Intraocular lens insertion for correction of refractive error, with preservation of the natural lens

Interventional procedures guidance
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nice.org.uk/guidance/ipg289

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. However, 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.

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.

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 intraocular lens (IOL) insertion for correction of refractive error, with preservation of the natural lens is available for large numbers of patients. There is good evidence of short-term safety and efficacy. However,

there is an increased risk of cataract, corneal damage or retinal detachment and there are no long-term data about this. Therefore, the procedure may be used with normal arrangements for clinical governance and audit, but with special arrangements for consent.

1.2 Clinicians wishing to undertake IOL insertion for correction of refractive error, with preservation of the natural lens should ensure that patients understand the risks of having an artificial lens implanted for visual impairment that might otherwise be corrected using spectacles or contact lenses. They should understand the possibility of cataract, corneal damage or retinal detachment, and the lack of evidence relating to long-term outcomes. Patients should be provided with clear information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.

1.3 Both clinicians and manufacturers are encouraged to collect long-term data on people who undergo IOL insertion, 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 There are several types of refractive error including myopia, hypermetropia and presbyopia.

2.1.2 Refractive errors can usually be corrected by wearing spectacles or contact lenses. Surgical treatments include photorefractive keratectomy (PRK), laser in situ keratomileusis (LASIK) and insertion of corneal implants.

2.1.3 The procedure may be indicated for people with a high degree of myopia, or those for whom wearing spectacles is difficult, for example because of a disability or professional requirements.

2.2 Outline of the procedure

2.2.1 The procedure is carried out with the patient under local anaesthesia. The pupil is dilated using topical medication, and a phakic IOL is inserted into the anterior or the posterior eye chamber via a small corneal incision. Depending on its

design, the phakic IOL is anchored to the iris, placed in the angle between the cornea and the iris, or positioned to float over the surface of the natural lens. A nylon suture is sometimes used to close the incision.

2.2.2 Several different devices can be used for this procedure.

> Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 In a randomised controlled trial (RCT) of 50 eyes (with the fellow eye as control), mean Manifest Refraction Spherical Equivalent (MRSE) was −0.95 ± 0.45 D in phakic IOL-treated eyes and −0.74 ± 0.67 D in LASIK-treated eyes at 1-year follow-up (p not significant). A non-RCT of 9239 eyes reported that mean post-procedural MRSE was −1.78 ± 2.03 D in phakic IOL-treated eyes, 0.36 ± 1.30 D in LASIK-treated eyes and −0.18 ± 0.5 D in PRK-treated eyes (level of significance not stated).

2.3.2 In a non-RCT of 769 eyes, correction to within 0.5 D of that intended was achieved in 69% (127/184) of phakic IOL-treated eyes and 57% (57/100) of LASIK-treated eyes at 1-year follow-up (p = 0.05).

2.3.3 A case series of 1140 phakic IOL-treated eyes reported that the proportion of eyes with uncorrected visual acuity (UCVA) of 20/20 or better increased from 0% (0/622) at baseline to 27% (62/231) at 3-year follow-up (significance not stated).

2.3.4 The Specialist Advisers stated that the key efficacy outcomes for this procedure include improvements in UCVA and best spectacle-corrected visual acuity (BSCVA), independence from optical aids and maintenance of quality of vision.

2.4 Safety

2.4.1 In a non-RCT of 9239 eyes, retinal detachment was reported in 4% (12/294) of phakic IOL-treated eyes, less than 1% (11/3009) of LASIK-treated eyes and less

than 1% (9/5936) of PRK-treated eyes (retinal detachments occurred after a mean of 20.5, 24.6 and 53.6 months, respectively).

2.4.2 A meta-analysis of 6338 eyes reported new-onset cataract development in 1% (15/1161) of eyes treated with angle-fixed anterior chamber IOL, less than 1% (20/2781) of eyes treated with iris-fixed anterior chamber IOL, and 9% (223/2396) of eyes treated with posterior chamber IOL (median follow-up 1 year). Anterior subcapsular cataract was reported in 2% (1/43) of toric phakic IOL-treated eyes in an RCT of 88 eyes at 2-year follow-up.

2.4.3 A case series of 399 eyes reported that explantation because of endothelial cell loss was necessary in 1% (3/399) of eyes (mean follow-up 4 years). In the same study, mean endothelial cell density decreased significantly from 2836 ± 398 cells/m^{m2} at baseline to 2791 ± 246 cells/mm^2 4 years after insertion of a phakic IOL ($p = 0.004$), and from 2755 ± 362 cells/mm^2 to 2698 ± 576 cells/mm^2 after insertion of a second type of phakic IOL at the same timepoint ($p = 0.002$).

2.4.4 A case series of 263 eyes implanted with a phakic IOL reported halo and glare symptoms in 60% (157/263) of treated eyes at 1-year follow-up (reported as 'significant' in 21% [54/263]).

2.4.5 The Specialist Advisers stated that key safety outcomes include glaucoma, loss of lines of BSCVA, reduced contrast sensitivity, night vision disturbances and the need for additional refractive surgery.

3 Further information

3.1 Clinicians must report any instances of intraocular lens removal because of adverse events to the Medicines and Healthcare products Regulatory Agency (MHRA).

3.2 NICE has published interventional procedures guidance on several procedures relating to refractive error and IOL insertion. For more information see our website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

7 January 2012: minor maintenance.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation