NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of macular translocation with 360° retinotomy 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.

Macular translocation with 360° retinotomy aims to improve vision. It involves cutting the macula and moving it to a nearby healthier area of the choroid layer. The macula is moved from its normal position by making a cut around the edge of the retina. This is called macular translocation with 360° retinotomy.

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

- Macular translocation with 360° retinotomy 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 (AMD) 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 is characterised by the growth of new neovascular vessels in the choroid layer underneath the macular retina, which can threaten vision if they leak and cause scarring. While the cause is unknown, there is a strong association with a history of smoking.

The visual prognosis of patients with wet AMD without treatment is poor. Some patients are diagnosed at an already advanced stage.

Lasers have been used to coagulate neovascular vessels in wet macular degeneration 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 the fovea lies over a healthier part of the choroid layer beneath it. The aim is to definitively move the site of the fovea to an area not affected by neovascularisation.

Macular translocation with 360° retinotomy involves making an incision around the whole periphery of the retina and rotating the retina. Following a vitrectomy, the retina is detached from the back of the eye using a saline solution. An incision is made around the entire perimeter of the so that it is only attached to the optic disc and is freely mobile. 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 muscle surgery in order to remove the torsion caused by the translocation and the silicone oil is drained.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to macular translocation with 360° retinotomy 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	Macular translocation with 360° retinotomy.
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 448 patients from two randomised controlled trials[1, 2], [10] one non-randomised controlled study[3] and five case series[4, 5, 6, 7, 8].

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

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy

Study details

Luke (2009)[1] Luke M (2007)[2]

Randomised controlled trial

Germany

Recruitment period: 2001 to 2004

Study population: Neovascularisation due to AMD

n = 50 (25 translocation, 25PDT)

Age: 77 years (mean)

Sex: 54% female

Patient selection criteria: > 50 years old, predominantly classic choroidal neovascularisation, BCVA 20/200 to 20/40, disease progression within 3 months, no prior treatment of neovascularisation or intraocular surgery (except cataracts), no opacity precluding fundus examination

Technique: General anaesthetic pars plana vitrectomy, 360° retinotomy with vitreous scissors, retinal detachment by hydrodissection. Neovascularisation lesion removed by sclerectomy, macular rotation. Counter rotation muscle surgery at 3 month follow-up. Versus PDT according to trial guidelines

Follow-up: 24 months (median) efficacy, 12 months safety

Conflict of interest/source of funding: None

Key efficacy findings

Visual acuity

Mean BCVA improved from 34.4 letters at baseline to 34.7 in the translocation group and worsened from 37.3 to 24.7 in the PDT group at 24-month follow-up (p = 0.052).

At 24-month follow-up, % and n

Visual acuity	Translocation	PDT	p
≥ 6 lines loss	8% (2/25)	24% (6/25)	0.25
3 to 5 lines loss	16% (4/25)	16% (4/25)	1.00
1 to 2 lines loss	12% (3/25)	24% (6/25)	0.73
No change	4% (1/25)	02% (5/25)	0.42
1 to 2 lines increase	32% (8/25)	16% (4/25)	0.32
≥ 3 lines increase	28% (7/25)	0% (0/25)	<0.01

Quality of life

Quality of life was assessed using the National Eye Institute Visual Function Questionnaire. Scored 0 to 100: higher scores represent better outcome.

Change from baseline to 24 months: mean score and standard error.

	Translocation	PDT	p
General health	+1.2 (3.0)	−1.9 (2.9)	0.44
General vision	+11.2 (3.5)	+8.0 (3.1)	0.28
Ocular pain	−1.5 (1.1)	−0.5 (1.6)	0.33
Social functioning	+9.3 (4.6)	+4.0 (2.9)	0.49
Mental health	+16.2 (5.4)	+8.6 (3.8)	0.14
Role difficulties	+5.0 (4.3)	+1.5 (3.1)	0.41
Dependency	+4.0 (5.0)	0.0 (3.2)	0.56

Key safety findings

Complications

44% (11/25) of patients treated with translocation had macular oedema at 12-month follow-up. 56% (14/25) of eyes had recurrent choroidal neovascularisation requiring laser photocoagulation, PDT, or both.

