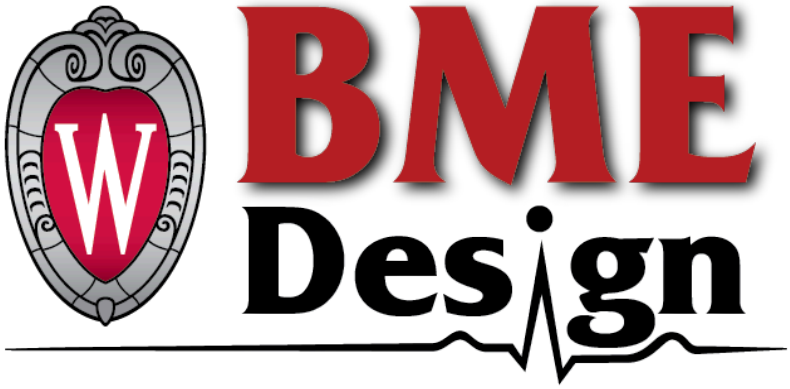

Stabilizer Device for Intracardiac Echocardiography (ICE) to Assist Structural Heart Interventional Procedures

Final Report

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BME 400

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Abstract

Heart disease is the leading cause of death in the United States and many heart procedures are complex and difficult for many doctors to perform [1]. An intracardiac echocardiography (ICE) catheter is a device used during structural heart intervention procedures to observe the area of interest in the heart of the patient using ultrasound. Once inserted, the ICE catheter is either held by an assistant or held down by a wet towel to prevent the movement of the imaging crystal at the tip of the catheter. The catheter, however, can easily shift out of place and disturb the image as the external portion of the catheter moves outside of the patient, causing issues and delays in the procedure. A device that holds the catheter's shaft while in use could solve this issue and prevent delays and complications. The team has been tasked with designing and building a novel ICE catheter mount system that allows the doctors to secure the placement of any brand ICE catheter. It should allow for height adjustment in order to align with the entry point into the patient. As it is used in a catheterization lab, the design must either be fully sterilizable or disposable in order to ensure proper sanitation in the catheterization lab. The device should also allow for minimal movement of the ICE catheter in order to ensure the image from the catheter is steady. The team's proposed solution to this problem is a three part device with height adjustable base and middle parts that are placed beneath the sterile drape and an adaptable clamp attached over the drape with magnets and an interlocking mechanism. A prototype of this device was fabricated and tested in comparison with the current method of securing the catheter handle. The device proved to be a significant improvement over the current method used in the catheter labs. Future work will focus on further testing and improving the design to create the best possible solution to the challenge of ICE catheter stabilization.

Table of Contents

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]. 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 [5].

In order to prevent such complications, the ICE catheter must remain still and secured into place throughout the duration of the procedure. 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 the therapeutic intervention. These methods, however, are not ideal as they either require additional labor, as with the tech holding the handle, or do not fully fix the handle into place, as with the wet towels. 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). The MitraClip catheter is used to treat mitral valve regurgitation percutaneously; in order to ensure the secure positioning of the catheter deployment device, the MitraClip System includes a stabilizer device that holds the handle of the catheter device at a fixed angle [6]. Similarly, the Edwards EVOQUE Tricuspid Valve Replacement System is a therapeutic transcatheter device to replace the tricuspid valve [7]. The EVOQUE System utilizes a stabilizer device that holds the catheter at an adjustable position atop a base plate and platform (Fig. 2). These proprietary devices provide stabilization solutions for specific therapeutic catheter systems, but do not fulfill the need for stabilization of imaging catheters. Therefore, a novel device suited for ICE catheter stabilization must be developed in order to address this gap in cardiac imaging and interventional procedures.

Fig. 1: MitraClip Delivery System with stabilizer device [6].

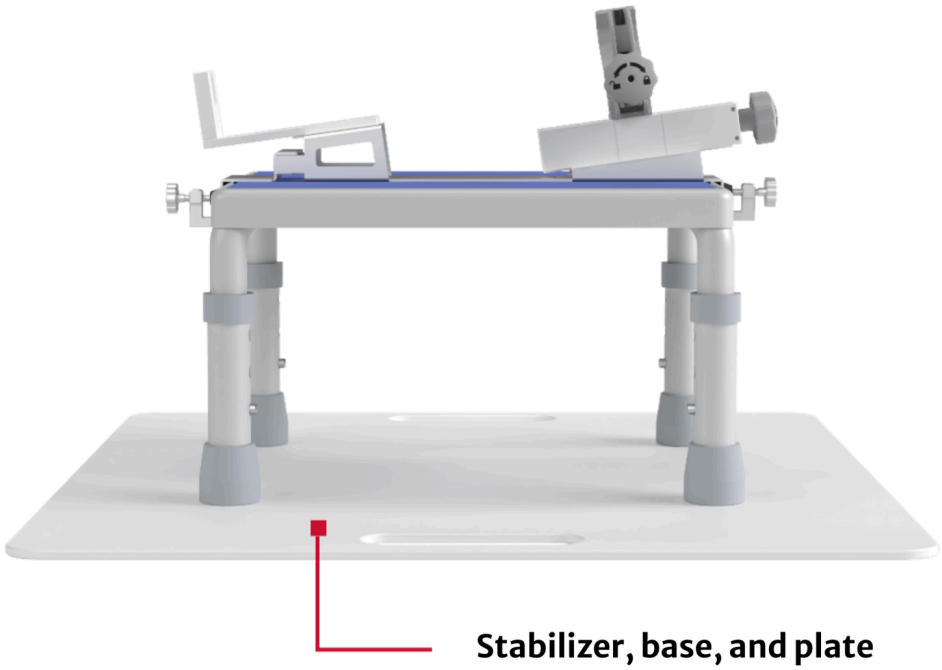


Fig. 2: Edwards EVOQUE Tricuspid Valve Replacement System stabilizer, base, and plate [7].

Background

The ICE catheter is used to obtain high-resolution, real-time images of certain areas of the heart for various cardiac procedures. This imaging device offers significant improvement over other procedures because it only requires a local anesthetic. In the past, physicians would have to use transesophageal echocardiographic probes (TEE) to image a similar area. However, TEE requires the patient to be under anesthesia [8]. Therefore, TEE creates serious risks compared to ICE because general anesthesia can cause cognitive problems such as neurotoxicity and neuroapoptosis [9]. ICE offers a less invasive, safer approach to cardiac imaging.

During a procedure, the ICE catheter is first inserted to image the area of interest. Specifically, it is injected through the femoral vein and guided into the right atria where the physician can use it to view other chambers of the heart [10]. Then, a therapeutic device is typically inserted to treat the problem or defect. The ICE catheter is able to produce an image because of the 64-element ultrasound transducer at the end of the probe [4]. This transducer is able to produce an image on an ultrasound machine, which the physician is able to use to visualize the patient's heart [11]. Also, ICE catheters use Doppler to measure flow through different components of the heart. [4]. Thus, this is an extremely powerful and useful tool in the field of cardiology. However, there are issues with stabilization of the catheter, as even slight shifts in catheter placement can affect the images produced by the transducer. The client, Dr. Amish Raval, is an interventional cardiologist who uses the ICE catheter for procedures. Dr. Raval has testified to his experience with ICE catheters, explaining that when the ICE catheter is set down after guiding it into place, it often moves out of the place of interest. During the procedure, as the patient breathes, their chest rises and falls. Therefore, the catheter gets shifted and displaced. Dr. Raval has requested the team to design and build a device that can attach to a variety of ICE catheters, regardless of brand or model, to ensure that it does not move during the procedure. This device must allow for the user to adjust the height of the catheter to accommodate patients of different sizes. Furthermore, the stabilizer must be sterilizable in order to be reused between patients. Complete design specifications are found in Appendix B.

Preliminary Designs

Design 1: Gooseneck

The 'Gooseneck' design features a chain of interlocking modular units which articulate with one another (Fig. 3). When in series, this produces a large range of motions with many degrees of freedom. One end is to be anchored to the operating table via a table clamp, which is applied over the sterile drape. Each unit is around 25 mm x 30 mm x 60 mm. The other end features a pole clamp which attaches to the ICE catheter handle at whichever point is convenient for the operator. The pole clamp, which has a rubber lining to prevent movement, is able to secure poles of varying diameters, which allows it to be compatible with different brands and

models of catheters. Because the design is modular, the length of the chain can vary to accommodate different situations. The units can also be taken apart to be more easily re-sterilized. When utilized in a catheterization lab, an operator or assistant will secure the table clamp to the operating table over the sterilized drape and then bend the arm to the desired orientation and position of the pole clamp. After the ICE catheter is inserted into the femoral vein, the handle will be secured into the pole clamp via the two wing bolts on the pole clamp.

