NICE guidance

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

Interventional procedures 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. 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 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 the Institute's information for patients ('Understanding NICE guidance') 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. 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.

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, refer to the Sources of evidence.

2.3 Efficacy

2.3.1 In a systematic review of 10 randomised controlled trials (RCTs), dependence on spectacles was reported to be 68% (316/467) and 95% (383/404) 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% vs 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% (78/101) and 46% (46/101) 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% (11/18) and 39% (7/18) 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 vs 0.93 points; p = 0.0824). In the systematic review, two RCTs reported decentration of multifocal IOLs in 8% (3/39) and 12% (3/25) 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% (7/24), 25% (8/32) and 13% (3/24) 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% (54/97) 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 The Institute has produced guidance on implantation of accommodating 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 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

10 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.