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Hemodynamic and thrombogenic analysis of a trileaflet polymeric valve using a fluid–structure interaction approach

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ABSTRACT

Surgical valve replacement in patients with severe calcific aortic valve disease using either bioprosthetic or mechanical heart valves is still limited by structural valve deterioration for the former and thrombosis risk mandating anticoagulant therapy for the latter. Prosthetic polymeric heart valves have the potential to overcome the inherent material and design limitations of these valves, but their development is still ongoing. The aim of this study was to characterize the hemodynamics and thrombogenic potential of the Polynova polymeric trileaflet valve prototype using a fluid–structure interaction (FSI) approach. The FSI model replicated experimental conditions of the valve as tested in a left heart simulator. Hemodynamic parameters (transvalvular pressure gradient, flow rate, maximum velocity, and effective orifice area) were compared to assess the validity of the FSI model. The thrombogenic footprint of the polymeric valve was evaluated using a Lagrangian approach to calculate the stress accumulation (SA) values along multiple platelet trajectories and their statistical distribution. In the commissural regions, platelets were exposed to the highest SA values because of highest stress levels combined with local reverse flow patterns and vortices. Stress-loading waveforms from representative trajectories in regions of interest were emulated in our hemodynamic shearing device (HSD). Platelet activity was measured using our platelet activation state (PAS) assay and the results confirmed the higher thrombogenic potential of the commissural hotspots. In conclusion, the proposed method provides an in depth analysis of the hemodynamic and thrombogenic performance of the polymer valve prototype and identifies locations for further design optimization.

1. Introduction

Valvular heart diseases (VHD), such as calcific aortic stenosis, aortic and mitral regurgitation, affect 2% of US population, increasing to 4.5% for patients over 65 years old (Go et al., 2014). Aortic stenosis is the most frequent disease, accounting for up to 43% of VHD (Roger et al., 2012). The only viable treatment to address aortic stenosis is the replacement of the calcified valve with a prosthesis. Both mechanical heart valves (MHV) and bioprosthetic heart valves (BHV) are considered mature and trusted technologies (Bezuidenhout et al., 2014). In most cases, MHVs offer a life-long durability and are implanted primarily in younger patients, whereas BHVs offer optimal hemodynamic performance but with limited durability, and are intended for older patients. As a result of their impaired hemodynamics, MHVs induce elevated flow stresses on the blood cells, especially shear stress activation of platelets, mandating lifelong anticoagulation therapy to mitigate the attendant risk of thrombosis and cardioembolic stroke. Performance of BHVs is eventually compromised by structural degradation and premature calcification (Bezuidenhout et al., 2014; Bluestein et al., 2010; Claiborne et al., 2012; Daebritz et al., 2004).

Flexible trileaflet polymeric heart valves (PHV) were first suggested almost six decades ago (Kuan et al., 2011) but suffered from a checkered history. Following advances in material and polymer science it was reintroduced in recent years to overcome the inherent limitations of MHVs and BHVs. An optimized PHV could combine the low thrombogenicity and high durability features of these two valves types while eliminating their deficiencies

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(Claiborne et al., 2011). In vitro and in vivo performances were assessed under various testing conditions to determine common fluid dynamic parameters (Bezuidenhout et al., 2014; Claiborne et al., 2012). These analyses were used for comparison with commercially available prosthetic valves and established the promising features of the novel polymer prostheses. However, there is still a need to further optimize the structural durability and the thrombogenic potential of the PHVs.

Our device thrombogenicity emulation (DTE) methodology combines in silico and in vitro approaches to evaluate and optimize the thromboresistance of cardiovascular devices in order to facilitate their long-term use (Bluestein et al., 2013). We previously applied this methodology to optimize various cardiovascular devices, such as ventricular assist devices (Chiu et al., 2013), MHVs (Alemu et al., 2010; Nobili et al., 2008a; Xenos et al., 2010), and for the first-stage optimization of a trileaflet PHV prototype (Claiborne et al., 2013b). In the latter study, the thrombogenic potential of the valve was assessed with the valve either in the fully open position during forward flow or with the valve closed during regurgitation. More realistic description of the dynamic flow field during the entire cardiac cycle can be achieved with fluid–structure interaction (FSI) methods. The FSI approach was previously applied for the analysis of flow in native valves (Carmody et al., 2006; Hart et al., 2003; Nicosia et al., 2003; Sturla et al., 2013), but not in prosthetic valves that can be optimized based on their thrombogenic potential. FSI can be utilized to study PHVs hemodynamics and can further be integrated into the DTE methodology in order to optimize the thromboresistance of PHVs.

The aim of the current work was to develop a novel FSI model that can mimic the experimental hemodynamic conditions of the valve as tested in a ViVitro Left Heart Simulator (ViVitro Labs Inc., Victoria, BC, Canada). In this study, the PHV that was tested was a surgical version of the polymer valve that has been developed in Stony Brook University (Claiborne et al., 2013b) and is being commercialized by Polynova Cardiovascular Inc. (Stony Brook, NY, USA). The FSI approach was employed for the full cardiac cycle to obtain a more reliable solution of the fluid shear stresses and the thrombogenic potential. Flow-related FSI results were compared with experimental data to validate their validity. Additionally, the thrombogenic potential of the valve was calculated from a large population of platelets flowing through the valve, with several regions of interest emulated experimentally and their corresponding platelet activity measured in vitro.

