BEYOND THE STANDARD: HOW DO THE CHARACTERISTIC OF THE AORTIC CONDUIT AFFECT THE PERFORMANCES OF HEART VALVES

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Introduction

When approaching the design and testing of a new heart valve prosthesis, the first step is the ISO 5840:2021[1]; in this Standard all needed information for pre-clinical and clinical trials is provided. In particular a pulsatile test is required to assess the hydrodynamic performances of the valve. While several requirements are listed there isn't a guide on which characteristics the conduits replicating the vessels should have. In the authors opinion this could be particularly inappropriate for the conduit downstream the aortic valve that should model the aorta but is often reduced to a straight and rigid conduit. This work concerns itself with modifying this conduit to introduce first the geometry, characterized by the Valsalva sinuses, and then the ascending aorta's compliance

Methods

To obtain the aortic phantom 3D printing was exploited. In order to print a physiological-like conduit a complete characterization was performed on the selected Elastic 50 A resin from Formlabs. The characterization included but was not limited to: tensile tests on samples differently oriented during printing, cyclic test, swelling and aging tests.
A previously developed pulse duplicator (Figure 1) [1], was modified implementing three different types of conduit downstream of the aortic valve: rigid and straight conduit, rigid conduit with Valsalva sinuses, compliant conduit with Valsalva sinuses. The pulsatile tests were performed on these three different set-ups; in each set up a mechanical, a polymeric, and a biological valve were tested.

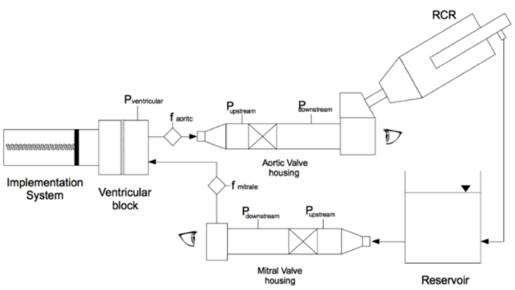

Figure 1: Schematic representation of the pulse duplicator used in this work

Results

From the material characterization we found that a conduit with 1.82 mm thickness would show the correct compliance; this conduit would also be able to withstand the pulsatile test. From the aging test we concluded that tests should be carried out in 5 days maximum to avoid the alteration of properties.
From the pulsatile test emerged that the introduction of the Valsalva sinuses led to a decrease in regurgitation (Table 1), and an increase in MSPD. The compliance instead provoked a decrease in the MSPD and, consequently, of the EOA (Table 2), but led to an increase in regurgitation.

Regurgitation	Mechanical	Polymeric	Biological
Standard	14.49	6.46	12.65
Rigid sinuses	8.60	5.57	13.50
Compliant sinuses	19.77	8.93	18.49

Table 1: Regurgitation results for each of the tested conditions

EOA	Mechanical	Polymeric	Biological
Standard	0.79 ± 0.09	1.35 ± 0.21	1.13 ± 0.23
Rigid sinuses	0.57 ± 0.01	1.47 ± 0.29	1.08 ± 0.08
Compliant sinuses	0.90 ± 0.11	1.10 ± 0.11	1.04 ± 0.36

Table 2: EOA results for each of the tested conditions.

Discussion

We proved the feasibility of fabricating an aortic phantom with 3D printing even if the time-dependent behavior remains a major drawback of this material.
The presence of the Valsalva sinuses introduced, as expected from theory, the formation of vortexes that aid the closure of the valve, reducing regurgitation. The increase in MSPD can be explained by the fact that, in order to keep the diameter downstream the sinuses at 34 mm and respect the anatomical ratios, the diameter upstream the sinuses is of 27 mm. When the compliance is introduced, the effect is mitigated from the deformability of the conduit. Since the conduit deforms and recoils at each cycle, during recoil a backflow is generated, increasing regurgitation of the valves

References

1. F. De Gaetano et al, International Journal of Artificial Organs, vol. 38, n. 11, 2015..