Custom Manufacturing of Bio-Realistic Organs for a Surgical Phantom

A Major Qualifying Project
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Abstract

The demand for surgical procedures and limited supply of physiologically relevant models have identified a need to create bio-realistic trainers for surgical residents. This project focused on developing a model of the right upper abdominal quadrant, for a laparoscopic right colectomy. Organs were isolated from a 3D abdominal rendering using Computed Tomography scans. Molds were developed in Blender and 3D printed in Polylactic Acid. Finally, they were injection molded with silicone elastomers, selected from mechanical testing on porcine abdominal tissues and various synthetic materials. This standardized manufacturing process allowed for the creation of full bio-realistic organs and can be used to bring a device to production and improve surgical residency training around the world.

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Chapter 1: Introduction

There is currently a high demand in the United States for inpatient surgical procedures and due to resident work hour restrictions, it has been difficult for surgical residents to gain experience in order to perform these procedures [1]. The number of cases covered by residents decreased from 85% to 60%, resulting in less experience in the operating room [2]. This was exacerbated by the COVID-19 pandemic during 2020 with a decrease in procedures and therefore a decrease in resident experience. The number of procedures residents took part in decreased by 33.5% in March 2020 to June 2020 compared to the same time period in both 2018 and 2019. Many elective surgeries including colorectal surgeries were either postponed or canceled to clear space for COVID-19 specific operations or in some cases the operating rooms were used as space for critical care patients [3]. In addition to this increase in surgeries that will need to be completed in the coming years due to these postponements, there is also a lack in the ability for residents to observe surgeons perform these operations. Although the pandemic has amplified this problem for a need for surgical procedures, there was already a need for an increase in surgeons and surgical resident training.

To become a surgeon, one must earn a bachelor's degree, attend medical school, complete 3-7 years in a residency program in their desired specialty and earn their board specifications to receive a state license. During their residency, residents are expected to work closely with an experienced doctor to observe and gain experience in their desired speciality. Traditionally they would follow a “see one, do one, teach one” approach where the resident would observe a surgery, perform the surgery, and then teach another resident how to perform the surgery. This approach not only risked patient safety, but it was not the most effective way to gain experience as more comprehensive models of teaching are required. It is shown that surgeons who practice more procedures, including ones done through residential training, have better success rates and are more likely to be chosen to perform a procedure. The more realistic the training is, the better prepared a surgeon is for a patient procedure, reducing the risk of patient safety.

To decrease the risk to patient safety and increase training for surgical residents, newer methods have been implemented into their training. Simulation-based training has become widely used, allowing surgical residents to practice basic skills in surgical skills laboratories rather than on a patient. Simulation, unlike traditional practice on patients, allows for mistakes to be made without the consequences of harm to an individual. It also allows for residents to practice non-surgical skills such as communication, crisis resource management, and practicing for an emergency setting in a non-emergency state [4]. There are many different types of simulation training, all with their own advantages and disadvantages. However, there is a need for a training model that realistically mimics the anatomy and behaviors of the human body.

The aim of this project was to design a surgical trainer that is bio realistic, cost effective, easily manufactured, easy to assemble, reusable, and provides translatable skills to be used by residents specializing in right colectomy surgeries. The model should mimic the anatomy and physiology of the right upper quadrant of the abdomen, have comparable mechanical and material properties to best simulate a patient procedure, and mimic human tissue interactions. It should also be lightweight, reusable, cost effective, and easily manufactured so that it can be easily produced and used in several hospitals and countries.

To achieve this aim, we went through the engineering design process to determine stakeholders, objectives, functions, and design alternatives. We determined the needs of the client as well as the surgical trainer while keeping the timeline and constraints of the project in mind. By analyzing different design alternatives and comparing them to each other, one design was chosen in which further mechanical testing was done. For the trainer to be bio realistic, we conducted testing on porcine tissue and compared the values to that of the synthetic materials. Mechanical testing was performed using an Instron 5544 to determine the mechanical properties of the final materials chosen to be used for casting.

Through our design process, we found that a standard manufacturing process was needed to ensure the organs are dimensionally accurate and mechanically bio realistic. With this biorealism in mind, the translatable skills are greater, as the synthetic organs mimic those found in the operating room. This process also allows for personalized healthcare, as custom organs can be made from an individual's CT scans and placed into a box trainer for training. A box trainer allows a trainee to practice their surgical skills through interactions between a physical model and actual surgical instruments. It allows the trainee to feel the true forces of manipulation and is an affordable option to practice outside of the operating room. We began with organ isolation using Vesalius 3D, a software application for high quality 3D visualization of anatomical structures from CT scans. This was followed by mold development in Blender, a 3D computer graphics software, 3D printing, material selection through mechanical testing, and organ casting. Through tensile and puncture tests based on ASTM standards, the elastic modulus and puncture resistance force of the stomach, colon, small intestine, and mesentery were collected and compared to that of two silicone elastomers to be used for casting. Molds were created for the colon, small intestine, liver, gallbladder, and right kidney. Our team cast a liver, kidney, and gallbladder, and isolated an entire colon from one individual.

These phantom organs have the potential to offer detailed training in laparoscopic surgical techniques without any risk to patient safety. Ultimately, this low-cost trainer will be composed of multiple bio-realistically accurate abdominal organs, teaching surgical residents the anatomy of the upper right abdominal quadrant and allowing them to practice their skills. This device should be implemented in the training module for new residents as it augments their learning by allowing them to make mistakes they can learn from in a simulated environment. The measured mechanical properties of the porcine tissue suggest that EcoFlex 00-10 and 00-30 were acceptable choices for synthetic organs. Based on the overlap of ranges for puncture resistance and elastic modulus, both EcoFlex 00-10 and 00-30 can be used for the colon, small intestine, and mesentery. The stomach's mechanical properties were not similar enough to these materials and will require further research.

Our recommendations for future iterations of the surgical trainer include: using our porcine mechanical data to identify additional materials to cast organs from, creating surrounding fats that encase the organs, using the standardized manufacturing techniques we developed using the Vesalius 3D software to model an entire abdomen that bleeds and provides direct feedback, and performing qualitative tests with surgeons by allowing them to use the completed trainer to provide feedback regarding the current model and iterate accordingly. The continued development of this device will improve training programs and patient outcomes.

This project is supported by Worcester Polytechnic Institute (WPI) and sponsored by Beth Israel Deaconess Medical Center (BIDMC). Research was done in close collaboration with Dr. Thomas Cataldo, an Assistant Professor of Surgery at Harvard Medical School, Professor George Pins of the Biomedical Engineering Department, and Professor John Sullivan of the Mechanical Engineering Department. The following sections discuss the need for surgical trainers, objectives the surgical trainer must fulfill, the project strategy, the design process , and the approach taken to complete the phantom.

Chapter 2: Literature Review

The following section is an overview of background information necessary for the understanding and completion of this project. Topics to be discussed include the anatomy of the organs and surrounding fats and tissues present in the right upper quadrant of the abdominal cavity, the right colectomy surgery, the need for surgical trainers, existing models, previous project research, clinical needs, and engineering needs.

2.1: Anatomy

The study of anatomy is imperative for both the surgeons performing medical practices, but also for the engineers trying to emulate the material and mechanical properties of the organs and recreate their structures. The scope of this project is focused on upper right colectomy, which occurs in the right upper abdominal quadrant (RUQ). The RUQ includes the stomach, small intestine/duodenum, transverse colon, liver, gallbladder, right kidney, mesentery, peritoneum, and adipose tissues. These functions, dimensions, and images of their structures will be discussed in Sections 2.1.1-2.1.8 below.

2.1.1 Stomach:

As one of the primary organs in the digestive system, the stomach is located right after the end of the esophagus and prior to the duodenum. Its main functions are to store food, aid in the digestive process, kill bacteria that may have entered the system, and push food into the small intestine [5]. In an experiment that used an Instron 1221 tensiometer, the stomach had an axial maximum stress of 0.7 MPa, and a destructive strain of 190%. For transversal specimens, the stomach had a maximum stress of 0.5 MPa, and the same destructive strain [6].

2.1.2 Duodenum and Small Intestine:

The duodenum makes up approximately the first 10 inches of the small intestine. It is in charge of absorbing carbohydrates, amino acids, lipids, calcium, and iron from the broken down food. The small intestine is located between the pyloric sphincter of the stomach and the large intestine's ileocecal valve opening. After food is initially broken down in the stomach, it is transferred to the small intestine where it is further broken down and the nutrients from the food are absorbed [5]. The maximum stress the small intestine can withhold is 0.9 MPa with a destructive strain of 140% [6].

2.1.3 Transverse colon:

The transverse colon is the largest section of the large intestine ranging from the ascending colon until the descending colon [7] and its function is to assist in digestion [5]. An experiment from the University of Edinburgh studied the mechanical properties of the ascending, transverse, descending, and sigmoid colon. From this experiment, the transverse colon had a burst strength of 1223 ± 701 g, a tensile strength of 98 ± 57 g/mm^2 and an elongation of 221 ± 187 % [8].

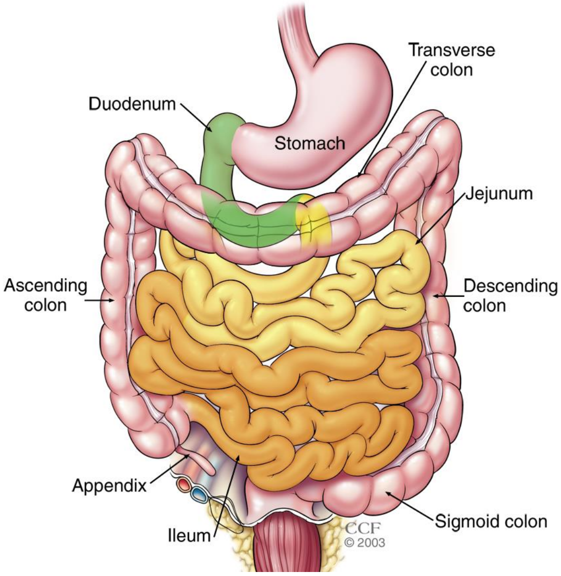

Figure 1. Diagram of the stomach, duodenum, small intestine, and colon [10].

2.1.4 Liver:

Located right below the diaphragm, the liver is the largest internal organ in the body. It serves many purposes including the production and secretion of bile, detoxification of the blood, conversion of glucose to glycogen fat, and secretion of glucose into the blood. The liver also produces albumin, plasma transport proteins, and other clotting factors [5]. In a study with 20 human cadavers, the liver was put under tensile and compressive loading. The results were that the liver had an elastic modulus of 12.16 ± 1.20 kPa under axial loading and 7.17 ± 0.85 transversal loading. For compressive loading, the elastic modulus in the axial direction was 196.54 ± 13.15 kPa and 112.41 ± 8.98 in the transverse direction [11].

2.1.5 Gallbladder:

Attached to the inferior surface of the liver, the gallbladder's main function is to both store and concentrate bile that has been drained by the liver for future dispersal [5]. A study was conducted to determine the mechanical properties of the human gallbladder under axial and transversal tensile loadings. The study tested the gallbladder at a strain rate of 5 mm/min and found that axial elastic modulus was 641.20 ± 28.12 kPa]. The transverse elastic modulus was 255.00 ± 24.55 kPa. The maximum under axial loadings was 1240.00 ± 99.94 and 348.00 ± 66.75 kPa under transverse loading [12].

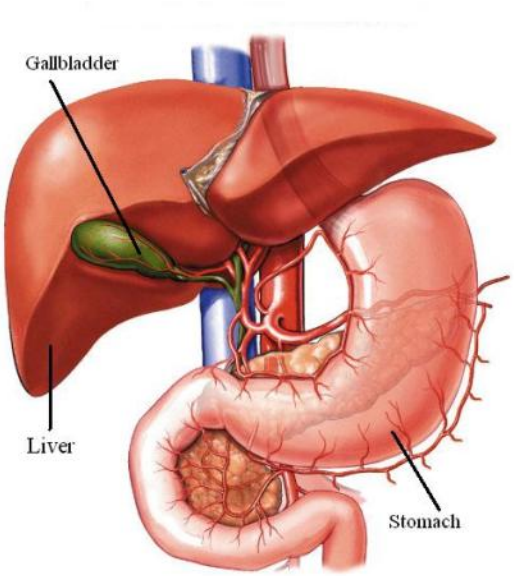

Figure 2. Diagram of the stomach, liver, and gallbladder [13].

2.1.6 Right kidney:

The right kidney is located below both the diaphragm and the liver, and to the right of the vertebral column. The kidney’s main function is to create urine in order to regulate the plasma and interstitial fluid environments in the body [5]. From an experiment that collected the mechanical properties of the kidneys from 20 male cadavers, the axial elastic modulus and failure stress and the transversal elastic modulus and failure stress were measured. The experiment found that human kidneys have an axial elastic modulus and failure stress of 180.32

± 11.11 kPa and 24.46 ± 3.14 kPa kPa and a transversal elastic modulus and failure stress of 95.64 ± 9.39 kPa and 31.00 ± 5.06 kPa [14].

2.1.7 Mesentery and Peritoneum:

The mesentery is an organ connected to the intestines ensuring that they remain suspended and do not drop to the pelvis [15]. The peritoneum is a cavity in which almost all of the abdominal organs are contained. The walls of the peritoneum are semi-permeable and allow for diffusion of water and other solutes both in and out of the cavity [16]. The mechanical properties of these organs are not well defined in literature and will require further testing to obtain mechanical data from.

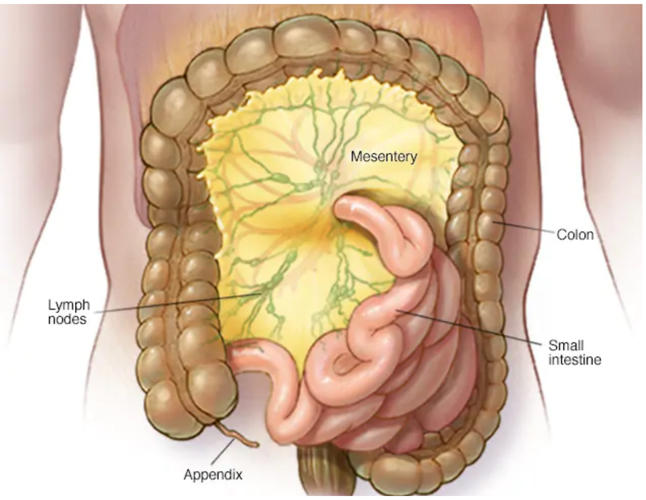

Figure 3. Diagram showing the location of the mesentery [17].

2.1.8 Adipose Tissues:

Fat, or adipose tissue, is loose connective tissue composed of adipocytes, cells that store fat. Originally, fat was thought of as a cushion and insulation to muscle and bones, but is now being highlighted for its role in energy storage [18]. The different types of fat include white, brown, and beige fat that can all be stored as either essential, subcutaneous, or visceral fat (Figure 4. & 5.). White adipose tissue is made of large white cells that provides extra energy storage. Brown adipose tissue is highly vascularized and is a light pink color. Brown fat burns fatty acids that keep us warm. Beige fat functions similarly to both white and brown adipose tissue, but is more known for burning fat and is a relatively new area of study [19].

All fat is biologically active; it secretes various hormones and other molecules that affect surrounding tissues. Essential fat is crucial to the health of the body. It can be found in the brain, bone marrow, nerves, and organ membranes. Essential fat regulates fertility, temperature regulation, and absorption of nutrients. Subcutaneous fat is the fat that lies in a layer just underneath the skin; fat here accounts for 90% of body fat in most people. The remaining 10% of body fat is located beneath the abdominal wall. It is known as visceral or intra-abdominal fat and is found around the liver, intestines, and other abdominal organs. Visceral fat is known to cause many health related issues because they produce cytokines which trigger inflammation. Subcutaneous fat produces a larger proportion of beneficial molecules [20].

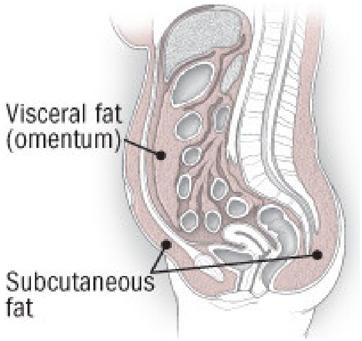

Figure 4. Visceral vs subcutaneous fat [20].

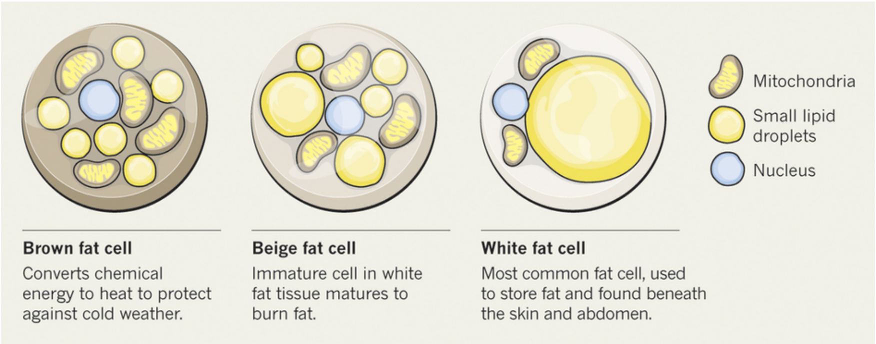

Figure 5. Types of fat cells [21].

2.2: Right Colectomy Surgery

With more than 600,000 colorectal surgeries performed each year, it is important that surgeons have experience performing the operation [22]. A colectomy is a surgical procedure that removes either part, or the entirety of the large intestine. Partial removal of the colon refers to a partial colectomy whereas the removal of the entire colon is a total colectomy [23]. A hemicolectomy is when part of the large intestine, specifically the colon, is removed due to a condition or if it has become cancerous. In a right hemicolectomy, the ascending colon, which connects the small intestine to the large intestine, is removed. Without the ascending colon, the small intestine gets surgically attached to the next area of the large intestine; the transverse colon, as seen in Figure 6. Removal of this organ can be done through laparoscopic or open surgery.

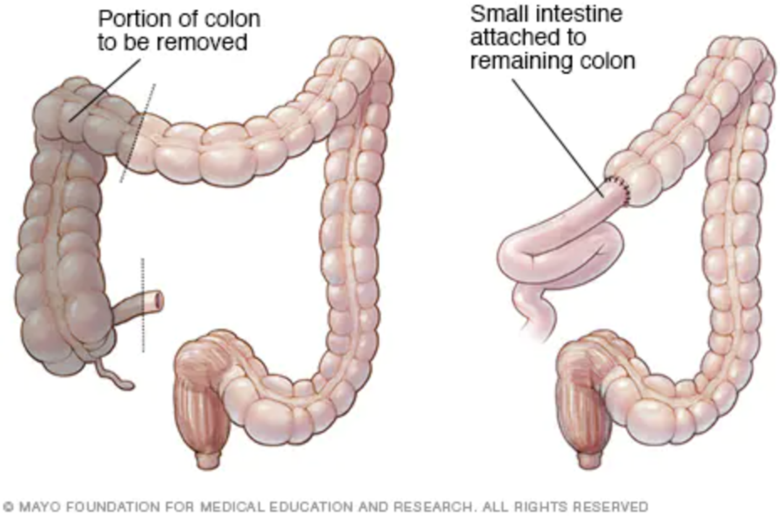

Figure 6. Representation of a right colectomy pre- and postoperative [24].

In a laparoscopic approach, small incisions around 1.0 to 1.5 cm in length, are made in the abdominal area and a laparoscope is inserted into the abdomen via the incision to view the organs [25]. The camera on the laparoscope displays the contents of the abdomen on a screen in the operation room. Supplementary surgical instruments enter the abdomen through other incisions and one larger incision is made for the colon to be removed through. Before the surgeon starts the removal, the abdomen is filled with carbon dioxide to expand and create more room for the surgeon to work with [25]. A laparoscopic approach to removing the colon is much less invasive than open surgery and reduces the risk of infection. Being less invasive, patients have a quicker recovery period and experience less pain.

Contrary to laparoscopic surgery, open surgery consists of removing surrounding tissue and skin and is therefore much more invasive. Open surgery also introduces the risks of bleeding, infections, and hernias [23]. Laparoscopic surgery is more commonly used due to advancements in technology as well as other factors regarding patient safety and cost. Although more beneficial for patients, laparoscopic procedures have some disadvantages. The 2D view on the screen is limited, and the smaller incisions leave the surgeon performing in unnatural positions.

Repetitive training is needed to prepare surgeons for operation and reduce any risks associated with the patient. Surgical training models can act as a guide to what they may see during an operation. The components of the surgical model must mimic those of the human abdominal organs in order to provide a realistic environment for the surgeon to practice on.

2.3: Need For Surgical Training Models

As a result of the rapidly evolving medical and technological fields, surgical procedures are becoming more intricate with new techniques. This offers a wide range of advantages for patients, such as increased safety, less invasive procedures, as well as fewer medical malpractices. However, there have been fewer opportunities for residents and surgeons to get experience as a result of regulations which prohibit students from working more than 80 hours per week. Experience in minimally invasive techniques, as well as endoscopic skills, has become increasingly important. Honing operative skills and surgical judgment will need to become more efficient. The use of simulation may reduce this learning curve caused by an era in which opportunities for surgical practice have been limited.

While cadaver dissection can be performed, there are many disadvantages to this technique. Chemicals used to preserve cadavers, such as formaldehyde and phenol, can be hazardous if they enter the body through inhalation, ingestion, injection or absorption. As a result of this, trainees are required to wear personal protective equipment (PPE) [26]. In addition, there are many ethical questions and concerns over the continued use of cadavers in surgical training for the future. With that comes a lack of donors and a high price of ~$2,000 for a cadaver [27].

However, it has been seen that repetitive training and practice, as well as practice outside of the high-pressure environment of an operating room, has been shown to improve surgical performance in many instances. In a study done to assess the effectiveness of virtual reality training, several surgical residents were evaluated on their ability to perform a gallbladder dissection. They found that students who went through simulated training performed gallbladder dissection 29% faster than those who did not experience simulated training. Non-VR-trained students were 9 times more likely to fail to make progress and were 5 times more likely to injure the gallbladder [28].

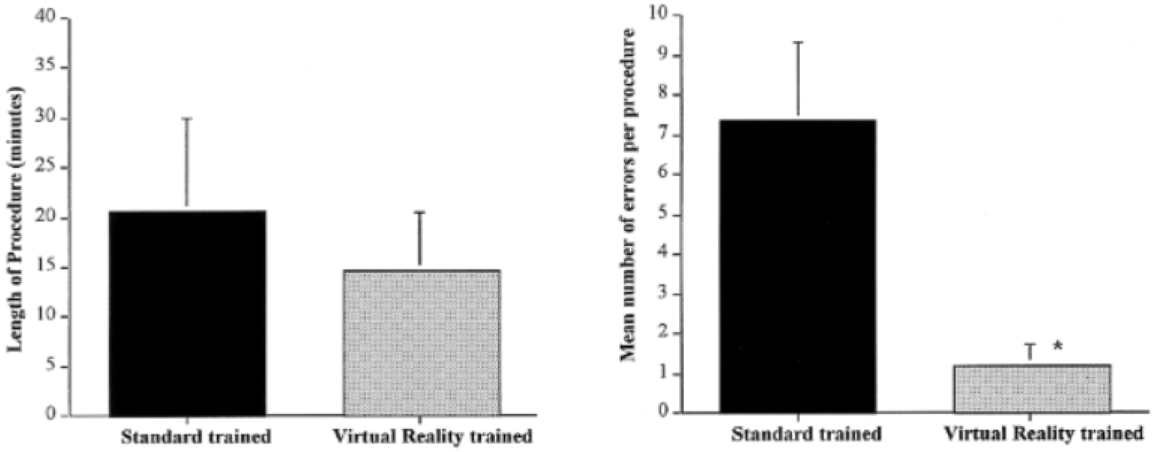

Figure 7. Comparison of residents trained the standard way versus those trained by virtual reality simulators [28]. These graphs show that standard training has a longer length of procedure times (left) and has a larger mean number of errors per procedure (right) compared to

virtual reality trained students.

The ability to create an environment that mimics a real surgical environment without any risk to the patient can help overcome many of the current issues with training procedures. Repetition of surgeries can occur until a surgeon is proficient, new techniques can be learned, new devices can be tested, and surgeries can be rehearsed moments prior, all without any potential harm to the patient [29]. The ability of models to provide a safe and standardized method for surgery without the risk of a real patient is tremendous. Surgeons and residents can refresh themselves and build confidence in certain procedures, as well as experiment with new skills and techniques. Intensive learning with skills that can be built sequentially with a gradual increase in difficulty could be available, which cannot be replicated on a real patient [30]. These simulated environments could reduce surgical errors, enable possible skills assessments, and lead to better detection of possible surgical errors.

2.4: Existing Models

As a way to supplement this lack of operating room experience, many have tried to find ways to bridge this gap between the ever evolving surgical and medical world and the need for out-of-surgery training and learning. Simulators such as box trainers, virtual reality simulators, and alternative synthetic cadavers have gained more use in medical training. Each model presents its own advantages and disadvantages, each looking to simulate environments replicating a natural environment. Box trainers can be used multiple times, are low-cost and can be portable. They provide tactile feedback and can teach basic laparoscopic skills, suturing and dexterity, and hand-eye coordination. In addition, these models can often be used multiple times before needing to be replaced.

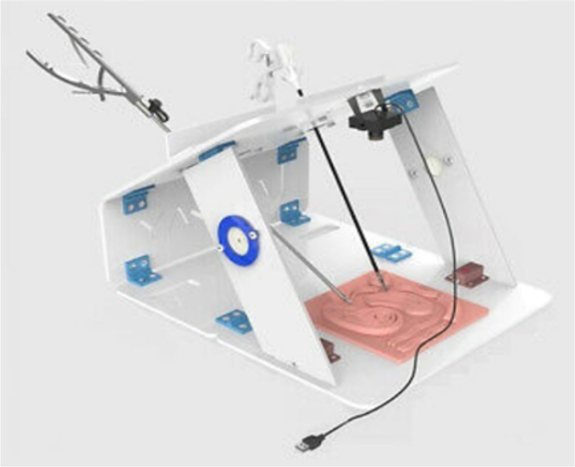

Figure 8. Surgical box trainer to practice laparoscopic skills [31].

While skills can be gained, one of the largest drawbacks is the lack of a bio-realistic environment. Many of these models can only be used to emulate simple tasks, and cannot provide a realistic environment for surgical practice. In addition, there is the need for direct observation by a trainer, limiting the amount of practice and exposure an individual can get [32].

Virtual reality simulators allow trainees to interact with a computer generated environment mimicking a natural one. However, these environments cannot truly mimic a realistic environment, nor do they contain the organs in the surgical procedure. These devices record different procedure metrics, allowing them to assess surgical skills, and provide feedback such as integrity of suture knots, operation time, and efficiency of motion.

Figure 9. Virtual reality surgical trainer for laparoscopic skills [33].

The ability for trainers to monitor easily and remotely means the trainee can utilize the system during out-of-surgery time. While these are great tools, they are extremely expensive, upwards of $10,000, making them only available to a limited demographic as a result of their high initial cost [32].

Companies such as SynDaver ® have developed synthetic human and animal models that can mimic tissues, body parts, and full bodies. These models are realistic as they have organs, bones, muscle, and vessels that mimic the properties of living tissues as well as provide direct feedback such as breathing and bleeding. However, they do not allow for practice of laparoscopic skills as they are designed for open surgery. In addition, they lack reusability as the model needs to be refrigerated and can expire after a period of time.

Figure 10. A synthetic cadaver sold by SynDaver ® [34].

These models are able to replace some mechanisms of other methods such as live animals, cadavers, and human patients [32]. However, they have experienced some downfalls with fully mimicking live organs as well as the tissues and fats layering throughout the body. Due to their composition, these models need to be refrigerated and can expire if not maintained properly. These models also come with a high initial cost, upwards of $70,000 [34]

2.5: Past Materials Used

A team of WPI students previously developed a model to try and address the needs for an affordable and realistic surgical model. The final design consisted of individually constructed organs that were placed in a box trainer in correct anatomical positions. The materials selected for each organ were based on mechanical properties and constructed mainly with silicone-based materials. It was noted that improvements should be made to increase the bio-realistic feel of the organs as well as the tissue and fat layers that would be naturally present in a surgical environment. Tissues were described as “too dense and did not adequately simulate the separation of organs…” [3]. This research was seen as a crucial step towards what would need to be improved upon in future models.

2.6: Clinical Need

Laparoscopic surgeries first began in 1987. This surgical technique was created to provide a less invasive surgical experience. Minimally invasive surgery reduces the size of incisions, avoids the use of manual traction devices, and minimizes the manipulation of various tissues [36]. Some of the positive outcomes associated with laparoscopic surgeries when compared to traditional or open surgery include reduced hospitalization times, shorter recovery times, minimized postoperative pain, less blood loss, and the need for fewer analgesics [37].

