NOVEL BIORESORBABLE PULMONARY VALVES: EXPERIMENTAL ASSESSMENT THROUGH AN ANIMAL TRIAL

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Introduction

Diseased heart valves are currently replaced by mechanical or biological substitutes. Both valve prostheses have their disadvantages. Mechanical prostheses require lifelong anticoagulant therapy while biological valves have a limited durability and reoperation is indicated [1]. In this unmet clinical need for novel artificial heart valves, there is a growing interest for tissue-engineered alternatives [1]. Specifically, a promising concept are bioresorbable valves. Here, a gradual decrease of the implanted synthetic scaffold material is accompanied with *in vivo* tissue formation, so called endogenous tissue restoration (ETR), ultimately leading to a new, natural and functional heart valve [2]. However, the involved processes are still unclear. We aim to better understand the influence of the scaffold characteristics such as wall thickness and fiber distribution on the scaffold degradation and ETR. The experimental data obtained in this study will be used to inform computational models that simulate the scaffold degradation and tissue growth processes. This can enable a simulation-based optimization of the scaffold characteristics.

Methods

The animal experiments were approved by the Animal Ethics Committee of KU Leuven and were conducted at the animal facility of KU Leuven. Eight sheep received a bioresorbable pulmonary valve. Two valve designs were tested, whereby four sheep received a thin-walled valve and four a thick-walled valve, with a six month follow-up. Baseline blood pressure was measured before surgery. Echocardiography and MRI were performed at regular timepoints during follow-up. Blood pressure was again measured at sacrifice. The pulmonary valve was explanted and samples were collected for histological microstructural analysis, gel permeation chromatography (GPC), and mechanical analysis via uniaxial and planar biaxial mechanical testing.

Results

All eight sheep completed the six months follow-up time. Macroscopic evaluation showed functional valves with newly formed tissue and partially degraded scaffold material, as shown in figure 1. The first insights on follow-up ultrasound imaging indicate functional pulmonary valves with an expected effective orifice area, normal gradients and cardiac output and low regurgitation scores. Data analysis of MRI imaging, microstructural and mechanical testing is currently ongoing.

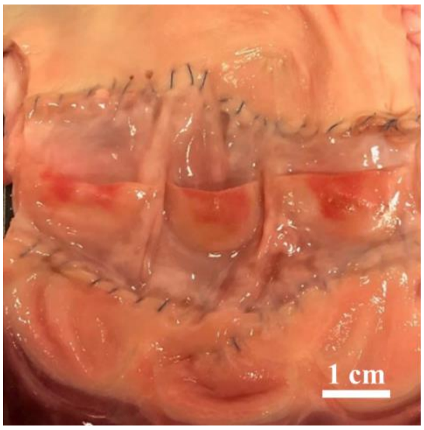

Figure 1: macroscopic image of a six months explanted pulmonary valve.

Discussion

The implanted pulmonary valves are not associated with complications or early deaths, analogous to previous studies [3]. No macroscopic differences can be observed between the thin- and thick-walled scaffolds. Ultrasound images also do not show differences between the two designs. The results on MRI imaging, histological and mechanical analysis will provide more information on the influence of scaffold microstructure and thickness on the scaffold degradation and ETR, and will be used in future work to inform computational models.

References

1. Rippel et al, World J. Surg, 36:1581-1591, 2012.
2. Serruys et al, EuroIntervention, 13:AA68-AA77, 2017.
3. Bennink et al, J. Thorac Cardiovasc. Surg, 155:2591-2601, 2018

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