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Effect of Hinge Gap Width of a St. Jude Medical Bileaflet Mechanical Heart Valve on Blood Damage Potential—An In Vitro Micro Particle Image Velocimetry Study

The hinge regions of the bileaflet mechanical heart valve (BMHV) can cause blood element damage due to nonphysiological shear stress levels and regions of flow stasis. Recently, a micro particle image velocimetry (μ PIV) system was developed to study whole flow fields within BMHV hinge regions with enhanced spatial resolution under steady leakage flow conditions. However, global velocity maps under pulsatile conditions are still necessary to fully understand the blood damage potential of these valves. The current study hypothesized that the hinge gap width will affect flow fields in the hinge region. Accordingly, the blood damage potential of three St. Jude Medical (SJM) BMHVs with different hinge gap widths was investigated under pulsatile flow conditions, using a μ PIV system. The results demonstrated that the hinge gap width had a significant influence during the leakage flow phase in terms of washout and shear stress characteristics. During the leakage flow, the largest hinge gap generated the highest Reynolds shear stress (RSS) magnitudes ($\sim 1000 \text{ N/m}^2$) among the three valves at the ventricular side of the hinge. At this location, all three valves indicated viscous shear stresses (VSS) greater than 30 N/m^2 . The smallest hinge gap exhibited the lowest level of shear stress values, but had the poorest washout flow characteristics among the three valves, demonstrating propensity for flow stasis and associated activated platelet accumulation potential. The results from this study indicate that the hinge is a critical component of the BMHV design, which needs to be optimized to find the appropriate balance between reduction in fluid shear stresses and enhanced washout during leakage flow, to ensure minimal thrombotic complications. [DOI: 10.1115/1.4027935]

Introduction

Despite the clinical success and widespread use of BMHVs, the reported incidence of thromboembolic complications is up to 4.3% per patient-years [1,2]. In BMHVs, clots are found in both upstream and downstream sides of the hinge geometry [2–4]. The hinge and pivot regions are known to cause blood element damage due to nonphysiological levels of low and high shear stresses within these regions [5–8].

However, methodologies for characterization of flow fields in the hinge region of a SJM BMHV is limited due to the 3D geometry involving in-plane butterfly-shaped design with curved-semicircular flow domain that has estimated depth and volume of $600 \mu\text{m}$ and $1.5 \mu\text{l}$, respectively [9]. In addition, the temporal scales involved in leaflet opening and closure are within 20–40 ms, which requires optical setup with high temporal and spatial resolution, further limiting the choice of experimental approaches.

Recently, Jun et al. [9] established an imaging system using 2D μ PIV to obtain global flow fields in a BMHV hinge in aortic position during diastole. This study enabled detailed characterization of the hinge flow field that was difficult to achieve from previous experimental methods [6,10,11]. Novel features of this system

included whole flow field characterization with high spatial resolution ($64 \mu\text{m}$), VSS fields, and a representation of the mating between the leaflet and hinge housing. The study focused on evaluating the blood damage potential during the diastolic phase in the aortic position, modeled under steady flow. Subsequently, the aortic diastolic leakage flow phase has been shown to have the highest thromboembolic potential of any phase of the cardiac cycle in BMHVs. However, high-resolution global velocity maps and flow characterization of different BMHV models under pulsatile conditions have not been investigated yet. Such information can allow better understanding of the blood damage potential from a fluid mechanics point of view by incorporating time varying acceleration of leaflet dynamics across three different hinge geometries [6,9–11].

To evaluate the performance and blood damage potential in BMHVs, parameters such as velocity magnitude, RSS, and VSS can be quantified from measured flow fields. The velocity magnitude can be used to assess the blood element washout capability of BMHV hinges. In addition, RSS and VSS levels can be correlated to shear stress induced blood damage [12–15]. Leverett et al. [14] demonstrated that red blood cell damage can be affected predominantly by VSS alone at thresholds of 150 N/m^2 . Subsequently, shear stress damage under turbulent flow was investigated by Lu et al. [15] using 2D laser Doppler anemometry, where a RSS level of 800 N/m^2 was defined as an estimated threshold for hemolysis. Similarly, platelet activation threshold was also investigated, and VSS levels ranging from 30

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to 100 N/m^2 with exposure times of 25–1650 ms were shown to lead to platelet activation. The RSS threshold for platelet activation on a physiological time scale is still not clearly known [16].

