NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of incisionless otoplasty

Incisionless surgery to correct protruding ears

Protruding ears can be distressing to the individual who has them. This procedure aims to improve the appearance of the ear without cutting into the skin. A hollow needle is used to divide the ear cartilage, and stitches buried under the skin are used to remould the ear.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in March 2011.

Procedure name

- Incisionless otoplasty

Specialty societies

- ENT UK: the British Association of Otorhinolaryngologists – Head and Neck Surgery
- British Association of Plastic, Reconstructive and Aesthetic Surgeons
- British Association of Oral and Maxillofacial Surgeons.

Description

Indications and current treatment

Protruding ears, also known as prominent ears, can be distressing to the individual who has them. They are most commonly diagnosed in infants and are a result of the normal cartilaginous folds failing to form within the ear. There are approximately 200 different surgical techniques to correct prominent ears. All attempt to address the compromise between preserving a natural appearance, against the challenge of ensuring permanent repositioning of this elastic cartilage. 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; and complications such as recurrence, haematoma, anterior skin necrosis, perichondritis, disfiguring cartilage damage and keloid formation may occur.

What the procedure involves

The aim of this procedure is to remould the cartilage within the ear without an incision.

The procedure is usually done with the patient under general anaesthesia, but it can also be done with the patient 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, an open hollow needle may be 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) along a new antihelix to secure a new shape for the ear cartilage and create a natural looking antihelix with less ear protrusion. The conchal cartilage may also be anchored onto the mastoid bone by a subcutaneous stitch attached to non-elastic tissue such as the periosteum.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to incisionless otoplasty. Searches were conducted of the following databases, covering the period from their commencement to 28 September 2011: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with prominent ears.
Intervention/test	Incisionless otoplasty.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on 24 patients from 2 case series[1,2].

Table 2 Summary of key efficacy and safety findings on incisionless otoplasty

Study details	Key efficacy findings	Key safety findings	Comments
Peled IJ (1995)[1] **Case series** Israel Recruitment period: not reported Study population: patients with prominent ears n = **11 (20 ears)** Age: not reported Sex: not reported Patient selection criteria: not reported Technique: knifeless otoplasty (needle is used to score the underlyingcartilage and subcutaneous sutures used to secure the ear in its new position) Follow-up: **6 – 30 months** Conflict of interest/source of funding: not reported	Number of patients analysed: **11** Author reports that 'in all 11 cases the results were satisfactory with no recurrence during follow-up'.	Not reported	**Follow-up issues**: • Completeness of follow-up not reported. **Study design issues**: • Retrospective study. • Lack of objective outcome measures.

Study details	Key efficacy findings	Key safety findings	Comments
Fritsch MH (1995)[2] **Case series** USA Recruitment period: not reported Study population: patients with prominent ears n = **13 (5 incisionless otoplasty)** Age: 8 years (mean, for 13 patients) Sex: 92.3% (12/13) male Patient selection criteria: not reported Technique: incisionless otoplasty in 5 patients and retention sutures with a post-auricular incision in the remaining patients. Follow-up: **6 months and 3 weeks (mean) [for 13 patients]** Conflict of interest/source of funding: not reported	Number of patients analysed: **13** Author reports that 'postoperative photos showed good correction'. In addition, it is stated that 'all patients and their families were satisfied with their resultant aesthetic improvement. The children noticed 'an immediate end to peer-pressure ridicule and torment'. Recurrence: suture breakage or knot unravelling occurred in 1 patient at the top of the pinna and the ear resumed its preoperative shape at 1 month. Where the stitch had failed, a replacement stitch was inserted with the patient under local anaesthesia and no further problems occurred. (This case is likely to have involved an incision but this not clearly stated in the report.)	No reports of haematoma, skin breakdown, numbness, hypertrophic scarring, perichondritis or epithelial inclusion cyst formation. No extrusion of the suture through the skin found.	**Follow-up issues**: • Completeness of follow-up not reported. **Study design issues**: • Retrospective study. • All patients treated as day cases.

Efficacy

Cosmetic outcome

In a case series of 13 patients, authors reported that photographs showed good correction and that all patients and their families were satisfied with the outcome[2].

Recurrence

The case series of 11 patients reported that all results were satisfactory with no recurrence during 6- to 30-month follow-up[1].

