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In vitro pulsatile flow hemodynamics of five mechanical aortic heart valve prostheses

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Abstract. In vitro measurements of velocity, turbulent shear stress, effective orifice area (EOA), and regurgitant fraction were performed on five new-generation low-profile mechanical aortic heart valve designs under pulsatile flow conditions. These were: Medtronic-Hall tilting disc, St. Jude Medical bileaflet, Björk-Shiley Monostrut tilting disc, Omni-Carbon tilting disc, and Duromedics bileaflet. In general, bileaflet valves have larger EOAs than the tilting disc design, especially in the larger sizes, due to the larger opening angles and lack of obstructive struts. The regurgitant fractions range from 8% for 21-mm valves to 13% for the 29-mm sizes. This increase was largely due to an increase in leakage volume as opposed to closing volume. Furthermore, the leakage volumes increased as the mean aortic pressures increased. The tilting disc valves generally have better regurgitant characteristics compared to the bileaflet valve designs, due to lower leakage volumes and to the smaller opening angle of the occluder providing a more rapid closure of the valve. The velocity and shear stress measurements showed that none of the current valve designs are ideal: all designs create areas of stasis and/or regions of low-velocity reverse flow and regions of elevated turbulent shear stresses capable of causing sublethal and/or lethal damage to the formed elements of blood. It is therefore unlikely that these valve designs will eliminate the problems of hemolysis, thrombosis, and thromboembolic complications.

Key words: Mechanical heart valves – Velocity – Turbulent shear stress – Regurgitant fraction – Effective orifice area

Cardiac valve substitutes have been in clinical use for 30 years. There are more than 50 specific types of such devices, which can essentially be classified into five generic designs: caged-ball valves, caged-disc valves, hinged (or tilting) disc valves, bileaflet valves, and tissue valves. Clinical experience with all of these valve substitutes has indicated that there are well-defined clinical consequences that must be recognized when choosing a prosthesis. These include imperfect hemodynamic (hydraulic) performance, thromboembolism and/or in situ thrombosis, limited durability, damage to the formed elements of the blood, and patient incompatibility. Susceptibility to infection and perivalvular regurgitation have also been defined as adverse consequences but are not clearly related to generic design characteristics.

Although the clinical results of valve replacement with currently available prostheses are satisfactory, imperfect hemodynamic performance has been a significant problem, especially when one considers the influence of hydraulic design on turbulence and stasis and their possible contributions to thromboembolism and hemolysis. To precisely define the in vitro hydraulic performance of a cardiac valve substitute before clinical trial, to minimize the chances for experiencing such hemodynamic liability clinically, detailed in vitro velocity and turbulent shear stress measurements should be conducted in appropriate mitral and aortic flow models. To this end, a pulsatile flow apparatus incorporating a laser Doppler anemometer (LDA) has been designed to simulate certain features of the human aortic root, the left atrium, and the left ventricle.

In the past few years, many investigators have used one-dimensional LDA systems to measure the in vitro velocity fields downstream of different prosthetic valve designs [1-3, 8, 9], but recently two-dimensional LDA systems have been used to measure velocity and turbulent shear stress profiles [5, 6, 10, 11]. Such two-dimensional in vitro measurements now have added clinical relevance with the advent of two-dimensional color-encoded ultrasound Doppler systems [4].

In order to assess the fluid dynamic performance of a prosthetic heart valve design, the following in vitro studies can be conducted: (1) pressure drop (difference or gradient), (2) regurgitant volume, (3) flow visualization, (4) velocity mapping, and (5) turbulence mapping. In this article we will describe in vitro velocity and turbulence
mapping, pressure drop and regurgitant volume measurement studies conducted with five mechanical prosthetic heart valve designs, which have been used clinically during the past decade. These were the Medtronic-Hall tilting disc, the St. Jude Medical bileaflet, the Bjork-Shiley Monostrut tilting disc, the Omni-Carbon tilting disc, and the Duromedics bileaflet. The studies were conducted under pulsatile flow conditions in the aortic position of a left heart simulator. The velocity and turbulence measurements were performed with a two-dimensional laser Doppler anemometer system.

Experimental apparatus and methodology

The prosthetic valves that were studied in the present investigation are listed in Table 1, together with their sewing and primary (or stent) orifice diameters. The valves were studied in the aortic position in the Georgia Institute of Technology left heart pulse duplicator system. A schematic diagram of the aortic flow chamber used is shown in Fig. 1b. Details of the pulse duplicator system and the aortic flow chamber have been published previously [5].

The aortic valve experiments were conducted at a heart rate of 70 beats/min, a systolic time of about 300 ms, a mean aortic pressure of about 90–100 mmHg, and a cardiac output of 6 l/min. Data to be presented in this paper were collected downstream from the valves at three different instances during systole: (1) halfway through the acceleration phase, (2) at peak systole, and (3) halfway through the deceleration phase. The instantaneous flow rates at these times were 18, 34, and 18 l/min, respectively. Data were collected over at least 100 cardiac cycles for each resultant data point.

