Validating and Manufacturing a Bio-realistic Surgical Phantom for Laparoscopic and Robotic Surgical Training

A Major Qualifying Project

Submitted to the Faculty of

WORCESTER POLYTECHNIC INSTITUTE

By

Caitlin Bonavita

Binh Diec

Alex Hill

Andrew Sifferlen

April 28th, 2023

George Pins, Ph.D, Advisor

Department of Biomedical Engineering

Thomas Cataldo. M.D, Sponsor

Beth Israel Deaconess Medical Center

Abstract

Surgical trainers are essential to improving the learning curve of surgical procedures in a patient-free environment. Residents and experienced surgeons utilize trainers to refine skills within unfamiliar or out of practice operations without placing patients in unnecessary risk. Although there are currently a diverse set of surgical trainers on the market, all fall short of accurately simulating the environment of a human body. The team developed a bio-realistic surgical trainer for laparoscopic right colectomy surgeries that outperforms current alternatives in simulating organ and connective tissue mechanical and anatomical properties. By 3D-printing molds based on CT scans of real organs, the team utilized polyvinyl alcohol and silicone to produce model organs. Members of the group manufactured multiple layers of synthetic mesentery with differing methodologies depending on the necessary thickness. Through validation procedures, the team has gained quantitative and qualitative results with the support of mechanical testing and surgeon feedback.

Acknowledgements

The team would like to acknowledge the following people for their contributions, expertise, and continuous support throughout the project:

Department of Biomedical Engineering

Professor George Pins

Lisa Wall

Beth Israel Deaconess Medical Center

Dr. Thomas Cataldo

Abbreviations

2D – Two Dimensional

3D – Three Dimensional

ACGME – Accreditation Council for Graduate Medical Education

ASTM – American Society for Testing Materials

BIDMC – Beth Israel Deaconess Medical Center

CT Scan – Computerized Tomography Scan

FLS – Fundamentals of Laparoscopic Surgery

IBD – Inflammatory Bowel Disease

IRB – Institutional Review Board

ISO – International Organization for Standardization

IT- Information Technology

PLA – Polylactic Acid

PLSC – Procedural Learning and Safety Collaborative

PVA – Polyvinyl Alcohol

PVC – Polyvinyl Chloride

QR – Quick Response

RCPSC – Royal College of Physicians and Surgeons of Canada

RUQ – Right Upper Quadrant

STL – Stereolithography

VR – Virtual Reality

Table of Contents

Authorship

Section	Author(s)	Editor(s)
Abstract	Andrew	Binh
1.0 Introduction		
Introduction	Caitlin	Binh
2.0 Literature Review		
2.1 Anatomy	Caitlin	Caitlin
2.1.1 Small Intestine and Duodenum	Caitlin	Caitlin
2.1.2 Transverse Colon and Ascending Colon	Caitlin	Caitlin
2.1.3 Adipose Tissue	Binh	Binh
2.1.4 Mesentery	Binh	Binh
2.1.5 Peritoneum	Binh	Binh
2.2 Right Colectomy Surgery	Caitlin	Andrew
2.3 Need for Surgical Trainers	Andrew	Caitlin
2.3.1 The Fundamentals of Laparoscopic Surgery (FLS) Test	Andrew	Andrew
2.4 Existing Models	Binh	Binh
2.5 Past Materials Used	Alex/Andrew	Andrew
2.6 Engineering Need	Andrew/Caitlin	Andrew
2.7 Needs Statement	All	Caitlin
3.0 Project Strategy		
3.1 Initial Client Statement	All	Binh
3.2 Defining Stakeholders	Binh	Andrew
3.3 Initial Design Objectives	Andrew	Caitlin
3.4 Constraints	Caitlin	Andrew
3.5 Revised Objectives	Caitlin	Andrew
3.5.1 Objective Tree	Caitlin	Andrew
3.5.2 Secondary Objective Descriptions	All	Andrew

3.5.3 Objective Rankings and Evaluations	All	Andrew
3.6 Standards and Requirements	Andrew	Binh
3.6.1 Board-Certification and Educational Program Accreditation	Andrew	Binh
3.6.2 Mechanical Property Testing	Andrew	Binh
3.7 Revised Client Statement	All	Binh
3.8 Project Management	Alex	Caitlin
3.8.1 Work Breakdown	Alex	Andrew
3.8.2 Gantt Chart	Andrew	Binh
3.9 Milestones	Binh	Andrew
3.9.1 Milestone One: Material Testing	Alex	Andrew
3.9.2 Milestone Two: Alternative Designs	Andrew	Caitlin
3.9.3 Milestone Three: Prototype Development	Binh	Alex
3.9.4 Milestone Four: Validation and Revision	Caitlin	Alex
4.0 Design Process	Caitlin	Andrew
4.1 Needs Analysis	Caitlin	Andrew
4.1.1 Design Needs	Caitlin	Andrew
4.1.2 Design Wants	Caitlin	Andrew
4.1.3 Needs and Wants Design Matrix	Caitlin	Andrew
4.2 Functions and Specifications	Binh	Caitlin
4.3 Conceptual Design	Alex	Caitlin
4.3.1 Brainstorm Design Elements	Binh	Andrew
4.3.2 Evaluation of Design Elements	All	Caitlin

4.3.3 Quantitative Assessment of Design	Binh	Andrew
5.0 Development and Verification of Final Design	Binh	Alex
5.1 Preliminary Testing	Andrew	Alex
5.1.1 Mesentery Material Mechanical Testing	Andrew	Alex
5.1.1.1 Puncture Testing	Andrew	Binh
5.1.1.2 Peel Testing	Andrew	Binh
5.1.2 Mesentery Manufacturing Testing	Binh	Caitlin
5.1.2.1 Mesentery Attachment Experimentation	Binh	Caitlin
5.1.2.2 Mesentery Thin Sheet Experimentation	Binh	Alex
5.1.3 Organ Manufacturing Testing	Caitlin	Alex
5.1.3.1 Molds	Caitlin	Alex
5.1.3.2 PVC Pipes	Caitlin	Alex
5.1.3.3 Sausage Casings	Alex	Caitlin
5.1.4 Miscellaneous Testing for Organs	Alex	Caitlin
5.1.4.1 Dye	Alex	Caitlin
5.1.4.2 Mineral Pockets/Bleeding	Alex	Caitlin
5.2 Complete Design of Surgical Trainer	Alex	Andrew
6.0 Final Design Validation	Binh	Alex
6.1 Survey	Caitlin	Alex
6.2 Quality Check Parameters	Alex	
6.2.1 Measure Anatomic Correctness	Alex/Andrew	
6.2.2 Measure Separability	Andrew	
6.2.3 Measure Reusability	Alex	Caitlin

6.2.4 Measure Replaceability	Andrew	Alex
6.2.5 Measure Ease of Use	Caitlin	Alex
6.2.6 Measure Manufacturability	Alex	Caitlin
7.0 Discussion		
7.1 Right Upper Quadrant Organs Analysis	Caitlin	
7.2 Mesentery Analysis	Andrew/Binh	Caitlin
7.3 Project Limitations	Andrew/Binh/Caitlin	Alex
7.4 Final Devise Analysis	All	Alex
7.5 Impact Analysis	Caitlin	Andrew
7.5.1 Economic Analysis	Andrew	Alex
7.5.2 Environmental Impact	Binh	Andrew
7.5.3 Societal Influence	Andrew	Caitlin
7.5.4 Political Ramifications	Alex	Andrew
7.5.5 Ethical Concerns	Binh	Andrew
7.5.6 Health and Safety Issues	Caitlin	Andrew
7.5.7 Manufacturability	Alex	Caitlin
7.5.8 Sustainability	Andrew	Alex
8.0 Conclusions and Recommendations		
8.1 Conclusions	Binh	Alex
8.2 Future Recommendations	Binh	Alex
Appendix A	Andrew	Caitlin
Appendix B	All	Caitlin
Appendix C	Alex	Andrew
Appendix D	Andrew	Alex
Appendix E	Andrew	Alex
Appendix F	Andrew	Alex
Appendix G	Andrew	Alex
Appendix H	Andrew	Binh
Appendix I	Andrew	Caitlin

Appendix J	Andrew	Alex
Appendix K	Andrew	Caitlin
Appendix L	Andrew	Caitlin
Appendix M	Alex	Andrew

List of Figures

List of Tables

Chapter 1: Introduction

More than 600,000 colorectal surgeries are performed each year in the United States [1]. The average surgeon completing a residency program operates around 21 cases out of the recommended 50-60 cases to become proficient in these procedures [2]. Post residency, 66% of colectomies are performed by surgeons with less than 11 cases a year, leading to 25% more complications compared to surgeons who perform at higher volumes [3]. Graduating Residents are not proficient, and many of the current procedures are performed by surgeons who simply don't go into operation enough. A national survey conducted by the Procedural Learning and Safety Collaborative (PLSC) between faculty and residents of 30 institutions found that "General surgery residents were not universally deemed competent to perform colorectal procedures even at the end of residency" [4]. There is a need for a method of getting residents that are completely unexperienced in colorectal surgeries into surgeries. A surgical trainer can aid this by speeding up the learning process through bio-realistic surgical practices. There is a clear correlation between the quantity of surgeries performed and the quality of surgeries [5] This means that with an increase in surgeries performed by a surgeon there is a better outcome for the patients. The Accreditation Council for Graduate Medical Education (ACGME) states an 80-hour weekly limit, averaging over four weeks for residents [6]. The application of resident work hour restrictions reduces the quantity of surgeries a resident can perform for safety purposes and in turn the timeline for the quality process at which the residents can perform for better outcomes has been extended. In addition to this enhanced surgical trainer would allow for surgeons working at low-volume hospitals to help maintain surgical skills more effectively.

There is also a need for surgeons working at low-volume hospitals as well as surgeons working at hospitals with limited access to practice equipment. For surgeons working in low-low volume hospitals, a surgical trainer would assist in maintaining skills when they aren't getting a sufficient number of surgeries a year to stay proficient. From the meta-analysis mentioned previously, a surgical trainer could provide more experience and therefore aid in providing better outcomes [7]. Some hospitals in developing areas have access to proper equipment, but don't have the means for training outside of a real surgery setting. In Figure 1, surgical residents in Malawi can be seen practicing colorectal surgery with laparoscopic instruments while using a carboard box to act as the abdomen. Cadavers can be very expensive and aren't sustainable. Therefore, there is a need for low cost, bio-realistic surgical trainers for these developing areas and smaller hospitals so they can become more accessible and provide a better outcome.

Figure 1: Malawi residents using cardboard surgical trainer [8]

Other methods of surgical training include virtual simulators as well as cadaver options. Cadavers provide for a somewhat bio realistic experience and proper anatomy. On the other hand, cadavers can often be very expensive and have a short shelf life [9]. There is a lack of current colorectal surgical models for laparoscopic surgery that are bio-realistic and provide translatable skills for residents in training.

The aim of this project is to design and validate a bio-realistic abdominal model for residents and surgeons to practice on within a box trainer to further develop and maintain their surgical skills. The goal for the bio-realistic abdomen is to contain a mesentery and right upper quadrant organs, be easy to use, and be reproducible. The mesentery and right upper quadrant organs are anatomically correct, simulate the mechanical properties of real organs to best mimic the environment of the right upper quadrant of the abdomen. The model is peelable/separable, reusable, replaceable, cost effective, and highly manufacturable.

In order to achieve these goals, the team followed the engineering design process by defining stakeholders, setting forth objectives and functions, brainstorming design alternatives, producing a prototype, and validating the device. The team was able to utilize the client's goals to generate a timeline and determine the needs and wants for the device. After comparing the design alternatives, the team decided on a design to perform mechanical testing with. The team determined the final material based on mechanical testing results from puncture and peel tests conducted using an Instron 5544.

To develop a bio-realistic abdominal model, the team split into two groups to focus on specifically designing right upper quadrant (RUQ) organs or mesentery. Each group brainstormed potential materials and manufacturing methodology to produce a physical prototype for surgeons to assess. This project's previous design teams laid a foundation by providing material data and suggested manufacturing methods, but the current members conducted an extensive variety of unique experiments to find the best design combinations. To ensure anatomical correctness within the device, the team used CT scans from anonymous

patients to create 3D printed molds to produce organs. Puncture and peel tests were performed, following ASTM standards, on each batch of polyvinyl alcohol (PVA) to ensure that the properties are consistent between batches. These mechanical tests also ensured that the selected material of PVA best simulated the properties of real organs when compared to data found from previous teams' testing and literature review.

After completing a prototype, the team validated the bio-realism of the abdomen through conducting surveys, approved by WPI IRB, with residents and surgeons at Beth Israel Deaconess Medical Center. The survey consisted of 11 questions that were answered utilizing a 7-point Likert scale that revolved around comparing the feeling and accuracy of the bio-realistic abdomen to a real abdomen.

The team was able to successfully create a bio-realistic abdomen to be used for practicing laparoscopic surgery based on the validation testing performed to confirm the device's ability to perform to specifications. For future iterations of this project, the team developed three recommendations: implementing a blood leaking model, further validation through resident and surgeon testing, and a more efficient method for manufacturing the device. The implementation of these recommendations could assist in completing the client's ultimate goal of transforming this project into a future interactive qualifying project (IQP).

Chapter 2: Literature Review

The goal of this project is to develop and design a cost-effective surgical training model of the right upper quadrant of the abdomen that is anatomically correct. To better understand the scope and focus of the project we investigated the anatomy of the Right Upper Quadrant (RUQ) of the abdomen. This included the corresponding organs and mesentery. The research also included right colectomy surgeries as this is the surgery of focus for the surgical trainer as well as competing devices on the market and past materials used.

2.1 Anatomy

The project scope will be focusing on bowel resection or colectomy of the upper right colon. Therefore, study of the anatomy, mechanical properties, and material properties of relevant organs, tissues, and mesentery is crucial to the success of the project. The surgery takes place in the right upper quadrant (RUQ) of the abdomen and includes the transverse section of the large intestine, small intestine, liver, and stomach as can be seen in Figure 2. The project the previous year focused on these surrounding organs, but for this project, the team will be focusing on the colon, small intestine/duodenum, adipose tissues, mesentery, and peritoneum.

Figure 2: Human Digestive System [10]

2.1.1 Small Intestine and Duodenum

The small intestine is also part of the digestive system and is responsible for breaking down food and absorbing nutrients. It is about 22 feet long and is made up of three parts: duodenum, jejunum, and ileum. The duodenum is the first part of the small intestine and is what connects to the stomach. It wraps around the pancreas at about 10 inches long and connects to the rest of the small intestine [10]. According to transversal testing on an Instron 1221, the small intestine has a max strain of 140% and a maximal stress of 0.9 MPa [11].

2.1.2 Transverse Colon and Ascending Colon

The colon is made up of four sections: ascending colon, transverse colon, descending colon, and sigmoid colon. The colon absorbs water and other nutrients from any indigestible substance and forms stool [12]. With respect to the small intestine, it wraps around and outlines it. As can be seen in Figure 3 the ascending colon is the beginning of the colon and is located on the right side of the abdomen. It receives the digesting food from the small intestine which is attached to the colon by the cecum [13]. It continues up vertically and continues to the transverse colon at a 90-degree angle and runs horizontally from right to left until the descending colon as can be seen in the figure. The transverse colon is also connected to the transverse mesocolon, which is a mesentery. On a study done on segmental colon length and mobility it was found that the ascending colon is around 20cm in length and the transverse colon is about 50cm in length [14]. In a study done by Western General Hospital and University of Edinburg it was found that the transverse colon has a cross sectional area of 14.1 ± 6.2 mm^2, tensile strength of 13.1 ± 4.2 (g/ mm^2), and an elongation percent of 221 ± 187 [15].

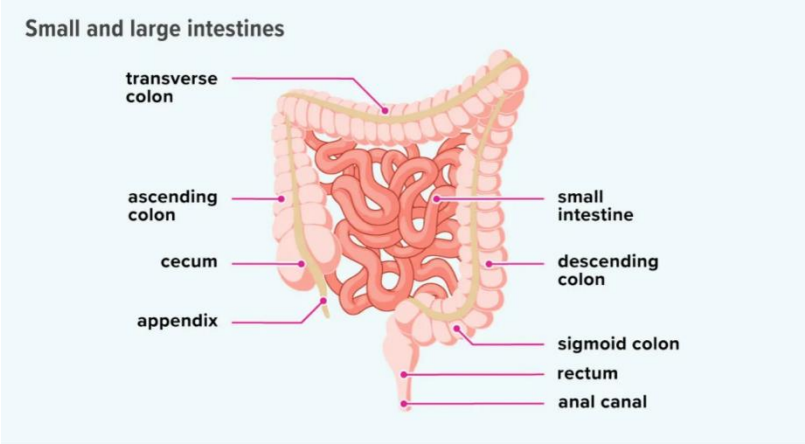


Figure 3: Large and Small Intestines [16]

2.1.3 Adipose Tissue

Adipose tissue is connective tissue where fat is deposited and stored. The adipose tissue is controlled by the nervous system and contains a dense capillary bed that is richer than that of muscle. Although it specializes in fat storage, it can fulfill other tissue functions as it is a part of other systems within the body [17]. Adipose tissue is found under your skin as subcutaneous fat, between your organs are visceral fat, and in the inner cavities of the bone as bone marrow adipose tissue. There are also two types of this tissue: white adipose tissue and brown adipose tissue [18]. For the purpose of this project, our team will focus on white adipose tissue, as brown adipose tissue is mainly present in infants. Adipose tissue is able to withstand 30% strain, but anything above that threshold will cause damage or the tissue will experience plastic deformation. Based on a study of 23 omental (visceral) samples and 28 subcutaneous samples,

the elastic modulus at 30% strain was found to be 32 ± 15.6 kPa and 11.7 ± 6.4 kPa respectively [19].

2.1.4 Mesentery

Mesentery is a continuous organ in the posterior abdominal wall that is comprised of highly cellular stroma and surface mesothelium. Stroma are cells and connective tissues that allow for the mesentery's structural support. A mid-region fold that is important for structural continuity subdivides this organ into the upper (pre-fold), mid, and lower (post-fold) regions [20]. The organ itself is made of several parts as depicted in Figure 4 below: the transverse mesocolon, small intestinal mesentery right mesocolon, mesosigmoid, and mesorectum. All the digestive organs, such as: the liver, gall bladder, pancreas, stomach, duodenum, and small intestine develop and remain within the folds of the mesentery. Since there is little to no testing done on the mesentery, there is not a lot known about the mechanical properties. However, since there is adipose tissue found within the mesentery, the mechanical properties are assumed to be similar to those of the adipose tissue.

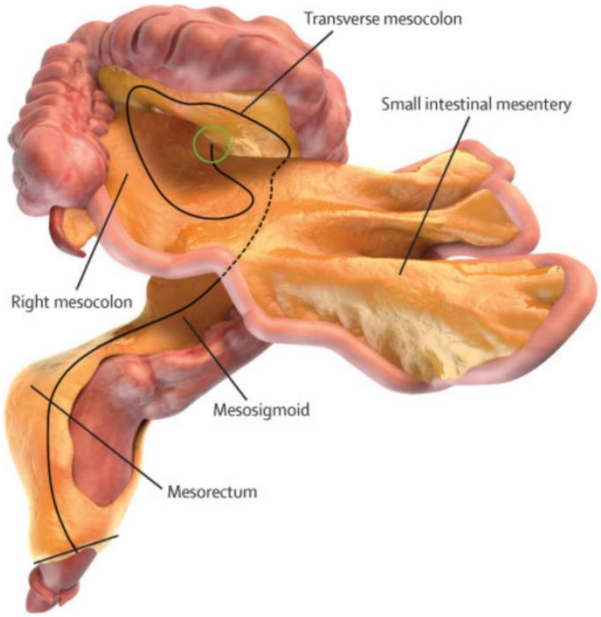


Figure 4: Mesentery Diagram [20]

2.1.5 Peritoneum

The peritoneum is the largest serous membrane within the human body, with a surface area of 1.8 m^2 [21]. There are two parts to the peritoneum, parietal and visceral, where the parietal lines the inner abdomen wall and the visceral covers the visceral organs. The two different parts of the peritoneum have different sensitivities where the parietal portion is highly sensitive to pressure, pain, temperature, and laceration, whereas the visceral is sensitive to

stretching and chemical irritation [21]. They are similar in terms of structural composition where they both consist of 3 layers: the mesothelium, basal lamina, and the submesothelial stroma. Since the peritoneum is similar to the mesentery and also consists of adipose tissue, the mechanical properties are assumed to be similar to that of adipose tissue.

2.2 Right Colectomy Surgery

A colectomy surgery may be needed if there is cancer or polyps, diverticular disease, or Inflammatory Bowel Disease (IBD). All or some of colon can be removed during a colectomy [22]. These are called total colectomy and partial colectomy, respectively. Over 600,000 colectomy surgeries are performed each year in the United States [1]. Hemicolectomy refers to either the right or left sections of the colon being removed. More specifically, a right hemicolectomy is when the ascending colon is removed, and the small intestine is then attached to the transverse colon as can be seen in Figure 5. This can be done through open surgery or a laparoscopic approach.

Open surgery requires a larger incision that creates a clear view of the organs in the abdomen, performing the procedure completely internally. Due to the large incision, there is an increased chance of infection as well as more scar tissue and a longer recovery time [23]. The laparoscopic approach uses a series of smaller incisions around an inch long to insert ports allowing surgical tools to enter the abdomen as well as a laparoscope to project a view of the organs onto a screen. Surgeons cut longer incisions of about two to three inches to lift the colon out of the abdomen [23]. After a surgeon lifts the colon through the larger incision, they remove the ascending colon, and then connect the intestine by staples or suture.

It was found that the benefits of laparoscopic over open surgery include a lower mortality rate, shorter hospital stays, better cosmetic results, as well as less postoperative pain: therefore, laparoscopic is more widely used today [24]. The procedure includes a good number of separating layers of mesentery and tissue, so there is a need for making this procedure as reproducible as possible in a box trainer setting. The box trainer would be important as it would allow residents to practice the skills of dissecting the colon from the mesentery as this is a large portion of the procedure.

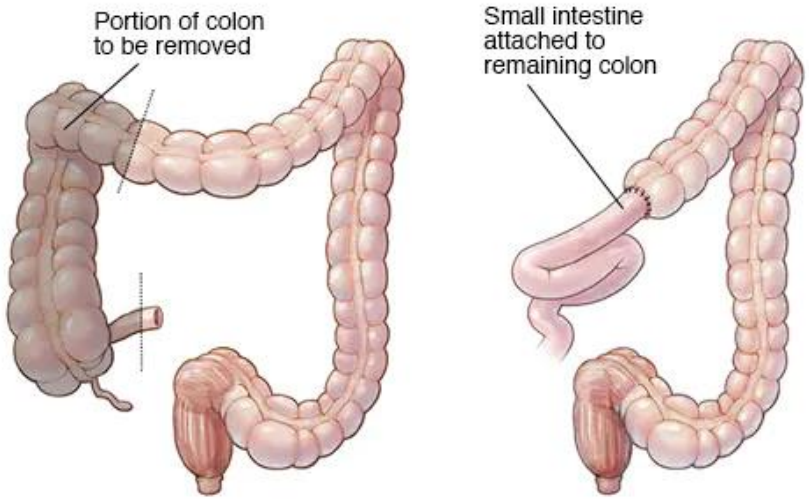


Figure 5: Right Colectomy Surgery [25]

2.3 Need for Surgical Trainers

Before graduation, resident surgeons "perform between 1,000 and 1,200 major operations" on patients with each procedure providing different techniques and steps to follow [26]. Surgical trainers allow residents to learn and practice routines in a patient-free environment, ultimately increasing preparedness to enter the operating room. Any simulation before a surgical procedure will benefit both the resident and patient. In one study, researchers tested twenty-four novices' laparoscopic skills and randomly split them into groups with different methods of training [27]. The groups used virtual reality, a box trainer, or no training. After the same number of training sessions, the researchers reassessed the novices' skills. The study found that those who used surgical trainers "had become significantly more economical in their hand movements" and those who used box trainers made fewer errors, as shown below in Figure 6 [27]. Surgical trainers are another form of practice and the closer to simulating a surgery, the better performance and preparedness a surgeon can provide.

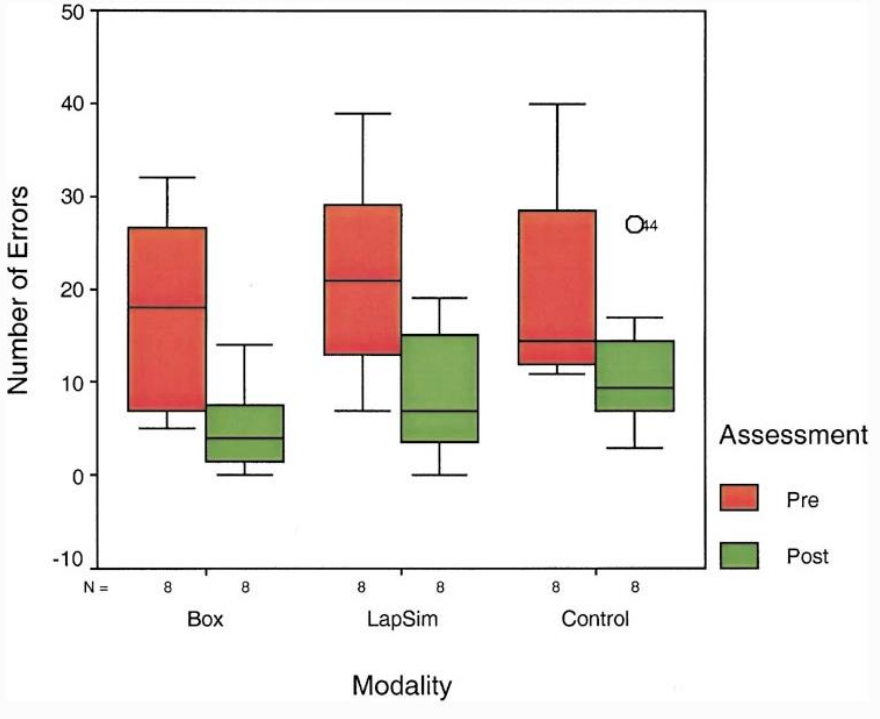


Figure 6: Surgical Trainer Comparison [27]

2.3.1 The Fundamentals of Laparoscopic Surgery (FLS) Test

Surgical trainers also quantify a surgeon's ability to perform specific techniques and provide a form of skill assessment before placing a patient's care in their hands. The FLS test is a two-part exam consisting of the demonstration of knowledge and physical skills of laparoscopic equipment. One objective of the test is to set a minimum standard for "basic cognitive and technical skills" necessary for laparoscopic surgery and create a quantifiable, validation method to measure those skills. Another objective is to provide surgeons with standardized practice and improve the quality of care of patients [28].

The first section of the FLS test consists of a "written component" that is a timed, multiple-choice exam taken on a computer. The exam evaluates "the understanding and application of the basic fundamentals of laparoscopy with emphasis on clinical judgement or intraoperative decision making" [29]. The second part of the FLS test is a set of manual skills. These evaluate efficiency, measured by speed, and precision, measured by accuracy, "of the surgeon's maneuvers using the FLS laparoscopic Trainer Box" [29]. There are five tasks in which a resident must complete in a given amount of time within a given number of repetitions. These repetitions can be either consecutive or non-consecutive depending on the task [30]. As shown in Figure 7 below, the tasks include peg transfer, precision cutting, ligation loop, suturing with extracorporeal knot, and suturing with intracorporeal knot respectively from top left to bottom right.

