Development of an Ultrasound-Guided Needle Insertion System

MQP Final Proposal 23-24

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Abstract

This project is a continuation of a proposed system that aligns the needle with the ultrasound image to improve the accuracy of Percutaneous Nephrolithotomy (PCNL) procedure. The device consists of an ultrasound probe, probe holder, acoustic reflector attachment, and optimal materials. Through image processing and analysis, 3% agarose was selected as the filling and stainless steel was selected as the optimal reflector as a replacement for glass mirrors. The attachment design was redesigned to a vertical position to improve the handling of the device and components were designed for manufacturability. These design changes proved successful during mock phantom and needle visualization testing done on the final version of the device. Finally, a set of improvements was recommended for future groups working on this device.

1. Background

1.1 Ultrasound Basics

An ultrasound is a device which can produce and receive sound waves. It works by having a transducer that emits an ultrasound wave, which can also detect echoes reflected to it. When a wave is emitted, it will pass through the cells in the body at a frequency between 1 and 18 MHz. Parts of the wave will be bounced back to the device where the time for the echo to be received and its strength are recorded by the transducer. This turns the vibrations into electrical energy. The energy is then sent to the ultrasonic scanner to process the information and create the image. Based on the processed time and strength, information pixels on the computer screen are illuminated with different intensities to display a complete image as seen in figure 1. Through this system you can differentiate between different tissue types based on how well they are able to reflect the waves[1].

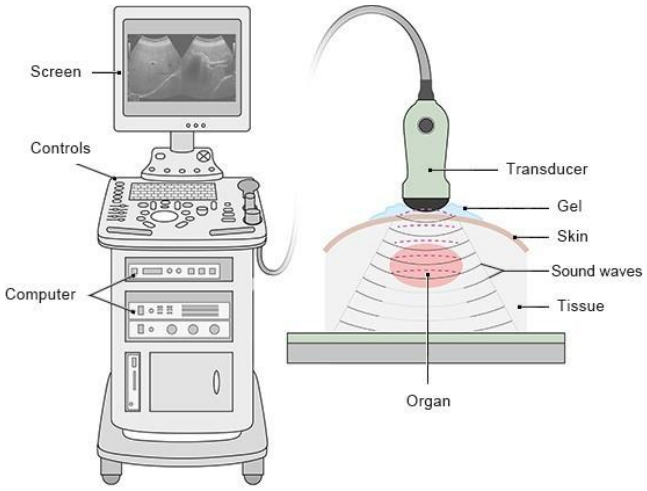


Figure 1 Displays how an ultrasound works as well as its connection to a computer (Informedhealth)[1].

When performing a needle guided operation in a patient, there are many different methods to gain information about the surgical site which operators tend to use. The main ones we will discuss are X-ray, CT, and MRI. To begin, each of the previously mentioned methods has the benefit of being able to evaluate tiny masses that are not visible on ultrasound. They also offer the ability to perform scans at a much larger scale. Negatives to these methods are the cost of implementation, space needed, the use of radiation, as well as the time needed to prepare the patient and device[2].

Currently there are no devices on the market offering the same benefits as the ultrasound guided needle insertion device but there are some with similar methods. To begin, the needle guided device shown below was developed for the purpose of assisting during a brachial plexus blockade procedure. The device clips on to the ultrasound and provides an angled needle guidance as seen in figure 2.

Figure 2 Ultrasound needle guided device[2].

Results from the device testing showed that when using the device, the median time to complete the brachial plexus blockade procedure was 3 minutes as opposed to without which was 4

[1] Informedhealth

minutes. Furthermore, “All the physicians reported that they would use the needle guidance again, and 90% would prefer it for in-plane blocks” showing market potential for devices of this nature[2]. Needs unmet by this design include a possible difficulty of maneuvering to the target site with an off centered needle insertion point.

Similarly, the previous device is the medical robotic device system to control two collaborative robots for ultrasound-guided needle insertions pictured in figure 3[3].

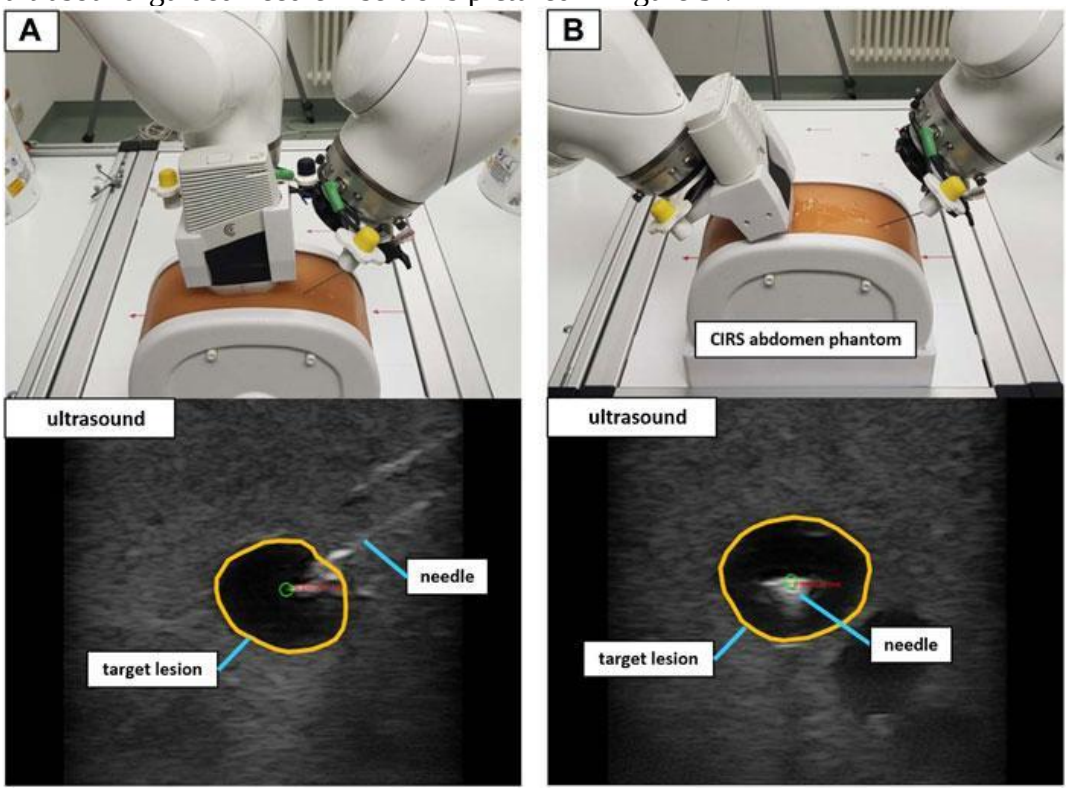


Figure 3 Medical robotic device system to control two collaborative robots for ultrasound-guided needle insertions[3].

[2] [2] VYdyanathan, 2022
[3] Berger, 2022

This device has many appealing characteristics, such as its ability to have robotic automated capabilities in the future and its ability to mitigate an operator's hand movements. Unfortunately, this device is very high in cost to manufacture and suffers from negative public opinion towards robotic operations. Similar problems came from an operator using an ultrasound in one hand while maneuvering the needle in the other. Needle insertion as a route of medical care has been around for many years with the appeal of allowing for subdermal targeted release of substances. As an added benefit of needle insertion methods, they allow for the procedure to be done in a minimally invasive method. Needle intervention can be used for many different operations and reasons. It can be used for the insertion of drugs, removal of liquid, and assistance in the insertion of tubes.

Figure 4 CIRS Phantom[4]

In ultrasound visualization testing, the CIRS Phantom is used to test ultrasound devices. It is made from Zerdine, a solid elastic water-based polymer and contains multiple grey scale targets in varying sizes. This allows for ultrasound devices to be tested based on how well the device can see the targets seen in figure 4[4].

1.2 Relevance and Importance

In many medical procedures, clinicians are faced with having to multitask the use of an ultrasound to view the patient's surgical site while performing the needle insertion. As seen in the insertion of contraceptive devices "Direct visualization of the tip of the needle throughout the insertion procedure is necessary, as recommended for avoidance of deep insertion. Unfortunately, the redesigned applicator restricts the view of the needle"[5]. As seen from the previous example there is a need for a device with the ability to produce a direct visualization of a needle throughout the insertion of a contraceptive implant. Our device can be impactful. In the following paragraphs it will become obvious there is a need for an ultrasound-guided needle insertion device.

Biopsy is a general term for procedures involving taking a small sample of body tissue, from almost anywhere in the body, for later diagnosis. The procedure can be used to diagnose many different types of abnormalities such as cancer, inflammation, and infection. In a core needle biopsy, an ultrasound can be used to guide the needle to the relevant point where the tissue can be extracted as seen in figure 5.

[4] [4] PNW Scientific, 2023
[5] Rowlands, 2017

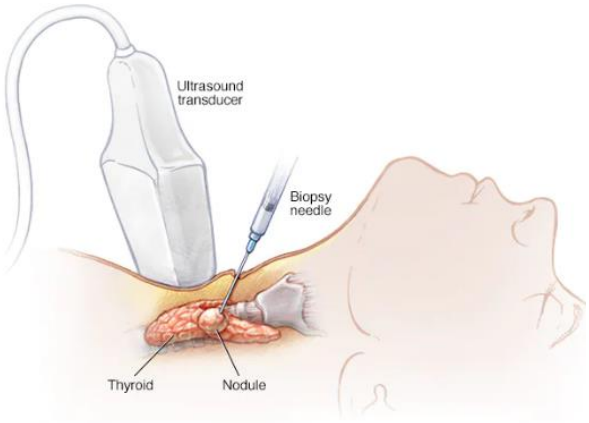


Figure 5 A core needle biopsy being performed to remove a sample from a Thyroid[6].

Biopsies are done in many different procedures such as bone marrow, excisional, needle, and sentinel node biopsy. The focus of our project's relevance will be on the bone marrow and needle biopsy as they both can be performed with the combination of an ultrasound and needle.

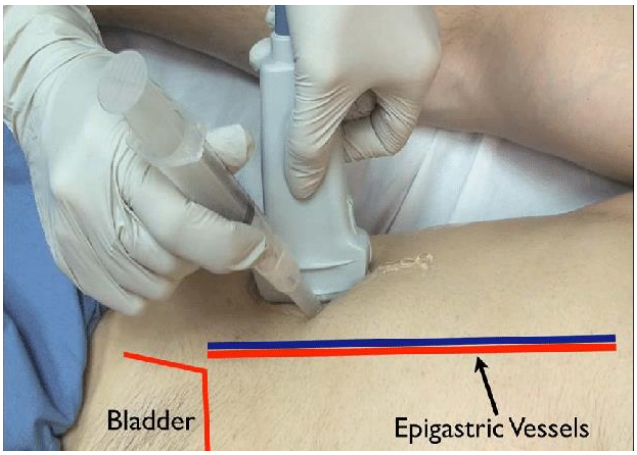


Figure 6 Shows the performance of a paracentesis operation in the lateral abdominal position[6].

Paracentesis, like biopsy, is a general term for procedures with the purpose of obtaining or draining ascitic fluid. In a normal human, there is little to no fluid in the abdomen but in the case that a buildup occurs, a paracentesis can be performed to alleviate the swelling and obtain a diagnosis. The purpose of the ultrasound in this procedure is to locate the point of swelling, determine the best insertion point, and finally guide the needle to the fluid[6]. In terms of this project any form of paracentesis can be relevant as they require the insertion of a needle to a specific target site seen in figure 6.

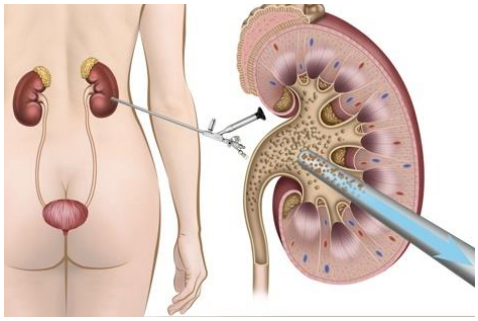


Figure 7 PCNL Procedure with a nephroscope inserted into a patient's kidney[7].

Percutaneous nephrolithotomy (PCNL) is a procedure in which a surgeon will begin by creating a small incision into the loin (area between the lowest ribs and the hip) of a patient. From the incision the percutaneous nephrolithotomy needle is guided to the pelvis of the kidney. From there a guide wire is passed through the needle into the kidney. Following that, the needle is replaced with dilators, working sheath, and finally the nephoscope via the guide wire into a patient's kidney in order to break up and remove kidney stones seen in figure 7[7].

Some complications with this procedure include injury to the colon, lungs, and renal blood vessels which we believe will be mitigated with the use of better guidance from the ultrasound-guided needle insertion device.

[6] Mayo Clinic
[7] Ennis et. Al 2014.

The main takeaway from all these procedures is the need for precision. There is also the increased chance of error from having to split the surgeon's attention between finding the best image angle in one hand with the ultrasound while performing the needle insertion in the other hand. As well, there is potential for an increased risk of error from the offset perspective given from the ultrasound being to the side of the needle insertion point[8].

1.3 Past Work

2020-2022

The Needle Insertion System for Ultrasound-Guided PCNL research started in 2020 at WPI. The first MQP team made breakthroughs in software and the mechanical design of the system creating the very first prototype. Their research included CAD designs, visual imaging, and PCB designs. The second year MQP team focused on the mechanical part and improving the CAD model. The design was updated to use gears and was built to encapsulate water so it could function on its own. The needle was able to be stabilized and seen through the imaging system.

2022-2023

We will be referring to the previous MQP (22-23) years design and the latest design that was created over the summer. The most recent MQP team worked towards making the design smaller, lowering the cost, modular, easy to sanitize, clinically compatible, a closed system and user friendly. The most recent design over the summer worked on the mechanical design and simplified it to a fixed mirror position and easily printable CAD design.

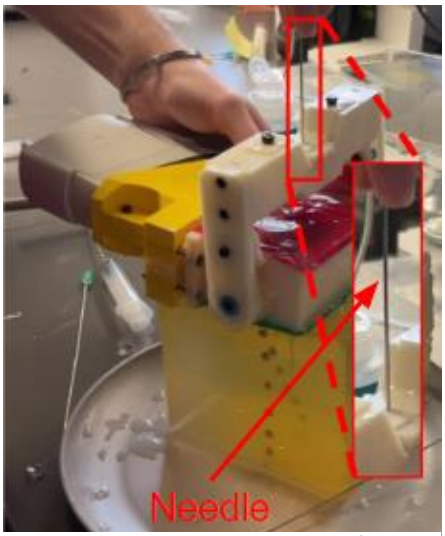


Figure 8 2022-2023 MQP Design[9]

On the mechanical side of the device the team worked on sealing the device and improving the housing model. The device consists of an arm assembly, box, mirror assembly, sandwich and probe as seen in figure 8. A gasket was designed to fit around the probe for waterproofing purposes. The previous CAD model was updated with a shaft seal, extended inner rotary shafts, an outer stabilizer bearing, removed nut holders and added screw holds. The final design was manufactured in one piece. A secondary seal of glue was added between the components in the final design to prevent leaks.

The team also worked towards enhancing the software of the device to improve visualization of the needle. Probe selection was the first advancement the team made by comparing three ultrasounds' probes and picking the Clarius C3 Gen 1 because it will work with the software changes needed and has a high range of frequency and depth. The software programs were analyzed, and algorithms were picked that would coincide with the ultrasound probe. These consisted of the python environment, needle visualization (OpenCV), Clarius CAST Connection, and a personal computer. The team advanced the algorithms with the necessary packages relating to the Clarius probe. These

[8] Brisbane Urology Clinic

improvements helped with the visualization of the needle line and tip and improved the accuracy and image quality. In the final prototype the needle was still hard to visualize due to more noise being present while using the prototype outside of a water tank.

The previous team investigated improving the materials on the device by analyzing the acoustic impedance of materials before selecting what is best for the device. The more similar the acoustic impedance is of the materials the sound will be disrupted less and the imaging will be clearer. The team worked towards analyzing the acoustic impedance through the given equations F=(Z1-Z2)^2/(Z1+Z2)^2 where F is equal to the fraction of sound between two materials and Z=d*c is the acoustic impedance (d=density, c=speed) of sound through material. The team constructed a mathematical representation to best match the impedance between two materials. Their baseline was the acoustic ultrasound probe and soft tissue of a patient.

Impedance for theoretical layers was analyzed along with potential materials. The types of layers begin with the Ultrasound probe matching layer with an ideal impedance of 2 MRayl, the Gel layer 1.95 MRayl, a solid layer 1.8 MRayl, liquid in the housing unit 1.8 MRayl, solid layer two 1.7 MRayl, gel layer 1.6 Mrayl, soft tissue average 1.6 MRayl. The materials analyzed consisted of latex 1.5 Mrayls, Yamauchi Rubber 1.19 MRayls, EVA 1.69 MRayls, PDMS 150 KRayls, olive oil 1.32 MRayls, glycerin 2.34 MRayls, brine (salt water) at 20C 1.483 MRayls[9].

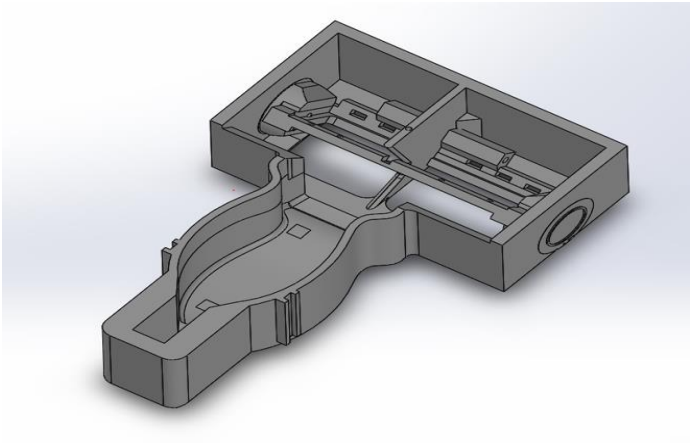


Figure 9 Summer 2023 Prototype

The most recent version of the device was developed over the summer. This prototype is a simplified version of the previous year's MQP. The device has a fixed mirror and was built to hold the ultrasound within the encapsulation. This allows for the device to hold water and improve the imaging visuals. The device can be easily reproduced and sanitized after use. The device seen in figure 9 is what our MQP team will be basing our design and experiments on.

[9] King et Al.

Table 1 Prototype Design Results and Recommendations[9]

Implemented Design (22-23)	**Future improvements**
Made from non-harmful components (PLA, Water + Glycerin)	Device can be altered to fit different kinds of probes
Easy to sanitize. Can be washed with soap (takes 1-2 minutes)	Made smaller in size and easier to handle
Leakage and waterproofing was improved (droplets occur after 20 minutes of use)	A refill valve or fix leakage
User friendly needle arm has resistance to maintain orientation	Run materials tests multiple times to confirm the data
Maintained low manufacturing cost	Mirror assembly bends from the tension of the box creating a blur zone
Followed engineering standards	Find new sealant that better secures the front seal
	Use 20 cm 18 gauge needles
	Better phantom testing
	In-vivo testing

Table 2 Engineering Standards[9]

Needs	Description	Guidelines
Safety	The device should be easily sterilizable for repeated use. The device should be compatible on body surfaces.	ASTM E1837-96(2007) ISO 10993-I: 2018, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021
Durability	Safety specifications for durability of devices.	ASTM F963-17
Product Life	Devices are made to endure and can be used multiple times before failing.	ASTM E1837-96(2007)
Limited Potential Misuse	The device should be designed for its intended purpose and not for any other use.	ISO 14971:2019

The previous MQP team left recommendations for future improvements along with ISO standards relating to the device (table 1 and table 2). The ISO is the international organization for standardization and following ISO standards for the device will help it meet FDA regulations. The FDA often takes ISO standards into consideration when deciding to approve medical devices. The main ISO standards medical devices should follow are ISO 13485-2016 and ISO 9001-2015. Based on these standards two of the main categories of ISO standards are related to safety and product life. This includes having a system in place to service the medical device and control its production. Within the safety standards there were standard protocols regarding sanitization and compatibility of the device. The previous team recommended fixing the problem of water leaking from the device to make the device more sanitary. We also decided that reducing the size of the device even more would help make it more compatible and easier for doctors to use. Within the standards on product life there were protocols relating to durability of the device and limited misuse. The previous team recommended more testing on the device to validate it. We plan on running tests multiple times to make sure the device can be used more repeatedly. To limit misuse, we are designing the device for PCNL's around the recommended 20cm 18-gauge needle. Following the previous teams recommendations as well as the ISO standards guide while making decisions on improving the device and creating objectives lead to the team being able to identify problems early on and maintain continuous improvement process standards.

2. Client Statement:

Each of the procedures mentioned has different needs and tools associated with operating. In some cases, X-ray, CT, MRI, or free hand options might be used, with each of these options having its own benefits and detriments. An ultrasound would be used over any of the previously mentioned methods in cases where a surgeon would want high maneuverability, with lower required cost, time, and no radiation. However, other methods might be used when the target location is too small to be seen on the ultrasound. Through the implementation of the Ultrasound-Guided Needle Insertion Device, we hope to alleviate the disadvantage of surgeons needing to split their attention between two objects in different hands as well as improve the visibility of the operator by aligning of the needle path and ultrasound image plane. So far, this project has developed a proof-of-concept device that can attach to an ATL P4-1 ultrasound probe and allows for the previously mentioned coincident needle view and constant view of the needle during insertion. This project aims to select the proper material in the device cavity, design of a mass-producible model, and analysis of its marketability.

3. Project Approach

3.1 Design Objectives

The main design objectives when working on the Ultrasound-Guided Needle Insertion Device attachment are categorized into determining the material filling of the attachment and the redesigning of the attachment to allow for surgeons to use it vertically (as referenced in the design changes section). We will have a successful project when we achieve a solid filling material with equal or greater visibility to the ultrasound and a vertically orientated attachment. The overall objectives are listed below:

1. **Finalize the attachment design that is mass production friendly.**

The first step in finalizing the attachment design is using a solid material to fill the device. Using gelatin or agar as coupling could minimize the stresses of leaking seen in previous prototypes while being easy to produce and handle. Tests will be conducted on similar materials to find the one that goes best with the new design. The material selection will also improve the imaging of the system to get better image quality by testing. The new design will be simplified and built from components that can be manufactured and easily found in the market.

