Stabilizer Device for Intracardiac Echocardiography (ICE) Catheter

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Abstract

Heart disease is the leading cause of death in the U.S., and many heart procedures are complex and difficult to perform. An intracardiac echocardiography (ICE) catheter is used during structural heart interventions to provide ultrasound imaging of the heart. Currently, the catheter is either held by an assistant or secured with a wet towel, but it can easily shift, disrupting the image and causing delays. A device that stabilizes the catheter shaft could prevent these issues. The team has been tasked with designing and building a novel ICE catheter stabilizer system that secures any brand of ICE catheter. The design must allow for height adjustment to align with the patient's entry point and be either fully sterilizable or disposable for use in a catheterization lab. It should also minimize catheter movement to ensure a steady image. The proposed solution is a three-part device with a height-adjustable base and middle sections placed beneath the sterile drape, while the top part with an adaptable clamp attaches over the drape using magnets and an interlocking mechanism. A prototype was fabricated and tested against the current method of securing the catheter handle, demonstrating significant improvement and offering a solution to the issue of ICE catheter instability.

1. Introduction

Despite countless advancements in the field of cardiovascular medicine, heart disease remains the leading cause of death in the United States [1]. Within this endemic, congenital heart disease affects at least 1% of all live births in the U.S., with one in four of the affected requiring specialized interventions [2]. Additionally, adults can acquire structural heart defects, which can include valve regurgitation, stenosis and septal defects, among others [3]. Increasingly, structural heart defects, whether congenital or acquired, can be treated in a minimally invasive way via catheter-based approaches. In such procedures, a physician inserts a catheter through a blood vessel in the groin and guides it to the heart to treat the defect. In order to successfully replace an affected valve or repair a defect, the physician must often use imaging technology such as an intracardiac echocardiography (ICE) catheter. This technology enables a physician to obtain high-resolution, real-time images of a patient's heart while simultaneously performing an therapeutic intervention [4]. This imaging system functions via an ultrasound transducer at the end of the catheter probe [4], which is inserted via the femoral vein and guided into the heart through the right atrium [5]. Thus, ICE catheters only require local anesthetic and not general anesthesia, providing a less invasive approach to cardiac imaging compared to other methods such as transesophageal echocardiographic probes (TEE) [6]. ICE catheters also use Doppler to measure flow through different components of the heart. [4]. This catheter is an extremely powerful and useful tool in the field of cardiology.

While these innovative imaging devices increase the accessibility of minimally-invasive cardiac interventions, some issues with the ICE catheters persist. In order to gain a clear visualization of the patient's cardiac structures, the catheter must remain completely still in the exact position that the physician guided it to. Otherwise, the imaging perspective may be lost, requiring readjustment of the catheter. If the physician has to readjust the position of the catheter, it increases and complicates the work of the physician, which creates more risk to the patient, increases the procedure time, and potentially increases radiation dose rates to the patient [7].

Currently, physicians employ the use of wet towels to weigh down the ICE catheter handle or, alternatively, have a technologist hold the handle while they perform a therapeutic intervention. These methods either require additional labor or do not fully fix the handle into place. Thus, there exists the potential for significant process improvements in the ICE catheter placement procedure.

While no direct solution has been offered to address the need to stabilize ICE catheters while in use, similar issues have been addressed for therapeutic catheters such as the Abbott MitraClip System (Fig. 1), which is used to treat mitral valve regurgitation. This system includes a stabilizer device that holds the handle of the catheter device at a fixed angle [8]. Similarly, the Edwards EVOQUE Tricuspid Valve Replacement System utilizes a stabilizer device that holds the catheter at an adjustable position atop a base plate and

platform (Fig. 2) [9]. These proprietary devices provide stabilization solutions for specific therapeutic catheter systems, but do not fulfill the need for stabilization of imaging catheters. Therefore, we propose a novel device suited for ICE catheter stabilization in order to address this gap in cardiac imaging and interventional procedures.

Fig. 1 MitraClip Delivery System with stabilizer device [8]

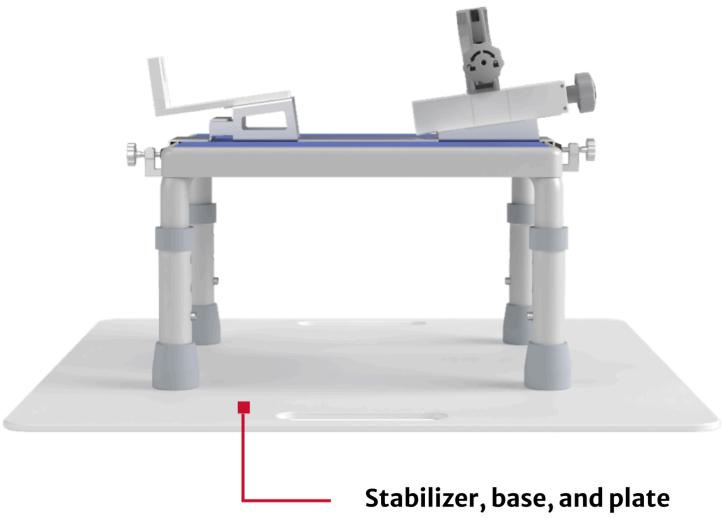

Fig. 2 Edwards EVOQUE Tricuspid Valve Replacement System stabilizer, base, and plate [9]

In this study, a prototype was developed to characterize the functionality of the ICE catheter stabilizer device. The prototype involved three separate parts, dubbed the base,

middle, and top parts. The base part consists of a flat base plate and singular offcentered vertical pole (Fig. 3). The middle part is able to slide vertically into the pole of the base part, and be secured at different heights via a pole clamp (Fig. 4). The top of the middle part features raised ridges in an x-shape along with two cutouts in opposite quadrants, in which magnets are seated. The bottom of the top part consists of grooves that mirror the x-shape ridges of the middle part, allowing them to fit together snugly. There are also two matching magnets in opposite quadrants of the bottom of the top part to match those in the middle part. The top of the top part is in a 'U' shape to form the saddle, in which the catheter handle rests (Fig. 5). The 'U' allows for any different brand or type of ICE catheter to be placed on the device as it is ubiquitous. A neoprene rubber strap (Fig. 6) was affixed to one side of the top part and attached to the other side over the catheter handle to secure it in place. Testing was performed on the prototype to assess the ability of the stabilizer to secure the ICE catheter and withstand any applied forces or displacements during interventional procedures. Additional testing was done to ensure the integrity of the sterile barrier while using the stabilizer device. The metrics of success evaluated included force required to destabilize the catheter, factor of safety of the device, and sterile drape material properties. Lastly, the device was assessed via a user survey of interventional cardiologists and catheterization laboratory personnel to gain feedback on ease of use, adjustability, and aesthetics. All testing with the device utilized two different ICE catheters in order to ensure the design was compatible with various catheter sizes and shapes. The two catheters used were the Siemens AcuNav 3D ICE Catheter (Fig. 7) and the Philips VeriSight Pro 4D ICE Catheter (Fig. 8). While both catheters are similar sizes, the Siemens features a tapered cylindrical shape while the Philips is shaped as a stepped shaft. By testing both catheter geometries in this stabilizer device, the device proves itself capable of adjusting to secure catheters of all shapes and sizes, offering a universal solution to the catheter stabilization need.

