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14. ABSTRACT
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 imulation 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.

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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.

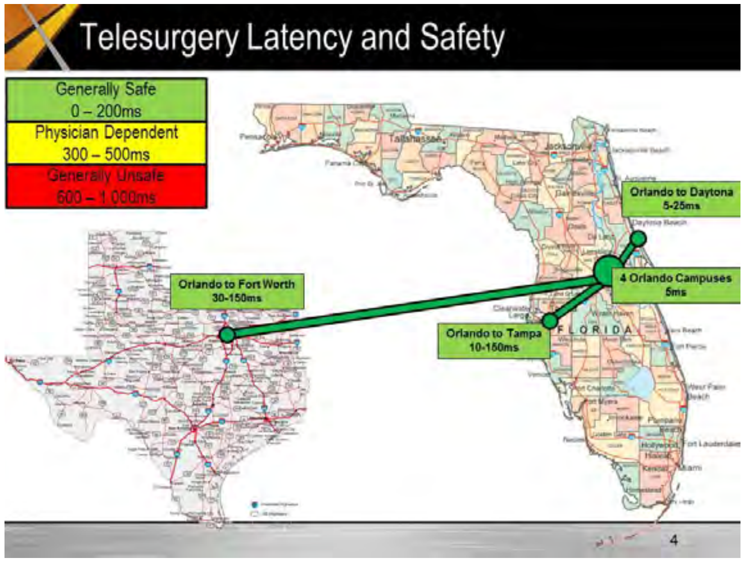
Milestone: Surgical rehearsal experiment results. Award + 540 days

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.

All telesurgery work was completed and reported in the previous year ending August 2013. See the previous annual report for details on this project.



During this current year the results of that work have been organized into a new conference presentation and a new journal submission. Those items are included in the appendix of published works in this report.

Automatic Surgery.

[Repeated from Sept 2013 annual report]
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 did not perform this experiment. The funds originally scheduled for this experiment were reallocated to other experiments.

Simulation: Military-use Validation

We are conducting 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 was included in the Sept 2013 annual report.

The second part was a subjective evaluation of all three of the simulators by MD's. The results of that comparison have been prepared in a report and presented at medical conferences. In summary, as a mode of teaching robotic surgery, the participants preferred the da Vinci Simulation System (DVSS) which attaches to the real surgical console. They found the dV-Trainer simulator to be acceptable for teaching and felt that it provided a significant economic advantage since it is stand alone and does not require access to a da Vinci surgeon's console. They felt that the RoSS simulator was a poor device which did not effectively replicate the performance of the real da Vinci robot and could not be effectively used in training.

We have captured the results of this experiment in a paper to be presented at the 2014 I/ITSEC Conference (Orlando, FL). The tables and graph below summarize the major findings. For a complete discussion see the copy of the paper which is included in the appendix of this report.

Table 2. Average scores from a 5-point Likert scale on face validity.

	DVSS	dV-Trainer	RoSS
Q1: The hand controllers on this simulator are effective for working in the simulated environment.	4.80	3.62	2.17
Q4: The device is a sufficiently accurate representation of the real robotic system.	4.65	3.45	1.82

Table 3. Scores on a 5 point Likert scale for content validity questions.

Likert Score	Strong Dis	Disagree	Neither	Agree	Strong Agree
***Q2:** The 3D graphical exercises in the simulator are effective for teaching robotic skills.*					
DVSS	0%	0%	0%	35.3%	64.7%
dV-Trainer	2.9%	5.9%	11.8%	50.0%	29.4%
RoSS	20.6%	38.2%	17.6%	17.6%	5.9%
***Q5:** The scoring system effectively communicates my performance on the exercise.*					
DVSS	2.9%	5.9%	2.9%	38.2%	50.0%
dV-Trainer	2.9%	2.9%	14.7%	55.9%	23.5%
RoSS	17.6%	20.6%	26.5%	29.4%	5.9%
***Q6:** The scoring system effectively guides me to improve performance on the simulator.*					
DVSS	0%	0%	8.8%	61.8%	29.4%
dV-Trainer	2.9%	2.9%	11.8%	61.8%	20.6%
RoSS	18.2%	18.2%	27.3%	33.3%	3.0%

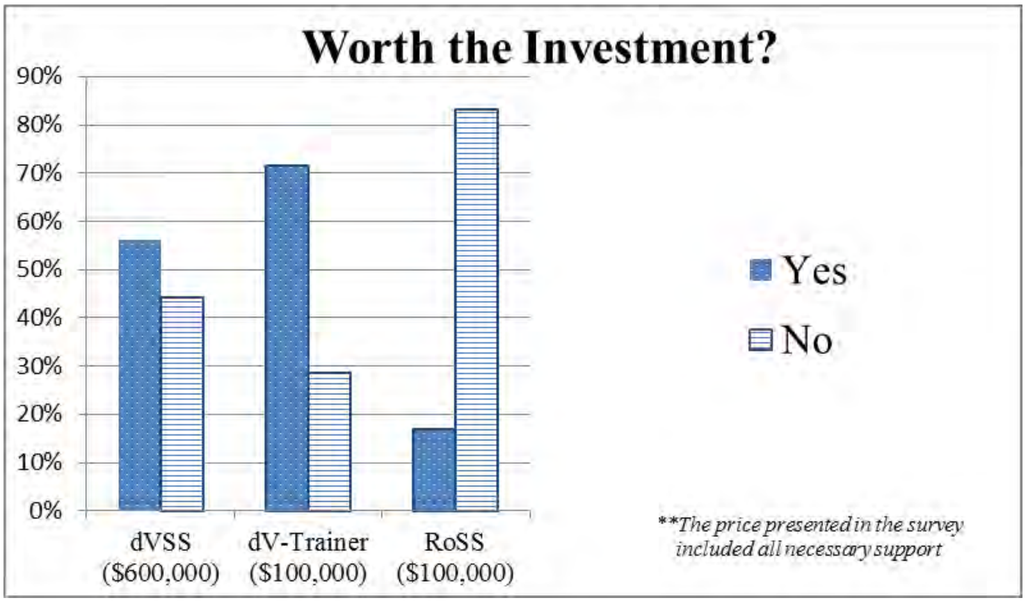
Table 4. Mann-Whitney U test level of significance on construct validity measures

	DVSS	dV-Trainer	RoSS
Time to Complete	$p<0.001$	$p<0.001$	$p=0.221$

Overall Score	p<0.01	p=0.061	n/a
Economy of Motion	p=0.216	p<0.001	p=0.566
Number of Errors	n/a	n/a	p=0.644

Table 5. Correlation between level of experience and simulator scores

	DVSS	dV-Trainer	RoSS
Overall Score	p=0.001	p=0.031	n/a
Time to Complete	p<0.001	p<0.001	p=0.181
Economy of Motion	p=0.105	p<0.001	p=0.390
Number of Errors	n/a	n/a	p=0.563

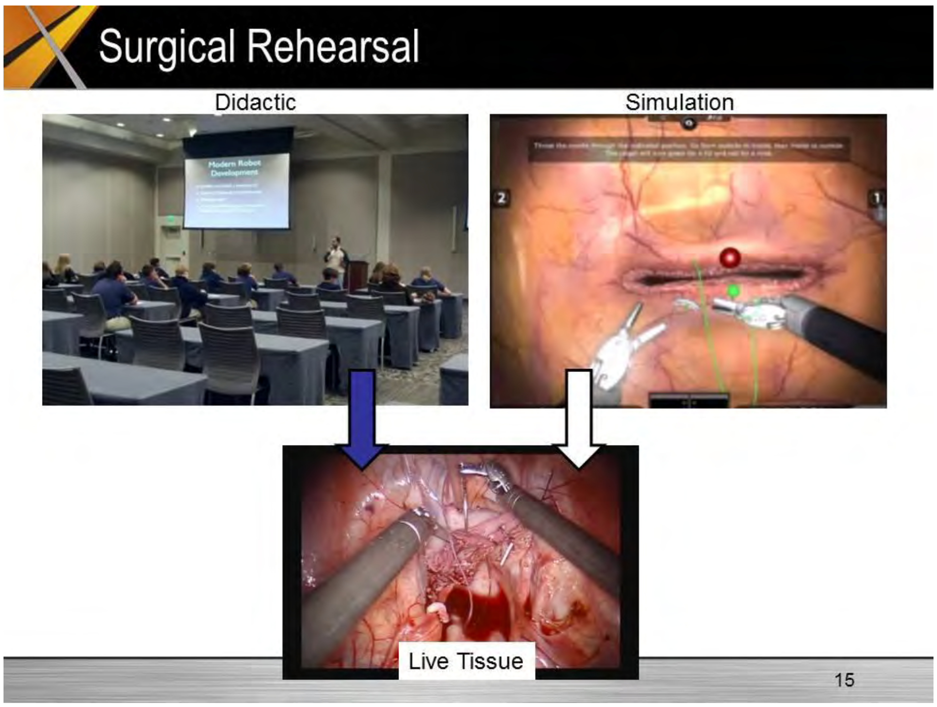


The third part of this study is an objective evaluation of the effectiveness of each simulator to improve the skills of a robotic surgeon. In this part we are measuring the amount of time and effort required for a surgeon to reach competency levels in the simulator. The subjects will return to the experiment 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. This experiment is currently underway.

Simulation: Surgical Rehearsal

This experiment compared the effectiveness of traditional classroom training to simulation-based training in preparing for a specific procedure. We designed the experiment to be carried out in conjunction with existing educational events using animals. This allowed us to perform the experiment without sacrificing any additional animals in the conduct of this study.

This study completed with 125 subjects (control=64, experimental=61) participating in the control and experimental groups. We found no statistical difference in the performance of those who prepared via traditional classroom methods and those who prepared via simulation-based rehearsal.



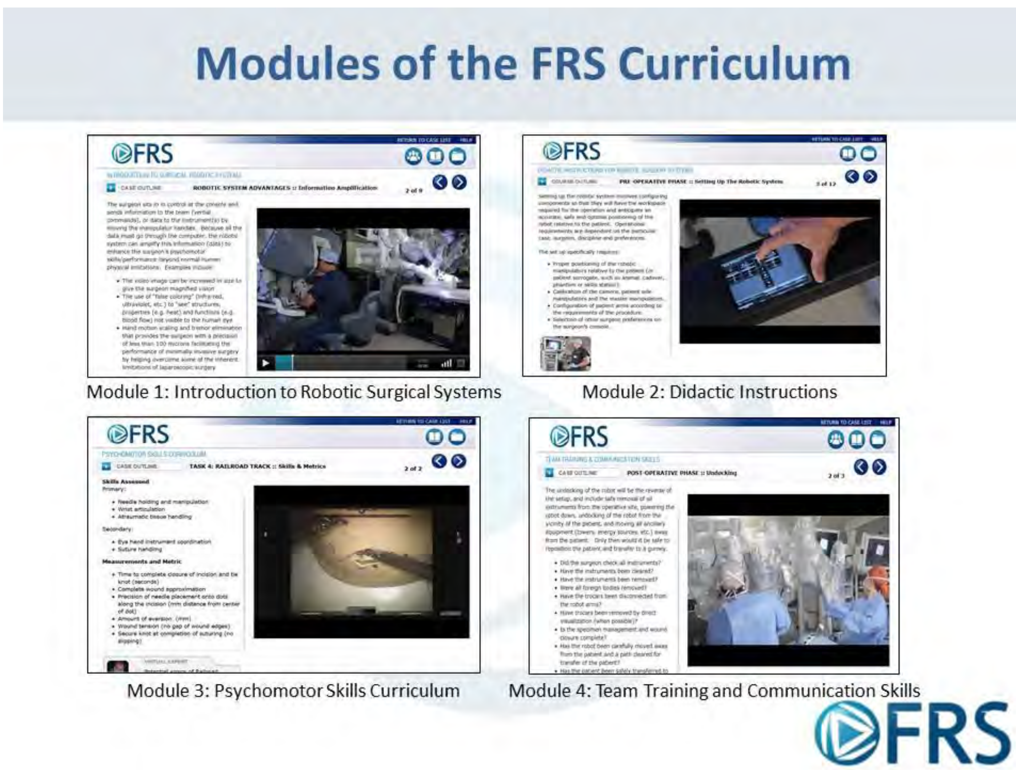
This experiment required that we identify a small procedure which existed as a simulation exercise and could be performed in an animal model. The most procedure-specific exercise in the dV-Trainer simulator is the suturing of an incision. This drove the selection of the procedure which would be used to measure performance on this experiment. We believe that the experiment showed no difference between the two groups because the suturing procedure was too easy for the experienced subjects who were enrolled. However, due to the limited availability of simulated procedures, it is not possible to create a more rigorous task to measure at this time.

Robotic Curriculum

We have completed the development of an online robotic surgery curriculum and a psychomotor skills testing device. Both of these were created through collaboration with leading robotic surgeons from around the world. These products have been transferred to surgical professional societies who are organizing a multi-site validation trail for the materials. This DoD grant is not providing funding to those validation trials. They are being carried out with commercial grant funding.

Online Curriculum

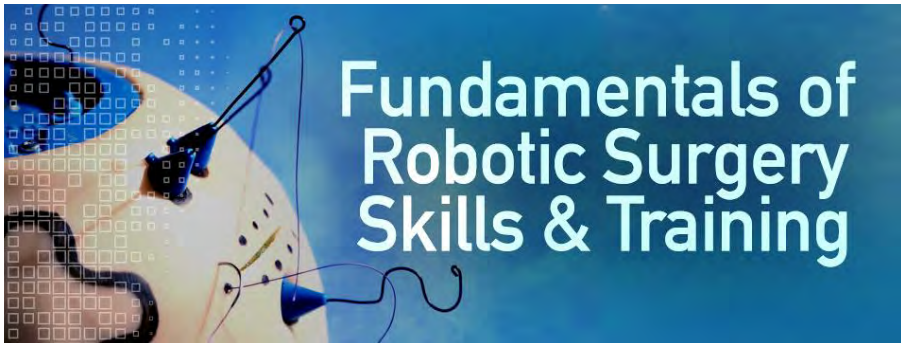
The online curriculum is open and available to all interested parties. It can be accessed at: http://FRSurgery.com/

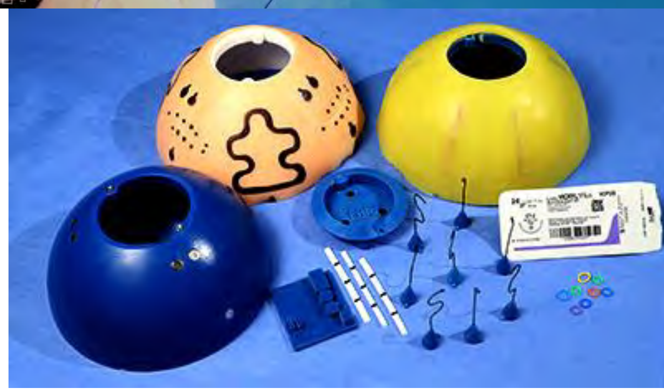


Psychomotor Skills Device

The psychomotor device has been completed and is in limited production. The development of this device has conducted under the funding of this grant. But government funds are not being used to produce these devices for use in the validation trials. Currently all production capacity is being used to fill the order of the sites which are conducting the validation trials (not part of this government funded grant).

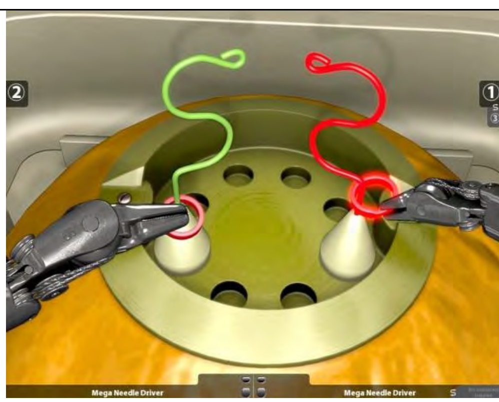
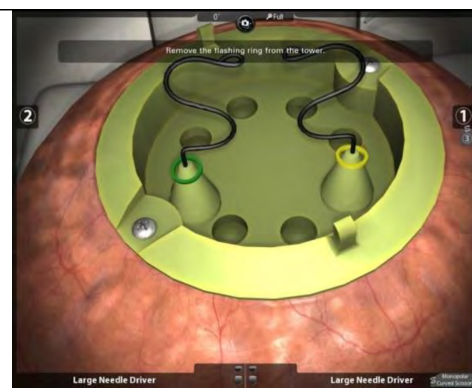
As production capacities increase we will make the device available for commercial purchase by all interested parties. Orders can be placed at:
https://www.nicholsoncenter.com/frskit





Simulator Exercises

During the development of the physical psychomotor device, two simulator companies showed an interest in adding the device to their portfolio of virtual exercises. As a result, using their own funding, these companies have created virtual exercises that match the physical device. These simulated exercises are also part of the validation trials that are being conducted.

 Simbionix exercise in DVSS	 Mimic exercise in dV-Trainer

Key Research Accomplishments

- *Telesurgery: Communications Latency.* Major hospital systems have sufficient telecommunication bandwidth to perform robotic telesurgery right now.
- *Robotic Curriculum.* Online curriculum in robotics has been developed. Psychomotor skills device has been developed. Both are now available to all surgeons who are interested.
- *Simulation: Surgical Rehearsal.* Simulation-based surgical rehearsal is currently focused on procedures which are too easy to offer an advantage over traditional methods of preparation.
- *Simulation: Military-use Validation*. Systems capabilities have been documented in published reports and journals. As an instructional tool surgeons prefer the DVSS for realism and the dV-Trainer for affordability. Surgeons do not accept the RoSS as a useful training device.

Reportable Outcomes

Publications

Tanaka, Perez, Truong, & Smith. “From Design to Conception: An Assessment Device for Robotic Surgeons”, *2014 Interservice/Industry Training Education and Simulation (I/ITSEC) Conference*. December 2014. [Best Paper Award for Emerging Concepts/Innovative Ideas Track]

Tanaka, Graddy, & Smith. “ Comparison of the Usability of Robotic Surgery Simulators”, *2014 Interservice/Industry Training Education and Simulation (I/ITSEC) Conference*. December 2014.

Smith & Simpson. “ Return on Investment for Robotic Surgical Simulators”, *2014 Interservice/Industry Training Education and Simulation (I/ITSEC) Conference*. December 2014.

Smith, Truong, & Perez. (2014) Comparative analysis of the functionality of simulators of the da Vinci surgical robot. J Surg Endosc, 1-12.

Perez, Xu, Chauhan, Tanaka, Simpson, Abdul-Muhsin, & Smith. “Impact of delay on telesurgical performance: Study on the dV-Trainer robotic simulator”. Submission to Journal of Urology 2014.

Smith, “The Future of Robotic Technology”, Robotic Surgery of the Head and Neck, Springer Press, 2015 (projected).

Martino, Siddiqui, et al. “Fundamentals of Robotic Gynecologic Surgery” Developing a Quality Improvement Project to Improve Patient Safety”, Society of Gynecologic Oncology, Annual Meeting on Women’s Cancer, March 2014.

Smith, Patel, & Satava. “Fundamentals of robotic surgery: a course of basic robotic surgery skills based upon a 14-society consensus template of outcomes measures and curriculum development”, *The International Journal of Medical Robotics and Computer Assisted Surgery*, October 2013. DOI: 10.1002/rcs.1559

Smith, “From FLS to FRS: The Fundamentals of Robotic Surgery are on their Way”, World Robotic Gynecologic Congress, Chicago, IL. 2013

Presentations

Truong, Tanaka, Simpson, Advincula, & Smith. “A Prospective Randomized Controlled Comparative Study on Surgical Training Methods and Impact on Surgical Performance: Virtual Reality Robotic Simulation vs. Didactic Lectures”, AAGL Global Congress on Minimally Invasive Gynecology, November 2014

Smith & Simpson. “Return on Investment for Robotic Surgical Simulators”, AAGL Global Congress on Minimally Invasive Gynecology, November 2014

Tanaka, Truong, & Smith. “Robotic Surgical Simulators: An Assessment of Usability and Preferences”, AAGL Global Congress on Minimally Invasive Gynecology, November 2014

Lendvay TS, White LW, Holst D, Kowalewski T, Harper JD, Sorenson M, Brand TC, Truong M, Simpson K, Smith R. Quantifying Surgical Skill Using the Wisdom of Crowds. American

College of Surgeons Clinical Congress, San Francisco, CA, October 26-30th, 2014. [Poster #PP2014-51161].

Simpson, Perez, Tanaka, Truong & Smith. "Validating the Efficacy of GEARS through the Assessment of 100 Videos", Society of Laparoendoscopic Surgeons Annual Meeting & Endo Expo, September 2014.

Truong, Tanaka, Simpson, Perez, Smith & Advincula. "Randomized Controlled Study Comparing Robotic Simulation Versus Didactic Teaching for Robotic Surgical Training: Opinions and Perspectives", Society of Laparoendoscopic Surgeons Annual Meeting & Endo Expo, September 2014. [Honorable Mention for the Paul Alan Wetter Award for Best MultiSpecialty Scientific Paper]

Smith & Tanaka. "Gamers in Surgical Simulation: A Comparison of Gamers, Surgeons, and Clinical Staff", Defense GameTech Users Conference, Orlando, FL, September 2014.

Lendvay T, Holst D, White L, Kowalewski T, Brand T, Sorenson M, Harper J, Truong M, Simpson K, Smith R. "Differentiating Surgical Skill Through the Wisdom of Crowds". American Urological Association Annual Meeting, Engineers in Urology Session, Orlando, FL, May 16-21, 2014 [Moderated Poster #82].

Lendvay, Simpson, Truong, & Smith. "Differentiating Surgical Skill through the Wisdom of Crowds", European Endoscopic Urology Society, April 2014.

Patel, Patel & Smith, "Feasibility of Robotic Telesurgery across a Multi-Campus Metropolitan Hospital System", Third Biennial Miami Robotics Symposium, April 2014.

Smith, "Robotic & Telesurgery Research", Stetson University Senior Tech Expo, March, 2014.

Satava & Smith, "Fundamentals of Robotic Surgery: Development and Validation of an Online Curriculum and New Psychomotor Testing Device", NextMed/MMVR Conference, February, 2014.

Satava & Smith, "Fundamentals of Robotic Surgery: Development and Validation of an Online Curriculum and New Psychomotor Testing Device", CAMLS-Halldale Summit on New Technology in Medicine, February, 2014.

Tanaka, Truong, Simpson, Perez, & Smith, "A Comparison of the Effectiveness and Usability of Robotic Simulators", Florida Hospital Internal Research Forum, January 2014.

Smith, "Robotic Surgery Education, Simulation & Telesurgery", Adventist Health System, Surgeon Executives Meeting, January 2014.

Truong, "The Fundamentals of Robotic Surgery Psychomotor Skills Prototype Development Video": Harrith M Hasson Award for Best Presentation Promoting Education and Training, 2013 SLS Annual Meeting in Reston, Virginia. Smith, "Robotic Surgery Education, Simulation & Telesurgery, Society for Laparoscopic Surgeons, Fellowship Summit, December 2013.

Smith, "Virtual Reality Simulation: The Future", Society for Robotic Surgery, Annual Meeting, November, 2013.

Smith, "Strategic Technology Leadership: The Role of the Technology Executive", MITRE Leadership Forum, October 2013.

Smith, "Robots in the Hands of your Surgeon", IEEE Orlando Chapter Annual Meeting, October 2013.

Smith, "Medical Simulation in Robotic Surgery", Lou Frey Institute of Politics and Government, University of Central Florida, September 2013.

Awards

Truong, Tanaka, Simpson, Perez, Smith & Advincula. "Randomized Controlled Study Comparing Robotic Simulation Versus Didactic Teaching for Robotic Surgical Training: Opinions and Perspectives", *Society of Laparoendoscopic Surgeons Annual Meeting & Endo Expo*, September 2014. [Honorable Mention for the Paul Alan Wetter Award for Best MultiSpecialty Scientific Paper]

Tanaka, Perez, Truong, & Smith. "From Design to Conception: An Assessment Device for Robotic Surgeons", *2014 Interservice/Industry Training Education and Simulation (I/ITSEC) Conference*. December 2014. [Best Paper Award for Emerging Concepts & Innovative Technologies Track]

Conclusion

Each of the research areas funded by this grant has made significant scientific contributions. The knowledge gained from this work is being shared through reports to the government and multiple presentations at both clinical and simulation conferences. We have also submitted multiple papers for journal publication.

This cooperative agreement was previously scheduled to end on August 31, 2014. However, we have received additional funding which has been added to the agreement. This new funding and the additional scope extend the agreement to August 31, 2016. Some of the research projects funded in the original scope of work are on-going and will be completed during the period of the extension.

Appendices

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

Surg Endosc
DOI 10.1007/s00464-014-3748-7

DYNAMIC MANUSCRIPT

Comparative analysis of the functionality of simulators of the da Vinci surgical robot

Roger Smith · Mireille Truong · Manuela Perez

Received: 14 November 2013 / Accepted: 10 July 2014

Abstract
Background The implementation of robotic technology in minimally invasive surgery has led to the need to develop more efficient and effective training methods, as well as assessment and skill maintenance tools for surgical education. Multiple simulators and procedures are available for educational and training purposes. A need for comparative evaluations of these simulators exists to aid users in selecting an appropriate device for their purposes.
Methods We conducted an objective review and comparison of the design and capabilities of all dedicated simulators of the da Vinci robot, the da Vinci Skill Simulator (DVSS) (Intuitive Surgical Inc., Sunnyvale, CA, USA), dV-Trainer (dVT) (Mimic Technologies Inc., Seattle, WA, USA), and Robotic Surgery Simulator (RoSS) (Simulated Surgical Skills, LLC, Williamsville, NY, USA). This provides base specifications of the hardware and software, with an emphasis on the training capabilities of each system.
Results Each simulator contains a large number of training exercises, DVSS = 40, dVT = 65, and RoSS = 52 for skills development. All three offer 3D visual images but use different display technologies. The DVSS leverages the real robotic surgeon's console to provide visualization, hand controls, and foot pedals. The dVT and RoSS created simulated versions of all of these control systems. They include systems management services which allow instructors to collect, export, and analyze the scores of students using the simulators.
Conclusions This study is the first to provide comparative information of the three simulators functional capabilities with an emphasis on their educational skills. They offer unique advantages and capabilities in training robotic surgeons. Each device has been the subject of multiple validation experiments which have been published in the literature. But those do not provide specific details on the capabilities of the simulators which are necessary for an understanding sufficient to select the one best suited for an organization's needs.

Keywords Robotic surgery · Robotic simulator · Training · Education · Comparative analysis

Electronic supplementary material The online version of this article (doi:10.1007/s00464-014-3748-7) contains supplementary material, which is available to authorized users.

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For every complex and expensive system, there emerges a need for training devices and scenarios which will assist new learners in mastering the use of the device and understanding how to apply it with value. In laparoscopic surgery, simulators have played an important role in improving the practice of surgery over the last 20 years [1, 2]. The same trends and values will likely apply to robotic surgery with the increased use of robotic technology for a growing variety of minimally invasive surgical procedures. 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. The objective of this paper was to provide

Fig. 1 Simulators of the da Vinci surgical robot

comparative data on the functionality of the three commercially available robotic simulators as shown in Fig. 1:

- da Vinci Skill Simulator (Intuitive Surgical Inc., Sunnyvale, CA, USA);
- dV-Trainer (Mimic Technologies, Inc., Seattle, WA, USA); and
- RoSS (Simulated Surgical Skills LLC, Williamsville, NY, USA).

Each of these possesses unique traits which make them valuable solutions for different types of users and learning environments. This report is on the first of a three part comparative analysis of these devices. The first examines the functionality of each of the simulators and illustrates these capabilities side-by-side for ease of evaluation by potential users of each device. The second is a subjective usability evaluation of the simulators on similar exercises by novice (medical students), intermediate (residents and fellows), and expert (attending surgeons) subjects. The third is measure of the degree to which each simulator improves the actual robotic skills of a subject who is engaged in a two months training program with the device. This paper presents the results of the first study defining the functionality of the devices.

Materials and methods

Our department purchased each of the simulator devices which are being evaluated in these studies. This allowed us to objectively evaluate and comment on each device without undue influence from the manufacturers. Each simulator company was aware of the comparison project and provided information on their device in response to queries by our researchers, as noted below. We began by reviewing the users' manuals for the devices to collect details about each system [3–5]. We then interviewed representatives of each of the manufacturing companies for additional functional details. Finally, we performed our own experiments with each device to identify important comparative features across all devices.

We conducted a systematic literature review of all three simulators. The PubMed database of medical research was searched for all references to the devices through March 2013. References from retrieved articles were reviewed to broaden the search. The data extracted from these studies include training exercise modules, scoring systems, costs, educational impact, and validation methods. We identified 45 studies investigating simulation in robotic surgery.

Finally, we submitted our comparative data on the systems to the manufacturers of the devices to verify the accuracy of the information. Each company verified that the data presented in this analysis were accurate.

Results

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

Table 1 Robotic simulator feature comparison

Features	DVSS	dV-Trainer	RoSS
System manufacturer	Intuitive Surgical Inc.	Mimic Technologies Inc.	Simulated Surgical Systems LLC
Specifications (simulator only)	Depth 7″	Depth 36″	Depth 44″
	Height 25″	Height 26″	Height 77″
	Width 23″	Width 44″	Width 45″
	120 or 240 V power	120 or 240 V power	120 or 240 V power
Specifications (complete system as shown in Fig. 1)	Depth 41″	Depth 36″	Depth 44″
	Height 65″	Height 59″	Height 77″
	Width 40″	Width 54″	Width 45″
	120 or 240 V power	120 or 240 V power	120 or 240 V power
Visual resolution	VGA 1,024 × 768	VGA 1,024 × 768	VGA 640 × 480
Components	Customized computer attached to da Vinci surgical console	Standard PC, visual system with hand controls, foot pedals	Single integrated custom simulation device
Support equipment	da Vinci Si surgical console, custom data cable	Adjustable table, touch screen monitor, keyboard, mouse, protective cover, custom shipping container	USB adapter, keyboard, mouse
Exercises	40 simulation exercises	65 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 and graphical reports	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 PC. Import via USB memory stick	Create student accounts. Customize curriculum	Create student accounts. Customize 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	$99,200	$126,000
Support equipment price	$500,000	$9,800	$0
Total functional price	$585,000	$109,000	$126,000

Data are for simulator configurations available as of December 2013

Features and capabilities

Da Vinci Skill Simulator (DVSS) (Intuitive Surgical Inc.)

The 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 fiber optic 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 use 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 drive the simulator. This ensures that the training experience is almost identical in feel to the real system, which can contribute to higher transfer of skills from the training sessions to the real system. Additionally, this minimizes the amount of time spent for learning the unique functionalities of the simulator device and allows the trainee to focus the majority of his/her learning experience on skills acquisition and proficiency development. Finally, there is the cost advantage for the simulator device itself. Because much of the hardware and software expenses are already embedded in 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 and accessibility of a simulator which requires the real robotic system. An attached DVSS simulator cannot be used without access to an actual surgeon's console and therefore is only functional when the robotic system is not in surgery. This implies that the trainee would only be able to use the simulator outside of normal operating room working hours and would need logistical access to the robot and the simulator. da Vinci robots are expensive devices and 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 networking cable that connects the major robotic 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. Given the possibility of regular and continuous simulation training with such device, in addition to actual surgical usage, the real equipment may experience usage rates that are many times higher than normal for the equipment. Since the da Vinci systems operate under a maintenance contract that covers most service costs, the additional costs of maintenance are not born by the hospital owner but by the equipment vendor. The primary impact to the owner would only be in availability for both real surgeries and training events due to increased maintenance.

dV-Trainer (Mimic Technologies Inc.)

The dV-Trainer is a separate, stand-alone simulator of the da Vinci robot. The surgeon'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 Technologies also developed the core 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 the DVSS and version 1.0 of the dV-Trainer are nearly identical. The current version 2.2 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 Fig. 3 and 4.

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 are collected.

Because the dV-Trainer replicates both the hardware and software of the da Vinci robot, it is a much larger system than the DVSS alone, though smaller than a real surgeon'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 the simulated hardware is different than the real equipment and does not exactly replicate the feel of the real robotic equipment. The dV-Trainer uses its own unique hand controls which are connected to three cables for measuring movement, rather than the more precise arms that are used in the da Vinci robot. The dV-Trainer foot pedals look and function almost identically to the robotic foot pedals.

Robotic Surgery Simulator (Simulated Surgical Systems LLC)

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 appearance 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. The simulator can be configured to imitate either the S or the Si model of the da Vinci robot.

The hand controls are modified SensAble Omni Phantom™, force feedback, 3D space controllers (3D Systems Inc., Rock Hill, SC, USA). These devices have a much smaller range of motion than the controllers on the da Vinci robot, so require more frequent clutching than the actual robot. The 3D image is generated by a single computer monitor with polarized glasses, which generates a visual scene with less depth of field than the actual robot.

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

Exercise modules

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

Once logged into each system, the instructor or the student navigates the instructional materials using the menu systems illustrated in Fig. 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.

Dvss

The DVSS contains 40 exercises organized into nine categories (Table 2). These begin with introductory video and audio instructions on how to use the robotic equipment and move through progressively more difficult skills (Table 3).

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 article.

Figure 3 presents screenshots of some of the key exercises in the simulator. These include the Peg Board, Ring Walk, Energy Dissection, and Interrupted Suturing exercises. The suturing exercises on this simulator were developed by Simbionix USA Inc. (Cleveland, OH) for integration into the DVSS. This expansion of the system demonstrates the ability of the simulator platform to blend together exercises and scoring systems created by multiple independent vendors.

dV-Trainer

Most of the simulation software for Intuitive's DVSS was developed by Mimic Technologies. Therefore, version 1.0 of the DVSS and the dV-Trainer contained nearly identical exercises, closely matching menu systems, and identical scoring mechanisms. However, over time the two sets of software have diverged, and the current versions of the simulators differ in functionality and appearance. The current version of the dV-Trainer (v 2.2) contains 65 exercises organized into ten categories.

Though many of the exercises are identical between the DVSS and the dV-Trainer, the graphics resolution and details have been improved in version 2.2 of the dV-Trainer software. Since this system is driven by a commercial PC, which can easily be upgraded, it is possible for the hardware and software to evolve as newer computer technologies are available.

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 Peg Board, Match Board, Tubal Anastomosis, and Energy Switching exercises.

RoSS

The RoSS simulator contains 52 unique exercises, organized into five categories, and arranged from introductory

Fig. 2 Comparative simulator exercise menus

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

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
RTN	VR exercises specifically build to match physical devices in use by the research training network of sites led by Lehigh Valley Hospital

to more advanced (Table 4), just as in the other two simulators. The RoSS system of exercises is unique in that they list fewer exercises but provide three different difficulty levels for most of them where each level is actually a unique exercise.

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

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

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

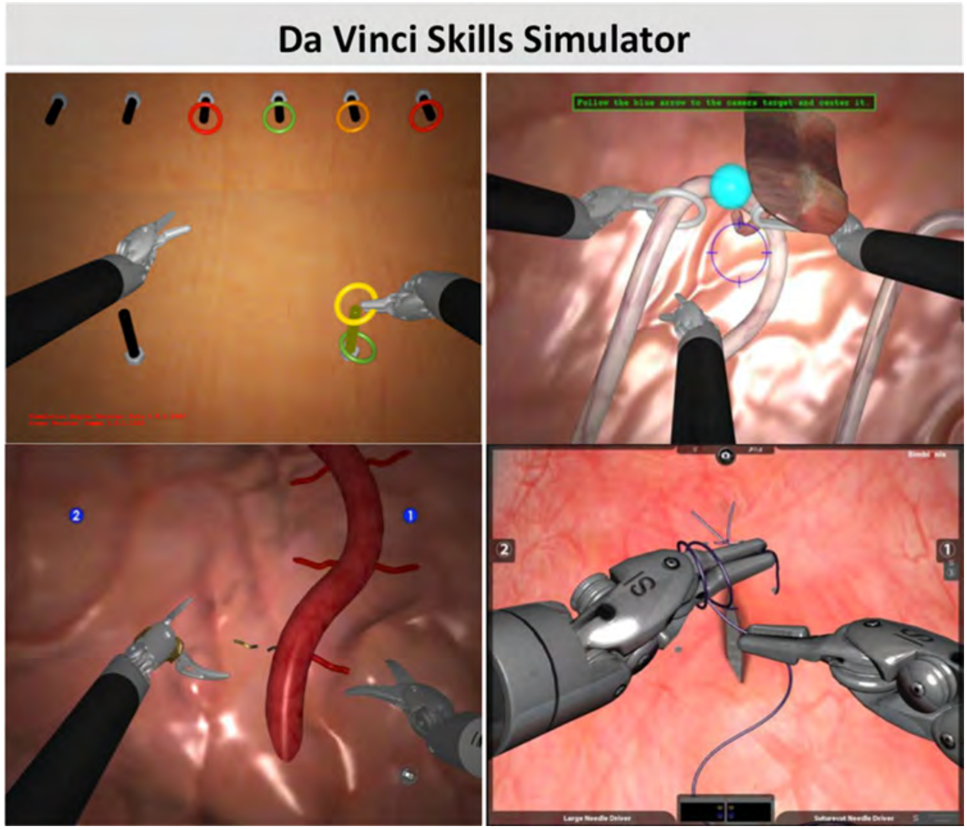

Fig. 3 Selected DVSS exercise images

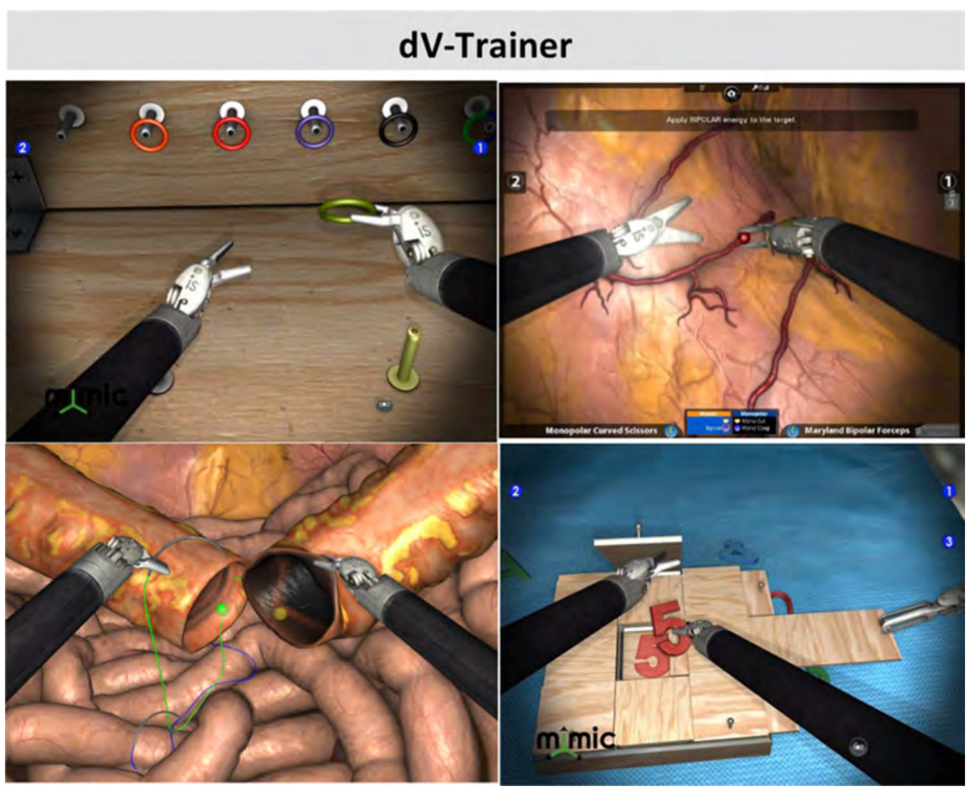

Fig. 4 Selected dV-Trainer exercise images

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

Figure 5 provides screenshots of the motor skills ball placement, intermediate vessel dissection, 4th arm tissue retraction, and HoST radical prostatectomy.

