COMPUTATIONAL MODELLING APPROACHES TO ASSESS THE IN VITRO PERFORMANCE OF A TAVR DEVICE

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Introduction

Transcatheter aortic valve replacement (TAVR) has emerged as an effective percutaneous treatment option for aortic stenosis, but the devices can be prone to early structural valve degeneration (SVD) due to mechanical damage or calcification.

Solid mechanics or fluid dynamics computational modelling approaches have been used to assess the performance of TAVR [1,2]. Fluid-structure interaction (FSI) approaches can investigate dynamic interactions between the device and adjacent blood flow. Such approaches have been applied in a limited fashion [3], but may be appropriate for analysis of pulsatile flow induced cyclical deflections of the valve leaflets and stent to understand the occurrence of SVD and overall device durability.

The objective of this study is to understand the impact of pulsatile flow induced leaflet and stent deformations on TAVR durability. To address this objective, we characterize the impact of pulsatile flow on the BHV and stent deflection using (a) a decoupled-Finite Element (FE) validated against experimental data and (b) a fully-coupled FSI model of a self-expanding TAVR device.

Methods

FE models of the ACURATE neo2 were developed using Abaqus/Explicit (Dassault Systemes), with representative material properties and pressure-based loading conditions. To account for the effects of the surrounding fluid in the FE model, a sensitivity analysis of the Rayleigh damping coefficient was conducted. Models were validated with in vitro test data of the ACURATE neo2 valve within a ViVitro Pulse Duplicator (ViVitro Labs). The impact of stent rigidity on the durability of the device was investigated using rigid boundary conditions, representative of first-generation, highly rigid Surgical Aortic Valve Replacement (SAVR) devices. These were compared to a model that incorporated a deformable TAVR stent (Fig. 1a). A fully-coupled FSI model of the TAVR device is in development, using the sub-grid geometry resolution (SGGR) method, which couples Abaqus CAE with FlowVision CFD (Capvidia, Leuven, Belgium).

Results

The FE model of the TAVR device showed good alignment with in vitro data, exhibiting a similar geometric orifice area, leaflet coaptation area and stent-commissure deflections. A high damping coefficient was required to capture the in vitro kinematics of the leaflets. For both rigid (SAVR) and deformable (TAVR) models, the peak maximum principal stress and strain

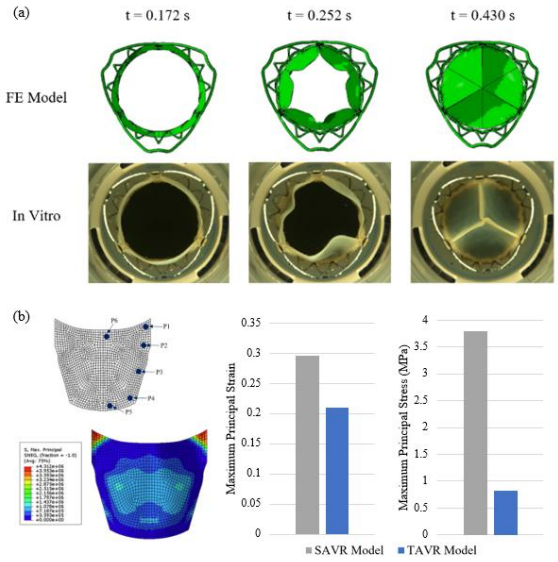

Figure 1: (a) Validation of FE model with deformable stent, (b) Leaflet stress-strain at commissure region (P1) for rigid (SAVR) and deformable (TAVR) models

occurred at the leaflet commissures (P1, Fig. 1b). Rigid boundary conditions greatly increased leaflet stresses.

Discussion

FE results predict that a rigid boundary condition, representative of a SAVR device, was associated with higher peak leaflet stresses in regions where failure has been reported in SAVR devices [4]. Thus, we propose that stent deflection may improve the durability of the BHV leaflets, reducing the risk of early SVD. Indeed, clinical trials reported a significantly lower rate of SVD in a self-expanding TAVR compared to SAVR devices [5]. However, it is important to note that models developed in this study do not account for device-specific variations in leaflet design. Additionally, the FE models cannot account for the effect of the surrounding flow, which induces complex pulsatile flow conditions on the device. A fully-coupled FSI model is in development to study pulsatile flow induced leaflet and stent deflections on TAVR device durability.

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