Published in final edited form as:

J Mech Behav Biomed Mater. 2016 July ; 60: 280–287. doi:10.1016/j.jmbbm.2016.01.016.

Reynolds Shear Stress for Textile Prosthetic Heart Valves in Relation to Fabric Design

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Abstract

The most widely implanted prosthetic heart valves are either mechanical or bioprosthetic. While the former suffers from thrombotic risks, the latter suffers from a lack of durability. Textile valves, alternatively, can be designed with durability and to exhibit hemodynamics similar to the native valve, lowering the risk for thrombosis. Deviations from native valve hemodynamics can result in an increased Reynolds Shear Stress (RSS), which has the potential to instigate hemolysis or shear-induced thrombosis. This study is aimed at characterizing flow in multiple textile valve designs with an aim of developing a low profile valve. Valves were created using a shaping process based on heating a textile membrane and placed within a left heart simulator. Turbulence and bulk hemodynamics were assessed through particle imaging velocimetry (PIV), along with flow and pressure measurements. Overall, RSS was reduced for low profile valves relative to high profile valves, but was otherwise similar among low profile valves. However, leakage was found in 3 of the 4 low profile valve designs driving the fabric design for low profile valves. Through textile design, low profile valves can be created with favorable hemodynamics.

Keywords

Textile valve; Turbulence; Surface roughness

Introduction

Bioprosthetic and mechanical heart valves are the most widely implanted heart valve prostheses to-date, but the former suffers from durability issues due to calcification and

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other factors, while the latter suffers from thromboembolic risk (Bezuidenhout and Zilla, 2014; Dasi et al., 2009; Oxenham et al., 2003; Sacks and Yoganathan, 2007; Zilla et al., 2008). To counter the latter issue, patients receiving mechanical valves require lifelong anticoagulant and antiplatelet therapies to mitigate the risk for thrombosis. These therapies can lead to hemorrhage and are known to cause the most drug-related deaths from adverse clinical events in the United States (Shepherd et al., 2012). Furthermore, mechanical valves are not well-suited for transcatheter implantation, limiting the potential patient population.

A series of studies have demonstrated that textile valves may provide flexible leaflets, allowing hemodynamics that mimic the native valve can be tuned for durability. To address durability, polyester textiles have been most widely investigated (Heim et al., 2008; Heim and Gupta, 2009). It has been especially demonstrated that polyethylene terephthalate (PET) textile material can be durable up to 200 Mio cycles without any sign of rupture if the fabric design is defined in a proper way (Vaesken et al., 2014; Vaesken et al., 2015). Moreover, the outstanding folding properties of fibrous material makes the material particularly resistant to crimping for catheter insertion purpose, even to low diameter (Khoffi et al., 2015). Low diameter insertion devices are particularly adapted for the trans-femoral route in the TAVI procedure. This route is clinically largely privileged because it requires only light anesthesia, but vessels are generally calcified and narrowed, which makes the access more difficult. In terms of interaction with biological tissues, 6 months successful implantations in juvenile sheep models have been reported recently (Vaesken and Heim, 2015).

Although textile valves are promising, the hemodynamics resulting from their design remains undefined. Hemodynamics are important in design because high shear stress, stagnant flow, and turbulence can all contribute to thrombosis, which can lead to heart attack or stroke (Bark Jr et al., 2013; Morshed et al., 2014). Of particular interest here, is whether or not textile fabrication can be controlled to manipulate the generation of turbulence. Owing to spatiotemporal fluctuations in stress, turbulence is a prominent factor that can result in blood damage either through hemolysis or platelet activation (Antiga and Steinman, 2009; Grigioni et al., 1999; Morshed et al., 2014). It plays a separate and enhanced role in inducing platelet activation relative to shear stress, alone (Kameneva et al., 2004). Here, we are interested in investigating different valve designs based on height to diameter ratios and weave patterns. We aim to reduce turbulence, while providing satisfactory hemodynamic performance.

