DEVELOPMENT OF A SHEATH TORQUING TOOL FOR MINIMALLY INVASIVE PROCEDURES

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Abstract

Atrial fibrillation is an irregular heart rhythm that affects at least 2.7 million Americans every year and is the leading cardiac cause of stroke. Furthermore, individuals over the age of 40 years have a one in four chance of developing this heart arrhythmia in their lifetime. Due to the abnormal electrical activity in the heart, atrial fibrillation is commonly treated with catheter-based procedures to eradicate the irregular, erratic rhythm. The authors and medical professionals at the University of Virginia Health System Atrial Fibrillation Center have indicated an issue with stability of intracardiac ultrasound catheters used in the Electrophysiology Labs that guide physicians during invasive procedures to eradicate heart arrhythmias, such as atrial fibrillation. The preliminary survey data reported many medical professionals indicating issues with the intracardiac ultrasound catheter's handle stability. This project was focused on developing two novel sheath designs that can improve the stability of the ultrasound catheter by redistributing the weight of the catheter handle. Follow-up surveys were conducted with users of the intracardiac ultrasound catheter to validate the device and gain feedback on the two novel sheath designs. Results show an average 7.46 out of 10 rating for the design's perceived efficacy in improving stability, with a standard deviation of 1.01. Furthermore, an average rating of 7.58 out of 10 was expressed for likelihood in using our device, with a 100% interest in trying the device. Future work for this study includes 3D printing of the sheath designs and optimizing the novel designs through iterations of self-testing, user-testing, and constructive feedback, as presented in this paper. The designs discussed in this paper show promising potential in improving stability of intracardiac ultrasound catheters, which can help minimize the probability of human error during catheter-based procedures and prevent heightening the risks of cardiac ablations.

Keywords: ablation, atrial fibrillation, cardiac catheterization, catheter, electrophysiology, imaging, intracardiac ultrasound catheter, medical device, rolling, sheath, survey, stability, torquing, ultrasound

Introduction

Atrial Fibrillation

Atrial fibrillation (AFib or AF) is one of the most common irregular heart rhythms that affect at least 2.7 million Americans and one in four Americans over the age of 40 years.[1,2] This number is an underestimate as the arrhythmia is often silent, or asymptomatic. Atrial fibrillation is due to abnormal electrical activity within the atria of the heart, characterized by chaotic and irregular signals being fired from multiple areas in the top two chambers to the bottom two chambers, or ventricles, of the heart, as depicted by Figure 1B. As illustrated by the electrocardiogram (ECG) waveform in Figure 1D, these abnormal electrical signals cause the heart to quiver, contract irregularly, and beat faster than normal. The behavior of a normal heart and a corresponding ECG is illustrated in Figure 1A and 1C, respectively.

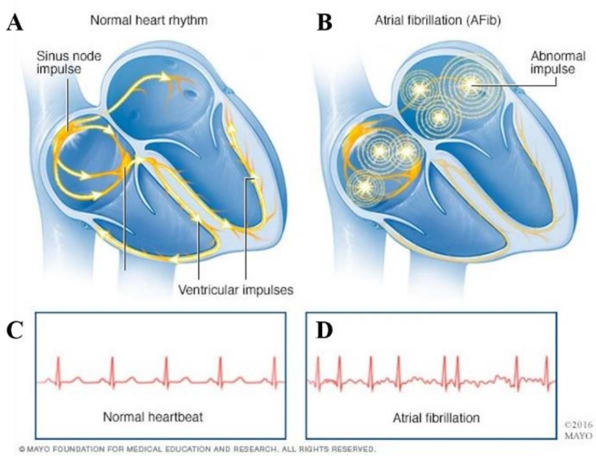

Figure 1. Atrial Fibrillation. (A) A normal heart experiencing regular electrical impulses. **(B)** A heart experiencing atrial fibrillation (AFib) with irregular and chaotic electrical signals being fired from multiple areas in the atria. **(C)** An electrocardiogram (ECG), or rhythm strip, of a normal heart rhythm. **(D)** Atrial fibrillation can be diagnosed by its recognizable appearance on an ECG: erratic waveform characterizing irregular quivering of the heart.[3]

Especially because the arrhythmia can be asymptomatic, if left untreated, AFib can weaken the muscles of the heart and increase the risk of heart failure among many other heart-related complications.[3] Due to turbulent blood flow in the heart which leads to a higher chance of forming blood clots, AFib can increase a patient's risk of stroke by fivefold, making it the leading cardiac cause of stroke.[4,5] As medical technology and techniques have evolved over the past few decades, treatments to reduce the risk of stroke and to treat AFib have also advanced, including anticoagulation, rhythm control medication, cardioversion, ablation, and other interventional cardiac procedures.[5]

Cardiac Catheterization

Over 1 million cardiac catheterizations (CC) are performed in the United States every year, making them one of the most widely performed cardiac procedures.[6] A cardiac catheterization is a procedure in which a long, thin tube is inserted through a blood vessel into the heart.[7] This tube, called a catheter, is inserted from a blood vessel, typically in the arm or leg, to gain access to the inside of the heart. Catheter-based procedures are performed for varying reasons including collecting intracardiac data, obtaining a view of the heart's interior, and performing ablations.

