White Paper

Why Robotic Surgery Simulation is Critical for Surgeons: The Benefits to Hospitals

Summary

Use of robot-assisted surgery has increased exponentially in the past decade. Despite this rapid uptake, there are no credentialing requirements or clear training recommendations surrounding this technology. Institutions are left to determine on their own how best to train and keep their surgeons current in order to address patient safety issues while minimizing cost burden. This white paper discusses the current industry-leading robotic surgical equipment and the solution Mimic Technologies has implemented to change the field of robotic surgery training.

Introduction

Robot-assisted surgery has quickly been adopted by institutions as the gold standard in the treatment of many diseases. Robotic surgery, proven to be as safe and effective as traditional surgical methods, allows for minimally invasive surgical (MIS) procedures for procedures that historically have been accessed by large incisions. The benefits of MIS procedures using robotics have been well-documented, and include reduced hospital stay, fewer blood transfusions, and a lower likelihood of developing post-operative respiratory and other surgical complications.[1] The demand for robotic surgical methods has skyrocketed in the past ten years and will only increase as technology continues to improve.

The market leader in robotic-assisted surgical equipment is Intuitive Surgical with its *da Vinci*® surgical system, introduced in 1999. *Da Vinci* is renowned for its surgical precision, range of motion, dexterity, visualization, and access. Over 2,000 *da Vinci* systems have been installed in institutions around the world and the install base is growing at a rate of 25% per year. *Da Vinci* has revolutionized the field of MIS, allowing for more complicated precision surgical procedures than ever before. Over 4000 manuscripts have been published that investigate the *da Vinci* robotic surgical system, primarily in the

[1] Hu J. C., Gu X., Lipsitz S. R. , Barry M. J., D'Amico A. V., Weinberg A. C., Keating N. L. Comparative Effectiveness of Minimally Invasive vs. Open Radical Prostatectomy. JAMA, 302 (14), 1557-1564.

areas of urology, cardiothoracic surgery, general surgery, gynecology, general topics, pediatrics, and otolaryngology.[2]

This white paper examines the challenges faced by the rapid implementation of this new technology, and how Mimic Technologies' dV-Trainer™ can bridge the gap to achieving proficiency for institutions using the *da Vinci* Surgical System.

Challenges

The *da Vinci* Surgical System has provided physicians with as simple and intuitive a platform as possible, but given the nature of the complex, routine surgical procedures, considerable time must be devoted to mastering it.

Physician training on the *da Vinci* system is critical to the success of any robotic surgical program. The power of such a brilliant system, however, can only be harnessed by knowledgeable, trained users. While this technology is improving patient care, it is bringing with it some targeted challenges.

Issues surrounding training and education of surgeons are critical considerations for all hospitals using the *da Vinci* Surgical System in their practice.

Patient safety

The primary concern of all hospitals is patient safety. The best estimates of patient safety data indicate that approximately 100,000 patients die each year from preventable medical harm. While this number includes preventable deaths from all causes, with medication errors being a large component, it speaks to the ongoing concern hospitals have with preventing patient harm. Any additional safeguards that could be put in place to train staff more efficiently and ensure patient safety would reap huge rewards.

While it has been shown that the *da Vinci* system meets or exceeds many endpoints in patient care, the outcome is dependent on the skill of the surgeon performing the procedure. To aid in this, Intuitive Surgical, the maker of the *da Vinci* system, provides two-and-a-half days of training to orient new users to the robot's advanced features. After the training has taken place, it is the responsibility of each individual institution and physician to complete the training and practice necessary to master the robot. The learning curve needed to master such a complex system suggests that it requires dedicated time to adequately prepare physicians to perform surgery using it and to maintain ongoing proficiency over time. Surgeons with extensive robotic experience have proposed that it takes at least 200 surgeries to become proficient in robotic-assisted techniques. This leaves each institution to determine on its own, with the best available information, how best to prepare its surgeons for the complexity of surgery using robot-assisted methods.

