In this talk logistics and outcomes of Eye bank prepared DMEK tissue will be presented.

Methods Laboratory studies of two different shipping protocols for DMEK (endothelium trifolded inwards and endothelium rolled outwards) will be presented. Clinical outcomes and complications of patients underwent to DMEK surgery with Eye bank prepared or surgeon prepared tissue will be presented. A Cost analysis of eye bank versus surgeon prepared endothelial grafts will be also part of the presentation.

Results There was no difference in endothelial cell viability between surgeon or eye bank prepared tissue. Surgeon-stripped DMEK grafts in the laboratory investigation showed significantly higher elastic modulus and adhesion force compared to prestripped and preloaded tissues (p<0.0001). In the clinical data, rebubbling rates of 48%, 40% and 15% were observed in preloaded, prestripped and surgeon-stripped DMEK grafts, respectively. The cost analysis showed that eye bank prepared tissues had higher surgical expenses compared to those prepared by the surgeon, while the post-operative care expenses were similar between the two groups.

Conclusion The Eye bank prepared tissues are a valid alternative to Surgeon prepared tissue, however need to be highlighted that with current method there is a decreased adhesion forces and elastic modulus in eye bank prepared tissues that may contribute to increased rebubbling rates.

Descemet membrane endothelial keratoplasty (DMEK) has become the goldstandard in the treatment of Fuchs endothelial corneal dystrophy and early stages of (pseudophakic) bullous keratopathy due to the safer ‘closed globe’ surgery, the fast and excellent visual recovery and low complication rates. In those cases, DMEK can often be performed in a standardized manner. Given the outstanding clinical outcomes, the spectrum of indications has expanded in the past years: thus, also more complex cases, such as eyes with advanced corneal edema, altered anterior chamber anatomy, failed lamellar grafts, failed penetrating keratoplasty, as well as, phakic, aphakic and vitrectomized eyes are being treated with DMEK. Although DMEK surgery in complicated eyes proved feasible, the procedure is technically more challenging because of the impaired visualization during surgery and the unpredictable graft behaviour. Surgical strategies to accomplish DMEK in complex eyes have been suggested and customization of recipient/donor characteristics (donor age, graft size) may facilitate the surgery. Still, clinical outcomes appear not as good as in standard indications and there is uncertainty concerning the long-term graft survival.

The European Cornea and Cell Transplantation Registry (ECCTR) is a multi-national database for corneal transplantation surgery. ECCTR is co-founded by the Health Programme of the European Union, the European Society of Cataract and Refractive Surgeons (ESCRS), EuCornea and the European Eye Bank Association (EEBA). Objectives of the database are to ascertain donor tissue availability, and to analyse the safety, quality, and efficacy of corneal transplantation based on real-world outcomes including patient reported outcome measures.

We describe a web-based system with a software interface for the input and output of data relating to eye banking and corneal transplantation surgery. Output of reports or export of own data is available on the web. Data is anonymous to all users, with the exception that reporting eye banks and surgeons have access to their own data. The system was designed to allow both manual input of data via the web and transfer of data from national registries, eye banks, and electronic medical record systems.

Established in 2016, the ECCTR has collected data on more than 13,000 transplants from 15 European countries—including information on the recipient, donor and eye bank processing, transplant procedure, and two-year follow-up with graft survival and failure and patient-reported outcome measures (PROMs). We present the key findings from the registry and invite eye banks to engage with the registry.

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Multiple research groups now theorize that tissue engineering will provide novel therapies for treating corneal endothelial cell (CEC) decompensation. In 2013, we initiated first-in-man clinical research (not an Investigational New Drug [IND] clinical trial) of a CEC injection therapy at the Kyoto Prefectural University of Medicine in Japan. In a clinical trial, cultured CECs (CECs) supplemented with a rho-associated protein kinase (ROCK) inhibitor were injected into the anterior chamber. In all of our first 11 cases, the corneal transparency was restored with the regeneration of a monolayer sheet structure of corneal endothelium. As proof of concept of CEC injection therapy was obtained, we are currently developing a cellular product to deliver this therapy to all patients. To that end, we have established an efficient cell culture protocol and
‘ready-to-use’ frozen cells. In this presentation, I will introduce the current status of our developments to provide a platform for discussing future therapies for treating corneal endothelial decomposition.

We will analyze why there is not yet an alternative process for mass production of corneal endothelial cells or clinical grade TEEK, systematically detailing the various bottlenecks identified, from the source of cells and media, to regulatory and economic aspects.

**P48-A109 OBSTACLES AND PERSPECTIVES IN TISSUE ENGINEERED ENDOTHELIAL KERATOPLASTY**

Endothelial bioengineering is the simplest form of corneal bioengineering as it consists of producing a large quantity of corneal endothelial cells and packaging them in a form that can be transplanted to the patient. It seems to be the most realistic solution to replace endothelial grafts made from donor corneas and thus allow, by domino effect, to reserve them for other indications of keratoplasty. Kyoto ophthalmologists (S Kinoshita, N Koizumi and N Okumura) were the pioneers of injection therapy by demonstrating its feasibility and safety, with an efficacy at 5 years comparable to that of conventional endothelial grafts. These pioneers split into two distinct entities, currently industrializing this therapy by injecting cells in suspension, in the USA (Aurion biotech) and in Asia (Actualeyes). In addition to injections, tissue engineered endothelial keratoplasty (TEEK) is a complementary research approach. They consist in reproducing in vitro grafts of the DMEK or DSAEK type by seeding the cultured cells on a ‘corneo-compatible’ support. Several have passed the preclinical stages and one is in clinical trial in Asia. Suspension cells and TEEK each have advantages and limitations that make them complementary in the management of corneal endothelial diseases.

**P49-A103 ALLOGENEIC LIMBO-DALK: A NOVEL SURGICAL TECHNIQUE FOR PATIENTS WITH CORNEAL STROMAL DISEASE AND LIMBAL STEM CELL DEFICIENCY**

Purpose
To describe a novel corneal surgical technique combining Deep Anterior Lamellar Keratoplasty (DALK) with grafting of allogeneic limbal stem cells (limbo-DALK) as treatment for eyes with corneal stromal pathology and limbal stem cell deficiency (LSCD).

Methods
This is a series of six Limbo-DALKs in five eyes of five patients. One patient received a second limbo-DALK after graft failure following the first procedure. Two of the donor corneas were HLA matched. Clinical records of included patients were reviewed retrospectively. All patients had been diagnosed with LSCD due to various pathologies. Analyzed data included demographic data, diagnoses and clinical history, graft visualization and thickness measurements by anterior segment OCT, visual acuity and epithelial status. Follow-up visits were 6 weeks and 3, 6, 9, 12 and 18 months postoperatively with final suture removal at 18 months and further follow-up examinations twice yearly thereafter.

Results
Two grafts showed total epithelial closure after 2 days, two after 14 days. In one eye, full closure of corneal epithelium did not occur after the first limbo-DALK, but could be achieved one month after second limbo-DALK. No endothelial graft rejection was seen.

Conclusion
Based on data from this pilot series, limbo-DALK seems to be a novel viable surgical approach for eyes with severe LSCD and stromal corneal pathology.