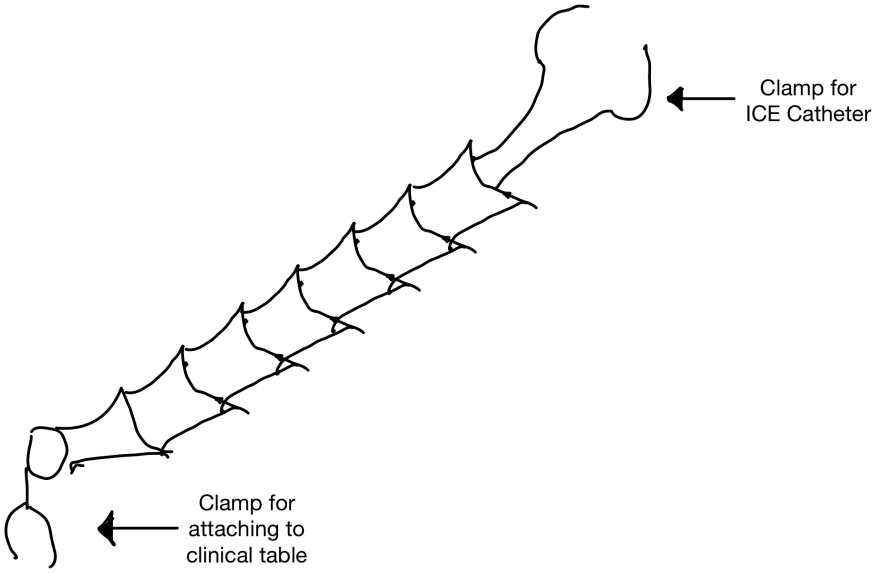


Fig. 3: 'Gooseneck' overall design

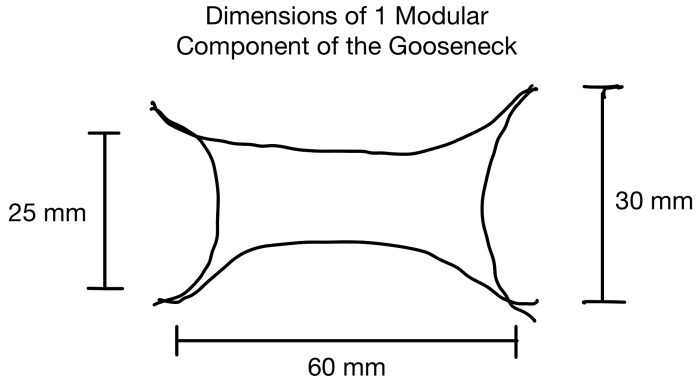


Fig. 4: 'Gooseneck' modular unit

Design 2: Bodyweight Holder

The ‘Body Weight Holder’ design features a thin metal base plate on top of which rests the patient's legs, holding the device in place (Fig. 5). Offcentered on the plate, so as to position it next to the medial surface of the thigh, is a vertical pole that is height adjustable via a quick release clamp. Atop this pole is a rubber lined pole clamp that is angularly adjustable via a screw on the side of the pole. The pole can be raised or lowered to position the catheter handle 75 mm to 200mm from the base plate, and the angular adjustment can be from 0° to -30° from parallel to the base plate. The pole clamp can accommodate poles of diameters from about 25 mm to 47 mm, making it compatible with different brands and models of catheters. The design can be rotated 180° to position the pole next to the other leg. The procedure for using the device includes sliding it under the patient’s legs while they are lifted by an assistant, placing the legs on top of the plate with the pole next to the medial surface of the patient’s thigh, and raising the pole to the appropriate level. The ICE catheter handle can then be secured in the pole mount after it has been inserted into the femoral vein, and the angle adjusted.

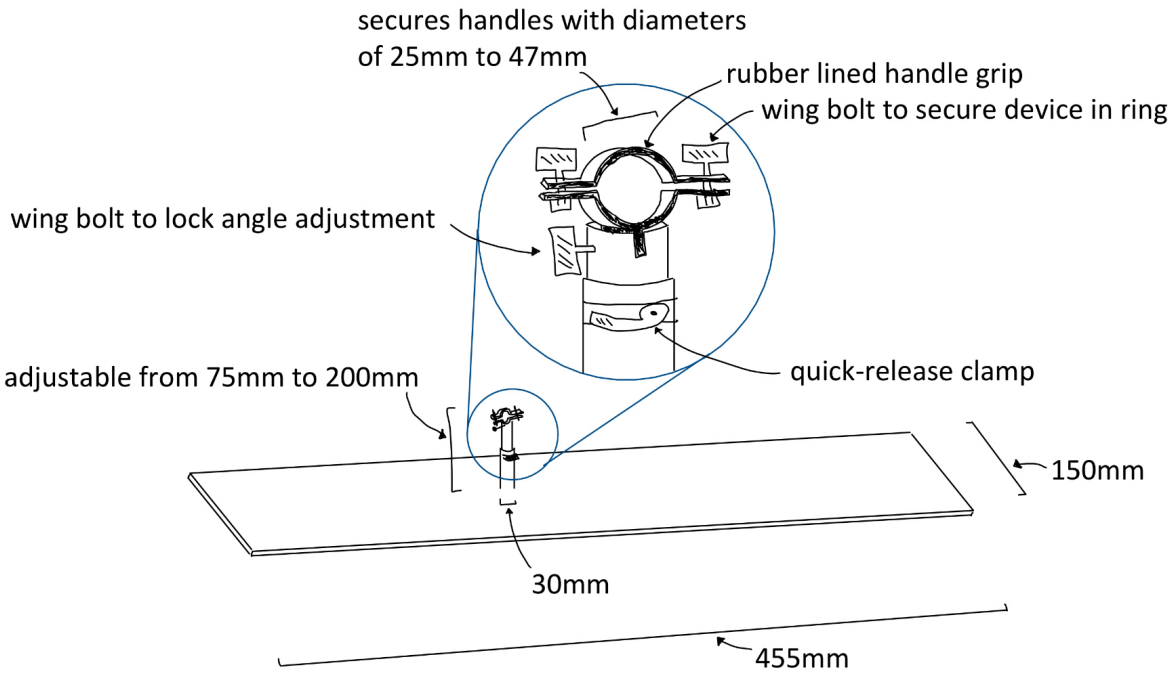


Fig. 5: ‘Body Weight Holder’ design

Design 3: Sliding Legs

The “Sliding Legs” design consists primarily of two cylindrical shafts, attached to a bottom plate, that support a base pad on which the shaft of an ICE catheter will rest. These cylindrical shafts are extensible via quick-release saddle clamps, the same mechanism that an adjustable-height bike seat utilizes. The height of the shafts will be able to be adjusted between 75 mm - 200 mm. The base pad connects to the cylindrical shafts via simple pin supports, which

will allow the base to rotate freely about these points. By simply altering the height of one or both of the cylindrical shafts, one can simultaneously adjust the angle at which the base pad, and by extension the ICE catheter, sits at. This angle is adjustable in the range of 0° (parallel to the table) to 29.5° (posterior shaft fully extended). To account for the displacement of the posterior shaft as the angle adjusts, depicted in Fig. 7, the posterior shaft will be attached to the bottom plate on a sliding track. The front shaft will be fixed in place on the bottom plate to provide stability to the device. Additionally, the base pad on which the ICE catheter will rest includes straps to hold the shaft in place. These straps will be rubber-lined to create friction between the plastic shaft and the straps in order to provide sufficient counter-torque to prevent unwanted rotation of the shaft.

