Preliminary study of the influence of compliant sinuses of Valsalva on Poli-Valve hydrodynamic performance

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***Abstract* — The role of the Valsalva sinuses was widely studied in the past. Nevertheless, the ISO Standard 5840 prescribe the test to be performed on new prototypes does not require the presence of the sinuses.**

Aim of this work is to evaluate the influence of the compliance of aortic conduct with the anatomical shape of Valsalva sinuses on the performances of three group of polymeric heart valve called Poli-Valve. The results were compared with data obtained by using a rigid conduit as recommended by the Standard.

***Keywords* — sinuses of Valsalva, prosthetic heart valve, compliance, vessel phantoms**

I. INTRODUCTION

THE presence of the Valsalva sinuses, firstly investigated by Leonardo da Vinci about four centuries ago, and the compliance of the aortic root influences the dynamics and kinematics of the aortic valve leaflets [1],[2].

In 1968 Bellhouse, who suggested that the sinuses have the function to host and expand the start-up vortex promoting leaflets closure, proposed a first investigation about the Valsalva sinuses roles. Vortices, which form in the sinuses during systole, control valve leaflet position and contribute to the prevention of jet formation during valve narrowing and smooth closure of the valve [2].

The compliance of the sinuses has been shown to contribute to the gradual and smooth valve opening and closure [2]. In the absence of sinuses, the turbulence of flow causes suboptimal opening of the valve with the consequent presence of a pressure drop and reduced effective orifice area (EOA) [3].

Other studies [4], [5] have confirmed that aortic valve root compliance and anatomy have significant influence on smoothness of valve closure, thereby avoiding the building up of abnormal stress in the leaflet, so contribute to a stress reduction on the valve leaflet [2], and on the coaptation of the aortic valve. Aortic root deformations probably minimize aortic cusp stresses by creating optimal cusp loading conditions and minimizing transvalvular turbulence [6]. The main result of complex mechanisms of ventricle contraction is to keep the stress on the valve leaflet to a minimum, allowing life-long valve durability [3].

The importance of including compliant root in aortic valve modelling has been described in [7],[8]. The need to use a compliant material for the aorta modelling is justified by the cruciality of elastic properties of the aortic wall tissue.

The aim of this work is the modification of a cardiovascular simulator to add compliant sinuses of Valsalva model downstream the valve housing to provide more physiological testing conditions and compare the performance of styrenic block-copolymer prosthetic heart valves (PHVs) [9] obtained under pulsatile conditions between rigid conduct and compliant Valsalva sinuses.

The polymeric heart valves tested in this work, called Poli-Valve, are the result of collaboration between the Laboratory of Biological Structure mechanics (LaBS) of Politecnico di Milano and the Department of chemistry and biotechnologies of the University of Cambridge

All the in-vitro tests were performed under pulsatile flow conditions using a cardiovascular simulator specifically design at our lab. Pressure drops and regurgitation were obtained both using a rigid conduit, as recommended by ISO 5840 Standard [10], and using a compliant aortic root, *ad hoc* manufactured.

II. METHODS

A. Test bench

The circuit specifically designed and built up to perform tests under pulsatile flow is shown in Figure 1.

The pulse duplicator consists of the following elements: the driving system made of a piston pump; the ventricular element, simulating the left ventricle; the aortic valve housing; the Resistance-Compliance-Resistance (RCR) analogue to replicate the peripheral compliance and the resistance (aortic and peripheral) of the cardiovascular system; the reservoir simulating the left atrium and the mitral valve housing (the same used for the continuous flow tests).

The pumping system was controlled by a software that allows the user to set different flow rate waveforms or different frequencies. The systolic flow rate was replicated by the Swanson and Clark [12] waveform while a modified Talukder and Reul [13] waveform was used to produce the diastolic waveform. The pumping system was filled up with distilled water at room temperature (25°C) according to ISO5840 Standard. The valves tested in the aortic position were firstly housed in cylindrical PMMA rigid tube as prescribed by ISO 5840:2015 Standard. All the tests were performed using also a deformable tube replicating both the anatomical shape of the Valsalva sinus and the compliance of the aortic arch.

