

# **NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE**

## **INTERVENTIONAL PROCEDURES PROGRAMME**

### **Interventional procedures overview of scleral expansion for presbyopia**

#### ***Introduction***

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

#### ***Date prepared***

This overview was prepared by Bazian Ltd in April 2003.

#### ***Procedure name***

- Scleral expansion for presbyopia.

#### ***Specialty society***

- Royal College of Ophthalmologists.

#### ***Description***

Presbyopia results from age-related deterioration of the lens in the eye. This leads to difficulty with accommodation (focusing on close objects).

Scleral expansion surgery involves making small incisions in the eye and inserting bands to stretch the part of the sclera (the tough fibrous layer of the eyeball) that lies beneath the muscles controlling accommodation (ciliary muscles). This is claimed to improve accommodation.

#### ***Efficacy***

The studies found provide no evidence of efficacy of scleral expansion bands for presbyopia.

One Advisor noted that the procedure was controversial as it was based on a novel theory of the mechanism of accommodation of the human eye, which was in direct opposition to the generally accepted theories of Young and Helmholtz.

## **Safety**

According to the literature, risks of scleral expansion bands for presbyopia include conjunctival perforation, migration and chronic inflammation.

According to the Specialist Advisors, potential adverse effects include increase in myopia, glaucoma, scleral thinning, conjunctival scarring, bleeding, endophthalmitis, and retinal detachment.

## ***Literature reviews***

### **Appraisal criteria**

Studies of scleral expansion for age-related loss of accommodation were included.

### **List of studies included in the overview**

No systematic reviews or randomised controlled trials were found.

One non-randomised controlled study was found.<sup>1</sup>

Two case series<sup>2,3</sup> and two case reports<sup>4,5</sup> were found.

## Summary of key efficacy and safety findings

Study details	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
<p>Qazi, 2002<sup>1</sup></p> <p>Non-randomised controlled trial: dominant eye operated on, other eye served as control</p> <p>USA</p> <p>n = 29 patients (dominant eye only) age range 51 to 60 years</p> <p>Exclusion criteria:</p> <ul style="list-style-type: none"> <li>• previous invasive eye surgery</li> <li>• sickle cell disease</li> <li>• hyperviscosity</li> <li>• microangiopathy</li> <li>• anticoagulants</li> <li>• allergies to substances used</li> </ul> <p>Follow up: 6 months</p>	<p>Change in reading acuity (using change in median score calculated using a formula incorporating accuracy and reading speed):</p> <p>At 20 cm:</p> <ul style="list-style-type: none"> <li>• operated eye: 0.41</li> <li>• control eye: 0.35</li> </ul> <p>(improvement in control and operated eyes; improvement greater in operated eye)</p> <p>p &lt; 0.03</p> <p>At 30 cm:</p> <ul style="list-style-type: none"> <li>• operated eye: 0.30</li> <li>• control eye: 0.35</li> </ul> <p>p = 0.54</p> <p>At 40 cm:</p> <ul style="list-style-type: none"> <li>• operated eye: 0.30</li> <li>• control eye: 0.26</li> </ul> <p>p = 0.896</p>	<p>No anterior segment ischaemia or malignant glaucoma</p> <p>Transient elevation of intraocular pressure: 1 person</p>	<p>Small study.</p> <p>Method of control selection could have led to overmatching.</p> <p>Valid outcome measures.</p> <p>Many significance tests performed.</p>

<p>Malecaze, 2001<sup>2</sup></p> <p>Case series</p> <p>France</p> <p>n = 6 patients (8 eyes), mean age 55 years:</p> <ul style="list-style-type: none"> <li>• 4 received scleral expansion bands to 1 eye</li> <li>• 2 received scleral expansion bands to both eyes</li> </ul> <p>Follow up: 1 year</p>	<p>Distant visual acuity unchanged after surgery</p> <p>Near visual acuity improved temporarily in 3 eyes but at day 360 was no better than before operation</p> <p>Amplitude of accommodation no different at day 360 than before surgery</p>	<p>2 segments perforated conjunctiva</p> <p>2 patients (3 eyes) wanted segments removed due to no benefit</p>	<p>Small uncontrolled case series.</p>
<p>Mathews, 1999<sup>3</sup></p> <p>Case series</p> <p>USA</p> <p>n = 3 patients</p> <p>Follow up 1 week to 1 month after surgery</p>	<p>Scleral expansion surgery did not restore accommodation</p>	<p>None presented</p>	<p>Small uncontrolled case series.</p>
<p>Vertrugno, 2001<sup>4</sup></p> <p>Case report</p> <p>Italy</p> <p>57 year old woman received scleral expansion surgery to both eyes</p>	<p>Uncorrected visual acuity at 40 cm improved from 20/80 to 20/30 in both eyes</p> <p>Gain in accommodative amplitude approximately 2.5 dioptres in both eyes</p>	<p>1 band migrated to surface and was removed at 11 months</p>	<p>Single case report.</p>

<p>Singh, 2000<sup>5</sup></p> <p>Case report</p> <p>USA</p> <p>46 year old woman received scleral expansion surgery to right eye</p>	<p>'post-operatively, she note decreased visual acuity for distance, but improved uncorrected near vision in the right eye'</p>	<p>Chronic pain and swelling requiring removal of scleral expanders at 3 to 6 weeks postoperatively</p>	<p>Single case report.</p>
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## **Validity and generalisability of the studies**

One controlled study was found.<sup>1</sup> Using the study participants' unoperated eyes as controls may lead to overmatching, so any similarity of outcomes between the groups may not be due to differences in treatment. The researchers performed many significance tests; this increases the chance of generating p values of less than 0.05 when no true difference exists.

Several very small case series and case reports were found. These are unreliable for assessing the safety and efficacy of scleral band expansion.

## **Specialist Advisors' opinions**

*Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.*

- Very novel.
- Controversial.
- Not efficacious.
- May not be safe.
- The proposed mechanism of action is disputed because it is directly opposite to the conventional view of the mechanism of accommodation of the eye.
- Unless substantial new evidence emerges for the benefits of the procedure and the veracity of the underlying theory, its adoption in the UK cannot be recommended.

## **References**

1. Qazi MA, Pepose JS, Shuster JJ. Implantation of scleral expansion band segments for the treatment of presbyopia. *American Journal of Ophthalmology* 2002; 134: 808-15.
2. Malecaze FJ, Gazagne CS, Tarroux MC, Gorrand JM. Scleral expansion bands for presbyopia. *Ophthalmology* 2001; 108: 2165-71.
3. Mathews S. Scleral expansion surgery does not restore accommodation in human presbyopia. *Ophthalmology* 1999; 106: 873-7.
4. Vetrugno M, Cardia L. Spontaneous extrusion of a scleral expansion band segment. *Annals of Ophthalmology* 2001; 33: 249-51.
5. Singh G, Chalfin S. A complication of scleral expansion surgery for treatment of presbyopia. *American Journal of Ophthalmology* 2000; 130: 521-3.