Textile Heart Valve Prosthesis: Early *In Vitro* Fatigue Performances

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Statement of Purpose:
Transcatheter aortic valve implantation has become an alternative technique to surgical valve replacement in patients with high risk for open chest surgery [1]. Today, the valves used in non invasive valve surgery are made up with biological tissue. The tissue associated with metallic stents is however fragile material and may be degraded during the crimping process. Textile polyester is less fragile material and could be an alternative solution to replace valve leaflets [2]. However, no information is available yet about the long term fatigue behavior of the textile material. The purpose of the present work is to give early results obtained in vitro with a textile valve solicited under 13 Hz cyclic loading.

Methods:
Valve manufacturing
The valve was obtained from a semi-lunar shaped tubular textile polyester membrane, which was assembled with a Delrin holding ring for an adapted positioning in the fatigue testing apparatus. The assembling was realized using a suture yarn following the scalloped shape and an additional one at the basis of the cusp to secure the fixation (Fig. 1).
Valve testing and evaluation
6 textile valve prototypes were tested simultaneously on a Dynatek Dalta M6 apparatus system at a 13 Hz cycling frequency (Fig. 2).

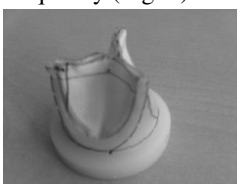

Fig.1 Prototype

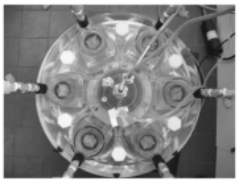

Fig. 2 Valve testing

After 40Mio cycles 3 of the tested valves were taken out of the bench. Hydrodynamic performances (regurgitation) were measured on the valve in a pulse duplicator at 70 bpm before and after cycling in order to assess the effect of cycling on the valve performances evolution. The material was then characterized from a physical (DSC) and a mechanical (extension test) point of view to assess the transformations undergone by the textile polymer.

Results:
Dynamic regurgitation
The cycling process induces a decrease in the dynamic regurgitation from 20% (due to fabric porosity) to 13%. This result is related to the decrease in the bending rigidity of the fabric construction. Basically, the rigidity due to inter-filament friction is lower after than before cycling as the fabric undergoes a yarn rearrangement process. The leaflet being less rigid, they close more rapidly.

Polyester material characterization
The DSC results presented in Fig. 3 show that heat flow decreases at melt temperature after 40 Mio cycles, whatever the valve cusp zone (edge, central, suture line).

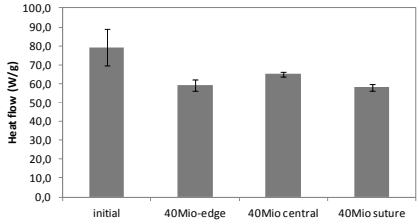

Fig. 3

This indicates a modification in the polymer crystallinity. The result is confirmed with the mechanical testing results performed on a fabric yarn (Fig. 4). It appears that the yield strength and modulus are reduced by nearly 25% with cycling. Ruptures occur between the molecular chains.

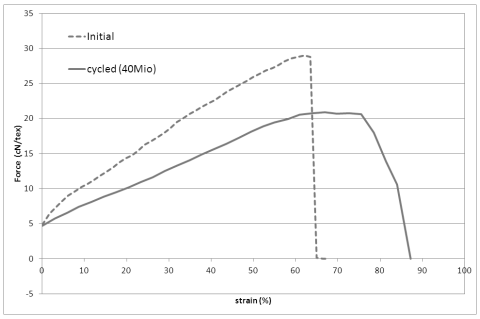

Fig. 4

Conclusion:
The early fatigue results obtained in this study show that degradation can be observed in the textile at 40Mio cycles. However, signs of rupture could be observed neither on the leaflet surface nor in the contact zones where the leaflets come together. The remaining valves have reached 100 Mio cycles. The global behavior of the fabric is encouraging.

References:
[1] Davidson, MJ et al. "Percutaneous therapies for valvular heart disease," *Cardiovascular pathology*, 15, 2006. 123-129.
[2] Heim, F, Durand, B, Chakfe, N, "Textile Heart Valve Prosthesis: Manufacturing Process and First in Vitro Performances," *Textile Res J*, 78, 2008. 1124-1131.