Published in final edited form as:

ASAIO J. 2012 September ; 58(5): 481–493. doi:10.1097/MAT.0b013e3182639a18.

The Influence of Device Position on the Flow within the Penn State 12 cc Pediatric Ventricular Assist Device

Markus Schönberger, Steven Deutsch, and Keefe B. Manning

Department of Bioengineering, The Pennsylvania State University, 205 Hallowell Building, University Park, PA 16802, USA

Abstract

Ventricular assist devices are a commonly used heart failure therapy for adult patients as bridge-to-transplant or bridge-to-recovery tool. The application of adult ventricular assist devices in pediatric patients has led to increased thrombotic events. Therefore, we have been developing a pediatric ventricular assist device, the Penn State 12 cc PVAD. It is designed for patients with a body weight of 5 to 15 kg and has a stroke volume of 12 cc. Clot formation is the major concern. It is correlated to the coagulability of blood, the blood contacting materials and the fluid dynamics within the system. The intent is for the PVAD to be a long term therapy. Therefore, the system may be oriented in different positions according to the patient's behavior. This study evaluates for the first time the impact of position on the flow patterns within the Penn State 12 cc PVAD, which may help to improve the PVAD design concerning chamber and ports geometries. The fluid dynamics are visualized by particle image velocimetry. The evaluation is based on inlet jet behavior and calculated wall shear rates. Vertical and horizontal model orientations are compared, both with a beat rate of 75, outlet pressures of 90/60 mmHg and a flow rate of 1.3 l/min. The results show a significant change of the inlet jet behavior and the development of a rotational flow pattern. Vertically, the inlet jet is strong along the wall. It initiates a rotational flow pattern with a wandering axis of rotation. In contrast, the horizontal model orientation results show a weaker inlet jet along the wall with a nearly constant center of rotation location, which can be correlated to a higher risk of thrombotic events.

In addition high speed videography illustrates differences in the diaphragm motion during diastole. Diaphragm opening trajectories measurements determine no significant impact of the density of the blood analog fluids. Hence, the results correlate to human blood.

Keywords

pediatric ventricular assist device; thrombosis; fluid dynamics; pulsatile; wall shear; particle image velocimetry; device position

Introduction

Cardiac insufficiency has a rate of occurrence of 3% in industrial nations with 400 thousand incidences per year in the USA. The overall risk of the disease for adults depends primarily on age and lifestyle. In contrast, congenital heart defects (CHD) are mainly responsible for pediatric heart failure. Up to 10 per 1000 live births are reported. An estimated 25% of these are in need of invasive heart surgery to prevent early death [1–4]. The disease can cause

Reprint/Negotiation/Corresponding Author: Keefe B. Manning, Ph. D., Department of Bioengineering, The Pennsylvania State University, 205 Hallowell Building, University Park, PA 16802, USA, Phone: 1-814-863-6318, Fax: 1-814-863-0490.

Disclosures: This research was not supported by any external funding.

effects like unnatural blood flow or altered heart rhythm. Different surgical approaches could be indicated and these depend on the disease characteristics. A heart implantation may be the final alternative to achieve healing of CHD [5]. Due to the lack of available donor hearts, especially for pediatric patients, mechanical circulatory support devices (MCS) are often necessary for bridge-to-transplant or bridge-to-recovery. These devices unload underperforming hearts by taking over some of the pumping function [4, 6].

Clot formation and hemolysis are existing problems in current support devices. Thrombogenicity is a function of the coagulability of blood, the surface characteristics of VAD materials and the fluid flow [7]. In contrast, hemolysis is related to high shear stresses depending on the fluid flow in combination with long exposure time. High stress regions for blood cells are the inlet and outlet valves in pulsatile pumps [8–11]. In addition to thrombus formation, frequent critical medical problems are sepsis, multi-organ failure and general infections [1].

The measurement of flow field velocities in left ventricular assist devices (LVAD) facilitates the identification of regions potentially causing thrombosis, clot formation and blood coagulation, and hemolysis [12]. The occurrence of both should be avoided to ensure long term ventricular support. Deutsch et al. [8] characterize four main activating effects in correlation with flow patterns: velocity, shear, wall shear rates and turbulence. Lysis is a function of shear stress magnitude and its applied time. Various studies postulate a laminar shear stress threshold of 1500 dynes/cm² for red blood cells [13, 14]. Thrombosis is associated with the large surface area, implantation requirements and long-term use of VADs [15]. The activation of thrombus formation is correlated with low wall shear stress and blood residence time. Hubbel et al. [16] found that a minimum shear rate of 500 s⁻¹ for polyurethane surfaces would minimize clot deposition. This corresponds to a wall shear stress of 18 dynes/cm² for a dynamic viscosity of 3.5·10⁻³ Pa·s. Additional experiments point to a wall shear rate larger than 1000 s⁻¹ to prohibit platelet activation on polymeric surfaces [17]. The overarching aim of this development is to improve the VAD fluid dynamic design to achieve minimum wall shear rates above 500 s⁻¹ and to avoid high shear stresses due to turbulence and strong shear flows [8].