The skills necessary for a surgeon to perform laparoscopic surgery are very different from those used in traditional surgery. The use of smaller incisions and longer instruments pose a different challenge. The fulcrum effect is also something laparoscopic surgeons need to become accustomed to; the fulcrum effect is created when the pivot point of an instrument requires hand movement in the opposite direction of the desired tool endpoint movement [38]. Apprenticeship models previously used when training new surgeons would no longer apply. New techniques created a need for a systematic teaching of skills that would have trainees perform skills rather than observe. Once skills were achieved outside of the operating room, the new surgeon could begin working on real patients. This training would allow the students to learn in a non threatening environment. They would be free of the pressures of operating on patients and would be provided with a controlled environment where they could make mistakes [39]. The typical “See One, Do One, Teach One” [40] training environment, where residents observe a surgery, then perform the procedure, and finally teach another trainee how to perform one, would not allow for the residents to make critical mistakes. If a resident is assisting a surgery with a real patient, they will be stopped before they make any errors because the patient’s well being is at stake. The need for effective training strategies of laparoscopic surgeons has driven research in this field.

2.7: Engineering Need

The need to effectively train residents in laparoscopic surgery techniques has led to the production of numerous types of training models. As previously mentioned, the trainers on the market are not bio realistic, are expensive, and do not have vasculature or surrounding fats. An ideal surgical trainer would be as realistic as possible; this would include accurate organ dimensions, colors, and mechanical properties as well as mimic organ responses to external stimuli. It would also be inexpensive and easily reproduced. Residents will be instructed to practice on these trainers multiple times before moving on to work with patients, so they will be used extensively. Being able to replace the organs easily will be crucial in allowing repeated use on the trainers. Additionally, some organs, that are not being directly operated on, can be designed to be more durable to last through multiple uses and simulate a realistic experience. The creation of a more realistic surgical phantom will provide residents with the skills required to operate on patients in the future.

2.8: Need Statement

Following the investigation of the current surgical trainers on the market, our team determined the need for a surgical phantom that will mimic the upper right quadrant of the abdomen to be used as a trainer for surgical residents. This phantom shall include bio realistic organs and surrounding tissues, including fats, with correct dimensions and mechanical properties. It should mimic the adhesive strength of the organs and tissues, while also tearing like human tissues. The device should also be manufactured at a low cost with high reproducibility while still providing a realistic surgical experience.

3.0: Project Strategy

3.1: Initial Client Statement

Our client is Dr. Thomas Cataldo, an abdominal surgeon from Beth Israel Deaconess Medical Center (BIDMC). He presented our design team with the goal to "Develop a scalable, cost-effective training tool to accelerate the learning curve for surgical [colorectal] residents." The task presented includes evaluating the strengths and limitations of current models, developing a bio-realistic section of the abdomen that fits into a robotic surgery system and has easily repaired, replaced, or reused components, and creating a scalable prototype to deploy as a commercial product.

3.2: Stakeholders

In engineering, it is imperative to define all the stakeholders of a project. A stakeholder is anyone "who has a stake in the project" [41]. The stakeholders are anyone who is affected by or can affect the project objectives. The stakeholders for our project can be split into three groups: clients, users, and designers. Clients are those who invest in the project and can be either individuals or institutions. Users are those who are impacted by the value and quality of the deliverable. The designers are those who develop a product that aligns with the wants and needs of the other stakeholders [42]. The breakdown of the stakeholders for this project are highlighted in Figure 11.

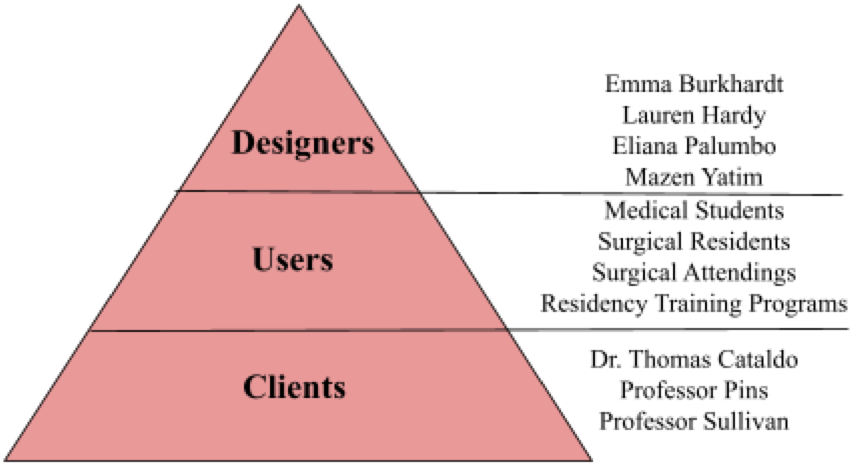

Figure 11. The stakeholders for this project include clients, users, and designers. This hierarchy displays the importance of each stakeholder, with the clients being the most important, followed by the users and designers.

Our main client is Dr. Cataldo, an Assistant Professor of Surgery at Harvard Medical School and a Colorectal Surgical Attending at BIDMC. He initially identified the need for a better trainer for surgical residents in 2019, and began a project with 5 WPI Undergraduate students. Dr. Cataldo acquired funding for the team from BIDMC, who also sponsored this MQP. Additionally, our clients include our two advisors for this project, Professor Pins and Professor Sullivan. They represent WPI and provide guidance and insight to the team in areas of biomedical engineering and mechanical engineering, respectively.

We have identified medical students, surgical residents, attending surgeons, and those associated with residency training programs as our users. Medical students and residents will have hands-on experience with the product to practice their surgical skills on. Attending surgeons will have the opportunity to practice on our model if they are preparing for a surgery that they do not normally perform and want to maintain their skills in a particular area. Finally, our model will need to be prepared for the surgeons, so we have included anyone associated with a residency training program as a user. Our model should meet the needs of our various users.

Lastly, the designers of our project include the members of our MQP team: Emma Burkhardt, Lauren Hardy, Eliana Palumbo, and Mazen Yatim. Our team is dedicated to developing a product that satisfies all the needs of our clients and users. To understand the needs and wants for our project, we will outline criteria that our product should satisfy to align with a successful outcome.

3.3: Initial Design Objectives

Through conversations with our advisors and sponsor, Dr. Cataldo, our team compiled a list of our objectives for the project. The final objectives include creating a model that is bio-realistic, manufacturable, cost effective, easy to assemble, reusable, and provides translatable surgical skills. Table 1. displays the ranking of objectives from most important (5) to least important (1) using a pairwise comparison. This comparison determines which candidate of the two being compared is preferred overall [43]. Creating a bio realistic model was ranked the most important, followed by providing translatable skills. Manufacturability and reusability were next, ranked equally. Cost effectiveness was second lowest and ease of assembly was ranked least important.

Table 1. Pairwise comparison of the final objectives.

	Bio-realistic	Manufacturability	Cost effective	Ease of assembly	Reusability	Translatable Skills	**Total**
Bio-realistic	X	1	1	1	1	0.5	**4.5**
Manufacturability	0	X	0.5	1	1	0	**2.5**
Cost effective	0	0.5	X	1	0	0	**1.5**

Ease of assembly	0	0	0	X	0	0	**0**
Reusability	0	0	1	1	X	0.5	**2.5**
Translatable Skills	0.5	1	1	1	0.5	X	**4**

3.4: Design constraints

Conversations between the clients and the designers of this project allowed our team to organize a set of constraints. First, our model needs to be non flammable. When interacting with surgical instruments, the organs and tissues must be non flammable. Second, the materials must retain their shape over time. The organs that will remain in the model for long periods of time and must keep their original dimensions to ensure the model remains bio realistic. Additionally, the selected materials must not produce any adverse reactions when they interact with each other or the surgical instruments. With regards to the budget of the project, our team was provided with \$1000. For common supplies, \$400 will be subtracted leaving the team with \$600 towards project cost. Finally, our project has a time constraint of completion by May 2022.

3.5 Final Objectives

Our team finalized our primary objectives and developed secondary objectives for each one. The final primary objectives include bio realistic, highly manufacturable, cost effective, ease of assembly, reusability, and translatable skills. The descriptions of each primary objective are outlined in sections 3.5.1-3.5.6. Their corresponding secondary objectives and their descriptions are outlined in Tables 2-7.

3.5.1 Primary Objective: Bio realistic

The training model should mimic the upper right abdominal quadrant, which includes the liver, stomach, gallbladder, duodenum, right kidney, small intestine, transverse colon, mesentery, and surrounding adipose tissues. The model should have similar dimensions to human abdominal organs (1:1), be anatomically correct, and should have similar mechanical and material properties to human tissues such as compressive strength, tear strength, tensile strength, elastic modulus, puncture resistance, and density.

3.5.2 Primary Objective: Highly Manufacturable

The training model should be highly manufacturable, meaning that there should be standard molds created for every organ and tissue that can be used repeatedly during the casting process to create identical models. These standard molds will allow for more precision during organ development and would make the process more time efficient, creating an easier transition into market and production.

3.5.3 Primary Objective: Cost Effective

This model should also be cost effective. The manufacturing costs to produce the initial model and replaceable parts should be kept low to encourage use, and allow for the possible use of the models in developing countries. The model should cost no more than $1,000 to purchase initially, and less than $1,000 each year for both replacement parts and maintenance.

3.5.4 Primary Objective: Ease of Assembly

The model should be easy to assemble since there will not always be an engineer around to set it up. Having a straightforward removal and replacement process will be important to allow for repeated use of the model. This process should take between 5 and 10 minutes to assemble.

3.5.5 Primary Objective: Reusability

The model should be reusable. There should be organs that remain untouched during surgical practice that do not need to be replaced, and there should be organs that are frequently operated on, that will be replaced after a certain number of uses; this number should be obtained by a series of mechanical tests following material selection and organ casting. The model should provide the same experience for the students during every use, so continual replacement will be necessary to ensure proper function of the model.

3.5.6 Primary Objective: Translatable Skills

The model should simulate a realistic environment that provides translatable skills to the surgeons practicing with it. The skills acquired from using the model need to be easily transferable to performing surgery on a live patient.

Table 2: Secondary objective descriptions for the bio realistic primary objective.

Primary Objective: Biorealistic	
Secondary Objective	**Description**

Anatomically Correct	The model should have similar dimensions to human abdominal organs (1:1) and should have the correct 3 dimensional orientation of the upper right quadrant.
Similar Mechanical Properties	The organs should have similar mechanical properties to human tissues such as compressive strength, tear strength, tensile strength, and puncture resistance.
Similar Material Properties	The organs should have similar mechanical properties to human tissues such as elastic modulus and density.

Table 3: Secondary objective descriptions for the highly manufacturable primary objective.

Primary Objective: Highly Manufacturable	
Secondary Objective	**Description**
Standard Molds	The device should include molds that are uniform to one individual's organ sizes. This will ensure the ability to create new organs easily with a one size fits all mold for replacement organs.
Reproducible	The molds are designed to be used over and over again. This ensures that the organs being molded will be the same size and shape each time they are produced.
Clear Manufacturing Techniques	The technique in which the casting and molding process is done should be outlined and specific to ensure that each organ is created in the same fashion.

Table 4: Secondary objective descriptions for the cost effective primary objective.

Primary Objective: Cost Effective	
Secondary Objective	**Description**
Manufacturing Costs	Standard molds should allow for smaller manufacturing costs and these molds will be reused.
Initial Product Cost	The initial cost of the product should be no more than $1,000.
Replacement Costs	Replacement costs account for replaceable and untouched organs. These costs will only occur when an organ needs to be replaced once it has been reused several times.

Table 5: Secondary objective descriptions for the ease of assembly primary objective.

Primary Objective: Ease of Assembly

Secondary Objective	Description
Easy Process	The device should come with instructions that are easy to follow and would allow for anyone using the device to insert the new components with ease and in the proper locations.
Time Efficient	The device should be able to be reassembled within a 5-10 minute span. This assembly includes taking out the used/torn components and replacing them with new parts.

Table 6: Secondary objective descriptions for the reusability primary objective.

Primary Objective: Reusability	
Secondary Objective	**Description**
Cost Effective	There will be organs that are untouched as well as others that will need to be replaced. The cost of these should be inexpensive.
Replacements after damage/use	Some organs will be able to be used several times while others may get damaged more often. Once damaged, it must be replaced.

Table 7 : Secondary objective descriptions for the translatable skills primary objective.

Primary Objective: Translatable Skills	
Secondary Objective	**Description**
Used in a box trainer	The model should be able to fit comfortably inside a box trainer for surgical manipulation.
Used with realistic surgical instruments	The model should be compatible with use of common surgical instruments.
Mimics human tissue interactions	The model should provide a realistic surgical environment that mimics human tissue responses to manipulation.

3.6: Evaluating and Ranking Objectives

Once the description for each objective was completed, the primary and secondary objectives were ranked from least important (1) to most important (5) by the designers (our MQP team) and clients (Dr. Cataldo, Professor Pins, and Professor Sullivan). The average scores of each objective were calculated to determine the order of importance of the primary and secondary objectives. The overall values for the primary objectives are in Table 8 and are listed in descending order of importance. Dr. Cataldo ranked translatable skills and bio realistic as both being the most important. Table 9 depicts the rankings of the secondary objectives in descending order from most important to least important. Overall ranking is shown in Table 9 with the primary objectives in the left column and the corresponding secondary objectives in the right column.

Table 8: Primary Objectives with rankings from the designer team and the clients.

Primary Objective	Designers	Clients			Average
		Prof. Sullivan	Prof. Pins	Dr. Cataldo	
Translatable Skills	4.5	5	5	5	4.9
Bio Realistic	4.75	4	4	5	4.4
Cost Effective	3.88	3	3	4	3.5
Reusability	3.75	3	3	3	3.2
Ease of Assembly	2	2	2	2	2.0
Highly Manufacturable	3	1	1	1	1.5

Table 9: Secondary Objectives with rankings from the designer team and the clients.

Primary Objective	Secondary Objective	Designers	Clients			Average
			Prof. Sullivan	Prof. Pins	Dr. Cataldo	
Translatable Skills	Mimics human tissue interactions	4.38	5	4	4	4.3
	Used in a box trainer	1.25	3	5	5	3.6

	Used with realistic surgical instruments	3.13	4	3	3	3.3
Bio Realistic	Anatomically correct	5	5	5	3	4.5
	Similar material properties	3.75	4	3	5	3.9
	Similar mechanical properties	3.75	3	4	4	3.7
Cost Effective	Replacement costs	3.25	5	5	5	4.6
	Initial product cost	2.75	4	4	4	3.7
	Manufacturing costs	3.88	3	3	3	3.2
Reusability	Cost effective	3.38	5	5	4	4.3
	Replacements after damage or use	3.5	4	4	5	4.1
Ease of Assembly	Easy process	3	5	5	5	4.5
	Time efficient	1.88	4	4	4	3.5
Highly Manufacturable	Reproducible	4	5	5	4	4.5
	Standard molds	3.25	4	4	5	4.2
	Clear manufacturing techniques	2.5	3	3	3	2.8

3.7: Revised Client Statement

Develop a surgical training model of the upper right abdominal quadrant that includes the liver, stomach, gallbladder, duodenum, right kidney, small intestine, transverse colon, mesentery, and surrounding adipose tissues. This phantom will include bio realistic parts that possess the mechanical properties and dimensions (1:1 ratio) of human abdominal tissues. The trainer will be reusable where the liver, kidney, and retroperitoneum will remain in the model, and additional organs and tissues can be ordered to replace the damaged ones. The trainer should cost users no more than \$1000 to purchase initially, with additional organ costs at less than \$1000 per year. Surveys will be conducted with residents and attendings to determine how realistic the model is and how translatable the skills learned on the model are to skills needed in the operating room.

3.8: Management Approach

This goal guides the objectives of the project as a whole, however constraints have to be taken into consideration when completing a project. The project's deadline of May 2022, budgetary concerns, and specific material functions also guided the path of the project as well. Our approach to developing this model are divided and described in the section below discussing steps and processes needed for completion of the project. If the team is unable to complete the proposed milestones, we recommend that future teams will continue where we left off.

3.8.1: Milestone 1

Develop organ and tissue models/files with the use of CT scans and Vesalius 3D software, as well as decide on an approach for manufacturing the molds. This milestone should be completed by the completion of B-term. The team plans on analyzing sets of de-identified CT and MRI scans to create models of the needed organs/tissues. The CT scans will be analyzed using a software known as Vesalius 3D. This data can then be extracted and developed into a 3D mold in Blender and AutoDesk MeshMixer. The mold design will be selected, and manufacturing of the molds will be conducted based on the process selected by the team at the deadline. Once the molds are created, the team will be able to begin casting organs/tissues using

3.8.2: Milestone 2

Identify, test, and select suitable materials for each portion of the model. This milestone should be completed the third week of C-term. The team will continue conducting research on suitable bio-realistic materials for the model, looking for materials with properties similar to those of the organs, tissues, and fats in question, as described in section 2.1. The design team will verify properties of the materials through the use of the Granta EduPack_® software, the MatWeb website, mechanical testing, relevant literature, and conversations with our clients.

3.8.3: Milestone 3

Generate models, select best design and confirm completion of design specification through testing and surveys. Iterate until the best design construct is found. This milestone will be completed by the end of C-Term. Following the completion of milestone 1 and 2, the team will conduct material testing on a larger scale to determine the material properties of the constructed organs/tissues/fats as well as the bio realistic feel of the materials. Appropriate testing will be done to verify the effectiveness of the individual parts and the model as a whole. Design constructs will be iterated until desirable properties and a full model is found.

3.8.4: Milestone 4

Milestone 4: Conduct a survey with residents and attendings to determine the effectiveness of our model. This milestone will be completed by the second week of D-term. Following the design iterations and completion of our model, the team will conduct surveys with surgical residents and attendings. Surveys will be conducted anonymously to encourage unbiased and truthful answers. In addition, feedback from our stakeholders will be taken into consideration and evaluated. This will evaluate the effectiveness of our design process and therefore the model as a whole.

4.0 Design Process

4.1 Needs Analysis

Once the primary and secondary objectives were finalized, the needs and wants of the project were developed to further narrow down the scope of the project. A list of all ideal requirements of the trainer was made and then distributed into two categories: needs and wants. Needs involve requirements that our team hopes to accomplish upon completion of the project given the time restraint and limited budget. Wants include requirements from the list that would be beneficial to our project, but may fall beyond the scope of it. Requirements in the wants list may be used for further projects to enhance our current model.

4.1.1 Design Needs

With the time frame and budget in mind, a list of design needs was created to solidify the scope of our project. Based on these, our model will mimic the human right upper abdominal quadrant including the right kidney, liver, small intestine, duodenum, transverse colon, mesentery, stomach, gallbladder, and surrounding adipose tissue. These organs must be a 1:1 ratio to real organs and have similar mechanical and material properties to that of normal organs. The organs must also stick together to mimic a realistic environment during surgery. Each organ will be made from materials that match their material and mechanical properties. The materials used must be inexpensive as to lower manufacturing costs and increase reusability. The model needs to be used more than once, with some organs being replaced more frequently than others.

4.1.2 Design Wants

The design wants are goals that are beyond the scope of our project, but could be used towards a future project. Ideally, this model would include the entire abdomen rather than just the right upper quadrant to be used for practice of other surgeries and better mimic an operating room environment. In the future, it would be helpful to have the trainer swivel rather than being stationary, similar to how surgeons maneuver their tools during surgery. We would also want to incorporate vasculature into the model to allow for bleeding and distinguish clear mistakes during practice. We would like to add more glue between the organs to make the separation harder, as it is during surgery. Lastly, we want to have models that resemble patients of various conditions. For example, another model could include a colon with polyps, as this is commonly seen in a right colectomy surgery.

4.2 Functions and Specifications

The functions and specifications of each primary objective and secondary objectives are diagrammed in Figure 12.

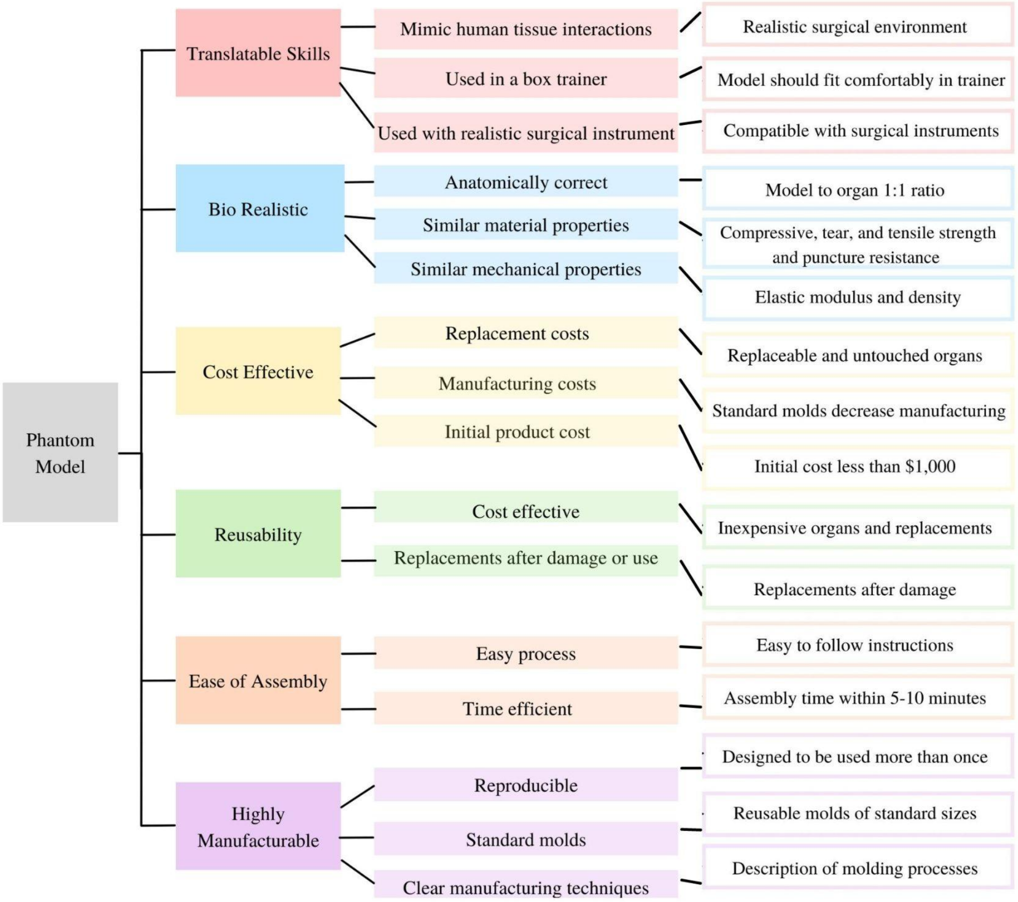

Figure 12. Primary and Secondary Objectives, Functions, and Specifications

It is critical that our model accurately allows residents to learn how to operate in the right upper quadrant of the abdomen. The skills learned with our model must be translatable to surgery with a patient. The model must provide a realistic surgical environment that mimics human tissue responses to manipulation in order to prepare residents. It must also incorporate common surgical instruments to allow residents to become accustomed to.

One aspect of the model being bio realistic is having a 1:1 ratio of human abdominal organs to the organs in our model. Anatomically correct organs and orientation will allow residents to practice on realistic sized organs to mimic the organs of a patient in the operating room. Table 10 displays the dimensions of each organ found in the upper right quadrant of the abdomen. Along with size, the organs must function similarly to real human organs. They must have similar mechanical properties to emulate organ interactions during a procedure. This allows residents to practice with a model that accurately represents what they may encounter during surgery. Table 11 displays the mechanical properties of each organ that will be included in our model.

Table 10: Right upper quadrant abdominal organ dimensions [44].

Organ	Size
Stomach	Length: 15-25 cm Volume: 1000-1500 mL
Small Intestine	Length: 6-7 m Width: 2.5-4 cm
Duodenum	Length: 25 cm
Large Intestine	Length: 1.5 m Width: 7cm
Ascending Colon	Length 132-147 cm
Transverse Colon	Length: 45 cm Width: 7 cm
Descending Colon	Length: 25 cm
Sigmoid Colon	Length: 17-57 cm
Liver	Length: 7-10.5 cm
Gallbladder	Length: 10 cm Width: 5 cm Volume: 30-80 mL
Right Kidney	Length: 10.9 cm Volume: 134 cm

Table 11: Mechanical properties of the organs in the right upper quadrant of the abdomen [44].

Organ	Mechanical Properties
Stomach	Maximum Stress: 0.7 MPa (axial) and 0.5 MPa (trans) Destructive Strain: 190%
Small Intestine	Maximum Stress: 0.9 MPa Destructive strain: 140%
Transverse Colon	Burst Strength: 1223 ± 701 g Tensile Strength: 98 ± 57 g/mm^2 Elongation: 221 ± 187%

Liver	Tensile E: 12.16 ± 1.2 kPa Compressive E: 196.54 ± 13.15 kPa
Gallbladder	Maximum Stress: 1.24 ± 0.099 MPa Tensile E: 641.2 ± 28.12 kPa
Right Kidney	Tensile E: 180.32 ± 11.11 kPa Failure Stress: 24.46 ± 3.14 kPa

The model must be cost effective and reusable. Therefore, the materials used for each organ must be affordable to allow for low manufacturing costs. The initial cost of the model should be less than $1,000 with additional costs accounting for the replacement of organs that are damaged. Replacement of the organs will vary depending on them, but should be inexpensive. Untouched organs, also known as the organs not being directly operated on, will not need to be replaced as frequently and therefore are less expensive. The cost of the model must also fall within our budget of $1,000.

We wanted our model to be easy to use and easy to assemble. The process of assembly must be easy and instructions will be provided to explain this process. Assembly time should not take more than 10 minutes. This may include putting the organs in their designated spots in the model and replacing organs as necessary.

Our final objective is highly manufacturable. We wanted our model to be easily reproduced so that it can expand beyond the scope of our project and reach other facilities. In order to do this, we created standard molds that can be reused to create organs. Our organs will also be manufactured to be used in the model more than once, to keep manufacturing costs low. Descriptions of the molding process will allow for easy and efficient additional molding if needed.

4.3 Industry Standards

Established educational programs that train future Doctors of Medicine (MD), in the United States, must meet the 12 standards presented by the Liaison Committee on Medical Education (LCME). The accreditation process is used to ensure that the graduating students are prepared for the next stage of their training and are equipped to enter the medical field. Of the 12 standards, our model falls under Standard 7: Curricular Content and Standard 9: Teaching, Supervision, Assessment, and Student and Patient Safety. Standard 7 ensures that the content being taught to the medical students prepares them for entry into a residency program and for the practice of medicine. It mandates that medical students are able to use their knowledge and apply them to the health of individuals and populations. This standard also ensures that the medical student is gaining communication and interprofessional collaborative skills, as well as considering societal problems, health care disparities, and medical ethics. Standard 9 ensures that the teaching, supervision, and assessment of medical students prepares them for realistic applications [45].

ISO 527 is the standard for determining tensile properties of plastics and plastic composites. This standard is performed on a testing machine, such as an Instron 5544, to apply a tensile force on a specimen. It measures the tensile strength, tensile modulus, elongation, and poisson's ratio. Various methods are used for different materials including rigid/semi-rigid thermoplastics, rigid/semi rigid thermosets, fiber-reinforced thermoplastic composites, fiber-reinforced thermoset composites, and thermotropic liquid crystal polymers [46]. For puncture testing, the ASTMD4833 serves as the standard protocol when measuring the puncture resistance forces of geomembranes.

Our model follows both standards by teaching residents the laparoscopic skills needed in the operating room while ensuring there is no risk to patient safety. The model allows residents to practice on a trainer repetitively, while gaining hands-on experience with bio-realistic organs that emulate the real surgical environment. With synthetic organs, the trainer is more ethical than practice on a human cadaver.

4.4 Conceptual Designs

Through conversations with all of this project's stakeholders, it was devised that the creation of a bio realistic model, that provides translatable surgical skills, is the most important objective. The model should also be highly manufacturable, reusable, cost effective, and easy to assemble. Each iteration of a model should aim to include each of these objectives, focusing on the highly ranked ones. The development of conceptual and alternative designs should result in the selection of a final design that the team will continue with.

Our conceptual design for our model can be found in Figure 13. This is an image of a SolidWorks assembly created to show the ideal relationship between the organs created for our model. The organs pictured include the liver, kidney, gallbladder, stomach, duodenum, colon and small intestine. These files are a mix of the organs that we have created with the help of Dr. Cataldo and his family, as well as some files from last year's team that are placeholders until our team finishes modeling the upper right quadrant. Only the upper right quadrant of the colon and small intestine can be seen in this image due to our project's specific location focus. If time allows, the full colon and intestines will be created. In this conceptual model, there would be a mesentery connecting the colon and small intestine (protruding into the paper). The CAD files for the individual organs and the assembly can be found in Appendix C.

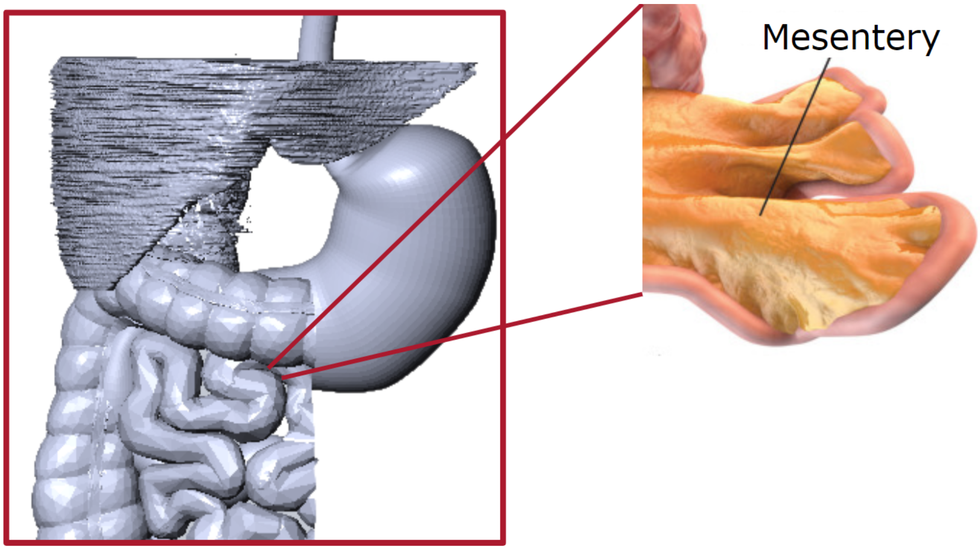

Figure 13. Solidworks assembly of a conceptual design of the upper right abdominal quadrant.

This design would be constructed out of materials with similar mechanical properties to the respective human organ's properties. Potential materials for each organ will be discussed in following sections. Each organ will also be dimensionally accurate. InVesalius 3.1 will be used to measure the actual dimensions of the organs from the provided CT scans of one individual. This will ensure that all the organs fit together exactly how they are oriented inside of the model patient. This visualization can be referred back to during this project to get a better understanding of what we want our model to look like.

4.5 Alternative Designs

Design 1 is as follows: manufacture the colon to match the realistic size, shape, and mechanical and material properties for one time use. All other organs in the right upper quadrant will be manufactured to match the realistic size, however their mechanical and material properties will not be as exact. All of the organs will be stuck together by both the mesentery and any other anatomical connections between organs. This design will utilize materials for the colon that are not reusable over multiple uses and may expire over time, requiring them to be replaced frequently. The benefits of this design is that the colon will have realistic mechanical and material properties, however these materials are non-reusable and may expire. In addition, due to the bio-realistic focus only being on the colon, the other organs can be manufactured easier and more inexpensively.

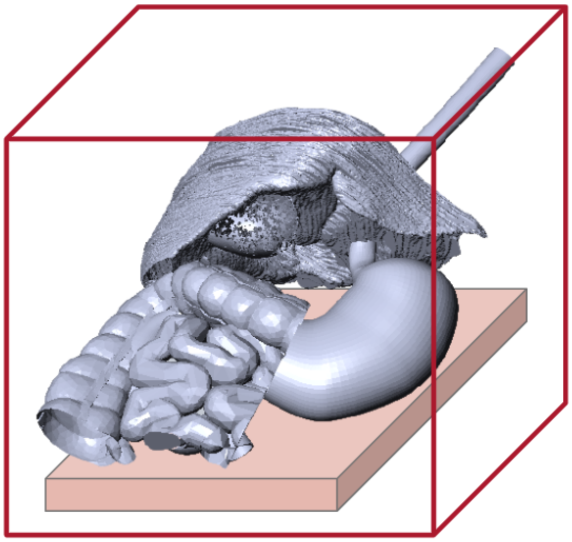

Figure 14. Schematic of the first alternative design inside of a box trainer.

Design 2 is as follows: manufacture the colon, adipose tissues, and surrounding organs of the right upper quadrant to be reused and practiced on multiple times before needing replacements. The colon and adipose tissue will be anatomically correct and mimic realistic material and mechanical properties as seen in the human body. The surrounding organs will be anatomically correct regarding size and shape, but they will not exhibit realistic material and mechanical properties. All organs and the adipose tissue will be placed in the correct anatomical position in the trainer and will be connected to each other by the mesentery. Their position of the surrounding organs is for reference in relation to the colon as they should not be manipulated during practice. The benefit of this design is that each component of the trainer is reusable, allowing for multiple practices before being replaced. Replacements should not be as frequent for the surrounding organs as they are not repeatedly operated on compared to the colon and adipose tissue. The reusability of this design decreases manufacturing and is more cost effective.

Both designs would be placed inside of a box trainer that lays flat on a table. This box will have holes in either the top of the sides of the box and would allow the insertion of laparoscopic tools to be utilized to practice surgery. The designs will also have layers of adipose tissues placed around and between each organ to simulate the visceral fat of the abdomen.

A meeting between the client, Dr. Cataldo, and the designers was held to determine which alternative design should be continued with. Each alternative design was proposed and discussed among those present. Discussions outlined both the benefits and drawbacks of each design and allowed for the group to weigh the advantages and disadvantages of each. It was decided that Design 2 was the design we should move forward with as we continue through the design process. This design was chosen based on its inclusion of adipose tissues as a landmark for the other organs inside of the trainer. Additionally, this design would be more cost effective due to its minimized replacement of organs.

4.6 Feasibility Study

One of the main objectives of this project is manufacturability; feasibility studies can be used to highlight the initial pilot experiments, relating to the manufacturability of the project, performed in the early stages of design. These studies will serve as the foundation for future testing and jump start the design process.

4.6.1 Injection Molding

Injection molding is a key feature of this project and is used to create the kidney, liver, and gallbladder. With injection molding, comes die/mold designing. Casting molds have very specific features that need to be tailored to the chosen application.

The first iteration of the liver design can be found in Appendix C. When printed, the design of the mold was not suited for proper injection molding. First, the sprues cut into the top of each mold were too small. When pouring the liquid silicone in, the hole would immediately overflow, no matter the liquid's initial velocity. To get any silicone inside of the mold, it would have to be slowly dripped into the mold. This dripping however caused excess porosity in the cast part because gas particles entered the stream when it was not under continuous flow. Additionally, the mold had around an inch of excess material on the side of it that could be eliminated to reduce cost and printing time. Half of this mold can be seen in Figure 15.

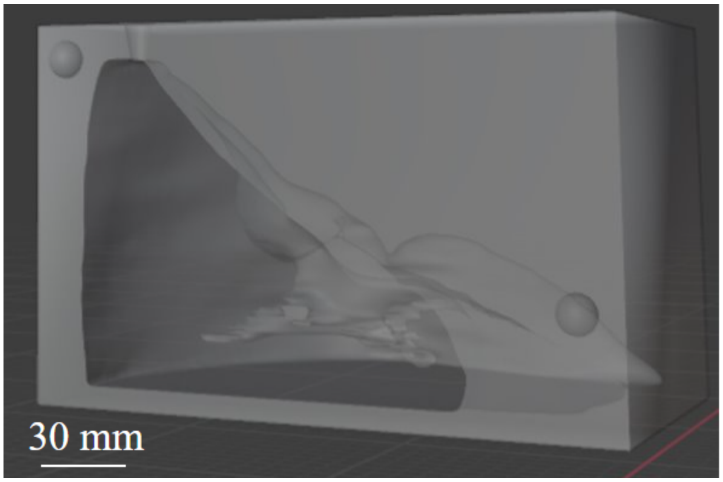

Figure 15. V.1 of the right side of the liver mold. A small sprue can be seen in the top left corner and the top right corner has excess material.

The second iteration aimed to alleviate the problems seen in iteration one. Larger holes were cut into the mold to allow easy flow into the mold cavity from the top (Figure 16.).

Sections of the mold were cut at a diagonal to preserve PLA, which cut down on mold cost and printing time. However, now this print does not stand up properly and needs to be placed inside of a larger bowl to keep the top level. Since the first mold was unusable, additional problems arose with iteration two that could not have been seen from the first. Once the mold was fully poured and cured, the removal process was extremely difficult. One side of the mold was very easy to get off, but the other side has a protruding arm in the middle to simulate a hole for vasculature to enter. This arm made it impossible to remove the part without ripping it in some way. A clean cut with scissors was made to extract the part. In future iterations this arm will be removed as the hole it makes is not necessary for our model.

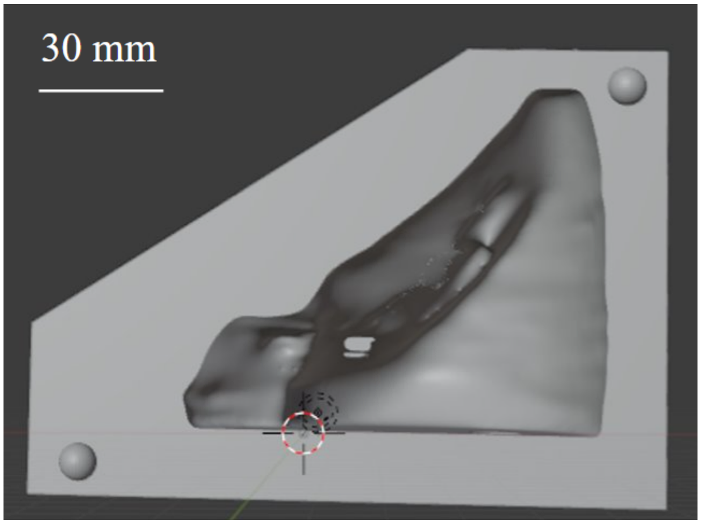

Figure 16. V.2 of the left side of the liver mold. A slanted cut in the top left corner can be seen to reduce material and a larger sprue can be seen in the bottom left corner.

4.6.2 3D Printing

Studies conducted in the areas of 3D printing included producing the most inexpensive molds without compromising their structural integrity. This meant reducing the printing time and the amount of material used. This included cutting extra material from the edges of the prints, but also learning about the different functions of the printing software used (3DPrinterOS).

Supports are utilized in 3D printing to ensure that the extruded material does not sink during the cooling process. It stabilizes the sections of the designs above it. Depending on the orientation of the design on the printing bed, supports will be added as necessary. Simple rotation of a design can eliminate the need for supports and limits material and time. Figure 17 below highlights the use of supports for the same mold. The right side has a lot of support and would cost $9.77 to print and would take 11:27 hours. The left has less support and would cost $8.33 and take 9:59 hours to print. Orientation saved over one dollar and an hour and a half.

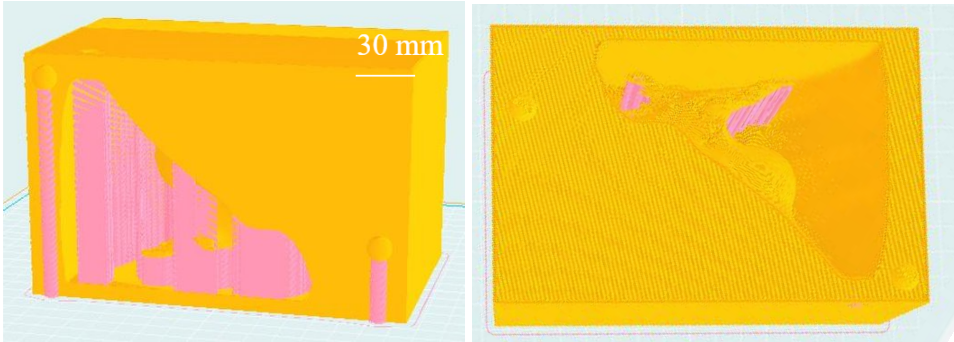

Figure 17. Schematic of the liver mold on the printing table with a side down (left) and the back down (right). The mold is yellow and the supports are pink, which are minimal in the right mold.

The 3D printer used to create the molds is the LulzBot TAZ 6. This printer comes with features that can be altered to optimize a print. There are many methods of printing to choose from with preselected features. Two of the most notable are the Tazbot Standard Print and High Speed Print. The standard has a layer height of 0.25 mm and infill density of 20%. The high speed setting has a layer height of 0.35mm and infill of 10%. The high speed prints much quicker because it deposits more material down with each pass and also only fills the solid pieces of the mold by 10%. For our project, PLA is strong enough with a lower infill density to support the low stresses of casting. For one part, our team was able to use the High Speed Print setting and even lower the infill to 8%. This reduced the printing time by 22 ½ hours and saved $8. Learning to minimize a print's cost and printing time is vital to preserve the team's budget for other expenses.

Lastly, scaling the molds up and down to create dimensionally accurate organs was also important. The organ and subsequent mold files were stls. These types of files only save the proportions of the part and not the overall dimensions. It was important to learn how to properly size the parts in 3D Printer OS for precise prints. In this software, you can scale a part up or down by selecting it and inputting the new length, width, or height. In Figure 18, an image of the liver mold in Blender can be seen. The overall length of the mold was measured, as well as the longest length of the liver cavity of the mold. The ratio between the two lengths can be used, along with the length of the liver in the CT scan, to scale the length of the mold to be printed. The mold can then be scaled up or down to create a dimensionally accurate liver.

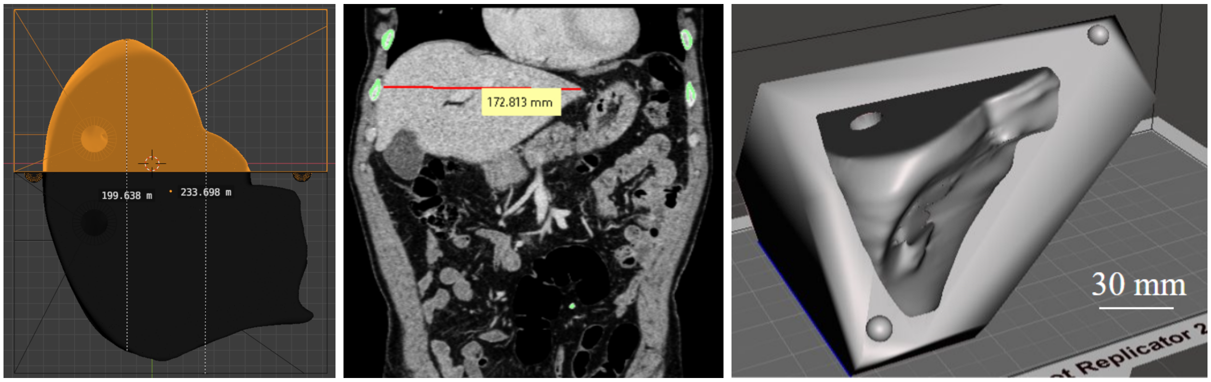

Figure 18. Image of the liver mold in Blender (left), CT scan in InVesalius 3.1 (middle), and the liver mold in Autodesk Meshmixer (right).

5.0 Final Design Verification

5.1 Quantitative Experiments

Quantitative tests must be done to determine the mechanical and material properties of the chosen materials to be used in the model. The results from these experiments will help us determine which materials are most suitable for the model and mimic human tissue accurately. The two tests that were performed were a tensile test (ASTM D412-16) and puncture test (ASTM D4833). Details and descriptions of each method are outlined in the subsequent sections.

Mechanical and material properties obtained from a bovine sample were used as baseline values for comparison to our synthetic materials to determine which materials are most feasible for our model. We performed these tests on the colon, small intestine, stomach, and mesentery.

Baseline mechanical property values for each organ have been determined from literature. Potential materials were chosen based on these values and tested on to determine their feasibility. The tensile test determined the ultimate tensile strength, elastic modulus, maximum force, and compliance. The puncture test determined the puncture resistance force of the bovine tissue and synthetic material.

5.1.1 Tensile Test: ASTM D412-16

The mechanical and material properties of each synthetic material needs to be measured to compare to the results from the porcine sample as well as literature. To gather the ultimate tensile strength (UTS), load to failure, strain to failure, elastic modulus, and compliance of the chosen materials, a tensile test was conducted. This test is a destructive test in which uniaxial tension is acted on the material until it fails. The UTS is the maximum stress the material can withstand before failure. Load to failure is the maximum force, in Newtons, the sample can withstand before failure. Similarly, strain to failure is the maximum elongation the material can withstand before permanently deforming. The elastic modulus can be calculated as the ratio of stress to strain to determine the stiffness of the material with a higher elastic modulus corresponding to a stiffer material. Lastly, compliance is the inverse of the elastic modulus.

The standard used for this test is the ASTM D412-16, which is the “Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers- Tension” [54]. These tests were conducted in Goddard Hall room 207 at Worcester Polytechnic Institute using the Instron 5544 with the uniaxial grips. The set up used for the uniaxial testing can be seen in Figure 19. below. The protocol for this setup can be found in Appendix G and H.

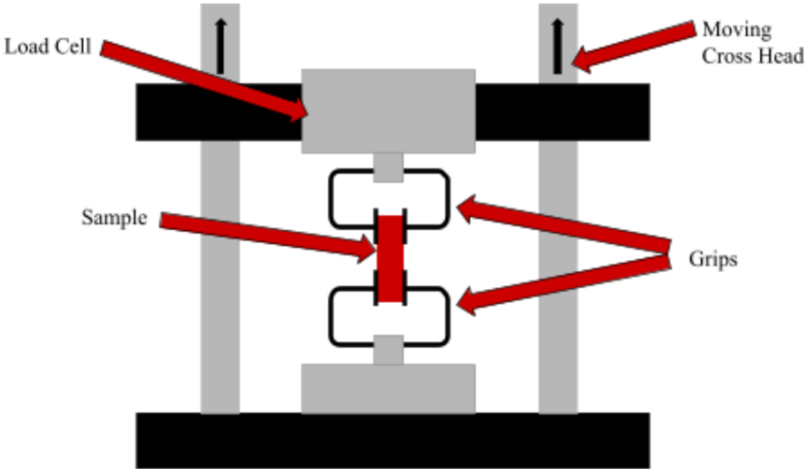

Figure 19. Instron 5544 Tension Testing Set Up [54].

The synthetic samples, EcoFlex 00-10 and EcoFlex 00-30, were cut into rectangular sections, per ASTM D412-16 Test Method A, and their length, width, and thickness were measured using a Mitutoyo digital caliper (± 0.01mm). Each measurement was taken 3 times and the average was calculated. The dimensions of each sample can be seen in Appendix G. The porcine tissue was also cut into a rectangular section and the same dimensions were taken.

To avoid damage to the force transducer, the safety stops were set in positions that would stop the test if needed. Each specimen was held by the screw-action grips. Using the Bluehill3 Software, the load was balanced, the elongation of the sample was zeroed before beginning the test, and a 1N tare load was acted on the sample. The sampling rate for the synthetic material and porcine tissue was100 mm/min. Once the material reached failure, or the test was manually stopped, the raw data was exported for analysis.

5.1.2 Puncture Test: ASTM D4833

Since the organs are to be manipulated with surgical instruments, we needed to determine the puncture resistance of each organ in the model. ASTM standard D4833 was used to determine the puncture resistance force as it is designed to measure geomembranes, which are synthetic materials that are thin, flexible, and permeable. This test allowed us to compare the puncture resistance forces of the synthetic materials to those of the porcine samples. The test was conducted on an Instron 5544. A puncture apparatus was placed below the Instron with the puncture tip pinned into the machine. The specimens were held in place between the 2 plates of the apparatus with a hole at the top of the structure to allow the puncture tip to compress through. The puncture tip descended at a rate of 100mm/min until the specimen ruptured. The maximum force was collected and recorded on Bluehill software and signifies the puncture resistance force of that specimen. The Bluehill software graphed this data as a function of force against penetration distance. Each specimen was tested 3-5 times using different samples and the average value of these trials corresponded to the value for the specimen.

5.2 Quantitative Test Results

Two quantitative tests were performed on both the animal tissue and synthetic material to compare results. Tensile tests were performed to gather data on the maximum force that the material can withstand, the ultimate tensile strength, strain at failure, elastic modulus, and compliance. The puncture tests gathered data on the puncture resistance force of these selected materials. The results of these tests are described in the following sections. The results from these tests were used to conduct a statistical analysis to compare the values of the animal tissue to the synthetic material. This allowed for a better understanding of what synthetic material would best mimic the organ or interest to be used during molding. Sections 5.2.1-5.2.2 discuss the results of each test individually.

5.2.1 Tensile Test Results

A tensile test was performed on the stomach, small intestine, colon, and mesentery of the porcine sample and EcoFlex 00-10 and EcoFlex 00-30 for the synthetic materials. These materials were tested to compare their values regarding the properties mentioned in Section 5.2 to determine which synthetic material would best mimic the organ of interest. This allows us to select a bio realistic material for the model. Table 12 below shows the averages and standard deviations of each material. Force vs. displacement and Stress vs. strain graphs are located in Appendix I for each trial.

Table 12: Tensile test results of the porcine sample and synthetic materials.

Sample	Sample Size (n)	Average Tensile F Max ± SD (N)	Average UTS ± SD (MPa)	Average Strain at Failure ± SD	Average Elastic Modulus ± SD (MPa)	Compliance
Porcine	4	58.33 ± 9.45	0.74 ± 0.21	55.60 ± 21.27	0.03 ± 0.02	55.00 ±

Stomach						33.17
Porcine Small Intestine	4	28.17 ± 13.51	6.03 ± 7.85	12.97 ± 3.92	0.49 ± 0.61	4.40 ± 2.64
Porcine Colon	4	15.83 ± 4.87	0.65 ± 0.39	20.40 ± 15.88	0.06 ± 0.04	33.32 ± 37.79
Porcine Mesentery	4	16.05 ± 3.3	0.49 ± 0.21	20.53 ± 7.6	0.04 ± 0.01	32.08 ± 13
EcoFlex 00-10	3	25.4 ± 2.1	1.41 ± 0.11	311.8 ± 7.5	0.0057 ± 0.0006	178 ± 19
EcoFlex 00-30	3	6.87 ± 1.6	0.38 ± 0.09	155 ± 31	0.0023 ± 0.006	444 ± 96

5.2.2 Puncture Test Results

Raw puncture resistance force was collected from Bluehill in N/mm and converted into N/m Matlab to be graphed. The force was determined as the first peak in the data, contrary to ultimate tensile strength which was the largest peak in the data. For the animal tissue, the raw puncture resistance force was normalized to account for the differences in thickness. The raw force was multiplied by the thickness of that sample and then divided by the average thickness of all the trials of that sample. The synthetic materials were all made in molds with a 3mm thickness, and therefore the normalization was not needed as the average was the same for each sample. The average and standard deviations of each material is recorded in Table 13 below and the puncture resistance force graphs can be seen in Appendix L.

Table 13: Average and standard deviations of the raw puncture resistance force and normalized puncture resistance force for animal tissue and synthetic materials.

Sample	Sample Size (n)	Average Raw Puncture Resistance Force ± SD (N)	Average Normalized Puncture Resistance Force ± SD (N)
Porcine Stomach	4	78.13 ± 0.99	78.4 ± 25
Porcine Small Intestine	4	19.6 ± 8.0	21.5 ± 12
Porcine Colon	4	18.1 ± 12	18.7 ± 14
Porcine Mesentery	4	18.9 ± 10.	17.4 ± 5.7

EcoFlex 00-10	3	22.6 ± 3.0	22.6 ± 3.0
EcoFlex 00-30	3	33.8 ± 4.2	33.8 ± 4.2

5.3 Qualitative Testing

Due to time constraints, qualitative tests were not performed with surgeons, however future qualitative tests will be done with surgical residents concerning their opinions on the casted organs. A survey should be conducted to determine the biorealism of the organs and how well the translatable skills are.

5.3.1 Qualitative Test Results

The qualitative test was not completed due to time constraints, but the results would include the opinions of current surgical residents on how bio realistic the casted organs are. This would ensure that the dimensions and feel of the organs mimic that of real human organs. Based on these results, further research should be done to determine a variety of suitable materials, as well as indicate the suitability of EcoFlex 00-10 and EcoFlex 00-30.

5.4 Material Verification

The results from the two quantitative tests were used to determine which synthetic material best mimics the organic animal tissue in order to maintain biorealism in the surgical trainer. The quantitative tests were analyzed using an ANOVA statistical analysis. As seen in Table 14, there was no significant difference in the mean values of elastic modulus of the porcine and synthetic materials as the p value was above the significance level of 0.05. For puncture resistance force, Table 15 depicts a p value below 0.05 in which a Bonferroni correction method test was conducted to compare the porcine organ values to the synthetic materials and determine where the significant difference is. Table 16 shows the p values from the Bonferroni correction method. From this table, it was determined that the stomach was significantly different from the colon and mesentery, as marked with an asterisk. For this analysis, n = 3 for synthetic materials and n = 4 and 5 for porcine tissue. From the p value results, final material selection was determined to be used for the stomach, small intestine, colon, and mesentery molds. Along with having similar mechanical properties, the materials selected must feel bio realistic to the residents. A qualitative test will be conducted to ensure the selected material qualifies for the desired organ.

Table 14: ANOVA statistical test of the elastic modulus.

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	0.7023	5	0.1405	2.13	0.111	2.81

Within Groups	1.121	17	0.06594	-	-	-
Total	1.823	22	-	-	-	-

Table 15: ANOVA statistical test of the puncture resistance forces.

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	11042.61	5	2208.52	11.22	6.66 x 10^{-5}	2.81
Within Groups	3346.71	17	196.87	-	-	-
Total	14389.32	22	-	-	-	-

Table 16: Bonferroni correction method test for puncture resistance forces.

	Puncture Resistance Forces P Values					
	Stomach	Small Intestine	Colon	Mesentery	EcoFlex 00-10	EcoFlex 00-30
Stomach	-	0.0067	0.0029*	0.0033*	0.014	0.027
Small Intestine	-	-	0.77	0.56	0.89	0.20
Colon	-	-	-	0.87	0.68	0.17
Mesentery	-	-	-	-	0.22	0.0077
EcoFlex 00-10	-	-	-	-	-	0.0072
EcoFlex 00-30	-	-	-	-	-	-

6.0 Final Design and Validation

6.1 Final Design

Previous sections described the three alternative designs that our team came up with, and from those designs, our team decided to move forward with Design 2. The team continued the development of the abdominal organs and adipose tissues of the right upper abdominal quadrant. The model organs were designed to be anatomically correct and mimic the mechanical properties of human organs. Each of the organs were manufactured individually and would eventually be placed inside of a box trainer. The organs were developed in InVesalius 3.1 and Vesalius 3D, their molds were created in Blender and Autodesk Meshmixer, and finally they were cast from materials whose mechanical properties were statistically similar to the true organs. The protocols for organ isolation, mold development, and organ casting can be found in the Appendix.

6.1.1 Final Design of the Organs

The first organ to be developed was the right kidney. With the help of Dr. Thomas Cataldo and his team at Beth Israel, our team isolated and created a mold for the kidney in InVesalius 3.1. The organ layers were traced from CT scans in this software, and a mold of it was created in Blender. The team smoothed the STL files and were able to print the molds on a Taz Lulzbot in the WPI Makerspace. The kidney was then cast from EcoFlex 00-30, since it had similar properties to the whole Ecoflex series, but did not require the extra softness that 00-10 provides, since the kidneys are simply in the background of the right colectomy and not the organ being operated on. In the future, a porcine liver sample should be tested to further research a more accurate material to cast the kidney from. Only the top section of the right kidney (Figure 20.) was molded because that is the only section that would be visible in the surgery. The dimensions of the cast right kidney are 86 mm in length, 83 mm in width, and 70 mm in thickness.

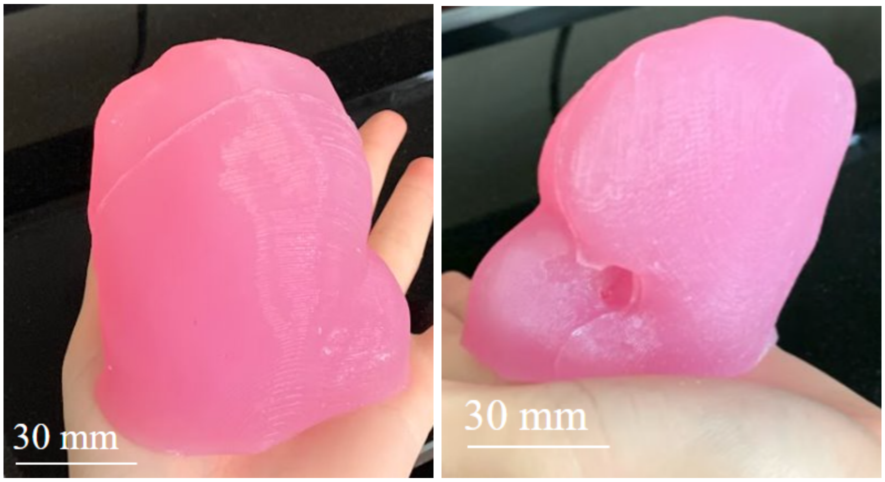

Figure 20. A front and side view of the fully cast right kidney in EcoFlex 00-30.

