A New Perspective on Minimally Invasive Procedures: Exploring the Utility of a Novel Virtual Reality Endovascular Navigation System

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Abstract

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Digital information is playing a larger role in the treatment of disease. Invasive procedures, such as open-heart surgery, have evolved into minimally invasive procedures that benefit from reduced trauma, scarring and recovery times. However, unlike their ancestors, minimally invasive procedures do not provide direct line of sight, and, as a result, require alternative means to depict the operative field. Modern medical images are digital representations of the operative field that are used to guide minimally invasive procedures, including endovascular procedures that occur in the blood stream. Because blood impedes light, light-based cameras, such as endoscopes, are extremely limited in their utility, requiring endovascular proceduralists to rely on non-light-based imaging. However, non-light-based imaging can be difficult to understand

due to the lack of visual depth cues in their display. In this dissertation, I explored a novel method of displaying endovascular imaging through the design, development and evaluation of a head mounted display catheter guidance system. Using my system, proceduralists performing a visually complex and potentially dangerous endovascular maneuver known as the transseptal puncture performed with greater accuracy and, subjectively, a better understanding of the operative field. It is my hope that the knowledge and artifacts generated during my work influence the implementation of improved medical practices.

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Acknowledgements

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Dedication

This dissertation is dedicated to my wife and daughter.

To my wife, Danielle Hayden: Thank you for continually pushing me. Every word in this dissertation stems from a motivation rooted in you. I couldn't have done this without you.

To my daughter, Aria James: Thank you for your curiosity, for showing me a new way to love, and for filling my heart with joy every time I think of you.

1 Chapter 1: Introduction

Minimally invasive procedures treat diseases affecting nearly every organ in the body. They are widely adopted alternatives to invasive cut and sew methods, such as open-heart surgery, due to their relatively significant clinical benefits, including reduced trauma, scarring and recovery times [1]. However, in addition to these benefits, minimally invasive procedures have considerable navigational challenges due to the lack of direct line of sight to the operative field [2]. These challenges are most apparent during endovascular procedures, the domain focus of this dissertation. During other minimally invasive procedures, such as laparoscopy, surgeons use light-based cameras to image the operative field. In contrast, because blood impedes light, endovascular procedures are forced to use alternative, often less intuitive and harmful imaging modalities—discussed further in chapter 2.

Recent advancements in stereoscopic head mounted displays (HMDs), such as virtual reality, present the opportunity to dramatically reduce endovascular navigational challenges by improving the visualization of non-intuitive, harmless imaging [3]. During my research, I explored the utility of HMD guidance through the design, development and evaluation of a novel virtual reality catheter navigation system named CathEye. In a comparative study, I found that physicians performed the transseptal puncture more accurately ($p < 0.05$) and, subjectively, with a greater understating of anatomy using CathEye relative to conventional fluoroscopic guidance. These results suggest HMDs have significant potential to improve clinical outcomes during the transseptal puncture and other visually complex minimally invasive maneuvers by reducing navigational challenges through the intuitive, high fidelity display of medical images.

1.1 Motivation

My research was motivated by the visual advantages of invasive procedures and the visual challenges limiting endovascular treatments. The human visual system, detailed further in chapter 2, was designed to see two images, one in each eye, that change as the head moves [4]. Information, especially complex information, is easiest to interpret when displayed this way (stereoscopically). Conversely, when information is not displayed stereoscopically it is more challenging to interpret. Medical images displayed on flat screens, for example, are more difficult to interpret than stereoscopic views of the same organ [3]. As procedures evolved from invasive to minimally invasive, the stereoscopic view of patient anatomy was replaced with monoscopic renderings on a flat screen. Though this shift resulted in significant risk benefits, they were accompanied by difficulties interpreting the operative field. I observed the results of this evolution firsthand while I observed procedures early on in my graduate student career. Below, I describe these observations as a series of anecdotes to highlight the key problems that influenced my research.

1.1.1 Invasive Procedures are Damaging to the Body

The patient was lying on the operating table with their chest cavity held open by metal retractors—their heart exposed and stopped (Figure 1.1). With a headlamp, the operating surgeon, starring intently, used a scalpel to slice open the heart and gain access to its internal structures. As he separated the cut, a small tube appeared. Inside was a collection of cancer cells that prevented the patient's heart from beating normally. With direct line of sight and great precision, the surgeon cut until the cancer was removed, then stitched the patient back together.

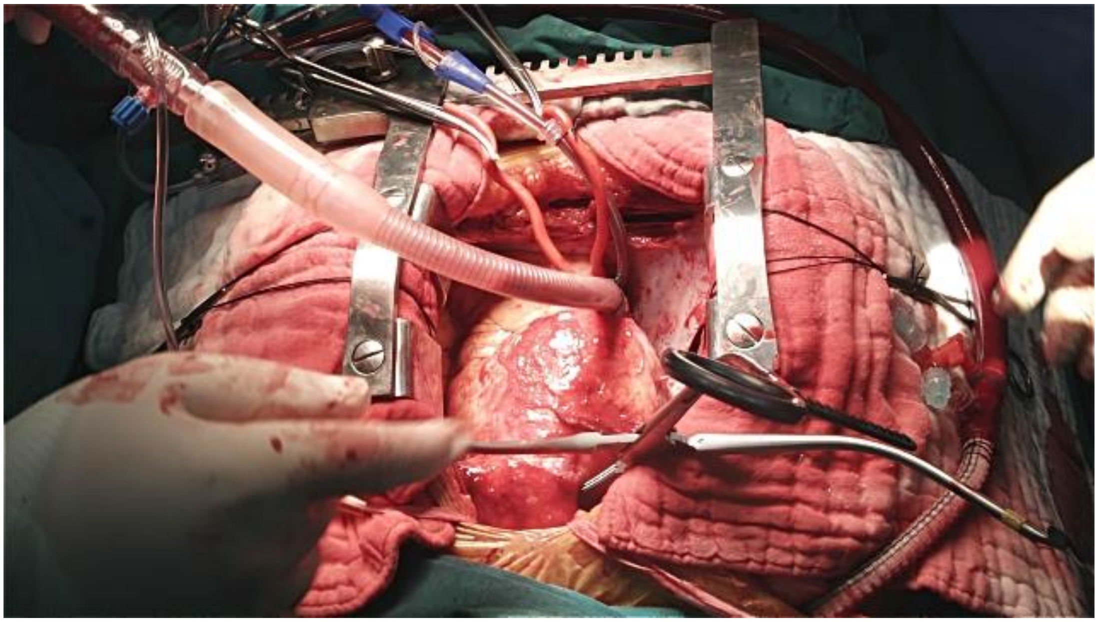

Figure 1.1 Depicts the invasive nature of open-heart surgery.

Though the procedure was extremely invasive, direct line of sight facilitated performance. Open-heart surgery results in lengthy recovery times and both internal and external scarring. However, because the patient was cut open, the surgeon could see the heart and his tools very clearly, which facilitated his interpretation of the operative field and instrument navigation. The significance of these observations became apparent when I watched a minimally invasive procedure.

1.1.2 Direct Line of Sight Is Not Available During Minimally Invasive Procedures

The second procedure I observed was a minimally invasive endovascular procedure. The patient had a weak valve on the left side of their heart that needed reinforcement. Instead of opening the chest, a small incision was made in the patient’s right thigh that provided access to a major vein. A catheter was pushed into the vein and navigated until it reached the heart. Because this took place beneath the skin in the patient’s blood stream direct line of sight was not possible.

Instead, the operator used medical images displayed on a flat screen (Figure 1.2) to render the procedural field.

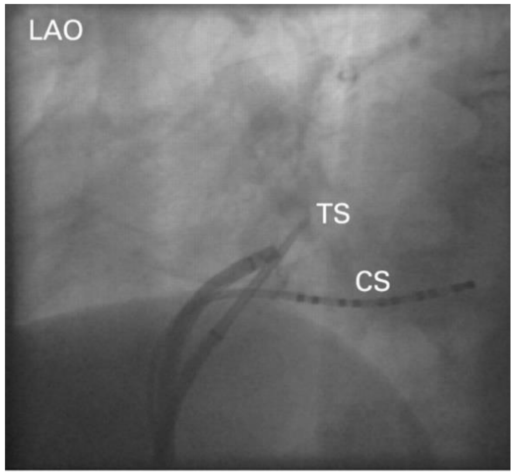

Figure 1.2 A fluoroscopic image of the heart.

As you can see when comparing Figure 1.1 and Figure 1.2, monoscopic images of the heart are far less intuitive than direct line of sight. This was most evident during the transseptal puncture portion of the procedure. As the proceduralist pulled his catheter down the inner wall of the heart, it fell into a small crevasse. This was indicated both visually as the catheter made a small movement on the fluoroscopic image and haptically as the catheter's handle subtly vibrated. During the next phase, as he prepared to puncture, his colleague placed an ultrasound probe down the patient's throat into their esophagus to capture 3D images of the heart. This allowed the operating physician to see the heart tissue tent, which was not visible in the fluoroscopic image, as he pushed his needle. Though the physician was using two imaging modalities, fluoroscopy and ultrasound, their inability to effectively describe 3D anatomy forced him to rely heavily on his subjective mental model of the patient's anatomy as he carefully advanced the needle and avoided potentially fatal perforations. After the needle was in a satisfactory position, he pushed the catheter over the needle to complete the transseptal puncture, then performed the remainder of the treatment on the left side of the heart.

This procedure clearly demonstrated the benefits of minimally invasive endovascular procedures and the visualization challenges associated with monoscopic renderings. The recovery time following an endovascular procedure is generally one to five days—significantly less time than the months of recovery following an invasive procedure. However, unlike the intuitive description of the operative field that invasive surgeons experience with direct line of sight, medical images displayed on a flat screen do not convey nearly the same degree of spatial detail, increasing the visual challenges associated with endovascular procedures. These visual challenges are exacerbated by harmful radiation.

1.1.3 Harmful Radiation Hurts Doctors and Patients

Like many physicians performing the transseptal puncture, the operator performing the endovascular procedure described above relied heavily on fluoroscopy to guide his catheter. Fluoroscopy, detailed further in chapter 2, uses a continuous stream of ionizing radiation, or x-rays, to generate images (Figure 1.2). X-rays are shined on the patient and many are absorbed by their body. The x-rays that are not absorbed are either collected and processed by a computer to generate an image or reflected into the operating room. To protect themselves from second-hand radiation exposure, the physician and his clinical staff wore heavy lead suits, which have been associated with long term musculoskeletal injuries [5], [6], such as severe neck and back pain.

In response to the detrimental effects of ionizing radiation on both patient and provider, there have been significant efforts [7]–[13] to evolve alternative imaging modalities and move catheter-based procedures away from fluoroscopy. However, although progress has been made, fluoroscopy is still the modality of choice during most transseptal punctures and many other catheter maneuvers. Improving how ultrasound and other harmless 3D imaging modalities are displayed may be enough to overcome this significant hurdle.

1.2 Solution Approach

A solution that addresses the above challenges must provide stereoscopic direct line of sight during endovascular procedures using a harmless imaging modality. Direct line of sight is the visible path from one's eyes to a target area. While the nature of minimally invasive procedures precludes true direct line of sight, algorithms that recreate 3D targets from medical images can be used in conjunction with stereoscopic HMDs to create a digital form of direct line of sight. However, because medical images do not precisely track instruments, the catheter would not be displayed in a manner that allowed the operator to adequately manipulate their instruments. Fortunately, cardiac mapping systems, described further in chapter 2, use sensor-based technology to track endovascular catheters with millimeter precision. However, commercially available cardiac mapping systems do not share tracking data with external software. An open-data tracking system would address this problem by exposing catheter location data with the HMD application, enabling it to understand and precisely visualize the catheter in context of the procedural field. Considering these solutions and the high degree of visual complexity associated with the transseptal puncture, I organized my dissertation work into the following three aims:

Aim 1: Develop an open-data endovascular navigation platform

Aim 2: Develop a head mounted display catheter guidance system to facilitate the transseptal puncture

Aim 3: Compare conventional vs HMD catheter navigation by novice and experienced operators in a cardiac phantom

1.3 Contributions to Science

I developed CathEye to overcome limitations in monoscopic displays (i.e. flat screens) by increasing the utility of harmless medical imaging. It is a virtual world that surrounds the operator, immersing them in the operative field. Using real time data from the open-data platform, the target organ and catheters are displayed to the user as if they were inside of the body. This creates a virtual direct line of sight that is unparallel to conventional display technologies. In a comparative study with 8 subjects (6 faculty and 2 fellows), we found that HMD guidance led to more accurate transseptal punctures and, subjectively, a more intuitive understanding of the operative field, especially for novices. This knowledge is particularly important given the recent rise in HMD funded research [14]. It is my hope that CathEye and the knowledge it generated aid future endovascular research and influence movements towards less complex, less harmful, more precise clinical practices.

I developed the open-data navigation platform to support the development of CathEye and potentially other forms of endovascular navigation research. It is extremely difficult to obtain data from commercially available catheter navigation systems, creating a wide gap for researchers who need navigation data. My platform hides the complexity of reading catheter coordinates and co-registering medical images behind an easy to use software library, so technologies that need navigation data can easily consume it. It is my hope that this platform facilitates a wide array of future research including by not limited to telerobotic and autonomous navigation.

1.4 Dissertation Structure

Chapter 2 discusses background that is important to the remainder of this dissertation. Chapter 3 details the design and implementation of the open-data endovascular navigation platform. Chapter 4 discusses the HMD guidance system, including the user-centered design approach taken during development. Chapter 5 evaluates the HMD guidance system against conventional fluoroscopic guidance. Finally, chapter 6 concludes with a discussion on important future work.

2 Chapter 2: Background

In the last chapter I described the benefits of direct line of sight during invasive procedures and detailed the cascading adverse effects the lack of direct line of sight has on endovascular procedures—in particular, how monoscopic screens, blood and non-light-based imaging create significant visual challenges for endovascular proceduralists. In this chapter, however, I dive deep into important details on the human visual system, endovascular procedures, the transseptal puncture and HMDs that justify my solution approach. I start with a discussion on the human visual system to detail the fundamental concepts behind the importance of direct line of sight and the challenges created by the lack thereof during minimally invasive procedures.

2.1 The Human Visual System

The human visual system uses visual depth cues to understand the position, size and structure of objects. Like the way a single word in a sentence conveys part of an idea, a single visual cue conveys part of the spatial and structural characteristics of an object in a scene. Thus, understanding each visual cue's function is extremely important prior to an in-depth discussion on visual challenges and potential solutions. To describe each depth cue clearly, I've separated them into two categories: monocular depth cues (i.e. those seen by a single eye) and binocular depth cues (i.e. those requiring both eyes).

2.1.1 Monocular Depth Cues

Figure 2.1 Demonstrates monocular depth cues.

Perspective projection is a monocular depth cue that makes objects seem smaller the further they are away, and makes parallel lines seemingly converge as their distance from the observer increases [15]. This is clearly seen in Figure 2.1. The trees on the sides of the road seem smaller the further they are into the scene, and the parallel lines outlining the sides of the road seemingly converge as they move away from the point of perspective. Each of these hints helps us understand the relative size and position of objects in the scene.

Occlusion is a monocular depth cue that helps us order objects in a scene. An object in front of another object occludes, or blocks, the object behind it, which helps the observer understand the relative position of both objects. Occlusion is part of what helps us understand that the bronze tree on the far left of Figure 2.1 is closer than the green tree that it partially occludes.

Familiar size is a monocular depth cue that helps us understand the depth of an object based on its relative size to an object that we are familiar with. For example, the relative sizes of the trees in Figure 2.1 helps us understand their depth in the scene.

Shading is another very important monocular depth cue that helps us understand the shapes of objects. For example, the shadows on the road in Figure 2.1 help us understand the parts of trees we cannot see. It is important to note that properly interpreting this depth cue relies on an understanding of the light source. If the position of the light source is understood, this can be a very powerful depth cue for understanding 3D structure.

Structure from motion is a monocular depth cue that helps us understand an object's shape as the object rotates. Our minds stitch together the different views of the rotating object to form an understanding of its 3D structure. For example, if a tree in Figure 2.1 slowly rotated 360^0, we would be able to integrate the different views of the tree to form its 3D structure in our minds.

Monocular motion parallax, not to be confused with structure from motion, is a monocular depth cue that helps us understand the shapes and depths of objects as the viewer's perspective changes. As it changes, the relative movement of objects in the scene provides an understanding of their depth and 3D structure. For example, if the photographer from Figure 2.1 were to take a new picture a few steps to the left or right, trees closer to the camera would be displaced more than trees further from the camera which would indicate their relative depths in the scene. In addition, newly visible parts of a tree in the second image would provide a better understanding of the tree's 3D structure.

2.1.2 Binocular Depth Cues

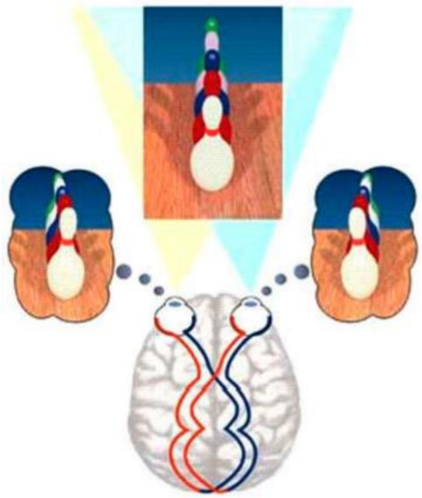

Figure 2.2 Depicts the process of stereopsis, where the mind merges two slightly different images seen by each eye into a single image that provides the perception of depth. Photo taken from [16].

Stereopsis is a binocular depth cue that helps us understand the position, size and structure of objects based on our cognitive interpretation of two slightly different images, one fed to each eye [17] (Figure 2.2). When objects are located within a few meters, this depth cue provides the most accurate description of relative depth between objects in a scene.

Binocular motion parallax is a binocular depth cue that helps humans understand the shapes and depths of objects as the viewer's perspective changes. It is very similar to monocular motion parallax except it uses stereopsis, or the interpretation of two slightly different images in each eye, to facilitate the spatial understanding of objects in a scene as the perspective changes.

2.1.3 The Procedural Significance of Binocular Depth Cues

Though monocular depth cues are important, binocular depth cues are the most important during near distance complex tasks requiring hand-eye coordination [18]—for example, during minimally invasive procedures. However, as described in chapter 1, binocular depth cues are not available during these procedures. As a result, proceduralists' ability to understand the operative field is severely limited, especially during challenging maneuvers. Instead of relying on objective, binocular data, minimally invasive proceduralists rely on a mental model of anatomy that is largely based on subjective data from past experiences [3]. This phenomenon makes minimally invasive procedures more difficult to learn and perform than they would be if binocular depth cues were available. This problem is most apparent during endovascular minimally invasive procedures and the transseptal puncture specifically.

2.2 Endovascular Procedures

Endovascular procedures, like other minimally invasive procedures, display images on monoscopic screens and therefore do not benefit from binocular depth cues. However, images displayed during endovascular procedures, unlike other minimally invasive procedures, also lack certain *monocular* depth cues, which makes understanding the operative field more difficult to understand. Where other minimally invasive procedures use light-based cameras that render images containing almost all monocular depth cues (i.e. perspective projection, occlusion, familiar size, shading, structure from motion), endovascular procedures render non-light-based images that do not contain all of these depth cues. The juxtaposition in Figure 2.3 depicts this difference quite clearly.

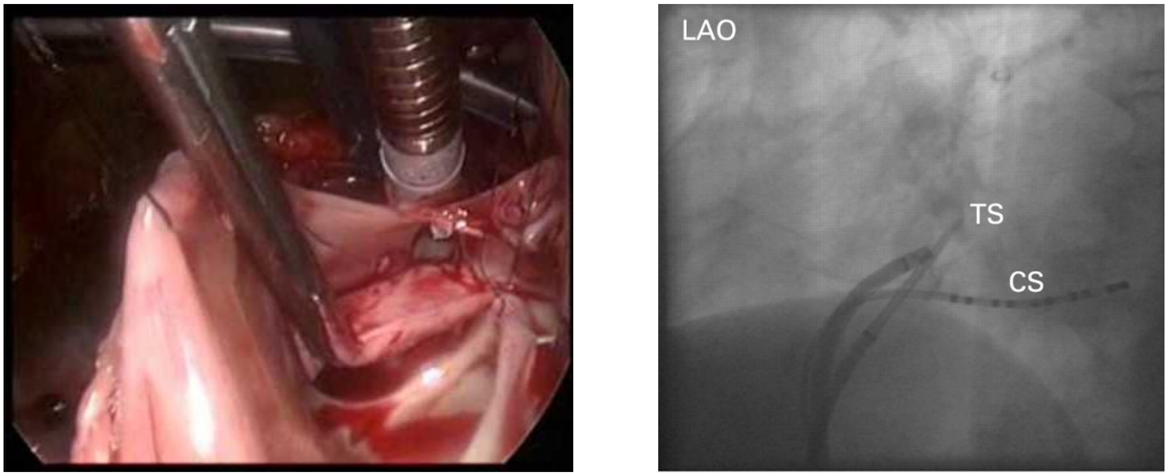

Figure 2.3 A light-based (left [19]) and non-light-based (right [2]) image of the heart.

