Simulation of Transcatheter Aortic Valve Replacement in patient-specific aortic roots: effect of crimping and positioning on device performance

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Abstract— Calcific aortic valve disease (CAVD) is a cardiovascular condition that causes the progressive narrowing of the aortic valve (AV) opening, due to the growth of bone-like deposits all over the aortic root (AR). Transcatheter aortic valve replacement (TAVR), a minimally invasive procedure, has recently become the only lifesaving solution for patients that cannot tolerate the standard surgical valve replacement. However, adverse effects, such as AR injury or paravalvular leakage (PVL), may occur as a consequence of a sub-optimal procedure, due to the presence of calcifications in situ. Additionally, the crimping required for delivering the valve via stenting may damage the valve. The aim of the present study is to comparatively assess the crimping mechanics of the commercialized Edwards SAPIEN valve and an alternative polymeric valve (PolyNova, Inc) and to evaluate the effect of different TAVR deployment positions using patient-specific numerical models. The optimal deployment location for achieving better patient outcomes was calculated and based on the interactions between the TAVR stent and the native AR. Results demonstrated that the PolyNova valve withstands the crimping process better than the SAPIEN valve. Furthermore, deployment simulations showed the role that calcifications deposits may play in the TAVR sub-optimal valve anchoring to the AV wall, leading to the presence of gaps that result in PVL.

I. INTRODUCTION

Aortic stenosis (AS) is a pathologic cardiovascular condition that affects 3 to 5% of USA population over 75 years old, thus becoming the most common valvular heart disease [1]. Calcific aortic valve disease (CAVD), which is found in the majority of AS cases, is a formation and build-up of calcium deposits on the leaflets of the aortic valve (AV) that leads to progressive stiffening and thickening of the valve (sclerosis). This would thereby result in a significant obstruction to the left ventricular (LV) systolic outflow and, more importantly, to a limited closure during diastole [2]. These symptoms are usually diagnosed in their severe stage when immediate intervention is needed.

According to both the ACC/AHA ESC/EACTS guidelines [3, 4], surgical aortic valve replacement (SAVR) should be performed in all symptomatic patients with severe AS, regardless of LV function, as survival is better with surgical treatment than with medicinal treatment. In recent years, the percutaneous transcatheter aortic-valve replacement (TAVR) was suggested as a less invasive option for patients with high operative risk [5, 6]. In this type of minimally invasive intervention, a stent with a mounted bioprosthetic valve is delivered via transfemoral or transapical approach and deployed on the stenotic native valve. To date, the only FDA-approved TAVR devices are the balloon-expandable Edwards Lifesciences SAPIEN and SAPIEN XT and the self-expandable Medtronic Corevalve. In all of them, the valves’ leaflets are sutured to the metallic stent and crimped on the delivery system prior to the procedure. As an alternative approach, a novel polymeric valve that was developed by our group [7, 8] is being commercialized by Polynova Cardiovascular, Inc. (Stony Brook, NY) and adapted to TAVR using a self-expanding stent. Polymer TAVR valves could represent a better solution in terms of device reliability by better withstanding crimping and deployment processes. Thus, the reduced mechanical damage could lead to better performance and durability of the device.

Although TAVR is preferable to medicinal treatment in inoperable patients and has equivalent outcome to SAVR in high risk patients [9], several adverse effects may occur as a consequence of a sub-optimal procedure. Among the most important, aortic root (AR) injury or paravalvular leakage (PVL) [10, 11] may result in cases when excessive or insufficient expansion forces were applied, respectively. In the latter case, failing to anchor the valve might lead to its migration into the left ventricle [12, 13] or toward the aortic side (embolization) [14]. The main reason for such intra- and post-procedural complications are related to the presence of large deposits of calcium in situ that lead to a valve malposition and a sub-optimal anchorage [15].

In the last few years, the mechanical behavior and hemodynamics of TAVRs were studied both numerically and in-vitro [16, 17]. To date, a comprehensive numerical model with both realistic patient-specific AR pathology and the whole prosthetic valve has not been developed. Moreover, no previous studies were directly aimed to guide surgeons for optimal deployment but mainly to test the effectiveness of the methods employed.

The aims of this study are to comparatively assess the crimping mechanics of Edwards SAPIEN and Polynova valve and to evaluate the effect of different TAVR deployment positions on a patient-specific anatomy. The deployment of Edwards SAPIEN valve in heterogeneous patient specific models was modeled in three axial locations, in order to replicate possible surgical options during the procedure. The optimal deployment location for achieving better patient outcomes was based on the interactions between TAVR stent and the native AR.

