NICE guidance

Corneal implants for keratoconus

Interventional procedures guidance
Published: 25 July 2007

www.nice.org.uk/guidance/ipg227

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 implants for keratoconus appears adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance.

2 The procedure

2.1 Indications

2.1.1 Keratoconus is a progressive disease in which the normal cornea becomes more irregular in shape over time resulting in astigmatism, and can progress to a stage where the cornea becomes thinner and begins to bulge into a cone-like shape.

2.1.2 This procedure can also be used for pellucid marginal degeneration: a non-inflammatory, peripheral corneal thinning disorder characterised by the erosion of the peripheral band of the inferior cornea.

2.1.3 In mild to moderate keratoconus, spectacles or a range of contact lenses may help as well as treatment with riboflavin eye drops. In more severe disease, penetrating or deep lamellar keratoplasty corneal grafting (transplantation) to restore the normal corneal shape may be required.

2.2 Outline of the procedure

2.2.1 Corneal implants are flexible, crescent-shaped rings of polymethyl methacrylate

that are placed in the periphery of the cornea. They affect refraction in the eye by physically changing the shape of the cornea, flattening the front of the eye, and so correcting the irregular corneal shape.

2.2.2 The procedure is undertaken under local or general anaesthesia. An incision is made in the cornea and channels are created in it by rotating a lamellar dissector or by using a femtosecond laser. One corneal implant segment is introduced to each channel. Various implants with a range of implant thicknesses are available for different degrees of correction.

2.2.3 If required, the implant can be removed at a later date.

2.3 Efficacy

2.3.1 Most efficacy data outcomes reported in the literature were up to 12 months' follow-up.

2.3.2 One case series (n=34 eyes) reported that best spectacle-corrected visual acuity (BSCVA) improved significantly from baseline to 6 months after insertion of corneal ring implants: 62% of eyes gained two to eight lines, 32% had no change and 6% lost two or more lines ($p<0.001$). An uncorrected visual acuity (UCVA) score of 20 out of 40 or more was recorded in 24% (8 out of 34) of eyes at 12-month follow-up, compared with 4% (2 out of 53) of eyes at baseline ($p<0.001$).

2.3.3 A second case series reported that UCVA had improved by two lines or more in 72% (53 out of 74) of eyes, and BSCVA had improved by two lines or more in 45% (33 out of 74) of eyes at 9-month follow-up (p values not reported). A third case series of 31 eyes reported that BSCVA had improved by two lines or more in 87% (27 out of 31) of eyes and UCVA had improved by the same amount in 81% (25 out of 31) of eyes at 12-month follow-up (p values not reported).

2.3.4 In one case series of 51 eyes, the mean refractive astigmatism decreased from 3.69±2.20 D (dioptres) at baseline to 2.21±1.96 D after surgery ($p<0.01$) (duration of follow-up not stated). A second case series of 13 eyes treated with corneal ring implants reported that mean corneal curvature improved from 48.46±3.72 D

at baseline to 45.32±3.01 D at 6-month follow-up, although this was not sustained at 3-year follow-up (47.00±3.57 D). A third case series of 100 eyes reported that mean corneal curvature improved from 50.1±5.6 D at baseline to 46.6±5.3 D at 1 year and 46.8±4.9 at 2 years ($p<0.001$ for both).

2.3.5 In one case series of 13 eyes with 3-year follow-up, all patients who were contact lens intolerant at baseline were able to wear a contact lens after surgery as a result of the change in corneal shape. For more details, see the overview.

2.3.6 The Specialist Advisers considered that the procedure aims to reduce astigmatism in keratoconus and reduce the need for corneal transplant, with a rapid recovery time and little ocular morbidity. They noted that it is performed in an attempt to delay corneal transplantation. However, there is some variation of effect from patient to patient and in advanced cases of keratoconus the effect on refraction may be too small to be useful.

2.4 Safety

2.4.1 One case series of 57 eyes reported that there were no intraoperative complications or clinically significant postoperative complications. In another case series, creation of a superficial channel perforated the Bowman's layer in 1% (1 out of 74) of eyes, although the implant was able to be successfully refitted.

2.4.2 In four studies, implant segment extrusion occurred in 0% (0 out of 58), 1% (1 out of 74), 14% (5 out of 36) and 20% (10 out of 51) of eyes. Bacterial infection following corneal implant procedures occurred in 0%, 0%, 3% and 2% of eyes, respectively.

2.4.3 A feeling of discomfort persisted in 2% (1 out of 57) of eyes in one study, and chronic foreign body sensation requiring removal of the implants occurred in 4% (3 out of 74) of eyes in another study. Corneal channel deposits were found in 31% (4 out of 13) of eyes in a third study although these did not affect visual outcome.

2.4.4 The most commonly reported visual disturbances were halos or glare which occurred in between 3% (2 out of 74) and 5% (3 out of 57) of eyes. For more

details, see the overview.

2.4.5 The Specialist Advisers noted that theoretical adverse events include occasional ring erosion and inflammation around the ring segments, intraoperative damage to the retina or optic nerve due to increased intraocular pressure, and a loss of effect over time.

2.5 Other comments

2.5.1 The Committee noted that a previous implant is unlikely to have an impact on the success of subsequent corneal implants.

3 Further information

3.1 NICE has published interventional procedures guidance on photorefractive (laser) surgery for the correction of refractive errors.

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 decision made, and has been written with patient consent in mind.

ISBN: 978-1-4731-6255-6

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.