HEMODYNAMICS ASSESSMENT OF THREE POLYMERIC HEART VALVES USING THREE-DIMENSIONAL PARTICLE IMAGE VELOCIMETRY

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INTRODUCTION

A promising direction in the artificial heart valve research is the use of polymeric material to create polymeric heart valves. Polymeric heartvalves contain flexible leaflets that function similar to the natural human heart valve. Compared to existing mechanical heart valves, polymeric valves promise to reduce complications arising from thrombosis thereby alleviating the need for lifelong anticoagulant therapy [1]. Furthermore, polymeric valves have the potential to minimize calcification related problems; currently a drawback of treated tissue engineered valves. Nevertheless, recent *in vivo* experiments reported thrombus formation at the leaflet-stent juncture of the polymeric heart valves [2, 3]. With very few i*n vitro* experiments to examine the flow characteristics of the polymeric valves, the assessment and determination of how various valve designs affect the fate of blood elements is difficult. A detailed characterization of the flow fields inside and in the vicinity of the polymeric heart valve is therefore necessary to study the relation between flow structures and the observed blood clots. The objective is to develop a qualitative and quantitative picture of the fluid dynamics within and in the vicinity of polymeric heart valves and to assess the importance of various design parameters on the flow structures.

METHODS

Tri-leaflet Polymeric Heart Valves

Three 23 mm tri-leaflet polymeric valves (Figure 1) are investigated in this study. These valves are prototype designs provided by AorTech Europe and were manufactured from high silicone content polyurethane copolymers (Elast-Eon^{TM}). The valve frame and stents were machined from PEEK (Poly-etheretherketone). The prototype A valve (Figure 1a) has a closed commissure design and a leaflet thickness of 80 µm while the prototype B (Figure 1b) has an open commissure design and a leaflet thickness of 120 µm. The prototype C (Figure 1c) has a semi-open commissure and a leaflet thickness of 120 µm. A closed commissure design is characterized by a narrow region between adjacent leaflets near the stent region, while an open commissure design ensures that the leaflets remain separated near the stent in an unstressed state (i.e. absence of a pressure gradient across the valve).

(a) (b) (c)

Figure 1. The Three Prototype Designs of Polymeric Heart Valve; (a) Prototype A, (b) Prototype B, (c) Prototype C

Particle Image Velocimetry (PIV)

Experiments were conducted to measure the velocity field within and in the vicinity of the three 23 mm tri-leaflet polymeric valves using 3D PIV. The valves were placed in the aortic position under physiological conditions in a pulsatile flow loop with a cardiac period of 860 ms. The velocity was measured in seven planes (of size 50 mm x 65 mm) parallel to the stent axis. Figure 2 shows the spacing between each measurement plane with the reference plane passing through the center of the valve. Ensembles of 250 image-quartets were captured for each of the 43 equally distributed time bins over the cardiac cycle. All components of the Reynolds shear stress tensor (RSS) were estimated from the captured velocity ensemble.

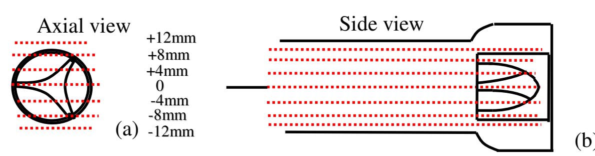

Figure 2. Location of measurement planes (dotted lines)

RESULTS

Peak flow in the three polymeric heart valves was characterized by a strong center orifice jet of approximately 2 m/s. During this phase the flow separated at the edge of the valve and re-attached about 40 mm downstream of the valve. The forward flow in the three polymeric valves displayed a flat profile at the trailing edge of the leaflets and became more parabolic at 30 mm downstream from the valve. A transient vortex ring was revealed at the peripheral of the center orifice jet during the onset of systole in the three polymeric heart valves.

The 3D reconstructed iso-surface of the velocity magnitude displayed a three-lobe flow profile, in which each lobe constituted elevated velocity corresponding to the jet issuing from each of the commissure region (Figure 3).

