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Robot-Assisted Real-Time Magnetic Resonance Image Guided Transcatheter Aortic Valve Replacement

Justin G. Miller, MD, **Ming Li, PhD**, **Dumitru Mazilu, PhD**, **Tim Hunt, BS**, and **Keith A. Horvath, MD**

Cardiothoracic Surgery Research Program, National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, Maryland, USA

Abstract

OBJECTIVE—Real-time magnetic resonance image (rtMRI) guided transcatheter aortic valve replacement (TAVR) has improved visualization, real time imaging, and pinpoint accuracy with device delivery. Unfortunately, performing a TAVR in a MRI scanner can be a difficult task due 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 12mm 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 3D reconstruction. The valve was remotely deployed by the surgeon via a graphic user interface.

RESULTS—In an acute, non-survival study, eight swine underwent robot-assisted rtMRI TAVR for evaluation of feasibility. Device deployment took 61 +/− 5 seconds. Post-deployment necropsy was performed to confirm correlation between imaging and the actual valve position.

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, deployment with pinpoint accuracy, and potentially communication between the imaging device and the robotic module which will prevent incorrect or misaligned deployment.

Corresponding Author: Keith A. Horvath, Building 10 Room B1D47, 10 Center Drive, Bethesda, MD 20892, Phone: 301-451-7098, Fax: 301-451-5459, horvathka@mail.nih.gov.

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OBJECTIVES

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 not appropriate surgical candidates or are high risk surgical candidates.[7, 8] Since approval by the Food and Drug Administration in 2011, transcatheter aortic valve replacement (TAVR) has become a viable treatment option for otherwise inoperable or high risk aortic stenosis patients. [7–9]

While 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.[10, 11] Pre-procedural imaging usually includes echocardiography in combination with multidetector computed tomography (MDCT) or computed tomography (CT) angiogram. The TAVR procedure is most commonly performed with a combination of fluoroscopy and transesophageal echocardiography (TEE). Post-procedural imaging also routinely uses a combination of fluoroscopy and TEE to confirm valve placement and cardiac function. [11–14] 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. [15–18] Real-time magnetic resonance image (rtMRI) guidance overcomes these limitations with improved soft tissue contrast in addition to a three dimensional visualization of the anatomic structures. MRI has the added benefit in that the pre-procedural, intra-procedural, and post-procedural imaging is completed with one device. rtMRI guidance is proposed to be the future of TAVR. [17, 19, 20] Unfortunately, performing a TAVR procedure while working in the bore of an MRI scanner can be a difficult task due to limited space and a potentially awkward working environment. Our solution was to design a MRI compatible robot-assisted device that was capable of inserting and deploying a self-expanding valve from a remote computer console. We present our preliminary results using this device to perform transapical TAVR in a swine model.

MATERIALS AND METHODS

Magnetic Resonance Imaging System

The imaging system has several components, which includes a 1.5 Tesla MRI, interactive image reconstruction software, and advanced pulse sequence technology.[21–23] A Magnetom Aera (Siemens Medical Solutions, Munich, Germany) was used for this experiment, which has a 145 cm long by and 70 cm wide bore. The bore size allows an 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, standard imaging sequences were used for pre-procedural planning and post-procedural assessment. Interactive Front End navigation software (Siemens Corporate Research, Munich, Germany), along with an interactive real-time pulse sequence (BEAT_IRTTT), was

used for real-time navigation during valve deployment. The Interactive Front End navigation software takes multiple slices, which are obtained in rapid succession and can be simultaneously displayed to provide a three-dimensional rendering. The software allows quick adjustment of the imaging planes to allow for real-time device tracking.[21–25]

Self-expanding Stent and Delivery Device

A self-expanding nitinol stent was designed and engineered for the experiment (Figure 1).[26] While there are nitinol stents that are commercially available, such as the CoreValve and SAPIEN valve, we designed our own stent for this experiment. While some stents' geometry utilizes a diamond cell shape, the design my 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 due to the self-anchoring properties of the pointed ends of the chevron. The stent was laser cut from a biocompatible nitinol tube to an expanded diameter of 26mm diameter and a length of 35mm.[27] The stent was then compressed with a custom made crimping device and inserted into the delivery device.[18] The stent expands to its open configuration upon release from the delivery system.