Table 1. Prosthetic heart valves used in the LDA study

<table>
<thead>
<tr>
<th>Valve</th>
<th>Sewing ring diameter (mm)</th>
<th>Internal stent or primary orifice diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic-Hall tilting disc</td>
<td>27</td>
<td>22.0</td>
</tr>
<tr>
<td>St. Jude Medical bileaflet</td>
<td>27</td>
<td>22.3</td>
</tr>
<tr>
<td>Bjork-Shiley Monostrut</td>
<td>27</td>
<td>22.0</td>
</tr>
<tr>
<td>Omni-Carbon tilting disc</td>
<td>27</td>
<td>22.0</td>
</tr>
<tr>
<td>Duromedics bileaflet</td>
<td>27</td>
<td>21.5</td>
</tr>
</tbody>
</table>

A 45% by weight aqueous glycerine solution with a viscosity of 3.5 cP was used as the blood analog fluid.

The velocity and turbulent shear stress measurements were conducted using a three-beam (i.e., two-dimensional) DISA 55X modular LDA system in both the forward and the back-scatter modes. The LDA system contained a Bragg cell (for flow directionality), and frequency counters for processing the Doppler signals. The frequency counters were digitally interfaced to a PDP 11/03 minicomputer via a buffer interface for online data collection and analysis. A detailed description of the LDA system and the experimental methodology has been published previously [5].

The two velocity components measured simultaneously were perpendicular to each other and formed a 45° angle with the axial velocity component. These two velocity components were decomposed and appropriately combined during the data processing operations to obtain the axial and radial velocity components and the turbulent shear stresses [7].

The pulsatile flow pressures were measured at taps I and II (see Fig. 1b) with Statham physiologic pressure transducers (P23 1D) interfaced to Honeywell bridge amplifiers (218-I). The pulsatile volumetric flow rate was monitored with a Carolina Medical electromagnetic flowmeter (FM 501) and a 25-mm (inner diameter) cannulating flow probe (EP 680). The analog signal outputs from the bridge amplifiers and electromagnetic flowmeter were interfaced to an Apple II plus microcomputer via a 16-channel analog-to-digital converter. The analog signals were digitized at the rate of 500–1000 samples per second and analyzed online by the microcomputer. Data were obtained from at least ten consecutive cardiac cycles.

The pulsatile flow pressure drop and regurgitation studies were conducted under the physiologic conditions described previously. The cardiac output was, however, varied from 2.0 to 7.5 l/min, at a mean aortic pressure of 90–100 mmHg, in order to obtain pressure drop and regurgitation measurements at four to five different cardiac outputs. The regurgitation volume measurements were divided into closing volume and leakage volume (Fig. 1a).

Results

Pressure drop and regurgitant volume measurement studies

For the pressure drop and regurgitation experiments, additional valves were used in order to obtain an understanding of the effect of valve size on hemodynamic performance (see Fig. 2). For these experiments only the Medtronic-Hall, St. Jude Medical, and Bjork-Shiley valves were used.

Fig. 1. a Flow cycle divided into forward flow, closing volume, and leakage volume. b Schematic diagram of the aortic flow chamber.
RF(\%)

\[
\text{EOA} = \frac{Q_{rms}}{51.6 \sqrt{\Delta p}}
\]

where \( Q_{rms} \) is the root mean square of the systolic flow rate (cm\(^3\)/s), \( \Delta p \) is the mean systolic pressure drop between taps I and II (mmHg), and EOA is the effective orifice area (cm\(^2\)).

The EOA is an index of how well a valve design utilizes its primary or internal stent orifice area. The results of these calculations are given in Table 2 and are averaged over a cardiac output range of 2.0–7.5 l/min. The Medtronic-Hall has an EOA of 1.74 cm\(^2\) for the smallest size of 20 mm, which then increases to 3.64 cm\(^2\) for a 27-mm valve. The Medtronic-Hall EOA results are consistently smaller than the results for the St. Jude Medical, which has an EOA of 1.21 cm\(^2\) at 19 mm and 4.05 cm\(^2\) at 27 mm. The valve with the smallest EOAs and therefore the valve which creates the most resistance to the flow is the Björk-Shiley Monostrut, which has an EOA of 1.07 cm\(^2\) for the 19-mm and 3.34 cm\(^2\) for the 27-mm size.

