Phase-resolved velocity measurements in the Valsalva sinus downstream of a Transcatheter Aortic Valve

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Abstract Two sets of phase resolved PIV measurements were performed in the Valsalva sinuses of a glass mock aortic root including three polymeric valve leaflets, before and after the implant of a Medtronic CoreValve TAVI device. The experiments were carried out in a hydro-mechanical cardiovascular pulse duplicator system (Vivitro Superpump System SP3891) reproducing physiologically equivalent aortic pressures and flows and conforming to the requirements of the standard ISO 5840. The aortic Reynolds number, based on the maximum instantaneous value of the systolic flow, was approximately 7000. The comparison between the two conditions is based on three flow characteristics, namely the phase resolved velocity field, the shear rate and the vorticity. A direct comparison of the phase resolved flow fields before and after TAVI highlights a significant variation of the flow during the early stages of valve opening and during valve closure, while similar counter-clock- vortical structures were identified when the valve is fully open. In general flow activities of the Valsalva sinus after TAVI were found to be reduced in strength and to occur mainly in the mid, top parts of the sinus, while the bottom part is more subject to stagnation.

1. Introduction

The aortic valve consists of three crescent shaped flaps of tissue of similar size (leaflets), faced by three corresponding pouches of the aorta (sinuses of Valsalva). The leaflets open and close passively, moved by the blood, preventing backflow. When they are dysfunctional, the quality of life of the patient can dramatically deteriorate, and their function needs to be restored with prosthetic devices. Open heart surgical replacement has been the most effective treatment of aortic valve disease in the past, but it is now less suitable for current and future patients’ population, which is mainly represented by old individuals subject to calcific aortic stenosis, who cannot undergo the stresses of an invasive operation (Passik et al. 1987, Ghanbari et al. 2008). This disease affects about 3% of individuals over the age of 65 (Otto et al. 1999) and more than 10% of adults over the age of 75 (Lindroos et al. 1993). Age related comorbidity and previous surgery (Roques et al 1999, Kvidal et al. 2000, Edwards and Taylor 2003) are common factors in this class of patients, and dramatically increase the risks of operative mortality. As a result, about one third of elderly patients with symptomatic aortic stenosis are deemed high risk and declined for surgery (Iung et al. 2003).

Transcatheter Aortic Valve Implantation (TAVI) has emerged in the last decade as one of the most effective solutions for high-risk patients. It allows the delivery of an artificial valve in the aortic position using a catheter inserted from a peripheral vessel, eliminating some of the main risks associated with conventional invasive operations, such as the need for thoracotomy, cardiac arrest/restart, extracorporeal circulation etc. Clinical experiences with TAVI devices, which have now been implanted in thousands of patients worldwide, have shown excellent short and medium term results (Rodés-Cabau et al. 2010, Attias et al. 2010). However, a better understanding of the hemodynamic implications of this novel approach is essential in order to improve the safety and sustainability of the technique. In fact, whilst standard surgical valves are sutured onto the annulus after dissection of the native leaflets and cleaning of the region, thus restoring physiological-like flow conditions (Figure 1a), TAVI devices are anchored into place by expanding a supporting frame.
(typically a metal mesh) into the leaflets of the diseased valve (Figure 1b). This necessarily produces alterations in the flow pattern that could promote forms of blood damage such as haemolysis (red blood cell rupture and release of haemoglobin) or thrombus formation (clotting of blood). In particular, these phenomena are directly associated with the level of shear stress; zones of flow recirculation, separation or stagnation; and vorticity (Tillman et al. 1984, Giersiepen et al. 1990, Alemu and Bluestein 2007, Morbiducci et al. 2009, de Tullio et al. 2012). In-vitro studies of the flow associated with TAVI devices to date have been limited, and mainly focused on the central systolic flow emerging from the valve orifice (Stuhle et al. 2011). However, the opening and closing dynamic of the valve is directly associated with the hemodynamics established in the sinuses of Valsalva (Bellhouse et al 1968, van Steenhoven et al. 1979), which is essential to preserve proper ventricular function and coronary flow, and minimize the mechanical stress in the valve tissues (Rainer et al, 1999).

In the present study, the impact of a Medtronic CoreValve® bioprosthesis on the hemodynamic in the Valsalva sinuses was analysed in vitro, by means of PIV. The physiological valve behaviour were reproduced in a hydro-mechanical cardiovascular pulse duplicator system, where the aortic valve system is modelled by a glass aortic root including three polymeric valve leaflets, replicating anatomical shapes and dimensions. The study indicates that the presence of the TAVI device produces significant modifications of the hemodynamic in the sinuses and of the operative mechanisms of the valve system.

