THE UNIVERSITY OF MELBOURNE

UOM COMMERCIAL LTD

A novel polymer for repairing corneal tissue

- A fully synthetic hydrogel film that supports regeneration and transplantation of corneal endothelial cells.
- The film is biodegradable and biocompatible, with no immune or other adverse reactions
- Its tensile properties makes it easy to manipulate during surgery
- Greater control during fabrication and processing; No risk of disease transmission

Background

▪Damage of the cornea endothelial cell (CEC) requires cornea transplants to restore vision. The endothelial cells can be damaged by: aging, inherited diseases (such as Fuchs' Corneal Dystrophy), trauma or previous intraocular surgery.

▪Severe cases require transplantation of the whole cornea, whereas some cases require the partial transplants where only the endothelial layer is replaced with the endothelial layer of a donor (Descemet's Stripping Endothelial Keratoplasty -DSEK).

Problems with cornea transplants:

- Cornea donors are becoming scarce due to the increasing number of patients.
- The transplants also carry rejection risks.

▪An **autologous transplant** of the endothelial layer would be ideal to overcome these problems.

Corneal autologous transplant approach

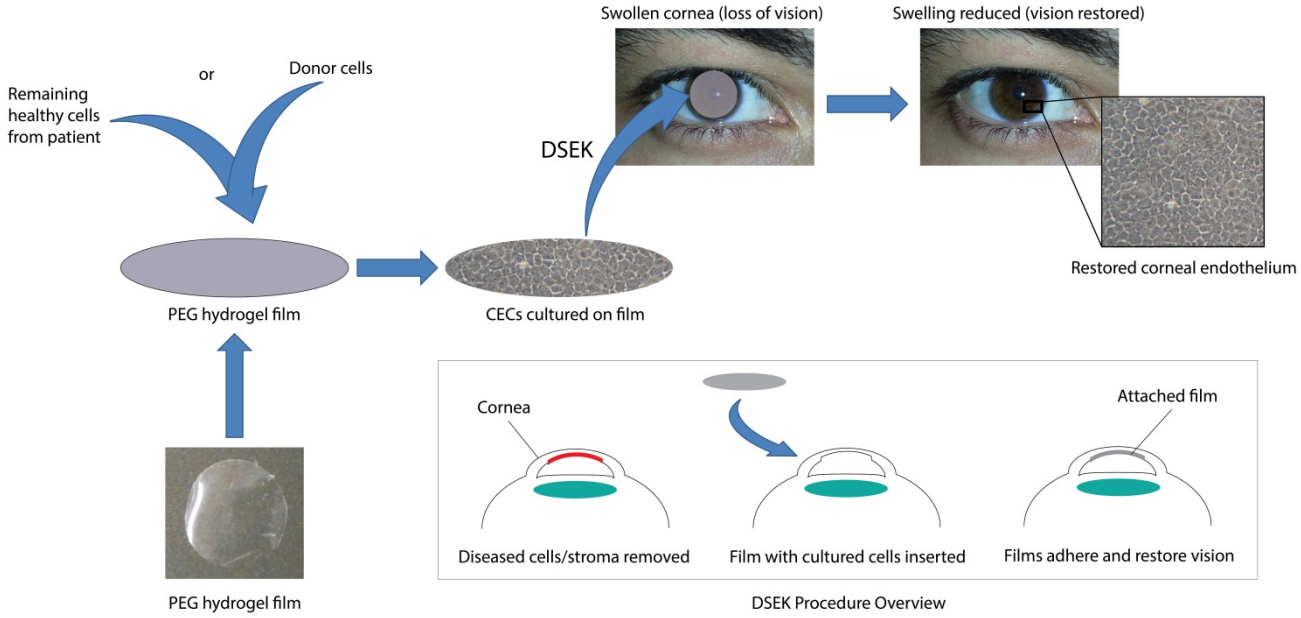
This comprises:

1. Tissue Engineering Corneal Endothelium (**TECE**): Growing corneal endothelium *in vitro* from patient's own cells using a **synthetic carrier** as a support
2. Implanting the **engineered tissue (**grown on the **synthetic carrier)** in the eye via a DSEK procedure.

