Total ear reconstruction

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Assessment report

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The Medicare Services Advisory Committee is an independent committee which has been established to provide advice to the Commonwealth Minister for Health and Aged Care on the strength of evidence available on new and existing medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform Government decisions about which medical services should attract funding under Medicare.

This report was prepared by the Medicare Services Advisory Committee (MSAC) with the assistance of Dr Jenny Doust and Dr Anne-Marie Murray from the Australasian Cochrane Centre, and Dr John Vandervord, who provided information on the procedure. Technical editing was by Biotext, Canberra. The Commonwealth Minister for Health and Aged Care endorsed the report on 6 March 2000.

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The total ear reconstruction procedure attempts to reconstruct a near-normal external ear in cases where the ear is absent due to a congenital abnormality or trauma. Cartilage is harvested from the patient's rib cage and modelled to form an auricle, which is implanted at the ear reconstruction site. The second stage of the operation finalises the position of the new ear.

Medicare Services Advisory Committee — role and approach

The Medicare Services Advisory Committee (MSAC) is a key element in the Commonwealth Government's strategy to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health and Aged Care on the evidence relating to the safety, effectiveness and cost-effectiveness of new and existing medical technologies and procedures, and under what circumstances public funding should be supported.

A rigorous assessment of the available evidence is the basis of decision making when funding is sought under Medicare. The medical literature available on the technology is searched and the evidence is assessed and classified according to the National Health and Medical Research Council (NHMRC) four-point hierarchy of evidence. A supporting committee with expertise in this area then evaluates the evidence and provides advice to MSAC.

MSAC's assessment of total ear reconstruction

Clinical need

Congenital deformities of the external ear are relatively rare. The incidence in Australia is estimated to be approximately 1 in 20,000 live births per year. Even when cases that occur as a result of trauma are included, only a small number of procedures (15 to 20) are therefore expected to be performed each year.

Safety

The principal complications of the procedure are due to necrosis of the skin overlying the graft site, protrusion of the donor cartilage and chest deformities at the site where donor cartilage was harvested. Perioperative complications include haematoma and pneumothorax. However, the complication rate is acceptable given the excellent outcomes of the reconstruction procedure.

Effectiveness

The total ear reconstruction procedure can build an ear that is nearly normal in terms of its cosmetic appearance. Although the complication rate is slightly higher than for the alternative treatment, the Branemark implant technique, patients and parents of patients may accept this higher rate of complication in order to achieve a more normal-looking ear, which subsequently requires less maintenance than is the case with a prosthetic implant ear. In cases of congenital abnormality, the timing of the surgery is controversial and requires a balancing of the psychological impact of an obvious deformity against the reduced complication associated with delaying surgery. The operation can be performed in both adults and children.

Cost-effectiveness

Insufficient data were available to assess the cost-effectiveness of the procedure. The procedure is technically complex and the surgery is time consuming.

Recommendation

MSAC noted that there is only level IV evidence (case-series studies) on total ear reconstruction and, as clinical trials are unlikely ever to be conducted, higher level evidence is unlikely to become available in the future. However, it acknowledged that given the small size of the patient population and their special needs, special considerations of access and equity should be taken into account in the assessment of this application. It also noted that the procedure should only be undertaken by suitably trained and experienced surgeons.

MSAC recommended that, on the basis of the available evidence on total ear reconstruction and considerations of access and equity, public funding should be supported for this procedure.

Introduction

The Medicare Services Advisory Committee (MSAC) has reviewed the use of total ear reconstruction, which is a therapeutic procedure for replacement of a deformed or missing external ear.

MSAC evaluates new and existing health technologies and procedures for which funding is sought under the Medicare Benefits Scheme in terms of their safety, effectiveness and cost-effectiveness, while taking into account other issues such as access and equity. MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

MSAC's terms of reference and membership are shown in Appendix A. MSAC is a multidisciplinary expert body, comprising members drawn from such disciplines as diagnostic imaging, pathology, surgery, internal medicine and general practice, clinical epidemiology, health economics, consumer affairs and health administration.

