

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of implant insertion for prominent ears

Some people's ears stick out more prominently than others. This does not affect hearing, but can cause distress if the person is unhappy with the appearance of their ears. Using local anaesthesia, 1 or 2 small curved implants are inserted under the skin of each ear through small cuts. The implants remain in place permanently. The aim is to pull the ears back so they look less prominent.

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Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional

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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 January 2019 and updated in May 2019.

Procedure name

- Implant insertion for prominent ears

Specialist societies

- British Association of Plastic Reconstructive and Aesthetic Surgeons
- British Association of Aesthetic Plastic Surgeons
- British Society of Facial Plastic Surgery
- ENT UK
- Royal College of Surgeons of England
- Royal College of Surgeons of Edinburgh

Description of the procedure

Indications and current treatment

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

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.

What the procedure involves

This procedure is done under local anaesthesia. One or more implants 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.

The position of any implant is discussed and agreed with the patient before the procedure and marked on the ear. The implant (a gold-coated curved nitinol device) 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.

Efficacy summary

Reduction in ear prominence

In a case series of 39 patients (22 aged 16 years or more and 17 aged 7 to 15 years; 75 ears and 131 implants), the mean helical-mastoid (H-M) distance decreased from 29.7 mm before the procedure to 18.7 mm 3 months after the procedure (37% reduction in ear prominence, level of statistical significance not reported). Eighteen patients asked for their implants to be left in place permanently and 21 patients agreed to have their implants removed at 6, 12 or 18 months after insertion. In the subgroup of patients who had their implants left in permanently, ear prominence had reduced by 34% at 3 months and by 35% at 18 months. In the subgroup of patients who had their implants removed, for adults who had implants alone, ear prominence had reduced by 3% after 12 months (n=3) and by 13% after 18 months (n=2). In adults who had implants and anterior scoring (n=7), ear prominence had reduced by 29% at 6 months. In the subgroup of children who had implants alone, ear prominence had reduced by 10% after 12 months (n=2) and by 14% after 18 months (n=5).¹

In a case series of 403 patients (766 ears, 1,200 implants), pre- and post-operative H-M distances were measured in a subgroup of 121 patients. The mean H-M distance decreased from 27.0 mm before the procedure to 18.0 mm after the procedure (34% reduction) and to 17.5 mm at 2 to 3 months (35% reduction).²

Recurrence, conversion to standard otoplasty and revision surgery

In the case series of 39 patients, the proportion of revision surgery was 15% (6/39). Two children who had their implants removed at 6 to 18 months had conversion to standard otoplasty to address recurrence of their prominence. Four patients (3 adults and 1 child) had re-insertion of implants after the end of the study with a satisfactory outcome.¹

In the case series of 403 patients, 1% (5/403) of patients had their implants removed at 3 to 34 months after treatment. Three of these patients had a conversion to standard otoplasty and the other 2 declined any further treatment. The reasons given for requesting complete removal were concerns over the

visibility of the implant (n=2), dissatisfaction with the outcome of treatment (n=2) and change of mind (n=1). In the same study, 4% (17/403) of patients (1% [17/1,200] of implants) had their implant position revised. In 15 patients, this was because of excessive visibility of the implant under the skin. However, 1 implant was repositioned to address residual asymmetry and another to address overcorrection of the prominence. All cases were the result of technical errors at the time of implantation, because of a failure to ensure that the implant was flush with the cartilage when deployed or a failure to ensure correct alignment of the implant with the skin markings. All patients needing revision had successful implant removal, repositioning, and redeployment. In all 17 patients, repositioning was done within the first 3 months after the initial treatment, before the scar tissue had matured.²

Patient satisfaction

In the case series of 39 patients, the median patient evaluation measure (PEM) responses relating to patients' perceptions of their appearance showed a statistically significant improvement when comparing the baseline and final assessments at 18 months for all questions ($p<0.001$). The questionnaire asked patients for a final satisfaction assessment. All responses also showed an improvement in median PEM responses except for the responses to Q5, relating to the appearance of the implants under the skin (no further details reported).¹

Safety summary

Ear pain

The pain of surgery subsided after 24 to 48 hours with simple analgesia (paracetamol or ibuprofen) in the case series of 39 patients.¹

Pain resolved by the second week after the procedure with no additional intervention or medication in the case series of 403 patients.²

