

**NHSBT Board Meeting**

26 March 2021

**A Patient Story: UK's First Conjunctival Transplant through International Collaboration**

In January 2021, Tissue and Eye Services (TES) were approached by a Consultant Ophthalmologist at a leading Ophthalmic Unit to help in treating a patient with a highly complex ophthalmic history.

The patient was an elderly gentleman whose quality of life had been severely impacted over several decades by a long-standing history of a rare condition called ocular mucous membrane pemphigoid. This is a chronic, autoimmune scarring of the conjunctiva which can be complicated by serious damage to the cornea. The conjunctiva is the tissue that lines the inside of the eyelids and covers the sclera (white of the eye).

**A Unique Medical Challenge**

Until 2018, the patient's right eye was pre-dominantly affected, leading to repeated episodes of breakdown of the corneal surface, and necessitating several successive cornea transplants. In 2018, the patients' left eye was severely affected by an episode of shingles which led to lasting complications, especially loss of sensation, with damage to the surface of the cornea and ultimately perforation. This meant that the left eye was now unfortunately affected by the combination of 2 rare conditions. From 2018 onwards, several successive cornea transplants were also required for the left eye, and on one occasion the patient had cornea transplants in both eyes on the same day.

Due to the severe and complicated nature of the patient's eye condition, several other treatment options were utilised, notably serum eye drops, amniotic membrane grafts, and imported human nerve growth factor. Unfortunately, none of these interventions led to lasting improvement. This left the patient, facing a life of severely reduced vision, and with very limited treatment options available to him.

The Ophthalmologist decided to explore a conjunctival transplantation as a next step. This is meant to protect a damaged corneal surface and promote healing by covering it with conjunctival tissue. Normally, this would be attempted with the patient's own conjunctiva by means of mobilising and moving it over the cornea. However, due to the poor condition of the patient's own tissue, this option was not available. The Ophthalmologist had even investigated the potential for a close relative of the patient to donate conjunctiva as a living donor, such was the level of the patient's need and the innovative nature of the concept of deceased donation. Having considered all circumstances and options, the preferred option was to perform a ground-breaking deceased donor conjunctival allotransplant.

**Collaboration to Save a Patients' Sight**

TES and other UK eye banks do not currently supply conjunctival tissue for clinical use therefore a bespoke arrangement needed to be made. Consideration was given to facilitating the donation and processing of conjunctiva as a specialist graft, however the training and regulatory requirements meant that we could not do this in the timeframe.

Following discussions, TES made the decision to collaborate with the Venice Eye Bank who could supply conjunctival tissue for a specific request. This bespoke order would require collaboration at all levels in the process to deliver the tissue the patient so desperately needed. Following detailed discussions, the team in Venice confirmed they would be able to provide the tissue and agreed to export the tissue on behalf of TES directly to the eye hospital. This required the Venice Eye Bank to modify their donation procedure specifically to meet this request.

Gaining appropriate regulatory permissions for the import required a pan-NHSBT effort. Quality Assurance (QA) assisted TES colleagues in discussions with the Human Tissue Authority (HTA) to confirm that due to the urgent patient need the conjunctival tissue could be imported on the TES HTA licence. This was agreed and it was determined that the tissue met the requirements of the EU Directive for Cells and Tissues. Approval was sought, and obtained, from the Italian Minister for Health to allow the Tissue to be exported, yet another example of the partnership working and commitment to patient care of both NHSBT and Venice Eye Bank.

