

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of limited macular translocation for wet age-related macular degeneration

Age-related macular degeneration (AMD) is an eye disorder affecting the macula, which is the area at the centre of the retina (the back of the eye) responsible for central vision (seeing things straight in front of you). Wet AMD happens because fluid leaks out of abnormally formed arteries and veins into the area under the macula (the choroid layer), causing scarring.

Limited macular translocation aims to improve vision. It involves cutting the macula and moving it to a nearby healthier area of the choroid layer.

A small incision is made in the retina to get to the outer layers of the eye. A 'tuck' is then made in these layers with a stitch, so that the macula lies over a different part of the choroid layer. This 'tuck' method is called limited macular translocation.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in October 2009.

Procedure name

- Limited macular translocation for wet age-related macular degeneration.

Specialty societies

- Royal College of Ophthalmologists.

Description

Indications and current treatment

The macula is the part of the retina that provides central vision. Age-related macular degeneration is the most common cause of blindness in developed countries. A small proportion of patients with AMD have wet AMD (also known as neovascular or exudative AMD). This type is characterised by the growth of neovascular vessels in the choroid layer underneath the macular retina. These neovascular vessels can threaten vision if they leak and cause scarring. While the cause of this growth is unknown, there is a strong association with a history of smoking.

The visual prognosis of patients with wet AMD without treatment is poor.

Lasers have been used to coagulate neovascular vessels in wet AMD but with limited effect. The procedure itself may permanently impair vision, especially if the vessels are subfoveal (very close to the fovea). Recurrence of neovascular vessels is also common.

For early-stage wet AMD, treatments include laser photocoagulation but with limited effect. The procedure itself may permanently impair vision, especially if the vessels are subfoveal. Other treatments include photodynamic therapy or 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.

What the procedure involves

Macular translocation involves moving the macula so that it lies over a healthier part of the choroid layer beneath it. Limited macular translocation involves making a short incision in the retina. The outer layers of the eye are then folded and secured with a stitch (this procedure is called scleral imbrication). This means that the underlying choroid is moved slightly in relation to the macula. The technique was developed as a less invasive alternative to macular translocation with 360° retinotomy.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to limited macular translocation for wet age-related macular degeneration. Searches were conducted of the following databases, covering the period from their commencement to 27 April 2009 and updated to 11 January 2010: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy).

Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with wet age-related macular degeneration.
Intervention/test	Limited macular translocation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on approximately 495 patients from 1 non-randomised controlled study¹, 3 case series^{2& 3,4,5}, and 1 case report⁶.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on limited macular translocation for wet age-related macular degeneration

