Transcatheter Fiber Heart Valve: Effect of Crimping on Material Performances

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Statement of Purpose: Trans-catheter aortic valve implantation (TAVI) 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. The processing and handling of this material is time consuming and make TAVI devices still expensive. Moreover, the crimping process necessary for catheter insertion purpose tends to degrade the material [1]. Synthetic materials are conversely much easier to handle and would be an interesting option to extend the procedure to less critical patients at lower costs in the future. Previous works showed that fibrous material, characterized by unique folding properties, could be considered as an alternative solution to replace valve leaflets. However, no information is available yet in literature about the effects of crimping on fibrous material. The purpose of the present work was to study the degradation of textile materials when these are compressed to low diameter under various conditions. Moreover results were compared with those obtained with biological tissues.

Methods:

Valve prototypes were obtained from shape setting tubular textile PET membranes. Fabrics with 2 different yarns were considered: (1) 35µm monofilament yarn, (2) 50 dtex multifilament yarn. The prototypes were crimped within a cylindrical braided stent using a commercial radial crimper down to 1mm diameter. 3 parameters were varied in the study: (1) the crimping duration (10 and 60 min), (2) the crimping diameter (3.5 and 1 mm), (3) the stent wire diameter (0.21 and 0.31 mm).

After crimping the material was first studied at microscopic level (SEM) in order to observe the sharpness of the folds in the fabric. Roughness tests were carried out on samples before and after crimping. Moreover, 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:

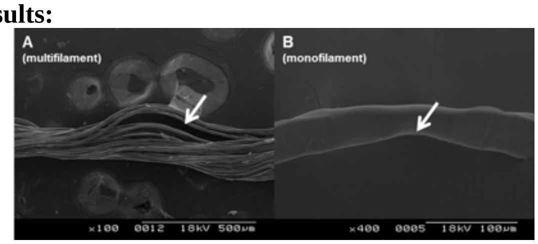

Figure 1. Crimping effect at yarn level

SEM images taken at yarn level show that crimping induces irreversible changes in the monofilament yarn cross section, while multifilament yarns become looser at yarn curvature level (Fig.1). Multifilament material tends to rearrange towards minimum deformation and reduced degradation. The modifications undergone at yarn level modify the topography of the fabric surface. The results obtained from the roughness measurements show that the mean surface roughness increases with the crimping procedure regardless of the fabric type (Fig. 2). Nevertheless, crimping increases the roughness to a larger extent for the multifilament fabric (95% vs 57% with $p<0.001$).

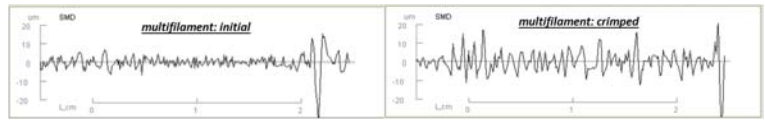

Figure 2. Typical roughness profiles

With regard to the breaking strength, the crimping duration appears to be the parameter, which induces most degradation in the textile material (Fig.3), whatever the yarn used. Crimping diameter is influent as well but to a much lower extent.

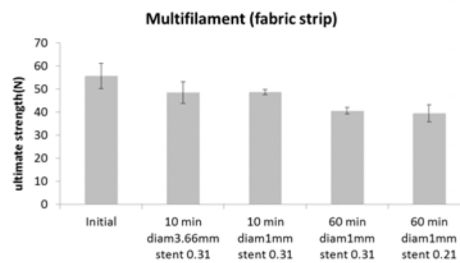

Figure 3. Loss in strength (textile)

However, the loss in strength is far less important (20% vs 50%) with textile material than with biological tissue (Fig.4).

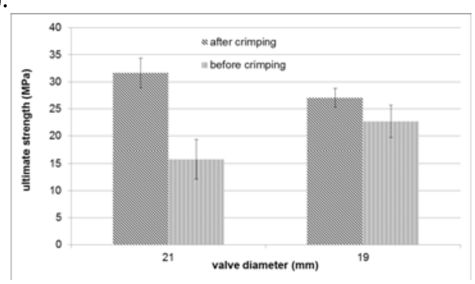

Figure 4. Loss in strength (biological tissue)

Conclusions:

Crimping fabric material to low diameter does slightly modify the surface topography and the mechanical properties. However textile resists crimping much better than biological tissue and could be an interesting candidate for manufacturing valve leaflets.

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.