Chapter 4
Overcoming Barriers to Wider Adoption of Mobile Telerobotic Surgery: Engineering, Clinical and Business Challenges

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Abstract Advances in technology yield many benefits to our daily lives. Our ability to integrate robotics, telecommunications, information systems and surgical tools into a common platform has created new approaches in utilizing less invasive means to treat both common and more complex disease states. A significant amount of investment has been made both from government funding and private sector or commercial funding in the research and development of systems in the area of robotic surgery and the application of telesurgery; and this has led to the development of clinically-relevant distribution of surgical expertise using a surgical robot and telecommunication link. This has predominately been in support of government-funded activities. While early work by Jacques Marescaux in Operation Lindberg and the extensive research performed using Intuitive Surgical's da Vinci, SRI's M7 and the University of Washington's Raven has shown tremendous promise in surgical care, there remains a variety of barriers to wider adoption of telerobotic surgery. These barriers are multidisciplinary and often interdisciplinary. Widespread application of telesurgery as a medical force multiplier depends upon resolution of these barriers, which include bandwidth, latency, quality of service (QoS), research, and reimbursement. The following summarizes how telesurgery has developed, what the challenges are and how they are being ameliorated for wider adoption.

4.1 Introduction

Over the last 20 years tremendous strides have been made in utilizing less invasive means to treat both common and more complex disease states. Armed with continued advances in technology, surgery has seen the widespread application of laparoscopic surgery and the introduction of robotic surgery. As recent as a

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few decades ago, leading figures in surgery disregarded the possibility that now exists – clinically relevant distribution of surgical expertise using a surgical robot and telecommunication link.

Integrating robotic systems, or more correctly, telemanipulation systems, in the practice of surgery, permits the surgeon to perform surgery from the patient's bedside or a distant location. Linking robotics used in surgery with communications – robotic telesurgery – has been shown to be possible and effective [1, 2]. This was first demonstrated in 2001 by Dr. Jacques Marescaux during Operation Lindbergh. He operated on a patient in France while he was in New York City [3]. Telesurgery has been subsequently developed through a robust international research effort. Telesurgical systems have also been used to mentor and proctor complex surgeries.

Much of the research that has been accomplished in the area of telesurgery has been funded by the United States Army's Telemedicine and Advanced Technology Research Center (TATRC). This research spans a variety of extreme environments and a variety of systems, including the Defense Advanced Research Project Agency [DARPA] – funded Trauma Pod (managed by TATRC), Intuitive Surgical's da Vinci Surgical System, SRI's M-7, and the University of Washington's RAVEN. There is continued interest in telesurgical capabilities that can deliver damage control and surgical subspecialty care throughout roles of care.

Widespread application of telesurgery as a medical force multiplier depends upon resolution of various challenges that include bandwidth, latency, quality of service (QoS), research, and reimbursement.

4.2 Definitions

Telesurgery can be defined in many ways and by many different people. Simply put its root words come from Greek words 'tele' – meaning far off and 'cheiourgia', which means working by hand. Today, telesurgery incorporates a wide variety of technologies, which often trump one another regarding definition. For example, in the mid 1990s, telemanipulators and telesurgery were used to describe the translation of hand movements from a master controller to end effectors on a slave a short distance away, perhaps 5 m via a hard-wired connection.

We define telesurgery as the ability to use information technology, telecommunications, and robotic systems to enable surgical intervention, where surgeon and patient are separated by a distance. Furthermore, it can also be used to describe educational and professional assessment techniques, surgical discussion among remote participants, and surgery using telemanipulation and telepresence. Telesurgery includes information technology, telecommunications and surgery. Other related terms include:

- *Teleconsultation* – clinical consultation where clinician and patient are separated by some distance
- *Telementoring* – a clinician or care giver is mentored from a distant site by a subject matter expert (SME)

- *Telepresence* – the manipulation of a device at a distant site in a manner that mimics a human is present
- *Telemedicine* – application of telecommunications in the delivery of healthcare
- *Surgical robot* – a powered, computer-controlled manipulator with artificial sensing that can be programmed to move and position tools to carry out a wide range of surgical tasks (telemanipulator)
- *Telesurgery* – remotely performed surgery through combined use of telecommunications and a surgical robot
- *Distributed* – Any system or component data set that is parsed out to various other systems or devices
- *Telesurgical* – A surgical system, usually robotic, that can be manipulated from a distant site
- *Shared Control* – A system that an individual operates while providing feedback on performance and stability.

4.2.1 Telepresence

Telepresence is a human/machine interface where by the human uses displays and a computer interface to interact with objects and people at a remote site as if physically located at the remote site. It is a sophisticated robotic remote control in which the user operates within a relative virtual reality environment. This has been used extensively in planetary exploration, undersea exploration/operations, military operations, and a host of other applications.

Telepresence surgery offers the expertise for those infrequently performed and technically-demanding procedures. It also offers a solution to surgical manpower shortages in remote and underserved areas. Perhaps, this would lead to improvements in outcomes and over time a decrease in overall costs.

4.2.2 Telementoring

Telementoring is the real-time interactive teaching of techniques by an expert surgeon or other subject matter expert (SME) to a student separated by some distance. Current proctoring and precepting have always been difficult to implement. They have been thought of as an inefficient use of expert surgeons' time.

Initial studies investigated telementoring from an adjacent room and from the separate building with the same institution. These studies found that there was not a statistically significant difference in outcomes. Initially, groups used two way and live video feeds to provide for adequate experience.

A number of groups have demonstrated the safety and feasibility of telementoring across long distances. Telementoring of advanced laparoscopic procedures has been performed from the U.S. to a number of international locations, including Ecuador, Austria, Italy, Singapore, Thailand, and Brazil. These experiences show feasibility of international telementoring from large academic centers to large urban centers within other countries. Telementoring has also demonstrated to climbers at base camp of Mt. Everest for ophthalmological examination. Recently, several groups have demonstrated the utility of telementoring between large academic centers and community-based centers.

Dr. Mehran Anvari and his group at the Centre for Minimal Access Surgery (CMAS) in Hamilton, Ontario established a Surgical Support Network on the Bell Canada Multiprotocol Label Switching (MPLS) VPN in 2002 [1]. The network provided telementoring support over a distance of more than 400 km for community surgeons with minimal laparoscopic experience. The network has allowed for the successful performance of advanced laparoscopic procedures without the high rate of complications frequently reported during the learning curve for laparoscopic procedures.

To be highly effective and engaging, telementoring usually requires high-bandwidth telecommunications, which provide lower latency and quality of service (QoS) as well as enhanced image quality and reduced background noise. Although high-bandwidth connections are essential, Broderick et al., demonstrated that low-bandwidth connections could successfully be used to transmit video. This was true only if the camera movements were slow in order to maintain image quality. Because many remote locations and developing countries do not have access to the latest technologies, flexible scalable low bandwidth solutions are crucial to widespread adoption of telementoring and telesurgery.

In October 2001, the FDA approved CMI's Socrates, the first robotic telemedicine device. Socrates was designed to facilitate telementoring. It allowed the telementor to connect with an operating room and share audio and video signals. Socrates was equipped with a telestrator that annotated anatomy for surgical instruction. Initially, the systems used Integrated Services Digital Network (ISDN). Early interactions between CMI and researchers at NASA's Commercial Space Center – Medical Informatics and Technology Applications Consortium (MITAC) in Richmond, VA led to a transition to Transfer Control Protocol/Internet Protocol (TCP/IP). This permitted the Zeus to be controlled from a remote site. It also permitted the development of the wirelessly-controlled RP-7 robot by InTouch.

The use of the Internet increases the flexibility and scalability of telementoring and telesurgery when compared to a dedicated VPN or other proprietary communications link.