The regurgitant fraction results shown in Fig. 2 show that the Medtronic-Hall valve has a regurgitant fraction of 7.99% (closing volume = 4.1 cm\(^3\) and leakage volume = 2.1 cm\(^3\)) for the smallest size of 20 mm; this increases to 13.24% for a size of 29 mm (closing volume = 5.9 cm\(^3\) and leakage volume = 5.0 cm\(^3\)). The Medtronic-Hall valve figures are generally lower than those for the St. Jude Medical valve, which has a regurgitant fraction of 7.87% (closing volume = 3.7 cm\(^3\) and leakage volume = 2.4 cm\(^3\)) for a size of 19 mm and 14.89% for a size of 29 mm (closing volume = 6.5 cm\(^3\) and leakage volume 6.0 cm\(^3\)). The valve with the lowest amount of regurgitation is the Björk-Shiley, which has a regurgitant fraction of 7.15% (closing volume = 3.9 cm\(^3\) and leakage volume = 3.34 cm\(^3\)).
### Table 3. Peak and mean turbulent shear stresses measured downstream of the different aortic valves

<table>
<thead>
<tr>
<th>Location</th>
<th>Location Details</th>
<th>Acceleration phase</th>
<th>Peak systole</th>
<th>Deceleration phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(dyne/cm²)</td>
<td>(dyne/cm²)</td>
<td>(dyne/cm²)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peak</td>
<td>Mean</td>
<td>Peak</td>
</tr>
<tr>
<td>Medtronic-Hall</td>
<td>7 mm, 7.5 mm above centerline</td>
<td>450</td>
<td>250</td>
<td>1200</td>
</tr>
<tr>
<td></td>
<td>7 mm, 6.25 mm below centerline</td>
<td>950</td>
<td>400</td>
<td>1000</td>
</tr>
<tr>
<td></td>
<td>13 mm, center-line</td>
<td>1200</td>
<td>600</td>
<td>1000</td>
</tr>
<tr>
<td></td>
<td>13 mm, 7.5 mm above centerline</td>
<td>400</td>
<td>320</td>
<td>1500</td>
</tr>
<tr>
<td></td>
<td>13 mm, 6.25 mm below centerline</td>
<td>1250</td>
<td>550</td>
<td>1450</td>
</tr>
<tr>
<td></td>
<td>16 mm, centerline</td>
<td>300</td>
<td>100</td>
<td>2000</td>
</tr>
<tr>
<td></td>
<td>15 mm, rotated 90°</td>
<td>300</td>
<td>170</td>
<td>1450</td>
</tr>
<tr>
<td>St. Jude Medical</td>
<td>8 mm, centerline</td>
<td>820</td>
<td>450</td>
<td>1150</td>
</tr>
<tr>
<td></td>
<td>8 mm, 6.25 mm above centerline</td>
<td>1600</td>
<td>1050</td>
<td>2000</td>
</tr>
<tr>
<td></td>
<td>13 mm, centerline</td>
<td>950</td>
<td>470</td>
<td>1500</td>
</tr>
<tr>
<td></td>
<td>13 mm, 6.25 above centerline</td>
<td>1400</td>
<td>800</td>
<td>2000</td>
</tr>
<tr>
<td></td>
<td>11 mm, rotated 90°</td>
<td>950</td>
<td>550</td>
<td>1700</td>
</tr>
<tr>
<td>Björk-Shiley Monostrut</td>
<td>8 mm, major orifice</td>
<td>260</td>
<td>60</td>
<td>1250</td>
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<tr>
<td></td>
<td>8 mm, minor orifice</td>
<td>480</td>
<td>160</td>
<td>1250</td>
</tr>
<tr>
<td></td>
<td>11 mm, centerline</td>
<td>1000</td>
<td>300</td>
<td>1700</td>
</tr>
<tr>
<td></td>
<td>11 mm, major orifice</td>
<td>260</td>
<td>60</td>
<td>1100</td>
</tr>
<tr>
<td></td>
<td>11 mm, minor orifice</td>
<td>400</td>
<td>150</td>
<td>800</td>
</tr>
<tr>
<td></td>
<td>15 mm, centerline</td>
<td>600</td>
<td>200</td>
<td>1650</td>
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<tr>
<td></td>
<td>17 mm, rotated 90°</td>
<td>800</td>
<td>290</td>
<td>1050</td>
</tr>
<tr>
<td>Omni-Carbon</td>
<td>8 mm, major orifice</td>
<td>300</td>
<td>80</td>
<td>1400</td>
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<tr>
<td></td>
<td>8 mm, minor orifice</td>
<td>730</td>
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<td>850</td>
</tr>
<tr>
<td></td>
<td>8 mm, centerline</td>
<td>400</td>
<td>60</td>
<td>1250</td>
</tr>
<tr>
<td></td>
<td>14 mm, major orifice</td>
<td>800</td>
<td>250</td>
<td>2000</td>
</tr>
<tr>
<td></td>
<td>14 mm, minor orifice</td>
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<td>120</td>
<td>1200</td>
</tr>
<tr>
<td></td>
<td>14 mm, centerline</td>
<td>530</td>
<td>190</td>
<td>1700</td>
</tr>
<tr>
<td></td>
<td>17 mm, rotated 90°</td>
<td>800</td>
<td>210</td>
<td>1800</td>
</tr>
<tr>
<td>Duromedics</td>
<td>13 mm, centerline</td>
<td>1120</td>
<td>300</td>
<td>1500</td>
</tr>
<tr>
<td></td>
<td>13 mm, 6.25 mm</td>
<td>650</td>
<td>380</td>
<td>2300</td>
</tr>
<tr>
<td></td>
<td>Lateral to centerline 13 mm, rotated 90°</td>
<td>800</td>
<td>260</td>
<td>1700</td>
</tr>
</tbody>
</table>

- = 1.69 cm³) for the 19-mm size and 12.60% (closing volume = 5.5 cm³ and leakage volume = 4.8 cm³) for the 29-mm size.