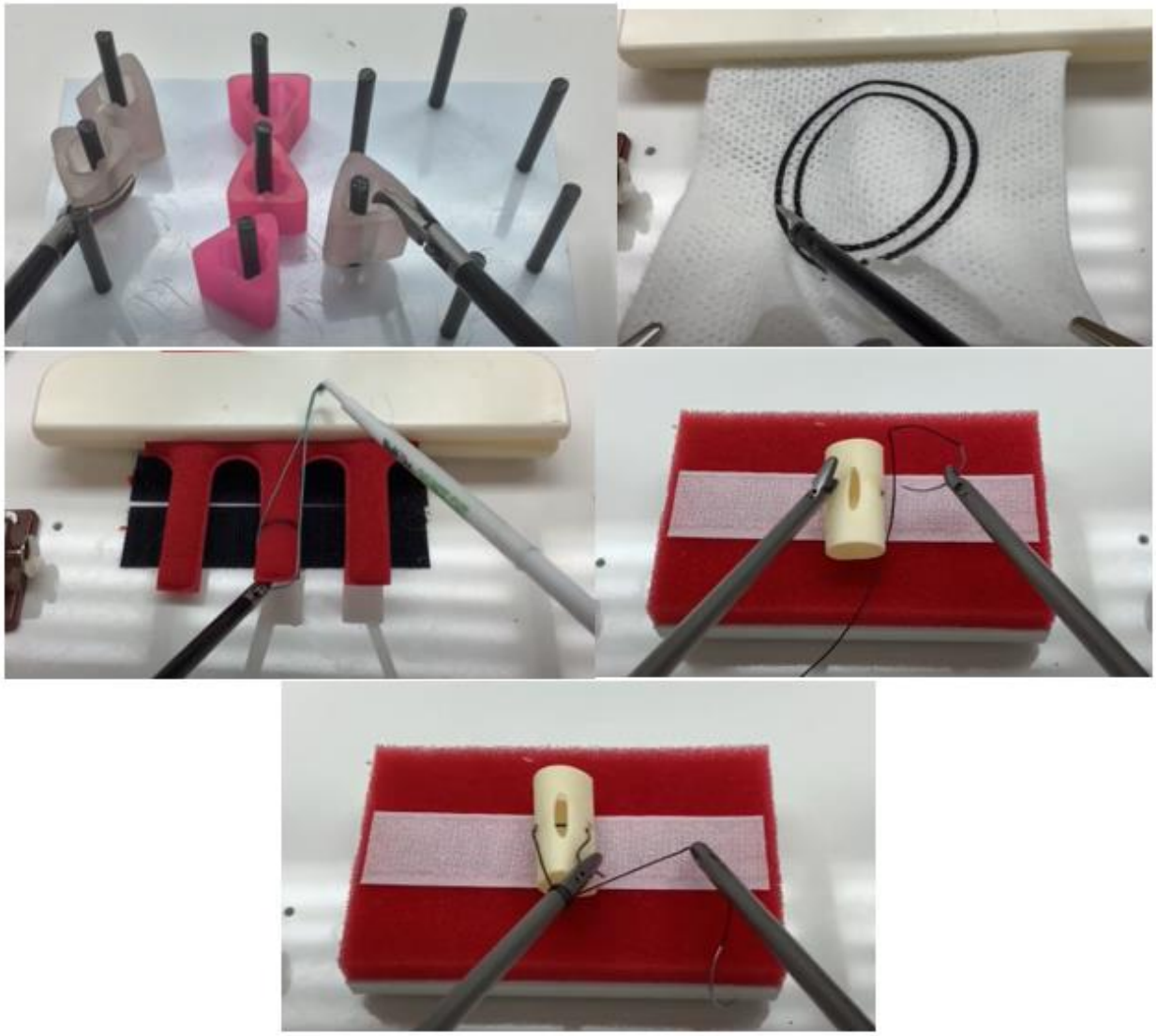


Figure 7: FLS Training System [31]

Although the FLS test is a necessary baseline, it is currently the only specific training requirement of the American Board of Surgery regarding laparoscopic surgery [32] The training helps surgeons practice the physical skills of using laparoscopic equipment but does not simulate surgery in any realistic capacity. There is a clear gap in laparoscopic training from picking up basic skills and operating on a living patient. Surgical trainers fill this deficiency, but the current models can be improved.

2.4 Existing Models

In attempt to provide residents with more laparoscopic training, there are simulators like box trainers, virtual reality, and synthetic cadavers that are utilized to gain basic laparoscopic skills and muscle memory. All of the pros and cons of each existing laparoscopic training model are listed in Table 1 below. Each current model has its own advantages, but they all share the

same disadvantage of not having a mesentery to practice on and a lack of a bio-realistic training environment.

Table 1. Pros and cons of the existing laparoscopic training models

Existing Model	**Pros**	**Cons**
Box Trainer	• Low Cost • Reusable • Practices muscle memory for basic skills	• Non-realistic Environment • No Physical Forces • No Organs
Virtual Reality	• Sensory Training • Bio-realistic Surgical Environment • Comprehensive Training Data	• No Bio-realism • No Physical Forces • No Mesentery
Synthetic Cadaver	• Expensive • Synthetic Organs	• Complex Setup • Difficult Upkeeping • No Mesentery

Current models of laparoscopic box trainers, similar to the one in Figure 8 below, are low cost and reusable. The box trainers contain tasks to complete within including, but not limited to, bead transfer, suture practice, and cutting practice. These tasks are used for evaluation and to help with hand-eye coordination, dexterity, and suturing skills [33]. Although the box trainer is effective in training simple skills, it is unsuccessful at replicating a realistic surgical environment. When performing the tasks, the users are not introduced to the physical forces and difficulties of the surgery such as cutting and burning through the mesentery.

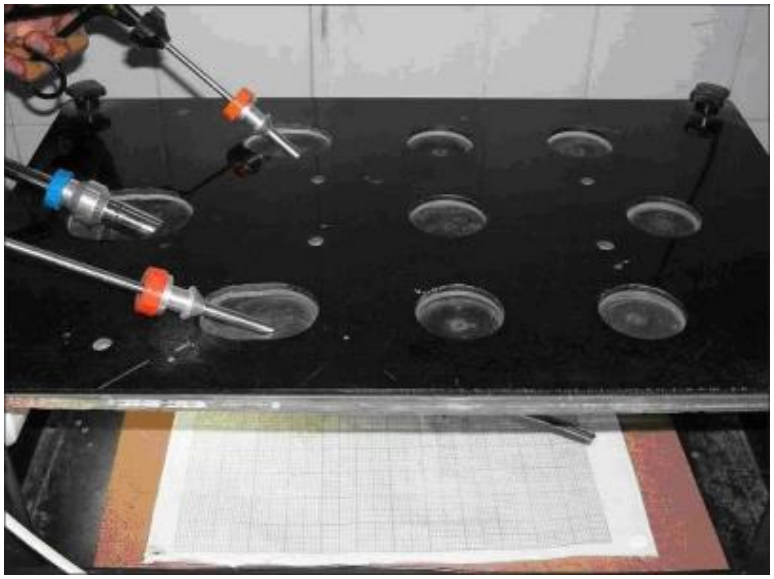


Figure 8: Box trainer used to practice laparoscopic surgery [33]

Virtual reality (VR) simulations allow users to practice simulated surgeries through the computer, as shown in Figure 9 below, without the use of real patients. The users are able to experience sensory training within the immersive environment without needing oversight. There are instructions and guides to go along with the assigned courses and goals. The VR simulator provides comprehensive data on performance metrics that can be used to gauge skill development [34]. Still, the users are only introduced to simple muscle memory tasks instead of the bio-realistic experience of being able to physically move organs and tear into tissues.

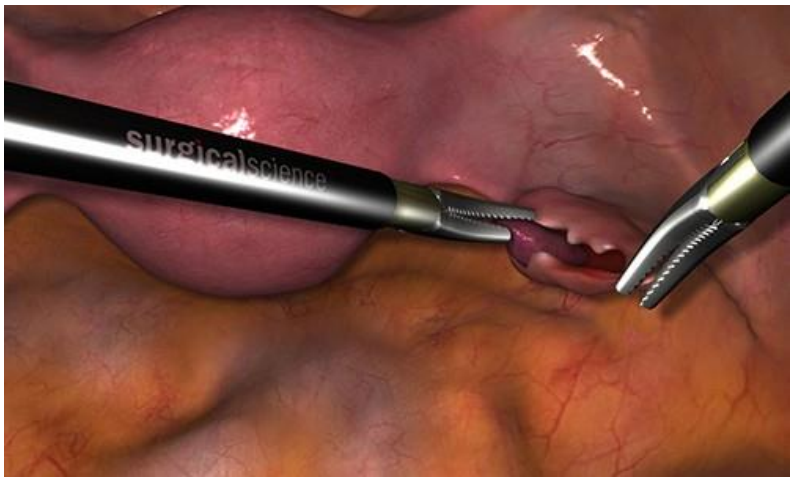


Figure 9: Example of virtual reality simulated environment [35]

Companies such as Syndaver Inc. work to create synthetic human cadavers that can be used for surgical practices, as shown in Figure 10 below. Although this synthetic cadaver is reusable it comes at a high cost of $60,000 for a full human body [36]. They are also difficult to upkeep as there is a lot of maintenance required to keep the body and the organs cared for and hydrated. There are specific instructions that must be carefully followed when unpacking and preparing the synthetic cadaver before use. For these preparations, one must properly unpack the synthetic cadaver, treat it with a special solution, set up the practice table, and test the water solution. After the body is prepared, one must also set up a circulation pump and irrigation hose to allow for the fluids to pump throughout the body and a drainage pump to drain any unwanted water [37]. In order to simulate the human anatomy and function, the synthetic cadaver has multiple pumps and drains throughout it. This method of training is highly beneficial as the users are able to work with synthetic organs, however this model is unsuccessful in including a vital organ that is crucial for laparoscopic colectomies, the mesentery.

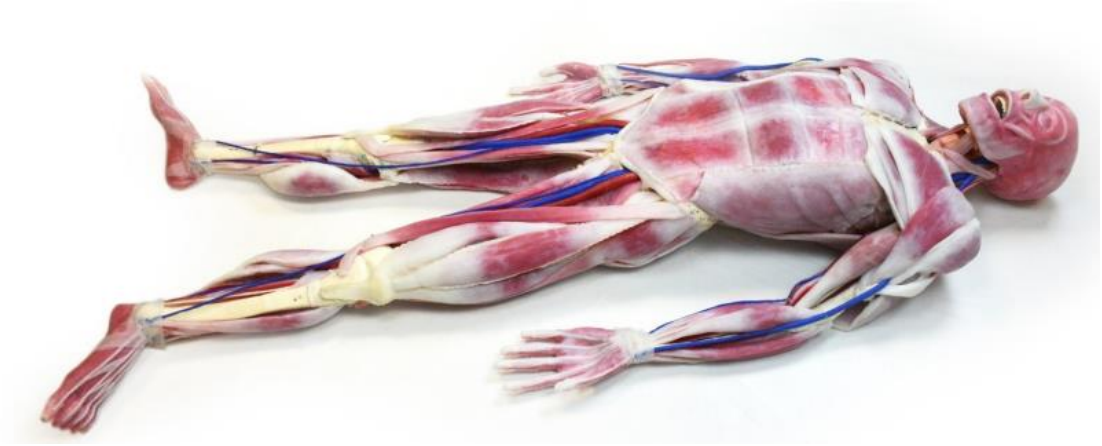


Figure 10: Syndaver's Synthetic Cadaver [36]

2.5 Past Materials Used

Over the previous year a team of WPI students had worked to develop a bio-realistic surgical phantom. In developing their final design, mechanical and material properties were determined through testing of bovine and porcine samples through different industry standards. The standards used for material qualification were tensile testing of standard ASTM D412-16 and puncture testing of standard ASTM D4833. This testing helped the team to conclude the suitable use of a synthetic silicone material known as Eco Flex 00-10 and Eco Flex 00-30. Using 3D printed molds developed from CT scans, material was injected to create the current 3D printed organs. This material was acceptable for use in molding the organs, but the team recommended that new synthetic materials be investigated for a better simulation of organs during surgery. The project focus falls within how surgeons manipulate organs moving, separating, and peeling within the abdomen. To create a better bio-realistic trainer, the current team continued last year's literature review of possible synthetic organs to be used. These researched organs can be tested, and their mechanical properties will be compared with previous testing to pursue better suited materials for use.

The previous project team was able to compare the mechanical properties of bovine and porcine organs with synthetic materials to design the surgical trainer due to peer-reviewed literature stating that porcine tissues are viable targets for mimicking human organs. A study from the University of Limerick investigated mechanical properties of porcine organs such as the "mesocolon, small intestinal mesentery, fascia, and peritoneum tissues" [37]. The researchers tested properties including "strength, stretch at failure, and stiffness" [37]. The main objective of the study was to create the foundation of a database for the mechanical properties of these tissues, since "no study has mechanically characterized" the porcine mesentery and other tissues. The most important finding from the study was that "porcine mesenteric and associated tissues … had similar tactile characteristics" to the human tissues [37].

2.6 Engineering Need

As mentioned in Section 2.4, current surgical training models do not simulate realistic surgery conditions. These methods provide surgeons with cartoonish and virtual ways to practice laparoscopic colorectal surgeries. Even the most authentic surgical models are not completely anatomically correct. These trainers do not include the mesentery or adipose tissue, which connect the tissues and organs of the abdomen. These realistic models lack a major part of what a surgeon must navigate through during procedures, are extremely expensive, and require extensive maintenance and assembly process.

There are many reasons why a more cost effective, bio-realistic surgical abdomen phantom has not been manufactured. There is a lack of access to data representing material properties of human organs and materials suitable for mimicking these attributes. Syndaver, the surgical model company mentioned in section 2.4, has cited multiple biomaterials, engineering, and mechanical design scientific articles on their patent documents as references to their work [38]. Many patents circulating the development of different anatomical simulation training devices. One specific paper, *The Effects of Testing Environment on the Viscoelastic Properties of Soft Tissues*, states that the mechanical properties of soft tissues vastly differ when isolated from the human body. There are multiple studies discovering these properties ex vivo, but this article manages to measure these properties simulating an *in vivo* perfusion pressure environment, the pressure necessary to push blood through all of the vessels in the area [39]. However, the only tissue this article measured was porcine liver and there is a lack in diversity among this testing procedure. All surgical models would benefit from further research using the perfusion methodology to match *in vivo* mechanical properties of soft tissues.

2.7 Needs Statement

There is a lack of current colorectal surgical models for laparoscopic surgery that are bio-realistic and provide translatable skills. Therefore, there is a need to produce a surgical trainer which accurately simulates mechanical organ properties and fills the gap between novice and experienced surgeons.

Chapter 3: Project Strategy

3.1 Initial Client Statement

Our client Dr. Thomas Cataldo, an abdominal surgeon from Beth Israel Deaconess Medical Center (BIDMC), presented our design team with the goal to produce a physical prototype of a phantom abdomen. This abdomen should include individual organs held together by a mesentery which resident surgeons can take apart to best simulate the feeling of surgery.

3.2 Defining Stakeholders

It is critical within engineering that all the stakeholders, also known as anyone who may be able to affect or be affected by the outcome of the project, are defined. For our project, the stakeholders are split into three categories: clients, users, and designers, as shown in Figure 11 below. The clients are the people or institutions that invest in the project and expect a deliverable. The users are those who will be utilizing the deliverable for its created purpose and who are impacted based on the quality of the product. The designers are those who take on all the needs of the other stakeholders to develop a product that meets all the necessary criteria.

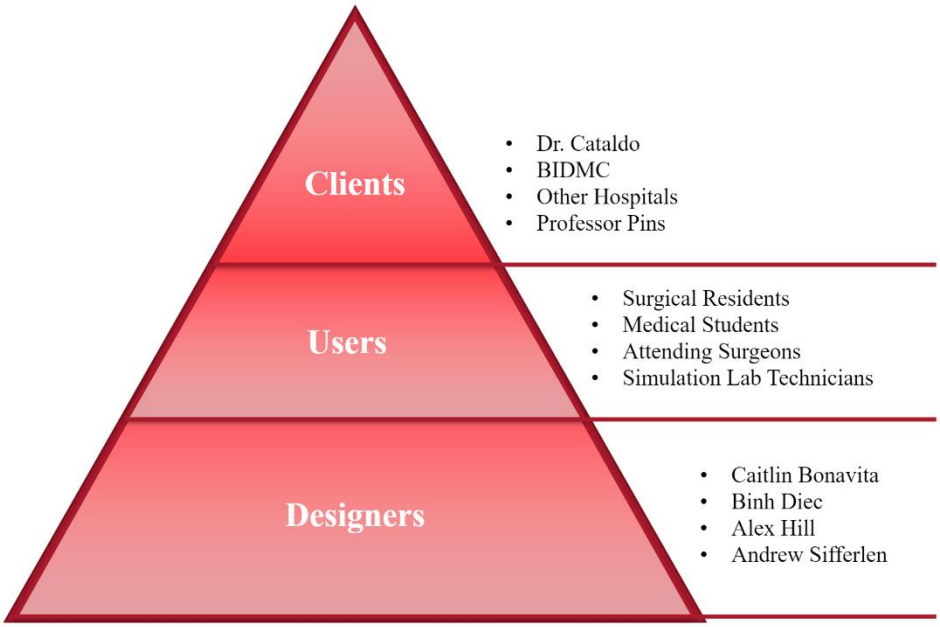


Figure 11: The hierarchy of stakeholders within the project including clients, users, and designers.

Figure 11 above shows the breakdown of the stakeholders for this project. The main client for the project is Dr. Cataldo, who initially identified the need for a realistic box trainer for surgical residents and sponsors the MQP. Another main client for the project is Professor Pins, who represents WPI and provides guidance for the project in terms of the design process for

biomedical engineering. Other clients include BIDMC, as they are the ones who will be investing in the product in the future to train their residents.

The identified users for our product are surgical residents, medical students, attending surgeons, and simulation lab technicians. The surgical residents and medical students will utilize the product to practice gaining hands-on experience in laparoscopic surgery. The attending surgeons will be able to maintain their skills by practicing on the product before performing the surgery. The simulation lab technicians will work with the product to upkeep the conditions as well as being knowledgeable able the product to troubleshoot any issues that other users may run into.

The designers of this product will be the members of the current project team: Caitlin Bonavita, Binh Diec, Alex Hill, and Andrew Sifferlen. The team will consider all of the stakeholders' criteria and develop a product that satisfies those needs. In order to have a successful outcome, the team will work alongside stakeholders throughout the design process to ensure that the product is satisfactory.

3.3 Initial Design Objectives

Over the past two years, previous project teams built upon the same primary objectives. Instead, the current team decided to develop more recent primary design objectives based on Dr. Cataldo and Professor Pins's present goals, but still incorporated the previous progress of the project. Towards the beginning of the academic year, the team discussed the scope and goals of the project with Dr. Cataldo, with notes in Appendix A. The team produced these new set of objectives through conversations with the client: translatable skills, mesentery, reproducibility, ease of use, and right upper quadrant organs. These targets follow along with the elements described within the initial client statement in section 3.1 and descriptions of each can be found in Table 2.

Table 2: The primary objectives for the project with their respective descriptions

Primary Objectives	Description
Right Upper Quadrant Organs	The surgical trainer includes the correct organs associated with the right upper quadrant. They must be either reusable or easily replaceable on top of being anatomically correct.
Mesentery	The surgical trainer should have structural integrity that holds all the organs in place while being able to be peeled apart and separated.
Ease of Use	The surgical trainer must be a simple to use device that is effective in translating surgical skills.
Reproducibility	The surgical trainer must be easily manufactured with little to no variation from model to model.

3.4 Constraints

The designers developed a table of constraints after meetings and conversations with the clients. Two design constraint categories were created which were material and technical. The following constraints can be seen with descriptions in Table 3.

Table 3: The main design constraints of the project with smaller categories and descriptions

Design Constraints		Description
Material	Material Properties	• Not flammable • Can interact with steel or other trainer materials
	Reusability	• Constant shape and size of organs • Easy to clean • Doesn't react with disinfectants
Technical	Cost	• Project completed by the end of D term 2023
	Timeline	• Budget must not exceed $1000 ($250 per person)

The first section of constraints is materials. This section is important because expensive medical equipment is being used and therefore it must be compatible with the environment. The

material can’t be flammable due to interactions with surgical instruments. It also needs to be reusable for multiple training sessions. To achieve this the organs can’t change size and shape over time to maintain being bio realistic as well as be detachable and easy to clean. These factors may limit the materials to choose from when exploring options to test for the models.

The second section is technical constraints and includes cost of resources as well as time. For this project the budget is $250 per person or $1000 total. The timeline of the project must also not exceed D term of 2023 as this is when the school year ends as well as project presentations are due.

3.5 Revised Objectives

The initial objectives were expanded into further sub-objectives and then laid out into an objective tree. The revised objectives go into detail of what each objective is going to accomplish and the goals surrounding them.

3.5.1 Objective Tree

The design team expanded on the initial objectives by breaking them down into secondary objectives. These secondary objectives help develop a deeper understanding of each primary objective in order to meet the goals for the final design. The final primary and secondary objectives can be seen in the objective tree in Figure 12 below.

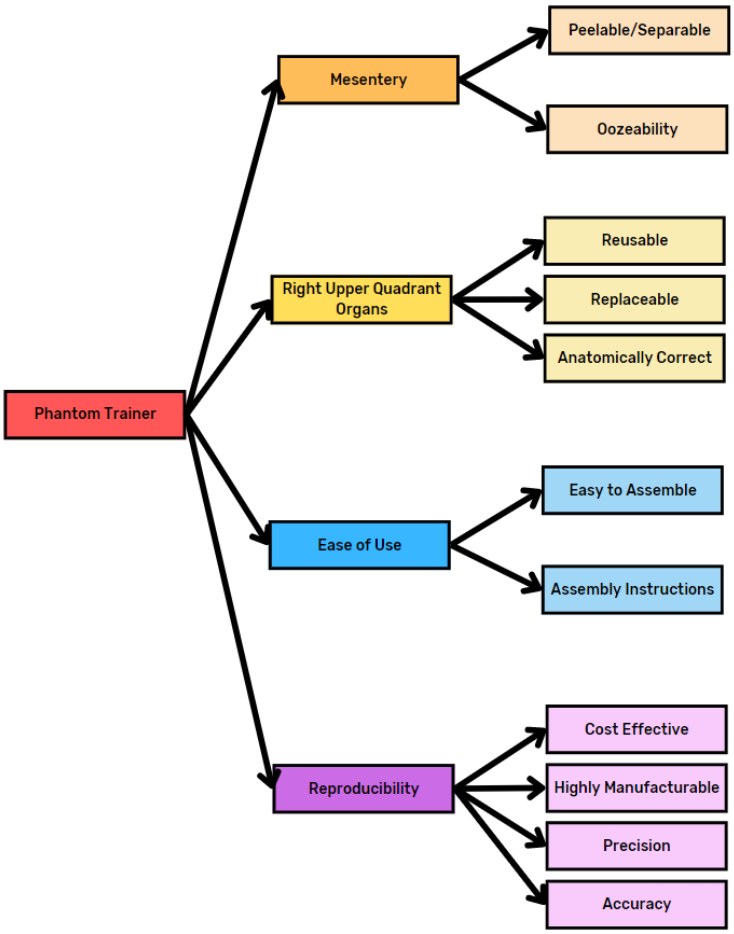


Figure 12: Team Design Objective Tree

3.5.2 Secondary Objective Descriptions

Each primary objective was analyzed and broken down into more specific secondary objectives. The descriptions for each secondary objective can be seen in Tables (4-7).

Table 4: Right upper quadrant secondary objective descriptions

Primary Objective: Right Upper Quadrant Organs	
Secondary Objective	**Description**
Reusable	Organs that should not be affected during training. i.e. kidney, liver, gallbladder
Replaceable	Organs that are operated on during training and must be replaced after use. i.e. Colon, duodenum, small intestines, mesentery
Anatomically Correct	The 1:1 ratio of artificial to actual organ size, the location of organs, how the organs respond to stress and strain from cutting/movement (mechanical properties) as well as the material properties.

Table 5: Mesentery secondary objective descriptions

Primary Objective: Mesentery	
Secondary Objective	**Description**
Oozeability	Ability to bleed when cut or pierced
Peelable/Separable	The model's ability to peel apart and be separated

Table 6: Reproducibility secondary objective descriptions

Primary Objective: Reproducibility	
Secondary Objective	**Description**
Cost Effective	The cost to 3D print and manufacture synthetic organs will be cheap
Precision	The quality and condition of the model must be the same when reproduced
Accuracy	Within multiple surgical models, they must be accurate to each other and not have differing properties
Highly Manufacturable	The process of model creation must be for hospitals to reproduce in large quantities

Table 7: Ease of use secondary objective descriptions

Primary Objective: Ease of Use	
Secondary Objective	**Description**
Easy to Assemble	Model is assembled within a 10–15-minute time frame
Assembly Instructions	Instructions provided to help guide assembly of model

3.5.3 Objective Rankings and Evaluation

After the final objective tree was finished, the team organized all the objectives into tables to conduct a pairwise comparison chart. The charts were then sent out to the clients to be ranked in order to determine the importance of each objective. The objectives were ranked on a scale from 1-5 with 1 being the least important and 5 being the most important. The design team also ranked both the primary and secondary objectives individually and their averages were taken. The results for the primary and secondary objective rankings can be seen in Tables 7-11.

Table 8: Right upper quadrant organs secondary objective rankings

Primary Objective: Right Upper Quadrant Organs				
Secondary Objectives	**Dr. Cataldo**	**Professor Pins**	**Team**	**Average**
Reusable		3	2	2.5
Replaceable		3	3	3
Anatomically Correct	2	4	4	3.3

Table 9: Mesentery secondary objective rankings

Primary Objective: Mesentery				
Secondary Objectives	**Dr. Cataldo**	**Professor Pins**	**Team**	**Average**
Oozeability	1	3	1	1.7
Peelable/separable	5	5	5	5

Table 10: Reproducibility secondary objective rankings

Primary Objective: Reproducibility				
Secondary Objectives	**Dr. Cataldo**	**Professor Pins**	**Team**	**Average**
Cost Effective	4	4	4	4
Highly Manufacturable	5	4	4	4.3
Precision	2	2	4	3.3
Accuracy	3	2	2	2.3

Table 11: Ease of use secondary objective rankings

Primary Objective: Ease of Use				
Secondary Objectives	**Dr. Cataldo**	**Professor Pins**	**Team**	**Average**
Easy to Assemble	3	5	2	3.7
Assembly Instructions	4	4	3	3.3

Based on the ranking of the secondary objectives, the most important objective, having an average ranking of 5, is the mesentery's ability to peel and separate. The other two objectives that will be prioritized are highly manufacturable and cost effective, as they had an average of 4.3 and 4 respectively. The less pressing objectives will relatively the same average of about 3.7 to 3.3 are easy to assemble, anatomically correct, precision, and assembly instructions. The objectives that are on the bottom of the ranking are replaceable, reusable, accuracy, and oozeability, where they all scored a 3 or lower.

3.6 Standards and Requirements

This section describes the standards for both surgical residency educational programs and testing procedures to gain information regarding mechanical properties of certain materials. The accreditation standards provide value to the surgical trainer and the material testing is necessary for the molding manufacturing method for the anatomy of the trainer.

3.6.1 Board-Certification and Educational Program Accreditation

For a resident surgeon to become board certified by the American Board of Surgery, they must complete a list of requirements including "a minimum of five years of progressive

residency education” in a program accredited by the ACGME (Accreditation Council for Graduate Medical Education) or RCPSC (Royal College of Physicians and Surgeons of Canada) [15]. The accreditation process of the ACGME ensures that a residency program prepares students “to perform the role of a surgeon at the advanced level expected of a board-certified specialist” [40]. ACGME provides a list of requirements of a graduate residency program that focuses on the development of “procedural skills and operative techniques” [40]. A surgical trainer should follow the requirements of the ACGME to ensure that its creation has accredited use and value for resident surgeons.