Proficiency scoring system

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 Fig. 6.

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.

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 milliliters 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

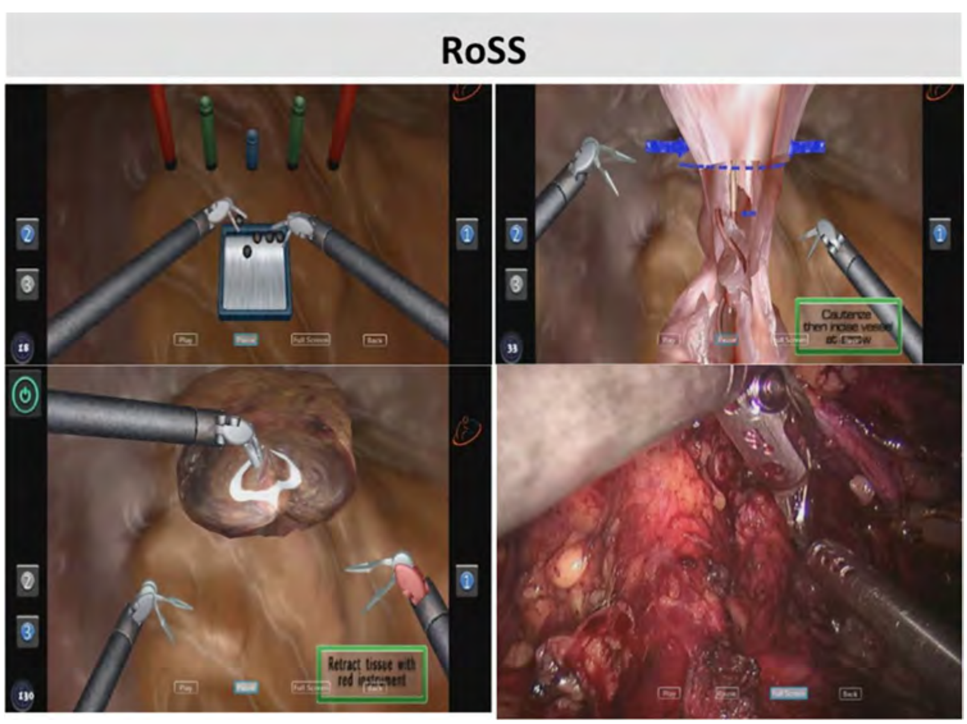

Fig. 5 Selected RoSS exercise images

Fig. 6 Example scoreboards from each simulator

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 work with robotic surgeons to establish 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 individuals who 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

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 applicable to all exercises. For details on the more specialized metrics, the reader may consult the user's manual for the simulator.

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

dV-Trainer

Originally, the DVSS and the dV-Trainer shared the same scoring method, but more recent versions of the dV-Trainer offer both this original "version 1.0" scoring method, as well as a new "version 2.0" method based on the proficiency measured from experienced surgeons. The skills measured are the same (Table 3), but the interpretation of those into a score is different. The instructor can

Table 5 DVSS and dV-Trainer scoring method

Overall score	Composite evaluation of the exercise performance
Time to complete	Number of seconds to complete the exercise
Economy of motion	Number of centimeters of instrument tip movement
Instrument collisions	Number of times that the instruments touched each other
Excessive instrument force	Number of seconds that excessive robotic force was applied against objects in the environment
Instrument out of view	Number of centimeters that an instrument tip moved outside of the viewing area
Master workspace range	Radius in centimeters than contains the movement of the instrument tips
Drops	Number of objects dropped from the grasp of the instruments

select the preferred scoring method for each curriculum that is constructed in the dV-Trainer. The newer scoring method uses total points earned rather than percentages. The passing and warning thresholds can be adjusted by the administrator.

RoSS

The principles behind the scoring system on the RoSS are the same as those for the DVSS and the dV-Trainer. However, most of the metrics collected are different. The standard measurements are shown in Table 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 (Fig. 6). Additional displays show the numeric score and its relative position to a passing threshold.

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

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 "DVSS 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 and the contents of the USB stick are completely erased and reloaded each time. 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 65 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, attending, 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.

Validation of devices

Validation studies serve to determine whether a simulator can actually teach or assess what it is intended to teach or assess. In medical simulation, there are generally accepted

Table 7 Validation of robotic surgical simulators

Validation	DVSS	dV-Trainer	RoSS
Face: subjective realism of the simulator	Hung [7] Kelly [8] Liss [9]	Lendvay [10] Kenney [11] Sethi [12] Perrenot [13] Korets [14] Lee [15] Schreuder [16]	Seixas-Mikelus [17] Stegemann, [18]
Content: judgment of appropriateness as a teaching modality	Hung [7] Hung [19] Kelly [8] Liss [9]	Kenney [11] Sethi [12] Perrenot [13] Lee [15]	Seixas-Mikelus [17] Colaco, [20]
Construct: able to distinguish experienced from inexperienced surgeon	Hung [7] Kelly [8] Liss [9] Finnegan [21]	Kenney [11] Perrenot [13] Korets [14] Lee [15] Schreuder [16] Connolly [22] Lendvay [23]	Raza [24]
Concurrent: extent to which simulator correlates with "gold standard"	Hung [19] Tergas [25]	Perrenot [13] Korets [14] Lee [15] Lerner [26]	Chowriappa, [27]
Predictive: extent to which simulator predicts future performance	Hung [19] Tergas [25] Culligan [28]		

validity classifications, which include face, content, construct, concurrent, and predictive validity [6]. Face and content validity are considered subjective approaches, while the other three are objective approaches to validation.

Table 7 provides a summary of the published validation studies for these simulators. All three have publications establishing face, content, construct, and concurrent validation. Only published studies investigate the predictive validity of the DVSS [19, 25, 28]. Recent presentations also explore the validity of the RoSS curriculum [29] and the RoSS' HoST procedural modules [30].

Conclusions

Simulators play an important role in providing a 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 can be 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.

This article represents the first part of a comprehensive analysis of robotic surgical simulators. The second part is a subjective opinion survey on the usability of the simulators. Subjects for this survey will include attending surgeons, fellows, residents, and medical students without prior experience using the simulation devices. The third part will include a select group of surgical fellows who will participate in a two-month experiment in which each practices on one of the simulators, while their performance is measured every 2 weeks to assess for changes and maintenance of skill levels. The experiment is designed to determine which simulator has the greatest positive impact on robotic surgical performance, and the degree to which those improvements are retained across a period of inactivity.

The three simulators described in this article 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 by this robot. Furthermore, da Vinci robots are predominantly used for daily surgery, decreasing their availability for training. There are currently no available studies directly comparing the three simulators, and therefore until those studies are performed, no universal recommendation can be made for one device over the other, and a decision to use one simulator over the other should be based on unique and individual needs.

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From the concept to surgical relevance:how to engineer the Fundamentals of Robotic Surgery training device?

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From the concept to surgical relevance:

how to engineer the Fundamentals of Robotic Surgery training device?

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Running head: The FRS psychomotor device development

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Mini abstract: This article exposes the process of a national initiative to develop the Fundamentals of Robotic Surgery psychomotor skills dome, an assessment tool to train and evaluate manual dexterity in robotic surgery. The tool gathers 7 basic tasks into a single testing device. The process introduced modifications to the initial design to account for ergonomics, standardization and costs.

Abstract

Objective: To expose the surgical and engineering process of development of the Fundamentals of Robotic Surgery psychomotor skills device.

Summary Background data: Exponential growth of robotic-assisted surgery raises the question of how to assess robotic surgery skills. The U.S Department of Defense and governing surgical societies convened consensus conferences to develop a national initiative, resulting in a curriculum: the Fundamentals of Robotic Surgery (FRS), comprised of an online curriculum and a psychomotor skills dome. This paper describes the production process used to develop the psychomotor skills dome.

Methods: Based on a review of the basic gestures in robotic surgery, 7 tasks were gathered on the dome to test manual dexterity: Docking, Ring Tower Transfer, Knot Tying, Suturing, 4th Arm Cutting, Puzzle Piece Dissection, and Energy Dissection.

Results: The development began with a computer-generated design, which was transformed into Low then High Fidelity Prototypes. Usability testing was conducted throughout the process and modifications were made to the design of the device to account for ergonomics, standardization, and cost.

Conclusions: Final CADs and specifications were sent to simulation and manufacturing companies for production. Experimental trials are underway to validate the effectiveness of the device in both teaching and in assessing specific skills in robotics.

Keywords: Fundamentals of Robotic Surgery; Surgical Education; Simulation; Psychomotor skills; Robotic Training; Robotic Assessment; Robotic Surgery; Psychomotor Device; National Surgical Assessment.

Introduction and background

Robotic surgery has been established as an innovative approach in surgery due to the development of a telemanipulator device, which introduced a new dimension into surgical tools. The da Vinci robot overcomes several laparoscopic limitations and facilitates the performance of minimally invasive surgery in complex procedures with 3D vision, 7-degree-of-freedom instrument movement, hand tremor elimination, motion amplification, and stabilization of the camera in many specialties.[1-4] Thanks to a computerized interface, the surgeon can manage the camera and three working arms with wristed instruments at the same time.[5-6] Nevertheless, the system also introduces a need for training to acquire the unique abilities to operate the device and a certification process to ensure a minimal standard of care for all patients undergoing robotic surgery.

After the Halstedian learning model,[7] training method has begun to evolve in which simulation is an essential part of the training process in the medical field.[8] This was first implemented during the late 1990s when a significant increase in complications was identified in association with the introduction of minimally invasive laparoscopic surgery. Educational material was created to "teach a standard set of cognitive and psychomotor skills to practitioners of laparoscopic surgery". The result was the Fundamentals of Laparoscopic Surgery (FLS) curriculum, which was developed as a 3-part program – online didactic training, hands-on skills training, and a high stakes written and skills exam- in laparoscopic surgery.[9] Today, robotic surgeons face a similar challenge and need a specific evaluation, which allows them to assess their knowledge and technical skills, guaranteeing a minimal standard of care for all patients.[10] Some institutions have attempted to develop and validate robotic training for individual specialties;[11-15] however the lack of a national standard has pushed surgical societies (e.g. SAGES –Society of American Gastrointestinal and Endoscopic Surgeons, SRS – Society of Robotic Surgery) to develop a unified approach and standard for robotic skills training.

The Department of Defense, Veterans Administration and 14 surgical specialty societies convened multiple consensus conferences to create the Fundamentals of Robotic Surgery (FRS).[16] Participants included a total of more than 80 subjects matter experts involving surgeons, psychologists, psychometricians, engineers, simulation experts, and medical educators, with an initial working group including Richard Satava; Timothy Brand; Sanket Chauhan; Rafael Coelho; Brian Dunkin; Susan

Dunlow; Larry Glazerman; Tim Kowaleski; Gyusung Lee; Ray Leveillee; Martin Martino; Sonia Ramamoorthy; Bernardo Rocco; Daniel Scott; and Rob Sweet.[17] Two principles guided the committees' development process. The first was to ensure a perfect understanding of the basics of robotic surgery including the use of the da Vinci robot. The second was to design a psychomotor skills program focused on the basic tasks specific to robotic surgery. In the first meeting an international body of leaders in robotic surgery convened to define cognitive, psychomotor and team training skills necessary for surgical competence. The team focused on identifying the necessary Outcomes Measures and Metrics that would be used to evaluate robotic surgeons. Using a Delphi model that was developed by the Rand Corporation to achieve consensus within dynamic and diverse groups of participants, the essential tasks necessary to perform robotic surgery were identified and prioritized.[18] The result was a matrix of 25 specific robotic surgery concepts, which was the core material used in the development and design of the FRS Curriculum.[16]

Since the purpose was to create a basic fundamental skills program, particular references to an anatomic location or to a specific procedure were avoided. At a later date, specialties will develop their own independent fundamentals beyond the basic FRS, which may refer to specific anatomy. Two assessment tools were developed: the first an online curriculum for knowledge and team training skills and the second a set of physical exercises gathered on a single device in the shape of a dome for psychomotor skills evaluation.[19] The second part is the subject of this work. The aim of this paper is to explain the process utilized to create, optimize and standardize the FRS committee's physical device based on their initial concept, which evolved through low and high fidelity prototypes prior to arriving at the manufacturing process. This device will be used for the psychomotor skill assessment in the FRS Curriculum. This device is known as the FRS dome.

Intellectual process: brainstorming & device design

From the 25 concepts, 16 were directly linked to psychomotor skills (Table.1). Those skills reflected the basic tasks in robotic surgery beginning with docking (the connection of the site cart patient with the previous positioned trocars), and most importantly using surgical gestures as dissection, cauterization and suture. The particularity of the da-Vinci system led to specific robotic tasks. The committee envisioned these tasks summarized in seven exercises positioned on a single integrated physical device, which would minimize intervention by a proctor and facilitate faster completion times. on the surface of a semi-spherical dome. Design consideration included compatibility with the surgical robot, the ability to address multiple learning objectives, cost effectiveness, usability, reliability and the inclusion of validated exercises. A preference was given to tasks that had existing evidence of validity.

Table.1: The 16 concepts directly linked with psychomotor skills in robotic surgery.

The seven psychomotor exercises are Docking and Instrument Insertion, Ring Tower Transfer, Knot Tying, Railroad Track Suturing, 4^{th} Arm Cutting, Puzzle Piece Dissection, and Vessel Energy Dissection (Table.2). As a historical reference, FLS is composed of 5 different tasks: Peg Transfer, Pattern Cutting, Ligaturing Loop, Suturing with an intra-corporeal knot, and suturing with an extracorporeal knot. Some of the seven dome tasks are similar to the FLS curriculum, while others are completely new for the specific needs of robotic surgery. Each of the tasks are described as follows and illustrated in later figures.

- ***Docking & Instrument Insertion***: Robot docking is an essential and unique process required to begin a robotic procedure. Trocar insertion must follow specific guidelines concerning trocar positioning, attachment to the robot arms, and patient cart positioning. These are all important preliminary elements for conducting a safe surgery and a mistake at this phase of the procedure can compromise the entire surgery.

- ***Tower Transfer***: Endowrist manipulation with 7-degrees of freedom is specific to robotic surgery. This exercise allows evaluation of these movements. There is an analogy between this exercise and the ring transfer exercises created by the Chamberlain group. But the FRS tower transfer is more difficult because of the displacement and rotation of the target towards in multiple dimensions.[20]

- ***Knot Tying***: This is a common task performed in surgery.[21] The FLS curriculum requires performing a suture with intra and extracorporeal knot tying. Both have been validated in FLS.[9] In robotic procedures however, only intracorporeal knots are used. Construct validity for this exercise in robotics has been previously demonstrated.

- ***Railroad Track Suturing***: Running suture is a basic task simplified by robotic instruments with their 7 degrees of freedom movement. The exercise has been validated in FLS for laparoscopy.[9]

Both knot tying and suturing exercises demonstrated construct validity in robotic surgery using the FLS curriculum materials,[22] thus, the FRS patterns were developed using different design with a similar concept.

- ***4^{th} Arm Cutting***: The da Vinci system has three instrument arms, in addition to one camera arm, which improve surgeon autonomy. Surgeons can only manage two instrument arms at once, but are able to switch to the third instrument arm and camera when needed. This specific robotic task has been demonstrated to be able to differentiate novice and expert levels.[22]

- ***Puzzle Piece Dissection***: Dissection is a critical task performed by surgeons. In the FLS curriculum, users dissect a circle printed on cloth material. Due to endowrist manipulation and 3D vision, the dissection is easier using the robot than during a laparoscopic procedure.[6] Therefore, this exercise utilizes puzzle piece, which is a more complex shape that is more difficult to accomplish.

- ***Vessel Energy Dissection***: This exercise evaluates fine dissection skills and the ability to use bipolar energy for cauterization. In robotic surgery, the surgeon controls the energy applied with the footswitch pedal. The surgeon has to conduct a very precise dissection of a vessel, which is embedded in synthetic fatty tissue before applying energy. Any damage during dissection will be easily identified by the release of colored fluid inside the simulated vessel.

Table 2: Description of the basic psychomotor skills associated with the seven FRS tasks.

Exercises Design & Arrangement

The design group envisioned each of the exercises occupying a space on the outer surface of a support structure, for which they selected a semi-spherical dome. They explored a number of arrangements of the exercises and patterns of flow from one station to the next on the surface of this dome. Different concepts were presented as paper sketches and crude physical models from the materials at hand in the meeting spaces. A "final" sketch that follows all criteria was delivered to a 3D digital artist to create static pictures of the device and exercises, as well as animation of the performance of each of these exercises (Fig.1).

Figure 1: The initial 3D graphic FRS dome design

Manual process: makestorming

Using the documentation from the design meeting and the computer generated images and animations; the authors took the first step in creating a physical prototype of the device. This physical brainstorming process, or "makestorming", was an essential step in determining whether:

- The single device could actually be created.
- The exercises could coexist on the surface of a dome.
- The exercises configuration could be performed with a surgical robot.
- The exercises were repeatable with a high level of standardization.
- The outcomes of each exercise could be measured.

Low fidelity prototypes (LFP) were created with inexpensive craft materials (Fig.2). The LFP testing allowed enhancement of the design in terms of usability and organization of the different exercises. The materials were sufficient to create a working prototype, which could be used to test fit, function and organization as described above.

Early in the makestorming process, we tested processes to ensure usability, face validity and content validity of the FRS Dome. Surgeons were video recorded completing all exercises and the recordings were reviewed, focusing on ergonomics, material behavior and appropriateness of the organization of the exercises (Fig.3). This allowed rapid trial and error testing of the technical aspect, clarifying requirements and proving usability.

A	B
C	D

Figure 2: Low Fidelity Prototype (LFP): LFP1 (A); LFP3 (B); LFP4 (C) & LFP5 (D)

Feedback was solicited from members of the design team around the globe regarding the results of prototyping and testing, as well as modifications to improve the effectiveness of the design. This resulted in dozens of major and modest improvements to the original design of the device. Each change was tested on subsequent and increasingly complex prototypes. Six distinct LFP models were constructed and tested in this manner.

The initial prototype (LFP1) was created using an 8” Styrofoam sphere as the support structure, a sheet of yellow felt material for the fat layer, a latex swimming cap for the skin layer, straws for the embedded vessels, and foam blocks for the ring towers (Fig.2A). The patterns were stenciled onto the surface with permanent markers. Towers were secured to the dome with magnets. The strength of the magnets used to secure the towers to the dome was important for achieving firm attachment while still allowing excessive force to detach them.

A	B

Figure 3: Early video captured usability test results on the low fidelity prototypes (A: LFP1; B: LFP5).

Multiple design problems were identified with the early iterations of the LFP’s:

- An 8” dome with one-inch towers was too large for the range of movement of the robotic arms. A smaller dome was needed to allow access to all exercises without moving the dome.
- Given the direct approach necessary for the exercises, it was not possible to visualize or accurately cut the large cloverleaf shape, which was first selected for the cutting exercise. A user could not reach the far backside of the dome where one of the clover leaf petals extended.
- The weight of the LFP was not substantial enough to prevent the robot arms from pushing it around during the exercises.

In LFP3, we introduced an elastic band for the 4^{th} arm-cutting task to replace the rigid tube and allow improved retraction (Fig.2B). This modification worked well and has remained nearly unchanged through the design phase. We also worked to reduce the size of the cloverleaf shape cutting pattern in an attempt to allow the user to successfully complete the 360 degree pattern cut. However, even with a smaller size, the users were unable to dissect the entire pattern. So, we began exploring significantly different patterns, which were primarily oriented toward the robotic camera.

In LFP4, we began to experiment with new cutting patterns, which could be accessed from a single direct view of the dome, which also created additional room for the other exercises (Fig.2C). The goal of a new pattern was to retain the difficulty of instrument manipulation found in the cloverleaf shape, but to do so in a smaller area and with multiple instances appearing on the surface. This one change to the pattern opened the design to the possibility of multiple iterative trials of all of the exercises on the surface. LFP4 also contained multiple versions of the suturing exercise to determine whether it should be embedded in the skin layer or attached to the surface as a separate item. On this prototype we introduced Velcro fasteners on the underside of the dome to attach it to the table-top so that the robot arms would not move it during use.

In LFP5, we arrived at a puzzle piece as an ideal complex shape to measure challenge instrument dexterity, and confined the design to a smaller area (Fig.2D). Based on the length of the blades of the da Vinci curved scissor instrument, we selected an acceptable size for the puzzle piece that allowed the necessary cuts and turns in the excising pattern. Prior experimentation with surface mounted suturing materials indicated that these were more difficult to assess objectively so the suturing exercise was embedded in the skin layer in this design.

Then, we shifted from common inexpensive materials to custom materials, which could be used in the final manufacturing of the device. These materials were significantly more expensive than the earlier set and began to represent the true texture, appearance, and performance of the final device, imitating skin and fat. This signaled the evolution to a High Fidelity Prototype (HFP) 7.

The HFP stage allowed us to find appropriate materials, to finalize the organization of the exercises for a better cost-effectiveness and to standardize the exercises. For each prototype, the tests performed were video-recorded for evaluation and feedback from various stakeholders in the project (Fig.4).

Figure 4: High Fidelity Prototype video-recorded tests

Appropriate materials

The dome structure at the HFP stage was created using a 3D photolithographic printer, which could create any custom design in three dimensions using plastic and rubber resins. Since we were still experimenting with the placement of the exercises, the first 3D printed dome structure was created with a dimpled golf ball-like surface. This allowed placement of support magnets at dozens of different locations on the surface (Fig.5A-C). The weight of this heavier shell material also solved the problem of anchoring the dome. The devices weight was now sufficient so that the natural movements of the robotic instruments on its surface did not displace it.

The cost of the CAD drawings and creation of one of these domes was over $1,000 using the specific machinery, materials, and software available in our facility. With the flexibility of 3D printing, we were also able to create a separate top cap for the dome. This concept was part of the original design, but was difficult to realize in the earlier LFP's. This cap provided the location in which the design committee originally envisioned housing two of the exercises. It also served as an anchor device for the top edges of the fat and skin layers.

<table>
<tr><td rowspan="2">A</td><td>C</td><td rowspan="2">B</td></tr>
<tr><td>D</td></tr>
</table>

Figure 5: Initial (A-C) and final (B-D) 3-D stereolithography printing shell and cap of the dome

For the fat and skin layers of HFP, we purchased silicone materials, which are used for professional medical moulage (i.e. simulated injuries and wounds). After testing multiple formulas we found specific silicone products that allowed us to create unique textures for the surface or “skin” layer (Ecoflex 00-30 Platinum Cure Silicone) and the underlying “fatty” layer (Ecoflex Gel Platinum Cure Silicone). With these materials we could create layers for less than $20 per pair, and were able to make custom blood vessels and elastic bands for the respective exercises.

Expert surgeons performed multiple surgical tests to evaluate initial face and content validities of this new dome. This included testing the new dissection shape with realistic materials, evaluating the skin and fat behaviors, and exploring the best placement of the different exercises. We were able to finalize the placement of the exercises and select specific material properties for the final product.

Cost effectiveness

The new pattern of the dissection exercise allowed the exercise to be repeated three times on the surface of the dome. Given this repeating pattern, the ring tower, knot tying and suturing exercises also could appear three times on the surface. As a result, a single set of skin and fat layers could be used for up to three complete exercise sets, significantly reducing associated costs.

We realized that the middle fat layer was only being accessed at three points where the blood vessels were embedded and therefore offered significant additional space for dissection exercises. This allowed us to add three more vessels so users could perform all exercises three times per skin layer and six times per fat layer. These vessels contained a red fluid simulating blood allowing for quick recognition of a failure during the dissection of the vessel from the fat layer.

Standardization

As the dome will be used for training and assessment, a high level of standardization is required. With the different tests conduct on the HFP, we noted that many configurations were possible. This variability was not compatible with the reliability necessary for an assessment device. The last step before manufacturing was to introduce standardized markers on the different pieces of the Dome. After settling on the final configuration of the exercises, a new shell was created with divots only in the specific location of the tower transfer and knot exercises (Fig.5B). Navigation markers were added on the dome shell, fat and skin layers to ensure proper alignment. A triangular mark was added on the lower edge of the dome at the location of each puzzle piece. Corresponding with the marks were triangular markers on the fat and skin layers, which aligned the embedded vessels to the appropriate location on the dome shell and directly beneath the puzzle pieces on the skin. A "tongue" was added to bases of the tower exercises that aligned with markers printed on the skin to standardize the orientation of each tower. Finally, the dome cap had three specific lines, which identified alignment for the towers positioned in the cap with (Fig.5D).

HFP10 presented all exercises and materials as they were expected to exist in the final product. At this stage, new surgical tests were conducted to assess final usability, ergonomics, face and content validity. This version was used as the basis for a specification document for constructing the device. This captured the final appearance, purpose, function, and assembly (Fig.6 A-B) and was intended to allow multiple companies to create identical versions of the device for sale.

A	B

C	D

Figure 6: The Computer Aided Design of the Dome (A-B)

and the last High Fidelity Prototype (C-D)

Using this final design for guidance, we constructed the first instance of a completed dome, "High Fidelity Final 1" (Fig.6 C-D). This experience allowed us to improve the specification document so it could be followed as an instruction set by external manufacturers. The document and HFF1 were delivered to a manufacturing company to begin small lot production of the FRS Psychomotor Testing device.

Conclusion

This article outlines the evolution of the Dome concept from the initial FRS committee expert brainstorming to the final prototype for manufacturing. Based on 16 objectives recognized as basics tasks of robotic surgery, this psychomotor device gathers 7 exercises from docking to suture and dissection. The evolution passed through low fidelity prototypes created with inexpensive materials to high fidelity prototypes with resin products, using different silicone combinations to create textures resembling human tissue. Ergonomics, cost-effectiveness and standardization were acquired through multiple tests during each stage of the process.

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Tables and figures legends

Table 1: The 16 fundamental tasks directly linked with psychomotor skills in robotic surgery

Table 2: Description of the basic psychomotor skills associated with the seven FRS tasks.

Figure 1: The initial 3D graphic FRS dome design

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Figure 3: Early video captured usability test results on the low fidelity prototypes (A: LFP1; B: LFP5).

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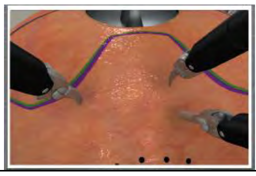
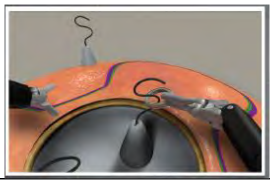
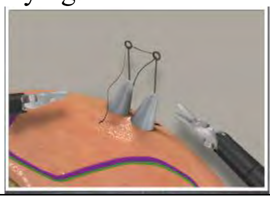
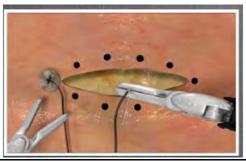
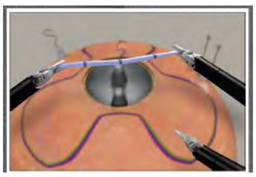
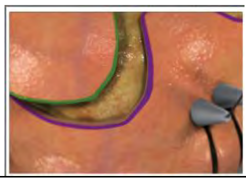
Figure 6: The Computer Aided Design of the Dome (A-B) and the last High Fidelity Prototype (C-D)

Table 1: The 16 fundamental items directly linked with psychomotor skills in robotic surgery.

Phase	**Items**	
Pre-operative	- Docking	- Robotic trocar
Intra-operative	- Energy sources - Camera control - Instrument exchange - Eye hand coordination - Dissection – Fine& Blunt - Needle driving - Knot tying	- Clutching - Wrist articulation - Multi-arm control - A-traumatic handling - Cutting - Suture handling
Post-operative	- Undocking	

Table 2: Description of the basic psychomotor skills attached to the seven FRS tasks.

Exercises	**Skills**
Task 1: Docking & Instrument Insertion: 	- Docking - Instrument insertion - Eye-hand coordination - Operative field of view
Task 2: Ring Tower Transfer: 	- Eye-hand coordination - Camera navigation - Clutching - Wrist articulation - A-traumatic handling
Task 3: Knot Tying: 	- Knot tying - Suture handling - Eye-hand coordination - Wrist articulation
Task 4: Railroad Track 	- Needle handling & manipulation - Wrist articulation - A-traumatic handling - Eye-hand coordination
Task 5: 4th Arm Cutting 	- Multiple arm control & switch - Cutting - A-traumatic handling - Eye-hand coordination
Task 6: Puzzle Piece Dissection 	- Sharp and blunt dissection - Cutting - A-traumatic handling - Eye-hand coordination - Wrist articulation
Task 7: Vessels energy dissection 	- Energy sources use - Sharp dissection - Cutting - Multiple arm control - A-traumatic handling - Eye-hand coordination

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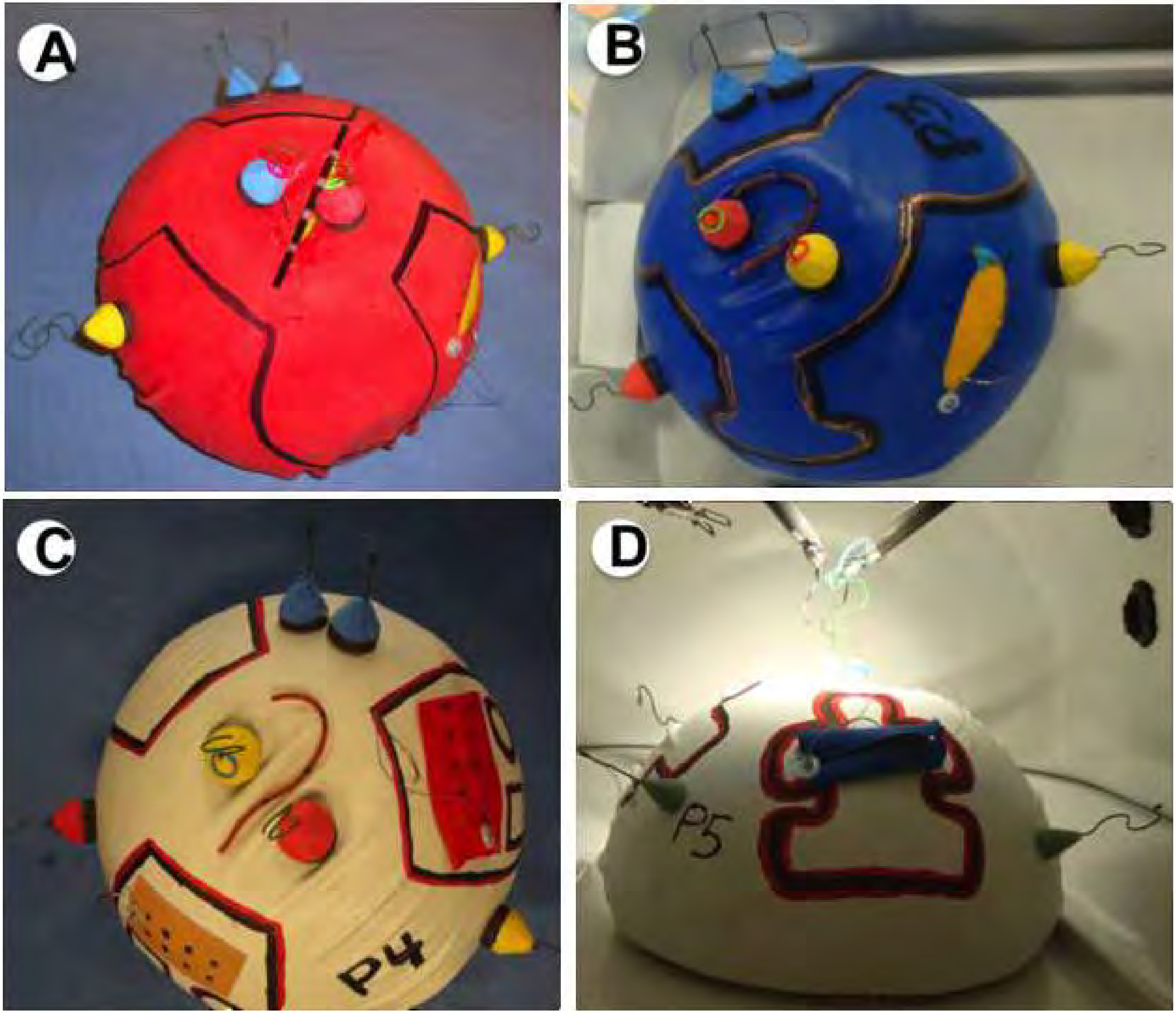

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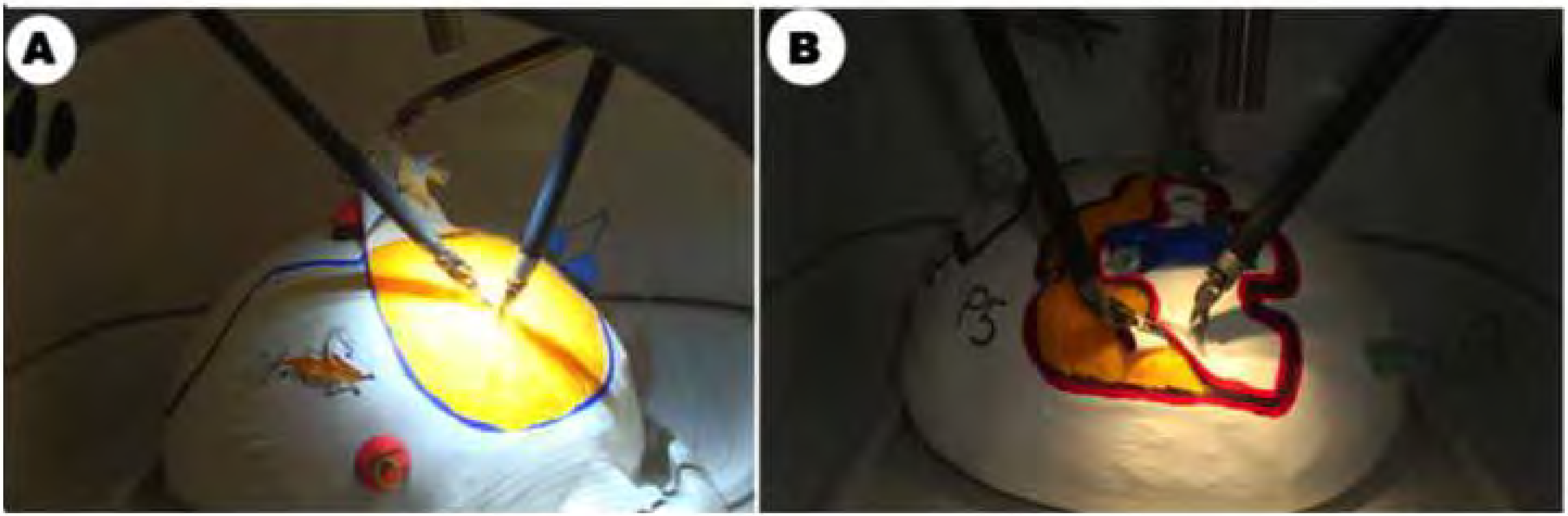

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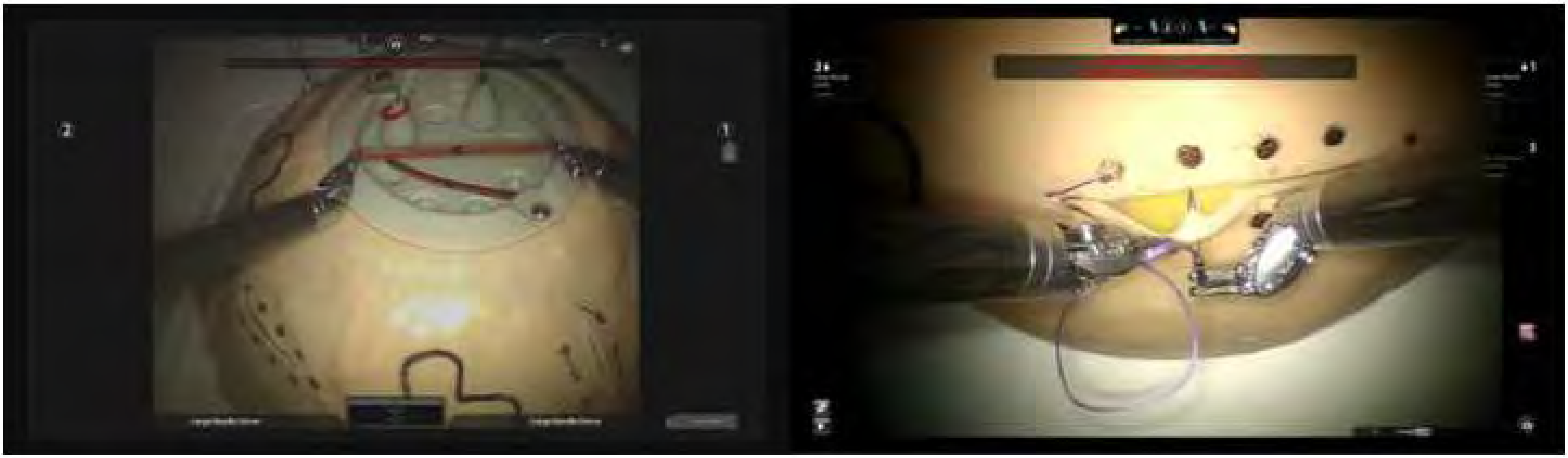

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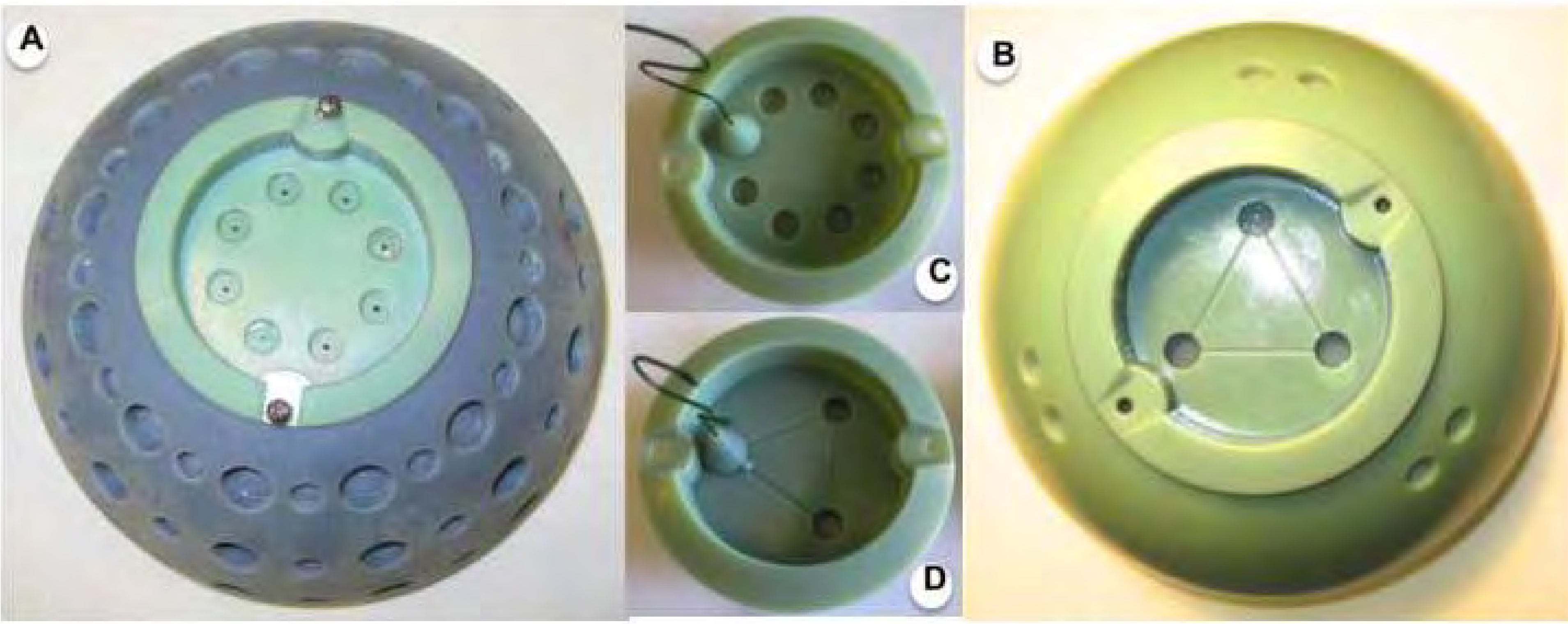