2. Materials and methods

The Medtronic CoreValve device consists of a self-expandable nitinol frame and a tri-leaflet porcine pericardial valve, with an integrated skirt of porcine pericardium aimed at reducing paravalvular regurgitation. It is available in three sizes (26, 29 and 31 mm), suitable for patients valve annuli ranging from 20 to 31 mm. The nitinol frame is hourglass shaped and has a wall thickness of approximately 0.5 mm and an overall length of about 55 mm. When implanted, it extends from below the aortic native leaflets to above the sino-tubular junction (distal end of the sinuses, where the root section become approximately circular), running contiguously to the Valsalva sinuses and the coronary ostia.

A hydro-mechanical cardiovascular pulse duplicator system (Vivitro Superpump System SP3891, Vivitro, Victoria, British Columbia, Canada), reproducing physiologically equivalent aortic pressures and flows, was used. The aortic valve system included a mock ascending aorta, and three polymeric leaflets. The ascending aorta was modelled by a glass root including the presence of the sinuses, characterised by an internal diameter at the sino-tubular junction equal to 27 mm. The polymeric valve leaflets, replicating anatomical shapes and dimensions (Thubrikar, 1990), were made of polyurethane, and had an internal orifice diameter equal to 23 mm.

A CoreValve of size 26 was used to study after TAVI conditions, being this model indicated for the orifice dimension of the mock valve system (23 mm). This prosthesis was expanded inside the polymeric valve following standard implantation procedure.

The experiments were performed conforming to the main requirements of the standard ISO 5840, at a physiological cardiac output of 4 l/min, with a heart rate of 70 beats per minute, systole occupying 35 % of the cardiac cycle and mean arterial pressure of 100 mmHg, using buffered saline solution as the testing liquid. Ventricular and aortic pressures and aortic flow were monitored during the entire cycle. The aortic Reynolds number, based on the maximum instantaneous value of the
systolic flow, was approximately 7000.

A 2D PIV system was employed to characterize the flow downstream the valve system, before and after TAVI. The system comprised a continuous 400 mW diode laser of 532 nm wavelength and a Dantec high speed intensified camera. The pulse duplicator and the camera were synchronised by a timing box to obtain 200 pairs of images for each of the analysed phase conditions. As the flow in the Valsalva sinuses resulted highly three-dimensional, the time delay between two consecutive images was set equal to $\Delta t = 2$ ms to prevent particle displacement in the direction orthogonal to the laser plane. The interrogation area was limited to the Valsalva sinus, which was approximately 14 mm by 19 mm in size, while the measurement spatial resolution was $\Delta x = \Delta y = 0.52$ mm, for a total of 28 by 39 velocity vectors in the axial and radial direction respectively. To minimize laser reflections, the metal frame supporting the TAVI device was painted black. The presence of moving boundaries during the opening/closing of the leaflet of the polymeric valve was addressed by applying a mask to the PIV images before proceeding with the adaptive correlation algorithm. The mask was customized for each phase conditions analysed. Phase-resolved PIV measurements were carried out at different time instants of the heart beat cycle, identifying the phases characterized by the most representative features during systole (ventricle contraction) and diastole (ventricle relaxation).

3. Results and Discussions

The phases/time instants presented in this work correspond to the bullet points ($A$, $B$, $C$, $D$ and $E$) in the diagram of Figure 2, representing the typical variation of the instantaneous flow rate with time during a single heart beat cycle. In particular, points $A$ and $B$ are related to the opening phase; point $C$ to the fully open valve; point $D$ to the closing phase; and point $E$ to the fully closed valve.

For each time instant, the flow characteristics observed before and after TAVI are compared in terms of phase resolved velocity field, shear rate and local vorticity (Figures 3-7). These are represented by adopting a Cartesian reference system placed on the axis of the aorta ($D = 27.2$ mm) at the base of the Valsava sinus. A reference instantaneous view from the valve outflow is included at the top of each figure, showing the shape of the leaflets and the opening/closing stage at the time instant considered. The first part of the results section addresses the flow difference observed during valve opening, and the second part focuses on valve closure.