2. **More data on device.**

Evaluation of device will be completed through testing on live subjects or similar objects. Multiple tests will be done to evaluate image quality, needle visualization and accuracy. Tests will be run multiple times to receive accurate data collection and will be analyzed to produce results on the device.

3. **The associated business plans.**

Financial and economic aspects will be evaluated such as costs, regulation process, and marketing potential. The device will be designed in a way that can be commercialized and marketed. Interviews will be performed to market the device to potential candidates and gain data on interests in the product.

3.2 Technical Approaches

One of the main goals of the project is to modify the design of the device in a way that can be mass producible. Since the older versions were all 3D printed to test the proof of concept, the components were all integrated into each other. The new design must be designed in such a way that each component can be manufactured on a large scale. Some potentially manufacturing ideas to investigate

include machining, injection molding, and 3D printing. This will be determined based on market research and potential customers and manufacturers.

The new design also plans to change the orientation of the US device from horizontal to vertical. The new model will be updated to include 2 mirrors instead of 1 to account for this change in orientation. Doing so will allow the entire device to be handled like an US machine.

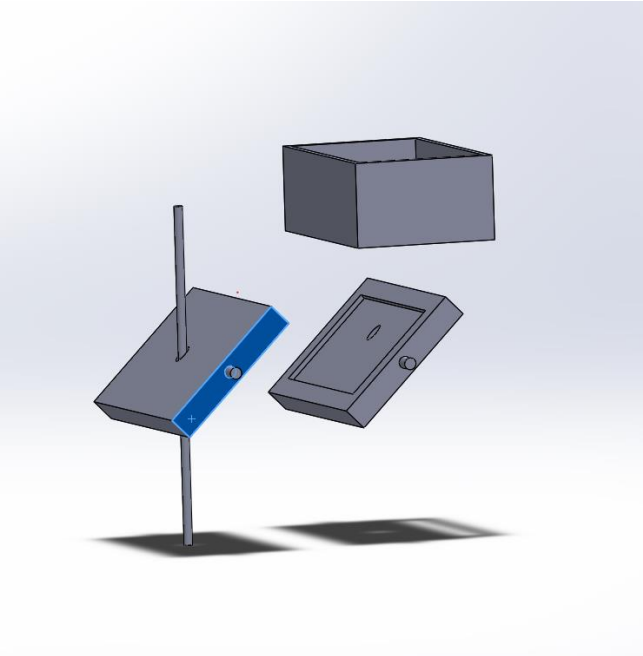


Figure 10 Initial concept design

While inspecting older versions of the model, it was found that the displayed image had a lot of repeated noise caused due to the interface material between the device and the test object. The new design plans to address this issue by testing for the best interface material and improving the point of contact between the device and the object to minimize air gaps. The older designs were filled with water to fill the device enclosure. However, there was always an issue of leakage. To solve this problem, the new device will test different materials of different viscosities and states such as gelatin and agar. The design will also be made leakproof.

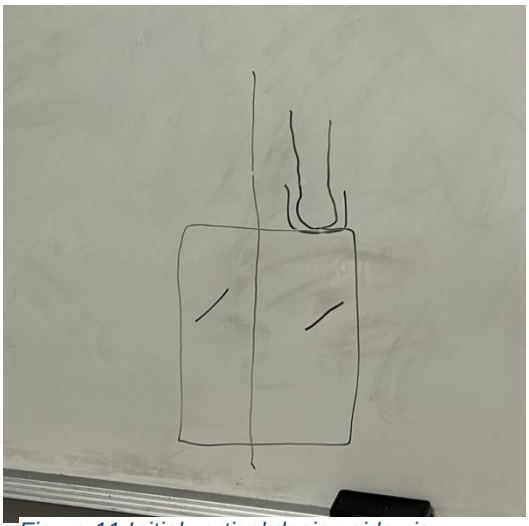


Figure 11 Initial vertical design side view

A new potential feature we plan to add to the design is having the device compatible with different insertion or cutting tools. Currently, the device only supports a guided needle. Having an adaptable feature to include needles of different sizes or different tools like scalpels will widen the market for the device shown in figure 10 and 11.

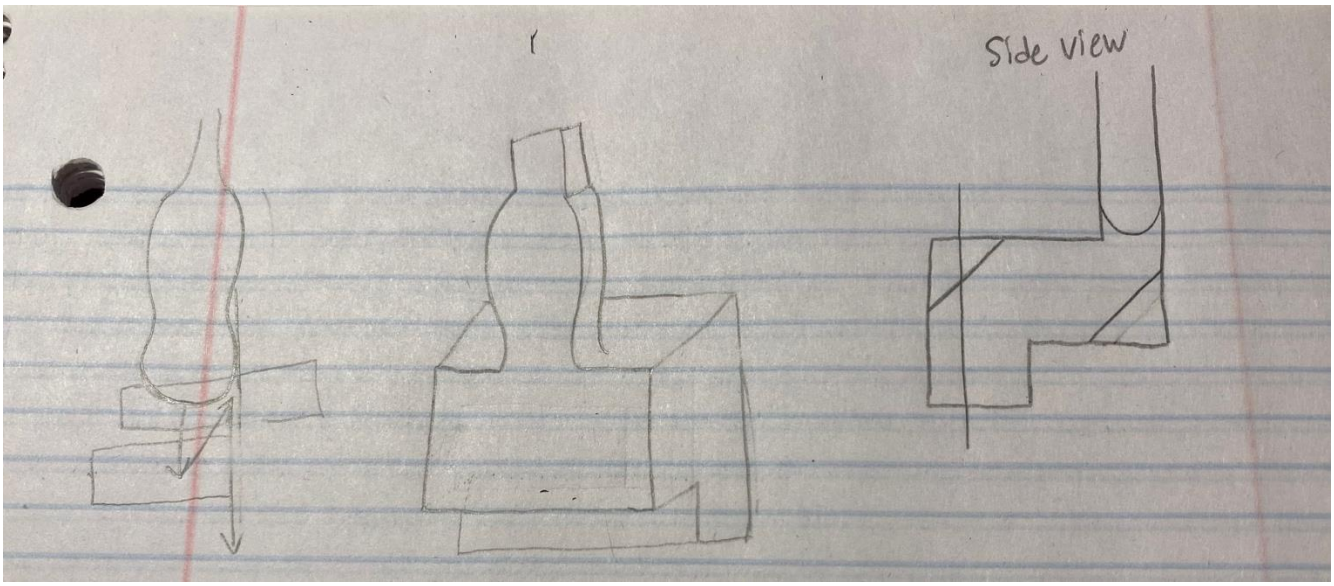


Figure 12 Multiple angles of the expected design of our device.

In figure 12, on the left it shows the main components, including the ultrasound aiming its waves off two mirrors. The middle illustration is the same as the left but with the encasement. To the right is the side view of the device, with the ultrasound on the top pointing to a mirror, which is aiming towards another mirror with the connected needle. The new design will be manufactured therefore the material for the outer shell and body should be chosen considering that the device would be used in a professional environment.

An important material we would need to decide on would be the liquid/gel that would fill the internal cavity of the device. There has been some research done by the previous MQP teams on materials based on transmission of US waves, but all the versions of the device had an issue of leakage. For the new device, the team will test materials of different viscosities and states (liquids and gels) to find the ideal material while considering the new design of the shell to be leak proof. The current interface material between the device and the object interferes with the image quality. Different materials will be tested based on several factors to select the best one that fits the conditions of the new design.

3.3 Experimental Plan

The material testing will use the prototype designed over the summer and we will be testing agar, gelatin and potentially a biopolymer. These tests will be performed by filling the previous prototype and testing the device on the phantom and comparing the image quality. The image quality will be compared to the baseline ultrasound view in water and the other materials tested in the device. The results will be quantified by visually and mathematically comparing the image results and impedance testing to the current standard of water.

The current development for the device prototype will include changing the orientation from horizontal to vertical and adding two mirrors. The bottom piece of device which connects to the patient will be curved. A potential prototype will include a gel bag that could substitute the curved bottom piece. A feature to guide needle will also be included.

Testing on the new prototype will consist of needle insertion testing to test the accuracy and signal to noise ratio testing. Testing will begin in a gel mold, followed by non-living animal trials. Results will be quantified by monitoring the insertion of the needle into the gel mold or animal carcass. The goal result will be a needle insertion coincident with the ultrasound image and the degree of change from the wanted results will be measured. The measured result will determine the accuracy of the needle insertion. Depending on the results the device may be altered to improve accuracy and re-tested.

The market analysis will begin with internet research on potential candidate procedures or applications for the device. The departments these procedures fall under will be determined to help further identify subjects to contact. Clinicians will be interviewed with questions and the data will be collected to further the marketing plan.

3.4 Design selection

A pairwise comparison chart seen in table 3 was used to determine the design objectives for this year's MQP. To determine what was going to be prioritized when designing the new ultrasound guided needle device, the objectives were compared in the chart. Through this we determined that making the device clinically compatible, accurate and marketable were the top three priorities. Having clear image resolution with a solid material and being user and manufacturing friendly are priorities as well.

Table 3 Pairwise Comparison chart of the design objectives

	Image resolution	Solid Material	Marketable	Data on device	Moldable attachment	User-Friendly	Manufacturing friendly	Clinical compatibility	Needle accuracy	
Image resolution		0.5	0.5	0.5	0.5	0.5	0	0.5	1	4
Solid material	0.75		0	0.5	0	0	0.5	0.5	0.5	2.75
Marketable	0.5	0		1	0	0.75	0.75	0.75	0.5	4.25
Data on device	0.5	0.5	0.5		0	0	0	0.75	0.5	2.75
Moldable attachment	0.75	0	0	0.5		0	0	0.5	0.75	2.5
User-friendly	0.5	0	0	0.5	0.75		0	0.5	0.5	2.75
Manufacturing friendly	0	0.5	0.75	0	0	0		1	0.5	2.75
Clinical compatibility	1	0.5	0.5	0.75	0.5	1	1		1	6.25
Needle Accuracy	1	0.5	0.5	1	0.5	0	0	1		4.5

3.5 Material Selection

Material selection will be determined based on which material can allow for the best visual properties when encased in the attachment. Estimates of image quality can be predicted using the materials acoustic properties which can be measured using acoustic impedance and attenuation coefficient. Since ultrasound is tuned to work with the human body, the material which creates the least attenuation will be one that best simulates the human body's propagation of ultrasound waves.

Material	Speed of sound SoS (m/s)	Mass density ρ (kg/m^3)	Acoustic impedance Z (10^6 kg/m^2s)	Attenuation α (dB/cm/MHz)	Nonlinearity B/A	Source
Fat	1478	950	1.4	0.48	10.8	(Gongetal., 1989; Mast,2000)
Breast	1510	1020	1.54	0.75	-	(ICRU,1998)
Kidney	1560	1051	1.64	1.0	7.4	(Mast,2000)
Cardiac muscle	1576	1060	1.67	0.52	7.1	(Mast,2000; ICRU,1998)
Liver	1595	1060	1.69	0.5	6.6	(Mast,2000; ICRU,1998)
Water	1480	1000	1.48	0.0025	5.2	(Dongetal., 1999; Havlice and Taenzer,1979)

Figure 13 Acoustic properties of typical soft tissues[10]

As shown above, when selecting a material, it will be best to maintain a density between 1020-1060(kg/m^3), acoustic impedance between 1.5 4-1.69($10^6 kg/m^2 s$), and an attenuation between 0.5-1(dB/cm/MHz). With these considerations the materials that will be tested include Gelatin, Agarose, Polyacrylamide (PAA) with a baseline of water. As seen in figures 14 and 15, displaying acoustic impedance and attenuation of gelatin, agarose, and polyacrylamide each fall within the ranges of acceptable values.

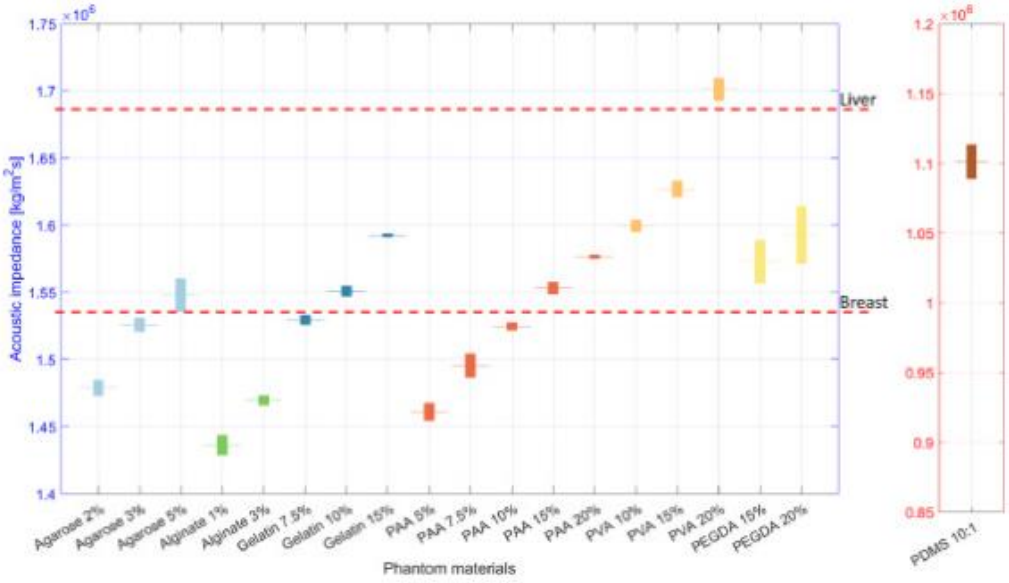


Figure 14 Acoustic impedance of different percent agarose, gelatin, PAA, PVA, and PEGDA with acoustic impedance of liver and breast shown as reference[10].

[10] Chen, 2022

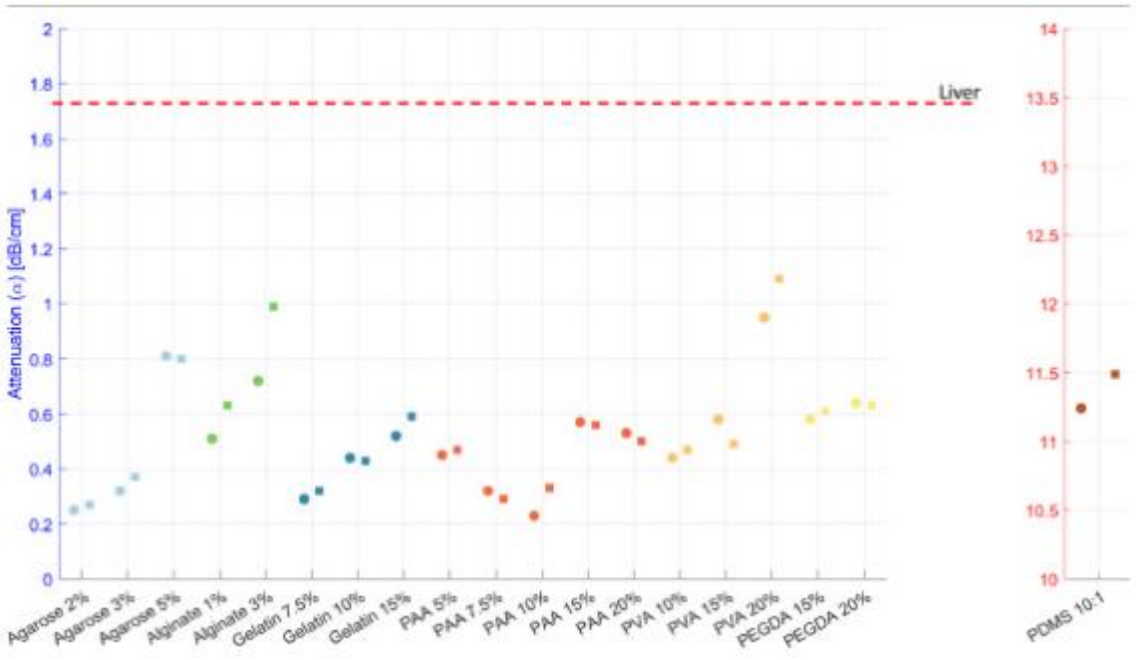


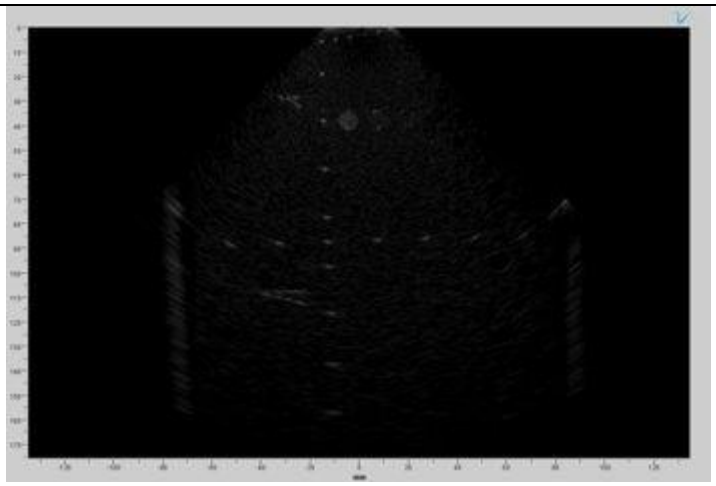
Figure 15 Attenuation of different percent agarose, gelatin, PAA, PVA, and PEGDA with attenuation of liver shown as reference[10].

3.6 Initial Testing and Analysis

Two rounds of testing were performed, the first-round tested whether water or ultrasound gel should be used to fill the space in between the attachment and the CIRS Phantom, pictured in figure 16.

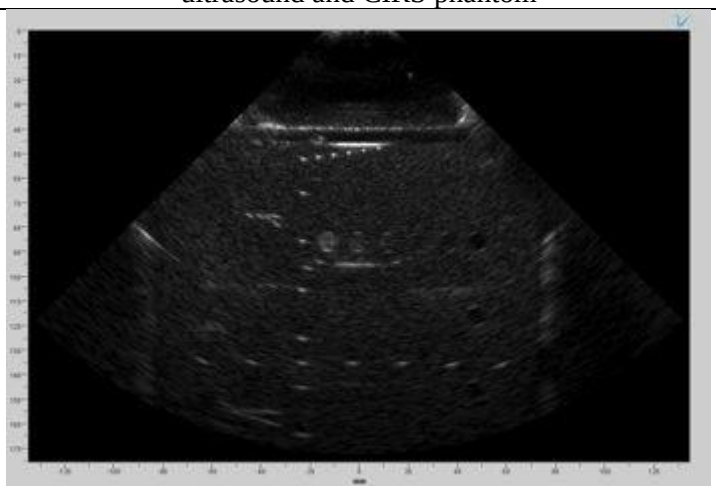
Figure 16 Representation of what the attachment (top) would look like placed on the CIRS Phantom (Bottom box)[11]

[11] Medicalexpo

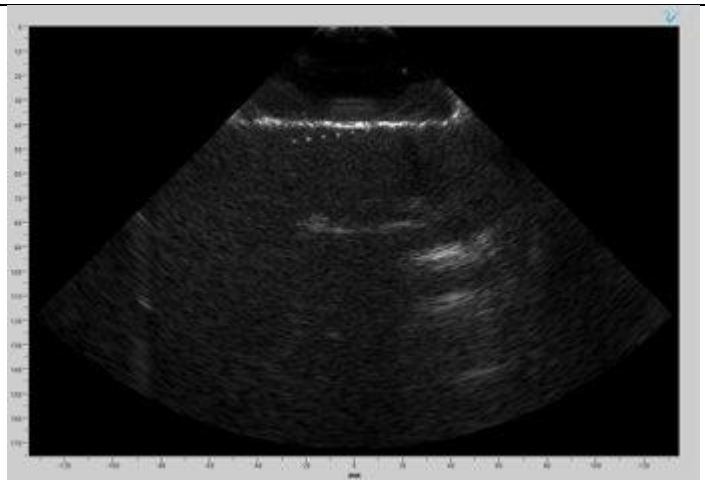


Ultrasound (no attachment) with water in between the ultrasound and CIRS phantom

In the first round of testing the attachment was filled with a gelatin mixture of roughly 8% weight to water gelatin. Water and ultrasound gel were chosen for this test because they are materials commonly found in the lab space and are known for their ability to not interfere with sound waves. Each test was repeated five times with the winning method being the one that shows the most contrast between the targets of the CIRS phantom and its background, representational results shown in figure 17.



Water in between the attachment and CIRS phantom



Ultrasound gel in between the attachment and CIRS phantom

Figure 17 testing to determine whether water or ultrasound gel should be used in between the attachment and the CIRS Phantom

From visual analysis of our results, using water in between the attachment and the CIRS phantom showed the most contrast with all targets being visible. Also, the image is comparable to the baseline, using only the ultrasound and water in between the ultrasound and CIRS phantom, which reinforces the benefits of using water in between the attachment and the CIRS phantom. In comparison, when using ultrasound gel in between the attachment and CIRS phantom we can only see the top row of targets with little contrast. From these results it was determined that we would continue using water in between the attachment and the CIRS phantom in the experiments below and to come.

The second round of testing was performed to compare the use of a gelatin filling in the attachment, water filling (using latex to support the water), and the full submersion of the attachment and CIRS Phantom, and compare each to the baseline of using only the ultrasound (no attachment) shown in figure 18:

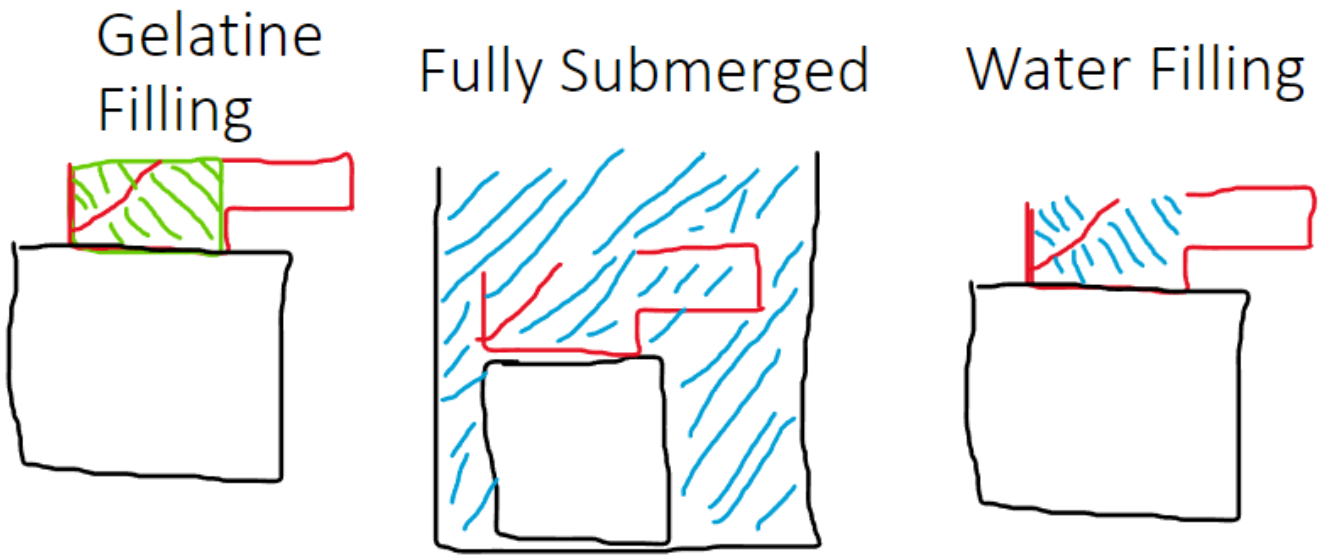
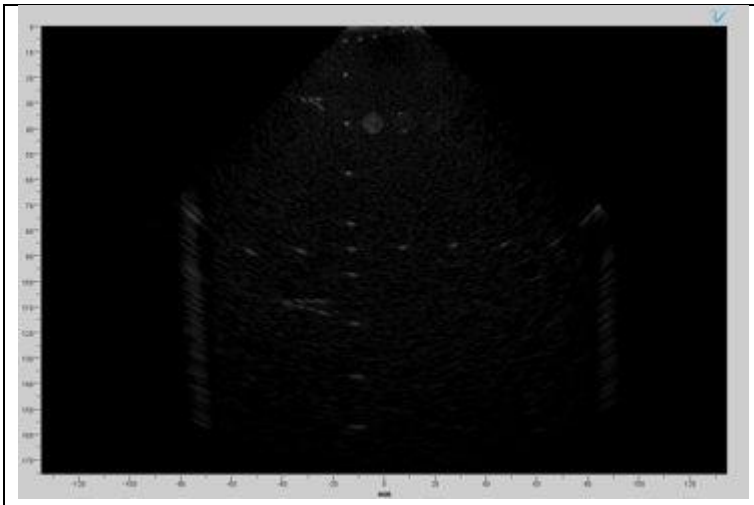
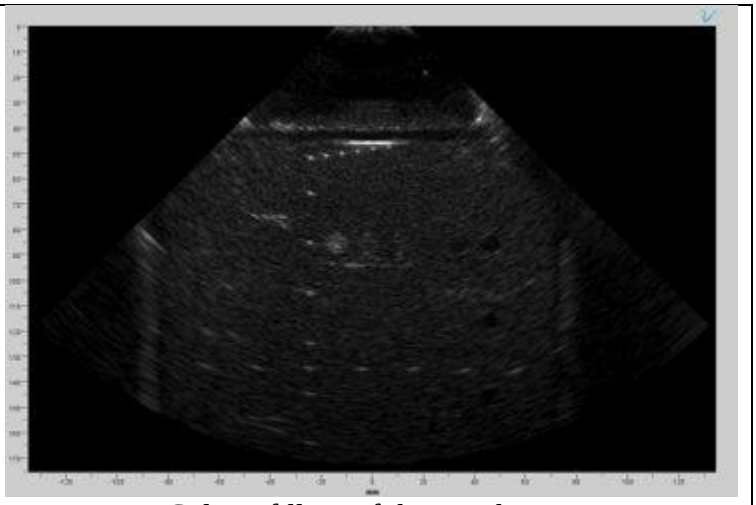


Figure 18 Representational image of gelatin filling vs water filling, vs full submersion

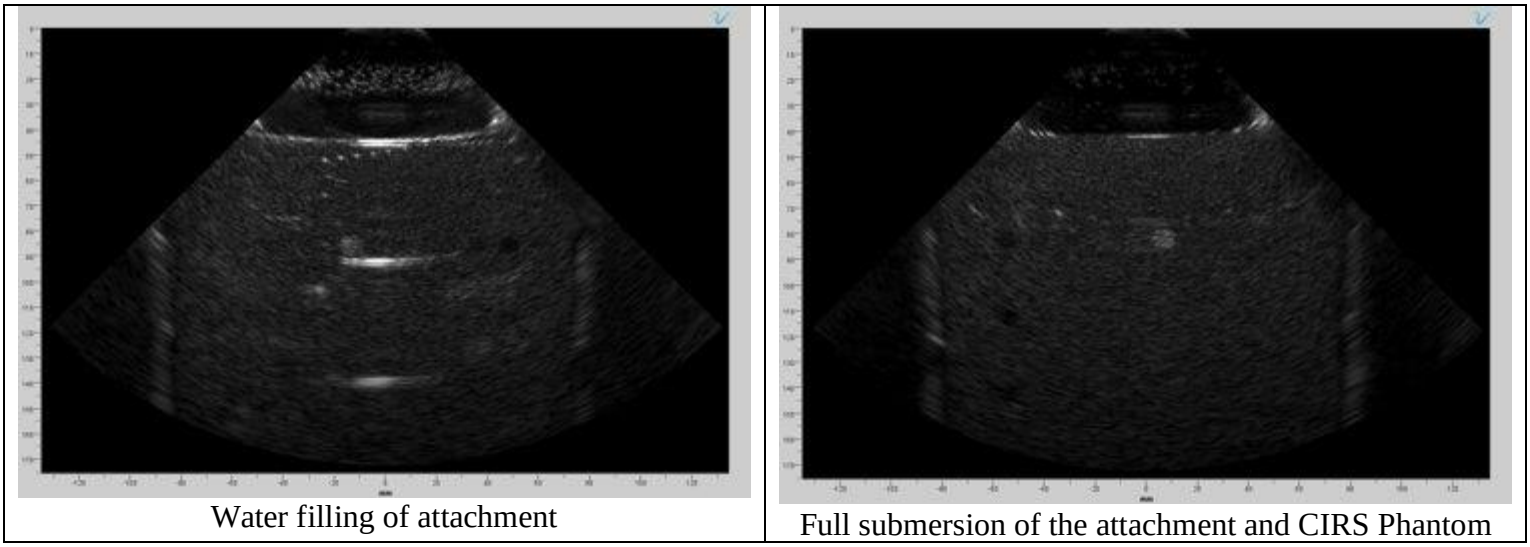
The purposes of this test were to learn how to create a gelatin filling and produce results, determine whether gelatin could be a viable filling option for the attachment, and compare the image quality of using a gel filling, a water filling, a full submersion to the baseline. Each test was performed five times with representational images shown below in figure 19.



Baseline, Ultrasound (no attachment)



Gelatin filling of the attachment



Water filling of attachment

Full submersion of the attachment and CIRS Phantom

Figure 19 Representation images of test 2, baseline vs gelatin filling vs water filling vs full submersion

From visual analysis it can be determined that the gelatin filling of the attachment produced the best results based on the contrast between the CIRS Phantom targets and the background.

3.7 Initial Design Plan

As mentioned above, the biggest modification to the existing models would be to change the orientation from horizonal to vertical to allow the handling of the device to be comparable to current US probes as possible. To do so, we will need to make some design changes to the current models.

First, the new design will use a set of two mirrors instead of one to make up for the change in orientation. Unlike the old models which were printed as a single part, the new model will be assembled by putting together multiple components so that the mirrors can be attached inside the housing. Since we plan to fill the enclosure with a liquid that turns solid, the components will need to be designed in a way that will make the device leak proof, a challenge previous designs also had trouble with.

The second design change will include a separate attachment in which the US probe can be placed and clipped onto the main housing. This will be designed in a way that will prevent air bubbles between the point of contact of the probe and the material filling which can diminish the image quality. Having such a feature will allow a quick and simple way to set up the device without having to worry about a lower image quality.

Once the prototype is designed and quality tested the selected material will be used in the new device and tested. Multiple tests will be run to finalize the design and gain data on the device. The data will then be used to push the device onto the market.

4. Project Strategy

4.1 Methodology

Design Objectives

The design objectives will be identified through research on past work on the device and additional sources. The information will be analyzed to determine the needs of the device and the future improvements that will need to be made. The design objectives will be based off this research and ranked using a pairwise comparison chart to determine the most important features.

Research and Development

The research stage will begin with research into different technical approaches and multiple initial designs. The initial designs will be sketched out and drafted in CAD. The designs will be analyzed based on their strengths and weaknesses and compared. The material will also be tested in the research stage. The previous prototype will be used to test different solid materials in order to determine which has the best visibility for the final design.

Modeling and Prototype

Once the initial design is chosen the necessary materials will be acquired to start the development of the device. The device will first be modeled in CAD and prototyped using a 3D printer.

Testing

After the initial prototype is developed multiple tests will be run on the device. Tests will be run using the prototype to determine the material needed to fill the area between the probe and the attachment. The initial image quality will be documented with the ultrasound first to set a baseline then multiple materials will be tested using the previous prototype. A material will then be decided to use to fill the device based on the results. The image quality of the new prototype that is built will also be tested to determine if the dual mirrors implemented improve the vision of the device. Lastly, a signal to noise test will be completed to compare the level of background noise to the desired signal levels of the device.

Marketing Analysis

During the development of the final design and prototype of the device a market analysis will be done. Part of this year's MAP is to determine the possibility of marketing the product for production. A high-level plan will be determined to complete the market analysis procedure. Surveys will be completed on the internet or through articles to list the potential candidate procedures or applicants. The specific departments the device falls under will then be listed. Clinicians will be interviewed to receive data and opinions on the device and suggest a plan for marketing.

Reiteration phase

The prototype will be tested and analyzed according to the design protocols. The data will be organized into a matrix to be able to further assess the initial prototype. These tests will provide data

on the performance of the device and help identify the strengths and weaknesses. This will allow for alterations to be made to improve the device before the final testing phase. The testing will be repeated until the product meets the design objectives that were set.

Final testing and analysis

Once the design is finalized and meets the objectives set by the team the final prototype will be tested and analyzed. Tests will be run to produce data on the functions of the device and its quality. The final tests will include lab tests on the image quality and functions of the device and a large animal clinical test. These tests will be used to analyze the effectiveness of the device and the completion of the design objectives. All findings and data will be formatted into a final report.

4.2 Project Deliverables

List of Deliverables

1. **Finalize the attachment design that is mass production friendly.**

The first step in finalizing the attachment design is using a solid material to fill the device. Using gelatin or agar as coupling could minimize the stresses of leaking seen in previous prototypes while being easy to produce and handle. Tests will be conducted on similar materials to find the one that goes best with the new design. The material selection will also improve the imaging of the system to get better image quality by testing. The new design will be simplified and built from components that can be manufactured and easily found in the market.

2.More data on device

Evaluation of device will be completed through testing on live subjects or similar objects. Multiple tests will be done to evaluate image quality, needle visualization and accuracy. Tests will be run multiple times to receive accurate data collection and will be analyzed to produce results on the device.

3.The associated business plan

Financial and economic aspects will be evaluated such as costs, regulation process, and marketing potential. The device will be designed in a way that can be commercialized and marketed. Interviews will be performed to market the device to potential candidates and gain data on interests in the product.

4.3 Risk Management Plan

Risk Management Plan

Table 4 Risk Management plan for Ultrasound MQP

Risk	Chance of Occurrence	Mitigation	Plan B

Materials don't come on time	Low	Materials will be ordered this term.	If necessary materials haven't come we can use what we already have from past projects or use materials around campus.
No proper responses on when to meet people for interviews to determine marketing plan.	Medium	Get in touch with people early and follow up on time.	Base marketing plan off of research.
Final device design isn't ready on time.	Medium	Make sure to make a plan each term with a work breakdown and key dates and stay on top of it.	If the final prototype is not acceptable for testing the old CAD design files and prototypes are kept safely for future reference.

Dual mirror version is not working	Medium	Continue working on different models with regular testing	Return to single mirror version

5. Material Testing

5.1 Material Selection

Material testing will include ultrasound imaging through three specific materials in the original prototype. Each material will be tested three different times at different percentages. Gelatin, agarose, and polyacrylamide were determined off their acoustic impedance and tissue mimicking abilities found in similar research.

Gelatin was commonly used in tissue-mimicking phantoms due to its homogenous colloid gel properties. It comes at a low cost and has acoustic properties like human tissue but is sensitive to temperatures and has a short lifetime. Previously in past projects, 15 percent gelatin was recommended to be tested. As a team, we determined 8, 12, and 15 percent based on the previous recommendations and percentages recommended from Pollet's research. Agarose is an agar-based gel that has been widely used for tissue-mimicking and is also a very cheap material. Unlike gelatin, agarose is not sensitive to temperatures but still has a short lifetime. Agarose was determined to be tested at 2%, 3%, and 5% due to its acoustic impedance range being closest to tissue at those percentages[12]. Polyacrylamide was determined to be tested at 7.5, 10, and 15 percent due to the acoustic impedance values being most like human tissues. It has been found to have fixed acoustic properties and geometry that can be used in tools and can be found on the lower range of acoustic impedance similar to human tissue[13].

A CIRS phantom will be used for this series of testing along with the Verasonics probe. The most recent prototype created in summer 2023 will be used for materials testing. The preliminary tests materials will include gelatin, agarose, and polyacrylamide (PAA) mixtures, protocols found in Appendix F.

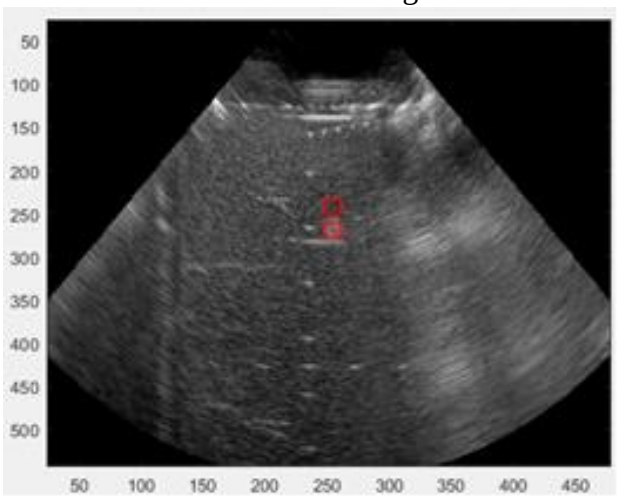
The ultrasound tests were run using a layer of water between the prototype and the phantom to avoid air interference as water was determined the best fit to be used between the two materials. Baseline tests were also run by submerging the device in water to be able to compare the solid material results to the previously used liquid. During the testing the mirror fixed inside the device got pushed askew by the solid material setting inside of it. To compensate for this mishap the ultrasound has to be angled inside of the device to make sure the ultrasound is reflecting at 45 degrees. This mainly happened with the gelatin testing.

5.1.1 Material Testing Analysis Procedure

As stated earlier in the protocols, 20 ultrasound images were taken of each material and its relevant image data was saved. In MATLAB, the image data was imported, converted to a matrix and averaged from the 4D data given by the ultrasound to a visible 2D image. Following, the data was logarithmically compressed to enhance low intensity pixels and display the dynamic range on screen.

[12] Polet et. Al 2021
[13] Menikou et. Al 2017

Using the newly visualized image, the target region, background region, and beam were selected and defined in the code as seen in figure 20 and 21. Using the defined sections, image quality analysis was performed in the form of a contrast to noise ratio analysis (CNR), a full width by half maximum analysis (FWHM), and a signal to noise ratio (SNR) analysis. The CNR is equal to QE*S/[Nb+Ns], the SNR is equal to S-N and the FWHM is equal to 2*parsG2(3)*sqrt(log(2))[14]. These values were calculated using a MATLAB script seen in appendix G.



FWHM is a statistical measure which describes the width of a normal distribution at two points where the curve's value is half its maximum. An image with a high FWHM would mean that it is a less sharp image and therefore would have a worse image quality, meaning a low FWHM is preferred. CNR is the contrast-to-noise ratio in the image and measures the difference between the tissue (or material) and the background noise. It is a measure of the image signal in each region. A higher CNR value is better as it means a greater contrast between your target and the background, which means a greater visualization of your target. SNR is the signal to noise ratio and is a physical measure of sensitivity of an imaging system. A better-quality image would have a higher SNR which typically has a value between 20 and 40[15].

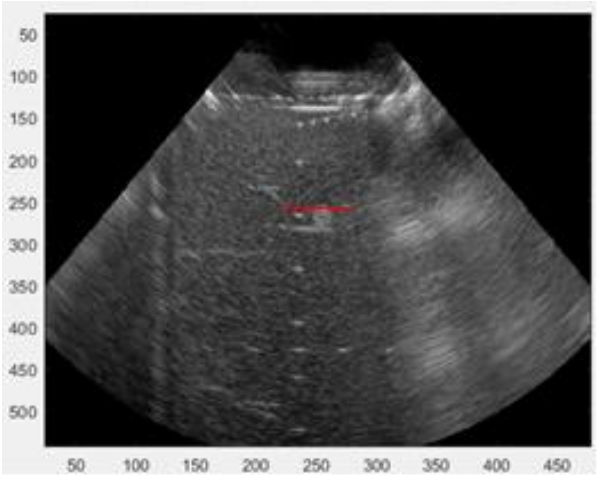


Figure 20 Beam region example

5.2 Testing Results

All material testing was done using the protocols found above. Each specific material was tested at three different percentages and the results were quantified and compared to a baseline test. To keep the variables at a minimum all tests were done in the single mirror version of the ultrasound-guided needle insertion device. The ultrasound was centered in the middle of the phantom and reset for every snapshot of data. The data was then analyzed based off the FWHM, SNR and CNR values, material cost and function, and images captured. The FWHM, SNR, and CNR were found using MATLAB.

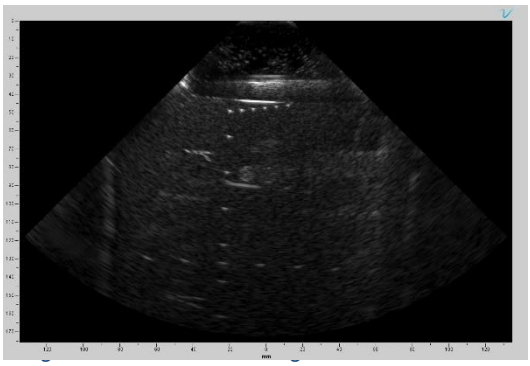
[14] Mathworks

[15] Magnotta, V. A. et Al. (2006)

5.2.1 Baseline results

Figure 22 Baseline device test

To create a baseline, we placed the ultrasound with the ultrasound-guided needle insertion device on top of the phantom inside of a tub of water as seen in figure 23. The entire device had to be submerged to avoid air affecting the ultrasound image. This baseline was chosen due to the human body consisting of mostly water, which the ultrasound probe is tuned to. As well, all previous tests had been run with water on all versions of the device and only liquid had been tested on the device previously so a liquid solution had to be the baseline to compare solid materials to. It can also be noted that the following material tests included a water-based material mixture. A representational image of the ultrasound view of the baseline test is provided in Figure 22.



5.2.2 Gelatin results

Figure 24 Cutout of gelatin to fit the ultrasound (above view)

The first round of material testing involved creating solid gelatin at 8,12, and 15 percent gelatin-to-water ratios. Higher concentrations of gelatin closer to 20-30 percent were considered but deemed too condensed to make with the boiling method and materials we had. The gelatin was made according to the protocol above and left to set overnight. After the gelatin had set in the device (seen in figure 24) a small square had to be cut out for the probe to fit. This space was filled with ultrasound gel to prevent the interference of air when using the ultrasound with the device seen in Figure 25. The results of this testing are shown below in figures 26 and 27.

Figure 25 Gelatin set in the attachment

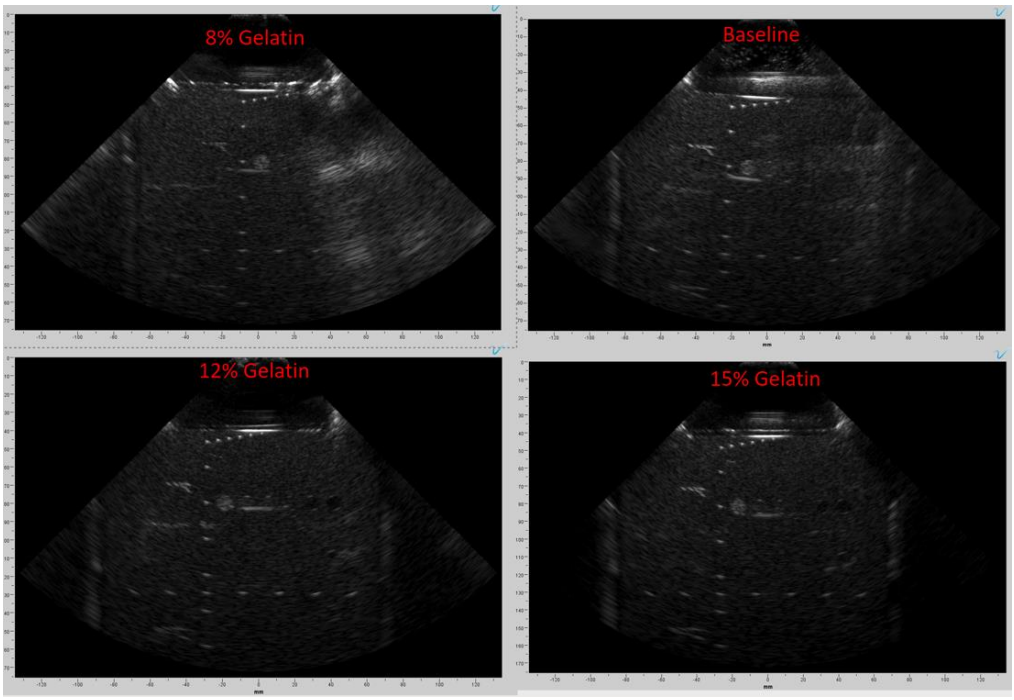


Figure 26 Gelatin Ultrasound Images for 8%, 12%, 15% Gelatin as well as a baseline (water) image.

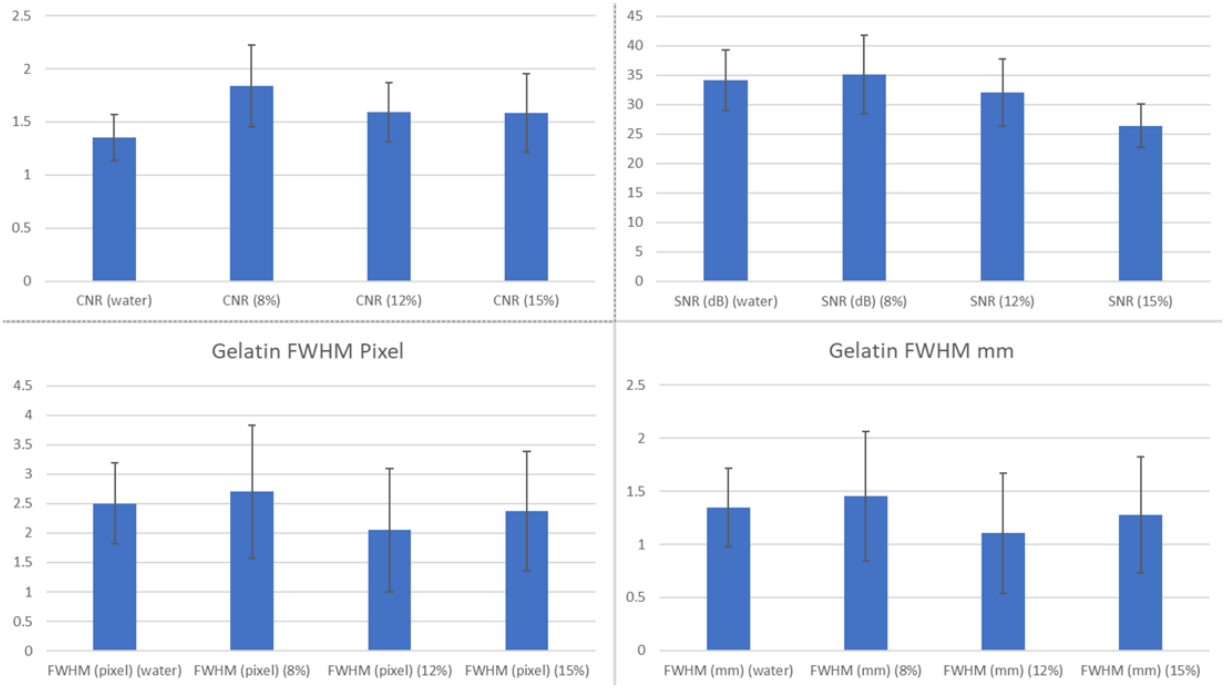


Figure 27 CNR, SNR, FWHM pixel and FWHM mm results for 8%, 12%, 15% Gelatin as well as a baseline (water).

From the results in figure 27, when compared to the baseline, 8% gelatin performed 1.4x better in the CNR test while 12% and 15% gelatin performed 1.17x better. In the SNR test, 8% gelatin performed 1.03x better while 12% gelatin performed 1.07x worse and 15% gelatin performed 1.29x worse. In the FWHM test, 8% gelatin performed 1.08x worse while 12% gelatin performed 1.22x

better and 15% gelatin performed 1.06x better. Eight percent and twelve percent gelatin were selected as the winners due to each having a test where it greatly outperformed the others as well as only one test where it performed worse than the baseline. Fifteen percent gelatin was not selected due to it being much worse in the SNR test when compared to the other materials as well as performing consistently lower in the other tests.

The gelatin trials were not statistically significant based off the ANOVA test. The column graph can be seen in figure 28 including the standard deviation and the mean. From this it can be determined that there is very little variance between the gelatin percentages.

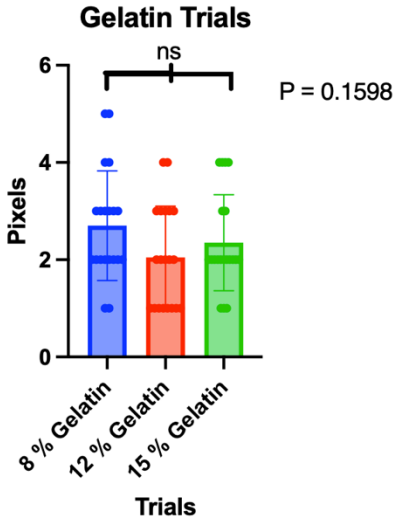


Figure 28 Column graph of gelatin trials.

5.2.3 Agarose results

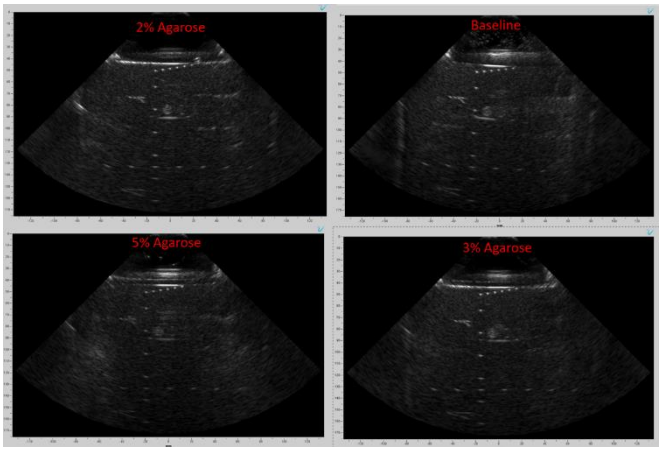


Figure 29 ultrasound images of Agarose tested at 2%, 3%, and 5% as well as a baseline test.

The second round of material testing involved creating solid agarose at 2, 3, and 5 percent agarose-to-water ratios. The agarose was made according to the protocol above and left to set overnight. Similar to gelatin, after the agarose had set in the device a small square had to be cut out for the probe to fit. This space was filled with ultrasound gel to prevent the interference of air when using the ultrasound with the device. Due to issues with the creation of agarose using a vacuum seal to remove air bubbles at first and the orientation of the ultrasound matching previous tests when imaging, 2% agarose and 3% agarose had to be remade and retested, the results of this second round of testing are shown in figures 29 and 30.

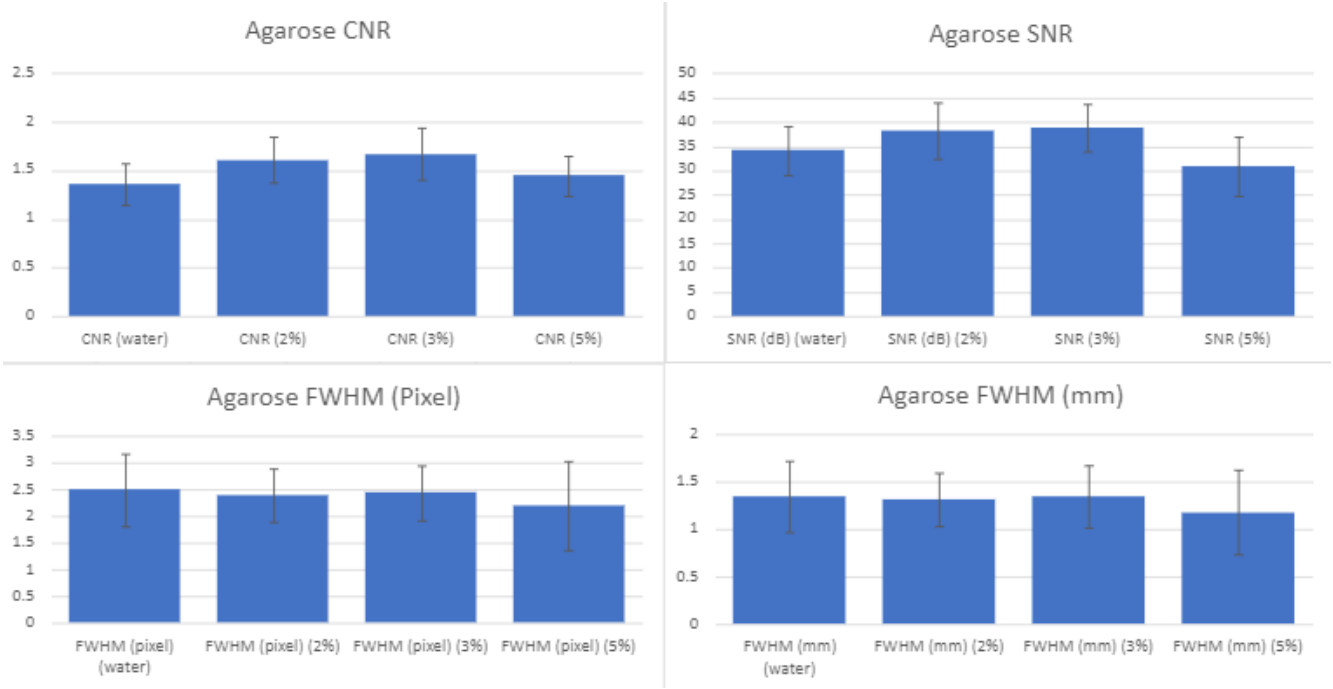


Figure 30 CNR, SNR, FWHM pixel and FWHM mm results for 2%, 3%, and 5% Agarose as well as a baseline (water).

Resulting from these tests, it was shown that in the CNR test 2% agarose was 1.19x greater than the baseline, 3% agarose was 1.23x greater than the baseline, and 5% agarose was 1.07x greater than the baseline. In the FWHM test 2% agarose was 1.04x less than the baseline, 3% agarose was 1.02x less than the baseline, and 5% agarose was 1.14x less than the baseline. In the SNR test 2% agarose was 1.12x greater than the baseline, 3% agarose was 1,14x greater than the baseline, and 5% agarose was 1.10x worse than the baseline. Basing our judgement from these observations, 5% agarose cannot be chosen as it is worse than the baseline in both the CNR and FWHM tests. It was determined that 3% agarose was the optimal agarose percentage from the ones tested since it is the greatest when compared to the baseline in the CNR and SNR tests.

The agarose trials were not statistically significant based off the ANOVA test. The column graph can be seen in figure 31 including the standard deviation and the mean. From this it can be determined that there is very little variance between the agarose percentages. These percentages were tested knowing they were very similar as 8% agarose was not compatible with the ultrasound imaging.

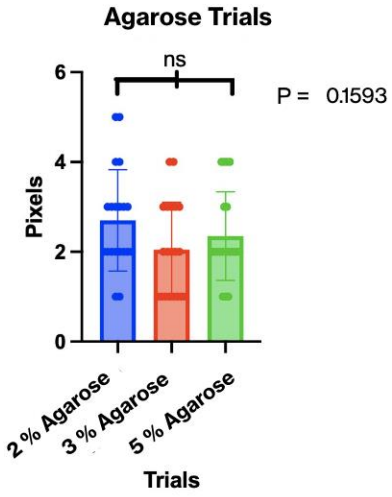


Figure 31 Column graph of agarose trials

5.2.4 Polyacrylamide results

The polyacrylamide had to be made in a chemical safe lab with the use of the hood due to bis-acrylamide being a neuro toxin. Due to having a minimal amount of acrylamide only the 5 and 20 percent solution were able to be made. The materials purchased came in 100 percent powder form, so each powered material was mixed with milliQ water to get the right percent solution needed in the protocol. The solutions were made under a hood and followed the protocol above. When making the polyacrylamide, there was very little gelling when the mixture was inserted into the attachment. This can be due to a number of reasons, our leading theory is not enough Ammonium persulfate and N, N,N 0,N 0-Tetramethylethylenediamine was added for the reaction to generate enough heat in the openly exposed device. Interestingly, when the waste material was combined at unknown concentrations in a disposal beaker it was much clearer visually than either the gelatin or the agarose which is consistent with the findings of Chen, et al. seen in Reference 10. Our findings are shown in figure 32. Polyacrylamide might be considered for future material testing but now, due to cost and safety risks when compared to making gelatin and agarose, we are no longer testing polyacrylamide.

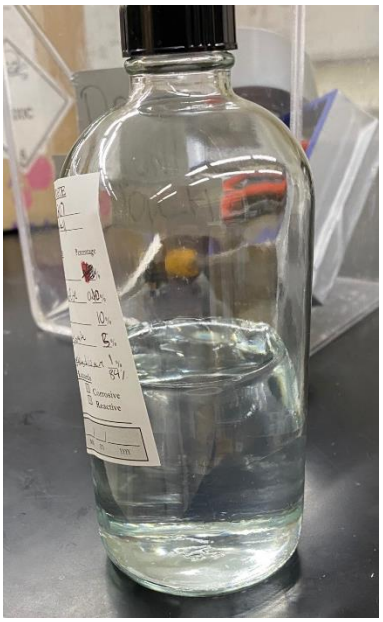


Figure 32 Polyacrylamide solution

5.2.5 Final comparison and conclusion.

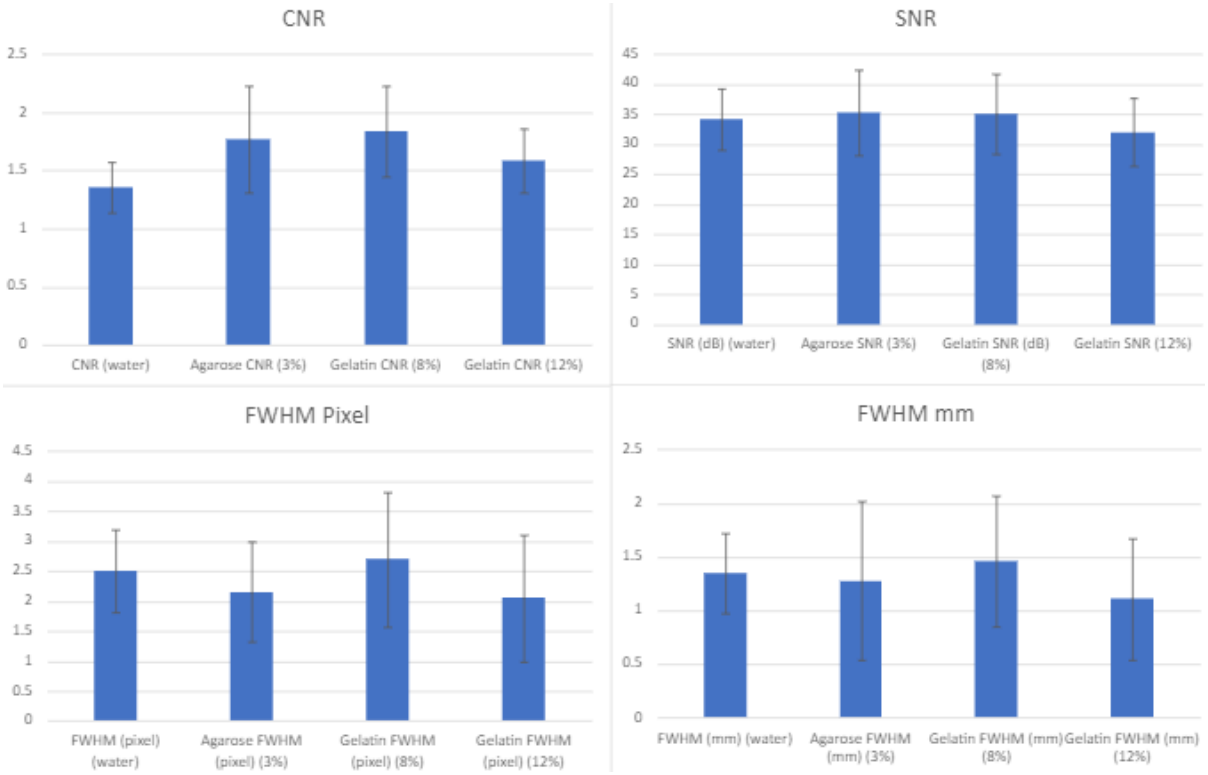


Figure 33 CNR, SNR, FWHM pixel and FWHM mm results for 3% agarose, 8% gelatin, and 12% gelatin as well as a baseline (water).

The top material percentage result from each material test was selected to be compared against one another. These comparisons were used to select the best material to use in the ultrasound-guided need insertion device. Resulting from these tests, it was shown that in the CNR test 3% agarose was .130x greater than the baseline, 8% gelatin was 1.36x greater than the baseline, and 12% gelatin was 1.17x greater than the baseline. In the FWHM test 3% agarose was 1.15x greater than the baseline, 8% gelatin was 1.08x worse than the baseline, and 12% gelatin was 1.22x greater than the baseline. In the SNR test 3% agarose was 1.03x greater than the baseline, 8% gelatin was 1.03x greater than the baseline, and 12% gelatin was 1.06x worse than the baseline. Additionally, agarose is the easiest material to prepare compared to the gelatin or polyacrylamide. Polyacrylamide contains toxic solutions which are very dangerous and costly. To order the four solutions to make the PAA solution it cost over $450 dollars. Polyacrylamide wasn't considered in the results due to it not being a manufacturing and medical device friendly option. Gelatin costs around $40 for 100grams while agarose costs $200 per 100 grams. This is a $160 difference in pricing but considering agarose take only 3 minutes to prepare while gelatin takes 30 plus minutes the time comparison evens out the costs. The final comparison between gelatin and agarose comes down to the data analysis.

From the data analysis seen in figure 33 it was determined that 3% agarose would be the optimal material for use in the ultrasound-guided needle insertion device since it was the only material to consistently outperform the baseline in each of the imaging tests. Three percent agarose has a high CNR and SNR value and a low FWHM value. While eight percent gelatin is a close second with similar consistencies the agarose's CNR value is lower by only 0.2 while gelatins FWHM value is higher by over 1. Agarose had a lower standard deviation for the CNR value meaning it was more consistent with the results in the analysis along with its FWHM. Considering preparation time and convenience, we concluded agarose outweighs gelatins.

5.3 Stainless Steel Testing

The previous MQP team used a glass mirror to reflect the ultrasound image, and all previous testing were done with the same. Glass is very commonly used for reflections due to its low impedance but is has difficulties in manufacturing, due to its brittle characteristics which can cause it to crack and shatter very easily, therefore research of a more manufacturing friendly option was conducted. Through research at Iowa State University, it was found that stainless steel reflects 88% of sound energy[16]. Twelve percent of this energy gets reflected into the second material at a water-steel interface. Overall, the dampening of sound energy was found to occur at a rate comparable to glass.

Tests were run in the original prototype from the summer similar to the materials tests above. Four total tests were conducted, two using water to fill the attachment and two using three percent agarose to fill the attachment. The independent variable in both sets of tests was the use of stainless-steel vs glass. The goal of the test was to validate our use of stainless steel polished to a mirror like finish as a reflective material in our attachment.

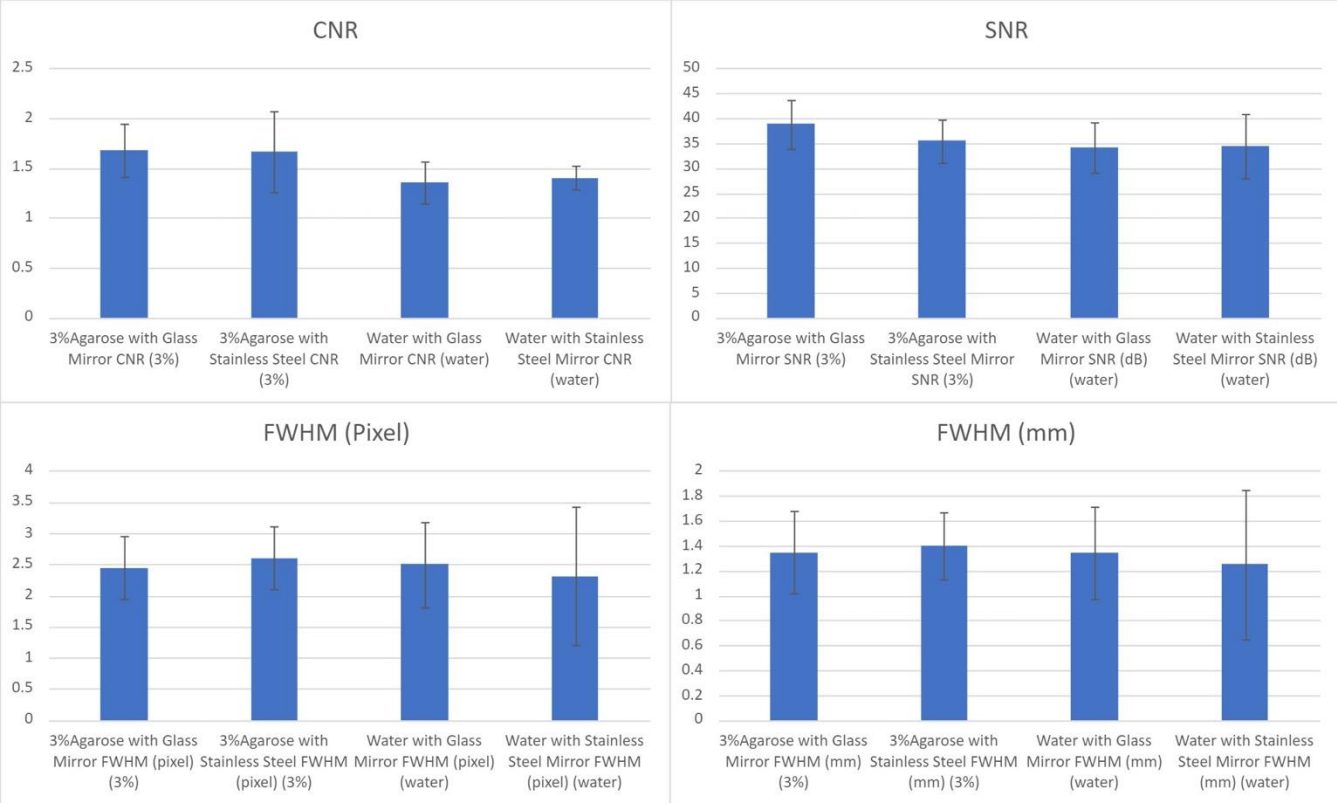


Figure 34 Stainless steel reflector test results.

