First- in- Human Experience with Real-Time 4D Holographic Therapy Guidance as an Intraprocedural Tool for Left Atrial Appendage Occlusion

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Introduction:

Standard of care for left atrial appendage occlusion (LAAO) with the Watchman™ FLX (Boston Scientific, Marlborough, MA) relies on 2D imaging modalities such as fluoroscopy and echocardiography. These imaging modalities have limitations in accurately depicting the spatial relationships of devices, complex cardiac anatomy, and the final implant deployment. EchoPixel (EchoPixel, Inc., Santa Clara, CA) Holographic Therapy Guidance (4D EP-HTG) is a novel imaging tool that attempts to resolve these limitations by providing interactive and real-time 4D holographic images of cardiac anatomy and devices. Here we present the early experience of the first 18 patients treated with 4D EP-HTG for intraprocedural guidance of Watchman™ FLX implants.

Methods:

We conducted an observational, prospective, early feasibility single-center study. 18 patients with atrial fibrillation and deemed eligible, underwent LAAO with Watchman™ FLX utilizing 4D EP-HTG in addition to standard of care imaging. The 4D Transespohageal echocardiography (TEE) images were acquired by a Vivid E95 Cardiac Ultrasound (General Electric Company, Boston, MA) and were streamed to the 4D EP-HTG system and displayed during each procedure in real-time. 4D EP-HTG was the primary imaging modality used in multiple steps of the procedure including transeptal crossing, advancement of catheters into the left atrial appendage (LAA), device deployment, device interrogation, and device release. Baseline patient characteristics, procedural details, and procedural outcomes were recorded and analyzed.

Results:

Baseline characteristics of patients include a mean patient age of 73 $\pm$ 6.0 years, 11 of 18 were male, average BMI was 32.9 $\pm$ 6.4, and average CHADS-Vasc score was 4.1 $\pm$ 1.3. All 18 procedures were successful without any intraprocedural adverse events. The average duration time of the procedure was 32.9 $\pm$ 10.6 minutes, with an average contrast volume of 44 $\pm$ 22.8 mL, and an average radiation dose of 465 $\pm$ 461 mGy. 15 of the 18 study participants were administered conscious sedation and 3 received general anesthesia. At the time of abstract submission date, 8 of the 18 study participants had completed a 45-day follow-up which demonstrated the LAA was successfully sealed for all 8 subjects.

Counclusions:

In this early first-in-human experience, 4D EP-HTG demonstrated technical success and was used safely to image and interact with intracardiac structures to guide Watchman™ FLX implants. The 4D EP-HTG system was used throughout the procedure to guide key steps including transeptal crossing, LAA access, device deployment, and the final assessment of the

device prior to- and post-release. In conclusion, 4D EP-HTG imaging can be used safely in LAAO and provides enhanced, real-time, 4D holographic imaging of cardiac structures and devices, which may ultimately improve outcomes in structural heart interventions.