subsequently develop a condition known as posterior capsule opacification (PCO). This arises from wound-healing responses that lead to fibrosis and partial lens regeneration, which collectively cause light scatter within the visual axis. PCO causes significant visual loss in approximately 20% of patients.

While animal systems are commonly employed by investigators to study PCO, the receptor profiles and mechanisms regulating features of PCO can differ between species. Translation of findings from animal studies to human is therefore fraught with difficulties. Human donor tissue provides an outstanding opportunity to investigate the molecular basis of human PCO and explore strategies to better manage the condition. To this end we perform cataract surgery in the laboratory on human donor eyes to generate a capsular bag that can be transferred to a culture dish and maintained in controlled conditions. Often using a match-paired format we have identified a number of factors and pathways that regulate key features of PCO to increase the biological understanding of the problem. In addition, the model has enabled putative pharmacological strategies to be tested and has played a key role in the development and evaluation of IOLs. Collectively, our work on human donor tissue has significantly advanced academic understanding of PCO and facilitated product development that will benefit millions of cataract patients.

# Theme 6 – Clinical outcome monitoring and transplantation registries

## 28 VALIDATION OF A CLOSED SYSTEM FOR DISPENSING SERUM EYE DROPS

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**Introduction** NHS Blood and Transplant Tissue and Eye Services (TES) offer a serum eyedrop (SE) service to patients suffering from severe ocular surface disease. SE are prepared from serum collected at blood donation sessions; the serum is diluted 1:1 with physiological saline. Formerly, 3ml aliquots of diluted serum were aliquoted into glass bottles in a Grade B clean room. Since this service was started, Meise Medizintechnik have developed an automatic closed filling system consisting of tubing-linked chains of squeezable vials. They can be heat-sealed closed, under sterile conditions, after the vials have been filled.

**Materials and Methods** TES R&D were asked to validate the Meise system to increase the efficiency and speed of SE production. Validation of the closed system consisted of a process simulation assessment, using bovine serum and simulating each step of the filling process, freezing to -80oC, checking the integrity of each vial and packing the vials into storage containers. They were then 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 re-checked visually and by squeezing in a plasma expressor.

Subsequently a shelf-life study was carried out on three batches of fully consented human allogeneic SE. The serum was dispensed into vials, frozen as above and stored for set time points 0, 1, 3, 6 and 12 months in a standard domestic freezer set at -15-20oC to mimic a patient's freezer. At each time point, 10 random samples of vials were removed, and the outer containers were tested for damage or deterioration, the vials for integrity and their contents for sterility and stability. Stability was assessed by measuring serum albumin concentrations and sterility by testing for microbial contamination.

**Results** No structural damage or leakage was found in any of the vials, or the tubing evaluated, after thawing, at any time point. In addition, all samples tested negative for microbial contamination and serum albumin levels were always within the expected range (3 – 5 Dg/L) at each set time point.

**Conclusion** These results demonstrate that Meise closed system vials can successfully dispense SE drops and the vials can be stored frozen without affecting integrity, sterility or stability. These vials have been in use in TES for 3 years saving clean room space and greatly increasing the numbers of patients that can use the SE service.

## 29 PRODUCTION OF ULTRA-THIN DECELLULARISED DERMIS TO TREAT SEVERE OCULAR DISEASES

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**Introduction** The ocular surface may be damaged by several ocular conditions such as chemical trauma, infection, neoplasia or autoimmune disease causing a loss of tissue and function leading to a painful loss of vision. Tissue regeneration is needed to re-establish homeostasis of the ocular surface and to preserve vision. Present replacement strategies have limitations ranging from availability of the same type of tissue to long-term stability. NHSBT currently produces decellularised dermis (DCD) for clinical allografting; comprising a "thin" (up to 1.0 mm) and a thick (>1.2 mm) DCD, used to treat non-healing leg ulcers or in rotator cuff repair. Even the thin DCD, however, is too thick for ophthalmic purposes. The objective of this study was to develop a new ultra-thin DCD for ocular allografting.

**Materials and Methods** Skin was retrieved, with consent for non-clinical use, from the back, front and back of the thighs of 3 different deceased donors, within 48 hours post-mortem. The tissue was cut into 5x5 cm squares and decellularised over 5 days as follows: decontamination with antimicrobials, de-epidermalisation (1M NaCl), hypotonic washes, detergent washes (with 0.01% SDS) and nuclease incubation. The DCD obtained was examined for integrity, handleability, residual remaining DNA and potential ultra-structural changes (by histology, DAPI and hematoxylin and eosin staining).

**Results** We obtained an intact ultra-thin DCD using the same standard GMP protocol, regularly used to decellularise skin for clinical use. Tissue handleability was comparable to amniotic membrane, as evaluated by the ophthalmic surgeons as well as tissue bank assistants. The mean thickness of the tissue was 0.25 mm (±0.11) at the end of processing (total N=18 samples from 3 donors). Histology confirmed successful removal of epithelial cells and integrity of the extracellular matrix.

