

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Trabeculectomy with a biodegradable collagen matrix implant for glaucoma

Glaucoma causes fluid to build up in the eye, which increases pressure in the eye. This damages the optic nerve, which connects the eye to the brain, and can lead to permanent sight loss. In this procedure, a small flap is cut in the white of the eye (a trabeculectomy) and sewn up with loose stitches. A tiny patch (collagen matrix) is put over the flap to help healing and prevent scarring. Fluid slowly drains out of the flap and the patch dissolves over time (biodegradable). The aim is to reduce pressure in the eye and slow or stop damage to sight.

NICE is looking at trabeculectomy with a biodegradable collagen matrix implant for glaucoma.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

**This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.**

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

## NICE interventional procedures consultation document, June 2022

Please note that we reserve the right to summarise and edit comments received during consultation 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: 18 August 2022

Target date for publication of guidance: January 2023

## 1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of trabeculectomy with biodegradable collagen matrix implant for glaucoma is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out [what standard arrangements mean on the NICE interventional procedures guidance page](#).
- 1.2 Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into [NICE's interventional procedure outcomes audit tool](#) (for use at local discretion).

## 2 The condition, current treatments and procedure

### The condition

- 2.1 Glaucoma is usually a chronic condition associated with raised intraocular pressure. It 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. There are several types of glaucoma but the most common type of glaucoma in the UK is primary (or chronic) open angle glaucoma.

### Current treatments

- 2.2 [NICE's guideline on glaucoma](#) describes its diagnosis and management. Treatment usually involves eye drops containing different drugs that either reduce aqueous humour production or increase its drainage. Surgical procedures such as trabeculectomy, drainage tubes, deep sclerectomy, viscocanalostomy, laser trabeculoplasty and cyclodiode laser treatment may also be used.

### The procedure

- 2.3 Trabeculotomy with an adjunctive biodegradable collagen matrix aims to modify wound healing and improve the drainage of aqueous humour to

lower intraocular pressure. It reduces or avoids the use of antimetabolites and antifibrotic agents (mitomycin C [MMC], 5-fluorouracil).

- 2.4 In this procedure, with the person under local (intracameral) anaesthesia, conjunctiva is lifted (or opening is created) to access the sclera, and then a partial-thickness scleral flap is dissected. Within the scleral bed a full-thickness opening (or a perforating scleral entrance) is created into the anterior chamber, to allow drainage of aqueous humour. Sometimes trabecular meshwork and adjacent structures are also removed. The scleral flap is then sutured loosely with 1 or 2 loops, to allow the aqueous fluid to drain into the subconjunctival space through the scleral hole. Cohesive viscoelastic is injected under the scleral flap. Then a subconjunctival biodegradable collagen matrix implant is placed directly on top of the scleral flap, and the conjunctiva is sutured (using continuous sutures) and closed around it.

### **3 Committee considerations**

#### **The evidence**

- 3.1 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 4 sources, which was discussed by the committee. The evidence included 2 systematic reviews and meta-analyses, 1 randomised controlled trial, and 1 case report. It is presented in [the summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in intraocular pressure, reduction in medication use, preservation of visual fields and quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: hypotony, pain, bleeding and infection.

3.4 Patient commentary was sought but none was received.

### **Committee comments**

3.5 The committee was informed that the biodegradable collagen matrix implant is made from porcine collagen.

3.6 The committee noted that a potential advantage of this procedure is that it avoids the use of mitomycin C as an adjunct to trabeculectomy, which can cause postoperative side effects such as thinning of the conjunctiva and bleb leaks.

3.7 The committee noted that most of the evidence was from adults with open angle glaucoma.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

July 2022

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