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Visualization of the hinge flow in a 5:1 scaled model of the medtronic parallel bileaflet heart valve prosthesis

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Abstract In this work, a flow visualization experiment was performed to elucidate features of the retrograde hinge flow through a 5 : 1 scaled model of the Medtronic Parallel bileaflet heart valve. It was hypothesized that this model would provide detailed flow information facilitating identification of flow structures associated with thrombus formation in this valve. The experimental protocol was designed to ensure fluid dynamic similarity between the model and prototype heart valves. Flow was visualized using dye injection. The detailed flow structures observed showed the hinge's inflow channel was the most suspect region for thrombus formation. Here a complex helical structure was observed.

1
Introduction

It is a tenet among designers of bileaflet mechanical heart valves that these prostheses should allow retrograde flow through the hinge mechanism of the closed valve. The presence of fluid between the leaflet and the valve housing mitigates friction effects allowing rapid response of the valve to the transvalvular pressure difference that is responsible for valve opening. It is also believed that this retrograde flow facilitates washing of hinge components thereby reducing the potential for buildup of thrombotic material in the valve's hinge. Vallana et al. (1992) point out the importance of hinge design in the overall design of bileaflet heart valve prostheses. This mechanism directly affects bileaflet valve durability, function, and thrombus formation potential. The relatively recent experience with the Medtronic Parallel valve underscores the importance of hinge design as it pertains to thrombus formation.

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After the successful completion of all preclinical testing, the aMedtronic Parallel valve was approved for clinical trials in Europe. It was during this stage of the regulatory procedure that an unacceptable level of thrombus was observed. Evaluation of explanted valves showed that the thrombus occurred predominantly in the valve's hinge regions. Medtronic withdrew the valve from subsequent trials and immediately initiated studies to ascertain whether the incidence of thrombus in these valves was related to a combination of patient and material factors. These studies were negative. This shifted attention to the fluid dynamics associated with the Parallel valve's hinge design.

Although the role of fluid dynamics in thrombus formation in prosthetic valves is not fully understood, it is generally accepted that turbulence generated in the flow field of the prosthesis is responsible for the high levels of hemolysis observed clinically. Examples of work on this theory include Horstkotte and Burckhardt (1995), Sutera and Joist (1992), and Yoganathan et al. (1992). In addition, the potential for thrombus formation may depend on the structures of the flow near the prosthesis. Sutera and Joist (1992) showed that in regions of stagnation or recirculation, damaged blood elements can accumulate and aggregate leading to thrombus formation. Thus, to characterize valve performance, areas of high turbulent stresses must be identified and flow patterns near these areas must be described. The current study focuses on the latter description using flow visualization to study flow within the hinge of the Parallel valve. Recent studies have focused on flow visualization and characterization of the turbulent stresses for this valve.

Two recent studies were performed using computational fluid dynamics (CFD), flow visualization, and laser Doppler velocimetry (LDV) to investigate the flow patterns within the hinge of the Parallel valve. The LDV study of Ellis et al. (1996) provided an excellent quantitative study of the velocity and turbulent shear stress at discrete points within the hinge region under conditions of physiologic unsteady flow. However, the full flow field could not be visualized based on these data due to the discrete nature of LDV measurements.

Full field, semi-quantitative velocity information was obtained from the CFD results of Gross et al. (1996). These velocity data were validated qualitatively by using hydrogen bubble flow visualization conducted in a 1 : 1 valve model with a clear housing. In this study, the wire responsible for bubble production was located upstream of the hinge. The unsteady flow streaklines were recorded using high-speed video imaging and the resulting flow patterns were observed

and documented. This study provided a good description of the flow within the hinge. However, it was limited due to the fact it was not possible to position the wire responsible for bubble production within the hinge mechanism itself. Thus, it was not possible to get detailed information about the flow patterns within the hinge. To fully study the flow within the hinge, it must be possible to introduce a visualization medium directly into the hinge flow.

An injection system built for the prototype valve would be too fragile for practical experimental use. In addition, a scaled model could elucidate finer features of the flow patterns observed in previous studies. For these reasons, a 5 : 1 scaled model of a clinical quality Medtronic Parallel valve was constructed. This model was used in a series of experiments to study the flow patterns within the hinge of the Parallel valve under steady flow conditions corresponding to peak retrograde flow for a Parallel valve in the mitral position.

