Chapter 9
The *da Vinci* Surgical System

Simon DiMaio, Mike Hanuschik, and Usha Kreaden

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9.1 Introduction

In this chapter we describe the evolution of the *da Vinci* surgical system from the very early days of Intuitive Surgical, through to 2009. In order to provide context, we begin with a short summary of the origins of telerobotic surgery itself. This involves a unique convergence of technologies and clinical needs, as well as several groups of individuals who independently recognized the role that robotics and telepresence technologies could play in medicine. The regulatory landscape has played – and continues to play – an important role in the development and use of surgical devices such as *da Vinci*. In this chapter, we describe some of the important aspects of device regulation and how they affect the deployment of medical devices such as ours. It should be noted that this story is told from the Intuitive Surgical perspective and is not intended to be exhaustive. Nevertheless, we hope that it provides some insight into the unique process of invention and development that has resulted in a marriage of technology and medicine that benefits hundreds of patients each day.

S. DiMaio (✉)
Intuitive Surgical Inc., 1266 Kifer Road, Sunnyvale, CA, USA
e-mail: simon.dimaio@intusurg.com

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9.2 The Origins of Telerobotic Surgery

The story of telerobotic surgery involves the convergence and intersection of two very different technologies and the emergence of a completely new approach to minimally-invasive surgery. The first of these technologies emerged in the 1940s and was called "telemanipulation." Robert A. Heinlein's 1942 science fiction short story, titled "Waldo," described a glove and harness device that allowed the lead character, Waldo Farthingwaite-Jones – born frail and weak, and unable to lift his own body weight – to control a powerful mechanical arm by merely moving his hand and fingers. It was not long before these kinds of remote manipulators – popularly known as "waldoes" – were developed in the real world for moving and manipulating hazardous radioactive materials. These devices made use of cables and linkages to allow an operator to safely stand on one side of a thick, leaded glass window while maneuvering a mechanical manipulator located in a radioactive environment on the other side of the glass partition. In the 1950s, Raymond Goertz and his contemporaries explored applications that required remote control over greater distances. They replaced the mechanical linkages with electrical sensors, signals and actuators, thus allowing for greater separation between the operators and their robotic "slaves," as well as for more complex applications [1] (Fig. 9.1).

In the medical arena, it is thought that the earliest ideas on endoscopic techniques date back as far as an Arabian physician named Albukasim (936–1013 A.D.). However, it was not until the early 1800s that Phillip Bozzini developed some of the first practical methods for observing the inside of the living human body – he used a light-guiding instrument that he named the *Lichtleiter* to examine the urinary tract, the

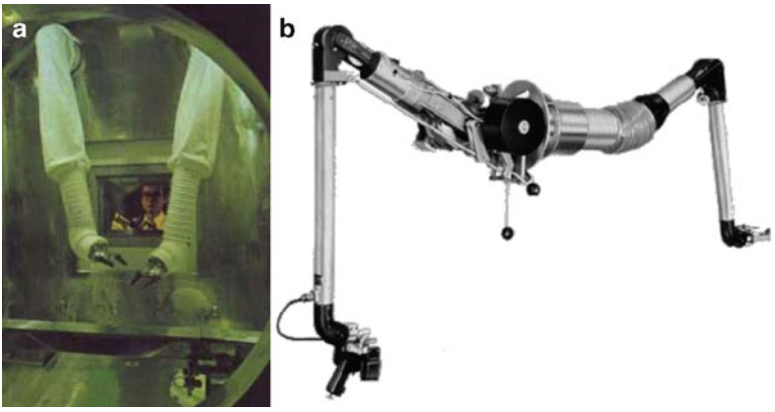

Fig. 9.1 Examples of mechanical teleoperators for manipulation within hazardous environments. At *right*, a Model H Telemanipulator from Central Research Laboratories (Red Wing, Minnesota)

rectum, and pharynx. The development of endoscope-like devices and their applications continued into the 1980s, at which time the emergence of Charge Coupled Devices (CCDs), video electronics and display technologies revolutionized the field and led to laparoscopic techniques for minimally invasive surgery, culminating in the first laparoscopic cholecystectomy in 1987, by French physician Mouret [2].

It would be another decade before the emergence of telerobotic minimally-invasive surgery—a decade in which some key pieces of technology began to emerge. The principles of telemanipulation had been further advanced for application to hazardous material handling, deep sea and space exploration. In the 1980s – with the rapid advancement of microelectronics and computing – virtual reality techniques started to develop the concept of immersive environments, with technologies such as head-mounted displays, graphically rendered synthetic 3D worlds, and haptic interfaces. By the late 1980s and early 1990s, laparoscopy had blossomed; however, limitations in the technique were being reached. The tools that were being employed for manual laparoscopy worked well for relatively simple surgical procedures that involved the excision of tissue and basic tissue closure – procedures such as laparoscopic cholecystectomy (removal of the gall bladder), oophorectomy (removal of an ovary or ovaries), and simple hysterectomy (removal of the uterus) were broadly adopted. At the same time, applications requiring complex reconstruction failed to adopt these laparoscopic techniques in a significant way. Sophisticated mechanisms, such as staplers and other tissue closure devices were developed; however, these still did not allow laparoscopic techniques to gain traction in the most complex of surgical procedures.

During the late 1980s and early 1990s, several groups began to see the potential cross-over between the telemanipulation and virtual reality principles that had been developed for material handling and remote exploration, and the challenges that were being experienced in minimally-invasive laparoscopic surgery. These groups observed the limitations of minimally-invasive surgical techniques at the time and recognized the impact that telerobotics could have in enabling new capabilities and applications. Below are just a few of the groups who first began to marry telerobotic technologies with minimally-invasive surgical techniques, and that would ultimately influence the development of the *da Vinci* Surgical System:

- Dr. Russell Taylor and his group, then at the IBM Watson Research Center (Yorktown Heights, NY), in collaboration with Dr. Mark Talamini, a general surgeon from Johns Hopkins University, developed the Laparoscopic Assistant Robotic System (LARS) – a "third hand" that allowed surgeons to manipulate a laparoscopic endoscope under joystick control [3].
- At the University of California at Santa Barbara, Dr. Yulun Wang developed a robotic system for NASA and later used it to manipulate an endoscope for laparoscopic surgery in 1992. This become the seed for the Automated Endoscopic System for Optimal Positioning (*AESOP*) system and a company called Computer Motion, Inc. Dr. Wang worked with Dr. Carlos Gracia, a leading endoscopic surgeon at San Ramon Regional Medical Center (San Ramon, CA) [4].

