

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary 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 placing a tiny soft gel tube into the eye to create a new channel to allow excess fluid to drain out. The aim is to reduce pressure in the eye.

The National Institute for Health and Care Excellence (NICE) is looking at microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

**This is not our final guidance on this procedure. The recommendations may change after this consultation.**

After consultation ends:

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

- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are 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 developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please 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 we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 22 January 2017

Target date for publication of guidance: April 2018

## 1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear information to support shared decision-making. In addition, the use of NICE's information for the public [[URL to be added at publication]] is recommended.
- Audit and review clinical outcomes of all patients having microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

1.3 NICE encourages further research into microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma, including randomised studies. Further research should include details of patient selection and long-term outcomes.

## **2 The condition, current treatments and procedure**

### ***The condition***

2.1 Open-angle glaucoma is a chronic condition associated with increased intraocular pressure, which 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.

### ***Current treatments***

2.2 Treatment is usually eye drops containing drugs that either reduce the production of aqueous humor or increase its drainage. Surgical procedures such as trabeculectomy, inserting drainage tubes, deep sclerectomy, viscocanalostomy or laser trabeculoplasty may also be used.

### ***The procedure***

2.3 Microinvasive insertion of a trans-scleral gelatin stent via the ab interno approach (placed surgically from the anterior chamber, outwards to the subconjunctival space) for treating open-angle glaucoma is a minimally invasive procedure. It involves implanting a gelatin stent, a collagen-derived drainage device, to reduce intraocular pressure. The collagen is derived from animal sources. The procedure creates an artificial bypass channel and drainage pathway from the anterior chamber into the non-dissected tissue of the subconjunctival space to improve drainage and outflow of aqueous humor.

2.4 This procedure can be done at the same time as phacoemulsification and intraocular lens insertion for treating cataracts.

2.5 Under local or topical anaesthesia, a small incision is made in the cornea, and the anterior chamber is filled with viscoelastic. A preloaded implant injector is then advanced through the same corneal incision and directed towards the scleral spur. The injector

needle is directed through the sclera to emerge under the conjunctiva, approximately 2 mm to 3 mm behind the limbus. The soft and permanent gelatin stent is then injected, to traverse the anterior chamber, sclera and conjunctival space. After placement is checked (using a gonioscopy mirror) the viscoelastic is exchanged for a balanced salt solution and the injector is withdrawn. The corneal incision is usually self-sealing but is sometimes sutured. Subconjunctival injection of mitomycin-C may be done during the procedure.

### **3 Committee considerations**

#### ***The evidence***

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 1 retrospective comparative case series, 4 case series and 3 case reports, and is presented in table 2 of the [interventional procedures overview](#). Other relevant literature is in the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduction in intraocular pressure and reduction in glaucoma specific medication.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: hypotony, loss of visual acuity and infection.

- 3.4 One [commentary](#) was received from a patient who had experience of this procedure, and was discussed by the committee.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

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