This report summarises the assessment of current evidence for total ear reconstruction for the replacement of a deformed or missing external ear.

Background

Total ear reconstruction

How it works

The total ear reconstruction procedure attempts to reconstruct a near-normal external ear in cases where the ear is absent due to a congenital abnormality or trauma. The congenital absence or hypoplasia of the external ear is often associated with deformities of the external ear canal and tympanic membrane, and sometimes requires additional surgery to attempt to restore normal hearing. The technique is also suitable in some cases where an ear may be lost due to trauma, such as dog bites or burns.

The technique of total ear reconstruction was developed by Dr R Tanzer in the late 1950s. It has since been refined by Dr B Brent, who developed a four-stage technique, and by Drs S Nagata and F Firmin, who have developed a two-stage technique. Currently, the two-stage technique is most frequently used. In this approach, the first operation involves harvesting of rib (costal) cartilage, followed by construction of a three-dimensional cartilage framework, placement in a pocket at the reconstruction site and transposition of the ear lobe. The second operation is performed six months later to elevate the ear and cover it with a flap and skin graft. Cartilage used for the ear reconstruction is harvested from the rib cage, usually from the same side as the ear deformity. The posterior perichondrium (the lining of the rib cartilage) is left at the donor site to prevent deformity of the chest wall.

The time required for the operation is dependent upon the experience of the surgeon. The first-stage operation takes approximately 5–6 hours and the second-stage operation takes approximately 3–4 hours (J Vandervord pers comm 1999).[1] Each operation is followed by a hospital stay of up to 2–3 nights.

The procedure is complex and only a few plastic or maxillofacial surgeons have been trained in the technique. As it is expected that only a small number of such operations will be conducted in Australia each year, it is important that the procedure be performed by a surgeon with expertise in this specialised area.

Intended purpose

Total ear reconstruction is indicated for deformity or absence of the external ear due to congenital malformation or trauma. The procedure can be used as a primary therapy for untreated patients or as a secondary therapy where a previous reconstructive or implant procedure has failed or is unsatisfactory.

[1] Dr John Vandervord, Plastic and Reconstructive Surgery, North Shore Medical Centre, NSW

Clinical need / burden of disease

Congenital ear deformity (anotia and microtia)

Anotia is the complete absence of the external ear and microtia the nearly complete absence of the external ear. The outer ear and middle ear are formed at about five weeks gestation. The inner ear forms at three weeks gestation from a separate embryological structure. Bilateral microtia occurs in 10% of all cases and there is often a family history of microtia or associated anomalies. Microtia may also occur as one of the many features of the hemifacial microsomia complex, or it may occur as a singular, isolated deformity. It is also found as a part of certain congenital syndromes, such as Treacher–Collins syndrome.

Microtia is often associated with congenital aural atresia — a condition in which the external ear canal fails to develop. While this condition may occur in the presence of a normally formed auricle, it is rare to find congenital microtia in the presence of a normal ear canal and tympanic membrane. Patients with microtia and congenital aural atresia complex may therefore also require reconstruction by an otorhinolaryngologist to attempt to achieve functional hearing levels. However, restoration of functional hearing levels is only attempted in a minority of cases where, for example, there is bilateral microtia with bilateral hearing impairment or unilateral microtia with decreased hearing in the normal ear.

This process requires coordination between the plastic surgeon and the otorhinolaryngologist, before any reconstructive procedure can occur. It is generally recommended that the first stage of the total ear reconstruction (which includes the initial placement of the donor cartilage) should precede repair of the aural atresia, as this appears to optimise the success of the implantation of the donor cartilage. In suitable cases, the auricle can be relocated at the same time as the aural atresia repair, by undermining the ear and surrounding skin and aligning the new ear canal with the new external auditory meatus. It has been reported that this maneouvre does not adversely affect the cartilage implant (Cole and Jahrsdoerfer 1990). Simultaneous restoration of the middle ear, external auditory meatus and auricle is a more complex procedure, taking up to eight hours and requiring both a plastic surgeon and an otorhinolaryngologist to be present (Firmin et al 1998).

