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ORIGINAL RESEARCH

EMERGING TECHNOLOGIES AND INNOVATIONS

First Experience With Augmented Reality Guidance for Cerebral Embolic Protection During TAVR

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ABSTRACT

BACKGROUND Augmented reality (AR) guidance holds potential to improve transcatheter interventions by enabling visualization of and interaction with patient-specific 3-dimensional virtual content. Positioning of cerebral embolic protection devices (CEP) during transcatheter aortic valve replacement (TAVR) increases patient exposure to radiation and iodinated contrast, and increases procedure time. AR may enhance procedural guidance and facilitate a safer intervention.

OBJECTIVES The purpose of this study was to develop and test a novel AR guidance system with a custom user interface that displays virtual, patient-specific 3-dimensional anatomic models, and assess its intraprocedural impact during CEP placement in TAVR.

METHODS Patients undergoing CEP during TAVR were prospectively enrolled and assigned to either AR guidance or control groups. Primary endpoints were contrast volume used prior to filter placement, times to filter placement, and fluoroscopy time. Postprocedure questionnaires were administered to assess intraprocedural physician experience with AR guidance.

RESULTS A total of 24 patients presenting for TAVR were enrolled in the study (12 with AR guidance and 12 controls). AR guidance eliminated the need for aortic arch angiograms prior to device placement thus reducing contrast volume (0 mL vs 15 mL, $P < 0.0001$). There was no significant difference in the time required for filter placement or fluoroscopy time. Postprocedure questionnaires indicated that AR guidance increased confidence in wiring of the aortic arch and facilitated easier device placement.

CONCLUSIONS We developed a novel AR guidance system that eliminated the need for additional intraprocedural angiograms prior to device placement without any significant difference in time to intervention and offered a subjective improvement in performance of the intervention. (JACC Adv 2024;3:100839) © 2024 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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ABBREVIATIONS AND ACRONYMS

2D = 2-dimensional

3D = 3-dimensional

AR = augmented reality

CEP = cerebral embolic protection

CT = computed tomography

TAVR = transcatheter aortic valve replacement

VR = virtual reality

Virtual reality (VR) and augmented reality (AR) enable users to visualize and interact with virtual 3-dimensional (3D) content in their environment. While VR is immersive and replaces a user's environment with an entirely virtual one, AR augments the environment with 3D virtual content, allowing for simultaneous visualization of natural and virtual content (**Figures 1A and 1B**, respectively). By providing enhanced, 3D visualization of virtual content, recent advances in VR and AR have demonstrated useful applications in medicine including surgical training and simulation, medical education, and rehabilitation.[1-3] Because of its immersive nature, intraoperative use of VR is hindered by the need for physicians to visualize the patient, equipment, personnel, and procedure room. AR, in contrast, integrates virtual content into the real-world environment of the user without obstructing the user's native view and is therefore well-suited for intraoperative use. It is especially powerful for visualization of information that is not readily available in a user's environment but is necessary or helpful for performance of a specific task.

Despite overall improvements in clinical outcomes after transcatheter aortic valve replacement (TAVR) in recent years, periprocedural strokes remain an important clinical focus due to the devastating impact that this complication can have for patients.[4] Cerebral embolic protection (CEP) devices were developed with the goal to reduce periprocedural strokes during TAVR. Although placement of CEP devices is very safe, use of the device has been shown to significantly increase contrast volume, fluoroscopy time, and procedure time when used during TAVR.[5]

We hypothesized that the use of a novel AR guidance system that displays virtual patient-specific 3D anatomical models would facilitate guidance in interventional cardiac procedures. To test this concept, we developed a novel AR guidance system that can be utilized for structural heart procedures or other cardiac interventions and examined the utility of this system in a proof-of-concept study for the placement of CEP devices during TAVR procedures. We predicted that by providing 3D visualization of patient-specific anatomy during procedures, AR guidance would enable device placement without a need for intraprocedural angiography as well as reduce times to filter deployment.