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II. METHODS

A. TAVR Crimping

The TAVR valves’ stent were obtained by applying parametric equations [18] in SolidWorks (SolidWorks, DS, Corp., Waltham, MA). The balloon expandable Edwards SAPIEN with stent size of 26 mm was considered. The stent is made of stainless steel (AISI 316 LVM) whereas the bioprosthetic leaflets are derived from bovine pericardium. The Polynova valve consists of a super-elastic nitinol stent and xSIBS (Styrene-block-IsoButylene-block-Styrene) leaflets, whose material properties were experimentally obtained from uniaxial tensile test [8]. The stent and leaflets were constrained to move together on their connective surfaces. The crimping process was simulated by applying radial displacement on a thin-walled cylindrical crimper. The fully crimped positions were defined as outer diameter of 8 mm (24 Fr catheter) for SAPIEN valve and 9 mm for Polynova valve (Fig.1). Contacts and constrains were appropriately defined in order to capture the complex leaflets’ folding during the stent elongation. The models were meshed and solved in ANSYS Explicit dynamics (Canonsburg, PA).

B. Patient-specific AR reconstruction

The AR geometries were obtained from two patients that experienced migration during TAVR procedure in Stony Brook University Hospital (SBUH). This study followed an IRB protocol approval from Stony Brook University. The anatomical patient-specific models were built from iodine-contrast Computed Tomography Angiography (CTA) scans via three dimensional (3D) segmentation of DICOM images. After contrast enhancement, intensity range thresholding was performed in ITK-SNAP [19] to lead the evolution of initialized contour snakes and to accurately extract the boundaries of the blood domain and the calcification regions. A range of 150-500 HU and >500 HU was employed to extract lumen and calcium deposits, respectively. The outer surface of the root’s walls was then obtained in MATLAB (Mathworks Inc., Natick, MA) by normally extruding the lumen surface with a constant thickness for the sinus and a variable-thickness for the AV native leaflets, between 1.56 mm at the sinus-leaflets interface and 0.39 mm at the leaflets free edges. The variable thickness of the soft tissue was then locally adjusted to completely embed the calcifications and to more accurately replicate the AR pathophysiology.

The size of the deposits was downscaled in order to take into account their blooming effect on CTA images that makes them appear bigger than they actually are. A solid model was then created in ANSYS Design Modeler (Canonsburg, PA) and the deposits were bonded to the surrounding soft tissue, thus mimicking the typical thicker and stiffer tissue behavior of the stenotic AV.

C. TAVR deployment

Pressure on the ventricular side of the leaflets was applied in ANSYS Mechanical in order to model the native leaflets opening by pushing the delivery system through the valve. The patient-specific AR model and the crimped TAVR valve were then assembled and the TAVR deployment was replicated in Finite Element Analysis (FEA). The axial positioning of the prosthetic valve with respect to the AV annulus plane was parametrized, to replicate different choices of the surgeon during the procedure. These positions were the midway, 70% of the stent length in the ventricular side and 70% in the aortic side (Fig.2). The distal cross-section of the AR was constrained allowing only rotational degrees of freedom whereas the valve was expanded via balloon inflation. The optimal deployment configuration is assessed based on the stent deformation, on the extent of the gaps between the stent and the AR wall, and on the peak values of stress in the native valve.

As a first step, the soft tissue of the native AR was modeled as hyperelastic material using Ogden law fitted to published experimental data from animal leaflets samples [20], whereas the calcifications were assumed to have homogeneous linear elastic response with Young modulus of 12.6 MPa [21]. In the next step, the soft tissue will be modeled as isotropic hyperelastic material calibrated with tensile-test measurements of excised pathologic leaflets from SAVR patients that were obtained from SBUH Tissue Bank. The calcium material model will be calibrated to nanoindentation measurements of the calcified part of the same specimens, applying a trapezoidal-shaped load that allows tissue response stabilization under solicitation. In order to map the calcification patterns on the samples, µCT scanning will also be performed beforehand.

Consequently, the AR blood domain was extracted from the resulted optimal deployed configurations. Two Computational Fluid Dynamics (CFD) analyses for each patient were then performed in order to estimate the PVL volume in diastolic phase and the peak blood velocity and transvalvular pressure gradient during systole. Accordingly, the valve was assumed to be in its fully open position under peak systolic flow conditions. Volumetric flow magnitudes and transvalvular pressure gradient were obtained from intra-procedural echo-Doppler measurements of the same patients.

![Edwards SAPIEN Polynova](image)

Figure 1: Representative views of the investigated TAVR valves

![Figure 2: FE model of a patient-specific AR and crimped SAPIEN valve in midway (left), aortic (middle) and ventricular (right) positions before deployment](image)
The flow measurements were applied as flow boundary conditions, while pressure gradients were used for verification purpose. These flow models will allow calculation of the thrombogenic footprints based on the stress accumulation along platelet trajectories. Platelets will be released in the domain and the scalar flow stress history for each of them will be calculated. Probability density function will enable assessing the thrombogenicity of the deployed device and localizing the hotspots regions where particles are exposed to the highest stress magnitudes.