A delivery device was also developed for inserting and deploying the stented prosthesis. The 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 prior to deployment. The delivery device is MRI compatible and fits into a 12mm trocar.[27]

Robot Assistance System

An MRI compatible robotic surgical assistant system was developed to deliver the aortic valve prostheses.[28, 29] The robotic assistance system consists of a positioning module,, a valve delivery module, custom designed software program, and a graphical user interface. The positioning module consists of a modified Innomotion MRI compatible robotic arm (Innomedic, Herxheim, Germany). The positioning module was used to hold the valve delivery module and to adjust 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 (DoF). These movements include axial, vertical and horizontal translation as well as pitch and yaw. The valve delivery module has 3 DoF, 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.[23] The combination of the movements between the positioning module and valve delivery module include all the movements that a human would use when inserting and deploying the stent. In order to maintain image quality and prevent heat transfer to the patient, the valve delivery module was made from non-conductive plastic materials, pneumatic actuators and magnetotranslucent fiber-optical encoders. The profile of the valve delivery module and positioning module allow it to fit into a standard closed MRI scanner (Figure 2). The primary control computer used a custom software program to control the robotic system via an optic network. For precision with valve deployment, the accuracy of the linear joints was around one millimeter and the accuracy of the rotational joints was one degree. [30] The

interactive control interface allows the user to plot the next move for the delivery device, such as increasing angulation or advancing the delivery device. While the robot is executing maneuver, the user can watch the device in real time. If any movement needs to be modified, the user can start, stop, change, or resume the delivery device motion at any time.

Animal Surgery Protocol

All experiments were performed in accordance with the protocols approved by the National Institutes of Health Animal Care and Use Committee. Induction included an intramuscular injection of Midazolam (0.5 mg/kg) and Ketamine (25mg/kg). After induction, the animals were intubated and then maintained on mechanical ventilation with Isoflurane (0.5–2.5%). The animals end tidal carbon dioxide, oxygen saturation, arterial blood pressure, and electrocardiographic telemetry were monitored throughout the entire procedure. The animal's body temperature was maintained with a forced-air warming blanket. Prior the start of the procedure, the animals received intravenous Amiodarone (150mg-300mg) for antiarrhythmic treatment and prior to trocar insertion they were anticoagualted with heparin (300 units/kg). After completion of the experiment, the fully anesthetized animals were euthanized with an intravenous injection of phenobarbital (150mg/kg). We recorded the times and details of the procedures.

Valve Deployment

Eight swine weighing between 45 and 55 kg underwent robot-assisted rtMRI-guided TAVR. The animals were sedated and intubated, then prepped and draped in a supine position. A 6cm subxiphoid incision was made and the pericardium was opened. Two concentric purse string sutures were placed around the apex of the heart. An incision was made in the apex and a 12mm trocar was inserted. The swine were then transferred to the MRI and a surface radiofrequency coil was secured to the anterior chest to enhance signal reception. The delivery device was loaded with the stent and the stent and delivery device were inserted into the opening of the trocar (Figure 3a). The positioning module and valve delivery module were then affixed to the MRI table and the delivery device was attached to the valve delivery module (Figure 3b, 3c). The MRI table with the robot and animal were then moved into the bore (Figure 3d). A pre-deployment scan was performed to confirm annulus and aortic root size and so the physician could plan the trajectory of the delivery device. For deployment, two imaging planes (long axis view and short axis view) were used to create a virtual real time three-dimensional reconstruction. The physician was able to adjust the delivery device during insertion and deploy the stent with the robot system via the graphical user interface and software program. The axial slices were shifted as needed to visualize the delivery device and maintain proper orientation for stent delivery. Under rtMRI guidance, the delivery device was advanced until it was across the aortic valve (Figure 4a). Once the delivery device reached the proper position, the device was slowly deployed (Figure 4b). While the stent was partially deployed, the physician could reposition the valve if needed to ensure correct and precise placement. Once the valve was deployed (Figure 4c), the delivery catheter system was withdrawn from the trocar (Figure 4d). Post-deployment images were acquired to confirm the position of the prostheses. Gated CINE-MRI was used to assess valve placement. A necropsy was performed on all animals following valve placement to grossly assess valve placement.[17, 21, 23, 31]

