Three-perspective multimethod analysis of medical extended reality technology.

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By

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List of Acronyms

2D	= two-dimension
3D	= three-dimension
AC	= anterior commissure
AR	= augmented reality
CT	= computed tomography
CTA	= computed tomography angiogram
CAD	= computer aided design
CAVE	= Cave Automatic Virtual Environment
CRW	= Cosman-Roberts-Wells
DBS	= deep brain stimulation
DICOM	= digital imaging and communications in medicine
DOF	= degree of freedom
FDA	= Food and Drug Administration
GUI	= graphical user interface
HMD	= head-mounted display
HMF	= head-mounted frame
HIT	= health information technology
IT	= information technology
IRB	= institutional review board
LCPD	= Legg-Calvé-Perthes disease
MC	= mid-commissure
MR	= mixed reality
MRI	= magnetic resonance imaging
PC	= posterior commissure
ROI	= return on investment
SWD	= stereoscopic wide display
VR	= virtual reality
XR	= extended reality

Definitions of Terms

This dissertation uses the following definitions:

Monoscopic is viewing an image from one viewpoint. A photograph, computer screen, and phone screen are examples of monoscopic viewpoints. Monoscopic viewpoints show the same image to both eyes.

Stereoscopic is viewing an image using two viewpoints. The viewpoints are offset to show a slightly different view to each eye. Humans, with two working eyes, naturally use stereoscopic vision to understand depth and distances to objects.

Virtual reality is a simulated immersive experience. The experience may be displayed on a projection screen/s, three-dimension television, CAVE, or head-mounted displays. All displays are stereoscopic to provide the user with depth perception.

Augmented reality is a simulated experience. The experience is overlaid on the user's real-world. Hardware used ranges from phones and tablets to head-mounted displays. Displays may be monoscopic or stereoscopic.

Mixed reality is a simulated hybrid experience where the physical and digital worlds co-exist and interact in real time. The experience may include haptics to engage the user further.

Extended reality is an umbrella term for virtual reality, augmented reality, and mixed reality.

Virtual experience is the combination of hardware and software which creates an experience for the user. The experience may use virtual reality, augmented reality, or mixed reality technology.

Solution is the product meant to solve a problem—specifically, a product designed to meet a particular need.

Application is a computer program that performs a particular task or set of tasks.

Medical environment is the location where technology is used; a quiet office space, moving vehicle, industrial setting, or, in the case of this dissertation, a medical setting.

Dissertation Summary

For nearly 30 years, extended reality (XR) technology has been proposed as the medical industry's future, and yet we continue to see the slow adoption of this technology. XR is an umbrella term for virtual reality (VR), augmented reality (AR), and mixed reality (MR). Three factors contribute to the adoption of XR technology: research (Mazur et al., 2018), user-centered design (Zweifach & Triola, 2019), and mature technology (Riener & Harders, 2012). Mature technology reflects Riener & Harder (2012) report that current XR technology was still immature and needed further development for advanced medical scenarios. Each year, more companies and researchers present feasible methods to replace traditional training and planning methods with high-quality simulations. Amidst the medical industry's technological advancements and interest; many simulations are severely simplified, and surgeons continue to *practice* medicine on live patients (Chan et al., 2013). The purpose of this research was to identify constraints, challenges, and opportunities that exist in the development, design, and usage of medical XR technology.

Justification of Research

The medical industry recognizes the need to develop high-quality simulations but is also risk-averse and conservative by training (Zweifach & Triola, 2019). Meanwhile, XR companies are actively developing XR solutions for the medical industry based on Silicon Valley's mantra of “fail hard, fail fast, fail often.” These two trains of thought are in opposition resulting in the slow adoption of medical XR technologies. Medical professionals seek mature technology with validated research to justify the technology fadoption for their specific user needs. Meanwhile, XR companies are trying to find a niche based on limited research and market-ready solutions while building a business case to justify the financial return on investment (ROI). This research analyzes the current status of medical XR technology from three perspectives.

User-Centered Design Framework

This research, guided by a user-centered design framework, improves the adoption of medical XR technology (Zweifach & Triola, 2019). User-centered design

(Kling, 1977) is an iterative process that uses various methods and tools to understand the user's needs (Figure 1). The five steps in the process include analyze, define, design, evaluate, and implement. The first step (analyze) focuses on the context of use and the user's needs. The second step (define) establishes the requirements based on the user's needs. The third step (design) creates a solution based on the requirements. The fourth step (evaluate) assesses the solution based on the requirements. The final step (implement) puts into practice the solution.

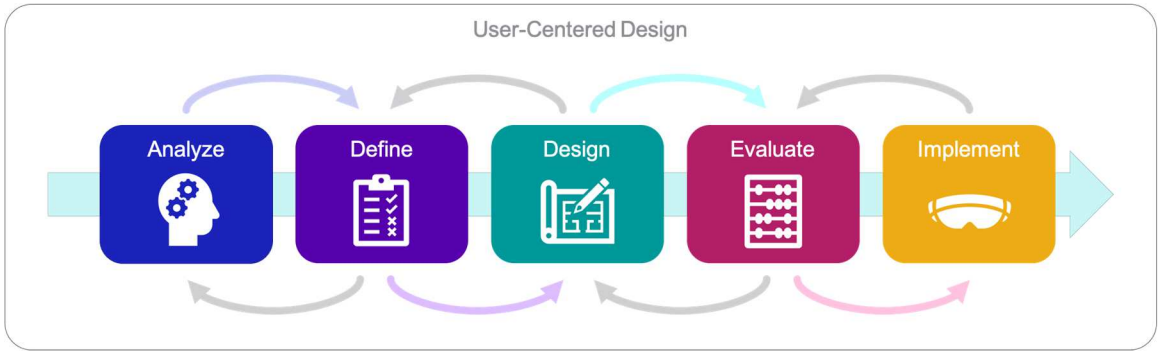

Figure 1. The user-centered design process.

Three Perspectives

The five steps of the user-centered design process were applied to develop three perspectives for this research (Figure 2). In chapters one through four, the first perspective analyzed clinical use cases from a clinical viewpoint for medical XR technology. Chapters one through three develop three clinical use cases. Chapter four surveys medical professionals who collaborated on the XR use cases to understand how they anticipated it fitting into their practice. These chapters presented the doctor's perspectives of using medical XR technology. The second perspective defined, designed, and evaluated a solution for a specific use case in chapter five. This chapter explored developing a medical XR technology to plan the placement of deep brain stimulation (DBS) electrodes and presented the developer's perspective of creating medical XR experiences. In chapter six, the third perspective reviewed implemented medical XR technology. This chapter reports survey results from individuals working to produce medical XR technology to understand their processes and attitudes and presented the industry's perspective of advancing medical XR technology.

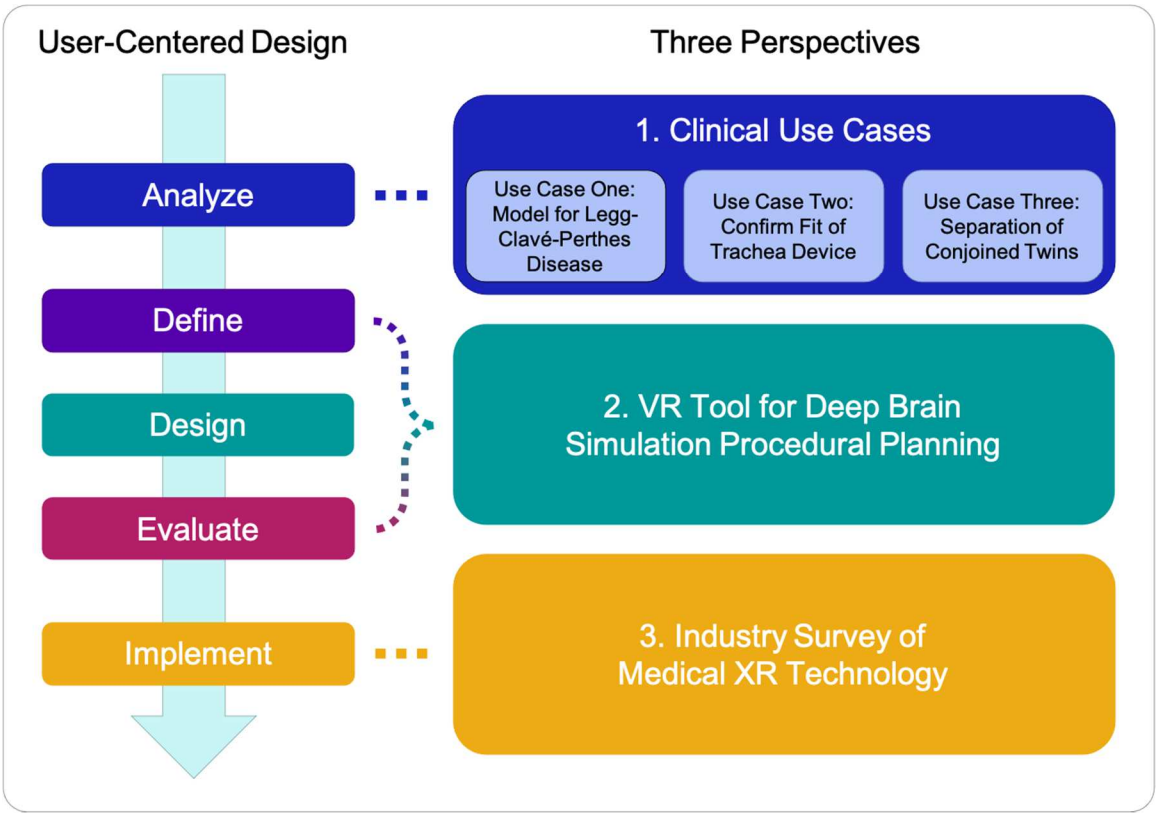

Figure 2. The user-centered design process aligned with the three perspectives of this research.

Perspective One: Clinical Use Cases (Case Study Research)

The first perspective in chapters one through four analyzed the user needs for a clinical setting. The demand for simulation-based training in the medical industry has increased as organizations began moving away from traditional cadaver laboratories and 'see one, do one, teach one' learning models (Riener & Harders, 2012; Stanney et al., 1998). Research has shown simulation improves clinical training, offers repeatability, and reduces teaching costs compared to traditional models (Delorme et al., 2012). VR is a valuable tool to create high-quality simulations (Juhnke, Mattson, et al., 2019) and has seen increased use in the medical industry (Chan et al., 2013). The purpose of this perspective was to develop user-driven medical simulations using a shared methodology and identify challenges and opportunities for medical VR technology.

The clinical use cases chapters present a series of use cases and the survey results from nine doctors involved with the cases. The use cases developed a pre-clinical model

of Legg-Calvé-Perthes disease (LCPD) (Chapter 1), sized a double-lumen endotracheal tube for a pediatric lung lavage procedure (Chapter 2), and planned the separation of conjoined twins (Chapter 3). The use case series examined how to visualize patient-specific anatomy and medical devices. The survey results presented these early adopters' perceptions and vision for VR technology fitting into their clinical workflows. Four learnings and future opportunities, from the doctor's perspective, were identified.

Perspective Two: Deep Brain Stimulation VR Tool (Applied Research)

The second perspective in chapter two developed two medical VR technologies to plan the placement of DBS electrodes. As the demand for simulation-based training in the medical field increases, developers look to the literature for best practices and guidelines to support design decisions. Unfortunately, few examples exist to demonstrate, evaluate, and validate XR technologies in general (Vi et al., 2019) before even considering the complex challenges which continue to limit the use of XR technology in the medical industry (Chan et al., 2013). The purpose of this step was to apply the user-centered design approach by combining the user-driven learnings from perspective one with the available literature and domain expert feedback to produce two VR experiences specific to DBS.

The DBS chapter develops a use case through four steps. The first step defined the procedural tasks for a complete clinical workflow. The second step investigated design guidelines for medical XR technology. The third step created three-dimension (3D) models appropriate for the DBS use case, and the fourth and final step designed two VR solutions to support the user's tasks.

Perspective Three: Industry Review (Grounded Theory Research)

The third perspective in chapter three explored how companies implement their medical XR solutions and documented gaps, challenges, and opportunities from an industry lens. From small start-ups to large corporations, a growing number of companies have developed XR technology for use cases across the medical industry. Early adopters' experiences are essential to understand as they drive adoption and guide future research (Zweifach & Triola, 2019). The academic literature is currently limited in scope to proof-

of-concept studies or small-scale studies that lack adequate controls and statistical power (Mazur et al., 2018). Additional environmental barriers exist in the adoption of medical XR technology (Zweifach & Triola, 2019). The purpose of this step was to research XR technology from the perspective of the medical industry to understand the landscape of technology development, including constraints, challenges, and opportunities during the development, design, and usage of XR technology.

The industry review chapter examines professional's experience developing medical XR technology. The medical industry is buzzing with the potential of XR technology as many try to find their niche. Individuals working in the medical XR technology were surveyed to define the state-of-the-art for why they are developing the technology, what hardware and software are using, how are they evaluating the usability of the solutions. The results explored the technology landscape, from demographics of participants and companies, their current progress, to their hopes for medical XR technology.

Connection between Perspectives

These three perspectives are necessary to explore the gaps, challenges, and opportunities of XR technology in the medical industry. The adoption of medical XR technology relies on a symbiotic relationship between XR companies and medical professionals. XR companies must develop compelling and attractive XR experiences that are clinically relevant to profit from their effort. At the same time, medical professionals seek clinical and economic evidence that the proposed solution will outperform existing technology at a lower cost (Laupacis et al., 1992).

The first perspective developed three use cases that represent three different ways to apply XR technology. The first was a preclinical model to understand human disease state. The second was a clinical model to predict patient outcomes based on the fit of a medical device. The third was a clinical model to make procedural plan decisions. These use cases were guided by clinical care teams and specifically designed for their needs, independent of financial viability. The use cases used existing XR technology to produce minimum viable products to learn about clinical needs. The results show how early

adopters perceive medical XR technology and their vision for using the technology in their clinical workflows.

The second perspective demonstrated the depth of medical XR technology by developing a single-use case. This used the first perspective's learnings to fully define a working prototype. One learning from the first perspective was the importance of matching the medical workflow for the procedural planning process in the XR experience. The technology design considered the many experts who contribute to the planning process and medical environment. The XR experience was designed specifically for the clinical need, independent of financial viability. The results demonstrate a method to develop a user-centered XR technology to meet a clinical need and integrate with the medical environment.

The third perspective flips the script to explore XR companies developing solutions for medicine. This research identified where they are running into roadblocks and what challenges they are facing. This knowledge highlights the unique position of medical XR companies, which derive from Silicon Valley's mantra of "fail hard, fail fast, fail often," but are working in the highly regulated medical industry where evidence is necessary for technology adoption and utilization. Due to the newness of XR technology, these companies are still figuring out how to succeed. The stakes are high, as research has shown 90% of software startups will fail (Giardino et al., 2014). It is critical to understand the position of these companies, as they are necessary for XR technology to become a mainstream tool in the medical industry.

This research demonstrates what is possible with medical XR technology and the challenges faced across the industry to reach adoption and utilization. Technology adoption and utilization are critical to advancement, especially as the medical industry tries to reduce its dependence on cadaver labs, animal models, and 'see one, do one, teach one' training models (Riener & Harders, 2012; Stanney et al., 1998). By highlighting the challenges and the opportunities, we can begin exploring how to successfully bridge the gap between the risk-averse medical community and the business-driven rapid iteration of software startups.

Conclusion

My dissertation's purpose was to examine the gaps, challenges, and opportunities remaining based on the current status of medical XR technology. This research applied a user-centered design approach; analyze, define, design, evaluate, and implement, to explore medical XR technology. The information presented in this dissertation will be of value to medical professionals, medical XR technology developers, and regulators. As medical XR technologies continue to grow, it is essential to understand the state of the technology and how these technologies are serving the needs of users.

Chapter 1

Perspective One: Preclinical Model for Legg-Calvé-Perthes Disease Case Study

Bethany Juhnke, Susan Novotny, Jennifer Laine, Ferenc Toth, and Arthur Erdman

Preface

Published in the Proceedings of the 2019 Design of Medical Devices Conference (Juhnke, Novotny, et al., 2019), here is the first of three published investigations into the use of VR technology in a clinical setting. This chapter investigates a preclinical model for Legg-Calvé-Perthes disease (LCPD) to non-invasively visualize the femoral head vasculature. The emphasis here is on preclinical models, which are used to better understand human disease states. This inquiry shows the value of VR technology to visualize complex human anatomy while non-invasively studying disease progression. This is the first chapter exploring clinical use cases in the first of three perspectives for this dissertation (Figure 3).

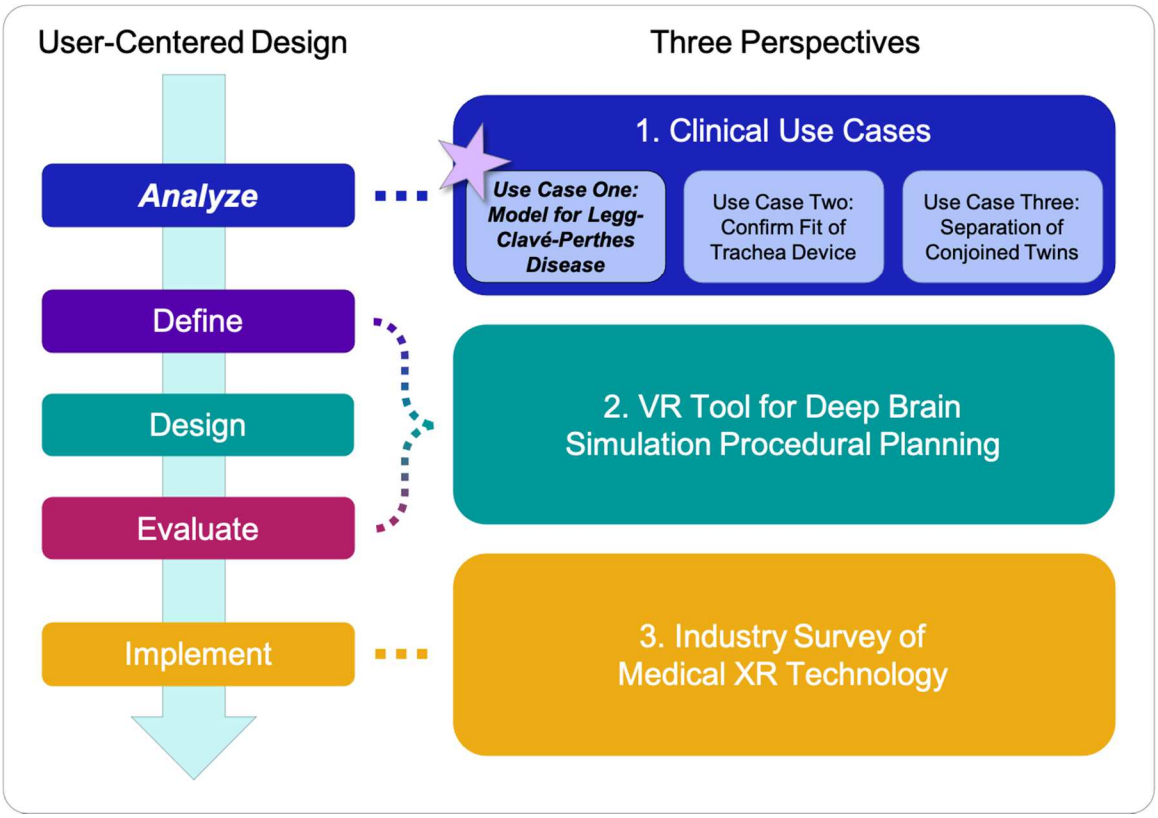

Figure 3. Chapter one investigates the clinical use case for a preclinical model for LCPD. This chapter is part of the first perspective to analyze clinical needs for VR technology.

Overview

Legg-Calvé-Perthes disease (LCPD) is a painful pediatric hip condition caused by an idiopathic disruption of blood flow to the femoral head. The bone subsequently becomes necrotic and fragile. This can result in significant femoral head deformity, leading to pain and early degeneration of the hip. Severity of avascular involvement of the femoral head correlates with long term outcomes, including hip arthritis and replacement. Preclinical models for LCPD present extreme cases of the disease and do not represent the spectrum of disease seen clinically. A virtual model was developed to explore advancing the preclinical model through new methods of visualizing the data. Overall, three opportunities to advance the preclinical model and our understanding of LCPD are presented.

Introduction

LCPD is a painful pediatric hip condition caused by an idiopathic disruption of blood flow to the femoral head. This disease process can lead to significant deformation of the femoral head and early hip degenerative arthritis. Patients typically present between the ages of 4 and 8 years, and boys are affected more often than girls (Loder & Skopelja, 2011). Incidence varies widely based on geography and ethnicity. In the United States, LCPD is estimated to affect 1/740 boys and 1/3500 girls (Molley & MacMahon, 1966). LCPD was first described by three independent physicians, Arthur T. Legg, Jacques Calvé, and Georg Perthes, in 1910. Despite being described over 100 years ago, the exact etiology remains unknown, and the treatment is controversial.

Background

LCPD involves an interruption of blood supply to the femoral head; however the etiology of the occlusion remains unclear. Clinical research on LCPD is difficult due to the rarity of the disease and the heterogeneous presentation of patients with respect to age, disease severity and stage of disease. Most studies have been retrospective in nature. Additionally, clinical research relies on imaging studies to assess the hip and its outcome. Tissue samples are rarely available because every effort is made to preserve the already injured femoral head. Preclinical models are consequently advantageous and heavily utilized to investigate the pathophysiology and treatment of the condition in a way that is not feasible in clinical studies.

A well-established inducible piglet model of LCPD has been developed to investigate the disease (Gong et al., 2011; Kim et al., 2001, 2004; Koob et al., 2007; Upasani et al., 2017). Specifically, the model entails an open arthrotomy of the hip and tying a ligature around the femoral neck. This completely occludes the blood flow to the femoral head (Kim et al., 2001; Zhang et al., 2010). Optical and computed tomography (CT) imaging have shown the success and reproducibility of ligatures to induce avascular necrosis of the femoral head (Zhang et al., 2010).

The current model, however, entails performing an invasive surgical procedure and it mimics only severe disease. Consequently, the translatability of the current model

has been questioned in two ways. First, the invasive nature of the procedure used to trigger osteonecrosis, and the associated morbidity of this procedure, fail to capture the spontaneous onset of disease in children. Second, this severe model may not adequately represent the many LCPD patients who present with mild or moderate disease. Thus, an improved animal model is needed. An ideal model would: 1) induce avascular necrosis with minimal added morbidity, and 2) be able to induce varied severity of vascular insult.

Prior to developing a minimally invasive model of LCPD, a characterization of the piglet vasculature is required in a range of young piglets. The goal of this study is to use VR technology as a noninvasive approach to visualize the piglet femoral head vasculature at a range of piglet ages. If the model is successful, VR also has potential future use to visualize the vascularity during other phases of the disease process, such as revascularization. This proposed animal model could facilitate research into new diagnostic, prognostic, and therapeutic approaches with the ultimate goal of enhancing patient care.

Methods

To characterize the normal vascular architecture of the hip region in young piglets, computed tomography angiogram (CTA) scans from three Yorkshire piglet specimens (age 4, 6, and 8 weeks) were processed for this report. Yorkshire pigs at this age have femoral heads comparable to children ages four to five years old; the age when LCPD first develops in children (Kim et al., 2012).

Briefly, three juvenile Yorkshire pigs were anesthetized with intramuscular administration of Telazole (10 mg/kg). Anesthetized pigs received 500 IU heparin intravenously (via the jugular vein) then they were euthanized with 100 mg/kg pentobarbital administered IV. Euthanized pigs were eviscerated, the right external iliac artery was identified and perfused with 120-180 mL of 20% $BaSO_4$ diluted in formalin.

Bilateral CTA imaging of each specimens' hind limbs were performed at the University of Minnesota's Veterinary School using a Toshiba Aquillon CT scanner with a pixel spacing of 0.576 mm and a slice thickness of 0.5 mm. Six different scans were

captured for the 4- and 6-week pig. Scans in the axial, coronal and sagittal directions were captured for bone (window center at 450 and window width at 4500) and an angiogram (window center at 70 and window width at 500).

The eight-week pig scan only had contrast in the left hind leg with bone and angiogram scans captured in the coronal direction. The CTA scans were compared in Mimics (Materialise, Leuven, Belgium) to determine which scan best delineated the boundaries between bone, vasculature, and the surrounding tissues.

An appropriate dataset was selected and segmented in Mimics. A region of interest, or working area, was created by cropping the mask to the section around the femoral head. A threshold of the scan was selected to define the edges of the bone (Figure 4A). The growing region tool was used to select the osseous regions and remove regions not connected to the bone (Figure 4B). The multiple slice edit tool was then used to highlight the entire bone cross-sections (i.e., including regions that were not captured in the bone threshold) in an effort to remove the non-osseous highlighted sections (Figure 4C). The resulting mask was considered “Bone” and set aside for later use.

A second mask was created to view the vasculature by applying a threshold (Figure 4D). A Boolean operation was applied to this second mask to subtract away the “bone” (Figure 4E) to create the “vascular” mask (Figure 4F).

Solid three-dimension (3D) models were calculated from the bone and vascular masks (Figure 4G). Due to the amount of clutter in the solid vascular 3D model, the region growing tool was used to follow large vessels (Figure 4H). The simplified vasculature model is shown in Figure 4I.

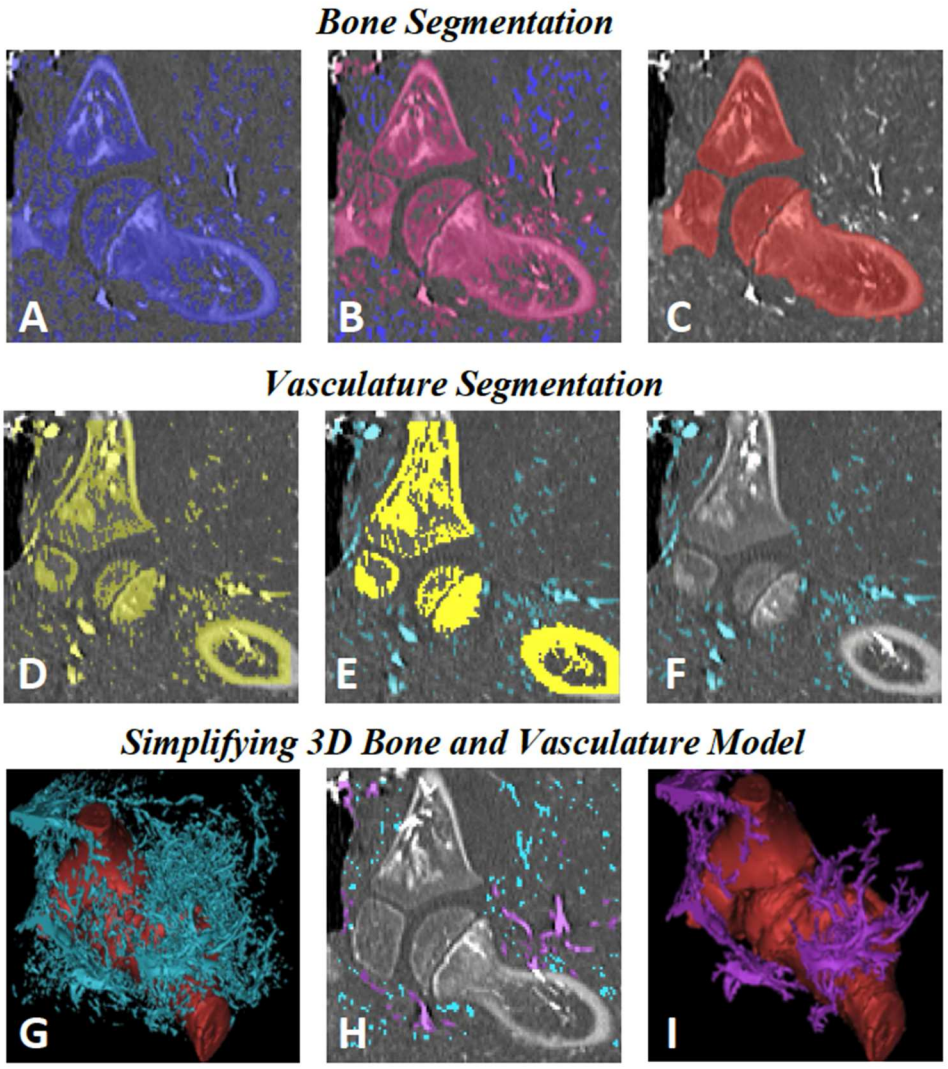

Figure 4. A bone outline was created with Mimics by thresholding the eight-week pig scan (A). A growing region operation removed extraneous artifacts not connected to the bone (B), The bone section was filled in using the multiple slice edit tool (C). A vasculature model was created with another threshold of the eight-week pig scan (D). A Boolean subtraction operation removed the bone volume (bright yellow) from the mask (E). The final vasculature mask is shown in light blue (F). A 3D solid bone and vasculature model were exported for eight-week-old pig (G). The vasculature model was simplified by selecting connected vasculature tracks (purple) (H). Final bone and vasculature models showed vessels running into the femoral head (I).

The final bone, vascular and simplified vasculature models were exported from Mimics as stereolithography (.stl) files, and were imported into MeshLab (ISTI-CNR, Pisa, Italy) as shown in Figure 5. Each model was colored using the 'per face color function' and exported as an OBJ/MTL file. Coloring OBJ/MTL files for a virtual visualization allows for visual differentiation between the individual models. The models

were loaded into the Immersive Touch Table available at the University of Minnesota Earl E. Bakken Medical Devices Center (Coffey et al., 2011). The immersive touch table displays 3D models on a stereoscopic display screen. The VR technology was used to view the final models and assess the vascular anatomy around the femoral head.

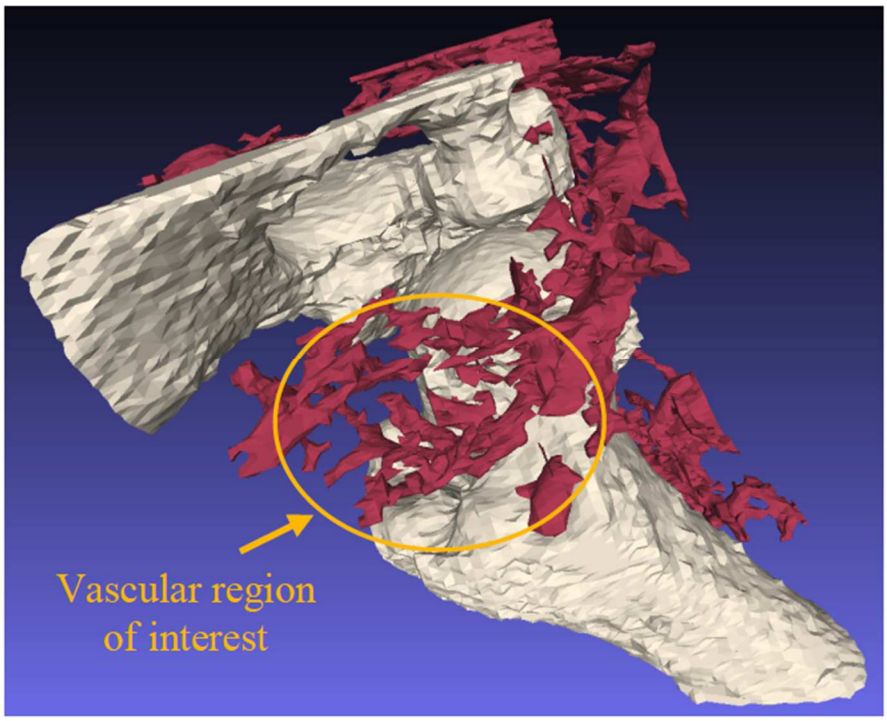

Figure 5. Final colored segmented models showing the bone and vasculature around the femoral head.

Results

For the 4- and 6-week-old specimen, the segmentation software was unable to accurately recreate the curvature of the small-diameter vasculature. Specifically, because the diameters of the vessels of interest were smaller than the resolution of the scan, the pixels associated with the vasculature did not overlap between sequential image slices. When this occurred, the pixels between subsequent scans became disconnected which prevented the continuous tracking of individual vessels, despite being visible on the CTA slice (Figure 6).

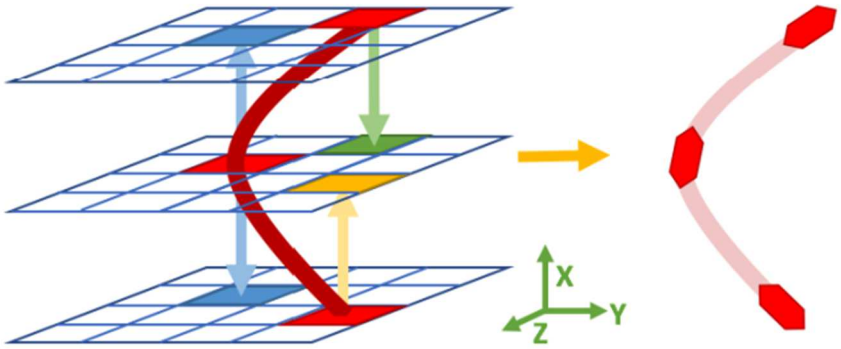

Figure 6. Pixels associated with vasculature not overlapping from one scan image to the next is difficult for a segmentation software to identify a continuous model. The final model will be disconnected 3D segments, instead of a smooth continuous representation of the vasculature.

The eight-week pig had the largest retinacular vessel size, which best permitted the continuous monitoring of single vessels within the region of interest. The boundaries between bone and vasculature were also easiest to segment in this specimen compared to the younger specimens. Retinacular vessels in 4- to 8-week pigs are comparable in size to pediatric patients who present with LCPD. The sizes of pediatric retinacular vessels are presented in Table 1.

Retinacular Vessels	**Range of Vessel Diameter**	**Average Diameter**
Postero-superior	0.125 mm - 1.875 mm	0.730 mm
Postero-Inferior	0.150 mm - 0.875 mm	0.467 mm
Anterior	0.025 mm – 0.525 mm	0.184 mm

Table 1. Size of retinacular vessels into the femoral head as measured from pediatric cadaver X-ray scans with an ocular micrometer at the lumen of the vessel (Tucker, 1949).

Discussion

The described VR based model provided a unique perspective to visually step into the 3D models of the normal piglet vasculature surrounding the femoral head. Viewing the vasculature in this way provides a unique understanding for the complexity of the undisturbed vascular architecture of the hip region. The information gleaned from this work will be helpful for subsequent work on a preclinical LCPD piglet model, aimed at better understanding the heterogeneity of the disease and its repair process. The methods used to generate the 3D model proved to be complex, requiring manual process to select

the appropriate imaging technique, segmentation process and visualization method needed. The sections below describe the lessons learned, and potential future directions for the utility of VR in the context of LCPD.

Imaging Technique

To enhance the ability to accurately visualize the normal vasculature in growing piglets for a VR based 3D models, it is necessary to scan regions of interest at higher resolutions with minimal slice thickness. Increasing the resolution of the scan, increases the number of times the anatomy is sampled, resulting in more data to fill in gaps to create a higher quality vasculature model. The current model was scanned at a very high resolution for a standard CT scanner, therefore to improve the resolution of the model, a micro CT scanner is a better choice for the next attempt to visualize the piglet vasculature. These improvements will reduce the number of disconnected pixels between subsequent scans (Figure 6).

Segmentation Process

Three considerations were realized for subsequent VR model production. First, selecting a region of interest for the segmentation reduces the segmentation process. Second, manual segmentation was necessary to develop a VR model for piglet hip vasculature due to the complexity of the anatomy. Third, the contrast in the blood during the CT scan made the blood and bone appear in the same range on the Hounsfield Unit (HU) scale, increasing the difficulty of the segmentation. To overcome the third consideration, the boundaries of the bone were selected in one mask and then subtracted from the vasculature mask to categorize voxels as bone or as vasculature.

Visualization Method

Utilization of VR immerses the viewer into the 3D models of the piglet femoral head giving a new perspective to the normal vasculature size, complexity, and architecture. An acclimation period was required for the viewer to orient themselves to the 3D anatomical perspective of the vasculature within the femoral head. The ease of manipulating the 3D model with the stereoscopic visualization system (i.e., rotation, translation, scaling), can result in the viewer quickly losing their frame of anatomical

reference. Spatial cues (i.e., unrelated objects placed in the space) were commonly necessary for the viewer to maintain anatomical orientation, within the complex 3D viewing environment of the femoral head. Once the viewer was acclimated, the VR model provided an appreciation of the femoral head vascular anatomy that was not previously realized with traditional imaging. The vessels branching from the femoral artery were easy to navigate, and follow down to the femoral head. Thus, viewing the undisturbed vasculature using stereoscopic visualization could be a helpful tool in assessing preclinical models of LCPD, and potentially years down the road, patients with LCPD.

Based on preliminary evaluation of the VR model, many opportunities present themselves.

1) ***Accurate depiction of the 3D undisturbed normal vasculature in piglets***. The results from this work indicate that the three major vessels that supply the femoral head are in the range of a submillimeter at 8 weeks of age, and smaller in younger piglets. Even under the most meticulous animal dissection or histological assessments, the potential for disruption of these vessels is possible. The 3D model generated in this study is the first known application of VR to examine the undisturbed depiction of the complexities of piglet vasculature surrounding the femoral head in a native orientation. The model allows for the opportunity to visualize the size, orientation, and interconnectivity of the vascular tree surrounding the femoral head, especially if the resolution of the scan allows for the tracking of the small vessels.

2) ***Utilization of VR to monitor disease progression and recovery over time.*** With continued refinements to the in vivo scanning methodologies, VR may be a potential mechanism to monitor the progression and recovery from LCPD, as previously done in other animal models (Duvall et al., 2004). Understanding the mechanisms of the disease, the onset of the disease and developing therapies to treat LCPD could be studied through longitudinal imaging studies within a single animal to better understand the disease (Figure 7).

3) ***Expand the utility of VR models to include perfusion magnetic resonance images (MRI) performed in children.*** The disruption of blood supply to the femoral head in children is often confirmed by a perfusion MRI (Kim et al., 2016; Schoenecker, 2014). Similar to the methodologies implied in this study, the perfusion MRI entails viewing the hip with and without contrast agent, to discern the location and extent of femoral head involvement (Figure 7).

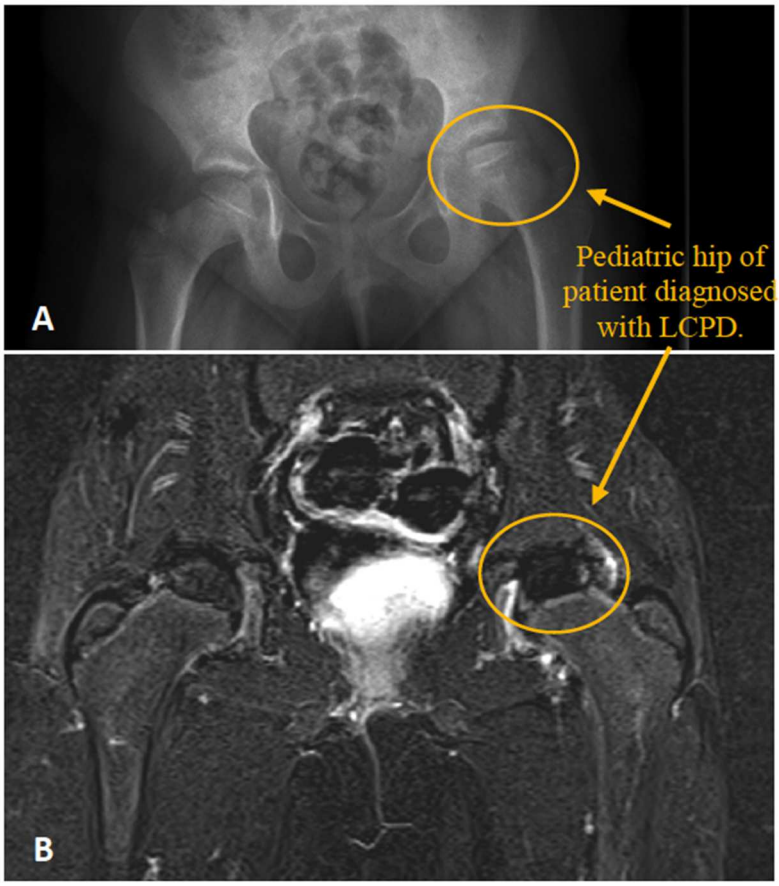

Figure 7. Partial necrosis (A) compared to complete necrosis (B) of the femoral head during LCPD progression.

Conclusion

Based on preliminary evaluation, VR technology could be used as a noninvasive approach to visualize the piglet femoral head vasculature. VR anatomical visualizations could open new doors to understand vasculature phase changes during LCPD progression, such as revascularization. This would allow better study of the severity of

the disease as seen in the clinic to facilitate research into disease diagnosis, prognosis, and therapeutic approaches to enhance patient care.

Chapter 2

Perspective One: Double Lumen Trachea Tube Device Fit Confirmation Case Study

Benjamin Kloesel, Bethany Juhnke, Laura Irvine, James V. Donadio IV, Arthur Erdman, and Kumar Belani

Preface

Published in the Journal of Medical Systems (Kloesel et al., 2021), this is the second of three published investigations into the use of VR technology in a clinical setting. This chapter investigates a clinical model to confirm the fit of a double lumen trachea tube inside a patient's anatomy. The emphasis here is on the clinical model, which are used to predict patient outcomes. This inquiry shows the value of VR technology to analyze how a medical device will fit in the patient's anatomy. This is the second chapter exploring clinical use cases in the first of three perspectives for this dissertation (Figure 8).

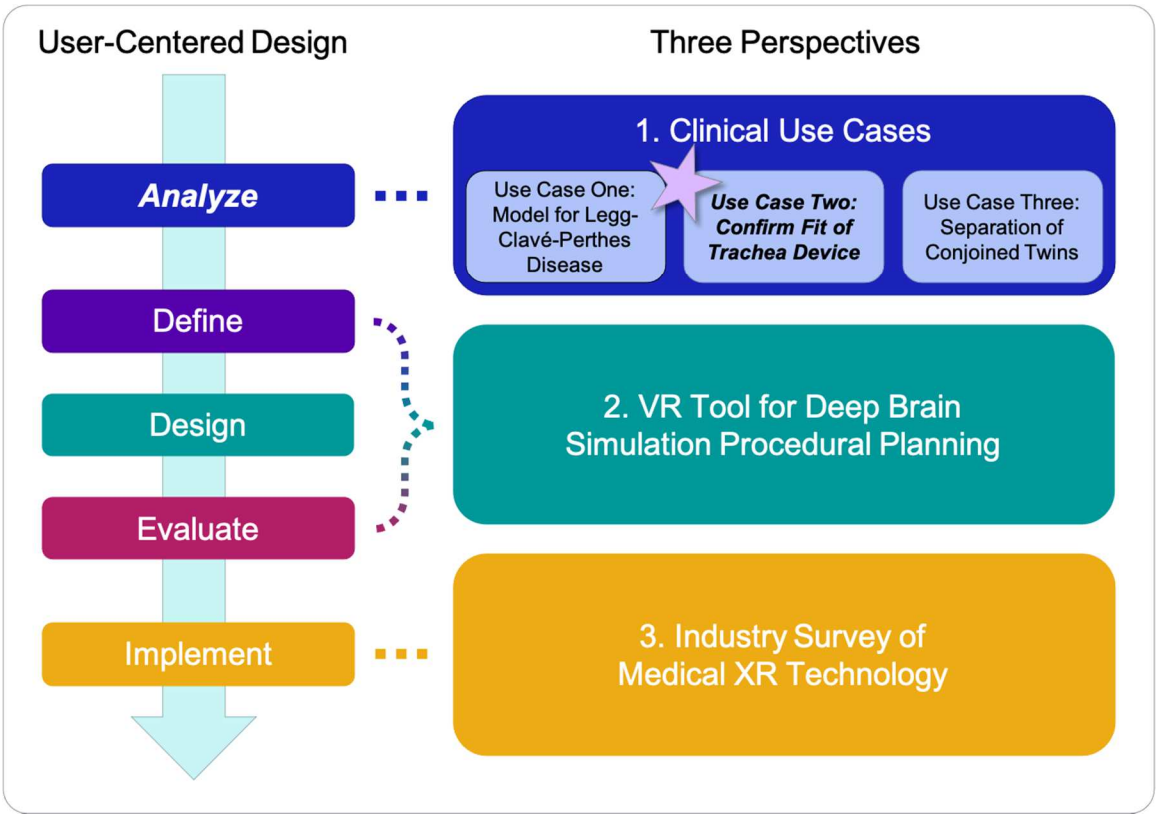

Figure 8. Chapter two investigates the clinical use case for a clinical model to confirm the fit of a double lumen trachea tube in patient's trachea. This chapter is part of the first perspective to analyze clinical needs for VR technology.

Overview

Technology improvements have rapidly advanced medicine over the last few decades. New approaches are constantly being developed and utilized. Anesthesiology strongly relies on technology for resuscitation, life-support, monitoring, safety, clinical care, and education. This manuscript describes a reverse engineering process to confirm the fit of a medical device in a pediatric patient. The method uses VR and three-dimension (3D) printing technologies to evaluate the feasibility of a complex procedure requiring one-lung isolation and one-lung ventilation. Based on the results of the device fit analysis, the anesthesiology team confidently proceeded with the operation. The approach used and described serves as an example of the advantages available when coupling new technologies to visualize patient anatomy during the procedural planning process.

Introduction

In recent years, medical advancements in diagnosis and treatment of diseases have been closely associated with progress in technology. Imaging capabilities have benefitted from improved computing power and the development of systems with faster scanning times and higher resolution. While in the past, imaging modalities were primarily used for the evaluation of a patient's anatomy and the diagnosis of diseases, now they can assist in planning of interventions such as surgery and radiation.

Case Study

We present a case of a pediatric patient diagnosed with Niemann Pick disease type B and pulmonary (lung) alveolar proteinosis. For the latter diagnosis, the patient needed to undergo sequential whole lung lavage to improve pulmonary function in preparation for possible hematopoietic stem cell transplantation to treat her Nieman Pick disease. In pulmonary alveolar proteinosis, lung surfactants (lipoprotein complexes that reduce surface tension and help to keep the lungs expanded) accumulate in the alveolar space, thereby reducing the available area for gas exchange resulting in shortness of breath, low blood oxygen levels and later respiratory failure (Griese, 2017).

General anesthesia is required for sequential whole lung lavage. The airway is usually secured with a double-lumen endotracheal tube to allow lung isolation (separation of the airways from the left and right lung). While one lung is continuously being ventilated, the other lung is subjected to repeated instillation of saline solution followed by evacuation of the instilled fluid (Awab et al., 2017). The therapeutic goal of this procedure is to wash out proteinaceous material in the lungs, which impairs gas exchange. Lung isolation is critical as inadequate separation of the lungs would lead to spillover of saline solution. Presence of large amounts of saline solution in both lungs would present as drowning and lead to significant morbidity and potentially death of the patient.

In adult patients, several lung isolation methods, such as double-lumen endotracheal tubes and bronchial blockers (catheter with inflatable balloon attached to the tip), have been described and are used in routine clinical practice (Falzon et al., 2017).

Both airway devices have been manufactured in smaller sizes to accommodate children, but due to the small size of pediatric airways, the smallest double-lumen endotracheal tubes can usually only be used in patients 8 years of age and older. This guideline is derived from pediatric patients that fall within a spectrum of normal physical development. In our case, the patient was 11 years old but diagnosed with growth delay and short stature: her height and weight were 1.18 m and 24 kg, respectively, corresponding to the 0.1 percentile for height and 0.43 percentile for weight. Based on this, we were concerned that a standard 26 French (Fr) double-lumen tube may be too large to be accommodated by the patient's airway. The use of a bronchial blocker was in theory possible, but while it would make a conventional surgery feasible (for example any surgical resection of the non-ventilated lung), it did not support a lung lavage for the following reason: during a lung lavage, one lung needs to be continuously ventilated, while the other lung requires lung isolation with a device that provides an access port through which lavage solution can be instilled and withdrawn (a double-lumen endotracheal tube). A bronchial blocker provides lung isolation but does not have an access port.

The complexities of this patient's diagnosis warranted an alternative evaluation to ensure the procedure could be performed safely and to minimize patient discomfort. Simulating the procedure in a safe environment had the following advantages: a) reduction of care team member stress on the day of the procedure; b) reduction of the risk of damaging the airway; and c) reduction of the risk of cancelling the procedure due to the inability to secure the airway. The purpose of this work was to confirm if a 26 Fr double-lumen endotracheal tube could be used to successfully intubate this pediatric patient.

Methods

Procedural planning processes incorporate medical knowledge, a patient diagnosis, and images of the patient's anatomy to formulate a medical protocol. For many medical procedures this is a routine process. Rarer cases with their increased complexities raise the uncertainty of procedural outcomes. The objective for this work

was to develop an efficient methodology that incorporates new technologies to reduce the procedural uncertainties surrounding a patient's anatomical size and the fit of a medical device. The new methodology was applied to a case where the medical team needed to confirm the fit of a medical device for a challenging pediatric patient.

Constraints

Selection of an airway device by conventional methods was, in our reported case, constrained by the patient and the procedure. If an operation requires one-lung isolation in an adult patient, multiple methods to secure the airway are available to the anesthesiologist. For pediatric patients, the size of the airway presents limitations and precludes the use of some airway devices. The procedure presented in this manuscript introduced further constraints as some airway devices that could typically be used in a pediatric patient would make the conduct of a lung lavage impossible.

The current standard to evaluate internal anatomical size is by having a radiologist read the images from a patient’s scan. The images are captured perpendicular to the patient’s body to show a cross-section of the anatomy. The trachea does not follow a plumb line from the mouth to the feet, but rather slopes backwards toward the spine. Therefore, capturing measurements through this method is inherently inaccurate because the anatomy runs at an oblique angle to the two dimension (2D) images. Due to the size of the patient for the procedure presented here, the team could not confidently select a procedural method based on the radiologist reading.

Evaluation metrics

Traditional elements of procedural success are efficiency of the procedure and patient outcome. For the purposes of this evaluation, we also considered the cost. At the time of this publication, the developed techniques are not reimbursable by insurance and therefore the cost of these services must be supported by research funds or passed along to the patient. The cost of these techniques is a critical driver towards hospital adoption and a barrier to entry; therefore, a hospital must see a return on their investment. The opportunity to reduce operating room time, reduce patient recovery time, or improve

surgeon confidence can significantly impact the cost of a procedure and are important reasons to include new technologies into the procedural planning process.

Results

The results of this work include three components: 1) a process that can be replicated to evaluate the fit of any medical device in a patient, 2) a clinical review of the models to confirm the method, and 3) a financial review to support the feasibility of the method.

Process

The first result of this work is a process that can be used to evaluate the fit of a medical device within a specific patient's anatomy. The following description is described within the context of our use case, as described previously. Anatomical models of the trachea, bronchi, and lungs were created from CT images. The double lumen endotracheal tube was reverse engineered to develop a computer aided design (CAD) model of the device. Two feasibility studies were prepared to confirm the fit of the device within the anatomy.

Anatomical model. CT images were captured of the patient's anatomy to create a model of the airways. A Siemens CT scanner captured the patient's chest without contrast at a scan resolution of 0.5 mmA~ 0.5 mmA~ 3.0 mm. The scans were segmented using Mimics (Materialise NV, Leuven, Belgium). A threshold of −1024 Hounsfield unit (HU) to −500 HU was applied to isolate the air volume within the trachea and bronchi. The air volume was wrapped at two thicknesses (0.5 mm and 1.5 mm) in 3-matic (Materialise NV, Leuven, Belgium) to create the walls of the trachea and bronchi walls. A Boolean subtraction removed the air volume from trachea and bronchi wall models. The ends of the models were cropped to access the air volume within the anatomical region. Models of the lungs and rib cage were segmented as solid models from the CT images to serve as a reference point during the procedure planning process.

Medical device model. A 26 Fr left-sided double lumen endotracheal tube was obtained from Teleflex Incorporated (Research Triangle Park, NC, USA). The double

lumen endotracheal tube was reversed engineered to produce CAD models in SOLIDWORKS (Dassault Systèmes, Vélizy-Villacoublay, France). The blue and white cuffs (balloons) on the device were modeled separately from the tube of the double lumen endotracheal device. The visibility of the blue and white cuffs will be toggled in the virtual environment to evaluate the size differential between the tube, cuffs, and anatomy.

Virtual reality environment. The 0.5 mm thick trachea and double lumen endotracheal tube models were aligned and colored in MeshLab (ISTI-CNR, Pisa, Italy) and exported to standard 3D object (.obj) files. The models were loaded into the VR based Interactive Multi-touch Table (Coffey et al., 2012, 2011) to display the models. The head-tracked stereoscopic glasses aligned the model to the visual perspective of the primary user. The system was used to evaluate the feasibility of inserting the double lumen trachea tube into the anatomy.

Three-dimension printing. The 1.5 mm thick trachea and bronchi model were printed with a Stratasys (Eden Prairie, MN) J750 3D printer. The model was printed with a material combination of VeroPureWhite, AgilusClear, and VeroClear to create a pliable transparent model to evaluate the fit of the endotracheal tube inside the anatomy (Table 2).

Material	Material Amount (g)
Vero Pure White	12
Agilus Clear	25
Vero Clear	17
Support Material	61

Table 2. Material used to make a 3D printed model.

Clinical review

The second result is a clinical evaluation and procedural confirmation for the effectiveness of the process in addition to conventional procedural planning methods. The patient's airway model and double-lumen trachea medical device model were evaluated twice in preparation for the procedure. The first evaluation used the virtual replica of the patient's anatomy, while the second evaluation used a physical replica.

Evaluation. The attending pediatric anesthesiologist for this case met with the medical device team and walked-through the airway in a 3D virtual environment. The 3D virtual environment allowed free manipulation of the rendered double lumen endotracheal tube and patient's anatomy.

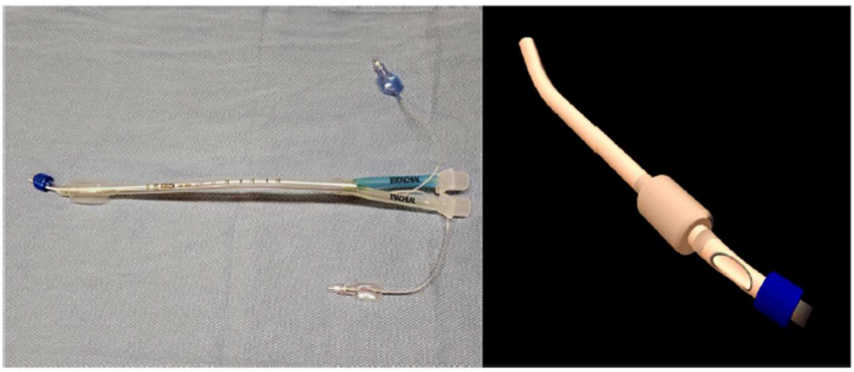

Figure 9. Double lumen endotracheal tube (left) and computer-aided design (CAD) model (right). The white and blue cuffs can be expanded to isolate each lung.

First, the patient's airways were measured. The 3D virtual model was necessary to rapidly identify cross-section planes perpendicular to the patient's airway. The cross-sectional planes were used to measure the anatomy at key locations. The narrowest diameter of the airway measured 9.1 mm at the trachea level and 8.1 mm at the left main bronchus level (Figure 9). The virtual measurements were compared to the 2D in-plane measurements captured by the team. The comparison confirmed that the anatomy was rendered at the same scale as the patient and also confirmed the inaccuracy of the measurements captured by the radiologist. The preliminary measurements were compared to the measured endotracheal tube outer diameter (8.5 mm at site that corresponds to placement in trachea, 7.5 mm at site that corresponds to placement in left main bronchus) were encouraging (Table 3).

Measurements	Trachea	Left Bronchi
2D plane measurements	9.8 mm	7.6 mm
Virtual measurements of patient's anatomy	9.1 mm	8.1 mm
Diameter of double lumen trachea tube	8.5 mm	7.5 mm
Expanded diameter of white cuff	19.8 mm	*N/A
Expanded diameter of blue cuff	*N/A	14.2 mm
*N/A = not applicable		

Table 3. Measurements of patient's anatomy and the double lumen trachea tube medical device to confirm the fit.

Second, the endotracheal tube model was virtually introduced into the trachea and bronchi passageways to confirm the fit of the device (Figure 10). During this fitting, the visibility of the blue and white cuff models was toggled to compare the tube and cuff diameters with the surface of the anatomy. The virtual fit evaluation confirmed the double-lumen trachea tube device would isolate the lung for the procedure.

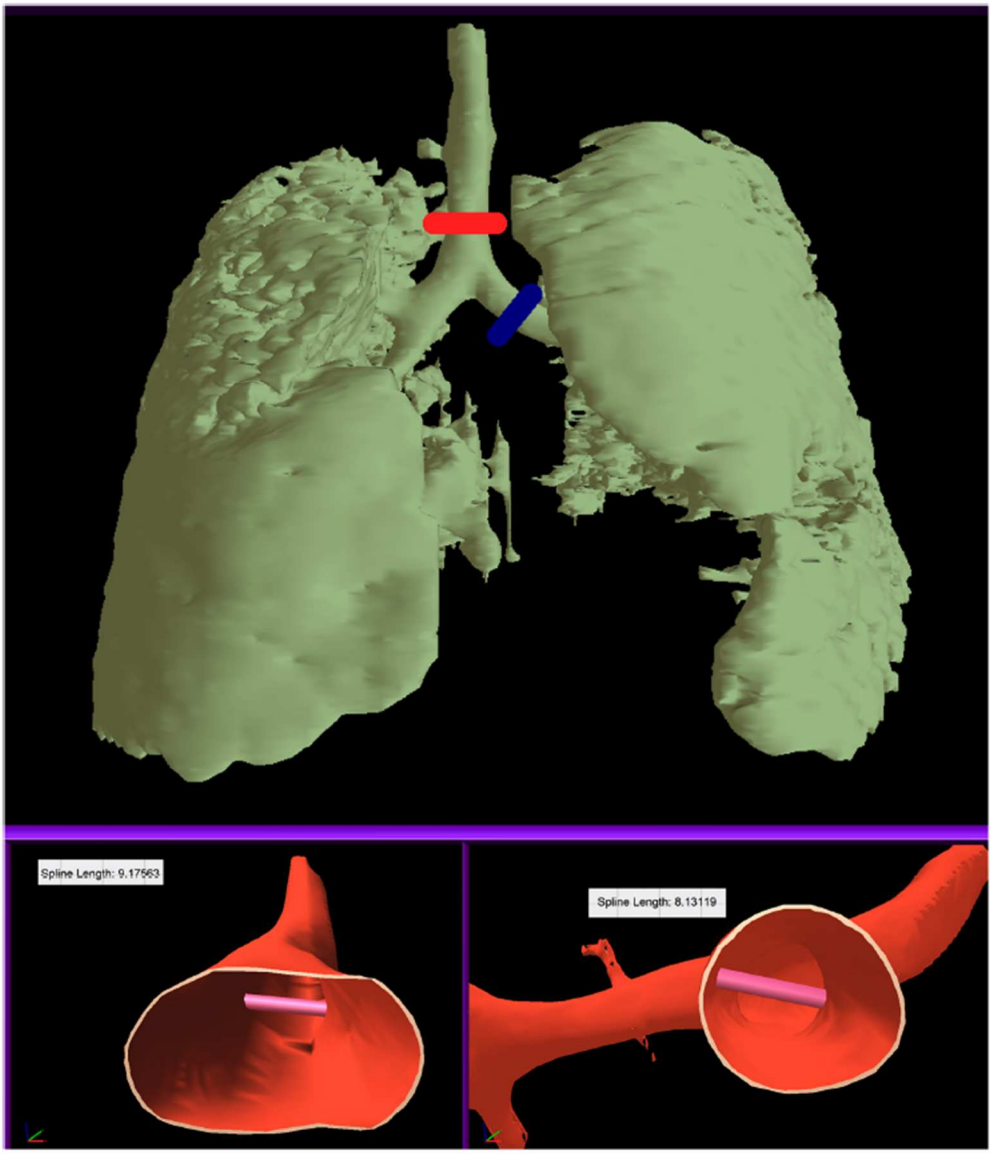

Figure 10. VR models of the trachea and lungs to compare multiple inner diameters of the trachea with the outer diameters of the double lumen endotracheal tube.

Finally, the 3D model of the airway was printed which allowed the simulated introduction of the real double-lumen endotracheal tube (Figure 11). In this last checkpoint, the airway size also proved to be large enough to accommodate the 26Fr double-lumen endotracheal tube.

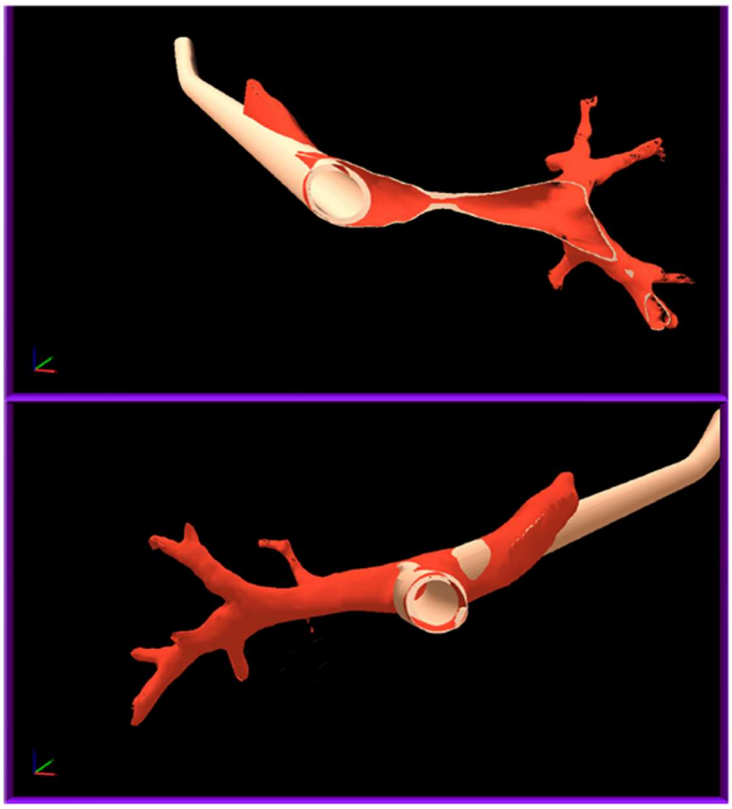

Figure 11. Virtual fit evaluation with the double lumen endotracheal tube placed inside of the trachea model.

Based on the virtual and physical evaluations, it was concluded that the use of the 26Fr double lumen tube in this particular patient was likely feasible and proceeded with the planned sequential whole-lung lavage (Figure 12).

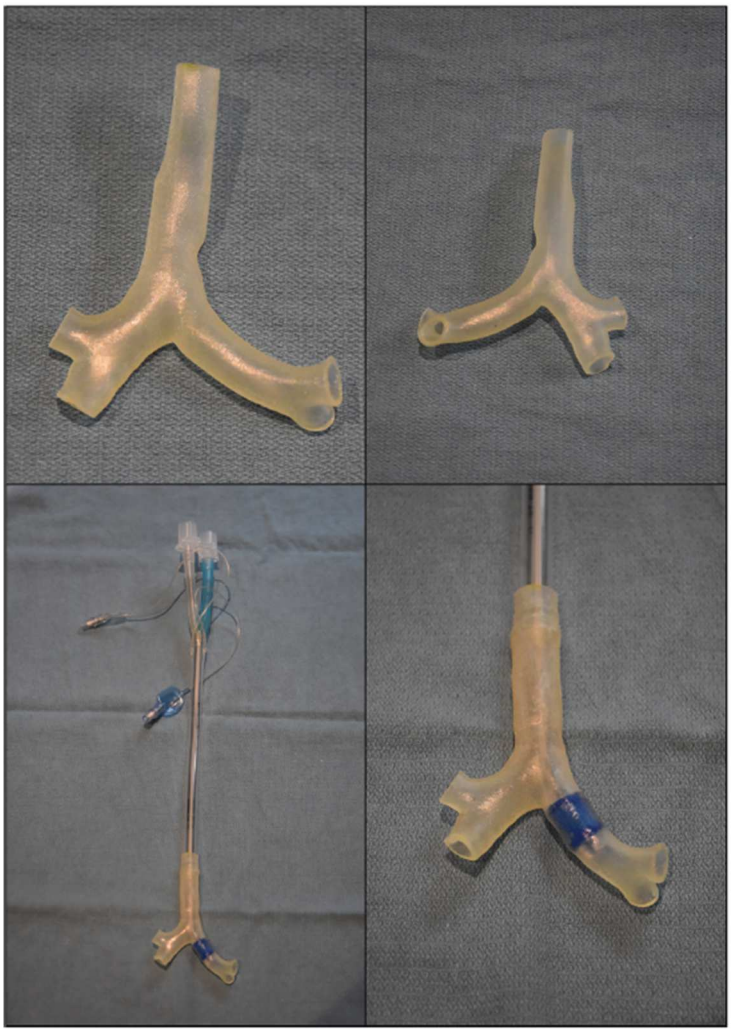

Figure 12. Fit evaluation using a 3D printed model of the patient's trachea and the proposed 26 Fr double lumen endotracheal tube from the manufacturer.

Confirmation. On the day of the procedure, a peripheral intravenous catheter was placed. The patient received midazolam premedication and was induced with propofol and fentanyl. After successful mask ventilation was established, the patient was given a neuromuscular relaxant (rocuronium). With the help of a C-MAC video laryngoscope (Karl Storz Endoscopy, El Segundo, CA), a Cormack-Lehane grade 1 view was obtained, and the 26 Fr double-lumen endotracheal tube was placed according to manufacturer's recommendations. Passage of the lubricated tube was noted to be smooth without resistance. Correct placement was confirmed by fiberoptic bronchoscopy (Olympus Exera BF-XP160, Olympus America Medical, Center Valley, PA). The blue and white

cuff were inflated according to manufacturer's recommendations and the patient was ventilated with the following settings: pressure-control, positive inspiratory pressure 24 cm H2O, respiratory rate 18/min, positive end-expiratory pressure 5 cm H2O, inspired oxygen concentration 100%. A second peripheral intravenous catheter and an arterial catheter for cardiorespiratory monitoring were placed and the procedure was started. Left lung isolation was successfully achieved, and the ventilator was adjusted to account for single-lung ventilation. A total of 5 L warmed 0.9% saline solution was instilled in aliquots and consecutively removed. The patient tolerated the procedure well. At the conclusion of the procedure, double lung ventilation was resumed, and the patient was brought to the intensive care unit where she was extubated on postoperative day #1. The patient underwent a successful right-sided lung lavage 7 days later. The same lung isolation method was used.

Financial cost

The third result was the cost to complete the virtual and physical evaluations. Healthcare costs across the United States continue to rise and healthcare providers continually evaluate the financial incentives of new methods. A financial analysis provides the evidence to support the feasibility of this method. The Bakken Medical Devices Center (BMDC) at the University of Minnesota supported this case. Their technical expertise includes anatomical segmentation, reverse engineering, VR, and 3D printing. The BMDC is an at-cost service center. The complexity of the task determines if a graduate student ($56.75 per hour) or undergraduate student ($18.91 per hour) completes the project. Machine time includes either software costs or physical machinery needed to complete the project. The final cost to complete the process for this procedure was $1522.26 (Table 4). The costs are dependent on the size and complexity of the patient anatomy modeled.

Service	Item	Time (hr.)	Cost ($)	Total ($)
Segmentation	Labor	7	$56.75	$397.25
	Machine time	7	$15.00	$105.00
CAD	Labor	20	$18.91	$378.20
	Machine time	20	$15.00	$300.00
Visualization	Labor	3	$56.74	$170.22
	Machine time	3	$15.00	$45.00
3D Printing	Materials	1	$15.24	$15.24
	Labor	1	$18.91	$18.91
	Machine time	3.5	$26.41	$92.44
			Total	**$1522.26**

Table 4. The costs for labor, materials, and machine use for the virtual and physical trachea and bronchi model.

