

Implantation of accommodating intraocular lenses for cataract

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 the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG209publicinfo).
 - 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. The Institute 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

Interventional procedure guidance 209

This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

12-month follow-up included only 67% (40/60) 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, refer to the 'Sources of evidence' section.

- 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% (3/24) of eyes with an accommodating lens required capsulotomy for posterior capsule opacification, compared with 25% (8/32) of eyes with a multifocal lens and 29% (7/24) of eyes with a bifocal lens (p value not reported). Two case series reported capsulotomy for posterior capsule opacification in 14% (37/263) and 18% (12/65) 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% (5/20) 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% (12/324) of eyes with an accommodating lens over a 12-month follow-up period. Persistent cystoid macular oedema was reported in 1% (3/304) of eyes.

- 2.4.4 A non-randomised controlled trial reported halos in 8% (2/24) 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, refer to the 'Sources of evidence' section.

- 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. The Institute has identified relevant audit criteria and developed an audit tool (which is for use at local discretion), available from www.nice.org.uk/IPG209

Andrew Dillon
Chief Executive
February 2007

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG209publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document: 'Interventional procedure overview of the implantation of accommodating intraocular lenses during cataract surgery', October 2006.

Available from: www.nice.org.uk/IP363overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1207. 'Understanding NICE guidance' can be obtained by quoting reference number N1208.

The distribution list for this guidance is available at www.nice.org.uk/IPG209distributionlist

Published by the National Institute for Health and Clinical Excellence, February 2007; ISBN 1-84629-371-5

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

© National Institute for Health and Clinical Excellence, February 2007. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of the Institute.