

Corneal endothelial transplantation

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 (www.nhsbt.nhs.uk).
- 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.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at www.nice.org.uk/IP715overview

2.3 Efficacy

- 2.3.1 A randomised controlled trial (RCT) of 28 eyes reported significant improvement in mean uncorrected visual acuity (UCVA) in 13 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

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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% (2/100), 9% (11/118) and 19% (3/16) 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% (10/118) and 8% (1/13) 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% [15/199]) than for PK (13% [92/708]) 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% [1/15]) than for PK (28% [26/92]) ($p = 0.063$). 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% (5/118) 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 patient safety and reduction of risk of transmission of CJD via interventional procedures (www.nice.org.uk/IPG196).

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/IPG304publicinfo. A large print version is also available.

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1887 for this guidance, N1888 for the 'Understanding NICE guidance' or N1893 for the large print version of 'Understanding NICE guidance'.

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