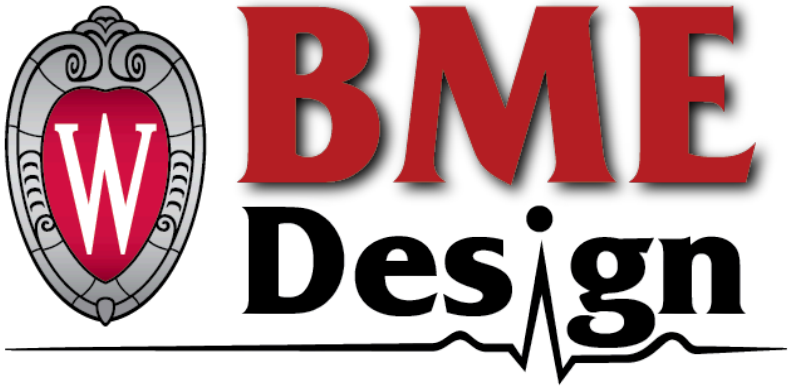

Stabilizer Device for Intracardiac Echocardiography (ICE) to Assist Structural Heart Interventional Procedures

Preliminary Report

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Date: October 9, 2024

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. However, the catheter 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 and angle 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 device with height-adjustable legs, a seamless angular adjustment mechanism, and secure straps that hold the handle of the device in a fixed position. Going forward, a prototype of this device will be fabricated, tested, and modified to provide 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 1 in 4 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 non-invasively 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. However, these methods 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].

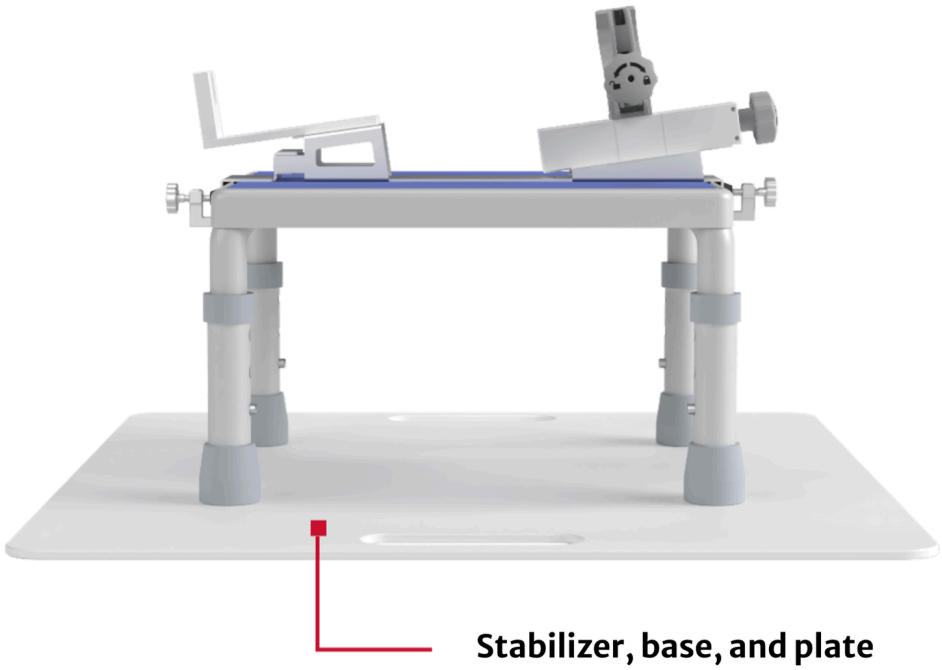


Fig. 2: Edwards EVOQUE Tricuspid Valve Replacement System stabilizer, base, and plate [7].

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 and the angle of the catheter once in place. Furthermore, the stabilizer must be sterilizable in order to be reused between patients. For further design specifications, one should refer to Appendix B.

