Design Considerations for Interacting and Navigating with 2 Dimensional and 3 Dimensional Medical Images in Virtual, Augmented and Mixed Reality Medical Applications

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Abstract. The extended realities, including virtual, augmented, and mixed realities (VAMR) have recently experienced significant hardware improvement resulting in an expansion in medical applications. These applications can be classified by the target end user (for instance, classifying applications as patient-centric, physician-centric, or both) or by use case (for instance educational, diagnostic tools, therapeutic tools, or some combination). When developing medical applications in VAMR, careful consideration of both the target end user and use case must heavily influence design considerations, particularly methods and tools for interaction and navigation. Medical imaging consists of both 2-dimensional and 3-dimensional medical imaging which impacts design, interaction, and navigation. Additionally, medical applications need to comply with regulatory considerations which will also influence interaction and design considerations. In this manuscript, the authors explore these considerations using three VAMR tools being developed for cardiac electrophysiology procedures.

Keywords: Extended reality · Mixed reality · Medical applications · Cardiac electrophysiology · Ultrasound · Medical device

1 Introduction

Rigorous standards have been developed for the design and evaluation of software on medical devices for clinical viability on increasingly complex hardware form factors and user input modalities, but have largely relied on fixed 2-dimensional (2D) displays or 3-dimensional (3D) workstations. When the performance of a medical device is combined

J. Y. C. Chen and G. Fragomeni (Eds.): HCII 2021, LNCS 12770, pp. 117–133, 2021.
https://doi.org/10.1007/978-3-030-77599-5_10

with the capabilities virtual, augmented and mixed reality (VAMR) platforms, the complexity in evaluation is dramatically increased, because novel assessment of the medical device is required in the context of novel VAMR hardware. Despite these challenges, there has been an increase in the number and complexity of medical devices that utilize the promise of VAMR technology to meet the needs of the user. Each user group has specific context, experience, and requirements of VAMR integrated medical devices. Classification by target end user, use case and use environment are critical for designing optimal navigation and interaction tools for VAMR medical applications.

Medical imaging can be generalized into 2D data, such as x-rays, patient vitals, and ultrasonography, or 3D data, such as CT scans and MRIs, which require different image interpretation modalities. Both types of medical imaging have roles in clinical practice. Successful integration of both 2D and 3D medical data in VAMR has the potential to enhance the ability to interpret and navigate these data in medical applications. Designing medical applications with meaningful interaction and navigation tools for 2D and 3D medical platforms have unique considerations.

To date, the authors have developed a mixed reality (MxR) solution to empower physicians who perform minimally invasive cardiac procedures. The Enhanced ELectrophysiology Visualization and Interaction System (ĒLVIS, now being marketed as the CommandEP™ System) has been developed to address the unmet needs in the cardiac electrophysiology (EP) laboratory, by displaying interactive images of the patient-specific cardiac anatomy along with real-time catheter locations in 3D [1–3]. These 3D data allow the physician to visualize the intracardiac geometry and electrical propagation across it with respect to therapeutic catheters that are used to treat cardiac arrhythmia [4]. Additionally, the authors are developing a MxR based ultrasound tool which displays the ultrasound image sector in 2D at it's true 3D location in space (from the tip of the ultrasound probe) and has the additional functionality of medical tool tip tracking to deploy this tool in interventional ultrasound procedures, such as vascular access. Lastly, the authors are developing a MxR tool to make measurements on medical images to assist in medical decision making—the initial use case for these measurements is in the cardiac EP laboratory, where measurements are made to determine the site of abnormal electrical activation to target for ablation.

In this manuscript, we will explore various interaction and navigation tools for medical VAMR applications using the 3 applications mentioned above, with a focus on the varying considerations between 2D and 3D medical imaging.

2 Overview of the Extended Realities

The extended realities currently include virtual, augmented, and mixed realities with the acknowledgement that future developments may further extend or subdivide this continuum. Fully immersive Virtual reality (VR) has important applications in both physician-centric and patient-centric applications spanning education, training, rehabilitation, and therapy. The primary tradeoff of VR hinges on the completely immersive experience, which allows complete control of the user experience of the environment, while simultaneously isolating or mediating the user's current, natural environment. For those use cases and environmental conditions that require meaningful interactions with the natural environment, VR may be prohibitive, but augmented and mixed reality technologies may be well suited [1, 4]. Augmented reality (AR) allows for the user to maintain their view of the natural environment and simply post, or augment, digital images into their environment. Mixed reality (MxR) blends digital augmentation with the natural environment by allowing the user to have meaningful interactions with those digital images, for instance, placing, rotating, zooming, or clipping, in their natural surroundings. A new generation of head mounted displays (HMDs) merged, or pass-through the surroundings into an extended reality, blending virtual and mixed reality in a fully occlusive display. To date, most clinical applications have targeted AR and MxR HMDs to maintain a minimally obstructed view through the HMD into the natural environment, providing the benefits of the platform while allowing the user to create eye contact and maintain peripheral vision in the natural environment. As hardware technologies advance, the distinctions and compromises between the extended realities will continue to diminish, expanding their respective applications for appropriate use cases.