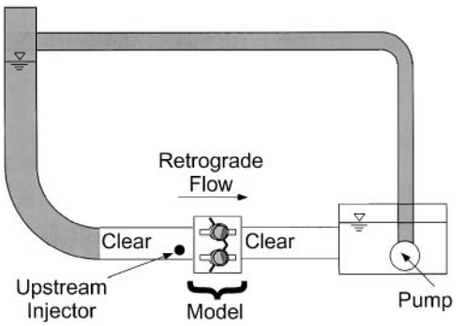

Fig. 1. Flow loop used to achieve high-pressure drops across the scaled valve model. The gray pipe sections denote opaque loop components while the clear sections and the valve model are labeled. In addition, the direction of retrograde flow is indicated

2
Experimental model and setup

2.1
Flow loop

The steady flow loop used in these experiments is shown in Fig. 1. This loop consisted of a constant head reservoir, a straight clear inlet section to the valve model, and a clear outlet section connected to a pump reservoir maintained at atmospheric pressure conditions.

The pressure head conditions were verified and maintained by ensuring the height of fluid above the valve hinge datum was correct for achieving the desired pressure difference. This was accomplished by using a sight glass installed in the elbow upstream of the clear inlet section.

2.2
Valve model

The clear plastic model, manufactured by the Medtronic Heart Valve Division (Minneapolis, MN), was an exact and fully functional 5 : 1 scaled model of a clinical quality 27 mm Medtronic Parallel mitral valve prosthesis. This model included full leaflet functionality and scaling of manufacturing tolerances commensurate with the geometric scaling. Fig. 2 shows a schematic of the Parallel valve; Fig. 2a is a front view of the prosthesis, while Fig. 2b shows the side view. The dotted rectangle in Fig. 2b shows the hinge studied in this flow visualization experiment. Figure 3 shows an enlarged view of the hinge assembly for the valve model. Terminology relevant to the hinge assembly is also defined in this figure.

The model was composed of two clear plastic blocks bolted together to form the full valve. The circular annulus of the valve was removed from the center of the block by initial rough-cuts and finishing by precision machining. The valve housing represents a slight flow obstruction. Therefore, it was necessary to create the valve housing as a raised surface during the finishing stages of the model's interior. In this way, the effects of this disturbance on the hinge flow were reproduced accurately.

Normal manufacturing tolerances associated with the production of a prosthetic valve allow a small amount of lateral

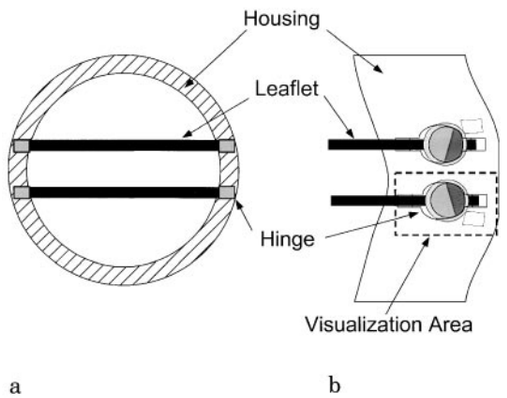

Fig. 2a,b. Schematic of medtronic parallel bileaflet valve in the opened position. **a** Shows the front view of the parallel valve as seen from upstream looking downstream **b** shows a side view of the valve. Here the valve's hinges and leaflets are indicated as well as the area where flow visualization was performed

leaflet mobility. Consequently, the width of the flow channel between the leaflet peg and housing wall, or the gap width, can vary between 50 and 200 μm in the prototype clinical valve. The scaling of manufacturing tolerances resulted in gap widths ranging between 250 and 1000 μm. These extremes in gap width defined the minimum and maximum gap width conditions for the experiments conducted.

Flow visualization was accomplished by aqueous dye injection upstream of the hinge, based on the retrograde flow direction, and at four distinct points on the periphery of the hinge assembly. The locations of these injectors are shown in Fig. 4.