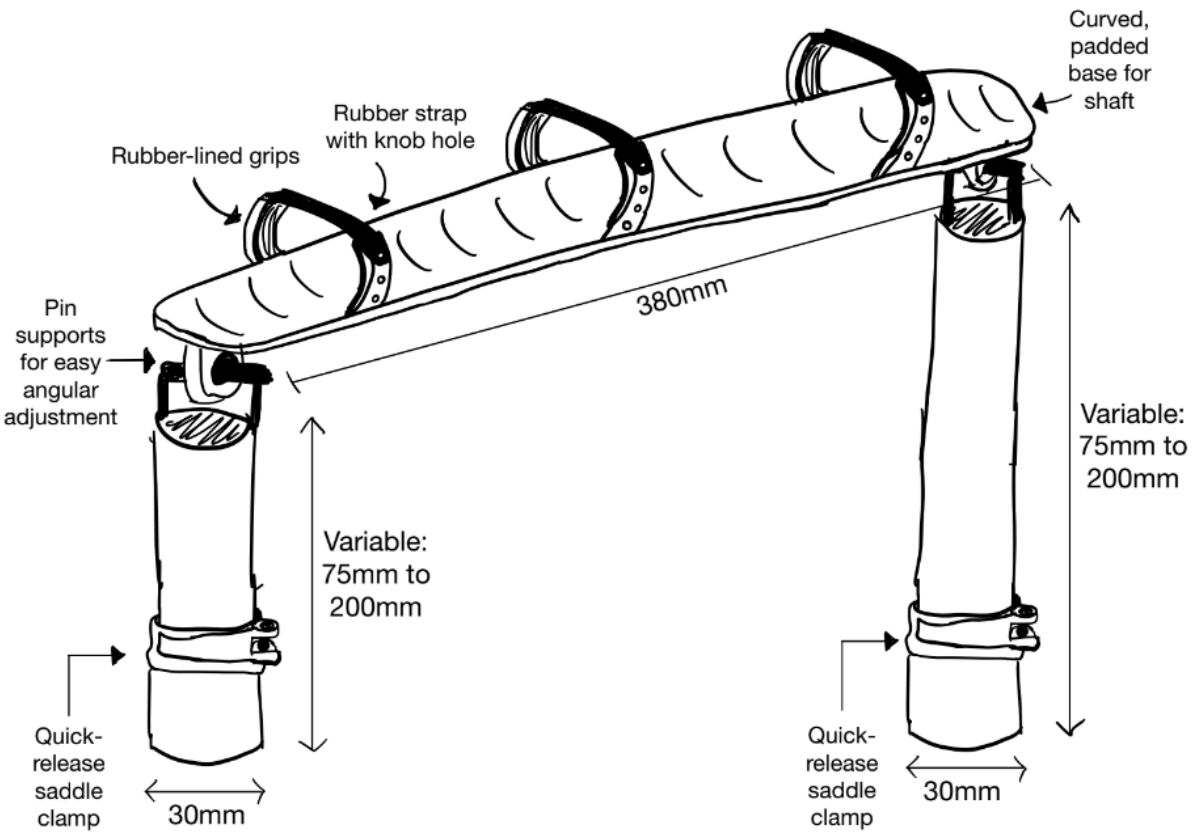


Fig. 6: ‘Sliding Legs’ stabilizer design

To use the Sliding Legs device, the physician or tech assisting will first place a platform over the knee and lower thigh of the patient below the sterile drape. Once the drape has been placed, the sterile Sliding Legs device can be placed on top of the platform. After initially inserting and advancing the ICE catheter into place inside the patient’s heart, the physician or tech can adjust the legs of the Sliding Legs device to the desired height and angle and secure in place via the clamps. Next, they will simply place the shaft of the ICE catheter onto the base pad

and secure the straps around the shaft. At this point, the physician will be able to leave the ICE catheter in position in the device while they perform the rest of the interventional procedure.

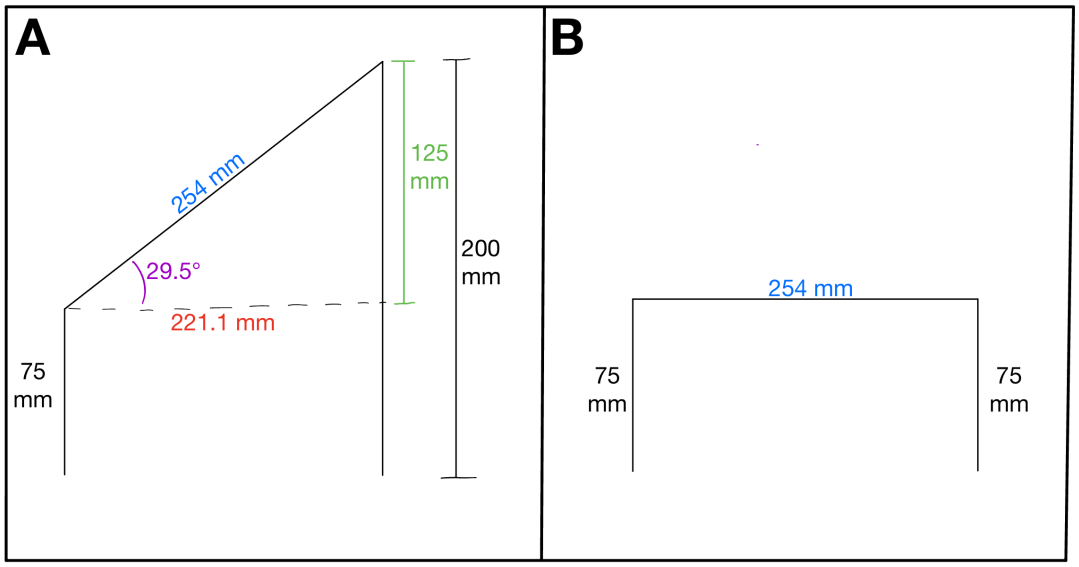


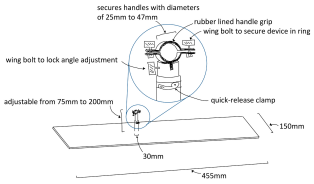
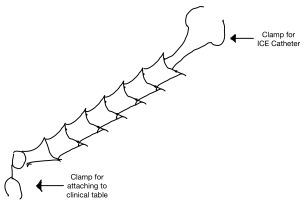
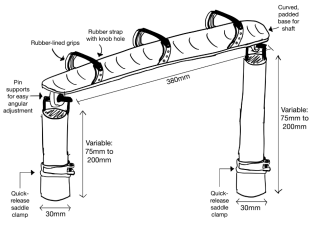
Fig. 7: A. Position & angle of the Sliding Legs design with a fully-extended posterior shaft. B. Position & angle of the Sliding Legs design with a fully-contracted posterior shaft.

Preliminary Design Evaluations

Design Matrix

To evaluate the three design ideas, the following design matrix was created based on seven design criteria, which are elaborated on further below.

Table 1: Design matrix for evaluation of the three design ideas.

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**	

Sterilizable

The sterilizability of the design is the most important design criteria as the device will be used in a catheterization lab and will need to be sterilized in order to be used in the lab. The device should be sterilizable through ethylene oxide, heat, or gas methods with ethylene oxide being the most commonly used method. The Body Weight Holder scored the highest as it is the most simple in structure and geometry; the Body Weight Holder also consists largely of smooth surfaces, which allows for easier penetration during sterilization. The Gooseneck Arm scored the

lowest as it would be required to be broken down to individual components to be sterilized. The Sliding Legs design scored in between the other designs as it consists of more complex components than the Body Weight Holder, which may be more difficult to sterilize, yet would not require full disassembly like the Gooseneck Arm.

Usability & Security

The usability and security of the design is important to the functionality of the design. The usability of the design encapsulates the ability of the doctor to access and use the controls of the ICE catheter while placed in the stabilizer device. The security of the design refers to the ability of the device to limit movement of the catheter. These two criteria were combined as they both assess the ability of the device to function in accordance with the preferences of the user. The Sliding Legs design and the Gooseneck Arm tied for the highest score in usability and security. The Gooseneck Arm attaches to only a small section of the catheter handle, which should not impede the physician from accessing the directional controls of the catheter, but could affect stability of the device. The Sliding Legs securely holds the catheter, resulting in a superior securement of the catheter, while still allowing for access to the catheter controls. The Body Weight Holder scored lower as it is only a one-leg system, which may not hold on to the catheter handle as securely as the other designs. However, it still allows for access to the device controls.

Adjustability

The adjustability of the function is another essential criteria to consider when evaluating the designs. Adjustability encompasses the range of motion of the device in the angular, vertical, and horizontal direction. This is critical for the function of the device as the catheter must remain in line with the insertion point near the groin of the patient; to do so, the device must enable the physician to secure the catheter in any position required. The Gooseneck Arm and the Sliding Legs designs both scored highly in this category as they can allow for adjustment of angle and height smoothly and freely. The Body Weight Holder scored slightly lower than the other designs because the positioning of the Holder would be fixed as it is held in place by the weight of the patient, which could somewhat limit the range of motion available for the device.

