

Limited macular translocation for wet age-related macular degeneration

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg339

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 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 the public](#) is recommended.
 - 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 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, intravitreal injections of antivascular 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 (sclera imbrication) so that the underlying choroid layer is moved slightly in relation to the macula.

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 case series of 151 patients reported that 41% (35 out of 86) of patients had best corrected visual acuity (BCVA) of 20 out of 100 or better, and 40% (34 out of 86) of patients had improved BCVA by 2 or more lines at 12-month follow-up (mean BCVA at baseline was 20 out of 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 out of 86) of eyes achieved median foveal displacement of 1,200 micrometres at 12-month follow-up (described as 'effective' translocation). A case series of 25 patients reported median foveal displacement of 1,142 micrometres (described as 'successful' translocation) in 68% (17 out of 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 out of 153) of eyes in a case series of 151 patients at follow-up between 1 and 13 weeks, with 84% (21 out of 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 out

of 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 out of 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 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

- 4.1 NICE has also issued [interventional procedures guidance on macular translocation with 360° retinotomy for wet age-related macular degeneration](#).

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Endorsing organisation

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