The light-based camera image (Figure 2.3 A) clearly contains the perspective projection, occlusion, familiar size, and shading monocular depth cues, and if we were to watch the camera's video feed we would see the structure from motion monocular depth cue. In contrast, none of these depth cues are clearly visible in the fluoroscopic non-light-based image (Figure 2.3 B), leaving much more to the imagination. Alternative non-light-based imaging modalities, such as 3D ultrasound and impedance-based imaging, described in more detail later in this chapter, depict more monocular depth cues than fluoroscopy, but none of these imaging modalities display depth as clearly as light-based imaging. As a result, understanding the operative field during endovascular procedures is significantly more challenging and potentially fatal during spatially complex tasks.

2.2.1 Transseptal Puncture (TSP)

The TSP is arguably the most spatially complex endovascular maneuver. It is commonly used by cardiologists to move catheters from the right atrium (RA) to the left atrium (LA) in order to perform lifesaving left heart interventions, including catheter ablation, percutaneous mitral valvuloplasty, left atrial appendage (LAA) closure, mitral valve repair, mitral valve replacement, mitral valve-in-valve therapy, pulmonary vein isolation, insertion of pulmonary assist devices, and antegrade treatment of left ventricular and aortic valve disease [2], [20]. It is, therefore, extremely important to perform the TSP. However, due to its spatial complexities that are exacerbated by the way images are displayed, the TSP is dangerous and challenging to learn and perform [2].

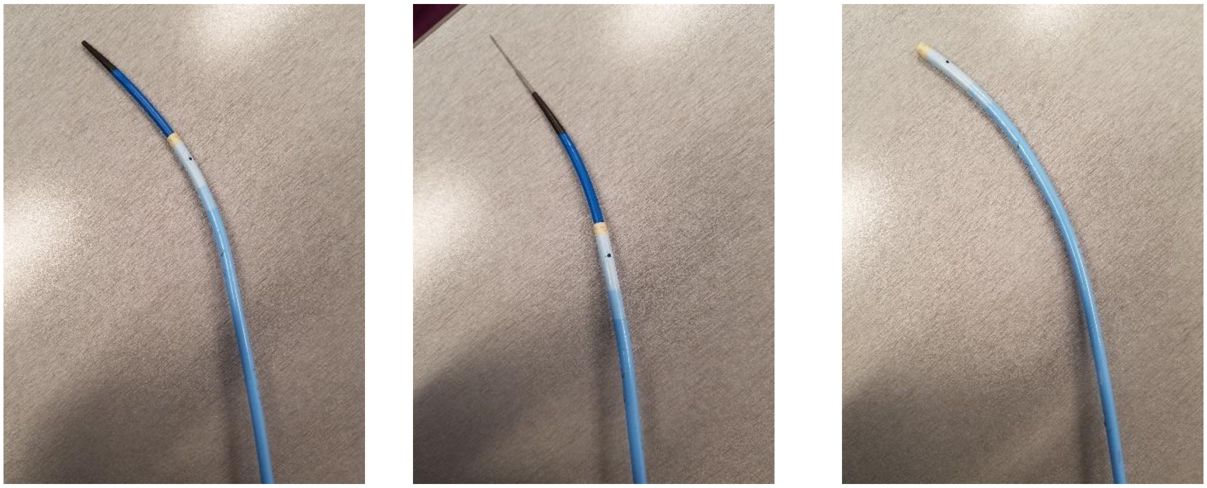

Figure 2.4 Transseptal sheath (light blue), dilator (dark blue) and needle (grey) at different stages during the TSP.

It is important to understand how the transseptal is performed to fully grasp its spatial complexities. During the maneuver, a cardiologist guides a sheath, dilator, and needle (Figure 2.4) into the heart through a small incision in the right thigh [2]. The needle is carefully positioned at the end of the dilator, but not extended beyond it at this stage (Figure 2.4BA). The assembly is then pulled down as a unit until the tip of the dilator engages the fossa ovalis (FO)—a thin part of the heart that separates the RA from the LA. With the assembly in place, the needle is advanced approximately one centimeter past the end of the dilator (Figure 2.4 B) to puncture the FO. The proceduralist must be careful not to push the needle too far and puncture opposite side of the LA—a potentially fatal accident that causes the heart to bleed into the pericardial sac—but must push far enough to puncture the flexible tissue. To verify the needle has crossed an appropriate distance, the operator injects contrast. If the FO was successfully punctured the operator will see the contrast fill the LA on their screen. Once verified, the dilator is advanced to widen the puncture, creating a small window into the LA and room for the sheath. The sheath is then pushed across into the LA while the dilator and needle are retracted, entirely removed from the sheath's lumen (Figure 2.4 C). With the hollow sheath now providing a tunnel from the outside world into to the LA, the TSP maneuver is complete, and the operator is ready to begin the remainder of the LA intervention.

Like backing up a car when parallel parking, puncturing the fossa ovalis at the correct location and angle sets the proceduralist up for the remainder of the LA intervention. If the puncture is made improperly, steering the catheter to the desired LA location (e.g. mitral valve, left atrial appendage, pulmonary veins) will be difficult, prolonging the procedure and increasing the potential for error [20]. A puncture at the correct location and angle, however, allows the procedure to progress with relative ease, relatively decreasing operating time and the potential for error [20].

To increase the odds of puncturing the FO in the best location, the proceduralist views images of the operative field. However, as discussed previously, these images lack visual cues that are important for understanding anatomical size, depth and structure, requiring the proceduralist to create a subjective mental model that increases the difficulty and risk of the procedure.

2.2.1.1 Complications

Puncturing in the wrong location can lead to deadly complications, most notably cardiac tamponade and aortic root puncture [21]. Cardiac tamponade generally occurs when the transseptal needle inadvertently exist the heart causing the heart to bleed into the pericardial sac. The pericardial sac is a thin layer of tissue cradling the heart. When it fills with blood it creates a high-pressure environment around the heart that restricts the heart from beating. This condition requires a cardio thoracic surgeon to repair and is associated with extremely high risk of death.

Aortic root puncture occurs when the transseptal needle inadvertently punctures the root of the aorta located on the left atrial side of the heart [22]. The aorta, the major artery in the body, begins to rapidly bleed into the heart and chest, which begin to inadvertently fill up with blood. This condition also requires a cardiothoracic surgeon to repair and is associated with extremely high risk of death.

Cardiac tamponade and aortic root puncture occur in about 1% of patients who undergo the transseptal puncture [21], [22], and are generally a result of a misunderstanding of the operative field as depicted by medical images. It is therefore important to understand conventional imaging techniques in order to develop an alternative approach to overcome their limitations and decrease the odds of these severe complications.

2.2.2 Conventional Imaging Techniques

There are three main forms of imaging that are used during the transseptal puncture, and endovascular procedures generally. These imaging modalities include fluoroscopy, ultrasound and sensor-based mapping. Each modality has characteristics that are important to my solution approach that I describe below.

2.2.2.1 Fluoroscopy

Fluoroscopy is the most common imaging modality used during endovascular procedures. It uses ionizing x-ray radiation to generate images that, when played in sequence, show a live view of the operative field, including medical devices and patient anatomy.

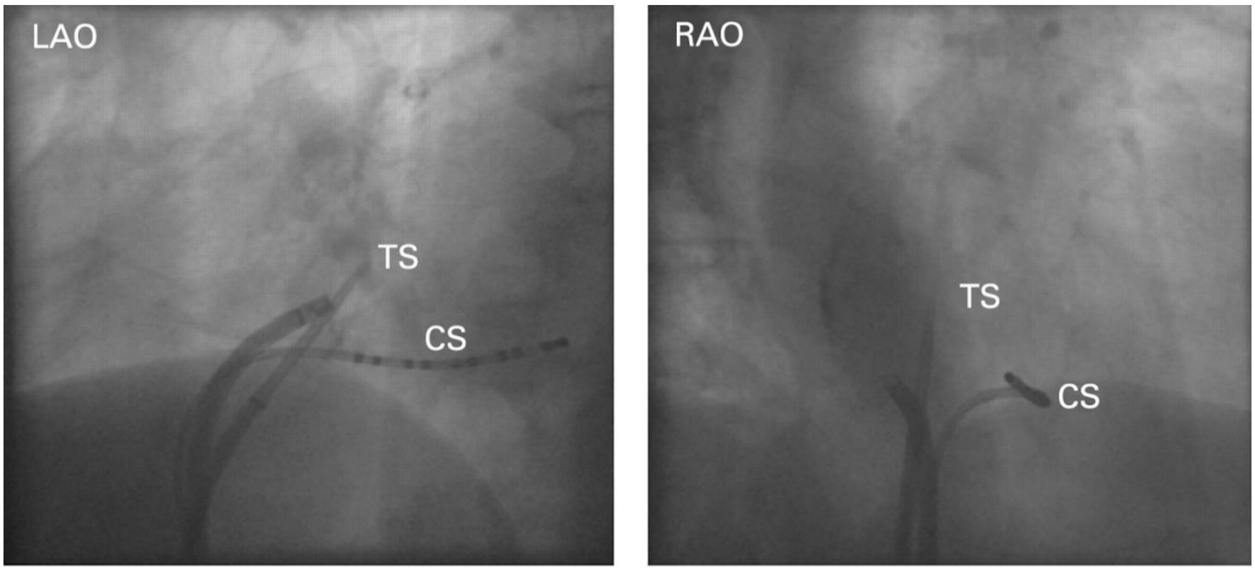

Figure 2.5 Fluoroscopic images taken during the TSP. The two images are taken from the left anterior oblique (LAO) and right anterior oblique (RAO) angles.

The images above depict X-rays of a heart undergoing a transseptal puncture. As described earlier, the goal of the transseptal puncture is to precisely puncture the fossa ovalis—a dime-sized indentation in the heart. However, as you can see in Figure 2.5, the fossa ovalis and other cardiac structures are not well visualized, and the image is lacking all monocular depth cues. This limited view forces the operator to mentally combine these images with their knowledge of cardiac structure to understand where they are in 3D space.

During the TSP, fluoroscopy shows the needle/dilator/sheath assembly “fall into” the FO. Combined with tactile feedback and a mental model of cardiac anatomy, the proceduralist uses this hint to determine where to puncture. However, making decisions based on crude visualizations, tactile feedback and a subjectively developed mental model of anatomy is very challenging. It is, in part, why the TSP has a steep learning curve and can remain difficult for experienced operators. In addition, because x-rays carry ionizing radiation, the use of fluoroscopy is physically harmful to the patient and operator, increasing risk for adverse effects such as skin burns and cancer [23]. In recent years there have been significant efforts to decrease the use of fluoroscopy through the use of alternative imaging [9][20].

2.2.2.2 Ultrasound

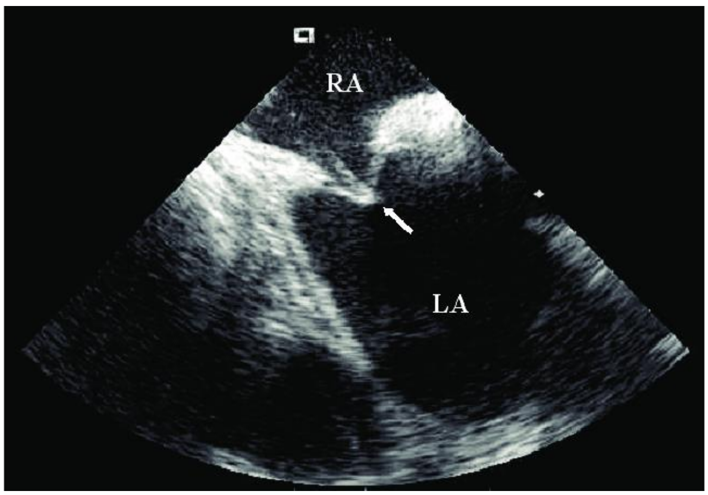

Figure 2.6 Depicts an intracardiac echo (ICE) image of the right and left atria during the transseptal puncture. The arrow is pointing at the transseptal needle.

Ultrasound, as an imaging modality, is harmless and frequently used to create live medical images. The task performed determines the type of ultrasound used. Many electrophysiologists, endovascular sub-specialists that deal with cardiac electrical signals, for instance, use intracardiac echo (ICE) during the transseptal puncture as an alternative to or in conjunction with fluoroscopy. Traditional ICE consists of a linear array of ultrasound transducers, or piezoelectric crystals, fixed to the tip of a catheter. Electrophysiologists position the ICE catheter near the puncture location to visualize the puncture needle, fossa ovalis and surrounding anatomy (Figure 2.6). As you may notice in the figure, cardiac tissue is visualized that is not clearly visible in fluoroscopic images. In addition, the live ultrasound image feed benefits from the monocular depth cue structure from motion, which is also not available in fluoroscopic imagery. However, because the resulting image is planar, it only visualizes a sliver of important information, leaving much to the imagination. This is evident in the above figure where only a small sliver of the transseptal needle is visible, as indicated by the white arrow. Due to this significant limitation, planar ultrasound alone has not been enough to replace fluoroscopy is primarily used as a supplement [20]. However, 3D ultrasound overcomes these limitations.

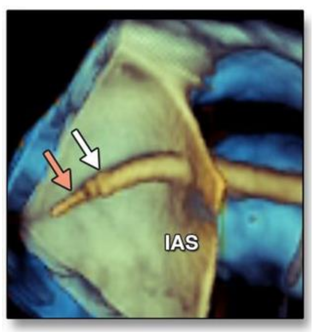

Figure 2.7 Shows a 3D transesophageal echo (TEE) image during the TS. Color is used to depict depth. Bright orange is closer while darker blue is further away. The transseptal needle is identified by the orange arrow and the sheathe is identified by the white arrow.

Other proceduralists use 3D transesophageal echo (TEE) to guide the TSP [24]. A 3D TEE probe contains a two-dimensional array of piezoelectric crystals that generates a 3D image

(Figure 2.7). The additional dimension of data relative to planar ICE makes imagery more descriptive and the operative field easier to understand, which decreases the visual complexity of the TSP. Volumetric algorithms process data from 3D TEE to create a visualization that includes digitally generated perspective projection, occlusion, familiar size, shading and structure from motion. Other than structure from motion which would be seen if the image was a live feed, each of these monocular depth cues can been seen in Figure 2.7, which resembles the light-based image of the heart depicted in Figure 2.3 A.

However, in addition to monocular depth cues, 3D TEE has significant drawbacks. It requires a large probe to placed down the throat, which often requires the patient be placed under general anesthesia and adds unpleasant throat pain to the patient's recovery. In addition, because the probe is controlled by a second physician, called an echocardiographer, additional cost is added to the procedure. These drawbacks make 3D TEE undesirable for most types of endovascular procedures.

2.2.2.3 Embedded Sensor Catheter Navigation Systems

Embedded sensor catheter navigations systems were developed to overcome challenges in other forms of imaging, namely the harmful effects of ionizing radiation and the lack of spatial detail. Using sensors embedded in the catheter, these navigations systems track and visualize catheters with millimeter precision [25]. The tracking system component records catheter location through a process like that of GPS, while the visualization system consumes the locational data to create a rendering for the operator that contains the same monocular depth cues available in light-based imaging. As a result, embedded sensor catheter imagery is arguably the most intuitive form of non-light-based imaging. Electrophysiologists were the first endovascular sub-specialty to adopt these navigation systems and, as a result, have experienced significant decreases in fluoroscopy time due and enhanced uses of ultrasound [10].

2.2.2.3.1 Tracking Component

There are two main types of embedded sensor tracking systems: electromagnetic (EM) and impedance (IMP) -based. My research used an electromagnetic tracking system. EM tracking systems have one EM transmitter and one or more EM sensors. The transmitter projects an EM field and, as sensors pass through this field, a force vector is measured to calculate the sensor's location and orientation in space [26]. During cases, the transmitter is placed near the patient and projects an EM field around target anatomy. During the transseptal puncture, for example, the transmitter is often mounted underneath the operating table adjacent to the patient's chest. As catheters with embedded EM sensors move through the patient's heart, coordinates (e.g. position [x, y, z] and rotation [a, r, e]) pinpoint the catheter's location and orientation in real time. This data enables the visualization component of the navigation system to show the catheter with significantly greater accuracy and flexibility relative to fluoroscopy and ultrasound.

2.2.2.3.2 Visualization Component

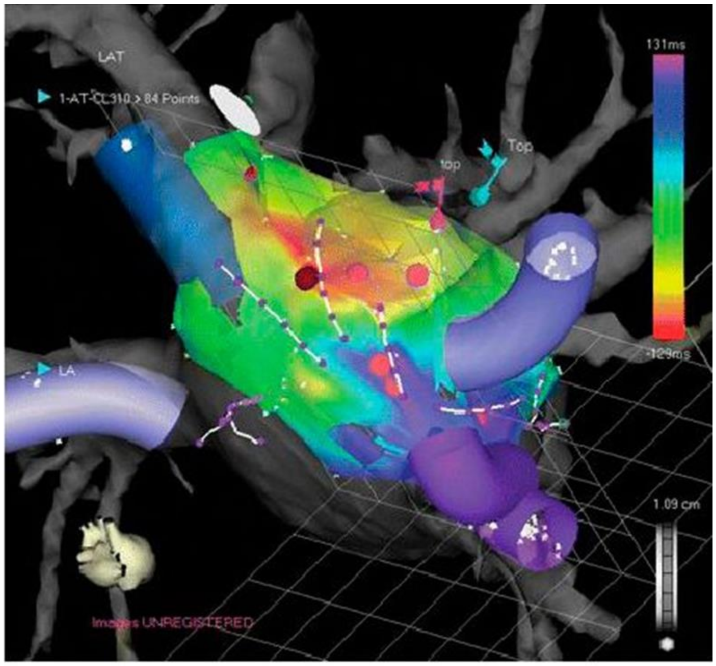

Figure 2.8 An image of the CARTO 3 electroanatomic mapping system.

The above image is a screenshot of CARTO (Biosense Webster, Irvine, California USA), the most commonly used catheter navigation system during electrophysiology procedures. CARTO uses both EM and IMP -based tracking systems to track and visualize catheters (seen as white lines in Figure 2.8) and build the image of the heart. CARTO uses the tip of the catheter like a crayon. As the catheter bumps into the walls of the heart, using the catheter’s location, CARTO’s algorithms draw the hart’s surface (Figure 2.8, grey). This creates a 3D dataset that, like the 3D TEE dataset, is used by algorithms to create the intuitive visualization above. However, because the surface of the heart is created from a series of points over time, this imaging modality alone cannot replace ultrasound and fluoroscopy. Unlike ultrasound, sensor-based visualizations do not display the heart’s structure in real time and, therefore, cannot be used to display, for example, the heart tissue tenting during that critical phase of the transseptal puncture. In addition, due to the point by point mapping approach to surface generation, this imaging modality initially displays a blank image, requiring a different modality, often fluoroscopy, to the guide the collection of the first set of points. Nonetheless, despite these limitations, sensor-based imaging is extremely valuable as demonstrated by its ability to enhance ICE.

