

Miniature lens system implantation for advanced age- related macular degeneration

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg565

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.

This guidance replaces IPG272.

1 Recommendations

- 1.1 Evidence on the efficacy of miniature lens system implantation for advanced age-related macular degeneration (AMD) shows that the procedure can improve both vision and quality of life in the short term. Data on short-term safety 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. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wishing to do miniature lens system implantation 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 1 eye, the risk of early complications, and the uncertainties about long-term efficacy and safety. Clinicians should provide patients with clear information in an appropriate format. In addition, the use of NICE's information for the public is recommended.
 - Audit and review clinical outcomes of all patients having miniature lens system implantation for advanced AMD (see section 7.1).

- 1.3 Patient selection should include detailed assessment to predict the patient's ability to cope with the changes in vision after the operation. Extensive visual rehabilitation after the procedure may be required.
- 1.4 This procedure should only be done by experienced cataract surgeons with appropriate training in the implantation of miniature lens systems.
- 1.5 NICE encourages further research and publication on which patients may benefit and on safety and efficacy outcomes, particularly longer-term results. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

- 2.1 Age-related macular degeneration (AMD) is the commonest cause of irreversible blindness in industrialised countries. It usually occurs in older adults and is associated with degeneration of the macula – a small area at the centre of the retina responsible for central vision, and for appreciation of fine detail and colour. There are 2 main types of AMD, the most common of which is atrophic or 'dry' macular degeneration. This dry form is characterised by thinning of the macular retina. It develops slowly, causing a gradual loss in central vision. The other type is neovascular or 'wet' AMD, which is characterised by the growth of new blood vessels behind the retina, causing retinal bleeding and scarring. The new vessels are described according to whether they can be seen clearly ('classic') or poorly ('occult') on fluorescein angiography. The onset and disease progression of wet AMD is much faster than in the dry form. Both types of AMD typically affect both eyes, although 1 eye may be affected before the other.
- 2.2 Optical aids such as magnifying glasses may help patients with dry or wet AMD to read and do tasks needing fine-detail vision. For wet AMD, there are several treatment options but most patients have repeated intravitreal injections of anti-vascular endothelial growth factor agents, with ongoing regular clinic review. There is currently no standard treatment for dry AMD.

3 The procedure

- 3.1 The aim of an implantable miniature lens system is either to magnify the image on the macula, or to optically move the image onto an undamaged part of the retina. Implantation of lens systems for advanced age-related macular degeneration (AMD) is usually done under local anaesthesia. The natural lens of the eye is removed through a small incision at the limbus (the area where the cornea meets the sclera) and the new lens system is inserted. Artificial lens systems consist of either a miniature telescope prosthesis implanted in the capsular bag of the natural lens, or of 2 separate lenses with 1 lens implanted in front of and 1 lens implanted behind the iris.
- 3.2 The technique for implantation varies according to the system being used. Generally, if a telescope prosthesis is used, a larger limbal incision may be needed. Viscoelastic fluid is used during implantation to facilitate insertion and is then removed by irrigation or aspiration. When a single miniature telescope prosthesis is used, images are magnified by the implanted lens system and focused on the macula. When a system of 2 separate lenses is used, the lenses are rotationally aligned to deflect a magnified image away from the most damaged part of the macula and towards a less damaged area. In both cases, the contralateral eye is used for peripheral vision. After implantation, patients need visual rehabilitation.

4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 In a non-randomised comparative study of 217 patients with age-related macular degeneration (AMD) comparing vision in an eye with an implanted telescope lens system with the fellow eye as control, 67% (128/192) of implanted eyes gained 3 or more lines in best-corrected distance visual acuity (BCDVA) compared with 13% (24/192) of fellow eyes at 1-year follow-up ($p < 0.0001$). At 2-year follow-up, 60% (103/173)

of implanted eyes had gained 3 or more lines in BCDVA compared with 10% (18/174) of fellow eyes ($p < 0.0001$). Mean BCDVA improved by 3.5 lines in implanted eyes compared with 0.8 lines in fellow eyes ($p < 0.0001$). At 5-year follow-up, the mean BCDVA improvement from baseline (\pm standard deviation) was 2.4(\pm 2.7) lines in all patients ($n=76$). The subgroup analysis, in which patients were stratified by age, showed that the improvement was 2.7(\pm 2.7) lines in those aged 65 to 75 years and 2.1(\pm 2.9) lines in those over 75 years.