- At MIT, Professor Kenneth Salisbury and his students developed innovative human–machine interfaces and haptics. One of his graduate students, Dr. Akhil Madhani, developed the "Black Falcon" as part of his doctoral work: a teleoperated surgical instrument with force feedback. Another alumnus of the Salisbury lab, David Brock collaborated with Dr. Gary Rogers, a general surgeon from the Boston University Medical Center (Boston, MA), and together they created a company called Brock–Rogers Surgical in 1996 (renamed endoVia Medical, Inc., in 2002) [5].
- Dr. Hari Das at the Jet Propulsion Laboratory (Pasadena, California) worked with ophthalmic surgeon Steve Charles. Funded by NASA, their Robot Assisted Microsurgery (RAMS) workstation also made the connection between telerobotics and minimally-invasive surgery [6].
- Professor Brian Davies and his team at Imperial College (London, UK) developed robotic mechanisms for prostate and neurosurgical applications – their I.C. PROBOT prostate surgery device was trialed in the early 1990s [7].
- Professor Blake Hannaford and his group at the University of Washington (Seattle, Washington) began experimenting with teleoperation and haptics for minimally-invasive surgical applications in the mid-1990s [8].
- Phil Green, then at SRI International (Menlo Park, CA), in collaboration with surgeons at Stanford University, as well as army surgeon Dr. John Bowersox developed the "telepresence surgery system," a device that would later contribute key components to early *da Vinci* prototypes.

9.2.1 Early Funding Sources

Several of the early pioneers in telerobotic surgery shared common funding from military sources. In the United States, Dr. Richard Satava, a program manager for the Defense Advanced Research Projects Agency (DARPA), became interested in the idea of robot-assisted battlefield surgery, and began funding telerobotics research programs in the early 1990s. The team at SRI – after starting with their own internal funding and funds from an NIH grant in the late 1980s – was one of the first to begin receiving support from DARPA. Dr. Yulun Wang received initial funding from DARPA to develop his early voice-activated robotic camera manipulator, while Dr. Salisbury and his group at the MIT Artificial Intelligence Lab were also funded by DARPA initiatives at this time.

The military vision for this technology was the idea that mobile telerobotic systems could be used to perform surgery on wounded soldiers immediately at the front lines of the battlefield, under the control of surgeons located out of harm's way, at remote locations. While this model of front-line surgery shifted toward front-line stabilization and rapid evacuation during the Iraq conflict, these DARPA funding initiatives can be credited with helping to provide a significant portion of the early support for telesurgery research.

9.2.2 The Intuitive Surgical Timeline

In 1994, Dr. Frederick Moll became interested in the telerobotic system that had been developed by SRI. He left, his employer at the time, Guidant to attempt to raise venture capital on his own and in 1995 was introduced to Rob Younge, co-founder of Acuson Corporation (a manufacturer of diagnostic ultrasound equipment). Fred Moll, Rob Younge and John Freund, a former venture capitalist from Acuson, collaborated to write a business plan and succeeded in raising initial venture capital for the newly incorporated company – Intuitive Surgical Devices (Fig. 9.2).

This was the beginning of a fast-paced technology development effort. Intuitive Surgical licensed the telepresence surgery technology from SRI and began hiring engineers. An engineering team was in place by April of 1996 and over the next 3 years this team developed three generations of technology prototypes that would support the first set of animal and human trials, eventually culminating in Intuitive's flagship product, the *da Vinci* Surgical System. Along the way, additional technology and staff came from many of the early pioneers in the field, including from Dr. Russell Taylor's laboratory at IBM Research, as well as from Dr. Ken Salisbury's group at MIT.

While awaiting FDA clearance in the United States, Intuitive Surgical began marketing the *da Vinci* System in Europe in 1999. The company raised $46 million in an Initial Public Offering in June, 2000 and a month later was granted FDA approval for applications in general surgery. The following year, in 2001, the FDA cleared the use of the system for thoracoscopic (chest) and radical prostatectomy surgeries.

Shortly before its Initial Public Offering in the year 2000, Intuitive Surgical was sued for patent infringement by its then competitor, Computer Motion – makers of the *Zeus* Surgical System that had launched in 1997. The *Zeus* System was based on their earlier product called *AESOP*, a voice-controlled endoscope manipulator that was the first surgical robotic device to receive FDA approval. The *Zeus* concept was to provide the laparoscopic surgeon with improved precision and tremor filtration. The *da Vinci* approach was somewhat different in the sense that it sought to recreate the feeling of open surgery, but with the potential benefits of minimally-invasive

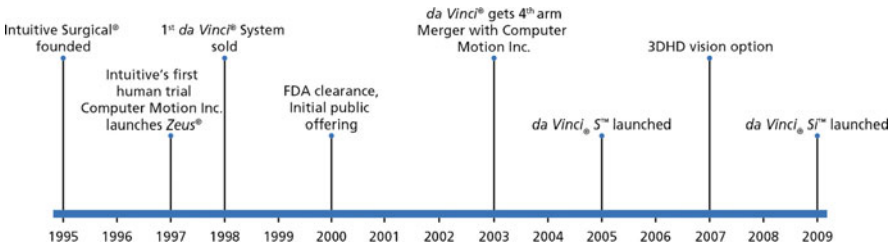

Fig. 9.2 The intuitive surgical timeline

access. To achieve this, the *da Vinci* System had to provide the surgeon with 3D stereo vision, intuitive and dexterous manipulation of surgical instruments inside of the patient. While the *Zeus* system was marketed primarily to laparoscopists, the *da Vinci* System was aimed at the open surgeon. Competition between the companies centered around the differences between these two philosophies. Initially, the *Zeus* was preferred by the general laparoscopic surgeon, while the *da Vinci* was adopted by the open surgeon who did not perform laparoscopic surgery. *Zeus* was smaller, had a lower price point, but was less capable. *da Vinci* was bulky and often accused of being over-engineered. By 1999, Computer Motion had begun to adjust their approach and started moving toward the course that Intuitive Surgical was on.