Considering valve design, it is of increasing interest to design low profile valves to avoid impacting flow in the aortic arch and coronaries after implantation. Here, we are interested in investigating how a change in profile can impact turbulence. If the valve profile becomes too low, then there is increased chance for regurgitation as the leaflets may not be characterized with enough material surface area to ensure sealing when the valve is in a closed position. Conversely, while a high profile provides additional contact surface area, it tends to be more obstructive, induces larger pressure drop across the device. Moreover, higher profiles may jeopardize the material durability as more folds will be generated in the leaflet over the cardiac cycle.

To optimize the hemodynamics of a textile valve in this study, we aim to explore 1) the effect of different aspect ratios between HV's inner diameter and its height 2) the influence of textile fabrication techniques on hemodynamic performance.

Methods

Valve Fabrication

The methods used to fabricate the textile valves are previously described in Heim et al. (Heim et al., 2011). Briefly, a fabric tube was placed on a support structure that was used to form the shape of the valve such that it is in a semi-closed position. For formation, fabric was heated at a temperature of 100 °C for 30 minutes. Valves were made with a low profile and a high profile corresponding to a height to diameter ratio (h/D) of 0.5 and 0.7 respectively, where h is the height, and D is the diameter of 23 mm.

For studying characteristics of a low profile valve, we considered 4 different weave conditions. These conditions are presented in Table 1. Durability, stiffness, and surface roughness all vary with the different weave and yarn conditions. Bending stiffness was measured with a cantilever bending tester (ASTM D1388-07A). Regarding the surface roughness, it was measured with a Kawabata's Evaluation System instrument (KES-FB4, KATO TECH Co., LTD., Kyoto, Japan), which is shown in Fig. 1. The effect of the stiffness and surface roughness on flow is of interest here to determine the construction that provides the best hemodynamic performance.

Constant Flow Experimental Conditions

Constant flow was applied across valves of various constructions to investigate the role of surface roughness and design on turbulence. A flow loop was designed with a submersible pump (G535AG20 Beckett Corporation, Irving, TX) that provides a flow rate of 20 and 35 L/min. Flow was monitored upstream of a mounting chamber using an ultrasonic flow probe (Transonic Inc., Ithaca, NY). Valves were inserted into the mounting chamber in line with PVC piping that returned flow to a reservoir containing the submersible pump. The mounting chamber was a transparent, rigid, acrylic cylindrical tube with an axisymmetric sinus. The tube was 280 mm long with an inner diameter of 25.4 mm. A straight flow development section of length $20D$ (D corresponds to diameter of the tube) and honeycomb flow conditioner were placed immediately upstream of the development section to align flow. A blood analog of a water/glycerin mixture was used for experiments with a viscosity of 3.5 cP and a density of 1080 kg/m³.

Pulsatile Flow Experimental Conditions

Physiological pulsatile flow was established using ISO 5840/2005 in a left heart simulator previously described in Ref (Forleo and Dasi, 2013) and is shown in Fig. 2. The loop was driven by a bladder pump, controlled by air pressure and solenoid valves through a custom LabView (National Instruments Corporation, Austin, TX) program. A mechanical heart valve was placed upstream of the pump to mimic the action of a mitral valve, while a mounting chamber was placed downstream. The inline flow meter used for constant flow was placed between the bladder and mounting chamber. Pressure transducers (ValiDyne

Engineering, Northridge, CA) were also placed upstream (ventricular side) and downstream (aortic side) of the fabric valves. Downstream of the chamber exists a compliance chamber and a resistance valve. Air pressure to the bladder pump, water level in the compliance chamber, and the downstream resistance were adjusted to obtain systolic/diastolic pressure ratio of 120/80 mmHg with a mean aortic pressure of 100 mmHg, a cardiac output of 5 L/min flow rate, and a pulsatile rate of 60 beats per minute with a systolic duration of 35%. These values were maintained within 10% throughout the experiment, except for the non-woven valve that exhibited substantial regurgitation, as further discussed in the results. The same blood analog was used from constant flow experiments.

