



Implant insertion for prominent ears

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www.nice.org.uk/guidance/ipg660

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 <u>Yellow Card Scheme</u>.

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 Recommendations

- 1.1 Current evidence on the safety and efficacy of implant insertion for prominent ears is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 Further research should include comparisons of this procedure with current best therapy. It should address issues of patient selection, such as age and type of ear shape, nature of ear implants used, long-term efficacy and safety outcomes, and patient-reported outcomes using validated quality-of-life measures.

2 The condition, current treatments and procedure

The condition

2.1 Protruding or prominent ears result when cartilaginous folds fail to form within the ear.

Current treatments

2.2 Surgery to correct protruding ears aims to reposition the elastic cartilage permanently while preserving a natural appearance. Cartilage-sparing techniques such as scoring, drilling and suturing of the cartilage may be used. Most techniques involve a post-auricular skin incision, although

there has been a report of an incisionless otoplasty.

The procedure

- 2.3 This procedure is done under local anaesthesia. One or more implants (gold-coated curved nitinol devices) are used to create or reshape the antihelical fold of the ear. The aim is to correct any ear prominence resulting from either poor definition or a lack of this fold.
- 2.4 The position of any implants is discussed and agreed with the patient before the procedure and marked on the ear. The implant is inserted using an introducer and released onto the anterior surface of the cartilage, immediately reshaping it and correcting the ear prominence. The incision is closed using 1 or 2 dissolvable sutures, and the wound is then dressed with sterile tape.
- Typically, 1 implant is used in each ear, but more may be needed. The procedure usually takes about 20 minutes for both ears.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 2 sources, which was discussed by the committee. The evidence included 2 case series. It is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.
- The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life and helical-mastoid distance.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: skin erosion over implants and infection.

3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 Most of the evidence reviewed came from adults. However, in NHS clinical practice, surgical correction of prominent ears is usually done in children and young people.
- The committee was concerned about the reported frequency of skin erosion over the implants.
- 3.7 The committee noted that the benefits may disappear when the implants are removed.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.