

# Corneal implants for keratoconus

## 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 20/40 or more was recorded in 24% (8/34) of eyes at 12-month follow-up, compared with 4% (2/53) 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% (53/74) of eyes, and BSCVA had improved by two lines or more in 45% (33/74) 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% (27/31) of eyes and UCVA had improved by the same amount in 81% (25/31) of eyes at 12-month follow-up (p values not reported).

## Interventional procedure guidance 227

### This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

2.3.4 In one case series of 51 eyes, the mean refractive astigmatism decreased from  $3.69 \pm 2.20$  D (dioptres) at baseline to  $2.21 \pm 1.96$  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  $48.46 \pm 3.72$  D at baseline to  $45.32 \pm 3.01$  D at 6-month follow-up, although this was not sustained at 3-year follow-up ( $47.00 \pm 3.57$  D). A third case series of 100 eyes reported that mean corneal curvature improved from  $50.1 \pm 5.6$  D at baseline to  $46.6 \pm 5.3$  D at 1 year and  $46.8 \pm 4.9$  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, refer to the 'Sources of evidence' section.

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% (1/74) of eyes, although the implant was able to be successfully refitted.

2.4.2 In four studies, implant segment extrusion occurred in 0% (0/58), 1% (1/74), 14% (5/36) and 20% (10/51) 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% (1/57) of eyes in one study, and chronic foreign body sensation requiring removal of the implants occurred in 4% (3/74) of eyes in another study. Corneal channel deposits were found in

31% (4/13) 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% (2/74) and 5% (3/57) of eyes. For more details, refer to the 'Sources of evidence' section.

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 The Institute has published interventional procedures guidance on photorefractive (laser) surgery for the correction of refractive errors ([www.nice.org.uk/IPG164](http://www.nice.org.uk/IPG164)).

Andrew Dillon  
Chief Executive  
July 2007

## Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from [www.nice.org.uk/IPG227publicinfo](http://www.nice.org.uk/IPG227publicinfo)

## Sources of evidence

The following document, which summarises the evidence, was considered by the Interventional Procedures Advisory Committee when making its provisional recommendations.

'Interventional procedure overview of corneal implants for keratoconus', January 2007.

Available from: [www.nice.org.uk/ip391overview](http://www.nice.org.uk/ip391overview)

## Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1298. 'Understanding NICE guidance' can be obtained by quoting reference number N1299.

The distribution list for this guidance is available at [www.nice.org.uk/IPG227distributionlist](http://www.nice.org.uk/IPG227distributionlist)

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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