Growing Aortic Valve: Development of a Biohybrid Heart Valve with Growth Capability for the Treatment of Paediatric Patients

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Abstract: Heart valve replacement in paediatric patients imposes unique challenges in terms of material and design requirements. While mechanical heart valves require permanent anticoagulation, they are not commonly used in children due to the high risk of life-threatening haemorrhages. On the other hand, biological heart valves do not require anticoagulation but degenerate quickly in children. Furthermore, both types of heart valves lack adaptation to the growing size of the child's heart, leading to frequent reinterventions to adjust the valve size.

The objective of this research study is to develop a biohybrid aortic valve that can adapt to the growing size of children's hearts. The biohybrid implant consists of a matrix of Elastin-Like Recombinars (ELR), which is being biologized by means of in-situ tissue engineering, and a growth capable textile scaffold structure, which gives the implant mechanical stability.

In order to create a textile scaffold structure that can adapt in a time-controlled manner to the increasing diameter and orifice area of the valve, a warp knitted structure was developed using non-degradable yarns (polyethylene-terephthalate & polyvinylidene-difluoride) that was specifically reinforced with biodegradable fibres (polylactide, polylactide-co-glycolide, polycaprolactone, silk). For integrating degradable fibres, direct integration into the warp-knitting process by means of combined lappings as well as subsequent tailored integration of reinforcing fibres into the warp-knitted structure were investigated. Samples were stored in temperature-controlled phosphate-buffered-saline in order to simulate degradation in-vivo.

Geometric and mechanical parameters of the scaffold structure were evaluated at different degradation points, including diameter, surface-area, tensile strength, elongation and radial compliance. Selective combination of fibres degrading at different rates and different geometric structures of the reinforcement structures resulted in a stepwise controlled increase of the valve diameter by up to 50 % and the valve orifice area by up to 60 %. Radial elongation of the scaffold structure at an inner mean pressure of 100 mmHg after degradation of the reinforcement fibers was 5 %, 26 % and 50 % for three different geometries of tailored integrated reinforcement structure. Degradation of directly integrated reinforcement fibers in a warp-knit structure with combined lappings led to an increase of diameter of 10 % and 22 % respectively for two different stitch densities of the textile structure. The achieved growth capacity of the scaffold structure corresponds to the growth of a paediatric heart valve over ten years with an implantation within the first year of life.

By combining a non-degradable textile base structure with a controlled degrading reinforcement structure, it was possible to fabricate a textile scaffold structure capable of growing with the valve in a defined time-controlled manner. These outcomes represent a decisive step towards a heart valve implant with growth capability for the treatment of young children.

KEYWORDS: ***HEART VALVE, BIOHYBRID, WARP-KNIT, DEGRADABLE***

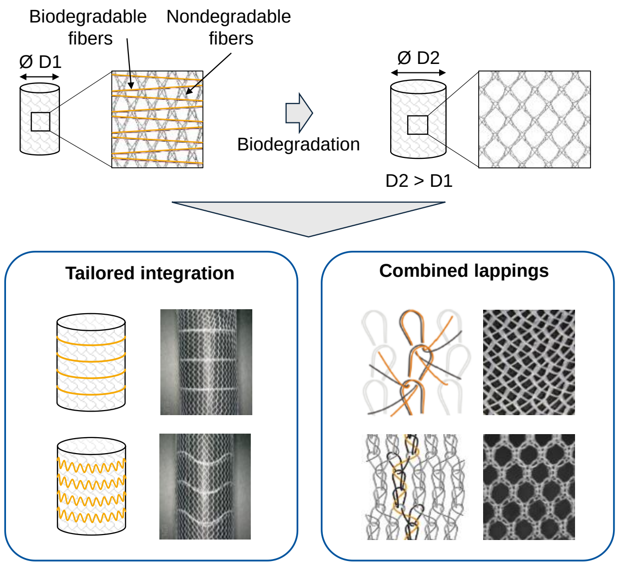

Figure 1 Concept of the growth capable textile scaffold structure