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TITLE: Comprehensive Training Module for the Repair of a Full-Thickness Injury to the Ureter

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1. INTRODUCTION

The goal of this project is to develop a complete training program, including didactic content, a hands-on desktop physical simulator, and a set of assessment rubrics addressing ureteral trauma repair techniques to help train general and trauma surgeons. Additionally, the instructional utility of the training platform will be evaluated.

2. KEYWORDS

Urology, trauma, reconstruction, surgery, training, simulation, ICTL, surgery in the deployed environment

3. ACCOMPLISHMENTS

What were the major goals of the project?

Specific Aim 1: Develop a curriculum and modular training platform that includes didactic content, a physical trainer, and assessment instruments that allows for training selected approaches to ureteral injury prioritized by an advisory committee of GU trauma experts.

Major Task 1: By developing a part task trainer that will allow urologists to practice traumatic ureteral repairs when they don't encounter enough patient cases (5/yr.) to maintain their competence and prepare general and trauma surgeons to perform these repairs if deployed to meet the needs of the DoD. (12 months) – **In progress**

- Subtask 1 – Perform Cognitive Task Analysis (CTA) to capture all salient information of procedure (2 months – **100% complete**)
- Subtask 2 – Develop instructional approach and didactic content in support of CTA (4 months – **35% complete**)
- Subtask 3 – Evaluate and design alternative solutions to core components as identified within CTA, select best approach (4 months – **75% complete**)
- Subtask 4 – Integrate all aspects of design into complete training platform (6 months – **5% complete**)

Milestone: TRL 5 prototype

Major Task 2: By developing the manufacturing process to move the part task trainer into a production environment we can reduce cost and support the training requirements of the providers. (6 months) – **Ongoing – task integrated into overall design.**

- Subtask 1 – Modify critical components for manufacturability (2 months)
- Subtask 2 – Select manufacturing processes for production and assembly at volume (2 months)

- Subtask 3 – Run test at volume to support utility study and verify manufacturing processes (4 months)

Milestone: Trainer developed to TRL 7, ready to assess training utility with clinicians and educators

Specific Aim 2: Evaluate the instructional utility of the training platform as perceived by clinical instructors, measured using a visual- analogue scale tailored to the metrics of simulator fidelity and training system utility.

Major Task 3: By aligning design and fidelity with the CTA of the procedure we maximize the utility and usability of the trainer for the learners (8 months) – **In progress**

- Subtask 1 – Study design to evaluate educational utility of the system and its components (1 month – **60% complete**)
- Subtask 2 – IRB & OHRO process (2 months)
- Subtask 3 – Data collection (3 months)
- Subtask 4 – Data analysis and document findings (2 months)

Milestone: Usability and utility assessed

What was accomplished under these goals?

Major Task 1: By developing a part task trainer that will allow urologists to practice traumatic ureteral repairs when they don't encounter enough patient cases (5/yr.) to maintain their competence and prepare general and trauma surgeons to perform these repairs if deployed to meet the needs of the DoD. – **In progress**

- Subtask 1 – Perform Cognitive Task Analysis (CTA) to capture all salient information of procedure
- Subtask 2 – Develop instructional approach and didactic content in support of CTA
- Subtask 3 – Evaluate and design alternative solutions to core components as identified within CTA, select best approach
- Subtask 4 – Integrate all aspects of design into complete training platform – Not yet initiated

Subtask 1: Perform Cognitive Task Analysis (CTA) to capture all salient information of procedure.

The CTA process was completed with the assistance of four practicing military and civilian urologists. This process identified the key salient information necessary to populate the curricular elements, and physical requirements of the part-task trainer.

Following its completion, the CTA product was verified by a panel of experts via a modified Delphi protocol. Surgeons with expertise in reconstructive urology participated in the first round (n=8) and

second round of review(n=7). At the conclusion of the modified Delphi protocol (on May 26, 2023), all surgeons reached consensus: that all of the items identified on the CTA were comprehensive and complete.

We generated a list of learning objectives, performed task deconstruction, and then matched learning objectives with optimal training modalities taking into consideration cost containment for what ultimately would need to be a deployable product (**Table 1**).

Table 1: Learning Objectives and Corresponding Training Modalities

Step	Objective	Modality
Pre-Op	To decide if a laparotomy should be performed	Didactic
Incision	To decide if the incision adequate for access to ureter and suspected location of injury	Didactic / Interactive Media
Retract Omentum	To decide if the field of view is prepared to review anatomy	Didactic / Interactive Media and Physical Trainer
Inspect Anatomy	To decide if there are any other injuries present that need to be attended to first	Didactic / Interactive Media and Physical Trainer
Manage Bowels	To decide if the bowels are appropriately managed to allow for ureter, and injury identification.	Didactic / Interactive Media and Physical Trainer
Identify Ureter	To decide if the ureters have been correctly identified, permitting the progression to ureter dissection.	Didactic / Interactive Media and Physical Trainer
Identify Injury	To decide if there are any ureteral injuries present, and their locations	Didactic / Interactive Media and Physical Trainer
Incise Posterior Sheath	To decide if ureter dissection may begin.	Didactic / Interactive Media and Physical Trainer

<i>(for Intermediate for Distal Repair Only)</i>		
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Step	Objective	Modality
Inspect Injury + Plan Dissection	To decide if ureter dissection may begin	Didactic / Interactive Media and Physical Trainer

Step	Objective	Modality
Dissection and Debridement	To decide the type, and extent of the repair needed	Didactic / Interactive Media and Physical Trainer

Step	Objective	Modality
Alignment	To decide if spatulation may begin.	Didactic / Interactive Media and Physical Trainer

Step	Objective	Modality
Spatulation	To decide if anastomosis may begin	Didactic / Interactive Media and Physical Trainer

Step	Objective	Modality
Begin Anastomosis	To decide to continue the completion of the anastomosis and place the stent.	Didactic / Interactive Media and Physical Trainer

Step	Objective	Modality
Place Stent	To decide if the anastomosis may be completed	Didactic / Interactive Media and Physical Trainer

Step	Objective	Modality
Complete Anastomosis	To decide if the Anastomosis was successfully completed	Didactic / Interactive Media and Physical Trainer

Step	Objective	Modality
Cover Anastomosis	To determine if the abdomen may be cleaned and inspected	Didactic / Interactive Media and Physical Trainer

Step	Objective	Modality
Clean + Inspect	To decide if it is time to close the abdomen.	Didactic / Interactive Media

Step	Objective	Modality
Close	To decide if it is time to close the incision.	Didactic / Interactive Media

Step	Objective	Modality
Post-Op	To decide the post-operative course of action	Didactic / Interactive Media

Subtask 2: Develop instructional approach and didactic content in support of CTA

For those learning objectives not addressed with the physical trainer and in line with the completion of the Delphi protocol, and verification of the CTA content, we began the process of content sequencing, in preparation for integration into an online learning management site, Moodle. In addition to content sequencing, we also identified media-based assets which will be necessary to support our text-based content. **Figure 1** depicts some of the media assets that will be necessary to support the content specific to the technical approaches which will be taught in the curriculum and completed by trainees on the physical simulator. Media assets have also been identified for the curriculum introduction sections, as well as the two patient cases that will be completed on the simulator.

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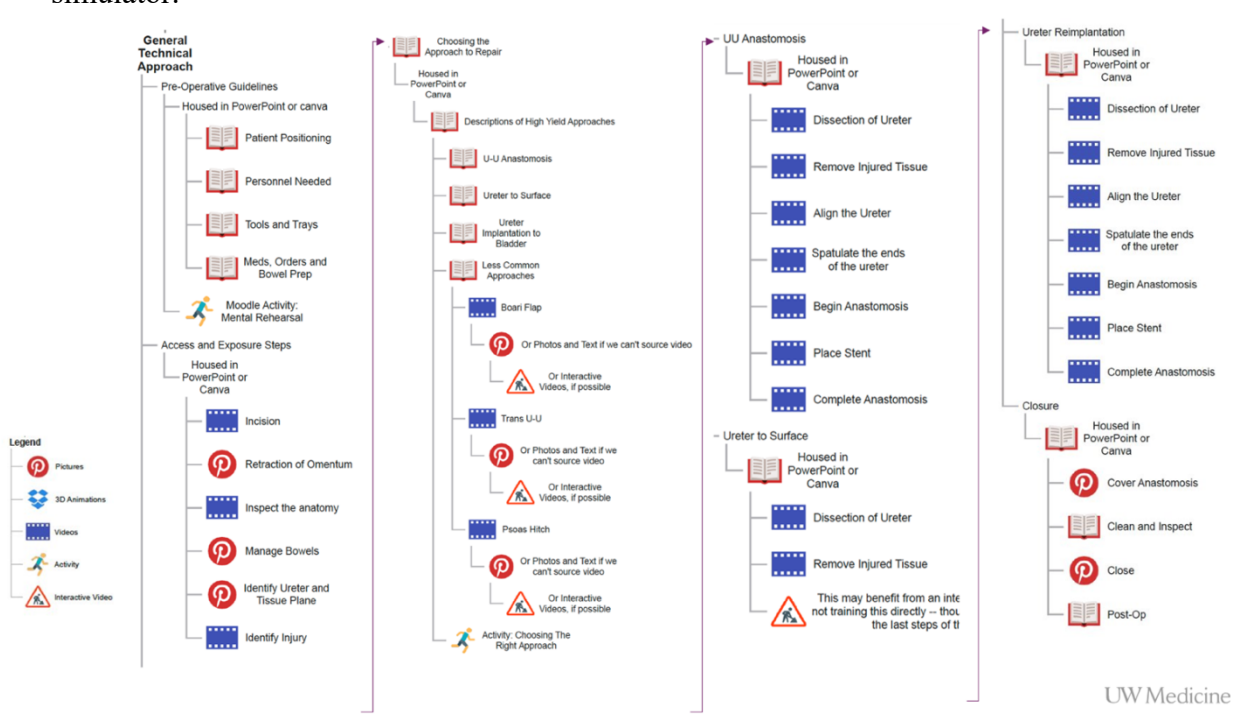


Figure 1: Media assets necessary to support the didactic and interactive elements of the training curriculum.