Previous ex-vivo studies by Travis et al. [8] and Fallon et al. [5] evaluated markers of platelet damage and platelet activation within different BMHV pivot designs, hinge gap widths, and valve sizes. The studies reported significant differences in markers of platelet damage and coagulation levels between BMHVs with different hinge gap widths. However, these studies lacked detailed flow characterization to explain the observed blood damage levels. Subsequently, Leo et al. [6] performed laser Doppler velocimetry (LDV) measurements on SJM BMHVs with varying hinge gap widths under mitral flow condition and reported that the regular gap width showed less thromboembolic potential than prototypes with either a smaller or larger gap, based on qualitative flow fields, peak velocities, and RSS values. A numerical study by Simon et al. [17] revealed 3D flow fields under aortic flow condition comparing SJM BMHVs with larger and standard hinge gap widths. Simon et al. concluded that the larger hinge gap width indicated a lower propensity for platelet aggregation, due to the presence of elevated shear stresses and relatively poor washout during the leakage flow phase in the SJM BMHV with standard hinge gap width. In terms of the implant location, Simon et al. reported that the forward flow and leakage flow patterns were more favorable in the aortic position than the mitral position [17,18].

However, the analysis conducted using LDV relied on peak values of measured quantities due to low spatial resolution ($203\text{ }\mu\text{m}$). A major limitation with computational fluid dynamics (CFD) is that only a rotational motion with one degree of freedom can be included in the fluid–structure interaction model, which may not capture the translational effects of leaflet under pulsatile flow [17]. Therefore, the focus of the present study is to investigate the influence of hinge gap width on flow fields within BMHV hinges using a high-resolution μPIV system under pulsatile flow conditions and to relate these results to the potential to cause blood element damage and thrombotic complications. These findings can provide a better understanding of the local regions of potential blood element damage within the BMHV hinge, in combination with previous results from in vitro LDV and CFD studies [6,11,17]. In addition, the new PIV flow field data may be used for the validation of the CFD approaches developed for characterizing the BMHV hinge flow fields [17,19].

Methods

Valve Model. The SJM BMHV hinge geometry has a smooth, butterfly-shaped cavity that retains semicircular leaflet ears (Figs. 1(a)–1(d)). Three clear housing BMHV prototypes with different hinge gap widths were manufactured by SJM, Inc. (St. Paul, MN), for the purpose of this study. The in-plane (axial) dimension of the hinge as well as dimension of leaflet was kept identical across the three valves. The leaflets of the valve are made from pyrolytic carbon with a graphite substrate containing tungsten. The transparent acrylic housing of the valve allows optical access to the hinge region. The term “hinge gap width” is defined as the radial distance between the deepest point of recess and the tip of the leaflet ear (Fig. 1(e)). An SJM BMHV with a gap width of $100\text{ }\mu\text{m}$ was used as a standard prototype (Standard). All parts of the clear housing Standard valve were manufactured with tolerances identical to those of clinical SJM valves. The hinge gap widths of the two modified SJM BMHVs were $50\text{ }\mu\text{m}$ and $200\text{ }\mu\text{m}$, which are referred to as a low leaker prototype (LLP) and a high leaker prototype (HLP), respectively. Unlike the Standard valve, the LLP and HLP valve models were manufactured with tolerances outside the range of clinical quality SJM valves, for the purpose of this study. The hinge gap widths for these models were scanned and measured from microcomputed tomography.

Measurement planes and locations identical to those used in the previous μPIV study conducted by Jun et al. [9] were selected. These planes are referred to as FLAT, $195\text{ }\mu\text{m}$, $390\text{ }\mu\text{m}$, and

$585\text{ }\mu\text{m}$ planes, based on their distance from the reference plane (flat level). The FLAT and $195\text{ }\mu\text{m}$ planes are referred to as the lower measurement planes, while the $390\text{ }\mu\text{m}$ and $585\text{ }\mu\text{m}$ planes are referred to as the upper measurement planes.

Flow Loop. The valve model was mounted in an in-vitro left heart simulator (Fig. 2) to replicate pulsatile physiological aortic flow and pressure conditions (Fig. 3). Systolic (opening) and diastolic (closure) motion of the aortic valve was replicated by a programmable linear piston actuator. During systole, a rapid ejection from the piston motion forced the aortic valve open, allowing fluid to flow from the ventricular side to the aortic side. At the end of systole, a rapid backward motion of the piston imposed a back pressure on the aortic side which forced the aortic valve leaflets to close. Subsequently, the remaining fluid was returned to the ventricular side through a bypass loop, which included a mechanical mitral valve. In addition to the piston motion, compliance and resistance elements were adjusted during the experiment in order to achieve accurate physiological hemodynamic conditions. The complete motion of the piston ensures physiologic adult aortic flow conditions, with a cardiac output of 5 l/min , 35% systole duration, and heart rate of 70 bpm (total cardiac cycle time of 860 ms).

The in vitro left heart simulator was operated by a motor (EMMS-AS-55-S-TSB, Festo Corporation, Hauppauge, NY) driven linear actuator system (DGE-25-300-ZR-R, Festo Corporation, Hauppauge, NY), where the piston arm made of polyether ether ketone slides in and out of a titanium tube. A silicone O-ring was used to ensure sealing between the piston and the inner wall of the titanium tube. The motion of the piston was directed from a motion profile created using the Festo configuration tool software, where the position, velocity and acceleration of the linear actuator were defined in order to simulate physiological aortic flow. These parameters were calculated within the maximum working length (300 mm) of the linear actuator, in order to generate physiological systolic and diastolic aortic flow from the forward and backward stroke motions, respectively.

