INTRODUCTION
Calcific aortic stenosis (CAS) is a formation of calcium deposits that thickens and stiffens the aortic valve’s leaflets, thus causes a significant obstruction to blood flow during systole and limits the closure during diastole. Currently, replacement of the stenotic valve with a prosthetic valve is the only effective treatment. In recent years, a minimally invasive option of transcatheter aortic-valve replacement (TAVR) is available for high-operative-risk patients. The prosthetic valve is comprised of a bio-prosthetic leaflets mounted on a metal stent that is deployed on the diseased leaflets and therefore ‘anchored’ only by contact between the native root and the stent. A possible suboptimal deployment location can cause longitudinal shift of the prosthesis during the deployment [1] or post-procedural migration [2] as a result of paravalvular leakage (PVL). Currently, despite several modeling attempts to replicate the procedure, few studies investigated different stent positioning. However, these models employed either a non-calcific aortic root (AR) geometry [3] thus neglecting the effect of the calcifications on the deployment outcome, or a self-expandable TAVR valve [4]. None of them modeled the influence on the PVL hemodynamics.

The aim of this work is to evaluate the effect of different TAVR deployment positions on the procedural outcome by specifically assessing risk for migration phenomena. As a first stage toward this goal, a finite element analysis (FEA) of Edwards SAPIEN valve crimping, with the prosthetic leaflets, was performed. Then, the crimped TAVR stent was deployed via balloon-inflation in a patient-specific calcified AR in three and in various locations. After a recoiling period, when the stents achieved their final position, the PVL will be evaluated by employing computational fluid dynamics (CFD) models of these configurations. Thrombogenic potential will be calculated from platelets particle flow through the paravalvular gaps.

METHODS
An 88-year-old male patient with annulus diameter of 23 mm was implanted with 26 mm Edward SAPIEN TAV in Stony Brook University Hospital. The valve was deployed via transfemoral approach and migration of the prosthesis into the LV cavity occurred after retrieval of the delivery system. The CTA scans of this case were collected after obtaining approval from IRB. The DICOM files were processed in the open source segmentation tool ITK-SNAP v3.2 to extract the blood lumen and the calcifications domains. The aortic vessel wall was extruded with a homogenous thickness while for the AV leaflets thickness varied proportionally to the radial location, resulting in thinner leaflets toward the free edge. The soft tissue thickness was then modified by to assure that the deposits are fully embedded in it. The shape and area of the AV opening were determined from the CT and echocardiography measurements.

The stent of the balloon-expandable Edwards SAPIEN is made of stainless steel (AISI 316 LVM) and was modeled as elastic material [5], whereas the bioprosthetic leaflets were modeled as hyperplastic [6]. The crimping process was simulated by radially displacing a cylindrical crimper in Abaqus Explicit 6.14 (SIMULIA, Dassault Systèmes, Providence, RI). The stent was meshed with 69,876 brick elements and the bioprosthetic leaflets with triangular-shell elements The stent was fully crimped to outer diameter of 8 mm. The balloon was meshed with 216,960 quadrilateral elements, its thickness was 0.06 mm, and its material was linear elastic [5]. The balloon deflation was modeled to fit inside the crimped stent.

The AR mesh was smoothed with ANSYS 15 Fluent Meshing obtaining a tetrahedrons-based mesh that can facilitate large deformations. The AR sinus, calcifications and each leaflet were modeled with independent material models. Three deployment configurations were simulated by placing the stent centroid in the AV
annulus plane, 30% shifted toward the aorta, and 30% shifted toward the left ventricle (LV) cavity and referred to as midway, distal and proximal, respectively (first row of Figure 1). In every model, the balloon was gradually inflated to a pressure of 1.38 atm and, once reached the full deployment, the stent was allowed to recoil.

The blood domain was extracted from each deployed configuration and the hemodynamics through the paravalvular gaps was investigated. Thrombogenicity is calculated from stress accumulation along the trajectories of platelets passing through these gaps. As a preliminary study, a novel TAVR valve’s model was employed. The fluid domain geometry was obtained from the Living Heart Model (SIMULIA, Dassault Systèmes, Providence, RI), inclusive of a healthy AR, ascending aorta and aortic arch. The pressure and flow boundary conditions were obtained from Olufsen et al. [7] and the CFD simulations were carried out in ANSYS Fluent 16.2.

RESULTS

Similar stress distribution patterns and magnitudes were observed in the distal and the midway cases, where the maximum value was in the contact region (Figure 1). The embedded calcifications experience higher stresses than the surrounding soft tissue (for example, 3.4 MPa vs. 0.5 MPa), as a result of the stiffer material properties. The proximal deployment resulted in higher stress magnitudes at the middle of the deployment and in overall lower stresses at the end of the deployment.

The anchorage strength and the landing zone of the three configurations were quantitatively assessed based on the contact between the stent and the AR in the final recoiled configuration. Spatial maximum contact pressures at the end of the recoil were then calculated, with the distal deployment resulting in the highest magnitude of 10.38 MPa, compared to the midway and proximal cases (6.26 MPa and 3.84 MPa, respectively). In the first period of the deployment (until 80%), the inflated balloon develops the characteristic “dog-bone” configuration and then it expanded rapidly. It can be seen from the quick increase in the area. At the beginning of the recoil, when the contact with the balloon stopped, a sudden drop of the contact area can be seen. The proximal deployment experienced a loss of almost 75% of the contact area at the end of the recoil when the stent dislocated to the LV (Figure 2).

The preliminary CFD analysis demonstrates that the strong systolic jet leads to a maximum wall shear stress on the aortic wall in front of the valve (Figure 3). The ascending aorta creates a right-handed helical flow. The wall shear stress magnitude on the aortic side of prosthetic leaflets was found to be the highest on the valve surface (90 Pa). Based on the final deployed configurations in the patient-specific AR, the diastolic flow in the distal and midway positions is being evaluated. Regurgitations through the paravalvular gaps appear to be more pronounced in the midway configuration. Higher thrombogenic potential is expected to be found in the gaps with higher flow rate.

DISCUSSION

This study investigated the impact of TAVR deployment position on the procedural success with a focus on the risk of device migration. The comparison of the three positions showed that proximal deployment could lead to migration into the LV. This case resulted in lower contact area, which led to higher localized contact pressure and higher stress levels in the native tissue. The distal and midway configurations had comparable outcomes that would probably lead to similar performance. The influence of the TAVR valve on the hemodynamics in the anatomical aortic arch was numerically modeled for the first time. We plan to model the flow through the paravalvular gaps with fluid-structure interaction and estimate the thrombogenicity of the various configurations. After further validation of the current methods, the proposed approach might be used as a predictive tool for procedural planning in order to ultimately prevent prosthesis migration. In addition, the calculated thrombogenic potential may help design better procedure, by reducing the risk for thrombus formation and stroke events.

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REFERENCES