Needle Insertion Mechanism for Ultrasound-guided Percutaneous Nephrolithotomy Access

MQP Report

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April 28th, 2022

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ABSTRACT

Percutaneous Nephrolithotomy (PCNL) is often considered the standard treatment for large renal calculi (kidney stones). While the surgical procedure is incredibly safe and well-tolerated, it presents risks like any other invasive operation. Ineffective needle insertion for percutaneous access can not only cause injury to nearby organs but also cause internal bleeding, infection, and urine leakage [1]. These challenges are primarily presented due to the lack of alignment between the ultrasound probe, needle, and the patient's tissue or targeted renal regions. While previous work achieved a moderately accurate alignment, they failed to produce clear images of the target which resulted in inconsistent data. Our goal with this project is to find the most stable and consistent method by which a needle can be inserted accurately and be released smoothly with a quick-release mechanism. We researched existing needle quick-release mechanisms and put together some designs that fit the scope of this project and printed the models for testing. We conducted an angle analysis of the needle at a resting position and at the extremes at which it can move along that axis. Through continuous redesigning, printing, and testing many iterations, we came to a design that is simple yet effective in performing stable needle insertion and easy release. Although our design is not perfect, it addressed the strong need for needle accuracy during an invasive procedure. With continued work, this device will make PCNL procedures quick and easy for the surgeon.

BACKGROUND

Client Statement

The goal of this project was to develop a needle insertion guidance tool that incorporated the ultrasound probe and the needle to allow for accurate and easy percutaneous access during PCNL. PCNL procedures present a relatively moderate compilation rate and are minor in nature when they do occur. In the current state, it is difficult to rely on the probe signal, the alignment of the needle, and accurate insertion concurrently. The previous MQP team created a design that focused on aligning the ultrasound signal and needle through the use of mirrors. Through improvements to that design, a more simplified version of this alignment can allow for accurate and reliable insertion.

Anatomy

The kidneys are two organs, approximately the size of a fist, and are located below the rib cage on either side of the spine. Each kidney is made up of two main parts: the outer layer, known as the renal cortex, and the renal medulla. The organs are also covered in protective fatty and connective tissues, to protect the organs by effectively shielding them [2], [3].

The kidneys are extremely important and are responsible for the filtration of nearly 200 liters of fluid a day from renal blood flow. In doing so, the kidneys remove excess salts, ions, metabolic waste, and toxins and pass them on towards excretion to the ureters and the urethra. They also maintain a healthy plasma osmolarity by retaining or removing the amount of water and dissolved solutes in the blood. In addition to this, they also produce ‘renin’, an enzyme that is released when decreased salt levels or low blood volume levels are detected, encouraging the production of erythropoietin, thus ultimately contributing to the production of red blood cells themselves. Unhealthy kidneys are extremely concerning as they can lead to the loss of normal function in the nervous, muscular, circular, and lymphatic systems [3]. To maintain the balance, kidneys make use of multiple mechanisms that include glomerular filtration, tubular reabsorption and secretion, and the storage of urine [2], [5], [6].

Ultrasound Imaging Technology

Ultrasound imaging is a mature technology and a common modality used in medical diagnosis for several purposes. It is used in abdominal, cardiac, neural, gynecological, urological and several other applications to visualize body structures that can range from muscles, joints, vessels, and organs [7]. It is also used to capture the movement of the body’s internal organs. It is preferred over other imaging techniques for its ease of use, non-invasive operation, and its lack of radiation. A handheld probe, also known as a transducer, is placed over the desired area and moved over the patient [8]. Ultrasound transducers generate and transmit ultrasonic waves from electrical pulses. The waves pass through tissue and are simply reflected to the transducer. Upon receiving the returning waves, the transducer converts them back into electrical voltages and signals using the principle of ‘delay and sum.' The principle relies on the knowledge that sound travels at a constant, known speed. Through this, the delay can be used to calculate the approximate position of the structures being imaged. Structures closer to the transducer will

reflect waves much earlier than structures farther from the transducer, thus allowing for the system to identify the location of anatomical structures and organs [7], [8].

During PCNL procedures, an ultrasound transducer is used to visualize the renal parenchyma, collecting system, surrounding organs, major vessels, and identify renal calculi. Once the relevant structures and sites of blockage due to calculi are identified via imaging, needle insertion can then be used to gain percutaneous access [5], [7], [9]. The utilization of ultrasound for PCNL is safe and effective, with high procedural success. This is due to the fact that no radiation is emitted, low-cost operation, and easy handheld use. The absence of radiation presence also makes it preferable for patients who have recurrent problems, are pregnant, or pediatric [9].

The Current State of PCNL Procedures and Technology

To design a project that meets high standards and achieves our goals, it is important to consider the current technologies and procedures used for PCNL. Through this process, study could find a proposed solution that competed with current standards and solutions on the market. Table 1 discusses the various specifications, advantages, and disadvantages of the several solutions and the proposed product.

Table 1. A table discussing the specifications, advantages, and disadvantages of available technologies and techniques [1], [5], [9], [10]–[12].

Product/Procedure	Specifications	Advantages	Disadvantages
Conventional PCNL Needle Intervention	- Blind access, no imaging technique used - Can also use fluoroscopy	- Fluoroscopy is highly accurate as a guide	- Radiation Exposure - Blind access can lead to serious complications - Not precise/accurate enough - Blind access is now mostly considered unethical
Ultrasound-guided Needle Intervention (without tracking device)	- Uses an ultrasound probe, can even be 3D - A needle is introduced after visualization of major anatomical structures, constant monitoring takes place	- More accurate and ethical than blind access - No radiation - Cost-effective as opposed to fluoroscopy and MRI modalities.	- Needle and probe not aligned. - Surgeons and technicians must use the dominant hand for needle access, probe hand not steady (multiple people required) - Experience and training required

Sonix GPS	- Live feedback on a larger, interactive screen. - Needles can be inserted from any direction. - Still requires the use of probe and needle separately	- More interactive and live feedback is available to operating theater surgeons, physicians, or technicians. - Needle does not have a specific plane - High visibility	- Needle and probe still have to be used separately on different hands. - Studies have found no visible improvement in time compared to legacy U.S guidance nephrolithotomy.
Harvard Biodesign Lab	- No specific needle tracking - Transducer movement, angle, and positions are very customizable. Angles and positions are very customizable.	- Fine movements and greater adjustability	

After the team used the comparison and product approaches discussed in Table 1, it was possible to identify important technical criteria in order of importance. Table 2 shows the pairwise comparison objectives.

Table 2. Pairwise comparison of objectives for this project.

