



## PROJECT SUMMARY

The NIHR Trauma Management MedTech Co-operative (NIHR Trauma MIC) collaborated with NuVision on the development of Omnigen® and OmniLenz® a unique, transportable biological matrix which can be utilised as an effective regenerative biotherapy for a range of wounds, in particular ocular surface trauma.

## CLINICAL NEED

There are 2 million corneal trauma cases globally each year. In the UK over 12,000 corneal injury cases are admitted to A&E annually, with 890,000 cases across Europe. Ocular trauma and corneal ulceration are significant causes of corneal blindness and are responsible for 1.5-2.0 million cases of monocular blindness every year (*Bulletin of the World Health Organisation, 2001*). Approximately half of all patients who present to an eye casualty department have suffered from ocular trauma.

Eye trauma is also a significant consequence of military conflict; 13% of all ground war injuries experienced by the British military are ocular related. Despite this, the military still does not have access to any dedicated emergency treatment interventions for injured eyes.

Amniotic membrane (amnion) is normally considered a waste product of birth, but via elective caesarean it can be collected intact under aseptic surgical conditions and reprocessed into an alternative transplant therapy. As a natural product, it contains a multitude of regenerative factors associated with tissue repair.

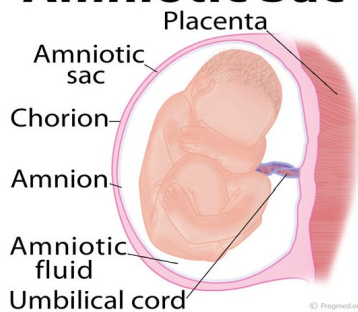
Amnion is backed with 80 years' of anecdotal clinical evidence as a highly versatile biocompatible surgical adjunct and biological dressings for burned skin, wounds and leg ulcers.

Amnion is currently widely used in ophthalmic surgery to treat disease and damage to the surface of the eye. It acts as an excellent scaffold for cell growth, facilitating epithelial wound healing and exerting anti-inflammatory, antiangiogenic, antifibrotic and antimicrobial effects. These characteristics, combined with high transparency, has made amnion ideally suited for application in ocular surface regeneration and healing.

Unfortunately the clinical usage of amnion has been severely constrained and is not readily available on demand within hospitals, especially in the treatment of an emergency eye injury case. Current treatments are still focused predominantly on chronic and reactive treatment interventions for eye conditions, rather than as a preventative strategy. The only existing amnion products in the UK are stored for clinical use via cryo-preservation at -80°C. The freezing process is known to damage the tissue and strip important trophic factors contained within the membrane, potentially compromising the regenerative function and clinical benefit. Freezing the tissue also requires heavily regulated and costly cold chain storage and logistics, increasing the complexity of storing amnion within hospitals.

Amnion can only be distributed for scheduled surgery once specially ordered on a named patient basis, taking up to 24 hours for delivery. Once delivered it has a shelf life of 48 hours

## Amniotic Sac



before it is discarded if unused. These limitations greatly restrict end-user access for scheduled surgery and as a result the market potential is massively under served with amnion not accessible as an emergency medicine for the routine treatment of acute ocular surface trauma injuries.

## THE SOLUTION

Ophthalmologists and traumatologists rarely have access to sight saving regenerative therapies in the hospital at the critical 'point of care' time. NuVision has noted this limitation and devised Omnigen®, an immediately accessible dry amnion-derived product that will have much greater utility and uptake, making amnion a realistic proposition for adoption by ophthalmic surgeons and onwards into emergency medicine. As Omnigen® is dry and contains no viable cells, the product can be stored at room temperature (25°C), and is ready to use once the sterile pack is opened. The ability to harness amnion as a stocked product means Omnigen® can be routinely accessed in emergency situations.

A range of pre-cut sizes of Omnigen® speeds up the treatment process. The treatment process has been simplified further with the development of OmniLenz®, bespoke contact lenses which secure Omnigen® to the ocular surface easily and comfortably. The simplicity also means that clinicians can train non-surgical healthcare professionals to apply OmniLenz® to patients during busy time periods or emergency situations.



## HOW WE SUPPORTED

The NIHR Trauma MIC assisted NuVision with numerous grant applications, helping to secure funding for an applicator prototype and for EU device approval. Assistance is currently being provided to help secure funding for a three year multi-centre randomised controlled trial (RCT). The associated data will be collated and published within clinical journals.

## OUTCOMES

Since launching in April 2016, NuVision has delivered around 2400 Omnigen® treatments to help save the sight of human and animal patients throughout the UK and internationally.