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Micro Particle Image Velocimetry Measurements of Steady Diastolic Leakage Flow in the Hinge of a St. Jude Medical® Regent™ Mechanical Heart Valve

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Abstract

A number of clinical, *in vitro* and computational studies have shown the potential for thromboembolic complications in bileaflet mechanical heart valves (BMHV), primarily due to the complex and unsteady flows in the valve hinges. These studies have focused on quantitative and qualitative parameters such as velocity magnitude, turbulent shear stresses, vortex formation and platelet activation to identify potential for blood damage. However, experimental characterization of the whole flow fields within the valve hinges has not yet been conducted. This information can be utilized to investigate instantaneous damage to blood elements and also to validate numerical studies focusing on the hinge's complex fluid dynamics. The objective of this study was therefore to develop a high-resolution imaging system to characterize the flow fields and global velocity maps in a BMHV hinge. In this study, the steady leakage hinge flow fields representing the diastolic phase during the cardiac cycle in a 23 mm St. Jude Medical (SJM) Regent BMHV in the aortic position were characterized using a two-dimensional Micro Particle Image Velocimetry (μ PIV) system. Diastolic flow was simulated by imposing a static pressure head on the aortic side. Under these conditions, a reverse flow jet from the aortic to the ventricular side was observed with velocities in the range of 1.47 to 3.24 m/s, whereas low flow regions were observed on the ventricular side of the hinge with viscous shear stress magnitude up to 60 N/m². High velocities and viscous shearing may be associated with platelet activation & hemolysis, while low flow zones can cause thrombosis due to increased residence time in the hinge. Overall, this study provides a high spatial resolution experimental technique to map the fluid velocity in the BMHV hinge, which can be extended to investigate micron-scale flow domains in various prosthetic devices under different hemodynamic conditions.

Keywords

Particle Image Velocimetry (PIV); Thrombosis; Blood damage; Mechanical Heart Valve (MHV); hinge flow; Fluid dynamics

Introduction

Over 55% of heart valve replacements utilize mechanical heart valves (MHVs),²⁷ with bileaflet mechanical heart valves (BMHV) currently the most popular design. BMHVs

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consist of two leaflets that insert into recessed hinges within an external housing and have been shown to be extremely durable with satisfactory bulk flow characteristics.² Despite its widespread use, the BMHV's hinge and pivot regions have been implicated by many researchers for their potential to cause hemolysis and thrombosis due to high fluid shear stresses and low flow recirculation regions imposed on blood constituents.⁵

Characterization of hemodynamics in the hinge region is a critical step to improve valve design, however it is difficult to obtain detailed fluid flow measurements in this region due to the small spatial scales involved. Previous studies have sought to quantify fluid flow parameters in the hinges of these valves. Leo *et al.* (2002)¹¹ investigated the hinge flow fields *in vitro* using Laser Doppler Velocimetry (LDV) inside 27mm Standard St. Jude Medical (SJM) BMHV prototypes with three different hinge gap widths. It was shown that thromboembolic potential was higher in prototypes with either a smaller and larger gap width than in the standard model. In addition, similar LDV studies were conducted comparing SJM and 23mm CarboMedics prosthetic heart valve BMHVs under physiological aortic and mitral valve conditions.^{10,22}

However, the major limitations with LDV experiments are the low spatial resolution and significantly long data acquisition period since it is a point measurement technique. To obtain 2D velocity fields in the BMHV hinge using LDV, a number of measurement locations and velocity measurements up to 130 and 21,500 were required, respectively.¹⁹

Among different designs of BMHVs investigated in these *in vitro* LDV studies,^{10,11,22} the leakage flow phase has been shown to have the highest thromboembolic potential of any phase of the cardiac cycle. A previous LDV study²² reported that the maximum velocity and turbulent shear stress measured in the hinge when the leaflets were fully closed were two or more times higher in magnitude than during any other phase. Subsequently, Fallon *et al.*⁴ and Travis *et al.*²³ conducted *ex vivo* studies to assess platelet activation and markers of platelet damage within different hinge designs during the leakage flow using a steady flow loop system. The studies concluded that clotting in a mechanical heart valve is most likely due to leakage flow through the hinge area and that hinge gap width had a significant effect on platelet secretion initiated by leakage flow.

More recently, numerical simulations of hinge flow fields under aortic conditions have been conducted, which revealed 3D velocity under pulsatile flow.²¹ In addition, Yun *et al.*²⁸ used, realistically modeled blood elements within the hinge region to quantify blood damage associated with different hinge designs including the SJM and Carbomedics BMHVs. These studies have enabled more detailed characterization of these flow fields, however validation of these computational methods with whole flow fields obtained from experimental work is still necessary.