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy.												
Study details	Key efficacy findings	Key safety findings	Comments									
<p>Pawlak D (2004)¹</p> <p>Non-randomised controlled study</p> <p>France</p> <p>Recruitment period: Not reported</p> <p>Study population: Subfoveal neovascularisation due to AMD.</p> <p>n = 65 (36 limited translocation, 29 PDT)</p> <p>Age: 75 years (mean)</p> <p>Sex: 62% male</p> <p>Patient selection criteria: ≥ 60 years, without degenerative myopia, visual acuity 20/63 or worse, symptoms < 3 months, no previous laser treatment in the peripheral temporal quadrants, no history of retinal detachment.</p> <p>Technique: local or general anaesthesia, pars plana vitrectomy and removal of any attached posterior hyaloids, injection of saline into the subretinal space to create dome-shaped retinal detachment. Imbrication of the sclera.</p> <p>Follow-up: 14 months translocation, 11 months PDT (mean)</p> <p>Conflict of interest/source of funding: not reported</p>	<p>Visual acuity</p> <p>Group mean (number of lines change from baseline)</p> <table border="1"> <thead> <tr> <th>Time point</th> <th>Translocation</th> <th>PDT</th> </tr> </thead> <tbody> <tr> <td>3 months n = 65 (36 vs 29)</td> <td>+0.7 lines</td> <td>-3.0 lines</td> </tr> <tr> <td>12 months n = 41 (21 vs 20)</td> <td>+0.5 lines</td> <td>-3.4 lines</td> </tr> </tbody> </table> <p>The change in visual acuity was more favourable in the translocation group than the PDT group at 1-year follow-up (p = 0.007).</p> <p>Laser treatment of new central neovascularisation was required in 83% of the patients in the translocation group at between 4 and 14-day follow-up. Additional surgery was required in 4 patients in the translocation group to displace a macular fold.</p> <p>There was recurrence of neovascularisation in 13 eyes in the translocation group at a mean follow-up of 4.8 months.</p>	Time point	Translocation	PDT	3 months n = 65 (36 vs 29)	+0.7 lines	-3.0 lines	12 months n = 41 (21 vs 20)	+0.5 lines	-3.4 lines	<p>Complications</p> <p>A scar due to PDT was reported in 30% (6/20) of patients at 12-month follow-up (not described further).</p> <p>Retinal detachment due to peripheral tear occurred in 5 eyes in the translocation group at a mean of 3.2-month follow-up, requiring additional surgery.</p> <p>Proliferative vitreoretinopathy occurred in 4 eyes in the translocation group (follow-up period not reported).</p> <p>A macular hole developed in 4 eyes in the translocation group in the immediate postoperative period, requiring silicone oil injection in 3 eyes.</p> <p>Lens opacification requiring phacoemulsification occurred in 11 eyes of the translocation group at a mean follow-up of 6.5 months. Diplopia developed in 7 patients, it was transitory in 3, and 4 patients needed vertical prisms.</p> <p>Overall 38% of eyes in the translocation group experienced 1 or more postoperative complications with a mean loss of BCVA of 4.8 lines.</p> <p>In the PDT group subretinal haemorrhage occurred in 3 eyes.</p>	<p>Follow-up issues:</p> <p>Retrospective follow-up, loss to follow-up not reported. Denominator for patients in the safety outcomes not clear.</p> <p>Study design issues:</p> <p>Patient selection criteria were different for the 2 study groups. If the patients qualified for either, they were asked to self-select.</p> <p>All translocation procedures undertaken by 1 surgeon.</p> <p>Length of follow-up was not significantly different between the groups (p = 0.065).</p> <p>Study population issues:</p> <p>Patients in the PDT group had significantly better mean BCVA score at baseline (by 4 lines) (p = 0.001).</p> <p>Patients in the translocation group had a significantly smaller size of new vessels at baseline (p = 0.036).</p> <p>Other issues:</p> <p>A number of different analyses were undertaken on change in visual acuity. Some were based on best-gain at any time during follow-up. Reporting is not clear.</p>
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3 months n = 65 (36 vs 29)	+0.7 lines	-3.0 lines										
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Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy.																																	
Study details	Key efficacy findings	Key safety findings	Comments																														
<p>Fujii G Y (2002)² and (2000)³</p> <p>Case series</p> <p>USA</p> <p>Recruitment period: 1996 to 1999</p> <p>n = 151 (153 eyes)</p> <p>Study population: Subfoveal neovascularisation due to AMD or other diagnosis.</p> <p>Age: not reported</p> <p>Sex: 57% male</p> <p>Patient selection criteria: Fluorescein angiographic documentation of choroidal neovascularisation.</p> <p>Technique: pars plana vitrectomy, retinal detachment by hydrodissection. Scleral imbrication (inferior or superior), and partial air-fluid exchange. Laser photocoagulation during the first week where translocation sufficient.</p> <p>Follow-up: 10.5 months (median) n = 151 (safety), 12 months (minimum) n = 86 (efficacy).</p> <p>Conflict of interest/source of funding: supported by a grant and private donors.</p>	<p>Operative success</p> <p>60% (52/86) of eyes achieved effective macular translocation with complete laser photocoagulation of the choroidal neovascularisation complex.</p> <p>Median foveal displacement was 1200 micrometres.</p> <p>Visual acuity</p> <p>n = 86. At 12 months patients with macular degeneration</p> <ul style="list-style-type: none"> • 20/100 or better: 41% (35/86) • improved by 2 or more Snellen lines: 40% (34/86) • deteriorated by 2 or more Snellen lines: 31% (27/86). <p>Mean BCVA improved from 20/160 at baseline to 20/150 at 12-month follow-up (measurement of significance not reported).</p> <p>Neovascularisation persisted or recurred in 17 of 52 eyes with effective translocation.</p>	<p>Complications</p> <p>Posterior segment complications were reported in 35% (53/153) eyes.</p> <p>Intraoperative</p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>Rate</th> </tr> </thead> <tbody> <tr> <td>Macular hole</td> <td>8% (12/153)</td> </tr> <tr> <td>Retinal break</td> <td>5% (8/153)</td> </tr> <tr> <td>Subretinal haemorrhage</td> <td>5% (7/153)</td> </tr> <tr> <td>Vitreous haemorrhage</td> <td>2% (3/153)</td> </tr> <tr> <td>Scleral perforation</td> <td>2% (3/153)</td> </tr> <tr> <td>Choroidal haemorrhage</td> <td>1% (1/153)</td> </tr> </tbody> </table> <p>Postoperative</p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>Rate</th> </tr> </thead> <tbody> <tr> <td>Retinal detachment (21 eyes requiring repeat surgery) 1 to 13-week follow-up</td> <td>16% (25/153)</td> </tr> <tr> <td>Retinal break</td> <td>8% (13/153)</td> </tr> <tr> <td>Macular fold up to 5-day follow-up</td> <td>5% (7/153)</td> </tr> <tr> <td>Vitreous haemorrhage</td> <td>3% (4/153)</td> </tr> <tr> <td>Choroidal neovascularisation</td> <td>2%</td> </tr> <tr> <td>Choroidal haemorrhage</td> <td>1% (1/153)</td> </tr> <tr> <td>Suspected endophthalmitis (treated successfully with antibiotics)</td> <td>1% (1/153)</td> </tr> </tbody> </table> <p>Overall BCVA at 3-month follow-up was significantly worse in eyes with any complication ($p = 0.0001$).</p> <p>Eyes with classic choroidal neovascularisation at baseline were significantly associated with postoperative retinal detachment in univariate analysis ($p = 0.021$).</p> <p>The incidence of retinal detachment and haemorrhage decreased significantly during the study period (analysed on blocks of 20 patients) ($p = 0.006$, and 0.027 respectively)</p>	Outcome	Rate	Macular hole	8% (12/153)	Retinal break	5% (8/153)	Subretinal haemorrhage	5% (7/153)	Vitreous haemorrhage	2% (3/153)	Scleral perforation	2% (3/153)	Choroidal haemorrhage	1% (1/153)	Outcome	Rate	Retinal detachment (21 eyes requiring repeat surgery) 1 to 13-week follow-up	16% (25/153)	Retinal break	8% (13/153)	Macular fold up to 5-day follow-up	5% (7/153)	Vitreous haemorrhage	3% (4/153)	Choroidal neovascularisation	2%	Choroidal haemorrhage	1% (1/153)	Suspected endophthalmitis (treated successfully with antibiotics)	1% (1/153)	<p>Follow-up issues:</p> <p>Retrospective follow-up. One patient with retinal detachment was assigned mean score of other patients with this outcome.</p> <p>For intraoperative and postoperative events incidence was assessed on the total number of eyes treated. For later events, cumulative incidence was calculated.</p> <p>There was no significant difference in baseline characteristics between patients followed up and not followed up at 3 and 6 months.</p> <p>Study design issues:</p> <p>All translocation procedures undertaken by 1 surgeon.</p> <p>Visual acuity outcomes were not evaluated in a standardised fashion.</p> <p>Study population issues:</p> <p>Patients with subfoveal choroidal neovascularisation secondary to AMD or other diagnoses.</p> <p>Other issues:</p> <p>Progression of cataract not evaluated systematically in this study.</p> <p>Study undertaken before FDA-approved Visudyne (PDT agent).</p>
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Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Buffenn A N (2001)⁵</p> <p>Case series</p> <p>USA</p> <p>Recruitment period: not reported</p> <p>Study population: Subfoveal neovascularisation due to AMD or other diagnosis.</p> <p>n = 250</p> <p>Age: 70 years (mean)</p> <p>Sex: 73% male – patients developing diplopia</p> <p>Patient selection criteria: not reported</p> <p>Technique: pars plana vitrectomy, retinal detachment by hydrodissection. Scleral imbrication (without resection), and partial air fluid exchange. Laser photocoagulation during the first week where translocation sufficient.</p> <p>Follow-up: not reported</p> <p>Conflict of interest/source of funding: Supported by a grant</p>	<p>Operative success</p> <p>n = 250</p> <p>Median foveal displacement was 1750 micrometres in the 13 patients with postoperative diplopia compared with the group median of 1200 micrometres.</p> <p>Visual acuity</p> <p>BCVA improved by 2 lines or more in 62% (8/13) of patients with diplopia. It was unchanged in 2 patients and was worse in 3 (the follow-up period to which these observations relate is not clear).</p> <p>BCVA ranged from 20/40 to 20/400 in the patients with postoperative diplopia compared with 20/40 to 20/800 in non-diplopic patients.</p>	<p>Complications</p> <p>6% (14/250) of patients treated with limited translocation reported intermittent or continuous diplopia.</p> <p>77% (10/13) patients had no measurable stereopsis.</p> <p>77% (10/13) patients showed strabismus on alternate cover testing.</p> <p>For 6 patients treated with prism only for diplopia, correction remained satisfactory in 5, at 2–21-month follow-up.</p>	<p>Possibly some of the same patients included in Fujii (2000).</p> <p>Follow-up issues:</p> <p>Retrospective follow-up. One patient lost to follow-up because diplopia could not be detected at examination.</p> <p>Only patients with diplopia were selected for examination.</p> <p>Not all patients underwent all outcome assessments. Selection criteria not described.</p> <p>Study design issues:</p> <p>All translocation procedures undertaken by 2 surgeons.</p> <p>Study population issues:</p> <p>Clinical and demographic characteristics at baseline for the denominator of patients treated is not reported.</p> <p>Other issues:</p> <p>Authors report that nearly 100% of patients that undergo total translocation with 360° retinotomy develop diplopia.</p>

