

before the beginning of the experiments (pre-wound) was assessed using the vital dyes trypan blue (TB, TB-S 0.25%, AL.CHI.MI.A. srl) and sodium fluorescein (Fluo). 1-heptanol soaked paper disks (6 mm) were applied in the centre of the corneas for 1' to trigger a chemical damage at the epithelial layer. Afterwards, sodium fluorescein and TB stainings were repeated to quantify the damaged area and to monitor healing progression. The damaged area (mm<sup>2</sup>) was calculated for each time point with Fiji software. Wound healing rate (HR, mm<sup>2</sup>/die) was calculated for both Fluo (HRF) and TB (HRTB) measurements using the previously described formula:

Arithmetical averages (HRFAVG and HRTBAVG) of HRs were calculated and correlated with Pearson correlation coefficient with the following donor's parameters: age, sex, post-mortem time (PMT, time between death and tissue procurement), stromal defects, septicaemia, body temperature, diabetes.

**Results** The execution of the heptanol wounding is highly reproducible, as highlighted by Fluo and TB staining. The average time for full recovery from wounding was  $3,8 \pm 0,41$  days for Fluo and  $3,5 \pm 0,63$  days for TB. Fluo and TB stainings are interchangeable as they significantly correlate (Pearson correlation coefficient = 0.630;  $p > 0.05$ ). A negative linear correlation was observed between HR and PMT (HRFAVG: corrected R<sup>2</sup>: 0.243,  $p = 0.003$ ; HRTBAVG: corrected R<sup>2</sup>: 0,132,  $p = 0.028$ ), but not with the other donors' parameters.

**Conclusion** Our wound/healing model might be of great interest for studies of epithelial regeneration kinetics and validation of drugs for the treatment of ocular defects. The inverse correlation between PMT and HR provides valuable insights for scientists investigating the regenerative properties of the corneal epithelium, as well as for eye bank personnel aiming to preserve the regenerative potential of corneal epithelium.

#### P21-A141 QUANTIFICATION OF BIOACTIVE FACTORS IN HUMAN SERUM EYEDROPS

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**Purpose** NHS Blood and Transplant supply serum eye drops (SED) for the treatment of severe dry eye syndrome, however, understanding of what components of SED contribute to their activity is limited. SEDs are produced from a patient's own blood or from an allogeneic donor source. The serum component is separated from the whole blood which is then diluted 50/50 with sterile saline, and contains bioactive molecules that are believed to help heal and maintain the ocular surface. The objective of this study is to quantify the amount of bioactive molecules in donor serum, and to understand how processing variables effects these factors.

**Methods** Samples of SEDs from 28 male allogenic donors were taken from ultra-low temperature storage and thawed. They were then centrifuged at 13,000 rpm at 4oC to remove potential contaminants such as residual red blood cells. Duplicate test samples were analysed for epidermal growth factor (EGF) and fibroblast growth factor (FGF) using ELISA kits. Analysis was carried out using Excel.

**Results** The age range of the donors was 17 to 79 years (mean 47.9).

Mean time from venepuncture to refrigerated storage was 6 hours 12 minutes with time ranging from 2 hours 40 minutes to 9 hours 35 minutes.

The concentration of EGF found in the diluted serum ranged from 0.048 to 1.90 ng/ml (mean 0.87 ng/ml), and FGF concentration ranged from 4.88 to 39.50 pg/ml (mean 12.37 pg/ml).

Analysis showed that there was no correlation between either age of the donor, or sample transfer time and growth factor concentration.

**Conclusion** Our study demonstrated that with both types of growth factors measured in the SED, a wide range of concentrations were found in the donor samples. Compared to published data EGF was at higher range while FGF was lower. Further analysis of other factors present in the donor serum is being undertaken to determine if any pattern can be found.

#### P22-A142 VALIDATION OF AN IMPROVED CLOSED SYSTEM FOR DISPENSING SERUM EYE DROPS

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**Purpose** NHS Blood and Transplant Tissue and Eye Services provide a serum eye drop (SED) service to patients suffering from severe dry eye syndrome. Currently SED are dispensed using an automatic closed filling system (TF) manufactured by Meise Medizintechnik (Germany). An improved version (ATS) has recently been introduced by Meise, based on patient feedback on the TF system. ATS vials are easier to open, with a more secure, tamper evident closure and a better quality nozzle.

To evaluate the suitability of ATS vials, a validation protocol, previously developed for TF vials, was repeated. It comprised assessment of their integrity following simulated storage and transport, and the stability and sterility of SED stored in them.

**Method** Firstly, a process simulation assessment was performed using bovine serum. Vials were filled, and frozen to -80oC. They were then removed from frozen storage and checked for damage, before being put into transport containers and shipped on a round-trip journey to simulate delivery to patients. On return the vials were thawed and the integrity of each vial checked visually and by application of a standard force.

Subsequently a shelf-life study was carried out using three batches of human SED. The vials were initially frozen to -80oC, then stored for set time points of 1, 3, 6 and 12 months in a standard domestic freezer set at 20oC (to mimic a home freezer). At each time point, 10 vials were thawed and examined for integrity, and the sterility and stability of the contents. Stability was assessed by measuring serum albumin concentrations and sterility by testing for presence of microbial contamination, under aerobic and anaerobic conditions.