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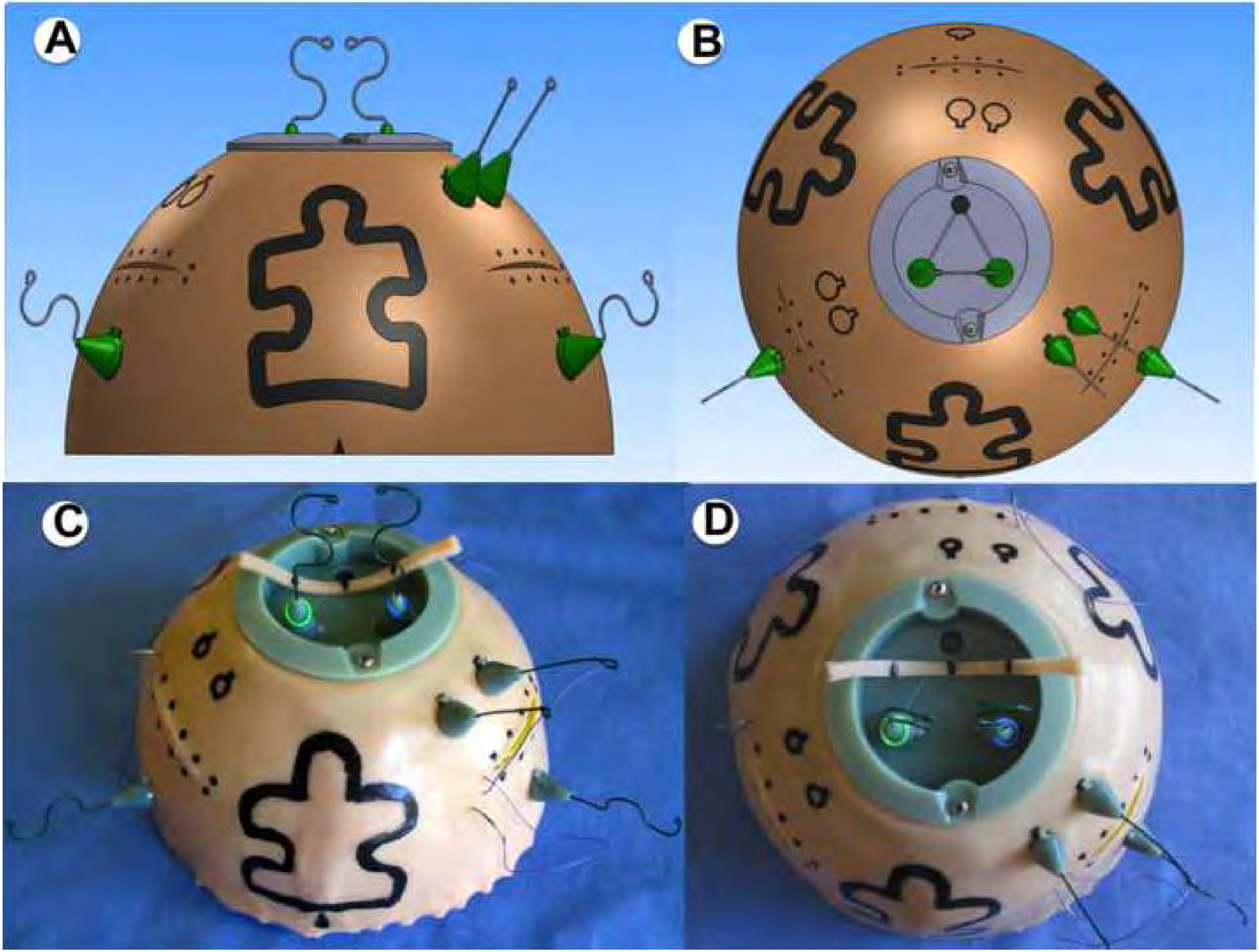

The Journal of Urology

Impact of delay on telesurgical performance: Study on the dV-Trainer robotic simulator

--Manuscript Draft--

Manuscript Number:	
Full Title:	Impact of delay on telesurgical performance: Study on the dV-Trainer robotic simulator
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Keywords:	Telesurgery; Telemedicine; Computer simulation; Robotic simulator; Internet.
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Abstract:	Purpose: The present study aims to evaluate the impact of different latency levels on robotic performances of surgeons on four simulated tasks. Materials and methods: During 3 robotic conferences, surgeons were enrolled to perform 4 tasks on a robotic simulator first without delay (Base) and then twice with a randomly assigned delay (Warm-up and Test) ranging from 100ms to 1,000ms. The simulator provided an automatic scoring system with an overall score based on several criteria such as time, motion, error metrics, etc. The performances were collected for statistical analysis using the repeated measures ANOVA. Results: The complete performances of 37 surgeons were collected. In latency stages (Warm-up and Test), overall score demonstrated a decreasing trend and task completion time increased gradually as latency increased. All metrics clearly deteriorated from non-latency stage (Base) to latency stages starting at 300-500ms for the easiest exercises and around 200ms for the more complex one. Performances improved from warm-up to test in all exercises and the improvement was more significant in more complex tasks. The mean error score significantly deteriorated from Base to latency stages at delays ≥ 500ms (p<0.01). Of the incomplete tasks with latency, 73.75 % were performed under delays ≥ 600 ms. Conclusion: The gradually increasing latency has a growing impact on performances, and the deterioration starts at 300ms. Delays equal or higher than 700ms are difficult to manage especially in complex tasks. Surgeons had the ability to adapt to delay and may be trained to improve their telesurgical performances.
Suggested Reviewers:	
Opposed Reviewers:	

William D. Steers

Editor-In-Chief

July 21th 2014,

Dear Editor

Re: Manuscript reference (JU-14-958)

Please find attached a revised version of our manuscript "Impact of delay on telesurgical performance: Study on the dV-Trainer robotic simulator", which we would like to resubmit for publication as an original article in The Journal of Urology. We revised the paper to answer all of the criticisms raised in the reviewing process. As you proposed in your e-mail, we resubmit the article as a new article.

Your valuable comments and those of the reviewers were highly insightful and enabled us to greatly improve the quality of our manuscript. In the following pages are our point-by-point responses to each of the comments of the reviewers as well as your own comments.
As the manuscript is resubmitted as a new article, the revisions are not highlighted.

In accordance with reviewer's suggestions, we made many changes:

Reviewer's critique:

<u>Introduction</u>
End of second paragraph, it is quoted that latency on the Internet is 700-900 ms. From where are that data?
We added a reference.

<u>Methods</u>
Each user only performed one latency delay (ie only at 100 ms) or did they perform each delay from 100 ms to 1000 ms?
Each user performed within a single latency. We did not have a user experience multiple latencies. Completing the experiment for a single latency required a time of between 30 minutes and 2 hours. It was not practical to get attending physicians to work longer than this. Additionally, if a subject were able to repeat the exercises with different levels of latency, they would be developing new skills and learning to improve their performance in these trials. Therefore, their data on second or third levels would not be comparable to other subjects who experienced a different progression through multiple latency levels.

To remove bias, were users blinded to the latency time they were experiencing?
Yes, subjects were blinded to the latency they received. We never told them what it was for their trials.

Results

Less than half of recruited participants completed their assigned exercises. Can it be concluded that those who did not complete did so because they were incapable of completing (ie from the severe latency) or could it also be from study logistical challenges (ie any flaw or additional challenge because of study design)?

Our experience with all subjects was that they exhibited a determination to complete the experiment. Depending on the level of latency, this could require between 30 minutes and 2 hours to finish the experiment. In most cases, the subjects chose to terminate an exercise when they found it too difficult to complete with their skill level and the assigned latency level. A few subjects completed two or three exercises and then returned to a conference, promising to return. Those who did not return were likely due to the logistics of the experiment and the location.

Incomplete data - since so much data were incomplete and thus not analyzed, better accounting should have been made of why they were not completed, not just by authors' conjecture.

When a subject attempted to complete an exercise and spent 10 minutes or more struggling, we are certain that their termination of the study was due to a lack of skill to perform at the given latency level. Only when subjects did not return, as described above, do we believe that logistics could be the cause of the incomplete data.

It seems difficult to compare across latency times when the authors are really comparing different users across different latency times. The study is not comparing how specific set of users fare across different latency times. Rather it looks at how different users fare across different latency times. This is a flaw in the study.

This is not a flaw in the study. As explained in a previous question, the experiment was designed to prevent a subject from learning through a progression of different levels of latency. Since different subjects would go through a different series of latency levels, none of their data would be comparable to the learning experience of other subjects. The experiment was not supposed to teach them to accommodate for latency, but to capture their existing ability to adapt to latency with a short warm-up. We rely on the demographic data and large numbers of subjects to identify common thresholds at which significant changes in performance occur.

We are not certain, but the reviewers comment may refer to the case in which we grouped subjects with latency levels higher than 700ms for the purposes of trend analysis. In that case, it is correct that the data in that group is not directly comparable to the data in other groups which contained subjects with a single latency level. As describe in the paper, there were not sufficient subjects at each of the higher levels to perform an analysis for each of 700ms through 1,000ms.

Discussion

I disagree with excluding "overly complicated exercises" such as Suture Sponge and Tubes. Arguably they are the closest match to clinical practice of robotic surgery. Why were they not included?

We used exercises close to real procedures, such as Thread the Rings, which is a suturing exercise and Energy Dissection. We avoided exercises like Suture Sponge because it is very long in time even without latency and may have led to experimental sessions or multiple hours for subjects with long latencies. We did use the Suture Sponge exercise in another experiment with medical students who were being trained to manage delay on the dV-Trainer. We found this exercise to be extremely long for those subjects and beyond the availability of attending surgeons for the experiment reported in this manuscript. Based on that experience, we believe it would have significantly increased dropout based on time constraints in this study.

We hope that the revisions in the manuscript and our accompanying responses will be sufficient to make our manuscript suitable for publication in the Journal of Urology.
We look forward to hearing from you at your earliest convenience.

Yours sincerely,
Manuela Perez, MD, PhD,

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Impact of delay on telesurgical performance:

Study on the dV-Trainer robotic simulator

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Running head: Telesurgery and performance degradation due to latency

Keys words: Telesurgery; Telemedicine/methods; Computer simulation; Robotic simulator; Internet.

Grant Information: Funding Source: U.S. Army Telemedicine and Advanced Technology Research Center. Grant #: W81XWH-11-2-0158

Disclosure: The authors have no personal disclosure or conflict of interest to mention.

ABSTRACT:

Purpose: The present study aims to evaluate the impact of different latency levels on robotic performances of surgeons on four simulated tasks.

Materials and methods: During 3 robotic conferences, surgeons were enrolled to perform 4 tasks on a robotic simulator first without delay (Base) and then twice with a randomly assigned delay (Warm-up and Test) ranging from 100ms to 1,000ms. The simulator provided an automatic scoring system with an overall score based on several criteria such as time, motion, error metrics, etc. The performances were collected for statistical analysis using the repeated measures ANOVA.

Results: The complete performances of 37 surgeons were collected. In latency stages (Warm-up and Test), overall score demonstrated a decreasing trend and task completion time increased gradually as latency increased. All metrics clearly deteriorated from non-latency stage (Base) to latency stages starting at 300-500ms for the easiest exercises and around 200ms for the more complex one. Performances improved from warm-up to test in all exercises and the improvement was more significant in more complex tasks. The mean error score significantly deteriorated from Base to latency stages at delays ≥ 500ms ($p<0.01$). Of the incomplete tasks with latency, 73.75 % were performed under delays ≥ 600 ms.

Conclusion: The gradually increasing latency has a growing impact on performances, and the deterioration starts at 300ms. Delays equal or higher than 700ms are difficult to manage especially in complex tasks. Surgeons had the ability to adapt to delay and may be trained to improve their telesurgical performances.

INTRODUCTION

Robotic surgery was noted to be in its infancy in 2004,[1] but now this advanced technology is on its way to young adulthood [2] and has even become a standard in complex surgery.[3] The mature experience will likely include the achievement of remote telesurgery, the future challenge for robotic surgeons.[4,5]

The first transatlantic human telesurgery procedure was performed in 2001.[6] Since the proof of concept, telesurgery remains a complex and uncommon process that holds promise in overcoming challenging situations (remote medicine for underserved regions, surgery in the battlefield, surgery in space, etc.). [7,8] Many teams have worked on the telesurgery process and try to achieve remote telesurgery procedure using available technical resources for the video flux transfer.[7,9,10] In telesurgery, the control signal sent from the master console is transferred over a network to the robot arm followed by a corresponding movement of the surgical instruments. The laparoscopic videos are then returned to the surgeon site. The information transmission requires an encoding, transmitting, and decoding process in which a time delay is inevitably produced. Latency is correlated with the amount of data transmitted and the quality of network. The first transatlantic human robotic remote procedure used sophisticated dedicated Asynchronous Transfer Mode (ATM) lines with a delay of transmission around 150ms.[6] Dedicated lines however are not always feasible in clinical routine. Given the cost effectiveness, an easily accessible resource such as the Internet would be a good and affordable choice, but the availability of the network would be at the price of a significant latency, measuring approximately 700-900ms depending on the speed of the network and the distance between to the two points.[11]

This latency may impact the surgical performances, and extent to which this happens must be clarified before the further implementation of telesurgery. Two levels need to be determined: first is the smallest latency detected by surgeons that will influence the performance and second is the latency that makes the surgery unsafe, which means a delay associated with an increase in errors. A previous study on this topic highlighted the impact of delay on performance degradation using the dV-Trainer®. The authors evaluated the effects of delay varying between 100-1,000 ms and found that latencies ≤ 300 ms had a small impact on performance. Subjective evaluation then suggested that surgery became quite difficult at delays ≥ 700ms. In this study, subjects were medical students trained to perform delayed exercises on the simulator.[12]

The present study aims to evaluate, on a large population of surgeons, the impact of different latency levels on performances in four simulated robotic tasks.

MATERIAL AND METHODS

Exercises:

We designed a prospective, randomized, observational study conducted on the robotic surgical simulator dV-Trainer® (Mimic technologies Inc, Seattle, USA). This tool has demonstrated face, content, construct and concurrent validity in previous studies.[13,14] Based on expert opinion, we chose 4 exercises (Figure.1) for the test that would be performed in a constant order from the easiest to the most complex - Peg Board 1 (PB1): pick up and transfer rings sequentially from the peg board to a single peg on the floor; Camera Targeting 2 (CT2): manipulate the camera to precisely focus and zoom on a target sphere; pick up and move a stone into a designated baskets; Thread the Ring 1 (TR1): pass a needle and suture through a number of flexible eyelets; and Energy Dissection 1 (ED1): isolate a large blood vessel by cauterizing and cutting small branching blood vessels that anchor the large vessel. Both basic (endowrist manipulation, camera control and clutching) and challenging (suturing, dissection) skills were covered with those exercises. We introduced fixed latencies into the programming system of the dV-Trainer between the gesture on the grips and the visual feedback on the console.

After Institutional Review Board approval, we recruited volunteers - fellow and attending surgeons- during 3 Robotic Conferences in 2012. Each subject received a unique Identification Number under which all data was collected and then completed a questionnaire concerning demographic data, surgical experience and related activities. The delays ranged from 100 to 1,000 milliseconds (ms) with increments of 100 ms. Each participant received a unique randomly assigned, delay under which they would perform the experiment on the dV-Trainer. They performed the delayed trials with a single latency and were blinded to the latency they received.

Procedure:

Before the trial on the simulator, each participant received a standardized short instruction on the dV-Trainer's usability defined as an acquaintance period. After that, they performed the 4 exercises in order with no delay. The results provided their baseline performance (Base). Subjects then performed the first delayed trial with the randomly assigned latency (Warm-up) and finally repeated the 4 exercises once again with the same delay (Test). The Warm-up period allowed them to get familiar with latency and to acquire short-term adaptation.

Metrics:

The dV-trainer involves a built-in scoring system. Values and scores of the following metrics were automatically recorded after each attempt: time to complete the exercise (seconds), instrument motion (centimeters), master workspace range (centimeters), excessive instrument force (seconds), instruments out of view (centimeters), instrument collisions and drops.

A proficiency-based overall score was then given based on the results of above metrics for each exercise. We also calculated the mean error score of the error metrics in each exercise. The error metrics include drops (in all the exercises but ED1), instrument collisions, excessive instrument force, instruments out of view, as well as blood loss and misapplied energy time (specific in ED1). The higher the mean score is, the lower the error rate.

Statistical methods:

All data was analyzed using R Statistical Software. Performances across exercises within the three periods (Base, Warm-up, and Test) were compared using the repeated measures ANOVA (mixed-effects model). Statistical significance was determined at $p < 0.05$

RESULTS

A total of 63 subjects enrolled in the study and were able to complete the baseline and delayed levels. Twenty-six were unable to complete the delayed trials (41.2 %). Some participants did not perform or finish all the exercises.

Complete data

Final data was derived from 37 subjects (30 attendings, 7 fellows) who completed exercises including both the base and the delay. Twenty-three had robotic experience, with an average of 2.7 years and a range of (1-9) years. The number of subjects at each latency level is presented in Table 1.

Overall tendency by exercise

Overall score in all latency stages (Warm-up and Test) demonstrated a decreasing trend as latency increased. Meanwhile, task completion time in latency stages increased gradually as the latency levels increased. A linear regression was fit to the task completion time in the Test stage of the four exercises ($p < 0.05$). Instrument collisions of PB1 in the Test stage demonstrated a similar increasing trend and was also fit to a linear regression ($p = 0.0378$). Overall score, task completion time, instrument motion, and errors clearly deteriorated from the non-latency stage (Base) to latency stages at 300 ms and above in PB1 (Figure 2). This deterioration of the performance was evident at 500 ms, 100 ms, and 200 ms in CT2 (Figure

3), TR1 (Figure 4), and ED1 (Figure 5), respectively. Performances improved from Warm-up to Test in all of the four exercises and the improvement was more significant in the complex exercises (ED1 and TR1), than in the basic exercises (PB1 and CT2).

Comparisons by latency group

The next analysis was comparing the performance of each exercise across latency levels using repeated measures. The comparisons between the three stages (Base, Warm-up, Test) were performed in task completion time (Figure 6), instrument motion (Figure 7), and mean error score (Figure 8). At 600 ms, only one person completed the TR1 exercise. Data of this exercise were thus not used for statistical analysis. At delays ≥ 700 ms, the subject number was limited at each latency level; the data was thus merged together for statistics (group 700-1,000 ms). Comparisons were performed with conglomerate data from both PB1 and CT2.

Task completion time was shorter in Test versus Base and Warm-up at 100 ms ($p < 0.05$). It clearly deteriorated from Base to the two latency stages (Warm up and Test) at delays higher than 300 ms, and the statistical significance was achieved at delays ≥ 400 ms ($p < 0.01$).

Instrument motion significantly increased from Base to the two latency stages at 400 ms, 500 ms, and 600 ms ($p < 0.05$). At 700-1,000 ms, instrument motion deteriorated from Base to Warm-up and then improved from Warm-up to Test ($p < 0.05$). There was no significant difference between Base and Test.

The mean error score significantly deteriorated from Base to latency phases at delay ≥ 500 ms (p < 0.05).

Incomplete data

Eighty incomplete exercises in latency stages derived from 26 subjects were identified. They included 18 PB1, 18 CT2, 26 TR1 and 18 ED1 (Table 2). Subjects were physically unable to complete these delayed exercises. Fifty-nine (73.75 %) tasks were not completed for delays ≥

600 ms, and 53 (66.25 %) were stopped by the subject at a mean time of 9.8 min (586.01 ± 14.54 sec) (Figure 9).

For Peg Board, mean drops for uncompleted delayed trials was 4.4 times higher than for un-delayed exercises, mean collision was 3.4 times higher, mean excessive force was 12 times higher, and mean instrument out of view was more than 10 times higher.

For Camera Targeting 2, the uncompleted delayed trials had a mean excessive instrument force that was 2.6 times higher than for un-delayed exercises and a mean instrument out of view which was 3.8 times higher. For Thread the Ring, for delayed uncompleted trials the mean for instrument collisions was 2.7 times higher than for un-delayed exercises and mean instrument out of view was 19 times higher. For Energy Dissection, the mean blood loss for uncompleted delayed exercises was more than 3 times higher than for non-delayed exercises (Table 3).

DISCUSSION

We aimed to determine the latency effects on surgical performances in real surgeons to establish the acceptable delays in telesurgery. Overall, the gradually increasing latency has an increasing impact on performances, and significant performance deterioration started at 300ms. Latencies of 100 and 200 ms seemed to have no clear effect, and the 100 ms group had improving performance from the Base to the Test stage. This improvement likely corresponds to the learning effects of basic simulator manipulation and further proves that 100 ms is of no significant influence. For the superior threshold, delays equal or higher than 700 ms seem to be difficult to manage especially in complex tasks. Only one subject was able to complete the most complex exercises at 700 ms and for delays from 800 to 1000 ms, only the easiest exercises (PB1, CT2) were finished. In the previous study with medical students, the same threshold was highlighted and the authors suggested telementoring as a safer choice.[12] Telementoring is an application of telemedicine that involves the remote guidance of a procedure when the operator has limited experience with the technique.[15] However, in this study, the error rate significantly increased from non-latency to latency stage at delays ≥ 500 ms, which may indicate an increase of surgical risk. We would consider this value as the superior threshold and telesurgery should not be recommended in this condition for delay untrained surgeons.[16] This does not mean that procedures have not nor cannot be performed at higher latency levels, however research is limited and lacks outcome data. In a previous published study, a nephrectomy was performed on a swine under a delay of 900 ms. Two surgeons performed the procedure, one in the remote site console and one in the local site console.[11] In this article, no objective data was provided including time to complete the procedure, error metrics or stress evaluation.

Surgeons have been shown to have the ability to adapt to delays.[17] In our study, performances improved from Warm-up to Test in all the four exercises. Training to the specific latency was achieved in all four exercises due to the ordering of the tasks. For example, subjects performed one attempt of ED1 with a certain delay in Warm-up and then completed one by one PB1, CT2 and TR1 in test stage before the final attempt of ED1. This further confirms that surgeons could be trained on delay to improve their telesurgical performances.

Our results also demonstrate that the impact of latency depend on the difficulty of procedures. Latency affected performances on different levels for the four chosen exercises; the performance deterioration started at a high delay (500 ms) for the simple exercise CT2 and at a low one (100 ms) in the more challenging TR1. This fact indicates that the minimum influential and the maximum acceptable delays could be different in surgical procedures with different complexity.

We chose challenging exercises with features similar to real surgical procedures, as with Thread the Rings and Energy Dissection; but avoided overly complicated and long exercises like “Suture Sponge” or “Tubes” considering that many surgeons were not sufficiently familiar (or proficient) with the robot and the simulator. In this study, few tasks were completed at delays, higher than 700 ms, so it is anticipated that the results would be even worse if applying more challenging exercises.

Participants appeared to be focused on task completion. The mean duration of attempt was 7.5 min. per each exercise. Even in the identified 80 incomplete exercises only a few subjects stopped shortly after beginning. This suggests that surgeons were interested in the telesurgical procedure and placed a reasonable effort into completing it, thereby minimizing bias. When subjects were unable to complete delayed exercises, the most clearly impacted elements in terms of error varied according to the exercise. Drops, collisions, excessive force and instrument out of view are most frequent in Peg Board and Camera Targeting due to the high level of instrument motion. The ring transfer between graspers explained the increase of drops and collisions in Peg Board and Thread the Rings. The ability to control bleeding was sharply diminished under higher levels of delay in Energy Dissection.

This study has potential limitations, even though we recruited more than sixty surgeons, and the final completion rate was lower than expected. Moreover, many surgeons failed to complete the process for tasks at high delays due to the difficulty of controlling the instruments. In addition, all subjects were novices in telesurgery and the effects of delay on their movements since this technology is currently only available in research settings.

A complementary study will be necessary to assess the performance degradation induced by latency on robotic surgery experts, and to identify the telesurgical training that could be used to overcome the challenges associated with this environment.

CONCLUSION

Surgical performances deteriorate gradually as latency increases. The impact of delay depends on the difficulty of the procedure. Overall, delays of 100-200 ms have no significant impact, and ≥ 500 ms cause an increase in surgical risk for untrained surgeons. Surgery becomes extremely difficult at delays higher than 700 ms and should be avoided except for telementoring. Surgeons have the ability to adapt to latency and they may be trained to improve their telesurgical performances.

Key of Definitions for Abbreviations

ATM line: Asynchronous Transfer Mode line
ms: millisecond
PB1: Peg Board 1
CT2: Camera Targeting 2
TR1: Thread the Ring 1
ED1: Energy Dissection 1

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Figure and table legends:

Table 1: Numbers of subjects in each exercise at different latency levels (ms= millisecond; *= data not used for statistical analysis)

Table 2: Numbers of incomplete tasks at each latency level (ms= millisecond)

Figure 1: DV-Trainer® exercises: Peg Board (A); Camera targeting (B); Thread the Ring (C) and Energy Dissection (D)

Figure 2: Change of metrics with latency in Peg Board 1: overall score (A), task completion time (B), instrument motion (C), instrument collisions (D)

Figure 3: Change of metrics with latency in Camera Targeting 2: overall score (A), task completion time (B), instrument motion (C), instruments out of view (D)

Figure 4: Change of metrics with latency in Thread the Rings 1: overall score (A), task completion time (B), instrument motion (C), instrument collisions (D)

Figure 5: Change of metrics with latency in Energy Dissection 1: overall score (A), task completion time (B), instrument motion (C), misapplied energy time (D)

Figure 6: Comparisons of task completion time cross exercise at different latency levels (* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$)

Figure 7: Comparisons of instrument motion cross exercise at different latency levels (* $p < 0.05$)

Figure 8: Comparisons of mean errors score cross exercise at different latency levels (* $p < 0.05$; ** $p < 0.01$)

Figure 9: End times of the incomplete exercises in latency stages at each latency level.

Key of Definitions for Abbreviations

ATM line: Asynchronous Transfer Mode line
ms: millisecond
PB1: Peg Board 1
CT2: Camera Targeting 2
TR1: Thread the Ring 1
ED1: Energy Dissection 1

Table 1

Table 1: Numbers of subjects in each exercise at different latency levels (ms= millisecond)(*data not used for statistical analysis)

Delay (ms.)	100	200	300	400	500	600	700	800	900	1000
Peg Board1	4	7	2	5	4	6	1	1	–	1
Camera Targeting2	3	6	2	5	4	4	1	1	2	1
Thread the Ring1	3	7	2	6	4	1*	1*	–	–	–
Energy Dissection1	4	7	2	7	3	3	1*	–	–	–

Table 2

Table 2: Numbers of incomplete tasks at each latency level (ms= millisecond)

Delay (ms)	100	200	300	400	500	600	700	800	900	1000
Peg Board1	1	1	2	-	1	1	2	2	7	1
Camera Targerting2	-	2	1	2	2	2	1	2	5	1
Thread the Ring1	1	1	1	1	1	5	2	4	7	3
Energy Dissection1	-	1	1	-	2	2	1	2	6	3
Total (80)	**2**	**5**	**5**	**3**	**6**	**10**	**6**	**10**	**25**	**8**

Table 3

Table 3: Incomplete exercise error data compared to un-delayed exercises for the same subjects

	Exercise Delay	Drops (mean)	Excessive force (s) (mean)	Collision (mean)	Instrument out of view (mm) (mean)	Blood lose (ml) (mean)	Misapplied energy (s) (mean)
Peg Board	No delay	0.5	1.4	3.7*	2.6		
	Delayed-Uncompleted	2.2	17.23	12.9	28.9		
Camera Targeting	No delay	0. 33	33.2	2.8	45.5		
	Delayed Uncompleted	0.25	88.2	3.1	173.25		
Thread the Ring	No delay	0.4	0.25*	4.8	1.1		
	Delayed Uncompleted	0.65	4.6	13.07	21.8		
Energy Dissection	No delay		3.8*	1.7		138.1	36.5
	Delayed Uncompleted		26.1	5.5		456.8	41.5

*One subjects deleted in un-delayed exercise because of incongruent data
Peg Board: one subject with 45 collisions
Thread the Ring: one subject with 76 excessive force
Energy Dissection: one subject with 229.4 excessive force

Figure 1

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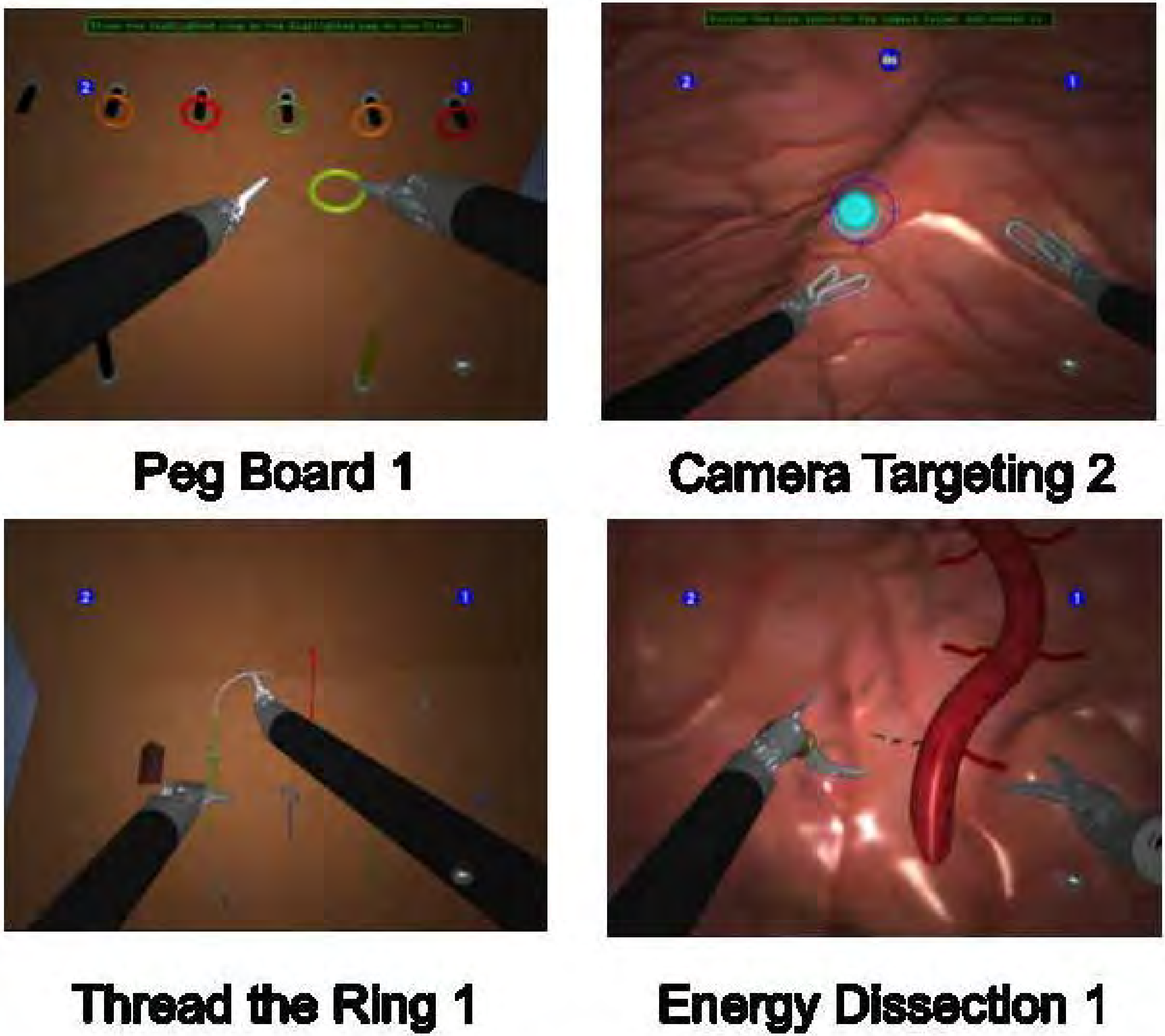

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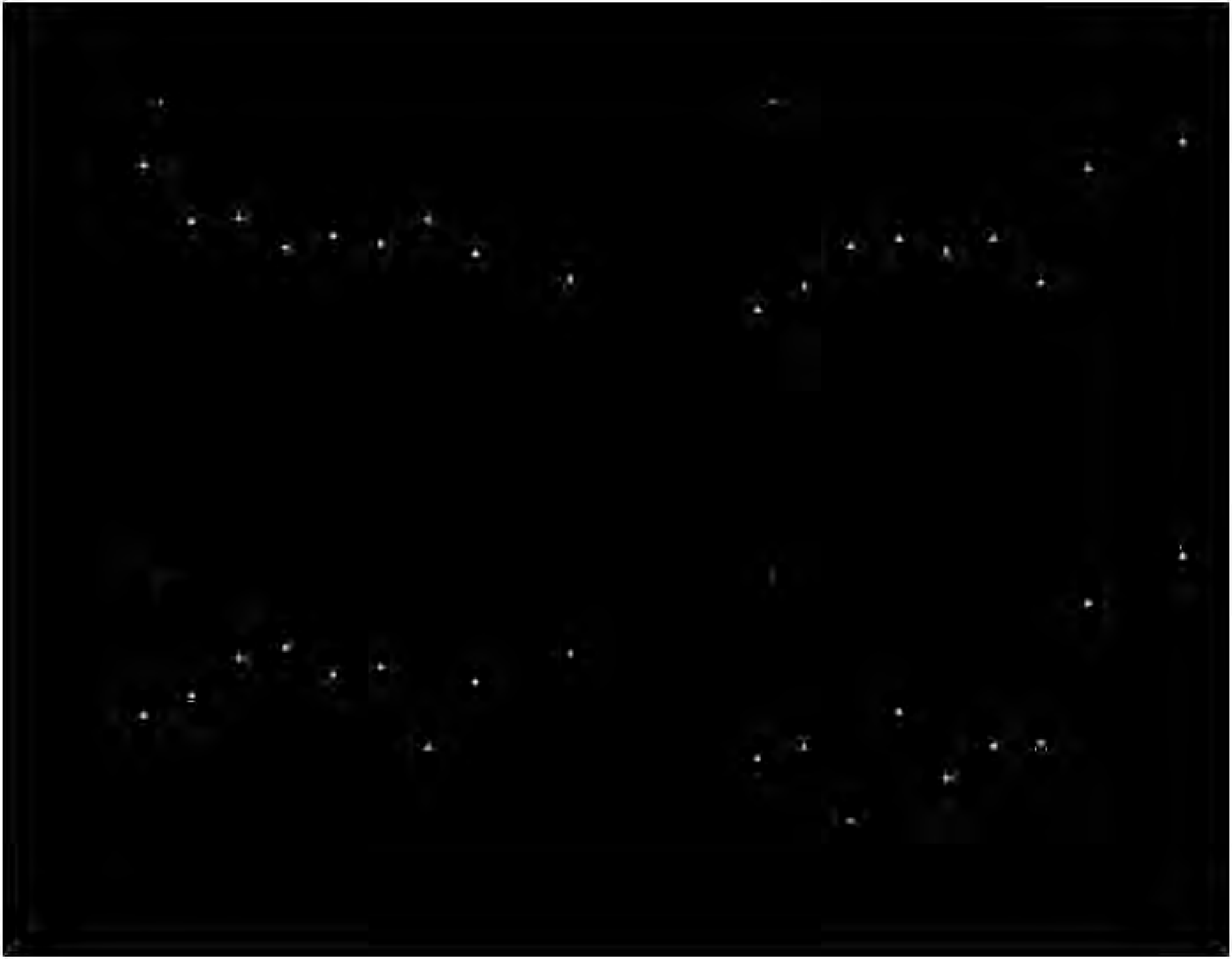

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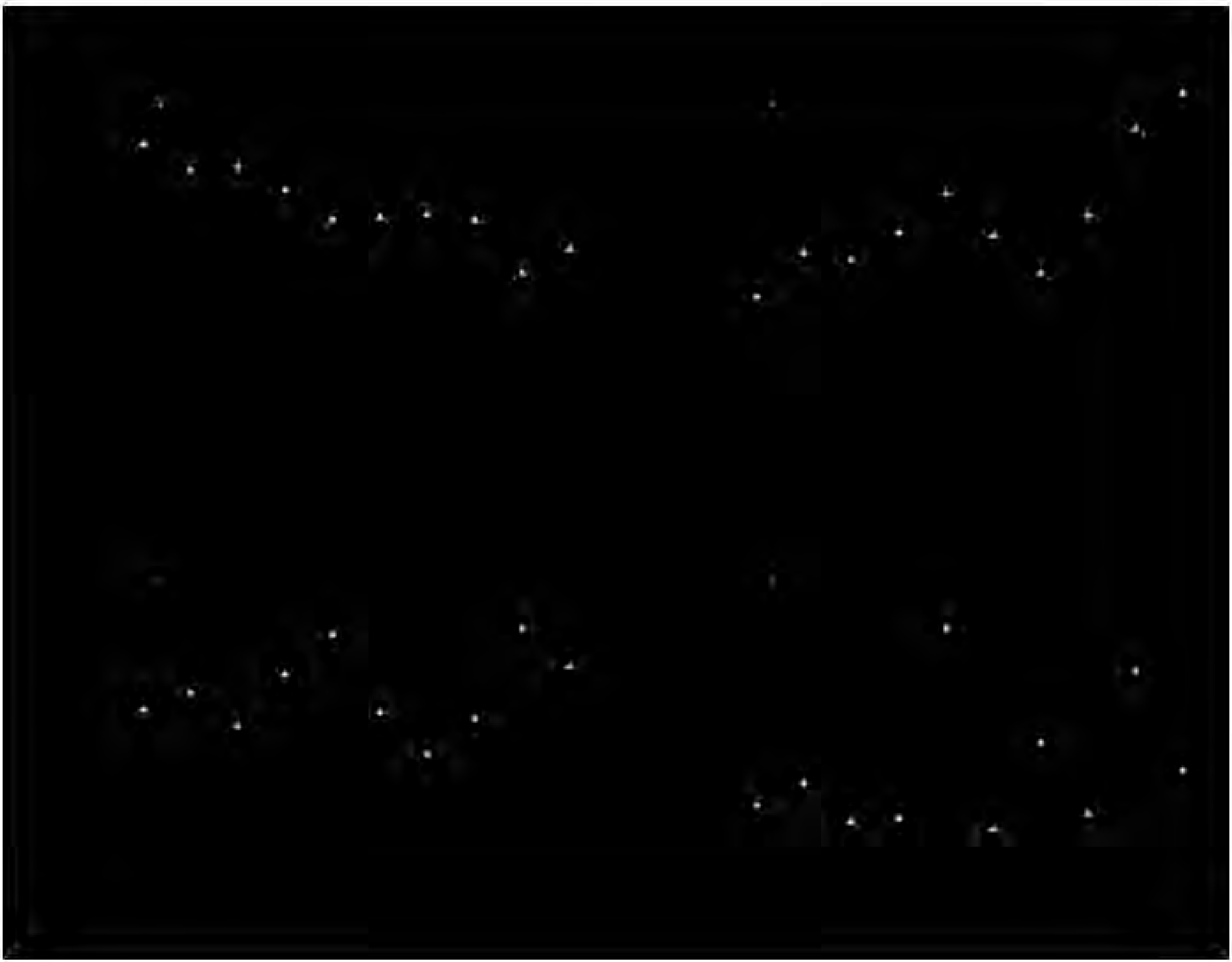

