NICE National Institute for Health and Care Excellence

NICE guidance

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

HealthTech 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.

Contents

This guidance replaces IPG289.

1 Recommendations

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 the public 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 intraocular lens (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.

2.3 Efficacy

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.

2.3.1 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 9,239 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 out of 184) of phakic IOL-treated eyes and 57% (57 out of 100) of LASIK-treated eyes at 1-year follow-up (p=0.05).

2.3.3 A case series of 1,140 phakic IOL-treated eyes reported that the proportion of eyes with uncorrected visual acuity (UCVA) of 20/20 or better increased from 0% (0 out of 622) at baseline to 27% (62 out of 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 9,239 eyes, retinal detachment was reported in 4% (12 out of 294) of phakic IOL-treated eyes, less than 1% (11 out of 3,009) of LASIK-treated eyes and less than 1% (9 out of 5,936) 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 6,338 eyes reported new-onset cataract development in 1% (15 out of 1,161) of eyes treated with angle-fixed anterior chamber IOL, less than 1% (20 out of 2,781) of eyes treated with iris-fixed anterior chamber IOL, and 9% (223 out of 2,396) of eyes treated with posterior chamber IOL (median follow-up 1 year). Anterior subcapsular cataract was reported in 2% (1 out of 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 out of 399) of eyes (mean follow-up 4 years). In the same study, mean endothelial cell density decreased significantly from 2,836±398 cells/m^{m2} at baseline to 2,791±246 cells per mm^2 4 years after insertion of a phakic IOL (p=0.004), and from 2,755±362 cells per mm^2 to 2,698±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 out of 263) of treated eyes at 1-year follow-up (reported as 'significant' in 21% [54 out of 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).

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 289 has been migrated to HealthTech guidance 183. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.