**Results** No vial damage or leakage was found at any time point in the ATS vials. No microbial contamination was

detected, and no change in albumin levels was detected in SED throughout the storage period.

**Conclusion** This study has demonstrated that the ATS vials are suitable for provision of SED for clinical use to patients. Feedback is now being gathered from a patient focus group relating to usability of the vials.

## EEBA 2023 Session III – Legal and Ethical Aspects of Corneal Transplantation

### P23-A137 CROSS-BORDER COOPERATION FOR CORNEAL DONATION BETWEEN LIONS EYE BANK SAAR-LOR-LUX, TRIER/WESTPFALZ IN HOMBURG/SAAR AND LUXEMBOURG

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**Purpose** With the increasing demand for corneas, eye banks must optimize and extend their sources of tissue donation. On the other hand, corneal transplantation is a specialized procedure performed in hospitals with high quality standards and ideally an integrated eye bank. In this report we would like to focus on an international win-win-win agreement between the Department of Ophthalmology at Saarland University Medical Center (Homburg/Saar, Germany), the LIONS Eye Bank Saar-Lor-Lux, Trier/Westpfalz and the four major non-university hospitals without corneal transplantation competence in Luxembourg.

**Methods** In 2012, at the initiative of the Luxembourgish Ministry of Health and Department of Ophthalmology (Homburg/Saar, Germany), an international agreement was established with the Centre Hospitalier du Luxembourg (Luxembourg). Administrative and legislative rules were developed. Luxembourgish nursing personnel attended a practical training program for corneal excision at the Department of Ophthalmology in Homburg/Saar allowing them to harvest the two first corneal donors on site by themselves during the first year. In the following years two more hospitals, the Centre Hospitalier Emile Mayrisch (Esch-sur-Alzette, Luxembourg) and the Hôpitaux Robert Schuman (Kirchberg, Luxembourg), joined the cooperation.

**Results** From 2012 until 2021, three hospitals in Luxembourg donated 779 corneas to the LIONS Eye Bank of the Saarland University Medical Center in Homburg/Saar (Germany). In return, 308 Luxembourgish patients have received a corneal transplantation at the Department of Ophthalmology in Homburg/Saar. In 2022, the extension continued and an agreement with a fourth hospital in Luxembourg at the Centre Hospitalier du Nord (Ettelbruck, Luxembourg) was signed providing even more donations.

**Conclusion** The cross-border collaboration for corneal donation and patient treatment has proven to be successful with both numbers of harvested donors and transplanted patients rising. However, international legislation for tissue donation needs to be accurately respected and a quality management system established to provide continuous quality of the donor tissue.

### P24-A114 BRINGING TOGETHER THE EYE BANKING COMMUNITY THROUGHOUT EUROPE AND BEYOND – PROMOTING EYE DONATION IN AFRICA

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**Purpose** It is estimated that globally there are more than 12.7 million corneal blinds with the vast majority of those living in the developing world. There is huge demand for corneal transplants worldwide as currently only one out of 70 patients can be provided with a cornea.

Following the spirit of EEBA in bringing together the international eye banking community we present on our efforts and vision in contributing to the elimination of avoidable blindness in Africa by promoting sustainable eye donation programs.

**Methods** At the congress of the South African Tissue Bank Association (SATiBA) in November 2022 a dedicated Round Table Discussion takes place on eye donation in Africa, organized by the World Union of Tissue Banking Associations (WUTBA) together with the Global Alliance of Eye Bank Associations (GAEBA), SATiBA and the German Society for Tissue Transplantation (DGFG). Individuals, national and global players in tissue medicine meet aiming to promote and advocate corneal donation in sub-Saharan Africa to establish patient care that is self-sustaining from within the countries.

In preparation for the meeting a questionnaire was completed by the participants to understand the current situation in individual countries: Responses by ophthalmologists, tissue bankers, awareness and tissue donation coordinators from Kenya, Uganda, Nigeria, Ethiopia, and South Africa were evaluated.

**Results** The survey revealed that all countries are establishing national health acts with references to tissue donation or have them in place with regulations still to be detailed. These are fundamental to strengthen confidence in tissue donation and to start developing donation infrastructures. In all countries there is doubt about donation after death showing the need for advocacy towards the public.

The aim of the Round Table is creating a momentum of networking and sharing experience to support the African countries in building local infrastructures and becoming independent from tissue imports in the future.

**Conclusion** What frameworks must exist to successfully establish donation programs in Africa? What help can be provided by countries and organizations that have stable donation programs? These and other questions will be attempted at the Round Table. Bringing together experts, bundling synergies, and creating a momentum to promote cornea donation on social, political, and community level will be a step towards the vision of creating a world in which nobody is needlessly visually impaired.

### P25-A123 INDO – GERMAN GIZ COLLABORATION – IMPACT AND WAY FORWARD IN GLOBAL EYE BANKING

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