[16] *Reflection and transmission coefficients*. Nondestructive Evaluation Physics : Waves. (n.d.). https://www.nde-ed.org/Physics/Waves/reflectiontransmission.xhtml

The data in figure 34 was able to validate our hypothesis that stainless steel is a possible replacement for glass. Seen is Figure 35, glass and stainless steel are not substantially different visually or through ultrasound image analysis, Figure 34. Through the image analysis, it was shown glass has a higher SNR than Stainless Steel by about 1.16x with the CNR for the two reflecting materials being the same. The FWHM values are also comparable with the glass being 1.16x greater than the Stainless Steel. Considering the small margin of difference between the two materials they are concluded to be interchangeable. Based on the interchangeability of Glass and Stainless Steel, Stainless steel was used for further testing and the final design due to it being easier to obtain and manufacture.

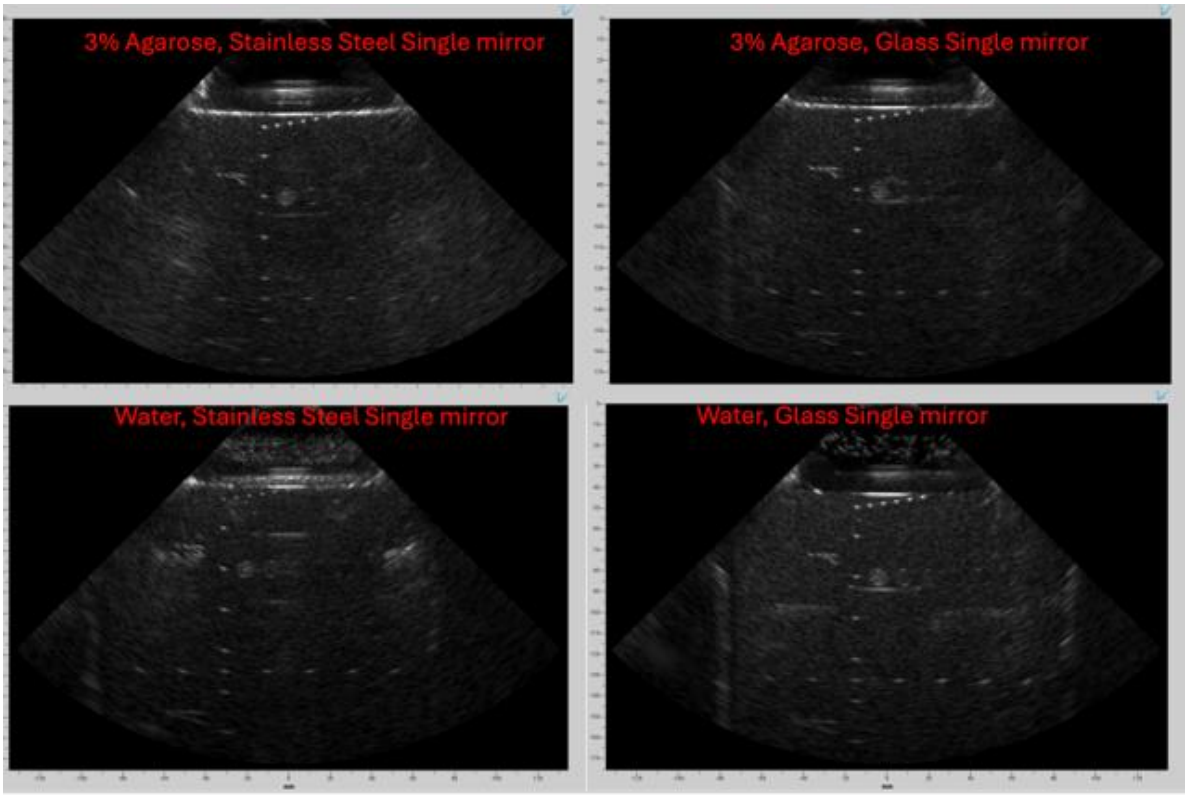


Figure 35 Visual of ultrasound images from stainless steel reflector comparisons.

6. Prototype Design and Testing

6.1 Initial Design Plan

The most notable difference in our device model compared to previous MQP teams was the orientation switch from horizontal to vertical, leading to a complete design change, necessitating the use of 2 mirrors instead of one. Our preliminary model of the device was built as proof of concept that the idea works and is feasible. The images below compare the latest single mirror design and our first double mirror design concept.

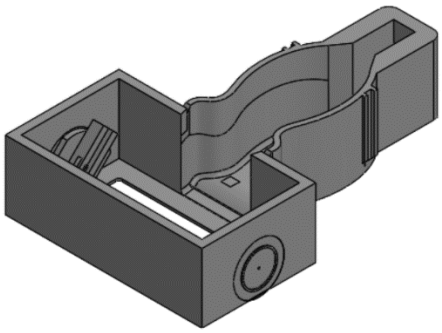


Figure 36: Latest Single Mirror Design

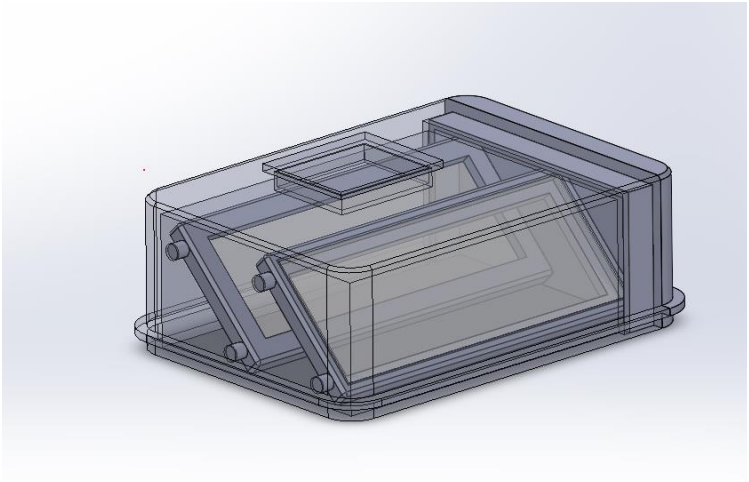


Figure 37: Version 1 of Double Mirror Design

Below, we will discuss how we developed the new model's design process and the changes made to later versions of the model.

6.2 Design Upgrades

Each version of the design underwent changes and modifications based on certain requirements, visual and device inspections, and testing of the previous version, as we will discuss below.

6.2.1 Version 1 (initial prototype)

The main objective of our first design was to test the new concept of changing the orientation of the US probe from horizontal to vertical by using 2 mirrors held at 45 degrees. The design was made assuming the entire assembly would be filled with some material to facilitate the travelling of the US waves.

The assembly consists of 3 components, a main housing in which the mirrors are placed, a mirror holder, and a cover to close the housing. The bottom of the assembly is left open to allow direct contact between the filled material and the target to prevent other materials from interfering. The image below shows how these components are assembled. The mirrors are taped to the mirror holder and the circular extrusions help guide the holder into place in the housing and the cover seen in figures 38, 39, and 40.

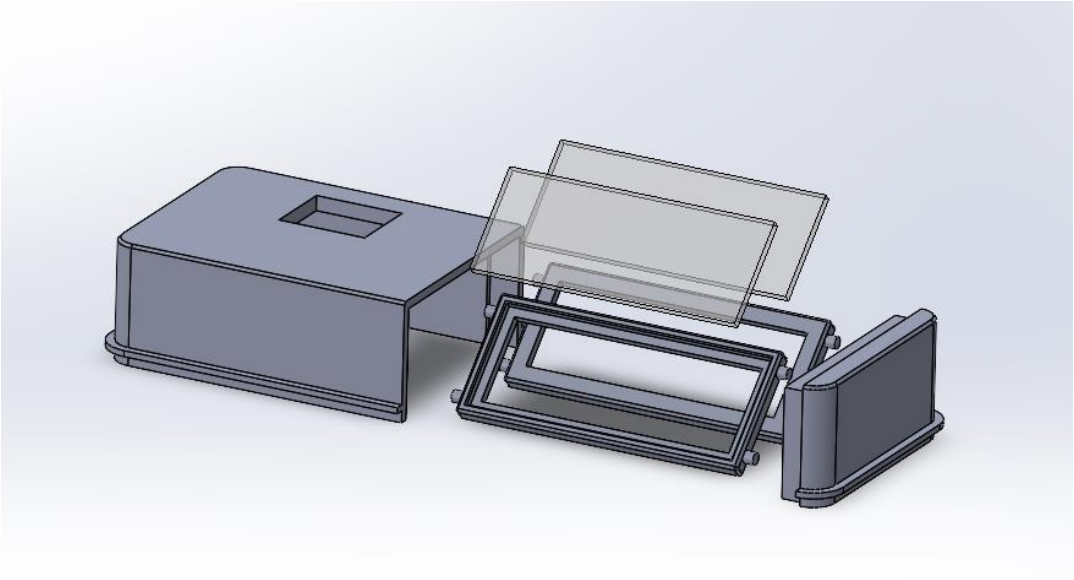


Figure 38: Exploded view to visualize assembly process.

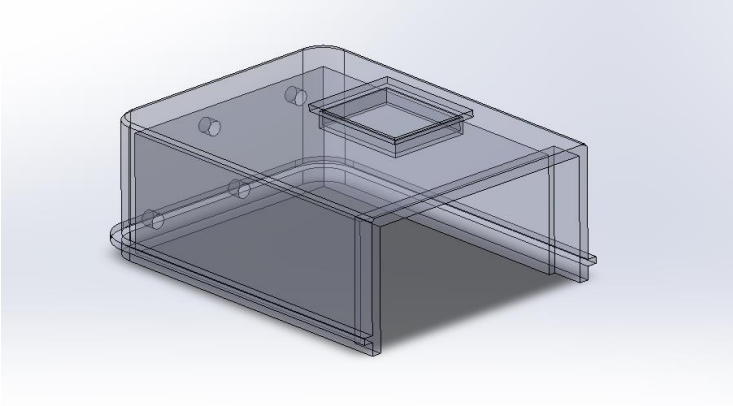


Figure 39: Version 1 Housing

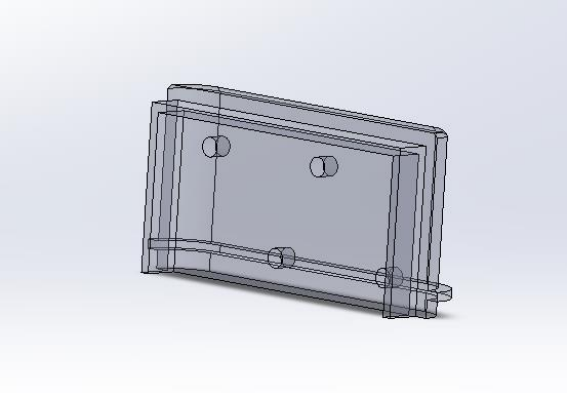


Figure 40: Version 1 Cover

This prototype was tested with the ultrasound while being completely submerged under water like the baseline test. The ultrasound didn't fit perfectly into the device and was pushed slightly sideways altering the image. The results can be seen in figures 41.

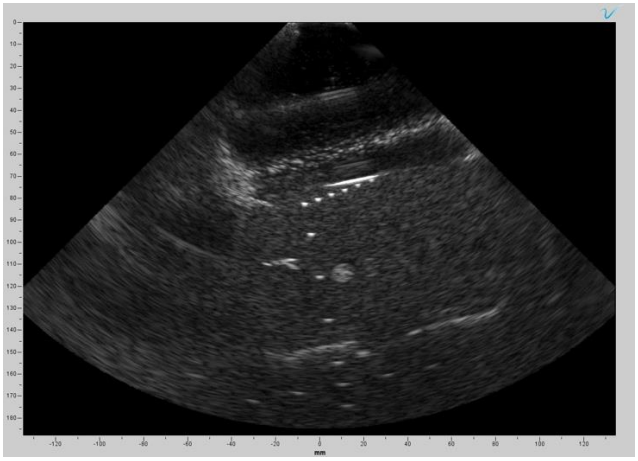


Figure 41 V1 Ultrasound Image

6.2.2 Version 2

The goal of this version was to reduce the overall size of the device. The distance between the 2 mirrors was minimized and the total distance for the US waves to travel to reach a target was also cut by reducing the overall height of the design. The shape of the extrusions was changed for simplicity and better printing accuracy. In addition, a US holder attachment was also made that would hold the US probe and clip onto the top of the device, as seen below. Another change we made was to print the cover and the mirror holder as a single part. This helps reduce the error in position and angle of the mirrors.

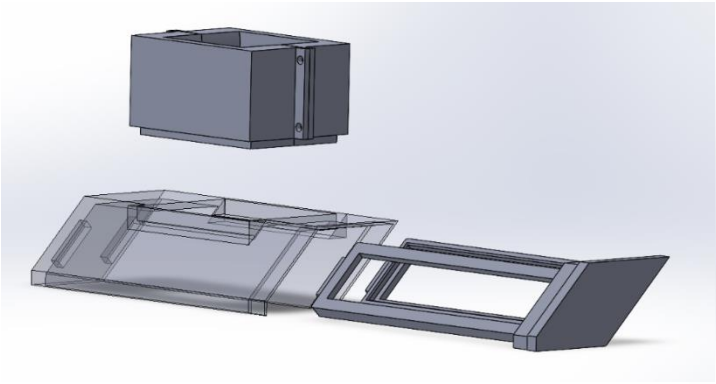


Figure 42 Version 2 exploded view

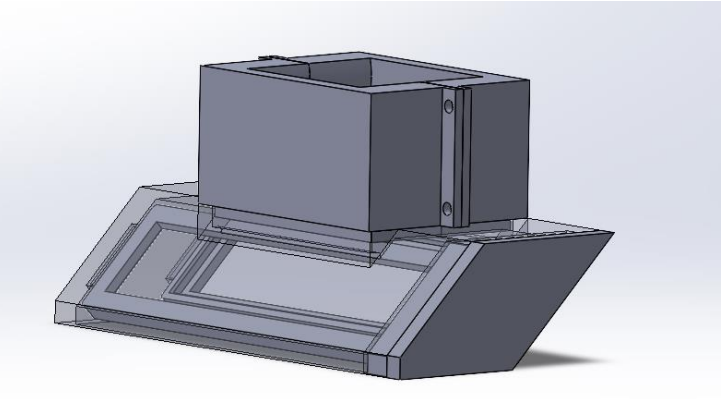


Figure 43 Version 2

Due to the complex shape of the US probe, the US holder attachment went through several iterations to find a better fit between the probe and the attachment. Each attachment was also modified and tested for fitment as the device versions progressed.

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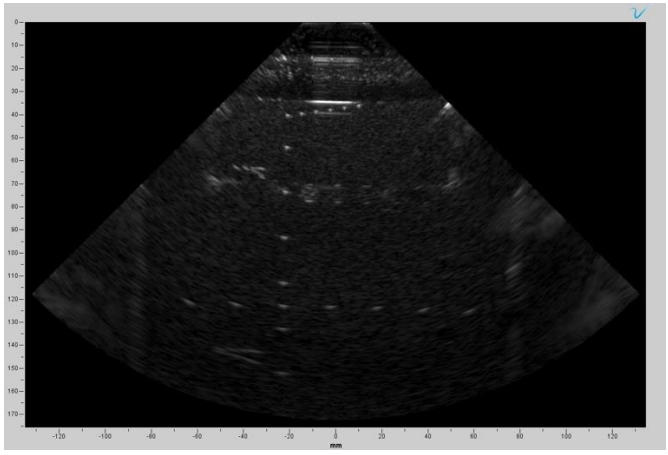


Figure 44 V2 Ultrasound image

This prototype was simplified into a more compact device with a clip that the ultrasound will fit in. The visual result from imaging can be seen in Figure 45. This prototype version was successful resulting in a straight vertical image with less impedances than the previous version.

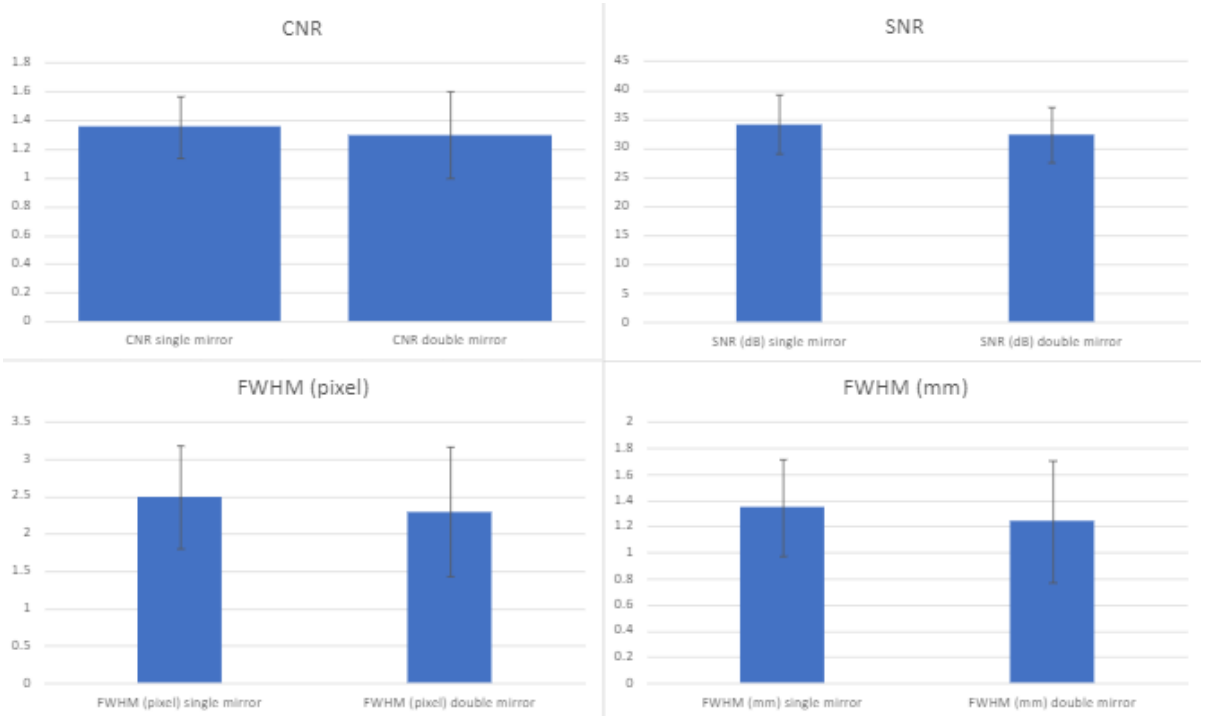


Figure 45 Baseline and V2 data analysis

In Figure 46 above, the baseline test with the previous prototype from the summer's data is measured against the V2's data. The two data sets have very minimal differences. The FWHM value of the V2 device is lower, meaning the images are sharper. Overall, the two versions are comparable as the summer version has a higher SNR and CNR by about .036% in the CNR test and 0.085% in the SNR test meaning the differences in image quality wouldn't be visible in the actual ultrasound imaging. Since there is such a small difference in the collected data, it can be concluded that the V2 prototype design is a successful design and competitive with the old designs.