The types of interactions that the end user requires with 2D medical data are distinct from what is required for 3D data. Medical professionals working with 3D medical data require more flexible 3D navigational tools with the ability to move, rotate, zoom, and slice into the data, where this functionality is not strictly required for the 2D counterparts. However, maintaining and expanding capabilities in 2D remain critical, such as the ability to measure and the ability to understand how 3D objects relate to and interact with a 2D image.

3 Developing and Developed Medical Applications in VAMR

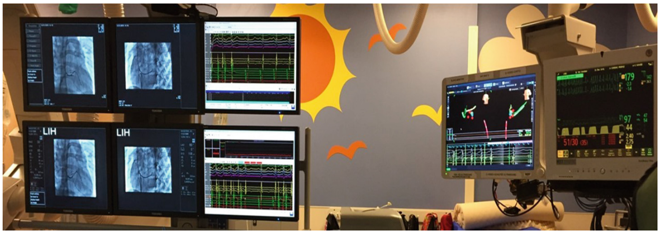

Fig. 1. The **Electrophysiology Laboratory** at St. Louis Children's Hospital. 4 systems are required (from left to right): fluoroscopy, electrograms, electroanatomic mapping, and vital signs.

To date, the authors have been developing 3 unique medical applications in VAMR to assist physicians who perform cardiac electrophysiology (EP) procedures [2]. These minimally invasive procedures are performed in patients with heart rhythm abnormalities using flexible catheters that are carefully threaded through larger vessels in the body, leading to the heart. The catheters are electromagnetically tracked and the positions they visit during spatial sweeps are used to create volumes that represent the endocardial surfaces of the heart in electroanatomic mapping systems (EAMS). After these geometries are created, the electrical data that is collected by the tip of the probe is overlayed on the geometry, creating an electroanatomic map. Using these maps, coupled with the direct electrical data signals from the distal tips of the catheters, the physician determines the location of the abnormal electrical activity and then targets it for ablation. These decisions require an understanding of both the cardiac anatomy and electrical system. Currently, these procedures are completed using several distinct systems (see Fig. 1) and require the user to selectively process the data from each system at the appropriate time.

These solutions are intended for use by cardiac electrophysiologists (end users) performing electroanatomic mapping procedures (use cases) in the cardiac electrophysiology laboratory (use environment), with some tools under active development and others having received FDA-clearance. Here we will describe each of the proposed uses, and how the user needs, and environmental factors impact the design.

3.1 Command EP System

The CommandEP™ system creates digital, real-time patient-specific 3D cardiac geometries during minimally invasive cardiac electrophysiology procedures. The system collects data obtained from commercially available EAMS and displays a real-time 3D patient-specific geometry of the heart (or chamber of the heart) with real-time catheter locations (see Fig. 2) [5]. In this system, physicians have a gaze-dwell, hands-free, sterile interaction method with the 3D object (see Sect. 4. Interaction). Currently, visualization of catheter position within the heart is accomplished with 2D screens that present biplane fluoroscopy or electroanatomic mapping to the interventionalist via orthogonal projections (see Fig. 1). The skill to mentally relate these images to the 3D cardiac anatomy remains a key challenge impacting patient outcomes, training of future cardiac electrophysiologists and intra-procedural collaboration. This visualization is particularly relevant for anatomic ablations, where the target is predetermined based on patient's anatomy.

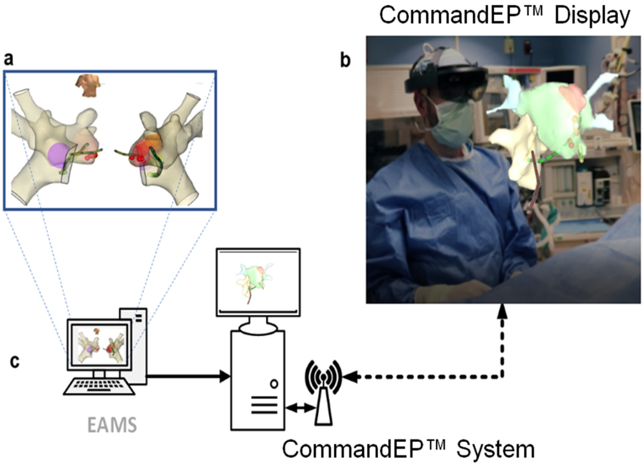

Fig. 2. CommandEP™ **System**. Data from commercially electroanatomic mapping systems can be wirelessly transmitted to the SentiAR Engine, which is loaded onto the Microsoft HoloLens HMD, and then display the electroanatomic maps with real-time catheter location in 3D.

Traditionally, manipulation of images requires relaying commands from the proceduralist to a nurse or technician, stationed at the EAMS workstation. If the proceduralist and proxy do not have a strong working background, communication may break down, requiring the proceduralist to instruct the proxy more directly from the computer console or break sterility to control the display themselves [3, 6].