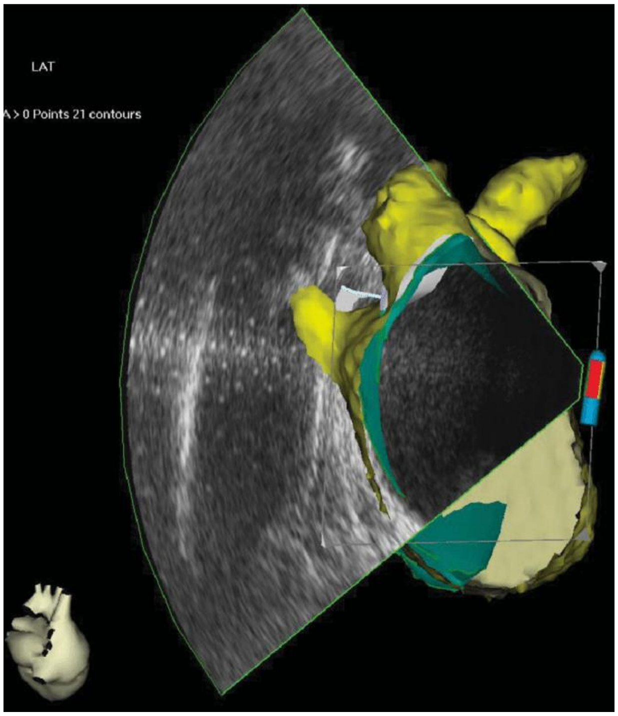

Figure 2.9 Depicts ICE co-registered to a CARTO image.

In addition to displaying the heart's surface, CARTO can overlay an ICE image (Figure 2.9). This added context is often used during the TSP to visualize the left side of the heart that has not been drawn. In addition, CARTO can be configured to combine ultrasound images over time. As the tracked ultrasound probe moves, CARTO's algorithms stack its images into a 3D surface that is combined with the surface generated with point by point mapping. However, despite this and other advanced features, fluoroscopy remains a mainstay and endovascular procedures remain visually complex due to their lack of binocular depth cues. Therefore, a need exists to explore next generation catheter navigation technologies.

Stereoscopic HMDs and their ability to render 3D datasets with binocular depth cues offer a unique opportunity to address the visualization challenges inherent in conventional endovascular imaging modalities. In order to understand these benefits, I provide background on the different types of stereoscopic displays and the research that laid the foundation for my work.

2.3 Stereoscopic Displays

While traditional screens such as monitors, phones and tablets are limited to monocular depth cues, stereoscopic displays use monocular *and* binocular depth cues to provide a natural way of viewing digital objects. As the viewer's perspective changes, the stereoscopic display sends slightly different images of a scene to the left and right eyes to create stereopsis and binocular motion parallax, the most important cues for understanding depth. In effect, stereoscopic displays depict objects as if they were real, creating the opportunity for more natural forms of human-computer interactions, such as digital direct line of sight. CathEye, detailed in chapter 4, provides this enhanced form of imaging. However, before I describe my solution approach it is important to understand the foundational research and technologies that it builds upon.

2.3.1 Conventional Stereoscopic Displays

Figure 2.10 A conventional stereoscopic display. Photo taken from (http://www.echopixeltech.com/).

Conventional stereoscopic displays (Figure 2.10) are flat monitors that send slightly different images to each eye to create stereopsis and binocular motion parallax. A 3D TV, for example, is a conventional stereoscopic display. As discussed below, research shows that these displays excel at communicating binocular depth cues where traditional monoscopic displays struggle [27]–[32]. However, conventional stereoscopic displays have limitations: they are stationary, which limits where they can be used; they are flat, which limits how users interact with digital objects; and users need to be in front of the screen, which limits the user's range of motion.

2.3.1.1 Mammography

Diagnosis and pre-operative planning were of the first clinical fields to adopt stereoscopic displays [27]. This comes as no surprise because these fields require a very detailed understanding of anatomical depth and structure that are communicated more effectively through stereoscopic displays.

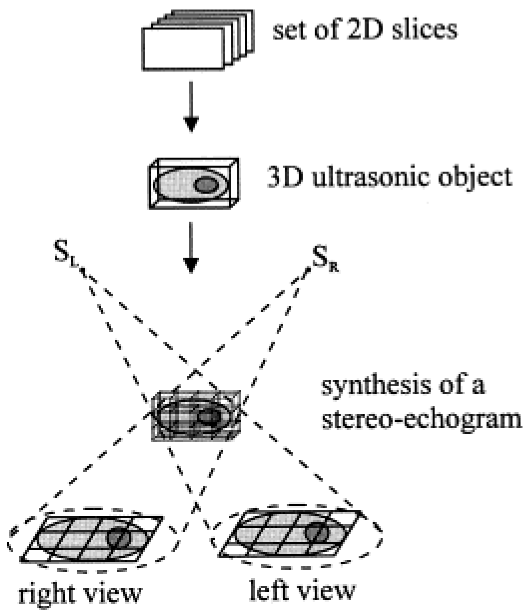

Figure 2.11 The principle of x-ray stereography [27].

X-ray stereography is one of the first applications of stereoscopic displays in medicine. In x-ray stereography, slightly different x-ray images are sent to each eye (Figure 2.11) to provide occlusion, stereopsis, and binocular parallax. This has been shown to facilitate the perception of depth and improve diagnostic accuracy. These outcomes are most evident in research studying the use of stereoscopic displays in mammography. A study that analyzed the effect of stereoscopic displays on diagnostic accuracy reported that radiologists who used stereoscopic displays to detect breast lesions did so with greater accuracy than radiologists who used standard (non-stereoscopic) displays [28]. In their publication, they suggest that these results are due to the radiologists' increased perception of depth, which allowed them to visually separate "difficult to spot" lesions from normal tissue in standard 2D projections. Similarly, Tanaka et al. explored the use of stereoscopic x-rays during the detection of breast cancer sentinel lymph nodes. They showed that stereoscopic displays delineated overlapping lymph nodes where conventional displays could not, which lead to improved detection accuracy [29].

However, x-ray stereography has its limitations. Obtaining a stereo pair of x-ray images requires double the dose of radiation, which has limited its use in the hospital. In addition, stereoscopic x-rays only depict a portion of anatomical structures, not the entire 3D structure, which limits what can be seen, and therefore, limits how x-ray stereography can be used to treat problems that require a complete understanding of 3D anatomy.

2.3.1.2 Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Rotational Angiography (RA) and Ultrasound (US)

Computed tomography (CT), magnetic resonance imaging (MRI), rotational angiography (RA) and ultrasound (US) are modalities that can produce 3D volumetric data. They have been used in conjunction with stereoscopic displays to facilitate the interpretation of anatomical depth and structure. After a scan, each of these imaging modalities produces a computer representation of the scanned object. The standard computer language for storing this information is called Digital Imaging and Communications in Medicine (DICOM). In this language, computers encode internal structures as a series of cross-sectional images, each representing a single anatomical slice that can be programmatically stitched together to form a volumetric representation of the encoded organ. Below, we discuss research that used stereoscopic displays to visualize these volumetric models to facilitate the interpretation of anatomy.

Using principles from x-ray stereography, Hernandez et al. developed a novel system for stereoscopically rendering ultrasound data as 3D volumes [27]. The stereoscopic images produced by their algorithm were very similar to those produced in x-ray stereography; however, because their technique was based on 3D ultrasound data as opposed to 2D x-ray data, their system could render stereoscopic images from any perspective around the 3D volume without harmful radiation. When viewed in rapid succession, these perspectives provided the illusion that the viewer was looking around the 3D object (i.e. the illusion of binocular motion parallax--the most important visual cue for understanding depth). In a single patient study, Hernandez et al. showed that a tumor was easier to detect when the patient's ultrasound data was viewed in their stereoscopic environment compared to the same data viewed as traditional tomographic images [27].

Diagnosis is only one area in which stereoscopic displays have influenced the interpretation of anatomical depth and structure. Planning for a stent placement requires an in-depth understanding of the size, length, and structure of blood vessels and their inner lumen along specific planes [30]. However, this 3D anatomical information is difficult to piece together when communicated through several tomographic images. To address this limitation, Zhou et al. developed AngioDex, a novel software package that enabled physicians to view, measure and edit CT and MRI data visualized as volumetric renderings through a conventional stereoscopic display (Figure 2.12). A key feature of their software displayed tomographic images as planar slices in the context of the volumetric rendering, which facilitated identifying and measuring structures. However, AngioDex was displayed through a conventional 2D stereoscopic display which limits the user's perspective because they need to stay in front of the screen and limits the setting in which the screen can be used because it requires a table to sit on or a wall mount. In addition, AngioDex used a physical wand as input, which may not be best suited for radiological environments.

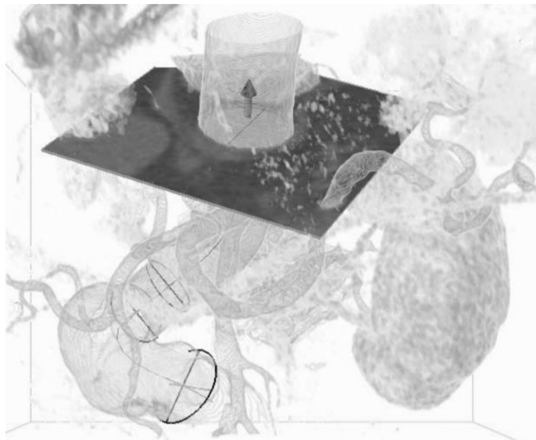

Figure 2.12 depicts a tomographic image embedded in a volumetric rendering of patient anatomy.

In a similar study Sun, Zhonghua et al. compared the use of stereoscopic displays to non-stereoscopic displays during the analysis of volume rendered anatomy from patients with abdominal aortic aneurysms treated with fenestrated stent grafts [31]. Their study was motivated by the inability of non-stereoscopic displays to adequately convey depth cues that facilitate the understanding of anatomical structure. Their results show that conventional stereoscopic displays provide additional information that assists users in identifying overlapping structures and fenestrated stent distortions.

Using a similar stereoscopic environment, Nelson et al. compared the use of stereoscopic displays to non-stereoscopic displays during the evaluation of volume-rendered fetal bony structures [32]. In their study, volume rendered structures were evaluated on a conventional workstation, then in a stereoscopic environment. They found that stereoscopic displays added structural detail, improved the identification of small, complex, and overlapping structures, significantly enhanced near structures compared to far structures, and overall provided better visualizations. In addition, they discovered that the introduction of a tomographic image within the rendered volume facilitated structural identification; the ability to remove overlapping structures helped users identify structures more efficiently; and users who combined motion cues with stereopsis learned the most from the stereoscopic environment.

These prior radiological studies demonstrate that stereoscopic displays facilitate understanding anatomical depth and structure using binocular depth cues. However, these studies are limited by their use of conventional stereoscopic displays and unnatural forms of human-computer interactions (e.g. input via pointer devices, mice and keyboards).

2.3.2 Stereoscopic Head Mounted Displays

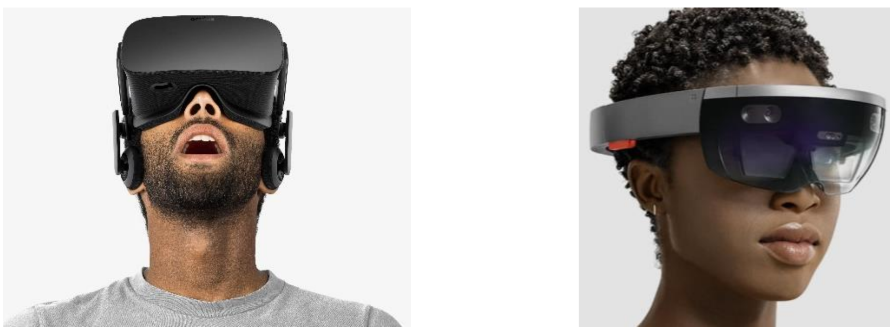

Figure 2.13 Two types of head mounted displays. VR (A) and OSTAR (B)

Stereoscopic HMDs address limitations in conventional stereoscopic displays by rendering imagery through a screen mounted directly in front of the wearer's eyes. In 1968, Ivan Southerland defined the HMD as a stereoscopic display mounted on the head that "surround[s] the user with displayed three-dimensional information" [33]. Today, there are several different types of these displays including virtual reality (VR) (Figure 2.13 A) and augmented reality (AR) (Figure 2.13 B). VR HMDs completely replace a user's view of the real world with a virtual world, creating the illusion that the user has been taken from their real reality and placed into a virtual, or simulated, reality. AR HMDs, on the other hand, add virtual objects to the real world, creating the illusion that digital objects exist within the user's normal reality. There are two types of AR HMDs: optical see-through augmented reality (OSTAR) HMDs and video see-through augmented reality (VSTAR) HMDs. OSTAR HMDs use see through glass to project virtual objects onto its user's retinas, while VSTAR HMDs use peripheral cameras and preprocessing to show the user a video feed of reality that has been augmented with virtual objects [34].

Both VR and AR HMDs allow the user to move around freely in a stereoscopic environment while interacting with digital objects in new and compelling ways. In chapter 4 I detail how I explored the use of both VR and AR to overcome the visual challenges associated with endovascular imaging by leveraging the imaging modalities and technologies described earlier in this chapter.

2.4 Background Summary

The human visual system leverages monocular and binocular depth cues to understand the world. When a depth cue is missing, the visual system attempts to fill in gaps with subjective knowledge. This phenomenon has a significant effect on perception during complex tasks, such as minimally invasive surgery, where depth cues become increasingly important for understanding the operative field. However, because medical images are displayed on monoscopic screens, binocular depth cues—the most important cues for understanding depth and structure—are unavailable during minimally invasive therapies. Endovascular procedures are a type of minimally invasive therapy that uses non-light-based imaging. This type of imaging is less intuitive than the light-based imaging used during other minimally invasive therapies, and therefore, will likely benefit most from binocular depth cues. The transseptal puncture in particular is a spatially challenging endovascular technique that is difficult to learn and perform despite the use of multiple imaging modalities, which include fluoroscopy, ultrasound and sensor-based imaging. Conventional stereoscopic displays and their ability to add binocular depth cues have been shown to enhance the understanding of anatomy, however, these displays are challenges by flat screens and limited human-computer interactions. VR and AR HMDs overcome these challenges through immersive display. In chapter 4 I describe how I used these technologies to explore the utility of stereoscopic, digital direct line of sight during the transseptal puncture.

3 Chapter 3: An Open-Data Platform for Endovascular Procedures

Data fuels the evolution of technology. When data are available, novel ideas become novel technologies, and “natural selection” tests the value of innovation relative to conventional practices. Conversely, when data are unavailable, ideas cannot evolve. In the medical technology industry, businesses fight to control evolution by limiting access to data. Current commercially available endovascular navigation technologies, for instance, keep data behind walled gardens to prevent others from developing competing solutions. This, unfortunately, limits the ability of catheter navigation research to readily explore new ideas. In this chapter, I describe an open-data platform that I designed and developed to break down these silos, to facilitate the creation of CathEye and other next-generation endovascular navigation technologies.

3.1 Why Open-Data?

Open data describes a method by which data are shared externally, eliminating the need for consuming technologies to create it. This method is commonplace in consumer technologies, most notably in navigation applications. In the context of navigation, data represents tracked objects and the environment. Therefore, an open-data navigation platform shares location and environmental data with external applications. Take Google Maps and Google Maps Platform, for instance. Google Maps is a popular car navigation application that uses the global positioning system (GPS) and digital map data to track and describe vehicles as they travel. Because GPS and environmental data are otherwise challenging to manage, Google developed Google Maps Platform, one of Google’s many open-data services, to share navigational data with the world. As a result, anyone with a computer can retrieve navigational data to build novel navigation applications without worrying about the complexities of satellite communication and terrain mapping. In effect, novel application developers can focus on novelty. This open-data paradigm has led to significant innovations in digital navigation as disparate as Waze, a crowdsourced traffic and vehicle navigation application; to Safe & Sound, an application that helps teen drivers focus on the rules of the road; to the United Parcel Service's (UPS) package tracking application.

When data are not available, however, the road to innovation is slow and inefficient. For example, if Google Maps Platform did not exist, the applications would have first needed to manage GPS and topology maps before beginning development on their navigation systems—an initial requirement that would have significantly delayed or, more likely, prevented innovation. Unfortunately, this type of initial headwind is commonplace in medicine because many medical applications are closed-data systems. In other words, they do not share data. This prevents or significantly hinders the evolution of technology. Endovascular navigation systems, detailed in the background section, for instance, keep data private despite generating data similar in structure to that exposed by Google Maps Platform. This private data practice constructs a significant hurdle, forcing innovators to abandon their ideas or build in-house tracking and mapping systems first. Neither of these options is ideal. It is possible that closed-data systems are the primary reason endovascular navigation systems have not experienced disruptive innovation since 1995—the year Biosense Webster (Irvine, California, USA) released the first anatomical mapping system [35].

Due to these data access restrictions, the potential to address visual challenges with HMD guidance as described in chapter 2, and the immense value generated through unencumbered technological evolution, I built an open-data platform for endovascular procedures which I detail below. In the next chapter I describe how it was used to develop CathEye.

3.2 Platform Design

Dr. Stephen Seslar and Dr. Kristen Patton, electrophysiologists at Seattle Children's Hospital, created a patient-specific plug-and-play cardiac catheterization simulator to explore the utility of 3D printing in electrophysiology (EP) simulation training [36]. Their results show that the simulator, consisting of an acrylic case, a 3D printed heart phantom, and the CARTO 3 EM navigation system, was an effective platform for endovascular research. I found their use of a 3D printed heart particularly interesting because it presented the opportunity to base the digital direct line of sight off of a physical object.

Their patient simulator provided a physical operative field that I used as the foundation for my work. In addition to their acrylic case and plug-and-play organ design, I added a series of hardware and software components that allowed me to track catheters and process their data in CathEye. I replaced the CARTO 3 system with an Ascension TrakSTAR [37]—an open-data and relatively inexpensive EM tracking system (for background on EM tracking see chapter 2). It consists of a transmitter, an electronics unit and a series of sensors. The transmitter projects a magnetic field over the heart to track sensors attached to catheters. Both the transmitter and sensors plug into the electronics unit, and the electronics unit plugs into a computer. As the tracking system generates catheter location and orientation data it is processed by the computer through a series of software modules I developed. These software modules are microservices that store, transform and/or transmit data between one another and third-party applications. I used these modules to send data to CathEye for display. Each hardware and software component is detailed further below.

3.2.1 Electromagnetic Tracking System

Figure 3.1 The Ascension trakSTAR tracking system hardware components: sensors (left), electronic unit (middle) and transmitter (right).

Electromagnetic (EM) tracking systems track objects using electromagnetic energy. In the current instance of the platform I used an Ascension trakSTAR (Figure 3.1)—a low latency open-data system consisting of a transmitter, sensors, electronics unit, and driver.

3.2.1.1 Electromagnetic Transmitter

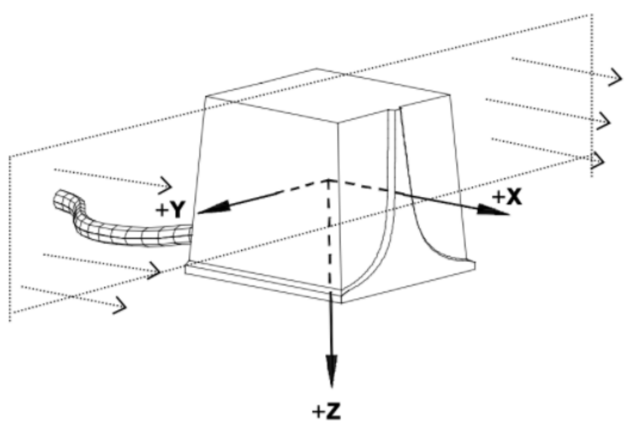

Figure 3.2 The transmitter coordinate system.

The transmitter generates an EM field, also known as a tracking volume, that is used to track sensors. It also provides a frame of reference for the static coordinate system seen in Figure 3.2. Internally, the transmitter consists of three perpendicular coils running in the X, Y, and Z directions. When a single coil is stimulated by a current is produces an EM field. The EU, described below, sends current through each coil, one after the other, every 100 Hz. As a result, over the course of a measurement frame three EM fields are produced, one along each axis, that allow the tracking system to track the location and rotation of sensors relative to the transmitter's origin.

3.2.1.2 Electromagnetic Sensor

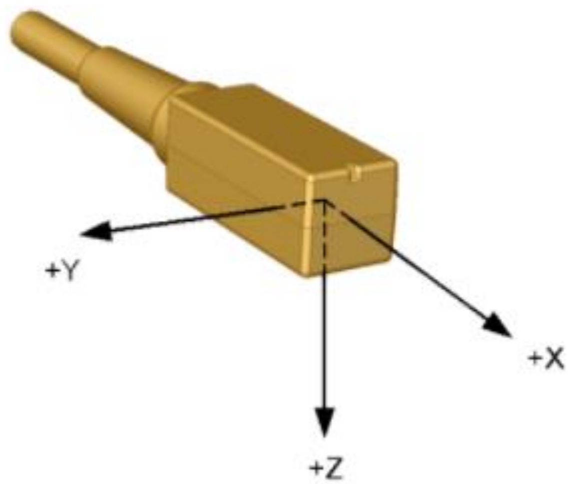

Figure 3.3 The EM sensor coordinate system.