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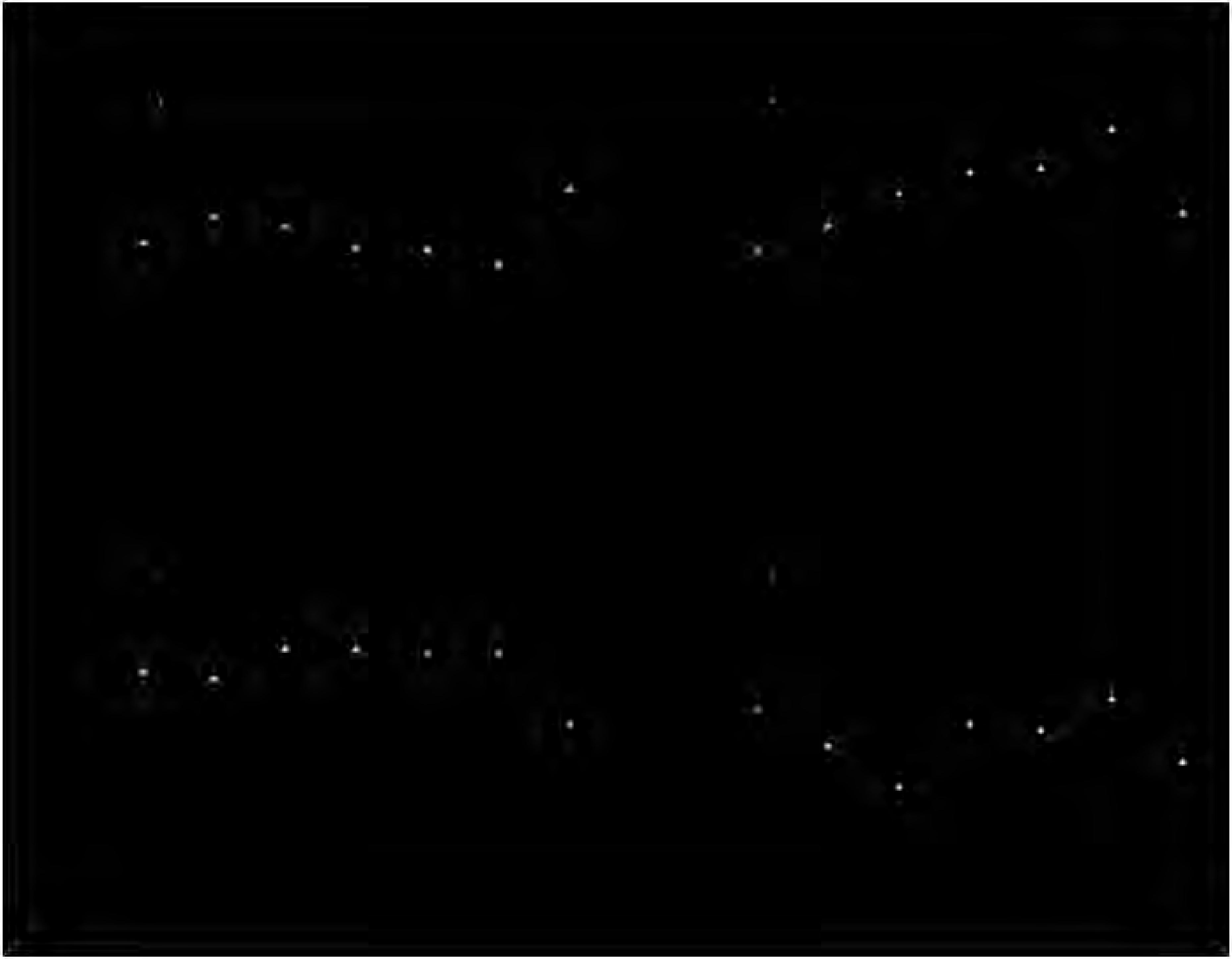

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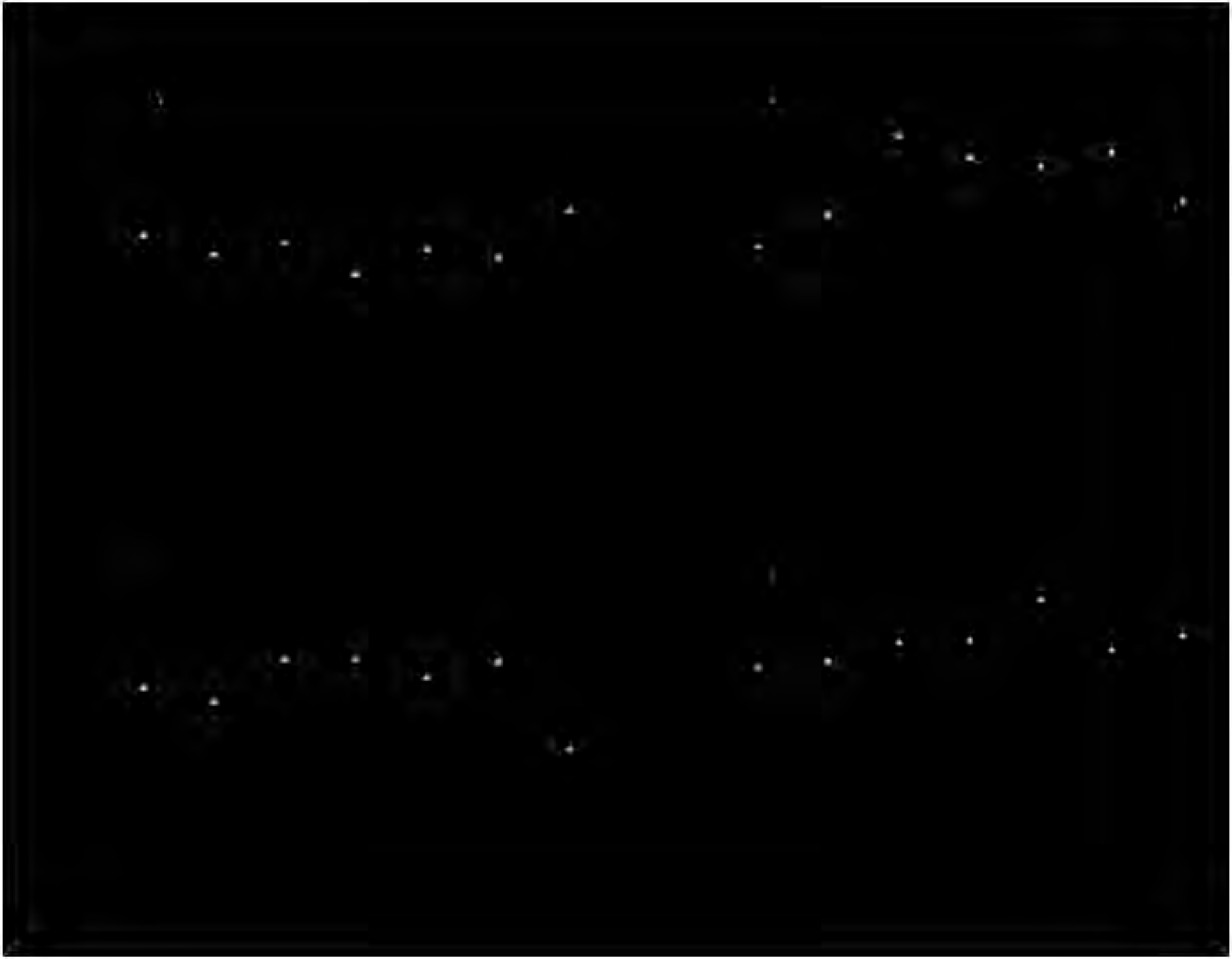

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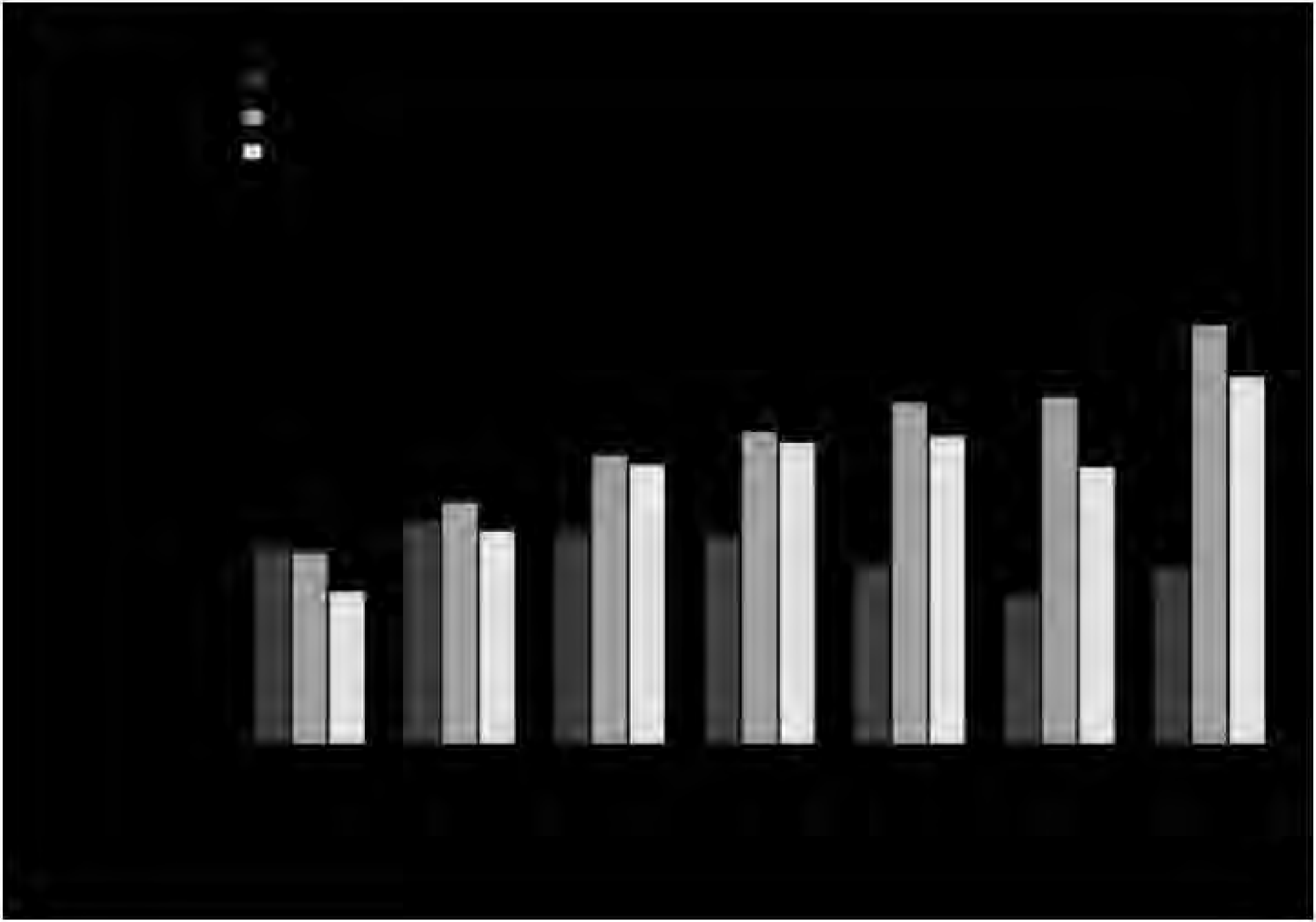

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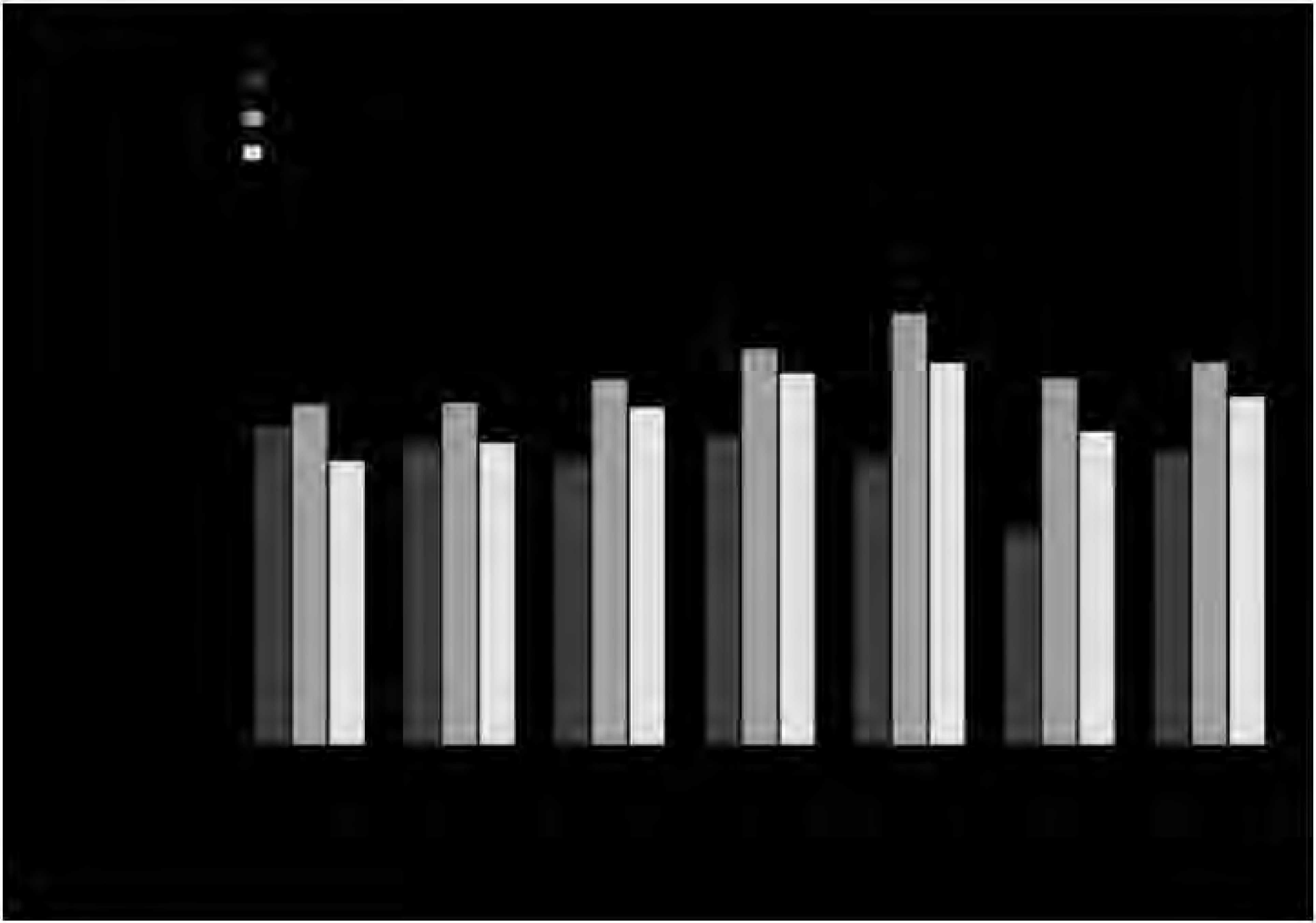

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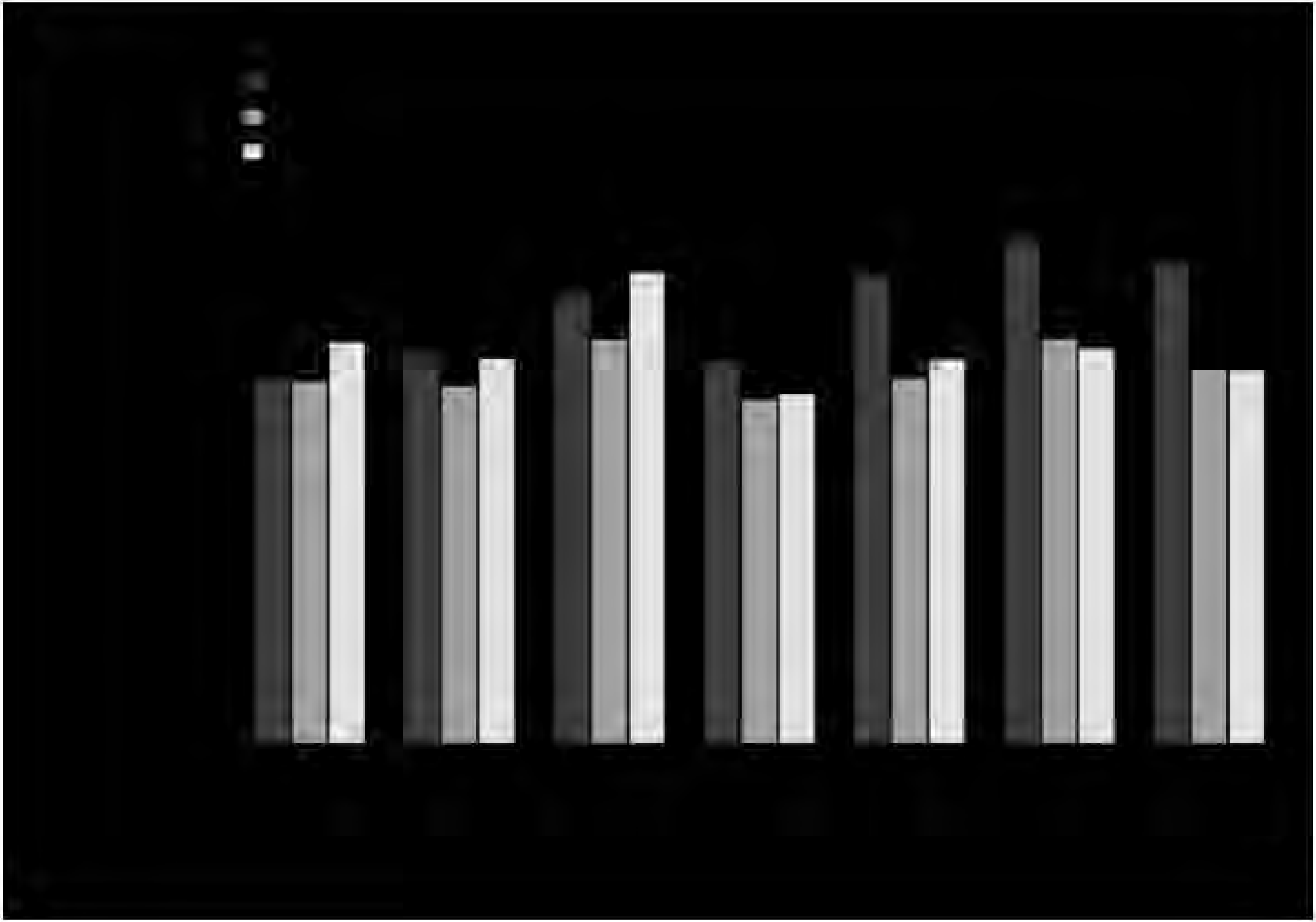

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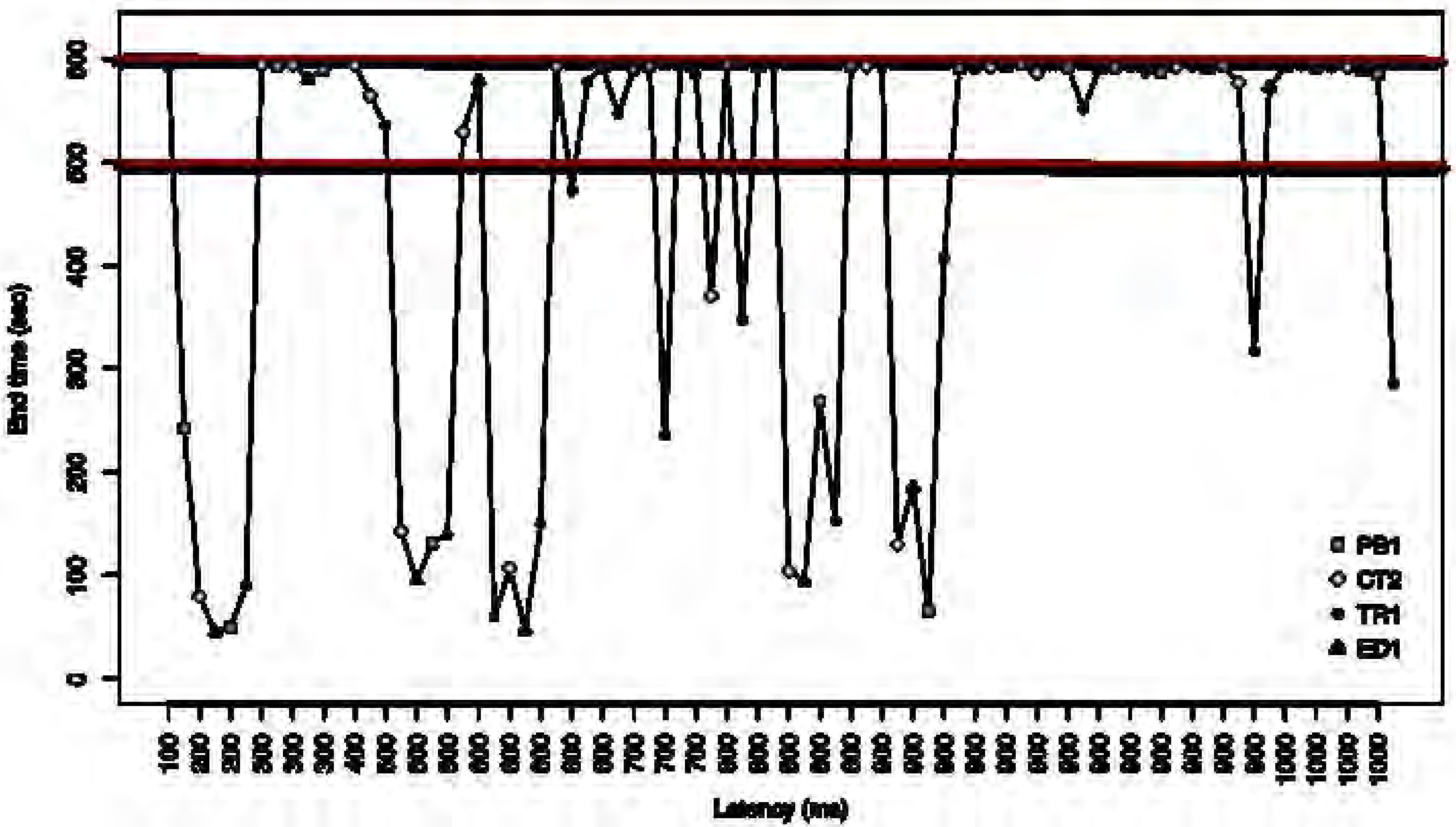

Comparison of the Usability of Robotic Surgery Simulators

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INTRODUCTION

Robotic surgery has introduced a new dimension into the surgical field. With the introduction of robotic technology between patient and surgeon, a need to master new skills has emerged. Medicine has come to the conclusion that the Halstedian training model (See one, do one, teach one) is no longer sufficient for teaching complex skills, especially robotic surgical skills (Cameron, 1997). A number of simulators have been developed to support training and skill assessment in robotic surgery. The currently available dedicated robotic simulators include: the da Vinci Skills Simulator (dVSS) by Intuitive Surgical Inc., also known as the "Backpack Simulator"; the dV-Trainer from Mimic Technologies Inc.; and the RoSS by Simulated Surgical Sciences LLC (Figure 1). The purpose of these simulators is to train surgeons prior to using the actual system and to allow them to acquire the necessary robotic skills to perform a safe surgery. All of these da Vinci simulators utilize a visual scene that is presented in a computer generated 3D environment providing challenging tests for practicing dexterity and machine operations. Originally, the simulated exercises trained basic robotic skills; however with advances in technology, surgeons can now train for specific procedures (e.g. nephrectomy and hysterectomy).

Figure 1. Simulators of the da Vinci robotic surgical system

Our hospital research laboratory has purchased each of these three simulators for the purpose of studying their effectiveness and applying them to the education of robotic surgeons, specifically for the Department of Defense (DoD). The DoD is interested in the effectiveness of the simulators to train military surgeons prior to and after returning home from deployments. This research is structured as three distinct stages.

From the first stage of this work, the authors summarized the objective characteristics of the three systems. This included descriptions of the exercises offered in each, metrics used to evaluate students, overview of the system administration functions, physical dimensions and configurations of the equipment, and comparisons of the costs of the devices and their support equipment (Smith & Truong, 2013). In the first simulator, the trainee sits at and operates the simulated environment using the actual da Vinci surgical console. The simulator is a custom computer appended to the surgical console through the actual surgical data port. While the simulator costs approximately

$100,000, the surgical console costs $500,000 incurring an investment of $600,000. Using this simulator, users can train using the actual hardware they would use during surgery; however, this requires the use of the surgical console that may be needed to conduct surgeries. Most hospitals may not have a dedicated training console, meaning that users would not have appropriate access to the simulator. The second is a standalone system that utilizes a graphic/gaming computer, connected to a custom desktop viewing and control device that replicates the hardware of the da Vinci surgeon's console. This system shares similar software with the dVSS, but does not require the use of any actual da Vinci hardware. The cost of this simulator is approximately $100,000. The third is composed of a completely customized replica of the da Vinci surgeon's console. Internally the simulator contains a graphic computer, a 3D monitor, and commercial Omni Phantom haptic controllers. This simulator uses unique software and is a little more than $100,000 (Smith &Truong, 2013).

This paper reports on the second stage of this research, in which the validity and usability of the simulators is examined. The third stage will be a measure of learning effectiveness using the systems.

Validity in Surgical Simulation

The validity of medical and surgical simulators is usually measured by the categories defined by McDougal (2007). This paper defines the most commonly recognized forms of validation as: *face, content, construct, concurrent, and predictive validity*. *Face validity* is typically assessed informally by users and is used to determine whether the simulator is an accurate representation of the actual system (i.e. the realism of the simulator). *Content validity* is the measure of the appropriateness of the system as a teaching modality. Experts who are knowledgeable about the device typically assess this via a formal evaluation. *Construct validity* is the ability of a simulator to differentiate between the performances of experienced users and those who are novices. *Concurrent validity* is the extent to which the simulator correlates with the "gold standard" and *predictive validity* is the extent to which the simulator can predict a user's future performance. Collectively, concurrent and predictive validity are known as criterion validity and are used as measures of the simulator's ability to correlate trainee performance with their real life performance. Face and content validity are most effective in evaluating the ability of a simulator to train a surgeon; however construct, concurrent, and predictive validity are most useful for evaluating the effectiveness of a simulator to assess a trainee.

The validity of all three simulators has been tested and reported separately for the da Vinci skill simulator (Hung, Zehnder, Patil, 2011; Kelly, Margules, Kundavaram, 2012; Liss, Abdelshehid, Quach, 2012), the dV-Trainer (Kenney, Wszolek, Gould, Libertino, Moinzadeh, 2009; Sethi, Peine, Mohammadi, 2009; Lee, Mucksavage, Kerbl, 2012) and the RoSS (Seixas-Mikelus, Kesavadas, Srimathveeravalli, 2010; Stegemann et al., 2013; Colaco, Balica, Su, 2012; Raza et al., 2013). To our knowledge only one publication has compared features of two of the simulators, but no comparative studies have been performed with all three of the systems (Liss MA, Abdelshehid C, Quach S., 2012). Thus, the current study aimed to compare all three commercially available da Vinci simulators and detail the findings for face, content, and construct validity for the three systems.

METHODS

Recruitment

Participants in this study included medical students, residents, fellows, and attending physicians. Participants were recruited from the University of Central Florida Medical School, courses held at the Nicholson Center, and two medical robotic conferences (World Robotics Gynecology Congress and Society of Robotic Surgeons Scientific Meeting). Subjects were excluded from participating if they indicated that they had participated in a formal robotic simulation-training course.

Each participant was categorized into one of three groups (i.e. Expert, Intermediate, or Novice) according to the self-reported number of robotic cases (i.e. procedures) he or she had performed. Individuals performing 0-19 robotic cases in which they had 50% or greater console time were categorized as Novices, individuals with 20-99 robotic cases were considered to be Intermediates, and individuals with 100 or more cases were considered to be Experts.

Materials

After being categorized into an experience level, each participant was assigned a specific order in which they used each of the simulators (Figure 2). This order system was used to identify and potentially eliminate any bias that may exist by using a specific system first. All participants completed one exercise on each of the simulators. The tasks chosen were Peg Board 1 in both the dV-Trainer and the dVSS and Ball Placement 1 in the RoSS. The same task was used for both the dV-Trainer and the dVSS because these systems share similar software and exercises. The RoSS software contains unique exercises and Ball Placement 1 is designed to teach the same skills as Peg Board 1.

Participant	Simulator Order
01	CBA
02	BAC
03	ACB
04	CBA
05	BAC
06	ACB
07	CBA
08	BAC
09	ACB

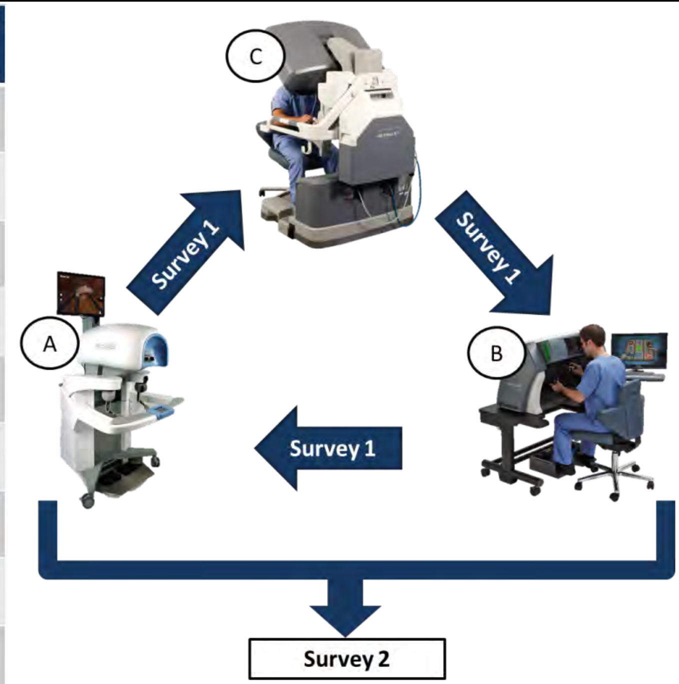

Figure 2. Rotating order of use by subjects, with survey order.

After each exercise on each simulator, participants completed a post questionnaire (Survey 1), which asked for feedback regarding their experience on that specific simulator. After using all three systems, subjects completed a second post questionnaire (Survey 2), which asked them to compare all three systems to each other. The participant's performance metrics were also collected from each of the simulators.

RESULTS

Demographics

Subjects were categorized as Novice (n=37), Intermediate (n=31), or Expert (n=37). Sixty-two percent of subjects were men and 38% were women with an average age of 43. On average, participants had 15 years in practice and 3 years of robotic experience. Seventy-six percent were attending physicians and 73% of participants were currently or had received robotic training, while 41% provided that they train residents and fellows. There were differences in the average age and number of years in practice of participants based on the classification of expert, intermediate or novice (number of robotic procedures). These are to be expected, since higher ages are required to achieve higher number of years of practice and larger numbers of robotic procedures.

Validation

The types of validity evaluated in this experiment were face, content, and construct. To analyze the systems for face validity and content validity, questions from Survey 1 were used. The questions were evaluated on a five point Likert scale (Strongly Disagree, Disagree, Neither Agree or Disagree, Agree, and Strongly Agree). Face validity was analyzed by expert and intermediate feedback as recommended by Van Nortwick et al. (2010) because these are the users most familiar with the robotic system; however, only expert feedback was used for content validity because they have the best ability to judge the appropriateness of the system as a training tool. For construct validity, performance metrics such as Overall Score, Time to Complete, Number of Errors, and Economy of Motion were analyzed (Table 1).

Table 1. Questions and data used for different levels of validity.

Type of Validity	Evaluation	Type of Participant	Question/Metric
Face Validity	Survey 1	Expert and Intermediate	Q1: The hand controllers on this simulator are effective for working in the simulated environment (Likert).
			Q4: The device is a sufficiently accurate representation of the real robotic system (Likert).
Content Validity	Survey 1	Expert	Q2: The 3D graphical exercises in the simulator are effective for teaching robotic skills (Likert).
			Q5: The scoring system effectively communicates my performance on the exercise (Likert).
			Q6: The scoring system effectively guides me to improve performance on the simulator (Likert).
Construct Validity	Simulator	Experts and Novices	Overall Score (points)
			Number of Errors (count)
			Time to Complete (seconds)
			Economy of Motion (centimeters)

Face Validity

The responses of Intermediate and Expert participants (n=68) were used to determine face validity (Table 2). A Chi-square test of independence was used to evaluate the distribution of scores for a specific simulator in relation to the order of the system's presentation to the subject. This analysis indicated that there was no difference in participants' answers according to the order in which the systems were presented; and established that no bias was present due to the presentation order ($p>0.05$). These questions asked participants to evaluate whether the hand controllers on the simulator were effective for working in the simulated environment (Question 1) and if the device is a sufficiently accurate representation of the real robotic system (Question 4). For both questions, the RoSS had the lowest average score, dV-Trainer had the second highest score, and the dVSS had the highest score of the three. A repeated measures ANOVA verified that the systems were scored differently for both questions ($p<0.001$).

Table 2. Average scores from a 5-point Likert scale on face validity.

	DVSS	dV-Trainer	RoSS
Q1: The hand controllers on this simulator are effective for working in the simulated environment.	4.80	3.62	2.17
Q4: The device is a sufficiently accurate representation of the real robotic system.	4.65	3.45	1.82

Content Validity

Expert (n=34) responses were used to determine whether the simulators were appropriate teaching modalities (Table 3). As seen in Table 3, 100% of participants either agreed or strongly agreed that the 3D graphical exercises in the dVSS were effective for teaching robotic skills while 59% disagreed or strongly disagreed that the RoSS' capabilities were effective. When asked if the scoring system effectively communicated their performance, 88% of dVSS users agreed or strongly agreed, while 79% of dV-Trainer users agreed or strongly agreed. Similarly, 91% and

82% of participants agreed or strongly agreed that the dVSS and dV-Trainer, respectively, effectively guided them to improve their performance, while only 36% felt the RoSS provided the same guidance.

Table 3. Scores on a 5 point Likert scale for content validity questions.

Likert Score	Strong Dis	Disagree	Neither	Agree	Strong Agree
Q2: *The 3D graphical exercises in the simulator are effective for teaching robotic skills.*					
DVSS	0%	0%	0%	35.3%	64.7%
dV-Trainer	2.9%	5.9%	11.8%	50.0%	29.4%
RoSS	20.6%	38.2%	17.6%	17.6%	5.9%
Q5: *The scoring system effectively communicates my performance on the exercise.*					
DVSS	2.9%	5.9%	2.9%	38.2%	50.0%
dV-Trainer	2.9%	2.9%	14.7%	55.9%	23.5%
RoSS	17.6%	20.6%	26.5%	29.4%	5.9%
Q6: *The scoring system effectively guides me to improve performance on the simulator.*					
DVSS	0%	0%	8.8%	61.8%	29.4%
dV-Trainer	2.9%	2.9%	11.8%	61.8%	20.6%
RoSS	18.2%	18.2%	27.3%	33.3%	3.0%

Construct Validity

The overall score, number of errors, time to complete, and economy of motion scores collected by the simulators for Experts (n=37) and Novices (n=37) were used to compare construct validity (Table 4). Overall score is a metric synthesized by multiple metrics and is specific to the individual simulator. Intermediate subjects were not included in the construct validity analysis because it was only necessary to look if the simulator could distinguish specifically between novice and expert users.

For the RoSS, the analysis has 23 missing data points because the system does not report scores when a user exceeds a maximum exercise time or chooses to terminate the exercise before completion. This resulted in a sample of 30 experts and 21 novices on that system. A Mann-Whitney U test showed that the distributions of time (p=0.221), number of errors (p=0.644), and economy of motion (p=0.566) were not statistically different for the experts compared to the novice group. The overall score metric is not automatically exported by the simulator and therefore was not analyzed for this sytem.

The dV-Trainer analysis of experts (n=37) and novices (n=37) had three missing values for economy of motion and completion time and five for the overall score metric, thus the analysis contained varying number of subjects. A Mann-Whitney U test showed that the distribution of the overall scores was not significantly different for the expert compared to the novice group (p=0.061). These tests did confirm statistical differences for economy of motion (p<0.001) and time to complete (p<0.001) for this system with a lower economy of motion value and shorter completion time for expert users compared to novices.

The dVSS analysis included all novice (n=37) and expert (n=37) participants. Using a Mann-Whitney U test, time to complete (p<0.001) and overall score (p=0.006) were significantly different for the expert compared to the novice group. The expert group had a higher score and a shorter completion time compared to the novice group. However, economy of motion did not show a statistical difference with this analysis (p=0.216).

Table 4. Mann-Whitney U test level of significance on construct validity measures

	DVSS	dV-Trainer	RoSS
Time to Complete	p<0.001	p<0.001	p=0.221
Overall Score	p<0.01	p=0.061	n/a
Economy of Motion	p=0.216	p<0.001	p=0.566
Number of Errors	n/a	n/a	p=0.644

The construct validity of the simulators was more specifically analyzed in terms of the self-reported number of cases of all participants (n=105) using a non-parametric correlation coefficient (Spearman's). For the RoSS, 30 participants were excluded from the analysis. For the participants that were included in the analysis (n=75), there was not a significant correlation between time to complete (p=0.181), number of errors (p=0.563), or economy of motion (p=0.390) with the total number of robotic cases performed.

For the dV-Trainer, four participants were excluded from the entire analysis and two participants were excluded from the overall score (Overall Score n=99; Economy of Motion and Time to Complete n=101). When analyzing the number of participants' robotic cases, there was a statistically significant correlation between overall score (p=0.03), economy of motion (p<0.01), and time to complete (p<0.01). The correlation value was negative for economy of motion and time to complete, showing that with a greater number of robotic cases, the time taken and distance moved decreased. The correlation was positive for overall score indicating that the participants' score increased with the number of robotic cases performed.