Particle Image Velocimetry (PIV) can provide whole flow fields with enhanced spatial resolution in hinge flows, overcoming limitations of previous experimental and computational techniques. PIV has been utilized to study regurgitant flow fields across and perpendicular to the B-datum line in 27mm SJM BMHV under physiological conditions, where a strong regurgitant jet and twin vortices near the leaflets were observed.¹³ More recently, Bellofiore *et al.*¹ used a scale-up model representative of an SJM BMHV to investigate the unsteady flow fields at the trailing edge of the leaflet with enhanced spatial and temporal resolution. However, this improvement requires a very large experimental system with nearly 160 L of fluid volume. Overall, PIV techniques used in these studies are designed for spatial resolution on the order of 1mm, which is too large for investigating the hinge flows, where the entire geometry has a width of about 3-4 mm.

μ PIV is a well-established technique to quantitatively measure flow behavior in small domains down to the nanometer scale.¹⁵ This meets the spatial resolution demands for experimental studies in BMHV hinge flow fields. Typical μ PIV studies are performed at low Reynolds numbers, with steady flow conditions in micron-scale uniform flow domains such as rectangular microchannels.²⁵ In addition, the total fluid volume of such systems is typically less than 20 ml.

In comparison, there are unique challenges to utilizing μ PIV in the BMHV hinge, where the fluid volume required to generate physiologic pressure across the human aortic valve ranges from 4 L to 10 L in *in-vitro* heart simulators used in relevant LDV and PIV studies.^{11,13,18,22} Despite this macro-scale flow domain, the hinge recess (1.5 μ L in volume) is orders of magnitude smaller, making it difficult to achieve a good seeding density when flow has to pass through the entire valve region. In addition, the choice of an appropriate objective lens is limited since magnification larger than 5 $\times$ will only resolve smaller areas of the hinge region, and magnification smaller than 3 $\times$ will have depth of field greater than the hinge recess gap. Consequently, the specific aim of this study was to develop a custom-designed μ PIV system to characterize the flow fields within a BMHV hinge.

Methods

Valve Model

A 23 mm SJM Regent BMHV valve with transparent body was directly obtained from the valve manufacturer for this study. All parts of the clear housing valve were manufactured with tolerances identical to those of clinical models (Figure 1-a). This transparent acrylic replica of the valve allows optical access to the hinge region. The leaflets of the valve were made from pyrolytic carbon with a graphite substrate containing tungsten. Figure 1-b shows two different views of the BMHV and Figure 1-c,d represent the hinge geometry and leaflets during the fully opened and closed positions. In this study, the BMHV leaflets were maintained in the closed position throughout the experiment since only aortic leakage flow during diastole was studied.

The spatial dimension of the hinge cavity is 3.5 by 3.5 mm and the depth of the hinge recess was approximately 600 μ m (Figure 1-c,e) based on the micro CT scan image of the BMHV hinge conducted by Simon.²⁰ The SJM hinge geometry has a smooth butterfly-shaped cavity that retains semicircular leaflet ears. The opening and closing angles of the leaflet relative to the horizontal axis indicated in Figure 1-c are 84° and 29°, respectively. This design has been shown to have favorable washout in terms of recirculation and local shear stress levels compared to other hinge geometries such as Carbomedics BMHV.^{10,22}

Measurement Locations

As illustrated in Figure 2-a, four measurement planes separated by 195 μ m were chosen with the bottom flat surface of the hinge selected as a reference plane. These planes are referred to as **FLAT**, **195 μ m**, **390 μ m** and **585 μ m** planes, based on their distance from the reference plane (flat level). The **FLAT** and **195 μ m** planes are referred to as the lower measurement planes, while the **390 μ m** and **585 μ m** planes are referred to as the upper measurement planes. In order to image the entire hinge region with the microscope lens, 2D-PIV images were acquired at three distinct sections (Figure 2-b). These were labeled as aortic, center or ventricular, according to their spatial location. The flow fields acquired at each of these locations were superimposed on the corresponding raw PIV images of the hinge using Tecplot (Tecplot Inc, Bellevue, WA, USA) to represent global velocity maps with background images of the leaflet and hinge geometry.

