the possibility of worsening distal conduction either as a result of complete transection of the HB or from progression of conduction system disease.

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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 *JACC: Clinical Electrophysiology* author instructions page.

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RESEARCH CORRESPONDENCE

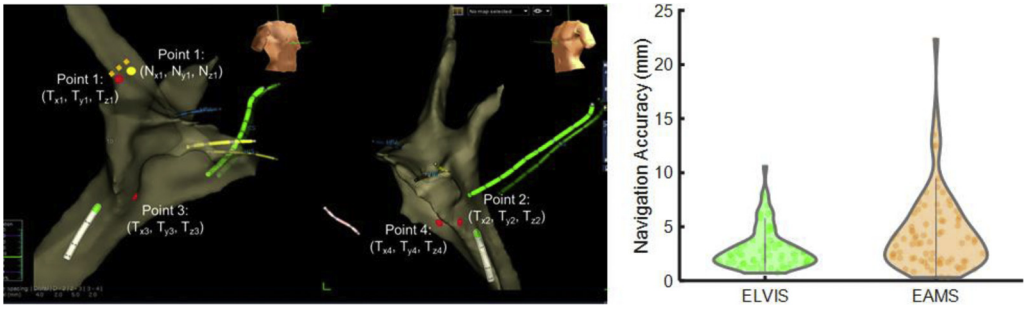
First-In-Human Use of a Mixed Reality Display During Cardiac Ablation Procedures

Extended reality health care applications are becoming increasingly affordable, less complex to implement, and more performant, resulting in the rapid expansion of applications in cardiology for patient and medical student education, patient rehabilitation, and real-time intraprocedural use (1). We describe the first-in-human prospective use of the Enhanced ELectrophysiology Visualization and Interaction System (ĒLVIS) implemented in an electrophysiology (EP) laboratory, providing the electrophysiologist with a real-time intraprocedural 3-dimensional (3D) digital images of the patient's electroanatomic maps, along with real-time catheter locations (Video 1).

The ĒLVIS system combines the HoloLens headset (Microsoft, Redmond, Washington) with proprietary SentEP software (SentiAR, St. Louis, Missouri) to display images from an electroanatomic mapping system (EAMS, EnSite Velocity, St. Jude Medical, St. Paul, Minnesota) (2). We hypothesized that providing the physician with these real-time 3D data would improve point navigation and accuracy.

To assess and quantify point navigation and accuracy, a protocol was designed in which physicians were asked to carry out a series of navigation tasks during the post-ablation waiting phase of the EP study (EPS) under 2 conditions: using ĒLVIS and using current standard of care. The study coordinator randomized the order of the conditions through a blinded envelope. Physicians were permitted to use the ĒLVIS system throughout the procedure. During the post-ablation waiting phase, after generating a geometry of a cardiac chamber chosen by the physician (5-min allotment per condition for geometry creation), 5 target markers were placed within the geometry using the EAMS. The sequence of navigation and anatomic location of the targets were ordered so that the physician had to move to disparate locations in the anatomy, rather than making small movements. Physicians were then asked to navigate to the markers sequentially under both conditions (60-second allotment per marker, per condition), resulting in matched data sets for analysis. The physicians alone determined when they were at the optimal navigation site, and a marker was placed at that site in the EAMS (Video 2). If physicians were not able to navigate to and mark the target within the time frame under either condition, the result was noted, and the point pair was excluded from the analysis. The navigated location x, y, z coordinates were then compared with the target x, y, z ground truth coordinates, as measured and recorded by the EAMS. A blinded reviewer calculated the Euclidean distance, a straight line, between the coordinates to determine the accuracy of the SentEP system.

FIGURE 1 Navigation Accuracy



(Left) During a first-in-human clinical study, physicians were asked to navigate to 5 points during the waiting phase of an ablation procedure. The error between the target Point 1 (T_{x1}, T_{y1}, T_{z1}) and the marked catheter location Point 1 (N_{x1}, N_{y1}, N_{z1}), is indicated by the **dotted orange line**. **(Right)** Physicians using the ĒLVIS system were significantly more accurate, 2.99 ± 1.91 mm **(green)** versus standard of care (EAMS) 4.50 ± 3.74 mm **(orange)**, $p < 0.005$, Wilcoxon signed-rank test.

A 20-min training session was completed by the operating EPs before first case enrollment.