Each sensor (Figure 3.3) consists of a sensing tip and a wire that plugs into the EU. As the sensor moves through one of the transmitter's EM fields a force vector is produced at its tip. This force vector is converted into an analog signal that travels down the sensor's wire and into the EU. Finally, the EU converts the analog signal into digital signal representing the sensor's location and rotation relative to the transmitter's origin.

3.2.1.3 Electronics Unit

Figure 3.4 The EU showing the transmitter port and sensor ports.

The EU is the centerpiece of the EM tracking system. It manages electric fields by powering the transmitter, and uses precise timing to calculate the position and orientation of sensors. The transmitter plugs into the transmitter port while up to four sensors can be plugged in to the sensor ports (Figure 3.4). Every measurement frame, the EU sends current to the transmitter through the transmitter port that, as described above, passes through on of the three transmitter coils to generate an EM field along one of the X, Y or Z planes. Sensors plug into one of the sensor ports. Force vectors applied to sensors passing through one of the EM fields is received by the EU through these ports. Because the EU knows which EM field is active when it receives the first vector, it is able to convert the force vector into a position and rotation along a single axis. This process is performed three times, once for each axis, during each measurement frame, which allows the EU to describe each sensor with 6Dof.

3.2.1.4 Driver

The driver, the final element of the EM tracking system, is kernel-level software that has access to special memory that it uses to communicate with the EU. The driver uses this memory to translate signals to and from the EU. In that respect, it is similar to a bilingual translator facilitating communication between two people from different backgrounds. Ascension, the electromagnetic tracking system manufacturer, developed this driver so third-party developers can create software that sends signals to the EU (e.g. to turn it on and off) and receive sensor coordinates in a digestible form. This effectively makes their system open data, which, as described above and demonstrated in the remainder of this dissertation, enables innovation. In the next section I describe the software I developed on top of this driver to control the transmitter and process catheter coordinates.

3.2.2 Software

I developed the platform software using a client-server pattern. Client software uses the driver to receive catheter location data from the EU, transforms it into a standard format the simulator understands, then transmits it to the server. The server stores the catheter data and retransmits it to external listeners. The client and server work together to share catheter location data to third party applications through a format and medium that are easy to understand and use.

3.2.2.1 Client

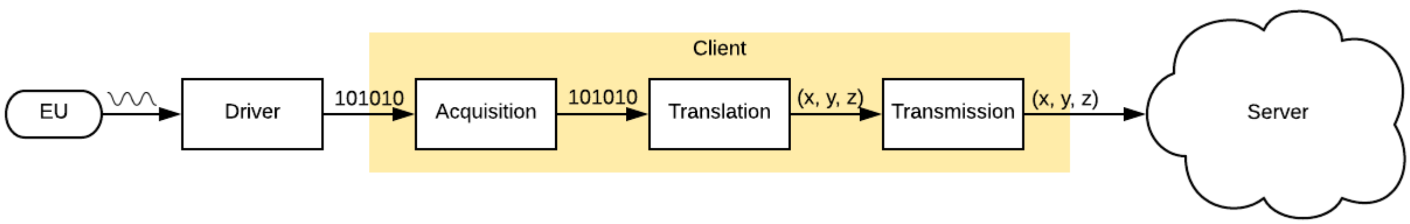

Figure 3.6 A data flow diagram depicting the client's three components

The client side acquires catheter location data from the EU driver, translates it into a standard format then transmits it to the server. These three tasks are divided into the following three distinct microservices: acquisition, translation, and transmission (Figure 3.6). Each is described below.

3.2.2.1.1 Acquisition

The acquisition service leverages the EU driver to receive catheter data from the EU. As described in Figure 3.6, the data are received in a complex format that would be difficult to use by the server and therefore must be translated to a consumable format.

3.2.2.1.2 Translation

The translation service transforms data from the driver's format into the standard format illustrated below. This format, represented in Javascirpt Object Notation (JSON) below, is easily understood by the rest of the simulation software.

```
{
    position: {
        x: "<x coordinate>",
        y: "<y coordinate>",
        z: "<z coordinate>",
    },

    rotation: {
        x: "<x axis rotation>",
        y: "<y axis rotation>",
        z: "<z axis rotation>",
    },

    created: "<date/time>",
}
```

3.2.2.1.3 Transmission

The transmission service sends translated data to the server over an authenticated web socket. A web socket is like an open tunnel through the internet that sends and receives data between two programs. At the start of a new simulation the transmission service establishes an authenticated connection with the server. During the simulation, after newly acquired data are translated, this service forwards the data through the web socket tunnel to the server. It is effect, the transmission service is a software development kit that facilitates communication with the simulation's server component described below.

3.2.2.2 Server

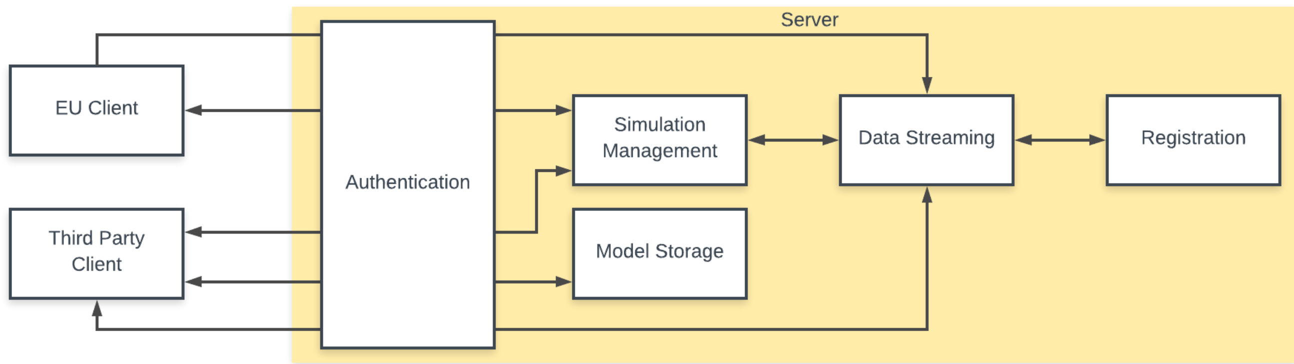

Figure 3.7 Server architecture diagram

The server is the centerpiece of the simulator's software. It is the glue that connects simulation data to third party applications, such as CathEye, described in the next chapter. To achieve this, I divided the server into a series of microservices (Figure 3.7) that enable the storage and retrieval of data in a secure, reliable and easy-to-use fashion. These microservices, each detailed below, include authentication, simulation management, data streaming, registration, and model storage.

3.2.2.2.1 Authentication

An important component of any service keeping non-public information, the authentication service gates communication to and from external services. It implements OAuth 2.0, a widely used authentication strategy, to verify users. All requests that enter the server must pass through this strategy. Only authenticated requests are routed to the appropriate downstream service.

3.2.2.2.2 Simulation Management

I designed the server to manage simultaneous simulations. When a user would like to start a new simulation, the user's client application sends a request to this service. Once received, this service dynamically creates a data streaming service (described below) and maps it to a unique simulation ID. The Client can then ask for a list of running simulations and join the one they are interested in.

3.2.2.2.3 Data Streaming

The data streaming service sends and receives data between clients who are registered for the same simulation. It is like a telephone service that streams voice between callers. However, the data streaming service is more than a simple proxy. It also stores every bit of information in a database so it can be queried retrospectively—a valuable feature I exploited in CathEye.

3.2.2.2.4 Registration

The registration service registers the model and catheter(s) so that they can be described with a single coordinate system. This process is paramount to accurately visualizing the model, which I detail in the next chapter. Here, I detail the registration process.

Tracking systems are standalone products that have their own coordinate system. For example, the Ascension trakSTAR, the tracking system used in this research, has a coordinate system whose origin is at the center of the transmitter (Figure 3.2). To register the model and the catheter(s) (tracked by the tracking system) I describe the origin of the tracking system relative to the model. First, I physically place the transmitter next to the 3D printed heart model (Fig 3.8 A). Second, I replicate the physical world using digital 3D models to spatially describe both objects in a single, common coordinate system. Finally, because the system knows the origin of the transmitter relative to the model, the registration service translates catheter coordinates from the origin of the transmitter into the single, common coordinate system. The result is catheter coordinates that can be accurately described in the model's context. The data streaming service uses the registration service to convert EU client coordinates to simulation coordinates before streaming to other clients. This allows other clients to describe the model and catheters in a single coordinate system.

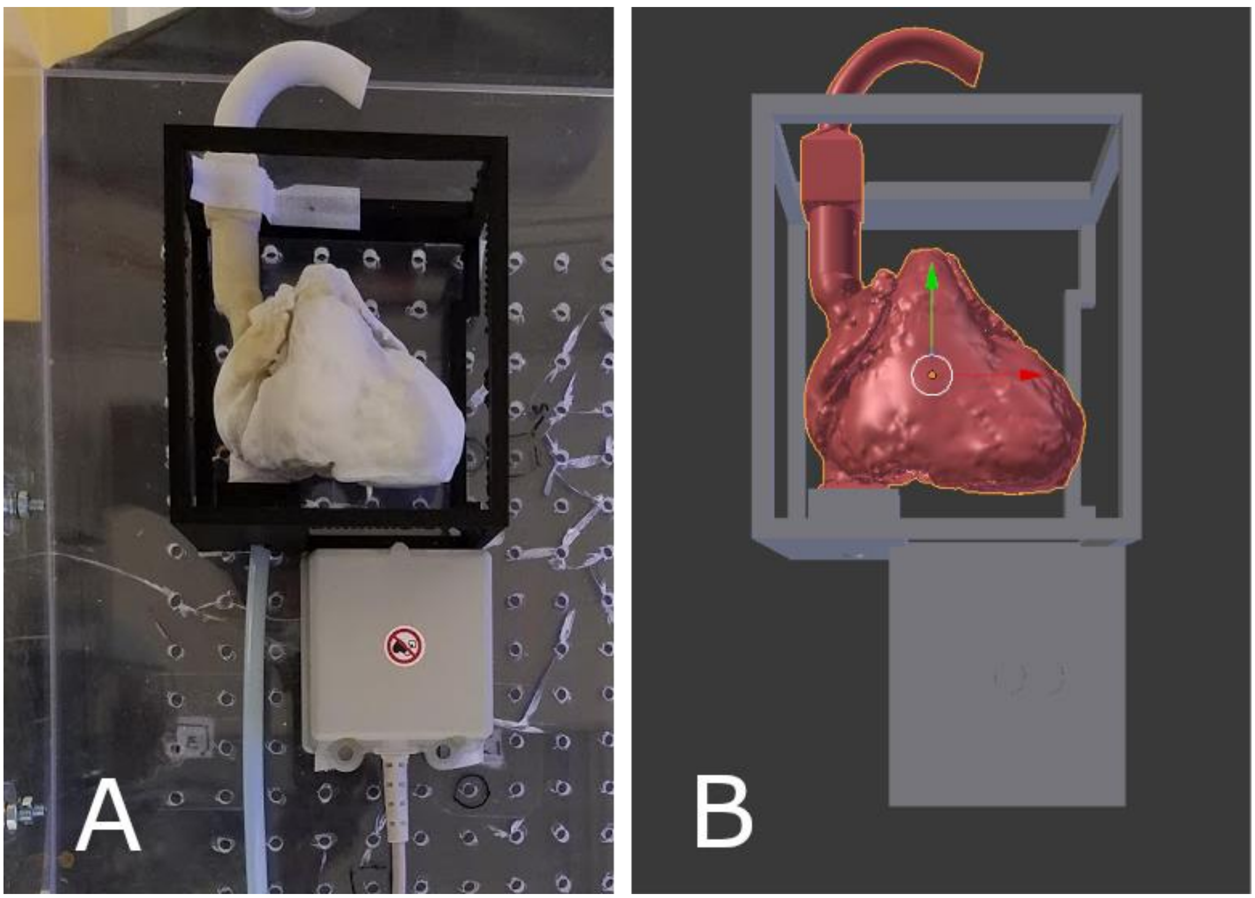

Figure 3.8 The physical (A) and virtual (B) model tracking system arrangement.

3.2.2.2.5 Model Storage

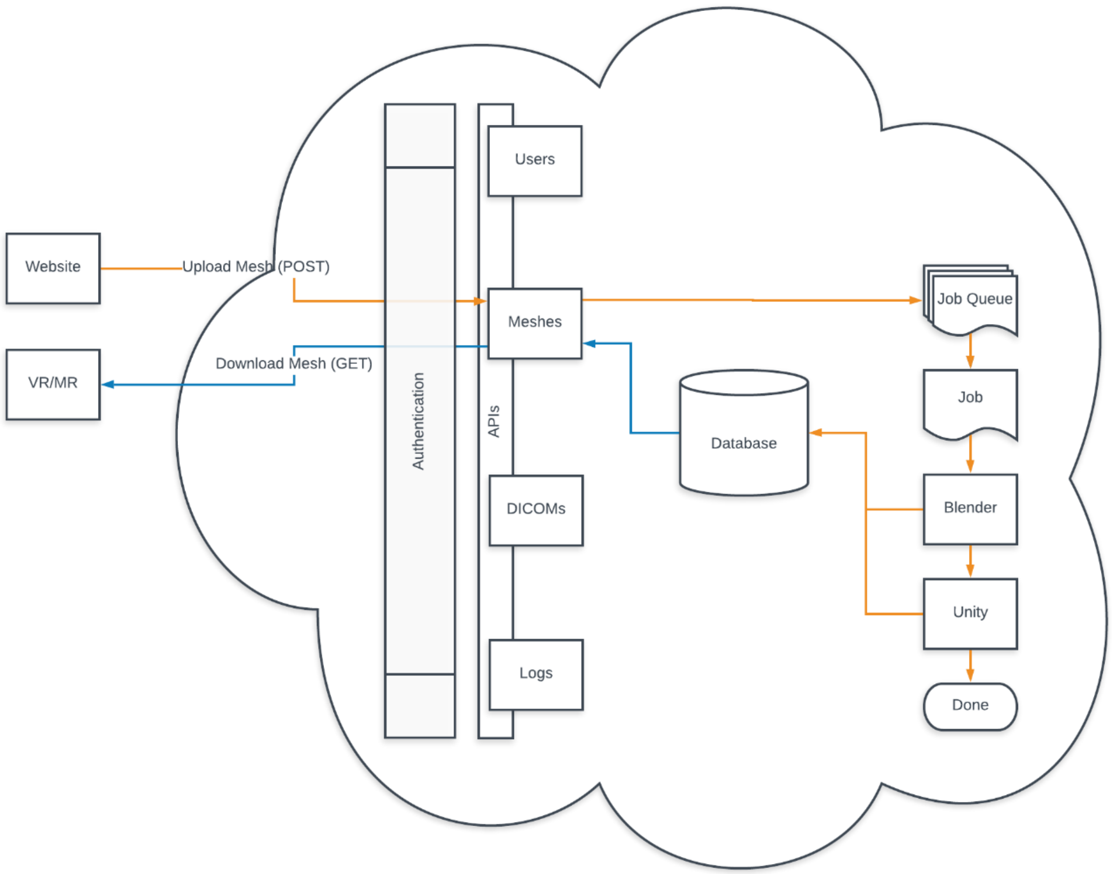

Figure 3.9 Model storage architecture. Shows the upload process (orange line) and download process (blue line).

The model storage service is a repository of 3D models that processes, stores and retrieves 3D models for simulations (Figure 3.9). Once a 3D model is printed, the same file that was used for the print is uploaded to this service ((Figure 3.9, orange line) which tells the simulator what the 3D print looks like. After the 3D model is uploaded, it is processed by a series of algorithms I developed in Blender (www.blender.org) and Unity (Unity Technologies ApS, San Francisco, CA, https://unity.com/), two 3D processing programs, that prepare the model for virtual reality visualization. When a simulation begins, the visualization is downloaded (Figure 3.9, blue line). I demonstrated this process in an example application.

3.3 An Example Application

In preparation for development with CathEye, I developed an application to test the platform’s functionality. Though I primarily used it for testing, it provides a great example of how the platform can be used to create endovascular navigation software.

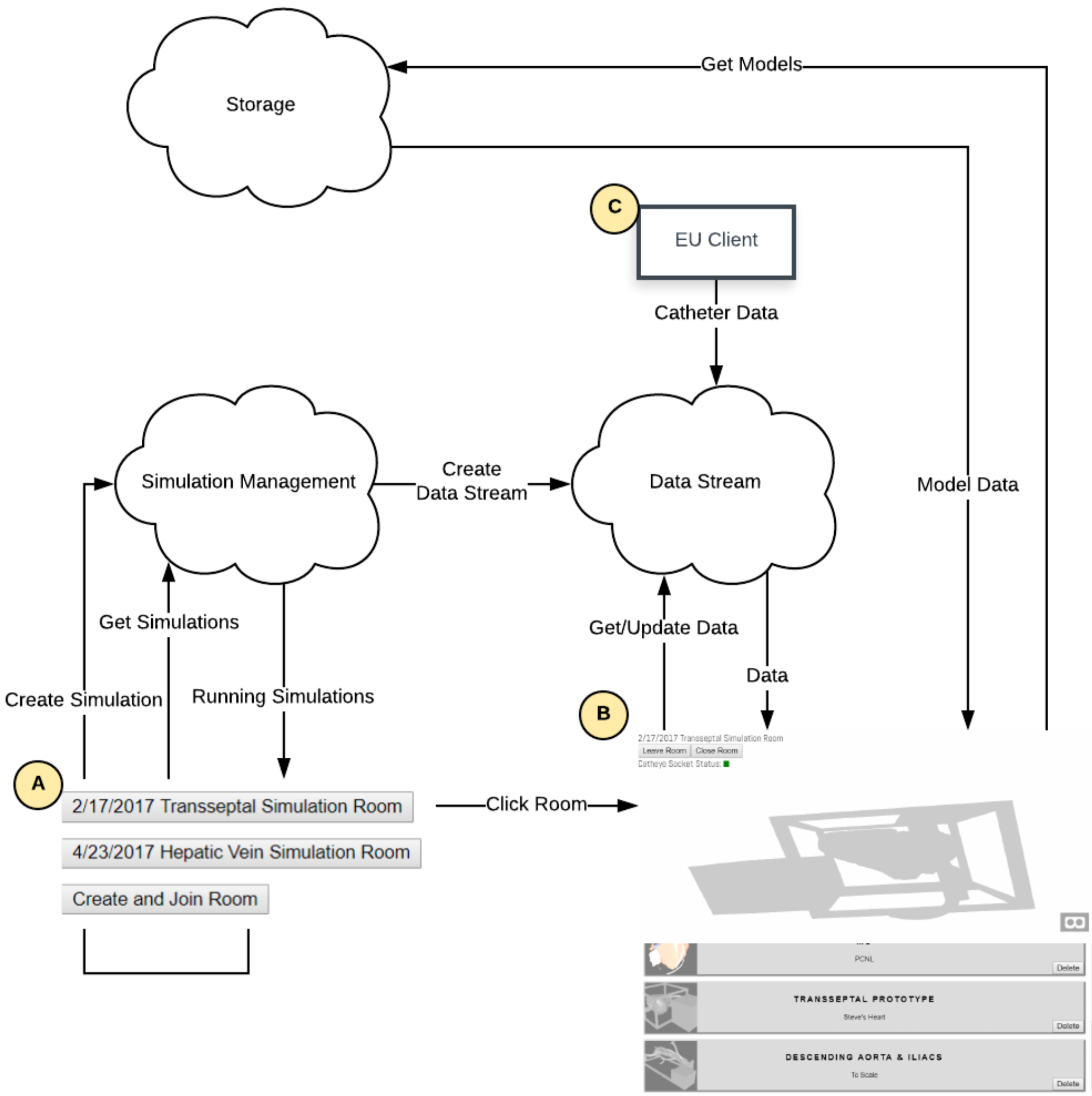

Figure 3.10 A process flow diagram illustrating how a user uses the example application and how the example application uses the open-data platform.