Catheters are commonly used during cardiac ablations to eradicate the origin of AFib. An ablation is a surgical procedure in which lesions are delivered through either (1) radiofrequency energy, which uses heat to create tissue damage, or (2) cryothermal energy, which creates tissue damage by freezing a target region.[9] Following the first line of therapy for AFib, which includes the use of anticoagulation, rhythm control medications, and cardioversion, catheter ablations have emerged as the most effective rhythm control strategy.[5,8]

Intracardiac Ultrasound Catheter

Intracardiac ultrasound is an imaging technique that uses pulse-echo signals to provide real-time visualizations of the heart's interior when performing catheter-based ablation procedures.[9] Cardiac ablations often involve multiple catheters at once, where some are used for three-dimensional (3D) mapping while others are used to ablate tissue, and require careful manipulation of the catheters within the heart. The intracardiac ultrasound catheter is a pertinent tool commonly used during cardiac ablations as it provides physicians guidance for visualizing and navigating the ablation and mapping catheters being used.[9] The tool enables physicians an understanding of any anatomical changes or complications that may occur during procedures.[10]

As typical ablation procedures can last from three to four hours, or often longer depending on the patient's medical history or physician techniques, many physicians are steering away from using fluoroscopy as an imaging modality as it emits radiation. Although the amount of radiation emitted may not be significant from one particular procedure, the lifetime accumulation of radiation exposure may be significant not only in patients who undergo diagnostic CT scans, other catheterization procedures, or repeat ablation procedures, but also in physicians and medical laboratory staff who use fluoroscopy for procedures on a daily basis.[11] In an effort to reduce exposure to radiation, many physicians are transitioning to using intracardiac ultrasound to provide precise imaging of endocardial structures during AFib ablations.[9]

During a typical catheter-based cardiac ablation, an intracardiac ultrasound catheter arrives at the heart by access through a vein in the groin area. Once inside the heart, the imaging tip of the ultrasound catheter can be manipulated to produce images of the desired locations. The intracardiac ultrasound catheter, such as the AcuNav Ultrasound Catheter (Biosense Webster, manufactured by Siemens Medical Solutions, Diamond Bar, USA) as shown in Figure 3, has four degrees of freedom: pitch, yaw, roll, and translate, as shown in Figure 2A.[12,13]

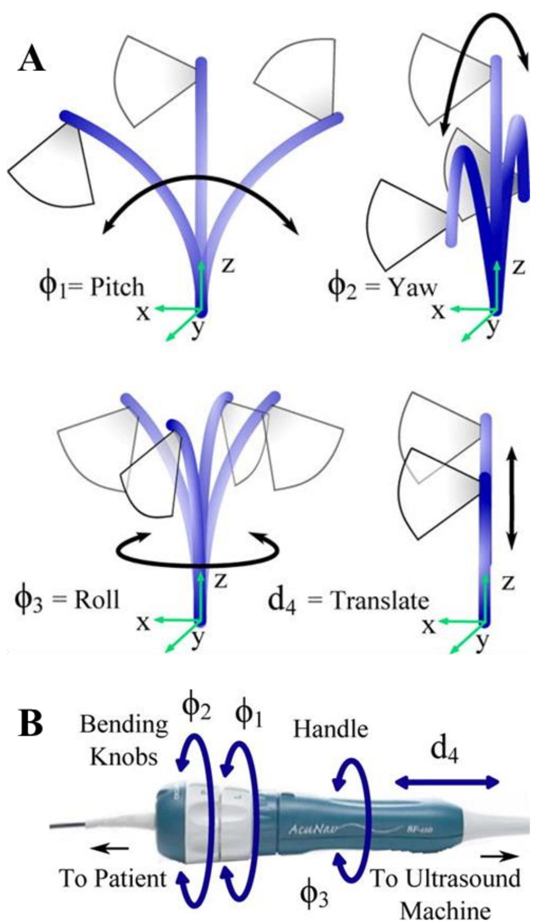

Figure 2. Intracardiac Ultrasound Catheter Degrees of Freedom and Corresponding Catheter Tip Motions. (A) The four ways to maneuver an intracardiac ultrasound catheter are illustrated with the plane and direction it can move in. **(B)** The ultrasound catheter handle is depicted, showing the maneuvers a user can make to manipulate the catheter.[13]

The pitch and yaw mobilities of the catheter tip, which allow for left-right and anterior-posterior movements, are accessed by control knobs on the handle, where they are labeled as “bending knobs” in Figure 2B.[13] The roll and translational movements are controlled by maneuvering the entirety of the handle.[13] The two control knobs at the handle can be locked by the user to maintain the degree of which the catheter tip is flexed. To find the desired location in the heart to image, the user can simultaneously manipulate the catheter handle in two additional ways: (1) rotating the handle clockwise or counterclockwise, or “torquing,” and (2) translating, or advancing, the catheter handle toward or away from the heart.

