NICE National Institute for Health and Care Excellence

NICE guidance

Tissue-cultured limbal stem cell allograft transplantation for regrowth of corneal epithelium

HealthTech guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG216.

1 Recommendations

1.1 Current evidence on the safety and efficacy of tissue-cultured limbal stem cell allograft transplantation for regrowth of corneal epithelium does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to use tissue-cultured limbal stem cell allograft transplantation for regrowth of corneal epithelium should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having tissue-cultured limbal stem cell allograft transplantation for regrowth of corneal epithelium (see NICE's interventional procedures outcomes audit tool).

1.3 Further research on long-term outcomes and the risks and benefits of long-term systemic immunosuppressant regimes would be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 The procedure is used to treat limbal stem cell deficiency (LSCD). The limbus is the part of the eye where the cornea joins the sclera, and where the conjunctiva, which covers the sclera, ends. Undifferentiated epithelial cells are produced at the limbus and differentiate to become corneal epithelial cells. Failure of this process can result in a variety of serious and intractable disorders of the ocular surface, including loss of corneal transparency which impairs vision. Limbal stem cells may be damaged by various disease processes or chemical injury.

2.1.2 The aim of treatment is to restore a healthy conjunctival and corneal surface. Simple treatments include topical steroids, ocular lubricants, bandage contact lenses and autologous serum. Patients with more serious LSCD may require surgical procedures such as conjunctival and keratolimbal allografts, possibly followed by corneal grafts. For patients with unilateral LSCD, the use of limbal stem cells from the fellow eye may be enhanced by tissue culture prior to grafting.

2.2 Outline of the procedure

2.2.1 Stem cells for allograft transplantation are harvested from the limbal corneal tissue of donor eyes (from either matched living relatives or cadaveric donors). The donor stem cells are obtained by excising a small area of the conjunctiva at the limbus, which is a minor procedure for the living donor. The tissue obtained is grown in culture and, once the cells have multiplied sufficiently, small sheets of cells, supported by an amniotic membrane or plastic, are transplanted onto the affected eye(s). The surgery is performed under local or general anaesthesia. A protective soft contact lens may be applied, and the eye is kept moist with artificial tears in the period immediately after surgery. The procedure can be repeated if necessary.

2.2.2 Systemic immunosuppressants are required to minimise the risk of graft rejection. The duration, type and dose of immunosuppressants vary and long-term use may be necessary.

2.3 Efficacy

2.3.1 Most studies reported efficacy outcomes relating to resolution of LSCD in terms of corneal re-epithelialisation and/or resolution of corneal vascularisation, corneal conjunctivilisation, inflammation/scarring, pain, photophobia and corneal opacity. Definitions of success varied between studies. Resolution of LSCD was achieved following tissue-cultured limbal stem cell transplantation in between 70% (7 out of 10) and 100% (4 out of 4, 7 out of 7, and 13 out of 13) of eyes.

2.3.2 In one case series, complete epithelialisation of the corneal surface was achieved in 80% (8 out of 10) of eyes by the time the amniotic membrane had dispersed. In another series, corneal epithelialisation was achieved in 46% (6 out of 13) of eyes at final follow-up (length of follow-up not stated). In a case series of 10 patients, corneal epithelialisation was incomplete; corneal epithelial defects (one of them persistent) were reported in 2 patients. In another case series of seven patients there were two transient epithelial defects which resolved after 2 to 3 weeks with topical antibiotic treatment.

2.3.3 The case series reported visual acuity following tissue-cultured limbal stem cell allograft transplantation in 40% (4 out of 10), 77% (10 out of 13) and 100% (7 out of 7) of eyes, although concomitant surgery to improve vision was undertaken in some patients. For more details, see the overview.

2.3.4 The Specialist Advisers stated that if the graft works well, the procedure is highly effective in producing visual benefit.

2.4 Safety

2.4.1 Bacterial infection following tissue-cultured limbal stem cell allograft transplantation occurred in 8% (1 out of 13), 15% (2 out of 13) and 25% (1 out of

4) of eyes. In one case series, corneal perforation occurred in 31% (4 out of 13) of eyes.

2.4.2 Post-procedural development of glaucoma requiring trabeculotomy was reported in 8% (1 out of 13) of eyes in one case series (follow-up not stated). One case series of seven patients with between 6 and 20 months follow up reported no significant postoperative complications. For more details, see the overview.

2.4.3 The Specialist Advisers stated that theoretical risks include transmission of infection by donor tissue and rejection of the graft. They also raised the theoretical possibility of subsequent limbal stem cell failure in the donor, requiring treatment at a later date.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 216 has been migrated to HealthTech guidance 139. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.