RESULTS

In an acute, non-survival study, eight swine underwent success robot-assisted rtMRI TAVR for evaluation of feasibility. The subxiphoid incision with trocar placement was 18 minutes +/− 6 minutes. The pre-deployment scan was used to measure the annulus and aortic root size and to plan the trajectory of the delivery device. The annulus sizes were 24mm +/− 3mm. Our custom-designed self-expanding stent with an expanded diameter of 26mm and length of 35mm was used for all eight experiments. There were no issues with stent deployment. The time for deploying the valve under rtMRI guidance was 61 seconds +/− 5 seconds. The post-deployment scans confirmed precise stent placement at 4mm below the annulus in all eight experiments. Post-deployment necropsy confirmed the correlation between imaging and the actual valve position (Figure 5). On necropsy, all eight animals had apposition of the bioprosthesis to the annulus and ascending aorta. All stents were deployed with the proximal end positioned 0 to 3mm below the annulus and without occluding the coronary ostia.

DISCUSSION

rtMRI has improved soft tissue contrast in addition to a three dimensional visualization of the anatomic structures, unlike traditional imaging for TAVR. In addition rtMRI avoids radiation exposure and contrast media. X-ray fluoroscopy exposes the patients and medical staff to significant doses of ionizing radiation, while rtMRI uses non-ionizing radiation, which has no known deleterious effects to health.[32] Unlike fluoroscopy, rtMRI guidance does not require the use of contrast media to aid in visualization.[15–17] Contrast media can lead to multiple complications, such as contrast-induced nephropathy and anaphylaxis.[33] Gadolinium can be used in a post-deployment, first-pass perfusion to evaluate myocardial perfusion, but it is not required for the procedure.[34] rtMRI guidance may be useful for TAVR patients with renal insufficiency, which is a contraindication to the procedure.[18, 35]

Traditional imaging for TAVR requires multiple imaging modalities; however, we have demonstrated in our previous experiments that rtMRI can be utilized as the only imaging modality for pre-deployment imaging, imaging guidance for valve deployment, and post-deployment scanning in TAVR procedures with a high accuracy of device delivery and reproducibility.[17, 22, 23, 36–39] Although rtMRI guided TAVR has come closer to a clinical reality, one of the limitations we realized during our multiple experiments is the difficulty of performing the procedure in the confines of an MRI suite and working inside the bore of an MRI machine. This led us to develop an MRI compatible robot-assisted device to aid in deployment. Our experiment has demonstrated the feasibility of using this device for transapical rtMRI guided TAVR. However, there are some limitations to this delivery method.

Some of the limitations of rtMRI imaging and robot assistance include non-MRI compatible implants, complexity and cost of delivery method, device deployment limitations, and effectiveness of our self-expanding nitinol stent. Unlike fluoroscopy and CT, the continuous interaction between an MRI's magnetic field with ferromagnetic materials lead to potential movement and heating of metallic objects. This can lead to tissue damage as well as damage

to electronic circuits. Because of this, patients must be carefully screened prior to rtMRI procedures. Imaging of patients with non-MRI compatible implants such as some implanted cardiac devices is contraindicated. [40–42] Patients with non-MRI compatible implants would be excluded from rtMRI guided TAVR. Another limitation is the complexity and resources that would be required to develop and run a robot-TAVR program. We realize the costs of hybrid MRI suites as well as a robotic delivery device would limit its use to only major centers with high-volume TAVR procedures. The device itself also has several limitations. In its current configuration, the robot assistance system is currently configured for a transapical approach. The device currently cannot advance a guidewire, so it is not able to perform a TAVR from a femoral, subclavian, or axillary access sites. Another limitation was stent migration between post-deployment perfusion and necropsy. All eight stents were precisely deployed at 4mm below the annulus and position was confirmed on post-deployment imaging. However, between post-deployment imaging and necropsy, the stents moved in position between 1mm and 4mm, this could be due the valve design, size mismatch, or the valve shifting during harvest for necropsy. While we are unsure of the exact variable which led to movement, we do know that between deployment and post-deployment imaging, all eight stents were deployed with millimeter precision.