After obtaining approval from the Western Institutional Review Board, patients age 6 to 21 years who were scheduled for EPS were identified and screened by the study team, and informed consent and assent were obtained. Two board-certified EPs (operator 1, n = 7; operator 2, n = 9) completed a total 16 cases that finished the protocol with the following diagnoses: atrioventricular nodal reentrant tachycardia n = 7, accessory pathway mediated tachycardia n = 7, premature ventricular contractions n = 2. There was no noted difference in navigation times point navigation (ĒLVIS 31 ± 14 s vs. EAMS 28 ± 15 s, p = 0.174). From these 16 patients, a total of 75 paired points (150 total points) were available for analysis. Five paired points (10 total points) were discarded for violation of the 60-second time limit. Wilcoxon signed-rank testing demonstrated a significant accuracy improvement with ĒLVIS, with an error of 2.99 ± 1.91 mm versus 4.50 ± 3.74 mm ($p < 0.005$) (**Figure 1**).

These data were the first to demonstrate that point navigation accuracy is significantly improved with a mixed reality display. Our study showed that improved visualization of existing information could amplify physician skill. This improvement in accuracy is likely to have clinical impact, as ablation lesions typically have a diameter of 6 mm (3). Without the use of the ĒLVIS 3D display, a significant fraction of lesions (34%) would be delivered outside the target area, as opposed to 6% with ĒLVIS 3D display. For anatomic ablations, such as pulmonary vein isolation for the treatment of atrial fibrillation (4), we expect that this improved lesion delivery will improve patient outcomes and potentially reduce the need for repeat procedures.

This enabling technology will provide a more intuitive visualization of currently displayed 2D images in a 3D stereoscopic display. The ability to place and remove dynamic 3D digital objects conveniently will provide further enhanced access to and control of information within the clinical space. Future potential improvements—including additional modes of sterile interaction, access to cloud computing resources, and remote consultation—may amplify physician control and skill and ultimately lead to improved patient access to care. Given the widespread promise of this technology, mixed reality has the potential to overtake and aggregate current displays in the cardiac catheterization laboratory.

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

TO THE EDITOR

Diabetic Cardiomyopathy Patients Are More Complex and Require a Nuanced Approach

We were interested to read the paper by Medhekar et al. (1) in which they investigated mortality rates in patients with a left ventricular ejection fraction (LVEF) ≤50% and comorbid diabetes mellitus (DM). Over a median follow-up of 3.35 years, 8,037 (45%) of their patients with LVEF of 36% to 50% had died, with DM as an independent predictor of all-cause mortality (adjusted hazard ratio [HR]: 1.25; $p < 0.001$). Interestingly, patients with DM and LVEF of 36% to 50% had increased mortality rates compared with patients with severe cardiomyopathy (LVEF ≤35%) but without DM. The authors suggest expanding indications for implantable cardiac defibrillators (ICDs) to those with comorbid LVEF of 36% to 50% and DM to reduce mortality rates (1).

It is undeniable that DM increases the incidence of diastolic dysfunction with rates of 50% observed in those older than 65 years of age (2). Nishi et al. (3) performed stress echocardiograms on 161 patients with DM to ascertain rates of subclinical heart failure and demonstrated increased rates of diastolic dysfunction at stress compared with rest (57% vs. 45%, respectively). The study by Medhekar et al. (1) only acknowledges systolic dysfunction, therefore, a significant confounding factor driving their worse outcomes is likely to be undiagnosed diastolic dysfunction.

The CHAMP-HF (Change the Management of Patients with Heart Failure) observational registry reviewed 4,970 patients across 152 U.S. sites and confirmed comorbid LVEF <40% and DM incurred increased hospitalization (adjusted HR: 1.35; range: 1.21 to 1.52; $p < 0.001$) and higher all-cause mortality (HR: 1.38; range: 1.16 to 1.65; $p < 0.001$) compared with patients without diabetes. Similar to Medheker et al. (1), they also noted low rates of optimal medical therapy at 27%, which represents a key area for improvement (4).

Zabel et al. (5) reviewed 2,327 patients with cardiomyopathy who met guidelines for prophylactic ICD insertion and noted no survival benefit in the DM subgroup (adjusted HR: 0.945; $p = 0.7797$). A meta-analysis of 3,345 patients also confirmed this finding (6). Therefore, generalized interventions in the DM cohort, such as ICD implantation as proposed by Medhekar et al. (1), may not confer the benefits the authors expect.

Although comorbid cardiomyopathy and DM incur a greater mortality, this is clearly more complex than their nondiabetic counterparts and a more nuanced approach than that proposed by Medhekar et al. (1) is required. We agree that robust randomized control trial data is essential prior to change in clinical practice.

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