Swelling or bruising of the ear

Swelling or bruising occurred in every patient in the case series of 39 patients, and increased within a few hours of treatment. However, it subsided in all patients within 7 days of treatment.¹

Swelling or bruising resolved by the second week after the procedure with no additional intervention or medication in the case series of 403 patients.²

Sensitivity

Temporary sensitivity related to the implant was reported by most patients but had disappeared in all patients by 12 weeks in the case series of 39 patients.¹

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Erosion of the skin over the implant

Skin erosion over the implant was reported in 13% (5/39) of patients (5% [7/131] of implants) within 12 months of the procedure in the case series of 39 patients. After removal of the implant, the patients were offered the option of reimplantation at the same site after 3 to 6 months. This offer was declined by all the patients.¹

Skin erosion over the implant was reported in 4% (15/403) of patients (1% [15/1200] of implants) within a mean 8-month follow up in the case series of 403 patients. The most common factors associated with erosion were concurrent, or history of, heavy smoking (5/15) and previous standard otoplasty involving degloving of the anterior skin (4/15). Most erosions occurred through the anterior skin, commonly at the upper pole where the skin of the ear is thinnest. One patient had erosion of the implant through the posterior skin. Thirteen of the implants removed because of erosion were subsequently re-implanted with a successful final outcome. The remaining 2 patients declined to have the affected implants replaced and 1 had a conversion to standard otoplasty.²

Infection

Infection was reported in 5% (2/39) of patients (2% [2/131] of implants) within 12 months of the procedure in the case series of 39 patients. Only 1 implant needed to be removed (it was extruding). The other patient was treated with oral antibiotics, leaving the affected implant in place. There was no recurrence of the infection by the final review at 18 months after insertion.¹

Infection was reported in 2% (7/403) of patients (less than 1% [7/1200] of implants) within a mean 8-month follow up in the case series of 403 patients. Five of the 7 patients with implants that became infected were successfully treated with a short course of oral antibiotics, and the implants were left in place. The other 2 patients needed implant removal. In both patients, the infections resolved after implant removal. After 2 to 3 months, both patients had a successful reimplantation with no further complications.²

Hypertrophic scar

Hypertrophic scars associated with the incisions to insert the implant were reported in 5% (2/39) of patients (2% [2/131] of implants) within 12 months of the procedure in the case series of 39 patients. One was associated with the extrusion of an implant. The other patient wished to have their scar treated with excision and an injection of 2 mg of triamcinolone acetonide.¹

‘Spock-ear’ deformity

'Spock-ear' deformity was reported in 1 patient at 3 months in the case series of 39 patients. This was corrected by removing the implant and replacing the same implant in a new position.¹

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, specialist advisers did not describe any anecdotal adverse events. They considered that the following was a theoretical adverse event: infection involving the cartilage with cartilage necrosis.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to implant insertion for prominent ears. The following databases were searched, covering the period from their start to 30 May 2019: 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 the [literature 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 when no clinical outcomes were reported, or when 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	Implant insertion.
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 IP overview

This IP overview is based on 442 patients from 2 case series^{1,2}.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are listed in the [appendix](#).

Table 2 Summary of key efficacy and safety findings on implant insertion to correct prominent ears

Study 1 Kang N V (2016)

Details

Study type	Prospective case series
Country	UK (single centre)
Recruitment period	2011-13
Study population and number	n=39 patients with prominent ears (131 implants were used to treat 75 ears)
Age and sex	Mean 24 years; 56% (22/39) female
Patient selection criteria	<u>Inclusion criteria:</u> male or female ≥7 years of age with a H-M distance >20 mm, fully able to understand the requirements of the study, and able to sign a witnessed/informed consent form. Smokers were accepted into the study if they had ceased all nicotine intake 3 months before treatment. <u>Exclusion criteria:</u> smoking, diabetes, malignancy, anticoagulation treatment, psychiatric or psychological treatment, or pregnancy. Patients were also excluded if they had prominence solely due to a deep conchal bowl, a documented wound healing problem, or a family history of keloid scarring.
Technique	Implant insertion using the Earfold treatment system. 7 patients had treatment with Earfold combined with anterior scoring. All patients were asked to have their implants removed at 6, 12, or 18 months after insertion.
Follow up	Mean 17 months
Conflict of interest/source of funding	The main author is the inventor of the earFold™ implant used for this study. He is also the chairman and chief technical officer for the company (Northwood Medical Innovations [NMI] Ltd) that distributes the earFold implant. He is a shareholder of NMI Ltd. Dr Kerstein has nothing to disclose. Funding support for the study was provided by the distributor (NMI Ltd) of the earFold™ implant. The hospital where the study was performed and NMI Ltd acted as co-sponsors for the study since the hospital is a part-owner of NMI Ltd. All implants and materials were provided free and gratis by NMI Ltd. None of the patients received any compensation to participate in the study, either direct or in kind. The principal author received no compensation of any kind to perform the study or to prepare the report.