4.3 The Rise of Telesurgical Robotic Systems

During the twentieth century, advances such as informatics, telecommunications, computers, and robotics have ushered in profound changes in medical practice and laid the foundation for great advancements in surgical therapies such as laparoscopy. This was largely due to advances in video technology. With the development of improved video technology, laparoscopy slowly gained acceptance. By the mid 1990s, a minimally invasive surgery (MIS) revolution was underway. MIS was proven to be efficacious, cost-effective, and of great benefit to the patient.

However, limitations in MIS, including 2D imaging, decreased range of motion four degrees of freedom [DOF], tremor, and poor ergonomics, posed challenges to surgeons. Although some of these limitations can be overcome through training and experience, unmet needs led to innovation and introduction of robotics into the practice of surgery.

Surgical telemanipulation systems such as Intuitive Surgical's da Vinci Surgical System® (Sunnyvale, CA) have had significant impact in patient care [4]. Such systems are often referred to as surgical robots. Currently, telemanipulator systems have no autonomous component, and therefore, 'robotics' is a misnomer. However, increasing automation suggest that the concept of 'robotics' is becoming increasingly more relevant. The da Vinci currently provides 3D imaging, as well as improved dexterity via 6 DOF, tremor reduction, and an ergonomic work station.

Robotic surgery systems have been commercially available since the early 1990s. Much of the technologies used in these systems were developed through government initiatives over the past three decades. The Defense Advanced Research Project Agency (DARPA) and the National Aeronautics and Space Administration (NASA) played a key role in the development of surgical robotics. DARPA's work led to Intuitive Surgical's da Vinci Surgical System® and NASA-funded research led to Computer Motion's Zeus platform. These systems permit a surgeon to manipulate tissue where patient and surgeon are separated by some distance. Both of these platforms have played key roles in telesurgery.

Discovery and innovation have been enhanced through mutually beneficial collaboration with government, academia and industry. These relationships have proven critical in the development of telesurgery.

"Surgical robots" are powered, computer-controlled manipulators with artificial sensing that can be programmed to move and position tools to carry out a wide range of surgical tasks. The current clinically-used surgical robot is not a smart medical system. The term "surgical robot" is a misnomer as the da Vinci is without significant task automation, and therefore, is properly described as a telemanipulator.

Surgical robots were proposed in the late Twentieth Century as a means to enable performance of complex surgical procedures, improve quality of surgical care, and permit telesurgery. Research and development began with NASA funding of Computer Motion, Inc (CMI) and DARPA funding of SRI International. SRI International developed the M7 telesurgical system and licensed the minimally invasive component of this research to Intuitive Surgical. CMI and Intuitive Surgical, Inc. waged legal battles regarding intellectual property contained within the Zeus (CMI, Goleta, CA) and the da Vinci systems until they merged in 2004. Since the merger, clinical use of the da Vinci has grown remarkably. There are over 1,000 da Vinci systems worldwide and these have been used to perform approximately 80,000 operations in 2008. The Zeus is no longer commercially available or supported technically.

Robotic systems were designed to address the current limitations evident in laparoscopic surgery, namely decreased range of freedom, tremor, 2D imaging, and fatigue. The earliest systems developed were to hold a camera or mill bone and not the multi-arm units that are currently being used. Engineers that first addressed and designed early robotic systems borrowed heavily from the robotic arm used by NASA on board the U.S. Space Shuttle. The first systems were mere modifications in fact and were used to introduce a stable camera platform.

The first robot approved for clinical use by the U.S. Food and Drug Administration (FDA) was in 1994. It was CMI's Automated Endoscopic System for Optimal Positioning (AESOP). When it was first introduced, the robotic arm was controlled either manually or remotely by a foot peddle or hand control. It was later modified to allow for voice control. The robot attached to the side of the operating table and had a multitude of adapters to allow for any rigid scope to be placed. Various groups conducted studies comparing the AESOP versus the surgical assistant, and found that the AESOP could adequately replace the need for a surgical assistant. It was postulated that the system could offer a cost saving advantage to hospitals.

Although AESOP was found to have some benefit, there were a number of limitations. The robot required certain modifications to accommodate the surgeon's operating style, and most surgeons were reluctant to change their way of operating. In medical centers where surgical residents were present, it was felt that there would be no clear cut cost benefit and there could be a detriment to surgical training.

The next generation systems were master – slave telemanipulators between the surgeon and the patient-side robot. Two systems that were approved by the FDA for clinical applications were the da Vinci and Zeus.

In the early 1990's, DARPA funded SRI to develop a surgical system for deployment on the battlefield to support trauma. This led SRI to the development of technologies that were eventually licensed to Intuitive Surgical, resulting in the development of the da Vinci. The da Vinci is an MIS robot comprised of three components – a master, a slave, and control tower. The surgeon sits the master, an ergonomic workstation, equipped with stereo video both providing observation of the surgical site. The master also has hand controllers, which translate hand and wrist movement to the end effectors. The master controls the slave system. The tower houses the video equipment and the insufflator. The slave has three or four arms. The central arm holds the camera and a variety of laparoscopic instruments (end effectors) are held by the other arms.

These instruments are equipped with an *EndoWrist*®, articulated tips of the instruments that provide 7 DOF. This permits more dexterous movement in surgical tasks such as dissecting and suturing. The da Vinci also offers excellent 3D imaging. The standard scope passes through a 12 mm trocar and the surgical instruments pass through 8 mm trocars. The instruments on the da Vinci model available in the U.S. are partially reusable and allow for a predetermined number of uses (ten for human use, 30 for research), requiring replacement. Development is underway to decrease the diameter of the instrument shaft and make them flexible (snake like) to achieve 5 mm in size. The slave is a large, heavy unit which sits next to the patient bed side. It is not attached to the patient bed.

The Zeus robotic surgery platform joined a family of systems from CMI including the AESOP robotic scope manipulator. In the Zeus platform, the AESOP is used as the camera, and two additional units similar to the AESOP are used to grasp the surgical instruments. The three units are attached to the operating table independently. The surgeon is seated at an ergonomic work station. Similar to the da Vinci, the end effectors articulate. The egg-shaped controllers are not as intuitive or easy to use as the da Vinci controllers. The camera is voice-controlled and in order to see the 3D image projected on a single screen, special polarized glasses must be worn. The control and quality of the images are not as good as those within the da Vinci.

Although each platform had telecommunication capabilities, the Zeus was initially adapted for long distance transmission of video and robotic control data. Through TATRC-funded research with Intuitive Surgical, the da Vinci Classic (first generation) system was modified in this way. The da Vinci platform required an extensive reconfiguration and temporary replacement of computer boards in the control system. This in part resulted in a new design for the da Vinci Si, which is more robust and does not require additional telecommunication modification for telesurgery. The latest version of this system, the da Vinci Si, has a dual console for telementoring, collaboration, and education. This capability is a result of collaborative research with academia, industry, and the U.S. Army's Telemedicine and Advanced Technology Research Center (TATRC).

4.3.1 Development of Telesurgery

Initially, NASA and Department of Defense (DoD) research focused on telesurgery. Telesurgery is defined as remote surgical care provided through combined use of a telecommunication link and a surgical telemanipulator. In September 2001, the first successful telesurgery occurred when Dr. Marescaux controlled a Zeus robot from New York City to remove a gallbladder of a patient in Strasbourg, France over an 8 Megabit per second (Mbps), 155 ms latency, fiber optic network. In 2003, Dr. Mehran Anvari controlled a Zeus robot in Hamilton, Ontario to perform 25 complex laparoscopic procedures in patients in North Bay, Ontario over a 45 Mbps, 144 ms Bell Canada virtual private network (VPN).