The purpose of the intracardiac ultrasound catheter is to provide real-time, live observations of the interior of the heart during an invasive procedure. Although successful in that aspect, current ultrasound catheter designs lack a way to stabilize the tool, or keep it from moving away, after a position is set. This is an issue identified with one of the degrees of freedom of the intracardiac ultrasound catheter: rolling. The rolling movement, which will be further referred to as “torquing” in this paper, is performed by rotating the handle in a clockwise or counterclockwise manner. After finding a desired view in the heart by manipulating the control knobs and maneuvering the catheter handle, a user will ultimately need to let go of the handle to proceed with other aspects of the procedure, such as handling the ablation catheter during a cardiac ablation. However, when the user releases the handle, the catheter has a natural tendency to revert back to its neutral position, therefore, throwing off the initially set view. We presumed this issue to be caused by friction of the ultrasound catheter inside the patient’s body when being turned against the other catheters and the cylindrical shape of the catheter handle itself. After reviewing literature and the current state of art, no efforts have yet been found to tackle this stability issue of the ultrasound catheter from a technological standpoint.

Cardiac catheterization procedures such as catheter ablations are associated with risks including vascular complications and pericardial effusion.[14] Recognizing that these risks could potentially be complicated with instability of a neighboring catheter, our team developed novel designs of a device that would provide stability to the intracardiac ultrasound catheter and thereby minimizing the risks that come with cardiac catheterizations.

There are several different intracardiac ultrasound catheter technologies that have been developed through the years. This study focused on the intracardiac ultrasound catheter commonly used in the University of Virginia (UVA) Health System Atrial Fibrillation Center, Charlottesville, VA, USA. As depicted in Figure 3, the present paper will focus on the clinical application of a phased-array ultrasound tipped catheter (AcuNav Ultrasound Catheter, Biosense Webster, Diamond Bar, USA) as it is the most commonly used catheter for intracardiac ultrasound imaging in the UVA Electrophysiology (EP) Lab.[12]

Figure 3. AcuNav Ultrasound Catheter. Phased-array ultrasound tipped catheters (Biosense Webster, manufactured by Siemens Medical Solutions, Diamond Bar, USA).[12]

Furthermore, a catheter ablation setup generally involves is a two-person job, and has sterile drapes all round, and multiple catheters being used and coming out of the patient's body simultaneously. These were factors considered when designing two novel sheath designs as solutions for the instability of ultrasound catheter handles.

Our overarching goal for this study was to develop a device that can counteract undesired movements of intracardiac ultrasound catheters. Sub-objectives included minimizing risks, reducing procedure time, reducing costs, and helping medical professionals to attain an overall improved experience with intracardiac ultrasound catheters.

Results

Identification of Design Constraints

With extensive research, no prior literature that identified user difficulty or frustration with manipulating intracardiac ultrasound catheters could be found. This study, therefore, conducts novel research and tackles an issue with the torquing of intracardiac ultrasound catheters through the development of novel sheath designs for catheter handles. The first step our team took was gathering insight on the current state of ultrasound catheter use in the UVA Health System EP Lab. This insight was obtained through a survey evaluating physicians and technicians, their experiences with using intracardiac ultrasound catheters, and any observed issues with the tool during procedures. The questions in this survey were designed to help the team confirm the project motivation and determine design constraints for the novel catheter handle sheath (Supplementary Figure 1).

Survey responses (n=12) were aggregated from attending physicians (5), advanced EP fellows (3), and cardiovascular technicians (4) between 3 months to 15 years of experience with using intracardiac ultrasound catheters. Key survey questions that gave insight on user experience and the responses received are extracted and shown in Table 1. All respondents expressed at least moderate levels of comfort with using the intracardiac ultrasound catheter (Q2). Eight respondents reported heavily relying on using ultrasound as a method of guidance during procedures, where this metric is defined as heavy dependence on the tool if in use (Q3).

Furthermore, 11 out of 12 users indicated that undesired torquing of the catheter handle occurs at least once during a procedure, and almost half (5) of the respondents indicated needing to make adjustments more than ten times during a single procedure (Q4). Four respondents indicated having difficulties with the torquing of the catheter handle, and three respondents expressed needing to make constant adjustment (Q5, Q5a). Lastly, four users indicated an issue with catheter handle torquing that should be addressed (Q5b).

Table 1. Key Questions of Preliminary Survey. Five questions are extracted from the preliminary survey and illustrated with the aggregated results. These questions focus on user experiences with the intracardiac ultrasound catheter. "ICE catheter" referred to intracardiac ultrasound catheters. **Heavily is defined as heavy dependence, if an intracardiac ultrasound catheter is being used by a physician during a procedure. Moderately is less than 70% reliance but greater than 20%. [15]

Q2: How comfortable are you with ICE catheters?	
Very Comfortable	7
Moderately Comfortable	5
Q3: How much do you rely on this method of guidance for procedure [when in use]?	
Heavily**	8
Moderately**	4
Q4: How often do you have to torque/counter-torque the catheter [per procedure]?	
1-5	2
5-10	4
>10	5
N/A	1
Q5: Do you encounter any difficulties with torqueing?	
Yes	2
Sometimes	2
No	7
N/A	1
Q5a: If so, how often do you need to make an adjustment?	
Constantly	3
Sometimes	2
N/A	7
Q5b: Do you perceive this as a problem that should be tackled?	
Yes	4
No	6
N/A	2

Further questions asked users to describe their current methods of keeping the ultrasound catheter in place during a procedure and their assessments of the technique(s) (Q6 through Q8 in Supplementary Table 1). Half of the respondents indicated no particular technique is established to maintain the stability of the catheter handle; these users reported making adjustments as needed throughout the duration of a procedure. The current techniques being used were reported by users as asking a technician or assistant to hold the catheter in place, using the water weight from a damp towel placed on top of the catheter handle to weigh the catheter down in place, or taking no action and adjusting the catheter as it moves out of place. Eight out of the twelve respondents reported sometimes to always needing to ask a technician for assistance to hold the catheter in place. Half of the respondents, which included two attending physicians and four technicians, expressed that current technique(s) are somewhat or not very effective, whereas the other half, including three attending physicians and three advanced EP fellows, expressed satisfaction with the efficacy of their technique(s).