	Ease of Use	Cost	Ability to maintain a sterile environment	Flexible and adaptable with PCNL tools and attachments	Portable	Imaging Accuracy and guidance	TOTAL
Ease of Use		1	0.5	0.5	1	0	3
Cost	0.5		0	0	0	0	0.5

Ability to maintain a sterile environment	1	1		1	1	0.5	4.5
Flexible and adaptable with PCNL tools and attachments	0	0	0		1	0	1
Portable	0.5	1	1	0.5		0	2
Imaging Accuracy and guidance	1	1	1	1	1		5

With the pairwise comparison chart, it was possible to identify the objectives necessary for the team. They include but are not limited to ease of use, cost, ability, and flexibility to maintain a sterile environment, portability and image accuracy, interaction, and guidance. Using the table, the most prioritized demands were observed to be imaging accuracy and guidance, closely followed by the ability to maintain a sterile environment to ensure procedure safety and accuracy. Adaptability with a variety of PCNL tools, probes, and attachments and cost remain as important goals but do not take precedence over other categories as it was vital to improve early prototypes and prove that the novel needle insertion process was viable and safe.

Previous MQP Project

In 2020, an MQP team attempted to solve the aforementioned issues with their own needle guide device. This system's core principle was to use a mirror attachment with a needle sheath to reflect an image aligned with the needle. This solution helped to alleviate needle tip visual issues while also eliminating the need to use two separate hands during the procedure. The needle-mirror system is rotated by a 2:1 gear ratio so that reflected ultrasound waves stay in line with the needle's position during movement. The device can be seen in Figure 1 below.

Figure 1. Previous MQP device prototype for PCNL US-guided needle insertion tool [13].

During testing, it was necessary for the device to be partially submerged in water for the ultrasound probe to read the images; however, testing proved successful despite this constraint. Despite the success in testing, in its current state, the device is not applicable for medical use as it must be partially submerged in a water bath. An example of said submersion can be seen in Figure 2.

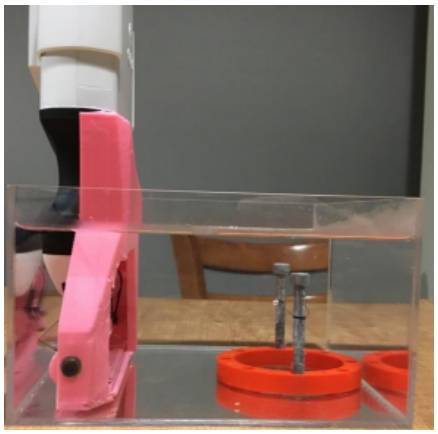


Figure 2. Previous MQP device prototype testing rig where the metal object was used to test accuracy [13].

The device was designed with a wireless ultrasound probe in mind for the ease of portability. However, during testing, the previous team noticed issues transmitting between the probe and the imaging. Poor network performance caused the connected phone app to continuously freeze. In order to connect to the probe, both the computer and mobile device had to be on the same wireless network, which contributed to the connection issues. In a medical setting however such reliance on a network would be unfavorable, as a result, the team planned to switch to a wired ultrasound probe. The previous team also experienced issues with ensuring and testing angle accuracy, since they were unable to find a viable solution towards verifying that the probe and needle insertion tool were aligned appropriately.

PROPOSED DESIGN

First Phase Brainstorming

Looking upon the improvements that could be made with the prior MQP group's design, the team collectively brainstormed solutions. A comprehensive list of design flaws to improve upon and a list of design requirements were created to aid in the brainstorming process. The list of design flaws to improve upon are listed below:

- Device needs to be submerged in water
- Device relied on aligning the needle to the target

As well, the list of design requirements are listed below:

- Be able to transport ultrasound waves without leakage
- Transmit ultrasound waves through box
- Align needle with ultrasound image in real-time
- Be safe and simple to use
- Improve convenience of PCNL procedure

The team's main focus was around the encapsulation portion of the design. If the device is able to hold and transport its own acoustic wave medium without any leakage it would greatly improve on the device's practicality. Initial research was done on self-healing polymers that could transport ultrasound waves to be used as the bottom of the encapsulation; however, these specific material property requirements made the material choice difficult. As a result, the team began to experiment with redesigning the device so that it would not need such a specific material. Initially, this idea began with removing the bottom of the box entirely, and instead creating a hollow shell that would stick to the patient through the use of suctioned air. Once stuck, water would be filled into the container with the patient's skin as the box's bottom. Then, the procedure would continue on as normal and end with the water being removed through a suction hose. This idea was scrapped due to the lack of reliability on different body types, concern for possible bruising issues, and the difficult routine.

The team continued on the track to remove the need for specific material choice. The next iteration of brainstorming came from the idea of making the needle stationary. If the needle is stationary, it removes any necessity for self-healing material. Instead, the team would be able to focus solely on the ultrasound permeability of the material. Creating a fixed position version of the device, greatly simplified the design and the learnability of its routine. With this design, the user would be able to move the entire device over the patient's body, rather than focus on adjusting the needle and mirror position. This greatly improves upon issues with needle alignment with the ultrasound. A conceptual model of the device can be seen below in Figure 3.

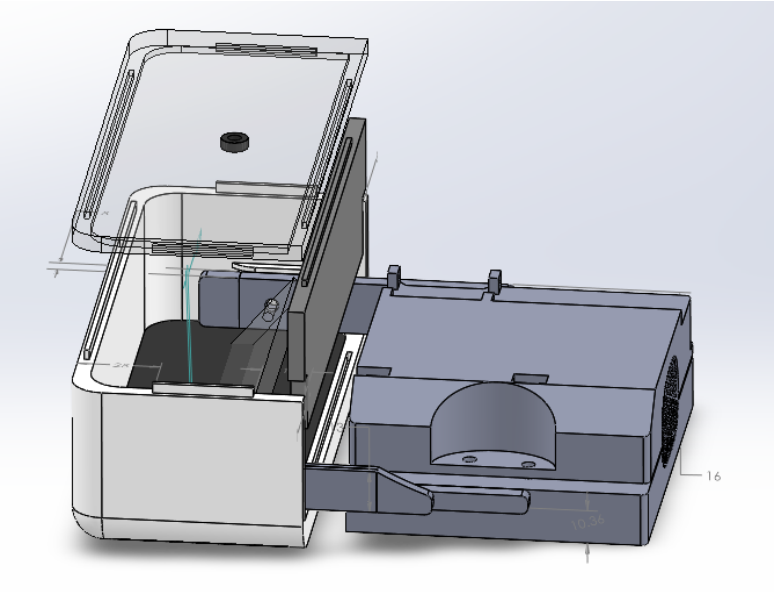


Figure 3. Conceptual model of the full proposed design.

Second Phase Brainstorming

After this idea was formulated the group split up into two groups, each focusing on a specific component of the device. One team focused on the encapsulation box of the device, while the other focused on the needle guide and removal technique. This report will from henceforth be focused on the needle guide and removal portion of the device. The main concept going into this section of the design phase was to create a needle guide device that would not be in the way of the mirrors and their reflected ultrasound waves. Referencing the conceptual photo in Figure 4, there were plans to create a relief slot for the needle that went around the encapsulated portion of the box so that the removal of the needle does not affect the media inside. Listed below are the design requirements for the needle guide specifically. The methods section details further the design process of the needle insertion mechanism.