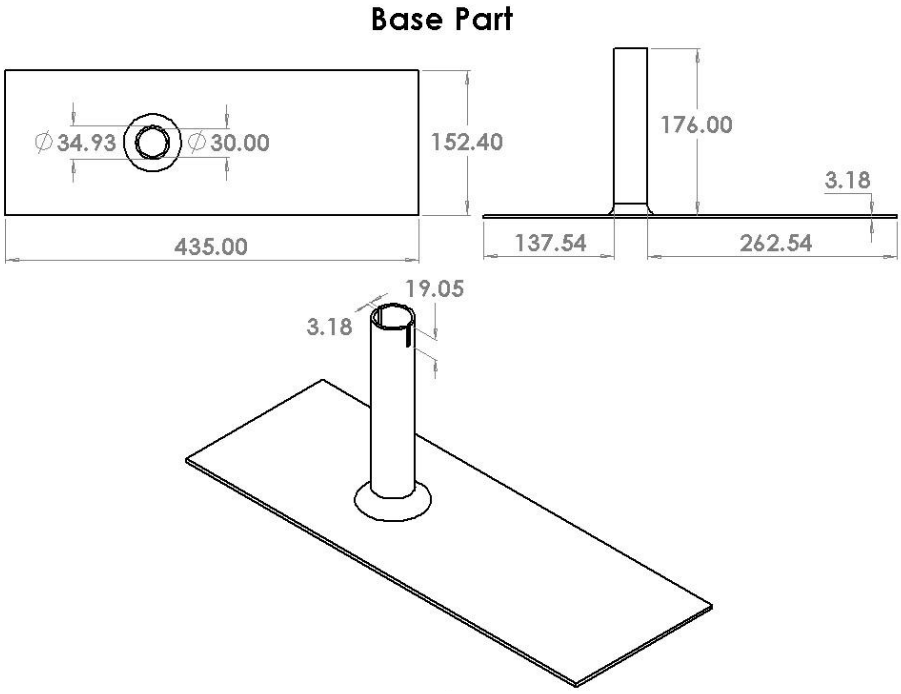

Fig. 3 Base part of prototype with dimensions in millimeters

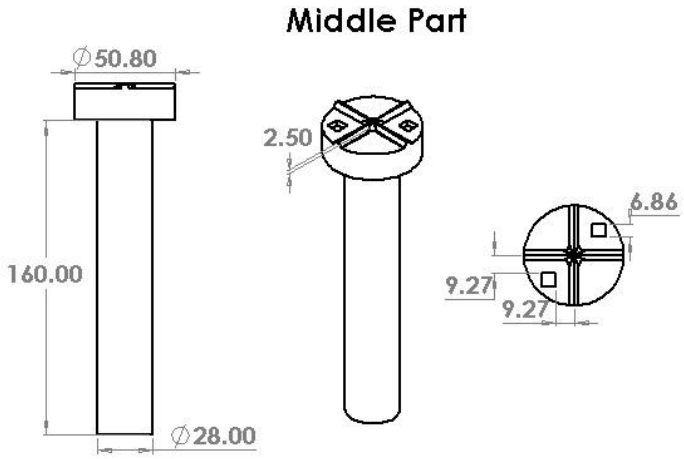

Fig. 4 Middle part of prototype with dimensions in millimeters

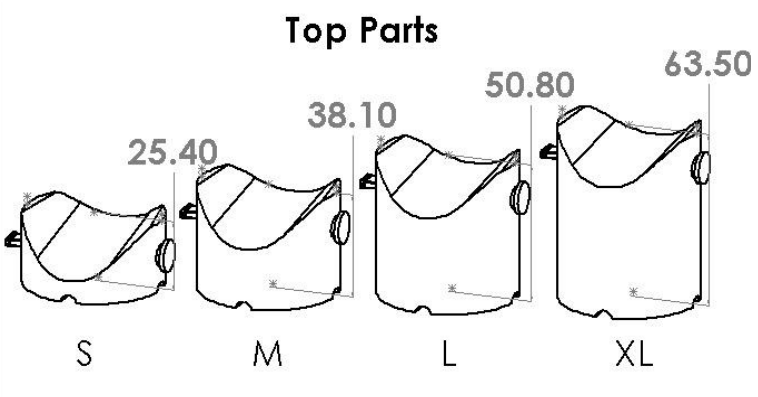

Fig. 5 Top parts of prototype with dimensions in millimeters

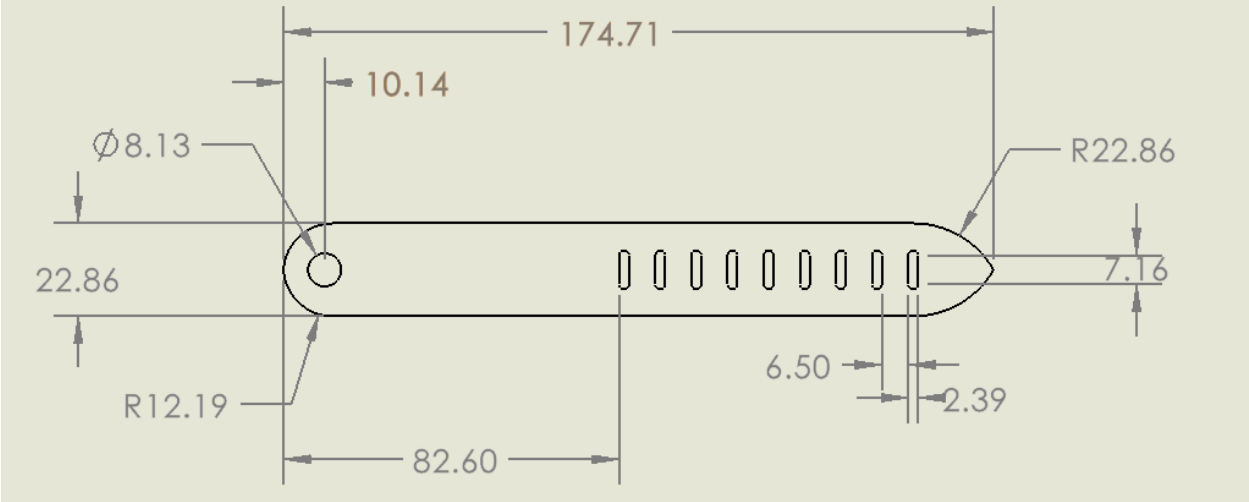

Fig. 6 Strap of prototype with dimensions in millimeters

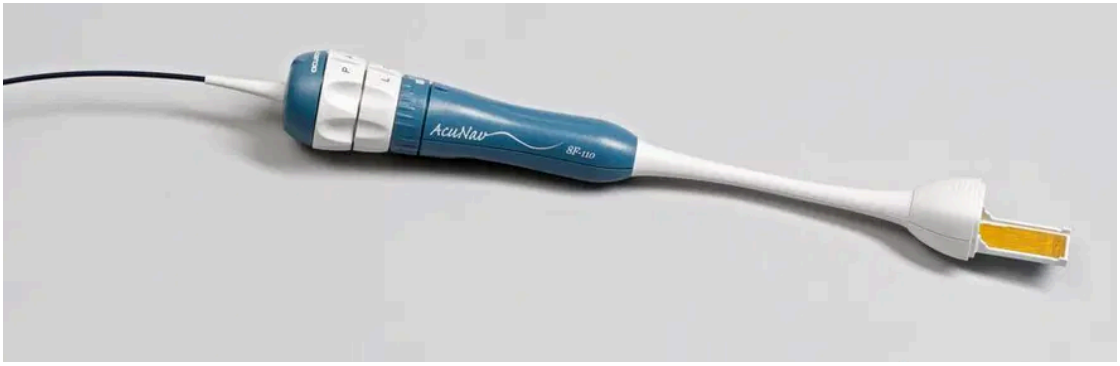

Fig. 7 Siemens AcuNav 3D ICE Catheter

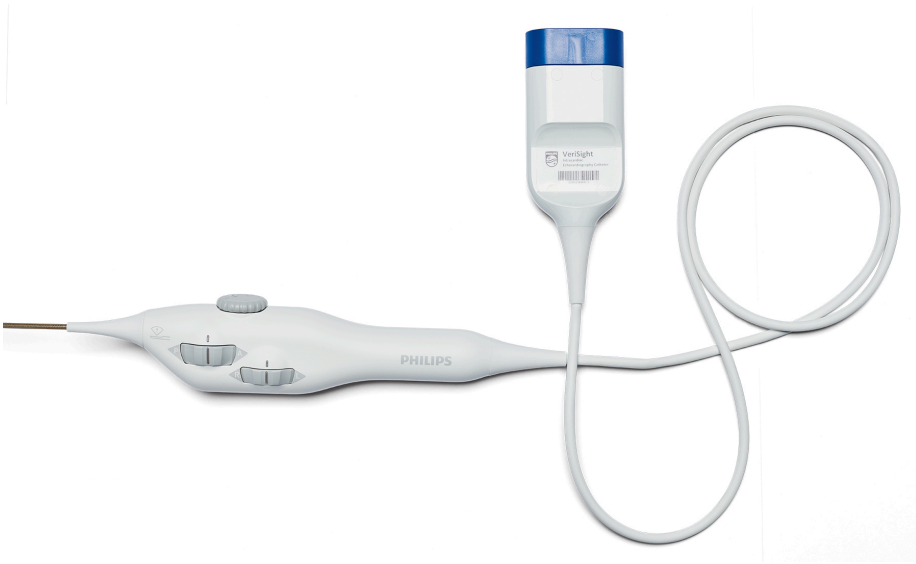

Fig. 8 Philips 4D ICE Catheter

2. Materials and Methods

2.1. Design Overview

The device consisted of three main components that are referred to throughout as the base part, the middle part, and the top part. When in use, the base part and middle part will be placed underneath the sterile drape barrier used in such procedures. The shaft of the middle part is inserted into the hollow shaft of the base part and secured at the desired height via a quick-release saddle clamp. The sterile drape is placed over the patient and the base and middle parts; subsequently, the top part is magnetically attached onto the middle part through the sterile drape and the catheter can then be secured into place with the strap on the top part. For visualization of the device components, refer back to Figs. 3-6.

2.2. Material Selection

The base and middle part of the device were made with AISI 4130 steel (McMaster-Carr), a low-carbon, chromium-molybdenum alloy with high machinability and weldability. It has a yield strength of 460 MPa [10]. The material is able to withstand sterilization via commonly used methods including autoclaving and ethylene oxide; however, these components are not required to be sterilized as they will remain below the sterile drape during procedures. The base will also include a quick-release clamp (PLATT), purchased via Amazon, that is made of aluminum alloy. This component can withstand ethylene oxide sterilization.

The top part of the device was printed using poly-lactic acid (PLA), a low-cost thermoplastic that can withstand temperatures of 57℃ and has high strength and stiffness.

