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IMAGES IN CV APPLICATIONS

Multimodal imaging of a self-expanding transcatheter aortic valve replacement (TAVR) procedure in a reanimated human heart and post-implant analyses

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Discussion

Transcatheter aortic valve replacement (TAVR) has become the standard of care for severe aortic stenosis patients considered as a high risk of mortality for conventional surgery. With multiple companies proposing different technologies designed to treat the disease percutaneously, the opportunity to directly visualize the TAVR procedure provides critical insights. Here we present novel visualization of the positioning, recapture, and final deployment of a CoreValve Evolut™ R (Medtronic, Minneapolis, MN, USA) within an isolated functioning human heart deemed nonviable for transplantation and reanimated using Visible Heart® methodologies [1, 2]. The TAVR case procedure was simultaneously recorded using videoscopes, fluoroscopy, and echocardiography (Online Resource 1).

The organ donor was a 50-year-old female with a cardiac history of atherosclerosis and symptoms of early stage aortic stenosis. Within 8 h of aortic cross-clamp and procurement, the heart was cannulated on the Visible Heart® apparatus and reperfused with Krebs–Henseleit buffer to maintain body temperature (37 °C). After defibrillation (34 joules), the specimen functioned autonomously with a normal sinus rhythm of 65 bpm and exhibited an average baseline systolic left ventricular pressure of 70 mmHg, measured via direct catheterization. A 29 mm Evolut™ R was implanted into the aortic annulus, measured via echocardiography at 26 ± 0.5 mm, using an 18 Fr EnVeo™ R delivery catheter system (Medtronic).

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The entire procedure was visualized and recorded, including initial positioning (Fig. 1a–d), prosthesis "pop out" and recapture, and final deployment (Fig. 1e–h). Two endoscopic cameras, positioned in the ascending aorta (Fig. 1a, e) and left ventricle (Fig. 1b, f), were used simultaneously with fluoroscopy (Fig. 1c, g) and echocardiography (Fig. 1d, h) to compare clinical, endoscopic, and videoscopic imaging. Post-reanimation, this human heart was perfusion fixed using 4% paraformaldehyde-pH-buffered pressurized (50 mmHg) solution delivered through the great vessels. The post-implant imaging and prosthesis frame reconstruction (Fig. 1i, j) was acquired using an X5000 high-resolution micro-computed tomography (micro-CT) system and efX-ct software (North Star Imaging, Inc., Rogers, MN, USA). Subsequently, the frame and leaflets were modeled (Fig. 1k) using Mimics medical imaging software (Materialize NV; Leuven, Belgium). The computational model of the valve frame was then 3D printed (Fig. 1l) using a uPrint SE Plus 3D Printer (Stratasys, Ltd., Eden Prairie, MN, USA).

The importance of accurate TAVR device positioning and the benefits of recapture features using the Evolut™ R self-expanding valve are uniquely highlighted in Visible Heart® footage (Online Resource 1) and depicted alongside post-implant micro-CT imaging, computational reconstructions, and a 3D printed model. The minimal calcific depositions on the native aortic valve correlated well as an aortic stenosis model, with mild inhibition of leaflet motions. These analyses enabled precise evaluation of device-tissue interactions between the prosthesis and aortic root within real human anatomy. Visible Heart® methodologies will be utilized for future TAVR evaluations to better understand existing and future challenges with these technologies. These investigational approaches provide novel educational value for physician training as well as critical insights for future medical device designs in the TAVR space.