The liver was the second organ fully cast. It was modeled using the same techniques as the right kidney and was produced before a Vesalius 3D license was obtained. There were 3 different versions of this mold produced. Originally, the mold was not scaled up properly, so it was much too small to cast a dimensionally accurate liver. To ensure no silicone was wasted, no liver was cast from this mold. A second mold was printed at the correct scale, but when it was cast from silicone, the team realized that there was a large arm protruding from one half of the molds. This arm aimed to create a deep hole in the liver to resemble the space between the lobes. However, while providing anatomical accuracy, this arm made it incredibly difficult to remove the liver from the mold. A small cut in the silicone was made to be able to remove the organ. In the final version of the mold, the arm was removed and smoothed over. This ensured the proper removal of the organ and this hole was not necessary in terms of functionality inside the box trainer. Due to time constraints, this mold was not printed and cast from, but is available for future teams to access. The liver was cast from Ecoflex 00-10 because it was most similar to the liver's properties from our preliminary research, and the liver is more malleable and soft than the denser kidney. Like the kidney, the top of the liver was not included in this model because it would not be visible in the surgical field of a right colectomy. The bottom portion of the liver will provide a landmark to orient the surgeon, so a complete model was not necessary at this time. The full cast liver can be seen in Figure 21. The dimensions of the cast liver are 184 mm in length, 79 mm in width, and 117 mm in thickness.

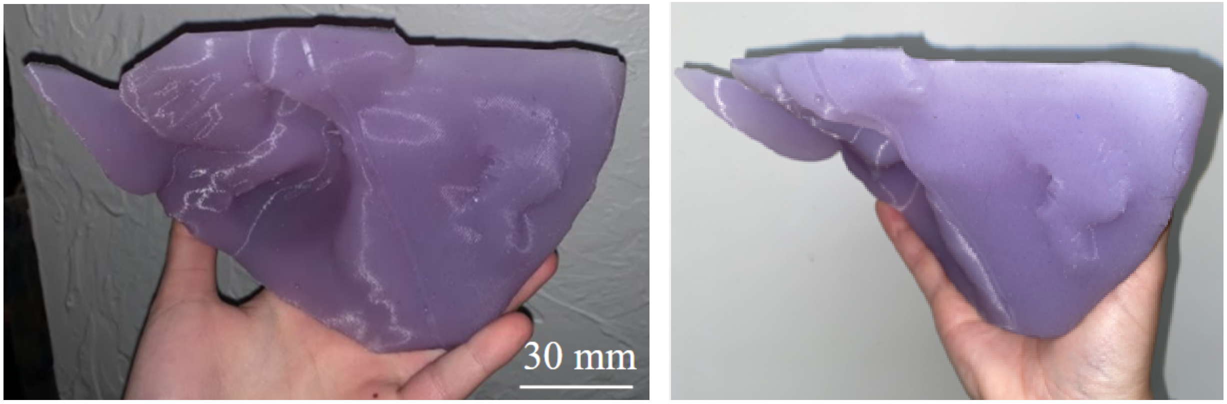

Figure 21. A back and side view of the fully cast liver in EcoFlex 00-10.

The gallbladder was the last organ successfully cast. Using the Vesalius 3D software and the extraction tool, the gallbladder was isolated from an individual's CT scans. The mold was created with the same process and was 3D printed in PLA. The gallbladder simply functions as an anatomical landmark for the surgeons, so its material properties did not need to be extremely accurate to the true organ. It was cast in Ecoflex 00-30 via injection molding. In reality, the gallbladder should have been created via hollow molding, but at this time the team was only prepared to create solid organs with our mold development process. In the future, the gallbladder should be created as a hollow organ with its respective fluids inside. The gallbladder can be seen in Figure 22 below. The dimensions of the gallbladder are 69 mm in length, 38 mm in width, and 35 mm in thickness.

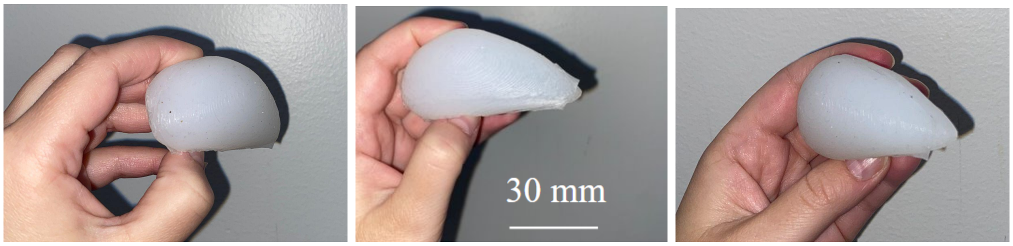

Figure 22. A front and two side views of the fully cast gallbladder in EcoFlex 00-30.

Finally, the large and small intestines were isolated from the same individual in Vesalius 3D. The small intestines can be seen in the middle picture of Figure 23, and the large intestine can be seen fully isolated on the right. Since the colon and full large intestine were the focus of this project, the team needed Vesalius 3D to create the most anatomically correct STLs of them. The Vesalius license was not obtained until more than ⅔ of this project were completed, so due to time constraints, the molds of the large intestine were not completed before the end of the term. When the team attempted to create a mold for the large intestine, the Blender software gave many errors when using the Boolean operator because the STL file was not completely solid. When exported from Vesalius, the model had many microscopic holes in it because of gaps in the stacked layers. If the team had more time, we would have solidified the large intestine file in XX and attempted to create the mold again. Future teams can access the small and large intestine STL files and continue our work on their development. Additionally, with the mechanical properties gained from our testing, they can select to cast them from Ecoflex 00-10, 00-30, or a new material that matches the property ranges previously mentioned.

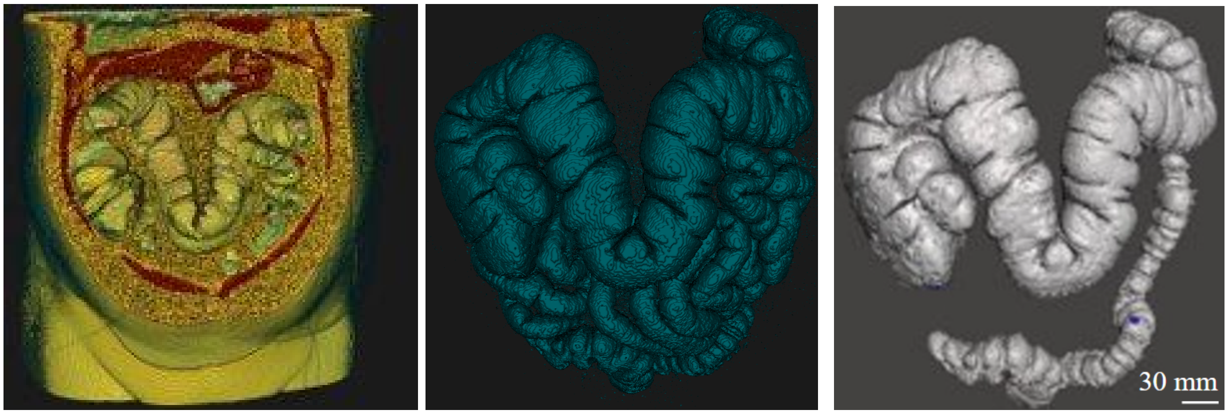

Figure 23. Final design of the colon and small intestine created in Vesalius 3D.

6.1.2 Final Design of the Box Trainer

The fully cast organs were then placed inside of a box trainer for better visualization of the model. The box trainer our team used was obtained from Dr. Cataldo at Beth Israel and can be seen in Figure 24 below. The organs were placed in their anatomically correct positions and we viewed through the camera on a laptop. The laparoscopic tools were placed inside the trainer by the team and were practiced for a better understanding of how the model would work. In the future, all of the cast organs should be placed inside the trainer and given to surgical residents and attendings to ask for feedback on.

Figure 24. The laparoscopic box trainer that the final design will be placed inside of.

6.2 Validation

To create the organs mentioned in section 6.1, the team designed a process that could be used to create organs from any individual. This process was utilized in every step of the organ creation process, and the final synthetic organs prove that this process allowed us to fulfill our ranked objectives and original goal. The standard manufacturing process created by our team can be found in Figure 25.

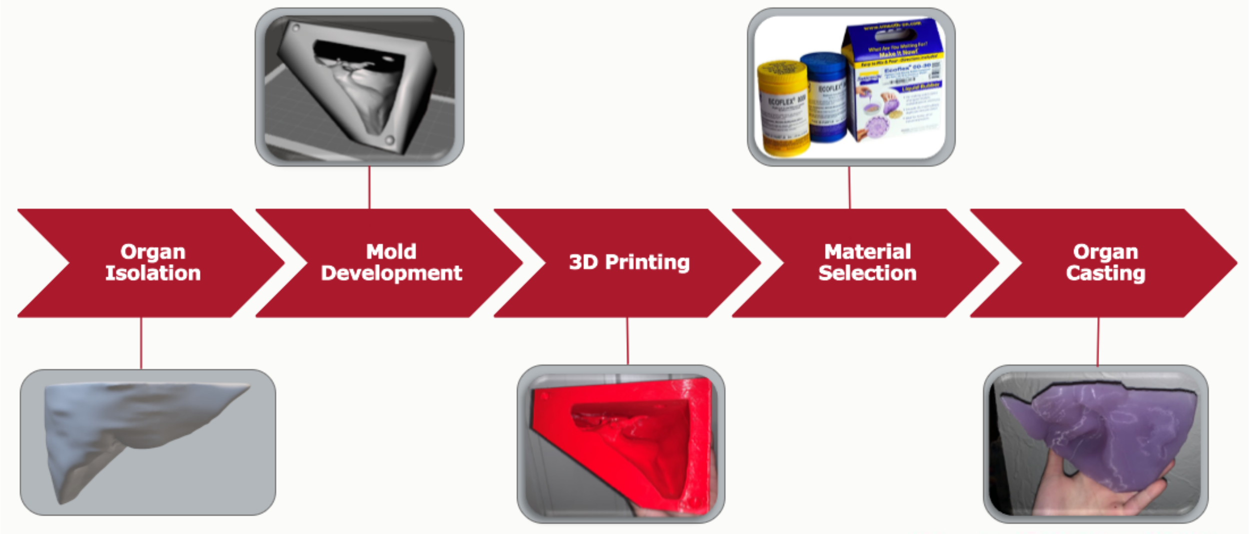

Figure 25. Custom manufacturing process that begins with organ isolation and ends with organ casting to create a fully synthetic organ. The process is aided with images from the progression of the liver.

Beginning with organ isolation, the team started with the free software, invesalius 3, which uses 2D planes from CT scans to create a 3D volume. To isolate an organ, you must manually trace the outline of it in each frame. Isolation in this software is incredibly time-consuming, taking over six hours to make half of one model, and it creates a 3D model with extremely visible layers. After more research, our team found the software Vesalius 3D, which creates a full 3D rendering of an individual's body from CT scans. This software has a lot of amazing tools for visualization and isolation, and we focused on using the extraction tool. We were able to receive further training on this software's tools from Geoffrey Wielingen, one of the creators of the software. This tool allowed us to cut around and remove tissue from the rendering until only the desired organ was left. We were now able to isolate organs and export them as an STL file in under two hours.

Mold development took place in the software Blender. Blender is a 3D computer graphics software that allows us to import our STL files from Vesalius 3D and converts them to meshes which allows for easier manipulation. To create a mold, we first put a cube around it. From there, we used a Boolean operator to create an inverse of the organ inside the box. Shaping the outside of the mold took place to reduce excess material and we also added holes in the top to allow the casting material to go in and air bubbles to come out during solidification.

Once we had our mold files, we could then 3D print them. We printed them on a Taz Lulzbot with PLA. We scaled them up appropriately so that the final product would be dimensionally accurate. We verified its dimensionality back to Vesalius 3D and used the length and widths of the organs from the CT scans, which hold their true human dimensions.

Next was material selection; we needed to find materials that were suitable for each organ, so we went to Beth Israel and gowned into the operating room to watch a surgical procedure. While this was useful to see the laparoscopic view and how the tissues were manipulated in surgery, we still needed to gain a better understanding of what the organs felt like and needed to gain further information in terms of material properties. To do this, we obtained a porcine gastrointestinal tract and cut samples into standard sizes for mechanical testing. Synthetic materials were also prepped for tensile and puncture testing.

The data from the mechanical testing was analyzed and used to determine which materials the organs could be injection molded from. The molds were filled with the appropriate material and were left to cure. After some processing, the team was left with a dimensionally and mechanically accurate synthetic organ.

6.3 Impact Analysis

The following sections discuss the impact of our surgical trainer in the context of economics, environment, societal, political, ethical, health and safety, manufacturability, and sustainability.

6.3.1 Economic Analysis

The potential economic impact of a cost effective and reusable bio-realistic trainer is that it would aid in the improvement of healthcare. The product would have great impact in the training of colorectal surgeons, as it would allow for increased simulate training for surgeons and as a result, decreased risk for patients. By adopting this simulated training as an addition to current training, hospitals would be able to train more residents and surgeons over a shorter period of time. This may be able to reduce the hospitals spending on training for colorectal surgeons, however a full analysis of spending and costs would need to be conducted. A bill of materials for the project can be found in Appendix O.

6.3.2 Environmental Impact

The organs in this model are designed to be reused over time until they are damaged. This means that it is not expected for there to be a significant environmental impact as the organs will not be consistently thrown out. With this in mind, when the organs are damaged they will need to be disposed of. While silicone elastomers cannot be recycled commercially, there are different processes in which they will eventually be able to be recycled [47]. In terms of options available now, some companies are on the forefront of this recycling process for silicone. For example, there are options in which you can send in used or old silicone products to be recycled and repurposed into alternative silicone products [48]. While this is something that is not easily available to all of those who would be using the model, this gives hope that in the near future options for silicone recycling will become a more standardized option. As this process becomes more standardized, the overall environmental impact will diminish to almost nothing as long as those using our product follow the recommended recycling of silicone materials.

6.3.3 Societal Influence

This model can be used in various settings to train abdominal surgeons. It will create more efficient training schedules and better outcomes for laparoscopic surgery. The biorealism and low cost of the model allows the trainer to be used by future surgeons of many different socioeconomic backgrounds. In the future, this model should be outsourced to low-income countries to serve as a training tool for surgeons to bridge the learning gap of unfamiliar equipment.

6.3.4 Political Ramification

The design, development, and manufacturing of this surgical trainer would have no political ramifications. The product would still have a global impact in terms of surgical training. The low cost would make the trainer available to hospitals all around the world, and the ability to reduce training in the operating room to observation only. The use of these trainers would allow for multiple rounds of practice before surgeons perform procedures on live patients. The reusability of the product would allow for these several rounds of practice as the parts are reusable and replaceable. Over time if parts become damaged they can be ordered and replaced at a low cost as opposed to purchasing entirely new models. Due to the low user cost of the product, the product would be accessible to hospitals around the world and would serve as a tool for training residents and increasing patient safety.

6.3.5 Ethical Concerns

To gather material properties outside of literature values, the team had to conduct tensile and puncture tests on porcine tissue collected from a pig gastrointestinal tract. The pig must be no longer living to perform these tests and therefore must be slaughtered prior to testing. In order to reduce the ethical concerns, our team gathered this tissue from a pig that was already scheduled to be slaughtered at a butcher shop. The organs that we obtained were not being used at the shop and therefore would have been put in waste otherwise. Performing tests on the porcine tissue allowed the team to gather insightful data regarding organ material properties that correlate to the human body.

Another ethical concern that arose when doing this project was the use of patients CT scans. The team tried to isolate abdominal organs from one patient's CT scans in order for them to correctly fit in the abdomen, but sometimes specific organs were difficult to isolate and therefore another CT scan had to be used. A public resource, the Cancer Imaging Archive, was used to obtain anonymous CT scans. Patient anonymity was maintained when using these CT scans.

6.3.6 Health and Safety Issues

The model does not have any issues regarding health and safety. This model actually reduces risk in the training of colorectal surgeons. Residents are able to train in a simulated environment as a transition to a live patient. The ability to use the model for repetitive skill training should reduce mistakes and patient risk. The organs included in the model are pre-made and will be sent directly to users to minimize set-up. The model requires no need for sterilization as it will be utilized outside of the operating room.

6.3.7 Manufacturability

This model has a higher potential of being manufactured in the future. The team created original 3D models of the kidney, liver, small intestine, and the colon. Future iterations of this project will need to do more research in areas of material selection for the various organs using our measured properties. Casting the organs from suitable materials will be imperative for the production of this model in a manufacturing setting. In terms of manufacturing techniques, injection, rotational, and compression molding should be used further to create organs that are solid and hollow. Selecting the most optimal technique for each organ will decrease the production time. This project has the long-term goal of manufacturing the trainer in whole, and future teams, in collaboration with BIDMC, should create a trainer that can be easily, quickly, and inexpensively manufactured in larger quantities.

6.3.8 Sustainability

The organs designed through the standardized process set forth by the team are to be made out of silicone elastomers. Silicone elastomers have a long shelf life and are able to be reused multiple times. The box trainer in which the organs will be encased allows for no additional storage or unnecessary packaging as the organs can be stored directly in the trainer. In addition the device and organs are designed to last a long time with minimal replacement pieces making the overall product sustainable.

7.0 Discussion

In this section, the final design of our model will be analyzed based on the following objectives: translatable skills, bio realistic, cost effective, reusability, ease of assembly, and highly manufacturable.

7.1 Analysis of Translatable Skills

For the model to provide translatable skills, the model must be able to fit comfortably inside a box trainer for surgical manipulation, be compatible with common surgical instruments, as well as provide a realistic environment that mimics tissue responses to the manipulation. Our standard manufacturing process provides a 1:1 organ to model ratio ensures that organs created are realistic but can be fit inside a standard box trainer. In addition, the organs are placed inside a Laparo Advance surgical box trainer, which allows for compatibility with a variety of laparoscopic surgical instruments as well as a camera view that allows for a more realistic operating room environment. As a result of time constraints, and the need to focus on 1:1 dimensionally accurate organs, human tissue responses to manipulation could not be created in this iteration of the model. Following iterations would look to determine materials that would be able to provide these responses.

7.2 Analysis of Bio Realistic

In order to be bio realistic, the model must have 1:1 organ to model ratio and the organs must exhibit similar mechanical properties to that found in the human body. The manufacturing process of the organs allows the organs to be made from CT scans of the same individual and therefore be dimensionally and anatomically correct as well as fit together. This also allows for sized organs to be made but still fit together in the trainer. The elastic moduli and puncture forces of the stomach, small intestine, large intestine, and mesentery were found from porcine tissue. Materials with similar values can be used to cast these organs and mimic these properties. Due to time constraints, we were unable to find materials for every organ, but started a process to determine whether or not a material is suitable for each organ. The next iteration would determine materials suitable for each organ, mold and cast more organs of the right upper quadrant, and conduct testing on further organs to determine the elastic moduli and puncture resistance force.

7.3 Analysis of Cost Effective

For the cost effective objective, the initial cost of the model should not exceed $1,000 and the cost of replacement organs must be less than $1,000 per year. Some organs will be untouched and therefore will not need to be replaced as often. Standard molds will also decrease manufacturing costs. Table O shows the cost breakdown of the manufacturing process.

7.4 Analysis of Reusability

For the model to be practiced on more than once, there must be reusable organs and the replacements of organs once they are damaged. Since the organs will be replaced after damage, they must be inexpensive and easy to cast. Residents will be able to train on a single model multiple times to gain more hands-on experience.

7.5 Analysis of Ease of Assembly

During this project, we were only able to fully cast three organs (right kidney, liver, and gallbladder), however, these organs can still simulate the assembly process of a full box trainer. These organs can be placed inside of the box trainer in under one minute, suggesting that the assembly of a trainer with fewer than ten organs would take under the 5-10 minute mark that we determined as our sub objective of ease of assembly. In addition to time effectiveness, the model also has an easy assembly process. The incorporation of a commercial box trainer requires training on the use of that particular trainer, in regards to the visualization of the camera and the insertion of the laparoscopic tools. While this training does take time, although not included in the assembly time, it is not a difficult process to learn. Placement of the organs inside of the trainer simply entails researching a picture of abdominal organs and placing them in such a way that mimics the anatomical positioning of the organs. In the future, if a mat is created that highlights exactly where each organ should be placed, this process will be even simpler.

7.6 Analysis of Highly Manufacturable

Ensuring our model was highly manufacturable, we kept reproducibility, standardized molds, and clear manufacturing techniques in mind, all which were obtained. The molds created for each organ were printed in PLA. They can continue to be used many times to cast organs from various materials, provided that they are cleaned properly. The continued use of these molds streamlines the process of creating large quantities of organs. The 3D models of the molds can also be used to create molds of a different, more durable material that can be used to speed up the curing process of the materials by adding heat. Lastly, clear manufacturing techniques were obtained by providing future teams with numerous videos and pictures of our manufacturing process, along with instruction manuals for each step in various softwares. Overall, this project achieved the highly manufacturbale objective and set up future teams for an easy transition to create more models.

7.7 Limitations

The overall goal of the project is to design and manufacture all organs in the upper right abdominal quadrant. While the team was able to develop and complete a standardized process to make synthetic organs, not all organs were able to be made due to time constraints. With this new process, future iterations of the organs for the device should be able to be made much faster.

In addition, the team was tasked with learning various different softwares during the design stages for creation of these standardized molds. In doing so a lot of time was spent finding softwares, learning them, and not being able to use them. While it is understood that this was part of the design process, the team could have spent more time in making the organs for the model if the ideal software had been used from the beginning. Future teams will be able to use the training provided by this year's team to be able to isolate and produce organs much earlier on in the year.

Validation testing was not able to be completed with surgical residents as recommended due to the fact that not all organs were made to be placed in the trainer. With this it was understood that the trainer would not mimic a realistic environment. Future iterations of the organs will be placed in the trainer and qualitative testing will be able to be conducted with residents practicing and giving feedback.

8.0 Conclusions and Recommendations

8.1 Conclusion

Our phantom organs allow residents to practice laparoscopic techniques without risking patient safety. The organs are reproducible and can be made cost effectively through the standardized manufacturing process. They offer a bio realistic training environment of the right upper abdominal quadrant for residents to use in training. This device should be implemented in the training protocol for new residents as it supplements their learning by allowing them to make mistakes they can learn from in a simulated environment.

The measured mechanical properties of the porcine tissue indicate that the chosen synthetic materials, EcoFlex 00-10 and EcoFlex 00-30, are acceptable to use for synthetic organs. Based on the statistical test performed, EcoFlex 00-10 and EcoFlex 00-30 can be used for the colon, small intestine, stomach, and mesentery in terms of elastic modulus. For puncture resistance force, EcoFlex 00-10 and EcoFlex 00-30 can be used for all organs however, the same material cannot be used for the stomach that is used for the colon and mesentery.

8.2 Recommendations

Our team has developed recommendations for future iterations. These recommendations include improving on the biorealism of the organs, incorporating more contents of the abdomen into the final design, conducting further mechanical testing, constructing an entire abdomen, and conducting validity tests with residents to gain feedback.

To improve on the biorealism of our current model, we recommend future teams conduct more material testing with various selections. They should use our data from the porcine tissue to compare to more synthetic materials to ensure they closely relate to each specific organ. Since EcoFlex 00-10 and EcoFlex 00-30 are sufficient for the stomach, colon, mesentery, and small intestine for both the elastic modulus and puncture resistance force, further materials should be tested on to have more specific conclusions. Also, more organs should be casted so that the right upper quadrant has all of the organs involved in the right colectomy. Along with more organs, future iterations should incorporate other aspects of the abdomen including adipose tissue and vasculature to mimic bleeding when mistakes are made.

Another recommendation our team developed was to make an entire abdomen to be trained on in a box trainer. While there are full abdomen trainers on the market, they are not used in a box trainer to practice laparoscopy. It is important that the contents of the entire abdomen fit into a box trainer appropriately, as they are in a human abdomen. Having an entire abdomen would better mimic the environment in an operating room, as our model only focuses on the organs of the right colectomy. It would also allow for the training of other laparoscopic procedures beyond a right colectomy.

Lastly, further validity tests and surveys should be conducted to ensure the synthetic organs accurately represent real human abdominal organs. Qualitative data should be obtained via surveys and interviews of surgical residents and attendings to determine how realistic the model is and how translatable the skills learned on it are to true surgery. Due to time constraints, our team was unable to conduct validity tests with current residents, but these tests would better determine which objectives were met and how well they were met to make improvements. These validity tests should be continuous, as more skills are learned and residents gain more practice. A long term goal of this project is to bring the device to production for sale to surgical residency programs around the globe. The continued development of this device will improve training programs and patient outcomes.