**Velocity and turbulent shear stress studies**

Since previous experience has shown that the flow fields and shear stress fields near the valves provide the most valuable information, half profiles were taken as close as possible to the valve superstructure and full profiles were obtained further downstream. At the locations where half profiles were obtained, it was not possible to obtain full profiles because one or more of the three laser beams were interrupted by the valve superstructure at some point in the traverse. Therefore, it was not possible to make velocity measurements as close to the valve superstructure as is possible with a two-beam LDA system. The downstream locations where the profiles were obtained varied from valve to valve. All downstream distances were measured from the center of the valve sewing ring.

In valves that produced a sharp jet-type flow, the turbulent shear stress had a steep rise within a very short radial distance. Hence the maximum turbulent shear stress measured could be lower than the peak turbulent shear stress actually existing in the flow channel. The wall shear stress was strongly dependent upon the location where the measurements were made. Measurements were made at locations where the wall shear stresses were thought to be the maximum. Wall shear stresses higher than the measured values could have existed at certain locations where measurements were not made. The wall shear stress values presented in the text are estimated from measurements made about 0.035 mm from the flow channel wall.

The figures of the in vitro flow field studies are presented as schematic diagrams and represent velocity and turbulence profiles obtained at peak systole. Table 3 lists the maximum and cross-sectionally averaged mean tur-
peak velocity in the minor orifice was lower than that in the major orifice, especially during the acceleration phase. A region of reverse flow was observed adjacent to the wall in the minor orifice region at peak systole, extending 2 mm from the wall with a maximum reverse velocity of $-25$ cm/s. The size of this region increased during the deceleration phase to 8 mm from the wall. No area of stagnation was observed in the region between the major and minor orifice jets. A small region of flow separation was observed adjacent to the wall in the major orifice region, as illustrated in Fig. 3a. In the minor orifice region, a profound velocity defect was observed 7 mm and 11 mm distal to the minor orifice strut (Fig. 3a). Furthermore, the region adjacent to the wall immediately downstream from the minor orifice was stagnant during the acceleration and deceleration phases, and had very low velocities ($<15$ cm/s) during peak systole.

In the major orifice region, high turbulent shear stresses were confined to narrow regions at the edges of the major orifice jet (Fig. 3b). The peak turbulent shear stresses measured at peak systole were 1200 dynes/cm$^2$ and 1500 dynes/cm$^2$, 7 and 13 mm downstream of the valve, respectively. During the acceleration and deceleration phases the turbulent shear stresses in the major orifice were relatively low.

In the minor orifice region high turbulent shear stresses were more dispersed than in the major orifice region, as shown by Fig. 3b. The turbulent shear stresses during the acceleration and deceleration phases were also high (Table 3). The turbulent shear stress profiles across the major and the minor orifices 15 mm downstream of the valve showed a maximum turbulent shear stress of 1450 dynes/cm$^2$ at the lower edge of the minor orifice jet. Since these high turbulent shear stresses in the minor orifice region were observed 15 mm downstream of the valve, it is probable that even higher turbulent shear stresses occurred in the minor orifice region closer to the valve, where they could not be measured because of the obstruction of the laser beams by the occluder.

St. Jude Medical bileaflet valve. The St. Jude Medical valve has two semicircular leaflets which divide the area available for forward flow into three regions: two lateral orifices and one central orifice. The major part of the forward flow emerges from the two lateral orifices. The measurements along the centerline plane 8 mm downstream of the valve show that at peak systole, the lateral orifice jet had a maximum velocity of 220 cm/s and the central orifice jet had a maximum velocity of 200 cm/s. The velocity of the jets remained about the same as the flow traveled from 8 mm to 13 mm downstream (Fig. 4a). The velocity profiles showed two defects which correspond to the locations of the two leaflets. The velocity measurements conducted during the acceleration and deceleration phases show that the flow was more evenly distributed across the flow chamber during the deceleration phase than during the acceleration phase. Regions of flow separation were observed around the jets adjacent to the flow channel wall as the flow separated from the orifice ring. The measurements across the central orifice...
Fig. 4. a Velocity profiles (cm/s) downstream of the St. Jude Medical valve at peak systole. Left: 13 mm downstream on the centerline; right: 13 mm downstream across the central orifice. b Turbulent shear stress profiles (dynes/cm²) downstream of the St. Jude Medical valve at peak systole. Left: 13 mm downstream on the centerline; Right: 13 mm downstream across the central orifice.