Flow Loop

To ensure adequate particle seeding in the hinge region without excessive particle aggregation or saturation, a low fluid volume system (500 ml) relative to *in vitro* heart simulators^{11,13,18,22} was designed (Figure 3-a,b). This system maintained a steady backpressure on the BMHV leaflets to study diastolic leakage flow. The fluid reservoir was mounted on a rigid tube oriented vertically with height of 1 m and inner diameter of 10 mm, creating the desired hydrostatic pressure. A peristaltic pump (Cole-Parmer Company, IL, USA) was used to generate continuous circulation of fluid in the loop in order to maintain the necessary backpressure. Pressure transducers (Deltran transducers, Utah Medical Inc, UT, USA) were located 2.54 cm upstream and downstream of the BMHV model. These were paired with a custom LabView program to acquire real-time pressure tracings (Figure 4). A flow control valve controlled the steady leakage transvalvular pressure (ΔP) for the experiment. The working fluid used was a mixture of 100% saturated Sodium Iodide solution, glycerin and water (79:20:1 by volume) with density of 1.62 g/cm³, matching the kinematic viscosity of blood (3.5 cSt) and index of refraction of acrylic (n = 1.49).

Particle Image Velocimetry system

Particle Image Velocimetry is a quantitative method of optical flow visualization that provides global fluid velocity fields in a region of interest. This technique is non-intrusive and measures the velocities of tracer particles suspended in the flow. PIV has been used to measure flow domains in BMHVs,^{1,13} prosthetic valves⁹ and tissue valves¹⁸ *in vitro*. However, these conventional PIV techniques do not have sufficient spatial resolution to study BMHV hinge flows. A μ PIV system integrates a microscope with a CCD camera where the depth of focus of the microscope is used under volume illumination from the laser beam to capture the maximum emission light from tracer particles.^{15,25} This allows for flow field spatial resolution at the micron level.

A LaVision Digital Particle Image Velocimetry (DPIV) system was adapted for this study. Polymethyl methacrylate (PMMA) particles coated with fluorescent Rhodium-B dye (D = 1-20 μ m) with density of 1.19 g/cm³ were used as the seeding particles (Dantec Dynamics, Denmark). The flow was imaged with a CCD camera (LaVision, Germany, Imager Intense 1376 $\times$ 1040 pixels) connected to a microscope (Edmund Scientific Microscope - 156939) with a 4 $\times$ magnification objective, numerical aperture NA = 0.1 and a long pass filter (λ = 570 nm) mounted on a motor-driven traverse system (BiSlide, Velmex Inc, USA) (Figure 3-a) to ensure accurate spatial positioning.

The CCD resolution was 6.45 μ m/pixel with maximum frame rate of 4.5 Hz. A dual cavity pulsed Nd:YAG laser (ESI Inc., Portland, OR) (λ = 532 nm, pulse duration = 9 ns) and appropriate optics were used to create a laser beam. The field of view was 3.0 mm $\times$ 2.2 mm, which covered 45% of the hinge geometry as shown in Figure 2-b.

PIV calibration was performed using a series of precision-machined acrylic blocks (± 0.0007 in) of varying thickness, equal to the depth of material through which the PIV plane was imaged. This depth was measured from a Micro CT scan of the valve model. Due to accurate refractive index matching between the working fluid and acrylic housing of the BMHV model, accurate *in situ* calibration was performed using this method. During the calibration process (Figure 5), the traverse position at which the objective lens and acrylic block surfaces were flush was set as the zero position. Subsequently, the objective lens was positioned away from the zero position until the calibration target was in focus. The distances that the objective lens had to be translated to focus at each measurement plane in the hinge region were 13.3 mm, 13.6 mm, 13.9 mm and 14.2 mm from the exterior surface

of the BMHV housing for the **FLAT, 195 μm , 390 μm and 585 μm** planes respectively. The position error was estimated to be 3.18 μm based on the resolution of the traverse system.

50 PIV image pairs were obtained at **dP = 80 mmHg** and **dP = 120 mmHg**. These two values were chosen to simulate the flow during two different time points during diastolic leakage flow, based on previously acquired pulsatile hemodynamic waveforms.²² The time spacing (Table 1) between the two PIV images was determined for each **dP** condition per location, such that the average particle displacement was about 16 pixels between pulses.⁷ The images were processed using DaVis 7.2 (LaVision, Germany), with a chosen interrogation window of 64×64 pixels in size and 50 percent overlap between subsequent windows, resulting in 64 μm vector spacing. Images were pre-processed using a sliding background subtraction filter to eliminate defocused particles near the leaflet ear at the lower measurement planes.

The image pairs were then processed using ensemble correlation, where a single vector field was computed from the summed-up correlation planes. In conventional PIV studies, a large number of processed vector fields are ensemble averaged to identify the dominant flow structures.^{1,13,18} Ensemble correlation is particularly advantageous for μPIV studies where seeding density is poor. This method detects the peak correlation after averaging all instantaneous cross correlation functions, thereby minimizing the number of erroneous measurements.¹⁴ Finally, the vector fields were post-processed with a median filter to remove erroneous vectors and recursive interpolation was used to fill-up empty spaces in the vector field.