3.1 Flow characterization during valve opening

A direct comparison between the phase resolved flow fields occurring downstream of the polymeric valve and of the TAVI device in the early stage of the valve opening is provided in Figure 3 (point $A$ of Figure 2). Figures 3 (a-b) show a significant difference in the flow fields before and after TAVI. In particular, the flow generated by the polymeric valve (Figure 3a) is characterized by a jet, which is locally orthogonal to the valve leaflet and follows the hemispherical profile of the sinus before being ejected into the aorta. This facilitates the valve opening, pushing the leaflets radially rather than axially. On the contrary, the flow field after TAVI (Figure 3b), exhibits a nearly horizontal jet at the top of the valve, which breaks into two streams as it approaches the sinus wall, one directed towards the bottom of the Valsalva sinus and the other one towards the aorta. The reason for this difference can be explained by considering that, in agreement with standard heart replacement protocols, the TAVI device is implanted inside the existing valve leaflets, which are kept in an open configuration during the entire cycle and are interposed between the prosthetic valve and the sinuses. As a consequence, when the leaflets of the TAVI device open, their jet is confined by the polymeric valve leaflets and can enter the Valsalva sinuses only from their free
edge. It should also be noted that the volume of the Valsalva sinus reduces significantly after TAVI. The average and peak velocity magnitude over the analysed area reduce from 0.2 m/s and 0.4 m/s for the polymeric valve to 0.046 m/s and 0.18 m/s after TAVI, respectively. This difference in velocity magnitude is reflected in the contour plots of the shear rate and vorticity provided in Figures 3a,.b and Figures 3c,.d for the two valves. Maximum phase averaged shear rate of 0.08 s\(^{-1}\) are encountered close to wall of the polymeric valve, while after TAVI the maximum absolute shear occurs on the horizontal jet at the exit of the top of the mock valve.

The difference between the two valve configurations is less evident in Figures 4 and 5 when phases time instants B and C (see Figure 2) at a later stage of the leaflet opening are considered. A qualitative comparison of the flow fields downstream of the valve before and after TAVI in Figures 4a and 4b respectively, shows several analogies. In both cases the main jet coming out the valve expands in the sinus and determines the formation of a counter-clock wise circulation at the top left hand side of the valve analogous to that occurring during the early stages of a vortex ring generation. Similar contour maps of the shear rate and vorticity are encountered with absolute maxima of 0.065 s\(^{-1}\) and 0.08 s\(^{-1}\), respectively.

Figure 5 is relative to the time instant C (see Figure 2). The circulation at the top left hand side moves higher towards the aorta and merges with the main jet coming out of the valve. Despite the qualitative similarities between the flow fields observed before and after TAVI, the average velocity magnitude of the polymeric valve is 0.065 m/s, more than double that determined with the TAVI device (0.0265 m/s). This difference is also present in the contour maps of the shear rate, Figures 4a and 4b, where the maximum absolute shear rate encountered in the flow generated before and after TAVI are \(\tau / \nu = 0.03\) s\(^{-1}\) and \(\tau / \nu = 0.02\) s\(^{-1}\), respectively.

### 3.2 Flow characterization during valve closure

The plots of the phase-resolved vector fields and contours of the shear rate and vorticity for the time instants D and E before and after TAVI are provided in Figures 6 and 7 during the valve closure phase. For both the time instants considered, a clockwise circulation loop can be easily identified for the polymeric valve. This loop is consistently present between the two instants D and E, as observed from phase resolved velocity fields determined at intermediate time instants (these are not shown in this article due to space limitations). With increasing time (Figure 6a and 7a), the centre of the circulation loop gradually moves towards the bottom (its coordinates at the time instants D and E are approximately (-0.55, 0.3) and (-0.55, 0.25), respectively). Their strength becomes smaller as higher degrees of valve closure are achieved, with absolute maximum shear rate and vorticity levels being 0.03 s\(^{-1}\) and 0.015 s\(^{-1}\) at time instants D and E. The presence of vortical structures in the Valsava sinuses is well known in the literature, and has been previously described in the seminal studies of Bellhouse et al. (1968, 1969), who suggested that they offer a natural mean to physiologically facilitate leaflet closure. However it is interesting to observe that Bellhouse et al. (1968, 1969) mainly referred to a counter-clockwise vortex, which they directly linked to the vortex ring formed at the valve edge in the early stages of the opening phase. The current results, instead, indicate that the vortex ring moves away from the valve when maximum opening is reached (Figures 4 and 5) and a vortex with opposite direction becomes dominant in the Valsalva sinuses during the valve closing dynamics.

The contour maps of the shear rate/vorticity and vector plots of the phase-resolved velocity fields for the time instants D and E after TAVI are provided in Figures 6b and 6d and Figure 7b and 7d, respectively. For these phases, the flow field after TAVI is characterised by major differences when
compared to the one of the polymeric valve at analogous times in the heart beat cycle (Figures 6a and 7a). The clockwise circulation has disappeared and a diagonal stream from bottom-left to top-right is present, while the region in the lowest part of the Valsalva sinus is characterized by a stagnation area with virtually no fluid movement. From the comparison between the vector plots before and after TAVI it might be inferred that the suction at the top of the valve during closure is drawing fluid towards the aorta and the leaflets of the TAVI device. Unfortunately, current measurements do not allow to ascertain whether this stream, once it passes the polymeric valve edge, forms a circulation similar to that of Figures 6a and 7a in the space between the TAVI valve leaflets and the polymeric valve. At time instants $D$ and $E$ the flow dynamics after TAVI is characterized by lower velocity magnitudes, with averages and peak values being 0.025 m/s and 0.11 m/s, respectively.

