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BAILOUT POST-TAVR PCI TECHNIQUES IN REANIMATED SWINE AND HUMAN HEARTS: PROCEDURAL IMAGING AND POST-PROCEDURAL MODELING TECHNIQUES

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ABSTRACT

Transcatheter aortic valve replacement (TAVR) has become a popular treatment option for severe aortic stenosis (AS) patients who present a high risk for mortality should they receive a surgical aortic valve replacement (SAVR). Coronary artery occlusion (CAO) following the implantation of the device is a potential complication with a high mortality rate, as CAO causes a deterioration of coronary perfusion, followed by cardiogenic shock and electrical instability. Due to this dangerous potential complication, bailout percutaneous coronary intervention (PCI) techniques, like the snorkel and chimney techniques, have been developed as an effective strategy for ensuring coronary perfusion is maintained following a TAVR procedure. Both snorkel and chimney techniques have been implemented in a reanimated swine and human heart respectively utilizing Visible Heart® methodologies. The procedures have been recorded utilizing endoscopic cameras, echocardiography, optical coherence tomography, and fluoroscopy. Post-procedural micro-computed tomography (micro-CT) was conducted to provide post-implantation imaging with approximately 60-micron resolution. The reconstructions are then segmented and used to create 3D renderings of these complex procedures. These methodologies are repeatable and can be used in a variety of conditions to be used in subsequent educational uses.

Keywords: transcatheter aortic valve replacement; chimney; snorkel; percutaneous coronary intervention; post-TAVR PCI; deployment; post-procedural imaging; micro-computed tomography; computational reconstructions; optical coherence tomography

NOMENCLATURE

TAVR	transcatheter aortic valve replacement
SAVR	surgical aortic valve replacement
AS	aortic stenosis
AI	aortic insufficiency
CAO	coronary artery occlusion
PCI	percutaneous coronary intervention
Micro-CT	micro-computed tomography

1. INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has grown in popularity as an alternative treatment option for aortic stenosis (AS) and/or aortic insufficiency (AI) when compared to the more traditional surgical aortic valve replacement. TAVR procedures, as recently as 2019 have surpassed all SAVR procedures as the most common treatment for AS [1,2,3]. During a TAVR procedure, the prosthetic valve is delivered via a delivery catheter through the femoral, brachial, or carotid artery to the aortic annulus, where it is deployed across the native leaflets, assuming the valve function. The displacement of the diseased leaflets improves systolic blood flow from the left ventricle. While the popularity of TAVR is growing, new bailout procedures are being developed to respond to the rare, but potentially devastating complications with these procedures.

One of these potential complications is coronary artery obstruction (CAO) caused by the native leaflets of the valve, or the prosthesis structure itself obstructing flow to the coronary arteries. These obstructions can lead to a sudden deterioration of hemodynamic status, myocardial infarction, or a number of others symptoms [4]. In addition, CAO can also make the coronary arteries inaccessible for future PCI procedures. In response to the potential for CAO, protective, and bailout stenting procedures have been developed to ensure that coronary perfusion is maintained following a TAVR.

One of these protective procedures is a chimney stenting technique. In this procedure, a guide wire is fed into the coronary artery at risk for CAO, and a stent is fed over it until a portion of the stent sits in the coronary artery, with another section remaining out of the coronary. As the TAVR is deployed, the stent is inflated simultaneously, causing the stent to wrap around the outside of the prosthesis, allowing continued coronary perfusion by displacing the native leaflet, and creating a path for blood to flow into the coronary [5]. This technique requires preprocedural imaging to signal that the native coronary ostium presents a high risk of CAO in order to be implemented, while other techniques can be implemented in the event of an unexpected CAO.

A snorkel stenting technique can be implemented should CAO appear following the TAVR procedure. This technique involves feeding a guidewire through the struts of the TAVR prosthesis and into the occluded coronary, from here a stent is guided over the wire and into the coronary, with a portion remaining in the aorta [4]. This allows for coronary perfusion to be continued, without the need for a coronary wire placed before the deployment of the prosthesis.