Preliminary Designs

Design 1: Gooseneck

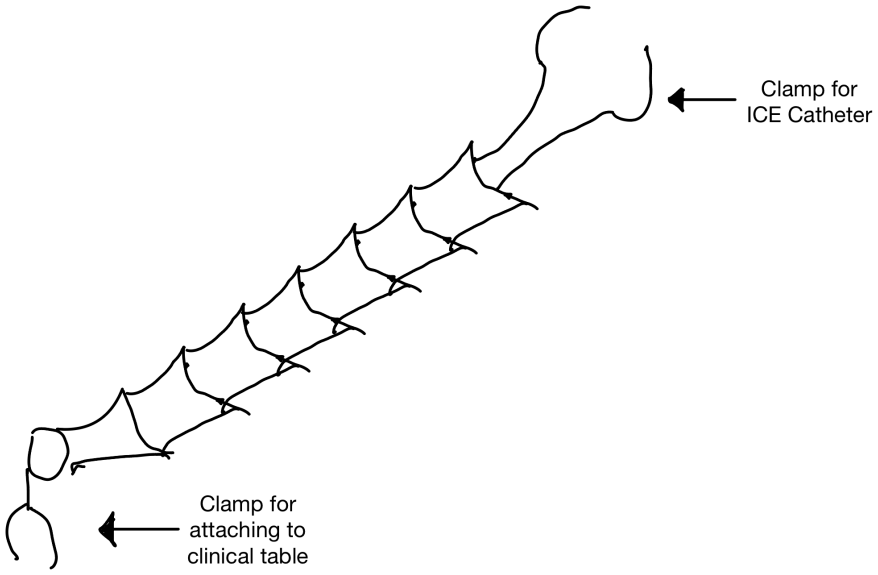


Fig. 1: ‘Gooseneck’ overall design

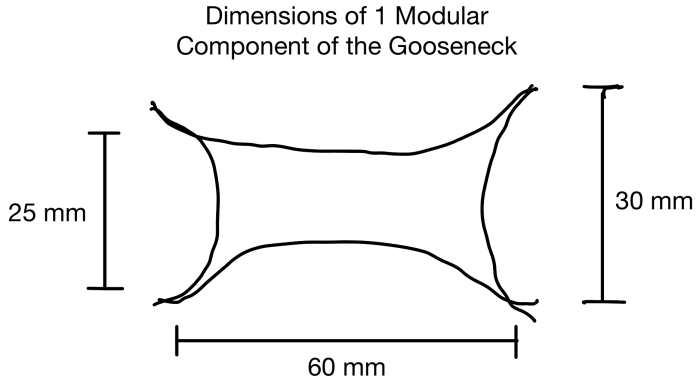


Fig. 3: ‘Gooseneck’ modular unit

The ‘Gooseneck’ design features a chain of interlocking modular units which articulate with one another. 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 25mm x 30mm x 60mm. 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.