The example application is a website that allows a logged in user to start, view and stop platform simulations. When the application opens (Figure 3.10 A), a request is sent to the platform's simulation management service API to retrieve a list of all running simulations. This

API is important because it allows third-party applications to programmatically detect and display which simulations are running. When a user selects one of the listed simulations, they are taken to a new page that displays all of its information (Figure 3.10 B), including the model that is being used and catheter positional data. This information is retrieved from the data streaming service and the storage service using their associated APIs. Because information is retrieved in real time over a WebSocket connection, as other connected clients change data, such as the tracking system client (Figure 3.10 C), the user will see the data on the simulation page update in real time.

It is important to note that the open-data platform is agnostic to the type of client. While the last paragraph describes a web application, the platform's APIs can be used to develop an application on any platform. I demonstrate this point in the next chapter when I describe how I used the platform to develop CathEye.

3.4 Limitations

The open-data endovascular navigation platform is not without its limitations. I developed most of the software using Node.js. However, Node.js is not as performant as other languages, such as C++. This limitation in speed may become important in a commercial system. In addition, it is worth noting that the Ascension trakSTAR EM tracking system used in this dissertation is not FDA approved and therefore cannot be used in patients, which restricts the platform's use in human subjects. This limitation, however, also highlights the importance of FDA-approved commercial systems to adopt the open-data model. In addition, the database structure I used is a product of several iterations. I anticipated this iterative approach and so chose MongoDB—an unstructured document database that facilitates rapid prototyping—as the main data store. While this was advantageous for iterative development it may not be the best database for a commercial system. A SQL database may be more appropriate depending on the commercial application's requirements. Finally, my choice of APIs was also a product of several iterations. If I were to design them again, I would try to reach a consensus with existing mapping system developers (e.g. Biosense Webster) to establish industry standards.

3.5 Platform Chapter Summary

Open-data systems fuel the evolution of technology. In this chapter I demonstrated their value in consumer technologies and their potential impact in medicine. Finally, I presented an open-data platform that represents a unique opportunity to accelerate innovation in the field of endovascular navigation.

Advanced endovascular navigation systems track catheters with sub-millimeter accuracy using tracking systems that produce spatial coordinates in real time. The data from these systems are currently used in proprietary closed-data systems. While these systems are the most advanced commercial catheter navigation systems on the market, because they do not share their data, they represent a significant obstacle to the pursuit of innovative endovascular navigation ideas. I described the novel open-data platform I designed and developed to circumvent this barrier and accelerate endovascular navigation research. At the end of this chapter I illustrated its use by describing an example web application I built that uses the open-data platform APIs to start, view, and stop endovascular simulations. In the next chapter I detail how I used the same platform to build a novel virtual reality endovascular navigation system.

4 Chapter 4: CathEye – A HMD Catheter Navigation System

Technology enables the advancement of medical treatments. VR and AR HMDs, as discussed in chapter 2, use binocular depth cues to make medical data easier to understand. However, little research has explored their utility during endovascular procedures—a visually complex medical sub-domain. In order to explore their potential, I designed and developed CathEye—a HMD catheter navigation system designed to facilitate the TSP. Multiple iterations of CathEye were developed in both VR and AR. A series of user tests led me to conclude with an implementation in VR. Chapter 5 presented results evaluating this VR-based implementation. Nonetheless, I believe both technologies have significant potential to facilitate endovascular navigation. I discovered this potential early on in my research career when I was focused on VR-based preoperative planning.

4.1 Bosc - Preliminary Work

Before I developed CathEye, I developed Bosc—an HMD pre-operative planning tool and 3D model viewer. I created Bosc to research the benefits of viewing anatomy with modern stereoscopic HMDs. During its use at the University of Washington (UW), University of California (UC) Irvine, Seattle Children's Hospital and British Columbia (B.C.) Children's Hospital, I learned a great deal about its application in clinical settings. The learnings that directly influenced the design and development of CathEye are highlighted below.

4.1.1 VR Creates a Deeper Understanding of Anatomy

Bosc was used by physicians and clinical researchers in multiple specialties and sub-specialties. As I solicited feedback from the different groups, I noticed a common theme: viewing anatomy in a stereoscopic HMD facilitated anatomical understanding and user interactions. This finding was consistent with the conventional stereoscopic display research discussed in chapter 2. However, because I was using an HMD instead of stationary, flat stereoscopic screens, I discovered important nuances that prior work had not discussed. These nuances were most apparent when Dr. Steinberg, a cardiologist at UW, viewed a ventricular septal defect (VSD) (Figure 4.1).

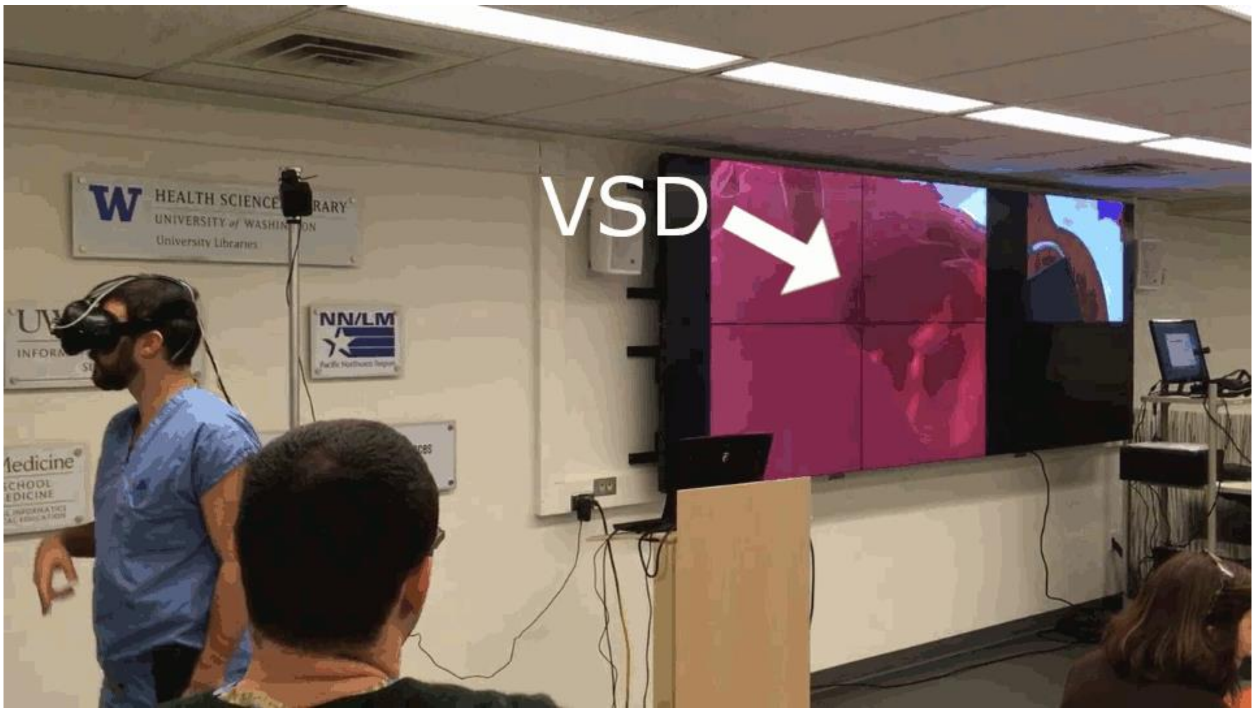

Figure 4.1 Dr. Steinberg (blue) puts his head through a VSD. View animation here.

A VSD is a hole in the heart between the right ventricle (RV) and left ventricle (LV). Patients with large VSDs are more likely to experience heart failure and/or pulmonary hypertension, while patients with smaller VSDs are more likely to heal without needing surgical intervention. As a result, understanding the size and shape of the VSD is important to risk assessment and treatment planning.

After putting his head through the VSD, Dr. Stenberg said he had never seen one quite so clearly. As discussed in the visual depth cue section in chapter 2, binocular motion parallax, structure from motion and relative size are extremely important visual cues for understanding depth and structure. Dr. Steingberg's visual system was able to quickly understand the size and shape of the VSD relative to his head as his head moved through it. This phenomenon showed that, in addition to a binocular display system, VR offered a way to interact with digital objects as if they were real—a welcome enhancement to conventional monitors and stereoscopic displays.

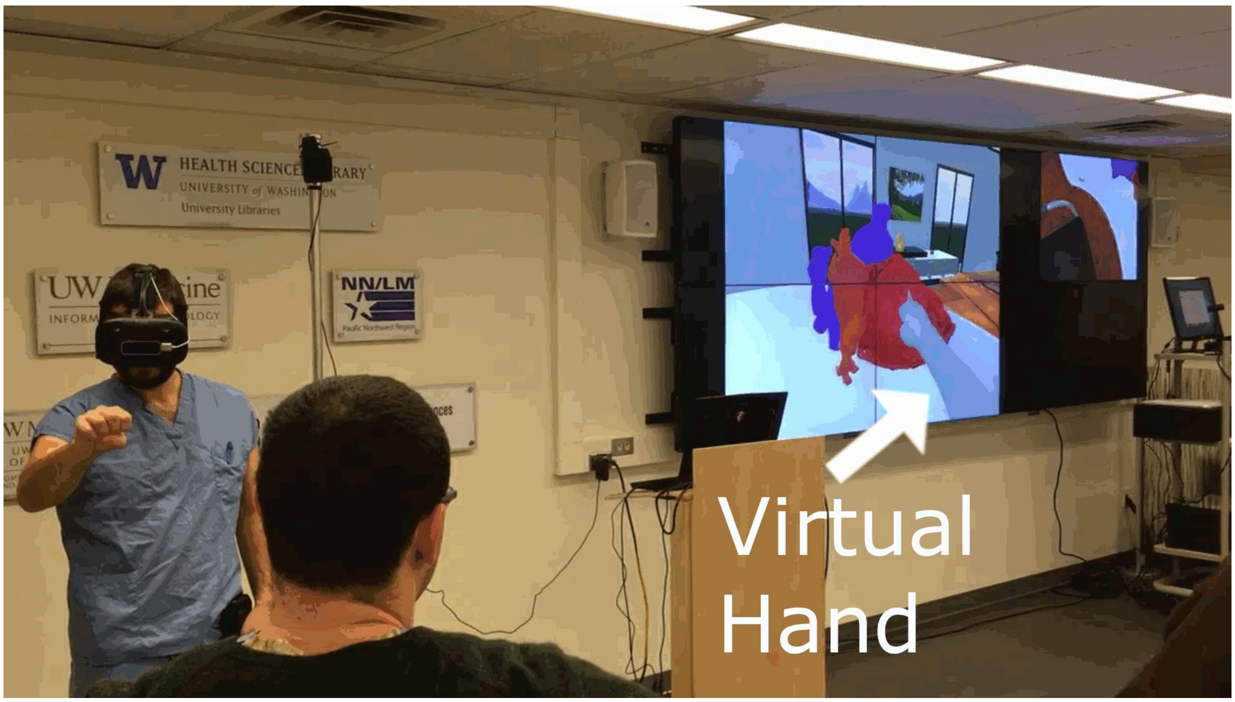

Figure 4.2 Dr. Steinburg grabbing the heart. View animation here.

Interactions are an extremely important, yet under-explored aspect of clinical HMD applications [3]. As Dr. Steinberg's experience suggested, understanding them has the potential to improve treatment. For example, in a traditional desktop application Dr. Steinberg might perform a series of mouse and keyboard gestures to rotate, zoom and otherwise explore the heart's structure. Using AngioDex, discussed in the background chapter, researchers used a stylus to manipulate organs on a stereoscopic display. However, in Bosc, as seen in Figure 4.2, to achieve the same task Dr. Steinberg simply reached out, grabbed, and rotated his hand. This observation suggested that stereoscopic HMDs, and VR in particular, relative to other display systems, can facilitate manipulating spatial data by using human-computer interactions that mimic everyday actions in reality.

4.1.2 VR Can Merge Physical and Digital Realities

Along those lines, many of the research groups that used Bosc wanted to bring something from reality into virtual reality, or vice versa. For example, to prepare for surgeries, the neurosurgery group at B.C. Children's wanted to bring endoscopes into virtual reality that they could preoperatively maneuver through a 3D model of their patient's brain. Similarly, cardiologists at Seattle Children's wanted a mechanism to preoperatively create virtual patches in VR that could be 3D printed and used in the OR to fill holes in their patients' hearts. These requests demonstrated the potential for virtual reality to communicate information that more directly translated to and from the real world. As I discuss in more detail later in this chapter, I explored this potential by developing a virtual reality sheath, dilator, and needle in CathEye.

4.1.3 Challenges to Preoperative Planning

The most significant thing I learned while working on Bosc was that VR does not fit into every workflow. The benefits of binocular vision, natural human computer interactions and merged realities are limited by how and when they are used. Physicians' busy schedules often limit the amount of time set aside for preoperative planning. For instance, several of the cardiologists I worked with, anecdotally, only preoperatively planned for about 5% of their cases, on average, which equated to roughly 10 cases per year. They did not plan for the other 95%. Consequently, in an ideal scenario, if adopted as their sole preoperative planning tool, Bosc would be used around 10 times per year per physician, or less than once a month.

I wanted to focus on a problem in dire need of a solution that would be used on a regular/daily basis. I began researching endovascular procedures and shifted my focus from pre-operative planning to intra-procedural guidance, taking with me what I learned about the benefits of stereoscopic HMD interactions.

4.2 Intra-procedural Guidance

Intra-procedural guidance describes the use of imaging to guide medical instruments during procedures. In chapter 2, I highlighted the importance of binocular vision and 3D imagery for endovascular procedures, focusing primarily on evidence demonstrating the potential benefits of HMD guidance during the transseptal puncture. However, I did not specifically discuss guidance research. That background is provided here, adjacent to CathEye's design, to facilitate the following discussion. I've organized this background into three sections: non-stereoscopic guidance, conventional stereoscopic guidance, and stereoscopic HMD guidance.

4.2.1 Non-Stereoscopic Intra-procedural Guidance

Saikus et al., in their paper titled *Interventional Cardiovascular Magnetic Resonance Imaging: A New Opportunity for Image-Guided Interventions* [38], highlights the importance of volumetric, or 3D, imagery during procedural navigation. In addition to other types, the authors recount the wide array of endovascular procedures that benefit from 3D guidance including coronary cauterization and stenting procedures [39]–[41], atrial septal punctures [42], [43], and electrophysiological studies and interventions [44]–[46]. The authors then argue that 3D renderings enable proceduralists to make more informed decisions during guidance due to the additional detail provided by the third dimension relative to planer views of the same structures. This evidence not only demonstrates that 3D imagery is useful during complex tasks, as discussed in chapter 2, but more specifically demonstrates the benefits during endovascular guidance. However, Saikus et al.'s review was limited by their use of monoscopic displays.

4.2.2 Conventional Stereoscopic Intra-procedural Guidance

Kockro et al. explored the correlation between conventional stereoscopic displays and improved surgical navigation [47]. In neurosurgery, there are many important and complex structures. To achieve positive outcomes, surgeons need to execute preoperative plans precisely. In their study, participating physicians performed procedures using conventional stereoscopic displays while viewing a video feed of the patient overlaid with a preoperative neurosurgical plan. The authors found that the stereoscopic environment facilitated understanding the size and shape of structures, again reinforcing existing evidence. The report of their qualitative data showed that surgeons using their system preferred navigating with the stereoscopic display over traditional methods, importantly highlighting a desire for long-term adoption. However, this study had several limitations. The main form of interaction was with a wireless mouse which has limited range of motion in 3D space. As suggested by my work with Dr. Steinburg, grabbing an head movement gestures may be a better way to interact with data in a stereoscopic envrionment. In addition, the polarizing glasses worn during the study hindered the participants' vision. Finally, the placement of the conventional stereoscopic display in the study required surgeons to look away from the patient during the operation, which is a common phenomenon during minimally invasive procedures and the transseptal puncture specifically. This form of human-computer interaction is significant because it restricts the ability to view the operative field and hands simultaneously, which degrades hand-eye coordination [48]. In their discussion, the authors state that an OSTAR environment, described in chapter 2, would provide a better mechanism to overlay the preoperative plan for intraprocedural guidance. In such an environment, a holographic rendering of the preoperative plan could be displayed directly on top of and around the patient's physical body, removing the need to look away. This would address the hand-eye coordination issue and potentially provide a medium for more natural interactions (e.g. hand gestures and gaze input) that make understanding and manipulating data easier during procedures.

4.2.3 HMD Intra-procedural Guidance

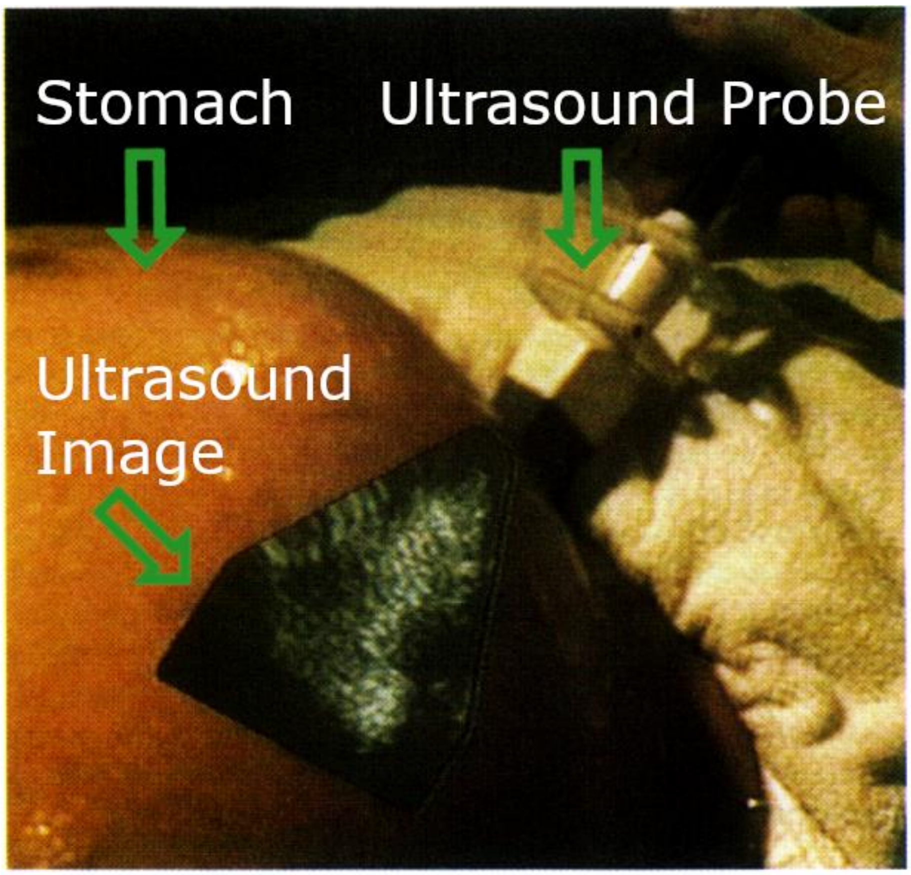

Figure 4.3 Shows an ultrasound image of a baby overlaid on top of a pregnant women's womb using a VSTAR HMD [49]

In 1992 Fuchs et al. in a paper titled *Merging Virtual Objects with the Real World: Seeing Ultrasound Imagery within the Patient* [49], used an in-house stereoscopic VSTAR HMD to visualize live ultrasound within a pregnant woman (Figure 4.3). They achieved this by co-registering an ultrasound probe and an HMD into a common coordinate system through a process similar to that used in the endovascular navigation platform described in chapter 3, then used live coordinates to display ultrasound in real time on top of the patient as if it were coming directly out of the probe. Their results demonstrated that it was feasible to co-register instruments and suggested significant benefit for surgical guidance. However, their study had several limitations. As previously described, VSTAR HMDs show a video feed of the real world, so if the headset fails the physician's view of the real world is blocked. In addition, their early system had low resolution, lacked important visual cues, had significant lag and minimal processing power. Each of these limitations has been addressed in recent years in HMDs (e.g. the Microsoft HoloLens) that are currently commercially available.