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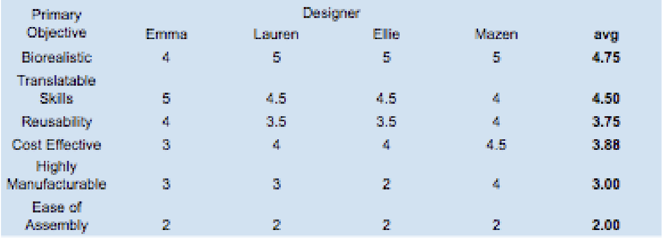
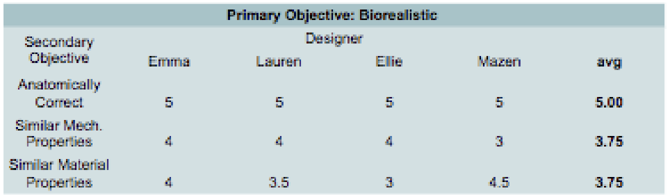
Appendices

Appendix A: Designer Stakeholder Objective Ranking

1 = least important
5 = most important

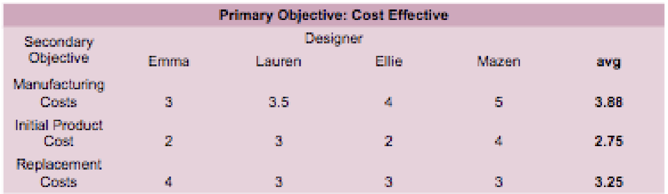


Primary Objective	Designer Emma	Lauren	Ellie	Mazen	avg
Biorealistic	4	5	5	5	**4.75**
Translatable Skills	5	4.5	4.5	4	**4.50**
Reusability	4	3.5	3.5	4	**3.75**
Cost Effective	3	4	4	4.5	**3.88**
Highly Manufacturable	3	3	2	4	**3.00**
Ease of Assembly	2	2	2	2	**2.00**



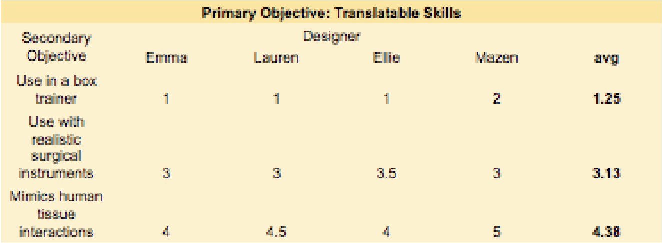
Primary Objective: Biorealistic

Secondary Objective	Designer Emma	Lauren	Ellie	Mazen	avg
Anatomically Correct	5	5	5	5	**5.00**
Similar Mech. Properties	4	4	4	3	**3.75**
Similar Material Properties	4	3.5	3	4.5	**3.75**



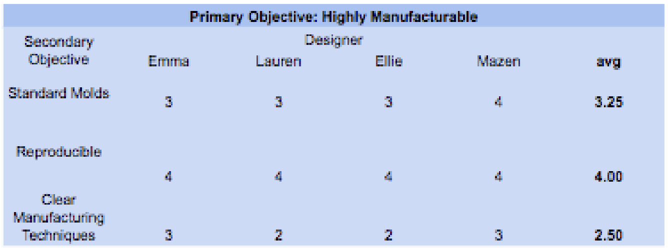
Primary Objective: Cost Effective

Secondary Objective	Designer Emma	Lauren	Ellie	Mazen	avg
Manufacturing Costs	3	3.5	4	5	**3.88**
Initial Product Cost	2	3	2	4	**2.75**
Replacement Costs	4	3	3	3	**3.25**



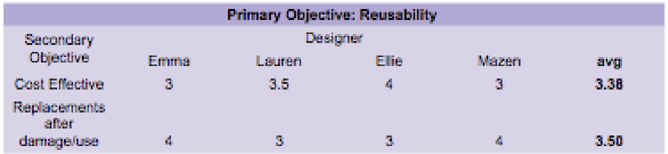
Primary Objective: Translatable Skills

Secondary Objective	Designer Emma	Lauren	Ellie	Mazen	avg
Use in a box trainer	1	1	1	**2**	**1.25**
Use with realistic surgical instruments	3	3	3.5	3	**3.13**
Mimics human tissue interactions	4	4.5	4	**5**	**4.38**



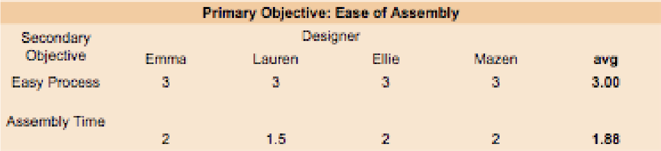
Primary Objective: Highly Manufacturable

Secondary Objective	Designer Emma	Lauren	Ellie	Mazen	avg
Standard Molds	3	3	3	4	**3.25**
Reproducible	4	4	4	4	**4.00**
Clear Manufacturing Techniques	3	2	2	3	**2.50**



Primary Objective: Reusability

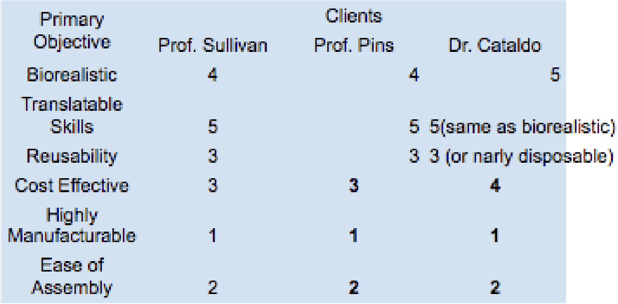
Secondary Objective	Designer Emma	Lauren	Ellie	Mazen	avg
Cost Effective	3	3.5	4	3	**3.38**
Replacements after damage/use	4	3	3	4	**3.50**



Primary Objective: Ease of Assembly

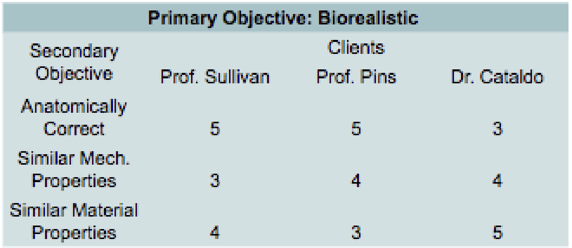
Secondary Objective	Designer Emma	Lauren	Ellie	Mazen	avg
Easy Process	3	3	3	3	**3.00**
Assembly Time	2	1.5	2	2	**1.88**

Appendix B: Client Stakeholder Objective Ranking



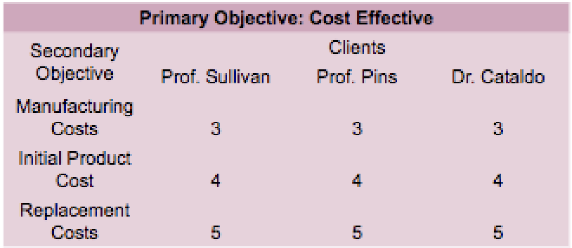
Primary Objective	Clients Prof. Sullivan	 Prof. Pins	 Dr. Cataldo
Biorealistic	4	4	5
Translatable Skills	5	5	5(same as biorealistic)
Reusability	3	3	3 (or narly disposable)
Cost Effective	3	**3**	**4**
Highly Manufacturable	1	**1**	**1**
Ease of Assembly	2	**2**	**2**

1 = least important
5 = most important



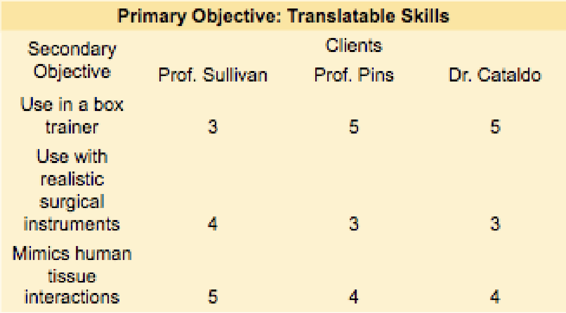
Primary Objective: Biorealistic

Secondary Objective	Clients Prof. Sullivan	 Prof. Pins	 Dr. Cataldo
Anatomically Correct	5	5	3
Similar Mech. Properties	3	4	4
Similar Material Properties	4	3	5



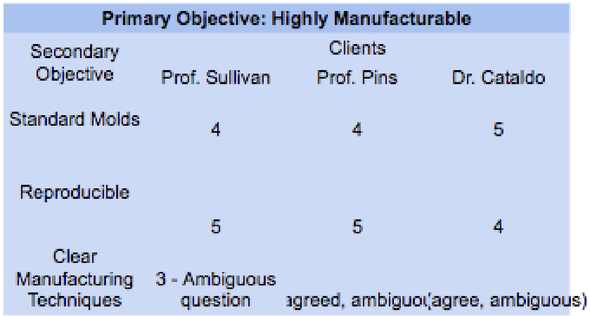
Primary Objective: Cost Effective

Secondary Objective	Clients Prof. Sullivan	 Prof. Pins	 Dr. Cataldo
Manufacturing Costs	3	3	3
Initial Product Cost	4	4	4
Replacement Costs	5	5	5



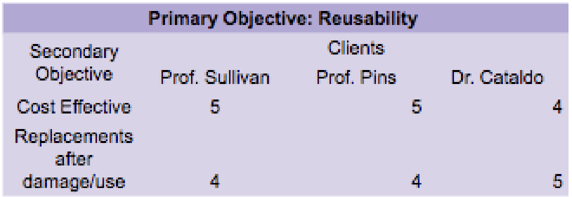
Primary Objective: Translatable Skills

Secondary Objective	Clients Prof. Sullivan	 Prof. Pins	 Dr. Cataldo
Use in a box trainer	3	5	5
Use with realistic surgical instruments	4	3	3
Mimics human tissue interactions	5	4	4



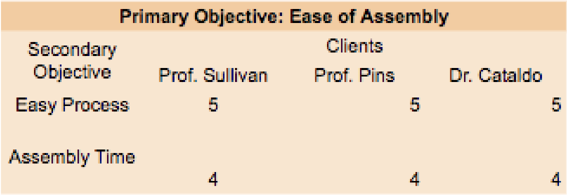
Primary Objective: Highly Manufacturable

Secondary Objective	Clients Prof. Sullivan	 Prof. Pins	 Dr. Cataldo
Standard Molds	4	4	5
Reproducible	5	5	4
Clear Manufacturing Techniques	3 - Ambiguous question	agreed, ambiguo	(agree, ambiguous)



Primary Objective: Reusability

Secondary Objective	Clients Prof. Sullivan	 Prof. Pins	 Dr. Cataldo
Cost Effective	5	5	4
Replacements after damage/use	4	4	5

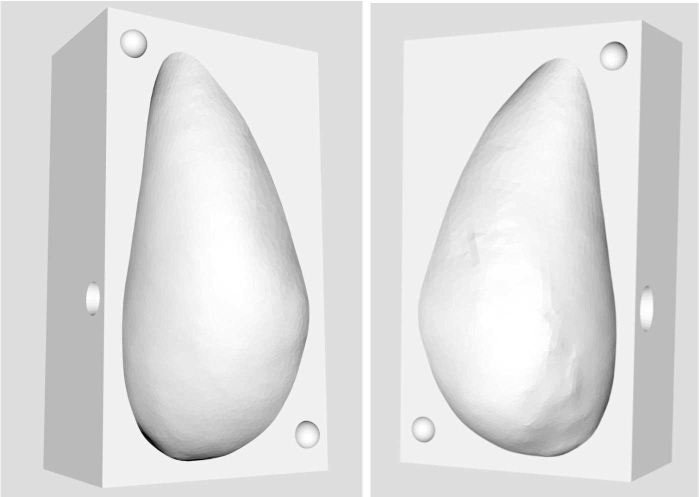


Primary Objective: Ease of Assembly

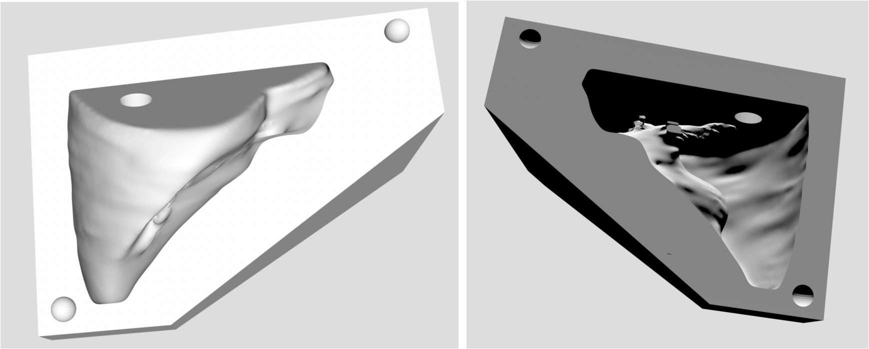
Secondary Objective	Clients Prof. Sullivan	 Prof. Pins	 Dr. Cataldo
Easy Process	5	5	5
Assembly Time	4	4	4

Appendix C : Organ Mold STL files

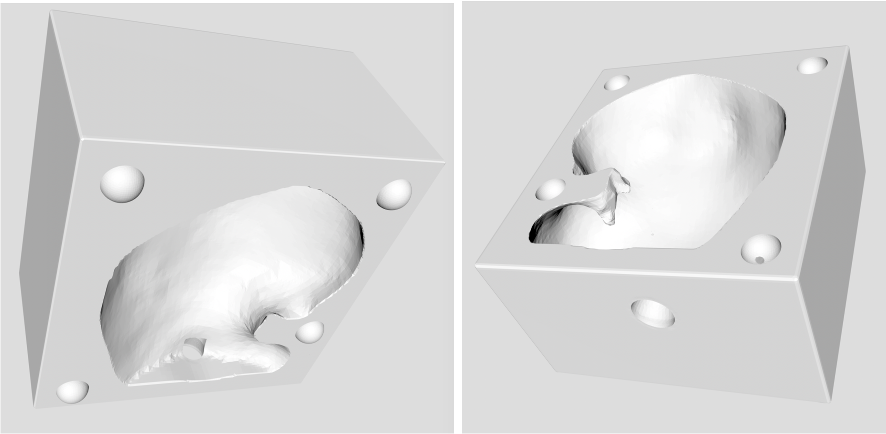
Gallbladder molds



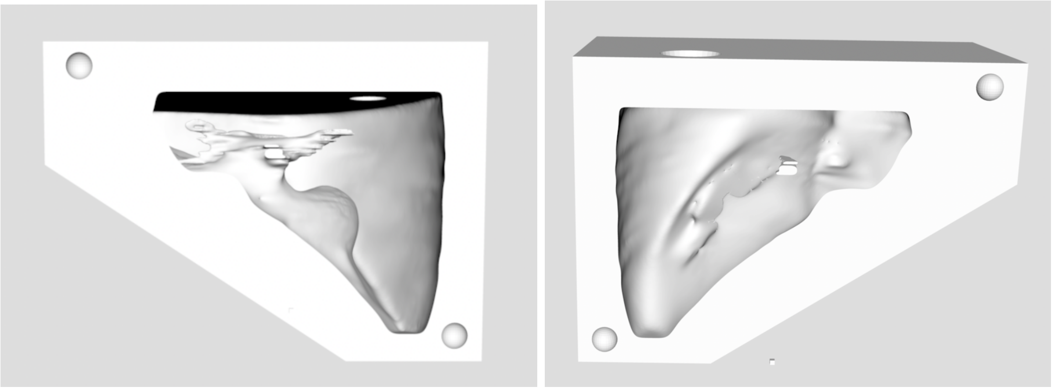
Liver molds



Kidney molds



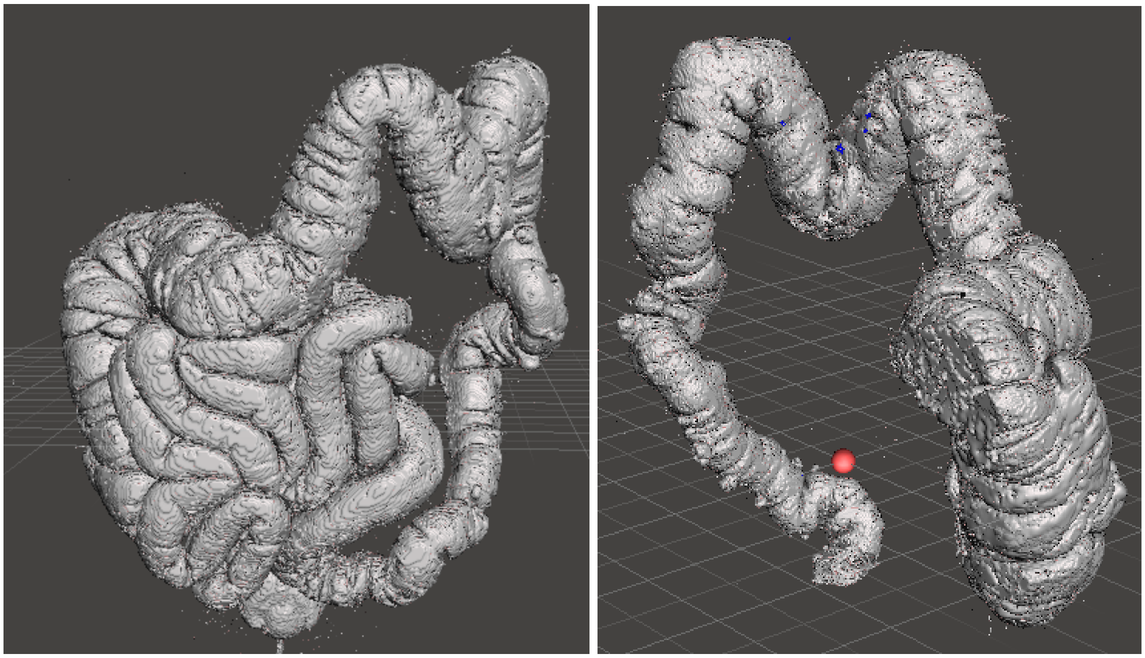
V2 Liver mold



Appendix D: Organ Isolation in Vesalius

Please contact the team or advisors for an instructional video on the organ isolation process in Vesalius 3D.

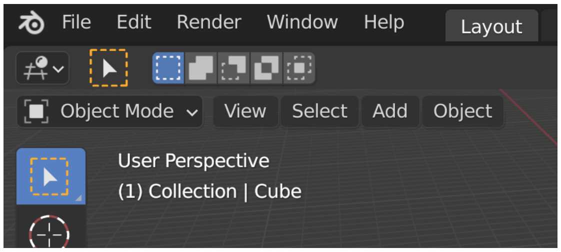
Large and small intestine



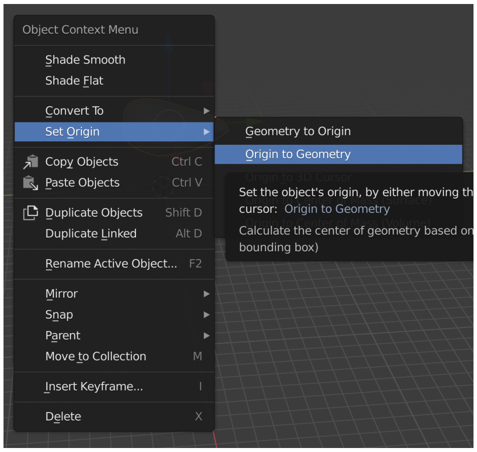
Appendix E: Mold Creation in Blender

A standard process for the creation of injection molds has been established through the utilization of an animation software called Blender. This software allows the team to import STL files of different organs and manipulate them in a mesh format to create the molds. The use of boolean modifiers to create sections and fittings is used, and the process will be described below:

1. Open Blender 3D Modeling Software to begin the creation process
2. Next, navigate to file→ import → select and import the desired STL file to be molded.
3. Once the desired file has been imported, make sure the software is in "object mode" in the upper left corner

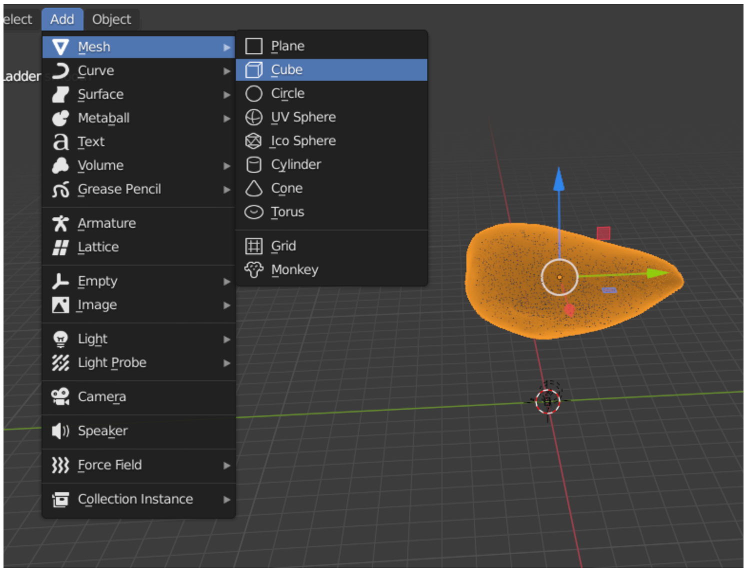


4. Next, the origin for the object needs to be centered to allow for easier maneuvering of the object. Right-click on the imported object, set origin, then set origin to geometry.

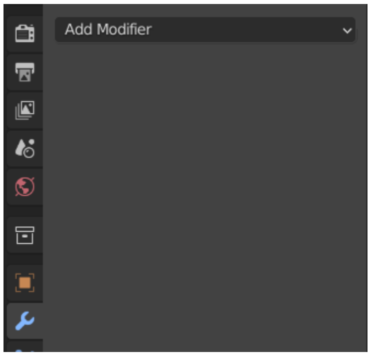


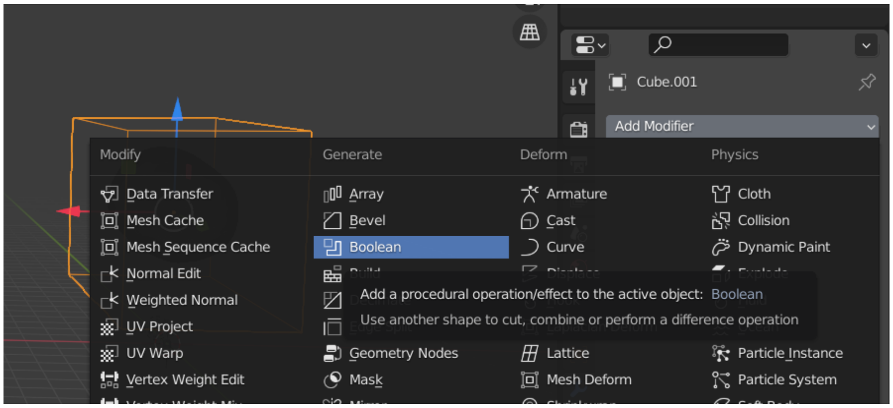
Set the object's origin, by either moving th
cursor: Origin to Geometry
Calculate the center of geometry based on
bounding box)

5. The outside of the mold now needs to be created. To do this, a cube mesh will be added to surround the object to be molded. Navigate to Add →Mesh→Cube.To resize the object use the shortcut 'S' to make the cube mesh larger than the STL file.



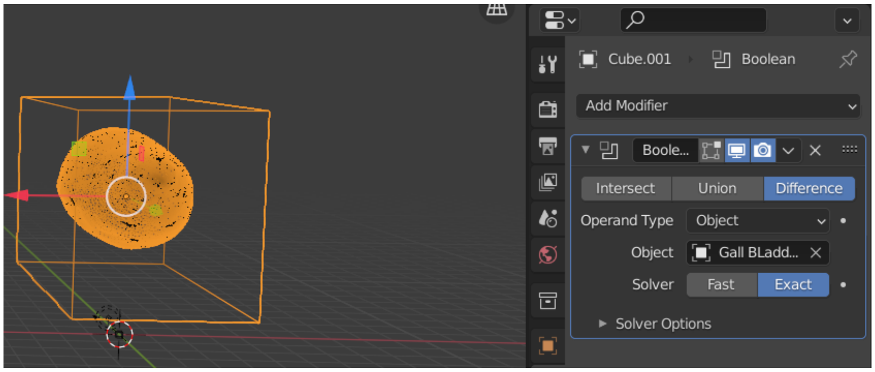
6. Next, we will need to create an inverse of the object to be molded within this larger cube. To do this, navigate to the modifiers tab→ add modifier→boolean modifier. Choose the difference option within the boolean modifier and apply the modifier to the outside cube, selecting the STL file as the object to be modified.





Add a procedural operation/effect to the active object: Boolean

Use another shape to cut, combine or perform a difference operation

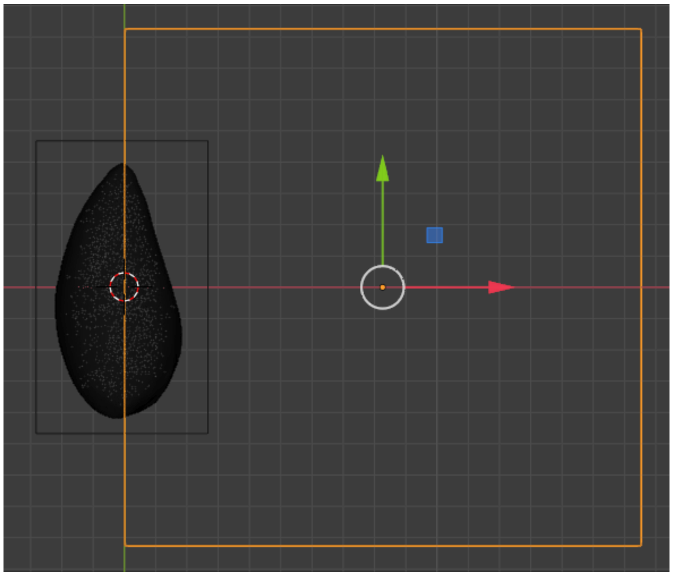


Operand Type: Object

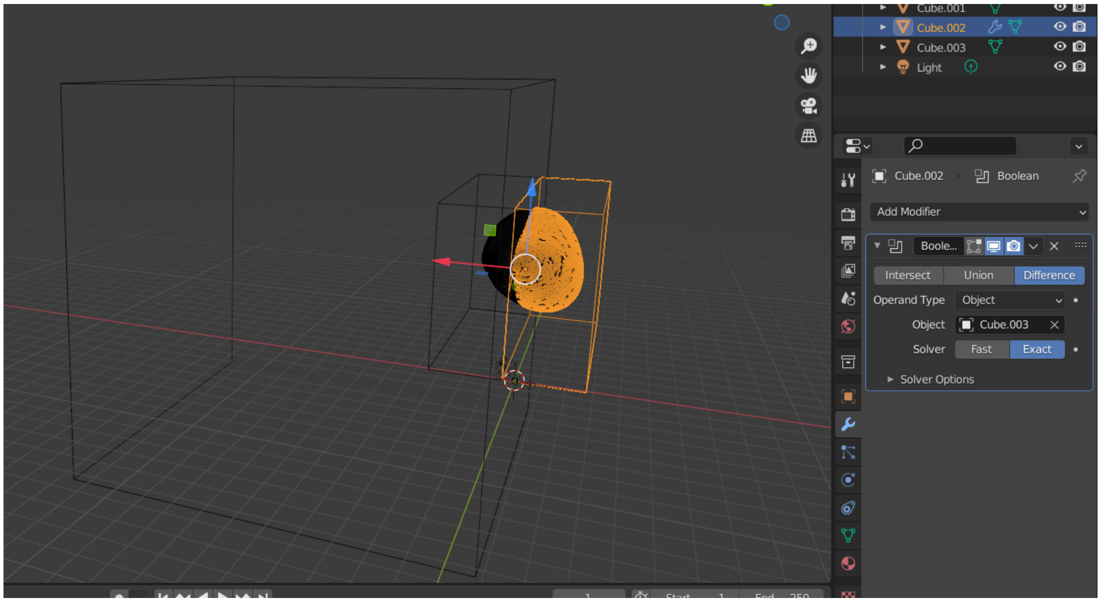
Object: Gall BLadd...

Solver: Exact

7. Once the boolean modifier has been applied, the original STL file can be deleted.
8. Next, create a duplicate of the modified cube using the shortcut “Shift + D” and overlay it over the original cube.
9. Add a new cube mesh that is larger than the original and duplicated objects, and place it to cut directly through the middle of the two duplicated cubes. This will be used to split the object in two.

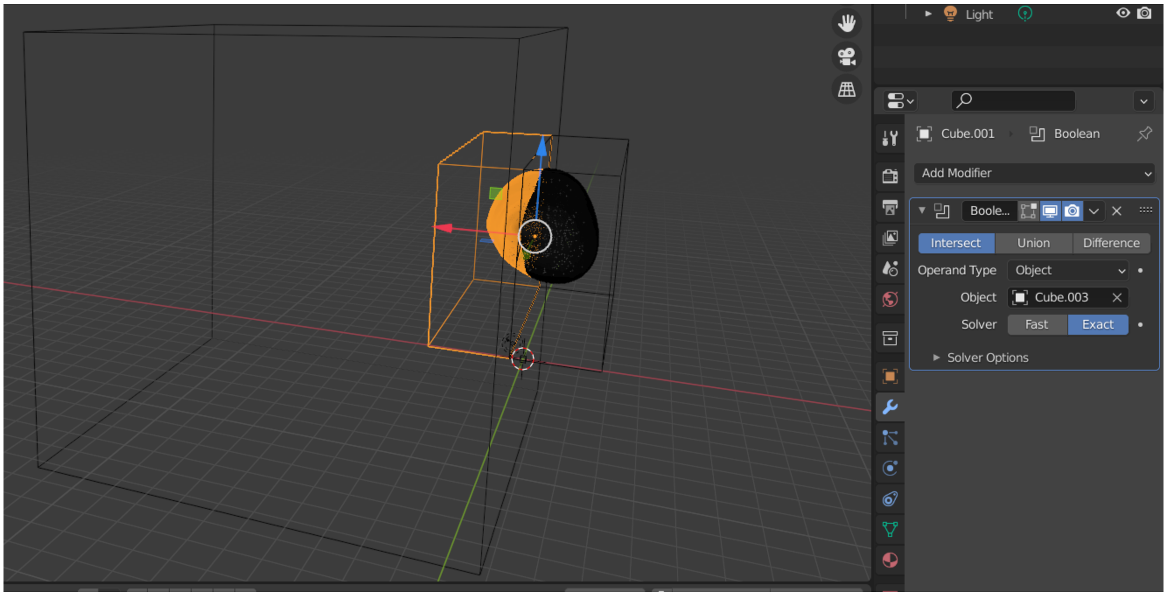


10. Select one of the duplicated cubes, and apply a boolean. Select difference within the boolean modifier tab, and choose the larger cube splitting the object. If done correctly, one half of the object should be highlighted. This will split one of the duplicated objects.



Operand Type: Object
Object: Cube.003
Solver: Exact

11. Select the other half of the object, apply a boolean modifier and choose the intersect option. The other half of the object should become highlighted. Use the large outer cube as the object to apply the modifier with. This will give you two separate objects, each ½ of the mold being created.