Shortly after Computer Motion brought forward its lawsuit, Intuitive Surgical counter-sued and the two fledgling companies became embroiled in a legal battle that severely limited growth on both sides. In 2003, as both companies were running out of funds, Intuitive Surgical and Computer Motion agreed to merge, thus ending the litigation between them. At that time, the *Zeus* System was phased out in favor of the *da Vinci* System, because of *da Vinci*'s additional capability.

9.3 The Evolution of the *da Vinci* Surgical System

When Intuitive Surgical made its start toward the end of 1995 the product vision included four key specifications, or product pillars. First and foremost, the system needed to be reliable and failsafe in order to be feasible as a surgical device; second, the system was to provide the user with intuitive control of the instrument; third, the instrument tips were to have six-degree-of-freedom dexterity as well as a functional gripper. The fourth pillar was that of compelling 3D vision. These product pillars supported the ultimate goal to regain several key benefits of open surgery that had been lost in the laparoscopic approach – while maintaining minimal invasiveness – by virtually transposing the surgeon's eyes and hands into the patient in a reliable and effective way. The technology that was licensed from SRI, IBM and MIT provided a starting point for realizing this vision.

In 1995, the SRI prototype system had four-degree-of-freedom instrument manipulators, plus a gripper. It had a simple master interface that allowed the user to command instrument motion, and a control system to intuitively match the motions of the instrument tip with commanded motions of the master interface. Kinematic similarities between the master and slave mechanisms simplified the mathematics behind this intuitive mapping. From this prototype, three generations of prototypes were derived over a period of 3 years, culminating with the *da Vinci* Surgical System – Intuitive Surgical's first commercial product to be shipped to customers.

The *da Vinci* System was named during the very first month of Intuitive Surgical's existence. The renowned renaissance icon, Leonardo da Vinci had combined art, science, anatomy and engineering throughout his career of invention and innovation: a combination that seemed to befit Intuitive's vision. Early prototypes were not named *da Vinci*, as this title was reserved for later. The first

prototype was named after Leonardo, but contracted to "Lenny" for fear that this first attempt would fail to meet expectations.

9.3.1 Lenny

Beginning from the SRI prototype, this first design iteration added a wrist at the end of the patient-side manipulator, thus increasing the total number of degrees of freedom at the tip of the instrument from five to seven. At that time, the instrument was not interchangeable, as shown in Fig. 9.3a. The kinematic similarity and intuitive mapping between the master and slave manipulators – as exhibited by the SRI prototype – were maintained. These patient-side manipulators were mounted to the operating table by means of a simple positioning mechanism that could be manually adjusted using a screwdriver and wrench (this is shown in Fig. 9.7a).

In order to visualize of the surgical field, a commercially available Welch Allyn 3D endoscope – shown in Fig. 9.4 – was mounted to an endoscope manipulator that was almost identical to that of the SRI prototype. This endoscope featured two CCD video chips mounted at the tip of the endoscope, each with an image resolution below that of Standard Definition NTSC video, but nevertheless sufficient to provide the user – seated at a control console – with stereo video of the surgical site. A commercial CrystalEyes display system was used to display the stereo video coming out of the Welch Allyn endoscope. This system alternated left- and right-eye video frames on a single video monitor, with the user having to wear a pair of active shutter glasses that alternated left and right eye views in synchrony with the display. The CrystalEyes system is shown in Fig. 9.8a.

The Lenny prototype was completed and taken to animal trials during the summer of 1996, with an initial focus on complex general surgery applications. A great deal of important learning occurred during this first set of in vivo experiments. For example, it was clear from the experience that the six-degree-of-freedom motion

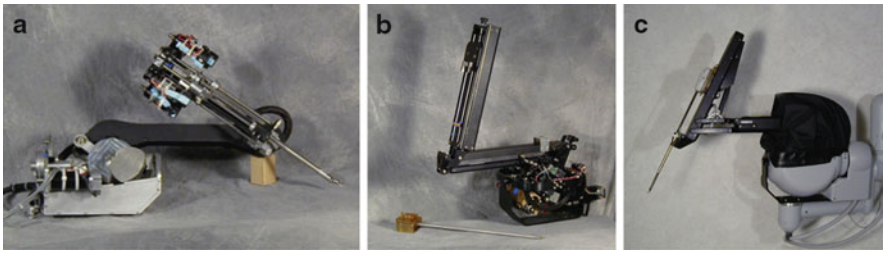

Fig. 9.3 Evolution of the patient-side manipulator (PSM). (**a**) the *Lenny* manipulator that was derived largely from the SRI prototype; (**b**) the *Mona* manipulator with its exchangeable instrument architecture; and (**c**) the *da Vinci* manipulator that ultimately became part of the commercial product

