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Realistic Simulated Organs for Ultrasound Guided Procedures

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Realistic Simulated Organs for Ultrasound Guided Procedures

A Major Qualifying Project Report submitted to the faculty of

WORCESTER POLYTECHNI0C INSTITUTE

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Submitted by:

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Chapter 1: Introduction

Diagnostic radiologists administer and interpret images obtained by medical devices, such as x-rays, computerized tomography scans, and magnetic resonance imaging. As trained professionals, radiologists can also diagnose patients, perform various procedures, confer with physicians, and recommend other treatment options. According to the American Medical Association data in the Neiman Almanac, a total of about 40,000 radiologists were working in the United States in 2013 ("Total Number of Radiologists"). Every year, another 1,000 students enter any of the 150 radiology programs in the country ("Advanced Data Tables: 2015 Residency Table").

As Worcester Polytechnic Institute students, the group's Major Qualifying Project~~'s~~ (MQP) will focus on ultrasound imaging. Ultrasounds utilize high frequency sound waves to create an image of the inside of the body without being invasive (ACR, 2016). Ultrasounds can be used to identify pain, swelling, or various other patient discomforts. A very important use of ultrasound imaging is for guiding needles through the body cavity to complete various procedures, such as fluid aspirations or catheter insertions (ACR, 2016). Radiology students must be highly trained in ultrasound imaging and guided procedures because these require a high level of skill.

The ultrasound curriculum of every program consists of the same essential guidelines: recognize the differences between normal and abnormal tissue, understand how the machine operates, gain acquisition skills to efficiently locate the desired tissue or organ, and learn the manner in which to manage patients (Baltarowich et. al., 2014). Once the students effectively demonstrate all of the knowledge listed above, students will practice ultrasound imaging on each other or use a computer simulator. However, students do not get the opportunity to perform ultrasound guided procedures until their residency. Ultrasound guided procedures, such as fluid aspirations, biopsies, and insertion of catheters, are invasive, and thus, are difficult to perform due to the technical skill required. Simulators have been utilized to teach the skills necessary for the procedures.

There are two different classifications of ultrasound simulators: high and low fidelity (Lewiss, Hoffmann, Beaulieu, & Phelan, 2013). High fidelity simulators, such as computer programs, virtual reality simulations, or dummies with mimetic organs, adequately demonstrate the technical background and finesse needed to execute the procedures (Lewiss, Hoffmann, Beaulieu, & Phelan, 2013). Computer programs and virtual reality simulators may be preferred due to their cutting-edge visual displays, case databases, and automatic feedback (Blum, Rieger, Navab, Friess, Martignoni 2013). Mannequins or dummies with mimetic organs offer a realism that cannot be achieved with computer programs or virtual reality simulators. They offer accurate ultrasound imaging qualities and imitate challenges, such as image optimization and anatomical obstructions ("FAST Exam Real Time Ultrasound Training Model"). Most medical schools, however, do not utilize high fidelity simulators due to the price, ranging from $3,000-$50,000 USD per unit (Lewiss, Hoffmann, Beaulieu, & Phelan, 2013).

Due to the cost of high fidelity simulators, medical schools seek other training options. Low fidelity simulators usually consist of perishable items, are homemade, and are very cost effective (Lewiss, Hoffmann, Beaulieu, & Phelan, 2013). For this reason, many medical school use this practice. However, due to the simplistic nature of a low fidelity simulator, it often lacks the accuracy needed to complete an ultrasound guided procedure in real-time. The state of the art for ultrasound practices at many schools consists of students conducting target practice with olives embedded within a steak or chicken breast (Lewiss, Hoffmann, Beaulieu, & Phelan, 2013). The goal of this method is to optimize the image of the olive and puncture it ("Diagnostic

Medical Sonography | Wallace State Community College", 2016). This is a very cheap way to get some general target practice with the ultrasound machine. This method is over simplified and lacks anatomical structures which creates a lot of room for improvement to the current gold standard of teaching. The group aims to create a simulation comparable to the quality of high fidelity simulators at a cost relative to low fidelity simulators. This accomplishes the primary goal of better training students for real-time procedures.

This device was created by following the many steps in the engineering design process. First, the group met with the client, Dr. Hussain, and created a client statement. In this step, the team broke down the problem and determined possible directions to take the project with an open mind.

The second step was background research, a crucial stage in the design process. The team members started by researching the functionality of an ultrasound machine, the current state of the art for ultrasound guided procedure training, and simulations created by others. Building a foundation for the project allowed them to explore all options within the design space.

The third step was to specify the project objectives. The team created a list of the primary and secondary objectives and ordered them by level of importance using a pairwise comparison chart. Keeping the objectives specific allowed them to distinguish a need from a want for the design.

The fourth step was to brainstorm solutions. Keeping an open mind allowed the team to develop innovative approaches to the problem. After creating a list of possible materials, the team then compared and contrasted each one based on the project objectives, allowing them to pick the materials that best fit the criteria. The chosen materials were compiled and tested. The team needed to follow this process for each tissue aimed to be mimicked in the body.

Information gathered through interviews, observation, and literature review allowed for a better understanding of current ultrasound simulators, ultrasound guided procedure teaching methods, and ways to make the process more efficient. The success of the device was based upon the qualitative feedback from students, residents, and the client as well as quantitative similarities between the mechanical properties of real tissues.

For this project, the client was presented with a final design, instructions on how to set up the simulation, and future recommendations. The main goal of this project was to better train medical students for ultrasound guided procedures. In the following sections, you will be able to follow the steps taken by the group to obtain the project deliverables.

Chapter 2: Literature Review

2.1 Description of an Ultrasound

An ultrasound is the means of obtaining images from inside the body using high frequency sound waves. As shown in Figure 1 below, a transducer, or probe, emits a high frequency sound wave which then travels through the body. Once the wave is emitted, there are three different options that could happen to that wave: 1) It is refracted through the material, 2) It is absorbed by the material, or 3) It is reflected off the material (*How Ultrasounds Work* 2016). Each tissue, bone, or organ within the body has a unique set of ultrasound properties that is a direct correlation with its density and state of matter.

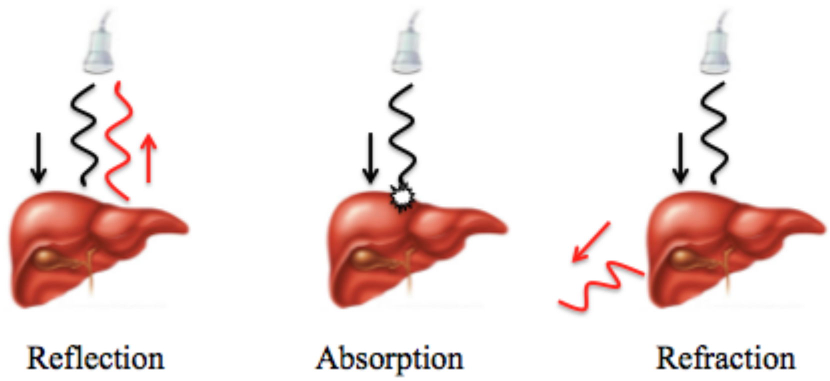
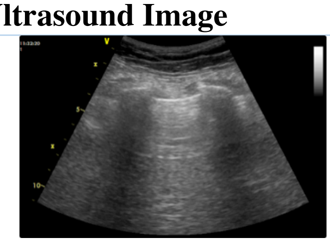
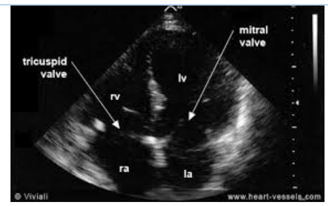
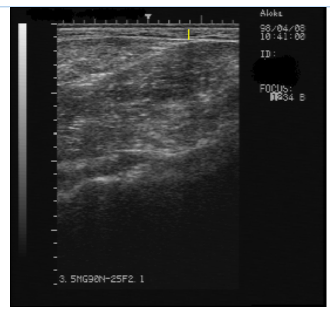
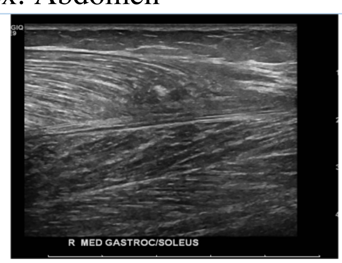
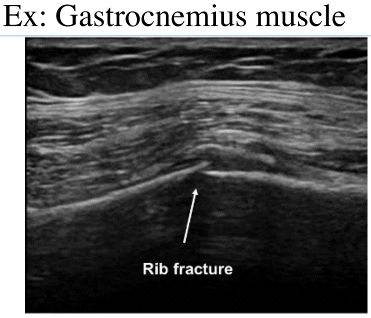


Figure 1 Reflection, absorption, and refraction display

Echogenicity is a tissue's ability to reflect or transmit sound waves in context to surrounding tissue. There are four terms to define echogenicity: anechoic, hyperechoic, hypoechoic, and isoechoic. Anechoic is used to define a completely black image due to the lack of boundaries. Hyperechoic materials produce a bright white ultrasound image usually due to an acoustic shadow. Hypoechoic tissues are those that produce moderate reflection, giving the appearance of 'fuzzy' image. Isoechoic tissue are those that appear similar to neighboring tissue (Ihnnatsenka & Boezaart, 2011). Table 1 below summarizes the echogenicity of common biological structures.

Table 1 Ultrasound imaging and characteristics of different tissues found in the body.

Image Characteristics of Various Human Tissues		
Medium	**Image Characteristics**	**Ultrasound Image**
Air	Poor quality due to scatter	 (Miller) Ex: Lungs

Water	Anechoic	 (Transverse Bladder Image) Ex: Full bladder
Blood	Anechoic	 (Displaying the heart and its 4 cavities) Ex: Heart
Fat	Hypoechoic to isoechoic	 (Fry) Ex: Abdomen
Muscle	Isoechoic	 (R Med Gastroc/Soleus) Ex: Gastrocnemius muscle
Bone	Hyperechoic	 (Fracture on Ultrasound) Ex: Fractured Rib

2.2 Ultrasound Guided Procedures

There are many different procedures that use guidance from an ultrasound machine. Since the machine can display images from inside the body, some precise procedures can be done less invasively. The steps for any ultrasound guided procedure are typically the same: 1) Hydrogel is applied to the skin and the transducer is placed in the desired area. The sonography is optimized. 2) The ultrasound image is used to guide the insertion of a needle or catheter into the skin and then into the desired target. 3) The target will be drained, aspirated, or biopsied depending on the procedure. The needle will be taken out and the procedure will be complete. An example of this can be shown in Figure 2.

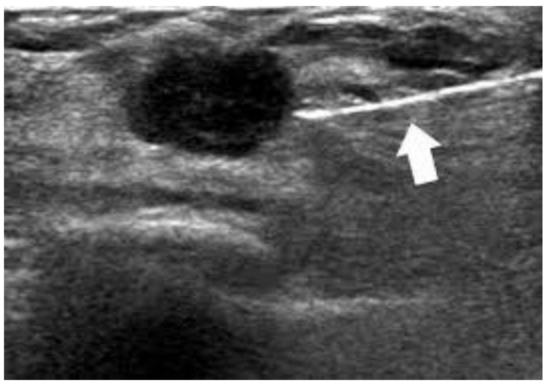


Figure 2 Needle being guided into an abscess under ultrasound guidance (Anmol)

Aspiration, drainage, and biopsy are the three main applications for these types of procedures in the abdomen (Jensen, 1984). An aspiration is a procedure to remove extra fluid from parts of the body. This procedure can be done to relieve the patient's symptoms or to obtain samples for further testing (Paquin, 2014). Abscesses, filled with pus or debris, usually cause discomfort. Draining abscesses is a procedure that would otherwise require open surgery. A biopsy is a sample of a tissue from the body taken to be further examined. (Holcomb, 1983).

2.3 Ultrasound Guided Procedure Current Teaching Method

In order to be certified in ultrasound guided procedures, students must meet a number of requirements. First, students must be able to understand the anatomy of the human body, recognize healthy versus unhealthy tissue, and distinguish different tissues under ultrasound imaging. Next, students must understand the ultrasound machine in its entirety. Third, students must be able to optimize the image of the desired target. In addition to the ultrasound techniques, students must master bedside manner. The students must be able to stay calm, cool, and collected in any situation that may occur. They must remain poised under possible complication and be able to comfort patients as these surgeries can be unsettling. Lastly, students will witness the procedures being done before performing the procedures themselves (Astolfi et. al., 2014).

The current gold standard for teaching ultrasound guided procedures if fairly simplistic. Students learn basic anatomy and the mechanics behind an ultrasound machine in textbooks and demonstrations. Image optimization is done by practice on one another as well as on an olive embedded within a pieces of chicken. Patient care is taught by both text and observation (Astolfi et. al., 2014).

2.4 Ultrasound Simulators

Ultrasound simulators can be categorized into two different sections: low and high fidelity. These classifications are based on how accurate the phantom material is to the actual sonic properties of human tissue. Phantom tissues can be classified into two categories as well: static and dynamic. Dynamic phantom tissue can display changes overtime while static phantom tissue remains stagnant (Lewiss, Hoffmann, Beaulieu, & Phelan, 2016). Usually, high fidelity simulators are dynamic being that they can be virtual reality or computer programs. Low fidelity phantoms are typically homemade, causing them to be static simulators.

Figure 3 Student imaging and olive embedded into a chicken breast [Untitled illustration of ultrasound practice]

Most low fidelity simulators, shown in Figure 3, would be a protein and paired with a target. These types of simulators are very easy to obtain, do not cost much, and are a great introduction to basic skills. However, this method is overly simplistic, non-reusable, and cannot train for more difficult procedures due to its unrealistic nature.

High fidelity simulators aim to mimic portions of the human body as closely as possible. These simulators are a comprehensive teaching tool that can train for almost any situation as shown in Figure 4. However, they are very expensive costing from $3,000 to $50,000 USD per unit. In general, the higher the fidelity of a phantom or simulator, the more expensive (Al-Elq, 2010).

Figure 4 High fidelity ultrasound simulator. (Thoracentesis Ultrasound Tissue)

2.6 Project Relation to the Larger Problem

Since the current teaching methods are so simplistic, students do not gain sufficient training until they are performing the procedures in real time. Ultrasound guided procedures are particularly complex due to the many different factors involved. Not only does it require accuracy and steady hands, but the person performing the procedures must also be able to navigate around barriers. Using a chicken breast with olives embedded within does help the students with target practice, but does not prepare students for possible complications.

Along with the anatomy of the current teaching method being too simple, there is no hands-on patient care teaching until students are in their residencies. This poses a problem with students learning about staying calm and collected under various complications.

The team aims to address these problem and improve the current ultrasound guided procedure simulations at a lower cost than that of current high fidelity models.

2.7 Homemade Simulators

In order to combat the issue of biologically and monetarily inadequate simulations for ultrasound guided procedures, many haven taken to creating low fidelity versions using a variety of materials. There are three common components between homemade simulations: a bulking agent, an ultrasound scatter material, and targets (Kendall & Faragher, 2007). A bulking agent is used to provide volume to the phantom. The scatter material simulates the natural ultrasound wave scatter that occurs within organs. Targets are for realistic practice in hitting a specific location within the phantom organ. There are copious amounts of combinations of the components listed above to create an ultrasound simulation, and a few materials of each are discussed in the following sections.

2.7.1 Bulking Agent

As mentioned above, the purpose of a bulking agent is to add volume to the phantom. It allows the phantom to be molded into whatever shape necessary and is the main component of the simulation as a whole. Some perishable bulking agents include cooking-grade gelatin, mixtures with evaporated milk, and agar (Chantler et al. 2004; Kendall & Faragher, 2007; Madsen, Frank, & Dong, 1998; Sorbi, Vazquez-Sequeiros, & Wiersema, 2003.; Zell et al., 2007).

Cooking-grade gelatin is easily located at a local grocery store, is moldable, and is non-toxic during preparation and use (Zell et. al.). It is very stable at room temperature, and with the help of additives, can exhibit many different sonic properties, allowing for multiple simulations of different organs. However, temperature differences cause a variance in the ultrasound images, and it is difficult to obtain uniformity with the additives as the gelatin hardens (Culjat, Goldenberg, Tewari, & Singh, 2010).

Evaporated milk, used in addition to cooking-grade gelatin or agarose, can be utilized in liquid or solid form, is easily found at a local grocery store, and is inexpensive (Madsen, Frank, & Dong, 1998). The combination of evaporated milk must be filtered in order to remove all particles that may inhibit the ultrasound image (Madsen, Frank, & Dong, 1998).

Another bulking agent is agar. Agar, usually utilized to culture bacteria or as a medium in gel electrophoresis, is a polysaccharide polymer that is extracted from seaweed. It is also easily molded, non-toxic, and has a high melting point (Burlew et. al., 1980; Sorbi, Vazquez-Sequeiros, & Wiersema, 2003; Chantler et. al. 2004). Agar has an improved temperature resistance and particle suspension (Culjat, Goldenberg, Tewari, & Singh, 2010). However, all the perishables mentioned above are susceptible to bacterial growth and are more fragile than their nonperishable counterparts.

Some nonperishable bulking agents include polyvinyl alcohol (PVA), polyacrylamide gel, and silicone (Zell et. al., 2007; Ophir, Nabil, & Jaegar; Madsen, Zagzebski, Banjavie, & Jutila, 1978; Scherzinger et. al., 1983). Polyvinyl alcohol is a water-soluble synthetic polymer used for adhesives and as a protective layer on textiles. Depending on the amount of copolymerization, PVA can exhibit many different sonic properties, making it a versatile bulking agent in this application. It also is low cost and has an indefinite longevity. However, PVA needs a twenty-four-hour freeze-thaw curing cycle, and in order to make it transparent, many other chemicals, such as dimethyl sulfoxide, must be added to obtain the desired properties (Zell et. al., 2007; Culjat, Goldenberg, Tewari, & Singh, 2010). Also, the powdered form of PVA can be a skin and eye irritant.

Polyacrylamide gel is also commonly used as the matrix in gel electrophoresis. When cured, it has the appropriate sonic properties of a soft tissue phantom. However, its monomer, acrylamide, is a carcinogen and neurotoxin. Special care must be taken, especially in the presence of high temperatures and UV light, which cause the polymer to depolymerize (Zell et. al., 2007; Culjat, Goldenberg, Tewari, & Singh, 2010).

Silicone, a synthetic rubber, also has great potential due to its longevity, stability, and ability to be molded and embedded by targets. It is also nontoxic during preparation and use. However, after a certain thickness, silicone does not image well due to its high metallic ion concentration (Culjat, Goldenberg, Tewari, & Singh, 2010; Zell et. al., 2007).

2.7.2 Ultrasound Scatter Material

As mentioned previously, in order to obtain an image, sound waves are propagated through the body, and the image is composed of the reflected waves. Scatter echoes also occur as reflections off of smaller boundaries within a material. Due to each organ's different anatomy, individual organs have a signature scatter. For instance, the liver would have less scatter because of its dense, uniform layers compared to the lungs, which are full of air and alveoli. It is because of this that many homemade ultrasound simulators incorporate a material to mimic this. Such materials include graphite powder, flour, cornstarch, calcium carbide, and Metamucil (Kondo, Kiitatuji, & Kanda, 2006; Zell et. al., 2007; Chen et. al. 2016). No exact research has been done on the selection of scatter materials.

2.7.3 Simulation Targets

A benefit to any simulation is the incorporation of target practices. Cysts, tumors, and extraneous fluids may be added in order to create realistic scenarios. Utilizing targets can increase the accuracy of the ultrasound image as well. Sacs or hollowed spaces filled with liquid would be acceptable for fluid aspirations (Ophir, Nabil, & Jaegar). In one simulation, a cyst was modeled with various materials such as diced carrots, elbow macaroni, peas, fingertips of surgical gloves, and saline solution (Sorbi, Vazquez-Sequeiros, & Wiersema, 2003).

Chapter 3: Project Strategy

3.1 Initial Client statement

Dr. Hussain, the client, is a professor and doctor at the University of Massachusetts Medical School (UMASS) interested in further developing the teaching methods of ultrasound guided procedures. Initially, the client tasked the project team with creating a wearable device that could be used to enhance ultrasound guided procedure training for students. The client statement from Dr. Hussain was constructed during the first meeting. He told the design team what he was looking for, and together they created the following statement: "To create a wearable device that imitates ultrasound imaging and needle puncture characteristics of human organs." The client wanted to better train students in ultrasound guided procedures by adding a patient care aspect. Patient care is a huge role during an ultrasound guided procedure and is not practiced until students are doing the procedures in their residencies.

3.2 Revised Client Statement

Dr. Hussain spends time teaching medical professionals of other countries in order to enhance the standard of medicine worldwide. Due to the Board of Registration of Medicine of Massachusetts's policy 234 CMR and many other federal and state laws, medical professionals of other countries cannot practice medicine in the state of United States without a state or federal issued license/approval (Health and Human Services, 2016). Since this is the case, the foreign doctors can learn techniques through oral presentations but cannot practice them. The current gold standard of teaching at UMASS and many other medical schools is as previously stated rudimentary, using chicken and an olive for target practice. A realistic simulation would allow Dr. Hussain to teach his practices in a life-like manner and also allow foreign doctors to practice procedures in the US or their host country.

After numerous meetings, the original client's needs emerged into a more concise statement. The updated client statement is as follows: "To create a realistic, inexpensive, safe, and user friendly simulation focusing on the kidney and liver in order to better train foreign professionals and medical students. The model must imitate ultrasound imaging and needle puncture characteristics of human organs."

Overall, this project is designed to better train students in all aspects of ultrasound guided procedures. This device needs to be realistic by having image and mechanical properties of real organs. This device needs to model the abdomen and include a simulated liver and kidney. This device needs barriers for students to avoid such as a vascular system. This simulator should be used concurrently with, or in replacement of, the current state of the art to maximize ultrasound guided procedure training. The device should have a series of targets to assess skill levels of the students using the simulator.

Originally, it was not stated which sections of the body would be focused on or how in depth the client wanted this device. By making the device anatomically correct with accurately represented organs, the device could better train students on precise procedures. With Dr. Hussain's experience in radiology, he believes that this form of training could lead to a higher success rate in this field. This simulator could also be a teaching tool for foreign physicians learning more novel procedures.

3.3 Design Requirements

Based on the final client statement, the team created a list of design requirements including objectives and constraints for this project. The goal of this project is to create a simulation device that mimics imaging qualities and mechanical properties of human organs to better train students and foreign trained professionals in ultrasound imaging and ultrasound guided procedures. Combinations of materials, such as gelatins and polymers, must be used to best simulate the image quality and mechanical properties of human organs. The device must be fairly simple, cost effective, and accurate to best teach students.

According to the client, the final simulation design should be safe, durable, wearable, realistic, accurate, precise, user friendly, and cost effective. A pairwise comparison chart found below in Table 2 was constructed by the team to best prioritize the objectives. The team separated the project objectives into two categories, primary and secondary objectives.

Table 2 Pairwise comparison chart of objectives

	Safe	**Durable**	**Wearable**	**Realistic**	**Accurate**	**Precise**	**User Friendly**	**Cost**	**Total**
Safe	N/A	1	1	1	1	1	1	1	7
Durable	0	N/A	0	0.5	1	0	0.5	1	3

Wearable	0	1	N/A	0	1	1	0	0	3
Realistic	0	0.5	1	N/A	1	0.5	0.5	1	4.5
Accurate	0	0	0	0	N/A	0.5	0.5	0	1
Precise	0	1	0	0.5	0.5	N/A	0.5	0	2.5
User Friendly	0	0.5	1	0.5	0.5	0.5	N/A	0.5	3.5
Cost	0	0	1	0	1	1	0.5	N/A	3.5

3.3.1 Primary Objectives

The primary objectives are to keep the device safe, realistic, user friendly, and cost effective. According to the client, the main goal is to better train students for real-life procedures. Since the students will be using real needles to make the simulation as life-like as possible, safety is of main concern. Also, the team had a preference for nontoxic materials for the safety of the users. The simulation must be realistic, meaning the organs must image and feel real to obtain the best results. The needle puncture as well as the image quality of each organ must be mimicked as closely as possible. Since the design will also be used to train medical professionals of other countries, the design needs to be user friendly. The cost of the device must remain less than that of available devices currently on the market, yet offer more realism than the state of the art.

Table 3 below shows the design team's primary objectives along with a brief description on how the objective will be met.

Table 3 Primary objectives as determined by the pairwise comparison chart

Safe	▪ Nontoxic materials ▪ Use of needle in simulation
Cost	▪ Cheaper materials ▪ Obtainability of materials
Realistic	▪ Image quality and needle puncture characteristics must be comparable to real human organs
User Friendly	▪ Simple directions ▪ Easy instructions and assembly

3.3.2 Secondary Objectives

The secondary objectives of this project are to make the device durable, accurate, precise and wearable. The device being durable would make each simulated organ last longer. In order to have the training progress, students must be able to assess their skill level. The accuracy and precision of the ultrasound image and needle puncture characteristics ideally would remain reproducible between simulators. The patient care aspect can be addressed by making the device wearable, offering more realism than the state of the art. Table 4 below displays the secondary objectives and a brief descriptions on how they can be achieved.

Table 4 Secondary objectives as determined by the pairwise comparison chart

Durable	▪ Self-healing phantom tissues ▪ Minimize the amount of perishable items
Accurate and Precise	▪ Image quality and mechanical properties remain within a reasonable standard deviation of actual values ▪ Image quality and puncture characteristics must be reproducible
Wearable	▪ Adjustable to fit different "patients" ▪ Be somewhat comfortable

3.3.3 Project Constraints

Along with the objectives of this project, there are a few constraints the team members needed to consider. The constraints included time, cost, lack of information, teaching limitations, and the complexity of the human body. Since the team only has from September of 2016 to April of 2017, they have to create a schedule and strictly follow a timeline. Because the redesigning and testing stages require the most amount of time, this will become the team's main focus. Money is always a factor when doing research or design work. The team needs to take into consideration how well this device would do on the market compared to the current state of the art. The team was given a total of $500.00 from WPI as described in the MQP guidelines.

Majority of the literature found on low fidelity simulations is outdated, and high fidelity simulations are patent-protected. This causes a large gap of potential ideas the team does not have access to. There are some restrictions in terms of the device's teaching ability and the complexity of the human body. The only way for a student to gain the utmost realistic practice is to perform on a live patient. Because this is not possible, the team understood this will be a limitation of the device as a whole. Additionally, the human body is very complex and the team hoped to simplify the abdomen while creating a detailed standard of practice.

3.4 Standards and Regulations

There are two sets of guidelines that will influence the design of the ultrasound simulator: medical school standards and device regulations. UMass, as an accredited institution, must follow the curriculum guidelines as explained by the Liaison Committee for Medical Education (LCME). Also, as a medical device, the simulator has certain safety and accuracy regulations created by the Simulation Interoperability Standards Organization (SISO) and the United States Food and Drug Administration (FDA).

3.4.1 Liaison Committee for Medical Education Standards

As mentioned before, LCME grants medical schools accreditation so long as the institution follows the standards set forth. In the *Functions and Structure of a Medical School*, enacted in 2016, there are a few curricular standards the device must follow. First, schools must foster students' critical judgment and problem solving skills (*Functions and Structure of a Medical School*). In order to do this, the curriculum must incorporate fundamental principles of medicine and provide opportunities for students to utilize those newly acquired principles in respect to different scenarios where health and disease is involved. The group's device, based on its purpose, essentially does just this. The device allows students to ultrasound tissue and critically interpret the image in order to recognize disease states or the lack thereof.

3.4.2 Device Regulations Defined by the Simulation Interoperability Standards Organization and the Food and Drug Administration

As previously mentioned, the SISO, in conjunction with the International Organization for Standardization (ISO), creates standards applicable specifically to simulators, and thus, this project. The standard most applicable to this device is SISO-GUIDE-001.1-20122 and SISO-GUIDE-001.2-20122, included in the Guide for Generic Methodology for Verification and Validation to Support Acceptance of Models, Simulations, and Data (GM-VV). The purpose of the GM-VV is to provide a technical framework that can apply to all models and simulations no matter which stage of development the device is in.

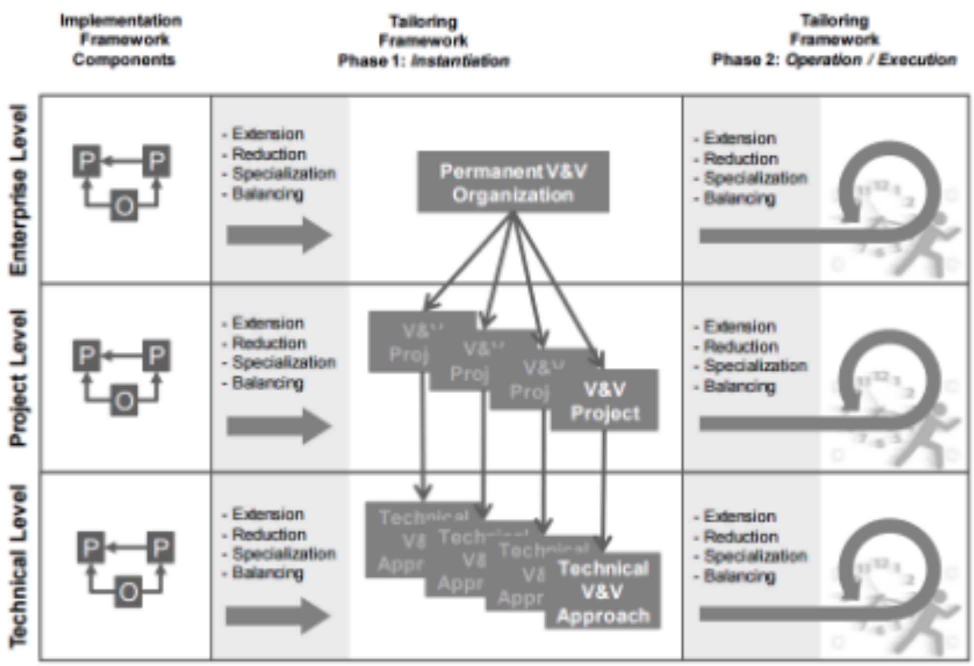


Figure 5 The intended framework to utilize in accordance to SISO-Guide-001.2-2013.21 (SISO-Guide-001.2-2013).

Based on Figure 5, a framework tailored to ensure the verification and validation processes of simulators will be organized. Within the process, the group focused on the project and technical levels. On the technical level, a generic engineering cycle is utilized. On the project level, a generic project structure helps manage all the technical verification and validation work (*SISO-Guide-001.2-2013*). Although this standard focuses more on the production of the simulation, the importance of following these steps is critical in the production and acceptance of the project's final device in the current market.

The FDA Center for Devices and Radiological Health (CDRH) has pertinent regulatory priorities related to this device. Some of these guidelines include biological risk evaluations and advanced tests and methods for predicting and monitoring medical device performance (Regulatory Science Priorities (FY2017)). Biological risk evaluations are to ensure the device, although not implantable, does not have any harmful chemicals, does not produce any immune responses, and does not contain any triggers (contaminants, manufacturing materials, residues, etcetera) (Regulatory Science Priorities (FY2017)). This specifically applies to the team's simulation because there were many different materials. As a safety concern, none of these materials individually, nor in combination with other material within the device, should have adverse effects on the user. Another guideline set by CDRH is that there must be advanced tests to better foresee any potential problems with the device (Regulatory Science Priorities (FY2017)). One method of adhering to this guideline is to fully understand the effects of degradation from oxidation, corrosion, flaking, and other methods of the materials.

3.5 Management Approach

For the duration of the project, the schedule detailed in Figure 6 represents the rough timeline. Of course, given the nature of the project, some tasks took longer than expected, and the schedule was updated frequently to reflect those changes. The main purpose of this schedule was to maintain an organized method of staying on track.

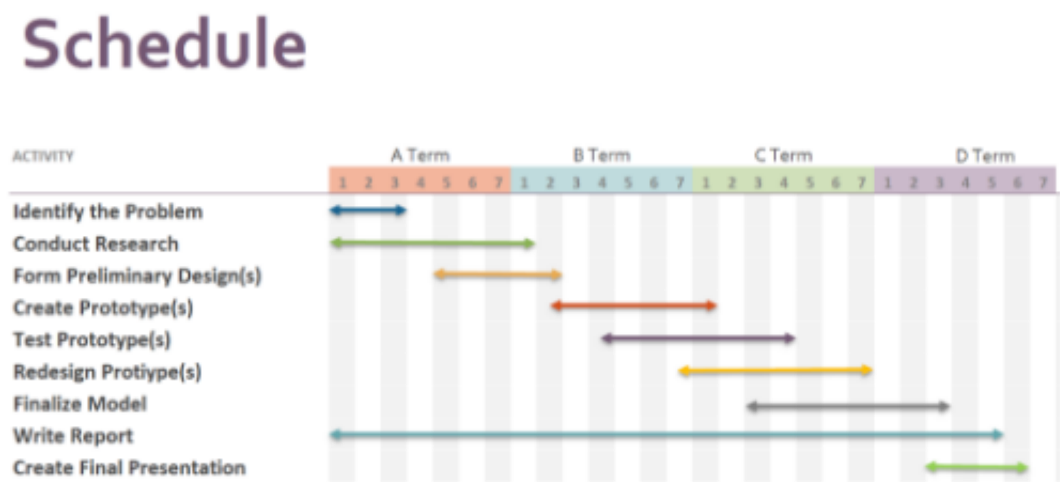


Figure 6 Gantt chart of the progression of the project throughout the school year

As previously mentioned in the Introduction, the design process was very repetitive. The Create Prototype(s), Test Prototype(s), and Redesign Prototype(s) stages had a large amount of overlap during the middle of the year due to this. During the Create Prototype(s) phase, different potential materials for each tissue was tested for their mechanical properties and ultrasound image. By the end of December, the team members had some potential materials chosen for each tissue. Then, the materials were arranged and tested together by UMass radiology professionals and medical students during the Test Prototype(s) phase. Based on their feedback, other designs, and ultimately a final model, were created.

Chapter 4: Design Process

4.1 Needs Analysis

The need of this MQP project is to create a simulation that allows radiology students and foreign trained doctors the practice necessary to perform ultrasound guided procedures. The device contains materials that mimic the ultrasound image and mechanical properties of human organs. With the knowledge and skill gained from this device, medical students could be better prepared for their medical residencies in the future.

As described by the LCME, every accredited medical school must define the learning experiences students encounter, whether it be real-life or simulation, to meet the objectives of the school. The school establishes types of scenarios that all medical students must have experience with, including types of illnesses, clinical conditions, and types of patients (*Functions and Structure of a Medical School*). Specifically at UMass, the objectives for radiology students are to understand the ultrasound machine's functions, how to optimize images, and to learn the correct diagnostic procedures. Due to various ethical reasons and their difficulty, ultrasound guided procedures are not fully directed in medical schools. However, a target practice is performed using olives embedded within poultry, and this is the gold standard for ultrasound guided procedure practice in many medical schools across the nation (Lewiss, Hoffmann, Beaulieu, & Phelan, 2013) As previously mentioned, there are high fidelity simulators ranging from $3,000 to $50,000. This is a price far beyond what medical schools are currently paying, and they are often not as durable as their prices suggest (Lewiss, Hoffmann, Beaulieu, & Phelan, 2013). An ultrasound simulation device can improve the training of radiology students not only at UMass but across the nation.

For such a device, there must be many specific requirements in order to offer the best training experience possible. The simulation must be accurate and precise in accordance to the anatomical positions of different organs and tissues in the abdomen. The image quality and mechanical properties must be reproducible in order to ensure consistency in the experiences of the medical students. Also, this ensures that students' learning experiences with the device will be easily relatable to live ultrasound guided procedures. In addition, the device must include targets in order to further hone students' skill sets. Table 4 below outlines the needs criteria of the device described above.

In addition to the needs of this project, there are wants as well. This device will ideally be affordable and user friendly. The total cost of the device should have an initial cost of no more than $900 with no more than $200 for maintenance per year. The materials within the device must be accessible for ease of use and maintainability. Finally, the device should be user friendly and safe for all students and professionals by having clear instructions and be simple to operate. The wants criteria described above can be found outlined below is Table 6.

4.2 Functions and Specifications

The function of this ultrasound guided procedure simulation is to provide a life-like teaching and assessment tool for students, foreign-trained doctors, and faculty. There were several functions the design team determined to be necessary for the frame of the simulation. These functions include mimicking the imaging quality and needle puncture characteristics of the upper abdomen, focusing on the liver and the kidney. This also includes choosing the appropriate orientation for the device, accurately placing barriers such as fat and blood vessels, and having a way to assess the skill level of the user of the device. The specifications are the measurements and values that were used to achieve the functions of the device, and these specific values can be mentioned in Section 4.1.

The orientation of the simulator includes both the positioning of the entire structure, and the organ placement inside the device. The simulator must be approximately 80-100 cm in thickness to mimic the correct dimensions of the average human. The organs that the project team will focus on the most is the liver and the kidneys. The liver is about 15.5 cm long and is located just below the diaphragm and rib cage. The right kidney are about 9-13 cm long and is located under the rib cage in the back of the abdomen ("Abdomen Normal Measurements - Radiography", 2016). Since this is the case, the simulation will need to accurately represent only a section of the lungs.