20% (5/25) of patients in the translocation group reported diplopia after counter rotation of muscles, and 8 patients had tilted vision.

In the PDT group 24% (6/25) of eyes had submacular disciform scarring, and leakage on angiographic assessment was found in 26% (9/35) of eyes at 12-month follow-up.

Outcome	Rate
Translocation	
Retinal detachment (vitrectomy and endotamponade reattachment in all)	24% (6/25)
Ocular hypotony	12% (3/25)
Insufficient macular rotation	4% (1/25)
Silicone in anterior chamber	4% (1/25)
Intraocular lens dislocation	4% (1/25)
Subretinal proliferative vitreoretinopathy membrane	16% (4/25)
PDT	
Retinal pigment epithelial tear (no progression to 12 months)	4% (1/25)
Local reaction at injection site	4% (1/25)
Back pain during PDT injection (not otherwise explained)	4% (1/25)

Comments

Follow-up issues:

- Consecutive patients recruited.
- Retrospective follow-up.
- One patient in the translocation group died and lost to follow-up at 12 months, 4 patients lost in PDT group (3 because of illness and 1 failure to participate. Last observations carried forward.
- BCVA outcomes assessed unblinded.

Study design issues:

- Randomisation stratified on size of neovascularisation lesion and BCVA, by independent department.
- All translocation procedures undertaken by the same surgeon.
- Phacoemulsification and intraocular lens insertion in phakic eyes in the translocation group.

Study population issues:

- Clinical and demographic characteristics at baseline not significantly different between groups.

Other issues:

- Authors state translocation should not be offered as a standard primary procedure.

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy

Study details	Key efficacy findings	Key safety findings	Comments
Joussen (2009)[10] **Randomised controlled trial** Germany and UK Recruitment period: 2002 to 2004 Study population: Exudative complications due to AMD. **n = 28 (13 translocation, 15 observation)** Age: 72 years (mean) Sex: 50% female Patient selection criteria: not reported Technique: 360° retinotomy with counter-rotation muscle surgery at second procedure in 9 patients. Versus observation or PDT (one of 13 patients only received PDT) **Follow-up: 12 months (median)** Conflict of interest/source of funding:	**Visual acuity** Visual acuity (change in number of lines with 4 correct letters read). Group man and standard deviation. **Translocation n=13** | **Observation n=15** | **p** 0.4±0.5 | 0.4±0.4 | 0.80 There was no statistically significant difference between the groups in terms of time course of visual acuity, reading performance, or contrast sensitivity. **Quality of life** There was no significant difference between the groups in any of the 12 subscales of eye specific quality of life at 12 months follow up.	**Complications** Safety outcomes were not reported on.	**Follow-up issues**: • Prospective study. 2 patients (1 from each group were lost to follow up and only had baseline data so were excluded from analysis. • 1 patient crossed over from control group to translocation group and 3 patients crossed over to control (refused surgery). **Study design issues**: • Multicentre study. • Randomisation 1:1 ratio, not otherwise described. • Sudy was stopped early due to poor recruitment and development of new pharmacological options. **Study population issues**: • There was no difference in functional or morphological characteristics between the groups at baseline **Other issues**: None.