For the dVSS, two participants were excluded from the analysis (n=103). When analyzing the metrics in terms of the total number of robotic cases performed, there was a statistically significant difference between overall score (p =0.01) and time to complete (p <0.01). The correlation value was negative for time and positive for overall score, signifying that with more robotic cases the time taken decreased and the score increased. There was not a statistically significant correlation between economy of motion and the total number of robotic cases performed (p=0.105).

Table 5. Correlation between level of experience and simulator scores

	DVSS	dV-Trainer	RoSS
Overall Score	p=0.001	p=0.031	n/a
Time to Complete	p<0.001	p<0.001	p=0.181
Economy of Motion	p=0.105	p<0.001	p=0.390
Number of Errors	n/a	n/a	p=0.563

Usability (Preference)

The questions from the Survey 2 were used to understand the preference of the subjects when using the simulators. All subjects were included in this analysis except for two participants who were dropped from the analysis because they did not complete the questionnaire. The participant's responses to the usability questions can be seen in Figure 3:

- *If you are (were) a program director, which simulator would you choose for your trainees;*
- *In which simulator were you physically more comfortable;*
- *Which simulator had the best hand controls;*
- *Which simulator had the best foot controls;*
- *Which simulator had the best 3D vision;*
- *Were you feeling stressed or annoyed by any of the simulators?*

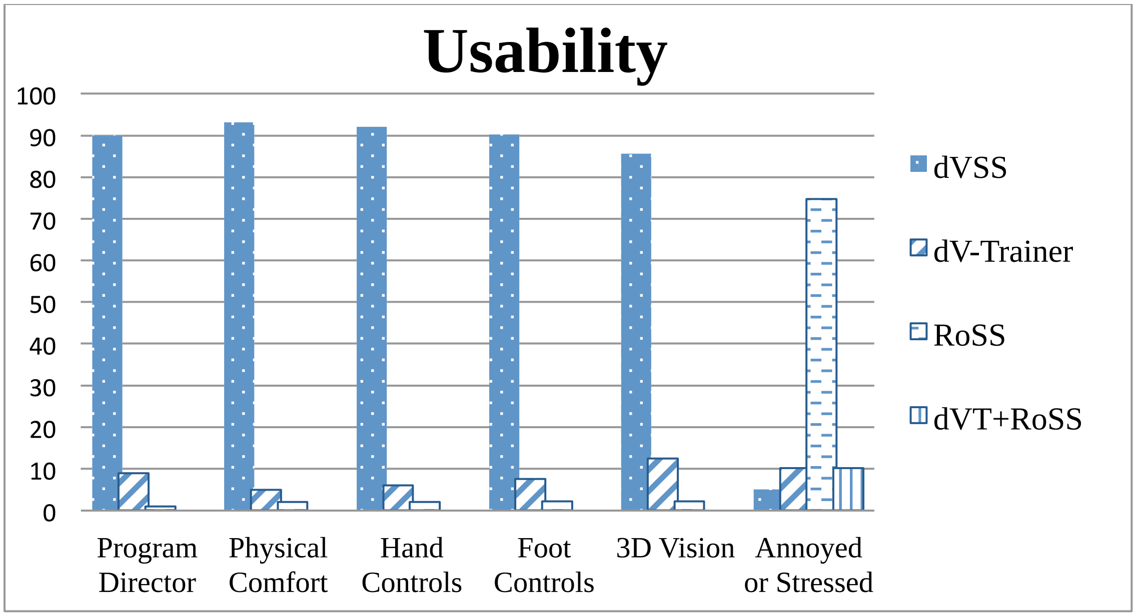

Figure 3. Description of usability responses

Overall, most participants preferred the dVSS and indicated that they would choose this device as a training system if they were a program director. Participants not only felt most comfortable in the dVSS, but also felt that the system had the best control and vision equipment. The least preferred system was the RoSS which most participants also agreed made them feel stressed or annoyed. Ten percent of participants also responded that they felt stressed or annoyed by both the dV-Trainer (dVT) and the RoSS.

Cost

All participants were also asked to provide feedback on their simulator preference in terms of the cost of the system. The responses were analyzed in terms of the frequency of the responses given. Most participants felt that the mimic dV-Trainer was worth the investment; while most felt that the RoSS was not worth the money. When asked about the dVSS, only 56% of participants agreed that it was worth the investment. Figure 4 provides a full description of the responses.

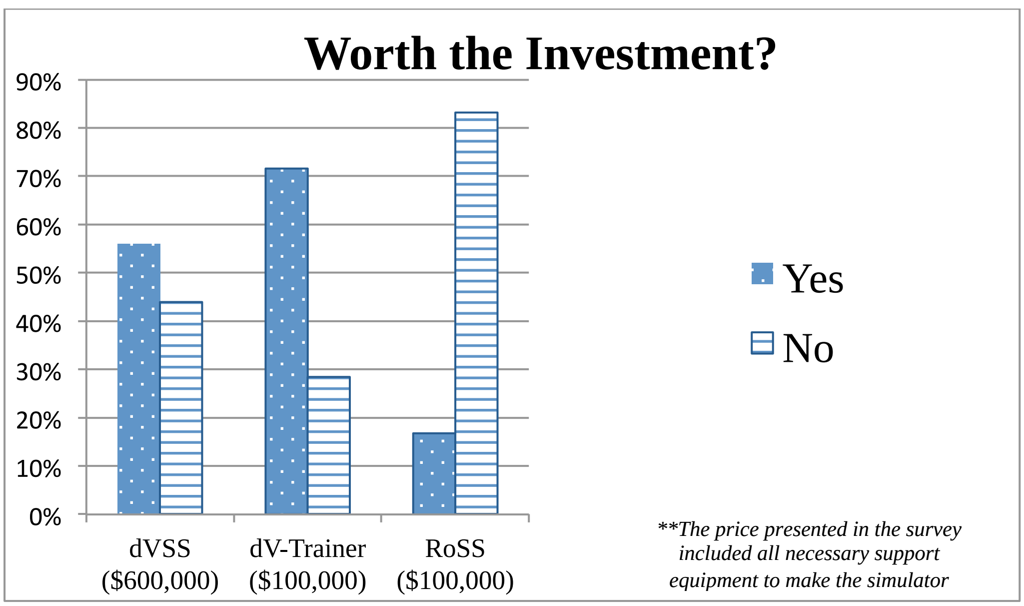

Figure 4. Description of cost preferences

DISCUSSION

The aim of this study was to conduct a comparison of the three commercially available simulators used to train surgeons on the daVinci robotic system. The study was performed for the US Army to assist them in making a purchasing and deployment decision regarding robotic simulators. Their interest is in re-training robotic surgeons who have been deployed to combat zones, where they have served as trauma surgeons for many months. Prior to resuming their robotic specialties, these surgeons need a program to both refresh and re-validate their robotic skills. This study provided information about the face, content, and construct validity as well as usability of the systems. The simulators were perceived to be different in their representation of the real robotic system. The dVSS was most preferred in terms of ergonomics and usability; however, most participants did not feel that this system was worth a $600,000 investment. In terms of cost, most participants agreed that the dV-Trainer had the best cost-effectiveness. The RoSS was the least preferred system for comfort and other usability aspects (i.e., hand controls, foot controls, and 3D interface), with most participants feeling stressed or annoyed when using the system. This study was unable to validate the face, content, or construct validity for this system.

The dVSS leverages the actual hardware used to perform robotic surgeries for use in the simulated environment, which allows for a more realistic experience, but decrease its availability and creates a higher cost for training than other robotic simulators. Economy of motion was not able to differentiate novices from experts in the dVSS, which could be attributed to the ease of use of the controllers allowing novices to move the controls as efficiently as experts. The generous workspace of the dVSS could also have an impact on the lack of difference. In contrast to the dVSS, the dV-Trainer is a standalone simulator and does not require the support of the daVinci hardware to operate. This allows for better accessibility and requires less of an investment for training. The overall score aspect of construct validity may not have shown a difference between novices and experts because of the way that the scoring is developed. The scoring system is constructed with a “ceiling” that prevents users from achieving a high overall score without attaining high scores across multiple metrics.

Currently, there is limited data available that confirms construct validity of the RoSS. Similarly to Raza (2013), this study was unable to confirm a difference between experts and novices in terms of time taken to complete the exercise. Time to complete, as well as economy of motion, is considered a highly relevant measurement of expertise levels for robotic surgeons (Perrenot, Perez, Tran, Jehl, Felblinger, Bresler, & Hubert, 2012). To our knowledge this three-part study is the first to compare all three available systems. This study involved the largest sample size and diversity of participants (i.e., experience levels, number of robotic cases, and subspecialty type) thus far in relevant publications. The lack of consistency in the available exercises and scoring systems across the three systems was a limitation to the study. Considerations for future research would be to use more complex exercises and increase the depth of the face and content validity evaluation.

Current research is focused on the effectiveness of the simulators and objectively measuring the transfer of training to the actual robotic system. All three simulators will be examined in this final stage of the experiment; however, the results of this three-part study will guide the choice of simulators used for future studies at Florida Hospital Nicholson Center and may also influence decisions at other laboratories. Also, this research may impact the purchasing decisions of customers for these devices.

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From Design to Conception: An Assessment Device for Robotic Surgeons

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ABSTRACT

The daVinci Surgical System offers surgeons improved capabilities for performing complex minimally invasive procedures; however, there is no standardized assessment of robotic surgeons and a need exists to ensure that a minimal standard of care is provided to all patients. The Department of Defense and governing surgical societies convened consensus conferences to develop a national initiative, resulting in a curriculum called the Fundamentals of Robotic Surgery (FRS). FRS is comprised of an online curriculum and a psychomotor skills dome.

This paper describes the production process used to create a psychomotor skills assessment device - the FRS Dome. The device was designed to measure the essential skills that are required of any robotic surgeon and to provide a basis upon which to grant or deny privileging with the robot. It was constructed to test seven tasks of manual dexterity: Docking, Ring Tower Transfer, Knot Tying, Suturing, 4th Arm Cutting, Puzzle Piece Dissection, and Energy Dissection.

The initial design of the device was created by a committee of experienced minimally invasive surgeons, with a background in testing protocols and materials. The design was rendered in computer animation, which kick-started a prototyping effort with physical materials. These included platinum cure silicone approximating human tissue and a 3D polyjet printer for the structural framework. Usability testing was conducted and iterative modifications were made to improve ergonomics, standardization, and cost requirements. Final CAD diagrams and specifications were created and distributed to medical and simulation companies for both physical and digital manufacturing. This development process demonstrates the evolution of a simulation and a physical testing device based on international expert consensus. The specifications are open source, allowing competitive production and future iterations. The goal of this paper is to discuss how this device evolved from an idea to a manufactured product and a digital simulation.

ABOUT THE AUTHORS

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Manuela Perez, MD, is a practicing General Surgeon at the University Hospital of Nancy-France, where she also serves as an Assistant Professor in General Surgery and Anatomy. Dr. Perez has been practicing medicine for 14 years and graduated with her PhD in Robotic Surgery, with a thesis entitled "Telesurgery: From Training to Implementation." Currently, she is working as a Research Fellow at the Florida Hospital Nicholson Center and working under a grant from the Department of Defense researching various aspects of Telesurgery.

Mireille Truong, MD, is a Minimally Invasive Gynecology Fellow at Columbia University, where she serves as an assistant attending and clinical instructor of Obstetrics and Gynecology (OB/GYN). During her residency in OB/GYN at the University of Illinois at Chicago, she received a number of awards and honors, including Administrative Chief Resident, the American Association of Gynecologic Laparoscopists' Special Resident in Minimally Invasive Gynecology Award and Best Overall Excellence in Gynecologic Care Award. She has dedicated her time to education of medical students and physicians via an array of academic and teaching appointments, professional organization board positions, peer-reviewed publications and presentations at various national and international conferences. Her research interests include surgical education, robotic simulation and minimally invasive gynecologic surgery.

Khara Simpson, MD is a second year fellow in minimally invasive surgery at Columbia University, where she serves as an assistant attending and instructor of obstetrics and gynecology. She completed her medical school education at Howard University College of Medicine where she was inducted into the Alpha Omega Alpha honor medical society. Following, she completed her OB/GYN residency at Johns Hopkins University and served as administrative chief resident. She recently completed a one year research fellowship at the Florida Hospital Nicholson Center focusing on robotic surgery simulation. Her additional research interests include resident education and simulation training, and best practices to promote cost effective care.

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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. 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.

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INTRODUCTION AND BACKGROUND

Robotic surgery has been established as an innovative approach in surgery due to a telemanipulator device, which introduced a new dimension into surgical tools. This device allows surgeons to manipulate robotic arms from a remote console to perform complex surgical procedures. Robotic surgical systems overcome laparoscopic limitations and facilitate the performance of minimally invasive surgery due to 3D vision, 7-degree-of-freedom instruments, tremor abolition, motion amplification, and stabilization of the camera (Patel et al., 2013; Hubens, Coveliers, Balliu, Ruppert, & Vaneerdeweg, 2003; Blavier, Gaudissart, Cadière, & Nyssen, 2007). The system also offers 10x magnification, wristed instruments, and a third working arm. Currently, the only system is Intuitive's da Vinci Surgical System (Figure 1).

Figure 1. da Vinci Surgical System

Robotic surgery has demonstrated safety and effectiveness for urologic, gynecologic, ENT, and complex general surgery procedures (Barbash, Friedman, Glied, & Steiner, 2014; Serati et al., 2014; Maan, Gibbins, Al-Jabri, & D'Souza, 2012; Luca et al., 2013; Zureikat et al., 2013). Exponential growth of minimally invasive procedures, particularly robotic-assisted procedures, raises the question of how to assess robotic surgical skills. This device also introduces a specific need for training and certification to ensure a minimal standard of care for all patients. Some institutions have attempted to develop and validate robotic training in regards to specific specialties (Chitwood et al., 2001; Geller, Schuler, & Boggess, 2011; Grover, Tan, Srivastava, Leung, & Tewari, 2010; Chowriappa et al., 2014; Jarc & Curet, 2014); however, the lack of a national standard has pushed surgical societies (e.g. the Society of American Gastrointestinal and Endoscopic Surgeons and Society of Robotic Surgery) to develop a unified approach and standard for robotic skills training (Zorn et al., 2009).

To develop a comprehensive model for robotic surgery, the Department of Defense, Veterans Administration, and fourteen surgical specialty societies convened multiple consensus conferences to create the Fundamentals of Robotic Surgery (FRS) curriculum. A similar education and training initiative was implemented for use in laparoscopic surgery, which resulted in the Fundamentals of Laparoscopic Surgery (FLS). FRS Conference participants included more than 80 subject matter experts (SMEs), consisting of surgeons, psychologists, engineers, simulation experts, and medical educators (Smith, Patel, Chauhan, & Satava, 2013).

The committee's vision of FRS was driven by two main goals: to ensure a perfect understanding of the basics of robotic surgery and to develop a psychomotor skills program that focused on basic robotic tasks. The intended users for this program are novice robotic surgeons, who could be residents or fellows and attending surgeons

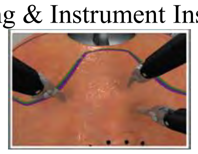
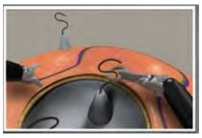
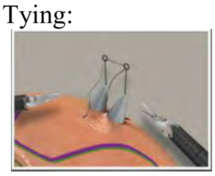
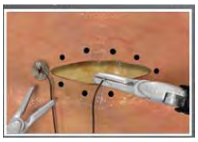
who have never used the robotic system. The committee began by outlining outcomes measures and metrics, which touched on the essential cognitive, psychomotor, and team training skills. This resulted in a prioritized matrix of 25 robotic surgery concepts, which is the core material used in the design and development of the FRS Curriculum (Smith, Patel, Satava R, 2013). Two assessment tools were created: an online curriculum for knowledge and team training skills and a device for psychomotor skill training and evaluation (Levy, n.d.).
This paper discusses the process for designing and creating the physical device, known as the FRS dome. The purpose is to share the evolution of an idea to a usable device. The dome was conceived by experts who identified a clear need for robotic education and collectively developed a solution to fill the gap. The medical field is a constant progression of new concepts, devices, and technology. This paper also outlines the framework for which others can develop and introduce new concepts in medicine and other domains.

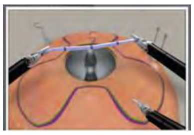
BRAINSTORMING AND CONCEPT DEVELOPMENT

Exercise Development

Of the 25 FRS concepts, 16 are directly linked with psychomotor skills. The FRS committee members then identified seven exercises that incorporated all 16 skills. These exercices include docking and instrument insertion, tower transfer, knot tying, railroad track, 4th arm cutting, puzzle piece dissection, and vessel energy dissection (Table 1). *Docking and instrument insertion* is an essential and unique robotic skill to begin a procedure. Failure at this stage of the procedure can compromise the surgery. Ring *Tower transfer* is a non-surgical exercise that introduces the utilization of endowrist manipulation and the 7 degrees of freedom to surgeons. *Knot tying* and *railroad track* are the base of a suturing exercise. The technology introduced in the wristed instruments facilitates the performance of these tasks. *4th arm cutting* is another task specific to robotics, which tests surgeon's autonomy. The 4th arm allows surgeons to manage three instruments by using a foot pedal to switch between working arms. *Puzzle piece* and *vessel energy dissection* are critical tasks which incorporate complex articulation of instruments and application of energy (i.e. cauterization and cutting).

Table 1: Description of the basic psychomotor skills attached to the seven FRS tasks.

Exercises	Skills
Task1: Docking & Instrument Insertion: 	- Docking - Instrument insertion - Eye-hand coordination - Operative field of view
Task 2: Ring Tower Transfer: 	- Eye-hand coordination - Camera navigation - Clutching - Wrist articulation - A-traumatic handling
Task 3: Knot Tying: 	- Knot tying - Suture handling - Eye-hand coordination - Wrist articulation
Task 4: Railroad Track: 	- Needle handling & manipulation - Wrist articulation - A-traumatic handling - Eye-hand coordination
Task 5: 4th Arm Cutting:	- Multiple arm control & switch - Cutting - A-traumatic handling - Eye-hand coordination

	
Task 6: Puzzle Piece Dissection: 	- Sharp and blunt dissection - Cutting - A-traumatic handling - Eye-hand coordination - Wrist articulation
Task 7: Vessel Energy Dissection: 	- Energy sources use - Sharp dissection - Cutting - Multiple arm control - A-traumatic handling - Eye-hand coordination

Device Development

The FRS committee envisioned all of the exercises contained on the outer surface of a single device. This would allow for the exercises to be administered quickly and easily, incur less cost, and ensure uncomplicated storage and transportation. The semi-spherical form (i.e. the dome), was quickly decided on as a shape which would integrate with the current robotic system. They depicted their ideas through simple drawings and crude models made from materials found on hand. During initial design planning, conference participants experimented with a variety of arrangements of the exercises on the dome.

A final sketch was developed and delivered to a 3D digital artist to create static pictures of the device, along with an animation of the performance of each exercise. The CGI provided the first formal images of the dome, which gave life to the device and proved feasibility. The realistic animations showed the exercises being performed and gave committee members a visual concept of how the device would function (Figure 2).

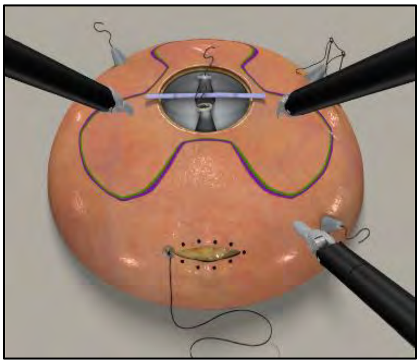


Figure 2. The initial 3D graphic FRS dome design

PROTOTYPING

The prototyping process began using the ideas developed in the design meeting and the CGI. This process would prove to be fundamental in confirming the design expectations. It was essential to determine if a single device could physically house all of the exercises effectively, if the planned architecture was compatible with the robotic system, and if the outcomes of the exercises could be measurable and reproducible.

Low-fidelity Prototypes

Low-fidelity prototypes (LFPs) were created using simple and inexpensive materials. None of the materials used in the LFPs were intended for inclusion in a final product. These materials were chosen because they were readily available, inexpensive, and easy to manipulate to test fit and function. These materials allowed rapid trial and error testing of the technical aspects, clarifying requirements, and proving usability. The testing of the LFPs was performed using the da Vinci Surgical System and was video recorded. These recordings were sent to FRS committee members to provide their feedback. Each LFP resulted in multiple improvements to the designs, which were tested on subsequent prototype versions.

The base model of the LFPs was created using half of an 8” Styrofoam sphere as the support structure, yellow felt material as the fat layer, a latex swimming cap for the skin layer, and straws for the embedded vessels. The base of the towers was constructed using synthetic foam blocks carved into a cone shape (Figure 3). The exercise patterns were drawn onto the surface using a permanent marker.

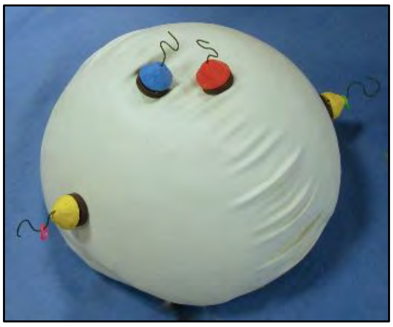


Figure 3. Base of Low Fidelity Prototypes

The LFPs evolved over six iterations, all of which introduced design improvements (Figure 4). At the earliest phase in LFP testing, it was quickly realized that the dome size was too large to fit under the robot arms appropriately. So, the dome size was decreased from 8” to 7”. Another modification made early in the LFP development was to change the 4th arm cutting band from a rigid tube to an elastic band. This allowed for the user to adequately stretch the band prior to each cut.

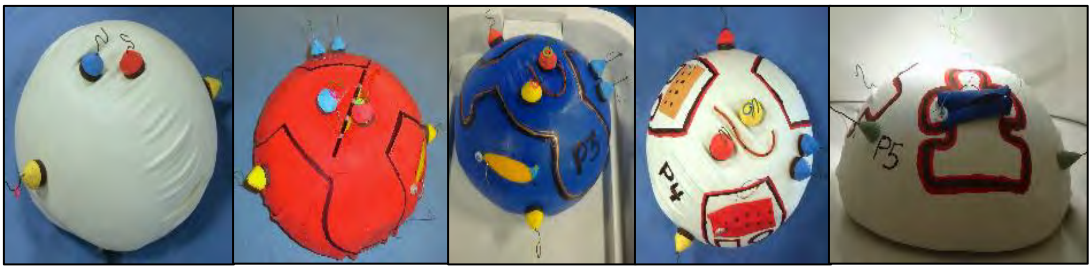


Figure 4. Iterations of LFPs

The suturing and dissection exercises involved the most modifications during the LFP stages. The original cloverleaf shaped, used for the dissection exercise, was found to be too large and did not allow for the surgeons to access the section of the shape that was located on the backside of the dome. The size of the pattern was reduced; however, this did not mitigate the accessibility issue. The team experimented with other options, such as splitting the clover leaf into three sections and adding smaller shapes to the center of the cutting area. This design was not practical because once the smaller shapes were cut, the latex receded and inhibited surgeons from cutting the surrounding shape.

Eventually, the dissection shape evolved to a puzzle piece which incorporated all of the prerequisites for the dissection exercise (i.e. an accessible shape and a complex design). By using this compact pattern it became clear that all exercises could be grouped into an area covering only one third of the surface of the dome. This opened the opportunity to replicate the cluster of exercises three times on the surface, reducing the materials and costs for repeatedly practicing with the device. Another obstacle was to build the suturing exercise with the adequate materials and placements, to ensure a realistic feeling of suturing. Originally, the incision was made into the latex swim cap, however the latex would tear away and recede after the incision was cut in this model. Two versions of the suture module were experimented with: an embedded silicone and an external latex model. Eventually an embedded silicone model was chosen as the most realistic and practical for the exercise. Ultimately the basic structural changes found in the low-fidelity prototyping were:

- The dome base needed to be reduced to 7”
- The dome base needed to be substantial in weight to keep from moving under the force of the robot
- A smaller, yet equally complex dissection shape was necessary
- The exercises set could be grouped to allow it to be repeated on the surface of a single dome

- The magnets which held the towers to the dome needed to be of sufficient strength to hold through the layers of fat and skin

High-Fidelity Prototypes

The high-fidelity prototypes (HFPs) were made using higher quality, custom materials. These materials had the desired qualities of the final product and could be used as a basis for the large scale manufacturing process. The styrofoam base from the LFPs was replaced with a support structure that was printed using a 3D polyjet printer (Figure 5). A polyjet type 3D printer works similarly to an inkjet printer in that it distributes layers of polymer to build the desired design, which is cured by UV light. This type of printer was chosen because of the versatility allowed by printing multiple materials at once. Also, the jet lays $16\mu m$ layers of liquid polymer which gives printed parts a finer resolution. Using this printer, a dome shell with a lid was created. The shell and lid had divots covering the surface which allowed for magnets to be moved to many different placements on the dome during design experiments. A small jig was also created using the 3D printer. Prior to the creation of the jig, the wires were made by hand, but the jig enables the standardized creation of the S-shaped and I-shaped tower wires. The price to print these items was approximately $1,000.

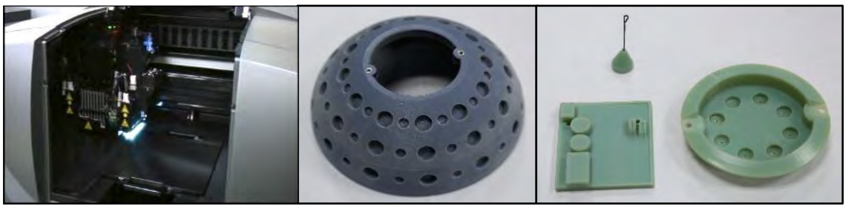


Figure 5. 3D printer with 3D printed dome, cap, towers, and jig

The synthetic tissue layers were created using Smooth-On platinum cure silicone products. These are two part silicones that can be colored and mixed with other additives to achieve the desired product attributes, such as durometer. The silicone used for the “fat” layer gave a gel-like and slightly sticky texture (Eco-flex Gel), while the “skin” silicone had a more firm and non-sticky quality (Ecoflex-0030). These silicones were chosen because they gave the closest resemblance to actual tissue properties. The fat silicone was poured directly onto the dome to the desired thickness. A clay mold was then made to replicate that thickness, which was used to form the skin layer (Figure 6). Embedded in the skin was a layer of polyester mesh, which helped to provide structure and stability of the skin. Small vessels were also created by quickly curing the silicone to a small tube. Using these materials we were able to create a set of synthetic tissues for less than $20.

Figure 6. Pouring of silicones and first HFP

The puzzle piece shape and the other markers were drawn on the skin surface using a permanent marker. The exercises were drawn on in different locations, sizes, and orientations for the first HFP. After testing the HFP on the robotic system, we finalized the size and orientation of the exercises on this new dome. This is important because as learned in the LFP stage, the exercises needed to be placed strategically to compensate for the range of movement of the robotic arms. Despite having 7 degree-of-freedom instruments, there are still limitations to the amplitude of the movement of the robotic arms. We also determined that three trials of each exercise could fit on one dome, so each work station (i.e. group of exercises) repeated at 120 degree increments on the dome. Eventually, we determined that after dissecting the three vessels significant space was available for more dissection in the fat layer. So, we added three additional vessels located to the right of the original vessels and out of range of potential damage from other exercises (Figure 7). By doing so, the fat could be used six times and the skin used three times, which incurs less of a manufacturing cost and ultimately training costs.

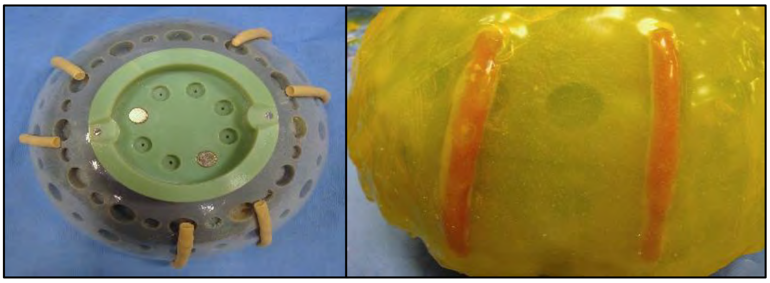


Figure 7. Vessel placement on dome and in fat

Over many iterative models, we improved our techniques and experimented with different materials and additives to achieve the desired qualities. For example we began adding a Thixotropic additive to thicken the mixture and allow us to cast the material onto a curved surface. We also tested different inks and techniques of printing the shapes and markers on the skin. However, most inks and paints could not be used on silicone, so we decided to use a silicone based paint product which cured the design to the silicone surface.

We 3D printed miniature dome models (2” in diameter) to begin testing molding materials. We created silicone molds and used a urethane plastic to cast the model. By doing this we realized that the original 3D printed material was porous and caused bubbling in the molding, leading to surface bubbles on casted models. So, a new full sized dome was printed in a smoother and less porous material which would be better for manufacturing. The new dome shell and cap was designed with divots only at the locations necessary for holding a tower (Figure 8).

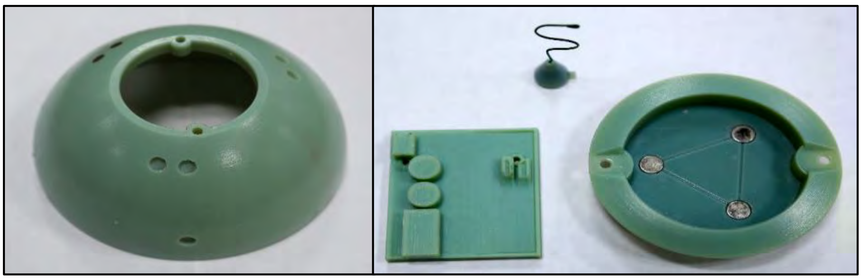
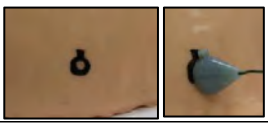
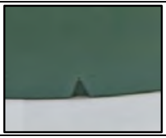


Figure 8. Final 3D printed dome shell

Since this device will be used for training and education, a high level of standardization is necessary. For this we added small markers which ensure that the pieces are assembled correctly and in a standardized manner for all participants. Table 3 details the standardization pieces.

Table 3. Description of the Standardization Markers

Standardization Markers	
Tower tongues 	Used to orient the towers in the correct direction for each exercise.
Triangle in lid 	Used to show proper orientation of the towers that are placed in the cap. The towers are placed in the two locations directly in line with the puzzle piece and with the tower tongues on the corresponding line of the triangle. This ensures that the S-shaped towers face the correct direction for all users.
Tower orientation markers 	These markers are used to show the placement of the towers on the skin and the orientation of the tower. The towers are placed on the marker with the tongue aligned with the tongue mark. This ensures that all towers face the correct way.
Triangles on dome shell	These small markers are located at 120 degree increments on the lower edge of the dome. They signify where the embedded vessels should be located when the tissue layers are placed on the shell.

	
Triangles on fat 	There are two types of triangle markers on the fat: open and closed. The closed triangles indicate the location of the first use vessels. When the fat is placed on the dome, the closed triangle is aligned with the triangle marker on the dome shell. After all three vessels are used, the fat is rotated and the open triangles are aligned with the triangles on the dome. This ensures that the vessels are in the accurate location for the dissection exercises.
Triangles on skin 	The triangle markers on the skin are aligned with the triangles on the fat layer. These ensure that the puzzle piece lies directly over the vessel and that the tower markers align with the underlying magnets.
Cap placement notch 	The notch in the cap ensures that users place the cap in the correct orientation. Since the magnet divots are placed in the shape of a triangle, the cap has to be secured in a specific orientation for the magnet divots to align properly.

In the final HFP, the exercises existed as they would in the manufacturing phase. Final testing was performed in order to ensure that all specifications were correct and to build a specifications document, which was used to create final CGI and CAD files (Figure 9).

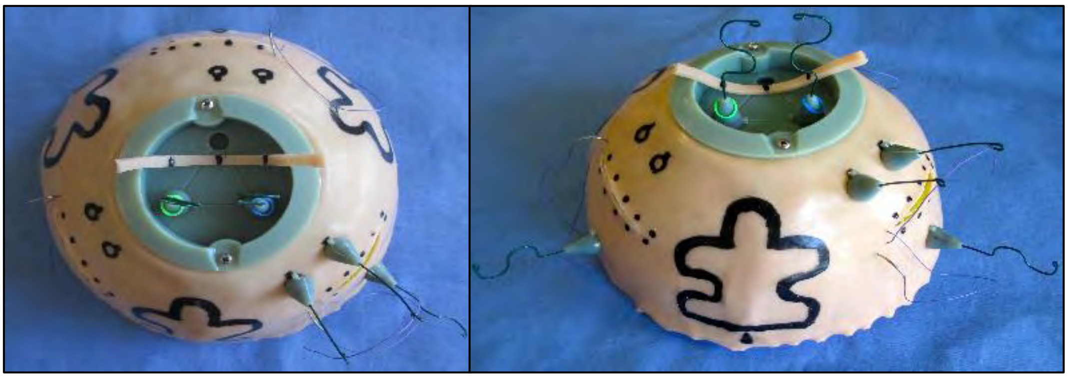


Figure 9. Final HFP

PRODUCTION

The final CGI, CAD, and specification document were sent to the manufacturing company and simulation companies to assist them in their development of physical and virtual domes (Figure 10).

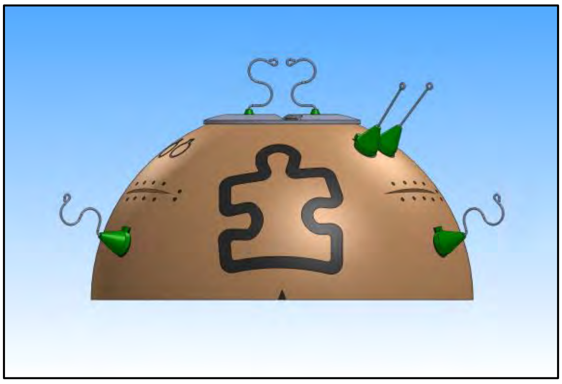


Figure 10. Final CGI

A local manufacturer, familiar with the materials used during prototype testing, used the dome and performed all of the exercises prior to beginning the process. This provided a first-hand experience of why certain material qualities were so important. The goals for this phase, in addition to mass production, were to maintain device integrity and minimize cost. Some of the materials used during prototyping were more expensive than what would be feasible for training centers. For example the $1,000 materials cost for the 3D printed dome was reduced to less than $25.

The simulation exercises of the FRS dome will be incorporated into two simulators: the da Vinci Skills Simulator (dVSS) and the Mimic dV-trainer. The dVSS is a simulation system which integrates with the actual console of the surgical system. This allows users to train using the exact hardware that they use when operating. The dV-trainer is a standalone system that uses custom hardware and software. To ensure that the simulated dome acted similarly to the actual dome, the research team evaluated the exercises in terms of qualities such as elasticity of materials and effects of excess force on the device. Maintaining the physical properties of the dome was paramount. Since the simulations will be unproctored, these features are important in designing the metrics.

CONCLUSION

Over the course of two years, we created an easily integrated device, using low cost but high-quality materials. This paper outlines the steps of the FRS dome from idea conception to the development of physical and virtual devices. The goal of this paper is to share the evolution and process for others interested in training and assessment devices. Since the FRS dome specifications are open-source, this also serves as an important resource for potential producers.

We have taken away several lessons from our experimentation that made our process a success including having a multidisciplinary team, soliciting frequent feedback, using easily adaptable designs, testing on small models, and using commercial materials during prototyping. Our multidisciplinary team of surgeons and engineers allowed for a diverse perspective during the construction of the device. The design changed many times and it was beneficial to start off using basic models that accommodated the varying designs. It was advantageous to work with actual manufacturing materials once we developed a functional prototype to better envision the final product and allow a smoother transition to the manufacturing phase. We recommend testing materials on small models, which will help cut time and costs. Finally if possible, work closely with the manufacturing teams at an early stage of development, particularly when working with virtual models. This will help to flesh out details and encourage collaborative development earlier in the process.

The next step of this work is to conduct formal validation testing of the curriculum including the device and related simulations via a pilot and national multi-site validation study. The FRS dome features basic robotic surgical skill exercises, which are applicable to most specialties. This basic device is scalable and will be the foundation for the future, more specialized FRxS devices (e.g., the Fundamentals of Robotic Gynecologic Surgery (FRGS) and the Fundamentals of Robotic Urologic Surgery (FRUS)).

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FEASIBILITY OF ROBOTIC TELESURGERY ACROSS A MULTI-CAMPUS METROPOLITAN HOSPITAL SYSTEM

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University of Central Florida College of Medicine; Orlando, FL

Learning Objectives:
At the completion of this presentation, participants should be better able to:

1) Understand the effect of latency on performance in robotic simulation
2) Understand the current technological limitations to telesurgery

Introduction and Objective:
Robot-assisted surgical technology has been used for remote telesurgery under unique controlled conditions. However, an objective scientific measurement of the effects of latency on performance and the feasibility of performing procedures with standard existing networks has not been previously conducted. This research measured the effects of various levels of latency on successful performance of procedures in a simulator, and further measured the real latency for data transfer within a multi-campus metropolitan hospital system. Together, these identify whether telesurgery can be safely performed in an existing multi-campus hospital environment.

Methods:
Robotic surgeons (N=92) participated in four simulation tasks using the dV-Trainer (Mimic Technologies, Seattle, WA), a simulator for the da Vinci surgical system (Intuitive Surgical, Inc., Sunnyvale, CA). Each subject performed the exercises with zero latency and then was randomly assigned a fixed latency between 100-1000 ms to repeat the exercises (N=71 completed). The simulator recorded performance data.

Next, four hospital campuses within 25 miles were selected to measure the latency in transferring a video recording of a robotic surgical procedure. Data packet delivery times were measured by software as the video was transmitted between all four locations via the hospital's existing communication network.

Results:
With latency, we found that subjects with less than 200ms could perform procedures successfully. Subjects between 300-500 ms had variable results. Subjects with latency above 600ms generally could not complete exercises successfully. Subject experience levels were not correlated with performance when latency was present.

Actual communication latency between hospital campuses ranged between 1-5 ms, with one outlier at 62 ms. Length of video transmission ranged between 11 and 70 minutes.

Conclusions:
The measured latency between four hospital campuses using existing networks was 40 times lower than necessary for successful surgery. We conclude that telesurgery using existing robotic and communication equipment is possible right now within a multi-campus hospital system.