Discussion

Technology in medicine has for a long time maintained an established role in diagnosis and treatment of diseases. In recent years, progress in this field has accelerated significantly, leading to new unique applications. The recent surgical literature features frequent examples of technology including digital design, 3D modeling, and 3D printing that are being used for preoperative procedure planning and trainee education (Andolfi et al., 2017; Chen et al., 2018; Ganguli et al., 2018; Tetsworth et al., 2017).

Anesthesiology is a field that has been a leader and traditionally been advancing patient safety with the help of technological inventions. Examples include, but are not limited to: the introduction of pulse oximetry (Van Meter et al., 2017) and capnography (Cook, 2016) to detect respiratory problems; the use of transesophageal echocardiography (Vegas & Meineri, 2010) to rapidly assess cardiac function and aid the cardiothoracic surgeon in evaluation of a repaired heart valve; and the implementation of advanced monitoring systems that utilize arterial waveform analysis within goal directed therapy protocols to improve patient outcomes in the perioperative period (Mehta et al., 2014). More recently, near infra-red spectroscopy is gaining increasing confidence in ensuring adequate oxygen delivery to the brain and kidney and the bispectral index is being utilized to titrate sedative effects of anesthetics.

The specialty of anesthesiology has so far been less visible in the area of 3D-technology, but interest is increasing as shown by recent publications. Pedersen et al.

(2017) developed a 3D-printed bronchial tree simulator and compared it with commercially available simulators for tasks including localization of right upper lobe bronchial lumen, bronchial blocker placement and fluid aspiration. Study participants rated the 3D-printed model overall significantly more realistic compared with the two commercially available simulators. In addition, the cost for the 3D-printed model was significantly lower. Chao et al. (2017) published a systematic review of the application of 3D printing technology in anesthesia. Their comprehensive analysis included the timeframe of January 1990 to June 2016. Thirty-four articles met inclusion criteria, 8 of which were related to the field of anesthesia. In those 8 articles, authors described the use of 3D printing for pre-procedure planning, preparation, education, and training. Wilson et al. (2015) were faced with a similar situation of a pediatric patient requiring lung isolation for whole lung lavage. The group also utilized a 3D-print model to practice various methods of lung isolation prior to the procedure. Given the age of the patient (6 years), a double-lumen endotracheal tube could not be used, and lung isolation was achieved by placement of two separate single-lumen endotracheal tubes and subsequent advancement of one single-lumen endotracheal tube into the left mainstem bronchus. While our patient underwent a similar procedure, this manuscript adds the novel use of digital 3D modeling and the use of a VR environment to assess lung isolation methods.

The rationale for using VR and 3D printing for a single patient was to validate the use of each emerging technology. VR and 3D printing are complementary technologies that can be leveraged in unique ways for medical use cases. In this use case, the first advantage of using a VR model was to capture measurements of the anatomy and compare them with the medical device. The second advantage was the ability to introduce the medical device into the anatomy and analyze the cross-sections at key locations. The cross-sectional views captured perpendicular to the airway showed if the medical device overextended into the tissue which could potentially have caused patient discomfort and airway injuries. Furthermore, prior to the procedure, the attending anesthesiologist was able to freely navigate the bronchial tree in a 3D environment which provided the opportunity to become familiar with the anatomy and to recognize potential problem areas.

The 3D printed model provided additional benefits not available with the VR model. The primary advantage was the ability to simulate the procedure and experience the tactile response when introducing the medical device. The tactile knowledge was transferred to the operating room for real-time feedback that the procedure was going as planned. We found the use of both technologies was important to increase procedural confidence. We envision a future where VR and 3D printing technologies are standard to plan every procedure.

Our case illustrates the possibilities of preoperative planning by using computer simulation and true-scale models obtained from patient imaging. The ability to evaluate feasibility of airway management techniques in the safety of a simulated environment greatly adds to overall patient safety. With respect to our case in the field of anesthesiology, securement of the airway is a critical step in patient management and, similar to the take-off in the commercial airline industry, represents a time period in which errors or unanticipated problems can rapidly lead to morbidity and even mortality. The scheduled procedure (lung lavage) required lung isolation for which options are quite limited in the pediatric population. Adding to the complexity of the situation was the fact that our patient's height and weight, which directly relates to airway anatomy and size, were small compared to children of similar age. The ability to use our airway device of choice (double-lumen endotracheal tube) in a virtual airway environment and in a 3D-printed airway model gave us assurance that its use would be feasible in this patient. As the use of VR technology grows, we anticipate increased access to medical device CAD models which will further reduce the cost of this method. If we had discovered that a fit was likely not achievable, alternative routes of airway securement could have been evaluated in the safe simulation environment, thereby avoiding a stressful situation on the day of the procedure, potential damage to the airway, and cancellation of the procedure due to inability to provide the necessary airway isolation.

Our case study has several limitations. As described earlier, the costs for the combined creation of an anatomical model, a device model, a VR environment, and a 3D printed airway model are currently high compared to traditional methods. Since this case

was a pilot feasibility evaluation, we decided to use all available technologies to gain additional experience with the overall process and to assess the value of each component. As further investigations into this area are conducted, clinicians and investigators may re-define the need for the different components. In addition, costs will likely decrease as mentioned in the previous paragraph. Another limitation is related to airway tissue pliability: cartilage rings found in the trachea and bronchi are rigid, but the posterior part of the airway is formed by a flexible membranous wall that results in expansion when subjected to a distending force. At this point, tissue flexibility is difficult to replicate in printed 3D models which should be kept in mind when assessing the medical device fit.

In conclusion, our manuscript describes a successful process to use 3D-modeling and 3D-printing technologies to confirm the fit of a medical device within a patient's specific anatomy prior to the procedure. With further advancements in technology and reductions in material and production costs, an appealing future prospect is the individualized evaluation of patients with difficult anatomies that may include computer modeling, 3D-simulations and 3D-models that can be used to study different airway securement approaches without endangering the patient's life. The high fidelity and realism are nicely depicted in a letter to the editor by Bustamante et al. (2016) where the authors show fiberoptic bronchoscopy pictures from a patient's airway compared to pictures from a 3Dprinted model.

Chapter 3

Perspective One: Preprocedural Plan for the Separation of Conjoined Twins Case Study

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Preface

Published in the Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine (Juhnke, Mattson, et al., 2019), this is the third of three published investigations into the use of VR technology in a clinical setting. This chapter investigates a clinical model to visualize the anatomical complexities of conjoined twins and plan the separation procedure. The emphasis here is on the clinical model, which are used to make decisions about a procedure plan. This inquiry shows the value of VR technology to determine the appropriate procedural plan. This is the third chapter exploring clinical use cases in the first of three perspectives for this dissertation (Figure 13).

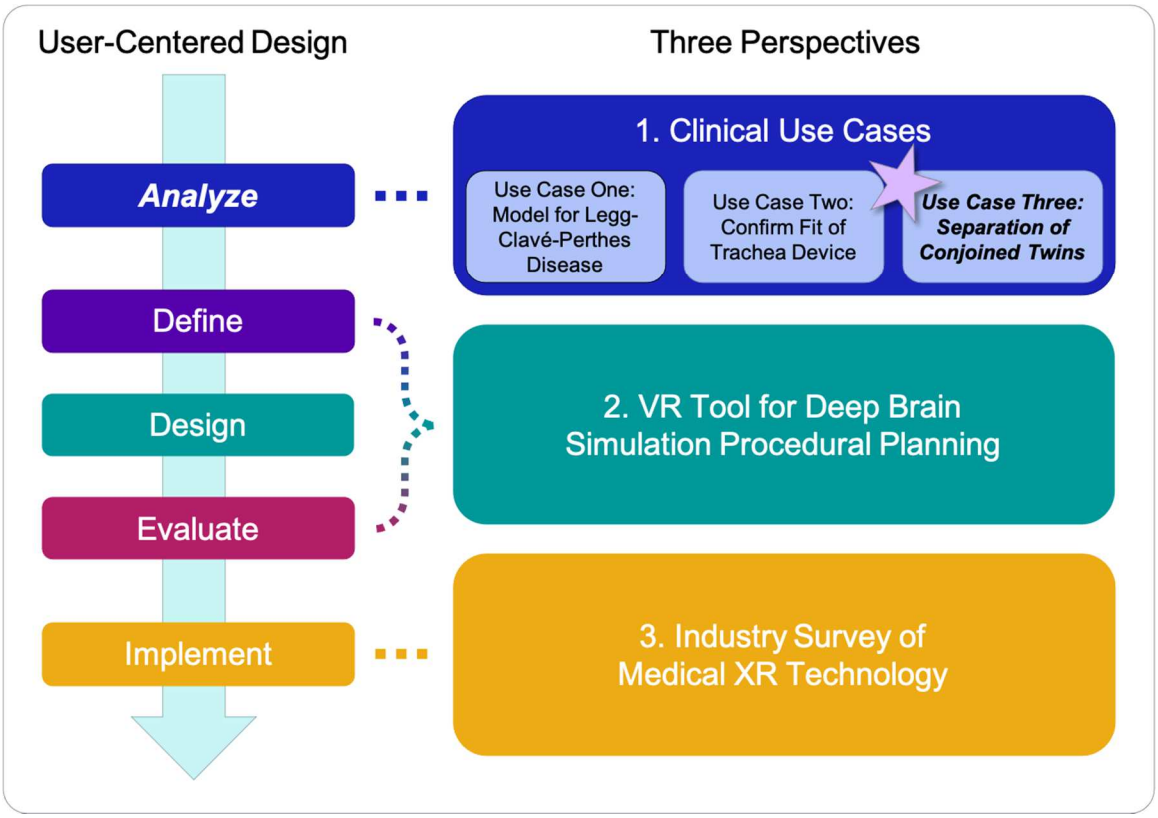

Figure 13. Chapter three investigates the clinical use case for a clinical model to determine the procedural plan to separate conjoined twins. This chapter is part of the first perspective to analyze clinical needs for VR technology.

Overview

We describe the use of VR technology for surgical planning in the successful separation of thoracopagus conjoined twins. Three-dimension (3D) models were created from CTA to simulate the patient's anatomy on a virtual stereoscopic display. Members of the surgical teams reviewed the anatomical models to localize an interatrial communication that allowed blood to flow between the two hearts. The surgical plan to close the 1-mm interatrial communication was significantly modified based on the pre-procedural spatial awareness of the anatomy presented in the virtual visualization. The virtual stereoscopic display was critical for the surgical team to successfully separate the twins and provides a useful case study for the use of VR technology in surgical planning. Both twins survived the operation and were subsequently discharged from the hospital.

Introduction

VR–based surgical simulators improve the doctor's spatial awareness of patient-specific anatomical features (Nowinski, 2005). Surgical plans developed in a virtual environment are transferable to the operating room and can practice teamwork skills to achieve safe and effective procedures (Ryu et al., 2017). Improved patient outcomes correlate with virtual pre-procedural planning (Ryu et al., 2017). For example, one study found operational success increased, 30-day mortality decreased, and there was an estimated cost savings by incorporating 3D imaging into the pre-procedural planning (Analbers, 2016). Higher level pre-procedural understandings of such clinical cases can reduce operating room times to offset the expenses associated with the purchase of virtual training equipment (Ryu et al., 2017).

It is well documented that repairing complex congenital heart defects is one area of medicine that has benefited from the application of advanced 3D technologies. For example, a clinical team in Spain found 3D-printed anatomical models helpful to plan the repair of a ventricular septal defect (Valverde et al., 2015). The 3D visualization increased spatial awareness of the complex cardiovascular structures prior to surgery (Analbers, 2016; Valverde et al., 2015). Furthermore, such procedures involving young children can significantly benefit from planning in a virtual environment, due to the small sizes of their anatomies. Conjoined twins are especially unique cases that require advanced planning to ensure the wellbeing of both patients. The separation of craniopagus conjoined twins in 1997 was the first record case of using VR for the preoperative separation planning (Nowinski, 2005). The medical team used a Dextroscope-based VR environment called VIVIAN designed for neurosurgeries. Subsequently, three conjoined twins separations were completed from 1997 to 2004 using the VIVIAN system (Goh, 2004; Logan, 2004; Nowinski, 2005).

Thoracopagus conjoined twins are connected at the chest and share a heart and may also share a liver and digestive system. The occurrence of thoracopagus conjoined twins is 1 in every 50,000–100,000 live births (Osmanagaoglu et al., 2011). Therefore, advanced planning is considered necessary to understand the complex anatomies

associated with thoracopagus conjoined twins, in preparation for a separation procedure. In summary, we present the first case to our knowledge of VR use to assist in the separation planning of thoracopagus conjoined twins.

Clinical Case

The subjects were a pair of thoracopagus conjoined female infant twins with union of the ventral aspects of each twin, from just below a common umbilicus to just above the manubrium. A fetal echocardiography and post-natal transthoracic echocardiography initially defined and further clarified their cardiac anatomies. The care teams at the hospital were color-coded for each twin, RED twin and BLUE twin, to provide the correct therapy to each patient during their extended hospital stay. The heart in the RED twin was located in the right chest and rotated rightward (dextroversion) and was otherwise considered structurally normal. The heart of the BLUE twin was normally positioned in her respective thorax, but elicited heart disease involving tricuspid atresia with dextro-transposition of the great vessels and a large interventricular defect/communication.

The pre-separation hemodynamics in the conjoined pair were complex. Using a transthoracic echocardiography and CTA, it was ascertained that an interatrial communication between the twins in the hepatic artery and internal thoracic and mammary arteries created blood flow from the RED twin to the BLUE twin. Conversely, the venous connections through the liver created blood flow from the BLUE twin to RED twin. In addition, there was a question of an interatrial cardiac vascular connection between the twins based on clinical information that could not be confirmed with traditional imaging. Critically, the interatrial cardiac connection increased the RED twin's share of the total preload between the two hearts and generated an increased share of the total cardiac output.

Methods

Imaging

CT angiograms of the chest and abdomen were performed with a Siemens SOMATOM Definition Flash scanner (Siemens Medical Solutions, Erlangen, Germany). Two high-pitch spiral acquisitions were performed with prospective EKG triggering; one 18 s after the intravenous power injection of 50% dilute Isovue 370 at 0.7 cc/s into the BLUE twin followed by a similar scan after injecting the RED twin. The first scan was performed on the BLUE twin and the second scan on the RED twin, in an attempt to limit the assumed presence of contrast artifacts in the RED twin's circulatory system. Considerations for the order of the scans included the known heart anomalies of the BLUE twin's heart and the possible connection between the atria of the BLUE and RED twin. The quality of the scans depended on the full flushing of the injected contrast from the heart cavities before starting the second scan. Importantly, each CT angiogram captured about a quarter of the other twin's anatomies, to aid in aligning the independent scans for computational modeling.

Segmentation

The anatomical data captured by the CT angiograms were segmented and analyzed with Mimics software (Materialise, Belgium). The cardiac blood volumes, lungs and thoracic skeletal anatomies were modeled from each twin's scan (Figure 14). Once both cardiac blood volumes were modeled, a surface thickness around the blood volume was created and the original blood volumes were subtracted to create hollow heart models. A joined hollow heart model showed the inside surfaces of these heart cavities. Solid models were also created for the lungs and skeletons. The final models were exported as stereolithography files (.stl).

Figure 14. Twin's final anatomical models presented to the surgical team. The skeletal structure, lungs and hearts were segmented for each twin. The RED twin's anatomical models were colored with warm colors with orange as the skeletal system, pink as the oxygenated side of the heart and purple as the deoxygenated side of the heart. The BLUE twin's anatomical models were colored in cool colors with green as the skeletal system and blue for the three-chambered heart. The original proposed surgical orientation was to have the RED twin positioned on the left side of the operating table and the BLUE twin would be positioned on the right side of the operating table.

The associated cardiac, lungs and skeletal models for each twin were aligned in the software 3-matic (Materialise, Belgium). Initially, the cardiac anatomies were aligned using the thoracic cage of the BLUE twin from each scan. Yet, aligning the thoracic cage of the BLUE twin failed to align the hearts captured in each scan sufficiently to confirm or deny an interatrial cardiac vascular connection. Therefore, the cardiac anatomies were realigned by matching the hepatic venous vasculature across both scans. This alignment represented a more accurate depiction of these patient's anatomies; the location of the RED twin's hepatic veins relative to the BLUE twin's heart varies significantly less than the location of the RED twin's thoracic cage in relation to the BLUE twin's heart.

The medical anomalies within each twin's anatomies were carefully considered during the segmentation process. Note that due to the small sizes of each patient, anatomical features could be perceived as noise and disregarded during the segmentation

process. After spending months completing numerous tests to determine the diagnoses of each of the conjoined twins, the medical team confirm that their anatomies were segmented and aligned correctly. The visualized anatomical models must accurately represent the determined diagnoses so to be useful for the procedural planning process.

Visualization

The STL models were assigned colors in MeshLab (Visual Computing Laboratory, Pisa, Italy). The models for the RED twin were colored in warm colors (red, purple and orange), while the BLUE twin's models were colored in cool colors (blue and green) (Figure 15). The colors coordinated with the hospital's naming convention for each twin during their care and the separation procedure. The models were exported as object (.obj) and material (.mtl) files. A text-based software specific scene file loaded the models into an in-house custom VR system (Coffey et al., 2012). The in-house custom VR system was a 96-in rear-projected stereoscopic screen (Dell S300 DLP; Dell, Round Rock, TX) with 50-in monitor (Samsung, Seoul, South Korea) using the Fourier transform infrared (FTIR)-based method (PQLabs, San Jose, CA) overlay to detect touch interactions. The space was tracked with five Flex 13 cameras (NaturalPoint OptiTrack, Corvallis, OR) to draw the screen perspective to the primary viewer. For the pre-procedural visualizations, the doctors who would perform the surgeries wore active shutter glasses (NVIDIA Corporation, Santa Clara, CA) to view the models on the stereoscopic display while interacting with the touch display to manipulate the models.

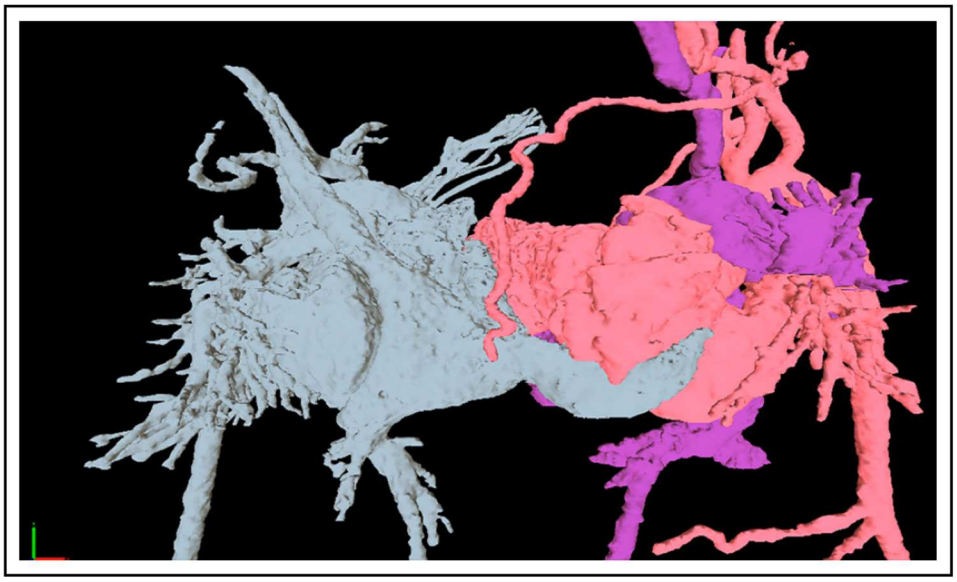

Figure 15. Two heart models. The heart of the RED twin was completely developed, with four chambers, and could be separated into the oxygenated (pink) and deoxygenated (purple) models of the heart. The BLUE twin's heart only had three chambers and therefore one model was created (blue). The models were created as surface models of the blood volume within each heart to reduce the visual clutter when presenting the anatomical data. The best view of the interatrial communication required the anatomical models to be flipped over in the 3D visualizations, which was contrary to the original pre-surgical plan.

Results

High-resolution anatomical models presented on a stereoscopic display with touch interaction provided a platform for detailed pre-surgical planning between the required multidisciplinary surgical teams. The stereoscopic images created a common space for the surgical teams to communicate in detail their concerns relative to the complexities of these patient's anatomies as well as the implications of such on the overall surgical plan. These anatomical complexities could not be visualized with traditional imaging modalities, but affected the surgical plan developed by the medical team. Navigating through the stereoscopic visualizations of these patient's anatomies resulted in key changes to the pre-surgical plan and was considered to critically contribute to the outcomes success of these operations.

Surgical team review of stereoscopic imaging

Members of the surgical teams reviewed the compilations of anatomical models and selected the best visualizations of the anatomies they needed for the surgical

preparation. For example, the cardiac surgical teams choose the hollow models of these patient's hearts for the perspective of standing inside the heart cavities or using a camera to view inside each heart. The lungs and skeletal models put the spatial relationships of the hearts in context and showed the required incision depths to reach the interatrial communication (Figure 16).

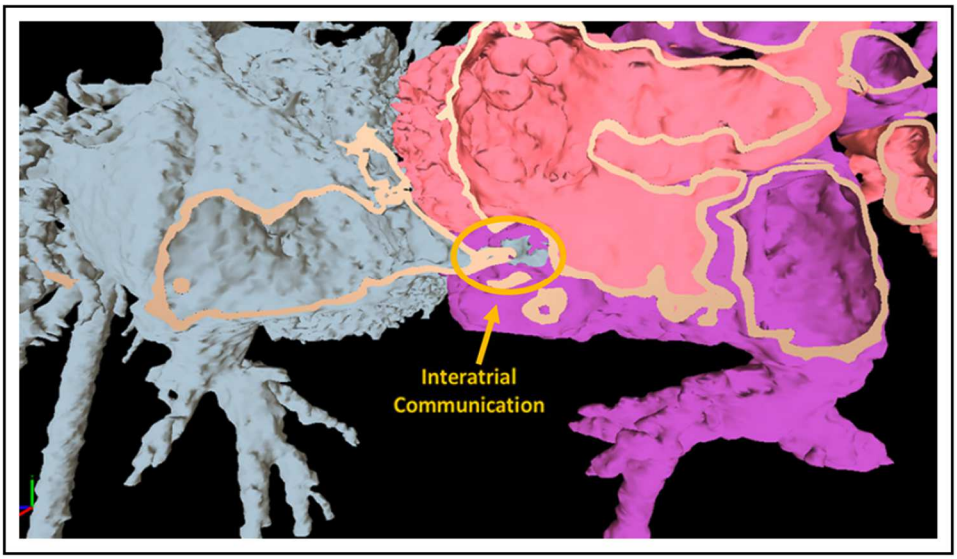

Figure 16. View of the interatrial communication. The interatrial communication was on the inside of a small fingerling feature that extended from the heart of the BLUE twin toward the heart of the RED twin. Thus, this blood flow between the twins would need to be closed before the twins could be separated. The 3D visualizations of the twin's anatomies gave new perspectives for the position of these connections that were not available within traditional imaging methods. The surgical team changed their pre-surgical approach based on the placement of these interatrial communication presented in the 3D visualizations.

Anatomical confirmation

It is important to note that prior to the stereoscopic visualizations there were concerns that the interatrial vascular connection allowed complex to-and-fro blood flow between the twins. Foreknowledge of the possible communication was the essential pre-planning knowledge for the subsequent successful surgical separation: as these connections can be associated with high mortality, and if present required careful divisions prior to complete cardiac separation (R. E. Andrews et al., 2015; McMahon & Spencer, 2006). Furthermore, the fetal and transthoracic echocardiography and conventional CT angiography did not provide enough information for the medical teams

to confirm the interatrial communication and the predominant directions of blood flows between the twins. Aligning the CT angiograms via the hepatic vein aided in assessing the potential communications between their atria—the right atrial appendage of the BLUE twin entering the thoracic cage of the RED twin and connecting to the right atrium of the RED twin. Furthermore, the stereoscopic computational models were used to confirm the presence of a 1-mm interatrial vascular connection, which was an important anatomical feature to consider during the presurgical planning.

Key surgical modifications

The surgical teams reviewed their initial considered surgical orientations based on the stereoscopic visualization presented by the imaging team. Based on preliminary imaging, the initial pre-surgical plan was to orient the RED twin on the left and the BLUE twin on the right. The BLUE twin would be moved to a cardiac operating room post-separation for additional surgical procedures (Figure 17). However, when the surgical teams viewed the computational anatomical models of both hearts, lungs and skeletal systems within the stereoscopic visualization navigation system to confirm the pre-surgical plan, it was determined that their plan should be modified. Specifically, after rotating the 3D images to view the interatrial connection, the surgical teams discovered that orienting the twins on opposite sides would provide better cardiac access for the separation. The incision to gain access to separate the blood flow between the hearts was thus relocated to the opposite side of their body for improved anatomical access. Thus, the clinical decision was modified, so to move the RED twin to a second operating room and the surgical team reevaluated the supporting equipment available in each operating room to complete additional twin specific post-separation surgical procedures. Modification to the overall pre-surgical plan based on the stereoscopic visualization likely contributed to a decrease in overall operating times, due to more efficient operating procedures.

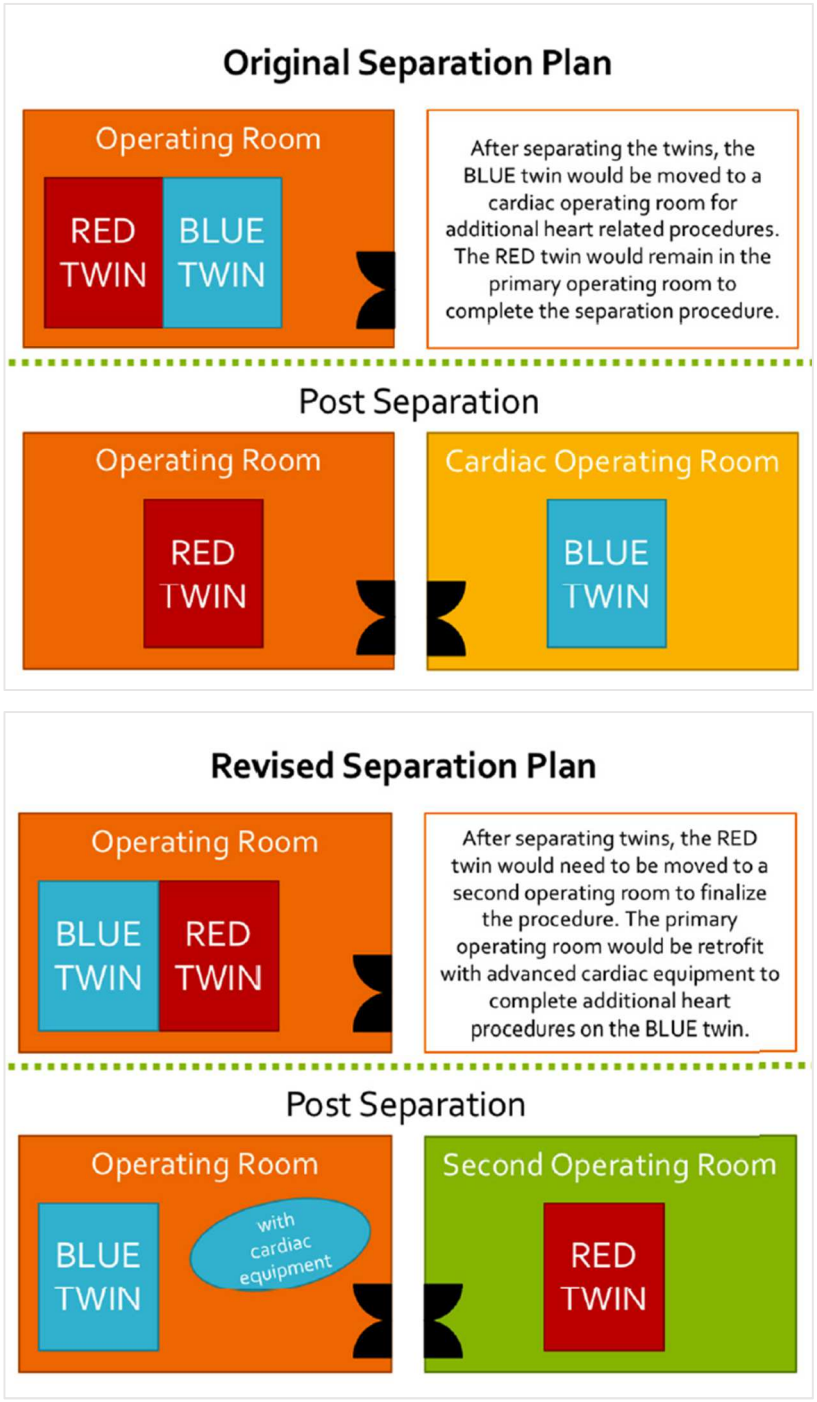

Figure 17. Original and revised surgical plan. The surgical teams revised their procedural plans based on the 3D visualizations of the twin's anatomies. Originally the BLUE twin would be moved to a cardiac operating room for additional procedures. Flipping the orientation of the twins changed the logistics post-separation, including which twin would be moved and what equipment would be required to complete additional post-separation procedures. Revising the overall surgical plan resulted in reduced operating times and a successful separation of these twin patients.

Stereoscopic visualization using CT angiography imaging for pre-surgical planning for the separation of thoracopagus conjoined twins was a critical factor in the successes of the operations for each of these twin's survivals. It has been reported that interatrial communications between conjoined twins have operative mortalities of nearly 90% (R. E. Andrews et al., 2015). In the case we describe here, the surgical teams' use of VR and 3D modeling technologies allowed for a successful separation without mortality or morbidity and the twins continue to thrive 2 years post-separation. Pre-procedural navigations through the stereoscopic visualizations provided a common collaborative space for the surgical teams to discuss pre-surgical implications of these twins' unique anatomical clinical presentations.

Discussion

Navigating through computationally generated stereoscopic visualizations were beneficial in the pre-surgical planning process of thoracopagus conjoined twins that were successfully separated at the University of Minnesota. While this article emphasized this specific clinical application, stereoscopic visualizations have many uses in other areas of pre-surgical planning. Until recently, 3D representations were previously only available through mental reconstructions after studying a series of two-dimensional images. Today, advanced 3D visualization technologies, such as VR, AR, and 3D printing, can now present realistic 3D patient-specific anatomical models to assist with pre-surgical planning. These MR platforms create collaborative spaces for medical professionals to discuss complex procedures while referencing common anatomical reconstructions.

Accessibility to advanced visualization methodologies depend on utilizing advanced algorithms for medical data. Algorithms can prepare anatomical data to match the visualizations and navigations needed for each clinical case. Commonly, each type of medical procedure requires a tailored visualization and navigation experience, which will be based on the following: (1) available imaging, (2) generated solid or hollow models, (3) additional required versus supplemental models for specific visualizations, (4) available or needed implanted devices, (5) required surgical tools, and (6) others. Today, 3D interactive platforms to visualize complex anatomies are a level above traditional

imaging modalities and will continue to improve. Our experience with pre-surgical planning during this case indicated that involved surgeons are interested in utilizing 3D pre-surgical planning and studying stereoscopic images to improve their understanding of complex anatomies.

We imagine a future where surgeons or surgical teams can download and immediately interact with stereoscopically displayed patient-specific anatomies. Advancements in visualization technologies will continue to improve the qualities of patient care provided around the world, as more case-specific data are analyzed for each given patient. Importantly, better patient outcomes as well as reduced costs of medical care due to improved pre-surgical planning and more efficient uses of operating room times are possible when 3D visualization navigation technologies are incorporated into the pre-surgical planning process.

Conclusion

Stereoscopic visualization for planning the surgical separation of thoracopagus conjoined twins was critical for a successful patient outcome. In this specific clinical case, the surgical teams could better understand the complexities of these twin's anatomies with the depth perceptions, navigations, and 3D awareness available with stereoscopic visualizations and they were able to determine exactly how these twins were anatomically connected. The discovery and localization of a unique 1-mm interatrial communication was considered vital for the survival of both twins during this overall complex clinical separation procedure. The iterative process to identify the best methods to present the 3D models in meaningful ways for the surgical teams contributed to the overall success of this procedure. Revising the overall separation surgical plan created better access to the interatrial communication and likely reduced the required operating time, by up to 90 min. Based on our experiences with this complex surgical case, advancing visualization techniques of medical anatomies will improve preoperative planning, reduce overall operating times and provide better patient outcomes, especially for such described complex cases.

Chapter 4

Perspective One: Clinical Use Cases Summary

Preface

This chapter summarizes the experiences of the clinical teams for the use cases presented in chapters one through three. The emphasis here is on the users. Users are the focus of the user-centered design process. Evaluating the user's perspectives towards VR technology provides context about how users may use a system and how they need the system to integrate with their environment. This inquiry shows the value of VR technology as a tool in medicine. This chapter concludes the analysis of the clinical use cases in the first of three perspectives for this dissertation (Figure 18).

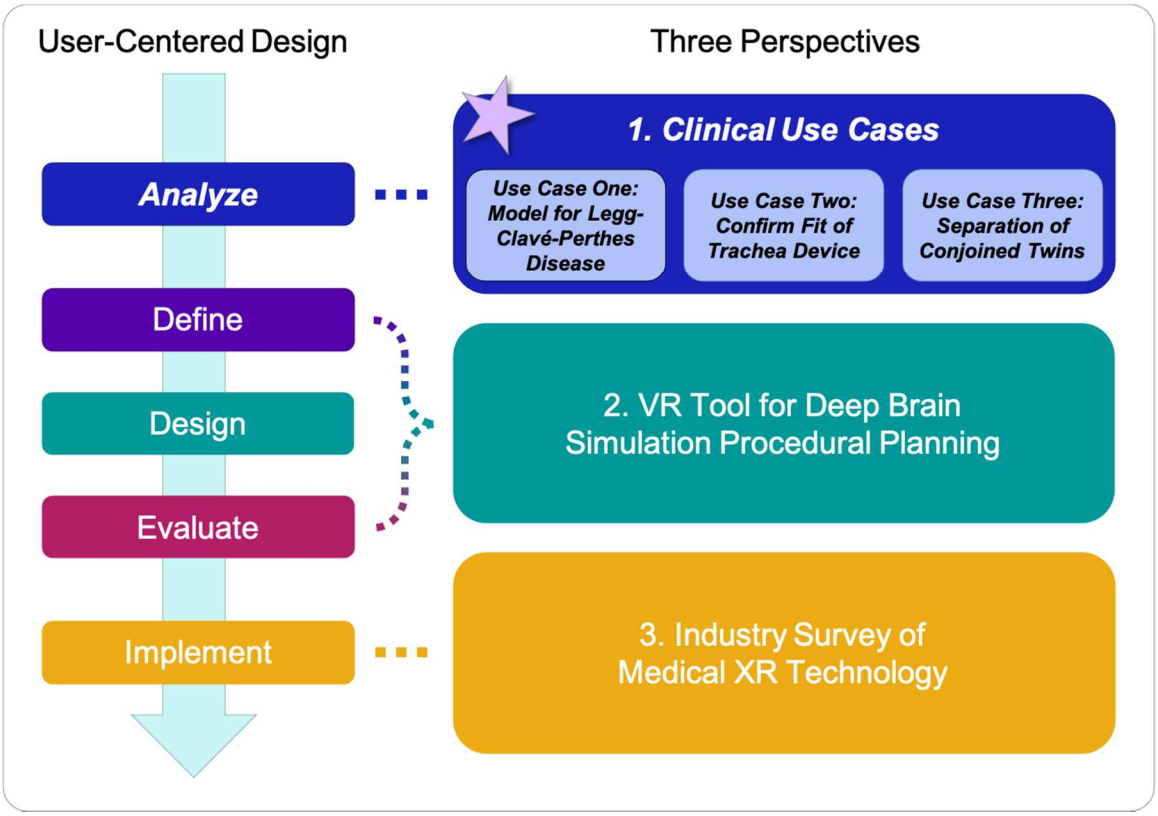

Figure 18. Chapter four summarizes the clinical use case from the perspectives of the clinical teams. This chapter is part of the first perspective to analyze clinical needs for VR technology.

Introduction

The demand for simulation-based training in the medical industry has increased as organizations began moving away from traditional cadaver laboratories and 'see one, do

one, teach one' teaching models (Riener & Harders, 2012; Stanney et al., 1998). Simulation improves clinical training, offers repeatability, and reduces the cost compared to traditional teaching models (Delorme et al., 2012). VR is a valuable tool to create high-quality simulations (Juhnke, Mattson, et al., 2019) and has seen increased use in the medical industry (Chan et al., 2013). This perspective aimed to analyze user-driven medical simulations using a shared methodology and identify challenges when using VR technology.

The three use cases presented in chapters one, two, and three were selected because they represent three different ways to apply VR technology. The first chapter presented a preclinical model to understand human disease states better. The second chapter presented a clinical model to predict patient outcomes when fitting a medical device. The third chapter presented a clinical model to make decisions about a procedural plan. As the chapters demonstrated, there are opportunities to apply VR technology to these different purposes. Those chapters specifically explored the what and how when developing medical VR technology. This chapter takes the results from the first three chapters one step further to understand the users. The results of this chapter analyze how early adopters perceive the technology and their vision for fitting the technology into their clinical workflow. This understanding helps bridge the gap between where clinicians want to be with the technology and how medical XR technology is being developed.

Background

Advances in computing technology have created opportunities to use VR in the medical industry. XR technologies in the healthcare market are expected to reach a value of $5.1 billion by 2025 with a 29.1% CAGR from 2017 to 2025 (Grand View Research, 2017). XR includes VR, AR, and MR. Advanced technologies, legislative expanded healthcare, improved economy, and an aging population are driving VR technology growth in the medical industry (Curran, 2017). Although excitement for VR technology within the medical industry exists, adoption continues to be slow. Many clinicians and medical faculty are risk-averse and conservative by training (Zweifach & Triola, 2019).

However, even with a risk-averse user base, highly skilled industries like healthcare appreciate the value of VR technologies (Zweifach & Triola, 2019).

VR technology has become a viable form of healthcare simulations due to its commercial availability and inexpensive hardware. The Oculus Rift (Oculus VR, Menlo Park, California, USA) and HTC Vive (HTC Corporation, Xindian District, New Taipei City, Taiwan), are easily set-up at home or in the office for numerous user needs. Corporations have invested in VR technology to design mechanical systems (Noon et al., 2012), evaluate driving conditions (Berg & Vance, 2017), and train pilots before transporting passengers (Okun et al., 2007). Amidst the accessibility of VR technology and interest to use, surgeons continue to *practice* medicine on live patients (Okun et al., 2007).

Medical VR software combines anatomical models, physics models, interactions, haptics, and visualizations to represent surgical procedures in virtual environments (Chan et al., 2013; Nowinski, 2005). Most medical simulations focus on medical training (Locketz et al., 2017), as generalized anatomy can teach foundational technical skills (Ryu et al., 2017). The focus is, however, transitioning to patient-specific anatomy to evaluate populations of anatomical features and procedural planning (Chan et al., 2013; Ryu et al., 2017).

Commercially available and open-source software are available to visualize patient anatomy. For example, the Living Heart Project (Dassault Systemes, Velizy-Villacoublay, France) explores realistic simulations of cardiovascular science. Sim4Life (Zurich Med Tech, Zurich, Switzerland) combines physics solvers and advanced anatomical models to analyze medical devices in the body. Numerous VR systems visualize patient-specific anatomy for training, education, and procedural planning; Osirix (Pixmeo SARL, Geneva, Switzerland), BodyViz (Visual Medical Solutions, LLC, Clive, Iowa, USA), and EchoPixel True 3D (EchoPixel, Inc., Santa Clara, CA, USA).

Visualizing patient-specific anatomy is the first step to leveraging VR technology for the medical industry. Researchers are developing medical simulations to analyze

patient-specific anatomy. The Scientific Computing and Imaging Institute (University of Utah, Salt Lake City, Utah, USA) develops software focused on analyzing and visualizing human anatomy. ITK-Snap (University of Pennsylvania, Philadelphia, Pennsylvania, USA), 3D Slicer (Fedorov et al., 2012), and InVesalius (Information Technology Center Renato Archer, Amarais, Brazil) segment medical anatomy to create three-dimension (3D) models. Unfortunately, many research simulations are not intended for regular clinical use.

Adjacent research has shown VR technology is a useful tool to incorporate patient-specific models and simulation data into a clinical practice (Nowinski, 2005). Both veteran and notice surgeons can benefit from practicing procedural skills using simulators, which are transferable to the operating suite (Ryu et al., 2017). Teamwork skills gained through simulated training ensure high-quality patient outcomes (Simpao et al., 2014). The cost of VR technology is considered a deterrent of technology adoption, however, VR training costs can be offset by reduced operating room times (Locketz et al., 2017). Research has shown doctors have a better understanding of the procedural concerns after using VR simulations (Ryu et al., 2017). VR technologies will shape the operating rooms' future (Nowinski, 2005) and need to be fully explored (Locketz et al., 2017).

Many benefits come from incorporating VR technologies into clinical care. Doctors found well-designed VR technology useful and easy to use (Torner et al., 2016), while improving their procedural decision-making (Ryu et al., 2017). Research has also shown increased operational success, decreased 30-day mortality, and associated cost savings when using 3D-imaging as part of the procedural planning process (Analbers, 2016). Increased procedure confidence has also been found after completing a VR rehearsal (Locketz et al., 2017). Overall, procedural planning with VR imaging shows benefits for patients and medical professionals.

Although research has shown many benefits of using VR technology in the medical industry, the adoption continues to be slow. Well-designed VR technology is essential to adoption (Torner et al., 2016), which requires an interdisciplinary team with

backgrounds in medicine, computer science, and engineering. Interdisciplinary collaboration between VR designers and those using VR systems is critical to design useful, functional, and focused solutions.

This chapter analyzed user needs from early adopters in the medical industry to develop focused VR solutions. Identifying user needs guides the interdisciplinary design process. Early adopters are critical to guide the development of tailored solutions. The series of use cases explored how to visualize patient-specific anatomy and medical devices. Each solution used the same methodology to build the VR experiences. The results present how early adopters perceive VR technologies and how they envision the technology fitting within their clinical workflows.

Methods

A clinical team drove each use case. During each preliminary meeting, the clinical team and the VR team discussed the clinical need, the available data, the available technology, technology limitations, and the timeline for each project. The clinicians had no previous VR experience in a clinical setting, although some clinicians had experienced VR during demos and at-home systems.

Next, the VR team acquired and evaluated the data from the clinical team. MRI and CT scans are neither captured nor stored based on VR visualization requirements, so it is essential to confirm the anatomical data's quality before proceeding. Scan capture protocols consider patient safety and a radiologist's ability to determine a diagnosis. Many scans have a slice thickness of 3mm or 5 mm, which are not sufficient for a VR visualization (less than or equal to 1 mm slice thickness). Scans are also typically downsampled by the hospital after diagnosis to reduce the electronic medical record size.

The team analyzed the selected MRI or CT scans before segmenting the data. The VR team needed assistance from the clinical team to call out anatomical features and determine the segmentation scope to drive visualization preferences (solid vs. hollow models, color, number of models, etc.). The data were segmented using Mimics (Materialise NV, Leuven, Belgium) and further refined in 3-Matic (Materialise NV,

Leuven, Belgium). If needed, the models were colored in MeshLab (ISTI-CNR, Pisa, Italy) and exported as an object (.obj) with material (.mtl) files.

The Immersive Touch Table displayed the use cases; see Figure 19 (Coffey et al., 2010, 2011). The 95" back-projected stereoscopic display screen created a collaborative shared space to refine the models. The interactive touch screen was uniquely designed for novice users. Many clinicians choose to manipulate their models via the touch screen. Review sessions were scheduled with each clinical team to iterate and tailor the models for their needs. The teams discussed the VR model's appropriateness for the clinical need during the final session and the next steps to advance the use case.

Members of each clinical team completed a survey to evaluate their experience with the virtual model. The survey was administered electronically after the final session. All questions were optional. Questions included the clinician's background, patient demographics, disease statistics, procedural details, rating the virtual experience, clinician's procedural confidence, process preferences, and if they would use VR in this realm again. Survey questions are in Appendix B: Clinical Use Case Survey Questions.

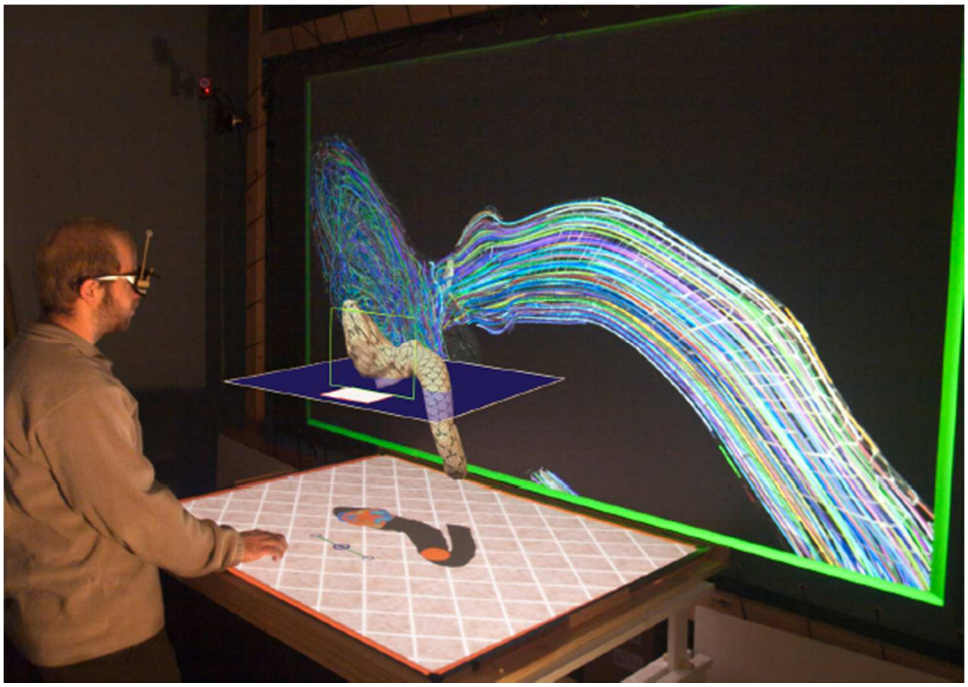

Figure 19. The Immersive Touch Table with a 95" stereoscopic back-projected screen and large touch screen for users to view 3D patient-specific anatomical models (Coffey et al., 2011).

Use Cases

Three clinical use cases for VR technology were developed over 18 months. The first use case was a noninvasive preclinical model to analyze the femoral head's vasculature during LCPD progression. This use case was presented in Chapter 1. The second clinical need was to confirm the fit of a standard-sized double-lumen trachea tube in a pediatric patient diagnosed with delayed growth and short stature. This use case was presented in Chapter 2. The third clinical need was to support procedural planning before the separation of conjoined twins. This use case was presented in Chapter 3. Finally, nine doctors familiar with these use cases completed a survey to summarize their VR technology experience.

Use Case One: Preclinical Model for Legg-Calvé-Perthes disease

Complete results presented in Chapter 1.

Preclinical Case. LCPD is a painful hip condition caused by a disruption in the femoral head's blood flow. LCPD presents in children between the ages of 4 and 8. The

etiology remains unclear, and the rarity of the disease increases the difficulty of clinical research. The preclinical model for LCPD is a well-established piglet model, as the anatomy and physiology of the hip region are comparable to pediatric hips. The preclinical model is used to investigate the pathology and treatments; however, it only mimics severe disease caused by an invasive surgical procedure. An animal model with various disease states and minimal morbidity would improve the animal model. Clinicians need to noninvasively analyze the vasculature surrounding the femoral head during disease progression.

Results Summary. The preliminary VR model showed a noninvasive visual of the femoral head vasculature (Figure 20). The clinical team reviewed how the three vessels curved around before entering the femoral head. The visualization highlighted three opportunities: 1) an accurate depiction of the 3D undisturbed normal vasculature in piglets, 2) the utilization of VR to monitor disease progression and recovery over time, and 3) expand the utility of VR models to include perfusion MRIs performed in children.

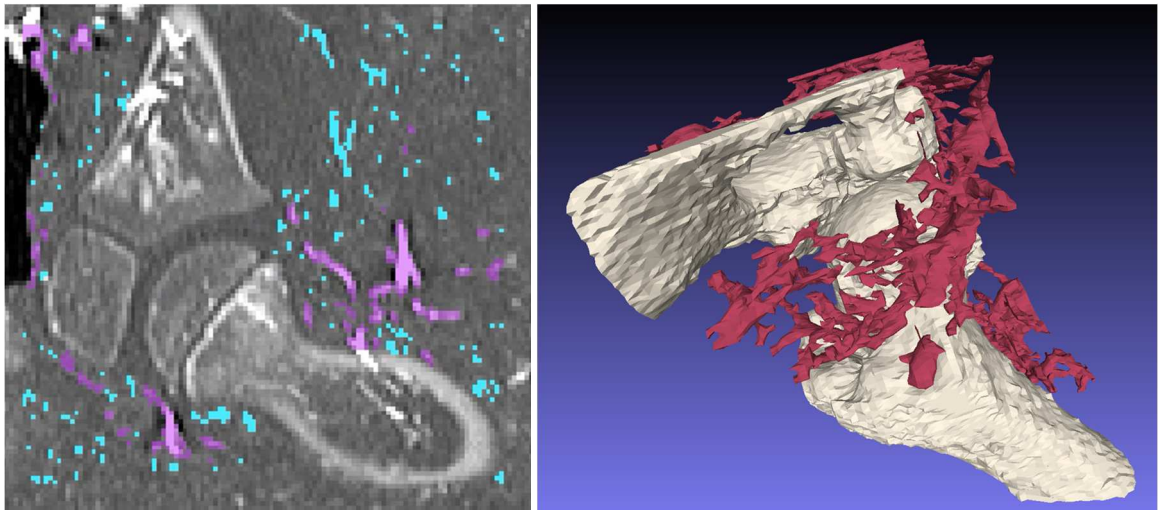

Figure 20. A 2D image of the piglet femoral hip with major blood vessels identified in purple and minor blood vessels in teal (left image). The 3D model of the piglet femoral hip in white and the major blood vessels in red (right image).

Although the VR based model provided a unique perspective into the anatomy, the models' quality was inadequate to meet the preclinical need. The standard CT scan used for the preclinical LCPD models was insufficient when segmenting the data. The

initial step of procuring the model must consider the model visualization requirements. A non-invasive method to analyze the femoral head's vasculature could positively impact the preclinical model for LCPD, disease diagnosis, and therapeutic approaches.

Use Case Two: Double Lumen Trachea Tube Device Fit Confirmation

Complete results presented in Chapter 2.

Clinical Case. Niemann Pick disease type 2 and pulmonary alveolar proteinosis presented in a pediatric patient. The therapy for pulmonary alveolar proteinosis is a whole lung lavage to remove excess surfactant in the lungs. This procedure uses a double-lumen endotracheal tube. The devices are sized for the adult population because pulmonary alveolar proteinosis is less common in children. Measuring the trachea using standard imaging techniques were inherently inaccurate because the anatomy runs at an oblique angle to the images. The clinical need was to measure the patient's trachea accurately and compare the medical device's fit within the anatomy.

Results Summary. The publication presented three results. The first result was a repeatable process to evaluate a medical device's fit in a specific patient's anatomy. The patient-specific anatomical model was segmented from DICOM (digital imaging and communications in medicine) images. The medical device is reverse engineered to create a virtual model. The virtual environment displayed the anatomy and medical device, and the anatomy was 3D printed (Figure 21).

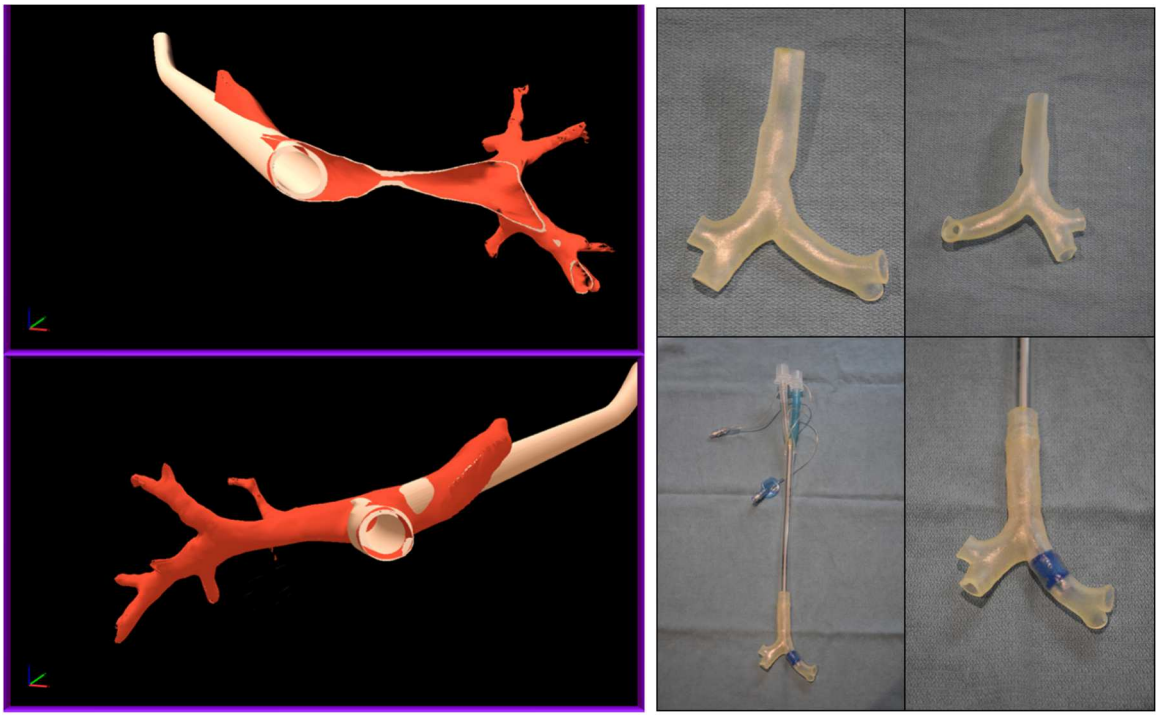

Figure 21. The double-lumen endotracheal tube placed in the virtual patient's anatomy model (left image) and a 3D printed anatomical model (right image).

The second result was a clinical evaluation to confirm the process's effectiveness compared to the conventional procedural planning method. The analysis started by visualizing the anatomy and medical device in a virtual environment. The anesthesiologist measured the patient's anatomy at the appropriate cross-sections. The measurements were checked against the two-dimension (2D) in-plane measurements from the radiologist to confirm the proper rendering scale. The medical device was placed in the anatomy, and the model visibility was toggled to check the fit at multiple locations. Next, the actual device was introduced into the 3D printed anatomy to perform a second check of the device fit. During the procedure, the medical device was placed based on the manufacturer's recommendations. The medical device fit as expected in the patient's anatomy, and the procedure was successfully completed.

The third result was the financial expense to complete the virtual and physical confirmations for the medical device's anatomical fit. The segmentation, computer-aided design model, virtual visualization, and 3D printed model costs $1522.26. A limitation

discussed with this use case is the cost of these methods. At the time of this publication, using these technologies in a clinical setting is not reimbursable by insurance. However, advancements in the technologies, standardizing methods, improving the algorithms to procedure the models, and routinely using the technologies in a clinical setting will reduce costs. As shown in this use case, the use of technology improved the clinical team's confidence in successfully introducing the medical device into the patient's trachea and ensuring positive patient outcomes.

Use Case Three: Preprocedural Plan for the Separation of Conjoined Twins

Complete results presented in Chapter 3.

Clinical Case. Thoracopagus conjoined twins occur every 1 in 50,000-100,000 live births. They are joined on the ventral side from below the umbilicus to above the manubrium. The twins always share a heart and may also share a liver and digestive system. Due to the complexity of the anatomy, a few sets of twins survive. An interatrial communication was confirmed using a transthoracic echocardiography and CT angiography, allowing blood to flow from one twin to another. Interatrial communications between thoracopagus twins have a 90% mortality during surgery. The anatomical complexity warranted advanced imaging to localize the interatrial bridge between the hearts. The clinical need was to create 3D anatomical models to investigate the complexities of a separation procedure further

Results Summary. The surgical team used the stereoscopic display for pre-surgical planning (Figure 22). Four surgical team members reviewed the anatomical models; lead surgeon, cardiac surgeon, and two anesthesiologists. The team, who had already planned the procedural steps, reviewed the virtual models. The first step was to stop blood flow between their hearts at the interatrial communication. While reviewing the models, the team realized that the original procedural plan would have put the twins in danger. The interatrial communication was on the opposite side of their body from the incision, a location confirmation traditionally unavailable with other imaging technologies. The surgical team revised their surgical plan based on the VR-based visualization.

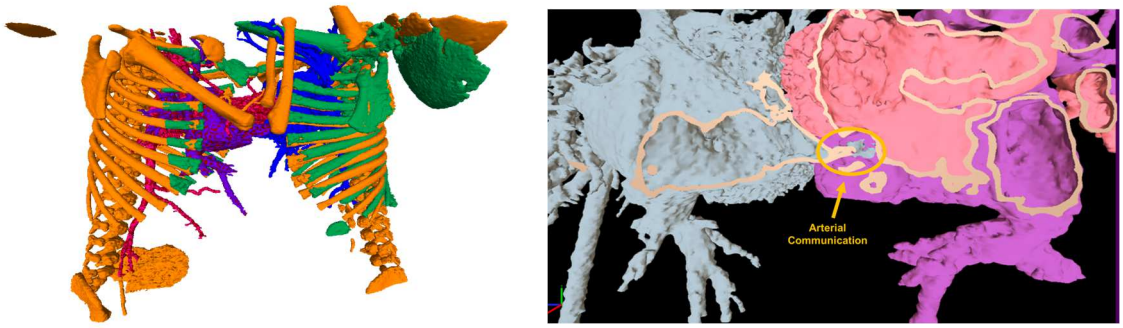

Figure 22. The models for the conjoined twins pre-procedural planning use case. The left image includes the skeletal systems and hearts as captured by the two CT scans. The right image shows the arterial connection between the two hearts. Stopping the blood flow.

The surgical team felt the team-based VR experience was invaluable to the process. Specifically, visualizing the cardiac anatomy facilitated the separation process and helped understand the closure after separation. The team-centered approach focused the discussion on the anatomy and preparing a complicated surgical plan. The twins were successfully separated without mortality or morbidity and continue to thrive three years post-separation. The pediatric cardiologists summed up the impact of the VR experience.

> [VR was] vital in planning the separation, down to the level of which direction the babies faced on the table - without this information, I think the likelihood of success would have been much lower, as an undetected heart connection has led to death in other similar cases.

Results

Nine doctors from the four use cases evaluated their experience using the technology. Some responses were incomplete and therefore, not included in the results. All survey questions are available in Appendix B.

Six doctors rated their use case as extremely difficult, one doctor rated their use case as somewhat difficult, and two rated their use case as neither easy nor difficult (Figure 23). The three use cases were pediatric focused, which is an underserved population of the medical device industry (Sutherell et al., 2010). Pediatric disease is commonly acute and chronic disease occurrence is rare. Therefore, randomized controlled trials to test device efficacy and safety are difficult with small patient

populations (Sutherell et al., 2010). Fewer pediatric patients means less financial incentive for medical device companies to invest in device development. Pediatric clinicians are familiar with seeking alternatives and commonly use medical devices off-label to solve clinical needs (Sutherell et al., 2010).

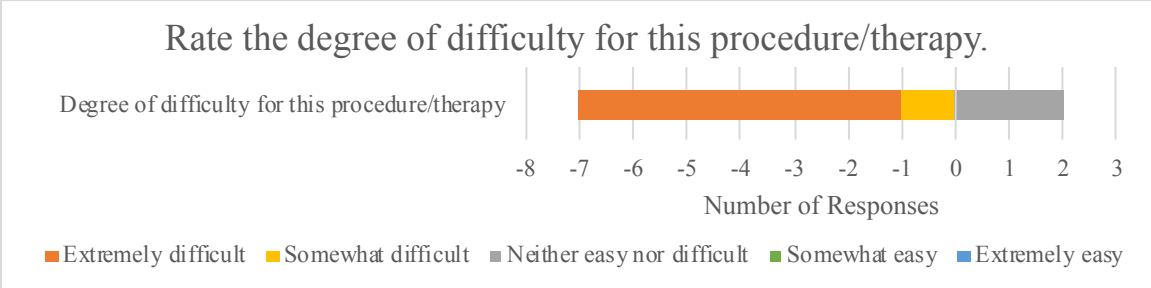

Figure 23. The clinicians rated the degree of difficulty for their use case based on their medical expertise. Six clinicians felt their procedure/therapy was 'extremely difficult,' one clinician selected 'somewhat difficult,' and two clinicians selected 'neither easy nor difficult.'

The clinician's confidence in patient outcome was split before using VR. One doctor selected 'far below average,' two doctors selected 'somewhat below average,' two doctors selected 'average,' and four doctors selected 'somewhat above average' (Figure 24). Patient outcomes that drive healthcare value include; survival, degree of health or recovery, time to recovery and time to return to normal activities, disutility of care or treatment process, sustainability of health or recovery and nature of recurrences, long-term consequences of therapy (Porter, 2010). A doctor's confidence independently affects performance and is an important measure to evaluate their willingness to perform a procedure, ask for support, and self-assess their skills (Connick et al., 2009).

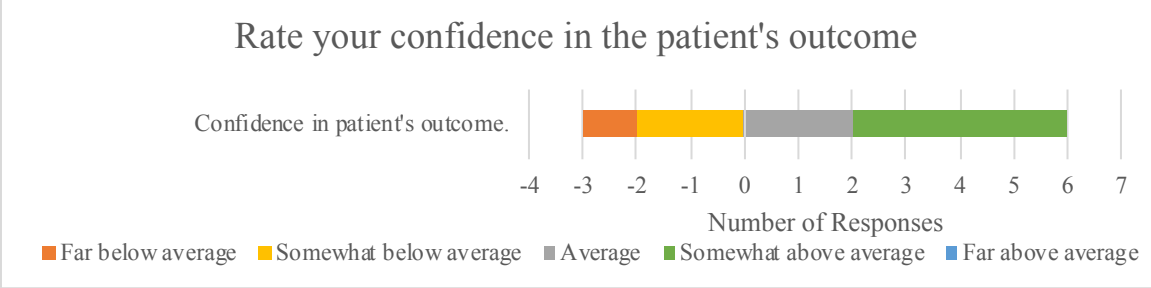

Figure 24. The clinicians rated their confidence with each patient's outcome based on the specific clinical need. One clinician rated their confidence 'far below average,' two clinicians selected 'somewhat below average,' two clinicians selected 'average,' and four clinicians selected 'somewhat above average.'

Five doctors' somewhat agreed' or 'strongly agreed' to the question: 'Has your confidence in the procedure changed based on using virtual reality?' (Figure 25). Four doctors did not respond to this question. Procedural confidence improves with physical training simulators (Goolsby et al., 2014) and VR simulators (Locketz et al., 2017). Hallas et al. (2011) also found procedural confidence continues to improve based on the number of training modalities used. The anesthesiologist commented on the double lumen trachea tube device fit confirmation use case commented.

[VR] increased [our] confidence of [the] breathing tube selection.

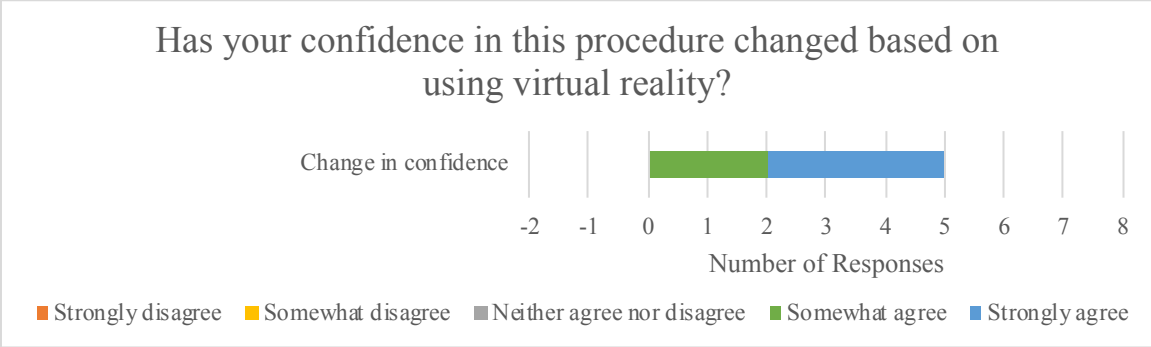

Figure 25. Five doctors reported their confidence changed based on the use of VR during their specific use case. Two clinicians selected 'somewhat agree' to their confidence changing and three clinicians selected 'strongly agree.'

Three doctors reported their operating room cost per minute was greater than $200. Five doctors did not respond to this question. The average operating room cost in 2004 was $62 per minute and ranged from $22 to $133 per minute (Shippert, 2005). The doctors' increase in cost for these use cases results from practicing pediatric use cases at

a research and academic medical center. Children's hospitals care for a sicker patient population than nonchildren's hospitals resulting in a higher cost of care (Merenstein et al., 2005). The cost of care between teaching hospitals and other hospitals is comparable when adjusted for patient outcomes (Burke et al., 2019).

Seven doctors shared many outcomes for the success of their patient/s. Two doctors did not respond to this question. The outcomes of success were all related to morbidity and mortality. Three doctors mentioned healing or improved parameters (morbidity), and five doctors said survival (mortality). Patient morbidity was a driving factor in developing a virtual progressive preclinical model for LCPD (Juhnke, Novotny, et al., 2019), as a missing or delayed diagnosis leads to higher morbidity rates (Froberg et al., 2011). Thirty-day mortality rates also decrease when using 3D visualizations during the pre-procedural planning (Analbers, 2016). Reducing morbidity and mortality are critical drivers for doctors looking to adopt the technology into their practice.

The doctors shared multiple ways in which the technology-aided in their process. The responses fell into four themes; procedural planning, anatomy knowledge, physiology knowledge, and a team approach. Understanding the relationship between anatomy and the medical device was necessary to validate the double-lumen trachea tube's procedural plan. Analyzing blood flow's physiology to the femoral head was the driving need to advance the preclinical model for LCPD. Finally, a technology designed to serve a collaborative team ensures the ~40 people in the operating room during the separation of the conjoined twins knew their roles for a positive outcome for both patients. All three use cases had elements of these four themes present.

Seven clinicians strongly agreed that 'the final virtual reality model met [their] expectations,' one clinician somewhat agreed with the statement, and one did not respond to the statement (Figure 26). The user-driven iterative development process tailored each experience to the needs of the clinical team. However, many more use cases were out of the scope of this study. It is important to remember the uniqueness of each use case. As we learn more about clinical needs and select appropriate technical solutions, we can expand virtual technologies and improve user experiences.