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy

Study details	Key efficacy findings	Key safety findings	Comments
Chen FK (2009)[3] **Non-randomised controlled study** UK Recruitment period: 2003 to 2005 Study population: neovascularisation due to AMD **n = 24 (12 translocation, 12 choroid patch graft)** Age: 75 years (mean) Sex: 54% female Patient selection criteria: not reported Technique: phacoemulsification with intraocular lens implant. Pars plana vitrectomy. Retinal detachment with fluid air exchange, 360° retinotomy with vitreous cutter. Counter rotation muscle surgery at 2-month follow-up. Versus choroid patch graft surgery following vitrectomy, phacoemulsification with intraocular lens implant at 2-month follow-up **Follow-up: 41 months translocation, 38 months patch graft (median)** Conflict of interest/source of funding: Supported by a grant	**Surgical characteristics** Choroidal adhesion at the macula precluded translocation in 17% (2/12) of patients in the translocation group. In the remaining patients 45° to 60° foveal rotation was achieved. Choroidal neovascularisation removal in one piece achieved in 75% (9/12) and insertion of graft in one move achieved in 92% (11/12) of patients in the patch group. **Visual acuity** At 36-month follow-up 25% (3/12) of patients in the translocation group and 0% (0/12) of patients in the patch graft group had an improvement in BCVA of 3 lines or more. **Group mean** **Visual acuity** / **Translocation** / **Patch graft** Baseline / 0.90 / 0.87 1 year / 0.67 / 1.43 2 years / 0.69 / 1.46 3 years / 0.69 / 1.38 p / 0.09 / < 0.001 Statistical difference between groups not reported.	**Complications** In all patients the retina was attached at 12-month follow-up. **Translocation group** Retinal detachment repair required in 25% (3/12) of patients. Additional surgery for residual silicone oil removal was required in 17% (2/12) of patients in the translocation group. Additional surgery for residual torsion of > 30° was required in 17% (2/12) of patients in the translocation group. **Graft group** Retinal detachment repair required in 33% (4/12) of patients. No patients (0/12) had significant submacular haemorrhage in the patch group. Intraoperative giant retinal tear occurred in 8% (1/12) of patients, treated with laser retinopexy.	**Follow-up issues**: • Retrospective study. **Study design issues**: • Case matching using the initial 12 patients treated with each technique. A blinded observer performed grading of baseline clinical characteristics. • Comparator of choroid patch graft. Involving isolating choroid, choriocapillaris, Bruch's membrane and the Retinal pigment epithelium from the uveal bed, and transpositioning it under the fovea and covering with the retina. **Study population issues**: • Patients in the translocation group were significantly younger (p = 0.05), and duration of symptoms before surgery significantly longer (p < 0.001). **Other issues**: • Authors report that rotation of the macula in translocation is more controlled and likely to be less traumatic to photoreceptors than patch graft insertion provided that total detachment has been induced.

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy

Study details	Key efficacy findings	Key safety findings	Comments
Aisenbrey S (2007)[4] **Case series** Germany Recruitment period: 1997 to 1999 Study population: exudative AMD **n = 90** Age: not reported, Sex: not reported Patient selection criteria: not reported Technique: not reported **Follow-up: 38 months (mean)** Conflict of interest/source of funding: Supported by a grant	**Visual acuity** At 12-month follow-up 27% (24/90) of patients in the translocation group had an improvement in BCVA of 3 lines or more. Acuity was stable in 41% (37/90) of patients and had deteriorated (> 3 lines lost) in 32% (29/90). At 38-month follow-up 17% (15/90) of patients in the translocation group had an improvement in BCVA of 3 lines or more. Acuity was stable in 39% (35/90) of patients and had deteriorated (> 3 lines lost) in 44% (40/90). **Group mean** **Visual acuity** — **Translocation** Baseline — 1.00 1 year — 1.07 Final follow-up — 1.26 Point estimate for measurement of significance not reported but 95% confidence interval 0.14 to 0.37 at final follow-up.	**Complications** ***Complications to 12-month follow-up*** Proliferative vitreoretinopathy retinal detachment occurred in 19% of patients (absolute numbers not reported). ***Complications arising from 12 months to final follow-up*** **Outcome** — **Rate** Proliferative vitreoretinopathy retinal detachment — 4% (4/90) Late recurrence (treated with laser photocoagulation) at 51-month follow-up — 1% (1/90) Cystoid macular oedema — 8% (7/90) Secondary retinal pigment epithelium extending to the new fovea — 61%	**Follow-up issues**: • Prospective study. At the end of the study 28% (25/90) had died. 70% were available at 2 years, 58% at 3 years, 42% at 4 years and 28% at 5 years. **Study design issues**: • Case selection criteria not reported. **Study population issues**: • No clinical or demographic characteristics were reported in this study. **Other issues**: • None.