Media Asset Procurement

Given the relative rarity of traumatic ureteral injury, and the acuity of patient presentation that accompanies such an injury the research team has elected to rely on pseudo-perfused cadaveric specimens (rather than actual surgical videos) for most media assets required to support the text-based curriculum.

The reliance on cadaveric specimens, rather than human patients will:

- Expedite the procurement of media assets.
- Ensure that patient care is not compromised in the interest of media capture.
- Allow for optimal camera positioning and lighting to collect the best quality media, including all salient maneuvers and anatomy.
- Ensure that the patient anatomy is compatible with standard instruction, and free from irregular variations and complications.

The UW Institutional Review Board has confirmed that no specific application or documentation is necessary to utilize cadaveric material for curricular purposes. An application to the Office of Human Research Oversight (OHRO) for Cadaver Use specific to this protocol was submitted and approved on 9/27/2023. Consequently, the research team has begun coordination efforts to plan a “perfusion pilot” (anticipated October 12th, 2023) using a cadaveric specimen, perfusion, and cannulation equipment at the UW WISH simulation facility. This pilot activity will provide an opportunity to test different approaches to perfusing the cadaveric specimen, to yield the best results, prior to coordinating dates and surgeons to complete the planned media capture.

Curricular Content Scaffolding

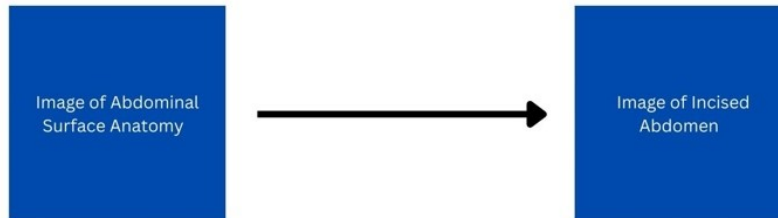
In lieu of media asset procurement, we have begun the process of preparing text-based content (derived from the CTA) for integration into Moodle. The following slides are exemplars of a subset of the preliminary content which will be positioned within the “Access and Exposure” section of the curriculum (**Figure 2**). Note that positioning (and nature) of the supporting media assets is indicated with blue boxes as placeholders.



ACCESS & EXPOSURE: MAKING THE MID-LINE INCISION

Access & Exposure: Making the Mid-line Incision

Objective: To make an incision that is adequate to access the ureter and the suspected location of injury



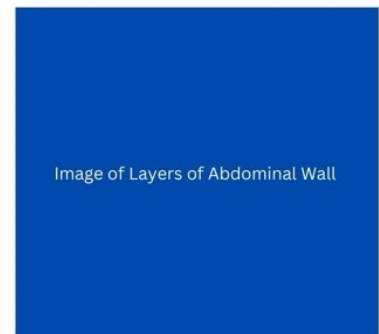
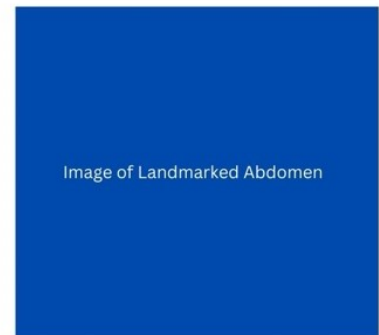
Access & Exposure: Making the Mid-line Incision

Step 1: Review Relevant Anatomy

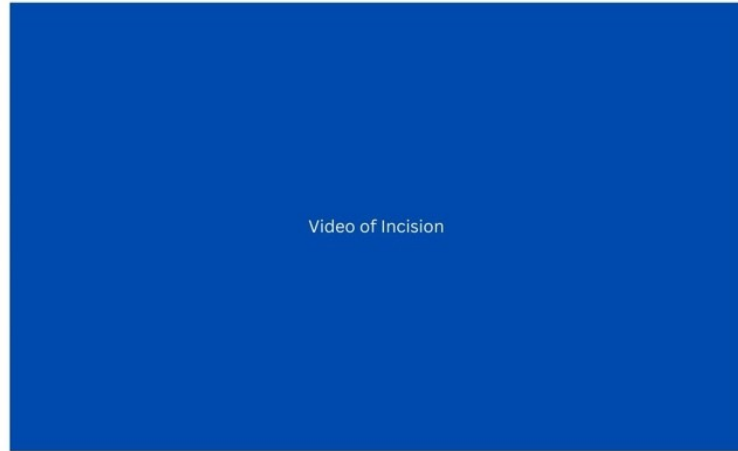
- Identify key landmarks
 - Xiphoid process
 - Pubic symphysis
 - Umbilicus

Step 2: Complete Midline Incision

- Using a scalpel, incise from the Xiphoid process (superiorly) to the level of a Pfannenstiel incision (inferiorly), and avoid the umbilicus.
- The incision should transect the entire anterior abdominal wall
 - Skin, subcutaneous fascia, the linea alba, endoabdominal fascia and the anterior sheath of the peritoneum



Access & Exposure: Making the Mid-line Incision



Access & Exposure: Making the Mid-line Incision

Technique Recommendations

- The incision should be continuous, without skyving and should be symmetrical in location
- Bleeders in the subcutaneous fascia should be addressed with cautery

Things to Watch Out For

- Hemoperitoneum
- Urine in the peritoneum
- Iatrogenic injuries to the bowel and bladder



When making your incision, stop when you can visualize the anterior sheath of the peritoneum. Before proceeding to incise the anterior sheath with the scalpel, attempt to lift the anterior sheath up and away from the body. When elevated, make a small window in it using your scalpel. This will allow access to the peritoneum without damaging the underlying structures.

Access & Exposure: Making the Mid-line Incision



Common Errors:

- Deviating the incision away from the mid-line
- Making the incision too small, limiting the exposure
- Making the incision too shallow

Ready for the Next Step?

You're ready to proceed to the next step when:

- Length and depth of the incision is appropriate to address the injury
- You can see the inferior border of the liver, and down as far as necessary to visualize the iliac vessels.

ACCESS & EXPOSURE: RETRACTING THE OMENTUM

Figure 2: CTA-Derived Content for “Access and Exposure” Portion of the General Technical Approach Piece of the Interactive Curriculum.

Interactivity of Curricular Elements

Efforts to integrate interactivity into the training curriculum housed on Moodle have been successful. Moodle supports several interactive technologies, and two have been identified for their ease of use and functionality specific to the intended interactions. PlayPosit and H5P have both been tested and found to be effective mechanisms for driving interactivity in learning content. PlayPosit (**Figure 3**) will be implemented to integrate interactivity in dynamic settings (video-based media), while H5P (**Figure 4**) will be leveraged to integrate interactivity into static media (still images).

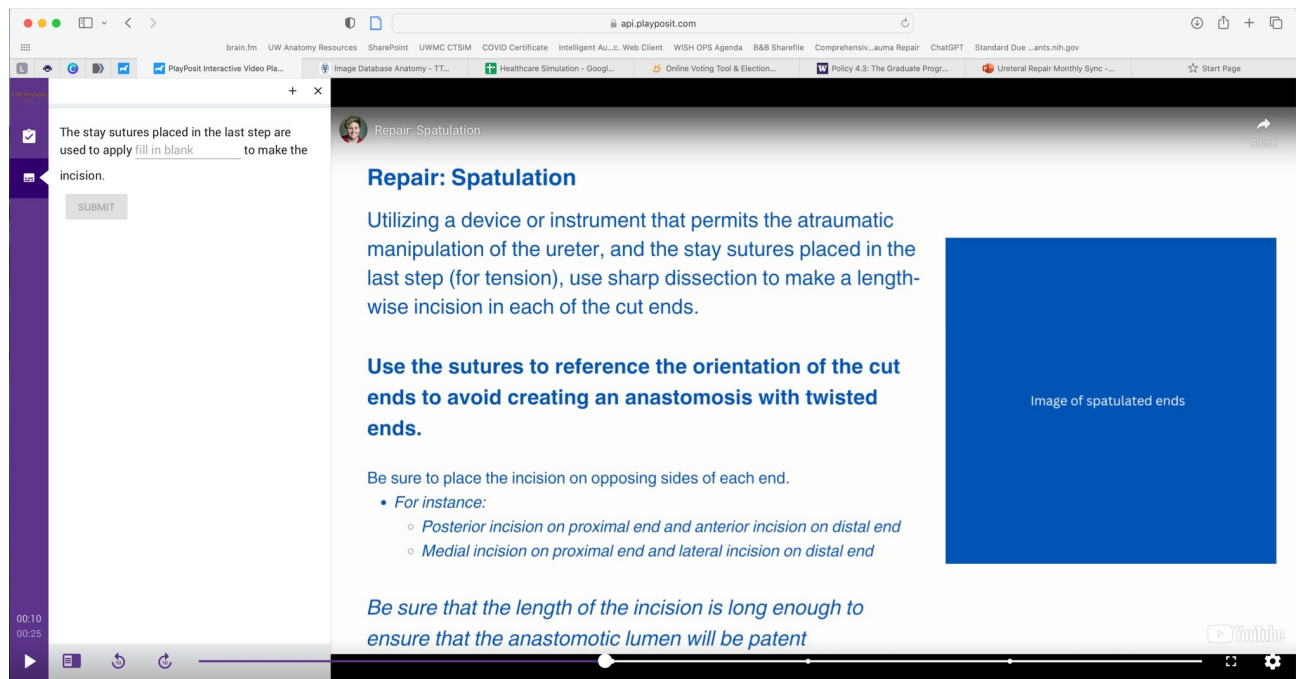


Figure 3: Visualization of interactivity resulting from integration with PlayPosit. Here a voice-over-PowerPoint presentation is paused automatically, prompting the user to respond to a question specific to the presented content.