PLA can be sterilized by ethylene oxide or gamma irradiation. Uncoated neodymium magnets (McMaster-Carr) were attached to the top part with a hot melt adhesive. Future iterations of the top part will be injection molded with a commonly used low-cost thermoplastic such as polycarbonate, polyethylene terephthalate, or polyethylene. Additionally, neoprene rubber straps (DGSL, Amazon) were attached to the top part.

2.3. Fabrication of Base and Middle Parts

The top section of the middle part, which houses the magnets and features one half of the interlocking “X” design, was fabricated using a Trak 2-OP, a computer numerical control (CNC) mill. The section was modeled in Solidworks and isolated from the shaft of the middle part. It was then imported into Mastercam and used to create the necessary toolpaths. The toolpaths were then converted to G-code, exported, and transferred to the Trak 2-OP. A pair of custom vice jaws were fabricated to hold 2” outer diameter cylindrical steel stock (McMaster-Carr) in the CNC vice, and the required tools were loaded into the mill. The program was then run, resulting in a completed top section of the middle part.

In order to form the base part and the middle part, there were two components that needed to be welded together. Stock metal was obtained from McMaster-Carr in the form of hollow rods at two different outer diameters (1-⅜” and 1-⅛”) as well as a 6”x36” steel sheet of ⅛” thickness. The 1-⅜” hollow shaft was welded to the base plate of the stabilizer and the 1-⅛” shaft was welded to the completed top section of the middle part. The 4130 steel was Metal Inert Gas (MIG) welded using a Millermatic 252. The MIG welder was set to use .03” ER70S-6 wire at 18V and a wire speed of 200. The material was preheated to 300F-400F in order to ensure a proper weld.

2.4. 3D Printing of Top Part

The top parts were 3D-printed through the Grainger Engineering Design Innovation Lab (University of Wisconsin-Madison). The top parts were first designed in SolidWorks, then converted to an STL file. The STL files were then opened on Bambu studio, which is the 3D printing slicing software used. The pieces were then placed on the build plate and parameters were adjusted appropriately for optimal printing. With the material set as PLA, the layer thickness was set at 0.28 mm with an infill of 20%. The organic support type was used as well. After printing was finished, the supports were removed manually and the top parts were ready for assembly.

2.5. Laser Cutting of Strap

In order to secure the catheter into the top part, a strap was fabricated via laser cutting. The strap was first designed in Adobe Illustrator with a stroke width of 0.001” and all vector cut components set to RGB Red, then uploaded to the Universal Control Panel software for export to the laser cutter. Material settings were adjusted for neoprene rubber

and material thickness was input as measured. The Universal Laser Systems model VLS4.75 was used for this process.

2.6. Assembly

The device was assembled by securing the quick-release clamp around the shaft of the bottom part. The middle part was subsequently inserted into the bottom part shaft and the clamp was fastened to hold the middle in place. Magnets were adhered into grooves on the top surface of the middle part and the bottom surface of the top parts with a methyl methacrylate adhesive. The top piece was then attached to the middle piece with the installed magnetic connection, and the neoprene rubber straps with holes were secured onto the notches on the sides of the top. Lastly, the base and middle parts of the device were spray painted with white solvent-based silicone spray paint (McMaster-Carr) to conceal metal welding imperfections.

2.7. Force Testing

The primary purpose of the device is to ensure the catheter handle is held securely in place during the procedure. This force test aimed to evaluate the strength and efficacy of the magnets and interlocking mechanism of the middle and top components on either side of the sterile drape, as well as the strength of the rubber strap used to secure the catheter to the top piece. The testing involved applying forces to the end of the catheter handle in the three different directions while it was secured either in the saddle of the top part or by wet towels, as is the current method in the catheterization lab. The forces required to dislodge the top part or the catheter from the device and the forces required to move the catheter while weighted down by the wet towels were measured using a force gauge and recorded. Bending forces were applied in a downward direction, torsional forces were applied in a perpendicular direction, and tensile forces were applied in an outward direction in line with the catheter. The bending forces were only applied to the catheter in the device to test its safety, as a bending force applied to the catheter held by the wet towels would only push it into the table. The first two orientations are representative of an operator or assistant bumping the catheter with their arm while it is secured in the device, while the third tensile force is representative of the breathing force of the patient pulling on the catheter. The catheter handle was secured in place using the rubber strap. Each of the three different forces were measured and recorded five times for each catheter both secured in the device and weighted down by wet towels. Additionally, each catheter was tested with two different top pieces, the smallest (S) size and the largest (XL) size, in order to test both possible setups in the extremes. The differences between the device and the wet towel method were then evaluated, as well as the differences between loading the 3D vs 4D catheter using a t-test. The device was expected to withstand significantly greater forces than the wet towel method. Pictures for every testing configuration are included in the Appendix F.

2.8. Surgical Drape Tensile Testing

The device is designed to span across the sterile drape during a procedure. The design has interlocking ridges and grooves that could lead to potential tears in the drape, breaching the sterile field. To evaluate the risk of this happening, the strength and durability of the surgical drape material was tested via tensile testing. The drape was cut into 5 cm by 10 cm samples, placed into a materials testing system (MTS) machine, and put into tensile loading. The samples were observed in order to find the maximum load, maximum strain, and Young's Modulus of the surgical drape. These factors show the drape's ability to resist tearing by the device. For further explanation of the testing protocol, refer to Appendix H.

2.9. SolidWorks Stress Analysis

When the assembled device is in use, there exists a possible failure mode in which force applied transversely to the base plate pole causes the weld between the base plate and shaft to break. In order to assess the strength of this weld and determine a factor of safety, a static stress SolidWorks Simulation was performed. A transverse force of 38 N was chosen based on the average weight of an American adult and anthropometric data for weight of a leg [11,12]. This force was applied perpendicularly to the top 30 mm of the shaft on the base plate, while the bottom of the base plate was fixed in place. A material of AISI 4130 annealed steel was applied to the simulation. Once these parameters were applied, the simulation was run. For a more detailed protocol, refer to Appendix I.

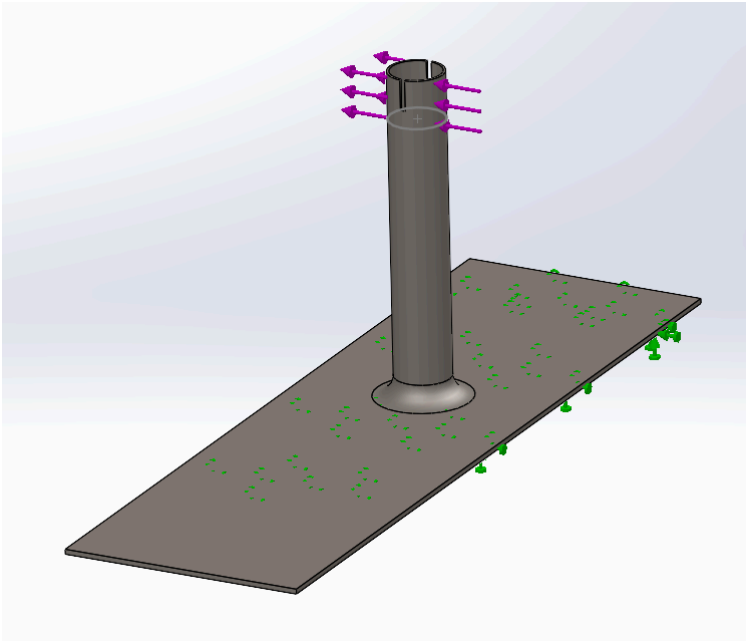

Fig. 9 Base plate and shaft in SolidWorks Static Force Simulation with transverse force applied to shaft and fixture on the bottom of the base plate

2.10. User Feedback Survey

In order to qualitatively evaluate the device, a team of physicians including the commissioning client were given a survey to rate the following topics: ease of use, height adjustment, ease of attaching and detaching the top part, level of security of catheter, difficulty of placing device below patient's legs, appearance, and interference of procedure. Each category was evaluated on a scale of 1 to 5 with 1 being the most negative score and 5 being the most positive score. The survey additionally included a question if the user would purchase the device if it cost less than $500.

3. Results

3.1. Prototype

The initial prototype, consisting of all three components 3D-printed from PLA, is pictured below in Fig. 5. The final prototype, fabricated from stainless steel and 3D-printed PLA, is pictured below in Fig. 11.

