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Technical Note

Mechanical degradation of biological heart valve tissue induced by low diameter crimping: An early assessment

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ABSTRACT

Transcatheter aortic valve implantation (TAVI) has become today an increasingly attractive procedure to relieve patients from aortic valve disease. However, the procedure requires crimping biological tissue within a metallic stent for low diameter catheter insertion purpose. This step induces specific stress in the leaflets especially when the crimping diameter is small. One concern about crimping is the potential degradations undergone by the biological tissue, which may limit the durability of the valve once implanted. The purpose of the present work is to study the effect of low diameter crimping on the mechanical performances of pericardium valve prototypes. The prototypes were compressed to a diameter of 1 mm within braided stents for 20 min. SEM observations performed on crimped material show that crimped leaflets undergo degradations characterized by apparent surface defects. Moreover mechanical extension tests were performed on pericardium strips before and after crimping. The strips (15 mm long, 5 mm wide) were taken from both crimped and native leaflets considering 2 different valve diameters, 19 and 21 mm. In order to prevent the premature drying of the pericardium tissue during the procedure, the biological tissue was kept in contact with a formaldehyde solution. Results show that the ultimate strength value decreases nearly by up to 50%. The modifications observed in the material may jeopardize the long term durability of the device. However, further tests are necessary with a larger amount of samples to confirm these early results.

1. Introduction

Over the last years, transcatheter (non invasive) aortic valve implantation (TAVI) has become an alternative technique to surgical valve replacement for over 100,000 patients around the world (Davidson et al., 2006; Cribier et al., 2002). The valve material used clinically in the TAVI procedure is biological tissue. This material proved to be very durable when mounted

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on a rigid circular ring and implanted through open chest surgery. But once associated with a metallic stent and crimped at low diameter for catheter insertion purpose, the material may become degraded. Kiefer et al. (2011) showed that significant tissue damage is observed at the surface layers of crimped leaflets for longer crimping durations. These observations were confirmed by Alavi et al. (2014). In the field of tissue engineered valves, when analyzing the effects of crimping on cell-seeded synthetic patches for the development of transcatheter valves, Scheuer et al. (2012) showed that the patches crimped for 30 min to a diameter of 10 mm present a decreased thickness of fibroblasts layer. Zegdi et al. (2008) proved that the crimping of biological valves may generate some no-visible defects within the leaflet thickness, which may limit the durability of the material on the long term. Other authors mention that cell and cell-matrix viability would decrease with the amount of crimping pressure. Thus, the use of smaller insertion devices would require working with thinner synthetic material (Metzner et al., 2010). In a fast growing market, less critical patients could be treated with TAVI in a near future. However, there is no data available about the effective durability of crimped pericardium. Durability being directly related to the mechanical properties of the tissue, it is of interest to investigate the mechanical damage undergone by the tissue during compression. 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 use of smaller crimping sizes would allow reducing the catheter size to 10 Fr catheters (around 3.3), instead of 18 Fr (around 5.9 mm), which is the smallest size currently available in clinical practice. The advantage of the trans-femoral approach is the need for only light anesthesia for the patient compared to the trans-apical approach. In a previous work, Heim et al. studied already the mechanical degradations undergone by synthetic valves crimped to low diameter values (Khoffi et al., 2014). They compressed valve prototypes made from polyester textile material to 1 mm diameter and studied the mechanical damage that occurred in the leaflets. Only little degradation could be identified in the textile material. The goal of the present preliminary work was to investigate if biological pericardium tissue resists crimping below commercially available catheter diameter values. For that purpose, pericardium valve specimens were crimped down to 1 mm for 20 min. The valve tissue was then characterized to assess changes in the mechanical properties. Moreover, the influence of the initial valve diameter on the degradation was investigated as well.

2. Materials and methods

2.1. Valve prototypes

The valve prototypes used in this work were commercially available surgical valves made from pericardium assembled with a polymer ring. For the purpose of the present study, the valve tissue was removed from the ring and then inserted in a custom made 21 mm diameter braided stent made from 0.2 mm nitinol wire. The stent was 20 mm high and designed with 12 cells over the circumference.

Two valve sizes were considered in this work (19 mm and 21 mm) in order to assess the influence of the diameter of the valve on the potential degradation sustained by the material. However, the same stent size and design were used for both valve diameters in order to apply the same loading conditions in both cases. 2 valve specimens were considered in this early work for each diameter and each configuration (crimped and no-crimped).

2.2. Valve crimping

A standard valve crimper was used for the procedure. However, the goal of this work was to assess the resistance of biological valve leaflets crimped to non-standard diameters. For that purpose, the leaflets had to be crimped below the standard clinical catheter size, which value is commonly between 18 and 24 Fr. The crimping diameter range being limited with the crimper used, 2 additional stents were used to surround the stented valve to be tested, which allowed increasing its external diameter (Fig. 1). The stented valve was then compressed for 20 min down to 1 mm, which corresponds here to the compressed valve diameter, excluding the stent thickness (Fig. 2). 1 mm compression diameter at valve level, would correspond to a catheter size of around 10 Fr considering the stent thickness. In order to prevent the premature drying of the pericardium tissue during the procedure, the biological tissue was kept in contact with a formaldehyde solution. For that purpose, the whole crimper was dipped in the solution over the whole crimping duration.

2.3. Material characterization

SEM photographs were taken before and after crimping in order to identify potential visual degradation on the samples surface due to the interaction with the stent wire. Observed samples were taken from different locations in the valve specimens. No analysis of statistical significance was done on the observations made from the SEM images. The interpretation was solely qualitative in this preliminary work.

Mechanical extension tests were then performed on pericardium strips (15 mm long, 5 mm wide) taken from both crimped and native leaflets. Due to the limited quantity of

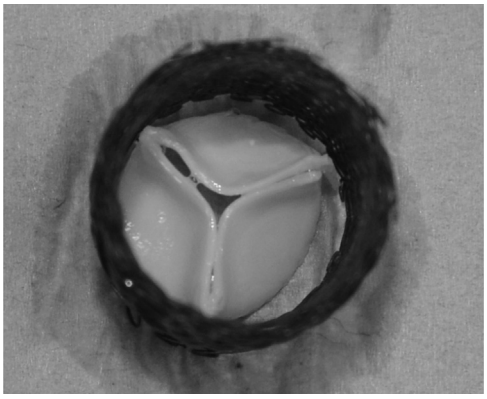

Fig. 1 – Valve insertion in braided stent.