CONCLUSIONS

These results demonstrate the feasibility of robotic assisted TAVR using rtMRI guidance. rtMRI guidance is unique in that this single imaging modality can be successfully utilized for pre-deployment, deployment, and post-deployment imaging; however, performing a TAVR while working in the confines of an MRI bore is an challenging task. rtMRI eliminates the deleterious side effects of traditional imaging for TAVR, which includes radiation exposure and contrast media. Our approach, by using a robotic system, may eliminate some of the challenges and may improve the success of TAVR. It provides superior visualization during the insertion process, deployment with pinpoint accuracy, and potentially communication between the imaging device and the robotic module which will prevent incorrect or misaligned deployment.

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Glossary of Abbreviations

CT	Computed tomography
MDCT	Multidetector computed tomography
rtMRI	Real-time magnetic resonance image
TAVR	Transcatheter aortic valve replacement
TEE	Transesophageal echocardiography

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Perspective Statement

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

Central Message

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

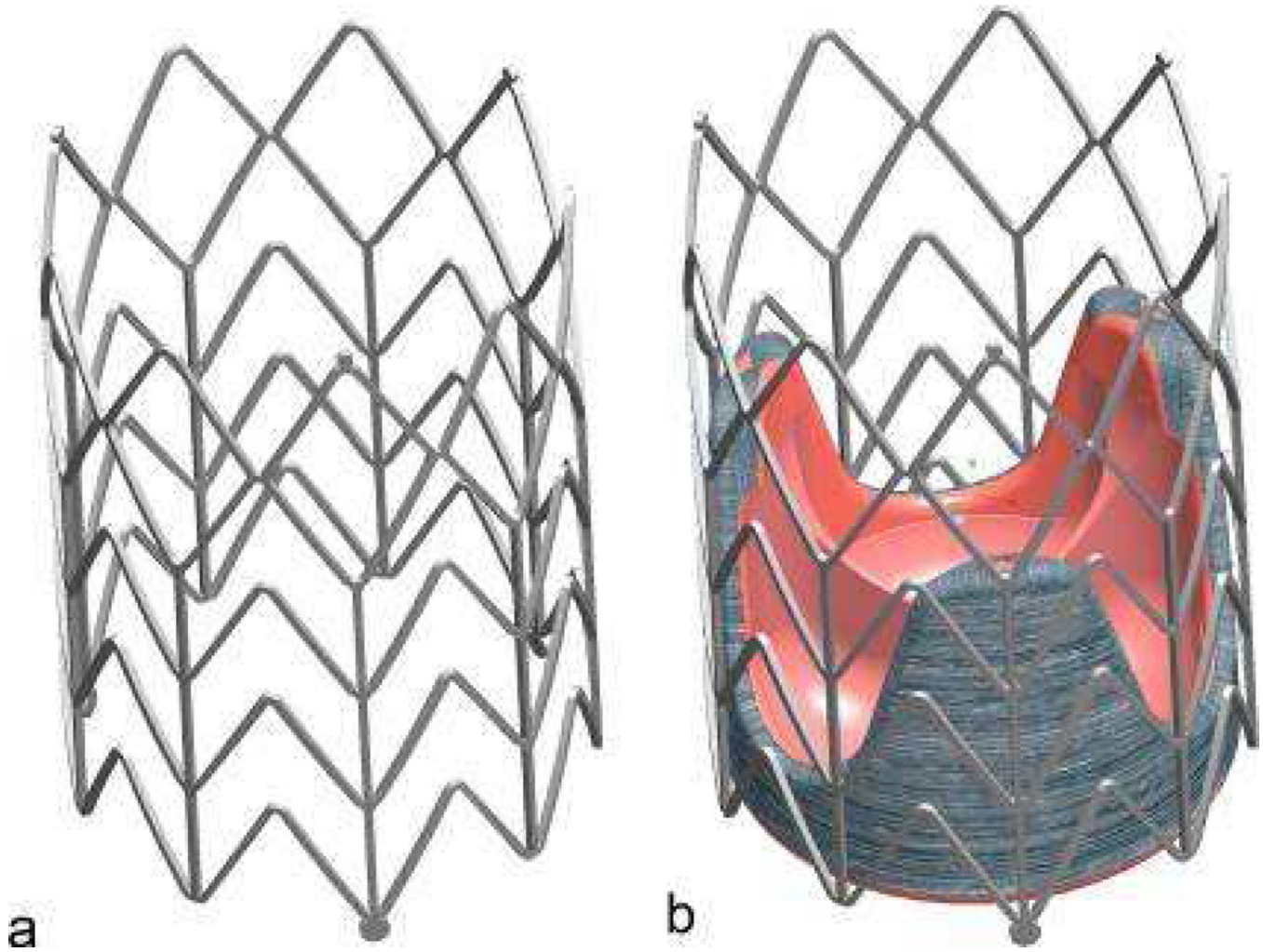

Figure 1.
(a) Self-expanding stent; (b) bioprosthetic valve affixed in self-expanding stent.