An ultrasonic flow probe (Carolina Medical) was attached to the end of the titanium tube and two pressure transducers (Deltran transducers, Utah Medical, Inc., UT) were located 2.54 cm upstream and downstream of the valve model to measure the real-time flow rate and pressure tracings using a custom LABVIEW program. The LABVIEW program was triggered by the linear actuator system, such that hemodynamic measurements were synchronized with the start of the cardiac cycle. 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/cm^3 , matching the kinematic viscosity of blood (3.5 cSt), and index of refraction of acrylic ($n = 1.49$).

Particle Image Velocimetry. The μPIV system used for this study has been extensively described in a previous study (Jun et al.). In brief, 200 PIV image pairs were acquired for the FLAT level and 100 PIV image pairs were obtained for all other ($195\text{ }\mu\text{m}$, $390\text{ }\mu\text{m}$, and $585\text{ }\mu\text{m}$) measurement planes. More image pairs were acquired at the FLAT plane for the purpose of statistical analysis using ensemble averaging. This was not possible in the other measurement planes due to low seeding density in the deeper levels of the hinge with a smaller cross-sectional area. In these deeper levels, ensemble correlation was used to calculate the average flow field [9]. Data were acquired at 23 time points throughout the cardiac cycle (Fig. 3). The time spacing (Table 1) between the two PIV images was optimized for each time point during the cardiac cycle to obtain an average particle displacement of about 16 pixels between pulses [9,20,21]. The PIV acquisition was also triggered by the linear actuator system for phase locked measurements.

Definitions of Calculated Quantities. The 2D velocity fields presented in this study use the reference system shown in Fig. 4(a), and the whole field velocity components are U and V in

Fig. 1 (a) SJM Bileaflet mechanical heart valve clear housing model [9], (b) general components of BMHV [10], (c) leaflets in fully opened position [9], (d) leaflets in fully closed position [9], and (e) side view of hinge recess [9]

the X and Y directions, respectively. To evaluate the thromboembolic potential of flow within the BMHV hinge, ensemble averaged velocity magnitude ($Vel = \sqrt{U^2 + V^2}$), maximum velocity (Vel_{peak}), VSS, and RSS were quantified from 2D PIV measurements. In areas of flow stasis ($Vel < 0.05$ m/s), activated platelets can endure a longer residence time, accelerating thromboembolism. Alternatively, a high velocity jet ($Vel > 1$ m/s) can potentially cause shear stress to blood elements above threshold values, resulting in hemolysis ($VSS > 150$ N/m²), and platelet activation ($VSS > 10$ N/m²) [22].

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 elements transitioning through the hinge region. The in-plane VSS can be defined as

$$VSS = \mu \left(\frac{\partial U}{\partial Y} + \frac{\partial V}{\partial X} \right) \quad (1)$$

RSS indicates the average momentum flux due to the fluctuating velocity component, representing turbulent stress which could initiate the process of platelet activation and hemolysis in artificial heart valves [15,16,23]

The in-plane RSS can be defined as

$$RSS = \rho \sqrt{\left(\frac{u'u' - v'v'}{2} \right)^2 + (u'v')^2} \quad (2)$$

where u' and v' represent instantaneous velocity fluctuation in the X and Y directions, respectively.

However, it must be noted that the RSS computed from the measured velocity fluctuations in this study is not the same as Reynolds stress arising due to turbulent velocity fluctuations. The cycle-to-cycle velocity fluctuations measured in this study are a

result of variations in the flow, pressure, and leaflet dynamics in addition to the turbulent velocity fluctuations. Consequently, the RSS computed using Eq. (2) is referred herein as an apparent RSS.

The pulse duplicator used in the current study generates rapid forward and backward motions of the piston, which give rise to the cycle-to-cycle fluctuations in the flow and pressures. In addition, the opening and closing dynamics of valve leaflets will affect the instantaneous position of the leaflet from one cycle to another. Similar cycle-to-cycle fluctuations were observed in previous studies with biological valves as well [24,25]. These observations from the in-vitro experiments can reflect physical phenomenon occurring in the human heart, as heart rate and blood pressure changes continuously over cardiac cycles. Subsequently, the blood elements near the surface of the leaflet will experience different magnitudes of shear stress and exposure time from cycle-to-cycle, which may affect the blood damage potential. A small variation in the leaflet dynamics can contribute to the velocity fluctuations in the hinge region [7,22,26]. Therefore, it is important to investigate the cycle to cycle velocity fluctuations in the hinge region quantified in the form of RSS.

In the current study, VSS and RSS were calculated from the mean and instantaneous 2D velocity fields obtained from the FLAT plane to compare shear stress fields across the three valve models.

