A Novel Transcatheter Aortic Valve Prosthesis

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Statement of Purpose: Non invasive surgery is more and more investigated today to replace diseased aortic valve [1]. This technology requires the use of a valve holding device called stent, associated with a foldable valve prosthesis. Most of the existing stents are not specifically designed to undergo heart valve solicitations and consequently tend to injure the aortic environment inducing complications. Moreover, the biological valve associated with the existing devices is less durable when implanted percutaneously. In this work, a specific stented valve for non invasive aortic valve replacement is presented. The stent is positioned through geometrical surface matching rather than exaggerated expansion force. It respects the aortic root features in order to minimize aortic tissue traumatism. To prevent valve leaflet degradation due to crimping, the prosthesis is made from polyester woven fabric, characterized with unique folding and resistance properties.

Methods: The stent geometry is defined with 4 main features as represented in Fig. 1, which shows the stent geometry matching the aortic root shape. Three shaped arms, radially deployed in the sinuses orient the prosthesis around the flow axis and prevent axial migration. A cylindrical braided head centers the device in the aorta. Axial leakage is prevented with a conically shaped basis. The valve prosthesis is sutured to 3 posts.

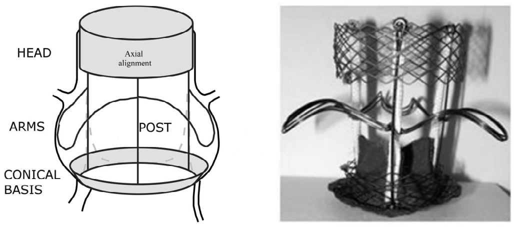

Fig 1.

All the stent parts are made with Nitinol wire material. The valve prosthesis is made from woven PET multifilament fine yarns. The whole device was tested in vitro in a compliant silicon mock aortic root under pulsed flow. The compliance of the device was assessed and the performances of the prosthesis were compared to those obtained for biological and mechanical commercially available prostheses. Moreover, in order to validate the textile concept and to test the textile material in a biological environment under reliable conditions, the valve alone was mounted on a rigid ring and implanted surgically in mitral position in a sheep model.

Results:

In vitro performances of the stented valve

Under pulsatile flow, from systole (a) to diastole (b) the stent shows good anchorage in the aortic root in spite of environment dimensional variations (Fig. 2).

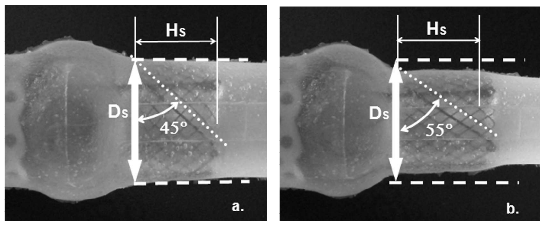

Fig. 2

When compared to commercially available prostheses, the stented valve performances are in the range of those expected. The dynamic regurgitation is 12%, close to the 10% for a Sorin Mitroflow and 15% for a St Jude bileaflet under same testing conditions.

In vivo performances of the textile valve material

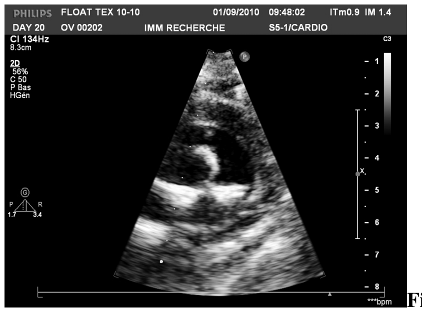

Fig. 3

The sheep model has survived for 8 weeks with satisfying valve function (Fig. 3) and was then sacrificed. The explant observed in Fig. 4 shows no tissue ingrowth on the valve inflow side, where the surface is washed with blood. Slight ingrowth is, however, observed on the outflow surface.


Fig. 4

Conclusions: The results presented in this work show that the stented valve prototype follows the dimensions variations of a compliant root environment, while the in vitro regurgitation performances are preserved. Moreover, the first results obtained with the fabric valve in vivo show that the material thrombogenicity is limited after 8 weeks implantation time. It is worth to investigate the material further to find the best adapted filament construction. The combination of the atraumatic stent with the highly foldable and resistant textile valve could be particularly suited for non invasive valve replacement.

References:

[1] Cribier A et al. Circulation. 2002;106:3006-3008.