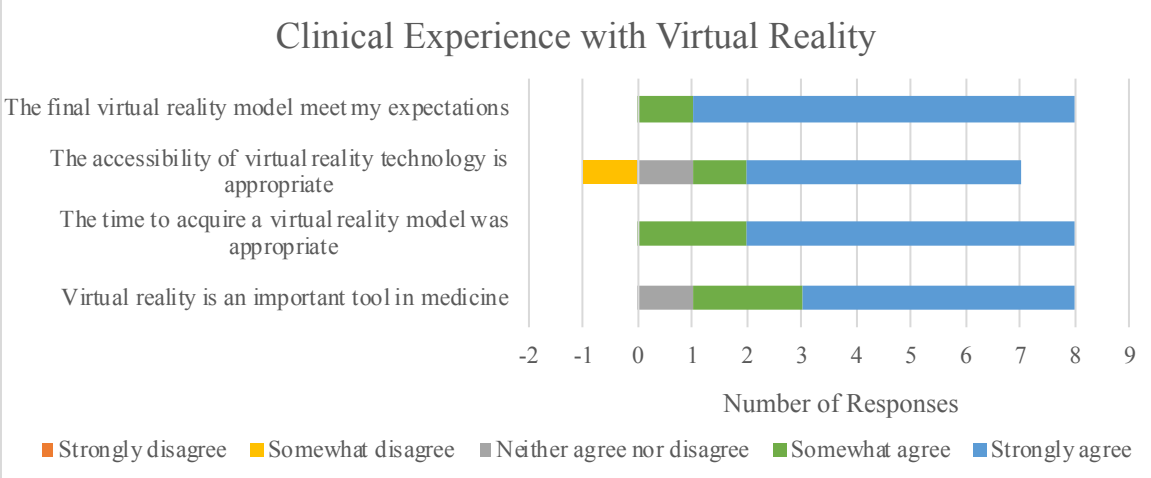

Figure 26. Overall, the clinicians felt the technology meet their expectations and was an appropriate tool in medicine. Clinicians who responded with 'strongly disagree' or 'somewhat disagree' are plotted to the left of zero, and responses of 'neither agree nor disagree,' 'somewhat agree,' and 'strongly agree' are to the right of zero.

Five clinicians strongly agreed that 'the accessibility of VR technology is appropriate,' one clinician somewhat agreed with the statement, one clinician neither agreed nor disagreed, one clinician somewhat disagreed, and one clinician did not respond to the statement (Figure 26). Convenient accessibility of the technology is vital to adoption and a clinician's time is at a premium. The VR technology was located in the basement of one hospital within a large network of healthcare facilities. Two of the three clinical teams did not practice at the primary hospital, which reduced the number of iterations or reduced the number of team members available for the in-person reviews.

The results for the statement 'the VR model is worth the expense' were excluded. Only a few clinicians knew the cost to complete the projects. Initially, research grants covered the cost to develop the use cases. A fee-for-service model was later adopted to align with existing programs. In the fee-for-service model, the clinician teams covered the cost of the projects. Anecdotal data suggests the change in funding models impacted the scope and duration of the projects. Therefore, presenting the data as a whole is inaccurate.

Six clinicians strongly agreed that 'the time to acquire a VR model was appropriate,' two somewhat agreed with the statement, and one did not respond to this

statement (Figure 26). The time to develop each use case ranged from 3 to 18 months and included multiple iterations. When the techniques become a standard of care, one clinician said they would expect VR models to be ready in 12-24 hours, and a second clinician said 1-3 business days. The method's efficiency depends on acquiring the data, transferring the data, segmenting the data, generating the models, and configuring the data into the VR environment.

Five clinicians strongly agreed that 'virtual reality is an important tool in medicine,' two clinicians somewhat agreed, one neither agreed nor disagreed, and one did not respond to this statement (Figure 26). Each use case presented included an analysis of the relationship between the human body and a product. The product being a medical device or the product being a surgical procedure; both require an understanding of the patient-specific anatomy to select the device's size or perform the procedure. The doctors commented that they felt the imaging was 'vital to understand the relevant anatomy for surgical planning,' especially when 'planning for a complex case.' Although, the technology needs to be further validated against existing methods, as one clinician stated: 'in vivo perfusion MRI can get us very far with rapid turnaround time and at a substantially lower price.' Therefore, it is essential to validate VR technologies for specific use cases to know if the new solution provides better outcomes than existing methods.

Finally, most clinicians reported that they would use VR again (Figure 27). Early adopters are necessary to continue driving the adoption of VR technology in the medical industry. As seen in each of these use cases, users as inventors play an essential role in realizing the technology opportunity (Zweifach & Triola, 2019). Creating, validating, and deploying new simulations is dependent on learning about procedures and tasks that would benefit from simulation (Chan et al., 2013). A clinical scientist commented on the future impact of the VR experience for the LCPD use case.

> It will give us an idea of the vascular anatomy in and around the femoral head of piglets. This will help us identify the size and redundancies of the vasculature.

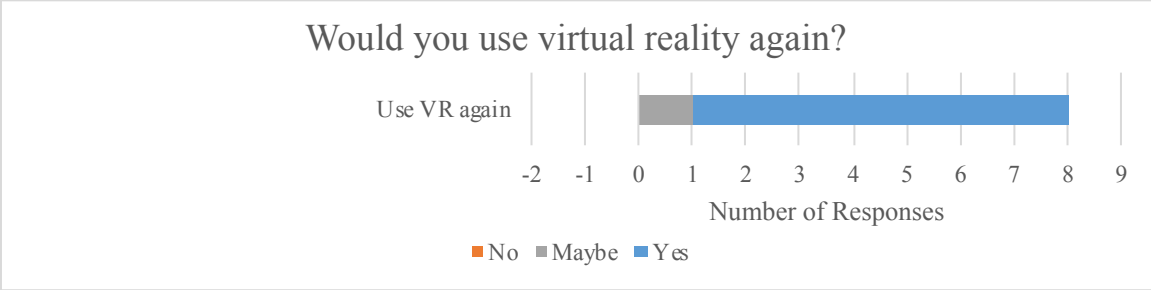

Figure 27. A majority of the clinicians indicated that they would use VR again.

Discussion

The results present clinicians' perceptions and experience with tailored VR experiences. The use cases were developed from a common methodology using the Immersive Touch Table (Coffey et al., 2010, 2011). The first use case developed a preclinical model for LCPD (Juhnke, Novotny, et al., 2019). The second use case confirmed the fit of a double-lumen trachea tube for a pediatric patient (Kloesel et al., 2021). The third and final use case devised a procedural plan to separate thoracopagus conjoined twins (Juhnke, Mattson, et al., 2019). The result of each solution added value to the use case, but the solutions remain proofs-of-concept. Additional work is needed to develop accessible VR technology for regular clinical use.

Many learnings developed from these use cases, four learnings will be outlined here. First, the quality of the final VR model is dependent on how the patient's data is captured and stored. In working with radiologists on these cases, they shared anecdotal data about balancing data quantity and scan speed when selecting scan settings. Higher resolution data is needed for smaller anatomical features but takes more time to capture, while quicker scans are easier for patients. After the radiologist reads and prepares a diagnosis, the data is typically down-sampled before storing the scan in the patient's record as storing scans is cost prohibitive. As the use of VR grows in the medical industry, reevaluating this data life cycle will be critical to develop useful tools. For example, a VR tool to guide a doctor when selecting an appropriately fitting medical device for a specific patient will only be possible if the software algorithm can learn from a database of anatomical models. Medical simulations can leverage VR technology when high quality data is available to develop appropriate models.

Secondly, benefits are often difficult to quantify when applying VR technology in the medical industry. As stated before, VR technology remains in its infancy in the medical industry. Researchers continue to explore technology designs to serve the clinical needs, but the use cases profiled above were more difficult than the average surgical procedure. The number of extremely difficult ratings and pediatric use cases suggests that the clinical teams had exhausted alternative options before pursuing the use VR (Figure 23). These rare cases are challenging to study because each case's details vary significantly, and they inconsistently present in the clinic. Many doctors from the conjoined twins' case talked about a once-in-a-lifetime experience for their professional careers. Over time, the medical industry will need to identify when VR technologies are beneficial for a specific use case.

Another anecdotal data point from the separation of the conjoined twins use case was the estimation of saving up to 90 minutes due to the procedural revisions based on the VR visualization (Juhnke, Mattson, et al., 2019). Without the care team performing a similar procedure, it is impossible to quantify the time savings. Decreased operating times have been shown to improve patient outcomes (Jackson et al., 2011). The reduced operating room times could offset the cost of investing in VR training opportunities (Juhnke, Mattson, et al., 2019).

The third learning involved the importance of accessibility to VR technology. As stated previously, the VR technology for these use cases was in one hospital's basement within an extensive healthcare facility network. Building VR suites into healthcare facilities would be most beneficial to clinicians. Identifying where the technology fits into a clinical workflow will help guide the physical location of VR technology in a healthcare facility. Algorithms to automatically segment patient-specific data will become invaluable to hospitals using VR technology as clinical use cases are expanded (Chan et al., 2013). Accessible technology and segmentation algorithms will elevate VR technologies to be used regularly before, during, or after a procedure.

The final learning revealed that collaboration is critical to the design of these technologies. All of the use cases profiled involved many members of the care team when

reviewing the datasets. Collaboration and team-based approaches are the medical industry culture. Each individual on a care team has specific roles and responsibilities to ensure the patient's safety. Many members of the care team would simply observe the procedural planning process. Although these care team members did not contribute to the planning process, anecdotal data indicated the value of observation. Observing the procedural planning process allows all team members to align their role with the patient care plan.

Limitations. The first limitation of this study is the lower number of use cases profiled. As stated in the background, these technologies are just in their infancy, and research has shown value in tailored solutions (Zweifach & Triola, 2019). However, studying tailored solutions is difficult to generalize across the medical industry. The second limitation involves bias in the survey results. The author of this dissertation participated in each use case and requested each clinician's participation in the study. It is unknown how much of this personal connection with the participants impacted their survey responses. The third limitation is the inconclusiveness of the survey questions. The survey questions were designed to be quick for the clinicians to complete. Not all questions were answered by each clinician, and many new questions presented themselves while analyzing the results.

Future Work. Many opportunities exist to continue to expand VR use cases for the medical industry. First, developing *segmentation algorithms* is necessary to reduce the time needed to create 3D clinical models. Second, exploring *cost-savings and reimbursement* when using VR technology in a clinical setting will increase technology adoption. Third, improving methods to quantify patient outcomes after using VR technology for procedural planning. These data will assist organizations in their advocacy of new medical simulation use cases.

Conclusion

This work contributed to an improved understanding of early adopters of VR technology in the medical industry. VR has been applied to the medical industry for nearly 30 years (Kaltenborn & Rienhoff, 1993) and continues to see low adoption. The

results show medical professional expectations of VR technology and guide developers to produce efficient solutions. Technology hurdles continue to limit the realism or possibility of VR simulation in the medical industry (Chan et al., 2013). As research explores VR technologies for the medical industry, it is essential to remember that there is an ever-growing opportunity to create, validate, and deploy new simulations while overcoming the logistical hurdles, economic realities, and entrenched traditions that hinder acceptance (Chan et al., 2013). Tailored VR solutions for the medical industry are essential to improve the adoption of these technologies.

Chapter 5

Perspective Two: Development of an VR Tool for Deep Brain Stimulation Procedural Planning

Preface

This chapter develops an original procedural planning tool for deep brain stimulation (DBS) using two VR technologies. The emphasis here is on defining, designing, and evaluating a VR solution. These steps apply the knowledge about users and clinical use cases from chapters one through four to develop a VR solution for a new use case. This inquiry demonstrates a method and the phases needed to develop a medical VR solution. This chapter develops a medical VR solution for the second perspective of this dissertation (Figure 28).

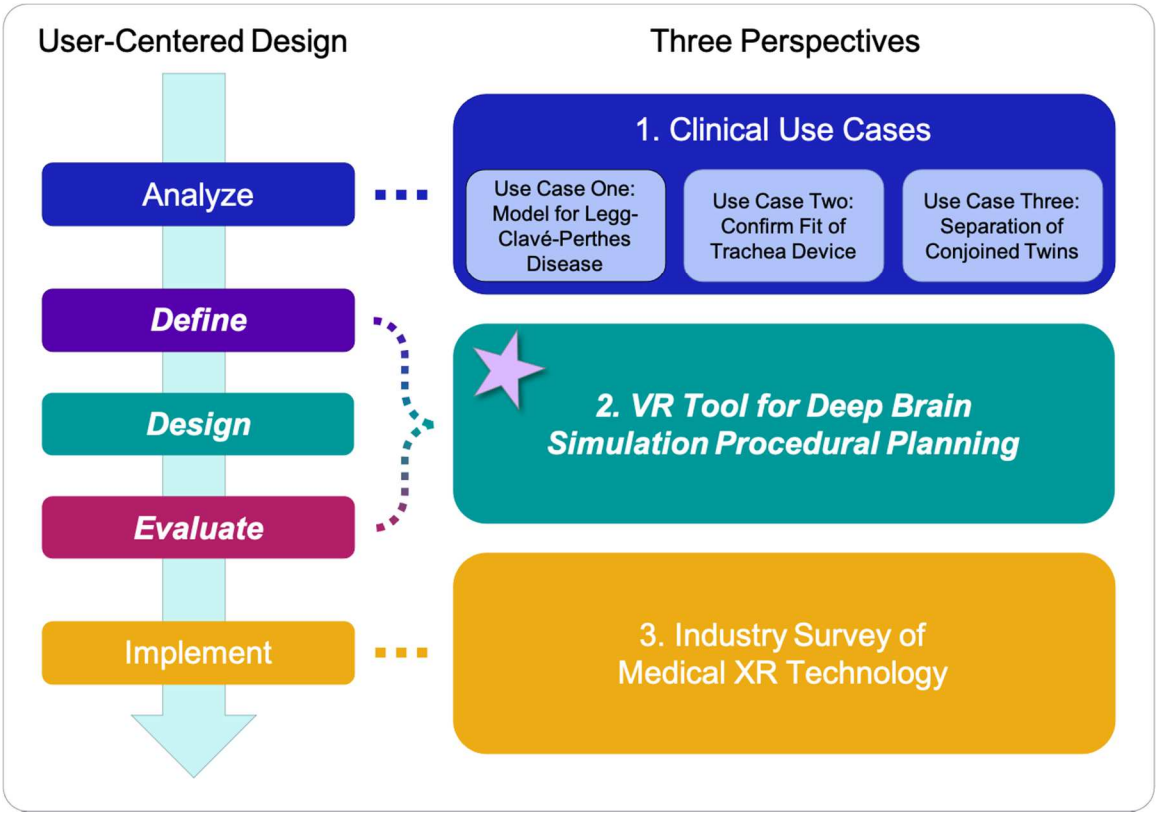

Figure 28. Chapter five develops a medical VR procedural planning tool for DBS. This chapter is part of the second perspective to define, design, and evaluate medical VR technology.

Introduction

As the demand for simulation-based training in the medical field increases, developers look to the literature for best practices and guidelines to support design decisions. Few examples exist to apply VR technologies to industry in general (Vi et al., 2019), and even fewer examples exist for the medical industry (Chan et al., 2013). The literature has pointed to an iterative design process as optimal to provide formative evaluations of medical XR technology (Zweifach & Triola, 2019). The purpose of this perspective was to combine the user-driven learnings from perspective one with the available literature and domain expert feedback to develop two VR applications for the DBS use case.

The use case of DBS was selected for two reasons. First, VR has a potential opportunity to improve the procedural planning process. In the current process, the surgeon mentally visualizes the procedural plan from a series of two-dimension (2D) images. This process of mentally reconstructing the patient's anatomy requires years of training for medical professionals. These planning processes, at the core, are spatial awareness tasks, which is an essential skill for surgeons to improve their patients' clinical outcomes and increase their confidence before a procedure (Stadie et al., 2008). One advantage of VR technology is to assist the evaluation of three-dimension (3D) spatial relationships, which has been shown to reduce clinician's mental workload when evaluating anatomical relationships compared to reconstructing anatomy from 2D images (Foo et al., 2013). The second reason DBS was selected was the depth of use case opportunities. The planning process includes many intricate steps; target location, electrode trajectory, microelectrode readings during implantation, stimulation shape, and stimulation strength. The advantages of VR technology coupled with the DBS depth provided a rich opportunity to develop solutions for the users, use cases, and medical environment.

Background

DBS interrupts the neuronal activity at the disorder's location of pathophysiology (Okun et al., 2007). The Food and Drug Administration (FDA) has approved DBS for

essential tremors, Parkinson's disease (Gardner, 2013; Okun et al., 2007), dystonia (Krause et al., 2004), obsessive-compulsive disorder (McIntyre et al., 2015), and epilepsy (Rossi et al., 2016). DBS shows promise for Tourette's syndrome (Okun et al., 2007; Perlmutter & Mink, 2006) and depression (Gardner, 2013; Perlmutter & Mink, 2006), and research continues into other brain-related illnesses (Okun et al., 2007). Education for neurological surgeries includes textbooks, human atlases, cadaver dissections, and intraoperative training (Henn et al., 2002), with apprentice models (learning by doing through mentor guidance) being the best approach to learn DBS techniques (Henn et al., 2002).

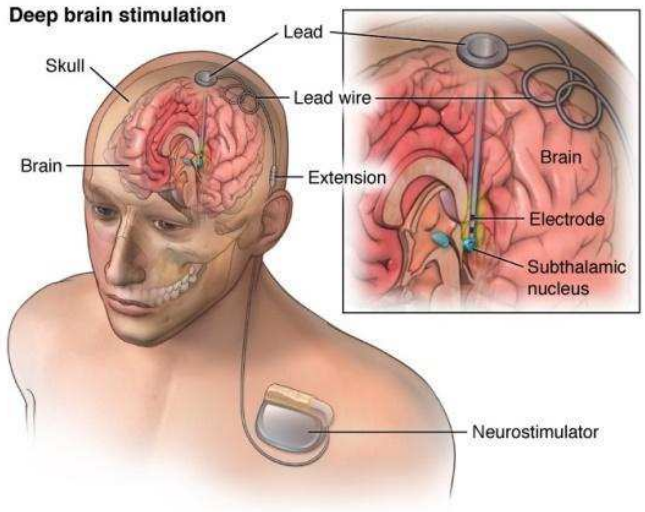

Figure 29. Placement of a DBS electrode in the subthalamic nucleus (STN) (Pilitsis et al., n.d.).

The implanted DBS device is called a '*neurostimulator*' and includes a programmable pulse generator and implantable electrode (Figure 29) (Okun et al., 2007). A DBS head-mounted frame (HMF) is secured to the skull and attached to a larger stereotactic frame. The frame's six degrees of freedom (DOF; X, Y, Z, θ, φ, ρ) align the electrode (Figure 30) to the stimulation location in the patient's brain (Gardner, 2013; Miocinovic et al., 2007; Okun et al., 2007).

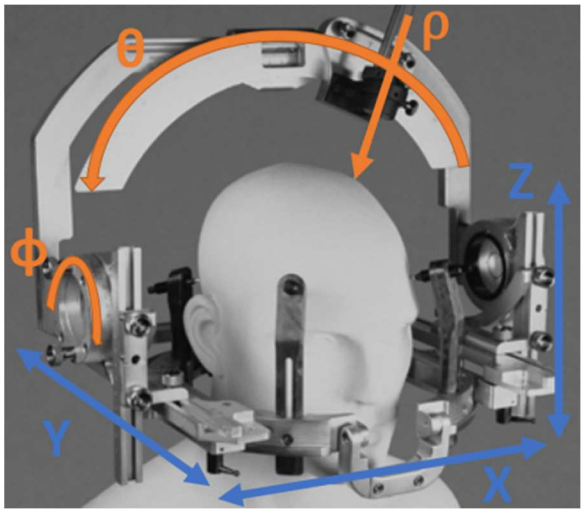

Figure 30. Coordinates systems used for a stereotactic frame. The blue cartesian (X, Y, Z) coordinates orient the frame to the target region. The orange spherical (θ, φ, ρ) coordinates align and advance the electrode trajectory. Original image from Integra Radionics, Inc. (Burlington, MA).

Surgeons select the patient's electrode placement by using 2D human atlases, neurophysiological microelectrode mapping, electrical data, and stereotactic positioning (Abosch et al., 2010). The surgeon takes high-resolution MRI to view the patient's brain before the procedure (Okun et al., 2007). The surgeon uses Cartesian coordinates (X, Y, Z) to select a target location (Abosch et al., 2010). Next, the surgeon compares the 2D patient images to the 2D human atlas images to choose an electrode trajectory angle (Miocinovic et al., 2007). Spherical coordinates define the electrode trajectory (θ, φ, ρ) from the skull to the target location. Human brain atlases include images from a handful of deceased individuals and limited in generalizability to all patients.

A five-port BenGun device (Figure 31A) is attached to the stereotactic frame to assist with advancing electrodes into the patient's brain. The neurosurgeon advances multiple microelectrodes into the brain to stabilize the brain and capture audible frequencies to locate the electrode's end in the anatomy (Okun et al., 2007; Telkes et al., 2016). Electrical signal data is compared to the brain atlas data (Abosch et al., 2010). The comparison confirms if the electrode is traveling along the correct trajectory. Anatomical differences, cell types, and experimental settings limit the comparison's accuracy (Perlmutter & Mink, 2006). A neurosurgeon will use only one or all five ports to select an

ideal track. The BenGun can be oriented as a '+' or as an 'x' to adjust the placement along different planes (Figure 31B) (Bus et al., 2018).

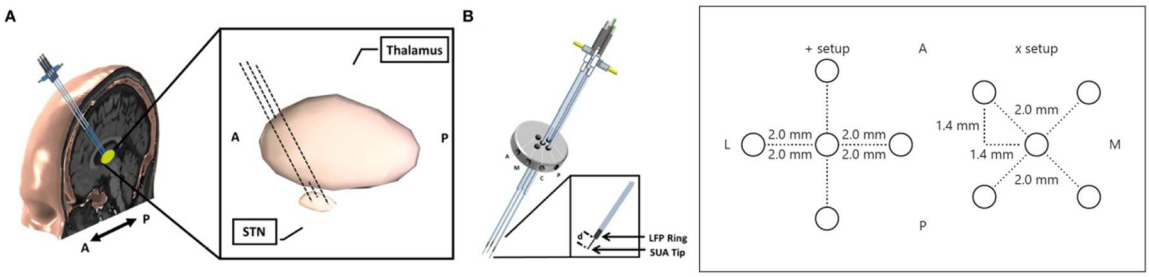

Figure 31. BenGun device (A) to guide electrodes during DBS. The device has multiple ports to select the optimal path for the electrode through the brain. The BenGun has two commonly used orientations (B), the '+' for adjustment in the x or y plane (anterior, posterior, medial, or lateral), while the 'x' for adjustments in the x-y plane (anteromedial, anterolateral, posteromedial or posterolateral) (Telkes et al., 2016).

One study highlighted the effect of different imaging technologies when planning electrode trajectories. In the study doctors placed 54 electrodes in 27 patients and made more than one electrode track for 14 of the 54 electrodes (25.9%) to confirm the position. The two groups of doctors used different imaging technologies to plan the target locations and trajectories. The first group created multiple tracks during 5 of 12 electrode placement procedures (42%), while the second group created multiple tracks during 9 of 42 electrode placements (21%) (Hamid et al., 2005). Multiple electrode tracks can cause permanent neural damage, increases the operating time, and may lead to increased risk of hemorrhage and mortality rates (De Vloo et al., 2018). The different number of tracks created between these two groups show the importance of anatomical visualizations to support the planning process.

Placement Accuracy of Electrode

Accurate electrode placement is critical for effective therapy response. Electrode placement research focuses on multiple aspects, including therapy response, adverse events, and electrode performance. Electrode replacement is due to infection, repositioning (removing the first electrode and implanting a new electrode), and mechanical device failure, which occurs in 4.7% ± 1.0% of patients at one year, 9.3%

±1.4% of patients at four years, and 12.4% ± 1.5% of patients at seven years postoperatively (Patel et al., 2015).

Repositioning inaccuracies may result in a mismatch between the assumed locations, microelectrode readings, and patient side effects (Bus et al., 2018). Bus et al. (2018) reviewed the placement error for 238 electrodes over two years. For 59 of the 135 (43.7%) patients, multiple tracks were created during the procedures, *and* interoperative CT scanner was available to analyze the final placement. Of the multiple tracks created, microelectrical recording data was available for 230 tracks. Doctors adjusted 87 of the 230 tracks (37.8%) based on feedback from the microelectrical data. Of the 87 tracks, the median radial error was 0.59 mm, with 21 (24%) adjustments exceeding 1 mm (Figure 32) (Bus et al., 2018).

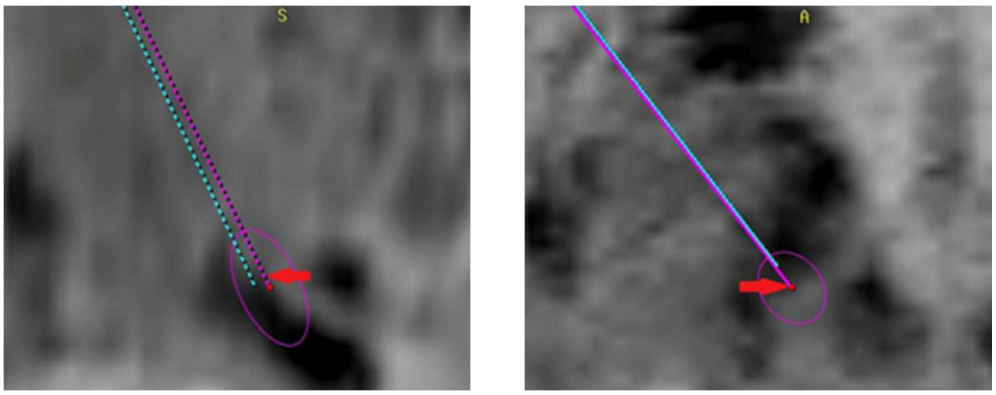

Figure 32. Difference between intended (purple) lead placement and actual (blue) electrode movement during the procedure (Bus et al., 2018).

Electrode trajectory angles selected by surgeons also vary. Surgeons, in general, develop preferences towards surgical techniques based on their training and outcomes of previous procedures. Hamid et al. (2005) compared their trajectories angles with three other teams, Rodriquez, Starr, and Bejjani, for Parkinson's disease. Hamid et al.'s reported using the sagittal angle of 38º for their procedures, compared to Rodriquez's team using a 45º angle and Starr's team using a 29.2º angle. Hamid et al.'s study reported the coronal projection angle as 17.5º, compared to Bejjani's team using a range of 20-30º as a lateral-to-medial angle and Starr's team using a 10.2º angle from a medial approach (Figure 33).

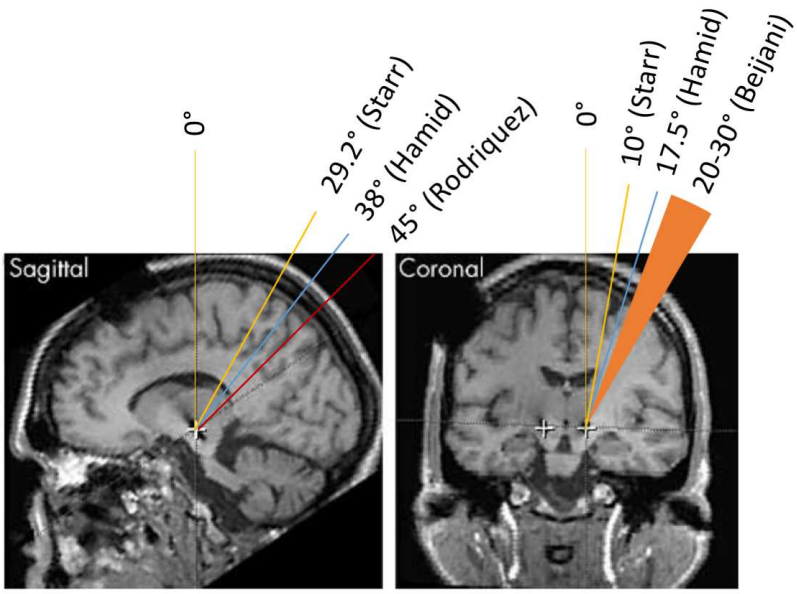

Figure 33. Trajectory angle variations used when implanting electrodes into the brain for Parkinson's disease (Hamid et al., 2005).

Advancing visualization techniques improves DBS surgeries and patient outcomes. Before the availability of patient-specific images, surgeons would use generalized 2D human atlas images to position the electrode. These methods continue to be used to train surgeons on DBS techniques. With the availability of patient-specific images, doctors are able to visually inspect 2D patient-specific images to select a target location and trajectory angle for each patient (Lehtimäki et al., 2016). Research shows advancing from 2D human atlas images to 2D patient-specific images 1) reduced the number of microelectrical tracks per procedure, 2) selected better trajectories for electrode placement, and 3) improved the identification of the lateral boundary of the subthalamic nucleus (Tonge et al., 2015).

Programming a Deep Brain Stimulation Electrode

The first electrode programming session is scheduled immediately after surgery or up to 6 weeks postoperatively, with routine visits scheduled until an effective therapy is found. The process to program a DBS electrode is inconsistent, inefficient, and can require unnecessary patient visits (Tonge et al., 2015). Most DBS electrodes have four contact rings (Figure 34). Each contact ring is programmed as an anode or cathode to

change the shape of the stimulated region. The common simulated regions are monopolar, bipolar, and double monopolar (Figure 34) (Picillo et al., 2016).

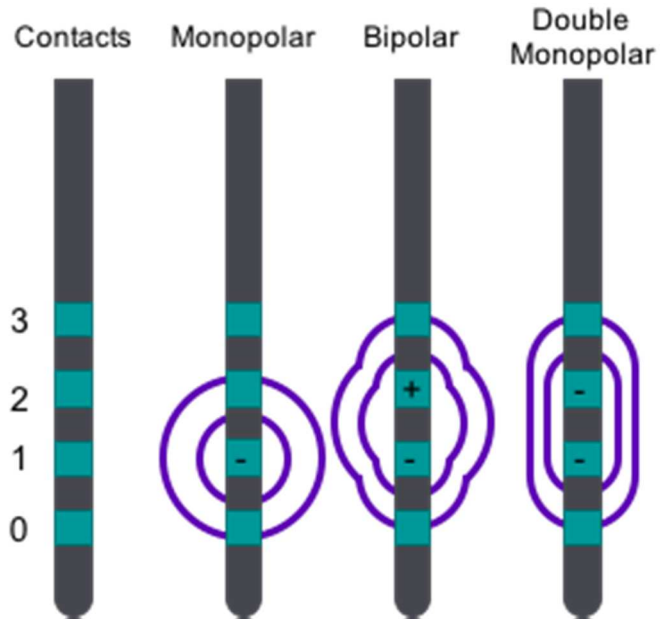

Figure 34. Standard DBS electrodes have four contact rings. Each contact ring can be programmed as an anode or cathode to change the stimulated region's shape. The common shapes are monopolar, bipolar, and double monopolar. The strength of the stimulation changes the volume of each stimulated region.

The number of contact rings at the electrode distal end increases the options to find an effective therapeutic setting. One study of 15 epilepsy patients analyzed 62 electrode contacts implanted during 30 treatments. Patients responded to 25 (40%) contact rings, while 37 contact rings (60%) were non-therapeutic. After modifying the electrical field's strength, 10 of the 15 patients responded to the therapy(Lehtimäki et al., 2016). Next-generation electrodes increase the number of contacts and include directional contacts to improve therapeutic quality but also increase the programming complexity (Figure 35). The programming process remains a time-consuming and challenging process for highly trained clinicians when programming only four contacts (Picillo et al., 2016). Other researchers are developing visualization tools to analyze the electrical fields and assist with programming the ever-increasing number of contacts (Baniasadi et al., 2020; Picillo et al., 2016).

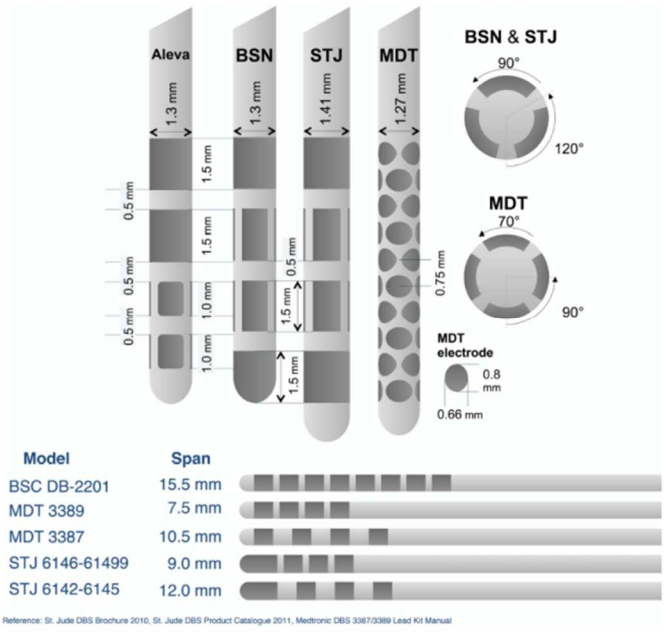

Figure 35. Comparison of Aleva, Boston Scientific (BSN), St. Jude (STJ), and Medtronic (MDT) next-generation DBS electrodes (Rossi et al., 2016). Abbott acquired St. Jude in 2017.

Current Software

A handful of tools are available to advance a doctor's spatial awareness for neurology. The first software, Cicerone, was designed to plan DBS procedures (Figure 36). The software visualizes patient MRI/CT images and co-registers the data with anatomical brain atlases. The user aligns the patient MRI data with anatomical brain atlases. Microelectrode recordings and DBS electrodes are overlaid on the patient's anatomy to select an electrode trajectory. The surgeon transfers the position information to a stereotactic HMF for the procedure (Miocinovic et al., 2007). A standard monoscopic computer screen displays the software.

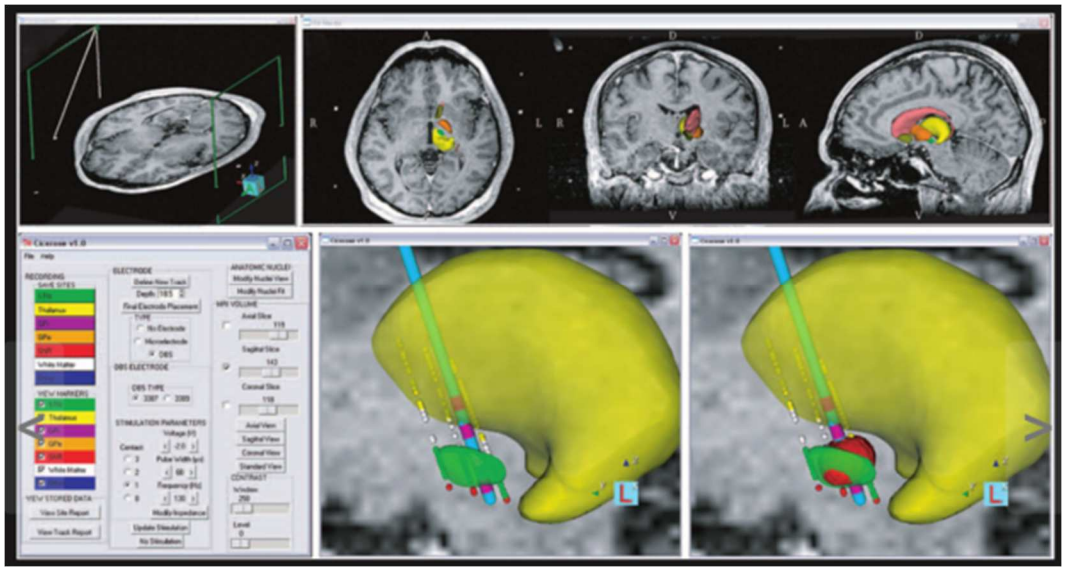

Figure 36. The Cicerone software application (Pabaney et al., 2015).

The second software is FastField, an open-source visualization toolbox to approximate electrical fields (Figure 37). The software considers the tissue properties, electrode orientation, and contact rings to predict patient-specific activation areas. Twelve electrodes from four companies are available in the software. The activation approximation was calculated in 200 milliseconds, making it easy for the user to iterate through the electrodes and orientations (Baniasadi et al., 2020). A standard monoscopic computer screen displays the software.

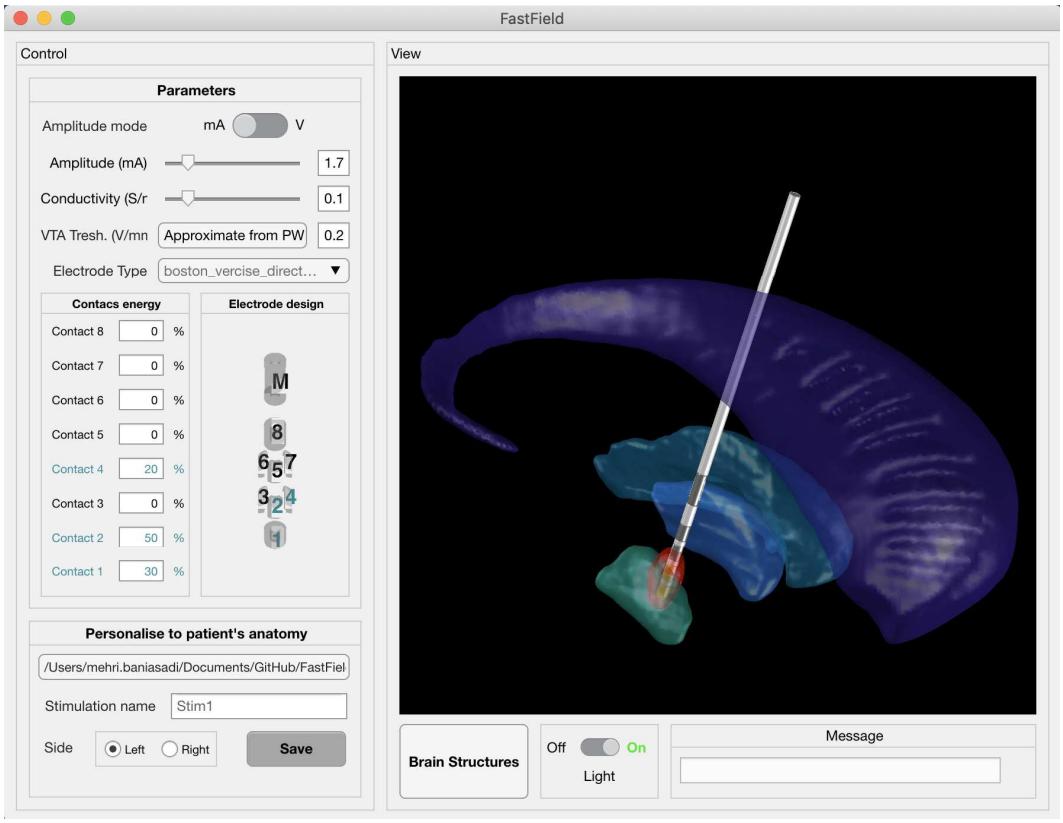

Figure 37. The FastField software application (Baniasadi et al., 2020).

Two software applications use stereoscopic visualization to plan neurosurgical procedures. The interactive stereoscopic virtual reality (ISVR) system, created in 2002 (Figure 38), plays back stereoscopic video captured during neurosurgical operations. The software increased medical students' access to surgical experiences and developed an awareness of neurosurgical approaches and navigation (Henn et al., 2002). The second-generation intraoperative stereoscopic QuickTime virtual reality (QTVR) system allowed users to interact with the anatomy as if performing the surgery (Balogh et al., 2004).

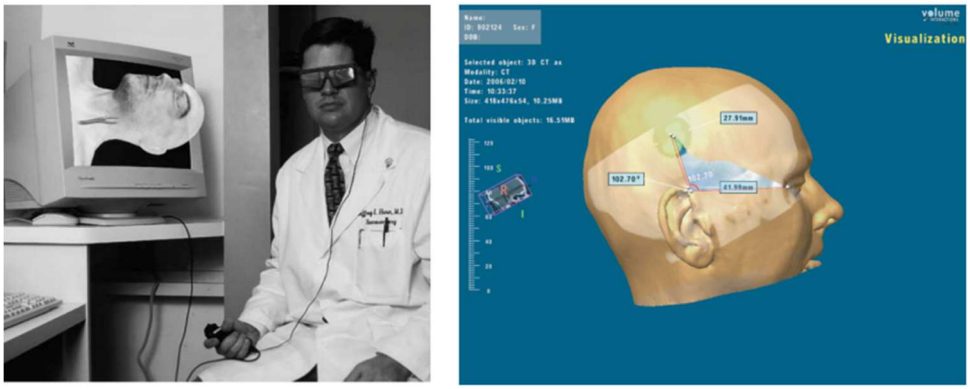

Figure 38. ISVR system (left) for training physicians after neurological surgeries (Henn et al., 2002). Dextroscope software (right) for planning brain tumor removal (Stadie et al., 2008).

The Dextroscope brings together the advantages of stereoscopic software and manually interacting with objects (Figure 38). The software uses 3D interaction tools instead of the traditional mouse and keyboard. A mirror reflects the visualization, so users can 'reach' into the simulation to plan, for example, a tumor removal surgery. The software is a comprehensive tool to evaluate the patient's anatomy and pathology to select appropriate tumor removal surgical techniques (Stadie et al., 2008).

Three issues of current 3D visualization techniques for DBS procedural planning are 1) the lack of vasculature data available when selecting the patient-specific electrode location, 2) the siloed steps in the planning process, and 3) a few steps still use 2D data to analyze the 3D anatomy. For example, after doctors select the target location, the doctor reviews a series of 2D patient brain images to select the electrode trajectory. Another part requires the doctor to reconstruct the electrode's trajectory within their mental model of the patient's brain; this trajectory transverses at an oblique angle to the 2D images.

Seven user needs statements were developed from these learnings about DBS. Literature reviews, conference presentations, and informal expert interviews guided user needs development. Users include surgeons, radiologists, technicians, and researchers, as many experts collaborate to provide DBS therapy. The seven user needs statements are as follows:

1. Surgeons need technologies to personalize the implant location, trajectory, and therapy based on the patient's anatomy,

2. Surgeons and researchers need to visualize patient blood vessels when planning an electrode trajectory,

3. Surgeons need a quick method to map a DBS electrode trajectory to the patient's anatomy the morning of surgery,

4. Surgeons need technologies specifically designed for the complexities of neurology,

5. Surgeons and researchers need to visualize patient fiber tracks with programming an electrode therapy,

6. Radiologists need technologies to improve communication with surgical colleagues, and

7. Surgeons and researchers need 'no obligation' technologies to explore new surgical approaches, medical device designs, and therapies.

Advancements in visualization technology are potentially a valuable tool to plan DBS electrode placement and programming. Research has shown that stereoscopic wide displays (SWD) are beneficial for spatial manipulation tasks and spatial understanding tasks (McIntire et al., 2012). The next logical step for the DBS community to advance DBS electrode placement and programming is to evaluate the electrode and anatomy relationship with 3D visualization techniques. However, research from the computer science community is also inconclusive on the benefits of 3D displays compared to 2D displays for various tasks (McIntire et al., 2012). Therefore, this research project designed VR technology to plan DBS electrode placement and programming.

The contribution of this perspective proposes two designs using VR technology for the DBS use case. Four distinct phases contributed to the two proposed designs. The purpose of phase one was to identify tasks taken by a neurosurgeon to plan a DBS

procedure. The purpose of phase two was to develop design guidelines for VR technologies for the medical industry. The purpose of phase three was to create models for the VR DBS use case. The purpose of phase four was to combine the task analysis, design guidelines, and models into two solutions for the DBS use case.

Methods

Technology enthusiasts theorize VR technology is the future of the medical industry. However, health information technology (HIT) must be integrated with the user's workload to decrease errors and reduce response times during critical situations (Bogner, 2009). This study was elaborated based on learnings from the three use cases presented in chapters one through four and iteratively adjusting the research direction depending on emerging evidence about this use case.

A four-phase iterative approach guided the development of two VR experiences for the DBS use case. The VR experiences were a large stereoscopic wide screen display and head-mounted display (HMD). Subject matter experts provided iterative feedback as the VR experiences progressed. DBS is a highly technical therapy that requires many specialists to plan the procedure. Iterative feedback was essential to target the workflow and final VR experiences that would match the clinical workflow and advance existing methods.

A four-phase iterative approach contributed to designing two VR experiences to plan DBS electrode placement and programming.

- *Phase 1* was to define the procedural tasks for a complete clinical workflow.
- *Phase 2* was to investigate design guidelines to develop the solutions.
- *Phase 3* was to create 3D models appropriate for the DBS use case.
- *Phase 4* was to design two VR solutions to support the user's tasks.

Throughout the four-phases, subject matter expert feedback was resourced to build out the workflow and VR experiences. DBS is a complex surgery, and this

complexity must be captured in a virtual tool to support the surgical workflow. Literature alone was insufficient to capture the true complexity and intricacies of a DBS surgery. Novice surgeons spend years training with experienced surgeons to learn the intricacies of this surgery. The subject matter expert feedback guided development by adjusting the scope of the VR experience meet the user's needs. Feedback sessions were scheduled throughout the development process and each session began with a demo. The experts critiqued the VR experiences, discussed missing components, and identified additional resources to support development.

Phase 1 - Task Analysis

The first phase defined the procedural planning tasks and overall workflow to create a DBS use case framework. The requirements guide the development of a comprehensive VR solution for this use case. The tasks were defined based on interdisciplinary discussions with DBS domain experts and literature reviews of the state-of-the-art. The VR functionality and user interactions were selected to support the doctor's tasks.

Phase 2 - Design Guidelines

VR technology for the medical industry must consider three academic research areas: VR, medicine, and usability (Figure 39). As design guidelines do not exist specifically for medical VR technology, literature was selected that covered two of the three areas. For each pairing, one academic textbook and a handful of articles were selected.

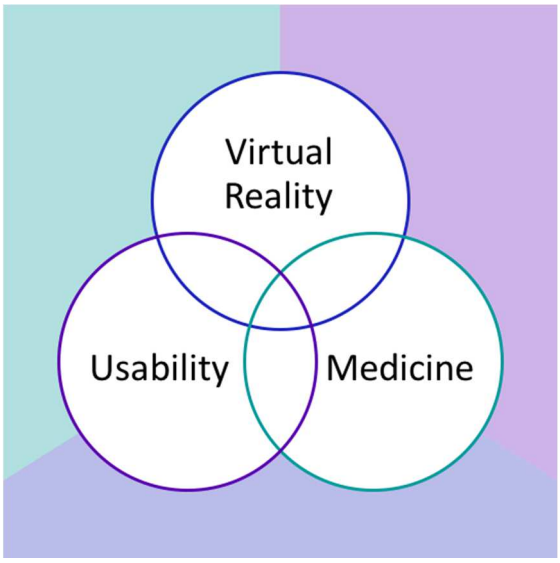

Figure 39. VR, medicine, and usability literature were reviewed to develop a VR technology design guideline in medicine.

Virtual Reality and Usability. The textbook selected was by Ware (2013) titled "Information Visualization," which guides the visualization of data in virtual environments from foundational research to applied research. Research informs guidelines as presented by Vi et al. (2019) who analyzed 68 academic, industry, and 2D design resources to develop the first set of design guidelines for VR technology based on the user's experience. Stanney et al. (1998) reviewed the literature to identify common human factors issues that impact the design of virtual environments. Lin & Woldegiorgis (2015) reviewed how users perceive distance with either an HMD or an SWD. Saredakis et al. (2020) evaluated the levels of environmental detail that lead to cybersickness. Finally, The CyberXR Coalition (2020) developed the first standards for immersive technology concerning accessibility, inclusion, ethics, and safety.

Usability and Medicine. The textbook selected was by Bogner (2009) titled "Human Error in Medicine," which accepts 'human error is a fact of life' and identifies error-prone conditions that result from the technology designs in healthcare systems. Gawron et al. (2006) analyzed medical errors and discussed appropriate tools to mitigate errors based on human factors engineering science. Finally, Turner et al. (2017) evaluated usability issues and unintended consequences while using HIT.

Virtual Reality and Medicine. The textbook selected was by Riener & Harders (2012) titled "Virtual Reality in Medicine," which explored the use of VR technology in healthcare from the foundational technology to how to apply the technology in medicine. Stadie et al. (2008) presented one of the first VR systems for neurosurgery. Chan et al. (2013) reviewed the development of VR for neurosurgery. Delorme et al. (2012) included haptic feedback into a neurosurgery simulator.

These articles contributed to the development of design guidelines for medical VR experiences. The design guidelines are presented in the results.

Phase 3 – 3D Models

The third phase created use case-specific 3D models. The modeling process included a literature review and reverse-engineering medical devices. The final models are patient-specific anatomy, medical devices, simulated data, and graphical user interface (GUI) images.

Anatomical Models. The Center for Magnetic Resonance Research, Department of Radiology at the University of Minnesota, provided the patient-specific anatomical models. The patient had a CT scan with a venogram. Venograms use contrast to analyze blood flow. All deep brain regions were manually segmented, along with reference and landmark anatomy. The models were saved as stereolithography (.stl) models, colored in Meshmixer (San Rafael, California, USA), and exported as an object (.obj) with material (.mtl) files. The deep brain regions were colored with blue and purple colors, vasculature-colored red, brain matter colored an off-white, and skull/skin colored a medium skin tone.

Stereotactic Frame Models. Two DBS stereotactic frames were reverse-engineered; a Cosman-Roberts-Wells (CRW; Integra Radionics, Burlington, Massachusetts, USA) frame and a Leksell (Elekta Medical Systems, Stockholm, Sweden) frame (Figure 40). The components were manually measured and modeled in SolidWorks (Waltham, Massachusetts, USA). Telkes et al. (2016) provided the BenGun dimensions. The models were saved as stereolithography (.stl) models, colored in Blender

(Amsterdam, Netherlands), and exported as an object (.obj) with material (.mtl) files. The model colors matched the real-world stereotactic frames.

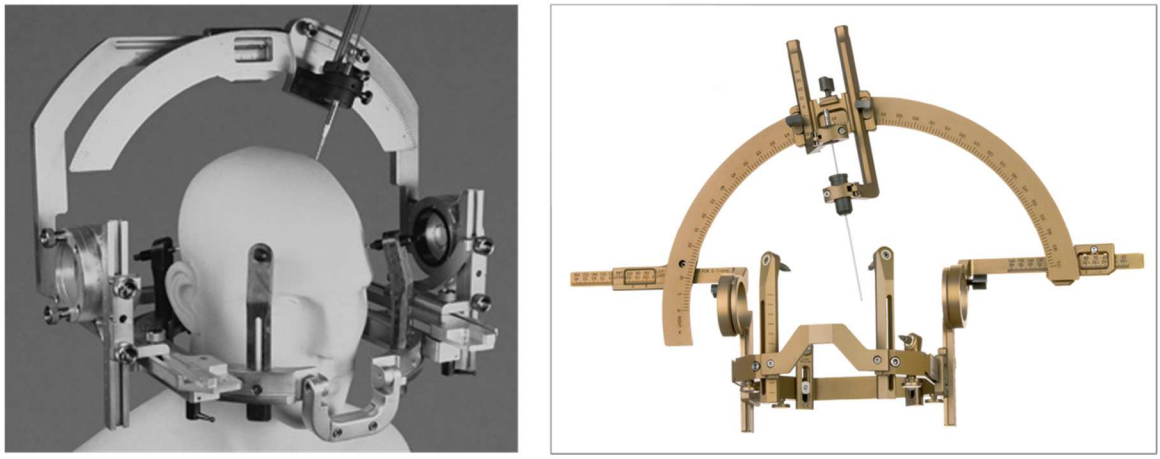

Figure 40. CRW (left) stereotactic frame (Integra Radionics, Inc., Burlington, MA) and Leksell (right) stereotactic frame (Elekta Medical Systems, Stockholm, Sweden).

Electrode Models. Common DBS electrodes were identified and reverse-engineered (Figure 41) based on dimensions from previous literature (Alonso et al., 2016; Anderson et al., 2018; Baniasadi et al., 2020; Rossi et al., 2016). Electrodes without FDA approval were excluded. The electrode's external surfaces were modeled in SolidWorks and were aligned to the BenGun and stereotactic frame models. The models were saved as stereolithography (.stl) models, colored in Meshmixer (San Rafael, California, USA), and exported as an object (.obj) with material (.mtl) files.

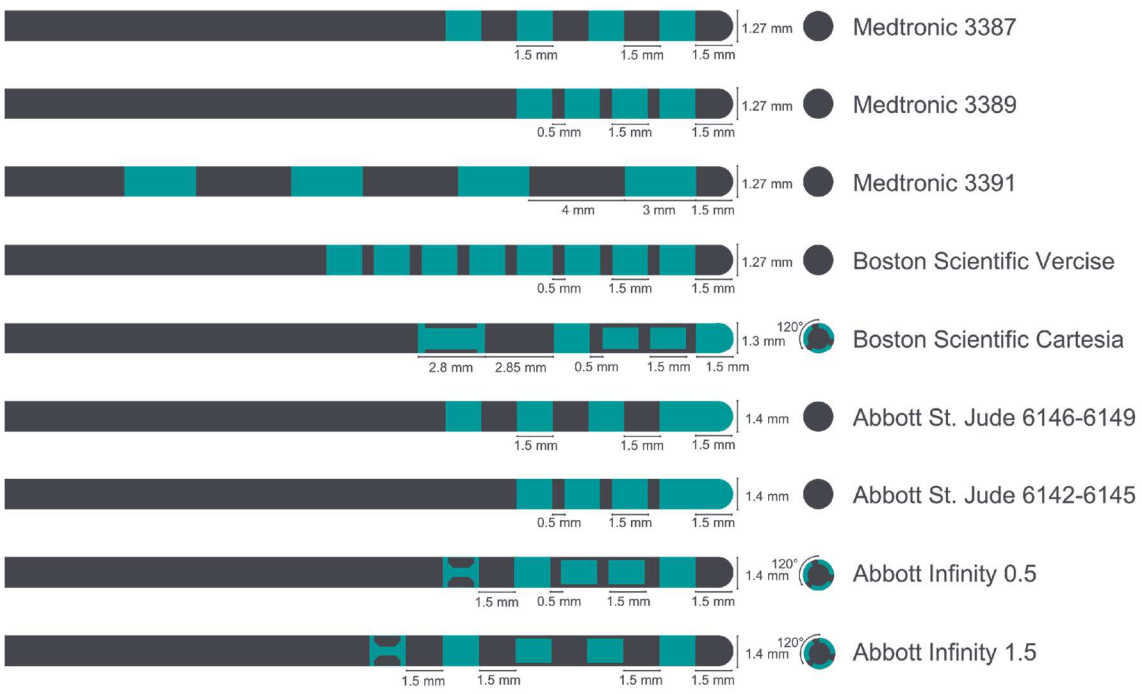

Figure 41. Common DBS electrode geometries. Each electrode pictured shows the side and end view. The electrodes are from Boston Scientific (Marlborough, Massachusetts, USA), Medtronic (Dublin, Ireland), and Abbott/St. Jude (Abbott Laboratories, Abbott Park, Illinois, USA).

Electrical Field Volume Models. Limited published research provided the shapes and sizes of the electrical field volumes. Twelve electrical field volumes were extrapolated from studies by Alonso et al. (2015) and Vasques et al. (2010). Researchers use three methods to model electrical fields: 1) electrode level, 2) tissue level, and 3) neuronal level. Tissue level modeling compares electrical field volume to the target region volume (Alonso et al., 2015). Over the past ten years, Alonso et al. (2016) and Vasques et al. (2010) have used finite element models to study DBS electrical field voltages, isofield shapes, isofield distances, and isofield curvature profiles. Vasques et al. (2010) theorized the electrical field size and shape by overlaying different electrical fields onto electrodes placed in a patient's brain. Alonso et al. (2016) used the equation of continuity to account for electrical conductivity changes between tissue types in the brain. Therefore, discrepancies exist about the electrical field volumes for DBS electrodes.

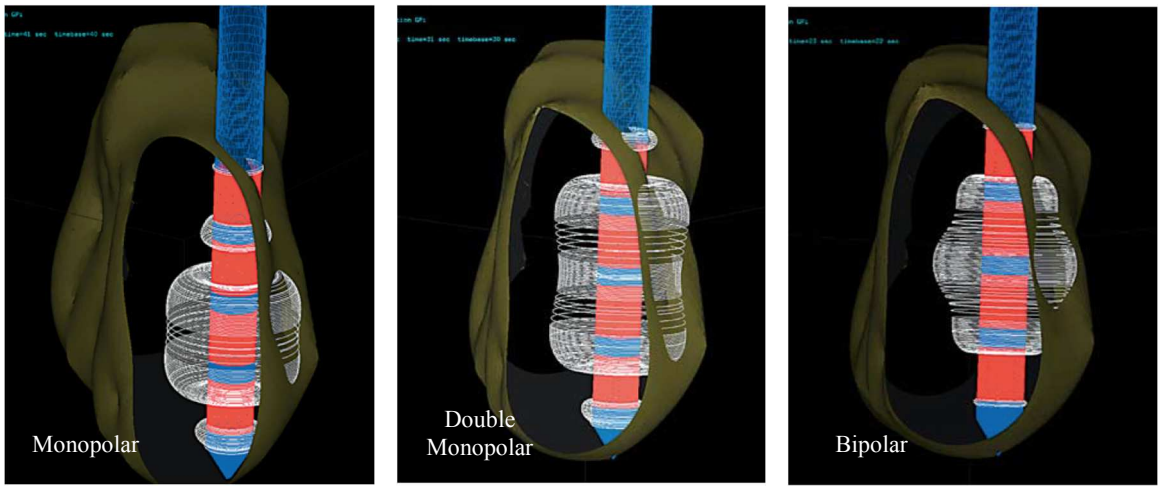

Figure 42. Monopolar, bipolar, and double monopolar electrical field shapes at a voltage of 1.5 V and visualized at isofield 0.2 V/mm (Vasques et al., 2010).

Electrode contacts can be cathodes or anodes, which create different shaped electrical fields. Monopolar, bipolar, and double monopolar (Figure 42) are common electrical fields for standard four contact ring electrodes (Vasques et al., 2010). Monopolar uses one contact ring as the cathode and the DBS box as the anode. Double monopolar uses two adjacent contact rings as cathodes and the box as the anode. In comparison, bipolar uses one contact ring as the cathode and an adjacent contact ring as the anode. The three common electrical field shapes at four strengths: 1V, 2V, 3V, and 4V, were modeled with SolidWorks. The models were saved as stereolithography (.stl) models, colored in Meshmixer (San Rafael, California, USA), and exported as an object (.obj) with material (.mtl) files.

Voltage (V)	Radius (mm)	Monopolar Volume (mm^3)	Double Monopolar Volume (mm^3)	Bipolar Volume (mm^3)
1	1.8*			
1.5 V		29.4^	48.1^	31.2^
2	2.5*			
3	3.0*			
4	3.5*			

Table 5. Electrical field data at 1V, 2V, 3V, and 4V for monopolar, double monopolar, and bipolar shapes. Alonso et al. (2015) presented the radius data for monopolar volumes at 1V, 2V, 3V, and 4V these are denoted by the asterisk (*). Vasques et al. (2010) introduced the volume data for monopolar, double monopolar, and bipolar volumes at 1.5V these are denoted by the caret (^).

The isolevel of 0.2 V/mm is presented more often in the literature (Alonso et al., 2015). The 0.2 V/mm isolevel was used by Alonso et al. (2015) to model the shape and radius of the monopolar isofield at 1V, 2V, 3V, and 4V; see data denoted by the asterisk (*) in Table 5. Vasques et al. (2010) modeled the 0.2 V/mm electrical fields at 1.5V for the monopolar, double monopolar, and bipolar shapes; see data denoted by the caret (^) Table 5. Both studies used the Medtronic 3389 electrode (Figure 41) with a contact ring spacing of 0.5mm and assumed the electrode's tissue was homogeneous. However, Alonso et al. (2015) and Vasques et al. (2010) did not publish enough data to complete Table 5.

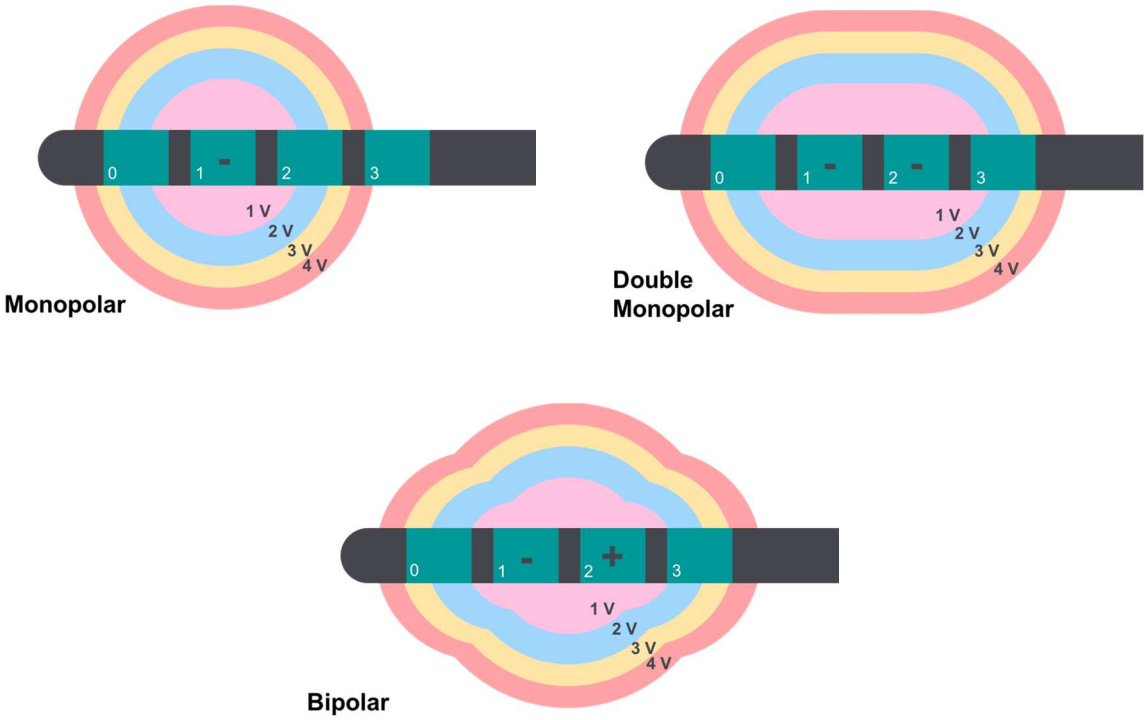

Figure 43. Monopolar (left), double monopolar (center), and bipolar (right) electrical field shapes at four strengths for DBS electrodes.

Alonso et al. (2015) and Vasques et al. (2010) studies informed assumptions about the volume shapes. The first assumption was that the electrical field is symmetrical when revolved around the electrode. The monopolar electrical field volume assumed a sphere shape centered at the contact ring (Figure 43). The double monopolar electrical field assumed a capsule shape spanning two contact rings based on the monopolar radius

(Figure 43). The bipolar electrical field volume (Figure 43) assumed a relative shape as presented by Vasques et al. (2010) (Figure 44). Two simpler shapes defined the relative shape; a large sphere (yellow) based on the monopolar radius and a smaller capsule shape (blue) with three-fourths of the sphere's radius.

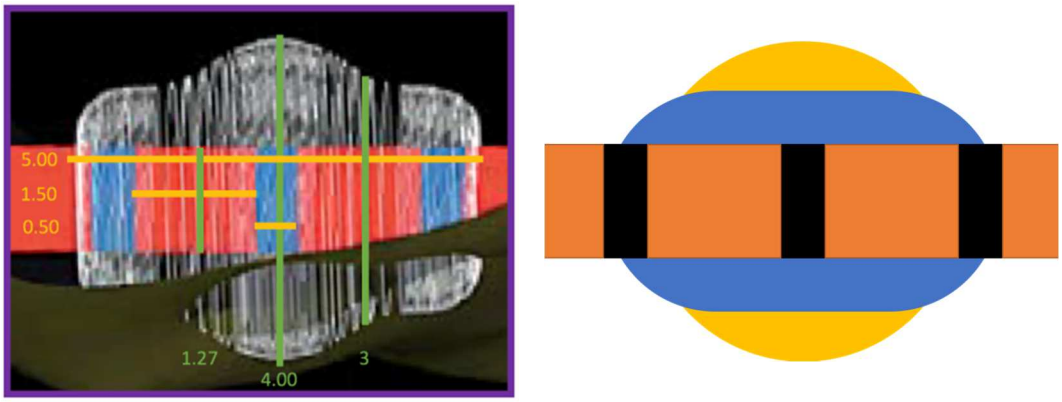

Figure 44. The bipolar electrical field shape from Vasques et al. (2010). Two shapes contributed to the bipolar electric field volume calculations: the sphere (yellow) between two contact rings and a capsule (blue) starting at the center of one contact ring and ending at the second contact ring center.

Graphical User Interface Models. Knowledge gained from the first three phases contributed to the GUI. GUIs are valuable when completing quantitative tasks like DBS procedural planning (Riener & Harders, 2012). The primary workflow tasks and secondary actions were separated into two menus and spatially laid out with the 3D models. The strengths of the two hardware configurations guided the GUI and it was converted to sprites (.png) using Adobe Illustrator (Adobe Inc., San Jose, California, USA).

Phase 4 - Proof-of-Concept Virtual Reality Designs

The task analysis framework, design guidelines, and models guided the development of two virtual configurations for the DBS use case. VR historically uses two hardware configurations: SWD and HMD. As VR technologies for the medical industry evolve, developers will explore which configuration works for different use cases. It is essential to identify technology that best serves the users, the use cases, and the medical

environment of use. Designing for two configurations enabled subject-matter-experts to iterate and evaluate which configuration fits this use case.

The VR configurations were developed in Unity (San Francisco, California), which is an XR toolkit used to deploy designs to multiple platforms. XR is an umbrella term including VR, AR, and MR. The previously described models were imported into Unity to develop the VR configurations based on the task analysis and design guidelines.

Results

The results are presented in the four-phases described above. The first result was a framework that captured the task analysis and DBS clinical workflow needs. The second result presents design guidelines for VR tools to evaluate a patient's anatomy and medical device's relationship. The third result developed models based on the task analysis and design guidelines. The fourth and final result proposes two VR tool designs for the DBS use case. This four-phase approach demonstrates an iterative process to develop a VR tool based on feedback from subject matter experts.

Phase 1 - Task Analysis

The first result was a framework of features for the VR DBS use case (Figure 45), which replicated the workflow. The workflow for the DBS procedural planning starts with importing a patient's dataset into the software. The doctor first identifies the anterior commissure (AC) point, posterior commissure (PC) point, and three reference points along the midline to register the patient's brain to the stereotactic frame. The doctor then confirms the orientation of the patient's brain and begins planning the procedure.

Next, the doctor aligns the electrode model's distal end with a target region in the patient's brain, using cartesian coordinates. The location of the electrode's distal end directly impacts the quality of therapy and the length of the electrode is oriented to avoid specific anatomy and vasculature. Conventional methods use 2D DICOM images to orient the electrode at an oblique angle through the images. The mental workload to review anatomy in 2D images is higher than reviewing anatomical structures with 3D visualizations (Foo et al., 2013).

The FDA has approved several electrodes for use in humans and doctors develop preferences for specific electrode designs as they build their practice. The placement of the contact rings within the anatomy drives the programming process to find an optimal therapeutic response. By reviewing the electrode design with the target location and trajectory orientation, doctors are able to confirm the patient's electrode placement.

The five-port BenGun attached to the stereotactic frame guides the electrode into the patient's brain. A port is selected based on microelectrode readings captured during the procedure based on the electrode's distal tip location. Doctors plan the procedure using the center port, but adjustments made during the procedure can result in over 1mm error in 24% of electrode placements (Bus et al., 2018). The inaccuracies are due to the electrodes' assumed location based on the microelectrode reading (Bus et al., 2018). Visualizing the BenGun options could improve the doctor's assumptions before the procedure.

The doctors use microelectrode readings to confirm the electrode location within the brain. As the surgeon advances the electrode into a patient's brain, electrical readings are captured of the tissue. The readings are cross-referenced in real-time with expected readings by physically overlaying the readings in the operating room. A virtual tool would allow doctors to reverse engineer the microelectrode readings from the electrode orientation before the procedure and generate new readings in real-time to support the surgery. Once the preliminary models are created, microelectrode readings would dramatically improve patient outcomes and the amount of time needed to find an ideal location during the procedure.