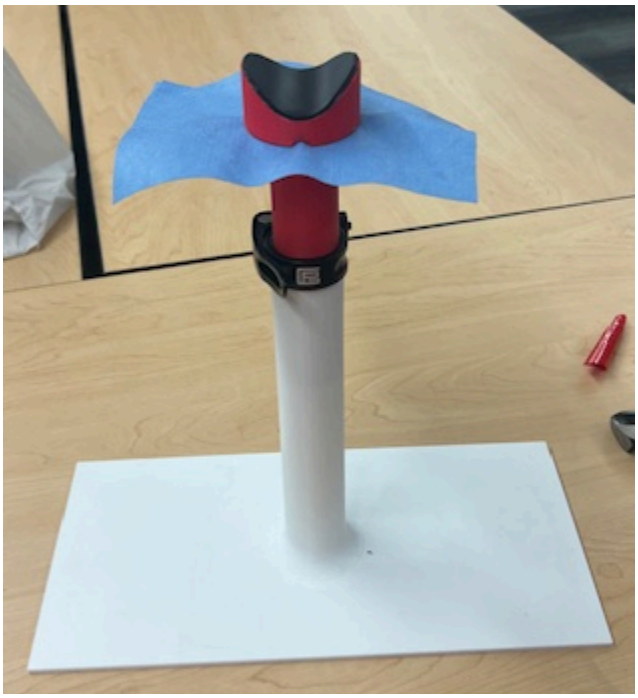

Fig. 10 Initial 3D printed prototype, consisting of top, middle, and base parts along with the pole clamp

Fig. 11 Final fabricated prototype, consisting of top, middle, and base parts along with the pole clamp and 4D ICE catheter

3.2. Force Testing

After completing the force testing, the data was obtained (as seen in Appendix G) and processed through Matlab as explained in Appendix E. Figs. 12-14 below provide a more in depth analysis of the data.

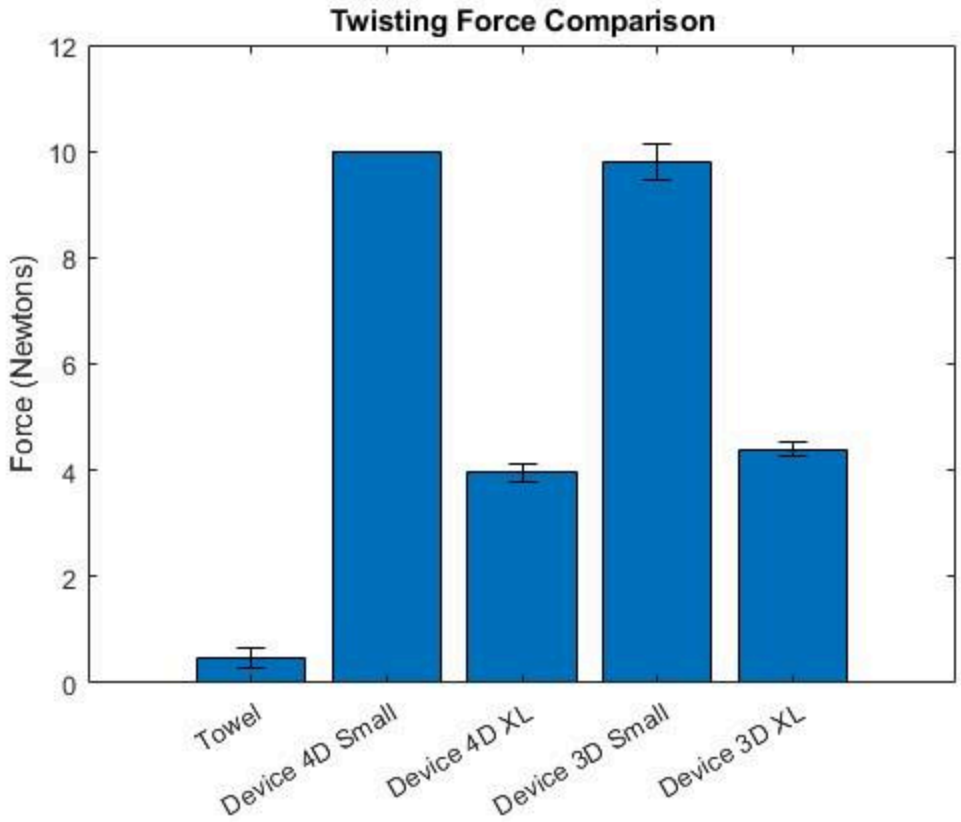

Fig. 12 Average twisting force, which is the force in the perpendicular direction relative to the catheter, to dislodge 3D and 4D ICE catheters comparing the current method with the devices' small and extra large top parts ($p < 0.001$)

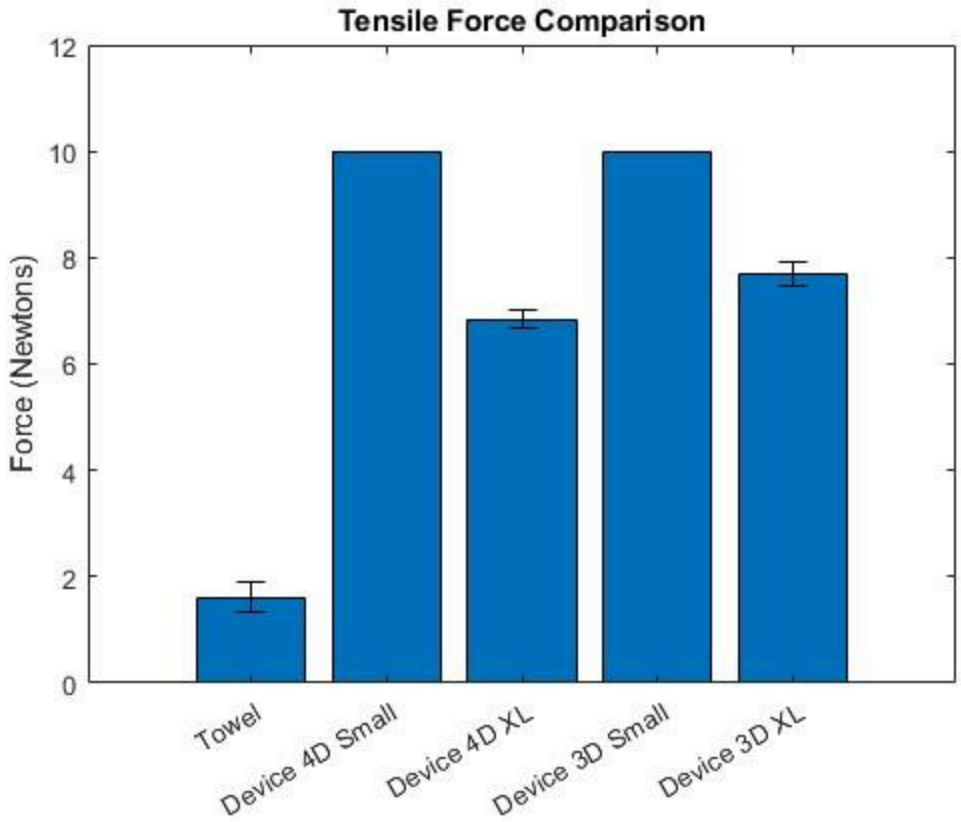

Fig. 13 Average tensile force, which is the force in the outward direction relative to the catheter, to dislodge the 3D and 4D ICE catheters comparing the current method with the devices' small and extra large top pieces ($p < 0.001$)

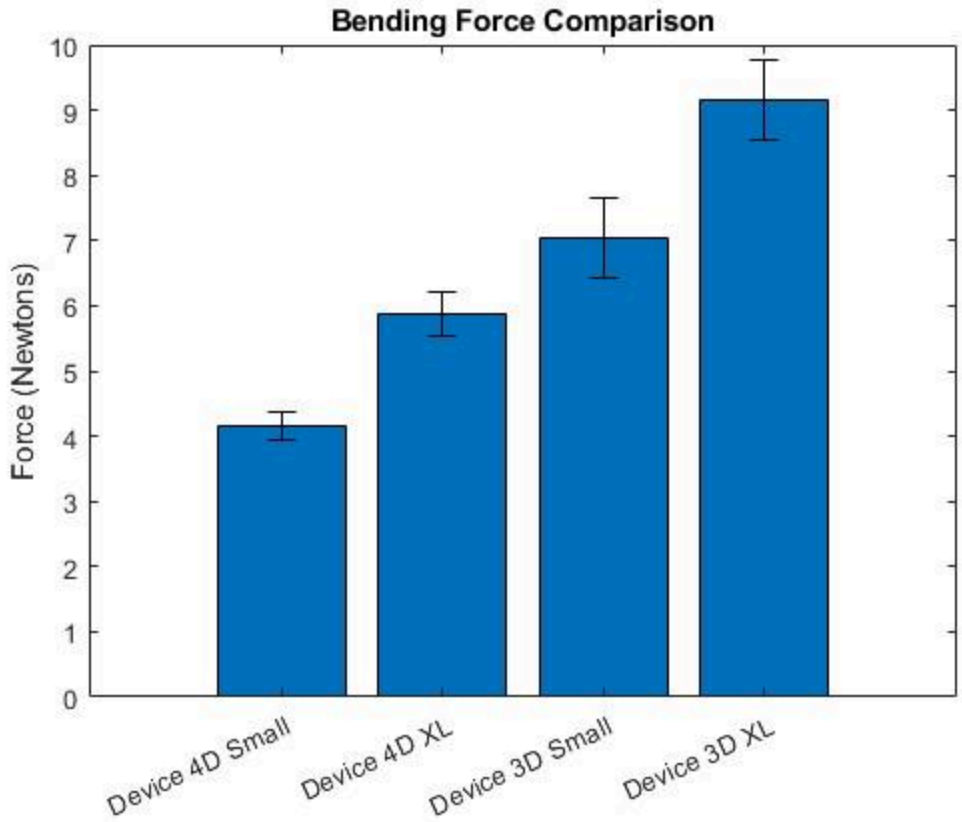

Fig. 14 Average bending force, which is the force in the downward direction relative to the catheter, to dislodge the 3D and 4D ICE catheters from the devices' small and extra large top parts ($p < 0.001$)

The device was able to withstand significantly more force in the tensile and twisting test compared to the current method for both the S and XL size top pieces, with p-values less than 0.001. For all p-values, see Appendix G. No force could be properly measured using the wet towels as it underwent bending so no comparison was made between the data. Also, in some trials, the device was able to withstand over 10 N, which was the maximum the force gauge could measure. Using this conservative value of 10 N, however, still yielded statistically significant results. Due to this, however, there are no standard error bars on some of the graphs that are the device undergoing tensile or twisting force. The maximum 10 N tensile force value can be approximately compared to holding a one liter water bottle, while the 10N twisting force is approximately equivalent to twisting off the lid of a jar or cap of a bottle.

