Robot-assisted real-time magnetic resonance image–guided transcatheter aortic valve replacement

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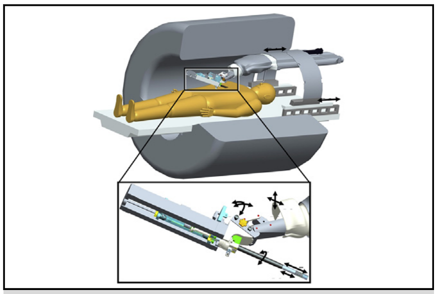
ABSTRACT

Background: Real-time magnetic resonance imaging (rtMRI)-guided transcatheter aortic valve replacement (TAVR) offers improved visualization, real-time imaging, and pinpoint accuracy with device delivery. Unfortunately, performing a TAVR in a MRI scanner can be a difficult task owing to limited space and an awkward working environment. Our solution was to design a MRI-compatible robot-assisted device to insert and deploy a self-expanding valve from a remote computer console. We present our preliminary results in a swine model.

Methods: We used an MRI-compatible robotic arm and developed a valve delivery module. A 12-mm trocar was inserted in the apex of the heart via a subxiphoid incision. The delivery device and nitinol stented prosthesis were mounted on the robot. Two continuous real-time imaging planes provided a virtual real-time 3-dimensional reconstruction. The valve was deployed remotely by the surgeon via a graphic user interface.

Results: In this acute nonsurvival study, 8 swine underwent robot-assisted rtMRI TAVR for evaluation of feasibility. Device deployment took a mean of 61 $\pm$ 5 seconds. Postdeployment necropsy was performed to confirm correlations between imaging and actual valve positions.

Conclusions: These results demonstrate the feasibility of robotic-assisted TAVR using rtMRI guidance. This approach may eliminate some of the challenges of performing a procedure while working inside of an MRI scanner, and may improve the success of TAVR. It provides superior visualization during the insertion process, pinpoint accuracy of deployment, and, potentially, communication between the imaging device and the robotic module to prevent incorrect or misaligned deployment. (J Thorac Cardiovasc Surg 2016;151:1407-12)



Valve delivery module and robot platform in the MRI bore with a patient.

Central Message

We show the feasibility of robot-assisted rtMRI-guided TAVR, which has benefits over current imaging and delivery technologies.

Perspective

Real-time MRI-guided TAVR overcomes the limitations of currently available imaging modalities; however, performing TAVR in an MRI scanner can be difficult, owing to limited space. We designed a robot-assisted device to deploy a self-expanding valve. This method provides superior visualization and deployment with pinpoint accuracy, and can prevent misaligned deployment.

See Editorial Commentary page 1413.

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Aortic stenosis is the most common type of valvular heart disease in the United States.[1-3] This disease process has a long latency period; however, patients rapidly decline after becoming symptomatic. Previously a patient's only chance for substantially prolonging survival was to undergo cardiopulmonary bypass with surgical aortic valve replacement.[4-6] Unfortunately, some of these patients were inappropriate or high-risk surgical candidates.[7] Since its approval by the Food and Drug Administration in 2011, transcatheter aortic valve replacement (TAVR) has become a viable treatment option for patients with otherwise inoperable or high-risk aortic stenosis.[7,8]

Although there have been multiple advances in valve development and valve delivery technology, the imaging modality has remained unchanged. Currently TAVR is performed with a combination of fluoroscopy and transesophageal echocardiography (TEE), which has multiple limitations. The TAVR procedure currently necessitates various imaging modalities for different stages of the procedure.[9,10] Preprocedural imaging usually includes echocardiography in combination with multidetector computed tomography (MDCT) or computed tomography (CT) angiography.

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Abbreviations and Acronyms

CT	= computed tomography
MDCT	= multidetector computed tomography
rtMRI	= real-time magnetic resonance imaging
TAVR	= transcatheter aortic valve replacement
TEE	= transesophageal echocardiography

Postprocedural imaging also routinely uses a combination of fluoroscopy and TEE to confirm valve placement and cardiac function.[10-13] Fluoroscopy has multiple limitations, including poor soft tissue contrast, a requirement for rapid ventricular pacing, radiation exposure to the patient and surgical team, and a risk of contrast-induced nephropathy.[14-17] Real-time magnetic resonance imaging (rtMRI) guidance overcomes these limitations with improved soft tissue contrast in addition to a 3-dimensional visualization of the anatomic structures. rtMRI has the added benefit of completing the preprocedural, intraprocedural, and postprocedural imaging with a single device.

rtMRI guidance has been proposed as the future of TAVR.[16,18,19] Unfortunately, performing a TAVR procedure while working in the bore of an MRI scanner can be a difficult task, owing to limited space and a potentially awkward working environment. Our solution to this problem was to design an MRI-compatible robot-assisted device capable of inserting and deploying a self-expanding valve from a remote computer console. Here we present our preliminary results using this device to perform transapical TAVR in a swine model.