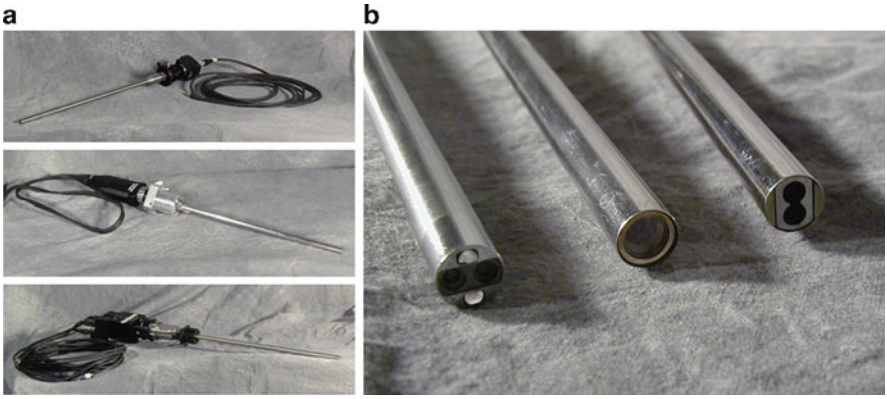

Fig. 9.4 Development of the stereo endoscope. From top to bottom (**a**) or right to left (**b**): the Welch Allyn stereo "chip on stick" endoscope; an Olympus endoscope with single optical train and rear-mounted CCDs; and the *da Vinci* endoscope with dual optical trains and dual three-chip camera heads

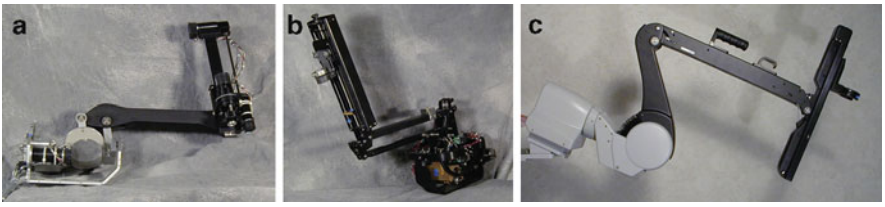

Fig. 9.5 Three generations of the Endoscope Control Manipulator (ECM): (**a**) the manipulator from the Lenny prototype, which was very similar to that of the original SRI system; (**b**) the Mona ECM; and (**c**) the *da Vinci* ECM

afforded by the new wrist, in addition to the intuitiveness of the motion mapping, were providing value that was worth their additional cost and complexity. On the other hand, the system was not reliable – it was fragile – and the visualization provided by the combination of the Welch Allyn endoscope and the CrystalEyes display system was poor. Moreover, the importance of the patient-side manipulator support mechanism and the ability to easily position and reposition the manipulators became clear. Lenny had a relatively short 6–9 month lifespan, but provided the key insights that would set the stage for a second generation prototype (Fig. 9.5).

9.3.2 Mona

Following the lessons learned from Lenny, several subsystems were dramatically redesigned leading up to the Mona prototype, named after Leonardo's renowned painting, the Mona Lisa. These would be the first to be tested during human surgery.

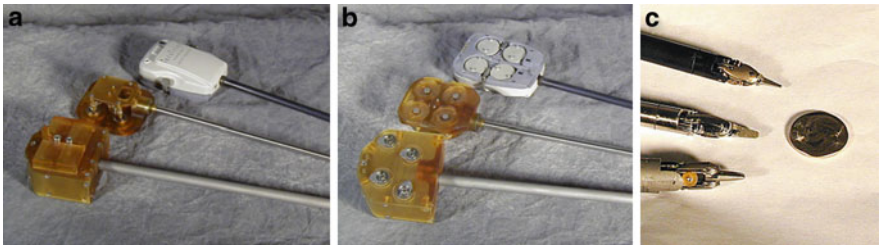

Fig. 9.6 Three iterations of *da Vinci EndoWrist*® instruments with wrists at their tips and a coupling mechanism at their rear that allowed for rapid exchange and the maintenance of a sterile barrier

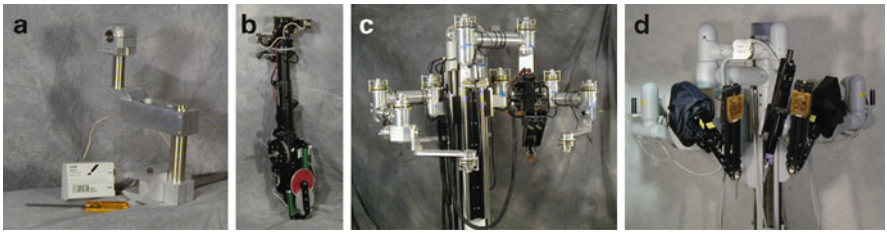

Fig. 9.7 Three generations of setup mechanisms that were used to support and position the instrument manipulators at patient-side. (**a**) The extremely simple mounting that was used to support the Lenny PSMs; (**b**) at early attempt at a repositionable setup arm that was used with the Mona prototype; (**c**) an early prototype of a cart-mounted setup system that provided stable, yet flexible positioning of the PSMs; and (**d**) the *da Vinci* patient-side cart that ultimately became the commercial product

Perhaps the most significant aspect of this re-design was that the patient-side manipulators were completely revised to accommodate an exchangeable sterile instrument architecture. This was a key feature missing in the Lenny prototype and essential for first human use. It meant not only that the system could accommodate many different styles of instruments for different surgical tasks, but also that these instruments could be separated from the non-sterile robotic manipulators and sterilized independently. The instruments themselves (shown in Fig. 9.6) were based on a low-friction cable and pulley design that was influenced by early work by Professor Kenneth Salisbury and his group at MIT.

A second significant focus was on the patient-side manipulator positioning problem that had been identified during experimental work with Lenny. A "setup" mechanism was developed to allow for flexible positioning of three manipulators positioned at the patient side. This mechanism was clamped to rails on the side of the operating table and used a system of gears, springs and linkages to support and dynamically counterbalance the robotic manipulators as they moved above the operating table. Two of these devices were mounted on one side of the table, while a third was mounted on the opposite side. A portion of this mechanism is shown in Fig. 9.7b.

In early 1997, the Mona prototype was used to perform Intuitive Surgical's very first human surgeries at the Saint-Blasius Hospital in Dendermonde, Belgium. This provided valuable clinical experience; however, a number of critical lessons were learned:

- While the new interchangeable instrument architecture was a significant step, the coupling between the instruments and the patient-side manipulators was sensitive to mechanical tolerances and lead to unreliable instrument engagement.
- Improvements in the master and slave interfaces focused new attention on the visualization system, with the realization that both image acquisition and display quality were not sufficient for clear and comfortable stereo viewing of the surgical field.
- Perhaps the most challenging aspect of the Mona prototype was the operation of the setup mechanisms. The table-mounted, counterbalancing mechanism proved to be unstable and inflexible, as well as being too heavy for the table rails to which they were mounted. It was clear that a radical change in the setup approach would be required.