Adaptability

The adaptability of the design is the ability of the design to secure many different brands of ICE catheters. As the catheters come in many different sizes and shapes, it is important to have an adaptable format of securing the catheter. The Gooseneck Arm had the highest score here as it has an adjustable clamp design to secure the catheter. The Sliding Legs and Body Weight Holder scored slightly lower as they did not provide the same overall adaptability and favored the design of the given ICE catheter.

Cost

The cost of a design is important to consider in all engineering designs. The project was given a goal to limit manufacturing cost of the device to $300, and designs were evaluated based on that standard. The Gooseneck Arm scored the highest as it would simply consist of multiple copies of the same modular piece that could be injection molded or milled easily. The other designs also scored highly as they will be relatively low-cost to fabricate with potential materials of stainless steel; however, the other designs involve more components that will need to be purchased for final device assembly, which would increase the cost of the device.

Ease of Fabrication

The ease of fabrication is important to lowering manufacturing costs and reducing potential mechanical errors in future use. The Gooseneck Arm scored the highest as it would simply be the same part fabricated multiple times to snap on to each other. The Sliding Legs and Body Weight Holder finished slightly lower as both designs involve installing more clamps, straps, and plates in the fabrication process.

Safety

Safety is an essential criteria to consider in medical device design as design choices can have significant impacts on patient well-being. For this project, safety refers to the ability of the device to limit possible malfunctions or failure modes, such as dropping the catheter handle; a failure mode such as this could potentially cause the catheter to rip or tear blood vessels inside the patient. While there is a relatively low chance of this occurrence, it is still important to consider. The Sliding Legs scores the best as the catheter handle is laying on a plate, not allowing the catheter to drastically move in the event of a malfunction. The Gooseneck scores the lowest as it could potentially be flimsy and be bumped out of place; additionally, the weight of the catheter could possibly deform the arm out of the intended position.

Proposed Final Design

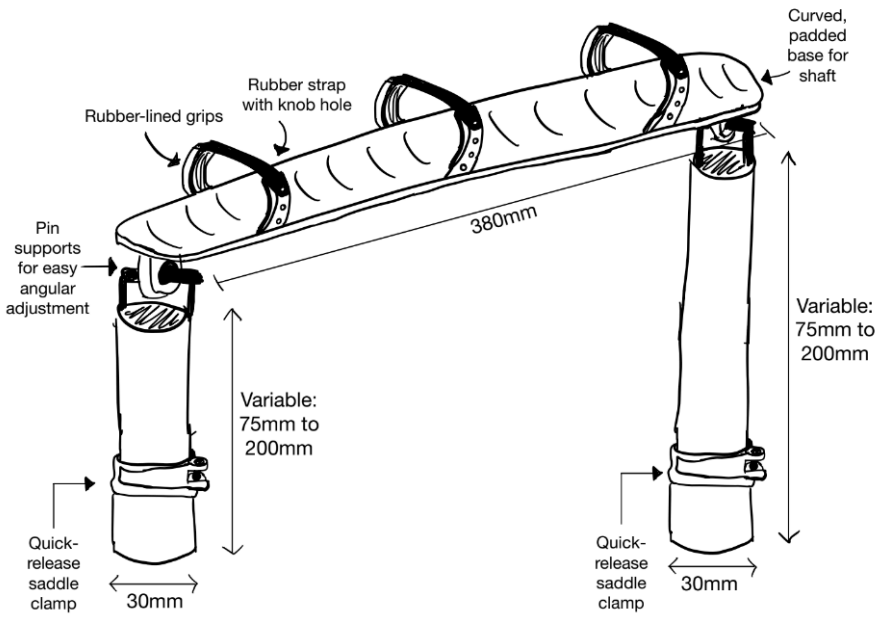


Fig. 8: 'Sliding Legs' Final Design

In the design matrix, the Sliding Legs design was evaluated to score the highest when considering the ease of use and the mechanism of adjustability. It also scored relatively high in the rest of the categories; as a result, the Sliding Legs design had the highest overall score. Additionally, the design is estimated to cost approximately $100-$150 for initial prototype fabrication, a value which could be reduced as material and component choices are finalized. Based on the results of the design matrix and team deliberation, the Sliding Legs design has been determined to be the proposed final design. Its easy usability combined with its simple yet effective design have led to this decision. Several aspects of the other designs may be incorporated into this design, including the base plate of the Body Weight Holder and the clamp attachments of the Gooseneck Arm. The team will incorporate these components, refine the design, and gain further insight from the client before beginning to fabricate a prototype.

Final Design

After sharing the design matrix and designs with the client, some criteria were deemed unnecessary, such as the angular adjustment of the catheter. After re-evaluating the desired functionality of the product, the client and the team incorporated design features from both the sliding legs and the body weight holder into the final design, as well as some additional features, including the magnetic connection between the middle and top piece in order to maintain the integrity of the sterile drape. The design is pictured below in Fig. 9-12.

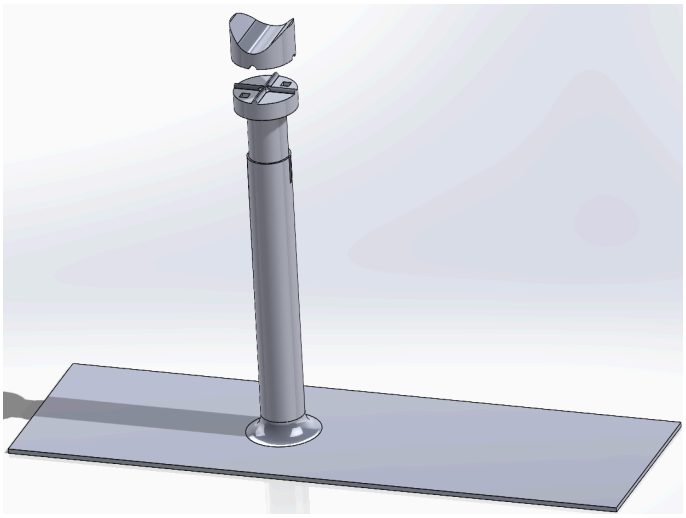


Fig. 9: Solidworks assembly; all three components combine to hold the catheter handle above the patient's leg and the sterile drape at the optimal height

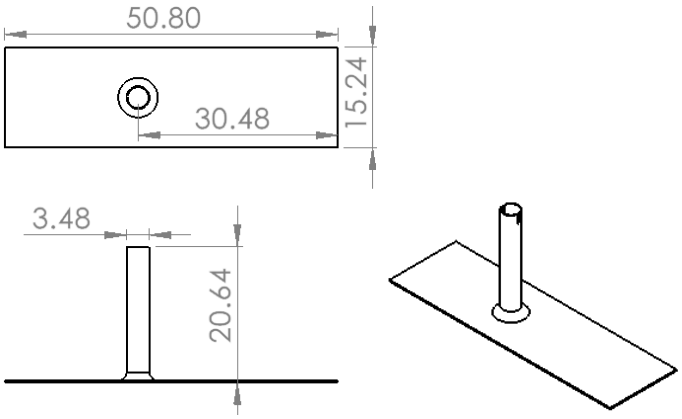


Fig. 10: Base part; the patient's legs shall rest atop the base plate on either side of the pole; dimensions listed in cm.

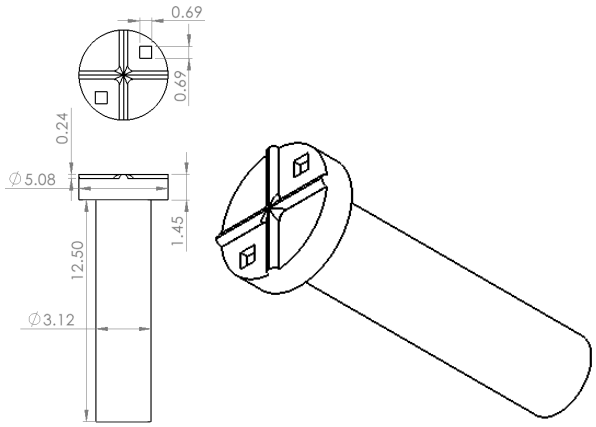


Fig. 11: Middle part; the pole can slide inside the base pole to adjust the height, and secured in place with a pole clamp; dimensions listed in cm.