The group needed to duplicate the skin, muscle layers, and blood vessels located in the upper abdomen. The human skin is about 2.2 mm thick including the subcutaneous and adipose layer. This layer must stick and move together to demonstrate natural behavior (Xing Liang & Boppart, 2010). The diaphragm must be 3.2-5 cm. thick. Major blood vessels that will need to be mimicked include the aorta, the inferior vena cava, and the renal veins. The simulated aorta must be less than 2.5mm thick, with a diameter of 2-3cm (Erbel & Eggbrecht, 2006). The simulated inferior vena cava must be 2mm thick with a diameter of 1.5-2.5cm (Prince, Novelline, Athanasoulis, & Simon, 1983). The simulated renal arteries must be about 0.25cm thick with a diameter of about 5mm (Turba, Uflacker, Bozlar, & Hagspiel, 2009).

Most importantly, the liver and kidney must be imitated accurately. Because of the budgeted amount, the team was not able to sonically test the materials. In replacement, the team relied the comparative echogenicity of the ultrasound images from medical professionals.

The last function of the simulator is to have a way of assessing the skill level of the student, doctor, or faculty member. A final specification includes that the organs within the device cannot break under any forces of ultrasound imaging or needle puncture. Table 7 below depicts the general functions determined for the simulator and the specifications used as benchmarks for testing the device and accomplishing the functions.

Table 5 Function means of simulation device

Functions	Measurements and Specifications	
Mimic the imaging and needle puncture characteristics of the upper abdomen (liver, kidney, lung)	Liver	15.5 cm long
	Kidneys	9-13 cm long
	Lung	N/A
Proper orientation	Position of organs must accurately represent the abdomen of a human:	
	Liver	Upper right abdomen, under ribs and diaphragm

<table>
<tr><td></td><td><table><tr><td><u>Kidneys</u></td><td>Under ribs, back of abdomen</td></tr><tr><td><u>Lungs</u></td><td>Under ribs</td></tr></table></td></tr>
<tr><td>Accurately place barriers such as fat and blood vessels</td><td>Blood vessels that need to be represented include the aorta, inferior vena cava, and the renal arteries.
<table><tr><th>Blood Vessel</th><th>Thickness</th><th>Diameter</th></tr><tr><td>Aorta</td><td>2.64 mm</td><td>2-3 cm</td></tr><tr><td>I.V.C.</td><td>2 mm</td><td>1.5-2.5 cm</td></tr><tr><td>Renal Arteries</td><td>0.25 cm</td><td>5.4 mm</td></tr></table></td></tr>
<tr><td>Skills Assessment</td><td>Different fluid pockets at different depths:
Easy, medium, hard difficulties
Different color fluid for each level
Sensor for each level</td></tr>
</table>

4.3 Conceptual Designs

In order for the design team to determine how to accomplish the functions, a functions and means table was created. Solutions that could accomplish each function were brainstormed and can be found in Table 8 below.

Table 6 Material means of the simulation device

Functions	**Means**			
Skin, muscle, fascia layers	Silicone	Gelatin-based materials	Agarose-based material	Collagen scaffold
Liver	Graphite and gelatin mixture	Latex filled with highly viscous liquid	Open cell foam and water	Oil, gelatin, and agar mixture
Kidney	Hydrogels	Gelatin with additives	Agar	Meat or soy
Lung	Sponge	Styrofoam	Cotton	-
Blood vessels	Rubber tubing	Plastic tubing	IV tubes	Silicone
Fluid pockets or tumor representations	Sensors	Latex	Rubber	Reusable colored liquid

4.3.1 Bulking Agent Design Selection

The liver and kidneys are some of the most important parts of the team's project. These phantoms must mimic both the needle puncture and imaging characteristics of a real human organs with more focus on the imaging component. Many materials such as gelatin, agar, polyvinyl alcohol, and ballistics gel where selected for testing based on past literature and studies. The materials tested and their results were compared in images, needle puncture, and cost. This information can be found in can be found in Figure 7 and Table 9 below.

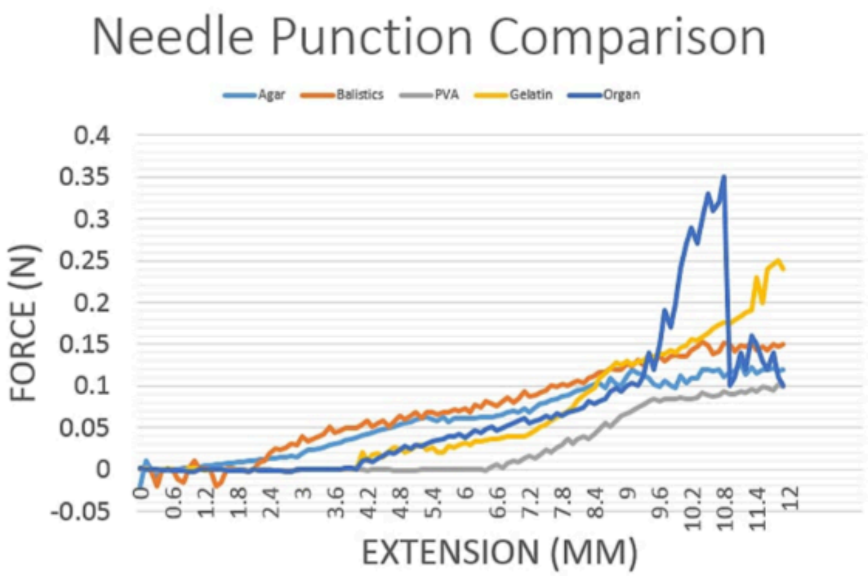
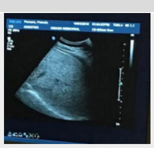
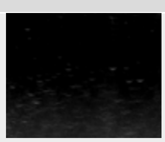
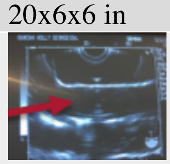
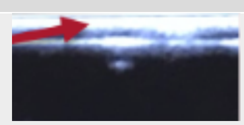


Figure 7 Needle puncture comparison between each bulking agent and a porcine liver

Table 7 Liver materials tested and results

Material	Porcine Liver	Gelatin	Ballistics Gel	Agar	Polyvinyl Alcohol
Cost	N/A	$0.46 per oz	$217.06 per 20x6x6 in	$13.81 per oz	$4.27 per oz
Image comparison					
Average Needle puncture force	0.24 N	0.20 N	0.15 N	0.11 N	0.09 N

The needle puncture was then analyzed using a two sample t-test assuming unequal variance. Each material was tested against a porcine liver with a null hypothesis of no difference in the average force and a hypothesis of 0.1 difference in averages, also shown in Appendix V. With an alpha level of 0.15, the null hypothesis could not be rejected with ballistics gel or the gelatin, and was rejected for the agar and polyvinyl alcohol. The needle puncture of the ballistics gel and gelatin closely resembled that of an actual organ.

Ballistics gel is premade and has a needle puncture that represents the constant force necessary on the porcine organ. However, ballistics get has a high melting point, making it nearly impossible to melt and remold into any shape. In addition, the ballistics gel is the most expensive material the team tested. When using ballistics gel as a bulking agent, needle tracts are left within the phantom, creating air pockets and inhibiting the quality of the ultrasound image. Agar is nontoxic with great particle suspension, but is very fragile and cultures bacteria very easily. Polyvinyl alcohol has a long lifetime, yet has a long production processes and can be an irritant in its powder form. Gelatin was the least expensive material tested as well as nontoxic. However, gelatin is non homogeneous and can be temperature dependent when stored.

Based on Table 9 and the information above, the team has chosen gelatin as the bulking agent for the simulation.

4.3.2 Scatter Material

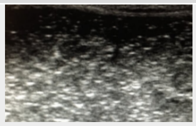
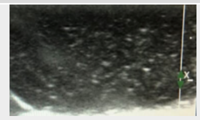
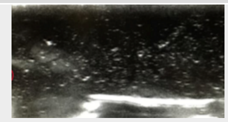
As mentioned previously, the purpose of the scatter material is to make the bulking agent, chosen in Section 4.3.1, appear more realistic. There are diverse choices in literature, including flour, graphite powder, cornstarch, calcium carbide, and Metamucil (Kondo, Kitatuji, & Kanda, 2006; Zell et al., 2007). Table 10, shown below, outlines some potential scatter materials that were researched.

The images in the table below were compared the liver and kidney images found in Figures 8 and 9, and a pairwise comparison was used. The values 0, 0.5, and 1 signify that the scatter material failed, somewhat achieved, or successfully achieved a similar ultrasound image. All the materials were used in a 1g: 1 cup of gelatin ratio, and the ingredients were mixed before blooming.

Figure 8 Ultrasound image of a human liver

Figure 9 Ultrasound image of a human kidney

Table 8 Comparison of Scatter Material

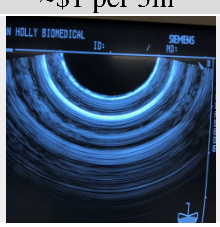
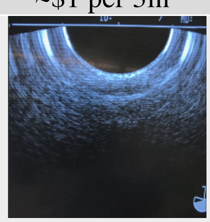
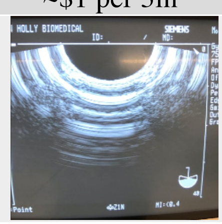
Material	Flour	Metamucil	Cornstarch	Sand (medium)
Cost	$0.58 per lb	$5.48 per lb	$1.56 per lb	$3.96 per lb
Ultrasound Image				
Image Score	1	1	0.5	0

Based on the information above, the team decided to utilize flour for the kidney and Metamucil for the liver.

4.3.3 Lungs Design Selection

The lungs in the team's simulation is not as important as other features. The lungs will need to image realistically but do not need the same needle puncture and mechanical properties. A comparison chart shown below in Table 11 was done by the team to determine which material would be used. The material cost and ultrasound images are compared.

Table 9 Comparison Chart between Styrofoam and sponge

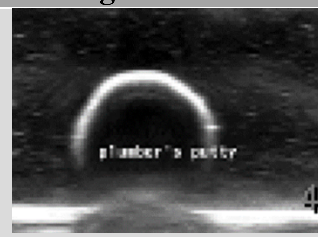
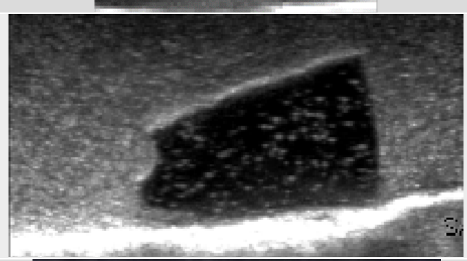
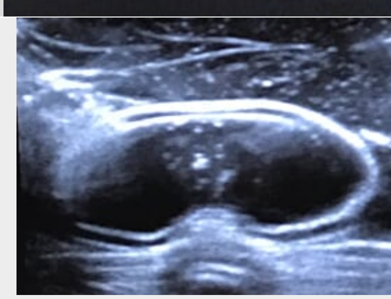
Trait	Styrofoam	Sponge	Cotton in a Bag
Cost	~$1 per 3in^2	~$1 per 3in^2	~$1 per 3in^2
Ultrasound Image			

Based on the imaging quality and the characteristics displayed in Table 11, the team decided to use sponge as the mimetic lung material.

4.3.4 Target Representation Design Selection

Adding a target component to the simulation allows the students to gain practice honing their skills. It also allows instructors to form realistic scenarios to their sessions. The team focused on the ultrasound image of the materials and their cost. The results can be found in Table 12 below.

Table 10 Potential Target materials

Material	Cost	Ultrasound Image
Plumber's Putty	$0.27 per oz	
Grapes (Peeled/ Unpeeled)	$0.47 per oz	
Hydrogel Bead	$16.36 per oz	
Ballistics Gel	$266.81 per ft^3	
Chicken (Raw)	$0.89 per oz	
Fish Oil Tablet	$0.07 per tablets	

The top materials based on Table 12 and qualitative responses from radiology professionals were grapes, plumber's putty, and fish oil tablets. These three materials were then compared against one another and to an ultrasound image of an abscess, shown in Figure 10.