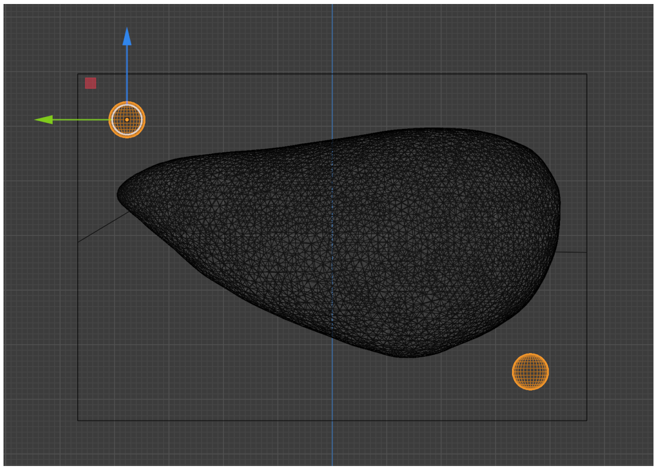


Operand Type: Object

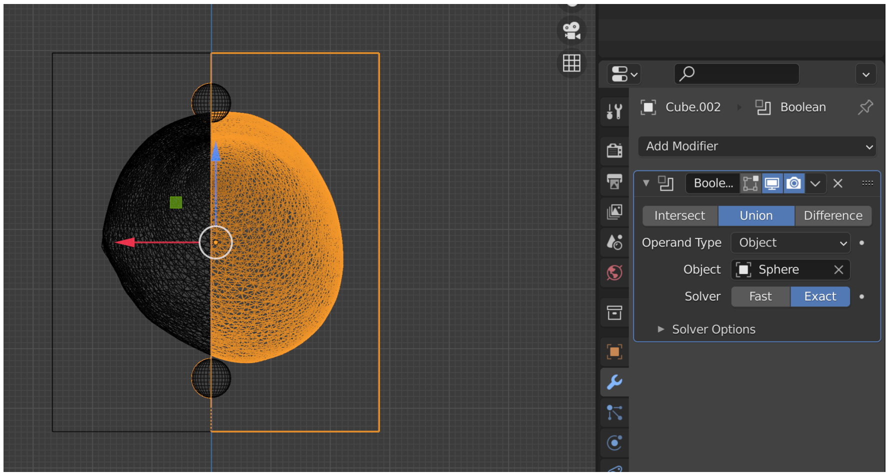
Object: Cube.003

Solver: Exact

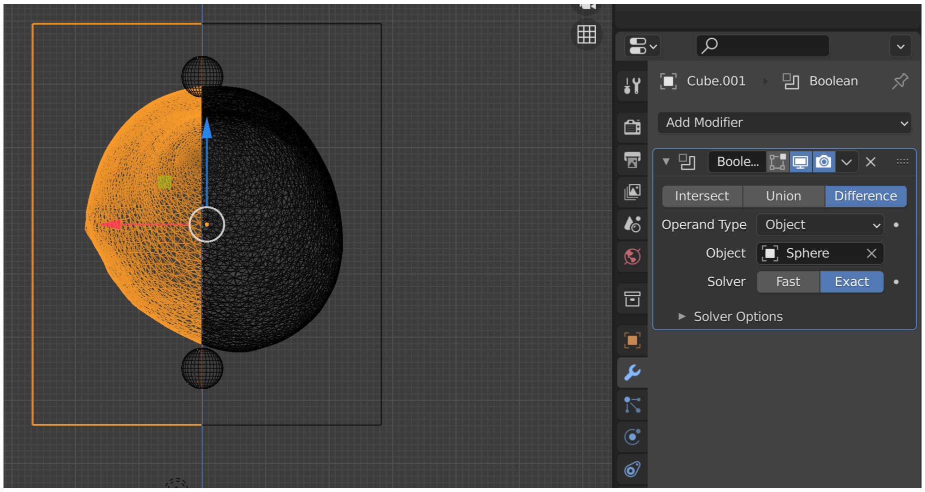
12. The larger cube splitting the mold can now be deleted.
13. Next, small fittings need to be created to line up the objects when molding is being conducted. To do this, two UV sphere meshes will be added by navigating to Add→Mesh→UV Sphere, and they should be lined up along the axis where the objects are split. The two spheres will then be placed in opposite corners of the mold. The sphere will then be joined, as to allow them to be manipulated as one object through the shortcut “Ctrl + J”.



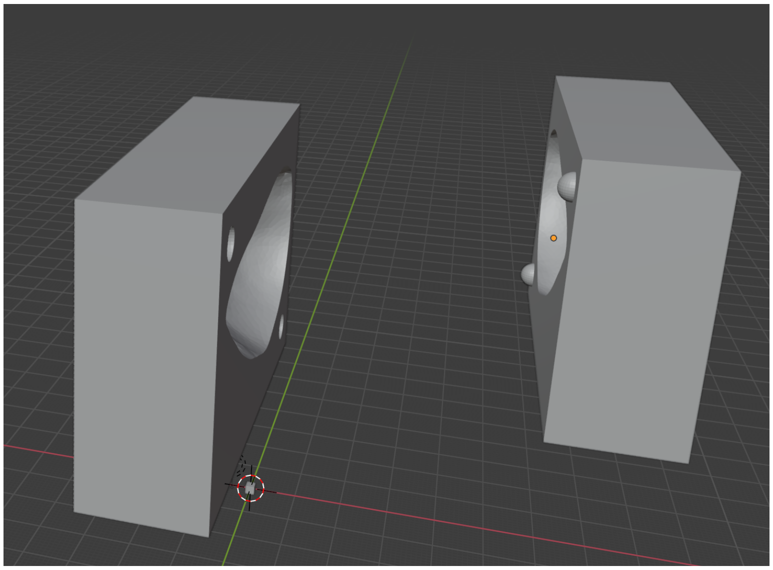
14. Once these are lined up correctly, another boolean modifier will be applied to each half of the boxes. Select on half and choose to apply a boolean modifier. The boolean type will be a union, select the spheres as the object and click apply.This should join half of the sphere to the face of one of the halves.



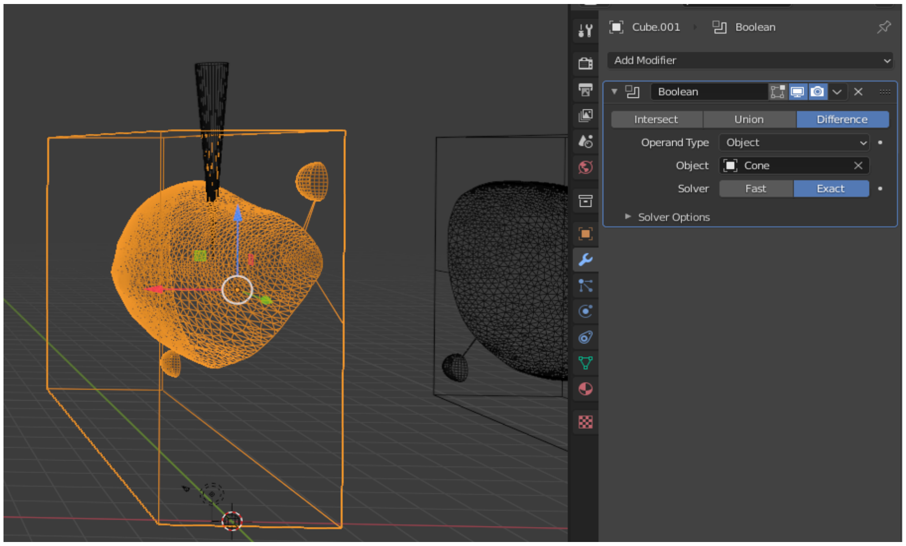
15. Next, select the other half of the mold, navigate to the modifiers tab and choose boolean. Select boolean type as a difference, choose the spheres as the object, and click apply. This will section out a cut of half the sphere on the face of the mold selected.



16. Once these steps are completed, you can delete the joined spheres, and you should be left with two separate halves of the molds. One with indentations of the spheres on the face, and another with half of the sphere protruding outward.



17. Next, cut outs in the top of the mold to be created to allow for both injection and release of air during the formation of the mold. To do this, a cone mesh will need to be added by navigating to Add→New Mesh→Cone. Move and manipulate the cone to create an appropriately sized and appropriately located hole.A boolean modifier will then be applied to the cone mesh to create two holes, one on top of one half of the mold and one one the other half as well. Select one half of the molds and navigate to Modifiers→Add Modifier→Boolean, and select the difference option within the modifier. Within the modifier options, select the cone as the object and click apply. Repeat this step for each half of the mold.



Cube.001 Boolean

Add Modifier

Boolean

Intersect | Union | Difference

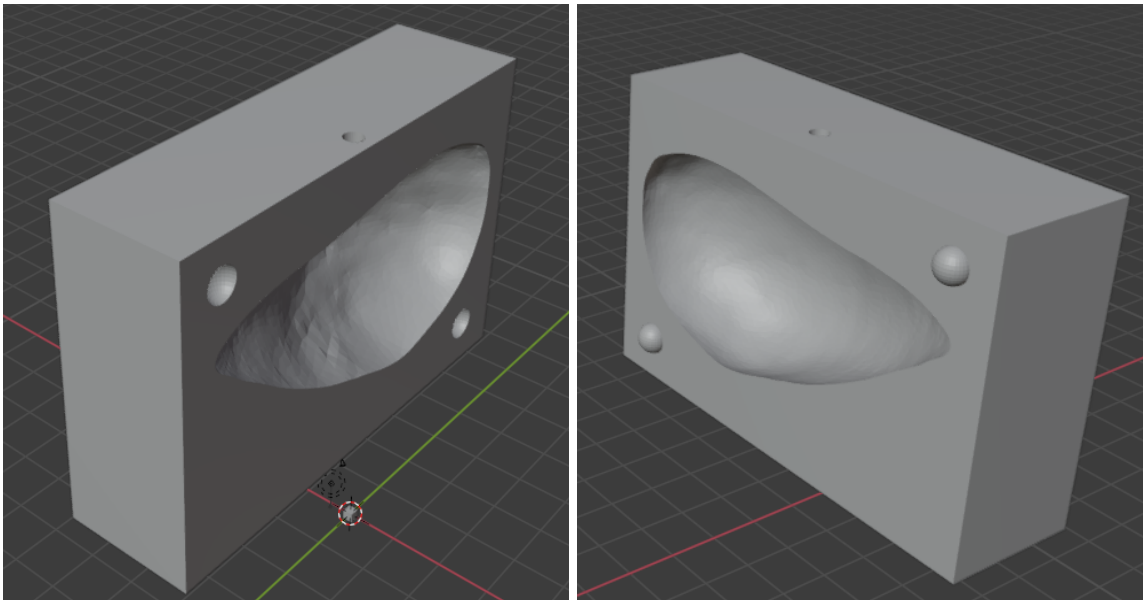
Operand Type: Object

Object: Cone

Solver: Fast | Exact

Solver Options

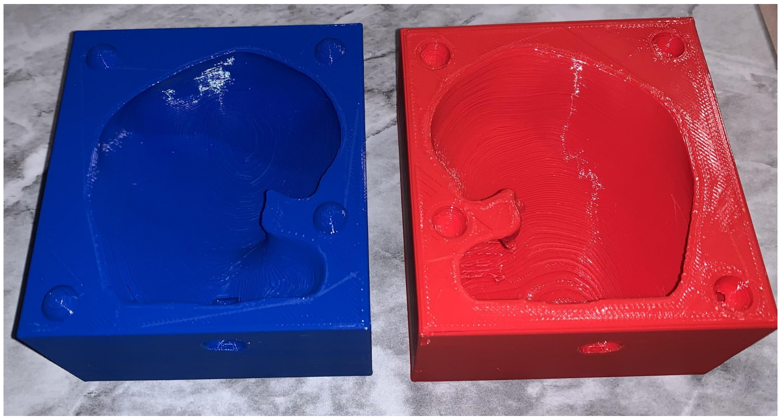
18. The cone can be deleted, and you will be left with two halves of a completed mold. One with a small hole on the top of each mold to allow for the application of the molding material, and one with a hole to allow for the release of air.



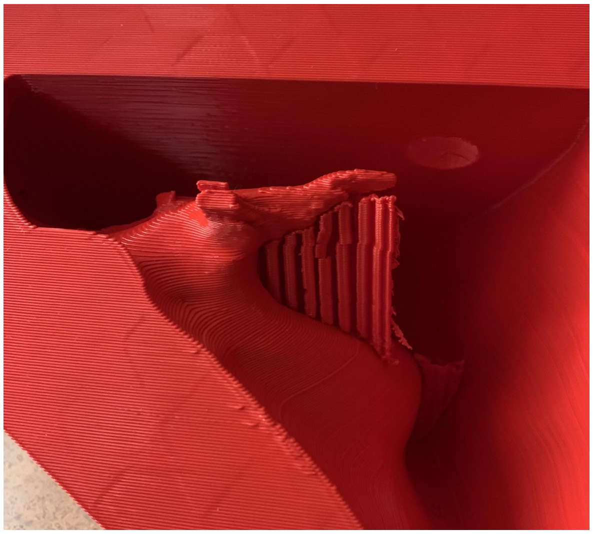
Appendix F: Injection Molding Process

The liver, kidney, and gallbladder were all created by injection molding. Once the mold of the organ was created, it could then be used to actually mold the desired organ. This process can be applied to any organ.

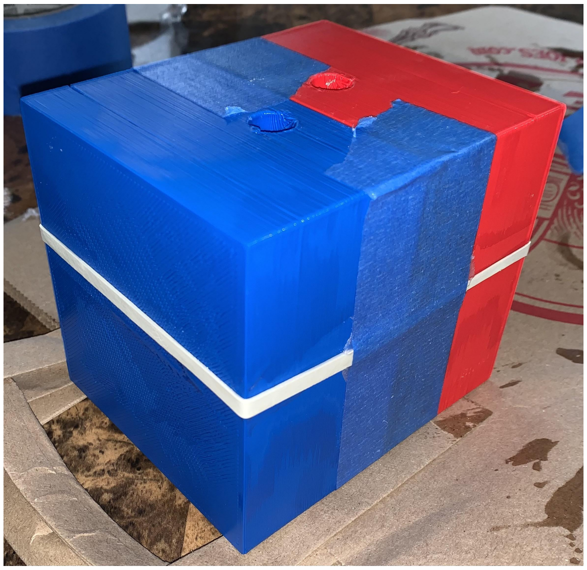
1. Obtain a mold for a desired organ, as well as a final material (for this example we will use EcoFlex 00-30) Note: a mold release can be sprayed onto the inside surface of the mold if desired.



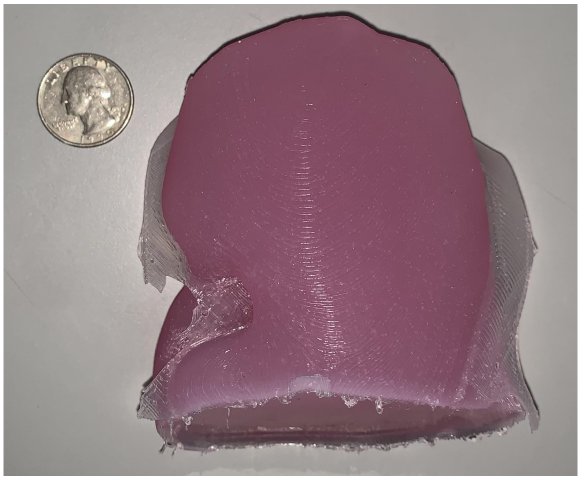
2. Remove structural supports from the mold with a small flathead screw if necessary.



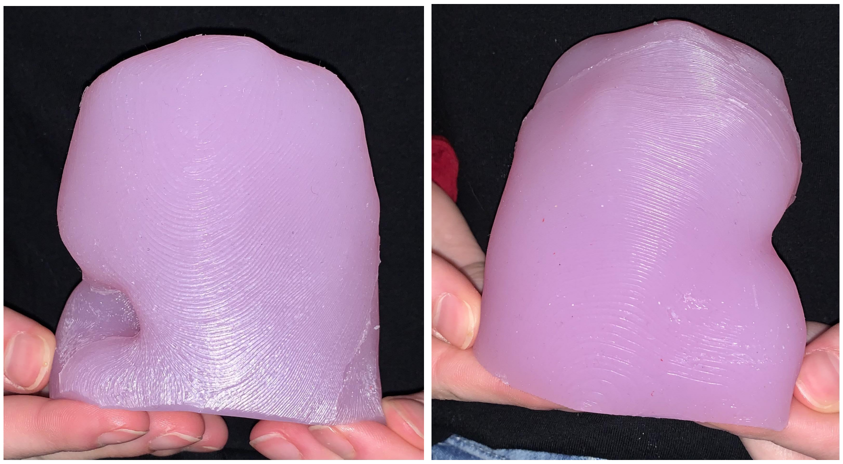
3. Hold the mold halves together, making sure the spherical cutouts are lined up and the edges of the molds line up. Note: It is important that the edges are closed tightly to minimize the amount of silicone that will drip out of the mold.
4. Ensure that the two sprue holes are facing upwards and then use tape or rubber bands to secure the halves of the mold together temporarily. Make sure not to cover either sprue.



5. Open the two bottles of EcoFlex 00-30 and follow the directions on the box. Add the two bottles in a 1:1 ratio by volume in a separate container and stir. Note: It is recommended that the two are poured in a disposal container and stirred with a disposable utensil.
6. If desired, add food coloring to the mixture to color the part.
7. Pour the mixture into the secured mold. Pour in one of the holes and leave the other open to allow air to flow out of the mold. Note: check the directions for the "pot life" of the material and pour the material in the mold before that time expires.
8. Fill the mold to the bottom edge of the sprue for fewer finishing steps.
9. Let the part solidify for the amount of time mentioned as the "cure time."
10. Once cured, the reinforcements (tape, rubber bands, …) can be removed.
11. Carefully begin to pry open the halves of the mold. Pull gently until the part starts to separate from the mold. Note: use your fingers to gently pull the part from the inner surfaces.
12. Fully remove the part from the mold halves and begin finishing steps. Use small scissors to cut the excess material that escaped the mold and dried between the edges.



13. Clean the mold for future use and add your new organ to the box trainer.



Appendix G: Synthetic Material Testing Protocol

Synthetic Materials Testing Protocol

Bio-Realistic Surgical Phantom
Major Qualifying Project
Department of Biomedical Engineering

Testing Days: January 27th and March 1st

Sample: EcoFlex 00-10 and EcoFlex 00-30
Source: Amazon

Instron Tests:
Tensile Testing (ASTM 412-16)
Puncture Testing (ASTM D4833)

Tasks to do before test day:

1. Print 3 molds for each test
    a. Tensile test: dogbone
        i. Tensile testing requires samples to be cut into a dogbone shape that are 25mm wide at the ends and 115 mm long with a 6mm gage that is 33 mm in length
    b. Puncture test: 4in x 4in circle and 3mm thickness
2. Resize puncture apparatus to have a 1.77 in diameter
3. Cast molds
    a. Pour appropriate amounts of Part A and Part B into a single mold
4. Place casts into the bell vacuum
    a. Let sit for approximately 3 minutes or until there appears to be no bubbles
5. Let cure
    a. Once there are no bubbles, remove the mold from the bell vacuum and let the cast sit for appropriate curing time (4-6 hours)
6. Repeat for each mold

Materials Needed:

1. 3D Prints
    a. 3x dog bone mold
    b. 3x circle mold
    c. Methylene Chloride
2. Cleaning products
    a. Cleaning sprays and paper towels available in SL219 and GH207
3. Other materials
    a. Plates for mixing
    b. Mixing tool
    c. Plastic bags
    d. Sharpie
    e. Saran wrap

Obtaining Sample:

1. Contact Lisa Wall to purchase needed materials online

Prepping Samples:

1. Remove casts from 3D printed molds
2. Place on saran wrap to avoid contamination due to stickiness

Tests to Perform:

We will use the ASTM standards on the Instron 5544 to perform two tests: Tensile Test and Puncture Test.

1. Tensile Test
    a. ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers- Tension
    b. Prep the Instron
    c. Dog Bone Samples
        i. Place sample in grips of Instron 5544
        ii. Set the rate of separation to 100mm/min
    d. Bluehill
        i. Test
        ii. Browse tensile test
        iii. Method
            1. Specimen > Geometry > Rectangular
            2. Control > Pre-Test > Add a 1N tear load
            3. Control > Data > set how often we want to set data
            4. Control > Strain > Extension
            5. Calculations > Set up > drag over what we need - max load, break, modulus yield
            6. Results > drag over feasible data
            7. Graphs (load/extension vs. time, stress vs. strain)
            8. Raw Data > time, extension, load, tensile strain, tensile stress
            9. Reports > Save
            10. Export Results > .CSV save
            11. Export Raw Data > .CSV save
            12. Include additional sample results - length, thickness, and width
        iv. Running Test
            1. Calibrate the Instron 5544
            2. Move cross head down, load sample, set mechanical stops
            3. Add 1N pre-load, zero extension
            4. Enter values for sample label, geometry, thickness, width, and length
            5. Add sample description
            6. Place safety shield in front of the machine
            7. Run the test
            8. Finish > Finish Sample > Save
            9. Remove sample and start another sample

2. Puncture Test
    a. ASTM D4833 Standard Test Method for Index Puncture Resistance of Geomembranes and Related Products
    b. Clamp the sample in between the stand and the top part of the puncture apparatus with the hole.The sample should be centered in the clamp.
    c. Attach the machine puncture probe to the top clamp.
    d. Test the sample at a speed of 150 mm/min until the puncture probe punctures through it.
        i.
    e. Read the puncture resistance from the greatest force registered on the recording instrument during the test.
    f. Calculate the average and standard deviation of puncture resistance
3. Bluehill
    a. Test
    b. Browse puncture test
    c. Method
        i. Specimen > Geometry > Circle
        ii. Control > Pre-Test > Add a 0.5N tear load
        iii. Control > Data > set how often we want to set data
        iv. Control > Strain > Extension
        v. Calculations > Set up > drag over what we need - max load, break, modulus yield
        vi. Results > drag over feasible data
        vii. Graphs (load/extension vs. time, stress vs. strain)
        viii. Raw Data > time, extension, load, tensile strain, tensile stress
        ix. Reports > Save
        x. Export Results > .CSV save
        xi. Export Raw Data > .CSV save
        xii. Include additional sample results - length, thickness, and width
    d. Running Test
        i. Calibrate the Instron 5544
        ii. Move cross head down, load sample, set mechanical stops
        iii. Add 0.5N pre-load, zero extension
        iv. Enter values for sample label, geometry, thickness, width, and length
        v. Add sample description
        vi. Place safety shield in front of the machine
        vii. Run the test

Appendix H: Animal Tissue Testing Protocol

Animal Tissue Testing Protocol

Bio-Realistic Surgical Phantom
Major Qualifying Project
Department of Biomedical Engineering

Obtaining Specimen: February 3, 2022
Testing Day: February 4 and 16, 2022

Specimen: Porcine GI Tract
Source: The Blood Farm Groton, MA

Instron Tests:
Tensile Testing (ASTM 412-16)
Puncture Testing (ASTM D4833)

Tasks to do before test day:

1. Machine puncture probe.
2. Call Bloodfarm to order, determine price, and confirm necessary storing of the porcine GI tract.
3. Call Bloodfarm on February 2, 2022 to confirm we are picking up the GI tract on February 3.
4. Determine a time that the Instron 5544 in GH207 is not being used.
5. Notify Lisa that we are working with animal samples and will have large amounts of biohazard.
6. Practice on chicken.

Materials Needed:

1. Cutting tools
    a. Tweezers
    b. Forceps
    c. Curved dissecting scissors
    d. Surgical dissection scissors (blunt)
    e. Scalpel
2. Cleaning products
    a. Cleaning sprays available in GH207
3. Other materials
    a. Cutting boards available in GH207
    a. Covering paper available in GH207
    b. Lab gloves
    c. Cooler and ice
    d. 50-gallon trash bags
    e. PPE

Obtaining Sample:

1. Animal samples collection guidelines
    a. Fresh tissues should be placed in a sterile cooler large enough to hold an entire hog GI tract with ice to ensure that a cold temperature is maintained during transportation

Prepping Samples:

1. Shapes and cutting samples
    a. Puncture testing requires samples to be cut into 4 inch diameter circles
    b. Tensile testing requires samples to be cut into a dogbone shape that are 25mm wide at the ends and 115 mm long with a 6mm gage that is 33 mm in length

Tests to Perform:

We will use the ASTM standards on the Instron 5544 to perform two tests: Tensile Test and Puncture Test.

1. Tensile Test
    a. ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers- Tension
    b. Prepping the Instron
        i. Place blue covering paper below the bottom anvil.
    c. Straight Specimens
        i. Place specimen in grips of Instron 5544
        ii. Set the rate of separation to 100mm/min
        iii. Transverse/axial specimens
    d. Bluehill
        i. Test
        ii. Browse tensile test
        iii. Method
            1. Specimen > Geometry > Rectangular
            2. Control > Pre-Test > Add a 1N tear load
            3. Control > Data > set how often we want to set data
            4. Control > Strain > Extension
            5. Calculations > Set up > drag over what we need - max load, break, modulus yield
            6. Results > drag over feasible data
            7. Graphs (load/extension vs. time, stress vs. strain)
            8. Raw Data > time, extension, load, tensile strain, tensile stress
            9. Reports > Save
            10. Export Results > .CSV save
            11. Export Raw Data > .CSV save
            12. Include additional specimen results - length, thickness, and width
        iv. Running Test
            1. Calibrate the Instron 5544
            2. Move cross head down, load sample, set mechanical stops
            3. Add 1N pre-load, zero extension
            4. Enter values for specimen label, geometry, thickness, width, and length
            5. Add sample description
            6. Place safety shield in front of the machine
            7. Run the test

        8. Finish > Finish Sample > Save
        9. Remove sample and start another sample

2. Puncture Test
    a. ASTM D4833 Standard Test Method for Index Puncture Resistance of Geomembranes and Related Products
    b. Clamp the specimen in between the stand and the top part of the puncture apparatus with the hole.The specimen should be centered in the clamp.
    c. Attach the machine puncture probe to the top clamp.
    d. Test the specimen at a speed of 150mm/min until the puncture probe punctures through it.
    e. Read the puncture resistance from the greatest force registered on the recording instrument during the test.
    f. Calculate the average and standard deviation of puncture resistance

Appendix I: ASTM D412 Tensile Testing Raw Data - Porcine Tissue

Tensile Testing
Specimen: Porcine

Sample Dimensions - Porcine Colon

	Average Sample Length (mm)	Average Sample Width (mm)	Average Sample Thickness (mm)
Sample 1	116.47	32.22	0.58
Sample 2	128.36	34.75	0.78
Sample 3	106.27	43.16	0.55
Sample 4	120.45	30.96	0.95
Sample 5	123.71	38.29	0.78
Avg+SD	119.05 ± 7.49	35.88 ± 4.42	0.73 ± 0.15

Sample Dimensions - Porcine Small Intestine

	Average Sample Length (mm)	Average Sample Width (mm)	Average Sample Thickness (mm)
Sample 1	140.72	37.63	0.43
Sample 2	147.52	36.16	0.79
Sample 3	112.85	34.97	0.46
Sample 4	148.58	31.58	0.36
Avg+SD	137.42 ± 14.50	35.09 ± 2.23	0.51 ± 0.17

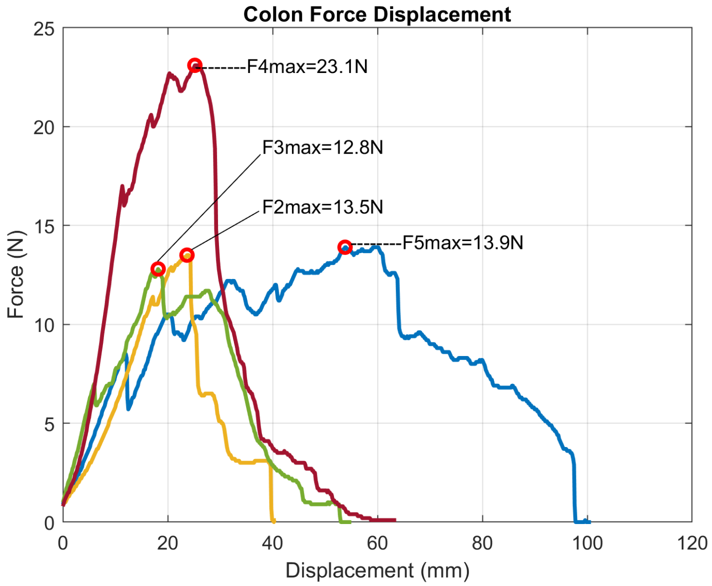
Sample Dimensions - Porcine Mesentery

	Average Sample Length (mm)	Average Sample Width (mm)	Average Sample Thickness (mm)
Sample 1	82.29	32.43	0.76
Sample 2	79.06	39.87	1.44
Sample 3	82.28	32.37	1.21
Sample 4	82.13	24.67	1.14
Avg+SD	81.44 ± 1.38	32.34 ± 5.37	1.13 ± 0.24

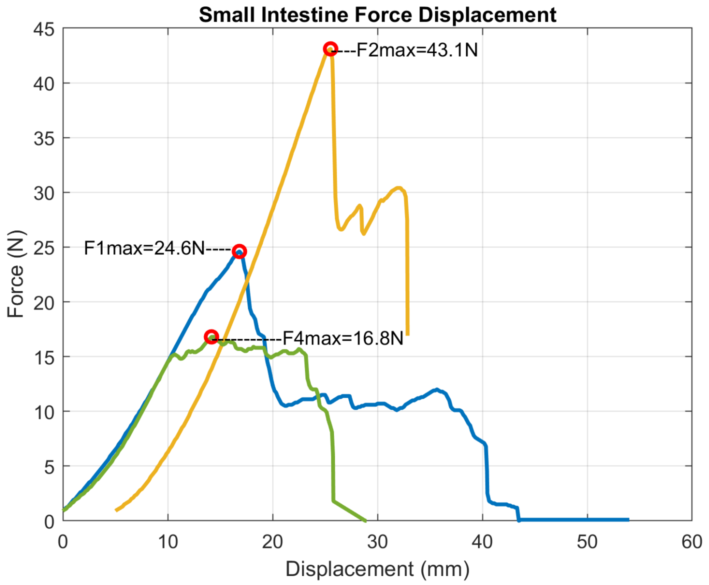
Sample Dimensions - Porcine Stomach

	Average Sample Length (mm)	Average Sample Width (mm)	Average Sample Thickness (mm)
Sample 1	134.66	33.69	2.07
Sample 2	103.30	33.70	1.99
Sample 3	107.93	28.67	3.53
Sample 4	141.02	33.77	2.48
Avg+SD	121.73 ± 16.35	32.46 ± 2.19	2.52 ± 0.61