Turbulent shear stress measurements showed that high turbulent shear stresses occurred at locations of high velocity gradients and at locations immediately distal to the valve leaflets (Fig. 4b). The flow along the centerline plane became more disturbed as the flow traveled from 8 mm to 13 mm downstream of the valve. The peak turbulent shear stresses measured along the centerline plane at peak systole were 1150 dynes/cm² and 1500 dynes/cm² at 8 mm and 13 mm downstream of the valve, respectively. The profiles across the central orifice show that the flow was very disturbed in this region. The maximum turbulent shear stress measured in the central orifice (see Fig. 4b; 1700 dynes/cm²) occurred at peak systole. Since these high turbulent shear stresses across the central orifice were measured 11 mm downstream, it is probable that even higher turbulent shear stresses occurred closer to the valve.

Björk-Shiley Monostrut tilting disc valve. The Björk-Shiley Monostrut valve produced three high-velocity jet-type flow fields during our testing (Fig. 5a). The three jets corresponded to the two outflow regions (one from the major and two from the minor orifice) and had approximately the same maximum velocities (200 cm/s) at peak systole.
systole. The region in between the major and minor orifice jets immediately distal to the valve occluder appeared to be stagnant and associated with velocity reversals at all three times at which measurements were taken. This region of low velocity extended 17 mm downstream of the valve.

The velocity measurements taken closest to the major orifice (8 mm downstream of the valve, 8 mm lateral to the centerline) showed a blunt jet type of flow throughout systole. A small region between the jet type of flow and the wall of the flow channel, which extended about 4.5 mm from the wall, appeared to be stagnant. The region became smaller and almost disappeared 11 mm downstream of the valve. The centerline velocity profiles taken 11 mm and 15 mm downstream of the valve showed that the flow emerging from the minor orifice had a very profound velocity defect at the center, which was a result of flow separation from the minor orifice strut.

The maximum velocity of the jet decreased from 180 cm/s to 150 cm/s as the jet traveled from 11 mm to 15 mm downstream from the valve.

The velocity profiles obtained in the minor orifice region 8 mm and 11 mm downstream of the valve showed very similar velocity fields. A jet type of flow field with a maximum velocity of 200 cm/s was observed at peak systole, with a relatively stagnant region adjacent to either side of the flow channel wall. A profound velocity defect was observed in the central part of the flow channel as a result of the flow separation from the minor orifice strut (Fig. 5a). The effect of the strut in the minor orifice region was still clearly observable 17 mm downstream of the valve. The velocity profiles taken across the major and minor orifices at this downstream location showed that only a small amount of forward flow occurred in the minor orifice region along this plane of measurement (Fig. 5a). The velocity profile did show that the flow field had started to recover from the flow separation caused by the minor orifice strut. The region distal to the valve occluder still appeared to be relatively stagnant.

The turbulent shear stress measurements showed that high turbulent shear stresses occurred at locations that corresponded to high velocity gradients (Fig. 5b). In the major orifice, high turbulent shear stresses were confined to a narrow region at the edges of the jet. In the minor orifice region, high turbulent shear stresses were measured at the edges of the jets, with maximum values of 1250 dynes/cm² and 800 dynes/cm² (Table 3) 8 mm and 11 mm downstream of the valve, respectively. The turbulent shear stress profile taken 17 mm downstream of the valve across the major and minor orifice regions clearly showed that the flow field distal to the minor orifice strut was extremely disturbed. Turbulent shear stress measurements along the centerline plane revealed high turbulent shear stresses occurring at locations adjacent to the minor orifice strut and at the edge of the occluder (i.e., the edge of the side jet).

**Omni-Carbon tilting disc valve.** Velocity profiles taken in the major orifice region 8 mm downstream of the valve showed a blunt jet type of flow during the acceleration phase and peak systole. The maximum velocities measured were 130 cm/s and 225 cm/s during the acceleration phase and at peak systole, respectively. Small regions of flow separation were observed adjacent to the wall of the flow channel at peak systole and during the deceleration phase. In the major orifice region, 14 mm downstream, a blunt jet type of flow field was observed at all three phases at which measurements were made (Fig. 6a).

The velocity profile taken along the centerline plane 8 mm downstream of the valve showed the flow field in the major orifice immediately above the occluder. During the deceleration phase, the flow was quite evenly distributed in the central part of the flow channel along this measuring plane. The region adjacent to the pivot guards was relatively stagnant during the acceleration and the deceleration phases. At peak systole, forward flow was observed adjacent to the pivot guards with a velocity of 35 cm/s. Measurements along the centerline plane 14 mm
downstream of the valve showed that the flow field had increased in magnitude, especially during the deceleration phase. The maximum velocities measured were 130 cm/s, 225 cm/s, and 125 cm/s during the acceleration, peak systole, and deceleration phases, respectively.