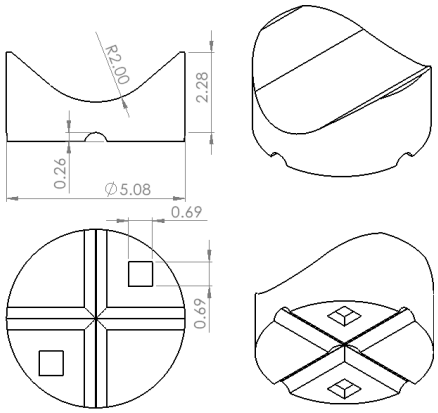


Fig. 12: Top part / catheter saddle; this piece magnetically attaches to the top of the middle piece over the sterile drape and holds the catheter handle on top; dimensions listed in cm.

The final design involves three separate parts, dubbed the base, middle, and top parts. The base part (Fig. 10) consists of a flat base plate and singular offcentered vertical pole, similar to that of the body weight holder design. The middle part (Fig. 11) is able to slide vertically into the pole of the base part, and be secured at different heights via a pole clamp. 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 (Fig. 12) 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. The 'U' allows for any different brand or type of ICE catheter to be placed on the device as it is ubiquitous. A silicon strap will be affixed to one side of the top part and will attach to the other side over the catheter handle to secure it in place.

To use the device, the catheter lab technicians will place the base and middle parts together down onto the operating table and place the foam leg supports on top of the base plate on either side of the pole. The patient will then be placed on the table with their legs on the foam supports, holding the device down onto the operating table. The height of the middle part will then be adjusted to the optimal height, before the sterile drape is placed over the patient and the device. The top part can then be magnetically secured to the middle part on top of the sterile drape. When the catheter is inserted in the patient in the desired position, the handle will be placed in the saddle of the top part and secured with the silicone strap.

Fabrication/Development Process

a. Materials

When considering the material choices for the device, a few factors must be considered. First and foremost, the material must be sterilizable via ethylene oxide or autoclave sterilization. While autoclave sterilization applies strict constraints for compatible material properties,

including that the material must withstand 121℃ for 30 mins [12], ethylene oxide sterilization imposes much less strict requirements. Materials undergoing ethylene oxide sterilization must withstand 1-6 hours at 37-63 °C, with a relative humidity of 40-80% [13]. Therefore, most commonly used thermoplastics and polymers, as well as metals, are compatible with ethylene oxide gas.

For initial prototyping, the three main device components were 3D-printed out of poly-lactic acid (PLA), which can withstand temperatures of 57℃ and has high strength and stiffness. Additionally, it is priced at $0.05 per gram through the UW-Madison Design Innovation Lab [14]. Using this material enabled rapid prototyping at a low-cost, which provided the team freedom to design in an iterative process. However, it is important to note that this material is not capable of undergoing autoclave (heat) sterilization.

For the upcoming proof-of-concept prototype fabrication, the three main device components will be made of AISI 4130 annealed steel alloy, which has a yield strength of 460 MPa [15]. Fabricating the device from steel will allow it to withstand both ethylene oxide and autoclave sterilization. This versatility will enable the device to serve a wider range of applications and customers.

Additional device components include the quick-release clamp, rubber lining, rubber straps, and magnets. The quick release clamp is made of aluminum alloy, while the lining and straps will be made of neoprene rubber. These materials exhibit excellent stability and minimal property changes following ethylene oxide sterilization [16], making them compatible with the requirements of this device. Lastly, neodymium magnets will be used in the device. If deemed necessary during sterilization testing, these magnets can be purchased with a nickel coating for added corrosion resistance.

b. Methods

In order to build the 3D printed stabilizer device prototype, the team first created an exact design using Solidworks. This model includes all proper dimensions and specifications as indicated in Appendix B. Then, the design was separated into three different stereolithography (STL) files for the top, middle, and base parts, which were 3D printed.

The 3D printing process was done at the UW-Madison MakerSpace using the Bambu Lab printers. The files were uploaded to the computers at the MakerSpace and subsequently sliced and exported to the printers. Lastly, once the printing was complete, the supports were removed and the products were sanded as needed. At this point, the individual components were assembled, resulting in a working prototype that will allow the team to evaluate the functionality of the design.

In the future, there will be a metal prototype to provide as a proof-of-concept model. In order to create this prototype, the middle solid tube will need to be cut via CNC lathe. The correct geometry will be obtained using a SolidWorks model with the appropriate dimensions. Then a CNC mill will be used to create the fit for magnets in the middle solid tube. In addition,

the hollow tube used for the base will need to be CNC lathed to obtain the proper dimensions. To make the top piece, the CNC lathe will be used to obtain the proper geometry.

In order to make the metal prototype cohesive, the pole of the base part and the base plate will be welded together. This will be done via MIG welding in the TeamLab. Since the device will be made out of 4130 stainless steel, the MIG will need to be preheated. Additionally, the settings for this will be 90% argon and 10% carbon dioxide with 175 amps applied [17]. The hollow pole of the base part will be set on the base plate off-centered in accordance with the Solidworks model, and the gun will be pointed forty five degrees between the two to obtain the correct weld. This will then be cooled off and checked for a proper weld. The CNC and MIG welding protocol to build this prototype are outlined in Appendix D.

c. Final Prototype

The assembled prototype is pictured below in Fig. 13. In order to produce a functional prototype, the metal components were 3D-printed out of PLA. All other components were assembled onto the prototype with hot glue as needed.

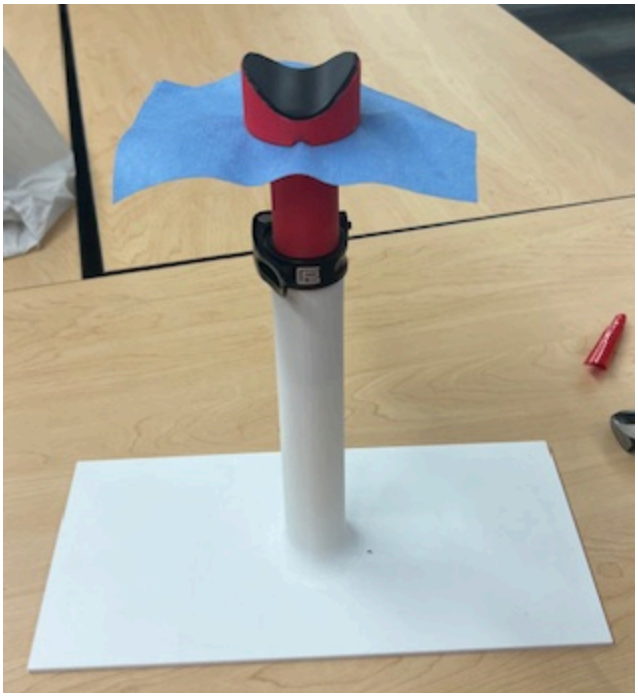


Fig. 13: Initial 3D printed prototype, consisting of top, middle, and base parts along with the pole clamp

Testing

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 aims 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. 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 cath lab. The forces required to dislodge the top part from the middle part across the sterile drape 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 (Fig. 14), torsional forces were applied in a perpendicular direction (Fig. 14), and tensile forces were applied in an outward direction in line with the catheter (Fig. 14). 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 duct tape, as the rubber straps had yet to be delivered. This is acceptable as the test is only addressing the magnetic connection between the middle and top parts, not the securement of 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. The differences for each catheter between methods were then evaluated. 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.

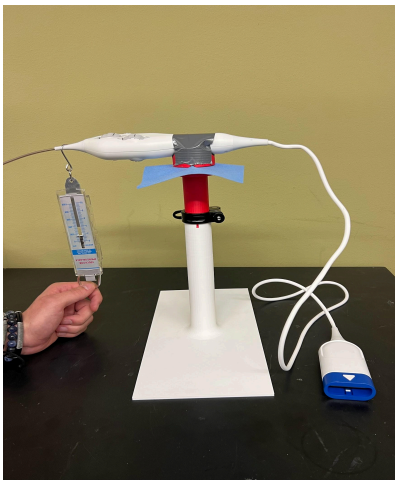


Fig. 14: Bending Force

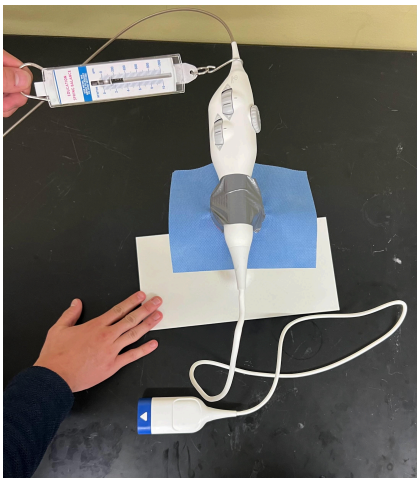


Fig. 15: Torsional Force

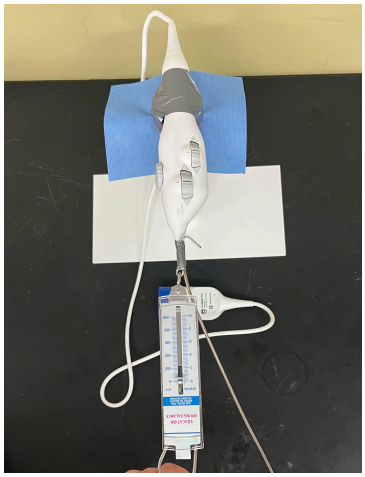


Fig. 16: Tensile Force

Weld Stress Concentration 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 [18,19]. 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 as this is the proposed material for metal fabrication. Once these parameters were applied, the simulation was run. For a more detailed protocol, refer to Appendix I.