In the current study, the depth of correlation determines the measurement depth where particles are effectively focused and contributes significantly to the correlation function.¹⁶ Using values for magnification ($4\times$) and numerical aperture (0.1) of the objective lens, seeding particle diameter (1-20 μm), value for threshold weighting function (0.1) where contribution of the particle becomes insignificant, and wavelength of the emitted light (532 nm), the minimum and maximum measurement depth (δ_{corr}) was estimated to be 120.2 μm and 317.4 μm , respectively using a theoretical equation.¹⁶ The maximum measurement depth was large considering the size of the hinge recess gap. However, to produce global velocity maps in the hinge region, the magnification of the objective lens could not exceed $4\times$ to maintain division of imaging locations below four. The choice of seeding particle diameter was also limited as illumination from 1 μm particles alone was not strong enough to yield good PIV signal when the low magnification lens was used. It must be noted that the theoretical maximum measurement depth is meant to be a very conservative estimate, assuming a uniform particle diameter of 20 μm and no image pre-processing. The image pre-processing and masking were used in this study during the PIV cross-correlation to subtract unfocused particles and background illumination.

Definitions of Calculated Quantities

The 2D velocity fields presented in this study use the reference system shown in Figure 6-a, where interrogation is in the X-Y plane. The whole field velocity components are U and V in the X and Y directions, respectively.

To evaluate the thromboembolic potential of the flow within the BMHV hinge, the velocity magnitude (V) and viscous shear stress (VSS) were quantified from the 2D PIV measurements. In areas of flow stasis ($V < 0.03\text{m/s}$), activated platelets can be exposed to a longer residence time accelerating thromboembolism.²⁸ A high velocity jet ($V > 1\text{m/s}$) can potentially cause shear stress to blood elements above threshold values for hemolysis and platelet activation.⁹

The VSS indicates the shearing between adjacent layers of fluid, which can be used as a metric to assess the loading experienced by the fluid on blood cells transitioning through the hinge region. The in-plane VSS can be defined as:

$$VSS = \mu \left(\frac{\partial U}{\partial Y} + \frac{\partial V}{\partial X} \right)$$

Uncertainty of velocity measurements

In PIV systems, the total uncertainty can be described as a sum of bias and precision errors.¹⁷ In the current system where μ PIV was used, precision errors for estimating repeatability cannot be quantified due to the use of ensemble correlation where only a single vector field was computed from summed up correlation planes.¹⁴ Bias errors can be caused by experimental limitations, including sensor artifacts and pixel displacement gradients. An uncertainty analysis was performed to estimate bias errors in the current μ PIV system following the error analysis conducted by Cooper *et al.*³

The velocity uncertainty can be calculated by dividing the smallest measureable distance by the pulse separation (Δt) during the data acquisition. The highest resolution used in this system was 1.97 $\mu\text{m}/\text{pixel}$, and the smallest displacement can be quantified as 0.1-0.2 times the resolution due to subpixel interpolation during the PIV processing. Table 1 represents uncertainties in velocity measurements at each location of acquisition, where the maximum value was 0.00985 m/s (0.3% of maximum velocity of 3.2m/s). Subsequently, uncertainty in velocity gradients can be calculated following the error propagation analysis suggested by Kline and McClintock.⁸ The uncertainty in VSS was calculated to be 2.47 N/m², which is proportional to the velocity uncertainty divided by the in-plane spatial resolution of 64 μm .

Normalized median test

The reliability of velocity vectors obtained from ensemble correlation can be evaluated using a normalized median test.²⁶ In the PIV system, erroneous vectors typically originate from interrogation windows exhibiting insufficient seeding particle density, which appear with unexpected velocity magnitude and direction relative to the neighboring vectors.²⁶ These erroneous vectors are detected and removed during the post-processing step based on threshold values set for the correlation peak ratio factor (Q) and median filter. Q refers to the ratio between the height of the first and the second correlation peak. In this study, $Q > 1.3$ was used, which allowed for elimination of spurious vectors calculated from the weak correlation peak. The median filter allows for rejection of a vector when it is outside the defined deviation range of the neighboring vectors ($\text{RMS} > 1.5$).

To estimate the maximum possible errors caused by invalid velocity vectors, a flow field location featuring both low flow region and peak velocity jet (390 μm plane, ventricular side) was analyzed. Figure 6-b shows the percent valid vectors as a function of number of image pairs processed, constructed similarly to previous μ PIV studies.^{14,24}

The normalized median test showed that the lowest percent of valid vectors from a single post-processed image pair was 99.4%, and by averaging 50 image pairs with ensemble correlation, a validity ratio of 99.6% was reached. The pre-processed image pairs were also tested using this method which were unaffected by median filtering and interpolation in the post-processing steps. A single image pair had a validity ratio of 89.5% and at 50 image pairs a validity ratio of 96.6% was reached. This analysis demonstrated that the final post-processed velocity field across the entire geometry is expected to have a reliability of velocity vectors close to 100%, indicating high fidelity of the data acquired.