Ventricular assist devices for pediatric use magnify the difficulties found within the development of adult VADs, due to their size and stroke volume. Therefore adult VAD systems are characteristically limited by the FDA to a patient with a body surface area of at least 0.7 m² [4, 18, 19].

In 2002 the Pediatric Circulatory Support Program was created by the U. S. National Heart, Lung and Blood Institute to develop VADs for pediatrics with a weight between 2 and 25 kg. As one of several research units, the Pennsylvania State University has continued the development of a pediatric ventricular assist device (PVAD). The current system is a pneumatically driven extracorporeal positive displacement pump with a stroke volume of 12 cc. It is dimensioned for pediatric patients with a body weight of 5 to 15 kg. The flow rate ranges from 0.5 to 1.3 l/min. The diaphragm is manufactured from seamless segmented polyether polyurethane-urea (SPEUU) and the casing is a titanium shell [20, 21].

The flow behavior of the PVAD has been evaluated in several studies by applying particle image velocimetry (PIV). In a previous study Björk-Shiley Mono Strut (BSM) tilting disc valves with an effective orifice area (EOA) of 1.1 cm² and 17 mm diameter showed better results in regard to inlet jet behavior than CarboMedics bileaflet valves [22]. Roszelle et al. [23] pointed out that a +15° rotation into the body from a horizontal line for BSM inlet and outlet valve was optimum (figure 1). Consequently, the current study uses BSM valves at an inlet/outlet rotation of +15°. Additional studies have evaluated the three dimensional flow

behavior within the Penn State 12 cc, and beat rate and stroke volume reduction for weaning application [19, 20, 24, 25].

The model orientation for the previous flow visualization studies of the Penn State 12 cc PVAD were all in a vertical position, which means the diaphragm mainly moves perpendicular to gravity. In pneumatic pulsatile pumps the membrane opening during the filling phase of the device chamber is driven by the applied pressure. The flow depends on the device geometry (e.g. valves, port angle), operating conditions (e.g. pressures, flow rates and beat rate) and the membrane motion. The diaphragm motion directly affects the flow pattern of pulsatile positive displacement pumps as the opening and closing characteristics depend on membrane material and driver settings [26]. Therefore the diaphragm opening and closing is affected by the fluid dynamics within the device, but influences it as well. Jin et al. [27] demonstrated different flow behavior in VADs would occur based on device orientation relative to gravity. Due to lower density, the air pressure seems to be impacted less significantly than the hydrostatic and dynamic pressure of the liquid. Hochareon [28] discussed the influence of the fluid density on pump filling in the Penn State 50 cc VAD in a vertical orientation. Measured trajectories of diaphragm motion showed similar results for different fluid densities. To date, no extensive research on the impact of gravity depending on the patient's orientation within the Penn State 12 cc pneumatic VAD has been done.

Materials and Methods

The flow was visualized with two dimensional particle image velocimetry (PIV) to acquire global flow as a function of operating conditions within an acrylic model of the Penn State 12 cc PVAD (see figure 1). The implantable polyurethane sac was replaced by a polyurethane diaphragm to enable PIV measurement in the acrylic model. The refractive index of the acrylic was 1.48, which closely matches the index of the blood analog fluid. PIV within the PVAD is extensively described in [25, 28, 29]. We used a Gemini PIV 15 system (New Wave Research, Inc., Fremont, CA) with two 532 nm polarized Nd:YAG lasers, which can deliver 120 mJ laser pulsations with a 5–10 ns pulse width. Cylindrical and spherical lenses expanded the laser beams into a 250 μm light sheet. A laser delay ΔT of 200 μs was used throughout the cardiac cycle. The PIV images were taken with a two megapixel CCD camera (Model 630057 PowerView Plus, TSI, Inc., Shoreview, MN) with a 50 mm F1.8 lens (Nikon, Corp., Tokyo, Japan). A laser pulse synchronizer (TSI, Inc., Shoreview, MN) managed laser pulsing and image capturing. The Insight[™] 3G software (TSI, Inc., Shoreview, MN) operated the PIV system. The camera and acrylic model assembly allowed a resolution from 35 to 50 $\mu\text{m}/\text{pixel}$ depending on the acquired plane.

The cardiac cycle of 800 ms was divided in 50 ms time steps to visualize the development of the flow within the chamber. High speed videos of the diaphragm opening in the Penn State 12 cc PVAD were acquired to evaluate the influence of different fluid densities in both model orientations. Beat rate, the outlet pressure, flow rate and end-diastolic delay were the test parameters, which had to match in both model orientations to allow adequate flow field comparison. Adjustable parameters were the drive line pressure, resistance and compliance.