METHODS

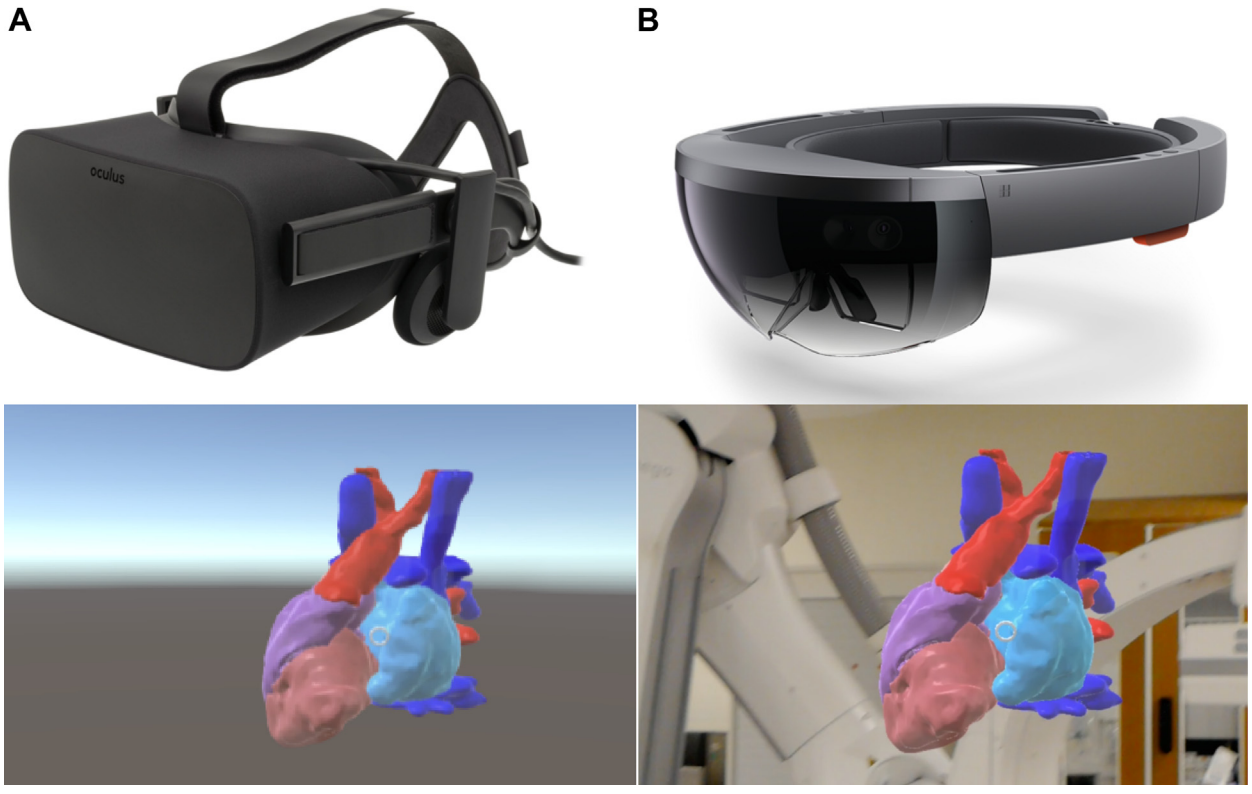
PATIENT POPULATION. Twenty-four patients presenting for TAVR between April and December 2018 were enrolled in the study. The AR cohort (n = 12) were patients with adequate computed tomography (CT) for semiautomated segmentation of the aortic arch. The control group (n = 12) included patients whose CT imaging was incompatible with semiautomated segmentation and would require manual segmentation. Patients from both arms were excluded if bilateral CEP filters could not be placed for anatomic reasons including inability to access the radial artery or to manipulate the Sentinel device due to arterial tortuosity. All patients were followed for clinical events while in the hospital and for 30 days after the procedure.

This prospective, nonrandomized cohort study was approved by the Institutional Review Board of Columbia University Irving Medical Center. All patients provided written informed consent.

3D MODEL GENERATION. Before each procedure, a 3D model of the aortic arch including carotid and subclavian arteries was segmented from the pre-TAVR CT angiography scan with 3mensio software (Pie Medical Imaging). Thoracic vertebrae were included in order to assist in manual correlation and alignment of the 3D model to anatomy seen on 2-dimensional (2D) fluoroscopy, which were able to be hidden once alignment was complete. 3D modeling was semiautomated such that the software provided a template which was manually adjusted to include desired anatomy. Of note, 3D models were generated only from pre-existing CT scans of patients acquired for TAVR planning, and no patient underwent additional imaging as part of the study.

AR SYSTEM. Design of AR guidance system and user interface. The 3D models were imported into the AR guidance system in Unity software (Unity Technologies) and deployed to the Microsoft HoloLens (Microsoft). The HoloLens is a commercially available, stereoscopic, optical see-through AR head-worn display that provides an overlay of virtual content into a user's environment through a transparent display.[6] It weighs 1.28 pounds (**Figures 1B and 2**). Virtual content displayed in the AR system included a patient-specific virtual 3D model of the aortic arch and branching vessels, and a virtual copy of live fluoroscopy (**Figure 3**).

FIGURE 1 Virtual and Augmented Reality



(A) VR technologies are immersive, replacing a user's environment with an entirely virtual one. An example of a VR head-worn display is the Oculus Rift. (B) AR adds virtual content to a user's native environment, creating a mixed real and virtual world view. An example of an AR head-worn display Is the Microsoft HoloLens. AR = augmented reality; VR = virtual reality.

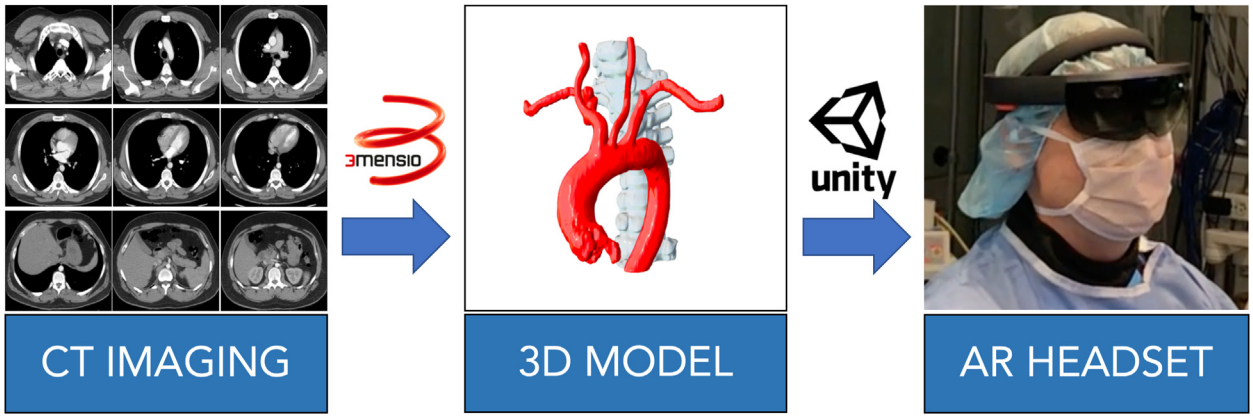
The novel AR user interface was developed using Unity software based on feedback from extensive user testing with physicians.[7] Though voice commands and hand gestures are native to many existing AR headsets including the HoloLens, the novel hands-free interface that uses head movement for interaction with virtual content is unique to the system and enables the physician user to manipulate virtual content without removing hands from instruments or the sterile field (Video 1).