Particle Imaging Velocimetry

The flow fields of valves in Table 1 were determined through time-resolved particle imaging velocimetry (PIV). Water/glycerin mixtures were seeded with 1–20 micron sized polyamide tracer particles (Dantec Dynamics, Denmark). These particles were excited by a laser sheet that was applied across midplane of the transparent valve mounting chamber using a Photonics Industries DM40-527 diode-pump Q-switched laser (Photonics, Bohemia, NY). Using a spherical lens ($f=1\text{m}$), the laser sheet was focused down to a thickness of ~ 200 microns.

A Photron Fastcam SA3 high-speed video camera (Photron, San Diego, CA) synchronized to the laser system via a high-speed controller (LaVision, Ypsilanti, MI) was used to capture positions of illuminated particles. The camera was set into a double-frame mode with each frame separated by $250\text{ }\mu\text{s}$. For constant flow images were taken at 1000 Hz, while for pulsatile flow, a set of images were taken once every cardiac cycle for 250 cycles. For the latter, the images were triggered using a phase-locked technique for accelerating flow, peak flow, and decelerating flow, with points represented in Fig. 2B. Refraction was corrected using a calibration in DaVis PIV software (DaVis 7.2, LaVision Germany).

PIV was post-processed using DaVis software. Cross-correlation vectors were obtained using 2 initial passes of a 32×32 pixel interrogation window with 50% overlap, followed by a final pass of an 12×12 interrogation window with 50% overlap.

Results

Fabric Properties

Four different fabric designs are under study, with each design described in Table 1. Structure of each design is purposely varied to evaluate the hemodynamic response of valves to bending stiffness, surface roughness, and thickness. The thinnest valve of 60 microns is made of a monofilament construction and exhibits the maximum bending stiffness relative to the other fabric designs. Monofilament fabric also exhibits the minimal surface roughness. Alternatively, multifilament fabrics exhibit a slightly lower bending stiffness, which reduces after calendering the fabric. The surface roughness also decreases for the calendered design. Alternatively, a non-woven design is the thickest and exhibits the largest surface roughness with a moderate bending stiffness.

Turbulence During Systole – Constant Flow

Reynolds Shear Stress (RSS) contours for flow across a high profile and a low profile multifilament valve are shown in Fig. 3A. RSS scales with the average velocity, as demonstrated by similar normalized RSS scales between studies at 20 and 35 L/min. The largest RSS value for the high profile valve occurs near the top of the valve in Fig. 3A. This region, which corresponds to the midpoint between two stent struts, parachutes out when the valve is open, as can be seen by bulge in the profile of the valve and in supplementary video 1. For quantification, RSS along the diameter of the valve is plotted in Fig 3B at the valve edge and at 1 diameter from the valve edge. At the valve edge there is little quantitative difference in RSS values between the two valve designs. However, RSS is quantitatively highest at the top of both valves, corresponding to a location between stent struts. Downstream RSS increases by approximately a factor of 2 for the highest profile valve. This region (1 diameter from the valve edge) reflects the large RSS value seen at the top of the high profile valve in Fig. 3A.

Since the low profile valve exhibits lower RSS and since this valve design is more desirable compared to a large profile valve, we evaluate how material roughness can impact turbulence on the low profile configuration. Contour plots of RSS for 4 textile construction techniques are shown in Fig. 4A. All fabrication techniques exhibit similar qualitative RSS at both 20 L/min and 35 L/min, with potentially lower RSS for the monofilament valve at 35 L/min. Quantitative RSS values were similar for all fabric designs, as shown in Fig. 4B.

