New and emerging treatments for corneal disorders

Nearly 5,000 people were diagnosed with corneal disorders in England during 2014. Corneal disorders, such as corneal dystrophies, advanced keratoconus, keratitis and corneal neovascularisation, can cause severe sight loss and be difficult to treat, potentially requiring a corneal transplant. The UK transplant registry recorded 3,789 donor corneal transplants in 2015-2016. Of those with a reported disorder, around one third were performed for sight loss due to corneal endothelial dysfunction, while regrafts, corneal ectasias, and corneal oedema post-cataract surgery accounted for a further fifth each. Donor corneas for transplant are limited, and transplants require life-long immunosuppression, therefore other treatment options are needed.

Current treatments for less severe corneal disorders include lubricants, corticosteroids, autologous serum and mechanical or laser removal of the outer layer of the cornea for abrasions and erosion; contact lenses, laser surgery or intrastromal corneal implants for corneal astigmatism; antibiotics, antifungals, antivirals and amoebicides for infectious keratitis; and allogeneic limbal stem cell transplants for limbal stem cell deficiency.

We searched a wide range of sources of intelligence to identify new and emerging treatments for corneal disorders, including: bibliographical databases; clinical trial registries; research funding databases; commercial pharmaceutical and medical technology databases; licensing bodies; industry news sites; ophthalmology groups and networks; horizon scanning databases; professional conference proceedings; and regulatory authorities. Technology developers were contacted where more information was required. We engaged an expert group, and the charity Fight for Sight convened two patient focus groups, to assess the innovation, impact, barriers to adoption and evidence base of the technologies identified.

Findings and therapeutic approach

One hundred and thirty technologies and procedures were identified: 28 cellular and biological therapies; 23 devices; 30 pharmaceuticals; and 49 procedures (Figure 1). Most developments were in clinical trials or reported as case studies. Tissue and stem cell (biological) therapies were predominately in development for severe corneal damage with resulting deficiency in corneal stem cells, persistent corneal damage, or corneal perforation. Devices included artificial corneas for transplant, scleral contact lenses and intraocular implants for astigmatism, as well as devices to perform non-invasive keratoplasty. Most drugs were in development for infection, symptom relief (e.g. inflammation), or were synthetic endogenous biological molecules to accelerate healing. Many developmental procedures were identified for disorders like astigmatisms (e.g. keratoconus and other
corneal ectasia) and endothelial disorders (e.g. Fuch’s endothelial dystrophy), including advances in cross linking, novel keratectomies and partial thickness corneal transplants.

![Diagram showing number of developments by technology type and indication group]

**Figure 1: Number of developments by technology type and indication group**

Of the 130 technologies identified, only 33 were being developed by a commercial developer, the remaining 97 were in development by an academic institution or a hospital, of which only 31 were in development in Europe. This means that many of the identified technologies are unlikely to become part of NHS care in the short to medium term, even though the patient focus groups and expert group determined them to be innovative and, in some cases, a much needed treatment option. In addition, some may fail to materialise if early results from clinical trials are not promising.

**Conclusions**

Although there are many technologies and procedures in development for the treatment of keratoconus and other corneal ectasia, emerging treatments for endothelial diseases, graft failure, and oedema post-cataract surgery appear to be lacking, even though these are the leading causes of sight loss in corneal disorders and the main indications for corneal transplant. In addition, many of the developments identified during this review were in not in European clinical trials, which may delay their adoption in the UK.

For further details of the technologies we identified and references, please read the full NIHR HSRIC report which is free to download.