The user interface enables several interaction techniques including translating, rotating, and scaling of virtual content using a combination of voice commands, hand gestures, and head movement (**Figure 4**). Hands-free translation attaches the model to the user's gaze for zero-order control of model position and orientation. Hands-free scaling and rotation use first-order control such that the speed of the interaction is determined by the angular deviation of their head orientation from that at the start of the transformation. A full description of the hands-free interface has previously been reported.[8]

Physician training. Prior to patient enrollment, the operating physician participated in a 30-minute training session to become familiar with the system. This involved detailed practice of each interaction technique alongside system engineers as well as practice in the interventional suite with a phantom model. This was followed by a quick refresher training of about 5 minutes before a case, if needed. The AR system was customized to the physician user to maximize comfort and ease of use, with adjustments including virtual content available in AR, relative positioning of the virtual 3D model and virtual live fluoroscopy, and available voice commands and interaction techniques. The same physician (T.V.) used the AR system in every case.

PROCEDURE. In control patients, an aortic arch angiogram was performed and the Sentinel CEP device (Claret Medicals) which consists of 2 filters

FIGURE 2 Augmented Reality System Components



A 3D model was generated with standard image segmentation software from pre-existing CT scans of patients. The 3D model was then imported into unity software and deployed TO the Microsoft HoloLens for use with the novel user interface. During procedures, a Physician Wore the HoloLens and Was Able to visualize and manipulate virtual content. 3D = 3-dimensional; CT = computed tomography.

was placed in the brachiocephalic and left common carotid arteries, was placed according to standard protocol under typical fluoroscopy guidance. In the AR group, the operating physician wore a HoloLens on which the AR system, including the 3D model of the patient-specific anatomy, was deployed. After preferred placement of virtual content within the procedure room, the physician placed the Sentinel CEP device. During filter placement, the operating physician was able to visualize and manipulate virtual content in addition to viewing standard fluoroscopy monitors to enable device placement (Figure 3).

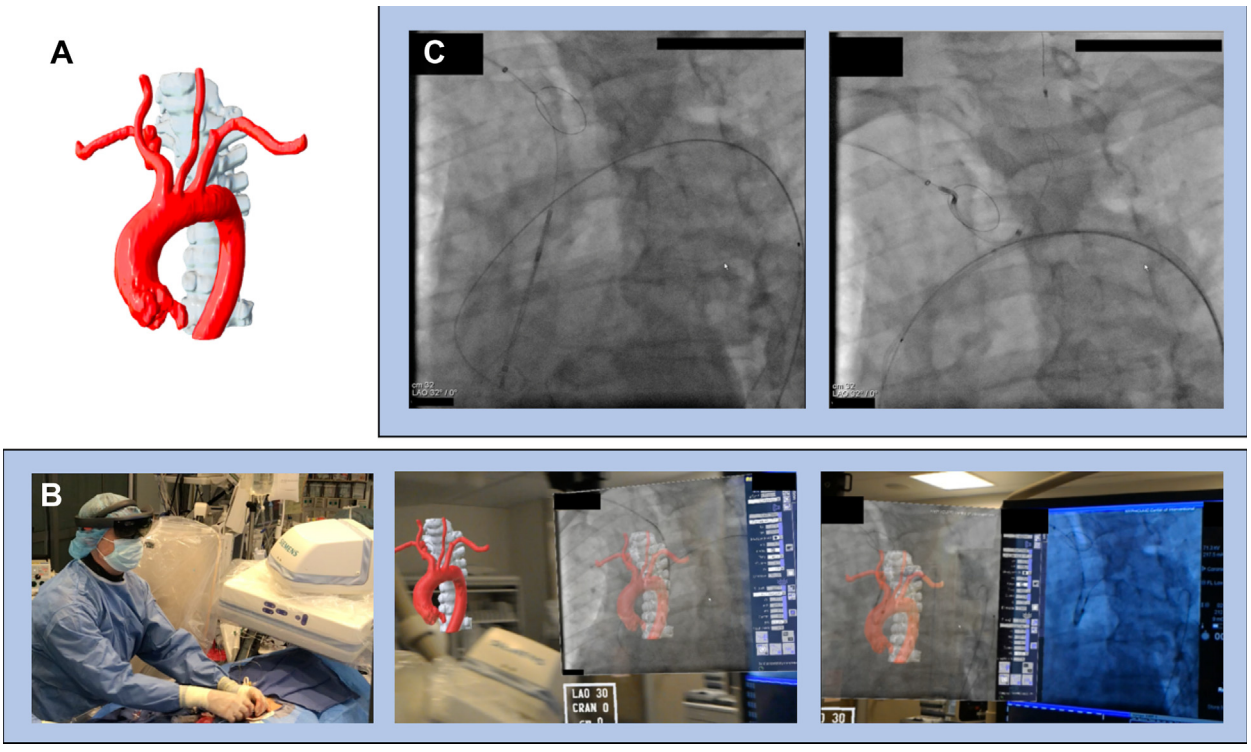
DATA COLLECTION AND OUTCOMES. Primary outcomes were iodinated contrast volume used to obtain angiograms prior to filter deployment, times to first and second CEP filter placement, and total fluoroscopy time during device placement. Additional outcomes included total iodinated contrast volume used during the procedure, creatinine at discharge, strokes at 30-day follow-up, and death from any cause at 30-day follow-up. A postprocedure questionnaire was administered after each procedure performed with AR to assess physician experience with the AR guidance system.

Full recordings of live fluoroscopy were obtained for each procedure. Once the physician had adjusted the fluoroscopy arm to the required rotation and scale, an angiogram of the aortic arch was performed when necessary to help guide filter placement, and contrast volume used was recorded. Time to first filter placement was measured from first visualization of the catheter in the right subclavian artery within the fluoroscopic image to full deployment of the filter in the brachiocephalic artery. Time to second filter placement was measured from time at which the catheter began advancing in the brachiocephalic artery to full deployment of the second filter in the left common carotid artery. Total fluoroscopy time was recorded including time of any active fluoroscopic image acquisition during device placement. Of note, the time required to obtain an angiogram in the control group was excluded from outcome measurements.