Hemodynamic Valve Performance – Pulsatile Flow

Valve performance is also evaluated under pulsatile conditions. Flow rates for each valve are shown in Fig. 5A. Flow for the high profile multifilament and low profile monofilament valves follow similar trends akin to the idealized flow curve shown in Fig. 1B. Both exhibit a closure volume corresponding to a time when there is reverse flow (negative value) followed by relatively no flow after the valve becomes fully closed. However, all other valve designs exhibit larger peak flow rates and a sustained leakage (negative value) after the valve is closed. These valves also have an ill-defined closing volume, due to the sustained leakage. The larger peak flow rate values are required to maintain a cardiac output of 5 L/min amidst the leakage.

Reverse flow during valve closure is quantified through the regurgitant fraction in Fig. 5b, calculated as the percentage of the time averaged value of reverse flow over the time averaged value of forward flow. The multifilament high profile valve maintains the minimal regurgitant fraction of ~18%, followed by the monofilament low profile valve, with a value of ~29%. All other regurgitant fractions exceed 40%, with the largest occurring for the non-woven low profile valve, which exhibits equal amounts of reverse and forward flow. To determine the reason for the leakage, valves are viewed from the streamwise direction for a qualitative comparison in Fig. 5C. With this view, it can be seen that the leaflet edge folded over for all low profile valves, other than the monofilament valve, which otherwise exhibits the largest bending stiffness. The non-woven valve appears to have the largest orifice during diastole. Edge folding can be visualized in supplemental videos 2–5.

Discussion

The results of this work brings out that both the profile height, as well as the construction type has an influence on the hemodynamic performance in the form of RSS and regurgitant fraction. Under constant flow conditions, we demonstrate that a low-profile textile valve exhibits a lower RSS during peak flow. As an added benefit, a low profile valve can reduce the potential amount of flow stagnation, which can otherwise support coagulation, and can minimize the risk for coronary obstruction (Fallon et al., 2008; Gurvitch et al., 2011; Webb, 2009; Yoganathan and Travis, 2000). To develop a low profile textile valve, we have found that it is necessary to control the construction to minimize the potential for folds in the fabric that can lead to leakage.

Reducing the valve profile height has many potential advantages and here we show that a reduction in height may reduce RSS. There are various features of the high profile valve that could influence turbulence. One feature is that the valve is longer, which provides an additional length for boundary layer development (Coles, 1956). In the current study we also found that the high profile valve exhibits parachuting during forward flow meaning that a bulge occurred in the valve between stent posts. This results in flow that is diverted outward and then inward toward the valve center. The directional change may influence the dynamics of the wake region downstream of the valve edge (Chen and Patel, 1988; Coles, 1956; Hoffmann et al., 1985; Rhie and Chow, 1983). Lastly, excess material can result in a free edge that may not have as much constraint as a low profile valve. Therefore, the fluid-structure interaction can result in instability of the valve edge, which can influence RSS (Evangelinos and Karniadakis, 1999).

Although the valve profile impacts RSS, the textile construction exhibited globally minimal influence on turbulence. It could, however, be observed that the monofilament was characterized with a slightly lower overall RSS profile compared to the other constructions in Fig. 4A at 35 L/min. Assuming that turbulence is highly influenced by the surface roughness, one could explain the observed result by the lower roughness of the monofilament (see table 1: $SMD=0.158\mu m$) (Achenbach, 1971; Krogstad and Antonia, 1999). This explanation remains preliminary as no significant differences could be observed among the other constructions, despite roughness variability. Additional testing must be performed on a larger number of valve prototypes to confirm these results.

One general observation, which could be made, is that the textile construction does impact leakage during diastole due to an orifice caused from folding of the textile into the low profile valves. This occurred for all low profile valves other than the monofilament construction, which has very little leakage, as seen in Fig. 5. This fabric construction is characterized by the largest bending stiffness value (table 1: 0.0165 mg.mm). The increased bending stiffness may provide the monofilament construction with the necessary support for the leaflet free edge when the valve is in the closed position. Alternatively, for the multifilament construction, a high profile valve fully closes, with minimal regurgitation, despite the large amount of regurgitation seen for the low profile valve of the same construction. In the high profile valve, there is an increased area of coaptation, which allows the free edge of a single leaflet to be structurally supported by surrounding leaflets.