The injector upstream of the hinge consisted of a 7.6 cm straight section of hypodermic tubing with an inner diameter of 1.6 mm. The tubing was bent 90° and passed through the wall of the upstream pipe section through a compression tube fitting. This steel tubing provided rigid support and good position control for a catheter tube that was inserted through the hypodermic tubing. Dye was injected through the catheter tube into the flow field of interest. This assembly provided variable positioning of the catheter injector in front of the

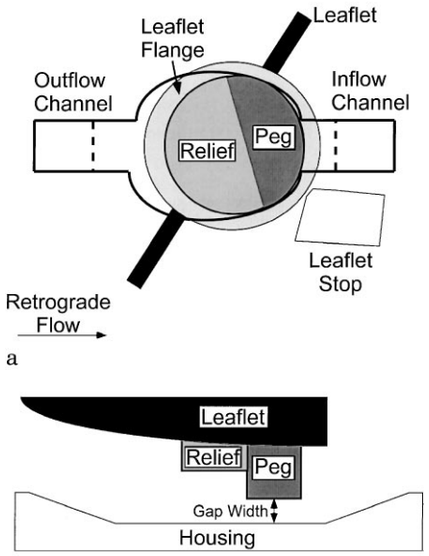

Fig. 3a,b. Schematic of Medtronic Parallel valve hinge mechanism. **a** Shows a side view of the hinge mechanism while **b** shows the top view. Terms used to describe parts of the hinge mechanism are also defined illustratively in this figure

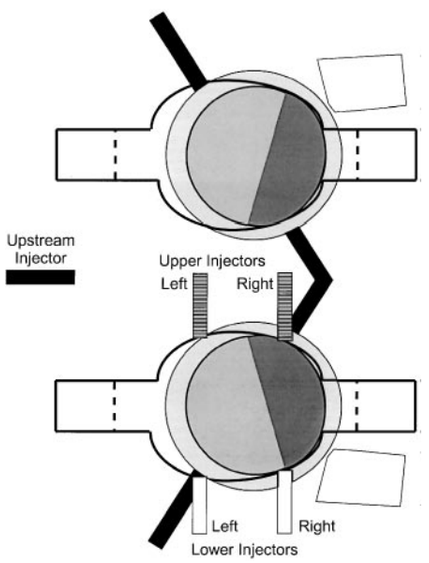

Fig. 4. Schematic showing locations of dye injectors used in the flow visualization experiments. Both hinges are shown in this figure to show the relationship between the hinge studied and the second hinge on the same side of the valve. The hinge studied in this work was the bottom hinge

hinge and leaflet flange. The position of this injector was varied as part of each experiment to facilitate the injection of dye lines into different regions of the hinge geometry.

The four injectors around the hinge periphery provided preferential injection of dye into the side regions of the hinge geometry. In all injection experiments, the dye was injected such that the retrograde flow entrained the dye lines and transported them through the hinge geometry. Since the dye was entrained in the hinge flow, this method inhibited accumulation of dye in separation regions due to minimal mass transfer between the main flow and areas of separation. Thus, regions in which the dye is absent may represent potential areas of separated flow.

Constant video recording of all experiments was accomplished using a standard VHS video system. This system consisted of a video camera (Digital 5100, Panasonic, Japan), VCR (AG-6300, Panasonic, Japan), and various lenses to facilitate magnified and wide-angle views of the hinge.

2.3 Establishing similarity

The work of Affeld et al. (1989, 1990) provided a good starting point for the similarity analysis of scaled heart valve models. In these works, unsteady bulk flow through monoleaflet heart valve prostheses was studied. Similarity matching using Reynolds, Strouhal, and Archimedes numbers was presented for unsteady flow.

Since the present experiments were conducted under conditions of steady flow, the Strouhal number was not a relevant dimensionless group in this case. In addition, to facilitate visualization of the hinge flow, the leaflets were fixed in the closed position. Therefore, the Archimedes number was not a relevant scaling parameter either.

For this internal flow, the relevant descriptive variables were taken to be the pressure drop across the hinge, fluid velocity within the hinge, fluid viscosity, and hinge gap width. An elementary application of dimensional analysis showed that the pressure coefficient depended upon Reynolds number and a ratio of characteristic lengths. Since the model used was an exact 5 : 1 scaled model of the clinical quality valve, the ratio of geometric lengths was the same between the model and prototype. Therefore, the pressure coefficient, C_p, depended exclusively upon Reynolds number.

$$C_p = \frac{\Delta p}{\frac{1}{2}\rho V^2} = f(Re)$$

In the foregoing equation Δp represents the pressure drop, ρ is the fluid density, V represents the bulk fluid velocity, and Re represents the Reynolds number based on hinge gap width.