In section IV. “Educational Program” of ACGME requirements, the first definition of a board-certified educational program mentions supporting the development of skillful physicians and a curriculum containing “competency-based goals and objectives… designed to promote progress” [40]. The inclusion of a surgical trainer in a residency program fulfills multiple sections of these requirements. The trainer provides residents with a core didactic activity (section IV.A.4.a), which includes simulations, and the ability to “demonstrate competence in technical... skills sufficient to safely perform essential/core procedures" (section IV.B.1.b.(2).(b)) [40]. Under the medical knowledge requirements, a bio-realistic surgical trainer classifies as “applied surgical anatomy” for section IV.B.1.c).(2).(a) [40].

3.6.2 Mechanical Property Testing

The International Organization for Standardization consists of experts in multiple areas of knowledge including quality management, environmental management, health and safety, energy management, food safety, IT security, etc. ISO 527 represents standards for “determining the tensile properties of plastics and plastic composites under defined conditions” [41]. These principles are suitable for the manufacturing style within this project of rigid and semi-rigid molding. The tensile properties include tensile strength, tensile modulus, strain, yield point, point of break, and Poisson's ratio [41]. ISO 527 is highly reproducible using machines such as the INSTRON 5544.

ASTM International is another organization which produces standards for testing, materials, products, services, and systems. The procedures include requirements for materials in similar industries to the ISO. The ASTM D4833 is a “standard test method for index puncture resistance” for materials used in production of the bio-realistic trainer [42]. Puncture resistance is the force required for an object to puncture the testing material and is another mechanical property necessary to compare artificial and animal tissue. The ASTM D903-98 and D1876 tests “measure the comparative peel properties of adhesive bonds between flexible adherends” [43]. The t-peel tests allow the team to compare a material’s peeling properties with that of the mesentery, which is the glue that holds abdominal organs in place. These standard tests represent the main procedures used to accomplish multiple project objectives and milestones.

3.7 Revised Client Statement

Our team was tasked to develop and design a surgical training model of the right upper quadrant of the abdomen that includes the following organs: right kidney, small intestine, duodenum, transverse colon, mesentery, stomach, gall bladder, and peritoneum. The surgical model will consist of bio-realistic organs that demonstrate 1:1 ratio dimension of human abdominal organs and tissues as specified in Section 6.2.1. The mesentery will have a peel force of 2.9 ± 1.8 kPa and puncture resistance of 18.9 ± 10 N. The trainer should cost less than $1000 for initial purchase and replaceable organs should cost less than $1000 per year. The replaceable parts should be reused 3-4 times before needing to be changed. Residents should be able to assemble and disassemble the trainer within 5-10 minutes and be able to practice the entire surgery in about 160 minutes.

3.8 Project Management

For the completion of this project, different tools will be used to manage and facilitate the progress of the project. A management plan must be laid out for the team to follow and stay on track with a project completion deadline of May 2023.

3.8.1 Work Breakdown

In order to keep the design team on track for the year, the current project team held weekly meetings with the clients as well as additional meetings with the student core team. To facilitate progress through the year, a rotating member each week was responsible for taking meeting notes to record old and new business as well as current thoughts and actions items discussed to meet weekly goals. In core team meetings, objectives are recurringly assigned and delegated to maintain progress towards the team goal of creating a bio-realistic surgical phantom. A team assignment document was also created to make sure the team was aware of any individual assignments they oversaw.

3.8.2 Gantt Chart

Since one of the major constraints on this project was time, the team developed a Gantt chart, shown in Figure 13 below, to define a comfortable pace for completing realistic tasks and stay accountable for deadlines. The students split the chart into quarterly terms reflecting the school year and filled in required deliverables as well as additional experiments and milestones specific to the team's project. The Gantt chart provided the team with a visual and quantifiable indicator of progress through percentage of a task completed. Members of the team update the chart as necessary. The group met multiple times a week to work collaboratively on major milestones and delegate specific sections of tasks for individual assignments. Each team member took responsibility for assignments, set personal deadlines, and asked for help if necessary.

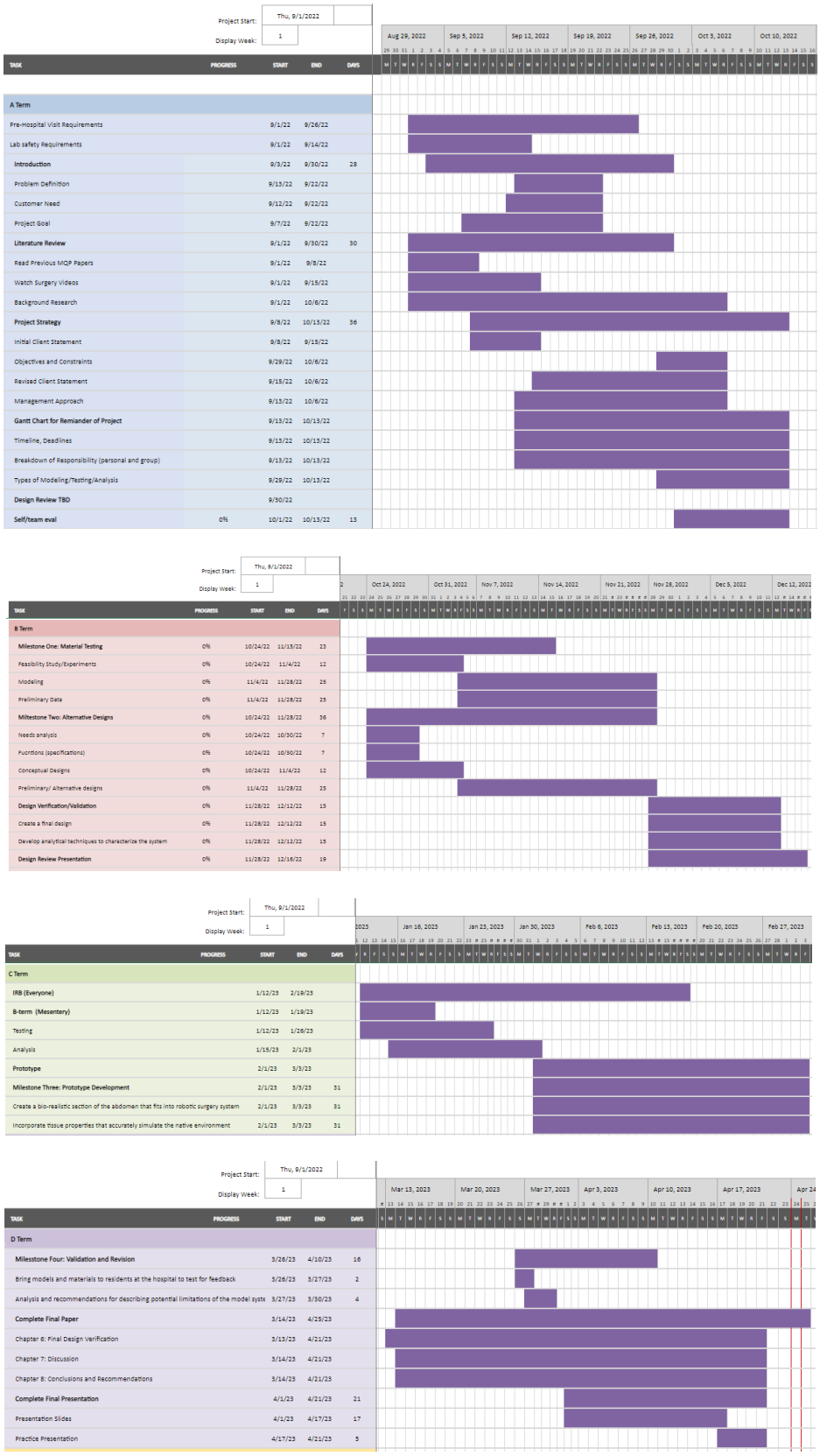


Figure 13: Gantt Chart

3.9 Milestones

Throughout the project, there will be milestones set in place to ensure that progress is kept on track. Although there are expected constraints such as a deadline of May 2023, budget restrictions, and material specifications, these milestones will be used as a focused project guide throughout the year. The project approach for developing the model is divided and described within the sections below, where there are specific steps and processes that need to be met for the completion of the project. If the team is unable to complete the milestones below, it is recommended that future teams continue the project where it is left off.

3.9.1 Milestone One: Material Testing

The first milestone the team must complete consists of a characterization of mechanical and material properties. This includes a literature review of mechanical specifications that will best simulate anatomical conditions displayed by organs during surgery. The team determined these specifications through ranking the importance of device requirements. Then, the team created a testing plan to observe these properties and best match mechanical properties documented in medical literature. Before moving into a final design, group members selected materials through testing conclusions. Completion of this milestone allowed the team to continue developing device prototypes.

3.9.2 Milestone Two: Alternative Designs

In conjunction with milestone 1, the team must illustrate multiple designs for specific components relating to the surgical model. These designs must be developed before the end of B-term, so the team may begin manufacturing physical prototypes at the beginning of C-term. The models must include bio-realistic material choices, anatomically correct model sizes, component specific requirements, etc. The designs may be completely different and withstand multiple iterations, but after further review the group will decide on a final design.

3.9.3 Milestone Three: Prototype Development

Once a final design for the model is chosen, the team will create a full prototype of the surgical model by the middle of C-term. This model will then undergo more testing to ensure that it fulfills the standards that were set forth, continually making improvements and iterations until the objectives are met. A final product that is ready for validation through resident testing should be completed before the beginning of D-term.

3.9.4 Milestone Four: Validation and Revision

To validate the prototype, the team will conduct a survey with the residents at the hospital to confirm if the objectives were met. The survey will be developed by the designers during C

term and after being confirmed by the IRB it can be conducted with the residents in D-term. This survey should include feedback on each of the objectives and materials being used in the project. If the team feels necessary, they should also conduct a previous survey halfway through C-term with the residents to confirm if they are on the right track. The same steps should be taken for this as the final survey.

Chapter 4: Design Process

For the design process the team determined the needs vs. wants and then started narrowing down the functions and specifications from this information. The team used the functions for each subsystem to brainstorm different materials and manufacturing process designs. After the team established conceptual and alternative designs, they ran feasibility experiments such as puncture and peel testing. Team members used the results from these tests along with Pugh Analyses to determine the final design selection. This process is outlined in further detail in the sections below.

4.1 Needs Analysis

After the team finalized and discussed primary and secondary objectives, group members determined whether each goal was a “need” or a “want” as shown in Table 12. This was done to further narrow down and differentiate the focus of the project for this year. The needs category includes objectives that are expected to be finished by the end of the year in order to consider the project successful. The wants category is for less important objectives that could be used to further improve upon aspects of the surgical model as a continuation, but don’t necessarily fall within the current scope of the project. These were determined through the chart rankings, research, and discussions with the client as well as within the design team. The objectives with the higher importance ranking from the analysis were needs and lower rankings were wants.

Table 12: Results of final wants and needs analysis

Needs	Description
Peelable/Separable	The artificial mesentery needs to have the ability to peel away from the organs
Replaceable	Make parts so that they can be cut up for practice and then replaced
Anatomically Correct	Ability to meet the feel, locations, and size dimensions of real human organs, following a 1:1 model to human organ ratio
Easy to Assemble	The box trainer should be able to set up in a reasonable time
Cost Effective	Keeping the design within the team budget
Highly Manufacturable	Have an efficient process for producing the system
Wants	**Description**
Oozability	Provide live feedback to residents through bleeding
Reusable	Make parts that can be used for multiple surgeries without having to be replaced
Assembly Instructions	Instructions for how to set up and store the box trainer as well as the materials inside

4.1.1 Design Needs

The goal for this project is to develop a box model of the RUQ of a human abdomen. The needs for this project were determined through various discussions between the design team and the clients as well as results from the pairwise analysis rankings from chapter 3. The wants for the project include the following information found in Table 12 above: peelable/separable mesentery, replaceable, anatomically correct, easy to assemble, cost effective, and highly manufacturable. All these categories received an average score of 3 or above from the ranking exercise as can be seen in Tables 8-11.

4.1.2 Design Wants

The wants for this project were also determined through various discussions between the design team and the clients as well as results from the pairwise analysis rankings from Chapter 3. The needs for the project include the following from Table 12 above: oozability, reusable, and assembly instructions. All these categories received an average score of 3 or less from the ranking exercise as can be found in Tables 8-11 under Section 3.5.3.

4.1.3 Needs and Wants Design Matrix

Following the completion of defining needs and wants, the team developed a design matrix. The purpose of the table is to organize what design specifications influence the different wants and needs. Table 13 shows the different needs and wants on the horizontal axis and the design aspects on the vertical axis. An "X" designated whether a want or need is influenced by a certain design aspect. For reference, the complexity of the design determines how easy the trainer will be to assemble and how the assembly instructions will be developed. This allows for the team to determine which design aspects to prioritize or change when considering a specific need or want.

Table 13: Design matrix of needs and wants

Needs	Peelable/ Separable	Replaceable	Anatomically Correct	Easy to Assemble	Cost Effective	Highly Manufacturable	**Wants**	Oozability	Reusability	Assembly Instructions
Size of Device			X		X					
Material of Organs		X	X		X	X			X	
Material of Mesentery	X	X			X	X			X	
Manufacturing of Organs		X	X		X	X		X		
Manufacturing of Mesentery		X	X	X		X		X		X
Complexity of Design				X						X

4.2 Functions and Specifications

Functions and specifications are important to validate the final product and keep the design team on track to complete the objective by the end of the year. The main function of the final product is to closely replicate material and mechanical properties of the RUQ, be cost effective, and be easily manufacturable. For these to be met, different subsystems of the design must meet specifications obtained through research and testing by the design team.

This is a tree that contains all the important factors for our design. Our goal is to design a phantom trainer, and in order to do so we have our four primary objectives: mesentery, right upper quadrant organs, ease of use, and reproducibility. For each of the primary objectives, there is a subset of secondary objectives that also have their own description that contains the function or specification that serves as a quantitative measure of each objective, as shown in Figure 14.

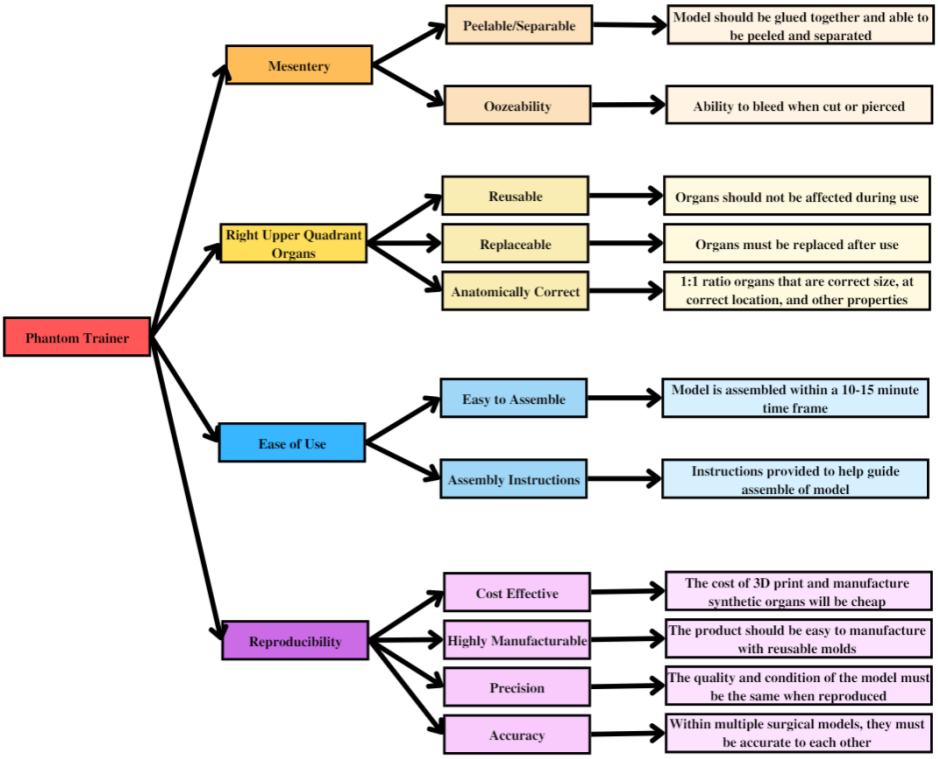


Figure 14: Objectives, Preliminary Functions, and Qualitative Specifications Tree.

Out of all the secondary objectives in the tree above, the most important functions of the trainer are peel able/separable, reusable, replaceable, anatomically correct, easy to use, and manufacturable. For the mesentery, the main function is for it to be peel able/separable from itself and the organs it surrounds. The peel force of the mesentery should fall within 2.9 ± 1.8 KPa to accurately mimic the properties of the real organ. The main functions of the right upper quadrant organs are reusable, replaceable, and anatomically correct. The organs that are not being operated on should be able to be used for more than one training session since they would not be experiencing little to no wear and tear. The organs that do get operated on should be easily replaced after 1 training session as they are not able to be reassembled after use. All the replacement organs should pass all quality control parameters, described in Section 6.2.1, to ensure consistency between the different training sessions. Any organ that is used within the trainer should have a 1:1 ratio to real organs in order to be anatomically correct. To ensure that the trainer is easy to use, it should take 10-15 minutes to fully assemble and prepare the trainer for surgical training with only 1-2 errors per assembly. The last required function of the trainer is its ability to be manufactured while meeting all quality control parameters. All of the cumulative parts of the trainer should cost less than $1000 total to manufacture, and any necessary replacement parts should cost less than $150 to produce. All the main functions and specifications discussed previously are summarized in Table 14.

Table 14: Functions and specifications

Functions	Specifications
Peel ability/ Separability	• Average peel force meets QC parameters accurately at 0.0029 ± 0.0018 MPa
Reusable	• Non operated organs can be used for more than 1 surgery training.
Replaceable	• Operated organs and mesentery can be replaced after 1 surgery training. • All replacements meet QC testing parameters precisely (Refer to sections 6.2.1)
Anatomically Correct	• Meet QC parameters accurately (Refer to sections 6.2.1) • Follows a 1:1 ratio of RUQ organs
Ease of Use	• Model is assembled within a 10–15-minute time frame. • Follow assembly instructions with 1-2 errors.
Manufacturable	• Meets QC parameters precisely (Refer to sections 6.2.1) • Cost less than $1000 to manufacture • Cost less than $150 to replace the necessary parts.

4.3 Conceptual Design

To start our design process, we had to address what specifications are required of a surgical box trainer to best simulate real anatomical use. A box trainer allows a surgeon or residents to practice their operating skills on a variety of manufactured components. Addressing the basics, surgical trainers have components that consist of an outer box or shield where laparoscopic equipment can be inserted and held. And the interior organ set that the practice techniques and simulated operation is to take place. The interior of our surgical trainer will include not only an extensive 3D printed organ system but includes a simulated mesentery system surrounding our organs to best simulate the anatomical environment as depicted in Figure 15.

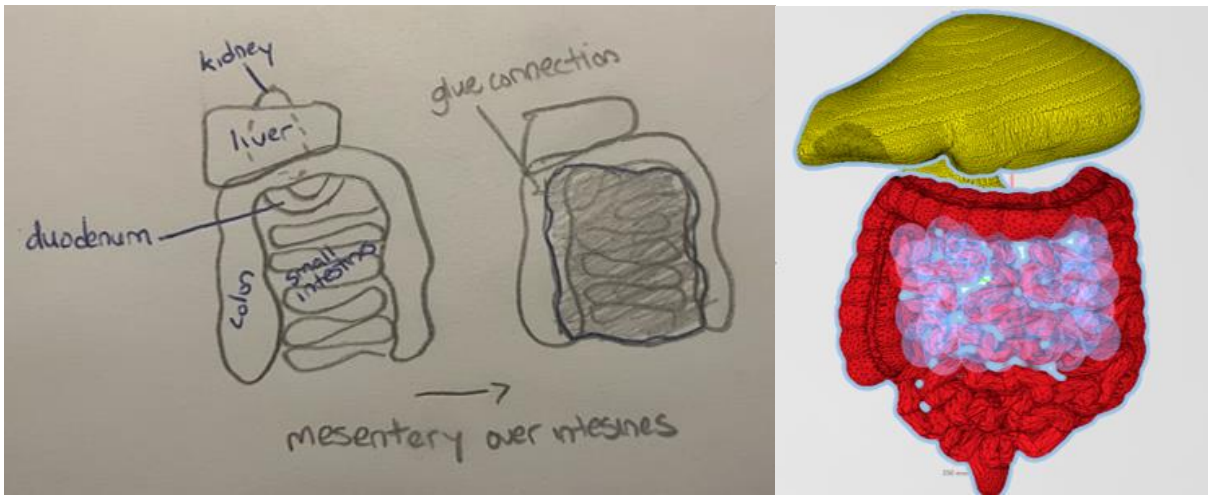


Figure 15: Two perspectives of the conceptual design of the organs within the box trainer.

4.3.1 Brainstorm Design Elements

In order to create a conceptual design, the team worked together to discuss different design aspects and share ideas. The group brainstormed, analyzed, and ranked design elements as shown in Figure 16. The design elements that the team found to be the most important are operated organs, non-operated organs, and mesentery.

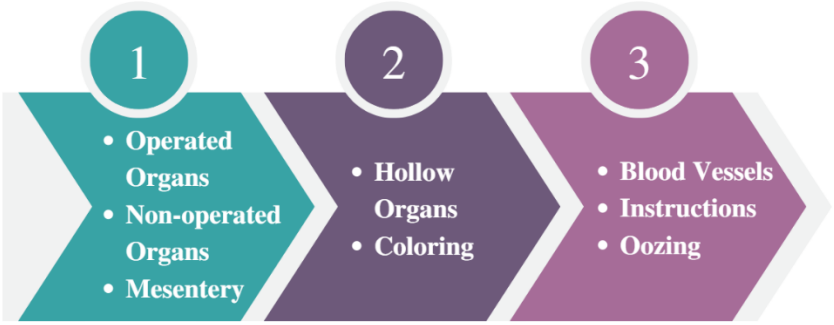


Figure 16: Brainstorming Flow Chart of Functions

Once the team established the prioritized design elements, each element was split into two sections, manufacturing and materials. The team brainstormed all the possible methods to achieve each subsection for the device while maintaining within the project constraints, as shown in Table 15.

Table 15: Means chart for device elements

Elements:	**Operated Organs**	**Non-operated Organs**	**Mesentery**
Means:	Manufacturing • 3D Printed Molds • Sausage Casings • PVC Pipes Materials • PVA • Gelatin • Silicone	Manufacturing • 3D Printed Molds Materials • PVA • Gelatin • Silicone	Manufacturing • 3D Printed Molds • Thin pieces of plastic pressed together Materials • Rubber Cement • Liquid Latex • Layered PVA

In the following section, the team evaluated each idea through pros and cons as well as Pugh analysis. In order to make a final design decision, team members performed further evaluation and testing for ideas that received the highest scores.

4.3.2 Evaluation of Design Elements

Manufacturing

Utilizing computer aided design to create 3D molds would be an effective method for manufacturing the organs to go within the surgical trainer. The purpose of using the 3D printed molds is to make the manufactured organs precise and accurate when making multiple organs. The use of molds allows the team to create 1:1 anatomically accurate organ based on CT scans received from project advisor Dr.Cataldo. These CT scans are inserted as STL files into a 3D builder computer program to create hollow molds using PLA filament. The molds can be lined with a sealer to decrease the amount of PVA leakage from the mold to best retain organ shape. The sealing methods used by the team includes weather strip foam and hot glue around all edges. These molds can be seen in Figure 17. The pros and cons discussed are summarized in Table 16.

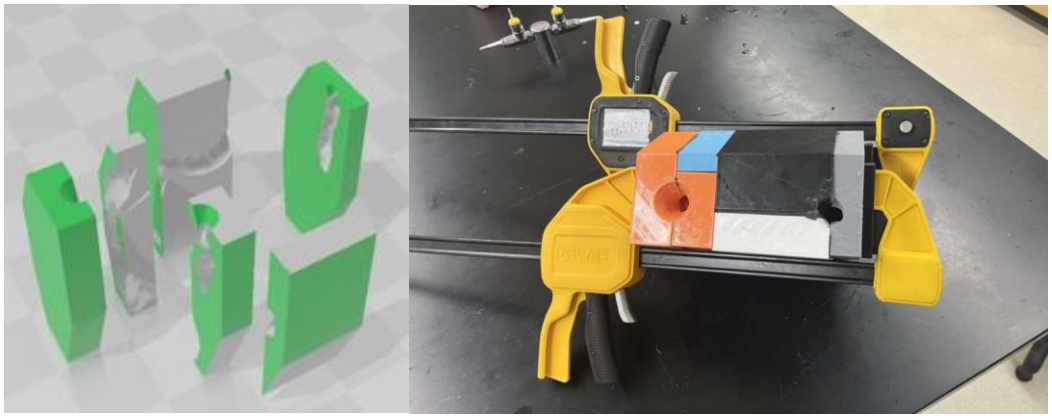


Figure 17: 3D printed molds on the computer (left) and in person (right)

Table 16: 3D printed molds for organs pros and cons

3D Printed Molds – Organs	
Pros	**Cons**
• Reusable • Ensures the organs are anatomically accurate • Cost effective • Creates exact replicas of each organ • The 3D prints are easily replaced	• Multiple pieces for the colon mold • Leaking if not properly sealed • Laborious manufacturing process

The purpose of using the sausage casing is to have the intestines hold an outside diameter while including hollowness. It would be an easy method for creating something that resembles the intestines that is not reusable. The team produced this by pouring PVA inside the sausage casing and inserting a dowel to hold space for the hollow section as can been seen in Figure 18. The pros and cons discussed are summarized in Table 17. The downsides of this design include the nonreusable design, having to cut open the casing to remove the dowel, and the conforming diameter. Another thing to consider is the sausage casing drying out and therefore sacrificing the accurate feeling of the intestines.

Figure 18: Diagram of the sausage casing with dowel design.

Table 17: Sausage casing for organs pros and cons

Sausage Casing – Organs	
Pros	**Cons**
• Making a hollow organ • Easily adjusted to desired size • Strong surface connection to PVA	• Casing dehydrates • Not reusable • Conforming diameter

A manufacturing method for producing the small intestine and possibly the colon would be to use a simple PVC pipe design as can be seen in Figure 19. The PVC pipe would have another internal pipe to create the hollow characteristic of the small intestines and the material would conform to the tubular shape. The advantages to this design can be seen in Table 18 and

include simplicity, specified outer and inner diameter, cost effective, and reusable. The disadvantages to this manufacturing method can also be seen here and include only being a potential method for the intestines, not based on a real CT scan, and it will likely not be viable for the colon as it has a specific orientation and proportions.

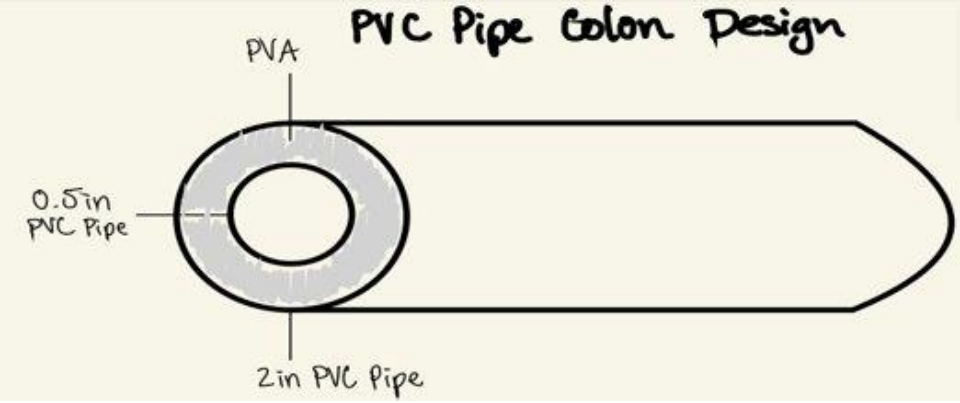


Figure 19: Diagram of the PVC pipe manufacturing design.

