circulators, surgical assistants, a pathologist, and scrub technician. Using the PVA kidney model with a 3 cm exophytic tumor placed within a standard box trainer and the SimMan 3G mannequin simulator, nine urology residents underwent a simulated LPN. The authors found that the simulation-based team training was not only beneficial for its surgical simulation but also because it allowed multiple team members to practice and prepare for a complex surgery with an emphasis on improved communication [123].

Also using a bench model for laparoscopic radical nephrectomy, Lee et al. created an interesting scenario in which urology residents were told to do a LRN, but the case was complicated by a renal hilar vessel injury [124]. To create the scenario, the authors placed a commercially available rubberized kidney part-task trainer (the Chamberlain Group, Great Barrington, MA) inside a standard box trainer. Standard silicone IV tubing and 1/2 inch Penrose drain were passed into the hilar region of the model to simulate the renal artery and renal vein, respectively. Irrigation fluid dyed red to resemble blood was then hooked up to both sides of the IV tubing and Penrose drain. The fluid was placed under pressure to allow for brisk bleeding. The model was then draped to hide all irrigation tubing. Residents were unaware there would be a vessel injury, which consisted of two 1 cm lacerations made to the superior portion of the renal vein (Penrose drain). When users began ligation of the renal artery (IV tubing), the water irrigation system hooked to the Penrose was initiated, creating "venous bleeding." The residents then had to deal with the injury in any way necessary, with endpoints of the study being complete hemostasis or a 2 L blood loss. All eight of the residents (PGY-2 to PGY-5) were able to complete the exercise before the 2 L blood loss endpoint. Senior residents (PGY 4-5) were found to perform significantly better than junior residents (PGY 2-3) in terms of task-specific checklist scoring (75.0 vs 57.9, $p = 0.004$), global rating scale (4.00 vs 1.75, $p = 0.002$), and "blood loss" (462 vs 1075 mL, $p = 0.022$).

As with previously mentioned procedures, animal models represent a viable and frequently used modality for surgical simulation. In addition to surgical training, animal models are often used in proof of concept studies to demonstrate new surgical techniques and instruments. Porcine models are popular for training in laparoscopic surgery as the pig abdominal cavity is of similar size and has anatomy comparable to humans. Rabbit models are also a possibility for laparoscopic nephrectomy simulation. Molinas et al. studied 10 gynecologists and 10 medical students in a rather large study of 200 laparoscopic nephrectomies on live rabbits [125]. Study participants were evaluating during laparoscopic nephrectomy using standard laparoscopic instruments on live rabbits. Each participant performed a total of 20 nephrectomies, and the study found that both the gynecologists and students improved performance when comparing his or her first nephrectomy to the last. Overall time to perform the surgery decreased for students from 44 min to 11 min and from 29 min to 11 min in the gynecologists, with the gynecologists having significantly shorter operation times for the first nephrectomy ($p < 0.0001$) but not significantly different for the last. The students also had more episodes of heavy or mortal bleeding than the gynecologists ($p = 0.0003$), but both groups significantly improved in this category until no bleeding episodes were seen in either group after the 15th nephrectomy for each participant.

In terms of virtual reality simulators for laparoscopic nephrectomy, the Procedicus MIST™ (Mentice AB, Sweden) nephrectomy VR simulator remains the most thoroughly evaluated [126]. The Procedicus MIST™ is a VR simulator launched in December 2007, which simulates both retroperitoneal and transperitoneal LRN. The simulator uses a standard computer, three foot pedals, haptic devices (with instruments), and two monitors (of which one is touch screen) [90]. Because of Xitact™ Instrument Haptic Port devices, the simulator allows the user to "feel" tissues, adding realism. The system uses a number of metrics to evaluate user performance, with the LRN simulation being divided into three separate tasks. The first task is dissection and transection of the ureter, beginning with the user in the retroperitoneum after balloon dissection, at which point they must identify the gonadal vessel and ureter, dissect the ureter from its adventitia, and divide it. The next task is dissection of the hilar fat to identify the renal vessels which must be further dissected and divided. As in real life, the perihilar fat and renal vessels are capable of bleeding. The final task is complete dissection of the kidney. The Procedicus MIST™ was first validated by Brewin et al. in a study of eight experts, ten urology trainees (urology residents), and ten novices (students). Valid was demonstrated with the experts rating all components of the simulator ≥3 on a 1–5-point Likert scale of realism, with particular emphasis on realistic graphics (mean 3.9) and instrument movements (mean 3.8). The simulator also demonstrated validity evidence with it impressively being able to differentiate the experts, trainees, and novices by assessing hemorrhage (experts 236 mL, trainees 377 mL, and novices 1110 mL; $p < 0.01$), errors (181 vs 294 vs 419, $p < 0.01$), task time (1310 vs 1459 vs 2240 s, $p < 0.01$), and instrument travel (24.5 vs 28.4 vs 37.0 meters,

$p < 0.01$). In contrast, Wijn et al. found in a later study that the Procedicus MIST™ did not distinguish between intermediate (<10 LRN performed) and experts (≥10 LRN) and therefore was "not suitable for implementation in a urologic training program" in its present form [127].

A recent amazing development in the world of simulation is the creation of patient-specific simulations, allowing surgeons to rehearse before surgery. This technology was first developed by Makiyama et al., in a study in which they successfully generated a VR simulator with specific patient anatomy (Fig. 7) [128]. The simulator uses dynamic CT images (1 mm slice early-phase CT on 64-detector spiral CT) of the patient of interest, and a complex model data generator extracts anatomic information and enters it into the simulator. The simulator allows for both transperitoneal and retroperitoneal approaches, and the kidney moves according to positioning (supine vs lateral). The simulator allows the surgeon to place the trocars and camera anywhere on the body. Once trocar placement has been decided, users can use a number of instruments including forceps, Maryland dissectors, scissors, hook device, clips, laparoscopic stapling devices, and entrapment bags. A foot pedal allows for the use of simulated electrocautery, and a scope handled by an assistant can be changed between 0, 30, and 45°. The simulator includes haptics, allowing for tactile feedback. Realistic bleeding is also an important aspect of the simulator, with the degree of bleeding depending upon the injury and type of vessel involved. Surgeons have the option of achieving hemostasis with gauze, forceps, or clips. In a follow-up study by Makiyama et al., validity evidence of the simulator was demonstrated in 13 preoperative simulations (7 nephrectomies, 4 partial nephrectomies, and 2 pyeloplasties) carried out by 3 surgeons [129]. On a 1–5-point Likert scale, the surgeons rated anatomical integrity to be 3.4 ± 1.1, utility of the simulations to be 4.2 ± 1.1, and confidence during subsequent surgery to be 4.1 ± 1.1.

Fig. 7 Patient-specific VR simulator. (From Ref. [128], with permission)

Pyeloplasty

There are currently five procedures identified by the American Urological Association's (AUA) Laparoscopic, Robotic, and New Surgical Technology (LRNST) Committee for which simulation would be beneficial [130]. One of those procedures is the laparoscopic pyeloplasty (LPP), done for ureteropelvic junction (UPJ) obstruction. This procedure is particularly demanding when done laparoscopically because it requires excision of the UPJ obstruction and spatulation of the renal pelvis and proximal ureter, and suturing of the anastomosis must be accomplished intracorporeally. Accordingly, the learning curve for laparoscopic pyeloplasty can be quite steep for beginners [131].

The current options available for laparoscopic pyeloplasty are bench and animal models. The Simulation PeriOperative Resource for Training and Learning (SimPORTAL) out of the University of Minnesota is responsible for the creation of a number of surgical simulation models. One such model is a high-fidelity physical renal pelvis/ureter tissue analog model that allows for simulation of laparoscopic pyeloplasty. Using organosilicate-based materials, Poniatowski et al. created the pyeloplasty simulation model by 3D printing a patient-specific mold [130]. The renal pelvis is approximately 6 cm in the superior-inferior direction and 3 cm in the anterior-posterior direction, with an attached 18 cm ureter with 0.8 cm diameter. The UPJ obstruction has an outer diameter of 0.5 cm with an inner diameter of 0.2 cm. The model can then be placed in a standard laparoscopic box trainer, and the procedure can be performed. Interestingly, the makers integrated lines going down the length of the model which can only be seen under UV light. These lines allow for Black Light Assessment of Surgical Technique (BLAST™) to be done after the exercise, specifically looking for alignment of the UV-sensitive lines, indicating proper alignment of the UPJ anastomosis. Poniatowski et al. presented validity evidence of the pyeloplasty model in a study of 31 attending clinical urologists. Evidence of validity was demonstrated with a questionnaire given to participants after using the model with participants giving the model an average score of 4.17 on a 5-point Likert scale for anatomical accuracy of the renal pelvis, ureter, and UPJ obstruction. Scores of 4.42 and 4.33 were given for the model reproducing skills for the anastomotic suturing and reproducing the skills of spatulation, respectively. Validity evidence was shown as those who had experience in performing a LPP in the previous 5 years performed better than those who had not in terms of increased patency ($p < 0.05$), decreased twisting ($p < 0.05$), and decreased leakage ($p < 0.10$) [130].

A more simple model is the "latex glove" laparoscopic pyeloplasty model set forth by Raza et al. [132]. The authors used a standard latex glove with a knot tied at the base of one of the fingers to create a model in which the knot represents a strictured UPJ and the palm represents the dilated renal pelvis (Fig. 8). The model was placed within a standard laparoscopic box trainer, and a laparoscopic dismembered pyeloplasty was then performed. In a small study of 5 participants ranging from experienced (> 20 laparoscopic pyeloplasties) to an inexperienced medical student, the more experienced participants were found to perform the procedure in significantly less time (47 vs 160 min, $p = 0.043$) and with better suturing [132]. Further studies into the applicability of this model into urological training are yet to be seen.

Fig. 8 "Latex glove" laparoscopic pyeloplasty model. (From Ref. [132])

Yang et al. have set forth a bench-top model for the simulation of a retroperitoneal laparoscopic dismembered pyeloplasty [133]. The creation of the model sounds rather complex, but the authors contend that it is relatively cheap and can be reused. The model consists a kidney made of commercially available plastic clay (such as Play-Doh®) with the middle part of the model being imbedded with a metal clip, allowing for the attachment of a carp swim bladder, to simulate a dilated renal pelvis. A separate 10 cm portion of porcine ureter was used as the model ureter, with it already being connected, as if the UPJ obstruction had already been excised. The model was placed within a box consisting of five hinged boards, which can be adjusted to mimic the limited working space of the retroperitoneum. The box is then used with standard laparoscopic equipment, as would be done with a standard box trainer. The authors found in a cohort of 5 surgeons that operative time significantly reduced after using the trainer (41.84 vs 25.04 min, $p < 0.01$) and the surgeons rated themselves better on a general self-efficacy score (22.20 vs 27.60, $p < 0.01$). The authors also compared complication rates of the surgeons in real patient cases before and after training and noted that after an average of 6.6-month follow-up, 1 of 15 patients experienced a restenosis and another experienced a prolonged urine leak, whereas there were no reported complications in a group of 15 patients at an average of 7.4 months after training on the model [133]. However, it is unclear if this study was powered to be able to detect significant differences in complications.

Animal models are quite popular for the training of LPP as well. Ramachandran et al. were the first to describe using the unique anatomy of the chicken esophagus to simulate LPP by using the chicken crop and esophagus to simulate the renal pelvis and ureter, respectively [134]. The crop of the chicken is a dilated segment of esophagus proximal to the stomach that primarily functions in food storage. Ramachandran et al. exposed the crop and esophagus of a dead chicken, and then cleaned and filled the crop/esophagus with water to simulate a dilated renal pelvis. An 8F feeding tube was then passed down the esophagus into the crop, and the esophagus was ligated with a silk suture. The model was then placed into a standard box trainer, and a dismembered LPP was performed. This model was initially studied in three urology residents in their final year of study, with each person doing four LPPs over the period of a month. The study found that at the first attempt, only one of three subjects could complete the task because of technical difficulties experienced during laparoscopic suturing. However, after the fourth attempt, all the subjects could complete a good-quality LPP in a mean time of 67.7 min, with each attempt taking less time and with better anastomosis suturing scores [134].

Jiang et al. then went on to demonstrate validity evidence for this model in a separate study of 15 participants divided into 3 groups based off of experience. Participants were studied on the time to completion, as well as with a quality score on a scale of 1–10 assessed by a blinded evaluator (exact tissue sutured, equality of bite sizes, equal stitch intervals, lack of tissue tear, and watertight anastomosis). The study found that the model was able to distinguish level of experience both by time to perform the task (33.80 min for experts vs 55.20 min for limited experience group vs 92.60 min in no experience group; $p < 0.001$) as well as in regard to a quality score (9.0 vs 7.2 vs 4.0; $p < 0.001$) [135].

There is one model currently described using live animals for LPP. Fu et al. were able to perform 60 LPPs (each side done 3 times) on 10 anesthetized Guangxi Bama minipigs (20–30 kg) using a specialized method they proposed [136]. The pigs fasted and underwent bowel preparation 10 h before surgery and then were placed under anesthesia and placed supine on an operating table. After getting access in a standard laparoscopic fashion, the renal hilum was exposed, and the ureter was divided close to the hilum and spatulated. Next, a piece of small bowel adjacent to the renal hilum was selected as a surrogate for an enlarged renal pelvis. The lower portion of the small intestine was then cut open, and after an antegrade stent was placed down the ureter, the "pyelotomy" was sutured to the previously spatulated ureter. Fu et al. studied this model with 5 trainees in an advanced laparoscopic urology fellowship, with each subject completing 12 LPPs over a 10-day period. The authors found that operative time significantly reduced after the trainees had performed 12 LPPs (135 vs 62 min, $p < 0.001$) and all subjects commented that the simulation was helpful and improved their laparoscopic skills [136].

Prostate

Urethrovesical Anastomosis

Since its introduction in 1997, the laparoscopic radical prostatectomy has largely been abandoned in favor of using robot-assisted laparoscopy [137]. The reasoning behind this is the difficulty of intracorporeal suturing and knot tying deep within the pelvis experienced with straight laparoscopy when trying to perform the urethrovesical anastomosis (UVA). Because the urethrovesical anastomosis is the most daunting portion of this procedure, there have been models created to help simulate and improve the skills needed to perform this task.

There are currently three described bench models, some of which use animal tissues, for simulation of the UVA. The first of which is a relatively simple model introduced by Nadu et al. [138]. The authors used pieces of chicken skin available at local supermarkets to fashion a urethra and bladder which could be sewn together in a laparoscopic box trainer. This was accomplished by fashioning the chicken skin into a 4 cm tubular structure (urethra) over a 16F urethral catheter. The bladder is created by folding over a piece of chicken skin and cutting a 1 cm orifice in the folded edge. The model is then tacked into a standard box trainer, and a UVA can be done at that time. In their initial study, Nadu et al. found that two advanced laparoscopy urology fellows substantially reduced the time required to perform the anastomosis, from 75 min initially to 20 min after performing on the model 20 UVAs [138]. These results were confirmed in a subsequent study by Yang et al., suggesting this simple model may help at least improve operative time in performing the UVA in a laparoscopic radical prostatectomy [139].

Sabbagh et al. have introduced a low-fidelity model for perfecting the UVA. This very simple model consists of a piece of latex tubing through which a Foley catheter can be passed and sutured to another piece of latex in the form of the bladder neck while placed in a standard laparoscopic box trainer. In their initial study, Sabbagh et al. randomly divided 28 senior surgery residents, fellows, and staff surgeons into 2 groups. The first group was the intervention group which practiced UVA on their low-fidelity model. Meanwhile, the second group practiced basic laparoscopic skills such as knot tying on a foam pad. The groups were later evaluated by a blinded grader on their ability to do five interrupted intracorporeal sutures on both the low-fidelity model and the foam pad. The study found that the intervention group scored significantly higher on a task-specific checklist (10.9 vs 8.1, $p = 0.017$) and global rating score (29.6 vs 22.8, $p = 0.005$) and in significantly less time (27.6 vs 38.3 min, $p = 0.004$) compared to the control group [140]. The authors subsequently published a prospective, single-blind, randomized study of their model in which the same cohort of 28 participants was again divided into the same intervention and control groups. The participants were then evaluated on their ability to do a UVA on an anesthetized pig. Again, the group that trained on the low-fidelity model did significantly better than the control group in terms of checklist score, global rating score, and end product rating, demonstrating that skills acquired in a low-fidelity trainer can be translated to more "real-life" situations [141].

There is currently one animal model simulating UVA, which has been proposed by Laguna et al. [142]. The authors used dead, plucked chickens that were at least 2.5 kilograms for their simulation. Using two subcostal incisions extended to the thighs, the authors removed all thoracoabdominal organs except for the esophagus and the stomach. An 18F catheter was placed through the esophagus, and the chicken was then placed within a pelvic trainer through which a standard laparoscopic camera and instruments could be used. Once in the box trainer, the specimen was transected completely at the esophagogastric junction. In their study of the model (Laguna et al.), 5 urologists of varying experience (ranging from never having done a laparoscopic radical prostatectomy to >250 performed) were instructed to sew the

UVA with 2 different suturing methods (6 interrupted sutures vs running single-knot suture). The study found that suturing time and operator experience were linearly related ($r = -0.724$, $p < 0.001$) and that the most inexperienced surgeon significantly reduced the time required to complete the anastomosis with interrupted sutures (320.5 vs 146.7 s per stitch, $p = 0.001$) [142].

Female Urology

Sacrocolpopexy

Sacrocolpopexy is a procedure often performed by urologists, particularly those with a focus in female urology. Considered by many to be the gold standard procedure to repair vaginal prolapse, sacrocolpopexy can be performed open, laparoscopically, or robotically. While there has been a push to perform this procedure in a minimally invasive fashion, minimally invasive surgery comes with the added difficulty of laparoscopic suturing. As such, a model for laparoscopic sacrocolpopexy was created. Tunitsky-Bitton et al. created a relatively simple bench model for laparoscopic sacrocolpopexy in which a RUMI Advanced Uterine Manipulation System (Cooper Surgical, Inc; Trumbull, CT) with attached sacrocolpopexy tip was covered with swimsuit material and placed within a standard FLS box trainer [143]. The authors studied this model with 5 experts (female pelvic medicine and reconstructive surgeons experienced with laparoscopic sacrocolpopexy) and 15 trainee participants (4th-year gynecology residents and fellows). Participants used the model to perform one step of the laparoscopic sacrocolpopexy procedure, posterior mesh attachment, because it is generally considered the most difficult portion of the procedure. The authors found that the model demonstrated validity evidence with experts performing significantly better than the trainee group in total score and every domain of the GOALS scale (33 vs 20.5, $p = 0.002$). Evidence of validity was also suggested as 75% (all experts) “agreed” or “strongly agreed” that the model was realistic and useful for training laparoscopic sacrocolpopexy [143].

Robot-Assisted Surgery

Robotic surgery represents the next step up from laparoscopy, with a number of advantages including improved ergonomics, instruments with “wrists,” and improved depth perception [144, 145]. Since it was first introduced, the number of robotic surgeries done around the world has grown exponentially. In 2014, the Intuitive Surgical (makers of the da Vinci surgical system) reported 570,000 robotic cases had been performed [146]. With this boom in popularity have come concerns that many surgeons have been inadequately trained prior to doing robotic cases [146]. Even within residency programs, which are specifically designed to train residents, many residents feel inadequately prepared to perform minimally invasive surgery at graduation [147, 148].

As was the case with laparoscopic surgery with the creation of the Fundamentals of Laparoscopic Skills curriculum, there has been the creation of the Fundamentals of Robotic Surgery (FRS). The FRS represents a push toward standardization of training in robotic surgery, with a particular curriculum based around the development of basic robotic skills through simulation exercises that can be applied to a number of specialties. The FRS is the first consensus robotic curriculum, as it is the result of a conglomeration of 14 international surgical societies [98]. As with the previously mentioned surgical modalities, robotic simulation consists of physical models, animal models, and virtual reality.

Basic Robotic Skills

The acquisition of basic robotic skills is absolutely essential for success in robotic surgery and as such is a cornerstone of the FRS program. In the world of simulation, particular focus is placed on the development of psychomotor skills, which has been shown to have a steep learning curve. The FRS program has 10 tasks which teach 16 psychomotor skills. These tasks are FLS peg transfer, FLS suturing and knot tying, FLS pattern cutting, running suture, dome with four towers for ambidexterity, vessel dissection and clipping, fourth-arm retraction and cutting, energy and mechanical cutting, docking task, and trocar insertion task [98]. For simplicity, these tasks are all performed on a single device, the “FRS dome” (Fig. 9).

Not only are there physical models such as those used in the FRS to develop robotic skills, but there has also been the

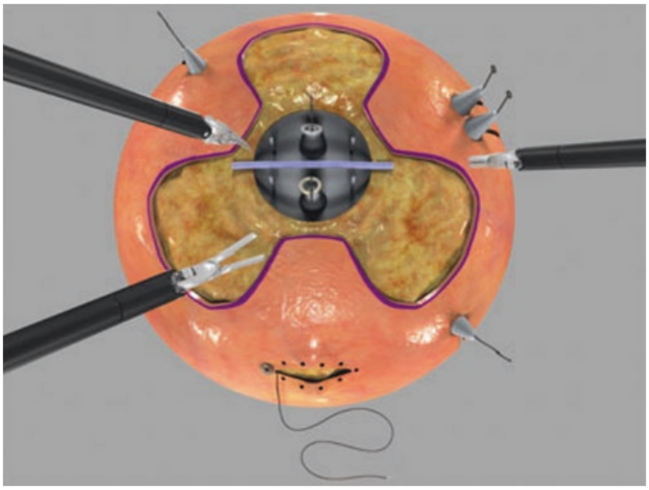

Fig. 9 Fundamentals of Robotic Surgery dome for acquisition of basic robotic skills. (From Ref. [98], with permission)

development of virtual reality simulation specific to robotic training. Robotic VR training has been dominated by three validated platforms: the Robotic Surgical Simulator (Simulated Surgical Systems, Williamsville, NY), dV-Trainer (Mimic Technologies, Seattle, WA), and da Vinci Skills Simulator (Intuitive Surgical, Sunnyvale, CA) [149]. The Robotic Surgical Simulator (RoSS) and dV-Trainer are both stand-alone devices with hand controls and foot pedals designed to imitate the da Vinci robot, whereas the da Vinci Skills Simulator (dVSS) is a “backpack” to a standard da Vinci surgeon’s console where the trainee uses the console with a training interface [150]. All three simulators work on basic robotic skills including grasping, suturing, and psychomotor exercises such as peg transfer and letter-board tasks. There are currently a number of studies available which have mounting validity evidence of all three simulators [150–156]. In an interesting study by Hung et al., the three platforms were cross-correlated by using structured inanimate exercises (bench models), the three VR simulators, and an in vivo robotic skills assessment on a porcine model [149]. The authors were able to confirm that virtual reality performance was strongly correlated with in vivo tissue performance.

Adrenal/Kidney

There is currently very little published simulation in the field of kidney-specific robotic surgery. As robotic surgery has not been around as long as laparoscopic surgery, this is not entirely surprising. There will likely be a movement to produce more kidney-specific robotic surgery simulations as there has been a recognized steep learning for nephron-sparing robotic surgery. As published by Mottrie et al., the learning curve of robotic partial nephrectomy for an experienced robotic surgeon is estimated to be approximately 30 cases to achieve a warm ischemia time of less than 20 min and improved complication rates [157].

Partial Nephrectomy

The first kidney-specific robotic simulation currently described comes from Hung et al. at the University of Southern California. In their 2012 paper, they describe an ex vivo porcine kidney model with an embedded 1.5 inch Styrofoam ball, simulating a renal tumor [158]. The model was created by using a 1 inch melon scooper to score the renal capsule, with a 15-blade scalpel then used to create the defect, with care taken to avoid involvement of the collecting system. Once the defect was created, the commercially available Styrofoam ball was simply affixed within the defect with superglue (Fig. 10). The authors estimated that the model cost approximately 15 USD and took an average of 7 min to create. They studied this model in a group of 46 participants divided into experts, intermediates, and novices based upon the level of robotic experience. The participants used a robot with the ProGrasp forceps and curved scissors (cautery and fourth robotic arm were not given) to excise the

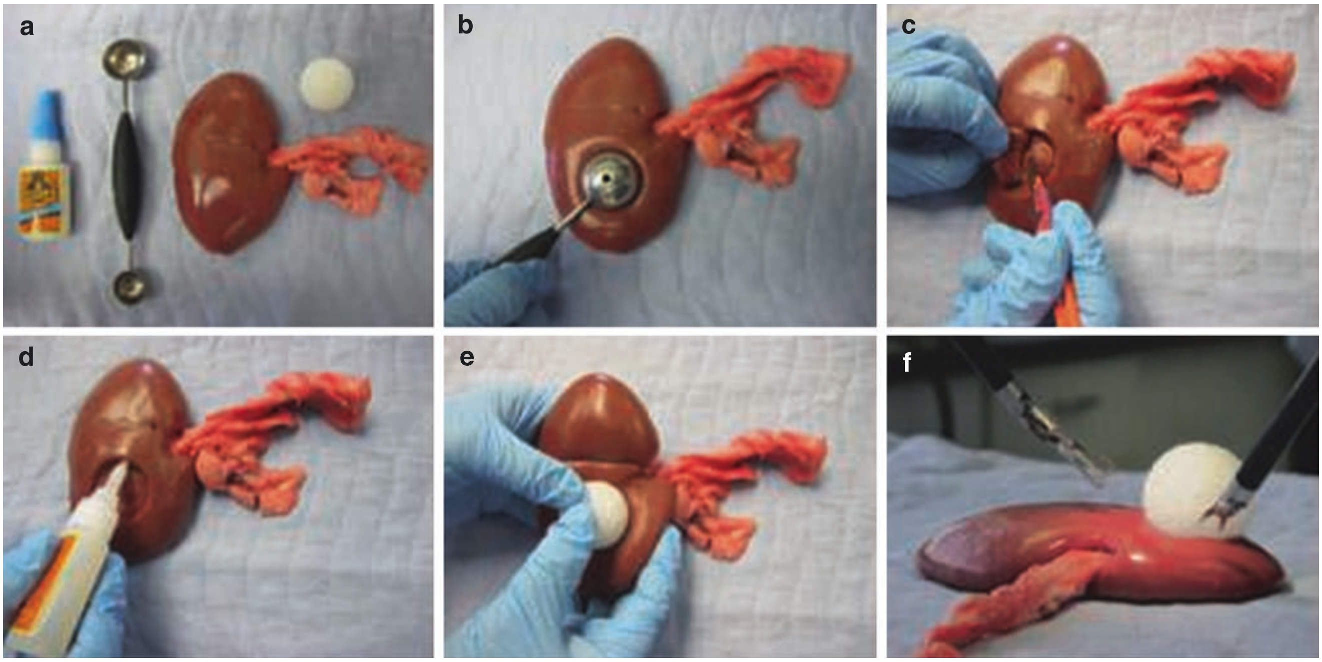

Fig. 10 Partial nephrectomy model proposed by Hung et al. (**a**) Equipment used in model, (**b**) melon scooper used to score renal capsule, (**c**) a 15-blade scalpel is used to create a defect, (**d**) superglue applied to defect, (**e**) foam ball affixed to model, (**f**) excision of foam tumor. (From Ref. [158], with permission)

Fig. 11 Robot-assisted partial nephrectomy foam ball excision operative view. (From Ref. [158], with permission)

tumor (Styrofoam ball) with a clear margin of renal parenchyma (Fig. 11). The authors boasted excellent results with this cohort of participants, with experts giving the model a "very realistic" rating and "extremely helpful" for training of residents and fellows. The model was also able to distinguish between levels of experience with experts performing significantly better than intermediates and novices in overall score, time, depth perception, bimanual dexterity, efficiency, tissue handling, and instrument and camera awareness [158]. As with many simulators, the reality of blood loss and hemorrhage is not available with this model and poses a weakness to its use especially for a model examining a procedure like partial nephrectomy.

Coming from the same group, there has been a recently published simulation platform created for robotic partial nephrectomy that utilizes both augmented reality and virtual reality [159]. The authors created this simulation platform from the existing dV-Trainer platform. The first component of the simulator is augmented reality (AR) in which actual surgical footage is overlaid with virtual instruments which the user can manipulate. During this time there is also narration from the operating surgeon, allowing for cognitive and technical tips to be learned by the user. The goal of the augmented reality portion of the simulation is to learn key aspects of the procedure via a number of interactive exercises. The simulation is divided into five modules each representing a key aspect of the procedure (colon mobilization, kocherization of the duodenum, hilar dissection, kidney mobilization, and tumor resection and repair). In the final module, there is an imbedded virtual reality exercise in which the user performs renorrhaphy on a modification of a previously validated suture sponge exercise from the Mimic simulation library. In their study of this new simulator, Hung et al. again divided 42 participants into expert, intermediate, and novice categories based upon robotic surgery experience. The authors found that the experts gave the simulation a median score of 8/10 in terms of realism. Experts also rated the platform highly in terms of its ability to teach relevant anatomy (9/10) and operative steps (8.5/10). Validity was suggested with experts performing significantly better than both novices and intermediates in a number of categories. Interestingly, the authors had the participants perform an in vivo porcine partial nephrectomy and found performance on the simulator correlated strongly with performance in the porcine partial nephrectomy ($r = 0.8$, $p < 0.0001$) [159].

Bladder/Ureter

There is currently little available in the way of bladder- and ureter-specific robotic simulators. This may be a consequence of the relatively recent move toward doing more bladder/ureter procedures in a robotic fashion. Hung et al. have published a relatively simple cystotomy repair simulation in which a 2.5 cm incision is made on the anterior surface of a porcine bladder and a watertight closure is made using a robot [150].

Ureteral reimplantation represents a growing field in minimally invasive surgery, as minimally invasive techniques have been shown to have similar functional outcomes similar to those of open procedures [160, 161]. Despite its increased prevalence, ureteral reimplantation remains a relatively infrequently done procedure that may be lacking in traditional urologic training, particularly those done in a minimally invasive nature. As such, simulation-based training has been developed for this procedure. There is currently one validated ureteral reimplantation model described in the literature. This model consists of a plastic box which has a simulated bladder and ureter held in place by alligator clips (Fig. 12). The bladder and ureters are made of a commercially available hydrogel material (LifeLike BioTissue, Canada). The simulated bladder was created with a 12 × 15 cm rectangular piece of the hydrogel. The simulated ureter was created with hydrogel as well with a 0.5 mm wall thickness, 6 mm in diameter, and 15 cm in length. A 1 cm incision was made in the "bladder," a 6F ureteral stent was passed through the ureter, and the anastomosis was then performed using a standard robot. Tunitsky et al. studied this model with 21 participants divided into "procedure experts" (>10 robotically assisted ureteral reimplant procedures performed), "robot experts" (fellowship-trained gynecologic surgeons with experience in a number of robot procedures), and "trainees" (4th-year urology residents as well as urology and urogynecology fellows) [162]. After completing the simulation, all of the experts "agreed" or "strongly agreed" that the model was realistic and useful. Using a Global Operative Assessment of Laparoscopic Skills (GOALS) scale, the authors demonstrated validity evidence by showing that procedure experts score significantly higher than both robotic experts and trainees ($p = 0.02$ and $p = 0.004$, respectively) and robotic experts performed significantly better than the

Fig. 12 Robot-assisted ureteral reimplantation model. (From Ref. [162], with permission)

trainees ($p = 0.05$). The authors have suggested that the model can be reused about 10 times with an approximate cost of $22 (excluding stent and suture cost).

Prostate

Urethrovesical Anastomosis

As was discussed in the laparoscopy section, the urethrovesical anastomosis (UVA) represents one of the integral steps in a prostatectomy, but it has a steep learning curve requiring surgeons to master intracorporeal suturing and anastomosis deep within the pelvis. As more and more prostatectomies are done robotically, there is a need for simulation for the robotic radical prostatectomy. By gaining proficiency in performing the UVA, one could go a long way toward becoming proficient at robot-assisted laparoscopic radical prostatectomy (RALRP).