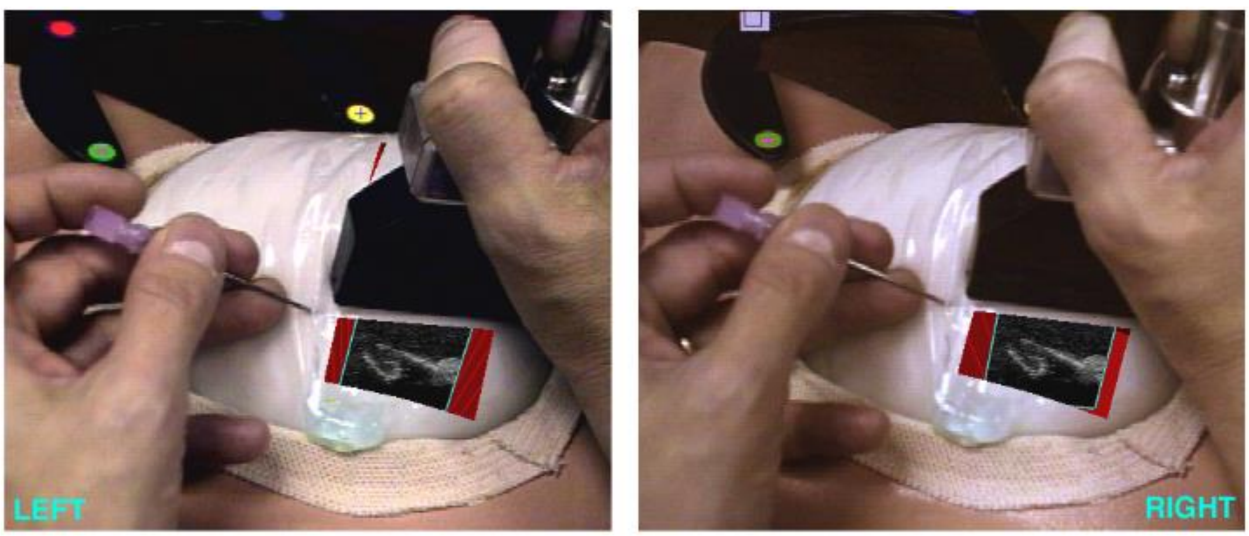

Figure 4.4 Shows stereoscopic images of a needle biopsy guided by an embedded VSTAR HMD image highlighted in red [50].

In a follow up study, using the same co-registration system described above, Fuchs et al. performed an in vitro needle biopsy guided by embedded ultrasound images rendered in a stereoscopic VSTAR HMD (Figure 4.4) [50]. The operating physician successfully guided a needle directly into the breast tumor, demonstrating the feasibility and benefits of VSTAR HMD guidance. Rather than looking at an adjacent display, the operating physician focused on the operative field, preserving the hand-eye coordination they would have lost looking away at a screen [48].

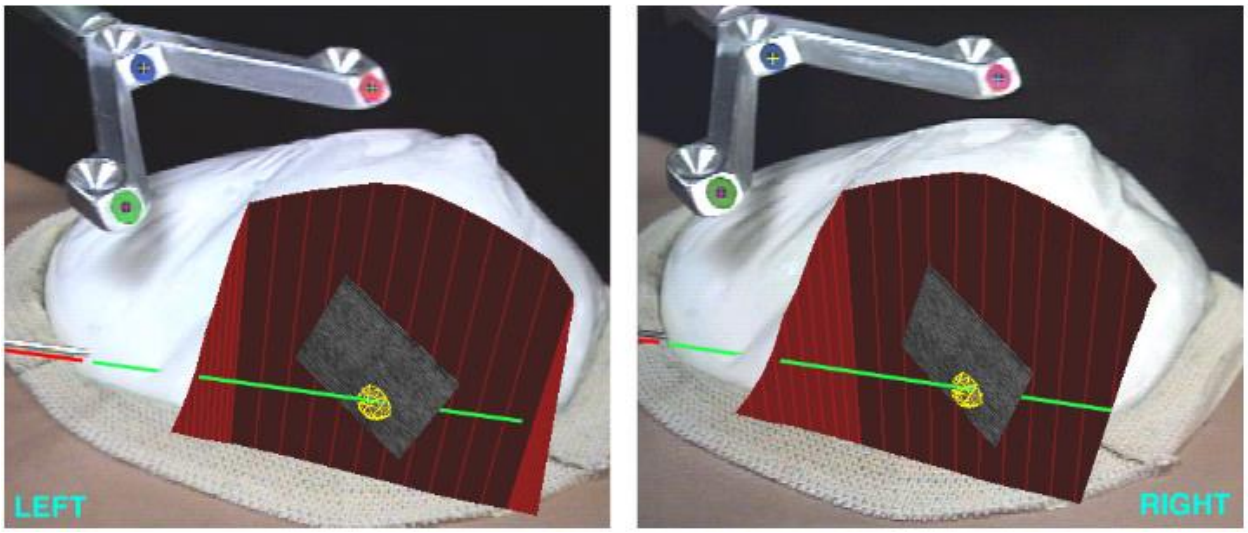

Figure 4.5 Shows the stereoscopic images of an overlaid ideal path to the tumor target.

After performing several biopsies with the ultrasound overlay, the researchers detached the tracking device from the ultrasound probe and attached it to the needle. This allowed them to programmatically detect the trajectory of the needle and juxtapose it with the ideal path directly to the target (Figure 4.5). The physician could see their current path's alignment, or misalignment, with the ideal path overlaid on top of the patient, which facilitated understanding where the needle was in space and what adjustments, if any, needed to be made to reach the target at the correct angle. Their novel approach demonstrated that HMDs have significant potential to improve the utility of existing medical data by reimagining how that data are displayed and used to guide medical instruments. It may have been a primary motivator for the development of catheter mapping systems, detailed in chapter 2. Nonetheless, their study had several limitations including cumbersome electromagnetic and visual tracking systems, poor image resolution, probe occlusion of ultrasound images, and a heavy 6Ib HMD. In addition, they reported that their tracking system was static, which, if used on a real patient, would require the patient remain still during the entire procedure. Despite these limitations, this work was foundational to HMD guidance research and crucial to the design and development of CathEye.

4.3 CathEye

As discussed in chapter 2, endovascular navigation is visually complex, particularly during the transseptal puncture. The problems associated with this complexity are rooted in the monoscopic screens that display information during conventional navigation. Specifically, the lack of binocular depth cues limits the utility of data, forcing proceduralists to rely too heavily on subjective-based reasoning, such as tactile feedback and mental models of anatomy, when they could rely on objective data. Stereoscopic HMDs can preserve this objective data and, as discussed earlier in this chapter, support intuitive human-computer interactions that could further facilitate navigation. Due to the widespread nature of the problems and the unexplored potential benefits of the solution, it was important to understand the utility of stereoscopic HMDs during complex endovascular navigational tasks.

CathEye is a stereoscopic HMD guidance system built to facilitate the transseptal puncture. It leverages the navigation platform, described in chapter 3, to visualize live medical data in a stereoscopic virtual environment built to exploit the human visual system. Chapter 5 discusses the results of a comparative study demonstrating the clear advantages of CathEye over conventional endovascular navigation systems. The remainder of this chapter focuses on CathEye’s design and implementation.

While the description of the user interface design is most important to this chapter, in order to give that discussion context it is important to explain CathEye's fundamental components. As such, I start with a discussion on CahEye's architecture.

4.3.1 System Design

CathEye was built using the Unity® game engine [51]. Unity® facilitated development by providing automatic HMD integration, a drag-and-drop 3D world building interface, and scripting APIs. While CathEye was running, Unity® generated stereo images of the CathEye virtual world at 60 frame per second (or 60 Hz) and rendered each pair of images in an attached HMD. As the user's head moved, Unity® updated the perspective of the stereo images, which provided binocular motion parallax. I used the drag-and-drop interface and scripting APIs to arrange virtual objects that reacted to environmental changes.

For example, I used the drag-and-drop interface to design a menu that displayed directly in front of the user. When CathEye started, it used the platform SDK, detailed in the last chapter, to populate the menu with a list of models that were previously uploaded to the platform. When the user selected a model a new simulation would start, triggering CathEye to download the model, display it in front of the user, and begin streaming sensor data from the platform in real time.

When a new sensor was detected, using the 3D models described below, CathEye's scripting logic dynamically created a virtual rendering of either the sheath, dilator or needle. Once created, as the sensor moved, CathEye's scripts adjusted the position and rotation of the associated 3D model. In effect, from the user's perspective the virtual sheath, dilator and needle mimiced the exact movements of their physical counterparts.

4.3.1.1 Sheath, Dilator and Needle 3D models

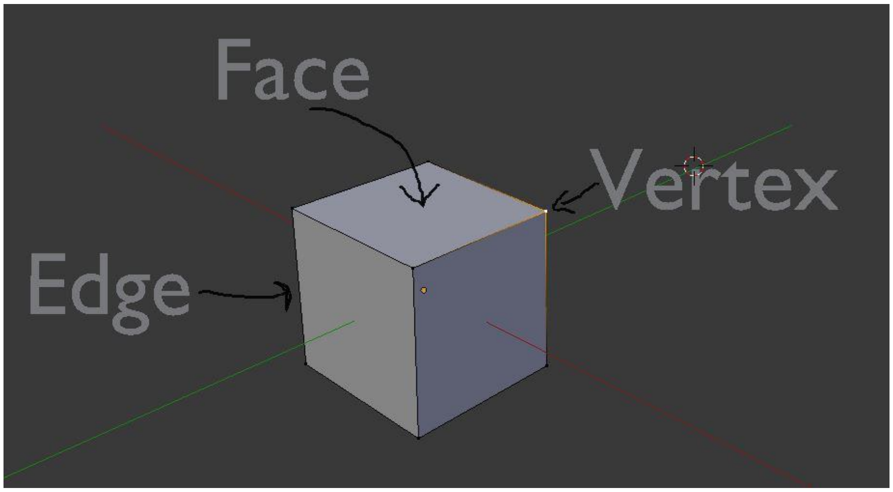

Figure 4.6 Depicts vertices, edges and faces in Blender (image link).

A 3D model is a collection of vertices, edges, faces and colors (Fig. 4.6). An edge connects two vertices, a face is bounded by multiple edges, and colors add visual detail to faces. Blender® [52] is an open source tool that facilitates 3D model building through the manipulation of vertices, edges, faces and colors. I leveraged Blender® to develop 3D models for the sheath dilator and needle using the following process.

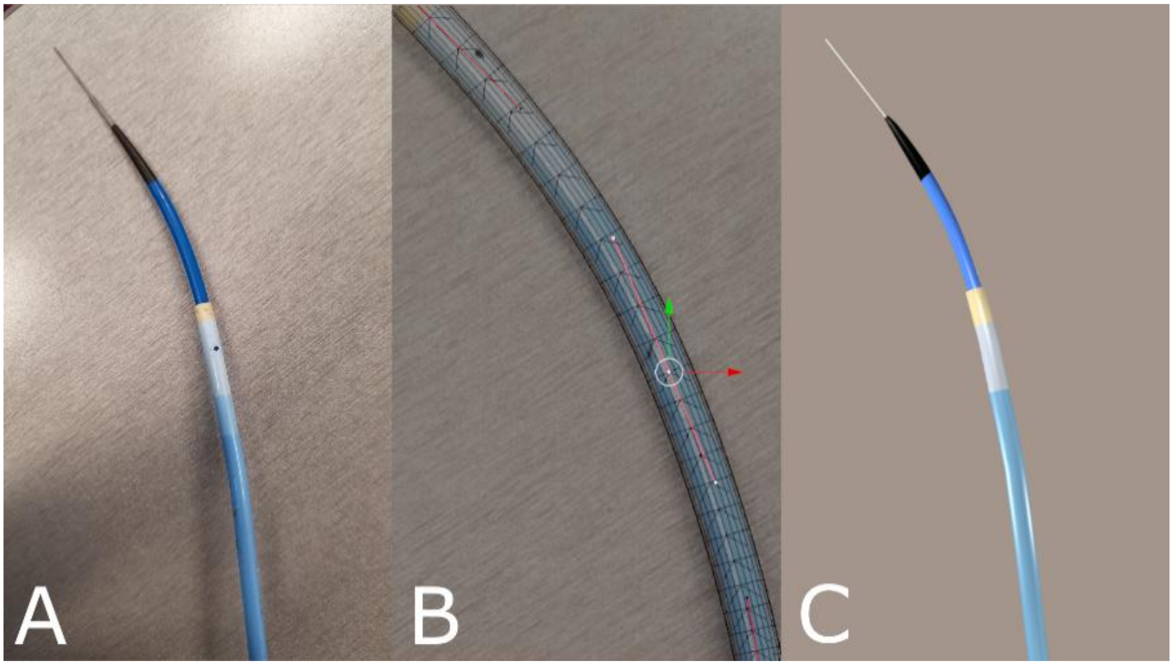

Figure 4.7. Shows the 3D model creation process. (A) is a picture of the physical sheath dilator and needle assembly; (B) depicts 3D model building in Blender®, and (C) is a digital rendering of the sheath, dilator and needle 3D models.

First, I took a picture of the physical sheath, dilator, and needle assembly (Figure 4.7 A) and imported the picture into Blender®. I then added a Bezier curve to Blender®'s 3D scene and began adjusting the points on the curve to overlap the center of the sheath, dilator, and needle in the picture. Using Blender®'s curve-to-mesh tool, I converted the Bezier curve into a series of connected cylinders (Figure 4.7 B) then adjusted their scale to match the image. I then selected cylinders that overlapped a particular colored region of the catheter and applied that color to the selected cylinders' faces (Figure 4.7 C). Finally, I divided the 3D model into 3 separate parts, one for each part of the assembly, then exported each 3D model as a separate FBX file—a portable 3D model description format. I then imported each FBX file into Unity® and linked them to scripts that dynamically loaded them when sensors were detected, as described above.

4.3.1.2 4.3.1.1 Sensor Assembly

As described in chapter 2, 3D mapping systems use electromagnetic and impedance-based tracking systems to track sensors that are embedded in catheters. As the sensor moves, the mapping system uses its coordinates to render a visualization of the catheter that is accurate to the millimeter. However, as detailed in chapter 3, commercially available mapping systems do not share data, which resulted in the development of the platform and the creation of a crude embedded sensor catheter system.

The goal of our embedded sensor system was to, as accurately as possible, visualize the distal (tip) end of the sheath dilator and needle. As a result, during our first iteration we taped sensors to the distal end of each device. Though this tracked the tips with great accuracy, it restricted the assembly's mechanics. During a real case, as described in chapter 2, when the dilator is positioned on the FO, the dilator is fully extended from the sheath and the needle is pulled into the dilator. When the operator is ready to puncture, the needle is advanced out of the dilator to pierce the heart's tissue. However, in our assembly, tape securing the sensor to the needle blocked the needle from retracting back into the dilator's lumen., Similarly, tape securing the dilator sensor blocked the dilator from retracting back into the sheath's lumen.

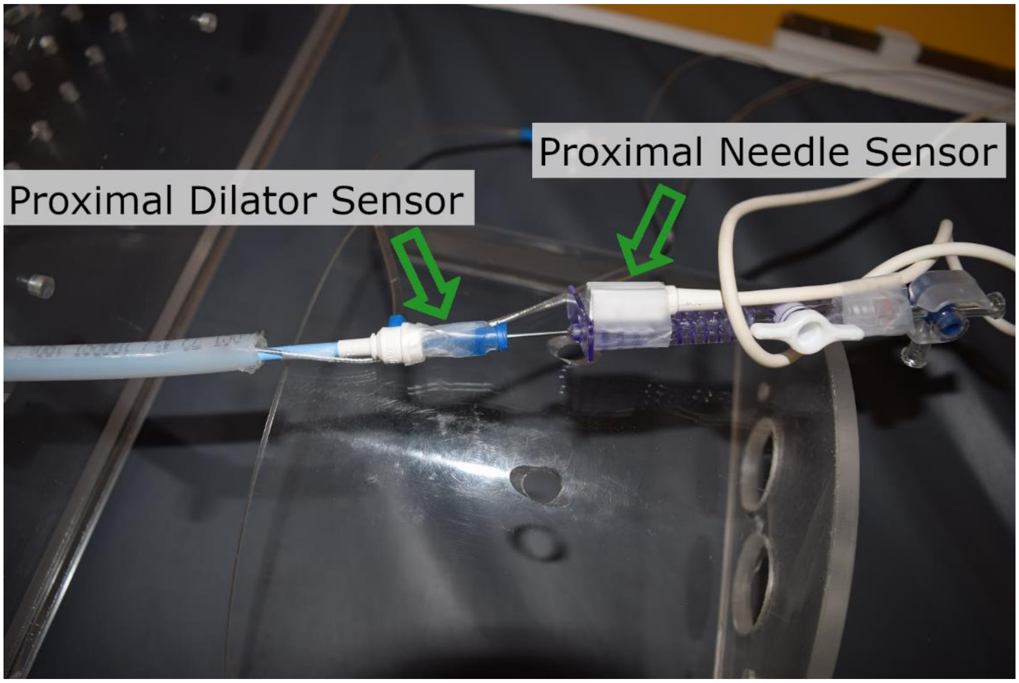

Figure 4.8 Sensors taped to the proximal end of the dilator and needle.

After a few more iterations a final design was chosen. It was a four-sensor system that included a sensor attached to the tip of the sheath, the tip of the dilator, the proximal end of the dilator, and the proximal end of the needle. The proximal sensors are shown in Figure 4.8. Though the tape on the distal end of the dilator restricted its movement it tracked the dilator's tip with great accuracy which enabled accurate measurements during the study. The tip of the sheath was also precisely tracked due to the sensor attached to its distal end. However, because the needle did not have a sensor attached to its distal end, the tip of the needle was not tracked directly. Instead, the needle's tip was estimated using the distance between the sensors on the proximal ends of the dilator and needle (Fig. 4.7). When the two sensors were close, CathEye's logic extended the virtual needle. Conversely, when the sensors were far apart the virtual needle was retracted. User testing, discussed further in the next section, verified this method could be used to facilitate the TSP.

4.3.2 User Interface Design

CathEye was developed to address the visual complexity issues associated with the TSP. It was, therefore, imperative to design a user interface that was optically descriptive and intuitive. To create such an interface, I took a user-centered design approach, working closely with Dr. Seslar, the original creator of the patient simulator who practiced congenital electrophysiology and the TSP on a regular basis.

Our primary goal for the first version of CathEye was to create the illusion that the proceduralist could see through the patient by embedding imagery within the operating field (Fig 4.8). This design took after the VSTAR needle biopsy navigation interface developed by Henry Fuch et al. [50] discussed earlier in this chapter.

4.3.2.1 Take 1: OSTAR Embedded Holograms

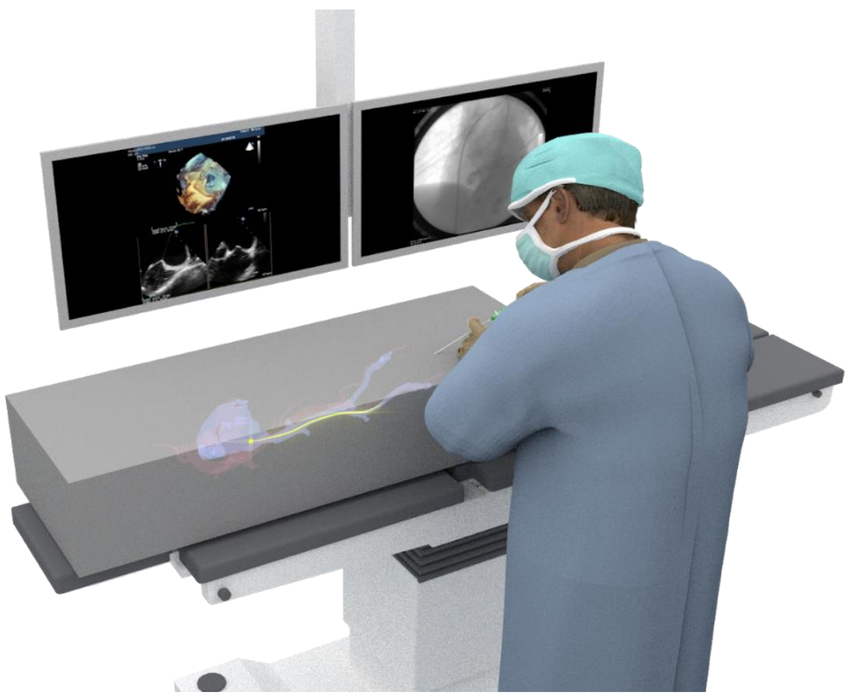

Figure 4.9 A conceptual image of the first version of CathEye showing embedded holograms depicting the heart and catheter within the simulated patient.

