

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

This document partially replaces previous guidance on macular translocation for age-related macular degeneration (interventional procedures guidance 48).

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 patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/guidance/IPG340/publicinfo).
- 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 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 1–2 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.

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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.

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, available at www.nice.org.uk/IP790overview

2.3 Efficacy

- 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% (7/25) and 0% (0/25) 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% (33/50), no improvement in 28% (14/50) and a loss of more than 2 lines in 6% (3/50) of patients at 21-month follow-up. A case series of 64 patients reported BCVA improvement of 1 line or more in 52% (32/61) and a loss of more than 3 lines in 11% (7/61) 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% (6/25) 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% (5/61) 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% (2/12) 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% (2/75) 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 anti-vascular endothelial growth factor agents are more commonly used for the treatment of AMD than surgical techniques. For more information see 'Ranibizumab and pegaptanib for the treatment of age-related macular degeneration' (NICE technology appraisal guidance 155), available from www.nice.org.uk/TA155

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), which is available from www.nice.org.uk/guidance/IPG340
- 3.2 For related NICE guidance see www.nice.org.uk

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. See www.nice.org.uk/guidance/IPG340/publicinfo
A large print version is also available.

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N2150 for this guidance, N2151 for the 'Understanding NICE guidance' or N2152 for the large print version of 'Understanding NICE guidance'.

This guidance represents the view of NICE, 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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