Due to the lack of established solutions for addressing unstable catheter torquing and several respondents quoting that it "would be convenient if [the catheter] did not move as much" and that it "would be nice to adjust [the catheter] less," our team confirmed the need to address the catheter handle torquing issue. Establishing a proper method to keep the guidance tool from moving out of place presents a more viable solution with less chance for error.

The preliminary interviews allowed us to identify the cylindrical shape of the catheter handle, the lack of a locking system, and, perhaps, the friction of the ultrasound catheter inside the patient's body when being turned against the other catheters to be the issues that contribute to instability in torquing of the catheter handle. The cumulative results of this preliminary survey are summarized in Table S1. Additionally, we identified that the catheter handle torquing issue is not due to the lack of available hands on site, but rather the number of catheters being used simultaneously during any given catheter-based procedure and available real estate.

Taking the next steps to combat the identified torquing issue, the team designed two novel sheaths that could be seamlessly implemented within catheter-based procedures.

Designing of a One-Piece Sheath

A one-piece sheath was designed in a three-dimensional (3D) modelling computer-aided design (CAD) software, Fusion 360. As depicted in Figure 4, this sheath is a singular-piece design taking the shape of an oblong (oval) shape with an opening, or hole, in the center for the handle of an intracardiac ultrasound catheter to be inserted. Indicated by the green arrow in Figure 4, the circumferential surface of the hole is lined with ridges, which we intended to be 3D-printed using a flexible, yet durable, material such as NinjaFlex Flexible Filament. The utility in the flexible interior is that it would allow the sheath to expand, if needed, to fit catheters of varying sizes and shapes. This feature would allow the sheath to be universally applicable with catheters that may benefit from a more stabilized handle, besides the intracardiac ultrasound catheter.

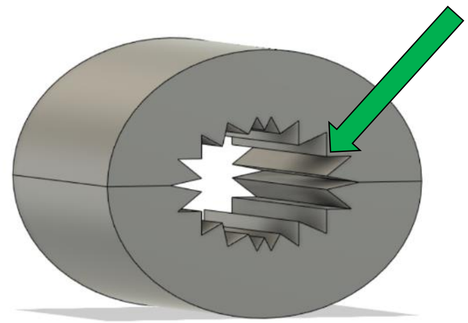

Figure 4. One-Piece Sheath Design. Computer-aided design (CAD) rendering of the one-piece sheath design. The device exhibits shape of an oblong (oval) shape with an opening, or hole, in the center (green arrow) for the handle of an intracardiac ultrasound catheter to be inserted. The inner surface of the hole is lined with flexible ridges to allow the sheath to expand, if needed, to fit catheters of varying sizes and shapes.[16]

Designing of a Two-Piece Sheath

A two-piece sheath was similarly designed in Fusion 360. As depicted in Figure 5, this sheath is made up of several parts: two structural and one connecting. The two structural parts of the sheath are identical to each other, taking the shape of an oblong (oval) semi-circle. Illustrated by the red arrows in Figure 5, the connecting part of this sheath design is a spring that acts as a hinge to connect the two structural parts, allowing the sheath device to open and close. The mechanism of this design is to enable the spring-loaded hinge to maintain a closed grip on the handle of an ultrasound catheter. When in the "opened" position, as depicted in Figure 5A, a catheter handle can be inserted within the opening. Because of the loaded spring, releasing the sheath device puts the it in the "closed" position (Figure 5B) and enables the device to clamp over and grip onto the catheter handle.

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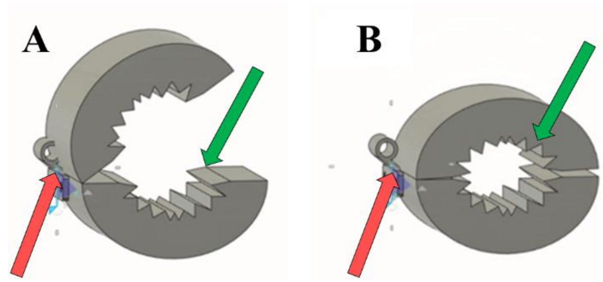

Figure 5. Two-Piece Sheath Design. Still images of a computer-aided design (CAD) animation of the two-piece sheath design. The pieces include two structural parts and one spring that acts as a hinge to connect the two structural parts. The device exhibits shape of an oblong (oval) shape that opens and closes through the spring-loaded mechanism. The mechanism of this two-piece design is to enable the spring-loaded hinge (red arrows) to maintain a closed grip on the handle of an ultrasound catheter. It features an opening, or hole, in the center (green arrows) for the handle of an intracardiac ultrasound catheter to be placed within. The "opened" position can be seen in configure **A**, and the "closed" position can be seen in configure **B**. The inner surface of the hole is lined with flexible ridges to allow the sheath to expand, if needed, to fit catheters of varying sizes and shapes.[17]