A novel substrate for TECE

Researchers at The University of Melbourne have developed a material with the appropriate features to repair corneal tissue using TECE:

- Synthetic; does not use animal products
- Biodegradable, minimally inflammatory and non-toxic
- Supports the attachment and proliferation of CECs
- Mechanically robust for easy handling
- 50 µm in thickness



A model for autologous corneal endothelium implants using this novel biodegradable polymer film as carrier

The University of Melbourne is one of Australia's foremost research and teaching institutions, with strengths in human and veterinary medicines, fundamental science and advanced materials science, engineering, information and communications sciences, animal and plant biotechnology.

The University has a very successful record of technology commercialisation and transfer through wide research linkages, licensing arrangements and start-up companies.

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The Science

Scientists at The University of Melbourne have developed a novel PEG-based synthetic hydrogel film that supports regeneration of a number of different cell types, including corneal endothelial cells isolated from small biopsies of healthy tissue. This opens the possibility to grow a patient's own cells in-vitro to replace damaged tissue without the need of organ donors.

The polymer film has been tested in an ovine model of corneal endothelial loss. Cells from healthy corneas were grown in the lab on this novel polymer hydrogel film, and implanted on sheep eyes that have been stripped of their endothelium.

The research shows that these Tissue Engineered Corneal Endothelium cells can be implanted by standard surgical methods, and once implanted onto the damaged area abate stromal oedema and maintain corneal clarity.

The hydrogel film is degraded after 50 days, leaving no sign of adverse reactions or toxicity.

Benefits of this novel polymer

-Eliminates the need for cornea donors (sourced from cadavers).

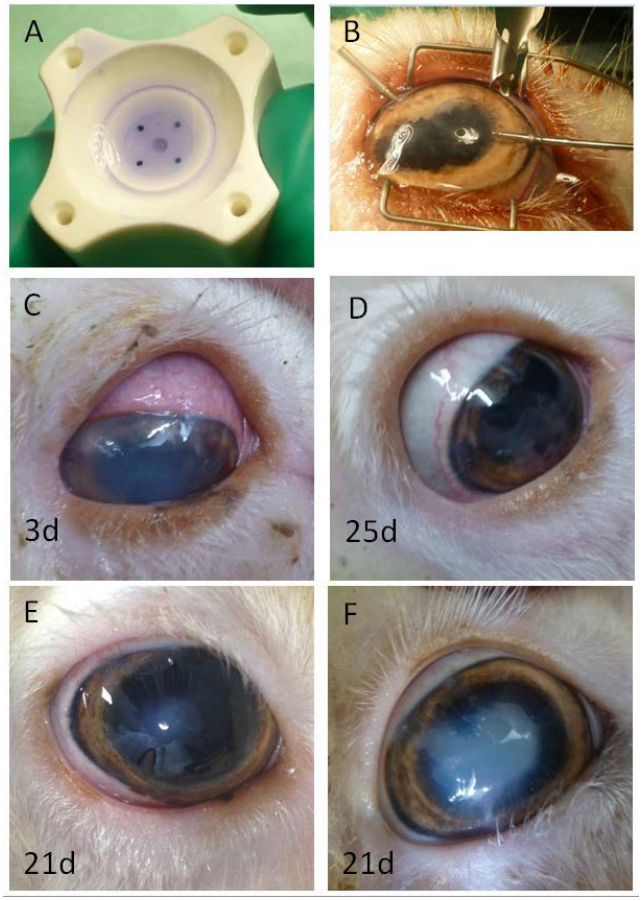
-Lowers the risk of patients requiring a second transplant due to tissue rejection (currently 10%).

-Eliminates the need for immunosuppression treatment.

Intellectual Property

Patent protection: The hydrogel film is the subject of a composition of matter and method of synthesis patent application.

PCT patent application PCT/AU2014/000391, filed on 10 April 2014.



Implantation of Tissue Engineered Corneal Endothelium in sheep eyes after manual stripping of CECs.
A) TECE grown and cut to 7.5mm diameter before insertion.
B) Insertion is as for the DSEK technique.
C) Treated eye from the same animal at 3 days post-surgery
D) Treated eye from the same animal at 25 days
E) Treated eye from a second animal at 25 days
F) A third animal with TECE negative control eye with oedema at 21d

To explore this license or evaluation opportunity, please contact:

Dr Ernesto Vargas

UoM Commercial Ltd
205-211 Grattan Street, Carlton VIC 3053 Australia
phone: +61 3 83443073 **fax:** +61 3 9347 5888 **email:** e.vargas@unimelb.edu.au

www.commercial.unimelb.edu.au