**Conclusion** We have successfully validated standard operating procedures for the production of ultra-thin DCD, in the attempt to obtain a valid alternative to amnion for the reconstruction of specific ocular regions (fornix, eye lids), where increased strength may be required. The thickness measurements at the end of processing suggest ultra-thin DCD obtained could represent a promising scaffold for regeneration of conjunctival tissue.

## 30 A NEW STEP ON AMNIOTIC MEMBRANE EXTRACT EYE DROPS (AMEED) DEVELOPMENT FOR THE TREATMENT OF SEVERE OCULAR SURFACE PATHOLOGIES

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**Introduction** Our tissue establishment developed a protocol for processing amniotic membranes as extracts to be re-hydrated and administered topically as eye drops, becoming a new approach to treat severe ocular surface pathologies. From 2015 to 2017 the safety and efficacy of the amniotic membrane extract eye drops (AMEED) were assessed in patients with severe ocular surface pathologies through clinical follow-up of ocular surface symptoms before and after regular application of the extract.

Between 2018 and 2019 a study of 36 patients (50 eyes) treated with topical AMEED was conducted comparing 2 groups of patients: Dry Eye Disease (DED) and Wound Healing Delay (WHD) showing global similar symptomatic improvement in both groups (DED 88.9% vs WHD 100%; p= 0.486) with the WHD group especially consisting in general relief (78%) and DED group reporting more pain improvement (44%) (p=0.011). Regarding patients with autologous serum as previous treatment, no statistical differences were found in subjective or objective improvement. An overall success was achieved in 94.4% of the cases and no adverse events were found. From January 2020 to November 2021 a growth stage has been observed including more patients while optimizing and scaling the process from donation to clinical use.

**Materials and Methods** We record data of placenta donation and preparation of AMEED vials from 1/1/2020 to 30/11/2021 and its clinical use including the indications for treatment, number of requesting ophthalmologists and number of patients.

**Results** In the study period a total of 378 placentas were processed to obtain AMEDD (61 in 2020 and 317 in 2021). The number of suitable vials obtained were: 1845 and 6464 respectively and 1946 vials are stored in quarantine pending release for clinical use.

A total of 9365 vials were sent for treatment of ocular surface pathologies to 31 hospitals (98% in Catalonia) and 69 requesting ophthalmologists.

The total number of patients treated was 204 and the indications for treatment were 82% DED and 18% WHD.

**Conclusion** After the new product development and introduction stages, a significant increase in the use of AMEED in Catalan hospitals was observed in 2020-2021. Follow-up data of these patients should be assessed to demonstrate its efficacy and achieve the maturity stage.

## 31 SETTING UP A BANK OF PRIMARY CELLS LINES OF PEDIATRIC AND ADOLESCENT SCLERA AND CHOROID TO STUDY POST-NATAL EYE GROWTH

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Twice as many teenagers in the UK are becoming short-sighted now, compared with the 1960s; many develop a dangerously high degree of short-sightedness ("progressive myopia") with a risk of sight-threatening conditions in adulthood, such as retinal detachment and glaucoma. The rise in short-sightedness is even more dramatic in the Far East, where over 95% of young men are now shortsighted. One crucial feature in short-sightedness is that the eyeball becomes longer, as the white coat of the eye (sclera) is becoming softer and stretchable. We do not know how exactly this happens, but it must involve the cells that make the collagen in the sclera. At the moment lengthening of the eyeball cannot be reversed and the few existing treatments can only slow myopia progression, not stop it. New and better treatments are needed but a clear understanding of the molecular mechanisms of post-natal eye growth in humans is lacking. Critically, because myopia develops in childhood at a physiological location prohibiting biopsies, we are lacking an understanding of the cellular components involved in human eye growth and myopia, and especially how the tissues that build the eye structurally, the sclera and the choroid, are modulated during normal eye growth. We have recently begun to establish a biobank of primary fibroblasts from the sclera and choroid of pediatric, adolescent and adult tissue, to better understand how the cell populations change in those tissue as the eye grows and settles at its final adult size and shape. We have already been able to demonstrate significant differences in the cells from young and old eyes, as well as regional differences between the posterior and the anterior sections of the eye. We plan to analyse in detail the cellular profiles of the sclera during postnatal eye growth to identify markers of the different stages of eye growth (from infant to elderly). This will allow us to better understand normal eye growth and identify potential markers and new drug targets to prevent and treat myopia. Because pediatric donor tissue is so rare, our unique cell bank will be critical to the development of future studies.

## 32 CORNEAL GUTTAE AFTER DESCEMET MEMBRANE ENDOTHELIAL KERATOPLASTY (DMEK)

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**Purpose** To report on the occurrence of corneal guttae after Descemet membrane endothelial keratoplasty (DMEK) in eyes operated on for Fuchs endothelial corneal dystrophy (FECD).

**Material and Methods** Case series of 10 eyes of 10 patients operated on for FECD at a tertiary referral center between 2008 and 2019. Average patient age was 61±12 years and 3