In the minor orifice region, the forward flow occurred in the central part of the flow channel. The maximum velocity measured 8 mm downstream of the valve at peak systole was approximately 225 cm/s. The region adjacent to the wall appeared to be relatively stagnant during the acceleration phase. At peak systole and during the deceleration phase, a small amount of forward flow was observed in this region. The velocities in the minor orifice jet did not appear to change significantly as the flow traveled from 8 mm to 14 mm downstream from the valve sewing ring (Fig. 6a). The velocity profiles taken 17 mm downstream of the valve across the major and minor orifices (Fig. 6a) showed that the minor orifice jet had a slightly higher maximum velocity than did the major orifice jet, especially during the acceleration phase and at peak systole. An area of flow separation was observed in the minor orifice region adjacent to the flow channel wall at peak systole and during the deceleration phase. The velocity profiles across the major and minor orifices also showed that the forward flow emerging from the minor orifice was sharply reduced during the deceleration phase.

Turbulent shear stress measurements taken 8 mm downstream of the valve in the major orifice showed that high turbulent shear stresses were confined to a narrow region at the edge of the jet. During the deceleration phase, the flow field became disturbed and high turbulent shear stresses were spread over a large part of the measuring plane (Table 3). Measurements obtained in the major orifice 14 mm downstream of the valve showed elevated turbulent shear stresses only at the edges of the jet during all three phases. Along the centerline plane, high turbulent shear stresses were also confined to a narrow region. The maximum measured turbulent shear stress increased from 1250 dynes/cm² to 1700 dynes/cm² as the flow traveled from 8 mm to 14 mm downstream of the valve (Fig. 6b). In the minor orifice region, high turbulent shear stresses occurred in a small region during the acceleration phase and at peak systole, but were spread over a large region during the deceleration phase. The turbulent shear stress measurements across the major and minor orifices (see Fig. 6b), indicated that the flow field in the minor orifice region was more disturbed than that in the major orifice region. The maximum turbulent shear stress measured (1800 dynes/cm²) occurred at the central edge of the minor orifice jet.

Duromedics Bileaflet valve. Experiments with this valve design were done 13 mm downstream of the valve along the centerline plane and 6.25 mm lateral to the centerline. Measurements across the central orifice (with the two leaflets opening and closing in the horizontal plane) were also made at the same downstream location.

The Duromedics valve design has two curved semicircular leaflets that divide the area available for flow into three regions: two lateral orifices and one central orifice.

The results of the velocity measurement studies show that the major part of the forward flow occurred through the two lateral orifices. The velocity profiles obtained along the centerline plane showed that the three jet-like flow fields that emerged from the three orifices had approximately the same maximum velocity of 210 cm/s (Fig. 7a). The profile obtained during the acceleration phase showed that the jet emerging from the central orifice was located in the central part of the aortic flow channel. The velocity profiles obtained at peak systole and during the deceleration phase showed that the jet-like flow from the central orifice was located more toward one side of the flow channel, rather than being centrally located. In addition, of the two velocity defects that separated the three jets, one was larger than the other (Fig. 7a).

The velocity profiles obtained 6.25 mm lateral to the centerline plane showed a distinguishable central jet only
during the acceleration phase. At peak systole and during the deceleration phase, only a small amount of forward flow emerged from the central orifice and it quickly merged into the flow from one of the lateral orifices. During the acceleration phase, the two lateral orifice jets were of the same size and velocity. At peak systole, one lateral orifice jet was larger and had higher velocities, the maximum velocity being measured at 220 cm/s. During the deceleration phase, the size and velocity of the side orifice jets equalized once again. The velocity profiles obtained across the central orifice clearly indicated that the forward flow mainly occurred in the central part of the aorta, with large regions of flow separation on either side of the jet (i.e., adjacent to the pivot/hinge mechanism of the valve, see Fig. 7a).

Turbulent shear stress measurements showed that high turbulent shear stresses were generally observed at locations corresponding to regions of high velocity gradients. The maximum turbulent shear stress measured across the centerline plane was 1500 dynes/cm² (Fig. 7b), with a mean value of 750 dynes/cm² (Table 3). The off-centerline turbulent shear stress measurements showed that the maximum turbulent shear stress along this plane was 2300 dynes/cm², with a mean value of 1250 dynes/cm² (Table 3). The maximum turbulent shear stress measured across the center orifice (see Fig. 7b) was 1700 dynes/cm².

Discussion

Effective orifice area

The EOA is related to the degree to which the valve itself obstructs the blood flow. A larger EOA corresponds to a smaller pressure drop and therefore a smaller energy loss. It is therefore desirable to have as large an EOA as possible.

Table 2 shows the EOA for the Medtronic-Hall, St. Jude Medical, and Björk-Shiley Monostrut valves in a range of sizes. As expected, the EOA increases with valve size. Comparing the Medtronic Hall and Björk-Shiley Monostrut tilting disc designs, it can be seen that the Medtronic-Hall has a consistently higher EOA than the Björk-Shiley Monostrut over the full size range. This higher EOA can be attributed to the Medtronic-Hall design, which provides a lower disturbance to the fluid due to its larger opening angle, thinner disc, and more streamlined strut compared to the Björk-Shiley Monostrut. The EOA results are also consistent with the downstream velocity measurements previously listed.