B. Phantom production

In order to obtain a deformable aortic root with the anatomical geometry, a mold of the desired shape was

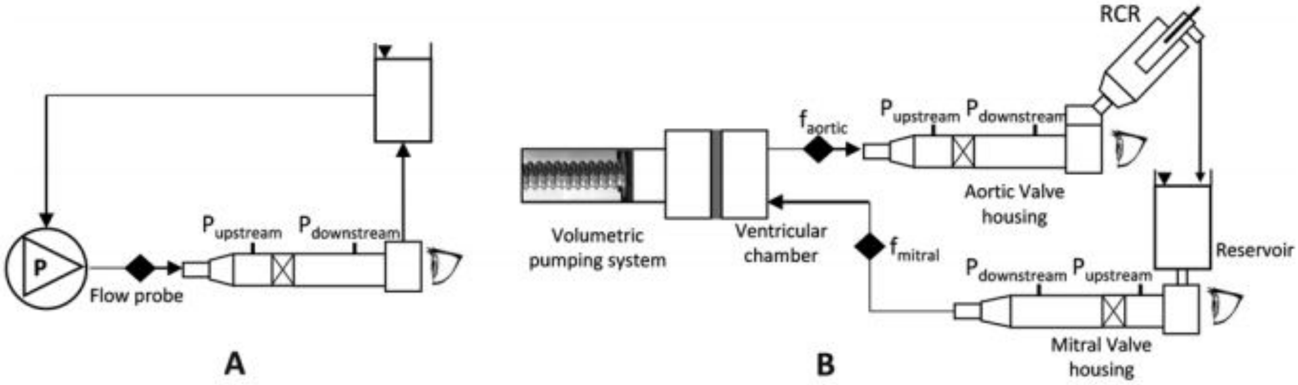

Figure 1. Outline of the test benches: (A) experimental setup for continuous flow tests. (B) experimental set-up for the pulsatile flow tests. The locations of upstream and downstream pressure and flow rate probes are shown on the sketch; the observation point from which pictures were taken is indicated by the eye symbol [9].

modelled via CAD (SolidWorks Corporation, Dassault Systemes). Then the mold was 3D printed using a solvable material (ABS, PVA).

Several mixture of silicone (ELASTOSIL E43) and turpentine has been selected in order to obtain the right value of compliance for the tube (1.5 ml/mmHg). ELASTOSIL E43 was chosen due to its low cost and high Young's modulus which can be easily reduced adding turpentine in the mixture.

Uniaxial Tensile tests were performed using an MTS Synergie on a rectangular strip (7 mm x 25 mm) in order to assess the Young's modulus of the samples obtained using several mixture. Then the Young's modulus of each different silicone mixture was indeed associated to the equivalent compliance of a tube with a 35 mm internal diameter.

Using the mixture of 70% of silicone percentage by mass it was possible obtain the Young's modulus (0.326 ± 0.015 MPa) which matches at the desired value of aortic root compliance.

The selected mixture was poured on the mold, distributed homogeneously and dried in the air. In the end, the silicone was detached from the mold and the phantom was ready to use (Figure 2). The aortic block was properly modified in order to easily add the compliant tube (Figure 3).

C. Prosthetic heart valves

The tested Poli-Valves were polymeric, supra-annular, trileaflet prosthetic heart valves prototypes, manufactured by injection molding technique using SEPS (Styrene- Ethylene-Propylene-Styrene) at 22% (percentage by mass). These valves were fabricated using the same method reported by De Gaetano et. al [9].

The two prototypes (valve A and valve B) tested in this work have an internal diameter equal to 21 mm (Figure 4).

The pulsatile tests were performed according to ISO 5840:2015 Standard. To assess the EOA, the frequency of the pump was set at 70 bpm, the stroke volume (SV) at 71 ml so as to obtain a simulated cardiac output of 5,0 l/min, with a systolic time equal to 35 % of the whole cycle. Pressure was set at normotensive conditions.

Regurgitant volumes were measured at three different pressure conditions representative of hypotensive, normotensive, and severe hypertensive conditions (50, 100, 150 mmHg) at three different heart rates (45, 70 and 120 bpm) and cardiac output of 5 l/min.