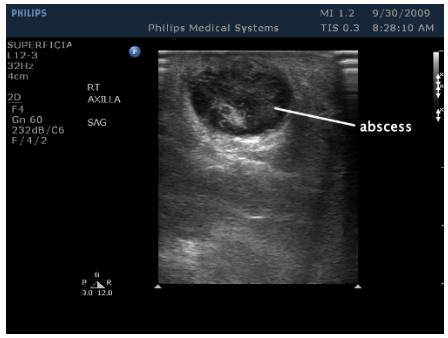


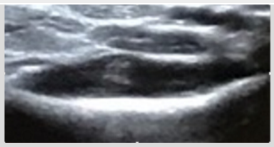
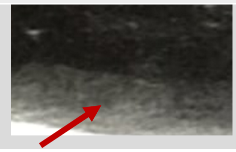
Figure 10 Ultrasound image of an abscess (Abscess cavity)

Grapes have intriguing images due to internal fibers, but abscess are more anechoic. On the other hand, plumber's putty has a hyperechoic effect, but does not contain enough detail within it to produce a natural image. Despite the double layer, fish oil tablets have a non-homogeneous appearance similar to that of the abscess. Because of this and its ability to be used as fluid aspiration practice, the fish oil tablet was chosen as a target for simulations.

4.3.5 Blood Vessel Selection

In addition to targets, the team wanted to incorporate more realistic, physiological structures within in the liver and kidney. This would allow for a more lifelike experience and allows instructors to control the difficulty level of the simulation. Due to the unique appearance of blood vessels under an ultrasound, the ability to manipulate the material as well as the appearance of the image was the main concern. The ultrasound images, manipulation rank on a scale of 0-1, and cost of the tested materials can be found in Table 13.

Table 11 Potential blood vessel materials

Material	Silicone Caulk	Vinyl Tubing (Filled with Liquid)	Gelatin with a Different Flour Concentration
Cost	\$0.65 per oz	\$0.11 per ft	\$1.04 per oz
Manipulation Ability	1	0.5	0
Ultrasound Image			

Based on the information above, the silicone caulk was chosen as a blood vessel representative because its ability to be manipulated easily and its resemblance to a blood vessel shown in Figure 11.

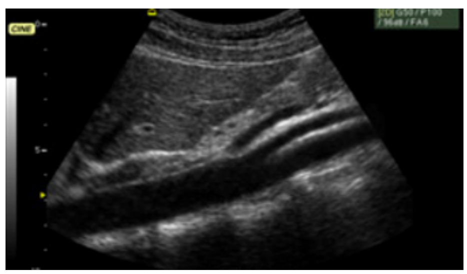


Figure 11 Ultrasound image of the abdominal aorta (Abdominal Aorta)

4.3.6 Mold for Mimetic Organs Design Selection

Since the organs need to be as realistic as possible, the molding process is key. The team compared and contrasted the many different methods, in Table 14 below.

Table 12 Potential molding techniques

Molding Option	Advantage	sadvantages
3D Printing	• Accurate detail • Mass produce	• Expensive (~\$100 per mold, per organ) • Printing material selection • Harder to get out of mold • Need 3D printer and CAD model

		• Need to print model and then print cast over it (More expensive)
Negative 3D Printing	• Accurate detail • Mass produce • Easily taken apart	• Expensive ~$150 per mold per organ • Material selection • Need 3D model online
Silicone Casting	• Accurate detail • Easy to get out of mold • Easy to make mold	• Must have organ to replicate • Cost ~$130 per mold (Both liver and kidney)
"Papier Mache"	• Cheap (~$10 per mold)	• Gelatin may disintegrate mold • Need real organ to mimic • Not as accurate
Cut-out from Gelatin Block	• Very cheap ($0 per mold)	• Not accurate • Harder to obtain desired dimensions (human Error)

Based on Table 14, the team took advantages and disadvantages into account and asked Dr. Hussain for his professional opinion. The team decided to create the mold by casting organs in silicone. The silicone molds were created using food grade *Smooth On Oomo® 30* which the team obtained through Amazon.com.

4.4 Alternative Designs

In order to obtain a realistic experience with the simulation, the team has created multiple initial and conceptual designs to be considered.

4.4.1 Design 1

For this design, the team wanted to create the most realistic experience as possible. In order to do so, a phantom would be created to mimic a cross section of a human abdomen as similarly as possible with all the anatomical structures. Since the project focuses on the liver and kidney, the right hemisphere would be replicated including the whole liver, whole right kidney, right lung, pieces of the rib cages, fat layers, muscle layers, dermal layers, and many more as seen in Figure 12 below.

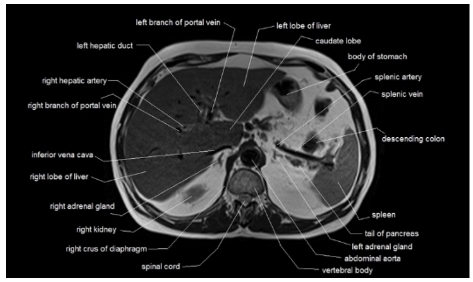


Figure 12 Cross-section of a human abdomen. Left side of this image is the hemisphere of focus. (MRI Abdomen Axial Cross Section)

This design would be in a rectangular shape and would utilize the materials selected in the previous sections. This would be a very realistic compared to a real patient. The liver and kidney would be to scale containing flowing vascular components in the liver and kidney and visible medulla in the kidney. Ribs, casting a shadow or resonance, would be an added difficulty to the practice. Both the liver and kidney can be blocked by ribs in different image optimization positions as seen in Figure 13 below.

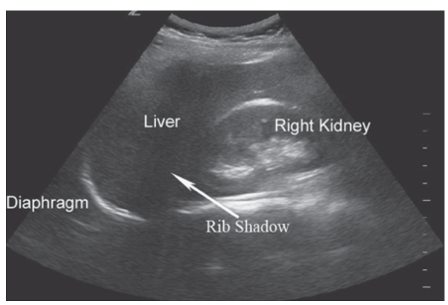


Figure 13 Ultrasound image of a right kidney being obstructed by a rib (Carmody, Moore, & Fellar-Kopman)

In addition, targets will be added to the phantom for procedure practice. The targets will be fish oil tablets at different depths as laid out in Section 4.3.4. This model will provide the most accurate and realistic practice of both ultrasound image optimization as well as guided procedures.

4.4.2 Design 2

In contrast to design one, the team wanted to create a more simplistic, and thus, more cost-effective design. Utilizing the cross-section of the distal abdomen concept, this design will contain less detail of the organs in order to emphasize target practice. This design will still be in a rectangular structure. A 'filler' concentration gelatin will be placed around the organs to complete the final block. The organs themselves will be made utilizing the silicone casting method chosen in Section 4.3.7. However, unlike design 1, the kidney and liver will be simplistic in comparison. The organs will contain more targets at various depths and simplified general vascular system composed of silicone caulk, the material chosen in Section 4.3.5.

4.5 Final Design Selection

Based on the design concepts in Section 4.4, a compromise of both was created as the final design. The team created a design with an epidermal and fat layer and realistic cavity filler.

In order to use gelatin as the bulking agent, there were two limitations the team needed to overcome: longevity and foam. As previously mentioned, gelatin is a perishable substance and lasts about 28 days before showing the initial signs of molding. Based on previous published literature, the team decided to try cinnamon leaf oil as an antibacterial. A longevity test can be seen in Figure 14 below.

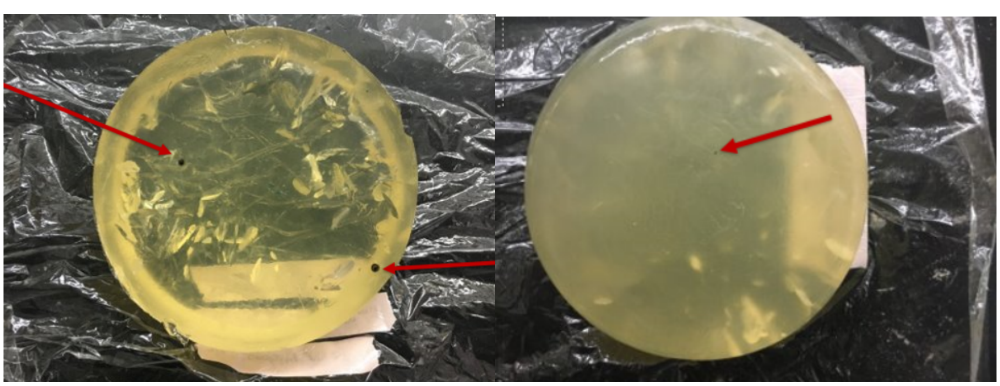


Figure 14 Gelatin with no oil (left) after 28 days. Gelatin with oil (right) after 92 days

In addition to the longevity, the cinnamon leaf oil reduced foam and air content in the phantom. The team attributed this to its antiseptic and pH-balancing abilities. Comparative images can be seen in Figure 15 below. The complete gelatin recipe can be found in Appendix II.

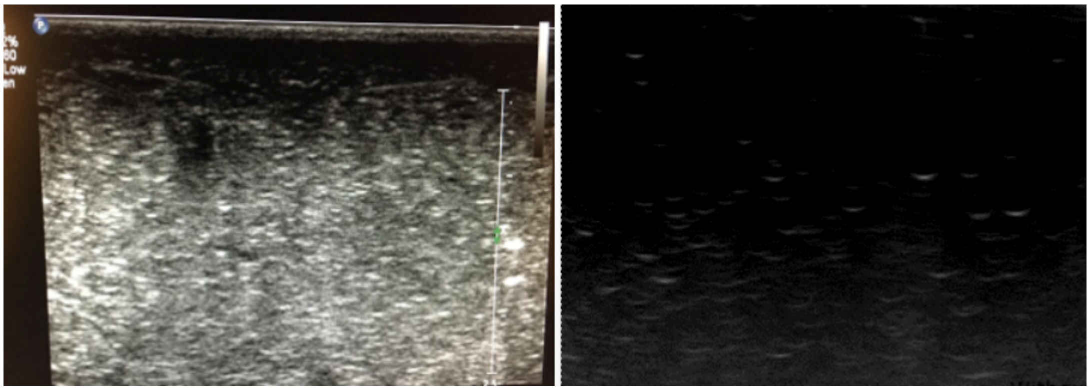
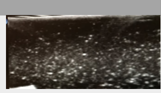
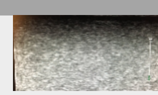
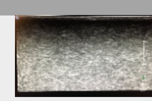


Figure 15 Ultrasound image of gelatin with no oil (left) and with oil (right)

Different concentrations of flour were manipulated to obtain the diverse gradients. In Table 15 below, the ultrasound images of gelatins with different concentrations of flour are shown.

Table 13 Ultrasound images of different concentrations of flour in 1 cup of gelatin

0 g of flour	**0.5 g of flour**	**1 g of flour**	**2 g of flour**	**3 g of flour**	**4 g of flour**
					

It was decided that the epidermis and fat layer were going to be 1 cup: 3.5g gelatin to flour ratio, and the cavity was going to be 1 cup: 0.5g gelatin to flour ratio. From this and the information in Section 4.3.2, the kidney is created with a 1 cup of gelatin to 0.5g of flour ratio, and the liver is created with a 1 cup of gelatin to 1g of Metamucil ratio.

The blood vessels and medulla in the kidney are created using silicone caulk. The hepatic portal veins in the liver and the medulla in the kidney were simplified, shown in Figure 16. These shapes were created by using *GE Silicone II Clear Kitchen and Bath Caulk*.

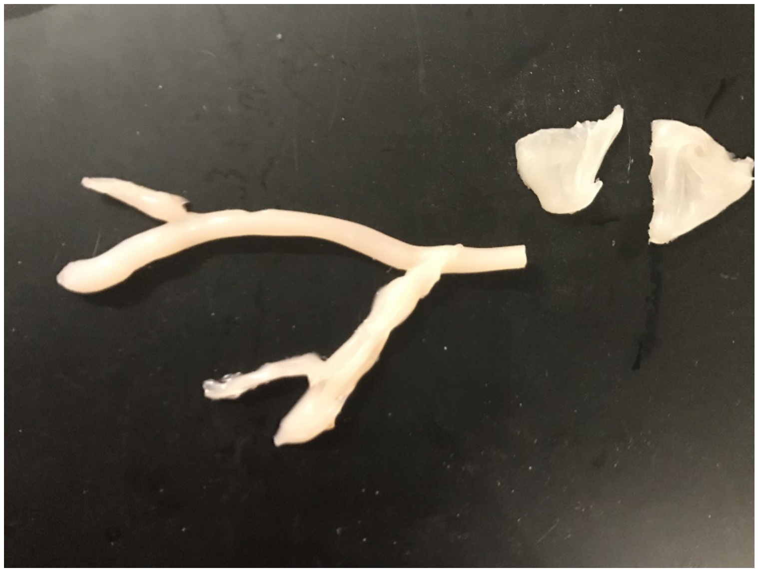


Figure 16 Simulated silicone blood vessels and medulla

Next, the molds were created. The organs were obtained by Adam's Farm House, a local butcher shop who graciously donated porcine and ovine livers and kidneys. The farm donated two of each type of liver and kidney. After obtaining the organs and measuring them, the team decided to mold porcine kidneys and ovine livers for this application, shown in Figure 17.