- 4.2 In a case series of 13 eyes (10 patients) implanted with an intraocular lens system, the mean best-corrected visual acuity (BCVA) was 1.37(\pm 0.34) logMAR preoperatively and 0.68(\pm 0.19) logMAR at 1-year follow-up ($p < 0.001$). In a case series of 6 eyes (6 patients) implanted with an intraocular telescopic lens, the mean gain in distance acuity was 3.66(\pm 1.88) lines and BCDVA had improved significantly at 6-month follow-up ($p=0.014$).
- 4.3 In the non-randomised comparative study of 217 patients with AMD comparing vision in an eye with an implanted telescope lens system with the fellow eye as control, 68% (130/192) of implanted eyes gained 3 or more lines in best-corrected near visual acuity (BCNVA) compared with 33% (64/192) of fellow eyes at 1-year follow-up ($p < 0.0001$). Mean BCNVA improved by 3.2 lines in implanted eyes compared with 1.8 lines in fellow eyes ($p < 0.0001$).
- 4.4 In the non-randomised comparative study of 217 patients, self-reported quality-of-life scores (assessed using the National Eye Institute's visual functioning questionnaire 25-item scores [NEI-VFQ-25]) improved by more than 7 points from baseline ($p < 0.01$) on 7 of 8 relevant subscales (vision specific subscales and psychosocial vision targeted subscales), at 1-year follow-up. Overall, the mean NEI-VFQ-25 composite score improved significantly by 6.1(\pm 14.4) points from baseline ($p < 0.0001$). In the subgroup analysis for age stratification both age groups (65 to 75 years, and over 75 years) showed clinically significant improvement in quality of life from baseline in most subscales, but it was higher in those aged 65 to 75 years (5-point change in individual subscale scores or composite scores is considered as clinically significant).

- 4.5 The specialist advisers listed key efficacy outcomes as best-corrected distance visual acuity, best-corrected near visual acuity, reading speed and improvement in quality of life.
- 4.6 Five commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Surgery was stopped in 5% (11/217) of patients because of complications such as posterior capsule rupture in 7 patients, choroidal effusion in 1 patient, choroidal haemorrhage in 2 patients and zonular dehiscence in 1 patient in a non-randomised comparative study of 217 patients.
- 5.2 Device explantation was reported in 6% (12/206) of patients in the non-randomised comparative study of 217 patients at 2-year follow-up. Two were removed because of surgical trauma resulting in condensation inside the telescope, 2 were removed during corneal transplantation, and 8 were removed because of patient dissatisfaction. All devices were replaced with a conventional intraocular lens.
- 5.3 Corneal decompensation was reported in 1% (2/206) of patients in the non-randomised comparative study of 217 patients at 1-year follow-up. Both needed device removal and corneal transplantation more than 1 year after the initial surgery.
- 5.4 Choroidal neovascularization after telescope implantation was reported in 2% (4/206) of patients in the non-randomised comparative study of 217 patients at 2-year follow-up. One patient had successful treatment with focal laser photocoagulation through the telescope without complications. Details about management of the neovascularization in the other 3 patients were not reported.
- 5.5 Increased intraocular pressure (IOP) within 7 days needing treatment was