Pressure drops and flowrate were acquired using an A/D acquisition board (DaqPad-6020E, National Instruments, Austin, Texas, USA) at the acquisition frequency equal to 200 Hz.

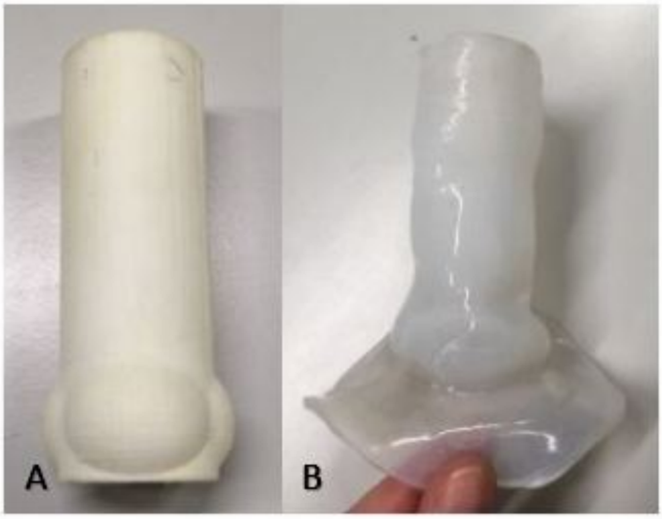

Figure 2. (A) Inner-core 3D-printed mold; (B) preliminary phantom obtained by pouring into the mould.

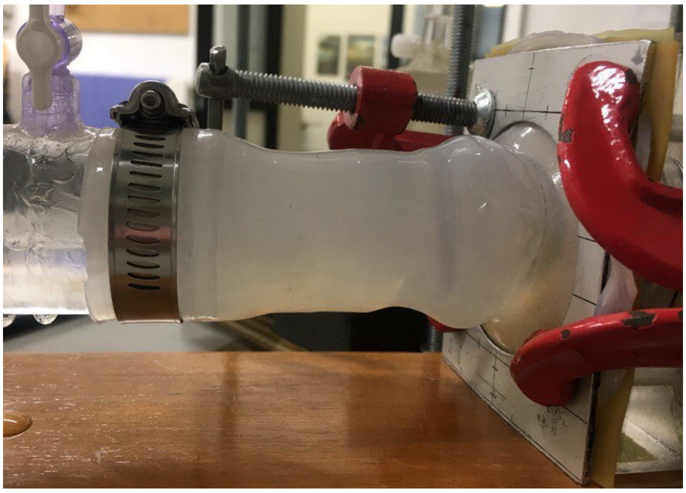

Figure 3. Compliant aortic root connected to the circuit

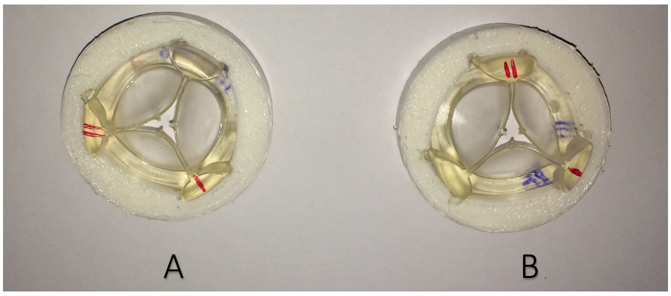

Figure 4. Prosthetic heart valves (A) and (B)

III. Results

In this section all the results showed by the two tested prototypes in both the configuration are summarized: with and without the compliant sinuses of Valsalva. Both EOA and total regurgitation fraction (TRG) were evaluated.

The EOA and TRG results were compared with the minimum performances requirement prescribed by the Standard (EOA > 1.05 cm^2 and TRG < 10%).