Design 2: Bodyweight Holder

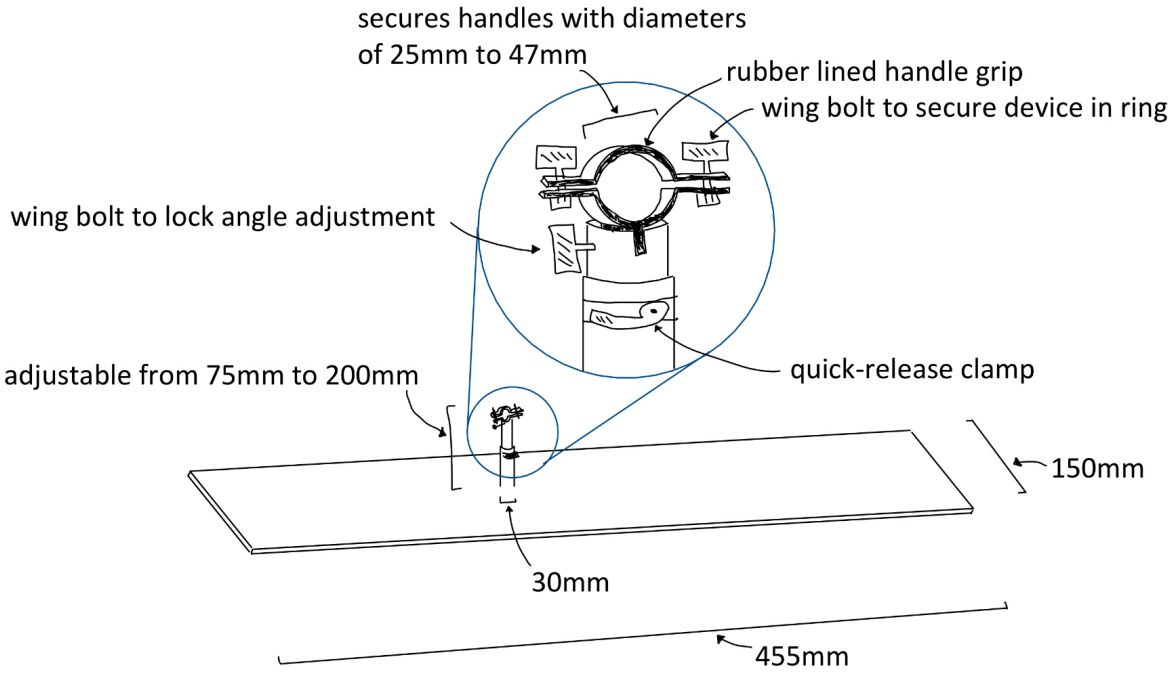


Fig. 4: 'Body Weight Holder' design

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. 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 75mm 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 25mm to 47mm, 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.

Design 3: Sliding Legs

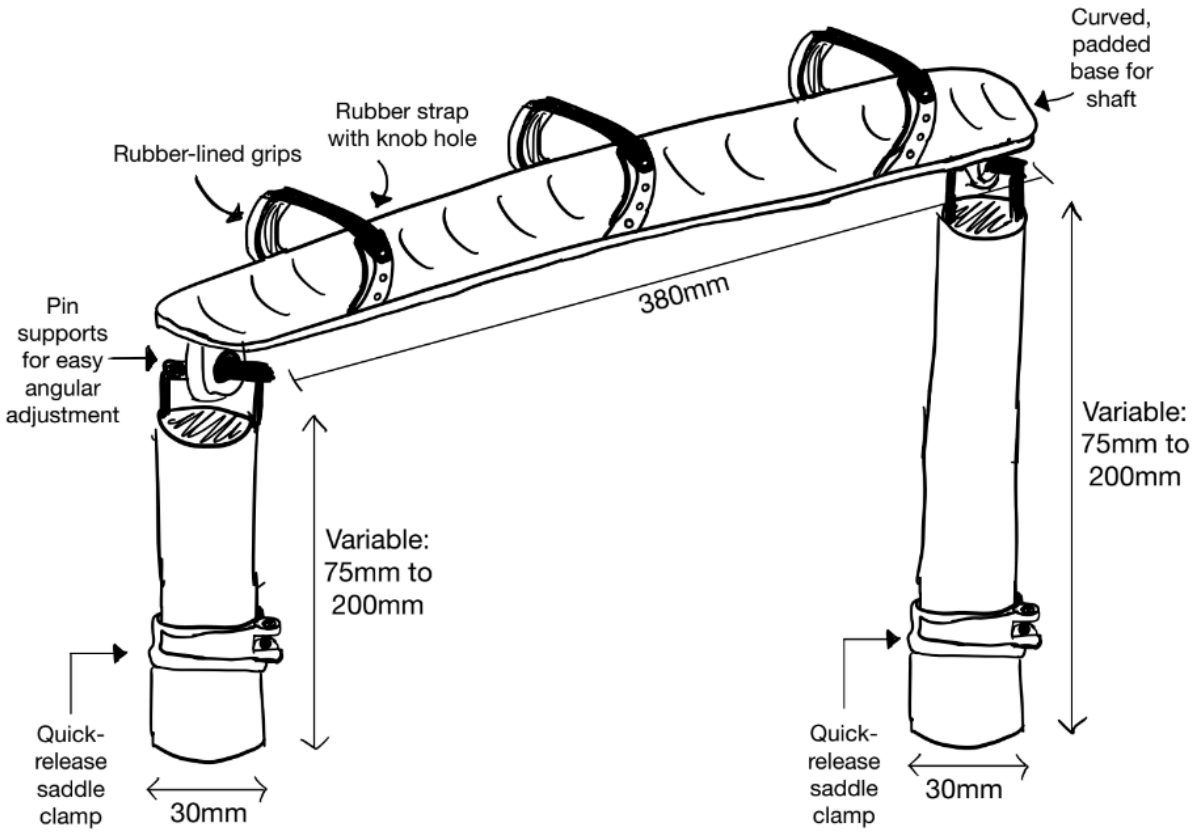


Fig. 5: 'Sliding Legs' stabilizer design

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. 6, 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.

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.