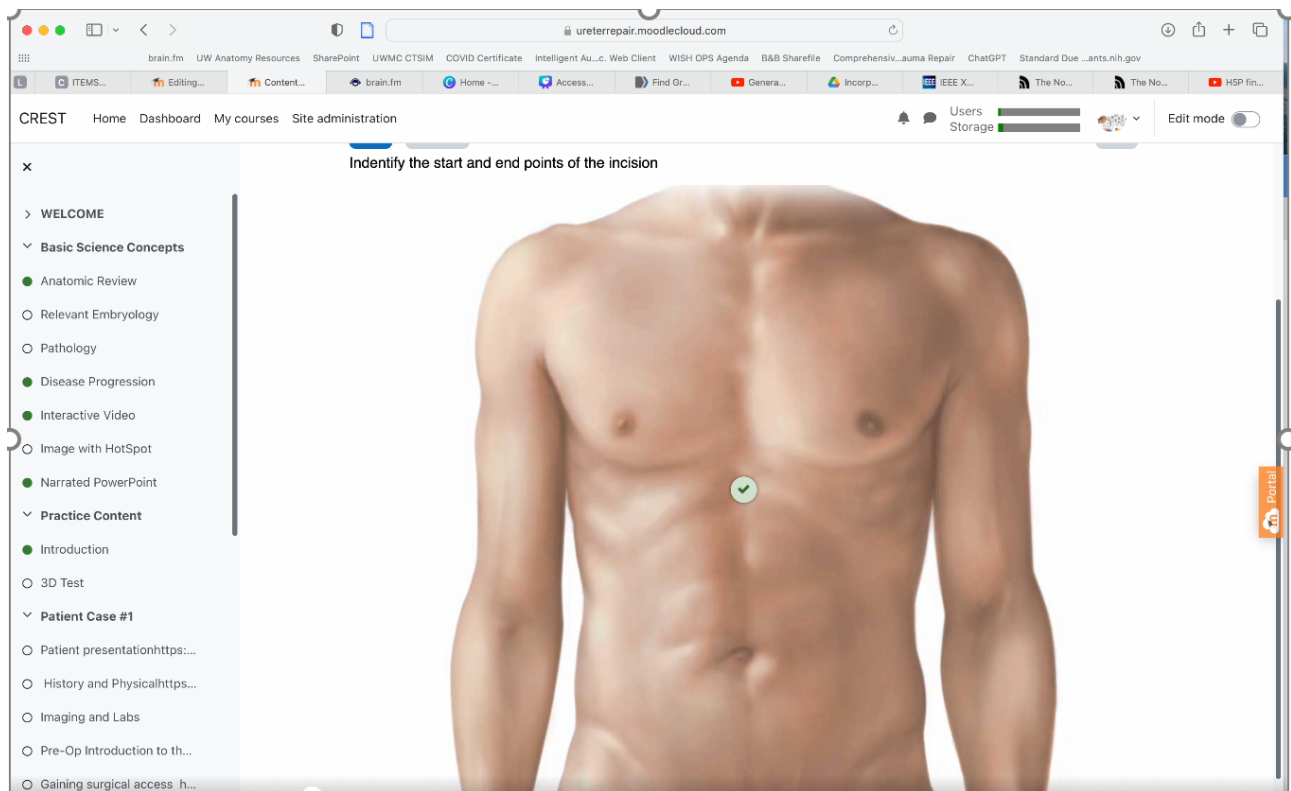


Figure 4: Visualization of interactivity resulting from integration with H5P. Here a user is provided with a prompt to interact with specific regions on a still image. The user is provided with feedback based on their selection accuracy.

Development of Trainee Assessment Instrument

At present, no widely accepted assessment instrument exists to evaluate the knowledge and skills specific to the performance of ureteral repair. To remedy this, the CTA end-product was investigated to identify all skills necessary for successful completion, Each skill was then mapped to a domain (Psychomotor/Dexterity, Medical/Procedural Knowledge, Cognitive & Medical/Procedural Knowledge, and Cognitive & Medical/Critical Thinking/Decision Making), and paired with a metric for evaluation. Each metric was then identified as either being integrated into the part-task trainer (automatic), or as requiring feedback from a trained observer. This preliminary process yielded a preliminary 47-point assessment instrument (**Figure 5**). This instrument will be piloted to a small cohort of subject matter experts for iterative review, and to collect evidence of the instrument's validity for use in this training context.

Step	Objective	
Spatulation	To decide if anastomosis may begin	Domain
Skill	Ureter Handling	Medical/Procedural Knowledge
Metric	Are only devices that permit the atraumatic manipulation of the ureter used?	Result
Feedback	<i>Contact with the ureter itself should be minimized to avoid tissue damage. Manipulation should occur by way of fine stays sutures, or the surrounding periureteral tissue wherever possible.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Step	Objective	
Begin Anastomosis	To decide to continue the completion of the anastomosis and place the stent.	Domain
Skill	Suture Placement	Cognitive & Medical/Critical Thinking/ Decision Making
Metric	Are the sutures placed in the correct orientation to minimize rotation?	Result
Feedback	<i>If the sutures are not oriented correctly, the two ureteral ends will attempt to roll away from each other, potentially causing twisting and ischemia?</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Step	Objective	
Begin Anastomosis	To decide to continue the completion of the anastomosis and place the stent.	Domain
Skill	Length and Tension	Medical/Procedural Knowledge
Metric	Are the ureteral ends long enough to form a tension - free anastomosis?	Result
Feedback	<i>If the ends are too short and are stretched to reach together, excess tension on the anastomosis may result.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Step	Objective	
Begin Anastomosis	To decide to continue the completion of the anastomosis and place the stent.	Domain
Skill	Suture Quality	Psychomotor & Dexterity
Metric	Are the sutures (running or interrupted) positioned evenly?	Result
Feedback	<i>Uneven positioned sutures pose a risk for poor distribution of tension and watertightness across the anastomosis.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Figure 5: Subset of items derived from preliminary 47-point assessment instrument. Yellow shading in the results section indicates a skill which may be assessed automatically by the technology housed in the part-task trainer.

Subtask 3: Evaluate and design alternative solutions to core components as identified within CTA, select best approach

Preliminary Design work based on product requirements

After 40 hours of requirements capture, the design team met for 25+ hours to establish the physical design concept of the trainer. Upon completion of this work, the following design concept was presented and agreed upon by the team.

The trainer will consist of the following components: A rigid 3D printed base cradle, a silicone abdominal sock, a standard surgical retractor, a silicone sheet of omentum, a silicone bowel insert, two disposable ureter pucks, a replaceable bladder cap, and a rigid transport case. Each of these components will be discussed in further detail in the sections below.

Base Cradle



Figure 6: Mockup of Base Cradle and Bookwalter retractor (Left) and a mockup of the physical control interface to control peristalsis and urine leakage (Right)

The Base Cradle acts as the base of the simulator and provides the main structural support to the surgical regions presented in the abdominal sock. It provides mounting locations on both the left and right side of the simulator for the retractor and is hollow to provide interior mounting locations for systems components. This will be considered a permanent section of the simulator and the interior will likely be accessible through a panel in the bottom cradle. The superior face of the simulator will include a control panel (example shown right) to control simulated peristalsis and to access a removable fluid reservoir to fill the system with simulated urine.

Abdominal Sock



Figure 7: Outline of silicone Abdominal Sock (pink) in relation to the rigid Base Cradle (gray)

The Base Cradle will support a silicone Abdominal Sock that will provide the primary surgical field to operate within. The interior of the sock will include the following structures as visual representations obscured by a painted layer of peritoneum: lower poles of kidneys, inferior lobe of the liver, large intestine, pancreas, white line of Toldt, aorta, IVC, ureters (outside the puck), gonadal veins, fat, and peritoneum. The exterior of the sock may be created as a separate part to ease the manufacturing process and will include an ovular incision sculpted through the anterior skin and fat layers. This will be a reusable component while still allowing for replacement in the event of irreparable damage.

Retractor



Figure 8: Example of the Bookwalter Retractor used in the trainer design

A Bookwalter retractor has been selected as the most appropriate retractor for this open laparotomy procedure by our anatomist. The model shown on the right has been ordered for review and will be 3D scanned and digitally reconstructed to aid in the anatomic sculpting and engineering design of the simulator.

Omentum “Sheet”

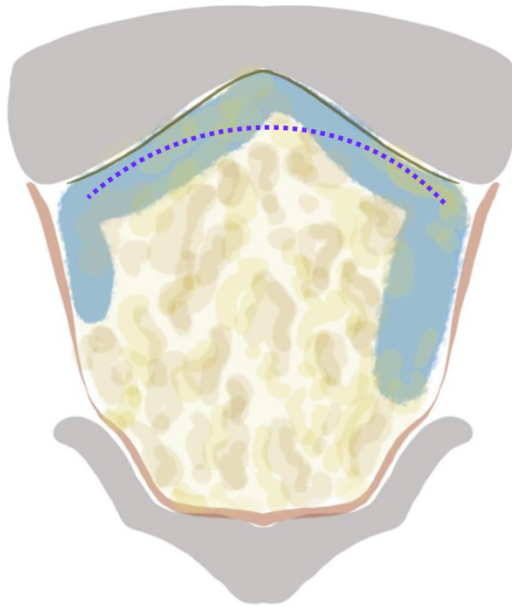


Figure 9: An outline of the Omentum (yellow) in relation to the large intestine (blue), Abdominal Sock (brown), Base Cradle (gray), and connection point (purple)

Once the laparotomy incision is created, the first step of the procedure is to reflect the omentum out of the way to gain access to the small intestine. To replicate this, an over molded sheet of silicone will be created and anchored to the superior side of the large intestine or to the base cradle. This component will be comprised of a slide-in anchoring attachment (likely printed in SLS TPU), cast into a sheet of silicone representing the omentum. This part is considered reusable while still allowing for replacement if needed.