Through a series of TATRC-funded research grants, telesurgery research and development shifted to other telesurgical systems: the da Vinci Classic, SRI International's M7, the University of Washington's BioRobotics Laboratory (BRL) RAVEN, and the University of Nebraska's 'In Vivo' Surgical Robots. Initially, researchers performed the first da Vinci telesurgery over the public Internet in March 2005. This was collaborative telesurgery in which surgeons at two physically separated sites simultaneously operated on a pig. Subsequently, University of Cincinnati and University of Washington researchers deployed the smaller, lighter weight RAVEN in the desert to perform mobile robotic telesurgery in May 2006.

To overcome satellite communication latency, they successfully used a small Unmanned Airborne Vehicle (UAV)-based communication platform.

Development and evaluation of surgical robotic technology for use in extreme environments began in 2004. Through a TATRC-funded grant, during the NASA Extreme Environment Mission Operations (NEEMO) 7 mission, researchers discovered that the Zeus robot was too large for deployment and use within the confined undersea Aquarius habitat. In the 2006 NEEMO 9 mission, the M7 was deployed in the operationally relevant analog Aquarius and simulated lunar telesurgery was performed. In the 2007 NEEMO 12 mission, the M7 was deployed in Aquarius and autonomously inserted a needle into a simulated blood vessel. In the 2007 NASA C-9 parabolic flight experiments, the M7 was proven flight worthy and demonstrated that acceleration compensation facilitates robotic suturing of simulated tissue during flight.

The initial DARPA investment in telesurgical systems led to the M7 and the da Vinci systems. DARPA recently invested in autonomous, deployable surgical robotics in the Trauma Pod program. The Phase I Trauma Pod program successfully developed semi-autonomous mobile platforms through the integration of telerobotic and automated robotic medical systems. The initial phase included automated functions typically performed by the scrub nurse and circulating nurse; these functions are now performed by semi-autonomous robots working in coordination with a telerobotic surgeon. DARPA continues to consider the Phase II Trauma Pod program. The Phase II program will develop automated robotic airway control, intravenous access, and damage control therapy. Finally, these systems will be miniaturized and incorporated into a tactical platform capable of operating in a battlefield environment.

4.4 Developmental Events

A series of important events transpired during the period between 2002 and 2006. These included some important meetings; such as a research strategic planning meeting, sponsored by TATRC in 2002 related to the Operating Room (OR) of the Future, a workshop sponsored by the Georgetown University Medical Center in March of 2004, entitled OR 2020, The Operating Room of the Future, and an Integrated Research Team (IRT) meeting sponsored by TATRC in September of 2004, entitled Surgical Robotics – The Next Steps. These meetings assisted in identifying the realm of telesurgery as a needed and important topic of advanced technology research.

A panel of 60 national and international experts was convened to draw a roadmap of research and funding needs related to robotic surgery. The panel began by considering the “ideal surgical robot” and articulated a range of requirements needed to achieve advancements in robotic surgery. Targeted research to validate use of the robot to improve outcomes in a specific procedure was suggested as a means to improve acceptance and adoption of robotic surgery. Fear might also have a role in slowing the adoption of surgical robotic technology: patients’ fear of robots, surgeons’ fear of injuring patients, and hospitals’ fear of liability should an error occur. To improve safety and quality, research should examine use of robotic surgical data with a “no fault” policy such as used with data provided by the “black box” used in commercial aircraft accident investigation. It was suggested that business and legal considerations in robotic telesurgery are best pursued in collaboration with experienced organizations such as the American Telemedicine Association (ATA).

Lack of multi/interdisciplinary collaboration was another barrier that the group felt could be overcome by funding specifically targeted to improve interdisciplinary research, design and commercialization. Group members did agree that failure to resolve intellectual property issues would impair and could potentially stop development of robotic surgery.

The working groups concluded that funding in excess of $380M would be required to advance robotic surgical assistants to the point of “crossing the chasm” into early acceptance, from the perspective that we are now at the stage of “early adopters” This places the effort in the realm of “Grand Challenges” on par with the National Nanotechnology Initiative, where many believe it rightly belongs. Early reports do demonstrate that these surgical robots can allow the performance of safer, faster surgery, but the technology is tightly bound to economies of scale as long as the current designs and poor business practices are utilized.

The primary hurdles that need to be overcome in order to even begin addressing the roadmap include funding; the resistance of funding agencies to fund, and academia to support, large-scale, distributed, multidisciplinary teams; the culture and communication barriers between the disparate groups that would need to collaborate; industry’s resistance to open architectures and large-scale collaboration. The “Grand Challenge” of developing surgical robotics should begin with a “grand” meeting where the relevant technologies, their current state, and the roadmap are described. While the IRT developed the roadmap, this meeting would develop the policies that will allow the roadmap to move forward. Relevant federal agencies such as NIBIB, NIH, NSF, FDA, NIST, stakeholders from industry, academia and professional and standards organizations would come together to address the hurdles.

4.4.1 Demonstrations of Telesurgery

In addition to convening of meetings, the DOD undertook two aggressive actions to advance technology related to telesurgery. DARPA planned and initiated the Trauma Pod research program to develop and demonstrate technologies that will enable a future generation of battlefield-based unmanned medical treatment systems. When fully developed, the Trauma Pod system will allow a human surgeon to conduct all the required surgical procedures from a remote location using a teleoperated system of surgical manipulators. Automated robotic systems will provide necessary support to the surgeon to conduct all phases of the operation.

Concurrently and separately, TATRC undertook to sponsor several research projects on a lesser scale that collectively advanced technology for telesurgical robotics and demonstrated the feasibility of remote telesurgery. These demonstrations included the following: the conduct of the first transcontinental telesurgery in the US, the conduct of collaborative experiments with NASA within the NASA Extreme Environments Mission Operations (NEEMO) program, the refinement of prototype microsurgery equipment as a model for portable surgery systems, robotic laser tissue welding, robotic replacement for surgical scrub technicians, control of time-delayed telesurgery, and the use of high altitude platforms for transmission of telesurgery signals.

The importance of these demonstrations and the earlier exploratory funding efforts lies in the attempt by DOD to motivate civilian funding institutes and other government funding agencies to assume responsibility for supporting telesurgery as a vital instrument of the national healthcare system. Although technical challenges to telesurgery must be overcome, the real barriers consist of perceptions that cultural, regulatory, reimbursement and safety issues are “too hard” to overcome.

4.5 The Current State of Telesurgery

There has been significant activity and milestones in telesurgery over the past two decades. TATRC or other government entities have funded the majority. The experience gained in each of these activities has yielded discovery and highlighted specific areas where concentration of effort must take place. There have been several earlier reported events that can be highlighted as precursors to telesurgery. Table 4.1 highlights the activities in a timeline. The early events have been characterized as telesurgery; they however, are considered more telemedicine. In addition, there have been numerous meetings and workshops concerning telesurgery that have been concomitant. This research has steadily increased our understanding and has led to new developments and initiatives. Research

Table 4.1 Telesurgery timeline

Year	Event
1964	Early bird – live surgical case observation
2001–2009	Various meetings and integrated research team initiatives
2001	Operation Lindbergh
2001–2004	Canadian telesurgery initiatives
2005–2007	DARPA trauma pod phase I
2005	NASA extreme environment mission operations (NEEMO) 7
2005	First U.S. transcontinental telesurgery – da Vinci
2006	NEEMO 9
2006	High altitude platforms for mobile robotic telesurgery (HAPsMRT)
2007	NEEMO 12

outcomes have led to new capabilities such as Intuitive's da Vinci Si, progressive steps toward semi-autonomous functions, and new robust robotic platforms.

4.5.1 Early Bird

Telesurgery is not a completely novel concept. Since the development of the telecommunication industry, medicine has willingly embraced the potential applications that it provides. In 1964, Dr. Michael DeBakey, a cardiothoracic surgeon in Houston, Texas performed the first televised carotid endarterectomy. The surgery was broadcast on a private network to a room of medical professionals located in Geneva, Switzerland, while Dr. DeBakey was in the operating room at Methodist Hospital in Houston, TX. This event marked the first medical use of America's first telecommunication satellite, Early Bird, launched by NASA in 1964.

