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NHS
National Institute for
Health and Clinical Excellence

Implantation of miniature lens systems for advanced age-related macular degeneration

1 Guidance

1.1 Evidence on the efficacy of implantation of miniature lens systems for advanced age-related macular degeneration (AMD) shows that the procedure can improve both vision and quality of life in the short term. Short-term safety data are available for limited numbers of patients. There is currently insufficient long-term evidence on both efficacy and safety. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake implantation of miniature lens systems for advanced AMD should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the need to adapt to having a lens system implanted into one eye, the risk of early complications and the uncertainties about long-term efficacy and safety. They should provide clear information. In addition, the use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG272publicinfo).
- Audit and review clinical outcomes of all patients having implantation of miniature lens systems for advanced AMD (see section 3.1).

1.3 Patient selection is crucial and should include detailed assessment to predict the patient's ability to process visual stimuli following the operation.

1.4 Further publication of safety and efficacy outcomes would be useful, specifically with regard to longer term follow-up. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 The macula is a small area at the centre of the retina and is responsible for central vision and the appreciation of fine detail and colour. Damage to the macula impairs vision and, in the UK, AMD is a common cause of blindness. There are two main types of AMD: 'dry' (or atrophic), which is the most common, and 'wet' (or neovascular). Both eyes are usually affected, sometimes sequentially.

2.1.2 For early-stage wet AMD, treatments include laser photocoagulation, photodynamic therapy or intravitreal injections of anti-vascular endothelial growth factor agents. Treatment options for dry AMD are currently limited. Patients with advanced AMD can benefit from optical aids such as magnifying glasses.

2.1.3 The presence of cataract requiring operative treatment may be an additional reason for considering implantation of a lens system for AMD.

2.2 Outline of the procedure

2.2.1 Implantation of lens systems for advanced AMD is usually performed under local anaesthesia. The natural lens is removed through a small incision at the limbus (the area where the cornea meets the sclera) and the new lens system inserted. Artificial lens systems can consist of a single miniature telescope prosthesis or a combination of individual lenses implanted separately. The exact technique for implantation may vary according to the system being used. In both procedures, a small piece of the iris is removed (iridectomy) to prevent pupillary block. After implantation, patients usually require visual rehabilitation.

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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.

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.

NHS Quality Improvement Scotland

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 A non-randomised study of 217 patients reported that 67% (128/192) and 68% (130/192) of eyes with an implanted lens system improved by three or more lines of best-corrected distance and near visual acuity, respectively, compared with 13% (24/192) and 33% (64/192) of non-implanted fellow eyes ($p < 0.0001$) at 1-year follow-up. Loss of two or more lines of best-corrected distance visual acuity was reported in 2% of implanted eyes and 9% of fellow eyes at 1-year follow-up ($p = 0.005$). In a case series of 35 patients (40 eyes), best-corrected distance visual acuity improved in all patients after a mean of 20 months.

2.3.2 The Specialist Advisers considered key efficacy outcomes to include near and distance visual acuity, reading speed and improved ability to navigate unfamiliar surroundings.

2.4 Safety

2.4.1 A non-randomised study of 217 patients reported that two patients developed corneal decompensation and underwent device removal and corneal transplantation (more than 1 year after the initial surgery).

2.4.2 In the same study, 5% (11/217) of procedures were aborted because of complications including posterior capsule rupture and choroidal effusion/haemorrhage. In this study and in a case series of 40 patients, implants were removed because of patient dissatisfaction (3/36), condensation in the telescope (2/217, 2/36) and diplopia (1/36).

2.4.3 In the study and case series, other complications included increased intraocular pressure requiring treatment (28% [57/206]) and corneal oedema (25% [9/36], 7% [14/206]).

2.4.4 Two Specialist Advisers reported corneal endothelial cell loss as an adverse event. They considered additional theoretical complications to include corneal decomposition and corneal and macular oedema. One commented that the procedure has more risks than standard cataract surgery.

2.5 Other comments

2.5.1 The Committee noted that there are several different lens systems available for this procedure and that the technique is evolving.

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/IPG272

3.2 The Institute has produced interventional procedures guidance on macular translocation, radiotherapy and transpupillary thermotherapy for AMD, and technology appraisals guidance on photodynamic therapy for AMD and on ranibizumab and pegaptanib for AMD. See www.nice.org.uk for more information.

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. See www.nice.org.uk/IPG272publicinfo A large print version is also available. NICE has also produced an audio version of 'Understanding NICE guidance'. This is available to download from our website (www.nice.org.uk/IPG272).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview, available at: www.nice.org.uk/ip375overview

Ordering printed copies
Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1654 for this guidance, N1655 for the 'Understanding NICE guidance' or N1679 for the large print version of 'Understanding NICE guidance'.

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.

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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