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy

Study details	Key efficacy findings	Key safety findings	Comments
Pertile G (2002)[5] **Case series** Belgium Recruitment period: 1999 to 2000 Study population: subfoveal neovascularisation and AMD **n = 50** Age: 76 years (mean) Sex: not reported Patient selection criteria: patients with a recent drop in visual acuity. All etiologies other than macular degeneration were excluded Technique: lens removed in all phakic eyes. Pars plana vitrectomy. Retinal detachment with injection of salt solution and fluid air exchange, 360° retinotomy with curved scissors. Counter rotation muscle surgery prior to translocation in 46 patients, following translocation in 4 patients. Choroidal neovascularisation treated with laser photocoagulation **Follow-up: 21 months (median)** Conflict of interest/source of funding: not reported	**Visual acuity** At 21-month follow-up 66% (33/50) of patients treated by translocation had an improvement in BCVA of 2 lines or more. Acuity was stable in 28% (14/50) of patients and had deteriorated (> 2 lines lost) in 6% (3/50). **Visual acuity** / **Baseline** / **Final follow-up** < 20/200 / 36% (18/50) / 16% (8/50) 20/200 to 20/125 / 50% (25/50) / 26% (13/50) 20/100 to 20/80 / 10% (5/50) / 18% (9/50) 20/60 / 4% (2/50) / 8% (4/50) 20/50 / 0% / 14% (7/50) 20/50 or better / 0% / 18% (9/50) Measurement of significance not reported. **Quality of life** 68% of patients able to read newspaper with glasses and reading aids.	**Complications** **Outcome** / **Rate** Choroidal haemorrhage (procedure stopped and continued weeks later – no other problems observed) / 4% (2/50) Proliferative vitreoretinopathy (treated vitrectomy epiretinal membrane peeling and silicone oil injection) / 18% (9/50) Recurrence of choroidal neovascularisation / 10% (5/50) Macular hole (treated by limiting membrane peeling and silicone oil tamponade) / 2% (1/50) Diplopia / 6% (3/50) Ocular muscle weakness / 2% (1/50) Temporary hypotony (intraocular pressure stable at 10 mmHg / 2% (1/50)	**Study included in original overview** **Follow-up issues**: • Consecutive patients treated. • Loss to follow-up not reported. **Study design issues**: • BCVA outcomes reported using categories that may not be mutually exclusive. • Visual acuity assessment not undertaken to a standardised protocol. **Study population issues**: • Five patients had received previous laser treatment for choroidal neovascularisation **Other issues**: • Authors state that further research is required to determine case selection, and optimum timing of treatment.

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy

Study details	Key efficacy findings	Key safety findings	Comments
Holgado S (2007)[6] **Case series** USA Recruitment period: 1999 to 2003 Study population: neovascularisation and AMD **n = 67** Age: not reported Sex: not reported Patient selection criteria: patients without a history of strabismus or diplopia Technique: not reported. Muscle counter rotation surgery undertaken up to 9 months after translocation surgery **Follow-up: 12 months (median)** Conflict of interest/source of funding: not reported	**Visual acuity** Group median (operated eye) **Visual acuity** / **Baseline** / **6–12 months** All patients (n = 67) / 20/100 / 20/68 Patients developing fixation switch and diplopia (n = 5) / 20/125 / 20/80 (see safety column)	**Complications** Before surgery all patients had better central vision in the eye intended for translocation surgery. 7% (5/67) of patients developed fixation switch and diplopia (better visual acuity in the operated eye but fixation with the fellow eye). 4 out of 5 patients with fixation switch and diplopia did not complain of subjective visual tilt. 4 out of 5 patients with fixation switch were treated with prisms, which were successful in 2 patients. 1 out of 5 patients underwent additional extraocular surgery in the fellow eye to reduce strabismus and match residual torsion. Diplopia persisted and the patient elected to wear a patch over the fellow eye.	**Follow-up issues**: • Prospective series, loss to follow-up not reported. **Study design issues**: • Study population consists of 67 of 73 patients initially treated with translocation who had attached retina at 6-month follow-up. **Study population issues**: • Clinical data of the study cohort not reported. **Other issues**: • Authors state that immediate postoperative decline in visual acuity leads to fixation switch to the fellow eye. In some patients fixation doesn't return to the operated eye even when acuity improves at 2–3 months.