Additionally, the forces required to dislodge the 3D vs. 4D ICE catheters were compared. With tensile and twisting forces applied to the 3D and 4D catheters on the S top piece, there was no significant difference between the amount of force required to dislodge the catheter ($p > 0.05$). However, there were significant differences for the tensile and twisting forces for the XL top piece as well as the bending forces for both sizes ($p < 0.05$).

Surgical Drape Tensile Testing

The tensile testing was completed with 3 samples of 5 cm by 10 cm. As seen in Table 1, the drape on average has a Young's Modulus of 7.65 MPa, a max load of 100.23 N, and a max strain of 0.55.

Table 1 Results from surgical drape tensile testing

	Young's Modulus (MPa)	Max Load (N)	Max Strain
Average	7.65 ± 0.95	100.23±8.33	.55±.007

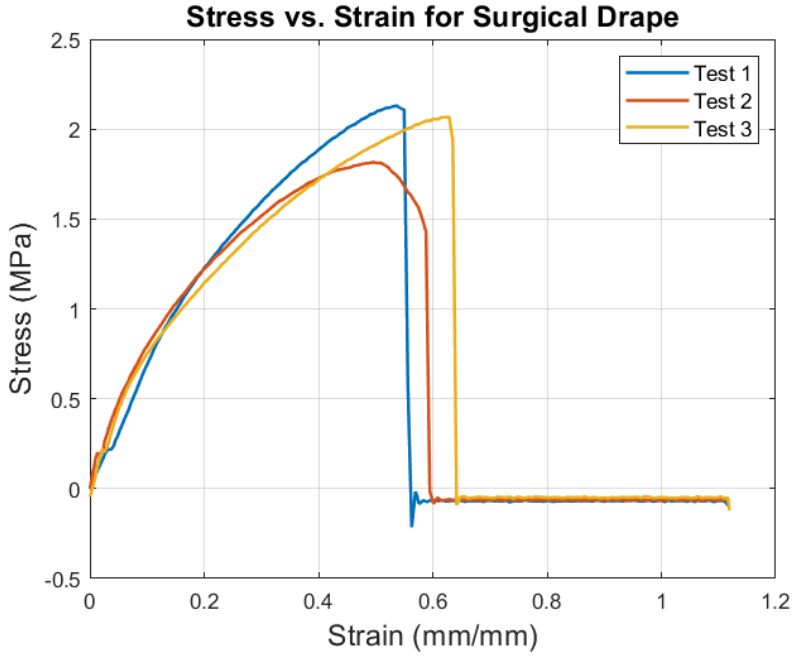

Fig. 15 Stress-strain behavior of the surgical drape for 3 trials

3.3. SolidWorks Stress Analysis

The application of a transverse 38 N force to the shaft of the base piece via SolidWorks Simulation resulted in a peak stress value of 4.8 MPa at the stress concentration along the weld (Fig. 16). This stress is a calculated equivalent Von Mises stress that accounts for all states of stress. To calculate the safety factor of the device, the material's yield strength of 460 MPa was used [10]. Thus, the factor of safety calculated by the simulation was 96.3 based on Distortion Energy Theory, which takes into account the yield strength and principal stresses.

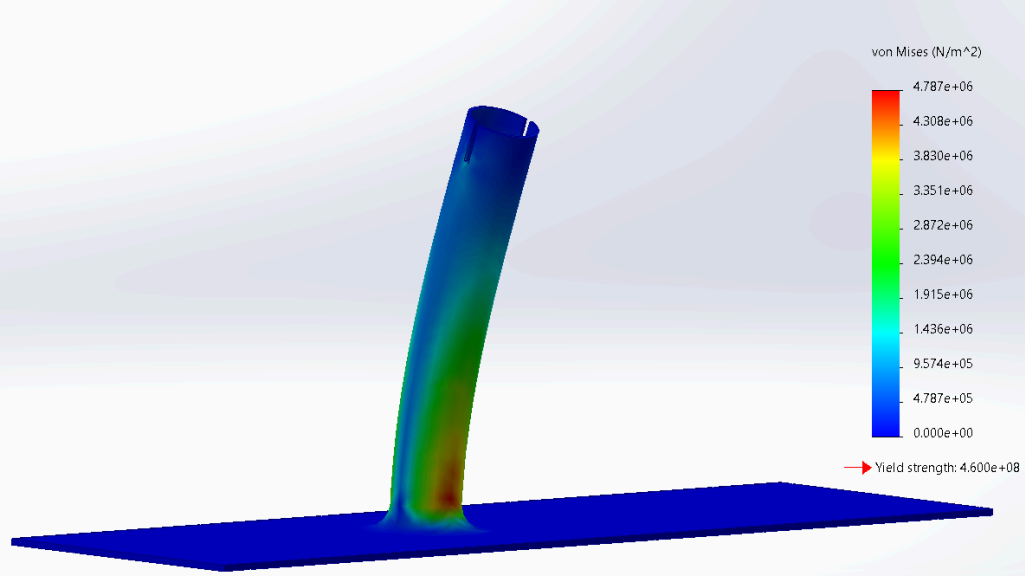

Fig. 16 Results of SolidWorks Static Force Simulation with transverse force applied to the top of the shaft

3.4. User Feedback Survey

The user feedback survey was conducted on the client and a team of physicians to get feedback on the prototype as seen in Table 2. Recall each category was evaluated on a scale of 1 to 5 with 1 being the most negative score and 5 being the most positive score. The client said he would purchase the device if it was less than 500 dollars. This survey was conducted in person on a cath lab bench. Note that the prototype was not in the finalized state when the survey was conducted, with no paint and handmade straps.

Table 2 User feedback survey results

Criteria	**Score**
Ease of use	4
Ease of height adjustment	5
Ease of replacing top part	5
Security of catheter	5
Ease of placement below patient	4
Aesthetics	4
Device interference during procedure	5
Purchase device if < $500?	Yes

4. Discussion

The results of the testing show that the final fabricated prototype performed better than the current stabilization method of wet towels. Because all of the p-values are below 0.05, there is statistically significant evidence that the null hypothesis can be rejected, meaning the device does withstand more force than the current wet towel method. The stabilizer was able to maintain at least 6 times more force than the wet towel in a twisting load with the XL top part and a force at least 15 times greater with the S top part. For tensile loading, the stabilizer was able to maintain at least 4 times more force than the wet towel with the XL top part and at least 5.8 times greater force with the S top part. Therefore, when the patient breathes, the device should not move as it takes more than 2 N to move the catheters on the stabilizer.

When the device performance was compared between the 3D and 4D catheters, it was found that there were some significant differences between the force required to dislodge the respective catheters. However, while the forces were significantly different in the cases of tensile and twisting forces between the 3D and 4D catheters, it is important to note that these forces are still significantly larger than the force required to dislodge from the wet towel. Thus, the prototype universally secures both 3D and 4D ICE catheters from applied forces significantly more so than the previous method of wet towels.

Additionally, the drape testing provided useful data to prove the interlocking mechanism between the middle and top parts is not at risk of tearing the sterile drape. Anything over the drape needs to be sterile, so the design features only the top part being on top of the drape. Thus, it is the only part of the device that needs to be sterile. Testing was needed to ensure that the magnets and interlocking x-shaped ridges will not tear the drape. In comparison to other materials, the Young's Modulus and ultimate strain of the drape was found to be similar to nylon and the max load is similar to that of cotton [13]. This shows the material is strong in comparison to most other fabric materials. This information can be used to infer that the surgical drape is very tear resistant for a textile and the device has little to no chance of propagating a tear in the material. Based on these results, the current magnets and interlocking mechanism can safely be used to hold the drape between the top and bottom part.

Although the device needs to be sterilizable, there are serious ethical considerations. One is that the hospital will mainly use ethylene oxide to sterilize the stabilizer. Ethylene oxide is a possible carcinogen that can have serious effects on the reproductive system, skin, and nerves [14]. Another concern is that the stabilizer fails and the catheter perforates the aorta [5]. This can be irrecoverable and the patient could die. Therefore, the device must be tested thoroughly and properly.

