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Physiological vortices in the sinuses of Valsalva: An *in vitro* approach for bio-prosthetic valves

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A B S T R A C T

Purpose: The physiological flow dynamics within the Valsalva sinuses, in terms of global and local parameters, are still not fully understood. This study attempts to identify the physiological conditions as closely as possible, and to give an explanation of the different and sometime contradictory results in literature.

Methods: An *in vitro* approach was implemented for testing porcine bio-prosthetic valves operating within different aortic root configurations. All tests were performed on a pulse duplicator, under physiological pressure and flow conditions. The fluid dynamics established in the various cases were analysed by means of 2D Particle Image Velocimetry, and related with the achieved hydrodynamic performance.

Results: Each configuration is associated with substantially different flow dynamics, which significantly affects the valve performance. The configuration most closely replicating healthy native anatomy was characterised by the best hemodynamic performance, and any mismatch in size and position between the valve and the root produced substantial modification of the fluid dynamics downstream of the valve, hindering the hydrodynamic performance of the system. The worst conditions were observed for a configuration characterised by the total absence of the Valsalva sinuses.

Conclusion: This study provides an explanation for the different vortical structures described in the literature downstream of bioprosthetic valves, enlightening the experimental complications in valve testing. Most importantly, the results clearly identify the fluid mechanisms promoted by the Valsalva sinuses to enhance the ejection and closing phases, and this study exposes the importance of an optimal integration of the valve and root, to operate as a single system.

1. Introduction

The formation of vortical structures into the Valsalva sinuses was already reported in the early XVI century (Keele, 1952; Robicsek, 1991). After the 60s, the development of heart valve substitutes stimulated new research in the cardiovascular community towards a better understanding of the flow dynamics occurring in the aortic root (Bellhouse and Bellhouse, 1968; Bellhouse and Talbot, 1969; van Steenhoven and van Dongen, 1979). It is now well accepted that the presence of the Valsalva sinuses influences the dynamics of the valve leaflets, and plays a relevant role in the washout of the sinus flow structures and in the blood supply of the coronaries (van Steenhoven et al., 1982; Peskin, 1982; Peacock, 1990; Rubenstein et al., 2012; Caro et al., 2012). However, the various and often contradictory interpretations provided in the literature for the fluid dynamics established within the sinuses (Leo et al., 2006; Yap et al., 2012; Moore and Dasi, 2014) still reveal a lack of understanding of the physiological flow conditions that these chambers promote in the aortic root.

A first mechanism was proposed by Bellhouse and Bellhouse (1968), who suggested that the sinuses have the function to host and expand the start-up vortex ring that generates at the valve exit during early systole, with the vortex also promoting leaflet closure. This vortex follows the ejected flow in proximity of the root axis, and has opposite direction close to the arterial wall (to avoid any ambiguity, this vortical rotation, as sketched in Fig. 1,

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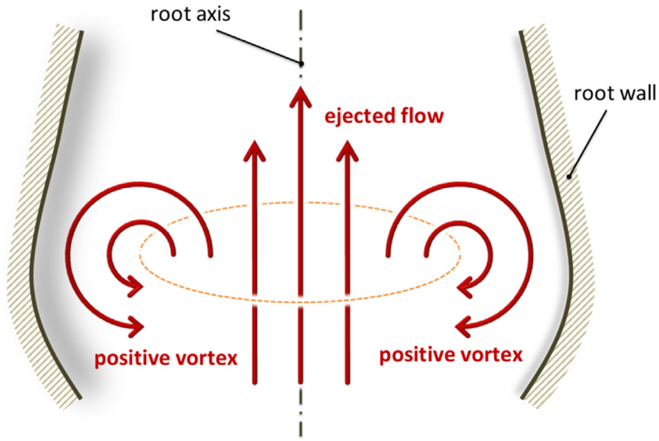

Fig. 1. Sketch describing a positive vortex ring formed during the ejection phase.

will be denoted as positive in the remainder of the paper). The vortex dynamics identified by Bellhouse have been confirmed by a number of numerical studies from different groups (Swanson and Clark, 1973; de Hart, 1997; de Hart et al., 2003; Korakianitis and Shi, 2006; Katayama et al., 2008), and are observed in recent *in vivo* works based on high intensity Magnetic Resonance Imaging (MRI) (Yang et al., 1998; Escobar Kvitting et al., 2004; Markl et al., 2005; Ranga et al., 2006; Markl et al., 2011), though the poor spatial and temporal resolutions of this measurement technique are insufficient to provide a conclusive answer on the dynamics.

Despite the general consensus on the presence of a vortex ring in the valve opening stage, recent *in vitro* investigations have reported more complex fluid dynamics, where the start-up vortex ring generated during valve opening is convected away towards the aorta, and a secondary vortex with opposite rotation forms and remains within the sinus until the valve begins to close (Leo et al., 2005, 2006; Dasi et al., 2009; Saikrishnan et al., 2012; Ducci et al., 2013). The numerical simulations of Fukui and Orinishi (2013) also reported the presence of multiple vortices within each sinus during the cardiac cycle, which depended on variation of the Valsalva Sinuses morphology (extension and depth).

This study provides an in depth investigation of the hemodynamics occurring within the aortic root, proposing justifications for the different flow modalities reported in previous studies. In particular, various combinations of aortic root geometries and prosthetic valves are studied *in vitro* on a pulse duplicator, using 2D Particle Image Velocimetry (PIV) to analyse the local flow characteristics. The different configurations are selected to reproduce idealised physiological conditions, as well as the common departures from clinical configurations often introduced in the described studies, such as mismatch of valve-root size, variations in the axial position of the valve (*e.g.* infra or supra-annular implant) and absence of the sinuses (as in valved-grafts).