One such simulator is the virtual reality-based "Tube 3" module designed by Kang et al. [163]. The Tube 3 is a module specifically made for simulation of the UVA on the previously discussed Mimic dV-Trainer (Mimic Technologies, Seattle, WA). On the Tube 3 modules, users can perform a virtual reality UVA using a number of techniques, and scoring metrics are automatically tracked by the Mimic Technologies. Kang et al. validated the Tube 3 module by dividing 20 urology attendings and residents into expert and novice categories and having them perform a UVA with a single-knot technique previously described by Van Velthoven et al. [163, 164]. The authors showed validity evidence in which the ten experts answered questionnaires about the Tube 3 module. All of the experts "agreed" or "totally agreed" that the technical skills required to complete Tube 3 were compared to those to perform a UVA during radical prostatectomy. Eighty percent of the experts deemed it to be useful for training others to do UVAs and that it would be helpful in measuring proficiency at performing UVAs. Validity evidence was also shown with Tube 3's ability to distinguish the expert from the novice group. The experts performed significantly better than the novices in a number of categories including the total task time, total score, economy of motion, and number of instrument collisions ($p < 0.05$). In a separate study, Kim et al. studied the Tube 3 module by having 11 urology residents and fellows train on the Tube 3 module and then perform a robotic double bowel layer closure (concurrent validation) and a robotic UVA, both on commercially available models [165]. The authors demonstrated that participants who trained with the Tube 3 module were significantly faster to perform the above tasks than those who did not train on Tube 3.

A second described UVA simulator comes from the University of New York at Buffalo, whom developed a haptic-enabled augmented-reality-based training module for UVA. The system referred to as "HoST," hands-on surgical training, augments a real surgery with virtual reality components in which users are given audio and visual didactics of a given procedure (in this case, UVA) and then perform the steps themselves in the previously described robot- assisted surgical simulator (RoSS). In a multi-institutional study randomized controlled trial by Chowriappa et al., the HoST was found to improve technical skills for performing a UVA with little cognitive demand. 52 urology residents and fellows (all with less than 25 h on a robotic console) were randomized to either the HoST training group or to control. All participants became familiar with the robot via fundamental skills of robotic surgery (FSRS) training on a RoSS console. The HoST training group then completed four, 20-min HoST modules, while the control group watched videos of UVA surgery for an equal amount of time. The groups were then scored on their ability to perform UVA on an inanimate model using a da Vinci robot. Validity evidence was suggested as 70% or more of the participants deemed the simulator to be realistic and would be helpful in learning to do UVA. The HoST group performed significantly better than the control group in terms of needle driving, needle positioning, and suture placement and on overall Global Evaluative

Assessment of Robotic Skills (GEARS) score ($p < 0.05$) [166]. Participants also performed a NASA Task Load Index assessment, and the HoST group was found to have less temporal demand, effort, and mental fatigue than the control group ($p < 0.05$).

Robot-Assisted Laparoscopic Radical Prostatectomy

The radical prostatectomy represents one surgery that has seen significant changes since the introduction of robot-assisted surgery. Because of the robot's ability for vision magnification and the use of small, long instruments which work well deep within the pelvis, there has been a dramatic shift in prostatectomies being done primarily open, to now most being doing with robotic assistance (RALRP) [167]. There have been multiple studies which have shown a rather steep learning curve for RALRP, with some suggesting that 250 cases may be necessary to gain proficiency at RALRP [168]. Increased experience with RALRP has been shown to result in fewer anastomotic strictures and a lower rate of cancer recurrence [169, 170]. As such, simulation training for RALRP has been developed to supplement the often inadequate RALRP exposure experienced during residency.

Alemozaffar et al. first described a unique simulation for RALRP in which a female porcine genitourinary tract tissue is fashioned into a male pelvic genitourinary model which can be used to simulate RALRP [171]. The authors started by making a plaster replica of the male pelvis with a fitted rubber pad to simulate the urogenital diaphragm. They then harvested the vagina, bladder, and ureters from a female pig. Through a number of steps, the porcine vagina was fashioned into a rectum and prostatic pedicle with the introitus becoming the prostate gland. The fallopian tubes were used to create seminal vesicles and the dorsal venous complex (DVC). The ureters were used to represent the neurovascular bundles running along the prostate. The recreated porcine anatomy is then placed into the pelvis model, which can then be used for simulation with a standard robot. The authors then had ten novices and ten experts perform the following steps of RALRP on the model: ligation of the DVC, division of the bladder neck, seminal vesicle dissection, ligation of the prostatic pedicle with sparing of the nerves, apical prostatic dissection with division of the urethra, bladder neck reconstruction, and UVA. The model showed validity evidence with experts giving it a 3.7/5 score of realism, with a particularly impressive 4.5/5 for the UVA portion of the simulator. Experts also supported validity with a score of 4.7/5 regarding the usefulness of the model for training of RALRP. Validity evidence was displayed as experts performed the procedure significantly faster (60.8 vs 121.4 min, $p < 0.001$) and with significantly higher OSATS performance scores (4.6/5 vs 2.6/5, $p < 0.001$) [171].

While not a specific RALRP, Volpe et al. recently validated a curriculum specific for RALRP called the European Association of Urology robotic training curriculum (ERUS curriculum) [172]. The ERUS curriculum was developed by a panel of experts in robotic surgery and consisted of 12 weeks of training divided into three stages: e-learning, an intensive week of simulation-based laboratory training including virtual reality and cadaveric and animal simulations, and 3 weeks of supervised modular training in RALRP until they ultimately carried out a full RALRP. Despite being a small study of only ten urology fellows, the authors demonstrated that the training program resulted in significant improvement of the fellows' performance during RALRP, with 80% being deemed by their mentors as safe and effective to perform a RALRP independently after the training program [172].

New to the market is the Robotix robotic prostatectomy VR simulator from 3D Systems (formerly Simbionix). In a series of modules, learners are guided through procedural tasks such as dissection of the bladder neck and bladder neck transection, division of the vascular pedicles and neurovascular bundles, apical dissection and division of the urethra, and urethrovesical anastomosis. Validity evidence is currently being gathered about this new product.

Open Surgery

Despite the increasing number of surgeries done with a minimally invasive approach, open surgery remains the backbone of urological surgery. Because of the growing number of surgeries being done in a minimally invasive manner, trainees have become increasingly inexperience with open surgery. As such, simulation in open surgery has recently come into favor as a way of gaining open experience without putting patients at risk. Currently available simulators for open surgery are comprised of bench models, cadavers, and animal models.

Human cadavers represent likely the best option for open surgery simulation, but cadavers are expensive and often not readily available. In a large study comprised of 81 urology residents and 27 urology faculty members, Ahmed et al. recently put forth a simulation program in which participants performed a number of procedures on fresh frozen cadavers [173]. These procedures included circumcision, vasectomy, orchiopexy, hydrocele repair, radical orchiectomy, open cystotomy, management of bladder perforation, transureteroureterostomy, Boari flap, psoas hitch, open surgical packing of the pelvis, and nephrectomy [126, 173]. Questionnaires of the participants indicated that the cadaveric simulations had good realism (mean score 3/5) and all procedures scored ≥3 out of 5 in terms of usefulness for learning anatomy and improving surgical skills. Interestingly, participants rated human cadaveric simulation to be the best form of training, followed by live animal simulation, animal tissue models, bench models, and virtual reality.

Because cadaver studies are simply procedures performed in the same manner as they would be in living patients, these will not be discussed individually. Described below are the few currently validated non-cadaveric models of open surgery.

Bladder

Suprapubic Tube Placement

Suprapubic tube (SPT) placement is a rather common procedure performed by urologists but is one often done in an emergent setting requiring trainees to "learn on their feet." Because the procedure is often learned alone and sporadically in emergent settings, trainees often have difficulty acquiring the skill and confidence to perform the procedure and elect to attempt difficult urethral catheter placement. To bolster the skills necessary for SPT placement, there are currently three validated bench models which can be used by trainees for procedural simulation.

The first SPT model called the "UroEmerge™ Suprapubic Catheter Model" was described by Shergill et al. in 2008 [174]. The authors created the model by injecting a 3 L bag of irrigation fluid with 10 cc of povidone-iodine (giving the fluid a urine color) and tying the bag with two tourniquets to simulate a full bladder (Fig. 13). This "bladder" was then placed within a plastic trainer housing and covered with a commercially available abdominal open and closure pad which simulates abdominal skin, subcutaneous fat, and rectus sheath (Limbs & Things, UK) (Fig. 14). Shergill et al. had 36 participants use the model for SPT insertion and scored their ability using a 0–5 visual analog scale. The authors found that before training the participants had an average score of 3.14 for the ability to do SPT placement which increased to 4.48 after the course. This suggests that this model may be a viable and easy method to help junior residents learn this procedure.

Fig. 13 UroEmerge™ Suprapubic Catheter Model with plastic trainer housing the simulated full bladder. (From Ref. [174])

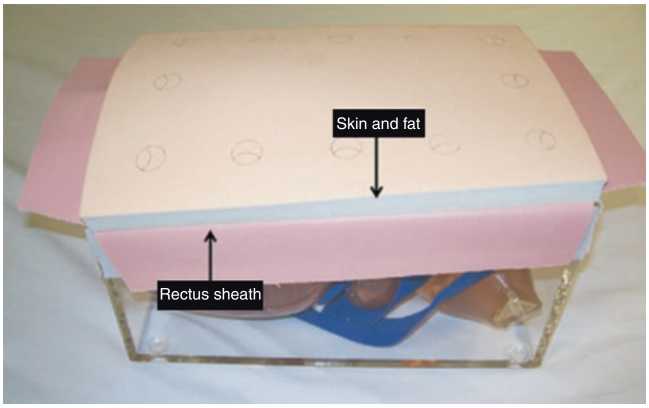

Fig. 14 UroEmerge™ Suprapubic Catheter Model contains an abdominal pad that simulates the skin and rectus sheath. (From Ref. [174])

A second model was subsequently published by Hossack et al. in 2013, which again is relatively simple in nature [175]. The model was made by filling a standard party balloon with tap water and affixing it with tape. The authors recommended "Mefix" tape (Molnlycke Health Care, Sweden) because it kept adherence to the balloon even when wet, prevented the balloon from popping, and provided realistic resistance to trocar placement. The balloon was then placed within a plastic container with a hole cut in the lid. On top of the balloon, a standard household sponge was placed (representing perivesical fat), on top of which, a 3-layer square of Transpore (3 M) tape was placed (rectus sheath) and finally covered with another sponge (abdominal wall fat). In their study with 30 surgical resident participants, the authors found that 96% felt the model accurately represented a bladder and 84% felt much more confident in performing SPT insertion [175].

The final and most recently published model was described by Singal et al. in 2015 [176]. The model was created by first making a bony pelvis from urethane foam and stabilized with resin glue. Plastic parts simulating the anterior superior iliac spine and pubic symphysis were embedded within the foam to provide palpable bony landmarks. The bladder was constructed from silicone rubber with attached IV tubing and Luer lock syringe for instillation of fluid. The bladder is then filled and placed within the bony pelvis and covered with multiple skin and fat layers (made of silicone rubber and gel wax). The model was studied with 25 rural general surgeons under the supervision of urologists. The surgeons scored the model well in terms of value as a training or testing model (4.1/5) and overall realism (3.9/5) [176].

Vas Deferens

Vasovasostomy

Vasovasostomy (VV), or vasectomy reversal, represents an option for men who have undergone vasectomy who wish to regain their fertility. While a good option for many patients, vasovasostomy represents a very technically demanding procedure because the structures are small and suturing is usually performed under a microscope because of the very small sutures used (often 9–0, 10–0, and/or 11–0).

In the only validated study of VV simulation, Grober et al. randomly assigned junior surgery residents to learn VV via a high-fidelity model (live rat vas deferens), a low-fidelity model (silicone tubing), or didactic training alone (control group) [177]. After training in their given randomization group, participants returned 4 months later for retention testing on the 2 models. The authors found that those who were randomized to either bench model performed significantly better than the didactic control group as evidenced by higher retention test checklist scores (25.5 vs 18.6, $p < 0.001$), higher global rating scores (27.0 vs 16.4, $p < 0.001$), and higher patency rates (69% vs 20%, $p = 0.05$) [177]. The authors did not distinguish scoring between the low- and high-fidelity model trained groups.

Conclusion

In this chapter we have discussed simulation in urology. This relatively new field is an exciting avenue exploring the possibility of allowing trainees to learn new skills and procedures in a controlled environment that does not jeopardize patient health. This is particularly important as the technologies available to urologists are constantly advancing and practicing urologists are finding themselves having to learn procedures outside of their traditional training. In this chapter we discussed simulators specific to cystoscopy, ureteroscopy, transurethral treatments of BPH, percutaneous procedures, laparoscopy, robotics, and open urologic procedures. As the field continues to grow, we expect new and exciting ways to educate trainees, particularly with the use of simulation.

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Simulation in Ophthalmology

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Introduction to Simulation-Based Training in Ophthalmology

Ophthalmology as a surgical discipline has existed for many years. Before 800 BC, cataract surgeries were performed using a needle to push the lens into the rear of the eye to restore vision [1, 2]. However, the benefit of the surgery was often poor as an infection often appeared and resulted in blindness or only partially restored vision. These cataract surgeons of ancient times, also called oculists, were itinerant therapists, travelling around from town to town. Asked how he had learned to remove cataract, one of them answered: "I learned it after having stabbed so many eyes out as I could carry in my hat" [3].

Fortunately, surgical training in ophthalmology has advanced since then. While simulation in ophthalmology with the use of animal models has existed for many decades, the first virtual-reality (VR) training model for ophthalmic surgical training was described in 1992 and was developed for the training of retrobulbar injections [4]. Several models for the simulation of intraocular procedures were described in the following years [5–8]. During the last decade, surgical VR training in ophthalmology has developed significantly as a result of improvements in technology. Ethical considerations, reductions in working hours, and changes in teaching methods have also made the development of different bench models, as an alternative to training on patients, very relevant [9].

Ophthalmic surgery covers a wide range of different procedures, extending from operations of sight- and life-threatening diseases to cosmetic procedures. Generally, they can be divided into eye surface surgery, intraocular procedures, and procedures performed on the ocular adnexa, such as eyebrow, eyelids, and lacrimal apparatus (Table 1). Largely all procedures performed *within* the eye or on the surface of the eye are microsurgical procedures, requiring an operating microscope. This also means that often all extremities are used simultaneously during the procedure with the feet controlling the microscope and instrument pedal. Cataract surgery is by far the most commonly performed surgical procedure in ophthalmology, and in some countries nearly all surgical ophthalmologists perform cataract surgery in addition to specializing in another subspecialty. Procedures performed on the ocular adnexa, including strabismus and oculoplastic surgery, are sometimes performed using an

Table 1 Overview of surgical procedures performed in ophthalmology

Eye surface surgery and intraocular procedures	Anterior procedures Cataract surgery (e.g., phacoemulsification and manual small incision cataract surgery) Conjunctival procedures (e.g., pterygium removal) Corneal transplantation (e.g., penetrating and deep lamellar keratoplasty) Glaucoma surgery Laser procedures (including photorefractive and phototherapeutic keratectomy) Posterior procedures (i.e., vitreoretinal surgery) Retinal detachment surgery Retinal procedures (e.g., epiretinal membrane peeling and macular hole surgery) Vitrectomy surgery
Ocular adnexa surgery	Oculoplastic surgery Periocular surgery (including ptosis surgery) Eyelid surgery Lacrimal surgery Orbital surgery including enucleation or evisceration Strabismus surgery
Miscellaneous procedures	Ocular tumor surgery (including iridectomy and choroidectomy) Trauma surgery

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operating microscope or surgical loupes, depending on the individual surgeon's preferences.

Resident training in ophthalmology always includes some degree of surgical training; however, the extent of subspecialties included and volume of procedures required or expected differ widely from country to country. In any case, the constant development of new technology makes it difficult to keep up with skills to be mastered – both in complexity and multitude. Also the number of procedures performed is expected to rise as the result of the aging population [10]. This makes simulation-based training even more relevant: exposing surgeons to surgical experience without endangering the patients (e.g., sacrificing an eye for the purpose of training an oculist).

The Ideal Simulation-Based Curriculum in Ophthalmology (Practical Approach)

The ideal simulation-based curriculum consists of relevant facilities (models), an efficient structure (curriculum), and dedicated time for the trainee to practice and develop the needed skills. First of all, we need to consider which procedures in ophthalmology should be practiced using simulation.

Which Procedures in Ophthalmology Should Be Practiced Using Simulation?

One of the big challenges in ophthalmic surgical training is indeed that the majority of the techniques used are microsurgical, which makes them challenging to learn and teach. There is a variety of reasons for that, including the use of specialized instruments and materials that mostly are unfamiliar to junior surgical trainees, the importance of visuospatial awareness, handling of delicate tissue, and the necessity of a high level of dexterity where even minute incorrect movements can cause injury. This in addition to the mere practical issue associated with the use of operating microscopes, making it impossible for the supervisor to simply hand over the instruments to the trainee without having to remove the inserted instruments from the eye and change seats. Only after this, the trainee can reinsert the instruments and continue the procedure. All these elements make microsurgical procedures more prone to the flaws of the apprenticeship method and make simulation-based training in ophthalmology very relevant. Moreover, many of the procedures have long learning curves in combination with severe risks: For cataract surgery, surgical competency still improves well above the first 80 cases [11–13], and even for experienced surgeons, there is a significant association between annual surgical volume and risk of postoperative adverse events [14]. In addition to severe complications such as posterior capsule tear and vitreous loss, also potentially dangerous, increased intraocular pressure on the first postoperative day appears more often following resident-performed cataract surgery [15].

In conclusion, many of the procedures performed in ophthalmology are relevant to train in a simulated setting, especially all of the microsurgical procedures, such as cataract, corneal, glaucoma, and vitreoretinal surgery.

The next question to be answered is for which procedures do we have applicable training models. A wide range of animal and cadaver models have been reported for the training of various intraocular procedures, glaucoma surgery, corneal surgery, and oculoplastic surgery [16]. Practically, it is often easier to get access to animal models, such as porcine eyes, compared to cadaver eyes. Disadvantages using animal models are the infection risk and unfamiliar anatomy: for example, thickness and biomechanical properties of the porcine cornea deviate from the human cornea [17, 18]. Then there is the issue with the absence of vascular flow in dead tissue: live animal models have the vascular flow, which make it more similar to the human model, but are also more costly and require a rather big setup. This may be beneficial for advanced courses but probably not worthwhile for surgical novices.

Inanimate models have been described for strabismus surgery, corneal transplant, cataract surgery, vitreoretinal procedures, and various models for the training of photocoagulation procedures [16]. And then there are the models, which have not been described in research literature yet, such as the Kitaro model for cataract surgical training. One of the most difficult steps of the cataract procedure, the opening of the lens capsule (capsulorhexis), can be trained on numerous simple models, including red globe grapes [19] and aluminum foil [20]. The advantages using inanimate models are that they are readily available, often cheaper, and there is no infection risk; but the similarity may be moderate. However, the degree of similarity may be sufficient for the training of basic ophthalmic surgical skills.

Similar to other surgical specialties, there has been an increase in the number of available virtual-reality training models (Fig. 1). For cataract surgery in particular, there has been an overwhelming development in the number of virtual-reality systems [5, 6, 21–23]. And even better, a significant effect of virtual-reality training compared to standard or no training has been shown for cataract surgery [24–27] in addition to dacryocystorhinostomy [28] and laser procedures [29, 30]. A recent study showed that not only surgical novices benefit from virtual-reality training but also surgeons with an intermediate level of experience (defined as <75 completed surgeries) improve significantly by 38% after undergoing virtual-reality training [31]. One of the most obvious disadvantages using virtual-reality models is cost. However, including virtual-reality models at training institutions may seem to be cost-effective, especially for larger residency programs [32, 33].

Fig. 1 Picture of the Eyesi virtual-reality simulator

Instructional Approach

An optimal training curriculum would consist of structured training programs for different training levels and dedicated time during clinical work for training/supervision. Regular training with spacing of sessions (distributed learning) is of paramount importance, in addition to deliberate practice, task variability, and part-task training [34]. The training should be proficiency-based; the trainee moves on to the next training level when having mastered a specific and well-defined skill set (mastery learning) [35]. Providing feedback to the trainee also impacts the learning outcome significantly [36]. Dyad practice – training in pairs – has shown to be equally effective as individual training and may reduce costs associated with simulation-based training [37]. None of these learning techniques have been investigated specifically in ophthalmology, but we assume that the same general approaches are applicable to ophthalmic surgery as for other surgical specialties.

In addition to the training of technical skills, also the training of nontechnical skills such as communication, decision-making, and teamwork is of importance and should be included in the curriculum [38].

When designing specific courses for each training level, there is one central question to be answered: Which skills are relevant for what time in the training program? It may not be relevant to teach surgical novices highly specialized vitreoretinal techniques, or use expensive and advanced lifelike training models, if they do not get involved in similar operations in the near future. A needs assessment may be undertaken to make informed decisions on course content [39].

Particularly concerning the training of technical skills, a single model may not be suitable for all purposes of training; different models can supplement each other and support different aspects of the training.

Basic Skills Training Using a Variety of Simulation Models

A basic microsurgical course aimed at surgical novices in ophthalmology would optimally include demonstration of basic techniques and instrument handling intermixed with practical, supervised tasks on animal models (e.g., suturing eyelids, sclera, cornea, and eventually cataract surgery) [40, 41]. An intervening period would include theoretical/cognitive training using interactive methods, such as the cognitive computer simulator described by Henderson et al. [42]. This cognitive computer simulator, the "Virtual Mentor," facilitates interactive training of decision-making in challenging cataract cases. A basic course would also include regular intermittent training of basic tasks on a virtual-reality simulator and/or inanimate, take-home models, such as red globe grapes [19] or aluminum foil [20], preceded by thorough introduction to the models and techniques used. This training period, structured around well-defined learning outcomes, should be followed by a supplement wet-lab course on porcine eyes after a couple of weeks or months, allowing for the acquisition and retention of skills.

This approach supports deliberate practice and effective acquisition of a specific technical skill set in a safe environment combined with knowledge on relevant theoretical frameworks. Training on a virtual-reality simulator would be an interactive way to get to know the steps and sequence of the cataract surgical procedure, in addition to the training of basic technical skills, including the use of an operating microscope.

Henderson et al. have provided an excellent description of setting up a wet lab [43]. If it is not possible to obtain porcine eyes, other animal eyes or cadaver eyes can be used for the purpose. Various techniques have been described to simulate cataract of the human eye, including formalin- and microwave-induced cataract [16]. At present, the only commercially available virtual-reality simulators in ophthalmic surgery are PhacoVision (Melerit Medical, Sweden) and Eyesi (VRmagic, Germany), of which the latter has been studied substantially more and includes training modules on both cataract and vitreoretinal procedures.

Handling Complications

Next step – an advanced microsurgical skills course – may include training of vitreoretinal surgical skills, corneal transplant procedures, and glaucoma surgery, depending on the structure of the surgical program at the specific institution. For advanced training, relevant models include virtual-reality simulators, animal models, and even skill training on live animal models as the last training step before operating on patients.

One important aspect of advanced microsurgical training is the training of handling complications. A survey among ophthalmic surgical trainees at a single institution in the UK revealed that a very low number of trainees felt confident managing cataract surgical complications [44]. Optimally, advanced microsurgical training courses include training of handling complications, including the training of both technical and nontechnical skills. Virtual-reality models seem ideal for technical training of handling complications, and currently, it is possible to train the handling of errant capsulorhexis, difficult cataract cases, such as white cataracts, and the performance of anterior vitrectomy on the Eyesi simulator. Future technical developments will probably make it possible to train other relevant adverse events. A highly relevant nontechnical skill that should be included in cataract surgical training is the selection of correct intraocular lenses [45]. Saleh et al. have described the first scenario-based simulation setup employed in ophthalmology using a mock operating room to train serious ophthalmic patient safety events, including wrong intraocular lens implantation and wrong eye operation [46]. In vitreoretinal surgery, Grodin et al. have shown performance improvement after implementation of courseware based on the Systems Approach to Training (SAT), a concept of task breakdown and analysis, which is traditionally used in the aviation industry [47].

Skills courses for subspecialist training and skill maintenance for highly specialized procedures seem very relevant: complication rates have shown to improve continuously even for high-volume cataract surgeons, and surgeon (and center) experience has shown to impact survival rates of grafts following endothelial keratoplasty significantly [14, 48]. This evidence underlines that training is lifelong and should be part of the training culture in surgical specialties [9].

Performance Assessment and Feedback

The goals and learning objectives for each of the courses should be transparent and presented to the trainees in advance. Directed feedback and evaluation should be included throughout the courses, and all tasks should be trained until proficiency has been reached; the trainee moves on to the next training level when having mastered a specific and well-defined skill set, and not after a fixed time interval [49]. Depending on the simulation model used, different tools for assessment of proficiency are applicable: automated assessment (e.g., virtual-reality simulator metrics) [26, 51], motion-tracking analysis [40, 52], and human rater assessment including global rating scales (ESSAT) and task-specific checklists (OWLSAT, CEIVITS, and OSACSS) [50, 41, 53–55]. It is necessary to consider possible sources of bias; objectivity is essential, including evidence on reliability and validity. Thus, the use of human rater assessments ideally includes the masking of raters and, often, training of raters is also needed. Additionally, cost and time must be taken into consideration: a cost analysis study concluded that the Eyesi simulator was most cost-effective for simulation-based surgical assessments in ophthalmology [33]. When the trainee moves into the operating room, additional assessment tools may be applied: outcome data (e.g., complication rates), various motion-tracking tools, and human rater assessment tools including human reliability analysis. Most importantly, multiple assessment tools are required to make reliable performance assessments of each surgical trainee [56].

Again, it is essential to define which skills are deemed relevant for which level of training. Furthermore, it is important to state the purpose of the assessment: Is the evaluation of skills intended for giving the trainee feedback for improvement (formative assessment), or is the purpose to measure the level of proficiency by comparing it against a benchmark level (summative assessment)? Some of the assessment tools are most useful for formative assessments, and other tools are developed exclusively for summative assessment purposes. However, both types of assessments are relevant for the effective acquisition of technical skills and should be included in ophthalmic surgical training programs.

Requirements for Proficiency-Based Training

Proficiency-based training, i.e., training to criterion, requires both explicit characterization of performance objectives and application of summative assessments, i.e., measurements of trainee performance. To ensure sound evaluations and decision-making, evidence of validity for the measurements used is a basic requirement. For cataract and vitreoretinal surgery, including a virtual-reality simulator such as the Eyesi in the training program enables the use of automated feedback and leads to relatively easy implementation of proficiency-based training. Proficiency-based training programs, including definition of relevant benchmark levels (pass/fail levels), have been developed for cataract surgical training on the Eyesi simulator [51, 57]. For those simulation models where a benchmark level has not yet been defined, or in case previous defined levels cannot be applied due to a different target group, validity of performance measurement results must be verified and relevant benchmark levels defined.

Due to the continuing development of technology and hereby changes in performance measurements, gathering validity evidence for the assessment tools is an ongoing process.

Current Use of Simulation in Ophthalmology

Traditionally, mostly wet-lab training on animal models has been used as training intervention in ophthalmology (Fig. 2). During the last decade, the implementation of virtual-reality training in resident training programs has been dominant in addition to wet lab. This is evident from the growing quantity of research literature based on the Eyesi simulator [16]. There has certainly been a primary focus on the training of technical skills, but training interventions with focus on non-technical skills are gradually gaining ground.

The structuring of training courses has traditionally been massed practice with half- or full-day courses at specific times during residency. Currently, a combination of time-based and proficiency-based training is used. When the trainees start operating on patients, the normal approach is a backward step-by-step technique where the trainee starts by performing the last step of the procedure until proficiency has been shown and then moves on to performing the last two steps of the procedure and so forth. However, training programs and instructional methods may differ from institution to institution and sometimes even from supervisor to supervisor.

After implementation of a structured cataract surgical curriculum, including training on the Eyesi simulator, studies have shown a reduction in operation time [58, 59], and one study reports a significant reduction in complication rates [60]. One example of a proficiency-based curriculum in cataract surgery is the Iowa Ophthalmology Wet Laboratory

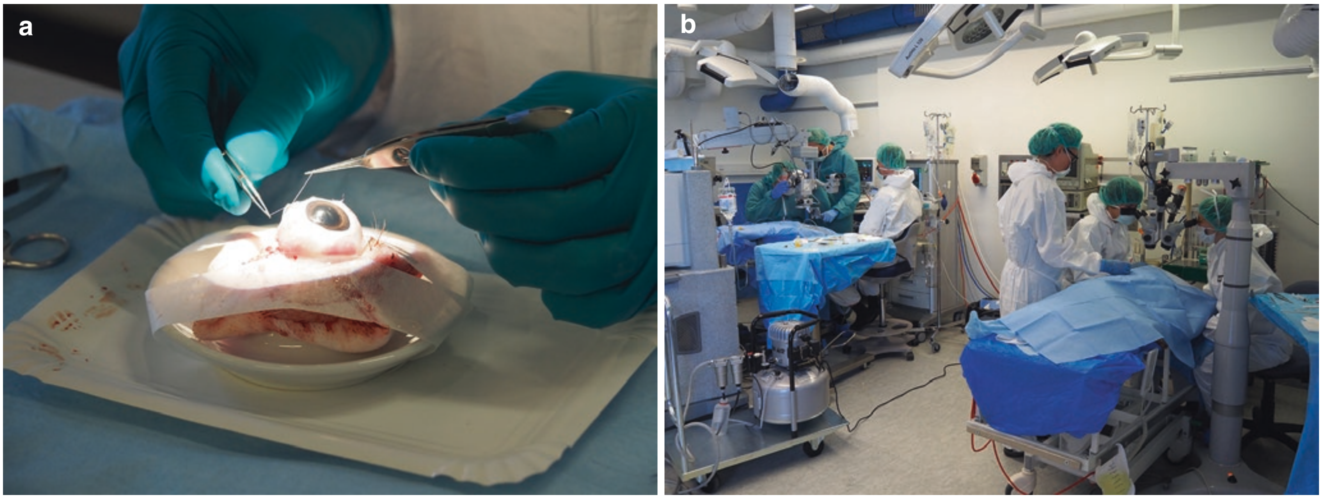

Fig. 2 Traditional wet-lab training in ophthalmology: **a**) using porcine eyes, or **b**) live pigs under anesthesia

Table 2 Example of learning objectives in a proficiency-based wet-lab curriculum in cataract surgery

First-year resident Iowa Ophthalmology Wet Laboratory Curriculum	
Objectives	
During the 10-week rotation at the Iowa City Veteran's Affairs Medical Center, the first-year resident will have five half-day sessions in the wet laboratory with staff supervision. Additional unsupervised individual practice time in the wet-lab is required, and the resident should maintain in his or her resident portfolio a log of supervised and unsupervised wet laboratory attendance	
As a prerequisite to the wet laboratory experience, residents are required to read *Cataract Surgery for Greenhorns** and *Phacodynamics*† in 2 weeks before beginning the service so that optimal time may be spent in the wet laboratory and operating room	
The objectives of the wet-lab are as follows:	
1.	To demonstrate fine motor and proprioception skills while operating under the microscope
2.	To demonstrate proficiency in working in a small surgical field as both a surgeon and assistant using the microscope
3.	To list the differences in phacoemulsification machines and the settings for each machine
4.	To describe the pedal settings on a phacoemulsification machine and demonstrate the use of the pedal for the microscope
5.	To demonstrate performance of five adequate corneal and scleral incisions for cataract or glaucoma surgeries using a cadaver or animal eye
6.	To identify the steps of phacoemulsification
7.	To demonstrate performance of the steps of phacoemulsification on pig or cadaver eyes
8.	To list the various types of ophthalmic sutures
9.	To demonstrate ability to pass corneal, scleral, and simulated conjunctival or skin sutures for closure

*Oetting TA. Cataract surgery for greenhorns. Available at http://webeye. ophth.uiowa.edu/eyeforum/cataract-oetting.htm. Accessed March 27, 2006
†Seibel BS. Phacodynamics: Mastering the Tools and Techniques of Phacoemulsification Surgery. 4th ed. Thorofare, NJ: SLACK Inc.; 2005.
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Table 3 Example of a proficiency-based cataract surgical training program on a virtual-reality simulator (Eyesi)

Module no.	Task name	Task description	Total no. of levels	Test level	Points
1	Intracapsular navigation	Aiming at objects within the capsule with the tip of instrument (abstract task)	3	2	0–100
2	Antitremor training	Following a circular path on the capsule with the tip of instrument (abstract task)	7	4	0–100
3	Intracapsular antitremor training	Following a circular path within the capsule with the tip of instrument (abstract task)	5	2	0–100
4	Forceps training	Collecting objects in the anterior chamber with the forceps (abstract task)	4	4	0–100
5	Bimanual training	Aiming at objects simultaneously with two instruments (abstract task)	5	5	0–100
6	Capsulorhexis	Performing a continuous curvilinear capsulorhexis (procedural task)	3	1*	0–100
7	Phaco divide and conquer	Performing phacoemulsification on a medium-hard lens (procedural task)	8	5	0–100
		Total score in two consecutive sessions			>600

*Capsulorrhexis: Weak zonula. No initial tear

Curriculum for first-year residents, comprising needs assessments on an individual level, pre- and posttests, and both formative and summative feedback. See Table 2 for the explicit performance objectives of the curriculum [50].