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy

Study details	Key efficacy findings	Key safety findings	Comments
Mruthyunjaya P (2004)[7] **Case series** USA Recruitment period: 1999 to 2002 Study population: subfoveal neovascularisation and AMD **n = 64** Age: 76 years (median) Sex: 55% women Median duration of visual loss: 8 weeks Patient selection criteria: patients 55+ years, BCVA 20/50 to 20/400, maximum 6 months since onset of central vision loss. No previous laser treatment at the centre of the fovea, or submacular surgery Technique: intraocular lens insertion in all phakic eyes. Pars plana vitrectomy. Retinal detachment with injection of salt solution, 360° retinotomy with vitreous cutter and removal of subfoveal lesion. Extraocular muscle surgery for tortional diplopia performed at 8 weeks **Follow-up: 12 months** Conflict of interest/source of funding: supported by a grant	**Visual acuity** **Visual acuity** / **Baseline n = 61** / **12 months = 61** > 20/40 / 0% (0/61) / 8% (5/61) 20/40 to 20/80 / 38% (23/61) / 21% (13/61) 20/100 to 20/200 / 44% (27/61) / 34% (21/61) < 20/200 / 18% (11/61) / 13% (8/61) (p = 0.03) At 12-month follow-up 52% (32/61) of patients in the translocation group had an improvement in BCVA of 1 line or more. BCVA had deteriorated (> 3 lines lost) in 11% (7/61). **Quality of life** Reading speed was analysed using the submacular surgery trials reading cards. Group median and range **Baseline n = 55** / **12 months = 55** Words per minute: 71 (2 to 141) / 105 (0 to 194) (p < 0.001) Analysis of baseline characteristics of age, gender, side treated, phakic status and duration of vision loss showed no association with outcome for visual acuity or reading speed.	**Complications** Events up to 12-month follow-up **Outcome** / **Rate** Cystoid macular oedema: 41% (25/61) Epiretinal membrane formation: 23% (14/61) Recurrent choroidal neovascularisation: 21% (13/61) Progressive retinal pigment epithelium atrophy: 11% (7/61) Retinal detachment (successfully reattached in all, with surgery in 1 patient): 8% (5/61) Intraocular pressure < 6 mmHg: 3% (2/61) New subfoveal haemorrhage: 3% (2/61)	**Follow-up issues**: • Prospective series, 97% follow-up at 6 months, and 95% at 12 months. • Not all patients were evaluated for all outcomes. **Study design issues**: • All procedures undertaken by one surgeon. **Study population issues**: • None. **Other issues**: • Authors state that lack of control group and small sample size may have introduced bias in patient selection.

Abbreviations used: AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; PDT, photodynamic therapy

Study details	Key efficacy findings	Key safety findings	Comments
Li KK (2008)[8] **Case series** UK/Hong Kong Recruitment period: not reported Study population: neovascularisation and AMD **n = 75 eyes** Age: not reported Sex: not reported Patient selection criteria: not reported Technique: phacoemulsification. Pars plana vitrectomy. Retinal detachment with injection of salt solution, 360° retinotomy and rotation of retina **Follow-up: not reported** Conflict of interest/source of funding: not reported	Efficacy outcomes were not reported.	**Complications** Retinal slippage (not otherwise described) occurred in 3% (2/75) of eyes. In both cases silicone oil had to be removed and the retina rotated again. In one case the retina had become incarcerated and prolapsed though one of the sclerectomies. Technique was modified to ensure all salt solution had been removed before silicone oil filling.	**Follow-up issues**: • Retrospective study of consecutive patients treated. **Study design issues**: • Surgical technique reported for the first 29 cases only. The technique was then altered. **Study population issues**: • None. **Other issues**: • None.