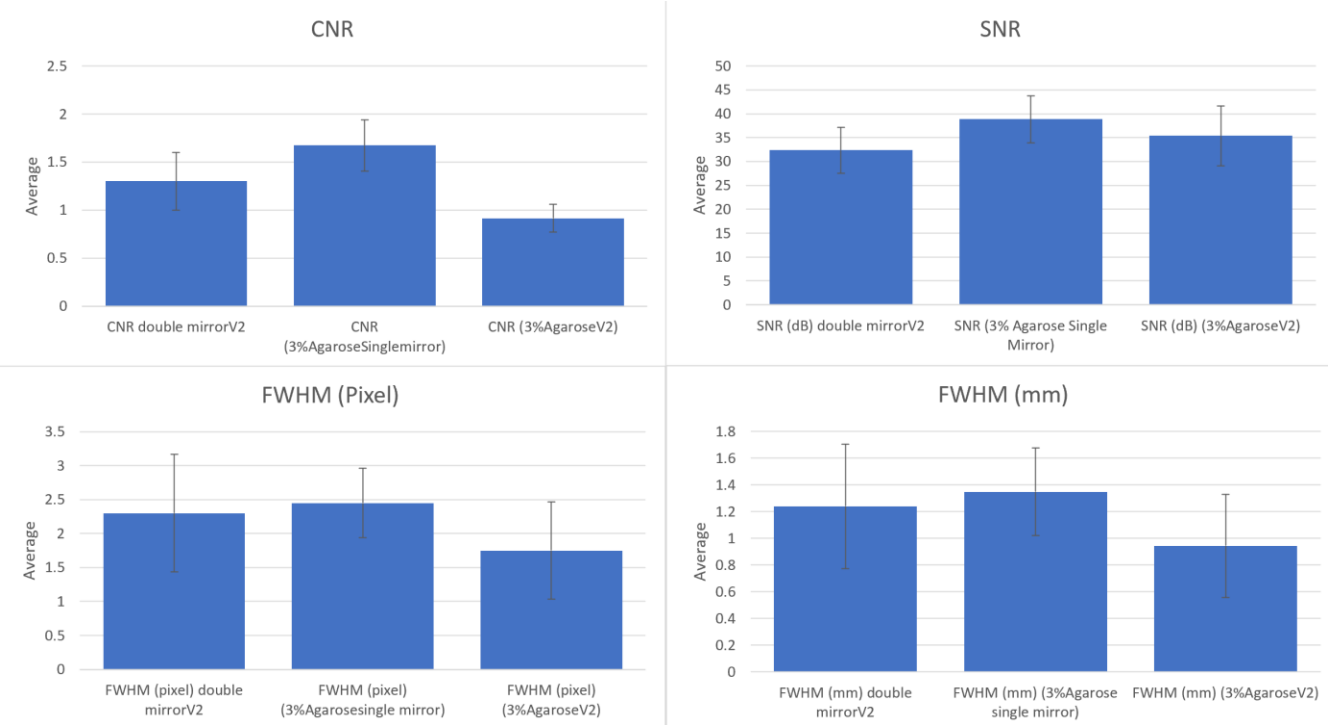


Figure 46 3% agarose in the double mirror compared to the 3% agarose in a single mirror and the double mirror with just water.

The V2 prototype was also tested with the selected material of 3% agarose as seen above in figure 47. Testing the second version of the attachment using agarose provided lower FWHM values, meaning the image was sharper when compared to the same second version of the prototype using water and the single mirror version using 3% agarose. The CNR value was lower as well, meaning there was less contrast between the target and the background. The SNR value was very similar between each of the tests, although it was slightly lower than the 3% agarose using the single mirror attachment. Overall, the image quality tests between the second version of the attachment in water and using 3% agarose were very similar while being slightly worse than the single mirror attachment. From these results the test with water had slightly better quality than the test with 3% agarose.

6.2.3 Version 3

Version 3 of the device was designed to solve some issues found in version 2. It was found that the area of waves sent from the probe was too big as parts of the mirror holder and mirror interfered with the path of the US waves. The mirror positioning was found to be wrong as described below. The total width of the device was also adjusted based on the distance the US waves travelled. Below is the redesigned version of the device.

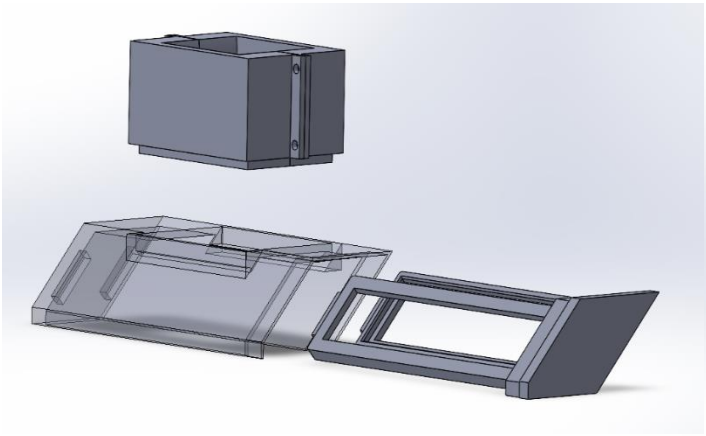


Figure 47: Version 3 exploded view

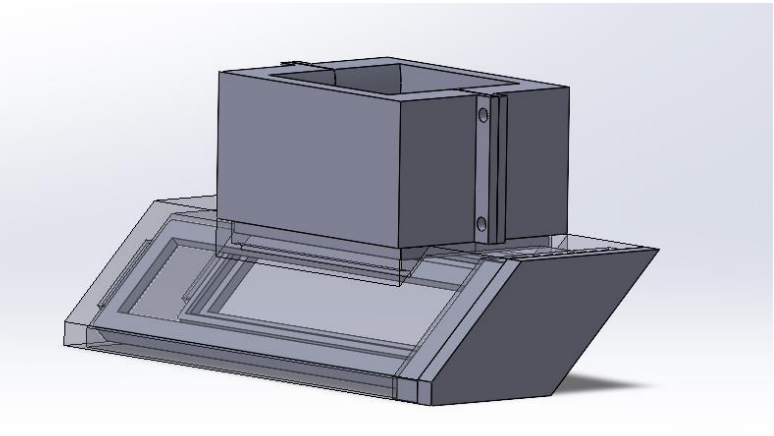


Figure 48: Version 3

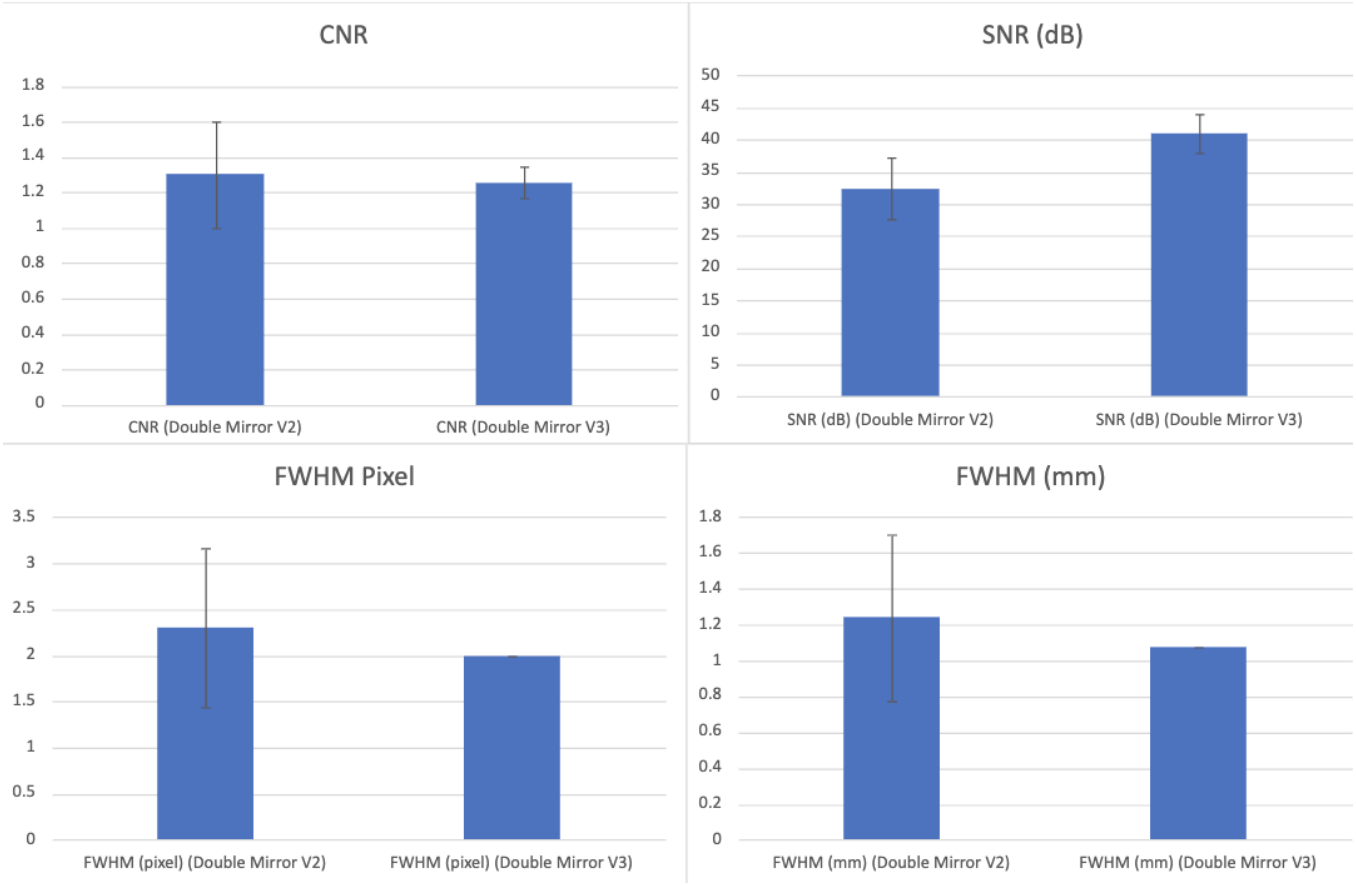


Figure 49 V3 double mirror attachment test in water versus V2 double mirror attachment in water.

In a direct comparison test between the second version of the double mirror attachment to the third version (figure 50), the third version outperforms in both the SNR and FWHM tests while underperforming slightly in the CNR test. From these results we can imply that the third version of the double mirror attachments improvements were successful.

6.2.4 Version 4

For this version of the device, we modified version 3 and added a slot where the needle would be inserted. The slot was positioned in a way that the needle would pass through the center of the

second reflecting surface, as seen in figure 51 and 52 below. The mirror holder on the side of the needle was changed to let the needle slot pass through.

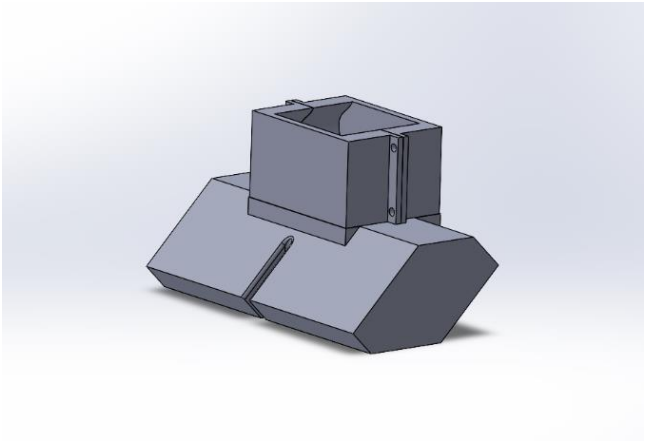


Figure 50: Version 5 Assembly View 1

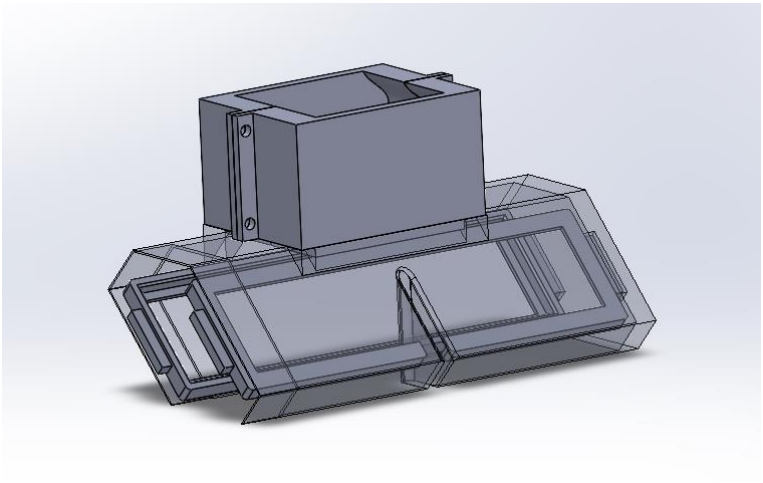


Figure 51: Version 5 Assembly View 2

6.2.5 Version 5

Since even a small change in features like surface finish or reflecting angle can magnify the error of the ultrasound image, the goal for version 5 was to reduce the chance of such an error by minimizing the number of components in the device. We did this by directly attaching the mirrors to the inner surface of the base. Because of this, this design uses 2 smaller mirrors that go on either side of the needle slot instead of the single mirror we had been using in previous versions. As seen in the image below, the solid boxes represent how the mirrors fit into the base. This change also allowed the overall size to be reduced as the holders for the reflective surface were no longer required.

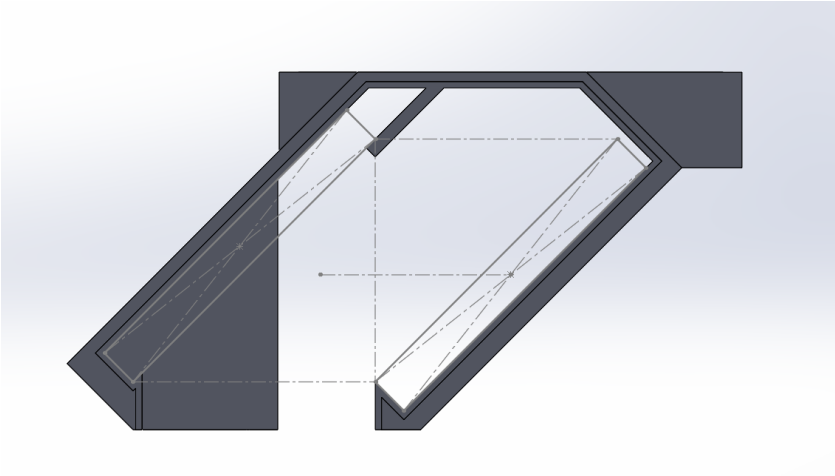


Figure 52: Solid boxes show how mirrors fit into the base.

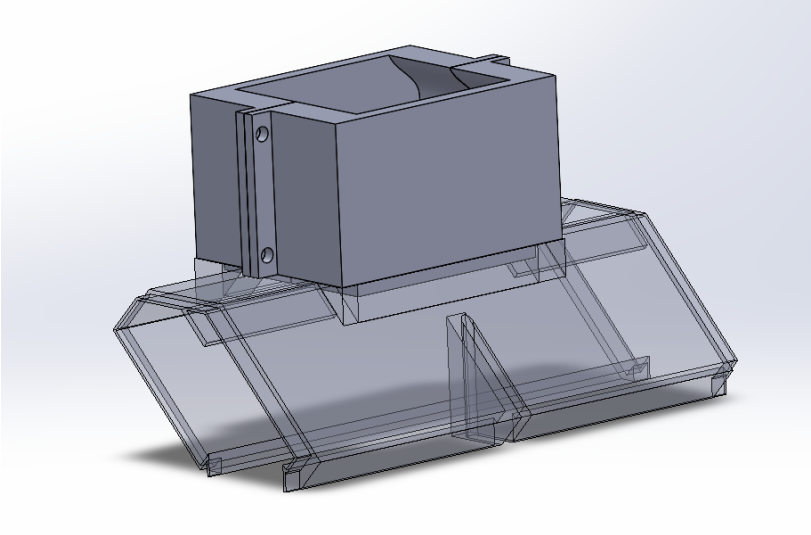


Figure 53: Version 5 Assembly

The next versions 4 and 5 were updated with a slit for needle insertion. The fifth version was tested on the phantom while submerged underwater. In the image in figure 55 the ultrasound image can be seen with a blur zone to the right of the grey scale dots. This blur zone is caused by the slit for the needle insertion and the space between the mirrors for this slit. The ultrasound doesn't have anything to reflect off so there is an area where nothing can be seen. This test with version 5 lead to the updates of version 6.

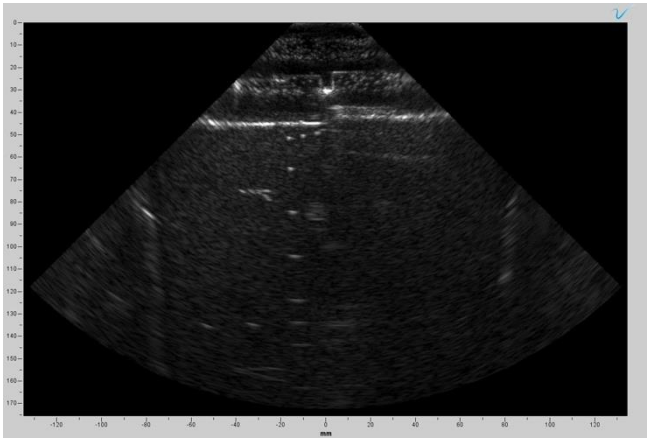
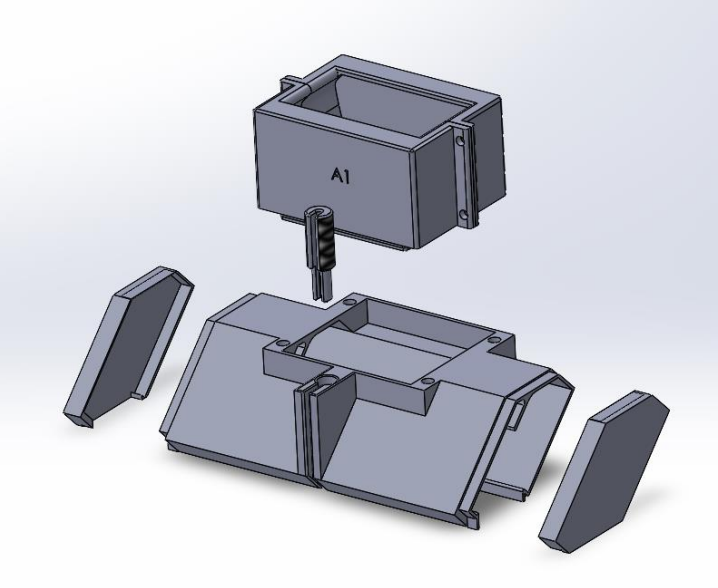


Figure 54 V5 Ultrasound image

6.2.6 Version 6

For this version, we moved the needle slit guide outside the device to resolve the blind spot created by the guide in the previous version. A needle locking mechanism was also added to the top of the guide. When activated (twisted 180 degrees), it limits the needle's movement, making it move vertically and thus improving the accuracy of needle insertion. As concluded from our reflective surface testing, we decided to use stainless steel instead of mirrors moving forward. Like in version 5, the stainless-steel plates would be attached directly to the base of the device. Finally, as seen from figure 56 and figure 57, magnets were added to the US holder and the base. This was done to fix the US holder to the base rather than pressing it in as it would damage the guide walls of the US holder. As discussed in the chapters below, this version was validated through needle visualization testing and a pig cadaver study for a more realistic test of the device.



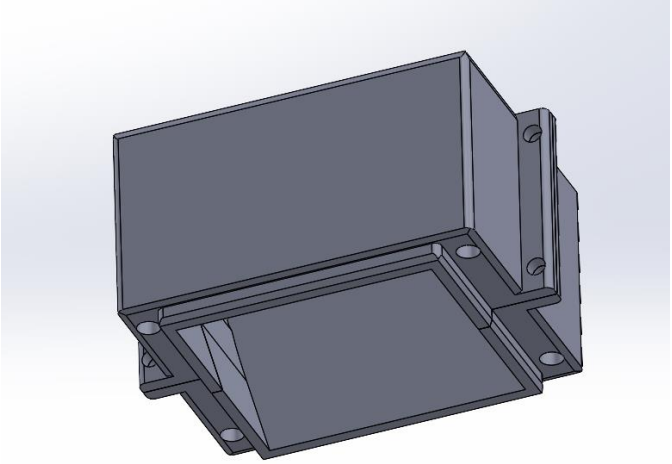


Figure 55 Version 6 exploded view

Figure 57 US Holder attachment with holes for magnets

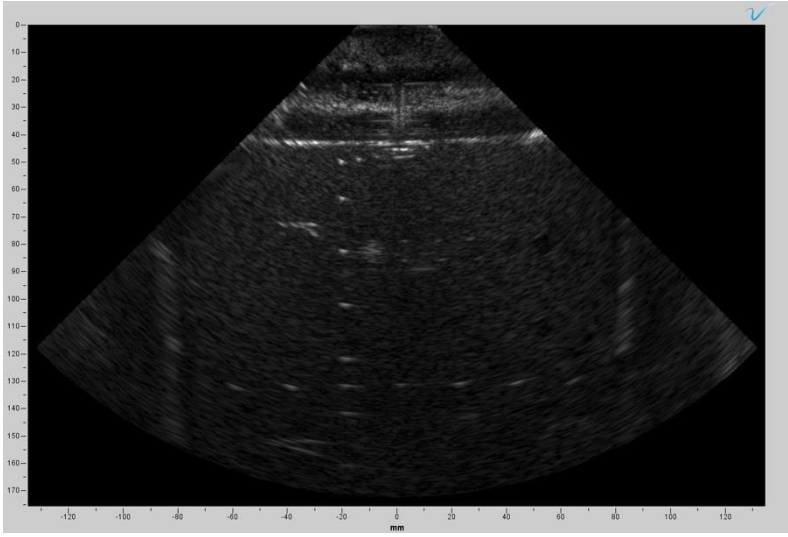


Figure 57 Version 6 Ultrasound Image

The sixth version was also tested on the ultrasound phantom while submerged under water. In this image (figure 58) the visual of the phantoms targets is a lot clearer. The blur zone was also eliminated by moving the mirrors closer together. This test proved the sixth version to be successful with reflecting the ultrasound image into the tissue and producing a quality image.

7. Device Validation

The final design of the device was tested using needle visualization methods to validate the functionality of the device.

7.1 Mock Phantom

To complete needle visualization testing, a homemade phantom was made to visualize needle insertion into an object. The previous MQP group recommended making a phantom out of gelatin and ceramic balls to complete needle image quality tests[9].

Materials:

- Acrylic box
- Gelatin
- Water
- Hot plate
- Metal stirrer
- Scale
- Metal pot
- Ceramic Balls

Mock Phantom Procedure

1. Make 8% weight by water gelatin solution.
2. Fill acrylic box with gelatin halfway and let it set.
3. Add ceramic balls or other artifacts.
4. Finish filling acrylic box with gelatin.
5. Let set for about two hours then mock phantom is ready to test on.

7.2 Testing Protocol

To complete the needle visualization testing the mock phantom was used to insert the needle using the final version of the attachment.