Timing of surgery and psychological considerations

The timing of surgery is influenced by both psychological and physical considerations. The ear is approximately 85% grown by the time a child is four years old. Surgery should be delayed until the child's rib growth is adequate to provide fabrication of a quality framework.

It is widely reported that children become aware that their ears are different around the age of four. Teasing often begins when the child starts school. In the first published report on ear reconstruction, Tanzer (1959) recommended that the procedure should be conducted in the preschool period to avoid the psychological trauma of a conspicuous deformity.

In contrast, Dr H Okajima and his team in Nagoya, Japan, delay the initial procedure until the child is approximately 10 years old, citing the following reasons:

- the chest circumference exceeds 60 cm at this age, which is sufficient for collecting the necessary amount of costal cartilage;
- the cartilage is flexible enough for frame construction;
- no thoracic deformation develops after collection of the costal cartilage; and
- sufficient hair-free skin can be collected at the site of construction of the auricle (Okajima et al 1996).

Not all people with microtia or anotia develop psychological problems as a result of their ear deformity and 'no treatment' is therefore also an option. Most studies of craniofacial anomalies, such as cleft lip and palate, estimate that 30 to 40% of children experience difficulties — internalising and/or externalising problems, learning disorders and/or social competence (Endriga and Kapp-Simon 1999). It is in these cases that the patient is most likely to benefit from reconstructive surgery.

Clinical need/burden of disease

The reported incidence of congenital deformity of the ear in Australia is about 1 in 20,000 live births per year (Hurst et al 1999), which would result in an average of 13 cases per year at the current birth rate of about 250,000 live births per year (Australian Bureau of Statistics 1999). The incidence of traumatic destruction of the external ear is unknown.

The applicant (J Vandervord, pers comm 1999) estimates a rate of 15–20 ear reconstructions per year in Australia for the correction of both congenital and traumatic ear deformity.

Existing procedures/comparator

An alternative procedure, the Branemark implant technique, involves placing specially made titanium implants into the mastoid bone of the skull underlying the ear in a series of two or three operations. An artificial external ear (prosthesis) made from silicone is then clipped onto the titanium implants. This technique is often referred to as bone-anchored titanium implants and osseointegrated procedures.

The Branemark technique was developed by Professor P Branemark at the University of Göteborg, Sweden. Branemark's research showed that commercially pure titanium could be placed into bone and, after a period of healing, load-bearing structures could be connected to the titanium implants (Wilkes et al 1994). The first clinical application was the attachment of bone-conducted hearing aids in 1977. From 1979 onwards, Branemark used the implants for retention of external prostheses in the head and neck region. Branemark and his associates were the first to describe the capacity of nonalloyed

titanium to integrate directly with bone in the absence of fibrous tissue ingrowth. This concept of 'osseointegration' is based on histologic evidence of viable bone growth onto and into the surface of titanium implants. In addition, nonalloyed titanium also demonstrates favourable interactions with surrounding cutaneous tissue (Burton et al 1996).

Nonoperative replacement with a prosthetic ear attached by means of an adhesive solution or mounted on the arm of spectacles is also used.

Marketing status of the device / technology

Not applicable because the total ear reconstruction procedure is a surgical technique.

Current reimbursement arrangement

The procedure is not covered under an existing Medicare Benefits Schedule item number but claims for the first-stage operation have been made under item number 45647:

- Face, contour restoration of one region, using autogenous bone or cartilage graft.

Approach to assessment

Review of literature

The medical literature was searched to identify relevant studies and reviews for the period between 1975 and 1999. Searches were conducted using MEDLINE, HealthSTAR and EMBASE.