3.2 Mixed Reality-Ultrasound (SentUS) System

At the start of each EP procedure, the electrophysiologist must obtain vascular access and leave a sheath in the vessel. The sheath is similar to a large bore intravenous access site with a hemostatic valve to prevent bleeding and allows the physicians to place catheters through the sheath directly into the vessel. The addition of ultrasound to guide vascular access has improved the efficiency and reduced the mechanical and infectious complications of vascular access [7, 8] However, the practical implementation of using ultrasound to guide vascular access is challenging. To start, this is a bimanual technique with the operator usually holding the probe in one hand (usually the nondominant hand) and the syringe/needle apparatus in the other hand (usually the dominant hand) allowing for fine manipulation for advancing the needle, holding back-pressure on the syringe plunger, and adjusting the angle of entry to the body. Simultaneously, the operator is looking at the ultrasound screen, often placing the target vessel in the center of the screen (see Fig. 3).

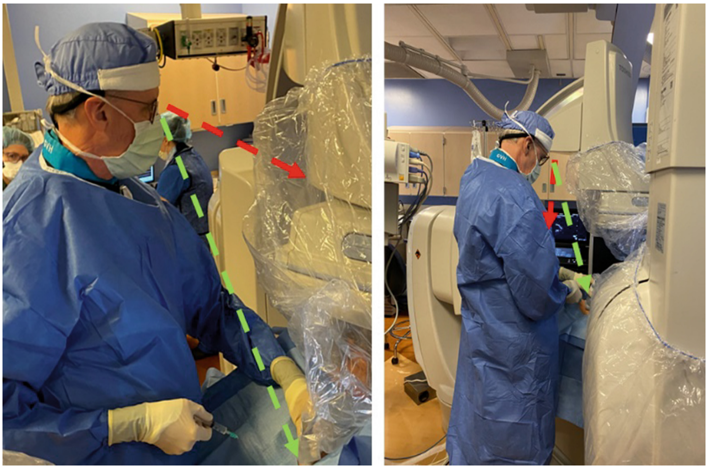

Fig. 3. Obtaining **Vascular Access using Ultrasound in the Electrophysiology Laboratory**. The operator is obtaining access in the right internal jugular vein using ultrasound. In the left panel, the operator is looking at the ultrasound screen (red arrow) while holding the ultrasound probe and needle/syringe apparatus with his hands to understand where the vessel is and where to puncture the skin. In the right panel, the operator is now looking at his hands (green arrow) rather than at the ultrasound screen (red arrow) while manipulating the needle to enter the vessel. (Color figure online)

Given the location constraints of where access is being obtained, the user frequently must look away from their hands to see the ultrasound machine resulting in the divergence between where they are looking and how they are moving their hands. This multisystem eye-hand-hand coordination can be very difficult to learn, particularly since it has been well described that the eyes play a pivotal role in the guiding of hand movements during actions that require eye-hand coordination [9, 10]. Additionally, ultrasound images do not often visualize the needle itself and therefore requires environmental cues to inform the physician of how close or far the needle tip is to the target structure.

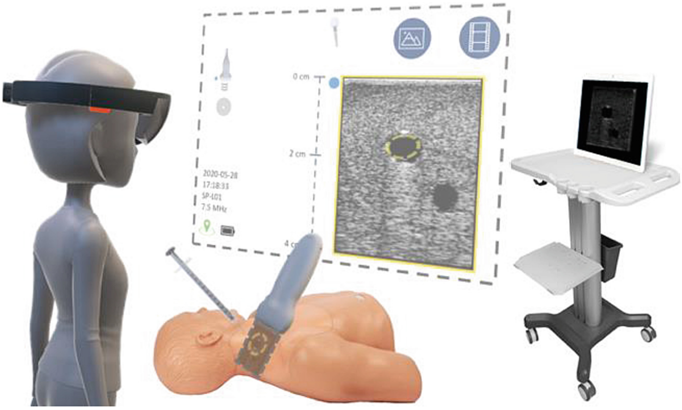

Fig. 4. Schematic **of SentUS Prototype**. Using this system, the user wears a HoloLens 2 head mounted display and is able to visualize the ultrasound data from the tip of the ultrasound probe to see the image in true 3D space, as well as a "billboard" display for the user to see the same data in a larger, ergonomically friendly space. Additionally, there is the ability to assess the position and location of the needle within the ultrasound sector (see Sect. 6. Early Lessons).

We have created a mixed reality ultrasound system that addresses these issues (see Fig. 4). Using a mixed reality headset, this system has the advantage of placing a "billboard" image of the ultrasound image in the user's field of view in such a way that they can perform this bimanual task and be oriented to be facing their hands. Compared to a conventional ultrasound device screen, the holographic display allows the user to position the display without being restricted by physical space constraints, resize the display to any desired size, and have the display orientation automatically adjust to the user's position throughout the procedure. In addition, the device features a second visualization of the ultrasound image directly projected from the tip of the ultrasound probe over the body, as though providing a cross-sectional X-ray view into the body. Integrated into the mixed reality display is a needle tracking system to allow the user to intuitively understand the trajectory of the needle relative to the target. This allows users to understand the relationship of the needle to the intended target and assess if the needle tip is close to the plane of the target, has gone past the plane, or is approaching the target.