Table 1 represents the range of pulse separations (Δt) during data acquisition and calculated velocity uncertainty for each measurement plane. The maximum value of velocity uncertainty was 0.0394 m/s (1.3% of maximum velocity of 2.99 m/s). Uncertainty in velocity gradients can be calculated following the same analysis conducted in the previous study by Jun et al. [9]. The uncertainty in VSS and RSS was calculated to be 4.94 N/m² and 8.45 N/m², respectively.

Fig. 2 Schematic of pulsatile micro-PIV experimental system

Results

Static Leakage Test. To ensure that an expected amount of leakage volume was flowing through the valve hinges, a static leakage flow rate was measured from the three SJM valves prior to the μ PIV experiment. A 1.5 m vertical column filled with water–glycerin solution was used to impose a static pressure head of 120 mmHg on the aortic side of the valve. Subsequently, the leakage volume was measured over 1 min for each valve and repeated five times to calculate the average leakage flow rate. The HLP, Standard, and LLP valves had static leakage flow rates of 490 ± 25 ml/min, 450 ± 14 ml/min, and 51 ± 6 ml/min, respectively. The leakage flow rate increased with hinge gap width. These measured flow rates were very close to the static leakage rates measured in previous studies. [7,22]

Hemodynamics. The pressure and flow waveforms obtained from the three BMHV models under pulsatile aortic conditions are shown in Fig. 3. Compliance and resistance elements were tuned such that the cardiac output, ventricular, and aortic pressure waveforms were comparable across the three valve models. The magnitude of diastolic leakage flow rate increased with respect to the hinge gap width, as previously shown.

Pulsatile Flow Features of Standard Valve. During the beginning of systole at 80 ms, an increase in forward flow velocity ($Vel \sim 0.5$ m/s) was seen at the FLAT plane. A recirculating flow structure was observed from the lateral and adjacent corners closer to the leaflet center, as was an onset of strong forward flow with fully opened leaflets at the FLAT plane. Recirculating flow from the lateral corner transitioned to a jet directed toward the aortic side at 120 ms. Peak forward flow was reached at 160 ms, where a coherent jet ($Vel_{peak} = 1.08$ m/s) and recirculating flow ($Vel_{peak} = 1.0$ m/s) were seen at the lateral and adjacent corners, respectively (Fig. 4(b)). Flow fields from 280 to 360 ms showed low velocity ($Vel < 0.1$ m/s) across the hinge domain without any coherent recirculation zones. Leaflets were fully closed at 380 ms at the end of systole. Similar flow fields were observed during systole at the $195 \mu\text{m}$ plane, with lower velocity magnitude ($Vel_{peak} = 0.5$ m/s at peak systole) and weaker velocity jets and recirculation zones. Subsequently, the $390 \mu\text{m}$ and $585 \mu\text{m}$ planes showed flow stasis ($Vel < 0.01$ m/s) across the hinge domain during systole.

The diastolic phase began at 380 ms with fully closed leaflets with low velocity ($Vel < 0.1$ m/s) across all measurement planes. A sharp increase in transvalvular pressure gradient resulted in reversal of flow. A significant increase in velocity ($Vel_{peak} > 3$ m/s) for the leakage flow fields was observed at 420 ms across all measurement planes. The transvalvular pressure gradient reached its

Fig. 3 Aortic flow and pressure waveforms from the three valve types

Table 1 PIV pulse duration and uncertainty of velocity measurements

Measurement plane	Cardiac phase	dt (in μ s)	Velocity uncertainty (m/s)
FLAT, 195 μ m, 390 μ m, 585 μ m	Diastole	5–20	0.0003–0.0394
	Systole	200–700	

maximum value (150 mmHg) at this time point, then gradually decreased to 120 mmHg at 480 ms, where it remained until the end of diastole. Leakage flow fields at the mid-diastolic phase across all measurement planes (Figs. 5(a)–5(d)) looked very similar to the steady leakage flow fields presented by Jun et al. (2013) [9]. Lower measurement planes showed a high velocity jet ($Vel > 1$ m/s) along the arc of the housing from the adjacent and ventricular corners with presence of a low flow region near the leaflet center on the ventricular side. From the aortic corner, incoming flow with a low velocity ($Vel < 0.1$ m/s) diverged toward the lateral corner with increased velocity ($Vel \sim 0.8$ m/s) as the leaflet ear was

obstructing the incoming flow. In the upper measurement planes, which are deeper into the hinge recess, incoming flow from the aortic side convected across the leaflet ear and accelerated as particles passed through the narrow gap of the hinge.

Velocity Comparison of Three Valve Models

Systole:

All three valves showed similar flow features across all measurement planes (Fig. 4 and Table 2). In the lower measurement planes, recirculating flow and forward flow jet structures built up

Fig. 4 Ensemble averaged flow fields (displaying every other vector) acquired from PIV for the three valves (FLAT plane) at the peak systolic phase. Velocity field from (a) LLP, (b) Standard, and (c) HLP. RSS field from (d) LLP, (e) Standard, and (f) HLP. VSS field from (g) LLP, (h) Standard, and (i) HLP.

toward the peak systolic phase ($t = 160$ ms) then gradually dissipated as the leaflets started closing. For all three valves, $Vel_{peak} = 1\text{--}1.2$ m/s occurred at the FLAT level ($t = 160$ ms), near the leaflet on the lateral side. In the upper measurement planes, low flow regions ($Vel < 0.3$ m/s) were present without any coherent jet or recirculation zones. Overall, no significant qualitative or quantitative differences were observed during systole among three valves.

