



# Tenotomy of horizontal eye muscles for nystagmus (with reattachment at their original insertions)

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www.nice.org.uk/guidance/ipg299

# 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 <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

#### 1 Guidance

- 1.1 The evidence on tenotomy of horizontal eye muscles for nystagmus (with reattachment at their original insertions) raises no major safety concerns, but current evidence on its efficacy is inadequate in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to undertake tenotomy of horizontal eye muscles for nystagmus (with reattachment at their original insertions) should take the following actions.
  - Inform the clinical governance leads in their Trusts.
  - Ensure that patients and their carers understand the uncertainty about the
    procedure's safety and efficacy and provide them with clear written
    information. In addition, the use of <u>NICE's information for the public</u> is
    recommended.
  - Audit and review clinical outcomes of all patients having tenotomy of horizontal eye muscles for nystagmus (with reattachment at their original insertions; see <a href="section 3.1">section 3.1</a>).
- Patient selection and follow-up should take place in specialist units with experience in the management of ocular motility disorders.
- 1.4 NICE encourages further collaborative data collection, including information on

visual acuity and quality of life, and may review the procedure on publication of further evidence.

## 2 The procedure

#### 2.1 Indications and current treatments

- 2.1.1 Nystagmus is an involuntary oscillatory movement of the eyes, usually from side to side, but sometimes the eyes move up and down or in a circular motion. Most people with nystagmus have impaired vision.
- 2.1.2 There are several types of nystagmus but there is no definitive classification system to describe them. Nystagmus may be present at birth, caused by defects in the eye or the visual pathway from the eye to the brain. It can occur in a wide range of childhood eye disorders and may be found in children with multiple disabilities. Nystagmus can also develop later in life as a symptom of a variety of conditions, including stroke, multiple sclerosis or head injury.
- 2.1.3 There is currently no curative treatment for nystagmus. Spectacles or contact lenses may be worn to improve visual acuity but they do not correct the nystagmus.

### 2.2 Outline of the procedure

- 2.2.1 Tenotomy for nystagmus is carried out with the patient under general anaesthesia, and involves division of the attachments of the two horizontal rectus muscles (lateral and medial) of each eye. A limbal incision is made in the conjunctiva and each muscle is detached from the sclera. The muscles are then reattached at their original places of insertion.
- 2.2.2 The aims of the procedure are to reduce the frequency and amplitude of nystagmus (how often and how far the eyes oscillate) and to improve visual acuity. The exact mechanism by which this procedure might improve nystagmus

is unknown.

### 2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>overview</u>.

- In a case series of ten adults treated with tenotomy, nine patients had increased and one patient had decreased expanded Nystagmus Acuity Function (NAFX) scores at 1 year (this score is an objective measure used to predict visual acuity on the basis of the patient's foveation period, defined as their ability to fix an image on the fovea, the most visually precise part of the retina). A case series of nine patients with infantile nystagmus reported that eight patients had increased NAFX scores (mean 60%) at 1 year. The NAFX score remained unchanged in one patient at 1 year. All nine patients had reduced nystagmus amplitude (mean 33%) and increased foveation period (mean 104%) at 1 year. In a case series of five patients with infantile nystagmus, two were assessed for eye movement. The NAFX scores improved by 8% in one child at 1 year and by 36% in the other child at 6 months.
- Two case series of five children and ten adults reported improvements in bestcorrected visual acuity of at least five letters on the Early Treatment Diabetic
  Retinopathy Study chart (corresponding to a one-line improvement on the Snellen
  chart) in four and five patients, respectively (assessed at 6 weeks and 12 months,
  respectively). The case series of nine patients reported that three patients had an
  improvement in visual acuity of at least one line, three had an improvement of a
  few letters and three had no change (method of assessment and follow-up was
  not described).
- In a case series of five patients, all patients had a reduced time to target acquisition (measured by infrared reflection or high-speed digital video) 1 year after the procedure (precise reduction not stated).
- 2.3.4 The Specialist Advisers considered efficacy outcomes to include best-corrected binocular visual acuity under varying gaze angles, null point width, stereoacuity,

ocular movement recordings, nystagmus, visual function in day-to-day life, quality of life, cosmesis and head posture.

### 2.4 Safety

- 2.4.1 No adverse events were reported in the literature.
- The Specialist Advisers considered theoretical adverse events to include damage to the retina or perforation of the globe, infection and misalignment of muscles causing redness, swelling, diplopia, induced strabismus and possible loss of vision. Revision surgery may be needed to correct these adverse outcomes. One Specialist Adviser stated that development of a conjunctival cyst had been reported in the literature.

#### 3 Further information

This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant <u>audit criteria</u> and has developed audit support (which is for use at local discretion).

#### Sources of evidence

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

### Information for patients

NICE has produced <u>information for the public on this procedure</u>. 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 <u>Healthcare Improvement Scotland</u>.