In this system, the presented ultrasound images are 2D images and offer no 3D imaging to the user. However, the needle tracking module provides an inference of 3D data by graphically displaying the anticipated trajectory of the needle.

3.3 Mixed Reality-Electrogram (SentEGM) System

During minimally invasive procedures, physicians obtain data and make measurements on those data to make decisions that are critical to the success of the intervention. During electrophysiology (EP) procedures, the gold standard for identification of tissue for ablation is through live electrogram (EGM) data. Performance

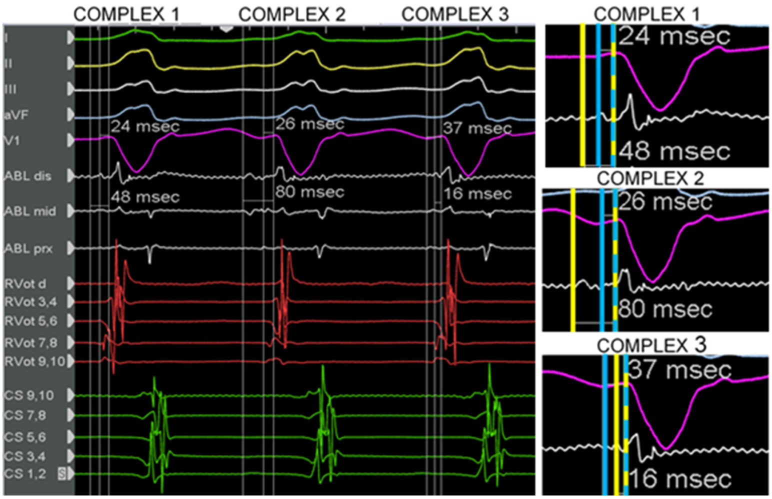

Fig. 5. EGMs **from a recent ventricular tachycardia ablation.** Caliper measurements are demonstrated for complex 1, 2 and 3 and zoomed in to the right comparing an expert EP (yellow) to a technician (blue) with overlapping lines marked as the yellow-blue dotted line. In complexes 1 and 2, the expert reading (yellow) is markedly longer as it includes the early, low amplitude signals on the white ablation-distal signal. In complex 3, the expert reader notes that the early portion of the signal is noise, rather than abnormal activity and excludes it from the measurement resulting in a shorter measurement than the technician. Radiofrequency lesions placed at the catheter location of complex 3 were not successful due to the misreading of the signals. However, lesions placed at the catheter location of complex 2, identified by re-reading by the expert were successful, resulting in arrhythmia termination. (Color figure online)

of measurements during these interventional procedures is currently hampered by technologies available in these laboratories with current workflows requiring either a second operator or technician to make these crucial measurements or the operating physician to break the sterile field to make measurements themselves, introducing inefficiencies and potential errors at a critical decision point during the procedure (see Fig. 5). Currently, the authors are developing the SentEGM system that will enable operating physicians to take real-time measurements in the operating room while maintaining the sterile field via a gaze-based mixed reality interface (see Fig. 6). This display will combine 3 screens into a single integrated, physician-controlled system, improving efficiency, reducing errors, and easing personnel requirements. Allowing performing physicians to make their own measurements with a hands-free interface has the potential to positively impact patient outcomes in multiple interventional specialties.

Fig. 6. SentEGM **System.** In this prototype of the SentEGM system, the user wears a Microsoft HoloLens HMD and is able to see the electrogram data alongside the CommandEP map data.

However, hands-free measurement and navigation of this data is highly challenging, as these fine types of hands-free, MxR human-computer interaction are nascent. In the CommandEP™ system, we designed a gaze-based interface on the Microsoft HoloLens 1 head mounted display (HMD) that allowed physicians to manipulate a patient-specific cardiac hologram. Physicians could rotate, zoom, and alter the opacity to best understand how to navigate. This gaze-based interface was successfully deployed to perform these big, coarser movements. The SentEGM system will hinge on the fine granularity for measurements, where changes in milliseconds and millimeters can cause significant changes in clinical outcome. Additionally, the development of "smart calipers" will supply a first measurement which can then be micro-adjusted using the gaze-based display and then confirmed likely using multiple navigation tools as described above.

4 Interacting in VAMR

Interactions in VAMR are the methods by which users select and control their virtual environment. Methods of interaction include gesture, gaze, voice, and eye tracking, though these discrete methods may be combined for more complex interactions. As these methods are being increasingly used and tested, optimal interactions will likely result in a method of selection followed by an alternate and secondary method for confirmation. Selecting the optimal method(s) of interaction requires a clear understanding of the end user, use case, use environment, and existing uses of the input mechanism that may drive interactional modalities. Often, clearly defining the end user and use case will make preferred methods apparent. Conversely, certain user needs and use cases may render some interaction methods unusable. For instance, a VAMR tool which is used by physicians to plan procedures may use an intuitive gesture dominant method, allowing for the end users to make both large movements and micro-movements to chart the preferred path during the procedure. This method often requires less training and is easily discoverable for the user. Tools which are used during sterile procedures and operations, however, must rely on methods that allow the physician to have their hands free to perform the procedure, and use gaze, voice or eye tracking (see Table 1). Training simulations using VAMR will also try to need to align with simulation environment as well as the intended use environment.