Bowel Insert

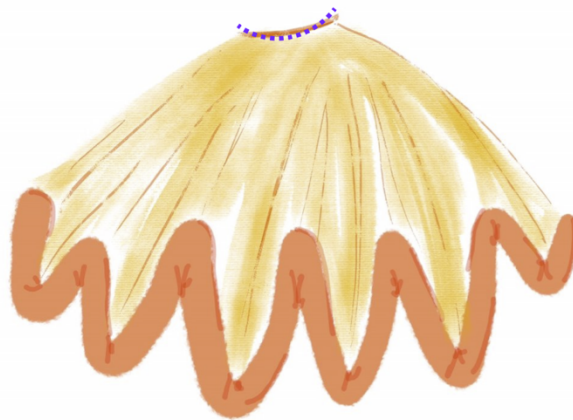


Figure 10: Diagram of Bowel Insert over-molding process. Purple indicates the anchoring location, yellow indicates the mesentery, and orange indicates the small intestine

After reflecting the omentum, the bowels need to be managed to gain access to the ureters themselves. To achieve this, a three-part bowel insert will be constructed to allow for realistic motion of the bowel during management. It will be constructed similarly to the omentum but with an additional step in the casting process to allow for the bowel and mesentery tissue to be created separately and over molded for strength and ease of manufacturing. This assembly will be anchored through the silicone abdominal sock to the rigid base cradle in an anatomically correct location to emulate the adherence to the posterior abdominal wall at the root of the mesentery.

Ureter Pucks

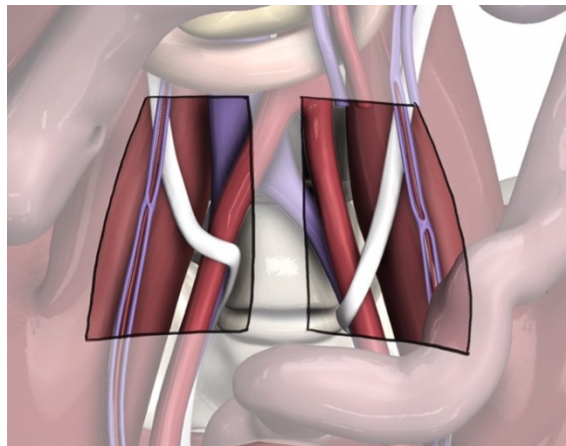


Figure 11: Early delineation of disposable hydrogel “puck” location

To minimize the disposable aspects of the trainer and keep costs low, we elected to create pucks of the general area that will be manipulated, dissected and anastomosed. Once accessed through the omentum and small intestine, the primary surgical site of the ureters will be visible. These regions will be considered disposable and created from hydrogel to allow for the use of electro-surgical devices. The left and right ureter pucks will include a representation of the posterior abdominal wall (musculature) on which the ureter rests, two transected ends of the ureter which include UV visible BLAST (Black Light Assessment of Surgical Training) indicators, gonadal veins which allow for assessment of error if cut, fat/connective tissue surrounding the ureter, and an outer layer of peritoneum. The puck will also include an anchoring feature to prevent accidental removal during use, and built-in connectors to connect the proximal and distal ends of the ureters to the regions outside of the puck.

Bladder Cap

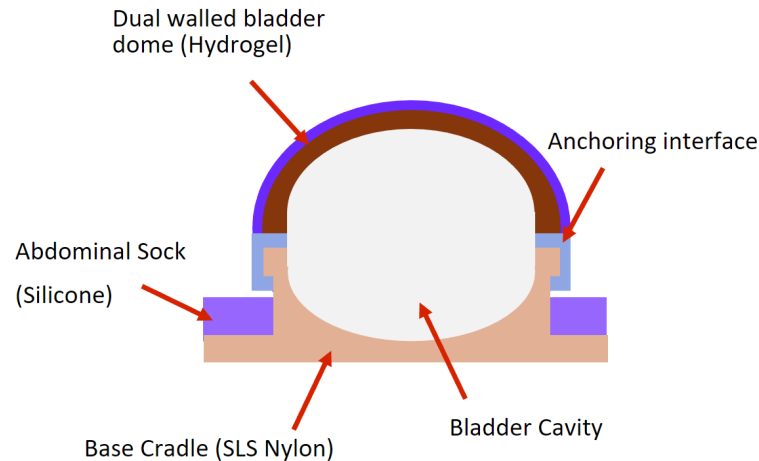


Figure 12: Cross sectional view of proposed bladder connection method

For the reimplantation of the ureter into the dome of the bladder, a hydrogel bladder-dome will be created to work in conjunction with the hydrogel ureter puck to allow for the distal end of the ureter to be implanted into the bladder. This Bladder Cap will consist of a dual-layered hydrogel dome and an anchoring feature to allow the dome to be connected to the base cradle to create the bladder cavity. A cross sectional view of the assembly can be seen in the figure above. Once assembled, the bladder cavity can be filled with simulated methylene blue dye to assess patency of the sutured ureters. This will be done through a foley catheter inserted into the bladder through the outer wall of the simulator.

Transport Case

Once the design of the simulator is complete, a suitable case will be selected to protect the simulator during transport. At present, a rigid pelican case with custom foam insert is thought to be the best approach. CREST has worked with local external suppliers to create similar cases to this in the past.

Low-cost actuation and assessment techniques

Review of procedure video and feedback from clinicians in the context of information gathering for the CTA pointed to ureter identification as a requirement with implications for sensing and actuation. When the ureter is manipulated, it exhibits reactive motion as well as spontaneous peristaltic motion. This motion is used in identifying the structure, yet it is quite subtle.

Urine Production

The kidneys produce urine at a rate of approximately 800 to 2000 ml/day or 0.5 to 1.5 ml/min continuously with regular fluid intake. The urine would leak from a damaged ureter into the abdominal cavity and be both a cue for identifying the ureter as well as a distractor as the liquid collects.

We have built a prototype fluid system that is capable of supplying the required flow rate of simulated urine to the renal pelvis. The initial test contained a peristaltic pump that could deliver a flow rate of 0.45 ml/min, closely matching typical continuous urine production. A small fluidic circuit of check valves allows the fluid to be delivered to either left or right ureter by running the

pump in a clockwise or counterclockwise direction. The miniature pump has since been replaced with a slightly larger, higher flow pump of similar construction. This larger pump can fill the dead volume of fluidic system and renal pelvis significantly faster thanks to a maximum flow rate of 5 ml/min. It will be throttled back to urine production flow rates once the initial fill is complete. The pump motor is controlled by a microcontroller via a variable speed brushless DC motor driver. Electronics have been breadboarded. They will be integrated on a custom printed circuit board once the design has been thoroughly tested and performance validated.

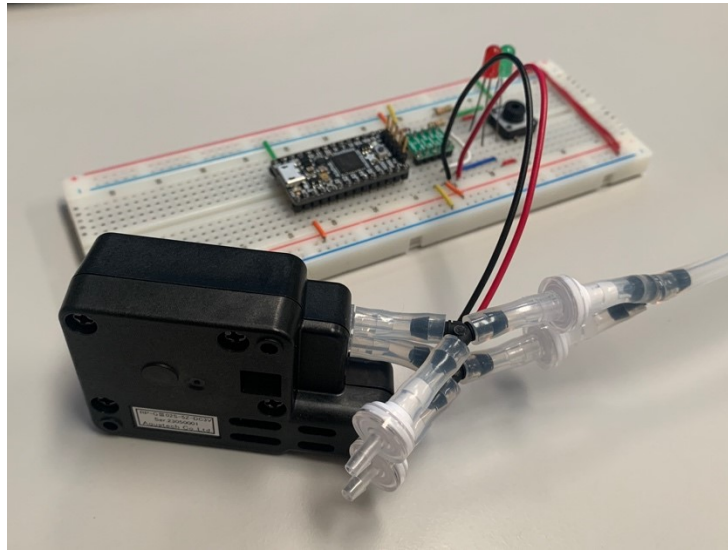


Figure 13: Prototype urine pump and pump motor driver

Ureter Peristaltic Motion

The peristaltic motion of the ureter is simulated by a mechanically driven actuator acting upon the underside of the replaceable ureter puck. The actuation will be achieved by an Archimedes screw shaped on the outside to apply pressure to the tissue layers above in a periodic fashion. The mechanism is currently being designed and will be 3D printed for prototype testing. The screw will be driven by a stepper motor.