Diastole:

The velocity magnitude during diastole was greater than during systole across all measurement planes for the three valves (Tables 2 and 3). Figure 6 compares the velocity fields measured from the HLP, Standard, and LLP valves at the mid-diastolic phase which represents the most dominant leakage flow structure with fully closed leaflets. At the start of reverse flow near the aortic side at the FLAT plane, all three valves showed lateral jets diverging away from the leaflet ear, but with different velocity magnitudes. The LLP valve showed the strongest lateral jet with a maximum velocity magnitude of up to 1.1 m/s. The Standard valve jet was weaker ($Vel_{peak} = 0.7$ m/s), and the HLP valve showed the weakest lateral jet ($Vel_{peak} < 0.4$ m/s).

On the ventricular side at the FLAT plane, a reverse flow was directed along the arc of the housing exiting toward the

ventricular corner, where differences were observed in terms of jet structure and velocity magnitude across the three valves. The HLP and Standard valves showed two coherent jets at the adjacent and ventricular corners, while the LLP valve exhibited a jet structure at the ventricular and lateral corners (Fig. 6(a)). At the $195\text{ }\mu\text{m}$ plane, similar trends and jet structures such as the lateral, ventricular, and adjacent jets were present with slight reduction in flow area.

In the upper measurement planes (Figs. 7(a)–7(c)), a strong reverse flow with uniform jet structure across the leaflet ear was observed across all three valves. The LLP valve showed flow stasis on the ventricular side near the leaflet ear. This flow stasis region was also observed in the HLP valve, but with a much reduced area. Subsequently, the highest peak velocity magnitude of these leakage jets was observed in the HLP valve, and the lowest in the LLP valve (Table 3).

Shear Stress Comparison of the Three Valves at FLAT Plane

Systole:

The highest shear stress levels during systole were recorded at the peak systolic phase ($t = 160$ ms) from the three valves at FLAT level based on the observation from the velocity fields. All

Fig. 5 Ensemble averaged velocity fields (displaying every other vector) acquired from PIV for the Standard valve at the mid-diastolic phase. Measurement plane at (a) flat level, (b) 195 μm above flat level, (c) 390 μm above flat level, and (d) 585 μm above flat level.

three valves presented a similar magnitude and distribution for RSS and VSS surrounding the lateral jet and recirculating flow structure in the adjacent corner. Unlike VSS plots, where similar levels of VSS were observed between the lateral jet and recirculation zones, RSS plots showed about $\sim 100 \text{ N/m}^2$ higher RSS levels

at the recirculation zones in the adjacent corner. This indicates that shearing due to the velocity gradients was similar at these two pockets, but fluctuation was higher in the recirculating flow. Overall, shear stress distribution and magnitude from the three valves did not show significant differences. The maximum VSS and RSS levels were around $\sim 40 \text{ N/m}^2$ and $\sim 200 \text{ N/m}^2$, respectively, at the peak systolic phase (Table 2).

Diastole:

RSS levels observed from the three valves in diastole were three or more times greater than at the peak systolic phase, indicating higher fluctuation in the leakage flow. Figure 6 represents comparison of the Vel, RSS, and VSS fields at the mid-diastolic phase. Table 3 compares the maximum RSS among three valve models. The HLP valve reported the highest RSS magnitude ($\sim 1000 \text{ N/m}^2$) among the three valves at the adjacent corner. The highest RSS region ($\sim 900 \text{ N/m}^2$) for the Standard valve was roughly halfway between the adjacent and ventricular corners. The LLP valve showed highest RSS magnitude ($\sim 400 \text{ N/m}^2$) near the ventricular corner as well as the presence of another high level of RSS ($\sim 300 \text{ N/m}^2$) at the lateral corner, which was not observed in the other valves. Overall, the RSS magnitudes increased with increasing hinge gap width, and locations of high fluctuation varied among the three valves.

Unlike RSS levels, VSS levels in diastole across the three valves were similar to the levels observed at the peak systolic phase. All three valves indicated high VSS magnitude ($\text{VSS} > 30 \text{ N/m}^2$) at the ventricular corner. Additionally, the HLP and Standard valves indicated regions of highest VSS magnitude ($\sim 50 \text{ N/m}^2$) near the adjacent corner, which was not present in the LLP valve. In the lateral corner, the VSS level increased with respect to the valve with smaller hinge gap width. Subsequently, the LLP valve indicated VSS magnitudes up to 30 N/m^2 at this region. Accordingly, the high shearing regions were similar between the HLP and Standard valves in terms of magnitude and locations. The LLP valve reported the lowest VSS magnitude among the three valves but with additional high shearing region at the lateral corner.