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Lewis H (2001)⁴</p> <p>Case series</p> <p>USA</p> <p>Recruitment period: 1999 to 2000</p> <p>Study population: Subfoveal neovascularisation due to AMD.</p> <p>n = 25</p> <p>Age: 70 years (mean) Sex: 40% male</p> <p>Patient selection criteria: ≥ 60 years, visual acuity 20/80 to 20/400, evidence of drusen in both eyes, new or recurrent choroidal neovascularisation involving the centre of the fovea, BCVA < 20/100 in fellow eye, no submacular haemorrhage.</p> <p>Technique: under local anaesthesia pars plana vitrectomy, retinal detachment by hydrodissection. Scleral imbrication by radial or circumferential outfolding secured by titanium clips. Small retinotomy. Partial air-fluid exchange.</p> <p>Follow-up: 6 months (minimum)</p> <p>Conflict of interest/source of funding: not reported</p>	<p>Operative success</p> <p>n = 25</p> <p>Median foveal displacement was 1142µm (range 0 to 3200 µm).</p> <p>68% (17/25) of eyes demonstrated extrafoveal neovascular membrane following translocation and were photocoagulated postoperatively.</p> <p>Visual acuity</p> <p>Median improvement in visual acuity was 2 lines.</p> <p>Median BCVA 20/188 (range 20/80 to 20/400) at baseline, improved to 20/173 (range 20/64 to 20/400) at 6-month follow-up.</p>	<p>Complications</p> <p>24% (6/25) of eyes developed focal areas of retinal pigment epithelium, and choroidal hypopigmentation.</p> <p>No patient developed intraocular haemorrhage, or postoperative retinal detachment.</p> <p>There was no recurrence of the choroidal neovascular membrane at 6-month follow-up</p>	<p>Follow-up issues:</p> <p>Retrospective follow-up. No loss to follow-up reported</p> <p>Study design issues:</p> <p>All translocation procedures undertaken by 1 surgeon. Case accrual method not reported.</p> <p>Study population issues:</p> <p>Duration of onset of neovascularisation not reported.</p> <p>Previous surgery not reported.</p> <p>Other issues:</p> <p>Different technique to other studies in this overview, using a scleral outfolding technique.</p> <p>Author states that randomised clinical trials are needed to determine the role of macular degeneration in the treatment of AMD.</p>