A postprocedure questionnaire including numerical and 5-point Likert scales and free-text responses was administered to the operating physician after each procedure to assess physician experience with AR guidance. The questionnaire included assessment of difficulty of arch anatomy and ease of vessel access, quality and ergonomics of the AR display, quality of virtual content, impact of the system on workflow, and system utility in comparison with standard 2D fluoroscopy (Supplemental Material).

STATISTICAL ANALYSIS. Continuous variables are presented as median (IQR) and compared using the Wilcoxon rank sum test, and categorical variables are reported as percentages and compared with the Fisher exact test. Statistical significance was defined using a 2-sided P value <0.05. Statistical analyses were performed using R 3.4.1 (R Foundation for Statistical Computing).

FIGURE 3 Intraprocedural View of AR Guidance System in Use



A Physician User Wore the Microsoft HoloLens and was able to visualize and manipulate a virtual 3D model of the patient's aortic arch and a virtual copy of live fluoroscopy in augmented reality while placing cep filters under fluoroscopy (A, B). AR facilitated safe and successful placement of both filters in 12 patients (C). 3D = 3-dimensional; AR = augmented Reality; CEP = cerebral embolic protection.

RESULTS

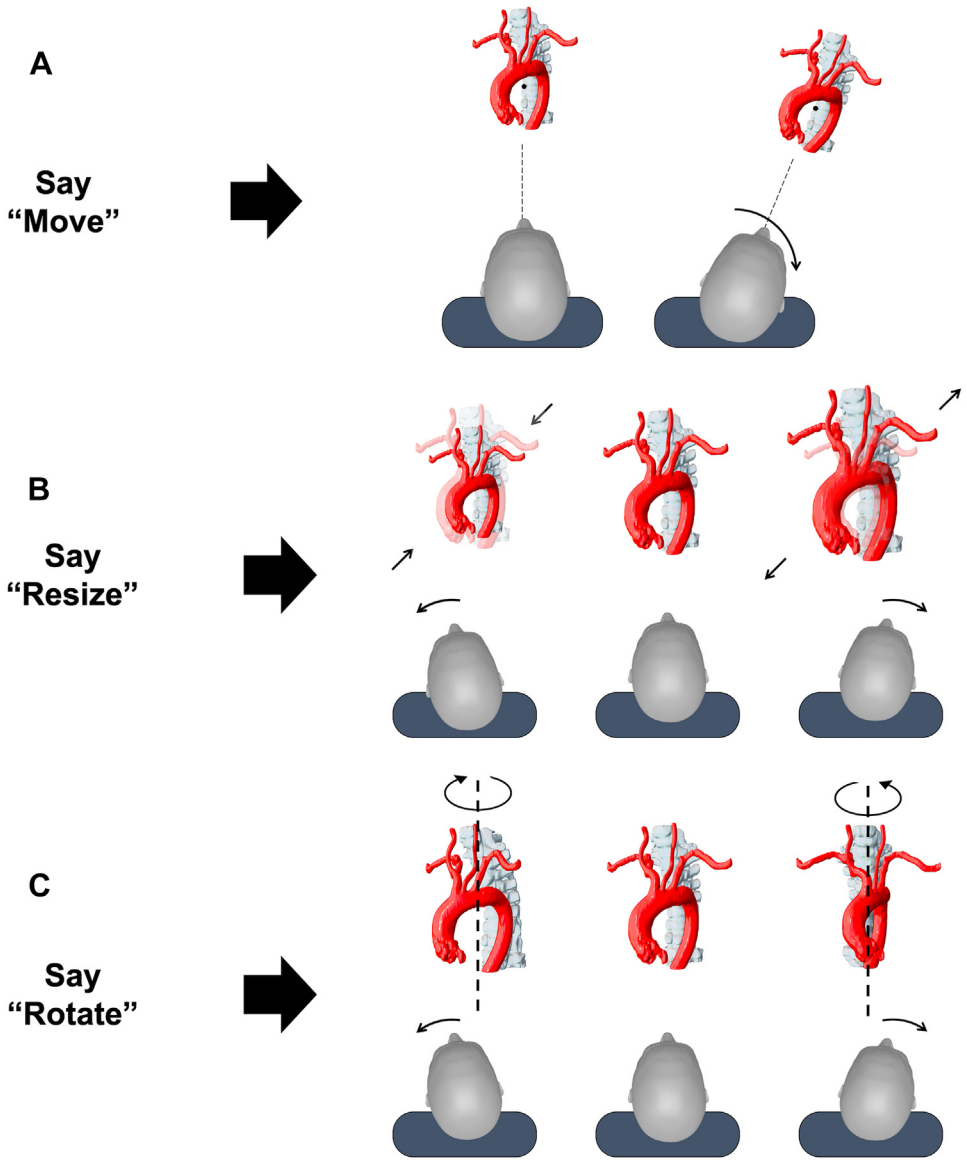
PATIENT CHARACTERISTICS. Patient baseline characteristics are presented in Table 1. Overall, the patients in both groups were very similar. The median baseline creatinine was similar between the 2 groups (AR group: 1.0 mg/dL [IQR: 0.8-1.2 mg/dL], control group: 1.1 mg/dL [IQR: 0.9-2.4 mg/dL], $P = 0.22$).