Comparison of the Sheath Designs

Similarities

Both sheath designs were constructed in a similar manner to counteract the natural tendency of an ultrasound catheter handle to roll away from a set position. The interior surface of the sheaths' openings features the same ridges made up of flexible material. These ridges were designed to grip onto the catheter handle and produce enough resistance to counteract undesired torquing of the catheter handle, while the weight of the sheath would be calculated to overcome the weight of catheter handles and potential pullback from neighboring catheters also being used during a procedure. The ridges featured in both of these designs are to enable the sheath device to fit not only intracardiac ultrasound catheters, but also any other catheters used during procedures that may benefit from a more stabilized grip. Both designs would require two hands from the user to make readjustments to a catheter handle that has been gripped by the sheath: one to hold onto or open-and-close the sheath device, and the second to manipulate the catheter handle to a new view. All exterior surfaces of both sheath designs will be solid and non-porous to aid in the re-sterilization process.

<u>Differences</u>

The main differences arise from user operation of the two sheath designs. The two designs each have their own advantages and disadvantages.

The one-piece sheath does not have moving parts. This feature allows for the one-piece design to be more sterile as there are no cavities or crevices in the device; this would also be beneficial for re-sterilization processes. Because this design is made up of a singular part, manufacturing the device would be simpler and more cost-effective. However, downsides are also present with a one-piece design that cannot be manipulated open. The size of the opening in the center of the device is constrained, even with consideration of the flexible interior. Because of the "closedness" of this sheath design, it will not be as adaptable to different catheter handle sizes and shapes. Additionally, this sheath would require users to insert the intracardiac ultrasound catheter before starting a procedure because the catheter would need to be plugged in. Disconnecting wires from the ultrasound catheter to slip on the one-piece sheath device would not be practical of efficient to a workflow. In other words, users must decide prior to starting a procedure whether or not a stabilizing sheath would be necessary, which is not the most practical or cost-effective because the need varies by case, total number of catheters being used, and patient anatomy.

The two-piece sheath has the feature of opening and closing to clamp over a catheter handle. This function allows the device to be compatible with more varying sizes and shapes of catheter handles. This design provides more flexibility not only in the application of different catheters, but also in the decision-making process of whether a stabilization device would be necessary or not. In other words, users do not need to decide whether a stabilization device is necessary prior to the beginning of a procedure. Rather, users can decide the necessary application of a sheath during a procedure when catheter handle instability is observed. As one respondent from the preliminary survey indicated, complete stability of the catheter handle is not always needed or appropriate. Depending on the particular task during a procedure, users may need translational capabilities and to continuously change the ultrasound view (Table S1).

However, because of a moving part in this design, the two-piece sheath will be less sterile than the one-piece design. The two-piece sheath can still be re-sterilized, but it may be more costly.

Device Validation

Follow-up surveys were conducted with twelve users of the intracardiac ultrasound catheter to obtain feedback on our two proposed sheath designs (Figure S2). Of the twelve, eleven respondents were the same medical staff surveyed in the preliminary questionnaire. Because one of the attending physicians could not be reached for the follow-up survey, another technician was surveyed after providing him with the relevant background information. The survey responses (n=12) were aggregated from attending physicians (4), advanced EP fellows (3), and cardiovascular technicians (5) between 3 months to 15 years of experience with using intracardiac ultrasound catheters, and are illustrated in Table S2. User experience, in years, with intracardiac ultrasound catheters and in the medical field did not significantly change with the change in one respondent. The questions of this follow-up survey were designed to gain insight on how users perceived our solution to the identified catheter handle instability issue.

Questions asked for quantitative ratings of conceptualized device efficacy and open-ended feedback. The aggregated responses of the questions of perceived device efficacy are illustrated in Figure 6.

On a scale of 1 to 10, where ten is regarded as the most effective, and one is regarded as not very effective, the average response for how effective our device would be in resolving the instability issue was a 7.46 ± 1.01, an efficacy average of 5 ± 3.03 in reducing procedure time, and an efficacy average of 4.29 ± 2.67 in reducing costs. A 7.58 ± 2.67 was reported for the likelihood of using one of our presented sheath devices for procedures while all twelve respondents indicated that they would like to try the device and then determine how often they would implement it in a regular procedure workflow. For all four questions of these questions, technicians (5) had the overall highest perceived efficacy of the sheaths, whereas advanced EP fellows (3) had the lowest perceived efficacy. The technicians also reported the highest likelihood to use the device, whereas attending physicians (4) and advanced EP fellows reported similar likelihoods.