2. Materials and methods

2.1. Numerical approach

The FSI numerical models were solved in the commercial explicit finite element solver LS-DYNA 971 (Release 5.1, LSTC, Livermore CA, USA). The interface between the structure and the flow was modeled through the "operator split" Lagrangian–Eulerian approach (Sturla et al., 2013). This method can couple non-conformal meshes for the fluid and solid domains, while the elements of the fluid grid are fixed and static. Therefore, this method is not subjected to the well-known remeshing and contact related issues that affect Arbitrary Lagrangian–Eulerian (ALE) or Cut-Cell methods (Marom, 2014). Similar to Immersed Boundary method, the coupling algorithm transfers forces between the fluid and the solid grid, while no-slip conditions are indirectly imposed as in the Fictitious Domain method (Marom, 2014). This numerical approach advancements entailed a significant computational cost: approximately 192 h on an Intel Xeon (2.93 GHz) workstation with 12 processors.

2.1.1. Geometry and finite element discretization

The three dimensional (3-D) geometries were generated using SolidWorks (Dassault Systèmes SolidWorks Corp., Waltham, MA). The PHV (Fig. 1A) was characterized by internal (D_i) and external (D_e) diameters of 19 and 26 mm, respectively. The height (H) of the supporting structure was 15.3 mm. The dimensions of the fluid domain, which replicates the ViVitro chamber, are also given in Fig. 1B. To move the boundary conditions further away from the region of interest, two rigid

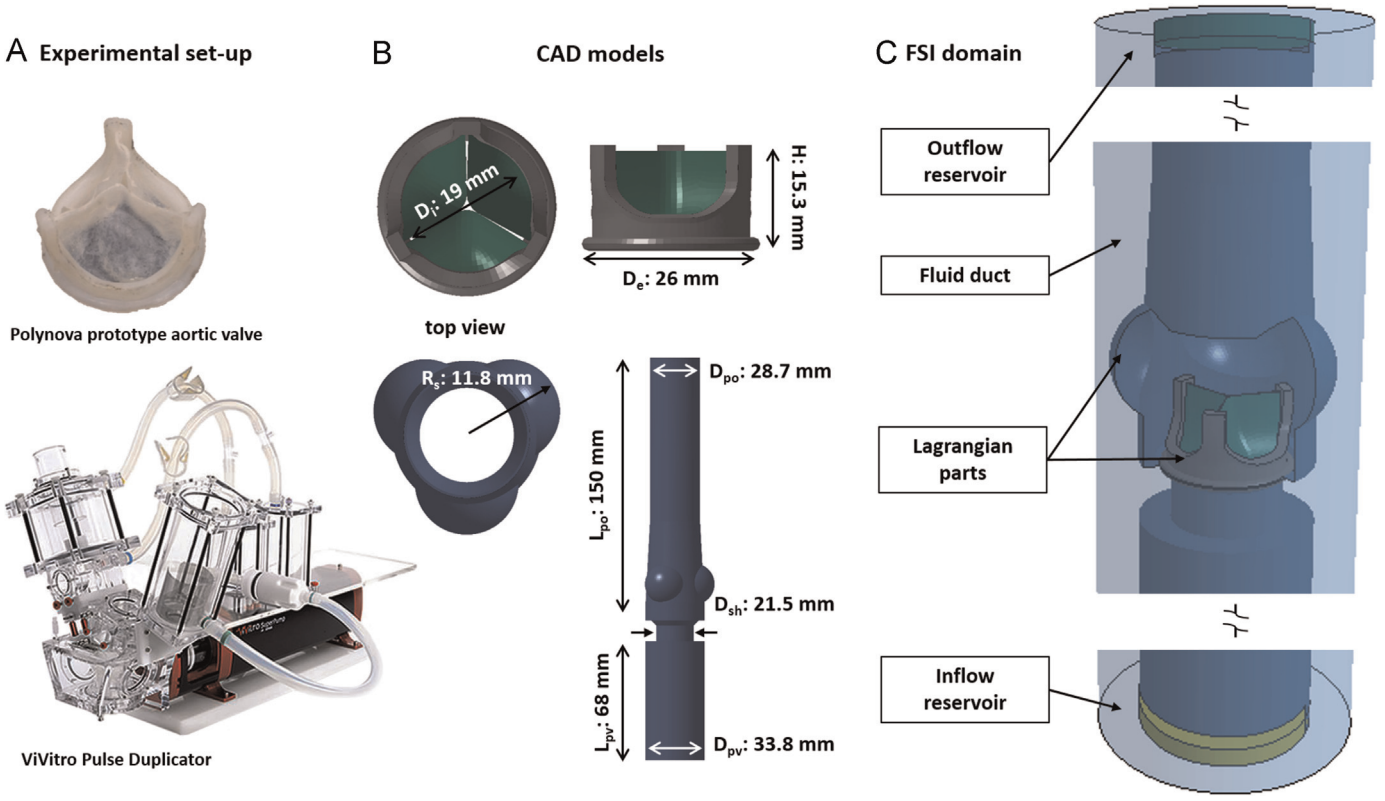

Fig. 1. (A) The experimental set-up: Polynova polymeric valve prototype and the ViVitro Pulse Duplicator. (B) Geometrical CAD models used to replicate the prosthesis and the fluid domain. Representative geometrical features are displayed. (C) Overall view of the parts composing the FSI domain. Eulerian parts: inflow, outflow reservoirs and cylindrical fluid duct. Lagrangian solid parts: ViVitro chamber, valve's supporting structures and leaflets.