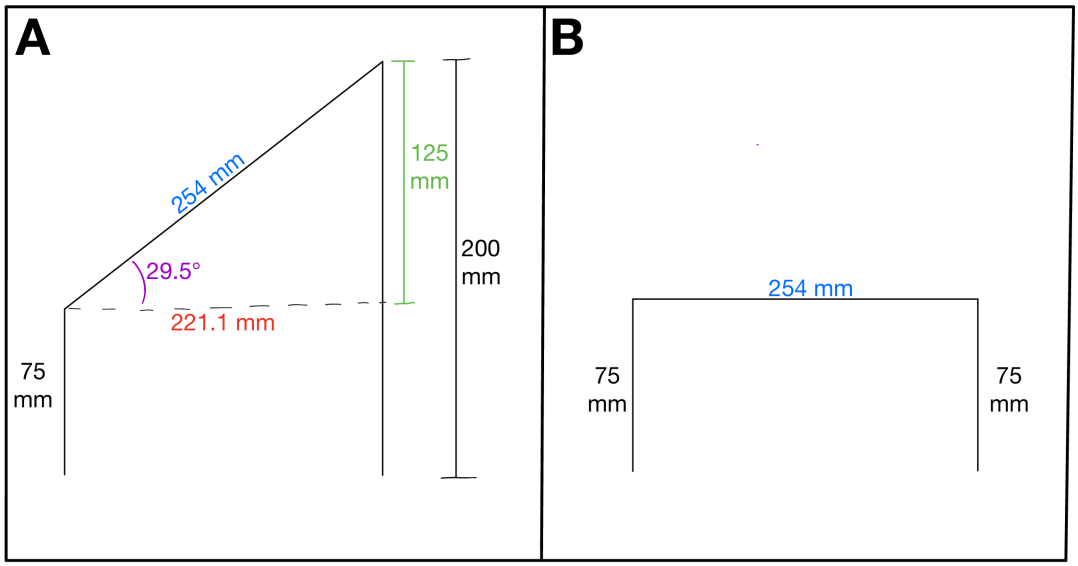
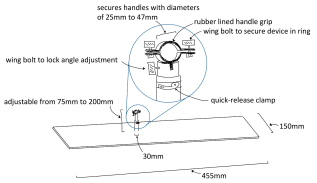
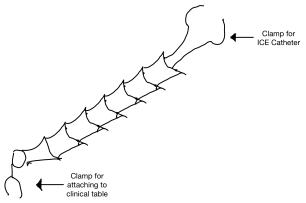
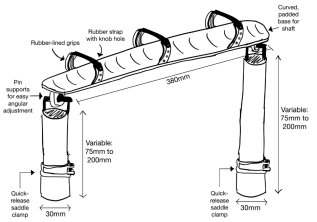


Fig. 6: A. Position & angle of the Sliding Legs design with a fully-extended posterior shaft. B. Position & angle of the Sliding Legs design with a fully-contracted posterior shaft.

Preliminary Design Evaluations

Design Matrix

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

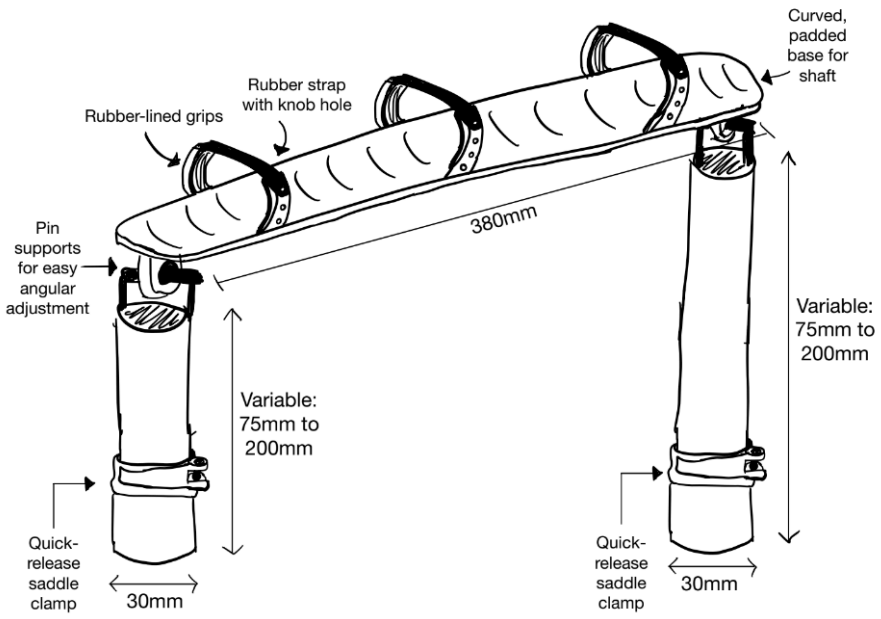


Fig. 7: 'Sliding Legs' Final Design

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.