SAFETY AND CLINICAL ENDPOINTS. In all 12 patients in the AR guidance group, AR facilitated safe and successful placement of CEP filters without the need to obtain aortic arch angiograms, thus significantly reducing contrast volume used during device deployment as compared with controls (AR group: 0 mL, control group: 15 mL, $P < 0.0001$) (Table 2, Video 2). This also led to a significant reduction in total contrast volume used throughout the entire procedure (AR group: 55 mL [IQR: 47.5-60 mL], control group: 77.5 mL [IQR: 61.5-93.8 mL], $P = 0.02$). There was no significant change in creatinine at discharge from preprocedure baseline levels in either group (AR group: 0.0 mg/dL [IQR: −0.08 to 0.1 mg/dL], control group: 0.03 mg/dL [IQR: −0.1 to 0.2 mg/dL], $P = 0.98$).

Times to first and second filter placement with AR guidance were 33 s (IQR: 20-55 s) and 138 s (IQR: 76-183 s), respectively, which were similar to control times, 28 s (IQR: 23-31 s) ($P = 0.67$) and 71 s (IQR: 52-114 s) ($P = 0.32$). Total fluoroscopy time during device placement was similar between both groups (AR group: 169 s [IQR: 112-252 s], control group: 94 s [IQR: 81-143 s], $P = 0.27$) (Table 2). CEP filters were placed and retrieved safely and without problems in all patients, and there were no clinical adverse events related to the use of the AR system. There were no strokes or deaths from any cause at 30 days in either group. One patient in the control group had a transient ischemic attack 1 day after undergoing TAVR without evidence of ischemia or infarct on head CT.

SUBJECTIVE ASSESSMENT. On postprocedure questionnaires, median complexity of aortic arch anatomy

FIGURE 4 Novel Hands-Free User Interface



With a combination of voice commands and head motion, a physician user can manipulate virtual 3D models in AR during the procedure without the need to remove his or her hands from the instruments and sterile field. Available interactions include translating, scaling, and rotating virtual content. Hands-free translation (A) uses zero-order control of model position and orientation based on the user's head movement. Hands-free scaling (B) and rotation (C) use first-order control in which the user controls the speed based on the angular deviation of their head orientation from that at the start of the transformation. While hands-free rotation (C) is shown here about a vertical axis, the axis of rotation is determined by the direction in which the user's head moves. 3D = 3-dimensional; AR = augmented reality.

was 6.0 (1 = least complex, 9 = most complex), median ease of navigation was 7.5 (1 = least challenging, 9 = most challenging), and median ease of vessel access was 7.5 (1 = least challenging, 9 = most challenging) in the AR group. 100% of responses indicated that the use of AR guidance did not interfere with safety of the procedure. AR guidance further helped perform the procedure more easily, and it increased confidence in wiring the aortic arch. 92% indicated that with AR guidance, the physician was able to rotate the C-arm less frequently to obtain different views and understand the patient's anatomy. This

was echoed in free-text responses which demonstrated that physician users were able to adjust the fluoroscopy arm to a specific, relevant view based on their understanding of the anatomy from the virtual 3D model. 83% of responses indicated that the AR display and 2D fluoroscopy was superior to using fluoroscopy alone, and 67% indicated that a virtual 3D model to view and manipulate in AR was more useful than an image of a 3D model on a 2D screen. 100% of responses indicated that the display was comfortable for the duration of the procedure. A summary of responses is shown in Figure 5.

SYSTEM PERFORMANCE. Regarding setup and performance of the software, on average, about 60 minutes was required to create the 3D models from CT, which depended on complexity of arch anatomy and performance of the semiautomated segmentation. Another 20 minutes was required to import the 3D models into the AR system, and about 15 minutes of system setup required on the day of the procedure. No manual 3D/2D calibration was required on the day of the procedure. Latency of live fluoroscopy vs virtual fluoroscopy was about 450 ms, limited by hardware used to obtain live fluoroscopy data from the fluoroscopy machine.

DISCUSSION

In this prospective study, we developed a novel AR guidance system that allows physician users to see and manipulate virtual 3D models of patient anatomy and virtual live fluoroscopy intraprocedurally and demonstrated the safety, feasibility, and clinical efficacy of the AR system in facilitating placement of CEP devices during TAVR procedures. The novel user interface, which includes hands-free interaction methods, was designed and developed based on physician feedback and was customized prior to the start of the study to meet the specific needs of the operating physician. In 12 patients treated by one operator, AR guidance facilitated safe CEP filter placement without the need to obtain aortic arch angiograms, significantly reducing contrast volume use prior to filter placement and total procedure contrast volume with no significant difference in times to filter placement or fluoroscopy time. On subjective assessment, AR was helpful in giving the operators the ability to view the anatomy they were navigating in 3 dimensions and examine it from different directions, as opposed to the standard 2D view provided by fluoroscopy. The AR system did not interfere with safety of the procedure and increased confidence in wiring of the aortic arch vessels.

TABLE 1 Demographic Data Comparison Between AR Guidance and Control Groups

	AR Guidance (n = 12)	Control (n = 12)	*P* Value
Age (y)	84 (79-87)	75 (73-85)	0.40
Female	5 (42)	8 (67)	0.41
Body mass index (kg/m^2)	24.2 (21.2-27.3)	29.9 (25.0-33.4)	0.03[a]
STS PROM score	4.7 (3.7-6.6)	5.0 (2.6-8.9)	1.00
Baseline creatinine (mg/dL)	1.0 (0.8-1.2)	1.1 (0.9-2.4)	0.22
CKD stage III or higher	5 (42)	9 (75)	0.21
NYHA functional class III/IV	7 (58)	6 (50)	1.00
Previous stroke	0	0	1.00
Hypertension	10 (83)	10 (83)	1.00
Diabetes mellitus	4 (33)	5 (42)	1.00
Atrial fibrillation	2 (17)	3 (25)	1.00

Values are median (IQR) or n (%). [a]*P* value is significant at $P < 0.05$.
AR = augmented reality; CKD = chronic kidney disease; STS PROM = Society of Thoracic Surgery predicted risk of mortality.