An example of a proficiency-based virtual-reality training program on the Eyesi simulator is the Copenhagen cataract surgical training program, which is compulsory prior to clinical practice in the Capital Region of Denmark (Table 3) [51].

How This Field Is Uniquely Applying Simulation for Training That Others Should Learn from?

In ophthalmology, long learning curves may indicate that also surgeons with intermediate experience may have effect of simulation-based training [31]. Using simulation models, interesting studies have been performed on other aspects of surgery, for example, evaluation of instruments [61], a voice-controlled vitrectomy machine [62], and robot-assisted surgery [63, 64]. One study has investigated the impact of auditory force feedback in vitreoretinal surgery and concluded that it leads to significantly improved performance in a simulated setting [66].

Future Directions

Further technical advancements are promising for the future potentials in simulation-based training in ophthalmology. Possibly, future possibilities will include the training of individual patient cases – mission rehearsal – on virtual-reality models.

Unfortunately, it seems like the biggest challenge is to implement instructional approaches that already have shown to be effective, such as spacing of sessions (i.e., distributed practice), continuous feedback (part of deliberate practice), and task variability (including different models and tasks). Administrative issues make it challenging to apply *distributed* training to a predefined *proficiency level* as compared to full-day training sessions of fixed duration in a surgical training curriculum. However, the increase in available inanimate and virtual-reality training models makes it easier to add intermittent training to traditional wet-lab courses due to automated feedback mechanisms and take-home training models.

Future research may focus on clarifying which components are best trained in wet-lab versus a virtual-reality environment. Also an extended understanding of transfer of skills (and direction) between procedures could lead to more effective surgical training programs in ophthalmology [66]. Finally, further knowledge on the impact of training interventions on patient-related outcomes and return-of-investment studies is needed.

Nevertheless, there are limits to *how much* we can optimize training programs, and ideal training should be a deliberate combination of structured simulation-based training, supervised experiential learning, and clinical experience.

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Simulation in Vascular Surgery

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Introduction

The current trend in surgical training is a move away from the traditional Halstedian apprentice model of graded responsibility to a more structured curriculum-based approach requiring documentation of proficiency [1]. Traditional resident educational paradigms have shifted as a result of changes in healthcare over the past decade. Mandated restrictions on resident work hours, shorter hospital inpatient length of stay, and the development of outpatient surgery have led to a striking reduction in training opportunities for surgical residents. In the setting of quality-assurance targets, increased public scrutiny and concern for healthcare quality and safety, and ethical concerns of "practicing" on patients, it is no longer acceptable, or appropriate, for residents at any level of training to practice new skills on patients, even if they have a patient's explicit consent [2–6].

Concurrent with these trends and their impact on general resident training, dramatic technologic advances have transformed the field of vascular surgery. Advances in technology, devices, and techniques have pushed the specialty from a subfield of general surgery into an entirely new area of expertise with its own independent board certification and training programs. Vascular surgery faces the additional challenges of a rapidly changing field in which technologies have drastically impacted the practice of vascular surgery. The scope of pathology once relegated entirely to open surgical management is shifting increasingly and exponentially toward endovascular interventions as endovascular therapies are increasingly utilized to treat patients with peripheral vascular disease, abdominal aortic aneurysms, and carotid artery disease [7–12]. The result is a field in which open operations are less often encountered by trainees, and those circumstances requiring an open procedure involve highly complex and challenging cases unsuitable as training material even for senior residents. This shift away from open vascular operations has resulted in both fewer open operations for training in traditional open vascular techniques and a need to introduce catheter-based techniques to novice vascular surgical trainees [13–16]. Nevertheless excellence in open surgical techniques is still required of surgical residents, and incorporation of endovascular training into the curriculum of vascular training is now considered essential [17, 18]. This has all occurred in the setting of paradigm shifts in vascular surgery training. Residents can now enter a vascular surgical training program directly out of medical school. This training model is becoming more popular, and the number of programs offering the 0–5 training curriculum continues to increase. These integrated 0–5 vascular residencies pose new educational challenges as residents entering the specialty have very limited or basic surgical skills and little to no endovascular experience.

In response to these external constraints, surgical skill and simulation centers have emerged at academic institutions across the USA. A consensus statement from the Society for Vascular Surgery (SVS), the American College of Cardiology (ACC), and the Society for Vascular Medicine and Biology (SVMB) published in 2005 encouraged simulation, stating that "In an effort to assist physicians with differing backgrounds and skills to reach a common benchmark of proficiency, metric-based simulation should be incorporated into training. This will provide skills acquisition in an objective manner, based on real-world situational experience" [19]. Surgical skills laboratories and simulation training allow for

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motor skill acquisition in a structured, stress-free environment free of adverse consequences to actual patients. Basic surgical skills are learned and practiced on models and simulators, with the aim of better preparing trainees for the operating room experience [20, 21]. Simulators offer the ability to perform multiple procedures while avoiding the real life time challenges of anesthesia induction, room turnover, and paperwork. Additionally, simulation can allow novices to perform repeated attempts at the same intervention without risk to a human patient. Simulation also provides an excellent opportunity for error analysis and simulated management of procedural complications [22]. Used properly, simulation offers an economic use of training time which is perhaps the most valuable resource to a residency program. In a recent survey of current trainees, 86% of respondents report that they believe there is educational value in simulation. Fifty-six percent of programs currently offer simulation training, most commonly in the form of peripheral endovascular simulators (70%), anastomotic models (58%), or endovascular aortic aneurysm repair simulation (53%), and more than a third of current fellows and senior residents (37%) have attended outside simulation courses [23].

This chapter will provide an overview of the results of available studies utilizing simulation to teach vascular techniques and discuss the potential benefits of using simulation in vascular surgery training.

Simulators Used in Vascular Surgery

Numerous simulation devices exist for vascular surgical training each with its own benefits and shortcomings. These models can be broadly characterized into five categories: low-fidelity synthetic, high-fidelity synthetic, animal, cadaveric, and virtual reality. Endovascular procedures lend themselves to simulation technologies much in the same way that laparoscopy does as 2D imaging leads to an ease of developing high-fidelity simulation.

The earliest versions of synthetic models for vascular trainees came in the form of benchtop anastomotic models. These required only a stable platform, graft material, suture, and basic instruments. With these mock-ups, structured, low-risk practice could be performed and was shown to be useful (primarily for junior residents) in improving skill [24]. Newer synthetic models range from simple to extremely high fidelity. Blood vessel anatomy can be synthetically simulated using devices as simple as a plastic tube to complex multi-material sculptures (Fig. 1). Synthetic models can be inexpensive and are the most broadly available tools for vascular simulation. Synthetic models can also be created for endovascular use. Systems of pressurized tubes can be used to simulate stent placement and catheter manipulation.

We know from the aviation literature that level of simulator fidelity needs to be matched to stage of skill acquisition. Low-fidelity simulators (e.g., synthetic models) are appropriate for early training (cognitive stage) of novice learners, whereas high-fidelity simulators are more appropriate for advanced and more experienced learners.

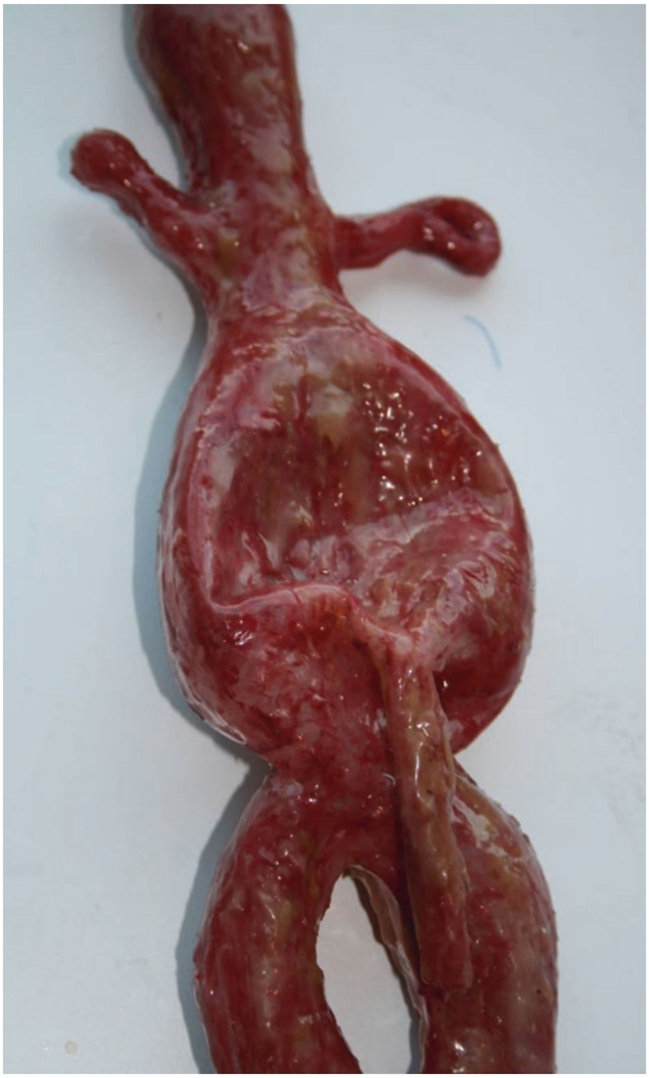

Fig. 1 Example of high-fidelity simulated synthetic abdominal aorta

Low-Fidelity Models

Low-fidelity simulations use materials and equipment that are different from those of the actual task considered. Partial-task trainers have always been applied to open surgery in the most basic forms. These models consist of 3D representations of body parts or body regions and provide functional anatomical landmarks useful for learning a particular skill. For example, plastic arms can be used for practicing venipuncture, or blue phantom models can be used for practicing ultrasound-guided percutaneous access skills. These basic models allow novice learners to practice the individual tasks of a procedure. The downside of using these models is that the interface with the user is passive and procedures are performed with no response from the simulator [25].

Whereas partial-task trainers allow for simulation of a specific or individual skill, procedure-specific trainers allow for simulation of a group of tasks in chronological order of an operation or part of an operation. These models are usually made from silicon or rubber and contain various levels of realism. Examples include the models manufactured by Limbs & Things (Bristol, Avon, UK). These inanimate models are used to practice open surgical skills including saphenofemoral junction dissection and ligation, carotid endarterectomy, and aortoiliac aneurysm repair (Fig. 2). These models are currently utilized in our own vascular skills lab to teach junior-level residents. These models are portable and easy to set up but tend to be relatively expensive requiring replacement of their main components. They will be discussed further below.

Fig. 2 Procedure-specific trainers allow for simulation of a group of tasks in chronological order of an operation or part of an operation. These models are manufactured by Limbs & Things (Bristol, Avon, UK) and are used to practice open surgical skills including saphenofemoral junction dissection and ligation, carotid endarterectomy, and aortoiliac aneurysm repair. Commercial companies (Limbs & Things, Bristol, Avon, UK) manufacture inanimate organ parts for saphenofemoral junction dissection and ligation, carotid endarterectomy, and aneurysm repair

Low-fidelity model partial-task trainers are also available for endovascular skills training. These models are relatively inexpensive (~$3000/unit) compared with the higher-fidelity models. These models are effective for learning basic endovascular skills and allow for tactile force feedback to be experienced by the learner while using real wires, catheters, balloons, and stents. Unfortunately, one-time use of the equipment can be costly, adding to the expense of training, and these models lack realism and face validity.

A low-fidelity endovascular model, the Simulator for Testing and Rating Endovascular Skills (STRESS), has recently been described [26]. This simple low-tech model consists of a light source covered by a container which holds a dry glass model of the abdominal aorta and renal and iliac arteries with various stenotic lesions, elongations, and tortuosities. The model does not require fluoroscopy, contrast, running water, balloons, or stents. A camera mounted above the glass model provides a view of the entire "abdomen" on a monitor (Fig. 3). Using computer software, a plain abdominal radiographical image is merged with the live-camera feed, replicating a plain fluoro-mode while blurring the few visible edges of the glass model. Real catheters and guide wires can be introduced into the introducer sheath prepositioned in the external iliac arteries. Wire and catheter skills can be practiced while looking at the computer screen, giving the impression of using fluoroscopy. Contrast angiography can be simulated in the live view, replicating a non-subtracted, single-shot, contrast injection, which disappears after a few seconds.

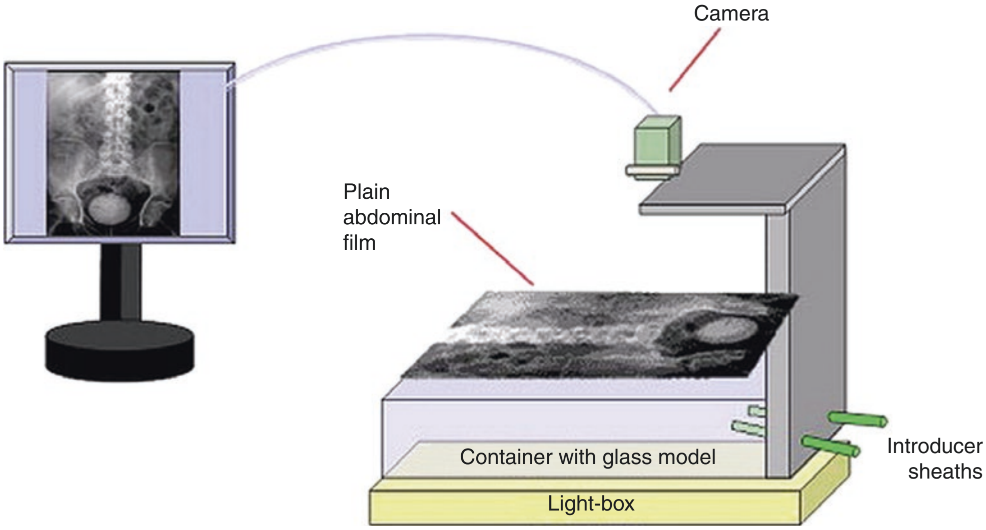

Fig. 3 Schematic drawing of the STRESS machine which consists of a light source covered by a container that holds a dry glass model of the abdominal aorta and renal and iliac arteries with different tortuosities and stenoses. A camera placed above the glass model provides a view of the entire "abdomen" on a monitor. Using computer software, a plane abdominal radiographical image is merged with the live-camera feed, replicating a plain fluoro-mode. Introducer sheaths are prepositioned

High-Fidelity Models

An example of a higher-fidelity synthetic system is the pulsatile flow aortic model developed by Vascular International Foundation and School (VI). A group in Europe dedicated to providing supplementary training for vascular surgeons through short, intensive courses with hands-on skills training (for both open and endovascular procedures), VI has been offering training for over 20 years. This model has been widely embraced in Europe, where work hours are limited to 48-h weeks, as a means for trainees with insufficient operative exposure to gain experience. Furthermore, as training models vary widely throughout the European Union, these standardized teaching methods can ensure some measure of homogeneity in training. These techniques of standardized training have proven to be superior in a randomized study compared to traditional techniques, with the standardized group demonstrating improved technical scores (95% vs. 75%) and global rating scores (84% vs. 67%) [27]. These short training courses have also been shown to improve technical performance and quality on both carotid patch angioplasty and open aortic repair [28, 29]. Their open aortic model (Figs. 4 and 5) features a pulsatile flow system and a mock-up of abdominal contents. Using a replaceable aorta, trainees are able to experience a realistic feel of the vessel wall when performing an anastomosis. The synthetic abdominal contents allow for the rehearsal of retractor and clamp placement. Another benefit of this system is the pulsatile flow which allows for identification of defects in the anastomosis. The main drawback of the model is price and limited portability which preclude daily use by residents.

Animal Models

Animal models offer a high degree of realism and animal labs are still used for open and endovascular training. We have used animal models in our institution to teach senior-level residents and endovascular fellows techniques for iliofemoral angioplasty and stenting as well as open aortoiliac artery replacement. Animal models have also been used as test models for endovascular devices. Arterial stenosis and aneurysmal disease can be artificially induced through endothelial injury or sutured patches, respectively [30–32]. Use of animal models is limited. The animals can be expensive, especially if used for only one or two procedures, require special facilities and instruments, and have anatomical and size differences compared with humans. Furthermore, there are ethical and legal constraints associated with using animal models. Despite these limitations, large animal models do offer a highly realistic training opportunity for advanced interventions that cannot be simulated by a computer model.

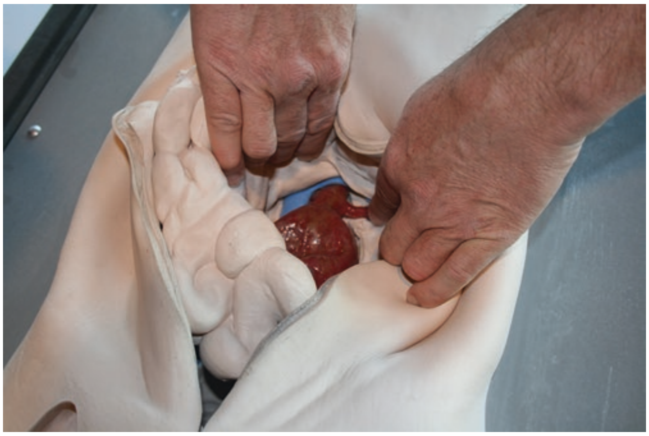

Fig. 4 Vascular International Foundation open aortic model

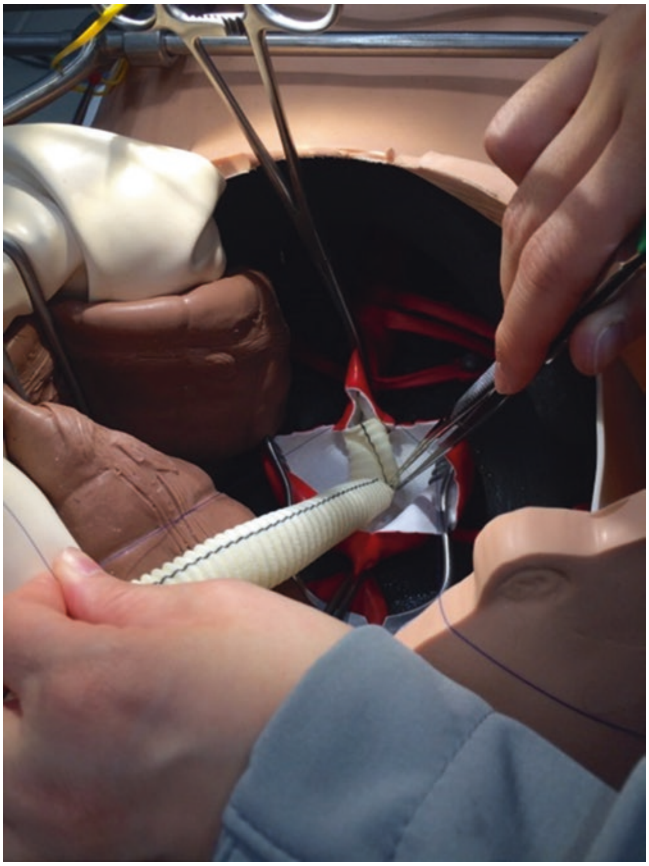

Fig. 5 Vascular International Foundation open aortic model

Human Cadavers

Human cadaver models provide realistic conditions for both open and endovascular training. Human cadavers remain a mainstay in medical school education and are making a resurgence in surgical training as well. The American College of Surgeons (ACS) and Association of Program Directors in Surgery (APDS) have recently mandated incorporation of phase II modules into the surgical curriculum. A large majority of the modules include human cadaver dissection and practice of sentinel procedures. Cadavers, like animal models, have also been utilized to test endovascular devices. Garrett and colleagues describe how pulsatile antegrade arterial flow can be established in the arterial system of a fresh human cadaver following a thrombolytic process [33]. Endovascular procedures with standard arterial punctures and closures have been performed using this model. While this cadaver model provides the most realistic model to practice open and endovascular skills, use of this model is limited by restricted availability and cost associated with preservation and storage of the bodies.

Virtual Reality Simulation

Virtual reality (VR) is defined as computer technology that allows for a user to perform an operation or procedure in real time using a simulated three-dimensional system. VR simulation has been used extensively in high-stakes industries such as the airline, nuclear, and oil industries. In the aviation industry, it has been effective in providing pilots a means of training without actually flying an airplane [34–36]. Successful utilization of simulation in aviation ultimately led to the development of simulation programs applicable to minimally invasive surgery with Satava first proposing the use of the surgical simulator in 1993 [21].

Endovascular therapy poses technical challenges similar to those experienced in minimally invasive surgery, including reduced tactile sensation, and the need to overcome the proprioceptive-visual issues of working in a three-dimensional field displayed on a two-dimensional fluoroscopy screen. Several endovascular VR simulators are commercially available and include the Procedicus Vascular Intervention System Training (VIST™) simulator (Mentice AB, Götenborg, Sweden), the ANGIO Mentor™ (Simbionix, Cleveland, Ohio), and the SimSuite® (Medical Simulation Corporation, Denver, Colorado). These high-fidelity simulators include haptic, visual, and aural interfaces that provide near-realistic representations of the real procedure. These simulators provide a variety of training applications and include modules for angioplasty and stenting of the carotid, renal, coronary, superficial femoral, and iliac arteries. More recent technology has allowed for simulated aortic aneurysm repair, neuro-interventions, closure of patent foramen ovale, deployment of a caval filter, and implantation of cardiac pacemaker leads.

Fig. 6 The Procedicus Vascular Intervention System Training (VIST™) simulator comprises a mechanical unit housed within a plastic mannequin cover, a high-performance desktop computer, and two display screens. Modified instruments are inserted through the access port using a haptic interface device. Performance is measured using metrics such as volume of contrast used, fluoroscopy time, and markers of stent placement accuracy

The Procedicus Vascular Intervention System Training (VIST™) simulator comprises a mechanical unit housed within a plastic mannequin cover, a high-performance desktop computer, and two display screens (Fig. 6). Modified instruments are inserted through the access port using a haptic interface device. Commercially available simulation modules can mimic arterial occlusive disease in the coronary, carotid, renal, and iliofemoral regions and over the wire lead placement for biventricular pacing. The learner selects appropriate instruments to perform virtual interventional procedures using the simulated fluoroscopic screen. Performance is measured using metrics such as total procedure time, fluoroscopy time, and markers of quality of performance such as stent placement accuracy (Table 1).

The ANGIO Mentor™ Ultimate endovascular trainer has a similar range of arterial procedures as the VIST™. It differs from the VIST™ in that there is greater emphasis on patient monitoring, drug administration, and response to physiologic disturbance. For example, atropine can be administered to correct for bradycardia related to simulated carotid sinus stimulation. Appropriate therapies can also be provided for hypoxia and hypertension. This device allows for simulated complications to occur so that management of the complication can be practiced in a virtual environment. Two more affordable and portable versions of the simulator are now available, the ANGIO Mentor™ Express and ANGIO Mentor™ Mini (Fig. 7). These devices have a similar simulation package with less peripheral attachments such that the Mini can be transported in a handheld case.

The SimSuite® is a larger simulator system with up to six interactive screens to facilitate multidisciplinary team training (Fig. 8). This system provides multispecialty training packages and personnel to support the training program. These simulators allow for pre-procedure briefing, patient

Table 1 Comparison of VR endovascular trainers

Device	Description	Modules	Assessment parameters	Validation studies
Procedicus VIST™	Part procedure simulator Haptic feedback Metric assessment	Neuro-interventions Coronary Carotid Renal Iliac/SFA	Quantitative metrics Qualitative metrics Clinical parameters Technical errors	Face validity Construct validity Transfer of training
ANGIO Mentor™	Part procedure simulator Haptic feedback Neurological and pharmacological responses Metric assessment	Coronary Carotid Renal Iliac/SFA	Quantitative metrics Qualitative metrics Clinical errors Hemodynamic features Handling of complications	Ongoing studies
SimSuite®	Part procedure simulator Haptic feedback Neurological and pharmacological responses	Neuro-interventions Coronary Carotid Renal Iliac/SFA Closure patent foramen ovale	Quantitative metrics Qualitative metrics Clinical parameters Technical errors Hemodynamic features Handling of complications	Training study Ongoing studies to determine construct validity and benchmark performance

Fig. 7 The ANGIO Mentor™ Ultimate endovascular trainer has a similar range of arterial procedures as the VIST™ with more advanced haptic technology. The ANGIO Mentor™ Express and ANGIO Mentor™ Mini have similar simulation packages but with less peripheral attachments such that the Mini can be transported in a handheld case

Fig. 8 The SimSuite simulator provides tactile "haptic" feedback and displays real-time imaging and physiologic information

intervention, and post-procedure analysis. Similar to the ANGIO Mentor™ system, response to patient physiology is a feature of this simulator.

Virtual reality simulators have an advantage over low-fidelity simulators in that they have software capable of providing metric feedback. Learner's skill can be objectively assessed, and output metrics can be used for objective evaluation and feedback of trainee progress. This provides an avenue for both self-directed learning and curriculum development. Some endovascular simulators also allow for surgical planning. Specific anatomical details of the patient from radiologic images can be installed into the simulator computer and the planned procedure can be rehearsed on the simulator prior to performing the same procedure on the patient. VR simulators have the added advantage of reuse ad infinitum and have no associated ethical issues related to their use.

There are, however, several limitations to using VR simulators for endovascular training. The most obvious limitation is the exorbitant cost of the simulator. Most of these devices cost more than $100,000 for a single unit and many additional thousands for maintenance over time. Endovascular simulators require regular maintenance and housing space. The need for constant software updates and calibration often necessitates a full-time technician to manage technical failures, regular calibration, and maintenance and updating of required software. In the current setting of vascular surgical training, with one or two fellows training at a given institution at one time, it is hard to justify the expense of a simulator when there is currently little data to support their validity and transferability. One proposed low-cost alternative is to set up regional centers where fellows could travel periodically for short training sessions [37]. Current training on the simulator is also limited by challenges in unrealistic tactile feedback and graphical interfaces. Significant improvement in haptic response and realism of the virtual environment are needed. Until the realism and the high cost of these simulators improve, it will be difficult to transition these devices out of the research labs into the training labs. Finally, it must be recognized that these devices are still partial-task simulators as they cannot teach some of the important skills associated with endovascular cases such as arterial puncture and closure.

In addition to use in training, vascular surgery simulation must be considered for its potential to revolutionize testing and assessment of vascular surgical skills.

Methods of Assessment

Traditionally competency in surgery has been defined as completion of a defined length of training or number of cases. In fact, this still holds true for endovascular procedures [38]. Other than some skills lab incorporation, there are currently no clear guidelines from the ACGME with regard to simulation training in vascular surgery. Additionally, at this time no US specialty board accepts simulation experience as a proxy for patient case logs. Operative log data lack content validity as they only indicate the volume of operations performed and do not capture procedural understanding, participation, or performance level. As such they are recognized to be an unreliable and indirect measure of technical skill [39, 40]. And it has been demonstrated that no correlation exists between the individuals' operative experience as reported by case logs and their technical performance [41]. There is now increasing recognition that the number of procedures performed and time in training does not equate to expertise. As a result, the trend in medical skills training is to move toward using objective assessment tools to demonstrate technical competence.

Formal testing of surgical dexterity is not a modern concept. Fellowship in the Royal College of Surgeons required a technical skill exam through the early 1940s. In the USA, the American Board of Surgery conducted intraoperative assessments on prospective candidates through 1952. Both practices were halted due to logistical problems such as time, cost, and standardization.

In a prospective randomized trial, residents' scores on the multiple-choice American Board of Surgery In-Training Exam (ABSITE) did not correlate with their technical ability measured by either skill testing or intraoperative assessment [42]. This supports the findings of a pilot technical skill assessment conducted with the European Board of Surgery Qualification in Vascular Surgery exam in 2002. European candidates performed a saphenofemoral junction ligation and a tibial artery anastomosis on open models. Additionally, dexterity was assessed with a knot-tying test. Internal consistency was demonstrated among the three technical exams, but the study found no correlation between technical ability and the candidates' scores on an oral knowledge examination. Currently, the multiple choice Vascular Surgery In-Training Exam (VSITE) is the only standardized test given during vascular surgery residency, and no standardized method exists for surgical skill evaluation. Written and oral examinations, the established markers of surgical competence, only assess knowledge base and clinical reasoning and do not evaluate technical performance or nontechnical skills critical to managing an operation or crisis scenario. In most programs, direct observation has been the only assessment tool utilized for the appraisal of technical ability. Simulation-directed surgical skill testing offers a potential solution to these issues.

There is some evidence supporting simulation as a valid means of skill testing in vascular surgery. Two studies have shown that performance of a carotid endarterectomy on a benchtop model can discriminate senior from junior trainees, but not more advanced levels [43]. Bench models may not properly evaluate complex decision-making and crisis resolution. Technical competence on a bench model may not translate into an independent environment. Therefore evaluating technical competence during crisis may help delineate these advanced trainees. Simulated procedures in high-fidelity operating room theaters have been used successfully in this regard [44].

The Imperial College Surgical Assessment Device uses electromagnetic sensors to track hand movements. Economy of motion during simple tasks such as knot tying has been shown well to correlate with dexterity in complex procedures. No correlation with endovascular skill has yet been demonstrated. Virtual reality systems can often offer direct feedback metrics such as procedure time, fluoroscopy time, handling errors, and contrast volume.

Observer assessments can be performed with checklists, global assessments, or some hybrid method.

Methods of assessing performance and improvement in performance in a surgical skill are essential to the development and implementation of a vascular surgical skills lab. Objective measures of skills performance utilized in skills training will be discussed below.

Time-Action Analysis

At its simplest, a scoring system for skills training may include time and errors. Time-action analysis has been used extensively as a method of objective assessment of performance in open and minimally invasive surgery [45–47]. The method can be applied to real life or simulator performance and involves breaking the procedure down into a series of steps with performance analyzed by how long the learner takes to complete the task [48, 49]. This procedure is very personnel and resource intensive because of required setup and video analysis. Decreased time to perform the task may indicate progression of skill, but the amount of time taken to complete the individual procedural steps does not in and of itself offer any measure of the quality of the performance. Therefore, time-action analysis may require supplemental markers to fully assess progression of skills.

