

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Trabecular stent bypass microsurgery for open-angle glaucoma

Primary open-angle glaucoma is a progressive condition that causes long-term increase of pressure within the eye. This damages the nerve that connects the eye to the brain (optic nerve) and may gradually lead to permanent loss of sight. This procedure involves inserting a hollow metal tube (stent) into the eye to drain fluid from the front chamber of the eye. The aim is to reduce pressure within the eye.

The National Institute for Health and Care Excellence (NICE) is examining trabecular stent bypass microsurgery for open-angle glaucoma and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about trabecular stent bypass microsurgery for open-angle glaucoma.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.

- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 18 November 2016

Target date for publication of guidance: February 2017

1 Draft recommendations

- 1.1 Current evidence on the safety of trabecular stent bypass microsurgery for open-angle glaucoma raises no major safety concerns. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit.

- 1.2 Trabecular stent bypass microsurgery for open-angle glaucoma should only be done by clinicians with specific training in the procedure.

2 Indications and current treatments

- 2.1 Open-angle glaucoma is a chronic condition associated with elevated intraocular pressure and leads to progressive damage to the optic nerve. Early stages are usually asymptomatic but as the condition progresses it causes visual impairment and, if untreated, blindness.
- 2.2 Treatment usually involves eye drops containing different pharmacological agents that reduce the production of, or increase the drainage of, aqueous humor. Surgical procedures such as trabeculectomy, drainage tubes, deep sclerectomy, viscocanalostomy, or laser trabeculoplasty may also be used.

3 The procedure

- 3.1 Trabecular stent bypass microsurgery aims to reduce intraocular pressure by creating a bypass channel between the anterior chamber and Schlemm's canal to improve drainage of aqueous humor.
- 3.2 This procedure is often combined with phacoemulsification and intraocular lens insertion for the concomitant treatment of cataracts. Using local anaesthesia, a small corneal incision is made and viscoelastic is inserted into the anterior chamber. Under gonioscopic guidance and using a special applicator, an L-shaped stent is slid through the trabecular meshwork (a small slit may be

necessary) and into Schlemm's canal. The position of the stent is verified, the viscoelastic is removed, and the applicator withdrawn.

3.3 More than one stent may be inserted during the same procedure.

4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

4.1 In a systematic review and meta-analysis of 2,143 patients from 32 studies, comparing stent insertion combined with phacoemulsification against phacoemulsification alone in patients with glaucoma and cataract, there was a statistically significant decrease in intraocular pressure (IOP) from baseline in the combined group compared against the phacoemulsification-only group at a follow-up of 12 to 58 months (standardised mean deviation [SMD]= -0.46, 95% confidence interval [CI] -0.87 to -0.06, n=4 randomised controlled trials [RCTs], $I^2=47%$, $p=0.128$). In a systematic review and meta-analysis of 248 patients (n=5 studies) with mild to moderate glaucoma treated by stent insertion alone, there was a statistically significant reduction in IOP from baseline after implantation of 1 stent at a follow-up of 6 to 18 months (SMD= -1.95, 95% CI -3.41 to -0.49, n=3 studies; $I^2=96%$, $p=0.000$) and of 3 stents at 6-month follow-up (SMD= -4.26, 95% CI -5.18 to -3.33, n=1 study). But there was not a statistically significant reduction in IOP from baseline after implantation of 2 stents at 6 to 12 months (SMD= -3.08, 95% CI -6.90 to 0.74, n=2 studies; $I^2=98%$, $p=0.000$). In the same study there was a 22% reduction in IOP from baseline

after 1-stent insertion at 18-month follow-up (n=1 study), and at 6-month follow-up there was a 30% reduction in IOP after 2-stent implantation (n=2 studies) and a 41% reduction after 3-stent insertion (n=1 study).

4.2 In the systematic review and meta-analysis of 2,143 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone, there was a statistically significant reduction in the number of topical glaucoma medications used after the procedure in the combined group compared against the phacoemulsification-only group (SMD= -0.65, 95% CI -1.18 to -0.12, n=3 studies, I^2 =58%, p=0.092). There was a weighted mean reduction in topical glaucoma medications per patient of 1.33 from baseline after insertion of 1 stent combined with phacoemulsification (n=3 RCTs), of 1.1 from baseline after insertion of 2 stents combined with phacoemulsification (n=1 RCT) and of 1.01 after phacoemulsification alone (n=3 RCTs).

4.3 In an RCT of 239 patients comparing stent insertion combined with phacoemulsification (n=116) against phacoemulsification alone (n=123) in patients with open-angle glaucoma not controlled on 1 medication, the proportions of eyes with corrected distance visual acuity of 20/40 or better in the combined group were 45% (49 eyes) before the procedure and 94% (99 eyes) at 12-month follow-up. In the phacoemulsification-only group, the proportions were 44% (53 eyes) before the procedure and 90% (101 eyes) 12 months after the procedure. In an RCT of 192 patients comparing implantation of 2 stents (n=94) against medical therapy (n=98), the proportions of eyes with best corrected visual acuity (BCVA) of 20/40 or better in the stent group were 84% before the procedure and 79% at 12-month follow-up. In the medical therapy group, the

proportions were 87% before the procedure and 84% at 12-month follow-up.