Table 2 Comparison of the ensemble averaged velocity (Vel), VSS, and RSS magnitude ranges for the three valve types at the lateral, adjacent, and ventricular jets at the peak systolic and mid-diastolic phases (FLAT level)

		LLP			Standard			HLP		
		Vel range (m/s)	VSS range (N/m^2)	RSS range (N/m^2)	Vel range (m/s)	VSS range (N/m^2)	RSS range (N/m^2)	Vel range (m/s)	VSS range (N/m^2)	RSS range (N/m^2)
Forward jets ($t = 160 \text{ ms}$)	Lateral corner	0.19–1.1	7.3–44	2.0–94	0.15–1.1	4.4–45	1.8–65	0.2–1.2	5.2–40	3.0–110
	Adjacent corner	0.26–0.98	2.5–35	4.5–152	0.25–0.90	6.5–41	5.9–97	0.23–0.79	5.1–45	2.0–173
Leakage jets ($t = 600 \text{ ms}$)	Lateral corner	1.1–1.4	6.4–38	226–341	0.42–0.86	0.3–28	4.5–62	0.24–0.34	0.5–2.2	27–88
	Adjacent corner	0.22–0.37	0.4–3.3	125–164	2.35–2.57	10–44	160–938	2.0–2.2	9.2–48	768–1142
	Ventricular corner	1.2–1.7	9–46	79–429	0.96–1.8	8.2–34	62–327	1.7–2.1	8.0–42	191–419

Table 3 Peak phase averaged velocity (m/s) across all measurement planes and RSS (N/m^2) comparison at FLAT level (mid-diastolic phase) from the three valve prototypes

Measurement plane	LLP	Standard	HLP
Flat	1.67 m/s (430 N/m^2)	2.57 m/s (938 N/m^2)	2.26 m/s (1142 N/m^2)
195 μm above flat level	1.77 m/s	2.73 m/s	2.86 m/s
390 μm above flat level	2.51 m/s	2.52 m/s	2.91 m/s
585 μm above flat level	NA	2.70 m/s	2.99 m/s

Fig. 6 Ensemble averaged flow fields (displaying every other vector) acquired from PIV for the three valves (FLAT plane) at the mid-diastolic phase. Velocity field from (a) LLP, (b) Standard, and (c) HLP. RSS field from (d) LLP, (e) Standard, and (f) HLP. VSS field from (g) LLP, (h) Standard, and (i) HLP.

Discussion

Effect of Hinge Gap Width on the Global Flow Field. The results presented in this study demonstrate that the hinge gap width had a more significant influence during leakage flow as compared to forward flow, in terms of washout and shear characteristics, which was not demonstrated clearly in previous studies [6,11]. In systole, flow in the three SJM valves was governed by the rapid forward ejection from the piston which maintained identical profiles of velocity, acceleration, and time period for all three cases within the hinge regions. In addition, only the FLAT plane had a dominant flow structure at the peak systolic phase. Measurement planes located deeper in the hinge recess had low flow regions ($Vel < 0.3$ m/s) without any coherent structures to be differentiated among the three valves. Also, the VSS and RSS fields were not significantly different among the three valves, as these parameters were calculated based on the measured velocity field. Therefore, the hinge gap width had minimal effect on the flow inside the hinge during the forward flow.

Previous hinge studies reported that in the SJM BMHV hinge region, leakage flow induces a much stronger jet than forward flow, which can potentially wash out stagnant blood elements

[6,7,17]. This was apparent from all three valves based on the measured flow fields. In diastole, the HLP valve revealed the strongest washout potential across all measurement planes. This was likely due to the large hinge gap width allowing particles to flow over to the ventricular side with much higher velocity than the other valves. The Standard valve also showed strong velocity jets at the adjacent and ventricular corners, but with lower magnitude than the HLP valve at the 195, 390, and 585 μ m planes.

The LLP valve exhibited the weakest washout potential among the three valves across all measurement planes in diastole. At lower measurement planes, the LLP valve indicated a stronger lateral jet structure than the other valves. However, a high velocity jet at this location will be less likely to contribute to the washout of blood elements located deep in the hinge recess. Even at the 390 μ m plane (Fig. 7(a)), the low flow region near the ventricular pocket was larger in area than for the other valves. This indicates that small blood elements such as platelets (~ 2 μ m diameter) can recirculate in this region and may not be washed out effectively either in systole or in diastole.

The hinge gap width altered magnitude and locations of shearing and fluctuations in the leakage flow based on the RSS and

Fig. 7 Ensemble averaged flow fields (displaying every other vector) acquired from PIV for the three valves (390 μm plane) at the mid-diastolic phase. Velocity field from (a) LLP, (b) Standard, and (c) HLP.

