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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Telesurgery: Years of experience do not improve ability to manage communication latency. Years of experience in laparoscopy do not transfer to better performance in robotic surgery. Current telecommunication networks are capable of supporting safe robotic telesurgery.

Surgical Rehearsal: System capabilities report on three simulators written and submitted. Subjective user evaluations of three simulators underway. Protocol written for objective skills improvement on simulators. .

Robotic Curriculum: Developed curriculum for robotic surgeon certification. Developed psychomotor testing device. Both will be in validation trials in coming months.

Automatic Surgery: Government recommends not pursuing this experiment.

15. SUBJECT TERMS

Telesurgery, Surgical Rehearsal, Robotic Surgery, Curriculum, Fundamentals of Robotic Surgery

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Introduction

This project is broken into three focus areas: robotic curriculum, telesurgery, and simulation. In each we are exploring various applications and extensions of the existing robotic surgical systems. Under robotic curriculum we are bringing together the leading surgeons and academicians to define the outcomes measures, curriculum, psychomotor devices, and high stakes testing that should be used to certify surgeons who wish to practice robotic surgery. Under telesurgery we are exploring the ability to perform telesurgery using a robot within a metropolitan area based on the currently available technology. Under simulation we are examining the impact of rehearsing a procedure in a simulator immediately before performing that same procedure on a patient. This area also includes a comparative evaluation of all of the robotic simulators that are available with a recommendation of the best fit for military surgeons.

Statement of Work

ORIGINAL STATEMENT OF WORK

There are three primary areas of this research: Telesurgery, Simulation, and Robotic Curriculum. (1) The telesurgery project will identify the characteristics of latency during telesurgery and investigate the application of principles of automatic surgery. (2) Under simulation, we will validate a simulator that can be used by military surgeons to maintain their robotic skills while deployed. We will then use this device to explore the feasibility of surgical rehearsal as a potential solution to the latency issue in telesurgery. (3) We will organize robotic surgery experts to develop a nationally accepted curriculum in the Fundamentals of Robotic Surgery (FRS).

Period 1

Telesurgery: Communications Latency Experiments. Identify communication latency, measure safe latency levels for each robotic movement, modify surgical procedures to be effective in this environment.
Milestone: Telesurgery latency experiment report. Award + 270 days

Simulation: Military-use Validation. Validate a robotic simulator for maintaining the robotic surgery skills of deployed military surgeons.
Milestone: Robotic simulator validation report. Award + 210 days

Robotic Curriculum: Consensus Conferences. Organize and host conferences of approximately 40 leading robotic surgeons from around the United States to include military surgeons. Identify the fundamental knowledge and skills that should be a foundation for every robotic surgeon.
Milestone: FRS consensus conference reports. Award + 180 days and 365 days

Period 2

Telesurgery: Automatic Surgery. Apply movements recorded in a robotic simulator to actual execution with the da Vinci robot on solid models. Explore ability to automatically execute surgery from a simulator recording.
Milestone: Automatic surgery experiment results. Award + 730 days

Simulation: Surgical Rehearsal. Experiment with the effectiveness of simulated surgical rehearsal on improving the outcomes of robotic surgery.
Milestone: Surgical rehearsal experiment results. Award + 540 days

FRS Curriculum Validation and Transition. Develop specific training tasks and passing criteria for the FRS curriculum. Process the curriculum through the certifying bodies.
Milestone: Telesurgery medical procedure results. Award + 730 days

Telesurgery

Communications Latency Experiments.

As of August 30, 2013, 107 subjects have participated in this experiment. We have completed the phase of subject data collection. We are now analyzing the data and publishing results. The data collected in the experiment has shed light on a number of details around robotic surgery. In general we find that the effect of latency on individual surgeons is not predictable by their levels of experience in either robotics or laparoscopy. The majority of subjects, though not all, can manage latency at 200ms and below. Between 300 and 500ms most subjects experience a drop in performance, but many are able to compensate for this effect and complete the exercises successfully. Between 600 and 1000ms most subjects are not able to compensate for the effects of latency and often fail to complete the exercise. Our conclusion is that latency levels below 200ms would be safe for telesurgery.

We have also conducted data transfer experiments between four campuses of the Florida Hospital system located within metropolitan Orlando. Within this controlled network we transferred video data collected during a surgery. This data was able to navigate the network to the destination with an average latency of 5ms or less during each experiment. This indicates that current telecommunications networks have the ability deliver data much faster than is required to support safe telesurgery.

Papers on both of these results have been submitted for presentation at conferences and are being prepared for journal publication.

The most current results of the telesurgery experiment are described in detail in the report on our work which was submitted to USA TATRC in August 2013. The complete report is included in this report in the appendices below.

Automatic Surgery.

In the early phases of this project, the government COR encouraged us to reconsider our efforts to explore automatic surgery. They felt that the robotic and simulator technologies currently available clearly indicated that experiments in this area would be premature because the outcome was expected to be negative. The government felt that the knowledge gained would not justify the funds expended. Our initial investigations into designing this experiment, including extensive discussions with the manufactures of the simulator and the robot, convinced us that the government was correct in this assessment. As a result, we will not be performing this experiment. The funds originally scheduled for this experiment will be reallocated to other experiments.

Simulation: Military-use Validation

We have begun a three part comparative evaluation of the available robotic simulator devices. The first part of this study was an evaluation of the system capabilities of the devices. This work was delivered as a report to USA TATRC in August 2013. The complete report is included in this report in the appendices below.

The second part is a subjective evaluation of all three of the simulators by MD's. This protocol has been approved and the experiment is underway. At this point we have collected survey data from approximately 25 subjects. We expect to collect data for at least an additional 25 before analyzing the data.

The third part of this study is an objective evaluation of the effectiveness of each simulator to improve the skills of a robotic surgeon. This part is in the protocol review process at this time. Once hospital and government IRB's have approved we will measure the amount of time and effort required for a surgeon to become competent. The subjects will return to the experiment every two weeks to measure the degree to which skills are retained and the amount of retraining that is necessary to re-attain competency. This information will assist in the development of a training protocol to maintain robotic competency, such as during the deployment of a robotic surgeon.

Simulation: Surgical Rehearsal

We have received approval from the hospital IRB and IACUC, as well as government HRPO and ACURO to conduct the surgical rehearsal experiment using surgeons and live porcine models. This experiment will compare the effectiveness of traditional classroom training to simulation-based training in preparing for a specific procedure. We have designed the experiment to be carried out in conjunction with existing educational events using animals. This allows us to perform the experiment without sacrificing any additional animals in the conduct of this study.

Robotic Curriculum

We have held four conferences of leading robotic surgeons from around the world. We have identified a list of 25 outcomes measures that robotic surgeons need to be able to demonstrate competence. Three different curriculums have been created – didactic, psychomotor skills, and team training. A multi-skills device for testing many of the outcomes has been designed, physical prototypes have been developed, and we are working on a process to produce larger numbers of the devices.

Presentation materials on the development of the curriculum and the psychomotor device are included in the appendices of this report.

We will conduct a pilot validation study of the curriculum and the psychomotor device in late 2013. A full, 10 site validation study will begin in March 2014.

Key Research Accomplishments

- *Telesurgery: Communications Latency*. Major hospital systems have sufficient telecommunication bandwidth to perform robotic telesurgery right now.
- *Robotic Curriculum: Consensus Conferences.* Online curriculum in robotics has been developed. Psychomotor skills device has been prototyped.
- *Simulation: Surgical Rehearsal.* Experimental protocol has been approved and is ready to begin.

Reportable Outcomes

Reports/Deliverables to Government

Smith. “Robotic Surgery Simulators: a comparative review of the system capabilities of simulators of the da Vinci surgical robot”. Submitted August 2013.

Smith. “Measuring Communication Latency Effects in Robotic Telesurgery”. Submitted August 2013.

Satava, Smith, & Patel. “Fundamentals of Robotic Surgery Consensus Conference 2: Curriculum Development”. Submitted April 2012.

Satava, Smith, & Patel. “Fundamentals of Robotic Surgery Consensus Conference 2: Validation Process”. Submitted April 2012.

Presentations

Truong & Smith. “Fundamentals of Robotic Surgery Psychomotor Skills Prototype Development Video”, *Society for Laparoscopic Surgery Annual Meeting*, August 2013.

Smith. “From FLS to FRS: The Fundamentals of Robotic Surgery are on their way”. *World Robotic Gynecologic Conference*, August 2013.

Advincula & Smith. “Contributions of Laparoscopic Surgical Experience to the Development of Robotic Proficiency”, *Society for Gynecologic Surgery Annual Meeting*, March 2013.

Smith, Chauhan, & Satava. “Fundamentals of Robotic Surgery Consensus: Outcomes Measures and Curriculum Development”, *NextMed: Medicine Meets Virtual Reality Conference*. February 2013.

Smith & Chauhan. “Using Simulators to Measure Communication Latency Effects in Robotic Telesurgery”, *2012 Interservice/Industry Training Education and Simulation (I/ITSEC) Conference*. December 2012.

Satava & Smith. “Fundamentals of Robotic Surgery (FRS): Overview and Results of First Two Consensus Conferences” Society for Laparoscopic Surgeons Annual Meeting, September 2012

Awards

Mireille Truong. Hassan Award for Best Presentation Promoting Education & Training. *Society for Laparoscopic Surgery Annual Meeting*

Mireille Truong. Best Video Presentation Multi-Specialty. *Society for Laparoscopic Surgery Annual Meeting*

Smith & Chauhan. Best Paper Nominee. *Interservice/Industry Training Education and Simulation Conference*

Conclusion

Each of the research areas in this grant is making significant scientific progress and contributions. The knowledge gained from this work is being shared through reports to the government and multiple presentations as both clinical and simulation conferences. We have submitted two papers for journal publication, but have not yet been accepted for publication.

This cooperative agreement was originally scheduled for a two year duration, ending on August 31, 2013. However, we requested and received a no-cost extension of the work for an additional year, to complete on August 31, 2014. We expect to complete the research during that period.

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Appendices

Copies of manuscripts, abstracts, and presentations of work resulting from this grant are included as appendices to this report.

Fundamentals of Robotic Surgery Curriculum

Conducted by:
Minimally Invasive Robotics Association*
Florida Hospital Nicholson Center**

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1 INTRODUCTION TO SURGICAL ROBOTIC SYSTEMS

1.0 Learning Objectives

1. Describe the advantages and limitations of minimally invasive surgery.
2. Describe the advantages and limitations of robotic surgery.
3. Identify the components of robotic systems.
4. Explain the functionality of robotic systems.

1.1 Minimally Invasive Surgery – Advantages and Limitations

1.1.1 Background

A great technological revolution in surgery occurred with the introduction of laparoscopic and other minimally invasive procedures, with enormous benefit to patients. Many randomized trials have demonstrated the benefits of minimally invasive surgery over traditional open surgery. The use of minimally invasive techniques has now penetrated significantly in some specialties, such as general surgery, gynecology, urology and cardiac surgery, and only slightly into other specialties, such as complex gastrointestinal surgery and otolaryngology.

There are several barriers to performing minimally invasive operations that will be explored in the next several subsections. Robotic surgery is a form of minimally invasive surgery that is able to overcome many of those limitations, while remaining minimally invasive. The following are the basic advantages of minimally invasive surgery, with emphasis on the advantages/limitations of minimally invasive approach. There is also an analysis on how the structure and functionality of robotic surgery systems are addressing some of these limitations.

Because minimally invasive access is common to all these systems, a review of the basic principles is necessary in order to establish a baseline reference to understanding the unique capabilities of robotic surgery systems. Since there are more than technical considerations in performing surgery, it is anticipated that all minimally invasive approaches will persist, with laparoscopic, videoscopic, robotic and other systems finding their appropriate best applications.

It is acknowledged that robotic surgery is not the answer for all surgical procedures. Certain preferences of non-robotic approaches have been identified including limited availability of personnel, cost-benefit issues, and impracticality of implementation. But for those surgeons who choose to pursue robotic surgery, the following curriculum will provide a common primer, or generic approach, across all specialties of the most important issues when performing operative procedures with a robotic surgery system. An attempt has been made to include information that could be anticipated to apply to most any tele-operated robotic surgery system. This curriculum is expected to be dynamic, with review and updates as more fundamental knowledge is gained and new systems are developed.

1.1.2 Video Imaging

Traditional video laparoscopes project two dimensional images of the operative field onto video monitors. The current generation of high-definition video monitors provides strikingly clear intra-operative images, frequently better than open surgery. Although, learning on a two-dimensional monitor to interpret monocular cues, such as shading, aerial perspective, relative size and occlusion provides enough visual information to indirectly appreciate depth perception, this requires great concentration and can be very tiring and anxiety provoking for some surgeons. The robotic surgical system does provide full 3-D imaging, however this is performed in a “surgical console” which has some inherent limitations as well, especially the lack of situational awareness of the rest of the operating team.

1.1.3 Motion Reversal ("Fulcrum Effect")

The trocar through which instruments are inserted into the operative site, such as abdomen, chest, etc. acts as a fulcrum causing reversal of the surgeon's hand motions relative to the motion of the tip of the surgical instruments. Moving the handle of a laparoscopic instrument down causes the tip of the instrument to go up, however robotic systems automatically compensate for this reversal with the resulting hand motions being in the "normal" natural direction.

1.1.4 Motion Amplification

The trocar also acts as a lever arm. Generally, the majority of a minimally invasive instrument is inside the patient. As a result of the lever action, hand motions of the surgeon are amplified generating greater excursion arcs of the instrument tips. For example, a one inch displacement of the instrument's handle might cause a three inch displacement of the instruments effector tip, also resulting in tremor of the tip of the instrument. Robotic systems have tremor filtering algorithms (see below) which help minimize such tremors.

1.1.5 Degrees of Freedom (DOF) in Instrument Motion

Using small, straight instruments through tiny ports limits the wide range of motion that is available in open surgery. The surgeon can move the instruments up and down, right and left, in and out and rotate them in each of those axes (pitch, yaw and roll), resulting in the classic "six degrees of freedom" (6DOF). Often the trocars force the instruments to assume a parallel orientation, thus limiting types of motion. The parallel alignment of the instruments make complex motions that are not in the direct axis of the instrument shaft, such as instrument tying, very difficult. In robotic surgery, an articulating 'wrist' provides an additional degree of freedom, thereby providing greater dexterity while maintaining the advantages of minimally invasiveness.

1.1.6 Stability of the Camera and Visualization

Often during minimally invasive operations, a human camera holder stands in uncomfortable positions, becomes tired and permits the camera to wander from the operative field. Moreover, the surgeon lacks direct control of the camera and may need to frequently let go of one of the instruments to manually adjust the camera position. However, the ability of the camera to be positioned very closely to the operative workspace provides a much higher resolution view than in open surgery. One of the disadvantages of this improved view is some instability as mentioned above.   Camera navigation and adjustment of view affect the stability of the camera visualization, though robotic systems have a higher reliability of stability which does come with some disadvantages in changing of positions.

1.1.7 Ergonomics

With open surgery and traditional laparoscopic surgery, the surgeon often stands in poor ergonomic positions. In minimally invasive surgery, unless the monitor is adjusted to the right height and placed directly in the surgeon's line of vision (i.e., a coherent eye, hand, monitor axis), the surgeon often stands in contorted positions increasing strain on his/her neck, back, shoulders and hips. Similarly, if the table is not adjusted to the proper height, the surgeon's arms are forced to assume tiresome positions. Indeed, these unnatural positions result in the surgeon operating mainly with the awkward motions of their elbows and shoulders (instead of the delicate motions of their hands and wrists), which can lead to significant discomfort and in extreme conditions, to orthopedic injuries. Robotic surgery systems have attempted to address these problems by devising an ergonomically designed ‘console’.

1.2 ADVANTAGES OF ROBOTIC SURGICAL SYSTEMS

1.2.1 Information System Components

Robotic surgical systems are computer systems, or information systems, with various sources of data input and output, including:

- Visual input from the monitor
- Auditory input through the speakers
- Haptic (the sense of touch) input through the manipulator handles
- Tele-operation through the remote operating arms and instruments (end effectors)

1.2.2 Information Amplification

The surgeon sits in in control at the console and sends information to the team (verbal commands), or data to the instrument(s) by moving the manipulator handles. Because all the data must go through the computer, the robotic system can amplify this information (data) to enhance the surgeon’s psychomotor skills/performance beyond normal human physical limitations. Examples include:

- The video image can be increased in size to give the surgeon magnified vision
- The use of “false coloring” (infra-red, ultraviolet, etc.) to “see” structures, properties (e.g. heat) and functions (e.g. blood flow) not visible to the human eye
- Hand motion scaling and tremor elimination that provides the surgeon with a precision of less than 100 microns facilitating the performance of minimally invasive surgery by helping overcome some of the inherent limitations of laparoscopic surgery

1.2.3 Three Dimensional Imaging

The image is transmitted through a telescope containing one or two video cameras. Usually, the camera system is stereoscopic, thus it will project a true three dimensional video image using a binocular imaging system much like field binoculars. Viewing the operative field in three dimensions increases the accuracy of depth perception, and may result in increased precision. In addition, three dimensional operative field viewing has proven to be less tiring and generates less anxiety during the operation.

1.2.4 Eliminate Motion Reversal (“Fulcrum Effect”)

The Robotic instrument controllers (master controllers) translate with great precision the motions of the surgeon’s hands to the tip of the surgical instruments. Moving the surgeon’s hand up, for example, moves the surgical instrument up. This returns the natural intuition of hand motion to the surgeon, and greatly simplifies the performance of complex tasks with the surgical instruments.

1.2.5 Favorable Motion Scaling

The surgeon can select specific levels of high definition motion scaling for both the instruments and the visual field. The surgeon might select, for example, a one to one translation of his hand motions to motion of the instrument or a 3 to 1 ratio or a 10 to 1 ratio; likewise the visual field can be increased by 2, 3 or even 10 fold.

1.2.6 Tremor Elimination

The computer interface serves to filter out tremors in the surgeon’s hands making very delicate motions of the robotic instruments possible. The limit of human performance for precision and accuracy by the very best surgeons is approximately 200 microns, however with robotic systems this precision can be improved by 5-10 fold for even the average surgeon.

1.2.7 Increased Degrees of Freedom (DOF) in Instrument Motion

In addition to the standard 6 DOF of non-robotic minimally invasive systems, the incorporation of a wrist like joint at the end of the end-effector permits movement of the instrument tip away from the long axis of the instruments. This added DOF overcomes parallax issues and facilitates complex motions such as dissection, suturing and instrument tying.

1.2.8 Stable Camera Platform

The surgeon moves the camera telescope to the position offering the best visualization of the operative field. The operative field of view remains fixed in place without tremor, rotation or migration while the surgeon manipulates the other surgical instruments to perform the operation. In addition, the surgeon does not have to continually try to instruct the assistant camera-holder exactly where to center the camera, thereby improving efficiency eliminating communication errors to the assistant. This is at the expense of the surgeon momentarily pausing the conduct of the operation to position the camera in the precise desired position.

1.2.9 Ergonomically Improved Surgeon Positioning

Ergonomics is the study of the relationship between workers and their environment. Careful equipment design can improve efficiency, productivity, comfort and safety, while minimizing operator fatigue. Robotic surgery systems allow the surgeon to adjust the console to the ergonomic positions that are most comfortable and to sit during the case. For example on current systems, the binocular visualization system moves up and down to provide a comfortable sitting position. The surgeon rests his/her forearms on a padded rest permitting the forearm, wrists and fingers to move freely while controlling the motions of the instruments in an ergonomically advantageous position.

1.2.10 Redundancy

Redundancy is an advanced safety mechanism offered by surgical robotic systems. There are multiple sensing mechanisms and high precision actuators suitable for surgical use to insure that if one component malfunctions, there are other backup components to continue the operation safely.

1.2.11 Fault Tolerance

Fault tolerance is an advanced safety mechanism offered by surgical robotic systems. The system recognizes errors and alerts the surgeon, allowing the operator to correct the error or to terminate the procedure before an error or patient injury could occur. Future systems will be providing even more sophisticated alerts and aids.

1.2.12 Graceful Degradation

Graceful degradation is an advanced safety mechanism offered by surgical robotic systems.
If a malfunction occurs, the component or the system doesn't totally fail instantly; rather a slow step-wise shutting down of the system occurs. For example, an error in one robotic arm does not shut down the whole system; it merely slowly and safely degrades system performance by slowly shutting down the one arm.

1.3 COMPONENTS OF ROBOTIC SYSTEMS

1.3.1 Overview

A typical robotic surgical system consists of the following elements:

- The surgeon’s console
- The remote manipulator arms
- The visualization support system
- Accessories and their controls, cables and connectors

1.3.2 Surgeon’s Console

One or more surgeon consoles control the surgical instruments at the operative field by using master manipulators while viewing a monitor presenting the operating environment. The surgeon console also integrates controls to configure the whole system and the ability to communicate with the rest of the operating team. Foot pedals and hand switches are available for system mode changes such as camera control or instrument operation.

1.3.3 Remote Manipulator Arms

A set of patient-side manipulators designed to pivot about the entry ports hold a variety of removable dexterous or flexible surgical instruments. These manipulators may be attached to passive articulating arms allowing their optimal positioning over the patient’s body. A wide range of instruments for cutting, suturing, application of energy, and other needs can be attached and replaced during the procedure as required for the surgery.

1.3.4 Monitor Interface (Including Alerts/Errors)

The input to the surgeon's monitor is generated by a stereo-endoscopic vision system that includes the camera, electronics, and a separate monitor for the operating team and assistants. Operating data can be presented and superimposed on the visual field of the operating surgeon and secondary displays allowing the surgical team to simultaneously view additional surgery specific information improving situation awareness. Alerts can also be superimposed on the visual field and important events can generate audio alarms making error detection easier. On screen annotations facilitate specific visual instructions such as indicating the planes of dissection or identification of target anatomy.

1.3.5 Secondary Consoles

Secondary consoles allow for training, assistance, remote surgery, and surgeon collaboration. These consoles allow control of the instruments and performance of the procedure if delegated by the primary surgeon. A system mode change permits the control of surgical instruments to be transferred between consoles.

1.3.6 Master-Slave Relationship

Current robotic systems translate surgeon commands into actions. They are not autonomous and are unable to perform any function without the input of the operator.

In the normal operating mode, the surgical instruments reproduce the surgeon’s hand motions at a configurable scale. For example, the system could be configured to operate at a “fine” scale where 5 mm of master motion produces 1mm of slave motion. The instruments maintain the same hand orientation regardless of motion scaling.

The camera is operated separately and differently from the remaining instruments. A mode switch disconnects the instruments (they will not move until there is a return to normal operation) and connects the camera to the surgeon’s motions permitting change in camera position, orientation, and zoom. For example, moving both hands in/out will move the camera out/in, respectively (zoom).

The system will not operate if the surgeon-robotic arm relationship is disrupted by overpowering the controls.

1.3.7 Instruments (End-Effectors) and Accessories

Unlike some minimally invasive instruments, robotic instruments allow for wristed motion at the instrument tip. This unique instrument design permits 7 DOF and 90 degrees of articulation. The wrist-like movement provides enhanced dexterity, precision and control for the surgeon. A wide range of instruments exist to enable a broad range of procedures in multiple specialties. The instruments are continuously being updated.

1.3.8 Energy Sources

There are a variety of thermal/energy sources to provide coagulation, cutting and dissection of tissues. The energy sources available for robotic systems include monopolar shears/paddles/hooks, bipolar graspers, ultrasonic shears, etc. Each of these has their own activation process.

1.3.9 Real-Time Information Enhancements

Because the robotic system is a computer-controlled information system, an extraordinary potential exists for access, integration and implementation of all forms of information and data to be displayed on the monitor in real time. This includes full situational awareness of the current status of the patient (real-time vital signs, alerts, etc.), archived data from medical record (both text and images), simulation (including pre-operative warm-up exercises, pre-operative planning and surgical rehearsal), and image-guided surgery (with overlays of various pre-operative images such as CT scan, MRI scan, ultrasound, PET and others).

1.3.10 Robotic Simulation

In addition, the design, mechanism, and visualization of the robotic system can all be simulated. This affords the opportunity of less expensive training platforms and self-directed practice and surgical rehearsal. Simulation training can be performed with reality-based (RB) and virtual reality-based (VR) curricula. Dry lab (RB) training is critical for robot set-up, docking, patient positioning, understanding differences in suture material/size, and recognizing grasp effects of instruments on tissue phantoms. VR platforms exist to accelerate learning curves for instrument manipulation, clutching, camera movements, thermal cautery devices, knot-tying, warm-up, and some procedure-specific rehearsal. Evidence suggests that novices and experienced robotic surgeons derive a technical skills performance boost after simulation warm-up prior to actual surgical performance; thus, imbedding such a protocol before robotic surgery may be beneficial.

1.4 SYSTEM FUNCTIONALITY

1.4.1 Adjusting the Robotic Console Settings

The surgeon's console provides a wide range of configurable options. Options may include:

- Console ergonomics
- Camera type
- Motion scaling
- Haptic feedback
- Digital zoom
- Control of any secondary consoles
- Control of energy and other devices

- Communications control

A secure sign-on procedure may be available to automatically recall your configurable settings. This may be done via a menu in the console touch screen, at the secondary display, or may require operation of controls on the console.

1.4.2 Ergonomics (for the Surgeon at the Console)

Prior to operating the instruments, it is essential to establish an operating workspace that permits free hand movement, comfortable body posture, and optimal visualization. Secondary hand and/or feet controls may permit reconfiguration of the surgeon's workspace to avoid collisions with console hardware, or with each other. It is important that these controls are easily accessible and in positions where they are not accidentally activated.

An essential component to maintaining appropriate ergonomics is recognizing fatigue symptoms such as eye fatigue, or body part discomfort and taking immediate steps to alleviate it.

1.4.3 Operating Master Controllers

The master controllers allow control of the instruments and the endoscope. Surgeons obtain control of the instruments by grasping these controllers using their thumb and index finger, only while their vision is engaged in the operating field (i.e. by having their forehead inside the view panel).

An inherent property of robotic systems is that when handling errors occur, an alarm or message can be displayed and control of the system may be temporarily suspended until the error is resolved. For example, the system will not operate if the masters-slave relationship is disrupted by overpowering the controls. Applying too much pressure on the controllers will generate an error and temporary locking of the instrument. If this happens releasing the pressure and trying to move them gently again will usually fix the problem.

To operate the camera, instrument control must be paused while the field of view is being adjusted. For example camera control is activated through a switching mechanism (i.e. a foot pedal, hand switch, or voice command). Camera focus is also adjustable.

1.4.4 Indexing/Clutching

Due to the motion scaling capability of a robotic system and changes in the field of view, operator hand controls may need to be periodically repositioned to the optimal operating position. Clutching is used when the master controllers reach their limits of movement (collide with the console walls or with each other), or the surgeon operating position becomes uncomfortable. During this adjustment the master controls move independently from the instruments while maintaining instrument orientation.

1.4.5 Visualization Capabilities

In addition to providing a stable camera platform and navigation, robotic systems may integrate advanced capabilities for visualization. This includes imaging beyond visual spectrum (i.e. near infrared), non-visual imaging (i.e. ultrasound), and integration of pre-operative imaging. For example, the 3D high-definition endoscopes are available in multiple sizes (12 mm and 8.5 mm diameters), different angular views (0, and 30 degree up and down), different angel of view (wide-angle 60-degree field of view) and digital zooming (current system provides 5 levels of zoom). Visualization systems typically have to be white balanced and calibrated for stereo visualization (stereopsis or 3D view) prior to the procedure using the appropriate calibration equipment (i.e. calibration block).

1.4.6 Motion Scaling

The robotic system has the capability of increasing (or decreasing) the distance the tip of an instrument moves relative to the distance the hand controller moves, which is referred to as motion scaling. This permits translation of large hand motions by the surgeon into small motions by the instrument. For example, a 3:1 scale factor translates 3 cm of movement at the master controllers to 1 cm of movement at the instrument tip.

1.4.7 Collision Avoidance

Because of the fulcrum nature of minimally invasive surgery instruments, they may collide both inside and outside the patient body, and operator hand controls may collide with each other on the console. Collisions can be reduced by optimal trocar placement and robotic arm positioning at the beginning of the procedure.

If a collision is encountered adjustments may need to be made at the bedside by repositioning of the arm manipulators. Similarly, clutching of the master controllers will mitigate surgeon hand collisions.

1.4.8 Arm Switching

Current Robotic systems may contain more than two arms, but given that the surgeon can only control two of them at the same time a mechanism exists to exchange control between arms. For example, to swap arm control between the active and inactive arms, the console surgeon must activate the swapping switch. When such swapping occurs the master controllers must first assume the orientation of the new instrument before any motion is permitted. This ability also permits the use of inactive arms for retraction, a stable camera platform, or other assistance.

1.4.9 System Operations

System operations begin with setting up the robot. The different components of the system have to be connected to ensure functionality. This is followed by customization and configuration of the operating interfaces (initialization and preferences).

In order to maintain sterility, disposable sterile barriers are required to cover the parts of the system that are within the operating field. Typically, the console that controls the instruments is outside the sterile field; thus, the surgeon does not have immediate access to the bedside.

Both the surgeon and the bedside assistant have the ability to disable all robotic system motion using stop buttons in the event of an emergency.

1.5 ASSESSMENT OF INTRODUCTION

A multiple choice test will be delivered based upon the above content to insure understanding and retention of materials.

2 DIDACTIC INSTRUCTIONS FOR ROBOTIC SURGERY SYSTEMS

2.0 Learning Objectives

1. Preoperative
    a. Summarize the necessary steps to conduct a safe, successful robotic operation in a timely manner.
    b. Identify critical errors and the ways to minimize the possibility of errors that may arise at subsequent steps of an operation.
2. Intraoperative
    a. Summarize psychomotor and the team-training and communication skills that must be accomplished to a benchmark of proficiency without critical error.
    b. Describe intraoperative steps to insure safety for the patient and the assistant.
    c. Review alert recognition, identification of source and correction of errors.
3. Postoperative
    a. Describe the safe removal all instruments/supplies while checking that there are no intra-operative patient injuries.
    b. Recognize methods to safely undock the robot and transfer the patient.

2.1 Overview

The material in this section, Didactic Instructions for Robotic Surgery Systems, is an introduction to the elements of the robotic surgical system and provides an overview of the cognitive, psychomotor and the team-training and communication skills that are necessary to conduct safe and successful robotic procedures. This represents the cognitive skills (knowledge base, judgment and decision making) required in each of the three phases of performing surgery: Pre-operative, intra-operative and post-operative.

While this section covers the basic operational elements of a typical robotic surgical system, it does not contain enough technical and engineering details to serve as a replacement for the specific manufacturer's user's guide and operations manual.

2.2 Pre-Operative Phase

The pre-operative phase begins when the team prepares the operating room (OR) for the patient to be transferred in and ends when the surgeon sits at the robotic console. It includes all three skills (cognitive, psychomotor and team-training and communication), however a significant portion of the skills are the team-training and communication skills.

2.2.1 Identifying the Components of the Robotic Console and Arms

Current robotic systems include the following parts:

- The Surgeon's Console
- The Remote manipulator arms
- The visualization support system
- Accessories and their controls and cables and connectors

The surgeon should identify these components of the system and ensure that connections are correct, robotic and accessory controls are accessible, and that the operating room is configured for safe operation. A walk-around is recommended prior to the procedure to confirm that all components are connected and cables are not likely to be disconnected by accident or become a safety hazard to the operating team.

2.2.2 Setting Up the Robotic System

Setting up the robotic system involves configuring components so that they will have the workspace required for the operation and anticipate the accurate positioning of the robot relative to the patient for safe and optimal positioning and use of the robot. Operational requirements are dependent on the particular case, surgeon, discipline and preferences.

The set up specifically requires:

a. Proper positioning of the robotic manipulators relative to the patient (or patient surrogate, such as animal, cadaver, phantom or skills station.
b. Calibration of the camera, patient side manipulators and the master manipulators.
c. Configuration of patient arms according to the requirements of the procedure.
d. Selection of other surgeon preferences on any additional console.

Upon configuration, the appropriate checklist must be completed.

2.2.3 Turning On and Calibrating the Robot

The primary surgeon must ensure that all components of the robotic system are powered on. A power-on initialization and self-check is typically performed automatically, but the initialization and self-check must be verified by the surgeon and other members of the team.

The calibration process must be performed and verified, including the checklist, prior to positioning the robot arms. The power-on sequences should be completed with no accessories installed on the patient side manipulators. The purpose of this step is to identify any possible calibration failure which might render the robot inoperative for surgery and which would require maintenance, repair and recertification before using the robot for a planned procedure. To prevent conversion during a procedure, should a failure occur, it is advisable to schedule system maintenance instead of attempting power-off/recalibration steps during a procedure.

A robotic surgical system will recognize and interactively guide the user for certain errors, but not all possible errors. Failed calibration and disconnected cables are detected and an audio alarm and message is displayed. If accessories remain installed on the robot for repeated training sessions, then a re-calibration step should be performed and manually monitored and assessed.

After system configuration, the appropriate checklist item must be completed.

2.2.3.1 ERRORS

The following generic errors will need to be specified for each particular robotic system:

Turning on and calibrating the robot

- Failure of power to turn on
- Failure to initialize and calibrate the system
- Failure to appropriately connect the system components (including cables) to ensure functionality
- Failure to recognize and address system error notifications

Checklist of the settings on the robot console

- Failure to set or verify the appropriate console settings
- Failure to use the checklist (check and respond)
- Ignoring or failing to recognize error messages
- Failure to recognize and address system error notifications

2.2.4 Positioning of Components (Console, Cart, Arms, Etc.)

The various components of the robotic system must be positioned in a way that prevents collisions with other equipment or the patient. For example, the extended arms of a cart-based manipulator may interfere with or break floor or ceiling mounted equipment. Care must be taken to orient the arms in the recommended stowing position prior to moving the cart base. Practice and familiarization is needed to safely operate the cart around patients.

Positioning of the cart depends upon the surgical procedure and surgical preference. The visualization system must be positioned where the assistants/operating team can safely view and interact with it.

The console should be positioned safely outside the sterile field such that the surgeon is able to view the operative field without having to step away from the console.

2.2.4.1 ERRORS

Accurate attention to the positioning of the equipment is critical:

- Incorrect positioning of equipment, patient bed, or OR staff that leads to preventable collisions
- Incorrect positioning of the console so there is not an adequate view of the operative field by the surgeon
- Failure to orient the robotic arms in the recommended stowing position prior to moving the cart base

2.2.5 Setting up the parameter thresholds and limits on the Robot Console (Check & Respond)

The robot console includes ergonomic positioning of (but not limited to) the following:

☐ Height of 3D viewer
☐ Viewing configuration such that the surgeon sees a focused 3D view
☐ Location/configuration of seating
☐ Location/reconfiguration of foot controls where appropriate
☐ Location/reconfiguration of accessory controls
☐ Location/reconfiguration of hand controls
☐ Location/reconfiguration of communication systems (speaker and microphone volumes)
☐ Motion scaling configuration for master-slave tele-operation
☐ Camera configuration/selection

Upon completion of moving and configuring the system components, verbal communication in the form of a robotic-specific checklist should be completed, using repeat and call back methodology. (More detailed checklists will be provided in the Team Training and Communication Skills module.)

2.2.5.1 ERRORS*:*

- Failure to set or verify the appropriate console settings
- Failure to use the checklist

2.2.6 Draping of Robot

Sterile draping of the robotic arms should occur before the start of the case. Attention should be given to avoid contamination of the draped arms while they are not being used. Drapes and sterile protections should not interfere with arm motions. Upon draping completion system sterility should be verified (i.e. No holes in drapes).

2.2.6.1 ERRORS:

- Contaminating sterile drapes or operative field
- Improper drape position that interferes with instruments or camera (e.g., docking and instrument exchanges, etc.)
- Inadequate sterile prepping the operative site

2.2.7 Patient Transfer Into Operating Room

The usual process for patient transfer to the OR is adequate for robotic procedures. To ensure the safety of the patient and surgical team members, the following basic steps should be implemented during the transfer process:

- ☐ Clear the path for the stretcher.
- ☐ Place the stretcher adjacent to the OR table and lock the wheels of the stretcher.
- ☐ Have adequate personnel to ensure a safe transfer.
- ☐ Explain the transfer procedure for the conscious patient.
- ☐ For the nonmobile patient, a patient transfer device, such as a roller should be used.
- ☐ For the nonmobile patient, the anesthesia provider should be responsible for protecting the head, neck and airway of the patient during transfer.
- ☐ The patient is moved to the center of the OR table with smooth and even movements.
- ☐ Safety straps are placed across the legs with a slight gap to assure it is not too tight.
- ☐ Confirm bony areas of patient’s body are well padded.
- ☐ Confirm that IV lines, indwelling catheters, drains, and monitoring system lines are secure and not entangled.

2.2.7.1 ERRORS

- Poor coordination and communication
- Not locking the wheels of the table or the stretcher
- Improperly positioning and securing the patient on the OR table

2.2.8 Positioning of the Patient and OR Table

Poor patient positioning may lead to poor exposure or patient movement during the procedure that may compromise patient safety. For example, upper abdominal procedures typically require reverse Trendelenburg position and pelvic procedures Trendelenburg position for good exposure during surgery. The surgeon must learn to use gravity to maximize exposure while preventing patient sliding on the operating table. A safe approach to prevent patient sliding/moving during surgery includes securing the patient well on the OR table and testing for patient sliding/movement during table manipulations prior to draping the patient and docking the robot. This may identify the need for additional patient securing or the limits of position manipulations.

Patient draping should follow standard sterile processes and is specific to the operation being performed. Inadequate prepping may lead to contaminations of the operating field especially if draping must be manipulated during the procedure. This can be prevented with wide prepping.

It is crucial that the OR table should not be adjusted during surgery while the robotic arms are engaged in the patient. Inadvertent movement of the OR table during surgery could potentially be prevented if it is locked or its power turned off (unplugged). If the table nevertheless is inadvertently moved, the surgeon must examine the external operative field to verify no injuries have occurred. Given that position changes cannot be made during the procedure when the robot is docked, surgeons need to have adequate planning of how they will obtain exposure in the absence of position changes.

2.2.8.1 ERRORS

Accurate attention to the positioning of the patient and OR table is critical:

- Incorrect positioning of patient resulting in patient movement during the procedure
- Moving the operating table (purposefully or inadvertently) after docking
- Inadequate sterile draping with exposed surfaces

2.2.9 OR Team Members and Their Positioning

The operating room team consists of the surgeon, scrub nurse, circulating nurse, surgical technician, surgical assistant(s) and anesthesia personnel. Each team member is vital for successful outcomes in robotic surgery. Each member must be knowledgeable in robotic surgery and understand the importance of communication and teamwork.

All members of the team, including the surgeon, should become very familiar with the setup, basic operation and troubleshooting the robotic system. In addition, the circulating nurse and surgical technician are critical for routine and advanced operations of the robot, and the surgical assistant should have an understanding the basics of minimally invasive surgery.

Although room configurations can vary significantly, the operating room should be able to accommodate all of the robotic components so there is a direct view of the patient from the surgeon. The operating room personnel must be able to comfortably perform their duties and have a clear path to move freely around the room if necessary to ensure patient safety. One possible configuration of the OR team set up is captured in the accompanying image.

2.2.9.1 ERRORS

- Positioning of OR team does not take into consideration potential problems that may occur during surgery.
- All members of OR team are not familiar with the setup, basic operation and troubleshooting the robotic system.
- Paths are not clear for personnel to move freely about the room.

2.2.10 Anesthesia administration

The surgeon should communicate with the anesthesia team at the beginning and during the case to ensure adequate paralysis of the patient throughout the procedure to avoid patient movement and resulting injury by the robotic arms. In addition, to prevent delays in the extubation of the patient, the surgeon should notify the anesthesia team in a timely manner about the anticipated procedure changes during the procedure or the anticipated completion.

2.2.10.1 ERRORS

- Surgeon does not communicate with the anesthesia team at the beginning and during the case.

- Surgeon does not notify the anesthesia team about procedure completion.

2.2.11 Patient Identification (Time Out)

The patient should be wearing an identifying marker and be identified more than once prior to the performance of a surgical procedure. First, the patient undergoing a surgical procedure must be properly identified by the surgical team members prior to transporting the patient to the surgery department. The patient should have at least two corroborating patient identifiers as evidence to confirm identity. Then, prior to the start of every robotic procedure a time out of the surgical team is taken to re-verify the identity of the patient. This time out should occur with the patient positioned, draped, and anesthetized on the OR table, and just before the skin incision of the surgical procedure is made as a final verbal confirmation of the correct patient, correct procedure to be performed and correct surgery site.

2.2.11.1 ERRORS

- Wrong patient
- Wrong site surgery

2.3 INTRA-OPERATIVE PHASE

The intra-operative phase begins with the preparation of the operative site (incision, trocar, etc.) and then focuses on the specific psychomotor skills that the surgeon must learn to be technically proficient in the use of the specific robotic system. This phase ends when the skills have been completed and the surgeon has powered down the robotic console.

2.3.1 Trocar Placement

Trocar positioning is specific to the procedure and robotic system. Trocar insertion technique is dependent on surgeon preferences. The type of access technique and the familiarity of the surgeon with this technique are critical. In general all access techniques (open and closed) can be performed safely by surgeons experienced with them. Of course, the common principle of all techniques is to avoid injuries during trocar insertion.

Surgeons should have an appropriate plan for where they will place their trocars to be able to accomplish their procedure safely. Common errors such as placing the trocars too close to each other (i.e. <10cm apart for abdominal surgery, although this may does not apply to single site surgery, and distances for other types of surgery will vary) is likely to lead to collisions of the robotic arms during the procedure and compromise its feasibility and safety. In addition, appropriate trocar placement in relation to the target anatomy is important. Distances that are too short or too long can be problematic.

When insufflation is performed in the currently available systems, robotic trocars need to be inserted until the thick black line can be visualized at the level of the internal surface of the cavity or space (i.e. the peritoneum in abdominal procedures, or the pleura in chest procedures, etc.). If this is not the case injuries to the port site can occur.

Surgeons need to check for appropriate position of the trocars prior to docking the robot, especially if part of the case up to the use of the robot was done with a non-robotic minimally invasive approach (e.g., laparoscopically or thoracoscopically).

2.3.1.1 ERRORS

Several errors can occur during trocar placement and vary with the cavity being entered. The following generic errors are identified:

- Injury to a major organ or vascular injury
- Inability to undock quickly enough in an emergency to achieve open access to operative site
- Not visualizing the tip of the trocar during insertion
- Not checking the port site and operative site for bleeding, injury, etc. after insertion
- Not checking the port site for proper level of trocar insertion
- Trocars placed too close together resulting in robotic arm collisions or making reaching operative site difficult (this may not be the case in single site surgery)
- Not checking for the appropriate position of the trocars prior to docking robotic arms

2.3.2 Orientation of the Surgical Cart to the Patient

The orientation of the surgical cart (robot) to the patient is dictated by the target compartment. Some examples of cart positioning include:

- Pelvis – position the cart at the feet, between the legs, or side-docked
- Flanks – position the cart alongside of patient
- Upper abdomen – position the cart over the shoulder
- Chest – position the cart alongside the chest
- Oral cavity -- position the cart alongside the shoulder
- Axilla -- position the cart over the shoulder

2.3.2.1 ERRORS

- Positioning of the surgical cart for the target compartment that limits maneuverability during surgery
- Positioning of the surgical cart that results in impingement of the arm on patent when operating
- Positioning of the surgical cart that interferes with the actions of the first assistant

2.3.3 Docking of Robot Cart and Arms

The robotic working arms are typically positioned on either side of the camera arm. The robotic arms can be docked in varying sequences to ensure minimizing likelihood of arm collisions.

- Docking can proceed from the right or left side first and go in sequence across the camera port and lastly to one or two other working ports on the opposite side
- Camera port first
- Camera port last (alternate)

Once the arms are all docked, attention must be taken to separate the elbows of the working arms from the camera arm to avoid arm collisions. To avoid bruising on the skin, each port should be manipulated (burped) to slightly evert the skin as opposed to depressing the skin into the patient. This also increases the distance of the trocars to the target anatomy which is especially important for the camera port in small spaces.

2.3.3.1 ERRORS:

- Insufficient separation of working arms from camera resulting in arm collisions
- Injury (bruising, etc.) to the patient

2.3.4 Instrument Insertion

When inserting the instruments, the instrument end effectors should be straightened before insertion to avoid puncture of trocar seals. The following is an example of a current robotic surgery system.

First engage the tip of the instrument into the diaphragm of the trocar seal, and then seat the housing of the instrument against the sterile adapter above the sterile adapter tracks. The instrument is then slid down into the sterile adapter tracks until the four spindles engage the instrument.

If the insertion is the first one of the case, the clutch button will need to be depressed to slide the instrument in and position the arm. If the insertion is a tool change, the clutch button does not need to be depressed to insert the new tool to the existing position (guided tool change). The instrument tip will be 2-3 mm proximal to the tip position of the previous instrument tip as a result of this software safety mechanism.

Instruments should be inserted under direct vision and guidance. In the absence of this safety measure collisions of the instruments with tissue can occur that may lead to preventable injuries. To avoid this risk it is advisable to unzoom the camera during instrument exchanges to widen the view field (the majority of the time it is not easy to visualize the internal tip of the robotic trocars during surgery). In addition, instrument insertion should occur slowly to have time to react if the instrument is not visualized as anticipated.

Importantly, a safety mechanism exists in that during instrument exchange the robotic system remembers the instrument position and will allow for the new instrument to go back to the location of the removed instrument. This mechanism is canceled if the robotic arm is clutched during the exchange; the OR team should therefore know to avoid clutching the arms during instrument exchanges. If clutching must be performed, then even more attention needs to be given to instrument insertion.

2.3.4.1 ERRORS:

- Clutching the arms during instrument exchanges (this deactivates the safety mechanism that the robotic system uses to remember the instrument position and allow for the new instrument to go back to the exact location of the removed instrument)
- Clutching the robotic arm during instrument exchange without monitoring the new instrument tip during reinsertion
- Instrument not completely inserted through trocar so its wrist is not visible past the cannula and it is not ready for surgical control (this is done by the assistant, not the console surgeon)
- Not maintaining view of instrument during its insertion
- Collision of instrument with tissue upon insertion
- Overpowering the master controls preventing master/slave alignment and instrument activation
- Attempting to remove the instruments when they are still attached to tissue or crossing inside the patient
- Surgeon or bedside assistants do not communicate clearly requests for instrument exchange, suture insertion, energy activation etc.

2.3.5 Final Review of Set Up

The surgeon must perform a final review of robot arms and instrument/trocar positions to ensure all connections are correct, that the position of the patient is correct and the patient is not impinged by the robotic arms. Should there be an incorrect position of an arm or trocar, the surgeon should remove the instrument before repositioning the arm and reinserting the instrument. When this review is complete, the surgeon may safely go to the console.

2.3.5.1 ERRORS

The surgeon does not perform the final review to detect the following errors:

- Patient positioning not verified
- Incorrect position of robot arms
- Incorrect position of instrument/trocar
- The arm or trocar position is changed without removing the instrument

2.3.6 Surgeon Transition to Console

The surgical procedure is conducted from the console, with assistance at the patient side. To insure the safest, most efficient and comfortable surgery (least stressful for the surgeon), there are four fundamental principles to follow:

- Establish the ergonomics of the console
- Set up the visual field and operative field
- Activate the instruments
- Prevent injury to patients

2.3.6.1 ERRORS

The four fundamental principles are not followed.

- Ergonomics of the console are not established
- Visual and operative fields are not set up properly
- Instruments are not activated properly
- Avoidable patient injuries occur

2.3.7 Establish Ergonomics of the Console

Prior to operating the robot, surgeon ergonomic positioning should be established for the duration of the procedure (please refer also to the ergonomics section in the introduction). Appropriate ergonomics are important to minimize surgeon fatigue during the procedure which may jeopardize patient safety and/or to avoid chronic musculoskeletal injuries.

Ergonomic settings can usually be established manually or recalled from stored system memory. For example, in existing systems surgeons have the ability to place the viewer, level of hand rest, and foot controls in a comfortable position and configure the 3D stereo vision.

The initial set up begins when the surgeon puts his/her head in the surgeon's console, hands on the master controls (input device handles) and configures the viewer and hand/foot controls in a comfortable position.

2.3.7.1 ERRORS

The surgeon does not establish appropriate ergonomic settings.

- Not adjusting level of hand rest
- Not adjusting position of foot controls

- Not adjusting height of seat to allow for inserting face on the forehead rest without stretching or bending over

2.3.8 Set Up Visual Field and Operative Field

After the surgeon has established an ergonomically comfortable field, he/she should proceed with setting up the visual and operating field. The visual field determines how much of the operative field is visualized and is determined by multiple factors such as the type of the videoscope (0, 30, 45 or 90 degree), magnification of the scope, focus, the distance from the center of the operative field, etc. The field must be adjusted so there is no obstruction of the surgeon's view by the various icons located along the periphery.

To set up the visual field, the surgeon must activate the visualization system and obtain the appropriate field of view for the respective procedure. The focus and level of zoom can be adjusted as needed. To increase safety, the surgeon should strive to maintain the widest field of view possible for the task performed, and to keep the operating instruments mainly in the center of the visual field that contains the organs/structures upon which he/she is operating. Frequent readjustments of the view field may be necessary during a procedure. Caution must be observed to insure that instruments (initially and during instrument changes) are not inserted outside the field of view, which could result in undetected injury to vital structures.

2.3.8.1 ERRORS

- The surgeon does not set up the visual field so it is not obstructed by icons
- Instruments are inserted outside of the surgeon's view

2.3.9 Activate Instruments

To activate the robotic instruments the surgeon must place his/her head inside the forehead rest of the console.