To our knowledge, this is the first study to demonstrate successful use of intraprocedural AR guidance with a head-worn display during cardiac transcatheter interventions. Previous animal studies have demonstrated feasibility of the use of the HoloLens during cardiac interventions, and others have shown its use while watching live cardiac interventions from outside the procedure room.[9,10] This rise in the development of new AR systems for use in cardiac interventions demonstrates an interest in harnessing this technology to enhance these procedures.[11]

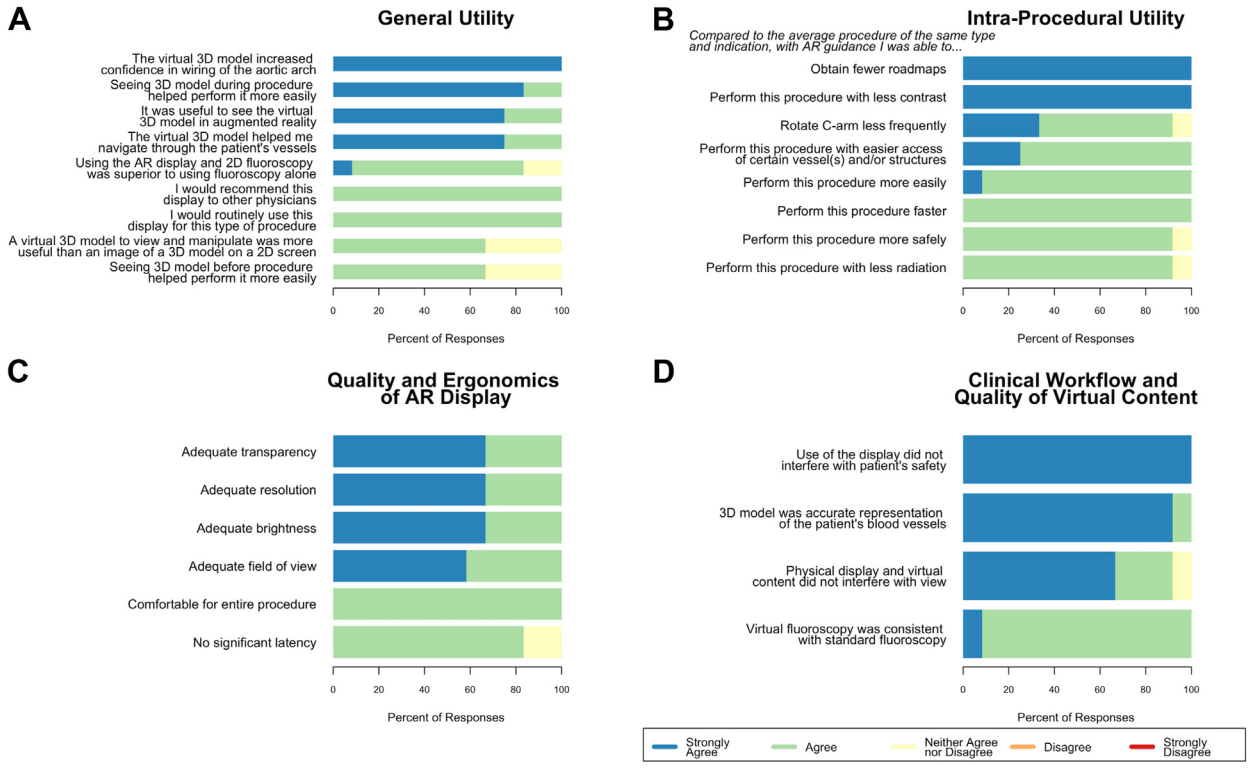
CLINICAL IMPACT OF AR. Inadequate visualization with 2D fluoroscopy during cardiac interventions can result in increased contrast volume, procedure time, and radiation dose. Contrast-induced nephropathy

TABLE 2 Outcome Comparison Between AR Guidance and Control Groups

	AR Guidance (n = 12)	Control (n = 12)	*P* Value
Contrast volume for arch angiogram (mL)	0	15 (15-15)	<0.0001[a]
Total procedure contrast volume (mL)	55 (47.5-60)	77.5 (61.5-93.8)	0.02[a]
Time to first filter placement (s)	33 (20-55)	28 (23-31)	0.67
Time to second filter placement (s)	138 (76-183)	71 (52-114)	0.32
Total fluoroscopy time (s)	169 (112-252)	94 (81-143)	0.27
Creatinine at discharge (mg/dL)	1.0 (0.8-1.2)	1.2 (0.9-2.5)	0.38
Change in creatinine, preprocedure to discharge (mg/dL)	0.0 (−0.08 to 0.1)	0.03 (−0.1 to 0.2)	0.98
TIA at 30-day follow-up	0	1 (8.3)	1.00
Stroke at 30-day follow-up	0	0	1.00
Death from any cause at 30-day follow-up	0	0	1.00

Values are median (IQR) or n (%). [a]*P* value is significant at $P < 0.05$.
AR = augmented reality; TIA = transient ischemic attack.

FIGURE 5 Physician Responses to Postprocedure Questionnaire



A questionnaire assessing the AR guidance system was administered to the physician user after each procedure. Aspects of the system evaluated on the questionnaire included its general (A) and intra-procedural (B) utility, quality and ergonomics of the display (C), quality of virtual content, and impact on clinical workflow (D). AR = augmented reality.

has been demonstrated to convey significant morbidity and mortality and is a common cause of iatrogenic acute renal failure.[12,13] Interventionalists must therefore carefully balance adequate visualization of anatomy using angiography and contrast-induced nephropathy risk reduction, with previously reported acceptable upper limits of contrast volume of 30 mL for diagnostic catheterization and 100 mL for percutaneous coronary interventions in patients with chronic kidney disease stage III or higher.[13] AR guidance enabled safe navigation of wires and catheters through a patient's vasculature without the use of additional contrast, demonstrating potential to reduce contrast-related complications.