As shown in figure 1, the acrylic PVAD was dimensionally similar to the internal sac (blood contacting surface) used clinically. Vertical and horizontal model orientations were studied to determine the influence of position on the flow development within the PVAD. In the vertical position, the gravity vector was parallel to the diaphragm. For the horizontal condition the model was rotated 90°, therefore the gravity vector was perpendicular to the diaphragm.

We acquired PIV planes both parallel and perpendicular to the diaphragm to help define the three-dimensional flow in the vertical and horizontal orientations. Three parallel and six normal planes to the diaphragm were analyzed (see figure 2). The normal planes at 7.5 mm were at the center of the inlet and outlet ports, respectively. Major and minor orifice flows were determined by normal planes at 3.75 mm and 11.25 mm. The parallel planes 7, 8.2 and 11 mm showed the flow pattern in the ports as well as in the body of the device. The diaphragm caused interference until 150 ms into the cardiac cycle.

The PVAD model was connected to a mock circulatory loop (MCL), developed by Rosenberg et al. [30], and modified for the pediatric ventricular assist device (Figure 3). The MCL has been used in several studies. The functionality has been described in [19, 20, 22, 23, 24].

The diaphragm was driven by a motor similar to the actual Penn State 12 cc PVAD. The inlet and outlet port flows were measured by ultrasonic flow probes (Transonic Systems Inc., Millis, MA). The atrial and arterial pressures and the pneumatic driver pressure were measured by pressure transducers (Maxxim Medical Inc., Athens, TX). The recorded data was displayed through the acquisition system Wavebook and Waveview software (IOtech Inc., Cleveland, OH).

The averaged flow, outlet pressure and end diastolic delay (EDD) had to be consistent to guarantee comparable boundary conditions for the flow patterns in the vertical and horizontal model orientations. The EDD is defined as the time between negative zero crossing of the inflow and a strong rise in the drive pressure and was set to 10 ms to ensure a complete diastolic chamber filling and systolic ejection. The outlet pressure was fixed at 90/60 mmHg (systole/diastole). The averaged inflow and outflow rate was averaged 1.3 l/min in both model orientations. The actual inflow and outflow behavior are shown in Figure 4 in combination with the pneumatic drive pressure.

A suitable blood analog based on glycerin and xanthan gum was developed by Long et al. [31]. Glycerin is used to achieve the viscous characteristics of human blood, xanthan gum to match the elastic properties. For a 40% hematocrit blood analog a deionized water solution with 16 % glycerin, 0.03 % xanthan gum, 50% sodium iodide and 33.97% water was mixed. Additionally, 10 μm glass particles were added to the analog as seed for the PIV to match the refractive index of acrylic. The solution density was about 1.70 g/cm³, human blood density is 1.05 g/cm³. The viscoelasticity of the blood analog was measured using the viscoelastic analyzer VILASTIC-3 (Vilastic Scientific, Inc., Austin, TX) within the shear range 1 to 1000 s⁻¹. The operating temperature of the blood analog was 20 °C.

The flow velocities and vector orientation were computed by knowledge of the particle displacement over the laser delay time ΔT . The captured raw data was preprocessed to improve the flow calculation. In addition, it was a primary stage for wall shear rate computations. After processing the flow and wall shear rates, data manipulation was used to obtain quasi three dimensional flow pattern plots with TecPlotTM Focus (Tecplot, Inc., Bellevue, WA). Roszelle et al. [3, 24, 25] describes the processing techniques. For the fluid velocity calculation, a Hart Correlator [32] was used in combination with a Recursive Nyquist Grid. In contrast to standard *fast Fourier transform* (FFT) techniques overlapping interrogation regions were possible. Each image was divided into interrogation windows (IW) of 32×32 pixels. Cross-correlation techniques were used to examine the displacement of the particles in each IW. For each time step 200 images were taken. The flow field results were averaged to minimize effects of flow fluctuation due to beat-to-beat variability within the PVAD.

The comparison of the wall shear rates helps to identify the thrombogenicity of the flow. The shear rate was computed along the defined walls from x_0 to x_1 (see Figure 5) by using the PIV velocity information for each time step throughout the cardiac cycle. The walls were separated into four segments S1 to S4 in the wall definition process. The wall shear calculation technique was described by Hochareon et al. [28], and used a centroid shifting technique to compute near wall velocities. The wall shear rate of 200 image pairs were calculated for each time step. Available data suggests, a wall shear rate above 500 s^{-1} reduces the chance of clot formation along the wall [16]. Therefore, the calculated wall shear maps were normalized by 500 s^{-1} .