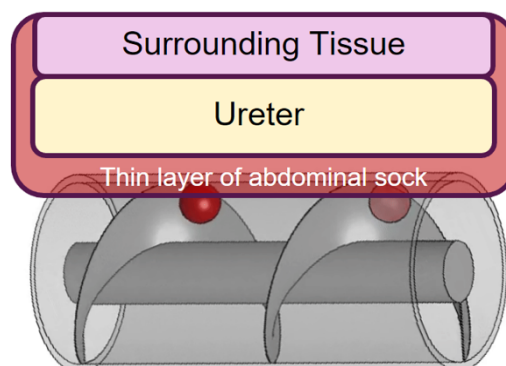


Figure 49: Concept diagram of Archimedes Screw driven peristaltic motion

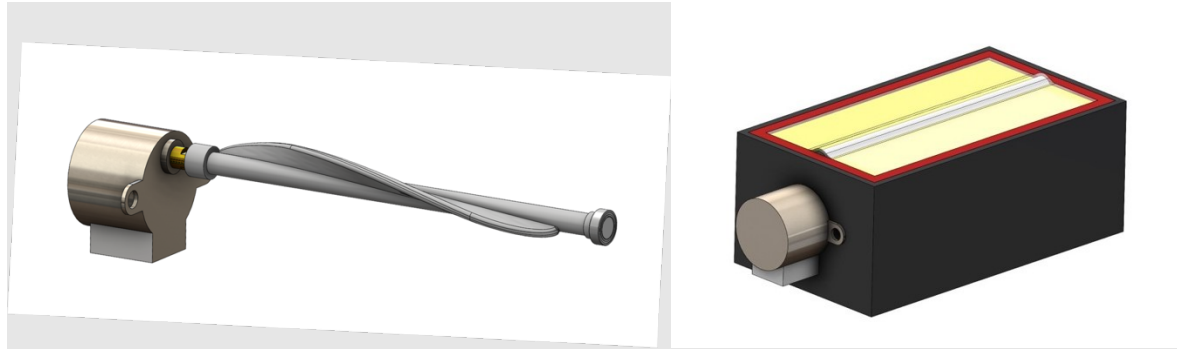


Figure 15: Prototype diagram of Archimedes Screw driven peristaltic motion

Electronics for controlling the stepper motor via motor driver from a microcontroller have been prototyped and tested. They will eventually integrate with the urine production pump drive on a single custom circuit board.

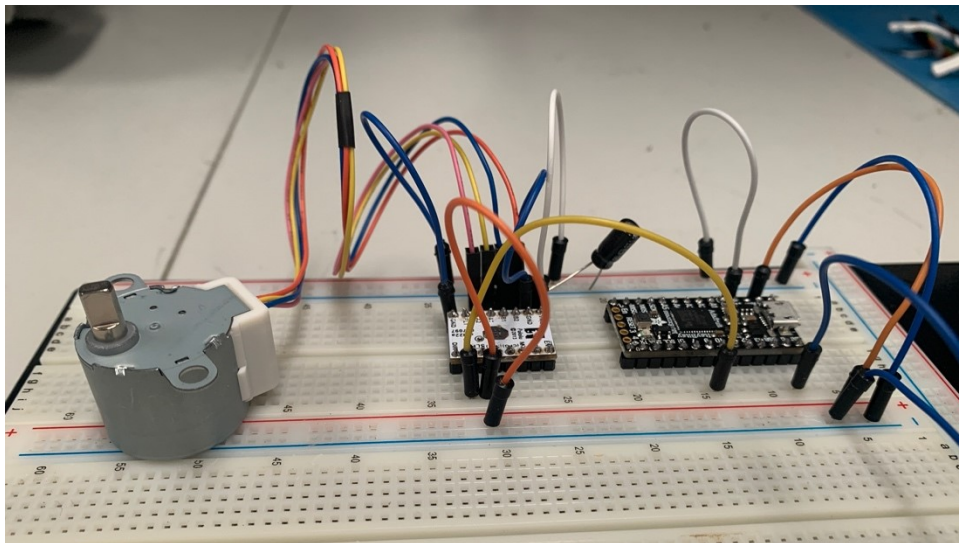


Figure 16: peristaltic motion motor prototype driver circuit



Figure 178: Prototype of the physical control interface to control peristalsis and urine leakage

The superior face of the simulator will include a control panel (prototype shown above) to control simulated ureter peristalsis and to access a removable fluid reservoir to fill the system with simulated urine. The prototype control interface was assembled from discrete switch and LED components. For the final control interface, we are developing a membrane switch panel that will be supplied by an outside vendor as a single unit greatly reducing cost, part count and assembly time and improving ruggedness.

Subtask 4: – Integrate all aspects of design into complete training platform – **5% Complete**

Progress has begun on the integration of the sculpted anatomic features into an engineered trainer system as outlined in the conceptual design phase in in subtask 3.

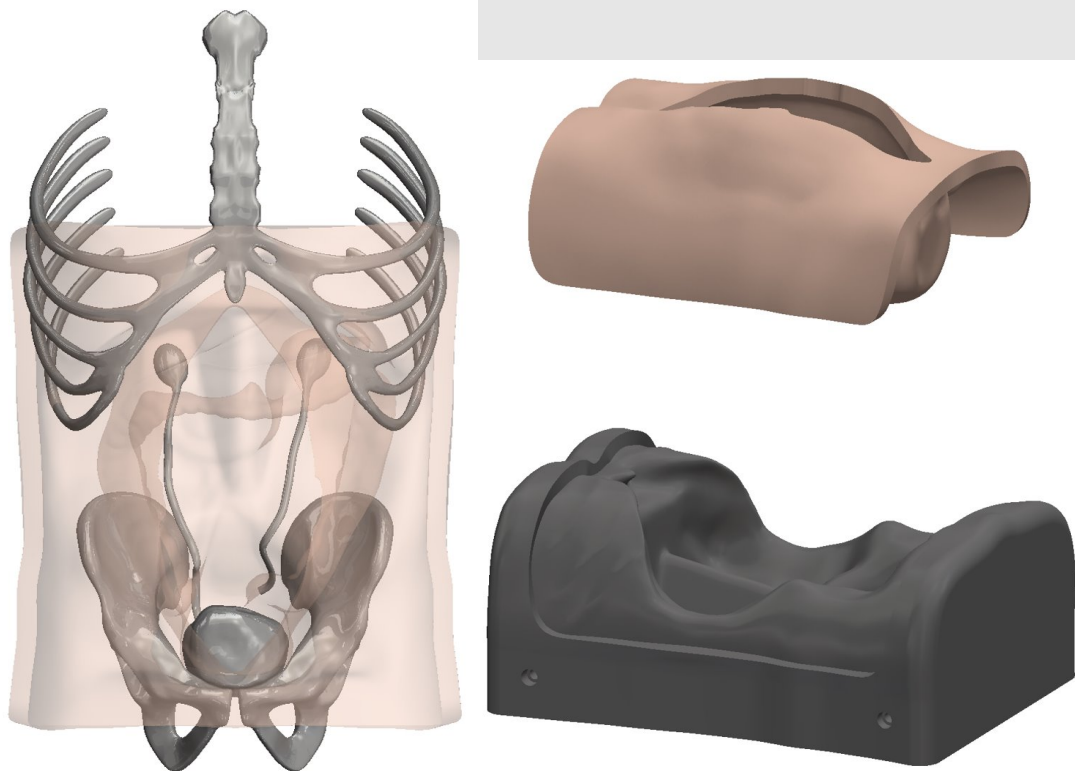


Figure 18: Anatomic accuracy of trainer (left) and exploded view of rigid base and silicone insert (right)

Care has been taken at each phase of the sculpting and integration process to ensure anatomic accuracy of the trainer. This has been taken directly from the DICOM segmentation process and verified by relevant SMEs. Where possible, anatomic features are included into the engineered form of the rigid base to add further fidelity to the trainer (e.g. the bony prominence of the pelvis shown in the figure above).

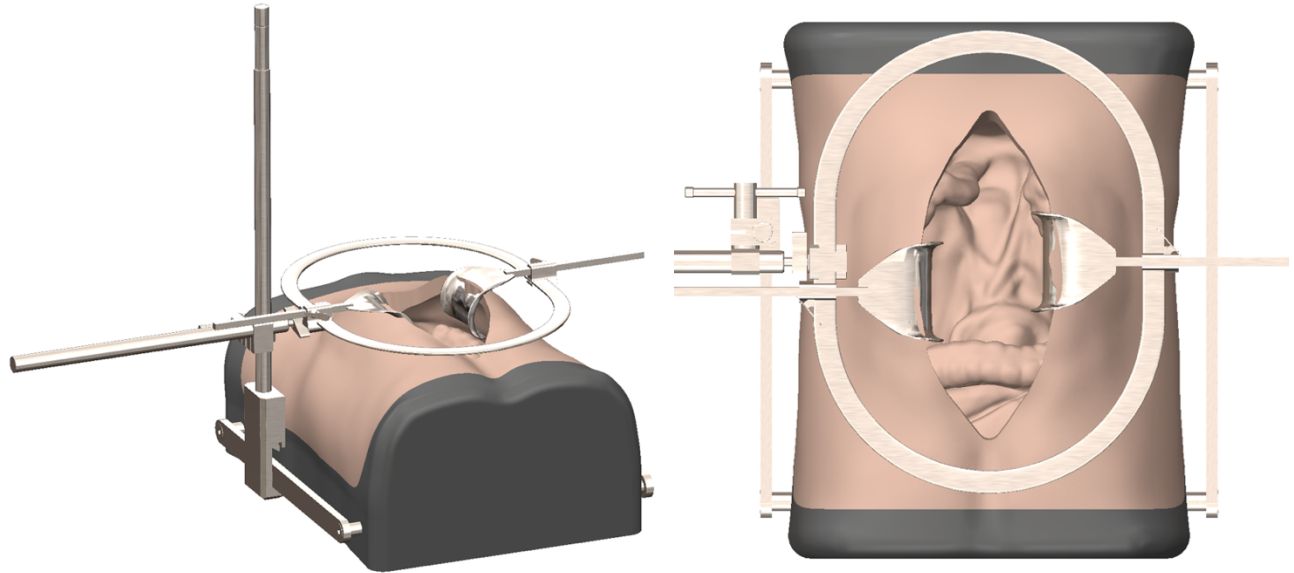


Figure 19: CAD design of integrated trainer with retractor rail and retractor installed

The geometry of standard surgical table bed rails has been included on either side of the trainer to facilitate surgeons' preferences in location when attaching the Bookwalter retractor. These 1 1/8" x 3/8" rails also allow for additional surgical tools to be attached and extend into the trainer to distribute internal stress throughout the base of the trainer when pulled upon by the internal retractors.