4.5.2 Operation Lindbergh

September 7, 2001, marked a major milestone in telesurgery. On this date, Professor Jacques Marescaux, Director of IRCAD/EITS in Strasbourg, France, conducted Operation Lindbergh. This seminal event created a dedicated network between New York City and Strasbourg, France. It was supported by French Telecom and CMI. The Zeus TS workstation was located in New York City and the robotic arms and patient were located in France. Dr. Marescaux and a team of surgeons successfully performed a cholesysectomy on a 68 year old female patient.

Before proceeding, Dr. Marescaux and his group had certain challenges that needed to be addressed. At that time no one had made an attempt to perform telesurgery over a significant distance. The concerns focused on the reliability of telecommunication lines and issues of latency. The feasible distance was thought to be only a couple hundred miles.

The first series of experiments estimated the maximum time delay compatible with the safe performance of telemanipulations at about 300 ms. They were able to achieve a mean time delay of 155 ms over transoceanic distances using a dedicated ATM link with bandwidth of 6–8 Mbps. This allowed the group to perform six laparoscopic cholecystectomies on porcine without complication.

4.5.3 Canadian Efforts

In 2003, Dr. Mehran Anvari, director of McMaster University's CMAS, performed one of the first hospital-to-hospital procedures, a laparoscopic Nissen Fundoplication. Using the Zeus TS platform, Dr. Anvari has performed more than 20 operations to date on patients in Ontario's North Bay located some 400 km away. CMAS has made the practice of telesurgery a reality. Dr. Anvari has sponsored training from his clinical site through telementoring programs and telepresence. This work was made possible by the favorable environment in Canada and with significant support from McMaster University, Bell Canada, and CSA.

Dr. Anvari's clinic in Hamilton, Ontario is connected to the facility in North Bay through a Bell Canada-provided network with significant bandwidth (45 Mbps MPLS VPN). The network had a measured latency of 135–104 ms. Adequate bandwidth was dedicated to Dr. Anvari's research and operational initiatives. This work demonstrated that surgery in a rural center was comparable to the quality of surgery in a large teaching facility.

Recently, the Anvari group has formed a consortium of academic and industry partners to evaluate telementoring and telerobotic surgery to extend the reach of surgeons at major teaching hospitals to successfully perform emergency surgical procedures on patients in remote settings and extreme environments. Engaging the expertise from the Canadian space technologies industry they are developing a new class of Image-Guided Automated Robot. They plan to adapt this technology to develop a mobile system for telementoring and telerobotic surgery through integration of wireless and satellite telecommunication, digital imaging, advanced physiologic sensors and robotic technologies. This creative approach may serve as a model for others to engage industry directly in the development of telesurgery systems.

4.5.4 NASA Extreme Environment Mission Operations

The military has a keen interest in research in extreme environments. They place men and women in such environments. NASA has similar mission characteristics. Through a partnership with the National Oceanic and Atmospheric Administration (NOAA), and the University of North Carolina at Wilmington, the NEEMO Project was established. NEEMO uses NOAA's Aquarius habitat off the coast of Key Largo, FL to conduct research in an extreme environment. The habitat also serves the U.S. Navy. It serves as an ideal laboratory for evaluating technologies and procedures for remote medical care in extreme environments (Fig. 4.1).

TATRC funded three different missions that focused on telementoring and telesurgery. During NEEMO 7, NEEMO 9 and NEEMO 12, research on the concepts of telesurgery and the tools – robotics and telecommunications was conducted. A key research question for these NEEMO missions was how well an operator could perform telerobotic surgical tasks when there is a time delay. Some latencies of 200–500 ms can be adapted too by the user(s).

Each mission successfully evaluated evolutionary steps from telementoring to remote control of the robotic system to semiautonomous functions. Each of these missions was also a collaboration of the U.S. Navy and the U.S. Air Force, as well as industry.

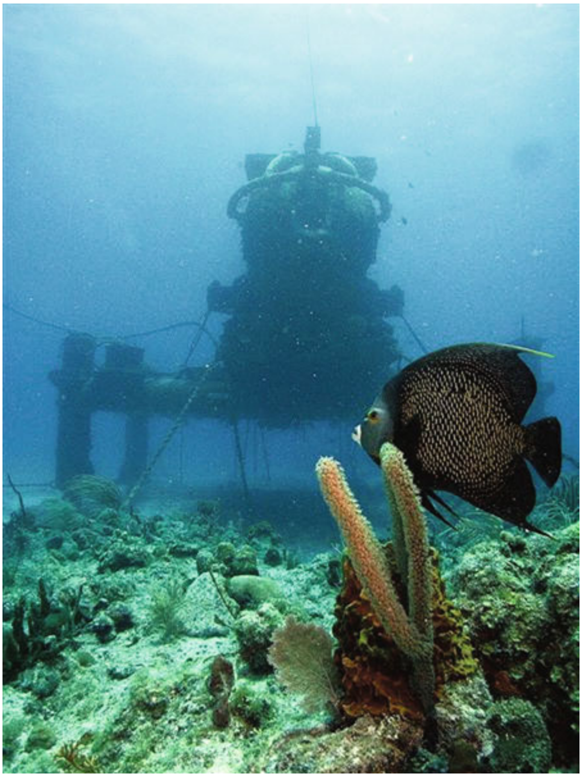

Fig. 4.1 Aquarius Habitat on the Atlantic Ocean floor off the coast of Key Largo, Florida. Courtesy of the U.S. Navy

They were relevant to the military in that the research identifies telecommunication and robotic needs and limitations in this environment that can help define evolving requirements. The TATRC-funded NEEMO missions served as ‘Technology Accelerators.’

4.5.4.1 Neemo 7

The objective of this mission was to serve as a proof-of-concept for telementored surgical care in an extreme environment.

Components of CMI’s AESOP were deployed in airtight bags/canisters and transported through 70 feet of water to the Aquarius Habitat. Once in the habitat, the system was set up and tested. Communications was accomplished between the habitat and CMAS via an MPLS VPN. This connection permitted interaction between the isolated crew (in the habitat) and a surgeon (M Anvari) located in Canada. The telecommunications network between the NURC and the habitat was via microwave with a total bandwidth of 10–15 Mbps. The performance of the network was characterized by a latency of 50–750 ms. There was noticeable jitter.

During this mission, Dr. Anvari mentored the crew through laparoscopic removal of gallbladder using the Zeus platform. A single arm of the Zeus was transported to the habitat but did not work well. Dr. Anvari felt that the mission was an overall success, but certain challenges still needed to be addressed such as robot size (bulkiness), packet loss, and overcoming jitter. Subsecond latency was shown to be overcome with technique and technology for telementoring.

4.5.4.2 Neemo 9

The NEEMO 9 mission objectives were to see if the crew could assemble a small scale, functional robotic platform that could be remotely controlled using the Internet as the communication system. The SRI M-7 robot was deployed to the habitat in the same way as in the NEEMO 7 mission. Once deployed, Dr. Anvari controlled the robot from over 1,300 miles away (Canada) and performed telemanipulated wound closure. A 2 s delay was introduced. This allowed for Dr. Anvari to see the feasibility of robotic surgery under these conditions.

In order to accomplish this task, the M7 was modified and deployed in airtight bags/canisters to the Aquarius habitat. Once in the habitat, the system was set up and tested. Connectivity from the habitat to shore was done wirelessly with approximately 10 Mbps and latency of 250 ms to seconds. Telesurgical tasks involved telementoring of several activities and the utilizing the M7. This resulted in better understanding of how what activities and tasks could be accomplished through automation, how to continue refining the size (foot print) of the robotic system, and the demonstration of the multi-functionality of the surgical robot.