Next the surgeon must place his/her fingers inside the controllers and gently move them to obtain control of the instruments. Applying too much pressure on the controllers will generate an error and temporary locking of the instrument. If this happens releasing the pressure and trying to move them gently again will usually fix the problem. It is also important to understand that if the forehead sensor is activated and the surgeon takes his/her fingers off the controllers after they have activated the instruments, the instruments could move uncontrollably, potentially leading to an injury. This should be avoided.

2.3.9.1 ERRORS

- Applying too much pressure on the controllers that generates a temporary locking of the instrument
- Taking fingers off the controllers after activating instruments that results in uncontrollable movement

2.3.10 Prevention of Injury to the Patient or Assistant

Specific procedures must be followed (see manufacturer protocol) to enhance safety and prevent patient injury when positioning the robot to the patient, docking the instrument manipulators, and installing/exchanging instruments. The bedside assistant must ensure that all the arms are free of collision with the patient. It may be difficult to visually appreciate whether the arms are pressing on the anatomy under the drapes; for example the legs (for pelvic surgery), the head or chest (for over the shoulder positioning – upper abdominal surgery), or patient arms on arm boards/at side (for flank surgery). The bedside assistant may need to verify positioning of the robot by sweeping the open space between the robot arm and patient with his/her hands by enabling manual motion of the instrument manipulators (clutching) and moving them to the steepest and shallowest positions.

During surgery, each inserted instrument must be visually monitored (manually by the assistant for first insertion or by the surgeon for exchanges) with the camera to its operating position. While some systems may provide assistive modes for instrument exchanges, these are only aids and do not excuse visual monitoring of instrument insertion.

It is also critical to ensure the safety of the surgical assistant. This is done by monitoring the assistant through frequent communication between the surgeon and assistant and establishing a safe working space for the bedside assistant when placing assistant ports. The surgeon must make sure that the console speaker is on so that the assistant can hear intentions of the console surgeon and make sure room noise is minimized so that the console surgeon can hear the bedside assistant.

The bedside assistant should avoid/minimize placing hands/arms in between two moving arms to prevent pinching or crushing. Especially for shorter bedside assistants, care must be taken to avoid positioning of their head near robot arms.

2.3.10.1 ERRORS

Safety must be observed for both the patient and the bedside surgical assistant.

- Failure to insure that all the arms are free of collision with the patient
- Failure to monitor the instrument insertion into the patient
- Failure to establish a safe working space for the bedside assistant when placing assistant ports
- Not turning on the console speaker so that the assistant can hear intentions of the console surgeon
- The surgeon and assistant not using call-back (repeating instructions) before conducting a specific action (instrument change, repositioning, etc)
- Not insisting that room noise is minimized so that the console surgeon can hear the bedside assistant.
- Bedside assistant places hands/arms/head in between two moving arms

2.4 POST-OPERATIVE PHASE

The post-operative phase begins with completion of the last step of the procedure (or task performed in basic skills) and ends when the patient is exiting the room and the final checklist is completed.

2.4.1 Checklist

At the end of each procedure and removal of the instruments, the surgeon must ensure that all foreign bodies and specimens have been removed from the patient and no undetected injuries have occurred. In order to accomplish this, it is important to re-inspect the operating field before finally removing the camera and all areas outside the operating field where an injury to tissues could have occurred (i.e. near trocar insertion sites). A checklist that verifies that foreign bodies introduced in the operative field have been removed and/or identification of specimens with a chain of custody have been removed and a check for injuries has been performed is essential. Failure to complete this step may lead to adverse patient outcomes and constitutes a critical error.

2.4.1.1 ERRORS:

- Not performing the checklist
- Retained foreign body or specimen
- Not communicating with call back all information about the specimen and verifying a chain of custody of the specimen removed by the first assistant (by name) to the circulating nurse (by name) and repeating the name of the specimen to the surgeon for confirmation.
- Unrecognized patient injury

2.4.2 Safe Removal of All Instruments, Supplies, Trocars

All instruments, supplies, and trocars used in a procedure should be removed carefully. In addition, they should be inspected to verify that no damage occurred to the instrument during the procedure that could have resulted in foreign body retention in the patient. Instrument, sponge, etc. counts should be verified correct by call-back between surgeon an circulating/scrub nurse

Dropping of instruments or equipment during removal can lead to patient/staff injury or damage the system. It may also lead to costly repairs (i.e. dropping and breaking the camera).

2.4.2.1 ERRORS:

- Attempting to remove instruments when they are still attached on tissue or crossing inside the patient
- Undocking the ports before the instruments are removed
- Clutching the robotic arm before instruments are removed, which could cause advancing the instruments towards the patient during removal
- Dropping instruments or other equipment during removal
- Discarding camera mount while removing drapes (mount is reusable)
- Not conducting the preliminary instrument, sponge, etc. count

2.4.3 Undocking the Robot and Turning Off the Console

Prior to undocking, final communication check is performed to insure that all instruments have been removed from the patient. Prior to instrument removal all instruments need to be free of patient tissues (see the previous section).

During undocking of the robot, the OR table position must be maintained and patient repositioning avoided. Moving the OR table before undocking constitutes a significant error that can lead to patient injury and should be avoided at all cost. When moving the robot away, care should be paid to avoiding collisions with the patient or damage of the robot by colliding with other OR equipment. The path the robot will follow during undocking must be cleared from obstruction by other equipment. Particular attention should also be given to the robotic cables and cords so they are not damaged during repositioning of the robot (i.e. robot cart running over cables).

The following is the process to undock the arms:

- First, safely remove the instruments
- Release the locking mechanism

- Disconnect the arms from the trocars
- Elevate the arms away from the trocars
- Move the robotic cart away from the patient making sure to clear its path (avoid arm collision with patient or other equipment)
- Turn off the power to the robotic console

2.4.3.1 ERRORS

Errors can occur to either the patient or to the equipment.

- Moving the OR table before robot is undocked
- Patient injury by the robot due to repositioning of the patient before undocking
- Collision with the patient or other OR equipment
- Not turning the robot off before attempting to move the patient from OR table to the gurney
- The robot cart running over cables and crushing them
- Damaging the table or gurney when repositioning the OR table

2.4.4 Closing Incisions

After the robotic cart has been removed from the patient, the OR table is usually brought back to its neutral position for incision closure. Incision closure for robotic surgery should be similar to standard recommendations for any incision closure, including specific approaches to closing small port incisions. Generally, fascial incisions related to ports >10 cm should be approximated with suture. For smaller incisions ≤ 5 mm, fascial closure may not be needed as the risk of port site hernia is very low. Inspection of the port sites as the patients wakes up and coughs may provide evidence of incomplete fascial closure with a distinct bulge under the closure.

It is good practice to inspect the non-camera trocar sites with the internal camera view during and after trocar removal. This will allow recognition of bleeding from a potential inadvertent injury of an abdominal wall vessel by the trocar. If this check is not performed unrecognized bleeding may continue and require reoperation or blood transfusion.

2.4.4.1 ERRORS:

- Failure to inspect the trocar sites with internal camera view after trocar removal
- Failure to recognize bleeding from a potential inadvertent injury of an abdominal wall vessel by the trocar

2.4.5 Transfer Patient From the OR Table to the Gurney

Upon reversal of anesthesia, patients may move erratically without balance. Assistants should monitor the patient on the OR table until the gurney is beside the bed. Standardized safe transfer practices must be followed. Safe transfer may involve a roller board or slide board placed underneath the patient to utilize low friction transfer to the gurney.

2.4.5.1 ERRORS:

- Table rails or table not lowered for the patient transfer
- Patient injury during transfer from the OR table to the gurney

2.4.6 Transport to Recovery Room

Standard safe practices for transport must be followed. A member of the primary surgical team must accompany the patient to the recovery room to facilitate adequate handoff of the patient to the recovery nursing staff.

Any drains should be double checked for security because of the recent moves from the OR table and the awakening of the patient.

2.4.6.1 ERRORS

- Safe transport protocol not followed
- Patient's condition not verified
- Staff not identified/directed to accompany patient to the recovery room
- Drains, catheters, etc. not checked for security

2.4.7 Final Post-Operative Check List Before Patient Leaves The Room

Before taking the patient from the room, the final post-operative checklist must be performed (see Team Training and Communication section)

2.4.7.1 ERRORS:

- The final post-operative checklist is not performed before the patient leaves the room

2.5 ASSESSMENT OF DIDACTIC INSTRUCTIONS

A multiple choice test will be delivered based upon the above content to insure understanding and retention of materials.

3 PSYCHOMOTOR SKILLS CURRICULUM

3.0 Learning Objectives

1. Familiarize oneself with the task trainer model and tasks to be performed
2. Task 1: Docking and Instrument Insertion
    a. Demonstrate safe docking of the robotic arms and insertion of the instruments through the ports into the ‘abdomen’ box.
    b. Bring the instrument tips into the operative field of view without error.
3. Task 2: Ring Tower Transfer
    a. Show effective navigation of the camera and use the camera clutch.
    b. Maneuver the instruments such that the potential of wristed instrumentation is utilized maximally for precise instrument tip positioning.
4. Task 3: Knot Tying
    a. Demonstrate the skills necessary to successfully place a suture.
    b. Demonstrate the skills necessary to successfully tie a square knot.
5. Task 4: Railroad Track
    a. Precisely control the needle and suture using the robot.
6. Task 5: 4th Arm Cutting
    a. Safely and effectively switch back and forth between the second and the fourth arm of the robot.
7. Task 6: Cloverleaf Dissection
    a. Safely and precisely perform fine dissection without damaging the surrounding or the underlying structures.
8. Task 7: Vessel Energy Dissection
    a. Identify and choose the unipolar and bipolar pedals correctly.
    b. Apply energy to precisely and safely seal and divide vessels.

3.1 Background and General Principles

The psychomotor skills curriculum is designed to train and assess the proficiency of surgeons interested in performing robotic surgery. The curriculum will ensure that only the surgeons who are skilled and well trained in the basic skills of robotic surgery can perform such complex procedures, making the patient the ultimate benefactor.

The psychomotor skills curriculum was developed through multiple consensus conferences, which brought together subject matter experts from multiple surgical societies, surgical educational societies, surgical boards and other governing organizations who agreed upon the critical skills, tasks, and most common errors that needed to be included in a comprehensive basic curriculum. The result was a table that defined the skills/tasks/errors, the desired outcome measures, and the metrics that should be measured. The measures that were deemed the most important by the subject matter experts were incorporated into the curriculum including the metrics for each skill/task/error and assessment tools. Twenty-six outcome measures were consolidated into the seven tasks that are described in this section. All the seven tasks will be completed as part of this curriculum and can be performed either on simulators, or physical models with the real robot.

3.2 Physical Model

The physical model is a trainer box (‘abdomen’) with a dome positioned inside. The dome has an outer diameter of 24 cms and is covered by a disposable artificial “skin”. The training box has 4 ports attached, including a camera port and three ports for the instruments. The ports are 9 cm from each other.

3.3 General Scoring Guidelines for Tasks

Depth Perception/Spatial Orientation/Accuracy

1	2	3	4	5
Constantly overshoots target, slow to correct		Some overshooting but quick to correct		Accurately directs the instruments to target

Force/Tissue Handling

1	2	3	4	5
Breaks model, ring, or suture; damages needle		Moves or bends wire; minor trauma to model or needle, frays suture		Handles model, suture, and/or needle well; traction is appropriate

Dexterity

1	2	3	4	5
Poor coordination of hands; repetitively drops ring or band; inappropriately drops needle or poor suture management		Suboptimal interaction between hands, any drops of ring or band. Suboptimal suture or needle management.		Expertly uses both hands; always transfers rings or bands without dropping. Optimal needle or suture management.

Efficiency

1	2	3	4	5
Uncertain movements with little progress		Slow, but movements seem reasonably organized		Confident, fluid progression, adjusts quickly

Scoring guidelines are adapted from Siddiqui et al. for the Robotics Training Network. Validity and reliability of R-OSATS: a novel assessment tool for robotic surgical training. Presented at the 2013 CREOG and APGO Annual Meeting, Phoenix, AZ.

3.4 Task 1: Docking and Instrument Insertion

3.4.1 Description of Tasks to Be Performed

Description

Proper docking and instrument insertion is crucial to any robotic surgery. This task trains safe docking and instrument insertion techniques to bring the instrument tips into the operative field of view without error.

Tasks

1. Dock the robotic camera arm to the camera trocar.
2. Dock other arms to instrument trocar.
3. Insert the video-scope into the camera trocar and secure the cable behind the arm.
4. Insert the long needle drivers in the two trocars of arms #1 and #2 and monopolar scissors in the trocar on the 4th arm.
5. Visualize the instruments as they emerge from the tip of the trocar

6. Confirm that all 3 instruments are in the field of view such that the entire dome and all instruments are completely visualized.

3.4.2 Skills Assessed, Metrics, and Errors

Skills Assessed

- Primary Skills Assessed:
    - Docking
    - Instrument insertion
    - Safety of operative field
- Secondary Skills Assessed:
    - Eye-hand instrument coordination

Measurements and Metrics

- Total time (minutes/seconds) until all three instruments are in view
- Accurate final position of trocars, instruments and robot arms
- Pathway (Optional)

Potential Errors

- Collision of an instrument or camera with the dome
- Camera arm not in the "sweet" spot (full visual field of the dome and test objects)
- Failure to secure the camera cable behind the camera arm
- Inserting instruments/camera into the wrong ports
- Non-visualization of an instrument tip during insertion into box *(critical/fatal error)*
- Instrument tips not in view after insertion
- Instrument-instrument collision following insertion of the instruments
- Failure to press the clutch (memory) button in the end of the setup

3.5 Task 2: Ring Tower Transfer

3.5.1 Description of Tasks to Be Performed

Description

Learning to navigate the camera and the surgical instruments using a robotic system is both completely different from open surgery (and laparoscopic surgery), but also designed to be totally natural and mimicking the same motions that are used in open surgery (but opposite those motions of laparoscopic surgery). This task trains camera navigation, effective use of the camera clutch, and wristed instrument maneuvering for precise instrument tip positioning.

Tasks

1. Pick up and remove the ring from the middle tower with one hand without touching the "S" wire.
2. Transfer the ring to opposite hand in mid-air.
3. Place the ring on the side tower without touching the "S" wire.

3.5.2 Skills Assessed, Metrics, and Errors

Skills Assessed

- Primary:

    - Eye hand instrument coordination
    - Camera navigation
    - Clutching
    - Atraumatic handling
    - Precise instrument tip positioning
- Secondary:
    - Wrist articulation
    - Ambidexterity

Measurements and Metrics

- Total time to transfer rings from middle to side towers (seconds)
- Total time for instrument-wire collisions (seconds).
- Instrument-instrument collisions (number of times)
- Number of ring drops

Potential Errors

- Dropping the ring
- Losing the ring *(critical/fatal error)*
- Breaking the ring *(critical/fatal error)*
- Breaking the wire *(critical/fatal error)*
- Failing to transfer hands
- Instrument-instrument collision
- Instrument-wire collision
- Popping off the wire/tower *(critical/fatal error)*

3.6 Task 3: Knot Tying

3.6.1 Description of Tasks to Be Performed

Description

Many complex surgical procedures require knot tying. In robotic surgery the surgeon must rely on the visual cues and experience to handle the suture carefully to avoid suture breakage and tissue tearing. This task trains successful suture placement and square knot tying.

Tasks

1. Tie a surgeon's knot to approximate the two eyelets such that they touch each other.
2. Back up the knot with two more throws (total 3 knots).

3.6.2 Skills Assessed, Metrics, and Errors

Skills Assessed

- Primary:
    - Needle and suture handling
    - Knot tying
- Secondary:
    - Wrist articulation
    - Eye hand instrument coordination
    - Ambidexterity

Measurements and Metrics

- Time to complete the knots (under tension)
- Approximation of the eyelets
- Security of the knot

Potential Errors

- Islets do not touch each other
- Air knot *(critical/fatal error)*
- Knot slippage or insecure knot *(critical/fatal error)*
- Suture breakage
- Instrument-instrument collision.
- Knocking off contacts with instrument *(critical/fatal error)*

3.7 Task 4: Railroad Track

3.7.1 Description of Tasks to Be Performed

Description

Precision is one of the major advantages of the robot, and is particularly important in needle holding and suturing. This task trains precise needle control and suturing during robotic surgery.

Tasks

1. Perform horizontal mattress suturing through the target points to approximate the tissue
2. Tie a knot at the completion of the suturing

3.7.2 Skills Assessed, Metrics, and Errors

Skills Assessed

- Primary:
    - Needle holding and manipulation
    - Wrist articulation
    - Atraumatic tissue handling
- Secondary:
    - Eye hand instrument coordination
    - Suture handling

Measurements and Metrics

- Time to complete closure of incision and tie knot (seconds)
- Complete wound approximation
- Precision of needle placement onto dots along the incision (mm distance from center of dot)
- Amount of eversion (mm)
- Wound tension (no gap of wound edges)
- Secure knot at completion of suturing (no slipping)

Potential Errors

- Wound separation (mm)
- Excessive eversion (mm)
- Tearing of tissue (mm of tears)

- Inaccurate targeting (mm from dots)
- Inaccurate suture technique (number of needle placements that are not in a mattress suture pattern)
- Suture breakage (number of times)
- Needle breakage *(critical/fatal error)*

3.8 Task 5: Fourth Arm Cutting

3.8.1 Description of Tasks to Be Performed

Description

In robotic surgery, the presence of the fourth arm allows the surgeon to have direct control of both the camera and an additional arm. However, controlling four arms (with only two hands) poses some challenges. This requires hand and foot coordination to activate one instrument while inactivating another with possible concurrent camera repositioning. This task trains the switching back and forth between a primary instrument and the 4th arm in a coordinated fashion.

Tasks

1. Pick up the vein with one hand and use the other hand to provide retraction.
2. Switch to the 4th arm and use the monopolar scissors to cut the vein transversely at the hash mark.
3. Switch back to the retracting instrument and readjust to provide adequate retraction.
4. Repeat switching to 4th arm, cutting and retraction till the entire vein' is cut at all the hash marks.

3.8.2 Skills Assessed, Metrics, and Errors

Skills Assessed

- Primary:
    - Multiple arm control
    - Cutting
- Secondary:
    - Atraumatic handling
    - Eye hand coordination

Measurements and Metrics

- Time to cut all three hash marks (seconds)
- Accuracy of cutting on hash marks (mm distance from center of hash mark)
- Retraction (adequate exposure of vein)
- Stretching of the vein (adequate tension on vein)

Potential Errors

- Inadequate tension of the vein (vein sags loosely)
- Tearing of vein
- Failure to switch arm
- Cut is not completely on the hash mark
- Dropping the vein
- Instrument – instrument collision

3.9 Task 6: Cloverleaf Dissection

3.9.1 Description of Tasks to Be Performed

Description

Fine dissection and tissue plane separation are important surgical skills. However injury to surrounding structures or tissue tearing can have serious clinical implications. This task trains for precise fine dissection such that the skin is incised on the marked lines while not injuring or tearing the underlying tissue.

Tasks

1. Cut the cloverleaf pattern between the lines without incising the underlying tissue or cutting outside of the lines.

3.9.2 Skills Assessed, Metrics, and Errors

Skills Assessed

- Primary:
    - Dissection
    - Cutting
    - Atraumatic tissue handling
    - Sharp and blunt dissection
- Secondary:
    - Eye hand coordination
    - Wrist articulation

Measurements and Metrics

- Time to completely dissect the cloverleaf (sec)
- Accuracy of remaining within the lines (mm)
- Tissue handling

Potential Errors

- Tearing of tissue
- Cutting outside the lines
- Incision of underlying tissue
- Instrument-instrument collision

3.10 Task 7: Vessel Energy Dissection

3.10.1 Description of Tasks to Be Performed

Description

In robotic electrocoagulation, activation is accomplished by the use of the foot pedals. Thus in robotic surgery if the incorrect pedal is pressed during electrocoagulation of a vessel, serious hemorrhage could occur. It is important to use the correct pedals. This task trains for the correct use of the pedals for electrocoagulation and accurately cutting between the sealed points.

Tasks

1. Incision and retraction of the flap upwards with the 4th arm
2. Dissection through the fat to expose the pulsating vessel
3. Seal the vessel using Maryland bipolar at the solid hash marks
4. Cut the vessel at the dotted hash mark

3.10.2 Skills Assessed, Metrics, and Errors

Skills Assessed

- Primary:
    - Accurate activation and use of energy sources (electrocoagulation)
    - Dissection of vessels and tissues
    - Cutting and coagulation of vessels
    - Multiple arm control
- Secondary:
    - Atraumatic handling
    - Eye hand instrument coordination

Measurements and Metrics

- Time to complete dissection, vessel sealing and vessel cutting (sec)
- Accuracy (mm)
- Quality of vessel seal (leaking)
- Blood loss (cc)

Potential Errors

- Injury to vessel (vessel leaks fluid)
- Tearing the flap
- Instrument-instrument collision
- Cutting/Energy applied outside the marks (or vessel leaking)

3.4 Take Psychomotor Test

Task 1 Score:

Task 2 Score:

Task 3 Score:

Task 4 Score:

Task 5 Score:

Task 6 Score:

Task 7 Score:

4 TEAM TRAINING & COMMUNICATION SKILLS

4.0 Learning Objectives

Introduction

1. Describe the unique demands of robotic surgery on team communication skills.
2. Discuss the four essential domains within the TeamSTEPPS® including communication, situational awareness, mutual support, and leadership.

Pre-operative

1. List the elements of the modified pre-operative WHO Safe Surgery Checklist.
2. List the elements of the Robotic Docking Checklist.

Intraoperative

1. Describe the challenges and benefits of the surgeons constrained field of view at the console.
2. List the elements of the Intraoperative Checklist.

Postoperative

1. Discuss the tendencies and risks of the OR staff 'letting its guard down' near the end of a surgical procedure.
2. Describe the need for a timeout before closing.
3. List the elements of the Undocking Checklist.
4. List the elements of the Debriefing Checklist.

4.1 Team Development and Communication Skills Overview

There are unique demands of robotic surgery, so team development and communication skills are essential to ensure patient safety and successful robotic surgery. Institutions committed to robotic surgery must help develop and train all members of robotic surgical team(s) to optimize team development, communication, and proficiency. The basic principles and elements of team training that will be articulated in the remainder of this program include:

- Team alignment with common objectives (shared mental model)
    - Surgeon acknowledges the need for each team member's role and limitations
    - Emphasize situation awareness limitations inherent in robotic surgery
- Inclusion of all members of the team
    - Enhanced importance of every team member's role
    - Be the eyes and ears of the surgeon
- Empowerment to speak up and act
    - Surgeon must rely on team member recognition of procedural flow and danger
    - Anyone can say "stop" if there is a perceived problem
- Shared ownership and responsibility
    - Encourage open multidirectional communication
    - Shared vigilance
    - Surgeon/team reliance on each other
- Person specific directives which clearly articulate to whom communications are addressed, which equipment/instrument is to be addressed, etc.
    - Reduced visual cues
    - Require more descriptive and detailed instructions
- Task management and completion

    - Confirm completion of task
- Reiterative/'Just in time' – immediate acknowledgement and response
    - Front load and repeat key steps of the procedure
    - Reiterative instructions and responses to acknowledge exactly what the activity is to be performed (call out)
    - Periodic team realignment
- Risk management/quality improvement- closed loop communications and post debriefing to improve the team functioning
    - Overview (big picture) of the entire process
    - Opportunities to improve
    - Robot-specific and general debriefing

There has been an enormous investment in developing team training curricula and checklists. The WHO checklist will be leveraged and expanded with robotic specific, team building checklists. Since goals are intentionally generic in order to allow for cross-specialty use, they should incorporate established team training procedures like TeamSTEPPS®, or other similar programs. The curriculum must be flexible to allow for procedure/specialty specific variance.

Although there may be other methods or options in developing curriculum for team training, communication and other non-technical skills, the following sections detail the critical issues in the framework of TeamSTEPPS®.

4.2 Degradation of Situation Awareness

The use of a robotic system imposes unique demands upon the robotic surgeon well beyond those of even the laparoscopic surgeon. In no other surgical arena is the surgeon so isolated from not only the patient but also the entire operative team (scrub nurse, circulating nurse, first surgical assistant/instrument technician, and anesthesia team). The almost 'blinded view' the robotic surgeon has of both the operative team members and the operative site requires the robotic surgeon to rely heavily upon clear and unambiguous communication with team members.

Current robotic surgery systems use telemanipulation, image guided and/or stereotactic surgical techniques which require the use of a surgical console. This requires intense focus on the monitor(s) of the workstation, resulting in increased attention on the very limited view of the operative field and a sacrifice of attention to the rest of the operating team and global view of the patient. Because each member of the operative robotic team is separated in space with siloed tasks there is a tendency for the entire team to develop a dangerous myopic view of the procedure and a decrease in situational awareness of the personnel and activities around the patient. With this degradation in situational awareness there is a concomitant and potentially dangerous increased risk to patient safety.

The solution is to improve communication among team members with particular focus on the communication between the surgeon at the console and the first assistant at the patient's side. The surgeon who is controlling the robotic arms is unable to see the assistant, and therefore must have very clear communication in order to avoid injury to the assistant who is in the immediate vicinity of the robotic arms.

4.3 Background on TeamSTEPPS®

Other industries, such as the nuclear industry and aviation, have developed rigorous communication protocols among the team members (e.g., crew resource management in aviation), which include:

1. Unambiguous requests or queries (*call-outs)*
2. Confirmation by the receiving person of the communication (*cross-check*)
3. Confirmation of the completion of the task (*check-back*)

In addition, a culture of safety must be developed by empowering all members of the team and requiring each member to be responsible for safety (*situational awareness and mutual support*). Finally, the team must recognize that leadership is the bond that brings all of these tools together to improve patient safety.

This process of developing leadership and communication skills as well as changing the team culture to empower all healthcare providers to speak-up and embrace their role in patient safety has been formalized by Department of Defense (DoD) and the Agency for Healthcare Policy and Research (AHRQ) in the TeamSTEPPS® (*Team Strategies and Tools to Enhance Performance and Patient Safety*) methodology. This approach is being adopted widely across the healthcare continuum. (Accessed 15 Nov, 2012 from the ARHQ webpage http://www.ahrq.gov/teamsteppstools/instructor/introduction.htm). It is beyond the scope of this educational program to addressing the full breadth of the TeamSTEPPS® comprehensive training system for simulation-based skills education, however, the essential parts of the curriculum will be emphasized regarding teamwork and communication. Specifically, competencies around the four essential domains within TeamSTEPPS® including communication, situational awareness, mutual support, and leadership will be described.

4.4 Communication

The hallmark of safe, clear, and concise requests and demands in the surgical arena, particularly where healthcare teams might be visually separate from each other is the process of closed loop communication. Effective communication must be:

- Complete – Convey all relevant information
- Clear – Convey information that is plainly understood minimizing any acronyms
- Brief – Convey information in a concise, organized, and prioritized manner
- Timely – Offering and requesting information in an appropriate timeframe, verifying authenticity, and validating and acknowledging information requested

Practicing and 'demanding' four simple temporally connected communication skills can significantly improve and model essential closed loop communication. These skills are:

- Requests
- Call-outs
- Cross-checks
- Check-backs

Robotic surgeons and healthcare teams should be trained in the importance of these skills and specific behaviors that improve their effectiveness.

4.4.1 Communication: Requests

Making a request during a procedure, at first glance, appears to be a simple task. There are, however, three essential components to effective and safe requests in most types of surgery:

- Making eye contact with the person to whom the request is directed
- Pointing at this same individual
- Announcing the individual's name

During Robotic surgery the first two components are not possible. This makes the performance of the last component absolutely crucial. Tracking the names of the healthcare team, particularly as team member rotate in and out of the room during a robotic procedure is essential. At times this practice may seem difficult and distracting, but it must be employed by the robotic surgeon.

4.4.2 Communication: Call-Outs

Call-outs have some similarities and some differences to the *requests* previously described. A call-out is a tactic used to communicate critical information during an emerging event. Call-outs often involve the transfer of unrequested information, whereas requests involve expected information or behaviors. Call-outs inform all team members simultaneously during emergent situations, help team members anticipate next steps, and often direct responsibility to a specific individual for carrying out a task. Frequently, to be effective, a call-out must be directed to a specific individual not just the team in general. Change of room personnel is an important time when a call-out should be used. Other times that a call might be used are when a team member notices a robotic tool is not appropriately mounted, a significant change in the patient's vital signs or status, or those times when vital equipment might not be available.

4.4.3 Communication: Cross-Checks

A cross-check is the part of closed-loop communication when the person to whom a request is made must repeat back the request in exact form. This is particularly true when a drug dose is involved. Without a cross-check of a request, the robotic surgeon has no confirmation that their request has been heard, heard accurately, and will be carried out. A unique cross-check is when a robotic surgeon repeats back the name(s) of operating room personnel that have rotated into the room, thereby affirming that he/she knows there are new personnel to whom requests must be made. Ultimately, any person making a request has the responsibility to make sure that a cross-check is completed.

4.4.4 Communication: Check-Backs

A check-back is a closed-loop communication strategy used to verify and validate that a requested task has been completed. An example of such a check-back would be the anesthesiologist announcing that the antibiotics have been completed. In many instances a check-back might be even more critical when a request has not been completed, thereby necessitating the robotic surgeon to reassign or reprioritize/re-sequence a task.

4.5 Situational Awareness

Competency around situational awareness/cross monitoring, a key domain of the teamwork process, is essential and intimately linked to competencies in the other three teamwork domains. The sharing each team member's situational awareness leads to the development of a 'shared mental model' of the patient, available resources, potential problems and a clear understanding of the procedure at hand. A shared mental model is a mental picture or 'sketch' of the relevant facts and relationships central to the procedure such that all members of the operative team are working on and from the same page.

Situational awareness results from cross monitoring, the process of actively scanning and assessing elements of the environment, the procedure and the functioning of the members of the team by each of the team members. Cross monitoring must be a continuous process because of the dynamic, ever-changing environment in which the surgical teams works. When performed correctly, cross monitoring allows other team members to anticipate needs and responsibilities of the team and allows for the sharing of new and emerging information. The process hinges on the willingness and ability of all the team members to share information. The success of developing a shared mental model through situational awareness and cross monitoring is largely dependent upon the leader's modeling and demanding good communication skills, fostering mutual respect of all team members, expecting team accountability, and encouraging team members to 'watch each other's back'. The willingness of every team member to speak up particularly when they are unsure of where the procedure is going, or are concerned about the patient's safety is the hallmark of situational awareness.

TeamSTEPPS® tools that facilitate the development of situational awareness and a shared mental model are described below and include a:

- Brief
- Huddle
- Debrief
- SBAR

4.5.1 Situational Awareness: Brief

A brief is a *short* session prior to start of a procedure to discuss the team composition, assign essential roles, establish expectation, discuss potential problems, and anticipate outcomes and likely contingencies. Particular attention might be paid to staff and provider availability and the potential for switching out during the case, workload among the team members, and issues around available resources. For robotic procedures a brief must be held prior to the patient being brought into the room.

4.5.2 Situational Awareness: Huddle

A huddle is characterized as ad hoc team meeting, frequently around a single patient and often prompted by a rapidly changing patient condition. The purpose of a huddle is to re-establish situational awareness, reinforce plans already in place and assess the need to change plans. Huddles are often even shorter than briefs. Huddles can be called by any member of the team, and in the case of a robotic procedure would not necessarily mandate the surgeon moving away from the robotic console.

4.5.3 Situational Awareness: Debrief

A debrief, also known as an after action review, is an informal, but critical information exchange session designed to improve team performance and effectiveness. An important aspect of a debrief is to elicit an assessment of the teams overall situational awareness of routine and critical issues that occurred during the procedure. Topics that should be explored include:

- Was communication clear and concise?
- Were the roles and responsibilities of each team member understood?
- Was the workload distribution equitable?
- Were errors made or avoided?
- Were there resources issues that surfaced?

4.5.4 Situational Awareness: SBAR

One of the best tools for quickly raising situational awareness is the SBAR. SBAR stands for:

- **S**ituation – What is the immediate issue that is driving the need for the patient procedure?
- **B**ackground – What are the salient clinical background pieces or context that immediately impacts on the patient and the procedure which is being performed?

- **A**ssessment – Unambiguously identifies the problem that is being addressed
- **R**ecommendation – Indicates accurately the immediate recommendations that will move this patient's care forward

SBAR is a technique that most frequently is used for communicating critical information that requires immediate attention and action concerning a patient's condition. However, SBAR is also a very useful tool for organizing care around a procedure, brief, debrief, huddle, and handoff of care.

4.6 Mutual Support

The third domain of team work and team communication is mutual support. Mutual support is the essence of teamwork. It is epitomized by the willingness of each member of the healthcare team to speak up at any moment throughout the procedure. The importance of mutual support is modeled by way the team leader promotes this activity. No single member of the team holds the corner on situational awareness or has answers to all of the issues that might arise during a procedure. Thus patient safety is significantly improved if all members of the team feel an obligation to speak up. In addition, through mutual support, team members foster a climate in which it is expected that assistance will be actively offered and sought as a method for facilitating the procedure as well as reducing the occurrence of error.

The willingness to undertake conflict resolution is a clear indication that mutual support between healthcare workers has matured for the team. Immediate and effective conflict resolution, particularly around information transfer or decision making can have immediate impact on patient safety. Two simple tools exist for resolving conflict during procedures will be described in the following sections:

- CUS
- Two-Challenge Rule

4.6.1 Mutual Support: CUS

CUS is a tool that is simply defined as:

- **C** - "I am concerned."
- **U** - "I am uncomfortable."
- **S** - "This is a safety issue."

CUS is a tool that can be used at times of conflict around diagnoses or decisions as to how procedures should continue. CUS is a simple awareness and call-to-action tool if patient safety is at risk.

4.6.2 Mutual Support: Two-Challenge Rule

The two-challenge rule states that it is a team member's responsibility to assertively voice concern (CUS) at least two times to ensure it has been heard. The team member being challenged, whether it is the robotic surgeon, scrub nurse, anesthesiologist, or other team member must acknowledge the challenge. If the outcome is still not acceptable, then the team member making the challenge is mandated to take a stronger course of action (i.e. utilize a supervisor or chain of command). Mutual support allows the healthcare team to come to mutually satisfying solutions, enhance patient safety and allow for the highest quality patient care without compromising relationships.

4.7 Leadership

The final domain of teamwork and team communication is leadership. Effective leaders organize the team, articulate clear procedural goals and make decisions through collective input of all of the healthcare team members. One of the most important characteristics of a team leader is the ability to empower all members of the team, regardless of 'power gradients', seniority, or hierarchy to speak up and challenge when appropriate.

Team leaders are able to prioritize and assign tasks, maintain situational awareness and reassign tasks when appropriate, model mutual support, ensure team planning through the effective use of briefs and huddles, and facilitate conflict resolution by encouraging CUS and two-challenge tools.

4.8 Team Communication in the Pre-Operative Phase

4.8.1 Overview

For the purpose of 'surgical' or 'procedural' communication skills, the pre-operative period is defined specifically as from the moment the patient enters the operating room until the surgeon sits down at the console to begin operating. Trocars (or retractors) are inserted as part of the pre-operative procedure (see also the Psychomotor Skills and Tasks section). The team is charged with accurately completing the general (WHO) and robot-specific checklists that are described in the following sections.

4.8.2 Pre-Operative Checklist (WHO Checklist)

As previously indicated, there have been decades of research, development and validation in team training curricula and checklists to help address surgical safety. The World Health Organization (WHO) has undertaken a global surgical safety initiative, which is called the WHO Safe Surgery Checklist. The checklist identifies important phases of an operation, each corresponding to a specific period in the normal flow of work that the surgery team has to complete before proceeding with the operation. The WHO Safe Surgery Checklist is used as the basis for the following preoperative checklists for robotic surgery.

4.8.2.1 General

☐ Has the patient confirmed his/her identity, site, procedure and consent?
☐ Is the surgical site marked?
☐ Are the anesthesia machine and medication checks complete?
☐ Does the patient have a known allergy?
☐ Does the patient have a difficult airway/aspiration risk?
☐ Does the patient have a risk of >500ml blood loss (7ml/kg in children)?
☐ Have all team members introduced themselves by name and role?
☐ Have the Surgeon, Anesthetist and Registered Practitioner verbally confirmed the patient's name?
☐ Have the Surgeon, Anesthetist and Registered Practitioner verbally confirmed the procedure, site and position that are planned?

4.8.2.2 Anticipated critical events: Anticipated critical events: Surgeon

☐ How much blood loss is anticipated?
☐ Are there are specific equipment requirements or special investigations?
☐ Are there any critical or unexpected steps about which the team should be informed?
☐ Has VTE prophylaxis been undertaken (if applicable)?
☐ Is essential imaging displayed (if applicable)?

4.8.2.3 Anticipated critical events: Anticipated critical events: Anesthesia team

☐ Are there any patient specific concerns?

☐ What is the patient's ASA grade?
☐ What monitoring equipment and other specific levels of support are required? (e.g. blood)

4.8.2.4 Anticipated critical events: Nurse/Operating Department Practitioners (ODP)

☐ Has the sterility of the instrumentation been confirmed (including indicator results)?
☐ Are there equipment issues or concerns?
☐ Are back-up instruments available?
☐ Is an emergency tray available?
☐ Are cables in appropriate position?

4.8.2.5 Has the surgical site infection (SSI) bundle been undertaken (if applicable)?

☐ Has antibiotic prophylaxis been given within the last 60 minutes?
☐ Has patient warming been initiated?
☐ Has hair removal been completed?
☐ Has glycemic control been appropriately implemented?

4.8.3 Robotic Docking Checklist

The WHO checklist is leveraged and expanded with robotic specific, team building checklists.

4.8.3.1 Anesthesia related

☐ Is the Airway Accessible?
☐ Are anesthesia lines accessible?
☐ Is the bed locked?

4.8.3.2 Patient related

☐ Is the patient positioned properly?
☐ Is the patient appropriately secured?

4.8.3.3 Robot related

☐ Are the robotic arms in appropriate positions?
☐ Has the robotic arm range of motion been tested?
☐ Is the video equipment properly configured?
☐ Does the video need to be saved?

4.8.3.4 Bedside assistant

☐ Is there accessibility to the patient?
☐ Are the monitors readily visible?
☐ Is the energy source accessible?
☐ Has communication with the surgeon and team been established?

4.8.3.5 Procedure specific

☐ Have specific needs of the procedure been recognized, discussed, and appropriately addressed?
☐ Has the level of risk of the procedure and high risk components of the procedure been discussed?

4.8.3.6 Trouble shooting – empower team for patient safety

☐ Is there a plan to account for foreign objects during the procedure and their removal (i.e. white boarding)?

☐ Has the team discussed how often periodic checks will be conducted to determine case progression, team member continuity, and other issues that need to be addressed?
☐ Has the team reinforced a protocol of regular communication with anesthesia?

4.8.3.7 Checklist complete

☐ Has the team acknowledged that the checklist is complete and they are ready to begin the procedure?

4.9 Team Communication in the Intra-Operative Phase

4.9.1 Introduction

The lack of visual and physical proximity of the surgeon to the rest of the team demands stringent communication among team members. Once the surgeon sits at the console which controls the robotic manipulators (or imaging device, x-ray source, etc.), the field of view is now constrained to that of the monitor. Although this greatly enhances the feeling of 'being in the operative site' (called telepresence), the remainder of the operating room is no longer visible. Thus, the role of communication during the surgical procedure becomes even more emphasized. The TeamSTEPPS® approach becomes even more critical under these circumstances. Examples include instrument change, camera adjustment, repositioning of trocar or arms, etc. The goal is to insure that all team members share the same mental model about the procedure, and communicate frequently. Most important is to have the surgeon updated on a regular basis to insure that there is 'progress' with the operation – procrastinating and lack of progress is an error that leads to complications further along in the procedure. When instruments are changed, it must be done efficiently and correctly, when specimens are removed they must be labeled and checked for accuracy, and the operative site must be reviewed to insure there were no missed errors or residual bleeding.

4.9.2 Intraoperative Team Communication

The following are guidelines for the intraoperative behavior of the team that should be reviewed at the final debriefing for efficacy and areas of improvement. Since each surgical specialty has its own set of unique surgical procedures, this list is only meant to be representative and not exhaustive.

☐ Do all team members share the same mental model about the procedure?
☐ Is there good team communication concerning instrument usage?
☐ Are instruments being changed efficiently and correctly?
☐ Are there periodic checks occurring to discuss case progression with the surgeon, team member continuity, and other issues?
☐ Are all foreign objects accounted for (i.e. white boarding) and removed?
☐ Are specimens checked and accurately labeled when they are removed?
☐ Have operative sites been thoroughly checked to ensure there are no missed errors or residual bleeding?
☐ Have there been any unexpected issues related to the robot or other surgical instruments/equipment?
☐ Have there been any unexpected surgical events or errors?
☐ Has there been regular communication with the anesthesia team?

4.10 Team Communication in the Post-Operative Phase

4.10.1 Introduction

The operating room team must be aware that there is a tendency to 'let their guard down' after the major portion of the procedure is completed. It is a time when staff might be anxious/hurried to finish and leave to get the next case started. In addition, this is a time when many team members are simultaneously busy (e.g. the anesthesiologist is extubating the patient, the scrub nurse is completing the instrument check and 'back table cleanup' and the circulating nurse is gathering instruments, equipment and supplies to be returned to central supply). Inattention to the overall situation may lead to slips and eventually errors, which is why all team members must be familiar with and adhere to useful postoperative checklists.

Upon completion of the procedure the surgeon will notify the team that a time-out must be taken before 'closing'. All instruments must be checked, specimens reviewed again, and the operative site checked, especially paying attention to the site where the trocars were inserted for tissue tearing, bleeding, retained foreign bodies, etc. The surgeon and/or first assistant will inform the anesthesia team when they will be closing and how long it should take.

The undocking of the robot will be the reverse of the setup, and include safe removal of all instruments from the operative site, powering the robot down, undocking of the robot from the vicinity of the patient, and moving all ancillary equipment (towers, energy sources, etc.) away from the patient. Only then would it be safe to reposition the patient and transfer to a gurney. A debriefing is needed as the completion event of the procedure.

4.10.2 Undocking

- ☐ Did the surgeon check all instruments?
- ☐ Have the instruments been cleared?
- ☐ Have the instruments been removed?
- ☐ Were all foreign bodies removed?
- ☐ Have the trocars been disconnected from the robot arms?
- ☐ Have trocars been removed by direct visualization (when possible)?
- ☐ Is the specimen management and wound closure complete?
- ☐ Has the robot been carefully moved away from the patient and a path cleared for transfer of the patient?
- ☐ Has the patient been safely transferred to the recovery room?

4.10.3 Debriefing

- ☐ What are the key concerns for recovery and management of this patient?
- ☐ Have any equipment problems been identified that need to be addressed, including robot error messages? If so, who will follow-up?
- ☐ What are the opportunities to improve?
- ☐ What are the lessons learned?
- ☐ Has each member of the team been given the opportunity to provide feedback?
- ☐ Was there closed loop communication for any quality improvement/risk management issues?
- ☐ If video was recorded, is it saved and stored?

4.11 Resources and References

Additional readings

1. Greenberg CC, Regenbogen SE, Studdert DM, et. al. Patterns of communication breakdowns resulting in injury to surgical patients. J Am Coll Surg. 2007 Apr;204(4):533-40.

2. Riley W, Davis S, Miller K, Hansen H, Sainfort F, Sweet R. Didactic and simulation nontechnical skills team training to improve perinatal patient outcomes in a community hospital. Jt Comm J Qual Patient Saf. 2011 Aug;37(8):357-64.
3. Link to TeamSTEPPS (accessed 15 Nov, 2012 from the ARHQ webpage http://www.ahrq.gov/teamsteppstools/instructor/introduction.htm).

4.12 Assessment for Team Training and Communication Skills

A multiple choice test will be delivered based upon the above content to insure understanding and retention of materials.

4.13 Simulations

These suggested simulations will be videotaped at Florida Hospital:

1. The circulating nurse sees a worsening hemorrhage on a secondary monitor and urgently calls "stop" and quickly describes what she sees. The anesthesiologist confirms that there must be a hemorrhage, because the patient's blood pressure is dropping rapidly and calls for blood. The surgeon decides that an emergent undocking is necessary, so he/she can open the patient. Watch the video and rate the team's communication skills and task performance.

2. During the procedure an instrument exchange occurs. The TeamSTEPPS® communication protocol is not used between the OR staff members and the robotic surgeon, which results in confusion and eventually an error. Determine how the communication could have been improved to avoid the error. Watch the video to see an ideal example of the TeamSTEPPS® communication protocol.

3. The surgeon is performing a robotic assisted hysterectomy. The case is proceeding nicely until there is an error message after putting a needle driver on the arm. The arm cannot be advanced. The message on the screen states no cannula detected. The bedside assistant uses the camera to check to see if the cannula can be seen from the laparoscopic view and it is indeed visible. What is the next step in troubleshooting this issue? Watch the video and determine what you would have done differently.

4. During the case for a robotic gastric bypass, when changing out the robotic arm instruments, a grasper that needs to be removed will not come off of the tissue it is holding. Determine what needs to be done in order to release and remove the instrument. Watch the video and see if your steps match the ones carried out by the OR team.

5. Using the Si robot, when turning on the components for the day, there robot starts alarming and the error message is, "no video connected." After checking all connections and making sure everything is plugged in, the robot is again turned on and the same error message appears on the screen. What is the next thing that should be done? Watch the video and see if your solution matches the one carried out by the OR team.

6. After changing the scope during a robotic procedure, one of the eyes appears to be foggy. Watch the video and see how the team trouble shoots the "eye" problem and fixes it. And then watch the same scenario but with the picture on the screen staying pink.

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APPENDIX A: ABOUT FRS

The Fundamentals of Robotic (FRS) is a joint industry (Intuitive Surgical, Inc) and Department of Defense (DoD) funded project jointly managed through Minimally Invasive Robotics Association (MIRA) and Florida Hospital Nicholson Center. The mission of FRS is to create and develop a validated multi-specialty, technical skills competency based curriculum for surgeons to safely and efficiently perform basic robotic-assisted surgery.

The basic curriculum for robotic surgery was created in a collaborative effort by multiple surgical specialties that use robotic systems for surgery. The FRS curriculum was conceived as a "full life cycle" development, which included three consensus conferences in the following topics:

1. Outcomes Measures : The first FRS consensus conference (FRSCC#1) brought together subject matter experts (SME) from multiple surgical societies, surgical educational societies, surgical boards and other governing organizations who agreed upon the critical skills, tasks, and most common errors that needed to be included in a comprehensive basic curriculum. The result was a table that defined the skills/tasks/errors, the desired outcome measures, and the metric(s) that should be measured. The table was rank ordered both as to sequence in which these occurred, as well as a second table that rank ordered the measurements in terms of their priority.

2. Curriculum Development: The second consensus conference (FRSCC#2) had four specific goals that will lead up to the completion of a curriculum for the FRS and the methods of training and assessing the full range of technical skills (cognitive, psychomotor, team training/communication) that are necessary to safely use a robotic surgery system. The goals are to:
    a. Review the Outcomes Measures Tables
    b. Select from those measures the ones which can be included into the curriculum development (and add any other critical measures that may have been missed)
    c. Review and adapt the curriculum template from ASSET (developed and published a curriculum template with wide consensus for surgical training)
    d. Complete the actual curriculum, including the metrics for each skill/task/error and assessment tools.

    Once this curriculum is completed and accepted by the participants of this conference, it will be distributed for comments.

3. Validation Study Design: The third consensus conference brought together robotic surgeons, researchers and psychometricians to design a validation study, to meet the most rigorous evaluation that would be acceptable for high stakes testing and evaluation.

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Fundamentals of Robotic Surgery
Consensus Conference III: Validation Study Design

Meeting Summary Report

MITIE, Houston, TX
November 17-18, 2012

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The Fundamentals of Robotic (FRS) is a joint industry (Intuitive Surgical, Inc) and Department of Defense (DoD) funded project jointly managed through Minimally Invasive Robotics Association (MIRA) and Florida Hospital Nicholson Center for Surgical Advancement (NCSA). The mission of FRS is to create and develop a validated multi-specialty, technical skills competency based curriculum for surgeons to safely and efficiently perform basic robotic-assisted surgery.

3 consensus conferences were planned in the following topics:

1. Outcomes Measures
2. Curriculum Development
3. Validation Study Design

These conferences will be followed by multi-institutional validation study with participation by multiple surgical specialties at each institution.

Lectures about Validation

1. Validation: Tools for Improving Curriculum and Assessment: Dr. Sara Kim, ISIS, University of Washington Medical Center
    a. Essence of validation
    b. Framework of validation
    c. Types of validation study designs
    d. Implications for FRS validation
2. Toward a Course Validation Template: Dr. Wallace Judd, Authentic Testing Corporation
    a. Defining tasks and skills
    b. Looking at a typical course
    c. Characteristics of validation tasks
    d. Course validation template
3. Validation Study Design & Methods: Dr. Anthony Gallagher, University College Cork
    a. Validation is a process
    b. Metrics for an optimal training program
    c. Validation: Why is it Important?
    d. What needs to be done to advance the validation process?
    e. Possible model for robotic validation studies

Break out sections

Measures and Metrics Group

1. The goal of the Measures and Metrics Group is to answer the question: what are the metrics?
2. Measurements and metrics, errors, and critical errors were determined for the 7 technical skill tasks
    a. Docking & Instrument Insertion
    b. Ring Tower Transfer
    c. Knot Tying
    d. Railroad Track
    e. 4th Arm Cutting
    f. Cloverleaf Dissection

        g. Vessel Dissection/Division
3. Metrics around team/communication issues for the high stakes exam (HSE) were also discussed

Study Design Group

1. The goal of the Study Design Group is to focus on the psychomotor component and conceptualize a validation study (or series of studies)
2. Define the research questions
3. Define an characteristics of an experts
4. What will be measured?
5. Study design
    a. Phase 1: Pilot at Florida Hospital Nicholson Center (logistics and refinements to model)
    b. Phase 2: Get face and content validity from the society leadership and boards
    c. Phase 3: Get face, content, and construct validity at test sites and society meetings
    d. Phase 4a: Get concurrent validity with video correlations
    e. Phase 4b: Get predictive validity – full research study at 10 sites
6. Validity questions

Open Forum

Following the main meeting, the floor was opened to everyone including industry to provide input and ask any questions. This was not part of the main meeting and had nothing to do with curriculum development, so there is no real or perceived conflict (bias) from industry.

