

Scleral expansion surgery for presbyopia

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg70

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 Guidance

- 1.1 Current evidence on the safety and efficacy of scleral expansion surgery for presbyopia is very limited. There is no evidence of efficacy in the majority of patients. There are also concerns about the potential risks of the procedure.
- 1.2 It is recommended that this procedure should not be used. NICE's information for the public complements this guidance in explaining the concerns about the procedure.

2 The procedure

2.1 Indications

- 2.1.1 Presbyopia is an age-related and progressive loss of focusing power of the lens in the eye. It leads to a gradual decline in the ability to focus on close objects.
- 2.1.2 Standard treatment for presbyopia is the use of corrective spectacles. As the condition worsens, prescriptions need to be changed accordingly.

2.2 Outline of the procedure

- 2.2.1 Scleral expansion surgery involves making small incisions in the eye and inserting bands to stretch the part of the sclera that lies beneath the ciliary muscles that control accommodation. This procedure is claimed to improve accommodation.

2.3 Efficacy

- 2.3.1 All studies identified were of poor quality. The evidence was limited to one non-randomised controlled study of 29 patients, two very small case series (of six and three patients, respectively) and two case reports. In the controlled study, in which the dominant eye was operated on and the other eye served as a control, improvement in median reading acuity score at 20 cm was reported as -0.41 for operated eyes and -0.35 for control eyes ($p < 0.03$), indicating that the improvement in operated eyes was greater. No significant difference in reading acuity was found at 30 cm or 40 cm. One case series reported that near visual acuity improved temporarily in 3 out of 8 eyes (38%), but it was no better than before surgery at day 360. In the same study, implanted bands were removed from three eyes upon patient request because of lack of benefit. In another case series of three patients, scleral expansion surgery failed to restore accommodation in any patients. For more details, see the [overview](#).
- 2.3.2 The Specialist Advisors considered the evidence to suggest that the procedure is not efficacious. One Advisor noted that the procedure was controversial because it was based on a novel theory of the mechanism of accommodation of the human eye that was in direct opposition to other generally accepted theories.

2.4 Safety

- 2.4.1 The complications reported in the identified studies were: two case reports of band removal because of band migration or chronic pain and swelling; two cases of perforated conjunctiva in a study of 8 patients; and one report of transient elevation of intraocular pressure in a study of 29 patients. For more details, see the [overview](#).
- 2.4.2 The Specialist Advisors listed the main potential adverse events as intraocular haemorrhage, retinal detachment, endophthalmitis, glaucoma, conjunctival scarring and scleral thinning.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for the public

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

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