There have been some documented cases of inexperienced surgeons performing robotic surgery resulting in unfortunate outcomes. In one such highly publicized case, a woman's urethras were accidentally severed during a routine hysterectomy at a small, 178-bed hospital in New Hampshire during a surgery using a robot-assisted surgical system. The patient subsequently filed a lawsuit against the hospital and

[2] Intuitive Surgical. www.intuitivesurgical.com. Retrieved October 13, 2011.

the physicians involved, assigning blame for the incident to the lack of appropriate training regarding the use of the robot.[3] Vipul Patel, a world-renowned robotic surgeon who is credited with performing over 4,000 robot-assisted prostatectomies, commented on this incident and others, stating, "These articles highlighted important problems. We agree surgeons need more education. They need more support from the hospital."[4]

There has been a movement in the surgical community to define credentialing requirements for institutions that use robotic-assisted surgical techniques. Lack of specific credentialing requirements and training recommendations leaves each institution to provide its own best estimate as to how much training its physicians need. For hospitals using the *da Vinci* system, many of which are small community hospitals with fewer than 200 beds, this is a critical issue. Smaller hospitals may not perform enough surgeries annually on the *da Vinci* robot to reach or maintain proficiency in using it.

"These articles highlighted important problems. We agree surgeons need more education. They need more support from the hospital."

– Vipul Patel

Training on the *da Vinci* Surgical System

There is a clear need for initial and ongoing training of physicians on the *da Vinci* Surgical System, both to establish proficiency and to maintain it. The cost of training on the *da Vinci* system, both fiscally and in terms of time management, is very high. Training using the system is necessary to ensure patient safety, but at the same time creates additional challenges.

While such training is crucial for ensuring patient safety, it would tend to monopolize the *da Vinci* surgical system and render it unavailable for surgeons performing revenue-generating procedures for the hospital. Additional costs would be incurred as training resulted in wear on instruments with a finite life-span. At high-volume hospitals, using the *da Vinci* system for training at all may be problematic for time management of the equipment in the operating room and may not be feasible given the demand placed on the equipment at these centers. In many cases, an additional *da Vinci* system would be required just to maintain the training burden. For most surgical centers, this additional cost would be prohibitive.

The Solution

Virtual Reality-Based simulation has a long history of providing effective training for routine or high-stress and dangerous situations. Although relatively new to the discipline of surgery, simulation has been used widely in the military, in nuclear power plant operations, and for airlines to train personnel effectively. Surgical Simulation moves the training from the operating room to the office. It revolutionizes the surgical training environment, permitting the efficient use of time and personnel, limits costs, and reduces patient safety considerations. In addition to its direct application in providing initial proficiency for training physicians, simulation is an excellent tool for surgical centers with low patient

[3] Carreyrou J. (2010 May 25) Botched Operation Using *da Vinci* Robot Spurs Lawsuit. The Wall Street Journal. Retrieved from online.wsj.com.

[4] Fernando Q. (2010 July 19) Robotic Surgery: How Safe is it? The Orlando Centennial. Retrieved from www.healthkey.com.

volumes or for those surgeons operating infrequently who need to "brush up" on their skills prior to performing a procedure. Robotic surgery experts believe it can take up to 200 iterations of a procedure for a physician to become proficient in using the *da Vinci* robotic system. Simulation allows for a cost-effective, iterative process required to gain this proficiency.

Computer simulators are the most comprehensive and realistic simulators available to the medical community to date. Recent advances have given simulators the same "look and feel" as actual surgery and provide a distinct advantage over legacy simulators, which can be cumbersome and less realistic.