- Hold needle during insertion
- No small removable parts
- Fit an 18G needle
- Needle sheath cannot block ultrasound image
- Minimum needle displacement

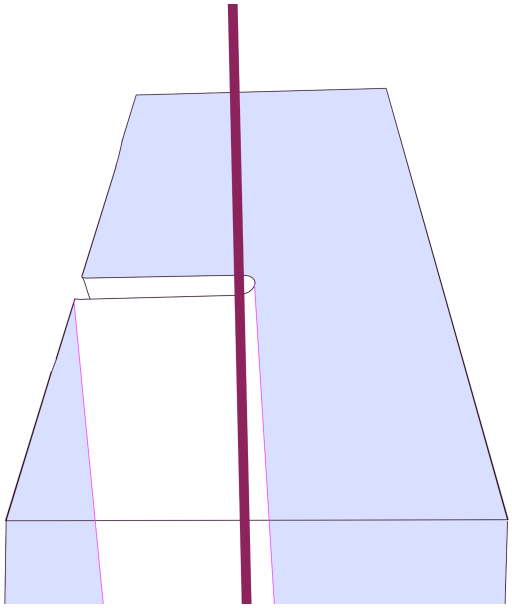


Figure 4. Conceptual model of needle mechanism design

METHODS

Design

Initial Designs

The device was split into three main variables to observe and improve upon. The first was the ability to lock the needle in and out of place, the second was the device's rotational pivot, and the third was the tolerance fits of the device. A majority of our experimental methods came from observing existing mechanisms to take inspiration from, and use to improve on the design of the device. Once a design was made, it would be modeled so that the aforementioned variables could be tested through the use of 3D printing.

The design process of brainstorming occurred through undetailed conceptual models, with several iterations of design changes each with its own set of pros and cons. The first is Design Number 1:

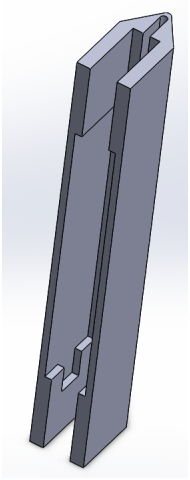


Figure 5. Design 1, a lock and key design

Design 1 is the most simplistic of the group and is the only device iteration which does not have variable two. Design 1 worked by having a separate key piece that could be placed inside the device's slot to hold the needle in place. While the device had the advantage of being simplistic, it had the major disadvantage of having a separate piece. Losing a small key in the surgery room would be unsafe and very inconvenient. As such the team strived to create a device that would function without any pieces separating. When testing, it was found that the fits were too tight.

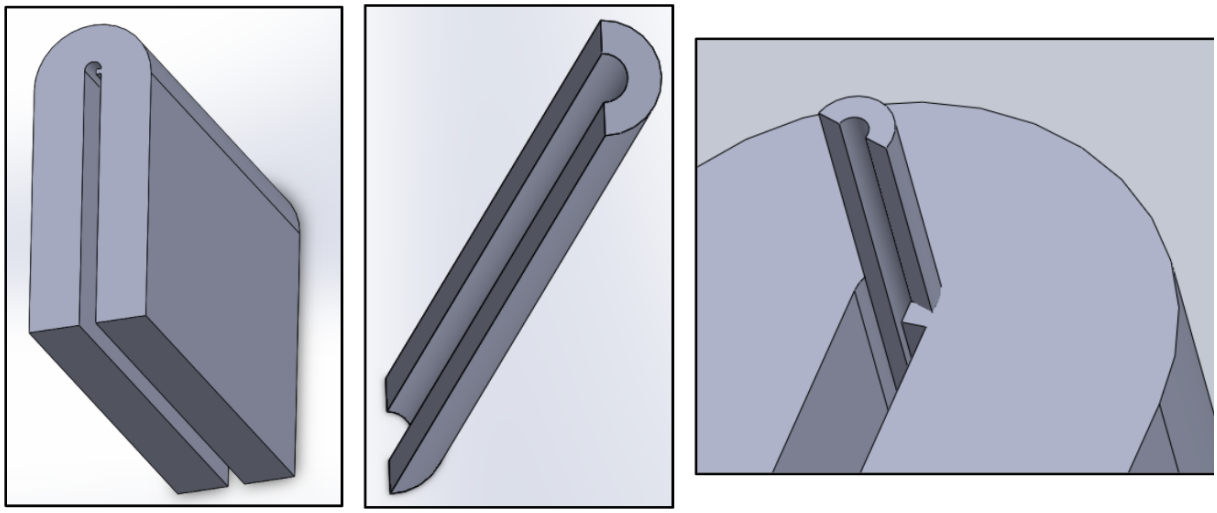


Figure 6. Design 2, rotating door inspired.

Design 2 took inspiration from a rotating door. The idea was that the door would rotate into two fixed positions: open and closed. This way the needle could leave when necessary. The base needle holder had a set extrusion that would stop the door at a fixed position. The idea was that there would be a second extrusion that would be controllable by the user. The extrusion would be on a spring and could be pulled back and then released when the door is set in place. This idea was dropped because it was later found that the small scale of the device made the idea of a spring mechanism very difficult to pull off. There was also difficulty pulling off the rotational mechanism, and the team could not design a pivot that did not impede on the device's function. As such, this design was scrapped. When testing, it was found that the fits worked, although the door piece had to be held in the device by hand. However the needle did not fit, the needle hole had to be made bigger in future designs.

