

Macular translocation with 360° retinotomy for wet age-related macular degeneration

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg340

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 IPG48.

1 Guidance

- 1.1 Current evidence on macular translocation with 360° retinotomy for wet age-related macular degeneration (AMD) shows that this procedure is efficacious in only a proportion of patients and that there is a potential for serious adverse events. Therefore, the procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake macular translocation with 360° retinotomy for wet AMD should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear information about both this procedure and alternative treatments (see [section 2.5.1](#)). In addition, the use of [NICE's information for the public](#) is recommended.
 - Audit and review clinical outcomes of all patients having macular translocation with 360° retinotomy for wet AMD (see [section 3.1](#)).

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Age-related macular degeneration (AMD) is the most common cause of blindness in developed countries. A small proportion of patients with AMD have wet AMD. Wet AMD is characterised by the abnormal growth of blood vessels in the choroid layer underneath the macular part of the retina. These vessels can threaten vision if they leak and cause scarring.
- 2.1.2 Current treatments for wet AMD include laser photocoagulation, photodynamic therapy (PDT), intravitreal injections of anti-vascular endothelial growth factor agents and implantation of miniature lens systems. Patients with advanced disease may benefit from optical aids such as magnifying glasses.

2.2 Outline of the procedure

- 2.2.1 The aim of this procedure is to move the macula so that it lies over a healthier part of the choroid layer that is unaffected by neovascularisation.
- 2.2.2 In macular translocation with 360° retinotomy for wet AMD, a vitrectomy is done and the retina is then detached from the back of the eye using an injection of saline solution. An incision is made around the entire perimeter of the retina so that it is freely mobile, and attached only at the optic disc. The abnormal choroidal vessels are removed and the retina is reattached with the macula rotated away from the original disease site. Once the retina is reattached the vitreous cavity is injected with silicone oil for tamponade. In a second operation approximately 1 to 2 months later, the whole globe is rotated in the opposite direction by dividing and reattaching the external ocular muscles in order to remove the resulting visual disturbance caused by the torsion, and the silicone oil is drained from the vitreous cavity.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and 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 [overview](#).

- 2.3.1 A randomised controlled trial (RCT) of 50 patients treated by the procedure or PDT reported an increase of 3 lines or more of best corrected visual acuity (BCVA) in 28% (7 out of 25) and 0% (0 out of 25) of patients respectively at 24-month follow-up ($p < 0.01$). A case series of 50 patients reported 2-line or greater BCVA improvement in 66% (33 out of 50), no improvement in 28% (14 out of 50) and a loss of more than 2 lines in 6% (3 out of 50) of patients at 21-month follow-up. A case series of 64 patients reported BCVA improvement of 1 line or more in 52% (32 out of 61) and a loss of more than 3 lines in 11% (7 out of 61) of patients at 12-month follow-up.
- 2.3.2 A non-randomised controlled study of 24 patients reported that mean BCVA improved from 0.90 to 0.69 logMAR in 12 patients treated by the procedure ($p = 0.09$) and worsened from 0.87 to 1.38 logMAR in 12 patients treated by choroidal patch graft at 3-year follow-up ($p < 0.001$).
- 2.3.3 The case series of 64 patients reported that median reading speed improved among 55 patients from 71 words per minute at baseline to 105 words per minute at 12-month follow-up ($p < 0.001$).
- 2.3.4 The RCT of 50 patients reported no difference in quality-of-life scores between patients treated by the procedure or PDT for general vision ($p = 0.27$) at 24-month follow-up.
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as attached retina following surgery, functional outcomes of BCVA, and reading speed.

2.4 Safety

- 2.4.1 Retinal detachment (requiring vitrectomy and endotamponade for reattachment) was reported in 24% (6 out of 25) of patients treated by the procedure in the RCT

of 50 patients. In case series of 90 and 64 patients, retinal detachment was reported in 19% (absolute figures not stated) and 8% (5 out of 61) of patients respectively (12-month follow-up for both studies).

- 2.4.2 In the non-randomised controlled study of 24 patients, residual torsion requiring a third procedure was reported in 17% (2 out of 12) of patients treated by the procedure (timing of events not stated).
- 2.4.3 Retinal slippage from the desired final location after translocation was reported in 3% (2 out of 75) of eyes in the case series of 75 eyes (number of patients not stated).
- 2.4.4 The Specialist Advisers stated that adverse events reported in the literature include proliferative vitreoretinopathy, macular oedema, diplopia and phthisis. They listed theoretical adverse events as recurrence of neovascularisation.

2.5 Other comments

- 2.5.1 The Committee noted that intravitreal injections of antivascular endothelial growth factor agents are more commonly used for the treatment of AMD than surgical techniques. For more information see [NICE's technology appraisal guidance on ranibizumab and pegaptanib for the treatment of AMD](#).

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant [audit criteria](#) and developed [audit support](#) (which is for use at local discretion).

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.

4 Other NICE recommendations on macular translocation

NICE has also issued [interventional procedures guidance on limited macular translocation for wet age-related macular degeneration](#).

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Endorsing organisation

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