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Technical Note

Fiber heart valve prosthesis: Influence of the fabric construction parameters on the valve fatigue performances

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ABSTRACT

Transcatheter aortic valve replacement (TAVR) has become today a largely considered alternative technique to surgical valve replacement in patients who are not operable or patients with high risk for open chest surgery. However, the biological valve tissue used in the devices implanted clinically appears to be fragile material when folded for low diameter catheter insertion purpose and released in calcified environment with irregular geometry. Textile polyester material is characterized by outstanding folding and strength properties combined with proven biocompatibility. It could thereof be considered to replace biological valve leaflets in the TAVR procedure. The textile construction parameters must however be tuned to obtain a material compatible with the valve requested durability. In that context, one issue to be addressed is the friction effect that occurs between filaments and between yarns within a fabric under flexure loading. This phenomenon could be critical for the resistance of the material on the long term. The purpose of the present work is to assess the fatigue performances of textile valve prototypes made from different fabric constructions (monofilament, multifilament, calendered mutifilament) under accelerated cyclic loading. The goal is to identify, which construction is the best suited to long term fatigue stress. Results show that calendered multifilament and monofilament fabric constructions undergo strong ruptures already from 40 Mio cycles, while non calendered multifilament appears more durable. The rupture patterns observed point out that durability is directly related to the flexure stiffness level of the fibrous elements in the construction.

1. Introduction

Non invasive valvular surgery, also called percutaneous surgery or TAVR (trans-catheter aortic valve replacement), has become today a technology of choice to relieve patients from valvular diseases like stenosis. Far less traumatic for the patient, this technique is also less expensive and less time consuming, which makes it very attractive for the medical world (Kidane et al., 2009; Webb, 2008). Its use is today limited to either non operable patients or patients with high risk for open chest surgery. But the

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part of trans-catheter procedures is expected to increase by 20% a year up to 2017 alone in Europe according to market forecast studies (Millenium Research Group, 2011). Thus, non-invasive procedures can be expected to concern non-critical patients in a more or less close future. However, in that context one of the main limits of existing devices is related to the fragility of the biological tissue, which is used as valve material (chemically treated bovine or porcine tissue). Actually, the crimping process at low diameter for catheter insertion purpose and the distortion of the stent once the device is implanted, induce specific stress in the leaflets (Van Nooten et al., 1999; Kiefer et al., 2011; Zegdi et al., 2008). Compression at low diameter is particularly interesting for the trans-femoral approach, which requires bringing the valve through the tortuous and already diseased vessel network. The advantage of that approach is the need for only light anesthesia for the patient compared to the trans-apical approach.

Due to lack of long term experience with TAVR, there's today only little result available in literature that demonstrates the limited durability of biological tissue implanted with the non-invasive procedure. However, the additional stress induced by the procedure may not be compatible with the final durability of biological tissue and could lead to early failure for the valve. Thus it is worth investigating the potential of synthetic materials as valve replacement materials, and textile could be an appropriate candidate. Several studies have been performed over the last years to assess the potential of textile as valve leaflet material. Heim et al. showed that woven polyester textile, used in grafting at large scale, could be suited to replace faulty human valve in terms of dynamic performances (Heim et al., 2008; Heim and Gupta, 2009). Moreover, the authors reported a first successful in vivo short term implantation (8 weeks) of a textile valve in a sheep model (Heim et al., 2013). Longer in vivo implantations are currently in progress. However, there's no result published in literature today about the long term durability of fabric valves under heavy cyclic loading. Basically, textile is a material, which is highly tunable. One can change the fabric type (non-woven, woven), the yarn type (mono or multifilament), the fabric construction (plain weave, satin, twill), the fabric processing (calendering or not). It is thereof important to investigate the potential of these changes on the long term durability before a fabric material can be considered as valve leaflet material. Actually, the critical point with textile is that, besides the outstanding flexibility of the material due the assembling of individual filaments, these filaments slide over each other when the material is flexed. In the valve application the flexing process occurs at heart rate each time the valve opens and closes. The repeated flexing induces repeated sliding and friction between filaments, which may lead to filament rupture and valve premature degradation. In order to assess how the filaments arrangement in one construction does influence that process, various fabric valve prototypes were tested under fatigue loading conditions in this early work. The samples were characterized for mechanical and structural properties before and after cycling. The paper reports about the degradations undergone by the different tested samples and presents the interpretation that can be made out of the observations.

2. Materials and methods

2.1. *Prototype manufacturing and testing*

The valve prototypes were manufactured according to a process already described in a previous work (Heim et al., 2011). They were obtained from shaping a tubular textile membrane. The characteristics of the different fabrics used are presented in Table 1. The fabric constructions were all plain weave structures made from either multifilament or monofilament yarn, varying thereof the interaction pattern between filaments. Plain weave presents the advantage of being the most stable textile construction, which is expected to address the valve long term durability issue in the best way. Moreover, the effect of calendering was also considered. In the calendering process the fabric is passed under heated rollers to reduce porosity and thickness, while it becomes smoother. The topography and smoothness of the fabric surface are thereof modified, which is important to control the interaction with the biological tissues in the in vivo environment. The effect of calendering on the interactions between filaments and on the textile durability is thus a critical issue as well. All the fabrics used didn't undergo any specific surface treatment.

For comparison purpose, the fabrics used in this work were chosen in a way to have a similar cover factor value (C_F). C_F gives an indication on the permeability to light for a given fabric and is defined here as the proportion of a projected view of a given area of fabric, which is covered by threads, and will have a scale from 0 to 1.

For each fabric, the theoretical bending stiffness B_{th} was calculated as the ratio of the stiffness to the sample width, e, and given by Eq. (1) (in the units of N mm)

$$B_{th} = EI/e \qquad (1)$$

Table 1 – Values of the construction factors for the fabrics of the study.

Sample	A	B	C
Yarn structure	Multifilament (non calendered)	Multifilament (calendered)	Monofilament
Thickness (μm)	250	100	150
Cover factor	0.90	1	0.92
Surface density (g/m^2)	78	78	45
Yarn density, warp (yarns/cm)	84	84	194
Yarn density, weft (yarns/cm)	38	38	194
Filament diameter (μm)	10	10	37
Yarn count (tex)	5.45	5.45	1.05
B_{th} (N mm)	0.023	0.023	0.044