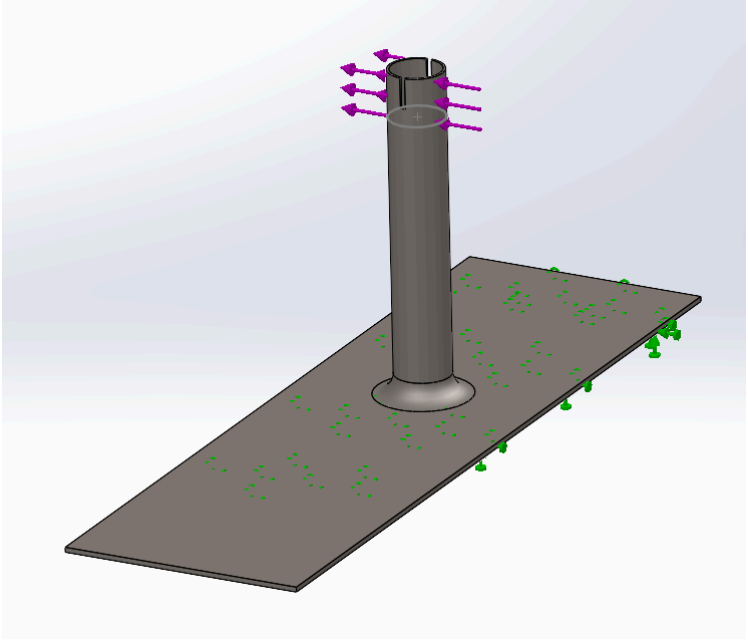


Fig. 17: Base plate and shaft in SolidWorks Static Force Simulation with transverse force applied to shaft and fixture on the bottom of the base plate.

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.

Results

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. The graphs below provide a more in depth analysis of the data.

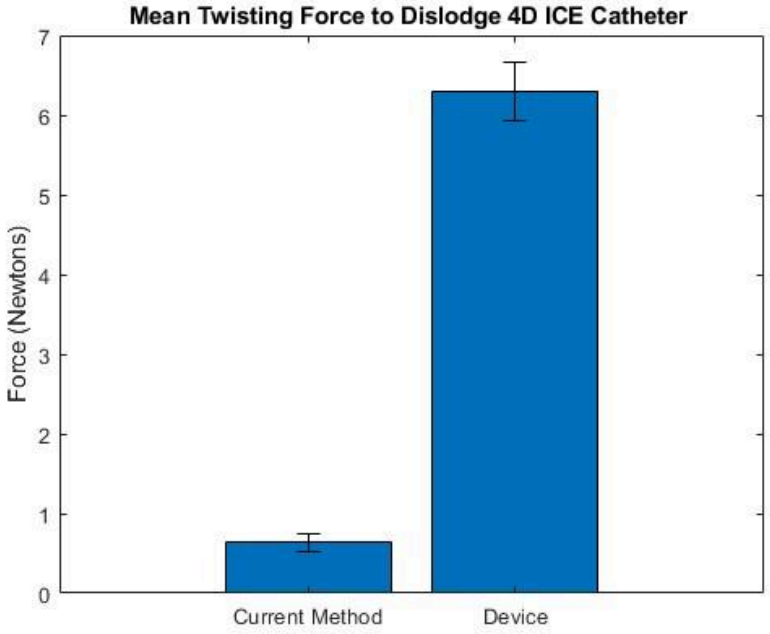


Fig. 18: Average twisting force to dislodge 4D catheter comparing the current method with the device ($p < 0.001$).

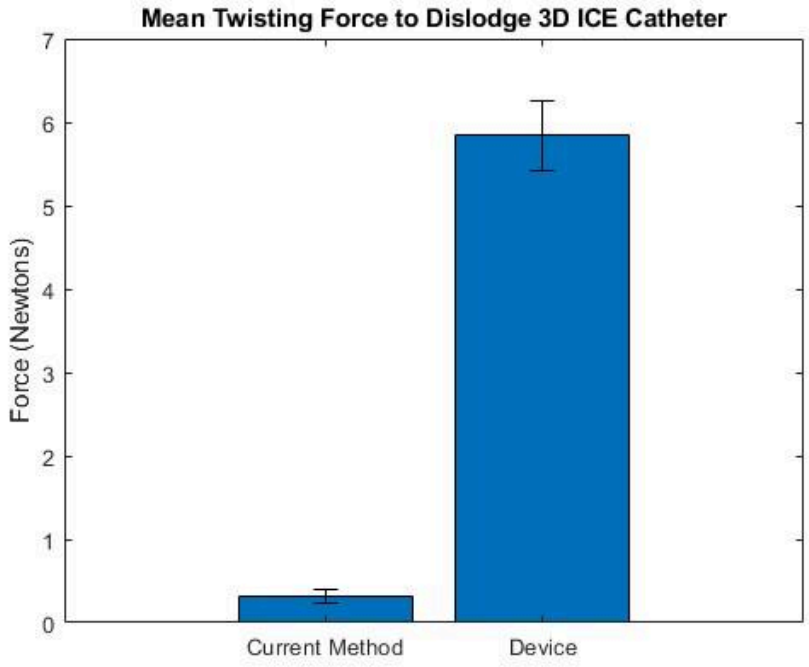


Fig. 19: Average twisting force to dislodge 3D catheter comparing the current method with the device ($p < 0.001$).

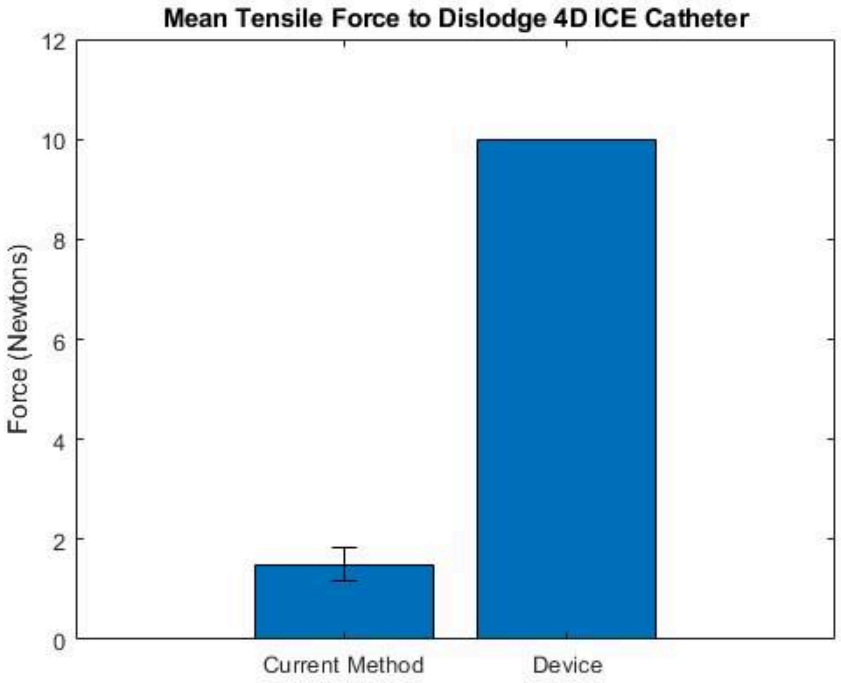


Fig. 20: Average tensile force to dislodge 4D catheter comparing the current method with the device ($p < 0.001$).