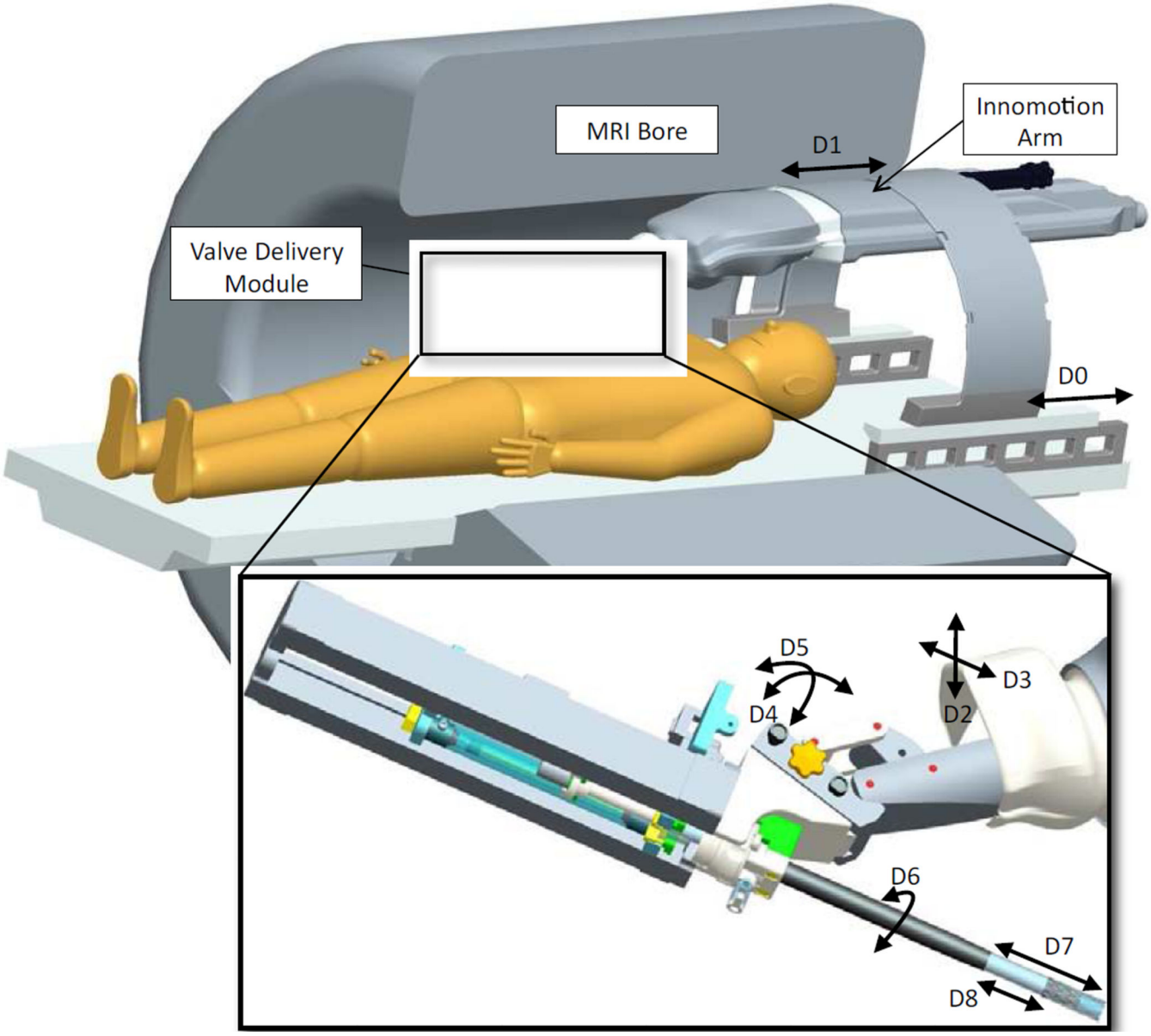

Figure 2.
Valve delivery module and robot platform in MRI bore with patient

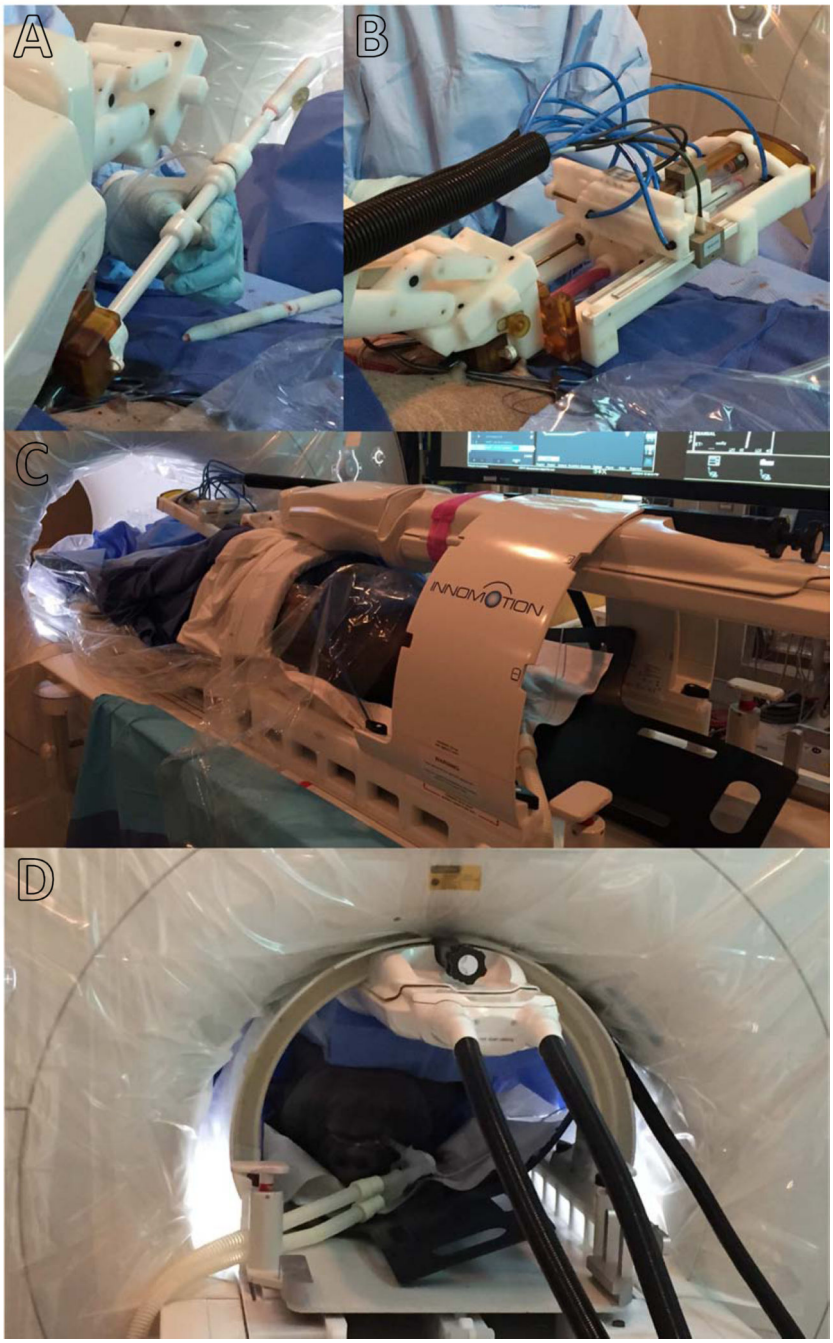

Figure 3.
(a) Insertion of delivery device and nitinol stent; (b) valve delivery module mounted on robotic arm; (c) patient and robot platform; (d) patient and robot platform in MRI scanner.

