A comparison between the influence of Bjork-Shiley monostrut and Carbomedics mechanical heart valves in the 50cc Penn State LVAD (V2) using PIV

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Introduction

In the United States, thousands of patients per year suffering from heart failure need a heart transplant. The number of available donor hearts is too low to provide all these patients. In a typical year over two thousand heart transplants are performed in the United States, however according to the American Heart Association thousands more Americans would benefit from a heart transplant if more donor hearts were available (AHA 2006). Ventricular assist devices have shown to be effective therapy for patients not eligible for heart transplants. Since the first clinical left heart bypass, performed by Hall et al. in 1962 much effort was made in the design and the design process of artificial blood pumps. An example of a successful product of an experimental process is the 70cc PennState pneumatic left ventricular assist device (LVAD) later commercialized as the Thoratec® VAD. This LVAD, the first permanent assist device, has been implanted clinically since 1976. Later, research on electric devices, with the advantage of a reduced risk of infection by eliminating the percutaneous leads when implanted, led to the development of the 70cc Arrow LionHeart™. This device was first implanted in 1999 at Hershey Medical Center. Success with this device and the fact that there is a need for a smaller device for the smaller adult patient population led to the development of a smaller scaled 50cc assist device, introduced at Penn State in 1998.

Red blood cell rupture, also called hemolysis, and thrombosis are severe consequences in artificial systems for long term use. Flow properties such as high shear stresses and flow stasis are believed to be the main causes for hemolysis and thrombus formation. As already shown in studies in the early 70’s, hemolysis and thrombus formation in artificial systems are related to shear stress (Goldsmith 1974). When the shear stress is too low it can cause aggregation leading to thrombus formation, and when it is too high hemolysis may occur. Baldwin et al. (1994) concluded that stress levels above 150-400 Pa were undesirable. Besides the stress level also the exposure time of cells to shear stress is a trigger for hemolysis. The visco-elasticity of blood cells makes them resistant to high shear stresses for short exposure times. Nevaril et al. (1969) reported that long term exposure to laminar shear stress on the order of 150 Pa could cause red cell lysis.

In vivo testing of the initial 50cc LVAD (V0) showed thrombus formation on the front and bottom wall of the perimeter⁴. Studying flow characteristics in the assist device can provide an indication of problem areas for thrombus formation. Phillips et al. (1972) were one of the pioneers on implementing flow visualization into the development process of assist devices. Since then a lot of progress has been made in the study of flow characteristics.

They found that changes in geometry of the chamber, valve orientation and valve type had an effect on flow characteristics and could help in reducing thrombus formation. To be able to further improve the design of the assist device, it is important to understand the hemodynamics in the chamber. Techniques such as hot film anemometry, laser Doppler anemometry (LDA) and particle image velocimetry (PIV) have been used to study the effects of changes made in the design of a device on the flow pattern in vitro (Deutsch et al. 2006).
To minimize clot formation in the device chamber a rotational flow pattern within the blood sac is desirable. Hochareon et al. (2003) performed a high speed video analysis to visualize flow in the 50cc device. They found a strong relationship between the early diastolic filling jet at the inlet port and a rotational flow pattern in the device during late diastole. A strong diastolic filling jet is desirable to maintain washout along the perimeter of the device.

In this study PIV is used to investigate possible locations of thrombus formation or hemolysis within a new design (V2) of the 50cc assist device in vitro. To get optical access to the device an acrylic test model of the implantable device is used. Flow velocities within the device are determined at different planes along the depth of the chamber and at several time instants of the cardiac cycle. The influence of two different types of valves is studied. A Bjork-Shiley monostrut (BSM) tilting disc mechanical heart valve is compared to a bileaflet CarboMedics (CM) valve. To be able to analyze the inflow and outflow characteristics high resolution measurements at different planes in the inlet and outlet ports are performed.
The Left Ventricular Assist Device (LVAD)

Background

The 70cc Arrow LionHeart™ LVAD
Today there is a wide variety of Left Ventricular Assist Devices. Progress in reducing weight, size, energy demands and implantation techniques of these devices makes them more and more suitable for long term use.

The fully implantable 70cc LionHeart LVAD which was developed at Penn State consists of multiple components as shown in Figure 1. The blood pump components including motor, blood sac and inlet and outlet valves are enclosed by a titanium case. The pump is driven by a motor that drives a roller screw attached to a pusher plate. The screw moves the pusher plate to compress the blood sac. The inlet cannula, where the blood enters the device, is attached at the left ventricular apex. The outlet cannula is attached to the ascending aorta.

29mm and 27mm Delrin monostrut valves are used in the inlet and outlet ports respectively. Since the first implant in a human in 1999, the device has showed to be successful as an alternative for cardiac transplant.