Images taken by a high speed video camera were used to measure diaphragm opening trajectories for two different blood analog fluids in the vertical and horizontal orientations to evaluate the possible influence of density on the diaphragm opening process. Five points were located along the diaphragm boundary. The motion perpendicular to the diaphragm plane was measured for each time until the diaphragm was blocked by the sealing ring. The results were averaged over 5 high speed videos. A xanthan gum, glycerin, and sodium iodide based blood analog (density 1.7 g/cm^3) and a 40 % glycerin solution (density 1.1 g/cm^3) were compared.

Error Analysis

Cooper et al. [22] applied an error analysis of the velocity measurement technique used at the Artificial Heart Laboratory (Department of Bioengineering, Pennsylvania State University). The bias and precision error was used to review the velocity results. The bias error with wall shear calculation was determined to approximately 20 %. Additionally, we calculated the precision error to evaluate the repeatability of our results. The precision error was computed within the 11 mm parallel plane for three different time steps (200 ms, 400 ms, 600 ms) at randomly chosen points. The average precision error was 2.5 %.

Results

With equal boundary conditions (beat rate: 75 bpm; outlet pressure: 90/60 mmHg; flow rate: 1.3 l/min; systolic duration: 340 ms; edd: 10 ms), the inflow behaves as a function of orientation. Up to the 100 ms time step, most parts of the acquired images are blocked by the opened diaphragm.

Diastolic Flow

During early diastole, the rotational flow starts to develop driven by the inlet jet, mostly through the major orifice of the valve. The jets are directed along the wall in both orientations.

At 150 ms the major jet begins to penetrate into the apex of the device in the vertical model orientation. This induces a rotational flow within the device, visible in all three parallel planes (Figure 6A). At the same time in the horizontal model orientation, a secondary inlet jet develops besides the major orifice inlet jet (Figure 6B). The orientation of the major orifice jet is directed to the middle of the chamber. Therefore, low flow areas occur in the bottom of the device in figure 4B at time step 150 ms. The normal major orifice plane n_{H1} in Figure 7B shows a shifted flow profile towards the lower edge. A counter flow begins to form in the bottom area, which correlates with the shifted inlet jet.

The mid diastolic flow behavior (200 to 300 ms time steps) is characterized by the full development of the rotational flow pattern with relatively constant inlet jets in both model orientations. Vertically (Figure 6A), the inlet jet flow remains through the major orifice. The jet velocity is high along the wall up to the outlet port region (p_V planes). A brief counter

flow in the n_{V3} plane (Figure 7A) at the 200 ms time step occurs, which disappears by the 250 ms. The n_{V1} planes are typified by strong jet filling the whole port with a maximum velocity close to the upper wall. The middle n_{V2} planes in Figure 7A correspond to the major orifice plane and show a strong jet along the wall. The center of rotation has started to form with a low velocity area. In Figure 6A the rotational axis RA_V shifts between the time steps 250 to 350 ms.

Horizontally, the major and minor orifice inlet jets within the planes $p_{H1,2,3}$ (Figure 6B) tend to merge three dimensionally into one at the beginning of mid diastole. This merge tends to increase with the time. This corresponds with the increased counter flow in $n_{H1,2,3}$ (Figure 7B) at 200 and 250 ms. A rotational flow pattern develops like in the vertical orientation, but it is driven by a significantly weaker jet along the wall. The rotational axis RA_H location (Figure 7B) remains at a constant location. For both orientations, the low flow field region within the center of rotation is similar as seen in Figure 6B and Figure 7B at 250 to 350 ms.

The diastolic duration is 460 ms. Therefore, the inlet valve is open at 350 and 400 ms. At the final time step during diastole, the valve starts to close slightly. Afterwards, the device is filled completely. In the vertical model orientation, the axis of rotation moves within the device. The low flow field area within the center of rotation becomes smaller with progressing diastole. The major orifice inlet jet along the wall remains strong in all three planes $p_{V1,2,3}$ through to 400 ms (not shown). In the middle of p_{V1} , a small area shows low flow velocities during the end diastolic period. This is also present in the p_{V2} planes.

Though the waveforms show similar shapes at the end of diastole (Figure 4), the flow along the wall remains weak in the horizontal orientation, especially in the parallel p_{H3} planes. The previous described merged jet is slightly visible in the 400 ms time step. The center of rotation persists at the same chamber location with an increased low flow area in comparison to the vertical results. Similar to the vertical orientation, an area close to center of rotation remains with low flow velocity.

The velocity profiles (Figure 8) of the $n_{V,H1}$ cross sections (CS) show different velocity distributions within the vertical and horizontal model orientation. The vertical peak velocities are shifted towards the upper inlet port wall, while the horizontal peak velocities are oriented to the bottom wall.

