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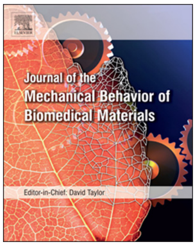

Research paper

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, 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 involving different fabric designs. 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.

1. 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 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

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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

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, similar to bioproshetic valves, but can be tuned for durability, unlike current bioprosthetic valves. 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, 2015). Moreover, the outstanding folding properties of fibrous material makes the material particularly resistant to crimping for catheter insertion purposes, even to small diameters (Khoffi et al., 2015). Small 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 remain 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 spatio-temporal 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.

2. Methods

2.1. *Valve fabrication*

The methods used to fabricate the textile valves are previously described in 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 min. 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.

2.2. *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