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MATERIALS AND METHODS

MRI System

The MRI system comprises several components, including a 1.5-T MRI unit, interactive image reconstruction software, and advanced pulse-sequence technology.[20-22] A MAGNETOM Aera MRI system (Siemens Medical Solutions, Munich, Germany) was used for this experiment. This device's bore size of 145-cm long × 70-cm wide provides adequate clearance above the patient for the robot system. The system can generate high-quality images at 5-10 frames per second with low latency for fully interactive, real-time imaging; however, in this study, standard imaging sequences were used for preprocedural planning and postprocedural assessment. Interactive Front End navigation software (Siemens Corporate Research, Munich, Germany), along with an interactive real-time pulse sequence (BEAT_IRTTT), provided real-time navigation during valve deployment. The Interactive Front End navigation software obtains multiple slices in rapid succession that can be displayed simultaneously to provide a 3-dimensional rendering. The software allows rapid adjustment of the imaging planes to allow for real-time device tracking.[20-24]

Self-Expanding Stent and Delivery Device

A self-expanding nitinol stent was designed and engineered for this experiment (Figure 1).[25,26] Although several nitinol stents are commercially available, including the CoreValve and SAPIEN valve, we designed our own stent for this experiment. While the geometry of some stents uses a diamond cell shape, this design may cause increased stress along the stent during the crimping process. Our stent design is based on a chevron shape, which minimizes stress along the chevron cell shape. The chevron shape also prevents stent migration, owing to the self-anchoring properties of the pointed ends of the chevron. The stent is laser-cut from a biocompatible nitinol tube to an expanded diameter of 26 mm and a length of 35 mm.[27] The stent is then compressed with a custom-made crimping device and inserted into the delivery device.[17] The stent expands to its open configuration on release from the delivery system.

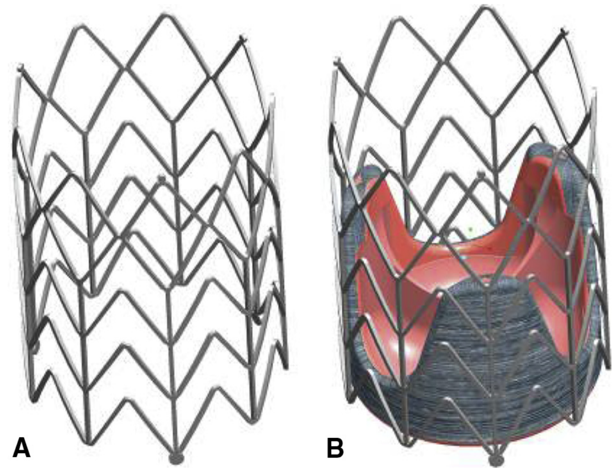

FIGURE 1. A, Self-expanding stent. B, Bioprosthetic valve affixed in a self-expanding stent.

We also developed a delivery device for inserting and deploying the stented prosthesis. This delivery device consists of an inner rod and an outer sheath, which are controlled by the robotic delivery module's pneumatic actuators. The outer sheath also protects the nitinol stent before deployment. The delivery device is MRI-compatible and fits into a 12-mm trocar.[27]

Robotic Assistance System

We developed an MRI-compatible robotic surgical assistant system to deliver the aortic valve prostheses.[28,29] This system consists of a positioning module, a valve delivery module, custom-designed software, and a graphical user interface. The positioning module consists of a modified Innomotion MRI-compatible robotic arm (Innomedic, Herxheim, Germany). The positioning module holds the valve delivery module and adjusts the planned trajectory of the valve delivery device. The positioning module was modified to hold and manipulate the valve delivery module and has 5 degrees of freedom. Movements include axial, vertical, and horizontal translation, as well as pitch and yaw. The valve delivery module has 3 degrees of freedom, which includes roll, translation, and insertion of the delivery device. The valve delivery module was designed to work in conjunction with the robotic arm to insert and deploy the stent.[22] The combination of the movements between the positioning module and valve delivery module include all of the movements that a human would use when inserting and deploying the stent.

To maintain image quality and prevent heat transfer to the patient, the valve delivery module is made of nonconductive plastic materials, pneumatic actuators, and magnetotranslucent fiber-optical encoders. The profile of the valve delivery module and positioning module allow the system to fit into a standard closed MRI scanner (Figure 2). The primary control computer uses a custom software program to control the robotic system via an optic network. For precision with valve deployment, the

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