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Evaluation of an aortic valve prosthesis: Fluid-structure interaction or structural simulation?

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ABSTRACT

Bio-inspired polymeric heart valves (PHVs) are excellent candidates to mimic the structural and the fluid dynamic features of the native valve. PHVs can be implanted as prosthetic alternative to currently clinically used mechanical and biological valves or as potential candidate for a minimally invasive treatment, like the transcatheter aortic valve implantation. Nevertheless, PHVs are not currently used for clinical applications due to their lack of reliability. In order to investigate the main features of this new class of prostheses, pulsatile tests in an in-house pulse duplicator were carried out and reproduced *in silico* with both structural Finite-Element (FE) and Fluid-Structure interaction (FSI) analyses. Valve kinematics and geometric orifice area (GOA) were evaluated to compare the *in vitro* and the *in silico* tests. Numerical results showed better similarity with experiments for the FSI than for the FE simulations. The maximum difference between experimental and FSI GOA at maximum opening time was only 5%, as compared to the 46.5% between experimental and structural FE GOA. The stress distribution on the valve leaflets clearly reflected the difference in valve kinematics. Higher stress values were found in the FSI simulations with respect to those obtained in the FE simulation. This study demonstrates that FSI simulations are more appropriate than FE simulations to describe the actual behaviour of PHVs as they can replicate the valve-fluid interaction while providing realistic fluid dynamic results.

1. Introduction

In the arena of heart valve prostheses, bio-inspired polymeric heart valves (PHVs) are excellent candidates to mimic not only the shape, but also the structural and fluid dynamic behaviour of the native valve (Kuan et al., 2011). Indeed, they aim at combining the main advantages from the mechanical and biological valve prostheses. PHVs exhibit good fluid dynamics and hemocompatibility performances, the same as biological valves. PHVs are also potential candidate for transcatheter aortic valve replacement (TAVR) (Yousefi et al., 2016b), a minimally invasive treatment for patients with significant contraindications for standard surgery (Smith et al., 2011). TAVR, which is a proven technology nowadays, consists in the insertion of a stented valve in the aortic root using a catheter (Cribier et al., 2002). In both applications of PHVs, used as a traditional valve prosthesis or as a TAVR, a number of critical aspects influencing prosthesis performance are still present; they require further investigation. As a matter of fact, in spite of their promising ability to replicate the function of native valves (Ghanbari et al., 2009; Rahmani et al., 2012), PHVs are not currently used for clinical applications due to their lack of reliability (Kheradvar et al., 2015).

A thorough characterisation of the hydrodynamic behaviour of polymeric valves is required to understand the characteristics of the device, since the behaviour of a heart valve is influenced not only by the geometry of the leaflets and their material properties, but also by the fluid passing through the valve. In this regard, fluid-structure interaction (FSI) models are becoming increasingly important for biomedical engineering applications, in particular to study the dynamics of human heart valves (De Hart et al., 2003b). For these reasons, in this work we develop a computational FSI model of a PHV and compare the results with structural finite element (FE) simulations where the presence of the fluid is not considered. In the literature, a number of computational studies on prosthetic heart valves have been performed neglecting the blood flow across the prosthetic valve but simply considering hydrostatic pressures acting on the structure domain (Gunning et al., 2014; Wang et al., 2015; Morganti et al., 2014). At the same

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time, the number of studies considering fluid-structure interaction is increasing, for instance, studies on the behaviour of the aortic root in the presence of native valves (De Hart et al., 2003a; Marom et al., 2012; Ranga et al., 2006; Sturla et al., 2013; Weinberg and Kaazempur Mofrad, 2007), and a few on prosthetic valves (Bavo et al., 2016; Wu et al., 2016; Borazjani, 2013). However, with exception of the work by Wu et al., none of the previous works has included experimental validations.

The aim of this study is to demonstrate how the FSI methodology is more reliable than the stand-alone structural analysis to replicate *in vitro* tests of a polymeric aortic valve. In particular, (a) we conducted pulsatile tests in an *in-house* pulse duplicator built up based on the guidelines of the ISO5840:2015 Standard, (b) we reproduced the *in vitro* conditions with both structure and FSI simulations, in order to (c) compare the numerical results against experiments in terms of valve kinematics, while providing additional information such as stress distribution and velocity fields.

2. Material and methods

2.1. PHV valve

The PHV prototypes similar to those presented by De Gaetano et al. (2015a) made of styrenic block copolymer (SBP) have been considered in this work (Fig. 1a). The PHVs are manufactured by moulding poly (styrene – ethylene – propylene – styrene) (SEPS) block copolymers with 22% percentage by mass (wt) polystyrene fraction. PHVs have extremely thin leaflets, which should hamper the flow as little as possible when opened, but need to prevent blood back-flow if closed. During closure, the leaflets are in mutual contact and a large transvalvular pressure gradient occurs. The leaflets are directly connected to the valve structure by three pillars as detailed in Fig. 1a. For the valve taken into consideration in this work, the three leaflets have different average thickness (two with a thickness of 0.36 mm and one of 0.39 mm). This difference was due to imprecision during the fabrication process and was taken into account when creating the computational model of the valve.

