Project title: Degradable, structurally optimised ligament replacement at the knee joint using a novel 3D hexagonal braiding technology - Hexa+

Partner: Körting Nachfolger Wilhelm Steeger GmbH & Co. KG

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Funding Agency: Zentrales Innovationsprogramm Mittelstand – ZIM des BMWi

Mission Statement
Anterior cruciate ligament injuries are among the most common injuries of the knee joint, with an incidence of 1:3500 inhabitants. Rupture of the cruciate ligament is often caused by increased internal rotation of the lower leg. Rupture therefore often occurs during running, football, rugby or skiing and therefore affects the younger, more active population.

Nowadays, cruciate ligament ruptures are usually treated surgically with autologous (the body’s natural) grafts. In this case, an intact ligament is taken from another part of the body in an additional surgical procedure and used as a cruciate ligament replacement. The disadvantages of this procedure are, apart from the additional surgery, the associated complications at the extraction site, the need for follow-up surgeries in 10 - 19% of treatments, the associated high costs due to rehabilitation and loss of working hours as well as the limited availability of autologous implants.

The disadvantages of autologous cruciate ligament replacement contrast with the active population and their need for unrestricted activity and mobility. The approach of a new synthetic cruciate ligament based on tissue engineering should enable an innovative treatment through high availability and optimised braid structure.

Approach
The aim of the Hexa+ research project is a structurally optimised artificial ligament replacement. To this end, a degradable 3D braid is being developed as a functional replacement for the anterior cruciate ligament. With the help of the development of a new 3D hexagonal braiding technology, the technical implementation of the necessary structural optimisation is implemented. To optimise the structure of the braid, various structural designs of the implant will be validated and corresponding process/machine concepts for implementation will be researched.
The degradable braid offers an innovative treatment option based on tissue engineering. Due to the regrowth of the body's own tissue, good properties in relation to long-term performance and tolerability can be expected.

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<th>State of the art</th>
<th>Deficits</th>
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**Aim**
Degradable, structurally optimised ligament replacement structures through novel 3D hexagonal braiding technology

- Iterative validation of product parameters at fibre/structure level
- Process Development & Evaluation of the Machine
- Product validation
- Degradable filaments (PCL)
- Braid production Hexa+
- Structurally optimised replacement structure

**Relevance**
- Market volume cruciate ligaments Germany approx. 15 million € / USA: 24 million € / Worldwide: 151 million €
- Innovation: Structurally optimised, degradable cruciate ligament prosthesis
- Significantly increased quality of life for patients

Figure 1: Mission Picture Hexa+

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