Results

Figures 7 and 8 represent the global velocity fields in the hinge collected from the aortic, center and ventricular sections with a representative PIV raw image of the hinge (Figure 6-a) used as a background to display the location of the leaflet. Table 2 presents the values of V_{peak} at all planes for the two dP conditions.

Velocity Vector Fields

FLAT plane—Figures 7-a and 8-a represent the leakage velocity fields inside the hinge region in the **FLAT** plane at $dP = 80$ mmHg and $dP = 120$ mmHg, respectively. At $dP = 80$ mmHg, a reverse flow entered from the arc of the hinge housing between the aortic and lateral corners. This incoming flow exhibited a low velocity magnitude ranging from 0.03 to 0.05 m/s. Here, the velocity was lower near the lateral corner, as flow collided with the leaflet ear and diverged away from the aortic corner. The rest of the incoming flow near the aortic corner continued to flow towards the narrow gap between the leaflet and sharp corner of the hinge recess located in the center region, where velocity reached 0.88 m/s at the smallest gap.

In the adjacent corner, a high velocity jet was observed ranging from 1 to 1.47 m/s (V_{peak}), following the path along the arc of the housing. This sharp increase in velocity was likely caused by particles exiting from the smaller flow domain in the adjacent corner between the leaflet ear and hinge housing.

In the ventricular corner near the center region, the flow velocity was lowest, ranging from 0 to 0.03 m/s. The leaflet ear obstructing the reverse flow entering from the aortic corner likely caused this low flow region. Increased flow velocity of up to 0.37 m/s was observed near the ventricular corner as a high velocity jet from the adjacent corner continued to flow towards this location. At higher transvalvular pressure ($dP = 120$ mmHg) as represented in Figure 8-a, qualitatively similar flow with increased velocity magnitude was observed at all locations of the hinge. The most significant increases in velocity were observed near the adjacent and ventricular corners, where the velocity magnitude rose from 1.23 to 2.62 m/s (V_{peak}) and 0.86 to 1.67 m/s, respectively.

195 μm plane—In the **195 μm** plane (Figure 7-b and Figure 8-b), qualitatively similar flow fields were observed with a slight reduction in the flow area as the two-dimensional plane was located deeper into the hinge recess. In the top section of the hinge where reverse flow entered at $dP = 80$ mmHg, flow divergence towards the lateral corner was more apparent than at the **FLAT** level as obstruction from the leaflet ear was smaller. Low flow (0.03 m/s) was observed near the aortic corner and gradually increased up to 0.32 m/s and 0.21 m/s as particles flowed towards the lateral corner and narrow gap near the center region, respectively.

In the adjacent corner, a jet with velocity magnitude ranging from 1.08 to 2.73 m/s occurred and continued to flow along the arc of the housing directed towards the ventricular corner. Similar to the **FLAT** plane, a low flow region with velocity magnitude ranging from 0.01 to 0.03 m/s was observed near the ventricular corner closer to the center of the hinge, due to the obstruction from the leaflet ear. At $dP = 120$ mmHg, a qualitatively similar flow field was observed with increased velocity magnitude up to 3.21 m/s (V_{peak}) at the adjacent corner.

390 μm plane—The flow field inside the hinge in the **390 μm** plane appeared different than the other two lower measurement planes (Figure 7-c and 8-c), due to the smaller cross-sectional area and velocity vectors resolved from particles flowing over the leaflet ear.

Further reduction in the flow field was observed at the aortic and ventricular side of the hinge. For the reverse flow at the aortic side, velocity magnitude gradually increased from 0.03 m/s to 0.65 m/s ($dP = 80$ mmHg) and 0.83 m/s ($dP = 120$ mmHg) as flow approached the narrower center region of the hinge. This reverse flow at the aortic corner convected over the leaflet ear towards the ventricular side, where velocity magnitude continued to increase from 1.66 m/s to 2.02 m/s.

The location of V_{peak} in the hinge was at the ventricular side near the center, which was different from lower measurement planes. On the ventricular side, $V_{peak} = 2.68$ m/s ($dP = 80$ mmHg) and 3.24 m/s ($dP = 120$ mmHg). The low flow region in the hinge was still observable on the ventricular side closer to the center but the area was smaller than the lower measurement planes, as particles flowed across the leaflet ear.