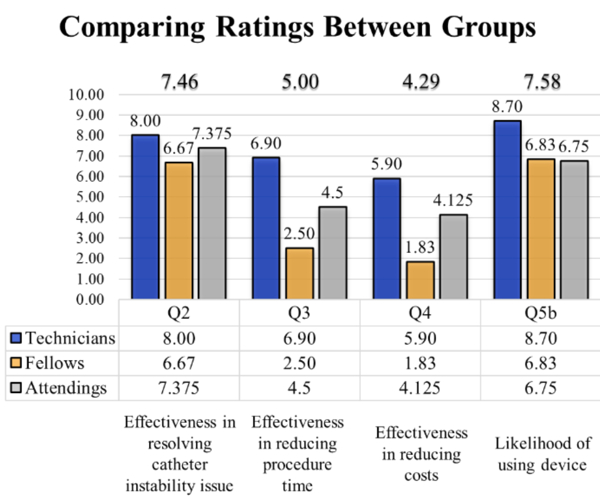

Figure 6: Mean Summary Statistics for Follow-Up Survey. The responses to the follow-up survey were aggregated and illustrated as a bar graph, where responses are grouped by respondent position in the Electrophysiology (EP) Lab. The questions corresponding to the results are shown at the bottom of the figure whereas the averages of all the responses are shown in bold above the bars. The questions asked for quantitative ratings of conceptualized device efficacy and likelihood to use the proposed sheath designs. Blue represents technicians, yellow represents advanced EP fellows, and grey represents attending physicians.[18]

Discussion

Analysis of Preliminary Survey Results

Q2 of the preliminary survey (Table 1, Table S1), which asked respondents to report their comfort levels with using intracardiac ultrasound catheters, was an important question to gauge current users' confidence in their ultrasound catheter use. Gauging confidence is a key metric as studies show that confidence is a crucial characteristic of healthcare success.[23] Seven out of twelve survey respondents reported feeling "very comfortable" and four respondents reported feeling "moderately comfortable" allows us to perceive that confidence is not an issue.

Q3 of the preliminary survey (Table 1, Table S1) asked respondents to evaluate their reliance on the ultrasound imaging as a method of guidance for procedures that they use an intracardiac ultrasound catheter during. This is an important question as it provides insight regarding the extent of ultrasound catheter reliance from users in the EP Lab. As shown in Table S1, having eight out of twelve respondents respond that they rely heavily on the ultrasound catheter as a method of guidance portrays the importance of having a stable, and therefore dependable, catheter. Kramer et al. (2014) discusses within their study ensuring medical device effectiveness is imperative and medical device reliability is crucial for success.[24]

Q4 asked users to interpret the average frequency they need to perform torquing on an ultrasound catheter handle as a follow up to Q3. The responses further supported the need for increasing reliability as eleven out of twelve respondents indicated that almost everyone experiences issues with the ultrasound catheter handle not staying in place. We were, therefore, able to conclude using the results from our preliminary survey that the issue with catheter handle stability must be addressed (Figure S1, Table S1).

Further questions of the preliminary survey asked for respondents to express their satisfaction with any current methods that are being used to combat instability in the ultrasound catheter handle (Q6 through Q7). The mentioned techniques included asking a technician or assistant to hold the catheter in place, using the water weight from a damp towel placed on top of the catheter handle to weigh the catheter down in place, or taking no action and adjusting the catheter as it moves out of place. Although eight of the twelve respondents found that their current methods are at least somewhat effective, all twelve of the respondents indicated that they would be interested in trying a more substantial solution, such as a sheath torquing tool. It is important to note that every user makes use of the ultrasound imaging tool differently and for different purposes during any given procedure. Therefore, the frequency of making adjustments (Q5a) may not be directly correlated to an issue existing with the stability of the catheter handle. It is important to note that when questions regarding torquing difficulty (Q5 and Q5b) were asked, users may not have understood the intended meaning of the question and specific aspect of handle-torquing we were referring to. Some respondents interpreted the question as asking if they physically struggled to rotate the catheter handle, in which they responded 'no,' and therefore may have expressed not having any issues with the catheter handle and no issues that needed to be addressed.

Analysis of Device Validation Results from Follow-Up Survey

The device validation survey results indicate that our catheter handle sheath devices may be effective in reducing torquing issues. An average rating of 7.46 out of 10 indicates how intracardiac ultrasound catheter users perceived our proposed devices to be of possible benefit. Furthermore, a low standard deviation of 1.01 indicates a lack in variance among user responses, despite having varying levels of experience. A consistent, positive response from all three groups (attending physicians, advanced EP fellows, and technicians) of our follow-up survey supports the efficacy of our designs. The two responses with lower perceived efficacy ratings were Q2 (5 ± 3.03) and Q3 (4.29 ± 2.67) which asked for respondents to theorize the possibility of our devices to reduce procedure time and costs, respectively (Table S2). This indicates that the device is not perceived by the respondents to reduce costs or procedure time. These two questions saw higher variation in the responses, with standard deviations of 3.03 and 2.67, which can be significant for questions asked on a scale of 1 to 10. All three groups had a consensus agreement on trying the device. This question saw the highest score among all others, quantifying the respondent's desire to try a device that could potentially mitigate catheter handle instability.

Although the sheath designs were perceived to not be the most effective in reducing procedure time or costs, all three groups expressed high interest in trying our proposed catheter sheath designs, supporting our project motivation and the necessity to address stability issues with intracardiac ultrasound catheters.

Additional feedback received from respondents are documented at the bottom of Table S2 and will be discussed for future work.