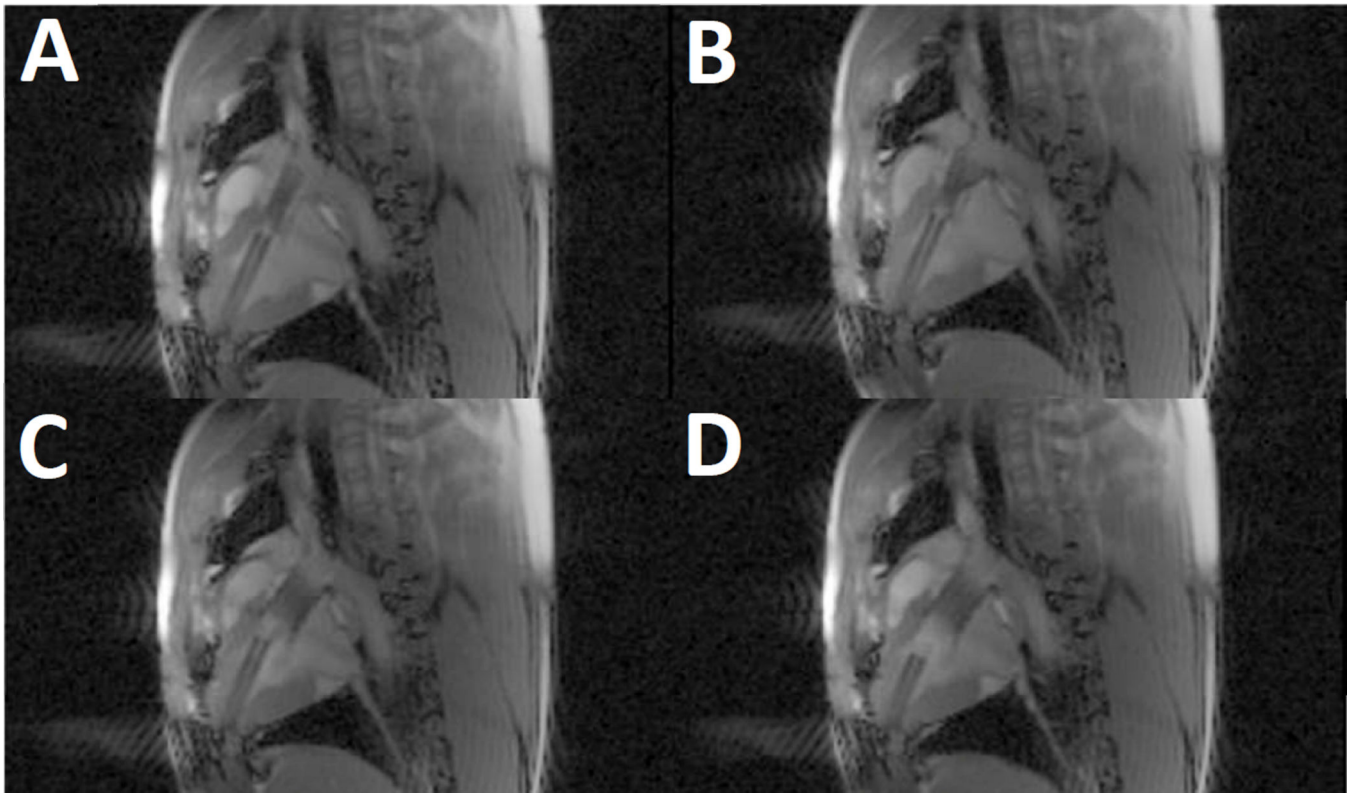

Figure 4.