Alternatively, there is minimal coaptation for the low profile valve, as seen in the supplementary videos. Therefore, there may be a fine balance between leaflet stiffness and the potential leaflet height involved in valve design that warrants further investigation.

With regard to the RSS, values for the low profile textile valves in the current study reach peak RSS values of 75–250 dynes/cm² 1 diameter downstream of the valve edge, which is similar to RSS values of bioprosthetic valves (100–250 dynes/cm²) (Yoganathan et al., 1986). As bioprosthetic RSS values are known to be relatively benign to platelets and erythrocytes, one can conclude that a textile material should not be harmful for platelets and erythrocytes from a hemodynamic perspective according to our observations. Certainly, hemolysis occurs at a much larger shear stress (Grigioni et al., 1999; Sallam and Hwang, 1983). Furthermore, for the exposure time of platelets to the RSS values, platelet activation from flow remains unlikely (Bark Jr and Ku, 2013; Bark Jr et al., 2012; Hellums, 1994).

The main limit of this early work is that the tests were performed on only one specimen of each sample. Observations cannot be interpreted at statistical level, even if trends are provided. However, the PIV analysis for the in vitro setup is consistent for a given specimen due to the highly controlled conditions. Future work must be done on a larger number of specimens in order to confirm these preliminary observations. Furthermore, the spatial resolution of PIV in the current study is limited. To capture features of the boundary layer where surface roughness has the largest impact, we would need much higher spatial resolution that exceeds the limits of our equipment. Although, we cannot resolve the features near the boundary, we can estimate RSS in the bulk fluid, which is understood to have the most impact on the blood response.

Conclusions

A low profile valve can reduce the Reynolds Shear Stress and can be designed so that it minimizes leakage during diastole. This work demonstrates that textiles can be engineered to provide favorable hemodynamic conditions for use as a prosthetic heart valve.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The authors gratefully acknowledge funding from National Institutes of Health (NIH) under Award Number R01HL119824. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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Figure 1.
Device that was used to measure surface roughness.

Figure 2.

A) Diagram of the left heart simulator. Major components of the flow loop are labeled. B) A typical flow curve produced by a bioprosthetic heart valve in the left heart simulator. The peak flow rate and closing volume are labeled. C) Raw PIV image with measurement points for RSS plots denoted with a red dash. Points are taken directly at the valve edge where a line freely passes through the chamber without crossing a leaflet. The second line is 1 diameter downstream of the valve edge.

Figure 3.

A) RSS contours for high (top) and low (bottom) profile multifilament textile valves. The RSS is normalized by the square of the average velocity B) RSS profiles at the leaflet edge and at 1 diameter in the streamwise direction from the leaflets edge. Plots are shown for the high profile and low profile multifilament valve at a steady flow rate of 20 L/min and 35 L/min.

Figure 4.

A) RSS contours for different textile valve constructions involving a low profile. B) RSS plots are shown at the leaflet edge and at 1 diameter in the streamwise direction from the leaflet edge for each low profile valve construction.

Figure 5.

A) Flow rates for various valves designs labeled in the legend for pulsatile experiments. B) Regurgitant fraction in units of the % of time averaged reverse flow over forward flow for each valve design. Standard error bars are shown for 3 runs of a single valve sample. C) End-on view of valves after closure.

Table 1

Characteristics of the valve materials used in the study

Sample	A	B	C	D
Yarn structure	Multifilament calendered	Multifilament non calendered	monofilament	Non woven
Thickness (μm)	73	134	60	152
Surface density (g/m^2)	52.2	73.7	45.2	73.9
Yarn density, warp (yarns/cm)	56	75	194	NA
Yarn density weft (yarns/cm)	42	50	194	NA
Yarn count (tex)	50	50	10	NA
Bending stiffness (mg.mm)	0.0077	0.0119	0.0165	0.0097
Surface roughness (SMD μm)	0.482	1.07	0.158	1.327