The marketability of the device is significant, as it has many applications and features a disposable sterilized piece which is to be sold and shipped in sterile packaging. According to Siemens, their ICE catheter has been in use for 20 years with over 2 million

procedures performed; this is just one brand of ICE catheter with many more out in the market. While the device was conceived and designed for ICE catheters during mitral valve procedures, the device has many other potential applications. Any procedure using a catheter with a cylindrical handle that is inserted into a femoral vein has potential compatibility with this product. Additionally, the steel base and middle parts of the device are reusable after cleaning as they do not need to be sterile under the sterile drape, but the top part is a sterile plastic piece that can be sold as individual units pre-sterilized. This allows for a more consistent revenue stream as these pieces must be reordered after every procedure. These top pieces also come in varying sizes, allowing for further adaptability and customization.

5. Conclusion

The goal of the project was to design and develop a manufacturable Intracardiac Echocardiography (ICE) catheter holder to ensure steady imaging feed from the ICE catheter. The holder must secure the device from all significant movement and be height adjustable. To meet this design challenge, the team built an initial 3D printed prototype of the final design, then fabricated the prototype out of CNC-milled and welded stainless steel as well as 3D-printed PLA. The design utilized a base plate held in place by the patient's body weight, magnets and an interlocking mechanism to connect across the sterile drape, and a quick release pole clamp for easy height adjustment.

The prototype showed statistically significant improvement in stability in comparison with current methods utilized in the catheterization lab. The device was stable, adequately height adjustable, and successfully held the two types of ICE catheter provided securely in place. However, some work remains to be done in the design and manufacturing process. Looking forward, the top piece of the device will be updated to add translational adjustability, allowing the user to slide the position of the catheter forward and backward as needed. As these design changes are being finalized, the design will be submitted for patenting and the possible manufacturing process will be evaluated.

Overall, the need for an adjustable stabilization device for intracardiac echocardiography catheters exists for physicians and catheterization laboratory personnel. There is a gap in the market as no device currently exists for the purpose of ICE catheter stabilization that can support most ICE catheters. By providing a reliable and easy-to-use solution for this problem, the device has the potential to simplify the catheterization lab workflow, which saves physicians time and increases the chances of good procedural outcomes by limiting the length of the procedures. This solution fulfills these needs and accommodates the design requirements to address the issue of stability of ICE catheters.

References

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Appendix

Appendix A: Expense Spreadsheet

Table 2: The expense spreadsheet for the design project

Material	Cost	Price Estimate	Vendor	Part Number
3D printed prototype	$6.97	$6.97	MakerSpace	n/a
Bike seat post clamp (34.9 mm size)	$8.99	$8.99	Amazon	769135257429
¼”x ¼” x ⅛” magnet (2)	$2.57	$5.14	McMaster-Carr	5848K11
¼” x ¾”x ¼” magnet (2)	$6.76	$13.52	McMaster-Carr	5848K83
1" Wide x 1/16" Thick x 10' Long Rubber sheet	$9.99	$0.42	Amazon	B08QZH58KD
2" Wide x 1/16" Thick x 10' Long Rubber sheet with adhesive backing	$12.98	$0.22	Amazon	B0BFHBXCRX
1-⅜” OD 4130 steel shaft - 1ft long	$29.37	$29.37	McMaster-Carr	89955K169
Sheet metal 4130 easy-to-weld steel 6”x36”	$63.80	$63.80	McMaster-Carr	4459T188
4130 steel rod 2”x1ft	$88.65	$88.65	McMaster-Carr	6673T34
Total		$143.21		

Appendix B: Product Design Specifications

Function

This device will be used for the stabilization of intracardiac echocardiography (ICE) equipment during structural heart intervention procedures. In order to clearly visualize a patient's cardiac structure, the ICE catheter and handle must remain still. According to the client, Dr. Amish Raval, even 3-4 mm of movement at the handle of the catheter can significantly affect the visualization of the ICE. Therefore, this device must function as an adjustable support fixture for the handle of the ICE catheter. This device will replace the current stabilization method used by the client, which typically consists of either a technician holding the handle of the catheter in place or wet towels laid on top of the catheter handle. Implementation of this stabilization device will enable the ICE catheter to remain in place while also allowing the physician to make adjustments to the catheter position throughout the procedure.

Client Requirements

The stabilizer device must:

- Have an adjustable height of 22.8 - 34.3 cm
- Allow for the manipulation of the ICE handle controls while it is secured/resting in the stabilizer
- Be able to be used for both the left and right legs
- Not interfere with the therapeutic device
- Not damage the surgical drape used in the procedure in order to maintain a sterile environment
- Be compatible with different brands/models of ICE handles
- Be made of metal and re-sterilizable via ethylene oxide, or be made of plastic, manufactured sterilized and disposable
- Cost less than $300 to manufacture

The research and development budget for the team is $1,000.

Design Requirements

1. **Physical and Operational Characteristics**
    a. *Performance Requirements:* The device must be able to securely hold the ICE handle in place while allowing for the manipulation of the ICE controls. It must also allow for vertical adjustment of the handle from 22.8 to 34.3 cm. In addition, it should be able to withstand common forces it may encounter in a surgical setting, such as bumps of the table.
    b. *Safety:* The stabilizer must be able to hold the catheter autonomously without the catheter being moved or displaced. Such displacements would provide procedural complications such as perforation of an artery or aorta or an atrioesophageal fistula formation (caused by thermal damage from the catheter in the esophagus) [1]. If the aorta is perforated, it causes immediate death in 40% of patients [2]. Additionally, the stabilizer must be properly stabilized between uses. Without proper sterilization, the device could cause serious infection or disease to the patient as the patient's femoral artery is exposed.
    c. *Accuracy and Reliability:* The device must allow complete access to the ICE catheter device's controls. The device must not allow for more than 2 mm of movement of the ICE catheter as even 3 mm of movement can misalign the system. The device should be able to work with any ICE catheter on the market and either be re-sterilizable or sterile and disposable.

d. *Life in Service:* The life in service of the stabilizer instrument is synonymous with the use duration of the device. The instrument must withstand a use duration of 30 minutes up to 3 hours in accordance with the typical length of cardiac catheterization procedures [3].
e. *Shelf Life:* The device must either be single-use or reused for numerous procedures. If a reusable instrument is designed, the device must be reusable for at least 500 procedures or 5 years, depending on the waste/device recycling procedures of the hospital or clinic in which it is used. Stainless steel surgical instruments can typically be used for over 20 years and thus the device may have the potential to be used beyond the required lifetime [4].
f. *Operating Environment:* This device will be utilized in catheterization laboratories (cath labs) which are sterile environments. All parts of the stabilizer above the sterile drape must be sterile, meaning the device must be manufactured and shipped as sterile and be disposable or must be re-sterilizable via ethylene oxide gas [5]. Additionally, the device must not damage or tear the surgical drape in any way as this would result in breaking the sterile field.
g. *Ergonomics:* The device must be fully functional with no additional human stabilization to the device. It should not interfere with any surgical procedures and must allow access to the ICE handle controls for the user to operate.
h. *Size:* The device should be as small as possible while maintaining its essential functions so as to not interfere with the other surgical procedures the ICE is supporting. If the route of a table mounted device is chosen, the device should not take up more than a 100 mm x 200 mm x 380 mm. If another design route is chosen, such as an articulating arm, the dimensions may vary as necessitated by the design. It must be able to secure a handle with a diameter of 46.45 mm at the widest and 25.14 mm at the narrowest, with some additional flexibility for adjustment of the device when used with different ICE models. There is limited space in the catheter lab for equipment; therefore, the device should take up a minimal footprint to allow the operator more room to perform the procedure and to leave space for other equipment.
i. *Weight:* As the device is intended to stabilize the ICE by securing its handle, it must have a weight of at least 1 kg to resist bumps and forces that would otherwise knock the ICE out of place. The device must not be overly heavy, however, as it should not be burdensome to set up or move; thus, the device should not weigh more than 6 kg. If alternative methods are used to secure the stabilizer to the table such as a clamp or suction cup, it could be acceptable for the device to weigh less than 1 kg.
j. *Materials:* The device must be made of a material that can withstand ethylene oxide gas sterilization. Specifically, the material must withstand a sterilization cycle of 1-6 hours at 37-63 °C and relative humidity of 40-80% [6]. Such materials could include stainless steel or thermoplastics such as PEEK; however, most commonly-used materials are highly compatible with ethylene oxide. Additionally, the material must be compatible with the chosen method of fabrication, which could potentially include CNC machining or 3D printing.
k. *Aesthetics, Appearance, and Finish:* The geometry and surface finish of the device must be compatible with gas sterilization if a reusable design is chosen; alternatively, the device should be sterile and disposable. The device should not provide a visually distracting appearance to the surgical procedures.

2. Production Characteristics

a. *Quantity:* One functional prototype of the device will be developed in order to gauge if the device integrates with the protocols for the procedure and test if the device meets all requirements.
b. *Target Product Cost:* According to the client, the device must cost under $300.