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 device body will be 3D-printed using polyethylene terephthalate glycol (PETG), which can withstand temperatures of 74℃ 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 will enable rapid prototyping at a low-cost, which provides the team freedom to design in an iterative process.

For future prototyping and eventual manufacturing, the device will be made of stainless steel, which 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.

b. Methods

In order to build the stabilizer device prototype, the team will first need to make an exact design using Solidworks. This CAD will include all proper dimensions and specifications as indicated in Appendix B. Then, the design will be separated into three different stereolithography (STL) files. These three separate files will include the two legs and the base, which will then be 3D printed.

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

Testing

Several tests will be performed on the prototype in order to assess its effectiveness. A force test will consist of a force of 5 N being applied axially and transversely to the catheter while it is held in the device, to ensure there is no excess movement of the catheter handle in the clamps. Additionally, a torque of approximately 75 N-mm will be applied to assess the ability of the device to prevent rotation of the catheter handle. The device should remain fixed to the operating table, the height and angle adjustments should not break or change, and the device should not translate in the clamps. If possible, the device will also be tested in a mock clinical setting to gather qualitative results and comments from medical personnel, as well as possibly in a mock procedure.

Discussion

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 [15]. 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.

In addition, future iterations of the device will be synthesized using CNC equipment. This will allow the device to be made out of materials that have a higher compressive strength and heat resistance, such as stainless steel. Hence, the stabilizer will be able to withstand more wear and tear from repeated sterilization cycles, whether ethylene oxide or autoclave sterilization is used, compared to thermoplastics such as PETG.

Conclusion

The goal of the project is to design and develop a manufacturable Intracardiac Echocardiography (ICE) catheter holder to ensure steady imaging feed from the ICE catheter. The holder needs to be able to secure the device from almost all movement and be able to adjust both through height and angle. The team will proceed forward with the Sliding Legs design as the proposed final design as it proved the most versatile and functional in achieving this goal. The design contains height-adjustable legs that enable simultaneous height and angle adjustment, as well as a plate with rubber straps to secure the catheter.

As the project progresses, the design may evolve to include portions of the other designs or new ideas that come forward during testing and development. The project has three main components to focus on: the catheter holder, the height and angle adjustment, and the mount of the device onto the catheterization lab table. The designs will initially be 3D printed for simple testing of the functionality. Once a proof-of-concept prototype is developed, the team will initiate testing on the design. Testing will include evaluation of each component of the design individually, as well as the full design altogether. Specific areas of the design may need to be modified in the future to better meet the design requirements and accomplish the overall goal of the design. The rubber strap plate may need to be adjusted for specific measurements of each catheter design in order to allow for adaptability between catheter models. The mount of the design may incorporate the Body Weight Holder base in order to improve the mechanism of attaching the device to the catheterization lab table. After initial testing is complete, the team will implement any required design changes. The design will then be modeled with CNC milling for a final prototype.

Overall, the need for an adjustable stabilization device for intracardiac echocardiography catheters exists for physicians such as the client, Dr. Raval; additionally, there is a gap in the market as no device currently exists for the purpose of ICE catheter stabilization.

The team's proposed solution will fulfill these needs and accommodate 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	Expected Vendor	Part Number
PETG 3D-printing filament	$0.05/gram	$10.00	UW-Madison Design Innovation Lab	n/a

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 75 to 200 mm
- Have an adjustable angle of 0° to -30° from parallel to the operating table
- Allow the ICE handle to translate approximately 75 mm towards and away from the point of insertion
- 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
- 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 75 to 200 mm and angular adjustment of 0° to -30° from parallel to the operating table. It should as well allow for about 75 mm of translational movement of the handle toward and away from the point of insertion only when desired by the operator. 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].

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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