WELCOME

Brian Duncan, MD, The Methodist Hospital, Houston TX

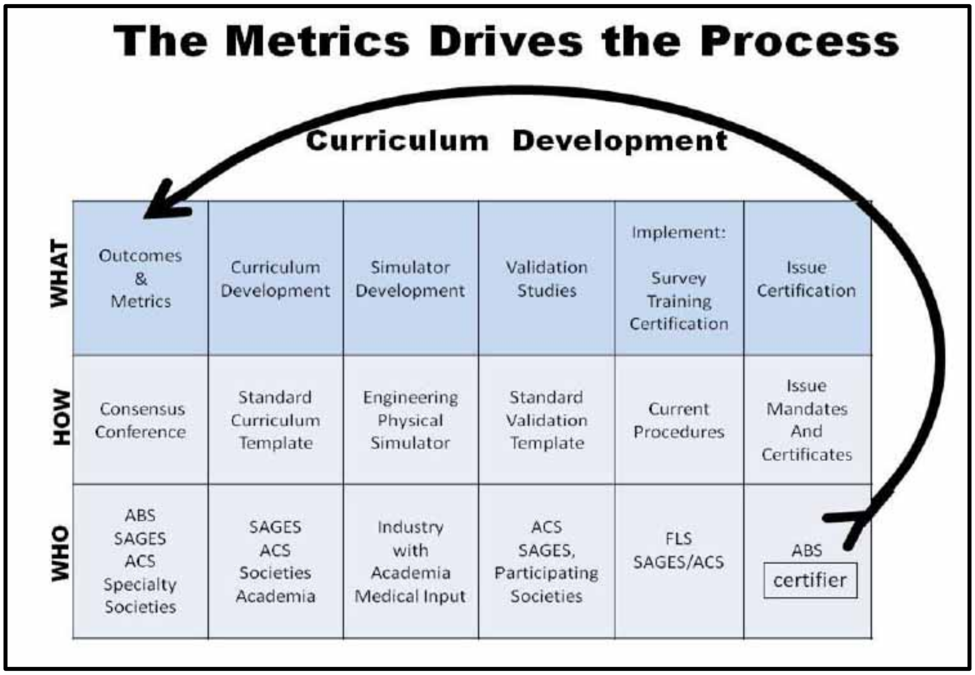
The meeting was held in The Methodist Institute for Technology, Innovation & Education (MITIE). MITIE is a comprehensive, state-of-the-art education and research center at The Methodist Hospital in Houston, Texas. Its educational mission focuses on physicians who wish to acquire new procedural skills and integrate new technologies into their practices. Its research mission is to enhance the use of image guided technology to guide procedures, incorporate robotic surgery into the image guided platform, and develop new technology and procedural techniques.

Introduction and FRS Project Background – Richard Satava, MD

The Fundamentals of Robotic (FRS) is a joint industry (Intuitive Surgical, Inc) and Department of Defense (DoD) funded project jointly managed through Minimally Invasive Robotics Association (MIRA) and Florida Hospital Nicholson Center for Surgical Advancement (NCSA). The mission of FRS is to create and develop a validated multi-specialty, technical skills competency based curriculum for surgeons to safely and efficiently perform basic robotic-assisted surgery.

The basic curriculum for robotic surgery will be created jointly by multiple surgical specialties that use robotic systems for surgery. The curriculum will be open source and adaptable for many methods of simulation – from physical models to full virtual reality. A shortcoming of previous curricula for simulators was that they were developed in cooperation with a single surgical expert in a single specialty, who alone determined the best method for the skills or procedures; however most often, the resulting curriculum, while clearly validated, did not have the outcomes measures that were acceptable to certifying bodies. To overcome this limitation, all major stakeholders were invited to participate.

The development of the FRS is conceived as a “full life cycle” development of the curriculum (see graphic below).



WHAT	Outcomes & Metrics	Curriculum Development	Simulator Development	Validation Studies	Implement: Survey Training Certification	Issue Certification
HOW	Consensus Conference	Standard Curriculum Template	Engineering Physical Simulator	Standard Validation Template	Current Procedures	Issue Mandates And Certificates
WHO	ABS SAGES ACS Specialty Societies	SAGES ACS Societies Academia	Industry with Academia Medical Input	ACS SAGES, Participating Societies	FLS SAGES/ACS	ABS certifier

"Full life cycle" development includes 3 consensus conferences in the following topics:

1. <u>Outcomes Measures</u> : The first FRS consensus conference (FRSCC#1) brought together subject matter experts (SME) from multiple surgical societies, surgical educational societies, surgical boards and other governing organizations who agreed upon the critical skills, tasks, and most common errors that needed to be included in a comprehensive basic curriculum. The result was a table that defined the skills/tasks/errors, the desired outcome measures, and the metric(s) that should be measured. The table was rank ordered both as to sequence in which these occurred, as well as a second table that rank ordered the measurements in terms of their priority.

2. <u>Curriculum Development</u>: The second consensus conference (FRSCC#2) had four specific goals that will lead up to the completion of a curriculum for the FRS and the methods of training and assessing the full range of technical skills (cognitive, psychomotor, team training/communication) that are necessary to safely use a robotic surgery system. The goals are to:
    a. Review the Outcomes Measures Tables
    b. Select from those measures the ones which can be included into the curriculum development (and add any other critical measures that may have been missed)
    c. Review and adapt the curriculum template from ASSET (developed and published a curriculum template with wide consensus for surgical training)
    d. Complete the actual curriculum, including the metrics for each skill/task/error and assessment tools.

    Once this curriculum is completed and accepted by the participants of this conference, it will be distributed for comments.

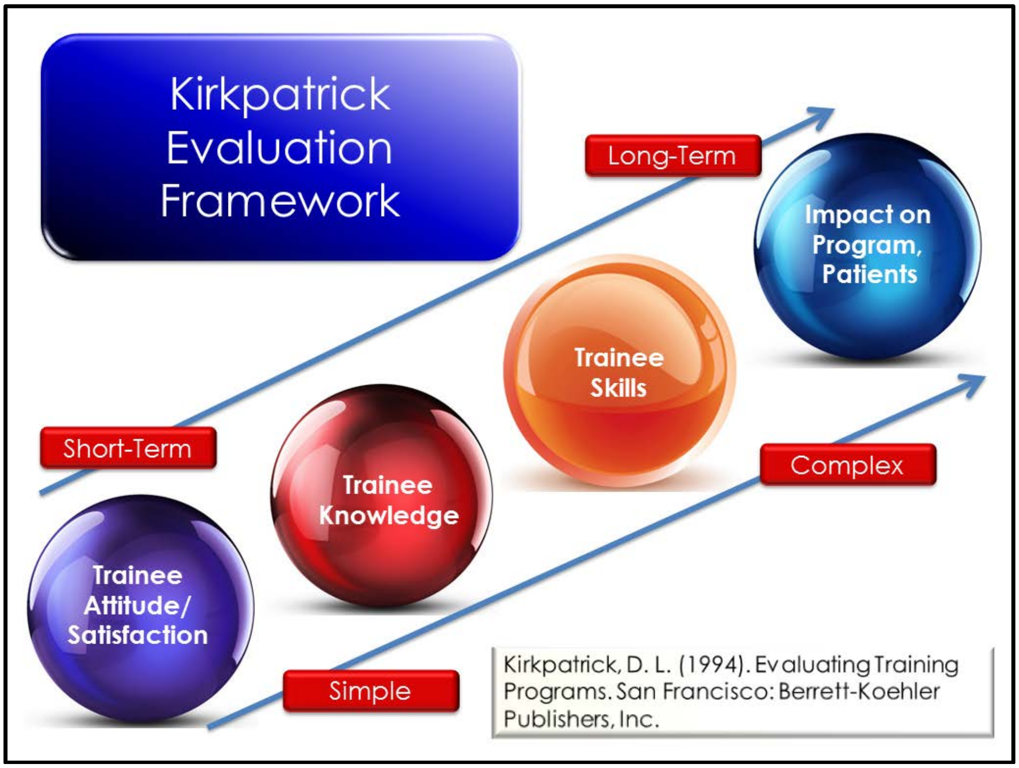
3. <u>Validation Study Design</u>: The third consensus conference will be for the design of the Validation Study, to meet the most rigorous evaluation that would meet criteria for high stakes testing and evaluation.

These conferences will be followed by multi-institutional validation studies with participation by multiple surgical specialties at each institution.

VALIDATION LECTURES

Validation: Tools for Improving Curriculum and Assessment by Dr. Sara Kim, ISIS, University of Washington Medical Center

1. Essence of Validation
    a. Collecting evidence from data in order to make an inference about what you are assessing.
    b. Two critical components that affect the quality of evidence you collect include: the range of behaviors you are observing based on tasks and how you measure and score trainees' behaviors.
2. Framework of Validation



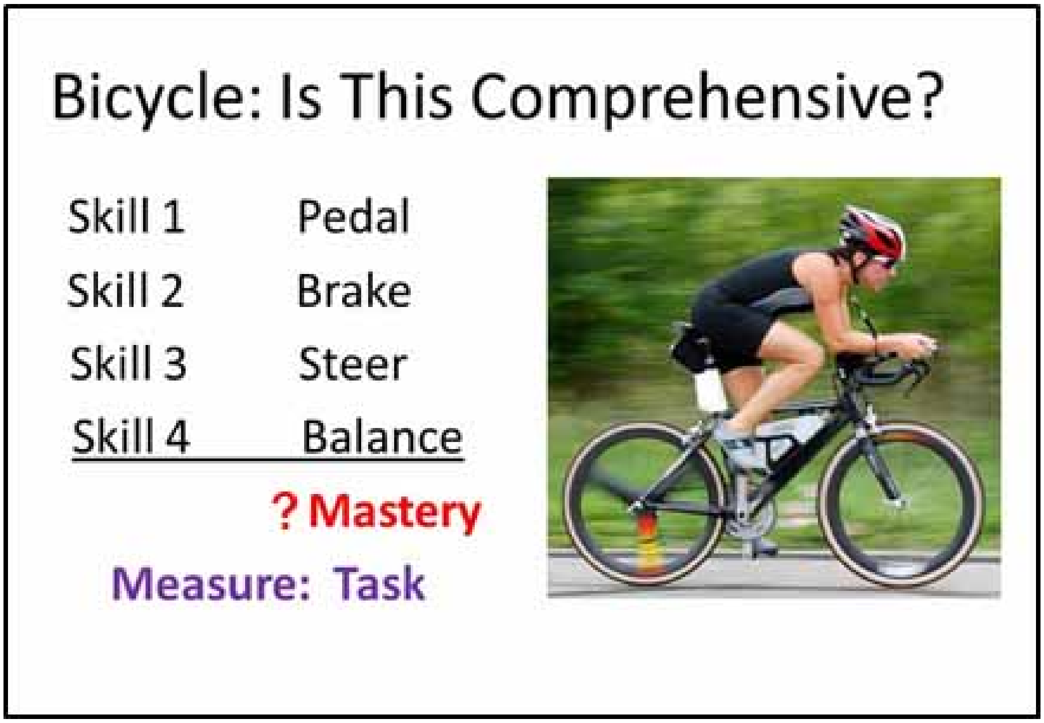
Kirkpatrick, D. L. (1994). Evaluating Training Programs. San Francisco: Berrett-Koehler Publishers, Inc.

    a. Generalization: Generalizability of the scores (association between the score a person receives on an assessment and the universe score—the theoretical score he/she would receive if taking the assessment an infinite number of times), or reliability, must be ascertained keeping the complexity of the assessment in mind.
    b. Extrapolation: Assessment scores are closely linked to the "construct" and there is a relationship between simulation assessment and patient care.

    c. Decision/Interpretation: Need evidence that assessment methods are defensible in interpreting scores and that there is a consequential impact of assessment (i.e. curricular change, healthcare efficiency).
3. Types of Validation Study Designs
    a. Task Based Studies
    b. Proficiency Based Studies
    c. Training Model Based Studies
4. Implications for FRS Validation
    a. Number, type and sequencing of tasks are critical to ensure adequate sampling of behaviors in validation studies.
    b. Paucity of training scenarios of graded complexity and difficulty levels (Sum of technical proficiencies across tasks = competency?)
    c. Team-based approach to robotic surgery should be an integral part of training to avoid collision of "multiple learning curves"
    d. Lack of consistent definitions for novices vs. experts, which impedes cross-study comparisons in validation literature.

Toward a Course Validation Template by Dr. Wallace Judd, Authentic Testing Corporation

1. Tasks and Skills
    a. Definition of a task: When you do something... there is an outcome.
    b. Don't confuse tasks and skills. The following are skills (not tasks):
        i. Knot tying
        ii. Docking
        iii. Instrument exchange
        iv. Suturing
        v. Multi-arm control
        vi. System settings
        vii. Ergonomic positioning
    c. Task mastery does not equal skill comprehension
    d. Paradigm task: A task that generalizes to other tasks
2. Looking at a Typical Course
    a. Within a course, one conducts a series of skills and verifies each of them
    b. The sum of the skills does not mean there has been mastery (see bike example below)
    c. The sum of the verifications does not mean there has been validation
    d. Bike example
        i. The sum of certain skills including pedaling, braking, steering, and balance do not necessarily mean mastery of bike riding
        ii. Are the skills listed above really comprehensive for bike riding?



Bicycle: Is This Comprehensive?

Skill 1	Pedal
Skill 2	Brake
Skill 3	Steer
Skill 4	Balance

? Mastery

Measure: Task

3. Validation Tasks <u>Must Be</u> ...
    a. Identical for all candidates
    b. Singular
    c. Reusable
    d. Stable
4. Course Validation Template
    a. Define scope of course
    b. Define blueprint
    c. Determine paradigm tasks
    d. Define skills required to do tasks
    e. Create alternative tasks
    f. Define overlay of complexity
    g. Write items
    h. Define item scoring
    i. Administer test tasks
    j. Rate candidates in course success
    k. Correlate course ←→ test score
    l. Correlation establishes course validity

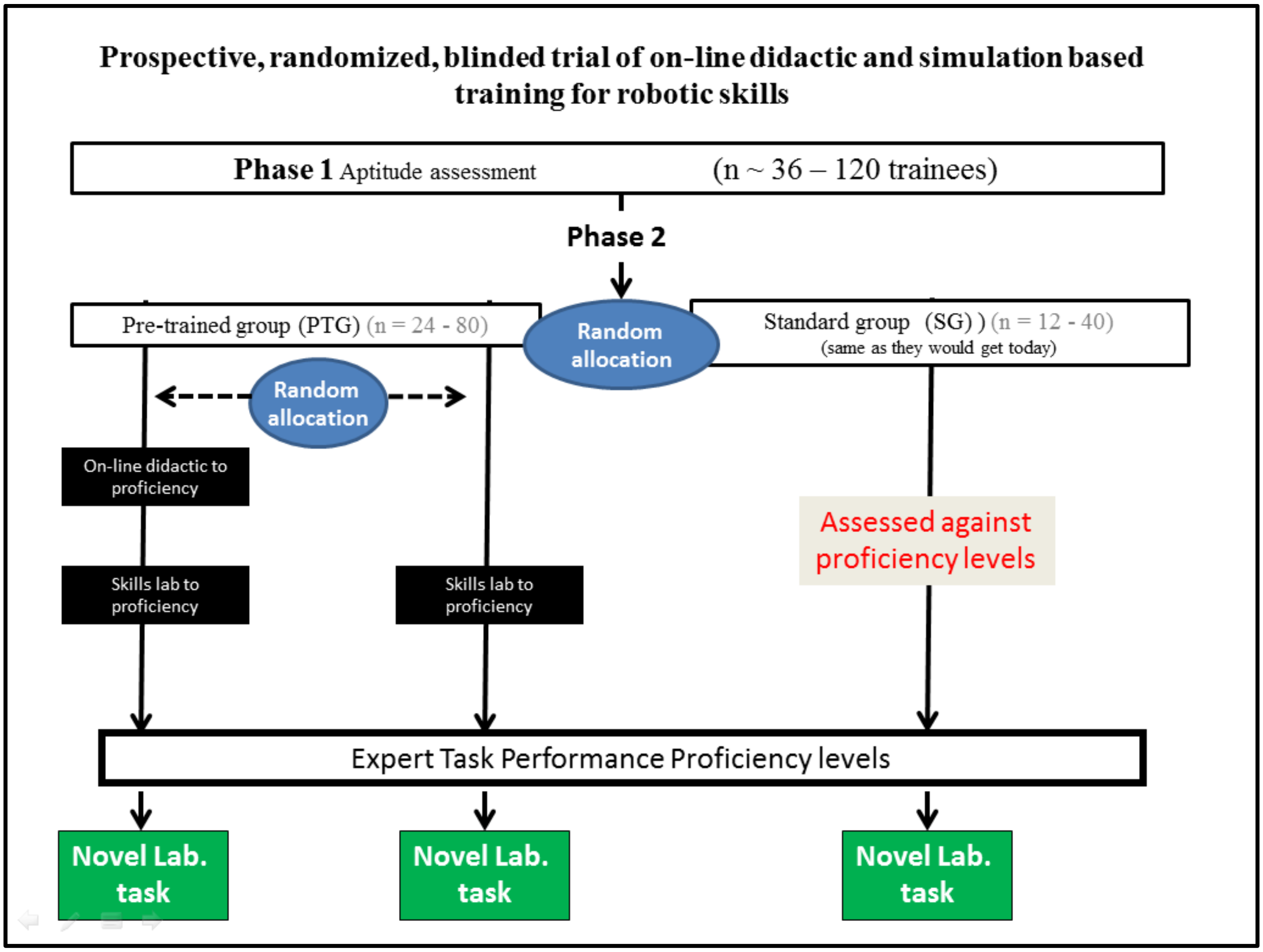
Validation Study Design & Methods by Dr. Anthony Gallagher, University College Cork

1. Validation is a Process
    a. Validation is about making it easy for individuals reviewing the studies to believe the results (i.e. making it easy for 'them' to say yes).

   b. Validation is also about creating compelling enough evidence to sway nay-sayers who are inclined not to believe the results (i.e. making it difficult for ‘them’ to say no)
   c. Minimally invasive surgeons are well versed in the process of validation
2. Metrics for an Optimal Training Program
   a. What to measure?
      i. Time (context dependent)
      ii. Errors (events)
      iii. Performance variability (consistency)
   b. Metrics for ‘proficiency-based progression’ training are not complex. Simply put, metrics are:
      i. What makes you cringe when you see another operator (or yourself) doing something that <u>really</u> shouldn’t be done!
      ii. What you try and train your trainees to do and not to do
3. Validation: Why is it Important?
   a. Different types of validation (Validity of an assessment is the degree to which it measures what it is supposed to measure.)
      i. Face-Content Validity
         - Danny Scott has laid the groundwork for robotic surgery in his article: Dulan G, Rege RV, Hogg DC, et. al. Content and face validity of a comprehensive robotic skills training program for general surgery, urology, and gynecology. *The American Journal of Surgery* Volume 203, Issue 4 , Pages 535-539, April 2012.
      ii. Concurrent Validity
      iii. Construct Validity
         - Danny Scott has laid the groundwork for robotic surgery in his article: Dulan G, Rege RV, Hogg DC. Developing a comprehensive, proficiency-based training program for robotic surgery. *Surgery* Volume 152, Issue 3 , Pages 477-488, September 2012.
         - Showed that tasks that look like they should be appropriate for training robotic skills are rated as such by robotic ‘experts’
         - Also showed they can differentiate between an expert and a novice
      iv. Predictive Validity
   b. Reliability
      i. Describes the overall consistency of a measure. A measure is said to have a high reliability if it produces similar results under consistent conditions.
      ii. Reliability includes test-retest, internal, inter-rater (a discussion for another day)
      iii. If a valid test is unreliable it is almost useless
   c. Assessments should be:
      i. Objective
      ii. Transparent
      iii. Fair
4. What Needs to be Done to Advance the Validation Process?
   a. On-line didactic
      i. Need to demonstrate validity with ‘appropriate’ numbers
         - N = >40 *(estimated from Berryhill et al., Urology 2008 and Gallagher et al. Ann Surg ToT/TER data; more is better*)

b. Skills lab
   i. Need to demonstrate construct validity with ‘appropriate’ numbers
      - N = >40 (more is better)
   ii. Establish construct validity and thus proficiency
      - What should be done with critical errors (e.g., forgetting about clutching status after resuming from ‘parked’)?
   iii. Who is going to be the ‘guardian’ of the proficiency levels?
   iv. What do your proficiency levels mean?
      - Predictive validity

5. Possible Model for Robotic Validation Studies



Prospective, randomized, blinded trial of on-line didactic and simulation based training for robotic skills

MEASURES & METRICS GROUP

Group Members

Group Leaders: Brian Dunkin & Martin Martino
Todd Larson
Tony Jarq
Tim Brand
Rodney Dockter
Naz Siddiqui
Arnie Advincula
Victor Wilcox
Paul Rose
Tom Lendvay
Jan Cannon-Bowers
Wally Judd
Alvin Goh
Paul Neary

Meeting Goals:

The goal of the Measures and Metrics Group is to answer the question: what are the metrics? The goal is not to decide success/non-success. The system developed should:

- Be easily produced and measured
- Not be reliant on manual counting/validating (electronic metrics are preferable)
- Should take a maximum of 1 hour to complete.

General Scoring Guidelines for Skill Drills

Adapted from Siddiqui et al. for the Robotics Training Network. Validity and reliability of R-OSATS: a novel assessment tool for robotic surgical training. Presented at the 2013 CREOG and APGO Annual Meeting, Pheonix, AZ.

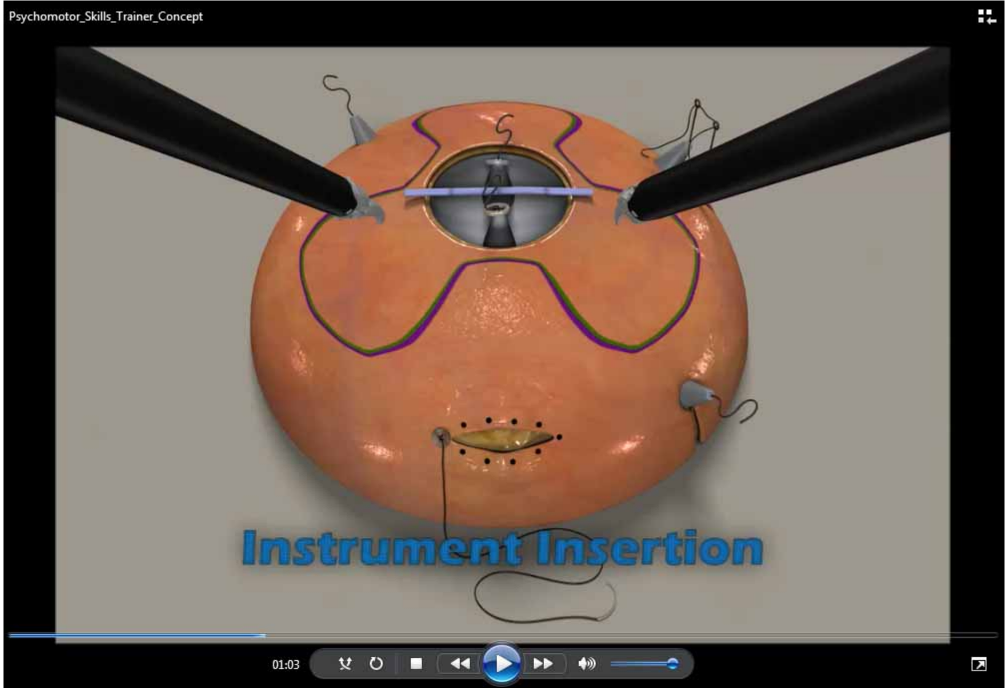
Depth Perception/Spatial Orientation/Accuracy				
1	**2**	**3**	**4**	**5**
Constantly overshoots target, slow to correct		Some overshooting but quick to correct		Accurately directs the instruments to target
Force/Tissue Handling				
1	**2**	**3**	**4**	**5**
Breaks model, ring, or suture; damages needle		Moves or bends wire; minor trauma to model or needle, frays suture		Handles model, suture, and/or needle well; traction is appropriate
Dexterity				
1	**2**	**3**	**4**	**5**
Poor coordination of hands; repetitively drops ring or band; inappropriately drops needle or poor suture management		Suboptimal interaction between hands, any drops of ring or band. Suboptimal suture or needle management.		Expertly uses both hands; always transfers rings or bands without dropping. Optimal needle or suture

management.

Efficiency				
1	**2**	**3**	**4**	**5**
Uncertain movements with little progress		Slow, but movements seem reasonably organized		Confident, fluid progression, adjusts quickly

1) Docking & Instrument Insertion

Exercise Image



Measurements and Metrics

Depth Perception /Spatial Orientation/ Accuracy	1	2	3	4	5
Force of Insertion	1	2	3	4	5
Dexterity (no instrument collision)	1	2	3	4	5
Efficiency (speed of entry - time in seconds)	1	2	3	4	5
Total Score:					/20

Errors

a. Instrument collisions occur
b. Instrument tips not in view
c. Insertion of instrument not visualized

Critical/Fatal Errors

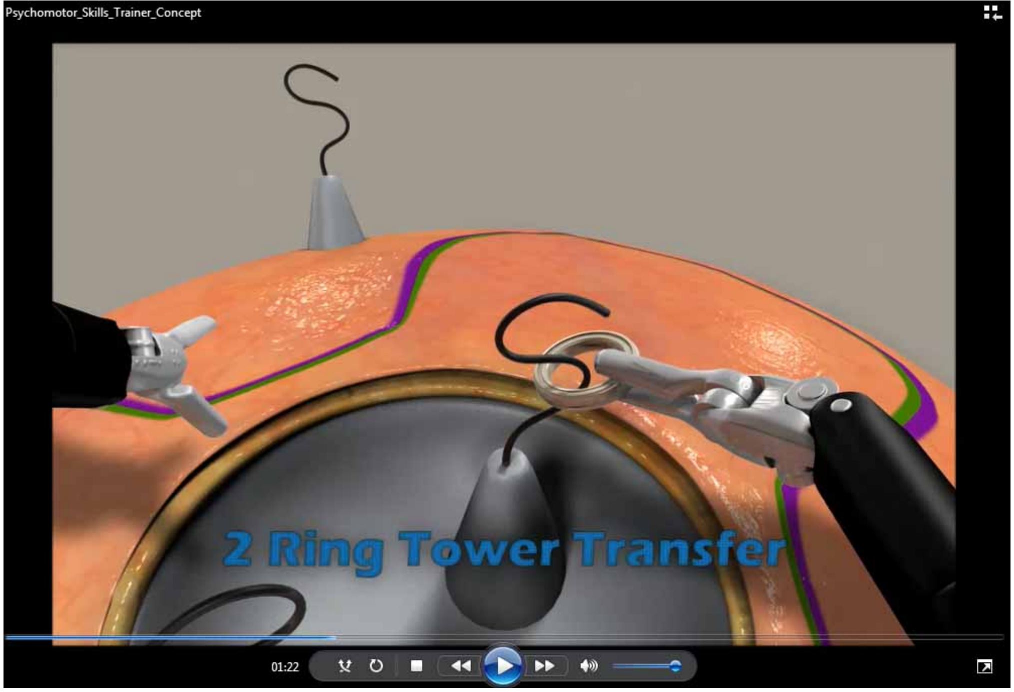
a. Instrument inserted into box
b. Inability to complete the exercise

Additional Discussion by the Group

- Should the trocars in abdomen be placed in a specific manner? Yes, need standard method. Measure that they can insert/remove in defined position (should be timed)
- How involved is proctor to correct movement before progression? Should have independent steps. Need to be able to reset and continue.
- Fatal errors vs. errors – discuss difference and acceptability. Is that part of test or pre-test practice?
- Time is one variable; touching is another variable to create a metric. Can we use plumb lines, known angles? Where are robot arms? What are the probabilities for internal/external collisions?
- Is camera in sweet spot? Can someone take a picture to determine optimal position? May need different kind of measuring tool – proctor or on-screen.
- Steps to dock (camera and at least two arms): close both flanges; determine pitch and yaw, clutch, and set up joint
- Task time starts from fixed starting position, not necessarily inserting ports at specific angles.

2) Ring Tower Transfer

Exercise Image



Measurements and Metrics

Depth Perception/Spatial Orientation /Accuracy	1	2	3	4	5

Force (ring and contact handling/force)	1	2	3	4	5
Dexterity (movement of rings and hand transfer)	1	2	3	4	5
Efficiency (time in seconds)	1	2	3	4	5
Total Score:					/20

Errors

- Dropping ring
- Touching contacts
- Failing to transfer hands

Critical/Fatal Errors

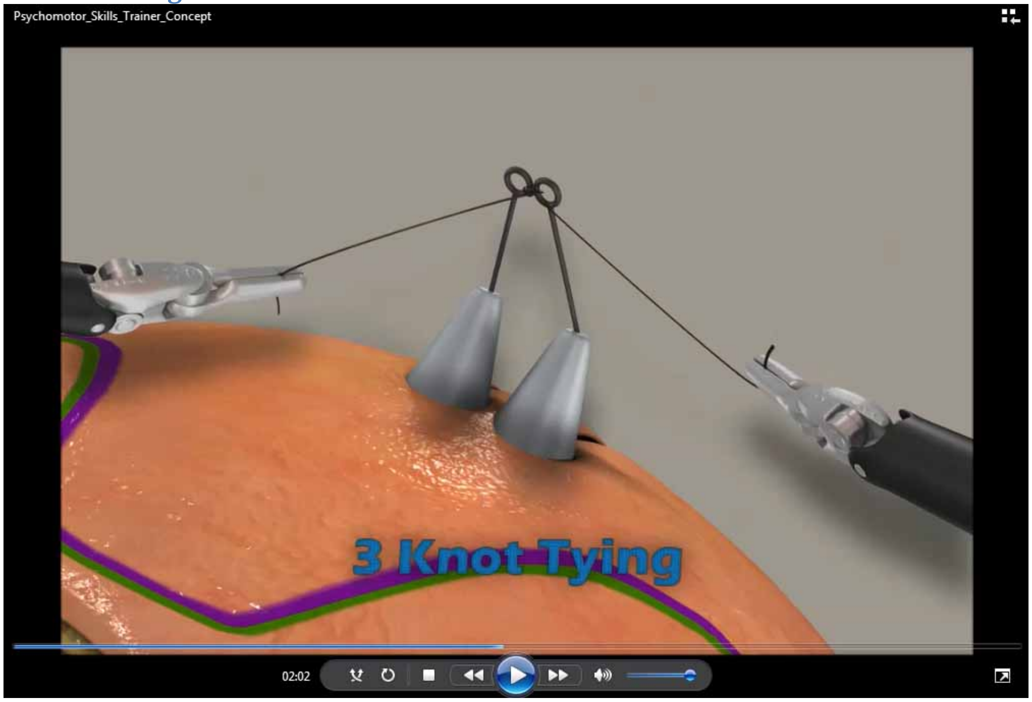
- Losing the ring
- Breaking the ring
- Popping off the wire/tower
- Inability to complete the exercise

Additional Discussion by the Group

- Different shape tower plug-ins – spiral and non-spiral ring contacts. Shape should be more complicated to force slow down.
- When do you reset? Lost ring? How should we define when a ring is "lost"? Set up should give access to every part of the box to allow for ring retrieval.
- How many ring drops do you count? Clock does not stop during drops. Non-recoverable errors are any that happened outside the box or outside the field of vision (blindspots) inside box.

3) Knot Tying

Exercise Image



Measurements and Metrics

Depth Perception /Spatial Orientation/ Accuracy	1	2	3	4	5
Force of knot tying/force on sutures	1	2	3	4	5
Dexterity (two handed knot tying)	1	2	3	4	5
Efficiency (speed measured in seconds)	1	2	3	4	5
Total Score:					/20

Errors

- Air knot – two rings do not touch
- Breaking suture (standardized 2.0 silk)
- Put dome on contacts so it reports lift BEFORE the suture breaks

Critical/Fatal Errors

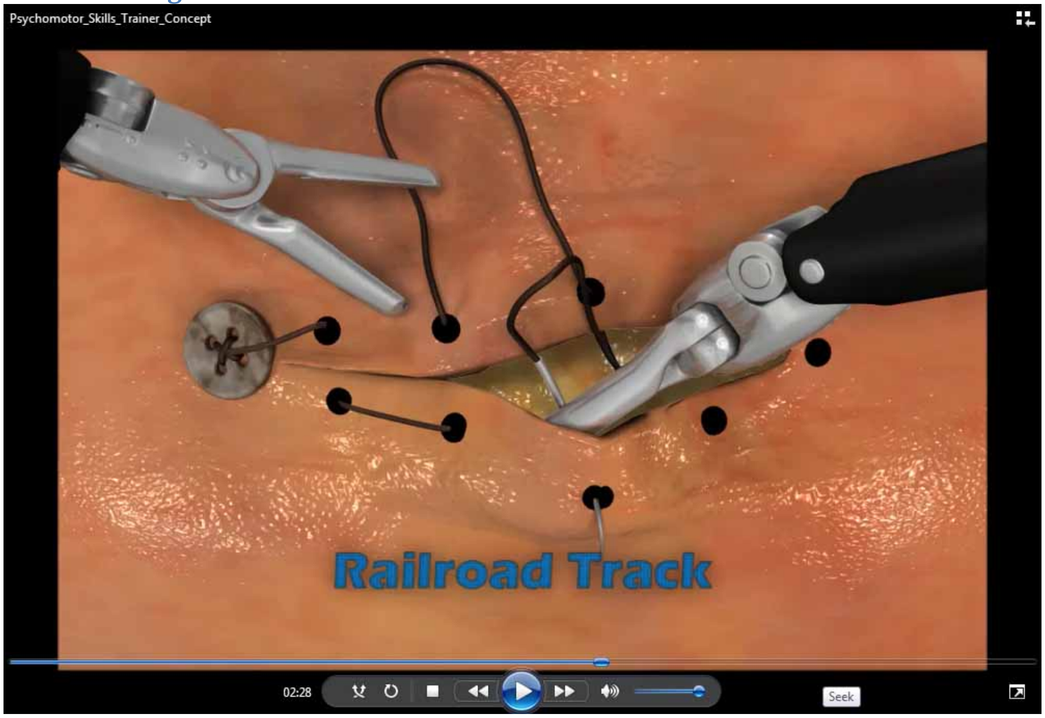
- Knocking off contacts with force
- Inability to complete the exercise

Additional Discussion by the Group

- Constrained by type of knot: square knot, surgeons knot, slip knot?
- Must do first double through (surgeon’s knot) and 2 half hitches (single throw)

4) Railroad track

Exercise Image



Measurements and Metrics

Depth Perception /Spatial Orientation/ Accuracy (going through designated circle)	1	2	3	4	5
Force on sutures and tissue	1	2	3	4	5
Dexterity (two handed suturing)	1	2	3	4	5
Efficiency (speed measured in seconds)	1	2	3	4	5
Total Score:					/20

Errors

- Going outside of designated circles
- Tearing through tissue
- Slack in railroad track suture
- Improper two hand transfer of needle

Critical/Fatal Errors

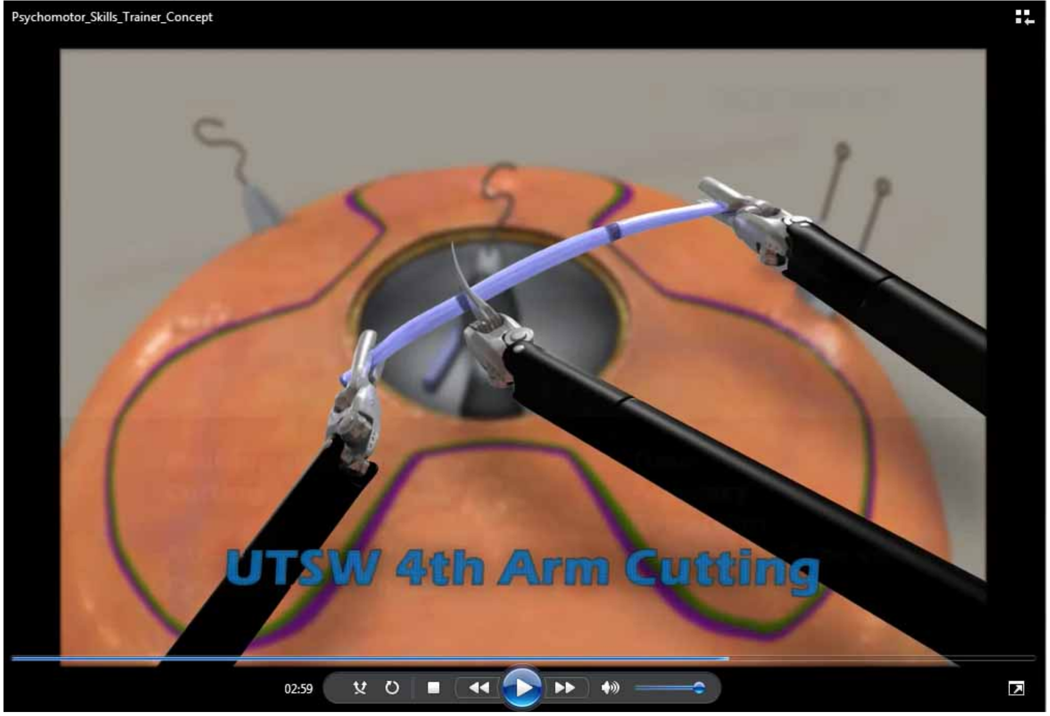
- Break needle
- Inability to complete the exercise

Additional Discussion by the Group

- Should there be left and right hand throws? Can there be backhand throws?
- Should the railroad track be in the vertical or horizontal orientation?
- Must come out of the dot (standard size dot and position)
- Measure closure, not the knot
- Should there be a button to start or start with a knot? If test runs long, use the button to start; if time allows, start with a knot

5) 4th Arm Cutting

Exercise Image



Measurements and Metrics

Depth Perception /Spatial Orientation/ Accuracy (cutting in the black mark)	1	2	3	4	5
Force on tube/simulated vein	1	2	3	4	5
Dexterity (proper use of 4th arm)	1	2	3	4	5
Efficiency (speed measured in seconds)	1	2	3	4	5
Total Score:					/20

Errors

- Not cutting in the black mark
- Not visualizing 4th arm before moving

- Breaking/tearing vein

Critical/Fatal Errors

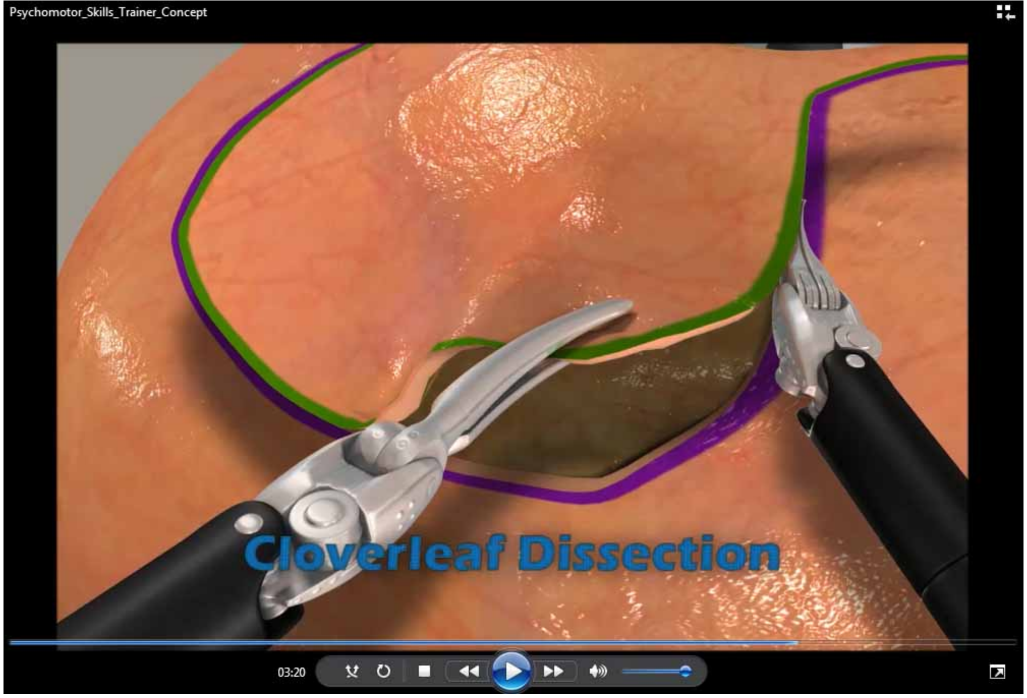
- Inability to complete the exercise

Additional Discussion by the Group

- Start with 4th arm out of view and then move it into view to begin cutting (Sequence icon to show camera movement before arm? Video recording to capture visualization of 4th arm before moving?)

6) Cloverleaf Dissection

Exercise Image



Measurements and Metrics

Depth Perception /Spatial Orientation/ Accuracy (cutting on the line)	1	2	3	4	5
Force on superficial tissue	1	2	3	4	5
Dexterity (Not cutting underlying tissue)	1	2	3	4	5
Efficiency (speed measured in seconds)	1	2	3	4	5
Total Score:					/20

Errors

- Cutting off line
- Tearing superficial tissue
- Cutting underlying tissue

Critical/Fatal Errors

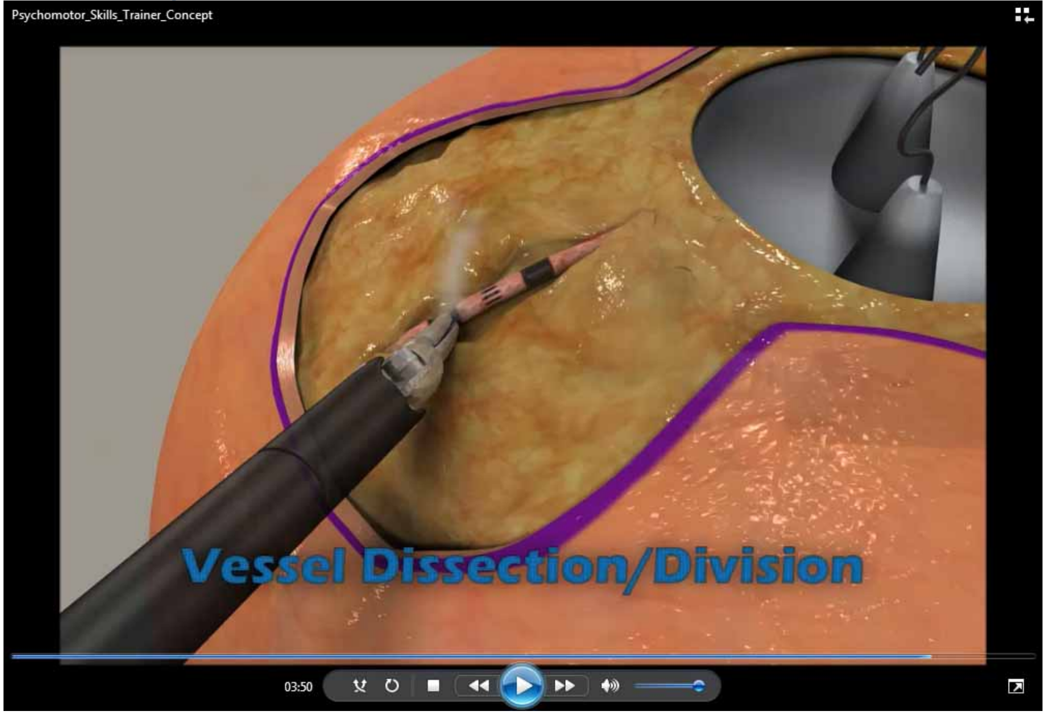
- Inability to complete the exercise

Additional Discussion by the Group

- Does the cloverleaf shape take too much time? Is it too complicated? The group felt the circle is not complex enough.
- It was discussed to change model to not remove the skin but lift and hold partial dissection with 4th arm. The group decided to only use two arms.
- Make sure to cut the whole skin off. The skin shouldn't stick to the underlying tissue.
- Can you automate the review of the accuracy of cutting the superficial the way that FLS does? But the FLS is not the best way to do it either, this is often said there needs to be a better way.
- How to decide if you lose points for a tear versus a cut. What is the measure that can be used to say you created a tear that was harmful? Is it a real time assessment on video?
- Could you put score lines/semi-perforated lines that would show a standard place to look for tears? The engineers will have to figure out how to do this. The number of tears should be counted.
- Is there a standard nomenclature to refer to the arms, so all the testing centers will be set up in the same way?

7) Vessel dissection/Division

Exercise Image



Measurements and Metrics

Depth Perception /Spatial	1	2	3	4	5

Orientation/ Accuracy (correct application of energy within black line)					
Force on tissue/vessel for dissection and division	1	2	3	4	5
Dexterity (Not cutting underlying tissue)	1	2	3	4	5
Efficiency (speed measured in seconds)	1	2	3	4	5
Total Score:					/20

Errors

- Application of bi-polar or mono-polar energy to inappropriate section
- Tearing/dislodging the vessel
- Improper use of foot pedals

Critical/Fatal Errors

- Inability to complete exercise

Additional Discussion by the Group

- We should consider a Bluetooth option for pedals and pressurized vessels.
- Will there be use of video icons to tell difference between energy sources, or sensors on pedal to notify proctor?
- Is it possible to get conductivity of materials for signaling?
- Some participants were worried that the cutting task would not capture real knowledge about energy use. Need to link the cutting action to energy use and audio cues.
- Should we have timestamps linked to video?
- Is it worth the added cost to make vessels beating? It is not that expensive and makes the exercise very similar to real surgery.
- The pedal configuration may not always be the same, but the task should be to “push the right pedal at the right time.”

Metrics Discussions Concerning Team Issues for High Stakes Exams (HSE):

The Measurement and Metrics group then began discussing the valid metrics of team training.

Who is the team?

This section should test the surgeon’s ability to work in a “team” that was defined as:

1) The Surgeon (the main focus is on the surgeon)
2) Bed-side assistant
3) Circulator
4) Anesthesiologist
5) Scrub nurse
6) 2nd assistant (after discussion it was decided that since the 2nd assist is not always common for all procedure, for the purposes of FRS, the 2nd assist would not be included)

What communication needs to be scored?

1) The communication being scored revolves around the commander’s intent
2) There should be an agreed upon verbal nomenclature
3) Then the scenarios should be established for the individuals being tested

Tasks and team training

Do we need to add metrics to each of the 7 tasks that relate to team training?

1) It was decided to leave communication and team management as a separate entity since the team training might be a distraction from the psychomotor skills tasks.

Communication challenges of the surgeon

When the surgeon is sitting at the console what are some of the things that are frustrating and challenging in communication?

2) Assistants switching in the middle of surgery without communication
3) Relying on verbal communication through speakers
4) Person specific communication impaired/chatter
5) No verbal feedback (need to use personnel names, agreed upon nomenclature, and closed loop communication)
6) Lack of situation awareness/analysis

Possible Team-based scenarios that can be implemented and tested

Set up scenario so proctor scores on specific behaviors to occur within intra-, inter-, and post-operative times

1) Instrument guided exchange (system has awareness of what is happening-memory will remain if you don't touch the clutch inappropriately)
2) Emergent undocking
3) Movement of bed position (impact on patient and anesthesiologist)
4) Unguided instrument insertion
5) Port problems (hemorrhage and port management)
6) Loss of pneumoperitoneum (ports out)
7) System/robot malfunction (error code)
8) Camera switching

Since there will be 3 parts to the FRS HSE (cognitive, psychomotor skills and team training/communication), the question was raised, "What if the learner does not pass all 3 parts? Can he/she come back and only do that part that wasn't passed?"

