



Incisionless otoplasty

Interventional procedures guidance Published: 27 March 2012

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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 impact of implementing NICE recommendations</u> wherever possible.

1 Guidance

- 1.1 Incisionless otoplasty comprises a variety of surgical techniques, carried out via minimal percutaneous access, that have been poorly described in the evidence, which includes a very small number of patients. The evidence on efficacy and safety is inadequate both in quality and quantity, and therefore the procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake incisionless otoplasty should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients and/or their parents or carers understand the
 uncertainty about the procedure's safety and efficacy, and provide them with
 clear written information. In addition, the use of NICE's information for the
 public is recommended.
 - Audit and review clinical outcomes of all patients having incisionless otoplasty (see <u>section 3.1</u>).
- 1.3 Further research on incisionless otoplasty should describe the precise surgical techniques used and should report both short- and long-term outcomes, including the need for further procedures.

2 The procedure

2.1 Indications and current treatments

2.1.1 Protruding or prominent ears result when normal cartilaginous folds fail to form

within the ear.

2.1.2 Surgery to correct protruding ears aims to reposition the elastic cartilage permanently while preserving a natural appearance. Cartilage-sparing techniques avoid radical excision, but reduce the cartilage spring by such measures as scoring, drilling and suturing. All techniques usually involve a post-auricular incision of the skin.

2.2 Outline of the procedure

- 2.2.1 Incisionless otoplasty avoids the use of a standard incision, which can sometimes be complicated by anterior skin necrosis or keloid scar formation.
- 2.2.2 The procedure is usually carried out with the patient under general anaesthesia, but it can also be done under local anaesthesia. Precise details of the procedure depend on the nature of the ear abnormalities, the needs of the individual patient and the preferences of the surgeon. In an optional first stage, a needle is inserted into the anterior aspect of the ear and used to score the anterior surface of the cartilage and render it more malleable. A posterior approach is then used to insert subcutaneous retention sutures (usually non-absorbable) to create a natural looking antihelix with less ear protrusion. Conchal cartilage may also be anchored onto the mastoid bone by a subcutaneous stitch attached to non-elastic tissue such as the periosteum.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 A case series of 13 patients (5 of whom were treated by incisionless otoplasty) reported that photographs showed good correction and that all patients and their families were satisfied with the outcome.

- A case series of 11 patients reported that all results were 'satisfactory' with no recurrence during 6- to 30-month follow-up.
- 2.3.3 The specialist advisers listed key efficacy outcomes as aesthetic ear correction and avoidance of recurrence.

2.4 Safety

- 2.4.1 No safety concerns were reported in the published literature.
- 2.4.2 The specialist advisers listed anecdotal adverse events as anterior skin necrosis, collapse of the ear necessitating reconstruction with costal cartilage, poor aesthetic outcome and bleeding.

2.5 Other comments

2.5.1 The committee noted the psychological distress caused by protruding ears and the potential benefit of effective treatment, in particular by procedures that minimise scarring. However, the limited publications available provided inadequate evidence to suggest that incisionless otoplasty is an efficacious procedure. The committee expressed particular disappointment at the paucity of the evidence base.

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 an <u>audit tool</u> (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>.