NICE guidance

Corneal inlay implantation for correction of presbyopia

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 The evidence for corneal inlay implantation for correction of presbyopia is limited in quantity and quality and comes predominantly from case series; there is some evidence of efficacy in the short term. In addition, there are reports that adverse effects occur frequently. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake corneal inlay implantation for correction of presbyopia should take the following actions:

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand that this is principally a cosmetic procedure that may reduce their need to wear spectacles or contact lenses. They should be made aware of other management options for presbyopia. They should be informed about the possible adverse events associated with the procedure and encouraged to balance these carefully against the expected benefits. Patients should be provided with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having corneal inlay implantation for the correction of presbyopia (see section 3.1).

1.3 Both clinicians and manufacturers are encouraged to collect details of complications and long-term outcomes following corneal inlay implantation for correction of presbyopia, and to publish their findings. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Presbyopia results from age-related deterioration of the lens in the cornea of the eye and usually begins to develop at around 40 years of age. This form of lens deterioration causes difficulty with accommodation (focusing on near objects).

2.1.2 Standard treatment for presbyopia is corrective spectacles or contact lenses. Surgery (monovision or blended-vision laser in situ keratomileusis [LASIK], or refractive lens exchange or replacement) may be considered in some patients.

2.2 Outline of the procedure

2.2.1 Corneal inlay implantation aims to improve near visual acuity and increase depth of focus. It may particularly benefit people who find it difficult to use spectacles or contact lenses, for instance, those with limited dexterity.

2.2.2 The procedure is usually performed on the non-dominant eye, under topical anaesthesia. The patient fixates their eye on a light source on a surgical microscope so that the surgeon can identify the target position on the centre of the visual axis. Laser or microkeratome techniques are used to create either a lamellar corneal flap or a pocket within the corneal stroma. The flap or pocket is separated with a spatula and a special tool is used to position the inlay within it, at the marked centre of the axis. The flap or pocket self-seals, holding the inlay in place. Patients are normally prescribed corticosteroids and antibiotic eye drops in the short term and artificial tears for as long as needed. The inlay can be removed or replaced if needed.

2.3 Efficacy

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.

2.3.1 A case series of 32 patients reported that mean uncorrected near visual acuity (UNVA) in the treated eye improved from J7/8 preoperatively to J1 at 3 years, and binocular UNVA improved from J6 to J1 ($p<0.00001$). Mean uncorrected intermediate visual acuity (UIVA) in the treated eye improved from 20/40 to 20/25 at 3 years ($p<0.00001$); binocular UIVA also improved from 20/32 to 20/20 ($p<0.001$). Mean uncorrected distance visual acuity (UDVA) in the treated eye decreased slightly from 20/16 to 20/20 at 3 years ($p<0.001$). The change in binocular UDVA was not statistically significant ($p=0.77$).

2.3.2 A case series of 39 patients reported an improvement in mean UNVA in the treated eye from 20/50 preoperatively to 20/20 in 22 patients followed up for 4 years ($p<0.001$). Mean UDVA in the treated eye changed from 20/20 to 20/25 after 4 years ($p=0.107$).

2.3.3 The case series of 32 patients reported an increase in mean reading speed per minute from 142 words before treatment to 149 words after a mean follow-up of 2 years ($p=0.029$). Mean reading distance decreased from 48.1 cm to 38.9 cm ($p<0.0001$).

2.3.4 The case series of 32 patients reported that the percentage of patients using glasses all or most of the time decreased from 88% to 6% at 3 years (absolute numbers not given).

2.3.5 A case series of 24 patients reported a mean satisfaction with the procedure of 5.0 (on a scale of 1 to 7 where higher scores show more satisfaction) at 2 years after treatment. Mean satisfaction with reduction in reading glasses was 5.3 in bright light and 3.1 in dim light, using the same scale. It was reported that 75% (18 out of 24) of patients said that they would have the procedure again, 21% (5 out of 24) were undecided and 1 patient said he would not have the procedure again (exact question not reported).

2.3.6 The Specialist Advisers listed key efficacy outcomes as improved unaided near or reading vision with maintained distance vision.

2.4 Safety

2.4.1 Removal of the inlay was reported in 4 patients in the case series of 39 patients because of a buttonhole flap (in 1 patient at 6 weeks), refractive shifts and reported glare and halos (in 2 patients after 3 months) and a thin corneal flap causing symptoms (in 1 patient after 17 months). Following removal of the inlay, visual acuity returned to pretreatment values in all 4 patients.

2.4.2 Inlays were re-centred after 6 months because of initial misplacement in 2 patients in the case series of 32 patients. Both patients' visual acuity for near, intermediate and distance improved after recentration (reported graphically).

2.4.3 Cataracts affecting visual function and needing surgical treatment developed in 5 treated eyes after 3 to 4 years in the case series of 39 patients.

2.4.4 Loss of visual acuity at 3 years was reported in 14 patients in the case series of 32 patients (2 lines of UDVA were lost by 4 patients, 1 line of corrected distance visual acuity [CDVA] was lost by 9 patients, and 3.8 lines of CDVA were lost by 1 patient).

2.4.5 Flap striae developed in 1 patient after 1 month in the case series of 32 patients, resulting in epithelial ingrowth that needed repeated flap lift and debridement and was resolved by suturing after 2 months.

2.4.6 Hyperopic shifts greater than +0.5 D were measured in 4 patients in the case series of 32 patients at 3 years' follow-up. Myopic refractive shifts were also noted in 4 patients.

2.4.7 Severe, moderate and mild halo was reported by 1, 8 and 11 patients respectively in the case series of 32 patients at 3 years. Mild or moderate halo had been reported by 3 patients before treatment. Five patients in the same study reported severe problems with night vision.

2.4.8 A significant decrease in photopic ($p<0.001$) and mesopic ($p<0.0001$) contrast sensitivity at all spatial frequencies was reported in a case series of 508 patients at 1 year after treatment.

2.4.9 Very mild edge haze around the cornea was reported at 2 years' follow-up in all the patients in a case series of 8 patients.

2.4.10 The Specialist Advisers listed additional theoretical adverse events as infectious keratitis, corneal scarring or opacification, corneal thinning and melting, difficulty measuring intraocular pressure, failure to adapt to near monovision, reduction in unaided distance vision and reduction in best spectacle-corrected distance visual acuity.

2.5 Other comments

2.5.1 The Committee recognised that although this procedure is usually undertaken for cosmetic reasons, some patients with presbyopia might be unable to use spectacles or contact lenses.

2.5.2 The Committee recognised that presbyopia is a progressive condition and therefore long-term data on efficacy and safety are important.

2.5.3 The Committee recognised that a number of inlays are available and they may differ in their efficacy, their safety and the way they work.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

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 guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.