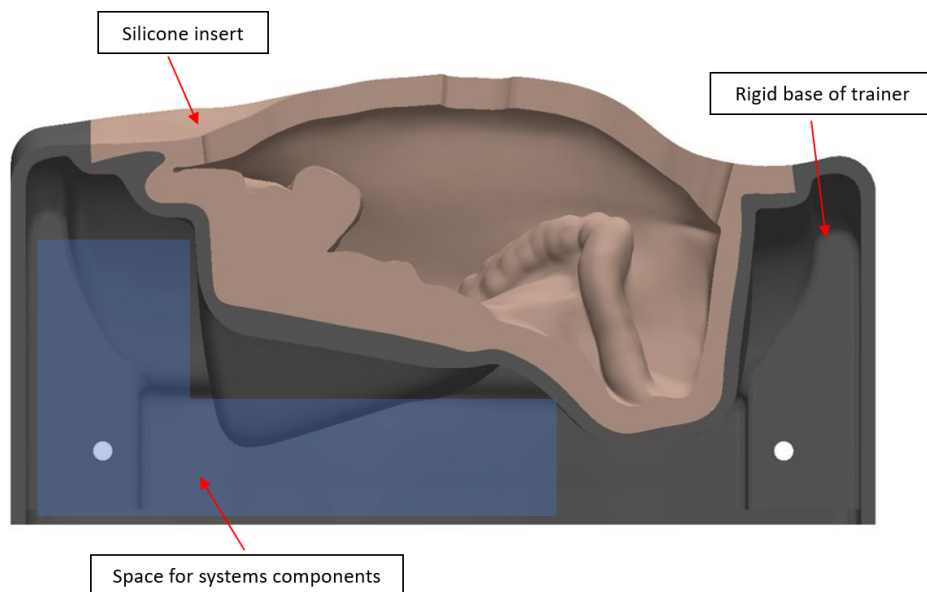


Figure 20: Cross section of trainer with expected location of systems components

Once surgical intervention sites are established within the CAD assembly, electrical and fluidic components will be added to the assembly. Sufficient space has been allocated for components while hollowing out the base of the trainer in the early phases of the design.

Testing materials and prototyping their fabrication has been an emphasis of research. Hydrogels are water-based materials that have properties that align with human tissue better than silicone. To match the desired tissue properties of hydrogels, CREST has tested and prototyped base materials, color additives, mesh integration, tensile strength, stretch ratio, its ability to suture, collapsibility, the application of electro-surgical instruments, fabrication methods through 3D-printed molds, packaging and storage solutions, and the tunable bonding of discreet layers.

Polyvinyl Alcohol (PVA) has been selected as our hydrogel of choice for its ease-of-use, tunability of properties, and low toxicity. The powdered PVA is added to deionized water to create a solution. The percentage of PVA, by weight, dictates the density of the material. Taking the material through freeze/thaw cycles will encourage crosslinking of the PVA and increases its tear resistance. The viscosity of the PVA can make casting through pouring or injecting difficult. CREST has found that a “press mold” or “squeeze mold” technique is successful in capturing mold details and preventing voids in the cast part.

Pigments, fibers, and fillers can be added to the PVA solution to further adjust the qualities of the PVA synthetic tissue.

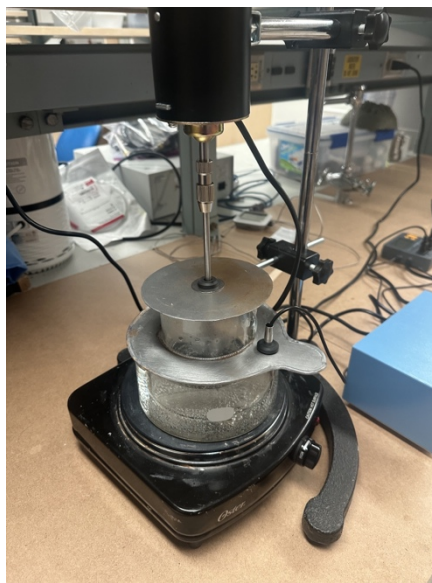


Figure 21: PVA mixing station to control heating and stirring of solution

CREST has prioritized replicating the properties of human ureter. Creating ureters that can be successfully sutured and withstand tension without shearing through the tissue is necessary to the training of the procedure. In addition, training will only be realistic if the ureter allows for the error of the suture pulling out of the ureter wall if undue force is applied. Extensive material creation and testing was done to create a ureter that withstands up to 3 Newtons of force, as is found in human ureter.

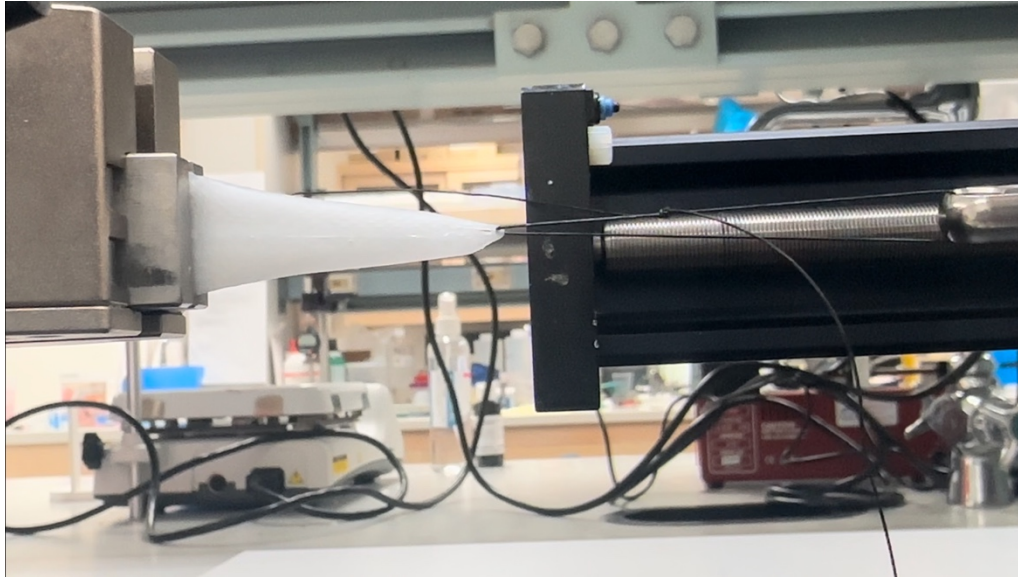


Figure 22: Load cell on robotic arm measuring the suture pullout force of hydrogel ureters

The molding process allows for over-molding of successive layers to build function within the walls of the ureter. The addition of an embedded, PVA mesh of a firmer durometer showed promising force distribution after suturing. This raised the pull-out force of the ureters but proved difficult to reach the metric of 3 Newtons or more.

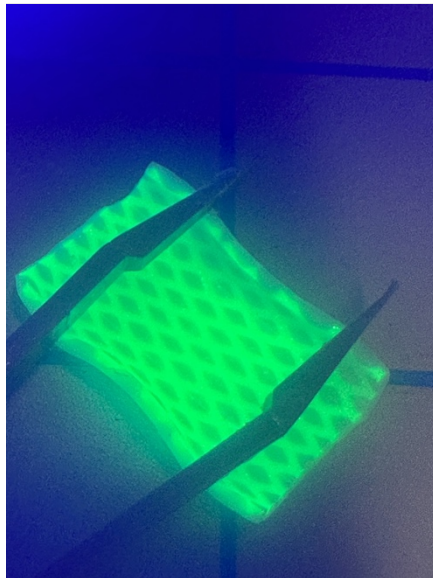


Figure 23: Dual-material hydrogel ureter showing embedded mesh that provides strength and UV-reactive mesh network

Additives such as pigment, flocking, fibers, and blood inclusions are possible to improve the visual fidelity of the simulated tissue. Color matching our synthetic tissues to the color of in-situ, human tissue is being developed.



Figure 24: Sample color palette of PVA (left) and PVA being mixed with simulated blood dispersion (right)

Some tissues found in the body are found in very thin sheets. The peritoneum, for example, is a durable layer that is difficult to fabricate with conventional casting techniques. CREST has found that PVA, thinned with solvents, will flow through a spray gun, allowing for an application of a thin layer over an existing surface.



Figure25: Example of thin membrane of PVA achieved through spray application

PVA is cast into 3D-printed molds that allow for quick iterating within the lab. Nylon mesh is wrapped around a stainless steel mandrel. PVA is applied and squeezed into place with mold tops and

secured with hardware. The resulting ureter is demolded and can be inserted into the next mold of the sequence to introduce additional tissues for the puck. We have shown that the resulting ureter can be charred with a flame to simulate a realistic, thermal injury.