VSS plots. The highest RSS level was observed at the adjacent corner of the HLP valve. At this location, the high velocity jet squeezed from the hinge recess gap impinged on the sharp corner of the hinge housing, which may contribute to the unsteady flow in this region. The other potential factor could be the sliding motion of the leaflet ear, which occurs naturally in diastole as a result of a rapid sweeping motion under pulsatile flow. The fluctuations in the flow field at the adjacent corner can easily be affected by the sliding motion due to the close contact with the leaflet ear.

A novel finding of this study was that the hinge gap width also appeared to influence the locations of high shearing and fluctuation regions across the three valves. This region was located further away from the adjacent corner with respect to the smaller hinge gap width. The high fluctuation regions were found near the edge of the strongest leakage jets on the ventricular side. The HLP and Standard valves presented similar magnitudes and distribution of VSS during the leakage flow, with the highest shearing occurring at the adjacent corner. Alternatively, the LLP valve showed high shearing at the lateral and ventricular corners, but with lower VSS levels than the other valves. These observations indicate that the gap width difference between the HLP and Standard valves had a negligible effect on the VSS fields, but the smallest hinge gap width from the LLP valve induced lower VSS values at the adjacent corner. This was due to its having the smallest area that would allow particles to flow along the adjacent corner. The high-resolution μPIV system allowed identification of these specific variations of fluid dynamic parameters across the three valves, which are difficult to detect using alternative techniques.

Blood Damage Potential. The blood damage potential from each valve model was estimated in this study using threshold levels investigated from previous studies [14–16,27]. Leakage flow fields obtained from the HLP and Standard valve showed RSS_{peak} values of 1140 N/m^2 (HLP) and 950 N/m^2 (Standard), which were above threshold levels for hemolysis suggested from Lu et al. [15]. The LLP valve had RSS_{peak} value of 430 N/m^2 , which did not exceed threshold levels for hemolysis. VSS_{peak} values reported from all three valves exceeded threshold levels for platelet activation but not hemolysis, based on critical values suggested from Leverett et al. and Lu et al. [14,15].

For washout potential during leakage flow, the LLP valve demonstrated the “worst case” scenario among the three valves, in terms of velocity magnitude and regions of flow stasis. This scenario could lead to the accumulation of activated platelets due to increased residence times within the hinge. Therefore, even though the LLP valve had lower levels of RSS and VSS than the other valves, the poor washout potential increases the chances for accumulation of activated blood elements for this hinge gap.

Comparison to Previous Studies. Detailed quantitative and qualitative comparisons of hinge flow fields between the μPIV and LDV techniques were discussed previously by Jun et al. [9]. Figure 8 illustrates the comparison of representative flow fields between the μPIV results from this study and CFD results (Standard valve) obtained by Simon et al. [17,18]. For the peak systolic phase (Fig. 8(a)), both results were consistent in structure and orientation of jets, which included a recirculating flow and a high velocity jet from the adjacent and lateral corner, respectively. The Vel_{peak} from the μPIV study at this phase was 1.1 m/s which was comparable to the Vel_{peak} (1.5 m/s) from the CFD study.

In diastole, both CFD and μPIV results showed qualitatively similar leakage flow fields across all measurement planes. In the lower measurement planes (Fig. 8(b)), both studies showed common leakage flow features including lateral, adjacent, ventricular jets, and a low flow region. The velocity range of these three jets was higher in the CFD study ($1\text{--}4.75 \text{ m/s}$) than in the μPIV study ($0.4\text{--}2 \text{ m/s}$). The largest difference was observed at the lateral corner, where results from the CFD study showed about two times higher velocity magnitudes than the μPIV study. Such a discrepancy might be attributed to a possible difference in hinge gap width and location of the leaflet ear between the CFD and experimental BMHV models.

In upper measurement planes, a uniformly structured jet passing across the leaflet center was observed in both studies with velocities ranging from 1 to 3 m/s . These measurement planes were deeper in the hinge recess, which were less influenced by the spatial location of the leaflet ear, hence representing a better match between the two studies than the lower measurement planes.

This study represents the first fully pulsatile flow μPIV measurements in the hinge region of a BMHV, by adapting the previously developed μPIV system for steady flow studies (Jun et al.). In both the steady and pulsatile flow studies, the highest thromboembolic potential was observed during the leakage flow phase under aortic conditions. Nevertheless, the current pulsatile flow μPIV study revealed a number of critical aspects that would have been difficult to investigate under steady flow conditions.

In order to differentiate characteristics across BMHV hinge designs with global velocity maps, a precisely controlled pulsatile flow system is required in the experimental setup to reproduce continuous hemodynamic cycles. The pulsatile experimental set up incorporates dynamic acceleration effects of leaflet motion on the hinge flow fields. This cannot be achieved from the steady flow loop setup where valve leaflets are in a static position throughout the experiment. The instantaneous velocity fields obtained from each cardiac cycle enabled calculation of RSS, representing fluctuation in the flow field in different phases, which was not identified from the previous study.