Risks of excess radiation exposure in fluoroscopy-guided interventions have been well described for both patients and operating interventionalists.[14] Fluoroscopy time during device placement was similar between groups and comparable to previously reported values of fluoroscopy time for Sentinel filter placement.[5] On subjective assessment, the physician user felt less of a need to acquire fluoroscopic images while placing the device, indicating a subjective increase in confidence performing the intervention with AR guidance.

While times to filter placement were slightly higher in the AR group, these differences were nonsignificant. Some of the differences may have been related to the operator learning curve and are therefore not surprising in this first clinical experience with AR. Even with optimal image guidance, it may be more challenging to wire arteries in some patients for anatomical reasons. Of note, we did not attempt to match patients based on anatomy prior to the procedure. Future studies including larger sample sizes and more complex interventions may more directly highlight the utility of AR in reducing procedure time associated with procedural navigation. Furthermore, because practicing interventionalists are most familiar with angiography for procedural guidance, introduction of a novel technology such as AR naturally presents an expected period of adjustment. As

AR becomes more ubiquitous in fluoroscopy-guided interventions, its benefits may become more evident. This is especially true for physicians still at the training level, in whom AR guidance may play a more direct role in development of their procedural techniques in the future.

The utilization of AR guidance for cerebral embolic protection in this study is just an example to highlight the potential of this technology. Of course, there are a number of potential uses that allow the interventionalist to bring prior imaging information directly to the procedure and review it or use it during the procedure rather than attempting to commit those images to memory. For instance, in TAVR, the aortic cusps can be displayed from multiple angles to mimic fluoroscopic views like the cusp overlap to guide implantation depth and reduce pacemaker rates. Also, for left atrial appendage closure, the anatomy could be visualized from multiple views guiding the optimal implantation of the closure device.

FUTURE INTRAPROCEDURAL AR SYSTEMS. Percutaneous interventions are replacing procedures previously only able to be performed through open surgery at a rapid and accelerating pace. The future of this development depends on major advances in imaging capabilities, which can be facilitated by technologies such as AR. One of the most promising aspects of AR is its ability to integrate customizable clinical content with great flexibility and transfer it seamlessly into the procedure room. In this study, we demonstrated the ability to display a virtual 3D model and a virtual copy of live fluoroscopy in the AR system. While the virtual 3D model eliminated the need for aortic arch angiography, the virtual copy of live fluoroscopy challenges our understanding of physical equipment necessary in an interventional suite. The demonstration of virtual live fluoroscopy shows that costly fluoroscopy monitors may not even be necessary in the future, presenting a significant opportunity to make interventional suites more cost-effective and ergonomic.

Content that is able to be displayed in AR ranges from any 3D data to anything that can be displayed on a standard computer display (**Central Illustration**). Future intraprocedural AR systems may begin to include other forms of live and pre-existing patient data, for example, full Digital Imaging and Communications in Medicine (DICOM) viewers, electronic patient records, and live virtual catheters updated in real time. AR may also open up new opportunities for advanced fusion imaging that will fully make use of the vast amount of preprocedural imaging available, including CT and magnetic resonance imaging (MRI). This enhanced procedural guidance facilitated by AR will expand the range and complexity of percutaneous interventions able to be performed.

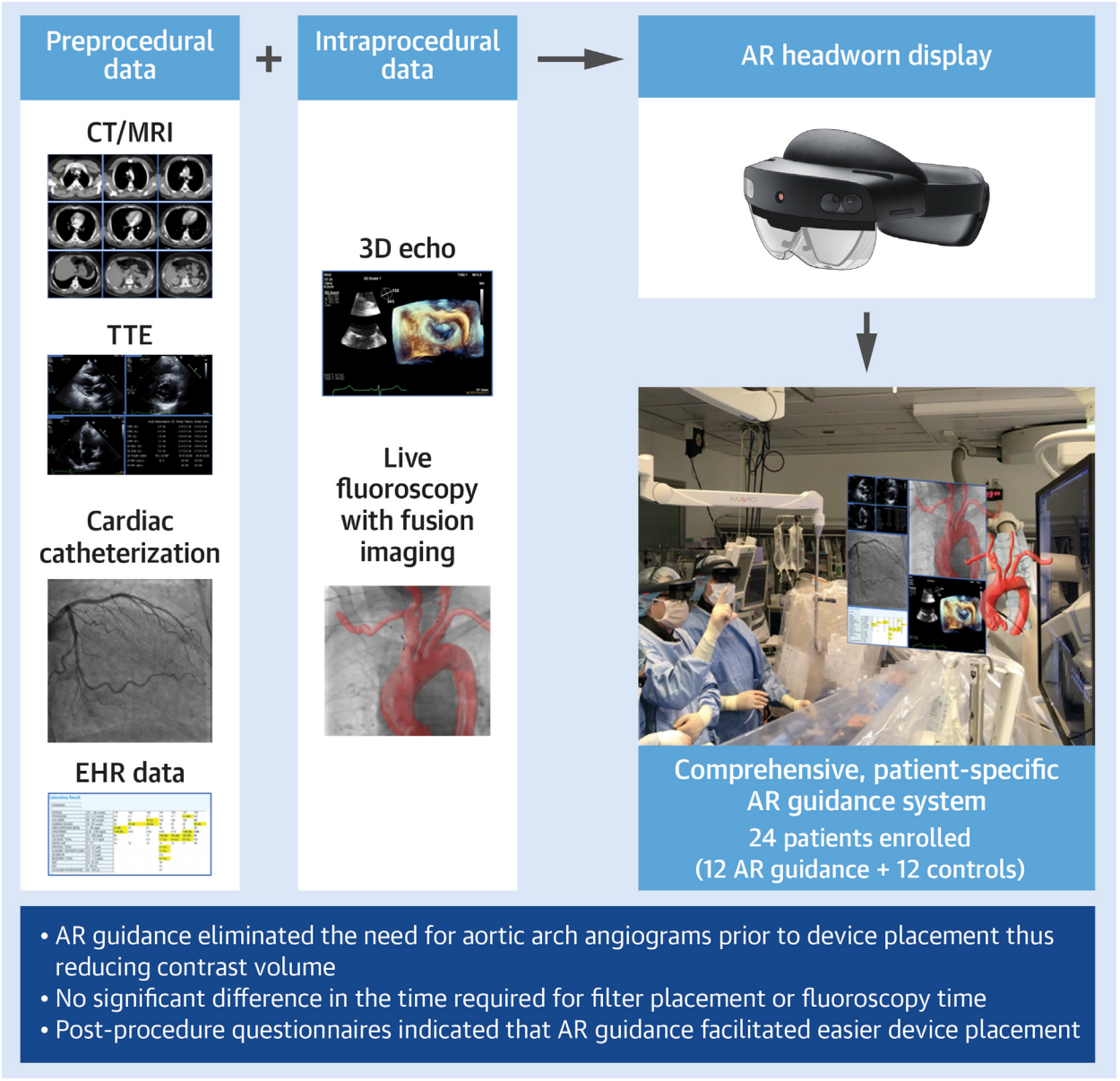
Recent technological advances in AR hardware further increase its potential for clinical use, including expansion of the stereoscopic field of view and improvement in resolution of virtual content.[6] Furthermore, improvements in 3D user interface design have been made that allow users to move, resize, rotate, and otherwise manipulate virtual content with a combination of voice commands, head movement, eye gaze, and hand gestures all while maintaining sterility.[15-18] This flexibility renders a personalized experience for each user and ensures that AR can be integrated into the physician workflow with ease.