- 4.4 In the RCT of 192 patients comparing implantation of 2 stents (n=94) against medical therapy (n=98), the vertical cup-to-disc ratio had not changed from baseline (change within ± 0.2) in 97% (90/93) of patients in the stent group at 1-year follow-up, and was worse than baseline (increase of more than 0.2) in 1 patient (n=93). In the medication group, the vertical cup-to-disc ratio had not changed from baseline in 99% (88/89) of patients in the stent group at 1-year follow-up and was better than baseline (decrease of more than 0.2) in 1 patient (n=89). In an RCT of 119 patients comparing implantation of 1 stent (n=38) against implantation of 2 stents (n=41) or 3 stents (n=40) the mean cup-to-disc ratios at 18-month follow-up were the same as preoperative values.
- 4.5 In an RCT of 100 patients comparing stent insertion combined with phacoemulsification (n=50) against phacoemulsification alone (n=50) in patients with open-angle glaucoma and cataract, the successful stent implantation rate was 96% (48/50). In a prospective case series of 19 patients treated by stent implantation and phacoemulsification, the stent was successfully implanted in all eyes (19/19).
- 4.6 The specialist advisers listed the following key efficacy outcomes: IOP reduction, glaucoma medication use and quality of life.

5 Safety

This section describes 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 [interventional procedure overview](#) [*add URL*].

- 5.1 Severe loss of corrected distance visual acuity (CDVA) was reported in 1 patient each in the combined group and in the phacoemulsification-only group in a randomised controlled trial (RCT) of 239 patients with open-angle glaucoma not controlled on 1 medication comparing stent insertion combined with phacoemulsification (n=116) against phacoemulsification alone (n=123). In the combined group, the loss of CDVA occurred after a stroke; in the phacoemulsification-only group, it occurred after macular traction, macular hole and macular oedema treated with vitrectomy. In the same study, CDVA worse than 20/40 was reported in 7 eyes in the combined group and in 9 eyes in the phacoemulsification group at 24-month follow-up. The causes reported were onset or progression of macular disease (n=6), posterior capsule opacification (n=2) and dry eye (n=2). Blurry vision or visual disturbance were also reported in 3% (4/116) of eyes in the combined group and in 7% (8/117) of eyes in the phacoemulsification-only group.
- 5.2 Increase in intraocular pressure (IOP) above 10 mmHg after the procedure was reported in 48% of patients in the combined group of 1 of the 32 studies included in a systematic review and meta-analysis of 2,143 patients with glaucoma and cataract comparing stent insertion combined with phacoemulsification against phacoemulsification alone. In the same systematic review, rise in IOP above 30 mmHg after the procedure was reported in 15% of patients in the combined group in 1 of the 32 studies. Elevated IOP was reported in 10% of patients in 1 of the 5 studies included in a

systematic review and meta-analysis of 248 patients treated by stent insertion alone.

- 5.3 Cystoid macular oedema was reported in 1% of patients in the combined group of 1 of the 32 studies included in the systematic review and meta-analysis of 2,143 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone. Macular oedema was reported in 2% (1/50) of patients in the combined group and in 4% (2/50) of patients in the phacoemulsification-only group in an RCT of 100 patients comparing stent insertion combined with phacoemulsification (n=50) against phacoemulsification alone (n=50), during the first year of follow-up.
- 5.4 Optic disc haemorrhage was reported in 1 patient in each of the combined groups in the RCTs of 239 patients and 100 patients that compared stent insertion combined with phacoemulsification against phacoemulsification alone. This occurred within 24 months and 1 year of follow-up in the respective studies.
- 5.5 Hyphema was reported in 2% to 4% of patients in 3 of the 32 studies included in the systematic review and meta-analysis of 2,143 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone, and in 3% of patients in 1 of the 5 studies included in the systematic review and meta-analysis of 248 patients treated by stent insertion alone.
- 5.6 Subconjunctival haemorrhage was reported in 2% of patients in the combined group in 1 of the 32 studies included in the systematic review and meta-analysis of 2,143 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone, and in 1% of patients in 1 of the 5
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studies included in the systematic review and meta-analysis of 248 patients treated by stent insertion alone.