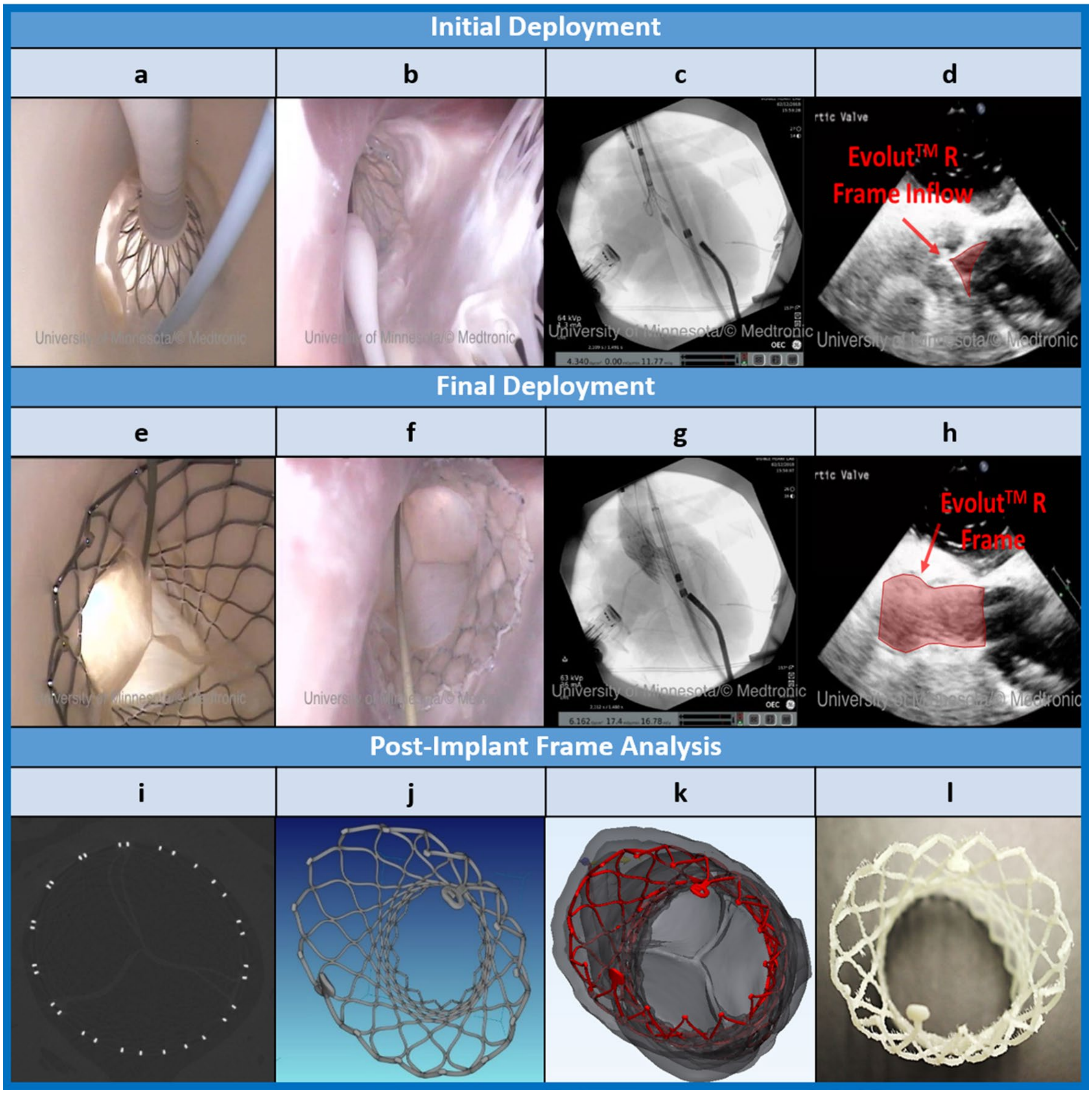

Fig. 1 Multimodal imaging and analyses of CoreValve Evolut™ R implantation within a reanimated human heart using Visible Heart® methodologies. Evolut™ R implantation was directly visualized using two videoscopes—the first videoscope in the aorta highlighted the delivery system capsule, pigtail contrast catheter, and device frame above the native valve (**a**, **e**) and the second videoscope in the left ventricle displayed the delivery system nose cone, guidewire, and device inflow in the left ventricular outflow tract (**b**, **f**). Footage of the frame self-expansion and function was supplemented with fluoroscopy (**c**, **g**) for contrast angiography and echocardiography, highlighted by the red outline (**d**, **h**). To simulate potential challenges during TAVR, the frame inflow was purposely positioned above the annular plane during the initial deployment attempt (**a**–**d**) to replicate a "pop out" event; i.e., an antegrade movement of the prosthesis above the native leaflets. As a result of this suboptimal positioning, the device was recaptured. The valve inflow was then positioned 2–3 mm below the annular plane for the final deployment attempt (**e**–**h**), to ensure the frame was appropriately seated within the aortic annulus. After confirming proper device positioning, the delivery system capsule was fully retracted to release the frame outflow and complete the valve implant. Post-implant frame analyses (**i**–**l**) were achieved using high-resolution micro-CT imaging (**i**). These datasets (21.1 micron voxel size) allowed for accurate reconstruction (**j**, **k**) and 3D printing (**l**) of the implanted Evolut™ R within this aortic stenosis heart model. The complete case procedure can be viewed in Online Resource 1

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Author contributions All authors contributed to the conception, design, and setup of this study. JDZS: Drafted manuscript, created TAVR video, prepared TAVR device and delivery system, imaged heart specimen, reconstruction and modeling, 3D printing. MGB: Edited manuscript and video, selected/implanted TAVR, imaged heart specimen, post-implant imaging analyses. PAI: Final revision and approval of manuscript and video, reanimated heart specimen, implanted TAVR, multimodal imaging of TAVR procedure.

Compliance with ethical standards

Conflict of interest PA Iaizzo has a research contract and education consultant arrangement with Medtronic. MG Bateman has ownership interest in Medtronic. JD Zhingre Sanchez has no conflicts of interest to declare.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent LifeSource secured consent from the organ donor's family to use this heart for research.

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