Textile Heart Valve Prosthesis: Long Term Fatigue Performances

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Statement of Purpose: Trans-catheter aortic valve implantation has become an alternative technique to surgical valve replacement in patients with high risk for open chest surgery. Today, the valves in clinical use are made up with biological tissue. This tissue is however fragile material when in contact with metallic stent struts and becomes degraded during the crimping process [1]. We showed in previous works that textile polyester, which is less fragile, could be an alternative solution to replace valve leaflets in terms of hydrodynamic performances. The unique folding properties of the fibrous material could allow the use of 12 Fr catheter size for implantation. However, no information is available yet in literature about long term fatigue behavior of textile material under accelerated loading conditions. The purpose of the present work is to give long term results obtained in vitro with a textile valve solicited under 14 Hz cyclic loading for over 200 Mio cycles.

Methods:
The tested valves were obtained from shaped tubular textile polyester (PET) membranes, and were assembled with a Delrin holding ring for an adapted positioning in a commercial fatigue testing apparatus. 6 textile valve prototypes were tested simultaneously at a 14 Hz cycling frequency. Tests were carried out up to 200 Mio cycles. However, in order to follow the modifications undergone by the material along the cyclic loading, 3 of the tested valves were taken out of the bench already after 40Mio cycles.
The material was first observed at microscopic level (SEM) and then characterized from a mechanical and physical point of view. Tensile tests were performed on fabric strips and yarns to identify changes in mechanical properties, while DSC analyses were conducted in order to assess the transformations undergone by the polymer.

Results.
Figure 1 shows the changes undergone by the fabric construction between 0 and 200 Mio cycles.

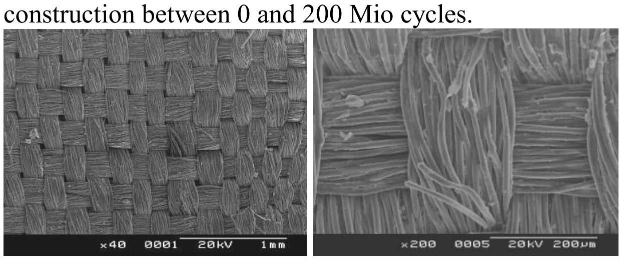

Figure 1. Fabric at 200 Mio cycles

One can observe that the fabric tends to relax over the cycling process. The yarns involved tend to become less crimped, which leads to the apparition of pores on the surface. Moreover, some rare filament ruptures can be detected.

The relaxation process observed at microscopic level has some direct consequences on the mechanical behavior of the fabric (Fig. 2). With less friction between yarns and filaments after cycling, the fabric tensile strength becomes lower. Moreover, with less crimp in the yarns, the deformation rate of the construction is reduced as well.

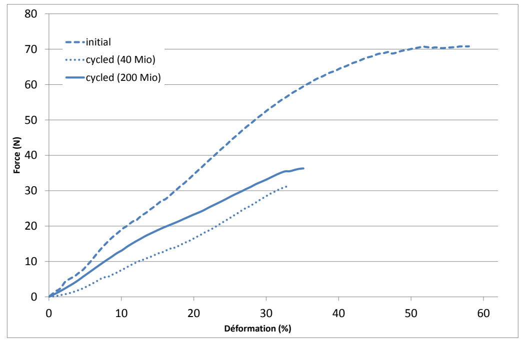

Figure 2. Tensile strength on strips

At yarn level, a drop in tensile strength occurs rapidly (30% after 40 Mio cycles), and then slows down to reach around 50% after 200 Mio cycles. The phenomenon is essentially due to the physical modifications undergone by the polymer (Fig.3).

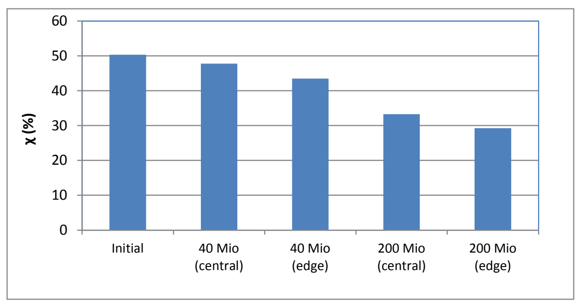

Figure 3. Crystallinity rate evolution

The material undergoes 40 % reduction in crystallinity rate after 200 Mio cycles. However, the change is not uniform on the whole surface of the valve. The edge, which bears the highest flexing load, is the most degraded zone.

Conclusions:
The long term fatigue results obtained in this study with PET textile valves show that the fabric undergoes degradation at different levels over time (relaxation and physical transformation). However, the valves were still functional after 200 Mio cycles, which demonstrates the mechanical potential of textile as valve material.

References:
[1] Kiefer, P et al. “Crimping may affect the durability of transcatheter valves: an experimental analysis”, *Ann Thorac Surg*,92(1),2011. 155-60.