Figure 17 Liver and kidney obtained from the slaughterhouse.

With the help of the machine shop and Thomas Partington, the team created a box made from Plexiglas. The size of the box was determined by using the dimensions of the liver and the kidney. Both the liver and the kidney were molded within the same box. The Box can be found below in Figure 18.

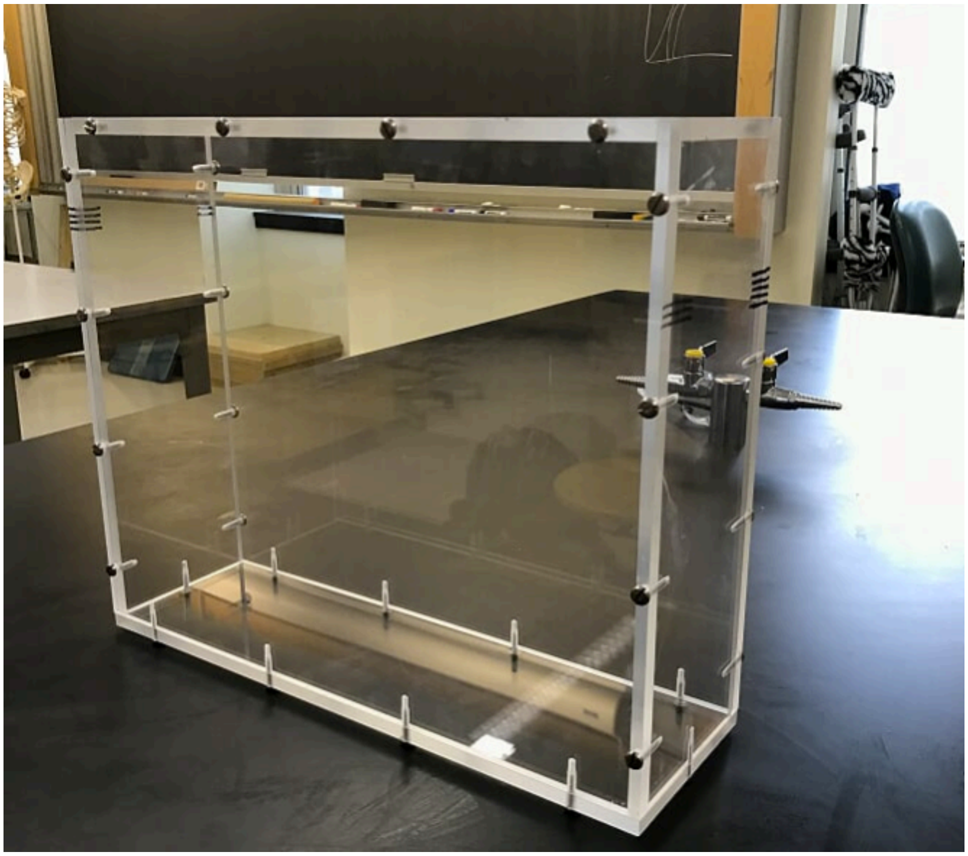


Figure 18 Plexiglas box (12x14.5x4 in) built to mold the organs with silicone

After the organs were obtained and the box was created, the team then followed the instructions to create the liquid silicone, and poured it over the liver and the kidney within the box as see in Figure 19.

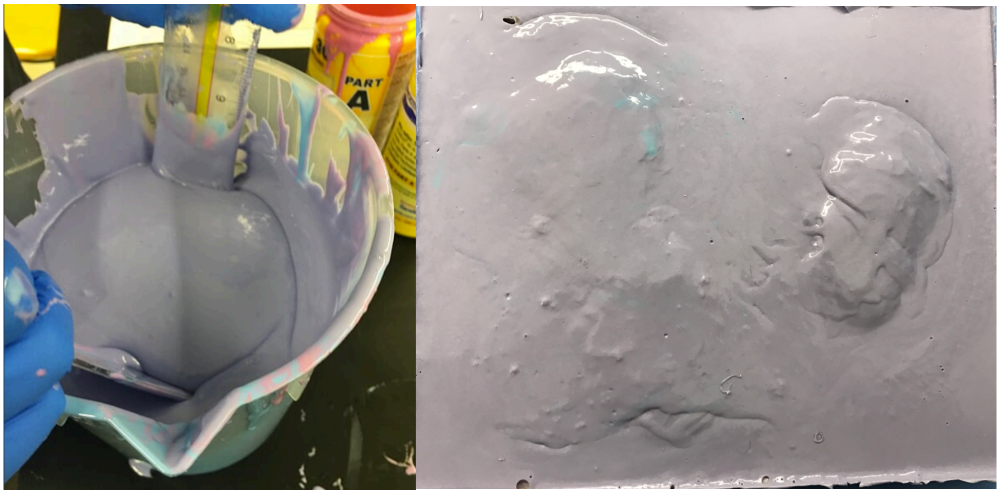


Figure 19 Mixing and pouring the silicone

Once the silicone was poured, the team the refrigerated the mold overnight. After a 48 hour curing time, the team took the hardened silicone with the organs inside out of the Plexiglas box. The team then began to cut the silicone to create the mold and retrieve the organs. This can be found in Figure 20.

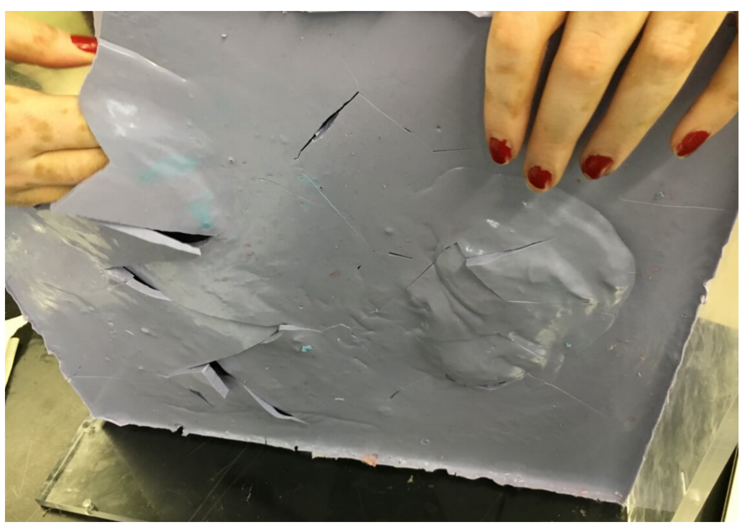


Figure 20 Finalized mold of the organs

After cutting out the organ, the team then created a hole for the gelatin recipe to be poured into each molding area. Completed gelatin-molded organs can be found below in Figure 21.

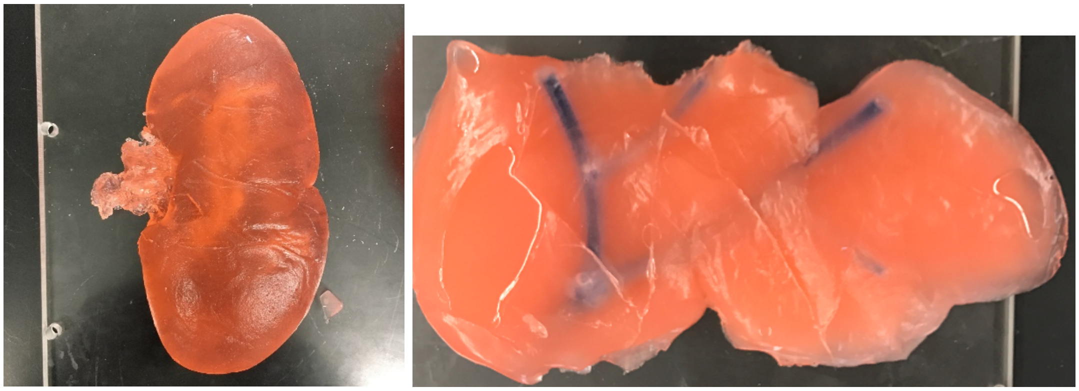


Figure 21 Final result of the gelatin mold

Once the molds were completed, all of the pieces were put together inside of a box. First the epidermis and subcutaneous fat layer was created, using 3.5g of flour per cup of gelatin, and allowed to harden for a minimum of 10 minutes at room temperature. Next, the cavity filler with 0.5g of flour per cup of gelatin was placed and allowed to harden for a minimum of 10 minutes at room temperature. The premade gelatin organs were then placed, and more filler was poured on top until the organs were completely covered. The complete box is shown in Figure 22.

Figure 22 Top (left) and bottom (right) view of the cross section gelation model

The corresponding ultrasound images of the liver and the kidney within the block can be seen in Figure 23 and Figure 24.

Figure 23 Kidney phantom ultrasound

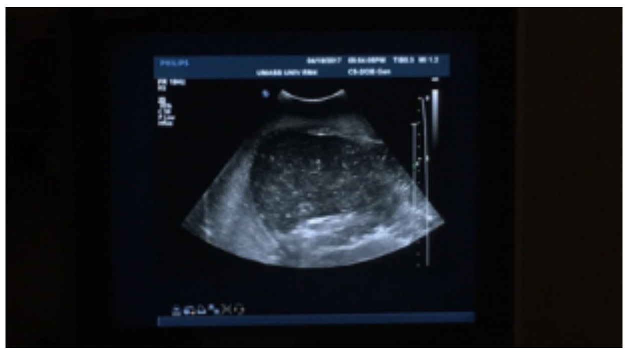


Figure 24 Liver phantom ultrasound

Chapter 5: Design Verification

In order to verify the design, two methods were used: quantitatively studying the needle puncture characteristics and qualitatively studying the opinions of UMass radiology students and professionals.

5.1 Needle Puncture Characteristics

The needle puncture characteristics of bulking agents were previously studied in Section 4.3.1. However, the team wanted to compare the difference in needle puncture between high and low fidelity simulators, the porcine liver, and the team's simulation. The low fidelity material tested was a chicken breast, purchased at a local grocery store. The high fidelity material was a silicone skin simulation, obtained through UMass Medical's simulation department. The comparison is shown below in Figure 25.

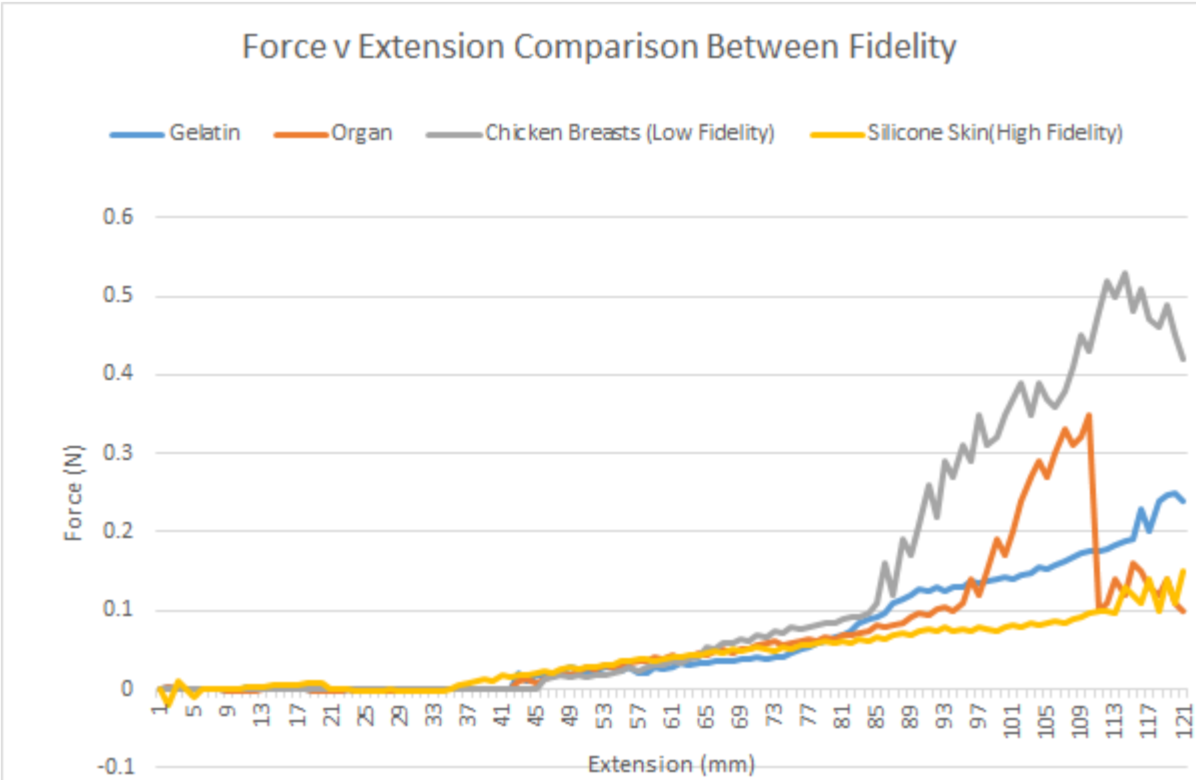


Figure 25 Measure of the force (N) of an 18G needle

Using the central limit theorem, a t-test was performed. Each simulation was individually tested against the porcine liver. The null hypothesis is that there will be no difference between the averages of the porcine liver and that of the chosen material. The hypothesis is simply there will be a difference of 0.01 in the averages of the porcine liver and the chosen material. The raw data of the statistical analysis can be found in Appendix VI. Using an alpha-level of 0.15, the null hypothesis was rejected for both the low and high fidelity. Using the same alpha level, the null hypothesis cannot be rejected for the team's gelatin. This means that the gelatin and porcine liver needle punctures averages closely resemble one another compared to the high and low fidelity simulators.