### **A Ground-breaking Transplant**

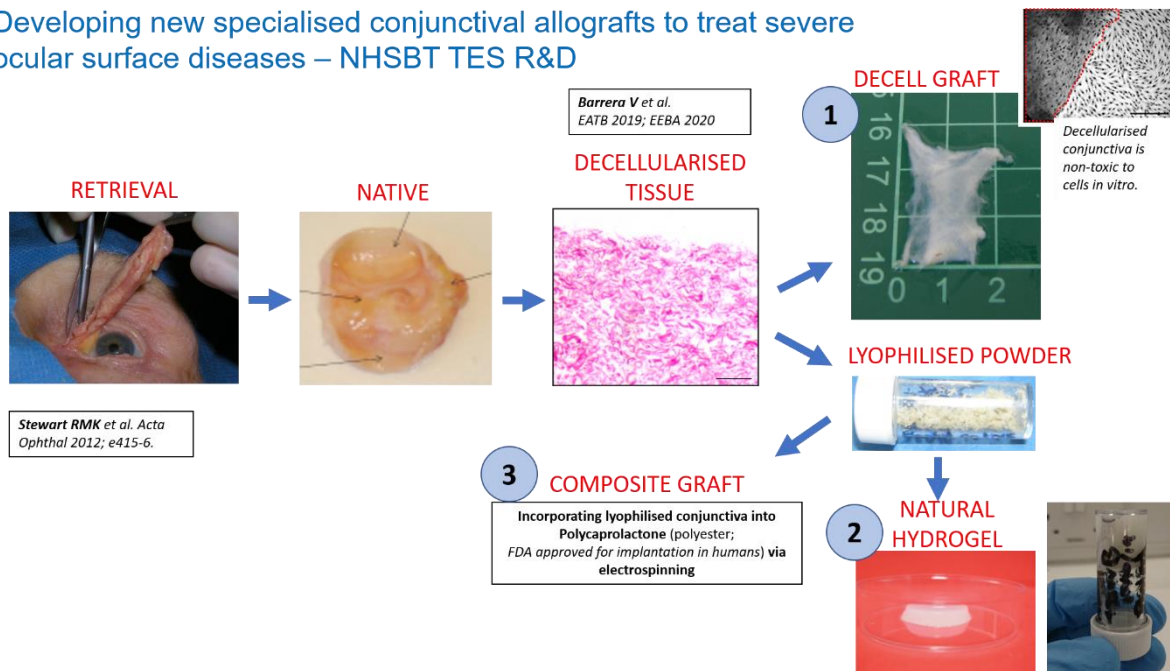
The tissue was couriered in hypothermic (2-8 °C) conditions and the globe with the conjunctival tissue was received at the eye hospital, with the transplant taking place later that day. The surgeon spent several hours carefully undertaking a challenging dissection of the conjunctival tissue, and then transplanting it under the patient's own conjunctiva and over the patient's cornea.

The aim is for the graft to provide a biological surface to protect and nourish the patient's corneal surface cells and ultimately promote healing. The patient went home after this very unusual procedure and is now followed up as an outpatient. Following these operations the vision is initially very poor, but as the conjunctival tissue thins and a more organised blood supply grows, the vision slowly improves often to a functional level. The patient has been on immunosuppressant medication for some time for the underlying condition, which should reduce the risk of allograft rejection. The result is the patient has an opportunity for improved vision and quality of life and, even while current vision has not significantly improved, the patient has the immeasurable benefit of hope for the future.

### **Looking to the future**

The TES R&D team have undertaken a survey and identified surgeons' interest in conjunctival grafts for a range of ocular surface disorders. Several different ways of presenting conjunctival grafts for transplant might become available, such as fresh, freeze-dried, decellularised, as well as further developments such as gels. This might allow adaptation of graft options for specific ocular conditions, availability of off-the-shelf products and facilitation of patient treatment earlier in the course of their disease. As one of the largest Eye Banks in the world and with a specialist team with a proven track record in innovating to improve patient care, such as serum eye drops, TES is considering the potential to extend services into this area, improving lives, enhancing NHSBT's national and international reputation and creating a product base capable of supporting patient needs into the future.

## Developing new specialised conjunctival allografts to treat severe ocular surface diseases – NHSBT TES R&D



Slide kindly provided by Dr V. Barrera, Postdoctoral Research Scientist, Tissue and Eye Services R&D.

### Acknowledgements

We would like to thank all our colleagues who collaborated with us to make this transplant possible and in particular Dr Diego Ponzin and Mr Gary Jones of the Veneto Eye Bank Foundation, Dr Valentina Barrera in the TES R&D team and Dr Helen Belfield, NHSBT QA.

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