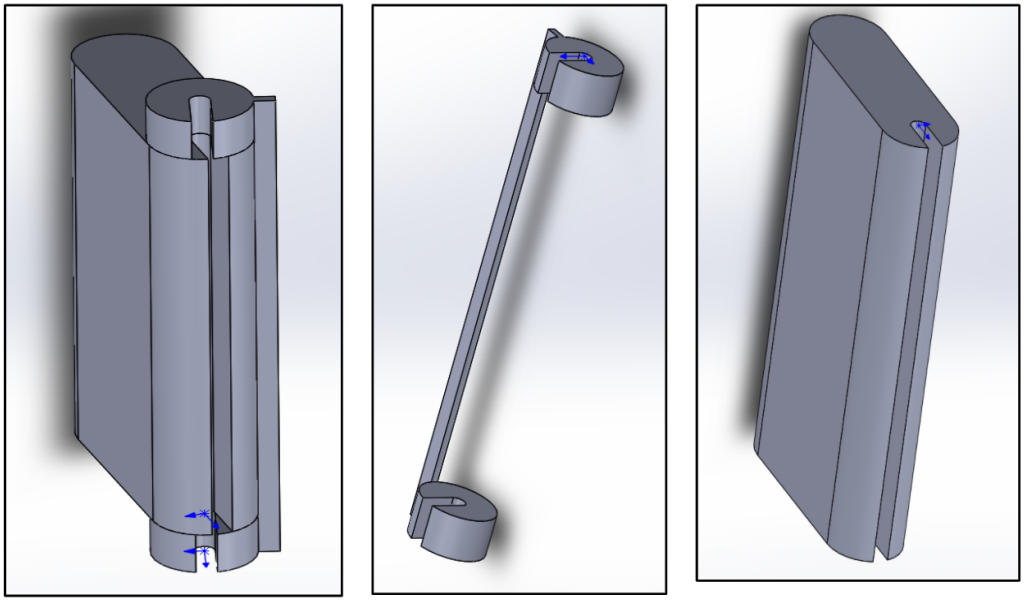


Figure 7. Design 3

Design 3 is a lot more refined. It took the fixed stop and attached it to the outside of the needle lock. It would be fitted together with a tight fit, and should not come apart. The fit of the two parts together would be the biggest challenge of this iteration. At that point in time, an exact method for locking the rotation was necessary as well. This design was favored by the team but required refinement. Following this, the team split off and improved on Design 3 separately.

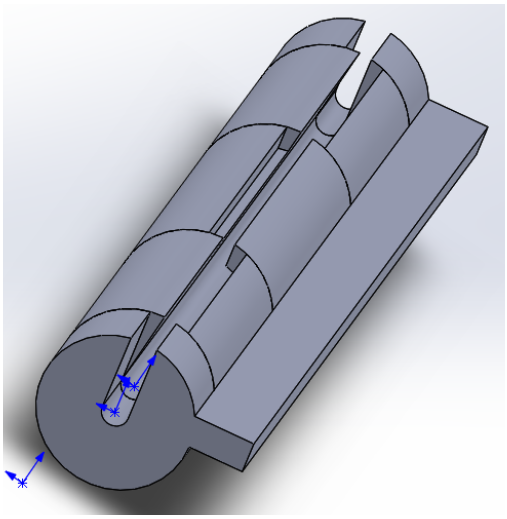


Figure 8. Design 3.2, sophistication of design 3.

Design 3.2 incorporates the intentions of design 3 and made it more realistic as a physical prototype. The inside pieces are stationary and fixed to the encasement. These pieces include the second and fourth opening with a piece inside the middle opening. The rotating piece includes the outer edges and the outer middle part. This would solve the issue involving how to secure the pieces together while allowing them to rotate together.

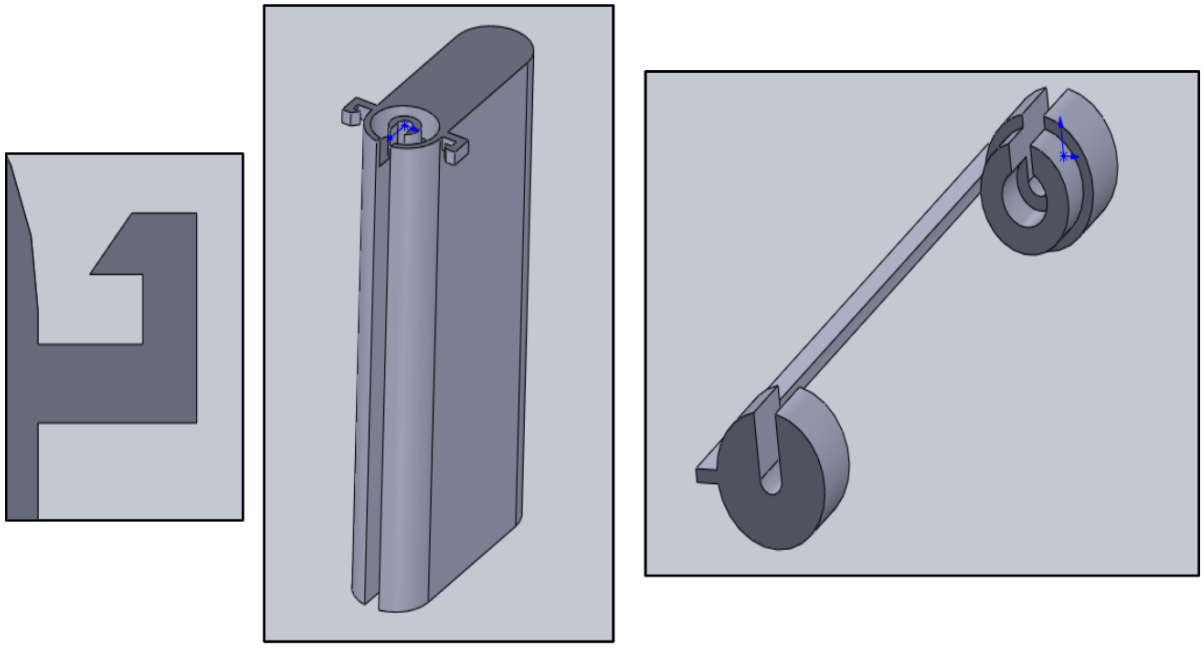


Figure 9. Design 3.3, incorporation of rotating stage and snap hooks.

Design 3.3 takes inspiration from two places. The first is a rotating stage, a known mechanism in which a fixed track is used to create rotation [14]. Using this as inspiration, both the needle holder and needle lock were designed to fit together. This allows for a rotational track, and for the parts to fit together in a more concise way.

The second means of inspiration came from a snap-lock mechanism, something that was observed to be on many children's toys or devices with battery holders on them [15]. A snap-lock mechanism is a simple method to lock something by bending plastic so that it can snap into and out of a lock [15]. The slope of the snap lock on the device should allow for the fixed extrusion to bend the lock and snap into place. This method of fixation was believed to be an ideal way to fix the needle lock's position on such a small scale. The most difficult part of this would be releasing the snap, which may require refinement (possibly a secondary extrusion fixed onto the snap lock to allow the user to bend).

Final Design Iterations

Following the last provided design iteration, the team focused mainly on minor edits from that point onward. In particular, edits were made with regard to part fits, which will be discussed more in the Fits section of this report. The first major design change to the device was to fit the mechanism to the box itself rather than the sectioned-off version that was being used for testing. This meant losing the bar and instead building up off of the lid. In order to optimize the ultrasound image that would return from the device, the middle of the box was left entirely alone aside from the needle relief slot. Through knowledge given by the encapsulation team, the

maximum width of the needle relief slot was known to be 3mm. Other than slight adjustments to the relief slot, the entire mechanism is laid on top of the device's lid.

Definitions regarding individual part names used throughout this report are described below.

