

# Scleral expansion surgery for presbyopia

## 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. The Institute'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 3/8 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, refer to the Sources of evidence (see overleaf).
- 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.

# Interventional Procedure Guidance 70

## This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

## 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, refer to the Sources of evidence.

2.4.2 The Specialist Advisors listed the main potential adverse events as intraocular haemorrhage, retinal detachment, endophthalmitis, glaucoma, conjunctival scarring and scleral thinning.

Andrew Dillon  
Chief Executive  
July 2004

## Information for the Public

The Institute has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from [www.nice.org.uk/IPG070publicinfo](http://www.nice.org.uk/IPG070publicinfo)

## Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

*Interventional procedure overview of scleral expansion surgery for presbyopia*, April 2003

Available from: [www.nice.org.uk/ip048overview](http://www.nice.org.uk/ip048overview)

### Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0628. *Information for the Public* can be obtained by quoting reference number N0629 for the English version and N0630 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL [www.nice.org.uk/IPG070distributionlist](http://www.nice.org.uk/IPG070distributionlist)

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