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy.			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Au Eong K G (2004)⁶</p> <p>Case report</p> <p>Singapore</p> <p>Recruitment period: 2001</p> <p>Study population: Neovascularisation due to AMD.</p> <p>n = 2</p> <p>Age: 56 years (mean)</p> <p>Sex: 50% male</p> <p>Patient selection criteria: not reported.</p> <p>Technique: pars plana vitrectomy, retinal detachment by hydrodissection. Scleral imbrication with sutures.</p> <p>Follow-up: 12 months (mean)</p> <p>Conflict of interest/source of funding: not reported</p>	<p>Patient 1</p> <p>History of bilateral phacoemulsification and intraocular lens insertion. Fluorescein angiography detected bilateral macular degeneration and subfoveal choroidal neovascularisation.</p> <p>At 4-day follow-up, angiography determined that the retina had moved inferiorly relative to the underlying tissue and the choroidal neovascularisation was subfoveal. It was ablated by laser photocoagulation. BCVA improved to 6/12-2 at 6 weeks and 6/12 at 3-month follow-up. At 1-year follow-up, there was no recurrence of the neovascularisation and BCVA had improved to 6/9-1.</p> <p>There was no diplopia or incyclotropia during follow-up.</p> <p>Patient 2</p> <p>History of bilateral myopia. BCVA 6/9 in right eye. Fluorescein angiography detected small idiopathic juxtafoveal choroidal neovascularisation. The lesion was ablated by laser photocoagulation but BCVA decreased to 6/30.</p> <p>Limited macular translocation undertaken, and by 5-day follow-up the retina was completely attached. The macula was also seen to have moved inferiorly relative to the underlying choroidal tissue, and the choroidal neovascularisation had become extrafoveal. There was no recurrence of choroidal neovascularisation and BCVA improved to 6/12 at 12-month follow-up. Diplopia symptoms disappeared by 5-month follow-up.</p>		<p>Follow-up issues:</p> <p>Retrospective follow-up.</p> <p>Study design issues:</p> <p>Both translocation procedures undertaken by 1 surgeon.</p> <p>First 2 patients treated at the centre.</p> <p>Atypical metric used to evaluate visual acuity outcomes. Not otherwise described.</p> <p>Study population issues:</p> <p>Case-selection criteria not reported.</p> <p>Other issues:</p> <p>Authors state that the three most important factors for good visual outcomes are patient selection, achieving desired amount of translocation, and avoiding complications.</p>