During this period of time, there was also a shift in the clinical landscape. The Nissen Fundoplication procedure, a complex general surgery application, was starting to be performed successfully by manual laparoscopic techniques. At the same time Heartport Inc. – industry pioneers in developing less invasive cardiac surgery products – was struggling with minimally-invasive cardiac surgery. These factors resulted in a shift of Intuitive's focus from general surgery toward cardiac surgery. This new focus, in conjunction with the experience of first human use with the Mona prototype, drove a third generation of prototype, one that would lead to a first commercial product offering.

9.3.3 da Vinci

Early experiments with the Mona prototype had highlighted severe shortcomings with the ability to position the instrument manipulators at the patient side in a flexible yet stable way. Other engineering activities at Intuitive came to a halt in order to focus on this problem of "setup." Several new concepts were developed, first with models constructed using toothpicks, then one-eighth-scale cardboard models and finally full-scale wooden models; several designs were constructed before settling on a design that was to be fabricated in metal. This design was mounted on a free-standing cart. It was bulky and heavy (weighing in at approximately 1,400 pounds), yet it delivered the patient-side manipulators where they needed to be in a flexible way and provided a stable working platform (Fig. 9.7c, d).

Shortcomings with the quality of the vision system were a second major concern at this stage. A new stereo viewer concept was developed, which shifted from the single-display shuttered approach to a dual-display approach, with one dedicated video display for each eye. An early prototype of this concept is shown in Fig. 9.8b;

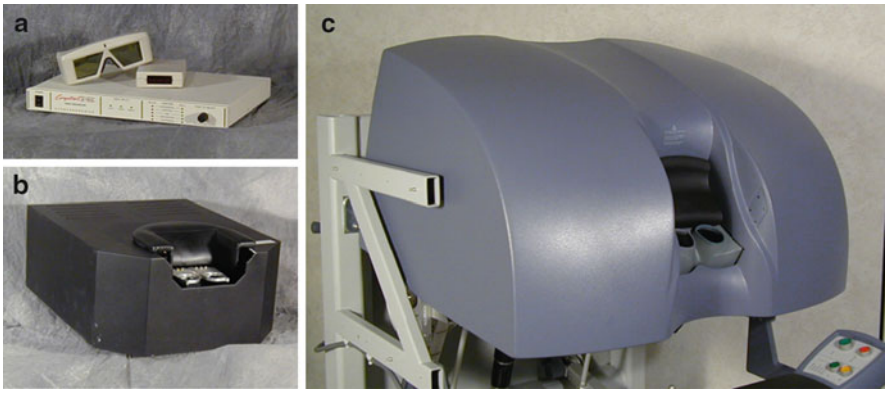

Fig. 9.8 Development of a stereo viewer. (**a**) The CrystalEyes shuttered eyeglass system used in the Lenny and Mona prototypes. A stereo viewer box containing two Sony CRT displays – a prototype that eventually lead to the *da Vinci* stereo viewer design. (**c**) The *da Vinci* high resolution stereo viewer

a pair of Sony CRTs, some mirrors and baffling not only simplified the stereo viewer, but also provided improved display image quality and a more compelling sense of depth and stereo. In order to provide improved video quality on the imaging side, the Welch Allyn endoscope – with its low-resolution distal video chips – was replaced by an Olympus design that used a single optical channel and a dual camera head located at the rear of the endoscope (Fig. 9.4). While image quality was improved, the stereo separation achieved by this design was inadequate. Therefore, it was decided to develop a custom endoscope design with portions of the optics work contracted to a company called Precision Optics Corporation (POC). This was a 12 mm endoscope with two independent sets of 5 mm rod lens optics packaged side-by-side, leading to two three-chip camera heads mounted at the rear of the endoscope.

The problem of temperamental instrument couplings was resolved with a new design based on the principle of the Oldham coupling, which dramatically reduced sensitivity to mechanical tolerances in the instrument and PSM interfaces. On the surgeon console side of the system, there were significant changes in the master interfaces, which evolved from a telescoping design (Fig. 9.9a) to a backhoe design that was kinematically dissimilar to the patient-side manipulators, but with larger range of motion and improved reliability (Fig. 9.9b).

At this stage, the technology had matured to the point that the latest in the succession of prototypes finally earned the name of *da Vinci*, and it was clear that the team saw this as their likely first product offering. The *da Vinci* prototype was taken to human trials in Mexico, France and Germany in 1998 and 1999, with a clinical focus on cholecystectomy and Nissen fundoplication procedures, thoracoscopic internal mammary artery harvesting and mitral valve repair. The setup problem had been resolved, the system now had good 3D vision quality, and the intuitiveness and dexterity of the surgical instrument control were proving to be invaluable. While

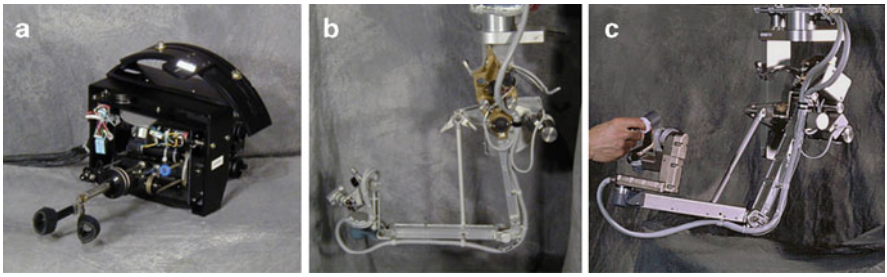

Fig. 9.9 Evolution of the Master Tool Manipulator (MTM) that is manipulated by the surgeon in order to control the patient-side manipulators and surgical instruments. (**a**) A telescoping MTM design that was used in both the Lenny and Mona prototypes; (**b**) a backhoe design that was developed for *da Vinci* in order to provide greater range of motion and improved robustness – this prototype was used for clinical studies with the *da Vinci* prototype; and (**c**) the MTM design that eventually shipped with the *da Vinci* product