The most complete study on flow characteristics in the 70cc assist device was performed by Baldwin (Baldwin 1990; Baldwin et al. 1994). In this study laser Doppler anemometry (LDA) was used to determine the mean velocity field and Reynolds stresses at 195 points in the chamber under physiological conditions. The flow in the main chamber had a characteristic rotational flow pattern through the chamber from the middle to the end of diastole. Other fluid dynamics studies on sac type ventricles reported similar results (Jin and Clark 1993; Jin and Clark 1994). This rotational pattern may contribute to washing of the perimeter of the device.

The 50cc LVAD

The first 50cc LVAD, introduced for patients with an average body weight of 30-60 kg is a scaled down version of the 70cc device. Studies performed by Hochareon et al using high speed video analysis for quantitative flow visualization in the 50cc device showed a strong relationship between the late diastolic rotational pattern in the chamber and the early diastolic inflow jet from the mitral valve (Hochareon et al. 2006). These findings are consistent with the results of studies performed by Baldwin et al. on the 70cc device (Baldwin et al. 1989).

Hochareon et al. also performed PIV studies on the 50cc device (Hochareon et al. 2004 (a), (b), (c)) and developed a method for estimating the wall shear rate from PIV results. The peak velocities found by Hochareon et al. were of the same order as those found by Baldwin et al (1994). The wall shear rates however, were found to be lower than those observed by Baldwin et al. in a 100cc device (Baldwin et al, 1988).

In vivo animal testing of the same device at Hershey Medical Center showed thrombus deposition at the perimeter and front wall of the device after 30 days (Yamanaka et al.)

Figure 1: The LionHeart 70 cc LVAD with its implantable components
Regions of low wall shear stress and flow stasis found by Hochareon et al. (2004) correlated to the location of thrombus formation.

**New design of 50cc LVAD**

In order to optimize the flow characteristics in the chamber to prevent thrombus deposition, a new design of the 50cc LVAD, the V2 model, was made. In this new design the inlet and outlet ports protrude further from the front wall of the V2 chamber. At the interface with the front wall, the ports are more flared outward toward the radial walls of the chamber. The new design is shown in Figure 2.

![Figure 2: representation of the acrylic model of the V2 LVAD. Left: front view, right: side view.](image)
Methods

Experimental setup

Test Chamber
To be able to study flow characteristics in the 50cc assist device, an acrylic model of the V2 design was developed. The front part of the test model consists of transparent acrylic for optical access and is shaped like the implantable flexible heart sac. The rear part of the model consists of a polyurethane diaphragm, the same material used for the complete implantable heart sac. Side and front views of the device are shown in figure 2. Two different kinds of mechanical heart valves were tested in the inlet and outlet ports that mimic mitral and aortic valves, the Bjork-Shiley monostrut tilting disc valve and the Carbomedics bileaflet valve. Figure 3 shows a picture of both valve types. The valve in the inlet port has a diameter of 23mm, the valve in the outlet has a diameter of 21 mm.

![Figure 3: left: Bjork-Shiley monostrut valve, right: Carbomedics bileaflet valve](image)

The orientation of both valve types in the inlet and outlet ports is shown in Figure 4 and Figure 5.

The BSM mitral valve is positioned at a 30 degree angle. Earlier studies on the effect of the mitral valve orientation performed by Kreider et al. (2005), showed a good rotational flow pattern throughout the device chamber. The Carbomedics valves are both placed at zero degrees. The CM valve has not been used in this model before. This orientation is initially chosen to check if the symmetry of the valves can be seen on the images. In the zero degree orientation the three typical inflow jets are expected to be clearly visible at the inflow site, right below the valves.

![Figure 4: top view of Bjork-Shiley valve orientation when valves are closed](image)
Figure 5: Top view of Carbomedics valve orientation at zero degrees. left: both valves closed, right: both valves open.
Mock circulatory loop

To obtain physiologic conditions, the model is installed in a mock circulatory loop which simulates the systemic circulation (Rosenberg (1981)). The circulatory loop contains two compliance chambers which mimic the atrial and aortic compliance. The compliance chambers are connected to the inlet and outlet ports of the 50cc model. The systemic resistance is controlled by compressing a tube between two metal plates. A reservoir between the systemic resistance and the atrial compliance controls the preload to the chamber. All parts are connected with flexible tubes. A schematic representation of the setup including the PIV system can be seen in Figure 6.

