

Corneal implants for the correction of refractive error

1 Guidance

1.1 Current evidence on the efficacy of corneal implants for the correction of refractive error shows limited and unpredictable benefit. In addition, there are concerns about the safety of the procedure for patients with refractive error which can be corrected by other means, such as spectacles, contact lenses, or laser refractive surgery. Therefore, corneal implants should not be used for the treatment of refractive error in the absence of other ocular pathology such as keratoconus.

2 The procedure

2.1 Indications

2.1.1 Myopic refractive error occurs when light from a distant object is brought into focus in front of the retina rather than on it. Near objects are seen clearly but more distant ones are blurred. This is usually because the eye is too long, but it may be due to the cornea being too steeply curved (this is called keratoconus; NICE has produced separate guidance on the use of this procedure in keratoconus).

2.1.2 Focusing (refractive) errors are usually corrected by wearing spectacles or contact lenses, both of which correct visual acuity and are acceptable solutions for the majority of patients. In addition, surgical treatments can be used to treat myopia, including laser refractive surgery.

2.2 Outline of the procedure

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

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.

2.3 Efficacy

2.3.1 In a matched case analysis, uncorrected visual acuity (UCVA) 3 months after the procedure was reported to be 20/20 or better in 75% (58/77) of eyes receiving corneal implants and 67% (84/126) of eyes undergoing laser refractive surgery. Statistical significance was not reported.

2.3.2 In two case series, UCVA of 20/20 or better 1 year after the procedure was reported in 74% of eyes (452 patients studied, but absolute numbers not provided) and 43% (35/79) of eyes. In the latter study, 20/20 vision or better rose to 64% (27/42) at 5 years. Statistical significance was not reported.

2.3.3 In a non-randomised trial, loss of two or more lines of best spectacle-corrected visual acuity (BSCVA) was reported in 9% (7/76) of eyes treated with corneal implants compared with 1% (1/126) of laser refractive surgery-treated eyes at 3-month follow-up. In one case series, this degree of visual loss was reported in 5% (4/79) of eyes at 1-year follow-up and 7% (3/42) at 5 years. In a second case series, two lines were lost in 4% (5/138) of eyes, and more than two lines were lost in 2% (3/138) of eyes at

Interventional procedure guidance 225

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.

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

12 months. However, none of these patients requested removal of implants. No statistical significance was reported.

- 2.3.4 The proportion of eyes in which correction of vision was within 1.0 D (dioptres) of the intended correction ranged from 68% (28/42) to 100% (16/16) in two case series. In the same case series, the proportion corrected to within 0.5 D ranged from 41% (17/42) to 81% (13/16). Statistical significance was not reported.
- 2.3.5 In one study, patient satisfaction was rated 'excellent' by 47%, 'good' by 41%, 'fair' by 9%, and 'poor' by 2% of 104 patients surveyed at 1-year follow-up. For more details, refer to the 'Sources of evidence' section.
- 2.3.6 The Specialist Advisers considered the expected benefits of the procedure to be a correction of low myopia with a rapid recovery time and minimal ocular morbidity. One Specialist Adviser noted that, although there is work demonstrating the safety and efficacy of this procedure for myopia of up to -3.0 D, it has not been widely used due to the simultaneous development of laser refractive surgery. One Adviser considered that a potential consideration is loss of effect over time.

2.4 Safety

- 2.4.1 The rates of corneal perforation in the included studies were 0% (0/21), <1% (3/452), and 2% (3/163). One case series reported a single case of infectious keratitis among 452 patients treated.
- 2.4.2 Reported visual complications following the procedure included poor night vision in 5%, glare in 1%, halos in 1% of patients, and photophobia in <1% of patients (absolute numbers not reported) in a case series of 452 patients. In another case series of 104 patients, reported complications included glare in 2% (2/104), halos in 2% of patients (2/104) and photophobia in 1% (1/104) of patients.
- 2.4.3 One case report described a patient with partial extrusion of an implant following thinning of the corneal stroma at 5 years' follow-up. The implants were successfully removed and BSCVA recovered to 20/25 at 4 weeks. For more details, refer to the 'Sources of evidence' section.

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1294. 'Understanding NICE guidance' can be obtained by quoting reference number N1295.

The distribution list for this guidance is available at www.nice.org.uk/IPG225distributionlist

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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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- 2.4.4 The Specialist Advisers noted that reported adverse events include photophobia, glare, foreign body sensation, extrusion, corneal perforation and infection, all of which may lead to implant removal. Additional theoretical adverse events cited by Specialist Advisers include ring erosion, inflammation, corneal melt and damage to the retina or optic nerve through increased intraocular pressure.

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).

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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/IPG225publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of corneal implants for the correction of refractive error', November 2006.

Available from: www.nice.org.uk/ip371overview