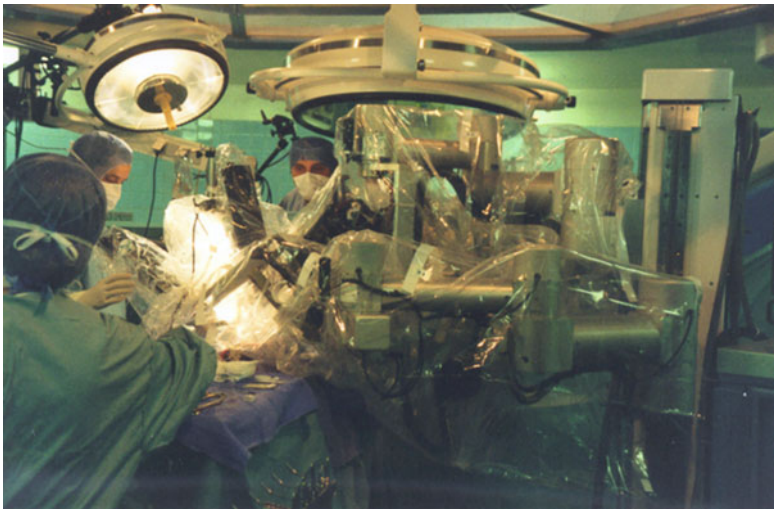

Fig. 9.10 Early cardiac trials in France and Germany during May of 1998

system reliability was still poor (there were frequent system errors and interruptions during early cases), the fault detection mechanisms that had been put into place meant that procedures could be completed safely (Fig. 9.10).

The four key pillars of the product were finally standing. It had taken more than two years from April of 1996 to develop a system with the complexity of a car (approximately 10,000 components) and to ship the very first product to a customer – the Leipzig Heart Center, Germany, in December 1998. Ten systems were shipped during the following year. This number was intentionally limited in order to continue to prove out the product and its market, while not overextending the still-fledgling company that was just beginning to learn how to manufacture and support products in the field (Fig. 9.11).

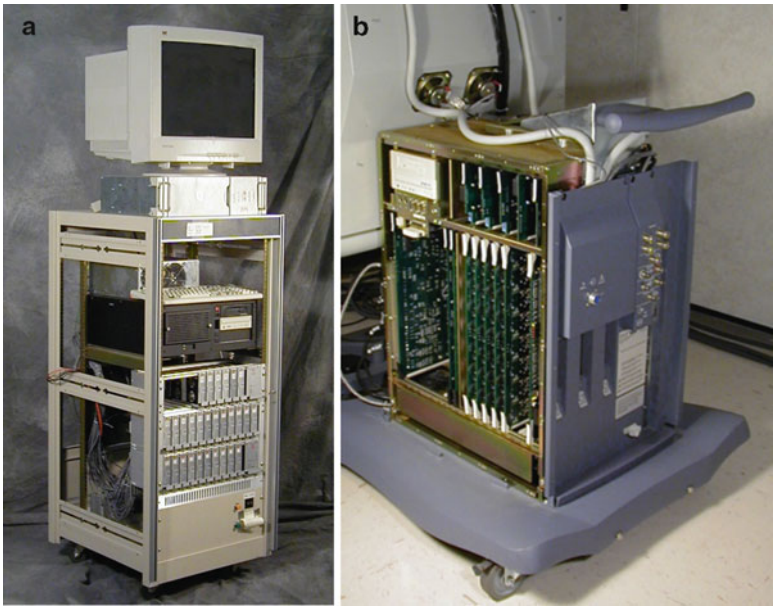

Fig. 9.11 Evolution of the electronics chassis from a PC-based servo and control system to the custom printed circuit assemblies housed within the *da Vinci* surgical console

9.3.4 Continuous Improvement and Development

The next 4 years were focused on stabilizing the reliability of the system and scaling up production and support teams. The evolution that brought an operative surgical robot to the marketplace in 1999 continued after the release of the first product.

On the *da Vinci* platform, slimmer 5 mm diameter instruments (as opposed to 8 mm instruments) were developed based on a novel vertebrae design. In 2003, a fourth arm was added to the patient-side cart in order to give the surgeon greater control over tissue retraction. This included a user interface to swap control among all arms. The suite of surgical instruments was expanded from six to over 50.

The *da Vinci S*^{TM} product release in 2006 focused on improving the patient-side experience by providing a more streamlined and ergonomic design that reduced set up time by half, with just half the number of set-up steps. The slave arms were smaller, lighter, more easily manufactured and serviced, with greatly expanded range of motion. The fourth arm was integrated into the design (as opposed to the retrofit arm that had been added to *da Vinci* in 2003). A smaller, simpler patient cart with fewer degrees of freedom helped to better balance the need for flexibility with simplicity in set-up. Distributed power and control were incorporated in order to minimize cabling. Visualization was improved with WXGA high definition

video (1280×768 pixel resolution; roughly equivalent to 720p) and matching image capture equipment. A patient-side touch-panel display and *TilePro*™ multi-input display were added for improved interaction and control. Moreover, significant architectural improvements were put into place to allow for greater reliability and fault tolerance, and faster development.

The latest in the product line, the *da Vinci Si* – launched in April, 2009 – focused the product development on refining the platform to meet the demands of a maturing market. Where the prior model (the *da Vinci Si*) focused on the patient cart, the *da Vinci Si* focused on the surgeon console and vision cart. The surgeon console received improvements in ergonomic adjustability to accommodate a greater range of users comfortably; as well as higher resolution 3D monitors (SXGA), internally cabled master controllers and a simplified user interface. Additionally, the footprint was reduced to make it easier to move around the operating room for small nurses (Fig. 9.12).