Efficacy

A randomised controlled trial of 50 patients reported that a significantly greater proportion of patients treated by macular translocation (28%, 7/25) demonstrated an increase of ≥ 3 lines of best-corrected visual acuity (BCVA) compared with patients treated by photodynamic therapy (0%, 0/25) at 24-month follow-up ($p < 0.01$)[1].

A randomised controlled trial of 28 patients reported that mean improvement in BCVA improved by 0.4 lines in both the group of patients treated with macular translocation and those in the control group (observation) at 12 months follow-up[10]. A non-randomised controlled study of 24 patients reported that mean BCVA had improved from 0.90 to 0.69 in patients treated by translocation and decreased from 0.87 to 1.38 in patients treated by a choroid patch graft at 3-years follow-up (measurement of significance not reported)[3]. A case series of 90 patients reported that mean BCVA decreased from 1.00 at baseline to 1.26 at 38-month follow-up (measurement of significance not reported)[4].

A case series of 50 patients reported that 66% (33/50) of patients had improved BCVA of 2 lines or more at 21-month follow-up. Acuity was stable in 28% (14/50) of patients and a loss of > 2 lines was reported in 6% (3/50) of patients[5]. A case series of 64 patients reported that 52% (32/61) of patients had an improvement in BCVA of 1 or more line, while 11% (7/61) had a loss of > 3 lines[7].

A case series of 64 patients reported that median reading speed improved significantly from 71 words per minute at baseline to 105 words per minute at 12-month follow-up ($p < 0.001$)[7].

A randomised controlled trial of 50 patients reported that there was no difference between the groups of patients having full macular translocation and those treated by PDT in terms of quality-of-life scores for general health ($p=0.44$), general vision ($p=0.27$), or mental health score ($p = 0.14$) at 24 months follow-up[1].

A case series of 50 patients reported that 68% were able to read a newspaper with glasses and reading aids at 21-month follow-up after translocation surgery[5].

Safety

A randomised controlled trial of 50 patients reported that retinal detachment (requiring vitrectomy and endotamponade for reattachment) occurred in 24% (6/25) of patients in the translocation group at 12-month follow-up[2]. Retinal detachment repair was required in 25% (3/12) of patients in the translocation group of a non-randomised controlled study of 24 patients and in 33% (4/12) of patients in the choroid patch graft group (follow-up period varied between groups)[3]. In two case series of 90[4] and 64[7] patients retinal detachment occurred in 19% and 8% of patients respectively.

Residual torsion following macular translocation and 360° retinopathy and subsequent counter rotation muscle surgery was reported in 17% (2/12) of patients in a non-randomised controlled study of 24 patients[3]. Ocular muscle weakness was reported in 2% (1/50) of patients at 21-month follow-up in a case series of 50 patients[5].

Choroidal haemorrhage requiring cessation of surgery was reported in 4% (2/50) of patients in a case series of 50 patients[5].

Macular oedema following translocation surgery was reported in 8% (7/90) of patients in a case series of 90 patients at 38-month follow-up[4] and in 41% (25/61) of patients in a case series of 64 patients at 12-month follow-up[7].

A case series of 67 patients reported that 7% (5/67) of patients developed fixation switch (to the non-operated fellow eye) and diplopia at up to 12-month follow-up[6].

A case series of 75 eyes reported retinal slippage from the desired final location following translocation in 3% (2/75) of patients, which led to a change in surgical technique (number of patients not reported)[8].

Validity and generalisability of the studies

- The 2 comparative studies available use different comparators.
- Few long-term data are available in a condition which is known to progress.
- Considerable difference in surgical technique between studies, particularly relating to muscle counter rotation surgery, and method of treating choroidal neovascularisation.
- Efficacy outcome measures are not consistent across studies, particularly those relating to visual acuity.

Existing assessments of this procedure

A Cochrane collaboration review ‘Macular translocation for neovascular age-related macular degeneration’ by Eandi et al. (2009)[9] identified only one relevant study (Gelisken et al. 2007), which is included in table 2 of this overview. The conclusions of the review were as below.