Additional discussion from the Group about team training

- Make a matrix of required measures per metric (automated vs. human elements to scoring)
- Use computer adapted testing – assess online instead of using proctor who may not be as knowledgeable. Keep proctor training to a minimum, but we will need to validate humans vs. computer so we know how productive one is over the other

STUDY DESIGN GROUP

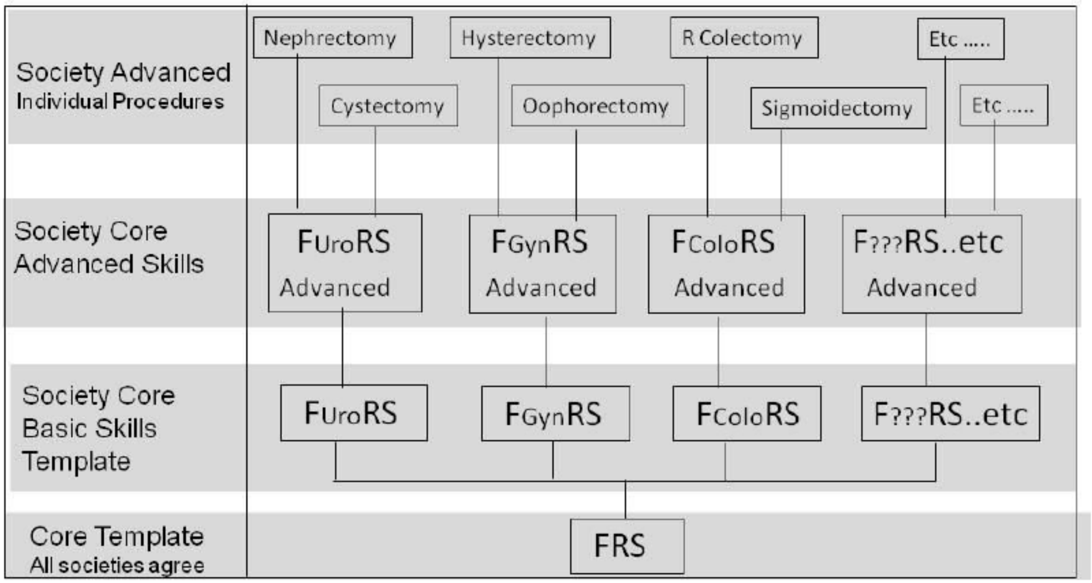
Group Members

Group Leaders: Jeff Levy & Rob Sweet
Rajesh Aggarwal
Garth Ballantyne
Sanket Chauhan
Tony Gallagher
Jacques Hubert
Sara Kim
Manuela Perez
Cyril Perrenot
Judith Riess
Rob Rush
Brendan Sayers
Mika Sinanan
Roger Smith
Dimitrios Stefanidis

Goals of the Breakout Group

- Focus on psychomotor component (not talking about curriculum any longer)
- Conceptualize a validation study (or series of studies)
- Look at the model as a simulator
- Focus on the trunk of the Sweet Tree (i.e. focus on the lowest level of the chart below and not on a clinical procedure)

“Sweet* Tree”



* Adapted from Rob Sweet, MD, Professor of Urology, University Minnesota, 2010

Define the Research Questions

- Is there a core set of abilities that a robotic surgeon should have?
- Are FLS trained surgeons better on the robot?
- Are there core abilities (validated pre-screen) that predict technical proficiency differences?
- Are their fundamental abilities that impact the safety and effectiveness of a robotic surgeon?
- Are there certain abilities that improve the learning curve for robotic surgeons?
- Is FRS a valid assessment tool?
- Does FRS certification (standards we define) improve (translate to) the clinical performance? (i.e. surgeons trained in FLS made fewer and less severe errors)
- How should the face, content and construct validity and the proficiency level be defined for the benchmark while ensuring inter-rater reliability

Specific Questions/Hypotheses within Construct Validity

- Do expert robotic surgeons perform above the benchmark performance?
- Does the performance on the FRS model correlate with expertise?
- Novice surgeons do not reach the performance metrics (hypothesis)
- Does PGY level correlate with performance?
- Does previous laparoscopic experience correlate with performance?
- Does previous microsurgery experience correlate with performance?
- Does the type of specialty correlate with performance? (hopefully not)

Definition of Experts (and other groups):

- Set a minimum required criteria for expert robotic surgeons as a pre-screen
    - More than 5 cases a month
    - More than 50% of cases are completed robotically
    - Clinically active
    - Could have fellowship training in robotics
- Ask experts who have met the required minimum criteria to submit a video of a procedure
- Relatively straightforward multi-specialty tasks for assigning groups (based on expert performance)
- Train the raters of the videos in objective parameters that verify expertise in robotic surgery. This will ensure inter-rater reliability.
- Make sure the raters are blinded
- Focus on safety not “how I do it” (objective criteria)
- Groups will be based on performance metrics rather than PGY levels, or experience levels

What Will Be Measured?

List of validation types

- Face
- Content
- Construct
- Concurrent

- Predictive (not until we have a curriculum)

Reliability

- Inter-rater
- Test-retest

Other Parameters

- Usability
- Acceptability

Study Design

- Phase 1: Pilot at Florida Hospital Nicholson Center (logistics and refinements to model)
- Phase 2: Get face and content validity from the society leadership and boards
- Phase 3: Get face, content, and construct validity at test sites and society meetings
- Phase 4a: Get concurrent validity with video correlations
- Phase 4b: Predictive validity – full research study at 10 sites (IRB will be needed for every site)

Notes

- Curriculum validation will join in phase 4
- Train-the-trainer happens during phase 1-3 in preparation for phase 4

Pilot Study Protocol

- Settings
    - Set the robot to standardized motion scaling settings
    - The person being tested can change ergonomic related factors
    - The person being tested can warm up for a maximum of one minute after the docking and instrument insertion task
    - There was a discussion if the S, Si, or both could be used for testing purposes. It was determined that using just the Si would be best.
- Number people for the pilot study
    - 10 experts, 10 intermediate, 10 novices (total 30)
- Inclusion criteria:
    - Must be a surgeon or surgeon-in-training
    - Must have done the online course and passed the online test
    - If intermediate/expert, must have Si experience
- Exclusion criteria:
    - Non-surgeon
    - Didn't complete online course
    - Medical students
    - Failed the online test
    - Experienced only with only S model and no Si experience
- Dimitrios Stefanidis and Sarah Kim volunteered to develop the FRS cognitive test
    - This test will also solve the purpose of face validity of the cognitive portion

Questions/Purpose for the Pilot Study

1) How long does it take to complete the exercises?
2) Are there differences between skills when using the daVinci S vs. Si models?

    a. The individual participating in the pilot will be asked what model they normally use.
    b. All testing will be done on Si.
3) How many individuals are necessary to administer the final study?
4) Power analysis data to help inform the "n" and resources necessary for construct study (existing studies can inform effect size)
5) Calibrate global rating score
6) Inform the curriculum design
7) Inform "expertise"

Demographic Data Collected

1) Age
2) Gender
3) Specialty
4) Hand dominance
5) Number of robotic cases
6) Number of robotic cases per month
7) Number of robotic cases in last 6 months
8) Number of robotic cases in the last 6 months that have involved robotic suturing (stapling/clipping/etc)?
9) Length of time in years/months doing robotic surgery
10) Greatest familiarity of robotics system (Si/S/Standard)
11) Involvement in fellowship/resident training including robotics
12) Number of laparoscopic cases
13) Involvement in simulator training (robotics)
    a. Number of hours spent on robotic simulators in the last 6 months (0, 0-10, etc)?
    b. Reason for use robotic simulators (course/warm up/research)
    c. Simulator used most
14) Past/present experience with video games (quantify)
15) Number of years in surgical practice

Validity Questions

- The questions was raised whether face and content validity questions should be asked after completing all tasks, or after each individual task

Face Validity:

- Question 1: Does the model appear at face value to represent the skills necessary to safely perform basic robotic surgery?
- If content is valid, is it is representative of the skill?

Content

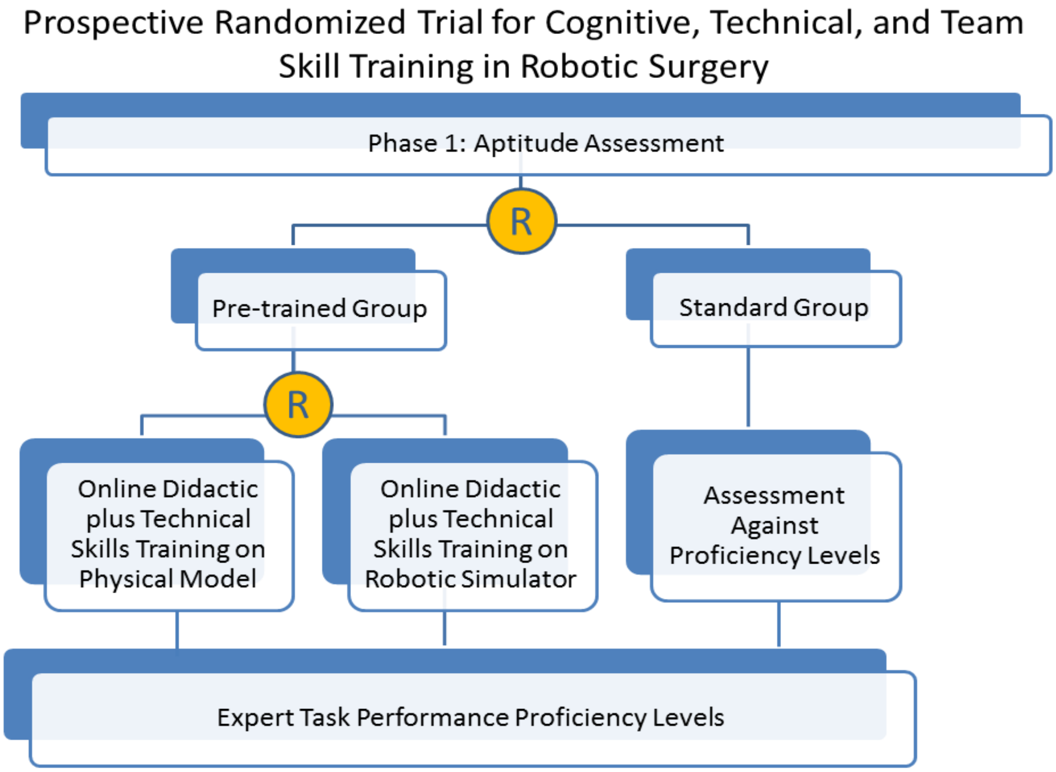
- Write questions that directly address whether each task accomplished the learning objectives that were defined
- Sanket Chauhan volunteered to develop the demographics questions
- Cyril Perrenot and Sara Kim volunteered to develop the face/content validity questions

Phase 4a Study

Concurrent study:

- The purpose is to calibrate the definition of expertise and support construct validity/linkage to Global Evaluation and Assessment of Robotic surgery Skills (GEARS)
- Include a specific number of experienced robotic surgeons (from previous phase)
    - They submit video (short segment).
    - They complete the questionnaire (aptitude test)
    - They perform tasks on simulator (dome)
    - The video is graded on GEARS
- Determine the correlation between simulator performance and GEARS score
- The actual procedure doesn't matter, but needs to have a "suturing" element
    - A 5 minute clip must be submitted
- Raters
    - Non-surgeon
    - Review two throws
    - There is a distinct starting and stopping point
    - Use GEARS evaluation

Study design review



Description of component of the study design

1) Phase 1: Aptitude test baseline assessment (all novices)
2) Randomize (R) main group

    a. Pre-trained group (see below)
    b. Standard group (same training as they would normally get today)
3) Randomize (R) Pre-trained group
    a. Online Didactic (Cognitive, Team Training) plus Technical Skills Training on physical model (dome)
    b. Online Didactic (Cognitive, Team Training) plus Technical Skills Training on robotic simulator
4) All three groups (2 pre-trained and one standard) must demonstrate performance proficiency levels

Criteria for institutions participating in Phase 4 studies

1) ACS/AEI accredited Institutes
2) Access to large number of subjects
3) Access to surgeons who are novice robotic surgeons with an interested in learning robotic surgery
    a. Minimum of seven robotic surgeons from at least 3 specialties involved
4) Support staff
    a. Staff familiar with behavior data collection and study design management
    b. Dedicated fellow/coordinator
    c. Staff acquainted with simulator and have on the spot Tech support
    d. Administrative support to help with IRB requirements (at least average IRB turn-around time)
5) Access to Si robot
6) Access to robotic simulator
7) Proven academic track record in surgical education record

OPEN FORUM NOTES

Following the main meeting, the floor was opened to everyone including industry to provide input and ask any questions. This was not part of the main meeting and had nothing to do with curriculum development, so there is no real or perceived conflict (bias) from industry.

General comments/questions included:

- A pilot study will be needed for the simulator too
- A simulator cannot do everything all at once as prescribed by the physical dome model
  - There are some limitations due to processing power
  - Tasks on a simulator, however, can be done individually and then the trainee would move on to the next task
- Need to collect some data for simulation in addition to the model
- There were doubts about the cost of the physical dome model being below $500
  - Need to determine what instruments and how many instruments are going to be used to determine costs
  - Remember, the main purpose of the physical dome model is for assessment, not training
  - The robotic simulators will probably be the most likely training model, along with lower fidelity physical models
- Materials on the currently conceived physical dome model can't simulate live tissues exactly, but can come close
- The goal of FRS is to be open source, but this might have issues from one model to another between companies. It is important to have tight standards to ensure validity.
- There may not be a need for a physical model in the future. The simulator is very robust.
- Are the simulation companies going to work in parallel to build simulated based training for high stakes examinations?

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FRS Psychomotor Dome:
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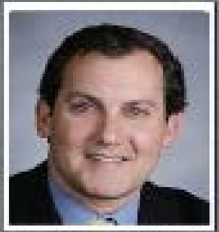
PSYCHOMOTOR SKILLS TASK GROUP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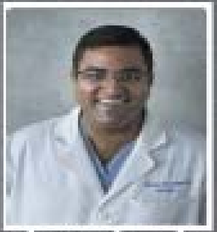
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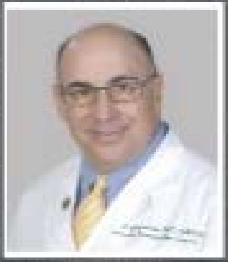
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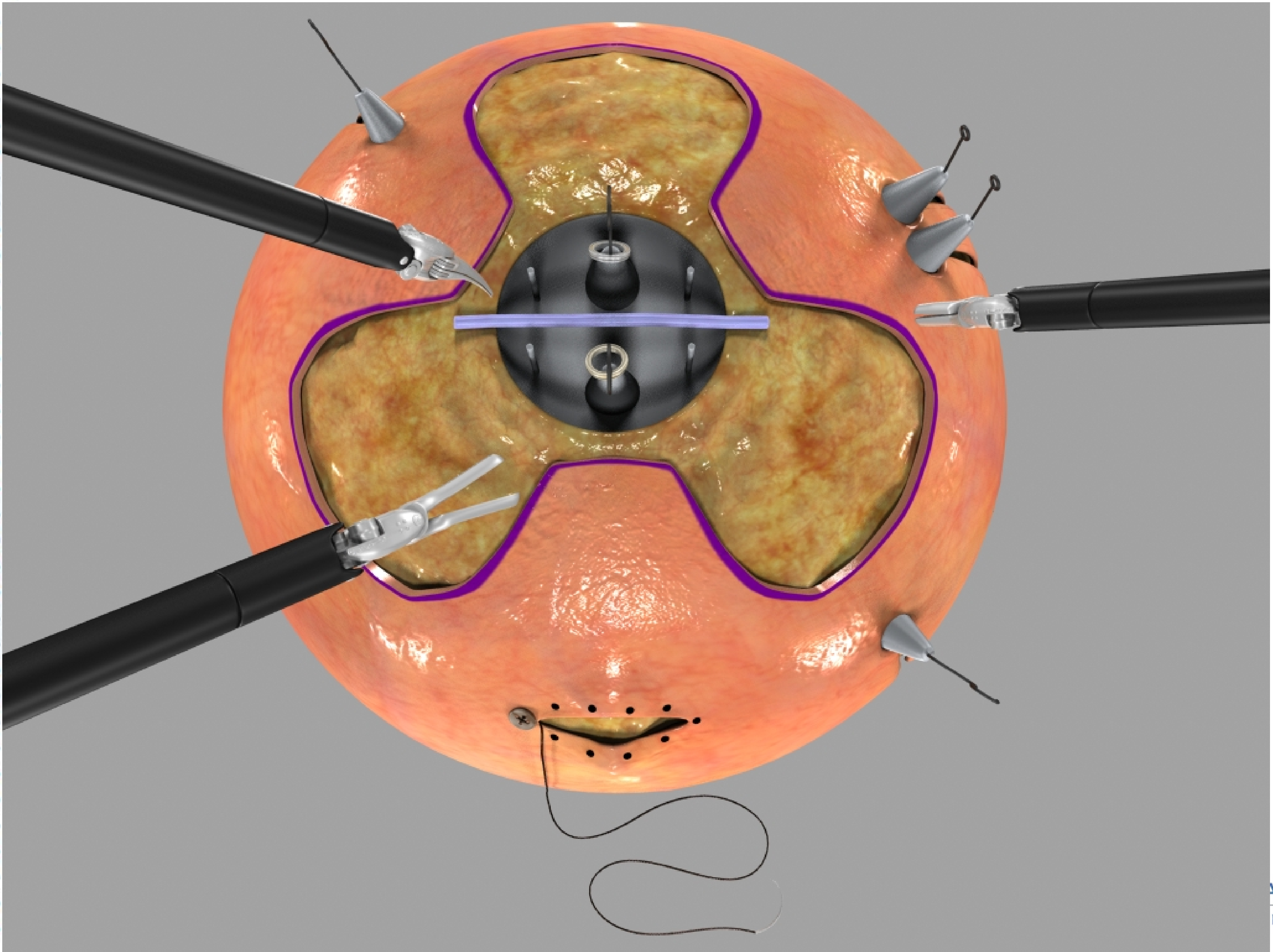
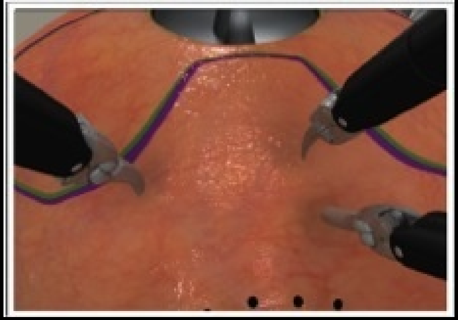
First Concept Design



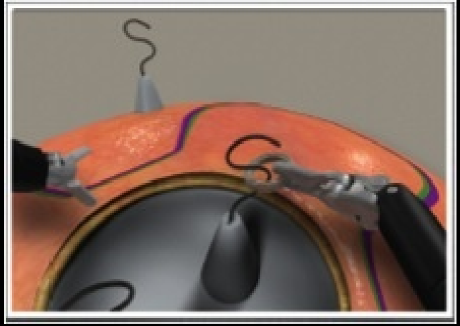
The FRS tasks

FRS TASKS

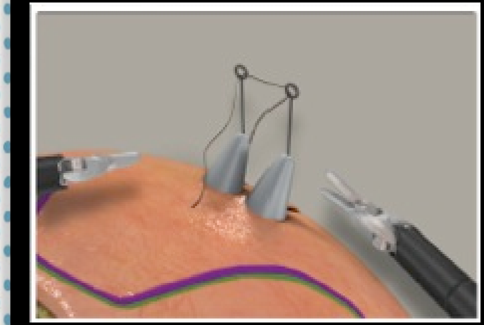
Task 1: Docking & instrument insertion



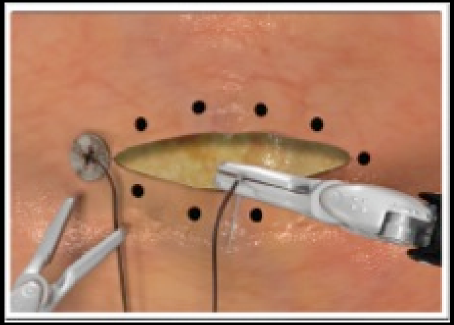
Task 2: Ring Tower transfer



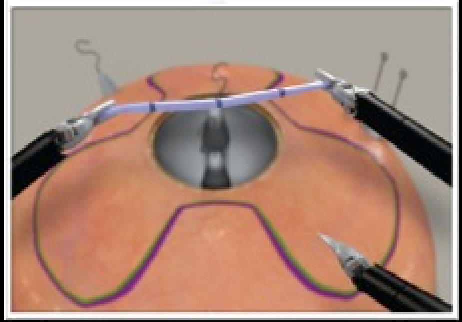
Task 3: Knot tying



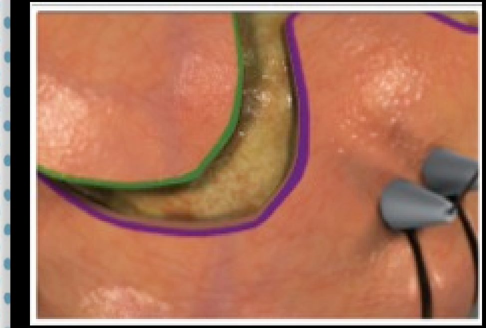
Task 4: Railroad Track



Task 5: UTSW 4th arm cutting

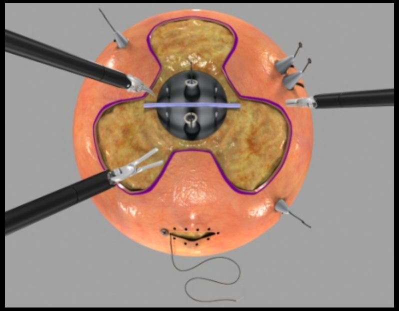


Task 6: Clover Leaf Dissection



Task 7: Vessel Energy Dissection

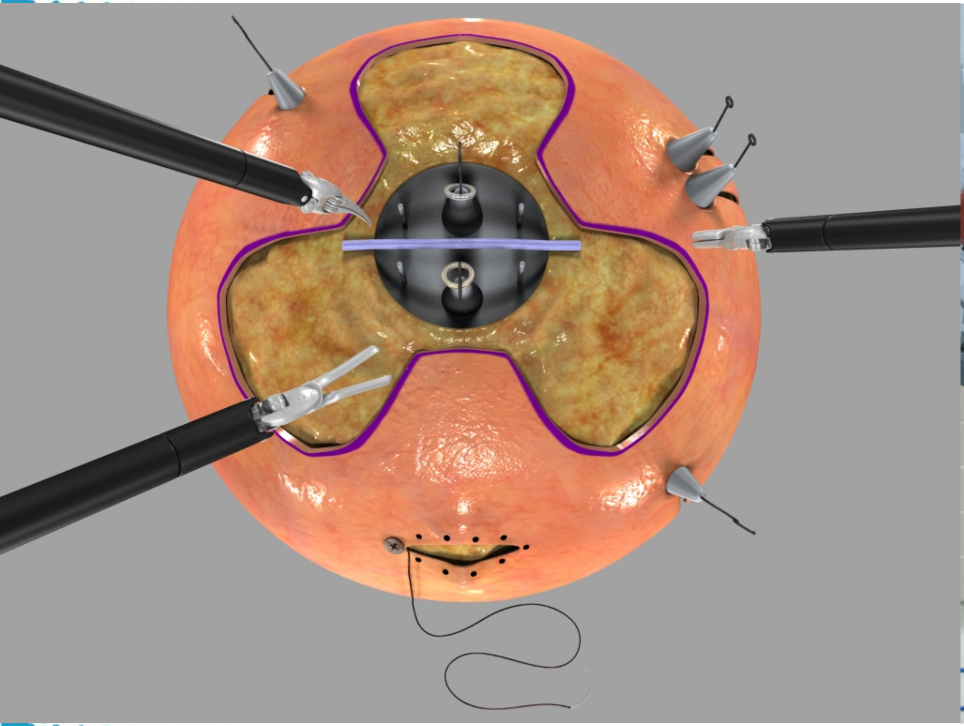
FRS DOME

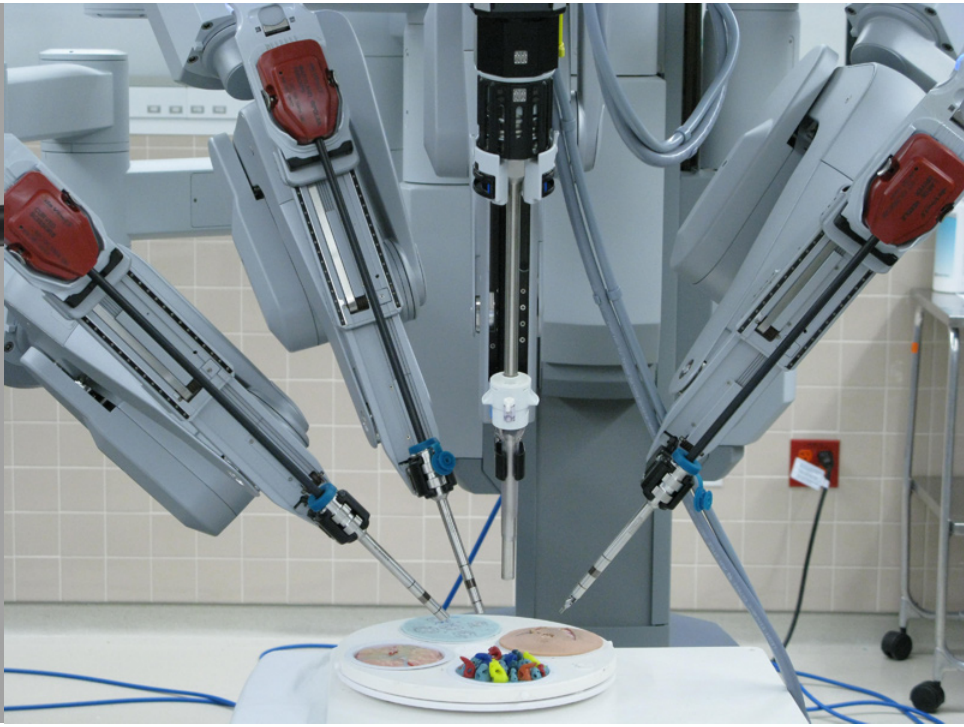


Will It Work Under the Robot?

Lessons Learned with Prototypes & Hands-on Testing.

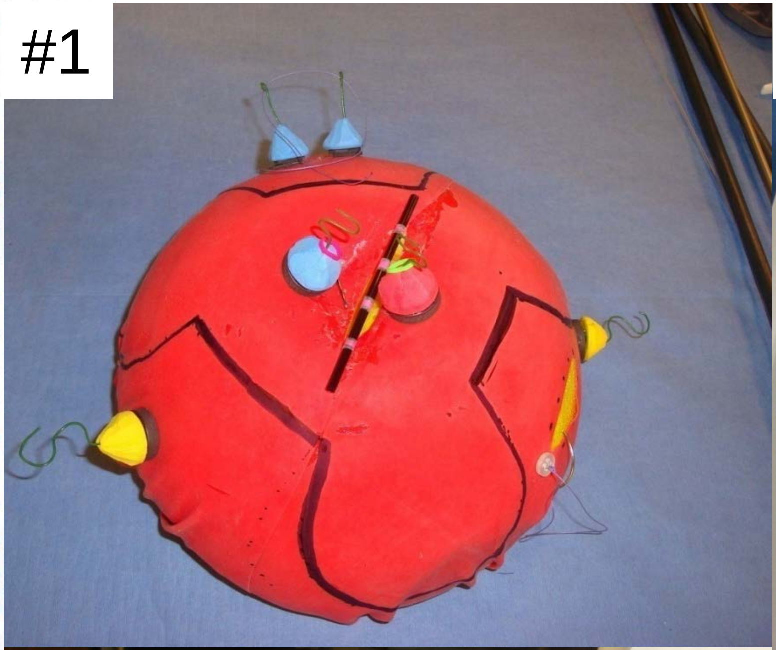
Primary Lesson: The design seems to be excellent overall.





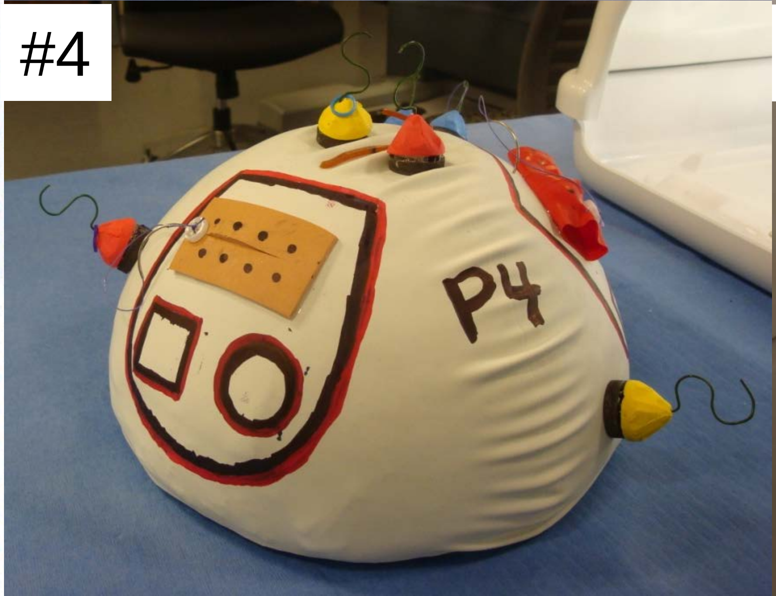
FHNC Prototypes

#1

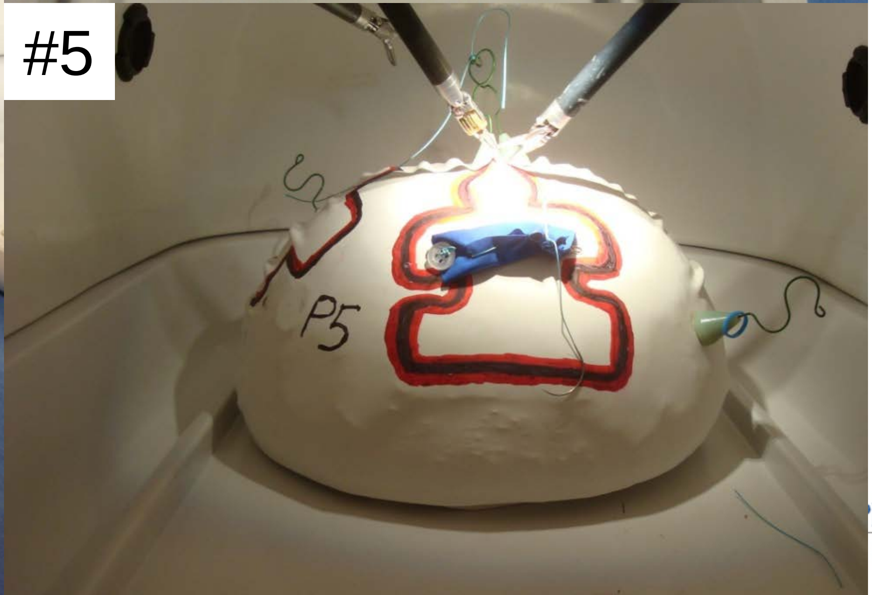


#3

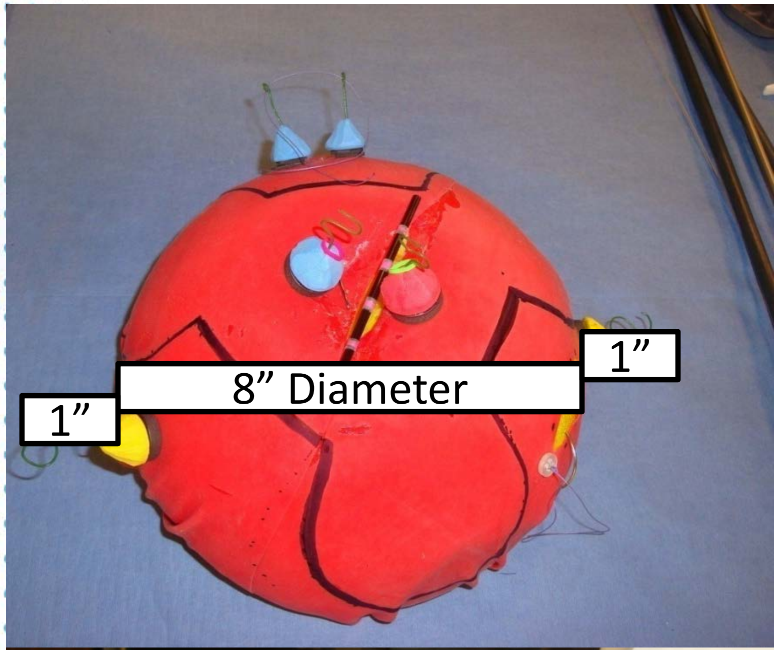
#4

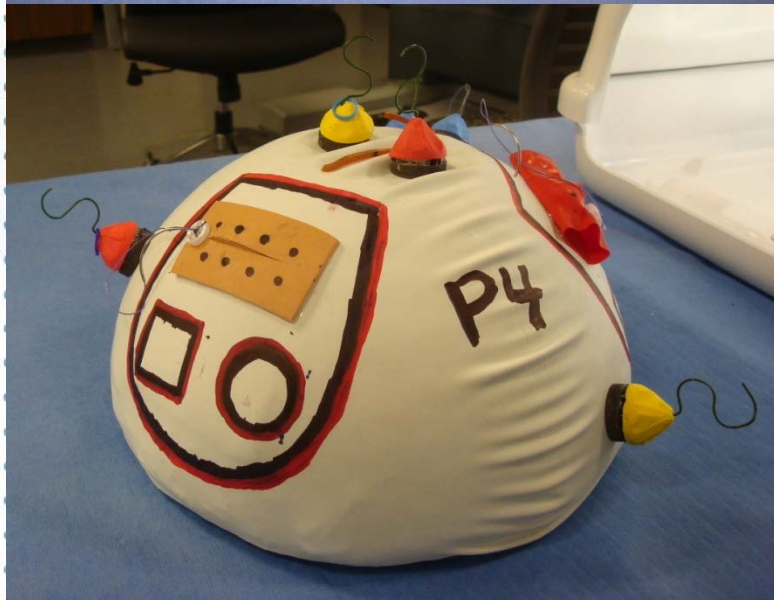


#5



Lesson 1: Size of Dome



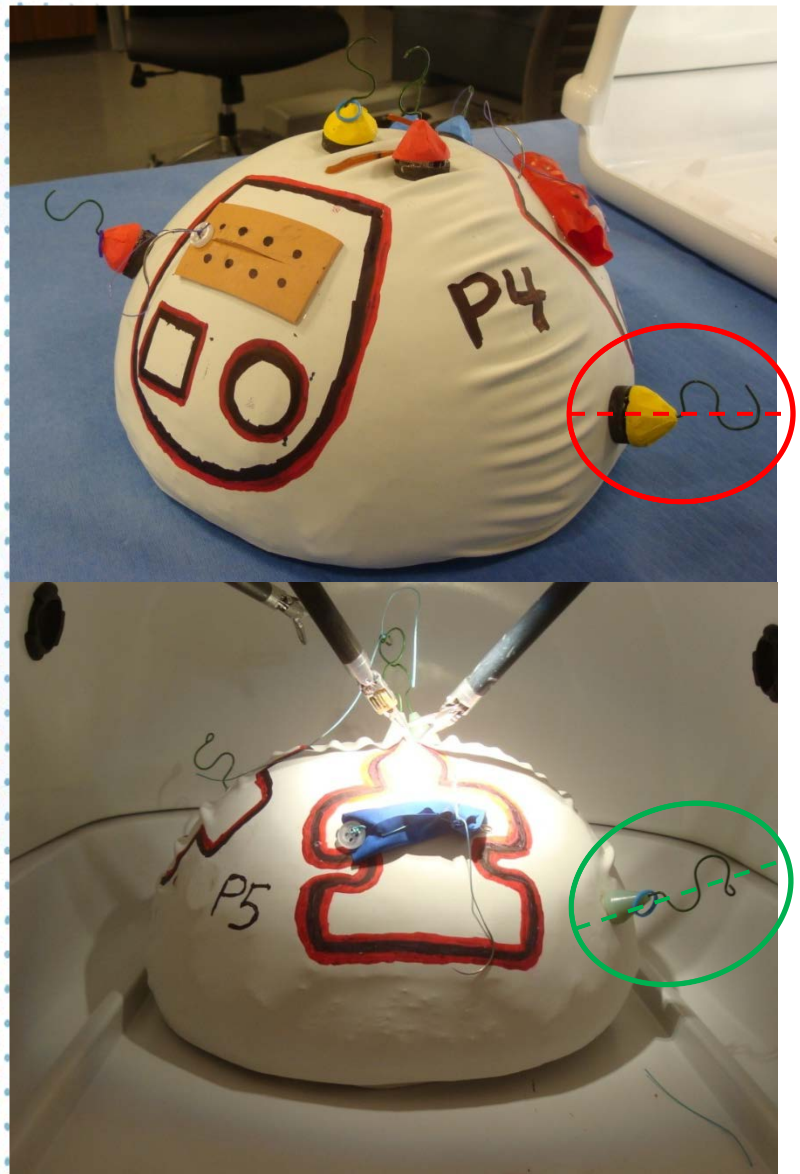


8” dome as originally specified is too big. Each tower adds approx 1” to create nearly 10” inches in travel distance.

The robot arms cannot complete both a close tower and a far tower with most docking positions.

We have created a 7” version for our next test and are considering as small as a 4” version.

Lesson 2: Tower Orientation

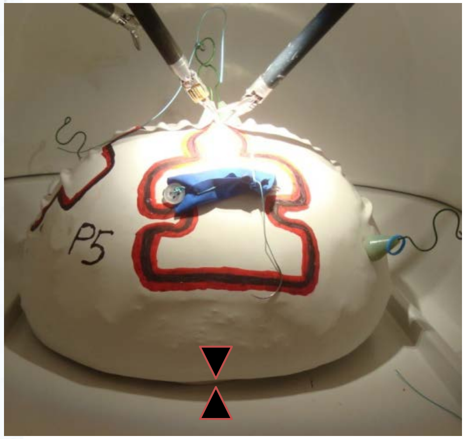


Tower at horizontal orientation allow gravity to interfere with successful exercise. Subjects correctly place rings on tower insulator, but gravity causes these to fall off onto the wire, scoring a mistake.

We moved the tower up to a positive angle so the rings stay where they are placed by the subject.

Lessons 3, 4, & 5: Standardize Positioning

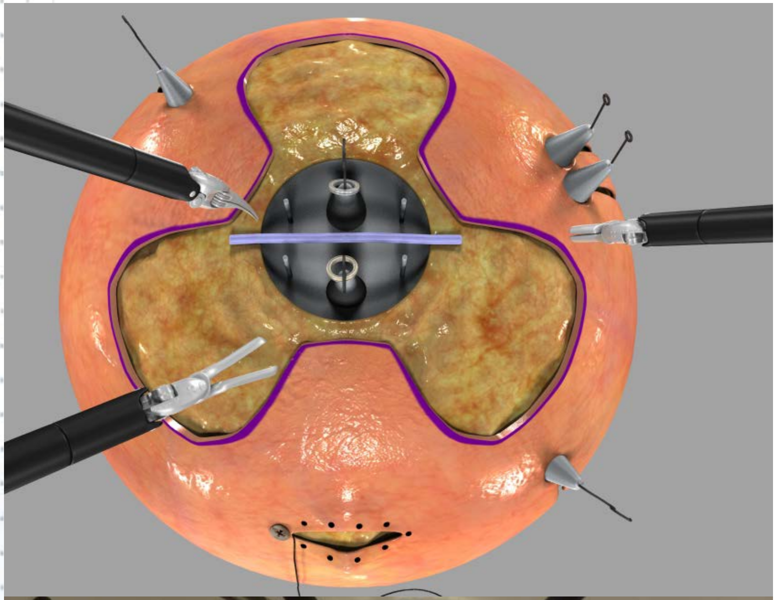
3 - Standard Robot Instrument Positions
- Add docking box with specified insertions.
- (Also support separate docking exercises)

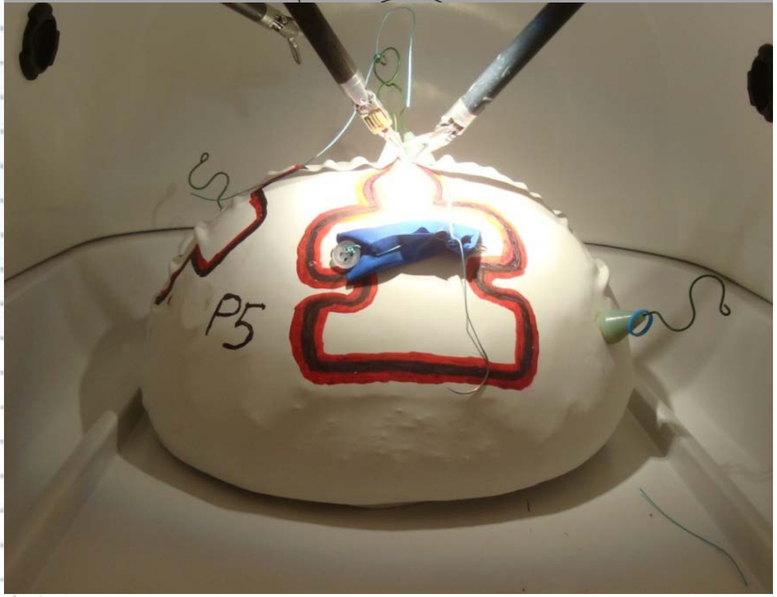


4- Standard Dome Position
- Alignment markers on box and dome.
- Velcro attachments on dome bottom.

5- Standard Tower Position/Orientation
- Alignment markers on tower and on dome.

Lesson 6: Surface Cut Shape



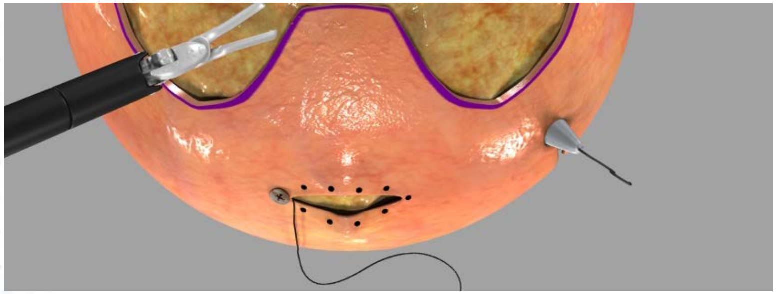


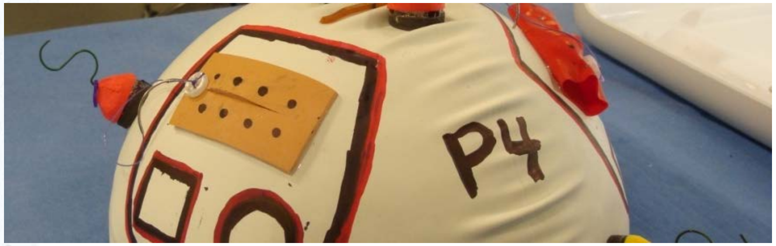
Unnecessarily large object to cut out. Long distance is one factor requiring a smaller dome. Shape is not challenging.

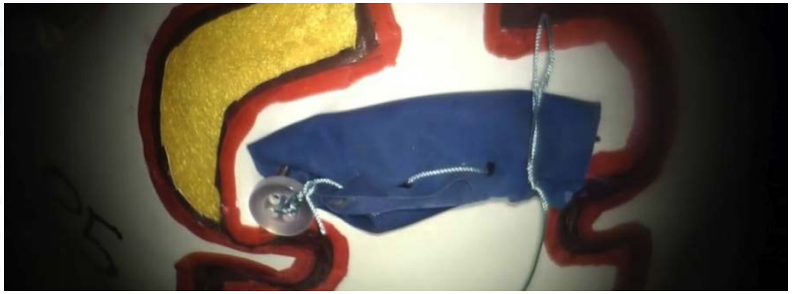
Recommend a more complex shape, using more wrist turns and changes in cutting direction.

Smaller shape allows multiple placements of the cutting exercise on the dome. Facilitates multi-use for practice sessions.

Lesson 7: Incision in Surface







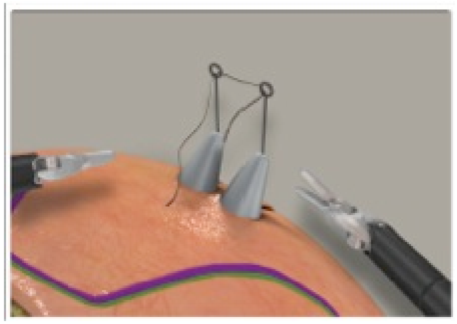
Placing incision in surface can lead to tears of the surface before and during the exercise. (Highly dependent on materials.)

It can also result in the subject sewing the surface layer to the underlying fatty tissue layer.

Recommend an attached suturing exercise

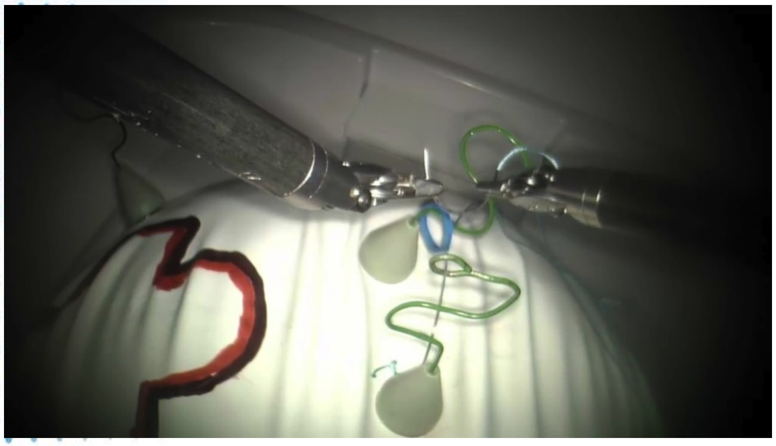
Exercise would also benefit from a knot at the end to hold tension on the stitch.

Lesson 8: Knot Tying



Specification calls for 8mm eyelets. These should be 2-3mm.

Knot tying exercise could also be combined with the S-tower exercises. It can be moved to top of dome. This would also facilitate multi-use dome.



Lesson 9: Energy Application

We have found one synthetic material that responds to energy, though we are not sure how accurate it is. Material is from Syndaver Inc.

The use of energy creates complications which should be discussed. (1) The availability of synthetic materials, (2) the additional equipment and cables to bring energy to the robot, (3) the difficulty of grounding the vessel embedded in the dome so that energy is effective, (4) the entire dome cannot be grounded.

Lesson 10: Multi-user Dome

If the cutting shape can be made smaller, it can appear multiple times around the dome.

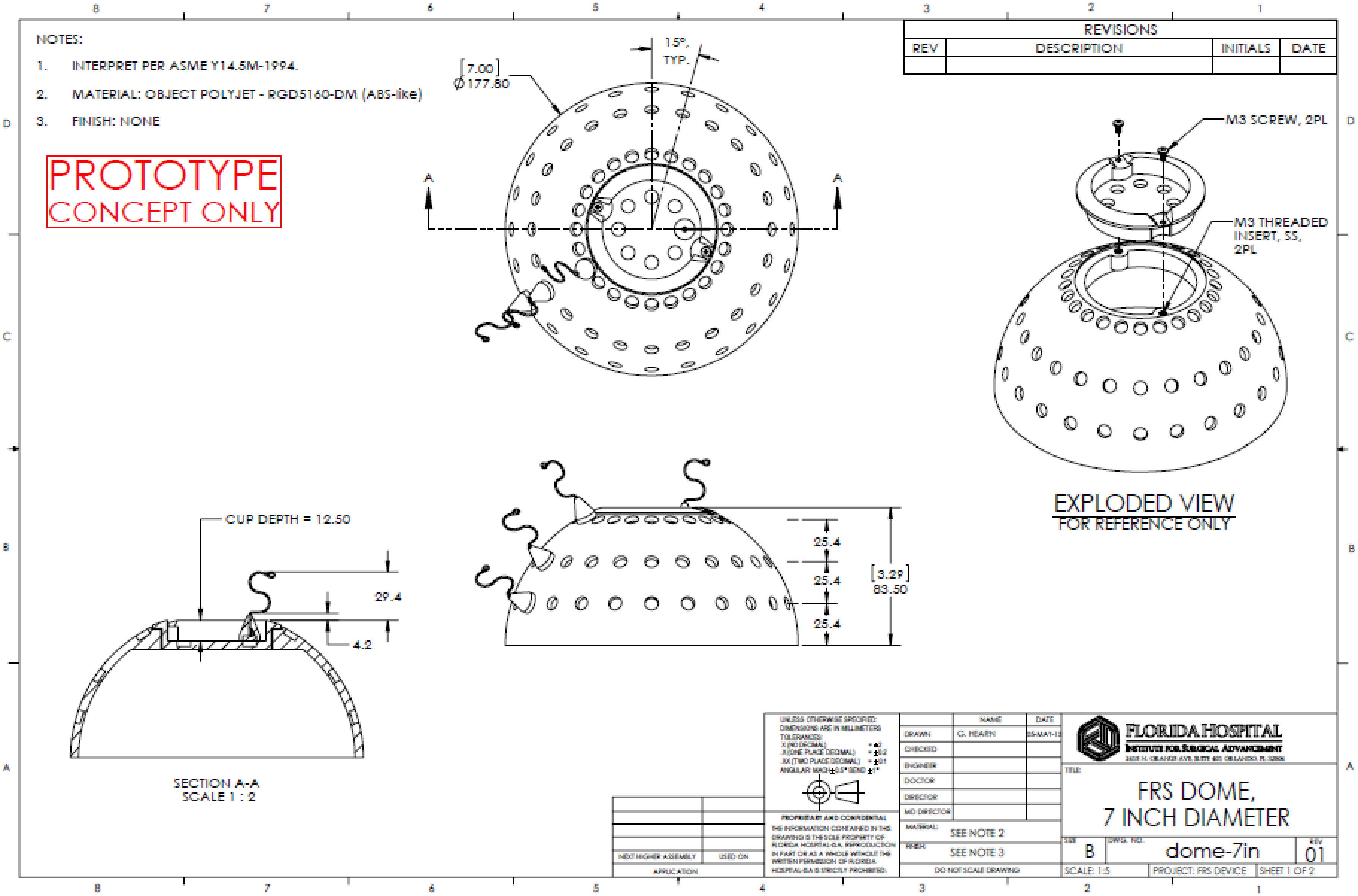
All destructive exercises can be replicated in each section.

The non-destructive exercises can be positioned to be accessible from all 3 user angles.

Design Lessons Learned

1. **Smaller Dome.** Too large for robot range of motion.
2. **Tower Orientation.** Positive incline angle to mitigate gravity.
3. **Instrument Position.** Need to standardize instrument position.
4. **Dome Position.** Need to standardize dome position.
5. **Tower Position.** Need to standardize tower position.
6. **Surface Cut Shape.** Unnecessarily large object. Difficult to reach extreme edges of dome. Difficult for simulator models.
7. **Incision.** Can lead to uncontrolled skin tears. Better if separate attached object.
8. **Knot Tying.** Smaller eyelets, longer suture, braided suture.
9. **Energy Application.** Materials that respond to energy. Complexity of including energy.
10. **Multi-Use.** Large enough to include multiple exercise instances.