Efficacy

A non-randomised controlled study of 65 patients reported that the mean number of lines of best corrected visual acuity (BCVA) gained was significantly greater following limited macular translocation (+0.5 lines) than following photodynamic therapy (-3.4 lines) at 12-month follow-up¹.

A case series of 151 patients reported that 41% (35/86) had BCVA 20/100 or better and 40% (34/86) had improved BCVA by 2 or more lines at 12-month follow-up².

A case series of 250 patients reported that BCVA improved by 2 or more lines in 62% (8/13) who also developed diplopia following surgery, that it was unchanged in 2 patients, and was worse in 3 (follow-up not reported)⁵.

A case series of 25 patients reported that median BCVA improved from 20/188 at baseline to 20/173 at 6-month follow-up (significance not reported)⁴.

A case series of 101 patients reported that 60% (52/86) of eyes achieved effective macular translocation, with a median foveal displacement of 1200 micrometres at 12-month follow-up².

A case series of 25 patients reported successful translocation (median foveal displacement 1142 micrometres) with an extrafoveal neovascular membrane in 68% (17/25) of patients⁴.

Recurrence of neovascularisation occurred in 13 eyes in the limited-translocation group of a non-randomised controlled study of 65 patients at a mean follow-up of 4.8 months¹.

Choroidal neovascularisation was reported in 2% of eyes in a case series of 151 patients (follow-up period and absolute numbers not reported)³. A case series of 25 patients reported that no patient had recurrence of choroidal neovascular membrane at a follow-up of 6 months⁴.

Safety

A non-randomised controlled study of 65 patients reported that overall 38% of eyes in the limited translocation group experienced one or more postoperative complications, with a mean loss of BCVA of 4.8 lines¹ (Absolute numbers not reported).

In the same study, retinal detachment occurred (requiring additional surgery) due to a peripheral tear in 5 eyes among the 38% of eyes in the translocation group that experienced one or more postoperative complication, 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 1 to 13-week follow-up, with 21 eyes requiring additional surgery³.

Also, 8% (13/153) of the eyes suffered a retinal break (not otherwise described). The frequency of retinal detachment decreased significantly in patients treated later in the series ($p = 0.006$). A case series of 25 patients reported no retinal detachment at a minimum follow-up of 6 months⁴.

A case series of 250 patients reported that 6% (14/250) experienced intermittent or continuous diplopia following limited macular translocation (follow-up period not reported)⁵. A case report of 2 patients reported diplopia in 1 patient, however symptoms disappeared by 5-month follow-up⁶.

Validity and generalisability of the studies

- There was considerable variation in surgical technique in terms of method and direction of scleral imbrications.
- There was potential duplicate reporting of patients across studies. This is highlighted where suspected.
- Few long-term data are available in a condition with known progression.
- Efficacy outcome measures are not consistent across studies, particularly those relating to visual acuity.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Macular translocation for age-related macular degeneration. NICE interventional procedures guidance 48 (2004). Available from www.nice.org.uk/IPG48

This guidance is currently under review and is expected to be updated in 2010.