4.5.4.3 Neemo 12

The NEEMO 12 involved two different surgical robotic systems; the M7 and the RAVEN. Each system was deployed to the habitat, setup, tested, and evaluated. Surgeons located in different parts of the U.S. were able to manipulate both systems easily across the Internet.

A key objective of the M7 deployment was to answer a fundamental question related to the ability to remotely control the robot, which was outfitted with an ultrasound probe on one arm and needle on the other. The surgeon, located in Nashville (live demonstration during the 2007 American Telemedicine Association [ATA] annual meeting), successfully drove the robotic arms in the habitat. A phantom blood vessel in the habitat was scanned using a Sonosite ultrasound probe, the remote surgeon then instructed the robot to insert the needle in to the blood vessel. This demonstration was the world's first semi-autonomous ultrasound-guided needle insertion. This event was conducted in TATRC's booth in the convention center. It was accomplished with COL Jonathan Jaffin, COL Karl Friedl, COL Ronald Poropatich and a number of other TATRC officials.

The RAVEN was also manipulated from Nashville and Seattle to conduct a series of SAGES Fundamentals of Laparoscopic (FLS) tests. Communications was accomplished using the Internet. A HaiVision high end CODEC was evaluated as well. The RAVEN used iChat for the Macintosh platform. The telecommunications that supported the overall link was a wireless Spectra 5.4 GHz bridge with 30 Mbps with a noticeable latency of 500–1,000 ms. This mission was deemed high successful.

4.5.5 First Transcontinental Telesurgery in the U.S

A partnership was created between the University of Cincinnati, HaiVision, Intuitive Surgical, Walter Reed Army Medical Center, and Johns Hopkins to evaluate the da Vinci system as a telesurgery platform. The da Vinci Classic control station was located at UC and the end effectors (patient side) was located at Intuitive Surgical's labs in Sunnyvale, CA. The two sites were connected via the Internet. In March 2005, a nephrectomy was performed on an anesthetized pig. This was repeated again in April 2005 between Denver, CA and Sunnyvale, CA, during the ATA meeting using the public Internet with no QoS guarantees. These experiments represented the first true telesurgery in the U.S., the first telesurgery using the da Vinci Surgical System, the first stereoscopic telesurgery, the first robotic collaborative telerobotic surgery (i.e., both local and remote robot surgeon consoles were used), and the first telesurgery over the Internet using non-dedicated bandwidth. This work led to development of the da Vinci Si, which permits telesurgery.

4.5.6 High Altitude Platforms for Mobile Robotic Telesurgery (HAPsMRT)

Telesurgery cannot be accomplished without a robust telecommunications system. In the summer of 2006, researchers from UC partnered with the University of Washington's BRL, HaiVision and Aerovironment to conduct a series of experiments designed to evaluate wireless communications and mobile robotic surgery. Through a TATRC-funded grant, UC conducted the HAPsMRT project.

A corner stone to HAPsMRT was the utilization of an asset normally used on the battlefield that supports telecommunications. This device, a UAV manufactured by Aerovironment, provided wireless communications so that the UW's U.S. Army-funded, RAVEN could be manipulated from a distant site, where surgeon and robot are separated. The experiment took place in the high desert (an extreme environment) in southern California.

Fig. 4.2 UW's RAVEN robot and Aeroviroments UAV in the high desert of Simi Valley, California

Fig. 4.3 Surgeon manipulating the RAVEN remotely in the high desert of Simi Valley, California

The controllers (master) and robot (slave) were deployed in this extreme environment. The two units were separated by a distance of approximately 200 feet. The UAV was launched in the experimental field. Flying approximately 500 feet above the test field, the UAV provided significant bandwidth (approximately 1.2 Mbps) for communication. This permitted a surgeon for the first time ever to manipulate a robotic system remotely and wirelessly using a UAV. The maximum range of these experiments was approximately 1 mile (Figs. 4.2 and 4.3).

4.5.7 NASA C9A Flight

Researchers from UC collaborated with SRI and NASA personnel to evaluate the deployment and utilization of a modified M7 on NASA's C9A aircraft. The goal was to get the system flight ready and evaluate the acceleration compensation capabilities of the system. The M7 was repackaged into a more suitable system for use on an aircraft. The C9A flies a parabolic profile, which provides approximately 25 s on zero gravity. During this phase of flight, research can be conducted in a variable g flight environment. Military trauma surgeons from United States Air Force (USAF) Center for Sustainment of Trauma and Readiness Skills (C-STARS) Critical Care Air Transport (CCAT) participated in the flight.

During this experiment, the M7 was affixed to the floor of the aircraft. The M7 controllers were remotely located adjacent to the experimental setup. The M7 was equipped with acceleration compensation. Over a series of days, researchers evaluated simple surgical tasks on the system to evaluate the feasibility of using robotic technology to improve access to and quality of surgical care during flight. The acceleration compensation was shown to work effectively. In addition, surgeon and non surgeon performance were evaluated (Fig. 4.4).

Robotic surgery and telesurgery can interject expert surgical care into remote extreme environments and thereby serve as a key component of future military medical care from the battlefield to critical care transport to geographically disperse medical facilities. In addition, such a capability can serve as an effective tool in addressing medical care needs in long duration spaceflight missions. As a critical element of a smart medical system, supervisory-controlled autonomous therapeutics represents a foundation of evolving medical care in these extreme environments.

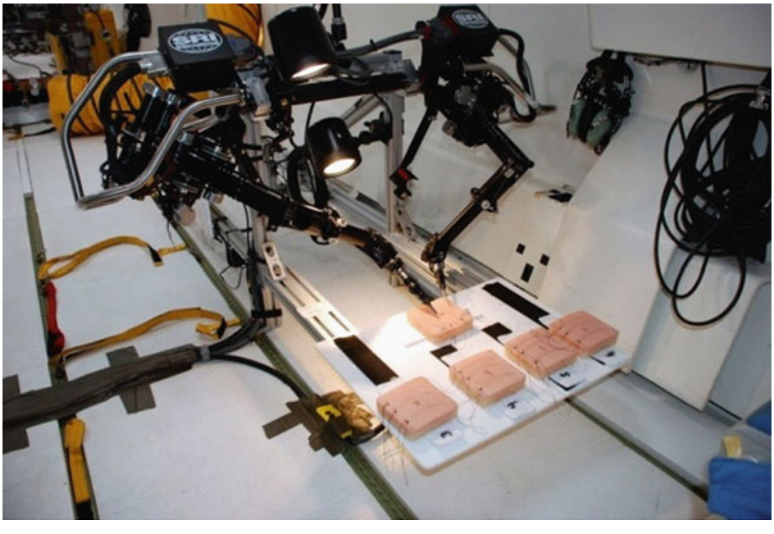

Fig. 4.4 Experimental layout of the SRI's M7 on NASA's C-9 aircraft. Courtesy of NASA

4.5.8 Battlefield Operation

The Army Medical Department (AMEDD) has characterized its mission in the following areas (A) provide, sustain, and enhance soldier health, (B) train, develop, and equip, and (C) delivery leading edge health services. The research presented above has focused on each of these elements. Over the past 10 years, there has been an increase in the use of robotics being deployed on the battlefield. While these devices take many shapes and missions, not to date have been surgical robotics. Research however continues in the development of deployable systems. The joint vision of robotics as a requirement is to develop systems that adapt, integrate, new robotic technologies to treat patients in fixed and mobile medical facilities and to locate, identify, assess, treat, and rescue battlefield casualties under hostile conditions. The technology and operational capabilities developed will be used as medical force multipliers.

4.5.9 Spaceflight Operations

Robotics and autonomous systems have been part of NASA's exploration portfolio for nearly five decades. While each system increases in complexity and fidelity, robotic surgical activities have only been conducted in a research environment. Robotic systems are deployed on the International Space Station and the surface of Mars. The European Space Agency has also worked with IRCAD/EITS to explore new technologies for surgical care.