Implanting an electrode into a patient's brain is a complex procedure requiring multiple types of data. A centralized workflow which houses all of the data would encourage cooperation between doctors, radiologists, scientists, and engineers to inform the surgical planning for complex anatomy (Robiony et al., 2007). The virtual tool can serve as a centralized checklist, which has been shown to improve communication and reduce the number of adverse events during complex neurointroventional procedures

(Fargen et al., 2013). Matching the workflow also creates a point of comparison to validate the virtual tool against existing methods.

The contribution of phase one is a clinical workflow for DBS. The workflow is captured in a framework which includes doctor's tasks, software functions, and GUI features to support the user. The framework then guides the VR experience. A virtual tool is beneficial for the DBS use case by providing a spatial awareness between the medical devices and anatomy which is critical to plan a DBS implantation.

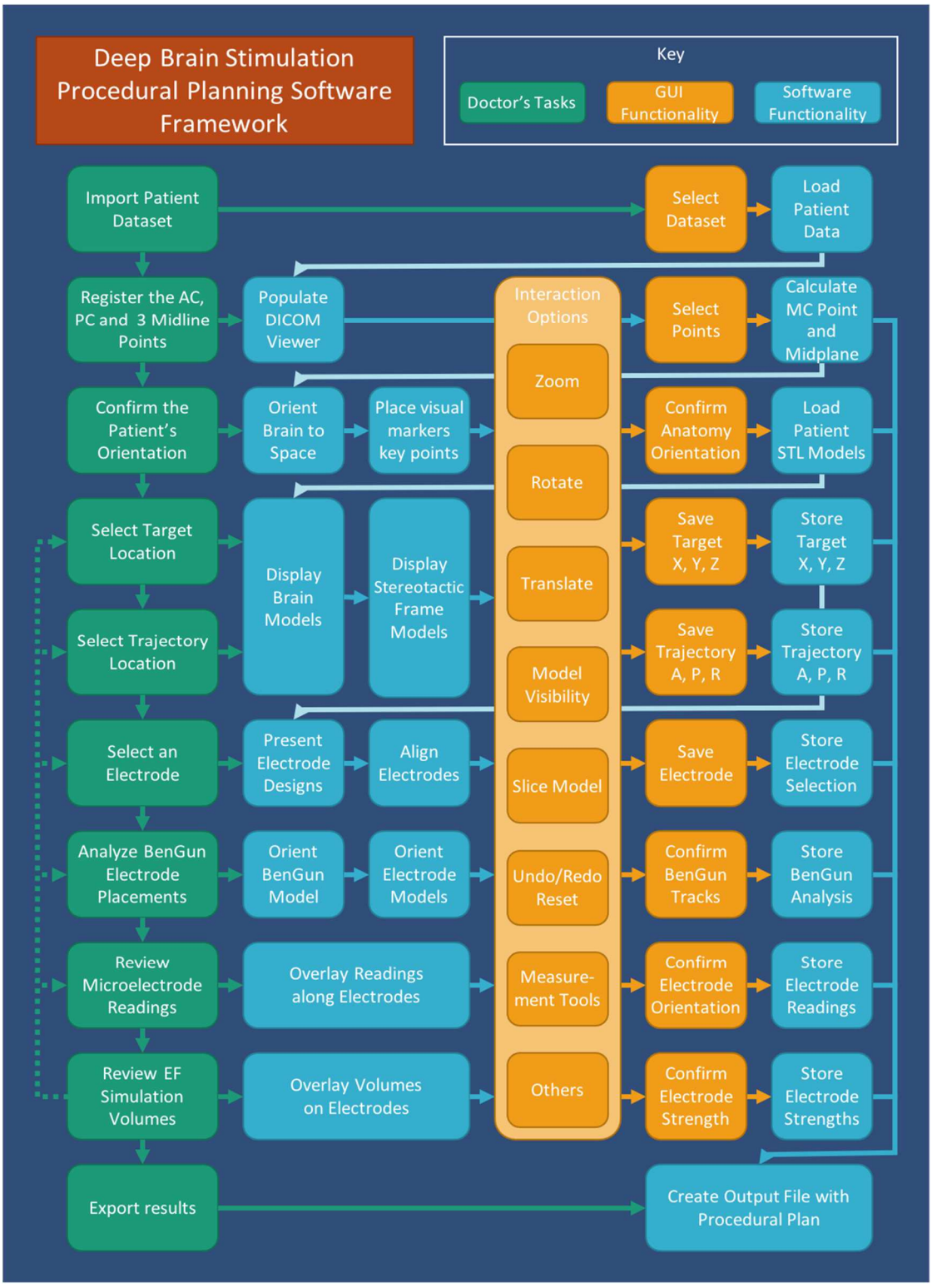

Figure 45. The framework of features needed for a VR DBS tool. Tasks the doctor must complete are in green. The software's computational functions are defined in blue, while software usability features are in yellow. The arrows show the flow of data.

Phase 2 - Design Guidelines

The third result was generalizable design guidelines. The intended audience for these design guidelines are designers and developers who are focused VR experiences with patient-specific anatomy and medical device visualizations. The guidelines assume the use of commercially available hardware and assume hardware companies applied human factors and usability guidelines during development.

Virtual Reality Technology for the Medical Industry – Design Guidelines

Medical Industry

Design VR technology specifically for the medical industry. Medical professionals have specific requirements for technology used in a medical setting, therefore user needs must be identified before designing a VR experience (Stanney et al., 1998). Medical simulation is one area that could be advanced through VR. Healthcare professionals use medical simulation to safely conduct training. Traditional medical simulations include task-based trainers, mannequin simulations, standardized patients, *in situ* trainings, and tissue-based simulations. The American Council of Graduate Medical Education has identified six common medical simulations; patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and system-based practice (Rehder et al., 2016).

Determine the benefits of VR technology for the specific use case. The interactive displays of VR systems have been shown to benefit medicine (Stanney et al., 1998), especially when 2D data is reconstructed into relevant 3D visualizations for simulating, planning, and predicting surgical outcomes (Chan et al., 2013). Simulations recreate real patient outcomes to create guided interactive learning opportunities (Rehder et al., 2016). Research has shown virtual simulations increase retention of learned skills when actively engaging users (Stanney et al., 1998), improve users spatial awareness of a procedure through repetition (Lin & Woldegiorgis, 2015), and influence the clinical decision-making process (Chan et al., 2013; Stadie et al., 2008). VR can also accelerate planning procedures and reduce overall costs (Ware, 2013). Specifically, medical VR

simulators are a more cost-effective training option than cadaver labs or training through real patient procedures (Chan et al., 2013).

Determine the risks of VR technology for the medical use case. Many factors increase the risk of medical errors occurring. Medical errors are due to inadequate information, inappropriate mental processing of information, inappropriate actions, and situational factors like stress, fatigue, or excessive cognitive workload (Bogner, 2009; Gawron et al., 2006). VR technology in medicine is classified as HIT. Researchers have found eight sources of medical errors associated with HIT: computer screen display, drop-down menus and auto-population, wording, default settings, non-intuitive or inflexible ordering, repeated prescriptions or automated processes, users' work processes, and clinical decision support systems (Turner et al., 2017). A user's ability to complete tasks with HIT is also dependent on the surrounding environment (Bogner, 2009; Gawron et al., 2006). HIT should be designed to integrate with the user's workload, decrease user errors, and reduce the response time in critical situations (Bogner, 2009). Another risk to consider with any new technology is how the technology changes the social constructs and collaborative nature of a medical environment (Stanney et al., 1998).

Develop a tailored framework for each use case. Although many VR developers promote the cost-competitive approach of applying a specific VR experience to many medical specialties, this strategy is not well suited for individual users and their specific medical workflow-based tasks (Turner et al., 2017). Medical VR technology should be designed for specific use cases, specific user needs, specific workflows, and specific environmental considerations (Stanney et al., 1998). The best use of VR technology is when the user's functional capacity, reliability, and performance all increase, while also decreasing the number of user errors within a medical setting (Bogner, 2009; Gawron et al., 2006).

Include the complete medical workflow in the virtual environment. The virtual tool must support the doctor through their entire process (Gawron et al., 2006; Stadie et al., 2008) and be optimized for the medical devices, surgical procedures, and doctor's goals (Riener & Harders, 2012). Research has shown enhanced user performance when

the workflow in the VR environment matches the user's cognitive process (Stanney et al., 1998). Another way to help the user adapt to the VR experience is to match the virtual world to the real world (Vi et al., 2019), this environment matching guides the user through the workflow.

Determine the limitations of completing tasks in a virtual environment. Users will perform tasks differently in different environments. A virtual environment may work well for some tasks and not well for other tasks (Gawron et al., 2006; Stanney et al., 1998). Human factors research can help determine which tasks are best performed by humans and which tasks are best performed by computers (Bogner, 2009). Ware (2013) identified many tasks that benefit from VR when visualizing data, such as fine depth judgment, accurate reaching, and navigating. Once tasks are selected and designed into the VR experience, it is critical to evaluate if the user performs as expected in the virtual world compared to the real world (Rehder et al., 2016).

Include metrics into the design of the virtual experience. Metrics provide feedback to a doctor about performance and are used to validate the design of a VR experience. Performance metrics may include medical device's placement, time on task, amount of tissue removed, etc. (Rehder et al., 2016). The overall user's experience should be the focus of validation studies and should include; navigation issues, sense of presence, and task outcomes (Stanney et al., 1998).

Guide users with contextual cues from the real world. Contextual cues embedded in the VR environment show users how to perform a task (Stanney et al., 1998). These cues help users start tasks, learn information, focus their attention, and simplify their choices (Vi et al., 2019). Cue redundancy is also helpful in VR environments to mimic learned human behavior. For example, human communication includes both verbal and physical cues to convey information (Stanney et al., 1998). Cues can also be used to inform the user of the dangers or consequences (Vi et al., 2019).

Allow users to choose the order in which they complete the workflow. Medical procedures are highly variable with sometimes unpredictable outcomes, which results in

users proceeding through a workflow in a nondeterministic order (Chan et al., 2013). Carefully designed experiences that consider the user's needs and environment of use, help users feel in control and facilitate learning and training (Izard et al., 2017).

Determine the scope of the VR experience based on the use case. Medical simulators are designed in two forms: tool-based or phantom-based (Riener & Harders, 2012). Users interact with medical devices or tools in a tool-based simulation and anatomy in a phantom-based simulation (Riener & Harders, 2012). Medical simulators include many components; medical knowledge, anatomical and medical device models, tissue simulations, fluid simulations, immersive environment, interaction techniques, haptic feedback, and collision detection (Riener & Harders, 2012; Stadie et al., 2008). The expertise to develop these components come from many different disciplines; computer science, physics, imaging, mechanical engineering, medical illustration, and medicine (Chan et al., 2013).

Design the VR system to support novice and expert users through the learning process. Novice and expert users' abilities and requirements are not always the same as they work to build their skillsets (Stanney et al., 1998). Novice users need to learn anatomy and develop basic procedural skills (Chan et al., 2013), while expert users are looking to refine their skills. A VR experience should cater to individuals at all levels of experience (Vi et al., 2019), especially as doctors become accustomed to using VR tools in their practices. Providing feedback about performance and mistakes is also necessary as users complete more difficult tasks (Delorme et al., 2012).

Develop design standards for the use case and be consistent with other medical virtual experiences. "Good design is standardized design" (Ware, 2013). Only adopt novel designs when the benefits outweigh the users' learning curve (Ware, 2013). Inadequate or ambiguous designs of HIT lead to human errors when delivering medicine (Bogner, 2009; Gawron et al., 2006). Objects should be recognizable, connections between data points should be clear, and data should highlight when a specific criterion is reached (Ware, 2013). The virtual space can be used to organize objects by grouping similar items. Groupings draw attention to linked features and reduce the user's mental

workload when performing tasks (Vi et al., 2019). The choice of VR hardware will change how the virtual space can be used and how the user explores the virtual space (Vi et al., 2019). Although the user experience is technology-dependent, mass adoption of these technologies requires the experience to be independent of location, time, and devices (The CyberXR Coalition, 2020). Consider designing the experience to be compatible with various hardware on the market.

Identify design principles appropriate for the use case. Many organizations have developed design principles for HIT with the goal to improve overall usability of these technologies. Examples of design principles for VR experiences include: "consistency of design and standards, visibility of system state, match between systems and world, minimalist design, minimization of memory load, informatics feedback, flexible and customizable systems, useful error messages, technology-induced error prevention, reversible actions, clear closure, user language utilization, user control, and appropriate help and documentation" (Turner et al., 2017).

Create simplistic and comprehensive virtual experiences. Comprehensive environments resonate more with users; but more is not always better. Irrelevant information competes for the users' attention and can draw the user away from the primary tasks (Vi et al., 2019). These unnecessary details add complexity into the development process and increases the real-time computational requirements (Delorme et al., 2012), which may cause latency issues for the user (Riener & Harders, 2012). Virtual environments are also very labor-intensive and costly to produce. A realistic house model may take three person-years to complete, while virtual scenes for the movie industry take 15 person-years to complete (Riener & Harders, 2012).

Be consistent with how features are designed throughout the VR experience. Users learn about the virtual environment based on their previous experiences. Due to this recall, it is important to preserve how the user views the VR environment as they switch from one task to another task (Ware, 2013). Similar representation of objects and user viewpoints are forms of visual feedback that reinforce and guide the user to the next interaction (Vi et al., 2019). Graphic symbols should be consistent within the VR

experience and across other VR experiences familiar to the users (Ware, 2013), while consistent navigational techniques help the user maintain their orientation in the spatial environment (Stanney et al., 1998). Users should clearly receive feedback from the virtual environment to show them what they are and are not able to do (Vi et al., 2019).

Consider the user experience at every step in the design process. Humans have physical and cognitive limitations when performing tasks in virtual environments (Gawron et al., 2006; Stanney et al., 1998). These characteristics drive users' acceptance of a virtual experience (Stanney et al., 1998) and can be exacerbated by the environments where the technology is being used. Healthcare environments are one example of inherently complex environments. The healthcare environment places extra burdens on users, as they are juggling numerous tasks when using HIT. Therefore, the design of these technologies need to consider the environment of use (Bogner, 2009). HIT, specifically VR technology, must 1) demonstrate the rationale of any decision-making process, 2) increase the functional capabilities of humans (Bogner, 2009), and 3) include any data uncertainty (Ware, 2013).

Evaluate the design for reliability and validity. Reliability assessments focus on the repeatability of outcomes, while validity assessments focus on the accuracy of outcomes. Assessments need to be structured (Rehder et al., 2016) and include multiple factors to understand how design decisions interact and impact the user experience (Lin & Woldegiorgis, 2015). Evaluations are most effective when they focus on task outcomes, the complexity of the VR experience, and the user's sense of presence in the VR environment (Stanney et al., 1998).

Design for human limitations. Many human limitations impact user's abilities to perform tasks in a virtual environment (Stanney et al., 1998). One limitation is a user's mental workload. A user's mental workload increases when interacting with a virtual environment and also negatively impacts performance (Stanney et al., 1998). Other limitations are cybersickness and stereoblindness. Between 12-60% of the population experience cybersickness (Stanney & Hash, 1998), and up to 10% of the population are stereoblind (Riener & Harders, 2012). Stereoblind users experience difficulties when

perceiving stereo images (Riener & Harders, 2012). VR technologies need to be designed for all users' abilities, especially as virtual technology becomes a standard medical tool.

Limit the use duration with VR technology. Users can experience eye fatigue after 30 minutes of use, which can negatively impact one's ability to perceive depth in the virtual environment (Stanney et al., 1998).

Include a required debriefing phase after each VR experience. Users need time for their visual system to adjust to the real world after a virtual experience (Stanney et al., 1998).

Anatomical and Medical Device Models

Accurately represent anatomy and medical devices in the virtual environment. The primary purpose of VR technology in the medical industry is to support the decision-making process—technologies aid doctors in making informed decisions to guide a clinical diagnosis. Therefore, representing the patient's anatomy and the medical devices accurately is essential to provide safe patient care.

Include the anatomical models that replicate the medical task. Model characteristics can vary based on the goals of the medical simulation. Create or select appropriate models to support the intended outcomes of the VR experience based on the user's goals and needs (Chan et al., 2013).

Select the appropriate data source for the patient-specific dataset. CT and MRI technology are common sources of patient-specific datasets. CT technology uses x-ray technology and best for bone models or with contrast to define the cavity. MRI technology creates a magnetic field to stimulate protons and best for soft tissues. Determine the appropriate imaging technique for the anatomy of interest (Riener & Harders, 2012) and the scan settings that fit the quality needs of the final virtual model (Juhnke, Novotny, et al., 2019).

Choose an appropriate rendering method to visualize the data. Anatomical data is typically rendered as a volume or as a surface. Volumetric data is directly rendered from

the source data. Direct volume rendering is more accurate than surface rendering but requires more computational resources (Chan et al., 2013). However, when introducing medical instruments, issues arise. Medical instruments are polygon-based models, which are surface rendered. A custom rendering method would accommodate volumetric anatomical data and polygon-based models (Chan et al., 2013). Volumetric data can be segmented using software to create polygon-based models; however, these require time and expertise to produce. Many research efforts are developing automatic or semi-automatic segmentation methods to ease the burden of segmenting anatomical data.

Use closed shapes to represent anatomy, if using polygon-based models. Closed shapes provide more information to the user about where one model stops and the next model starts. The difference between the model's surfaces can highlight gaps or overlaps (Juhnke, Mattson, et al., 2019; Kloesel et al., 2021). Changing the color, shape, and size of the objects can add attributes to the anatomy (Ware, 2013).

Include blood vessels in the virtual environment. Users benefit from SWDs when viewing 3D pathway-like structures (Ware, 2013). Blood vessels are an integral part of a patient's physiology (Riener & Harders, 2012) and should be included when reviewing anatomy, especially procedural planning VR experiences (Delorme et al., 2012). Blood vessels have traditionally been excluded from software-based medical simulations presented on computer screens because they clutter the model and detract from the experience (Miocinovic et al., 2007).

Include bone models as landmarks in the VR environment. Bone models provide essential reference points for a surgical procedure (Izard et al., 2017) and help transfer knowledge from the preoperative plan to the intraoperative procedure (Chan et al., 2013).

Use standard colors for anatomical models. Medical illustrations are common training tools in medicine. The illustrations present anatomy as accurately as possible with the goal to educate students (Hodges, 1989). Realistic colors serve as cues to orient

the user to the virtual models (Izard et al., 2017). Matching well-established standards improves the efficiency at which a student will learn the presented material (Ware, 2013).

Use color to organize or differentiate models if needed for a specific task. Color is beneficial to classify and separate models quickly (Ware, 2013).

Use lighter colors to code large sections of reference anatomy and transparencies to show internal models (Ware, 2013). Reference models, like blood vessels and bone, help doctors transfer knowledge from the virtual world to the real world (Chan et al., 2013). Research has also found virtual displays enhance the user's ability to understand models within models when the outer model is semi-transparent (Ware, 2013).

Avoid applying generic textures and graphic patterns to patient-specific models. Texture mapping is a standard practice when creating VR environments. For example, a brick texture can be applied to an unlimited number of walls for the appearance of a brick wall. However, standardized textures can also cause aliasing in a VR environment. Texture aliasing occurs when a texture is scaled, rotated, or mapped onto a surface and either distracts or interferes with the user interpreting the model due to the surface texture (Ware, 2013). Patient-specific models have a natural shape and texture from the segmentation process. If needed, textures must be carefully designed as they impact interpretation and virtual distance measurements (Lin & Woldegiorgis, 2015). High-quality artist-rendered textures increase realism but also increase computational needs when viewing the models and are unrealistic for routine patient-specific medical models (Delorme et al., 2012). Results from Part 1 indicate that medical professionals expect models to be ready within 1-3 business days.

Use simple shapes (spheres, cylinders, cones, and boxes) to place landmarks in the environment (Ware, 2013)**.** Landmarks are specific locations not captured in the anatomical models that serve to guide the doctor when analyzing the patient's data.

Include simulations to create a realistic virtual environment. Realistic simulations are the most challenging features when developing virtual environments (Rehder et al., 2016). Many researchers are developing realistic simulations and methods

to use the simulations in real-time. One challenge when developing realistic simulations is capturing appropriate tissue properties. Tissue properties are challenging to study ex vivo, and VR rendering engines lack the power to perform the real-time computations necessary to keep pace with the user (Chan et al., 2013; Riener & Harders, 2012; Stadie et al., 2008). As the use of VR continues to grow in the medical industry, expect to see more availability of realistic virtual simulations.

Include medical devices in the virtual experience. Medical devices are an important component of a virtual experience for the medical industry. The fit, size, shape, and how a medical device interacts with the human body is important knowledge for doctors. Tool-based training simulators help doctors analyze the medical device's properties in the patient-specific anatomy (Riener & Harders, 2012; Stadie et al., 2008).

Use shaded tubes or other extrusions to represent trajectories. Trajectories are pathways that show motion. These pathways may show blood flow directions or how a medical device passes through anatomy. To assist the user, include periodic bands or other markings to orient the trajectories in the anatomy (Ware, 2013). Stereoscopic displays help users perceive trajectories in 3D space (Ware, 2013).

Use real-world coordinate systems to place models in the virtual environment. Many medical procedures use precise coordinate systems to administer therapy to a patient (Riener & Harders, 2012). Matching the coordinate systems helps users transfer the knowledge from the virtual world to the real world (Stanney et al., 1998).

Orient the models to match the real-life perspective of the user. Users recognize objects by matching their viewpoint with previous real-life experiences stored in their memory (Ware, 2013). The virtual environment should include adequate detail for users to make connections and understand what is needed for the task (Delorme et al., 2012). These connections between the virtual and real viewpoints promote learning and improve the transfer of skills between the environments (Stanney et al., 1998).

Environment

Create a realistic medical environment. The success of VR's in the medical industry depends on users believing the experience is trustworthy and real (Lin & Woldegiorgis, 2015). Users are looking to interact with virtual anatomy, just like real anatomy, explicitly using their hands to manipulate the anatomy (Izard et al., 2017; Riener & Harders, 2012), while medical devices should appear realistic by including handles, features, orientation, and deformability, if appropriate (Delorme et al., 2012).

Create an immersive environment to improve a user's sense of presence. Immersion is a combination of visuals, audio, and narrative elements to capture the user's attention (Vi et al., 2019). Research has shown immersing users in a virtual environment similar to their real world experience results in a higher positive transfer of skills from the virtual to the real world (Stanney et al., 1998). Skills transfer is important for the medical industry when VR experiences are used to educate, train, and plan procedures that impact patient care. Users' perception of presence is dependent on the vividness of the VR environment and how much they can interact with the environment (Stanney et al., 1998). Combining elements from the real world into the virtual environment creates a multisensory experience and intuitive interface design (Stanney et al., 1998).

Avoid dressing up the virtual environment with animations or attractive objects. Users have a higher transfer of knowledge when working with accurately displayed data (Ware, 2013).

Use stereoscopy to help users understand complex spatial relationships. Stereoscopy is the primary depth cue when understanding complex 3D spatial relationships (Chan et al., 2013). Anatomical models are an example of complex 3D spatial relationships. When working in stereoscopy, users will perform tasks differently depending on how the tasks are placed in the VR environment. Tasks near the user that require fine depth judgments and accurate reaching benefit the most from stereoscopy, while motion parallax is less important for these tasks (Ware, 2013). When objects are close together, stereoscopy helps the user understand objects' relative depths compared to

the user's perspective (Ware, 2013). Stereoscopy is most effective within 10 meters of the user and optimal when objects are at arm's reach (Ware, 2013).

Provide secondary depth cues to support the primary depth cues. Users benefit from additional depth cues when performing complex navigational tasks (Stanney et al., 1998). These secondary depth cues include occlusion, relative size, relative density, height in the visual field, aerial perspective, motion perspective, convergence, accommodation, texture, linear perspective, brightness, lighting and shading, kinetic depth, kinetic occlusion, and gravity (Lin & Woldegiorgis, 2015). Choose the appropriate depth cues to support critical tasks in the 3D data visualization (Ware, 2013). For example, halos add to the occlusion depth cue by differentiating overlapping objects and one technique only places halos along the overlapping edges of an object to visually separate the objects (Ware, 2013).

Avoid placing objects in the user's personal space. Virtual environments have three regions of space: personal space is within 1.5 m of the user, action space is from 1.5-30 m away from the user, and vista space is beyond 30m from the user (Lin & Woldegiorgis, 2015). Users should determine which actions occur in their personal space, this is accomplished by initially placing objects at a comfortable distance from the user and allowing them to move towards objects (Vi et al., 2019). Personal comforts in a VR environment include physical, psychological, and environmental factors (Vi et al., 2019).

Design the environment to reduce cybersickness. Cybersickness is the leading cause of discomfort for users in a virtual environment. Between 12-60% of the population will experience some level of simulator sickness (Stanney & Hash, 1998). Designers are responsible for reducing cybersickness (Vi et al., 2019), as cybersickness is the most important health and safety factor affecting VR technology adoption (Stanney et al., 1998). Mental rotation exercises are good predictors of those who are more or less susceptible to cybersickness (Stanney et al., 1998) and the Simulator Sickness Questionnaire is the most common method to measure cybersickness after a VR experience (Weech et al., 2019).

Reduce visual clutter in the virtual environment. Visual clutter negatively impacts the user's experience. Research has shown simplified environments cause lower levels of reported user cybersickness (Saredakis et al., 2020). Irrelevant information competes for the user's attention when completing tasks in a virtual environment (Vi et al., 2019). Research has also shown more accurate measurement estimates when working in a sparse scene (Lin & Woldegiorgis, 2015). More models in a VR environment are also cost-prohibitive as they increase the computational requirements needed to run the VR experience (Delorme et al., 2012).

Reduce visual latency. Slow loading graphics are another factor that contributes to cybersickness. Users can experience cybersickness if the graphics lag by as little as 15 ms (Riener & Harders, 2012). As more models increase the real-time computational requirements; aim for 60 Hz for graphics and 1000 Hz for haptics (Delorme et al., 2012).

Reduce the amount of data in the user's peripheral view. Objects moving in the user's peripheral view is a third factor that contributes to cybersickness. A wider field of view increases the user's sense of immersion but also increases cybersickness (Stanney et al., 1998). Place objects within an allowable field of view to reduce the need to turn one's head or body to interact with the virtual environment (Vi et al., 2019). Research has also found that restricting the user's field of view when moving through the environment can reduce cybersickness (Fernandes & Feiner, 2016). When considering the field of view into the VR environment design, be cautious of hardware manufacturer's published field of view estimates, as these are often inaccurate (Stanney et al., 1998).

Use light to help users analyze the anatomy and medical devices. Lighting impacts how the user perceives shapes and cavities in a VR environment (Izard et al., 2017). The brain is more effective at determining an object's shape when only a single light source is used (Ware, 2013). Shadows from multiple light sources are more confusing than helpful for the brain to perceive virtual shapes (Ware, 2013). Research has also shown users make more accurate distance judgments when working in a rich, bright environment (Lin & Woldegiorgis, 2015).

Evaluate the purpose of cast shadows. Cast shadows in a VR experience can positively or negatively impact a user depending on the design of the environment. If the models are arranged in 3D space, avoid cast shadows in these environments. Cast shadows between models cause user confusion, especially when it is unclear which model is casting the shadow (Ware, 2013). If the models are arranged relative to a flat surface, use cast shadows in these environments. Shadows cast to a flat surface can tie objects together and provide additional depth cues (Ware, 2013). If the purpose of the VR experience is to replicate a camera's view with a single light source used internally during a surgical procedure, use cast shadows to replicate the camera view and procedural experience (Delorme et al., 2012).

Change the luminance of objects based on their proximity to the user. Luminance is the amount of light emitted from the surface of an object and adds another depth cue to the VR environment. Models farther from the user should be faded into the background by either lightening the model when using a light background or darkening the model when using a dark background (Ware, 2013).

Keep the camera view with the user. A user's physical movements or actions should be the only method to change the user's view of the virtual environment. Users feel in control of the virtual experience when their physical movement changes their viewpoint (Vi et al., 2019). Two types of spatial navigation are available to support a user's task; turntable or helicopter (Ware, 2013). Turntable is when the user rotates the models while the user remains stationary, and helicopter is when the user moves around the models while the models remain stationary. The natural movement of a user provides a secondary depth cue called motion parallax, which further supports tasks in the virtual environment (Ware, 2013).

Choose the right visual perspective for the task. VR environments can be 'drawn' from either a linear or parallel perspective. Perspective depth cues are secondary cues in a virtual environment. Linear perspective is the most helpful when the primary task is to translate objects through the virtual environment (Ware, 2013). However, when combining linear perspective with cast shadows and motion parallax (depth cue from user

motion), linear perspective has a negative effect by increasing user errors (Ware, 2013). Parallel perspective combined with kinetic depth (depth cues from model rotation) have a negative effect by distorting objects when rotating models (Ware, 2013).

Provide auditory feedback to confirm a user's action. Auditory feedback is a secondary cue in a VR environment. Human communication naturally includes primary and secondary cues to exchange information (Stanney et al., 1998). Visual, audio, and narratives help capture and immerse a user in the virtual experience (Vi et al., 2019). When designing audio feedback, remember to keep continuous sounds under 80 dBA (Stanney et al., 1998).

Include haptic feedback to enhance the virtual experience. Haptic feedback provides even more cues to help users immersive themselves in the VR environment (Stanney et al., 1998). Most patient-specific virtual experiences for the medical industry only focus on VR's visual component (Riener & Harders, 2012). Research has shown challenges arise when trying to accurately couple deformable-body simulations with haptic responses in a closed-loop, responsive manner (Chan et al., 2013).

Interacting with the Virtual Environment

Design the interface to support the user. The interface of a VR experience is everything visible to the user. Cues designed into these visuals signal to the user how to perform a task; guiding the user to the easiest path to complete the virtual tasks (Ware, 2013). Cues can be presented in many forms: images, moving or static objects, written or spoken words, models, or GUIs (Ware, 2013). As a designer, it is important to select which cues are appropriate for the user's task (Ware, 2013). For example if the task is to find patterns, a highly interactive and fast interface is necessary to support the user (Ware, 2013).

Include natural interactions for the user. User actions are the primary way they interact with the interface of the VR environment. Natural interactions in the virtual environment match the user's real-world actions to complete a task. Users develop a sense of being in charge of their own experience when the environment responds as

expected (Vi et al., 2019). One example of this, would be matching the direction of the user's hand movement to the direction the object either translates or rotates (Stadie et al., 2008; Ware, 2013). Another example would be allowing the users to use both hands to interact with the VR environment if they perform the real-world task with both hands (Delorme et al., 2012). It is important to design effective interactions for users, as research has shown interactions in the virtual environment increase mental workload, which can negatively offset any human performance gains (Stanney et al., 1998). The next step in developing natural interactions is pairing voice commands with the gestures to improve how users communicate with the virtual environment (Ware, 2013).

Consider controller-based interaction. As described, natural interactions are important in the design of intuitive virtual experiences. Controller-based interactions may be appropriate based on the task. Natural interaction with anatomical models may involve a real surgical instrument to ensure the correct transfer of motor skills from the virtual world to the real world (Chan et al., 2013). Research found authentic interactions with anatomical models in a virtual environment helped plan patient-specific surgical procedures (Riener & Harders, 2012). There are benefits for the user to have a physical item to hold while interacting with the virtual environment. Users interacting with the virtual environment through controllers tend to experience less cybersickness compared to stationary locomotion (Saredakis et al., 2020) and adapt better to conflicting depth cues (Stanney et al., 1998).

Display the user's hands or controllers in the virtual environment with graphical proxies. Research has shown co-locating a user's hands into the virtual environment is a useful cue when performing tasks (Chan et al., 2013; Ware, 2013). Co-locating a user's hands means placing virtual models (hands, controllers, simple shapes, etc.) as a visual representation to signal where the user's hands are located in the virtual world. If the virtual experience is designed for team-based tasks, these graphical proxies can also support communication in the virtual environment by providing a bridge between the visuals and spoken language (Ware, 2013).

Place objects within the virtual environment to reduce the physical demand on users. Although users are working in a virtual environment, they still have physical limitations. Objects should be placed in locations throughout the virtual environment so the user can view the models for extended periods of time and use relaxed motions to physically interact with the models (Vi et al., 2019). Users can experience fatigue during long sessions or repeating motions to interact with virtual models (Vi et al., 2019). Repetitive motions can also cause physical injury. Incorporate ergonomics and appropriate usage procedures into the virtual experience to help mitigate physical injury (Stanney et al., 1998). Remember, the user may also be physically supporting heavy and bulky equipment to participate in the virtual experience (Riener & Harders, 2012).

Include tools and appropriate depth cues to support users who need to measure distances. In general, users are not accurate when making distance judgments in a virtual environment. Comparing the sizes of objects (i.e., object A is larger than object B) is easier in a virtual environment than estimating the size of an object (i.e., the object has a width of X) by real-world standards (Ware, 2013). If distance measurements are needed for the task, design the environment so the user takes the measurement from themselves to the object (egocentric) and the measurement is captured within arm's length of a user (peripersonal space) (Lin & Woldegiorgis, 2015). Research has shown virtual measurements under these conditions are the most accurate (Lin & Woldegiorgis, 2015). Occlusion, height in the visual field, binocular disparity, motion perspective, and relative size are also important depth cues to support distance measurements (Lin & Woldegiorgis, 2015). Technology differences also impact distance measurements. Users are better at estimating a measurement near them when using an SWD than an HMD (Lin & Woldegiorgis, 2015).

Provide a graphical user interface to support quantitative tasks. A GUI can present task-specific information about a medical device or therapy to support highly accurate and quantitative tasks (Riener & Harders, 2012). Carefully designed GUIs provide the most useful cues for a particular task (Ware, 2013). Research has provided useful guidelines for 2D interfaces. Fitt's Law can help determine where to place a GUI

based on button sizes needed to achieve desired user response time (Ware, 2013). When designing buttons, also contrast text color with the background button color and use shading to emphasize flat displays (Ware, 2013).

Features and Functions

Include functions to support the user while completing tasks. Functions are important to support the user as they complete virtual tasks. These functions should simplify the user's workflow so users can focus on important decisions in the virtual environment (Vi et al., 2019).

- *Register data.* Automatically register patient-specific anatomical models to the virtual environment (Chan et al., 2013).

- *Fly-through.* Enable the user to fly-through the patient's anatomy. A fly-through is an important step to confirm a diagnosis (Riener & Harders, 2012) and strengthen confidence in a procedure (Kloesel et al., 2021). For camera-guided procedures, align the fly-through perspective to the camera's tip (Stadie et al., 2008).

- *Zoom.* Enable users to zoom in and out of the models. Set the zoom scaling rate to 3-4x per second so users can keep their awareness of the virtual environment (Ware, 2013).

- *Object Clicking.* Allow users to double click on an object to scale and center the object in the workspace (Ware, 2013).

- *Visibility.* Allow users to hide, minimize, or turn off elements (Vi et al., 2019).

- *Clipping Plane.* Include a clipping plane to ground the models. A reference plane is one of the most effective tools to help users estimate objects' size (Ware, 2013).

- *Measurement Tools.* Provide a measurement tool. Distance judgments in virtual environments tend to be inaccurate, as users struggle to transfer spatial knowledge to the real world (Lin & Woldegiorgis, 2015). Relative distance measurements

should be available in standard units of measure (meters, inches, etc.) (Lin & Woldegiorgis, 2015).

- *Tasks Metrics.* Provide metrics to assist the user's completing tasks (Rehder et al., 2016). For example, provide recommendations about the appropriate placement of a medical device in the patient's anatomy.

- *Hover over.* Include a hover over feature to provide more information. A hover over feature is a low-cost action to learn more about a model or task (Ware, 2013).

- *Undo and Redo.* Include easily accessible undo and redo functions. Allow users to freely explore the application while providing protections to avoid mistakes (Vi et al., 2019).

- *Reset.* Allow users to quickly reset the models while exploring the environment (Vi et al., 2019).

- *Help.* Provide users additional assistance when learning the application (Vi et al., 2019).

- *Output Results.* Allow users to export the simulation results. Users recall procedural details better after one week when presented with written text compared to an animation (Ware, 2013).

User Customizations

Enable users to customize the virtual environment. Customizations help users adjust to the virtual environment. These adjustments allow the user to personalize their comforts. Examples of comforts include; personal boundaries, physical limitations, social considerations, brightness, etc. (Vi et al., 2019). Customizing an experience improves the users' efficiency when completing tasks (Vi et al., 2019).

- *Zoom.* Allow expert users to adjust the zoom rate (Ware, 2013).

- *Hand dominance.* Allow users to select their hand dominance when performing tasks. Users naturally perform tasks with their dominant hand. The dominant hand (usually the right) will tend towards detailed selections and model manipulations, while the non-dominant hand (usually the left) will tend towards frame-of-reference information (Ware, 2013).

- *Stereo Blind or Cybersickness.* Enable the user to turn-off the stereoscopic viewing function. Stereoscopic viewing is not accessible to everyone. Approximately 10% of the population are stereoblind (Riener & Harders, 2012), and 12-60% experience cybersickness (Stanney & Hash, 1998). As VR becomes mainstream in the medical industry, the data displayed by these systems must be accessible to all users.

- *Text Narrative.* Enable the user to turn-on text narratives. Text in a VR environment adds many benefits for the users. Text supports those with hearing disabilities in the virtual experience (Izard et al., 2017) and provides another cue for those potentially working in louder environments to overall improve the user experience.

Hardware Specifics

Leverage the strengths of the hardware. Commercially available hardware is designed for many different purposes. The original intent of the hardware design may not fit the use case being developed. Poorly fit technologies have technical limitations that impact the overall user experience. As VR technology becomes ubiquitous in the medical industry, researchers and companies will identify the best technologies for specific use cases. At a high level, there are advantages and disadvantages to HMD and SWD hardware. HMDs are advantageous for immersing users in an experience but are usually single-user experiences. SWDs are advantageous for collaborative group discussions, but users feel less immersed with these experiences. Developers should take advantage of technology strengths when designing a user experience (Vi et al., 2019).

- *Screen Resolution.* Use high-resolution screens, especially in the horizontal direction, and include anti-aliasing techniques to improve graphic quality (Ware, 2013). These recommendations to create higher-quality graphics leads to users making fewer misjudgments in the virtual environment (Lin & Woldegiorgis, 2015).

- *Perspective.* Include head-coupled visual perspective to improve the users' sense of presence in the environment (Ware, 2013).

- *Position.* For SWDs, place models 'behind' the screen and avoid clipping the model at the screen edges (Ware, 2013). Models placed behind the physical stereoscopic screen are more comfortable to view than objects floating in front of the screen (Lin & Woldegiorgis, 2015). Research has shown users are most successful when the viewing volume in the VR environment is between -25% and +60% of their view-to-screen distance (Ware, 2013). For example, if the user is standing 10 feet from the VR screen, then the viewing volume or working space should start 2.5 ft in front of the screen and end 6 ft behind the screen. Viewing the environment outside of this working space is difficult for the user to interpret correctly (Ware, 2013).

The contribution of phase two is a set of generalizable design guidelines for medical focused VR tools, which has not previously been seen in this industry. VR tools create spatial environments to evaluate the relationship between medical devices and patient-specific anatomy, while the guidelines help inform designers during the early stages of development. Shared knowledge of previous work allows designers to continue moving the field forward by designing higher quality user experiences.

Phase 3 – 3D Models

A library of VR assets, including models, images, artwork, software code, audio files, or any other file type, was created for the DBS use case. This library includes 3D models of patient anatomy, two stereotactic frames, nine electrodes, and twenty-eight

electrical field volumes, along with sprites (graphics used for 2D objects in the virtual environment) for the GUI.

Anatomical Models. The deep brain regions include the caudate, external globus pallidus (GPe), internal globus pallidus (GPi), putamen, red nuclei (RN), substantia nigra (SN), subthalamic nucleus (STN), and thalamus. The reference and landmark models include the brain matter, skull, vasculature, AC point, and PC point (Table 6). The multiple regions were segmented to test different use cases with the VR tools using only one patient's dataset. During routine use of this tool, only the regions of interest would be segmented per the surgeon's preference. All regions of interest were segmented from the DICOM scans and saved as separate stereolithography (.stl) models.

Anatomy	**Purpose**
Head/Skull	Used to align HMF to the stereotactic frame
Brain Matter	Locational awareness
Vasculature	To avoid hemorrhages during surgery
AC Point	Landmark for alignment with the stereotactic frame
PC Point	Landmark for alignment with the stereotactic frame
STN	Target for Parkinson's and OCD
SN	Structure of interest for Parkinson's
RN	Good landmark
GPi	Target for Parkinson's and Dystonia
GPe	Good landmark, possible Parkinson's target
Thalamus	Target for tremor and epilepsy
Putamen	Motor functions and good landmark
Caudate	Motor functions and good landmark

Table 6. DBS anatomical regions of interest and the purpose for the DBS procedure.

The mid-commissure (MC) point was calculated at the midpoint between the AC and PC points. The patient's anatomy was aligned by positioning the MC point at (0,0,0) (Figure 46) (ParvareshRizi et al., 2010). The line connecting the AC and PC points was parallel to the X-Z plane. The brain midline was orthogonal to the X-Z plane and aligned with the Y-Z plane (King et al., 2017; Papavassiliou et al., 2004). Doctors use this alignment to position the patient's head within the stereotactic frame for the DBS procedure. The final anatomical models are presented in Figure 47.

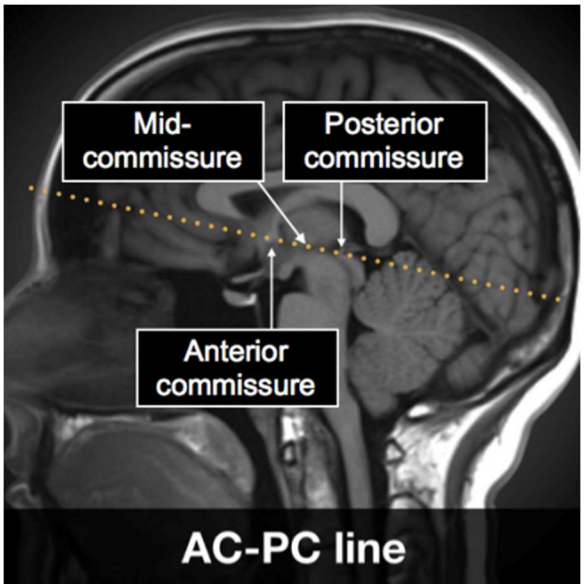

Figure 46. AC and PC points occur in the brain's midline and create the AC-PC line. The MC point was the midpoint between the AC and PC points. The MC point was the origin (0,0,0) coordinate to align the stereotactic DBS frame to a patient's head. The AC-PC line was parallel to the X-Z plane and the brain midline orthogonal to the X-Z plane. Original image from Murphy et al., (n.d.).

Stereotactic Frame Models. The CRW and Leksell frames were measured to create virtual 3D stereotactic frame models. Each frame includes numerous components to align the electrode for surgery. The DBS frame components were simplified to capture the DOF (Table 7);

- The base model is secured to the patient's head,
- Vertical sliders adjust the Z-axis on the Cartesian coordinate system,
- Horizontal slider/s adjust the Y-axis on the Cartesian coordinate system,
- Rings adjust the phi coordinate on the spherical coordinate system,
- The arc adjusts along the X-axis on the Cartesian coordinate system,
- The electrode support slides along the arc to set the theta angle on the spherical coordinate,
- The BenGun provides five port placement options during the procedure (Figure 48), and

- The electrode driver advances the electrode into the patient's brain along the spherical coordinate system's radius.

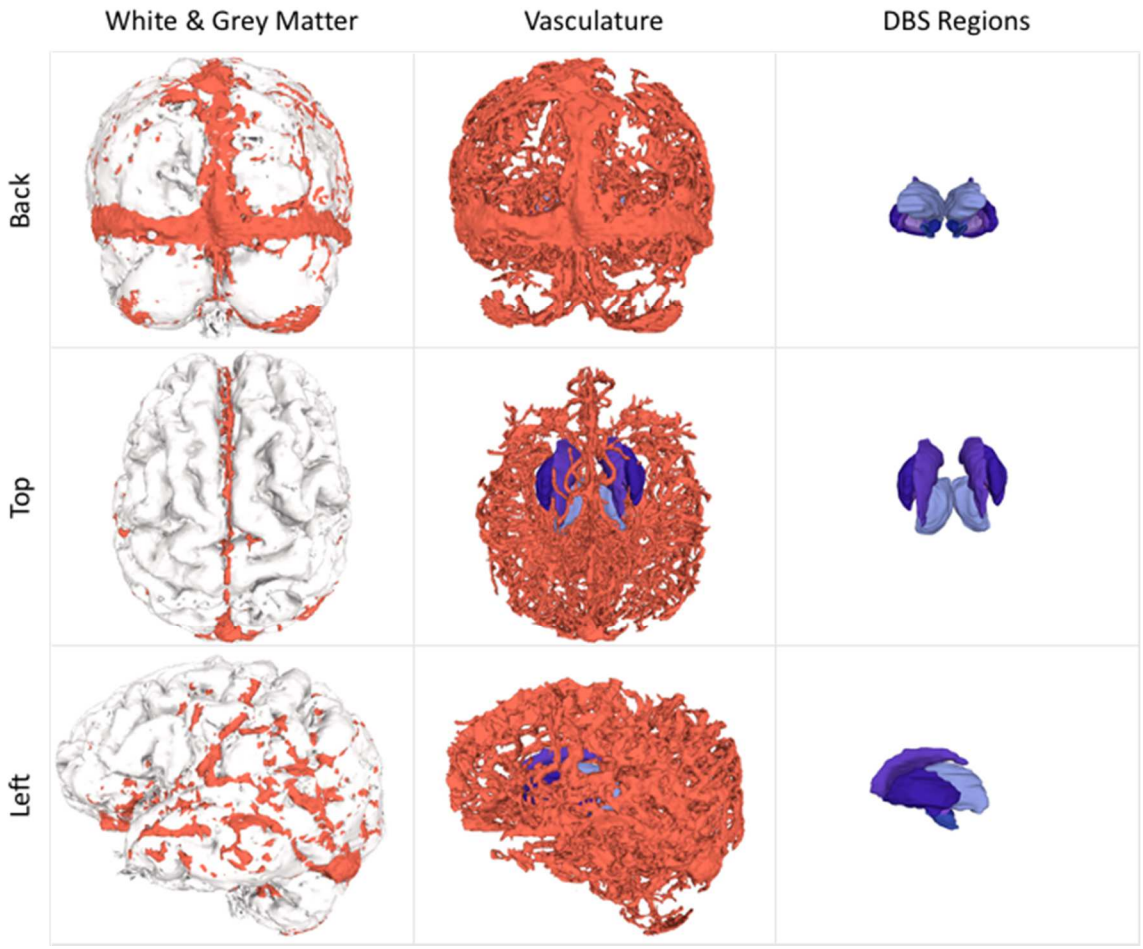

Figure 47. Models of the brain for DBS. The view direction is on the left. The first column shows the DBS anatomy with the white and grey matter and vasculature. The second column shows the DBS anatomy and vasculature. The third column shows the DBS regions.

Models	**DOF**
Base	Reference
Vertical Sliders	Cartesian – Z axis (Z)
Horizontal Slider/s	Cartesian – Y-axis (Y)
Rings	Spherical - phi (φ)
Arc	Cartesian – X-axis (X)
Electrode Support	Spherical - theta (θ)
BenGun	Port Variations
Electrode Driver	Spherical - radius (ρ)

Table 7. Frame components for each DOF.

These eight components define the six DOF to perform a DBS electrode placement. The final model assemblies are presented in Figure 49. Appendix C presents the CRW frame images, and Appendix D presents CAD assembly drawings. Appendix E presents images of the Leksell frame, and Appendix F presents CAD assembly drawings. Appendix G presents CAD drawings of the BenGun, as used in this VR system.

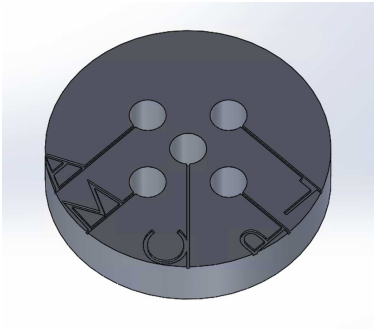

Figure 48. BenGun model to modify the port placement.

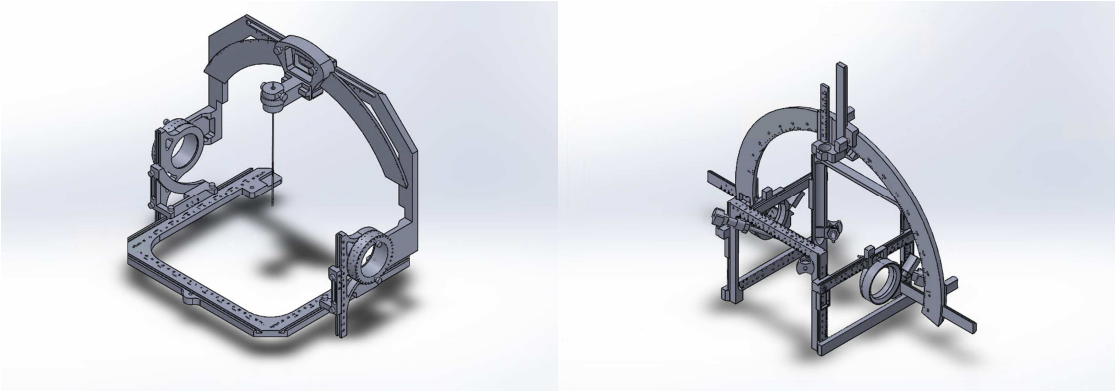

Figure 49. CAD model assemblies of CRW stereotactic frame (left) and Leksell stereotactic frame (right).

Electrode Models. Nine common DBS electrodes were reverse-engineered; Medtronic 3387, Medtronic 3389, Medtronic 3391, Boston Scientific Vercise, Boston Scientific Cartesia, Abbott St. Jude 6146-6149, Abbott St. Jude 6142-6145, Abbott St. Jude Infinity 0.5, and Abbott St. Jude Infinity 1.5 (Figure 50). These models were FDA approved for DBS therapy at the time of this publication. The most common electrode design has four contact rings to provide programming options based on final placement. Medtronic first released four contact ring electrodes in 1997. Directional leads are newer

technology designs. Abbott released their Infinity directional lead in 2016, and Boston Scientific released their Cartesia directional lead in 2019. Appendix H presents CAD drawings of all electrode models.

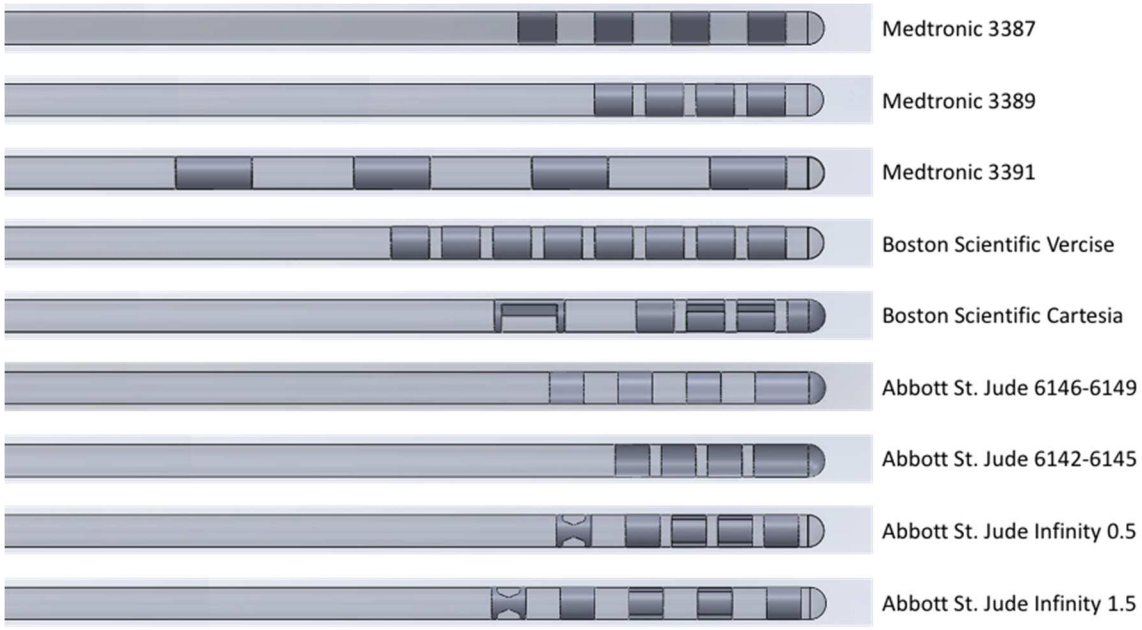

Figure 50. Electrode models for the DBS procedural planning. At the time of this publication, nine electrode designs are approved by the FDA for humans. Medtronic has three four-contact ring electrodes on the market. Boston Scientific has an eight-contact ring electrode and a directional lead. Abbott St. Jude has two four-contact ring electrodes and two directional leads on the market.

Electrical Field Volume Models. Electric field volumes at four input voltages and three shapes were extrapolated from the studies by Alonso et al. (2015) and Vasques et al. (2010) for the Medtronic 3389 electrode. Additional volumes were calculated for double monopolar and bipolar shapes with contact ring spacings of 1.5mm and 4mm. Table 8 presents the final volumes for each electrical field. The shape assumptions resulted in a capsule double monopolar shape and combination sphere and capsule bipolar shape shown in Figure 51. Scaled drawings for the double monopolar and bipolar volumes are available in Appendix I, J, K and Appendix N, O, P and organized by electrode contact spacing. Volume calculations for the bipolar electrical fields are presented in Appendix L and Appendix M based on the volume shape.

Voltage (V)	Radius (mm)	Monopolar Volume (mm^3)	Double Monopolar Volume (mm^3)			Bipolar Volume (mm^3)		
Electrode Spacing			***0.5mm***	***1.5mm***	***4mm***	***0.5mm***	***1.5mm***	***4mm***
1	1.8	24.43*	44.79	54.97	95.68	34.55	40.28	57.45
1.5	1.9	29.40^	48.10^	n/a	n/a	31.20^	n/a	n/a
1.5	2.2	42.80	72.39&	87.18&	146.36&	57.38&	65.94&	91.59&
2	2.5	65.45*	104.72	124.35	202.89	79.69	90.73	123.86
3	3	113.10*	169.65	197.92	311.02	128.45	144.06	191.77
4	3.5	179.59*	256.56	295.05	448.99	194.28	214.40	279.27
Dimensions Available in Appendix			***I***	***J***	***K***	***N***	***O***	***P***

Table 8. Electrical field volumes extrapolated at four voltages, three shapes, and three contact ring spacings. The voltages are 1V, 2V, 3V, and 4V. The shapes are monopolar, double monopolar, and bipolar. The contact ring spacings are 0.5mm, 1.5mm, and 4mm. Alonso et al. (2015) presented data for monopolar volumes at 1V, 2V, 3V, and 4V these are denoted by the asterisk (*). Vasques et al. (2010) proposed the data for monopolar, double monopolar, and bipolar volumes at 1.5 V these are denoted by the caret (^). Both studies used the Medtronic 3389 electrode. The data denoted by the ampersand (&) was extrapolated from the Alonso et al. (2015) and followed the Vasques et al. (2010) data trend to guide the volume development.

A polynomial trendline fit to Alonso et al.'s (2015) radius data calculated the 1.5V radius of 2.2mm; see denoted with an ampersand (&) in Table 8. Alonso et al. (2015) and Vasques et al. (2010) results are not in agreement due to their different methods but can validate how the volumes trend for the double monopolar and bipolar volumes seen Vasques et al. (2010). The calculated volumes denoted by an ampersand (&) in Table 8, for the monopolar electric field at 1.5 V was 42.74 mm^3, compared to Vasques reported volume of 29.4 mm^3, a difference of 69%. The double monopolar and bipolar volume differences were 66% and 58%, respectively.

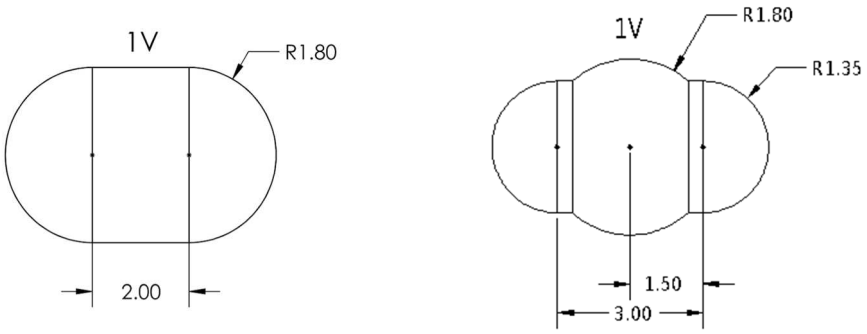

Figure 51. The double monopolar and bipolar scale drawings for 1V and 0.5mm contact spacing.

Finally, this contribution created twenty-eight electrical field volume models for the DBS use case; see Figure 52. The exported stereolithography (.stl) models were colored grey with a 50% transparency to show the underlying electrode geometry. The volume and electrode models were aligned before importing them into the VR environment (Figure 53).

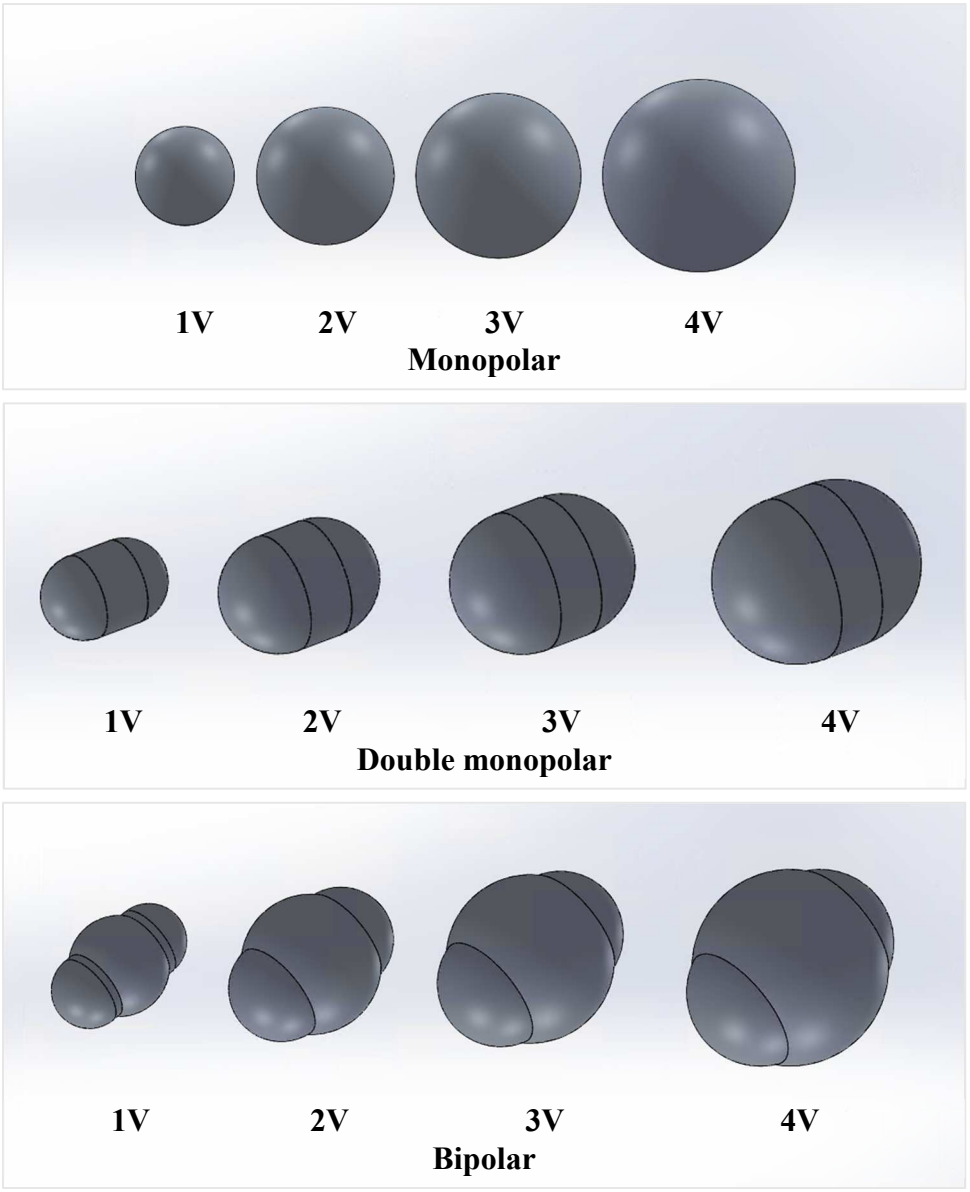

Figure 52. The final electrical field volume models for monopolar, double monopolar, and bipolar. These volume models are for electrodes with 0.5mm contact ring spacing. The models are organized from left to right at increasing voltages; 1V, 2V, 3V, and 4V. Not shown here, additional models were created for the double monopolar and bipolar shares at 1.5 mm and 4 mm contact ring spacings.

Many assumptions were made to model the electrical fields. The main assumptions are that the electrical field shapes are correct and the sizes are accurate. This analysis calculated the size of the electrical fields based on available literature. However, it is essential to remember that this work's goal was not to advance the science of

electrical field volumes but to demonstrate VR tools' value to advance visualization techniques for DBS procedural planning.

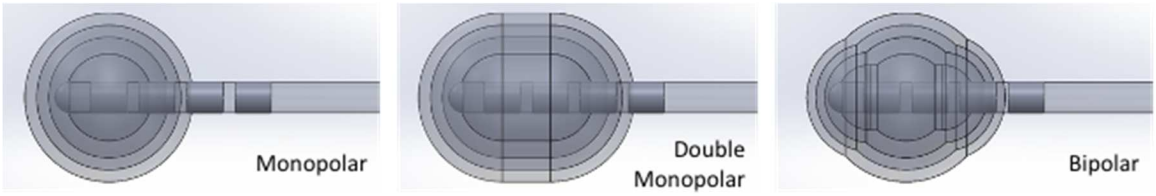

Figure 53. The final electrical field volume models aligned with the Medtronic 3389 Contact 0. The smallest volume around each electrode was for the voltage of 1V, followed by 2V and 3V. The largest volume around each electrode was for the voltage of 4V.

Graphical User Interface Models. The task analysis, design guidelines, and 3D models guided GUI designs for the DBS use case. GUI designs were developed for both VR experiences. In both designs, the primary workflow tasks were separated from secondary actions. The task analysis captured the primary workflow tasks; target, trajectory, electrode, BenGun, microelectrode, and electrical field volume (top line of Figure 54). The design guidelines guided the secondary actions; view, models, slicer, user study (bottom line of Figure 54). Separating the primary tasks and secondary actions support users while navigating the virtual environment. Users see the progression of tasks displayed in one menu and other tools to support decision making in a second menu. Users click to open each tab and view the available functions to interact with the DBS models.

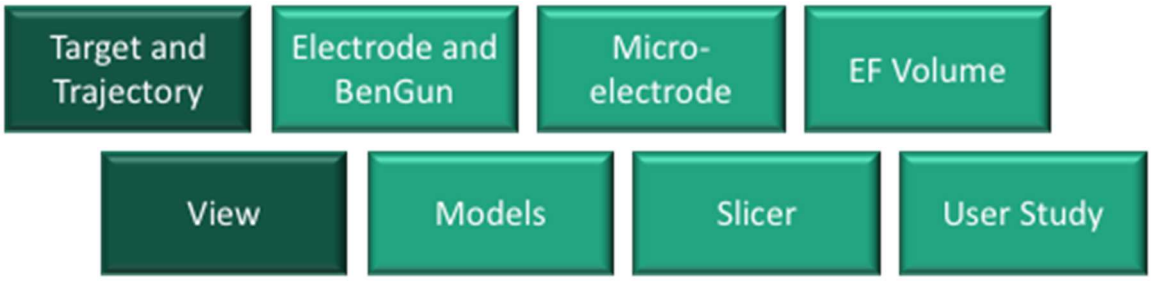

Figure 54. The top row of GUI buttons follows the doctor's primary workflow. The workflow goes from left to right to select the target location, select the trajectory orientation, identify an appropriate electrode, choose a BenGun port to reach the target, evaluate the microelectrode readings, and analyze the electrical field (EF) volumes. The bottom row of buttons are secondary actions; view of the models, models visibility, a slicer plane through the models, and options to conduct a user study.

The final models include numerous sprites to build the virtual GUIs (Figure 55). The individual graphics create texture for interactive 2D objects. Text is added in the virtual environment to manage viewing quality. The sprites make flexible layouts to adjust the design in the virtual environment. Functionality can be added to the environment while maintaining the design aesthetics.

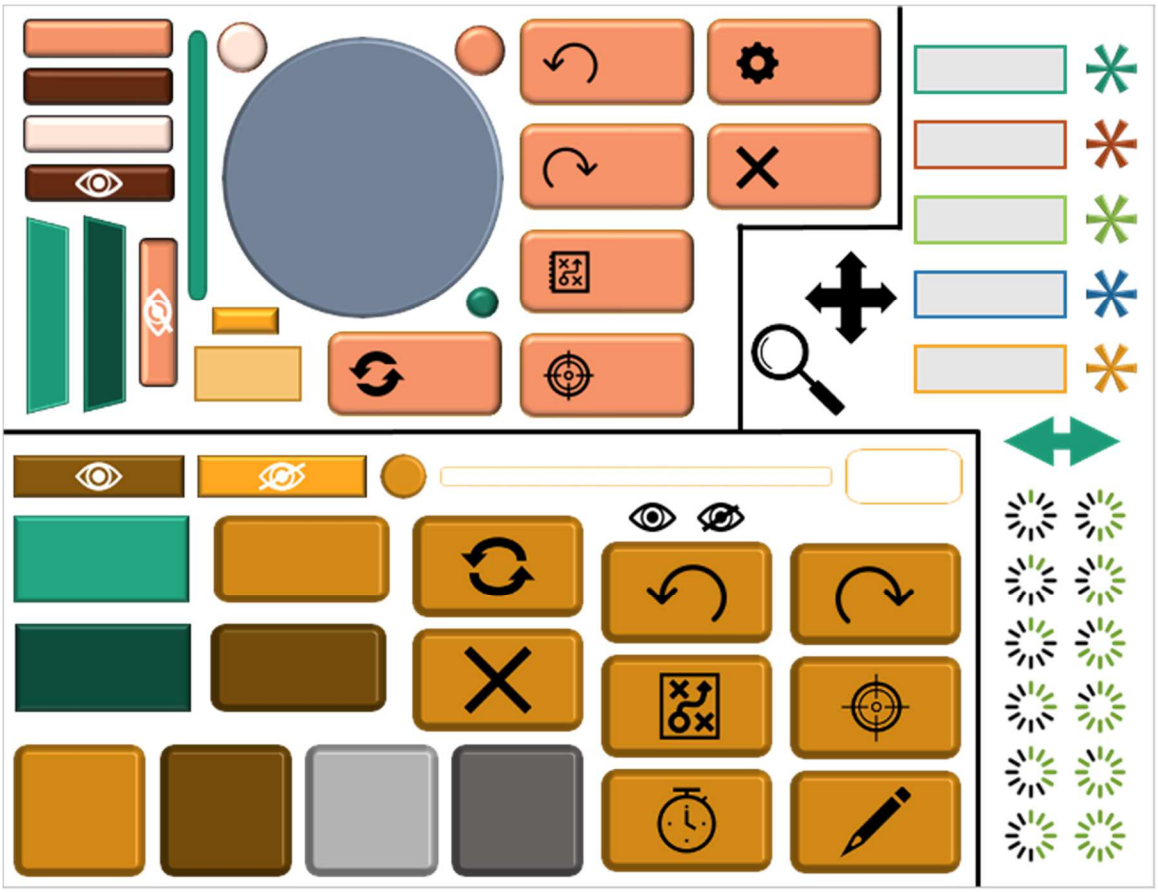

Figure 55. Sprite sheet with GUI assets for both DBS use case virtual configurations. Graphics in the top-left are for the SWD. Graphics in the bottom-left are for the HMD. The graphics on the right are for the patient data registration at the beginning of the workflow.