Figure 4.10 Actual image of the first version of CathEye where Dr. Seslar can see holographic navigational information through the HoloLens OSTAR HMD

As described in chapter 2, the HoloLens is an OSTAR HMD that embeds holograms in reality. It achieves this by scanning the world with forward facing cameras and placing holograms within and around scanned objects. Leveraging this functionality, we embedded navigational holograms in and around the patient simulator (Fig. 4.9 and 4.10). A fiducial marker (Fig. 4.10) was placed on the EM transmitter and scanned by the HoloLens to co-register the simulator's coordinates system with CathEye's holographic coordinate system. This enabled CathEye to accurately embed a hologram of the catheter within the 3D printed heart model, providing the illusion that the proceduralist had direct line of sight. However, unlike in the report of the Fuchs VSTAR needle biopsy interface, we found that this type of visualization had significant limitations.

During a needle biopsy, the directional movement of the proceduralist's hands guides a rigid needle towards a target along a straight line. It is likely that seeing their hands in the same context as the target and projected path benefits hand-eye coordination because the movement of their hands directly controls the needle. In contrast, during endovascular procedures, the proceduralist manipulates the proximal end of the catheter to control the catheter's distal end some distance away. In practice, the movement of the proceduralist's hands do not intuitively map to movements of the catheter's tip. This differs significantly from biopsy needle mechanics which likely explains why we found embedded holograms during catheter manipulation to have little effect on hand-eye coordination. In addition, for Dr. Seslar to understand where his catheter was located within the heart's cavernous structure, he had to physically walk around the heart. Though this type of visualization was compelling, it was not ergonomically sound—constantly walking around a patient would be physically challenging and endovascular procedures can last up to 6 hours. For these reasons, Dr. Seslar reported that, although he could see which part of the anatomy the catheter was in, the holographic overlay was not an improvement over conventional methods.

4.3.2.2 Take 2: OSTAR Floating Hologram

To address the limitations in the last approach, we added a translucent hologram of the heart floating over the simulator. This allowed Dr. Seslar to see a stereoscopic rendering of the heart and the catheter as it moved beneath the heart's walls. In addition, he could rotate and zoom the hologram with a series of air pinch gestures. However, while the floating hologram helped Dr. Seslar understand the position and location of his catheter, it was not as effective as we had hoped. His catheter was in the heart but CathEye was giving Dr. Seslar an outside-in perspective. This forced him to look past the translucent walls of the hologram to understand the operative field beneath it. This was a step backwards from CARTO 3, described in chapter 2, which cut away the heart walls in its visualizations to provide an unobstructed view. We were curious if recreating such as view in holographic form would improve Dr. Seslar's ability to see underlying structures.

4.3.2.3 Take 3: OSTAR Virtual Catheter Camera

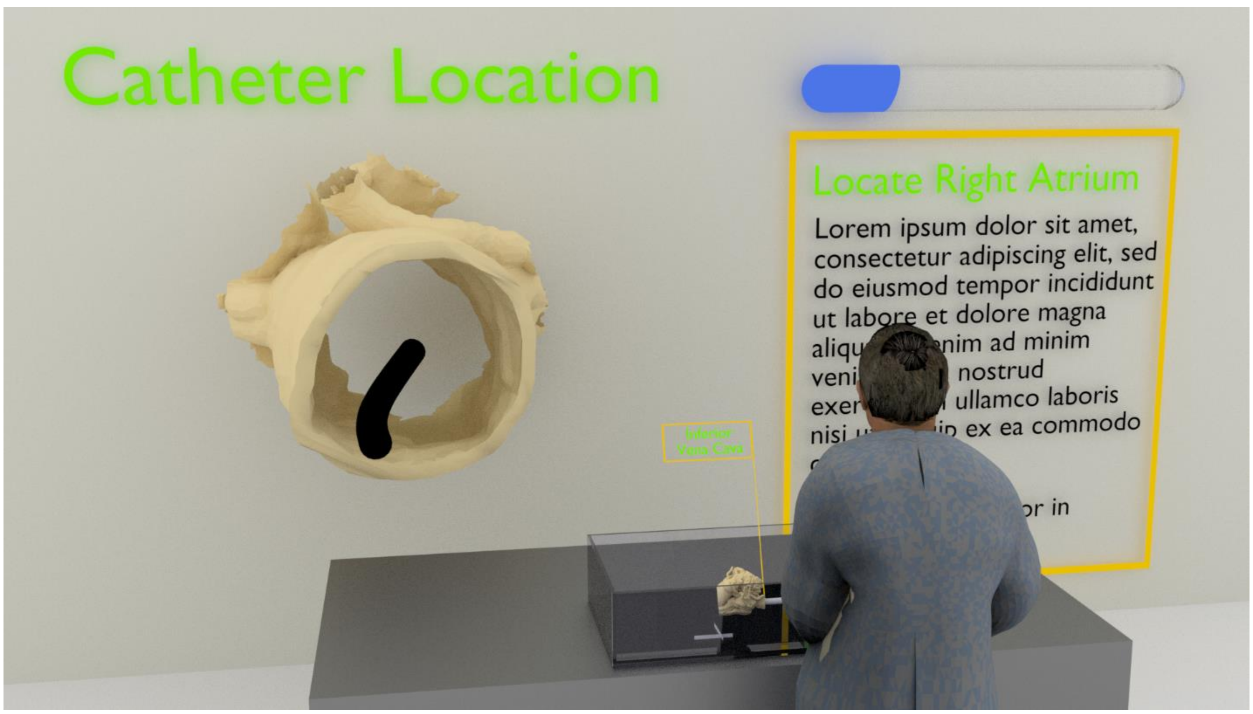

Figure 4.11 A conceptual image of the third version of CathEye where a cut away image of the heart (left) was displayed above the simulator.

In this iteration we created a virtual endoscopic view (Figure 4.11, left) by placing a virtual camera on the tip of the virtual catheter. This gave Dr. Seslar a first-person holographic view as he navigated. It was a significant improvement over the translucent visualization because it allowed him to see internal structures with an unobstructed view. However, due to the camera's placement on the tip of the catheter, Dr. Seslar could only see what was directly in front of it. However, because the heart consists of cavernous chambers, he often needs to view structures behind and to the side of where his catheter is facing. Fluoroscopy and CARTO 3 attempt to address this issue with multiple global views of the heart, but these views force proceduralists to mentally stich the views back together, which is challenging to do effectively [3]. Due to limitations in its original placement, we moved the camera from the tip of the catheter to a third-person perspective above and looking down at the catheter. While this allowed Dr. Seslar to see his catheter and surrounding structures, it reintroduced the problem from take 2—sometimes structures would get in between the catheter and the virtual camera, obstructing his view. Nonetheless, we found this view to be promising and began brainstorming solutions.

4.3.2.4 Take 4: OSTAR Immersive Environment

Cardiologists, especially electrophysiologists, often work in the heart's chambers. When in these chambers, their work is usually focused on a certain area. During the initial phase of the TSP, for instance, they are focused on the FO. As a result, to facilitate the TSP, Dr. Seslar wanted a stereoscopic perspective focused on the FO that also gave him the flexibility to view other structures as needed. As such, during this iteration we used OSTAR place Dr. Seslar *inside* of the right atrium with a direct view of the FO and the ability to change his view by moving his head. While this provided a beneficial and natural interaction, it was limited by the HoLolen's small field of view—although he was immersed in the heart, it did not appear that way because only a small portion of the heart was visible at any point in time. This pseudo-immersion made the heart more difficult to understand than the last iteration because not enough of the virtual scene was rendered. We addressed this issue by using a VR headset with a larger field of view.

Virtual reality headsets are completely immersive. We considered this before we developed the next iteration, wondering how important seeing reality would be. Specifically, in a clinical setting, we were worried that fully immersing Dr. Seslar in VR would cut him off from the OR, hindering his ability to perform the TSP and communicate with his colleagues. However, attempts have been made to move proceduralists from the operating room [53]–[55]. Stereotaxis, for example, develops a magnetically steered catheter system that allows electrophysiologists to control catheters with a joystick and communicate with their colleagues from a different room [54]. In addition to stereotaxis, there are several robotic catheters on the market that can be controlled at a distance [56]. Considering these technological advancements, we hypothesized full immersion would not be too restrictive. In fact, prior work suggests VR is ideal during complex remote navigation tasks [57].

4.3.2.5 Take 5: VR Immersive Environment

Figure 4.12 An EP at Seattle Children's navigating a catheter while she's surrounded by a virtual rendering of the heart in a VR HMD.

Finally, we took the visualization from take 4 and rendered it in a VR headset. In effect, Dr. Seslar was truly immersed inside of the heart as he navigated. After testing from several different perspectives, including from within the RA looking at the FO, Dr. Seslar found this version of CathEye orders of magnitude better than conventional visualizations. We performed a series of preliminary studies with Dr. Seslar's colleagues (Figure 4.12) who thought the visualization was promising. Less experienced EPs found CathEye more useful relative to experienced EPs. Fellows, for example, said they would benefit from this type of visualization in their day-to-day practice due to clarity of the operative field. This highlighted the effectiveness of virtual direct line of sight and the challenges associated with building a mental model of anatomy. Attendings, on average, felt they could navigate just as easily with conventional methods, which is likely due to their experience with the technique and, as a result, their pre-existing mental model. One attending mentioned that, although they wouldn’t use CathEye now, it would have been useful when they were a fellow. This was in line with what other research demonstrated—that stereopsis becomes less useful as tasks become easier [3], [58]. Although fellows and attendings differed in their probability of use, they agreed on one fundamental limitation. Though CathEye did well to convey navigational information, it did not display other essential data. Navigation is a subset of endovascular procedures. During EP cases, for example, in addition to navigating a catheter, proceduralists perform other tasks including the analysis of electrical signals, ablations, and implanting devices. As a result, in order to use CathEye during a real case, the VR environment would have to display more information. This limitation is discussed further in Chapter 6.

4.4 Summary

HMD catheter guidance is a promising avenue of research that has the potential to significantly improve complex navigational tasks. My preliminary work with Bosc—a VR preoperative planning tool—and prior intra-procedural guidance research highlighted this potential and laid groundwork for CathEye—a novel HMD catheter guidance system. I presented its software architecture, focusing on fundamental components, and described the user-center design approach taken during the development of CathEye’s user interface. In the next chapter I describe CathEye’s evaluation during a comparative study.

5 Chapter 5: CathEye vs Fluoroscopy

This chapter primarily consists of an underdeveloped manuscript written in collaboration with co-authors Dr. Stephen Seslar, MD, PhD, and Dr. Wayne Monsky, MD, PhD. When complete, we plan to submit the manuscript to the Journal of the American College of Cardiology. The expected readers are cardiologists who are familiar with endovascular procedures, the transseptal puncture and its visual challenges. However, the audience was assumed not to have a background in stereoscopic displays. The text reflects these assumptions. In addition, the text does not reference other sections of this document and, consequently, periodically reiterates elements in other chapters. Finally, we did not reference CathEye by name in this manuscript.

The transseptal puncture (TSP) is a minimally invasive endovascular procedure that allows operators to gain access into the left atrium (LA) from the systemic venous circulation for diagnostic and therapeutic procedures. Conventionally, it is performed under fluoroscopic guidance. However, the procedure is difficult to learn and, if performed incorrectly, can lead to significant adverse clinical consequences such as cardiac perforation, pericardial effusion, and tamponade. In addition, as the complexity of the interventional procedures that are being performed in the LA increase, it has become necessary to select the puncture site for interventions with greater precision. When performed under 2-dimensional (2D) fluoroscopic guidance, the procedure requires a robust mental model of the 3-dimensional (3D) anatomy that takes considerable time and experience to develop. Recent advances in intracardiac echocardiography (ICE) have helped but integrating this 2D information also requires considerable skill, and challenges exist in maintaining ultrasound visualization during the puncture itself. In contrast to the 2D planar nature of fluoroscopy and ICE, virtual reality (VR) is an immersive visualization experience that creates an intuitive 3D user-perspective [15]. In this context, the user can be virtually placed inside a 3D rendering of a patient's heart and navigate the transseptal puncture from this vantage point. We believe that this approach could ultimately shorten the learning curve and make the transseptal procedure safer. We hypothesized that VR-based transseptal guidance would subjectively be more intuitive and allow for greater confidence in choosing a puncture site, particularly for novice operators. In addition, we anticipated that VR guidance would reduce procedure time and improve the accuracy of the puncture site. The purpose of this single-center pilot study was to test these hypotheses in a simulated transseptal procedure using a 3D printed cardiac phantom.

5.1 Methods

Subjects consisted of Seattle Children's Hospital Interventional Cardiac Catheterization and Electrophysiology faculty, as well as fellows from the University of Washington Pediatric Cardiology Training Program.

5.1.1 Protocol

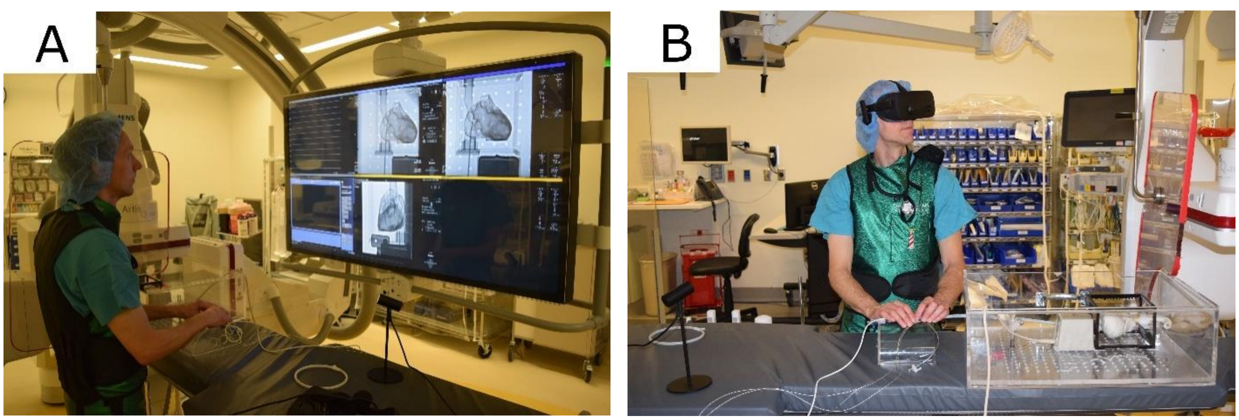

Figure 5.1 Physician performing a simulate transseptal puncture using (A) fluoroscopic and (B) virtual reality guidance.

The experiment was performed in the Electrophysiology Laboratory at Seattle Children's Hospital. Study team research coordinators obtained informed consent. Subjects were then asked to complete a pre-survey consisting of biographical data about the study participant. Following this, participants were instructed to pull a card from a bin to determine with which imaging modality (fluoroscopy or VR) they would begin. After donning a lead apron and vest, and with appropriate shielding in place, each subject performed 6 simulated transseptal puncture procedures alternating between the 2 imaging modalities (3 fluoroscopically-guided, 3 VR-guided; Figure 5.1 A & B). The research team took care to make sure the VR HMD was properly fitted to the subject. All trials began with the needle-dilator-sheath combination positioned at the same place in the superior vena cava with the needle at the tip but not protruding from the sheath. Subjects were instructed to select a site for puncture as close to the center of the simulated fossa ovalis as possible and, once across the fossa ovalis, to advance the dilator and sheath such that the tip of the sheath was at the left atrial free wall near the origin of the left upper pulmonary vein. Both fellows were given basic instructions and provided a demonstration by one of the investigators (SPS) on how to perform TSP. During each trial the following data points were collected:

- Time (in seconds) from start position to subject declaring they have selected a site for puncture
- Accuracy (in millimeters) of the chosen site for puncture. The simulator recorded the location of each selected puncture site and computed the distance from the selected site and the true center of the simulated fossa ovalis
- Total time (in seconds) to perform the TSP from beginning to end
- Total distance (in mm) traveled by the needle from start to finish for each run

After completing the 6 transseptal punctures, subjects were asked to complete a post-survey.

5.1.2 Transseptal simulation platform

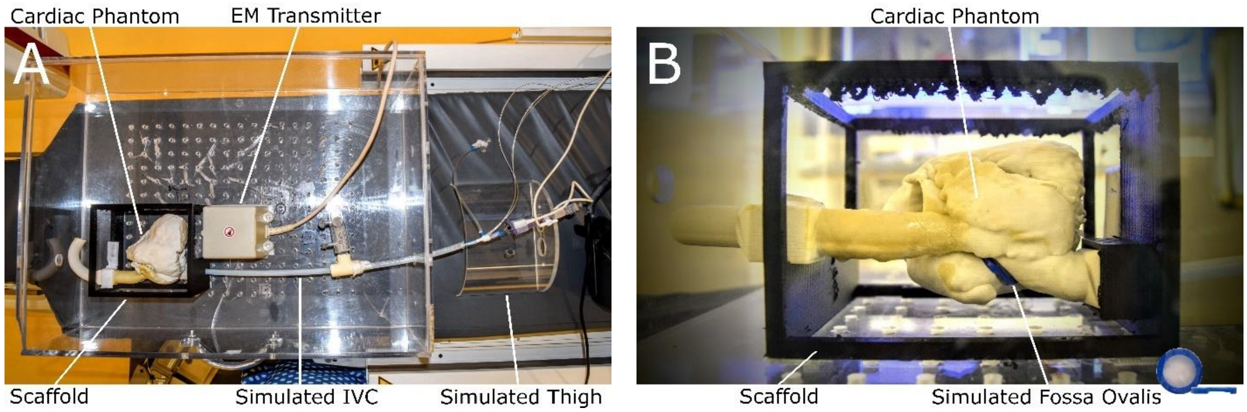

Figure 5.2 (B) Over-head photograph of transseptal simulator. (A) Close up side view of cardiac phantom

A 3D printed heart model was generated using DICOM images obtained from a cardiac MRI performed on one of the research team members (SPS) in a 1.5 Tesla MRI scanner using standard clinical sequences. Segmentation of the DICOM images was performed using Slicer (www.slicer.org). The resultant .STL file was further modified using Blender (www.blender.org) to include a slot between the right and left atria where we could insert a removable simulated fossa ovalis. The 3D heart model was then printed using a Z-Corporation powder bed printer (Z Corporation, Rock Hill, SC, USA). The removable simulated fossa ovalis consisted of a flexible plastic ring, approximately the size and shape of the fossa ovalis, on to which was affixed a piece of general-purpose office tape, which served as the simulated fossa ovalis (Figure 2B). The heart model was then placed in a custom made (www.blender.org) scaffold printed out of polylactic acid (PLA) using a Flashforge Creator printer (Flashforge, City of Industry, CA, USA) to hold the heart in a fixed and appropriate orientation to mimic the cardiac position in a healthy supine adult human (Figure 2A). This scaffold was, in turn, fixed with Velcro® tape to the floor of the simulator (Figure 2B). The transseptal puncture was performed using a Preface Sheath and Dilator (Biosense Webster, Diamond Bar, CA, USA) and a BRK transseptal Needle (Abbot, Abbott Park, IL, USA).

5.1.3 Virtual Reality Set-up

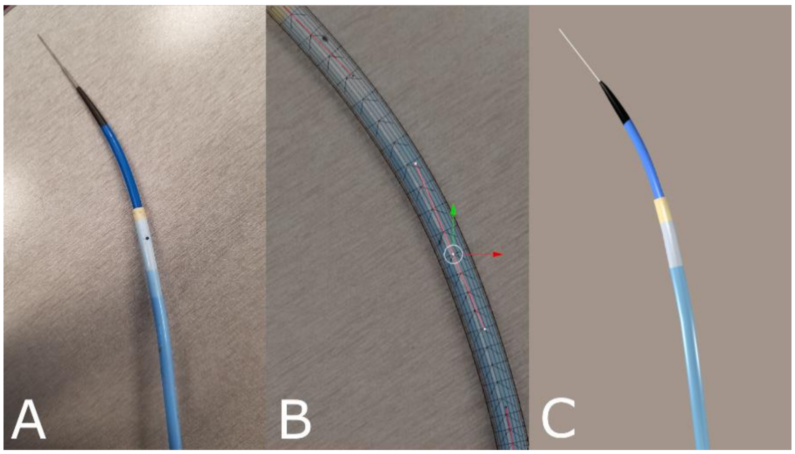

Figure 5.4. Creating 3D models of the transseptal equipment. (A) Photograph of the actual equipment. (B) Mesh created in Blender. (C) Rendering in VR.