Analysis

Follow-up issues: Thirty-seven patients returned for their final follow-up assessment at 18 months after treatment.

Study design issues:

- The primary outcome measure was the H-M distance measured with a millimetre ruler. The H-M distance was defined as the maximum distance (millimetres) from the mastoid to the most prominent part of the helix when viewing the patient in an anteroposterior direction.
- Patient satisfaction was assessed using a standardised PEM questionnaire, which was not validated. The PEM was created by the senior author based on a similar (validated) questionnaire used to evaluate Patient Recorded Outcomes after hand surgery. Each patient in the study was asked to complete the PEM 3 times: before treatment, 3 months after treatment, and at the conclusion of the study.

Study population issues: The study included 22 adults (≥16 years) and 17 children (aged 7 to 15 years).

Key efficacy and safety findings

Efficacy							Safety
Number of patients analysed: 39							
Reduction in ear prominence (H-M distance per ear [mean and %])							
	Before the procedure (H-M distance)	3 months	% reduction in ear prominence after 3 months	% reduction in ear prominence after 6 months	% reduction in ear prominence after 12 months	% reduction in ear prominence after 18 months	
All patients (n=39)	29.7 mm	18.7 mm	37%				
Patients with implant left permanently (n=18)			34%			35%	
Adults with implant alone					3% (n=3) ^a	13% (n=2) ^a	
Adults with implant and anterior scoring				29% (n=7) ^b			
Children with implant alone					10% (n=2) ^a	14% (n=5) ^c	

^a implants removed at 12 months
^b implants removed at 6 months
^c implants removed at 18 months

Revision surgery and recurrence: 15% (6/39)

- Of the 21 patients who had their implants removed at 6 to 18 months, 2 patients (both children) subsequently had revision surgery using standard otoplasty to address recurrence of their prominence.
- 4 patients (3 adults and 1 child) requested re-insertion of gold-plated implants after the conclusion of the study with a satisfactory outcome from this treatment.

Patient satisfaction (PEM questionnaire – all questions were answered on a Likert scale (1 to 7))

- Comparison of the median PEM responses relating to the patients' perception of their appearance (Part 2, Q1 to Q10) showed a statistically significant improvement when comparing the baseline and final assessments for all questions ($p<0.001$).
- Part 3 of the survey asked subjects for a final satisfaction assessment. All responses also showed an improvement in median PEM responses with the exception of the responses to Q5, relating to the appearance of the implants under the skin.

Most patients were able to return to work or school within 1 week of the surgery.

	% patients	% implants
Erosion of the skin over the implant*	13% (5/39)	5% (7/131)
Infection**	5% (2/39)	2% (2/131)
Hypertrophic scars associated with the incisions to insert the implant***	5% (2/39)	2% (2/131)
'Spock-ear' deformity at 3 months****	3% (1/39)	1% (1/131)

*After removal of the implant, the patients were offered the option of reimplantation at the same site after 3-6 months. This offer was declined by all the patients.

** Only 1 implant needed to be removed (it was extruding). The other case was successfully treated with oral antibiotics, leaving the affected implant in place. There was no recurrence of the infection in this case by the final review at 18 months after insertion.

***One was associated with extrusion of an implant. Only 1 patient wished to have treatment of their scar. This was done by excision and an injection of 2 mg of triamcinolone acetonide. This treatment was successful.

	****This was corrected by removing the implant and replacing the same implant in a new position.
Abbreviations used: H-M, helical-mastoid; PEM, Patient Evaluation Measures.	

