NICE guidance

Implantation of accommodating intraocular lenses for cataract

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg209

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 suggests that there are no major safety concerns associated with the implantation of accommodating lenses for cataract. There is evidence of short-term efficacy in correcting visual acuity but there is inadequate evidence that the procedure achieves accommodation. Therefore, the procedure should not be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake implantation of accommodating lenses should take the following actions.

- Ensure that patients understand the uncertainty about the procedure's efficacy, and provide them with clear written information. In addition, use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having implantation of accommodating lenses (see section 3.1).

1.3 Publication of long-term efficacy outcomes of the procedure will be useful, particularly on the effects on accommodation. NICE will review the procedure in due course.

2 The procedure

2.1 Indications

2.1.1 A cataract is the opacification of the eye's natural lens. It usually develops over a period of time, causing a gradual deterioration in eyesight, and may eventually

lead to blindness.

2.1.2 Surgical treatment involves replacing the patient's opacified lens with an artificial lens, which is usually of fixed power (monofocal), requiring the use of reading spectacles for near vision. More recently, intraocular lenses have been developed that allow both distance and reading vision without glasses. These can be either multifocal lenses, which enable both near and distance vision by virtue of the design of the lens itself, or accommodating lenses, which move within the eye in a similar manner to the human lens. Cataract surgery is usually performed under local anaesthesia.

2.2 Outline of the procedure

2.2.1 An ultrasound probe is used to break the opacified lens into tiny pieces, which are removed through a small incision in the cornea (phacoemulsification). An accommodating lens rather than a standard intraocular lens is then inserted through the incision. The aim of the procedure is to allow the eye to focus on near as well as distant objects, reducing the need for spectacles.

2.3 Efficacy

2.3.1 Only one randomised trial reported that both the patient and the examiner were blind to which lens had been implanted. Two randomised controlled trials reported a statistically significant larger degree of accommodation with accommodating lenses than with monofocal lenses: 1.9 dioptres (D) versus 0 D ($p<0.05$), and 1.01 D versus 0.5 D ($p=0.01$).

2.3.2 Four randomised controlled trials reported significantly better distance-corrected near visual acuity for eyes with an accommodating lens than for eyes with a standard intraocular lens; follow-up ranged between 6 and 12 months. In one of these studies, the difference was statistically significant at 6 months (J9.3 versus J12.4, $p=0.004$) but not at 12 months (J11.5 versus J12.8, $p=0.1$), although the 12-month follow-up included only 67% (40 out of 60) of eyes. (Note that a larger J number means less visual acuity.) In another of these studies, 66% of eyes

(numbers not reported) with accommodating lenses had distance-corrected near visual acuity of 20/40 or better at 6 months, but this decreased to 49% of eyes at 12 months. The other two studies only reported follow-up to 6 months. No eyes with the standard intraocular lens implant achieved distance-corrected visual acuity of 20/40 or better. For more details, see the overview.

2.3.3 Two Specialist Advisers considered this procedure to be a minor variation of an existing procedure. One Specialist Adviser commented that the technology is in the early stages and that more efficacious lenses are likely to be developed in the future. The mechanism of action of accommodating lenses is unclear.

2.4 Safety

2.4.1 A non-randomised comparative study reported that after 12 months' follow-up, 13% (3 out of 24) of eyes with an accommodating lens required capsulotomy for posterior capsule opacification, compared with 25% (8 out of 32) of eyes with a multifocal lens and 29% (7 out of 24) of eyes with a bifocal lens (p value not reported). Two case series reported capsulotomy for posterior capsule opacification in 14% (37 out of 263) and 18% (12 out of 65) of eyes with an accommodating lens after mean follow-up of 12 and 23 months, respectively.

2.4.2 One randomised controlled trial of 42 eyes reported anterior and posterior capsule opacification in 86% of eyes with an accommodating lens, compared with 25% (5 out of 20) of eyes with a traditional lens (follow-up 12 months; p value not reported). Another randomised controlled trial of 42 eyes reported mild posterior capsule opacification in 21% of eyes with an accommodating lens and 22% of eyes with a monofocal lens after 6 months' follow-up (p value not reported).

2.4.3 A randomised controlled trial reported intraoperative haemorrhage in the anterior chamber in 1 of 40 eyes (3%) with an accommodating lens. A case series reported cystoid macular oedema in 4% (12 out of 324) of eyes with an accommodating lens over a 12-month follow-up period. Persistent cystoid macular oedema was reported in 1% (3 out of 304) of eyes.

2.4.4 A non-randomised controlled trial reported halos in 8% (2 out of 24) and flare, flashes or glare each in 1 of 24 eyes (4%) with an accommodating lens. Higher

rates of halos, flare and glare were reported by patients with a multifocal or bifocal lens. For more details, see the overview.

2.4.5 The Specialist Advisers listed potential adverse events as including lens decentration, posterior capsule opacification, lens or haptics buckling, development of capsular contraction syndrome and loss of quality of vision.

2.5 Other comments

2.5.1 It was noted that the evidence reviewed on this procedure relates to the treatment of cataract and not to the correction of presbyopia.

2.5.2 It was also noted that accommodating lenses are at a relatively early stage of development and that the technology is evolving rapidly.

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 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 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.