3D Printer CAD Diagram



NOTES:

1. INTERPRET PER ASME Y14.5M-1994.
2. MATERIAL: OBJECT POLYJET - RGD5160-DM (ABS-like)
3. FINISH: NONE

PROTOTYPE
CONCEPT ONLY

REVISIONS			
REV	DESCRIPTION	INITIALS	DATE

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
TOLERANCES:
.X (NO DECIMAL) = ±1
.X (ONE PLACE DECIMAL) = ±0.2
.XX (TWO PLACE DECIMAL) = ±0.1
ANGULAR: MACH ±0.5° BEND ±1°

PROPRIETARY AND CONFIDENTIAL
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	NAME	DATE
DRAWN	G. HEARN	5-MAY-13
CHECKED		
ENGINEER		
DOCTOR		
DIRECTOR		
MD DIRECTOR		

MATERIAL: SEE NOTE 2
FINISH: SEE NOTE 3
DO NOT SCALE DRAWING

NEXT HIGHER ASSEMBLY | USED ON
APPLICATION

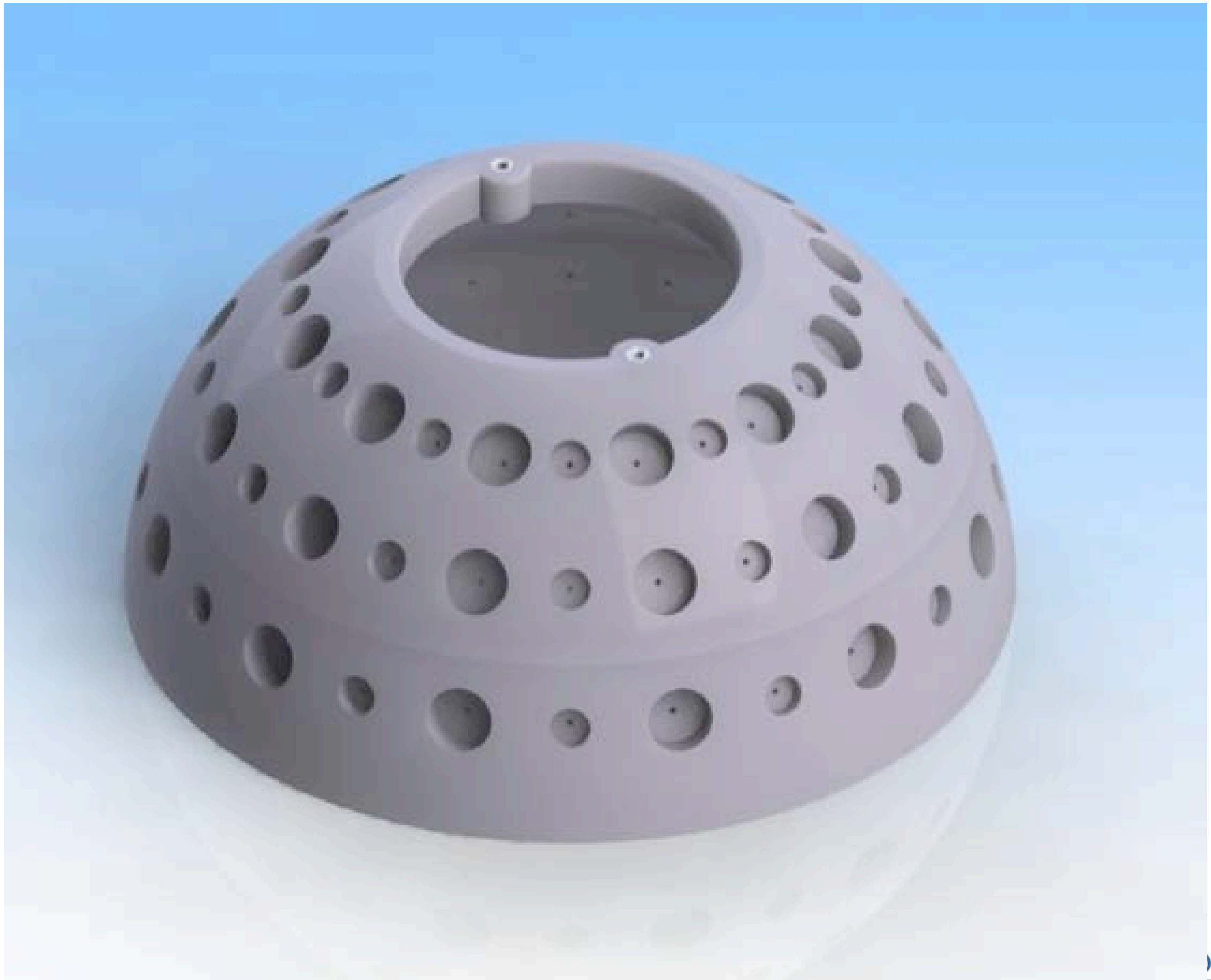
FLORIDA HOSPITAL
INSTITUTE FOR SURGICAL ADVANCEMENT

TITLE: FRS DOME,
7 INCH DIAMETER

SIZE: B
DWG. NO.: dome-7in
REV: 01
SCALE: 1:5
PROJECT: FRS DEVICE
SHEET 1 OF 2

Prototype Design with Dimple Field

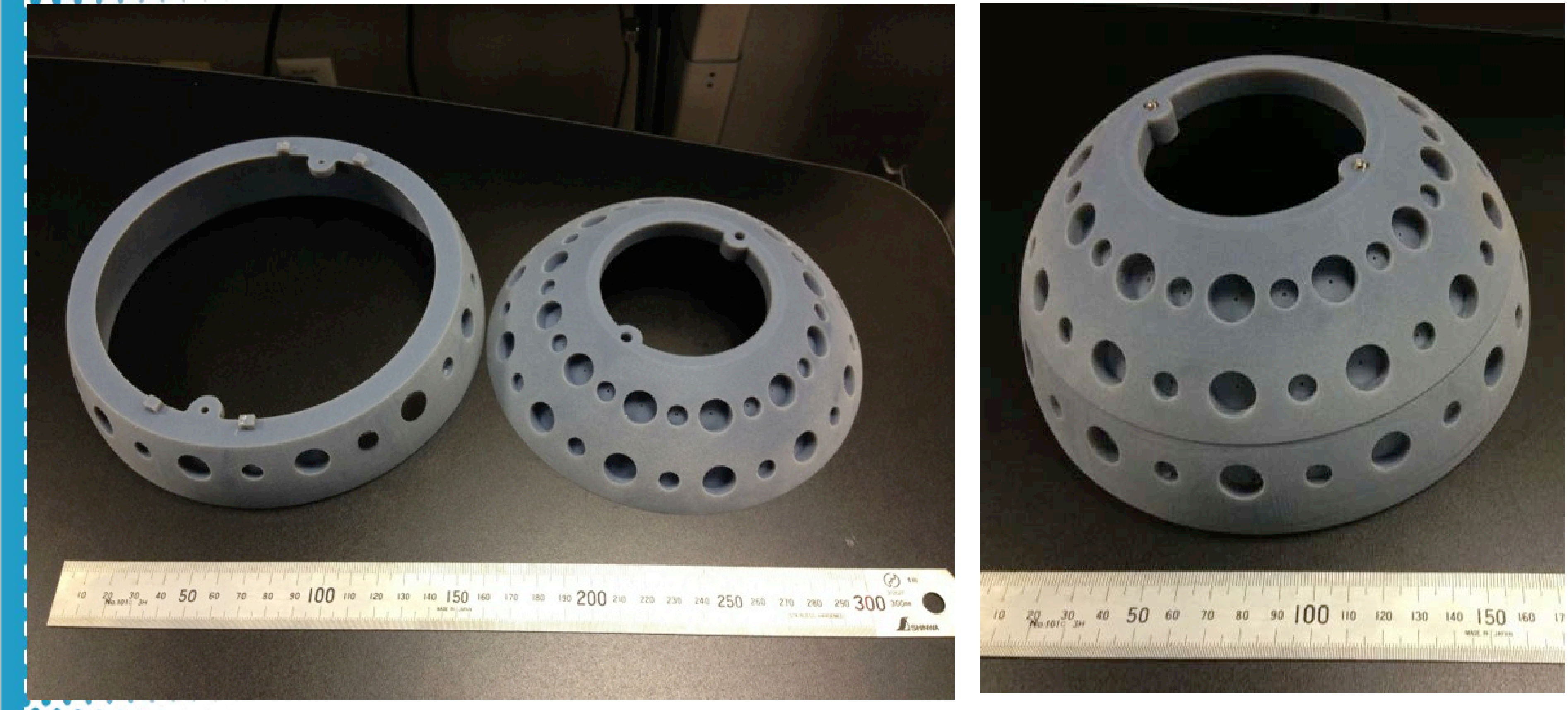
(top cap not shown)



First 3D Printed Dome

(top cap not shown)

Three piece design improves manufacturing.



Next Steps

- Presentation to Executive Committee.
- Presentation to FRS Psychomotor Team.
  - Respond to direction
- Additional testing with 3D printed version and new materials.
  - Price 3D printer production.
- Search for small lot manufacturer.
  - Need detailed written specification.

MEASURING COMMUNICATION LATENCY EFFECTS IN ROBOTIC TELESURGERY

US Army TATRC Grant # W81XWH-11-2-0158

Principal Investigator:

R.D. Smith, Florida Hospital Nicholson Center, Celebration, FL

August 30, 2013

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ABSTRACT

Robotic surgical technology was originally developed by the US Army and DARPA as a tool to enable telesurgery at a distance. The Intuitive da Vinci system now provides a robotic surgical tool in a traditional operating room. But research continues into the extension of this capability to patients that are remote from the surgeon's location. In this report we describe the interim results of experiments into the effects of communication latency on the safe execution of robotic telesurgeries.

The first experiment was carried out with the Mimic dV-Trainer, a simulator of the da Vinci robot, which was configured to insert defined levels of latency into the visual and command data streams between a surgeon and the operating field. Subjects were asked to perform four basic robotic surgical exercises. They were allowed to rehearse these in a zero latency environment and with a randomly assigned latency between 100ms and 1,000ms. Then each subject performed each exercise for measurement and analysis in our research.

This experiment measured the degradation of human surgical performance across a range of latency conditions. The data collected thus far suggests that more experienced surgeons are not more successful at managing the effects of latency than less experienced surgeons. For all levels of experience there appear to be three different performance areas under latency. Subjects with 100 to 200ms of latency generally show little or no degradation in performance. Subjects with 300 to 500ms of latency generally exhibit measurable and visible degradation in their performance, but many of these surgeons are able to cope with this effect by slowing their movements and being more deliberate in their actions. Subjects with 600 to 1,000ms almost universally exhibit an inability to perform the procedures effectively. The coping skills that worked at lower levels are no longer sufficient to compensate for latency at these higher levels.

The second experiment explored the actual latency levels for recorded video streams recorded on the da Vinci robot which was delivered from one campus of Florida Hospital to another within the Orlando metropolitan area. This streaming experiment was designed to closely replicate the largest data deliver category in the robotic system, the dual high definition video signals. The latency measured in this experiment consistently fell between 1ms and 5ms, which is significantly lower than a surgeon's ability to detect that latency in our first experiment.

Together these experiments suggest that telesurgery within well equipped hospital campuses may be possible right now. The data suggests that the latency that can be delivered by modern communication networks is well below the surgeons' level of perception. Though these experiments seem to indicate the possibility of telesurgery today, they were performed with surrogates of the real da Vinci robotic system. We believe it is important to configure the actual robot for a telesurgery experiment which we continue to pursue.

BACKGROUND

Robotic surgery has been the topic of science fiction and scientific research for decades. As early as 1942, Robert A. Heinlein published the story “Waldo” in *Astounding Science Fiction*. He described the use of gloves and a harness to allow Waldo Jones to control mechanical arms of any size from large industrial and construction equipment to miniature tools for electronic and surgical work. The Industrial Revolution gave us many of the tools needed to extend the capabilities of the human body, but the Information Age gave us the computerized control systems necessary to effectively manipulate these devices. Surgical robots are a marriage of mechanical, electrical, optical, and software systems that can empower a human surgeon to peer into a patient's body with magnified stereo vision, probe the internal organs, and perform effective surgery without fully opening the patient's body.

In 1985, the PUMA 560 was used to accurately place a needle for a brain biopsy using CT guidance (Kwoh et al, 1988). In 1988, the PROBOT at Imperial College London, was used to perform prostate surgery. In 1992, Integrated Surgical Systems introduced ROBODOC to mill precise fittings in the femur for hip replacement. Intuitive Surgical leveraged the research work of the Defense Advanced Research Projects Agency (DARPA) and used those technologies to create the da Vinci Surgical System which they introduced in 1997. Computer Motion followed a similar path and fielded the AESOP and ZEUS robotic systems (Figure 1), which were later acquired by Intuitive Surgical (Satava, 1998; FDA, 2005).

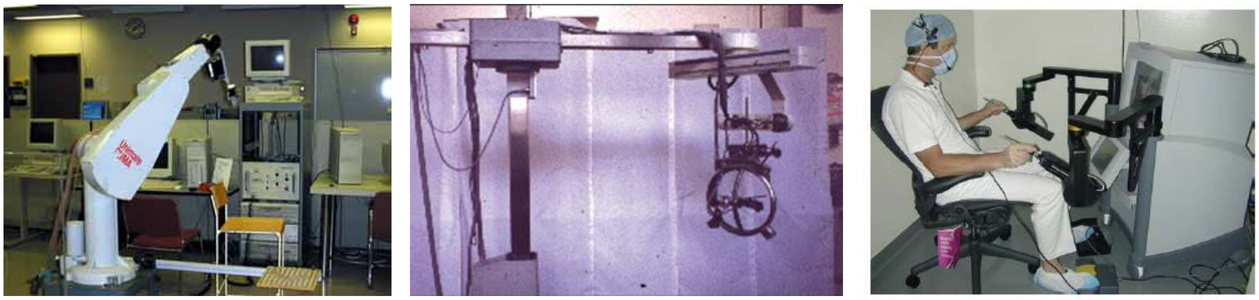


Figure 1. Puma, PROBOT, and ZEUS Surgical Research Robots

DA VINCI ROBOT

Intuitive Surgical's da Vinci robot is currently the only FDA approved device for robotic surgery on human patients. This system senses the surgeon's hand movements and translates them into scaled-down micro-movements to manipulate tiny instruments inside the body. It also detects and filters out any tremors in the hand movements, so that they are not expressed robotically. The camera used in the system provides a true stereoscopic picture transmitted to and viewed through a surgeon's console (Figure 2).

Devices like the Zeus and the da Vinci opened the door for the realization of surgery-at-a-distance, a.k.a. telesurgery, in which a surgeon is able to extend his reach and perform surgical procedures at a significant distance from the patient. This capability has been demonstrated under unique conditions by multiple experiments (Himpens, 1998; Janetschek, 1998; Fabrizio, 2000; Sterbis, 2007). Our research project at the Florida Hospital Nicholson Center is demonstrating the maturity of the existing telecommunication infrastructure within a hospital system to support daily, on-demand telesurgery right now. Our experiments are based on the da Vinci surgical robot (Intuitive Surgical, Inc.) and the dV-Trainer simulator (Mimic Technologies, Inc.)

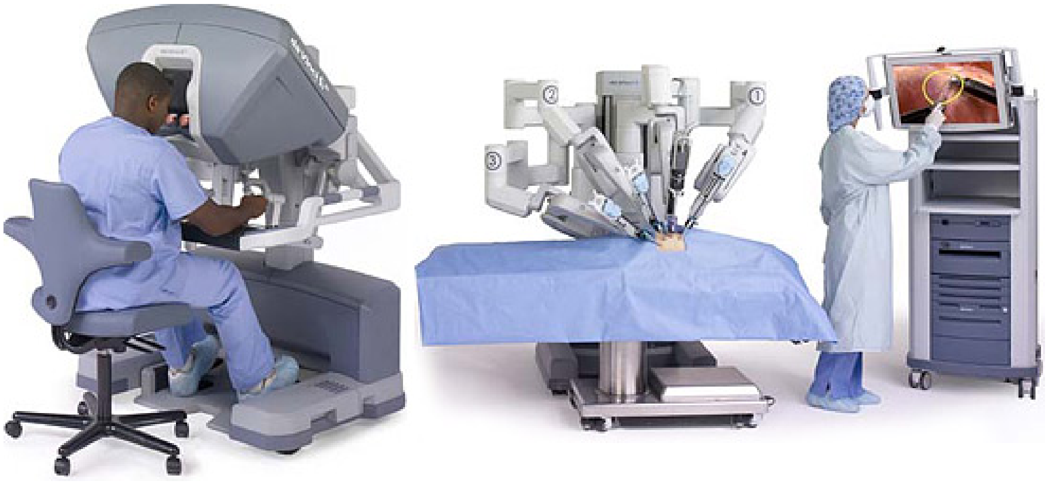


Figure 2. da Vinci Surgical Robot (Intuitive Surgical, Inc.)

There are four data streams of interest within the da Vinci system (Figure 3). This data is exchanged between the independent surgeon's operating console and the robotic patient cart with the manipulating arms. All of this data flows through the "vision cart" which contains the necessary computer and communication equipment to tie all three parts of the system together.

The most visible data streams are the dual high definition video images that come from the patient cart, relayed through the vision cart, and delivered t the surgeon's console for display to the human operator (surgeon). This data consumes the largest amount of the communication bandwidth in the system.

Because the surgeon is positioned with his/her head in the console, it could be difficult for him/her to communicate with the rest of the surgical team. Therefore, the console contains a microphone which captures the surgeon's verbal communication and relays that to the surgical team via speakers mounted on the monitor attached to the vision cart. Similarly, there is a microphone on the same monitor which captures the audio of the surgical team and relays it to speakers mounted in the surgeon's console next to his ears. These two audio exchange data streams require much less bandwidth than the dual video streams.

Finally, there is the unseen, but essential robot command data stream. When the surgeon moves the controls or uses any of the pedals on the surgeon's console, this generates a stream of movement commands for the robotic manipulators attached to the patient cart. These commands result in all of the kinetic actions taken by the robot to perform the surgery. These commands represent a small volume of network traffic compared to the video streams, but they are the most essential surgical data within the entire system.

The success of any telesurgery system will be driven by the quality of delivery of these data streams, most essentially the robot commands, followed by the video streams. Audio data is important, but alternatives exist for exchanging this information between the members of the surgical team.

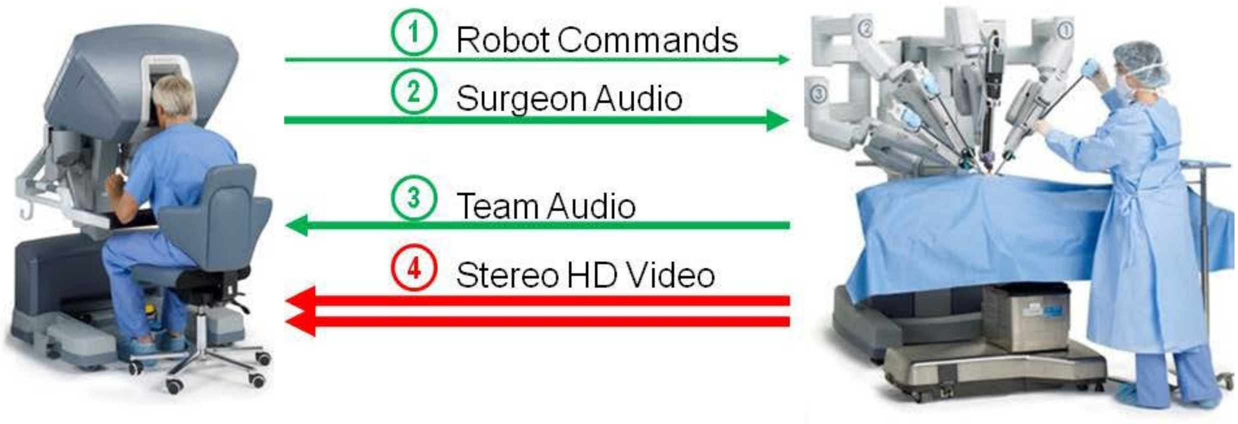


Figure 3. Data transfer between the physician console and patient-side equipment.

PART 1: SURGEON MANAGEMENT OF LATENCY EFFECTS

We explore the effects of communication latency on surgeon performance. This latency effect is created using the dV-Trainer simulator (Figure 4) of the da Vinci surgical robot (Hung, 2011; Kennedy 2009). The simulator allows the insertion of specific levels of controlled latency so that the user's physical movements are not manifest by the simulated instruments until after the defined latency period has elapsed.

Figure 4. dV-Trainer Simulator (Mimic Technologies, Inc.)

During actual telesurgery, the messages sent between the surgeon's machine and the remote patient station will be delayed due to the speed of light and the message routing that occurs on the internet. Determining how much latency can be safely tolerated in surgery is an important question (Anvari, 2005 and 2007). This experiment hypothesizes that there are two distinct thresholds of performance under increasing latency (Figure 5). The first is the level of latency at which a surgeon can first detect that his or her movements are being affected by the communication link. Any communication latency lower than this level is imperceptible and potentially non-invasive to the surgical procedure. Hence, if such levels can be achieved in the real world, then telesurgery may be safe for human surgery right now. The second level is the point at which the surgeon's performance is degraded to the point that the surgery cannot be performed safely (Marescaux, 2002; Lum, 2009). This level is identified through both simulator measured performance and the expert opinion of the surgeon. Between the first and second thresholds, a surgeon may be able to successfully control the effects of latency and perform a safe and successful procedure. Beyond the second threshold, telesurgery would be considered unsafe with the available equipment.

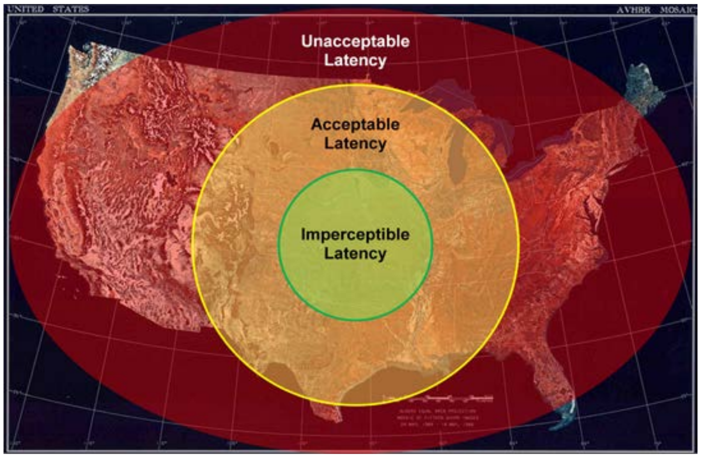
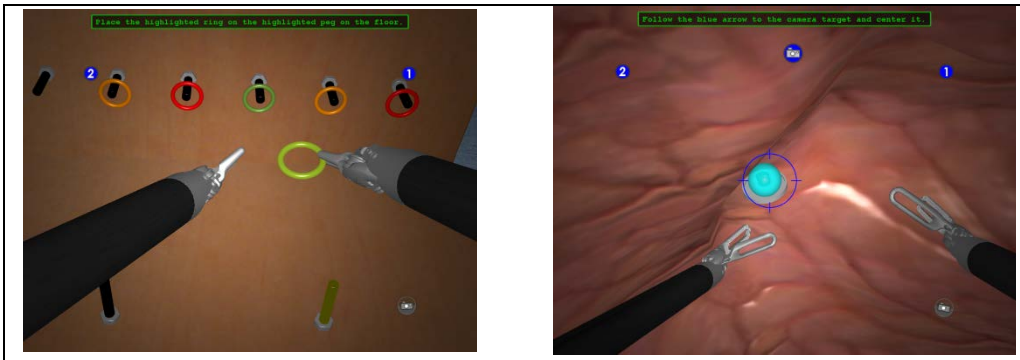


Figure 5. Conceptual Diagram of Communication Latency Thresholds.

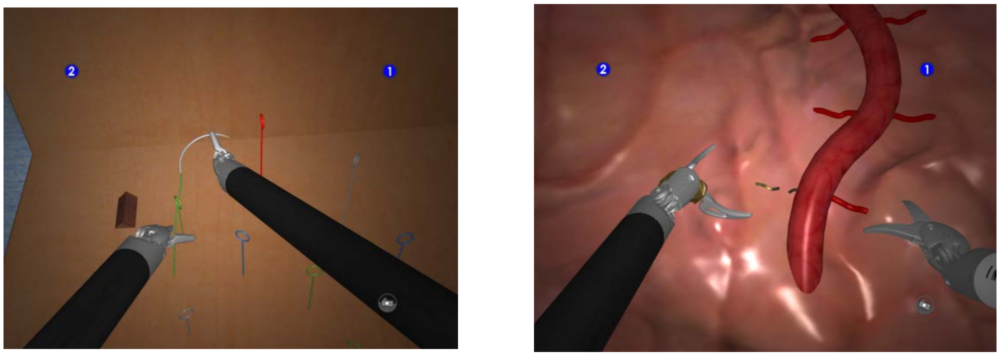
We further hypothesize that more experienced surgeons will be more successful at managing the effects of latency and would be the best practitioners for this extension of robotic surgery. If this hypothesis is correct, then surgeons with more experience should achieve higher scores and shorter completion times in the simulation experiment that we are performing.

In our first experiment, subjects performed the four simulated surgical skills exercises shown in Figure 6. These represent many of the core skills that are required in robotic surgery. Each subject performed each exercise three times. First, the subject was given an opportunity to perform the task without any imposed latency. This baseline insured that they were able to successfully operate the controls under normal conditions. Second, they were allowed to perform each of the exercises at their randomly assigned latency level. These repetitions provided the learning necessary to achieve a sustained level of proficiency within a latent environment (Rayman et al 2006). Finally, each subject repeated all four exercises at the same randomly assigned latency level and their performance was measured for analysis in the study.



(a) Pegboard 1

(b) Camera Targeting



(c) Thread the Rings

(d) Energy Dissection

Figure 6. Simulated Surgical Skills Tasks

A single, constant latency level between 100 milliseconds (ms) and 1,000ms at increments of 100ms was randomly assigned to each subject (e.g. 100ms, 200ms, 300ms. 400ms, etc.). A proctor was available to instruct subjects in the use of the equipment and to guide them through the curriculum of the protocol. However, this proctor was not allowed to give suggestions on performance of the exercises or to tell the subject the specific level of latency that they were experiencing.

Data Collection

Experimental data was collected by the simulator software and manually via questionnaires. Research proctors administered a Pre-Test questionnaire on the level of surgical experience and related activities of the subject. All personal and performance data was anonymized to insure that the identity of the subject could not be linked to the data that was collected. The proctors also administered a Post-Test questionnaire at the conclusion of each of the skills exercises during the final performance stage. The simulator software automatically collected multiple measures of the subject's performance. This provided data for all subjects at zero latency, during their familiarization stage with latency, and during the final stage which is the focus of the analysis. This data will allow us to perform multiple analyses of the skills of robotic surgeons both with and without communication latency.

Pre-Test Questionnaire

The Pre-Test questionnaire identified multiple items of demographic, experience, and practice data on the subjects. These included: age, gender, dominant hand, surgical status, years of surgical experience, years of laparoscopic experience, years of robotic experience, number of weekly procedures in laparoscopy and robotics, and experience with laparoscopic and robotic simulators, as well as with video games and musical instruments. Additional questions captured their opinion on the use of simulation in surgical education and certification.

This data was then matched to the data from their performance in the simulator.

Simulator Performance

During the experiment, the simulator itself collected a number of data points on each subject's performance. These included: time to complete, overall score, total hand motion in centimeters, master working space, number of instrument collisions, number of items dropped, excessive instrument force, distance instruments out of view, incorrect use of electrical energy, simulated blood loss, and number of broken blood vessels.

Post-Test Questionnaire

When the subjects completed their final repetition of each of the four skills exercises, the proctor administered a post-test questionnaire which asked the subject for their opinion on the stress induced by the simulation with latency. This included measures of the mental and physical demands of the task, the pace of the task, their opinion on their level of success, the amount of effort expended, the level of mental discouragement experienced, and their perceived complexity of the exercise.

Results

Of the 107 subjects who began the experiment, several were unable to complete all of the tasks due to the limited amount of time that they could devote to the experiment. Others found the experiment too taxing and elected to terminate their participation before completion. As a result, we collected complete data sets without latency on 92 subjects.

This data was analyzed to determine the level of correlation between the subjects' experience and their performance both with and without latency. For the non-latency sample size of 92 and $\alpha=0.05$, the Pearson Product Moment

Correlation (PPMC) value is 0.205. This means that for a correlation coefficient of two variables in this size of sample to be significant, it must be larger than the PPMC value.

Table 1. Correlation Coefficients without Latency

Exercise	Overall Score	Time Complete
Pegboard 1	0.141	-0.110
Camera Targeting	0.201	-0.173
Thread the Rings	0.156	-0.225
Energy Dissection	0.267	-0.217

In an environment without any latency imposed we found a positive correlation between years of robotic experience and overall performance score, as well as a negative correlation between experience and the total time to complete the exercise (Table 1). Without latency, a relationship can be seen for both overall performance score and time to complete the exercise (Figures 7 & 8). Both of these indicate that more experience leads to better performance in the simulator. Though this correlation is consistently supportive that surgeons with more experience perform non-latency exercises better than those with less experience, the magnitude of these correlations is not sufficient to differentiate this trend from the random effects due to other causes.

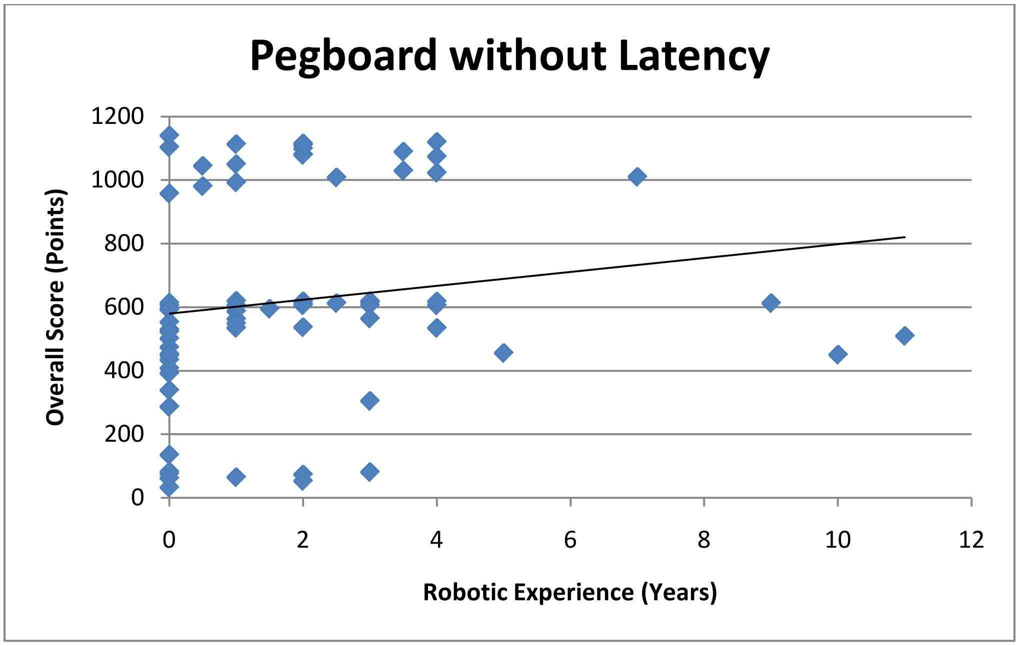


Figure 7. Correlation between Robotic Experience and Overall Score for the Peg Board exercise without communication latency.

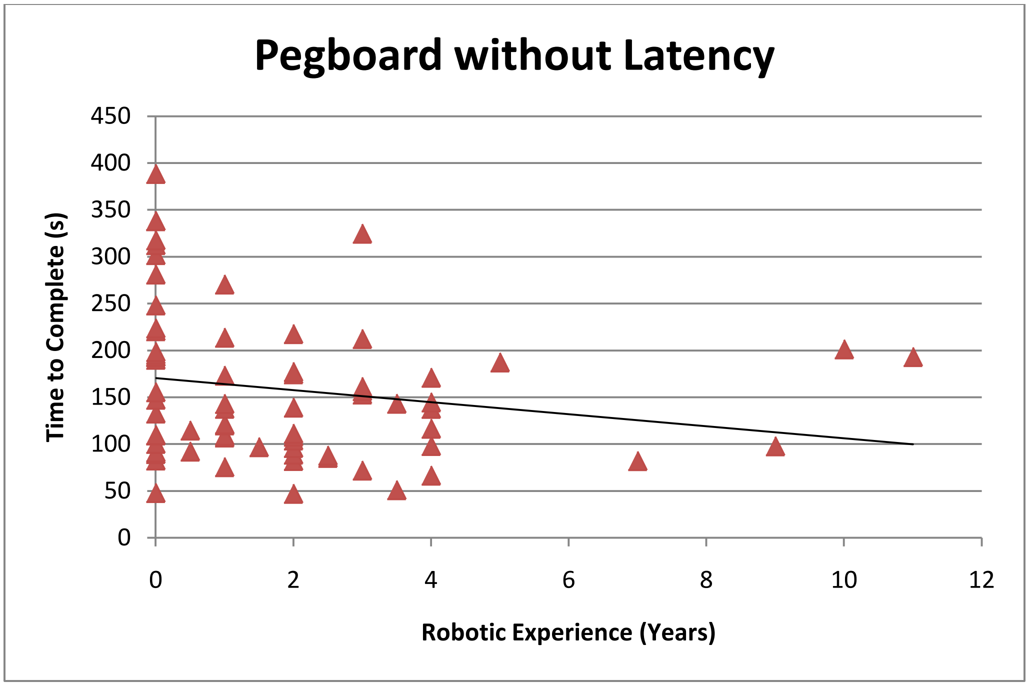


Figure 8. Correlation between Robotic Experience and Time to Complete for the Peg Board exercise without communication latency.

When latency is added, a simple correlation coefficient is not sufficient for analyzing the effect of robotic experience on performance. Each subject received a randomly assigned latency, of which there were 10 possibilities. Within the current sample, only 71 subjects completed the exercises with latency.

The scatterplots shown in Figure 9 and 10 illustrate the relationships between subjects who received the same latency values. Each data point is a different subject. The points connected by a line all shared the same latency level. Therefore, if years of experience in robotic surgery made a significant contribution to the surgeons' abilities to manage latency, then the lines on the "Overall Score" (Figure 9) would have some consistency increasing from left to right on the plot. Similarly, they would show some consistency decreasing on the "Time to Complete" plot. Neither of these trends appears to be significant in the scatter plots. There are a few cases in which an improved score or a lower time exists. But there are an equal number of trends which are the reverse of that, as well as a large number that zigzag in all directions.

These graphs indicate that, in general, surgeon experience does not contribute to the ability to manage latency in telesurgery,

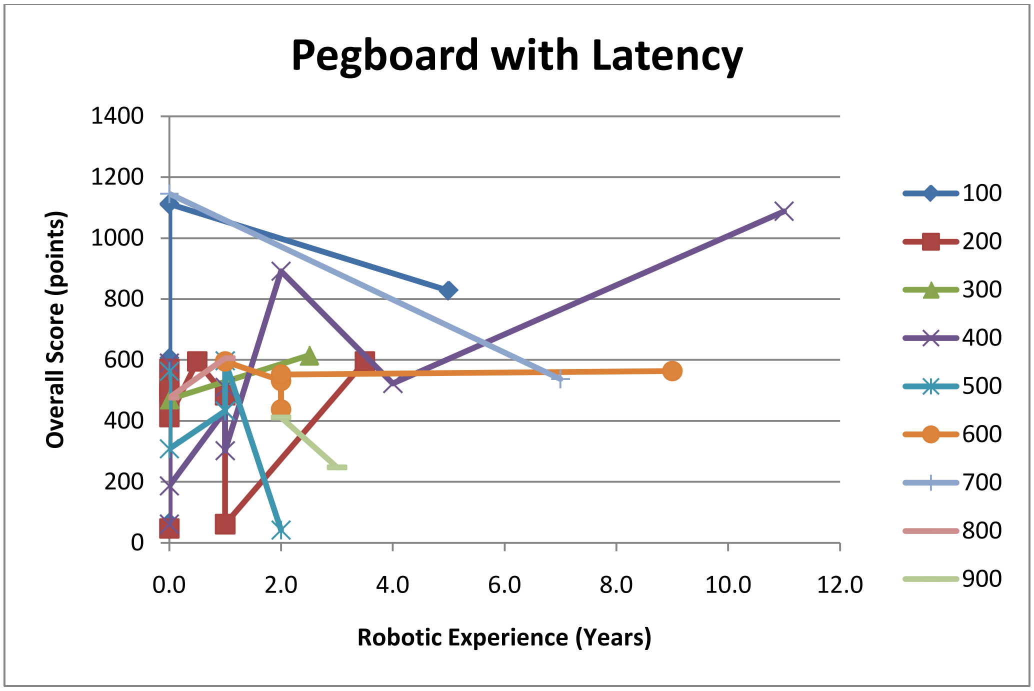


Figure 9. Correlation between Robotic Experience and Overall Score for the Peg Board exercise with various communication latencies.

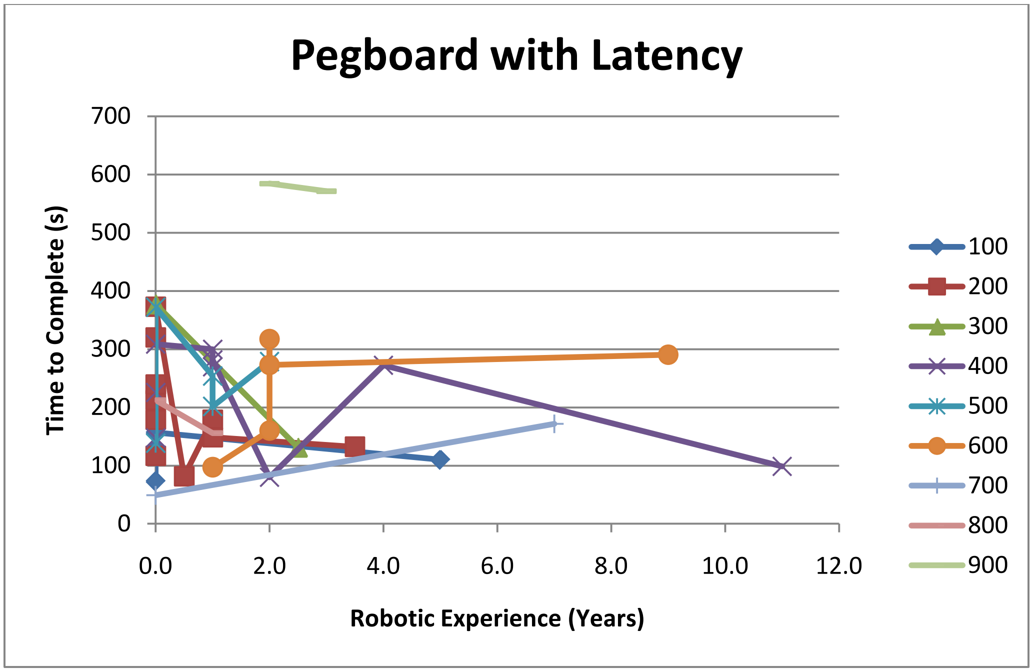


Figure 10. Correlation between Robotic Experience and Time to Complete for the Peg Board exercise with various communication latencies.

The data suggests that surgeons who have more experience in robotic surgery are not better equipped to self-manage the challenges presented by communication latency in telesurgery. Subjects with little experience are as likely to successfully manage latency as are surgeons with more experience.

This same trend holds when comparing independent variables like total surgical experience and laparoscopic experience to the scores achieved in the simulator with latency.

Latency Management

We found that the majority of surgeons could successfully manage both 100ms and 200ms of latency to a degree that allowed them to achieve comparable scores in the simulator to their performance with no latency. Further, we observed that in the range between 300ms and 500ms, most surgeons showed measurable signs of degradation of performance. However, many surgeons were able to compensate successfully at these levels. At latency levels between 600ms and 1,000ms, nearly all surgeons lost the ability to effectively control the instruments to complete the assigned exercise. These results are summarized in Table 2.

Table 2. Summary of Telesurgery Latency Experiments

Latency Level	Conclusion	Comments
100ms	Generally Safe	Most subjects demonstrate an ability to successfully manage this level of latency without specialized training.
200ms		
300ms	Physician Dependent	Some surgeons manage these levels of latency safely, while others cannot. This ability does not correlate with years of experience or number of robotic cases performed. We cannot identify the factor that predicts performance. With training and experience in a latent environment, many surgeons can learn to perform successfully at these levels.
400ms		
500ms		
600ms	Generally Unsafe	Nearly all surgeons demonstrate performance which is uncontrolled and often fail to complete the exercises. Only a small number of rare individuals were able to manage latency at these levels to successfully complete an exercise. Surgeons can learn to improve their performance at these levels, but results are difficult to predict.
700ms		
800ms		
900ms		
1000ms		

Conclusions

The lack of correlation between experience and telesurgical performance under latency refutes our original hypothesis that a more experienced surgeon would more successfully manage the effects of latency. This negative finding has led to speculation on the cause of these results. Several may be possible, but each will require additional experimentation. First, experienced surgeons may be very talented, but fixed in their methods of performing surgery. This may lead them to perform poorly under latency because it is difficult for them to modify their behaviors, where inexperienced surgeons are less ingrained and more adaptable to the situation. Second, since the simulator is a computer-generated virtual environment, it is possible that surgeons who have more experience in simulators, virtual worlds, and computer games may have developed a proficiency for solving problems in this kind of environment. They may also have experienced latency in those environments and developed techniques for compensating for it. Third, the ability to manage latency may be related to the physical and biological wiring of an individual. This could be a similar phenomenon to the tendency for some people to experience simulator sickness, while others do not suffer from it. These speculations are worthy of further investigation.

This experiment did successfully identify latency levels which may be considered safe for human surgery. Latency below 200ms was either imperceptible by the surgeon or made little difference in his/her ability to perform the skills necessary. Between 300ms and 500ms the effects of latency on an individual surgeon was unpredictable. Some surgeons were able to successfully compensate at these levels. Unfortunately, our experiment was not able to identify a demographic trait which was correlated with this ability and might be considered a significant contributing factor. Latency levels above 500ms consistently deterred successful completion of the exercises and can be considered generally unsafe for telesurgery. Confidence in the levels of latency which would be safe for telesurgery is an important factor informing the objective and conclusions of the second experiment to be described in this report.

PART 2: INTER-CAMPUS LATENCY MEASUREMENTS

In the second experiment we measured the actual communication latency for robotic surgical video between multiple hospital campuses in the Orlando metropolitan area (Orlando, Celebration, Winter Park, and Altamonte). These campuses were chosen because they are the locations which use the da Vinci robot in the operating room and are therefore potential users of a telesurgery capability (Figure 11, red pins). They are also locations at which future experiments with the robot itself can be performed. Florida Hospital has four additional hospital campuses in the Orlando metroplex to which we could test latency, but which do not perform robotic surgery (Figure 10, yellow pins). These were not included in the latency measurement experiment.

The physical distance between the four campuses ranges between 4 and 23 miles. Each campus is connected to a high-speed communication network that does not have firewalls that would normally slow traffic on a wider internet connection between diverse business customers. As a result, we expected the performance of packet delivery to be very good.

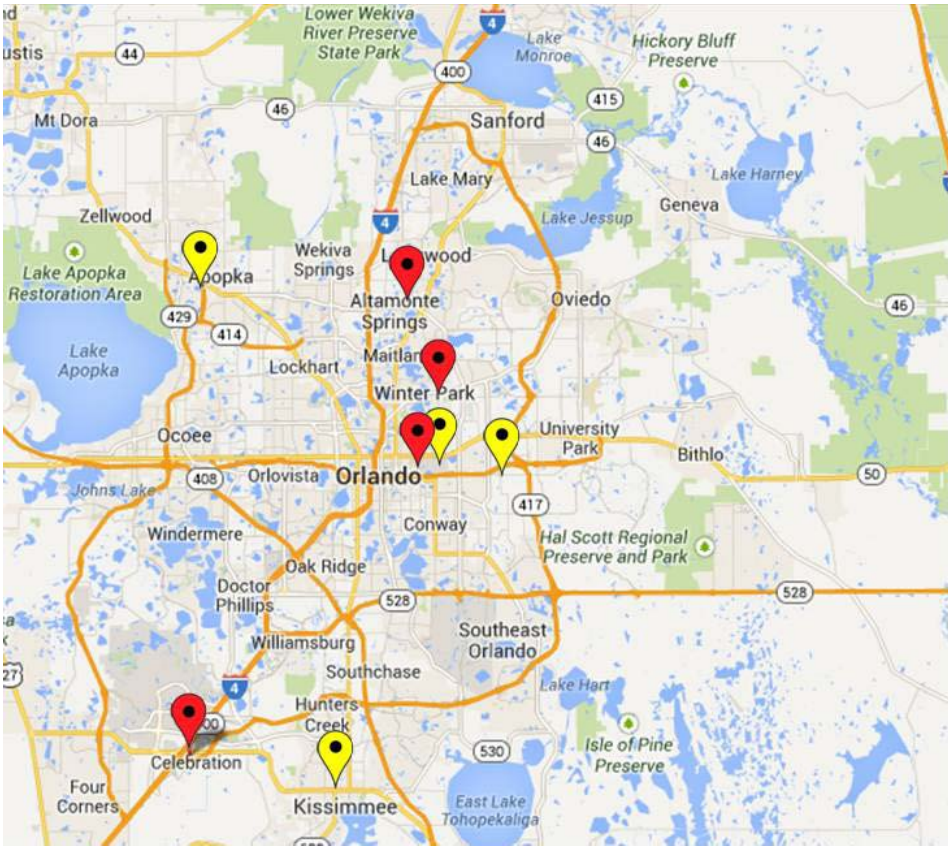


Figure 11. Surgical video latency measurement locations (red pins).

Video Sample

The video file which was used for this experiment was a five minute recording taken from an actual surgery using the da Vinci robot. This file was streamed between two server computers equipped with packet sniffer software which is able to measure the delivery time for every network packet sent between the two computers. The sending computer was set to stream the video at a rate identical to a real time event. Upon completion of delivery of the video content, the sending computer was programmed to repeat the sending of the file for s specified number of minutes to capture data on packet delivery over periods longer that the duration of the video file itself.

Baseline Performance

Baseline tests were run with both the sending and receiving computers on the same campus and traffic routed into the metropolitan intranet. This configuration allowed the technicians to directly view both computers simultaneously to insure that a connection was being made. From a network topology perspective, these baseline tests were nearly identical to a multi-campus case because the traffic from the sending computer was directed into the intranet and traversed nearly the same network route that would be used to a different campus. Therefore, this data is included in the table below and our analysis.

Multi-campus Latency

Following the same-campus verification experiments at the Orlando campus, the sending and receiving computers were positioned at the various campuses of interest in the study. The average latency for these connections consistently varied between 1millisecond (ms) and 5ms (Table 3 & Figure 11). The data for each experiment was consistently within this very tight range. In one experiment between the Orlando and Winter Park campuses we noticed a very large, out of range, latency level of 62ms. Further investigations indicated that the program being used to send packets was being interfered with by updates to the Windows operating system at the time of the test. When we restarted and reran this experiment, it also fell within the 3-5ms range.

At the highest level (5ms) the latency experienced is 40 times faster than is required to maintain a safe telesurgery according to our first experiment on latency tolerance and management. In fact, our first experiment indicated that a surgeon would not be able to detect the latency experienced in any of the cases in this second experiment, including the one with the interference by the Windows operating system.