As outlined in Figure 1, there are five main criteria for any successful *da Vinci* surgical simulator. First, the system must be realistic and accurate in its simulation. Inasmuch as the *da Vinci* system is the most widely used system, fidelity to it is paramount. Secondly, the system must have a strong partnership with Intuitive Surgical, the manufacturer of *da Vinci*. Without this crucial relationship, the nuances of the *da Vinci* system would be impossible to recreate in a simulator. Thirdly, it must be validated by independent institutions. Validation is a critical step, as it is required before any surgical center will commit to a system's purchase and integration into its program. Fourthly, it must provide accelerated physician learning and objective performance assessment. The surgical simulator must include relevant training scenarios and software that allow for the assessment of surgical skills and tracking of proficiency over time. Finally, any successful surgical simulator must be cost-effective. Training, while critical to the success of any surgical program, is not revenue-generating, so any strategies employed to improve physician training must be sufficiently cost-effective for the institution to consider using it (see Appendix: The Frost & Sullivan ROI study for Medical Simulation Training).

Requirements of a Successful *Robotic* Surgical Simulator

- **Realistic and accurate simulation**
- **Strong partnership with Intuitive Surgical, the makers of the *da Vinci* robot.**
- **Validated by independent institutions**
- **Provides accelerated physician learning and objective performance assessment**
- **Accessible and Cost effective**

Figure 1

Mimic Technologies has met these requirements by creating a unique computer simulator that is revolutionizing training for robot-assisted surgery.

Why the dV-Trainer is the definitive solution

The *da Vinci* Surgical System, the leader in its field, is brilliant and vast in its capabilities but it is complex and can require many years to master, especially for low-volume surgical centers. Mimic simulation devices and software provide an incomparably more efficient and cost-effective training than training on the *da Vinci* robot alone.

Mimic's dV-Trainer was the first commercially available simulator for robotic surgery. The first prototype was installed at Indiana University's Department of Urology in February, 2007. It remains the only surgery simulator that meets all five requirements for a *da Vinci* surgical simulator training tool.

Realistic and accurate simulation

dV-Trainer uses a compact hardware platform *(Figure 2)* that closely replicates the experience of the world leading *da Vinci* surgeon console. Its power lies in its virtual-reality robotic simulator platform, which features a binocular three-dimensional visual output. dV-Trainer simulation exercises are built on Mimic's proprietary simulation platform, MSim™ (*Figure 3*). A flexible architecture ensures that new *da Vinci* instruments and techniques can be incorporated. No longer are trainees required to practice procedures on live patients or on less-instructive inanimate objects. dV-Trainer uses realistic simulation of actual surgical tasks to train doctors prior to their participation in the operating room.

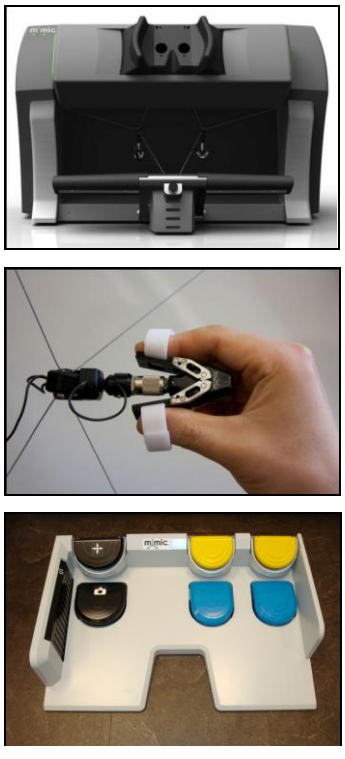

Figure 2

Strong partnership with Intuitive Surgical, the makers of the *da Vinci* robot.

The hardware platform and simulation exercises for Mimic's dV-Trainer were designed closely with Intuitive Surgical to accurately replicate the *da Vinci* surgeon console. This results in unparalleled realism when comparing the simulated exercises to the actual experience of using the *da Vinci* system. Combining the excellence of *da Vinci* and the safety of Mimic's simulation ensures accurate and relevant training scenarios, resulting in better outcomes for patients.