Error Analysis

The 1999 National Academy of Science Institute of Medicine report, “To Err is Human,” raised awareness of patient safety issues [50]. “Error in the performance of an operation” was cited as one of the leading causes of patient deaths in hospitals. The uncontrolled introduction of laparoscopic cholecystectomy made the public and surgical community more aware of the implications that surgical training could have on patient safety [51]. Cost issues related to surgical complications have made third-party payers keenly aware of training and surgeon competency; as a result, human reliability and error analysis is now an evolving field in healthcare.

Error scores have been proposed as discriminators of technical skill though inherent difficulties exist in defining surgical or medical error as there is no standardized taxonomy [52]. It is, however, possible to differentiate technical skill by examining both the frequency and type of error committed during laparoscopic cholecystectomy and pyloromyotomy [53–55]. To date error analysis in endovascular training and assessment is at an early stage with no reported studies examining this question in vivo. Modern simulator technology allows reporting of catheter and device handling errors. Patel et al. reported a reduction in the composite catheter handling error scores of interventional cardiologists performing a virtual carotid angiogram following simulator training [56].

Motion Analysis

Motion analysis may offer a less time-consuming option. Efficient and purposeful hand movements are a discriminator of technical skills in surgery [57]. The technology is already available, and indeed surgical dexterity is currently assessed using this modality for the open surgery portion of the European Board of Surgery Qualifications in Vascular Surgery (ESBQ VASC) examination. The Imperial College Surgical Assessment Device (ICSAD) is used to track hand movement in three dimensions using electromagnetic sensors with a composite score based on economy of motion and qualitative analysis [58]. Clearly this technology is associated with significant cost. Nonetheless, this is a potentially exciting area for future research with no published studies to date examining hand motion analysis in the open vascular and endovascular arena.

Objective Structured Assessment of Technical Skills (OSATS)

Beyond simple metrics, rating of technical performance by expert observers remains an important assessment tool. In 1996 at the University of Toronto, Faulkner, and colleagues, under the direction of Richard Reznick, introduced the Objective Structured Assessment of Technical Skills, or OSATS. A global rating scale (GRS) is a quantitative assessment tool based on appraisal of seven aspects of quality in operative performance. Each component is evaluated on a 5-point grading scale. The items included respect for tissue, time and motion, instrument handling, knowledge of instruments, use of assistants, flow of operation/forward planning, and knowledge of the specific procedure [24]. This method has been demonstrated to differentiate between experience levels in both open and minimally invasive surgery [59–61].

A modified GRS has been shown to differentiate endovascular experience and training using a VR simulator. Hislop et al. have proven the construct validity of an OSATS-derived Modified Reznick Scale (MRS) for post hoc video-based rating by two blinded observers during a virtual selective carotid angiography [62]. The first two studies examining VR transfer of training to the catheterization lab both used the modified rating scales [63, 64]. Tedesco et al. have demonstrated that a single-blinded expert observer was able to discern differences in endovascular experience during a virtual renal artery stent procedure using a structured global rating scale [65]. Although the EVEREST study included only experienced interventionalists, interventionalists who scored high on the OSATS-derived generic rating scale were more likely to be experienced in CAS [66].

Procedure-based assessments possess high inter-rater reliability ($G > 0.8$ using three assessors for the same index procedure), excellent construct validity, and positive user satisfaction and acceptability (trainees and reviewers). The tool, however, is very procedure-specific and long (checklist of up to 62 items) which limits its practicality for use in evaluating common but increasing complex hybrid open and endovascular procedures.

Procedure-specific checklists used in conjunction with GRS have been shown to be effective and reliable assessment tools of surgical dexterity using synthetic and cadaveric models as well as in live operating [67, 68]. Post hoc video analysis, though not mandatory, does reduce the potential for bias. The main disadvantage of this mode of assessment is that a large amount of time is required from expert assessors. Full-length video viewing is required as edited video assessment appears to reduce the reliability of assessment [69]. Based on a systematic review of methods of assessment, checklists and global rating scales presently appear to be most accepted as the "gold standard" for objective technical skill assessment. Their use in the OR, however, has been limited partly due to the variability of operative procedures (i.e., they do not all conform to a standardized checklist), the time required for completion of these tools, and faculty familiarity with these tools and their application. Furthermore, benchmark levels of performance for these assessments have not been defined. While these shortcomings should not prevent their use for formative assessment (assessment for learning, i.e., feedback and discussion), they may prohibit use for high-stakes examinations (summative assessment).

VR Simulators

The major advantages of VR simulation are the ability to automatically and instantly provide an objective performance report based on quantitative and qualitative assessment parameters. Error scores and rating scales can be used in combination [62, 63, 70]. Used in a standardized setting, it is possible to distinguish between subjects of different levels of experience [71–73]. Assessment of nontechnical skills, such as appropriate drug administration and physiologic monitoring, is also possible with most of the current generation of simulators.

The validity of this method of assessment is under evaluation as discussed below. Currently, performance reporting remains unsatisfactory, quantitative measures of performance related to procedure time and use of the c-arm are well reported, but further work is necessary for developing more subtle indicators of performance and judgment such as clinical outcome and technical error. Though further work is required, simulation-based assessment is potentially a mechanism for selecting candidates for surgical or interventional training programs and may be a requirement for recertification or gaining credentials to perform procedures [74].

Relationship Between Nontechnical Skills and OR Performance

While not actual measures of surgical performance, self-reported operative competence and stress levels appear to be important markers of coping ability. The evidence suggests that effectively coping with stressful events in the OR has a beneficial impact on technical skills performance [75]. Similarly, the relationship between nontechnical (communication, decision-making, situational awareness, and leadership skills) and teamwork skills and technical performance in the OR is strong, and it is now widely reported that deficiencies in teamwork, rather than simply poor technical ability, contribute more commonly to adverse events in the OR [75].

The Evidence for Simulation in Open Vascular Skills Training

Sidhu and colleagues from the University of Toronto have demonstrated that laboratory training does improve basic vascular skills [76]. Acquisition of skill was significantly affected by model fidelity and level of training as measured by checklist and final product analysis. Practice on high-fidelity models (cadaver brachial arteries) improved skill acquisition for both junior and senior residents learning vascular anastomosis techniques, as compared with low-fidelity models (plastic tubing). This was the first study to address the combination of the effects of level of training and model fidelity on skill acquisition. These findings conflicted with previous studies performed at the same institution that demonstrated equivalency of low- and high-fidelity models for plastic surgery and urology procedures [77, 78]. This work suggests that there is more benefit in using higher-fidelity models for more experienced learners. In other words, for optimal motor learning, the level of difficulty during the skill acquisition must be adjusted to the learner's current expertise level.

A saphenofemoral junction model was used by Wolfe and Darzi to assess the surgical competence of learners of all levels of experience, from senior house officers to experienced consultants, by using the procedure-specific Imperial College Evaluation of Procedure-Specific Skill (ICEPS) rating scale in conjunction with the Objective Structured Assessment of Technical Skill (OSATS) global rating scale [43]. The saphenofemoral junction groin model (Limbs & Things, Bristol, UK) depicted the human saphenofemoral junction and its tributaries. This model allows for incision of the skin and dissection through the superficial fatty and deeper fascial layers. The fluid-filled long (greater) saphenous vein and its four groin tributaries can be identified and ligated and the saphenofemoral junction disconnected. This study showed that surgical performance continues to improve significantly beyond consultancy. Importantly this study demonstrated the construct validity and high interobserver reliability of the ICEPS rating scale supporting its use in formative and summative assessment.

Carotid endarterectomy (CEA) is an operation that is associated with substantial risk should the operation not be performed appropriately. A synthetic benchtop model (Limbs & Things, Bristol, UK) has been developed in conjunction with St Mary's Hospital, London, UK. This model consists of a plastic box and supporting structures with a replaceable latex carotid artery containing adherent plaque. John Wolfe and colleagues demonstrated that this bench model is a valid tool for the evaluation of basic technical skills in the performance of CEA. Use of the model in a simple, easily reproducible benchtop environment discriminated between junior and senior vascular trainees by both evaluations of video performance and end-product scores [44]. The model, however, failed to discriminate between senior trainees and consultant surgeons, with these two groups performing at the same level in all assessments. This demonstrates the inherent weakness of using these benchtop models for training more advanced learners. Decision-making, judgment, situation awareness, and leadership skills cannot be evaluated in this situation. More complex simulations, i.e., simulated operating rooms, may be needed to discriminate between more senior trainees and consultants. That being said, these simple models allow the basic steps of a procedure to be taught to trainees in a non-pressurized environment where the patient is not at risk. Use of this model allows for acquisition of the basic skill components of a CEA (order of the clamp placement and removal, site of the arteriotomy incision, and basic considerations of the endarterectomy) before moving to the operating room. Also, video review has the advantage of identifying errors in performance that can be demonstrated to trainees, providing valuable feedback [79].

Because of the previously noted trend toward preferential endovascular repair, the incidence of open aortic surgery is significantly decreasing. Records from Medicare beneficiaries from 1995 to 2008 and ACGME records from 1999 to 2008 demonstrated that the average annual number of open AAA repairs performed by vascular fellows decreased from 44.1 to 21.6 in this time period. Also noted was a concomitant increase in endovascular repair of AAA with approximately 78% of AAA repairs in 2008 done by EVAR [80]. The efficacy of simulation training for open AAA repair was investigated by Robinson et al. [81]. They randomized a group of senior residents to one of two simulation training sessions. The first was performed with vascular attending oversight, and the second session was an identical course conducted with a skills lab coordinator. The authors reported that the less experienced residents demonstrated greater improvement after simulation training and that those mentored by a vascular attending had a significant improvement in overall operative competence, but those overseen by a skills lab coordinator did not. Their primary conclusion was that simulation training efficacy was dependent on vascular staff involvement. The study was not, however, able to demonstrate that improvement in the simulation lab correlated with improvement in the OR.

Another study noted that 24 senior general surgery residents participating in 5 structured 4-hour cadaver skill sessions where they performed 5 different vascular exposures, including the supraceliac aorta, demonstrated significant improvement in both the mean pre- and post-oral examination scores ($P < 0.001$) and the mean operative confidence scores ($P < 0.001$) for each individual exposure [82].

The Evidence for Simulation in Endovascular Skills Training

Driven by the need to validate endovascular VR training, three specialties involved in the endovascular treatment of vascular diseases in Europe have joined forces as the European Virtual reality Endovascular RESearch Team (EVEREST). The goal of this group is to improve training of the present and future endovascular therapists through combined research and curriculum development. It is understood that before endovascular simulators can be universally applied to vascular training programs, demonstration of reliability, feasibility, and validity is necessary. It is incorrect to assume that a realistic simulation equates to an effective training or assessment model [83].

Perhaps more than in any other vascular bed, simulation can play a vital role in instructing interventions in the cervical carotid circulation and therefore deserves special attention here. Since carotid interventions provide a small absolute risk reduction, even a rare technical error can override a surgeon's margin of efficacy. Additionally, small missteps during a carotid stent placement can result in severe morbidity and even mortality. Clearly these procedures must be assiduously learned prior to attempting independent performance. There are few true high-volume centers, however, and a paucity of experts to train novices. In the USA, multispecialty consensus statements issued by the American College of Cardiology, American College of Physicians, Society for Cardiovascular Angiography and Interventions, Society for

Vascular Medicine and Biology, and Society for Vascular Surgery provide recommendations on the training and credentialing for CAS and other catheter-based interventions [19, 84]. This statement reflects a recent worldwide shift in focus toward outcome-based education throughout the healthcare professions. This paradigm change derives in part from attempts by academic institutions and professional organizations to self-regulate and set quality benchmarks, but chiefly it represents a response to public demand for assurance that doctors are competent [33].

This stance was adopted by the Food and Drug Administration (FDA) with the approval of a CAS system in August 2004 [85]. The FDA supports the use of simulation training as a component of physician training for CAS. Another requirement of the FDA approval for CAS was the initiation of a post-marketing surveillance study to assess the safety of the new device in everyday use and to assess its safety in the hands of operators with varying levels of experience. Two such post-marketing surveillance studies provide promising results [86, 87]. These studies evaluated the performances of experienced endovascular physicians who sought to learn a new procedure by using short training courses.

Validity

An overview of the published papers that have sought to support the validity of various modules of computer-based simulators is provided in Table 2 [62–65, 70–73, 88–99]. Most research has been conducted using the Vascular Interventional Surgical Trainer (VIST, Mentice, Gothenburg, Sweden).

Patel et al. revealed that participants of the Guidant CAS 2-day regional training course using the VIST simulator had improved performance across five test trials as assessed by the metrics (catheter handling errors, procedure time, fluoroscopy time, and contrast volume) [70]. This study represents the largest collection of such data to date in carotid VR simulation and is the first report to establish the internal consistency of the VIST simulator and its test-retest reliability across several metrics. These metrics are fundamental benchmarks in the validation of any measurement device. Composite catheter handling errors represent measurable dynamic metrics with high test-retest reliability that is required for the assessment of high-stakes procedural skills.

A supervised 2-day virtual CAS training course for experienced endovascular physicians on the ANGIO Mentor™ simulator provided similar results. Post-course interventions were performed faster, with less radiation, and with fewer catheter handling errors. Spasm of the internal carotid artery occurred less frequently. Post hoc ratings by two experienced CAS physicians showed excellent inter-rater reliability, reduction in number of observed errors, and an increase in quality of performances when comparing the group's pre- and post-course performances.

Dayal et al. evaluated the use of simulation to train novice and advanced interventionalists in carotid angioplasty and stenting (CAS) [72]. After didactic instruction, each participant performed CAS followed by training on the

Table 2 Overview of VR endovascular assessment and training studies

Study	Simulator device	Module	Face validity	Construct validity	Training potential	Transfer of training to in vivo
Wang et al. (2001) [73]	Accutouch	Cardiac lead placement		Yes		
Dayal et al. (2004) [72]	VIST	Carotid	Yes	Yes	Yes	
Hsu et al. (2004) [88]	VIST	Carotid	Yes	Yes	Yes	
Nicholson et al. (2006) [89]	VIST	Carotid	Yes			
Aggarwal et al. (2006) [71]	VIST	Renal		Yes	Yes	
Hislop et al. (2006) [62]	VIST	Carotid		Yes		
Berry et al. (2006) [90]	VIST	Renal	Yes	No		
Patel et al. (2006) [70]	VIST	Carotid	Yes		Yes	
Chaer et al. (2006) [64]	VIST	Iliac/SFA				Yes
Passman et al. (2007) [91]	SimSuite	Iliac/renal/carotid	Yes		Yes	
Dawson et al. (2007) [92]	SimSuite	Iliac	Yes		Yes	
Berry et al. (2007) [63]	VIST	Iliac	Yes		Yes	Yes
Neequaye et al. (2007) [93]	VIST	Iliac/renal			Yes	
Van Herzeele et al. (2007) [96]	VIST	Carotid	Yes	Yes		
Van Herzeele et al. (2008) [94]	ANGIO Mentor	Carotid	Yes		Yes	
Tedesco et al. (2008) [65]	VIST	Renal		No		
Van Herzeele et al. (2008) [95]	VIST	Iliac		Yes		
Berry et al. (2008) [97]	VIST	Carotid		Yes		
Glaiberham et al. (2008) [98]	VIST	Renal		Yes		
Klass et al. (2008) [99]	VIST	Renal			Yes	

VIST simulator and performance of a second graded CAS. Participants had reduced procedural and fluoroscopic time and improved wire and catheter techniques. These results were consistently better for experts than novices. This supported the construct validity of the simulator that it can accurately reflect the skill of the individual.

Hsu et al. conducted a similar randomized trial comparing performance of CAS by skilled and untrained interventionalists [88]. After a pretest, participants were randomized to receive supervised practice on the Procedicus VIST simulator or no practice. Procedural time and successful completion improved significantly and correlated with previous experience, thereby supporting construct validity of the simulator. The majority of the participants rated the simulator as realistic with good force feedback supporting face validity. These participants also agreed that training on endovascular simulators should be mandatory prior to performing CAS in actual patients.

Studies carried out by the EVEREST group differed from these two studies. Only physicians with the basic endovascular skills and appropriate medical background to treat carotid artery stenoses were included [71, 94–96]. Experienced interventionalists were found to have shorter procedural and fluoroscopic times and improved wire and catheter techniques for CAS. These findings confirm the ability of the simulator to accurately reflect the skill of an individual, again supporting its construct validity [62, 71–73, 94, 96–98].

Learning Curve

The term "learning curve" used in the context of skills training refers to the time taken and/or the number of procedures an average practitioner needs to be able to perform a procedure independently with an acceptable outcome [100]. Learning curve can be measured in terms of patient outcomes (morbidity or mortality) or as measures of surgical procedure (blood loss and operative time) [101]. Mastery of the clinical tasks of an endovascular procedure often follows a steep learning curve; this has obvious implications for patient safety, particularly when novices are performing invasive procedures on real patients.

Lin et al. analyzed the outcomes of sequential groups of patients undergoing CAS and demonstrated decreased procedure-related complications, fluoroscopic time, and contrast volume used with increased experience [102, 103]. Simulation-based training may allow the early part of this learning curve to take place without exposing the patient to unnecessary risk. Other studies examining the potential for using VR systems in endovascular skills training have analyzed the learning curves of both novice and expert subjects. Results are mixed. Dayal et al. demonstrated improved simulated performance of CAS procedure by novice subjects. Expert performance was not improved following training [72]. Hsu et al. showed significant improvement in both novice and expert subjects [88]. Aggarwal et al. analyzed the learning curves of experienced open vascular surgeons and demonstrated improved performance (procedure time and contrast used) following VR simulator training using a renal artery stenting model [71]. A second study from this unit showed that while there is an expected learning curve in performing endovascular tasks, endovascular skills were widely applicable, and once learned these skills could be readily transferred between different simulated procedures [95]. Similar improvements in simulator training have been reported for iliac and renal angioplasty [92, 93].

These training studies suggest that repetitive practice on the endovascular simulator benefits the novice learners more than the expert subjects. Learning curves are shortened as the novice becomes more familiar with the simulator. Psychomotor skills gained with simulator practice can become automated by the time the procedures are performed in real patients [104].

Transfer of Skills

Skills transfer, i.e., significant improvement in operative performance following a period of dedicated skills training, has been demonstrated following VR training in laparoscopy [105, 106]. Recent evidence of skills transfer using VR simulation for endovascular skills training is encouraging. Berry et al. demonstrated improvements in both combined global rating scale and task-specific checklist after repetitive practice in both the porcine and VR groups. The improvement was shown to transfer from the VR simulator to the porcine model [63]. Only one randomized trial in the endovascular field has examined skills transfer from the VR to the OR [64]. Surgical residents with no prior endovascular experience were enrolled. All participants received the same didactic introduction and were randomized to receive either mentored simulation training (max 2 h) on a standardized iliofemoral angioplasty/stenting model or no simulation training. The simulator-trained group received significantly higher ratings on a supervised real iliofemoral procedure compared with the control group. Large randomized controlled trials need to determine whether simulated training in other endovascular procedures also translates into improved skills and if these skills are maintained over time.

Performance Benchmarks

Simulator-derived performance reporting allows the learning curve of an individual trainee to be tracked. Practice can continue until a predetermined benchmark level of skill (based on the median performances of highly experienced physicians in the field) can be demonstrated. Further work is required to define appropriate benchmark levels of skill both within VR simulation and in vivo. Personalized training such as this may be a more effective way of training than undertaking a set number of repetitions [106]. This style of training is known as proficiency-based training – please see the chapter on this topic for more details.

Design and Implementation of a Stepwise Proficiency-Based Vascular Training Curriculum

Successful incorporation of simulation into residency programs is dependent on the effectiveness of the curriculum. Although a particular simulator may be associated with numerous facets of validity, it is the curriculum that dictates how rapidly trainees will learn [25]. The curriculum ultimately dictates how effective a particular simulator will be in providing clinically relevant and useful skills. An effective skills curriculum should encompass goal-oriented training; a cognitive component; deliberate, distributed, and variable practice with appropriate methods for instruction and feedback; an amount of overtraining and maintenance training; and sensitive and objective metrics for measuring skill proficiency [51].

Examples of Comprehensive Vascular Skills Training Programs

The OHSU Program

Most of the emphasis in teaching vascular skills have focused on advanced endovascular techniques. With the introduction of the 0/5 training programs in the USA where residents enter vascular training directly from medical school, there is a need to teach vascular skills early in training. To this end, we have developed a vascular skills lab with a basic curriculum appropriate for novice surgical residents. Skills taught in our skills lab include performance of an ankle-brachial index (ABI) and vascular-specific physical examination, interpretation of noninvasive vascular laboratory studies, ultrasound-guided percutaneous vascular access, ultrasound assessment of venous conduits for bypass grafting and dialysis access, techniques of performing basic vascular anastomoses, interpretation of imaging studies pertinent to vascular surgery (angiography, CTA, MRA), radiation safety, fluoroscopy, and basic catheter skills (Table 3).

We have utilized a rather broad definition of vascular "surgical skills" and have incorporated features beyond just technical skills into the laboratory. We feel that these nontechnical skills are essential components of vascular surgical training for novice trainees. These nontechnical skills have been identified as skills that residents have the least confidence in because of the variable opportunities on the differing services to patient exposure. We therefore incorporated these "surgical skills" into the curriculum to eliminate learning opportunities based on random exposure to the skill set and because our current training format does not allow for specific time commitment to the learning of these skills.

Table 3 Basic vascular surgery skills

Performance of ankle-brachial index (ABI) and vascular physical exam
Interpretation of noninvasive vascular laboratory studies
Ultrasound-guided percutaneous vascular access
Ultrasound assessment of venous conduits
Identification of basic vascular instruments
Basic technique for vascular anastomoses
Radiation safety and fluoroscopy
Basic catheter skills
Interpretation of vascular imaging studies

Description of Laboratory Modules

Vascular-specific skills are grouped into four modules in our laboratory with each module organized around a specific theme. Modules are 2 h in length and each module is initially covered in one session. The modules incorporate (1) a didactic portion which includes a group lecture with handouts of the lecture for self-learning and if appropriate a video demonstration of the skill, (2) hands-on exposure of the different skills, (3) practice of the individual skill, and (4) post-module questionnaires evaluating course content and teaching techniques. Pre-module and post-module cognitive and skill tests are administered.

Ultrasound Basics

A didactic lecture format familiarizes trainees to the basic principles of ultrasound physics and to the principles of central venous catheterization. Participants are taught anatomic landmarks to safely place arterial and central venous catheters and are provided an algorithm to maximize safety in placement of arterial and central venous catheters. Complications that can occur with percutaneous access are discussed and treatment algorithms to manage these complications addressed.

Residents are also given a brief orientation on the SonoSite™ portable ultrasound machine with instruction on transducer selection, anatomy, and orientation, as well as how to optimize the ultrasound image through changes in gain and depth. These skills are practiced on simple synthetic models. Ultrasound-guided percutaneous access techniques are then practiced. Simple synthetic models are used initially, using a standard Cook™ micropuncture introducer set; these skills are then applied to more lifelike models.

Percutaneous access techniques on a prosthetic internal jugular vein, subclavian vein, and common femoral artery are practiced and ultrasound-guided placement of a central venous catheter performed. Performance of the skill is measured using a task-specific checklist and a global rating scale.

Finally, trainees are instructed on how to use the ultrasound for visualization of venous conduits. The greater and lesser saphenous, basilic, and cephalic veins are identified on a model. The trainees then use each other as models to learn ultrasound visualization of these conduits. Learners are required to measure and record the diameter of individual venous segments.

Vascular Laboratory Interpretation

The key components of vascular anatomy and the vascular physical examination are reviewed. The use of a continuous wave Doppler to perform an ABI is described as is interpretation and clinical significance of audible monophasic, biphasic, and triphasic continuous wave Doppler signals. Residents practice performance of ABIs on each other.

A PowerPoint lecture introduces residents to the noninvasive studies available for evaluating upper and lower extremity arterial disease. Residents are instructed on interpreting normal and abnormal Doppler-derived waveforms, segmental pressures, duplex studies of native arteries and bypass grafts, toe pressures and toe/brachial indices (TBI), and laser Doppler examinations. Trainees also learn to interpret vein mapping studies of the greater and short saphenous veins as well as cephalic and basilic veins. They are introduced to vascular laboratory studies for detection of deep venous thrombosis and valvular reflux. Carotid, renal, and mesenteric duplex examinations are described and interpretation criteria for carotid, renal, and mesenteric artery stenosis presented.

Residents are given handouts with a succinct summary of the material covered in the didactic session. Interpretation of standardized vascular lab work sheets using vascular lab cases is practiced. Answers to the “unknowns” are reviewed and feedback provided in a group discussion.

Vascular Instruments and Anastomotic Techniques

Trainees are introduced to instruments, sutures, and basic techniques required to perform a vascular anastomosis. Participants are first taught the names and characteristics of the instruments used for vascular isolation, clamping, and suturing. They are also familiarized with sutures and needle types used in constructing a vascular anastomosis and are introduced to prosthetic grafts utilized for dialysis access, arterial bypass, and open aneurysm repair. A handout including basic vascular techniques and a picture of commonly used vascular instruments is provided.

A video clip demonstrating the proper technique of an end-side vascular anastomosis is reviewed and discussed. Using benchtop models and grafts, the trainees are then taught to create transverse, longitudinal, and circumferential arteriotomies. Trainees perform basic vascular anastomoses, including patch angioplasty, end-to-end, and end-to-side closures. Participants then practice these skills. Concurrent and summary feedback is provided to each resident. Performance of the skill is measured using a task-specific checklist and global rating scale.

Vascular Radiology

This module is designed to prepare the trainees to pass the required OHSU Hospitals and Clinics non-radiologist fluoroscopy physician test: Trainees are instructed to study the OHSU fluoroscopy training manual prior to beginning the module. Participants are taught basic radiation physics and instructed on the biological effects of radiation, how radiation exposure is monitored, and in the use of lead protective clothing, i.e., lead glasses, shields, and gloves. Techniques used to obtain the sharpest fluoroscopic images while limiting X-ray dose rate to the patient and operator are described. The learners are also introduced to the control panel of a C-arm and instructed on how to acquire, view, and store intraoperative images on the hospital digital imaging system.

Differing contrast agents, drug interactions, and complications related to contrast administration are described, and residents learn to identify and have a working knowledge of the sheaths and catheters most commonly used for intraoperative angiography and venography and to understand the steps in performing an intraoperative angiogram or venogram.

Finally, residents are taught to interpret basic normal and abnormal imaging studies pertinent to vascular surgery including CT angiograms and digital subtraction angiography. A collection of unknown normal and abnormal studies is interpreted by the residents. These studies are reviewed and discussed as a group.

Review of Our Data

Preliminary data clearly indicates the vascular skills laboratory is well received by the learners. Residents believe that all of the lab modules meet their educational objectives and that the content is appropriate and applicable to their training needs. Technical skills improved, and post-module cognitive test scores were significantly higher than pre-module tests for all modules tested. Interestingly we found that senior residents scored no differently than junior residents on cognitive testing suggesting that the skills lab should be introduced early in the surgical training program. We recognize that this curriculum has imperfections. Early in the course, it became clear that we had too much material and too many tasks in each module. It also became obvious that we did not provide enough time for deliberate practice and scheduled reinforcement of the technical skill. Our current lab curriculum has made provisions for these findings. We have also expanded our curriculum to include cadaver and porcine models for our more senior residents.

The LSU Program

At LSU, the Fundamentals of Vascular Surgery Symposium is held annually for integrated vascular surgery residents from around the USA. The pilot program for the open skill testing (FVS) occurred in October 2012. Twenty surgical trainees completed three vascular skill assessment models, each under the observation of two experienced assessors blinded to their training level. Two models were designed to simulate an end-to-side anastomosis (ES) and a patch angioplasty (Patch). A third model required suturing around a clockface design printed on patch material (Figs. 9 and 10) to emulate radial suturing as would be performed on a proximal aortic anastomosis. The model is placed in a clear plastic tube to simulate the depth of the abdominal cavity (Fig. 11). Trainees are given 5 min to perform the task of suturing around the entire "clock" with a 3-0 SH suture. Residents' scores on this simulation correlate strongly with their operative experience (Spearman's rho = 0.789, $P < 0.001$). Benefits of the clockface model include its relatively low cost and ease of transport, allowing trainees to practice away from the hospital.

ACGME log experience was recorded. Secondary evaluations of all three finished models were then performed by four blinded assessors. Inter-rater reliability among the seven assessors was high (Cronbach's α = 0.93). Evaluations acquired by direct observation correlated well with participants' training level/experience for all three models (ES r = 0.85, Patch r = 0.71, CF r = 0.82). Highest correlation with training level/experience was obtained with a combined score for each participant incorporating all observed ratings on each model ($r = 0.93$). Evidence for construct validity was collected by demonstrating each model's ability to discern junior (Pre-MD to PGY2) from senior (PGY 3–5) trainees (ES $P < 0.005$, Patch $P < 0.05$, CF $P < 0.001$). Internal consistency was confirmed for each participant on all three models (Cronbach's α = 0.89). Finished product evaluation demonstrated fair to poor correlation with training level/experience (ES $r = 0.51$, Patch $r = 0.53$, CF $r = 0.24$). These results supported construct validity for three vascular skill

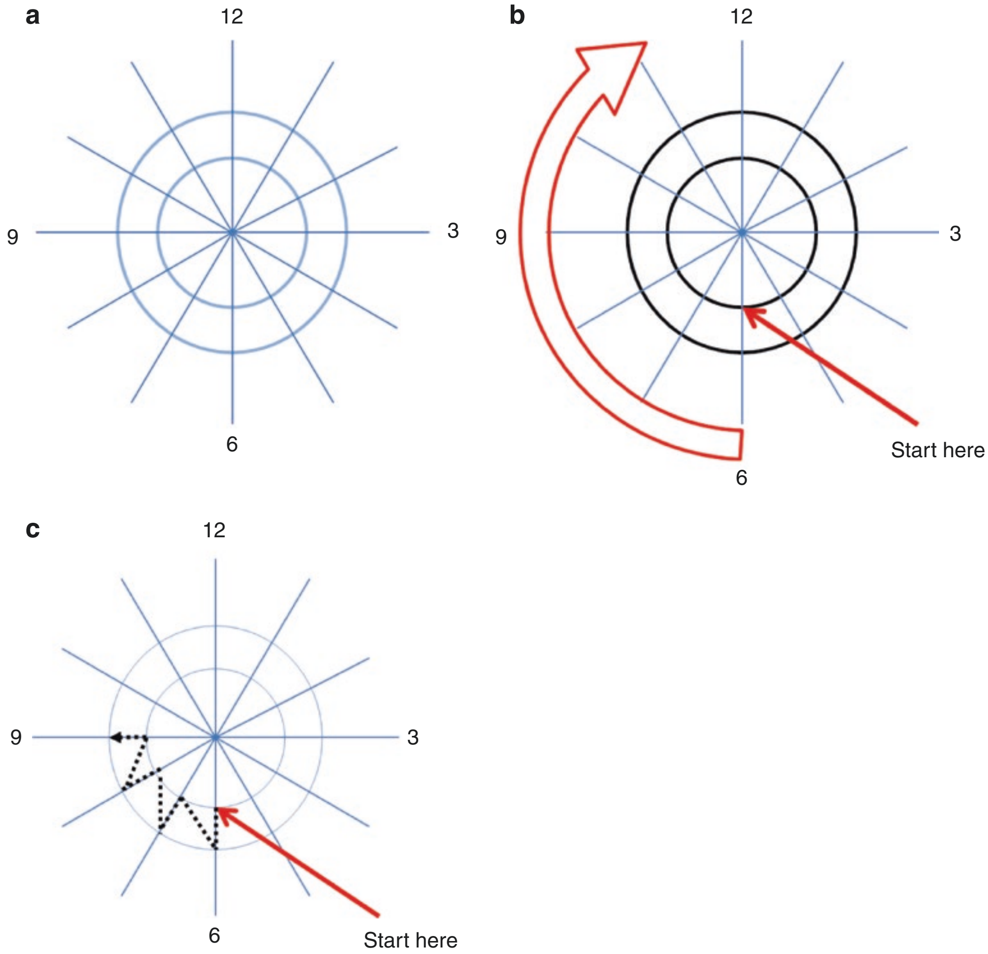

Fig. 9 (**a**–**c**) LSU clockface model instructions

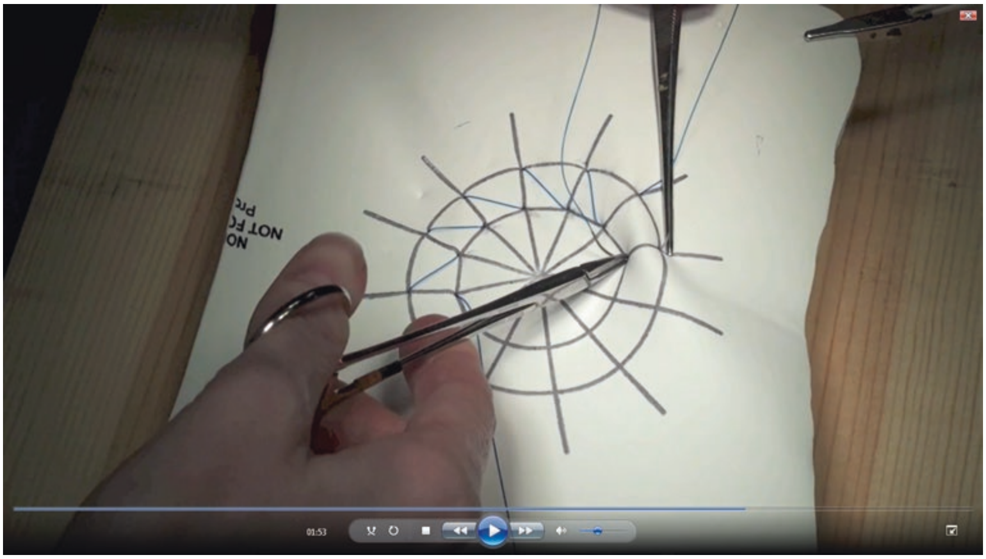

Fig. 10 Clockface model demonstration

Fig. 11 Plastic tube in which the clockface model is secured to simulate the depth of the abdominal cavity

assessment models. Our data also demonstrates that the most accurate assessments are obtained by direct observation with trained evaluators.