585 μ m plane—This measurement plane was the deepest inside the hinge recess (Figure 7-d and 8-d). As expected, reduction in the hinge flow region was greatest compared to other measurement planes. The velocity magnitude appeared similar to the **390 μ m plane**, but the orientation of the velocity jet was more uniform towards the ventricular corner. On the aortic side, reverse flow entered the flow domain with ~ 0.11 m/s, then gradually increased as flow passed through the narrower gap near the center region directed towards the ventricular corner. The highest velocity jet was located near the center in the ventricular side, which was similar to the **390 μ m plane**, where $V_{peak} = 2.69$ m/s ($dP = 80$ mmHg) and 3.11 m/s ($dP = 120$ mmHg).

The Reynolds number of the hinge flow was estimated using the observed peak velocities, hinge gap width and kinematic viscosity of the working medium, which were 78 and 93 at $dP = 80$ mmHg and 120 mmHg, respectively.

Viscous Shear Stress Fields

Figure 9 and 10 represent the VSS fields at each dP condition across all measurement planes. At the FLAT plane under $dP = 80$ mmHg (Figure 9-a), VSS values ranged from 0.07 to 0.48 N/m² near the aortic corner where reverse flow entered through the hinge. This gradually increased up to 7.21 N/m² near the leaflet and wall of the hinge housing closer to the center region as flow was passing through the narrower gap. In the adjacent corner of the hinge, regions of maximum VSS value (~ 55 N/m²) correlated with the edge of the jet, as expected. The next highest region of VSS (~ 23 N/m²) was at the intersection between the ventricular corner jet and low flow region. The VSS plots for the FLAT plane at $dP = 120$ mmHg (Figure 10-a) and 195 μ m plane for all conditions (Figure 9-b and 10-b) were very similar to those of the FLAT level, with larger regions of high velocity gradient (VSS > 50 N/m²) at the adjacent and ventricular corners due to the increased V_{peak} and jet area. The maximum VSS value remained close to ~ 60 N/m² for each plot.

At 390 μ m (Figure 9-c, $dP = 80$ mmHg), the highest VSS (~ 60 N/m²) was observed along the edge of the jet located near the center region represented in blue, directed towards the ventricular corner from both $dP = 80$ mmHg and 120 mmHg. This blue velocity gradient line represents the intersection between the low flow region and the high velocity jet ($V > 1$ m/s), which was expected to experience the highest level of shearing. A similar VSS plot can be seen at $dP = 120$ mmHg (Figure 10-c) as well, with more noticeable high VSS regions near the center of the leaflet, due to the increased velocity magnitude at this condition. At the 585 μ m plane (Figure 9-d and 10-d), the highest VSS was observed near the edge of the jet, similar to the 390 μ m plane.

Discussion

Global velocity field in the hinge

As shown in Table 1, V_{peak} on the ventricular side increased with higher dP as expected. The flow field within the hinge region had a reverse flow pattern with presence of a high velocity jet and low flow regions on the ventricular side, but no coherent vortex structures were observed.

For **FLAT** and **195 μm** planes, reverse flow was observed in the adjacent corner and low flow regions were present at the ventricular corner due to the obstruction from the leaflet ear. At deeper levels within the hinge recess (**390 μm** and **585 μm** planes), low flow regions were reduced and reverse flow jet was observed at the ventricular corner near the center location as reverse flow was directed across the hinge recess gap.

Higher velocity jets were measured at deeper levels within the hinge recess with $V_{\text{peak}} = 3.24 \text{ m/s}$. The VSS fields across all four measurement planes indicate that VSS was higher on the ventricular side due to the interaction between a high velocity jet at the adjacent corner and low flow regions at the ventricular corner.

The global velocity maps in the **FLAT** and **195 μm** planes suggested the potential for platelet activation and their longer residence time, due to the coexistence of the high VSS and the larger low flow region than the upper measurement planes. In the **390 μm** plane, regions of low flow were reduced and the fluid jet traveled over to the ventricular side from the aortic side, exiting the hinge region. VSS magnitude of up to 60 N/m^2 was still observed along the edge of the jet similar to the lower measurement planes.

At **585 μm** , low flow regions were minimal and the direction of the high velocity jet was most uniform compared to the other planes, which can be associated with the low hinge Reynolds number. These flow patterns indicate strong washout of blood elements in the deeper levels of hinge recess, which is a favorable design feature. The strong jet with uniform direction can potentially wash out activated platelets and even RBCs that may get blocked in the small regions of hinge recess. This aspect may be a primary advantage leading to clinical success of the SJM BMHV.

Comparison to previous studies

The current study is the first experimental study to obtain the complete flow fields within the hinge region of a SJM BMHV in the aortic position under steady leakage flow. The four measurement planes and transvalvular pressure conditions were selected for the purpose of comparison with previous experimental and computational studies of hinge flows.^{9-11,19,21,22,28} Among these studies, detailed quantitative and qualitative comparisons with LDV and CFD studies by Simon *et al*^{19,20} were conducted, due to the methodological similarity with the current study. However, several differences exist between the two methods that need to be clarified.

