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Challenges In Manufacturing An Amnion Alternative For Corneal Regeneration

S.L. Wilson, A Hopkinson

Division of Ophthalmology in Visual Sciences, University of Nottingham, Queen's Medical Centre, NG7 2UH, UK

The current worldwide cornea shortages have led to the development of feasible, long-term substitutes to cadaveric donor tissue. Amniotic membrane is a clinically successful material used to reconstruct damaged corneal surfaces. However, its reliance upon the host tissue, availability, donor variation, infection risks and the fact that it is currently unsuitable for complete corneal regeneration have warranted the need for alternative solutions. Alternatives in current clinical or pre-clinical development include keratoprotheses, tissue engineered constructs, xenografts and the use of acellular matrices.

With respect to corneal regeneration, there are many challenges, not least that the corneal structure is unique and difficult to replicate. When manufacturing corneal tissues, the choice of material is vital as the list of requirements is extensive. They must be biocompatible, (preferably) optically transparent, flexible, and strong, as to withstand manipulation in culture, potential suturing, irrigation and handling during surgery. Manufacturing process need to be simple and consistent, preferably at high speed and low cost.

Two fundamental objectives of corneal regeneration are the maintenance of healthy cell phenotypes and the replication of the native tissue architecture. If both factors are not satisfied, the result is often regenerated tissue mimicking that of scarred native tissue.