- reported in 28% (57/206) of patients in the non-randomised comparative study of 217 patients. Increased IOP beyond 7 days needing treatment was reported in 3% (6/206) of patients in the same study. No further details were reported.
- 5.6 Hypopyon (treated with topical steroids) was reported in 11% (4/36) of patients in a case series of 40 patients (40 eyes). No further details were reported.
- 5.7 Posterior capsule opacification (treated successfully with a Nd-YAG laser capsulotomy) was reported in 30% (3/10) of patients in a case series of 10 patients (13 eyes).
- 5.8 Inflammatory deposits on the device were reported in 25% (51/206) of implanted eyes and pigment deposits on the device were reported in 11% (23/206) of implanted eyes in the non-randomised comparative study of 217 patients. No further details were reported.
- 5.9 Loss of 3 or more lines of best-corrected distance visual acuity (BCDVA) or best-corrected near visual acuity (BCNVA) occurred in less than 1% (1/173) of implanted eyes compared with 8% (13/174) of fellow control eyes ($p=0.0013$) in the non-randomised comparative study of 217 patients. No further details were given.
- 5.10 In the non-randomised comparative study of 217 patients with age-related macular degeneration, comparing an implanted telescope lens system with fellow eye controls, the loss of 2 or more lines in BCDVA was significantly less frequent in implanted eyes compared with fellow eyes (2% compared with 9%; $p=0.005$) at 1-year follow-up. In the subgroup analysis for age, 3 patients (9%) in each group (65 to 75 years, and over 75 years) had lost more than 2 lines of BCDVA at 60-month follow-up. Both groups had greater vision loss in the fellow eyes (65 to 75 years, 16% [$n=5$]; compared with 28% [$n=9$] in those over 75 years).
- 5.11 Ocular adverse events were reported in the non-randomised comparative study of 217 patients up to 60 months after the procedure, including: iris prolapse in 6% (12/206) of patients, iris incarceration in 1% (3/206), iris damage in 4% (9/206), iris transillumination defects lasting

more than 21 days in 5% (11/206), iritis lasting more than 30 days in 6% (12/206), iris atrophy more than 7 days after surgery in 6% (12/206), guttata in 8% (16/206) and posterior synechiae in 7% (15/206). No further details were reported.

- 5.12 Endothelial cell density (ECD) was reduced by 20% below baseline at 3-month follow-up and by 25% at 1 year, compared with fellow eye controls, in the non-randomised comparative study of 217 patients with age-related macular degeneration implanted with a telescope lens system. The mean cell loss from 1 year to 2 years was 2%. In the subgroup analysis for age, ECD loss was less in those aged between 65 and 75 years than in those over 75 years (35% compared with 40%) at 60-month follow-up. The decrease in ECD was correlated with post-surgical oedema ($p < 0.0001$), suggesting that endothelial damage occurred during surgery, rather than during the postoperative period.
- 5.13 Transient complications reported in a case series of 40 patients included corneal oedema in 25% (9/36) of patients, fibrin at the pupil in 33% (12/36), synechias in 19% (7/36), hyphema in 11% (4/36), conjunctivitis in 6% (2/36), uveitis in 8% (3/36) and cyclitic membrane in 3% (1/36). Persistent complications included pupillary cyclitic membrane in 1 eye, synechias in 2 eyes and posterior capsular opacification in 4 eyes.
- 5.14 Ocular pain due to mild corneal epithelial trauma was reported in 20% (2/10) of patients in a case series of 10 patients. This resolved with no complications.
- 5.15 Other complications reported in the non-randomised comparative study of 217 patients included corneal abrasion in 5% (11/206) of patients, foreign-body sensation in 3% (7/206), anterior chamber inflammation lasting beyond 30 days in 2% (actual numbers not reported), device dislocation in 1% (3/206), sub-retinal haemorrhage in 2% (5/206), vitreous haemorrhage more than 7 days after surgery in 2% (4/206), vitreous in the anterior chamber more than 7 days after surgery in 4% (8/206) and vitreous loss in 4% (9/206).
- 5.16 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they

have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers reported no anecdotal adverse events. They considered that the following were theoretical adverse events: increase in falls due to the differences in magnification in each eye for devices that give larger magnification, and failure to improve vision for devices that have lower magnification.

6 Committee comments

- 6.1 The committee noted that there are several different lens systems available for this procedure, and that these vary in complexity. The majority of evidence comes from 1 device.
- 6.2 The committee noted that the technology and the techniques used in this procedure are evolving.
- 6.3 The committee noted that there is a [National Institute for Health Research-funded multicentre randomised controlled trial in progress \(the MIRROR trial\)](#) and suitable patients should be recruited to this or other similar studies when possible.
- 6.4 The committee noted that patient commentaries were varied. Some patients reported good improvement in quality of vision, but others reported difficulty in coping with high magnification images and did not achieve a satisfactory improvement in vision.

7 Further information

- 7.1 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed [NICE's interventional procedures outcomes audit tool](#) (which is for use at local discretion).
- 7.2 For related NICE guidance, see the [NICE website](#).

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).