4.6 Challenges and Barriers

The authors ascribe to the potential advantage to healthcare from a mobile robotic telesurgery system and specify barriers to the employability and acceptance of such a system. We believe that a collaborative effort could design a portable robotic system for telesurgery and develop that system through successful animal trials. Recent advances in engineering, computer science and clinical technologies have enabled prototypes of portable robotic surgical platforms. Specific challenges remain before a working platform is suitable for animal trials, such as the inclusion of image-guidance and automated tasks.

Barriers exist to the development of a mobile robotic surgical platform. These include technical challenges of refinement of robotic surgical platforms, reduction of weight, cube, complexity and cost, and expansion of applications of technology to several procedures. Clinical challenges involve the protection of patient rights and safety, selection of surgical procedures appropriate for the system, the application of surgical skill to evaluate hardware and the application of surgical lore to software programs. Finally, business challenges include resolution of intellectual property considerations, legal liability aspects of telesurgery, patient safety and Health Insurance Portability and Accountability Act (HIPAA), reimbursement and insurance issues, FDA approval of the final product and development of a commercialization plan.

The conduct of telesurgery is not without challenges and barriers. The following are key challenges and barriers to broader application and adoption of telesurgery. For telesurgery to reach its potential there are certain challenges that must first be addressed. Although the practice of telemedicine has been well established, telesurgery has some unique challenges that must be taken into consideration.

4.6.1 Engineering Challenges

There are a number of engineering challenges, including design, material, maintenance, etc. The focus of our attention here is on the following.

4.6.1.1 Technology

Telesurgery is highly dependent on a number of successfully implemented technologies in several disciplines. These include robotics, telecommunications and information systems. Each component has a high technology readiness level (TRL) in the range of 7–9. This level signifies a proven system. As an integrated system, the TRL is in the 3–5 range signifying a concept or experimental system. While some integrated systems are ready for clinical trials, further development and validation is required prior to the TRL increasing to an acceptable level. The TRLs are based on the DoD's Defense Acquisition Guidebook (July 2006) and DOD Directive 5000.1. NASA and the FAA also follow similar guidelines.

When considering a system, several factors must be included in the analysis of what technologies are integrated. These include need, access to technology (price and availability), access to maintenance capabilities, redundancy, reliability, interoperability, and ease-of-use. As in telemedicine, this important step is required to adequately define the requirements, which in turn drive the choices of technology.

4.6.1.2 Access

There are varying levels of access in the integration of telesurgery, including access to systems, access to spare parts, and access to maintenance.

Telesurgical systems may be widely distributed in a future scenario whether on the same area of the battlefield theater or in a rural hospital. They may be linked to surgical expertise in a distributed model or at a central location. The system(s) may have some portability to them, but nevertheless the patient must be brought to the system.

Regarding maintenance and spare parts, this must be readily available and easily accessible to accommodate needs as they arise.

4.6.1.3 Redundancy

Redundancy in telesurgery includes both personnel and systems. Two systems linked together, where surgeon is in one location and patient is another requires personnel redundancy at the patient side, where surgeon will have to intervene in case of communication failure. While this will be a challenge initially, it will be resolved as the systems become more autonomous and reliable.

A second area of redundancy requires a reliable and robust communication system, which insures QoS and avoids inadvertent loss of signal during telesurgery. This is a significant cost issue that must be overcome to permit wider adoption.

4.6.1.4 Reliability

A successful telesurgery system will rely on a variety of systems and people. The robotic system and the communication system (and link) must be reliable. The systems cannot fail during surgical procedures. With proper design and operations, this has not been an issue. The surgical teams must also be able to provide effective surgical care should systems fail or communication is lost.

4.6.1.5 Interoperability

All systems and components should be interoperable. Both the expert site (location of surgeon) and the far site (patient location) must have system components that can cooperatively interact with other medical systems. Telesurgery systems should be capable of robust interaction with supporting technologies such as imaging. Furthermore, all operating room systems should use hardware and software standards that facilitate interoperability. This requires manufacturers to work closely together (similar to Continua [www.continua.com]) so that components seamlessly interact with one another.

4.6.1.6 Maintenance

Telesurgical systems are large and complex and must be maintained. Like any system, maintenance of system components must be accomplished by highly skilled individuals. Scheduled maintenance, training of those personnel, standardized procedures and spare parts must be institutionalized. It cannot be ad hoc. Development and integration into other systems must include this key component.

4.6.1.7 Ease-of-Use

Any system built and deployed must not be difficult to utilize. While all systems, used in the operating room theater, have varying levels of complexity, most require advanced training; they must be capable of being utilized by staff – not additional vendor-specific personnel, which adds more overhead to the operating room. In telemedicine, a key disadvantage has been that simple systems such as cameras and video-teleconferencing are often challenging to operate and therefore, cause user frustration and fatigue. Telesurgery systems must be plug-and-play. This often results in highly-specialized healthcare workers shying away from the use of helpful technology and in some cases eliminating interest in further development.

4.6.1.8 Haptics: Man Machine Interfaces

The ability to project a sense of touch is an important attribute in telesurgery. As the surgeon has moved farther away physically from the surgical site with laparoscopy and robotic surgery, the sense of touch or tactile feedback is no longer present. Current telesurgery systems do not have haptics due to instability above relatively low latency. Haptics is of potential value in telesurgery and has been an area of active research. Force feedback, through servo motors, accomplishes some levels of tactile or haptics. As telesurgery evolves, technology will keep pace and the sense of touch should continue to be evaluated as a potential tool in performing robotic surgical intervention.

4.6.1.9 Telecommunications

Telesurgery is heavily dependent on availability and reliability of a telecommunication network with significant bandwidth. The telecommunications and information technology network must be able to ensure that there will be minimal degradation of picture, minimal or zero latency and high data quality. A high QoS is necessary for telesurgery as opposed to telemedicine. Low packet loss, limited jitter, etc. is important so that robotic system can safely and consistently operate at a distance.

For example, when the distant surgeon moves a controller and the surgical tool moves in the body cavity milliseconds later, this is low latency. Surgeons can compensate for delays of 200–300 ms without any substantial decrease in performance. Delays that are longer than 500 ms are associated with significant decrement in surgeon performance and this not acceptable. Each communication modality has minimal delays. To illustrate further, consider a news service on duty somewhere on the opposite sides of the world. When two individuals are talking to one another, there is a short delay. This is due to the speed of communication. Often communications are accomplished via multiple satellite hops, network segments, and routers, each of which contributes to latency.

Satava addressed this early in the 1990s as robotic surgery was becoming more of a reality. Previous research reported by Marescaux, Anvari, and Broderick et al. has addressed latency in increasingly complex experimental testbeds.

Several current network topologies have been available and evaluated for telesurgery. These include Integrated Services Digital Network (ISDN), ATM, MPLS VPN, Transmission Control Protocol (TCP)/Internet Protocol (IP) User Datagram Protocol (UDP), wireless microwave, digital radio waves, and unmanned airborne vehicles (UAV).

ISDN is a circuit-switched telephone network which enables transmission of digital voice and data over ordinary telephone wires. It provides better quality and higher speeds. ISDN lines are readily available throughout most metropolitan areas and allows for short delays. ISDN lines are considered suitable, but not ideal and its use in the U.S. is waning. It is secondary to low bandwidth per line and lack of scalability.

ATM is a cell relay data link layer protocol which encodes data traffic into small fixed-sized cells. ATM is a connection-oriented technology, in which a connection is established between the two endpoints before the actual data exchange begins. It provides dedicated high bandwidth connections that are reliable and safe. It is readily available throughout the world and is the only technology that guarantees a predefined QoS. Dr. Marescaux used ATM in Operation Lindberg in September 2001.