The visual components of the virtual reality environment consisted of the cardiac and scaffold models describe above, in addition to models for the sheath, dilator and needle. The sheath, dilator and needle models were custom created in Blender (www.blender.org) using the following process. First, top-down and side view pictures were taken of each instrument (Figure 4A). Then vertices, edges and faces were aligned to the pictures in Blender to form a realistic mesh (Figure 4B). Finally, Colors were added for visual effect (Figure 4C). Each model, including the cardiac and scaffold models, were uploaded to the virtual reality software as FBX model files. Two preset views were created. The first view was in the RA looking towards the septum (Figure 5.5 A) and was primarily used to position the dilator and puncture the fossa. The second view was near the mitral valve looking toward the LA side of the fossa ovalis (Figures 5.5 B & C) and was primarily used to advance the sheath while retracting the dilator and needle. When in one view, the operator was given a "rear-view" camera image of the other view as seen in figure 5A-C). Lights were placed in key locations on the virtual instruments and in the RA and LA to facilitate guidance with shadows. A computer with an NVIDIA GTX 1080 graphics card was used to render the virtual environment at 60 frames per second. These frames were displayed in an Oculus Rift head mounted display (HMD; Oculus VR, Menlo Park, CA, USA) that was attached to the computer.

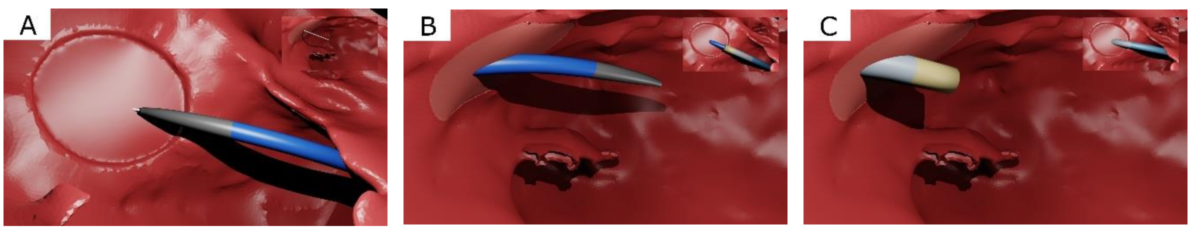

Figure 5.5. Visualization of transseptal puncture in VR. (A) Right atrial perspective, dilator positioned, needle puncturing. (B) Left atrial perspective, dilator across. (C) Left atrial perspective, sheathe across.

5.1.4 Data Analysis

Summary statistics are presented as counts and percentages for categorical data and mean values and standard deviations for continuous data. Participants were randomly assigned to the first method of visualization and then alternated methods for a total of 3 per method per participant. Tests for differences between the methods of visualization were carried out using mixed linear regression models with robust standard errors controlling for experience (attending vs. fellow), and years of experience, with a random effect for the participant. Analyses and summaries were performed using StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LLC.

5.2 Results

A total of 8 subjects (6 faculty and 2 fellows) completed the protocol. On average, the faculty subjects were highly experienced in TSP, while neither of the fellows had ever performed one. None of the subjects had significant prior experience in VR (table 5.1). All transseptal attempts were completed successfully by all subjects regardless of whether fluoroscopy or VR was used for guidance. VR guidance was associated with significantly greater accuracy (P = 0.013), but a longer total distance traveled by the needle (mean of 22.5 cm vs. 20.5 cm for fluoroscopy; P=0.04) when compared to fluoroscopic guidance. Accuracy, measured as the mean distance from the puncture site to the true center of the simulated fossa was 3.5 ± 3 mm using VR guidance compared with 10 ± 10 mm using fluoroscopy. The times to puncture site selection and total times for TSP were not statistically different between the 2 groups (table 5.2).

Subject	**Fellows**	**Faculty**
Years out of training	NA	16 ± 10
Years of fellowship completed	1.75 ± 1	NA
# of TSP performed	0	152 ± 133
Guidance • Fluoroscopy • ICE • TEE	 NA NA NA	 100% 50% 17%

Ave # Prior Experiences Using VR (recreationally or professionally)	1	2.4

Table 5.1 Subject data summary

	Effect of Trial Type[ǂ] (VR with Fluoroscopy as reference)	
Measure	β (95% CI)	P value
Accuracy from Target (mm)	-7 [-12, -1]	0.013
Total Time (s)	710 [-9389, 10808]	0.890
Total Distance (mm)	20 [1, 39]	0.040

Table 5.2 Mixed Linear Regression for Accuracy, Times, and Distances

[ǂ] Models adjusted for Experience (attending vs. fellow) and years of experience.

All subjects completed the post-survey. On average, subjects rated VR guidance as “easier,” “more precise,” and “more efficient” than fluoroscopic guidance. No subject experienced disorientation or adverse symptoms requiring termination of the session. Though there were too few subjects for meaningful statistical analysis, fellows overall seemed to rate the VR experience higher than faculty (Figure 5.6).

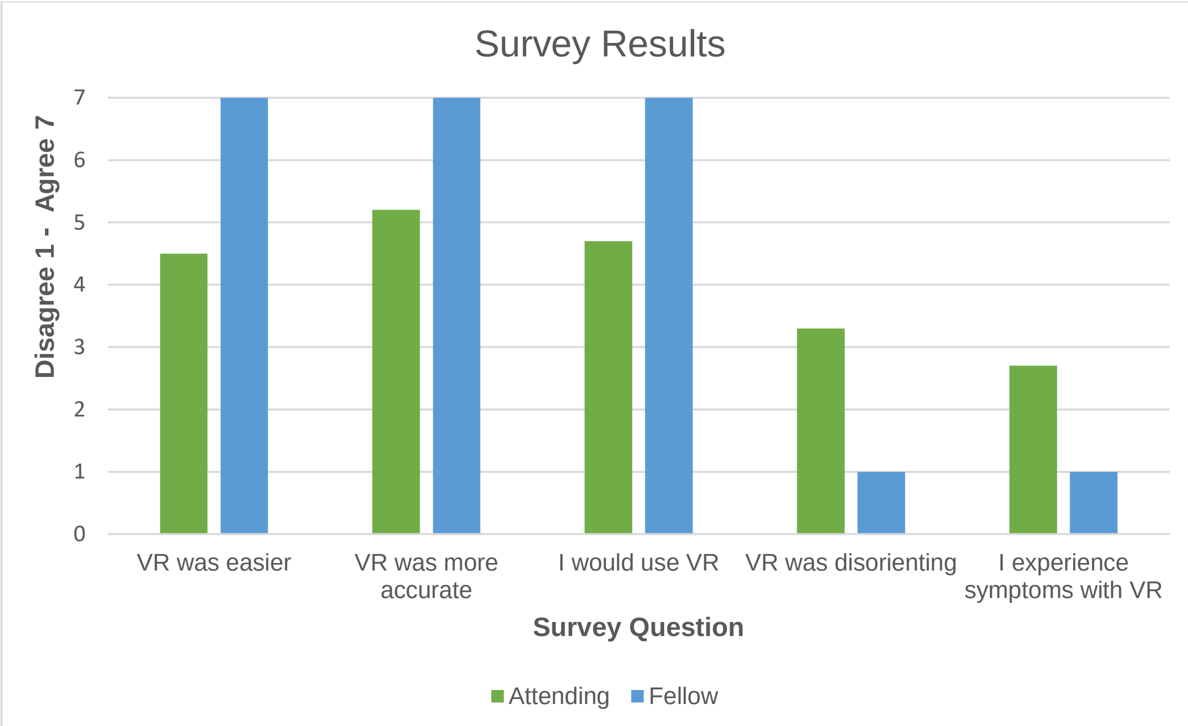

Figure 5.6. Post-protocol survey results

Several subjects provided subjective comments. There were two comments related to the VR environment. One subject commented that it was uncomfortable when the sheath and dilator appeared to move "through" the wall of the virtual 3D model from their perspective. Another commented that they didn't experience any adverse effects in VR. With respect to registration of the virtual reality visualization to the physical model, one subject commented that they were not sure if the virtual image had "true" registration. Two others commented that VR was well registered with reality. Finally, one comment was related to the addition of new features, stating that color coding structures in the LA would be beneficial to positioning for interventions following a successful transseptal puncture.

5.2.1 Discussion

This study demonstrates proof of concept feasibility of VR guidance for TSP. Both experienced faculty and novice-fellows performed transseptal punctures more accurately when using VR relative to fluoroscopy. Furthermore, the majority of participants felt that navigating in VR was easier (more intuitive) than with fluoroscopy, and all but one agreed that they would use VR instead of fluoroscopy if it were approved for clinical use.

Not surprisingly, our study demonstrated that novice performers derived greater benefit from the VR experience than did experienced users. Having built a reliable and sophisticated mental model, experienced practitioners have less need for the intuitive clarity provided by VR. Even with this enhanced mental model, however, experienced providers were substantially more accurate in choosing the site for puncture using VR when compared to fluoroscopy. This has important implications for more complex left atrial interventional procedures such as left atrial appendage occlusion or mitral clip placement. For these procedures, where you cross the atrial septum significantly influences how well the procedure can be accomplished. In addition, for inexperienced users, training simulators that use VR might facilitate the development of a robust mental model and thus speed the learning curve, even for fluoroscopically guided procedures.

The advent of alternative imaging modalities, such as electromagnetic and impedance based navigation systems, and ultrasound, has decreased the use of fluoroscopy during catheter interventions, particularly for electrophysiology procedures [59]. There are a number of published case series demonstrating the feasibility of entirely fluoroless procedures [9], [13], [60], [61]. However, despite this, fluoroscopy remains the imaging modality of choice during TSP by most interventional and electrophysiology providers [12], [62]. VR HMDs have an inherent ability to make 3D information easier to understand and interact with, which may be an important catalyst for changing this paradigm. However, if we are to safely and effectively integrate VR HMDs into clinical workflows, we must first understand the implications of such a shift in practice.

Though the results of this study are quite promising, there are some important hurdles to overcome. Most notably, the near-universal implementation of non-fluoroscopic navigation systems in electrophysiology has not been realized in other endovascular fields such as interventional cardiology and radiology. The development of such fluoroless navigation tools, tailored to the specific needs of these fields will be necessary to overcome this barrier. The second barrier to widespread implementation of VR navigation during clinical cases is physician adoption. Though most of our subjects reported a positive experience, some found VR disorienting or nauseating. Though modern VR HMD's have greatly improved compared to earlier iterations, there is still work to do for both hardware and software developers to make the experience more comfortable, especially for longer use periods. In a previous study (unpublished), we found that some providers did not like the experience of being isolated from the operating room that VR produces. In this context, it is possible that augmented reality (AR) might be another valuable approach. Finally, for safety reasons, it is critically important that registration of the virtual world with the physical world be precise. In our simulated platform, we were able to achieve near exact registration because we used a rigid non-beating model fixed to the floor of our simulation platform. The challenges of registering the elastic structure of a beating heart in real time, though clearly possible, will require careful execution. We are presently developing technology to incorporate real time intracardiac echocardiography (ICE) images into VR for this purpose.

5.3 Limitations

Many operators now use intracardiac echocardiography (ICE) or transesophageal echocardiography (TEE) as an adjunct to fluoroscopy. In our study, however, the technical challenges of making our simulation environment compatible with ultrasound were cost prohibitive. We acknowledge that the addition of ultrasound guidance in our study may have improved the performance of the fluoroscopic trials. Our study was also limited by a relatively small sample size, particularly for inexperienced providers. Finally, our highly controlled rigid model simulated platform also limits extrapolation to a beating heart scenario in a live clinical case as discussed above. Nonetheless, the technical challenges to overcome to realize VR-guided TSP are readily achievable with technology presently available. What is needed is the collective will to move beyond what we are used to and embrace what may be a fundamentally superior visualization technology.

5.4 Conclusion

Our findings support the feasibility of VR HMD guidance systems of the transseptal puncture procedure. We found that VR guided TSP was more accurate and intuitive than those guided by Fluoroscopy. For novice providers, VR guidance could potentially accelerate the learning curve. For experience providers, the enhanced accuracy afforded could facilitate complex left atrial procedures. Further efforts should be aimed at breaking down the barriers to clinical implementation of this technology.

6 Chapter 6: Future Work and Conclusion

The results from the last chapter suggest that CathEye, an HMD-based guidance system, has the potential to facilitate the TSP during real clinical cases, and may facilitate other endovascular maneuvers. If CathEye were used during real cases it could decrease life threatening errors, such as cardiac tamponade and aortic root puncture discussed in chapter 2, in addition to decreasing the barrier to entry for novice proceduralists. These effects would have significant benefits on patient safety and provider comfort and confidence. However, in order to realize these benefits several milestones need to be achieved including the incorporation of dynamic imaging and the acquisition of FDA approval.

6.1 Preparing CathEye for Clinical Use

As I discussed in chapters 3, 4 and 5, CathEye's display methodologies are based on pre-operative images. This is sufficient for simulated procedures in 3D printed models but needs to be further developed to be used to treat living patients. While pre-operative imagery is enough for navigating a 3D printed model, it is ill-suited for clinical cases. Though pre-operative images are representative of the patient's anatomy at the time the images are taken, the patient's anatomy may shift between the time the images were taken and the time the procedure begins. In this case, if the pre-operative images are used the proceduralist is at risk of receiving old information that could lead to an error, such as cardiac tamponade, aortic root puncture, or similarly severe error during a maneuver that is not the TSP. Therefore, before CathEye is ready for clinical use it must support dynamic imagery.

6.1.1 Dynamic Imagery

Cardiac mapping systems, such as CARTO 3, are ideal for incorporating dynamic imagery into CathEye. As described in chapter 2, cardiac mapping systems consist of two main components: a component that generates data and a component that visualizes data. These components are analogous to the patient simulator (data generation) and CathEye (data visualization). In a cardiac mapping system, however, data are used to create a flat image displayed on a monitor. Using a similar mechanism for data transfer that I used to transmit data from the patient simulator to CathEye, a conventional mapping system could be modified to transfer data from its data generation component to CathEye. In my initial designs I deliberately split the patient simulator (data) from CathEye (visualization) to make replacing the data component with a different system relatively easy from a technological/implementation perspective. However, the business model employed by mapping system companies, as discussed in chapter 2, prevents CathEye from accessing mapping system data. Therefore, the primary hurdle to overcome to display dynamic imagery in CathEye is an agreement with at least one mapping system company that would enable CathEye to stream in data from their mapping system in real time.

Such an agreement seems more feasible with time. Large medical companies are recognizing the value of data sharing due to its implications on business strategy and product development. When a single system shares its data with external systems it can facilitate the development of new products and support data-driven decision making, both of which can significantly contribute to a company's growth. Netflix, for example, has grown into a digital media goliath, in part, because it generates, shares and analyzes large amounts of data collected from its users. Netflix's data processing pipelines give them insights into what their users want and the ability to produce targeted media and recommendations, which have helped them grow a dedicated user base. Many other consumer technology companies have used similar data-sharing techniques that have resulted in favorable outcomes, and medical companies are beginning to recognize the benefit. I recently spoke with a medical company (whose name I cannot mention) that is interested in developing a data sharing platform to facilitate internal product development and data analysis so they can make more targeted sales. This shift in business strategy presents opportunities for partnership because they do not currently have the expertise to build a data sharing platform and are considering outsourcing the work to an external company. If a company with CathEye were to receive such a partnership from a mapping system company, they would have the opportunity to prepare CathEye for clinical use.

6.1.2 FDA Approval

Once CathEye incorporates mapping system data, the final major milestone to achieve is FDA approval. Dr. Seslar and I have had several conversations with FDA consultants to understand what it would take to get CathEye FDA approved. After those conversations, we believe CathEye is a likely candidate for 510k approval because it has predicates (other systems that it is based on), such as EchoPixel, that received 510k approval. During the FDA approval process, we would need to define system requirements and perform a series of studies demonstrating CathEye meets the aforementioned requirements and is safe for clinical use. This work would likely happen in close collaboration with the mapping system company (e.g. CARTO) to ensure the end-to-end system (i.e. CARTO + CathEye) was FDA approved and safe for clinical use.

6.2 Exploring CathEye in Interventional Radiology

Before concluding this dissertation I would like to highlight the potential CathEye has to facilitate other endovascular maneuvers. In parallel to the transseptal study discussed in chapter

5, I have been doing similar work with Dr. Wayne Monsky, an interventional radiologist. Like electrophysiology and interventional cardiology, interventional radiology (IR) is an endovascular subspecialty in which proceduralists (interventional radiologists) navigate catheters through the blood stream. However, unlike the focus of this dissertation, interventional radiologists treat diseases outside of the heart, in the vascular system. The vascular system can be thought of as a series of highways and roads that route blood to every major organ in the body. It consists of large relatively straight vessels, such as the aorta, that are relatively easy to navigate, and smaller winding vessels, such as the mesenteric arteries, that are relatively challenging to navigate. In addition, many vessels connect, or bifurcate, at sharp angles, challenging proceduralists to bend their catheters in shapes that make precise maneuvers difficult. These challenges are all exacerbated by the use of fluoroscopy, the most commonly used imaging modality in IR, that is associated with the host of visualization challenges highlighted in chapter 2.

Due to the significant navigational challenges in IR, the limitations of fluoroscopy and potential to address them with CathEye, Dr. Monsky and I began working together to explore the use of CathEye in his field. In our preliminary research [63] we found that CathEye decreased the time it took to navigate to specific vessels in addition to, subjectively, improving ease, precision, confidence and efficiency. This early work demonstrates the potential positive impact CathEye can have in IR. However, much more work needs to be done. CathEye's user experience was designed to facilitate the TSP, which may not provide the best experience for proceduralists in IR. For example, during the TSP proceduralists works in the atria. Two views, one in the RA and the other in the LA, were used in the chapter 5 study to display all information necessary to perform a successful TSP. However, during an IR procedure the catheter moves a much further distance while it twists and bends around bifurcating vessels. In our preliminary work, keeping up with the position of the catheter required between 5-10 preset views, and jumping between them was often disorienting. To address limitations in the version of CathEye designed for the TSP, in future work I plan to evaluate an alternate method of display that facilitates understanding the forest from the trees while simultaneously providing detailed information about where the catheter is located during complex turns. I believe OSTAR, discussed in chapters 2 and 4, is well suited for this type of display. I plan to revisit the initial designs of CathEye (iterations 1 and 3) that I discussed in chapter 4 due to their ability to give a high-level description of the operative field while simultaneously providing an internal view of the catheter in context of anatomy.

6.3 Conclusion

Endovascular procedures provide lifesaving treatments for severe diseases in nearly every major organ in the body. However, as discussed in detail in chapters 1 & 2, endovascular procedures are visually challenging, primarily due to the method by which medical images are displayed. This is most evident during the TSP, a dangerous and visually challenging procedure that is most commonly guided by fluoroscopic images displayed on a flat monitor. To overcome the visual challenges associated with conventional guidance, I developed CathEye—an HMD-based catheter navigation system to facilitate the transseptal puncture. CathEye is important to endovascular medicine because it is alternative form of visualization that, based on my study results, has the potential to make the transseptal puncture and other endovascular maneuvers easier to learn and perform safely. CathEye is important to health informatics because it provides a basis for human-computer-interaction design for HMD interfaces in procedural medicine. With the rise in popularity of HMDs and their potential positive impact on procedural medicine, understanding interface design is important to understand now more than ever.

In addition to CathEye, I believe the open-data simulator offers significant contributions to endovascular medicine and health informatics because it facilitates benchtop studies, the development of new technologies (e.g. CathEye), and data analysis. Proprietary data practices in procedural medicine, particularly by mapping system companies, prevent researchers from acquiring the data necessary to explore and improve catheter guidance. This limits researchers' ability to quantitatively understand and analyze how catheters move, which in turn limits the types of medical applications that are created from research. The open-data simulator addresses these issues by generating and exposing data about the operative field, including catheter location data, to researchers in a well formatted language that is easy to compute over. In my work I demonstrated how this data can be used to perform in-depth data analysis and develop novel technologies that push the boundaries of medical practices.

We need to keep up with the pace of technology. My hope is that the work in this dissertation is used to guide future HMD-guidance research and develop open-data platforms that allow us to generate, consume and share data more efficiently.

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