Bridging deep gaps in translation and tissue: a blueprint for TEP development from a corneal sealer

Consortium coordinator:
Dr. rer. nat. Anna Resch
Institute for Pharmaceutical Sciences
Pharmaceutical Biology and Biotechnology
Albert-Ludwigs University of Freiburg

Project Partner:
Prof. Dr. med. Günther Schlunck
Eye Center
University of Freiburg Medical Center

Around 1.6 million people worldwide are blind as a result of eye injuries and around 19 million have impaired unilateral vision. Severe injuries to the cornea of the eye usually have to be closed by sutures and, in the event of complications, may even require transplantation of corneal or amniotic membrane grafts. Suturing corneal perforations or grafts can induce scarring, inflammation and ultimately lead to corneal opacity.

Our aim is to develop a safe alternative for the sutureless closure of deep corneal wounds or for the fixation of the amniotic membrane in order to avoid irritation and visual impairment. To this end, we will develop a corneal adhesive that contains specialized, living corneal cells, so-called keratocytes, embedded in a protein-based hydrogel adhesive. This hydrogel adhesive is applied in liquid form and subsequently photopolymerized within a short time. The embedded cells can remodel the tissue by breaking down the hydrogel adhesive and replacing it with natural corneal tissue consisting of special collagen fibers. The adhesive is able to seal wet and even leaking wounds, it is elastic and contains no toxic components. We will characterize the prototype thoroughly, and study the preliminary (immune) toxicity in a rabbit study.

We will furthermore build an early basis for a quality-by-design manufacturing strategy by compiling a quality data package to facilitate the efficient transition to further development steps in the future. We will share our experience from this early development process with other developers - particularly from the academic sector - by examining the regulatory framework and providing an exemplary regulatory strategy that can serve as a blueprint for future development of similar products.