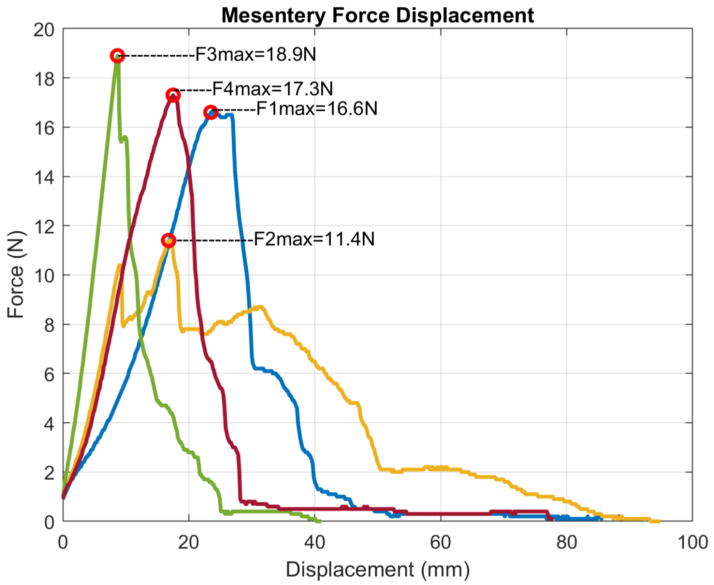
Force-Displacement Graphs - Porcine Colon



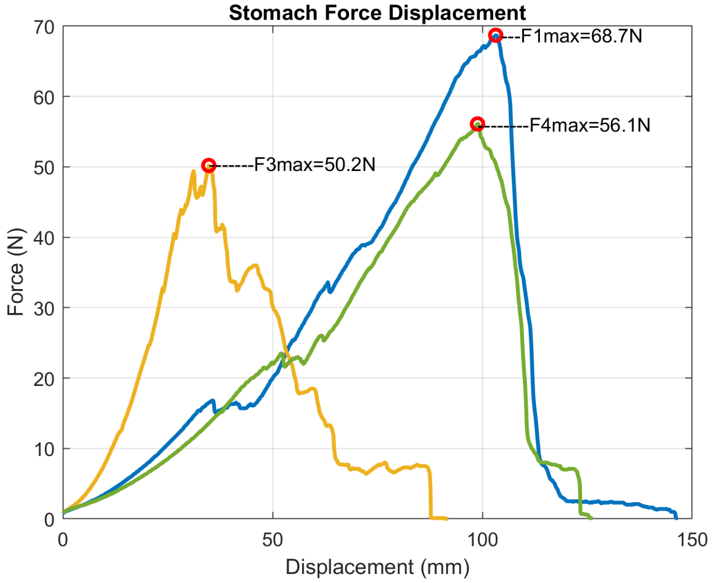
Force-Displacement Graphs - Porcine Small Intestine



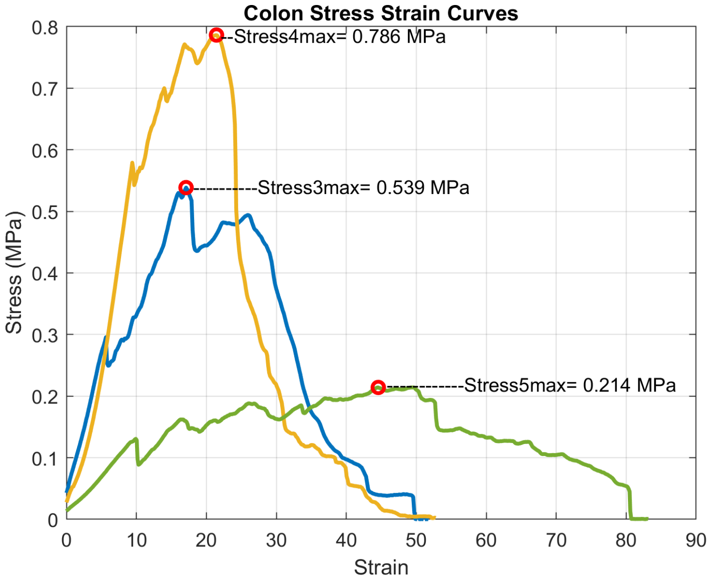
Force-Displacement Graphs - Porcine Mesentery



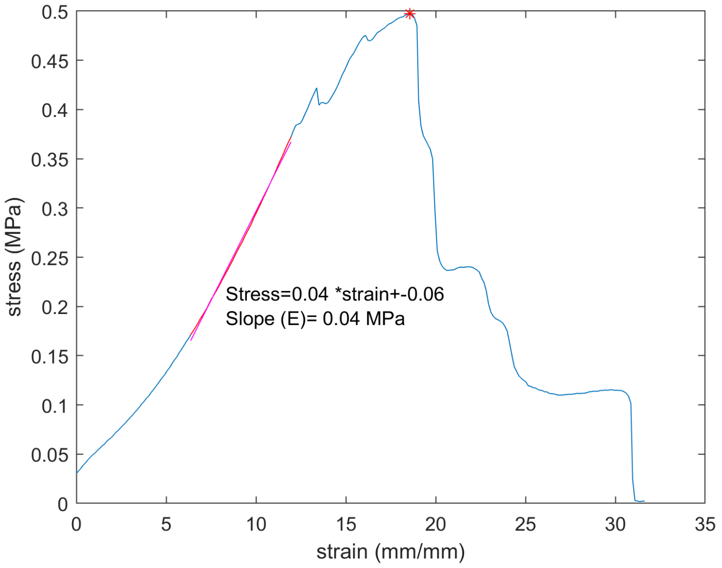
Force-Displacement Graphs - Porcine Stomach

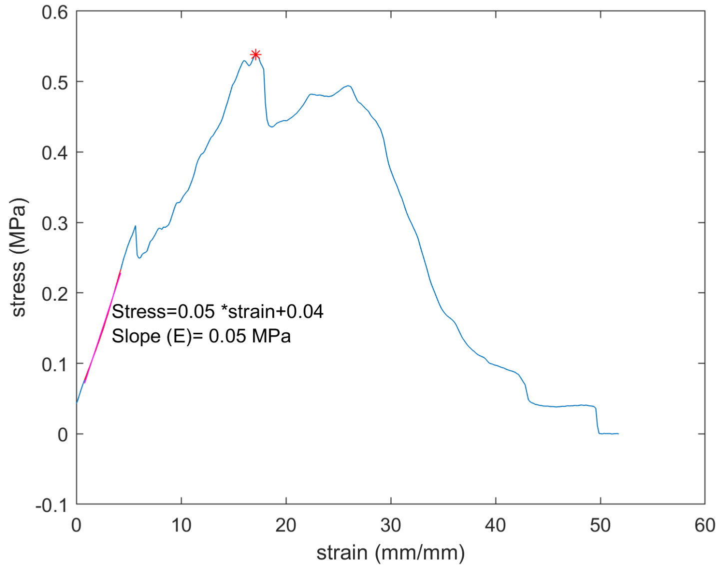


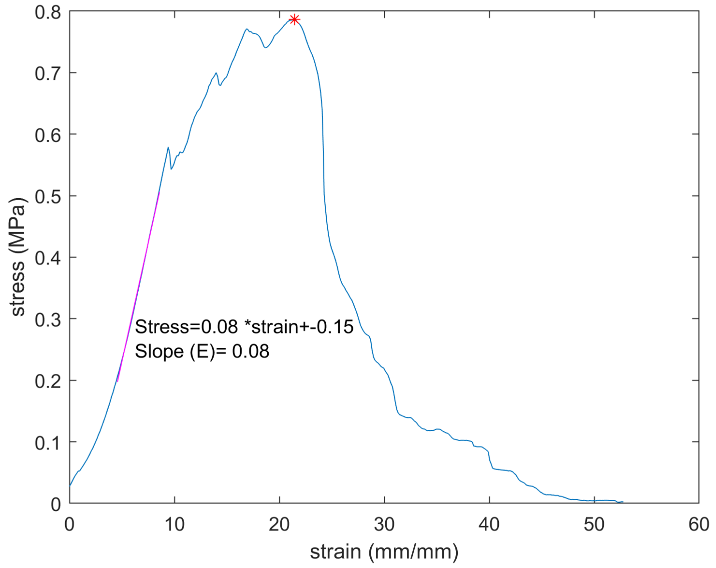
Stress-Strain Graphs - Porcine Colon



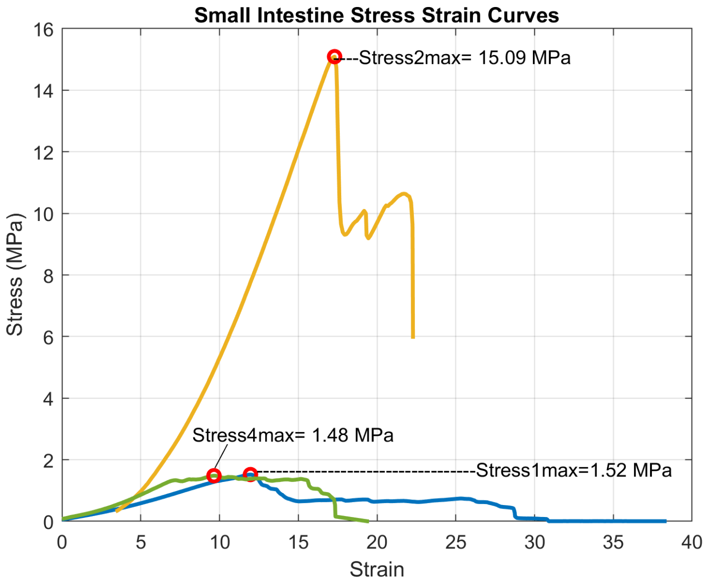
Stress-Strain Graphs with Modulus - Porcine Colon Trials


0.5
0.45
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
stress (MPa)
0
5
10
15
20
25
30
35
strain (mm/mm)
Stress=0.04 *strain+-0.06
Slope (E)= 0.04 MPa

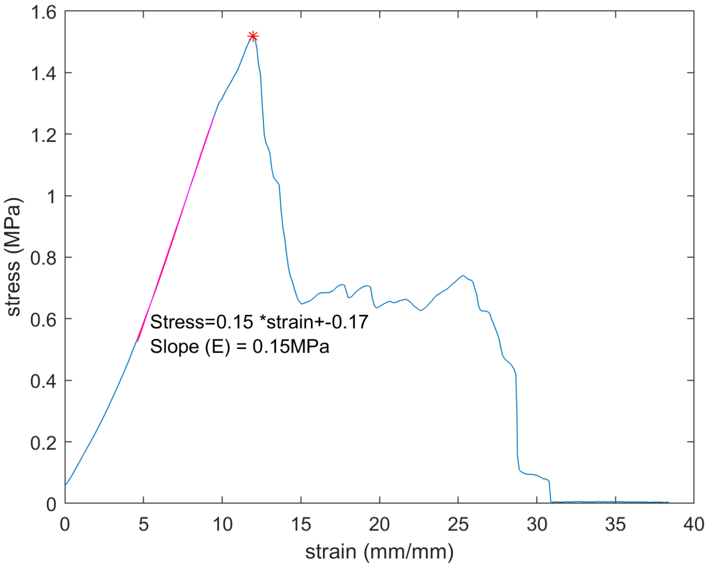

0.6
0.5
0.4
0.3
0.2
0.1
0
-0.1
stress (MPa)
0
10
20
30
40
50
60
strain (mm/mm)
Stress=0.05 *strain+0.04
Slope (E)= 0.05 MPa

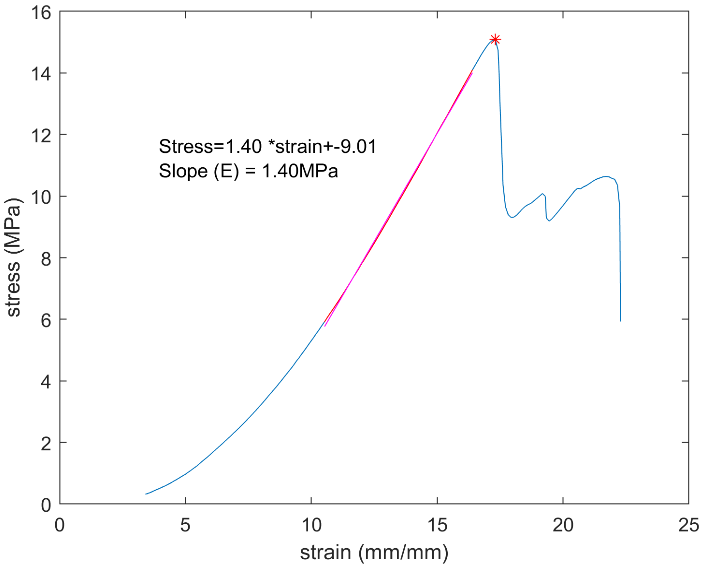


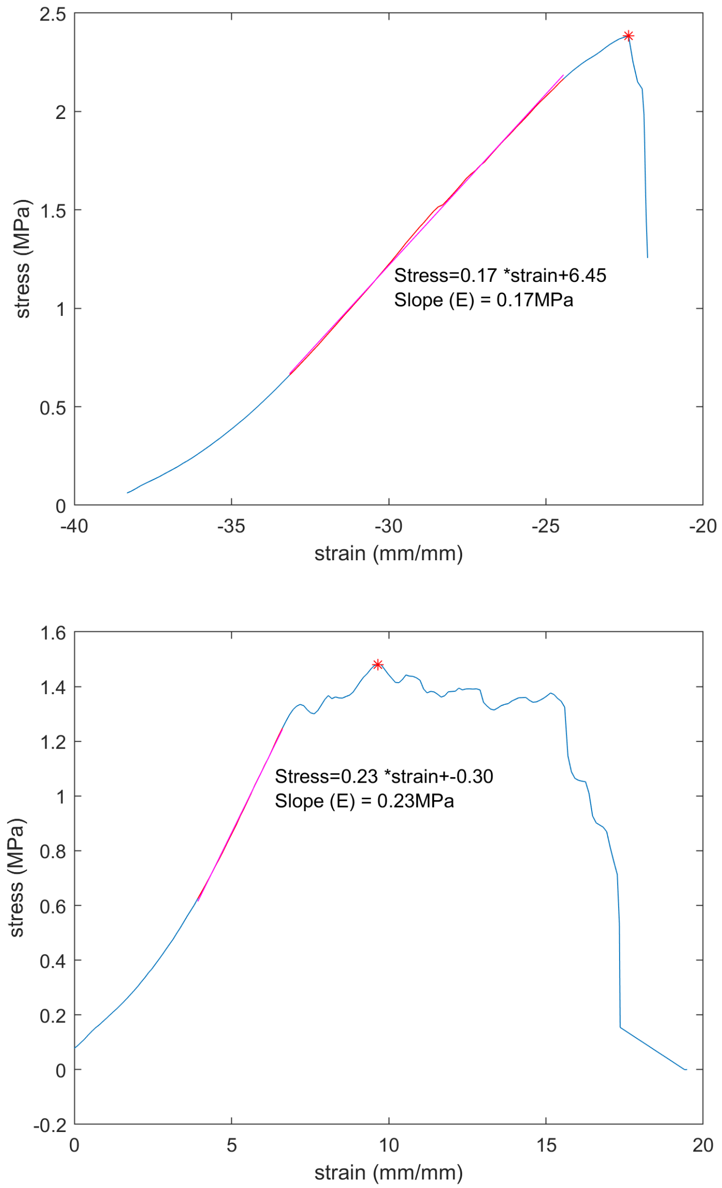
Stress-Strain Graphs - Porcine Small Intestine



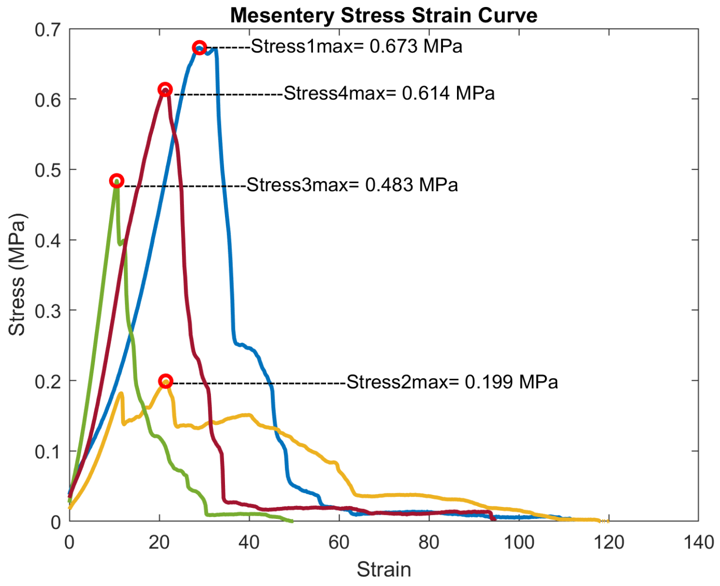
Stress-Strain Graphs with Modulus - Porcine Small Intestine Trials


stress (MPa)
strain (mm/mm)
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
5
10
15
20
25
30
35
40
Stress=0.15 *strain+-0.17
Slope (E) = 0.15MPa

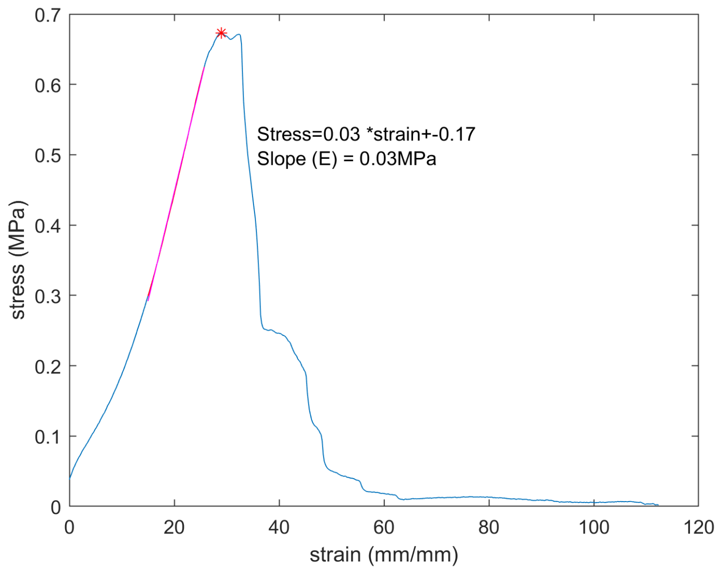

stress (MPa)
strain (mm/mm)
16
14
12
10
8
6
4
2
0
0
5
10
15
20
25
Stress=1.40 *strain+-9.01
Slope (E) = 1.40MPa

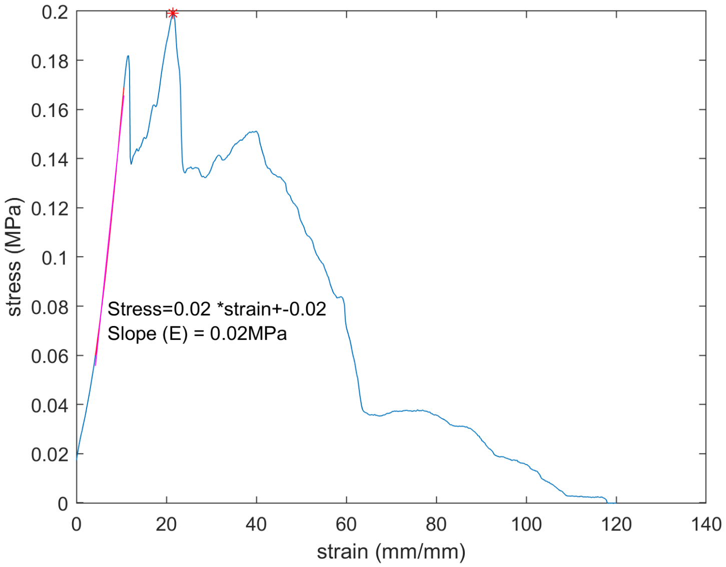


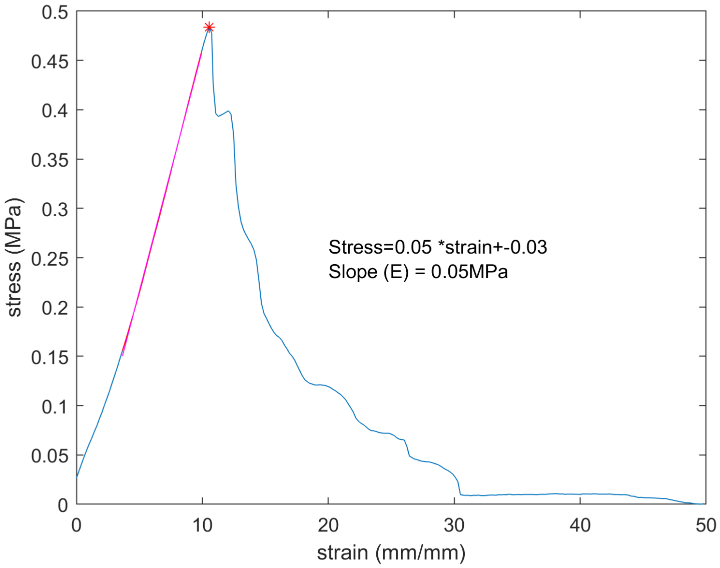
Stress-Strain Graphs - Porcine Mesentery

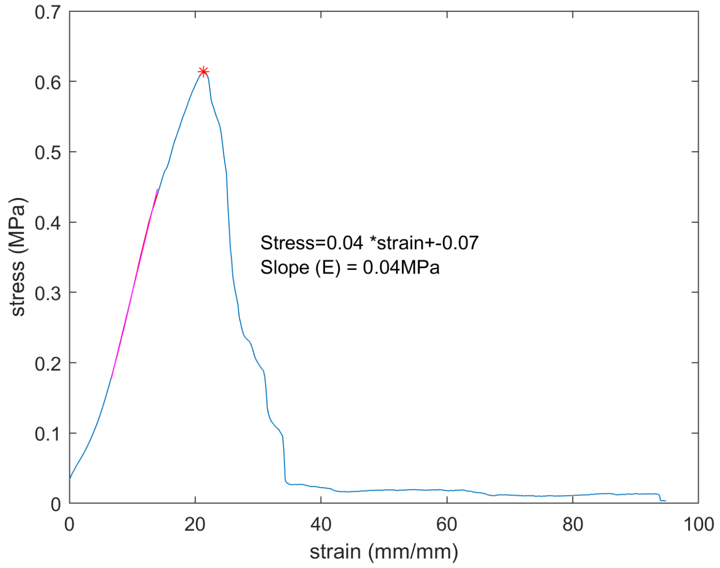


Stress-Strain Graphs with Modulus - Porcine Mesentery Trials

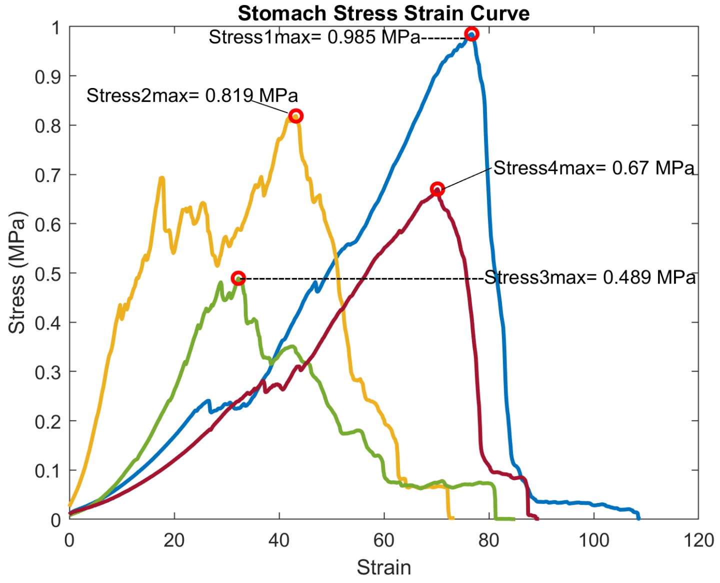



0.2
0.18
0.16
0.14
0.12
0.1
0.08
0.06
0.04
0.02
0
stress (MPa)
0
20
40
60
80
100
120
140
strain (mm/mm)
Stress=0.02 *strain+-0.02
Slope (E) = 0.02MPa

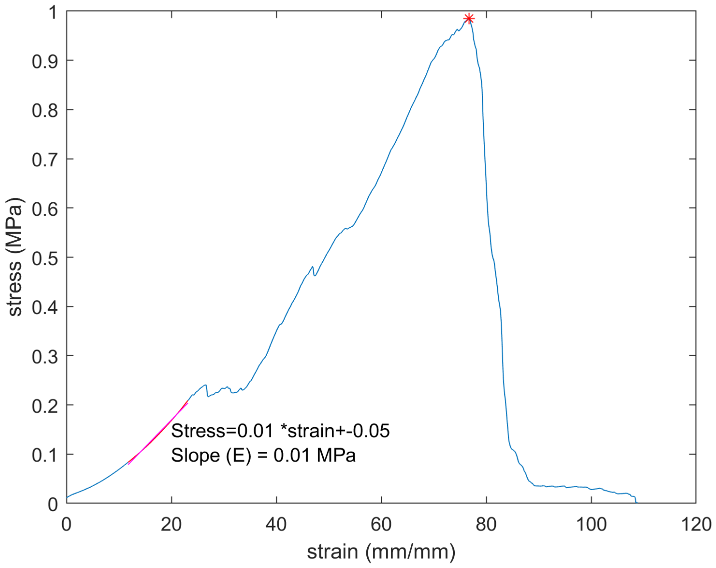

0.5
0.45
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
stress (MPa)
0
10
20
30
40
50
strain (mm/mm)
Stress=0.05 *strain+-0.03
Slope (E) = 0.05MPa

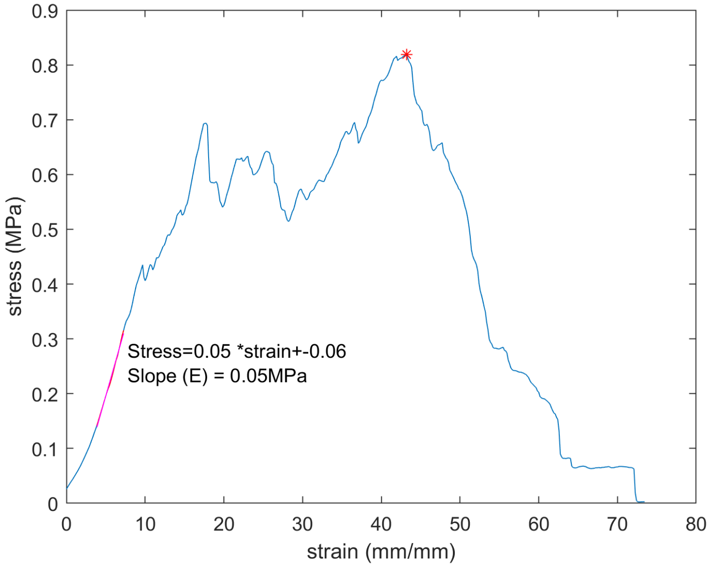


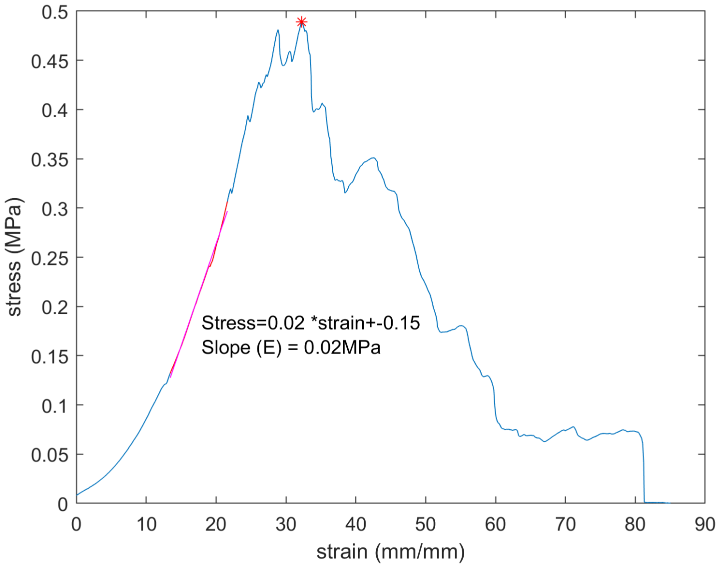
Stress-Strain Graphs - Porcine Stomach



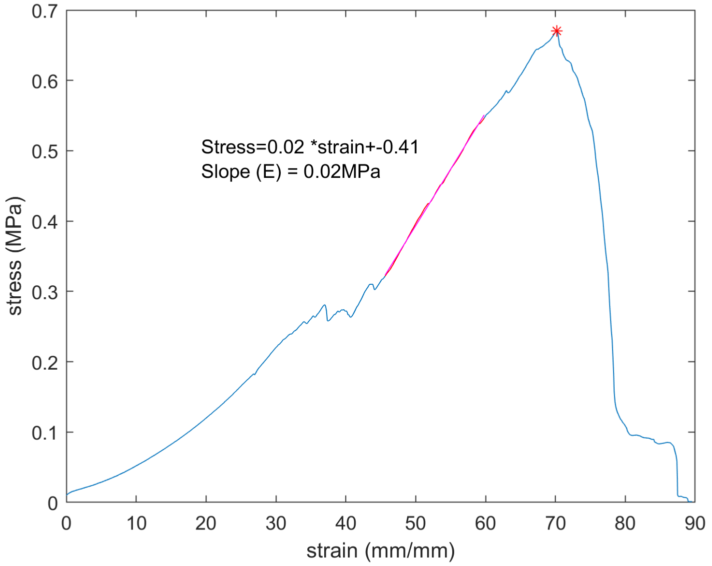
Stress-Strain Graphs with Modulus - Porcine Stomach Trials