The contribution of phase three is a library of virtual assets for the DBS use case. High-quality assets are essential to creating immersive VR tools and capture the user's attention (Vi et al., 2019) to immerse them in the experience. This immersion leads to a greater transfer of skills from the virtual world to the real world (Stanney et al., 1998). The assets match the real-world task, so users can trust and believe that the experience is realistic when performing tasks and making decisions (Lin & Woldegiorgis, 2015).

Phase 4 - Proof-of-Concept Virtual Reality Designs

The final result was two VR experiences for the DBS use case. The designs were developed from the task analysis framework, design guidelines, and models. The first design was an SWD with a 24" touch screen, and the second design was an HMD with handheld controllers. These two VR experiences have advantages and disadvantages

when deployed in the medical industry. The SWD and touch screen were advantageous in that they aligned with the medical industry's collaborative and team-based culture by enabling a shared experience, however the configuration was not a fully immersive experience. The HMD was advantageous as a fully immersive experience but less supportive of the collaborative and team-based culture seen in medicine. These VR experiences must fit the medical professionals' needs, the DBS use case, and the medical environment of use.

Register the Patient's Data. The workflow for both configurations starts with registering the patient's data to the stereotactic frame. The doctor selects five key locations in the patient's brain; the AC point, the PC point, the first midline point, the second midline point, and the third midline point. The MC point was calculated halfway between the AC point and the PC point. The line connecting the AC and PC points aligns to the X-Z plane. The remaining three points along the brain's midline are orthogonal to the X-Z plane and parallel to the Y-Z plane. This task was best performed on a standard monoscopic computer screen, as the doctor interacts with the patient's 2D MRI scans to determine the point locations (Figure 56). The doctor chooses the points along the screen's bottom and then places a marker on the 2D scans. Once all points are selected, the doctor saves the data and moves to the virtual experience. A 2D GUI design on a computer screen was appropriate for this workflow step, as spatial awareness with VR is irrelevant when analyzing 2D DICOM images. See Appendix Q for this part of the workflow.

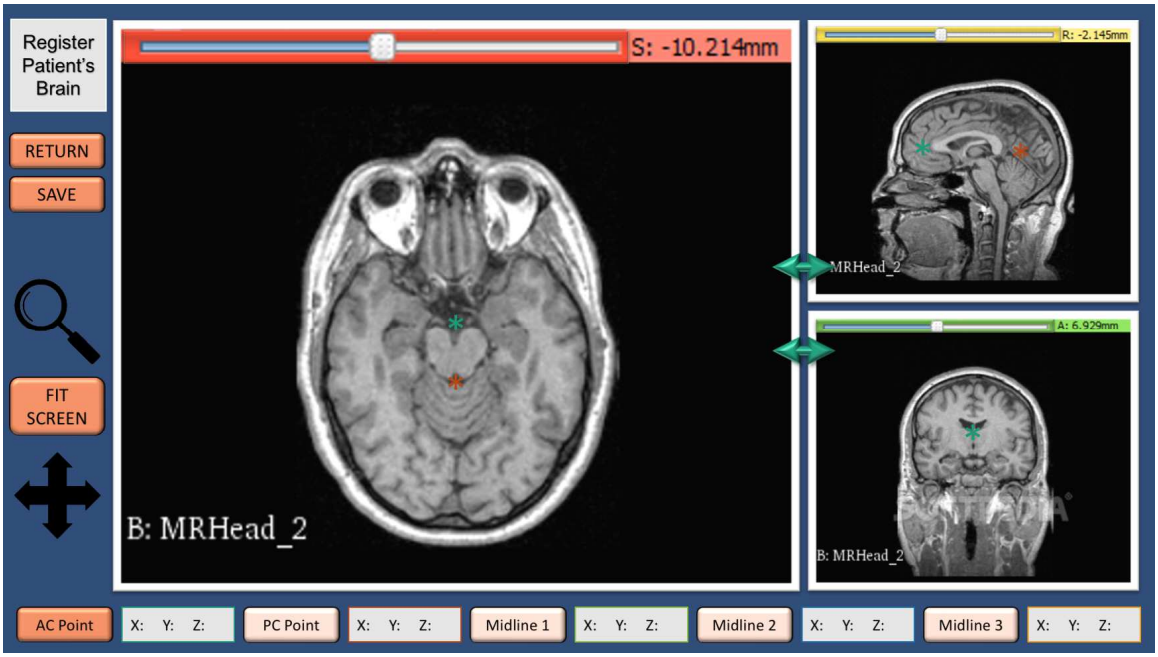

Figure 56. The doctor selects key locations in the patient's brain using this GUI before the software registers the patient's anatomy with the stereotactic frame. The doctor scans through the three axes of 2D images and selects five key locations. They choose points along the bottom, then drop the marker on the scans before moving to the next point. Once all points are selected, they save the data and move to the virtual experience.

Design One: Stereoscopic Screen Display with Touch Interaction. The first VR configuration was designed for the collaborative and team-based culture of medicine. Medicine requires collaboration between many medical specialties and communication of the plan to medical support staff. The adage of 'if a picture is worth a thousand words, then a model is worth a thousand pictures' holds in medicine. A screen displayed VR-based model creates a multi-person shared experience, where care team members can participate or observe the planning process. Improving communication methods between staff members improved patient safety during a procedure (Fargen et al., 2013).

The system uses a 75" stereoscopic virtual screen and a 24" interactive touchscreen (Figure 57). Users position the touch screen directly below the stereoscopic screen or off to the side, as seen in Figure 57. This design was based on the Immersive Touch Table (Coffey et al., 2010, 2011) used in Step One: Clinical Use Cases and designed for novice users. The patient's anatomy aligned with the stereotactic frame was centered on both screens and faces away from the user to mimic the doctor's perspective

during the DBS procedure. The two presentations of patient data improve accessibility and create a bridge between new and existing technologies. Most users find low-immersion virtual desktop systems comfortable to use (Weech et al., 2019). However, even low-immersion VR technologies are not accessible to all, as a portion of the population experiences cybersickness or are stereo blind (Riener & Harders, 2012; Stanney et al., 1998). Varying immersion levels need to be designed into every VR system to ensure the patient's data and diagnostic planning procedures are accessible to everyone providing patient care.

Figure 57. One VR design configuration for the DBS use case a 75" SWD (left) and a 24" touch screen (right). Users position the touch screen in front or next to the stereoscopic screen based on their preferences.

Users manipulate the models by interacting with the touch screen. The patient's anatomy is centered on the screen and aligned to the stereotactic frame. The user can rotate and zoom the model on the touch screen and large stereoscopic screen by directly interacting with the touch screen. The touch screen displays two sets of tabs on either side of the display (Figure 58). The left tabbed menu presents the primary workflow tasks,

while the right tabbed menu presents secondary actions for the user to interact with the models.

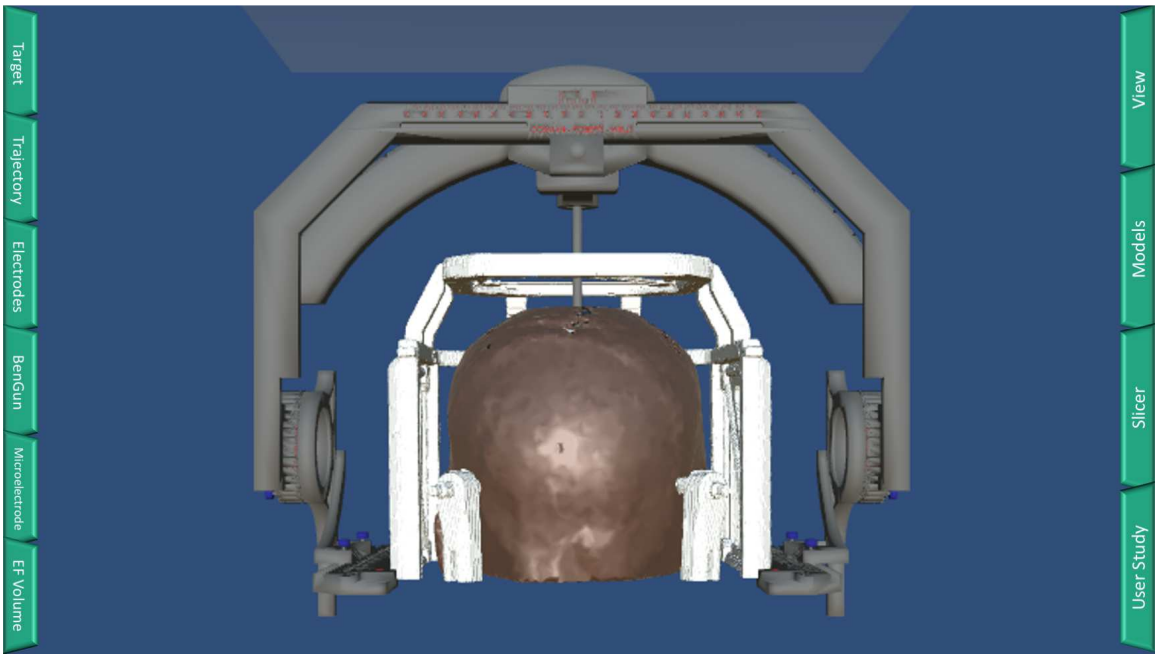

Figure 58. The opening GUI for the DBS use case. Two menus are available on either side of the patient's anatomy and stereotactic frame. The primary workflow tasks are on the left side, and the secondary actions are on the right side.

The workflow tabs are organized from top to bottom to follow the standard process doctors take to plan a procedure. A benefit that was seen here, and not in others, was the inclusion of all workflow steps in one software which make it possible to quickly return to any step in the planning process. The planning process starts with the doctor selecting the target location and then the trajectory orientation. Both tabs include macro sliders and micro buttons to determine the six DOF for the electrode (Figure 59).

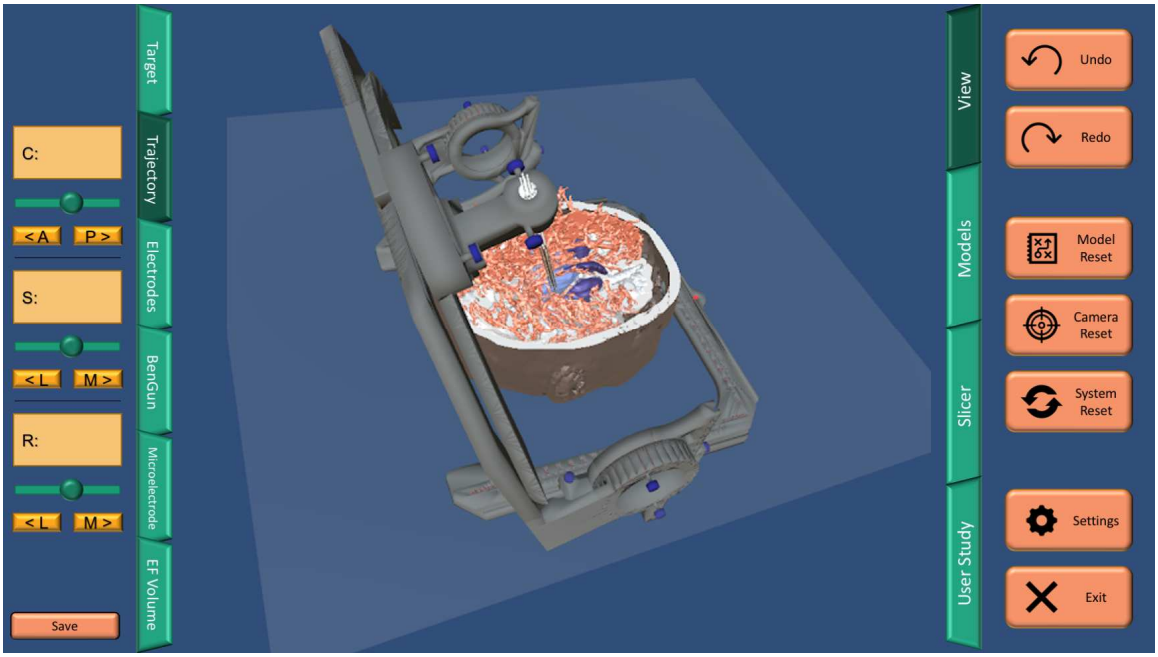

Figure 59. The left trajectory tab presents adjustment for the orientation of the electrode. The right view tab shows options to change the view of the models.

Next, the doctor evaluates electrode options based on the anatomy (Figure 60). All electrode designs approved by the FDA are available for review based on the target and trajectory selected. Many doctors, as they build their practice, develop preferences for specific electrode designs. The view electrodes button shows the available electrode designs. The fourth tab reviews the BenGun variations when placing the electrode (Figure 61). The BenGun has five ports used to stabilize the brain during the procedure and shift the electrode based on real-time microelectrode readings. Users toggle the visibility of electrodes in each BenGun port to compare where the electrode will end in the patient's brain.

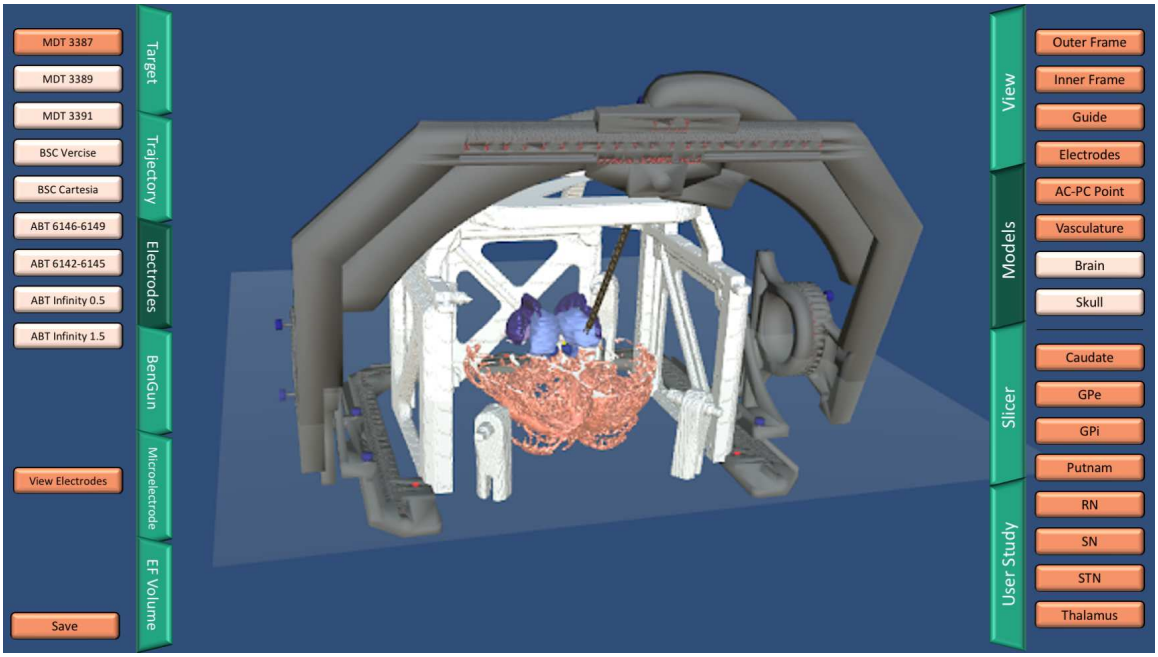

Figure 60. The left Electrodes tab shows the DBS electrodes approved by the FDA. The right Models tab lists the patient's brain and the stereotactic frame models, and clicking on the button toggles the model's visibility.

The fifth tab has space for data about microelectrode readings. Microelectrodes readings are captured by doctors during a procedure to confirm the trajectory. This tab will have functions to overlay readings along to electrode's length to produce a prediction reading during the planning process and can also be used in real-time to confirm the trajectory during the procedure. Future work is needed to build out the functionality for this step in the workflow.

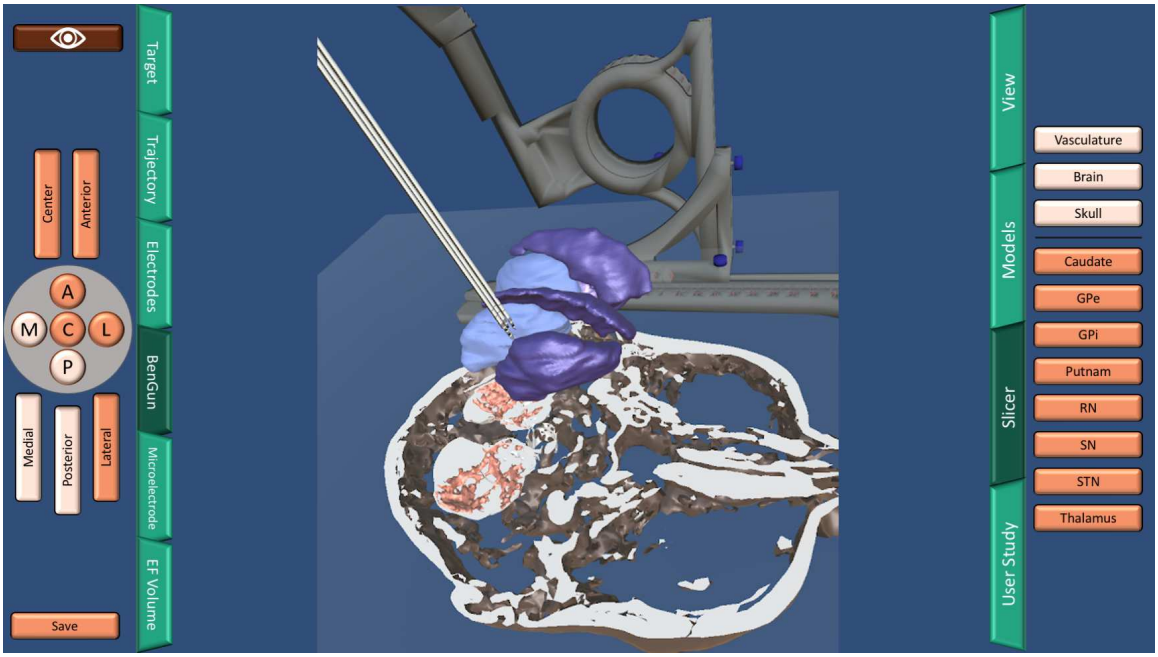

Figure 61. The left BenGun tab shows buttons to toggle electrodes' visibility in the five port locations: center, anterior, posterior, medial, and lateral. The right Slicer tab removes specific user-selected models from the view. Users drag the slicer plane to hide portions of the anatomy.

The sixth tab was electrical field (EF) volumes (Figure 62). Electrical field volumes are used to predict how much tissue will be activated by the DBS electrics. Traditionally, clinical therapists would iterate through all programming options over a series of visits to find the best settings for the patient. New directional leads increase the programming options and thus increase the time to find a suitable programming setting. This visualization informs the decision-making process by guiding the clinical therapist to viable options based on stimulation volumes prior to working with the patient and hopefully reducing the time needed to program an electrode. Users select the view volumes button to see shape, contact, and strength options.

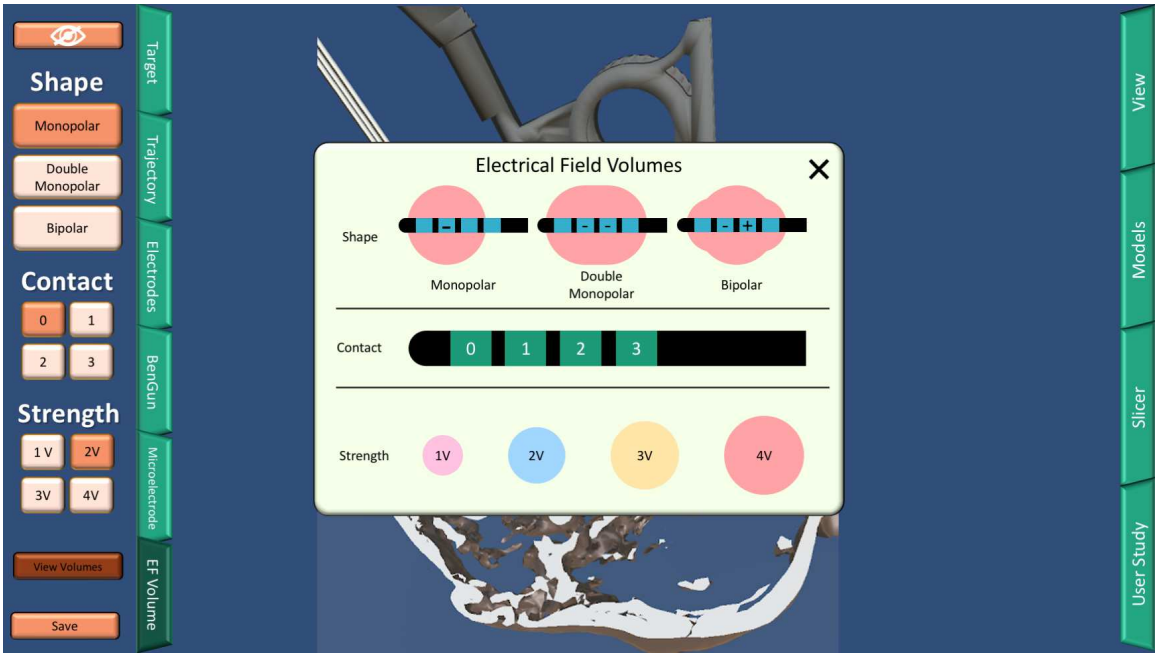

Figure 62. The left 'EF (electrical field) volume' tab presents options when programming a DBS electrode: shape, contact, and strength. Users view and iterate through options to evaluate the appropriate settings based on the placement of this electrode. The View Volumes button shows information about each of these options.

Secondary actions are presented on the right-justified menu. These actions are used to explore the patient's data: change views, toggle model visibility, slice through the anatomy, and conduct a user study. In the view tab, users can undo and redo their actions, reset the models, change settings, and exit the simulation (Figure 59). The model visibility was toggled in the models' tab (Figure 60). The slicing plane reveals features of the anatomy hidden by other models (Figure 61). Finally, the user study tab has functions to evaluate the user's performance in the application to place electrodes for DBS. The user study tab may be replaced with user performance metrics once deployed for routine use. See Appendix R for the complete GUI progression for this configuration.

Design Two: Head-Mounted Display. The second VR tool was designed for an immersive experience using an HMD. The device immerses users in the virtual environment with a full field of view. Research has shown high-immersive experiences improve spatial understanding, reduce information clutter during task completion, and

increase participants' bandwidth to perceive complex datasets (D. A. Bowman & McMahan, 2007).

The HTC Vive Pro was used for this configuration (Figure 63), wherein users move their bodies or use the controllers to view and rotate the models. The patient's anatomy aligned to the stereotactic frame was centered in the workspace. Two floating GUI menus provide additional controls and are positioned on either side of the models; the left menu has the primary workflow tasks, and the right menu has the secondary actions. The dominant hand controller performs task-specific controls, while the non-dominant hand controller performs model interactions (Ware, 2013).

Figure 63. The second VR tool design for DBS procedural planning using an HMD.

The primary workflow tasks are organized from left to right in the GUI (Figure 64). They include selecting a target location and a trajectory orientation, analyzing the electrode placement with BenGun port variations, confirming the placement with microelectrode readings, and simulating electrical field volumes (Figure 64). Individuals

can use their dominant hand controller for finer scale operations and task completion (Zhai, 2004), which includes adjusting the electrode target within millimeter accuracy.

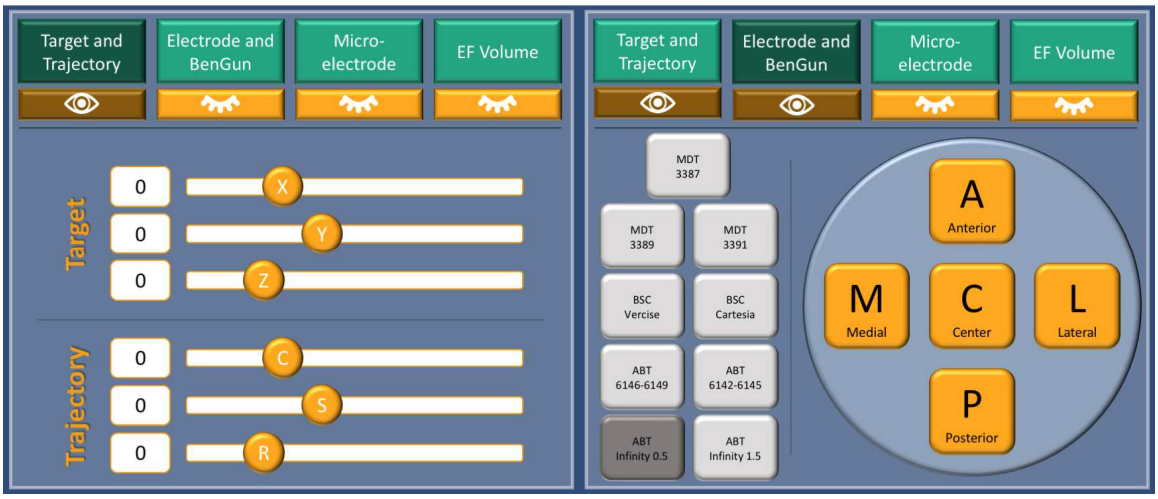

Figure 64. The GUIs for the primary workflow tasks. Users start at the left with the target location and trajectory orientation. Next, users choose an electrode and BenGun port for the procedure. In the third step, users review microelectrode readings, followed by the fourth step of reviewing electrical field volumes.

The menu on the right side of the anatomical models includes secondary actions. These actions include manipulating the model by rotating, translating, or scaling the models; changing the visibility of models; and slicing through the model (Figure 65). Participants prefer to use their non-dominant hand when starting tasks, macro-scale operations, and defining the frame of reference (Zhai, 2004), for example, adjusting the view and visibility of the models throughout the procedural planning process. See Appendix S for the complete GUI progression for this configuration.

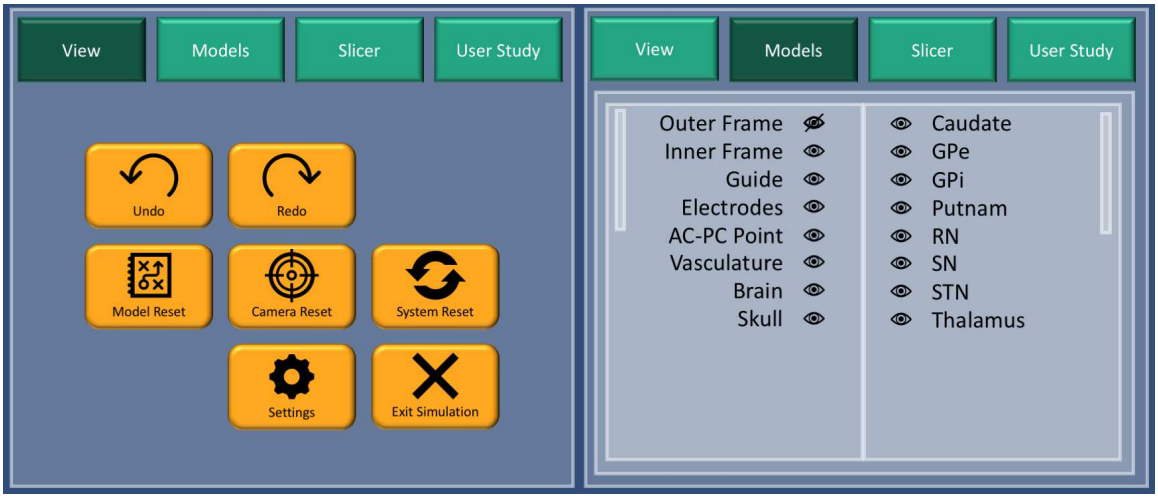

Figure 65. The GUIs for the secondary actions. Users start on the left with the view tab. Next, the models' tab toggles the visibility of each model. In the third step, users change the slicer plane to change the model's transparencies. The user study tab tracks the users' performance when using the application.

The contribution of phase four is the proposal of two VR tools for the DBS use case. The tools include the same task analysis, design guidelines, and 3D virtual models, combined in ways that meet two different needs: 1) a tool for communication and collaboration or 2) a tool to fully immerse oneself into the spatial relationship between a medical device and patient-specific anatomy. Medical focused VR tools are in their infancy, and exploration is still needed to understand how VR tools fit within medical workflows to simplify procedural steps, improve procedural knowledge, or advance existing methods.

The final VR tools presented here are generalizable to other use cases. Analyzing the spatial relationship between a medical device and a patient's anatomy is an essential surgical skill for improving patient outcomes and increasing procedural confidence (Stadie et al., 2008). Spatial awareness is not specific to DBS, meaning the workflow tasks and GUI design can be tailored for other areas of medicine. The methods to interact with the models and the right GUI options are transferable to other use cases. The ability to deploy the solution to different VR hardware technology increases accessibility to VR experiences as appropriate for each user, each use case, and each medical setting.

Discussion

The results presented a four-phase approach to develop VR technology for the DBS use case supported by iterative subject matter expert feedback. The first result presented a framework for the VR tools based on a task analysis. Comprehensive reviews of medical workflows are difficult to retrieve from academic literature. Medical workflows are developed over many years and include many different experts; researchers, surgeons, nurses, anesthesiologists, hospital administration, facilities management, supply chain management logistics, and sterile reprocessing. Although pieces of the workflow reside in separate bodies of knowledge, this knowledge is necessary for VR tool developers to create solutions that will benefit the medical industry. Including 'champion clinicians' in the development process is another way to gather workflow knowledge.

The second result suggests design guidelines for VR tools in the medical industry. The guidelines focus on visualizing and analyzing the relationship between the patient's anatomy and medical devices. These VR experiences apply to medical education, training, procedural planning, intraoperative assistance, and informing decisions about potential medical device designs. Future developers can use these design guidelines to apply best practices to their projects.

The third result presented a library of assets to develop a VR system for DBS. Anatomy, medical devices, simulations, and GUI models were developed for the two proposed VR designs. One limitation of the stereotactic frame models is that they were both reverse engineered from physical models. Reverse-engineering a model can introduce inaccuracies between the real and virtual models. DBS therapy relies on millimeter accuracy to provide patients with effective therapy. One limitation of the electrical field volume model is the literature-derived assumptions that determine each electrical field's volume. Further research is needed to validate the virtual models.

The fourth result proposed two designs of VR tools for the DBS use case. The SWD emphasized collaboration and communication between medical professionals. The HMD emphasized immersion into the virtual environment. Each design met six of the

seven need statements presented at the beginning of these steps, with the final need defined in future work. First, surgeons need a quick method to map a DBS electrode trajectory to the patient's anatomy the morning of surgery. This need was met by including the entire task analysis workflow into one software. Second, surgeons need technologies to personalize the implant location, trajectory, and therapy based on the patient's anatomy. Using patient-specific anatomy in this software met this need. Third, surgeons need technologies specifically designed for the complexities of neurology. These VR tools are designed specifically for the DBS use case. Fourth, surgeons and researchers need to visualize patient blood vessels when planning an electrode trajectory, overlaying them on the patient's anatomy. Vasculature was captured during the modeling process and included in the VR environment.

Fifth, radiologists need technologies to improve communication with surgical colleagues. Both designs start by reviewing the 2D images read by a radiologist before transitioning into the VR environments. Sixth, surgeons and researchers need 'no obligation' technologies to explore new surgical approaches, medical device designs, and therapies. Both designs are flexible and allow users to iterate between tasks in the planning process. These designs can be used to explore other therapy electrode placements and compare placements across patient populations. Finally, surgeons and researchers need to visualize patient fiber tracks with programming an electrode therapy. Fiber track data is not in either design but defined in future work.

This work's primary limitation is the lack of a user study to validate both designs and identify the best design for the use case. A user study was the next logical step to finalize this research; however, it was not feasible to conduct a user study with medical professionals using shared equipment while the COVID-19 pandemic persisted. User studies are critical to validate designs and confirm that the technology is accurate to the real world. Further research is needed to conduct validation testing of both designs.

Challenges. There are challenges when developing VR technologies for the medical industry. The first challenge is accessibility to clinical champions and appropriate users. Medical professionals are busy people, but their expertise is invaluable

to the development of VR technology. Many times, to conduct usability testing, the users require specific knowledge of the medical procedure; however, reaching unbiased statistical significance can be difficult with a small number of users familiar with that procedure. The second challenge is clinicians at academic institutions want to innovate but are often thinking much farther into the future. The third challenge for companies wanting to work in this space is the limited ROI. VR tools require specific skills and monetary capital to achieve an appropriate product design. Tailored solutions for one specialty in medicine may not be financially viable. These challenges deter developers from focusing on holistic solutions that fit within the medical environments of use.

Future Work. Many opportunities exist to continue expanding the two systems for the DBS use case. DBS is a complex area of medicine, with many specialties collaborating to provide patient care. First, a *blood vessel proximity rating* would calculate the electrode placement's proximity to the blood vessels. Blood vessels within five millimeters of the electrode concern surgeons because of the hemorrhage risk (Pabaney et al., 2015). A proximity rating would guide surgeons toward electrode trajectories with less risk of puncturing a blood vessel. Second, include *fiber tracks* with the patient's brain model. Fiber tracks transmit the electrical signal into the brain. Aligning the electrode to the fiber tracks ensures the therapy effectively propagates through the patient's brain (Baniasadi et al., 2020). Third, develop *electrical field volumes for directional electrodes* and validate the current electrical field volumes. Directional electrodes have been on the market for two years and researchers are actively developing models to predict therapeutic responses (Alonso et al., 2015, 2016; Anderson et al., 2018; Baniasadi et al., 2020; Paff et al., 2020; Vasques et al., 2010). Fourth, incorporate *microelectrode readings* along the electrode. Microelectrode readings confirm the electrode orientation during the procedure (Abosch et al., 2010; Bus et al., 2018; De Vloo et al., 2018; Hamid et al., 2005; Pabaney et al., 2015).

Additional work is also needed to develop both designs further. First, *new VR technology* is released regularly. New technologies may improve the quality of the user experience for this specific DBS use case. VR technology is in its infancy, and significant

changes are expected in just the next few years. Second, add *tracking* to the SWD design. A tracked environment allows users to use hand-held controllers to interact with the models. Third, design *natural interactions* for the medical team. Natural interactions ease the cognitive workload when performing tasks and optimize the experience by reducing outdated menus. Fourth, conduct *usability testing* to iterate on the VR designs. As VR technology evolves, developers will continue to learn best practices for designing the technology and how to apply the technology to specific industries. These future works will continue to advance VR technology for the DBS use case.

Future Use Cases. VR tools could open new opportunities for other DBS use cases. A holistic VR tool creates a standard frame of reference to explore other methods, technologies, and therapies. VR tools could assist with training surgeons using non-invasive methods, reducing the need for cadaver models and 'see-one, do-one, teach-one" teaching models. The tools could explore electrode placements to stimulate other brain regions and provide therapy for other diseases. The tools could support medical device manufacturers as they develop next-generation technologies. Finally, the VR tools could be integrated with robotic-assisted technologies as these technologies continue to grow in medicine.

Conclusion

This work contributed to advancing the use of VR in the medical industry. The four phases of development and final proposal of two VR designs for the DBS use case show how VR technology can impact the medical industry. The framework placed the design of a VR tool within the context of an existing medical workflow. Medical workflows are developed based on the evidence presented in the literature and reviews from subject matter experts. The VR tool workflow should fit the medical workflow to simplify the procedural steps, improve procedural knowledge, or advance existing methods. For example, various VR-based technologies, such as SWD, CAVE, HMD, AR, and others can create different user experiences. The design of VR tools has implications on the usability and acceptance of a solution. Studying VR tools within the intended medical workflow creates the evidence to determine if the solution improves outcomes,

diminishes performance, or is not statistically significant. Designing VR tools specifically for the medical industry ensures tools meet the clinical needs and improve patient outcomes.

Chapter 6

Perspective Three: Industry Implementation of VR in the Medical Industry

Preface

This chapter surveys current medical XR companies to understand the technology landscape. The emphasis here is on the implementation of medical XR technologies, as many companies contribute to the technology landscape. This study builds on the knowledge from chapters one through five to document the current state of medical XR technology from an industry perspective. This inquiry identifies the constraints, challenges, and opportunities that remain by surveying medical XR technology companies. This chapter is the third perspective of this dissertation (Figure 66.).

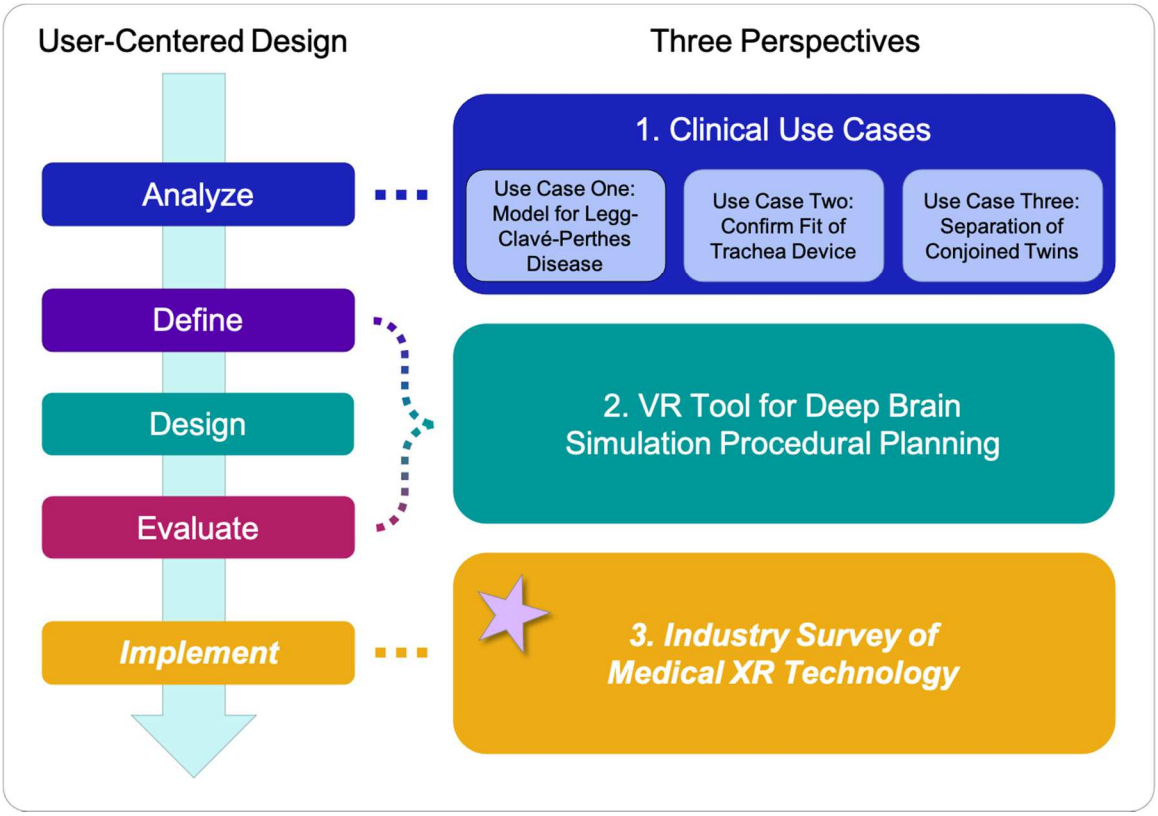

Figure 66. Chapter six surveys how companies implement medical XR technology. This chapter is part of the third perspective to implement medical XR technology.

Introduction

The demand for simulation-based training in the medical industry has drawn interest from small start-ups to large corporations. Many companies are developing simulation-based trainings using XR technology. Understanding the patterns of early adopters is essential as they drive adoption and guide future research (Zweifach & Triola, 2019). Current academic literature is limited in scope to proof-of-concept studies or small-scale studies that lack adequate controls and statistical power (Mazur et al., 2018). Additional environmental barriers exist and must be considered when using XR in the medical industry (Zweifach & Triola, 2019). The purpose of this step was to research XR technology from the perspective of the medical industry. This research will advance the understanding of the technology landscape, including constraints, challenges, and opportunities during the development, design, and usage of XR technology.

The analysis of companies developing medical XR technology was selected for two reasons. The first reason was the full implementation of XR technology in the medical industry requires participation from companies. Research alone will not generate mass adoption and utilization of these technologies. Companies are necessary partners to develop concepts further, define business models, maintain the technologies, and support medical groups as they transition to using new techniques. The second reason was to understand these early adopters of XR technologies. The current profiles of companies are driving and shaping the future use of medical XR technology. The choices these companies make, their struggles, and the products they produce will impact the technology's future. This chapter reviews the companies developing medical XR technology. This understanding helps bridge the gap between how companies are developing medical XR technology and the learnings from the use cases presented in chapters one through five.

Background

XR Technology

Over the past 60 years, computer technology has made significant advancements. Devices that once took up large rooms now fit in the palm of our hand. Computer screens

have more pixels per inch than can be perceived by the human eye, and the cost of technology has drastically reduced in price. Many times, an industry will drive the development of specific computer technology. For example, the defense and telecommunication industries drove the advancement of the internet. The manufacturing industry drove the advancement of robotics technology. Currently, the gaming industry is driving the advancement of XR technology. Often technologies developed for one industry are later applied to solve needs in other industries. The medical industry is one example of an industry trying to use new technology to solve their needs.

Research has shown the advantages of using medical XR technology. XR experiences for the medical industry include many components; anatomical models, physics models, haptics, and visualization to mimic surgical procedures (Chan et al., 2013; Nowinski, 2005). Most experiences are designed for training and use generalized models to teach foundational technical skills (Ryu et al., 2017) or use patient-specific anatomical models to simulate a surgical procedure (Locketz et al., 2017). As the medical industry continues to learn about the technology, the focus is shifting to patient-specific anatomical models for procedure-specific exploration and surgical planning (Chan et al., 2013; Ryu et al., 2017).

The medical industry is seeing many benefits of using XR technology. These benefits include; learning skills in a low-stakes environment (Ryu et al., 2017); practicing teamwork and communication skills (Simpao et al., 2014); understanding procedural concerns before the surgery (Ryu et al., 2017); improving decision-making outcomes (Ryu et al., 2017); increasing operational success by decreasing 30-day mortality (Analbers, 2016); and improving procedural confidence (Locketz et al., 2017). Research has also shown that VR training can reduce operating time (Locketz et al., 2017) and other cost savings (Analbers, 2016). Doctors who use these early systems find they prefer well-designed VR technology because they are practical and easy to use (Torner et al., 2016). These technologies will shape the medical industry's future; therefore, it is imperative to understand how the technology will reach the masses.

Industry Reviews

The vision for XR technology was first presented in 1965 by Evan Sutherland (Berg & Vance, 2017; Brooks, 1999). Since then, research and industry efforts have explored the technology from numerous perspectives. Basic research has advanced the hardware components, derived software languages, and studied how users perceive virtual experiences. Applied research has taken these components to build use cases for specific industries; gaming, education, manufacturing, defense, automotive, construction, etc. How the technology is applied to meet user's needs are truly endless, but we continue to see slow adoption of the technology in the medical industry.

Research has described the scope of XR technology used in industry for a handful of industries, including manufacturing (Berg & Vance, 2017; Choi et al., 2015), construction (Kaushal, 2019), and automotive (Lawson et al., 2015, 2016). Brooks (1999) presented the first review of VR simulations used in industry. This article profiled VR systems for the automotive industry, entertainment industry, architecture industry, and mental health industry. At the time of publication, Brooks (1999) claimed the technology "barely works" and identified many technical and system-level improvements to advance the VR technology.

A more recent study by Berg & Vance (2017) focused on product design and manufacturing and found seven industries: aerospace, agriculture, automotive, construction, consumer goods, energy, and military, all using VR technology. They surveyed 18 facilities and interviewed 62 people to understand individuals' roles, hardware and software used, the use of the technology, and the internal processes to use the technology. Berg & Vance (2017) updated Brooks (1999) claim of 'barely works" to "It works!" and summarized technology advancements since Brooks outlined seven challenges facing industry use. Berg & Vance (2017) also identify new technology challenges.

Two articles have focused on the adoption and challenges of using XR technology from a clinical perspective. Andrews et al. (2019) reviewed available solutions and how they had been used clinically for cardiology. They identified a few challenges limiting

adoption, which include display technology, physical interactions, and user feedback. Although Andrews et al. (2019) reported the advantages of using XR technologies for cardiology use cases, they also acknowledged that no clinical trials for AR or XR were published to validate the technology's use.

Basoglu et al. (2018) analyzed the factors that contribute to adopting AR smart glasses by physicians in the Turkish medical industry. They identified seven factors that impacted a physician's perceived usefulness and ease of use for AR technology, which contributed to their attitude toward the technology and their final intention to use it. Compatibility, ease of reminding, and speech recognition factored into their perceived usefulness. In comparison, ease of learning, ease of medical education, external influence, and privacy factored into their perceived ease of use. These factors are a combination of technology challenges, design of the technology, the environment of use, and regulatory aspects.

Numerous research efforts have explored and developed specific XR technologies for the medical industry, but research about companies developing this technology is lacking. This chapter provides insights about companies working in the XR space to document individual and company demographics, who and what factors drive the technology, the company's intent for the technology, and hardware and software technologies selected for their use cases. Finally, the results show the idealized benefits from the company's perspectives and their challenges to realize this technology. The results can guide future research.

Methods

A survey of industry professionals was conducted to understand better the current state of XR technology in the medical industry. This study was conducted through an online survey sent to professionals focused on medical XR technologies. See Appendix T for survey questions. Participants were recruited through two methods. First was posting to online community boards of professional organizations, which focused on XR, user experience, and human factors.

The second method of recruitment was connecting with individuals through the professional networking website, LinkedIn. An initial list of companies and professional groups helped identify individuals who may develop medical XR technologies. Identified individuals were contacted with background information about the author, the author's intention, and asking if their company was developing or using XR technology in the medical industry. Based on their response to the previous question, an invitation was extended to participate in the study.

Two areas of XR technology in the medical area were excluded. The first was applications focused on entertainment, or the experience included gamification components. The second was mental health or rehabilitation-focused experiences. These spaces suspend the user's disbelief by presenting an XR environment that may not be possible in the real world and require lower fidelity than other XR applications for medicine (Berg & Vance, 2017; Brooks, 1999).

Results

The study results are presented in eight sections; recruitment, demographics, motivations, resources, company operations, solution testing, challenges, and the future of medical XR technology. The recruitment section captures the challenges of studying this space early in the adoption of the technology. The demographics section includes information about participants and the companies they represent. The motivations section explores which factors are driving these companies to develop medical XR solutions. The resources section documents which resources companies are using, including personnel, existing technologies, and research; hardware technologies; and software technologies. The company operations section reviews when companies are using and how companies are using XR technology. The solution testing section documents how companies evaluate the design quality.

The challenges section analyzes the difficulties, hurdles, and obstacles companies are facing to develop these technologies. The themes from this section are interpreted to guide current and future companies in the XR technology space. Finally, the future of medical XR technology was explored through the lens of those currently working in this

space. These results point towards future research, industry alignment with the technology, and the steps necessary for the technology to become ubiquitous in the medical industry.

Throughout these sections, a few key terms are used. *Number of participants* means that participants were only able to select one response, and therefore the total across the graph adds to forty. *Number of responses* means that participants were able to select multiple answers to a question, and therefore, the maximum number of responses per question was forty. *Solution* refers to the final XR technology product developed by a company to serve a specific use case.

Recruitment

XR technology developed for the medical industry is relatively new. Research has shown the benefits of this technology, and the industry is working to develop appropriate technologies to meet user's needs. These positions in development would place XR technology in the early adopter phase on the adoption curve. This section discusses the results of the recruitment process and points towards other areas of research worth exploring.

Overall, 740 people were contacted to participate in this research study. Individuals were recruited for eight months from April to November 2020. The individuals represented 434 companies from across the globe. Forty-two professionals choose to participate in the study, and two were removed due to only being focused on rehabilitation, therapy, or mental health. Individuals declined for a number of reasons, including recommending a colleague; intellectual property concerns; the company produced XR hardware; the company was not working in the XR space; the company was not working in the medical industry; the company was neither doing XR development nor in the medical industry; the company was focused on rehabilitation, therapy, or mental health; the participant was a researcher, regulatory, or consultant; or they simply did not respond. Table 9 lists the number of individuals contacted with the percentage of contacts.

Responses of Contacts	Number of Contacts	Percentage of Contacts
Completed Survey	40	5.4%
Recommended a Colleague	29	3.9%
Intellectual Property Concerns	22	3.0%
Hardware company	9	1.2%
Not XR	53	7.2%
Not Medical Industry	60	8.1%
Neither XR nor Med Industry	38	5.1%
Rehabilitation, Therapy, Mental Health	44	5.9%
Researcher, regulatory, or consultant	35	4.7%
No response	410	55.4%
Total	**740**	**100%**

Table 9. Responses of contacts, the number of each response, and the overall percentage of contacts during this study's recruitment process.

The recruitment results showed 5.4% of contacted individuals participated in the study. Brooks (1999) was also surprised by the limited number of systems in production at various companies. However, there were some exciting results from this data. A noticeable amount of work was being done in the rehabilitation, therapy, or mental health space concerning XR technologies. These results show 44 participants; however, many individuals were not contacted if their company description focused on rehabilitation, therapy, or mental health use cases.

Another interesting finding related to how many people either expressed intellectual property concerns or declined for that reason. The XR experiences these companies are developing through software are highly vulnerable. XR experiences can take years to build, especially with the added complexities of the medical industry. The intellectual property concerns were expected and designed into the survey questions; by avoiding direct questions about their XR technology and providing multiple-choice questions for participants to opt into a response. This vulnerability reflects the early adoption phase of medical XR technology, where one wrong step or a competitor could sideline their company's investment.

Demographics

The survey asked for demographic information about both participants and their companies. Participant demographics included age, gender, and education. Company demographics had location, focus, company size, participant's position at the company, the participant's role in the XR technology development process, the number of years developing the XR technology, and development status. This section discusses the unique skill sets and company configurations to support XR development.

Participants. Participants ranged in age from 24 to 60 years, with a median age of 37. Ten participants were female, and thirty participants were male. Participants reported that at least 70% have a master's degree. Participants reported a wide range of degree topics, including spoken languages, design, engineering, sciences and social sciences, human factors, business, biology and zoology, and public health. The degrees were organized into six categories; business, design, engineering, general, science, and social science (Figure 67). Berg & Vance (2017) also found a diverse background is necessary to have the skill set required for XR technology. They proposed developing a new-career path focused on [XR]-specific skills and felt it was essential for the use of these technologies to continue advancing.

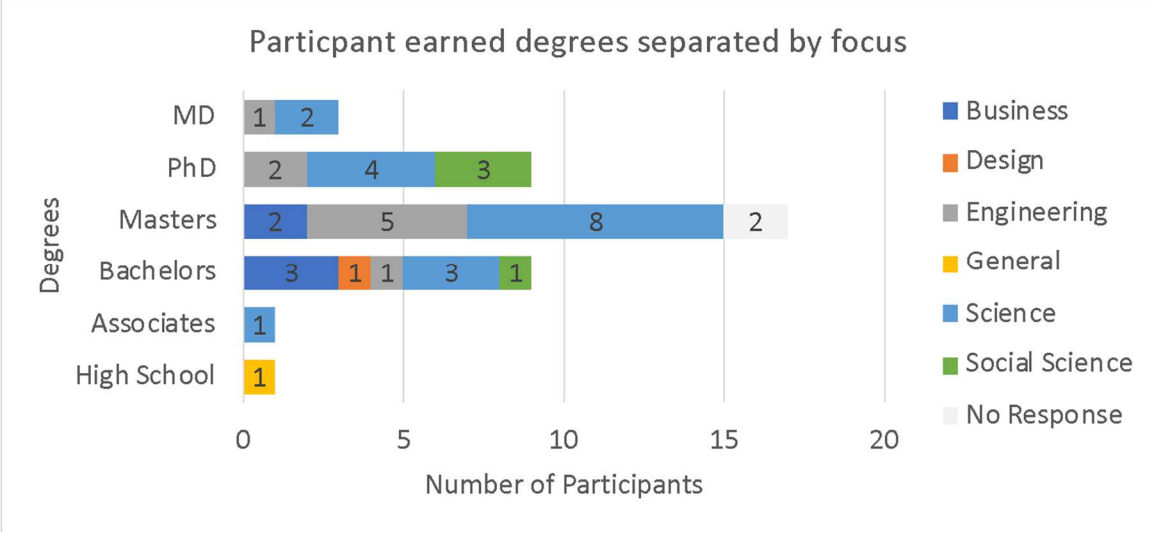

Figure 67. Highest degree earned by participants separated by degree focus. Seventy percent of participants have earned at least a master's degree.

Companies. Participants were located worldwide, with 68% located in the United States and 32% located outside of the United States (Table 10). As stated in the methodology, recruitment was conducted using online platforms to connect XR technology developers.

Within the USA	
California	7
Connecticut	1
Delaware	1
Florida	4
Maryland	3
Minnesota	3
New Jersey	1
New York	3
Pennsylvania	2
Tennessee	1
Washington	1
Total	**27 (68%)**

Outside the USA	
Australia	1
Canada	4
Denmark	1
Germany	1
India	1
Oman	1
Switzerland	1
Ukraine	1
United Kingdom	1
Not reported	1
Total	**13 (33%)**

Table 10. Participant reported company headquarter locations.

Participants selected two ways to use XR technology to; support a clinical need or design a medical device. They could choose one or both options. To Support a Clinical Need, companies are using the technology for patient care. This would be comparable how a hospital would have an MRI machine to capture scans, an exam table for patients to sit, or a stethoscope to listen to a patient's heart. In these cases, the XR technology is the medical device being designed and evaluated by the company. To Design a Medical Device, companies are using the technology as a tool to complete a design-oriented task. This would be comparable to how a technology company would use Solidworks to do CAD work, PowerPoint to create a presentation, or YouTube to learn a new skill. In these cases, the XR technology is not the medical device being designed or evaluated. Of the forty companies, nine used the technology to design a medical device, twenty-three companies used the technology to support a clinical need, and eight companies were doing both (Table 11). These categories are used to present the results below.

Focus	Number of Participants
To Design a Medical Device	9
To Support a Clinical Need	23
To Support a Clinical Need and To Design a Medical Device	8

Table 11. The number of participants whose companies develop medical XR technology for the two focus areas; to design a medical device, to support a clinical need, or both focuses.

One-quarter of the participants worked at companies with less than ten employees, and a majority (25) of the companies are considered small companies (< 100 employees). Most companies have a single focus of either to design a medical device or to support a clinical need. Large companies (> 10,000 employees) reported focusing on both medical device design and clinical needs (Figure 68). These results highlight larger company's abilities to direct more resources toward XR development. The majority (68%) of individuals who participated in this study were individual contributors/operational employees or executives (Figure 69).

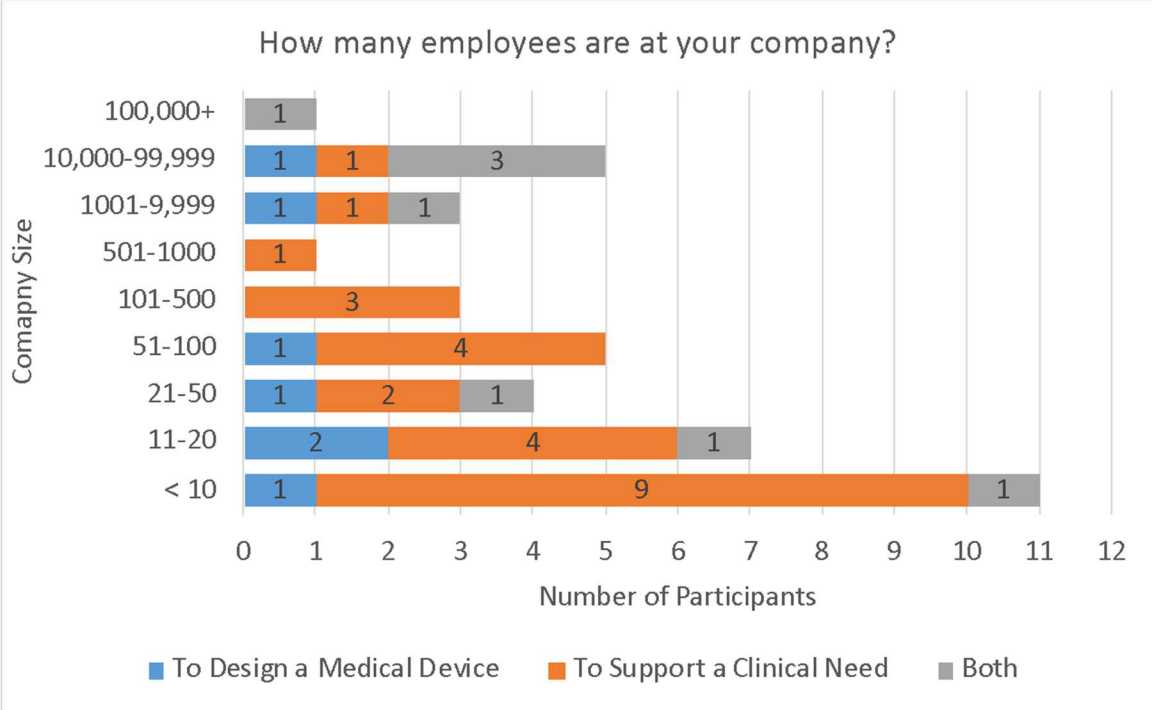

Figure 68. The company sizes separated by focus area.

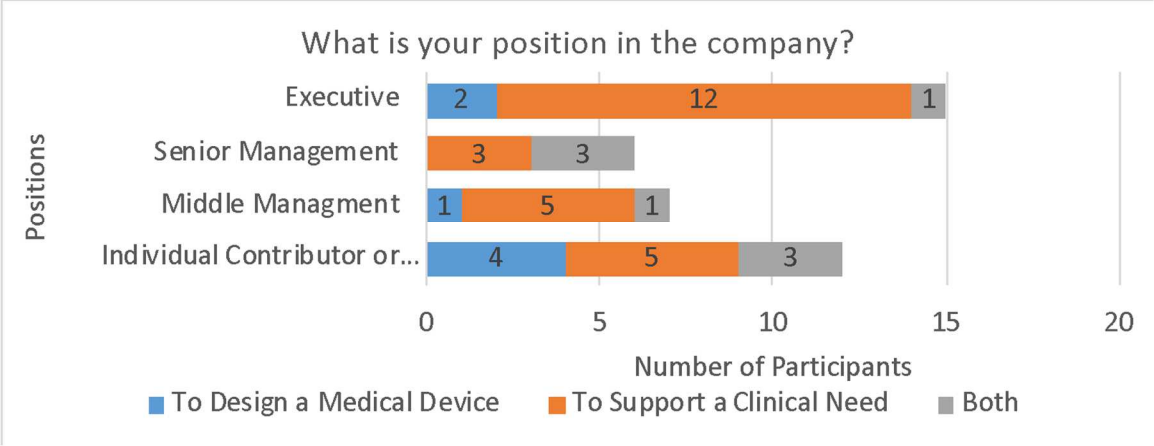

Figure 69. Participant's positions at their company are separated by focus.

Next, participants selected their XR responsibilities at their company. The chosen roles were defined by Berg & Vance (2017) and included maintainer, operator, user, builder, and manager. (Table 12). Participants were primarily managers and builders. Twenty-five participants selected a single role in their company, while the remaining fifteen participants selected between one and five roles (Figure 70). Company size and focus area did not contribute to the number of roles selected by participants.

Category	Responsibilities
Maintainer	Tasks within this category comprise of configuring, calibrating, and upgrading both software and hardware components of a VR system. Exploring new technology and troubleshooting existing technology falls into this category.
Operator	Operators manage the scheduling of the system and help users interact with the system. Responsibilities range from turning on and preparing the hardware to altering software settings to support individualized use cases.
User	These are people who use VR for the benefits the systems provide. Users rarely have responsibilities that support the VR facility itself. Organizationally, users are outside of the other categories.
Builder	Before data can be loaded into the virtual environment, it must be acquired, converted, and touched up. Builders prepare digital content to be integrated into the virtual environment. Interactions and animations are added once content is prepared. They communicate with users to ensure the VR experience meets the intended goals.
Manager	Responsibilities consist of organizing large projects, managing staff, and setting goals for the VR facility. Tracking the use of the VR system can be an important part of ROI calculations.

Table 12. Participant roles as defined by Berg & Vance (2017).

Six participants shared their role as a driver or as quality. Drivers guide the XR development by providing ideas, product visions, or instigating the idea. Berg & Vance (2017) would categorize drivers as users. However, the literature will often reference a champion as a unique contributor to medical innovation (Zweifach & Triola, 2019). Drivers or champions see themselves separate from the general users, who are peers or medical students. Participants also identified quality as their role in the company. Quality control is a critical component of medical device companies, and these people have different focuses when working with the technology. Quality includes assessing if the product design matches the product requirements from software, hardware, or usability perspective.

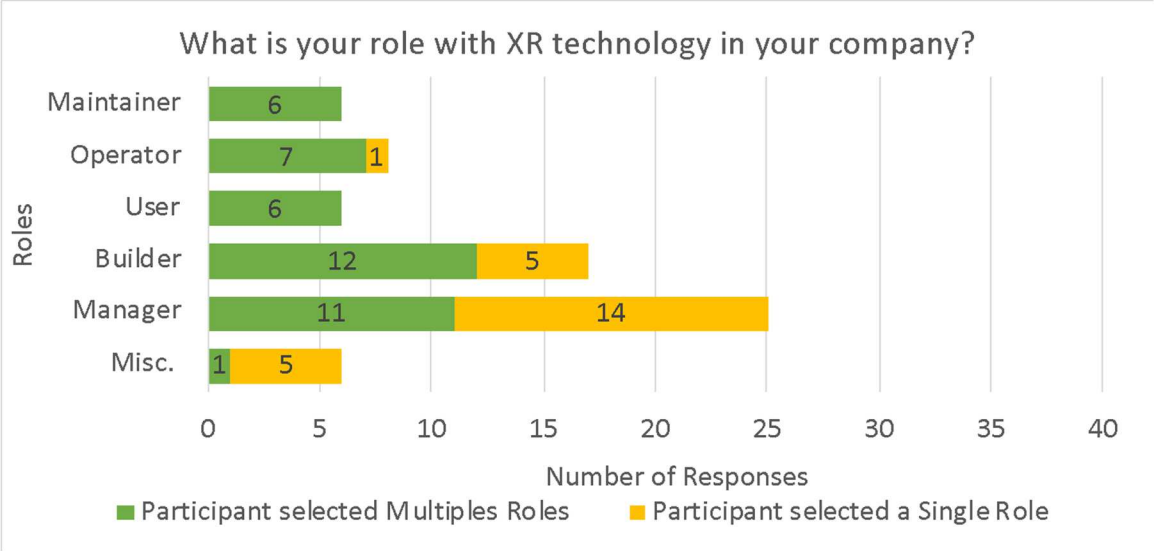

Figure 70. Participant's roles when developing XR technology at their company separated by if the participant selected one role or multiple roles.

Participants reported most of their companies have been investing in XR technology for one to five years (31) (Figure 71). Although the first publications of VR in the medical industry were published over 30 years ago (Kaltenborn & Rienhoff, 1993; Riva, 2002), the release of commercially viable HMDs in 2014 increased the development of medical XR solutions. Participants reported their company had developed XR technologies for 1-5 years. These early adopters are working with earlier versions of these newly commercialized technologies. Interestingly, there was no correlation between the number of years investing in these technologies and the company's size.

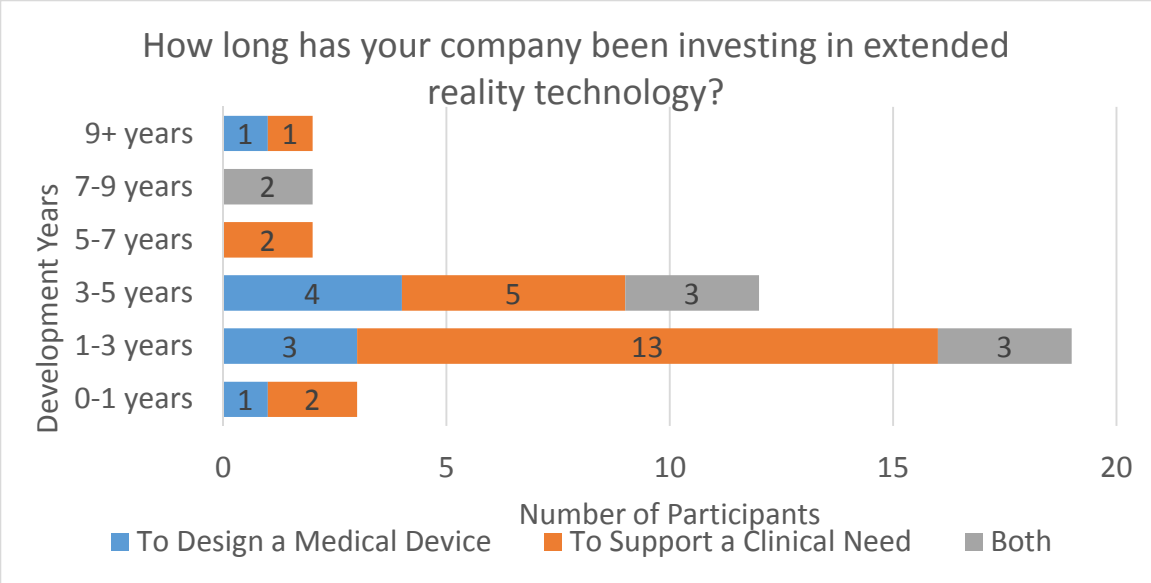

Figure 71. The number of years companies have developed XR technology separated by the focus.

Participants reported that their company was at various points in the development process (Figure 72). Twenty-two participants said their company was actively developing or purchasing a system, and twelve participants reported their company had deployed or purchased a system. There was no correlation between the development status and the number of years a company developed its product. Brooks (1999) also found a significant number of industry systems remained in the pilot development phase and predicted that VR technology would be widespread within five years.

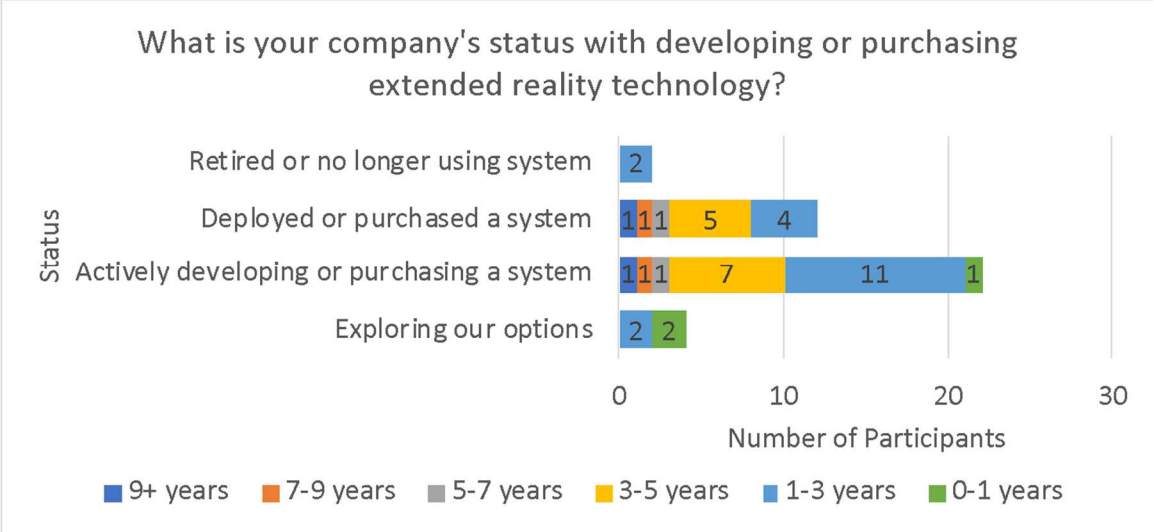

Figure 72. Company's statuses in the XR development process separated by the number of years developing the technology.