Table 18: PVC pipes for organs pros and cons

PVC Pipes – Organs	
Pros	**Cons**
• Specified diameter for small intestines • Cost effective • Simple • Reusable	• Only works for intestines and bowels • Not based on CT scan

A 3D printed mold for manufacturing the mesentery would provide the team with a reusable, consistent, and cost-effective method to mass produce sheets for the surgical trainer. However, the mesentery must wrap around the entire surgical trainer. The size of the mold would be larger than most printing beds of 3D printers and would require multiple attachable sections. With multiple sections, sealing would be extremely important and may jeopardize the product. With thin layers of mesentery, the mold must be pressed, and material may leak in between sections. The team cannot produce the same type of 3D printed molds as organs since there are no CT scans of the mesentery available. The mesentery is within the entire abdomen, intertwined between organs. The 2D mold would most likely be a large rectangular sheet. The pros and cons discussed are summarized in Table 19.

Table 19: 3D printed molds for mesentery pros and cons

3D Printed Molds – Mesentery	
Pros	**Cons**
• Reusable • Produces a film with consistent thickness • Cost effective • The 3D prints are easily replaced	• No CT scans of the mesentery • Size restrictions

The team found thin, congruent plastic sheets which stacked on top of each other with ease. The team can place a gasket in between the sheets to produce a film at consistent thickness. The plastic sheets are cheap and reusable but take up a large amount of space. If necessary, a refrigerator must have enough to contain the sheets. Similar to Table 19, the plastic sheets do not guarantee anatomical correctness like the 3D printed molds for organs. The pros and cons discussed are summarized in Table 20.

Table 20: Plastic sheets with gasket for mesentery pros and cons

Plastic Sheets with Gasket - Mesentery	
Pros	**Cons**
• Reusable • Produces a film at consistent thickness • Adjustable thickness • Cost effective	• No CT scans of the mesentery • Large surface area – large refrigeration space necessary

Materials

PVA was chosen chemically to create synthetic organs that are operated within the RUQ organ system. PVA is a hydrophilic water-soluble polymer that exhibits similar mechanical properties to real human organs. The polymer is a cost-effective substance that can be manufactured in lab space. Examples of these organs can be seen in Figure 20. The pros and cons discussed are summarized in Table 21.

Figure 20: PVA organ model

Table 21: PVA for operated organs pros and cons

PVA – Operated Organs	
Pros	**Cons**
• Correct organ feeling • Similar mechanical properties • Easy to replace • Cost effective • Bioinert	• Lengthy manufacturing process • Laboratory materials needed for production • Needs to be kept in water or sealed when not being used

Another simple material idea discussed by the design tea included using gelatin to make the operated organs. The smooth texture and easily puncturable surface would create a somewhat real looking and feeling organ as can be seen in Figure 21. For manufacturing the gelatin could be poured into any of the previously mentioned manufacturing methods for organs and would solidify in the fridge. Gelatin is a very cost-effective material, and it is easy to manufacture. The only downside to this is that it doesn't completely meet the mechanical properties the design team is looking for and the gelatin dehydrates easily when left out or even in the fridge if not used within a certain amount of time. The pros and cons discussed are summarized in Table 22.

Figure 21: Picture of gelatin sample made with 3D mold.

Table 22: Gelatin for operated organs pros and cons

Gelatin – Operated Organs	
Pros	**Cons**
• Cost effective • Easy to manufacture	• Dehydrates easily • Doesn't meet mechanical properties

Silicone was chosen to create synthetic organs that are not operated within the RUQ organ system. Silicone is an easy cost-effective material for the fabrication of these organs that serve as landmarks in the RUQ organ system. Silicon does not exhibit similar mechanical properties such as PVA, though it can be reused during all training sessions. This is because the material does not hydrate and is a non-conforming material that is easily fabricated. The pros and cons discussed are summarized in Table 23.

Table 23: Silicone for organs pros and cons

Silicone – Organs	
Pros	**Cons**
• Reusable • Doesn't dehydrate • Cost effective	• Doesn't mechanically simulate organs • Incorrect organ feeling

Since the team is making some of the organs out of PVA and it is very versatile material, the team decided to test out making thin layers out of PVA to see if it could make an effective mesentery. There are many advantages to making the mesentery out of PVA that outweigh the cons. PVA films are easily layered and stick to each other better than rubber cement and liquid latex do. The consistency and tearing quality of the PVA is close to that of the mesentery. Since the mesentery has to be set up within the trainer, it is also beneficial that the material is bioinert

so that it can be maneuvered without requiring gloves. The cost of PVA is also fairly low, which allows the mesentery to be easily replaced for a low price. Some disadvantages of PVA are the lengthy manufacturing process and the proper laboratory set up and equipment that is required to make it compared to rubber cement and liquid Latex. It also has to be kept within water or in a sealed environment when not in use otherwise it will dehydrate and shrivel. The pros and cons discussed are summarized in Table 24.

Table 24: PVA for mesentery pros and cons

PVA – Mesentery	
Pros	**Cons**
• Easily layered • Correct consistency • Self-adherent • Tears apart • Bioinert • Cost effective • Easy to replace	• Lengthy manufacturing process • Laboratory materials needed for production • Needs to be kept in water or sealed when not being used

When conducting initial research for materials to make the mesentery out of, the team discovered rubber cement. The team found videos and images of rubber cement being peeled off different surfaces and this resembled the "webbing" of the mesentery that the team was trying to replicate. When testing the rubber cement, it was found that it adheres to itself very well, especially in a thinner form. Rubber cement is also low costing, as it was $4 for 4 fl oz of rubber cement. However, there are disadvantages to rubber cement as a material to make the mesentery out of. One of the biggest cons of rubber cement is that it does not stick to PVA, therefore if we have organs made of PVA then it would not effectively adhere to those organs. It is also difficult to make a film from rubber cement as it deflates as it dries and becomes very thin and fragile. It is also a dangerous material to use as it is flammable. The pros and cons discussed are summarized in Table 25.

Table 25: Rubber cement for mesentery pros and cons

Rubber Cement – Mesentery	
Pros	**Cons**
• Has a web like texture • Self-adherent • Cost effective	• Doesn't stick to PVA • Difficult to make film • Flammable

The team originally found liquid latex while investigating materials in movie production to imitate human organs. Based off additional research into different adhesives, liquid latex has an effective "peeling" effect, displaying web-like structures when being peeled from the surface

as shown in Figure 22. The advantage of liquid latex is that it is easy to pour into molds, has little shrinkage when dried, and is relatively cheap. Liquid latex does not stick to PVA, which is unfortunate as PVA may be the main material for some organs. Also, it was difficult to find a consistent supply of liquid latex in stores. According to the peel testing in Section 5.1.1.2, the peel strength of liquid latex specimens was far greater than the target value representing the material is not anatomically accurate. The pros and cons discussed are summarized in Table 26.

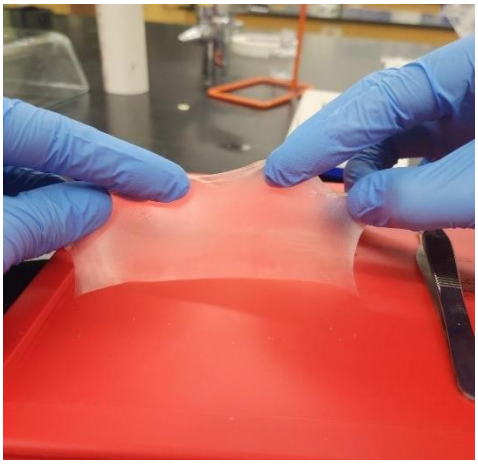


Figure 22: Peeling Liquid Latex

Table 26: Liquid latex for mesentery pros and cons

Liquid Latex – Mesentery	
Pros	**Cons**
• Tears apart • Self-adherent • Cost effective	• Doesn't stick to PVA • Peel strength too high • Difficult to obtain in large amounts

4.3.3 Quantitative Assessment of Design

The team utilized a Pugh Analysis to quantitatively determine each design element's ability to satisfy the required functions and specifications of the trainer. The results of the Pugh Analysis allow for the team to decide on which elements to incorporate into the overall design of the trainer. The calculation for the weighting of each objective can be found in section 3.5.3 Objective Rankings and Evaluation.

The Pugh Analysis, shown in Table 27, is an example made for each design element. If the design element satisfies the objective, then it receives a +1 that is then multiplied by the weight. If the design element does not satisfy the objective, then it receives a –1 and is multiplied by the weight. If a design element somewhat satisfies the objective might have the ability to satisfy the objective, then it receives a 0 and is multiplied by the weight. All the of the objectives multiplied by the weight for a single design element are summed up to determine the score of for that element.

Table 27: Pugh Analysis of the RUQ operated organs manufacturing

Objective	3D Printed Molds	Sausage Casings	PVC Pipes
Anatomically Correct	+1 (3.3)	-1 (3.3)	0 (3.3)
Cost Effective	+1 (4.0)	0 (4.0)	+1 (4.0)
Highly Manufacturable	+1 (4.3)	0 (4.3)	+1 (4.3)
Reusable	+1 (2.5)	-1 (2.5)	+1 (2.5)
Total:	14.1	-5.8	10.8

A summary of the Pugh Analysis scores can be seen in Table 28 where the highest score out of all the design elements is highlighted in yellow. All the completed Pugh Analysis matrices can be found in Appendix B. The highest scoring element has a higher probability of being incorporated into the final design.

Table 28: Pugh Analysis results summary

Organ Manufacturing			
Operated Organs			Non-Operated Organs
3D Printed Molds	Sausage Casing	PVC Pipes	3D Printed Molds
14.1	-5.8	10.8	14.1

Organ Materials					
Operated Organs			Non-Operated Organs		
PVA	Gelatin	Silicone	PVA	Gelatin	Silicone
12.6	5	5	5.1	1.5	7.1

Mesentery Manufacturing	
3D Printed Mold	Plastic Sheet with Gasket
6.8	10.8

Mesentery Materials		
Rubber Cement	Liquid Latex	PVA
4.3	12.6	17.6

Chapter 5: Development and Verification of Final Design

After conducting qualitative and quantitative analysis for each element of the project, the team was able to decide on the elements to incorporate into the final device design. The material selection that the team conducted resulted in all the organs that are being surgically manipulated (operated organs and mesentery) being made with PVA and organs that are meant to be left intact (non-operated organs) may be made with PVA or with silicone. Appendix C contains the procedure necessary to prepare PVA solutions. The method of creating the colon and small intestine, as they are typically hollow organs, was narrowed down to utilizing a 3D-printed mold or two PVC pipes, where one creates a solid organ and the other creates a hollow organ respectively. The mesentery will be created in thin films using large sheets with a gasket in order to ensure a controlled the thickness and size. The goal of the analysis was to create an overall design that incorporated all the highest scoring elements, ensuring that the elements worked well together.

5.1 Preliminary Testing

The team conducted a variety of experiments to determine the feasibility in using specific materials and manufacturing methods for each design as well as verify meeting specifications. These tests provided the team with enough insight to pursue components for greater evaluation within the design process or stop tracking a set of materials in preliminary stages to save resources. Alongside these studies, group members reviewed scientific literature in search of quantitative standards in which to test for.

5.1.1 Mesentery Material Mechanical Testing

Mechanical testing provided the team with quantitative measurements to compare design materials with scientific literature and previous project reports on whether the prototype fulfilled the functions of anatomic correctness, separability, and manufacturability. After observing laparoscopic colorectal surgeries at Beth Israel Deaconess Medical Center, the team decided that they only need to evaluate the mechanical properties of the mesentery. During surgery, the laparoscopic equipment punctured and peeled layers of mesentery off the gastrointestinal organs. Within a safe procedure, the surgeons never punctured these organs. Team members did not research unnecessary mechanical properties according to their observations. Through strict procedural mechanical testing via an Instron, the team compared materials used within the surgical trainer to that of actual organs.

5.1.1.1 Puncture Testing

Over the course of this project, teams have followed ASTM D4833, the Standard Test Method for Index Puncture Resistance of Geomembranes and Related Products, to evaluate the puncture strength of various materials. The comparison of this mechanical property between synthetic materials and a porcine gastrointestinal tract allows this year's project team to quantify the specification of anatomical correctness following the previous team's findings.

In order to prepare a 3mm specimen for testing, the team filled a pre-made square mold with a specific design material. After following the procedure in Appendix D to develop a test specimen, a team member clamped the design material within the wooden fixture as shown in Figure 23. The current group members applied procedures found in Appendix D. Previous project team's conducted similar testing protocols. These operations included specifically manufactured Instron attachments. As shown below in Figure 23, the box clamps the specimen in place while a machined attachment with a 3D-printed tip compresses the material through a 45mm diameter circle. The first project team built the box clamp, the second project team developed the metal attachment, and the most recent group printed the tip. This exemplifies the progress and development of a multi-year MQP.

Figure 23: Overall Puncture Test Fixture

As mentioned in Section 5.1.1, the team observed the physicality of the mesentery within a surgical environment. After maneuvering around arteries and organs, the surgeon pierces and burns the surface of the mesentery to open multiple layers of connective tissue. The goal of the puncture test is to compare the puncture strength of synthetic materials with that of the mesentery. According to the previous MQP projects, the target specification for mesenteric puncture strength is 18.9 ± 10 N [47]. The more similar in mechanical property, the more bio-realistic the surgical trainer will be.

The team measured and recorded the average puncture resistance of the Liquid Latex and PVA within Table 29. The team did not pursue the puncture test for rubber cement since the material is flammable and failed to pass a constraint, from Section 3.4, for materials used within the surgical trainer. The puncture resistance force graphs can be found in Appendix E. PVA and Liquid Latex average puncture resistance were within the target value, but overall PVA was closer. With a 95% confidence interval and p value of 0.000219, we reject the null hypothesis and therefore the difference between the samples are statistically significant.

Table 29: Average and standard deviations of the puncture resistance force for design materials

Sample	Sample Size (n)	Average Puncture Resistance Force ± SD (N)
Liquid Latex	3	27.7 ± 2.5
PVA	9	10.6 ± 4.6

5.1.1.2 Peel Testing

A key aspect of our project is the ability to move organs around and separate different layers of the mesentery. It is vital that the surgeons performing the surgery can rearrange the positioning of the organs for a clear view of the surgical site without causing damage to the patient with surgical tools. The surgeon must be able to peel apart and burn through sections of the mesentery to isolate the region of the colon that is getting resected. To test the peel ability of our materials, we created a peel test method following ASTM D1876, the standard for Peel Resistance for Adhesives, T-Peel Test, as shown below in Figure 24. This test will allow us to quantify the force it takes to separate two materials that are adhered together.

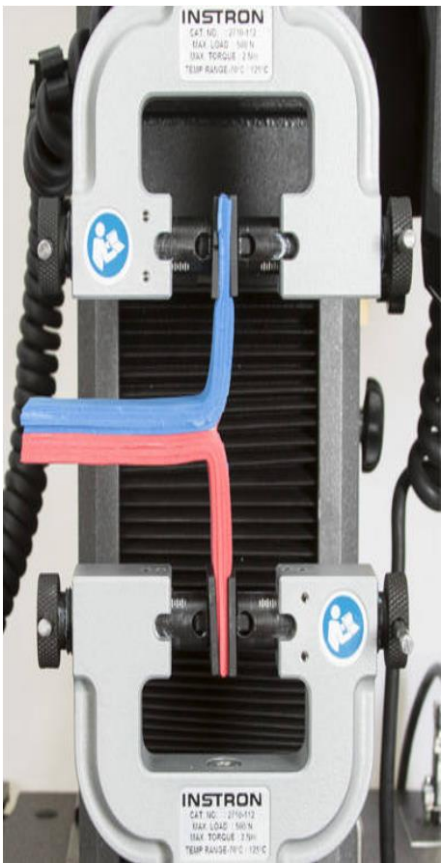


Figure 24: ASTM D1876 Instron-Specimen Setup [46].

The team followed Appendix F. to prepare peel test specimens. Once the specimen was fully dry and prepared, we loaded the sample onto the Instron as shown below in Figure 25, making sure that the pieces are gripped tightly and evenly. We used the peel test method found in Appendix F that was created as per the standard above until the sample failed or finished peeling apart. Team members exported and analyzed data to gauge the amount of force it took to peel the material apart.

Figure 25: Setup of the Peel Test of our PVA specimen.

The goal of the peel test is to compare the amount of force it requires to peel apart two materials that are adhered to one another to the force it takes to peel apart the mesentery and the organs attached to it. According to the previous MQP projects, the target specification for average mesenteric peel strength is 2.9 ± 1.8 kPa [47]. The closer the material property is to this strength, the more accurate the trainer will be.

The team did not pursue the peel test for rubber cement since the material is flammable and failed to pass a constraint, from Section 3.4, for materials used within the surgical trainer. The peel testing graphs can be found in Appendix G. The peel test curve should display a plateau as a consistent stress would separate the two strips. However, there were many imperfections within the connection within specimens including bubbles. These imperfections forced the Instron to increase stress necessary to effectively surpass the imperfections and continue to peel the strips away from each other. With this in mind, the team analyzed the average peel stress avoiding higher peaks. The team recorded the average peel strength of the liquid latex and PVA within Table 30. The average peel stress for liquid latex far exceeded the target value. The team conducted a paired t-test between the liquid latex and PVA sample averages. With a 95%

confidence interval and p value of 0.0015, we reject the null hypothesis and therefore the difference between the samples are statistically significant.

Table 30: Average and standard deviations of the peel stress for design materials

Sample	Sample Size (n)	Average Peel Stress ± SD (kPa)
Liquid Latex	3	116.6 ± 024.7
PVA	7	1.15 ± 0.50

5.1.2 Mesentery Manufacturing Testing

When the team decided to utilize PVA for the mesentery after mechanical testing of the different material options, the next step was to focus on different methods of manufacturing the PVA. The first test that the team conducted was producing a batch of PVA at a lower concentration to observe the consistency and properties. From that batch of 5% PVA, the team tested different drying methods to create a thin dried layer on the outside of the PVA pieces. The team observed the viability of using liquid latex or rubber cement to adhere PVA pieces together.

With the regular 10% PVA, the team compared the consistency of the PVA when it was only frozen once to when it was frozen twice. Continuing with the single freeze PVA, the team experimented with embedding Polyfill into the PVA to see how it would change the integrity and properties. The PVA without Polyfill was placed into water to test upkeeping methods and to observe the PVA's ability to stick to itself after being exposed to water. The team added 2-3 drops of food coloring to a batch of PVA to test its ability to maintain color and possibly create different colored layers and organs. The team tested different materials, such as glass, PDMS, and plastic, to see which method was best for creating thin sheets of PVA. All the PVA testing that the team performed with PVA is summarized in Figure 26. Further protocols for all these tests can be found in Appendix I and discussed in Section 5.1.2.2 below.

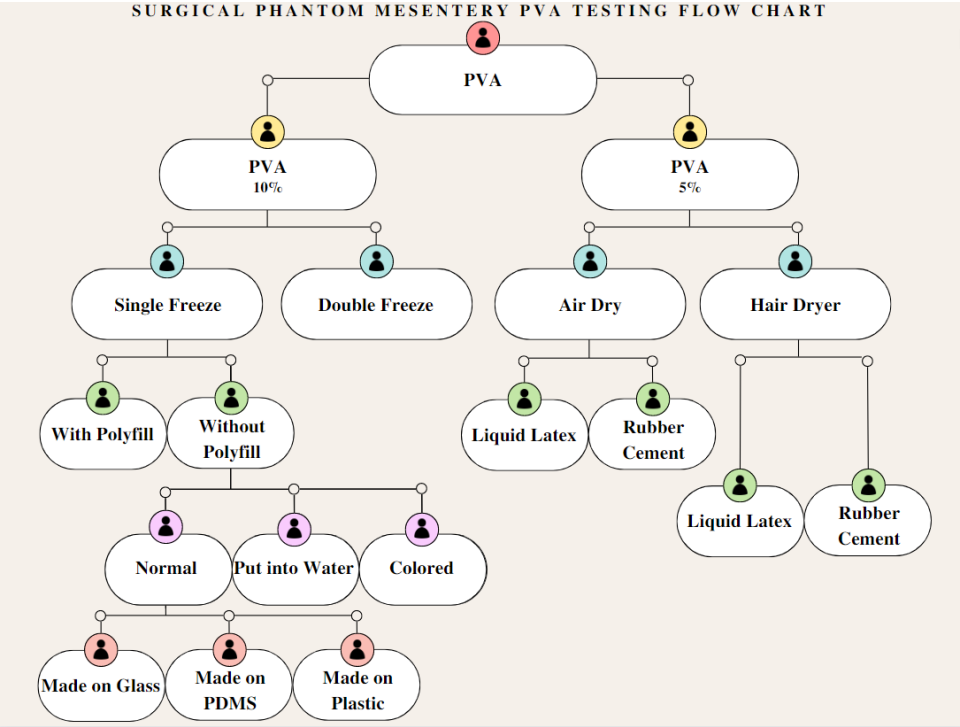


Figure 26: Flow Chart for PVA Mesentery Testing

5.1.2.1 Mesentery Attachment Experimentation

There were a series of experiments and tests performed to see if the materials can adhere to PVA as well as the effectiveness of drying out the PVA. The different drying methods that the team tested were using a hair dryer, air drying, and a control of not drying the PVA. There were two materials used on each drying method: rubber cement and liquid latex. This resulted in 6 different test strips, as shown in Table 31. The procedure for drying the PVA as well as applying the adhesives can be found in Appendix H.

Table 31: Different drying methods with different adhesion methods

Drying Method	**Adhesion Method**
Hair Dryer	Rubber Cement Liquid Latex
Air Dry	Rubber Cement Liquid Latex
No Drying	Rubber Cement Liquid Latex

Out of all three of the drying methods, the most effective and efficient method was using the hair dryer. The team decided that the standard for "dry" was when the PVA piece no longer stuck to the paper towel and no liquid residue on the paper towel. Based on that standard, the hair

dryer was able to dry the PVA sufficiently in 10 minutes, whereas the air-drying method took 25 minutes. These results are summarized in Table 32.

Table 32: Drying Method Results

Drying Method	Drying Time (min)
Hair Dryer	10
Air Dry	25

The dried pieces of PVA were then cut into fourths and each set of 2 pieces were glued together using a different adhesive, following the pairings in Appendix H. The adhesion experiment found that neither rubber cement nor liquid latex was viable for gluing PVA together. The rubber cement was unable to fully dry between the two pieces and created a white residue on the perimeter as seen on the left of Figure 27. It was also very easy to peel the two pieces apart, where there was little to no resistance, deeming it ineffective. The liquid latex was able to dry between the PVA pieces and adhere the pieces together with a thin white layer as seen on the right of Figure 27. However, similarly to rubber cement, the pieces were not adhered together sufficiently, where there was little to no resistance when peeling the pieces apart. Therefore, the team had to discover a new method of attaching PVA together.

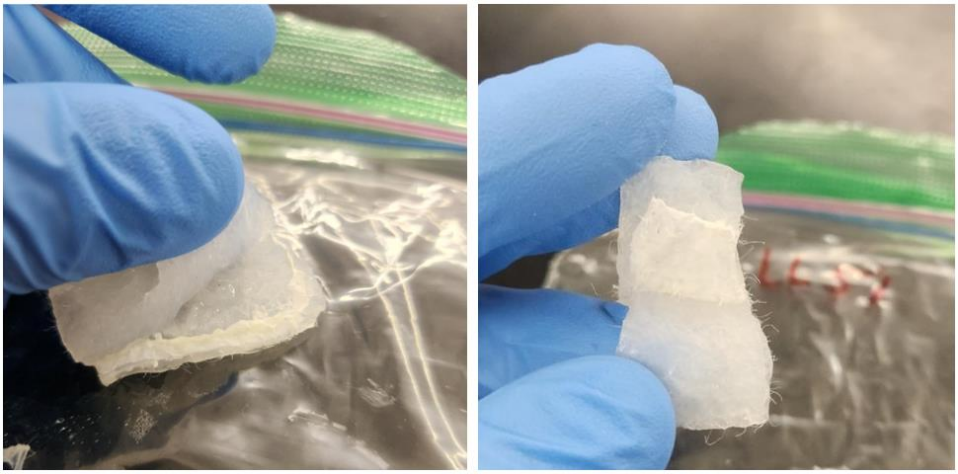


Figure 27: PVA pieces adhered together using rubber cement (left) and liquid latex (right)

5.1.2.2 Mesentery Thin Sheet Experimentation

After creating half of a test kidney out of PVA, the team discovered that there was a possibly of creating a thin layer of PVA to replicate the mesentery. To test the validity of this discovery, the team poured PVA between two pieces of plastic that fit perfectly on top of each other to create a thin sheet. This was then placed in the freezer for 12 hours and then left out to thaw after the 12 hours had elapsed. The full procedure for creating the thin sheets of PVA can be found in Appendix I. This test was proven successful as the PVA was solidified and able to be peeled off the plastic as sheet of PVA. The thickness of the sheet was thin, as shown in Figure 28, so it was difficult to remove the PVA sheet as one big piece. However, the team was able to remove several large pieces of the PVA sheet for further testing.

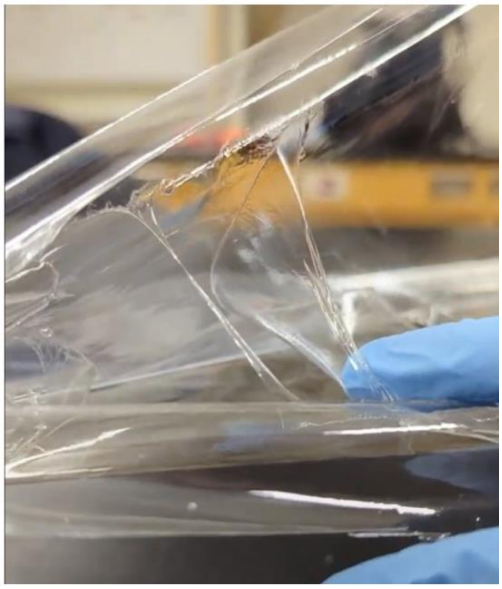


Figure 28: Peeling the PVA sheet off the plastic

With one of the large pieces of PVA that the team was able to obtain, it was discovered that the PVA is self-adherent at such a small thickness. With this, the team was able to successfully wrap a sample piece of PVA with the sheet. To test the sheet's ability to replicate the tearing properties of the mesentery, laparoscopic tools were used to spread the sheet apart as seen on the left of Figure 29. This test was deemed successful as the PVA sheet presented sufficient tear properties when being manipulated by the laparoscopic tools. To further test this the team used another large piece of the PVA sheet to cover a small intestine made from PVA, as shown on the right of Figure 29. This test was also successful, as the small intestine wrapped in a PVA sheet was able to be placed within the laparoscopic trainer and manipulated to simulate the movements of a real surgery. Therefore, the team decided to continue testing with PVA sheets as a method for creating a mesentery.