The integration of AR systems such as the one described here will undoubtedly be influenced by cost of both capital equipment and personnel time. Commercially available AR headsets today cost a few thousand dollars. This system also requires personnel with 3D modeling experience and on-site support personnel to help with deployment during a procedure. Future studies including cost-benefit analyses of AR in the interventional suite are needed to determine whether the potential value added offsets the cost of integration of AR.

While this first proof-of-concept study focused on placement of CEP devices during TAVR due to volume and standardization of these procedures and availability of 3D imaging for all patients, we anticipate that further integration of AR guidance into additional components of the TAVR procedure and other cardiac interventions would reveal an even greater benefit due to improved visualization of patient anatomy and enhanced procedural guidance. Intellectual investment in the form of scientific and clinical research in the near future will be necessary in order to realize AR's full potential for procedural guidance, not only in cardiac interventions but in any fluoroscopy-guided intervention.

STUDY LIMITATIONS. Our study is a single-center, observational study with a small sample size, which raises questions of generalizability. The semi-automated segmentation method used to generate 3D models in the AR guidance group requires a CT scan with iodinated contrast for the software to distinguish the aortic arch from surrounding tissues. Thus, it was not possible to include patients with non-contrast CT scans in the AR group using the semi-automated segmentation method in this study. With continued technological development in automated

CENTRAL ILLUSTRATION **Augmented Reality Guidance System for Cardiac Interventions**



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The novel AR guidance system enables visualization and manipulation of patient-specific virtual 3D content during a cardiac intervention while maintaining sterility. Available virtual content is customizable to the physician user and may include preprocedural data such as CT, TTE, and EHR data and intraprocedural data such as live fluoroscopy and 3D echocardiography. Virtual 3D content is deployed onto an AR head-worn display for intraprocedural use by a physician user. the novel, customizable 3D user interface, developed with extensive physician feedback, enables hands-free manipulation of virtual content while maintaining sterility. 3D = 3-dimensional; AR = augmented reality; CT = computed tomography; EHR = electronic health record; TTE = transthoracic echocardiography.

and semiautomated image segmentation software, the AR system will become more compatible for use in a broader patient population.[19] Despite demonstrating a significant difference in the primary outcome of contrast volume, the sample size was small and the study was not randomized. Patients in AR and control groups were not matched for baseline characteristics or differences in aortic arch anatomy.

In this study, a single operator was used to test the AR system and the data collected from the questionnaires reflect the experience of a single user. Future larger studies that are randomized will be required to further investigate the effect of AR guidance on other aspects of interventional procedures and outcome measures. Future studies will require evaluation of this technology with a broader range of operators and settings. Furthermore, future studies should include comparisons between AR and plain image CT in order to further explore the impact of a true 3D view that AR provides. Nevertheless, this study provides important insights into the feasibility of AR guidance during cardiac interventions.

CONCLUSIONS

In this study, we developed an AR guidance system with a novel user interface that facilitates hands-free interaction. We demonstrated that AR guidance enabled safe and successful placement of CEP filters without the need for angiography in TAVR procedures. This early feasibility study supports our belief that by providing customizable visualization and user-friendly manipulation of virtual content, AR holds potential to not only enhance current procedures but also facilitate advances in the type and complexity of fluoroscopy-guided interventions in the future.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: Augmented reality guidance can safely facilitate CEP device placement while reducing the need for angiography during TAVR.

TRANSLATIONAL OUTLOOK: Image guidance technologies such as augmented reality have potential to improve cardiac interventions. While this study demonstrates feasibility in procedural guidance during TAVR, future development and clinical testing will further elucidate its intraprocedural impact in a wider range of transcatheter interventions.

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KEY WORDS **augmented reality, image guidance, mixed reality, TAVR, virtual reality**

APPENDIX **For supplemental material and videos, please see the online version of this paper.**