The diaphragm is compressed by a Teflon pusher plate driven by a Superpump (Vivitro Systems Inc Victoria BC, Canada) which consists of a piston-in-cylinder pump head driven by an electric motor. A Linear Variable Displacement Transducer (LVDT) is connected to the shaft of the pump to determine and adjust the stroke length of the pusher plate. The waveform is formed by a Waveform Generator (Vivitro Systems Inc Victoria BC, Canada) connected to the power amplifier of the pump. The waveform generator is programmed at a sinusoidal curve with a systolic duration of 37% and a beat rate of 86 bpm. The stroke length of the pusher plate is 15mm. Flow rate and pressure were measured at the inlet and outlet ports using ultrasonic flow probes (Transonic Systems Inc., Ithaca, NY, USA) and pressure transducers (Maxxim Medical, Athens, TX USA), respectively.
The flow rate is approximately 3.5 L/min, the inlet pressure has a range of 30/6 mmHg, the outlet pressure is 120/80 mmHg. The flow, pressure and LVDT data are transferred to a computer through a data acquisition system (Wavebook/512, IOtech Inc. Cleveland OH, USA). An example of the flow and pressure waves is shown in Figure 7.

A sodium iodide solution, developed by Long et al. 2005, which mimics the characteristics of 35% hematocrit blood, is used as blood analog fluid. It consists of 50% sodium iodide, 34.37% water, 15.5% glycerin and 0.03% Xanthan gum. This fluid has a refractive index of 1.49, closely matching the refractive index of the acrylic chamber. The water based property of the fluid makes good particle mixing possible. The disadvantage of this solution is that it colors yellow after a period of time, filtering the fluid with a fine filter of 2 microns usually decolorizes the fluid.
Particle Image Velocimetry (PIV)

Flow characteristics in the chamber are obtained using planar PIV. With this technique instantaneous image capturing of an entire flow field becomes possible. To determine the motion of the fluid, particles are seeded in the fluid. In this case 10µm hollow glass spheres (Potter Industries Inc., Volle y Forge, PA, USA) are used. The diameter of the seeding particles should be small enough to closely follow the flow, but not too small to make sure they scatter enough light. For liquid flows a diameter of 10-20µm is typically used. The principle behind PIV is a thin laser light sheet that illuminates the particles in the fluid. Two consecutive images are acquired of the flowing particles with a digital CCD camera. The displacement field is determined from the motion of the tracer particles between the two images. The images are divided into rectangular sections, called interrogation areas. The displacement is found by cross correlation of corresponding interrogation areas in two subsequent recordings. The velocity field can be obtained by dividing the displacement with the known time separation.

PIV settings
With the use of a dual pulsed Nd: YAG laser (New Wave Research Inc., Fremont, CA, USA) and a cylindrical lens, a 0.5 mm thick light sheet is formed to visualize the fluid motion. Figure 8 shows the laser light sheet orientation. The dual-pulsed laser makes it possible to capture images with a very small separation time. With a 1024x1018 CCD camera (TSI Inc., St. Paul, MN, USA) two consecutive images are captured of the particles in the moving fluid. The camera is mounted on a traverse construction so it can be moved in three directions. The positioning of the laser and camera according to the model is shown in figure 6.

The displacement of the particles in the second image in relation to the position in the first image is a measure for the movement of the fluid. The displacement of the particles is determined using a cross correlation algorithm provided by the Insight 6 software (TSI Inc., St. Paul, MN, USA).

Data are collected at three planes along the depth of the chamber parallel to the pusher plate. The planes are located 3mm, 5mm and 8mm from the front wall of the chamber. Per plane images were captured during the cardiac cycle at 10 time steps from 25ms to 500ms from the beginning of diastole. High resolution measurements in the inlet and
outlet port are taken at the center of the port, 3mm towards the back and 4mm to the front of the model. The ports are divided in a top and bottom plane to obtain a resolution of 1.7 Gpix./m². This is a ten times higher resolution than used for the images of the complete chamber. The location of the measurement planes in the chamber can be seen in figure 2. In the inlet port, per plane, data was taken at 25, 50, 75, 100, 150, 200, 300, 350 and 400ms from the beginning of diastole. In the outlet, per plane, the data was taken at 350, 400, 450, 500, 550, 575, 600, 625 and 650ms from the beginning of diastole. The mirror and the lens are mounted on a small traverse with millimeter scale so they can be moved simultaneously to locate the light sheet at a different plane. Two hundred image pairs were captured per measurement plane per time-step in the cardiac cycle. An external trigger was used on the inflow waveform to correlate the images to the moment in the cardiac cycle.
Results

The results of the experiments performed using the BSM valves and the CM valves show a lot of differences in the flow patterns. Below an overview of the images of the 5mm plane of both valve types is shown. Images of 10 measured time steps from the start to the end of the cardiac cycle are shown. The last timeframe, 600ms, is not displayed because the diaphragm blocked the view in that timeframe.