Technology appraisals

- Photodynamic therapy for age-related macular degeneration. NICE technology appraisal 68 (2003). Available from www.nice.org.uk/TA68
- Pegaptanib and ranibizumab for the treatment of age-related macular degeneration. NICE technology appraisal 155 (2008). Available from www.nice.org.uk/TA155

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr C Patel (Royal College of Ophthalmologists), Prof D Wong (Royal College of Ophthalmologists)

- One Specialist Adviser considered the procedure to be a minor variation of an already-established procedure, which is unlikely to alter its safety and efficacy.
- The main comparators are laser photocoagulation, photodynamic therapy, and nowadays intravitreal injection of anti-Vascular endothelial growth factor (VEGF) agents.
- The key efficacy outcomes to evaluate this procedure may include visual acuity, reading speed and quality of life
- Adverse events noted personally or anecdotally include retinal detachment, diplopia, cataract and macular fold.
- Adverse events reported in the literature include suprachoroidal haemorrhage.
- Additional theoretical adverse events may include endophthalmitis and recurrence of the condition.

- This is a procedure that was in vogue some time ago. Both limited translocation and translocation with 360° retinotomy have declined in popularity following the development of effective pharmacological treatments.
- The main constraint is the degree of retinal translocation achieved.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme was unable to obtain patient commentary for this procedure.

Issues for consideration by IPAC

- There have been few additional publications since the Committee originally considered this procedure in 2004.
- IPAC is also considering guidance on total macular translocation with 360° retinotomy for wet age-related macular degeneration.
- No comparative data comparing limited macular translocation to intravitreal injections are currently available.

References

- 1 Pawlak D, Glacet-Bernard A, Papp M et al. (2004) Limited macular translocation compared with photodynamic therapy in the management of subfoveal choroidal neovascularization in age-related macular degeneration. *American Journal of Ophthalmology* 137: 880–887
- 2 Fujii GY, de Juan E Jr, Pieramici DJ et al. (2002) Inferior limited macular translocation for subfoveal choroidal neovascularization secondary to age-related macular degeneration: 1-year visual outcome and recurrence report. *American Journal of Ophthalmology*. 134: 69–74
- 3 Fujii GY, Pieramici DJ, Humayun MS et al. (2000) Complications associated with limited macular translocation. *American Journal of Ophthalmology*. 130: 751–762
- 4 Lewis H. (2001) Macular translocation with choriocleral outfolding: a pilot clinical study. *American Journal of Ophthalmology*. 132: 156–163
- 5 Buffenn AN, de JE, Fujii G et al. (2001) Diplopia after limited macular translocation surgery. *Journal of the American Association for Pediatric Ophthalmology and Strabismus*. 5: 388–394
- 6 Au Eong KG. (2004) Initial experience of macular translocation in Singapore – one-year results. *Annals of the Academy of Medicine, Singapore* 33: 641–648

Appendix A: Additional papers on limited macular translocation for wet age-related macular degeneration

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Albini, T. A., Rao, N. A., Li, A., et al. (2004) Limited macular translocation: a clinicopathologic case report. Ophthalmology 111 (6) 1209-1214	n = 1 FU = 2 years	The fovea was translocated without causing apparent change in the underlying retinal pigment epithelium, Bruch's membrane, or choriocapillaris. Although there may be some photoreceptor loss, the excellent visual recovery suggests that the retinal pigment epithelium underlying the translocated fovea is functionally adequate.	Larger studies are included in appendix A. Mostly non-clinical outcomes reported.