Table 3. Average Latency in Video Streaming Experiments

Stream From	Stream To	Average Speed	Length of Test	Notes	Date
Orlando	Orlando	3 ms	11 min	PC wired to Laptop wireless	5/6/2013
Orlando	Orlando	1 ms	35 min	Both wired	5/7/2013
Orlando	Orlando	1 ms	11 min	Both wired	5/13/2013
Celebration	Orlando	5 ms	11 min	Both wired	5/13/2013
Celebration	Orlando	5 ms	70 min	Both wired	5/16/2013
Celebration	Celebration	2 ms	11 min	PC wired to Laptop wireless	5/16/2013
Orlando	Celebration	4 ms	11 min	Both wired	5/17/2013
Orlando	Celebration	4 ms	24 min	Both wired	5/17/2013
Celebration	Orlando	5 ms	24 min	Both wired	5/22/2013
Celebration	Orlando	4 ms	11 min	Both wired	5/22/2013
Orlando	Winter Park	62 ms	11 min	Sending Computer Malfunction	6/5/2013

Orlando	Winter Park	4 ms	11 min	Reboot and retest campus pairs	6/5/2013
Winter Park	Orlando	5 ms	35 min	Both wired	6/5/2013
Orlando	Altamonte	5 ms	11 min	Both wired	6/6/2013
Orlando	Altamonte	4 ms	35 min	Both wired	6/6/2013
Altamonte	Orlando	4 ms	11 min	Both wired	6/7/2013

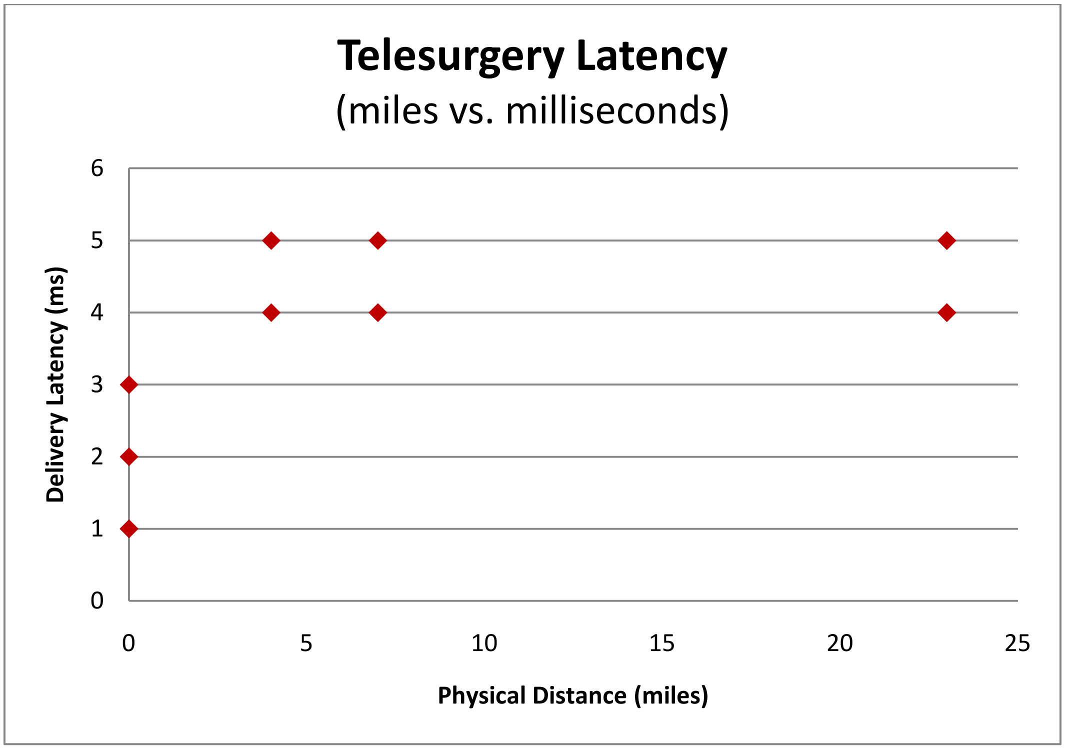


Figure 12. Latency vs. Distance between Orlando metropolitan campuses.

Conclusions

The second experiment attempted to create an environment which replicates the most challenging data delivery problem for robotic surgery, the efficient delivery of video data to the surgeon performing the procedure.

Our conclusion is that using current robotic and networking equipment it is now possible to perform telesurgey between campuses of a metropolitan hospital system. A closed intra-network which does not require firewall protection between connections is an ideal environment, but also an environment that is widely available in modern cities and hospital systems.

FUTURE WORK

Though these experiments were designed to approximate the effects of communication latency in robotic telesurgery, there remain a number of untested variables whose effects on an actual surgery cannot be measured by the experiments. The da Vinci robot actually uses four different data streams in its communication between the physician and the patient-side equipment. Our experiments have explored the effects of latency on just the delivery of the video streams. The command and audio streams will also compete for bandwidth in a real telesurgery environment. Though we estimate that the volume of that data is very small in comparison to the video data, the interactions that might be caused have not been addressed in these experiments. Therefore, additional, more elaborate experiments are being designed to explore these interactions.

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Robotic Surgery Simulators

a comparative review of the system capabilities of simulators of the da Vinci surgical robot

US Army TATRC Grant # W81XWH-11-2-0158

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This is Part 1 (Systems Capabilities) of a three part study of robotic simulators.

Part 2 (Subjective Usability Survey) and Part 3 (Comparative Skills Improvement) to follow.

Table of Contents

Introduction

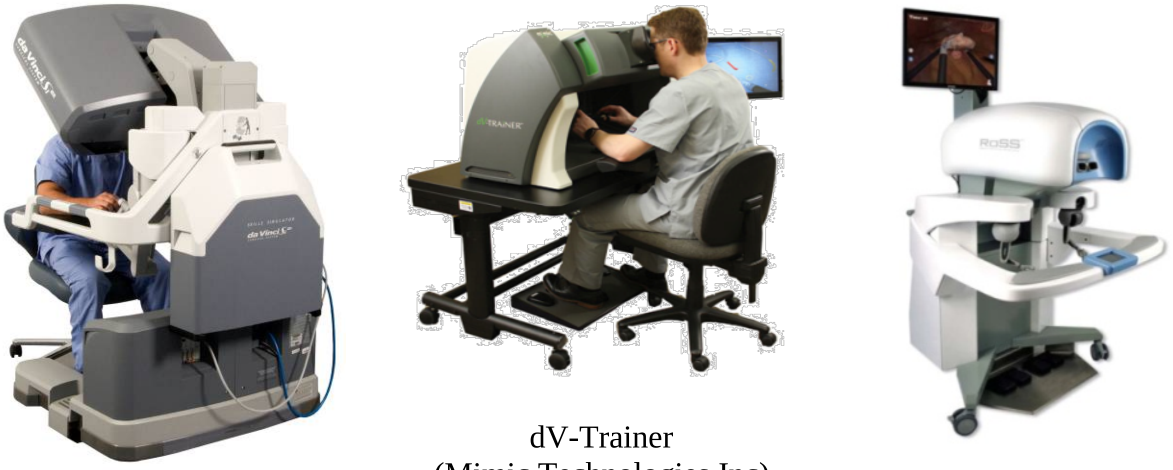
For every complex and expensive system, there emerges a need for training devices and scenarios that will assist new learners in mastering the use of the device and understanding how to apply it with value. This has proven to be true in aviation, nuclear power control, and medicine among other fields. Laparoscopic surgery simulators have played a valuable role in improving the practice of surgery over the last 20 years and the same trends and values will likely apply in robotic surgery. The complexity, criticality, and cost associated with the effective application of the da Vinci surgical robot have stimulated the commercial creation of simulators which replicate the operations of this robot. Each of these simulators provides a slightly different perspective and solution to the problem.

This book explores the characteristics and differences between all of the currently available devices. The details provided here are structured to equip readers with sufficient knowledge about the simulators to make their own decisions about which best meets their needs. Each of them possesses unique traits which make them valuable solutions for different types of users. It is not our intent to make a universal recommendation of one device over the others. Readers should draw their own conclusions based on their unique needs for a device.

The three current simulation devices for the da Vinci robot are the:

- da Vinci Skills Simulator (Intuitive Surgical Inc.),
- dV-Trainer (Mimic Technologies Inc.) and
- Robotic Surgery Simulator (Simulated Surgical Systems Inc.).

These are commonly referred to as the DVSS or “Backpack”, dV-Trainer, and RoSS respectively (Figure 1).



DVSS
(Intuitive Surgical Inc)

dV-Trainer
(Mimic Technologies Inc)

RoSS
(Simulated Surgical Systems LLC)

Figure 1. Simulators of the da Vinci surgical robot

Each of these devices is manufactured by a different company and provides a unique hardware and software solution for training and surgical rehearsal. The capabilities and features of each are described in this book and summarized in Table 1.

Table 1. Simulator Feature Comparison

	Skills Simulator	**dV-Trainer**	**RoSS**
System Manufacturer	Intuitive Surgical Inc.	Mimic Technologies Inc.	Simulated Surgical Systems LLC
Specifications (Simulator only)	Depth 7” Height 25” Width 23” 120 or 240V power	Depth 36” Height 26” Width 44” 120 or 240V power	Depth 44” Height 77” Width 45” 120 or 240V power
Specifications (Complete System as shown in Figure 1)	Depth 41” Height 65” Width 40” 120 or 240V power	Depth 36” Height 59” Width 54” 120 or 240V power	Depth 44” Height 77” Width 45” 120 or 240V power
Visual Resolution	1080p	1080p	720p
Components	Customized computer attached to da Vinci surgical console	Standard computer, visual system with hand controls, foot pedals.	Single integrated custom simulation device
Support Equipment	da Vinci surgical console, custom data cable	Adjustable table, touch screen monitor, keyboard, mouse, protective cover, custom shipping container	USB adapter, keyboard, mouse
Exercises	35 simulation exercises	51 simulation exercises	52 simulation exercises.
Optional Software	PC-based Simulation management	Mshare curriculum sharing web site	Video and Haptics-based Procedure Exercises (HoST)
Scoring Method	Scaled 0-100% with passing thresholds in multiple skill areas	Proficiency-based point system with passing thresholds in multiple skill areas	Point system with passing thresholds in multiple skill areas
Student Data Management	Custom control application for external PC. Export via USB memory stick.	Export student data to delimited data file.	Export student data to delimited data file.
Curriculum Customization	None	Select any combination of exercises. Set passing thresholds and conditions.	Select specifically grouped exercises. Set passing thresholds.
Administrator Functions	Create student accounts on external	Create student accounts. Customize	Create student accounts. Customize

	PC. Import via USB memory stick.	curriculum.	curriculum.
System Setup	None.	Calibrate controls.	Calibrate controls.
System Security	Student account ID and password.	PC password, Administrator password, Student account ID and password.	PC password, Administrator password, Student account ID and password.
Simulator Base Price	$85,000	$95,000	$107,000
Support Equipment Price	$502,000	$9,100	$0
Total Functional Price	$587,000	$104,100	$107,000

[Note: Data is for systems available as of April 2013.]

Section 1: System Design

Da Vinci Skills Simulator (Intuitive Surgical Inc.)

The da Vinci Skills Simulator (DVSS) consists of a customized computer package that attaches to the back of the surgeon's console of an actual da Vinci Si robot. This simulator connects to the surgeon's console via a single proprietary networking cable identical to that used to connect the components of the actual robotic surgical system.

Advantages

Attached simulators of this type are usually referred to as "embedded trainers" because they take advantage of the equipment that has already been constructed, purchased, and installed for the operation of the real system. These kinds of simulators are especially common in military facilities which face limited space and weight constraints. They can significantly reduce the hardware that must be purchased solely for simulation purposes. The U.S. Navy uses these kinds of simulators aboard ships to reduce weight and space requirements, enabling them to train while the ship is at sea.

Another significant advantage of an attached simulator is that it allows the trainee to use the actual controls from the real system to control the simulation. This insures that the training experience is almost identical in feel to the real system, which can contribute to higher transfer of skills from the training sessions to the use of the real system. In learning to use the simulator system, the trainee also has a minimum amount of unique information to learn about the training device. A larger degree of the simulator experience actually contributes to proficiency with the real system.

Finally, there is a cost advantage for the simulator device itself. Because much of the hardware and software expenses are already embedded in the real system, the simulator can be very economical to purchase.

Disadvantages

Attached simulators like the DVSS also come with inherent disadvantages to balance their positive traits.

The largest drawback is the availability of a real system to be able to use the simulator. An attached DVSS simulator cannot be used without access to a real surgeon's console. da Vinci robots are expensive devices which hospitals typically attempt to maximize use of in order to recoup their investment. In a very active surgical hospital, it can be difficult to obtain access to a surgeon's console to support training with this simulator.

The DVSS is designed to connect to the surgeon's console using the same proprietary networking cable that connects the major robot components. This makes the attachment and set-up process very easy for clinicians to master. However, it also means that the DVSS can only be used with the Si model surgeon's console. The previous S and Standard models use a different set of cables which are not compatible with the simulator.

Similar to the military's experience with embedded and attached simulators, heavy usage of the DVSS comes with a corresponding heavy use of the surgeon's console. The Army and Navy have discovered that these types of simulators put more usage hours on real equipment controls which lead to more maintenance costs for those devices. Since it is possible to train almost constantly, the real equipment experiences usage rates that can be many times higher than normal for the equipment. Because the da Vinci systems operate under a maintenance contract that covers all services, the additional costs of maintenance are not born by the hospital owner, but by the equipment vendor. The primary impact to the owner would only be in the area of availability for both real surgeries and training events due to downtime associated with maintenance.

As mentioned under advantages, the cost of an attached simulator is typically much lower than other forms. But that is countered by the fact that the customer must purchase or have available a real piece of equipment to support the use of the simulation.

dV-Trainer (Mimic Technologies Inc.)

The dV-Trainer is a separate, stand-alone simulator of the da Vinci robot. The surgeon's console, controls, and vision cart are mimicked in hardware, while a 3D software model replicates the functions of the robotic arms and the surgical space.

Mimic developed the initial simulator software for the DVSS and used the same package in version 1.0 of their own dV-Trainer. As a result, the exercises in those versions of the systems are nearly identical. The current version 2.0 of the dV-Trainer has a number of new exercises which are not found in the DVSS and the graphics have been upgraded so the visual presentation is no longer identical. The differences in visual presentation can be seen in the figures later in the book.

The dV-Trainer consists of three major pieces of equipment and a number of smaller support pieces. The largest pieces are the "Phantom" hood which replicates the vision and hand controls of the da Vinci surgeon's console, the foot pedals of the surgeon's console, and a high-performance desktop computer which generates the 3D images and calculates the interactions with the surgeon's controls. Smaller support equipment includes a touch screen monitor, keyboard, and mouse to enable an instructor to guide the student through exercises and allow an administrator to manage the data that is collected. There are also a network router and video splitter that connect all of the equipment together. Finally, there is an optional adjustable table with a mount for the PC, monitor, networking equipment, and the Phantom head. This adjustable table is offered as an option for the simulator, but it provides advantages which make it a very advantageous option. This table allows ergonomic adjustments which closely replicate those of the real robot. The table also makes the entire system much easier to package, move within a facility, or ship to other sites.

Because the dV-Trainer replicates both the hardware and software of the da Vinci robot, it is a much larger system than the DVSS alone, though smaller than a real surgeon's console with the DVSS attached. It has the advantage of providing a training system that is completely independent of the need for any piece of the real surgical robot. The simulator can be configured to imitate either the S or the Si model of the da Vinci robot.

The disadvantage of this kind of system is that all simulated hardware is not quite the same as the real equipment. There is always a trade-off between the lower price and the perfect accuracy of a simulator. Also, the simulator must be updated separately when the real equipment is modified.

A user or student can perform most of the exercises on the dV-Trainer that are available on the DVSS, along with many newer exercises that are not available on the DVSS. Both simulators offer new suturing exercises, though they are different for each simulator.

Robotic Surgical System (Simulated Surgical Systems Inc.)

The RoSS is also a complete, stand-alone simulator of the da Vinci robot. This device is designed as a single piece of hardware that has a similar design to the surgeon's console of the robot. The hardware device includes a single 3D computer monitor, hand controls that are modified commercial force feedback devices, pedals that replicate either the S or the Si model of the da Vinci robot, and an external monitor for the instructor. Customers must purchase either the S or Si version of the device.

The company has developed a set of 3D virtual exercises that are unique from those found in both of the other simulators. They also provide an optional video-based surgical exercise in which the user is guided through the movements necessary to complete an actual surgical procedure. At this writing, these modules are available for radical prostatectomy, cystectomy, and hysterectomy. These guided videos take advantage of the force feedback capabilities of the hand controllers to push and pull the student's hands to follow the simulated instruments on the screen. They require the student to perform specific movements accurately during the video before the operation will proceed.

Section 2: Simulation Exercise Modules

Each simulator allows an administrator or instructor to manage and organize student performance according to unique login credentials for the student. Alternatively, they all have a universal “guest” account to make the system accessible to anyone, but without the ability to uniquely identify and track the performance of a specific student.

Once logged into each system, the instructor or the student navigates the instructional materials using the menu systems illustrated in Figure 2. Since the Intuitive Skills Simulator (DVSS) and the Mimic dV-Trainer provide very similar exercises and organizations, the navigation through the exercises is similar in form, though different in visual appearance. The RoSS simulator uses a very unique arced orbital menu for progressing through exercises.

Each simulator provides on-system instructions for every exercise in the form of textual documents and video demonstrations with spoken audible instructions.

Skills Simulator	dV-Trainer	RoSS

Figure 2. Comparative Simulator Exercise Menus

DVSS

The DVSS contains 35 exercises organized into nine categories. These begin with introductory video and audio instructions on how to use the robotic equipment, and move through progressively more difficult skills.

Table 2. DVSS Exercise Categories

Surgeon Console Overview	An introduction to the controls of the da Vinci robot.
Endowrist Manipulation 1	Basic hand movements and usage of the wristed instruments.
Camera and Clutching	Basic foot clutching for both the camera and the third arm.
Endowrist Manipulation 2	Intermediate use of the hands and wristed instruments.
Energy and Dissection	Use of the energy pedals and associated instruments.

Needle Control	Focused exercises for dexterous manipulation of a curved surgical needle.
Needle Driving	Repetitive exercises for needle driving.
Games	Challenging and entertaining game environments to apply the skills learned.
Suturing Skills	Suturing exercises with needle, following suture, knot-tying, and tissue closure.

To prepare the student for success in each exercise, the simulator offers written instructions on the objective of each exercise prior to performance. There is also a narrated video of an instructor performing the exercise while explaining the necessary steps.

Upon completion of each exercise, the system automatically proceeds to a scoreboard showing the student's performance on the exercise. Details on the scoring systems of each simulator are discussed later in the book.

Figure 3 presents screenshots of some of the key exercises in the simulator. These include the Ringboard, Ring Walk, Energy Dissection, and Interrupted Suturing exercises. The suturing exercises on this simulator are a new addition which was developed by Simbionix USA Inc. for integration into the DVSS. This expansion of the system was also meant to demonstrate the ability of the hardware platform and underlying management software to blend together simulation exercises and scoring systems created by different vendors.

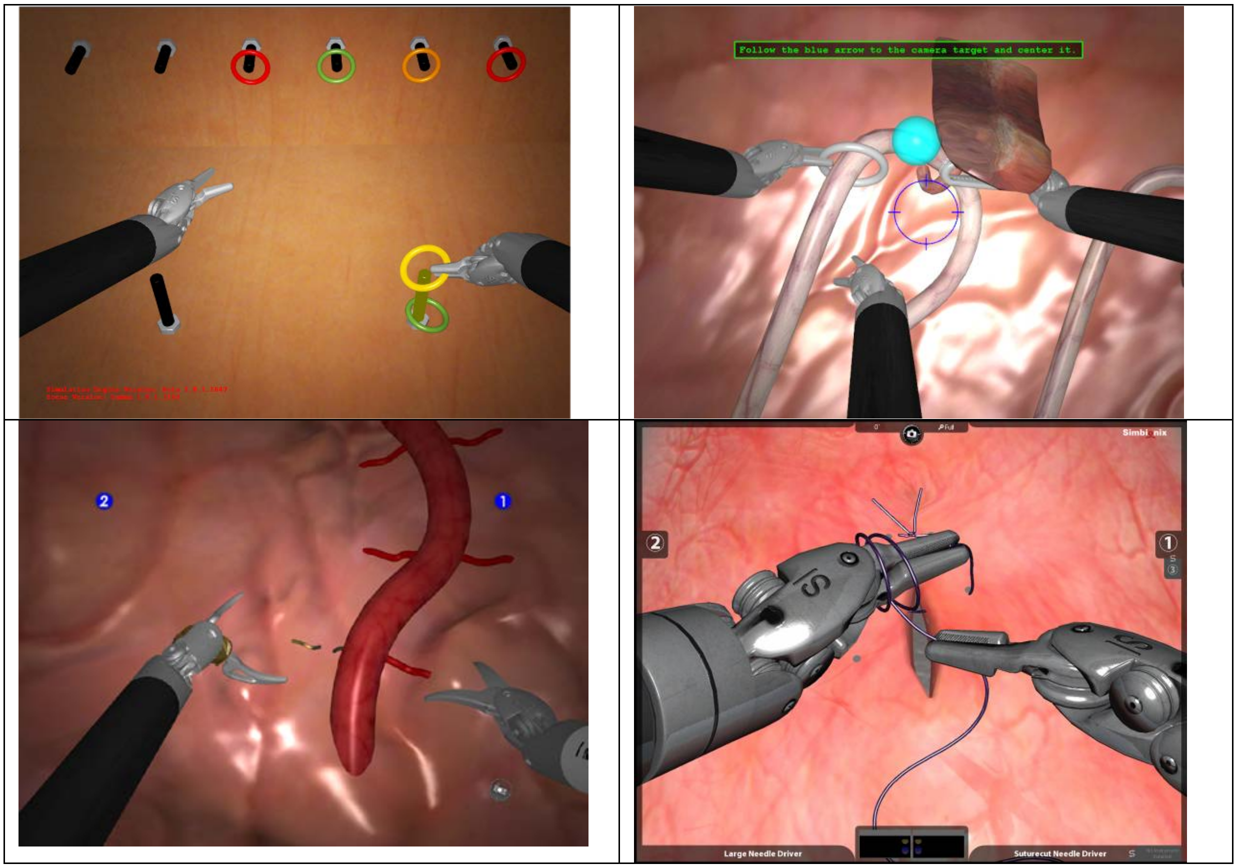


Figure 3. Selected DVSS Exercise Images

dV-Trainer

Most of the simulation software for Intuitive's DVSS was developed by Mimic Technologies. Therefore, version 1 of the DVSS and the dV-Trainer contained nearly identical exercises, closely matching menu systems, and identical scoring mechanisms. However, over time the two sets of software have diverged and the current versions of the simulators differ in functionality and appearance. The current version of the dV-Trainer (v 2.0) contains 51 exercises organized into nine categories. This device also includes video and audio instructions on how to use the robotic equipment, moving through progressively more difficult skills.

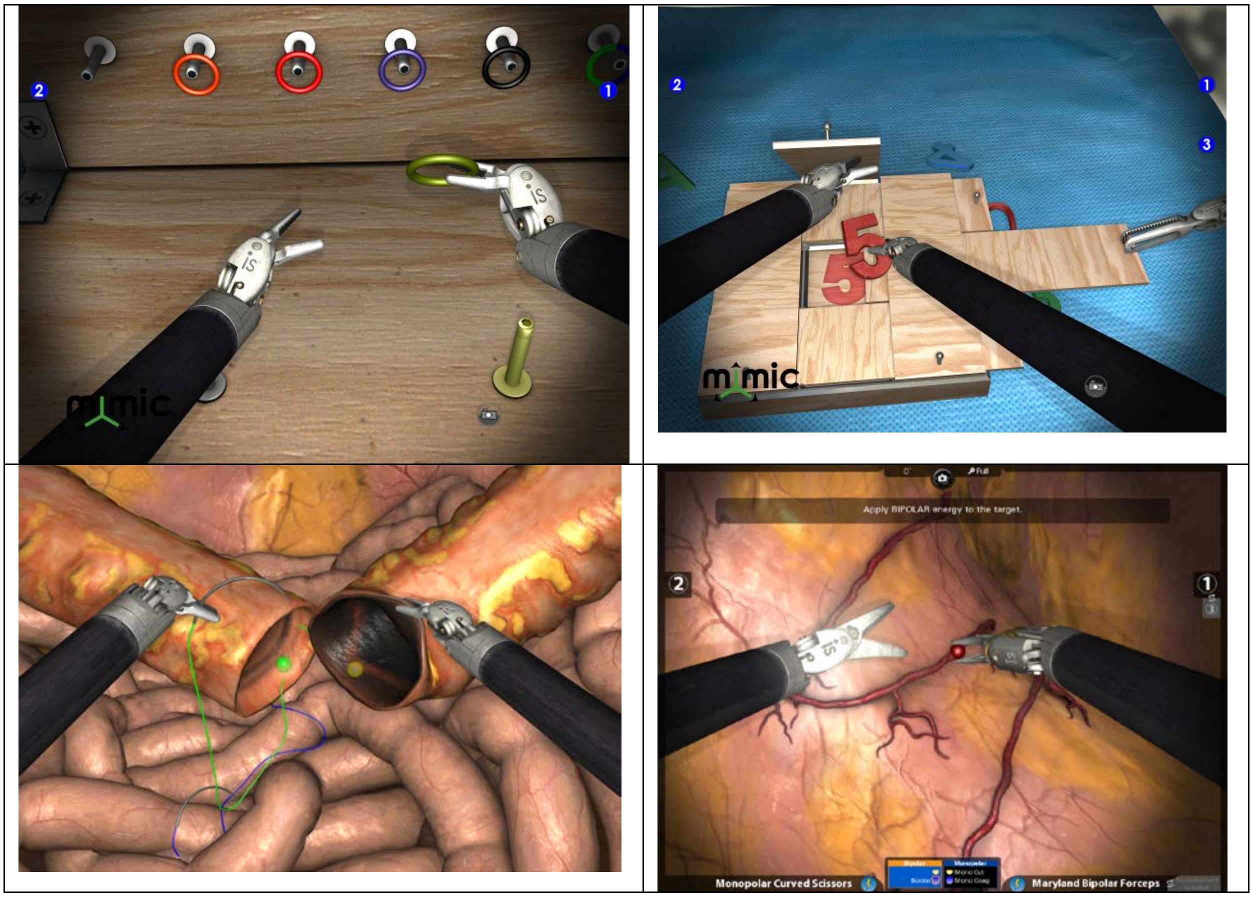
Table 3. dV-Trainer Exercise Categories

Surgeon Console Overview	An introduction to the controls of the da Vinci robot.
Endowrist Manipulation	Basic and intermediate use of the hand controllers and wristed instruments.
Camera and Clutching	Basic foot clutching for both the camera and the third arm.
Energy and Dissection	Use of the energy pedals and associated instruments.
Needle Control	Focused exercises for dexterous manipulation of a curved surgical needle.
Needle Driving	Repetitive exercises for needle driving.
Troubleshooting	Introduction to error recovery on the da Vinci robot.
Games	Challenging and entertaining game environments to apply the skills learned.
Suturing Skills	Suturing exercises with needle, following suture, knot-tying, and tissue closure.

Just as with the DVSS, the dV-Trainer simulator offers written instructions on the objective of each exercise prior to performance. There is also a narrated video of an instructor performing the exercise while explaining the necessary steps. Upon completion of each exercise, the system automatically proceeds to a scoreboard showing the student's performance on the exercise.

Figure 4 presents screenshots of some of the key exercises in the dV-Trainer simulator. These include the Ringboard, Matchboard, Tubal Anastomosis, and Energy Switching exercises.

Though many of the exercises are identical between the DVSS and the dV-Trainer, the graphics resolution and details have been improved in version 2.0 of the dV-Trainer software. Since this system is driven by a commercial PC which can be upgraded rather easily, it is possible for the software to evolve and be replaced more easily than for a custom hardware package like the DVSS which would require upgrades to some of the components inside the customized device.



Apply BIPOLAR energy to the target.

Figure 4. Selected dV-Trainer Exercise Images

RoSS

The RoSS simulator contains 52 unique exercises, organized into 5 categories, and arranged from introductory to more advanced, just as in the other two simulators. The RoSS system of exercises is unique in that they list fewer named exercises, but provide three different levels for most of them. Each of these levels is actually a variation on the exercise design in which Level 1 is the easiest, Level 2 is intermediate, and Level 3 is advanced.

Table 4. RoSS Exercise Categories

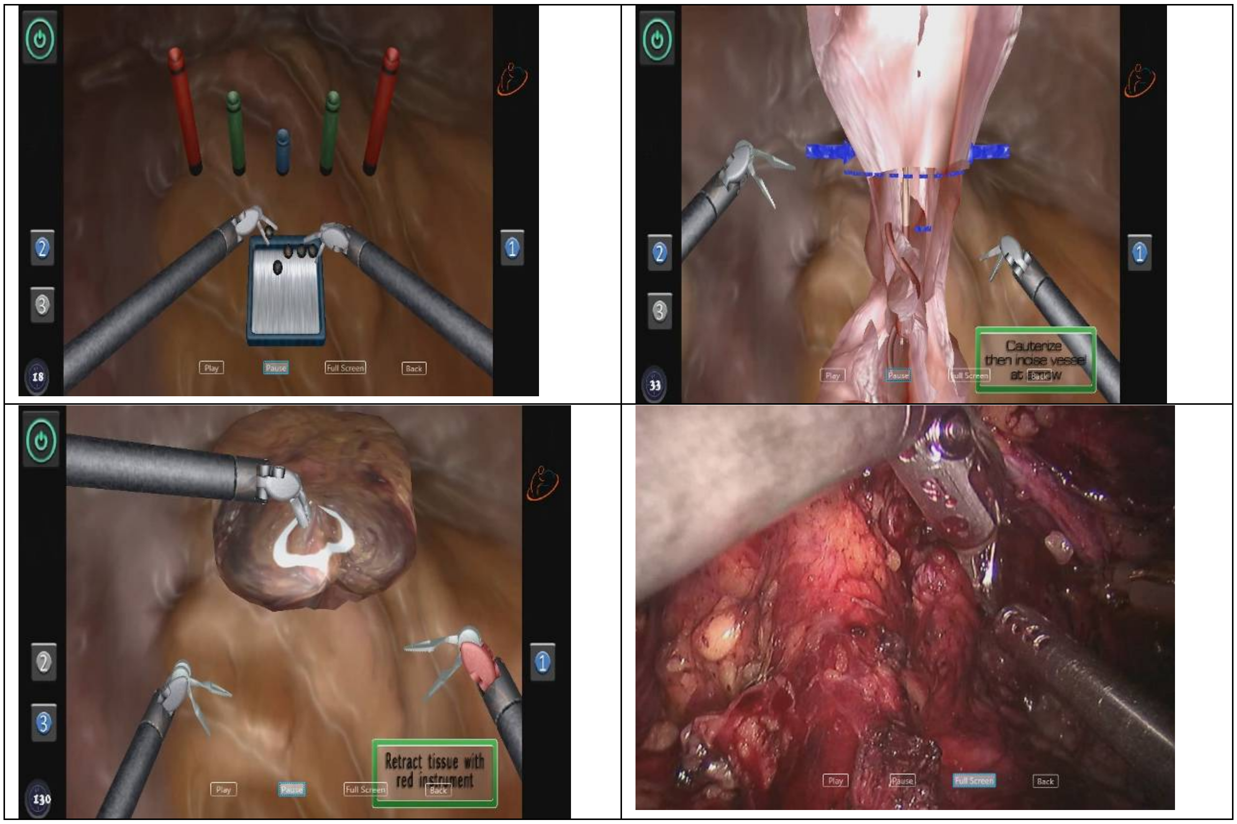
Orientation Module	Introduction to the surgeon controls of the da Vinci robot.
Motor Skills	Development of precise controls of the instruments, including spatial awareness.
Basic Surgical Skills	Instruction on handling a needle, using electrocautery pedals and instruments, and the use of scissors on the robot.
Intermediate Surgical Skills	Control of the fourth arm, blunt tissue dissection, and vessel dissection.
Hands-on Surgical Training	Video and haptic-guided instruction through specific surgical procedures.

Similar to the other simulators, the RoSS includes a narrated video showing an instructor performing the exercise. Upon completion of an exercise, the simulator automatically proceeds to the scoreboard for the exercise.

The RoSS contains a unique capability that is not found in either of the other simulators. The company refers to this as “Hands-on Surgical Training” or “HoST.” This is an integration of surgical skills exercises with a video of an actual surgery. The company offers a HoST module showing radical prostatectomy, cystotomy, and radical hysterectomy. Videos of actual surgical procedures play in the surgeon’s visual space. These are overlaid with animated icons which instruct the student to perform specific actions during the progression of the surgery video. The necessary actions are prompted with audio instructions. For the HoST exercise to progress, the student must perform the specific actions at specific times. The simulator will pause the video and allow the student to repeat the action until it is performed as required by the instructions.

The hand controllers of the RoSS simulator are created by modifying a commercially available 3D haptic computer input device called the Omni Phantom™. This product uses internal motors and gears to apply haptic feedback to the hand movements of the user. For the HoST exercises, the simulator uses this capability to move the student’s hands in synch with the movements of the surgeon’s instruments in the master video.

Figure 5 provides screenshots of the Motor Skills Ball Placement, Intermediate Vessel Dissection, 4th Arm Tissue Retraction, and HoST Radical Prostectectomy.



Cauterize then incise vessel at

Retract tissue with red instrument

Figure 5. Selected RoSS Exercise Images

Section 3: Proficiency Scoring

Each of the three simulators provides a different scoring method. All three use the host computer to collect data on the performance of the student at the controls in multiple performance areas. With this data, they provide a score for specific performance traits, as well as combining all of these into a single composite score of performance for the entire exercise. The algorithm used to create this composite score is described in the user's manuals of each of the simulators. Examples of each of these scoreboards are shown in Figure 6.

Within a simulator, many of the scoring metrics are applied to every exercise, such as the time to complete the exercise. But some exercises have unique metrics that are not applicable to all of the other exercises, such as blood loss volume. In this book we will describe some of the more universally applied metrics, though not all of the unique measurements which are collected for every exercise. Interested readers can consult the simulator's manual for detailed descriptions of all of the metrics across all of the exercises.

In addition to the objective metrics that can be collected by the computer, the developers of each simulator have been challenged to provide thresholds which indicate whether the student's score is considered a "passing" or "failing" performance. All three have identified threshold scores which would indicate acceptable and warning scoring levels. These are commonly interpreted as "passing" (above acceptable threshold) and "failing" (below warning threshold), with a "warning" area between the two thresholds. These thresholds create green, yellow, and red performance areas which can be used to visually communicate the quality of the student's performance in each area of measurement. Each simulator also provides a single composite score for the entire exercise.

For most exercises on all three simulators, higher measurements of performance, such as the time to complete, instrument travel distance, and blood loss, indicate poorer performance; while lower values in these areas indicate better performance. As a result, the collected metric needs to be reversed to create a point system which gives high points for good performance and low points for poor performance. The method used to achieve this is described in the simulator's user manual for the dV-Trainer and can be solicited from the manufacturer for the other two systems.

Each of the simulators gives the student a single overall score for performance on an exercise. To achieve this, an algorithm was needed to combine very different types of metrics. For example, the number of seconds to complete an exercise needs to be combined with liters of blood loss, centimeters of instrument movement, number of instrument collisions, and other similarly varied metrics. As in most educational environments, this is achieved by converting each metric into a score which falls between some defined minimum and maximum value. Most people understand this concept from their academic experience in which all assignments were graded in the range from 0% to 100% or between 0 points and the maximum total points for all assignments. These normalizations make it possible to create a single composite score of the student's performance across multiple assignments. This same approach has been used in the simulators, where the resulting composite metric may be a total point score or a percentage.

The simulator manufacturers all work with experienced robotic surgeons to assist in establishing the relative values of each measure used in the composite score, just as they did for the threshold levels described earlier. Because these evaluations are the opinions of the specific people who have collaborated with the company on the development of the system, the dV-Trainer and the RoSS both provide the ability for a system administrator to adjust these levels to meet the needs of unique curriculum, courses, and students being evaluated.

DVSS dV-Trainer RoSS

Figure 6. Comparative Simulator Scoreboards

DVSS

As described earlier, the DVSS performance scoring method has a number of metrics which are applied to every exercise and others which are only used for exercises in which they are relevant. Table 5 presents the metrics which are available on all exercises. For details on the more specialized metrics, the reader should consult the user's manual for this simulator.

Because the DVSS is a closed, turn-key system with an ease of use similar to the actual surgical robot, most of the data displays and threshold adjustments found in the other simulators are not available in this device. Generally, the simulator settings are determined by the manufacturer and cannot be changed by the user.

Table 5. DVSS and dV-Trainer Scoring Method

Overall Score	Composite evaluation of the exercise performance.
Time to Complete Exercise	Number of seconds to complete the exercise.
Economy of Motion	Number of centimeters of instrument tip movement.
Instrument Collisions	Number of times that the instruments touched each other.
Excessive Instrument Force	Number of seconds that excessive robotic force was applied against objects in the environment.
Instrument Out of View	Number of centimeters that an instrument tip moved outside of the viewing area.
Master Workspace Range	Radius in centimeters than contains the movement of the instrument tips.
Drops	Number of objects dropped from the grasp of the instruments.

dV-Trainer

Originally, the DVSS and the dV-Trainer shared the same scoring method, but more recent versions of the dV-Trainer offer both this original "version 1" scoring method, as well as a new "version 2" method based on the proficiency measured from experienced surgeons. The skills measured are the same, but the interpretation of those into a score is different. The instructor can select the preferred scoring method for each curriculum that is constructed in the dV-Trainer.

Users will notice that the newer scoring method uses total points earned rather than percentages. The passing and warning thresholds can be adjusted by the administrator. The philosophy, validity, and effects associated with these settings are more detailed than is necessary for understanding the use of the simulator. Interested readers should consult the user's manual and published literature for details on the two scoring mechanisms.

RoSS

The principles behind the scoring system on the RoSS are the same as those for the DVSS and the dV-Trainer. However, most of the metrics collected are different. The standard measurements are shown in Table 6. Like each of the other simulators, there are multiple displays of the performance data for a student. The initial display presented at the completion of an exercise shows a horizontal bar which is colored green, yellow, or red to indicate passing or failing. The magnitude of the bar is a rough measure of the quality of performance. Additional displays show the numeric score and its relative position to a passing threshold.

As with the other two simulators, special metrics are used when they are relevant to a specific exercise. These are not described here, but interested readers can solicit these from the manufacturer.

Table 6. RoSS Scoring Method

Overall Score	Composite evaluation of the exercise performance.
Camera Usage	Optimal movement of camera.
Left Tool Grasp	Optimal number of tool grasps with left hand tool.
Left Tool Out of View	Distance left hand tool is out of view.
Number of Errors	Number of collision or drop errors in an exercise.
Right Tool Grasp	Optimal number of tool grasps with right hand tool.
Right Tool Out of View	Distance right hand tool is out of view.
Time	Time to complete the exercise.
Tissue Damage	Number of times that instruments damaged tissue with excessive force or unnecessary touches.
Tool-Tool Collision	Number of times tools touched each other.

Section 4: Simulator System Administration

All of the simulators contain system configuration and student management functions which require a special administrator account to access and modify. These allow instructors to create curriculum and scoring methods which are unique to the lessons they are offering. They also allow an instructor or administrator to create new student accounts and export student scores for evaluation and analysis outside of the simulator device. Some course instructors use this capability to create custom performance reports for students who attend the courses.

DVSS

For the DVSS, most of the administrator functionality is fixed within the delivered system. The administrator can create specific user profiles for the simulator using a dedicated program on a separate external PC. This program, the “da Vinci Skills Simulator Manger”, allows the administrator to create a profile for the user. The profile can then be loaded onto a USB memory stick and inserted into the USB port on the DVSS. The simulator will automatically read this data in and display the user names at the login screen.

Similarly, the USB memory stick can be inserted into the DVSS and the performance data collected from exercises performed by each user will be automatically loaded onto the USB stick. This stick can then be inserted in the PC and the data will be loaded into the management software on the external PC and exported to a delimited file for formatting and analysis in a spreadsheet program.

The entire transfer process is automated such that the contents of the USB stick are completely erased and reloaded each time it is inserted into the PC or the DVSS. The stick cannot safely be used for any purpose other than as the transfer mechanism between the two devices. This method is meant to create an ease of use similar to the real robot.

dV-Trainer

The administrator on a dV-Trainer has the ability to create new user accounts, specify S or Si representation, create new curriculum, set passing thresholds, and export user data for analysis.

The simulator contains 51 exercises, any combination of which can be organized into a curriculum for a specific course. The administrator creates the new curriculum name and then adds each exercise that should be part of the curriculum. This set of exercises can be organized into phases or folders to match the course that is being taught. For example, an instructor may have a curriculum that consists of a warm-up with easy exercises, pre-course evaluations, and post-course evaluations. These would appear as three separate sections within the curriculum.

The administrator can export data from the simulator according to multiple criteria. The export may include all of the data on the machine, or subsets defined by the unique user ID, date range, completion status, or a specific exercise.

The capabilities provided for an administrator of the dV-Trainer are significantly more robust than those available on the other two simulators.

RoSS

The RoSS administrator account is used to create student accounts. Each user can then be assigned a specific subset of the entire simulator curriculum.

For the RoSS system, the administrator can assign portions of the curriculum hierarchy which are applicable to a specific user. The curriculum is organized such that customization consists of selective subsets of the hierarchy of exercises, rather than the ability to select specific exercises in unique combinations.

The administrator can also edit the passing thresholds for each exercise. This allows a site to create curriculum which is considered passing for practitioners at different levels, such as medical students, residents, attendings, and specialists.

The scores can be exported as individual delimited data files for each student account. These can then be removed from the system for analysis and recording.

Section 5: Validation of Devices

Virtual reality simulators have been shown to be effective tools for training in multiple fields such as aviation and the military. These have been used for new skills acquisition as well as maintenance of skills in a risk-free learning environment. The surgical field has recently shown the value for simulation, most notably demonstrated for laparoscopic training. Several studies have demonstrated the benefits of virtual reality surgical simulators such as shorter operating times, decreased learning curve, and fewer medical errors. With the advancement of surgical robotic technology and its rapid implementation as a surgical tool, comes the need for adequate and effective training in order to ensure patient safety. It would follow that the benefits shown for laparoscopic surgical simulation would parallel those for robotic surgical simulation. Recent research demonstrates that robotic simulators are valid training tools and suggests that robotic surgical simulation can help bridge the gap between the safe acquisition of surgical skills and effective performance during live robot-assisted surgery.

Validation studies serve to determine whether a simulator can actually teach or assess what it is intended to teach or assess. There are generally accepted validity classifications, which include face, content, construct, concurrent and predictive validity (McDougall, 2007). Face and content validity are considered subjective approaches while the other three are objective approaches to validation. Face validity evaluates the simulator’s realism via informal assessment by non-experts. Content validity evaluates the simulator’s appropriateness as a teaching tool via formal assessment by experts. Concurrent validity determines the degree to which the simulator correlates to the “gold standard” as an assessment tool while predictive validity determines the degree to which the simulator correlates to future performance of transferable skills to the operating room. Finally, the most valuable validation approach is construct validity, which is defined as the ability for the simulator to discriminate between various levels of experience, i.e. novice, intermediate, and expert.

Table 7 provides a summary of the published validation studies for these simulators. All three have publications establishing face, content, construct, and concurrent validation. There is only one published study on the predictive validity of the DVSS (Hung, 2012). Recent presentations explore the validity of the RoSS curriculum (Stegemann, 2013) and the RoSS’ HoST procedural modules (Ahmed, 2013).

Table 7. Validation of robotic surgical simulators

Validation	DVSS	dV-Trainer	RoSS
Face	*Hung 2011* *Kelly 2012* *Liss 2012*	*Lendvay 2008* *Kenney 2009* *Sethi 2009* *Perrenot 2011* *Korets, 2011* *Lee 2012*	*Seixas-Mikelus 2010* *Stegemann, 2012*
Content	*Hung 2011* *Kelly 2012* *Liss 2012*	*Kenney 2009* *Sethi 2009* *Perrenot 2011* *Lee 2012*	*Seixas-Mikelus 2010* *Colaco, 2012*
Construct	*Hung 2011* *Kelly 2012* *Liss 2012* *Finnegan 2012*	*Kenney 2009* *Korets, 2011* *Perrenot 2011* *Lee 2012*	*Raza, 2013*
Concurrent	*Hung 2012*	*Lerner 2010* *Perrenot 2011* *Korets 2011* *Lee 2012*	*Chowriappa, 2013*
Predictive	*Hung 2012*		

Section 6: Conclusion

Simulators play an important role in providing training experience and a platform for evaluation of novices who are trying to master complex skills in many fields. When a task is simple, consequences for failure are minimal, and equipment is inexpensive, there is little motivation for creating a dedicated simulation device. However, when the task to be mastered is complex, there is a need for a device that can objectively measure the performance of the trainee and provide feedback that leads to improved performance. When the consequences of a mistake are lethal, there is a need for a safe environment in which to develop expertise without threatening the wellbeing of others. When equipment or disposables are expensive to use, there is a need for a tool that can provide at least entry-level familiarization and skill development without undue financial demands. All three of these conditions are characteristic of the process for learning robotic surgery. So it is not surprising that market forces have led to the creation of multiple simulators of the robotic system and the skills to use it.

The three simulators which are described in this book offer a different value proposition to potential purchasers and to novice learners. The da Vinci Skills Simulator, dV-Trainer, an RoSS are complex systems which are significantly less costly than the actual da Vinci robotic surgical system and can be operated at a fraction of the cost of the instruments required for this robot. The intent of this book is to present the characteristics of each system to enable intelligent and informed purchasing and usage decisions.

Acknowledgements

The authors want to thank the following representatives of each simulator company for their assistance in collecting data, images, and videos, as well as verifying the accuracy of the contents of the book. Peter Dominick, Intuitive Surgical Inc.; Jeff Berkley, Mimic Technologies, Inc.; and Kesh Kesavadas, Simulated Surgical Systems, LLC.

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Friday, September 7, 2012 1:45- 5:30pm (St. George C& D)

Fundamentals of Robotic Surgery (FRS): Overview and Results of First Two Consensus Conferences

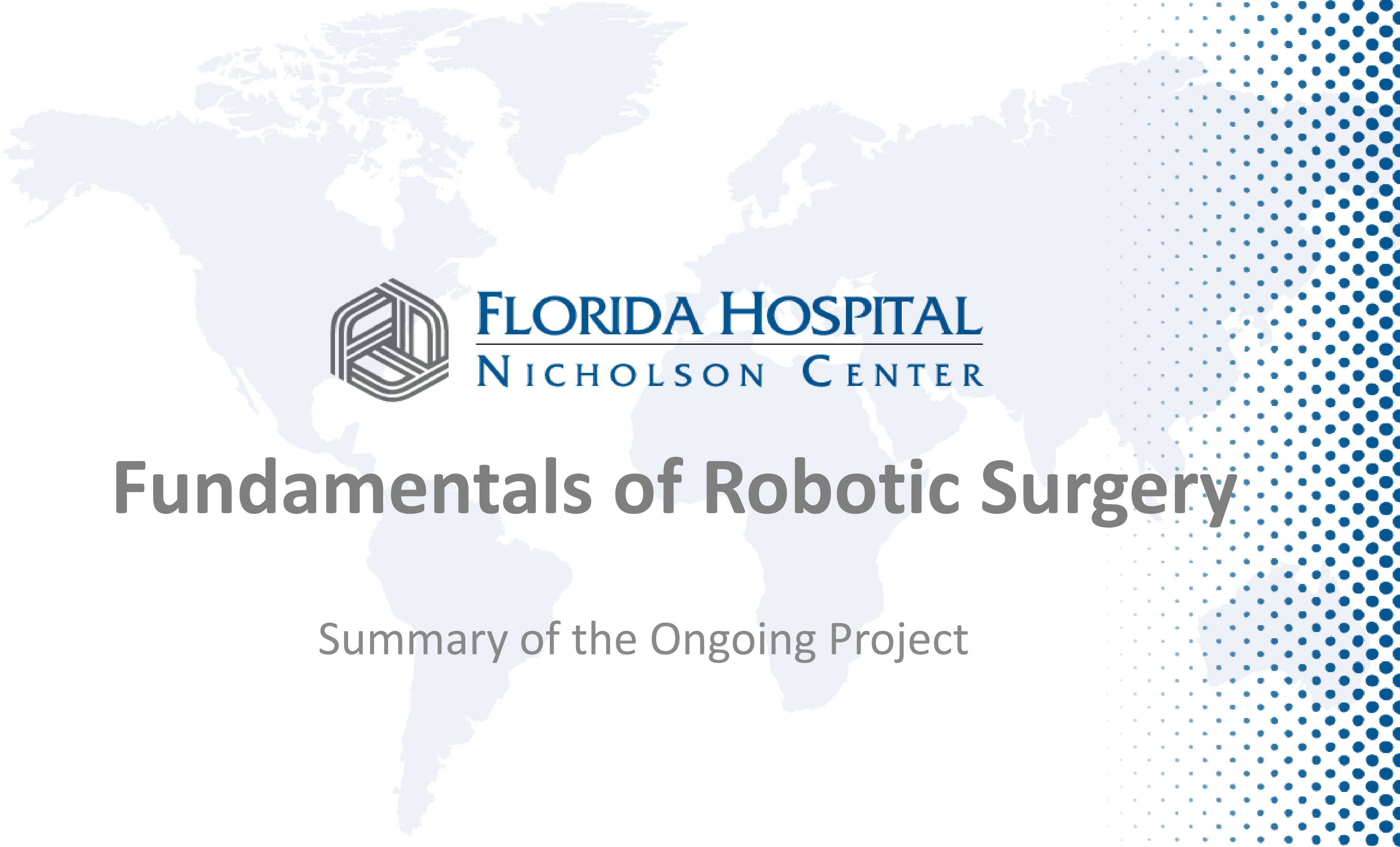
Faculty
Richard M. Satava, MD, FACS
Roger Smith, PhD

Objective: To describe the development process of the FRS curriculum and document results of the project to date

Methods: Full life-cycle curriculum development using a combined classic and modified Delphi process and adaptation of the Alliance of Surgical Specialties for Education and Training (ASSET) templates for curriculum development

Results: The full life-cycle curriculum process was presented and accepted. Outcomes Measures for 26 skills were defined, with associated metrics, errors and testing methodology by a consensus conference that included surgical educators, accrediting organizations, residency review committees, multiple specialty societies, and multiple surgical certificating Boards. The FRS curriculum was developed using the ASSET Curriculum Development Template that resulted in the division of the tasks into 3 categories (pre-operative, intra-operative and post-operative), and inclusion of the 26 skills into 7 specific tasks. (1 pre-operative, 5 intra-operative and 1 post-operative) plus 5 Fundamentals of Laparoscopic (FLS) tasks The next consensus conference will be the Validation Study Design, followed by a multi-institutional validation study by 10 participating American College of Surgeons – Accredited Educational Institutions.

Conclusions: A rigorous methodology was utilized to define the critical Outcomes Measures for the FRS curriculum. A curriculum of 7 tasks was developed in accordance with the ASSET curriculum template. Input from subject matter experts from surgical education professionals and stakeholders in governing bodies, certifying organizations and multiple surgical societies resulted in a multi-specialty FRS curriculum that will be validated and offered to certification boards for their consideration.



