ABSTRACT: SIMULATION OF INFLUENCE OF INTRASTROMAL CORNEAL LENTICULE IMPLANTATION

Background: Corneal stromal lenticule is a part of corneal stroma, which arises as a by-product of a refractive procedure ReLex SMILE. Its implantation has successfully been used in treatment of wide spectrum of severe diagnoses such as nonhealing corneal defects or ectasia. There have also been published cases where the lenticule was used in refractive indication such as hyperopia or presbyopia correction. In these indications, a greater emphasis on the refractive outcome is necessary, however, there is still not enough data available on the basis of which we would be able to choose the most suitable lenticule for a specific patient.

Purpose: To evaluate changes in corneal refractive parameters after implantation of a stromal lenticule of different thickness. We assume that the refractive outcome depends on optical power of the used lenticule. The other important goal is to analyse possible methods of corneal lenticule preparation and storage and prove the possibility of using one donor cornea for more patients. We want to build a safe approach which would increase the efficiency of the surgery and shorten the waiting time for donor corneal tissue.

Methods: We performed an ex vivo non-human study on normotonic porcine eyeballs divided into two groups, for 4D and 8D lenticule implantation. Corneal stromal lenticules were obtained as a by-product from a laser procedure ReLEX SMILE. We evaluated corneal refractive parameters measured on Oculus Pentacam© device before and immediately after the intrastromal lenticule implantation. In order to analyse the preparation and preservation methods we provided morphological (histology, scanning electron microscope) examination of human corneal tissue which went through tested procedures and compared them to a fresh reference cornea. We also evaluated surgical handling with the tissue. The studied preparation methods were microkeratome dissection and femtosecond laser preparation. Analysed preservation methods were hypothermia, cryopreservation in -80 degrees Celsius in DMSO (dimethyl sulfoxide) and storage in room temperature with glycerol. Some intrastromal lenticules and lamellae in each group were previously irradiated by gamma irradiation of 25 kGy.

Results: In both groups, the intrastromal implantation in the depth of 300um led to a significant increase of central corneal pachymetry and corneal anterior steepening. Induced changes in other studied parameters were not statistically significant. There were no significant differences in refractive changes between the 4D and 8D groups after lenticule implantation.

Corneal stromal implants prepared with microkeratome had smoother surface of the incision than after femtosecond laser formation. Femtosecond laser preparation caused more irregularities on the surface, however using femtosecond laser enabled to make more than five lenticules from one donor cornea. Gamma irradiation led to damage of stromal collagen fibrils, loss of their regular arrangement and transparency. Glycerol storage caused dehydration without significant loss of the tissue transparency. Cryopreserved tissue without previous gamma irradiation showed most regular structure of the fibrils comparable to a reference fresh cornea.

Conclusion: Intrastromal corneal lenticule implantation induces changes in corneal refractive parameters. It induces a significant increase of an anterior corneal steepening without any significant influence on posterior corneal flattening or corneal astigmatism. Based on this study, we can assume that the lenticule thickness does not have a direct impact on studied parameters. The feasible creation of more stromal implants from one donor cornea was proved by femtosecond laser as well as microkeratome and we were able to form them after DMEK lamellae extraction. Gamma irradiation caused damage of the collagen fibres, their network arrangement which correlated with a loss of transparency and stiffer structure which impair surgical utilisation of the tissue. The best results from the preserving methods were gained in cryopreserved samples, which were comparable to a reference fresh cornea. We believe that cryopreservation is a safe method allowing successful clinical use even after long-term storage.