There is insufficient evidence from randomised controlled trials on the effectiveness of macular translocation, which also carries important risks. Furthermore, this technique is difficult to perform and a long surgical training is required. Future studies might include patients with small neovascular lesions that failed to respond to current pharmacological therapies and who are willing to accept the risks associated with surgery to try to improve visual acuity.

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.

- Implantation of miniature lens systems NICE interventional procedures guidance 272 (2008). Available from www.nice.org.uk/IPG272

Technology appraisals

- Ranibizumab and pegaptanib and for the treatment of age-related macular degeneration. NICE technology appraisal 155 (2008). Available from www.nice.org.uk/TA155
- Guidance on the use of photodynamic therapy for age-related macular degeneration. NICE technology appraisal 68 (2003). Available from www.nice.org.uk/TA68

Specialist Advisers' opinions

Mr L Da Cruz (Royal College of Ophthalmologists), Mr D Wong (Royal College of Ophthalmologists).

- One specialist adviser categorised this procedure as established and no longer new.

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

- The key efficacy outcomes for this procedure include attached retina following surgery, and functional outcomes of BCVA and reading speed.

- The main comparator would be retinal pigment epithelial patch grafting, although macular translocation with 360° retinopathy is used for cases that have no other treatment.

- Adverse events reported in the literature include retinal detachment, proliferative vitreoretinopathy, macular oedema, diplopia, and phthisis.
- Additional theoretical adverse events may include residual torsion, and recurrence of neovascular membrane.
- The procedure is only used in massive subretinal heamorrhages.
- Uncertainly regarding the efficacy of the procedure may relate to whether photoreceptors are already irreversibly damaged.
- Although the risks may be high the potential benefit may be very high.
- The procedure can be completed only in a hospital with access to regular vireoretinal surgery.
- The procedure is likely to be available in less than 10 specialist centres. Fewer people are doing it than four years ago, and very few operations are likely in the next 2 years.

Patient Commentators' opinions

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

Issues for consideration by IPAC

- IPAC are also considering guidance on limited macular translocation for wet age-related macular degeneration.
- The evidence relates to periods before the mainstream introduction of newer intravitreal injection treatments. Therefore, the place of this procedure in the present era is difficult to determine based on reviewed evidence.

References

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Appendix A: Additional papers on macular translocation with 360° retinotomy 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
Abdel-Meguid A, Lappas A, Hartmann K et al. (2003) One year follow up of macular translocation with 360 degree retinotomy in patients with age related macular degeneration. British Journal of Ophthalmology 87: 615–21	Case series n = 39 follow-up = 12 months	Macular translocation surgery is able to maintain or improve distant vision in the majority of patients with exudative age-related macular degeneration	Larger studies are available in table 2
Baer CA, Rickman CB, Srivastava S (2008) Recurrent choroidal neovascularization after macular translocation surgery with 360-degree peripheral retinectomy. Retina 28: 1221–7	Case series n = 56 follow-up = 2 years	The development of choroidal neovascularisation occurs via a signaling mechanism from the fovea.	Larger studies are available in table 2
Cahill MT, Stinnett SS, Banks AD (2005) Quality of life after macular translocation with 360 degrees peripheral retinectomy for age-related macular degeneration. Ophthalmology 112: 144–51	Case series n = 50 follow-up = not reported	Macular translocation with 360° peripheral retinectomy was associated with improvement in vision-related quality of life. The amount of improvement was greatest in patients with postoperative improvement in visual function, and the best postoperative vision-related quality of life was seen in patients with better postoperative visual function.	Very few details available in article. Studies with longer follow up are included in table 2
Eckardt C, Eckardt U, Conrad HG (1999) Macular rotation with and without counter-rotation of the globe in patients with age-related macular degeneration. Graefes Archive for Clinical and Experimental Ophthalmology 237: 313–25	Case series n = 30 follow-up = 3 to 18 months	Macular rotation succeeded in restoring reading vision in about half of cases of exudative age-related macular degeneration.	Larger studies are available in table 2
Fujikado T, Asonuma S, Ohji M et al. (2002) Reading ability after macular translocation surgery with 360-degree retinotomy. American Journal of Ophthalmology 134: 849–56	Case series n = 34 follow-up = 7.6 months	The improvement in reading ability was significant in eyes with both age-related macular degeneration and choroidal neorevascularisation.	Larger studies are available in table 2