Application of the energy equation to the experimental configuration showed that the velocity through the hinge was a function only of the pressure drop across the hinge. This was underscored by the fact that the minor loss coefficients associated with the sudden contraction and expansion experienced by the fluid passing through the hinge are functions of the upstream to downstream area ratios. These ratios were unaffected by scaling because geometric similarity was maintained.

The preceding discussion elucidates the inertial character of the flow. For this reason, it was decided that Reynolds number matching should be accomplished by using a viscosity five times greater than blood in the model to counterbalance the effects brought about by geometric scale-up. In this way, the Reynolds number and, subsequently, the pressure coefficient were matched between the prototype and model.

2.4
Experimental conditions

The experiments were designed to provide physiologic Reynolds number matching between the prototype and model by adjusting the fluid viscosity in the model. Due to lateral mobility of the valve leaflets, the two extreme leaflet positions resulting in minimum and maximum gap widths in the hinge were studied. Under physiologic flow conditions, the 27 mm Parallel mitral valve should experience a peak retrograde flow velocity of approximately 5 m/s through the hinge. This corresponds to local Reynolds numbers of 69 and 281 for the minimum and maximum gap width cases, respectively. These Reynolds numbers are based on gap width and a nominal blood viscosity of 3.5 cSt.

3
Results

This section presents the flow patterns observed during this experiment. These results are presented based on locations within the hinge; this is done to facilitate a lucid and orderly presentation.

3.1
Flow patterns through central hinge section

The two flow patterns observed in the central section of the hinge were produced by introduction of dye from the upstream injector. Both of these patterns, numbered one and two for convenience in discussion, are shown by dotted lines in Fig. 5.

In pattern one, the dye lines were convected into the hinge mechanism along the housing of the valve. The dye streaks were centrally located within the hinge as shown in Fig. 5. A flow bifurcation, letter "A" in Fig. 5, was observed in the dye lines at the bottom of the hinge. Here, a portion of the flow followed the step created by the elevation change between the peg relief and the peg itself; this flow exited the hinge mechanism near the lower right injector. The remaining dye lines, including those in the central and upper sections of the hinge, impacted the side of the peg resulting in deflection upward toward the inflow channel. In the minimum gap width case, the region between the leaflet flange and the leaflet stop was observed to be devoid of dye independent of the location of the upstream injector. This may indicate a region of potential flow stasis and thus a region favorable for accumulation of damaged blood elements and subsequent thrombus formation. Under conditions of maximum gap width, dye was observed in this region indicating that adequate washing of this region may occur under the maximum gap width condition.

The second flow pattern observed in the central section of the hinge, labeled with the number two, occurred when the dye entered the hinge and impacted or passed near the leaflet flange. In this pattern, the flow was observed to roll up as it traveled around the junction between the flange and the peg relief forming a junction vortex. This vortex wrapped around the peg relief and traveled along its face for a short distance before rolling up onto the surface of the relief. Once on the surface of the relief, the flow traveled through the remainder of the hinge following a path similar to the first flow pattern. The observed junction vortex appeared to wash the outflow side of the peg quite well.

3.2
Flow patterns through lower hinge section

Flow patterns through the lower section of the hinge were observed by rotating the upstream injector toward the lower section of the hinge and by injection of dye through the injectors located at the bottom of the hinge mechanism. The flow patterns elucidated by dye lines from these injectors are shown in Fig. 6.

Dye lines originating from the upstream injector, shown by dotted lines, followed three patterns. In the first pattern, labeled number one, the dye was entrained quickly into the flow exiting the hinge area upstream of the leaflet. In the second pattern, labeled number two, dye was pulled up toward the outflow channel and then directed downward into the hinge mechanism following the junction between the peg relief and the leaflet flange. The last pattern, labeled number three,