Materials:

- Mock Phantom
- Verasonics Machine and Probe
- Needle
- Final Design
- Agarose
- Ultrasound Gel

Needle Visualization Procedure

1. Set up the mock phantom and targets.
2. Prepare device with agarose filling.
3. Insert ultrasound probe into device.
4. Use ultrasound gel between the device and the phantom.
5. Start the system and begin ultrasound imaging.
6. Alight device center above target.
7. Insert needle using device.
8. Save image when needle tip is directly 10 mm above the target.
9. Freeze the image and save the data.
10. Repeat step 8 twenty times, lifting the device off the phantom and replacing it each time. It is recommended to keep the device in the same position as the phantom for each image for better analysis.

An image will be frozen and then analyzed, including FWHM, SNR, CNR. CNR code will be used to compute the values. The code generates a background region and puts coordinates within the circle to give the value. The range should be between 1.2 to 1.8.

7.3 Visualization Testing

The final design of the device consisted of a 3% agarose filling and stainless steel reflectors with the device having a needle slit and lock for accuracy. The first round of needle visualization testing was done using a mock phantom consisting of 8% gelatin and water with ceramic balls dispersed in the middle layer. A needle was inserted with assistance from the Ultrasound Guided Needle Insertion Device shown in figure 59 with its corresponding ultrasound visualization shown in figure 60.

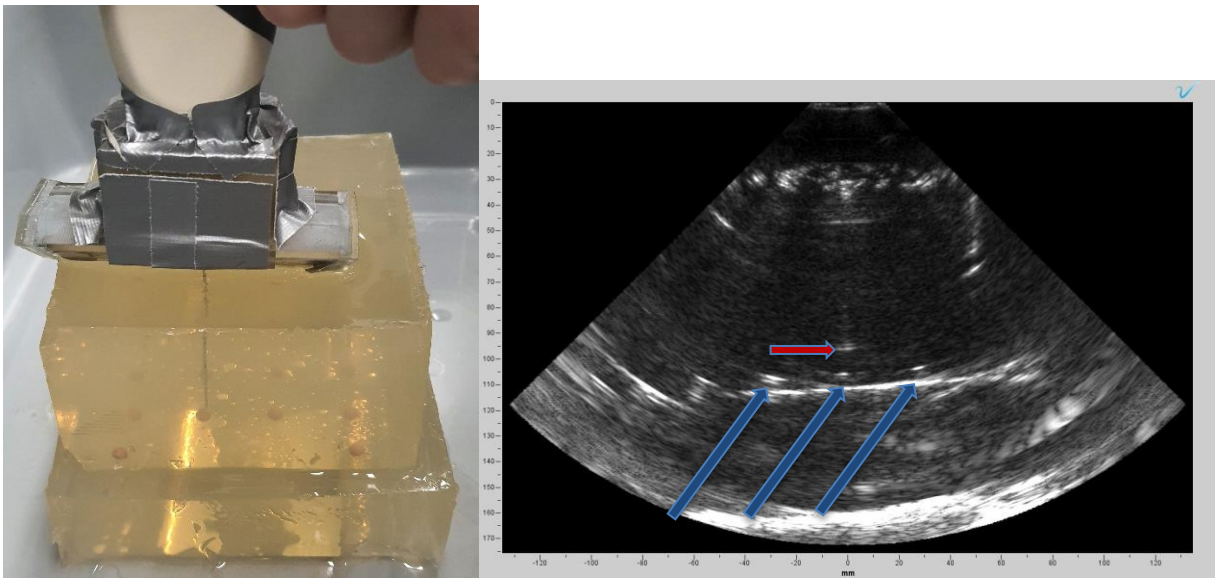


Figure 58 Needle insertion into gelatin mock phantom. Needle tip is shown by the bright spot pointed to by the red arrow. Ceramic balls are shown as bright dots pointed to by blue arrows.

Figure 59 Needle tip is shown by the bright spot pointed to by the red arrow. Ceramic balls are shown as bright dots pointed to by blue arrows.

In the gelatin mock phantom, we can see promising results as the needle tip remains in line with the ultrasound visualization and can be seen distinctly in the ultrasound visualization for an accurate insertion. Following this test, needle visualization testing was done on non-living cow meat with results shown in figure 61 below.

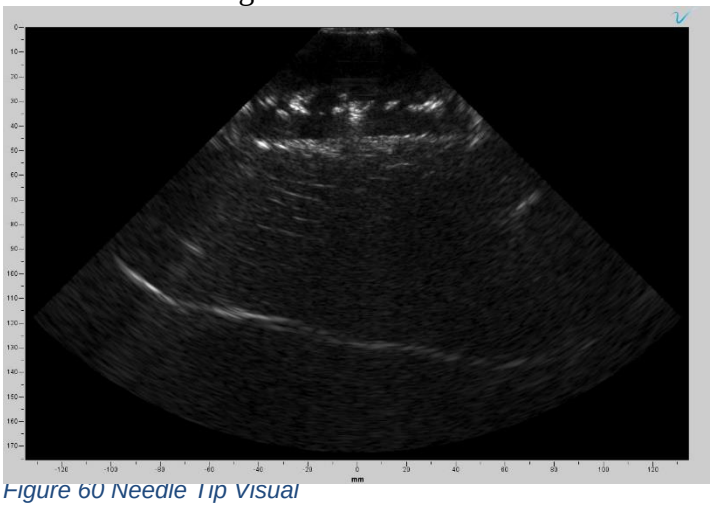


Figure 60 Needle Tip Visual

The visualization testing was run to validate the accuracy of the needle within the device on a mock phantom. Although a gelatin mock phantom is not like tissue, these results can be used to prove the accuracy and image quality of the device. The test was run using the final design filled with 3% agarose and a metal reflector. The mock phantom was filled with two lines of ceramic balls at the center or bottom edge of the first gelatin square. The device was then lined up over one of the ceramic balls using the ultrasound and

the needle was inserted above. The test was run twenty times, and the needle was aligned to hit the ceramic ball as if it were a kidney stone. In figure 63

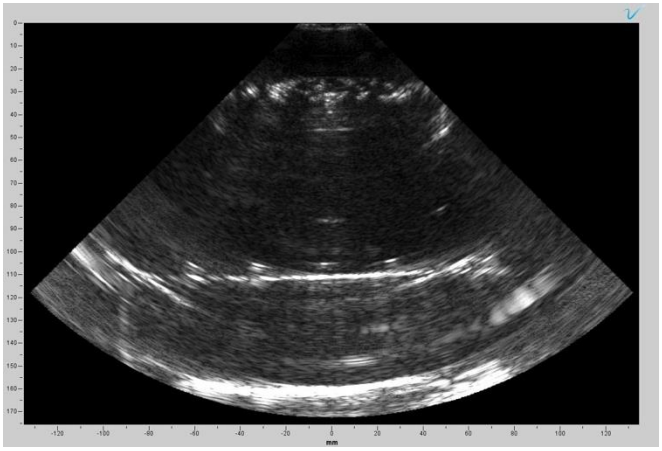


Figure 62 Needle insertion into non-living cow meat. Needle tip can be seen as a dim spot pointed to by the red arrow.

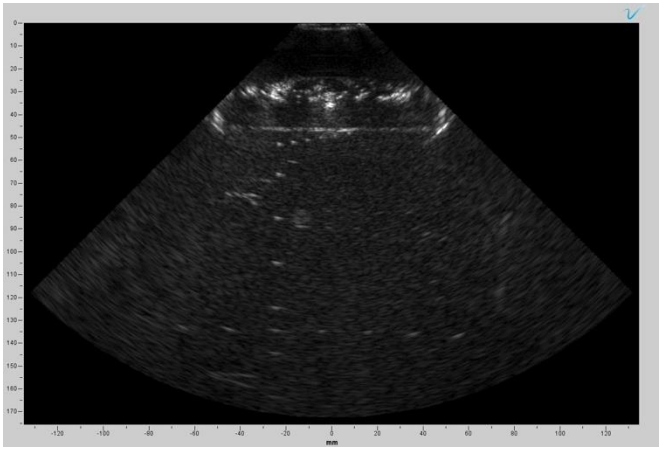


Figure 61 V7 Ultrasound Image

, the image shows the ceramic ball targets and the needle ¾ of the way inserted.

During needle insertion we noticed needle visualization was lost after 20mm of insertion into the meat. This can be due to the different material properties of the cow meat and how well the needle can be seen by ultrasound. We plan on visualizing the needle in the future by adjusting the ultrasound image processing settings to better visualize the needle.

It was tested using the material testing protocol in chapter 5 on the mock phantom as well. The material test was run to determine the quality of the image being produced through the design. The image produced can be seen below in figure 62.

The analysis of the image quality tests can be found in the results seen below in figure 64. The results show the CNR value being .02x higher on the phantom than on the needle visualization. This difference is very minimal which is a good result for the needle visualization meaning the contrast to noise ratio for the needle to its target is very similar to the phantoms results. The SNR value fluctuated a little bit more being 0.75x higher on the phantom. Considering the difference is still minimal the single to noise ratio of the device with the needle is still within a good quality meaning the needle visual is accurate. The FWHM was 7x higher with the needle visualization on the mock phantom. This means the image was significantly less sharp than on the phantom. Although the resolution was a lot lower when visualizing the needle tip, the tip visual was improved significantly and resulted in accurate insertions.

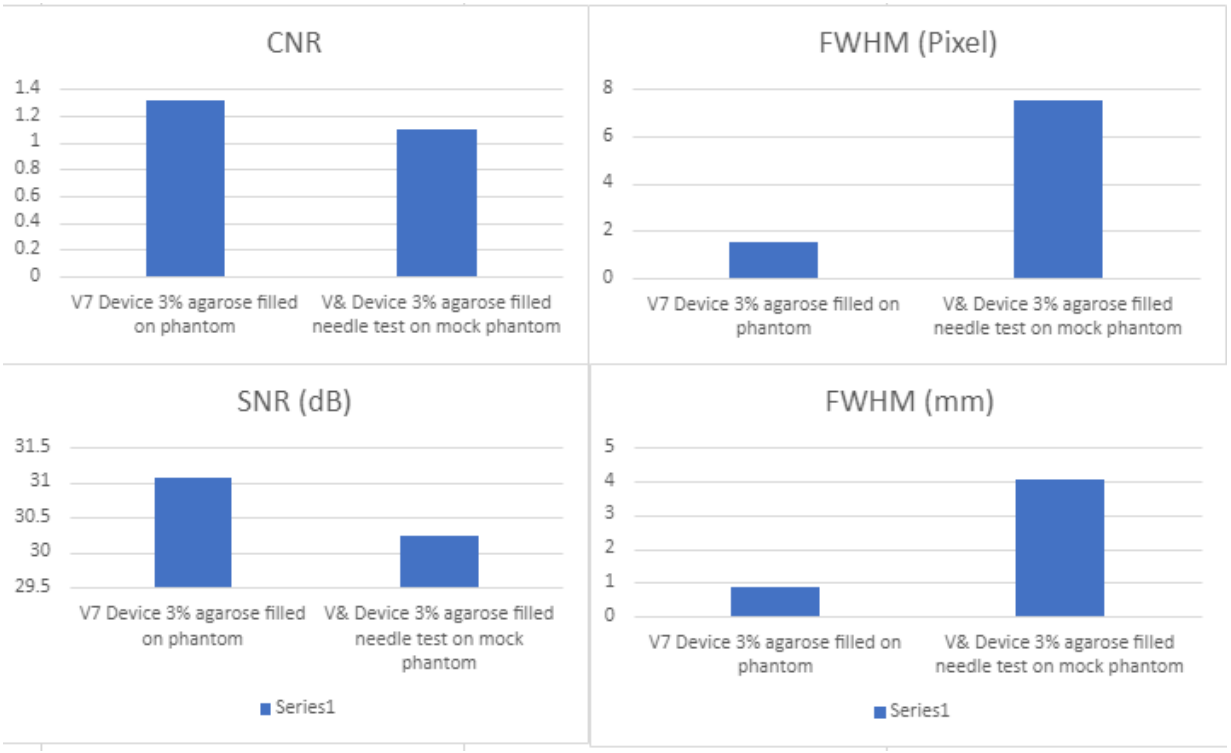


Figure 63 Image analysis.

7.4 Pig Cadaver Test

The final phase of our teams' needle visualization tests for the ultrasound-guided needle insertion device consisted of a pig cadaver study. The final device design was tested by recreating a PCNL procedure on a pig cadaver as seen in figure 65 below. The testing procedure consisted of locating the kidneys in the cadaver using ultrasound probe and marking insertion locations using a tape outline and sharpie. The device was then used to locate the kidneys and the needle was inserted. A slit had to be made to allow for needle insertion into the cadaver. Videos were recorded during the needle insertion of the cadaver of the ultrasound screen and of the procedure. Once the needle was inserted a CT scan was taken of the cadaver to determine if the needle infiltrated the kidney. This procedure was performed twice.

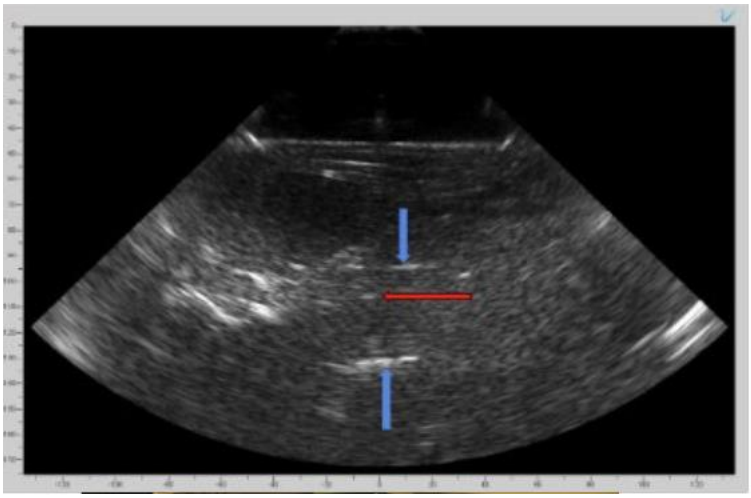


Figure 65 Ultrasound image of kidney and needle

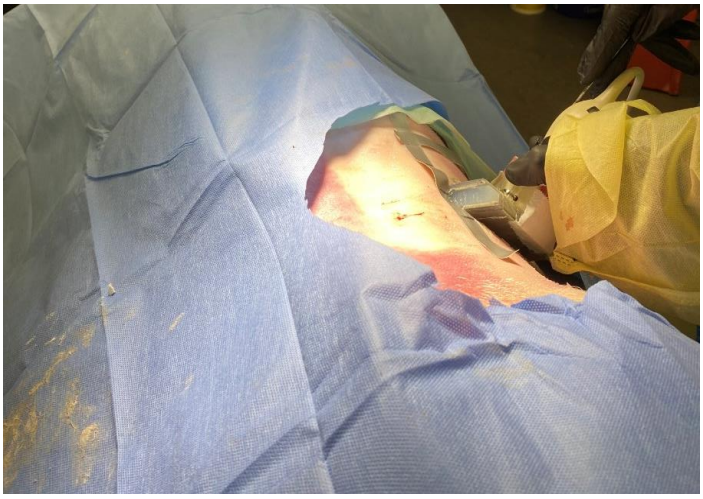


Figure 64 Device on pig cadaver

In figure 66 above the ultrasound image can be seen from the successful trial of the cadaver tests. In the image the blue arrows point to the edges of the kidney and the red arrow points to the needle tip that is visible. Figure 67 below shows the CT scan from a 45-degree view, and it shows the needles successful insertion. The needle was also felt inside the kidney after the insertion proving it to be successful.

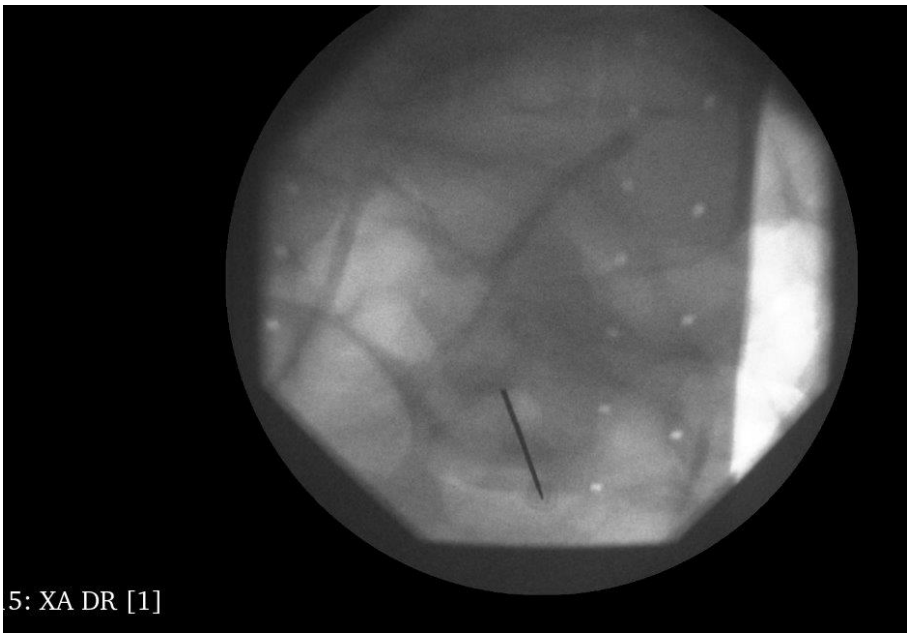


Figure 66 CT scan of needle insertion from 45

9. Final Design and Future Improvements

9.1 Final Design

Figure 68 shows our final version of the device. Version 6 was modified based on our results from the needle visualization testing and the pig cadaver test. First, since the magnets were not strong enough to hold the weight of the base with the stainless-steel plates as well as the agarose filling, supports were added to the front and rear to provide a solid connection. Next, extra supports were added to the bottom of the base and one end of the device was made as part of the device. This was done to maintain the parallel angles between the sides of the reflective surfaces as the sides would bend under the weight of the stainless-steel plate and the heat of the agarose solution when poured into the device.

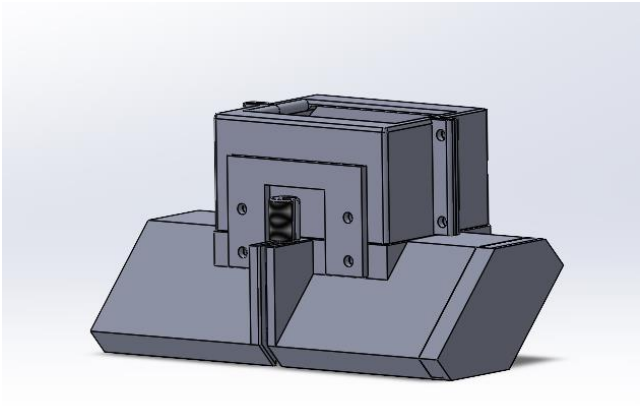
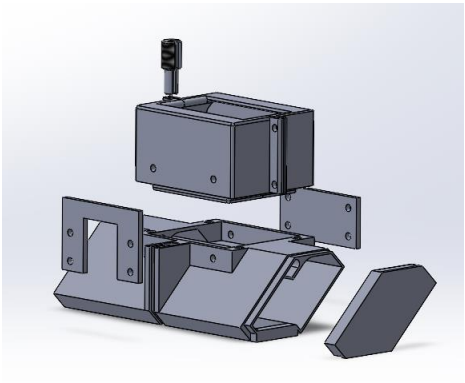
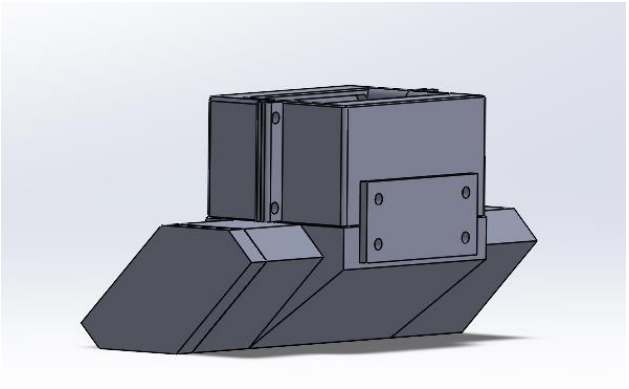


Figure 67 Final Version





9.2 Discussion

The main objectives of the MQP we're optimizing the device design and gaining more data on the device. Seen in table 5 the objectives were broken down into three sections the internal material optimization, mirror material selection and the design changes. All three sections updates seen below were concluded successful. Each was tested and the data provided in previous sections proves the devices capabilities of improved visualization and simpler design.

Although the device was successful within the regulated tests there is still more research that can be done to compare optimal materials and designs. Materials like gelatin and agarose cannot endure long time periods before drying out but there are replacements with similar acoustic properties that could be viable such as gel wax. Along with the materials changes the design was updated by minimizing the contact window and in the future could be made to fit the curvature of the patient's body. This could be done with molding technology.

Table 5 Objective discussion

Objective	Improvements	Status
Internal Material Optimization	Selecting 3% Agarose	**Successful**, Allows for the best visualization, of all tested materials
Mirror Material Selection	Selected Stainless Steel, Mirror-like Finish	**Successful**, Material selected based on its reflective properties and ease of manufacturing
Design Changes	Optimizing device design, structure, and needle visualization	**Successful**, Compacted device that holds form when molding and during use

9.3 Future Improvements

With the completion of the ultrasound-guided needle insertion device for PCNL procedures the team leaves behind recommendations for future device improvements seen in table 6. The device is currently at a stage where it is a disposable single used device and needs further needle visualization testing before it can be pushed to the market. It is also recommended to create a plan and analysis for the manufacturing possibilities of the device. These improvements will help verify the devices capabilities and it's potential to be a competitive device on the market for PCNL procedure.

Our team's recommended marketing analysis plan begins with creating an interview question guide. Using this guide, plan on reaching out to currently practicing PCNL surgeons and determining how well our ultrasound attachment can fit the needs listed in the background. Assuming the needs are determined to be successfully met by the surgeons, research should begin on manufacturers who can mass produce the device and the best ways to bring awareness of the attachment to the relevant populations. An initial effort can be made to market it directly to the PCNL surgeon population, but other applications and thus populations can be targeted too.