Table 1. Interaction modes and use cases in medical applications.

	Gesture	Gaze	Voice	Eye tracking
Patient-facing applications (including therapy and rehabilitation)	X			
Medical education	X	X		
Pre-procedural planning	X	X		
Intra-procedural use		X	X	X

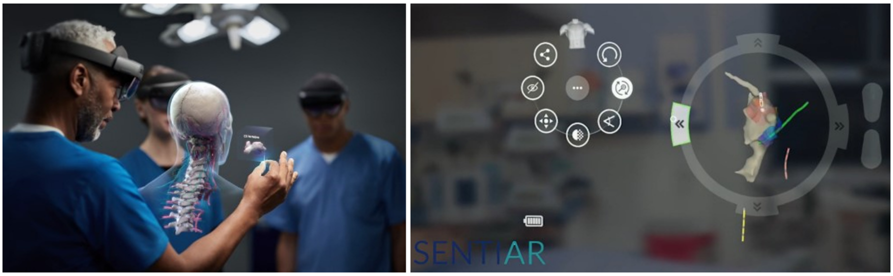

Fig. 7. Interaction **paradigms** in mixed reality (MxR) applications. Gesture interfaces (left) can enable users to grab holograms to reposition, resize, and rotate them. Because users primarily operate gesture interfaces using their hands, they are intuitive and natural to use but can be difficult to operate during clinical interventions when users may need to manipulate surgical tools. Gaze interfaces such as the CommandEP interface (right) can enable hands-free interaction during sterile interventions. Left image depicts the Microsoft HoloLens 2. Used with permission from Microsoft. Original Source: https://news.microsoft.com/hololens2_healthcare2/.

Early in development, creators of medical applications must understand the intended environmental conditions and how this can positively or negatively influence modes of interaction. For instance, developing interaction experiences in VAMR in outpatient, clinic-based, non-sterile environments allows for more flexibility and variation in interaction modes to maximize the user experience. Ambient noise levels tend to be fairly low and use of medical jargon is more limited. In contrast, interactions in VAMR in sterile, procedural environments, such as the operating room, will have stringent user requirements and increased risk levels, resulting in more constrained interaction methods—in these use environments, interactions must consider maintenance of the “sterile field” which directly affects patient safety. Additionally, in these procedural environments there is often frequent use of medical jargon, higher ambient noise levels and tonal normal function sounds and alarms generated by various equipment. Reliability of interaction methods should also be considered when developing VAMR medical applications. In higher-risk environments, inadvertent triggering of features may be distracting to the physician and in the high-risk scenarios can possibly negatively affect a patient outcome. For this reason, reconfirmation of activation may be more widely used in future development.

4.1 Methods of Interaction in VAMR

Gesture. The use of hand motions, or gestures, to interact in VAMR to activate (or select) is an important and intuitive interaction method due to the familiarity of users with hand-based interaction (Fig. 7). The use of hands allows the user to immediately feel comfortable using the system and provides a sense of intuitiveness to the system. However, given the current hardware options available, the types of gestures are still limited in accuracy and reliability, vary by platform and implementation, and ultimately require some degree of training to use effectively. These methods of interaction can be quite useful for pre-procedural planning, or for patient-facing use cases (particularly rehabilitation) as they require larger, more deliberate movements for activation. Optimal use environments for this type of interaction will have open spaces where the end user can move their arms and hands without disturbing other equipment. Other systems use hand-held controllers to support more accurate or reliable hand-based input interactions and can replace or reduce the magnitude of arm movement. The use intra-procedural use cases that we have targeted do not lend themselves well to gesture control as physicians are often using their hands to perform the procedure and are working in a constrained sterile environment.

Gaze. Gaze control allows the user to make head movements to navigate through the digital images in the extended reality. Conceptually, gaze may be considered analogous to operating a pointer such as a mouse cursor in a 2D interface, but considerations must be made to match design with intuitive gaze-based actions. Further, design considerations that inform mouse-driven interfaces can be applied to gaze interfaces as well. In general, gaze controls become easier to activate when the size of the controls is increased and the angular distance the gaze cursor must travel to the controls is decreased. This balance between distance to and size of the target, which is described by Fitts's law [11], must be considered against making software interfaces overly dense or cluttered. Cluttering is critical in MxR interfaces since crowded interfaces can obstruct the users' ability to interact with their physical surroundings and can increase incidence of inadvertent activation. When using gaze, a secondary method is required for activation or selection of an item, akin to a mouse click. In the case of the CommandEP™ system, we implemented a gaze-dwell system, allowing the user to hover over a menu item to select/activate it. Dwell times ranged from short to long dwell times (in the range of 300–1000 ms) depending on the kind of activation. During human factors testing, physician end users commented that they preferred shorter dwell times and interface adjustments were made accordingly, due to the new mapping of head direction to cursor input. Other potential secondary methods that can be used with gaze, such as voice or eye-based confirmation may be important adjunctive methods to confirm navigational commands.