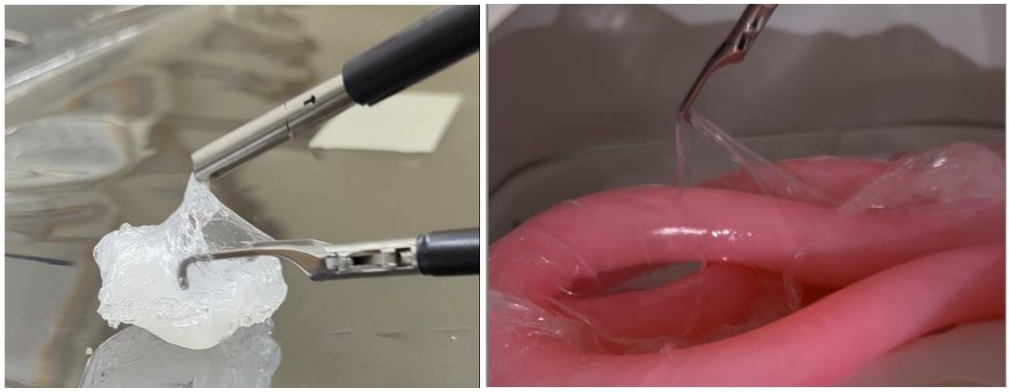


Figure 29: Utilization of laparoscopic tools to manipulate the PVA sheets that are wrapped around a PVA sample (left) and small intestine made of PVA (right)

Based on the team's research knowledge of PVA's ability to increase in strength with each freeze cycle, the next experiment performed was double freezing a large piece of PVA. The

team placed a large piece of the PVA sheet over a Pyrex pan and placed it back into the freezer for 12 hours. The Pyrex pan was then removed and the PVA was left out to thaw, resulting in a double frozen PVA sheet as seen on the left of Figure 30. The integrity of the sheet was tested by utilizing the laparoscopic tools to tear through the PVA, which can be seen on the right of Figure 30. The team found that double freezing the PVA sheet caused it to be too strong and it became similar to the consistency of rubber. Therefore, the team decided to continue further testing by only creating thin sheets of PVA with one freeze cycle.

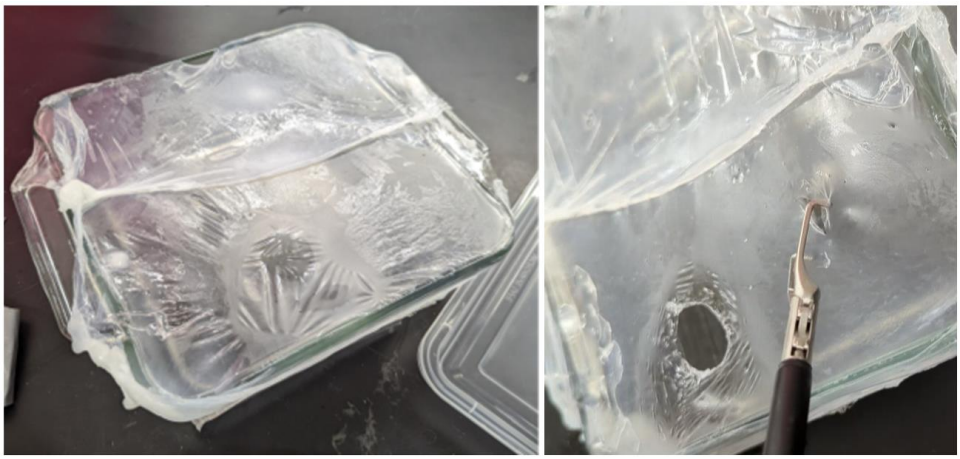


Figure 30: Large piece of PVA that went through two freeze cycles (left) and tear testing of double frozen PVA (right)

With some excess PVA, the team was able to perform a small experiment to color and embed Polyfill into the PVA sheet. The first step of the process was to pour PVA into the Pyrex pan, where blue coloring was then added and mixed thoroughly until the color was uniform. On the left half of the Pyrex, a thin layer of Polyfill was placed into the PVA, ensuring that it was embedded and not only on the surface. The Pyrex pan was then placed in the freezer for 12 hours and then left out to thaw afterwards as seen on the left of Figure 31. The full procedure for this experiment can be found in Appendix I.

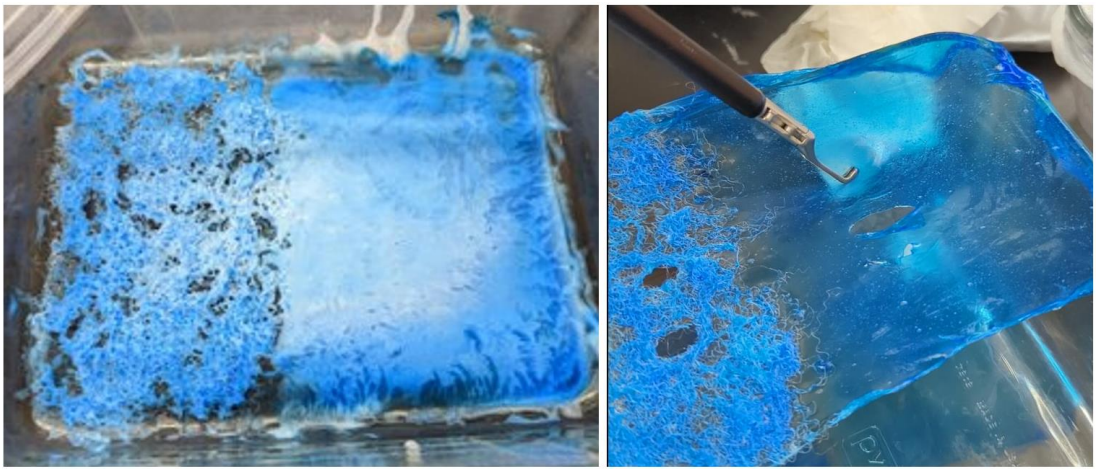


Figure 31: Colored single frozen PVA sheet with Polyfill embedded on the left half (left) and tear testing of the PVA sheet (right)

Once the PVA was fully thawed, the sheet was observed to see if any coloring separated from the PVA or did not mix completely. The team found that the blue coloring stayed within the PVA and stayed uniform through the freeze cycle. The PVA sheet was then draped over the edges of the Pyrex pan and manipulated using laparoscopic tools, shown on the right of Figure 31, to determine if the coloring had any effect on the tear properties of the PVA. It was found that there was no adverse reaction between the PVA and the coloring, as the colored PVA performed similarly to that of the uncolored PVA. The laparoscopic tools were also used to tear the left portion of the PVA that contained Polyfill. It was determined that the embedded Polyfill made it difficult to tear apart the PVA and that it no longer displayed properties of that similar to the mesentery. Therefore, the team decided that the final manufacturing of the mesentery can be colored but will not contain Polyfill.

The team conducted one final experiment to determine the ideal material to use as the mold for creating the PVA sheets. The three different materials that were tested are glass, PDMS, and plastic. This testing had an addition of a gasket to ensure that all three PVA sheets had the same known thickness, which will also be utilized in the final manufacturing process. This experiment followed the same procedure that can be found in Appendix I. It was found that the PVA sheet was easily removed from all the tested materials, as can be seen in Figure 32. The team determined that the most effective material to use as a mold for the PVA sheets is plastic, since it is easily obtained and creates larger sheets of PVA.

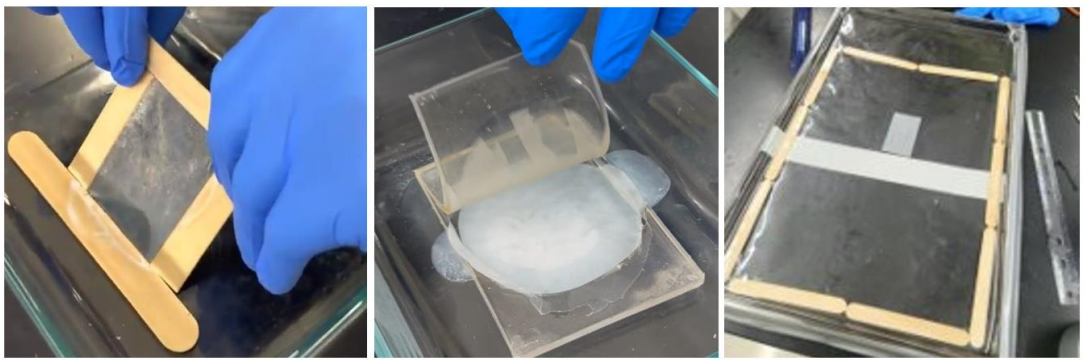


Figure 32: PVA sheets produced on glass (left), PDMS (middle), and plastic (right)

5.1.3 Organ manufacturing testing

The teams flow chart for manufacturing upper right quadrant organs is shown in Figure 33 below. Displayed are the possible pathways we experimented with during the design process. Consisting of two main sections being the operated and non-operated organs.

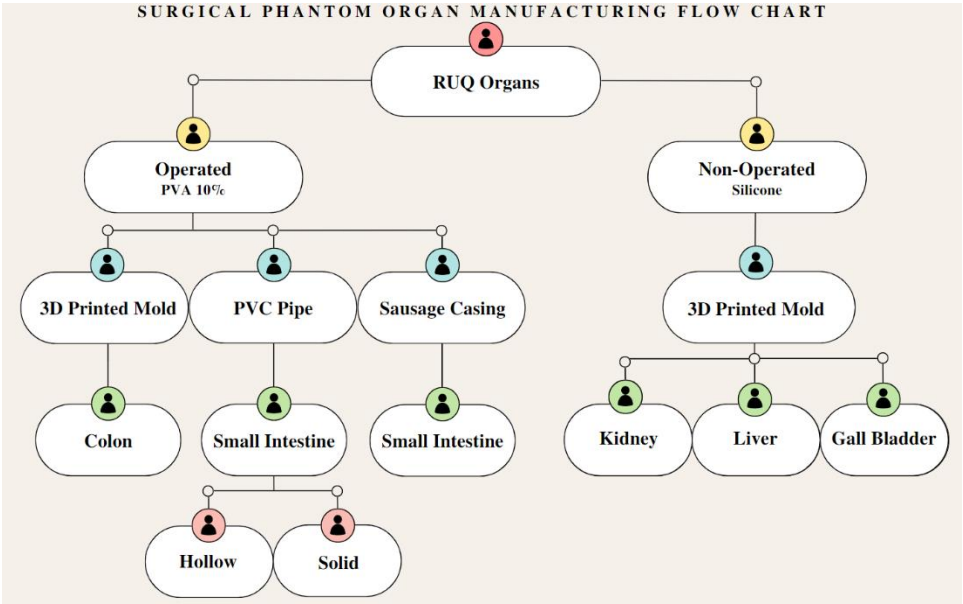


Figure 33: Manufacturing Flow Chart for Organs

5.1.3.1 Molds

The molds used for this project were 3D printed using PLA filament. Molds were created for the following organs: colon, kidney, liver, gallbladder. The 1:1 anatomically correct organ manufactured in these molds were validated after fabrication in order to test for accuracy and precision to the initial input CT scanned organ parameters. Issues arose during testing of these molds due to the ability for PVA solution to leak out the cracks in between mold sections. This was combatted using weatherstrip to line the inside of the molds to prevent leakage. With this seal, the molds are then clamped and filled with PVA solution.

Once fabricated, the molds must go through checks to qualify them as good quality to be used in the surgical trainer. To meet these specifications, organs are tested on their final weight and dimensions to make sure they are within an acceptable standard for use.

5.1.3.2 Small Intestine Manufacturing

As discussed in chapter 4 the design team experimented with the use of PVC pipes as a mold for the small intestine. First the design team started with a regular PVC pipe with no dowel insert. The PVA was poured into the tube with the use of a funnel and placed standing up in a walk-in freezer overnight for about 12 hours. The next day the PVC pipe was removed from the freezer and left to dethaw at room temperature for about 8 hours. The PVA was then removed from the mold and dyed as can be seen in Figure 34.

Figure 34: PVC Tube Manufacturing

Next the design team experimented with the small intestine PVC pipe mold by adding another small PVC pipe into the center. This would allow for the inside of the small intestine to be hollow, and the smaller pipe would be held in the center by endcaps. After the same process was performed the PVA was removed from the tube. It was found that there were some issues with the consistency of the inner diameter that caused some tearing where the walls were super thin, but overall, the hollow design is a more accurate representation of the small intestine. This tearing problem can be solved by using a more rigid inner tube.

5.1.3.3 Sausage Casings

Sausage casings were experimented with as a suitable mold for the fabrication of a small intestine. Through experimentation, these casings were deemed unfit for the production of the small intestine for many reasons. One being the inability to control a set diameter throughout the length of the casing as can be seen in Figure 35. The casing wall was shown to conform to the PVA and not set in a uniform position. After a freezing and thawing cycle, it was observed that the casings had little structural integrity with the PVA. There were positive observations seen with the surface connection of PVA to sausage casing which displayed a great connection to each other. Though, with too many negative aspects of the design, it was ruled unsuitable for use.

Figure 35: Picture of the final sausage casing result for small intestine.

5.1.4 Miscellaneous Testing for Organs

Further tests were done on the produced operated PVA organs with the intention of creating a bleed model, as well as coloring of anatomically correct coloration of the organs. The goal of bleeding is desired for the surgical trainer, though not necessary for use. These experiments were intended to find solutions to better the realistic aspect of the surgical phantom.

5.1.4.1 Dye

Food coloring was used to give color to the organs to help enhance the trainers realistic view as an internal RUQ organ system. The food coloring was used in small amounts and applied to the PVA organs after fabrication. The dye was observed to stain the organs, retaining the color through hydration in water after production. This experiment was successful in creating a realistic view of the internal organs.

5.1.4.2 Mineral Pockets/bleeding

A bleed model was pursued by the team through experimentation of differing methods. The first experiment was done using 1-2mm diameter silicone tubing that was pressurized with food coloring to replicate blood as can be seen in Figure 36. This experiment had many limiting factors due to the laborious need to hand place all tubing through the organs. The silicone tubing proved to be too stiff and unable to replicate the feeling of human blood vessels, as well as fail to bleed in a correct biological manner.

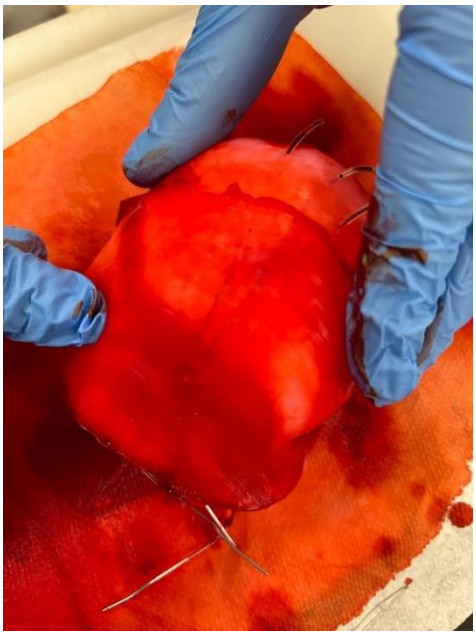


Figure 36: Picture of Silicone tubing Blood Vessels in PVA

A second experiment to pursue this model was conducted using mineral oil to replace blood. This was done with oil due to its hydrophobic nature and ability to create pockets within the PVA. The experiment was carried out by first using food coloring to dye the oil to give it a color similar to blood. This dyed oil was injected into PVA was settled in the liquid state to create pockets within the organs. Once frozen and thawed, the oil pocket was observed to remain intact within the organ. Once the organ was operated on, a cut that went through one of these oil pockets rendered a more realistic bleed model of how a biological organ would react. This experiment will be improved upon by later teams in pursuit of creating a realistic bleed model in the surgical trainer.

5.2 Complete Design of Surgical Trainer

The surgical trainer consists of many components with varying materials to create a realistic RUQ organ system. The main materials the team used for organs are PVA solution and silicone. The group members chose PVA solution to fabricate the trainers' replaceable organs. These are the organs that will be operated on during a procedure, colon and small intestine, and are required to exhibit mechanically correct properties of biological organs. The team chose PVA since it exhibits such properties which were determined through various material tests. For the organs that are not operated on, liver, kidney, and gallbladder, the team chose to use silicone to fabricate these components. The group members chose silicone since it is long lasting and does not hydrate. These organs do not need to be mechanically similar to biological organs as they are not operated on and serve as location landmarks within the RUQ organ system. All operated and non-operated organs are fabricated using PLA molds as well as PVC tubing. The last component is the organ mesentery found within a human RUQ. This material is fabricated with PVA formed in layered sheets that are wrapped around and under the organs to serve as the membrane coating

the organ system. The team chose PVA to display the mesentery since it simulates correct mechanical properties. Together these organs will be layered in a correct anatomical position within the surgical trainer to create a synthetic RUQ organ system shown in Figure 37 below.

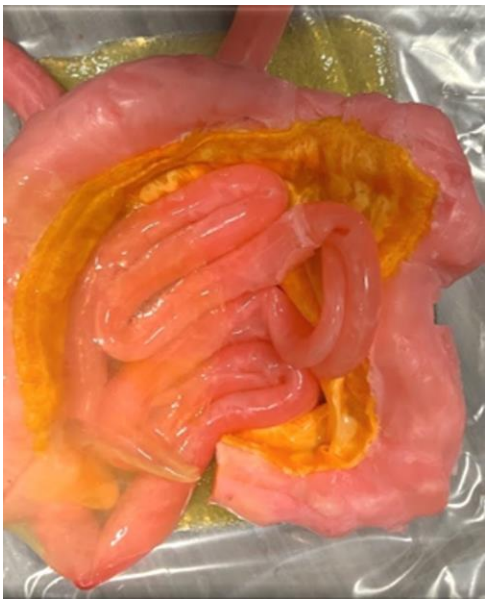


Figure 37: Picture of the surgical trainer final design

Chapter 6: Final Design Validation

After completion of a final prototype, surveys and quality checks were performed on different aspects of the device to assess if the objectives were met. The tests that were used to evaluate the success of each part are summarized in Table 33. The methods and results of these tests are further discussed in the following sections of this chapter.

Table 33: Table of validation testing

Primary Objective	**Testing Method**	**Data Collected**
Anatomically Correct	• Measuring organ weights • Measuring puncture	• Weight of organs within a range • Force it took to puncture PVA
Peelability/separability	• Measuring peel	• Force it took to peel apart
Replaceability	• Measure how many times the organs can be reused	• Observation of organs after being used
Ease of Use	• Survey residents	• How real the organs felt • How easy it was to train with
Manufacturability	• Cost to manufacture • Production time	• Cost of each organ based on PVA used • Time to took to make each organ and assemble

6.1 Survey

For our design validation the team decided that direct feedback from the surgeons would be most beneficial due to their experience. The team made a survey that would allow for the residents to practice on the surgical box trainer and then provide feedback on the design with questions based on the objectives. The survey can be seen in Appendix K and the results can be seen in Appendix L. The survey was also IRB approved by WPI as can be seen in Appendix J.

The team developed the survey utilizing Microsoft forms and a quick response (QR) code was made for convivence. The questions reflected on the accuracy of the surgical trainer's components in simulating a human abdomen. Each question related to the feeling of performing laparoscopic surgery, the location, and the size of the sections of the protype. These ultimately lead to validate objectives including anatomically correct and peelable/separable. To answer the questions the participants answered on a Likert scale from strongly disagree to strongly agree and then had a chance to provide additional information and requests for the future iterations in a comment section.

The team setup the model in a surgical box trainer in the Sim Lab in Beth Israel Deaconess Medical Center. The box trainer had laparoscopic surgical instruments for use as well as a camera projecting the inside of the trainer onto a monitor that can be seen in Figure 38 below. The team collected responses from participants with varying surgical skillsets including

an attending and the chief resident. There were 4 participants total and each participant practiced on the trainer for around 10 minutes and then filled out the survey using the QR code.

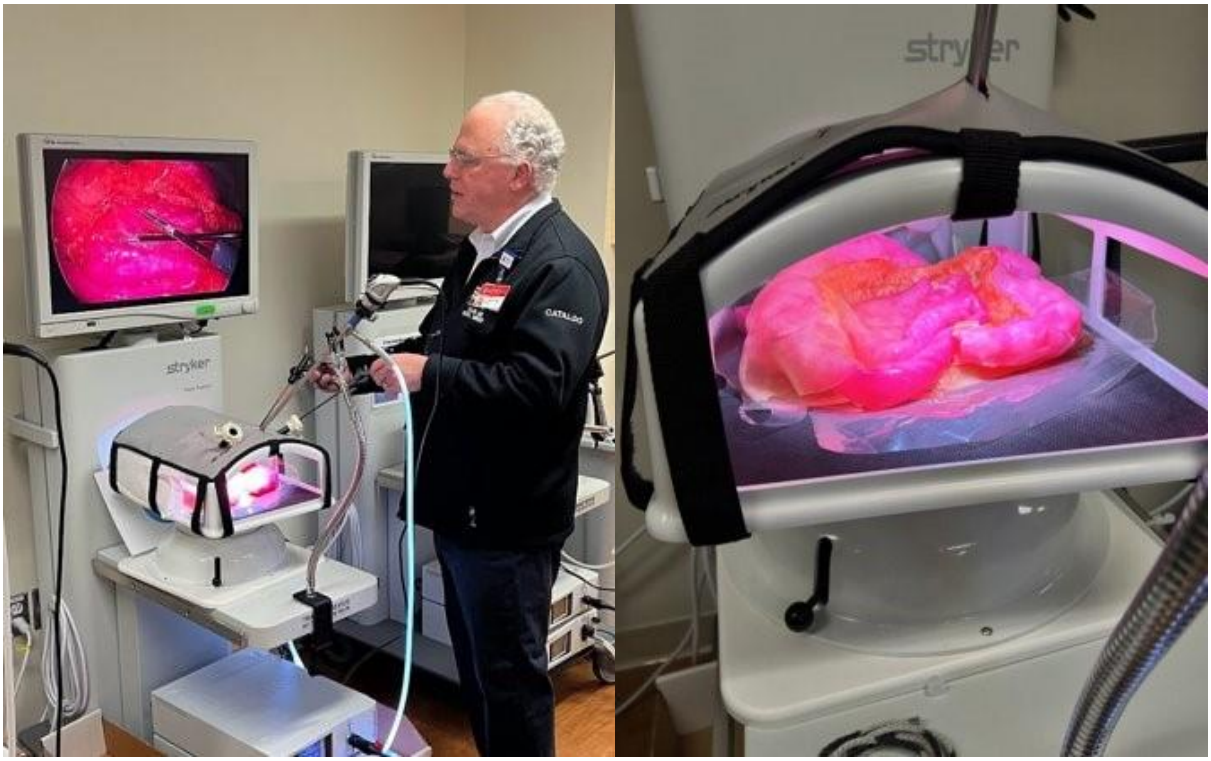


Figure 38: Setup for the surgeon feedback survey

Overall, the goal was to satisfy the client and other than a few notes, Dr. Cataldo was more than satisfied with the result. One limitation of this survey was an unsatisfactory sample size, but the feedback provided was sufficient and crucial for the betterment of the model.

Every participant agreed that the synthetic organs and overall model was bio realistic. Most of the responses reflected the feeling of the mesentery simulated a real abdomen in laparoscopic surgery, but the appearance could be improved. Every participant from the survey agreed or strongly agreed that the team's prototype provided valuable technical surgical experience, is a beneficial way to practice developmental skills, and would use the trainer again or recommend it to another peer. Additional comments for feedback included making the colon hollow to better simulate the feeling as well as adjusting the mesentery thicknesses. Overall, with these results the team was able to further validate anatomical correctness as well as the peel ability and separability of the model.

There were numerous restrictions that limited the survey because of the project's schedule and the available resources. Due to the surgeons' busy schedules, it was difficult for the team to get a good sample size within the given timeframe. The team would have also liked to revise the model using the initial surgeon feedback and have another round of surveys to see if the initial issues had been solved. This was ultimately not possible because of time constraints.

6.2 Quality Check Parameters

To validify the surgical trainer design, certain quality check parameters are applied to the manufactured organs to ensure the realistic properties of the device. These quality check parameters are important to not only provide the user with a realistic simulation of surgery, but to create a well-trained practice option for residents and surgeons. The parameters include checks of the manufactured PVA for anatomical correctness through weight and dimension tests, along with puncture and pull testing. These tests enable the team to provide an anatomically correct surgical trainer.

6.2.1 Measure Anatomic Correctness

The weight and dimensions for measuring anatomical correctness of our operated PVA Colon and Small Intestine are shown in Table 34 below. The weights for each organ have been set through measuring three of each manufactured organ. Based on the differing weights of these organs, tolerances were set based on the average, as well as the standard deviation of the weights. Though the weights are not completely anatomically accurate, it was deemed more important for the ability to produce consistency within our weights. This same idea is applied to our dimensional measurements for each organ. These measurements can be related to a certain degree of anatomical correctness and help us to quantitatively assess our organ manufacturing methods and where errors can occur.

Table 34: Operated organs weight and dimensions

Organ	Weight	Dimensions
Small Intestine 	225 ± 50g	Length: 1.22 m Outer Diameter: 25.4 mm Inner Diameter: 12.7 mm
Colon 	650 ± 50g	Ascending: No more than 88.9 mm width Transverse: No more than 38.1 mm width Descending: No more than 63.5 mm width

In order to validate the final design's anatomically correct mechanical properties, the team produced batches of PVA and followed the same procedure in Appendix D to record puncture strengths. The team considered a batch of PVA to be "accurate" if the puncture strength reflected 18.9 ± 10 N, the value from previous project team's reports of average porcine mesenteric puncture strength [45]. The team tested nine PVA specimens following the procedure in Appendix D. Appendix E displays the graphical results for puncture strength (N) over displacement (m). In an ideal set of data, as shown in Figure 39, each specimen's puncture resistance increases gradually until the custom Instron attachment breaks through the PVA subject. The team records the maximum force from the data. The shaded area and red line within Figure 39 represent target values for a bio realistic puncture strength mentioned above. The average puncture resistance force within Specimen 1 falls within the target values. The average puncture strength from all tested PVA subjects is 10.6 ± 4.6 N, which also falls within the target value, validating the anatomic correctness of the final design's puncture resistance force via mechanical testing.

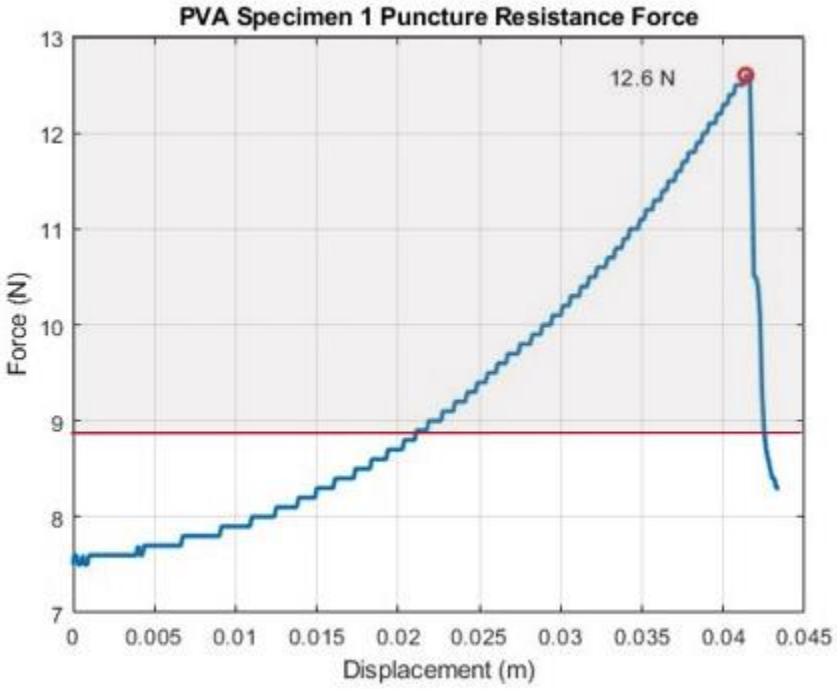


Figure 39: PVA Specimen 1 puncture resistance force graph

6.2.2 Measure Separability

One quantitative method to measure accuracy and precision within separability of mesentery for batches of PVA was through mechanical peel testing. The team produced batches of PVA and followed the same procedure in Appendix F to record peel strengths. The team considered a batch of PVA to be "accurate" if the peel strength reflected 2.9 ± 1.8 kPa, the value from previous project team's reports of average porcine mesenteric peel strength [45]. The team

tested eight PVA specimens following the procedure in Appendix F. Group members utilized the first specimen as a practice run and did not record any data. Appendix G displays the graphical results of the next seven PVA subjects' tensile stress (kPa) over time (s). In an ideal set of data, as shown in Figure 40, each specimen's tensile stress increases gradually and eventually plateaus until the subject is completely peeled off or entangles and breaks off. The team calculates average tensile stress from the relevant plateau data. The shaded area and red line within Figure 40 represent target values for a bio realistic peel stress mentioned above. The average peel stress within specimen 7 falls within the target values. The average peel stress from all tested PVA subjects is 1.15 ± 0.50 kPa, which also falls within the target value, validating the separability of the team's model via mechanical testing.