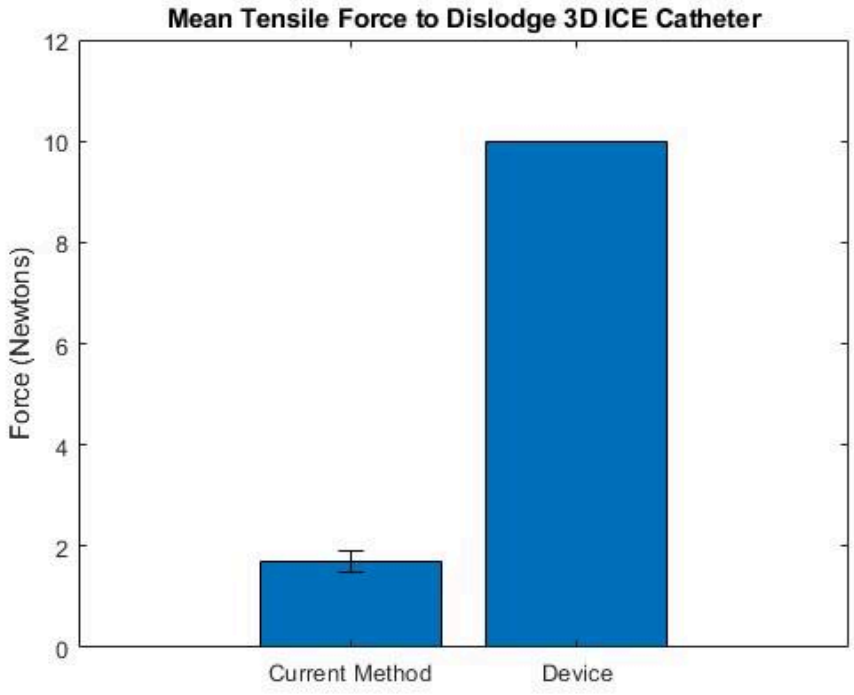


Fig. 21: Average tensile force to dislodge 3D catheter comparing the current method with the device ($p < 0.001$).

The device was able to withstand significantly more force in the tensile, twisting, and bending test compared to the current method. The p-values for the 4D catheter comparing current method and device are 1.14E-11 and 7.95E-10 for tensile and torsional test, respectively. For the 3D catheter, the p-values comparing the stabilizer and the current method are 2.03E-13 and 5.57E-09 for tensile and torsional, respectively. No force could be properly measured using the wet towels as it underwent bending. Also, for the tensile tests, 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 the graphs that are the device undergoing tensile force.

Weld Stress Concentration 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. 22). 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 [15]. 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.

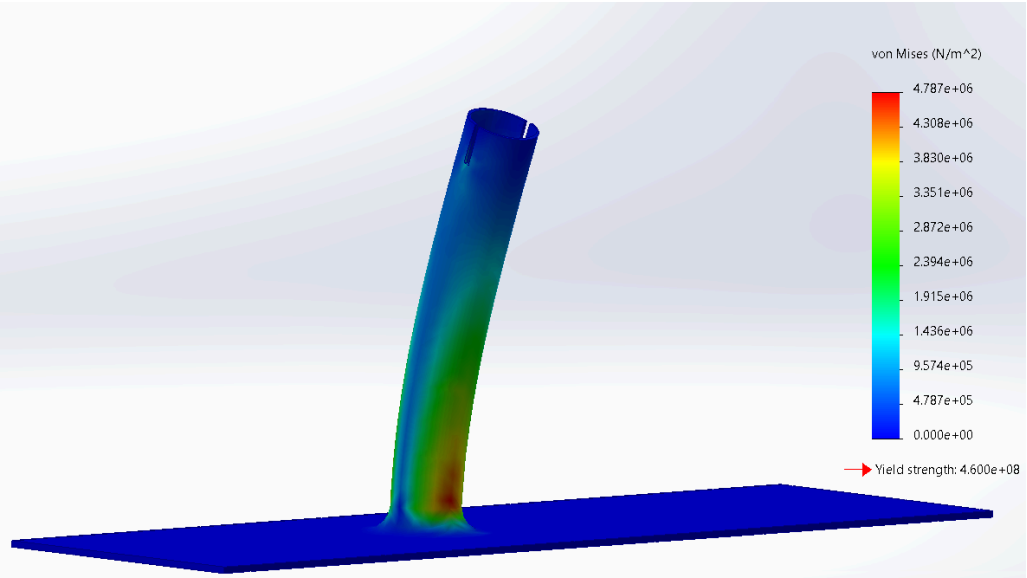


Fig. 22: Results of SolidWorks Static Force Simulation with transverse force applied to the top of the shaft.

Surgical Drape Tensile Testing

The tensile testing was completed with 3 samples of 5 cm by 10 cm. As seen in Table 2, 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 2: 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

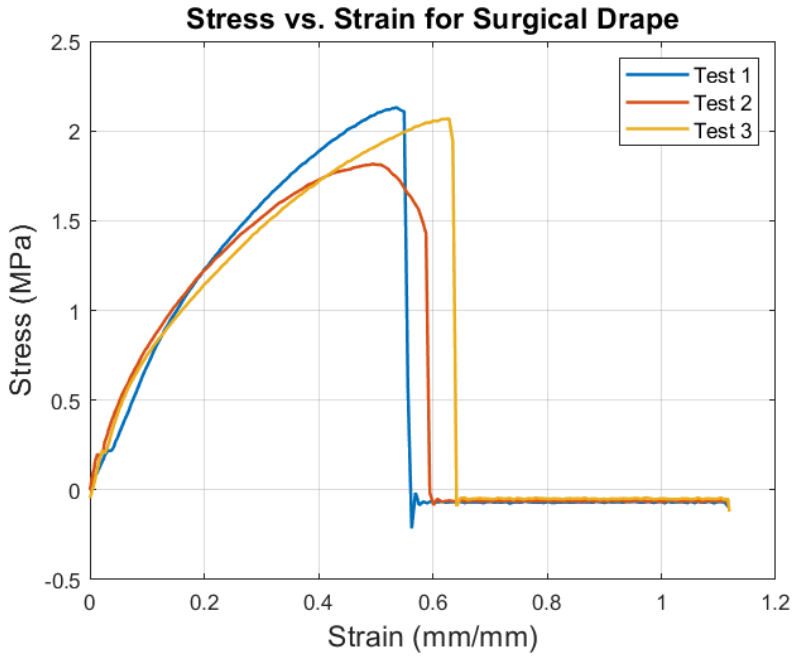


Fig. 23: Stress-strain behavior of the surgical drape for 3 trials.

Discussion

The results of the testing show that the 3D printed prototype performed better than the current method of wet towels. The force testing shows p-values of 1.14E-11 for the device as opposed to the current method in tensile with the 4D catheter, 7.95E-10 for twisting with the 4D catheter, 2.03E-13 for tensile with the 3D catheter, and 5.57E-09 for twisting with the 3D catheter. The other p-values are not listed as the current method could not withstand a bending force before it visibly moved. 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. Also, if values were obtained for the current method bending force, they likely would have been significant as the 3D prototype was able to withstand 4.14 and 2.72 N on average for the 3D and 4D ICE catheter, respectively (refer to Appendix G for this data). Therefore, when the patient breathes, the device should not move as it takes more than 2 N to move the catheters on the stabilizer. This directly meets one of the critical design specifications provided in Appendix B.

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 [20]. 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 [21]. Another concern is that the stabilizer fails and the catheter perforates the aorta [10]. This can be irrecoverable and the patient could die. Therefore, the device must be tested thoroughly and properly.

Future iterations of the device will be made out of 4130 stainless steel. Due to shipping and billing issues, a fully metal prototype could not be realized this semester. Therefore, it was made out of PLA this semester as an initial proof-of-concept prototype. A fully metal prototype will be constructed next semester to be further tested. As found in the SolidWorks simulation, the metal design will yield a safety factor of 96.3, which is significantly higher than the accepted range of 1.25 - 4. This high safety factor indicates little possibility of the weld between the shaft and the base breaking, meaning the design is sturdy and strong enough to be used in the cath lab.

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. 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 cath lab. The device was stable, adequate height adjustable, and held the two types of ICE catheter provided. However, significant work remains to be done in the design and manufacturing process. Following client approval, any modifications necessary will be made to the design and straps will be added to the top saddle component of the device. The design will then be fabricated out of metal to produce a more realistic and fully-sterilizable prototype. The prototype can then be transferred to the client for use in the cath lab to test functionality and get user feedback. The idea of creating different modular top parts to accommodate other types of catheters and surgical equipment will also be explored. Once the design is finalized, the design can be submitted for patenting and discussed for manufacturing.