In comparing the St. Jude Medical bileaflet valve to the Medtronic-Hall and Björk-Shiley Monostrut tilting disc valves, it can be determined that the bileaflet valve has in general the largest EOA, although in the smaller sizes (23 mm and 21 mm) the EOA of the Medtronic-Hall is similar. This shows that the St. Jude Medical bileaflet design is relatively efficient in allowing the passage of fluid, which is most likely due to the absence of supporting struts and the larger opening angle of the two leaflets. The size 20 mm Medtronic-Hall valve has superior pressure drop characteristics compared to the size 19 mm St. Jude Medical and Björk-Shiley Monostrut valves. This is significant when considering the use of smaller size mechanical valves for pediatric applications and in patients with small aortic annuli.

Regurgitant fraction

Figure 2 shows the regurgitant fraction for the Medtronic Hall, St. Jude Medical, and Björk-Shiley Monostrut valves over a range of valve sizes. The bars are subdivided into leakage and closing volumes shown in cubic centimeters per beat, with the total regurgitant volume shown as a percentage of total forward flow per beat. It should be noted that for all the valves studied, the regurgitant volumes (both closing and leakage volumes) as measured in cubic centimeters per beat were independent of the cardiac output. However, leakage volume increased as the mean aortic pressure increased. All valves demonstrate a small change in regurgitant fraction in the smallest sizes, but then a steady and almost linear increase as the valve size increases.

A better understanding of the cause of the increase in regurgitant fraction can be obtained if the closing volume and leakage volume are examined separately. For example, the increase in the leakage volume in the Björk-Shiley Monostrut valve between the 21 mm and 29 mm sizes is approximately twice the increase in closing volume, showing that the increase in regurgitant fraction is largely due to the change in leakage volume.

A comparison of valve types shows that the Björk-Shiley Monostrut has the lowest regurgitant fraction, the Medtronic-Hall the second lowest, and the St. Jude Medical the highest in all orifice sizes. These differences can be related to the design of the valve and in particular to the built-in leakage characteristics of the closed valve and orientation of the open occluder. The smaller the opening angle of the disc, the easier and quicker it can be closed by the reversed flow. The Björk-Shiley Monosrutt, which opens to an angle of 70°, therefore closes quicker than the Medtronic Hall, which has an opening angle of 75°. The Björk-Shiley Monostrut therefore has a lower closing volume. Similarly, the St. Jude Medical valve, which has the largest opening angle of 85° and is the most streamlined valve, closes the slowest and therefore has the largest closing volume.

As stated previously, the leakage volume increases as the mean aortic pressure increases. For example, for the size 25 mm Medtronic-Hall, St. Jude Medical, and Björk-Shiley valves, the leakage volume increased from 3.7, 4.7, and 3.3 cm³/beat to 5.0, 6.2, and 4.8 cm³/beat respectively as the mean aortic pressure increased from 90 mmHg to 150 mmHg. The increase in leakage volume increased the regurgitant fractions (at a cardiac output of 5 l/min) to 11.96%, 13.77%, and 11.30% for the size 25 mm Medtronic-Hall, St. Jude Medical, and Björk-Shiley valves, respectively.

It can be seen that there is a “trade off” in valve design between having a valve that is streamlined in the open direction so that as small a pressure drop as possible is
produced, and having a valve that is nonstreamlined in the closing direction so that closing is rapid and regurgitation is kept to a minimum.

Hemolytic, thrombotic, and thromboembolic effects

**Medtronic-Hall tilting disc valve.** The wall shear stress created by the valve (700 dynes/cm²) could cause sublethal damage to the endothelial lining of the aortic wall. The measured turbulent shear stresses (1900 dynes/cm²) could lead to sublethal and/or lethal damage to red cells and platelets. Therefore it is not surprising that mild hemolysis and thromboembolic problems are clinically observed with this prosthesis. The leakage backflow occurring through the small clearance of the central pivot hole (when the valve is closed) created turbulent shear stresses of the order of 700 dynes/cm². These turbulent shear stresses, although not very great (compared with the turbulent shear stresses measured in the bulk flow downstream of the valve), could lead to severe damage to the blood elements due to surface effects. The region of flow separation in the minor orifice could lead to excess tissue overgrowth along the sewing ring. The wake observed downstream from the strut in the minor orifice region could make this strut a possible location for thrombus formation. In addition, fibrous tissue growing along the sewing ring adjacent to this location might encapsulate this metal surface. If thrombus formation and/or tissue overgrowth started at these locations, the region of the wake could become larger and worsen the obstruction to flow. The region of stagnant flow observed at the edge of the occluder, adjacent to the stops, could trap damaged blood elements which might subsequently adhere to the occluder and lead to thrombus formation. Thrombus formation and/or tissue overgrowth on the metal surfaces could lead to valve dysfunction by impairing the proper pivoting motion of the occluder.