The vision cart and associated camera assembly were revised: The touch-screen monitor became widescreen and supported a higher resolution (WXGA+, 1440×900 pixel resolution). Prior to the *da Vinci Si*, the camera controllers were separately controlled, requiring that users perform two steps each time they wanted to adjust one setting (e.g., white balance). Taking all of these vision controls into the system internally made it possible for synchronized 3D vision control. In addition, the size of the camera head was reduced to make it easier to handle and advanced controls were added to simplify vision system setup.

Lastly, *da Vinci Si* was built to support two consoles operating in concert with a single patient-side system. An instrument "give-and-take" paradigm allows surgeons to share control of the *da Vinci* instruments, for the purpose of enhanced surgeon training, as well as for enabling collaborative surgery (Fig. 9.13).

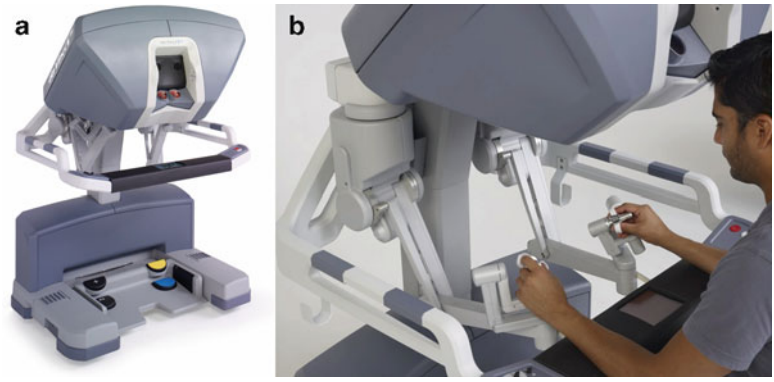

Fig. 9.12 The *da Vinci Si* surgical console (**a**) and redesigned master interfaces (**b**)

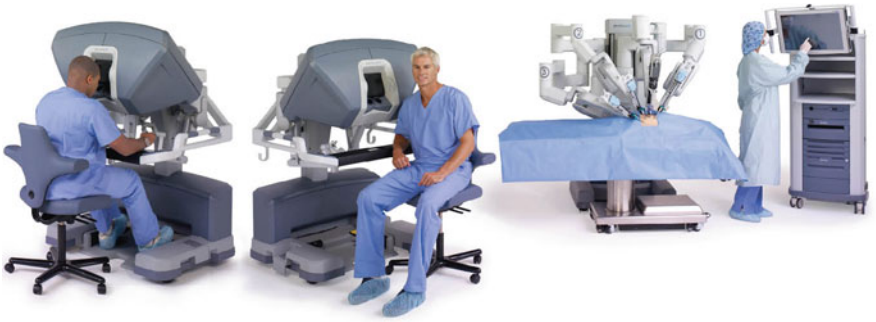

Fig. 9.13 The complete *da Vinci Si* System with dual surgical consoles offered as a optional capability

9.4 The Regulatory Landscape

In the United States, the governing body that regulates medical devices is the U.S. Food and Drug Administration (FDA). This agency was given the authority to regulate medical devices in 1976 under the Medical Device Amendments [9]. In 1990, the Safe Medical Device Act further built upon the Medical Device Amendments to provide a regulatory structure by which medical devices could ensure safe and effective use [10]. In general, devices are classified into three main categories; Class I devices representing the lowest risk, followed by Class II devices and lastly Class III devices which involve those of highest risk. The determination of classification of a medical device depends on the risk it poses to the patient and the user as well as its intended use [11]. Class III devices are typically those that sustain life, such as cardio-pulmonary bypass systems. Class II devices are typically tools whose misuse or failure may cause serious injury. Class I devices are typically those whose misuse or failure are unlikely to result in serious injury.

As pioneers in computer-assisted surgical devices, Intuitive Surgical and Computer Motion were responsible for many first-time decisions made by the FDA for regulating robotic medical devices. One such example was the determination of the classification of the *da Vinci* Surgical System, which was initially evaluated as a Class III device but was later moved to class II by FDA just prior to its approval in 2000. Today, Class II devices include those that fall under a "fly by wire" definition – the type of control system for an airplane or spacecraft, in which the controls are actuated by electrical impulses, as from a computer [12].

Over the past decade regulators have worked hard to understand the numerous computer-assisted systems under consideration for clearance and have only recently created an internal nomenclature by which they are able to categorize a particular device. FDA has created three main categories in which current computer-assisted medical devices fall. The first category is "stereotactic devices or navigational systems" which includes devices for computer-controlled breast biopsies, orthopedic navigation systems and stereotactic systems for navigation in neurology and

radiation therapy delivery systems. The second category includes "fly-by-wire systems," where the surgeon's movements are mimicked much like the controls for a pilot. Tele-operators like the *da Vinci* System fall within this category. Systems designed to perform autonomous clinical tasks under indirect supervision fall into the third category of computer-assisted medical devices. Because most computer-aided devices going through the FDA clearance process were developed in the last decade, the nomenclature above is still not well-known outside of industry and FDA [12].

Pulling together the concepts above, the regulatory pathway that a new computer-assisted device will travel through FDA depends upon its architectural type, its risk to the health of the patient and provider, as well as its intended use. Submissions rely upon providing regulatory agencies a combination of clinical data, bench-top data, verification and validation information. In a recent paper by Janda and Buch, a summary of computer-assisted devices by regulatory class and common requirements for testing, validation and clinical data was shared. While there may be exceptions, Table 9.1 provides some guidelines as to the burden of testing and clinical proof required to take a computer-assisted medical device to market.