VPNs via MPLS networks are well suited to telesurgery as it provides traffic isolation and differentiation without substantial overhead. These networks are widely available and used for medical (and banking) applications. It was successfully used in Anvari's Canadian series of experiments.

TCP/IP is the basic communication language or protocol of the Internet. IP is responsible for moving packet of data from node to node. TCP is responsible for verifying the correct delivery of data from one point to another using hand shaking dialogues. Robot commands are typically sent via TC/IP.

UDP is a simple transmission model (as compared top TCP) without handshaking dialogues for guaranteeing reliability, order of packet arrival, or data integrity. Audio and video are often sent via UDP.

Wireless Microwave radio systems are used to transmit and receive information between two points using line-of-sight configurations. A typical microwave radio consists of a digital modem for interfacing with digital terminal equipment, a radio frequency (RF) converter (carrier signal to a microwave signal) and an antenna to transmit and receive. This has been used during the NEEMO telesurgery research.

UAV is a remotely piloted aircraft, often called a drone. They range in size from tiny insect-sized to full-size aircraft. Such aircraft provide varying levels of bandwidth and low latency secondary to relatively low flight altitudes. UAVs were successfully used for the first time in surgery during the HAPsMRT research.

Bandwidth is the rate of data transfer, throughput or bit rate measured in bits per second. Bandwidth is determined by the type and capacity of the medium used such as fiber optic, copper or wireless.

QoS represents a guaranteed level of performance regarding data flow across a network. Examples include bit rate, delay, jitter, packet dropping probability and bit error rate.

Latency is the time it takes for a packet to traverse a network. Latency is a major factor in telesurgery performance. Past telesurgery research has focused on reduction and mitigation from the effects of latency.

Jitter is the inconsistency or variation in the time packets arrive at a destination. Jitter is often caused by network congestion or dynamic route changes.

4.6.2 Non-Technical Challenges

There are numerous non technical challenges, including personnel, cost, licensing, credentialing, FDA approval, etc. Each of these plays a significant role in the broader adoption of telesurgery.

4.6.2.1 Personnel

The integration of technological innovation can disrupt standard operations, by changing the process and structure of tasks performed. Changing operations and culture involves personnel from each step of the process. If telesurgery is to take hold in the clinical environment, personnel from all areas of the healthcare must be involved in the design and implementation.

The organizational culture of the institution or the operating department can impede or halt adoption of disruptive technology. Personnel must go through training of some level depending on the individual’s role. This is an important issue. The real challenge or barrier is the paradigm shift that results. The literature often reports on the struggles of implementation due to the unacceptability of new technologies that are purported to make things easier.

While these challenges are present, they can be managed with appropriate curriculum, training, and involvement of key stakeholders in development and targeted application of technology.

4.6.2.2 Cost

Today, healthcare costs are 18% of the gross domestic product in the U.S. There is significant interest in healthcare reform at all levels. In the short term, telesurgery will not have a positive impact on cost as there are many costs associated with telesurgery. These include the cost of the robotics systems, the cost of telecommunication, the cost of personnel, the cost of infrastructure, the cost of training personnel and the cost of research and development.

In addition to cost, a growing concern in American surgery and worldwide is the increasing shortage of general surgeons. This shortage is borne from a number of issues, including a growing population and fewer individuals pursuing general surgery careers. Both the American Board of Surgery and the American College of Surgeons recognize this as a major crisis. This will cause patients to wait longer for surgical treatment, which will have a deleterious effect on healthcare costs and quality. In the long term, distributed and automated surgical care should improve quality, access and cost of care.

Cost of Technology

Telesurgery utilizes sophisticated and complex technology. The cost is often very expensive with the robotic components being the most expensive. For example, the current cost of the da Vinci Si (Intuitive Surgical) is approximately $1.3M, which is accompanied by an annual service contract of $135,000 for a minimum of 5 years or an additional $675,000. In order to optimize the da Vinci, an updated operating suite, capable of supporting networking and telecommunications, must be used. This is also an additional cost. While reduced costs for individual patients may be of some benefit, telesurgery must be proven to be of clinical benefit as well.

There are also costs associated with other ancillary technologies that are used to support telesurgery. These systems include other robotic systems, technologies that drive communications (routers, coder/decoder [CODECs], switches, etc.), computer peripherals (displays, storage devices, etc.), and other interface devices that are used in the operating environment.

Although academic centers may well be able to afford such expenditures, smaller community hospital may not. One of the potentials of telesurgery is the ability to offer telementoring and teleproctoring to rural community settings, and thereby allow expert consultation to people without the cost and burden of moving them far from their homes and families to larger centers. As more systems are deployed and there are more competitors, capital investment and operating costs will be modified. In order to realize the potential of telesurgery, the issues of scalable, cost effective robotics and telecommunications must be addressed.

Cost of Communication

The concept of telesurgery cannot be realized without a robust and reliable telecommunications system. While the availability of bandwidth has increased worldwide and the cost has decreased due to strong economies of scale, it is still a significant cost component of doing telemedicine and telesurgery. However, the cost for copious amounts of bandwidth to support telesurgery is still prohibitive. The Asynchronous Transfer Mode fiber optic communications system used to support Operation Lindbergh (transoceanic telesurgery event in 2001) was in excess of a million dollar, primarily because it was dedicated link for that specific event. The cost of communications must be reasonable for telesurgery to be a significant adjunct. Telesurgery utilizes significantly more bandwidth than other forms of telemedicine and requires low latency and high QoS. The cost of telecommunications for telemedicine is insignificant because the requirements are lower than those for telesurgery. These requirements to support telesurgery add substantial overhead, which drives the cost of communications higher.

The cost of telecommunications includes not only the bandwidth but the various routers, switches, and interface devices at both the transmission site and the receiving site, patient site and surgeon site, respectively.

Cost of Personnel

Personnel to support telesurgical procedures are comprised of a wide variety of highly trained and highly skilled individuals. This includes surgeons at both sites (remote surgeon and patient side). Technical personnel are required at both sites to provide technical support for telecommunication systems and the robotic systems, including preparation, testing nominal operations, and troubleshooting. The patient side requires a surgical team to support the surgeon. At this stage in the evolution of telesurgery, the number of individuals necessary for success is high. It is envisioned that this number will decline once the systems are more robust and the level of comfort and reliability are acceptable. As indicated above, the growing shortages of doctors will create a higher cost structure due to high demand and limited supply. Simply put, the cost of care will increase due to perceived shortages.

Another cost associated with personnel is that of training. All individuals involved in the application of telesurgery will require some form of training based on their assigned duties. The cost of this training must be considered both in creation of curriculum and delivery.

Cost of Inaction (Opportunity Cost)

Today, whether in the military or civilian communities, there are more surgeons retiring than there are being trained. Coupled with projected increase in surgical need in a growing and aging population, there is an ever worsening shortage of surgeons. This shortage is especially severe in rural and extreme environments. As the aforementioned technologies become more integrated in the practice of medicine (telemedicine) and surgery (telesurgery), these challenges will be met.

4.6.2.3 Liability

Telesurgery permits expert consultation and participation. State and international borders may be crossed and jurisdictional conflicts may occur. Complications are an inevitable part of surgery. If these occur, the burden-of-proof to delineate physician error or technical fault must be established. In order for telesurgery to be embraced, physicians must be confident that liability will be accurately accessed. The Society of American Gastrointestinal Endoscopic Surgeons (SAGES) has suggested deferment of clinical implementation until the technology has been validated. In today's litigious society, this will be an important hurdle to overcome.

Not only are state laws and national laws an issue, key international laws complicate the situation. Some effort has been put forth to address these issues, including those involved in teleradiology. These early efforts have laid a foundation from which to move forward.