Appendix B: Related NICE guidance for limited macular translocation for wet age-related macular degeneration

Guidance	Recommendations
Interventional procedures	<p>Macular translocation for age-related macular degeneration. NICE interventional procedures guidance 48 (2004)</p> <p>1.1 Current evidence on the safety and efficacy of macular translocation does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.</p> <p>1.2 Clinicians wishing to undertake macular translocation should take the following action.</p> <ul style="list-style-type: none"> • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's Information for the Public is recommended. • Audit and review clinical outcomes of all patients having macular translocation. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.
Technology appraisals	<p>Ranibizumab and pegaptanib for the treatment of age-related macular degeneration. NICE technology appraisal 155 (2008)</p> <p>1.1 Ranibizumab, within its marketing authorisation, is recommended as an option for the treatment of wet age-related macular degeneration if:</p> <ul style="list-style-type: none"> • all of the following circumstances apply in the eye to be treated: <ul style="list-style-type: none"> ○ the best-corrected visual acuity is between 6/12 and 6/96 ○ there is no permanent structural damage to the central fovea ○ the lesion size is less than or equal to 12 disc areas in greatest linear dimension ○ there is evidence of recent presumed disease progression (blood vessel growth, as indicated by fluorescein angiography, or recent visual acuity changes) <p>and</p> <ul style="list-style-type: none"> ○ the cost of ranibizumab beyond 14 injections in the treated eye is met by the manufacturer

	<p>1.2 It is recommended that treatment with ranibizumab should be continued only in people who maintain adequate response to therapy. Criteria for discontinuation should include persistent deterioration in visual acuity and identification of anatomical changes in the retina that indicate inadequate response to therapy. It is recommended that a national protocol specifying criteria for discontinuation is developed.</p> <p>1.3 Pegaptanib is not recommended for the treatment of wet age-related macular degeneration</p> <p>1.4 People who are currently receiving pegaptanib for any lesion type should have the option to continue therapy until they and their clinicians consider it appropriate to stop</p> <p>Photodynamic therapy for age-related macular degeneration. NICE technology appraisal 68 (2003)</p> <p>1.1 Photodynamic therapy (PDT) is recommended for the treatment of wet age-related macular degeneration for individuals who have a confirmed diagnosis of classic with no occult subfoveal choroidal neovascularisation (CNV) (that is, whose lesions are composed of classic CNV with no evidence of an occult component) and best-corrected visual acuity 6/60 or better. PDT should be carried out only by retinal specialists with expertise in the use of this technology</p> <p>1.2 PDT is not recommended for the treatment of people with predominantly classic subfoveal CNV (that is, 50% or more of the entire area of the lesion is classic CNV but some occult CNV is present) associated with wet age-related macular degeneration, except as part of ongoing or new clinical studies that are designed to generate robust and relevant outcome data, including data on optimum treatment regimens, long-term outcomes, quality of life and costs.</p> <p>1.3 The use of PDT in occult CNV associated with wet age-related macular degeneration was not considered because the photosensitising agent (verteporfin) was not licensed for this indication when this appraisal began. No recommendation is made with regard to the use of this technology in people with this form of the condition.</p> <p>1.4 Patients currently receiving treatment with PDT could experience loss of well-being if their treatment is discontinued at a time they did not anticipate. Because of this, all NHS patients who have begun a course of treatment with PDT at the date of publication of this guidance should have the option of continuing to receive treatment until their clinical condition indicates that it is appropriate to stop.</p>
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Appendix C: Literature search for limited macular translocation for wet age-related macular degeneration

Databases	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	27/04/2009	Issue 2, 2009	4
Database of Abstracts of Reviews of Effects – DARE (CRD website)	27/04/2009	N/A	1
HTA database (CRD website)	27/04/2009	N/A	2
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	27/04/2009	Issue 2, 2009	8
MEDLINE (Ovid)	27/04/2009	1950 to April Week 3 2009	82
MEDLINE In-Process (Ovid)	27/04/2009	April 24, 2009	7
EMBASE (Ovid)	27/04/2009	1980 to 2009 Week 17	56
CINAHL (NLH Search 2.0 or EBSCOhost)	27/04/2009	N/A	1
BLIC (Dialog DataStar)	27/04/2009	N/A	1

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	exp Macular Degeneration/
2	(macul* adj3 degenerat*).tw.
3	AMD.tw.
4	ARMD.tw.
5	(age* adj3 relat* adj3 macul*).tw.
6	(macul* adj3 edema*).tw.
7	or/1-6
8	(sclera* adj3 imbricat*).tw.
9	rotat*.tw.
10	Macula Lutea/
11	(macul* adj3 lutea*).tw.
12	10 or 11
13	9 and 12
14	translocat*.tw.
15	12 and 14
16	Macula Lutea/tr, su [Transplantation, Surgery]

17	(macul* adj3 translocat*).tw.
18	8 or 13 or 16 or 15 or 17
19	7 and 18
20	limit 19 to ed=20040101-20090423
21	Animals/ not Humans/
22	20 not 21