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Fundamentals of Robotic Surgery:
Development and Validation of an Online Curriculum and New Psychomotor Testing Device

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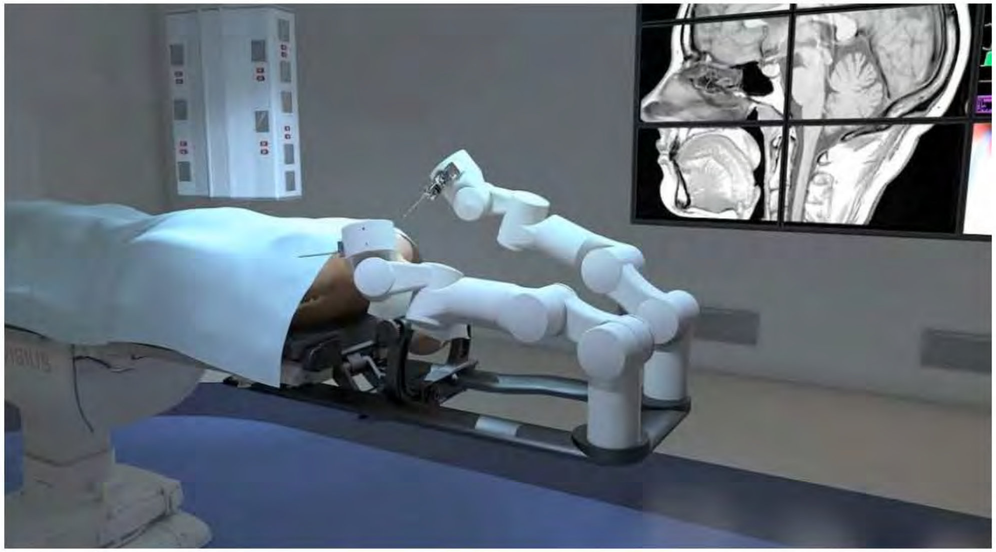
NEXTMED / MMVR21
MEDICINE MEETS VIRTUAL REALITY

Better Robotic Surgeons

Growing Robotic Assisted Surgery



Simulator Contributions

- Intuitive Surgical Inc
- Skills Simulator

- Mimic Technologies Inc
- dV-Trainer

- Surgical Simulation Inc
- RoSS Simulator

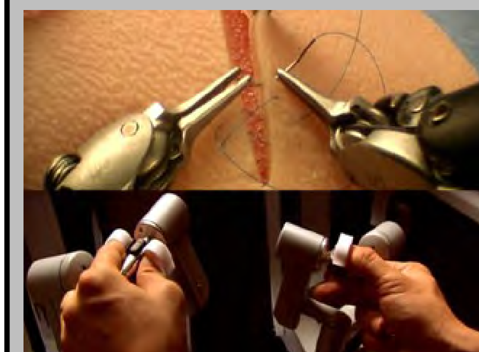
Nicholson Center Robotic Courses

Basic Skills

α

Advanced Course

β



Masters Course

γ

DVSS

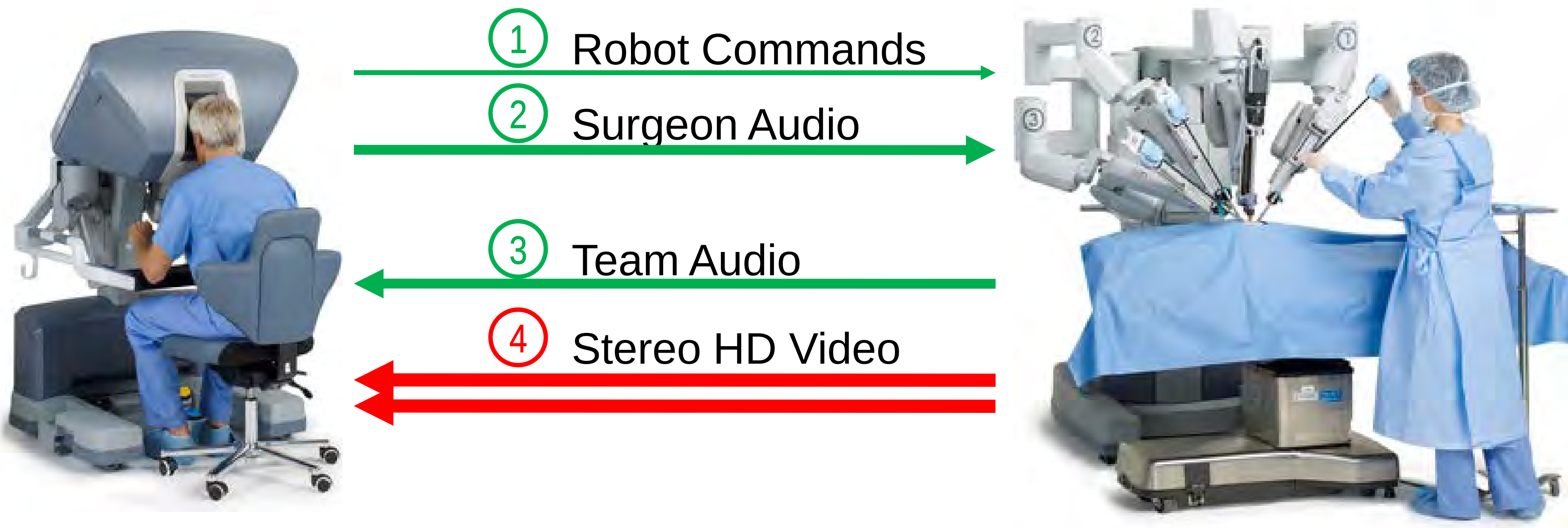
dV-Trainer

dV-Trainer

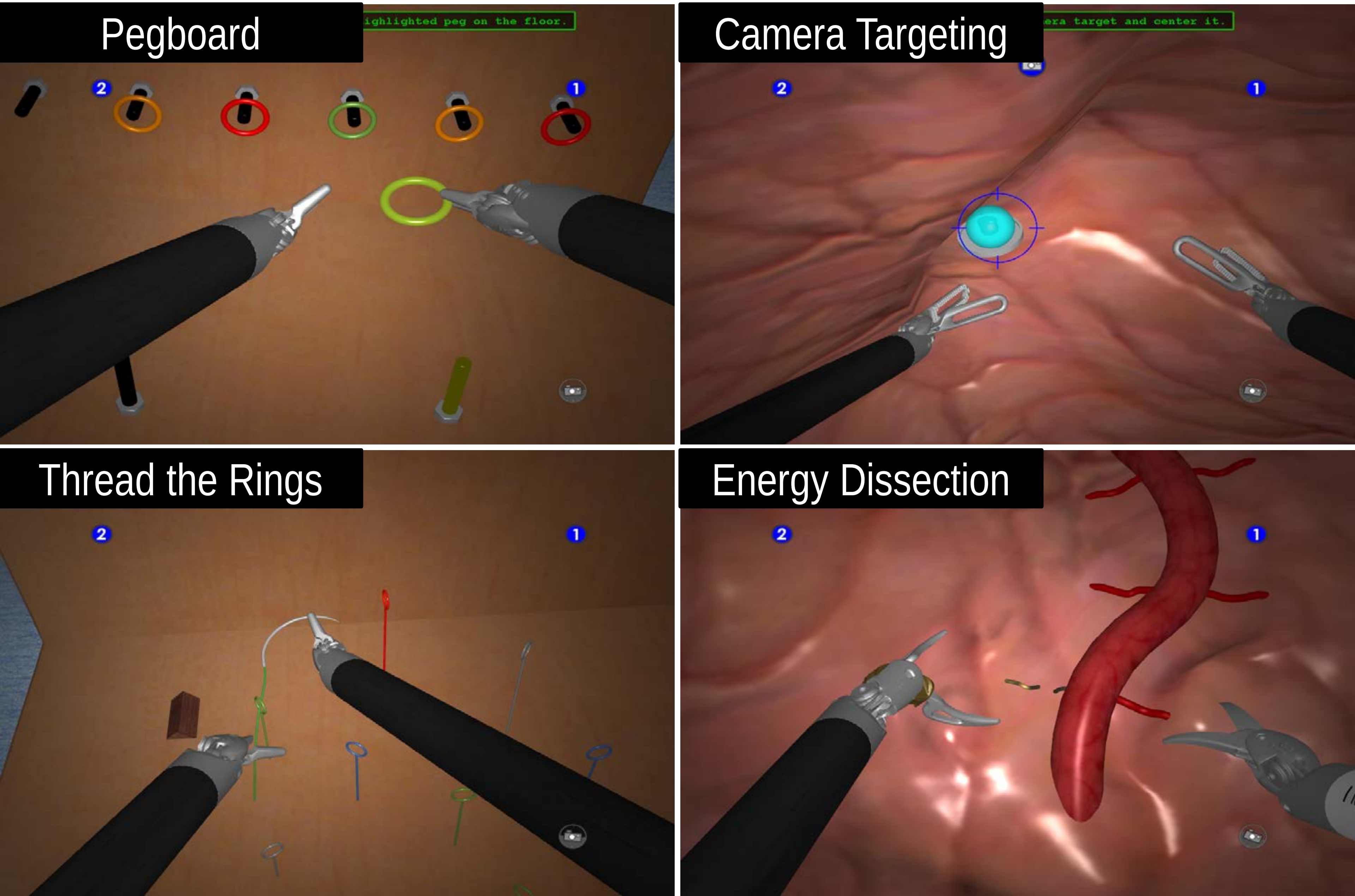
Robotic & Simulator Experiments

1. Telesurgery – Metropolitan, Statewide, Nationwide
2. Simulator Comparison – Capabilities, Usability, Skills Development
3. Surgical Rehearsal – Didactic vs. Simulator
4. Fundamentals of Robotic Surgery – Didactics, Psychomotor, Team Training
5. FRxS – GYN, URO, ColoRect, CardioThorac, Spinal
6. 3D Spatial Skills - Gamers vs. Doctors
7. Suture Training – Simulator vs. Robot

Telesurgery Communication Latency



Simulation in Telesurgery



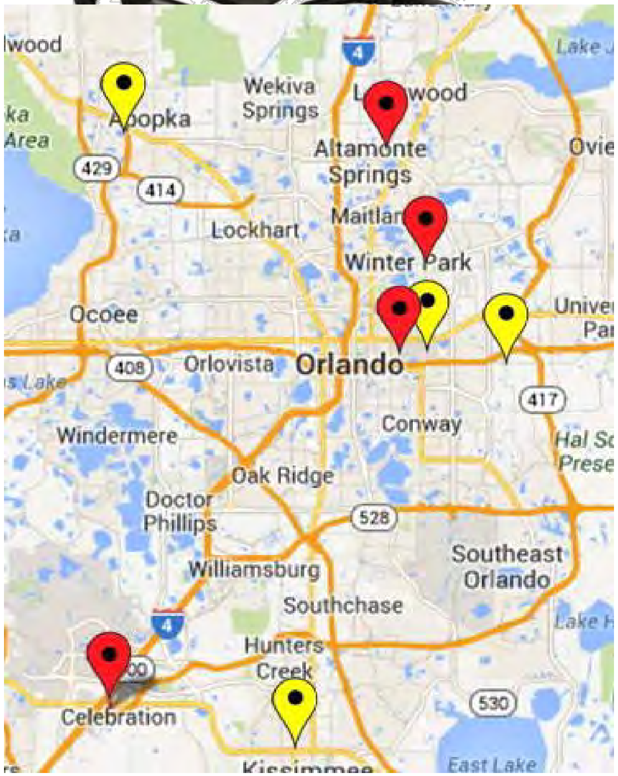
Videos with and without Latency

Pegboard: 0ms Latency

Pegboard: 500ms Latency

Telesurgery Experiment Results

Latency Level	Conclusion
100ms	Generally Safe
200ms	
300ms	Physician Dependent
400ms	
500ms	
600ms	Generally Unsafe
700ms	
800ms	
900ms	
1000ms	



Stream From	Stream To	Physical Distance (miles)	Average Speed (millisecs)
Orlando	Orlando	0	3
Orlando	Orlando	0	1
Orlando	Orlando	0	1
Celebration	Celebration	0	2
Orlando	Winter Park	4	4
Winter Park	Orlando	4	5
Orlando	Altamonte	7	5
Orlando	Altamonte	7	4
Altamonte	Orlando	7	4
Celebration	Orlando	23	5
Celebration	Orlando	23	5
Orlando	Celebration	23	4
Orlando	Celebration	23	4
Celebration	Orlando	23	5
Celebration	Orlando	23	4

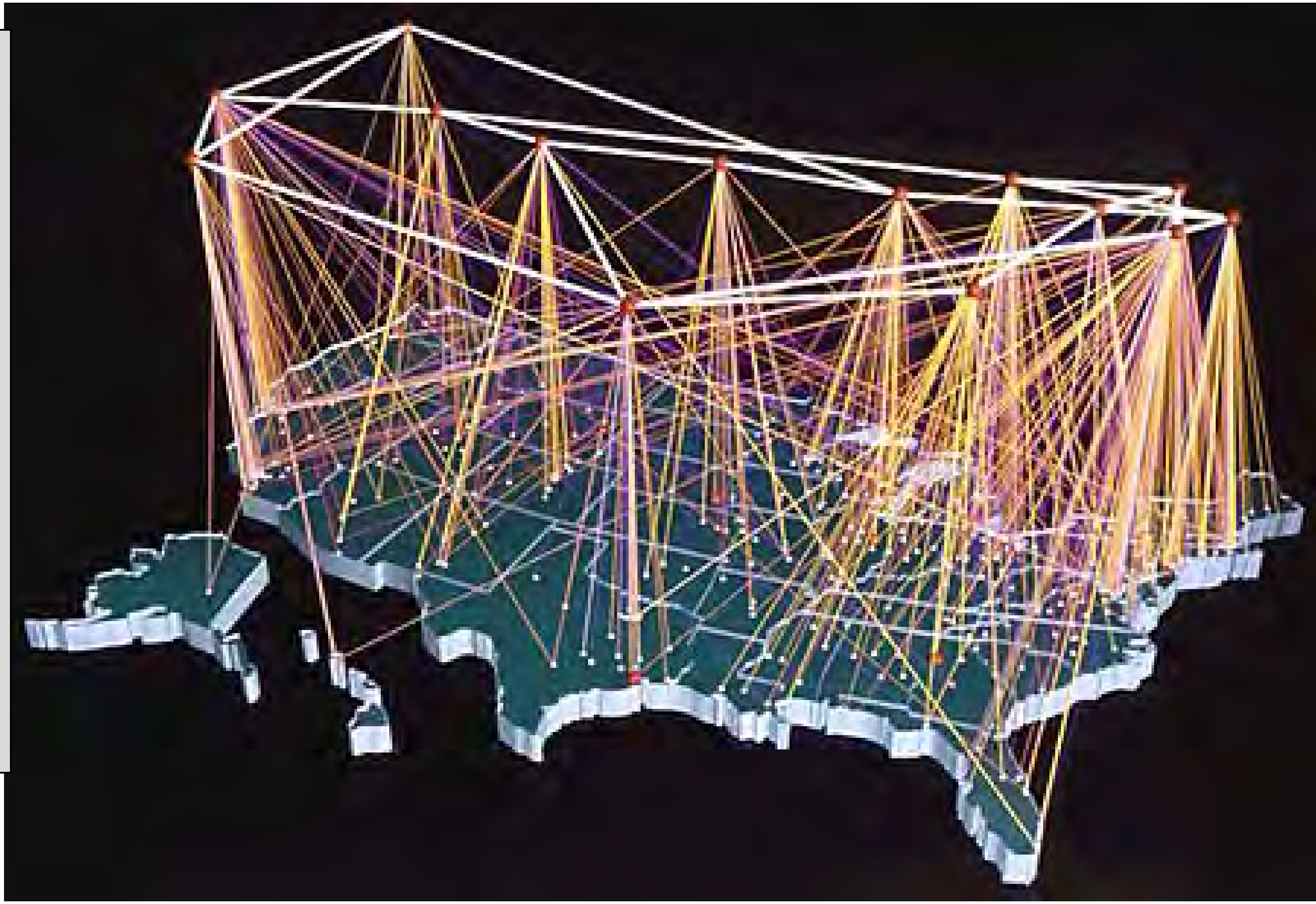
Nationwide Telesurgery

Metropolitan
Orlando Campuses

Statewide
Florida Campuses

Nationwide
Orlando,
Denver,
Fort Worth,
Loma Linda, CA

International
No Thanks!



Simulator System Comparison

- Intuitive Surgical Inc
- Skills Simulator
- VR Environment
- Self-contained PC plugs into the surgeon's console

- Mimic Technologies Inc
- dV-Trainer
- VR Environment
- Unique hardware and software device

- Surgical Simulation Inc
- RoSS Simulator
- VR Environment
- Unique hardware and software device

Simulator Video Samples

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Comparative analysis of the functionality of simulators of the da Vinci surgical robot

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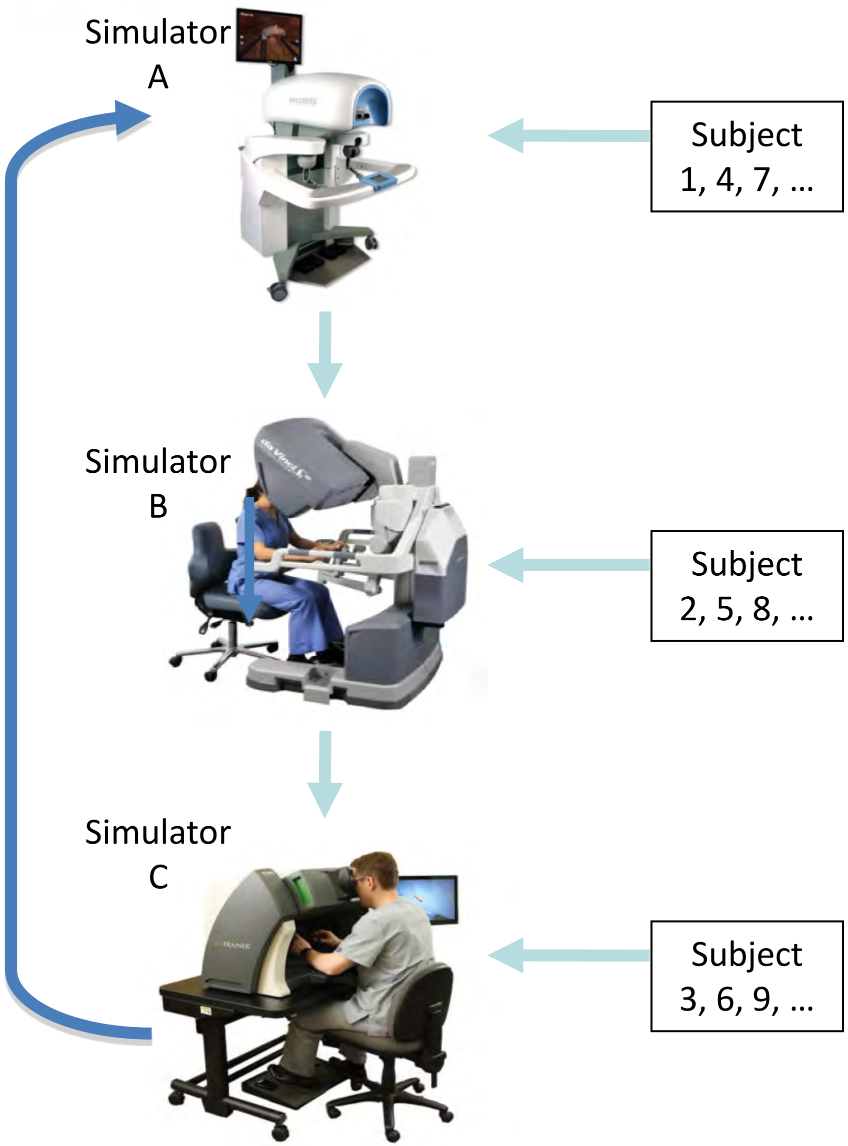
Robotic Simulator Feature Comparison

Features	DVSS	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	VGA 640 x 480	VGA 640 x 480	VGA 640 x 480
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	56 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 PC. Import via USB memory stick.	Create student accounts. Customize curriculum.	Create student accounts. Customize 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

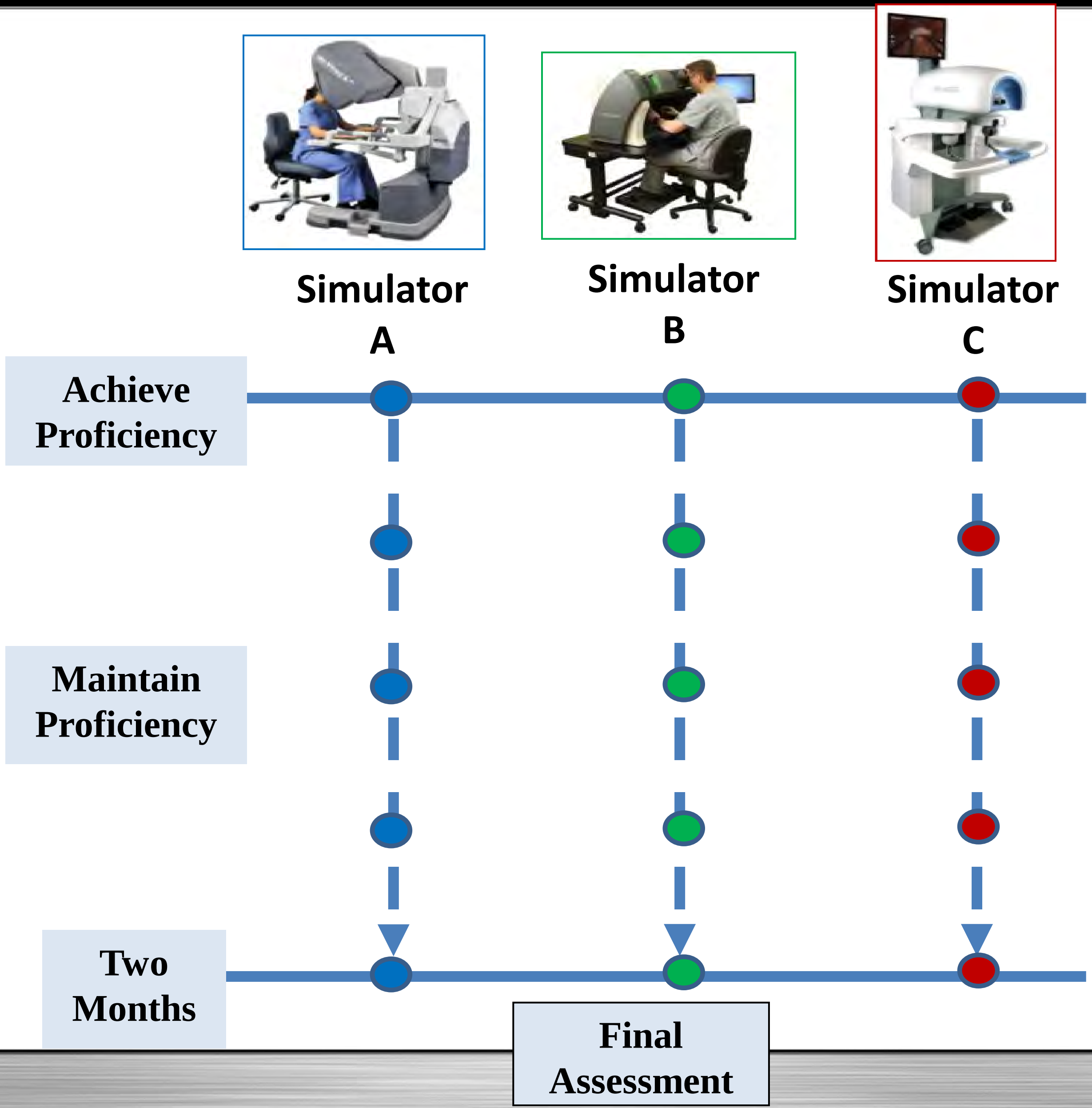
Simulator Usability Experiment



Questionnaire #1:

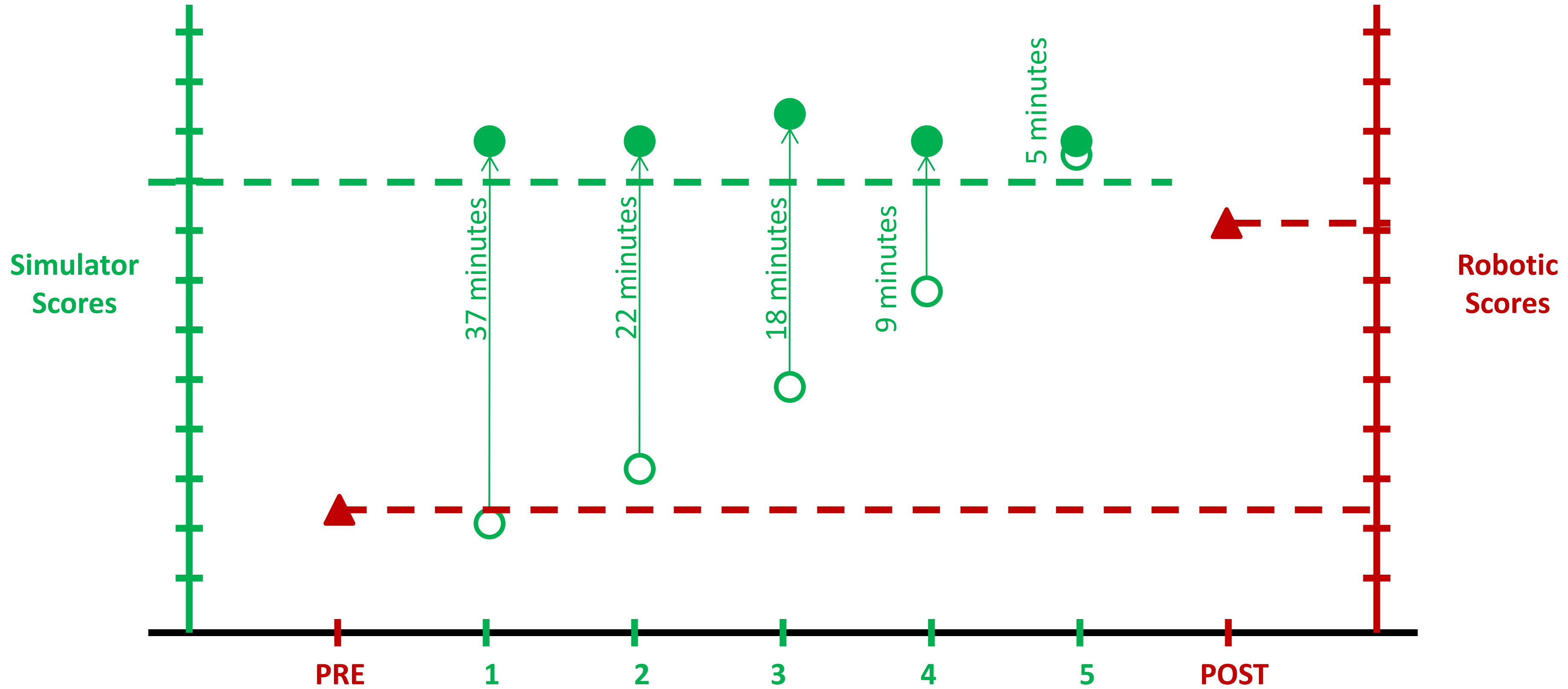
1. The hand controllers on this simulator are effective for working in the simulated environment.
2. The 3D graphical exercises in the simulator are effective for teaching robotic skills.
3. The hand controllers are well synchronized with the 3D graphical world objects.
4. The device is a sufficiently accurate representation of the real robotic system.
5. The scoring system effectively communicates my performance on the exercise.
6. The scoring system effectively guides me to improve performance on the simulator.
7. I believe this device would be an effective tool for maintaining robotic surgical skills when a surgeon is not able conduct regular operations.
8. Researcher intervention was required.

Simulator Effectiveness Experiment



Simulator Effectiveness Objectives

Conceptual Results



Doctors vs. Gamers

Computer Gamers

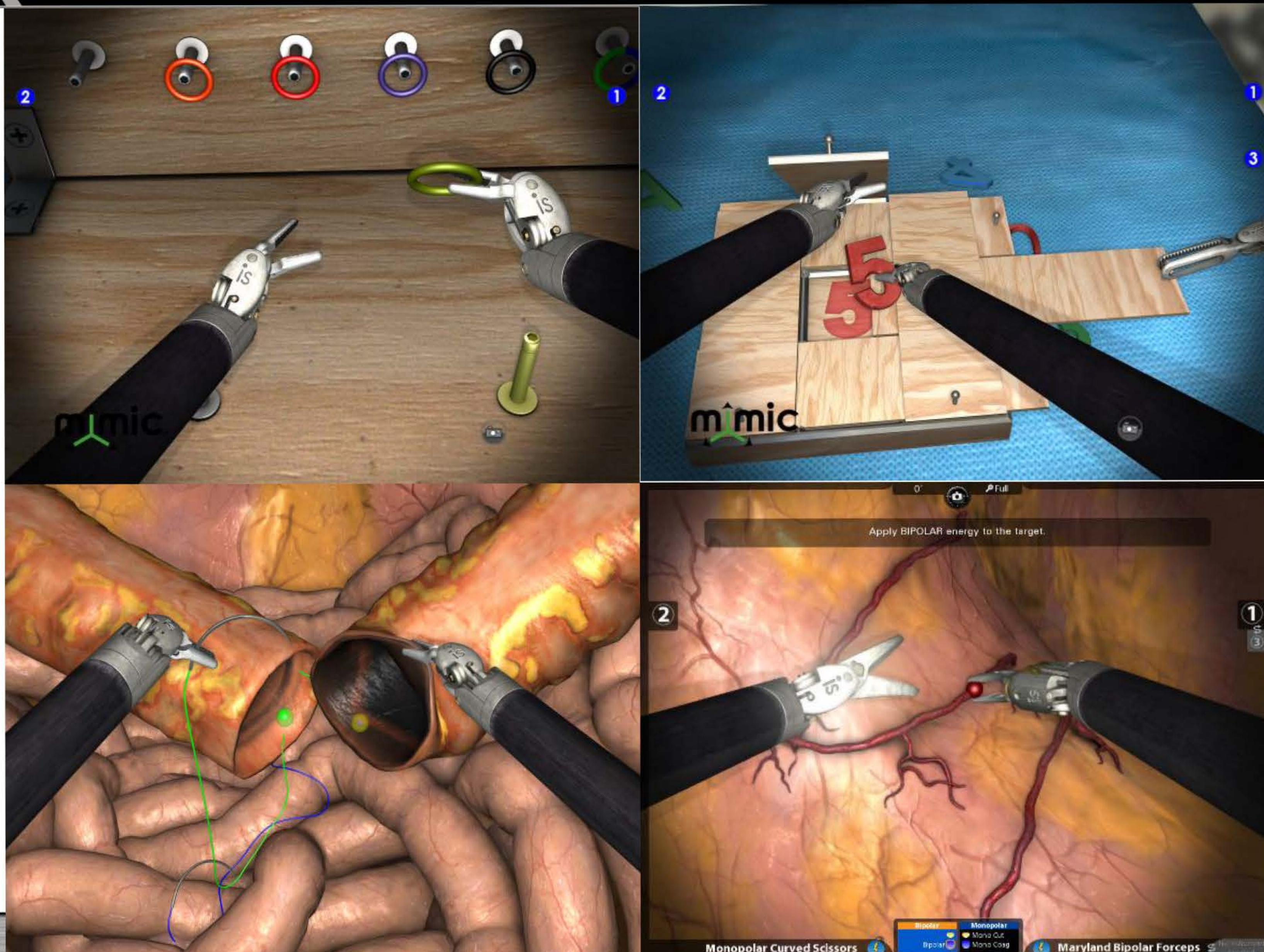
Medical Students

Average Joes
(Control Group)

- Mimic Technologies Inc
- *dV-Trainer*
- VR Environment
- Custom hardware and software device

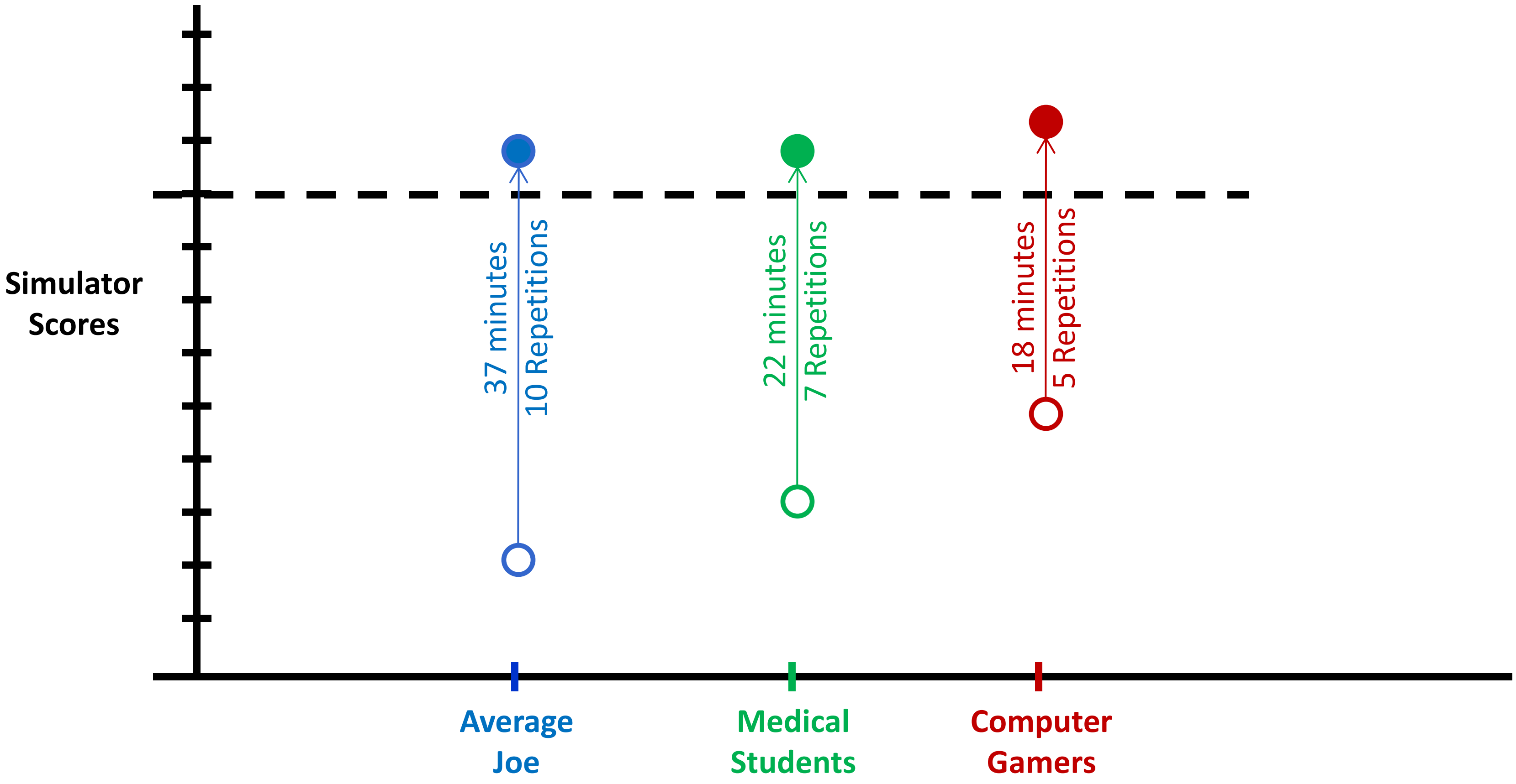
Which Group Masters Simulated Surgical Tasks Faster?