The goals of the course are twofold:

1. *For vascular surgery residents*: With a faculty to resident ratio approaching 1:1, attendees spend 3 days receiving hands-on instruction in vascular techniques. Special emphasis is placed on procedures less commonly performed during residency such as open thoracoabdominal aortic approaches, subclavian/tibial vessel exposures, and complex endovascular procedures.
2. *For program directors*: Using vascular skill assessment models, the course faculty spend hours observing and grading each attendee. This feedback is provided directly back to the program director. These outside assessments of residents' skill are a unique and valuable resource for portfolio building, milestone development, and individualized simulation curriculum design.

The course curriculum includes instruction (fresh cadaver lab, endovascular skill stations, open skill stations, didactics) and assessment (FVS, FEVS). There are also opportunities for simultaneous teaching and assessment ("Suturing with the Experts," planning stations for EVAR measurement). Course content has been adjusted based on attendee feedback, most notably increasing the cadaver content, shortening the didactics, and providing more hands-on instruction and immediate feedback.

As a measure of educational effectiveness, all residents complete a pre- and post-self-assessment of confidence in nine vascular skills. Pooled results from the first 3 years demonstrate a statistically significant improvement in each proficiency including performance of carotid stent ($p < 0.05$), thoracoabdominal aorta exposure ($p < 0.001$), and EVAR planning based upon CTA measurement ($p < 0.01$). All attendees (100%, 48/48) reported being either "Very" or "Extremely" satisfied with the education experience. Questionnaires were sent to each program director after the course and a 93% response (28/30) was achieved. All reported being either "Very" or "Extremely" satisfied with the skill assessments generated by the course, and 96% of the responders (27/28) felt the reports would be useful in helping the residency program address the attendees' strengths and weaknesses.

From this experience, we feel the following components are useful in creating a valuable vascular surgery simulation course:

1. High faculty to attendee ratio (minimum 1:2)
2. Low attendee to simulation station ratio (maximum 2:1)

3. Large fresh cadaver component
4. Emphasis on procedures rarely performed during residency
5. Limited didactics
6. Focused individual skills training and feedback to attendees
7. Focused individual skill assessment and feedback to program directors

The Fundamentals of Endovascular Surgery (FEVS) model was developed in both silicon and virtual reality versions. Twenty individuals (with a range of experience) performed four tasks on each model in three separate sessions. Tasks on the silicon model were performed under fluoroscopic guidance, and electromagnetic tracking captured motion metrics for catheter tip position. Image processing captured tool tip position and motion on the virtual model. Performance was evaluated using a global rating scale, blinded video assessment of error metrics, and catheter tip movement and position. Motion analysis was based on derivations of speed and position that define proficiency of movement (spectral arc length, duration of submovement, and number of submovements).

Performance was significantly different between competent and noncompetent interventionalists for all three performance measures: motion metrics, error metrics, and global rating scale. The mean error metric score was 6.83 for noncompetent individuals and 2.51 for the more experienced group ($P < 0.0001$). Median global rating scores were 2.25 for the noncompetent group and 4.75 for the competent users ($P < 0.0001$). The FEVS model successfully differentiated competent and noncompetent performance of fundamental endovascular skills based on a series of objective performance measures. Furthermore, we were able to successfully demonstrate that performance on an exact replica VR model correlated to performance on the physical model, further lending support to the validity of this platform. This model is now being proposed to serve as a platform for skill testing for all trainees, and multi-institution trials of both models were planned for launch in 2018.

Future Studies

The intent of simulation training is to shorten and flatten the learning curve for real procedures. To date no studies have objectively investigated the degree to which VR endovascular simulators satisfy this demand. Research needs to be conducted, similar to that performed in the airline industry and laparoscopic field, to calculate the transfer-effectiveness ratio (TER) for vascular simulator-based training curricula [107, 108]. Transfer-effectiveness ratio is calculated as the difference in number of trials or time taken to achieve performance criterion (in the air) between untrained and simulator-trained pilots divided by total training time received by the simulator-trained group. This ratio allows you to calculate how time-effective the addition of a simulator would be in a training program in relation to initial outlay costs. Ratios >0.5–1.0 are achieved by training programs containing modern flight simulators and 2.28 by proficiency-based training curricula including laparoscopic simulators [109].

Credentialing and certification of surgeons as part of continuing education is not a new concept. Currently, the American Board of Surgery utilizes the six core competencies established by the ACGME for their Maintenance of Certification (MOC) program. This program insists on continual learning over time. To ensure MOC, physicians need to demonstrate (1) evidence of professional standing through maintenance of an unrestricted license, hospital privileges, and satisfactory references, (2) evidence of commitment to lifelong learning through continued education and periodic self-assessment, (3) evidence of cognitive expertise based on performance on a secure examination, and (4) evidence of evaluation of performance in practice, using tools such as outcome measures and quality improvement programs, and evaluation of behaviors such as communication and professionalism [51]. Although technical skills training and simulation are not part of the ABS MOC program, future studies in this area would be important. Research conducted on more senior learners with limited endovascular skill is needed. Simulation could potentially play an important role in the reentry of these physicians into mainstream practice and maintenance of technical skills for "certification." Physicians who have completed training may benefit from continuing education and simulator-based training to support their continued learning and improvement of cognitive and technical skills. Repetition, self-assessment, and the opportunity for feedback are the cornerstones for deliberate practice as defined by Ericsson [85, 86].

Similar to athletes and musicians, physicians may benefit from "warming-up" on a simulator before an elective procedure. The opportunity for endovascular therapists to practice complex endovascular procedures before performing them in the actual patient is currently being evaluated. Imagine a patient with a symptomatic CAS, challenging anatomy, and high anesthetic risk. The software "PROcedure Rehearsal Studio™" (Simbionix, Cleveland, Ohio, USA) rapidly loads the patient's CT scan data from a CD onto the simulator and generates a digital three-dimensional model of the patient's clinically relevant anatomy from the scan data; subsequently a simulated interventional environment is created. This enables interventionalists to try different approaches with a range of endovascular tools prior to treating the actual patient [110]. This technology is indeed exciting and may have an impact on health economics (reduction in operating and fluoroscopy time, number of tools reduced, cost of the procedure) and eventual outcomes for the patient.

The importance of teamwork in preventing medical error is well recognized [111, 112]. Future research aims to enhance nontechnical skills of both physicians and teams by simulator-based training. A virtual interventional suite allows the endovascular therapist and the interventional team (anesthetist, radiographers, theater nurses, and angiography suite nurses) to work in a realistic environment on simulated tissues. They can be exposed to complex or rare life-threatening events and learn how to manage crisis situations in a simulated interventional suite allowing feedback by knowledgeable instructors without exposing patients to risk [113, 114].

Conclusion

In the era of rapidly expanding technology, shorter vascular training paradigms, and ever-increasingly public scrutiny of surgical outcomes, the vascular and endovascular skills training and simulation center has been embraced for the training of the next generation of vascular specialists. Simulators are an exciting and necessary development in the training of vascular surgeons. Their use in training should be accompanied by a structured curriculum with competency assessment.

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Simulation in Transplant Surgery

Joana Ochoa and Anil S. Paramesh

Introduction

Transplant is one of the most strictly regulated fields in medicine today. It not only involves the procurement of an organ and transplant of the organ into a recipient but also involves a large network of providers who are caring for the donor and orchestrating the appropriate allocation and delivery of organs to their correct destination. This multidisciplinary team has an additional layer of complexity in that many of the team members do not interact with each other directly and may be located in completely different areas of the country. Thus, the development of a strict set of protocols has been essential in the ability to provide communication between teams located at the donor hospitals, organ procurement organizations (OPOs), and transplant centers. The amount of organization at all these levels has not been established without the trials and tribulations of error.

The process begins with barriers to successful organ donation. In many instances, donors may be at remote hospitals, where there is difficulty in broaching the subject of organ donation with family members of critical patients. This may prohibit the consent for organ donation. Local doctors may be unfamiliar with the significant hemodynamic changes that occur with brain death, and donors may be lost prior to the opportunity to proceed to the operating room (OR) for donation. Additionally, the OR may not be familiar with the setup for organ procurements, especially with unique situations like donation after cardiac death (DCD), where patients are declared dead in the OR prior to organ procurement. Such surgeries may be rare for smaller hospitals and there is much that can go wrong. Once these organs are procured, they must be appropriately labeled, packaged, and then sent out for transplant to centers around the country. There are potentially many pitfalls that can occur during this phase.

One such case that highlights the need for organization at all levels is the unfortunate and much publicized story of Jesica Santillan. Jesica was a 17-year-old girl who underwent a heart and lung transplant in 2003. Toward the end of the surgery, it was realized that the donor and recipient were blood type incompatible [1]. There was a breakdown of communication that caused a simple but catastrophic mistake that led to the patient's tragic death. Other avoidable but documented mistakes include sending the incorrect organ to the wrong location (i.e., sending liver to someone who needs a kidney), incorrect packaging of organs, and sending a right-sided kidney to a donor who was expecting the left-sided kidney.

Needless to say, at the recipient end, organ transplantation surgery is complex involving critically ill patients. There can be a very steep learning curve to master the operative techniques, and many of these patients do not tolerate complications well. Transplant centers are strictly scrutinized both by government bodies and insurance companies, so there is little room for failed operations. It can hence be difficult to train a surgeon to become proficient with these procedures.

Simulation training is a great avenue that may help to avoid potential protocol violations and help train future surgeons to be prepared for this field. The repercussions of violations in the accepted protocols of transplant include the loss of insurance contracts and/or accreditation so the need to have a well-structured organization with trained and knowledgeable staff at all levels is necessary. In this chapter, we will discuss the current research and methods used to incorporate simulation training in the field of transplant surgery and the results of these measures.

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Simulation Models for the Organ Procurement Team

Consenting for Organ Donation

The coordinators from the local OPOs are often the first personnel involved in the transplant process and have the difficult task of speaking with a family regarding the gift of donating their loved one's organs. This is obviously no simple task given how quickly the transplant team must move in order to ensure the donors' body remains in good condition and the organs are able to be used for transplant. These conversations are delicate and cannot be entered half-heartedly. Such encounters may even result in altercations and legal actions. These coordinators undergo training to be able to respond to all of the family's needs and questions during these early conversations. Simulation training of these coordinators can be very helpful for these scenarios. Karabilgin et al. reported on a protocol of a simulated donor family encounter (SDFE) which was incorporated into their training of organ transplant coordinators [2]. Standardized patients were used to represent various members of a patient's family. Coordinators were tested on their ability to use the techniques they learned about during their training to deliver news such as brain death to the family and also alleviate concerns related to any religious beliefs regarding organ donation. The participants rated the SDFEs very valuable in their preparation to handle these difficult situations in the real clinical setting.

The use of digital games for educational purposes has also been adopted. Such games have been used by the Spanish National Transplant Organization with the goal of teaching a hospital coordinator how to evaluate a potential donor and to determine if any and which organs can be used [3]. The game provides immediate feedback to the players about correct or incorrect decisions that were made in the evaluation process. The game provided over 500 different patient scenarios with multiple levels of difficulty.

Critical Care Management of the Donor

Care of the brain dead deceased donor is another aspect that has benefited greatly by the use of simulated patient scenarios using mannequins. In many OPOs, coordinators and doctors go through organ donor management training in conjunction with a medical director. The mannequin model is an excellent method in which this training can be conducted because they can mimic physiologic changes that are often seen in donors and can simulate changes based on any interventions from the caregiver. It also provides the opportunity to gain exposure to uncommon scenarios in managing these hemodynamically unstable organ donors, which allows the coordinator to gain knowledge and experience in treating a variety of medical situations. There is discussion whether such training should become mandatory for anyone involved in the management of potential organ donors [4].

Intraoperative Procedures During Procurements

The current procurement process set forth by the United Network for Organ Sharing (UNOS) is detailed and comprehensive. The donor-assigned UNOS ID numbers and blood type are all confirmed before the start of the case which both the surgeon and transplant coordinator are a part of. At the time-out, these are reconfirmed and the organs to be procured are listed as well [5]. Once the organs have been removed from the donor, they are packaged in a very particular way with color coding (Fig. 1) in order to prevent any mix-ups in organs. All these processes are highly regulated, and participants have been required to undergo training via simulation and a live run-through or by watching videos of the process in order to ensure that the organ is packaged and labeled appropriately and can be sent to the assigned recipient [6]. These simulated educational videos are often times the only format in which staff can be educated regarding policies and procedures especially when they are located in a remote donor facility that is performing the procurement.

It is also essential in the procurement process for the surgeon to be knowledgeable about the anatomy and the aspects of the transplant itself to recover a healthy organ with minimal injury. One report by Taber et al. [7] showed that the incidence of organ loss from injuries during procurement was 0.3% in the procurement of over 19,000 organs. Interestingly, when procurement injuries of this severity were discovered, direct feedback was given to the procuring surgeons with subsequent reduction of organ loss in the months following the procurement injuries. This emphasizes the importance of educating surgeons in the procurement process to maximize the number of successful organ procurements and thus organ transplants.

Organ Recipient Team Simulations

Simulations for the operating room team including surgeons and trainees are also important in optimizing the care and efficiency of transplanting an organ to the recipient. Transplant can be an excellent educational experience for the surgical trainee given the anatomy and different techniques one is introduced to. A variety of simulations have been created in order to give surgical trainees the experience they need to have the skills to be an active participant in a transplant operation.

Fig. 1 Shows packaging and labeling color variations that are used in simulation training to ensure the right organ and label goes into the right container

Kusaka et al. [8] describe the use of a three-dimensional (3-D) printer model to enhance the medical education of trainees, students, and young staff as well as to assist in surgical planning and thus reduce surgical complications when performing kidney transplants. Using CT scans, they created anatomically accurate 3-D models of living kidney donors and the recipients and preoperatively performed the mock surgeries using the kidney and pelvic cavity replicas. The use of 3-D virtual simulation has also been established in liver simulation models as an anatomical guide in performing liver resections, which can be invaluable for complicated partial donor hepatectomies [9].

The use of cadavers as a simulation model in medical and surgical training is well established and provides an opportunity to learn without any risk of harming a patient. There are limitations to this modality as the preservation techniques used to maintain cadavers cause changes in the tissue that alters their original texture and elasticity. This makes replicating surgical techniques with the appropriate tactile feedback that is useful for trainees to experience prior to entering the operating room very difficult. One embalming technique is showing much promise in being able to replicate actual live human tissue. Cabello et al. [10] described the use of the Thiel's embalming method to preserve cadavers which allows vascular structures to remain permeable and the tissues to retain the plasticity similar to live tissue. In this study, trainees were guided through the procedures of both procurement of the kidney and the implantation, by a staff attending. This method does allow the inexperienced surgeon to learn the appropriate techniques needed for a successful transplant in a low stress environment with acceptable similarities to normal tissue.

Simulation training has also been used in "nontraditional" transplants as well. To improve outcomes of facial transplantation, Sosin et al. [11] describe seven mock face transplants they completed using cadavers and preoperative imaging of both the donor and recipient cadavers. They found that preoperative information they obtained from the computer-aided tissue analysis provided predictable aesthetic results and allowed their team to improve their total operative time with each mock transplant. Their finding is important in order to create a systematic approach to a difficult, tedious, and long procurement and transplant process. Their computer-aided models allowed them to accurately identify the tissue defects and osteotomy sites that would provide the desired aesthetic effect in the donor.

The use of animal tissue has also been described for surgical training as it can mimic human tissue more closely than synthetic material. In an effort to find a less expensive modality to teach the techniques for hair transplants, the use of pork skin and excess hair and skin retrieved from anti-wrinkle operations have been described as a successful tool for practice [12]. In the study, plastic surgery residents were given directions on how to perform the procedure and then were allowed to practice the procedure. They qualified to perform the hair transplants if they were able to perform the procedure under a pre-specified timeframe. They found that the residents were able to increase their proficiency and decrease their total operative time after practicing with the pork skin.

With the advent of laparoscopic and robotic surgery, more procedures are being completed with minimally invasive techniques and the popularity forcibly causes all surgical specialties to move away from open techniques. In the field of transplant, laparoscopic nephrectomies or partial hepatectomies from living donors are now routine. The role of robotic surgery in kidney transplants is evolving and has been shown to be feasible and safe [13]. Khanna and Horgan [14] developed an ex vivo kidney transplant model for surgeons to simulate a robotic-assisted kidney transplant. A trained laparoscopic surgeon with certification in robotic surgery performed the vascular anastomosis using a porcine kidney and iliac vessels inside a laparoscopic abdominal simulator platform. The simulation was videotaped in order to provide feedback to the surgeon. The venous and arterial anastomoses were investigated with direct visualization and saline injection. During the simulation, there was improvement in warm ischemic time, and no leaks evident in the anastomosis after the first two ex vivo kidney transplants.

Simulations in transplant are not just limited to the surgical trainee. The difficulty of monitoring and responding to the hemodynamic changes in a patient undergoing a liver transplant can be very difficult for the anesthesiologist. Aggarwal et al. [15] describe a month-long training program developed to train anesthesia residents to respond to the changes encountered during a liver transplant using live patient-based and mannequin models as well as online didactic materials. The course simulates every encounter with a liver transplant patient including preoperative evaluation, operating room setup, and intraoperative evaluation. Residents demonstrated improved knowledge base and confidence with the procedure based on pre- and post-training questionnaires.

Conclusion

Successful transplantation requires significant coordination from many moving pieces. There is the potential for many pitfalls and the best outcomes can be achieved by following the standard of care that has been rigorously established through the use of protocols. It is important for all parties to be familiar with procedures and policies regarding organ transplantation. Simulation training is a very valuable resource for transplant, given that these are not high volume surgeries, and the stakes are high. While there has not been much research reported in regard to the use of simulation training in transplant surgery, the current studies that exist are encouraging. More needs to be done to determine the cost analyses and the effects that these programs have on the incidence of near misses or improper allocations, procurement injuries, and recipient complications.

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Simulation in Plastic Surgery

Tanisha Hutchinson, Gregory Kelts, and Peter A. Hilger

Introduction to Simulation in Plastic Surgery

Surgical simulators are widely used throughout the field of plastic surgery, both in training and in practice. With a general shift toward competency-based assessment, simulation has become increasingly incorporated into the curricula of plastic surgery training programs both as a way to develop surgical skills and as a means of determining proficiency [1]. Types of simulators used in plastic surgery range from animated videos used to demonstrate the steps of a procedure, to synthetic benchtop models, to fresh perfused cadavers used to simulate flap dissections and microvascular anastomoses.

One of the earliest examples of simulation in plastic surgery was a leaf and clay model described in the Sushruta Samhita, an ancient Hindu medical text. Sushruta, a pioneering Indian surgeon, used this model to demonstrate the steps of a forehead nasal flap in 600 BC [2]. Early, present-day simulators in plastic surgery include a microsurgical kit, which emerged in 1999, and was used to train residents on end-to-end vascular anastomoses [3, 4]. The first known cleft palate surgical simulator described in 2007 was designed to recreate the challenges of cutting and suturing in a confined space [5].

Synthetic simulators have been extensively shown to aid novice trainees in gaining surgical skills and being able to translate those skills into the operating room [6–9]. The field of plastic surgery has utilized many different types of simulators, from low-fidelity synthetic models to high-fidelity animal and human cadaver models. Computer-assisted models and 3-D printing have also played a role in the increasing use of simulation in plastic surgery practice and in the education of trainees.

Physical Simulation

Benchtop Models

A wide variety of simulators have been employed as teaching aids for plastic surgery trainees, to assist in understanding, designing, and practicing local flaps. Due to the medical-legal and ethical drawbacks of having novice trainees acquire surgical skills on live patients, many plastic surgery training programs increasingly favor the use of simulators in initial training and teaching. Furthermore, synthetic benchtop models are widely available, easily reproducible, and circumvent the cost and risk of zoonotic disease transmission associated with animal models [10]. Inanimate benchtop simulators range from lower-tissue fidelity synthetic models using simple materials like foam or even paper to higher-tissue fidelity synthetic models that are designed to mimic real skin and subcutaneous layers. Low-fidelity tissue models have been touted for their low cost and wide availability. For example, a two-dimensional Z-plasty simulator comprised of a neoprene sheet stretched across a small platform to mimic skin tension lines has been used to simulate simple scar repair. The Z-plasty is first designed on the neoprene sheet with its central limb in orientation with the proposed "scar." The underlying hard platform allows easy cutting of the flap, while the elasticity of the neoprene provides a realistic representation of flap closure [11]. Several three-dimensional models have also been used to simulate local facial flaps. These range from mannequin heads covered in cling film to simply teach the cognitive skill of design of local facial flaps to an acrylic skull model covered with separate silicone layers to represent skin and subcutaneous

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soft tissue for design and execution of local facial flaps like the rhomboid flap and Z-plasty [12, 13]. Several other models use various materials including foam paper, leather, or gelatin "skin" to mimic soft tissue and allow cutting and rearrangement of the material for the practice of local facial flaps [14–16]. Work by Sajan et al. assessing educational models for the teaching of local facial flaps showed that both two-dimensional and three-dimensional models were reliable in assessing trainee performance. The three-dimensional organosilicate facial model used in the study, however, showed increased reliability in distinguishing novice trainees from intermediates, and intermediates from experts when drawing various local flaps and performing Z-plasty suggesting that three-dimensional models may be the more ideal assessment tool [17].

In addition to teaching local facial flaps, synthetic benchtop models have also been used to simulate more advanced techniques like cleft palate repair and craniosynostosis repair. Simulation models are rare in these specialty fields; however, high-fidelity simulators have been used with good success. A creative three-dimensional model using multicolored 3″ × 3″ sticky notes to represent oral mucosa, palatal muscle, and nasal mucosa has been used to demonstrate the anatomical arrangement of tissues in Furlow double-opposing Z-plasty for cleft palate repair [18]. This model is a cost-effective and easily reproducible method of teaching the difficult to conceptualize geometry and steps involved in palate repair. Another model employs a conical jug to represent the hard palate, with layered latex and foam representing mucosal layers and muscle (Fig. 1). This model was designed to recreate the practical challenges of cleft repair including poor visualization in a small cavity and suturing in a limited space at awkward angles [5]. This simulator can be used to practice dissection of tissue planes, rearrangement of tissues, and closure of tissue flaps in the correct anatomical arrangement. Another simulator based on a tomographic scan of a 22-month-old is possibly the most complex and anatomically accurate cleft palate simulator. Along with cleft simulation, this model displays detailed musculature and soft tissue layers that are matched to the tensile strength of these tissues previously described in the literature and a simulated oral cavity that can be suspended with a Dingman retractor. This simulator has been successfully used in a workshop setting to simulate von Langenbeck repair and was subjectively found to be a realistic and valuable training tool, while participants showed objective improvement in theoretic knowledge of cleft palate anatomy and repair after a workshop including the simulator [19].

Available simulators for craniosynostectomy are even more limited. Fresh, cadaveric sheep crania have been used for years to simulate techniques used in craniosynostosis sur-

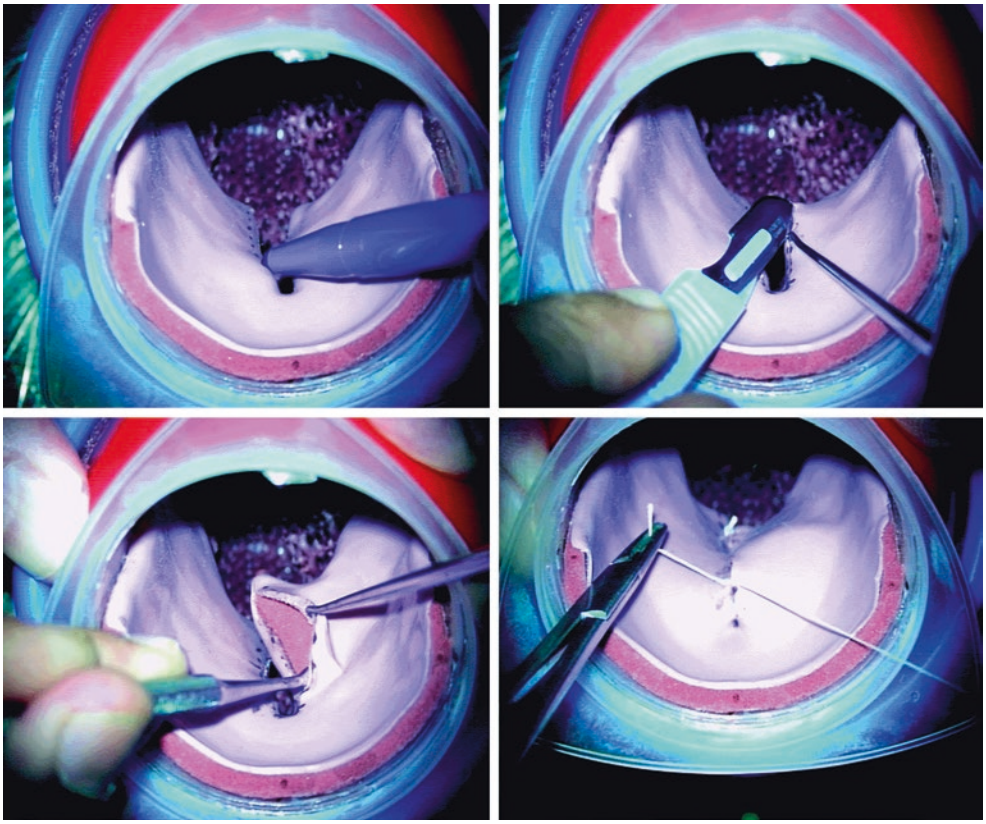

Fig. 1 Cleft palate simulator view under microscope. Top left, the incision is marked. Top right, the incision is made with a #15 blade. Bottom left, the simulated oral mucosa is separated from the velar muscle. Bottom right, the oral mucosa is sutured. (Reproduced with permission of Ref. [5])

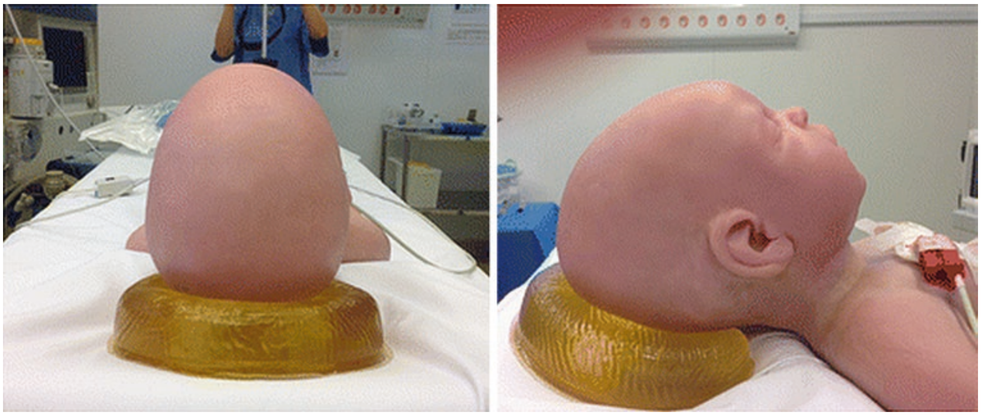

Fig. 2 Anatomical simulator for pediatric neurosurgery (ASPEN). Full-body pediatric craniosynostectomy model, based on CT scan images of a 6-month-old pediatric patient. (Reproduced with permission of Ref. [21])

gery due to their relatively low cost [20]. A synthetic model referred to as the "anatomical simulator for pediatric neurosurgery" (ASPEN) has been developed for training craniosynostectomy, specifically for a scaphocephaly-type malformation (Fig. 2). The simulator is a full-body pediatric model, whose skull is based off of CT images of a 6-month-old female patient. All aspects of scaphocephaly correction can be performed on this simulator from the skin incision, to subperiosteal dissection, to skull remodeling with absorbable microplates (Fig. 3). The model includes fiberglass molds in the shape of a skull which allow osteotomies to be performed and allow the model to be imaged pre- and post-operatively. In addition, the simulator allows for the possibility of handling intraoperative bleeding via the superior sagittal sinus [21].

In addition to the soft tissue and craniofacial simulators, two groups have developed simulators for breast surgery. Kazan and colleagues developed a benchtop mammoplasty part-task trainer (MPT) to provide technical training and provide a medium to objectively assess resident skills [22]. This trainer consists of a multilayer single breast model consisting of latex skin, subcutaneous tissue, fat, and rib. In its current form, this simulator allows trainees to make a skin incision, dissect an adequate pocket for a breast implant, place a breast implant, and then close the wound [22]. The creators plan that future iterations of this simulator will improve on the design by including bilateral breasts, the pectoralis major muscle layer, and a full rib cage to improve the anatomic fidelity of the model. In a similar vein, Zucca-Matthes et al. describe the use of a mastotrainer, to facilitate mammoplasty techniques [23] (Fig. 4). This simulator consists of a simulated female thorax with two ptotic breasts. Like the trainer created by Kazan et al., this simulator consists of synthetic skin covering subcutaneous tissue. The artificial tissue is draped over a reusable plastic base to facilitate multiple uses. This simulator allows trainees to perform both reductive mammoplasty techniques and breast augmentation, and in addition could facilitate oncoplastic resections as well [23]. Both of these training options could provide valuable practice in a controlled environment for trainees learning mammoplasty, prior to operating on live patients.

