

Trabeculectomy with a biodegradable collagen matrix implant for glaucoma

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg750

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 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 field 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 Trabeculectomy 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, 5-fluorouracil).
- 2.4 In this procedure, with the person under local (intracameral) anaesthesia, the conjunctiva is lifted (or an 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, and that the safety of the device has not been established in pregnancy, or in babies or children.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).