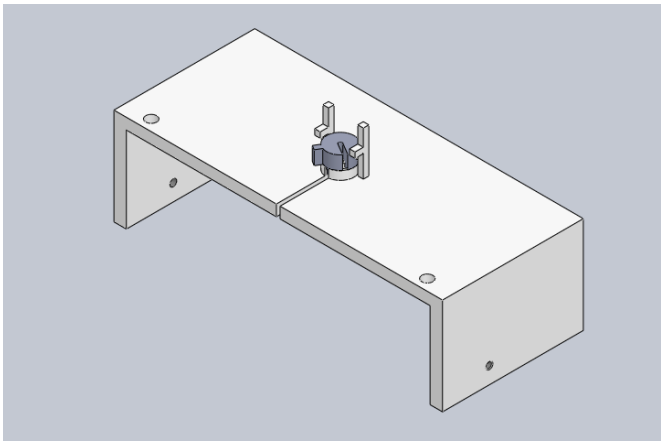
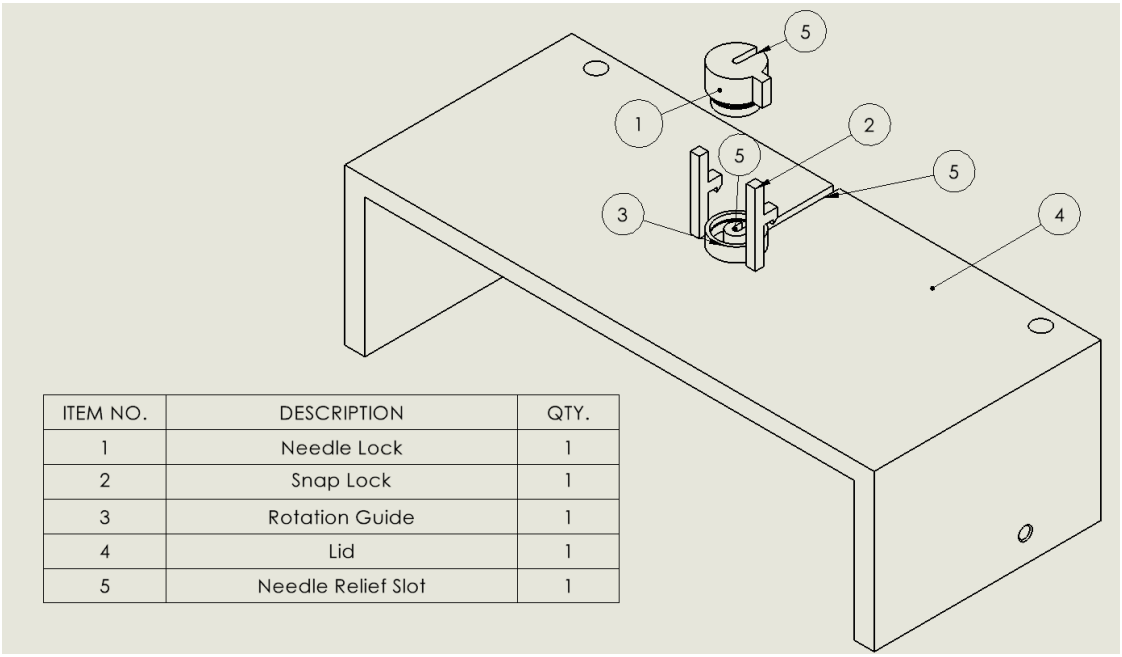


Figure 10. Needle mechanism integrated with the lid of the box.



ITEM NO.	DESCRIPTION	QTY.
1	Needle Lock	1
2	Snap Lock	1
3	Rotation Guide	1
4	Lid	1
5	Needle Relief Slot	1

Figure 11. Needle mechanism schematic with a bill of materials

Fit Testing

A majority of the work done for this project was through the use of 3D printers. A requirement prior to prototyping was a strong understanding of accessible 3D printing and the different necessities that comes with creating functional parts. At first, the team made use of a

cheaper and quicker printer but found that its lower quality parts were insufficient for the project. A majority of prints for this project were done through the use of an SST 1200es printer which used a dissolvable support material.

An important aspect of 3D printing and modeling is the use of tolerances. If, for example, a key is modeled to be the same size as the hole it fits into, then the key and lock will not fit together. Either the hole needs to be slightly larger, or the key needs to be slightly smaller. The range of distance needed for parts to fit together as desired is called a tolerance. Tolerances are also vital to functional design because the range of distance can determine how loose or tight a fit is.

The SST 1200es printer guide was referenced as a way to better understand the process behind it, however, there was no tolerance guide found. Instead, the printer guide only listed the tolerance of ABS plus filament that could be fed into the nozzle. Due to the lack of a tolerance guide, this nozzle tolerance, +/-1.5-2.0 mm, was used as a means to predict the possible printer error that could occur. In addition, general ABS tolerance guides (in this case, plaster molds) were used as a means to try and predict different fit tolerances. A tolerance of +/- 0.05mm was used for hole sizing and +/- 0.38mm was used for flat fit tolerances. The final piece of knowledge used to predict tolerance sizing was the understanding that, in 3D printing, holes are always undersized in comparison to the model [16], [17].

As such, the predicted ideal tolerances for the model were +/-1.88mm-2.38mm for flat fits and +/-1.6mm-2.1mm for holes [17].

Angle Testing

The needle's range of motion within the device became a vital part of understanding the device's functionality. For the sake of accurate ultrasound imaging, the needle’s range of motion had to be as close to 0° as possible. In order to test the needle's range of motion several pictures were taken of the device laying on a flat surface. Two orientations were observed, both of which can be seen below in Figures 12 and 13. Per orientation, twelve photos were taken. One of these photos was of the needle untouched in order to see the needle's resting angle, while the other eleven were of the needle being moved in different directions in order to get a sense of the needle’s motion range. After each photo was taken, built-in camera software could be used to ensure that the device was laying straight against the horizontal axis. An example displaying a photo prior to edit and post-edit can be seen in Figures 14 and 15.

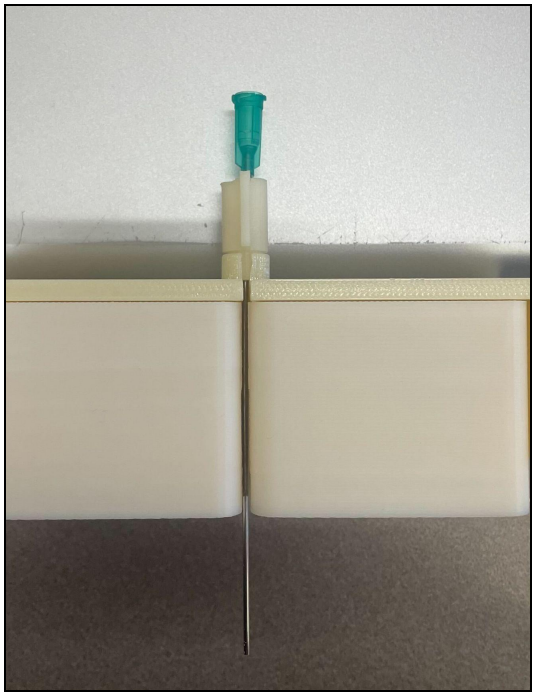


Figure 12. Orientation.