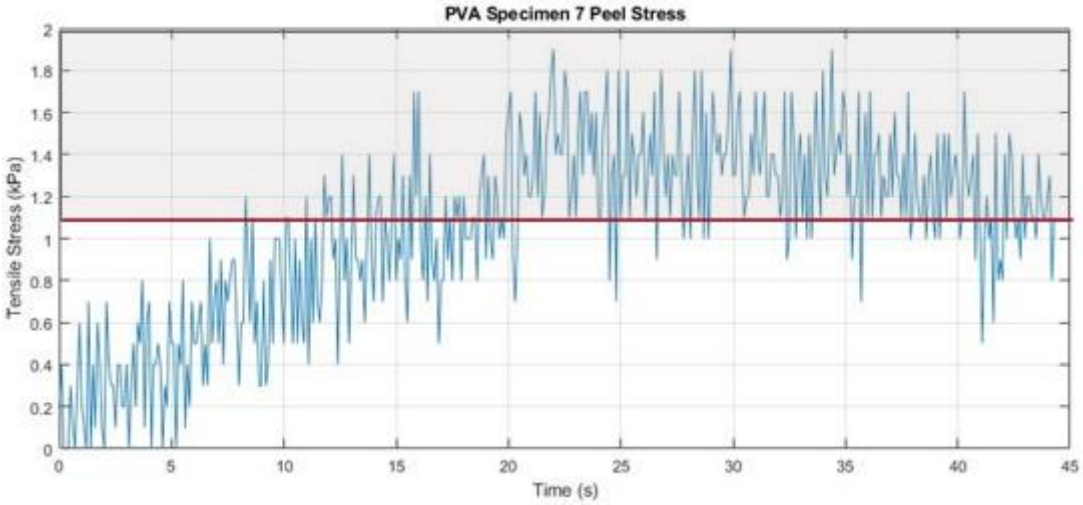


Figure 40: PVA Specimen 7 peel stress graph

One qualitative method to measure the accuracy of separability of the mesentery was through surgeon feedback after manipulation of the prototype surgical trainer with laparoscopic equipment. Section 6.1 provides detailed information on the surgeon feedback survey and Appendix L represents the results received from the participants. According to the surgeon feedback survey, 75% of the respondents at least somewhat agreed that the mesentery in the surgical trainer model accurately feels as if performing laparoscopic surgery. Both the chief resident and attending surgeons, who have the greatest amount of experience among the pool of participants, somewhat agreed. Although not directly stated within the question, the team expressed that the feeling of the mesentery correlates to the assessment of the model mesentery's separability.

6.2.3 Measure Reusability

Within the trainer there is a distinction between our operated and non-operated organs. Our operated organs are the only part of the trainer needing to be replaced. Through bringing our trainer Beth Israel Deaconess Medical Center, we found that the non-operated organs weren't touched, and our trainer could be used 3-4 times. These are our PVA organs consisting of a

Colon, small intestine, and mesentery/fat sheets. After being operated 3-4 times, the operated organs can be replaced by manufacturing a new set of PVA organs. Our manufacturing process is sustainable as it reuses these molds used for organ creation. These molds can be used over and over again to continually create and manufacture organs.

6.2.4 Measure Replaceability

The manufacturing process for all organs, besides the small intestine and mesentery, involves using 3D printed molds. By repeating the manufacturing process detailed in Section 5.1.3.1, these model organs can be replaced with high precision. The team reuses the same molds to ensure all replaced model organs will have the same shape and size. To validate the accuracy of every replaced organ, the group can obtain a sample of each PVA batch and conduct mechanical testing to confirm puncture resistance adequately falls within the target values as specified in Section 6.2.1. The manufacturing process for the mesentery is less controlled than the 3D printed molding process, but with future advancements in developing mesentery sheets, the process can be easily repeated. All replacements meet the parameters stated above to pass a quality check.

6.2.5 Measure Ease of Use

To measure the ease of use of the model the team originally decided to time how long it would take for a subject to set up the organs and mesentery in a box trainer. The team decided in the final design that it would be easier to have the organs preassembled and glued together with an adhesive in the correct anatomical position to reduce any user error or confusion. After in house assembly the single entity would be put in a vacuum sealed bag to prevent the product from drying out and then shipped to the customer. This decision allows for the user to simply remove the organs from the packaging and place it in the trainer. This was timed by the team for an average of 30 seconds. This also eliminates error as it doesn’t require the user to do any assembling besides orientating it in the trainer correctly.

6.2.6 Measure Manufacturability

To measure the manufacturability of our surgical trainer, the team has addressed components circulating the cost, ability to apply quality checks to a completed trainer, and ease of manufacturing. After doing a cost analysis, the components found within the trainer came out to being less than $150 to complete as can be seen in Appendix M. This does not include the materials used to create the organs, including molds and lab equipment. Our team found the process to complete a single trainer to take around a 24-hour period. Most of this time is attributed to the necessary time needed to freeze PVA. With the refinement of this process, it can be streamlined and placed into a highly manufacturable setting to efficiently produce surgical trainers. When a surgical trainer's organs are ready, our team has set quality checks in place to validate the trainer before being completed. These checks go over the organs weight, dimensions,

and mechanical specifications to check the anatomical accuracy of organs. After these checks have been completed, the cost of the trainer will be under $150, which is much lower than the current trainers on the market. The replacement of the operated organs will also cost less than $150 and can be quickly manufactured and quality checked to be added to an existing trainer.

Chapter 7: Discussion

7.1 Right Upper Quadrant Organs Analysis

The main objective for the RUQ organs was for them to look and feel as close to a real abdomen as possible. This was determined by the puncture strength and dimensions being comparable to those of real RUQ organs as well as the locations of each organ being accurate. The non-operated organs also needed to be reusable for multiple practices and the operated organs needed also needed to be replaceable. The reusable organs were made with durable material too, and the replaceable organs were produced with molds in order to make them replaceable.

Throughout the design process the team was able to accomplish making a hollow small intestine as well as making a complex large intestine to more accurately simulate a bio-realistic environment. For the small intestine the team started off using sausage casing and then moved onto a PVC pipe. After determining that the solid intestine was too firm and was not easy to manipulate the team decided to add inner tubing to the PVC pipe to make for a hollow intestine. For the large intestine the team inverted a CT scan to create a mold. After multiple trials the team was able to make a complex mold that allowed for the large intestine to be easily removed without damage. The non-operated organs made by previous teams including the kidney, the liver, and the gallbladder were also used in the final design. The design processes for both organ types in more depth can be seen in Chapter 4.3.2 and the manufacturing processes in Chapters 5.1.3.1 and 5.1.3.2.

The manufacturing methods for both categories were similar while the materials used differed. For the operated organs the team made a batch of PVA, poured the PVA in the mold, froze the mold, and then dethawed. After this process was completed a chosen dye color could be rubbed onto the surface, but a better method for this needs to be established as the dye transfers easily. For the non-operated organs, the previous year's team prepared silicone and then poured the silicone into the mold. After the mold sets the organ could be removed. The PVA processes is described in more detail in Appendix C.

7.2 Mesentery Analysis

The team’s primary objective for the mesentery was bio-realism regarding appearance, location, and mechanical properties. These properties focus on puncture resistance and peel strength similar to what a surgeon experiences during an operation. Secondary objectives revolved around simulating vasculature within mesentery and “oozeability” of fake blood during model manipulation. Based on the goals and objectives set forth, the team was able to successfully create a mesentery comprised of multiple layers of PVA to be utilized within the surgical trainer.

When creating the mesentery, the team focused on ensuring that it had all the functions and specifications that were established from the beginning of the project. The group researched

multiple different materials to match the appearance and feeling of a real mesentery. Simulating the “feeling” of performing laparoscopic surgery on the model mesentery includes adhering onto the other organs and the mechanical properties resulting in manipulation of the trainer. The team conducted a wide range of experimentation with potential materials for the component, detailed in Section 5.1.2.1. Section 6.2.1 describes the mechanical property testing performed to validate the anatomic correctness of puncture strength and peel force. The team’s results solidify the success of these objectives as they fall within target values.

There are two main manufacturing processes that depend on the thickness of the mesentery. Thin layer mesentery relies on pouring PVA in-between two gasket-separated plastic sheets while thicker layers of mesentery rely on pouring PVA into a glass container. While attempting to seal the 3D printed molds after pouring in PVA, the team noticed that some PVA leaked in-between the parts and created a thin layer. This incidence sparked the team to conduct multiple different experiments involving compressing PVA, which eventually led to plastic sheets.

The main limitation that the team faced when trying to manufacture the mesentery was starting from scratch since previous teams did not focus on developing this component of the surgical trainer. After diving into literature review, the group found little to no research into the mechanical properties of mesentery within peer-reviewed articles. To find a target value for these properties, the group extrapolated data points based off similar tissues and fats within the body. Although the previous project teams did not work on a mesenteric model, they did perform mechanical testing on porcine mesentery samples. By utilizing data collected from puncture and peel testing and secondary literature, the current team defined specifications for the prototype.

7.3 Project Limitations

There were some limitations for the manufacturing process of PVA including the PVA taking longer than expected to be shipped. The team only has access to a small stir bar on a stir plate rather than an industrial impeller. This meant that sometimes the PVA wouldn’t fully incorporate and bunch up due to the lack of force in the stir bar and the stir bar would get stuck when the consistency would thicken. This also meant that the PVA could only be made in small batches, and therefore took much longer for the team to produce enough PVA for manufacturing. Additionally, the freezer space provided in the lab only allowed for small molds to be made, so the larger molds like the intestines needed to be frozen off campus.

During the design process, the team faced supply chain issues regarding PVA. The delay between the supplier's original shipping date and obtaining the materials lasted three months. This unexpected stall slowed the team’s progress revolving around experimentation. With varying thicknesses necessary to accurately simulate human mesentery, the team altered PVA concentrations within batches and continued to collect data regarding mechanical properties. In addition to the mesentery experimentation, the group utilized PVA in the development and experimentation of the operated right upper quadrant organs. PVA was crucial to the progress and success of the project, as the delay hindered the timeline significantly.

7.4 Final Device Analysis

After completion of the prototype, the team found many parts of the design during a final analysis that can be improved upon for future use. The process for creating the surgical trainer can be broken up into three parts. This consists of creating the non-operated organs, the operated, and the mesentery/fat sheets. The non-operated organs are cast by using 3D printed molds and using silicone gel. This includes the kidney, liver, and gallbladder. Similarly, the operated organs are cast using a 3D printed mold, and a PVC pipe with metal inner tubing using 5% PVA. This includes the colon created with the mold, and the hollow small intestine using the PVC pipe and inner metal tube. Lastly, the mesentery was created using thin plastic sheets where PVA can be poured and spread. The fat sheets are created within glass pans and spread out to a thicker height. All PVA created items are frozen, thawed and then dyed to create our organ system. With all the components, superglue adhesive is used to stick mesentery and fat above and below the colon and small intestine following human anatomy. The team accomplished many things with the establishment of the device by creating an anatomically correct upper right quadrant organ system. Our operated PVA organs and non-operated PVA organs used together are perfect materials for our surgical trainer. Both the mesentery and the organs were assembled in anatomically correct positions using a superglue adhesive and stored in a vacuum sealed bag for storage. After bringing the prototype to BIDMC to be tested by the residents and surgeons, it was determined that the device could be improved in certain aspects. One being the change of mesentery to be a thicker sheet to better simulate human anatomy. It was also analyzed that a hollow colon would be more realistic and easier for surgeons to manipulate. Other than these changes to the prototype, a refined manufacturing process can be used to streamline our process and test the device under more surgeons.

7.5 Impact Analysis

The following sections will discuss these important topics: economic, environmental, societal influence, political ramifications, ethical concerns, health and safety issues, manufacturability, and sustainability. Each of these sections will analyze the potential impacts the final design may have if produced and implemented into the world.

7.5.1 Economic Analysis

With the development of a cheap, bio realistic, highly manufacturable surgical trainer on the market, the competition of other training models, such as expensive synthetic cadavers, may lower in cost. This may provide hospitals of all resource levels with a wider variety of surgical training, since each model may become more affordable. Surgeons have the ability to practice on an accurate model of the human intestines and potentially other procedural sites in the future, leading to an improvement in proficiency among residents, low volume surgeons, and those new to laparoscopic equipment. Doctors will provide patients with decreased risks of complications

and less visits to the operation room. Hospitals and patients may save money with the release of this team's surgical model on the market.

7.5.2 Environmental Impact

There is limited environmental impact expected from our device as PVA is not detrimental to the environment when it is in the form of a hydrogel. PVA is only detrimental when in liquid form. Although silicone is a thermoset, the model organs manufactured are reusable and should not experience damage during training, therefore having little environmental impact as they are not consistently disposed of. Upon disposal of silicone organs, there have been developing technologies to recycle or repurpose silicone. Although not all users will have access to this technology, the possibility of recycling silicone reduces its environmental impact.

7.5.3 Societal Influence

Since the manufacturing process of the surgical trainer is cost effective, it will be financially viable to provide models to surgeons in low-resource hospitals and in developing countries for drastically lower prices than other customers. Surgeons from any hospital may utilize the surgical trainer to shorten the learning curve of a specific operation or the use of laparoscopic equipment within a bio realistic environment. By purchasing better training models, higher-resource hospitals may donate older training models to lower-resource hospitals. The effects of releasing a greater quality surgical trainer into the market may trickle down into increasing accessibility and improvement in healthcare for developing countries and under-resourced communities in the United States.

7.5.4 Political Ramifications

The design, development, and the manufacturing of the surgical trainer would have no political ramifications. If the product is eventually brought to the market, it can have a great impact on the current state of surgical training. The efficiency and ability to simulate anatomical organs while being sold at a low cost would make the trainer available and wanted in hospitals around the world. It not only has the ability to limit resident operation training but enhances the quality of surgery being done. With the trainer being reusable, it allows for residents to practice surgery in multiple rounds and be able to replace organs at a low cost. Because of this low cost, the trainer can be made available to all hospitals in the world and serves as a new standard of surgical training equipment to increase patient safety.

7.5.5 Ethical Concerns

There are few ethical concerns pertaining to the final device due to the device not entering the human body. All the materials used within the device are bioinert and raise minimal safety concerns upon contact or use. There was no animal testing performed when creating the

device, as all our comparison data was obtained by teams prior and other research papers. The main ethical concern is the use of patient CT scans, however these scans are obtained through a public resource, the Cancer Imaging Archive, where all the patients are anonymous. The team ensured to maintain the anonymity of the patients when utilizing the CT scans.

7.5.6 Healthy and Safety Issues

Besides minor risks associated to surgeons with silicone allergies, there are no health or safety concerns with the model. This model lowers risk in the education of colorectal surgeons. As a bridge to working with real patients, residents practice in a simulated setting using a model to practice repeated skills. Errors and patient danger can be decreased by training. To reduce setup time, the model's organs are already built and will be sent directly to users. Since the model will be used outside of the operation area, sanitation is not necessary.

7.5.7 Manufacturability

This surgical trainer will have the ability to be highly manufactured with an improved and streamlined process. The team's creation of an entire upper right quadrant organ system using PVA and silicone can be cast by using 3D printed molds and easily obtained materials. In a manufacturing setting, the process of making PVA and multiple molds can be used to make many trainers at once. Production can be further simplified with greater quality material molds as well as area for manufacturing. Our team has achieved last year's goals of being able to quickly and inexpensively manufacture a trainer as a whole. Future directions of our team include a refined process for manufacturing trainers that are up to validation standards. With an improved process, the surgical trainer is able to be manufactured in a quality where it can be further tested in hospitals, as well as immediately help in the field of surgical training.

7.5.8 Sustainability

The team’s surgical trainer utilizes silicone and polyvinyl alcohol within the three main components. Non-operated, silicone organs will survive many trainings sessions due to the nature of the operation and the longevity of silicone. After testing many storage procedures, the team found that the entire model can survive in an air-tight plastic bag, without water, in a climate no greater than room temperature. A team may need to conduct future studies relating to the finite duration the surgical trainer can last in the desired conditions. The team developed the final design with generally cheap materials and cost-effective manufacturing processes providing a sustainable product.

Chapter 8: Conclusions and Recommendations

8.1 Conclusion

The bio-realistic organs that the team produced were able to be validated through mechanical testing, 3D printing, and surgeon feedback. This validation testing allowed the team to determine the effectiveness of the device and its ability to perform to the specifications that were discussed in Section 4.2. Based on the mechanical testing performed on the PVA used to produce the operated organs and mesentery, the device had puncture and peel values that fell within the target values to validate the anatomical correctness of the organs and the separability of the mesentery. Utilization of 3D printed molds to produce the operable organs allowed for further assurance of the anatomical correctness by providing the 1:1 ratio of organ shape and size. The ability to reuse the molds also allows for the manufacturing process of the organs to be cost effective and provides an effective method for producing continuous organs to replace those that are maneuvered during training sessions. The results from the surveys that were conducted with the residents and surgeons at the hospital validated the bio-realistic representation of the RUQ. The team was able to gauge the integrity of the mesentery and its ability to peel away from itself and other organs through feedback from the residents and surgeons that tested the device. When transferring the bio-realistic abdomen from the vacuum seal bag to the surgical box trainer, the team was able to measure the time it to complete this process to validate the easy of assembly and use of the device.

8.2 Future Recommendations

For future iterations of this project, the team developed three recommendations: implementing a blood leaking model, further validation through resident and surgeon testing, and a more efficient method for manufacturing the device. The implementation of these recommendations could assist in completing the client's ultimate goal of transforming this project into a future interactive qualifying project.

The team was able to perform some experimentation to incorporate oozing and blood leaking into the model but was unable to continue due to the scope of the project. For the future, it is recommended to perform more testing with integrating pockets of oil or tubes within the mesentery to mimic blood vessels that are throughout it. Implementing this will allow for a more realistic experience for the residents and surgeons when performing laparoscopic surgery using this device.

The recommendation for further testing and surveys with more residents and surgeons will help further validate the bio-realism and accuracy of the device as this year's team experienced a small sample size. A larger sample size will further authenticate the statistical significance of using the device to train for laparoscopic surgery. It will also allow for feedback

on changes that can be made to the model for better accuracy and continuous improvement to ensure the bio-realism of the right upper quadrant.

The current method for producing this device is very time consuming and inefficient, therefore it is a recommendation to find a more efficient method for manufacturing the device. It is recommended that the team invests in an immersion blender to decrease the time it takes to create a batch of PVA. It might also be beneficial to find a different material to create the colon mold out of to increase the limit of how many times a singular mold can be used to produce organs before needing replacement as the current PLA printed molds can be easily damaged during organ removal.

With the implementation of these modifications and recommendations, this device would help decrease complications caused by human error that may occur during laparoscopic surgery due to lack of experience and training.

References

[1] "Colorectal Surgery in Long Branch | Monmouth Medical Center," *RWJBarnabas Health*. https://www.rwjbh.org/monmouth-medical-center/treatment-care/surgery/surgical-services/minimally-invasive-surgery/minimally-invasive-surgical-procedures/colorectal-surgery-colectomy/ (accessed Oct. 10, 2022).

[2] Damle RN, Macomber CW, Flahive JM, Davids JS, Sweeney WB, Sturrock PR, Maykel JA, Santry HP, Alavi K. Surgeon volume and elective resection for colon cancer: an analysis of outcomes and use of laparoscopy. J Am Coll Surg. 2014

[3] Shanker BA, Soliman M, Williamson P, Ferrara A. Laparoscopic Colorectal Training Gap in Colorectal and Surgical Residents. JSLS. 2016 Jul-Sep;20

[4] J. V. Vu, B. C. George, M. Clark, S. J. Rivard, S. E. Regenbogen, and G. Kwakye, "Readiness of Graduating General Surgery Residents to Perform Colorectal Procedures," *Journal of Surgical Education*, vol. 78, no. 4, pp. 1127–1135, Jul. 2021, doi: 10.1016/j.jsurg.2020.12.015.

[5] H. Bauer and K. C. Honselmann, "Minimum Volume Standards in Surgery – Are We There Yet?," *Visc Med*, vol. 33, no. 2, pp. 106–116, May 2017, doi: 10.1159/000456041.

[6] "Research and Testimony." https://www.acgme.org/what-we-do/accreditation/clinical-experience-and-education-formerly-duty-hours/research-and-testimony/ (accessed Oct. 16, 2022).

[7] M. L. Mayer, H. A. Beil, and D. von Allmen, "Distance to care and relative supply among pediatric surgical subspecialties," *J Pediatr Surg*, vol. 44, no. 3, pp. 483–495, Mar. 2009, doi: 10.1016/j.jpedsurg.2008.08.015.

[8] Dr. Beth Stubing, Nkhoma Mission Hospital. Lilongwe, Malawi. (July 21, 2022.) Received Sept.1, 2022

[9] "Using Cadavers: Pros and Cons," *Maverick Medical Education - Medical Training Courses*. https://www.maverickmeded.com/blog/using-cadavers-pros-and-cons (accessed Oct. 10, 2022).

[10] "Small Intestine: Function, anatomy & Definition," *Cleveland Clinic*. https://my.clevelandclinic.org/health/body/22135-small-intestine (accessed Oct. 16, 2022).

[11] V. I. Egorov, I. V. Schastlivtsev, E. V. Prut, A. O. Baranov, and R. A. Turusov, "Mechanical properties of the human gastrointestinal tract," *Journal of Biomechanics*, vol. 35, no. 10, pp. 1417–1425, Oct. 2002, doi: 10.1016/S0021-9290(02)00084-2.

[12] L. L. Azzouz and S. Sharma, "Physiology, Large Intestine," in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2022. Accessed: Oct. 16, 2022. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK507857/

[13] P. Kahai, P. Mandiga, C. J. Wehrle, and S. Lobo, “Anatomy, Abdomen and Pelvis, Large Intestine,” in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2022. Accessed: Oct. 16, 2022. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK470577/

[14] M. Phillips, A. Patel, P. Meredith, O. Will, and C. Brassett, “Segmental colonic length and mobility,” *Ann R Coll Surg Engl*, vol. 97, no. 6, pp. 439–444, Sep. 2015, doi: 10.1308/003588415X14181254790527.

[15] D. A. Watters, A. N. Smith, M. A. Eastwood, K. C. Anderson, R. A. Elton, and J. W. Mugerwa, “Mechanical properties of the colon: comparison of the features of the African and European colon in vitro.,” *Gut*, vol. 26, no. 4, pp. 384–392, Apr. 1985, doi: 10.1136/gut.26.4.384.

[16] “How Long Are Your Intestines? Length of Small and Large Intestines,” *Healthline*, Sep. 18, 2019. https://www.healthline.com/health/digestive-health/how-long-are-your-intestines (accessed Oct. 16, 2022).

[17] “THE PHYSIOLOGY OF ADIPOSE TISSUE | Physiological Reviews.” https://journals.physiology.org/doi/pdf/10.1152/physrev.1948.28.4.451?casa_token=-a62zpuvo-4AAAAA:lbBD4Ds_dvnrovtjJN9Q7XAiHz1tSdoiM7oSzzBYz-E5UtJ5hTQuE3W_0Chqxn6mseQUCSq-rWMa (accessed Oct. 16, 2022).

[18] “Adipose Tissue (Body Fat): Anatomy & Function,” *Cleveland Clinic*. https://my.clevelandclinic.org/health/body/24052-adipose-tissue-body-fat (accessed Oct. 16, 2022).

[19] N. Hammad, J. C. Mansfield, E. Green, and J. Bell, “The Mechanical Properties of Human Adipose Tissues and their Relationships to the structure and Composition of the Extracellular Matrix,” *AJP Endocrinology and Metabolism*, 305(12), Oct 2013, doi: 10.1152/ajpendo.00111.2013.

[20] J. C. Coffey and D. P. O’Leary, “The mesentery: structure, function, and role in disease,” *The Lancet Gastroenterology & Hepatology*, vol. 1, no. 3, pp. 238–247, Nov. 2016, doi: 10.1016/S2468-1253(16)30026-7.

[21] J. O. A. M. van Baal *et al.*, “The histophysiology and pathophysiology of the peritoneum,” *Tissue and Cell*, vol. 49, no. 1, pp. 95–105, Feb. 2017, doi: 10.1016/j.tice.2016.11.004.

[22] “Laparoscopic Surgery for Colorectal Cancer,” *UTMC*. https://www.utmedicalcenter.org/medical-care/medical-services/procedures-treatments/laparoscopic-surgery/ (accessed Oct. 16, 2022).

[23] P. J. Guillou *et al.*, “Short-term endpoints of conventional versus laparoscopic-assisted surgery in patients with colorectal cancer (MRC CLASICC trial): multicentre, randomised controlled trial,” *The Lancet*, vol. 365, no. 9472, pp. 1718–1726, May 2005, doi: 10.1016/S0140-6736(05)66545-2.

[24] C. D. Athanasiou, J. Robinson, M. Yiasemidou, S. Lockwood, and G. A. Markides, “Laparoscopic vs open approach for transverse colon cancer. A systematic review and

meta-analysis of short and long term outcomes," *International Journal of Surgery*, vol. 41, pp. 78–85, May 2017, doi: 10.1016/j.ijsu.2017.03.050.

[25] "Right hemicolectomy," *Mayo Clinic*. https://www.mayoclinic.org/tests-procedures/colectomy/multimedia/right-hemicolectomy/img-20007591 (accessed Oct. 16, 2022).

[26] "Surgical Residency Program," *Massachusetts General Hospital*. https://www.massgeneral.org/surgery/education-and-training/surgical-residency-program (accessed Oct. 10, 2022).

[27] Y. Munz, B. D. Kumar, K. Moorthy, S. Bann, and A. Darzi, "Laparoscopic virtual reality and box trainers: is one superior to the other?," *Surg Endosc*, vol. 18, no. 3, pp. 485–494, Mar. 2004, doi: 10.1007/s00464-003-9043-7.

[28] "FLS Objectives," *Fundamentals of Laparoscopic Surgery*, Aug. 12, 2010. https://www.flsprogram.org/index/fls-objectives/ (accessed Oct. 10, 2022).

[29] "Testing Information," *Fundamentals of Laparoscopic Surgery*, Aug. 05, 2010. https://www.flsprogram.org/testing-information/ (accessed Oct. 10, 2022).

[30] "Technical Skills Training Curriculum," *Fundamentals of Laparoscopic Surgery*, Sep. 16, 2022. https://www.flsprogram.org/technical-skills-training-curriculum/ (accessed Oct. 10, 2022).

[31] Y. B. Chen, A. Chen, T. Pham. "Fundamentals of laparoscopic surgery (FLS) manual skills exam: Tips and tricks," *Youtube*, Jun. 30,2021 [Video file]. Available: https://www.youtube.com/watch?v=IwrNTRVXuJQ. [Accessed: Oct. 10, 2022).