Animal Models

Several animal models have been used in the training of suture technique and local flap simulation due to their inherent structural similarity to human tissues. Pig feet, porcine cadaver heads, chicken thigh, and turkey thigh are among the most commonly used. Porcine skin is a popular choice because of its similarity to human skin in epidermal thickness, subcutaneous fat, hair follicles, and sweat glands. Galliform tissues like chicken and turkey are also useful models for simulation given that the dermal layer is similar to facial dermal thickness [24, 25]. Animal tissue models are often easily obtainable from a local grocery store or local slaughterhouse for a relatively low cost. They have been used to practice a wide variety of plastic surgery techniques including basic suture technique, excision of "skin lesions" and wound closure, skin grafts, and transposition and advancement flaps [10, 25, 26]. Less commonly, ox tongue has also been used for the practice of suture techniques and simulation of grafts and local flaps [27]. Most animal tissue used for simulation in plastic surgery is used in its native form. However, some have combined animal tissue with inanimate models. Mannequin heads draped in porcine skin were used in a teaching course for trainees to practice designing and raising flaps before using cadaveric heads [28]. Like inanimate benchtop models, even a small 5 min intervention with an animal bench model has been shown to improve performance of local facial flaps, aesthetic outcome, and quality of local facial flaps [29]. Both animal models and synthetic models have been shown to be fairly comparable in the acquisition of suture skills, elliptical incision, and rhomboid flap skills for novice trainees. Additionally, both high-fidelity and low-fidelity bench models significantly improve the acquisition of skills and surgical skill confidence when compared to didactic materials alone [30–32].

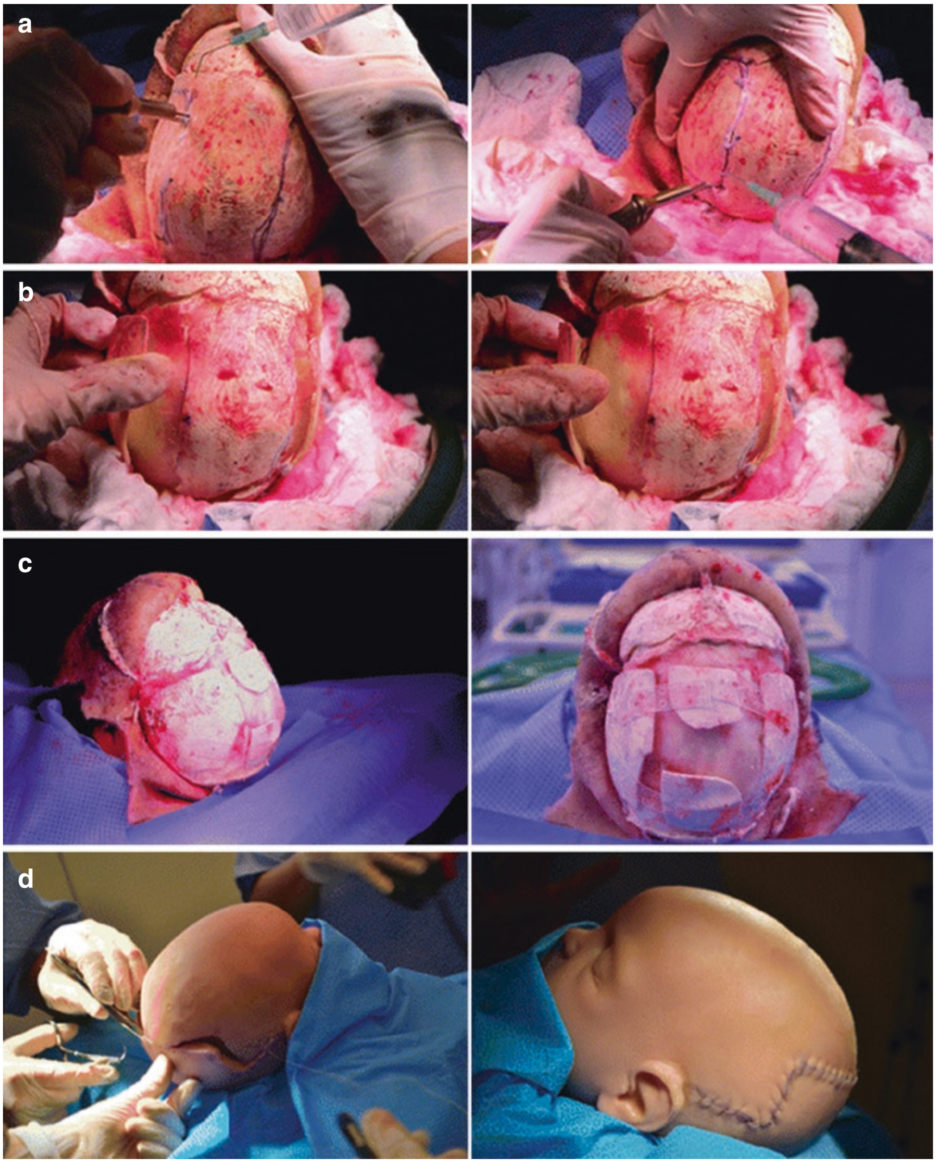

Fig. 3 (**a**) Osteotomies are made after subperiosteal dissection is complete. (**b**) Renier's "H" technique osteotomies are completed. (**c**) Cranial reconstruction with absorbable miniplates. (**d**) Scalp incision closure. (Reproduced with permission of Ref. [21])

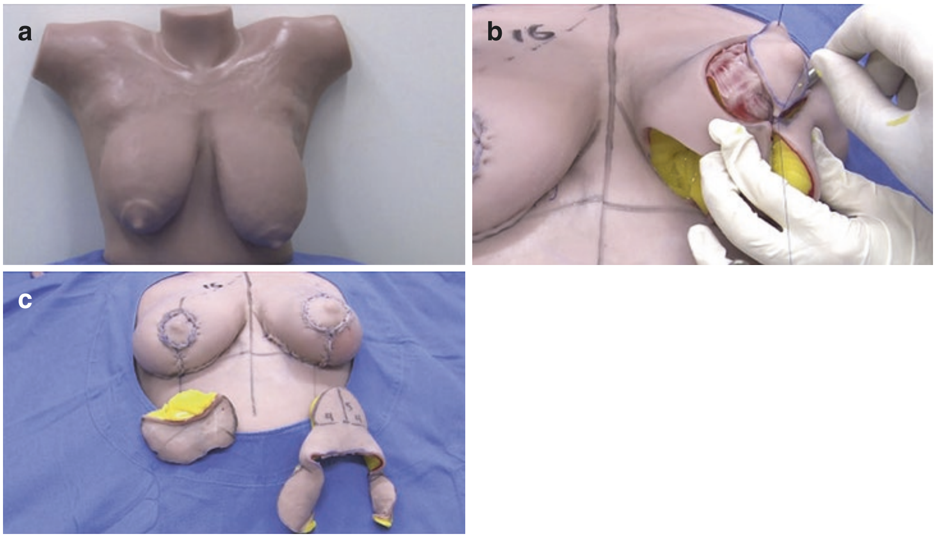

Fig. 4 (**a**) Mastotrainer model in the upright position. (**b**) Superior pedicle mammoplasty is performed and skin is re-approximated. (**c**) Skin closure is complete. The excised tissue from the superior pedicle mammoplasty is shown on the patient's left, and the excised tissue from inferior pedicle mammoplasty is shown on the patient's right. (Reproduced with permission of Ref. [23])

Microsurgery Simulation in Plastic Surgery

Microsurgery is technically challenging and known to have a prolonged, steep learning curve. Like in many other fields, simulation provides a means of safe skill acquisition, thus reducing risk to patients. A survey of roughly 50% of US plastic surgery residency programs in 2014 showed that 69% of those surveyed provide microsurgical simulation for their trainees [32]. Types of simulation included online didactic curriculum and/or laboratory with animal model or synthetic vessel. There is a general consensus that simulation improves competency in microsurgery. 60% of US plastic surgery program directors included in one study agree that simulation should even be mandatory [33]. However, there is no current consensus on what type of simulation or how simulation should be incorporated into microsurgery training curricula. A systematic review of current evidence in 2013 revealed that a laboratory-based, low-fidelity microsurgery model can aid trainees in gaining transferable skills, increase retention of skills, and improve technical performance [34]. The live rat femoral artery model has long since been the standard for microsurgical training; however, many other living and nonliving models exist.

Synthetic Models

Several simple synthetic models have been used in microsurgical training that provide a basic platform for technical skills acquisition before graduating to more costly live models. For instance, a rubber practice pad or a practice cardboard can be used to develop microsurgical suturing and knotting techniques. The practice card contains a sheet of polyurethane for suturing and knot tying, and the cardboard contains illustrated instructions for practice exercises with increasing levels of difficulty. Use of the practice card prior to performing anastomoses in a rat femoral artery model has been shown to increase the rate of anastomotic patency when compared to using the rat femoral artery model alone [35]. Latex sheets can be used to practice microsurgical suture technique on a straight incision. Latex tubes and prefabricated synthetic tubing like silicone, polyethylene, and polytetrafluoroethylene (PTFE) tubes can be used for suture, knot tying, and anastomosis practice. Of these materials, PTFE is the most similar in handling to human vessels. The Practice-Rat system consists of two polyethylene tubes wrapped with a pseudo-adventitia and can be used to practice end-to-end and end-to-side anastomoses, as well as interposition vein grafts. The “vessels” are also connected to luer fittings, which allow for the simulation of circulation and checking the anastomotic seal [36, 37].

Animal Models

Non-vital animal models closely resemble the handling characteristics of human tissue, but without the more stringent ethical regulations. They can be used to teach all techniques required for clinical microsurgery including suturing, knot tying, macrodissection, microdissection, and anastomotic patency check. Disadvantages of non-vital models include the inability to replicate the in vivo risk of thrombosis and a limited shelf life. Cold stored vessels can be harvested, typically from sacrificed rats and rabbits, and stored at 4 °C for up to 7 months for use in microsurgical training. Fresh chicken and pig leg models have also been used. Fresh chicken is a useful model due to the availability of vessels from the neck, thoracic inlet, pelvis, wing, and legs. It is also reported that the chicken common carotid is comparable in size and handling to the human digital artery. Pig legs provide vessels of varying sizes, and their nerves are structurally similar to human nerves, making it an ideal model for microneurosurgical simulation [36, 37]. The epigastric flap in the non-vital rat model provides consistent anatomy for the practice of flap harvesting. Pedicle dissection and anastomosis with the femoral vessels can then be carried out. Also, the rat hind limb anatomy is similar to that of the human thumb and is a useful teaching model for digital replantation [38]. The earthworm has also been utilized as a microsurgical training model in end-to-end and end-to-side anastomoses due to their wide availability and range in sizes that are similar to human vessels. This model also circumvents some of the cost and surgical preparation time associated with other animal models [39].

In the live, anesthetized rat model, many different vascular and organ systems provide training opportunities for the microsurgical trainee, which is perhaps why it is the most widely used model. For instance, the carotid artery, infrarenal aorta, and femoral artery can all be used for the practice of arterial end-to-end or end-to-side arterial anastomoses. The vas deferens also provides a useful model given its length and ability for the trainee to perform multiple anastomoses. It is also smaller than the arterial models mentioned, requiring 10-0 or 11-0 sutures for anastomosis and a higher level of skill. The portal vein/vena cava system and aorta to vena cava anastomosis provides good training for anastomosing vessels of different diameters, flows, and structures. The sciatic nerve can be found on the posterior side of the leg and once isolated can be cut and used to simulate simple epineurial anastomosis [40].

Perfused fresh human cadavers have also been proposed as a high-fidelity training model for several plastic surgery techniques. In a study by Carey et al., this model was used to simulate basic techniques like simple wound closure, as well as free flap harvest and microsurgical anastomosis (Fig. 5). The primary simulation model used was radial forearm free

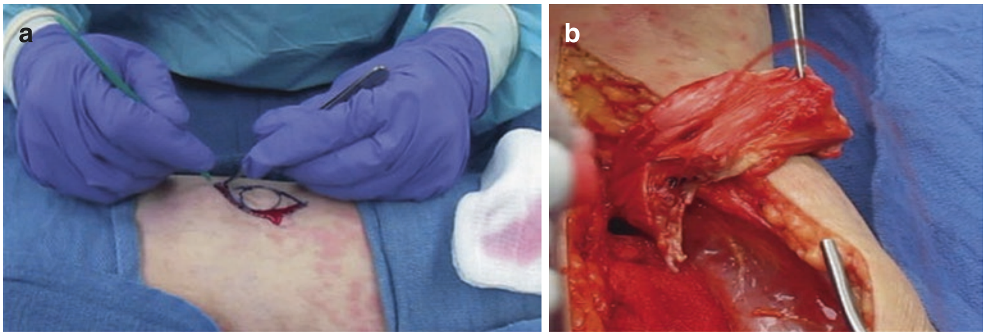

Fig. 5 (**a**) Fresh perfused cadaver model demonstrates a bleeding dermal edge when cut. (**b**) The cadaver model demonstrates his pressure arterial bleeding, with transection of a gastrocnemius flap pedicle. (Reproduced with permission of Ref. [41])

flap anastomosed to recipient vessels in the neck. Advantages of the fresh perfused cadaver include an obvious anatomical similarity to what would be encountered in the clinical setting and the ability to work under a pressurized, perfused system (Fig. 6). However, limited availability and ethical regulations prevent high-throughput use of this model [41].

Little difference has been found in outcomes for simulation training using low-fidelity models like silicone tubing or high-fidelity animal models like rat vas deferens; and both models have been shown to outperform didactics alone in microsurgical drill scores and anastomotic patency rates and increase retention of those skills [42].

Computer-Assisted Simulation

Emerging technologies in computer software have allowed advances in both education and in presurgical planning. Although likely the least developed area of simulation in plastic surgery, computer-assisted learning is another avenue by which surgical skills can be taught, with endless reusability and without the ethical conflicts of human or animal models. A multimedia software module that allows self-directed learning of how to perform a rhomboid flap has been shown to improve theoretical knowledge and flap execution when compared to self-directed learning with printed text and illustrations [43]. Smile Train and myFace are examples of Web-based virtual surgery simulators offering free educational modules in cleft lip/palate repair and craniofacial surgery, respectively [44]. This type of technology can also be used in virtual surgical planning, with patient CT images being converted to three-dimensional (3-D) images for analysis and treatment planning [45]. A virtual reality simulator developed by Stanford has been used for training in microsurgery and microanastomosis. The simulator allows virtual performance of vessel end-to-end anastomosis using the viscoelastic properties of endogenous vessels to create a realistic feel [1]. Three-dimensional (3-D) printing has a wide range of applications including creating anatomic models for trainee and patient education, creating patient-specific custom implants, providing operative templates for surgical planning, and even providing a scaffold for the growth of living cells in tissue engineering [46]. 3-D printing, also known as additive manufacturing, is a computer-controlled process by which material is deposited in successive layers to produce a 3-D end product. It has the potential to produce artificial and biologic implants given its ability to utilize a wide range of materials. 3-D

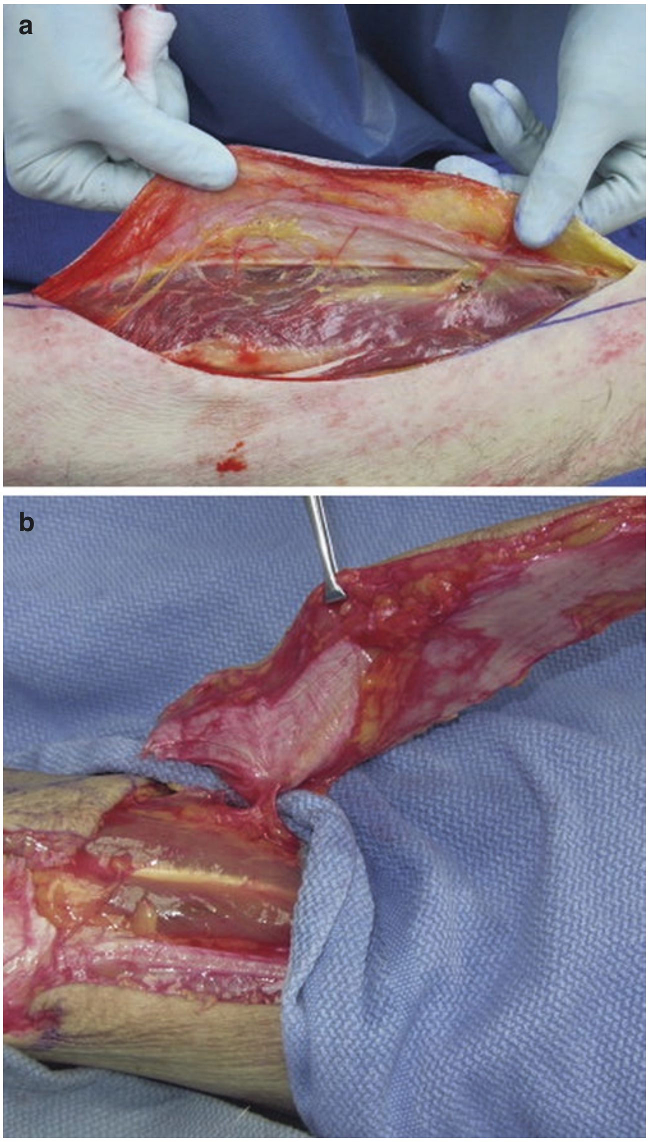

Fig. 6 Flap harvest of an anterolateral thigh flap (**a**) and a posterior tibial perforator flap (**b**). (Reproduced with permission of Ref. [41])

printers have the ability to produce customized implants that can improve patient outcomes and decrease operative time and cost. This is particularly useful in the field of craniomaxillofacial reconstruction given the complexities and distinct anatomy of the human face. For example, 3-D printers have been used to make pre-bent reconstruction plates based on patient imaging in maxillary and mandibular reconstruction [46]. 3-D printers have also been used to generate tissue-engineered bone grafts and biologic scaffolds with osteoconductive properties that can mature into mineralized tissues with similar density and structure to endogenous bone. Additionally, 3-D printing can also be used to make customized anatomic models that allow use of both the visual and tactile senses for trainee and/or patient education [47].

The Future Role of Simulation in Plastic Surgery Education

Increasing pressure from regulatory councils like the Accreditation Council for Graduate Medical Education (ACGME) in the United States and the Royal College of Physician and Surgeons of Canada to find ways to effectively assess trainee performance and demonstrate competence has led to an increasing role for simulation in plastic surgery and other surgical fields. Furthermore, simulators have been classified by the ACGME as the most desirable tool for evaluation of surgical skill. It is likely that educational leaders may shift to designing a simulation-based assessment curriculum that compliments predefined milestones of the specialty [1]. Periodic assessments using this format can provide real-time information regarding deficiencies in skills and allow early intervention. Although several simulation models exist for various aspects of plastic surgery, more work needs to be done in validating these models as useful training devices and assessment tools.

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Simulation in Orthopedic Surgery

Jonathan P. Braman

Like any other surgical field, students of orthopedics have long used animal models to learn anatomy and practice surgical technique. As in any field, closing a wound can be learned from working on a similar animal tissue. In addition, because of the important and somewhat unique role that "approaches" (usually through internervous planes) play in orthopedic surgery, cadaveric simulation has long been a part of the manipulative aspects of orthopedic surgical education. At the same time, however, orthopedic surgery is unique among the surgical specialties in that many of the procedures that are required to treat patients require manipulation of musculoskeletal structures. As a result, there is a long-standing tradition of practice on colleagues and volunteers for such things as reduction of fractures and joints. Additionally, with the invention of casting as an important tool for the orthopedic surgeon, casts and splints can be applied and cut off numerous times without harming the person on whom the cast is applied. As a result, many of these skills have been trained in this fashion for generations.

Artificial bones for practicing orthopedic surgical skills were developed decades ago. These have played a central role for techniques of bone manipulation and shaping. In the late 1970s, Dr. Frederick Lippert at the Seattle Veteran's Administration Hospital and the University of Washington partnered with a polymer manufacturer to create synthetic bones that could be cut and manipulated in order to simulate the activities that residents would experience in total joint reconstruction and in fracture repair. He created a Psychomotor Skills Training course that led to a company, Sawbones®, which continues to manufacture synthetic bones for use in surgical education today [1]. These have become extremely important not only in the training of surgical residents, but in the continued development of surgeons in practice. They are particularly useful for learning new instrumentation, for instance when a new type of joint replacement implant comes out. They are also very useful for practicing fracture fixation and learning principles of open reduction and internal fixation (image http://www.sawbones.com/Catalog/Orthopaedic%20Models/Knee/1145-49).

More recently, during the 1980s and 1990s, arthroscopy became more popular for the treatment of patients. Newer, less invasive techniques developed and soon simulation followed as well. Low-fidelity anatomic models were the first on the market to allow surgeons to learn the techniques in a dry environment. In the last 10 years, there have been a flurry of arthroscopic simulators that vary from physical systems to virtual systems with haptic feedback. In fact, orthopedic surgery was one of the first specialties to have their governing body coordinate development of a simulator. In the late 1990s, the American Board of Orthopaedic Surgery, the American Academy of Orthopaedic Surgeons, and the Arthroscopy Association of North America combined to develop the virtual reality arthroscopic knee simulator (VR-AKS) first prototype of the virtual knee arthroscopy [2].

The American Board of Orthopaedic Surgery (ABOS) continues to recognize the important role that simulation plays in the training of orthopedic surgeons. As a result, in 2013, the ABOS mandated the inclusion of simulation as a part of the curriculum during the intern year of training. They provided an online curriculum as a starting point for discussion of what modules might be of benefit [3]. These modules were a combination of basic skills such as "sterile technique," or "casting and splinting," and more complex concepts like "arthroscopic surgical skills." The ABOS also launched a request for proposals and selected several recipients of grant funding for simulation in orthopedic surgery in 2014. Further, recent emphasis by the ABOS has focused on understanding the role that simulation can play in orthopedic training [4]. Attendees at this conference discussed that status of ongoing research into low-fidelity simulation and goals for further research in this area. The enthusiasm from the board is also reflected by the interest of the broader orthopedic community in studying many of these simulators

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and/or curriculum in a rigorous way. The orthopedic community is increasingly recognizing the important role that simulation can play, and the discussion has begun to evolve to other discussions such as how to assess and reduce decay of skill [5].

Nonanatomic Surgical Simulation

There are many different options for nonanatomic surgical simulation. Most of the devices that have been developed have focused on arthroscopy training, since much of open surgery can be simulated using cadavera, artificial bones, or nonhuman tissues.

Arthroscopic Skills

BASEC

The Basic Arthroscopic Skills Evaluation and Curriculum (Fig. 29.1) is the product of a standardized backward design process by a panel of expert arthroscopists. In the manner outlined by Sweet et al. [6], the panel deconstructed general arthroscopic skills with the specific goal of making them non-joint specific (e.g., equally applicable to knee, elbow, or shoulder arthroscopy) and focused on the novice arthroscopic surgeon. Iterative design was then used until the panel developed two modules: triangulation and object manipulation. Triangulation emphasizes the need to control the field of view then access targets using a standard arthroscopic probe. Errors in placement are detected automatically based on the internal design of the simulator. Bimanual work is emphasized by the setup of the simulator – the task cannot be completed without using both the left and the right hands to probe targets. Object manipulation emphasizes the next level of skill development by requiring the transfer of pegs from a series of pins to a staging station, then transferring them again to the other side. This process is repeated in reverse, thereby ensuring that bimanuality is trained as well. In a study comparing arthroscopic experts to novice arthroscopists, this device was able to demonstrate that experts came to a steady state of mastery within three trials while novices did not. Additionally, it was found to have content aspects of validity with novices and experts alike [7]. Further work has allowed this to be linked to a learning management system that automatically detects errors and allows objective assessment of benchmarks. This allows residents to practice more independently and even be assessed while minimizing faculty time. Additionally, it has been shown to improve the skill of intern arthroscopists on a cadaver knee. In a randomized, blinded educational study with a crossover design, exposure to the simulator improved intern skills using a validated assessment tool, compared to no use of the simulator [8].

The Fundamentals of Arthroscopic Surgery Training (FAST) curriculum is another low-fidelity system for teaching arthroscopic skills (Fig. 29.2). It was launched in 2011 as a joint project of the ABOS, the American Academy of

Fig. 1 BASEC is a two-module product that allows scoring to be recorded by an online learner management system using any laptop computer with Internet access

Fig. 2 The FAST system allows users to practice different arthroscopic skills using modular design. It also allows training without an arthroscope by using direct visualization. (Courtesy of Pacific Laboratories and the Arthroscopy Association of North America)

Orthopaedic Surgeons, and the Arthroscopy Association of North America to provide curriculum for arthroscopic skills training residents [9, 10]. The curriculum consists of six modules conceived to allow increasing skill development with the arthroscope and with object manipulation during arthroscopic surgery. These emphasize the basic principles of arthroscopy, triangulation skills, interventional arthroscopy, suture anchors, passing suture through tissue, and arthroscopic knot tying. The validation of this curriculum has focused on the device that can be used in conjunction with FAST that allows objective assessment of knot integrity. This device allows knots to be tied around a metal mandrel using any arthroscopic knot technique. Following this, each suture loop is placed under static stress of 15 lbs for 15 s with failure defined as 3 mm or more of loop expansion [11] (https://www.sawbones.com/fast-arthroscopy-workstation-standard-with-knot-tester.html). Further work by this group has demonstrated that residents show that their cadaveric arthroscopic Bankart (shoulder labral repair) technique improves with a simulation-based and proficiency-based curriculum [12].

Fluoroscopic Skills

A fundamental skill for orthopedic trauma surgeons is fluoroscopic guidance. This skill requires positioning of a metallic device or reduction of a fracture into the correct position in three-dimensional space. This skill has traditionally taught through the use of clinical fluoroscopy equipment. When taught in the operating room, it results in increased exposure of patients, learners, and staff to radiation as the novice uses more images than experts. Yehyawi et al. created and validated a simulated fracture model for the distal aspect of the tibia (pilon fracture) [13]. This complex fracture requires indirect reduction since the soft-tissue envelope in these injured patients does not tolerate broad open dissection without compromising wound healing. As a result, it serves as a useful model for fluoroscopically guided indirect reduction. In their simulator, radiolucent artificial bones with a standardized pilon fracture are encased in synthetic soft-tissue envelope and must be manipulated indirectly using standard fracture reduction tools and pinned in place using K-wires. This is performed with the use of a clinical C-arm fluoroscopy. This has been shown to have construct validity.

A second task that has been studied by this group is wire navigation. They developed a simulator that allows the placement of a pin inside an artificial proximal femur. Using sensors, they are able to provide a “fluoroscopic” view of the position of the pin in this bone without using live fluoroscopy. This greatly enhances the safety of the exercise and reduces the cost as well by eliminating the need to use clinical fluoroscopy machines. The learner can practice the skills indefinitely without exposure to ionizing radiation. This process has been further refined to allow feedback on the position of the pin to help the learner improve on placement. Metrics programmed into the simulator allow for feedback on the angle of placement, orientation in the femoral neck, as well as the traditional metric for pin placement success – tip-apex-distance [14].

Fundamentals of Orthopaedic Surgery (FORS) was developed at UC Irvine to be a cost-effective mechanism for teaching residents many of the skills used in the orthopedic operating room. This curriculum was designed to allow anyone to generate these modules from readily available items purchased at a local hardware store. They described six modules that could be created for $350. These modules included the following: fracture reduction, three-dimensional drill accuracy, simulated fluoroscopy-guided drill accuracy, depth-plunge minimization, drill-by-feel accuracy, and suture speed and quality. This curriculum was studied by exposing novices to it and demonstrated that novices could be trained quickly to the point where they completed the tasks at the level of a junior resident. This curriculum has been made available [15].

Virtual Reality Models

Numerous companies have developed virtual simulation products that use virtual reality and anatomic simulation. Most of these are focused on arthroscopy as it is well-suited to the virtual reality world. Many of these include haptic feedback and online mentoring. The ToLTech ArthroSim product was generated from the collaboration of the ABOS, AANA, AAOS, and Touch of Life Technologies (Aurora, CO). This started as a knee arthroscopy simulator with haptic feedback and has evolved to include modules for the shoulder as well. This product has online virtual mentoring as a part of the curriculum. Currently, it is only capable of simulating diagnostic arthroscopy. When randomized, residents in the group exposed to the simulator had better ability to complete the content-specific checklist and better skills with probing. Visualization skill was not improved with this tool [16]. This device has also demonstrated the ability to differentiate novice arthroscopists from experts based on time to task completion [17].

Another virtual simulator is the VirtaMed ArthroS (Zurich, Switzerland). This device also allows simulation of joint-specific shoulder or knee skill development. It has the ability to provide passive haptic feedback and allows collection of data from the learner in terms of time to completion and the level of adequacy of the diagnostic arthroscopy. Validation of this product has focused on face and construct validity, and it has been able to demonstrate both in published studies [18, 19]. There are five modules available for this platform. The first of these emphasizes the FAST curriculum created by AANA. This is a nonanatomical computerized version of the FAST workstation. It concentrates on visualization and horizon control as well as telescoping and triangulation, as well as including 30° and 70° optics. The second module focuses on anatomic virtual models and uses similar skills in the virtual reality joint to further improve basic skills. The third module is formal diagnostic arthroscopy of the knee and the shoulder. These include different simulated pathologic lesions such as meniscal tears, chondral surface damage, and superior labral lesions. The surgical skills can be further developed by interventional simulations that require the learner to develop meniscal punch skills, use of a shaver, and bur. These skills are used in a variety of simulated pathologic joints allowing the learner to develop skills used in various situations. The final module allows removal of a diseased ACL tear and identification of the correct positions for tunnel placement [20]. All of these skill-development exercises are supported by an online virtual mentor that helps the learner navigate the curriculum and provides feedback during simulation. Only the diagnostic arthroscopy modules have been studied and reported in the peer-reviewed literature.

Simbionix (now 3D Systems) (Littleton, C0) also has a virtual reality simulator called the ARTHRO mentor also known as the insightArthroVR. This is similar in that it uses virtual reality and an online virtual mentor to teach learners about different skills. It also incorporates the FAST curriculum into the digital world. It also allows significant flexibility of the positioning of the virtual patient, allowing lateral or beach-chair shoulder arthroscopy simulation. Robotic arms attached to the equipment used in the device allow haptic feedback. Additional attachments allow development of skills with foot pedals in addition to the camera, grasper, and probe. Advanced knee modules allow further anatomic skill development and practice with meniscectomy. The shoulder module allows diagnostic arthroscopy as well as debridement and SLAP and Bankart repair. Lastly, a hip module allows development of hip diagnostic arthroscopy skills in the lateral decubitus or supine position [21]. Efficient completion of the shoulder portion of the curriculum has been demonstrated to correlate with year in residency training and prior arthroscopies performed [22]. Metrics for the knee portion of the simulation have been validated and pass-fail levels published [23]. Finally, in a randomized study, the exposure of novice arthroscopists to this simulator resulted in improved performance on a cadaveric knee arthroscopy when compared to a traditional didactic and arthroscopy-based curriculum [24].

All three of these simulators were evaluated side-by-side and found to have similar face validity [25]. The ArthroS had the highest overall face validity, but only the external appearance of the device achieved statistical significance.

Open Surgical Simulation

As mentioned above, much open surgical simulation has focused on cadaveric work. Attempts have been made to make this more objective and create assessments from this work. Van Heest et al., at the University of Minnesota, examined a hand surgery curriculum focusing on open carpal tunnel surgery. Their work demonstrated that using a traditional OSATS model, inadequate knowledge correlates with failure of the surgical portion, but adequate pretest knowledge is insufficient to predict successful surgical performance [26]. Additional work by this group showed that a traditional OSATS score, score on a content-knowledge examination, and in-training exam scores did not correlate with biomechanical stability in a simulated distal radius fracture model [27].