Motivations

Companies have many reasons and motivations for developing XR technology for the medical industry. Industries in the early adopter phase present many opportunities for companies. These companies can benefit from being first in the market and can guide how the industry develops. This section discusses drivers and motivators within companies, including factors driving development, the purpose of the solution, and the benefits these companies see for the medical industry.

Many factors are motivating or driving companies to develop XR technologies. The nine factors included in the survey were; accelerate development, assess scaled designs earlier, competitive advantage, illustrate contextual constraints, improve patient care, increase training and education, lower prototyping costs, reduce development risks, and misc. (Figure 73). Competitive advantage, improve patient care, and increase training and education were the most selected reasons driving the development of XR technology. The number of factors selected by participants ranged from one to five, with a majority (27) of participants selecting two or three factors from the list.

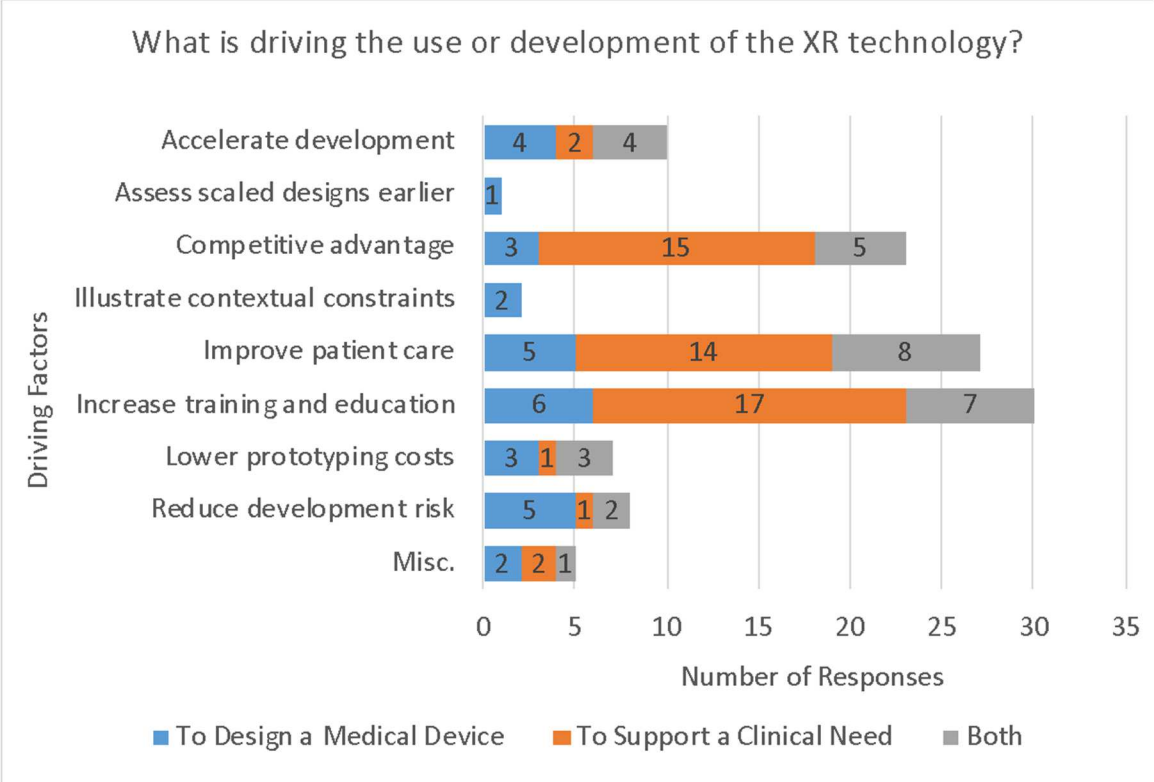

Figure 73. Factors driving the use or development of XR technology for the medical industry.

Companies are applying the driving factors in many different ways to define the purpose of their technology. Most companies (39/40) had some focus on clinical use cases (Figure 74). Participants also identified other focus areas, including interpersonal skills, manufacturing, customer service, and quality. Interestingly, nearly half (18) participants selected either one or four purposes (Figure 75), but there were no clear groupings in the purposes companies have chosen. The responses highlight how foundational XR technology can be applied across medical devices and clinical use cases. One consideration that may contribute to participants selecting multiple purposes was the ease of adding another use case to an established technology. Software designs can include many functionalities to serve many user needs.

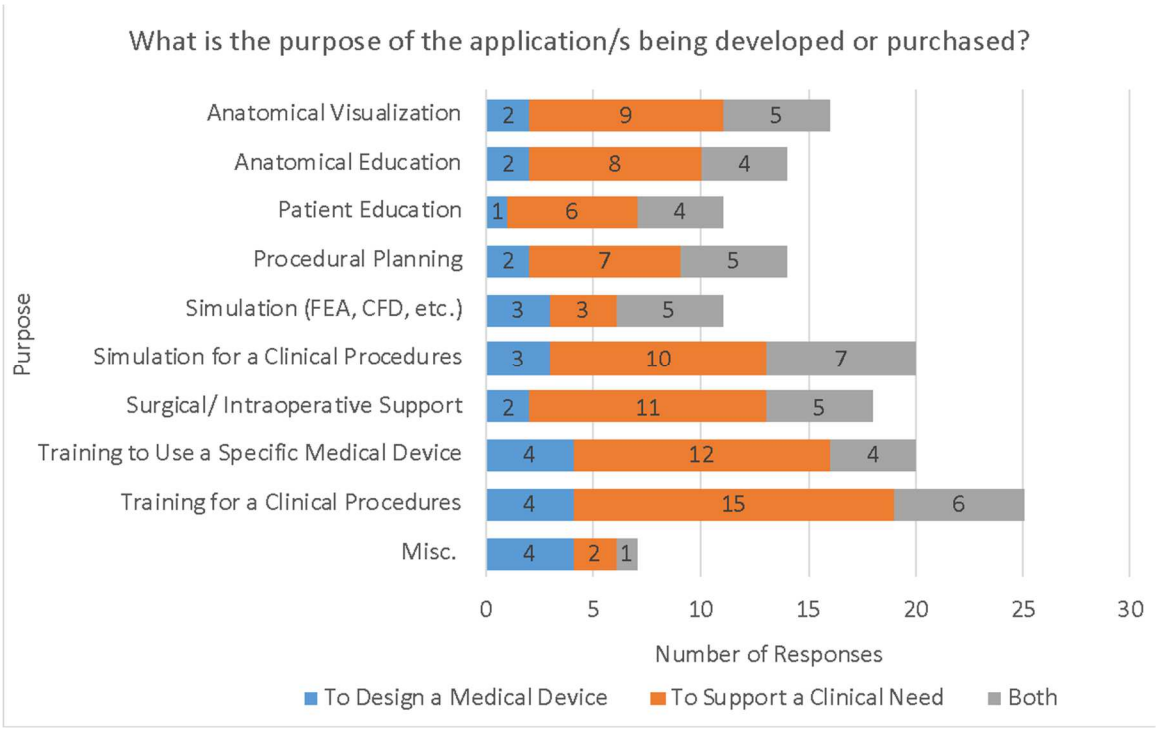

Figure 74. The purposes of the XR technology developed by the companies.

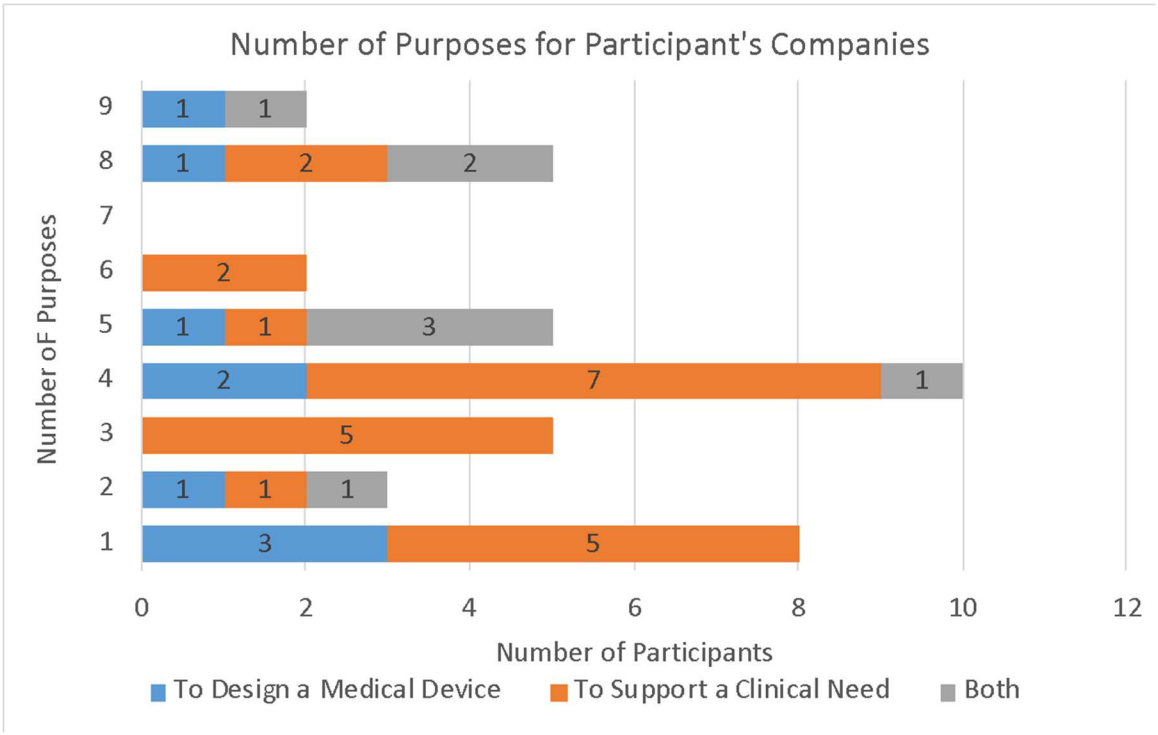

Figure 75. The number of purposes selected by participants.

Benefits of XR Technology. Companies see many benefits for XR technology to impact their medical device design process or as a solution for a clinical setting. Education, training, and innovation received most participants' responses in this study (Figure 76). Education and training are common use cases seen in academic literature and the marketplace. These spaces align well with current XR technology's scope because they typically include some level of gamification in the system's design. The gaming industry was driving XR technology development, so it was easy to see that medical XR experiences align with the current technology drivers. The other benefit highlighted by the study participants was the ability to drive innovation in the industry. As stated before, research has shown the value of medical XR technology. The companies developing these technologies see the potential and are actively advocating for the technology as early adopters.

After education, training, and innovation, the three groups deviated from the benefits selected; participants working in the medical device space selected cost savings, decision making, and safety (Figure 76). Participants developing for the clinical area also choose safety and time savings. Participants developing for both spaces picked communication and time savings. As more research explores XR technology in the medical industry, the nuances of appropriate use cases and the benefits will be identified. For example, Kloesel et al. (2021) reported the cost of using XR technology to confirm a device's fit in a pediatric patient. They provided this datapoint because the cost of these techniques is a critical driver towards hospital adoption and demonstrating the ROI. As more articles are produced, the value of using these technologies will be compared to existing methods.

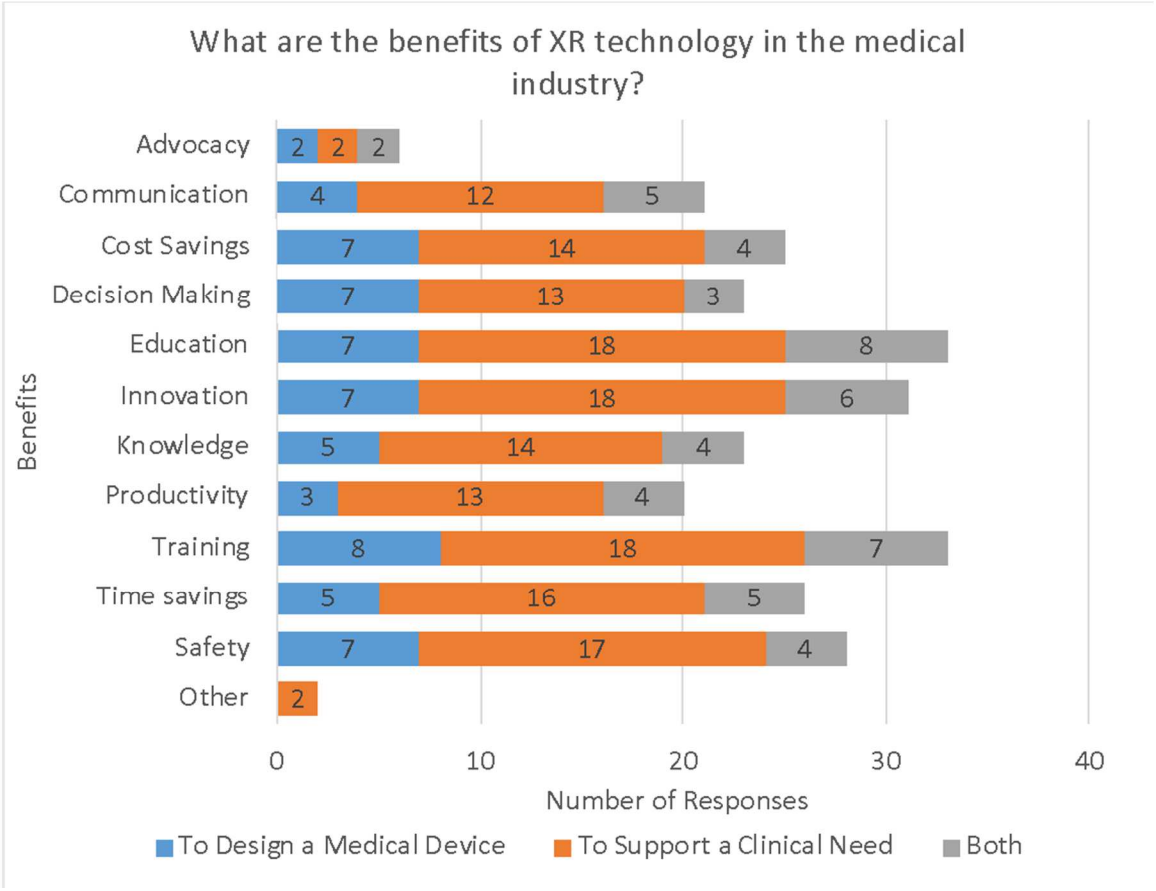

Figure 76. Benefits of using XR technology in the medical industry as perceived by those developing the technology.

Problems and Decisions. Participants who were designing a medical device and supporting a clinical need were asked different questions about what they solve using XR technology. For participants focused on designing a medical device, the question was 'what types of problems are best solved using extended reality technology?' For participants focused on supporting a clinical need, the question was 'what decisions about a clinical need do you make while using extended reality technology?'

Four topics appeared in responses from participants for both the problems solved and decisions made using XR technologies. These topics included training, anatomical visualization, decision making, and workflow. Training was essential to train students and medical staff about surgical procedures; skills acquisition and knowledge retention; replicate real-world experiences; scale traditional training methods; and experience

multiple scenarios. Anatomical visualization enabled users to have the same perspective as their colleagues and an improved view when analyzing the models. Decision-making was discussed as a part of the process to develop medical devices and surgical procedures. Finally, the workflow was important to understand the dynamic medical work environments to enhance procedures' efficiency.

Two additional topics appeared from participants designing medical devices, including collaboration and prototyping. The first was collaboration and remote work, while the second was prototyping. Collaboration and remote work were important for users to collaborate in real-time, collaborate and work remotely. Virtual prototyping was important for early phase experience with a design idea before preparing physical prototypes of medical devices and for iterating through design changes.

Four additional topics appeared from participants that support clinical needs. The topics were surgical planning, patient safety, user needs, and cost. Surgical planning was important to guide surgeons towards a more accurate procedure by simulating the procedure's outcomes. Patient safety was necessary to improve patient care, privacy, and security during the patient's experience. User needs were important to anticipate the surgeon, physician, and medical staff's needs before the procedure. Cost was the final topic mentioned by participants and they said XR technology helped reduce the cost of a procedure by confirming the procedural details.

New Opportunities with XR Technology. Participants identified many opportunities that XR technology offers their processes that are currently unavailable with other technologies. A few topics from the problems and decisions section presented in these responses including training; collaboration and remote work; visualization; surgical planning; and prototyping. Three additional issues appeared in the responses for new opportunities with the technology. These topics are immersion, interaction, and customer engagement. Immersion was necessary as participants could immerse themselves in the virtual experience, which had a wider field of view, better resolution, and fewer distractions than 2D screens. The interaction was significant as these technologies allow spatial interaction with the medical devices or procedure details in a

richer three-dimension (3D) environment with immediate interaction and response from the models. Finally, user engagement was important to engage patients to learn about their procedure and engage surgeons to learn about medical devices.

Resources

Companies use numerous resources to develop their XR technologies. Resources include personnel and existing knowledge, the hardware selected, and the software used. Personnel and existing knowledge guide the direction of the technology. Companies then choose appropriate hardware and software to develop the solution for the specific use case. Knowledge of the resources used for these technologies shows where the medical industry is headed compared to other industries. This section discusses the resources used by companies to develop their medical XR experience.

Personnel and Existing Knowledge. Companies use personnel and existing knowledge as resources to guide technology development (Figure 77). As seen in the demographic section, the participants of this study had very diverse backgrounds. The most common personnel resourced by companies was domain experts with twenty-seven responses, followed by a tie of twenty-five responses between programmers with XR experience and company leadership. Usability experts received twenty-two responses. An interesting result was only nine participants indicated they use 'programmers with BS in computer science.'

Another resource used by participants was knowledge of solutions already on the market and academic research. These types of resources were less popular among the participants. 'Other extended reality solutions on the market' and 'human factors research' both received seventeen responses, followed by thirteen computer science research responses. On average, participants shared that their companies use four personnel and existing knowledge resources.

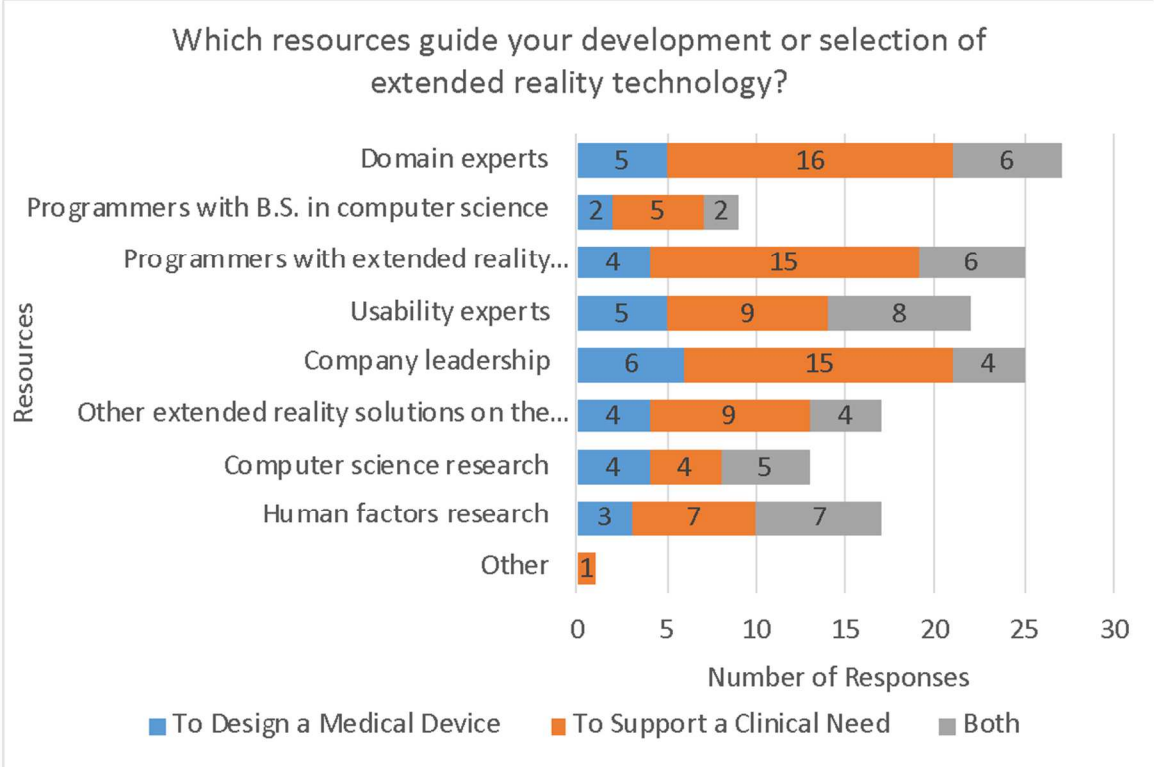

Figure 77. The resources used by companies to develop medical XR technology.

Hardware Technologies

Commercially available hardware is guiding how companies develop XR technology for their purpose (Figure 78). Most companies (32/40) are using virtual HMDs, followed by augmented HMDs (18/40), and AR using mobile technologies (phone, tablet, etc.; 17/40). No companies reported using CAVE systems, and five companies said using stereo projection VR environments. These companies are using both virtual and augmented HMDs, along with the stereo projection VR environments.

The results of these questions are interesting because they are a complete shift from previous research into the use of XR technologies in specific industries by Berg and Vance (2017). In their article, a majority of participants reported using CAVEs (13/35) and Powerwalls (12/35), and usage of HMDs (7/35) and portable systems (5/40) were selected less often across multiple industries. Reviewing the timing of Berg and Vance's (2017) study shows how quickly technology preferences can shift. They conducted their survey from the fall of 2014 to the spring of 2015, which was amid the first releases of

commercially available head-mounted technologies; Google Glass (May 2014), Google Cardboard (June 2014), and Samsung Gear VR (November 2015). Five years after Berg and Vance's (2017) research, there was a shift from CAVEs and Powerwalls to virtual and augmented HMDs as the predominant technology.

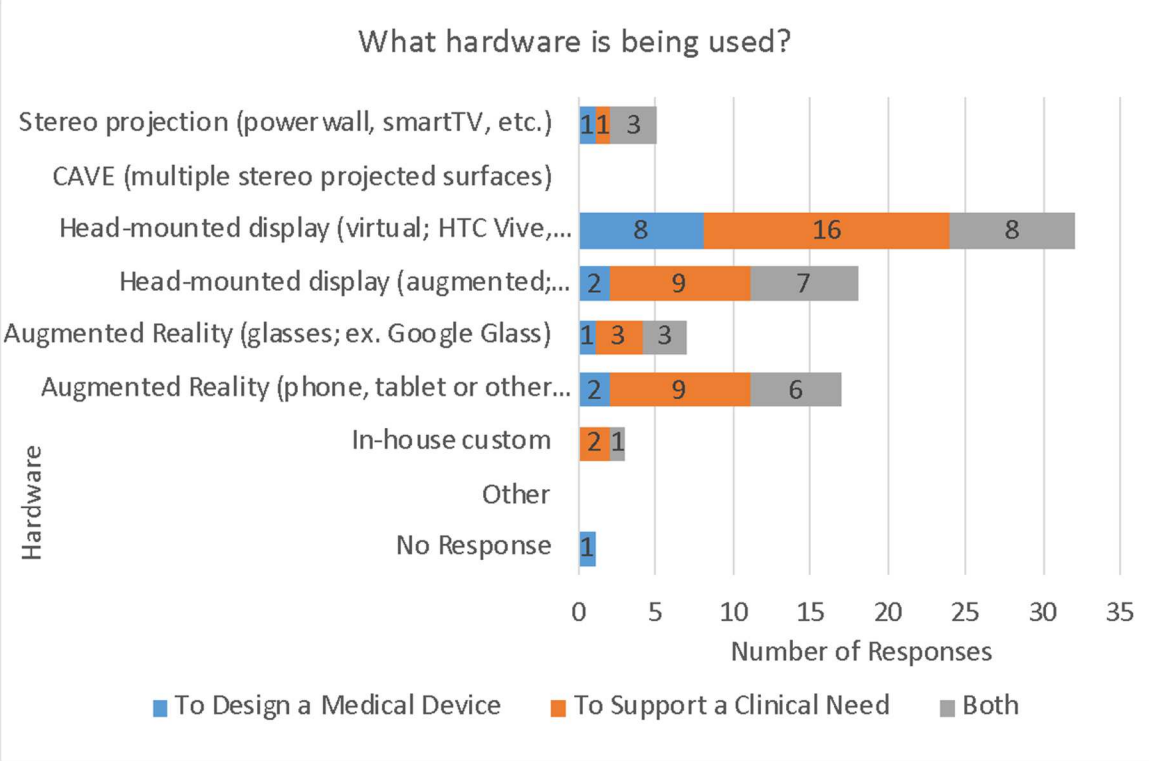

Figure 78. Hardware used by companies to develop medical XR technology separated by focus area.

Software Technologies

Companies primarily use commercial software packages to develop their XR solutions (Figure 79). Most of these companies are using Unity to build their technology. Other commercial software used includes; Autodesk, Azure, Matlab, ThinkWorx, Unreal Engine, Visual Studio, Vuforia, and Z-space. For open-source software, participants mentioned; ApertusVR, ITK, MRTK, openXR, OVR, Python, Slicer3D, Three.js, and VTK. Three 3D modeling software were mentioned; Blender, Creo, and Maya.

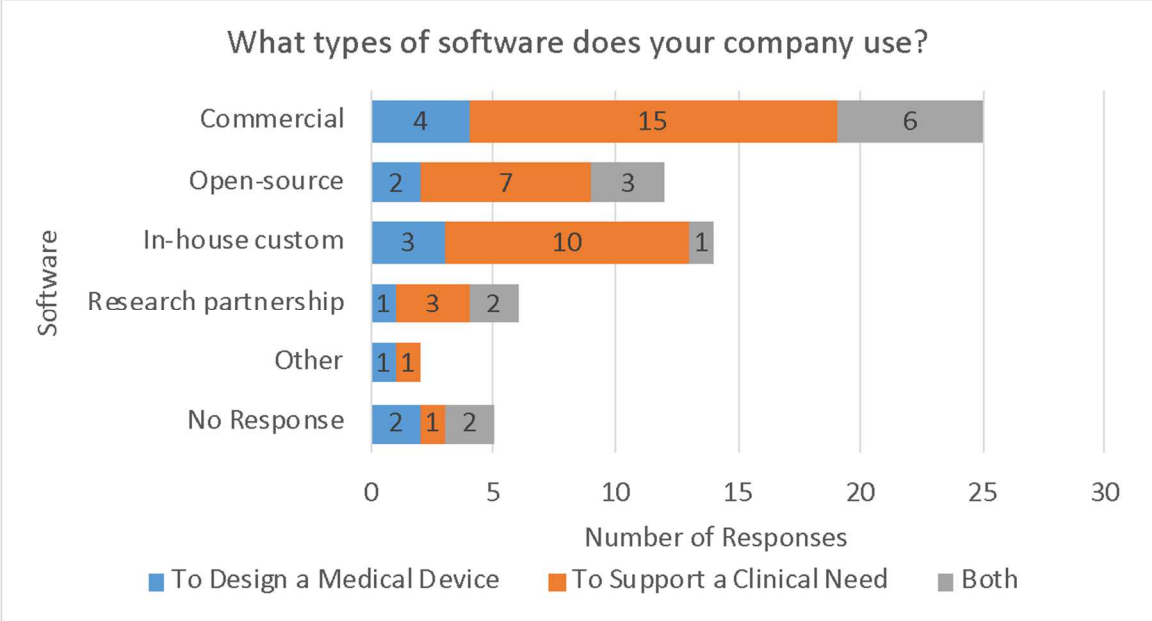

Figure 79. Software used by companies to develop medical XR technology separated by focus area.

The personnel and existing knowledge, hardware, and software results show how companies are developing their own solutions. The majority are selecting and using one hardware technology, while there is less consensus on the number of personnel and existing knowledge and software resources used (Figure 80). Eighteen different companies are developing solutions with a single hardware technology. The focus on one hardware is reasonable, as it takes time and resources to learn how to design for different hardware. Companies are then using multiple software packages to complete their solution. This may be due to the fact that a single software does not meet all of the company's needs when focused on the medical industry.

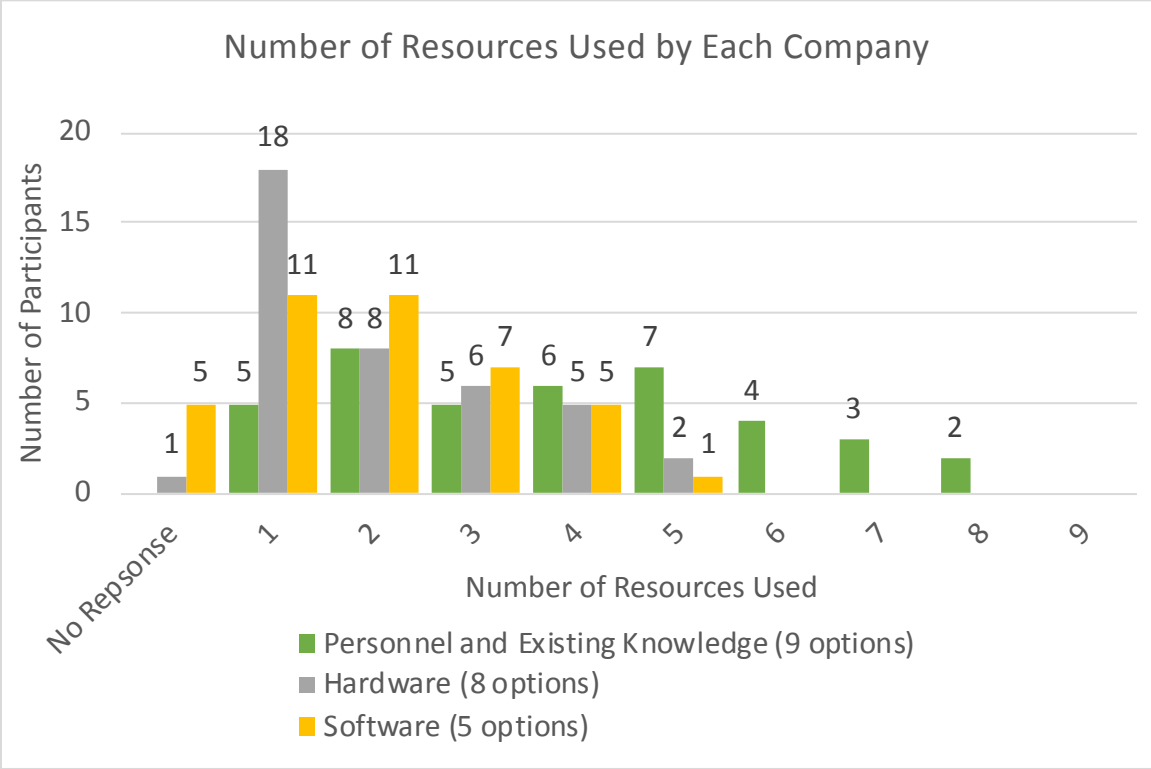

Figure 80. The number of resources used by companies for personnel and existing knowledge, hardware, and software.

Company Operations

The next step in the analysis was to understand how companies are using the resources identified above. Participants shared when and how they use XR technology in the medical device design process or a clinical setting. These results were cross evaluated to determine how participants used the technology at certain times in their processes (when). Participants also identified how they access the technology available to them. This section discusses companies' operations around when and how they are using XR technology.

When Companies Use XR Technology. Companies are using XR at many points in designing a medical device or supporting a clinical setting (Figure 81) processes. Companies using XR technology to design a medical device use the technology primarily to prototype and secondarily to perform testing. Companies using XR technology to

support a clinical need use the technology primarily for training or simulation and secondarily for medical education.

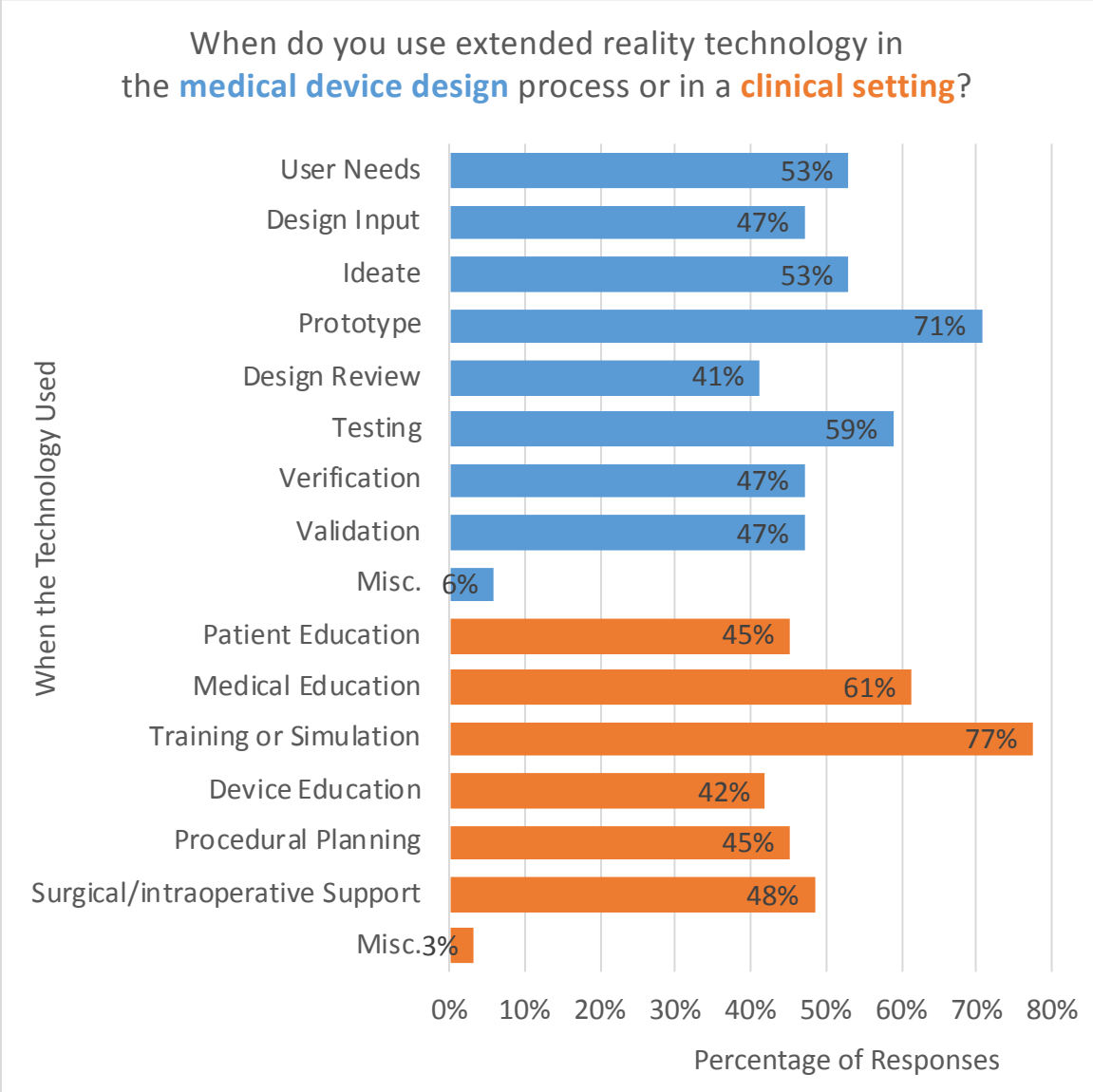

Figure 81. When companies use medical XR technology in their medical device design process or a clinical setting.

How Companies Use XR Technology. After understanding when companies use XR technology, the next step is to evaluate how they use it (Figure 82). Companies using the technology to design a medical device use it primarily for simulation and testing, and

secondarily for design development. Companies supporting a clinical need primarily use the technology to visualize human anatomy.

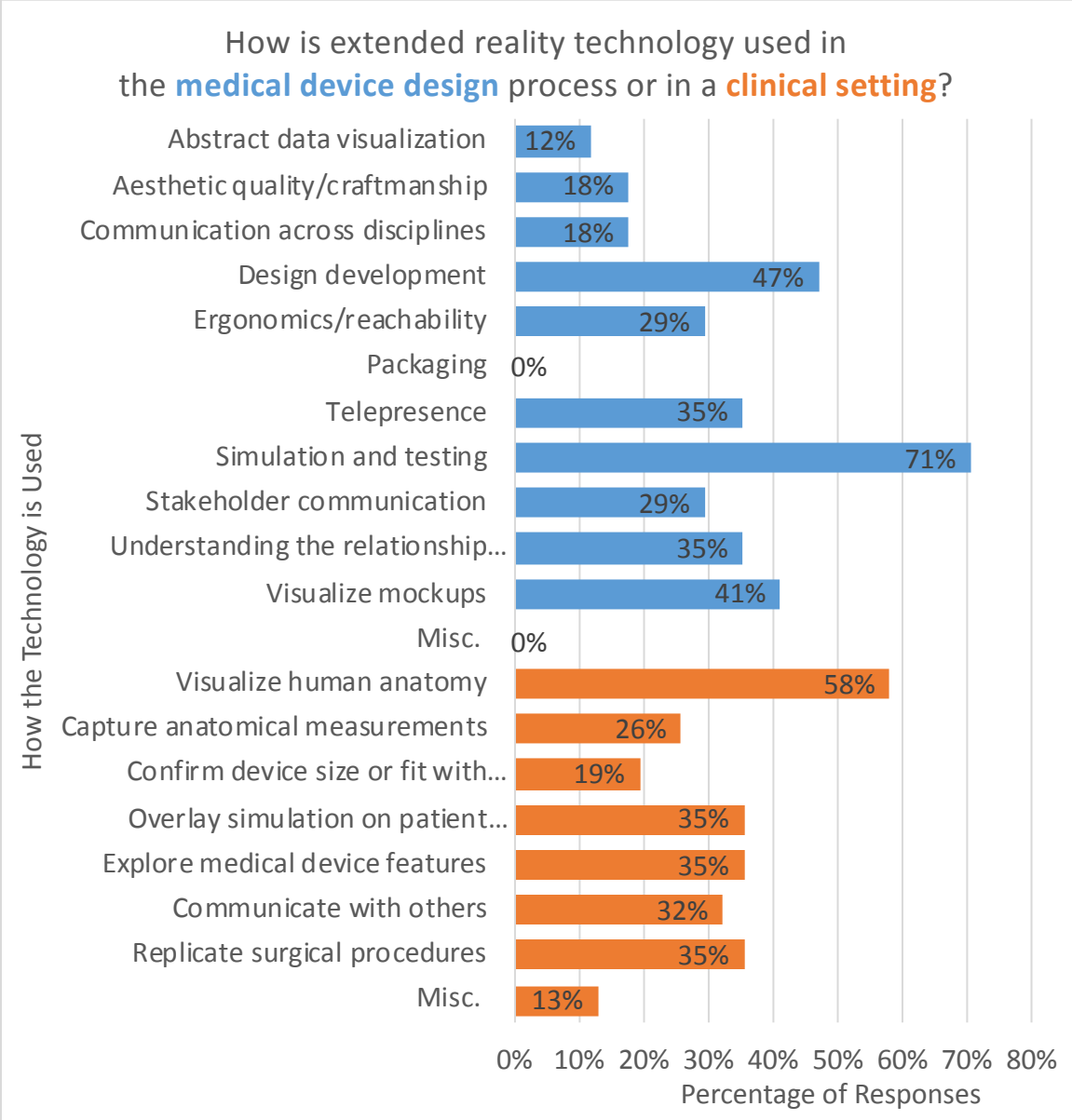

Figure 82. How companies use medical XR technology in their medical device design process or a clinical setting.

Participant's responses were cross evaluated to understand the correlation between when and how they use medical XR technology. Cross evaluating the data showed the different ways (how) participants used the technology at specific points in

their processes (when) (Table 13). The percentages were calculated by counting how many companies selected a task (how) for the specific process step (when). For example, nine participants reported using XR technology to determine 'user needs,' and of those companies, three reported using it for 'abstract data visualization.' Therefore, 33% was written for the correlation between the when of 'user needs' and the how of 'abstract data visualization.'

The data showed some expected and some unexpected trends. Here are the expected trends.

- For participants using XR technology for 'design review (when),' 100% of them used it for 'simulation and testing (how).' This shows that simulation and testing is an important tool for companies doing design reviews.

- 'Simulation and testing (how)' correlated high across all stages of the medical device design process (when). This is important because it shows a significant usage of XR technologies for simulation and testing.

- 'Visualize mockups (how)' correlated high with the 'design input (when)' at 88% of companies, 'ideate (when)' at 78% of companies, and 'design review (when)' at 86% of companies. This shows that visualizing a medical device concept is important at the early phases of the design process (design input and ideate) and to confirm (design review) the design meets the requirements.

- Another expected result was 'testing (when)' had the lowest correlation with 'communication across disciplines (how)' (20%).

- 'Telepresence (how)' also scored low across the design process (when).

The cross-evaluation for the medical device design process also showed some unexpected trends.

- When companies were determining 'user needs (when)', they were less likely to use XR technology for 'abstract data visualization (how)' (33%) and to

‘communication across disciplines (how)’ (22%), but more likely for ‘simulation and testing (how)’ (100%). This correlation was unexpected because identifying user needs is when companies pull together abstract data to contextualize the potential users and understand the product needs from many perspectives. Typically, a company will perform simulation and testing on a developed medical device, which is after the user needs are defined. This result may be a coincidence and also may be due to a lack of development into the use of XR technology to explore users’ needs.

- Another unexpected result was ‘stakeholder communication (how)’ correlated the highest with the ‘validation (how)’ step in the design process (63%) and lowest with ‘user needs (when)’ and ‘ideate (when)’ both at 33%. Typically, stakeholder communication occurs during the user needs and ideate phases to define the product requirements.

- ‘Communication across disciplines (how)’ also scored low across the design process, even though the participants in this study have backgrounds in many disciplines.

Design Medical Devices		How									
		Abstract data visualization	Aesthetic quality/craftsmanship	Communication across disciplines	Design development	Ergonomics/reachability	Telepresence	Simulation and testing	Stakeholder communication	Understanding the relationship between anatomy and the device	Visualize mockups
When	User Needs	33%	22%	22%	56%	56%	33%	100%	33%	56%	56%
	Design Input	38%	25%	25%	63%	75%	25%	88%	38%	63%	88%
	Ideate	33%	22%	22%	67%	67%	33%	89%	33%	67%	78%
	Prototype	25%	25%	25%	58%	50%	50%	83%	42%	58%	58%
	Design Review	43%	43%	29%	71%	71%	29%	100%	57%	71%	86%
	Testing	30%	30%	20%	60%	50%	30%	90%	50%	50%	60%
	Verification	38%	38%	25%	75%	63%	25%	100%	50%	63%	75%
	Validation	25%	38%	25%	75%	50%	38%	88%	63%	50%	63%
Key for cell color: 0-25% 26-50% 51-75% 76-100%											

Table 13. Percentage of companies at specific steps in the design process (when) cross evaluated with the particular tasks in the design step (how). For example, at the 'user needs' step, 33% of companies use medical XR technology for 'abstract data visualization.'

The responses for participants supporting clinical needs were also correlated (Table 14). This analysis also had expected and unexpected outcomes.

- Most companies are using XR technology to 'visualize human anatomy (how)' at all steps in the clinical process (when). 'Visualize human anatomy (how)' is used the least (46%) for 'device education (when)'.

- 'Device education (when)' had a high correlation with 'explore medical device features (how)' at 62% and an unexpectedly low correlation (15%) with 'confirm device size or fit with anatomy (how).' This result is important because it shows companies have separated themselves into the visualizing anatomy or visualizing

medical devices, but not using the technology to do both. Previous research has shown an opportunity to combine these two spaces to assist clinical teams (Kloesel et al., 2021).

- 'Replicate surgical procedures (how)' had a high correlation (53%) with both 'medical education (when)' and 'surgical/intraoperative support (when).' These correlations were expected as examples existed in the literature, but it was surprising that the correlation was not higher.

- 'Confirm device size or fit with anatomy (how)' also scored low across the clinical process. This is important to note as companies are not developing XR technologies to assist doctors to analyze the relationship between a medical device and the patient's anatomy.

Support Clinical Needs		How						
		Visualize human anatomy	Capture anatomical measurements	Confirm device size or fit with anatomy	Overlay simulation on patient anatomy	Explore medical device features	Communicate with others	Replicate surgical procedures
When	Patient education	71%	36%	21%	43%	36%	43%	29%
	Medical education	74%	37%	26%	47%	47%	42%	53%
	Training or simulation	63%	33%	21%	42%	42%	38%	46%
	Device education	46%	23%	15%	31%	62%	46%	46%
	Procedural planning	86%	50%	43%	50%	43%	36%	43%
	Surgical/intraoperative support	80%	47%	33%	53%	60%	47%	53%

Key for cell color : 0-25% 26-50% 51-75% 76-100%

Table 14. Percentage of companies at specific steps in the clinical process (when) cross evaluated with the particular tasks in the clinical step (how). For example, at the 'patient education' step, 71% of companies use medical XR technology to 'visualize human anatomy.'

Protocols for Using XR Technology. Each company has developed protocols for when their employees can access and use the XR technology (Figure 83). Protocols for

using XR technology vary by if the organization is designing a medical device or using the technology in a clinical setting. Participants working in clinical settings prefer to schedule sessions with the technology (77%), compared to participants in the medical device design process who prefer impromptu sessions with the technology as needed (65%). These results can guide organizations as they are designing and developing their XR facilities for the medical industry.

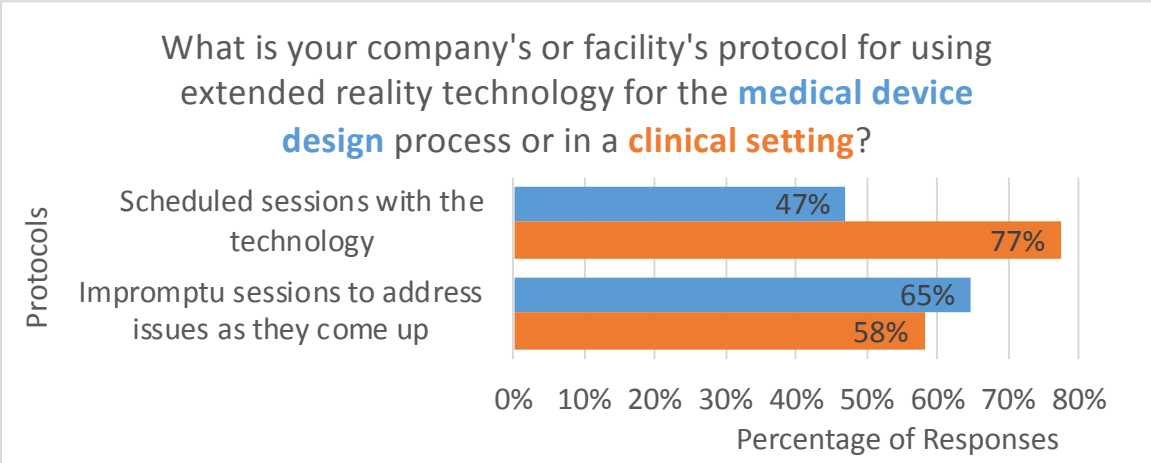

Figure 83. The company or facility's protocols for using the XR technology. Participants selected either 'scheduling sessions with the technology' or 'impromptu sessions to address as they come up.'

Solution Testing

After a company has developed a solution, testing is necessary to verify and validate the solution against the original product requirements. Four types of testing occur with most software. Testing methods include unity testing, integration testing, system testing, and user testing. As this work is primarily focused on usability and designing for the user, most questions were related to user testing. This section evaluates how companies are testing their solutions.

Types of Testing Completed. A vital component of the medical device process is to evaluate the quality of the technology design. Participants choose between four types of testing; unity testing, validating the program; integration testing, validating the design; system testing, validating the system/architecture; and user testing, validating against requirements. Four of the forty participants indicated that their company did not test their

XR technology, which is significant as this represents 10% of the companies surveyed. Their responses are listed as ‘do not test technology’ in the following question. As presented in chapter five, user guidelines and XR technology design directly impact users’ ability to interpret data and ultimately make informed decisions. Most participants reported testing the developed solution was important to their company. Unity, integration, and system testing received the same number of responses. Simultaneously, there was a noticeable increase in the number of participants who responded user testing was important for their company (Figure 84).

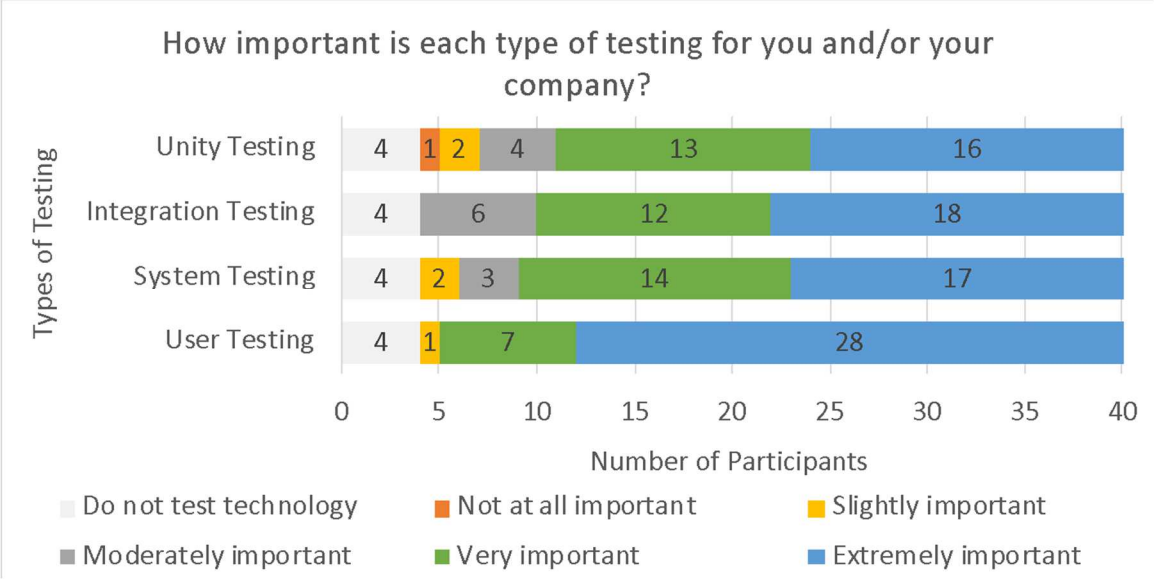

Figure 84. The importance of different testing methods for XR technology based on responses from participants.

Reasons to Test a Solution. Companies have many reasons to conduct testing on XR technologies and choose different testing forms appropriate for their solution. Most companies (33/40) perform testing to ‘identify defects and errors during development’ and learn ‘insights to improve the overall user experience’ (30/40). Other testing options presented in the survey included ‘system design validation’ (26/40), ‘find issues with complete workflows’ (24/40), ‘gather unbiased user options’ (23/40), and ‘match design criteria to real-world needs’ (26/30). Overall, on average, participants selected four types of testing from the six options, with twelve participants selecting all six types of testing (Figure 85).

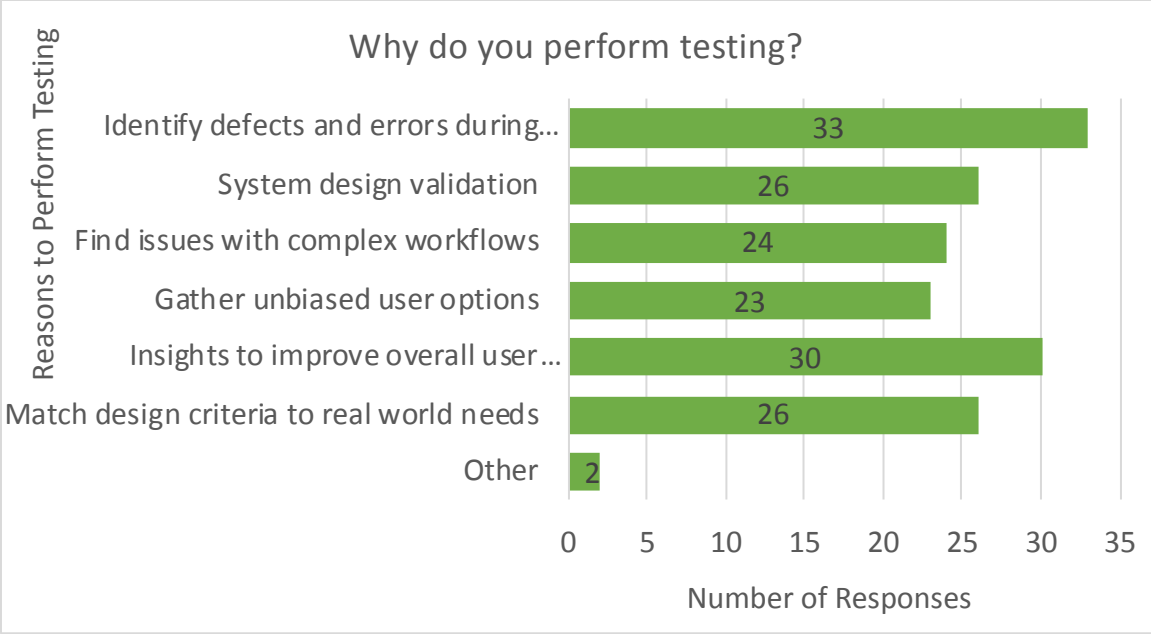

Figure 85. The reasons companies perform testing of their XR technology for the medical industry.

Internal and External User Testing. Many types of testing are available to evaluate XR technology. The questions for this study focused on usability testing. Participants indicated if they complete testing internal or external to their company. Conducting interviews or demos was the most common type of testing used by companies; twenty-four completed 'interviews or demos' internally and fourteen complete 'interviews or demos' externally. The next most common type of testing was 'cognitive walkthroughs,' followed by 'summative or comparison evaluations' and 'post-hoc questionnaire' (Figure 86). Overall, on average, participants said their company completes two types of user testing internally and one type of user testing externally.

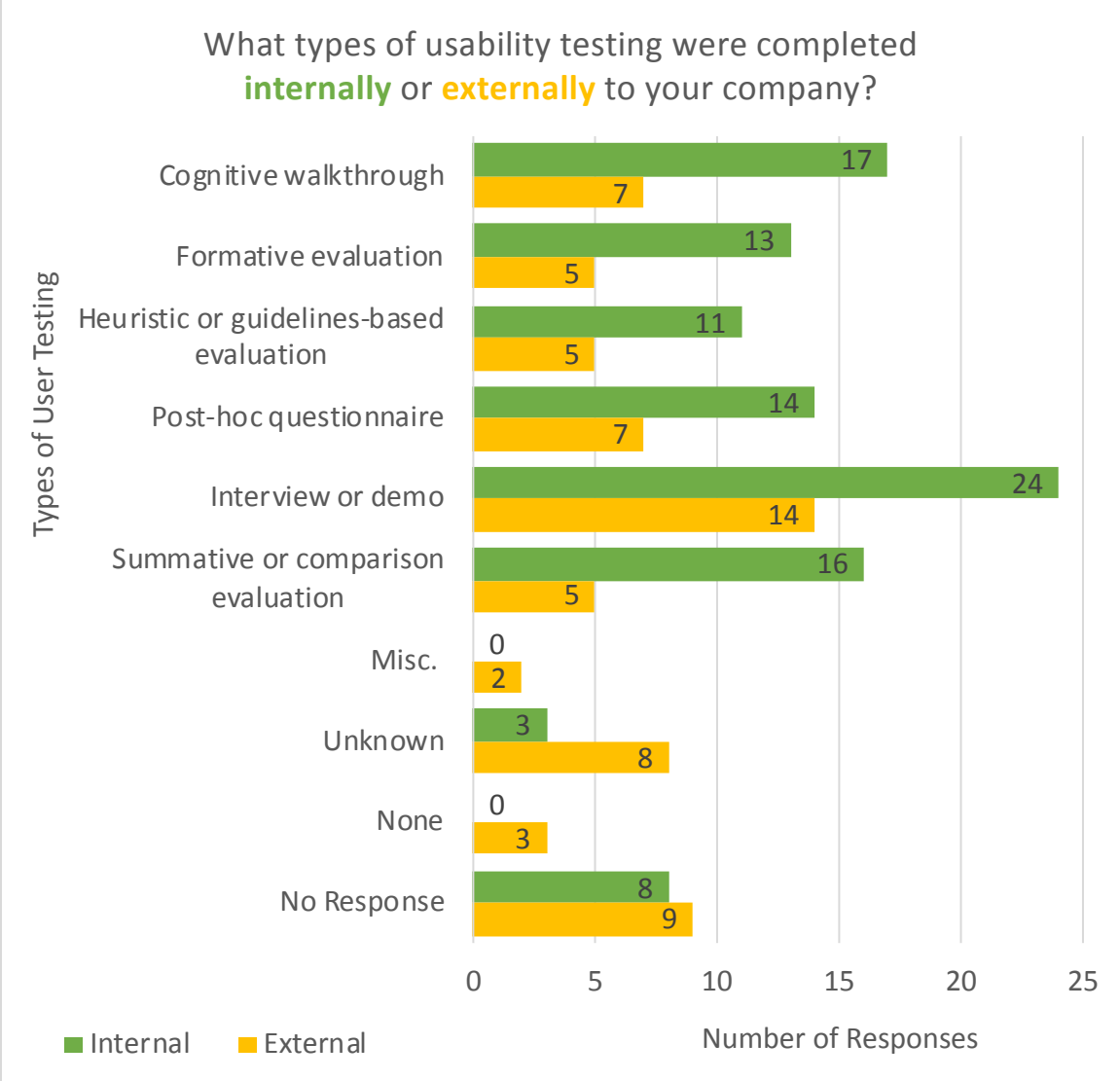

Figure 86. The types of user testing completed by companies either internally to their company or externally to their company.

Guidance for User Testing. Knowledge about appropriate methods to develop technology and perform testing comes from a variety of sources. Research, guidance, and standards are available for various industries to guide developers towards safe, effective, usable, and reliable designs. Overall, participants felt more work was needed in this space to support the development of XR technology for the medical industry. Participants were split on if 'appropriate methods exist for extended reality usability testing.' Ten participants strongly agreed with the statement, six participants somewhat agreed, nine

participants neither agreed nor disagreed, five participants somewhat disagreed, two participants strongly disagreed, and eight did not respond to this question (Figure 87).

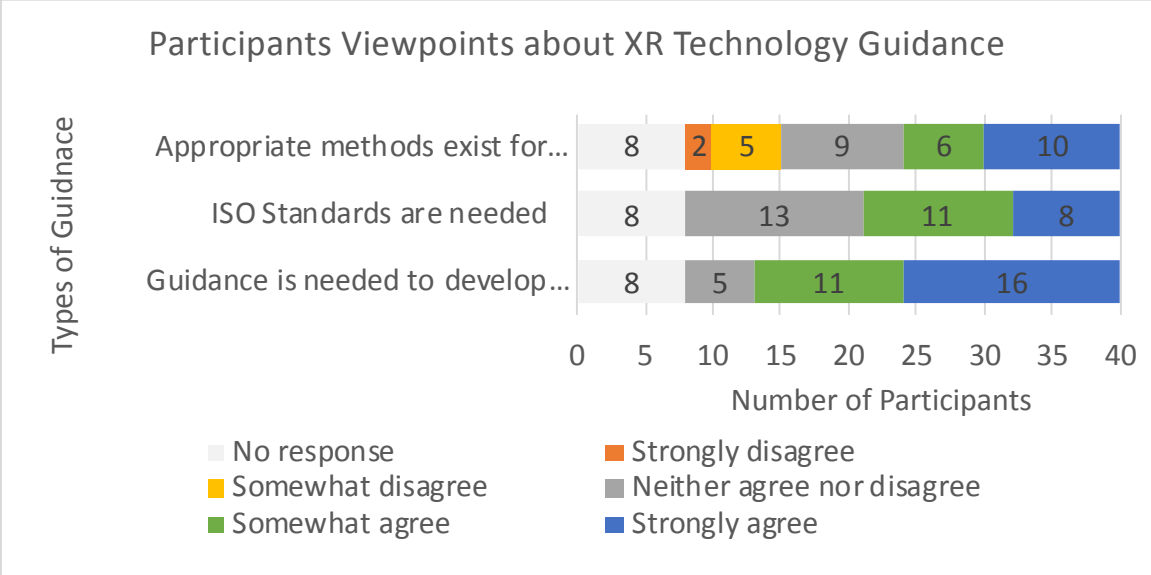

Figure 87. Participants' viewpoint about available XR technology guidance.

Participants agreed that ISO standards are needed. Eight participants strongly agreed with the statement, eleven participants somewhat agreed, thirteen participants neither agreed nor disagreed, and three did not respond to the statement (Figure 87). At the time of this survey, a few separate guidance documents are available from specific focus areas. The first is a white paper from ISO/IEC JTC 1 called Guidelines for Developing VR and AR Based Education and Training Systems. It was released in 2019 (ISO/IEC JTC 1, 2019) and described the ISO standards for the XR training space. The second is ISO standard 9241: Ergonomics of human-system interactions last released in 2010 and provides requirements and recommendations for human-centered design principles for digital products (ISO 9241, 2010). Others may be available in sections of other ISO standards; however, the guidance is incomplete due to the technology's novelty.

Participants also agreed that guidance is needed to develop XR design criteria. Sixteen participants agreed with this statement, eleven participants somewhat agreed, five participants neither agreed nor disagreed, and eight participants did not respond to this

statement (Figure 87). Guidance comes from a variety of sources, including research, professional organizations, and government agencies. Most guidance for the medical industry comes from the FDA. The FDA has released three sets of guidance: hardware as a medical device, software as a medical device, and interoperability guidance. Those working in the medical device industry are most familiar with medical device guidance, which applies to hardware-based technology. The software as a medical device guidance has numerous examples to help companies determine if they need to seek regulatory approval and acknowledges that the field of software as a medical device continues to evolve. The final interoperability guidance encourages technology developers to consider how their technology works with users and other technologies, either as a medical device or used in a medical environment. Depending on the intent and design of XR technology for the medical industry, the company may need to seek FDA approval.

Challenges

Participants face many challenges by themselves and as companies when developing XR technology for the medical industry. Five challenge themes emerged from participant's responses about their challenges; infrastructure, personnel, business case, internal adoption, and external adoption. Infrastructure and personnel must be obtained to develop the experience. Business cases are the justification and funding necessary to support development. Finally, internal and external adoptions are critical to advance medical XR technology. These five themes are current challenges for XR developers.

Difficulties. Participants rated the difficulty of activities associated with four of the challenge themes (Figure 88). The most difficult activities were securing funding for XR technology, followed by starting an XR facility. The easiest activity based on participant's responses was employing individuals with the appropriate skillsets. The pipeline to develop individuals with relevant skill sets takes the longest to complete, especially knowing the average degree for all participants in this study was a master's degree, which takes six years to finish. Participants also rated starting an XR facility, measuring ROI, and technology adoption within the company as difficult. Berg & Vance (2017) also reported that their interviewees faced difficulties setting up a VR facility.

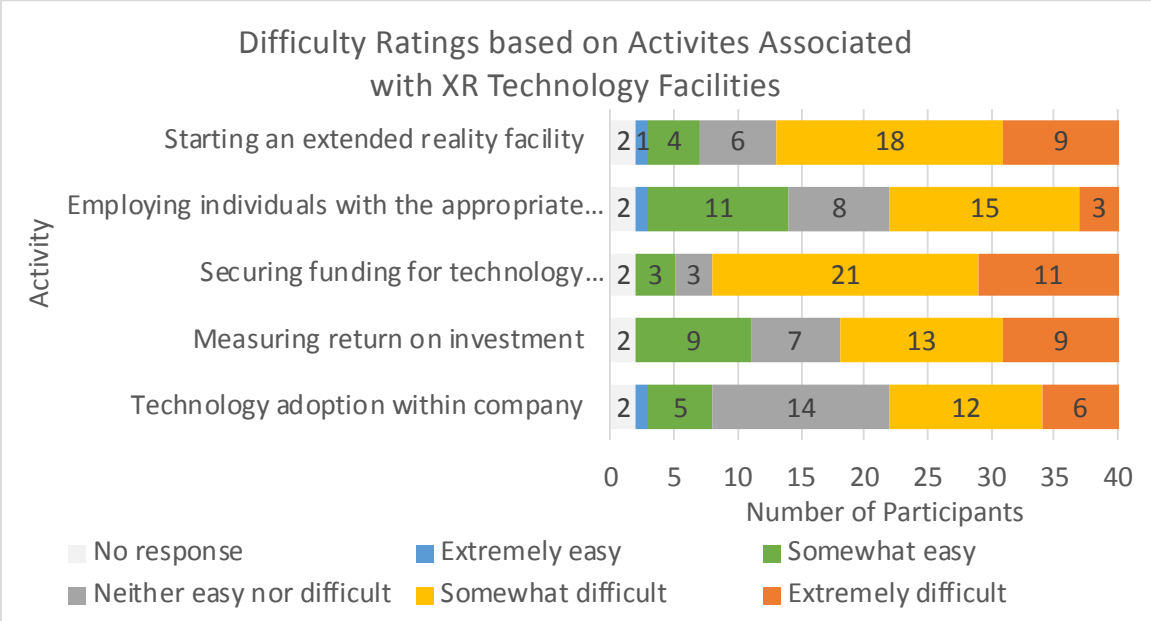

Figure 88. Participants responses to statements about the difficulty of activities associated with starting an XR technology facility at their company.

Hurdles. Along with setting up an XR facility, companies must overcome many hurdles to see technology adoption within the industry. Participants rated five hurdles faced by the industry to see long-term adoption of this technology (Figure 89). The cost of the technology was the most significant hurdle, followed by awareness. Access and quality received an equal number of responses. Turn-around time received the fewest responses. Participant's shared additional hurdles worth noting: content, usefulness, open-source, and technology in a medical setting.

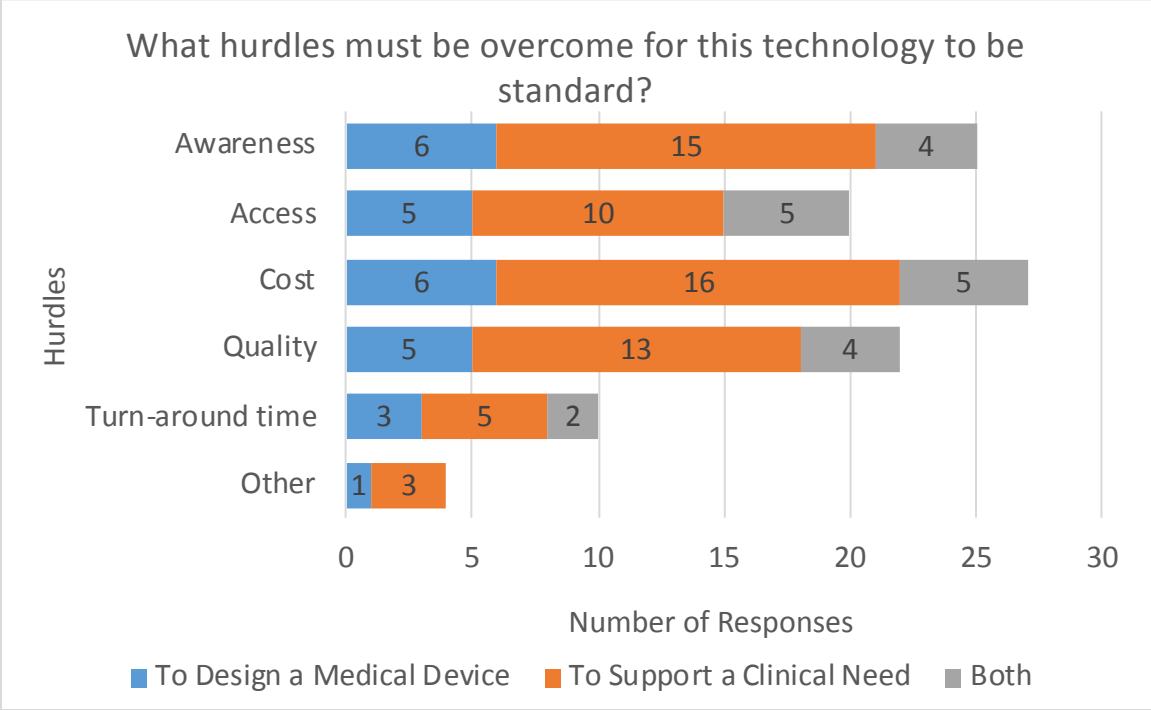

Figure 89. The hurdles faced by companies when developing medical XR technology.