A. EOA

The Standard provides the equation to calculate the EOA:

$$EOA = \frac{q_{V_{RMS}}}{51{,}6 * \sqrt{\frac{\Delta p}{\rho}}}$$

Where EOA is the Effective Orifice Area (cm^2); $q_{V_{RMS}}$ is the root mean square forward flow (ml/s) during the positive differential pressure period; Δp is the mean pressure difference (measured during the positive differential pressure period - mmHg); ρ is the density of the test fluid (g/cm^3). The EOA for two valves under different conditions are reported in Table I .

Table I.
EOA

Valve	EOA [cm^2] without sinuses	EOA [cm^2] with sinuses	EOA [cm^2] ISO
A	1.35 ± 0.13	1.48 ± 0.12	≥ 1.05
B	1.28 ± 0.12	1.51 ± 0.03	

The EOA seems to be higher in the compliant configuration, even if there are no significant statistical differences due to the number of the analyzed prototypes.

B. Regurgitation

The total regurgitation fraction is expressed as a percentage of the forward flow volume through the valve. It shall include closing volume, transvalvular leakage volume, and paravalvular leakage volume. Regurgitant volumes were measured at three different pressure conditions representative of hypotensive, normotensive, and severe hypertensive conditions (50, 100, 150 mmHg) with three different heart rates (45, 70 and 120 bpm) at the same cardiac output of 5 l/min. To obtain the needed backpressures at the set flowrate and frequency, it was necessary to change the resistance of the circuit. Backpressure was evaluated during diastole phase as the average transvalvular pressure difference.

Regurgitation fractions for the two valves under three different backpressure conditions are reported in Table II and Table III.

It can be noticed that in general, the total regurgitation fraction complies with the Standard (≤ 10%) and this value is reduced with the use of compliant sinuses, supporting the theory that the compliant sinuses of Valsalva facilitates the proper and fast closure of the valve leaflets.

Table II.
Regurgitation Valve A

Frequency	Backpressure	TRF without sinuses	TRF with sinuses
50 bpm	50 mmHg	12.95%	9.89%
	100 mmHg	10.40%	11.08%
	150 mmHg	10.49%	9.98%
70 bpm	50 mmHg	14.15%	9.74%
	100 mmHg	10.97%	11.32%
	150 mmHg	11.24%	10.14%
120 bpm	50 mmHg	13.54%	8.14%
	100 mmHg	11.79%	9.91%
	150 mmHg	12.98%	12.62%

Table III.
Regurgitation Valve B

Frequency	Backpressure	TRF without sinuses	TRF with sinuses
50 bpm	50 mmHg	9.36%	7.44%
	100 mmHg	9.02%	9.00%
	150 mmHg	10.13%	10.10%
70 bpm	50 mmHg	10.92%	6.97%
	100 mmHg	8.94%	9.02%
	150 mmHg	9.56%	9.85%
120 bpm	50 mmHg	11.38%	6.52%
	100 mmHg	11.24%	8.25%
	150 mmHg	12.48%	9.11%

IV. Conclusion

As widely reported in the literature, the presence of compliant aortic root reduces backflow and influences the EOA. The same effect was observed also in this preliminary study however, further tests will be performed on a larger number of prototypes. Al the prototypes teste in this work exceed the minimum performance required by the standards in both the configurations.

As show in the Table II and Table III at the lowest backpressure (50 mmHg) in the rigid tube increasing the frequency the regurgitation increases, while using the compliant tube the regurgitation became lower. It's possible to observe the same behavior at the highest backpressure (150 mmHg): using the straight tube increasing the frequency the regurgitation increases while the tests performed using the compliant tube reproducing anatomical shape of the Valsalva's sinus showed a constant regurgitation.

It has to be emphasized that this study including only two valves, shows a strong tendency behavior even if not permitting to make conclusions from the statistical point of view.

As a matter of fact, the configuration test using a compliant conduct with the anatomical shape of the Valsalva sinuses, provides much more reliable results if compared to the test performed using a straight tube. This new test bench configuration it very usefully before approach in-vivo study even if, due to high reproducibility is better used standard straight tube for the preliminary in-vitro test.

A test bench should reproduce not only the right pressure and flowrate waveform of the desired anatomical district but also the boundary condition like geometry and compliance.

The compliance, probably, could have a predominant role if compared to the only geometry but other study should be performed in this direction.

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