Study 2 Kang N V (2018)

Details

Study type	Case series
Country	UK (6 surgeons) and Croatia (1 surgeon)
Recruitment period	2013-14
Study population and number	n=403 patients (766 ears; 1,200 implants) with prominent ears
Age and sex	Mean 35 years; 37% (149/403) female
Patient selection criteria	<u>Inclusion criteria:</u> All consecutive male or female patients ≥ 7 years of age attending a participating author's clinic who had treatment for prominent ears with Earfold implants between February 2013 and September 2014 were included. Most had ear prominence due to unfolding of the anthelix. This series also included patients with a deep conchal bowl (>16 mm) and patients who had treatment using a combination of Earfold implants and conchal bowl reduction. <u>Exclusion criteria:</u> no satisfactory correction during preoperative assessment using Prefold positioners, concurrent infection, current malignancy, anticoagulant treatment, active psychiatric or psychological treatment, pregnancy.
Technique	Implant insertion using the Earfold treatment system only (397 patients) or combination of Earfold and conchal reduction (6 patients).
Follow up	Mean 8 months
Conflict of interest/source of funding	Editorial support for this article was funded by Allergan plc. Norbert V. Kang is the inventor of the Earfold implant. He was formerly the chairman and chief technical officer for the company [Northwood Medical Innovations (NMI) Ltd] that supplied the Earfold implant. NMI Ltd has now been acquired by Allergan. None of the other authors listed have any conflicts of interest. The Article Processing Charge was paid for by Allergan plc.

Analysis

Follow-up issues:

- All patients were asked to return for a final follow-up visit at 2 to 3 months after treatment and were also encouraged to return at any time if they had concerns about the outcome of their treatment.
- 36% (145/403) of patients returned for a follow up.

Study design issues:

- This is an interim report based on an ongoing analysis of safety in a series of patients treated for prominent ears with the Earfold implant.
- Adverse events were reported as a percentage of the total cohort under review (403 patients) and not as a percentage of the patients who returned for review. This method of reporting was based on the assumption that patients would return for review if they had an adverse event and, likewise, that those patients who did not return for review had not have an adverse event and were most likely satisfied with their outcomes.

Study population issues:

- 6% (25/403) of patients were less than 15 years old.
- The mean number of implants per patient was 3.
- 45% of patients had 1 implant in each ear. Five patients had 5 implants to treat bilateral prominence (3 implants in 1 ear and 2 in the other).
- 10% of patients had a unilateral prominence.
- 36 patients had a conchal bowl of more than 16 mm.

Key efficacy and safety findings

Efficacy				Safety												
Number of patients analysed: 403				Adverse events												
Reduction in ear prominence (H-M distance per ear [mean and %])				The most commonly reported adverse events were acute post-operative pain , swelling , and bruising of the ears. In all patients, these resolved by week 2 posttreatment with no additional intervention or medication. Most patients were able to return to work or school within 1 week.												
	Before the procedure (H-M distance)	After the procedure	Final follow-up visit													
n=121 patients	27 mm	18 mm -9mm (-34% reduction)	17.5 mm -9.5 mm (-35% reduction)	Adverse events needing treatment or intervention: 10% (39/403)												
				<table border="1"> <thead> <tr> <th></th><th>% Patients</th><th>% Implants</th></tr> </thead> <tbody> <tr> <td>Revision of the implant's position^a</td><td>4% (17/403)</td><td>1% (17/1200)</td></tr> <tr> <td>Implant erosion^b</td><td>4% (15/403)</td><td>1% (15/1200)</td></tr> <tr> <td>Infection^c</td><td>2% (7/403)</td><td><1% (7/1200)</td></tr> </tbody> </table>		% Patients	% Implants	Revision of the implant's position^a	4% (17/403)	1% (17/1200)	Implant erosion^b	4% (15/403)	1% (15/1200)	Infection^c	2% (7/403)	<1% (7/1200)
	% Patients	% Implants														
Revision of the implant's position^a	4% (17/403)	1% (17/1200)														
Implant erosion^b	4% (15/403)	1% (15/1200)														
Infection^c	2% (7/403)	<1% (7/1200)														
Conversion to standard otoplasty or implant removal: 1% (5/403)				<p>^aThis was usually due to excessive visibility of the implant under the skin (15 patients). However, 1 implant was also repositioned to address residual asymmetry and another to address overcorrection of the prominence. All cases were the result of technical errors at the time of implantation, comprising either a failure to ensure that the implant was flush with the cartilage when deployed or a failure to ensure correct alignment of the implant with the skin markings. All patients requesting revision had a successful implant removal, repositioning, and redeployment. In all 17 cases, repositioning was carried out within the first 3 months after the initial treatment, before the scar tissue had matured.</p> <p>^bThe most common factors associated with erosion were concurrent or history of heavy smoking (5/15) and previous standard otoplasty involving degloving of the anterior skin (4/15). Most erosions occurred through the anterior skin, commonly at the upper pole where the skin of the ear is thinnest. One patient had erosion of the implant through the posterior skin. Thirteen of the implants removed because of erosion were subsequently re-implanted with a successful final outcome. The remaining 2 patients declined to have the affected implants replaced and 1 requested conversion to standard otoplasty.</p> <p>^cFive of the 7 patients with implants that became infected were successfully treated with a short course of oral antibiotics, and the implants were left in place. However, 2 patients needed implant removal because of infection. In both patients, the infections resolved after implant removal. After 2 to 3 months, both patients had a successful reimplantation with no further complications.</p>												

