

Limited macular translocation 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 limited macular translocation 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 limited macular translocation 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/IPG339/publicinfo).
- Audit and review clinical outcomes of all patients having limited macular translocation 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, 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 limited macular translocation for wet AMD is to move the macula so that it lies over a healthier part of the choroid layer that is unaffected by neovascularisation. The technique was developed as a less invasive alternative to macular translocation with 360° retinotomy.

2.2.2 Limited macular translocation involves making a short incision in the retina to allow fluid to be injected under the retina, so detaching it from the underlying choroid. The outer layers of the eye are then folded and secured with a stitch (scleral imbrication) so that the underlying choroid layer is moved slightly in relation to the macula.

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/IP80aoverview

Interventional procedure guidance 339

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.

2.3 Efficacy

- 2.3.1 A case series of 151 patients reported that 41% (35/86) of patients had best corrected visual acuity (BCVA) of 20/100 or better, and 40% (34/86) of patients had improved BCVA by 2 or more lines at 12-month follow-up (mean BCVA at baseline was 20/160). A non-randomised controlled study of 65 patients reported that mean improvement in BCVA was significantly greater following limited macular translocation (+0.5 lines) (n = 21) than following photodynamic therapy (-3.4 lines) (n = 20) at 12-month follow-up (p = 0.007).
- 2.3.2 In the case series of 101 patients, 60% (52/86) of eyes achieved median foveal displacement of 1200 micrometres at 12-month follow-up (described as 'effective' translocation). A case series of 25 patients reported median foveal displacement of 1142 micrometres (described as 'successful' translocation) in 68% (17/25) of patients (follow-up not stated).
- 2.3.3 In the non-randomised controlled study of 65 patients, recurrence of neovascularisation was reported in 13 eyes treated by limited macular translocation at mean follow-up of 4.8 months.
- 2.3.4 The Specialist Advisers listed key efficacy outcomes as visual acuity, reading speed, quality of life and recurrence of the condition.

2.4 Safety

- 2.4.1 The non-randomised controlled study of 65 patients reported that 38% of eyes treated by limited macular translocation (n = 36) experienced 1 or more postoperative complications (absolute figures not stated). A mean BCVA loss of 4.8 lines was reported for these eyes.
- 2.4.2 In the non-randomised controlled study of 65 patients, retinal detachment due to a peripheral tear, and requiring additional surgery, was reported in 5 eyes among the 36 patients treated by limited macular translocation at a mean follow-up of 3.2 months. Postoperative retinal detachment occurred in 16% (25/153) of eyes in a case series of 151 patients at follow-up between 1 and 13 weeks, with 84% (21/25) of these requiring additional surgery. The frequency of

retinal detachment decreased significantly in patients treated later in the series (p = 0.006). A retinal break (not otherwise described) was reported in 8% (13/153) of eyes in the case series of 151 patients.

- 2.4.3 Intermittent or continuous diplopia after limited macular translocation was reported in 6% (14/250) of patients in a case series of 250 patients (management and follow-up not stated). Diplopia was reported in 1 patient in a case report of 2 patients (symptoms resolved without additional surgery by 5-month follow-up).
- 2.4.4 The Specialist Advisers identified suprachoroidal haemorrhage as an adverse event reported in the literature. They listed anecdotal or observed adverse events as cataract and persistent retinal fold in the macular area. They considered theoretical events to include endophthalmitis.

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/IPG339
- 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/IPG339/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 N2147 for this guidance, N2148 for the 'Understanding NICE guidance' or N2149 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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