Simulator Exercise Samples



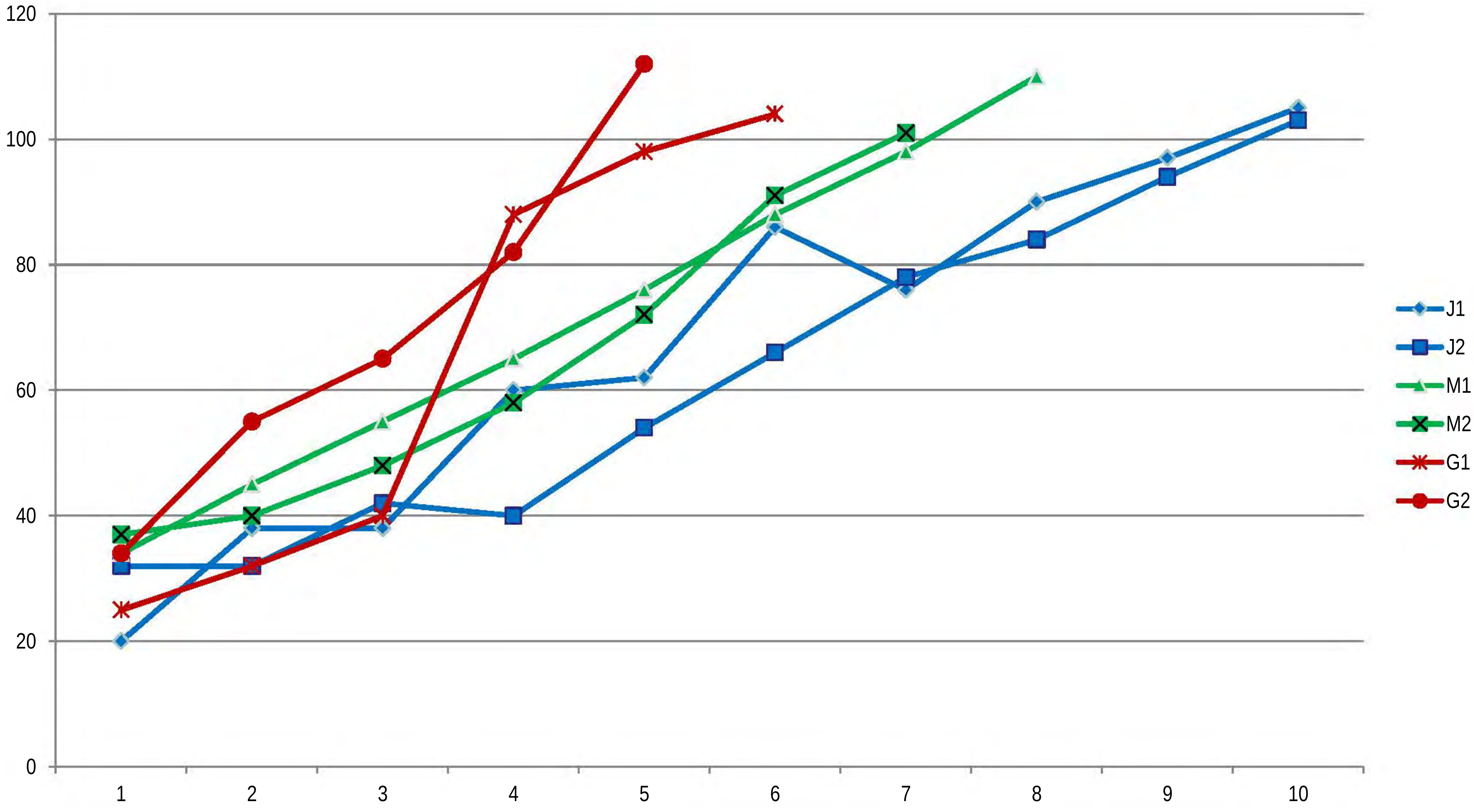
Comparative Performance

Conceptual Results



Comparative Performance

Conceptual Results



Surgical Rehearsal with Simulator

Pre-Test Questionnaire

Randomized Assignment

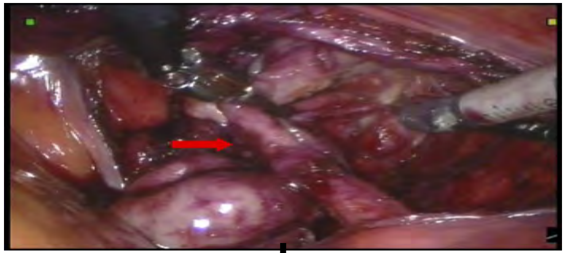
Group A: Lecture

Group B: Simulator

Paper Exam

Simulator Data

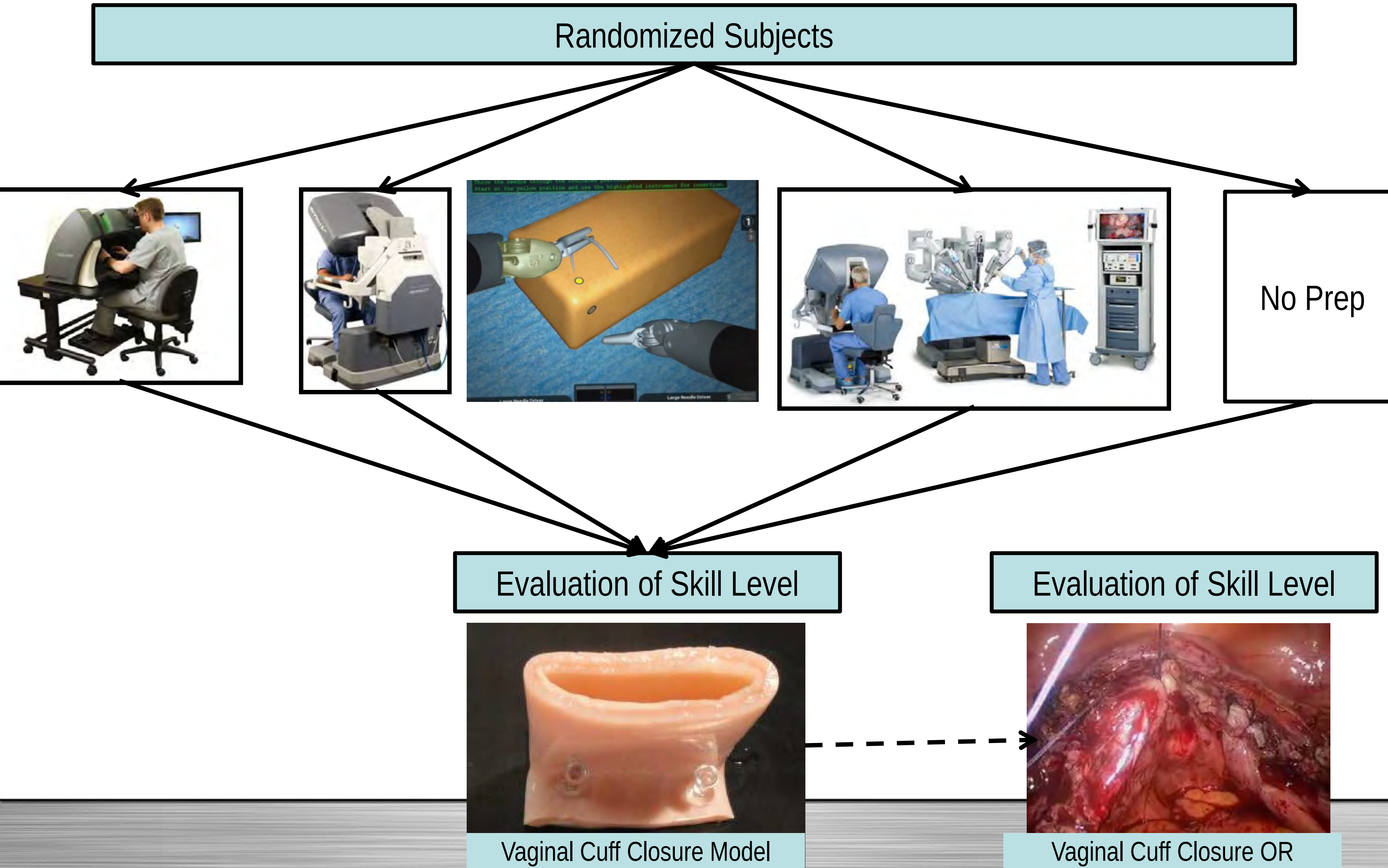
Robotic Procedure



Post-test Questionnaire

Video Recording Evaluation

Suture Training Modes



Fundamentals of Robotic Surgery

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

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 (Nov 17-18, 2012)
4. Online Course Materials (Oct-Dec 2013)
5. Psychomotor Device Development (Oct-Dec 2013)
6. Validation Studies (2014)
7. Transition to Objective Testing Organization (est. 2015)

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FRS Outcomes Measures

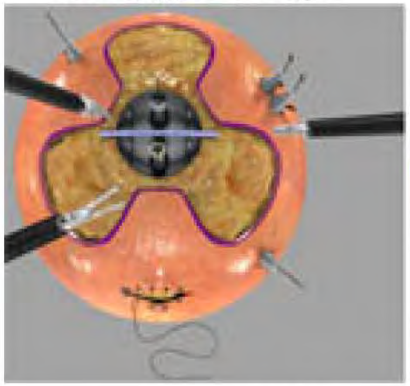
Pre-Operative	Intra-Operative	Post-Operative
System Settings	Energy Sources	Transition to Bedside Asst
Ergonomic Positioning	Camera Control	Undocking
Docking	Clutching	
Robotic Trocars	Instrument Exchange	
OR Set-up	Foreign Body Management	
Situation Awareness	Multi-arm Control	
Closed Loop Comms	Eye-hand 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	

Online Courseware Sample

See separate file

Psychomotor Device Evolution

Prototype Concept



Prototype 1

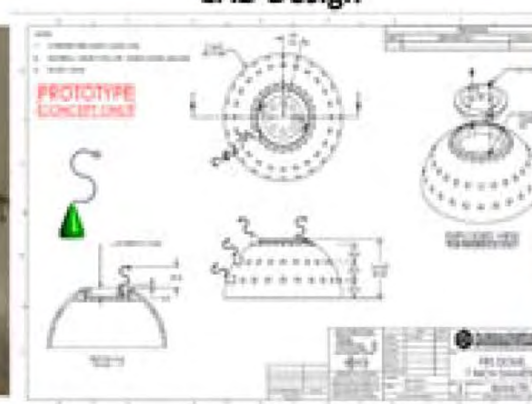
Prototype 2

Prototype 3

Prototype 4

Prototype 5

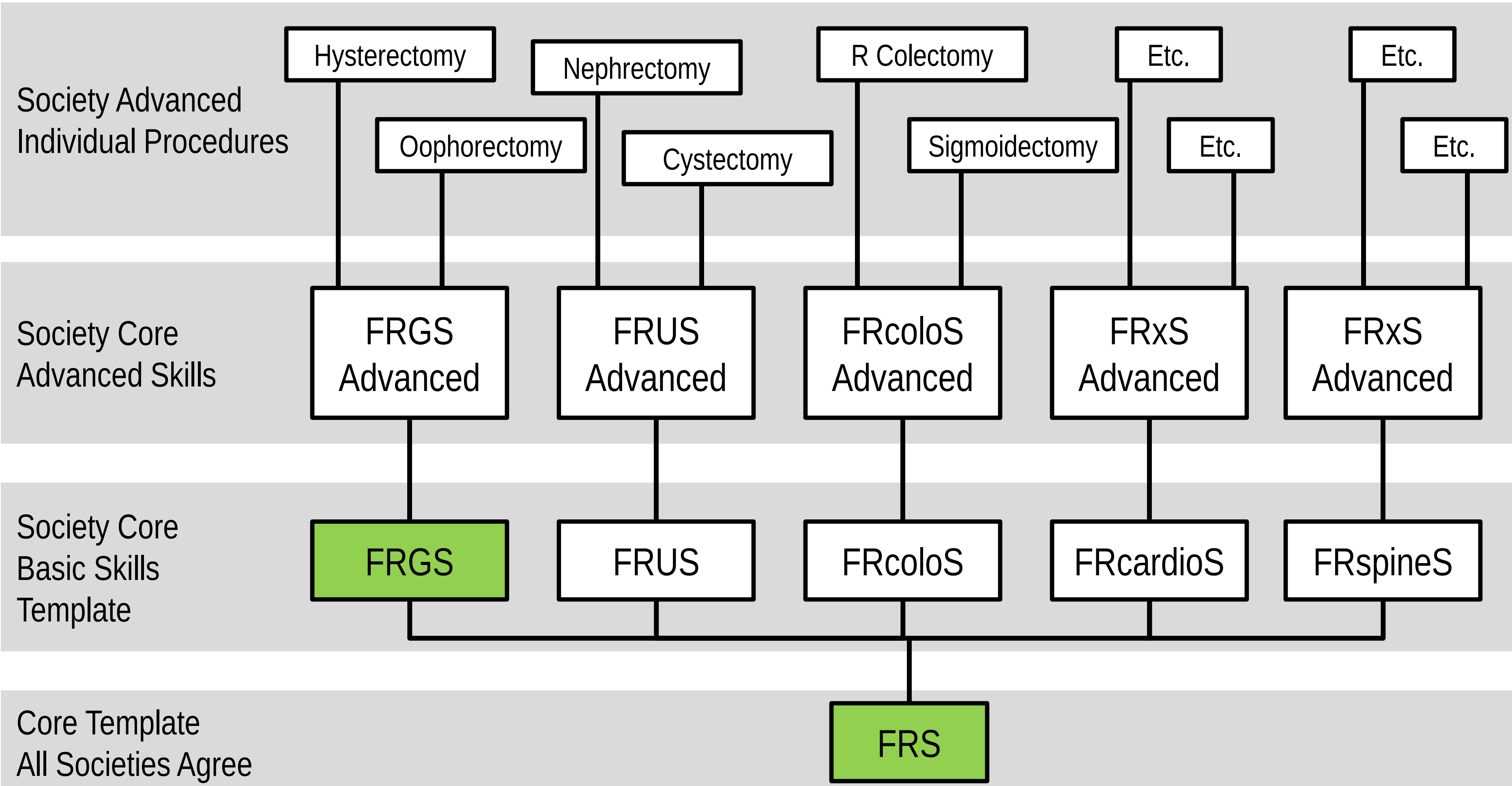
CAD Design



Prototype 8

FRS Psychomotor Dome Video

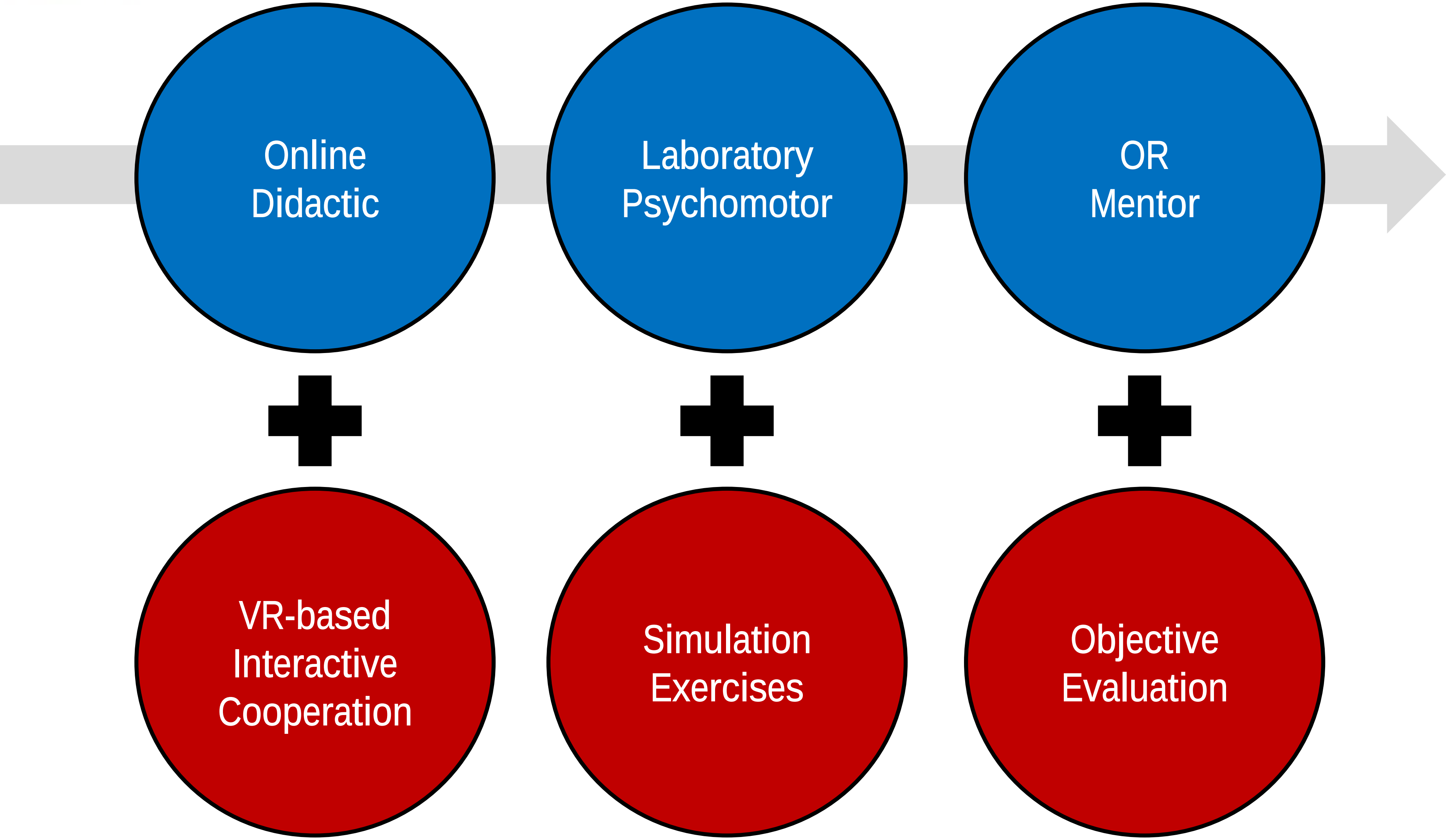
FRS for Specialties ("Sweet Tree")



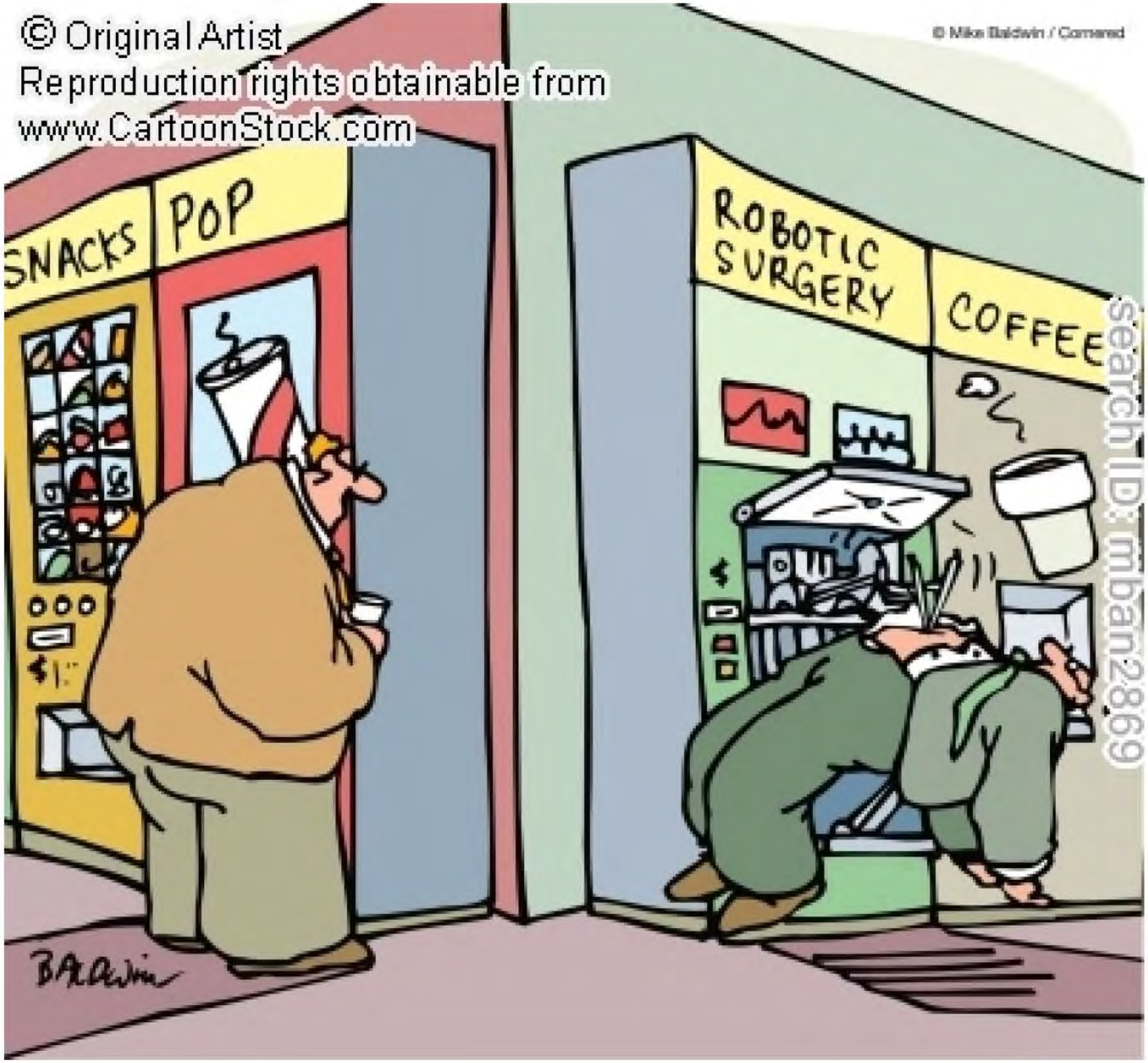
Virtual Worlds for Robotic Surgery

HumanSim Preview for iPad is available on iTunes

Robotic Surgery Education Evolution



Coming to your local mall …



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Gamers in Surgical Simulation: A Comparison of Gamers, Surgeons, Medical Students, and Clinical Staff

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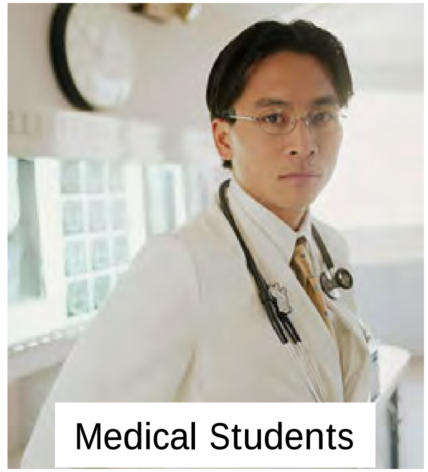
Gamers vs. Doctors on Simulators

Computer Gamers



Medical Students

Expert Surgeons

dV-Trainer

Lay Persons

Clinical Staff

Orlando Area Collaboration

UCF

IEA

FULL SAIL®
Real World Education

UNIVERSITY OF CENTRAL FLORIDA
College of Medicine

mimic®

Experiment

Hypothesis 1: Medical students, clinical staff, and lay persons achieve equivalent performance on the dV-Trainer.
Hypothesis 2: VGEs are equivalent in simulation-based skills to experienced surgeons.
Hypothesis 3: VGEs scores on psychological tests of perceptual and cognitive skills are equivalent to those of expert surgeons.

Subjects: FH Surgeons, UCF Medical Students, UCF FIEA & Full Sail Game Programming Students, FH Clinical Staff, FH Laypersons

Device: dV-Trainer Simulator (Mimic Technologies Inc.)

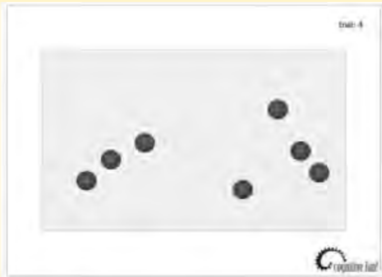
Tasks: Questionnaires, Perceptual Tests, Simulation Exercises

Experimental Process

Activity	Estimated Time to Complete
Consent	5
Pre-test Questionnaire	5
Perceptual Tests	10
dV-Trainer Warmup	3
8 Trials on the dV-Trainer	40
Post-Test Questionnaire	5
Total Time	68 mins

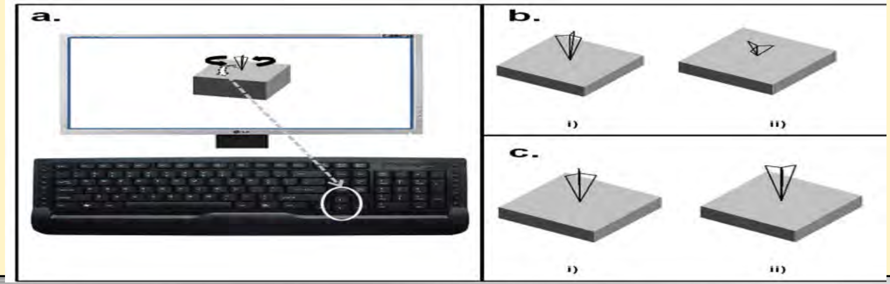
Perceptual Tests

Flanker Compatibility



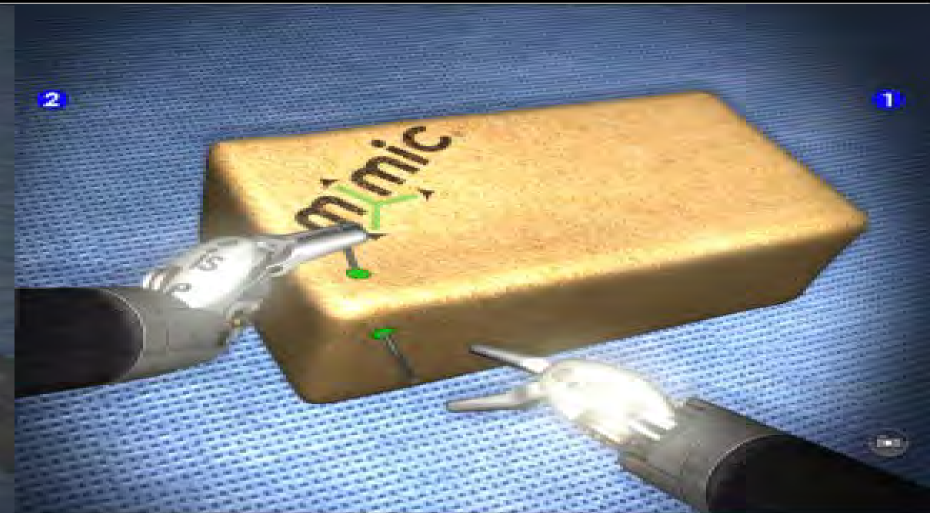
Enumeration task

Multiple Object Tracking



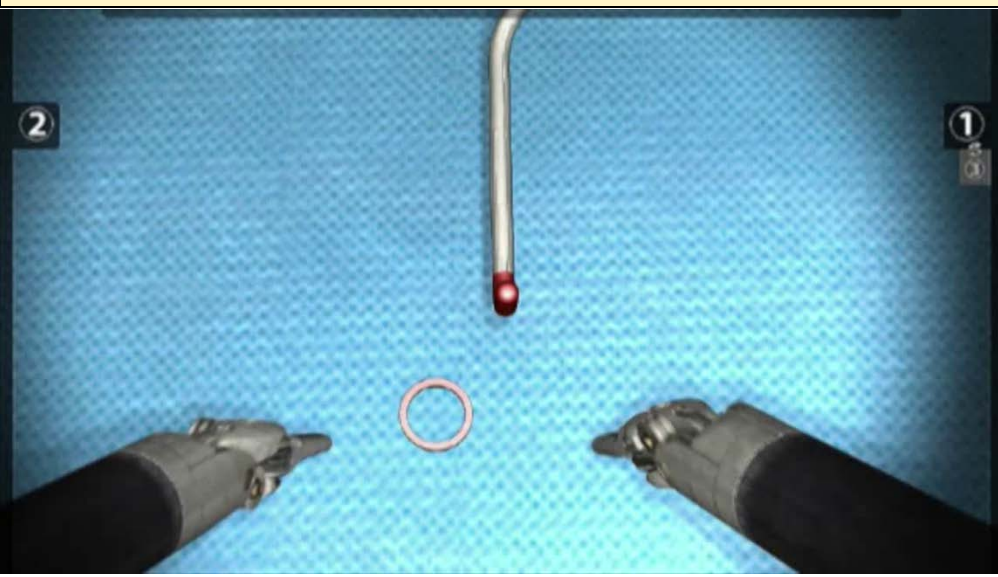
PicSOr

Simulator Tasks



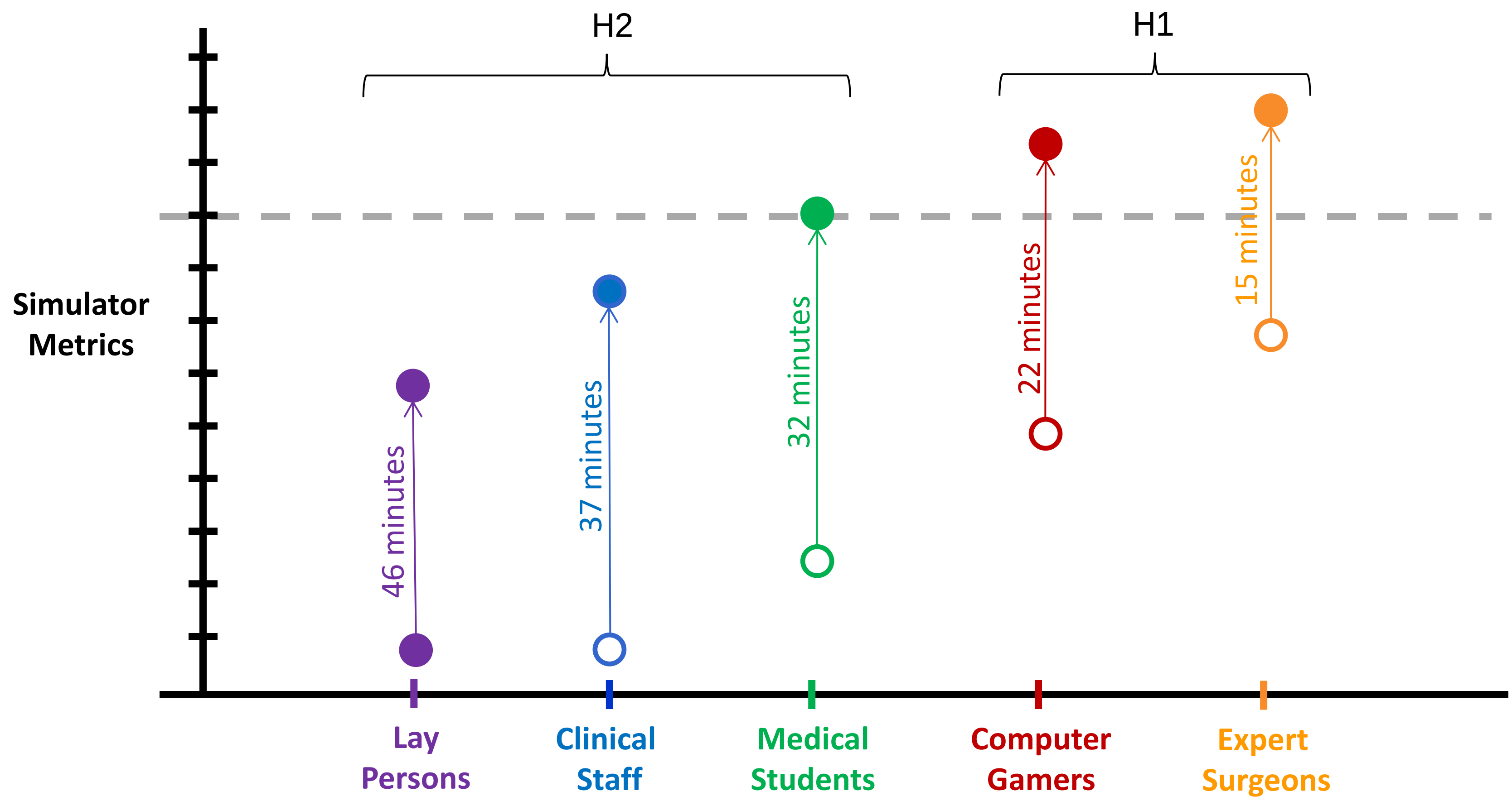
Ring & Rail

Suturing



Comparative Performance

Conceptual

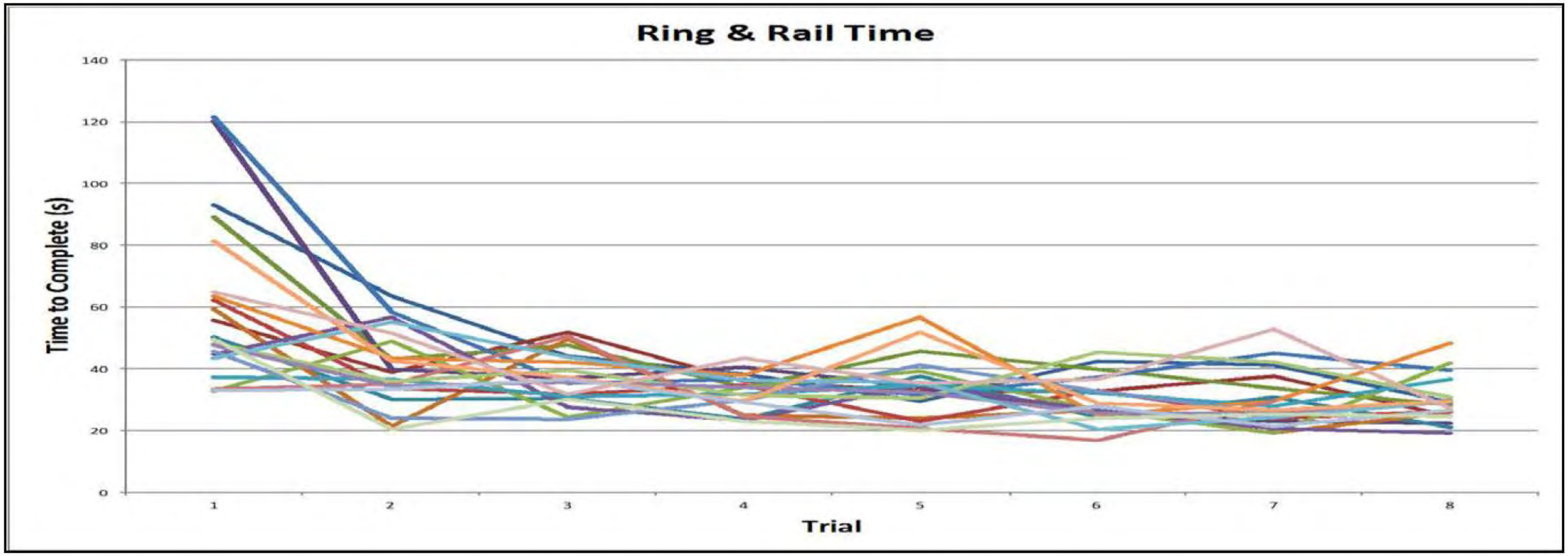


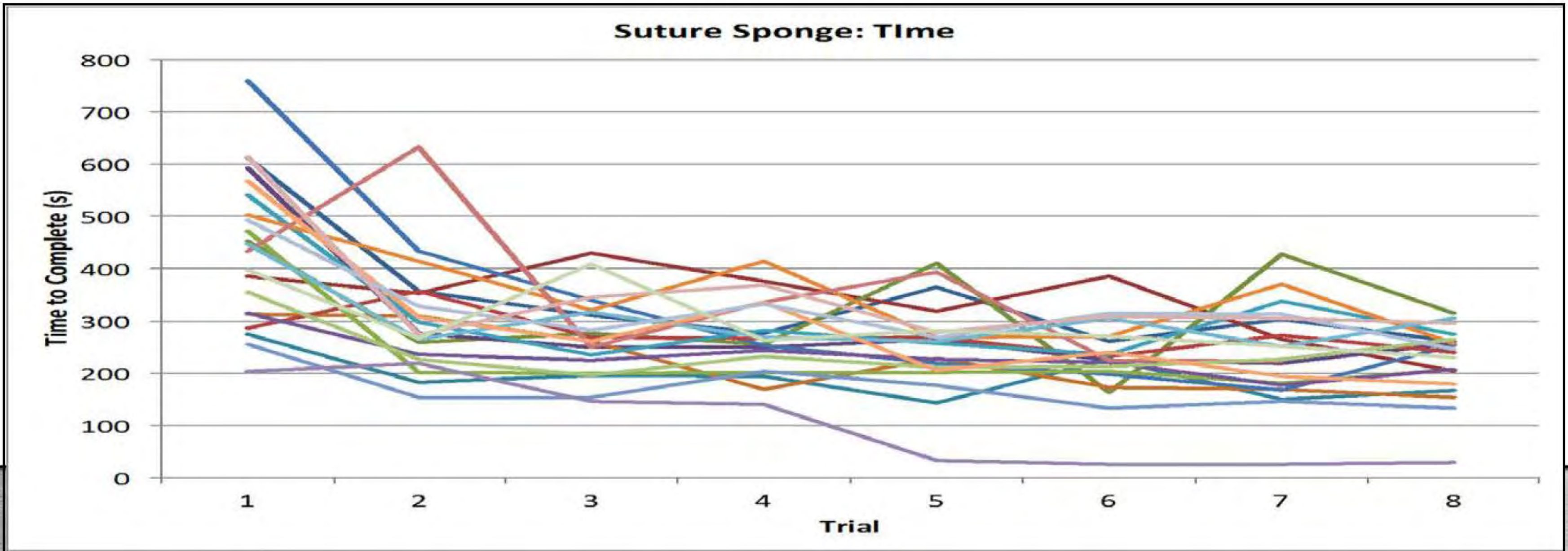
Powering the Study

Task	Mean Score	Minimum and Maximum Diff	Difference detected at 80% power with N=125 (Δ/2)
Ring and rail	1055	14 (79)	25
Suture sponge	371	14 (907)	192

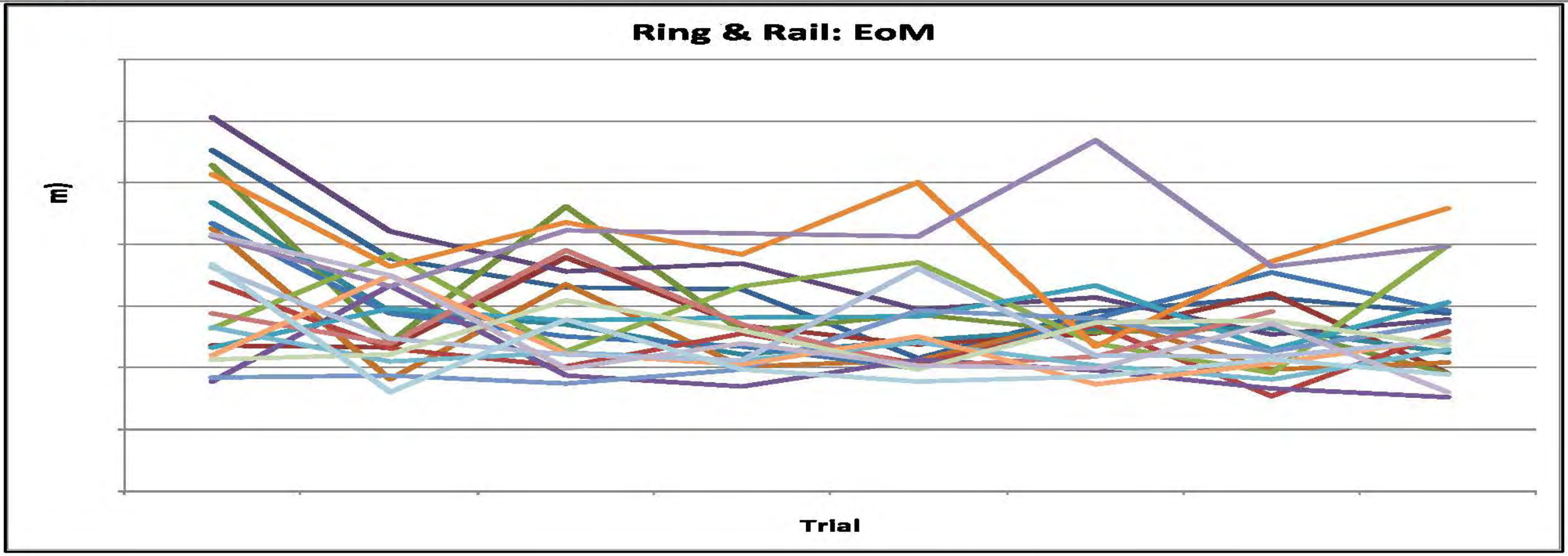
Task	Mean Time to Complete	Minimum and Maximum Diff	Difference detected at 80% power with N=125 (Δ/2)
Ring and rail	68	3 (29)	9
Suture sponge	682	67 (543)	120