Abbreviations used: H-M, helical-mastoid.

Validity and generalisability of the studies

- The evidence base was limited to 2 case series.
- Children and adults were included in the studies, with the mean age being 24 years in study 1 and 35 years in study 2.
- There was only 1 type of implant used in the studies, but the modified version was used in study 2.
- When combining with Earfold, various techniques were used in the studies (anterior scoring was applied in study 1 and conchal bowl reduction in study 2).
- Several implants could be used for 1 ear and the implants could be left in place or removed after a few months according to the patient's wishes.
- There seemed to be a learning curve associated with this procedure.
- The maximum length of follow up is mean 17 months.

Existing assessments of this procedure

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

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Incisionless otoplasty. NICE interventional procedures guidance 422 (2012). Available from <http://www.nice.org.uk/guidance/ipg422>

Additional information considered by IPAC

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

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individual opinion and is not intended to represent the view of the society. The advice provided by specialist advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. One Specialist Adviser Questionnaire for implant insertion to correct prominent ears was submitted and can be found on the [NICE website](#).

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Company engagement

A structured information request was sent to 1 company who manufactures a potentially relevant device for use in this procedure. NICE did not receive a completed submission.

Issues for consideration by IPAC

Ongoing study:

[NCT03194269 Long Term Prospective Uncontrolled Study Of Earfold™ For The Treatment Of Prominent Ears](#). This is an open-label, prospective, uncontrolled, single arm, post-marketing study of the long-term safety and performance of EARFOLD® Implantable Clip System. Estimated completion date: October 28, 2020.

References

1. Kang N V and Kerstein R L (2016) Treatment of prominent ears with an implantable clip system: a pilot study. *Aesthetic Surgery Journal* 36(3), NP100–16
2. Kang N V, Sojitra N, Glumicic S et al. (2018) Earfold implantable clip system for correction of prominent ears: analysis of safety in 403 patients. *Plastic and Reconstructive Surgery – Global Open* 6(1), e1623

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	30/05/2019	Issue 5 of 12, May 2019
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	30/05/2019	Issue 5 of 12, May 2019
HTA database (CRD website)	30/05/2019	n/a
MEDLINE (Ovid)	30/05/2019	1946 to May 29, 2019
MEDLINE In-Process (Ovid)	30/05/2019	1946 to May 29, 2019
MEDLINE Epubs ahead of print (Ovid)	30/05/2019	May 29, 2019

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) – MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- 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 Reconstructive Surgical Procedures/
- 2 "Prostheses and Implants"/
- 3 Otologic Surgical Procedures/
- 4 (pinnaplast* or otoplast*).tw.
- 5 (ear adj4 reconstruct* surg*).tw.
- 6 (ear adj4 (pin* or reduce* or correct* or otoplast* or implant*)).tw.
- 7 (Implant* adj4 (clip* or insert*)).tw.

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8 reconstruct* surg* proced*.tw.
9 otolog* surg* proced*.tw.
10 or/1-9
11 *Ear Cartilage/ab, su [Abnormalities, Surgery]
12 Ear, External/ab
13 Ear Auricle/
14 ((deform* or protud* or probuter* or bat* or prominent* or extern* or cartil*
or auric* or jug*) adj4 Ear*).tw.
15 or/11-14
16 10 and 15
17 earfold.tw.
18 16 or 17
19 Animals/ not Humans/
20 18 not 19
21 limit 20 to ed=20190109-20190531

Appendix

There were no additional papers identified.