PRECLINICAL BIOMECHANICAL ASSESSMENT OF HEART VALVE PROSTHESES THROUGH FLUID-STRUCTURE INTERACTION ANALYSIS

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Introduction

Computer modelling has increasingly attracted interest in the field of medical device development. Credible simulations can effectively complement and partially replace *in vitro* tests, thereby reducing time and costs associated with the device development process [1]. Specifically, fluid-structure interaction (FSI) simulations have emerged as the most comprehensive *in silico* approach for the investigation of prosthetic heart valves biomechanics, accounting for both valve leaflets kinematics and fluid dynamics [2]. This work introduces a FSI framework for the analysis of the fluid dynamics of bileaflet mechanical aortic valves (BMAVs), enabling the evaluation of the impact of valve positioning and design on flow structures. The framework can also replicate the preclinical bench tests recommended by standard ISO 5840:2021 for assessing valve hydrodynamic performance and evaluating thrombogenic and hemolytic aspects induced by fluid mechanics, potentially substituting *in vitro* experiments.

Methods

Two geometrical models of BMAVs, resembling Abbott Regent (Abbott Laboratories) and On-X (Artivion) valves, were generated with SolidWorks (Dassault Systèmes) (Fig. 1A). An idealized geometrical model of a straight aortic root including the sinuses of Valsalva was implemented according to a previous study [3]. Each BMAV model was assembled with the idealized aortic root, considering three scenarios corresponding to a rotation angle of 0°, 15°, 30° with respect to the axis of reflection symmetry of one aortic sinus. The resulting models were meshed in HyperMesh (Altair). FSI simulations were conducted using LS-DYNA R14.1 (Ansys Inc.), with an “operator split” Lagrangian-Eulerian approach. Physiological ventricular and aortic pressure waveforms were imposed at the inlet and outlet of the fluid domain, respectively. The no-slip condition was applied at the solid-fluid interface. The aortic wall was assumed as rigid.

Results

The color maps of the velocity magnitude at peak systole show that the FSI framework captures the three-jet configuration of the systolic flow past BMAVs (Fig. 1B-C). Results highlight that valve rotation angle does not affect markedly BMAVs hemodynamics (Fig. 1B). Conversely, the different valve designs impact the velocity field, with the On-X valve characterized by markedly different velocity profiles, as shown e.g. in the case of an identical rotation angle of 30° for the two valves (Fig. 1C). The effective orifice area (EOA) for the Regent valve was equal to 2.04 cm^2, 1.72 cm^2 and 1.85 cm^2 for a rotation angle of 0°, 15° and 30°, respectively. Corresponding values for the On-X valve were 1.90 cm^2, 1.81 cm^2 and 1.77 cm^2. All the computed values satisfy ISO requirements (EOA $\geq$ 1.45 cm^2).

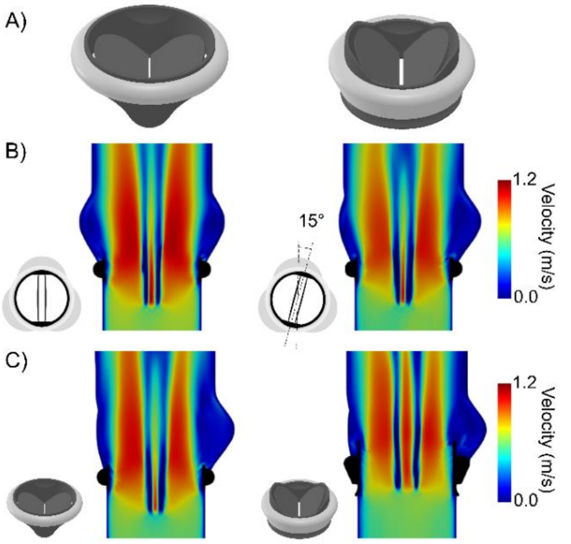

Figure 1: A) CAD models of the Regent (left) and On-X (right) valves; B) color maps of velocity magnitude on a long-axis section at peak systole for the Regent valve with rotation angle of 0° (left) and 15° (right); C) color maps of velocity magnitude on a long-axis section at peak systole for the Regent (left) and the On-X (right) valve with a rotation angle of 30°.

Discussion

The proposed FSI framework enables a comprehensive analysis of BMAV hemodynamics, potentially supporting preclinical device evaluation. Preliminary results demonstrate the framework’s suitability for investigating the impact of valve design and positioning. Additionally, fluid velocity fields can also be further analyzed to extract flow features related to adverse biological events. Finally, after proper validation, the simulation setup can be easily adapted to replicate *in vitro* pulsatile tests recommended by international standards, potentially substituting bench tests to verify adequate hydrodynamic performance and assess blood damage potential.

References

1. Viceconti et al, Methods, 185:120-127, 2021.
2. Nobili et al, J Biomech, 41:2539-2550, 2008.
3. Carbonaro et al, Struct Multidiscip Optim, 2021.