FLORIDA HOSPITAL
NICHOLSON CENTER

Fundamentals of Robotic Surgery

Summary of the Ongoing Project

FRS Summary for Distribution at SLS 2012, Boston, MA

Grants Leadership

PI: Richard Satava, MD
Minimally Invasive Robotics Assoc

Source: Intuitive Surgical Inc.

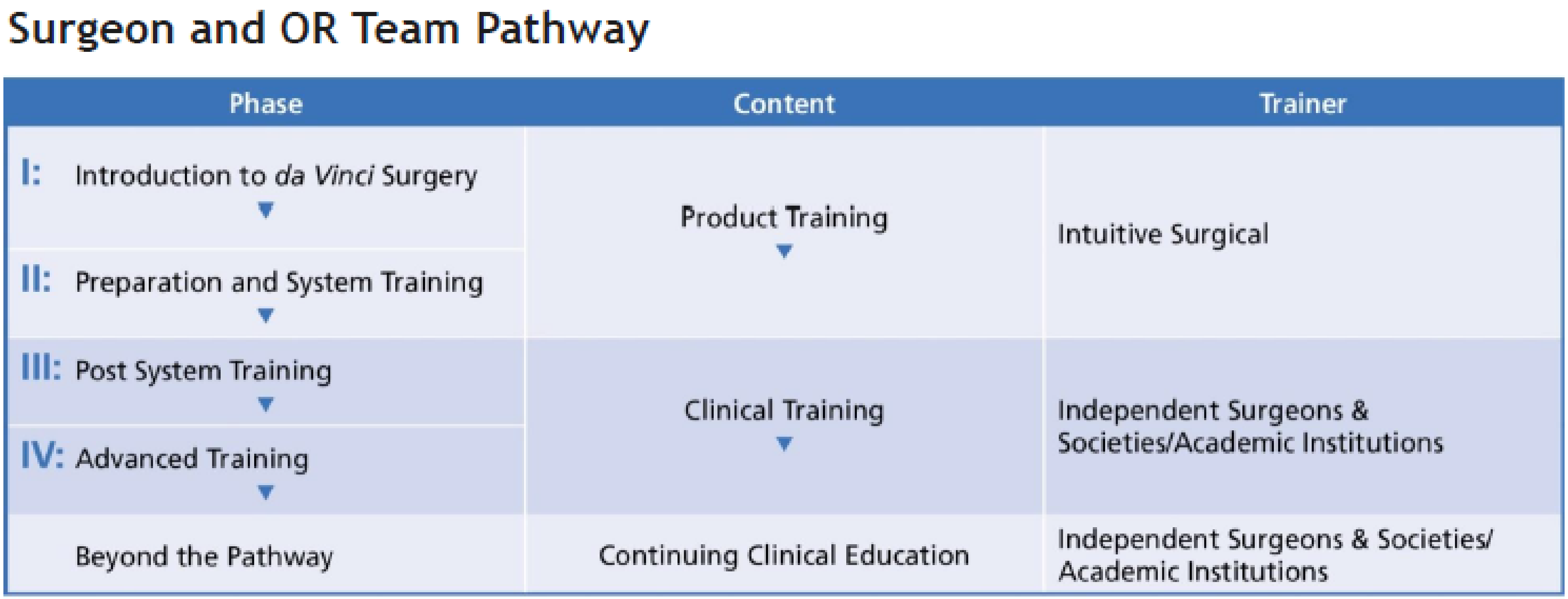
PI's: Roger Smith, PhD & Vipul Patel, MD
Florida Hospital Nicholson Center

Source: US Department of Defense

* This work was supported by an unrestricted educational grant through the Minimally Invasive Robotics Association from Intuitive Surgical Incorporated.

** This effort was also sponsored by the Department of the Army, Award Number W81XWH-11-2-0158 to the recipient Adventist Health System/Sunbelt, Inc., Florida Hospital Nicholson Center. "The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office." The content of the information does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.

Intuitive Surgical's Training Pathway



Surgeon and OR Team Pathway

Phase	Content	Trainer
I: Introduction to *da Vinci* Surgery ▼	Product Training ▼	Intuitive Surgical
II: Preparation and System Training ▼		
III: Post System Training ▼	Clinical Training ▼	Independent Surgeons & Societies/Academic Institutions
IV: Advanced Training ▼		
Beyond the Pathway	Continuing Clinical Education	Independent Surgeons & Societies/ Academic Institutions

- Phases I-II focus on product training, while phases III-IV focus on clinical training
- Beyond the pathway, skills are honed with continuing clinical education

FRS Mission Statement

Create and develop a validated multi-specialty, technical skills competency based curriculum for surgeons to safely and efficiently perform basic robotic-assisted surgery.

Note: The intent is to create a curriculum that is device-independent. This is admittedly difficult given the single approved surgical robot at this time. Therefore, significant attention is being paid to material that is device-flexible in anticipation of future robots.

Participating Organizations

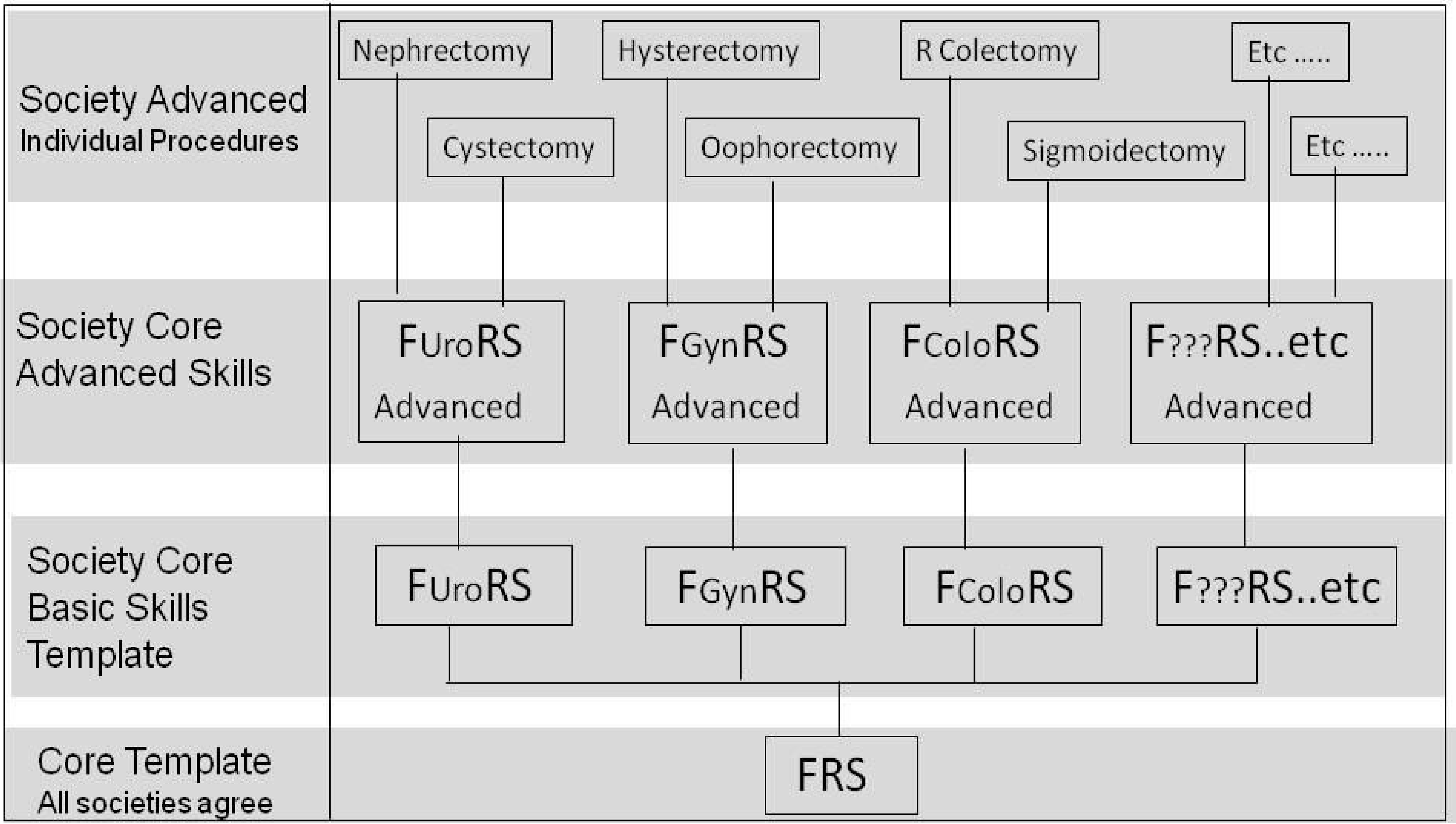
- **American Association Gynecologic Laparoscopy (AAGL)+**
- American College of Surgeons (ACS)
- American Congress of OB-Gyn (ACOG)
- **American Urologic Association (AUA) +**
- American Academy of Orthopedic Surgeons (AAOA)
- American Assn of Thoracic Surgeons (AATS)
- American Assn of Colo-Rectal Surgeons (ASCRS)
- American Assn of Gynecologic Laparoscopists (AAGL)
- **Florida Hospital Nicholson Center***
- **U.S. Department of Defense (DoD)***
- U.S. Department of Veterans Health Affairs (VHA)
- **Minimally Invasive Robotic Association (MIRA)***
- Society for Robotic Surgery (SRS)
- **Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) +**
- American Board of Surgery (ABS)
- Accreditation Council of Graduate Med Education (ACGME)
- Association of Surgical Educators (ASE)
- Residency Review Committee (RRC) – Surgery
- Royal College of Surgeons-Ireland (RCSI)
- Royal College of Surgeons-London (RCSL)

*** Funding Organizations**
+ Executive Committee

Florida Hospital
Nicholson Center

Development of Curriculum from common template

“Sweet* Tree”



Society Advanced
Individual Procedures

Nephrectomy
Cystectomy
Hysterectomy
Oophorectomy
R Colectomy
Sigmoidectomy
Etc .....
Etc .....

Society Core
Advanced Skills

FUroRS Advanced
FGynRS Advanced
FColoRS Advanced
F???RS..etc Advanced

Society Core
Basic Skills
Template

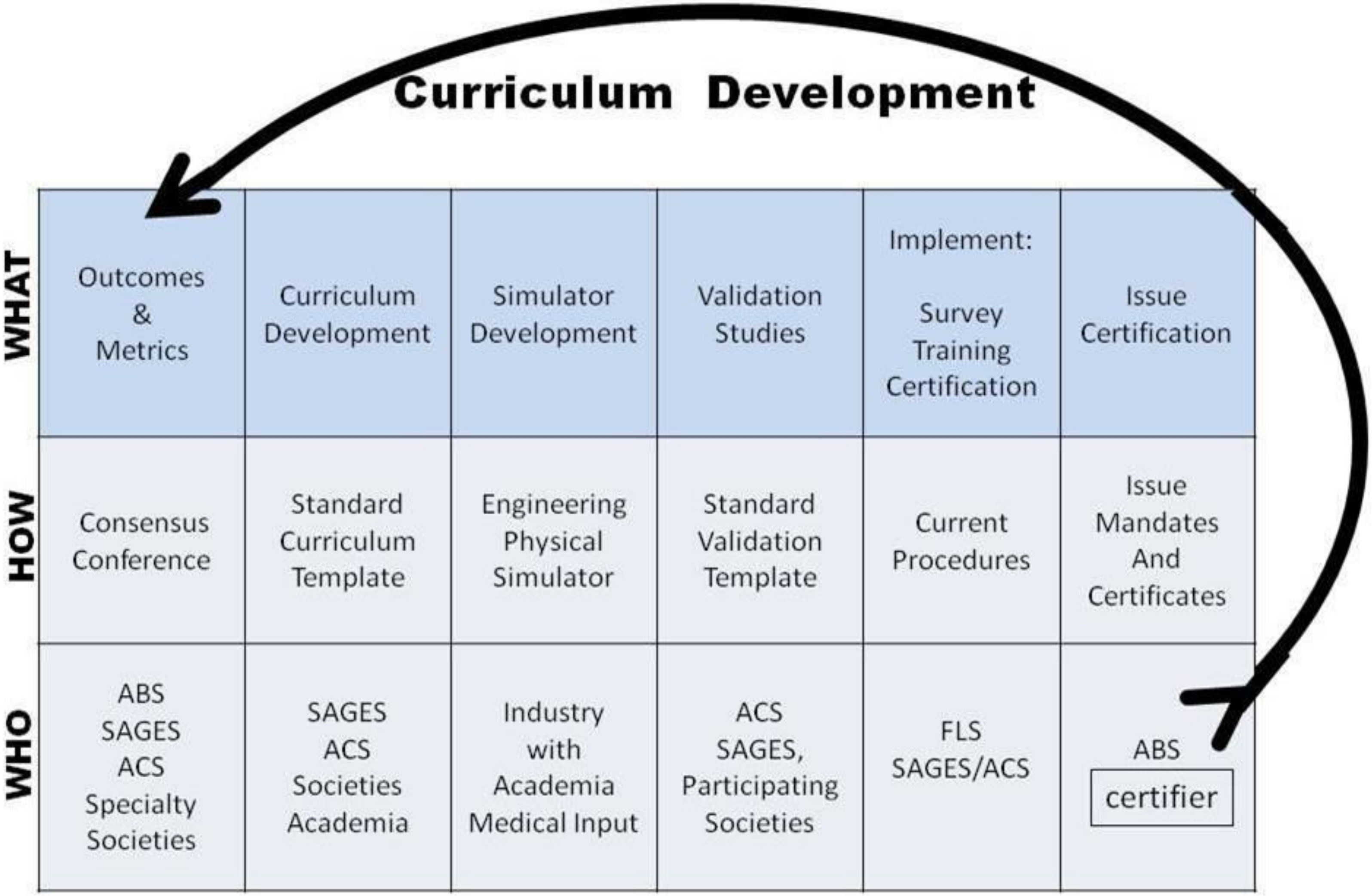
FUroRS
FGynRS
FColoRS
F???RS..etc

Core Template
All societies agree

FRS

* Adapted from Rob Sweet, MD, Professor of Urology, University Minnesota, 2010

The Metrics Drives the Process



Curriculum Development

WHAT	Outcomes & Metrics	Curriculum Development	Simulator Development	Validation Studies	Implement: Survey Training Certification	Issue Certification
HOW	Consensus Conference	Standard Curriculum Template	Engineering Physical Simulator	Standard Validation Template	Current Procedures	Issue Mandates And Certificates
WHO	ABS SAGES ACS Specialty Societies	SAGES ACS Societies Academia	Industry with Academia Medical Input	ACS SAGES, Participating Societies	FLS SAGES/ACS	ABS certifier

Creator: Rick Satava, MD, Univ of Washington

Consensus Conference Process

1. Outcomes Measures (Dec 12-13, 2011)
2. Curriculum Outline (April 29-30, 2012)

2.5 Curriculum Development (Aug 17-18, 2012)

3. Validation Criteria (November 17-18, 2012)
4. Validation Studies (2013)
5. Transition to Objective Testing Organization (est. July 2013)

- Expert Discussion and Contributions
- Modified Delphi Voting Mechanism

#1 Outcomes Measures

Pre-Operative	Intra-Operative	Post-Operative
System Settings	Energy Sources	Transition to Bedside Asst
Ergonomic Positioning	Camera Control	Undocking
Docking	Clutching	
Robotic Trocars	Instrument Exchange	
OR Set-up	Foreign Body Management	
Situation Awareness	Multi-arm Control	
Closed Loop Comms	Eye-hand Instrument Coord	
Respond to System Errors	Wrist Articulation	
	Atraumatic Tissue Handling	
	Dissection – Fine & Blunt	
	Cutting	
	Needle Driving	
	Suture Handling	
	Knot Tying	
	Safety of Operative Field	

Faculty Members: Outcomes Measures

Arnold Advincula, MD	American Assoc of Gynecologic Laparoscopists & ACOG
Rajesh Aggarwal, MD	Royal College of Surgeons - London
Mehran Anvari, MD	Minimally Invasive Robotic Association (MIRA)
John Armstrong, MD	USF Health, CAMLS (now Florida Surgeon General)
Paul Neary, MD	Royal College of Surgeons - Ireland
Wallace Judd, PhD	Authentic Testing Corp.
Michael Koch, MD	American Board of Urology
Kevin Kunkler, MD	US Army Medical Research & Materiel Command TATRC
Vipul Patel, MD	Global Robotics Institute - Florida Hospital Celebration Health
COL Robert Rush, MD	US Army Madigan Healthcare System
Richard Satava, MD	Minimally Invasive Robotic Association (MIRA)
Danny Scott, MD	Society of American Gastro and Endoscopic Surgeons (SAGES)
Mika Sinanan, MD	University of Washington
Roger Smith, PhD	Florida Hospital Nicholson Center
Dimitrios Stefanidis MD	Association for Surgical Education
Chandru Sundaram, MD	American Urological Association
Robert Sweet, MD	American Urological Association
Edward Verrier, MD	Joint Council on Thoracic Surgery Education

Outcomes Definitions (Sample)

Task Name	Description	Errors	Outcomes	Metrics	Importance Rating					
					1	2	3	4	Total Score	Rank Order
Needle driving	Accurate and efficient manipulation of the needle.	Tearing tissue, Troughing the needle, Needle scratching, Wrong angle on entry/exit, Adjacent organ injury, (more)	Accurate and efficient placement of needle through targeted tissue, Following the curve of the needle, without associated tissue injury	Time, accuracy, tissue damage, material damage	0	0	3	6	33	3
Atraumatic handling	Haptic comprehension. Using graspers to hold tissue or surgical material without crushing or tearing.	Traumatic handling, Tissue damage or hemorrhage	Manipulates tissue and surgical materials without damage	Metric-respect for tissue, Stress and strain indentation and deformation	0	0	3	6	33	4

#2 Curriculum Development

Didactic & Cognitive	Psychomotor Skills	Team Training
Lecture-based	**Principle-based**	**Checklist-based**
Intro to Robotic System	Based on Physical Models (Virtual Models are Derivative)	#1: WHO Pre-Op
Pre-Operative Activity	3D Exam Tools	#2: Robotic Specific
Intra-Operative Activity	Use Tasks that have Evidence of Validity	#3: Undocking & Debriefing
Post-Operative Activity	Multiple Outcomes Measured per Exercise	#4 Crisis Scenarios
Each Activity includes: Goals, Conditions, Metrics, Errors, Standards	Cost Effective Solution	
	High Fidelity for Testing, Lower Fidelity for Training	
	IRR Requires Ease of Administration	

Faculty Members: Curriculum Develop

- Arnold Advincula
- Abdulla Al Ansari
- David Albala
- Richard Angelo
- James Borin
- David Bouchier-Hayes
- Timothy Brand
- Geoff Coughlin
- Alfred Cuschieri
- Prokar Dasgupta
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- Brian Dunkin
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- Gary Dunnington
- Ricardo Estape
- Peter Fabri
- Vicenzo Ficarra
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- Piero Giulianotti
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- James Hebert
- Robert Holloway
- Santiago Horgan
- Lenworth Jacobs
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- Chandru Sundaram
- Robert Sweet
- Amir Szold
- Raju Thomas
- Oscar Traynor
- Thomas Whalen
- Gregory Weinstein

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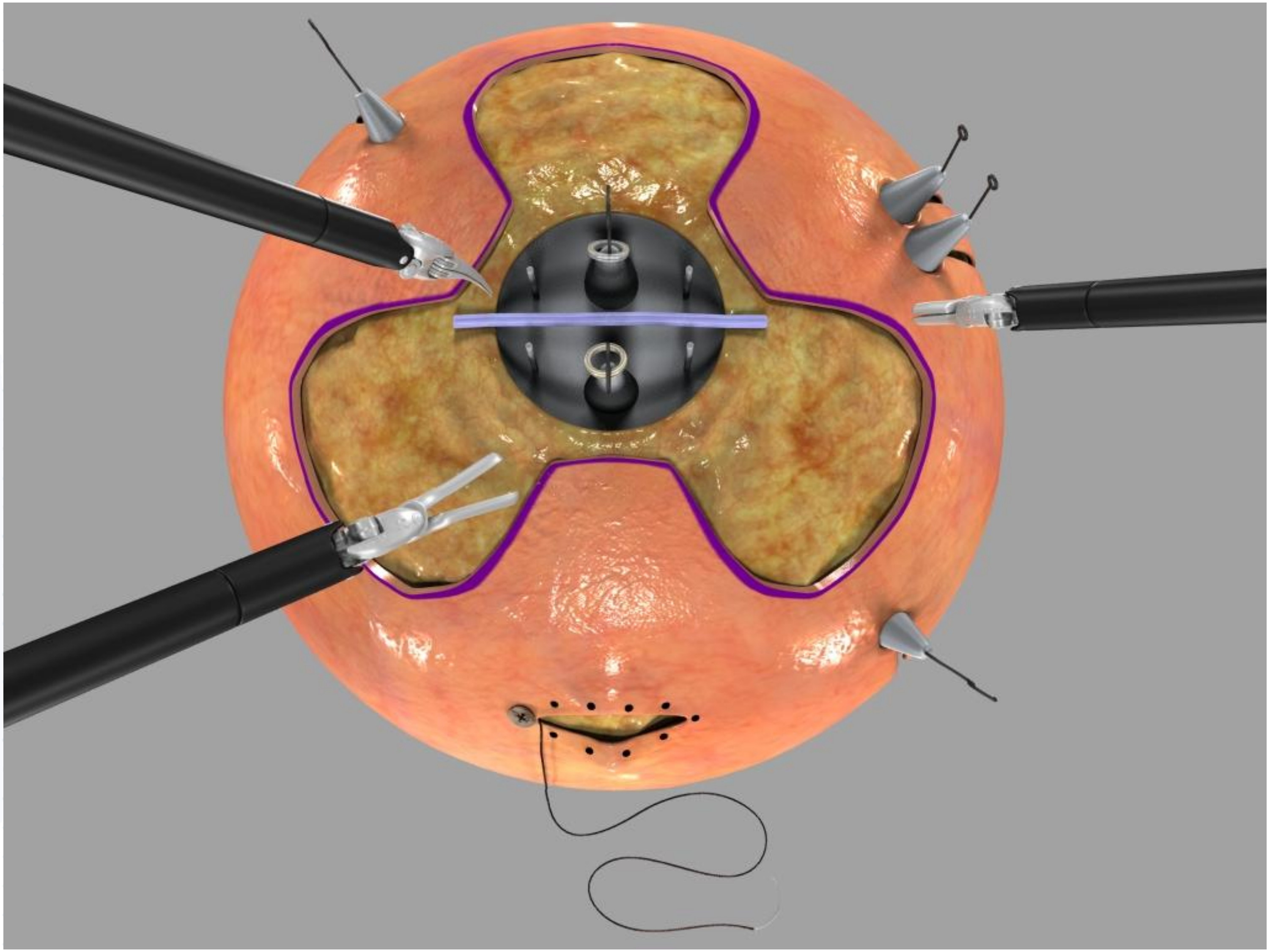
Didactic Knowledge (Sample)

Title	**Description**	**Desired Presentation Format (Images/checklists/videos..)**
Trocars placement: trocar entrance injury, incorrect position, spacing and location, incorrect insertion depth, port-site injury	• Ports placed in areas of previous scars • Not checking for injuries after placement • Tip of the trocar not visualized during insertion	Video demonstrations of safe use of open cutdown, Verress needle, and Optiview techniques. Ideally video showing injuries occurring Video of arm collisions at the bedside due to inappropriate trocar placement Video or picture showing injury to port site when port not inserted appropriately Images of correct and incorrect port positions (outside view and inside)

Psychomotor Multi-Skill Device Design



Team Training and Communication (Sample)

Checklist 1: Pre-operative
Checklist 2: Robotic Docking
Checklist 3: Intraoperative (see above)
Checklist 4: Undocking
Checklist 5: Debriefing

Checklist 3: Intraoperative Checklist (Pauses at Critical Steps in the Procedure and time-based - hourly)

- Is there good team communication concerning instrument usage and transfer?
- Are all foreign objects accounted for (i.e. white boarding) and removed?
- Are the periodic checks occurring to discuss case progression, team member continuity, and other issues?
- Has there been regular communication with anesthesia?

Testing Environments

Primary:
Robot

Derivative:
Simulator

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#3 Validation Conference

- Criteria
  - Validate the curriculum and passing criteria that will be used to grant certification

- Multi-Institutional Study
  - 10 independent sites
  - ACS AEI accredited
  - Faculty in at least 2 specialties

Conclusions

- Objective curriculum in robotic surgery is needed for certification
- Development of such a curriculum is underway by a multi-specialty working group of experienced surgeons

Thank You!

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Using simulators to measure communication latency effects in robotic telesurgery

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ABSTRACT

Robotic surgical technology was originally developed by the US Army and DARPA as a tool to enable telesurgery at a distance. The Intuitive da Vinci system now provides a robotic surgical tool in a traditional operating room. But research continues into the extension of this capability to patients that are remote from the surgeon's location. In this paper we describe the interim results of experiments into the effects of communication latency in the safe execution of robotic telesurgeries. These experiments were carried out with the Mimic dV-Trainer, a simulator of the da Vinci robot, which was configured to insert a defined level of latency into the visual and command data streams between a surgeon and the operating field. Subjects were asked to perform four basic robotic surgical tasks. They were allowed to rehearse these in a zero latency environment and with a randomly assigned latency between 100ms and 1,000ms. Then each subject performed each task for measurement and analysis in our research.

This experiment measures the degradation of human surgical performance across a range of latency conditions. This paper reports on interim analysis which compares the level of experience of the surgeons to their performance in a latency effected environment. The data collected thus far refutes our hypothesis that more experienced surgeons would be more successful at managing the effects of latency and would perform better than those with less experience. Subjects in our experiments show no correlation between experience and successful performance under latency.

ABOUT THE AUTHORS

Roger Smith, PhD, is an expert in the development of simulation devices and training programs. He has spent 25 years creating leading edge simulators for the Department of Defense and Intelligence agencies, as well as accredited methods for training with these devices. He is currently the Chief Technology Officer for the Florida Hospital Nicholson Center where he is responsible for establishing the technology strategy and leading technology implementation through the development of alliances with industry, the military, academic institutions, physician networks and governing medical associations. This includes identifying, executing and managing industry, military and federally funded simulation, modeling and training projects. He has served as the CTO for the U.S. Army PEO for Simulation, Training and Instrumentation (PEO-STRI); VP and CTO for training systems at Titan Corp; and Vice President of Technology at BTG Inc. He holds a Ph.D. in Computer Science, a Doctorate in Management, and an M.S. in Statistics. He has published 3 professional textbooks on simulation, 10 book chapters, and over 100 journal and conference papers. His most recent book is *Innovation for Innovators: Leadership in a Changing World.* He has served on the editorial boards of the *Transactions on Modeling and Computer Simulation* and the *Research Technology Management* journals.

Sanket Chauhan, MD, is a Robotic Urology Fellow at the University of Minnesota Medical School. Prior to this he was with the Florida Hospital, Global Robotics Institute and an instructor of Urology at the University of Central Florida's College of Medicine. Dr. Chauhan's research interests include developing new technologies for the future of surgery, telesurgery, surgical education, advanced surgical technologies, surgical simulation and the use of virtual reality and augmented reality in surgery. He has published more than 25 papers in peer reviewed journals and has authored 3 book chapters. Dr Chauhan is committed to surgical education using next generation VR based simulators. He is a member of the program committee for International Association for Science and Technology for Development (IASTED) Robotics and Control conference in 2010, and the World Robotic Surgery Symposium.

Using simulators to measure communication latency effects in robotic telesurgery

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HISTORY OF TELESURGERY

Robotic surgery has been the topic of science fiction and scientific research for decades. As early as 1942, Robert A. Heinlein published the story "Waldo" in *Astounding Science Fiction*. He described the use of gloves and a harness to allow Waldo Jones to control mechanical arms of any size from large industrial and construction equipment to miniature tools for electronic and surgical work. The Industrial Revolution gave us many of the tools needed to extend the capabilities of the human body, but the Information Age was required to create the computerized control systems necessary to effectively control these devices. Surgical robots are a marriage of mechanical, electrical, optical, and software engineering that can empower a human surgeon to peer into a patient's body with magnified stereo vision, probe the internal organs, and perform effective surgery without fully opening a patient's body.

In 1985, the PUMA 560 was used to accurately place a needle for a brain biopsy using CT guidance (Kwoh et al, 1988). In 1988, the PROBOT at Imperial College London, was used to perform prostatic surgery. In 1992, Integrated Surgical Systems introduced ROBODOC to mill precise fittings in the femur for hip replacement. Intuitive Surgical leveraged the research work of the Defense Advanced Research Projects Agency (DARPA) and used their advances to create the da Vinci Surgical System which they introduced in 1997. Computer Motion followed a similar path and fielded the *AESOP* and ZEUS robotic systems (Figure 1), which were later acquired by Intuitive Surgical (Satava, 1998; FDA, 2005).

Figure 1. ZEUS Surgical Research Robot

Intuitive's da Vinci robot senses the surgeon's hand movements and translates these into scaled-down micro-movements to manipulate tiny instruments inside the body. It also detects and filters out any tremors in the surgeon's hand movements, so that they are not expressed robotically. The camera used in the system provides a true stereoscopic picture transmitted to a surgeon's console (Figure 2).

These devices opened the door for the realization of surgery-at-a-distance, a.k.a. telesurgery, in which a surgeon is able to extend his reach and perform surgical procedures at a significant distance from the patient. This capability has been demonstrated under unique conditions by multiple experiments (Himpens, 1998; Janetschek, 1998; Fabrizio, 2000; Sterbis, 2007). Our research project at the Florida Hospital Nicholson Center is demonstrating the maturity of the existing telecommunication infrastructure within a hospital system to support daily, on-demand telesurgery right now. Our experiments are based on the da Vinci surgical robot by Intuitive Surgical and the dV-Trainer simulator by Mimic Technologies.

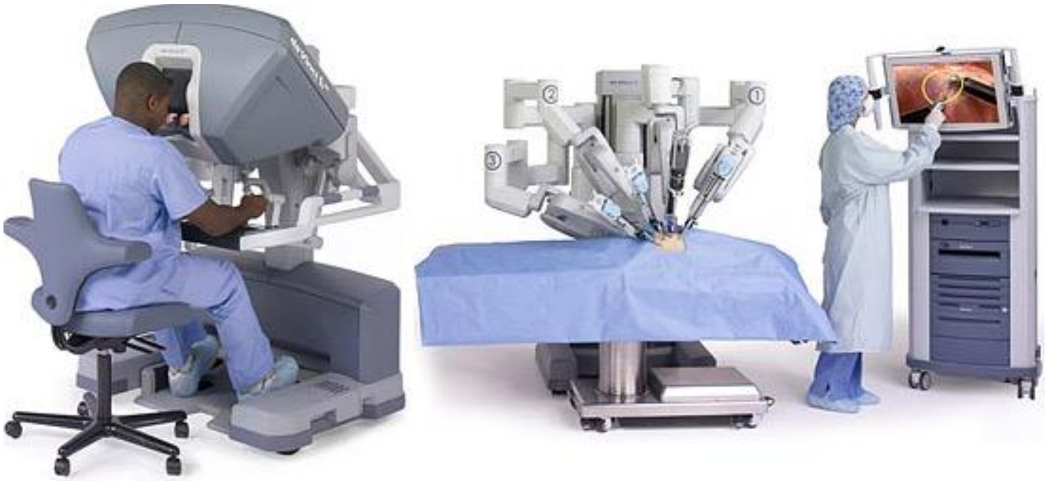


Figure 2. da Vinci Surgical Robot

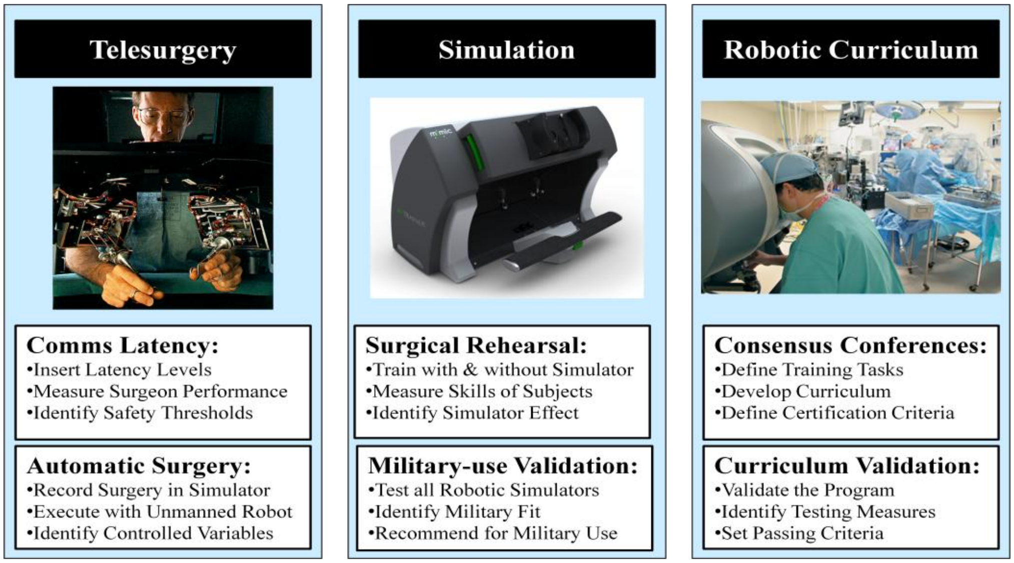


Figure 3. Nicholson Center Grant Research Focus

FLORIDA HOSPITAL RESEARCH PROGRAM

In April 2010, Congressman Allen Grayson directed a grant to Florida Hospital's Nicholson Center for research into clinically effective advances in robotic and telesurgery. This $4.2 million grant has funded multiple research projects focusing on telesurgery, simulation-based surgical rehearsal, and the creation of a standard robotic curriculum (Figure 3).

TELESURGERY EXPERIMENTAL DESIGN

This paper describes the interim results of our first experiment in telesurgery. This explores the effects of communication latency on surgeon performance. This latency effect is created using the dV-Trainer simulator of the da Vinci surgical robot (Hung, 2011; Kennedy 2009). This simulator allows the insertion of specific levels of controlled latency so that the user's physical movements are not manifest by the simulated instruments until after the defined latency period has elapsed (Figure 4).

Figure 4. Mimic dV-Trainer Simulator.

During actual telesurgery the messages sent between the surgeon's machine and the remote patient station will be delayed due to the speed of light and the message routing that occurs on the internet. Determining how much latency can be safely tolerated in surgery is an important question (Anvari, 2005 and 2007). This experiment hypothesizes that there are two distinct thresholds of performance under increasing latency. The first is the level of latency at which a surgeon can first detect that his or her movements are being affected by the communication link. Any communication latency lower than this is imperceptible and potentially non-invasive to the surgical procedure. Hence, if such levels can be achieved in the real world, then telesurgery may be safe for human surgery right now. The second level is the point at which the surgeon's performance is degraded to the point that the surgery cannot be performed safely (Marescaux, 2002 and Lum, 2009). This level is identified through both simulator measured performance and the expert opinion of the surgeon. Between the first and second thresholds, a surgeon may be able to successfully control the effects of latency and perform a safe and successful procedure. Beyond the second threshold, telesurgery would be considered unsafe with the available equipment (Figure 5). Given the limited data set that has currently been collected, we further hypothesize that more experienced surgeons will be more successful at managing the effects of latency and will therefore receive higher scores in the simulated test environment. This paper reports on the analysis of the collected data on this smaller, more focused hypothesis.

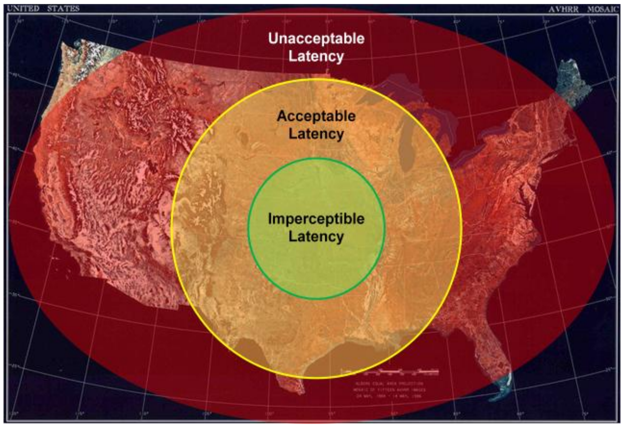
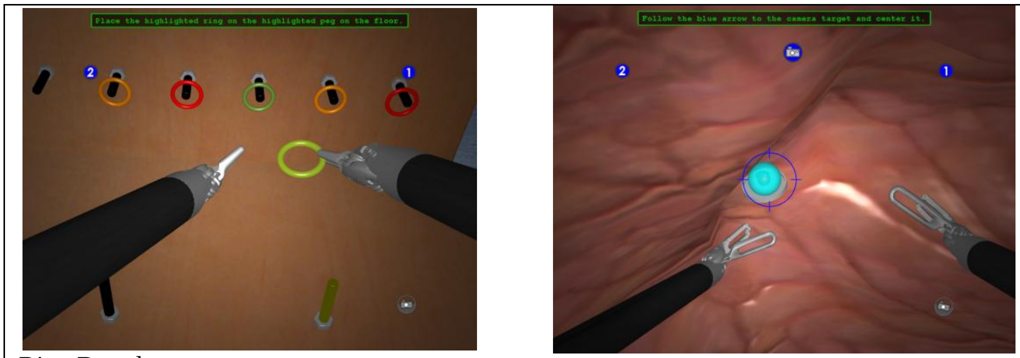


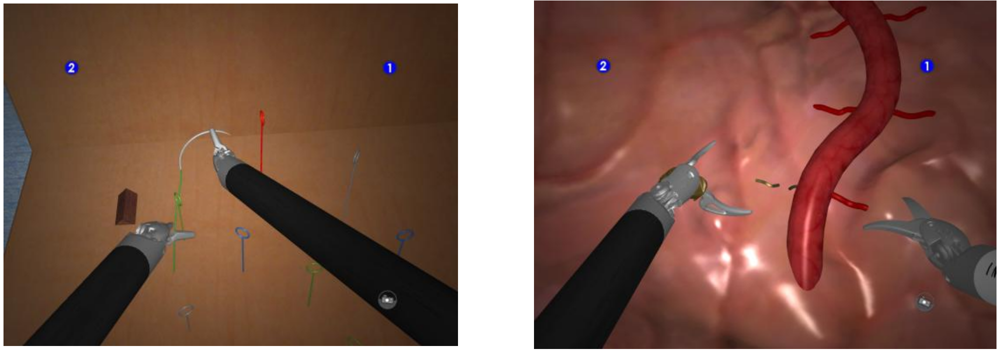
Figure 5. Conceptual Communication Latency Thresholds.

In our experiments, subjects performed the four simulated surgical skills tasks shown in Figure 6. These represent many of the important skills that are required in human surgery. Each skills task was performed three times. First, each subject was given an opportunity to perform the task without out any imposed latency. This baseline insured that they were able to successfully operate the controls under normal conditions. Second, they were allowed to perform each of the four tasks at a randomly assigned latency level. These four repetitions provide the learning necessary to achieve a sustained level of proficiency within a latent environment (Rayman et al 2006). Finally, each subject performed all four tasks at the randomly assigned latency level and their performance was measured for analysis in the study.

A single latency level between 100 milliseconds (ms) and 1,000ms at increments of 100ms was randomly assigned to each subject. A proctor was available to instruct subjects on the use of the equipment and to guide them through the curriculum of the protocol. However, this proctor was not allowed to give suggestions on performance of the exercises or to tell the subject the specific level of latency that they were experiencing.



Ring Board Camera Targeting



Needle Threading Energy Application

Figure 6. Simulated Surgical Skills Tasks

SIMULATED TELESURGERY DATA COLLECTION

Experimental data was collected by the simulator software and manually using a questionnaire. Research proctors administered a Pre-Test questionnaire on the level of surgical experience and related activities of the subject. All personal and performance data was anonymized to insure that the identity of the subject could not be linked to the data that was collected. The proctors also administered a Post-Test questionnaire at the conclusion of each of the skills exercises during the final performance stage. The simulator software automatically collected multiple measures of performance of the subject's performance. This provided performance data for all subjects at zero latency, during their familiarization stage with latency, and during the final stage which is the focus of this paper. Together all of this data will allow us to perform multiple analyses of the skills of robotic surgeons both with and without communication latency.

Pre-Test

The Pre-Test questionnaire identified multiple items of demographic, experience, and practice data on the subjects. These included: age, gender, dominant hand, surgical status, years of surgical experience, years of laparoscopic experience, years of robotic experience, number of weekly procedures in laparoscopy and robotics, and experience with a robotic simulator, and experience with video games and musical instruments. Additional questions captured their opinion on the use of simulation in surgical education and certification.

This data was then matched with the data on their performance on the simulator.

Simulator Test

During the experiment, the simulator itself collected a number of data points on each subject's performance. These included: name of exercise, time to complete, cumulative score, total hand motion in centimeters, master working space, number of instrument collisions, number of items dropped, excessive instrument force, distance instruments out of view, incorrect use of electrical energy, simulated blood loss, and number of broken blood vessels.

Post-Test

As the subjects completed each of the four focus exercises, the proctor administered a post-test questionnaire which asked the subject for their opinion on the stress induced by the simulation with latency.

These included measures of the mental and physical demands of the task, the pace of the task, their opinion on their level of success, the amount of effort expended, the level of mental discouragement experienced, and their perceived complexity of the exercise.

DATA ANALYSIS

During the first phase of the study reported in this paper we collected data from 35 experienced surgeons at two locations. The first was from those attending the World Robotics Gynecology Conference at the Disney Contemporary Resort and the second was from those attending the Advanced Robotics course taught at Florida Hospital Nicholson Center.

Of the 35 subjects who began the experiment, several were unable to complete all of the tasks due to the limited amount of time that they could devote to the experiment. Others found the experiment too taxing and elected to terminate their participation before completion. As a result, we collected complete data sets on only 21 of the participants.

The data from the pre-test, post-test, and simulation test were all loaded into an Access database, SPSS statistical software, and an Excel spreadsheet for analysis. This paper presents analysis performed with the Excel spreadsheet. The linear modeling work with SPSS is ongoing.

For the subjects included to this point, a set of graphs illustrate the relationship between two variables in the experiment. These are combinations of the years of robotic or laparoscopic surgical experience (independent variables) compared to overall performance scores and total number of mistakes (dependent variables) both with and without latency. These graphs illustrate performance on each of the four assigned exercises for three different repetitions, the first with no latency, the second a warm-up on their assigned latency, and the third the measured performance with assigned latency. The graphs for the Peg Board exercise are shown in this paper (Figure 7, 8, 9, 10).

The analyzed data suggest that there is a positive correlation between the number of years of robotic experience and the overall score that a subject will achieve in a simulated environment with no latency (Figure 7). Correspondingly, there is a negative correlation between experience and number of mistakes that occur in a simulated environment with no latency (Figure 9). However, for the subjects included in the test to this point, there is no consistent correlation between years of robotic experience and their performance in a simulated environment which includes any amount of latency (Figure 8 & 10). The results that are illustrated in these graphs are similar to those obtained for each of the exercises described above.

This suggests that surgeons who have more experience in robotic surgery are not better equipped to self-manage the challenges presented by communication latency in telesurgery. Subjects with little experience are as likely to successfully manage latency as are surgeons with more experience.

This same trend holds when comparing total surgical experience and laparoscopic experience to the scores achieved in the simulator with latency included. This lack of correlation between experience and telesurgical performance refutes our original hypothesis that a more experienced surgeon would more successfully manage the effects of latency, suggesting that telesurgery would be more successful when performed by a surgeon with more experience in traditional (no latency) procedures. This negative finding has led to speculation on the cause of these results. Several causes may be possible, but each will require additional experimentation. First, experienced surgeons may be very talented, but fixed, in their methods of performing surgery. This may lead experienced surgeons to perform poorly under latency because it is difficult for them to modify their behaviors, where inexperienced surgeons are less ingrained and more adaptable to the situation. Second, since the simulator is a computer-generated virtual environment, it is possible that surgeons who have more experience on simulators, virtual worlds, and computer games may have developed a proficiency for solving problems in this kind of environment. They may also have experienced latency in these environments and developed techniques for compensating for it. Third, the ability to manage latency may be related to the physical and biological wiring of an individual. This would be a similar phenomenon to the tendency for some people to experience simulator sickness, while others do not suffer from it. These speculations are worthy of further investigation.

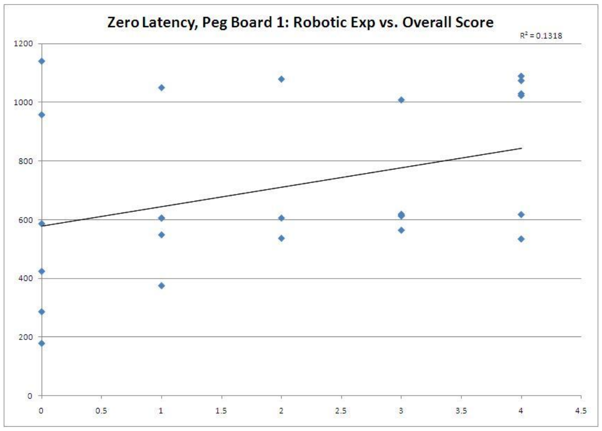


Figure 7. Correlation between Robotic Experience and Overall Score for the Peg Board exercise without communication latency.

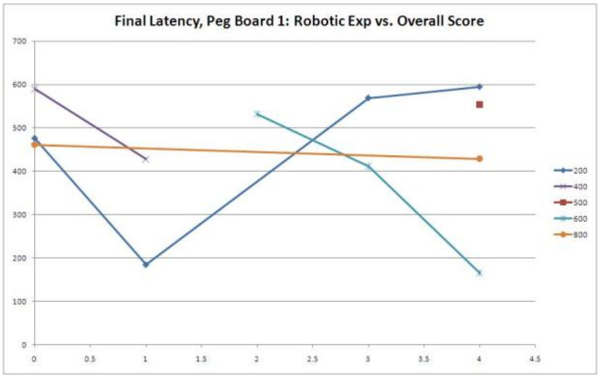


Figure 8. Correlation between Robotic Experience and Overall Score for the Peg Board exercise with communication latency.

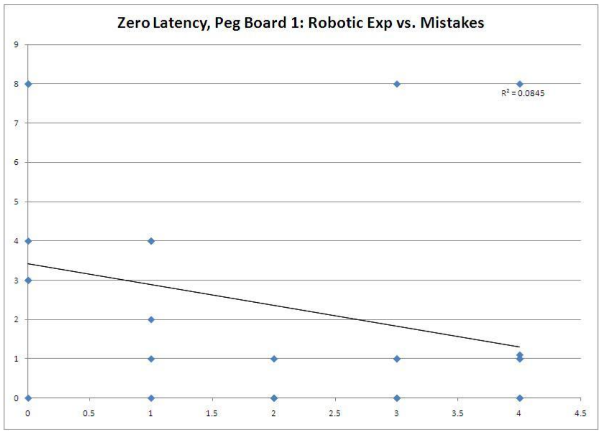


Figure 9. Correlation between Robotic Experience and Number of Mistakes for the Peg Board exercise without communication latency.

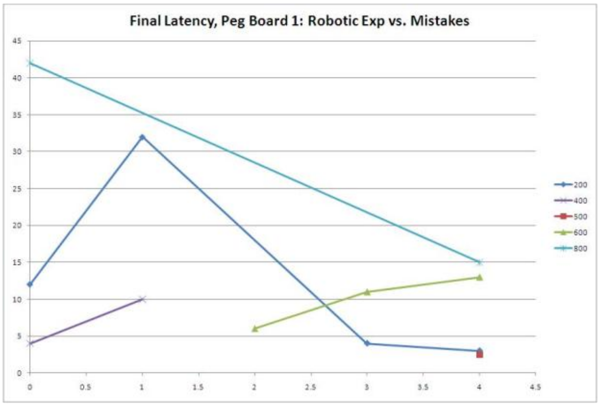


Figure 10. Correlation between Robotic Experience and Number of Mistakes for the Peg Board exercise with communication latency.

RESULTS

The objective of this experiment was to identify the degree to which a surgeon can compensate for the effects of latency that are present in a telesurgery environment. The long-term goal is to identify the thresholds where safe and successful surgery can be performance. In this initial analysis of the data we were exploring the hypothesis that surgeons with more robotic experience would be able to more successfully manage the effects of latency. Our findings to this point refute this hypothesis. In the data collected there is no correlation between robotic experience and the ability to achieve a higher score in the simulator or to commit fewer errors when latency is inserted into the procedure.

This experiment continues to collect sufficient data points to identify the lower and upper thresholds for successfully managing latency effects in telesurgery. We do not yet have sufficient data to answer that question.

ACKNOWLEDGEMENTS

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Contribution of laparoscopic surgical experience to the development of robotic simulator proficiency

Advincula AP, Abdul Muhsin H, Smith RD

Objective: To determine the degree to which a surgeon's years of laparoscopic experience contribute to the acquisition of robotic surgical skills and the achievement of proficiency.

Methods: Surgeons were tested in their ability to perform four different simulated robotic surgical skills using the dV-Trainer simulator (Mimic Technologies, Inc., Seattle, WA) of the da Vinci Surgical System (Intuitive Surgical Inc., Sunnyvale, CA). The subjects completed a pre-test questionnaire to provide demographic and experience data, which included the number of years of practice in both laparoscopic and robotic surgery. Each subject performed four exercises using the simulator: pegboard, camera targeting, thread the rings, and energy dissection. The simulator collected multiple performance metrics during each of the exercises. A Pearson's correlation was calculated on the relationship between the number of years of laparoscopic and robotic experience (independent variables) with their overall proficiency score on the robotic simulator (dependent variable).