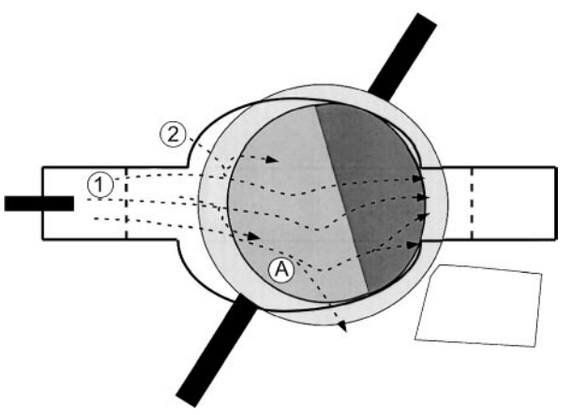

Fig. 5. Dye lines through the center section of the Parallel valve hinge. The numbers are used to delineate the two principal patterns observed by introducing dye from the upstream injector. The letter "A" denotes an observed flow bifurcation in this configuration

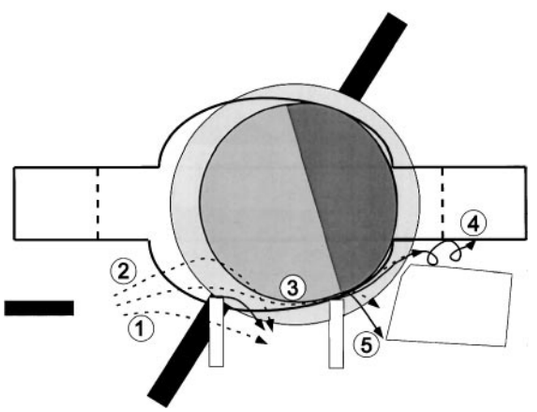

Fig. 6. Dye lines through the lower section of the Parallel valve hinge. These lines were observed by introducing dye from the upstream and lower hinge injectors. The dye lines from the upstream injector are shown as dotted lines while those from the lower hinge injectors are shown as solid black lines. The flow patterns are numbered to differentiate the various flow patterns observed

showed dye entering the hinge mechanism where it appeared to follow the contour of the peg flowing along the peg-flange junction. This dye line was observed to exit the hinge mechanism either just before the leaflet stop or between the leaflet stop and the inflow channel.

Dye lines that originated from the lower right injector, shown by solid black lines in Fig. 6, were observed to follow two different paths. On one path, labeled number four, dye lines followed the peg-flange junction and exited the hinge between the leaflet stop and the inflow channel. A small helical structure was observed as the fluid traveled across the leaflet stop. On the other path, labeled number five, the dye was diverted sharply downward upon exiting the tip of the injector. This dye exited the hinge mechanism between the lower right injector and the leaflet stop.

All dye lines originating from the lower left injector, also shown by a solid black line in Fig. 6, were diverted downward sharply. These dye lines exited between the two injectors in the lower hinge section.

3.3
Flow patterns through upper hinge section

Flow patterns in the upper section of the hinge were observed primarily using the upper injectors within the hinge mechanism. The observed flow patterns are shown in Fig. 7.

Dye lines from the upper left injector, shown by dash-dotted lines in Fig. 7, traveled across the peg face remaining in the upper section of the hinge mechanism. These lines exited the hinge in the inflow channel and became part of a large helical flow structure observed in this part of the valve. This structure is discussed in more detail in the next section of the paper.

Two flow patterns were observed by introduction of dye from the upper right injector. These patterns are also shown by dash-dotted lines in Fig. 7. In both patterns, the dye initially followed the peg-flange junction. Some dye lines were observed to detach from the peg-flange junction and exit the valve's hinge mechanism just above the inflow channel. These dye lines were quickly entrained into the high velocity flow in the inflow channel and exited the area of interest rapidly. More commonly, the dye lines flowed along the peg-flange junction slightly further than in the previous pattern. These dye lines crossed the inflow channel, impacted the leaflet stop, and rolled up into a helical pattern that traveled across the surface of the stop as shown in Fig. 7. This helical pattern may act to scour the surface of the leaflet stop providing excellent washing for this component of the hinge mechanism. In contrast to the leaflet stop, the area of the peg face at the tip of the upper right injector was observed to be devoid of dye. This region may not be washed adequately to prevent accumulation of damaged blood elements and subsequent thrombus formation.

3.4
Other areas: inflow channel and between valve hinges

The retrograde flow through the inflow channel was observed to produce a complex helical flow pattern. Fig. 8 illustrates the flow patterns observed for the dye injection experiments performed. The small regurgitant jet is confined on three sides by the inflow channel. Therefore, it is believed that the complex helical flow pattern was a consequence of vorticity generated in the shear layers of the turbulent regurgitant jet.