Voice Control. Although voice is an intuitive command and input modality, the technical and design challenges of voice control are not limited to VAMR. Although navigating through the extended realities using voice can be done but should often be implemented alongside other navigation tools in medical applications. Proper understanding of the use environment, including typical words and vocabulary used in the environment are critical when defining "wake" words to reliably activate the system while avoiding accidental activations. Additionally, a unique challenge of voice control is the discoverability of commands, requiring users to either have visual reminders of possible commands or recall commands from memory. Advances and expansions in accents and natural language have made voice control a more tractable navigational tool. Ongoing developments are underway to explore the use of voice control and transcription during intra-procedural use cases.

Eye Tracking. The HoloLens 2 (Microsoft, Redmond, WA) has brought integrated eye tracking technology to a broad audience, and recent development efforts have demonstrated eye tracking to be an intuitive navigational adjunct. In contrast to gaze, eye tracking as an input is unfamiliar and straining for cursor control but is intuitive for communicating focus. Eye tracking can be used to determine what VAMR buttons or objects the user is looking at and respond accordingly, without requiring head motion from the user. While eye tracking may seem to offer superior ease of use to gaze, designs incorporating eye tracking should consider that users may need to look away from buttons or controls when using them. For example, users rotating a 3D model with a hands-free interface need to look at the model during rotation to determine when the desired view has been reached. In this instance, gaze controls are a better choice than eye tracking. Conversely, eye tracking on its own might result in inadvertent selections of buttons as users look across the display or as users learn the interface, though design considerations will be important in interface development and testing to ensure inadvertent activation is avoided. In the future, implementations will be similar to voice control in that eye tracking can be used as an adjunct to gaze or gesture. Using eye tracking as a confirmatory action will likely be of benefit in the future. For example, if a user's gaze cursor hovers over a button, but the user is not looking at the button, an inadvertent selection can be avoided. Eye tracking will also provide developers with opportunities to understand how end users are using and exploring their VAMRs, and may over time allow for an intention-based design where, after collecting and analyzing numerous procedures, the user is presented with the most relevant data they will need at that point in the procedure. This type of intelligent design will also allow for development of clinical decision support tools to aid physicians performing increasingly complex procedures. It is anticipated that these sorts of tools will have a significant impact in medically underserved areas.

5 Navigating in VAMR

Navigation of medical applications in VAMR environments is highly dependent on the type of extended reality and digital images in the virtual environment. Display in VAMR may be either 2D (or "flat") or truly 3D data projected in the extended reality—the dimensionality of the data is of critical significance for how the end user will navigate and interact in the VAMR environment. For those virtual screens, or 2D data posted in the VAMR space, interactions for navigating these images will be specific to the data displayed but is often limited to changes in location and size. For true 3D data in virtual environment, the navigation of the object can be much richer, including rotation and clipping, which can improve both the visualization and the comprehension for the end user.

5.1 Navigating 3-Dimensional Data in VAMR

Navigating 3-dimensional medical data in VAMR allows the user to have a more comprehensive understanding of the anatomy. From the ability to rotate to familiar fixed angles and projections to recreate mental models of anatomic structures, to the ability to freely rotate a structure and analyze the anatomy in a way previously not seen, navigating medical 3D images in VAMR provides the user the ability to understand individual, patient specific, anatomies in ways previously inaccessible. During the Cardiac

Augmented Reality (CARE) Study, where cardiac electrophysiologists were presented with patient specific 3D cardiac anatomies during interventional procedures, 87% of respondents felt that use of the system allowed them “to discover something new about the anatomy.”

5.2 Navigating 2-Dimensional Data in VAMR

The types of interactions that are required to navigate and interact with 2-dimensional images are potentially more limited and may have established input patterns. Allowing the end user to alter the size, location, and contrast of the 2D image with VAMR is of fundamental importance but assessing the navigational needs in the context of the overall use is valuable. Making measurements on these 2D images are an important consideration for medical applications, and additional context from 3D annotations (such as 3D anatomical reference) on 2D data can improve navigation and interpretation. Intra-procedural mixed reality allows for the development of a medical device to address this problem.

5.3 Intention Based Design

The design of an intuitive and useful interface requires that the most critical data and controls be the easiest to access by the user. However, discerning user preferences and needs is highly challenging and quite individualized. Users can struggle to communicate the prioritization of tools or data, and the result is that many of their interactions are intuitive and subconscious.

The high-speed eye-tracking from the next generation HMDs, such as the Microsoft HoloLens 2, will allow for evaluation of intent and focus during human factors (HF) evaluation and system use. These intent data will quantify the time spent viewing various data streams from the first-person perspective. This information, which would be unique to this platform can then be fed back into the design process to improve the interface and overall workflow integration.