4. Conclusions

Phase resolved PIV measurements were carried out in a model of the aortic valve system, to establish the flow dynamics variation occurring in the Valsalva sinuses before and after implant of a TAVI device. Vorticity, shear rate and vector fields were analysed for five selected time instants of the heart beat cycle, three being more representative of the flow dynamics occurring in the valve opening stage and two during closure.

The analysis of the flow downstream of the valve before TAVI indicated that, in the early stages of the opening, the local movement of the leaflet, determined by the pressure difference across the valve, pushes the fluid along the Valsalva sinus hemispherical wall with significant radial and axial velocity components. As the valve keeps opening the main jet coming from the centre starts to roll at the edge of the valve and a clear counter-clockwise rotating vortex, similar to a vortex ring, forms at the top of the Valsalva sinuses. Once completely developed, the vortex moves upwards towards the aorta. During closure, instead, a persistent clockwise rotating vortex occupies most of the Valsalva sinuses, with its centre moving downwards as the leaflets gradually move back to their fully closed position. The main function of this vortex is thought to physiologically help valve closure.

When the TAVI device was implanted, significant variations were identified in the Valsalva sinus flow dynamics. In the early stage of valve opening, the presence of the fully opened polymeric leaflets, simulating the native valve, acts as a wall, blocking the jet created by the opening of the TAVI leaflet and redirecting the fluid towards the free edge of the polymeric leaflets. Here the flow enters horizontally the top part of the Valsalva sinuses. During later stages of opening the two configurations, before and after TAVI, flow patterns result similar, with a counter-clockwise rolling up structure that, once completely formed, moves into the aorta. The closing time instants are again very different. The flow in the Valsalva sinuses exhibits a diagonal stream from bottom-left to top right that merges into the main flow of the valve. The clockwise vortical structure that is present in the polymeric valve and is supposed to physiologically help valve closure is not present. In general it can be concluded that the flow activities of the Valsalva sinus after TAVI are reduced in strength and occur mainly in the mid, top parts of the sinus, while the bottom part is more subject to stagnation. This characteristic should be investigated more in depth, as it might be critical for the formation of thrombi.
References

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Figure 1. Sections of an aortic root without, (a), and with a Medtronic CoreValve TAVI device (b).

Figure 2. Characteristic flow diagram of a heart beat with bullet points indicating the phase instants selected for PIV analysis.
Figure 3. Comparison of the phase-resolved velocity vector fields and contour plots of the vorticity and shear rate before and after TAVI at time instant $A$: (a) shear rate intensity downstream of the polymeric valve; (b) shear rate intensity downstream of the TAVI device; (c) vorticity intensity downstream of the polymeric valve; (d) vorticity intensity downstream of the TAVI device.
Figure 4. Comparison of the phase-resolved velocity vector fields and contour plots of the vorticity and shear rate before and after TAVI at time instant $B$: (a) shear rate intensity downstream of the polymeric valve; (b) shear rate intensity downstream of the TAVI device; (c) vorticity intensity downstream of the polymeric valve; (d) vorticity intensity downstream of the TAVI device.
Figure 5. Comparison of the phase-resolved velocity vector fields and contour plots of the vorticity and shear rate before and after TAVI at time instant $C$: (a) shear rate intensity downstream of the polymeric valve; (b) shear rate intensity downstream of the TAVI device; (c) vorticity intensity downstream of the polymeric valve; (d) vorticity intensity downstream of the TAVI device.
Figure 6. Comparison of the phase-resolved velocity vector fields and contour plots of the vorticity and shear rate before and after TAVI at time instant $D$: (a) shear rate intensity downstream of the polymeric valve; (b) shear rate intensity downstream of the TAVI device; (c) vorticity intensity downstream of the polymeric valve; (d) vorticity intensity downstream of the TAVI device.
Figure 7. Comparison of the phase-resolved velocity vector fields and contour plots of the vorticity and shear rate before and after TAVI at time instant $E$: (a) shear rate intensity downstream of the polymeric valve; (b) shear rate intensity downstream of the TAVI device; (c) vorticity intensity downstream of the polymeric valve; (d) vorticity intensity downstream of the TAVI device.