The region between the valve hinges was the last area investigated in this work; this area was studied using dye entrained from the upstream injector. The resulting flow pattern is shown in Fig. 9. The dye from the injector was split and directed toward the hinge mechanisms. In all of the experiments, the region between the leaflet flanges and adjacent to the leaflet surfaces appeared to be stagnant. Direct injection of dye between the leaflets showed an accumulation of dye in this area. Thus, this area was not washed well during retrograde flow. In addition, because this region is near the valve housing and between the leaflet flanges, it is doubtful that good washing occurs during forward flow. Therefore, this area may represent another location where damaged blood elements could accumulate.

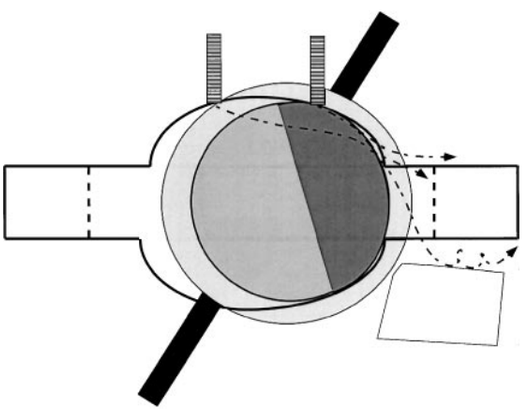

Fig. 7. Dye lines through the upper section of the Parallel valve hinge. These lines were observed by introducing dye from the upper hinge injectors. The dye lines from these injectors are shown as dash-dotted lines

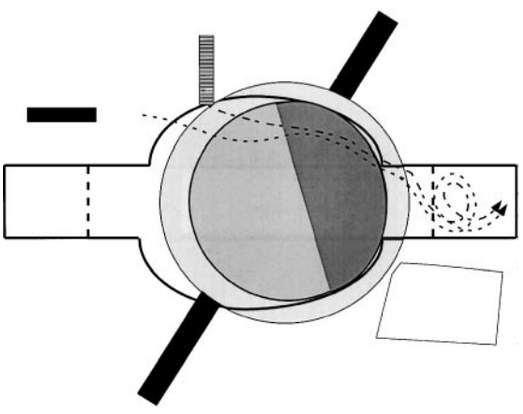

Fig. 8. The complex helical flow structure shown in the inflow channel of the valve. This structure was observed via dye injection from the upstream injector and the upper left hinge injector. Dye lines from the upstream injector are shown by the dotted line while those from the upper left injector are shown as a dash-dotted line

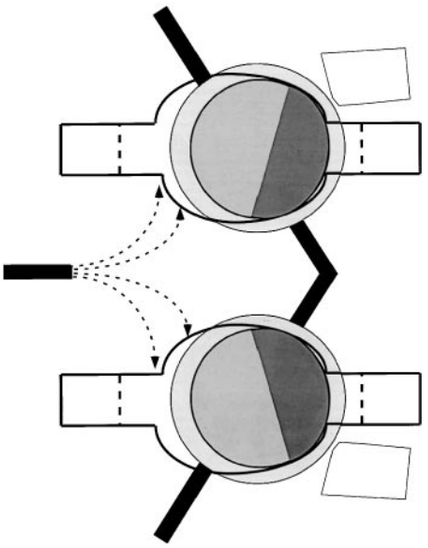

Fig. 9. Flow pattern observed when dye is injected between the hinge mechanisms of the Parallel valve. The dye is quickly drawn to the hinge mechanisms leaving the space between the leaflets unwashed under conditions of retrograde flow

4 Discussion

The first point that should be addressed is the credibility of a steady flow experiment for elucidating flow through cardiac devices. To address this question, the results of this study were compared to the unsteady flow results reported by Ellis et al. (1996) and Gross et al. (1996).