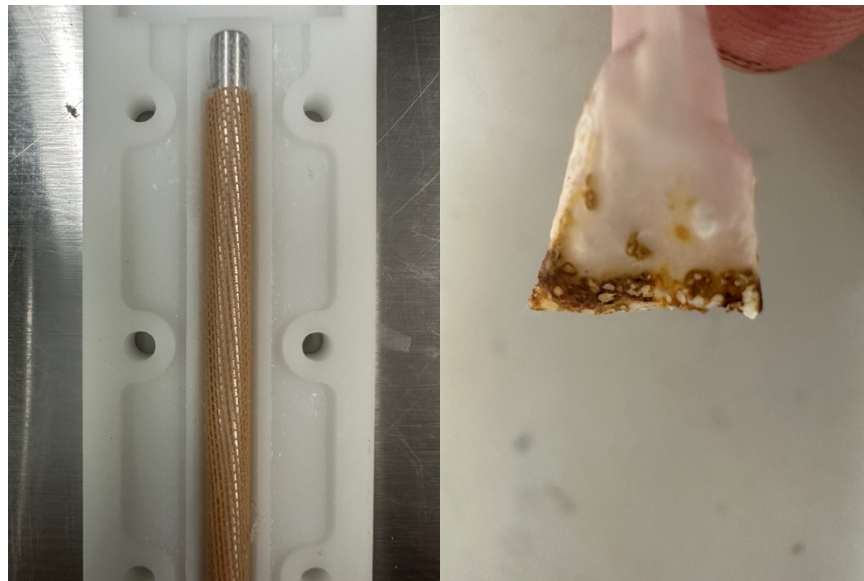


Figure 26: Mandrel and mesh prepared for PVA molding of ureter (left) and example of simulated thermal injury to ureter (right)



Figure 27: Prototyping multi-layer pucks with embedded, injured ureters

Silicone, a material used in the majority of training simulators, does not have water content, and therefore, is unable to be dissected with an electro-surgical device. Surgeons will often use a device, such as a Bovie, to dissect tissue away from a damaged ureter for access and create an incision in the bladder to prepare for reimplantation of the ureter. This necessitated the exploration of hydrogels as a material to create the simulated tissue in the regions of intervention in the trainer.

Our testing has shown successful dissection with a Bovie. Once a full puck is created, we will be testing the smoke plume created by the device to better understand any health risks of the material at those temperatures. A fume extractor, not unlike those becoming more common in O.R.s during electrosurgery, is used to capture any fumes and smoke created during the procedure.

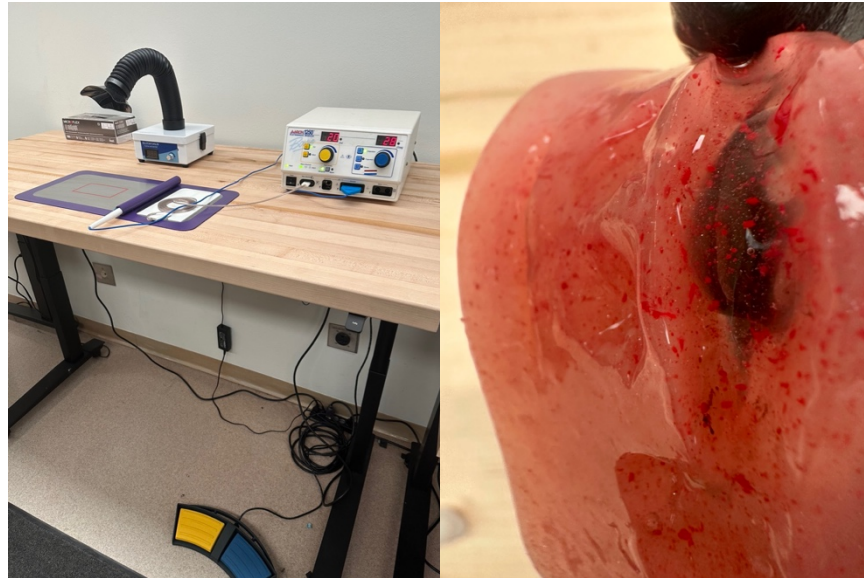


Figure 28: Electrosurgical Bovie testing station (left) and example of dissected tissue (right)

The water content of the PVA and the sealed storage needed for the pucks have the potential of creating microbial growth. We are currently testing packaging and storage solutions that will increase the shelf life of the PVA pucks and will prevent unwanted growth. Maintaining the synthetic tissue properties is important to ensure the consistency of training across users and time.



Figure 29: Potential bacterial/mold growth on PVA (left) and testing storage solutions (right).

The bladder used in the trainer will present two tissue types within the bladder wall, (mucosa, muscle) to allow for a two-layer suture. The bladder is also considered a disposable part that will be removed after dissection and reimplantation of the ureter is complete in order to reset for the next

training. Prototyping has been done to test fabrication methods, recipe variation, mesh integration, and its ability to lock easily on a mounting feature.

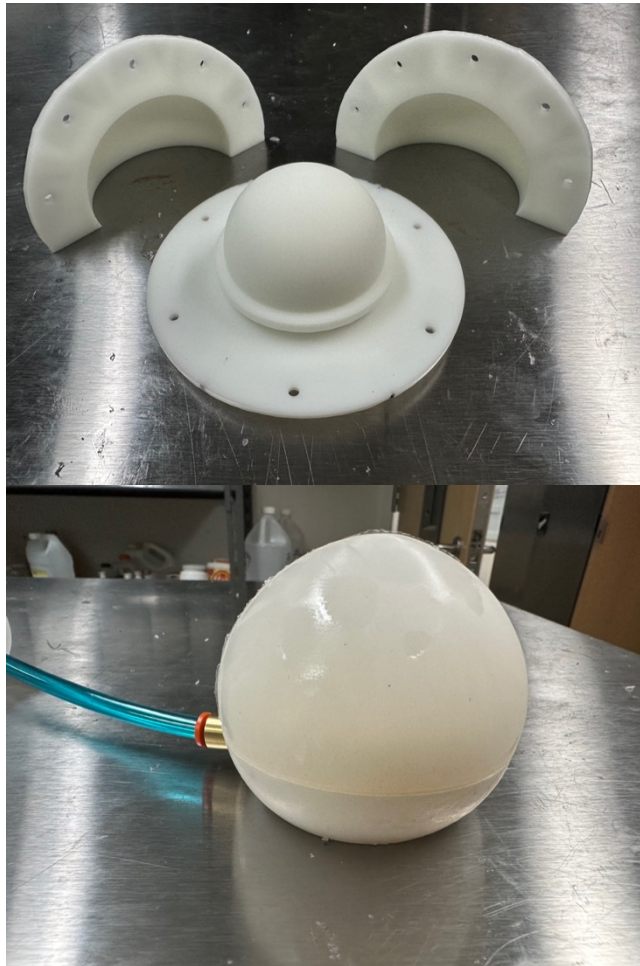


Figure 30: Example of 3D-printed mold shells (top) and bladder dome prototype (bottom).

Feedback from clinicians gives the design team at CREST the necessary information to progress with prototyping and gives support to the design direction. By using the draft evaluation tool (figure X on page 30), CREST was able to determine a ureter variety that will be used for the trainer.



Figure 31: Comparison of PVA ureter samples. The chosen ureter, right, includes nylon mesh

The culmination of these individual tests allows CREST to create examples of the embedded pucks that will be used in the trainer. Psoas muscle, periureteral tissue, ureter, and peritoneum are created as separate recipes and use different application techniques. Testing the completed puck for appearance, its ability to dissect and suture accurately, and lock into the greater abdominal cavity are current priorities. Clinical feedback sessions help to direct future development.

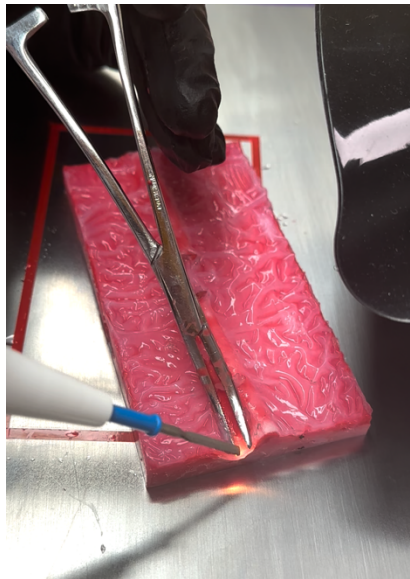


Figure 32: Bovie electrosurgical device dissecting puck prototype

Major Task 2: By developing the manufacturing process to move the part task trainer into a production environment we can reduce cost and support the training requirements of the providers.
– Ongoing – task integrated into overall design (see “Changes” section).

- Subtask 1 – Modify critical components for manufacturability
- Subtask 2 – Select manufacturing processes for production and assembly at volume
- Subtask 3 – Run test at volume to support utility study and verify manufacturing processes

Specific Aim 2: Evaluate the instructional utility of the training platform as perceived by clinical instructors, measured using a visual- analogue scale tailored to the metrics of simulator fidelity and training system utility.

Major Task 3: By aligning design and fidelity with the CTA of the procedure we maximize the utility and usability of the trainer for the learners

- Subtask 1 – Study design to evaluate educational utility of the system and its components
- Subtask 2 – IRB & OHRO process
- Subtask 3 – Data collection – **Not yet initiated**
- Subtask 4 – Data analysis and document findings – **Not yet initiated**

Subtask 1: Study design to evaluate educational utility of the system and its components.

This experiment proposes prospective observational study to quantify the usability and utility of the novel ureter repair trainer, relative to a commercially available alternative trainer. The experiment will leverage the expertise of skilled urologists (n=12-14) from both military and civilian backgrounds to evaluate the usability and utility of both trainers, using a purpose-built evaluation instrument.

Recent efforts have yielded a draft evaluation instrument, which will be used in the planned study. The draft evaluation instrument includes four preliminary constructs that underpin the usability and utility of the trainer: Needle puncture, Suture Drag, Collapsibility and Visual Deformation. Each of these constructs will be evaluated on a visual analogue scale (ranging from “Poor” to “Spot On” in the context of the trainer’s representation of human tissue.