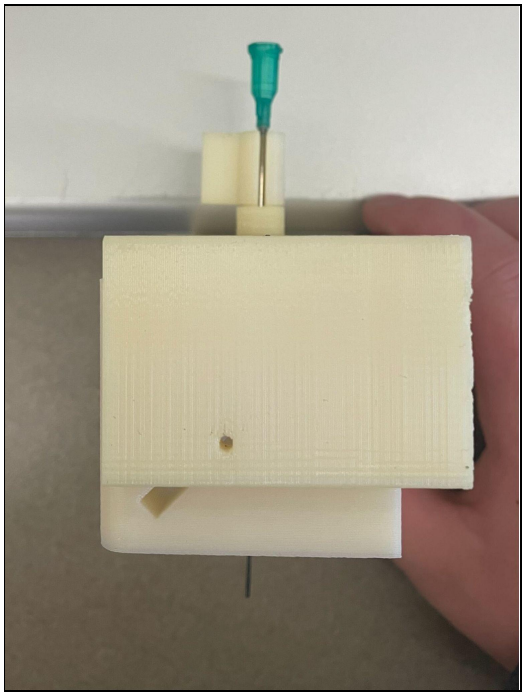


Figure 13. Orientation 2.

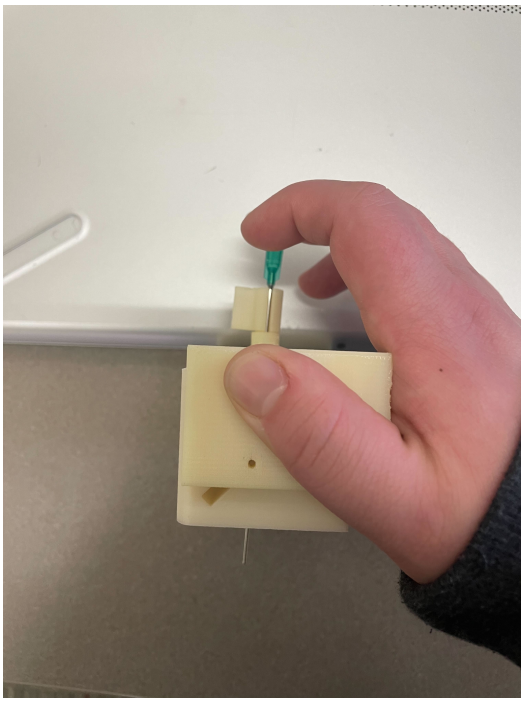


Figure 14. Angle analysis photo prior to edits.

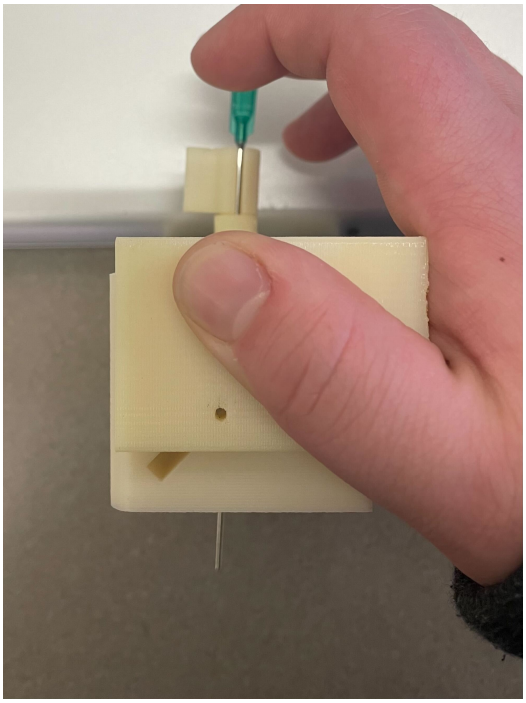


Figure 15. Angle analysis photo post edits.

The final step of the analysis was done through the use of AutoCAD. Each photo was imported into AutoCAD with a one-scale ratio. After importation, two lines were placed over the photos. One was the center of the axis, and the other was the needle line. The angle could then be measured using AutoCAD's built-in measuring tools. The resting angle, the maximum angle, and

the minimum angle per orientation were the main data focal points as they gave a decent idea of needle motion range. An example depicting the angle analysis in AutoCad can be seen in Figure 16.

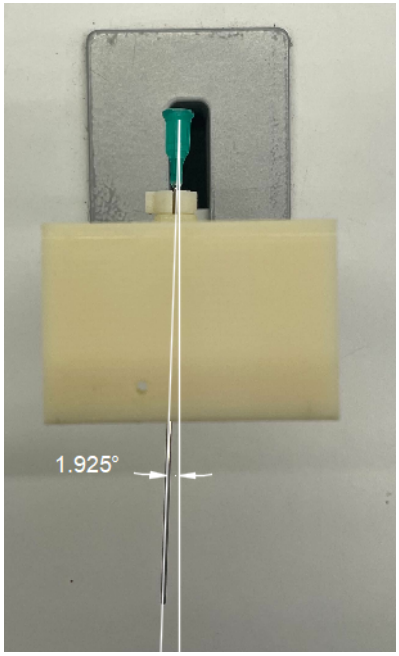


Figure 16. Angle analysis results as displayed in AutoCAD.

RESULTS

The completed design process for the needle quick-release mechanism resulted in a combination of a few aspects of the previous designs that were created earlier this year. The mechanism is integrated into the lid of the encapsulation box and includes a rotating locking piece that fits into a customized slot to prevent it from falling out but allows for smooth rotation into the locked and unlocked positions. This design underwent several rounds of fit testing and angle testing to become what is now the final iteration of the mechanism.

Fit Testing

The fits and tolerances of the parts ended up being far less predictable than expected and required a lot of trial and error. In some instances, fits that worked prior in another print iteration, they would not work in the next. This was most likely due to printing errors. One major error that could not be fixed through model changes was a notch that would bend inward on the needle relief slot and refuse needle exit. This error can be seen below in Figure 17. A few iterations of the device were created that fluctuated the relief slot size in an attempt to relieve this error, however with all reasonable radius changes the error persisted. This meant that cutting the notch out with an X-ACTO knife was a requirement for all iterations prior to testing.

Figure 17. A close-up of the printing error found in the needle relief slot.

Predicted tolerances ended up being too high values, requiring sanding down prior to fit. After sanding down the needle lock, the team was able to achieve the perfect tight fit rotation that eliminated the need for snap locks entirely, further simplifying the final design. The change intolerance was measured through calipers and put into the model.