Obstacles. The survey identified many obstacles faced by participants and their companies when trying to develop their technology. Twenty-four interrelated obstacles were identified within the five challenge themes. The twenty-four obstacles were organized into four categories: 1) business and 2) technical obstacles from an individual perspective, and 3) business, and 4) technical obstacles from a company perspective. The obstacles are organized by category and then ordered by design process steps. However, the order is relative as the obstacles are interrelated, and organizations may face obstacles at different times.

Individual Business Obstacles

- Understanding the User Need. This obstacle aligned with the challenge theme of external adoption. Identifying customers and their needs were challenging. Market penetration has been slow for XR technology in the medical industry. Participants have found that customers are 'extremely conservative decision makers' and are typically unaware of XR technology's benefits. Participants shared they often have to educate customers before being able to make a

technology sale. This slow adoption of this technology has been challenging for participants.

- Locating the Resources. This obstacle aligned with the challenge theme of infrastructure. Resources were challenging for participants to locate. Commercially available hardware was difficult for companies to acquire, and often the customer did not have the correct hardware. Participants working with specific technologies commented that generally, the technology was 'still immature and relatively far from board deployment.'

- Evaluating the Quality. This obstacle aligned with the challenge theme of external adoption. Testing the quality of an XR design was challenging. Participants shared that their companies must invest to support rigorous testing. Still, often user testing was not seen as central to development or validation and 'often seen as a "bonus" and not as integral.' Participants also shared that developing XR testing capabilities was a challenge. One participant said: 'I've done quality assurance testing for years, but testing in VR is a lot different from software and video game testing.'

- Defining the Value Proposition. This obstacle aligned with the challenge theme of the business case. The value proposition was challenging for participants to determine. At this point in the adoption of XR technology, there are very few examples of successful solutions. Completing a cost-benefit analysis has many aspects which are not well defined by the existing market. These aspects include understanding the specific need for medical XR technology, understanding the value across multiple solution modalities, understanding how a solution will fit in the market, developing an appropriate use case, validating the product created and justifying credibility with the solution. These aspects are necessary to develop a proper business model for the company. Participants often found the value proposition was challenging to explain to potential customers, especially when trying to move a customer past the idea of the experience being a gimmick and to the point of realizing the technology's potential.

- Purchasing the Resources. This obstacle aligned with the challenge theme of the business case. Once the resources were identified, the next challenge was purchasing the resources. The cost of the hardware and the cost to develop a solution were obstacles for companies. Participants shared that they must consider the tradeoffs between maintaining a high-quality product and reducing the development cost.

- Assuring the Key Opinion Leaders. This obstacle aligned with the challenge theme of internal adoption. Participants shared they have experienced resistance within their own company, specifically when trying to secure interest from key opinion leaders and upper management support. Another internal group that was resisting XR technology was the information technology (IT) departments. Participants indicated that it was challenging to find support within their companies at the early stages of development before a clear value proposition was available.

Individual Technical Obstacles

- *Developing the User Experience.* This obstacle aligned with the challenge theme of external adoption. Participants shared obstacles they must consider when creating a user experience. The user experience is essential to the adoption of XR technology. User's comforts, user's knowledge of the technology, the user's age, and the overall user experience influence the technology adoption.

- *Learning Along the Curve.* This obstacle aligned with the challenge theme of infrastructure. Participants shared that the learning curve was very steep when working with XR technology for the medical industry. Due to the technology's infancy, the hardware and software available are not always aligned and often lack appropriate documentation and standard techniques.

- *Building the Resources.* This obstacle aligned with the challenge theme of infrastructure. As the participants and their companies learned about developing XR technology, they found many unknowns about the technology. Significant

research and exploration were needed to educate the company about these new technologies. Areas where companies need to continue building their knowledge, include comfort, ergonomics, fatigue, eyestrain, responsiveness, visual quality, and tools for rapid development/deployment of digital models.

- *Defining the Outcomes.* This obstacle aligned with the challenge theme of internal adoption. XR experiences for the medical industry include many features. Some features require more development than others. Challenging features for participants include tracking users with motion sensors, hardware to run an emulator, sound configurations, converting ideas to 3D models, a low field of view, and aligning virtual models with the human body.

- *Selecting the Speed.* This obstacle aligned with the challenge theme of personnel. The technology was evolving rapidly at the time of this work, yet participants felt developing XR technology was very slow. Participants shared that the constant software updates and technology advancements were challenging to keep up with, while they felt like the tools available are slow to use compared to 2D prototyping options.

- *Shaping the Infrastructure.* This obstacle aligned with the challenge theme of infrastructure. Participants shared that as individual contributors, they had extensive knowledge about the needs of an XR facility. A company's infrastructure impacts an individual's ability to contribute to the development. Internet access to support high-resolution imaging and logistics to manage the technology; storing, cleaning, updating, tracking, fixing, troubleshooting devices, and deploying devices have been obstacles for participants.

Company Business Obstacles

- *Determining the Stakeholders.* This obstacle aligned with the challenge theme of internal adoption. It was essential to identify who needed to align within the company to develop XR technology. Lack of interest and need for permission from upper management were obstacles within companies. Another obstacle was

IT departments, as they wanted to wait to support the technology. Companies also found coordinating many external stakeholders as key opinion leaders were challenging.

- *Finding the Funding.* This obstacle aligned with the challenge theme of the business case. Finding funding to develop an XR experience was the most shared obstacle for companies. Many healthcare institutions do not have funding for innovation, there is competition for project funding, and investors tend to be non-technical.

- *Choosing the Technology.* This obstacle aligned with the challenge theme of infrastructure. Participants indicated that their companies struggled with choosing appropriate technologies due to hardware accessibility and unclear information about appropriate software and software updates. Another challenge for companies was developing internal processes to ease the transition between technologies without losing the current momentum.

- *Measuring the Return on Investment.* This obstacle aligned with the challenge theme of the business case. Participants also indicated measuring the ROI was challenging. Measuring the ROI at scale with healthcare customers was difficult, especially when early versions of the solution simply did not generate enough ROI. Companies found it difficult to justify to customers the value of transiting from 'traditional methods' to XR technology because the ROI was unknown. Another challenging factor was the length of time needed to develop a proof-of-concept.

- *Educating the Customer.* The theme was external adoption. Educating the customer was an obstacle for participants. There was a lack of knowledge in the medical industry about XR technology and the potential benefits. Many times, the companies needed to train the customer about the benefits and uses of the XR experience.

- *Following the Regulatory Guidance.* This obstacle aligned with the challenge theme of external adoption. Current guidance for XR technology in the medical industry was incomplete and therefore created a challenge for traditional medical device companies familiar with stringent guidelines. Other regulatory organizations, such as IRB approvals, intellectual property, and data privacy laws, also create challenges for XR technology developers because the industry has moved so fast, and there remain so many unknowns.

Company Technical Obstacles

- *Building the Team.* This obstacle aligned with the challenge theme of personnel. The next obstacle for companies from a technical perspective was building out their team. Finding individuals who have appropriate technical or clinical skill sets to support XR development was a challenge.

- *Building the Infrastructure.* This obstacle aligned with the challenge theme of infrastructure. Developing the infrastructure to support the development of XR technology was a leading obstacle for companies. Although XR technology was virtual, those developing the technology still need physical space to work. The resources required by contributors include maintaining, managing, and building the technology; logistics for cleaning, updating, and managing deployed devices; and internet limitations at external customer locations.

- *Supporting the External Infrastructure.* This obstacle aligned with the challenge theme of external adoption. Participants shared that even with a quality XR experience, the external location's infrastructure may not meet the requirements. External infrastructure concerns include IT, WIFI, data storage, and scheduling the technology for users.

- *Managing the Resources.* This obstacle aligned with the challenge theme of infrastructure. Participants said their companies struggled with managing technical XR resources. Currently, hardware and software are a fractured ecosystem of technologies. The technologies fail to work well together and

companies lack the necessary resources to support development. Often APIs to support specific hardware do not integrate with previous software. With constantly changing technologies, companies must continually manage, maintain, and build new technology. Software updates are difficult to keep up with, and sometimes updates will render previous progress useless.

- *Keeping the Speed.* This obstacle aligned with the challenge theme of infrastructure. Participants felt it was challenging to keep up with the technology. They felt constant pressure to release cutting-edge technology with the latest XR technologies. However, these solutions required extensive research, development, and funding before the technology quickly became obsolete.

- *Finalizing the Outcomes.* This obstacle aligned with the challenge theme of infrastructure. Finally, participants said that even after they have completed their solution, the technical demonstrations to compliance bodies are challenging due to XR technology's novelty.

Interpretation of Results

Finally, the motivations, resources, company operations, and challenges, the obstacles identified by participants were reframed for current and future companies. The challenges were organized to show how the themes are interrelated. As seen in Figure 90, the twenty-four obstacles are organized into two categories; individual contributors; and managers and executives. Each category was further organized into two sub-categories; business and technical. This graphic's goal was to present the many moving pieces that individuals and companies manage to produce XR technology for the medical industry. These moving pieces require a specific level of attention to detail to be successful.

Figure 90. Interpretation of themes to guide future XR technology for the medical industry.

Future of Medical XR Technology

Medical XR technology is a rapidly expanding area of research and development. XR technology may positively impact the medical industry, but the appropriate technology fit remains unknown. Technical advancements will continue to guide medical

XR technology in the years to come. Participants look forward to what "could be" with the technology. This section discusses the hopes for the future, technology wishes not currently possible, and what they see as making the technology ubiquitous.

Hopes. As the medical industry looks to XR technology's future, those actively doing the work are exceptional assets to learn about future directions. Participants had one hope for this technology: simply to see medical XR technology as just another tool. They felt the technology must move past being entertainment and become the new normal of patient care. This result is contrary to Berg & Vance (2017), who reported that companies in their study found the technology to be simply another tool in the toolbox. Overall, participants in this study were hopeful for medical XR technology's future.

Wishes. Participants of this study were acutely aware of what was needed for sophisticated medical XR technology. They had two wishes for XR technology; technology advancements; and access with collaboration. The first wish of technology advancements includes; more powerful local and cloud processing capabilities, haptics gloves to simulate touch, accurate positional tracking, and high-quality visuals of patient-specific data. These technology advancements contribute to larger goals: creating a single XR app that works across all devices, replacing all physical monitors with virtual monitors for spatial and contextual smart data as needed, and building in 3D virtual spaces that easily translate to the manufacturing world.

The second wish was access with collaboration. Participants said they wished more clinics, medical schools, healthcare companies, and hospitals could access XR technology. Many responses implied the need for reciprocity between developers and the medical industry. Developers wished for easier ways to educate medical professionals about XR technology and, in return, create collaborations to guide future products. This result conflicts with Basoglu et al.'s (2018) work to identify physicians' adoption factors. They noted that technology providers must drive AR technology adoption, as physicians are averse to demands from new technologies (Basoglu et al., 2018).

Ubiquitous Technology. Finally, to achieve these hopes and wishes, XR technology must become ubiquitous. Participants highlighted four ways to accomplish this; business case, standards, user experience, and adoption. The first way, business case, was to reduce the cost, improve the quality, and produce solutions quicker. As one participant stated: 'The industry is still trying to find the right combination of cost-effective and powerful processing.' Identifying a clear goal or purpose and the value generated impacts the technology's future in this industry. It will be essential to identify methods to scale the technology and create large training facilities for medical students. Berg & Vance (2017) proposed tracking facility usage as one tool to estimate the ROI and tracking findings and outcomes with individual projects based on VR technology.

The second way to achieve ubiquitous technology was to develop industry standards. Participants shared the need for standards and oversight to advance this technology. They shared a few examples of anticipated standards. Support from associations to develop standards would guide the technology at an industry level, and robust clinical trials are another example to produce validation evidence to demonstrate investment return. One participant recommended more government support to develop these edge case technologies instead of reinforcing existing antiquated paper-based methods.

The third way to achieve ubiquitous technology was to improve the user experience. Participants identified four opportunities to improve the user experience; ergonomics and comfort; ease of use and setup; robust technology for the medical environment; and personalize use cases. The XR industry must address the first two user experience issues. User issues involving ergonomics, comfort, ease of use, and setup relate to all industries using XR technology. These are common issues for the XR industry and a primary reason for the slow technology adoption. As technology continues to advance and components become smaller, these hardware issues will reduce users' burdens.

The other user experience issues were related to how the technology was applied to the medical industry. Participants shared that medical XR technology must be robust to

support clinical workflows. They shared that medical XR technology will change how medicine is administered, and therefore the design must consider patient safety. The technology will impact care providers' mental workload, ergonomics, efficiency, physical space, communication models, ease of setup, and sterility. Another response received was about personalizing the technology to appropriate use cases. One participant said that the technology would be ubiquitous 'when developers understand that XR can't be a solution for everything and when physicians' needs are heard and met.' As the technology continues to grow in the medical industry, those using the technology in training and residency programs will adopt the technology easier. Basoglu et al. (2018) also found AR technology must be designed for job-specific tasks to improve the technology adoption rate.

The fourth way to achieve ubiquitous technology was to guide the technology adoption. Educating the medical community about this technology is one way to influence the adoption. The medical industry is naturally averse to being early adaptors to new technologies. They, first, look for research evidence to prove the technology's effectiveness. As research evidence develops, more key opinion leaders will be introduced to the technology, which will build the case for mass-market adoption. Basoglu et al. (2018) acknowledged the adoption of [XR] technology 'will be a result of a[n XR industry] push and not a [medical] market pull,' as the solutions do not provide superior functionality to existing methods based on physician perceptions.

Discussion

The results were presented in eight sections to document medical XR technology from an industry perspective. The sections were recruitment, demographics, motivations, resources, company operations, solution testing, challenges, and the future of medical XR technology. The recruitment section results showed how the medical industry perceived this technology. These companies are early adopters and have invested resources to understand and drive the future of medical XR technology. The demographics section results spoke to those who are developing this technology. Most participants had at least a master's degree, and their degrees were from a wide variety of areas. As this

technology continues to grow, companies will need more employees with specific skill sets. It may be necessary to create training programs and career paths to help individuals develop the skill sets to support this work (Berg & Vance, 2017).

The motivation section results explored the factors driving companies to develop medical XR technology. Participants and companies have many motivations for working in this space. The resources section results documented the resources companies are using to build their solution. As this technology appears to be a field closely tied to computer science, only nine participants said their companies use programmers with bachelor's degrees in computer science. Twenty-five participants said their companies use programmers with XR experience. Future work is needed to evaluate these pipelines of talent and skillsets need for medical XR technology companies' skillsets. The results also showed how quickly the XR industry shifted when new technology was released. No companies in this study were using CAVE's, compared to five years ago, Berg & Vance (2017) found most companies were using CAVE or Powerwall type technologies.

The company operations result reviewed when and how companies are using medical XR technology. The results show us how companies cover many use cases within the medical industry and give a glimpse of how users want to use the technologies by connecting the tasks (how) and the activities (when) of using the technology. The solution testing results evaluated how companies are testing their solution. Future research would help guide developers appropriate testing methods for XR technology, as stated by one participant: "Learning new ways to [quality assurance] test. I've done [quality assurance] testing for years, but testing in VR is a lot different from software and video game testing."

The challenges section results analyzed the difficulties, hurdles, and obstacles companies face to develop medical XR technology. The interpretation of challenges shows the obstacles companies are facing to create their experience. Identifying methods to support these companies will help drive the adoption of the technology. Finally, the future of medical XR technology results explored where the participants and their companies envision this technology shaping the medical industry. The results identify

future research paths, aligning the medical industry with XR technology, and the next steps for the technology to become ubiquitous.

Limitations.

This study had three main limitations. The first limitation was the small sample size of participants using the technology as a tool to design medical devices. The hype for this technology from researchers, professional organizations, and news releases from companies shows that work was being done in the space. As mentioned in the recruitment process, many people had concerns about the intellectual property of their technology. The smaller sample size for the group developing XR as a tool to design medical devices limited the opportunity to compare this group with the clinical needs group.

The second limitation was the scope of this study. Previous published studies have not explored XR technology from a medical industry perspective; therefore, it was challenging to develop the questions. The result was a survey that covered the breadth of medical XR technology, but not necessarily the field's depth. The third limitation was the terms used throughout the study. The terms' design a medical device' and 'support a clinical need' were defined before recruitment and guided the study design. However, the recruitment process revealed that the industry might not use the same terms as presented in this study.

Future work.

Many opportunities exist to advance medical XR technologies in the industry. First, the results showed new methods are needed to test the XR experience. Second, participants expressed the need for guidance and standards to guide their company through the technology development process. Third, an extensive amount of work is being done in the rehabilitation, therapy, and mental health spaces. Documenting the scope of these spaces would help guide the future of medical XR technologies.

Conclusion

The contribution of this research was a comprehensive overview of companies developing and using medical XR technologies. Eight results sections reviewed the

medical XR technology space from who is doing the work through their hopes for the future. The results articulated the current status of the technology and the resources selected by companies to drive innovation. The results also explored where companies are challenged in their pursuit of creating their XR experience. The knowledge gained from this study identified gaps in our understanding of the technology use, which can drive future technology developments and guide new research to support these spaces. Overall, this study highlighted the complexity of medical XR technology and the challenges to reach ubiquitous XR technology in the medical industry.

Dissertation Conclusion

This dissertation's principal research goal was to understand medical XR technology's status and the gaps, challenges, and opportunities during the development, design, and technology usage. This dissertation followed the user-centered design approach to outline three different perspectives surrounding the technology (Figure 91). The first perspective in chapter one through four analyzed the user's needs of medical professionals working in a clinical setting. The second perspective in chapter five developed two medical VR technologies to plan the placement of DBS electrodes. The third perspective in chapter six explored how companies implement their medical XR solution and documented gaps, challenges, and opportunities from an industry lens.

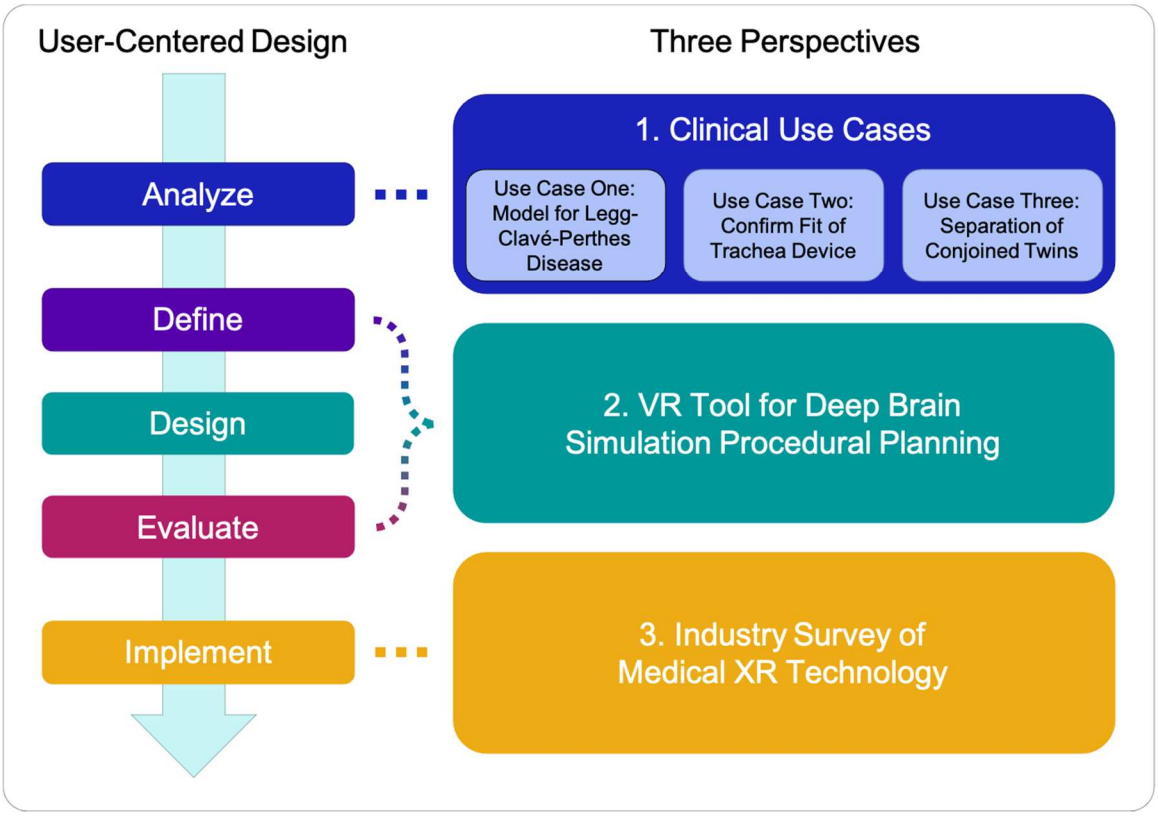

Figure 91. The user-centered design process aligned with the three perspectives of this research.

This body of work has shown that additional work remains before we see the complete adoption and use of medical XR technology. Opportunities exist from technical, social, and organizational challenges to improve user's experiences and expectations.

These opportunities exist across the disciplines contributing to medical XR technology (Figure 92). The results show both medical professionals and medical XR technology developers are excited about this technology's future. However, it is critical to bridge the gap between the medical professionals who are risk-averse and conservative by training and the developers who prescribe to a 'fail hard, fail fast, fail often' mantra. Both sides acknowledge the need to develop high-quality simulations, but consensus on reaching this shared goal must be established. The results presented here show opportunities to advance medical XR technology to achieve these shared goals and meet the user's needs.

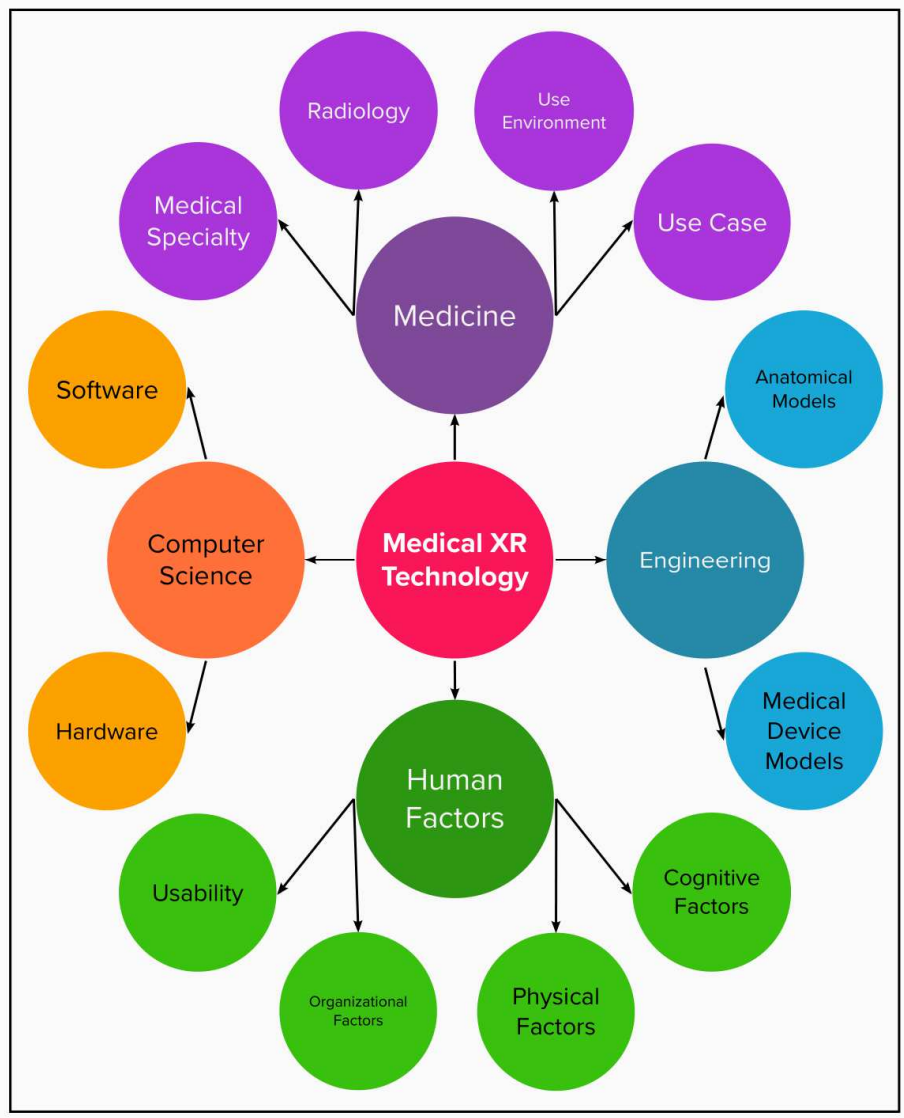

Figure 92. Disciplines contributing to medical XR technology. This graphic shows the complexity of developing XR experiences for the medical industry.

Ultimately, medical XR technology is the future of medicine. Working XR experiences have been demonstrated in both research and industry. The technology provides numerous benefits unavailable with current technologies. The results presented here can inform future research, technology designs, company implementations, and best practices for medical XR technologies.

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Appendix A: Publications

Journals

1. Martinez-Escobar, M., Peloquin, C., **Juhnke, B.**, Peddicord, J., Jose, S., Noon, C., Foo, J. L., & Winer, E. (2011). Development of a Customizable Software Application for Medical Imaging Analysis and Visualization. *Medicine Meets Virtual Reality 18: NextMed*, *163*, 343.
2. Foo, J. L., Martinez-Escobar, M., **Juhnke, B.**, Cassidy, K., Hisley, K., Lobe, T., & Winer, E. (2013). Evaluating Mental Workload of Two-Dimensional and Three-Dimensional Visualization for Anatomical Structure Localization. *Journal of Laparoendoscopic & Advanced Surgical Techniques*, *23*(1), 65-70.
3. Escobar, M. M., **Juhnke, B.**, Hisley, K., Eliot, D., & Winer, E. (2013, March). Assessment of visual-spatial skills in medical context tasks when using monoscopic and stereoscopic visualization. In *SPIE Medical Imaging* (pp. 86730N-86730N). International Society for Optics and Photonics.
4. **Juhnke, B.**, Berron, M., Philip, A., Williams, J., Holub, J., & Winer, E. (2013, March). Comparing the Microsoft Kinect to a Tractional Mouse for Adjusting the Viewed Tissue Densities of Three-Dimensional Anatomical Structures. In *SPIE Medical Imaging* (pp 86731M-86731M), Image Perception, Observer Performance, and Technology Assessment.
5. Johnson, S., Orban, D., Runesha, H.B., Meng, L., **Juhnke, B.**, Erdman, A., Samsel, F., and Keefe, D.F. (2019). Bento Box: An Interactive and Zoomable Small Multiples Technique for Visualizing 4D Simulation Ensembles in Virtual Reality. *Frontier in Robotics and AI 6:61*
6. **Juhnke, B.**, Mattson, A., Saltzman, D., Azakie, A., Hoggard E., Ambrose, M., Iaizzo, P., Erdman, A., and Fischer, G. (2019) Use of Virtual Reality for Pre-Surgical Planning in Separation of Conjoined Twins: A Case Report. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*, 0954411919878067.
7. Kloesel, B., **Juhnke, B.**, Irvine, L., Donadio, J., Erdman, A., and Belani, K. (2021). Computer-Generated Three-Dimensional Airway Models as A Decision-Support Tool for Preoperative Evaluation and Procedure-Planning in Pediatric Anesthesiology. *Journal of Medical Systems*, *45*(2), 21.
8. Pei, J., Griffin, L., Ashdown, S., Fan, J., **Juhnke, B.**, and Curry, C. Study of Breast Shape During Running Using 4D Scanning Technology. *Under Review*.
9. Pokorny, C., **Juhnke, B.,** and Griffin, L. Standardized Functional Hand Grasp Method for 3D Scanning. *Under Review.*

Proceedings

1. Besada, J., **Tourek, B.,** Keefe, D., and Erdman, A. (2016) A Virtual Heart Valve Implant System: Characterizing the Value and Implementation Effort for Each Feature. *2016 BMES/FDA Frontiers in Medical Devices Conference*, Washington, D.C., May 24, 2016.
2. Johnson, S., Jackson, B., **Tourek, B.,** Molina, M., Erdman, A., and Keefe, D. (2016) Immersive Analytics for Medicine: Hybrid 2D/3D Sketch-Based Interfaces for Annotating Medical Data and Designing Medical Devices. *In Proc. of the*

2016 ACM Companion on Interactive Surfaces and Spaces (pp. 107-113). Association for Computing Machinery.

3. **Tourek, B.,** Orban, D., Meng, L., Runesha, H.B., Keefe, D., and Erdman, A. (2017) Review of Cardiac Pacemaker Lead Designs for Computational Models in a VR Environment. *Proceedings of the 2017 Design of Medical Devices Conference*. *2017 Design of Medical Devices Conference*. Minneapolis, Minnesota, USA. April 10–13, 2017. V001T09A010.
4. **Juhnke, B.**, Mattson, A., Saltzman, D., Azakie, A., Hoggard E., Ambrose, M., Iaizzo, P., Erdman, A., and Fischer, G. (2018) Preparing for Conjoined Twins Separation Through Virtual Reality. *Proceedings of the 2018 Design of Medical Devices Conference. 2018 Design of Medical Devices Conference.* Minneapolis, Minnesota, USA, April 9-12, 2018. V001TO8A009. ASME.
5. Morgan, L., Hiremath, G., Ameduri, R., **Juhnke, B.**, Mattson, A., Fay., D., Saltzman, D., Azakie, A., Hoggard, E., Iaizzo, P., Erdman, A., Fischer, G., and Ambrose, M. (2018) Cardiac Imaging and Virtual Reality Use in Management of Thoraco-omphalopagus Conjoined Twins. *14th SPR Advanced Symposium on Pediatric Cardiovascular Imaging.* Walnut Creek, California. October 14, 2018.
6. Orban, D., Johnson, S., Runesha H.B., Meng, L., **Juhnke, B.**, Erdman, A., Samsel, F., and Keefe, D. (2018) Comparison of Multiple Large Fluid-Structure Interaction Simulations in Virtual Reality. *IEEE 8th Symposium on Large Data Analysis and Visualization (LDAV)* (pp. 110-111). IEEE.
7. **Juhnke, B.**, Novotny, S., Laine, J., Toth, F., and Erdman, A. (2019) Virtual Model for Legg-Calvé-Perthes: Preliminary Work to Develop a Minimally Invasive Preclinical Model. *Proceedings of the 2019 Design of Medical Devices Conference. 2019 Design of Medical Devices Conference.* Minneapolis, Minnesota, USA. April 15-18, 2019. V001T07A005. ASME.
8. Griffin, L., and **Juhnke., B.** (2019) Application of dynamic anthropometry for product design. *2019 AHFE International, 10th International Conference on Applied Human Factors and Ergonomics,* Washington, D.C., July 26-28, 2019.
9. Griffin, L., **Juhnke, B.**, Seifert, E., Pokorny C., and Doran, K. Method to Capture and Analyze the Waist-Hip-Thigh Body Region of Seated -Standing 3D Scans. *3DBODY.TECH2019 – 10th International Conference and Exhibition on 3D Body Scanning and Processing Technologies*, Lugano, Switzerland. October 22-23, 2019.
10. **Juhnke, B.,** Ahsan, M., Rothweiler, P., & Erdman, A. (2020). Extended Reality Tools for Deep Brain Stimulation: A Framework and Design Concepts for Procedural Planning. In *2020 Design of Medical Devices Conference*. American Society of Mechanical Engineers Digital Collection.
11. Sokolowski, S. L., Griffin, L., **Juhnke, B.,** Pokorny, C., & Bettencourt, C. (2020, July). Qualitative Survey Methodology and Data Collection for Performance Glove Design and Fit. In *International Conference on Applied Human Factors and Ergonomics* (pp. 575-581). Springer, Cham.
12. Pokorny, C., **Juhnke, B.,** & Griffin, L. (2020, July). A Visible Functional Grasp to Measure the Complete Hand. In *International Conference on Applied Human Factors and Ergonomics* (pp. 589-596). Springer, Cham.

13. **Juhnke, B.,** Pokorny, C., Griffin, L., & Sokolowski, S. (2020, July). Lend a Hand for 3D Scans: Scanning Methodology and Data Collection for Tool and Glove Design. In *International Conference on Applied Human Factors and Ergonomics* (pp. 567-574). Springer, Cham.
14. **Juhnke, B.,** Pokorny, C., Griffin, L., & Sokolowski, S. (2020, December). Development of a Civilian 3d Hand Scan Database. In *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* (Vol. 64, No. 1, pp. 995-999). Sage CA: Los Angeles, CA: SAGE Publications.

Presented Abstracts

1. Griffin, L., **Juhnke, B.**, and Seifert, E. Landmarking Method to Capture Dynamic Anthropometric Measurements of the Waist-Hip-Thigh Body Region. *2019 International Textile and Apparel Association Annual Conference*. Las Vegas, Nevada, USA, October 25-29, 2019.
2. Griffin, L., **Juhnke, B.**, and Seifert, E. Dynamic Anthropometric Analysis of the Waist-Hip-Thigh Body Region. *2019 International Textile and Apparel Association Annual Conference*. Las Vegas, Nevada, USA, October 25-29, 2019.

Seminars

1. **Tourek**, **B.,** Lin, C., Coffey, D., Orban, D., Keefe, D., and Erdman, A. (2015) A User Evaluation of Software to Optimize the Medical Device Development Process Using Finite Element Analysis Predictions. *Department of Mechanical Engineering*, University of Minnesota, Minneapolis, Minnesota, February 27, 2015.
2. **Tourek**, **B.,** Orban, D., Tanasoiu, B., Birali Runesha, H., Keefe, D., and Erdman, A. (2016) Inverse Design Process: New Methodology to Design Medical Devices with BIG DATA. *Minnesota Supercomputing Institute Research Exhibition 2016*, University of Minnesota, Minneapolis, Minnesota, April 26, 2016.
3. **Tourek, B.**, Orban, D., Runesha H.B., Keefe, D., and Erdman, A. (2017) Inverse Design Process: Generating the BIG Data to Efficiently Visualize a Complete Design Space. *Minnesota Supercomputing Institute Research Exhibition 2017,* University of Minnesota, Minneapolis, Minnesota, April 25, 2017.
4. **Juhnke, B.**, Ahsan, M., Rothweiler, P., and Erdman, A. (2019) Virtual Reality for Deep Brain Stimulation: A framework to develop procedural planning software. *Institute in Engineering in Medicine Fall Retreat, University of Minnesota, Minneapolis, Minnesota, September 23, 2019*.

Appendix B: Clinical Use Cases Survey Questions

Provider Information

- What is your name?
- What is your specialty?
- What is your affiliation?
- How many years have you been practicing?

Patient's Information

- What is the patient's age?
- What is the patient's gender?

Disease Details

- What is the disease diagnosis?
- What are the odds of the disease occurring?

Procedure / Therapy Details

- What is the procedure or therapy for this patient?
- Is the procedure medically necessary or elective?
    - Medically necessary, medical necessary but elective, elective
- Rate the degree of difficulty for this procedure/therapy:
    - Extremely easy, Somewhat easy, Neither easy nor difficult, somewhat difficult, Extremely difficult
- Rate your confidence for this patient's outcome:
    - Far above average, Somewhat above average, Average, Somewhat below average, Far below average
- Operating time cost per minute:
    - <$25, $25-$50, $50-75, $75-$100, $100-$125, $125-$150, $150-$175, $175-$200, >$200
- What outcomes define success?
- What is your previous experience with virtual reality models?
- How will a virtual reality model aid in this procedure/therapy?

Outcome

- Has your confidence in this procedure changed based on using virtual reality?
    - Much higher, Higher, About the same, Lower, Much lower
- Time (hours) to complete this procedure/therapy:
    - <0.5, 0.5-1, 1-3, 3-5, 5-7, 7-9, 9-11, 11+
- Please respond to the following statements
    - Strongly agree, Somewhat agree, Neither agree nor disagree, Somewhat disagree, Strongly disagree
        - Virtual reality is an important tool in medicine
        - The time to acquire a virtual reality model was appropriate
        - The virtual reality model is worth the expense
        - The accessibility of virtual reality technology is appropriate
        - The final virtual reality model met my expectations

- The cost of the virtual reality service was:
    - Far too little, Too little, About right, Too much, Far too much
- What is an acceptable turnaround time for you to receive a virtual reality model?
    - 0-12 hours, 12-24 hours, 1-3 business days, 3-5 business days, 5-10 business days, 10-15 business days, 15-20 business days, 20+ business days
- How did a virtual reality model of the patient's anatomy aid in this operation?
- What other visualization tools would have been helpful for this procedure?
- Which patient outcome areas were impacted by the VR model (select all that apply)?
    - Survival, Degree of health or recovery, Time to recover and time to return to normal activities, Disutility of care or treatment (e.g., diagnostic errors, ineffective care, treatment-related discomfort, complications, adverse effects), Sustainability of health or recovery, and nature of recurrences, Long-term consequences of therapy (e.g., care-induced illnesses) (Porter, 2010).
- Would you use virtual reality again? Why did you select this answer?
    - Yes, Maybe, No
- Do you have any final comments about your experience, improvements, recommendations, or 'what-if _____ was possible' suggestions?
- Do you have further comments on how a virtual reality model added value to this procedure?

Appendix C: Images of Cosman-Roberts-Wells (CRW) Frame

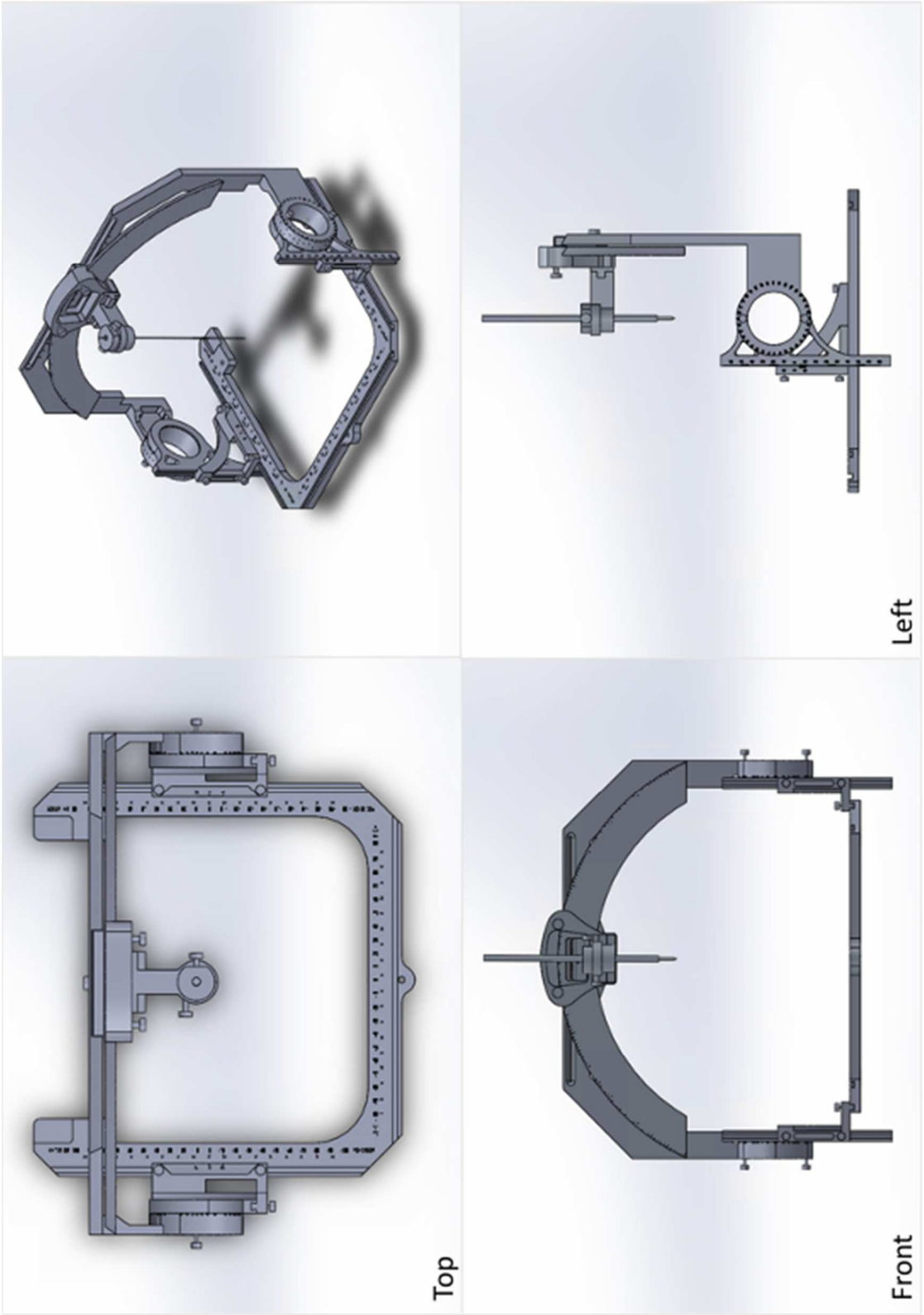

Figure 93. CAD models of the Cosman-Roberts-Wells DBS frame.

Appendix D: Assembly Drawings of Cosman-Roberts-Wells (CRW) Frame

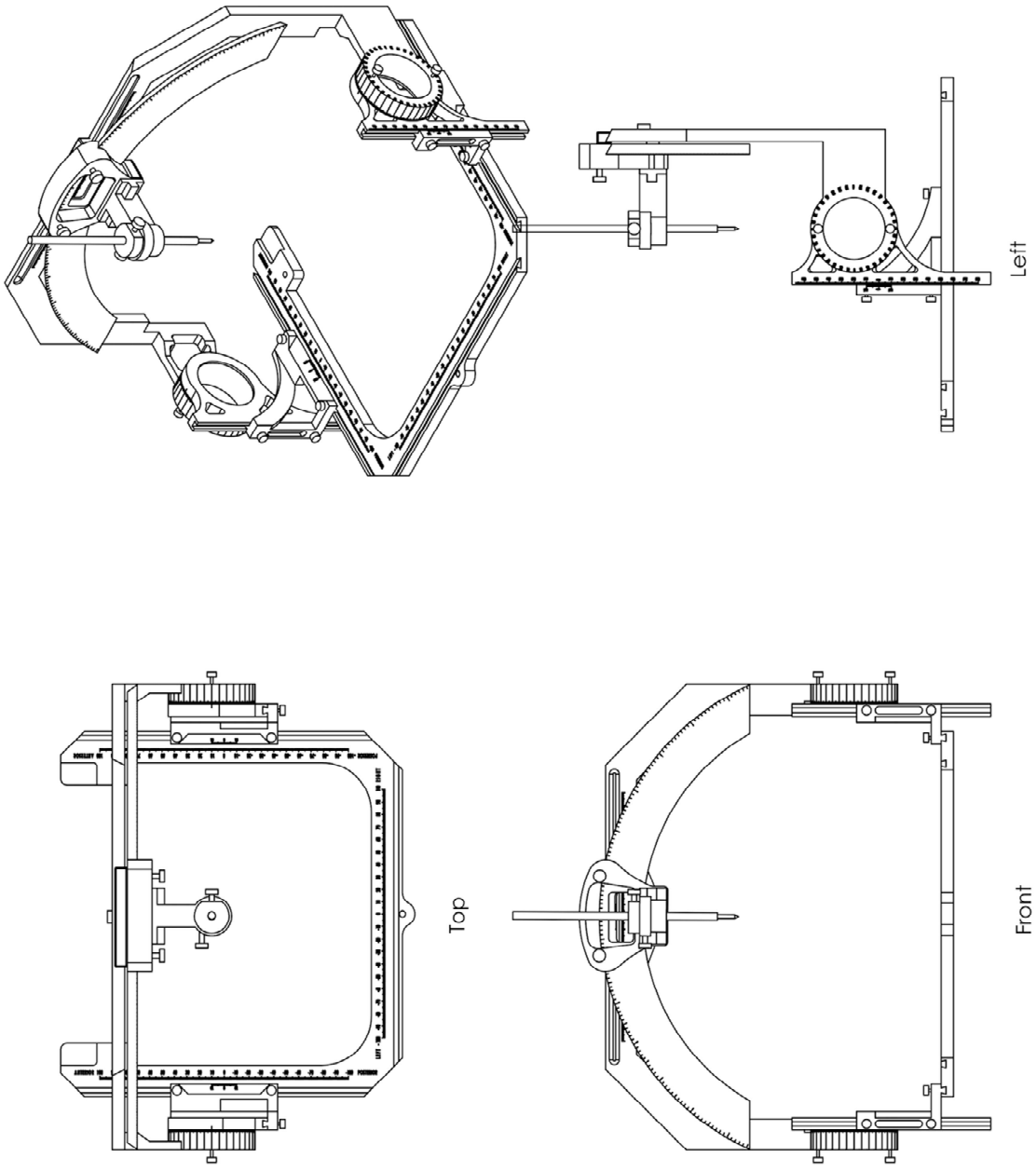

Figure 94. Assembly drawings of the Cosman-Roberts-Wells DBS frame.

Appendix E: Images of Leksell Frame

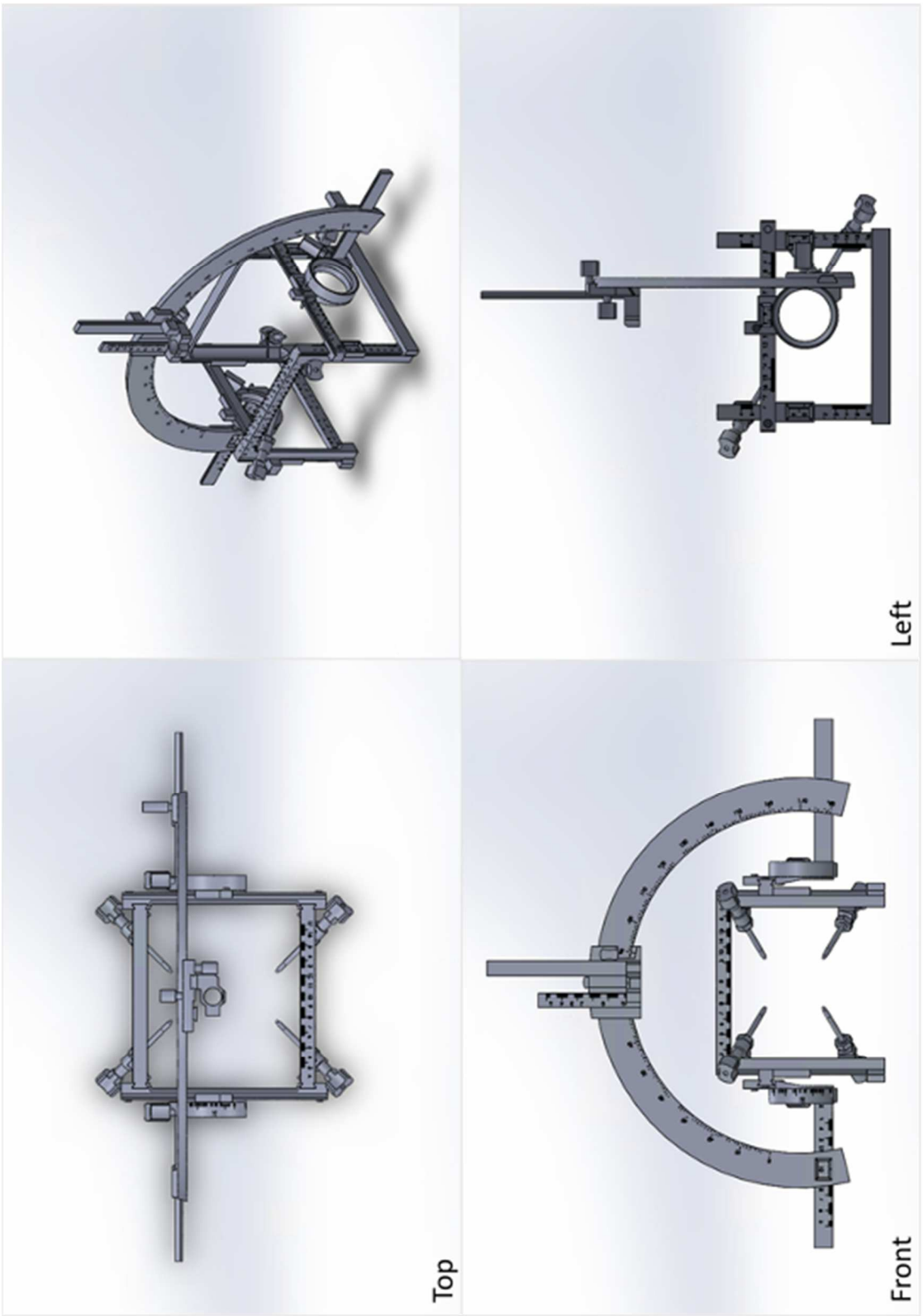

Figure 95. CAD models of the Leksell DBS frame.

Appendix F: Assembly Drawings of Leksell Frame

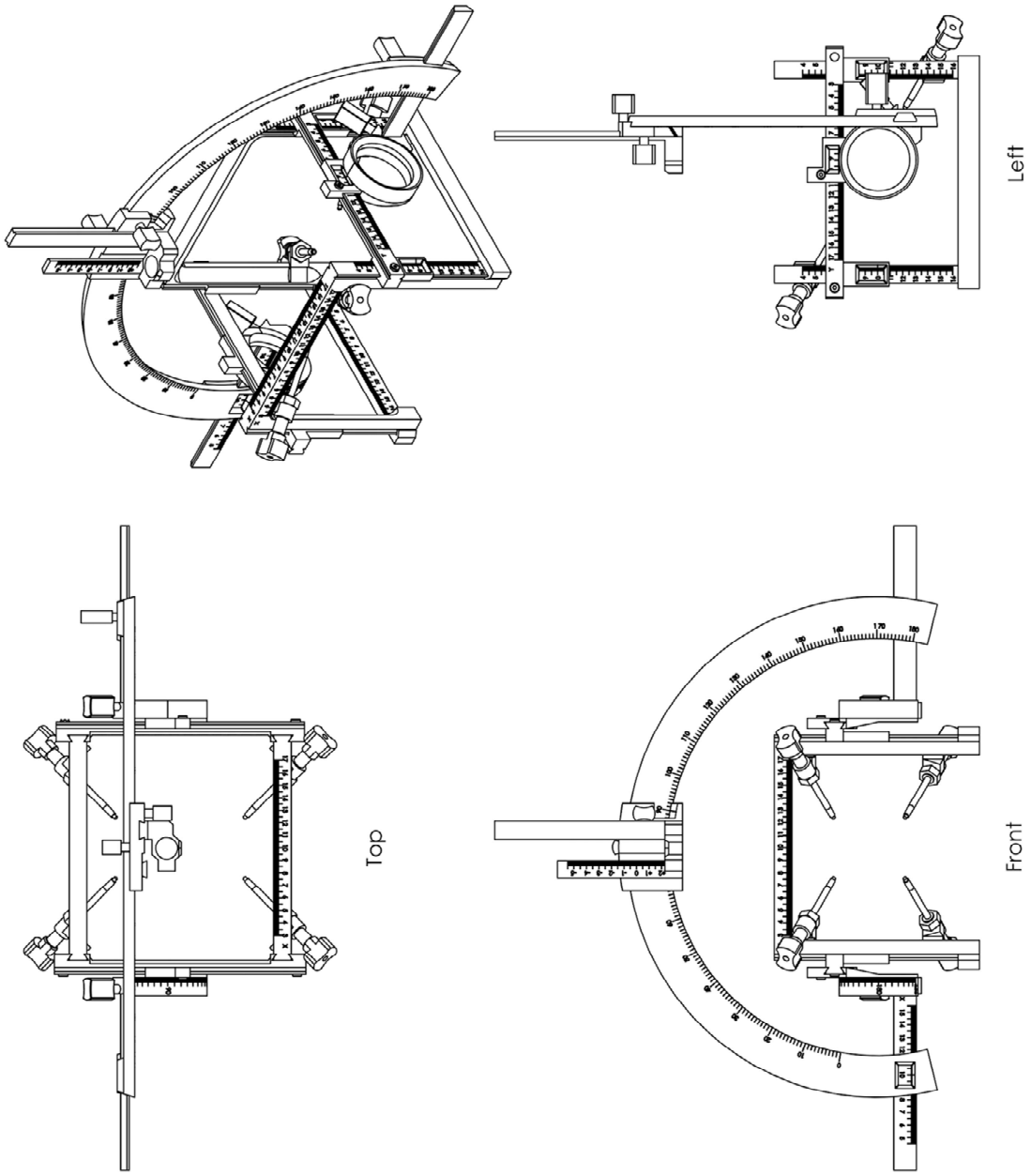

Figure 96. Assembly drawings of the Leksell DBS frame.

Appendix G: BenGun Model

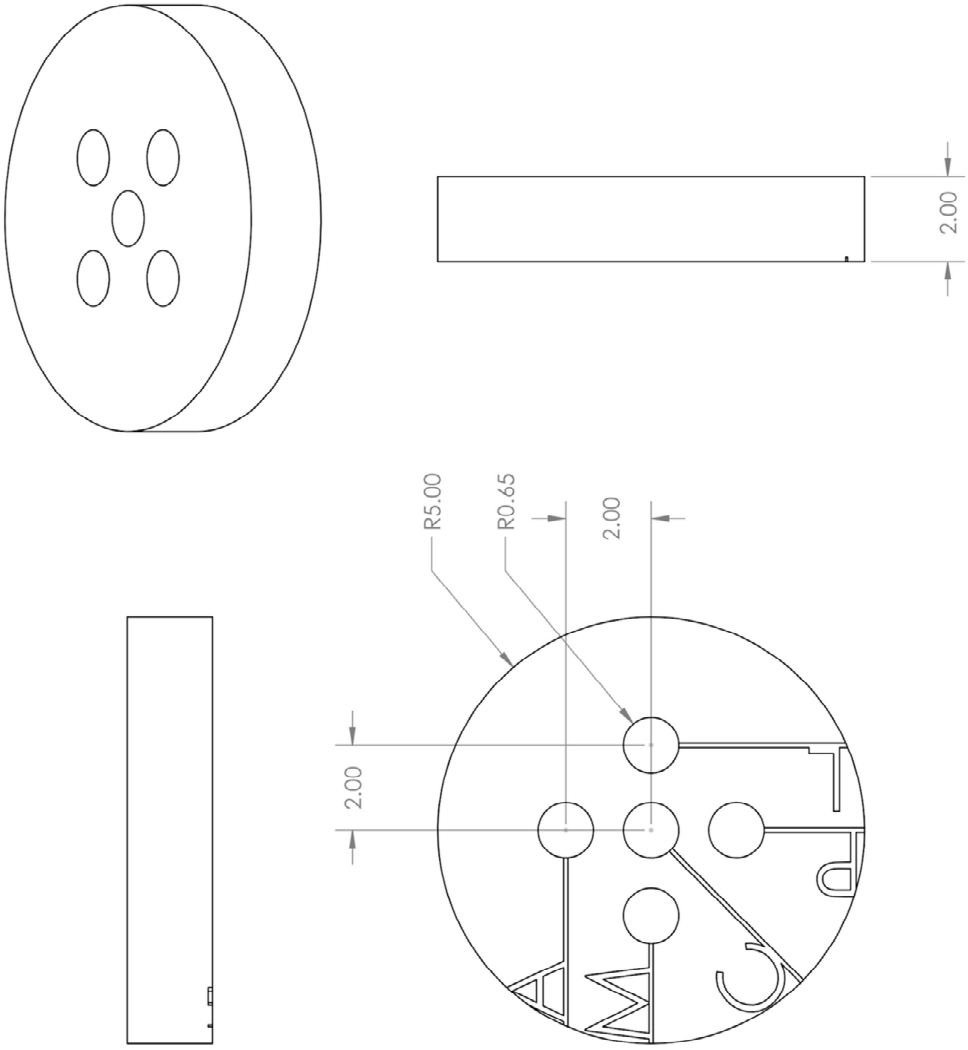

Figure 97. CAD drawings of BenGun device for the DBS procedure.

Appendix H: Electrode Models

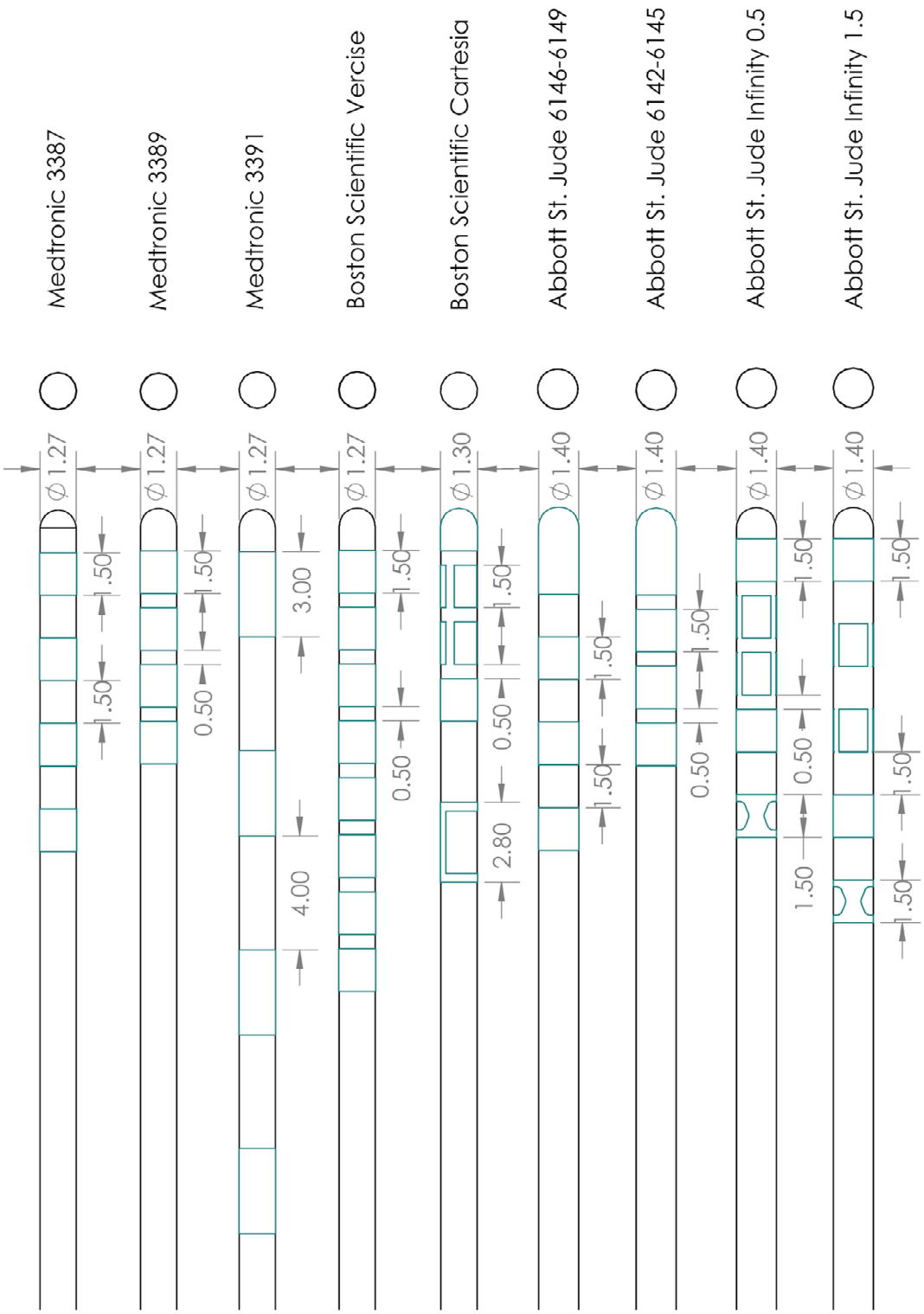

Figure 98. CAD models of DBS electrodes.

Appendix I: Double Monopolar Electric Field Volumes at 0.5mm Contact Spacing

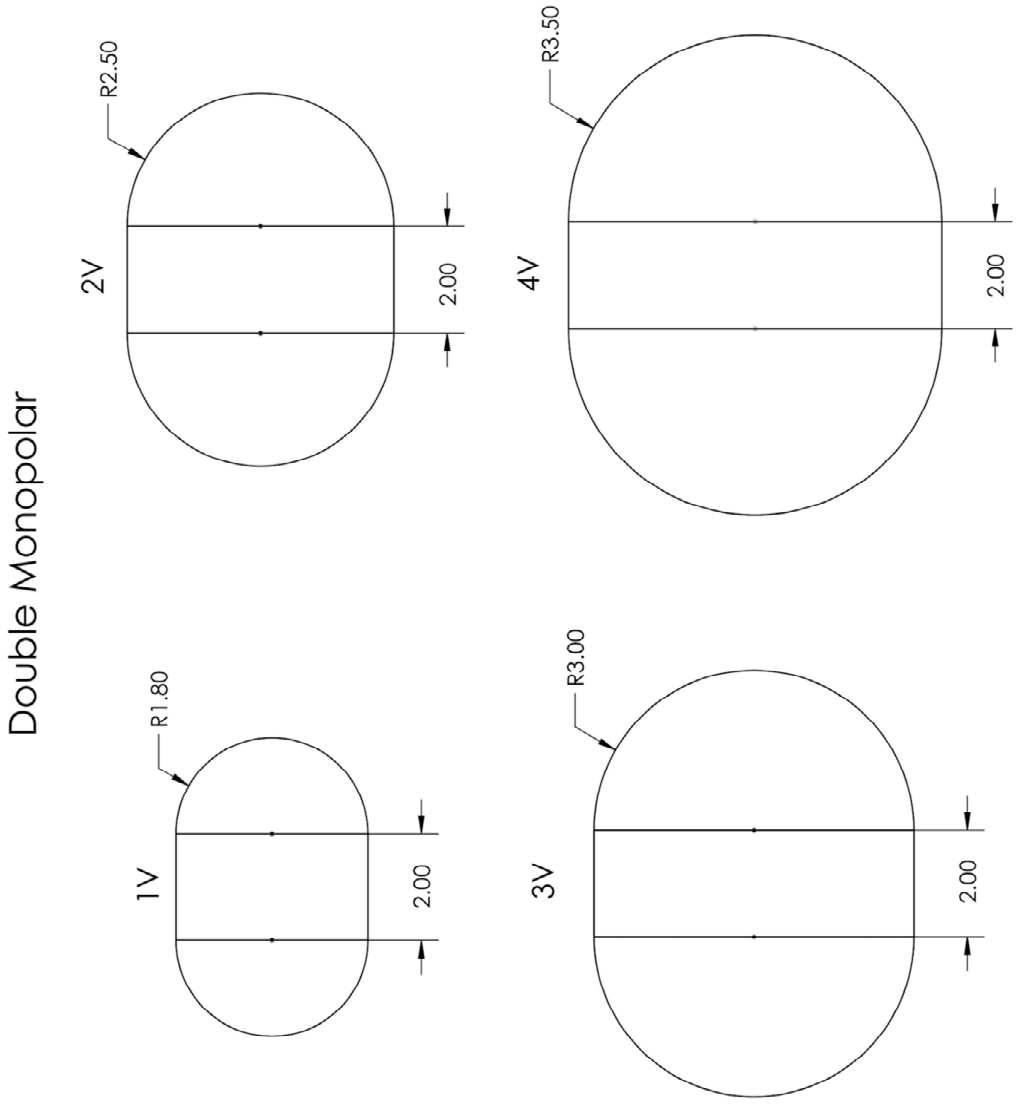

Figure 99. Scale drawings of the double monopolar electrode field volumes for 0.5 mm spaced ring contacts.

Appendix J: Double Monopolar Electric Field Volumes at 1.5mm Contact Spacing

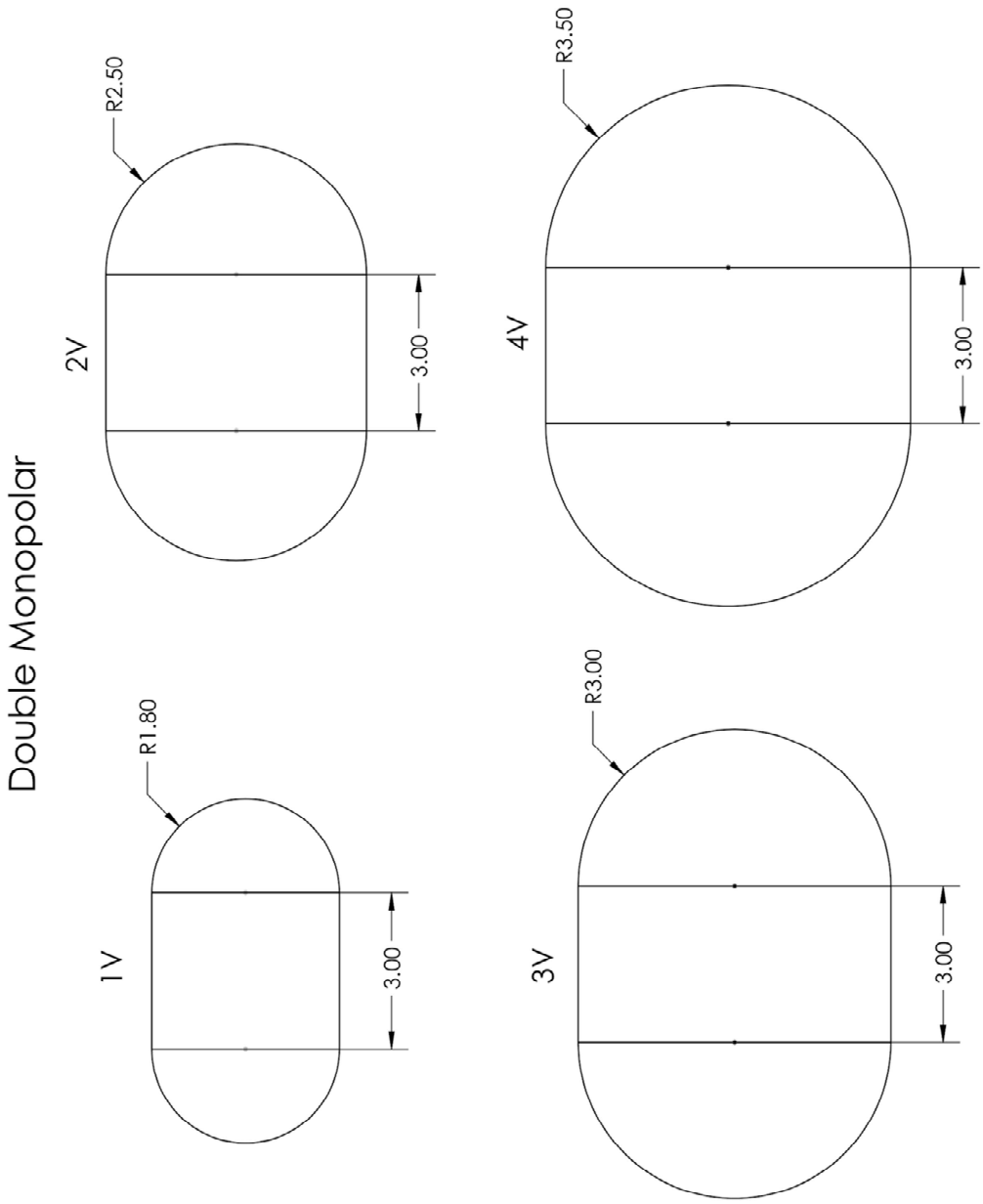

Figure 100. Scale drawings of the double monopolar electrode field volumes for 1.5 mm spaced ring contacts.