**St. Jude bileaflet valve.** The wall shear stresses observed in this valve were relatively low (630 dynes/cm²), but could cause sublethal damage to the endothelial lining of the aortic wall. The high turbulent shear stresses (2000 dynes/cm²) could cause sublethal and/or lethal damage to blood elements. It is therefore not surprising to observe mild hemolysis and thromboembolic events with this valve. The leakage backflow through the minor orifice showed that flow separation occurred at the edge of the occluder and then adhered to the disc. This part of the disc does not move much when the valve opens and closes. Damaged blood elements adhering to this part of the disc are not likely to be "washed away" and may increase the chances of thrombus formation. Velocity profiles taken in the minor orifice and across the major and minor orifices showed that flow separation occurred from the strut structure in the minor orifice outflow region. The region of flow separation adjacent to the sewing ring in the minor orifice region could encourage the growth of excess fibrous tissue along the sewing ring.

**Omni-Carbon tilting disc valve.** The Omni-Carbon valve design produced turbulent shear stresses as high as 2000 dynes/cm², which are large enough to cause sublethal and/or lethal damage to the blood elements and lead to hemolysis and/or thromboembolic problems. The occluder of the Omni-Carbon valve opens to a 79° angle and has a low pivot axis, allowing more flow through the major orifice region than through the minor orifice region. The region adjacent to the pivot guards was relatively stagnant during the acceleration and deceleration phases, and thus could be vulnerable to thrombus formation. The flow field produced by this valve during the deceleration phase was very unstable and disturbed, which could be a result of the large opening angle and the low pivoting point of the occluder. Furthermore, hydrodynamic instability of the occluder was occasionally observed during the deceleration phase.

**Duromedics bileaflet valve.** This bileaflet valve design also created elevated turbulent stresses that were capable of causing sublethal and/or lethal damage to blood elements, which in turn could lead to hemolysis and thromboembolic complications. The region of flow separation adjacent to the sewing ring could lead to tissue overgrowth. The velocity profiles taken across the central orifice of the Duromedics valve showed a large region of flow separation and/or stagnation on either side of the

**Björk-Shiley Monostrut tilting disc valve.** Clinical studies of the Björk-Shiley valve indicate that the valve can cause mild hemolysis. The wall shear stresses (650 dynes/cm²) created by this valve design could cause sublethal and/or lethal damage to the endothelial lining of the aortic wall. The turbulent shear stresses (1700 dynes/cm²) produced by the valve are large enough to cause sublethal and/or lethal damage to the red cells and platelets, thereby reducing their half-lives. Clinically, it is not surprising to observe hemolysis and thromboembolic problems with this prosthesis. The in vitro studies have indicated that the valve creates two unequal regions of flow: a region of relative stasis below the outflow face of the disc and a region of low flow through the minor orifice. Thrombus formation could occur on the aortic face of the disc and along the strut in the minor orifice region. A region especially vulnerable to thrombus formation would be the edge of the disc, near the centerline plane. The high velocity, jet-like flow adjacent to the flow channel wall leads to high turbulent shear stresses which could damage the blood elements. The damaged blood elements could easily be trapped in the region of stagnant flow below the edge of the occluder and then adhere to the disc. This part of the disc does not move much when the valve opens and closes. Damaged blood elements adhering to this part of the disc are not likely to be "washed away" and may increase the chances of thrombus formation. Velocity profiles taken in the minor orifice and across the major and minor orifices showed that flow separation occurred from the strut structure in the minor orifice outflow region. The region of flow separation adjacent to the sewing ring in the minor orifice region could encourage the growth of excess fibrous tissue along the sewing ring.
central orifice, adjacent to the pivot mechanism of the valve (Fig. 7a). The elevated turbulent shear stresses (as high as 1700 dynes/cm²) measured adjacent to these regions of flow separation and/or stagnation could cause sublethal and lethal damage to the cellular blood elements. The damaged blood elements could then be trapped within the regions of flow separation and/or stagnation and adhere to the surface of the valve adjacent to the pivot mechanism. Since the regions of the pivot mechanism of the Duromedics valve design are never fully washed during the cardiac cycle, as in the St. Jude Medical valve design, thrombus formation may occur in these regions.

Conclusions

The velocity and turbulent shear stress fields created by the Björk-Shiley Monostrut, Omni-Carbon, and Duromedics aortic valve designs are comparable to those created by the Medtronic-Hall tilting disc and St. Jude Medical bileaflet valve designs. These new-generation low-profile mechanical valves are clearly hemodynamically superior to the older generation of mechanical valves (i.e., caged-ball, caged-disc, and first-generation tilting disc valves). The regurgitation characteristics, however, especially leakage, are still less than ideal and should be improved. All five valve designs created regions of flow separation or stagnation, or both, adjacent to the valve superstructure. In addition, all five designs created elevated turbulent shear stresses on the order of 1000 dynes/cm², which are large enough to cause sublethal and/or lethal damage to blood elements. Therefore these valve designs will not eliminate the problems of hemolysis, thrombosis and thromboembolic complications, and hemolysis.

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