Comparison of the current results with those reported by Gross et al. (1996) showed most of the flow patterns observed in this study were also observed in unsteady flow visualization and computational simulations. The only exceptions were the junction vortex shown in Fig. 5 and the helical flow pattern across the leaflet stop shown in Figs. 6 and 7. It is theorized that these structures do not exist in unsteady flow because of the movement of valve components. Movement of the hinge mechanism associated with valve function and the impact of the fully opened leaflet with the stop disturb the local flow field to an extent where the period during which the valve is closed is not of sufficient length to allow these structures to develop. The strong entrainment of fluid into the hinge mechanisms shown in Fig. 9 was also not observed in the work of Gross et al. (1996). In a clinical quality valve, small leaks exist between the leaflets and around the valve periphery. in the current study, all such leaks were sealed to prevent extraneous retrograde flow away from the hinges. This implies that the only path for fluid through the valve was through the hinge mechanism.

The LDV results of Ellis et al. (1996) also exhibit some of the features observed in this study. Results associated with peak retrograde flow through the hinge show the deflection of flow toward the inflow channel. In addition, the LDV studies show the strong helical nature of the structure observed in the inflow channel of the valve.

The comparison of the current results with those presented in the literature serves to provide some validation of the current model results. Having established that this steady flow work qualitatively represents what occurs under conditions of unsteady flow, attention is now turned to the implication of the current results.

Figure 5 shows a region of flow stagnation between the branches of the flow bifurcation previously discussed. This region is between the lower right injector and the leaflet stop. Here very little dye was observed. It is doubtful that this region will be washed in forward flow, as the flow is likely to be separated behind the stop itself. Thus, this region may not be washed sufficiently in forward or retrograde flow.

The flow pattern depicted in Fig. 9 may represent another stagnant zone in the valve flow field. LDV data have been collected by the third author 1 mm upstream and downstream of the valve under conditions of physiologic, unsteady flow. These data showed that the area between the valve hinges near the housing was essentially stagnant during all phases of the flow cycle. Thus, blood elements that enter this area will probably remain trapped.

Another region that appears to remain unwashed under retrograde flow conditions is the tip of the peg at the orifice of the upper right injector. Under all conditions, including direct injection from the upper right injector, this region appeared devoid of dye. Although the movement of the hinge mechanism may agitate the fluid in this region, it is doubtful that the disturbance will be sufficient to clear accumulated blood elements from the hinge. If the blood elements are cleared from the hinge, it is doubtful that these elements will have sufficient momentum to clear the stagnation zone on the inside wall of the valve housing between the hinges.

While all of the areas of flow stagnation may contribute to the thrombus formation within the hinge of the Parallel valve, the most suspect region is the inflow channel of the hinge. The complex helical flow structure that was observed in the inflow channel might provide a mechanism for thrombus formation as follows. Blood elements damaged within the hinge become trapped in the core of this complex helical flow pattern upon valve closure. Damaged elements accumulate and form a larger thrombus. Thrombi that are washed from the inflow channel could become attached to the housing wall. The stagnant flow near the housing may indicate that this could be a potential area of secondary thrombus nucleation and growth.

This mechanism also depends on the flow structure observed in the inflow channel during the forward flow phase of the heart cycle. Gross et al. (1996) report that the complex flow structure persists throughout the forward flow phase. However, the structure is weaker during forward flow. Its strength could be sufficient to hold the damaged elements which have been trapped during retrograde flow and allow subsequent deposition of damaged elements during the next retrograde flow period.

Gross et al. (1996) also provide a composite scanning electron micrograph produced from the hinge of a Parallel valve removed from a human recipient. The micrograph shows the formation of a large thrombus in the inflow channel and deposition of thrombus material near the tip of the peg corresponding to a point near the inlet of the upper right dye injector in the present model. These were identified as stagnant

flow regions in the current study. Thus, this clinical evidence appears to show growth of thrombus at regions that correspond to regions of stagnant or strongly recirculating flow in the current study.

5
Conclusions

The current study provides a detailed look at the flow patterns within the hinge of the Parallel valve. The flow patterns in the current model agreed well with patterns observed by Ellis et al. (1996) and Gross et al. (1996) using a 1 : 1 model of the Parallel valve. In addition, regions of flow stagnation detected in the current model agreed with sites of thrombus formation observed in an explanted valve. This provided some confirmation that observations based on the steady flow results obtained in this study could, potentially, be extrapolated to the Parallel valve hinge under conditions of unsteady flow. In addition, because of the larger size of the current model, some of the flow patterns observed in the current work may not have been visible in the 1 : 1 models. Thus, a scaled model of prosthetic heart valve flow may prove beneficial for those seeking to observe structures within the small hinges of such valves.

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