The *da Vinci* Surgical System was first seen by the U.S. Food and Drug Administration in 1997 and the first clearance received by Intuitive Surgical was for the visualization of tissue using the robotically controlled endoscope. At its inception, the system was classified as a Class III device requiring clinical data demonstrating safety and effectiveness in order to be cleared for active use (i.e., cutting, cauterizing suturing, ligating etc.). A description of the regulatory submissions over the last 10 years pertaining to the *da Vinci* platform evolution discussed earlier in this chapter is shown in Table 9.2. This table does not include the numerous instruments and

Table 9.1 Summary of the classification of computer-assisted devices and their testing requirements

Device type	Regulatory class	Bench testing	Animal testing	Software validation	Clinical data
Preoperative planning	II				
Stereotactic frames	II	X			
Computer-assisted or navigation/intraoperative planning	II	X			
Robotic operating assistants	II or III	X			
Fly-by-wire Systems	II or III	X			
Robots	Unclassified	X	X		

Adapted from Janda and Buch [12]

Table 9.2 Device clearance history

Platform	Year of clearance
da Vinci Surgical System (standard)	2000
4th arm	2003
da Vinci Surgical System (S)	2006
da Vinci Surgical System (Si)	2009

Table 9.3 Clinical indication clearance history

Indication	Year of clearance
Visualization and tissue retraction (da *Vinci*)	1997
Endoscopic visualization (*da Vinci*)	1999
Laparoscopic/general surgery	2000
Thoracoscopic surgery	2001
Radical prostatectomy	2001
Mitral valve repair	2002
ASD closure	2003
Coronary anastomosis For CABG	2004
Cardiac tissue ablation/microwave energy	2005
Broad urology indication	2005
Broad gynecology indication	2005
Pediatric indication	2005
Coronary anastomosis for beating heart CABG	2008
Transoral otolaryngology (ENT)	2009

accessories that have gone through the premarket notification process. In total, there have been 35 separate regulatory submissions to the U.S. FDA regarding the *da Vinci* platform as of December 2009.

As mentioned above, clearance for a Class II device by the FDA is made for a specific set of indications, approved uses of the device for which FDA reviews evidence of the device's safety and efficacy for its intended use. Table 9.3 describes the history of regulatory submissions specific to new clinical indications for the *da Vinci* Surgical System. The clearance of new indications for the *da Vinci* System has required submission of clinical data to the FDA demonstrating its safety and efficacy through the performance of both prospective clinical trials and analysis of retrospective clinical trial data.

As public agencies seek to understand the impact of new technologies on health-care outcomes and costs, peer-reviewed clinical publications and evidence-based medicine have become increasingly important. Intuitive tracks the creation and publication of peer-reviewed publications on clinical uses of *da Vinci* Surgical Systems. The current library includes over 2,000 PubMed-indexed publications representing multiple surgical specialties, the vast majority of which were researched and written independent of Intuitive. Figure 9.14 shows publications by surgical specialty from 1998 to June 2009. The *da Vinci* clinical library is increasing at a current rate of approximately 90–110 publications per month. While some critics cite the lack of clinical evidence for the efficacy of robotic surgery, the peer-reviewed literature is, in fact, both deep and compelling across many clinical applications.

For companies seeking to commercialize computer-aided interventions, the regulatory process can be daunting. Submissions and communications with regulatory bodies worldwide range from discussions of electronics design, imaging systems and embedded software to clinical trial design and patient outcomes analysis. In the past decade, regulatory agencies worldwide have made investments in learning both the base technologies in our field and in understanding their clinical use. In general,

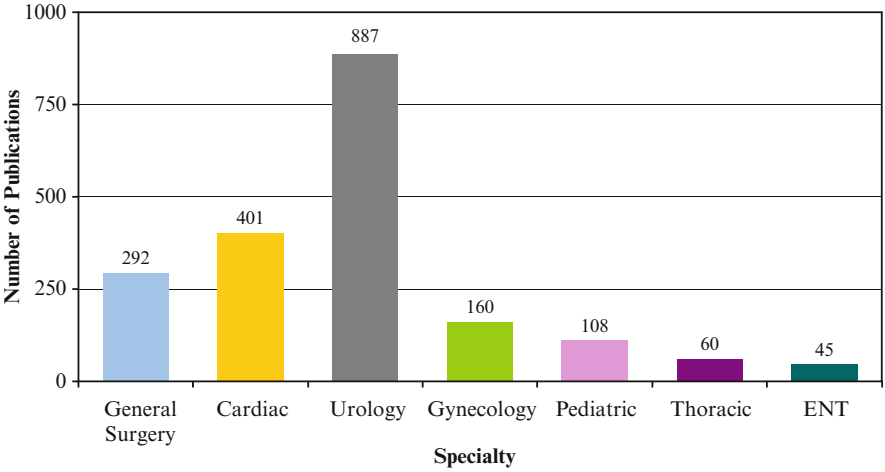

Fig. 9.14 *da Vinci* Publications from 1998 – June 2009 by Surgical Specialty

the level of scientific sophistication in the clinical and technical reasoning and documentation has increased over time. Success in bringing products to the market has required a cross-functional approach (engineers, clinicians and regulatory experts) on the part of both industry and regulatory agencies to examine the opportunities and risks presented by computer-aided intervention.

9.5 Conclusion

The development of telerobotic surgery from science fiction to reality over the last two decades has brought together many different disciplines in medicine, engineering, science and industry. In particular, the clinical and engineering research communities put into place many of the key foundations of this technology and jointly recognized the value of a marriage between their fields – an insight that provided a key catalyst for creating a completely new way of performing surgery. Regulatory bodies, too, had to innovate and adapt their processes in order to strike a balance between the benefits and potential risks of this new technology, with the health and safety of patients being their ultimate priority and a tremendous responsibility.

It is on the shoulders of giants that an industry has been built. As a community we look forward to the innovations that the readers of this book are yet to imagine and to build, in order to power the next revolution in surgery. Multi-disciplinary collaboration has clearly been a key component of the development of our field to-date and will become increasingly important as new capabilities are realized and new applications are explored. This teamwork between clinical scientists, surgeons and OR staff, academic researchers, engineers, regulatory groups and many others will help to transition novel ideas into technologies that will ultimately benefit patients and their families in remarkable new ways.

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