The Visible Heart® Laboratories have developed methodologies [6,7] to conduct these procedures in reanimated swine, and on rare occasions human, hearts utilizing the necessary clinical imaging modalities that would be typically used in these procedures like fluoroscopy, echocardiography, and optical coherence tomography (OCT). In addition, post-procedural micro-computed tomography (micro-CT) can be conducted following these techniques to create high-resolution 3D renderings of these procedures to be used for subsequent educational purposes. These methodologies have been implemented with a snorkel technique placed in a reanimated swine heart and a chimney technique placed in a reanimated human heart.

2. MATERIALS AND METHODS

Utilizing Visible Heart® methodologies a swine heart was reanimated while being perfused with a transparent Krebs-Henseleit buffer [7]. This allows for the internal anatomy of the hearts to be directly visualized using endoscopic cameras. Next, echocardiography was used to measure the diameter of the aortic annulus of the heart. Using this measurement, a prosthesis was selected for the TAVR. The valve was loaded into the delivery catheter and passed through the aorta of the heart until reaching the aortic annulus. For the snorkel procedure, the valve was deployed across the aortic annulus, then a coronary guide wire was placed into the coronary artery using fluoroscopy for visualization of the procedure. A stent was then selected and placed with a section remaining through the prosthesis and in the aorta. In addition to the main inflation of the stent, the distal end of the stent was flared to allow for improved coronary perfusion. This procedure can be found in Figure 1.

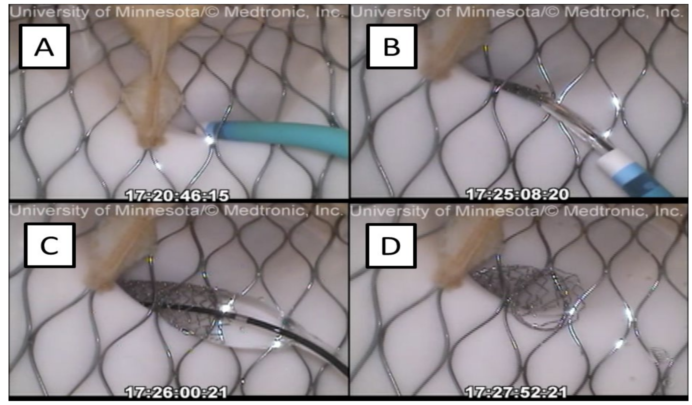

FIGURE 1: Endoscopic view of snorkel procedure conducted in a reanimated swine heart. A) A guide catheter was advanced across the struts of the prosthetic valve. B) A stent is advanced over a guide wire, through the guide catheter until it reaches the desired position in the coronary ostium. C) The stent is inflated. D) The delivery systems are retracted.

The Human heart was acquired through collaboration with LifeSource. The heart was deemed not viable for transplant and subsequently donated to the Visible Heart® Laboratories for research use. The heart was reanimated using the same methodologies mentioned for the swine heart [7]. In addition to the echocardiography measurement of the aortic valve diameter for the prosthesis sizing, a guidewire was placed into the desired coronary ostium of the human heart using fluoroscopy for visualization. An OCT catheter was fed over the coronary wire and used to measure the diameter of the coronary vessel. This measurement was used to select the size of the coronary stent used in the chimney technique. From here, the selected valve was loaded into the delivery catheter and fed to the aortic annulus. The selected coronary stent was placed into the desired ostium and placed so that the desired amount of the stent remained outside of the coronary vessel. Both the prosthesis and the stent were simultaneously deployed, and all delivery systems were retracted. The stent wrapped around the outside of the prosthetic valve and the distal end of the stent was flared with the stenting balloon to help direct flow to the coronary vessel. This procedure can be found in Figure 2.

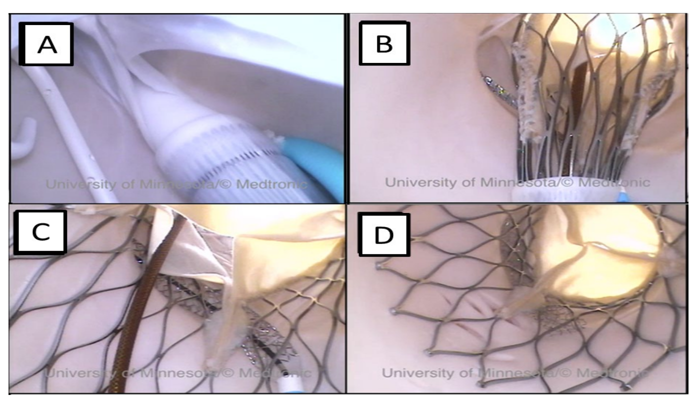

FIGURE 2: Endoscopic view of chimney procedure conducted in a reanimated swine heart. A) The prosthetic valve is guided across the aortic annulus, and the guide catheter is placed across the coronary

vessel. B) The prosthetic valve is partially deployed and the guide catheter is retracted. C) The prosthetic valve is fully deployed, and the stent is inflated. D) The delivery devices are removed.