Nguyen NX, Besch D, Bartz-Schmidt K (2007) Reading performance with low-vision aids and vision-related quality of life after macular translocation surgery in patients with age-related macular degeneration. Acta Ophthalmologica Scandinavica 85: 877–82	Case series n =1 5 follow-up = 19 months	Our results indicated improvement in patients' subjective evaluations of visual function, without significant improvement in visual acuity	Larger studies are available in table 2
Suesskind, D., Voelker, M., Bartz-Schmidt KU (2008) Full macular translocation following photodynamic therapy in neovascular age-related macular degeneration. Eye 22: 834–37	Case series n = 12 follow-up = 26 months	In the present study, full macular translocation in PDT-non-responders stabilised or improved visual acuity in the majority of the eyes in a mean follow-up period of nearly 2 years	Larger studies are available in table 2
Terasaki H, Ishikawa K, Suzuki T et al. (2003) Morphologic and angiographic assessment of the macula after macular translocation surgery with 360 degrees retinotomy. Ophthalmology 110: 2403–8	Case series n = 23 follow-up = 10 months	The newly located macula after macular translocation surgery with a 360° retinotomy had cyctoid macular oedema on fluorescin angiography and normal macular configuration with normal thickness in optical coherence tomography.	Larger studies are available in table 2
Toth CA, Freedman SF (2001) Macular translocation with 360-degree peripheral retinectomy. Impact of technique and surgical experience on visual outcomes. Retina 21: 293–303	Case series n=26 follow-up = 12 months	With modified translocation surgery central vision has been salvaged for almost 1 year of follow-up in patients presenting with vision loss from subfoveal choroidal neovascularisation and age-related macular degeneration.	Larger studies are available in table 2 Possibly same patients as Aisenbrey (2007)

Appendix B: Related NICE guidance for macular translocation with 360° retinotomy for wet age-related macular degeneration

Guidance	Recommendations
Interventional procedures	**Macular translocation for age-related macular degeneration. NICE interventional procedures guidance 48 (2004)** 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. 1.2 Clinicians wishing to undertake macular translocation should take the following action. • 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. **Implantation of miniature lens systems NICE interventional procedures guidance 272 (2008)** 1.1 Evidence on the efficacy of implantation of miniature lens systems for advanced age-related macular degeneration (AMD) shows that the procedure can improve both vision and quality of life in the short term. Short-term safety data are available for limited numbers of patients. There is currently insufficient long-term evidence on both efficacy and safety. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake implantation of miniature lens systems for advanced AMD should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the need to adapt to having a lens system implanted into one eye, the risk of early complications and the uncertainties about long-term efficacy and safety. They should provide clear information. In addition, the use of the Institute's information for patients ('Understanding NICE guidance') is recommended.

	• Audit and review clinical outcomes of all patients having implantation of miniature lens systems for advanced AMD 1.3 Patient selection is crucial and should include detailed assessment to predict the patient's ability to process visual stimuli following the operation. 1.4 Further publication of safety and efficacy outcomes would be useful, specifically with regard to longer term follow-up. The Institute may review the procedure upon publication of further evidence.

Technology appraisals	**Ranibizumab and pegaptanib for the treatment of age-related macular degeneration. NICE technology appraisal 155 (2008)** 1.1 Ranibizumab, within its marketing authorisation, is recommended as an option for the treatment of wet age-related macular degeneration if: • all of the following circumstances apply in the eye to be treated: – 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). **and** • the cost of ranibizumab beyond 14 injections in the treated eye is met by the manufacturer. 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. 1.3 Pegaptanib is not recommended for the treatment of wet age-related macular degeneration. 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. **Photodynamic therapy for age-related macular degeneration. NICE technology appraisal 68 (2003)** 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. 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. 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. 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.

Appendix C: Literature search for macular translocation with 360° retinotomy 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