When using the BSM valves the jet seems to form a stronger rotational motion along the chamber wall than in case the CM valves were used. The fluid seems to reach the outlet ports earlier in the chamber when using BSM valves instead of CM valves. Looking at a time frame in early diastole, e.g. 25ms and a frame halfway through the cycle, 300ms, the movement of the fluid seems further developed along the bottom of the chamber in the results of the BSM valves. Images acquired later in the cycle indicate an overall stronger rotational flow along the perimeter of the chamber when using BSM valves.

An unexpected characteristic is visible in the dataset shown in Appendix A. At the very beginning of diastole, at 25 ms, an inflow is present which is not nearly as strong at 50 ms., this means that the inflow decreases during diastole. In the two other planes the same pattern is appearing. In the results of the CM valves, shown in figure 12, the effect is not as obvious but there still is a small decrease in flow velocity from 25 to 50ms.

In figure 9 and 10, images of the inletports are shown. Figure 9 shows the inflow at 75ms from the beginning of diastole from both valve types and figure 10 the inflow at 200 ms from beginning of diastole. In both figures the images are acquired at the center of the ports (see figure 3). As can be seen in those figures the valves cause a difference in the shape of the inflow jet. The CM mitral valve causes a more spread inflow. With two major jets and one smaller jet in between those two, the inflow is divided symmetrically over the port. The Bjork-Shiley mitral valve causes a more concentrated single inflow jet which develops faster along the right perimeter of the device than the wider jet of the CM valves. Also the velocities of the flow in the inlet in case of the BSM mitral appear higher than the more spread flow caused by the CM valve.
Figure 9: PIV images of the V2 LVAD taken at 5mm from the front of the model at 11 time steps during the complete cardiac cycle. Left: for the CM valves, right: for the BSM valves.
Figure 10: Inletports, left: inletport of data taken with CM valve, right image of inletport with BSM valve at the center plane of the port, 75ms from the beginning of diastole.
Figure 11: Inletports, left: image of inletport of data taken with CM valve, right image of inletport with BSM valve. both taken at the center plane of the port, 200 ms from beginning of diastole
When comparing the flow in the outlet port of both datasets the flow in the results using CM valves seems to reach a higher value. The maximum outflow starts a little bit later as was mentioned before, but when looking at the close up images of the outlet ports also a higher flow velocity can be noticed when comparing figures 11 and 12.

Figure 12: PIV images of the outlet port taken at 3mm in mid-systole. left: results of CM valves, right: results of BSM valves
Figure 13: PIV images of outlet port at the 3mm plane in mid-systole. left: results with CM valves, right: BSM valves.
Discussion

The data taken along the depth of the complete chamber shows differences between the LVAD with BSM and the CM valves in the inflow and in the development of the flow pattern in all three planes. The different valves cause a different shaped inflow jet that influences the flow characteristics at a later point in the cardiac cycle (see figure 9-10). The Bjork-Shiley mitral valve causes a strong inflow jet concentrated at the right side of the inlet port. The jet develops in a rotational movement along the perimeter of the chamber. The development of the flow, visible in figure 9, shows a stronger rotation along the wall in the results of the LVAD with BSM valves than with CM valves. The CM valves cause a more spread inlet flow and the flow develops later along the perimeter, and shows a weaker movement along the wall.

The flow drop that is visible in the early diastole cannot be explained directly. The effect is clearly more present in the results of the BSM valves. The fast rotation of the valve may contribute to this phenomenon and cause a retrograde flow. Since the surface of the BSM valve is bigger than the surface of the CM valve, this effect will be bigger in this case.

There could also be some backward flow because the fluid distal to the valve is rotating. Or, despite the fact that the pusher plate should detach from the diaphragm when moving out of the chamber to ensure passive filling, there is still suction by the movement of the diaphragm causing negative pressure in the chamber.

Furthermore the higher flow velocities that are visible in the results of the CM valves are hard to explain. Because the difference in velocity between the two valve types is quite small, the higher flow rates observed may be not significant within the accuracy of the experiment. Therefore, more experiments with higher accuracy should be performed.

Overall, the flow characteristics seem to be better in the device when BSM valves are used with the mitral valve orientated at an angle of 30 degrees than when CM valves are inserted at zero degrees. The flow shows a stronger rotational pattern during late diastole caused by a stronger and more concentrated inflow jet with the BSM valves. However to actually draw conclusions questionable outcomes need to be reproduced and the dataset has to be expanded with extra experiments. With more experiments a better comparison can be made between these two types of valves.

To get to know more about the influence on the flow characteristics by the CM valves it would be useful to take data with the mitral valve at a different angle. At this point it is not sure what orientation of the CM mitral valve will cause the best inflow. Because of the symmetry of the inflow, to start with the mitral valve orientated at 90 degrees would be recommendable; also an orientation 30 degrees would be an interesting experiment, since for the BSM this orientation appeared to be the best.
- American Heart Association 2006
- Hochareon et al 2006