The LDV study was conducted under physiological pulsatile flow at the aortic position whereas the current PIV study was performed under steady leakage flow at fixed dP values representing two time points in diastole. The depth of correlation of the PIV measurement was between $120.2 \mu\text{m}$ and $317.4 \mu\text{m}$ whereas the LDV setup had an ellipsoid probe volume with major and minor axes of $21 \mu\text{m}$ and $140 \mu\text{m}$ respectively.⁹ Despite the differences between these two methods, the general qualitative leakage flow field was quite similar (Figure 11-a ,b), where reverse flow from the aortic side was squeezed through the ventricular side. Additionally, good agreement was shown in terms of the location of the high velocity jet and low flow region in the ventricular side. The leakage jet at the lateral

corner on the aortic side that was seen from LDV study at flat level was not observable from the current PIV results. This is due to scattered laser light in the PIV image at the lateral corner, which limited the visibility of particles at this particular location.

Table 2 compares V_{peak} from the LDV and current PIV study at $\Delta P = 120$ mmHg across all four measurement planes. The LDV values presented in this table were chosen from the mid-diastolic phase where ΔP across the valve was approximately 120 mmHg based on the pulsatile pressure waveforms.²² As the aortic side has an incoming jet with much lower flow velocities than the jets in the ventricular side, the peak velocity values at these regions were close to the LDV results. On the ventricular side, V_{peak} obtained from PIV was higher than the corresponding LDV measurements across all planes. The higher V_{peak} from PIV is likely due to the enhanced spatial resolution (64 μm vs. 203 μm) as well as possible user errors associated with manual positioning of LDV measurement locations. In addition, the number of data points present in the LDV study was fewer, particularly in upper measurement planes due to the difficulty of locating the LDV probe near the wall of the hinge housing. Another reason could be from the larger PIV measurement plane thickness, due to which velocity vectors in the intermediate planes may also be resolved using PIV.

The current PIV results showed good qualitative agreement with the CFD study across all measurement planes.²¹ In the **FLAT** and **195 μm** planes, similar high velocity jets were observed in both studies - along the arc of housing near the adjacent corner and in the near end of the ventricular corner (Figure 11-c). The location of low flow regions on the ventricular side matched closely between the two studies, where the vertical distance of this region estimated from the sharp corner in the center was 1.19 mm and 1.16 mm from the CFD and PIV studies, respectively at the FLAT level.

The CFD study showed a leakage jet at the lateral corner on the aortic side that was not observed from the PIV study due to the aforementioned scattered laser light in the PIV images. In the upper measurement planes, both studies showed greater presence of a uniform ventricular jet exiting the hinge at high velocity. This suggests that the CFD studies are able to capture the relevant flow structures that have been characterized here using PIV. From a quantitative standpoint, peak velocity values obtained from CFD studies were closer to the current PIV results than to the previous LDV study. Nonetheless, the peak velocity magnitude from CFD studies were still greater than PIV results, potentially due to the limitations associated with numerical study, such as idealized boundary conditions and a smaller degree of freedom with leaflet motion.

One aspect that is lacking from the CFD study is the true representation of the mating between the leaflet and hinge housing. In the numerical study, the only degree of freedom provided in the fluid-structure interaction model is rotational motion. The current experimental setup allows visualizing the actual leaflet within the hinge recess during the valve closure, which provides an advantage in characterizing different jets from a particular location.

These fluid mechanical assessments can be tied to what has been clinically observed with MHVs. Two important fluid dynamic parameters associated with thromboembolic complications in BMHVs are high shear stress and low flow recirculation regions.²⁸ The shear stress imposed on the surface of platelets can lead to platelet activation, and low flow regions exacerbate this process by providing longer residence time for these activated platelets, ultimately resulting in thromboembolism. Gross *et al.*⁶ reported that the viscous shear stress level at 10 N/m^2 can be defined as a threshold for the platelet activation. The threshold level for the hemolysis was near 100 N/m^2 according to Leverett *et al.*¹², which was greater than the peak viscous shear stress reported in this study. Thus, it is expected that

the valve model studied here showed greater potential for the platelet activation than the hemolysis across all conditions, which may lead to sublethal damage to blood elements. In particular, the coexistence of the high VSS and low flow regions from the lower measurement planes may favor thromboembolic complications.

