

From Design to Conception: An Assessment Device for Robotic Surgeons

Alyssa Tanaka, M.S.

Florida Hospital Nicholson Center

Celebration, FL

Alyssa.tanaka@flhosp.org

Manuela Perez, M.D.

University Hospital of Nancy

Nancy, FR

m.perez@chu-nancy.fr

Mireille Truong M.D., Khara Simpson M.D.

Columbia University Medical School

New York, NY

Mireille.truong@gmail.com, kmsimpmd@yahoo.com

Gareth Hearn, Roger Smith, Ph.D.

Florida Hospital ISA, Florida Hospital NC

Orlando, FL, Celebration, FL

Gareth.hearn@flhosp.org, roger.smith@flhosp.org

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

Alyssa D.S. Tanaka, M.S. is a Systems Engineer at Florida Hospital's Nicholson Center. Her research work focuses on robotic surgery simulation and effective surgeon training. Her current projects include rapid prototyping of surgical education devices, the validation of a robotic surgical curriculum and evaluation of robotic simulation systems. She is a Modeling and Simulation PhD student at the University of Central Florida and previously earned a M.S. in Modeling and Simulation, Graduate Simulation Certificate in Instructional Design, and a B.S. in Psychology and Cognitive Sciences from the University of Central Florida.

Manuela Perez, M.D. 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, M.D. 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, M.D. 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.

Gareth Hearn a Mechanical Engineer at the Institute for Surgical Advancement, part of Florida Hospital Orlando. He is responsible for the Prototype Design Lab which is focused on minimally invasive surgical devices and positioned to accelerate the product development cycle. He has 8 years' experience working in the Dept. of Defense training and simulation industry. He is pursuing a Master's in Systems Engineering at the University of Florida and has previously earned a B.S. in Mechanical Engineering from UF.

Roger Smith, Ph.D. 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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m.perez@chu-nancy.fr**

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**Columbia University Medical School
New York, NY
Mireille.truong@gmail.com, kmsimpmd@yahoo.com**

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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.).

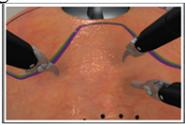
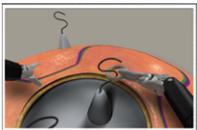
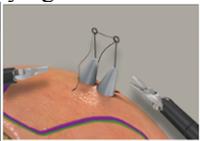
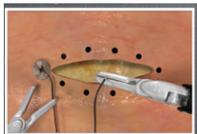
This paper discusses the process for designing and creating the physical device, known as the FRS dome. The purpose is to share the evolution of an idea to a usable device. The dome was conceived by experts who identified a clear need for robotic education and collectively developed a solution to fill 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.

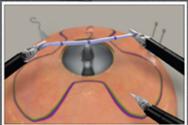
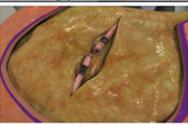
BRAINSTORMING AND CONCEPT DEVELOPMENT

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 exercises 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
<p>Task 1: Docking & Instrument Insertion:</p> 	<ul style="list-style-type: none"> - Docking - Instrument insertion - Eye-hand coordination - Operative field of view
<p>Task 2: Ring Tower Transfer:</p> 	<ul style="list-style-type: none"> - Eye-hand coordination - Camera navigation - Clutching - Wrist articulation - A-traumatic handling
<p>Task 3: Knot Tying:</p> 	<ul style="list-style-type: none"> - Knot tying - Suture handling - Eye-hand coordination - Wrist articulation
<p>Task 4: Railroad Track:</p> 	<ul style="list-style-type: none"> - Needle handling & manipulation - Wrist articulation - A-traumatic handling - Eye-hand coordination

<p>Task 5: 4th Arm Cutting:</p> 	<ul style="list-style-type: none"> - Multiple arm control & switch - Cutting - A-traumatic handling - Eye-hand coordination
<p>Task 6: Puzzle Piece Dissection:</p> 	<ul style="list-style-type: none"> - Sharp and blunt dissection - Cutting - A-traumatic handling - Eye-hand coordination - Wrist articulation
<p>Task 7: Vessel Energy Dissection:</p> 	<ul style="list-style-type: none"> - 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).

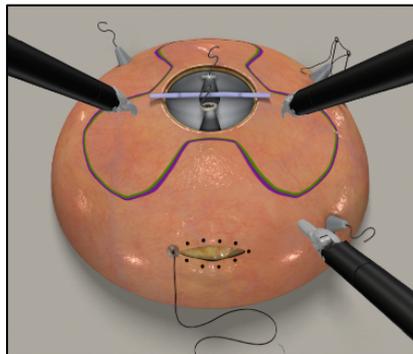


Figure 2. The initial 3D graphic FRS dome design

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 shape, 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 that 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 the 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 exercise sets could be grouped to allow them 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, allowing 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, which 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 lower costs for the materials used during training.

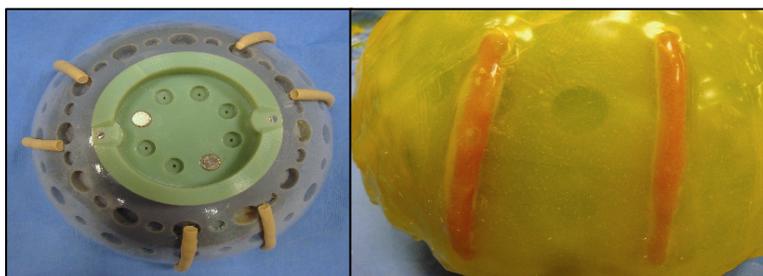


Figure 7. Vessel placement on dome and in fat

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 cannot be used on silicone. 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).

