

Corneal endothelial transplantation

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg304

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.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of corneal endothelial transplantation (also known as endothelial keratoplasty [EK]) is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and consent.
- 1.2 NHS Blood and Transplant (formerly UK Transplant) runs a corneal transplant register, and clinicians should submit details about all patients undergoing corneal endothelial transplantation to this register.
- 1.3 The procedure should only be carried out by surgeons with specific training in this technique.
- 1.4 NICE encourages publication of long-term outcomes from register or research data.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 The corneal endothelium is a single layer of cells comprising the cornea's innermost layer. It helps maintain corneal transparency by removing excess fluid. Endothelial dysfunction leads to corneal clouding, resulting in visual impairment. Common causes of corneal endothelial dysfunction are Fuchs' dystrophy (a genetic disorder) and degeneration (bullous keratopathy). Other causes are trauma, infection and iatrogenic damage.

- 2.1.2 Current surgical treatment for corneal endothelial disease is penetrating keratoplasty (PK; whole cornea transplantation), which requires multiple sutures to anchor the donor cornea in the recipient eye.

2.2 Outline of the procedure

- 2.2.1 Corneal endothelial transplantation uses a range of techniques to replace diseased corneal endothelium with a cadaveric donor endothelial graft, while retaining healthy portions of the patient's cornea. It may be performed under local or general anaesthesia. A scleral incision is made and an anterior chamber tunnel created. The diseased endothelium is dissected from the cornea and donor endothelial graft inserted through the scleral incision and placed against the posterior aspect of the host cornea.
- 2.2.2 Topical and/or systemic antibiotics, steroids and immunosuppressants are often prescribed after surgery.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 2.3.1 A randomised controlled trial (RCT) of 28 eyes reported significant improvement in mean uncorrected visual acuity (UCVA) in 13 endothelial keratoplasty (EK)-treated eyes, from 0.81 (standard deviation [SD] 0.19) to 0.60 (SD 0.20) at 6-month follow-up ($p=0.01$). In 15 PK-treated eyes, no significant UCVA improvement from baseline was reported at 6-month follow-up (0.94 [SD 0.38] to 0.87 [SD 0.30]; significance not stated). A non-randomised comparative study of 177 eyes (129 EK-treated) reported significantly better UCVA after EK than after PK at 15-month follow-up ($p=0.05$), without significant difference in contrast sensitivity between the groups (median follow-up 12 months).
- 2.3.2 The non-randomised comparative study of 177 eyes reported that the

astigmatism incidence was significantly lower after EK than after PK ($p < 0.0001$; mean follow-up 15 months).

- 2.3.3 A registry reported significantly different 1-year graft survival rates of 77% (95% confidence interval [CI] 63 to 86) and 98% (95% CI 91 to 99) among 75 EK- and 88 PK-treated patients with Fuchs' dystrophy, respectively ($p = 0.0002$). Significantly different 1-year graft survival rates of 79% (95% CI 65 to 88) and 88% (95% CI 75 to 94) were reported among 55 and 76 EK- and PK-treated patients with pseudophakic bullous keratopathy, respectively ($p = 0.04$).
- 2.3.4 Specialist Advisers listed key efficacy outcomes as UCVA, visual rehabilitation speed, and quality of life measures such as the Visual Function Index (VF-14) score.

2.4 Safety

- 2.4.1 Two case series and an RCT of 100, 118 and 28 eyes (13 EK-treated) reported PK conversion in 2% (2 out of 100), 9% (11 out of 118) and 19% (3 out of 16) of procedures planned as EK.
- 2.4.2 The studies of 100, 118 and 28 eyes reported need for repeat EK in 2% (2/98), 8% (10 out of 118) and 8% (1 out of 13) of eyes.
- 2.4.3 A non-randomised comparative study of 907 eyes (199 EK-treated) reported significantly lower graft rejection rates for EK (8% [15 out of 199]) than for PK (13% [92 out of 708]) at 2-year follow-up ($p = 0.04$). The non-randomised comparative study of 907 eyes also reported that graft failure after rejection was lower for EK (7% [1 out of 15]) than for PK (28% [26 out of 92]; $p = 0.063$). A non-randomised comparative study of 177 eyes (129 EK-treated) reported no significant difference between EK and PK in graft rejection ($p = 0.78$) or primary graft failure ($p = 0.91$) rates (mean follow-up 15 months).
- 2.4.4 The non-randomised comparative study of 177 eyes reported that graft dislocation was significantly more common after EK than after PK ($p = 0.0004$).
- 2.4.5 In a case series of 263 EK-treated eyes, cumulative endothelial cell loss (not

otherwise defined) in a subset of 34 eyes with 2-year follow-up was 34% at 6 months, 36% at 12 months, and 41% at 24 months.

- 2.4.6 A case series of 118 EK-treated eyes (41 with concomitant cataract surgery) reported retinal detachment in 4% (5 out of 118) of patients (sequelae and follow-up not described).
- 2.4.7 The Specialist Advisers listed adverse events reported in the literature or anecdotally as graft dislocation, graft failure and rejection, interface opacification, and loss of BSCVA (best spectacle-corrected visual acuity).

2.5 Other comments

- 2.5.1 The Committee noted that UK Transplant Register data show lower graft survival rates after EK than after PK. The difference in graft survival between the two procedures is narrowing with increased experience in EK use. Endothelial keratoplasty can be repeated, while PK revision is more difficult. The Committee therefore felt that the current evidence on efficacy of the procedure was adequate, provided that thorough data collection continues, to allow future review of outcomes.
- 2.5.2 The Committee noted that the techniques for this procedure continue to evolve.
- 2.5.3 Anterior eye procedures are classified as having a medium risk of Creutzfeldt-Jakob disease (CJD) transmission.

3 Further information

- 3.1 NICE has published [interventional procedures guidance on reducing the risk of transmission of CJD from surgical instruments used for interventional procedures on high-risk tissues](#).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).