Systolic Flow

At the beginning of systole, the inlet valve is closed and the outlet valve is open. The flow of interest is on the outlet port side. In contrast to diastole, the systolic flow is quite similar between the orientations, but with stronger velocity peaks in the vertical orientation at the outlet valve (Figure 7A and B). Up to 550 ms, the flow shows rotational behavior. A strong outlet jet is visible in all three planes in both model orientations. In the horizontal orientation, the jet is slightly shifted away from the outside wall, which will after the wall shear rate. The outlet jet in $p_{V1,2}$ is stronger in the vertical orientation at the 600 ms time step. At the same time in the horizontal orientation, the diaphragm inhibits the main area of p_{H3} and parts of p_{H2} , which influences the outlet jet formation. In the parallel and normal planes, the diaphragm blocks large parts of the flow field during end systole, especially at the 700 and 750 ms time steps, which are not shown. In both orientations, the rotational flow is stopped and the flow main direction is towards the outlet port. Regurgitation through the outlet valve is visible at the end of the cardiac cycle.

Computed Wall Shear Profiles

The 11 mm parallel plane is chosen to show the significant differences in the wall shear distribution between horizontal and vertical model orientation.

In the vertical orientation, the strong rotational flow pattern results in sufficient shear rates (range between 500 and above 1500 s^{-1}) along all four wall sections during diastole. The smooth passage of diastolic rotational flow to an effectual outlet jet leads to a nearly uninterrupted wall shear rate above the clot formation threshold as shown in Figure 10A. The apex shear rates are the highest in all three vertical parallel planes, with a maximum of 2000 s^{-1} . During systole, a second peak of 550 s^{-1} is calculated (Figure 11).

The wall shear maps of the horizontal experiments show similar characteristics, but with weaker shear rates. At the S1 to S2 (Figure 10B) transition, there are poor wall shear rates. The apex location wall shear rates surpass the clot formation threshold during mid-diastole in Figure 11. The wall shear rates induced by the outlet jet are comparable, with slightly lower peaks.

Influence of Fluid Density on Chamber Filling

During early diastole, the measured trajectories of the diaphragm show a similar opening behavior in both orientations. At the beginning of the inflow, the valves are slightly open in both orientations. The diaphragm is fully stretched. Until 100 ms into the cardiac cycle, the diaphragm and valve motion are identical. The collapsing process of the polyurethane diaphragm is slightly more distinctive in the vertical than in the horizontal orientation at 150 ms with a larger area enclosed by the folding line (Figure 12).

The opening slopes in Figure 13 show similar behavior for both orientations, independent of the fluid density. At zero position is set at the smallest distance between the top of the diaphragm and the wall. The maximum opening is reached, when the device is fully filled. The opening can be divided into a starting phase with a slightly increasing filling until 100 ms and a more rapid filling phase immediately afterwards, until the end of the visualization of the diaphragm motion at 250 ms.

In the vertical orientation, the inflow can be divided into three types of behavior during the diastolic filling phase: a slight start caused by valve motion, a strong increase up to a flow rate of 2.5 l/min, and a more gentle increase to the maximum of 3.5 l/min until the inlet valve closes. At the beginning of ejection, the inflow and outflow show strong fluctuations which correspond to regurgitation. The outflow velocity peaks at 5.5 l/min.

Horizontally, the initial inflow occurs before the filling phase starts. Valve motion causes a peak flow with 0.5 l/min, however the valve closes completely afterwards before the actual beginning of the filling phase. A strong rise to a flow rate up to 2.5 l/min and a plateau phase to 3 l/min take place during diastole. The regurgitation, occurring vertically after diastole, is weaker with no massive negative drop of the inflow. The outflow has similar shape as vertically with a maximum flow rate of 5.5 l/min.

During diastole, the opening trajectories of the diaphragm are quantified with high speed camera images. Measurements are possible until 250 ms into the cardiac cycle at which point the sealing ring blocks the field of vision within the acrylic model. The folding process of the diaphragm begins around 150 ms after the start of inflow. The measurement range includes about 100 ms of the folding process during diastole, which shows the major differences in the diaphragm surface behavior. Although the diaphragm image is blocked after 250 ms into the cardiac cycle, the measured time period is large enough to draw conclusions from the trajectories. The diaphragm opens slowly until 100 ms. Afterwards, the slopes of the trajectories increase considerably for both the vertical and horizontal orientations. The accelerated opening can be related to the beginning of a folding process (described in Figure 12) between 100 and 150 ms. Although, the measurements show no strong discrepancies in the opening characteristics, the folding process behavior shows

significant differences. Vertically, the opening can be described as rolling; the horizontal process is more uniform.