An unexpected error with the device fits was the way the lid and box fit together. Notably, the lid was often not centered when being placed onto the box despite SolidWorks assemblies showing no significant issues. An example of this misalignment can be seen below in Figure 18. This caused significant issues with the functionality of the part as the needle was often not aligned with the needle relief slot without manual adjustment. Several iterations were created attempting to fix this error: such as changing the location of the lids relief slot to match the box. However, by the end of the project, major errors still occurred with this particular alignment that required manual adjustment.

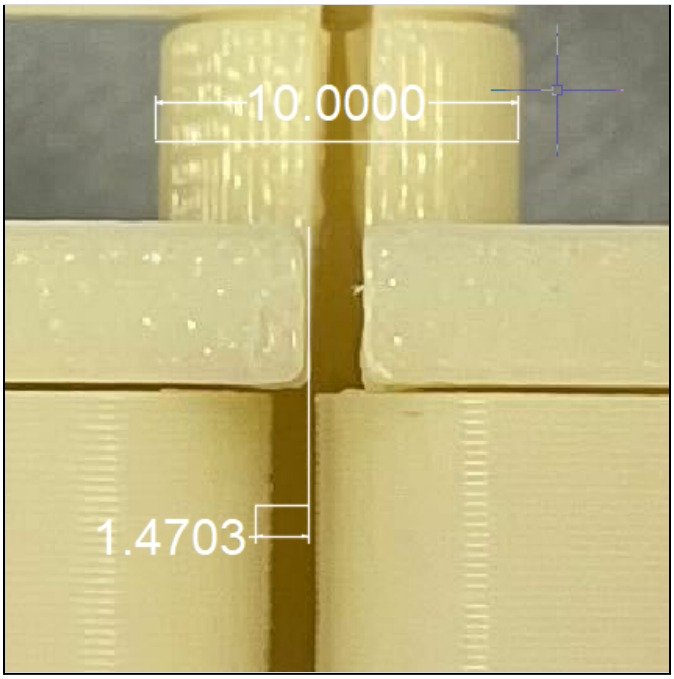


Figure 18. An example of the box and lid misalignment with AutoCAD analysis intended to show displacement numerically.

The final tolerances and their corresponding fits are listed below. The holes notably had a lack of consistency, and the needle fits had an unexpected range depending on the depth that they had in the part (the box's needle fit tolerance is higher than the needle lock, for example).

Hole fit +/- 0.28 mm
Needle fit (needle lock) +/- 0.035 mm
Needle fit (lid) +/- 0.115 mm
Needle fit (box) +/- 0.215 mm

Angle Analysis

Initial angle analysis trials showed major concerns with motion range. The initial range of motion showed a resting angle of 1.393° and range of 0.292° to 2.192° for orientation one. While orientation two had a resting angle of 7.155° with a range of 1.628° to 7.784°. This caused a design change to the needle lock, which was to make it longer in hopes of correcting the alignment.

From conducting the final needle angle analysis, it was found that from orientation one the needle naturally rests at 0.987° from the center axis, while from orientation two of the box, the needle naturally rests at 2.173° at the center vertical axis. For orientation one, the motion range is from 0.0274° to 1.1271°. For orientation two this range is from 0.186° to 3.526°.

The full set of angle trials and data can be seen below in Table 3.

Table 3. Final results of displaying all angle trials for both orientations, including resting.

Trial	Resting	1	2	3	4	5	6	7	8	9	10	11
Orientation 1	0.987°	0.751°	0.636°	0.417°	0.274°	0.515°	0.949°	1.271°	0.967°	0.388°	0.491°	0.415°
Orientation 2	2.173°	0.186°	3.364°	0.392°	3.340°	3.526°	2.829°	0.260°	0.293°	3.253°	3.206°	0.922°

Angle analysis revealed a secondary, unexpected result, which was the tilt of the needle lock following applied pressure. As seen in Figure 19 the needle lock has lifted from its position with pressure, meaning that with enough applied force it could come off and become a hazard in the operating room.

Figure 19. A close-up depicting the slight lift and tilt of the needle lock during testing.

Final Design

Following all design changes, the final product can be seen below in Figures 20 and 21. The last display of the final design in Figure 22, which is a GIF portraying the action of removing the needle from the box.

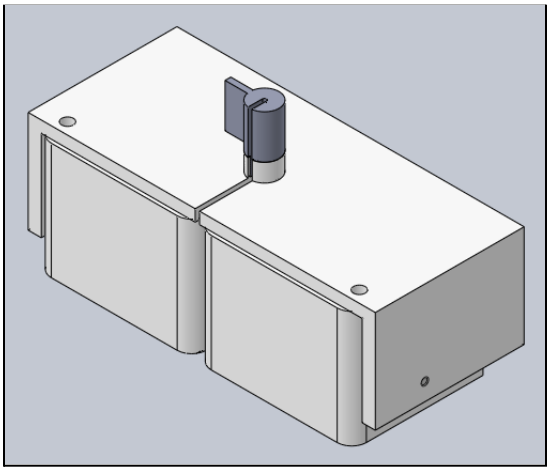


Figure 20. A modeled assembly of the final design is depicted in SolidWorks.

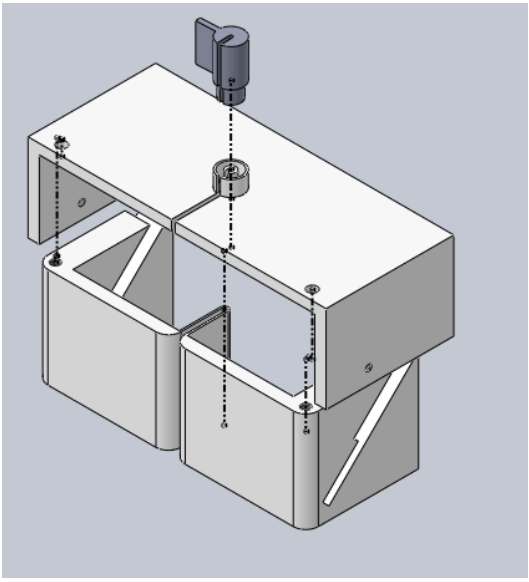


Figure 21. An exploded assembly of the final design is depicted in SolidWorks.