The case series of 13 patients (5 of whom were treated by incisionless otoplasty) reported suture breakage or knot unravelling occurring in 1 patient at 1 month. A replacement suture was required (it is unclear whether this patient had been treated by incisionless otoplasty)[2].

Safety

No safety concerns were reported.

Validity and generalisability of the studies

- The evidence base is limited to two small case series that are more than 15 years old.
- No objective analysis of outcome
- No long-term (3+ years) follow-up.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

There is currently no NICE guidance related to this procedure.

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr Ken Stewart and Mr Greg O'Toole (British Association of Plastic Reconstructive and Aesthetic Surgeons) and Mr Christopher Raine (ENT UK: British Association of Otorhinolaryngologists – Head and Neck Surgery).

- Alternative titles: Otoplasty by anterior cartilage scoping with a needle.

- One Specialist Adviser had performed the procedure at least once and the other two have never performed the procedure.
- All Specialist Advisers consider this to be a novel procedure of uncertain safety and efficacy.
- Comparator: Otoplasty using posterior suturing technique (standard prominent ear correction).
- One Specialist Adviser stated that they had abandoned this procedure and stated that the procedure should not be approved outside a clinical trial unless efficacy and long-term benefit can be demonstrated.
- One Specialist Adviser stated that the procedure does not address the two most common pathologies: anterior rotation of the conchal bowl and underdevelopment of the antihelix.
- One Specialist Adviser stated that such minimalist surgery is unlikely to correct prominent ears reliably. He has seen a few cases but the results have been poor and should only be considered for patients who lack an antihelical fold.
- Key efficacy outcomes: aesthetic ear correction and avoidance of recurrence.
- Anecdotal adverse effects: bleeding, bruising, anterior skin necrosis, poor aesthetic outcome and collapse of the ear necessitating reconstruction with costal cartilage.
- Training and facilities: specialist registration in plastic surgery. One of the Specialist Advisers stated that training should not be offered for this procedure.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme sent questionnaires to two trusts for distribution to patients who had the procedure (or their carers). NICE received no completed questionnaires.

Issues for consideration by IPAC

None

References

1. Peled IJ. (1995) Knifeless otoplasty: how simple can it be? Aesthetic Plastic Surgery 19: 253–5.

2. Fritsch MH. (1995) Incisionless otoplasty. Laryngoscope 105: 1–12.

Appendix A: Additional papers on incisionless otoplasty

There were no additional papers identified.

Appendix B: Related NICE guidance for incisionless otoplasty

There is currently no NICE guidance related to this procedure.

Appendix C: Literature search for incisionless otoplasty

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	25.03.2011	Issue 1 of 4, Jan 2011
Database of Abstracts of Reviews of Effects – DARE (CRD website)	25.03.2011	n/a
HTA database (CRD website)	25.03.2011	n/a
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	25.03.2011	Issue 1 of 4, Jan 2011
MEDLINE (Ovid)	25.03.2011	1948 to March Week 2 2011
MEDLINE In-Process (Ovid)	25.03.2011	March 2, 2011
EMBASE (Ovid)	25.03.2011	1980 to 2011 Week 11
CINAHL (NLH Search 2.0/EBSCOhost)	25.03.2011	n/a
BLIC (Dialog DataStar)	25.03.2011	n/a

Trial sources searched on 25.03.2011

- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov
- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database

Websites searched on 25.03.2011

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	((ear or ears) adj3 (deform* or prominen* or protrud* or bat* or lop* or cup* or protub*)).tw.
2	Ear Deformities, Acquired/
3	(conchal adj3 reduct*).tw.

4	(antihelical adj3 fold*).tw.
5	Ear, External/
6	Ear Cartilage/
7	or/1-6
8	otologic surgical procedures/
9	Reconstructive Surgical Procedures/
10	((otologic* or reconstruct*) adj3 surg* adj3 (procedure* or technique*)).tw.
11	Plastic surgery/
12	(plastic* adj3 surger*).tw.
13	or/8-12
14	Suture Techniques/
15	Sutures/
16	(stitch* or suture*).tw.
17	(cartilage* adj3 (scor* or spar* or weak* or remould* or mould* or reshap* or shap*)).tw.
18	or/14-17
19	7 and 13 and 18
20	(incision* adj3 (otoplast* or pinnaplast*)).tw.
21	19 or 20
22	Animals/ not Humans/
23	21 not 22