Future Work

Due to the coronavirus disease (COVID-19) that impacted project timelines and intended results, our team was unable to accomplish some desired goals of this project. University facilities had closed after Spring Break, disabling us from proceeding with 3D printing our designs. Consequently, we were unable to perform self-testing or test our designs with users in the UVA EP Lab. In an effort to receive feedback on our proposed designs, we conducted follow-up interviews (Figure S2) as a method of device validation.

This study could be furthered by continuing the design process. Once University facilities re-open, the novel designs can be 3D-printed. After the prototypes are 3D-printed, testing of the devices can be performed by the team themselves prior to testing with users. This would allow the team to iterate and improve upon the prototypes before presenting them to medical experts for testing. The prototyped designs should be presented to the same demographic of physicians and technicians from the UVA EP Lab. Before conducting human testing, IRB approval must be met in order to meet ethical guidelines. After receiving feedback from medical professionals, the designs should be reiterated and presented to them again. Once design satisfaction is achieved, CAD load-bearing simulations and mechanical Instron machine testing should be considered in order to analyze device resiliency. This would allow for choosing the optimal materials, such as polycarbonate for the outside body of the sheath, and a flexible yet durable material for the inner surface of the device.

Further feedback received from respondents of the follow-up survey expressed changes to the overall shape of the sheath designs. Suggesting valid points, a few respondents explained that having a device wider at the bottom than at the top can help add to stability, and changing the shape from a rounded-oblong device to a device with flat sides, such as a hexagonal shape, can also help add to overall stability. Aggregated in Table S2, these suggestions would be beneficial and should be considered for future work on this project.

Materials and Methods

Designing of Device Prototypes

Sheath prototypes were designed using the CAD software, Fusion 360. Printing of an initial design of a hinge to connect the parts of one of the sheath designs was performed using the LulzBot Taz 5 3D printer. The filament used for 3D printing the hinge prototype was polylactic acid (PLA).

Conducting Surveys with Users of the Intracardiac Ultrasound Catheter

Two surveys were conducted through the duration of this project. The preliminary surveys (Figure S2) were conducted with users as in-person interviews, where members of the team transcribed the users' responses. These responses were then digitized and compiled on Microsoft Excel and aggregated to find patterns and correlations. The follow-up surveys (Figure S3) were conducted with users virtually over video- or phone-calls, where user responses were also transcribed, compiled, and aggregated. Tables, figures, and graphics created by the team were constructed using Microsoft Office tools.

End Matter

Author Contributions and Notes

A.L., A.P., N.M., K.M., and M.M. designed research, A.L and A.P. performed research, A.L. and A.P. analyzed data; and A.L. and A.P. wrote the paper.
The authors declare no conflict of interest.

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ICE Catheter Torquing iCore Questionnaire

Today's Date & Team Member: ____________________

Name of Interviewee: ____________________

Title/Position, Years of Experience: ____________________

1) How long have you used ICE catheters for (years) and how often do you use them?

2) How comfortable are you with ICE catheters?

3) How much do you rely on this method of guidance for procedure?

4) How often do you have to torque/counter torque the catheter (0-5, 5-10, >10)

5) Do you encounter any difficulties with torquing?

   a) If so, how often do you need to make an adjustment?

   b) Do you perceive this as a problem that should be tackled?

6) What is your current method for keeping catheter in place?

   a) How often do you ask a tech to hold it in place?

   b) What is your strategy to hold the catheter in place right now if you don't have an assistance?

7) How effective do you think your current method(s) are?

8) How do you suggest the current ICE catheter design can be improved? Any limitations?

   a) If we could come up with something to make this better, what would you like to see in your dream device?

   b) Would you be willing to try it?

9) Any additional comments?

Thank you for your time. We really appreciate your responses!

Supplementary Figure 1. Preliminary Survey. Questionnaire developed to gain insight on current intracardiac ultrasound catheter use in the University of Virginia Health System Atrial Fibrillation Center. The questionnaire was used to survey medical staff from the Electrophysiology Labs. "ICE catheter" referred to intracardiac ultrasound catheters.[19]

Follow Up Interview: Questions

1. Do you have any questions regarding the devices?

2. How effective do you think this device would be in resolving the catheter instability issue (e.g. handle not staying in place, or user needing to make constant re-adjustments)? (1-10)

3. How effective do you think the device would be in reducing procedure time? (1-10)

4. How effective do you think the device would be in reducing costs? (1-10)

5a. Based on the designs, would you make use of the device? (Y/N)

5b. How likely would you use the device? (1-10)

6. What do you like and/or dislike about the designs?

7. If you could, what would you modify about the design?
What (else/more) would you like to see?

Supplementary Figure 2. Follow-Up Survey. A short survey was conducted with users of the intracardiac ultrasound catheter at the University of Virginia Health System Atrial Fibrillation Center. These questions were used to receive constructive feedback on the team's proposed designs for a sheath torquing tool.[20]

