NICE guidance

Corneal implants for the correction of refractive error

Interventional procedures guidance
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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 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 out of 77) of eyes receiving corneal implants and 67% (84 out of 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 out of 79) of eyes. In the latter study, 20/20 vision or better rose to 64% (27 out of 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 out of 76) of eyes treated with corneal implants compared with 1% (1 out of 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 out of 79) of eyes at 1-year follow-up and 7% (3 out of 42) at 5 years. In a second case series, two lines were lost in 4% (5 out of 138) of eyes, and more than two lines were lost in 2% (3 out of 138) of eyes at 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 out of 42) to 100% (16 out of 16) in two case series. In the same case series, the proportion corrected to within 0.5 D ranged from 41% (17 out of 42) to 81% (13 out of 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 a 1-year follow-up. For more details, see the overview.

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 out of 21), <1% (3 out of 452), and 2% (3 out of 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 out of 104), halos in 2% of patients (2 out of 104) and photophobia in 1% (1 out of 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 out of 25 at 4 weeks. For more details, see the overview.

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 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.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.