- 5.7 Anterior chamber collapse was reported in 2% of patients in the combined group in 1 of the 32 studies included in the systematic review and meta-analysis of 2,143 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone. Hypotony was reported in 3% of patients in 1 of the 5 studies included in the systematic review and meta-analysis of 248 patients treated by stent insertion alone.
- 5.8 Intraocular inflammation was reported in 1% of patients in 1 of the 5 studies included in the systematic review and meta-analysis of 248 patients treated by stent insertion alone.
- 5.9 Cataract progression was reported in 3% (4/119) of patients (2 in the 1-stent group and 2 in the 3-stent group) in an RCT comparing implantation of 1 stent (n=38) against implantation of 2 stents (n=41) or 3 stents (n=40) in patients with primary open-angle glaucoma not controlled on ocular hypotensive medication; the patients were treated by cataract surgery.
- 5.10 Goniosynechiae or iris synechiae each were reported in 1% of patients in 1 of the 5 studies included in the systematic review and meta-analysis of 248 patients treated by stent insertion alone. Focal peripheral anterior synechiae were reported in 30% (15/50) of patients in the combined group and in 4% (2/50) of patients in the phacoemulsification-only group in the RCT of 100 patients comparing stent insertion combined with phacoemulsification (n=50) against phacoemulsification alone (n=50), within 2 years of follow-up.

- 5.11 Vitreous wick incarcerated in paracentesis was reported in 2% of patients in the combined group in 1 of the 32 studies included in the systematic review and meta-analysis of 2,143 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone.
- 5.12 Vitreomacular traction was reported in 2% (1/50) of patients in each group in the RCT of 100 patients comparing stent insertion combined with phacoemulsification (n=50) against phacoemulsification alone (n=50), within 2 years of the procedure.
- 5.13 Posterior capsule opacification was reported in 3% and 1% of patients and in 6% (7/116) of eyes in the combined group in 1 of the 32 studies included in the systematic review and meta-analysis of 2,143 patients, in the systematic review and meta-analysis of 248 patients, and in the RCT of 239 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone within 24 months of the procedure, respectively.
- 5.14 Epiretinal membrane was reported in 2% of patients in the combined group in 1 of the 32 studies included in the systematic review and meta-analysis of 2,143 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone.
- 5.15 Iris atrophy was reported in 2% of patients in the combined group in 1 of the 32 studies included in the systematic review and meta-analysis of 2,143 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone.

- 5.16 Uveitis (iritis) was reported in 2% of patients and in 1 (n=116) eye treated by stent insertion and phacoemulsification in the systematic review and meta-analysis of 2,143 patients and in the RCT of 239 patients, respectively.
- 5.17 Dry eye was reported in 2% of patients in the combined group in 1 of the 32 studies included in the systematic review and meta-analysis of 2,143 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone. Soreness or discomfort was reported in 1 patient in the RCT of 192 patients comparing implantation of 2 stents (n=94) against medical therapy (n=98); this was treated with nonsteroidal anti-inflammatory medications.
- 5.18 Descemet folds were reported in 1 patient in each group at 1-month follow-up in the RCT of 100 patients comparing stent insertion combined with phacoemulsification (n=50) against phacoemulsification alone (n=50); they both resolved before the 3-month follow-up visit.
- 5.19 In the systematic review and meta-analysis of 2,143 patients (n=32 studies) comparing stent insertion combined with phacoemulsification against phacoemulsification alone, stent malposition was reported in 2-18% of patients in 6 studies, stent occlusion was reported in 4-15% of patients in 4 studies and blockage of the opening of the stent lumen was reported in 15% of patients in 1 study.
- 5.20 In the systematic review and meta-analysis of 248 patients (n=5 studies) treated by stent insertion alone, a need to reposition the stent was reported in 2% of patients in 1 study, stent not visible

upon gonioscopy was reported in 13% of patients in 1 study, and stent replacement was reported in 5% of patients in 1 study.

- 5.21 Secondary surgical interventions were needed in 4% (5/116) of eyes in the combined group and in 5% (6/117) of eyes in the phacoemulsification-only group in the RCT of 239 patients comparing stent insertion combined with phacoemulsification against phacoemulsification alone within 24 months of follow-up (including patients who had more than 1 surgical re-intervention). In the combined group of 116 patients, the secondary surgical interventions were stent repositioning (3% [3/116]), stent removal and replacement (1 patient), Nd:YAG laser for stent obstruction (1 patient), trabeculoplasty (1 patient) and focal argon laser photocoagulation (1 patient). Secondary glaucoma surgery was reported in 1 patient in the combined group and in 2 patients in the phacoemulsification-only group in the RCT of 100 patients comparing stent insertion combined with phacoemulsification (n=50) against phacoemulsification alone (n=50), during the second year of follow-up.
- 5.22 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse event: stent dislocation. They considered that the following was a theoretical adverse event: stent movement during MRI scan.

6 Committee comments

- 6.1 The committee noted that more than one device is available for this procedure and that the evidence on the safety and efficacy of the procedure is predominantly from one device.
- 6.2 The committee noted that patients may have more than 1 stent inserted during the procedure.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 This guidance is a review of NICE's interventional procedure guidance on [trabecular stent bypass microsurgery for open angle glaucoma](#).

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