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Patient-Specific Computational Approach for Trans Catheter Aortic Valve Replacement (TAVR): Pre-Procedural Planning for Enhancing Performance and Clinical Outcomes

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1 Introduction

Transcatheter aortic valve replacement (TAVR) has emerged as a life-saving solution for inoperable elderly patients with end-stage calcific aortic valve (CAV) disease [1]. However, valve migration, paravalvular leakage (PVL), and thrombus formation may limit its expansion into younger, lower-risk patients [2]. Peri-procedural complications such as prosthesis migration and PVL may occur as a result of suboptimal placement, leading to poor device performance, and higher risk of re-intervention. Furthermore, cardiac conduction abnormalities (CCAs) have been repeatedly reported that may be triggered by mechanical compression exerted by the stent on the membranous septum (MS) and left bundle branch (LBB) of the AV node upon deployment. Those may require post-procedural implantation of a pacemaker. Previous numerical studies attempted to address these complications but did not include the effects of heart beating on the valve post-deployment performance [3]. Utilizing the electro-mechanical Simulia Living Heart Human Model (LHHM), the effects of heart beating, coupled with a fluid-structure interaction (FSI) simulations, were studied to evaluate TAVR performance and complications. Patient-specific models were reconstructed from CT images. Biomechanical and fluid structure interaction (FSI) simulations were conducted in these models to study the effect of TAVR deployment and positioning on stent anchorage in both self-expanding and balloon inflated TAVR valves, and its effects on the degree of post-procedural PVL and risk of CCAs was quantified.

2 Materials and Methods

High-resolution aortic root (AR) patient-specific models (n = 5) were reconstructed from pre-TAVR CT scans of patients suffering from PVL and CCAs after TAVR. Aortic valve (AV) leaflets were modeled with variable thickness and calcifications were embedded in the aortic root to better mimic the stenotic tissue [1]. TAVR valves were modeled and their deployment was simulated via an Abaqus Explicit FEA. Stent anchorage was quantified in terms of contact area and mean pressure with the AV whereas risk of CCAs was quantified by calculating the maximum logarithmic strain in the region of the MS and LBB as function of time. A transient post-deployment CFD analysis was then performed in ANSYS Fluent to assess degree and distribution of PVL as total regurgitant volume and effective regurgitant orifice area during diastole. Validation was performed with the same patient-specific post-TAVR echo Doppler measurements.

A self-expandable TAVR valve (Evolut R; Medtronic, Inc.) implantation procedures were simulated in the electromechanical LHHM model (Abaqus Explicit 6.14; Dassault Systèmes). Three implantation depth locations (aortic, midway, and ventricular) were modeled to study the valve anchorage. The anchorage was evaluated based on the calculated contact area between the stent's outer frame with the native CAV over time [3]. FSI simulation of the deployed TAVR was conducted to study the valve hemodynamics, degree of PVL, and its throbogenicity using FlowVision (Multi-Physics Manager 3.10; Capvidia) and a finite element solver (Abaqus Explicit 6.14) during the FSI analysis fluid and structural solution, respectively.

3 Results and Discussion

Three PVL and two CCAs cases have been reconstructed and analyzed with three positions (aortic, midway, ventricular) and two balloon expansions (nominal and over-expansion).

Positioning led to a 47% reduction in PVL regurgitant volume in the best scenario, thus leading to remarkably different post-procedural outcome (Fig. 1). PVL location and grading performed according to the ASE guidelines showed strong agreement with echocardiographic data for all the patients investigated. Ventricular positioning of the CoreValve resulted in almost double ($log\varepsilon_{max} \approx 10\%$) maximum logarithmic strain in the LBB region in proximity of the cardiac conduction fibers, thus suggesting an increased risk for CCAs. Figure 1A, B, and C represent a deployed stent in LHHM, the stent configuration at the end of 3rd cardiac cycle, and the stent anchoring contact area over time, respectively. The optimal stent anchorage was observed when the stent was deployed more towards the ventricular side (Fig. 1B; right) and migration was observed when the implantation was more towards aorta (Fig. 1B; left). Therefore, the TAVR valve configuration from the ventricular positioning was used during the FSI analysis (Fig. 1D). Recirculation zones were observed in the sinuses throughout systole and a helical flow pattern was formed in the aortic arch region during peak systolic phase. During diastole, PVL flow was observed near the commissures. PVL degree and thrombogenicity quantification through PVL gaps are currently being studied to determine the optimal valve positioning.

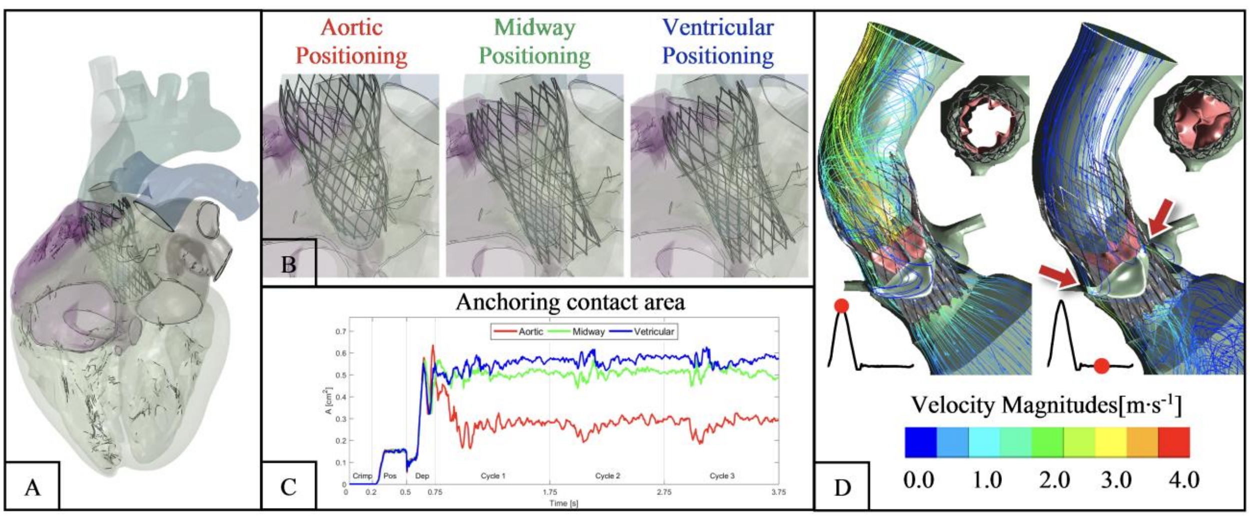

Figure 1. (A) Deployed Evolut R in LHHM; (B) stent configurations at 3 implantation depth locations; (C) contact area on CAV over time to evaluate anchorage (D) The deployed TAVR valve flow velocity streamlines after 3rd cardiac cycle. Arrows point to the PVL flow through commissures.

4 Conclusions

A computational approach was developed by employing FEA and CFD techniques to investigate prosthesis anchorage and post-TAVR hemodynamics in retrospective clinical cases affected by PVL and CCAs. The presented numerical analysis is first of its kind to study TAVR valve structural and hemodynamics performances during heartbeat. This study demonstrated that rigorous and realistic patient-specific numerical models could potentially serve as a valuable tool to assist in pre-operative

TAVR planning and transcatheter aortic valve selection to ultimately reduce the risk of clinical complications. This numerical methodology can also serve as a predictive tool for valve design optimization and and as guideline for achieving enhancing pre-procedural planningbetter clinical outcomes of TAVR patients.

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