Simulation has also been used for teaching. Injections and many different models have been developed. One study demonstrated a reduction in their skill decay when they reviewed the online portion of the curriculum prior to distant retesting. This was after a curriculum that used anatomic knee and shoulder models and a formal curriculum [28].

Removing a cast can generate heat. If done incorrectly, it can cause thermal damage to the patient. As a result, Brubacher et al. looked at using thermocouples to develop a model for teaching proper cast removal technique. They were able to develop a simulator that detected the difference between accepted “good” technique and “poor” technique based on the amount of heat generated beneath the cast. “Poor” technique consistently produced heat to the level that would cause skin damage in patients. This system allows teaching using feedback by temperature probe [29].

Compartmental syndrome is another critical nonoperative skill for orthopedic surgery residents to master. As they are often the first-line evaluator in the emergency department, it is imperative that they are able to determine the presence or absence of elevated compartmental pressures. Manometric compartmental assessment is performed regularly in the emergency department. Models exist for this as well and are included in the ABOS curriculum as examples. The curriculum to teach it didactically and with simulation has been validated and showed good increase and maintenance of skills [30].

Little scientific work has been published on the simulation of nontechnical skills in orthopedic surgery. Schmitz et al. in a multicenter multidisciplinary simulation assessment looked at whether residents could be taught skills that would help them discuss with patient family members regarding end of life discussion and the disclosure of a complication. Using a validated OSCE format, they were able to demonstrate that exposure to the simulation experience helped all residents improve in their performance in these two content domains. Use of the online and face-to-face curriculum did not improve performance over simple repetition of the simulation experience [31].

Conclusions

Orthopedic surgery has a long-standing history of using simulation as a tool for education of resident and practicing surgeons. The important role that simulation plays in orthopedic education is recognized by the American Board of Orthopaedic Surgery and similar bodies worldwide. Furthermore, simulation has become an increasing area of scholastic work in orthopedic surgery. The majority of simulation activities that are performed in orthopedics are technical in nature, with most of them being surgical technique driven. At the same time, orthopedics has many types of nonsurgical skills that need to be developed in order to achieve competence, and simulation is increasingly filling this area as well. Opportunity exists for orthopedic education and simulation in communication with patients and other nontechnical skills.

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Simulation in Obstetrics and Gynecology

Thomas P. Cacciola and Martin Martino

Introduction

“See one, do one, teach one” has been a longstanding tradition for the practice of both medicine and surgery. While that may certainly be a viable method of teaching and learning, it is now outdated and somewhat impractical. With the ever-increasing demands on a physician’s time, increasing compensation based on patient outcomes, and the increased push toward evidence-based medicine, the best time to learn a new procedure is not necessarily in the moment, or on a new patient. Increasing medical knowledge and research makes it difficult to stay current on the “best practice.” Patients are increasingly more concerned that they are being used as “practice.” Therefore, the role of and need for simulation in the teaching of medical students, residents, and fellows have been ever increasing. Learning surgical technique on patients is not only time-consuming and oftentimes dangerous for patients but also expensive in terms of increased operating room time and thus costs [1].

Simulation is not a new phenomenon in the practice of medicine. In fact, the idea of first learning on inanimate objects and cadavers has been present for centuries. In obstetrics and gynecology, however, there are unique learning opportunities for which simulation is particularly suited. Simulations have been shown in both surgical and OB-GYN residents to be beneficial with regard to both patient safety and technical skills [1–3].

Simulation and simulators do not always have to be incredibly realistic or lifelike. They do not have to be high fidelity. However, they do have to be able to recreate a real-life scenario adequately. From basic role-play to low-fidelity models for procedures or situations and to the extremely high-fidelity computer simulators, all simulation has its utility in a tool kit for medical and surgical learners. This chapter will attempt to elucidate the current simulation methods used in training residents and fellows in obstetrics and gynecology in a logical and organized fashion.

History

Simulation in obstetrics and gynecology was described as early as the 800s [4] where figurines were used to demonstrate childbirth. In the 1600s obstetric simulations were used to teach midwives how to deal with difficult birthing processes via mannequin torsos [5]. False pelvises and mannequins, utilized with either dead children or mannequins, were developed in the 1700s in France and Britain to better teach the birthing process. Fast-forward to the mid-to-late 1900s when there was a transition to full-size, interactive training models, which started to simulate the birthing process realistically [6]. In the 1990s, the simulator known as NOELLE was developed. NOELLE is a life-sized high-fidelity birthing mannequin complete with mechanical system for simulating a vaginal delivery as well as a fetal heart rate simulator.

Surgical simulation in gynecology has evolved from an apprenticeship model to one that incorporates simulation in major ways. Simulation started with simple figurines and moved to task trainers and surgical skills training such as suturing drills and basic surgical techniques. High-fidelity systems incorporated recently allow learners to participate in advanced procedures, such as laparoscopy or robotics, with realistic accuracy. Laparoscopic virtual reality (VR) simulations showed an increasing benefit on operative technique and surgical efficiency [7]. Production of

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high-fidelity simulations can shorten the learning curve and allow both experienced surgeons and novices to become more familiar with and more proficient at new surgical techniques [8].

Simulation in recent years has expanded to include not only procedures but also emergencies and uncommon but life-threatening events. The team-based, multidisciplinary approach is particularly effective in reducing adverse outcomes and improving performance.

Currently, the need for simulation in obstetrics and gynecology has been recognized and addressed both domestically and internationally. ACOG and the Society for Maternal-Fetal Medicine (SMFM) have developed official programs and recommendations for simulation training. SMFM in their publication *Seminars in Perinatology* put forth an entire special issue entitled *Simulation in Maternal-Fetal Medicine* [9–21]. ACOG has several recommendations as well, with clear goals and objectives and a formal curriculum for simulations aimed at teaching the vital and oftentimes most high-risk aspects of obstetrics and gynecology [22, 23].

Debriefing and Feedback

With any sort of simulation, debriefing and feedback prove to be the most important elements in cementing knowledge in the mind of the learner. It provides an opportunity to explore and reflect on the performance during simulation. It allows for the discovery of aspects of the simulation that went well, aspects that need improvement, and areas for personal and group growth. In medicine, David Gaba pioneered the use of simulation and feedback in the field of anesthesia. He was extremely fond of debriefing as an "integral part of the process of any experiential-learning technique" [24]. Important aspects of debriefing can follow several models, such as those produced by the Center for Medical Simulation in Cambridge, Massachusetts. They follow the three stages of debriefing which include reactions, understanding, and summarization:

1. The reaction stage is where participants are able to regroup from the experience, review what happened, and begin to understand learning objectives.
2. The understanding phase is where participants are able to explore events of the simulation, apply new learning and skills, and expand those new skills to more general situations.
3. The summary phase is where participants are able to review events that transpired and the learning after that and to discuss broad aspects of lessons learned which could be utilized in the future [25].

Communication

TeamSTEPPS

The TeamSTEPPS (Strategies and Tools to Enhance Performance and Patient Safety) is a program formed as a collaboration between the Department of Defense (DoD) and the Agency for Healthcare Research and Quality (AHRQ). TeamSTEPPS focuses on structure, communication, leadership, situational monitoring, and mutual support. It offers an evidence-based approach to communication and teamwork with a goal of enhanced patient safety. Training and application are customizable for any healthcare setting. In obstetrics and gynecology, TeamSTEPPS is particularly useful in teaching junior house staff and residents appropriate communication skills. The SBAR is a particularly important tool for residents to learn. It is a basic method for communicating critical information in a succinct rapid fashion. It consists of the current situation, pertinent background information, and an assessment and ends with recommendations or a request. For example, a junior resident calling a senior or attending in an emergency can rapidly present information, assessment, and plan.

Since formation, the TeamSTEPPS approach has been applied and tested in numerous settings showing consistent improvement in patient outcomes. For example, in obstetrics and gynecology, Nielsen and Mann looked at implementation of such measures in a labor and delivery setting and noted a significant 23% decrease in adverse events after implementation [22].

Obstetric Simulation

In 2012, a publication entitled "Quality Patient Care in Labor and Delivery: A Call to Action" was published. Endorsed by the American Academy of Family Physicians, American Academy of Pediatrics, American College of Nurse-Midwives, American Congress of Obstetricians and Gynecologists, American College of Osteopathic Obstetricians and Gynecologists, Association of Women's Health, Obstetric and Neonatal Nurses, and Society for Maternal-Fetal Medicine, it addressed the need for collaborative "patient-centered" care of obstetric patients. It emphasized the need for effective communication, shared decision-making, teamwork, and quality measurement [26].

Traditionally, obstetric simulation was used to teach skills and procedures. More recently, it has been used to incorporate new technology, improve multidisciplinary communication and teamwork, and focus on patient safety [27]. Additionally, it is used successfully to teach how to appropriately deal with rare, yet significant, events in safety and in a controlled setting.

Simulation can be both diagnostic and therapeutic when applied to different scenarios. It can allow observers and participants the opportunity to identify patterns of error during certain clinical scenarios. It can also allow for the guided improvement in those areas and then use the test/retest model to look for improvement. Repeated simulation thus allows for continuous improvement at both the individual and the department/institution levels.

ACOG Simulation

ACOG recognized the importance of simulation in the training of new physicians. They developed the ACOG Simulations Consortium, which has published several modules available on the ACOG website. The simulations encompass both obstetrics and gynecology. Topics include fourth-degree laceration repair, breech delivery, eclampsia, ovarian cystectomy, postpartum hemorrhage, salpingectomy, salpingo-oophorectomy, shoulder dystocia, and vaginal hysterectomy [19, 20]. The simulation packets are broken down into realistic goals, both in didactics and practical applications. Several levels of objectives include:

- Level 1 focuses on declarative knowledge and allows learners to recognize issues.
- Level 2 is objectives for recognition during simulated performance.
- Level 3 is the ability to recognize issues and complications in clinical practice [19, 20].

Through this multistep approach, it is possible to guide novices to better understanding and competence in these important skills.

Shoulder Dystocia

A shoulder dystocia is any delivery that involves any extra obstetric maneuvers following downward traction on the fetal head to affect delivery of the shoulders [23]. According to ACOG, it occurs in approximately 0.6–1.4% of deliveries. However, it can cause serious fetal and maternal complications. The risk of permanent brachial plexus injury, for example, is slightly less than 10%. Shoulder dystocia and its sequela carry a major source of litigation for obstetricians [23].

Given the relatively low incidence and high risk of morbidity, it is important for physicians to learn how to appropriately deal with shoulder dystocia [28, 29]. A British study [25] observed 450 shoulder dystocia simulations, attempted to identify the 7 most common errors in shoulder dystocia management, and then attempted to describe correct management techniques. Improvement in areas of communication, calling for a neonatologist, applying suprapubic pressure, gaining access to the posterior vagina, trying different maneuvers, clear documentation, and clear communication with the patient were all areas that needed improvement. The importance of these was shown to improve actual clinical practice as well [24, 29, 30].

In 2006 Crofts and colleagues presented a simulated practice mannequin and subsequent follow-up data with the PROMPT (Practical Obstetric Multi-Professional Training) simulator. They showed that both high- and low-fidelity simulation training improved management of shoulder dystocia. However, they noted that the use of a high-fidelity trainer with force perception training provided additional clinical benefits [31].

In 2016, Weiner and Collins published longitudinal data following PROMPT training, which showed that annual training was associated with improved obstetric outcomes including decreased brachial plexus injury and hypoxic-ischemic encephalopathy, among others [32].

Postpartum Hemorrhage

Postpartum hemorrhage remains one of the leading causes of maternal morbidity and mortality worldwide and in the United States [33]. As this is mostly preventable, The Joint Commission issued a Sentinel Event alert and a subsequent joint publication from ACOG and SMFM in late 2016 addressing severe maternal morbidity [34, 35]. The recommendation for criteria for severe maternal morbidity encompassed only two screening tests: transfusion of four (4) or more units of blood and pregnant/postpartum admission of a woman to an ICU [34, 35]. This reduction in postpartum hemorrhage will therefore be able to decrease severe morbidity and mortality significantly.

Training in the recognition and management of postpartum hemorrhage is mostly performed using low-fidelity simulations, traditional didactic lectures, and interactive software [36, 37]. These focus on early recognition, appropriate medication administration, timely movement to the operating room, and accurate estimation of blood loss [38]. Methods for more accurately estimating blood loss have been trialed, including graduated bags and canisters, the use of checklists, the weighing of sponges, and visual estimation or "eyeballing" based on pictorial estimation [37, 39]. The implementation of a training and simulation program has, in some instances, such as in the study by Egenberg et al. in Norway, proven beneficial and has possibly decreased blood loss, postpartum transfusion, and rate of dilation and curettage as well as uterine artery embolization [40].

Eclampsia

Eclampsia is a significant obstetric emergency that is relatively uncommon in the United States and other industrialized nations, occurring in approximately 2–3% of severely preeclamptic women who have not received seizure prophylaxis [12]. It carries a significant risk of both maternal and fetal morbidity and mortality. It generally occurs as tonic-clonic seizures in either the antenatal period, though it was observed in the postpartum period as well. It has been associated with preeclampsia, although its association is not clearly linear.

ACOG has published a specific simulation course for recognition and management, which involves recognition of risk factors, prompt treatment of seizure with magnesium sulfate (if not contraindicated), and appropriate recognition of magnesium toxicity. Simulation usually involves patient actors, the shaking of mannequins, or high-fidelity simulators that can portray seizure activity [22]. A randomized trial by Fisher et al. showed that simulated training was superior to traditional lecture training [41].

Further research is necessary to establish if these interventions can make a clinical difference, as most only looked at outcomes in a simulated or post-test scenario. However, simulation has been helpful in creating "eclampsia boxes" in some hospitals, which contain all the necessary supplies for management of eclampsia in one convenient space [42].

Operative Vaginal Delivery

Operative vaginal delivery has become less prevalent in the United States in recent years yet remains an important skill set in the practicing obstetrician and gynecologist. The ability to perform an operative delivery rapidly and safely can mean the difference in maternal morbidity, particularly in terms of fetal outcomes. Therefore, it is imperative to be able to teach this valuable skill. One important study by Dupuis et al. examined the effect of birth simulator use on an obstetrician's ability to place forceps blades correctly on a simulated fetus. They found that simulation increased the accuracy of placement with each successive attempt and that trainees needed approximately 35–80 attempts to place them with 100% accuracy [43].

The major problem with simulation of operative vaginal delivery is fidelity of simulator. It is difficult to simulate the tissue and appropriate feel accurately to carry over from simulation to clinical practice. Improvements in technology and 3D printing have begun to address this problem, as in the example of the Boston Children's Hospital SIMPeds program, a joint effort between pediatric surgery and the movie special effects industry, which aims to 3D print more accurate and realistic models for research and simulation [44].

Maternal Cardiac Arrest

Although hemorrhage is the leading cause of maternal mortality overall, cardiovascular disease is the leading cause of maternal death in the United States according to a study by Berg et al. [45]. This trend leads to an increasing need for training in cardiac emergencies and cardiac arrest for the pregnant patient.

While the ACLS and NRP algorithms have been repeatedly validated and updated, they start with the mother or the child, but not with both. Critical care in pregnancy dictates starting resuscitative efforts of the mother based on the ACLS algorithm. ACOG recommends that fetal perimortem cesarean delivery be performed approximately 4 min after cardiac arrest for both maternal and fetal benefits, as fetal survival is unlikely if more than 15–20 min have elapsed since maternal arrest [46].

Simulations in the management of maternal cardiac arrest have been performed most effectively in a "mega code" scenario with multiple participants. Typically, a high-fidelity simulator, such as NOELLE, is used. The simulator can be fashioned in a way to perform a mock cesarean delivery with low-fidelity inserts, such as foam and pieces of steak, to simulate fat and fascia, respectively [47]. To our knowledge, at this time, there is no high-fidelity simulator that can be used to simulate maternal cardiac arrest and to reliably/accurately simulate an emergent cesarean delivery.

Simulation has the benefit of effectively training obstetricians in management of cardiac arrest. As in other scenarios, repetition and debriefing seem to be the keys to improvement. Adams et al. showed significant increases in knowledge, confidence, and performance in critical performance steps after resident simulation, although the study was unable to demonstrate clinical improvement [47]. Similarly, Fisher et al. demonstrated an improvement in performance after maternal cardiac arrest simulation for maternal-fetal medicine staff [48].

Simulation in Gynecology

Basics

Simulation in gynecology differs from that in obstetrics as it focuses on surgical technique and proficiency for each individual, as opposed to the multidisciplinary approach that has benefited obstetrics. It still involves, however, the adaptation of routine or critical events in a controlled setting with opportunity for reflection and debriefing. Application of simulation in gynecologic training includes skills/task trainers, laparoscopic trainers, and virtual reality/haptic trainers.

Skills and Task Training

There are several different pelvic models in use today, which are able to provide specific task training. Pelvic models can be used to teach the basic bimanual pelvic exam, suturing skills, how to place an intrauterine device (IUD), how to perform hysteroscopic procedures such as resections or sterilizations, and procedures such as loop electrosurgical excisional procedure (LEEP) LP or cone biopsy. Some of these models are relatively low fidelity, and others combine basic models with computerized technology and virtual reality to offer realistic procedure performance and simulation.

Laparoscopic Simulation

Laparoscopy has become the standard of care for many gynecologic procedures. Laparoscopic training in gynecology is modeled on that of general surgery. The use of box trainers has traditionally been the simulation of choice for several reasons. First, they can be relatively inexpensive to fashion, with a box, trocars, and camera being available in most institutions. Secondly, the tasks performed can be as simple, or as complex as desired. Objects such as beads and pegboards placed in the box for skills improvement, or synthetic organs can be used to simulate real procedures. The main drawback to box trainers is the difficulty with providing feedback to the learner unless directly observed, as most box trainers do not have recording functionality. A second drawback is one of realistic procedures and haptic feedback. At this time, most mannequin/simulated tissue is a poor replication of the actual surgical experience. However, some of these limitations have been bridged by video-/computer-based hybrid simulation models or virtual reality simulators, which will be discussed below.

Laparoscopic training curricula were formed and tested in several settings. Multiple studies evaluated simulator training in laparoscopic surgery and noted that simulator training improved performance, shortened duration of surgery, and improved flow and self-efficacy [7, 49–51].

A universally accepted scoring system for laparoscopic surgical skills is yet to be developed; however several models have been proposed. The Global Operative Assessment of Laparoscopic Skills (GOALS) system is a widely used scoring system (Table 1). It is based on a rating scale consisting of five items which evaluate bimanual dexterity, depth perception, tissue handling, and autonomy [49]. This system was initially developed and validated for fellows performing laparoscopic cholecystectomy but has since been validated in gynecologic laparoscopic procedures. Another assessment tool widely used is the objective structured assessment of technical skills (OSATS) (Table 2), introduced by Martin et al. and Reznick et al. [52, 53]. These were a set of grading criteria, initially validated in a simulation setting, which have since been used to expound upon real-life scenarios in the operating room. Larsen et al. expanded on the general principles of the OSATS and evaluated performance in the operating room on live patients during laparoscopic salpingectomy with a rating scale called objective structured assessment of laparoscopic salpingectomy (OSA-LS), which was then validated [50]. Looking at the above scoring systems, the OSATS has been the most widely used across multiple specialties and procedures. However, the need for a universal scoring system persists. A universal scoring system will help to standardize and objectively evaluate learners, which can help to improve both teaching and performance in real-world surgical cases. To do so, there is a need to develop more scoring tools for specific gynecologic procedures. While a universal scoring system is the ultimate goal, more research is needed in this area.

Table 1 Global Operative Assessment of Laparoscopic Skills (GOALS)

Depth perception				
1	2	3	4	5
Constantly overshoots target; wide swings; slow to correct		Some overshooting or missing of target but quick to correct		Accurately directs instruments in the correct plane to target
Bimanual dexterity				
1	2	3	4	5
Uses only one hand; ignores nondominant hand; poor coordination between hands		Uses both hands but does not optimize interaction between hands		Expertly uses both hands in a complimentary manner to provide optimal exposure
Efficiency				
1	2	3	4	5
Uncertain, inefficient efforts; many tentative movements; constantly changing focus or persisting without progress		Slow but planned movements are reasonable organized		Confident, efficient, and safe conduct; maintains focus on task until it is better performed by way of an alternative approach
Tissue handling				
1	2	3	4	5
Rough movements; tears tissue; injures adjacent structures; poor grasper control; grasper frequently slips		Handles tissues reasonably well; minor trauma to adjacent tissue (i.e., occasional unnecessary bleeding or slipping of the grasper)		Handles tissues well; applies appropriate traction; negligible injury to adjacent structures
Autonomy				
1	2	3	4	5
Unable to complete entire task, even with verbal guidance		Able to complete task safely with moderate guidance		Able to complete task independently without prompting

Table 2 Objective structured assessment of technical skills (OSATS)

Respect for tissue				
1	2	3	4	5
Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments		Careful handling of tissue but occasionally caused inadvertent damage		Consistently handled tissues appropriately with minimal damage
Time and motion				
1	2	3	4	5
Many unnecessary moves		Efficient time/motion but some unnecessary moves		Clear economy of movement and maximum efficiency
Knowledge and handling of instrument				
1	2	3	4	5
Lack of knowledge of instruments		Competent use of instruments but occasionally appeared stiff or awkward		Obvious familiarity with instruments
Flow of operation				
1	2	3	4	5
Frequently stopped procedure and seemed unsure of next move		Demonstrated some forward planning with reasonable progression of procedure		Obviously planned course of procedure with effortless flow from one movement to the next
Use of assistants				
1	2	3	4	5
Consistently placed assistants poorly or failed to use assistants		Appropriate use of assistants most of the time		Strategically used assistants to the best advantage at all times
Knowledge of specific procedure				
1	2	3	4	5
Deficient knowledge needed specific instructions at most steps		Knew all important steps of procedure		Demonstrated familiarity with all aspects of operation

Virtual Reality

Virtual reality (VR) simulators and combined hybrid simulation systems bridge the gap between task trainers/mannequins and the operating room. They offer training in both cognitive and psychomotor skills, which is paramount to the training of competent surgeons. Widespread access to computers has led to the development of both low-fidelity training modules (i.e., training in the manipulation of an object in 3D space) and high-fidelity virtual reality (VR) immersion technology (i.e., training in complete surgical procedures).

Multiple studies looked at the effect of virtual reality simulation and improvement in surgical outcomes. A review of the literature by Larsen et al. in 2012 points to at least 12 high-quality studies (grade IA–IIB) to support the use of VR simulation in the training of gynecologic surgery [7]. Looking at operative time in human studies, a decrease in operative time of 17–50% was noted in groups undergoing VR simulation training, with a similar reduction in animal models. Similarly, studies by Aggarwal [54], Ahlberg [51], and Larsen [2], looking at simulations of complete surgical procedures, also show large reductions in operating times. Ahlberg looked at error reduction in residents performing cholecystectomy and found a significant reduction in the number of errors made (three times reduction), as well as decreased operating time by approximately 58% [51].

Robotic Simulation

Over the course of the last two decades, the use of robotic surgery has increased, with increasing pressure on training institutions to provide training in robotic-assisted surgical techniques. Robotic surgery has revolutionized advancements in minimally invasive surgery and has led to use in multiple specialties, particularly gynecology and gynecologic oncology. The design of the robotic system is primed for the integration of simulation into training as there is a training module built into some of the da Vinci Surgical Systems (Intuitive Surgical Inc.). Additionally, there are three dedicated robotic simulators: the dV-Trainer (Mimic Technologies), the Robotic Surgical Simulator (RoSS, Simulated Surgical Systems, LLC), and the newest which is the RobotiX Mentor (Simbionix). These systems all have built similar exercises and drills, which teach users basic and advanced robotic skills, and then score the user's performance for later review. Performances can be tracked to show improvement [55].

Looking at learning curves, from Lim et al., compared to conventional laparoscopy, robotic surgery required a smaller number of cases to obtain proficiency [56]. In 2010 the Robotic Training Network, or RTN (robotictraining.org), was formed which developed a standard curriculum for developing proficiency at the robotic console. The curriculum focuses on both bedside assistant and console surgeon and incorporates a proficiency test using the robotic objective structured assessment of technical skills (R-OSATS) tool [57]. This tool has been used in over 60 institutions across the United States for the training of residents and fellows in multiple specialties including gynecology. With regard to gynecologic oncology fellows, it is reported that a minimum of 50 cases of robotic hysterectomy is required to surpass the learning curve; however, the dual-console system could allow for increased proficiency as it allows for instruction and feedback in real time during a case [58, 59] (Fig. 1).

In 2013, the Fundamentals of Robotic Gynecologic Surgery (FRGS) was developed through consensus and

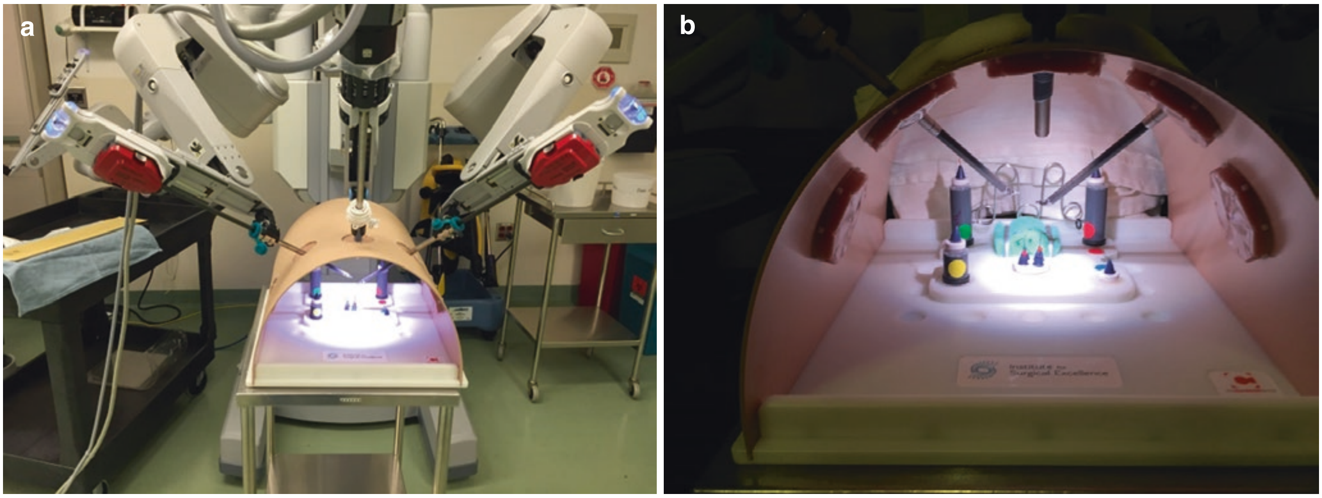

Fig. 1 (**a**, **b**) R-OSATS robotic trainer

adapted to VR simulation. This consensus conference included representation from multiple specialty societies and was fully supported by the Department of Defense through a grant. This curriculum is nearing completion with validation studies to begin in the near future. Also, in 2013 the RTN became part of the Fundamentals of Robotic Surgery (FRS) consensus conference, which is a joint educational program developed through a grant from the Department of Defense and Intuitive Surgical Inc. FRS training is currently in the process of being validated and is being managed by the Institute for Surgical Excellence (ISE) (www.surgicalexcellence.org), giving robotic surgical training a prominent place in the world of surgery.

The Future

Crowdsourcing and the Cloud

Current methodology for the evaluation of trainees in surgical assessment is via direct observation by an expert surgeon. The trainee can perform on a simulated procedure or task or can be performing an operation under direct supervision. Simulated tasks have the benefit of being able to be video-recorded with or without audio recording. As mentioned above, these forms of assessment are highly validated.

Recently, efforts to have evaluations performed by objective expert reviewers, including physicians and non-physicians, are underway. Crowdsourcing is one such proposed method. This involves the posting of a task (such as scoring a recorded surgical drill) on an online forum. Crowdworkers are members of the public who may or may not have any prior medical training. Trained specifically for the task posted, after completion, they receive compensation. Chen et al. looked at the C-SATS (Crowd Sourced Assessment of Technical Skill) web-based grading tool and used it to compare assessments of untrained crowdworkers to the assessments of expert surgeons. They found that crowdsourcing led to a rapid, inexpensive agreement of surgical skills with global performance scores given by expert surgeons [60].

Polin et al. sought to evaluate if R-OSATS expert ratings could be replicated by crowdsourcing recordings of surgical drills. Crowdsourced surgical drill recordings were scored and then compared to those same recordings as scored by expert reviewers. They found that crowdworkers R-OSATS scores were highly correlated with those of expert reviewers and that crowdsourcing was fast, inexpensive, and scalable. Further, they were able to suggest a minimum of 15 crowdworkers needed to receive a score similar to an expert reviewer [61]. Other studies have confirmed the reliability of crowdsourced assessments in surgical fields such as urology, as well as other medical subspecialties such as ophthalmology and pathology [62, 63]. Interestingly, both Polin and Chen noted that it took hours to obtain responses from the crowd, whereas it took several weeks to receive responses from the expert surgeons.

Virtual Portfolios

Being able to upload video to the crowd for analysis can help learners by assessing their surgical skill. Therefore, a future possibility in cloud-based performance analysis is that a particular surgeon could be able to store recent examples of procedures in the cloud, have those video clips evaluated and scored by the crowd, and then use them to further improve upon their surgical skills. Should their surgical skills be questioned, the surgeon could then bring their video portfolio as proof of surgical skill or could perform certain simulated tasks and have those evaluated by crowd-workers. Theoretically online portfolios could be brought to credentialing boards for proof of competency. At this time, however, the tools to adequately assess real-world surgical practice in a reliable manner have not yet been developed.

New Directions

Although the ability to successfully establish a safe learning environment and improve patient care using low-fidelity simulation has been possible and feasible, new technology will be able to bring high-fidelity training to much larger groups of people. Barriers to high-tech training include cost, availability, and ease of use.

Research into the effectiveness and sustainability of both new and current simulation techniques needs to be undertaken. Evidence-based innovation in discovery needs to be fostered at the institutional, societal, and governmental levels.

Multidisciplinary and individual simulation in obstetrics needs to continue to occur. Training in routine and rare circumstances using both low- and high-fidelity models and situations should lead to increased comfort, confidence, and competence.

A formal curriculum for all gynecologic trainees needs to be developed and tested. For the robotic system, the R-OSATS and the curriculum devised by the RTN and FRS are excellent examples of what can be accomplished. The important thing is the formulation of a standardized method for the evaluation and training in all areas of gynecology, including open, robotic, laparoscopic, and hysteroscopy surgery. A dedicated curriculum then needs to be followed by a standardized method of evaluation.

Summary

Over the course of the last several decades, simulation practices have been integrated more and more into the teaching and training of those in the field of obstetrics and gynecology. Data has supported the use of simulation in multiple fields including obstetrics and gynecology as well. Simulations and simulators used can be low fidelity or high fidelity, but the majority seem to have translated into positive outcomes. Whether all simulator skills are applicable to real-life obstetrics and gynecologic practice is yet to be seen. It is therefore extremely important that research continue in these areas in order to ensure that the simulations performed are effective and useful and can translate into improved patient care and outcomes.

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Part V

Conclusion

The Future of Surgical Simulation

Richard M. Satava

Introduction

In order to look into the future, it is necessary to set a baseline current status of surgical simulation, keeping in mind that there are over 90 years of nonmedical simulation experience as well as over 250 organizations which have been using simulation. In addition, looking outside of surgery often provides insight into potential future trends in technology, methods, processes, applications, and regulations that will significantly impact the directions that are possible for surgical simulation.