Organizations such as the Centers for Medicare & Medicaid (CMS) and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) are looking at these issues. To date the focus has been on telemedicine and its role in healthcare. Specifically, they have focused on the originating site retaining responsibility for overseeing the care and safety of the patient. JCAHO has released statements regarding this in statement MS13.01.01 with regard to credentialing and privileging process at the originating sites. While there are no specific guidelines for telesurgery from either CMS or JCAHO, the development of them will be based on what currently is available for telemedicine and what is under development. While these issues are different with respect to military medicine, it is nevertheless a significant issue for wider adoption of telesurgery in support of multinational forces.

While telesurgery is still a novel approach, liability will evolve based on need and empirical outcomes.

4.6.2.4 Licensing and Credentialing

Telesurgery is an emerging field, and guidelines for establishing minimum system configuration, proficiency, and competency have not been established. A curriculum and practice guidelines need to be established, whereby the participants must perform a standardized set of procedures that are recorded and measured for performance. After completing these tasks the participant is granted competency. In order for this process to be respected, it is recommended that one of the reputed surgical societies develop and sanction these guidelines. Licensing would allow for a benchmark that can be looked to for excellence. Licensing for medical practice is a state's rights issue and therefore, is controlled by states individually. In addition, organizations like CMS and JCAHO weigh in as well. The recent debate on national healthcare in the U.S. will impact how this is reformed.

All medical establishments (hospitals and ambulatory care organization) in the U.S. are accredited by the JCAHO. The FDA approves all medical devices used in surgery. Each practicing surgeon must also have a credential file in order to practice at a facility. The JCAHO has not addressed telesurgery to any great detail but they have addressed telemedicine. They work closely with CMS as well in addressing new and challenging issues on delivery of healthcare. These guidelines include originating sites responsibilities, performance metrics, adverse outcomes of a sentinel event, and or complaints. The eventual incorporation of telesurgery in clinical practice will require further review of this process and CMS will be a part of this process due to reimbursement issues.

4.6.2.5 Ethics

Even thought the surgeon and patient are separated in telesurgery, the same ethics apply. In fact, there must be more vigilance as patient data, images and outcomes may be controlled from a distance site. Much work must be done in this area to ensure that patient privacy is maintained and that all participants are aware and operate under commonly agreed to ethical standards, that of the patient-physician relationship and fulfilling the needs of the patient. Van Wynsberghe and Castmans have provided a very cogent review of ethics in telesurgery. The moral aim of medicine and surgery continue just using advanced technologies.

4.6.2.6 User Acceptance

Telesurgery in a military setting is challenged by extreme environments, trauma applications and culture. However, secondary to this, the military has funded much of the research and development in this area. The military believes the investment in and incorporation of these new tools will add significant value. While the Trauma Pod's next phase has not been funded to date, the military is nevertheless interested in moving nascent technologies forward to enable better healthcare for the warfighter.

Application of telesurgery has been successfully demonstrated in a number of settings. While the initial results are very promising, user acceptance both from surgeon and patient must be realized. Of course key military command personnel also must accept this technology for future operational use. Military use requires doctrine, requirements and development of robust technology via additional research and development.

Wider adoption in non military settings will be achieved through education, experience and involvement through the entire life cycle – inception to integration to utilization. Integration of this capability is revolutionizing the status quo; changing legacy systems and protocols requires all levels of personnel involvement and education, including the patient.

4.6.2.7 Financial

In civilian medicine, capital equipment, operations, and maintenance must be offset by revenues. Today, medical systems are very expensive. The cost of these will come down with increase in availability and use.

Many telemedicine and most telesurgery initiatives have been funded by large government grants. While this funding is key to initiating and building a capability, they often do not provide sustainability. With the impending projected shortages of surgeons, physicians, nurses and allied health professionals and the growing need of an aging population, telemedicine and telesurgery services will be significant adjuncts in meeting these challenges. Cost effective, sustainable business models must be developed.

Further development of telesurgery requires additional research and development, including animal experiments, human clinical trials, and finally, FDA approval. From a technical perspective and in clinical evaluations both in animals first and then in humans, this will require a significant investment. A robust research agenda, matched to specific unmet needs, must be promulgated. As telesurgery is clinically proven to improve quality, access and cost of care, sustainable use within government and civilian health systems will be become widespread.

Reimbursement of telemedicine, and certainly telesurgery are challenging particularly in the U.S. primarily due to current policies, regulations, and reimbursement schemas. While this is being resolved for telemedicine, telesurgical reimbursement awaits clinical use to prod the system.

Investment in telesurgical systems, especially in research and development is very expensive. This investment must be made though if telesurgery is to move forward. Any investment of this size must be predicated on unmet needs and perceive value added. If the investment is shown to save lives, then it may be deemed worthwhile and be of benefit in both military and civilian medicine.

4.6.2.8 Research Data – Evaluation

To date, there has been significant research conducted in telesurgery. However, more research is required to further develop systems, protocols, procedures and techniques. Further research and development will evolve from animal trials to human clinical trials. The data garnered from this research will help define and streamline future research initiatives. The great challenge and barrier to further research and development is sustainable funding through government grants and/or investment by industry.

4.6.2.9 Animal Trials

A robust research effort is required. To date, limited animal work has been performed. Further acute and large animal studies must be conducted to confirm efficacy and safety of specific systems. These animal studies provide solid quantitative data on the system and surgeon performance that will further our understanding and implementation of robust telesurgery capabilities. Animal work will help with the development of appropriate procedural improvements.

4.6.2.10 Human Clinical Trials

Once the systems have been successfully evaluated and validated in animal trials, human clinical trials will be designed and undertaken. Rigorous clinical trials to validate safe and efficacious use of systems for surgeon/health system adoption and FDA approval must be conducted. These must be conducted as multi-center trials, which provide a strong, scientific platform for evaluating all components of a telesurgery system in a true clinical setting. A large number of varied clinical cases would have to be conducted to be statistically significant. To date only a handful of human tests have been performed, including those by Marescaux and Anvari.

4.7 A Strategic Solution

Establish a set of research recommendations, criteria, and milestones. Enable research and strategic investment that matches unmet need.

4.8 Conclusions

Over the past three decades, basic, fundamental and applied research in a variety of disciplines has resulted in the development of systems capable of supporting surgical intervention where patient and surgeon are separated. From its earliest beginnings in the 1990s, telesurgery has rapidly grown from a wired system, where the system is in close proximity to the patient, to intercontinental demonstrations. This research has identified needs and limitations in systems and devices, which in turn has help define evolving requirements.

A significant amount of research and discovery in telesurgery has involved a key group of individuals and organizations. While this group is relatively small, it has predominately been driven by funding from TATRC, which has used these efforts as a technology accelerator. Many of these initiatives have resulted in highly effective collaborations between government, academia, and industry. Each activity has led to progressively more autonomous functions. From the wired system, called telesurgery in the mid 1990s by Intuitive Surgical to the UC-lead research in the high desert of California using a UAV, long distance, wireless surgery is possible. Scientific and technological advances will continue to shape medical decision making

The major challenges to wider adoption are being addressed in other areas of telemedicine, robotics, and telecommunications. Further research is necessary to address those challenges, including latency, animal trials and human trials. While some challenges can be ameliorated by technique, some must be overcome by new technology.

While doing an extensive literature search and interacting with subject matter experts, it is clear that the notion of providing surgical care to a remotely-located patient is at hand. Several rather expensive reports have been produced that highlight industrial capabilities in the field of robotic surgery. The peer-reviewed literature is extensive; and the concomitant scholarly text and technical reports provide a unique overview and in-depth review of where telesurgery is and where it is going.

We believe that this chapter will add value as reference on the subject of telesurgery. Clearly the technologies and capabilities that telesurgery can bring to the delivery of surgical care for the warfighter are significant.

This chapter will serve as a summary of telesurgery at a point in time. Continued debate on healthcare reform and national needs will drive the next generation of research initiatives and eventual integration across the spectrum of medicine and healthcare.

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