5.2 UMass Survey

In order to test our design, we conducted a study based off of previous literature (Heinzow et. al., 2013). There was a group of 25 medical residents from UMASS Memorial that participated. Participation was voluntary, and the students could pull out of the experiment at any time. Prior to the test, the team gave a copy of and read allowed a consent form that each participant signed and received an additional copy of. The IRB approved consent form can be found below in Appendix I. Each student took a pre- and post- survey, found in Appendix VII.

Based on these questions, seven categories could be obtained from the data: organ appearance, ultrasound image quality, realistic ultrasound image, ease of use, reproducibility, knowledge gained, and overall experience. The results can be found in Table 16 below as well as the average scores of each category in Figure 26.

Table 14 Percent responses of the study (Not rounded), n=25

Table	Subhead
Organ Appearance	96%
Ultrasound Image Quality	80%
Realistic Ultrasound Image	64%
Easy to Use	92%
Reproducibility	32%
Knowledge Gained	76%
Overall Experience	80%

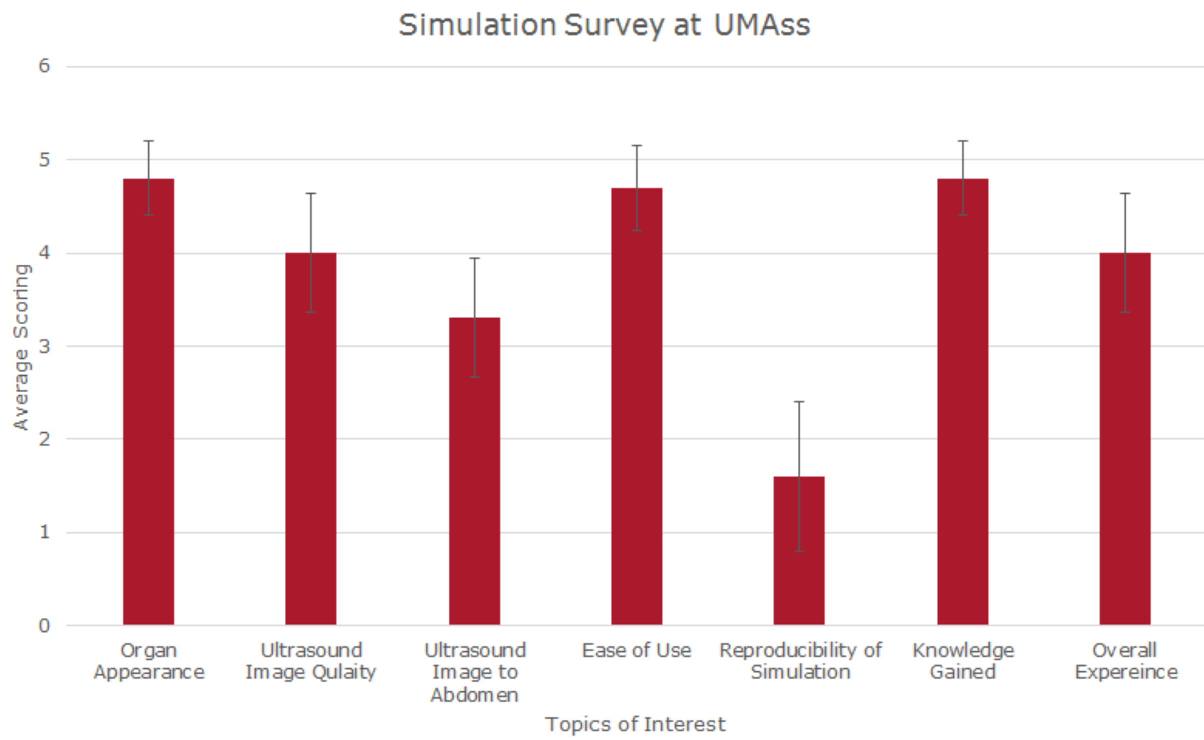


Figure 26 Simulation survey percent error graph

The team's device excelled in organ appearance, ease of use, knowledge gained, and overall experience compared to that of the state of the art. However, the lowest scores included reproducibility of the of the ultrasound image from simulation to simulation and the ultrasound comparison of a human abdomen. The team is aware of the ultrasound image to abdomen comparison and discussed in the design constraints in Section 3.3.3. The reproducibility from block to block can the attributed to the random settling of scatter material. This is perceived as benefit to the team for no two abdomens images similarly.

Chapter 6: Final Design and Validation

6.1 Economics

Based on evaluation, each full block costs $26.70, and the breakdown of this cost can be seen below.

Table 15 Cost of the team's simulation

Material	Amount	Cost	Total Cost
Gelatin	54 ounces	$0.46 per ounce	$24.84
Flour	12 grams	$0.01 per gram	$0.12
Metamucil	2 grams	$0.012 per gram	$0.02
Silicone Caulk	2 ounces	$0.65 per ounce	$1.30
Fish Oil	6 tablets	$0.07 per tablet	$0.42

A comparable Blue Phantom paracentesis ultrasound simulation costs $5,510.96 with a replacement tissue insert that costs an additional $3,430.96 ("Abdomen"). On the other hand, a low fidelity simulation costs a total of $3.72, $3.60 for the chicken breasts and $0.12 for the olives.

A total of 334 of the team's simulations can be made with the total price of the high fidelity simulation. On the other hand, 7 low fidelity simulations can be made with the amount spent on one of the team's simulations. The quality and cost of the simulation is where the team estimated to be. The cost is not substantially higher than the low fidelity simulation but still offers aspects of a high fidelity. Also, as so long as one has the recipe, this can be recreated anywhere for the same relative value.

6.2 Environmental Impact

Our device is completely nontoxic except for the silicone caulk used for the vascular system. If this silicone caulk were to be disposed of in an improper way, it could have some potential environmental impact. However, understanding that the silicone should not end up in a landfill, the team recommends that users of the device reuse the silicone when creating new blocks. When the device has started to parish or has been used numerous times, the user can break the device apart to obtain the silicone pieces and then dispose of the rest. The silicone pieces can be used in the next block and will be able to be used over and over again from block to block.

6.3 Societal Influences

Since this is a teaching tool, it has the potential for positive societal influence. Students and medical professional of other countries have the ability to improve their ultrasound image optimization, ultrasound procedure practices, as well as overall exposure. In the team's verification processes, the team witnessed a first year resident successfully executing a biopsy with the instruction of a fourth year resident on his third try. This proves to the team that this device could be a unique and effective teaching tool easily implemented to the current curriculum. With potentially better trained professionals and students, post operation complications could decrease as well as time taken to do the procedures. Overall, this could not only benefit the medical field, but could improve patient care and outcomes as well.

6.4 Political Ramifications

The device will help benefit the medical industry in other countries. By providing such a cheap and accurate alternative to ultrasound practice, medical professionals of other countries will be able to practice these operations before conducting them. When medical professionals of other countries come to the United States, they are not allow to perform procedures due to state and federal restrictions such as the Board of Registration of Medicine of Massachusetts policy 234 CMR. With this device, medical professionals will be able to come to the United States to learn medical procedures as usual, but will have an opportunity to learn the practices by actually performing the procedures in a life-like setting. After they have been taught the procedure and practice, they can take the recipe for the gelatin and create it themselves ensuring long term practice and improvement of skills sets.

6.5 Ethical Concerns

One of the main ethical concerns of the device is the origin of gelatin. Gelatin is created by granulating a mixture of porcine, ovine, and bovine bone and cartilage. These bones and cartilage are the remains found at slaughterhouses after the useful pieces have been collected. As one can imagine, the team's model may cause problems with vegans and those of specific religious beliefs, who do not use any products that contain animal byproducts. The team is aware of this limitation.

Another concern of the device is the 18 cups of water required to create each simulation. If a drought is occurring or if plentiful water is not available, then creating the simulation will pose a problem.

6.6 Health and Safety Issues

The device as a whole is does not pose a health or safety issue. However, needles are used in conjunction with it and are a safety risk. The user of the simulation must be cautious of the instruments they are utilizing. Also, the entire simulation is theoretically edible except the silicone. However, although it is washed, the silicone mold does come into contact with biohazardous materials, and the resultant gelatin should not be eaten anyway.

6.7 Manufacturability

The gelatin is very easily reproduced, taking about 4 hours total to have a solid gelatin phantom. However, the models in which to make the organ shapes are less reproducible. The silicone mold provides variability of the organs molded, providing room for disease state organs to be introduced to the device. Once a silicone mold is made for this device, it will last for a very long time. The team has created multiple blocks to prove that this device is reproducible.

There are two different ways the team believes the device could be manufactured. First, the team could sell the device as a block with instructions on proper disposal of and number of uses. The team could have an incentive to get users of the device to send back the silicone pieces after use to ensure recycling. A second method of manufacturing would be to sell a kit. This kit would have the silicone mold and all the ingredients necessary to create a block. The ingredients would be clearly labeled and pre-measured to ensure quality of the box. This method would allow for users to create their own blocks overtime.

6.8 Sustainability

As previously stated, the majority of the simulation is not sustainable as it is perishable. However, the mimetic blood vessels are made of silicone caulk which is sustainable and can be reused simulation to simulation. Some instruments in making the simulation, such as the silicone mold and Plexiglas box, are also sustainable as they can be used indefinitely or until they need to be replaced.

Chapter 7: Discussion

This device could be a great teaching tool and easily implemented into the current teaching curriculum at UMASS medical. This device could allow for a more realistic practice for foreign train professional training session as well as allow for more realistic practice world-wide. However, the team recognizes that there could be further work done.

First, the team would like to make different difficulty level boxes. Realizing that skill progression is correlated with difficulty level, a beginning, intermediate, and advanced box could be created. A beginner level box could include gelatin of different concentrations with as many targets as possible. The shape of the 'organ' phantom would not need to be as important as the number of target to ensure basic technique and practice. An Intermediate box could be similar to the design the team currently has with more anatomical structure than the beginner box. The advanced box could have even more anatomical structures, a flowing vascular system, barriers such as bone, a moving component to simulate patient breathing, and even a wearable competent to add a patient care aspect. Due to the wearable-aspect being a second objective but just not in the scope of this project, the team has some basic design recommendation for a wearable device. Some advanced designs could be as follows:

(1) Design one has an overall dome-like structure. The dome was chosen to be as life-like as possible as compared to a box-like structure. It has an elastic waistband on either side with Velcro to allow for adjustability. There is a protective layer on the lower part of the simulator that is impenetrable to the 20 gage needle the students will be using. This is added for protection to the wearer of the device. The device will have lungs, a spine, ribs, a flowing vascular system, and of course the mimetic liver and kidneys. The "shells" of the device are the parts that are not replaceable and will never be removed from the device. These parts include the vascular system, the spine, the ribs, and the lungs. The liver and the kidneys will each be replaceable. The space between each barrier and organ will be filled with flour concentrated gelatin. This will provide a better mechanical resistance, overall structure, and ultrasound image.

(2) Design two has an over box-like structure. The box was chosen to provide more stability within the unit as well as more area and angles for the students to optimize organ images. It has a belt on either side with a normal belt loop with multiple belt holes to securely fasten the device. There is a protective layer on the bottom of the device to ensure the safety of the wearer. This layer can be made from surgical steel and will be impenetrable to a 20G needle. These liver and kidney will be replaceable and have different targets at different depths embedded within them to provide different difficulties of practice. Other barriers include a vascular system, bones, the lungs, and a spine. A moving component will be added to simulate breathing.