Appendix K: Double Monopolar Electric Field Volumes at 4mm Contact Spacing

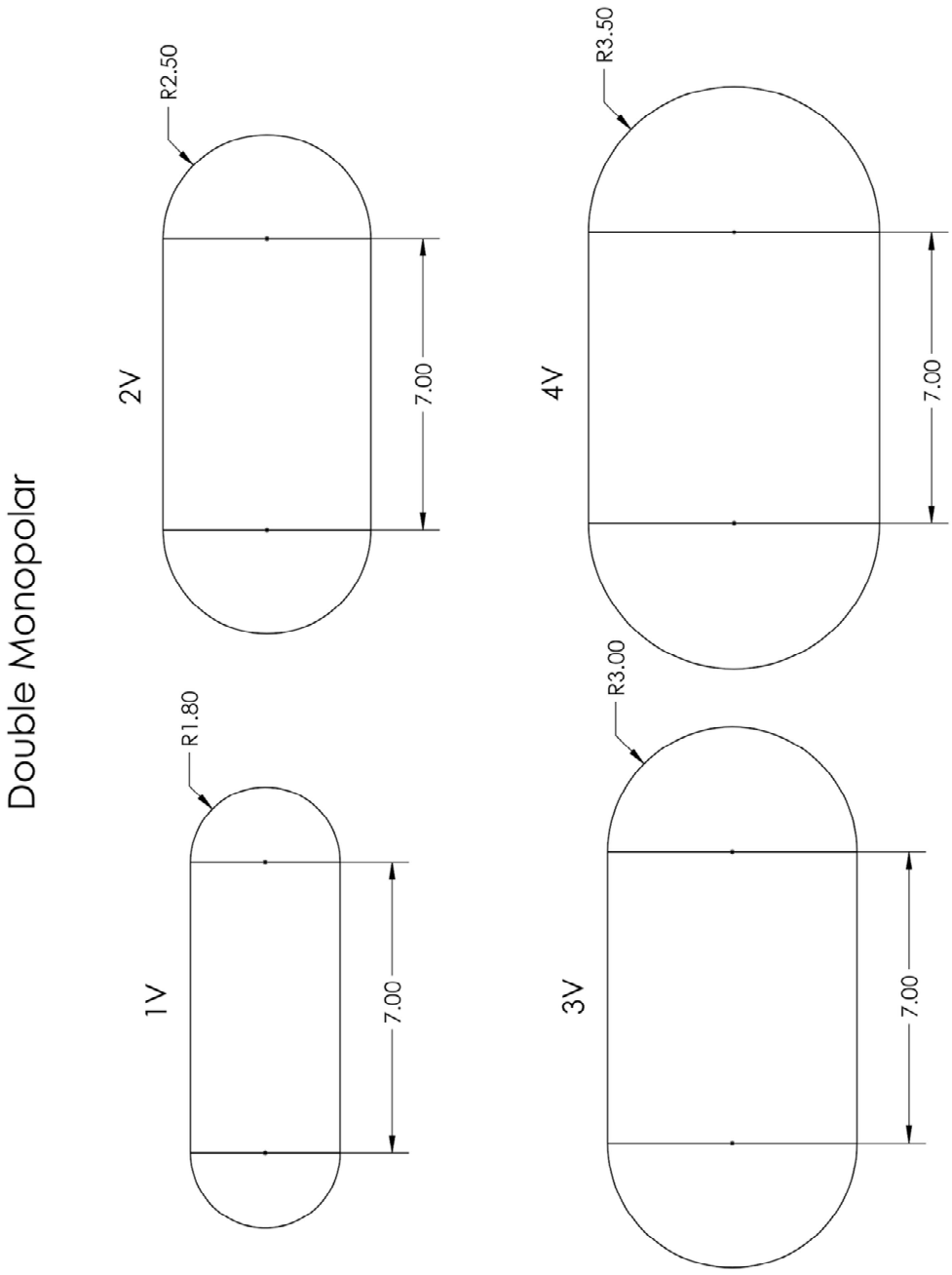

Figure 101. Scale drawings of the double monopolar electrode field volumes for 4 mm spaced ring contacts.

Appendix L: Bipolar Electric Field Volume Calculations when X < Es

$$X = \frac{{R_1}^2 - {R_2}^2 + {E_S}^2}{2E_S}$$

$$X_A = \sqrt{{R_1}^2 - {R_2}^2}$$

$$V_{X<E_S} = V_{centerSphere} - 2V_{centerSphereCap} + V_{endSphere} + 2V_{cylinder}$$

$$V_{X<E_S} = \frac{4}{3}\pi {R_1}^3 - 2\pi(R_1 - X_A)^2\left(R_1 - \frac{(R_1 - X_A)}{3}\right) + \frac{4}{3}\pi {R_2}^3 + 2\pi {R_2}^2(E_S - X_A)$$

Appendix M: Bipolar Electric Field Volume Calculations when X > Es

$$X = \frac{{R_1}^2 - {R_2}^2 + {E_S}^2}{2E_S}$$

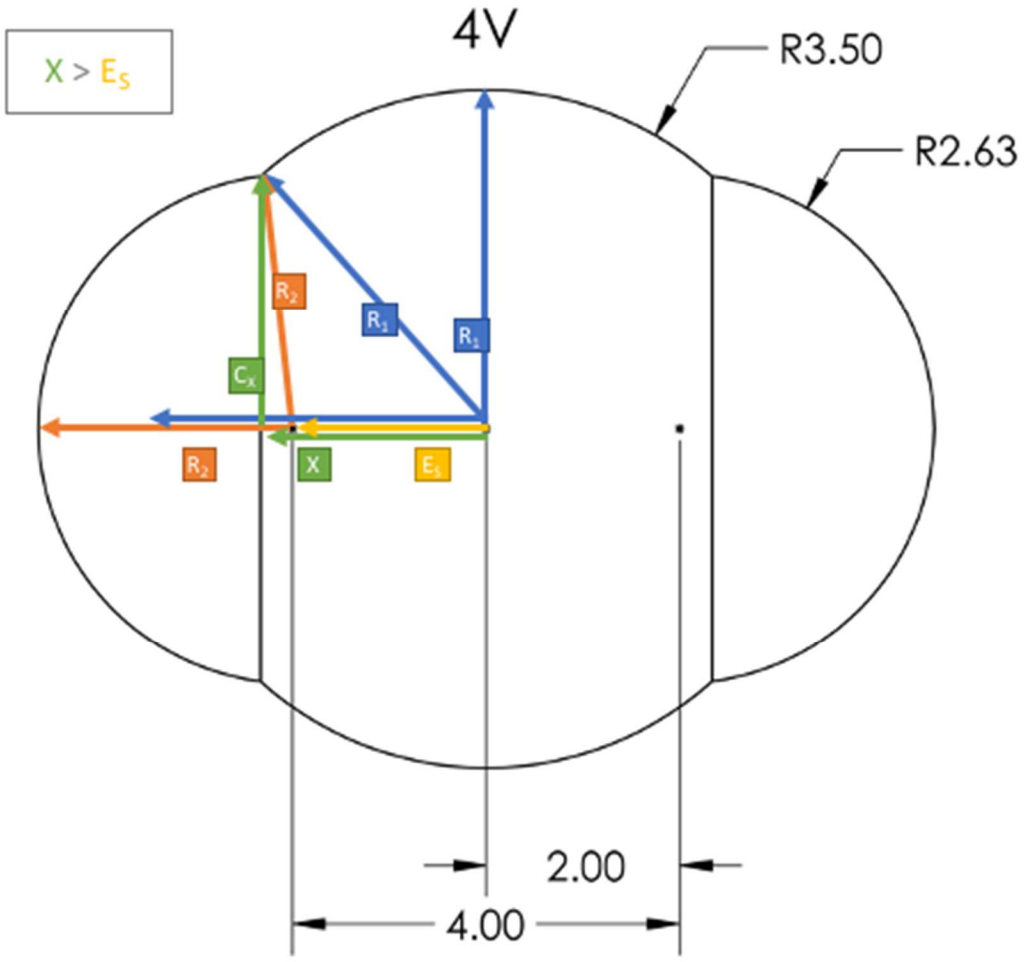

Figure 102. Dimensioned drawing of the bipolar electric field volume cross-plane showing variables to calculate the volume.

$$X = \frac{{R_1}^2 - {R_2}^2 + {E_S}^2}{2E_S}$$

$$V_{X>E_S} = V_{centerSphere} - 2V_{centerSphereCap} + 2V_{cap}$$

$$V_{X>E_S} = \frac{4}{3}\pi {R_1}^3 - 2\pi(R_1 - X)^2\left(R_1 - \frac{(R_1 - X)}{3}\right) + 2\pi(R_2 + E_S - X)^2\left(R_2 - \frac{(R_2+E_S-X)}{3}\right)$$

Appendix N: Bipolar Electric Field Volumes at 0.5mm Contact Spacing

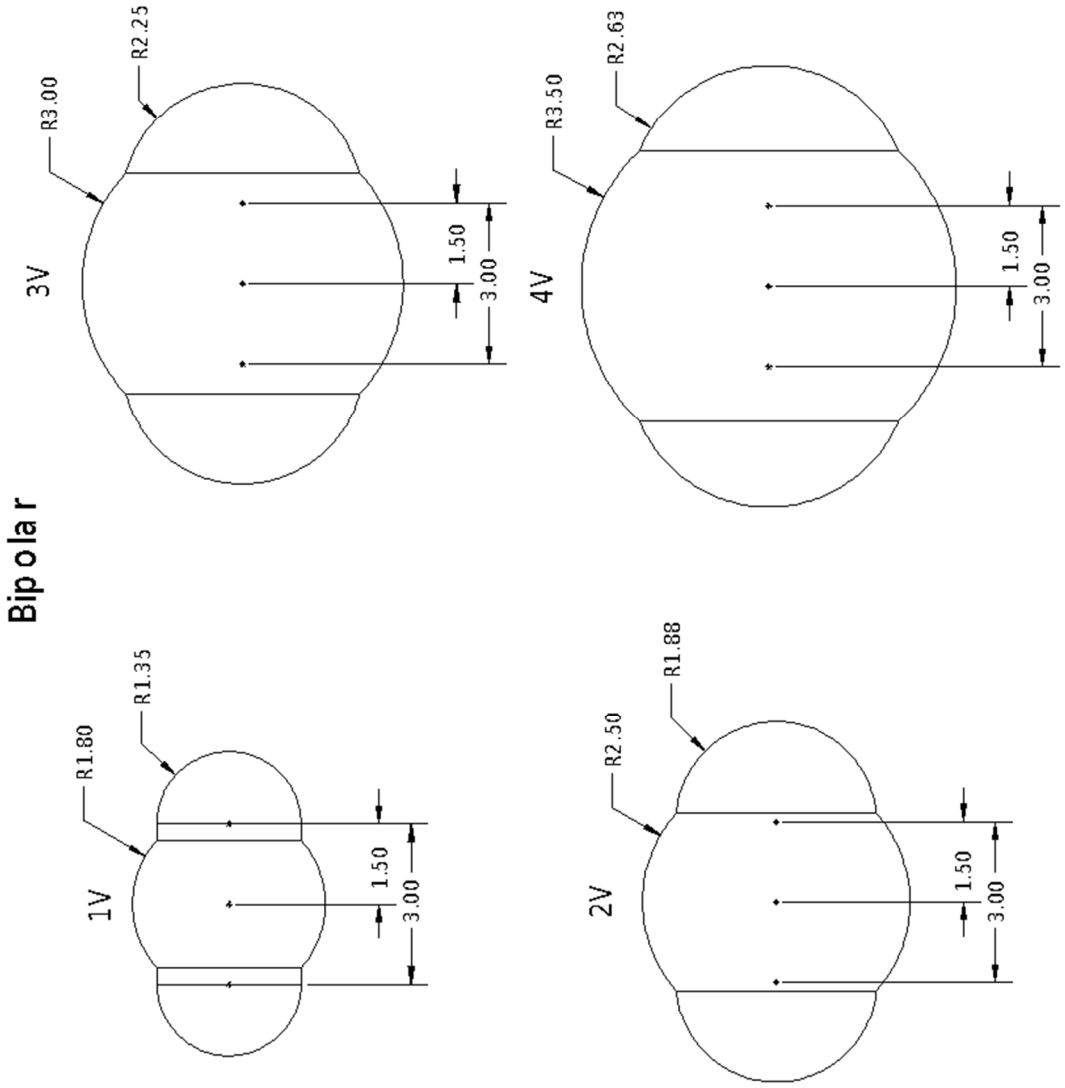

Figure 103. Scale drawings of the bipolar electrode field volumes for 0.5 mm spaced ring contacts.

Appendix O: Bipolar Electric Field Volumes at 1.5mm Contact Spacing

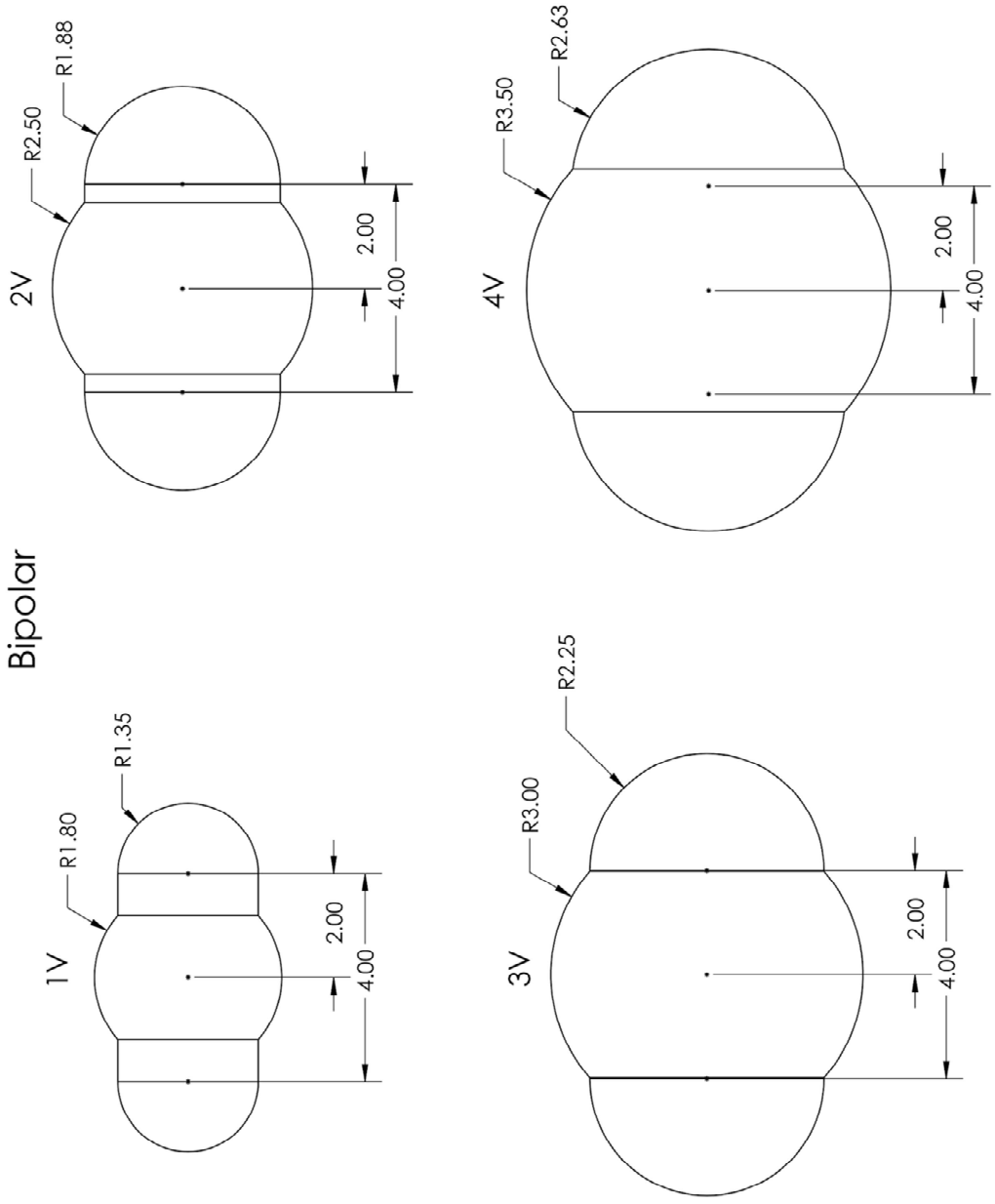

Figure 104. Scale drawings of the bipolar electrode field volumes for 1.5 mm spaced ring contacts.

Appendix P: Bipolar Electric Field Volumes at 4mm Contact Spacing

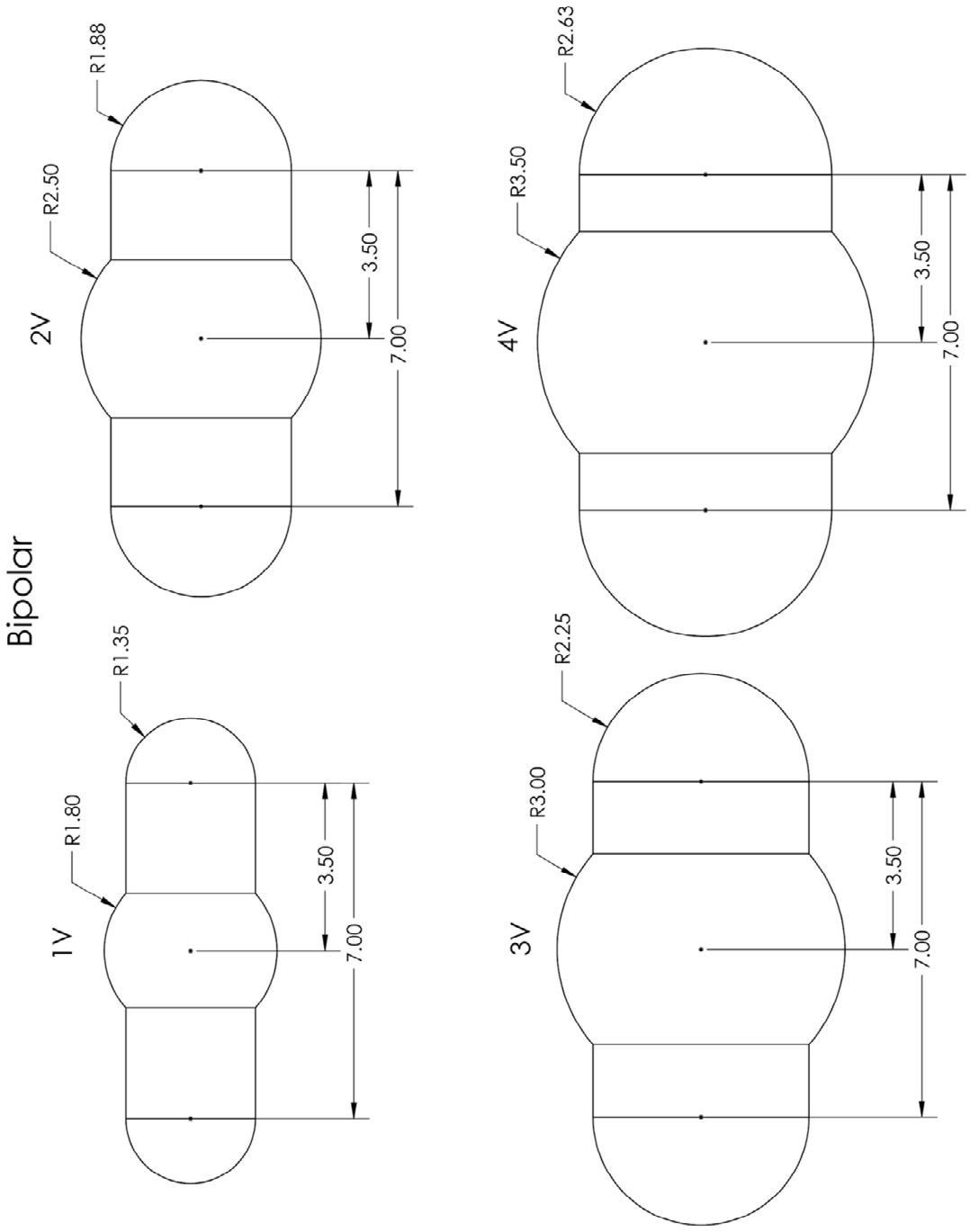

Figure 105. Scale drawings of the bipolar electrode field volumes for 4 mm spaced ring contacts.

Appendix Q: Graphical User Interfaces to Register the Patient's Data

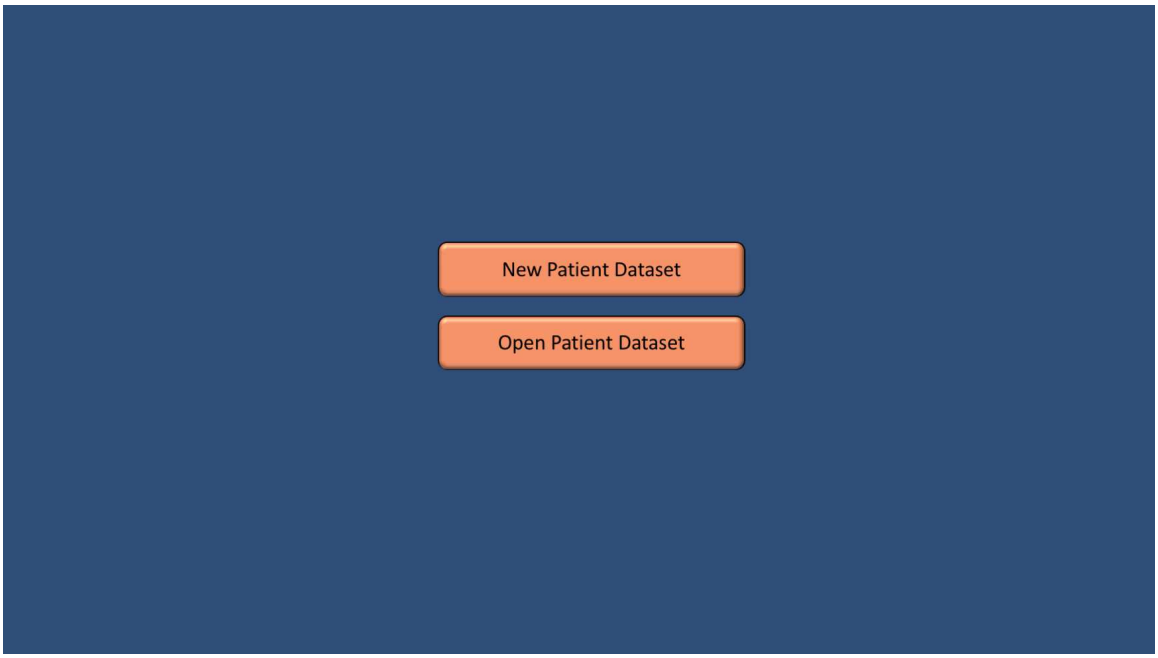

Figure 106. Screen one loads the patient's dataset into the VR experience. The doctor selects to load a new dataset or open a previous dataset.

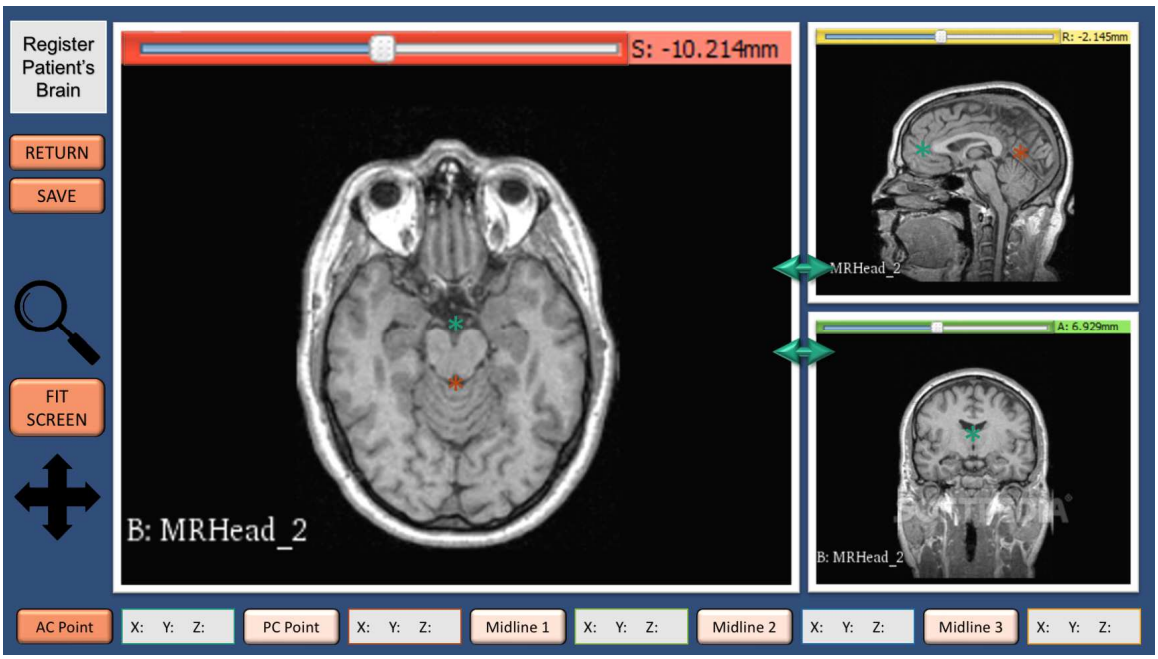

Figure 107. Screen two the doctor identifies five key points in the patient's anatomy. Figure D.15. Screen two the doctor identifies five key points in the patient's anatomy.

Figure 108. Screen three the software loads the patient's models and aligns the models with the stereotactic frame.

Appendix R: Graphical User Interfaces for the Stereoscopic Screen Display with Touch Screen Configuration

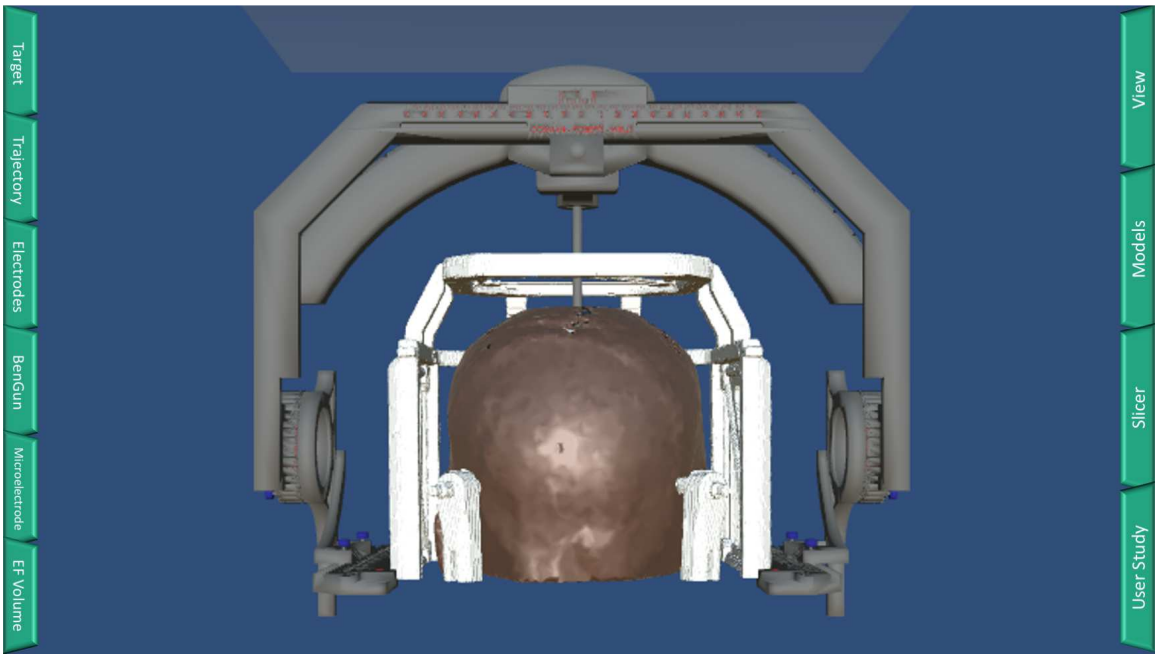

Figure 109. Screen one is the opening GUI. The primary workflow tasks are available in the tabs on the left side. The secondary actions are available in the tabs on the right side.

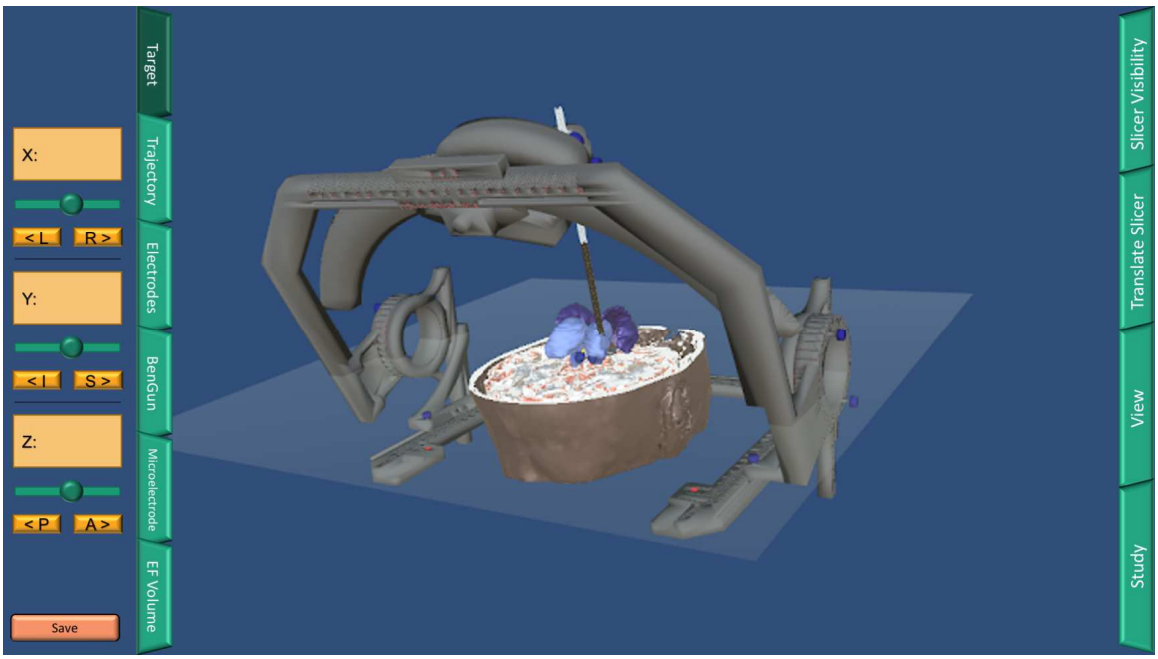

Figure 110. Screen two shows users the electrode's target location options using the sliders for macro-adjustments or the buttons for micro-adjustments.

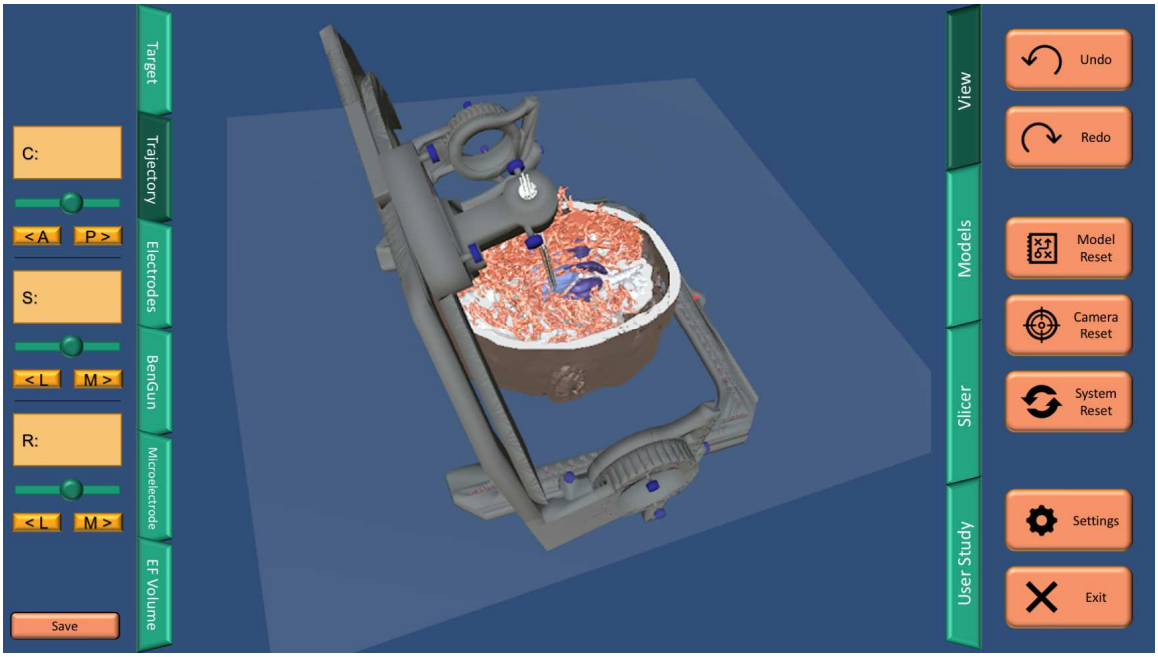

Figure 111. Screen three, on the left, users select the electrode's trajectory orientation using the sliders for macro-adjustments or the buttons for micro-adjustments. On the right, users undo or redo actions, reset the models, change the settings, or exit the simulation.

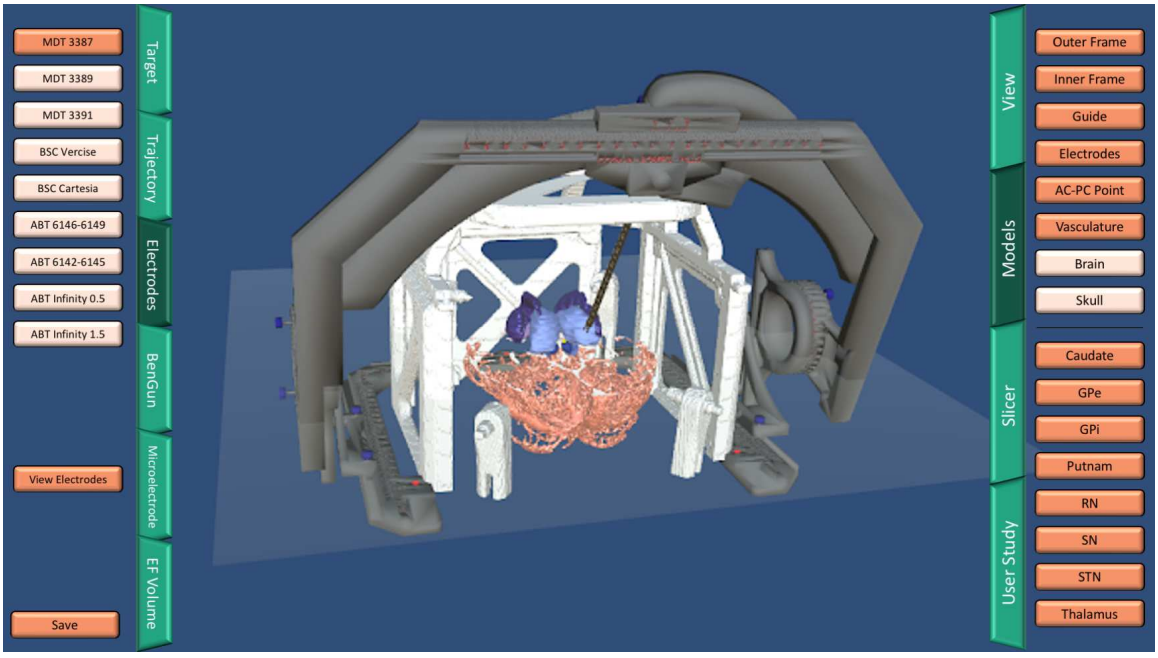

Figure 112. Screen four, on the left, users select their preferred DBS electrode or explore other electrode designs for this patient. On the right, users toggle the visibility of the numerous models in the environment.

Figure 113. Screen five, on the left, users select view electrodes to open the GUI in the middle of this screen. The centered image shows the different DBS electrode designs available in the system.

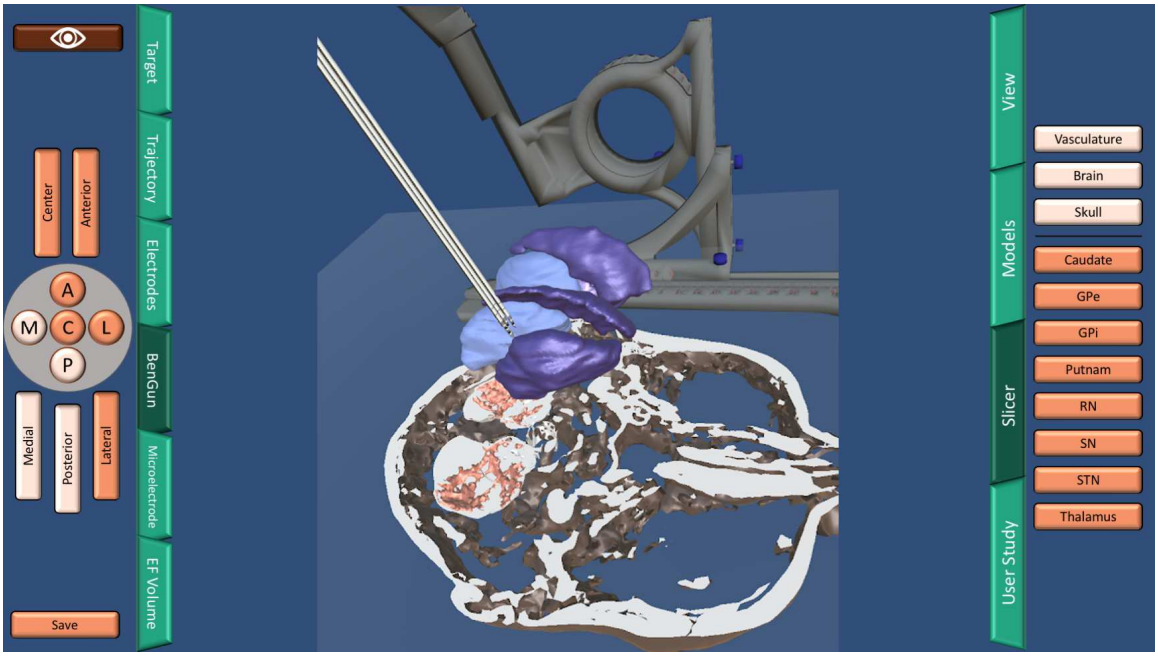

Figure 114. Screen six, on the left, users select BenGun ports for the DBS procedure. Users review the ports to analyze where the electrode's distal end ends in the patient's brain. On the right, users select the models to slice through. Selected models are transparent above the slicer plane and visible below the slicer.

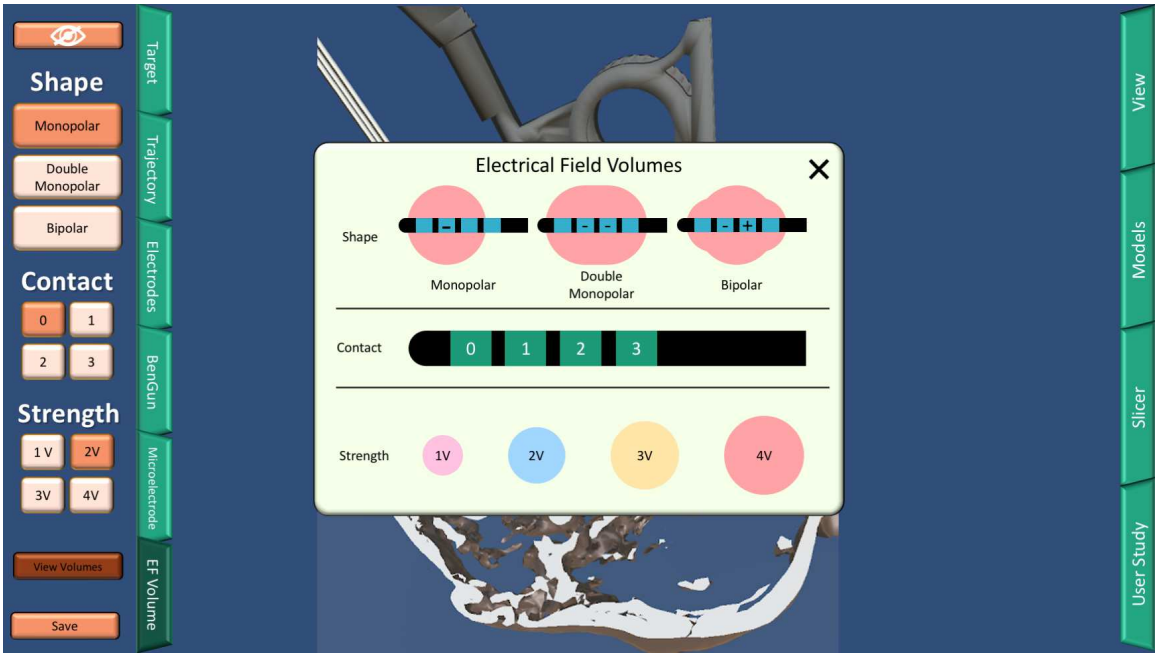

Figure 115. Screen seven, on the right, users review the shape, contact ring, and strength of the electrical field volume. The center image shows information about each variation.

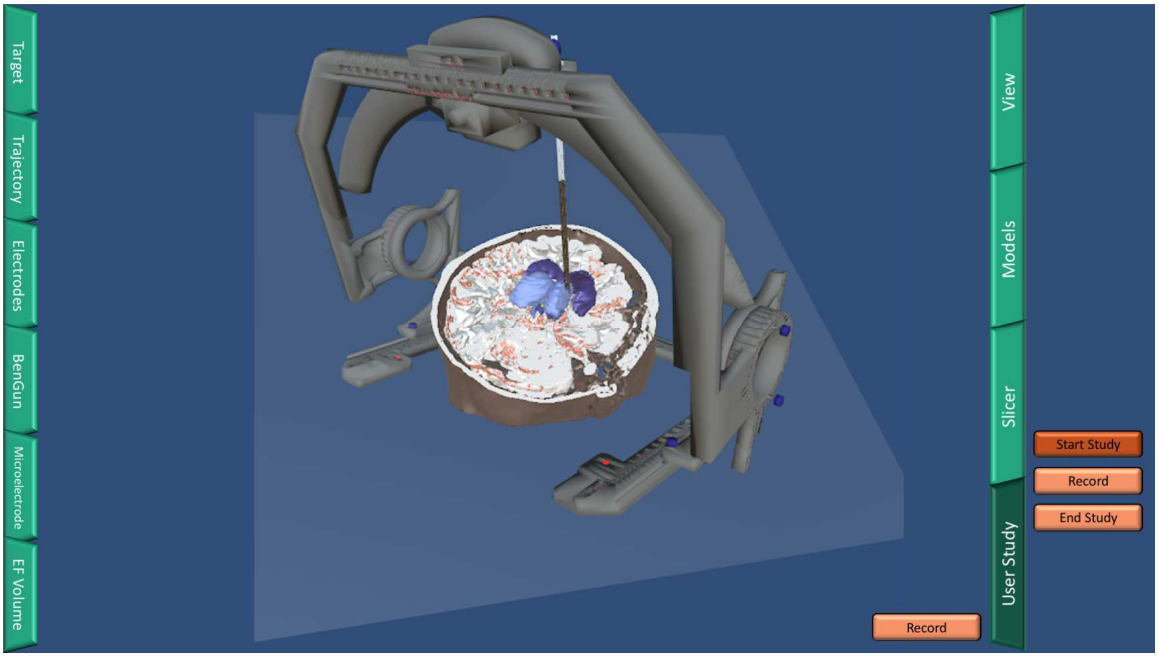

Figure 116. Screen eight, on the left, users track their performance within the simulation to compare their outcomes to evaluate the solution's effectiveness.

Appendix S: Graphical User Interfaces for the Head-Mounted Display Configuration

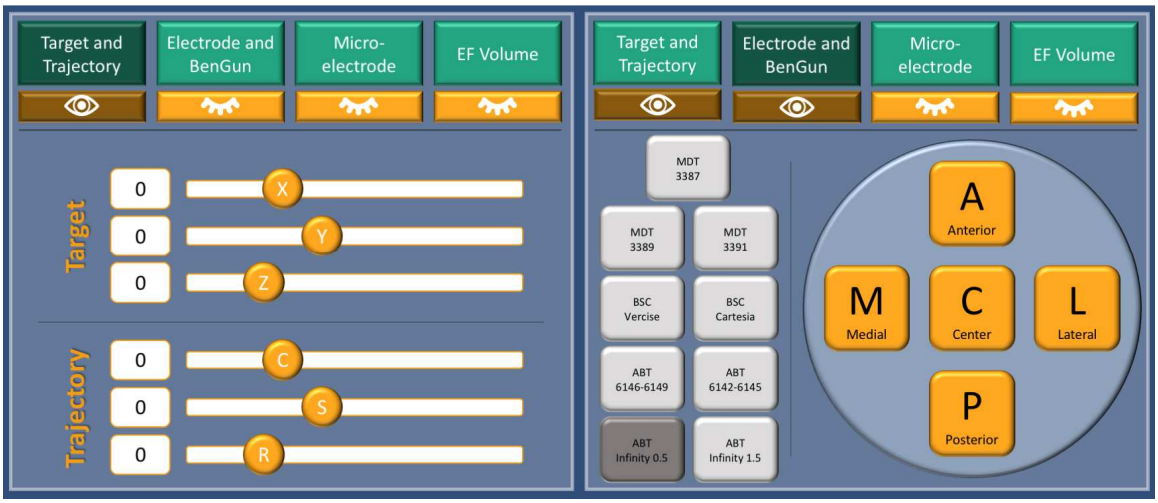

Figure 117. Menu one, on the left, is the first task for users is to select the DBS electrode's target location, followed by the trajectory orientation. Menu two, on the right, users select a preferred electrode for this patient and evaluate how the BenGun ports align the electrode to the patient's anatomy.

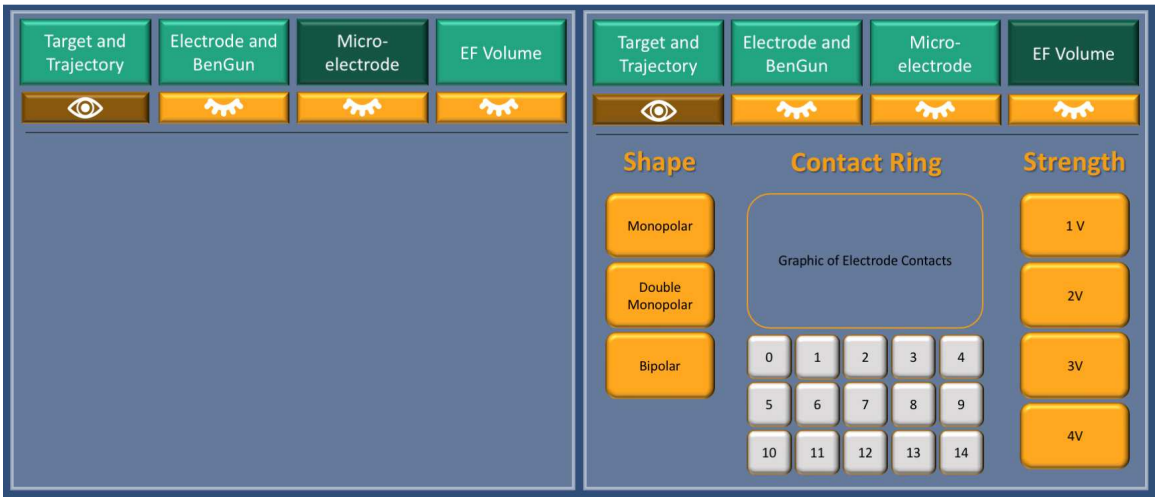

Figure 118. Menu three, on the left, users review microelectrode readings based on the electrode's target location and trajectory orientation. Menu four, on the right, users evaluate the electrical field volumes and select the shape, contact right, and strength of the electrical field for the patient based on their specific anatomy.

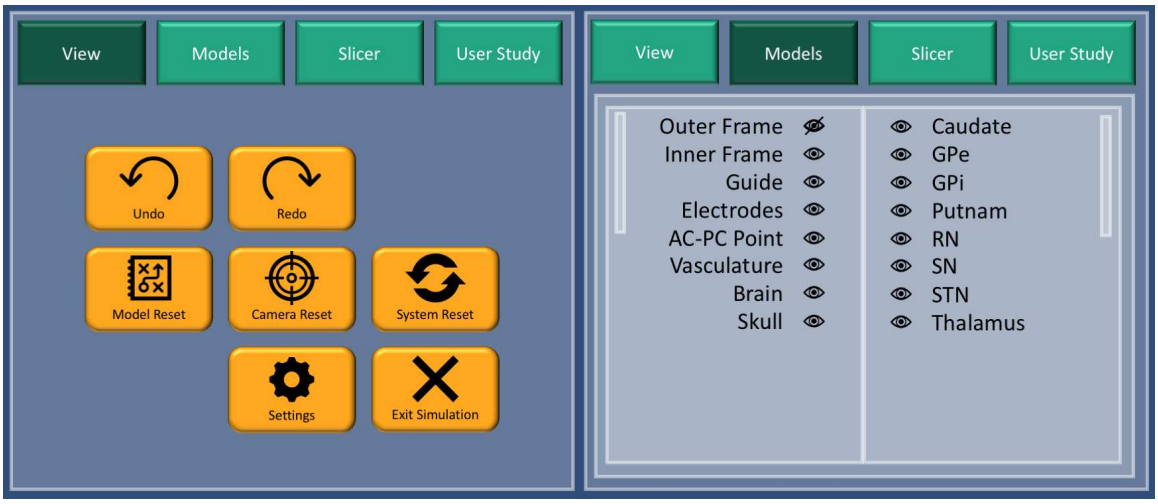

Figure 119. Menu five, on the left, user buttons to undo and redo actions, reset the models, change the settings, and exit the simulation. Menu six, on the right, users toggle the visibility of models.

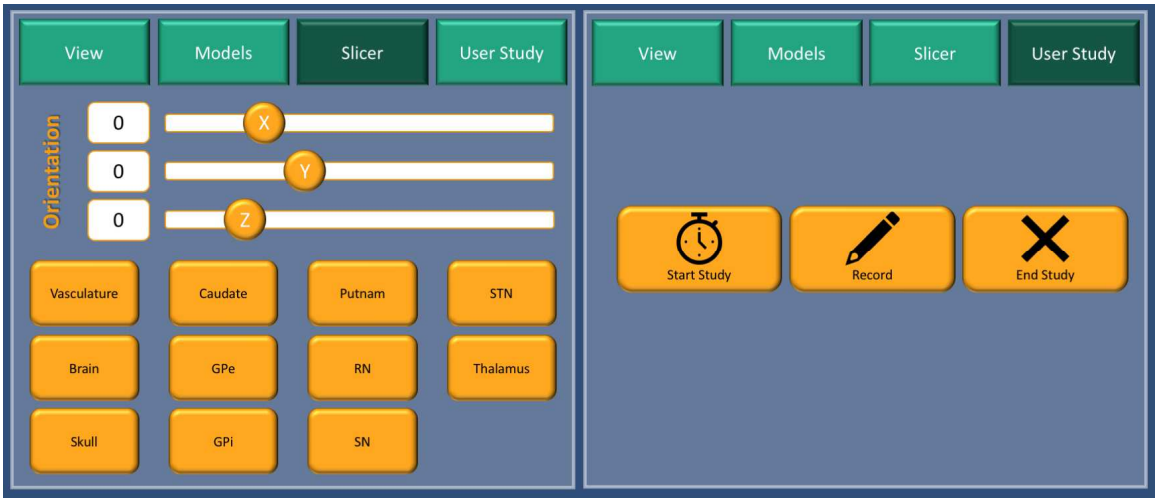

Figure 120. Menu six, on the left, users select the models impacted by the slicer plane. The slicer plane makes sections of the model above the slicer transparent, while the lower section is visible. Menu seven, on the right, options when performing user studies to evaluate the user's performance.

Appendix T: Industry Survey Transcript

Industry Survey

Contact: Bethany Juhnke
Email: toure023@umn.edu

Question:

Inclusion Criteria:

- Professionals developing or using XR technology for medical device design
    - Including: management, builders, users, maintainers. and operators.
- XR experience must be realistic and focused on gaining knowledge about a medical device
    - Examples include visualizing the design of a medical device, simulating performance of a medical device, educating others about medical device features, or training others to use a medical device.
- Exclusion: anatomy education XR solutions and therapy, as most of these solutions include gamification.
- All company sizes

Survey Introduction
Thank you for taking the time to share your experience with me. First, I hope you and your family are doing well during this time of uncertainty and have adjusted to the new normal.

I am a PhD candidate in Mechanical Engineering at the University of Minnesota in Minneapolis, MN. I, myself, was weeks away from capturing my final usability data when everyone started social distancing practices in response to COVID-19. With the uncertainty surrounding when we will be able to return to our previously scheduled programming, I have refocused my dissertation to ask how you use extended reality (virtual, augmented, mixed, etc.) technologies in your workplace. I want to know how you and your company are using, developing, and testing extended reality technologies to advance the design/adoption of a medical device or to support a clinical need.

I understand you may not be able to answer all my question. My goal with the survey is to better understand the state of the art for extended reality technology in medicine. Please answer the questions to the best of your knowledge.

The topics of the survey include:
1. Your demographic information
2. Information about your company
3. The design of your extended reality (virtual, augmented, mixed, etc.) system

4. The use of the technology for medicine (support a clinical need and/or to design medical devices)
5. The testing conducted on extended reality system
6. Your thoughts on benefits, obstacles, hurdles, and the future of the technology

The survey will take approximately 30 minutes to complete.

The records of this study will be kept confidential. In any sort of a report we might publish, we will not include any information to identify a subject or company. Research methods will be stored securely, and only researchers will have access to the records.

If you have any questions about the research study, please email me (Bethany Juhnke) at toure023@umn.edu.

Thank you again for sharing your time and experience with me.

Bethany

Electronic Consent: Please select your choice below:

Clicking on the "agree" button below indicates that:

- **You have read the above information**
- **You voluntarily agree to participate**
- **You are at least 18 years of age**

If you do not wish to participate in the research study, please decline participation by clicking on the "disagree" button.

- ☐ **Agree**
- ☐ **Disagree**

Definitions
The following terms will be used throughout the survey.

- **Extended Reality (XR):** includes virtual reality, augmented reality, mixed reality, etc. Our naming conventions may be different for these technologies, but the general idea is the same. We are using technology to alter how humans experience the world. All systems have a visual component supported by sound, touch, haptics, tracking, etc.
- **To Support a Clinical Need**: you are using the technology for patient care. Similar to how a hospital would have an MRI machine to capture scans, an exam table for patients to sit or a stethoscope to listen to a patient's heart. In these cases, the extended reality technology IS the medical device that needs to be evaluated.

- **To Design a Medical Device:** you are using the technology as a TOOL to complete a design-oriented task. Similar to how a technology company would use Solidworks to do CAD work, Powerpoint to create a presentation, or YouTube to learn a new skill. In this case, the extended reality technology is NOT the medical device being designed or evaluated.

Demographics

- What is your gender?
  - Female, Male, Genderqueer/Non-binary, Other _____, Prefer not to disclose
- What year were you born?
  - _____
- What is your highest education level?
  - High School, Associates, Bachelors, Masters, PhD, MD, Other _____
- What was your major in school?
  - _____

(1) Company Information

- Where is your company headquartered?
  - US State or Country
- What is the size of your company?
  - 0-10 employees, 11-20 employees, 21-50 employees, 51-100 employees, 101-500 employees, 501-1000 employees, 1001+ employees, 10,000+ employees, 100,000+ employees
- What is your position in the company?
  - Individual Contributor or Operational Employee, Middle Management, Senior Management, Executive
- Who is driving the use/development of extended reality technology? (select all that apply)
  - Individual Contributors or Operational Employees, Middle Management, Senior Management, Executive
- What is driving the use/development of the extended reality technology? (select all that apply)
  - Accelerate development
  - Lower prototyping costs
  - Assess scaled designs earlier
  - Illustrate contextual constraints
  - Reduce development risk
  - Competitive advantage
  - Improve patient care
  - Increase training and education
  - Other ____
- How long has your company been investing in extended reality technology?
  - 0-1 years, 1-3 years, 3-5 years, 5-7 years, 7-9 years, 9+ years

- What is your role with extended reality technology in your company? (select all that apply)
    - Maintainer (configuring, calibrating, upgrading software and hardware)
    - Operator (scheduling, help users, support individual use cases)
    - User (benefit from intended use of extended reality)
    - Builder (prepare digital content and extended experience)
    - Manager (organizing large projects, staffing, goal setting for extended reality facilities)
    - Other: _____
- How do you use extended reality technology? (select all that apply)
        - **To Support a Clinical Need**: you are using the technology for patient care. Similar to how a hospital would have an MRI machine to capture scans, an exam table for patients to sit or a stethoscope to listen to a patient's heart. In these cases, the extended reality technology IS the medical device that needs to be evaluated.
        - **To Design a Medical Device:** you are using the technology as a TOOL to complete a design-oriented task. Similar to how a technology company would use Solidworks to do CAD work, Powerpoint to create a presentation, or YouTube to learn a new skill. In this case, the extended reality technology is NOT the medical device being designed or evaluated.
    - To Support a Clinical Need
    - To Design a Medical Device
- Do you or your company complete testing when developing or purchasing extended reality technology?
    - Yes or No

(2) XR Technology System Design

- What is your company's status with developing or purchasing extended reality technology? (select all that apply)
    - Exploring our options
    - Scoping design criteria for system
    - Actively developing or purchasing system
    - Deployed or purchased a system
    - Retired or no longer using system
    - Other _____
- What is the purpose of the application/s being developed or purchased? (select all that apply)
    - Anatomical Visualization
    - Anatomical Education
    - Simulation (FEA, CFD, etc.)
    - Simulation for a Clinical Procedure
    - Training to Use a Specific Medical Device
    - Training for a Clinical Procedure

    - Procedural Planning
    - Surgical/Intraoperative Support
    - Other _____
- What models are included in the simulation? (select all that apply)
    - Medical device model/s
    - Human or animal anatomy model/s
    - Other: _____
- What hardware is being used? (select all that apply)
    - Stereo projection (powerwall, smart TV, etc.)
    - CAVE (multiple stereo projected surfaces)
    - Head-mounted display (virtual; HTC Vive, Oculus Rift, etc.)
    - Head-mounted display (augmented; Hololens, Magic Leap)
    - Augmented Reality (glasses: ex. Google Glass)
    - Augmented Reality (phone, tablet or other device)
    - In-house custom
    - Other: _____
- What types of software does your company use? Please share the names of the software used in the space provided (select all that apply).
    - Commercial _____
    - Open-source _____
    - In-house custom _____
    - Research partnership _____
    - Other _____
- Which resources guide your development or selection of extended reality technology? (select all that apply)
    - Other XR solutions on the market
    - Company leadership
    - Domain experts
    - Programmers with B.S. in computer science
    - Programmers with extended reality experience
    - Usability experts
    - Computer science research
    - Human factors research
    - Other: _____

(3) To Design of Medical Devices

Survey Logic: This section will appear if the respondent selects 'To Design a Medical Device' from Question: How do you use extended reality technology?

- When do you use extended reality technology in the design process? (select all that apply)
    - User Needs, Design Input, Ideate, Prototype, Design Review, Testing, Verification, Validation, Other _____
- What is your company's protocol for using extended reality technology? (select all that apply)

    - Scheduled sessions with the technology: at stages in the design process
    - Impromptu or ad-hoc: used to address issues as they come up
- How is extended reality technology used in the design process? (select all that apply)
    - Abstract data visualization
    - Aesthetic quality/craftmanship
    - Communication across disciplines
    - Design development
    - Ergonomics/reachability
    - Packaging
    - Telepresence
    - Simulation and testing
    - Stakeholder communication
    - Understanding the relationship between anatomy and the device
    - Visualize Mockups
    - Other _____
- What types of problems are best solved using the extended reality technology?
    - _____
- What does extended reality technology offer your design process that is unavailable with other technology?
    - _____

(4) To Support Clinical Needs

Survey Logic: This section will appear if the respondent selects 'To Support Clinical Needs' from Question: How do you use extended reality technology?

- When do you use extended reality technology in a clinical setting? (select all that apply)
    - Patient education
    - Medical education
    - Training or simulation
    - Device education
    - Procedural planning
    - Surgical/Intraoperative support
    - Rehabilitation
    - Therapy
    - Other _____
- What is your facility's protocol for using extended reality technology? (select all that apply)
    - Scheduled sessions with the technology: used routinely
    - Impromptu or ad-hoc: used to address issues as they come up
- How is extended reality technology used in clinically? (select all that apply)
    - Visualize human anatomy
    - Capture anatomical measurements
    - Confirm device size or fit with anatomy

    - Overlay simulation on patient anatomy
    - Explore medical device features
    - Communicate with others
    - Replicate surgical procedures
    - Other _____
- What decisions about a clinical need do you make while using the extended reality technology?
    - _____
- What does extended reality technology offer your clinical practice that is unavailable with other technology?
    - _____

(5) Validation Testing

Survey Logic: This section will appear if the respondent selects YES in Company Information

- **Do you or your company test or validate solutions when developing or purchasing XR technology?**
- How important is each type of testing for you or your company? (5-point Likert: Extremely important to Not at all Important)
    - Unity Testing, validating the program
    - Integration Testing, validating the design
    - System Testing, validating the system/architecture
    - User Acceptance Testing, validating against requirements
- Why do you perform testing? (select all that apply)
    - Identify defects and errors during development
    - System design validation
    - Find issues with complex workflows
    - Gather unbiased user opinions
    - Insights to improve overall user experience
    - Match design criteria to real-world needs
    - Other_____
- Do you or your company complete usability testing to evaluate the design of the extended reality technology?
    - Yes, No
        - If No, remainder of testing questions are skipped.
- For the developed/purchased solution/s used by your company, what types of usability testing were completed **internally**? (Definitions at bottom by (D. Bowman et al., 2002) (select all that apply)
    - Cognitive Walkthrough
    - Formative Evaluation
    - Heuristic or Guidelines-Based Evaluation
    - Post-hoc Questionnaire
    - Interview/Demo
    - Summative or Comparison Evaluation
    - Other: _____

    - Unknown
    - None
- For the developed/purchased solutions used by your company, what types of usability testing were completed **externally**? (Definitions at bottom by (D. Bowman et al., 2002) (select all that apply)
    - Cognitive Walkthrough
    - Formative Evaluation
    - Heuristic or Guidelines-Based Evaluation
    - Post-hoc Questionnaire
    - Interview/Demo
    - Summative or Comparison Evaluation
    - Other: _____
    - Unknown
    - None
- Please respond to the following statements (5-point Likert: strongly agree to strongly disagree)
    - Appropriate methods exist for XR usability testing
    - Usability testing is a priority during development
    - ISO Standards are needed
    - Guidance is needed to develop extended reality design criteria
    - User testing is performed by individuals within our development group
    - User testing is performed by individuals within our company
    - User testing is performed by individuals outside out company

(6) Benefits, Obstacles, Hurdles and Final Thoughts

- What are the benefits of this technology for medicine? (select all that apply)
    - Advocacy, Communication, Cost Savings, Decision Making, Education, Innovation, Knowledge, Productivity, Training, Time savings, Safety, No Tangible benefits, Others: _____
- Please rate the level of difficulty for each activity (5-point Likert: very difficult to very easy)
    - Starting an extended reality facility
    - Securing funding for technology development
    - Technology adoption within company
    - Employing individuals with the appropriate skillsets
    - Measuring return on investment
- What business obstacles have **you (individually)** faced to implement the technology?
    - _____
- What technical obstacles have **you (individually)** faced to use the technology?
    - _____
- What business obstacles have **your company (system)** faced to implement the technology?
    - _____

- What technical obstacles have **your company (system)** faced to use the technology?
    - _____
- What hurdles must be overcome for this technology to be standard? (select all that apply)
    - Awareness, Access, Cost, Quality, Turn-around time, Others: _____
- What are your hopes for the future of extended reality technology, applications, and experiences used for medicine?
    - _____
- What do you wish you were able to do with extended reality technology that you currently could not do now? Why?
    - _____
- In your professional opinion, what is it going to take to make this technology ubiquitous in medicine?
    - _____
- Would you be willing to answer additional follow-up questions? If so, please enter your name, and email.
    - _____

Thank you
Thank you for taking the time to complete my survey. I am excited to analyze the results and gain a clearer perspective about how extended reality technologies are being used in the medical industry.

Do you know anyone else who is using extended reality technology for medical device design? Please share my email with them or their email with me. My email is toure023@umn.edu.

Thank you again! I look forward to continuing this conversation.

Bethany Juhnke
toure023@umn.edu

Appendix U: Usability Methods

Definitions from [1]D. Bowman et al., 2002

Cognitive Walkthrough: an approach to evaluating a user interface based on stepping through common tasks that a user would perform and evaluating the interface's ability to support each step. This approach is intended especially to help understand the usability of a system for first-time or infrequent users, that is, for users in an exploratory learning mode.

Formative Evaluation: an observational, empirical evaluation method that assesses user interaction by iteratively placing representative users in task-based scenarios in order to identify usability problems, as well as to assess the design's ability to support user exploration, learning, and task performance. Formative evaluations can range from being rather informal, providing mostly qualitative results such as critical incidents, user comments, and general reactions, to being very formal and extensive, producing both qualitative and quantitative (for example, task timing, errors, and so on) results.

Heuristic or Guidelines-Based Expert Evaluation: a method in which several usability experts separately evaluate a user interface design (probably a prototype) by applying a set of "heuristics" or design guidelines that are relevant. No representative users are involved. Results from the several experts are then combined and ranked to prioritize iterative (re)design of each usability issue discovered.

Post-hoc Questionnaire: a written set of questions used to obtain demographic information and views and interests of users after they have participated in a (typically formative) usability evaluation session. Questionnaires are good for collecting subjective data and are often more convenient and more consistent than personal interviews.

Interview/Demo: a technique for gathering information about users by talking directly to them. An interview can gather more information than a questionnaire can and may go into a deeper level of detail. Interviews are good for getting subjective reactions, opinions, and insights into how people reason about issues. "Structured interviews" have a defined set of questions and responses. "Open-ended interviews" permit the respondent (interviewee) to provide additional information, ask broad questions without a fixed set of answers, and explore paths of questioning that may occur to the interviewer spontaneously during the interview. Demonstrations (typically of a prototype) may be used in conjunction with user interviews to aid a user in

about the interface.

Summative or Comparative Evaluation (both formal and informal): a statistical comparison of two or more configurations of user interface designs, user interface components, and/or user ITs. As with formative evaluation, representative users perform task scenarios as evaluators collect both qualitative and quantitative data. As with formative evaluations, summative evaluations can be formally or informally applied.

[1]Bowman, D. A., Gabbard, J. L., & Hix, D. (2002). A survey of usability evaluation in virtual environments: classification and comparison of methods. *Presence: Teleoperators & Virtual Environments*, *11*(4), 404-424.