[32] "Training Requirements | American Board of Surgery." https://www.absurgery.org/default.jsp?certgsqe_training (accessed Oct. 10, 2022).

[33] A. K. Dhariwal, R. Y. Prabhu, A. N. Dalvi, and A. N. Supe, "Effectiveness of box trainers bin laparoscopic training," *J Minim Access Surg*, vol. 3, no. 2, pp. 57–63, 2007, doi: 10.4103/0972-9941.33274.

[34] "Training simulators for laparoscopy - LapSim®," *Surgical Science*. https://surgicalscience.com/simulators/lapsim/technology/ (accessed Oct. 17, 2022).

[35] "It Bleeds. It Breathes. It's a Lifelike Artificial Human Corpse! | Live Science." https://www.livescience.com/61089-syndaver-synthetic-humans.html (accessed Oct. 17, 2022).

[36] Synjosh, "SynDaver Care | SynDaver." https://syndaver.com/syndaver-care/ (accessed Oct. 17, 2022).

[37] "Reports Summarize Colorectal Research Study Results from University of Limerick (Mechanical characterisation of porcine non-intestinal colorectal tissues for innovation in surgical instrument design)," *Medical Devices & Surgical Technology Week*, pp. 790–790, Aug. 2018.

[38]“Patent | SynDaver,” Feb. 27, 2020. https://syndaver.com/category/patent/ (accessed Apr. 27, 2023).

[39] “The Effects of Testing Environment on the Viscoelastic Properties of Soft Tissues | SpringerLink.” https://link.springer.com/chapter/10.1007/978-3-540-25968-8_2#citeas (accessed Dec. 15, 2022).

[40] C. Fox, “Common Program Requirements,” *General Surgery*, p. 66.

[41] 14:00-17:00, “ISO 527-1:2019,” *ISO*. https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/standard/07/58/75824.html (accessed Oct. 10, 2022).

[42] “Standard Test Method for Index Puncture Resistance of Geomembranes and Related Products.” https://www.astm.org/d4833_d4833m-07r20.html (accessed Oct. 10, 2022).

[43] Z. Sun, B. D. Gepner, S. H. Lee, M. L. Oyen, J. Rigby, P. S. Cottler, J. J. Hallman, and J. R. Kerrigan, “Effect of Temperature and Freezing on Human Adipose Tissue Material Properties Characterized by High-Rate Indentation: Puncture Testing,” *J Biomech Eng.* 144(3): 034502, Mar 2022, doi: 10.1115/1.4052577.

[44] C. Noble, N. Smulders, R. Lewis, M. J. Carre, S. E. Franklin, S. MacNeil, and Z. A. Taylor, “Controlled peel testing of a model tissue for diseased aorta,” *Journal of Biomechanics*, vol. 49, no. 15, pp. 3667-3675, Nov 2016, doi: 10.1016/j.jbiomech.2016.09.040.

[45] “Laparoscopic right colectomy with extracorporeal anastomosis-standard approach,” YouTube, Apr 2018, retrieved from: https://www.youtube.com/watch?v=q6tU6pos9F8&t=223s (accessed on Dec. 16, 2022).

[46] “ASTM D1876 Peel Resistance for Adhesives, T-Peel Test.” http://www.instron.com/en-us/testing-solutions/astm-standards/astm-d1876 (accessed Oct. 16, 2022).

[47] E. Burkhardt, M. Yatim, L. Hardy, and E. Palumbo, “Custom Manufacturing of Bio-Realistic Organs for a Surgical Phantom,” *Worcester Polytechnic Institute*, 2022.

Appendices

Appendix A: Client Statement Discussion Notes

This document paraphrases the discussion between the project team and the client, Dr. Cataldo, to gain insight on the project and develop an initial client statement displayed in section 3.1.

Question: What is the end goal of this year's project?

Answer: A physical product with manufactured individual organs glued together and able to be taken apart to best simulate laparoscopic abdominal surgery. Residents and robots can operate on this trainer, it should look and feel real, and cannot be cartoonishly simple.

Question: What is the main challenge of the surgery in mind that this trainer should simulate?

Answer: Going through the mesentery and fat under and around the colon. Lifting up the colon, separating it from everything else by isolating and dividing the mesentery and blood vessels from the patient.

Question: What organs are expected in this trainer from highest to lowest priority?

Answer: The colon, mesentery, retroperitoneum, small intestine, duodenum, liver, kidney, gallbladder

Question: What organs do you expect to bleed in this surgical model?

Answer: Bleeding is a lower priority, but a part of the functionality of a trainer is that surgeons should be able to make mistakes and have sensitivity. There should be the same risk strength to poke bile ducts. The liver and gall bladder should have some obstruction and resistance to motion.

Question: What physical characteristics should these organs display in terms of durability or replaceability?

Answer: The organs should have the same rip strength and poke resistance as the actual organs. Not too easy to damage, but it should be possible for residents to make mistakes operating on it. For example, an operator should be able to put a hole in the colon if they are not careful enough. The liver and kidney are landmarks and should not be damaged surgically.

Question: What are any specific desires for this year's project referring to materials and methodology?

Answer: Try to avoid silicone and start researching hydrogels like Poly-vinal Alcohol (PVA) or research materials used in Hollywood special effects. The team can conduct Instron tests to compare mechanical properties to human organs, but there is no need to get animal tissue since previous years already recorded that data. Use the STL files given to you as the previous teams have already isolated organs.

Appendix B: Pugh Analysis Matrices

Table 35. Pugh Analysis of the RUQ Operated Organs Manufacturing

Objective	**3D Printed Molds**	**Sausage Casings**	**PVC Pipes**
Anatomically Correct	+1 (3.3)	-1 (3.3)	0 (3.3)
Cost Effective	+1 (4.0)	0 (4.0)	+1 (4.0)
Highly Manufacturable	+1 (4.3)	0 (4.3)	+1 (4.3)
Reusable	+1 (2.5)	-1 (2.5)	+1 (2.5)
Total:	14.1	-5.8	10.8

Table 36. Pugh Analysis of the RUQ Non-Operated Organs Manufacturing

Objective	**3D Printed Molds**
Anatomically Correct	+1 (3.3)
Cost Effective	+1 (4.0)
Highly Manufacturable	+1 (4.3)
Reusable	+1 (2.5)
Total:	14.1

Table 37. Pugh Analysis of the Mesentery Manufacturing

Objective	**3D Printed Molds**	**Plastic Sheet with Gasket**
Cost Effective	0 (4.0)	+1 (4.0)
Highly Manufacturable	+1 (4.3)	+1 (4.3)
Reusable	+1 (2.5)	+1 (2.5)
Total:	6.8	10.8

Table 38. Pugh Analysis of the RUQ Operated Organs Materials

Objective	**PVA**	**Gelatin**	**Silicone**
Replaceable	+1	+1	0
Anatomically Correct	+1 (3.3)	0 (3.3)	-1 (3.3)
Cost Effective	+1 (4.0)	+1 (4.0)	+1 (4.0)
Highly Manufacturable	+1 (4.3)	0 (4.3)	+1 (4.3)
Total:	12.6	5	5

Table 39. Pugh Analysis of the RUQ Non-Operated Organs Materials

Objective	**PVA**	**Gelatin**	**Silicone**
Reusable	-1 (2.5)	-1 (2.5)	+1 (2.5)
Anatomically Correct	+1 (3.3)	0 (3.3)	-1 (3.3)
Cost Effective	0 (4)	+1 (4)	+1 (4)
Highly Manufacturable	+1 (4.3)	0 (4.3)	+1 (4.3)
Total:	5.1	1.5	7.5

Table 40. Pugh Analysis of the Mesentery Materials

Objective	**Rubber Cement**	**Liquid Latex**	**PVA**
Anatomically Correct	0 (3.3)	+1 (3.3)	+1 (3.3)
Replaceable	+1	+1	+1
Peelable/Separable	-1 (5)	0 (5)	+1 (5)
Cost Effective	+1 (4)	+1 (4)	+1 (4)
Highly Manufacturable	+1 (4.3)	+1 (4.3)	+1 (4.3)
Total:	4.3	12.6	17.6

Appendix C: PVA Preparation Protocol

Materials needed:

1. Poly (vinyl alcohol) M_w 146,000-186,000, 99+% hydrolyzed (Sigma-Aldrich, 9002-89-5)
2. Deionized water
3. Glass beakers
4. Electronic Scale
5. Weigh boat
6. Stir bar or impeller motor
7. Heat Plate capable of 100°C
8. Heat protective gloves
9. Proper PPE (Personal Protective Equipment)
10. Fume hood (not required)
11. Freezing area

Protocol:

1. Measure 100g of Poly (vinyl alcohol) using an electronic scale
2. Fill glass beaker with 900ml DI water

NOTE: This dilution was performed to produce a 10% PVA solution

3. Pour weighed PVA into beaker filled with water
4. Turn on hot plate and set to 100°C, let sit for 10 minutes
5. Place beaker onto hot plate, and insert stir bar into beaker while turning on the magnetic mixer
6. Let sit for 1 hour, or until solution is cloudy and all PVA is dissolved
7. Pour PVA into desired mold or plate using heat protective gloves

NOTE: If pouring into organ mold, make sure to clamp and seal molds beforehand to limit PVA leakage from mold

8. Place PVA filled mold or plate in freezer for 12 hours (-20°C)
9. Remove and thaw at room temperature for 10 hours

Appendix D: Design Material Puncture Testing Protocol

Specimen Preparation:

1. Obtain 4in x 4in x 3mm rectangular molds from previous project teams or print new molds
2. Follow Appendix C to produce PVA solution
3. Pour liquid latex or PVA into mold
    a. If testing Liquid Latex, keep filled mold in room temperature
    b. If testing PVA, place filled mold into freezer
4. Wait 24 hours, then retrieve the filled mold
    a. If testing Liquid Latex, remove specimen from mold
    b. If testing PVA, remove filled mold from freezer, let it thaw for 10 minutes, then remove specimen from mold
5. Repeat for each mold

Materials Needed:

1. 3D Prints
    a. 4in x 4in x 3mm rectangular mold
2. Design Materials
    a. Liquid Latex
    b. PVA (Contact Lisa Wall to purchase material online)
3. Cleaning Products
    a. Cleaning sprays and paper towels available in GH207
4. Other Materials
    a. Wooden box for the bottom test fixture
    b. Machined puncture Instron attachment for the top test fixture.
    c. Clamp for wooden box
5. Utilities found in GH207

Test to Perform:

ASTM D4833 Standard Test Method for Index Puncture Resistance of Geomembranes and Related Products

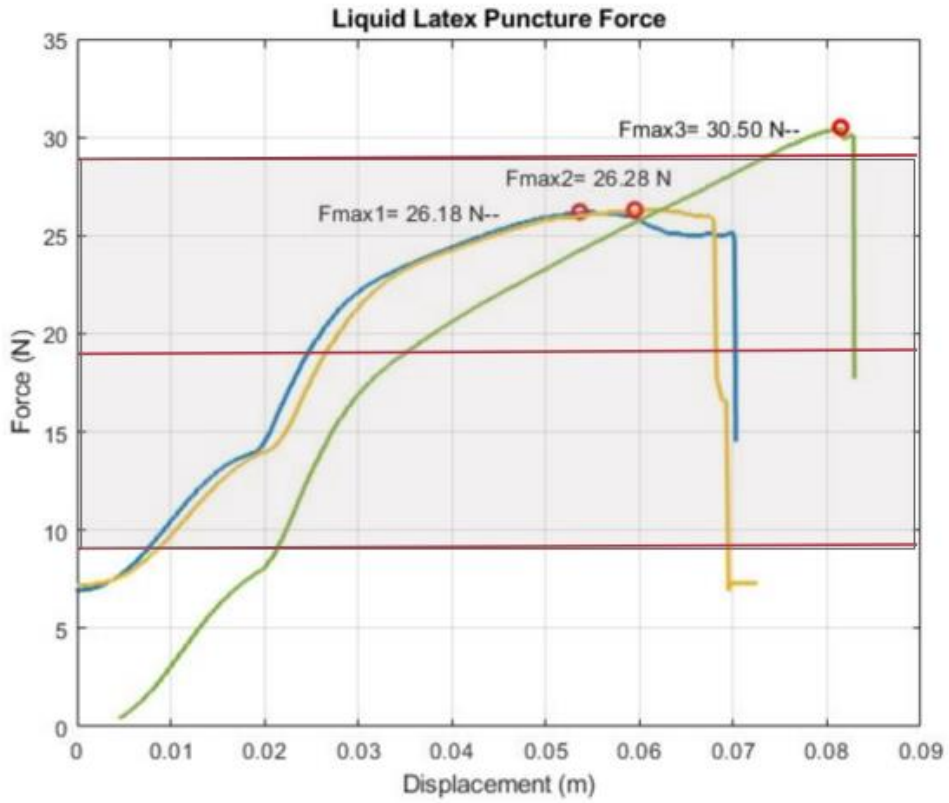
1. Summary
    a. Use the Clamp to keep the specimen in-between the top section of the wooden box.
    b. Attach the machined puncture Instron attachment to the top of the fixture
    c. Test the sample at a speed of 150 mm/min until the specimen is fully punctured
    d. Record the maximum compression force from the testing report
    e. Calculate the average and standard deviation of puncture force.
2. Bluehill Settings
    a. Select a compression test method and follow next steps OR use project team's pre-made method

b. Specimen – Geometry – Circle
c. Control – Pre-test – Add a 0.5N tear load
d. Control – Data – Set data frequency to 20 pts per second
e. Control – Strain – Displacement
f. Calculations – Set up – Drag over “Max Load, Break, Modulus Yield”
g. Results – Drag over “Maximum Comp. Force, Yield Strength, Compressive Strength”
h. Graphs – Force vs Time, Displacement vs Time, Stress vs Strain
i. Raw Data – Time, Displacement, Force, Compressive Strain, Compressive Stress
j. Reports – Save
k. Export Results - .CSV save
l. Export Raw Data - .CSV save
m. Include additional sample results – length, thickness, and width

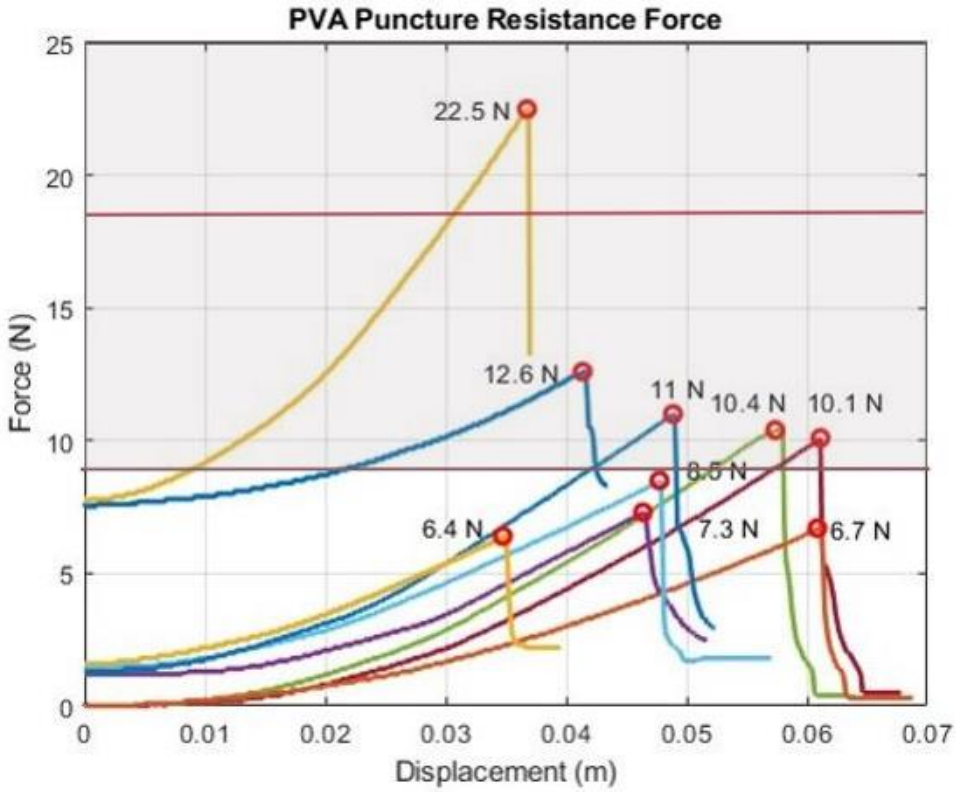
3. Running Test
    a. Calibrate the Instron 5544 force transducers
    b. Move cross head down, load sample, set mechanical stops
    c. Add 0.5N pre-load, zero the displacement
    d. Enter values for sample label, geometry, thickness, width, and length
    e. Add sample description
    f. Place safety shield in front of the Instron
    g. Run the test

Appendix E: Puncture Testing Graphs

Force-Displacement Graphs – Liquid Latex



Force-Displacement Graphs – PVA


PVA Puncture Resistance Force
Force (N)
Displacement (m)
22.5 N
12.6 N
11 N
10.4 N
10.1 N
8.5 N
6.4 N
7.3 N
6.7 N
0
5
10
15
20
25
0
0.01
0.02
0.03
0.04
0.05
0.06
0.07

Appendix F: Design Material Peel Testing Protocol

Specimen Preparation:

1. Obtain 150 x 25.2 x 1.07 mm rectangular molds from previous project teams or print new molds
2. Pour liquid latex into two molds
    a. Keep filled molds in room temperature
3. Wait 24 hours, then retrieve the filled molds
    a. Remove strips from molds
4. Apply another layer of Liquid Latex on ¾ of each strip and attach
    a. Ensuring at least a 1½ in unattached from both pieces
    b. Keep filled molds in room temperature
5. Wait 24 hours, then retrieve specimen
6. Repeat for each specimen

Materials Needed:

1. 3D Prints
    a. 150 x 25.2 x 1.07 mm rectangular mold
2. Design Materials
    a. Liquid Latex
3. Cleaning Products
    a. Cleaning sprays and paper towels available in GH207
4. Other Materials
    a. Tensile grip Instron attachment for top and bottom test fixture
5. Utilities found in GH207

Test to Perform:

ASTM D1876 Standard Test Method for Peel Resistance for Adhesives

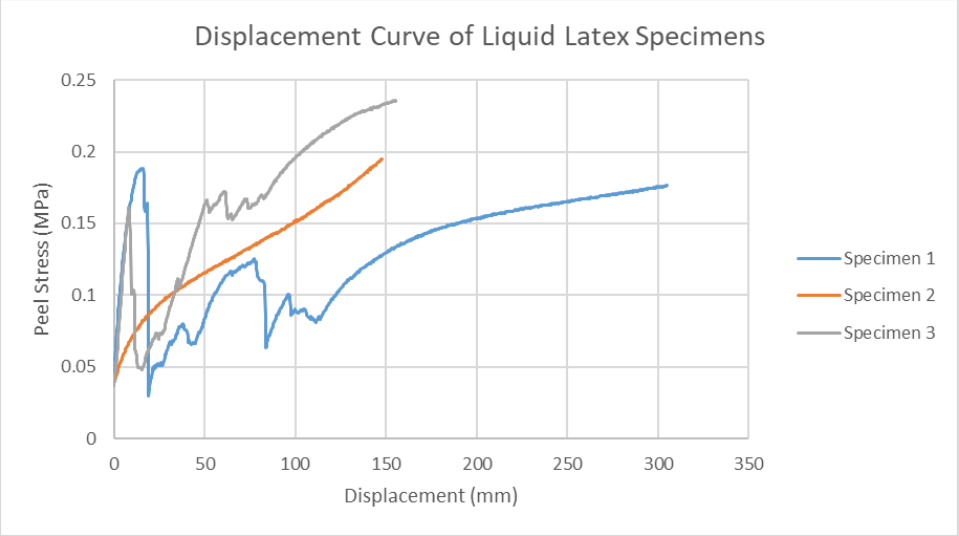
1. Summary
    a. Secure the separate strips to the top and bottom tensile grip Instron attachments
    b. Test the sample at a speed of 150 mm/min until the specimen is fully punctured
    c. Record the maximum tensile force from the testing report
    d. Calculate the average and standard deviation of tensile force.
2. Bluehill Settings
    a. Select a tensile test method and follow next steps OR use project team's pre-made method
    b. Specimen – Geometry – Rectangular
    c. Control – Pre-test – Add a 1.0N tear load
    d. Control – Data – Set data frequency to 20 pts per second
    e. Control – Strain – Displacement

f. Calculations – Set up – Drag over “Max Load, Break, Modulus Yield”
g. Results – Drag over “Tensile Stress at Maximum Force, Tensile Strain at Maximum Force, Maximum Force, Young’s Modulus, Tensile Stress at Tensile Strength, Tensile Strain at Tensile Stress”
h. Graphs – Force vs Time, Displacement vs Time, Stress vs Strain
i. Raw Data – Time, Displacement, Force, Tensile Strain, Tensile Stress
j. Reports – Save
k. Export Results - .CSV save
l. Export Raw Data - .CSV save
m. Include additional sample results – length, thickness, width, area

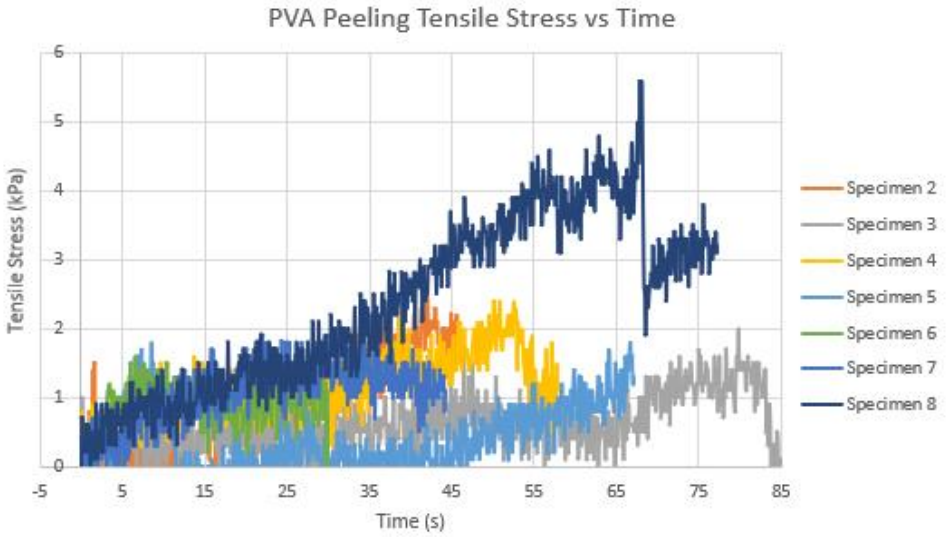
3. Running Test
    a. Calibrate the Instron 5544 force transducers
    b. Move cross head down, load sample, set mechanical stops
    c. Add 1.0N pre-load, zero the displacement
    d. Enter values for sample label, geometry, thickness, width, and length
    e. Add sample description
    f. Place safety shield in front of the Instron
    g. Run the test

Appendix G: Peeling Testing Graphs

Stress-Displacement Graphs – Liquid Latex



Stress-Time Graphs – PVA



Appendix H: Mesentery Attachment Experimentation Procedure

Specimen Preparation:

1. Follow Appendix C to produce PVA solution
2. Pour 5% PVA into a glass Pyrex container to fill until thickness reaches 5mm
3. Place container into freezer and wait 24 hours
4. Retrieve the container from the freezer and wait 15 minutes until the PVA thaws
5. Cut the sheet of PVA into 5 equal length and width strips
6. Cut each strip into 4 equal length and width rectangles

Materials Needed:

1. Container
    a. Glass Pyrex
2. Design Material
    b. PVA
    c. Liquid Latex
    d. Rubber Cement
3. Cleaning Products
    e. Cleaning sprays and paper towels available in GH207
4. Other Materials
    f. Scissors
    g. Ruler
    h. Hair Dryer
    i. Fan
5. Utilities found in GH207

Experimentation Spreadsheet:

	Square #	1	2
Method of Drying	1	Hair Dryer	Hair Dryer
Method of Glue		Rubber Cement	Liquid Latex
What it's gluing to		5%	5%
Method of Drying	2	Air Dry	Air Dry
Method of Glue		Rubber Cement	Liquid Latex
What it's gluing to		5%	5%
Method of Drying	4	control	No Drying
Method of Glue		Rubber Cement	Liquid Latex
What it's gluing to		5%	5%
Method of Glue		Rubber Cement	Liquid Latex
What it's gluing to		5%	

Following the Experimental Spreadsheet, each rectangle of 5% PVA is given a method of drying and method of glue. Depending on the methodology, the team followed procedures listed below.

Method of Drying:

1. Hair Dryer
    a. Apply a hair dryer at medium setting for 10 minutes
2. Air Dry
    a. Hang up and direct a fan at medium setting for 25 minutes
3. No Drying
    a. Do not dry the specimen, keep as control

Method of Gluing:

1. Rubber Cement
    a. Apply a layer of rubber cement to both sides of the 5% PVA after drying method
    b. Wait 10 minutes for rubber cement to dry
2. Liquid Latex
    a. Apply layer of liquid latex to both sides of the 5% PVA after drying method
    b. Wait 10 minutes for liquid latex to dry

Appendix I: Mesentery Thin Sheet Experimentation Procedure

Specimen Preparation:

1. Follow Appendix C to produce PVA solution

Materials Needed:

1. Container
    a. Glass Pyrex
    b. Two Plastic Sheets
    c. PDMS
2. Design Material
    d. PVA
3. Cleaning Products
    e. Cleaning sprays and paper towels available in GH207
4. Other Materials
    f. Scissors
    g. Popsicle sticks
    h. Blue food coloring
    i. Rubber Cement
    j. Laparoscopic equipment
    k. Polyfill
5. Utilities found in GH207

Single Freeze Protocol:

1. Cut plastic sheet edges so it can fit in freezer
2. Pour 10% PVA into plastic sheet, over it with another plastic sheet, place in freezer
3. Wait 24 hours, retrieve sheet from freezer
4. Wait 10 minutes until thawed
5. Remove PVA from sheet
6. Cover organ with PVA sheet, manipulate with laparoscopic equipment

Double Freeze Protocol:

Repeat “Single Freeze Protocol” steps 2-4

1. Reuse plastic sheet
2. Pour 10% PVA into plastic sheet, over it with another plastic sheet, place in freezer
3. Wait 24 hours, retrieve sheet from freezer
4. Wait 10 minutes until thawed, place back in freezer
5. Wait 24 hours, retrieve sheet from freezer
6. Wait 10 minutes until thawed, remove PVA from sheet
7. Cover organ with PVA sheet, manipulate with laparoscopic equipment

Polyfill and Coloring Protocol:

1. Pour 10% PVA into Glass Pyrex container until the bottom of the glass is completely covered
2. Add 2-3 drops of blue food coloring to PVA
3. Disassemble Polyfill and spread it into one side of the PVA
4. Place container into freezer and wait 24 hours
5. Retrieve the container from the freezer and wait 15 minutes until the PVA thaws
6. Manipulate with laparoscopic equipment

Gasket Protocol:

1. Plastic Sheet
    a. Reuse plastic sheet
    b. Place popsicle sticks with a known thickness in a plastic sheet to create a rectangle.
    c. Pour 10% PVA into plastic sheet until the rectangle is full, cover it with another plastic sheet, spread out PVA as necessary with a ruler
    d. Place in freezer, wait 24 hours, retrieve sheet from freezer
    e. Wait 10 minutes until thawed
    f. Observe ease to remove PVA from sheet
2. Glass
    a. Place popsicle sticks with a known thickness in the glass Pyrex container to create a rectangle
    b. Pour 10% PVA into Glass Pyrex container until the rectangle is full
    c. Place in freezer, wait 24 hours, retrieve sheet from freezer
    d. Wait 10 minutes until thawed
    e. Observe ease to remove PVA from glass
3. PDMS
    a. Place PDMS gasket in the glass Pyrex container
    b. Pour 10% PVA into Glass Pyrex container until the circle is full
    c. Place in freezer, wait 24 hours, retrieve sheet from freezer
    d. Wait 10 minutes until thawed
    e. Observe ease to remove PVA from PDMS

Appendix J: Institutional Review Board (IRB) Protocol

In order to conduct the surgeon feedback survey, the team followed protocols necessary to receive approval from the WPI Institutional Review Board (IRB). The protocol includes filing an application, describing research methods, listing survey questions, and providing an Informed Consent Form. The research methods, consent form, and approval letter can be found below:

Research Methods:

"To determine the success of the artificial abdomen trainer, the team plans to conduct an activity and survey with medical residents and surgeons at Beth Israel Deaconess Medical Center in Boston, MA. The activity consists of placing the prototype inside of a commercial laparoscopic box trainer and allowing the participants to manipulate the artificial abdomen. The commercial laparoscopic box trainer does not consist of any dangerous instruments and the participants would not come in contact with the artificial abdomen as they would be using tools that extend into the trainer. After using the surgical trainer on the team's prototype for 5-10 minutes, the participant can fill out a survey. The survey gains anonymous information regarding the year of residency, then information via a Likert scale on statements about the performance of the prototype. With this scale, the residents can choose a response from seven options agreeing or disagreeing with the statements. Lastly, the survey allows the participants to add any additional comments. If for any reason the additional comments add unnecessary information, like personal information, then that information will be omitted from research and publication. Otherwise, the additional comments may be anonymously quoted with publication and consent of the participant."