Valve deployment from the delivery device. (a) Delivery device advanced across aortic valve; (b) sheath retracting to deploy valve; (c) valve deployed; (d) delivery device backing out.

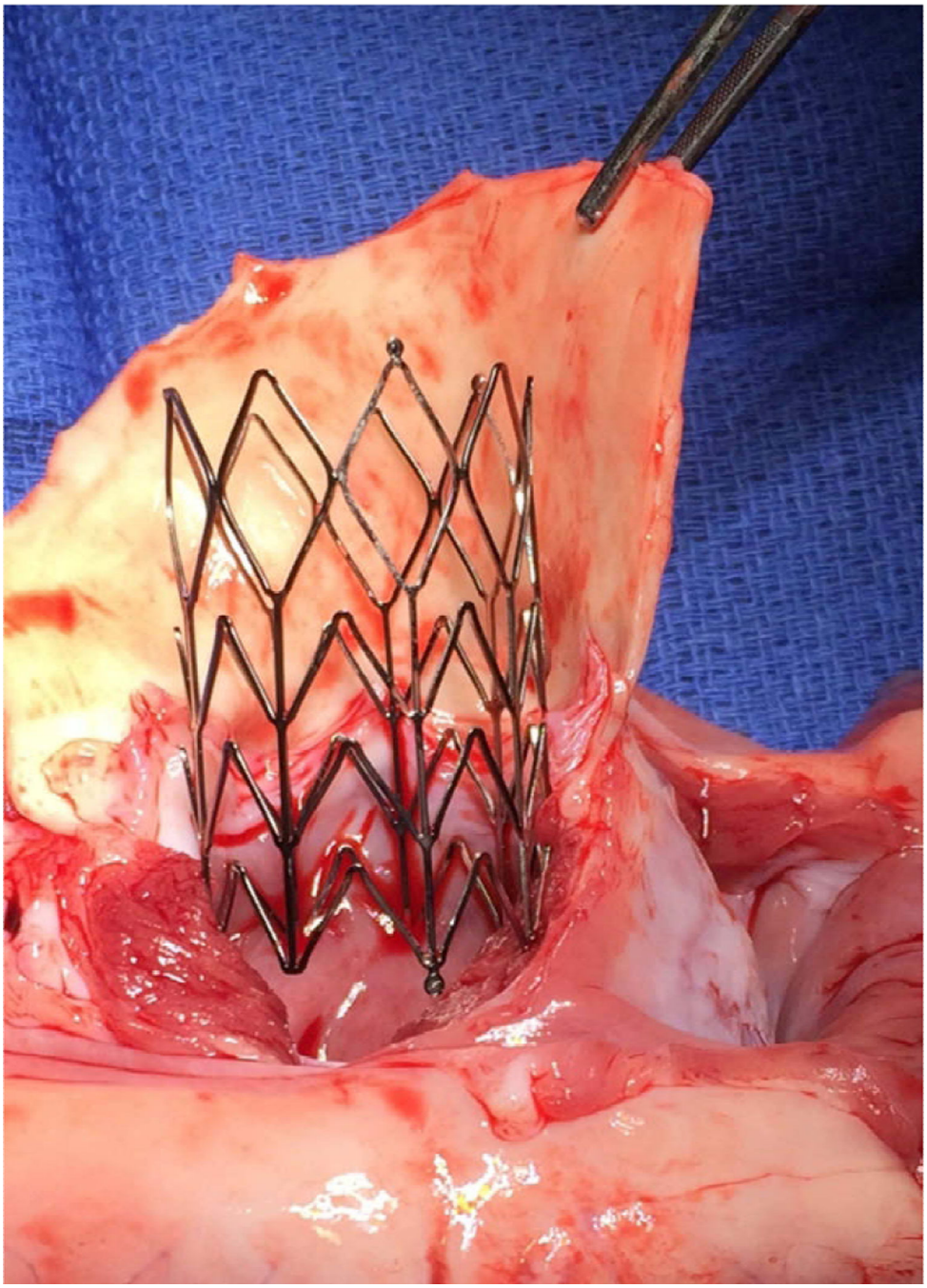

Figure 5.
Necropy showing valve placement.