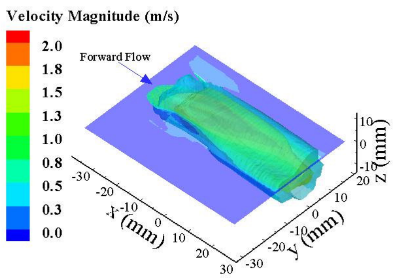

Figure 3. Iso-surface plot of velocity magnitude downstream of the polymeric heart valve

This flow feature was much more distinct in prototypes A and B, and was less apparent in prototype C. This may be because prototype C has a larger flow opening at its commissural region during systole, and thereby minimizing the flow velocity difference across the forward jet. Regions of elevated RSS corresponded well with regions of large velocity fluctuations (high RMS values). These were typically seen during systole, 1) along the edge of the center orifice jet, which extended from the inside of the valve and into the distal portion of the flow chamber, 2) the trailing edge of the valve, and 3) the distal region of the flow chamber where most turbulence mixing occurred. During diastole, high RSS was observed inside the valve corresponding to leakage jets. Elevated principle RSS values as high as 5000 – 30,000 dynes/cm^2 were observed in the shear layer region between the center jet and the chamber wall, the trailing edge of the valve, as well as at the distal part of the flow chamber where the center orifice jet mixed with the surrounding fluid. During diastole, principle RSS of more than 30,000 dynes/cm^2 was observed in the leakage jet inside the valve. Principle RSS values of less than 100 dynes/cm^2 were measured outside the valve during diastole.

Comparison of the three polymeric valves revealed no significant difference in the flow field distribution of the flow downstream and outside of the valves. However, most of the observable flow differences were inside the valves. The general flow feature during the leakage phase inside the three prototype valves was that of flow 'splitting'; with a portion of the flow directed towards the center of the valve, i.e. towards the leakage jet, and the remainder of the flow moving towards the stent inflow region. Well-defined leakage jets were seen at the high central region inside both prototypes A and B but not in prototype C. In valve C, retrograde flow was typically seen along the trailing edge of the valve and occasionally seen with the leakage flow at the high central region. In addition, results from prototype C also showed a much larger leakage flow along the commissure region compared with the prototypes A and B, which mainly produced leakage jets at the high central regions. Furthermore, principle RSS magnitudes of about 5000 dynes/cm^2 were observed in the leakage jet in prototype C which was significantly lower than those observed in the other two valves (>30,000 dynes/cm^2). In prototype B, the 4 mm offset measurement planes revealed vortex structures near the top and bottom stent post regions during diastole. However, these flow structures were not apparent in the other two valves.

DISCUSSION

The results of the present study indicate that commisural design and leaflet thickness may influence the thrombogenic potential of tri-leaflet polymeric valves. The following regions of high shear rates were identified; 1) the vortex ring corresponding to the starting jet during the onset of systole, 2) the edge of the center orifice jet, which extended from the inside of the valve and into the distal portion of the flow chamber, 3) the trailing edge of the valve, and 4) the distal region of the flow chamber where turbulence mixing occur during systole, and finally 5) the leakage jets inside the valve during diastole.

The three-lobe iso-surface of the flow profile downstream of the valve was attributed to the opened configuration of the leaflets during systole. The split flow phenomenon was believed to be caused by the oscillation of the valve during diastole. This split flow may enhance the transportation of the activated/lysed blood elements towards the stent regions. The findings of this study were qualitatively corroborated in the preliminary animal trial studies performed by Wheatley et al [1]. Explanted polymeric valve similar in design to the current prototype valves showed that clots were found along the stent inflow region as well as at the high central region of the leaflets.

The experiments in this study were developed to provide an improved qualitative and quantitative understanding of the functionality and potential thrombogenecity of the polymeric heart valves beyond that available from previous studies. The results of current work provide new insight into the roles that subtle design features, such as the commissural designs and leaflet thickness may have on the potential for blood damage.

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