6 Development and Early Lessons

Through the development, bench testing, contextual inquiries, human factors and clinical testing, there have been many early lessons learned. These early lessons will serve as the base on which more data should be generated for optimal design for medical VAMR applications.

6.1 Command EP System

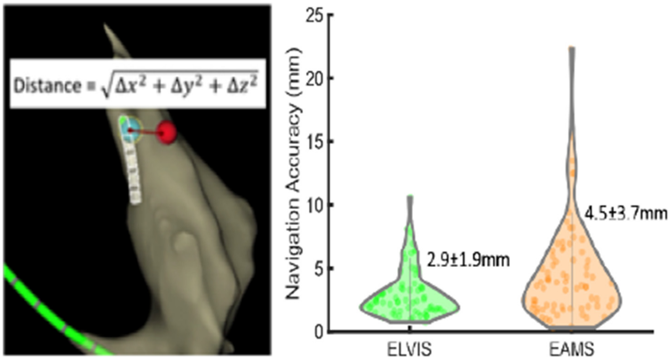

Fig. 8. Clinical **Assessment of Accuracy**. Left: Physician decides whether they are on target. Blue dot is physician's navigation point, red dot is the target. Right: Accuracy data from 150-point navigation tasks using the SentiAR system versus EAMS. Adapted from Avari Silva, J.N., et al., First-In-Human Use of a Mixed Reality Display During Cardiac Ablation Procedures. JACC Clin Electrophysiol, 2020. **6**(8): p. 1023-1025.

The improvement in visualization provided by the CommandEP™ System is the most immediately tangible value-add to the electrophysiologist. In the CommandEP™ system, we designed a gaze-based interface on the Microsoft HoloLens 1 HMD that allowed physicians to manipulate a patient-specific cardiac hologram, empowering the physician to rotate, zoom, and alter the opacity to best understand how to navigate. Post-procedure surveys demonstrated that 83% of physicians found manipulation of the hologram to be the most valuable feature with 87% of physicians discovering something new about the anatomy [3]. Considerable resources were devoted to developing an intuitive, hands-free interface for CommandEP™ via iterative human factors testing that allowed the physician to control EAMS data.

In the Cardiac Augmented Reality (CARE) Study, there were additional study tasks the physicians were asked to complete during the post-ablation waiting phase of the procedure. These tasks included the generation of a cardiac geometry followed by sequential navigation to 5 discrete points within the geometry using the current standard of care versus CommandEP™. The data demonstrated that the interface led to clearer care team communication [3], and improved navigational accuracy [12] (see Fig. 8).

6.2 Mixed Reality-Ultrasound (SentUS) System

This system is slated for early formative human factors testing for iterative improvement in the user experience design and user interface design in Spring 2021. The interface has the unique challenge of displaying the 2D ultrasound image plane, and additionally interpolating how a needle will intersect with the desired target in the image. This combination of 2D and 3D imaging has proven challenging.

Currently, the needle tracking tool allows the user to place the target within the circle for alignment (see Fig. 9). The needle tip information is displayed as the gray line which intersects with the target. The chevrons to the left and right of the target move closer together as the needle approaches the given target within the circle, with the grey line having a green color. Once the needle is at the target, the lateral chevrons intersect to form an "X" with the needle shaft remaining green. Once the needle has gone past the plane of the target, the chevrons move away from the central target, with the directionality pointing outwards, and the shaft of the needle becoming a red color, giving a graphical representation to the user that they are past the target, a situation that can lead to procedural complications.