(3) Design three is a vest with pockets to place the organs within. The vest and pocket idea is simplistic in nature and lower in cost. This design could have a vinyl pocket in which kidney and liver gelatin models are placed for easy access. The liver and kidney will be encased in a filler concentrate gelatin to ensure a realistic experience. A flowing vascular system and ribs will be within this device. Each pocket with have a protective casing to ensure safety of the wearer. Mineral oil will be used inside the vinyl pockets to better 'seal' the possible needle track marks.

Second, the team would like to see the device tested on a larger population of students and foreign trained professionals. The device was tested on UMASS students of various years and licensed radiologists. The team would like to see the results of other medical program students as well as the use of this device in a foreign doctor training session. This would allow for a greater understanding of just how this device could be implemented into programs across the country.

Third, the team would like to implement disease state blocks. This would allow for a more realistic experience for a variety of situational procedures. The team believes that this could be done with the current model of silicone casting. The disease state blocks were simply not within the scope of the project but could be implemented at any time.

Lastly, the team would like to more accurately test the sonic properties of the device in a quantitative manner. With a limited budget and lack of available equipment, the team was unable to test the sonic properties, such as acoustic impedance and attenuation, and therefore relied on image comparison by radiologist professionals. With the use of the necessary equipment, the device could be slightly changed to ensure an even more realistic experience.

Chapter 8: Conclusion

Overall, the team's simulation model meets the client statement as well as the primary objectives. The device is cost effective as it is 300% cheaper than a high fidelity simulation. It also provides a realistic experience, as 80% of the UMass Medical students and professionals believed this simulation experience is better than the current state of the art. The device is also safe as mainly non-toxic, degradable materials were used, and the other non-degradable materials are reusable from block to block. The simulation is user friendly as the recipe is clear and self-explanatory as well as the block is simple to use once it is made.

The main point of the client statement is to have a better teaching technique for medical students and foreign-trained doctors. The team witnessed a first year medical student successfully perform a biopsy utilizing the simulation on his third try. Many fourth year students also mentioned how this simulation would have made individual practice more realistic and useful. The simulation lessens the large gap between the current teaching methods within UMass Medical's curriculum. Also, it is so simplistic that the simulation can be made and utilized in radiology programs around the world for foreign-trained doctors. Further exploration of the recommendations mentioned in Section 7 can allow for even more simulations and better practice for radiologists of all skill levels.

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Appendix

Appendix I. IRB approved consent form

Informed Consent Agreement for Participation in a Research Study

Student Investigators: Briana Rodriguez and Mikayla Bolduc

Contact Information: Mikayla Bolduc
WPI
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Title of Research Study: Realistic Simulated Organs for Ultrasound-Guided Procedures

Sponsor: None

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

Purpose of Study:
In this experiment, we investigate the knowledge pre and post using the simulation device that the team has created. Our goal is to learn about the benefit this device can do to teach others in the field of ultrasound-guided procedures.

Procedures to be followed:
You will be seated in a group conference room. There will be no interaction between participants. You will take a 5-question survey about ultrasound-guided procedures. You name and all information provided will be anonymous. Each participant will then have a simulator and list of instructions. After completing the list of instructions, a short information session will be held to explain how to use the tools and the concepts behind the procedures. Each participant will then receive another simulation and list of instructions. After the list has been completed, each participant will be asked to complete a small post survey. All information provided will remain anonymous.

Risks to participants:
There are no foreseeable risks.

Benefits to research participants and others:
Each participant could leave this research with more knowledge in the field of ultrasound and ultrasound guided practice.

Record keeping and confidentiality:
Records of your participation in this study will e held confidential so far as permitted by law. However, the study investigators, the sponsor or its designee and, under certain circumstances, the Worcester Polytechnic Institute Institutional Review Board (WPI IRB) will be able to inspect and have access to confidential data that identify you by name. Any publication or presentation of the data will not identify you.

Compensation or treatment in the event of injury:
There is no foreseeable risk of physical injury. In the unlikely event of physical injury resulting from participation in the research, you understand that medical treatment may be available from WPI, including first aid emergency care, and that your insurance carrier may be billed for the cost of such treatment. No compensation for medical care can be provided by WPI. You further understand that making such medical care available, or providing it, does not imply that such injury is the fault of the investigators. You do not give up any of your legal rights by signing this statement.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact:
Mikayla Bolduc, Student Investigator, Biomedical Engineering Department at WPI, 100 Institute Road, Worcester, MA 01609 (Phone®207)399-4991, Email: mjbolduc@wpi.edu)

Your participation in this study in voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit. Data obtained in this experiment will become the property of the investigators and WPI. If you withdraw from the study, data already collected from you will remain in the study.

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

______________________________ Date:______________________
Study Participant Signature

____
Study Participant Name (Please Print)

APPROVED
WPI IRB 1
3/16/17 to 3/15/18

______________________________ Date:______________________
Signature of person whom explained this study

Appendix II. Gelatin Recipe

Knox *Original Unflavored Gelatin* was used. The steps to create it is listed below.

1) Mix gelatin gradually into slightly cold water in a 3 oz. gelatin to 237 mL (1 cup(water ratio
2) Add 6 drops of cinnamon leaf oil to 1 cup of water
    a. Add scatter material if necessary
3) Allow mixture to bloom for 15 minutes at room temperature
4) Heat until 30^{o}C and allow to melt until completely melted (usually 10-15 minutes)
5) Pour into greased mold. To add targets:
    a) Pour a portion of the melted gelatin mixture and add targets. Allow to harden for 15 minutes.
    b) Repeat (a) in 15 minute intervals
6) Place in refrigerator until hardened (usually 30 minutes)

Appendix III. Agar Recipe

Nutrient Agar by Seaweed Solution Laboratories™ was used. The steps to create it is listed below.

1) Mix agar into cold water for a 5g:1 mL ratio in a sterile environment
2) Stir until agar is suspended
3) Bring mixture to a temperature of 75°C, while stirring
4) Pour mixture into final mold, cover, and allow to sit for 1 hour
5) Place model in refrigerator to avoid bacteria culture

Appendix IV. Polyvinyl Alcohol

The polyvinyl alcohol (PVA) used is *PVA High Purity Powder* by Consolidated Chemical™. The steps in creating the PVA is detailed below.

1) Add 37.5g of PVA to 75mL of room temperature water to form 1g of PVA to 2 mL of water ratio
2) Continuously stir at 65°C until mixed
3) Place in freezer at –10°C
4) Perform 2 freeze-thaw cycles (repeat steps 2-3)

Appendix V. Raw Statistical Analysis for Bulking Agent Needle Puncture

The statistical results were analyzed using a two sample t-test assuming unequal variances in Microsoft Excel. The results below were at analyzed an alpha-level of 0.15 and using the one tail values.

t-Test: Two-Sample Assuming Unequal Variances				
	Organ	*Gelatin*		
Mean	0.064825326	0.061535115		
Variance	0.006889228	0.005133272		
Observations	121	121		
Hypothesized Mean Difference	0.01			
df	235			
t Stat	-0.673138073		t<tcrit	canno reject null hypothesis
P(T<=t) one-tail	0.250760441		p>a	cannot reject null hypthesis
t Critical one-tail	1.038725453			
P(T<=t) two-tail	0.501520882			
t Critical two-tail	1.444252051			

Figure 27 T-test values for porcine liver versus gelatin

t-Test: Two-Sample Assuming Unequal Variances				
	Organ	*PVA*		
Mean	0.064825326	0.027498486		
Variance	0.006889228	0.001410328		
Observations	121	121		
Hypothesized Mean Difference	0.01			
df	167			
t Stat	3.299549916		t>tcrit	reject null hypothesis
P(T<=t) one-tail	0.000591887			
t Critical one-tail	1.039661664			
P(T<=t) two-tail	0.001183774			
t Critical two-tail	1.44618322			

Figure 28 T-test values for porcine liver versus polyvinyl alcohol

t-Test: Two-Sample Assuming Unequal Variances				
	Organ	*Ballistics Gel*		
Mean	0.064825326	0.072941558		
Variance	0.006889228	0.00275065		
Observations	121	121		
Hypothesized Mean Difference	0.01			
df	203			
t Stat	-2.029667058		t<tcrit	cannot reject null hypothesis
P(T<=t) one-tail	0.021847746		p<a	cannot reject null hypothesis
t Critical one-tail	1.039087692			
P(T<=t) two-tail	0.043695492			
t Critical two-tail	1.444999052			

Figure 29 T-test values for porcine liver versus ballistics gel

t-Test: Two-Sample Assuming Unequal Variances				
	Organ	*Agar*		
Mean	0.064825326	0.060852066		
Variance	0.006889228	0.00177874		
Observations	121	121		
Hypothesized Mean Difference	0.01			
df	178			
t Stat	-0.712059853		t<tcrit	cannot reject null hypothesis
P(T<=t) one-tail	0.238679977		p>a	reject null hypothesis
t Critical one-tail	1.03946158			
P(T<=t) two-tail	0.477359955			
t Critical two-tail	1.445770349			

Figure 30 T-test values for porcine liver versus agar

Appendix VI. Raw Statistical Analysis for Simulation Needle Puncture

The statistical results were analyzed using a two sample t-test assuming unequal variances in Microsoft Excel. The results below were analyzed at an alpha-level of 0.15 and using the one tail values.

t-Test: Two-Sample Assuming Unequal Variances				
	Organ	Gelatin		
Mean	0.064825326	0.061535115		
Variance	0.006889228	0.005133272		
Observations	121	121		
Hypothesized Mean Difference	0.01			
df	235			
t Stat	-0.673138073		t<tcrit	cannot reject null
P(T<=t) one-tail	0.250760441		p>a	cannot reject null
t Critical one-tail	1.038725453			
P(T<=t) two-tail	0.501520882			
t Critical two-tail	1.444252051			

Figure 31 T-test values for porcine liver versus gelatin

t-Test: Two-Sample Assuming Unequal Variances				
	Organ	Chicken Breasts (Low Fidelity)		
Mean	0.064825326	0.124710612		
Variance	0.006889228	0.028382857		
Observations	121	121		
Hypothesized Mean Difference	0.01			
df	175			
t Stat	-4.093199088		t<tcrit	cannot reject null hypothesis
P(T<=t) one-tail	3.24376E-05		p<a	reject the null hypothesis
t Critical one-tail	1.039513646			
P(T<=t) two-tail	6.48753E-05			
t Critical two-tail	1.44587778			

Figure 32 T-test values for porcine liver versus chicken breast (low fidelity)

t-Test: Two-Sample Assuming Unequal Variances				
	Organ	*Silicone Skin(High Fidelity)*		
Mean	0.064825326	0.043032661		
Variance	0.006889228	0.001482965		
Observations	121	121		
Hypothesized Mean Difference	0.01			
df	169			
t Stat	1.417702275		t>tcrit	reject the null
P(T<=t) one-tail	0.079059413			
t Critical one-tail	1.039623342			
P(T<=t) two-tail	0.158118825			
t Critical two-tail	1.446104137			

Figure 33 T-test values for porcine liver versus silicone skin (high fidelity)

Appendix VII. IRB Pre- and Post-Survey

The survey will consist of 5 questions:

1. Year of residency?
2. Have you ever taken an ultrasound-guided procedure course before?
3. How familiar are you with ultrasound-guided procedures involving the liver or kidneys on a scale of 1 to 5.
4. How comfortable are you with performing ultrasound-guided procedures of the liver or kidneys on a scale of 1 to 5.
5. Have you ever used an ultrasound guided procedure simulator before?

After each student has finished this survey, they will be provided with one of the teams' simulators. These simulators are made from cooking grade gelatin and contain no toxic materials. Each student will follow written instructions with no prior instruction. The procedure the students will follow is below:

6. Please turn on the ultrasound machine and set it to the correct settings needed for deep tissue

7. Ultrasound the phantom and point out when you see certain "organs"
8. Please locate the tumor and aspirate the liquid using guidance from the ultrasound and the medical tools provided.

The tools provided will be a 20-gage needle and the ultrasound machine. After each subject has finished this, they will take a short information session with senior residents also working on this project with the student investigators. After this, each participant will conduct the experiment again using the same instructions above. After this procedure is done, a post survey will be completed. The questions are as follows:

9. After completing our simulation, how familiar are you with ultrasound-guided procedures involving the liver or kidneys on a scale of 1 to 5.
10. After completing our simulation, how comfortable are you with performing ultrasound-guided procedures of the liver or kidneys on a scale of 1 to 5.
11. In your opinion, do you believe this simulation could help better train residents for ultrasound-guided procedures of the liver and kidneys?
12. In your opinion, do you believe this simulation could help better train residents for ultrasound-guided procedures of the liver and kidneys?
13. Do you have any additional comments for the project team?