2.2. Hydrodynamic tests

Pulsatile tests were conducted on an in-house pulse duplicator (De Gaetano et al., 2015b). The following components were part of the pulse duplicator (Fig. 2): (i) a driving system made of a piston pump; (ii) a ventricular element, simulating the left ventricle; (iii) an aortic valve housing; (iv) a Resistance-Compliance-Resistance (RCR) analogue to replicate the aortic resistance, the compliance of the cardiovascular system, and the peripheral resistances; (v) a reservoir simulating the left atrium and (vi) a mitral valve housing. A dedicated software allows the user to set different flow rate waveforms with different frequencies. Systolic and diastolic flow rates were replicated with sinusoidal waveform. The pumping system was filled up with distilled water at 22 °C according to ISO5840:2015 Standard. The transvalvular pressure drop was measured at a constant frequency of 70 bpm and two flow rates: (i) 4 l/min (Test A), and (ii) 4.5 l/min (Test B). A high-speed video system (Canon EOS 70D, Tokyo, Japan) mounted in front of the aortic valve housing allowed to capture the valve kinematics during the *in vitro* tests.

2.3. Numerical simulations

Structural FE and FSI simulations were performed. The FE and FSI models were created with Rhinoceros 5.0 (Robert McNeel & Associates, USA) and discretized with Hypermesh (Altair Engineering, Inc., USA) and ICEM CFD 15.0 (ANSYS, Inc., Canonsburg PA, USA). All simulations were performed on an Intel Xeon workstation with 8 processors at 2.4 GHz using the commercial finite element solver LS-DYNA 971 Release 7.0 (LSTC, Livermore CA, USA and ANSYS, Inc., Canonsburg PA, USA).

The valve and its housing were modelled using the actual dimensions of the samples (Table 1). The valve was modelled with 141,810 8-node hexahedral solid elements with both reduced and fully integrated (Fig. 1b) to prevent hourglass problems. A mesh sensitivity analysis was performed for the valve on three different models with coarse (12,420 elements with one element in the leaflet thickness – Mesh 1 in Fig. 3), medium (141,810 elements with three elements in the leaflet thickness – Mesh 3 in Fig. 3) and fine (600,456 elements with five elements in the leaflet thickness of – Mesh 5 in Fig. 3) meshes. Results showed the independency of the mesh for the displacement of the leaflets, and the medium mesh is enough to get reasonable results on stress situation of the valve.

The PHV was considered as a linear elastic material with a Young modulus of 3.2 MPa obtained by fitting experimental data from Serrani et al. (2016), a density of 830 kg/m^3, and a Poisson's ratio of 0.49.

The valve housing, representing the aortic root, was considered as rigid, mimicking the experimental setup, and was discretized with 26,352 quadrangular shell elements (Fig. 1c).

For the FE simulations, the experimental transvalvular pressure drop (Fig. 4) was directly applied on the surfaces of the leaflets. Furthermore, the external ring of the valve (Fig. 1a) was constrained in all directions, to mimic the fixing of the valve in the housing. A surface to surface self-contact between the leaflets was defined to simulate the valve closure.

A fluid domain containing the structural elements, i.e., the valve, was created (see Fig. 1d). It consisted of a control volume with an inlet and an outlet part at its ends. The independence of the fluid-dynamic results from the element size of the fluid mesh was performed using the optimal structural mesh determined previously. The sensitivity analysis of the fluid mesh indicated that a control volume discretized with 110,304 8-node hexahedral Eulerian elements with single integration point and 0.37 mm as minimum characteristic length was sufficient. The properties of water (density of 1000 kg/m^3 and dynamic viscosity of 0.001 Pa s) were assigned to the fluid, modelled as a Newtonian fluid; a bulk modulus of 22 MPa, instead of

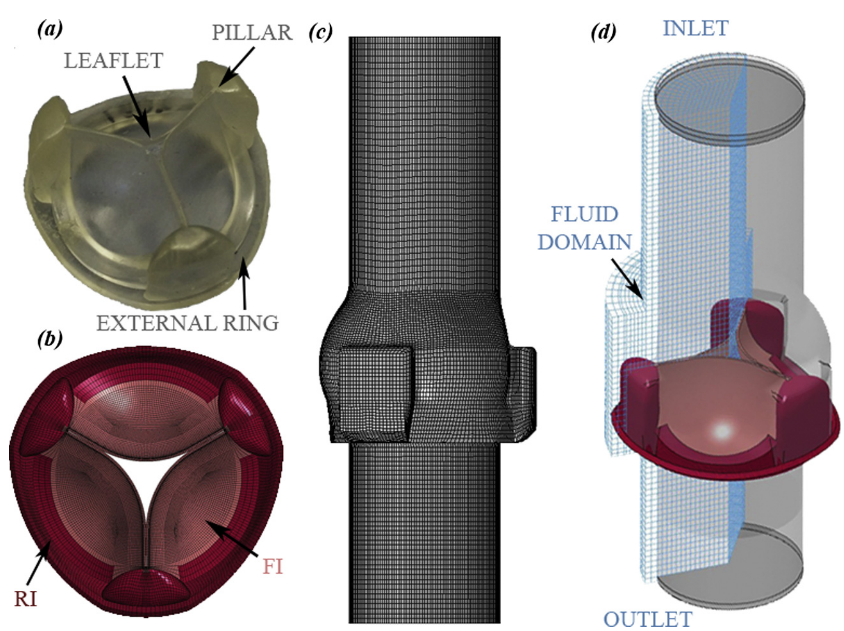

Fig. 1. Prosthesis Heart Valve (PHV) sample with pillars, external ring and leaflets (*a*) and the corresponding (*b*) model of the PHV with reduced (RI) and fully integrated (FI) elements; mesh of the aortic valve housing (*c*); FSI model including the valve, the compartment and the fluid domain with inlet and outlet parts (*d*).