Informed Consent Form:

Informed Consent Agreement for Participation in a Research Study

Investigators: Caitlin Bonavita, Binh Diec, Alex Hill, Andrew Sifferlen

Contact Information: cebonavita@wpi.edu, bdiec@wpi.edu, achill@wpi.edu, ajsifferlen@wpi.edu

Title of Research Study: Validating and Manufacturing a Bio-realistic Surgical Phantom for Laparoscopic and Robotic Surgical Training

Sponsor: Beth Israel Deaconess Medical Center and Worcester Polytechnic Institute

Introduction
You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study:
Our project is to produce a benchtop surgical trainer consisting of a physical prototype of a phantom human abdomen. This phantom abdomen should include individual organs held together by a mesentery which resident surgeons can take apart to best simulate the feeling of surgery. To simulate the feeling of abdominal surgery we created a benchtop model of the human abdomen using off the shelf synthetic polymers (see photo attached). The purpose of this study is for the surgical residents to assess the level of satisfaction of this surgical training tool.

Procedures to be followed:
The subject will be asked to practice abdominal surgery with the benchtop surgical trainer using endoscopic surgical tools to assess the abilities and similarities to real abdominal tissues and organs. Figure 1 consists of a conceptual drawing of the prototype.

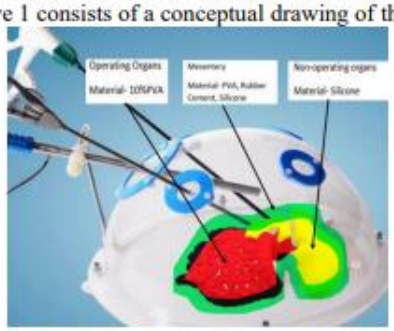


Figure 1: Conceptual Drawing of Benchtop Surgical Trainer

APPROVED BY
WPI IRB-1
3/15/2023

The subject will participate in this activity for roughly 10 minutes similar to what is depicted in Figure 2. The residents will have the ability to use laparoscopic equipment to manipulate the benchtop trainer. After the practice is completed, they will then be asked to fill out a survey that evaluates their experience with the trainer.

Figure 2: Malawi residents using surgical trainer

Risks to study participants:
There are no foreseeable physical risks associated with the study. The prototype is meant to simulate the abdomen of a human being including right upper quadrant organs and mesentery. For this procedure the surgical residents will be poking at silicone organ prototypes with their surgical tools restrained inside the training device.

Benefits to research participants and others:
The subject participating in the study may benefit from practicing surgical skills depending on how successful the prototype is. The immediate goal is to assess the strengths and weaknesses of the surgical model. The subject may benefit from knowing their participation helped the team refine and validate the surgical trainer. This may spiral into a far greater impact after the study. The goal of this project is to create a benchtop model to mimic the right upper quadrant of the abdomen so that colorectal surgical residents can learn to perform surgical noninvasive surgical procedures without harming animals or humans. The purpose of this study is to assess how well this tool performs and meets the needs of the surgical residents.

Alternative procedures or treatments available to potential research participants:
There are no alternative procedures available to potential research participants.

Record keeping and confidentiality:
Records of your participation in this study will be held confidential so far as permitted by law. However, the study investigators, the sponsor or it's designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name.

Any publication or presentation of the data will not identify you. Confidentiality will be maintained by not recording any personal information within the study. Within the survey, participants may include additional comments, but any personal information will be removed from the records.

Compensation or treatment in the event of injury: You do not give up any of your legal rights by signing this statement. There is no risk of harm from this study; therefore, there is no compensation.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact: The contact information of the Worcester Polytechnic Institute student investigators are found at the top of the document. The WPI faculty advisor of the project team, Professor George Pins, can be contacted via email at gpins@wpi.edu. The BIDMC faculty supervisor, Doctor Thomas Cataldo, can be contacted via email at tcatald1@bidmc.harvard.edu. In addition, the contact information for the IRB Manager, Ruth McKeogh, is 508-831-6699 via telephone and irb@wpi.edu via email. The Human Protection Administrator, Gabriel Johnson, can be contacted via telephone at 508-831-4989 and via email at gjohnson@wpi.edu. This section is required.)

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____ Date: _____

Study Participant Signature

_____

Study Participant Name (Please print)

APPROVED BY
WPI IRB-1
3/15/2023

_____ Date: _____

Signature of Person who explained this study

Additional clauses to add to Consent Agreements, as appropriate:

The treatment or procedures used in this research may involve risks to the subject (or to an embryo or fetus, if the subject is or may become pregnant), which are currently unknown or unforeseeable.

There are no additional costs to the subject that may result from participation in this research.

Significant new findings or information, developed during the course of the research, may alter the subject's willingness to participate in the study. Any such findings will be promptly communicated to all research participants.

Should a participant wish to withdraw from the study after it has begun, the following procedures should be followed: Inform the WPI student investigators, WPI faculty advisor, or BIDMC supervisor via the contact information found in the document. There are no consequences for early withdrawal for the subject and the research. If a subject would like, any information collected during their participation can and will be omitted from the study.

Special Exceptions: Under certain circumstances, an IRB may approve a consent procedure which differs from some of the elements of informed consent set forth above. Before doing so, however, the IRB must make findings regarding the research justification for different procedures (i.e. a waiver of some of the informed consent requirements must be necessary for the research is to be "practicably carried out.") The IRB must also find that the research involves "no more than minimal risk to the subjects." Other requirements are found at 45 C.F.R. §46.116.

WPI IRB Approval letter:

WORCESTER POLYTECHNIC INSTITUTE

100 INSTITUTE ROAD, WORCESTER MA 01609 USA

Institutional Review Board

FWA #00030698 - HHS #00007374

Notification of IRB Approval

Date:	14-Mar-2023
PI:	George D Pins
Protocol Number:	IRB-23-0397
Protocol Title:	Survey of Residents at Beth Isreal Deaconess Medical Center
Approved Study Personnel:	Pins, George D~Sifferlen, Andrew J~Bonavita, Caitlin~Hill, Alex C~Diec, Binh~
Effective Date:	14-Mar-2023
Exemption Category:	3
Sponsor*:	

The WPI Institutional Review Board (IRB) has reviewed the materials submitted with regard to the above-mentioned protocol.We have determined that this research is exempt from further IRB review under 45 CFR § 46.104 (d). For a detailed description of the categories of exempt research, please refer to the IRB website.

The study is approved indefinitely unless terminated sooner (in writing) by yourself or the WPI IRB. Amendments or changes to the research that might alter this specific approval must be submitted to the WPI IRB for review and may require a full IRB application in order for the research to continue. You are also required to report any adverse events with regard to your study subjects or their data.

Changes to the research which might affect its exempt status must be submitted to the WPI IRB for review and approval before such changes are put into practice. A full IRB application may be required in order for the research to continue.

Please contact the IRB at irb@wpi.edu if you have any questions.

Appendix K: Surgeon Feedback Survey Questions

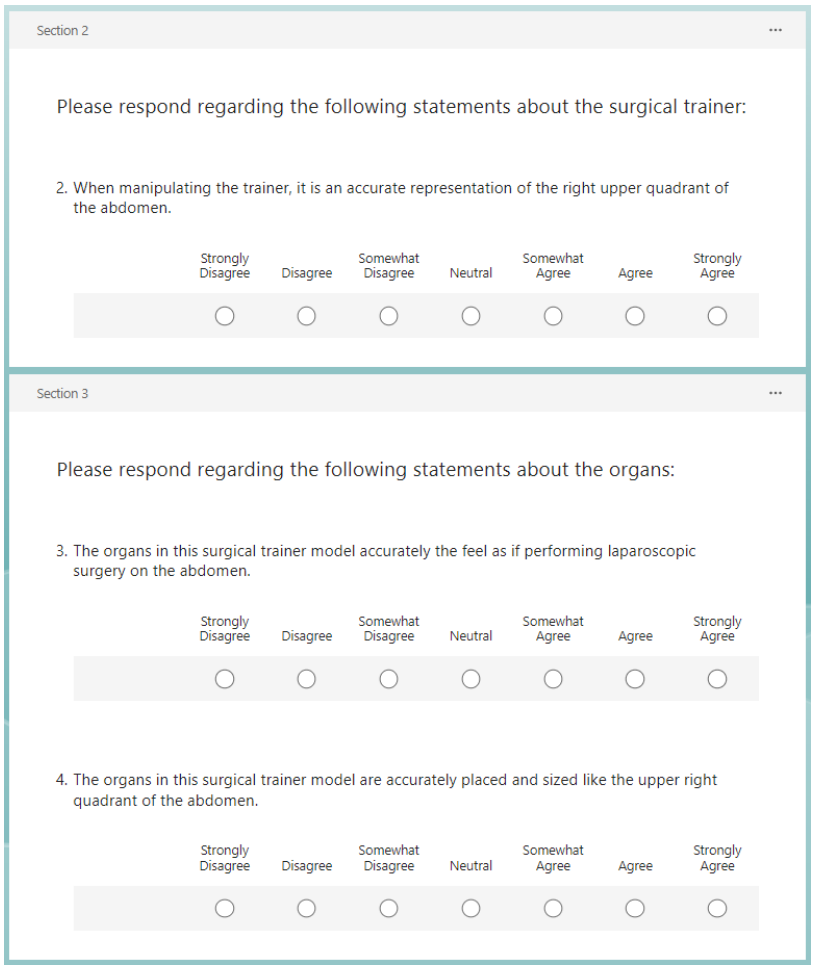
Validating a Bio-Realistic Surgical Phantom for Laporoscopic and Robotic Surgical Training

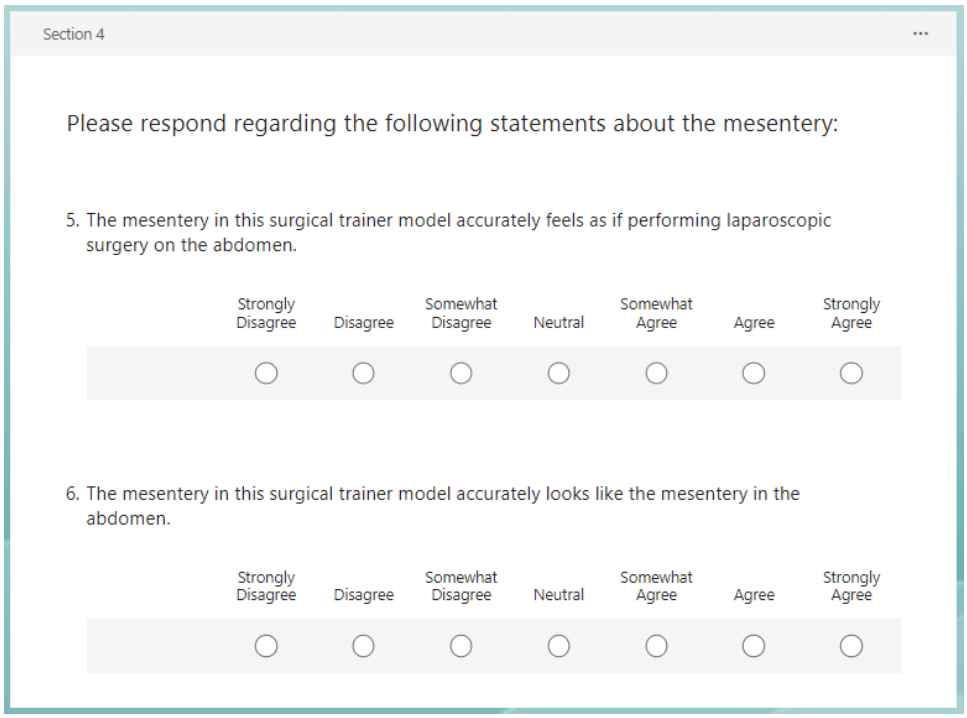
We are a group of university students from Worcester Polytechnic Institute (WPI), an engineering college in Worcester, Massachusetts, with a focus on project-based learning. We are currently completing a project for our fourth year in university under Professor George Pins, our advisor. Our project is to produce a physical prototype of a phantom abdomen. This abdomen should include individual organs held together by a mesentery which resident surgeons can take apart to best simulate the feeling of surgery. The goal of this study is to assess the level of satisfaction of the surgical training we are creating. We would like to inform you that this activity and survey are voluntary, and you may withdrawal at any time. The activity consists of using a laparoscopic box trainer to manipulate the phantom abdomen. The survey does not include any personal information and you do not have to answer any questions you do not feel comfortable with answering. The results from this survey will remain anonymous and with the consent of the participant, will be published along with the research. If you wish to proceed, please spend some time with the box trainer and then complete this survey, which will take less than five minutes.

Section 1 ...

1. I am a:

- ○ Student
- ○ PGY-1
- ○ PGY-2
- ○ PGY-3
- ○ PGY-4
- ○ PGY-5 (Chief)
- ○ PGY-6 (Fellow)
- ○ Attending


Section 2
Please respond regarding the following statements about the surgical trainer:
2. When manipulating the trainer, it is an accurate representation of the right upper quadrant of the abdomen.
Strongly Disagree
Disagree
Somewhat Disagree
Neutral
Somewhat Agree
Agree
Strongly Agree
Section 3
Please respond regarding the following statements about the organs:
3. The organs in this surgical trainer model accurately the feel as if performing laparoscopic surgery on the abdomen.
Strongly Disagree
Disagree
Somewhat Disagree
Neutral
Somewhat Agree
Agree
Strongly Agree
4. The organs in this surgical trainer model are accurately placed and sized like the upper right quadrant of the abdomen.
Strongly Disagree
Disagree
Somewhat Disagree
Neutral
Somewhat Agree
Agree
Strongly Agree


Section 4
Please respond regarding the following statements about the mesentery:
5. The mesentery in this surgical trainer model accurately feels as if performing laparoscopic surgery on the abdomen.
Strongly Disagree
Disagree
Somewhat Disagree
Neutral
Somewhat Agree
Agree
Strongly Agree
6. The mesentery in this surgical trainer model accurately looks like the mesentery in the abdomen.
Strongly Disagree
Disagree
Somewhat Disagree
Neutral
Somewhat Agree
Agree
Strongly Agree

Section 5

Please respond regarding the following statements about the overall surgical trainer:

7. I believe that I was gaining valuable technical surgical experience while manipulating this trainer.

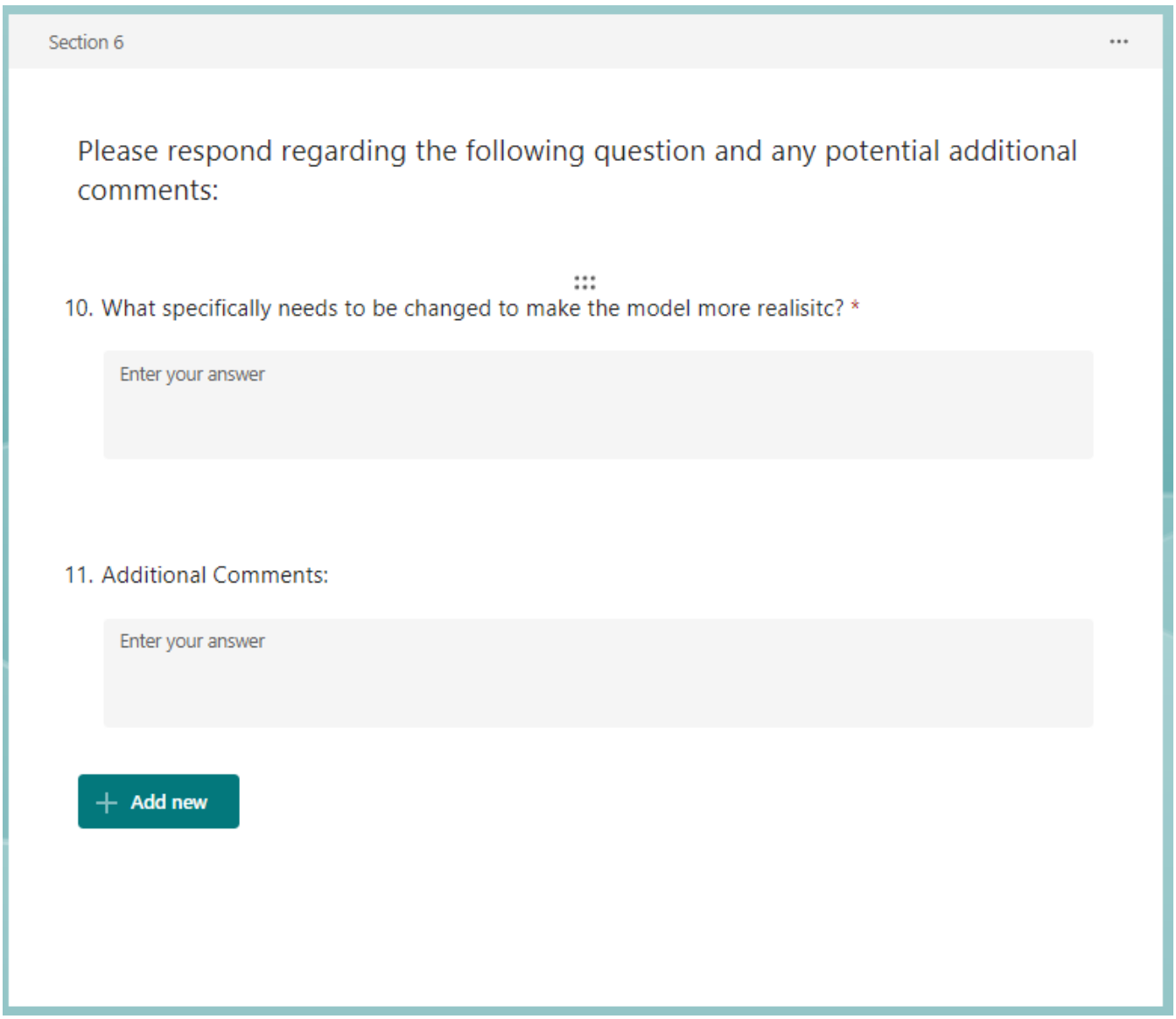
	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	○	○	○	○	○	○	○

8. This surgical trainer is a beneficial way to practice developmental skills for laparoscopic surgery.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	○	○	○	○	○	○	○

9. I would use this surigcal trainer again or reccomend it to another student/surgeon.

	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
	○	○	○	○	○	○	○

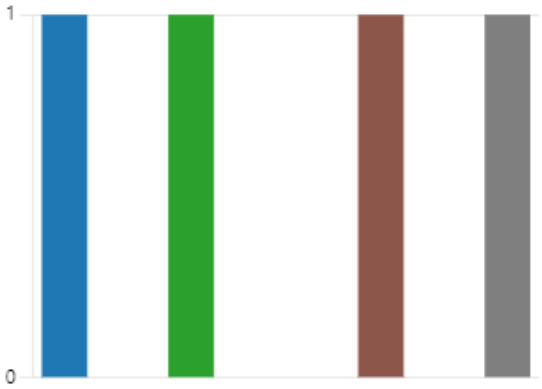

Section 6
Please respond regarding the following question and any potential additional comments:
10. What specifically needs to be changed to make the model more realisitc? *
Enter your answer
11. Additional Comments:
Enter your answer
Add new

Appendix L: Surgeon Feedback Survey Results

1. I am a:

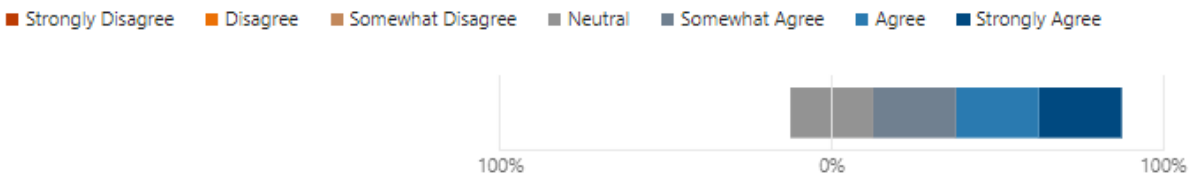
More Details

Student	1
PGY-1	0
PGY-2	1
PGY-3	0
PGY-4	0
PGY-5 (Chief)	1
PGY-6 (Fellow)	0
Attending	1



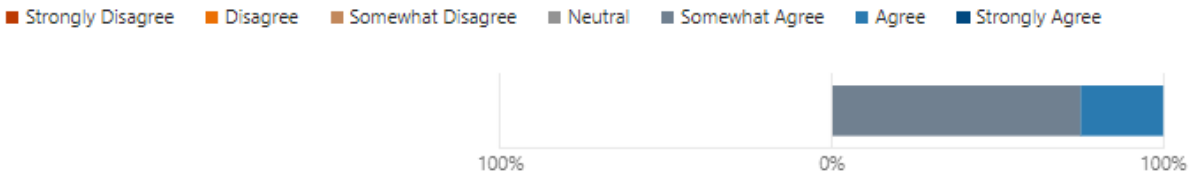
2. When manipulating the trainer, it is an accurate representation of the right upper quadrant of the abdomen.

More Details



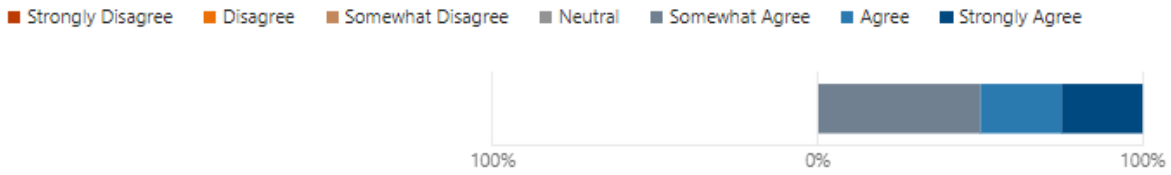
3. The organs in this surgical trainer model accurately the feel as if performing laparoscopic surgery on the abdomen.

More Details



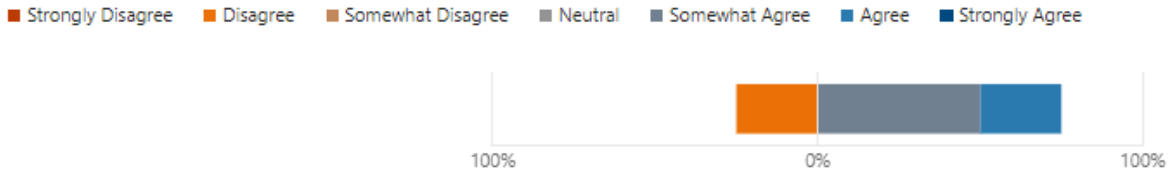
4. The organs in this surgical trainer model are accurately placed and sized like the upper right quadrant of the abdomen.

More Details



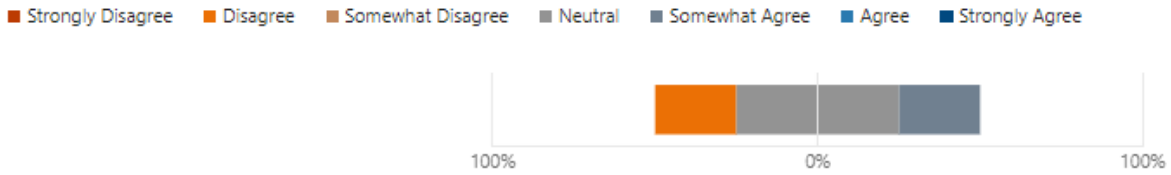
5. The mesentery in this surgical trainer model accurately feels as if performing laparoscopic surgery on the abdomen.

More Details



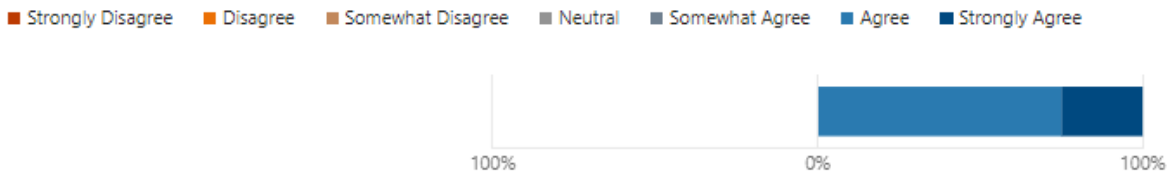
6. The mesentery in this surgical trainer model accurately looks like the mesentery in the abdomen.

More Details



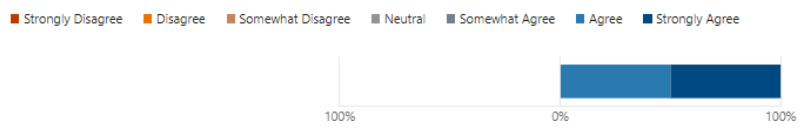
7. I believe that I was gaining valuable technical surgical experience while manipulating this trainer.

More Details



8. This surgical trainer is a beneficial way to practice developmental skills for laparoscopic surgery.

More Details



9. I would use this surigcal trainer again or reccomend it to another student/surgeon.

More Details

10. What specifically needs to be changed to make the model more realisitc?

More Details

4
Responses

Latest Responses

"Improve the mesentery and glue the parts together. Needs a retroperitoneu..."

"All the beeps and people talking to you, like the real OR"

"Colon is too rigid, needs to be hollow and have better grip."

11. Additional Comments:

More Details

1
Responses

Latest Responses

"Very well done!"

10. What specifically needs to be changed to make the model more realisitc?

4 Responses

ID ↑	Name	Responses
1	anonymous	Mesenteric is gelatinous and does not tear as tissue does. Portions of mesentery open to air, inaccurate picture. Model easily movable, does not stay together as well
2	anonymous	Colon is too rigid, needs to be hollow and have better grip.
3	anonymous	All the beeps and people talking to you, like the real OR
4	anonymous	Improve the mesentery and glue the parts together. Needs a retroperitoneum.

Appendix M: Bill of Materials in Final Design

Cost analysis	Ammount	Price $
PVA - Colon	x1	43.2
PVA- Small Intestine	x1	25.2
PVA - Mesentery Sheet	x2	2.54
PVA - Fat Sheet	x3	12.7
Silicone - Gallbladder	x1	3.12
Silicone - Liver	x1	39
Silicone - Kidney	x1	11.7
Super Glue Adhesive	x1	6.49
Total Price (Just Materials)		143.95$