Validated by independent institutions

Independent validation is of the utmost importance to both surgeons and hospital administrators. Multiple, peer-reviewed research studies have validated the dV-Trainer's use as a robotic surgery training tool.[5,6,7,8] The dV-Trainer has demonstrated face, content, construct, and concurrent validity. Recent studies have shown that the dV-Trainer is comparable to dry-lab training on the *da Vinci* robot (concurrent validity), and efforts are underway to assess the predictive validity of the simulator.

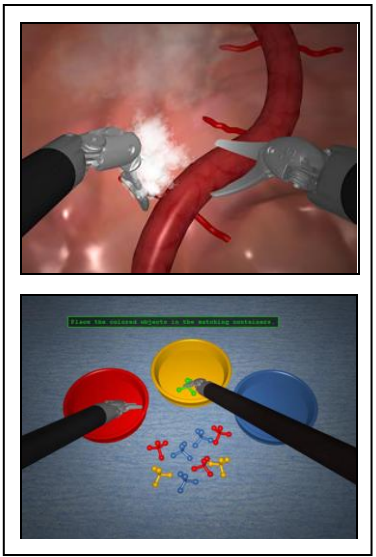

Figure 3

[5] Lendvay T., Casale P., Sweet R., and Peters C. Initial validation of a virtual-reality robotic simulator. *Journal of Robotic Surgery*. 2008 September; 132:242-4.
[6] Lerner M. A., Ayalew M., Peine W. J., and Sundaram C. P. Does training on a virtual reality robotic simulator improve performance on the da Vinci surgical system? J Endourol. 2010 Mar; 24(3): 467-72.
[7] Sethi A., Peine W., Mohammadi Y., and Sundaram C. Validation of a Novel Virtual Reality Robotic Simulator. *Journal of Endourology*, 2009 March; 23(3): 503-8.
[8] Kenney P. A., Wszolek M. F., Gould J. J., Libertino J. A., and Moinzadeh A. Face, content, and construct validity of dV-trainer, a novel virtual reality simulator for robotic surgery. Urology. 2009 June; 73(6): 1288-92.

Benefits of the dV-Trainer

Tangible benefits to all surgical centers can be realized with the dV-Trainer. Training with the dV-Trainer can improve patient safety, provide accelerated physician learning and objective performance assessment, and be cost-effective all at the same time.

Improves patient safety

Additional training for surgeons is essential to ensure patient safety in surgical centers. The dV-Trainer can improve patient safety by providing this critical training in three distinct scenarios:

- The dV-Trainer provides surgeons with extensive training prior to performing *da Vinci*-assisted surgery on patients.
- It allows for re-familiarization with the robotic interface after a period of inactivity with the *da Vinci* system.
- It enables cognitive and motor skills warm-up prior to surgery.

"We are using the dV-Trainer to get surgeons up to speed again after they have gone more than 4 months without a case. It's a great way for surgeons to re-familiarize themselves with the robotic interface."

Dr. John Lenihan
USAF Reserves, Flight Surgeon
Medical Director of Robotics and Minimally Invasive Surgery
MultiCare Health Systems

Provides accelerated physician learning and objective performance assessment

Incorporation of the dV-Trainer in surgical centers has the potential to improve surgeon efficiency and decrease procedure times. The dV-Trainer closely replicates the *da Vinci* system behavior and response, resulting in reliable and safe training. Training on a system so closely resembling the surgical equipment speeds up the surgeon's learning curve and enhances system familiarization.

***MScore*'s Comprehensive Metrics**

- **Time to Completion**
- **Economy of Motion**
- **Instrument Collisions**
- **Number of Drops**
- **Instruments Out of View**
- **Master Workspace Range**
- **Blood Loss**
- **Broken Vessels**
- **Excessive Instrument Force**
- **Misapplied Energy**
- **Overall Score**

Figure 4.

An integrated software package is critical for assessing and documenting surgical skills. Tools for managing user accounts, securing records, and for sorting and exporting performance data allow for individualized reporting for each distinct user. The dV-Trainer provides a comprehensive series of over 40 varied exercises for skills training and system awareness. Training protocols are customizable, enabling educators to create personalized training curricula for different users. *MScore*™, an application for skills assessment, is integrated and gives the surgeon comprehensive metrics to evaluate performance in critical areas (*Figure 4*). Mimic is implementing a new proficiency-based scoring system based on expert data that can be customized by the training institution and serve as a platform for surgeon credentialing.

Accessible and Cost-effective

With the rising cost of healthcare, including the costs of post-operative complications and legal actions against hospitals, institutions using robotic surgical equipment cannot afford to minimize the importance of surgical simulation. The more pre-operative surgical skills training, both basic and advanced, that can be performed using the dV-Trainer, the lower the cost burden of post-operative complications and patient safety breaches. The dV-Trainer can be placed outside the operating room in a simulation center, vastly improving the accessibility of training to residents, fellows, and novice robotic surgeons.

The dV-Trainer can realize cost savings for training over the life of the *da Vinci* system. The cost of the dV-Trainer is a fraction of the overall cost of purchasing a *da Vinci* system. Use of the dV-Trainer does not require access to the *da Vinci* Surgical System, thereby freeing up the *da Vinci* for revenue-generating surgical procedures. It does not require skilled personnel to set up nor assistance from a proctor, as the *da Vinci* system does when used for training. The dV-Trainer allows for simulated training that does not consume costly finite-use instrumentation and materials.

Summary

The dV Trainer is essential preparation for today's robotic surgery. It has a successful track record of collaboration with industry leaders, as shown by its partnership with the world leader in robotic surgical equipment, Intuitive Surgical, to create the dV-Trainer. By closely tying its surgical simulator to Intuitive Surgical's *da Vinci* system, Mimic has the potential to significantly grow the field of robot-assisted surgery by allowing a cost-effective, realistic training solution. The synergistic relationship between Intuitive Surgical and Mimic Technologies enables rapid advances in the field of robot-assisted surgery. Mimic has documented success in validation studies performed by outside institutions, confirming its status as the leader in robotic surgery simulation. Surgical simulation plays a critical role in assuring patient safety and realizing cost savings at centers employing a robotic surgery program — and that role begins with Mimic.

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About Mimic

Mimic Technologies is a pioneer and leader in Robotic Surgery Simulation. Founded in 2001, our passion is to fuse virtual reality and surgical robotics to create revolutionary products and unique services that will profoundly impact people's lives.

Jeff Berkley, Mimic's CEO and founder, began working as a consultant for a surgery simulation company in 1996, where his focus was real-time continuum mechanic based modeling of soft tissue. Jeff saw first-hand how doctors were reluctant to accept virtual surgery as a valid tool for medical training, given the lack of realism that technology provided at that time. Jeff saw an opportunity to build a company that could solve some of the technological challenges necessary to overcome the doctor's objections. With these problems solved, surgical simulation has the potential to revolutionize the healthcare industry.

It was during Jeff's PhD work at University of Washington's Human Interface Technology Laboratory that Jeff founded Mimic Technologies with the primary objective of providing new solutions that enable a truly realistic simulation experience through software and hardware.

Mimic is a privately held company incorporated in the state of Washington. It has been awarded a number of research grants from DARPA and TATRC, and has completed consulting projects for a number of medical device and simulation companies.

How two hospitals are using our technology: The future of robot-assisted surgery

Mimic Technologies and Nicholson Center for Surgical Advancement at Florida Hospital are partnering to provide advanced robotics training to surgeons from all over the world. By leveraging Mimic's advanced virtual reality technology, Mimic and the Nicholson Center will collaborate to create next generation learning tools. Not only will these tools enhance training that will take place at the Nicholson Center, they will eventually allow for remote proctoring through collaborative virtual environments. Through such advances, Mimic and the Nicholson Center will strive to set a new standard for surgeon training with the ultimate goal of improving surgical outcomes and patient safety.