3. Miscellaneous

a. *Standards and Specifications:* As defined by the FDA in the Code of Federal Regulations, Title 21, Part 880.5210, an intravascular catheter securement device is a Class I (general controls) medical device [7]. While the FDA does not specifically call out an intracardiac catheter stabilization or securement device, a similar stabilization accessory for the MitraClip System is a Class I device [8]. Class I devices must only meet the requirements of the General Controls provisions of the CFR Title 21, Subchapter H in order to prove the device's safety and efficacy [9]. Additionally, ISO 13485, which includes requirements for regulatory purposes of medical devices, states that the design and development process outputs must be documented in a form suitable for verification against the design and development requirements [10].
b. *Customer:* The customer of this device requires that the device improves upon the current method of ICE catheter stabilization. Customers for this product include physicians and hospital or medical clinic staff. The device must streamline the process of performing interventional heart procedures with the goal of improving accuracy and efficiency of the procedures.
c. *Patient-Related Concerns:* The device must be inclusive for use with all patients. Patients undergoing structural heart intervention procedures may be likely to have increased waist circumference or waist to hip ratio as these metrics are predictive of cardiovascular disease [11]; thus, the functionality of the device must be independent of patient size. Additionally, the device must not cause discomfort for the patient during the procedure.
d. *Competition:* There are many ICE catheter stand and clamp systems on the market. The Abbott MitraClip and Triclip are held up by a stand that allows for the attachment of a mitral valve replacement device at an angle to allow for the user to easily access the controls [12]. Furthermore, the Edwards EVOQUE comes on a base plate that has a stabilizer to hold a tricuspid valve replacement device. This also comes with adjustable leg height and clamps [13]. Both the EVOQUE and the MitraClip are similarly sized to ICE catheters.

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Appendix C: 3D Printed Prototype Fabrication Protocol

Materials:

- SolidWorks File
- Flash drive
- Computer

3D Printing Procedure:

1. Convert SolidWorks models to STL file and save them to a flash drive.
2. Open STL files and import into 3D printer slicing software - Bambu Studio.
3. Place pieces on the build plate and set printing parameters.
4. Layer thickness - 0.28 mm
5. Infill - 20%
6. Support type - organic
7. Slice the file, export to flash drive.
8. Complete payment information with Makerspace form.
9. Start 3D print on the printer.

Appendix D: Stainless Steel Prototype Fabrication Protocol

Materials:

- SolidWorks File
- CNC Lathe
- CNC Mill
- MIG Welding
- Permits for CNC
- Permits for MIG Welding
- 4130 steel rod 2"x1ft

- Sheet metal 4130 easy-to-weld steel 6”x36”

CNC Lathe:

1. Open SolidWorks file of the solid middle tube
2. Obtain 4130 steel rod 2”x1ft
3. Convert SolidWorks file into G code
4. Select correct tools and speeds
5. Secure part in spindle and load tools
6. Begin program
7. Repeat the process for hollow middle tube and top part

CNC Mill:

1. Open SolidWorks file of Solid Middle tube
2. Obtain solid middle tube after it is done with CNC Lathe and Sheet metal 4130 easy-to-weld steel 6”x36”
3. Convert SolidWorks file into G code
4. Isolate the top part with the magnets
5. Create toolpaths, selecting optimal end mill bits
6. Upload G code to CNC mills
7. Secure part in vice and load correct tools into the machine
8. Begin program
9. Repeat the process for top part, hollow middle tube, and base

MIG Welding:

1. Obtain hollow middle part and base
2. Use PPE
3. Turn on MIG machine
4. Ensure the filling is appropriate
5. Use 75% argon and 25% carbon dioxide
6. Use 200 amps
7. Make sure hollow middle part and base are in appropriate placement based on SolidWorks (off-centered by 30.48 cm)
8. Put gun 45 degrees between base and hollow middle tube
9. Begin weld
10. Cool weld and check that it looks sufficient
11. Turn everything off

Appendix E: Force Testing Protocol

Materials:

- 4D ICE Catheter
- 3D ICE Catheter
- Prototype
- Duct tape
- Spring force gauge
- Wet towels (2)

Procedure:

1. Place 3D ICE catheter into the saddle of the prototype.
2. Hook the spring gauge onto the front end of the catheter in the vertical direction, perpendicular to the axis of the catheter.

3. Apply a downward force with the spring gauge until the magnets in the prototype become disconnected. Record this force value.
4. Repeat step 3 for a total of 5 trials.
5. Hook the spring gauge onto the front end of the catheter in the transverse horizontal direction, perpendicular to the axis of the catheter.
6. Apply a transverse (twisting) force to the prototype via the spring gauge until the magnetic saddle twists off of the prototype. Record this force value.
7. Repeat steps 5-6 for a total of 5 trials.
8. Tape the hook of the spring gauge to the front end of the catheter in the axial direction.
9. Apply a tensile force with the spring gauge to the catheter until the magnets in the prototype become disconnected. Record this force value.
10. Repeat steps 8-9 for a total of 5 trials.
11. Repeat steps 1-10 with the 4D ICE catheter.
12. Wrap the 3D ICE catheter with one of the wet towels, then drape the second towel over the top of the 1st towel.
13. Repeat steps 5-10 with the 3D catheter in the towels.
14. Repeat step 12 with the 4D ICE catheter.
15. Repeat steps 5-10 with the 4D catheter in the towels.
16. Once all force values have been collected, upload data into MATLAB.
    a. The following code can be used to graph the data:

```
device_4d_bendingXL = [4.2, 4.0, 3.8, 3.8, 4.0];
device_3d_bendingXL = [4.6, 4.4, 4.2, 4.4, 4.4];
device_4d_bendingS = [10.0, 10.0, 10.0, 10.0, 10.0];
device_3d_bendingS = [10.0, 10.0, 9.8, 9.2, 10.0];
towel_bending = [0.8, 0.6, 0.7, 0.6, 0.5, 0.2, 0.4, 0.3,
0.4, 0.3];
mean_device_d4_bendingXL = mean(device_4d_bendingXL);
mean_device_d3_bendingXL = mean(device_3d_bendingXL);
mean_device_d4_bendingS = mean(device_4d_bendingS);
mean_device_d3_bendingS = mean(device_3d_bendingS);
mean_towel_bending = mean(towel_bending);
std_device_d4_bendingXL = std(device_4d_bendingXL);
std_device_d3_bendingXL = std(device_3d_bendingXL);
std_device_d4_bendingS = std(device_4d_bendingS);
std_device_d3_bendingS = std(device_3d_bendingS);
std_towel_bending = std(towel_bending);
means = [mean_towel_bending, mean_device_d4_bendingS,
mean_device_d4_bendingXL, mean_device_d3_bendingS,
mean_device_d3_bendingXL];
stds = [std_towel_bending, std_device_d4_bendingS,
std_device_d4_bendingXL, std_device_d3_bendingS,
std_device_d3_bendingXL];
figure(1);
bar(means);
hold on;
errorbar(1:5, means, stds, 'k', 'LineStyle', 'none',
'CapSize', 10);
xticks(1:5);
xticklabels({'Towel', 'Device 4D Small', 'Device 4D XL',
'Device 3D Small', 'Device 3D XL'});
xtickangle(30);
```

```
ylabel('Force (Newtons)');
title('Twisting Force Comparison');
set(gca, 'FontSize', 14);
ylim([0 12]);
hold off;
```

b. The following code can be used to obtain p-values for the data:

```
%% Force testing
% Device vs. Towel
[h,p] = ttest2(Tensile4D_t,Tensile_d)
[h,p] = ttest2(Twisting4D_t,Twisting4D_d)
[h,p] = ttest2(Tensile3D_t,Tensile_d)
[h,p] = ttest2(Twisting3D_t,Twisting3D_d)

% 4D vs 3D
[h,p] = ttest2(Bending3D_d,Bending4D_d)
[h,p] = ttest2(Twisting3D_d,Twisting4D_d)
% for tensile, p>0.05

% Mean values
bending4D_d_mean = mean(Bending4D_d)
bending3D_d_mean = mean(Bending3D_d)
twisting4D_d_mean = mean(Twisting4D_d)
twisting3D_d_mean = mean(Twisting3D_d)
tensile4D_t_mean = mean(Tensile4D_t)
tensile3D_t_mean = mean(Tensile3D_t)
twisting4D_t_mean = mean(Twisting4D_t)
twisting3D_t_mean = mean(Twisting3D_t)
```

