NICE guidance

Implantation of multifocal (non-accommodative) intraocular lenses during cataract surgery

Interventional procedures guidance
Published: 25 June 2008

www.nice.org.uk/guidance/ipg264

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 on the implantation of multifocal (non-accommodative) intraocular lenses (IOLs) during cataract surgery raises no major safety concerns. Current evidence on the procedure's efficacy shows that it can provide good near and distance vision without the need for spectacles, but this is at the risk of a variety of potential visual disturbances. Clinicians wishing to use multifocal (non-accommodative) IOL implants during cataract surgery should therefore do so with normal arrangements for clinical governance and audit, but with special arrangements for consent.

1.2 Clinicians wishing to undertake implantation of multifocal (non-accommodative) IOLs during cataract surgery should ensure that patients understand the risks of experiencing halos and glare, and the probability of reduced contrast sensitivity. Patients should also be made aware that lenses may be difficult to remove or replace. Patients should be provided with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Patient selection should take into account factors that may prevent patients from wearing spectacles, such as disabilities that interfere with spectacle use, because these may be additional indications for the use of multifocal lenses.

2 The procedure

2.1 Indications and current treatments

2.1.1 A cataract is the opacification of the eye's natural lens, usually causing gradual eyesight deterioration and potentially leading to blindness.

2.1.2 Current treatment involves replacing the opacified lens with an artificial lens, which is usually of fixed power (monofocal); this requires patients to use spectacles for near vision. Intraocular lenses (IOLs) have been developed that aim to give uncorrected vision (without spectacles), either because they are multifocal or because they have the capacity to change shape within the eye, in a similar manner to the native lens (accommodating lenses; see section 3.1).

2.2 Outline of the procedure

2.2.1 The surgical procedure is the same as that of a cataract operation but involves implanting a multifocal IOL. Multifocal IOLs have different areas of refractive powers, allowing near and distant objects to be focused on the retina simultaneously, with the brain selecting out the required image for attention. Various devices can be used for this procedure. Cataract surgery is usually performed under a local anaesthetic.

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 details, see the overview.

2.3.1 In a systematic review of 10 randomised controlled trials (RCTs), dependence on spectacles was reported to be 68% (316 out of 467) and 95% (383 out of 404) in multifocal and monofocal IOLs, respectively (odds ratio [OR] 0.17, 95% confidence interval [CI] 0.12 to 0.24). A non-randomised controlled trial of 280 patients

reported that 92% and 80% of patients with multifocal and monofocal IOLs, respectively, did not need spectacles in the intermediate range (p=0.004; absolute numbers not reported). A second non-randomised trial of 495 patients reported more frequent spectacle independence with multifocal IOLs compared with monofocal IOLs (80% versus 8%; p<0.0001).

2.3.2 The non-randomised controlled trial of 495 patients reported better uncorrected near visual acuity with multifocal IOLs (0.02±0.12 logMAR) than with monofocal IOLs (0.41±0.18 logMAR; p<0.0001). A further non-randomised controlled trial of 102 patients reported uncorrected distance acuity ≥20/40 and near acuity of Jaeger line 3 text ('J3') or better in 77% (78 out of 101) and 46% (46 out of 101) of patients with multifocal and monofocal IOLs, respectively (p<0.0001). A case series of 671 patients reported distance acuity ≥20/40 and near acuity of J3 or better in 50% of multifocal IOL patients in the absence of preoperative pathology and postoperative macular degeneration.

2.3.3 Two of the RCTs included in the systematic review reported a statistically significant increase in patient overall vision satisfaction with multifocal IOLs compared with monofocal IOLs; two other RCTs reported no difference.

2.3.4 The Specialist Advisers considered key efficacy outcomes to include spectacle independence, uncorrected near and distance vision, postoperative refractive error, contrast sensitivity and quality of life.

2.4 Safety

2.4.1 In four RCTs in the systematic review, significantly more patients reported halos and glare with multifocal IOLs than monofocal IOLs (OR 3.55, 95% CI 2.11 to 5.96). A non-randomised controlled trial of 18 patients reported that photic symptoms occurred in 61% (11 out of 18) and 39% (7 out of 18) of eyes treated. The non-randomised controlled trial of 495 patients reported no significant differences in glare score between patients with multifocal IOLs and monofocal IOLs (0.80 points versus 0.93 points; p=0.0824). In the systematic review, two RCTs reported decentration of multifocal IOLs in 8% (3 out of 39) and 12% (3 out of 25) of patients, respectively.

2.4.2 A non-randomised controlled trial of 40 patients that included these outcomes reported posterior capsule opacification requiring treatment in 29% (7 out of 24), 25% (8 out of 32) and 13% (3 out of 24) of patients treated with bifocal, multifocal and accommodating IOLs, respectively, at 1 year (level of significance not stated). In a case series of 72 patients (97 eyes) treated with multifocal IOLs, laser capsulotomy was required in 56% (54 out of 97) of eyes, at a mean follow-up of 34 months.

2.4.3 The Specialist Advisers considered key safety outcomes to include dysphotopsia and the need for replacement of multifocal IOLs with either multifocal or monofocal IOLs. They listed adverse events to include problems with intermediate vision, reduced contrast sensitivity, halos, glare, 'waxy vision' and reduced tolerance to astigmatism.

2.5 Other comments

2.5.1 The Committee noted that this technology is evolving with the aim of reducing side effects.

3 Further information

3.1 NICE has produced interventional procedures guidance on implantation of accommodating intraocular lenses (IOLs) for cataract.

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.

ISBN: 978-1-4731-6281-5

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.