Lead by Dr. Jacques Hubert, the University Hospital of Nancy, France, is conducting regular training courses to teach surgeons from all over Europe to use the *da Vinci* Surgical System. The hospital purchased one dV-Trainer in 2008 and two more in 2009. Dr. Hubert and associates offer a two part course that includes lectures, videos, simulation and *da Vinci* training. In the first phase of the course, surgeons spend three days alternating between lectures and simulation training. On the fourth day, surgeons get their first chance to practice with a *da Vinci* system. The trainees then return two months later for additional training on the dV-Trainer and the *da Vinci*. Trainees have given the course glowing reviews, with many requesting to visit again and pay for additional time on the Mimic simulators.

Appendix: The Frost & Sullivan ROI study for Medical Simulation Training

The Mimic Technologies dV-Trainer provides multiple training benefits to surgeons and hospital systems.

In a well-known and often-cited 2004 study, Frost & Sullivan, in conjunction with the American Hospital Association and Health Research and Education Trust and Immersion Medical, Inc. published a comprehensive Return on Investment Study for Medical simulation training. This ground-breaking study revealed multiple potential benefits for patients, surgeons, and hospitals when medical simulation training is implemented.

Financial Benefits

• **Operating room or procedural time savings** – This benefit is based on the premise that practicing on a simulator improves technique, resulting in faster procedures with fewer errors and offering the opportunity to perform more procedures.

• **Instructor time savings** – There is a financial benefit when less personal instruction is needed, since trainees have learned independently on the simulator.

• **Reduction in errors that cause complications and cancellations** – If learning on simulators rather than live patients results in fewer complications and cancellations, the costs associated with errors will be reduced. Plus, while the cost of a complication may be small, it may be as large as a multi-million-dollar malpractice suit.

• **Financial value of faster time to competence** – Many believe that the faster trainees can achieve proficiency, the more valuable they are to the institutions that employ them.

• **Reduction in equipment repair and spoilage costs** – Learning basic techniques on the training simulator results in reduced repair costs.

• **Reduction in alternative training costs** – These may include cadavers, mannequins, or other models, and animal labs or tissues.

• **Revenues from selling practice time on the simulator** – Institutions may generate revenue through sponsoring training courses or through workshops that incorporate simulator use.

Non-Financial Benefits

• **Recruiting** – One of the unexpected benefits of owning a simulator is the interest shown in them by potential recruits.

• **Evaluating trainees** – The Mimic software provides an objective assessment of trainees for monitoring their progress.

• **Credentialing new hires** – Another benefit identified was the simulator's usefulness in evaluating the skills of potential new-hires.

• **Better quality of care** – One of the top priorities for all hospitals is to provide better quality of care.

• **Trainee satisfaction** – The study found that most trainees were thrilled to be able to develop their skills on a simulator prior to trying their technique on patients.

Benefits to the Patient

Due to the many benefits of minimally invasive procedures, their use continues to rise. Reduced hospital stays have reduced post-procedure pain and enabled shorter recoveries, resulting in reduced costs. And because most such procedures require advanced surgical skills, devices that help teach the necessary techniques are likely to be increasingly valued. Users of simulators report that they value their system's haptics technology for giving them the "feel" of procedures, and believe it contributes directly to a reduction in costs. Simulators provide a safe learning environment, while also offering objective feedback and a wide variety of skills-training exercises.

Some of the expected qualitative benefits include:

• **Shorter operating times**, based on increased opportunity for residents to train on simulators and become proficient. The less time a patient spends in the operating room, the less risk of harmful anesthesia effects and complications and the better chance of reduced recovery time.

• **Fewer complications**, which reduce patient discomfort and lead to:
- Shorter recovery time
- Lower costs for pain medications, infection control, etc.
- Avoidance of emergency surgery to mitigate the complication