0.5
0.45
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
stress (MPa)
0
10
20
30
40
50
60
70
80
90
strain (mm/mm)
Stress=0.02 *strain+-0.15
Slope (E) = 0.02MPa



0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
stress (MPa)
0
10
20
30
40
50
60
70
80
90
strain (mm/mm)
Stress=0.02 *strain+-0.41
Slope (E) = 0.02MPa

Appendix J: ASTM D412 Tensile Testing Raw Data - Synthetic Material

Tensile Testing

Specimen: Synthetic

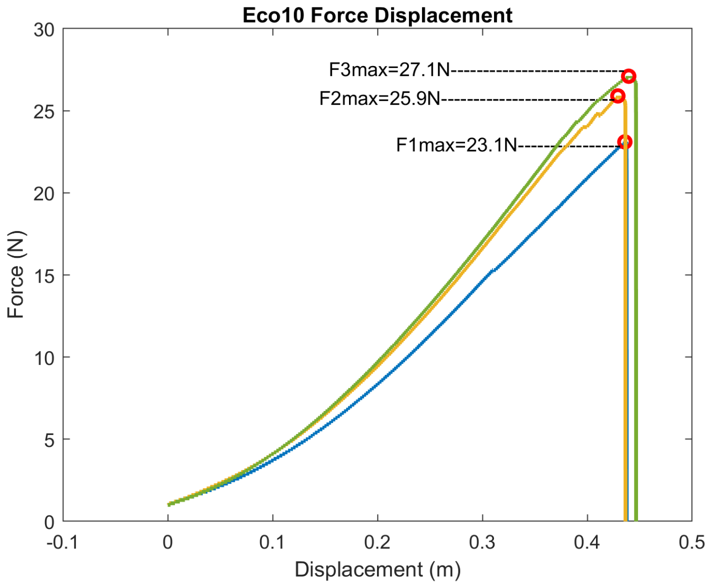
Sample Dimensions - EcoFlex 00-10

	Average Sample Length (mm)	Average Sample Width (mm)	Average Sample Thickness (mm)
Sample 1	118.64	6	3
Sample 2	125.85	6	3
Sample 3	138.78	6	3
Avg+SD	127.76 ± 8.33	6	3

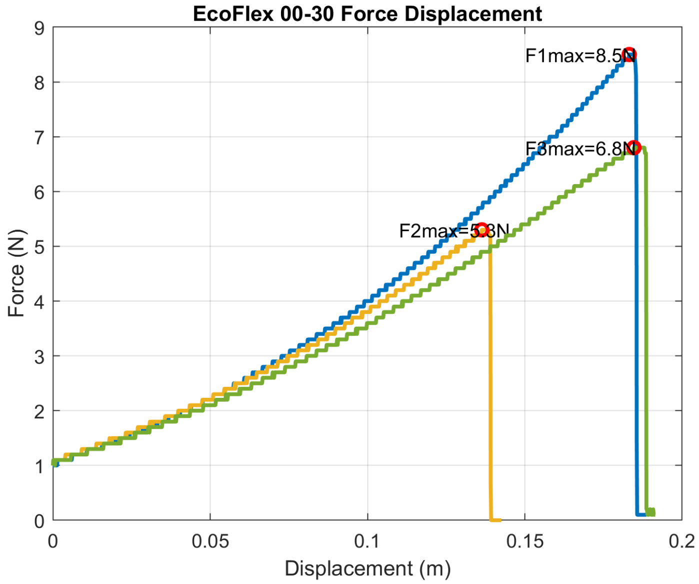
Sample Dimensions - EcoFlex 00-30

	Average Sample Length (mm)	Average Sample Width (mm)	Average Sample Thickness (mm)
Sample 1	141.32	6	3
Sample 2	140.08	6	3
Sample 3	137.75	6	3
Avg+SD	139.72 ± 1.48	6	3

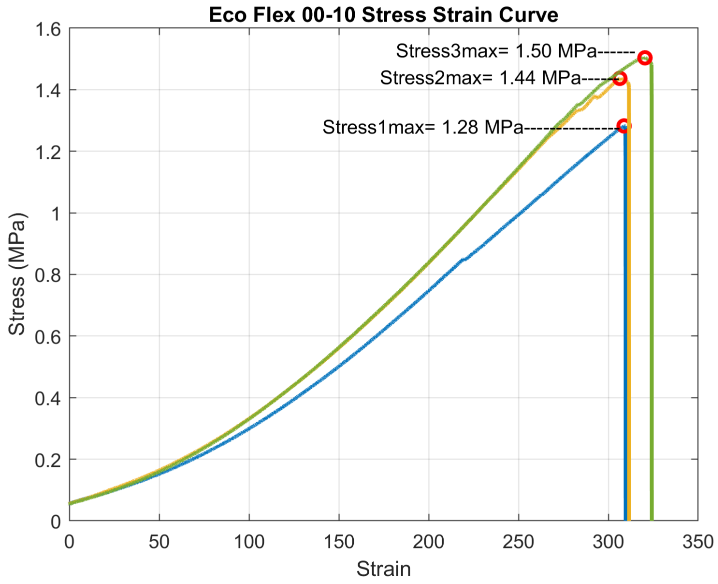
Force-Displacement Graphs - EcoFlex 00-10



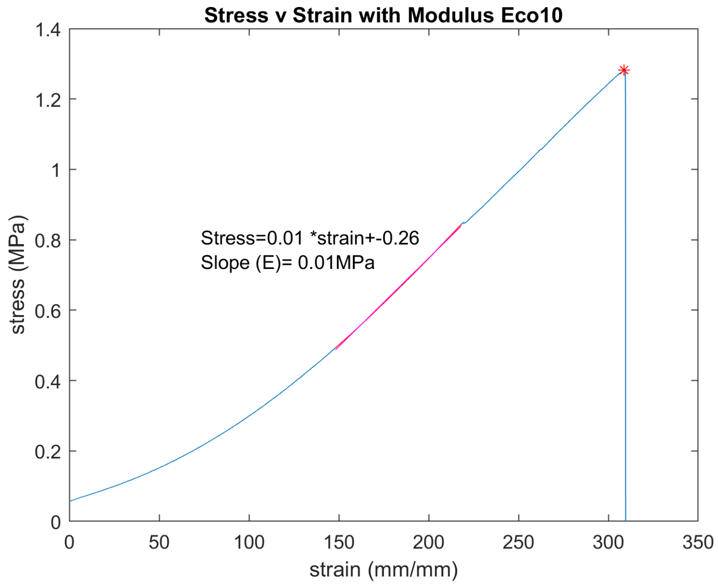
Force-Displacement Graphs - EcoFlex 00-30

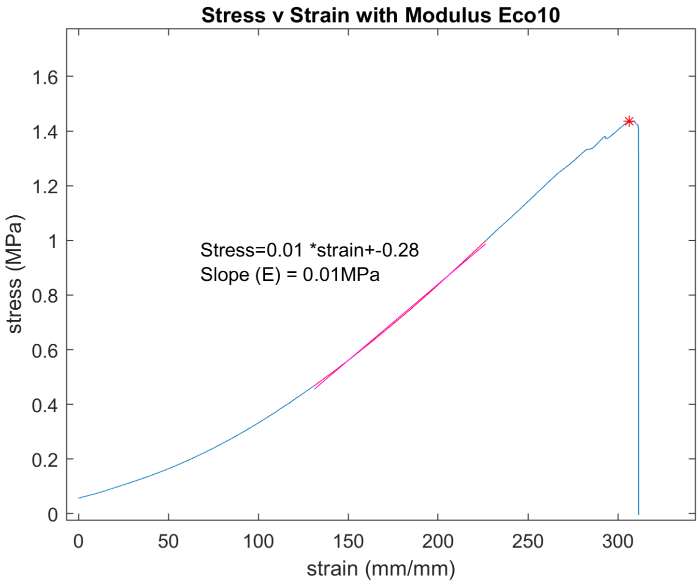


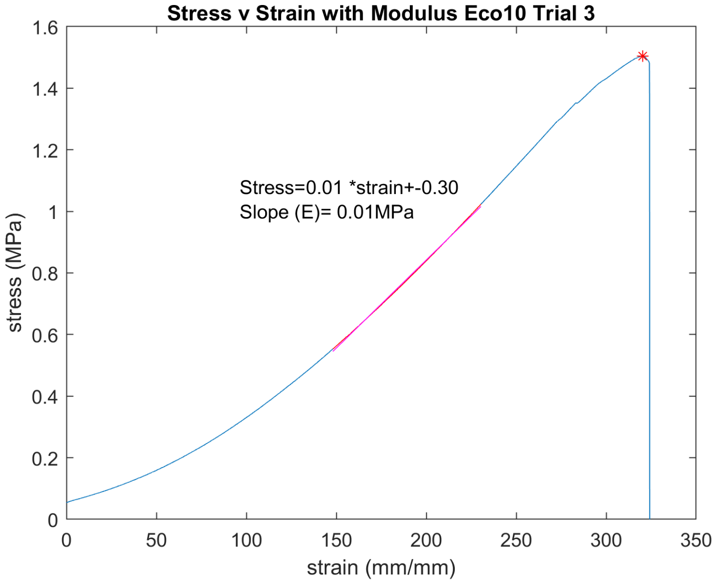
Stress-Strain Graphs - EcoFlex 00-10



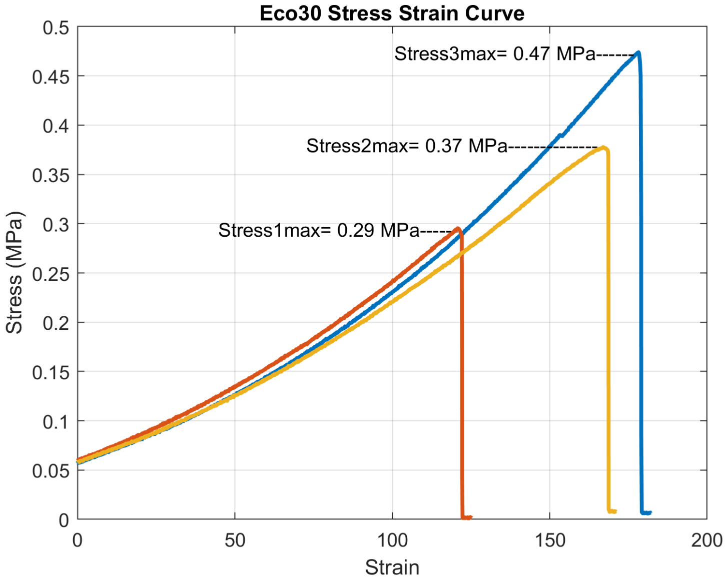
Stress-Strain Graphs with Modulus - EcoFlex 00-10



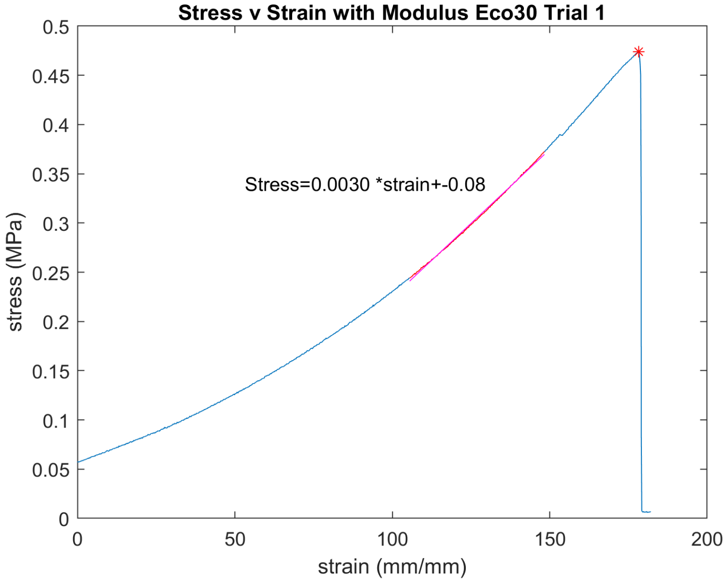


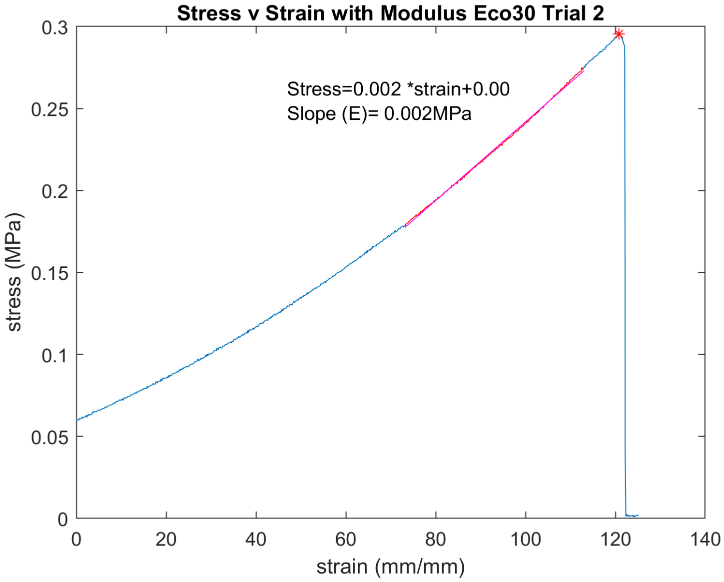


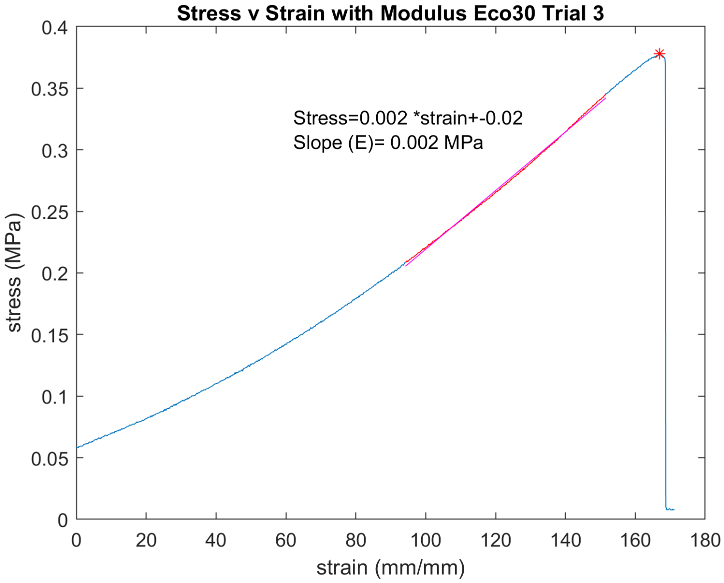
Stress-Strain Graphs - EcoFlex 00-30



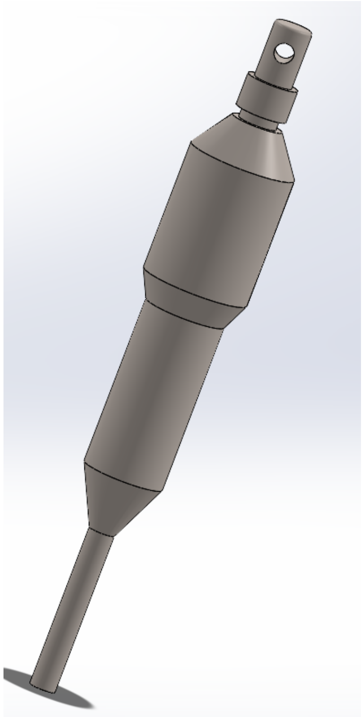
Stress-Strain Graphs with Modulus - EcoFlex 00-30




Stress v Strain with Modulus Eco30 Trial 2
Stress=0.002 *strain+0.00
Slope (E)= 0.002MPa
stress (MPa)
strain (mm/mm)
0
0.05
0.1
0.15
0.2
0.25
0.3
0
20
40
60
80
100
120
140


Stress v Strain with Modulus Eco30 Trial 3
Stress=0.002 *strain+-0.02
Slope (E)= 0.002 MPa
stress (MPa)
strain (mm/mm)
0
0.05
0.1
0.15
0.2
0.25
0.3
0.35
0.4
0
20
40
60
80
100
120
140
160
180

Appendix K: Puncture fixture



Appendix L: ASTM D4833 Puncture Testing Raw Data - Porcine Tissue Puncture Testing

Specimen: Porcine

Sample Dimensions - Porcine Colon

	Average Sample Diameter (mm)	Average Sample Thickness (mm)
Sample 1	45.0	1.07
Sample 2	45.0	0.81
Sample 3	45.0	0.87
Sample 4	45.0	0.94
Sample 5	45.0	1.09
Avg+SD	45.0	0.96 ± 0.11

Sample Dimensions - Porcine Small Intestine

	Average Sample Diameter (mm)	Average Sample Thickness (mm)
Sample 1	45.0	0.53
Sample 2	45.0	0.34
Sample 3	45.0	0.30
Sample 4	45.0	0.33
Sample 5	45.0	0.27
Avg+SD	45.0	0.35 ± 0.09

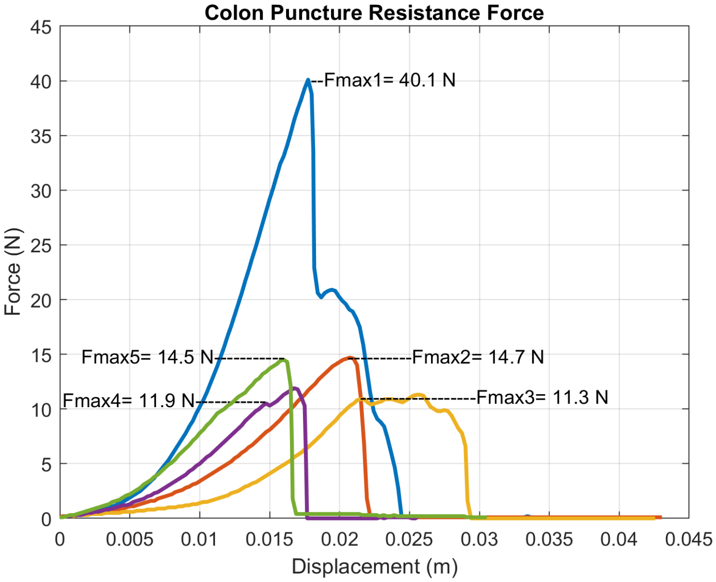
Sample Dimensions - Porcine Mesentery

	Average Sample Diameter (mm)	Average Sample Thickness (mm)
Sample 1	45.0	1.55
Sample 2	45.0	1.00
Sample 3	45.0	1.14
Sample 4	45.0	1.93
Avg+SD	45.0	1.41 ± 0.36

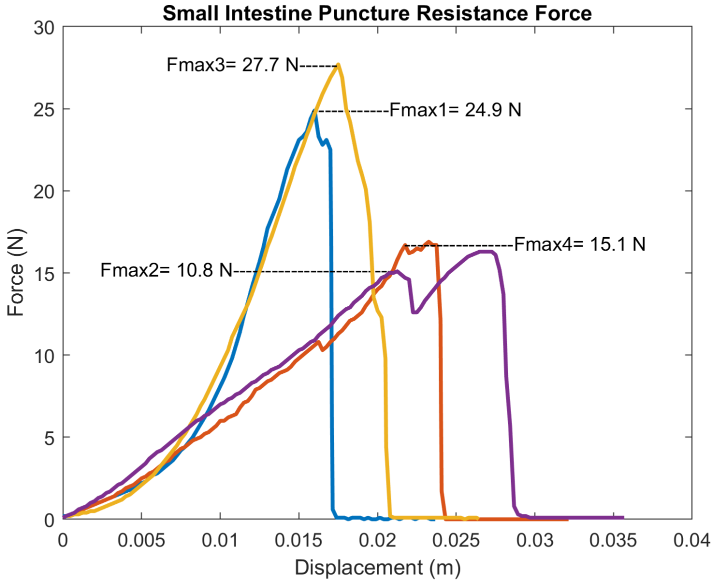
Sample Dimensions - Porcine Stomach

	Average Sample Diameter (mm)	Average Sample Thickness (mm)
Sample 1	45.0	4.37
Sample 2	45.0	2.60
Sample 3	45.0	2.14
Sample 4	45.0	3.35
Avg+SD	45.0	3.12 ± 0.84

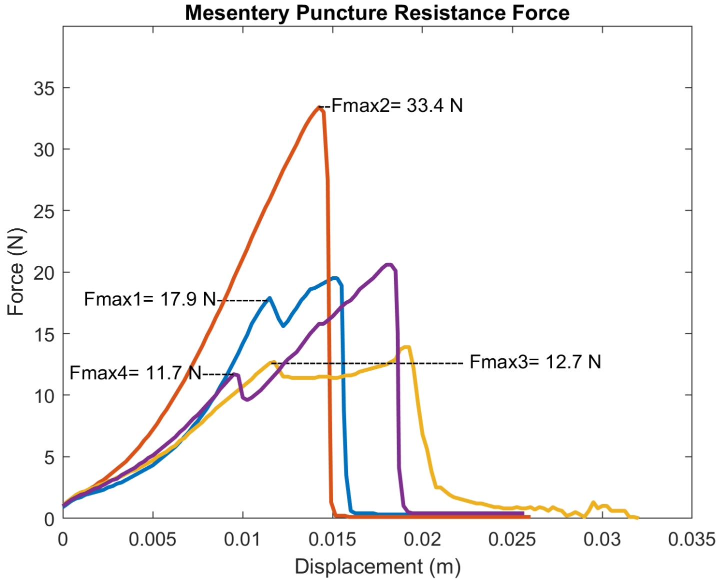
Puncture Resistance Graphs - Colon



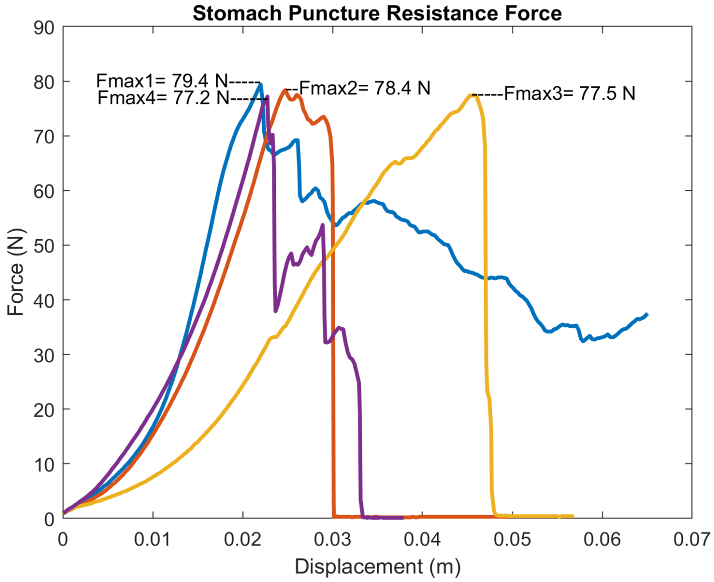
Puncture Resistance Graphs - Small Intestine



Puncture Resistance Graphs - Mesentery



Puncture Resistance Graphs - Stomach


Stomach Puncture Resistance Force
Fmax1= 79.4 N-----
Fmax4= 77.2 N------
--Fmax2= 78.4 N
-----Fmax3= 77.5 N
Force (N)
Displacement (m)
0
10
20
30
40
50
60
70
80
90
0
0.01
0.02
0.03
0.04
0.05
0.06
0.07

Appendix M: ASTM D4833 Puncture Testing Raw Data - Synthetic Material

Puncture Testing

Specimen: Synthetic

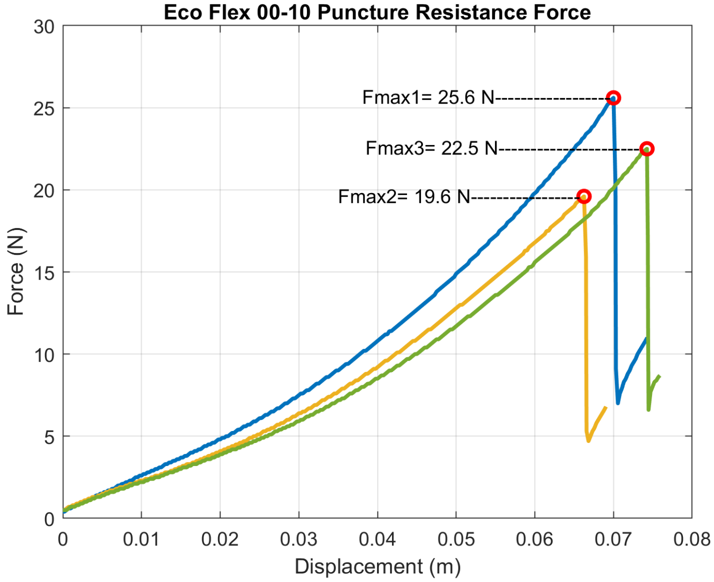
Sample Dimensions - EcoFlex 00-10

	Average Sample Diameter (mm)	Average Sample Thickness (mm)
Sample 1	45.0	3.0
Sample 2	45.0	3.0
Sample 3	45.0	3.0
Avg+	45.0	3.0

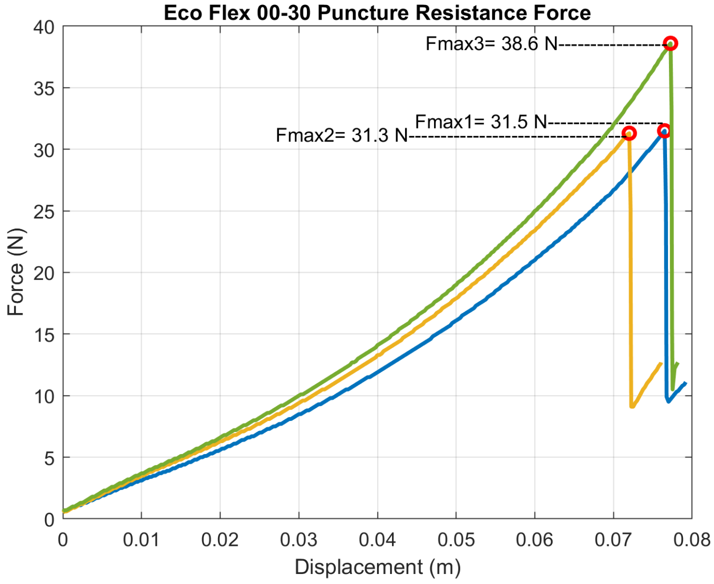
Sample Dimensions - EcoFlex 00-30

	Average Sample Diameter (mm)	Average Sample Thickness (mm)
Sample 1	45.0	3.0
Sample 2	45.0	3.0
Sample 3	45.0	3.0
Avg	45.0	3.0

Puncture Resistance Graphs - EcoFlex 00-10



Puncture Resistance Graphs - EcoFlex 00-30



Appendix N: Cast Organ Dimensions

	Right Kidney	Liver	Gallbladder
Length (mm)	86	184	69
Width (mm)	83	79	38
Thickness (mm)	70	117	35

Appendix O: Bill of Materials in Final Design

<table>
<tr><th></th><th colspan="2">Right Kidney</th><th colspan="2">Liver (V1&2)</th><th colspan="2">Gallbladder</th></tr>
<tr><td rowspan="2">3D Printed Molds</td><td rowspan="2">$3.9</td><td rowspan="2">$3.9</td><td>$8.3</td><td>$5.8</td><td rowspan="2">$0.69</td><td rowspan="2">$0.69</td></tr>
<tr><td>$7.1</td><td>$6.5</td></tr>
<tr><td>Molding Material</td><td colspan="2">$19</td><td colspan="2">$24</td><td colspan="2">$6.4</td></tr>
<tr><td>Total</td><td colspan="2">$27</td><td colspan="2">$38</td><td colspan="2">$7.8</td></tr>
</table>

	Ecoflex 00-10	**Ecoflex 00-30**
Cost	$36	$32
Weight	2 lbs (0.90 kg)	2 lbs (0.90 kg)