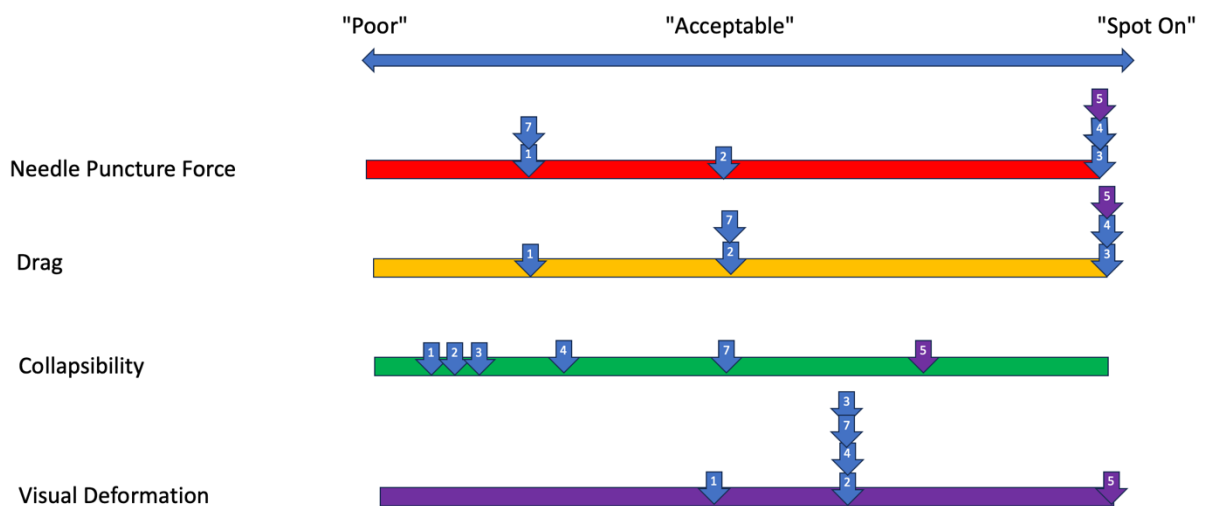


Figure (33): Diagram illustrating preliminary data collected during the piloting of the draft evaluation tool (n=1). Formulation 5 shows the most promise as a candidate.

The draft evaluation tool was piloted successfully (n=1) and will be re-evaluated in an iterative fashion with additional subject matter experts (n=5) as additional constructs are added and refined. Data collected during this extended piloting process will stand as validity evidence to support the evaluation tools' use in this context.

Subtask 2: IRB & OHRO process

Preliminary conversations with the University of Washington Institutional Review Board representative allocated to medical and surgical education projects have taken place. These conversations, in which the planned usability and utility study have been described in detail, have suggested that the proposed protocol will be exempt from federal review regulations. Based on the results of these discussions, the team will continue to work closely with the IRB representative to prepare the IRB application and ensure that all ethical and compliance standards are met. Upon receiving UW IRB approval or exemption, all relevant documentation will be provided to the Office of Human Research Oversight (OHRO) for approval, prior to the start of any data collection efforts.

What opportunities for training and professional development has the project provided?

Nothing to report.

How were the results disseminated to communities of interest?

Nothing to report. We do anticipate dissemination next year as the studies are completed.

What do you plan to do during the next reporting period to accomplish the goals?

Q5 plans:

1. Work on the integrated CAD assembly will continue during the next reporting period and is anticipated to progress significantly during that time. Ongoing hydrogel and material testing will also continue through the next reporting phase and will be used in parallel to the updated CAD models to begin to create hydrogel geometries specific to the puck regions.
2. Material development will continue in order to mimic the functional requirements of the anatomic structures. We anticipate making the decision on which materials we aim to use to simulate the following structures:
 - A composite bladder allowing for the reimplantation procedure.
 - A multi-material disposable puck consisting of the layers surrounding the ureter.
3. We will continue assessing storage conditions to enable longer shelf-lives for the disposable components. We aim to test sterilization techniques, their effect on the mechanical properties of the simulated tissues, and the longevity of the pucks.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

This project has already yielded a curricular scaffold for training and assessing ureteral trauma reconstruction that will fulfill the ICTL. Once we complete the assessment instruments and validation experiments, we will contribute to assuring the readiness of our surgical workforce to manage these rare but morbid injuries.

What was the impact on other disciplines?

There have been several engineering developments during this project that have broader implications beyond the primary deliverable of the curriculum for ureteral trauma training including simulating peristalsis and integration and connection of silicon with hydrogels as a hybrid training material solution as well as the development of materials to simulate connective tissues to allow for dissection. These approaches will facilitate other simulation training applications across the spectrum of healthcare professions and disciplines.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS**Changes in approach and reasons for change**

Based on the successes with breadboard models of critical design elements, the team decided to run efforts for component design in parallel with design for manufacture. This concurrent design approach allows the team to consider transition to commercialization in more depth than originally planned. This does not impact on either cost or timeline but will lead to a better design overall.

Actual or anticipated problems or delays and actions or plans to resolve them**Ongoing Issues:**

Issue: Maintaining staffing given other funding, as a grant-funded lab.

Mitigation: We have applied for multiple other projects including:

- JWMRP BAA ("Comprehensive Training Module for Pelvic Damage Control Surgery") – follow on to current project
- CRRP BAA ("A Physiologically Reactive Airway Trainer for Difficult Intubations: Assessing Training and Retention")
- 3 King County Medic One add-on projects to improve our AJAMS airway,
- Services agreement with Boston Scientific Corporation to collect data for tool validation.

- NIH R21 (“Development of a synthetic afferent arteriole from actuated soft materials with accurate vessel dynamics driven by a mechanistic physiological model of the kidney”)

Resolved Issues

Issue: Obtaining video content can be challenging given acuity and rarity of the procedure.

Mitigation: Obtaining procedural videos and images using a fresh-frozen, pseudo-perfused cadaveric specimen. This will facilitate the on-demand, customized acquisition of anatomic images and procedural videos in a timely fashion that is not contingent on the presentation of a rare condition and does not impact patient care.

Issue: Labor dispute at University of Washington affecting research scientists and engineers slowing work progress due to ongoing strike.

Mitigation: Team is working on items that are possible and will try to make up time once the contract is resolved.

Changes that had a significant impact on expenditures

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report.

Significant changes in use or care of human subjects

Nothing to report.

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications. Nothing to report.

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers and presentations.

Nothing to report.

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Robert Sweet, MD
Project Role:	Principal Investigator, Subject Matter Expert
Researcher Identifier:	rsweet@uw.edu
Nearest person month worked:	2
Contribution to Project:	Dr. Sweet has led the project and contributed to the CTA process as a subject matter expert

Name:	David Hananel
Project Role:	Co-Investigator
Researcher Identifier:	dhananel@uw.edu
Nearest person month worked:	3
Contribution to Project:	Mr. Hananel has performed work in the areas of CTA process and identifying initial development targets

Name:	Victoria Roach
Project Role:	Co-Investigator
Researcher Identifier:	vicroach@uw.edu
Nearest person month worked:	4
Contribution to Project:	Dr. Roach has performed work in the areas of study and instructional design, anatomy instruction, and human factors considerations, created anatomic bill of material

Name: Jonathan Wingate
Project Role: Co-Investigator
Researcher Identifier: jwingate@uw.edu
Nearest person month worked: 1
Contribution to Project: Maj. Wingate has contributed as a subject matter expert in describing the procedure and contributed to the CTA process

Name: Alex Gong
Project Role: Materials Scientist
Researcher Identifier: atg16@uw.edu
Nearest person month worked: 4
Contribution to Project: Research hydrogels for ureter and connective tissues
Product testing protocol

Name: Jason Speich
Project Role: Fabrication Scientist
Researcher Identifier: jspeich@uw.edu
Nearest person month worked: 4
Contribution to Project: Flexible shell concept alternatives, design and development of artificial structures

Name: Dan Burke
Project Role: Digital artist
Researcher Identifier: burke326@uw.edu
Nearest person month worked: 4
Contribution to Project: Dan Burke started to prepare the 3D anatomic assets based on anatomic bill of material required for this procedure

Name: DJ Traina
Project Role: Mechanical Design Engineer
Researcher Identifier: djtraina@uw.edu
Nearest person month worked: 4
Contribution to Project: Product testing protocol
Evaluate Connectors, Vendors, Materials with team,
Processes with team

Name: Rainer Leuschke
Project Role: Control Systems Engineer
Researcher Identifier: rainer@uw.edu
Nearest person month worked: 3
Contribution to Project: Low-cost actuation and assessment

Name: Kristina Cizas
Project Role: Project Manager
Researcher Identifier: kcizas@uw.edu
Nearest person month worked: 2
Contribution to Project: Timeline and budgetary management

Name: Judith Hagadorn
Project Role: Subject Matter Expert
Researcher Identifier: judithch@uw.edu
Nearest person month worked: 1
Contribution to Project: Dr. Hagedorn has contributed to the CTA process as a subject matter expert

Name: Hunter Wessels
Project Role: Subject Matter Expert
Researcher Identifier: wessels@uw.edu
Nearest person month worked: 1
Contribution to Project: Dr. Wessels has contributed to the CTA process as a subject matter expert

Name: Alexander Skokan
Project Role: Subject Matter Expert
Researcher Identifier: ajskokan@uw.edu
Nearest person month worked: 1
Contribution to Project: Dr. Skokan has contributed to the CTA process as a subject matter expert

Name: Alshakim Nelson
Project Role: Subject Matter Expert
Researcher Identifier: alshakim@uw.edu
Nearest person month worked: 1
Contribution to Project: Professor. Nelson has contributed his expertise in hydrogel development as a subject matter expert.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report.

What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

Quad chart submitted.

9. APPENDICES

None