Discussion

Because of the increased port angles, the Penn State 12 cc PVAD has an increased three-dimensional flow pattern relative to the 50 cc pump. However, the flow development shows mainly two dimensional effects in the vertical model orientation. A strong inlet jet develops along the wall during diastole in all three parallel planes. The jet penetrates into the apex of the device and reaches high velocities along the entire wall with rotational flow formation. The center of the rotation shows a shifting axis location and angle during the chamber filling phase. The normal planes of the inlet illustrate a peak jet through the major orifice of the +15° oriented inlet valve, which was evaluated as the most beneficial orientation for strong inlet jet development in previous studies [23]. The peak of the velocity profile is near the upper wall in the inlet port. Therefore, the peak flow occurs into the major orifice area. The strong jet along the upper wall within the middle port normal plane supports this conclusion.

In contrast, the horizontal model orientation experiment shows significant three-dimensional counter flow in the normal planes at the bottom location during early diastole, time steps 100 to 250 ms. At the same time, the inlet jet shifts into the middle of the device as shown in the parallel plane data. Therefore, the inlet jet drop along the wall may be correlated with the recirculation. The peak of the velocity profile in the inlet port drifts towards the bottom wall. This drives a stronger recirculation pattern in the apex region, which directs the inlet jet towards the rotational axis. The recirculation ends, when the beginning folding process accelerates the diaphragm motion. The inlet jet through the minor orifice is stronger than in the vertical orientation; however it is not totally captured in the minor orifice normal planes. Due to the different velocity profiles, the inflow may be blocked by parts of the valve strut and disk before entering the device. This may cause three-dimensional flow patterns at the inner wall of the inlet port, which increases the strength of the minor orifice jet. Both, major and minor orifice, jets emerge to one strong single jet close to the rotational axis, with the strongest appearance in the 7 mm plane. The location of the center of rotation is relatively constant in all parallel planes during diastole, which causes a low velocity region. This may be correlated to thrombosis. The weak jet along the wall implies low wall shear rates and are calculated for the three parallel planes.

The comparison of the opening trajectories with different fluid densities showed no significant differences. In the vertical orientation, the rolling effect is visible in the glycerin solution and the blood analog fluid. Horizontally, the folding process evenly occurs in both liquids as well. The extension of these results to human blood behavior in the Penn State 12 cc pVAD seems reasonable.

It should be noted that the flow that develops in the PVAD is truly three-dimensional. However, previous work comparing 2D and 3D flows demonstrated that while 2D PIV does not capture the fully 3D flow, it does an excellent job as long as normal planes are included in the analysis as has been done here [33].

Conclusion

Overall, differences in the flow behavior and the diaphragm motion demonstrate a significant influence of the gravity on the flow development under normal operating conditions for the PVAD (75 bpm, 90/60 mmHg, 10 ms EDD). In both model orientations, vertical and horizontal, the boundary conditions result in a complete filling and ejection. The

wave forms are similar, thus the working conditions allow comparison of the flow and diaphragm motion.

Velocity and wall shear profiles support the conclusion that horizontal positioning of the PVAD is likely more thrombogenic than is the vertical during diastole. There are no important differences in the flow fields during systole. Differences in the motion of the diaphragm and valve leaflets as a function of orientation are the most likely cause of the flow field changes.

Acknowledgments

This study was supported by NIH-NHLBI HV48191.