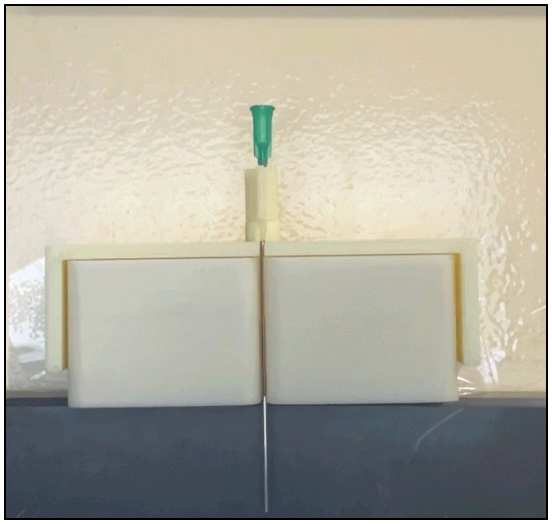


Figure 22. A GIF depicting the final design being used for needle release.

DISCUSSION

The three components that this project was broken down into were successful and resulted in an overall successful design. With the data that we collected from our design process, the fit testing, and the needle angle testing we were able to design a needle quick-release mechanism that works and looks clean. A needle can slide easily into the hole when the mechanism is in the locked position and slides out through the designated slit when the mechanism is in the unlocked position.

It is important to note that before the needle angle testing was conducted, we were turning the locking mechanism 180° which had resulted in what we considered an unacceptable movement of the needle. By playing around with the needle and the positioning of the locking part, we determined that turning the lock 90° rather than 180° resulted in the least amount of movement of the needle. Due to 180° rotation being an unwanted use of the device, a future consideration for the design may be a way to prevent such rotation from happening: such as through the use of an extrusion on the lid. The increased length of the needle lock, while fixing the motion range of the needle, also created some unintended leverage effects. Another future consideration would be a way to prevent the needle lock from lifting.

The needle's range of motion, while showing improvement, is another contender for future design changes. While the team is certain that the range of 0°-3.5°in orientation two is an unacceptable variation; it is unknown if orientation one's motion range of 0°-1.3 *is* acceptable. The device was unable to be tested with ultrasound imaging, and therefore this leaves a large area for research with the design left to be done. While the motion range in orientation two will require stabilization regardless, another possible fix to the needle angle may be to adjust the mirror angle to account for natural resting needle alignment. For these future developments in reducing needle motion in orientation two, it is important to understand that the motion range is allowed due to the needle relief slot. In orientation one, the walls of the needle relief slot prevent motion in the horizontal direction. However, in orientation two, there is a full range of motion in one horizontal direction, allowing for an increased movement range.

With regards to fit testing, the variations between models caused by printing errors proved to be a strong limitation of the project. Future development may want to consider the use of a plastic mold process in order to get more consistent results with the parts, however, this would likely require a new set of tolerance testing. The team's tolerance predictions seem largely skewed by the use of the SST 1200e printer's nozzle tolerance, which inflated the predicted tolerance sizes to be far too large. While the ABS casting tolerances alone are far closer to the final results, it should be noted that they also were not suitable for prediction due to the low tolerance for holes, which made up a majority of fit adjustments. A better process for tolerance testing in the future, should the idea of changing the manufacturing process come to fruition, would be through the use of optimized trial and error. This could be done by creating a cylinder key and a hole multiple times with slight tolerance variations in order to find the ideal fits required.

CONCLUSION

A majority of predictions, such as those with regards to fit tolerances and printing quality, were not correct. However, despite all the changes in design direction and the long struggle with part fitting, the team was able to greatly simplify the previous MQP design. Simplification of design can often be considered a feat of engineering on its own; and despite all the design flaws highlighted in the discussion section of this report, the team feels confident that the device is on the right track. A majority of design requirements for the needle guide were met, with the only exceptions being the needle locks removability with pressure and the needle displacement in orientation two.

Limitations of this study include:

- **The lack of ultrasound-related testing with regard to accurate needle imaging.** To fully understand whether or not the movement of the needle is acceptable, it needs to be tested that the needle holds true to the target. The device is intended to be used with ultrasound imaging in mind and should be tested with such.
- **The lack of a reference for acceptable needle motion range.** There were no studies that were found that spoke about the acceptable range of motion of the needle. There was no data to compare in relation to an actual ultrasound test and this would result in a qualitative study rather than a quantitative one. Future developments should perform research for this range.
- **Inconsistent printing quality and print tolerances.** Printing the same part usually resulted in many different fits of the parts and this was difficult to account for when reprinting and modifying designs. A majority of time was spent waiting for updated prints, and inconsistencies pushed back the timeline. A more consistent prototyping process would be ideal.

RECOMMENDATIONS

Below is a summary of the recommendations that the team has for any future developments with this project.

- Modify design to accommodate different needle sizes
    - In the event that this device goes to a clinical setting it is very possible that multiple needle sizes would be preferable. Investing time into accounting for these alternate fits may be beneficial. The current idea to solve this would be separate needle lock parts with different needle gauge sizes, while the box and lid needle diameters fit for the largest possible size.
- Modify lid and box alignment to not require manual adjustment
    - The current state of the lid and box alignment is skewed, which in turn affects the alignment of the device's needle diameters. At this current point in time, manual adjustment is required to properly align the lid and the box. By modifying the design to fit properly without manual adjustment, a lot of time can be saved and the device can become more consistent. The current idea to solve this issue is to change the method by which the lid connects to the box. Currently, the lid slides into place through the use of a slanted extrusion that matches two slanted holes on the sides of the box. This method of attachment is not water-tight and does yield accurate alignment. Research into common plastic design techniques to create a simple snap design may be preferred.
- Consider manufacturing process to account for consistent tolerances and possible errors
    - As previously mentioned, the inconsistency with printing quality heavily impeded the project in terms of time. In the future, a more consistent method would be highly preferable, especially for clinical use. It is believed that a plastic mold method would be an ideal and consistent method.
- Attempt to fix natural needle alignment to be closer to 0° at all orientations, or adjust mirror angle to account for natural alignment
    - As previously mentioned, the needle has a motion range that is unacceptable in orientation two. Halting the motion of the needle in this direction is necessary. The reason the needle is able to move more in orientation two is due to the needle release slot. As such, a possible way to prevent such motion could be to include a secondary lock at the bottom of the box as presented in earlier designs. Another possibility to prevent motion would be to create a mechanism that will push against the needle when in one position, but let go in another.
- Prevent 180° rotation of needle lock
    - A common engineering principle is to discourage misuse of a device. Currently, there is nothing to stop a user from rotating the needle lock 180°, which heavily increases the needle’s range of motion. Prevention of 180° rotation is then important for the safety of the patient and for the sake of stable imaging. A

possible fix for this would be to include two small extrusions on the lid that the needle lock's handle can hit, thus preventing further rotation.

- Keep needle lock from lifting with pressure
    - Currently, with pressure, the needle lock can tilt and lift. Not only does this increase the needle's range of motion due to a lack of stability, but it also allows risk for the needle lock to accidentally be removed during the procedure and become a hazard in the operating room. A possible fix for this would be to increase the length of the lid's rotating guide and the small "key" extrusion of the needle lock. This will increase the stability and help lower tilt.

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