The most important revolution that simulation has introduced is in skills training (as opposed to pedagogical knowledge), so technical (and nontechnical) skills will be the focus of this speculation. The central core principle is that simulation provides the methodology and technology to quantitatively measure skills performance. Skills have not previously had quantitative metrics to determine acquisition of skills, rather subjective qualitative impressions during clinical practice have been used with the apprenticeship model. Because simulation is conducted separate from clinical practice, simulation is a "safe harbor" where surgeons, from novice to expert, can practice without harm to patients – with "permission to fail" and learn from mistakes without jeopardy to patients.

In short, what simulation provides is measurement of technical skills performance in an educational environment (usually a simulation center) separate from patient care in order to train a surgeon in improving patient safety. This is the current status of surgical simulation. It should be noted that the attention *is not* on simulators, but it *is* upon the content of the educational curriculum. In addition to emphasizing the correct steps of a procedure, the curriculum is focused on avoiding errors (in a safe environment), which improves patient safety.

Therefore, a summary of the current status of surgical simulation can be defined as procedural training (technical and nontechnical skills) which uses full life-cycle curriculum development [1] of proficiency-based progression (PBP) [2] courses which are used for initial training of novices, new procedure training for practicing surgeons, lifelong learning, and remediation. The results of the training can be used for privileging, credentialing, maintenance of certification, and, most importantly, self-evaluation and improvement.

While it is clear that the above current status is not in practice at all simulation centers, the evidence in the literature clearly establishes full life cycle and PBP as the preferred current methods, which for clarity, will be summarized below before speculating on their future impact.

In order to insure accurate understanding of the next generation of simulation, it is important to establish the definitions of the critical factors as well as the scope of simulation. The standard source for scientific definitions is the Oxford English Dictionary (OED) [3], for which definitions are listed in Table 1. These proposed definitions (for words underlined in *italics*, see accurate OED definition in Table 1) are specific to surgical simulation, and to avoid ambiguity, they have been carefully selected for relevance and accuracy, with the original OED definition in Table 1 to support the more specific explanation of the definition in the text. Some words have more than one definition; for example, *curriculum* can be either a list of the courses in a program or the steps within a specific course. For the purpose of this manuscript, the reference for curriculum will be that of a single course.

The individual components of any surgical procedure can be determined by "task deconstruction" [4]. For surgical simulation, a procedure is *deconstructed* into its simpler activities; thus, a procedure is broken down into *tasks* (and subtasks), which are further simplified into their component *skills*.

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Table 1 Definitions (*italics by the author)*

Aptitude: Natural capacity, endowment, or ability. A talent *for* any pursuit

Assessment: The measurement of a learner's potential for attainment (or their actual attainment) of performance

Benchmark: A point of reference (*value*) against which things may be compared

[*Note*: This is *not* the score, the score = 100%; that is, the learner must achieve the benchmark value]

Cognition: The action or faculty of knowing

Competency: Having the necessary ability, knowledge, or skill to do something successfully

Crowdsourcing: The practice of obtaining information or services by soliciting input from a large number of people, typically via the Internet and often without offering compensation

Curriculum: 1. The subjects comprising a program of study in a school or college

2. The content and specifications of a course of study

Deconstruct: To undo the construction of, to take to pieces.

Education: The systematic instruction, teaching, or training in various academic and nonacademic subjects given to or received by a child, typically at a school; the course of scholastic instruction a person receives in his or her lifetime. Also: instruction or training given to or received by an adult

Fidelity: The degree to which a sound or picture reproduced or transmitted by any device resembles the original

Formative Feedback: An ongoing process which takes place throughout the learner's course of study and provides them with the [*immediate*] feedback and guidance necessary to enable them to improve their performance

High-stakes test: Test with important consequences for the test-taker

Knowledge: The fact or state of having a correct idea or understanding of something; the possession of information about something

Metrics: A set of figures [numbers] or statistics that measure results.

1. Quantitative: A value or component that may be expressed in numbers
2. Qualitative: Distinctive [unambiguous] attribute or characteristic possessed by something

Outcomes measures: [descriptive] Quantifiable consequence(s) of an action, set of actions, or procedure

Practice: To perform (an *activity*) or exercise (a *skill*) repeatedly or regularly in order to acquire, improve, or maintain proficiency

Proficiency: Consistently meeting a high level of skill

Progression: Process of advancing to a further or higher stage

Real time: Designating or relating to a system in which input data is processed so quickly so that it is available virtually immediately as feedback to the process from which it emanates

Registry: An official list or directory of persons (or occas. things) belonging to a particular category, having a particular status, or holding a particular qualification

Skill: (*specifically psychomotor skills*). Capability of accomplishing something with precision and certainty; practical knowledge in combination with ability; cleverness, expertness, etc. Also, an ability to perform a function, acquired or learned with practice

Summative feedback: Takes place at the end of their course of study and measures the learner's attainment against the specified learning objectives [*outcomes measures*] of the syllabus or program

Test: A procedure intended to establish the quality, performance, or reliability of something, especially before it is taken into widespread use

Task: A piece of work or an exercise given to a subject in a psychological test or experiment

Training: The action of teaching a person a particular skill or type of behavior

The chosen definition for *education* is the overarching activity of systematic instruction, which includes knowledge and skills (though other aspects can be included). *Knowledge* is limited to acquiring and "understanding," whereas skills imply a physical activity (Fig. 1). (Note: *cognition* or cognitive skill is the activity of applying the knowledge during a specific physical activity, including abilities such as judgment, decision-making, etc.). Since simulation is principally used for skills, it is presumed that the individual will already have the basic knowledge about anatomy, physiology, preoperative preparation, and postoperative care, such that skills are focused upon the operative procedure. Therefore, the scope of this manuscript is the actual surgical activities (skills, tasks, procedures) and is limited to the activities from the entrance into the operation room (OR) until the completion of the procedure with an exit from the OR.

Within the context of skills, there are three components: the *cognition* skills (context-specific knowledge of the course which must be completed, tested, and then applied during the hands-on skills, such as steps of a procedure, common errors, decision-making, etc.), the hands-on technical skills (psychomotor, visuospatial, and perceptual), and the non-technical skills (i.e., team training, communication, etc.). It is acknowledged that this ontology is extremely simplified; however, the subject of simulation is so complex that this simplification is justified to provide clarity and uniformity which allows concentration on the technical skills, even though admitting to several other cognitive functions (e.g., mental rehearsal, judgment, decision-making, etc.) that are critical for full procedures. There are some "gray areas," such as "mental rehearsal" [5], which is defined here as a cognitive skill.

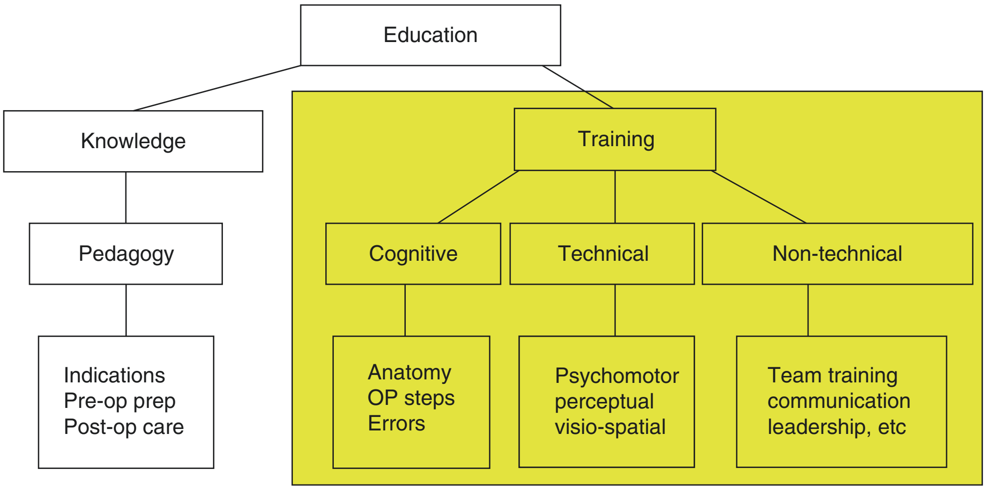


Fig. 1 Taxonomy for education and training

Simulation brings a rigor to surgical technical skills which have not been previously used, even though the processes and technologies have been available. Skills require a hands-on component that includes the efforts of a *trainer*, for *training* and *assessment* are two sides of the same coin, and involves physical interaction between faculty and learner. *Teaching* is a more generic term that refers to both didactic instruction and skills. The trainer should provide *formative feedback* by immediately intervening when an error is made during the activity, as well as *summative feedback* at the completion of a trial of a skill or task. Once training is successful, it requires *practice* to reach proficiency (see below) and be eligible for *high-stakes testing* at the completion of that specific skill, task, or procedure.

Other critical definitions are defined in the context of the remainder of the manuscript.

The current standard for clinical practice of patient care with scientific proof is evidence-based medicine – and evidence-based medicine requires *evidence-based education*.

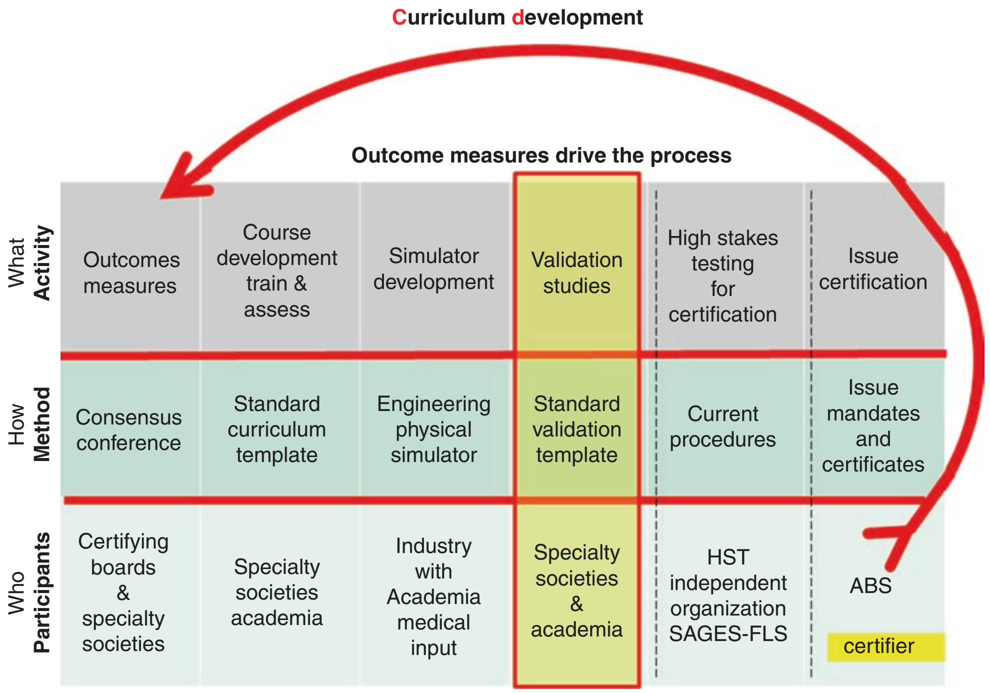
Skills Training Courses for Surgical Simulation

There are two major components necessary for a simulation course – the curriculum (content) and the simulator (technology). In 2003, Dr. Ajit Sachdeva, MD FACS (Director of Education, American College of Surgeons [ACS]), reset the thinking about simulation with the simple statement, "It's about the curriculum, not the simulator" [6]. While both components are essential in order to develop a new skills training course, experience has shown that developing a curriculum by setting the *outcomes measures* (goals) is the most critical issue.

Curriculum Content

The full life-cycle curriculum development is a time-honored method of developing skill courses which has recently been adopted/adapted for surgical simulation. Figure 2 demonstrates the components – in the context of surgical simulation. The methodology begins with the defining of the skills, tasks, or steps of the procedure through the process of "task deconstruction." The next step is to define the outcomes measures and *metrics*, which should be done by a consensus conference of subject-matter experts. The outcomes should be unambiguously described (to insure an inter-rater reliability of greater than 0.80) and then the appropriate metrics chosen (quantitative values when possible). Not only correct steps but common errors must be included in the outcome measures and metrics. This is the basis for creating the curriculum content, both cognitive (with didactic instructions) as well as the cognitive and psychomotor skills for the simulator. The didactic portion must be completed with a final test, to insure that the learner understands what is supposed to be done. Only after these steps are complete can the simulator be developed, because the device needs to be able to incorporate, acquire, and report all the data that were defined by the content. At the completion of the simulator, the entire system needs to have a validation trial which proves that the course teaches what it is supposed to teach.

Proficiency-based progression (PBP) [7] is based upon adult learning theory and outlines both the principles of course development and of the training. The hallmarks are (1) the course is not constrained to a specific amount of time for learning but for a *benchmark* value – the learner must continue training, as many trials as needed, to reach the benchmark value. (2) Skills and tasks are taught with simplest first, and once achieved, progressing to the more difficult skills. *Proficiency* means that the learner continues training on the skill/task until benchmark value is achieved



What **Activity**	Outcomes measures	Course development train & assess	Simulator development	Validation studies	High stakes testing for certification	Issue certification
How **Method**	Consensus conference	Standard curriculum template	Engineering physical simulator	Standard validation template	Current procedures	Issue mandates and certificates
Who **Participants**	Certifying boards & specialty societies	Specialty societies academia	Industry with Academia medical input	Specialty societies & academia	HST independent organization SAGES-FLS	ABS certifier

Fig. 2 Full life-cycle curriculum development

for two consecutive trials; this is in contradistinction to *competency*, which is a more global term that means that the learner has the necessary ability, knowledge, and/or skill to do something successfully (usually only proven once), and frequently includes more measures than skills alone. Proficiency is specific to technical skills and requires consistency in performance, whereas competency applies to all education parameters. A learner can be proficient (highly skilled) but not competent (may lack judgment, decision-making, etc.); likewise, a learner can be competent (able to successfully complete a procedure, but with a few minor mistakes) but not be proficient. Thus, the goal of all skills simulation training should be to proficiency, which in PBP training means that each skill/task in a course is completed until benchmark is achieved, then progression is to the next, more difficult skill/task, and so on until the course is complete.

Demonstrating Proficiency

One of the major keys to simulation is setting the benchmark. This is accomplished by having experienced/expert surgeons take the course, with each skill/task completed to their level of proficiency, as determined by two consecutive trials without improvement (i.e., their learning curve) – this value is that specific expert's "benchmark" value. The benchmark for each skill/task is then set by taking the mean of all the surgeons' benchmark values, which roughly corresponds to the Dreyfus and Dreyfus model [8] of measuring performance (Fig. 3). Once the benchmark is set, the training of the learner is to continue to perform a skill/task until the benchmark value is achieved on two consecutive trials before progressing to the next skill/task. There is no time limit; the variable is number of trials until benchmark is met. This is the method by which each learner is able to clearly and quantitatively demonstrate his/her proficiency.

Simulator Development

Once the skills, tasks, and outcomes measures/metrics have been defined in the consensus conference, the engineers and computer scientists can develop the simulator (or the simple objects selected). The final benchmark values need to be added after either a pilot study (by experts) or the validation trial has begun with the expert performance. While the engineering details are not germane to the curriculum, it is essential that clinical and educational input be continuously included in the simulator's development.

Surgical skills simulators span the gamut from simple Penrose drains for suturing and knot tying to highly sophisticated computer-enhanced mannequins and synthetic cadavers or computer-based virtual reality (VR). Numerous reviews have been performed on available simulators, as well as included in this textbook, so no litany of the available simulators in each of the surgical specialties is included here, though an example of a review of robotic simulators is provided [9]. Also, as indicated above, the critical part is not the simulator, it is the simulation content.

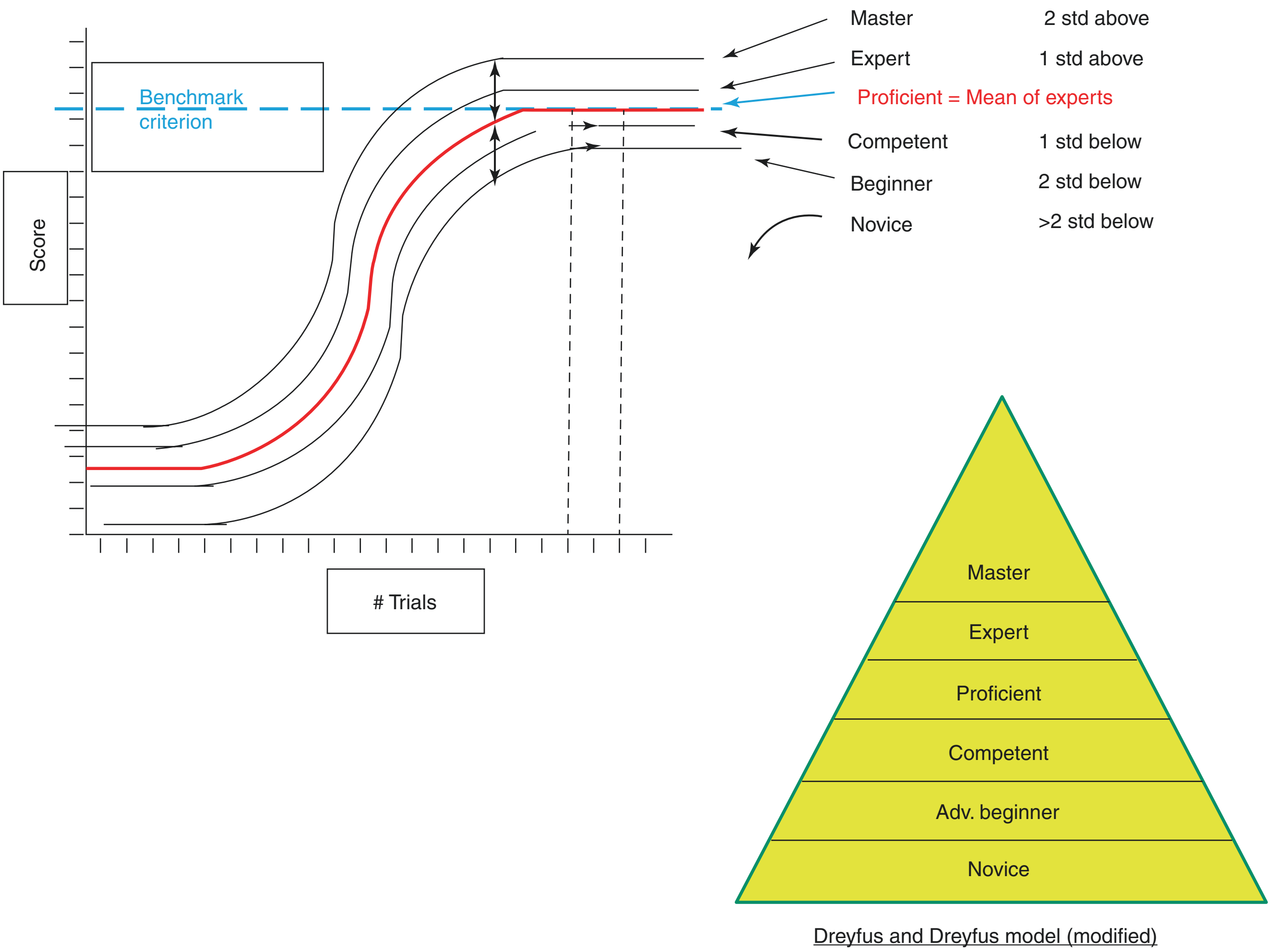


Fig. 3 Setting the benchmark corresponding to the Dreyfus and Dreyfus model

Validation Trial Design and Validation Study

It is desirable that a final validation study be conducted, though it may not be practical for all courses that are designed. The validation and publication of results would provide the evidence of the quality of the course. Currently, the accepted validity measures are face, content, concurrent, construct, and predictive validity, though there are new proposals that these established measures be replaced by similar "construct" validities. For those who are interested in the methodologies of validation trials, numerous books and publications exist, especially in the behavioral psychology literature.

High-Stakes Exam and Certification

For courses which are intended to become standards (such as ATLS, FLS, etc.) that would be adopted by the appropriate certifying boards as requirements, there needs to be development of a *high-stakes exam* by an independent organization, in which the appropriate society or board is involved in developing or reviewing. Having an independent organization administer the high-stakes test is essential in order to remove all chance of bias during testing and certification. The principle is that those who train an individual should not be those who certify the individual, thus avoiding bias in evaluation of a learner's skill. Within the domain of medicine, medical/surgical societies have education as one of their main missions; the independent separate organizations of boards have their primary mission as high-stakes testing and certification.

Team Training and Communication Skills (Nontechnical Skills)

The importance of nontechnical skills deserves special attention because, as complexity of surgical devices and the surgical procedures increases, there will be more reliance on the surgical team, as we have seen with image-guided procedures and robotic surgery. The surgeon is immersed in the operative techniques, often remote from the patient, and the surgeon depends upon assistants to carry out certain tasks to complete the procedure. Accurate communication is essential to team coordination and needs to be trained as rigorously as the technical portion of the procedure. There has been excellent progress in standardizing team and communication skills by adopting similar methodologies from the aviation industry and military (crew resource management). In fact, the military sponsored the successful TeamSTEPPS approach to team training, communication, and crisis management in medicine. The majority of training has been using mannequins and specific scenarios, which has been followed by rigorous debriefings. What has been lacking is a post-scenario testing to determine whether the student has actually learned from the exercise. While extremely valuable, there needs to be a method to validate the proficiency of the team members.

Future Directions

With the initial chapters providing in-depth evidence of the individual components of surgical simulation and the above baselines proposed as the current status of surgical simulation, there are certain trends in curriculum and technology which become apparent. This is especially true when surveying nonmedical industries which frequently have much more advanced technologies or training processes. In addition, by the time of publication of this manuscript, a number of these more advanced technologies/processes will be accepted and make this speculation obsolete, while others may never come to fruition.

Curriculum Development

It is highly likely that PBP curricula (courses) will continue to increase and provide the evidence of performance. The next steps will be transitioning of this evidence (and or certification) to the hospital credentialing and privileging committees in order for them to make more objective decisions. The long-term goal is to have more uniformity of the courses that are developed, as well as interoperability such that redundancy and duplication of effort are avoided and a much larger variety of courses become available. No single simulation center has the resources to create all of the courses which are needed for the vast majority of their learners, and thus sharing, adopting, and adapting curricula and courses among centers is the future which is needed to provide a variety of robust training at all levels.

There is a need to not only train residents and fellows, but basic surgical courses will be mandatory in the later medical school levels [10], not simply student observership but rather acquisition of basic surgical technical skills through simulation courses. This will enable surgical PGY1 residents to begin their first year "running," with basic skills under their belt and in a position to learn and perform simple surgical procedures from the very beginning of their surgical training. It will be feasible for medical students interested in surgery to determine their technical skills *aptitude* for surgery [11] during their rotations (by training and testing in the simulation center), perhaps providing encouragement to those with high natural abilities and providing enlightenment to those who do not have such abilities, so they may practice more or perhaps even choose a nontechnical medical discipline. In other industries, such as military, aviation, sports, etc., not everyone can become exactly what they would like to be – they must pass multiple preliminary evaluations to provide evidence that they have the capability (aptitude) to be a candidate for training to be a pilot, a submariner, pitcher, etc. Yet there is reticence to test (other than scientific knowledge) whether a person has the psychomotor skills to become a surgeon.

New curricula will also be needed for maintenance of certification, remediation, and introduction of new technologies and procedures for the practicing surgeon. The practicing surgeon already has skills; however, everyone has skills degradation [12] over time, and there is public pressure to provide evidence that surgeons are currently both knowledgeable and technically proficient. Simulation provides a tool for training and assessment, which should be customized to the needs of the individual practicing surgeon in order to maintain proficiency throughout their career.

There has been remarkable progress in team training and communication; the major problem, however, is that the current practice of full scenario-based team training is no more than what Professor Tony Gallagher has termed "an educational experience" [13]. The learners perform a scenario, then have a debriefing (which is very valuable – summative feedback); however, there is no test to determine whether they have actually learned the necessary skills. Explaining to a learner what they have done correctly and what errors they made provides no assurance that in future similar situations they will perform correctly. A repeat scenario, with no errors (test), is the evidence necessary to determine proficiency in team cooperation and communication. The TeamSTEPPS is a very good foundation; however, it needs to be supplemented beyond assessment (debriefing) with the proof that a posttest to proficiency provides.

Simulators

There is much controversy about what future simulators will be like. As indicated above, simulators must be built around the needs of the curriculum (course), not upon an individual surgeon's or engineer's idea for a new training device. Thus, future simulators will be designed around the optimal outcome (anatomically, physiologically, etc.) of a specific procedure. One of the most important issues revolves around the concept of *fidelity*, which is how close the simulation resembles the real-world objects, activity, or processes. The most common mistake is that fidelity only applies to how "realistic" the simulation looks, behaves, or feels (haptics). However, the most important aspect of fidelity [14] (especially in simulation) is what could be called "educational fidelity" – that is, how closely the simulated skill/task/procedure activity matches the intended real activity. For example, basic skills (accuracy, ambidexterity, suturing, etc.) may be best learned in simple objects like ring-on-peg or foam which have very low visual fidelity but very high educational fidelity. As skill is acquired (by proven performance to proficiency), then there is a need for not only educational fidelity but also visual, haptic, behavioral, etc. fidelity. Nothing is worse than a simulation that looks and feels realistic (as in live animal model), but educational training teaches the wrong method of tying a knot or placing a suture. At this time, the highest fidelity for accurately teaching and assessing simple basic skills is with simple objects (like a laparoscopic box trainer), even though computers can also accurately train and assess simple skills equally well or sometimes better (see below). Adult education principles indicate that the simple skills must be "mastered" (i.e., proficiency) before moving to the more complex tasks and procedures. In the future, synthetic tissue and computer and VR simulators will eventually be able to provide high fidelity to the other components (visual, haptic, and behavioral fidelity) and at an affordable price. When this occurs (as has already been done in aviation), the power (and promise) of VR computer simulation will be reached, with capabilities that cannot be attained with living tissue (animal and human practice). For example, synthetic cadavers which embed sensors ("sensorized" cadavers, similar to today's sensorized mannequins) and VR computer simulators will not only provide realistic training but also immediate (formative) and summative feedback with "intelligent tutoring systems" [15] or a "virtual mentor" (like those in aviation, military, etc.), reducing the need for faculty oversight during initial training and practice. Additional advantages of less expensive mannequins, synthetic cadavers, and VR simulators (relative to real cadavers) include replacement "parts" (organs, tissues, etc.) instead of an entire new cadaver, the immediate automatic downloading and analysis of performance in an educational registry, and the ease of creating literally any pathology in addition to normal anatomy, physiology, etc. for training and patient-specific surgical rehearsal (either in VR or on a sensorized cadaver). Another alternative is using tissue engineering to "grow" (or 3-D bioprint) synthetic organs/tissues for the purpose of training and practice.

Certification, Maintenance of Certification (MoC), and Privileging

Application of simulation to the processes critical to surgeons, hospitals, payors, and organizations (societies, boards, etc.) can benefit greatly from the objectivity which simulation provides, not as a sole determinant but as an important component of their overall certification. To the practicing surgeon, the critical issue is hospital privileges, which provide their access to operating rooms and teams to support their surgical activity. Hospital privileging committees (and state licensing boards) depend upon the evidence of surgical boards for certification and upon CME (and other parameters) for MoC to initially permit a surgeon to practice or renew their practice at the hospital level. In the immediate future, increasing numbers of surgical skills/procedures will be subject to evidence from technical skills simulators to support decisions on surgical privileging. Surgical societies and boards are exploring and will eventually implement continuous MoC. This may be through more frequent periodic simulations or perhaps with periodic review of selected videos of a surgeon's procedures.

The burden of reviewing videos is an almost prohibitive method for peer review of surgeon performance; however *crowdsourcing* has been demonstrated to be a reliable and repeatable method for such reviews [16] – and at extremely low cost. Evidence is that properly trained non-surgeons can evaluate technical basic skills as accurately as expert surgeons trained in video review. The use of crowdsourcing will be an important tool for many of the stakeholders. However, the greatest value is principally to the practicing surgeon, who can anonymously have his performance reviewed with feedback, in order to use self-directed learning and training to improve his own performance. Such video review (and results) could also be available at the surgeon's request to other organizations such as hospitals, societies, or surgical boards.

Another new trend is the use of *real-world data* (RWD) [17] collected in a *registry*. Specific to healthcare, a registry, such as the National Surgical Quality Improvement Program (NSQIP), is a proactive database (registry of surgical procedures, complications, etc. for patient safety improvement) which is collected in real time (or actually near-real time) of the raw data concerning surgical procedures, entered at the time, or very close to the time, of the actual event (procedure, complication, etc.), as opposed to data entered after review, analysis, and processing. The intent is to collect unbiased data for quick analysis, rather than to wait for a scientific clinical trial (which could take years) to report such data in peer-reviewed publications. The value is to provide real-time monitoring of performance in surgery in support of continuous MoC, education/training, and other activities which would benefit from access to current data in decision-making, strategic planning, etc.

It is envisioned that in the not too distant future, simulation will become essential to the entire processes of initial training, assessing, certifying, privileging, MoC, lifelong (self-) learning, and (if necessary) remediation of the technical skills of all practicing physicians. It is also possible that the use of simulation for surgical rehearsal (principally for complex surgical procedures) will not only become commonplace but may become mandatory in selected cases.

Conclusion

Evidence-based medicine requires evidence-based education. Simulation can provide such evidence for training technical (and nontechnical) skills for surgeons. Although the current value is mainly in initial training – for novices in gaining their initial skills in a safe environment or for practicing surgeons to learn new procedures – but in the future it is mainly for providing self-directed learning and MoC. The use of assessment tools, such as crowdsourcing of videos of training or continuous MoC, will become standard because of their accuracy, lack of bias, and cost-effectiveness.

By adopting full life-cycle curriculum development, more standardized and interoperable courses – among institutions and across specialties – will provide a richer training environment that includes not only novices but also practicing physicians. As more sophisticated simulators evolve, more complex procedures will be available for both generic surgical procedures but also for learning a wide variety of pathological conditions (“digital libraries”) that will allow training beyond proficiency to expertise and perhaps mastery. The use of PBP for training and assessment will soon become the most common form of training. If current barriers such as nonreimbursable payment for patient-specific simulations are eliminated, then patient-specific surgical rehearsal of complex procedures will become commonplace. Finally, by overcoming practical issues of cost, resources, personnel, and protected time, truly quantitative training and assessment will become ubiquitous, if it can be accomplished in reasonable time and at affordable costs, especially for team training and communication skills.

Simulators will take longer to reach the levels of sophistication which current aviation, military, etc. simulators have, due to the complexity of living systems (i.e., patients). Most important is that the simulation community emphasizes educational fidelity – avoiding current practices of trying to train more complex tasks on too simple of a simulator, or too simple of a procedure on a sophisticated and expensive simulator. Modular mannequins and synthetic cadavers will enrich the learning experience, and addition of ubiquitous sensors and intelligent tutoring software to them will greatly enhance their value by automatically providing formative and summative feedback (in absence of faculty). However, there will always be the need for faculty mentoring and proctoring on real patients as the final step before credentialing and privileging; no matter how sophisticated the simulator, human judgment of surgeon performance will be essential.

Ethical issues abound, regarding reliability of computer-based assessment or high-stakes tests using simulators. Just as artificial intelligence programs can very accurately interpret radiologic images and electrocardiographic tracings but the final diagnosis is determined by a physician, so too will final determination of surgeon competence require final interpretation by a surgeon. Ever increasing advanced technologies like tissue engineering pose the most profound challenges, such as issues whether growing “human cadavers” for surgical training and transition to practice is morally or ethically permissible.

The tipping point for surgical simulation is now; this revolutionary technology (and its accompanying curriculum development) which is currently in its infancy is on its way to its destiny as the skills training method of the future.

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Index

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