Appendix F: Force Testing Configuration Images

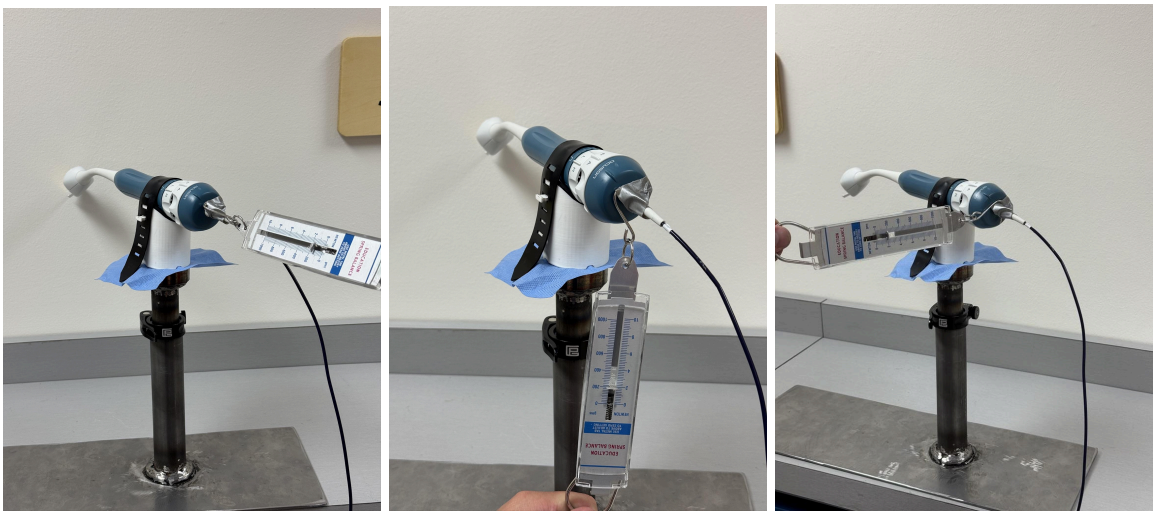


Fig. 1: 3D ICE Catheter in tensile (left) bending (middle) and torsional (right) force test configurations in device

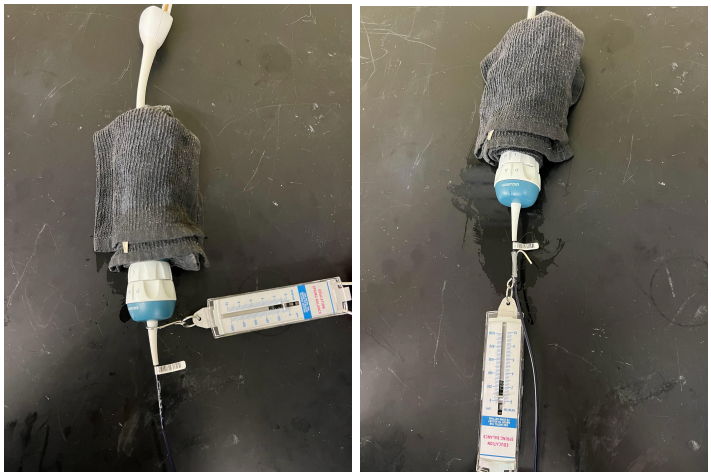


Fig. 3: 3D ICE Catheter in torsional (left) and tensile (right) force test configurations weighted with wet towel

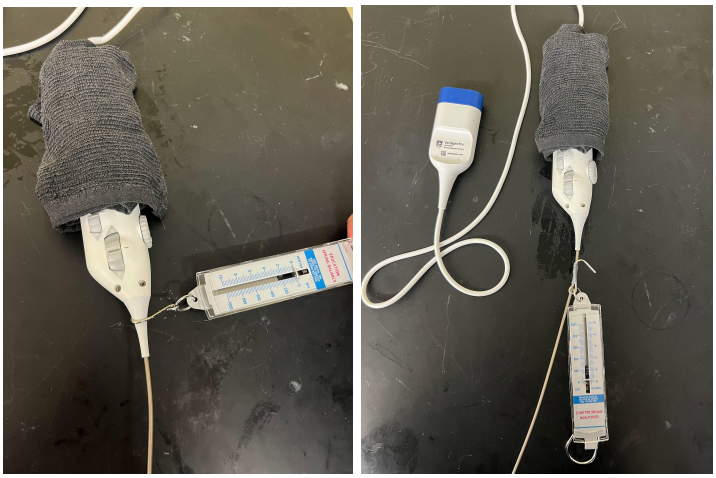


Fig. 4: 4D ICE Catheter in torsional (left) and tensile (right) force test configurations weighted with wet towel

Appendix G: Force Testing Data Tables

Table 1: Raw data of force testing

4D ICE Catheter in Device S			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	3.8	10.0	10.0
2	4.2	10.0	10.0

3	4.4	10.0	10.0
4	4.2	10.0	10.0
5	4.2	10.0	10.0
Mean:	4.16	10.0	10.0
3D ICE Catheter in Device S			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	7.2	10.0	10.0
2	7.8	10.0	10.0
3	6.4	10.0	9.8
4	6.4	10.0	9.2
5	7.4	10.0	10.0
Mean:	7.0	10.0	9.8

4D ICE Catheter in Device XL			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	5.6	7.0	4.2
2	5.8	7.0	4.0
3	5.6	6.8	3.8
4	6.4	6.8	3.8
5	6.0	6.6	4.0
Mean:	5.88	6.8	4.0
3D ICE Catheter in Device XL			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	9.0	7.4	4.6
2	9.8	7.6	4.4
3	9.8	7.8	4.2
4	8.8	8	4.4
5	8.4	7.6	4.4
Mean:	9.2	7.68	4.4
4D ICE Catheter with Wet Towels			

Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	n/a	1.1	0.8
2	n/a	1.2	0.6
3	n/a	1.6	0.7
4	n/a	1.7	0.6
5	n/a	1.9	0.5
Mean:		1.5	0.64
3D ICE Catheter with Wet Towels			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	n/a	1.4	0.2
2	n/a	1.8	0.4
3	n/a	1.6	0.3
4	n/a	1.8	0.4
5	n/a	1.9	0.3
Mean:		1.7	0.32

Table 2: P-values comparing wet towel method to the device with 3D and 4D catheters, as well as S and XL top pieces.

	Towels vs. 4D, S	Towels vs. 4D, XL	Towels vs. 3D, S	Towels vs. 3D, XL
Tensile Force	0.00000061	0.00001867	0.00000008	0.00000051
Twisting Force	0.00000001	0.00000144	0.00000073	0.00000118

Appendix H: Drape Tensile Testing Protocol

Materials:

- Drape
- Scissors
- Ruler/Tape Measure
- MTS machine
- Tensile Grips
- 10 kN load cell

Procedure:

1. Cut drape into 3 samples of 5 cm by 10 cm

2. Check to ensure proper load cell and tensile grips are attached to the MTS machine. If not remove previous load cell and grips and replace with proper equipment.
3. Turn on both the MTS machine and MTS software. Load up a tensile test format on the software and set speed at 1 mm/s
4. Load a drape sample into tensile clamps ensuring no slipping out of grip will happen. It should leave about 5 cm of gauge length to displace.
5. Turn off the lock on the MTS controls and move the crosshead up until the load appears positive on the software then zero both the crosshead and the load.
6. Click run test and enter data for the sample (width: 50 mm, thickness: 1 mm, gauge length: 50 mm, target strain: 100%). Click enter once all information is ensured to be correct. This will commence the test and cause the crosshead to raise. Once the break has happened, hit stop test and reset to zero.
7. Remove broken drape sample and load up new sample and repeat for all samples.
8. Export raw data for calculations and matlab graphing.
9. Clean up the MTS machine and ensure everything is restored to how you found it.

Appendix I: SolidWorks Stress Analysis Protocol

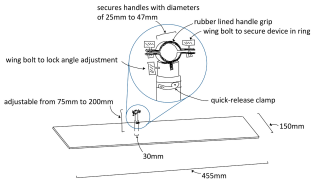
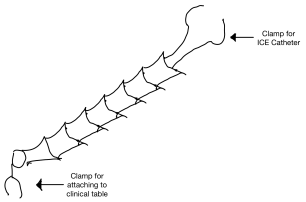
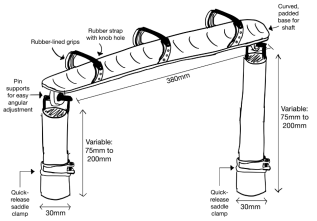
Materials:

- SolidWorks model of prototype

Procedure:

1. Open model in SolidWorks.
2. Open SimulationXpress Analysis Wizard.
3. Apply a fixture to the bottom of the base plate of the device.
4. Apply a transverse load of 38N to the top 20mm of the shaft.
5. Apply the material: AISI 4130 (annealed) Steel
6. Run Simulation.
7. Click to show Stress results (von Mises stress)

Appendix J: Design Process

Criteria	**Weight**	**1.** Body Weight Holder 		**2.** Gooseneck Arm 		**3.** Sliding Legs 	
Sterilizable	25	**5/5**	**25**	2/5	10	4/5	20
Usability & Security	20	3/5	12	**4/5**	**16**	**4/5**	**16**

Adjustability	15	3/5	9	**5/5**	**15**	**5/5**	**15**
Adaptability	15	3/5	9	**4/5**	**12**	3/5	9
Cost	15	4/5	12	**5/5**	**15**	4/5	12
Ease of Fabrication	5	3/5	3	**4/5**	**4**	3/5	3
Safety	5	4/5	4	3/5	3	**5/5**	**5**
Total	100	74		75		**80**	