Supplementary Table 1. Results of Preliminary Survey. Preliminary questionnaires were conducted at the University of Virginia Health System Atrial Fibrillation Center. The questionnaire was used to survey n=12 medical staff, including attending physicians (5), advanced fellows (3), and cardiovascular technicians (4). The survey shows aggregated years of experience with in medicine and with the intracardiac ultrasound catheter. Q1 through Q8b show the questions asked and responses received from the individuals, with their responses processed and put into categories. Additional comments at the bottom of the table include additional feedback received about experiences with the catheter being explored. Q6b and Q8a have been omitted for many of the answers were repetitive and/or non-relevant to the project. "ICE catheter" referred to intracardiac ultrasound catheters.
*Regularly is defined as four to five times a week, or every day. Occasionally encompass two to three times a week. Infrequently is defined as one to two times a month.
**Heavily is defined as heavy dependence, if an intracardiac ultrasound catheter is being used by a physician during a procedure. Moderately is less than 70% reliance but greater than 20%.[21]

Preliminary Survey: Composite Results (n=12)

DEMOGRAPHICS	
Position	
Attending Physician	5
Advanced Fellows	3
Cardiovascular Technician	4
Sex	
Male	10
Female	2
Average Years of Experience [medical career]	
Attending Physician	8.8 ± 4.97
Advanced Fellows	0.67 ± 0.72
Cardiovascular Technician	11 ± 7.79
Overall	7.5 ± 6.6
Average Years of Experience [w/ultrasound catheter]	
Attending Physician	9.2 ± 5.56
Advanced Fellows	0.67 ± 0.72
Cardiovascular Technician	9.75 ± 6.08
Overall	7.25 ± 5.56
QUESTIONS	
Q1: "…how often do you use [intracardiac ultrasound catheters]?"	
Regularly*	7
Occasionally*	3
Infrequently*	2
Q2: How comfortable are you with intracardiac ultrasound catheters?	
Very Comfortable	7
Moderately Comfortable	5
Q3: How much do you rely on this method of guidance for procedure [when in use]?	
Heavily**	8
Moderately**	4
Q4: How often do you have to torque/counter-torque the catheter [per procedure]?	
1-5	2
5-10	4
>10	5
N/A	1

[Continued…] Supplementary Table 1. Results of Preliminary Survey

Q5: Do you encounter any difficulties with torqueing?	
Yes	2
Sometimes	2
No	7
N/A	1
Q5a: If so, how often do you need to make an adjustment?	
Constantly	3
Sometimes	2
N/A	7
Q5b: Do you perceive this as a problem that should be tackled?	
Yes	4
No	6
N/A	2
Q6: What is your current method for keeping catheter in place?	
Heavy Object (e.g. wet towel, rag, drapes)	5
Technician Assistance	1
None, readjust as needed	6
Q6a: How often do you ask a tech/are you asked to hold it in place?	
All the time	2
Sometimes	6
Rarely to Never	3
N/A	1
Q7: How effective do you think your current methods are?	
Effective	6
Somewhat Effective	2
Not Very Effective	4
Q8: How do you suggest the current ICE catheter design can be improved? Any limitations?	
A Solution to Instability Issue	7
N/A	5
Q8b: Would you be willing to try it?	
Yes	12
No	0

Additional Comments

- "Some procedures attempt to not use x-ray, so [we] rely completely on ultrasound […and…] it would be convenient if [the catheter] didn't move as much."
- "A […] more stable position would save time."
- "When you let go [of the catheter], it reverts pretty quickly."
- "[The catheter] won't stay steady in desired location […and…] the operation tends to be a two-person job."
- "[It] would be nice to adjust less."
- "Sometimes [I] need to make minor rotations. It's a dynamic process. You'd rather watch a movie than look at a picture."

Supplementary Table 2. Results of Follow-Up Survey. Short interviews were conducted with n=12 medical staff, eleven of which were the same respondents from the preliminary survey. Questions asked for constructive feedback on the sheath designs and perceived efficacy of the proposed designs in resolving the intracardiac ultrasound catheter torquing issue, reducing procedure time, and reducing costs. Included in the last column is also the aggregated ratings for how likely each respondent would use the proposed devices. All twelve respondents indicated that they would be interested in trying the designs in person.[22]

Position	Efficiency in resolving overall issue	Efficiency in reducing procedure time	Efficiency in reducing costs	Likelihood to use
Attending (n=4)	7.375 ± 0.750	4.5 ± 3.109	4.125 ± 2.955	6.75 ± 3.304
Fellow (n=3)	6.67 ± 0.289	2.5 ± 1.323	1.83 ± 1.041	6.83 ± 1.893
Technician (n=5)	8 ± 1.224	6.9 ± 2.793	5.9 ± 2.162	8.7 ± 2.636
Attending (n=4)	7.375 ± 0.750	4.5 ± 3.109	4.125 ± 2.955	6.75 ± 3.304
Total (n=12)	7.46 ± 1.010	5 ± 3.038	4.29 ± 2.667	7.58 ± 2.669

Additional Comments:

- “[consider a] hexagonal shape because of a flat side. [The] round design might still let [the catheter handle] roll”
- “If we can get [the devices] resterilized, [it would be help reduce costs]. If the tech doesn’t have to scrub in for a second time, would save money on gloves or another gown”
- “I like two piece design more as it seems more universal”
- “A big advantage [is that] it looks simple”
- “Design is simple and straightforward”
- “Not too many moving parts [means] less things can break”
- “Seems easy to learn [and] not complicated or tedious”
- “Would be good for general anesthesia”
- “May be difficult with conscious sedation [because] patient could move”
- “May be difficult to stabilize on … uneven surfaces … or body parts”
- “Hard to say without seeing it in person”