Overall, the need for an adjustable stabilization device for intracardiac echocardiography catheters exists for physicians such as the client, Dr. Raval. 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. The team's solution fulfills these needs and accommodates the design requirements to address the issue of stability of ICE catheters.

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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 90% argon and 10% carbon dioxide
6. Use 175 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. Use duct tape to secure the catheter onto the saddle.
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_twisting = [6.9, 6.2, 6.3, 5.9, 6.2]
towel_4d_twisting = [0.8, 0.6, 0.7, 0.6, 0.5]
mean_device_d4_twisting = mean(device_4d_twisting)
mean_towel_4d_twisting = mean(towel_4d_twisting)
std_device_d4_twisting = std(device_4d_twisting)
std_towel_4d_twisting = std(towel_4d_twisting)
%%
means = [mean_towel_4d_twisting, mean_device_d4_twisting];
stds = [std_towel_4d_twisting, std_device_d4_twisting];
figure (1);
bar(means);
hold on;
errorbar(means, stds, 'k', 'LineStyle', 'none', 'CapSize', 10);
xticks([1 2]);
xticklabels({'Current Method', 'Device'});
ylabel('Force (Newtons)');
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

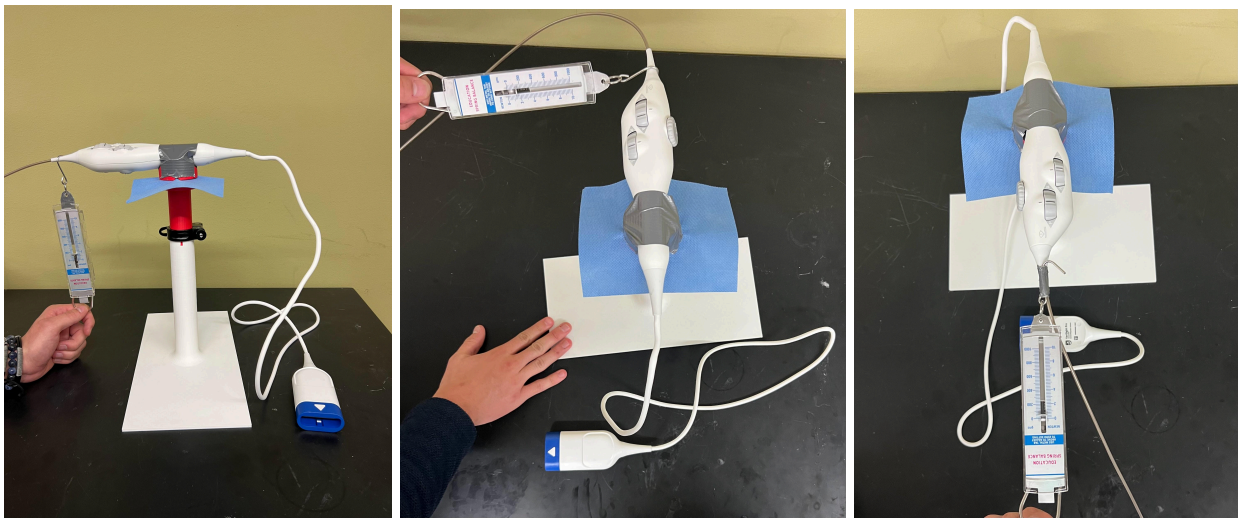

Fig. 1: 4D ICE Catheter in bending (left) torsional (middle) and tensile (right) force test configurations in device

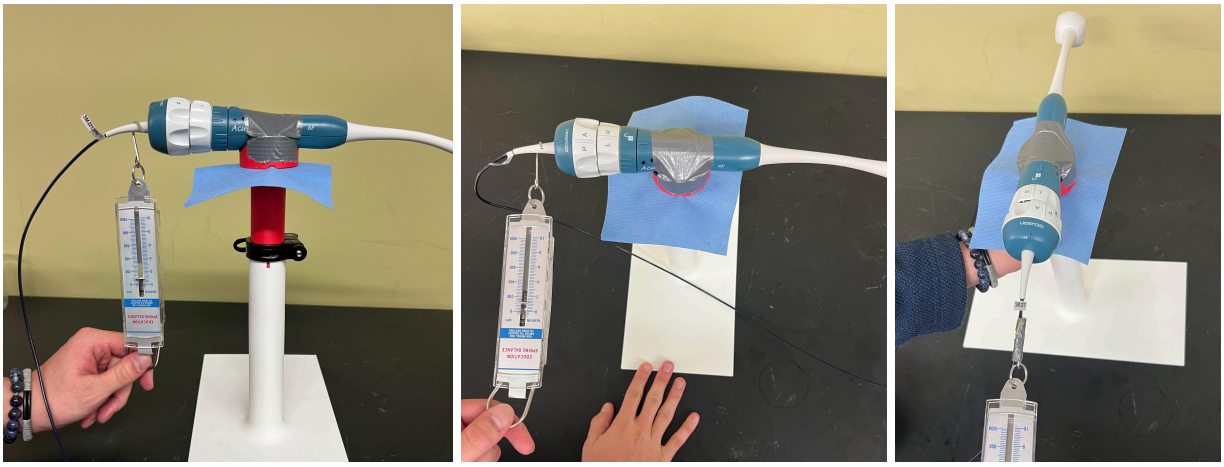

Fig. 2: 3D ICE Catheter in bending (left) torsional (middle) and tensile (right) force test configurations in device

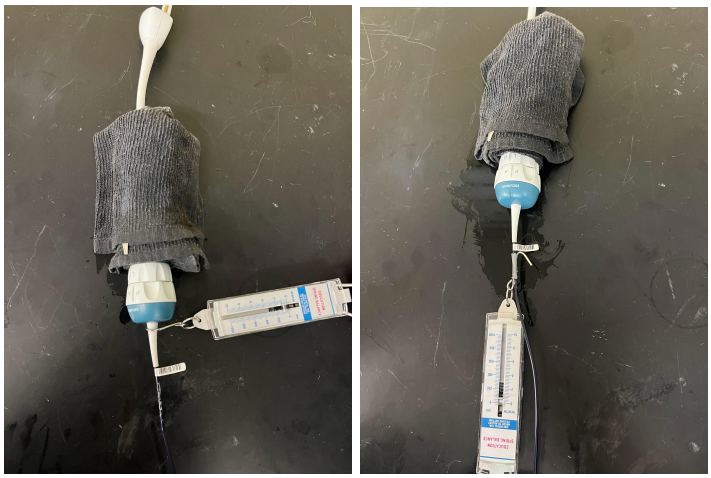

Fig. 3: 3D ICE Catheter in torsional (left) and tensile (right) force test configurations weighted with wet towel

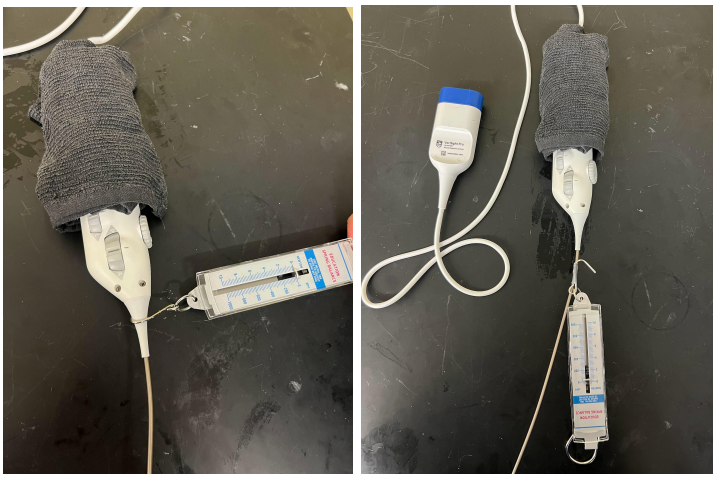

Fig. 4: 4D ICE Catheter in torsional (left) and tensile (right) force test configurations weighted with wet towel

Appendix G: Force Testing Data Tables

Table 1: Raw data of force testing

4D ICE Catheter in Device			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	3.2	10+	6.9
2	2.6	-	6.2
3	2	-	6.3
4	3	-	5.9
5	2.8	-	6.2
Mean:	2.72		6.3
3D ICE Catheter in Device			
Trial	Bending Force (N)	Tensile Force (N)	Twisting Force (N)
1	4.4	10+	5.4
2	3.9	-	6.5
3	4	-	6.1
4	4.6	-	5.8
5	3.8	-	5.4
Mean:	4.14		5.84
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

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)