Fig. 8 Comparison of the simulated (CFD) [18] and experimentally (PIV) measured hinge flow structures [9]. Measurement plane at (a) flat level at the peak systolic phase, (b) flat level at the peak systolic phase (CFD), (c) flat level at the mid-diastolic phase (PIV), and (d) flat level at the mid-diastolic phase (CFD).

These unique aspects of BMHV flows found in the current μ PIV study such as evaluating cycle to cycle variation and global velocity maps under microscale flow domains are not restricted to the hinge region. Previous studies indicated that large recirculation regions are formed upstream of the valve during the leakage phase [28,29]. In addition, strong regurgitant jets were observed in the B-datum plane and peripheral leakage regions located in the neighborhood of the hinge [29,30]. These combined factors can potentially trap damaged blood elements at these locations resulting in thromboembolism. However, these flow features are outside the scope of this study, which focus on flow fields within the hinge regions.

The established technique from this study can be used to assess other critical regions in a BMHV such as leakage flow through the B-datum gap, and flow fields in the immediate vicinity of a hinge during the period of valve closure. This study has shown the fully pulsatile flow characteristics of the three valve models with intricate hinge flow structures. In addition, the study has demonstrated the application of the high-resolution μ PIV system, which can aid in the design optimization of BMHVs.

Limitations. A few limitations exist in this study due to the experimental factors encountered during the investigation of complex hinge flows. First, due to the limited seeding density at the upper measurement planes, the ensemble averaging technique was only used at the FLAT plane to calculate RSS values. However based on previous studies, the FLAT plane has been shown to indicate the highest thromboembolic potential [6,10,11,17,27], which was investigated in detail in this study. Second, a cyclic variation in velocity measurement exists primarily due to the cycle-to-cycle variation of the leaflet kinematics as well as fluctuations introduced by the flow and pressure in the system. Although it is difficult to isolate the cycle-to-cycle variations of the loop, a precisely controlled pulsatile flow system was used in this study in an effort to keep these fluctuations to a minimum. Subsequently, the cycle-to-cycle variation in velocity was captured from the RSS fields. It should be noted that there is a delay

of ~ 15 ms between the ensemble averaged flow and crossing of ventricular and aortic pressures in the beginning of forward flow (Fig. 3). Such mismatch is due to the cycle to cycle fluctuations which arise from the pulse duplicator used in the study.

Third, the current study uses a low-volume pulsatile tester that requires a fluid volume of ~ 500 ml to generate physiological transvalvular pressure across the aortic valve. Subsequently, in order to minimize the fluid volume as much as possible, large scale compliance elements were not used in the setup. Therefore, the pressure waveforms appear flattened and less physiological than the other in-vitro studies [6,10,11,24]. Nevertheless, the current study focuses on rigorous comparison of flow fields across three valves at the peak systolic and mid-diastolic phases where most dominant flow structures exist, which we were able to achieve.

The 2D global velocity maps presented in this study represent the dominant velocity components in each of the imaging planes across the hinge, caused by a reverse axial flow across the semicircular geometry of the hinge. Nevertheless, as the hinge region is a complex 3D structure, out-of-plane flow will also be an important variable to be studied [17]. However, measurement of the third velocity component is currently beyond the scope of this study. It was ensured that the imaging plane is oriented such that the dominant velocity components are captured in this study. To reduce the effect of out-of-plane particles on velocity calculation, images were pre-processed using a sliding background subtraction filter to eliminate defocused particles.

Finally, the current study focuses on rigorous comparison of flow fields at the peak systolic and mid-diastolic phases where most dominant flow structures exist with minimum fluctuations introduced by the flow and pressure in the loop. Nevertheless, flow unsteadiness and leaflet dynamics during the valve impact-rebound duration will also be an important phase to be studied. Future studies should use a particle tracking and/or stereoscopic PIV techniques to resolve unknown parameters such as full exposure time and the third velocity component.

Conclusions

The present study investigated the effect of hinge gap width on flow fields in SJM BMHVs. The hinge gap width was found to alter shear stress levels and washout potential during leakage flow but had minimal effect during the forward flow. RSS levels increased with respect to the larger hinge gap width with altered location of high fluctuation regions in the three valves.

The results from this study suggest that the BMHV hinge design is a fine balance between reduction of fluid shear stresses and areas of flow stasis during leakage flow, and needs to be optimized to ensure minimal thromboembolic complications. Overall, the current study demonstrates the ability of high-resolution μ PIV to assess the fluid flow fields within the hinges of BMHVs, which can be extended to investigate microscale flow domains in critical regions of other cardiovascular devices to assess their blood damage potential.

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Nomenclature

BMHV = bileaflet mechanical heart valve
cSt = centi-stokes
CFD = computational fluid dynamics
LDV = laser doppler velocimetry

PIV = particle image velocimetry
 RSS = apparent Reynolds shear stress
 SJM = St. Jude medical
 Vel = velocity magnitude
 VSS = viscous shear stress
 μ PIV = micro particle image velocimetry

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