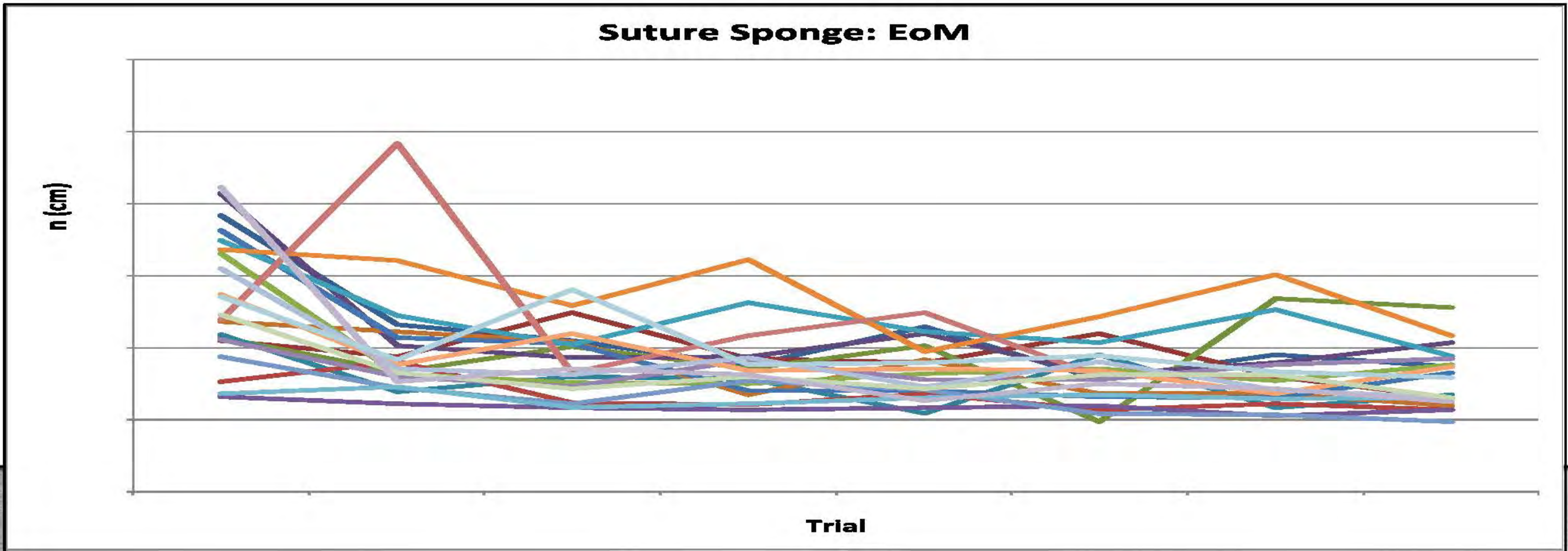
Medical Student Performance



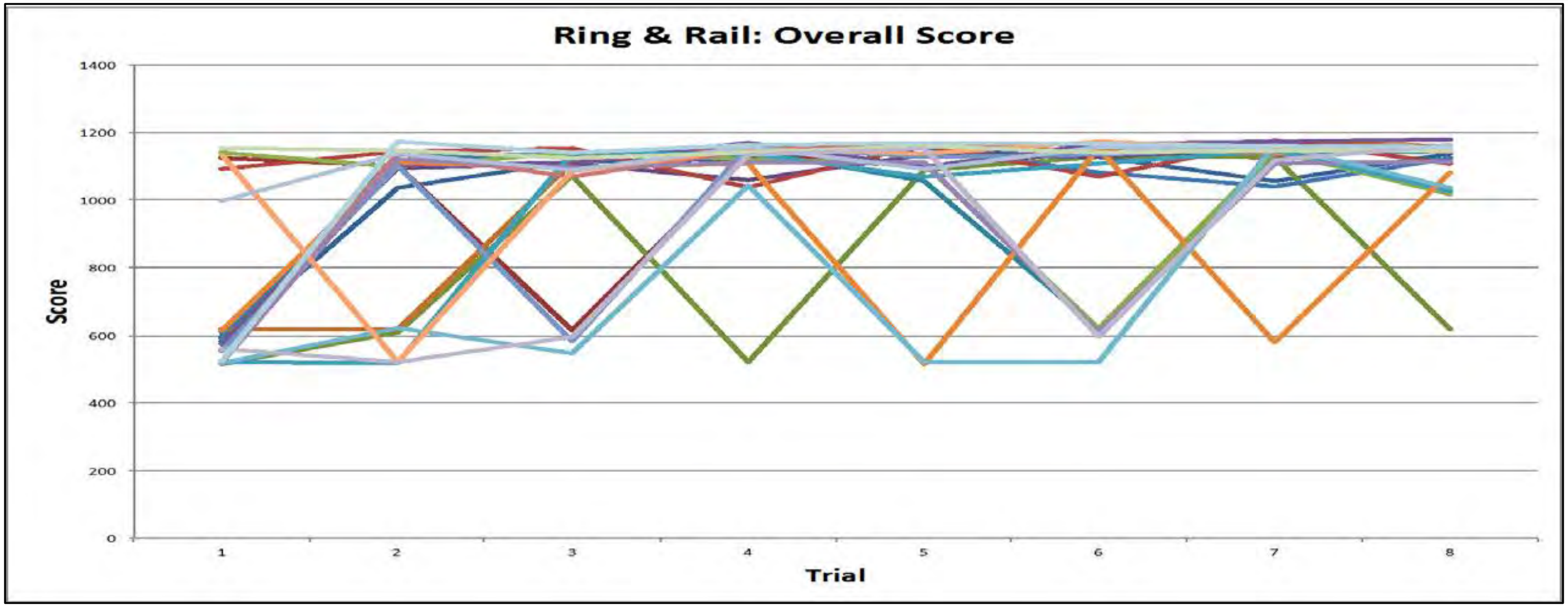


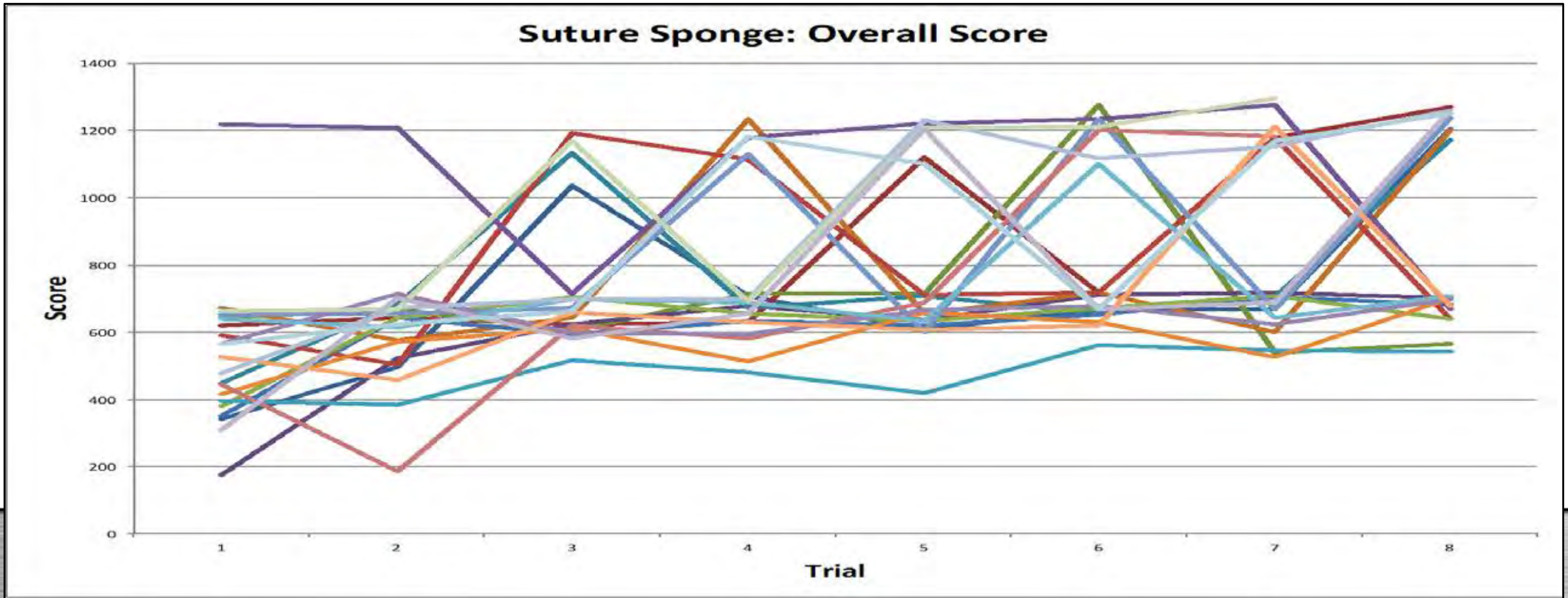
Medical Student Performance



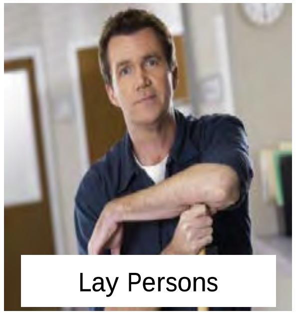


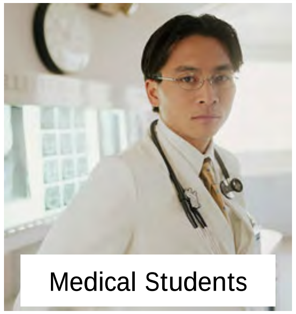
Medical Student Performance

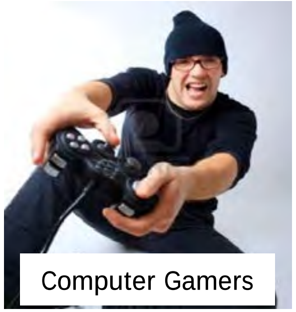




Value of Results







H2: Potentially Lay Persons are not viable subjects

H2: Potentially Clinical Staff can be used as novice subjects in some studies of robotic surgery

H1: Potentially VGEs should be excluded from novice populations in robotic surgery studies

H3: Potentially the perceptual abilities of Expert Surgeons and VGEs are similar.

The Effectiveness and Usability of Robotic Simulators

Alyssa Tanaka, Mireille Truong MD, Khara Simpson MD, Manuela Perez MD, Roger Smith PhD

FLORIDA HOSPITAL
NICHOLSON CENTER

Overview

- **Introduction**
- **Hypothesis**
- **Methods**
- **Results**
- **Conclusion**

Introduction

Skills Simulator

- Intuitive Surgical Inc
- VR Environment
- Self-contained PC plugs into the surgeon's console

dV-Trainer

- Mimic Technologies Inc
- VR Environment
- Unique hardware and software device

RoSS Simulator

- Surgical Simulation Inc
- VR Environment
- Unique hardware and software device

Introduction

- **Face Validity:** The realism of the simulator.
- **Content Validity:** Judgment of the appropriateness of the simulator as a teaching modality.
- **Concurrent:** The extent to which the simulator correlates with the "gold standard."
- **Construct Validity:** Indicates whether the simulator is able to distinguish an experienced surgeon from an inexperienced surgeon.
- **Predictive Validity:** The extent to which the simulator predicts future performance.

McDougall, E. M. (2007). Validation of surgical simulators. Journal of Endourology, 21(3), 244-247.

Introduction

Phase 1: Systems Capabilities Evaluation

↓

Phase 2: Subjective Usability Analysis

↓

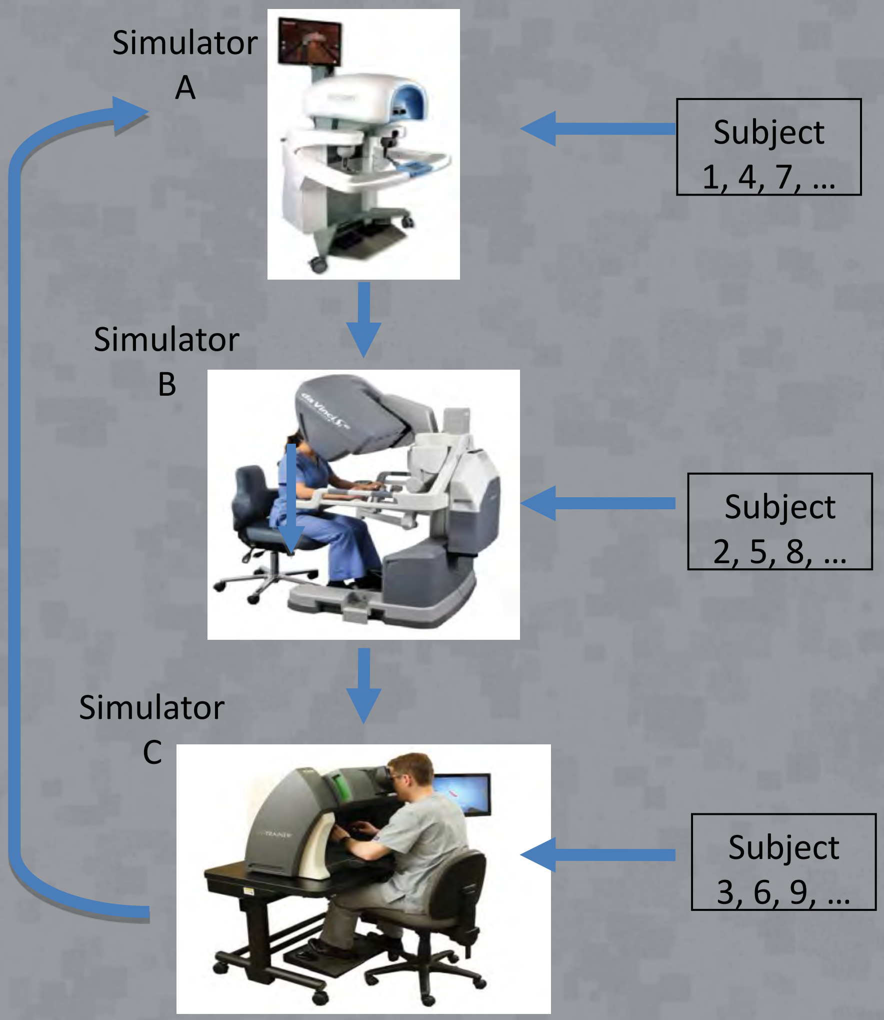
Phase 3: Objective measurement of skill Acquisition

Hypothesis

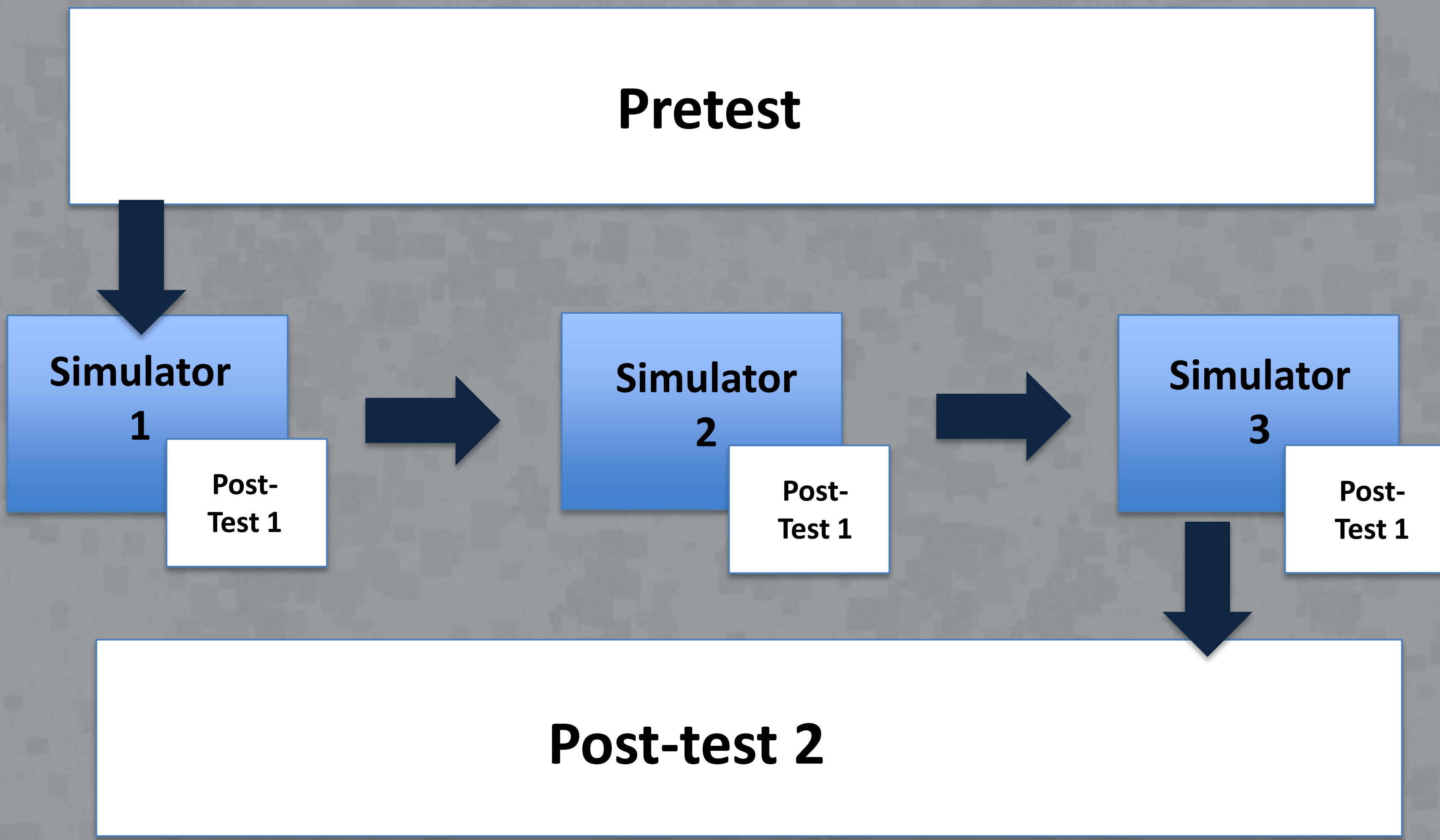
- H_0: There is no difference between the content, face and construct validity of the three simulators.
- H_a: There is a difference between the content, face and construct validity of the three simulators.

Methods

- **Novice:** 0-19 robotic cases
- **Intermediate:** 20-99 robotic cases
- **Expert:** 100+ robotic cases



Methods


Pretest
Simulator 1
Post-Test 1
Simulator 2
Post-Test 1
Simulator 3
Post-Test 1
Post-test 2

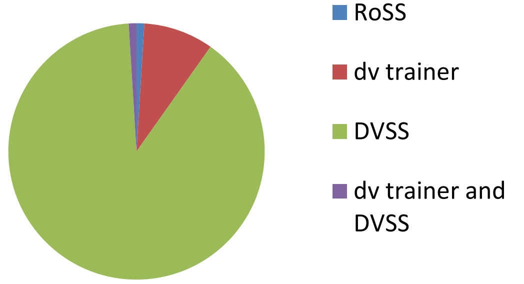
Simulator Demonstration

[Video clip from all 3 devices was embedded here.]

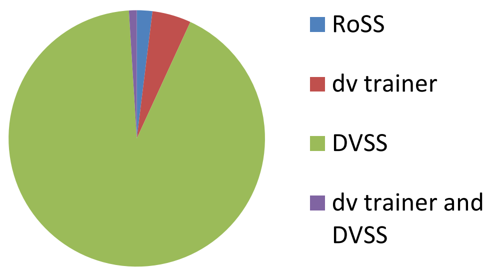
Results

Novices: n= 36 **Intermediates:** n=30 **Experts:** n= 34

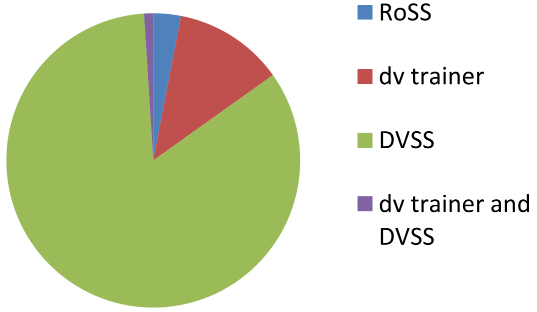
What would you choose for trainees?



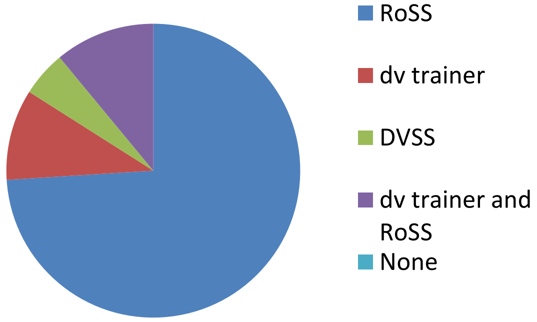
Which was physically most comfortable?



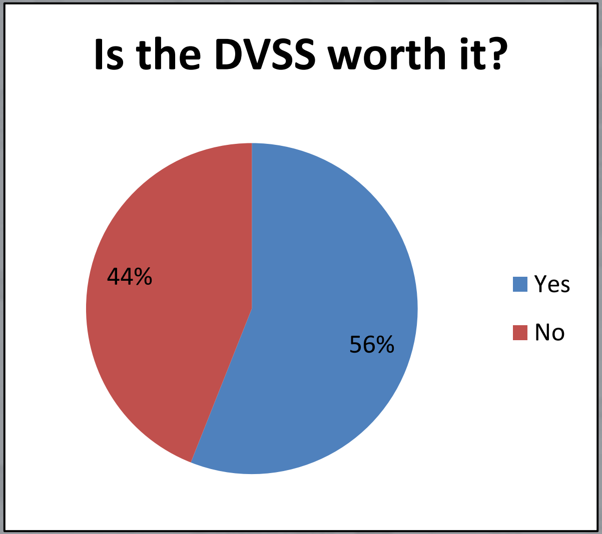
Overall, which did you most like?

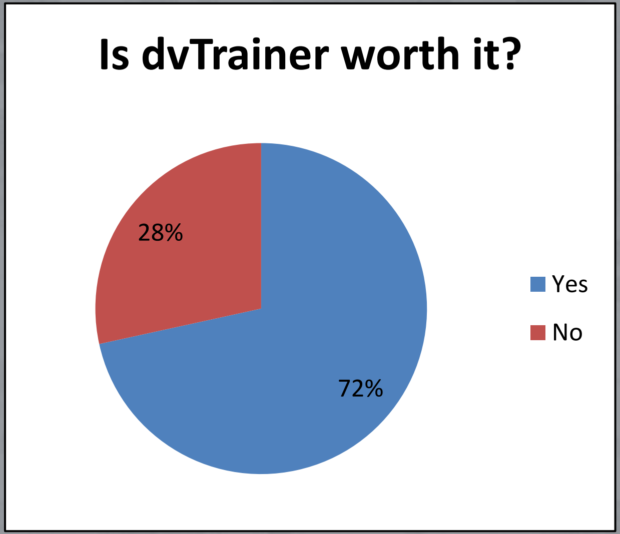


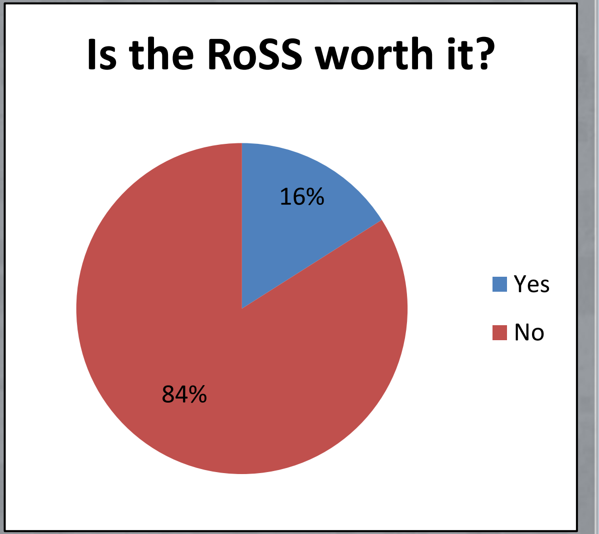
Which made you feel stressed?



Results


Is the DVSS worth it?
44%
56%
Yes
No


Is dvTrainer worth it?
28%
72%
Yes
No


Is the RoSS worth it?
16%
84%
Yes
No

Conclusions

- Beginning analysis
  - Face and content validity from questionnaires
  - Construct validity from simulation scores
- Give guidance to purchasers on the simulator most preferred
  - RoSS
    - least preferred in terms of usability
    - Not worth the cost
  - dv-trainer
    - Worth the cost
  - Skills simulator
    - Most preferred
    - Worth the cost
- Future Research: objective evaluation of skill acquisition and retention

From:	Mireille Truong
To:	Smith, Roger; Tanaka, Alyssa; PEREZ Manuela; Khara Simpson; Graddy, Courtney
Cc:	Arnold Advincula
Subject:	Fwd: MIS14 Online Abstract Submission Form
Date:	Saturday, May 17, 2014 3:08:16 AM

Hi all!

Hope all is well in Floridaland.

I just wanted to let you know that I submitted the abstract below to SLS. (this is slightly different than the one submitted to AAGL). It's an abstract on the perspectives of the subjects on simulation vs didactics using the answers from the questionnaires :)

Mireille

---------- Forwarded message ----------
From: **Society of Laparoendoscopic Surgeons (SLS)** <no-reply@wufoo.com>
Date: Sat, May 17, 2014 at 3:01 AM
Subject: MIS14 Online Abstract Submission Form
To: mireille.truong@gmail.com

MINIMALLY INVASIVE SURGERY WEEK 2014

presented by SLS and Affiliated Societies

September 10-13, 2014
Caesar's Palace Las Vegas
Las Vegas, Nevada, USA

Thank you for your abstract submission for Minimally Invasive Surgery Week 2014.

MIS14 Online Abstract Submission Form

First Name *	Mireille
Last Name/Surname *	Truong
Degree: *	MD Fellow
Your Specialty (choose one) *	Ob/Gyn

Are you a Resident-in-Training? *	No
Address *	New York, NY 10023 United States
Telephone Number *(include area code or city and country codes, if applicable.)* *	
Fax Number *(include area code or city and country codes, if applicable.)* *	
Email *	mireille.truong@gmail.com
University/Hospital Affiliation *	Columbia University Medical Center
1a. Additional Author/Presenter Name and Degree	Alyssa Tanaka, MS
1b. Hospital / Institutional Affiliation(s) for Co-Author:	Nicholson Center Florida Hospital
2a. Additional Author/Presenter Name and Degree	Roger Smith, PhD
2b. Hospital / Institutional Affiliation(s) for Co-Author:	Nicholson Center Florida Hospital
3a. Additional Author/Presenter Name and Degree	Courtney Graddy, MS
3b. Hospital / Institutional Affiliation(s) for Co-Author:	Nicholson Center Florida Hospital
4a. Additional Author/Presenter Name and Degree	Khara Simpson, MD
4b. Hospital / Institutional Affiliation(s) for Co-Author:	Nicholson Center Florida Hospital
5a. Additional Author/Presenter Name and Degree	Arnold Advincula, MD
5b. Hospital / Institutional Affiliation(s) for Co-Author:	Columbia University Medical Center
6a. Additional Author/Presenter Name and Degree	Manuela Perez
6b. Hospital / Institutional Affiliation(s) for Co-Author:	Nicholson Center Florida Hospital
Title of Presentation *	Randomized controlled study comparing robotic simulation versus didactic teaching for robotic surgical training: opinions and perspectives

Type of Submission *	Scientific Paper
Submission Category *	Multispecialty

Abstract Text (250 words or less) *

Objective:
To compare surgical trainees and trainers' perspectives on two robotic surgery training approaches: didactic lecture versus surgical simulation.

Methods :
Prospective randomization of subjects with various surgical experience levels to two different surgical training groups: didactic lecture (DG) or robotic simulation (SG). Each group had the same amount of training. Prior to and after the training sessions, subjects completed questionnaires evaluating their training experience (including preparedness for surgery), and perspectives of both training methods, regardless of their assigned group. Subjects subsequently performed a robotic cystotomy repair on a live porcine model, followed by completion of a post-procedure questionnaire.

Results:
Both groups (total n= 125; DG n=64; SG n=61) were similar in age, gender, role, and total number of robotic cases. The majority of subjects had prior robotic simulator use, DG>SG ($p = 0.04$). Both groups felt that neither one training method alone was sufficient for robotic surgical training, both before and after the training session. The didactic group (70%) felt more prepared than their simulation counterparts (45%) to perform a robotic procedure after their training session. However, both groups would select simulation for training if they could only chose one method (SG 87%, DG 90% before training; SG 93%, DG 94% after training).

Conclusions:
Although surgical trainees and trainers agree that simulation should be included in robotic surgical training, a multi-modality approach that includes both robotic simulation and didactic teaching is preferred. The effectiveness of the combination of both methods on surgical training and performance need to be further explored.

Will your participation include discussion of any commercial products or services? *	No
Within the past 12 months, did you and/or your spouse/partner have an affiliation and/or relevant financial relationship with a commercial interest that produces, markets, re-sells, or distributes health care goods or services, consumed by, or used on, patients with the exception of non-profit or government organizations and non-healthcare related companies? *	No
Grant/Research *	Yes
List Corporation(s)/Organization(s) for Grant Research *	grant from the United States Army Medical Research and Materiel Command (USAMRMC) and its laboratories

	identified herein through the U.S. Army Medical Research Acquisition Activity (USAMRAA)
Consultant *	No
Speakers Bureau *	No
Stock Shareholder *	No
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My participation DOES / DOES NOT include the discussion of the use of products for which they are not labeled (i.e. off label use) or are still investigational. *	Does Not
I agree to make my presentation in an unbiased manner. *	Yes
Will your participation only include generic names? *(Please note: You must answer NO if your presentation includes a product name, such as "daVinci Robot".)* *	Yes
Are you receiving financial compensation from the company(s) listed on this disclosure for your participation in this activity? *	No
Signature *(type your full name)* *	Mireille Truong
Enter Today's Date *	Friday, May 16, 2014

GEARS Study

SLS Abstract

Validating the Efficacy of GEARS through the Assessment of 100 Videos

Objective: To evaluate the use of the GEARS assessment to distinguish varying robotic surgical experience. To identify additional variables that may increase the reliability and accuracy of GEARS.

Methods: Videos were collected for 104 medical students and surgeons performing a simple cystotomy closure on an animate model. Subjects were divided into three groups based on their robotic experience. Reviews were performed by three surgeons (inter-rater reliability 0.95 cronbach's alpha) using GEARS, errors and tasks assessments. Statistical analysis was performed to determine the validity and internal consistency of GEARS as well as its correlation with the independently developed errors and tasks check lists.

Results: There were differences between task time, GEARS, error and task metrics across experience groups (p = 0.01). For the individual categories of GEARS, all were able to differentiate between experience groups. Bimanual dexterity and efficiency were the best at differentiating intermediates (26-100 robotic cases) from experts (>100). In the evaluation of errors, missed targets, needle drops, tissue damage, and instrument collisions were statistically different among groups and instruments out of view, needle re-loading, tissue re-grasping were not. Instrument collision and needle drops showed the greatest differentiation among groups. GEARS had internal consistency (cronbach's alpha 0.88) and construct validity (p=<0.001).

Conclusions: This is the first study to confirm the ability of GEARS to differentiate robotic surgical experience at all levels of training. While errors and task assessment also showed differences among experience levels, they were less reliable than GEARS.

INTRODUCTION:

The inception of robotic surgery has changed the face of surgery by providing an additional means to completing more complex procedures in a min. invasive fashion. While there are obvious parallels with traditional laparoscopic surgery, endowrist manipulation and lack of haptic feedback represent significant differences. Due to its unique interface, robotics has necessitated device specific training and evaluation. To this aim, several robotic surgical simulators have been developed and validated. The Fundamentals of Robotic Surgery (FRS) is also being trialed and validated to offer specialty non-specific didactic and simulation training, including a high stakes test.

For objective in-OR and video assessment, the global evaluative assessment of robotic skills (GEARS) is used most often. GEARS, similar to GOALS (a validated laparoscopic objective assessment tool), is a six-item objective assessment using a Likert scale. The six fundamental skills assessed are: depth perception, bimanual dexterity, tissue handling, efficiency, autonomy, and robotic control. The first five skills are the same as GOALS. The five point likert scale has definitions associated with 3 of the 5 scores. GEARS has been found to have construct validity, and good intra and inter-rater reliability (Goh et al 2012). No studies have been done evaluating its ability to differentiate levels of expertise and which skills sets/categories best correlate to proficiency/surgeon expertise level. We propose to evaluate the above as well as to test additional structured objective assessments (error based and task based scoring) to better categorize GEARS.

Our hypothesis is that collisions and tissue damage will be highly associated with novice performance and instrument out of view will be a less discriminatory factor for experts.

BACKGROUND

GOALS was created from the concept of OSATS which includes the objective assessment of skills and a task assessment.

METHODS

Archived videos and assessments were reviewed for 100 surgeons performing a simple cystotomy closure. Previous assessements included the GEARS and an addendum questionnaire regarding errors and task assessment. The errors were designed to correlate with each of the GEARS items. (Look below). Reviews were performed by three independent reviewers whose interrater reliability was .95 via cronbach's alpha. The trained reviewers were all familiar with robotic surgery and included two minimally invasive fellows and an attending surgeon. Training consisted of reviewing the GEARS, encouraging full use of the scale, and a focus on documentation of only confirmed errors. Reviewers were blinded to the experience level of the surgeons. Intra questionnaire correlation was performed within the GEARS as well as with the addendum questionnaire to determine internal consistency. An ICC was performed for the total GEARs score as well as with the deletion of each item. A similar process was performed for the task and error portion of the questionnaire. Finally the overall scores of each (GEARS, task, error) were compared to see if there was a relationship. The mean and median scores were calculated for each based on experience levels. Compare each item with experience level to determine which item most correlated with the three experience categories. Scatterplot graphs were performed comparing the number of robotic surgeries peformed with the total GEARS scores, errors, and tasks. Confirm that the developed errors and task questions correlated with the initially identified items in GEARS.

GENERAL ANALYSIS

1. Mean and median score for each experience group for the GEARS, errors, and task assessment. Determine if these differences are statistically different. HYPOTHESIS: there will not be a statistically significant difference between intermediates and experts but it will be present between novices and experts. RESULTS – There were statistically significant differences across all experience levels.

2. Identify which components of the GEARS or errors or task assessments where there are statistically significant differences – item by item by analysis.

3. Looking at correlation between the items with no statistical significance to determine if associated task or error components gave better differentiation between the two groups.

SUB-ANALYSIS

1. Identify relationships between the associations between GEARS items and the errors and task (see below) HYPOTHESIS:

2. Come up with a total score/equation including the GEARS, errors (neg scoring), and tasks….compare that to the different experience levels and see if there is a statistically significant difference among the groups

RESULTS

CONCLUSION/DISCUSSION

Considerations – We did not fully evaluate the benchmark of autonomy. As noted above subjects were given the same task to complete without assistance. Reviewers in most cases gave

LIT REVIEW: Google scholar search term GEARS

<u>GEARS: Original study</u>

Jan 2012 Goh et al – Journal of Urology

- Used expert consensus to identify an objective assessment tool for the eval of robotic surgeons – GOALS with an additional variable for robotic control

- Determined to have good internal consistency and reliability. Also established construct validity but interestingly enough could not differentiate PGY-6 (avg surgical cases 30) from expert level surgeons (avg surgical cases 190)

- 4 attg surgeons, 25 trainees (PGY4-6)

<u>Teaching surgical skills – Reznick NEJM 2006</u>

Reviews changes in medical education and considerations for the future

Traditional halstedian model of education stems from education through volume of patients. With current advances in medicine the people are living longer, increasing the complexity of conditions. Certain conditions are becoming increasingly more rare as well. We also have to contend with work hour shortages. To improve/strengthen training and exposure – we are turning to simulation for orientation and to improve outcomes.

Learning Tools and simulation in Robotic Surgery: State of the Art – Citation Pubmed

-Fitts and Posner's 3 stage theory of motor skill acquisition – suggests that in the first phase the learner is more focused on the steps of the material and typically is less coordinated. This suggests that maybe this stage of learning should be performed in a non-lethal environment

Perform searches on FLS/OSATS/Goals/Include RTN

Conclusions – (Discussion) Unable to differentiate between intermediate and expert level surgeons with GEARS alone. Need another variable or term for surgical skills.

-Limitations – Did not fully assess autonomy – everyone defaulted to a 5.

Meeting Notes 4/28/14

Correlations between GEARS and errors

1. Depth perception – Intstrumentation
2. Bimanual dexterity – Needle Handling and
3. Tissue Handling – Tissue handling
4. Efficiency – Time
5. Autonomy – Nothing/didn't fully evaluate
6. Robotic Skills – Instrumentation and needle handling and tasks

Florida Hospital Internal Research Conference
Abstract Submission Form

Title: A Comparison of the Effectiveness and Usability of Robotic Simulators

Names & Titles: Alyssa Tanaka, Mireille Truong MD, Khara Simpson MD, Manuela Perez MD, Roger Smith PhD

Affiliations of Author and/or Department: Nicholson Center

Category: Clinical/Innovation

ABSTRACT

Background: Simulation was first introduced into robotic surgical training with the goal of teaching surgeons new skills and assessing a surgeon's skill acquisition over time. A number of robotic simulators have been introduced to support these aims. The three daVinci surgical robotic simulators that are currently available for training include the daVinci Skills Simulator (Intuitive Surgical), the dV-Trainer (Mimic Technologies) and the RoSS (Simulated Surgical Systems). Given that the introduction of these technologies is still relatively recent and the field of minimally invasive surgery has seen rapid advancement, there is a need to develop effective training curriculums and to identify simulation devices that will best achieve these goals. While there have been multiple validation studies evaluating each of these simulators, to our knowledge, there are no other studies that compare the manufacturer specifications and the usability of all three robotic simulators.

Purpose: To compare the value and usability of the three daVinci robotic surgical system simulators while evaluating for face and content validity.

Methods: The first phase of the analysis is an objective review and comparison of the system design and capabilities of each of the simulators. A systematic literature review was conducted to retrieve information on the training exercise modules, scoring systems, costs, educational impact, and validation methods of each of the three simulators. The findings from the literature search were then submitted to the manufacturers of each system for the review of the accuracy of the information.

The second phase of the analysis is a subjective evaluation of the usability of the systems. Data is being gathered via opinion-based questionnaires from medical students and surgeons of various expertise levels. The participants first complete a demographics questionnaire detailing their background information including their experience with minimally invasive surgery and robotic surgery. Subjects then complete one exercise on each of the simulators in a randomly assigned order and provide feedback describing their experience immediately following completion of each exercise. After completing all exercises, the participants complete a final

questionnaire providing feedback on their overall experience using all three simulators. Exercises selected on each simulators tested similar skills and were of same difficulty level.

Results: The results of the first phase of the study detail the characteristics, exercise modules, scoring systems, costs, validity, advantages, and disadvantages of each simulator and provide a comprehensive chart comparison of the three simulators.

For the second phase of the study, we will perform an interim analysis of subjects completed to-date. This analysis will be presented at the conference.

Conclusion: Each of the simulators possesses specific qualities and capabilities that could be beneficial to a variety of different users and training programs.

Please select Print from the file menu to print your Abstract.

43rd AAGL Global Congress on Minimally Invasive Gynecology

Abstract Number: 450754
Presenting Author: Mireille Truong, Fellow
Correspondence Contact: Mireille Truong, MD
Institution: Columbia University Medical Center
Address: 200 W 60th Street, apt 18H
City / State / Zip / Country: New York, NY, 10032, United States

DISCLOSURE INFORMATION

Author: Mireille Truong

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Off Label: I do not have any "off label" uses in my presentation

Signature: I verify, that all of the above disclosures are true.

Signature Name: Mireille Truong

Signature Date: May 1, 2014 2:06 am

Author: Alyssa Tanaka*

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Signature Name: Alyssa Tanaka

Signature Date: May 1, 2014 2:07 am

Author: Khara Simpson*

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Signature Name: Khara Simpson

Signature Date: May 1, 2014 2:09 am

Author: Arnold Advincula*

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Signature: I verify, that all of the above disclosures are true.

Signature Name: Arnold Advincula

Signature Date: May 1, 2014 2:31 am

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QUESTIONNAIRE INFORMATION

1. Application for: Abstract or Poster

2. Type of Abstract: Educational

3. Category: 2. Education

4. Type of Award: Jerome J. Hoffman Award for Best Postgraduate Paper on MIGS (Residents and Fellows in training and from any program may apply)

5. Is this abstract original? Yes

Title: A prospective randomized controlled comparative study on surgical training methods and impact on surgical performance: virtual reality robotic simulation vs didactic lectures

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Objective: To compare two learning methods, structured didactic lecture versus virtual reality surgical simulation, and evaluate their effects on surgical performance.

Design: Prospective randomized trial

Setting: Community teaching hospital and robotic gynecologic surgery courses

Patients: Medical students (n=6), residents (n=14), fellows (n=28), and attendings (n=76) were enrolled

Interventions: Subjects, based on surgical experience level, were randomly assigned to either the Simulation Group (SG), which rehearsed on the dv-Trainer robotic simulator; or to the Didactic Group (DG), which received a structured lecture. After completing a written post-preparation test, all participants performed a video-recorded cystotomy repair on a live porcine model. Time and performances were compared using GEARS and independently

developed error and task metrics.

Measurements & Main Results: Total n= 125 (52 novices, 42 intermediates, 27 experts). Both groups (DG n=64; SG n=61) were similar in age, gender, role, and total number of robotic cases. The majority of subjects had prior robotic simulator use, DG>SG (p = 0.04). Mean cystotomy repair time was similar in both groups (DG=224min; SG=219min, p=0.83). The overall performances between SG and DG were not significantly different (p value= 0.18 – 0.83) but when controlled for experience level, SG (vs DG) novices had more errors and lower task assessment scores (p value 0.03 and 0.05). No differences were noted between learning groups amongst intermediates and experts.

Conclusions: Simulation and didactic approaches both offer certain advantages for surgical training. Although differences were not seen between the two training methods, many factors may have influenced these results such as simulator training type, task complexity and length; realism of simulation exercise to actual procedure; and differences in information presented with each method. Both cognitive and psychomotor skills are required for surgical competence; therefore the effect of the combination of both modalities rather than a single modality for surgical training should be further explored.

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