2. Material and methods

In this study, all experiments were carried out using a hydro-mechanical pulse duplicator (Vivitro Superpump System SP3891, ViVitro Labs Inc., Canada), with pressure catheters monitoring the pressure upstream and downstream of the aortic valve. These, combined with the instantaneous volumetric flowrate, allowed estimation of the following characteristic parameters: the pressure drop across the valve, the effective orifice area of the valve, the energy loss of the valve, and the closing volume. Tests were performed imposing a physiological flowrate of 4 l/min, a heart rate of 70 bpm with 35% of systolic time, and a mean aortic pressure of 100 mmHg. The mean and standard deviation ($\pm$SD) of the estimated parameters are reported in Table 1. Further information about the testing instrumentation is provided in the Appendix.

Local fluid dynamics were investigated by means of 2D PIV, which is a laser based, non-intrusive optical technique, providing measurements of instantaneous velocity vector fields by correlating the displacement of seeding particles on a laser plane over a time interval Δt, selected to catch the flow features of each of the analysed instants. The system set up is represented in Fig. 2a, where the positions of the camera and laser with respect to the valve root configuration are represented. Measurements were carried out on a root cross section (sagittal plane), bisecting one of the sinuses. A phase-resolved approach was selected to analyse the PIV data, because it allowed to meet the main objective of the study, which is to identify and compare the large scale flow features for different valve-root configurations. Camera and laser were synchronised with the pulse duplicator, and five reference instants associated with specific flow features were selected to characterise the hemodynamics of the valve-root configurations during each cardiac cycle. It should be noted that the reference instants can occur at different times of the cycle for the different valve-root setups. The reference instants, represented in Fig. 2b on the diagram of the cyclic flowrate obtained for the optimal surgical configuration (the features allowing the identification of the reference instants were similar for all studied configurations), correspond to the times when the ejected flow exhibits/reaches the following conditions:

A) maximum increasing flowrate;
B) peak flowrate;
C) maximum decreasing flowrate;
D) most significant change of curvature in the decreasing region;
E) zero flowrate.

Further information on the PIV settings used is provided in the Appendix.

A set of mock aortic roots was built to assess the impact of the sinuses and of the aortic root proportions on the flow downstream of the valve, and replicate common testing arrangements. A reference diameter of 25 mm at the sino-tubular junction (STJ) was selected, as this is representative of an average size for adult humans (Davis et al., 2014). An additional root was manufactured, where the STJ size was increased to 29 mm, and used to verify the effect of valve undersizing. Valsalva sinuses were modelled based on the geometric proportions described by Swanson and Clark (1973), the epitrochoidal top view profile defined by Reul et al. (1990), the leaflet angles identified by Thubrikar et al. (1981), and the sagittal plane sinus profile suggested by Grigioni et al. (2005). All roots were made of optically clear, solvent free, low viscosity silicone elastomer (MED-6015, NuSil Technology, CA, USA, refractive index $n=1.4$). For this study, it was preferred to opt for thick-wall roots, with negligible compliance. Though this is an approximation, the root elasticity depends on a number of factors including the geometry and materials of the chamber and, *in vivo*, the age and healthiness of the tissues or, in the presence of a graft, the prosthetic materials and its degree of cellular infiltration. Hence, it was decided to exclude this variable.

To reduce optical distortion, the refractive index of the working fluid was matched to that of the silicon root by adding potassium iodide (KI) to distilled water until the distortion of a grid placed at the back of the silicone root was minimal (see Fig. 2d). Due to the large number of comparative experiments requiring the same bioprosthetic valve, it was preferred not to match blood viscosity by adding glycerine, so to avoid any change in the tissue mechanical properties which could have made the comparison of the different sets of results ineffective (Wright, 1979). Though this approximation is accepted by international regulations for testing of bioprosthetic valves (ISO 5840, 2009), it may result in some departure from the physiological behaviour.

For the valve model, porcine bioprostheses were preferred, due to their similarity with healthy human aortic valves in terms of shape, thickness and material (Thubrikar, 1990). In particular, LabCorp TLPB stented porcine surgical prostheses of size 25 (*i.e.* 25 mm external stent diameter) and size 29 (*i.e.* about 25 mm internal diameter) were used. The size 25 valve was chosen to achieve optimum surgical matching of the device with the 25 mm roots, whilst the larger valve uses leaflets extracted from a porcine aortic root with a STJ diameter equal to about 25 mm, providing a better description of the native anatomy.

The following five different valve-root configurations were studied, as illustrated in Fig. 2c:

i) *physiological configuration*: 29 mm valve (25 mm leaflets) in aortic root (including sinuses) of STJ diameter equal to 25 mm with a groove to host the stent thickness – describes an idealised healthy native situation, where the influence of the stent is minimised.
ii) *optimal surgical configuration*: 25 mm valve in aortic root (including sinuses) of STJ diameter equal to 25 mm – describes an optimum implantation of the prosthetic valve in a supra-annular position;
iii) *sinusless surgical configuration*: 25 mm valve in straight cylindrical root of diameter equal to 25 mm – describes the flow in the absence of sinuses;
iv) *sub-annular configuration*: 25 mm valve in aortic root (including sinuses) of STJ diameter equal to 25 mm – describes an infra-annular implantation of the prosthetic valve (8.5 mm below the ideal position), and is the default positioning for the valve housing in many commercial pulse duplicators (Lim et al., 1997, 1998, 2001);