IN SITU TISSUE ENGINEERED HEART VALVE BASED ON WOVEN TEXTILE SCAFFOLD

Thomas Schmitz-Rode[1], Sebastian Jansen[1], Jan Niklas Thiel[1], Michael Neidlin[1], Torsten Hüner[2], Stefan Jockenhövel[1], Ulrich Steinseifer[1]

1. Institute of Applied Medical Engineering – AME, Helmholtz Institute for Biomedical Engineering, RWTH Aachen University, Aachen, Germany

2. ac.biomed GmbH, Aachen, Germany

Introduction

Bioprostheses with leaflets made from decellularized animal tissue represent the current state of the art in heart valve replacement. These valves are prone to calcification and structural degeneration, which limits their lifespan and requires repeated surgical interventions. The goal of this project is to investigate a leaflet scaffold based on a load-oriented woven textile. It is designed to provide structural integrity and can be further processed with a hemocompatible and bioactive coating for in situ tissue engineering.

Methods

Mechanical testing was used to preselect the fabric configuration, followed by porosity testing. The woven scaffolds were coated with TPU chloroform (Carbothane PC-3585A, Lubrizol) and mounted in a balloon expandable TAVI stent. Accelerated wear tests were performed under simulated physiological load in a LinA testing device (AME-HIA and ac.biomed GmbH). The function of the leaflets and signs of wear were assessed by high-speed camera recordings, photography and microscopic examination. Favorable textile scaffold - stent designs were tested with a higher number of load cycles. In addition, finite element analysis (FEA) was performed to investigate the stresses in the leaflet material and individual warp threads at the leaflet-stent interface during valve closure.

Results

After design optimization, current lab samples withstand more than 200 million load cycles. Critical failure zones, especially near the commissures, have been mitigated by adapting the weave pattern and the way the weave is attached to the stent. The FEA revealed areas of high stresses in the woven textile and quantified the influence of stent flexibility on the load dynamics. The latest R&D results on these aspects will be presented.

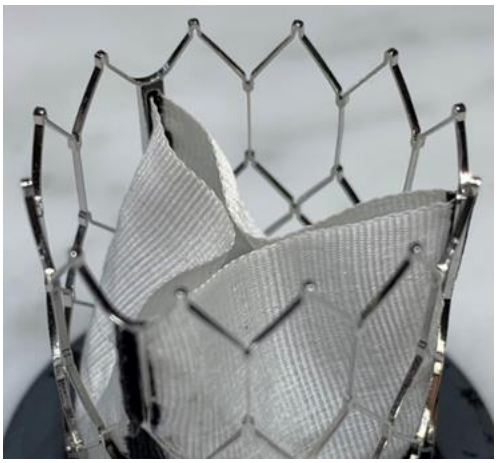

Figure 1: Textile heart valve scaffold tested with 200 million load cycles

Conclusions

Current results promise to achieve reasonable durability of a valve composed of woven leaflet scaffolds. Further hemocompatibility, cell colonization, and calcification testing are required to confirm suitability as an in situ heart valve replacement.