References

1. Spillner J, Kopp R, Finocchiaro T, et al. Assisted circulation. an overview from a clinical perspective. *Biomed Tech.* 2009; 54:255–267.
2. He J, Ogden LG, Bazzano LA, Vupputuri S, Loria C, Whelton PK. Risk factors for congestive heart failure in US men and women. NHANES I epidemiologic follow-up study. *Arch Intern Med.* 2001; 161:996–1002. [PubMed: 11295963]
3. American Heart Association. Statistical Reference Book. Texas: 2005.
4. Fynn-Thompson F, Almond C. Pediatric Ventricular Assist Devices. *Pediatr Cardiol.* 2007; 28:149–155. [PubMed: 17265106]
5. Hoffman JI, Kaplan S. The Incidence of Congenital Heart Disease. *J Am Coll Cardiol.* 2002; 39:1890–1900. [PubMed: 12084585]
6. Potapov E, Stiller B, Hetzer R. Ventricular assist devices in children. Current achievements and future perspectives. *Pediatr Transplantation.* 2007; 11:241–255.
7. Daily BB, Pettitt TW, Suter SP, Pierce WS. Pierce-Donachy Pediatric VAD. Progress in Development. *Ann Thorac Surg.* 1996; 61:437–443. [PubMed: 8561622]
8. Deutsch S, Tarbell JM, Manning KB, Rosenberg G, Fontaine AA. Experimental Fluid Mechanics of Pulsatile Artificial Blood Pumps. *Annu Rev Fluid Mech.* 2006; 38:65–86.
9. Avrahami I, Rosenfeld M, Einav S. The Hemodynamics of the Berlin Pulsatile VAD and the Role of its MHV Configuration. *Ann Biomed Eng.* 2006; 34:1373–1388. [PubMed: 16838127]
10. Finocchiaro T, Heinke S, Behbahani M, et al. Methods of Design, Simulation, And Control for the Development of New VAD/TAH Concepts. *Biomed Tech.* 2009; 54:269–281.
11. Manning KB, Herbertson LH, Fontaine AA, Deutsch S. A Detailed Fluid Mechanics Study of Tilting Disk Mechanical Heart Valve Closure and the Implications to Blood Damage. *J Biomed Eng.* 2008; 130:041001–041008.
12. Pierce WS, Brighton JA, O'Bannon W, et al. Complete Left Ventricular Bypass With a Paracorporeal Pump. Design and Evaluation. *Ann Surg.* 1974; 180:418–426. [PubMed: 4547165]
13. Leverett LB, Hellums JD, Alfrey CP, Lynch EC. Red Blood Cell Damage by Shear Stress. *Biophys J.* 1972; 12:257–273. [PubMed: 5016112]
14. Baldwin JT, Deutsch S, Geselowitz DB, Tarbell JM. LDA Measurements of Mean Velocity and Reynolds Stress Fields Within an Artificial Heart Ventricle. *J Biomech Eng.* 1994; 116:190–200. [PubMed: 8078326]
15. Hanson SR. Device Thrombosis and Thromboembolism. *CardioVasc Pathol.* 1993; 2:157S–165S.
16. Hubbel JA, McIntire LV. Visualization and analysis of mural thrombogenesis on collagen, polyurethane and nylon. *Biomaterials.* 1986; 7:354–363. [PubMed: 3778995]
17. Balasubramanian V, Slack SM. The Effect of Fluid Shear and Co-Absorbed Proteins on the Stability of Immobilized Fibrinogen and Subsequent Platelet Interactions. *J Biomater Sci Polymer Edn.* 2002; 13:543–561.
18. Bachmann C, Hugo G, Rosenberg G, Deutsch S, Fontaine AA, Tarbell JM. Fluid Dynamics of a Pediatric Ventricular Assist Device. *J Artif Organs.* 2000; 24:362–367.

19. Manning KB, Wivholm BD, Yang Y, Fontaine AA, Deutsch S. Flow Behavior Within the 12-cc Penn State Pulsatile Pediatric Ventricular Assist Device. An Experimental Study of the Initial Design. *J Artif Organs*. 2008; 32:442–452.
20. Roszelle BN, Deutsch S, Manning KB. Flow Visualization of Three-Dimensionality Inside the 12 cc Penn State Pulsatile Pediatric Ventricular Assist Device. *Ann Biomed Eng*. 2010; 38:439–455. [PubMed: 19936926]
21. Baldwin JT, Borovetz HS, Duncan BW, et al. The National Heart, Lung, and Blood Institute Pediatric Circulatory Support Program. *Circulation*. 2006; 113:147–155. [PubMed: 16391168]
22. Cooper BT, Roszelle BN, Long TC, Deutsch S, Manning KB. The 12 cc Penn State Pulsatile Pediatric Ventricular Assist Device. Fluid Dynamics Associated With Valve Selection. *J Biomech Eng*. 2008; 130:041019–041033. [PubMed: 18601461]
23. Roszelle BN, Deutsch S, Manning KB. A Parametric Study of Valve Orientation on the Flow Patterns of the Penn State Pulsatile Pediatric Ventricular Assist Device. *ASAIO*. 2010; 56:356–363.
24. Roszelle BN, Cooper BT, Long TC, Deutsch S, Manning KB. The 12 cc Penn State Pulsatile Pediatric Ventricular Assist Device. Flow Field Observations at a Reduced Beat Rate With Application to Weaning. *ASAIO*. 2008; 54:325–331.
25. Roszelle BN, Deutsch S, Weiss WJ, Manning KB. Flow Visualization of a Pediatric Ventricular Assist Device During Stroke Volume Reductions Related to Weaning. *Annals of Biomedical Engineering*. 2011; 39:2046–2058. [PubMed: 21404124]
26. Hochareon P, Manning KB, Fontaine AA, Deutsch S, Tarbell JM. Diaphragm Motion Affects Flow Patterns in an Artificial Heart. *J Artif Organs*. 2003; 27:1102–1109.
27. Jin W, Clark C. Experimental Investigation of the Motions of the Pumping Diaphragm within a Sac-Type Pneumatically Driven Ventricular Assist Device. *J Biomechanics*. 1994; 27:43–55.
28. Hochareon, P. Dissertation. Doctor of Philosophy, College of Engineering, Pennsylvania State University; University Park (Pa, USA): 2003. Development of Particle Image Velocimetry (PIV) for Wall Shear Stress Estimation within a 50cc Penn State Artificial Heart Ventricular Chamber.
29. Raffel, M.; Willert, CE.; Wereley, ST.; Kompenhans, J. Particle Image Velocimetry. A Practical Guide. 2. Berlin (Germany): Springer Verlag; 2007.
30. Rosenberg G, Phillips WM, Landis D, Pierce WS. Design and evaluation of the Pennsylvania State University mock circulatory system. *ASAIO*. 1981; 4:41–49.
31. Long JA, Ündar A, Manning KB, Deutsch S. Viscoelasticity of Pediatric Blood and its Implications for the Testing of a Pulsatile Pediatric Blood Pump. *ASAIO*. 2005; 51:563–566.
32. Hart DP. Super-resolution PIV processing by recursive local-correlation. *J Visualization*. 1999; 10:187–194.
33. Roszelle BN, Deutsch S, Manning KB. Flow visualization of three-dimensionality inside the 12 cc Penn State pulsatile pediatric ventricular assist device. *Ann Biomed Eng*. 2010; 38:439–455. [PubMed: 19936926]