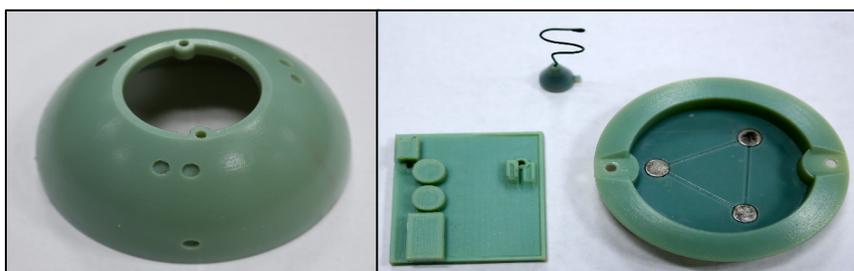


Figure 8. Final 3D printed dome shell

Since this device will be used for training and education, a high level of standardization is necessary. For this we added small markers that ensure 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	
<p>Tower tongues</p> 	Used to orient the towers in the correct direction for each exercise.
<p>Triangle in lid</p> 	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.
<p>Tower orientation markers</p> 	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.

<p>Triangles on dome shell</p> 	<p>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.</p>
<p>Triangles on fat</p> 	<p>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.</p>
<p>Triangles on skin</p> 	<p>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.</p>
<p>Cap placement notch</p> 	<p>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.</p>

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).

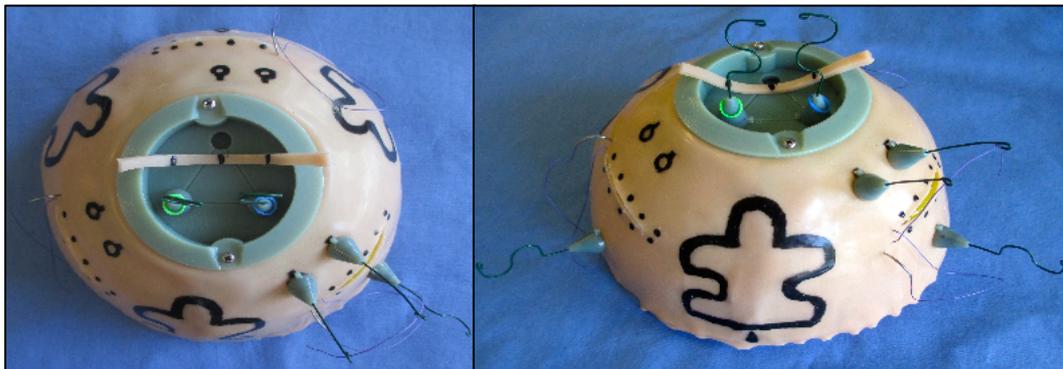


Figure 9. Final HFP

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).

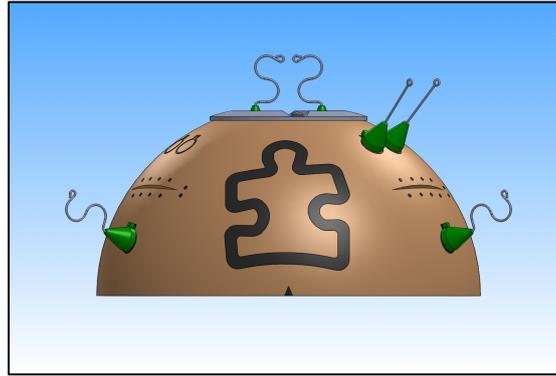


Figure 10. Final CGI

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 (Figure 11). Both systems contain the six FRS exercises, but vary in their software and hardware. 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. These simulations give the users experience performing the FRS exercises without requiring the use of the entire robotic surgical system. Generally, the systems are dedicated resources to the hospital surgical department and difficult to reserve for training purposes. The simulators also allow unlimited practice sessions without consuming the physical materials of the dome. The research team worked with each of the simulator companies to create and test multiple prototype versions of the exercise software. Our extensive experience with the real materials and our surgeons' experience with human surgery allowed us to critically evaluate the simulated behaviors of materials and the scoring methods. This feedback has led to significant improvements in the accuracy and usability of the simulators.



Figure 11. Mimic dV-Trainer and Sionix's dVSS simulated dome exercises

Maintaining the simulated physical properties of the dome was paramount. Since the simulations may be used without proctors, the physical behaviors have a considerable impact on the scoring metrics and guidance that is given for improving performance. The research team evaluated the simulated exercise properties including elasticity of materials, flexibility of sutures, simulated gravity, and the effects of excess force on the virtual device to ensure that it behaved similar to the real dome. The real materials however were also limiting to some of the desired qualities, particularly in the vessel dissection exercise. The silicon-based materials act as insulators, preventing cauterization of the small vessel. Both simulators allow the user to apply energy for cauterization, as well as receiving a visual indication that the vessel is losing blood, prompting the user to manage the situation appropriately.

Some of the metrics also varied between the physical and simulated domes. While the physical dome is scored via expert video reviewing, the simulator can more objectively assess a user's performance. This allows the

simulated exercises to score some errors more accurately, such as instruments being out of view for a specific amount of time and over a specific distance.

The research team will include these simulations in a pilot study and provide the simulation companies further formative feedback on the usability of their systems, to mitigate complications that may occur during the larger multi-site validation study that will follow. This pilot study will also establish preliminary scoring benchmarks based on expert performance, which will be used to guide the multi-site validation study.

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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