Limitations

Some limitations exist in this study primarily due to the complex geometry and physiological conditions in the BMHV hinge region coupled with the experimental factors from this technique. First, the current study only investigated the diastole leakage flow under steady dP conditions. However, the strongest flow structures within the hinge primarily occur during diastole,^{4,22,23} which we can still visualize here. Additionally, this study was aimed at establishing a technique for utilization in future studies. Secondly, the PIV system was limited to two-dimensional velocity fields despite the presence of complex three-dimensional flow in the hinge region.²¹ The current experimental methodology provides a global velocity map obtained individually from three different sections of the hinge, as a compromise between the spatial resolution of the data and the field of view obtained. Finally, the steady nature of the system used here does not allow for capturing transient effects associated with leaflet motion or turbulence effects. Ensemble correlation cannot be used to capture turbulence in the system. Future studies should utilize traditional cross-correlation techniques to conduct statistical analysis and turbulence measurements.

Conclusions

In the current study, a μ PIV system was developed to characterize the global flow fields in the hinge region of BMHVs. The present studies were conducted under steady leakage flow conditions, representing aortic hemodynamic conditions during diastole. The flow dynamics in the hinge were very complex across all measurement planes during the leakage flow. At lower levels within the hinge recess, a leakage jet and low flow regions were seen at the ventricular side of the hinge region, which can be correlated to the shear stress-induced blood damage leading to platelet activation in the valve. The flow fields at deeper levels within hinge recess showed strong velocity jets with uniform direction that can aid washout of blood elements. These particular traits compare very closely to previous LDV and CFD studies conducted with similar valve models.^{11,21,22,28} Overall, this technique demonstrates improved capability in characterizing whole flow fields in the micron-scale domain compared to other experimental methods. The methodology established in this paper can be extended to different MHV designs and other implantable cardiovascular devices, where micro-scale flow studies may be critical to assessing the potential for hemolytic and thromboembolic complications.

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Figure 1.

(a) St. Jude Medical Bileaflet Mechanical Heart Valve clear housing model, (b) General components of BMHV,¹⁰ (c) leaflets in fully opened position, (d) leaflets in fully closed position, (e) Side view of hinge recess.

Figure 2.

(a) Measurement planes in the hinge recess gap, (b) Measurement locations in the hinge.

(a)

(b)

Figure 3.

(a) Schematic of experimental system, (b) three-dimensional illustration of Micro-PIV setup.

Figure 4.
Pressure measurements during the PIV acquisition.

Figure 5.
Hinge PIV calibration setup.

(a)

(b)

Figure 6.

(a) Raw PIV image at the center location in the hinge with seeding particles visible on the leaflet surface and ventricular and aortic corners. Fluorescent particles illuminate light from the laser beam. (b) Normalized median test at the measurement plane of 390 μm above flat level on the ventricular side, representing a fraction of valid vectors.

Figure 7. Global velocity map in the hinge at transvalvular pressure of 80 mmHg. Measurement plane at (a) flat level, (b) 195 μm above flat level, (c) 390 μm above flat level, (d) 585 μm above flat level.

Figure 8.

Global velocity map in the hinge at transvalvular pressure of 120 mmHg. Measurement plane at (a) flat level, (b) 195 μm above flat level, (c) 390 μm above flat level, (d) 585 μm above flat level.

Figure 9. Viscous shear stress fields in the hinge at transvalvular pressure of 80 mmHg. Measurement plane at (a) flat level, (b) 195 μm above flat level, (c) 390 μm above flat level, (d) 585 μm above flat level.

Figure 10.

Viscous shear stress fields in the hinge at transvalvular pressure of 120 mmHg.

Measurement plane at (a) flat level, (b) 195 μm above flat level, (c) 390 μm above flat level, (d) 585 μm above flat level.

Figure 11.

Comparison of the two-dimensional leakage flow velocity field at $195\mu\text{m}$ above flat level in 23mm SJM BMHV hinge among different methods, (a) PIV, (b) LDV,¹⁹ (c) CFD.²¹

Table 1

Uncertainty of velocity measurements at each location in the hinge.

Measurement plane	dt (in μ s)	Velocity Uncertainty (m/s)
FLAT	20 – 100	0.00197 - 0.00985
195 μ m	20 – 100	0.00197 - 0.00985
390 μ m	20 - 50	0.00394 - 0.00985
585 μ m	20 - 50	0.00394 - 0.00985

Table 2

V_{peak} (in m/s) from ensemble correlation of 50 image pairs. Results from previous LDV measurements at $dP = 120\text{mmHg}$ are presented for comparison.

	FLAT plane	195 μm plane	390 μm plane	585 μm plane
$dP = 80\text{mmHg}$	1.47	2.73	2.68	2.69
$dP = 120\text{mmHg}$	2.62	3.21	3.24	3.11
LDV ($dP = 120\text{mmHg}$)	1.64	1.96	2.27	0.49