a) CAD Model of the PVAD **b) Observed Model Orientations**

→ Main diaphragm motion during diastole

c) BSM Valve Orientation **Figure 1.**

(A) Schematic CAD drawing of the Penn State 12 cc PVAD acrylic model used for PIV. The dimensions correspond exactly to the clinical Penn State 12 cc PVAD. (B) Vertical and horizontal model orientations for PIV measurement and to high speed videography. (C) Björk-Shiley Monostrut valve orientation for the inlet and outlet valves, which are rotated 15°.

a) Parallel planes **b) Normal planes** **Figure 2.**

(A) PIV parallel planes: At the zero position the first marginal flow is visible. The parallel planes with 7, 8.2 and 11 mm distance are chosen to be compared with previous studies. (B) PIV normal planes: The zero position for the inlet and outlet ports occurs at the left and right chamber edges, respectively. The 7.5 mm plane represents the normal middle of the inlet or outlet. The normal planes 3.75 and 11.25 mm on both sides are added to visualize the minor and major orifices valve flow patterns

Figure 3.

The acrylic model of the Penn State 12 cc PVAD is connected via tubes to compliance chambers (CC) and a reservoir (R). Pressure probes (P1, P3) detect the diastolic/systolic pressure. The PVAD is driven by a pneumatic driver (PD), the pressure is measured at P2 with a pressure probe. A resistance plate (RP) regulates the pressure within the system. At F1/F2 position, the inflow/outflow is measured with flow probes.

Figure 4.

The inflow/outflow were measured at the locations indicated in Figure 3. The average flow is 1.3 l/min in both device orientations.

$p_{VH1,2,3}$ parallel planes 7, 8.2 and 11 mm in vertical or horizontal orientated model

t trigger time into the cardiac cycle after zero crossing of inflow

RA_{VH} vortex rotation axis vertical or horizontal

Figure 5.

The parallel plane coordinate system (x_0 to x_1), with the wall sections S1 to S4, are used for the wall shear rate calculations.

Figure 6.

PIV diastolic flow fields (t: 150 ms to 350 ms) in the parallel planes for (A) the vertical orientation and (B) the horizontal orientation.

Figure 7. PIV diastolic flow fields (t: 150 ms to 350 ms) in the normal planes for (A) the vertical orientation and (B) the horizontal orientation.

Figure 8.

Velocity profiles in cross sections (CS), shown in figure 5, at 200, 250, and 300 ms in mid-diastole for the (A) vertical and (B) horizontal orientations.

$p_{VH1,2,3}$ parallel planes 7 mm, 8.2 mm and 11 mm

t trigger time into the cardiac cycle after zero crossing of inflow

Figure 9.

PIV systolic flow patterns at 550 ms and 600 ms in the (A) vertical and (B) horizontal orientations.

Figure 10.

Wall shear rates (11 mm plane parallel plane) are plotted for each section (S1–S4) through the entire cardiac cycle (0 to 800 ms) for the (A) vertical and (B) horizontal orientations. The data is normalized by the 500 s^{-1} threshold.

Figure 11.

Wall shear rates at the apex wall location at the 11 mm parallel plane throughout the cardiac cycle with the vertical orientation denoted as squares and the horizontal orientation denoted as circles. In the vertical orientation, the 11 mm plane shows the highest apex shear rates peak at 1800 s^{-1} .

Figure 12.

The collapsing diaphragm is described as a folding process with the vacuum engaged in the bottom of these images.

Figure 13.

The diaphragm opening for each condition shows similar ascending slopes. After 250 ms, the diaphragm visualization is blocked by the sealing ring.