Results: A total of 54 subjects participated in the experiment and 42 completed all four tasks in the robotic simulator. The subjects reported a range of experience in laparoscopic surgery between 4 and 34 years, and in robotic surgery between 0 and 11 years. Subjects indicating zero years of robotic experience were excluded from the study, reducing the sample size to 30 surgeons. Using the Pearson Product Moment Correlation with 28 degrees of freedom and α=0.05, a significant correlation threshold of 0.349 was established. There was a statistically significant negative correlation between years of laparoscopic experience and the overall proficiency score in two of the four robotic surgery exercises (ring board = -0.361; ring thread = -0.454) and a negative correlation which did not achieve statistical significance in the two remaining exercises (camera targeting = -0.152; energy dissection = -0.228).

Conclusions: Using a robotic simulator to measure the proficiency of surgeons with both laparoscopic and robotic surgical experience we found a statistically significant negative correlation between the number of years of laparoscopic experience and proficiency in two of four exercises and a trend toward a negative correlation in the other two exercises. This analysis suggests that extensive laparoscopic experience may have a negative impact on the learning curve associated with robotic surgery.

NextMed/MMVR 20, San Diego, CA, Feb 20-23, 2013

Fundamentals of Robotic Surgery: Outcomes Measures and Curriculum Development

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Abstract. To standardize the curriculum and certification of robotic surgeons, a series of consensus conferences have been used to compile the outcomes measures and curriculum that should form the basis for the Fundamentals of Robotic Surgery (FRS) program. This has resulted in the definition of 25 specific outcomes measures and the creation of curriculum for teaching those via didactic lecture, psychomotor skills labs, and team training activities. This work has been supported and/or reviewed by the leading surgical societies involved in the use of robotic surgery.

Introduction

In 2004, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) launched the validated Fundamentals of Laparoscopic Surgery (FLS) curriculum and, together with the American College of Surgeons (ACS), promoted the FLS as a minimum standard before a surgeon should be allowed to perform laparoscopic procedures independently [1]. In 2009, The American Board of Surgery (ABS) mandated that in addition to Advanced Cardiac Life Support (ACLS) and Advanced Trauma Life Support (ATLS) a certificate documenting the successful passing of the FLS exam be included in the application in order to be eligible to sit the examination for certification in General Surgery [2].

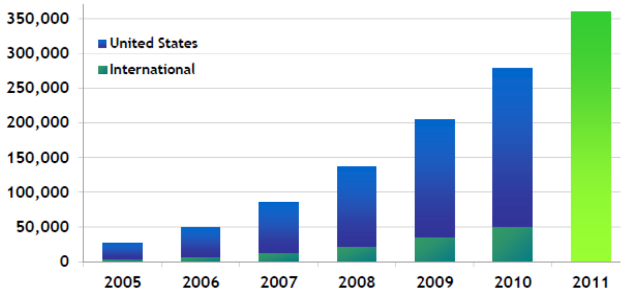


Figure 1. Growing number of robotic surgical procedures
Source: Intuitive Surgical, Inc Investor Prospectus, Feb, 2012

During the last decade, robotic surgery has transitioned through a similar evolution to laparoscopic surgery and is being recognized as an important surgical approach by multiple surgical specialties. Furthermore, it shows every sign of continuing the adoption of more diverse surgical procedures, as manifest by the fact that in calendar year 2011, approximately 350,000 robotic surgical procedures were performed (Figure 1). The number of procedures being performed by robotic surgery has been constantly rising in urology, gynecology, colorectal, pediatric and numerous other specialties. Expert robotic surgeons and numerous surgical societies and certifying organizations have advocated the need for the creation of a unified approach and standardized curriculum for basic training and certification in robotic surgery skills [3]. There have been efforts to develop a core curriculum for certifying robotic surgeons [4,5]; however, these have been fragmented, with different approaches and outcomes measures emerging from each. This has resulted in conflicting, competing and redundant curricula for the training and the assessment tools for robotic surgery. In addition, these curricula have generally lacked the human and financial resources necessary to complete the most comprehensive, multi-institutional validation that is necessary to gain acceptance at a national level.

Through the combined support of two grants, one to the Minimally Invasive Robotics Association and the other to Florida Hospital Nicholson Center, we have created a process and a group of participants which unify the previous attempts to develop a robotic curriculum and expand to a much larger foundation of surgical societies with a stake in this new technology. These grants provide the necessary funding to carry the effort through multi-institutional validation with the support of participants who represent all surgical specialties that are currently performing robotic surgery.

Methods & Materials

Participation in this effort was invited from multiple certifying boards, professional surgical societies, and associations that represent international practitioners and regulators of various surgical specialties as well as the United States Department of Defense (DoD) and Veterans Health Administration (VHA) (Table 1). The conference participants are members of these organizations or agencies and are selected to be able to provide insight into the needs of their organizations, but they do not represent an endorsement or acceptance of the results, and participation does not imply acceptance by the societies, boards or agencies. However, the AUA, AAGL, and SAGES elected to appoint and send representatives who could officially speak for their organizations' needs for a robotic curriculum and officially accept the results of the consensus conferences. This project is an effort to provide the stakeholders with the best scientific evidence upon which to base their decisions regarding implementation of a fundamental curriculum to meet their needs while reducing redundancy, competition and duplication of effort.

Table 1. Invited Organizational Representation in Fundamentals of Robotic Surgery.

American Association Gynecologic Laparoscopy (AAGL) *
American College of Surgeons (ACS)
American Congress of Obstetrics and-Gynecology (ACOG)
American Urologic Association (AUA) *
American Academy of Orthopedic Surgeons (AAOA)
American Association of Thoracic Surgeons (AATS)
American Association of Colo-rectal Surgeons (ASCRS)
Minimally Invasive Robotic Association (MIRA)[†]
Society for Robotic Surgery (SRS)
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) *
American Board of Surgery (ABS)
Accreditation Council of Graduate Medical Education (ACGME)
Association of Surgical Educators (ASE)
Residency Review Committee (RRC) – Surgery
Royal College of Surgeons-Ireland (RCSI)
Royal College of Surgeons-London (RCSL)
Royal College of Surgeons-Australia (RCSA)
U.S. Department of Defense (DoD)[†]
U.S. Department of Veterans Health Affairs (VHA)

* : Official Representative Participation
† : Funding organizations.

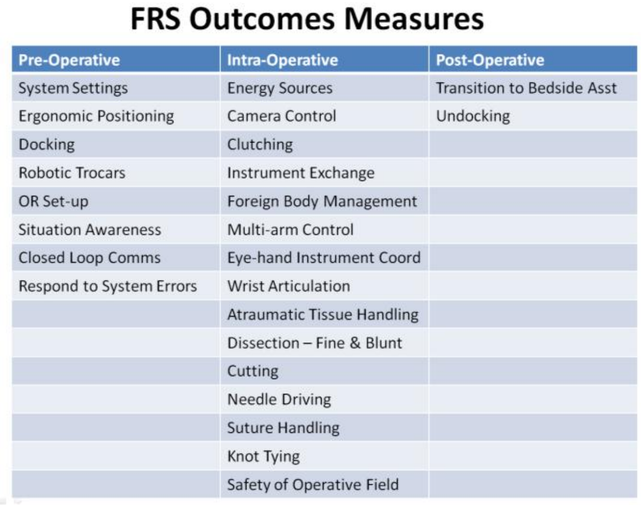
Each consensus conference was conducted over a two-day period using a modified Delphi method [6]. This methodology consisted of a facilitator who captured the input and guidance of the participants. This input was then analyzed for common concepts to create a list of critical items in robotic surgery. Previously published material from a single institution's curriculum was used as a template for initial idea generation [7,8]. The individual outcomes measures and curriculum materials were itemized and votes taken on their importance according to each participant. This method led to a composite ranking which was captured in a draft report. The report containing the first group ratings was then sent to each participant for their private deliberation. Each participant then submitted a second set of scores which were informed by the first composite scores, but anonymous to other group members. This modified Delphi Method led to a higher level of consensus around the measures and the curriculum. It also identified those items for which there was little group support. Those items were removed from the list of outcomes measures and from the outline of the curriculum.

The first conference on outcomes measures was attended by 20 participants that included surgeons, scientists, educators, and facilitators. The ranking of the tasks identified was done by a subset of nine experienced surgeons. Participants who were not surgeons abstained from the scoring process.

The second conference on curriculum development was attended by 38 surgeons, scientists, educators, and facilitators. This group reviewed and became familiar with the material from the first conference. Thereupon, they were divided into three working groups to develop curriculum that focused on didactic and knowledge-based information, psychomotor skills, and team training and communications. Similarly, the actual ranking of the material developed was limited to experienced surgeons within the group.

Results

The first consensus conference resulted in a list of 25 outcomes measures which the group agreed should be mastered by a surgeon seeking privileges in robotics. These included 8 pre-operative, 15 intra-operative and 2 post–operative tasks which are shown in Figure 2. The resulting report also provides detailed definitions, descriptions, errors, outcomes and metrics for each of these tasks [9].



FRS Outcomes Measures

Pre-Operative	Intra-Operative	Post-Operative
System Settings	Energy Sources	Transition to Bedside Asst
Ergonomic Positioning	Camera Control	Undocking
Docking	Clutching	
Robotic Trocars	Instrument Exchange	
OR Set-up	Foreign Body Management	
Situation Awareness	Multi-arm Control	
Closed Loop Comms	Eye-hand Instrument Coord	
Respond to System Errors	Wrist Articulation	
	Atraumatic Tissue Handling	
	Dissection – Fine & Blunt	
	Cutting	
	Needle Driving	
	Suture Handling	
	Knot Tying	
	Safety of Operative Field	

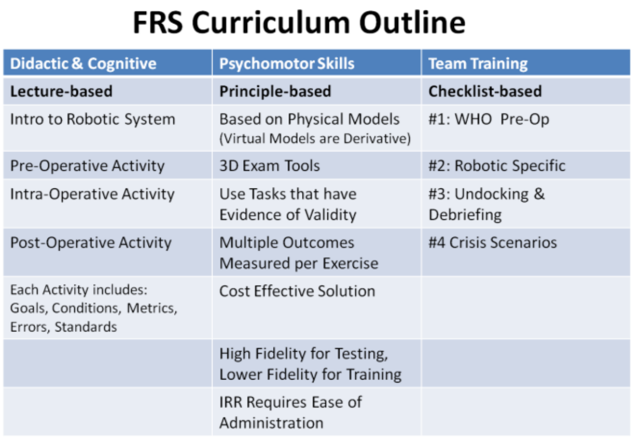
Figure 2. FRS Outcomes Measures.

The second consensus conference on curriculum development resulted in outlines and principles for the creation of a curriculum to teach the previously identified list of tasks and knowledge (Figure 3).

Didactic and Knowledge. The didactic and knowledge working group created an outline of the material which should be taught in lecture format. This will include:

1. Introduction to robotic surgical devices.
2. Pre-operative set-up of equipment and positioning of staff.
3. Intra-operative use of a robot, surgeon ergonomics, visual field control, and necessary instruments and supplies.
4. Post-operative steps for removing a robot and transitioning to bedside control.

Each of these included an explicit list of errors that can occur in the process.



FRS Curriculum Outline

Didactic & Cognitive	Psychomotor Skills	Team Training
Lecture-based	**Principle-based**	**Checklist-based**
Intro to Robotic System	Based on Physical Models (Virtual Models are Derivative)	#1: WHO Pre-Op
Pre-Operative Activity	3D Exam Tools	#2: Robotic Specific
Intra-Operative Activity	Use Tasks that have Evidence of Validity	#3: Undocking & Debriefing
Post-Operative Activity	Multiple Outcomes Measured per Exercise	#4 Crisis Scenarios
Each Activity includes: Goals, Conditions, Metrics, Errors, Standards	Cost Effective Solution	
	High Fidelity for Testing, Lower Fidelity for Training	
	IRR Requires Ease of Administration	

Figure 3. FRS Curriculum Outline and Principles.

Psychomotor. The psychomotor skills working group prefaced their work with seven principles that should be applied in selecting or designing a skills device for robotic surgery. Those principles were:

1. The tasks should be 3 dimensional in nature.
2. The tasks designed for testing should be such that they have multiple learning objectives that incorporate multiple tasks from the first conference report. The tasks designed for training will have more focused learning objectives.
3. Implementation of the tasks and the resultant method for teaching should be cost effective.
4. High fidelity models should be used for testing. Training can use lower fidelity devices or methods.
5. Tasks should be easy to administer to ensure Inter-Rater Reliability (IRR).
6. The tasks should be designed for implementation with physical objects and devices. Future implementation in VR with a simulator would be derivative of the physical model.
7. Preference should be given to tasks that have existing evidence of validity

The group then identified 16 of the 25 tasks which contained psychomotor features. To address these, they proposed ten tasks which could be used to measure these skills. Three tasks were drawn from FLS, others were selected from existing educational programs, and designs for new task devices were proposed.

1. FLS peg transfer
2. FLS suturing
3. FLS pattern cutting
4. Running Suture
5. Dome with four towers
6. Vessel dissection and clipping
7. UTSW 4th arm retraction and cutting
8. Energy and mechanical cutting
9. Docking task (new design)
10. Trocar insertion task (new design)

For each of these the group also identified the associated task description, conditions, metrics, and errors.

Team Training and Communications. The team training and communications working group prefaced their work by defining the importance of team training in a robotic environment. They identified the following principles as essential to successful team-based operations and training.

1. Inclusion
2. Empowerment
3. Person specific
4. Reiterative
5. 'Just in time'
6. Ownership
7. Risk management/quality improvement- closed loop

They stated that existing programs like TeamSTEPPS can be applied to robotic teams. Their curriculum follows a checklist format and is conceptually derived from the standard WHO checklist. For robotic training they recommended the following checklists:

1. Pre-operative. Addressing General situation, surgeon, anesthetist, nurse/OPD, and surgical site infection.
2. Robotic Docking. Addressing anesthesia, patient, bedside assist, procedure-specific checks, and trouble shooting.
3. Intra-operative. Addressing the communication that occurs within a team throughout the operation.
4. Undocking and Debriefing.

A third consensus conference is scheduled for August 2012 to write the detailed material that will be included in the didactic and team training sections of the curriculum; and where specific psychomotor skills devices will be identified, designed and selected.

Conclusions & Discussion

Two consensus conference involving members from major stakeholder organizations in surgical training, governance, and certification across multiple specialties have been conducted to arrive at a consensus regarding the most important outcome measures for the safe conduct of robotic surgery and the curriculum to teach those skills and knowledge. The development of FRS is multi-specialty, system agnostic and follows decades of experience in other industries at developing such education and training platforms. Using the curriculum for training and assessment should result in a surgeon who has proficiency in basic robotic surgery skills and is capable of passing the requirements of high stakes testing and evaluation. At some future time, this testing and evaluation would be administered by an appropriate independent, objective and authoritative organization, which would adopt the materials developed through this consensus process.

Acknowledgments
This project is a collaboration of leading robotic surgeons and educators. The following have all participated in and contributed to the creation of the materials reported here: A. Advincula; R. Aggarwal; A. Al Ansari; D. Albala; R. Angelo; M. Anvari; J. Armstrong; G. Ballantyne; M. Billia; J. Borin; D. Bouchier-Hayes; T. Brand; S. Chauhan; P. Coelho; A. Cuschieri; B. Dunkin; S. Dunlow; V. Ficarra; A. Gallagher; L. Glazerman; T. Grantcharov; D. Hananel; J. Hebert; R. Holloway; W. Judd; K. Kim; M. Koch; T. Kowalewski; R. Kumar; K. Kunkler; G. Lee; T. Lendvay; R. Leveillee; J. Levy; G. Maddern; S. Magnuson; M. Marohn; D. Maron; M. Martino; P. Neary; K. Palmer; E. Parra-Davila; V. Patel; S. Ramamoorthy; K. Rha; J. Riess; B. Rocco; R. Rush; R. Satava; D. Scott; N. Seymour; M. Sinanan; R. Smith; D. Stefanidis; C. Sundaram; R. Sweet; E. Verrier; G. Weinstein

This work is collaboratively supported by grants to the Minimally Invasive Robotics Association and to the Florida Hospital Nicholson Center.

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[9] Satava RM, et al. Fundamentals of Robotic Surgery Consensus Conference I: Outcomes Measures. Surgery (in press).

From FLS to FRS:
The Fundamentals of Robotic Surgery are on their Way

Roger Smith, PhD
Florida Hospital Nicholson Center
roger.smith@flhosp.org

www.nicholsoncenter.com

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FRS Mission Statement

Create and develop a validated multi-specialty, technical skills competency based curriculum for surgeons to safely and efficiently perform basic robotic-assisted surgery.

Grants Leadership

PI: Richard Satava, MD
Minimally Invasive Robotics Assoc

Funding: Intuitive Surgical Inc.

PI’s: Roger Smith, PhD & Vipul Patel, MD
Florida Hospital Nicholson Center

Funding: US Department of Defense

* This work was supported by an unrestricted educational grant through the Minimally Invasive Robotics Association from Intuitive Surgical Incorporated.

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Participating Organizations

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- American College of Surgeons (ACS)
- American Congress of OB-Gyn (ACOG)
- American Urologic Association (AUA) +
- American Academy of Orthopedic Surgeons (AAOA)
- American Assn of Thoracic Surgeons (AATS)
- American Assn of Colo-Rectal Surgeons (ASCRS)
- American Assn of Gynecologic Laparoscopists (AAGL)
- Florida Hospital Nicholson Center*
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- American Board of Surgery (ABS)
- Accreditation Council of Graduate Med Education (ACGME)
- Association of Surgical Educators (ASE)
- Residency Review Committee (RRC) – Surgery
- Royal College of Surgeons-Ireland (RCSI)
- Royal College of Surgeons-London (RCSL)

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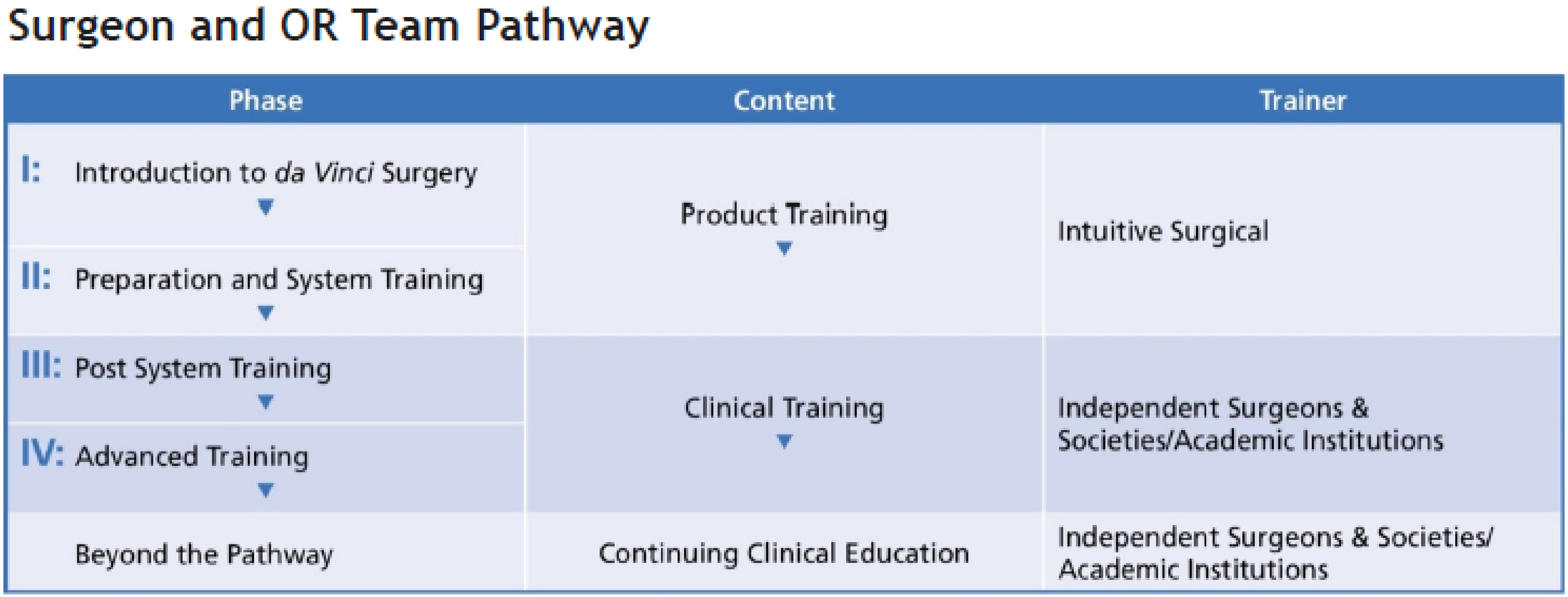
Intuitive Surgical’s Training Pathway



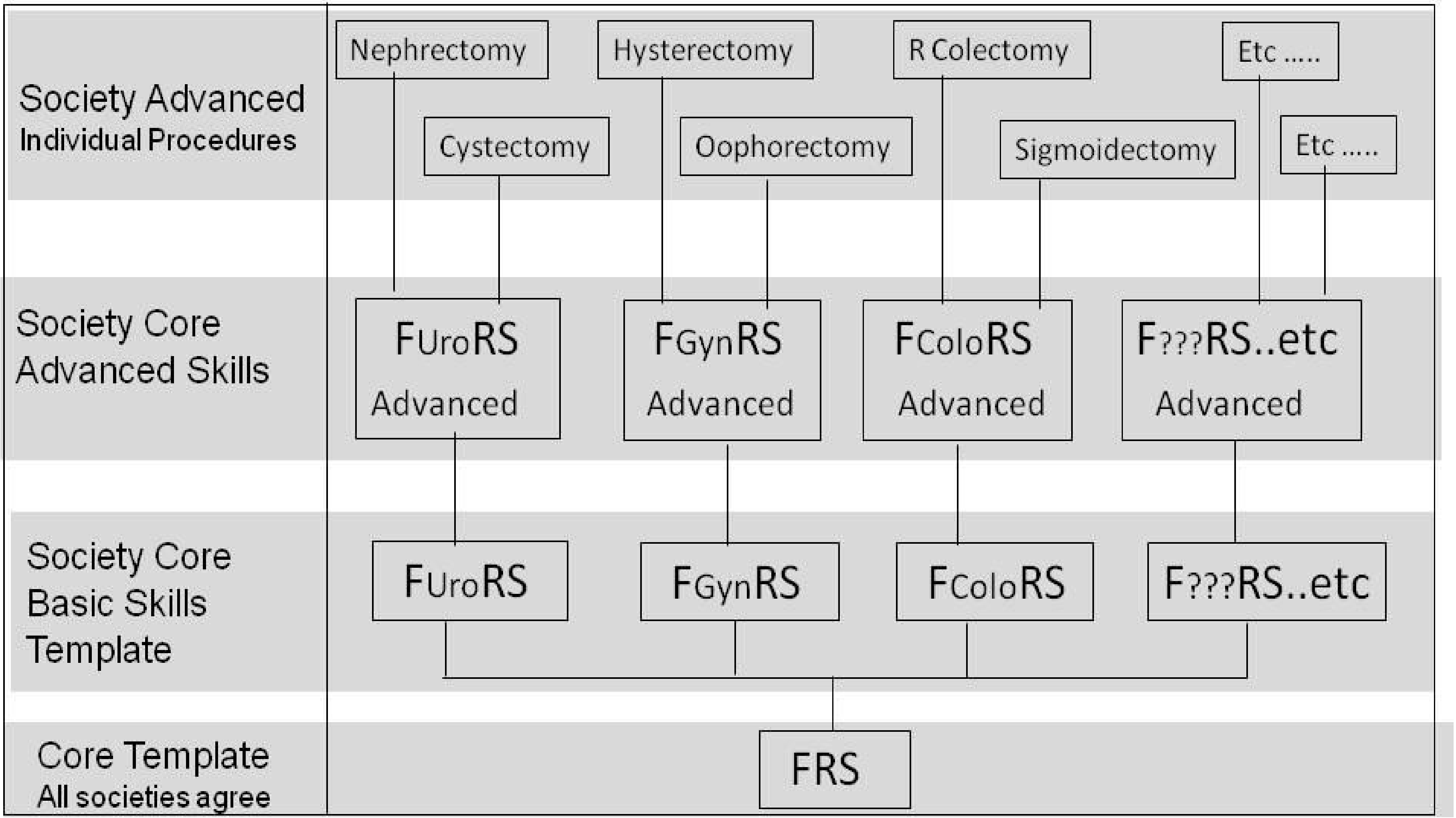
Surgeon and OR Team Pathway

Phase	Content	Trainer
I: Introduction to *da Vinci* Surgery ▼	Product Training ▼	Intuitive Surgical
II: Preparation and System Training ▼		
III: Post System Training ▼	Clinical Training ▼	Independent Surgeons & Societies/Academic Institutions
IV: Advanced Training ▼		
Beyond the Pathway	Continuing Clinical Education	Independent Surgeons & Societies/ Academic Institutions

- Phases I-II focus on product training, while phases III-IV focus on clinical training
- Beyond the pathway, skills are honed with continuing clinical education

Development of Curriculum from common template

“Sweet* Tree”



Society Advanced
Individual Procedures

- Nephrectomy
- Cystectomy
- Hysterectomy
- Oophorectomy
- R Colectomy
- Sigmoidectomy
- Etc .....
- Etc .....

Society Core
Advanced Skills

- FUroRS Advanced
- FGynRS Advanced
- FColoRS Advanced
- F???RS..etc Advanced

Society Core
Basic Skills
Template

- FUroRS
- FGynRS
- FColoRS
- F???RS..etc

Core Template
All societies agree

- FRS

* Adapted from Rob Sweet, MD, Professor of Urology, University Minnesota, 2010

Consensus Conference Process

1. Outcomes Measures (Dec 12-13, 2011)
2. Curriculum Outline (April 29-30, 2012)

2.5 Curriculum Design (Aug 17-18, 2012)

3. Validation Criteria (November 17-18, 2012)

4. Curriculum Development (Jun-Sept, 2013)
5. Psychomotor Device Development (May-Sept, 2013)
6. Validation Studies (2014)
7. Transition to Objective Testing Organization (2014)

- Expert Discussion and Contributions
- Modified Delphi Voting Mechanism

25 Outcomes Measures

Pre-Operative	Intra-Operative	Post-Operative
System Settings	Energy Sources	Transition to Bedside Asst
Ergonomic Positioning	Camera Control	Undocking
Docking	Clutching	
Robotic Trocars	Instrument Exchange	
OR Set-up	Foreign Body Management	
Situation Awareness	Multi-arm Control	
Closed Loop Comms	Eye-hand Instrument Coord	
Respond to System Errors	Wrist Articulation	
	Atraumatic Tissue Handling	
	Dissection – Fine & Blunt	
	Cutting	
	Needle Driving	
	Suture Handling	
	Knot Tying	
	Safety of Operative Field	

Curriculum Structure

Cognitive

PSYCHOMOTOR SKILLS CURRICULUM

CASE OUTLINE

TASK 3: KNOT TYING :: Description Of Task

1 of 2

- ✓ **Course Details**
  - ✓ Course description
  - ✓ Expert Faculty Contributors
  - ✓ Learning Objectives
- ✓ **Overview**
  - ✓ Background and General Principles
  - ✓ Physical Model
  - ✓ General Scoring Guidelines for Tasks
- ✓ **Task 1: Docking/Instrument Insertion**
  - ✓ Description of Task
  - ✓ Skills & Metrics
- ✓ **Task 2: Ring Tower Transfer**
  - ✓ Description of Task
  - ✓ Skills & Metrics
- **Task 3: Knot Tying**
  - ✓ Description of Task
  - Skills & Metrics

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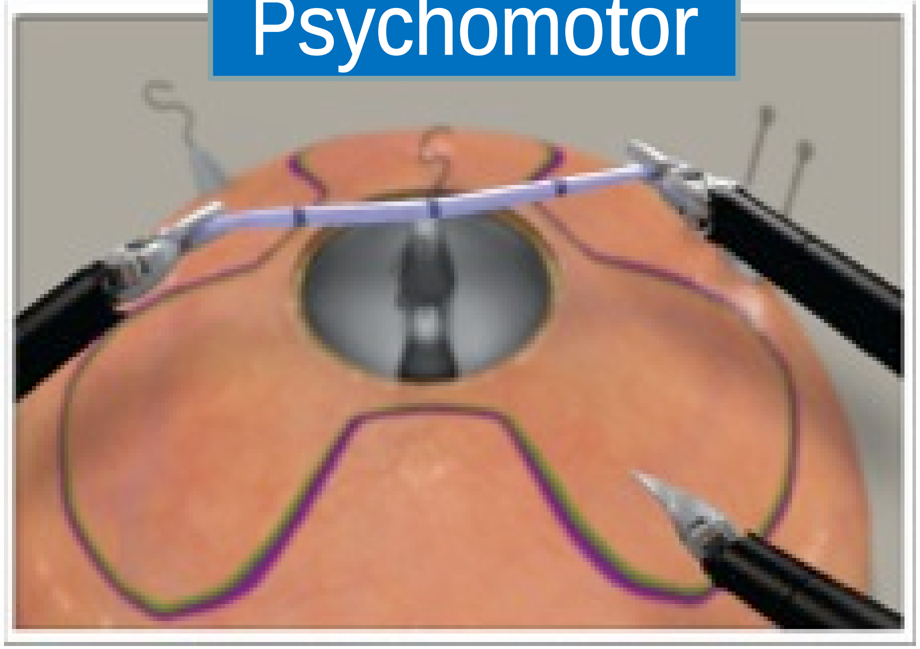
Psychomotor



TEAM TRAINING & COMMUNICATION SKILLS

CASE OUTLINE

SCENARIO REVIEW :: Scenario 2 Review

6 of 16

The OR staff must embrace the entire team to create a culture of shared responsibility and excellent communication to improve patient safety and outcomes. Communication protocols among the team members include:

- Requests: Unambiguous requests or queries
- Cross-checks: Confirmation by the receiving person of the communication
- Check-backs: Confirmation of the completion of the task

This new video for Scenario Two is a much better example of effective communications skills.

Team Training

Online Didactic Curriculum

TASK 3: KNOT TYING :: Description Of Task

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Online Didactic Curriculum

“Bad” Example with Rating Scale

SCENARIO REVIEW :: Scenario 2 Rating

4 of 16

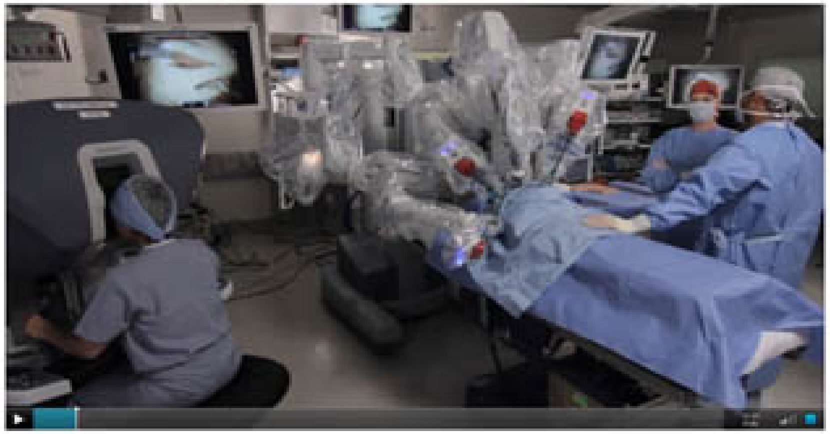
For surgeons who choose to pursue robotic surgery, the following curriculum will provide a common primer, or generic approach, across all

Rate the team communication and response.

	Extremely Poor				Excellent
Did the surgeon completely convey all relevant information?	○	○	○	○	○
Were requests properly made?	○	○	○	○	○
Were cross-checks appropriately made?	○	○	○	○	○
Were check-backs appropriately made?	○	○	○	○	○
Did the OR staff communicate in a concise, organized, and prioritized manner?	○	○	○	○	○

The scenario presented is fictitious. The procedure is being performed on inanimate tissue.

Enlarge Video to Full Screen



Type in Textbox Changes Needed

SCENARIO REVIEW :: Scenario 2 Reflect

5 of 16

What communication skills could have been improved in this interaction to optimize the outcome?

Review “Good” Example

SCENARIO REVIEW :: Scenario 2 Review

6 of 16

The OR staff must embrace the entire team to create a culture of shared responsibility and excellent communication to improve patient safety and outcomes. Communication protocols among the team members include:

- Requests: Unambiguous requests or queries
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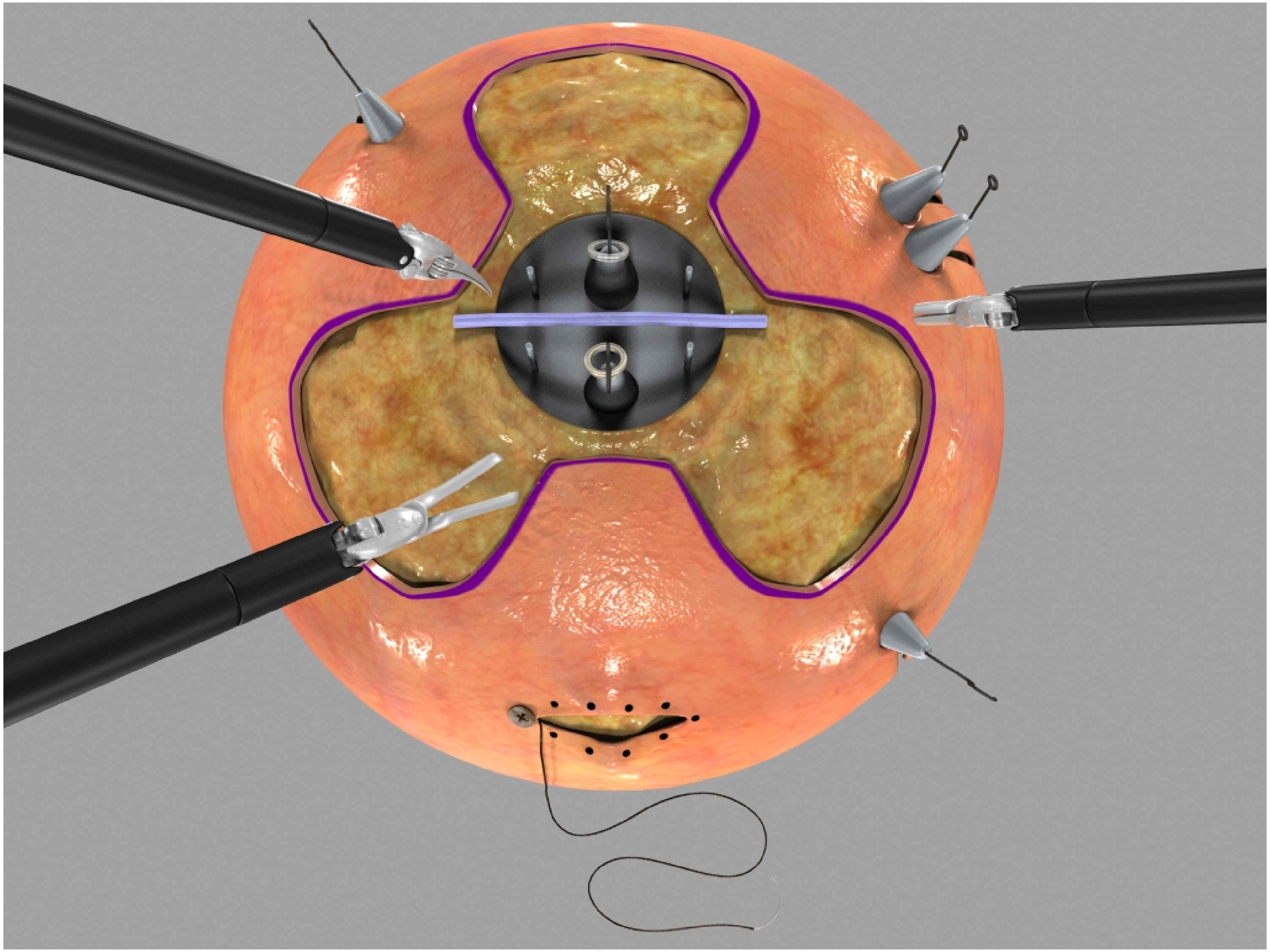
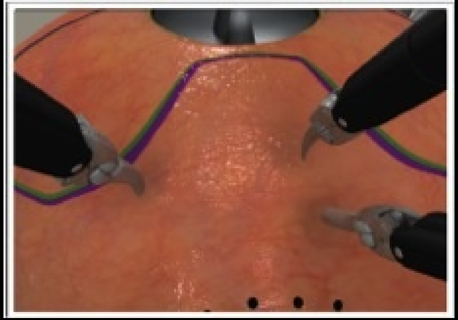
Psychomotor Dome Concept

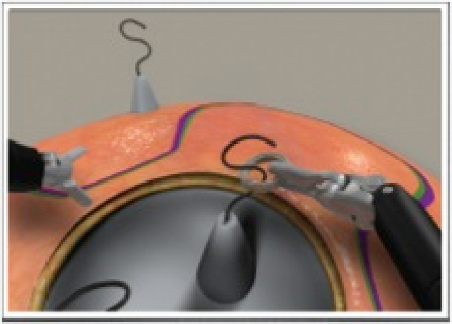


FRS TASKS

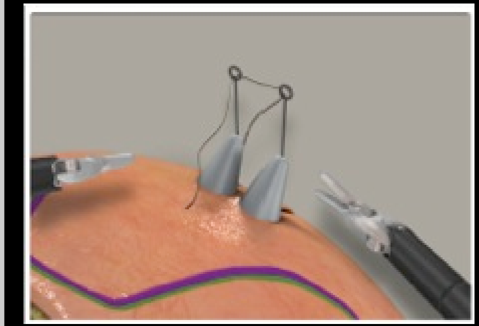
Task 1: Docking & instrument insertion



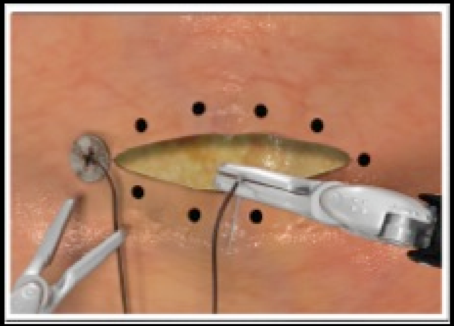
Task 2: Ring Tower transfer



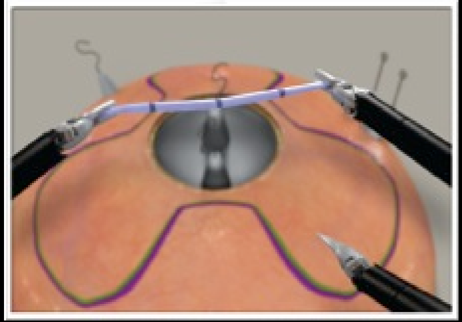
Task 3: Knot tying



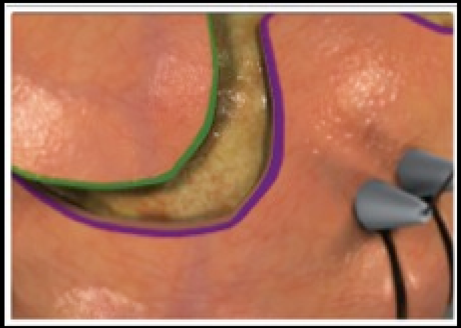
Task 4: Railroad Track



Task 5: UTSW 4th arm cutting

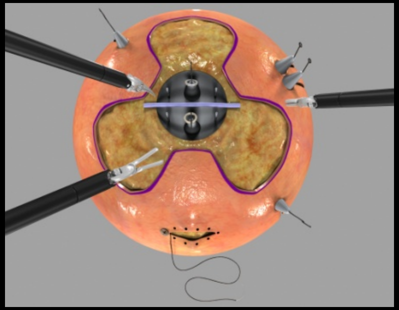


Task 6: Clover Leaf Dissection



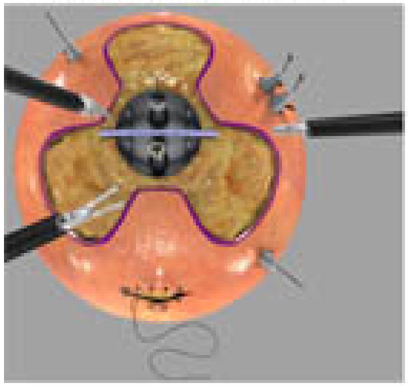
Task 7: Vessel Energy Dissection

FRS DOME



Psychomotor Device Prototypes

Prototype Concept

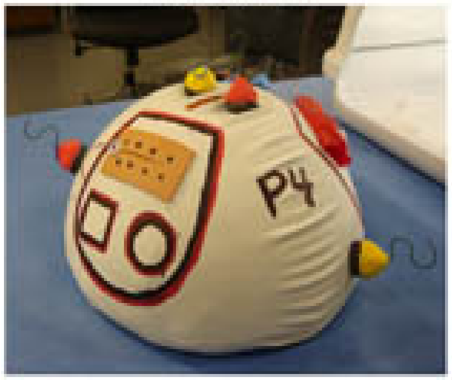


Prototype 1

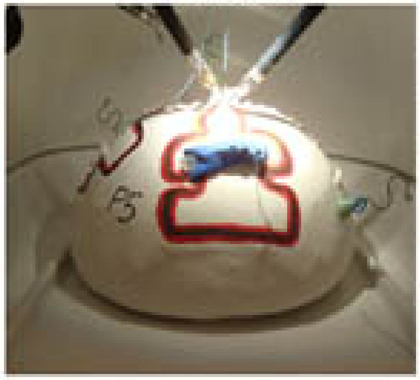
Prototype 2

Prototype 3

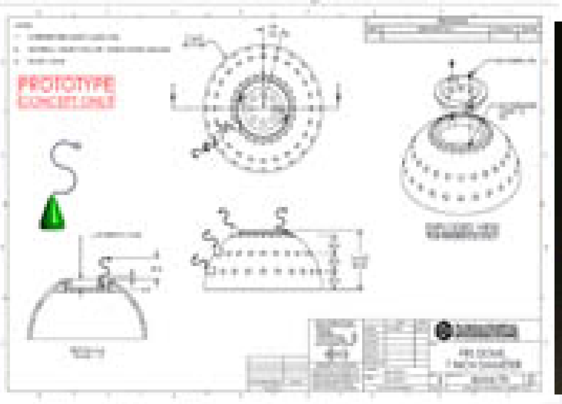
Prototype 4



Prototype 5



CAD Design

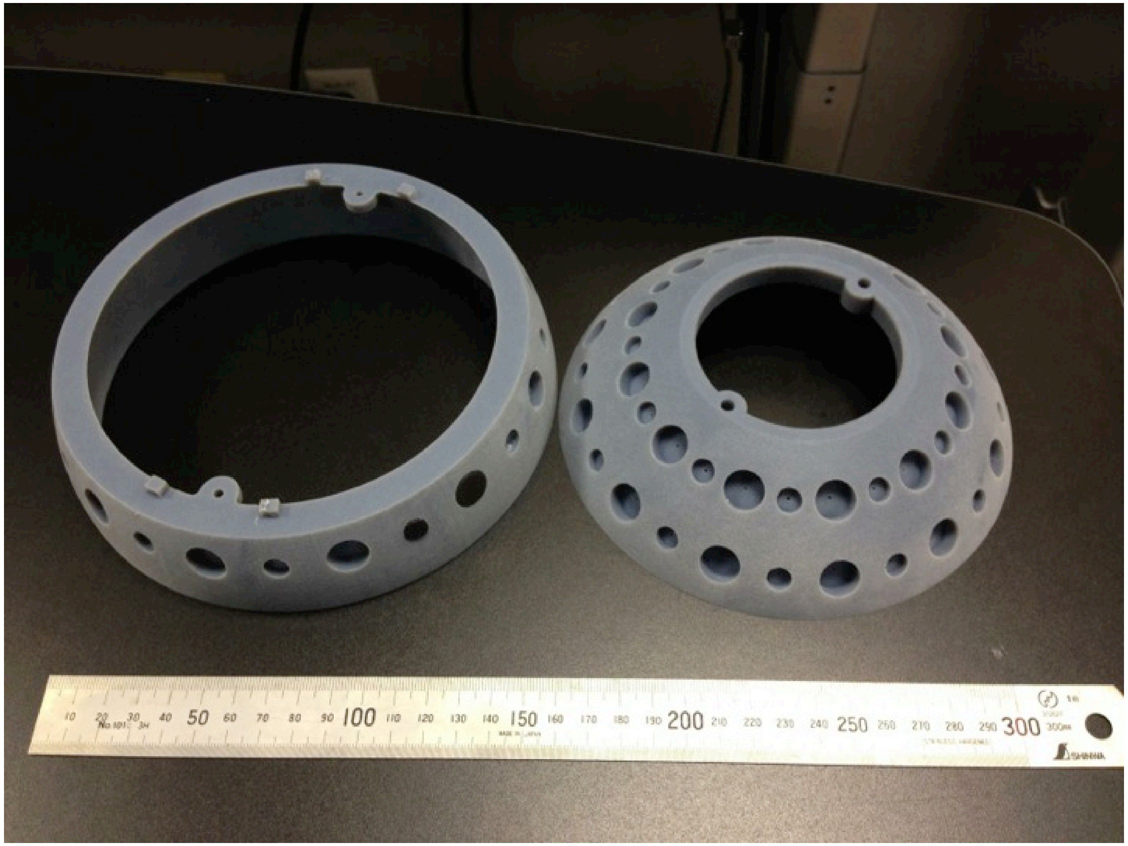


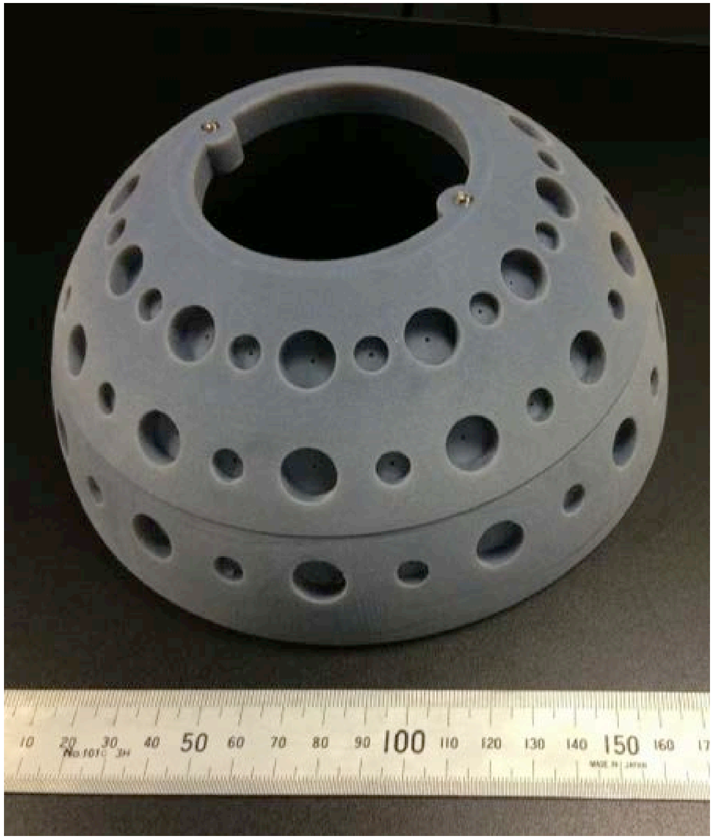
1st 3-D Printed Model

First 3D Printed Dome

(top cap not shown)

1. **Exploring design to support manufacturing.**
2. **Fine tuning the FRS tasks.**
3. **Creating multiple domes for validation trials.**





MINIMALLY INVASIVE SURGERY WEEK 2013

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1a. Additional Author/Presenter Name and Degree	Roger Smith, PhD
1b. Hospital / Institutional Affiliation(s) for Co-Author:	Florida Hospital Celebration Health/Nicholson Center

Title of Presentation *	Fundamentals of Robotic Surgery Psychomotor Skills Prototype Development Video Objective:
Type of Submission *	Video
Submission Category *	Multispecialty

Abstract Text (250 words or less) *

Objective:

The fundamentals of laparoscopic surgery (FLS) is a known comprehensive surgical assessment and teaching module that has been incorporated into laparoscopic surgery training curricula. With the rapid advancement of robotic surgery, there is a need to develop similar methods to provide effective training in the Fundamentals of Robotic Surgery (FRS), as there is currently no validated robotic surgical curriculum to date. The objective of this video is to demonstrate the development of a psychomotor robotic surgery skills training device.

Method:

A dome shaped, all-in-one prototype was created from simple household materials. This prototype device evaluates seven skills,including: docking and instrument insertion, arm and wrist manipulation, knot tying, suturing skills, utilization of arm four, cutting and dissection, energy use and dissection.

Results:

The total time for a novice to intermediate learner to complete all exercises was fifteen minutes. The total cost for this prototype was approximately fifteen dollars. This model proved to be largely reusable with only the skin of the dome needing to be removed and replaced for the next learner. Magnets used allowed for easy placement and removal of devices on the outside of the surface skin.

Conclusion:

This prototype demonstrates the feasibility of developing an economical all-in-one model to teach and evaluate an array of basic robotic surgical skills. With further development and modifications, this prototype will identify design details necessary for a finished product to be used in a robotic surgical curriculum. Future models should incorporate the ability for objective measurement and evaluation of user performance.

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Will your participation only include generic names? *(Please note: You must answer NO if your presentation includes a product name, such as "daVinci Robot".)* *	No
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