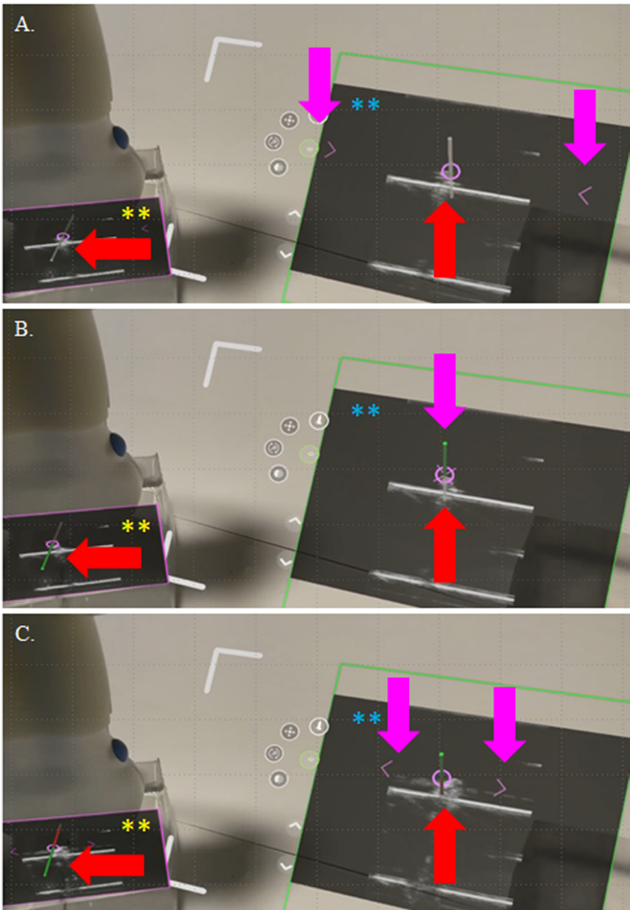

Fig. 9. SentUS **Prototype**. The SentUS prototype imaging a vascular access phantom is shown above. In these images, the ultrasound probe is in the left side of the image with the ultrasound image displayed at the tip of the probe (yellow asterisks). The "billboard" display (blue asterisks) is to the right of the ultrasound probe. In these images, the interface for the needle tracking, or tool tracking, is shown as displayed by the grey line (see red arrow) with the chevrons denoting directionality (purple arrows). (Color figure online)

Given the data from the CARE study and the demonstrable improvement in accuracy, we have designed an early feasibility, pre-clinical study to assess this tool using vascular access phantom models. The hypothesis is that the SentUS system will improve accuracy and efficiency as compared to conventional ultrasound vascular access techniques. To test this hypothesis, users will be asked to obtain vascular access in 2 separate phantoms. Assessing accuracy will involve measuring the distance of the vessel puncture site to the center of the vessel. To assess efficiency, we will measure the time it takes to complete the task (in seconds). Additionally, the number of access attempts (a predictor of complications) will be recorded as well as the number of needle adjustments.

6.3 Mixed Reality-Electrogram (SentEGM) System

After > 100 interactions with end users evaluating CommandEP™, the majority identified EGMs as essential to their procedural practice and requested integration of these data into the MxR display. During formal ĒLVIS human factors (HF) validation, 2/8 physicians reported that their "eyes deviate because I'm looking at my electrograms on a different screen" and 3/8 physicians expressed that displaying EGM data alongside the EAMS in MxR "would be huge." This feedback suggests real-time EGM access during the electrophysiology (EP) study to enable physicians to watch for certain EGM characteristics during the procedure would be of value to the end user.

However, making measurements in MxR will prove to be a difficult hurdle, as these micro movements will be laborious, time-intensive and may cause frustration for the end user. As such, the development of "smart calipers" will supply a first, coarse measurement which can then be micro-adjusted using the gaze-based display and then confirmed—likely using multiple navigation tools as described above. Integration of EGM visualization and interaction will require significant development and novel approaches to allow performing physicians to measure accurately and efficiently, while maintaining sterility. Smart Caliper development will greatly facilitate this effort. Developing an interface to allow physicians to obtain intra-procedural measurements will have applications beyond cardiac electrophysiology, including interventional cardiology and interventional radiology.

7 Regulatory Considerations

Medical applications have additional regulatory considerations that influence interaction and navigation design considerations. Highly predictable interfaces that consider medical use environments and users, which will promote positive patient outcomes and not introduce substantial error or risk that may negatively impact patient outcomes are preferred. Understanding medical extended reality applications has been a recent focus of the US Food and Drug Administration (FDA), and this enhanced understanding will likely result in more regulatory guidance for medical applications. In February 2020, the FDA hosted a public workshop entitled "Mixed Extended Reality: Toward Best Evaluation Practices for Virtual and Augmented Reality in Medicine." The participants in this workshop included hardware developers, medical software developers, scientists and clinicians with an interest in medical VAMR to start openly discussing the difficulties of developing these technologies and how the FDA can partner and regulate to safely bring these novel technologies through the regulatory process. It is anticipated that a white paper from this workshop will soon be published and provide an initial review of the discussion.

8 Future Directions

Currently, each system in the EP lab has its own monitor that displays a fixed data stream regardless of procedure phase. The integration of multiple systems allows the display of data as it is needed in a format that the physician can readily interpret and interact with. Thus, while the physician is measuring EGMs or delivering an ablation, the EGM signals from key electrodes that the physician requires for an effective ablation are displayed. Conversely, while the physician is gaining access, only EGMs from the catheter being placed are shown.

The design of an intuitive and useful interface requires that the most critical data and controls be most easily accessible to the user. However, discerning user preferences and needs is highly challenging. Users struggle to communicate the prioritization of tools or data, because their intuition and interactions are often subconscious. The high-speed eye-tracking from next generation HMDs, will allow evaluation of interaction intent and focus during HF evaluation and system use. This intent data will quantify the time spent viewing different data streams within the device. This information, unique to this platform, will then be fed back into the design process to improve the interface and overall workflow integration.

9 Conclusion

In conclusion, critical understanding of the end user and use case are the primary drivers for development of interactions and navigation tools for medical applications in VAMR. Understanding the type of medical imaging presented to the ended user, the use case and environment and intended use will all impact the interaction and navigation methods deployed. New hardware developments coupled with regulatory considerations will influence future applications to help improve patient outcomes.

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