Table 6 Recommendations for the future

Current Status	Improvement
Disposable device	**Improve to make multi use device**
Further needle visualization testing	**Human cadaver PCNL surgery** **In-vivo animal PCNL surgery** **In-vivo human PCNL surgery**
Manufacturability	**Create market plan and analyze mass producibility**

10. Conclusion

10.1 Economics

Through the material testing, the team kept in mind the cost of creation of the device and took steps to ensure that the device was as cost effective as possible without compromising the quality of the device. This was done through the remodeling of the device which cut down useless space, saving material cost, as well as in the selection of agarose. Which is a cost-effective hydrogel with the necessary properties for the device. In the selection of stainless steel for the mirror to allow for cheaper manufacturing and acquisition. In addition to the cheaper device costs, the application of this technology in hospitals aims to decrease the time of operation and the risk of mistakes while operating, both of which to save money for the vast amount of people who need PCNL surgery.

10.2 Environmental Impact

Our system is composed of a plastic shell, with an agarose filling and a stainless-steel mirror. When looking at the manufacturing and disposal of the device we can begin by looking at the plastic component. Since the device is 3d printed we can have more leniency with how we source our materials and so can choose to use recycled plastic to make an environmentally sustainable device. When the device is finished being used it can be cleaned off to remove the agarose and any biohazards, then the plastic can be melted. The melted plastic can be made back into 3d printing filament for a cycle of reuse. The second component of the device, agarose, is a sugar made from marine algae, allowing us to have minimal environmental worries as algae is a naturally sustainable material and the disposal of agarose is not harmful for the environment. Finally, the last component of the device, stainless steel, would be entirely capable of being reused at the end of the products' life cycle with some polishing to ensure its reflective properties.

10.3 Societal Influence

To begin, in the production of our device, jobs will be made as we mass produce agarose, mirror like stainless steel, and source our plastic. Following that as a company is formed around this device, we will need a marketing team, business development team, and research and development team. To make sure that as a company we are staying competitive and creating a device that leads the market.

10.4 Political Ramifications

Currently, as discussed in the background, there are many similar devices that offer inferior services within the same price range. In the medical device stage if companies are not able to adapt their technology to keep up with innovation, they will lose relevance, a potential effect of our device.

10.5 Ethical Concerns

Having the capability to be sourced from reusable and sustainable materials, shortening the time of operations, and reducing the chance of complications from operations. Our device will allow for our patients to lead healthier lives in a healthier environment.

10.6 Health and Safety Issues

Our device aims to achieve two main goals: decrease the time of operation and decrease the risk of surgical complications. Operation time will be decreased as the surgeon will no longer need to calculate the angle of insertion of their needle and needle depth relative to the ultrasound on varying patient anatomies. With decreased surgery time that means less time under anesthesia and less variables for the operating team to consider. By removing the calculations mentioned earlier that also means less potential for mistakes, decreasing risk. With our device we are also able to allow the surgeon to focus on one task of guiding the needle to the target in one hand instead of having the needle in one hand and the ultrasound in the other. Attempting to balance guiding both at the same time is risky so our device will decrease risk of complications.

10.7 Manufacturability

The manufacturability of our device was a design criterion we kept in mind throughout the development of our device. The entirety of the production process would take one day with almost all the time spent waiting for the device to be 3d printed and waiting for the agarose to solidify. A working flow of operations would begin with a continuous loop of printing out new devices as that would be the main bottle neck. Following that stainless steel rectangles would be cut and polished to a mirror like finish. Agarose would be boiled in water, and finally you would attach the stainless-steel pieces to the plastic shell and pour in the agarose for a complete product. Overall, the reproduction of the device would be a very simple process.

10.8 Sustainability

Demand for energy needed for the creation of this device would come from the 3dprinter, a heat source to boil the agarose, and the metal cutter for the stainless steel. Each of these devices would be connected to a source of electricity which would be an environmentally renewable energy source depending on how the electricity is sourced. This section of our device would rely entirely on the electrical grid of the area where the device is being developed and so a consideration of the local energy sources when finding a manufacturer can be made.

10.9 Engineering Standards

Engineering standards are essential in ensuring the quality, safety, and efficacy of medical devices. Our device, designed for location and treatment of kidney stones, falls within the scope of medical devices and thus must adhere to higher standards. The project team has chosen to align with the International Organization for Standardization (ISO) standards, recognizing their global acceptance and regulatory significance. The key ISO standards for medical devices, ISO 13485:2016 and ISO 9001:2015, emphasize quality management systems, encompassing design, development, production, and servicing processes.

Our team placed particular emphasis on several core principles embedded within ISO standards, starting with the implementation of a systematic approach for identifying, controlling, and preventing issues throughout the product lifecycle. Following that through our design process we committed to ongoing enhancement of our product and processes to optimize performance and quality. Finally, we dedicated our work to making informed decisions grounded in data and empirical evidence.

The team's adherence to ISO standards led to the following advantages:

- ISO standards provide a framework for implementing quality management systems. By adhering to these standards, our team was able to streamline our processes, reduce errors, and create a device that meets the market's requirements. Further, potential issues were identified and mitigated proactively, ensure good experimental outcomes.
- Certification to ISO standards demonstrates a commitment to quality, safety, and environmental responsibility. This enhances our projects credibility and reputation, both among customers and stakeholders. ISO certification serves as a mark of trustworthiness and competence, potentially opening new business opportunities and markets for the device not just locally but globally as well as ISO standards are recognized worldwide.
- ISO standards often emphasize efficiency and optimization of processes. By adopting these standards, our team was able to identify inefficiencies, minimize waste, and improve resource utilization. This emphasis in efficiency and optimization lead to greater thought in cost savings through reduced operational expenses, improved productivity, and better utilization of resources, with the expectation of ultimately leading to improved profitability.

Despite the benefits, the team also encountered challenges with maintaining ISO compliance:

- Navigating through the complex and ever-changing landscape of ISO standards was a difficult task as not all standards are applicable, but all applicable standards had to be located to the best of our ability.
- Maintaining our design process to match ISO standards required the team to consistently check our work as any deviation could lead to compliance issues.

Through our discoveries, the main ISO standards that applied to our device included:

- Device compatibility on body surface level: ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021,ISO 10993-23:2021
- Safety specifications for durability of the device: ASTM F963-17
- The device is made to endure and can be used multiple times without failure: ASTM E1837-96(2007)
- The device is designed for its intended purpose and not for any other use to limit the potential of misuse: ISO 14971:2019

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Appendix

Appendix A

MQP Gnatt Chart

	A-Term	B-Term	C-Term	D-Term
Material Selection				
Material Testing				
Design Prototype				
Prototype Testing				
Market Analysis				

Appendix B

B-term timeline.xlsx

Week	Objective	Action items	Completion/Notes
23-Oct	Material selection/testing	Print multiple of the same prototype ? Get mirrors to fit the device Obtain all materials that will be tested Start material quality testing with baseline mixture	
	Attatchment design	Print first prototype	
	Market analysis		
30-Oct	Material selection/testing	Start material quality testing with selected materials Process data from tests	
	Attatchment design	Analyze/test first prototype	
	Market analysis		
6-Nov	Material selection/testing	Continue material quality testing Process data from tests	
	Attatchment design	Update/improve design	
	Market analysis		
13-Nov	Material selection/testing	Continue material quality testing Process data from tests and document	
	Attatchment design	Update/improve	
	Market analysis		

20-Nov	Material selection/testing	Continue material quality testing Process data from tests and document	
	Attatchment design	Update/improve design	
	Market analysis		
27-Nov	Material selection/testing	Finish material quality testing Process data from tests and select best material	
	Attatchment design	Finalize prototype	
	Market analysis	Start research	
4-Dec	Material selection/testing	Create homemade phantom Start image quality testing	
	Attatchment design	Begin combined testing	
	Market analysis	Determine candidate procedures	
11-Dec	Material selection/testing	Continue image quality testing Process data from test	
	Attatchment design	Begin combined testing	
	Market analysis	Determine departments to identify contacts	

Appendix C

List of Dependencies

Dependencies owned	Dependencies needed
● ATL P4-1 Ultrasound probe ● Onedrive/Google drive ● Solidworks ● Previous work ● Access to 3D printer and machine shop ● Gelatin/Agar ● Ultrasound gel	● Work and storage space ● Access to the lab ● Polyacrylamide ● Agarose ● Prototype ● Any new materials to fill cavity (biopolymers) ● New needles (18 gauge, 20cm) ● Setting clinical trials

Appendix D

Key Dates

Table for A-term.

Task	Sub-Task	Date	Progress
Proposal	Background	09/21/2023	75%
	Client statement	09/21/2023	75%
	Relevance and importance	09/21/2023	75%
	Past work	09/21/2023	75%
	Technical approaches	09/21/2023	75%
	Methodology	09/21/2023	75%
	Deliverables	09/21/2023	75%
	Dependencies	09/21/2023	75%
	Key dates	09/21/2023	75%
	Risk management plan	09/21/2023	75%
Introduction	Literature review	9/28/2023	
	Revised past work	9/28/2023	
	Revised client statement	9/28/2023	
Design Section	Design objectives	10/05/2023	
	Pairwise comparison chart	10/05/2023	
	Technical approaches	10/05/2023	

	Initial Testing and Analysis	10/05/2023	
Methods	Design selection	10/13/2023	
	Initial design plan	10/13/2023	
	Material selection	10/13/2023	
	Order materials	10/13/2023	
	CAD model	TBD	
Planned Experiments for B-term	Material testing	TBD	
	First prototype	TBD	
	Gnatt chart	TBD	
Prepare for B-term	Work breakdown	10/13/2023	

Appendix E

C-term timeline.xlsx

Target Deliverables	1. Have finalized prototype 2. Complete needle visualization testing 3. Experimental testing on metals vs mirrors 4. Begin and complete Market analysis

Week	Deliverable	Action items	Completion/Notes
10-Jan	Material selection/testing	1. Research needle visualization test protocols. 2. Prep metals to fit device 3. Finalize mock phantom protocol	
	Attachment design	1. Test needle design. 2. Continue to test metal to fit device.	
	Market analysis	1.Continue to determine candidate procedures/contacts	
16-Jan	Material selection/testing	1. Write needle visualization test protocols 2. Make mock phantom 3. Continue to prep metals 4. Finalize needle design.	
	Attachment design	1.Make edits if necessary	
	Market analysis	1.Continue to determine candidate procedures/contacts	

22-Jan	Material selection/testing	1. Start needle visualization testing with final prototype. 2. Continue to prep metals 3. Reach out about animal testing?	
	Attachment design	1.Continue to make small improvements to the design.	
	Market analysis	1.Start market analysis	
29-Jan	Material selection/testing	1. Continue needle visualization testing with final prototype. 2. Metal vs. mirror testing on summer prototype	
	Attachment design		
	Market analysis	1. Continue market analysis	
5-Feb	Material selection/testing	1. Continue needle visualization testing with final prototype. 2. Metal vs. mirror testing on summer prototype 3. Other testing	
	Attatchment design		
	Market analysis	1. Continue market analysis	

12-Feb	Material selection/testing	1. Continue needle visualization testing with final prototype. 2. Metal vs. mirror testing on summer prototype 3. Other testing	
	Attachment design		
	Market analysis	1. Continue market analysis	
19-Feb	Material selection/testing	2.Conclude and analyze testing results	
	Attachment design		
	Market analysis	1. Conclude market analysis	
26-Feb	Material selection/testing	1.Finalize MQP report 2. Powerpoint?	
	Attachment design		

Appendix F

Gelatin Protocol

Materials:

- Verasonix machine and probe
- CIRS phantom
- Prototype
- Gelatin
- Water
- Duct tape
- Hot plate
- Metal stirrer
- Scale

Creating and Testing the Gelatin Filling Procedure

1. Gelatin will be tested at 8%, 12%, and 15% weight by water.
2. To prevent gelatin from filling the handle where the probe goes, place duct tape on the opening between the attachment area and the probe.
3. Place 3D printed cover over bottom of the device and attach with duct tape.
4. To create the solution measure gelatin to 8% by weight gelatin and 92% water.
5. To obtain 8% gelatin by weight to water measure out 40 grams of gelatin into a beaker and fill the rest with water up to 500 mml.
6. Combine and add an extra 300 mml of water as a precaution to water evaporating while the mixture is being heated.
7. Heat the solution to around 121 degrees Celsius for 30 minutes and boil down to 500 mml of solution.
8. Once the gelatin is dissolved into the solution let cool down to about 60 degrees Celsius and remove any bubbles that formed in the solution.
9. Pour the solution into the prototype and allow it to cool for two hours[17].
10. When the solution is set in the prototype remove the duct tape and cover and insert the probe into the device.
11. Place the probe/device on top of the system with water in between the phantom and the probe/device.
12. Start the system and begin ultrasound imaging.
13. Freeze the image and save the data.
14. Repeat step 13 twenty times lifting the device off of the phantom and replacing it each time. It is recommended to keep the device in the same position as the phantom for each image for better analysis.

An image will be taken and frozen and then the image quality criteria will be analyzed, including FWHM, SNR, CNR. CNR code will be used to compute the values. The code generates a background region and puts coordinates within the circle to give the value. The range should be between 1.2 to 1.8.

[17] Gelatin protocol was adapted from SigmaAldrich

Agarose Protocol

Materials:

- Verasonix machine and probe
- CIRS phantom
- Prototype
- Agarose
- Water
- Duct tape
- Microwave
- Scale

Creating and Testing the Agarose Filling Procedure

1. Agarose will be tested at 2%, 3% and 5% weight by water.
2. To prevent agarose from filling the handle where the probe goes, place duct tape on the opening between the attachment area and the probe.
3. Place 3D printed cover over bottom of the device and attach with duct tape.
4. To create the solution measure gelatin to 5% by weight agarose and 95% water.
5. To obtain 5% gelatin by weight to water measure out 14g of gelatin into a beaker and fill the rest with water up to 300 mml.
6. Place plastic wrap over the top of the beaker and poke a small hole in the top to prevent the solution from boiling over.
7. Microwave for 1-3 minutes in 30-45 second intervals stirring in-between until agarose is completely dissolved.
8. Pay close attention to the solution to avoid overboiling it.
9. Once the agarose is dissolved into the solution let cool down to about 60 degrees Celsius and remove any bubbles that formed in the solution.
10. Pour the solution into the prototype and allow it to cool for two hours[18].
11. When the solution is set in the prototype remove the duct tape and cover and insert the probe into the device.
12. Place the probe/device on top of the system with water in between the phantom and the probe/device.
13. Start the system and begin ultrasound imaging.
14. Freeze the image and save the data.
15. Repeat step 13 twenty times lifting the device off of the phantom and replacing it each time. It is recommended to keep the device in the same position as the phantom for each image for better analysis.

An image will be taken and frozen and then the image quality criteria will be analyzed, including FWHM, SNR, CNR. CNR code will be used to compute the values. The code generates a background region and puts coordinates within the circle to give the value. The range should be between 1.2 to 1.8.

[18] Agarose protocol was adapted from Goldbio

Polyacrylamide Protocol

Materials:

- Verasonix machine and probe
- CIRS phantom
- Prototype
- Acrylamide
- N,N 0-Methylenebisacrylamide
- Ammonium Persulfate
- N,N,N 0,N 0-Tetramethylethylenediamine
- Duct tape
- Scale
- Glass cover
- Vacuum chamber

Example of casting protocol from Andreas Pollet[12:]
Chambers with 15mm radius 6mm high PMM ~4,2ml volume so 5ml made.
PAA recipes 5ml total volume
Prepare 10% AP solution: 0,1g AP in 1 ml stock.
All samples with 25µl AP (10%) and 7,5µl TEMED

Table 7 Example solution measurements

	5%	11%	15%	20%
A (40% sol)	625µl	1375µl	1875µl	2,5ml
BA (2% sol)	250µl	1000µl	1,5ml	2ml
H2O (MQ)	4,1ml	2,6ml	1,6ml	0,5ml

Creating and Testing the Polyacrylamide Filling Procedure

1. PAA is made by combining Acrylamide, N,N 0-Methylenebisacrylamide solution, Ammonium persulfate, and N,N,N 0,N 0-Tetramethylethylenediamine.
2. It is important to make the ammonium persulfate fresh, since the activity will drop over time.
3. To avoid difficulties with crosslinking it is recommended to degas the solutions of acrylamide and bis acrylamide and mix the solutions without introducing air. Oxygen can inhibit the reaction.
4. Measure out acrylamide (A, Sigma-Aldrich, A8887) (5%, 7.5%, 10%,15% and 20% wt)
5. Measure out N,N 0-Methylenebisacrylamide solution (2%) (B-A, Sigma-Aldrich, M1533) (10%, 15%, 20%, 30% and 40% volume)
6. Measure out Ammonium persulfate (AP, Sigma-Aldrich, A3678) (0.05% wt for all samples)
7. Measure out N,N,N 0,N 0-Tetramethylethylenediamine (TEMED, Sigma-Aldrich, T9281) (0.15% volume)
8. Combine A and BA in MilliQ water.
9. Add AP and TEMED.

10. Directly after adding AP and TEMED Pour the solution into the prototype and cover it with a glass plate to prevent air inhibiting the crosslinking reaction and ensuring a flat surface.
11. Depending on the concentration the reaction will either happen within a minute or take up to 10 minutes to fully crosslink[12].
12. When the solution is set in the prototype remove the duct tape and cover and insert the probe into the device.
13. Place the probe/device on top of the system with water in between the phantom and the probe/device.
14. Start the system and begin ultrasound imaging.
15. Freeze the image and save the data.
16. Repeat step 13 twenty times lifting the device off of the phantom and replacing it each time. It is recommended to keep the device in the same position as the phantom for each image for better analysis.

An image will be taken and frozen, the img data will be saved and then the image quality criteria will be analyzed, including FWHM, SNR, CNR. CNR code will be used to compute the values. The code generates a background region and puts coordinates within the circle to give the value. The range should be between 1.2 to 1.8.

Appendix G

```
clear all; clc;
```

```
%% load important image parameters
% with CNR target bkg regions and beam profile overlaid
% probe info from "Trans" struct
load('P4-1_Trans.mat');
p.c = 1540e3;   % sound speed [mm/s]
p.f0 = 2.5e6; % [Hz]
p.wl = 1/p.f0*p.c; % [mm]
% pixel increment info from "PData.PDelta" matrix
load('P4-1_PData.mat');
p.ss_y = p.wl * 0.5;  % [mm]
p.ss_x = p.wl * 0.875;  % [mm]
```

```
%% image data processing
% load data
load('V7withmetal-agarosefilling-gelatinphantom1.mat');

% convert to matrix
data_mtx = cell2mat(ImgData);

% 4D to 3D matrix
data_mtx_size = size(data_mtx);
data_mtx_3d = reshape(data_mtx,[data_mtx_size(1),data_mtx_size(2),data_mtx_size(4)]);

% average to 2D
data_mtx_2d = mean(data_mtx_3d,3);

% log compression
data_mtx_2d_norm = data_mtx_2d ./ max(data_mtx_2d(:));
data_mtx_2d_log = db(data_mtx_2d_norm);

% visualize ultrasound image [quick version]
imagesc(data_mtx_2d_log, [-70, 0]);

% image axes
x_axis = [1:size(data_mtx_2d,2)].*p.ss_x;
y_axis = [1:size(data_mtx_2d,1)].*p.ss_y;
```

```
%% quantification, use data before log compression
% take target region
target_region_x_start = 230;
target_region_x_end = 240;
```

```
target_region_y_start = 255;
target_region_y_end = 270;
target_region = data_mtx_2d(target_region_y_start:target_region_y_end, ...
    target_region_x_start:target_region_x_end);

% take background region
bkg_region_x_start = 230;
bkg_region_x_end = 240;
bkg_region_y_start = 230;
bkg_region_y_end = 245;
bkg_region = data_mtx_2d(bkg_region_y_start:bkg_region_y_end, ...
    bkg_region_x_start:bkg_region_x_end);

% compute CNR
cnr_value = CNR(target_region,bkg_region);

% select beam profile
beam_profile_y = 326;
beam_profile_x_start = 190;
beam_profile_x_end = 240;
beam_profile = data_mtx_2d(beam_profile_y, ...
    beam_profile_x_start:beam_profile_x_end);

figure;
plot(beam_profile);

% compute FWHM
FWHM_value = FWHM(beam_profile);
FWHM_value_mm = FWHM_value * p.ss_x;

% compute SNR
SNR_value = SNR(beam_profile);
```

```
%% visualize ultrasound image [formal version]

% show image
figure;
imagesc(x_axis, y_axis, data_mtx_2d_log, [-70, 0]);
colormap gray;
xlabel('Lateral direction [mm]');
ylabel('Axial direction [mm]');
title('gelatin, 8%');

% highlight CNR target/bkg region
hold on;
```

```
% highlight CNR target/bkg region
hold on;
target_rect_x = target_region_x_start * p.ss_x;
target_rect_y = target_region_y_start * p.ss_y;
target_rect_w = (target_region_x_end - target_region_x_start) * p.ss_x;
target_rect_h = (target_region_y_end - target_region_y_start) * p.ss_y;
rectangle('Position', [target_rect_x ...
                       target_rect_y ...
                       target_rect_w ...
                       target_rect_h],'EdgeColor','r','LineWidth',1);
hold on;
bkg_rect_x = bkg_region_x_start * p.ss_x;
bkg_rect_y = bkg_region_y_start * p.ss_y;
bkg_rect_w = (bkg_region_x_end - bkg_region_x_start) * p.ss_x;
bkg_rect_h = (bkg_region_y_end - bkg_region_y_start) * p.ss_y;
rectangle('Position', [bkg_rect_x ...
                       bkg_rect_y ...
                       bkg_rect_w ...
                       bkg_rect_h],'EdgeColor','w','LineWidth',1);

% highlight beam profile location
yline(beam_profile_y*p.ss_y,'-r','Beam profile');
```