III. RESULTS

Stress distributions on both TAVR valves were investigated during the crimping procedure, to assess the regions of maximum stress concentration on the device and the risk to mechanical damage of the prosthetic leaflets. In the fully crimped configuration, the maximum stress levels in the stents were higher in the SAPIEN than the Polynova valve, 65.3 GPa vs. 33.8 GPa, respectively (Fig. 3). The highest stress levels in the Polynova stent were observed on the aortic side of the struts where buckling occurs, whereas for SAPIEN valve the highest stresses were observed on the strut joints.

The same trend was found in the leaflets, with maximum Von Mises values of 16 MPa and 3.4 MPa in SAPIEN and Polynova valve, respectively. The location of the maximum stress on the leaflets was observed in the subcommisural triangles near the leaflets bonding with the metallic frame in both valves. The mismatch in stiffness between the stent and the softer-material of the leaflets played a key role in the definition of the stress concentration in this region. The minimum stresses for both valves were observed at the belly region of the leaflets, in regions that are far from the foldings. Given the different material of the valves, normalization of the obtained maximum Von Mises stresses with respect to the ultimate tensile stresses [8, 22] was performed. The normalized values are 9.1% and 24.7% for the novel Polynova and SAPIEN valve, respectively, thus indicating that xSIBS valve experiences a stress condition that is further from the dangerous range of deformations that leads to material failure (Fig. 3).

The deformed crimped position of the SAPIEN valve was placed in situ in the patient specific root with the balloon of the delivery system. The orientation of the device was kept to be normal to the AV annulus plane. The anchorage of the valve and the stress field caused by the valve deployment was assessed for the three different axial configurations. Stresses within the wall and the interaction of calcium-soft tissue were investigated during the whole deployment procedure. Given their higher stiffness, higher stress levels were found in the calcium deposits than in the soft tissue, thus leading to a higher gradient across the border of the calcifications (Fig. 4). At the beginning of the valve balloon-expansion, the deposits and the surrounding soft tissue moved in solidarity; however, in the late stage of the crimping bigger and sharp deposits rip apart the soft tissue, thus becoming exposed and in contact with the device.

The future use of more realistic stiffer soft-tissue properties from pathologic valves might prevent this phenomenon.

For the two patients investigated, who experienced valve migration during the procedure, incomplete expansion of the valve occurred. The distance between the outer surface of the stent and the AR inner wall was quantified and the maximum values were observed around the largest calcium deposits, leading to higher deformation of the prosthesis. These locations are expected to suffer from PVL occurrence in the following flow analysis. The risk-minimizing deployment configuration was assessed for both patients.

Lastly, diastolic CFD analysis demonstrated and confirmed the occurrence of PVL in the regions with largest gaps from the valve. In the systolic CFD model the pressure gradient across the valve was lower than 10 mmHg, a significant hemodynamic improvement after the TAVR intervention.
IV. CONCLUSION

The current study presented comparison of two TAVR valves and three deployment positions based on the stress distributions during the crimping procedure and the following deployment in patient-specific roots. It was followed by hemodynamic assessment of the PVL phenomena in the resulted deployed configurations.

The crimping simulations showed that Polynova performed better in terms of stress withstanding, whereas in the deployment simulations the reconstructed calcifications prevented a complete anchoring of the stent to the patient’s AR, thus leading to a higher risk of migration.

The optimized deployment configurations were found and based on the actual patient’s pathology. Hence, such accurate patient-specific AR models that include the vessel wall thickness and calcification deposits could help develop guidelines for TAVR interventions while assuring good anchoring and preventing valve migration. Modeling the material properties based on experimental measurements of stenotic human leaflets could lead to more accurate calculation of the pathophysiologic tissue response.

Additionally, optimizing the positioning of the valve during deployment, as well as suggesting alternative approaches to TAVR valves tailored to patient’s specific pathology, e.g. polymeric valves, may offer better procedural outcome. Ongoing studies in the CFD models include calculation of thrombogenic footprints based on stress accumulations along platelets trajectories. Fluid Structure Interaction (FSI) analyses will be performed to further capture the mechanical behavior of the valve through the entire cardiac cycle.

Finally, in vivo studies will be performed in an ovine model to examine the influence of TAVR stent design, valve leaflet material choice and landing zone location. Valve thrombogenicity, with associated markers of hemolysis and inflammation, will be examined as well.

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REFERENCES