Following both of the PCI procedures, the hearts were prepared for micro-CT scanning. The hearts were scanned on an X3000 high-resolution micro-CT system, and the anatomies, TAVR, and stents were reconstructed with the corresponding eFX-CT software. The reconstructions were then segmented on Mimics Materialise software. Examples of the segmentations can be seen in Figure 3.

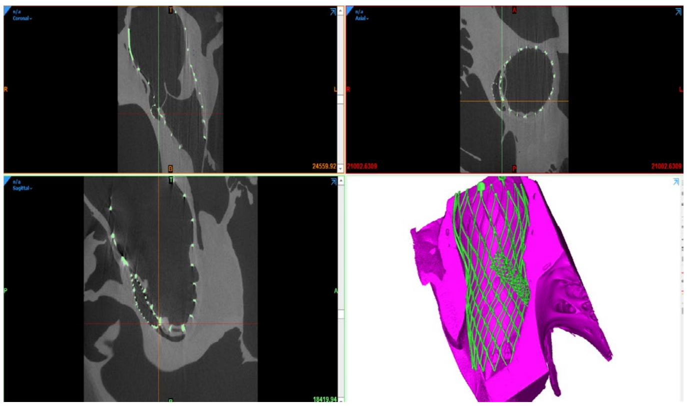

FIGURE 3: Mimics Materialise segmentations software with the uploaded reconstruction of a chimney stenting procedure used to generate the 3D model of the valve frame and stent.

3. RESULTS AND DISCUSSION

The direct visualization of these procedures allows for precision device placement that can be used in teaching modules to be used by future procedure developers and physicians. The video footage collected from the endoscopic cameras can be correlated to more challenging clinical visualization techniques, like fluoroscopy and echocardiography, to create educational guides for proper placement techniques for these complex procedures.

The post-implant 3D models generated from these procedures, shown in Figure 4, provide valuable information on how the frame of the device may affect coronary access and perfusion. These models have been used in fluid modeling through ANSYS Fluent. These flow models help illustrate the effects of TAVR on coronary perfusion and how bailout PCI can help restore flow to the vessels.

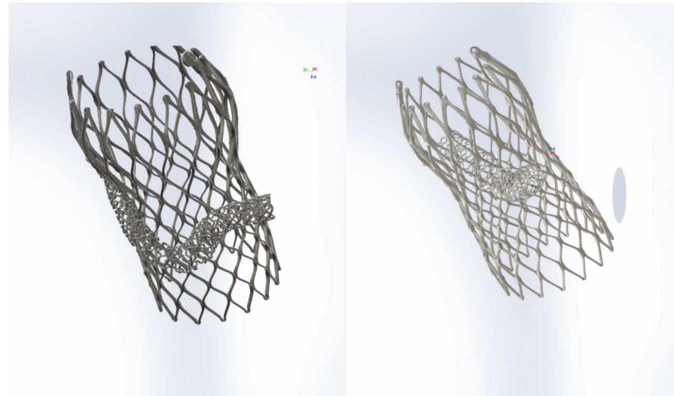

FIGURE 4: 3D models of a chimney stenting technique (left) and a snorkel stenting technique (right) generated from micro-CT scans of procedures conducted in real anatomies.

The methodologies developed for these procedures can be repeated in other procedures, like valve-in-valve techniques, to generate computational reconstructions of these techniques in unique anatomies.

4. CONCLUSION

The unique visualization methodologies developed in these procedures allow for the precision placement of both the snorkel and chimney stenting techniques. In addition, the post-procedural computational modeling developed shows the importance of placement in both TAVR and in post-TAVR PCI techniques in preventing CAO that correspond with real anatomies. These methodologies will be implemented with other valve replacement therapies, and other associated bailout techniques. Ultimately, the methodologies developed for these procedures create educational opportunities and provide key insights into the development of TAVR and associated bailout techniques.

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