The search terms used included:

(ear OR auricle OR auricular OR microtia OR anotia)
AND
(reconstruction OR otoplasty OR cartilage OR prosthesis OR implant
OR osseointegration OR plastic surgery OR Branemark)

The selection of published clinical experience took into account the significant refinement of the procedure over the last two decades, and the quality of available clinical studies.

The inclusion criteria were:

- two-stage total ear reconstruction procedure using autologous costal cartilage; and
- clinical studies and/or case reports, with or without control group.

The exclusion criteria were:

- publications describing the procedure/technique;
- reviews; or
- early clinical studies/case reports before the introduction of two-stage technique.

The evidence presented in the selected studies was assessed and classified according to the National Health and Medical Research Council hierachy of evidence (NHMRC 1999), which is shown in Table 1.

All studies that were included were noncontrolled clinical case reports (ie case series) without appropriate comparison with the nominated comparator (NHMRC level IV evidence). Subjects appeared to be representative of the patient groups for whom funding is sought on the Medicare Benefits Schedule. The patient follow-up period varied from one year to 20 years. A comparison of the procedure with the titanium implant technique was not attempted due to limited clinical data.

Table 1 NHMRC designation of levels of evidence

I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time series with control group.
III-3	Evidence obtained from comparative studies with historical control, two and more single arm studies or interrupted time series without a parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test and post-test.

Source: NHMRC 1999

Expert advice

A supporting committee with expertise in plastic surgery and ear, nose and throat surgery was established to evaluate the evidence and provide advice to MSAC from a clinical perspective. In selecting members for supporting committees, MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations and consumer bodies for nominees. Membership of the supporting committee is shown in Appendix B.

Results of assessment

Is it safe?

Complications can arise at both the donor and ear reconstruction sites. The most comprehensive information regarding the range of complications that can occur was reported in a paper on complications of surgery of the external ear by Furnas (1990). The most significant complications are:

- inaccurate positioning of the ear or poorly designed cartilage framework;
- pneumothorax (collapse of the lung) and atelectasis (incomplete expansion of the lung) at the time of obtaining rib grafts;
- ischaemia of the skin overlying the graft (in extreme cases this can result in skin necrosis of the covering flap);
- complications due to the tissue expander, such as leakage, malposition, skin erosion, infection and extrusion of the expander;
- ischaemia of the transposed earlobe;
- haematomas and seromas;
- pressure necrosis due to the patient sleeping on the reconstructed ear;
- hypertrophic scars and keloids;
- disruption of helix-baseplate attachment; and
- resorption of cartilage.

The literature was reviewed for reports of these or other adverse events. The incidence of complications was not noted in the majority of the publications and only a few recorded details of cases where further surgery was required. Some results were reported as the total number of ears that underwent surgery and others by the total number of stages of the whole procedure. It is therefore not possible to compare incidence rates between the studies.

Complications at reconstructed ear site

Okajima (1996) reported that, of 497 reconstructed ears, 76 underwent additional surgery but the complications involved were not listed. Aguilar (1996) reported that of 31 patients who underwent a four-stage procedure, there were nine complications (unlisted) and eight revisions were required. Firmin (1998) reported 352 ear reconstructions with the following complications:

- 20 cases of partial necrosis;
- 12 cases of protrusion of wire sutures; and
- 10 cases of partial failure of the skin flap.

Bhandari (1998) reported on 76 patients, of which complications arose in seven cases. Brent (1992) reported 606 cases with a complication rate of 1.6% (three infections, two haematomas and five cases of skin loss with cartilage exposure). Osorno (1999) reported on 110 consecutive patients with congenital microtia who received total ear reconstruction using the same technique as Brent. In this series there was one haematoma, one infection, two cases of partial skin loss and three cases of hypertrophic scars. Overall, while the data are limited, it appears that complications at the ear site may arise in between 2 and 10% of patients.

These complications arise because the procedure is intricate and is associated with technical difficulties. Aguilar (1996), who has reconstructed 69 ears, recommended that all plastic surgeons interested in auricle reconstructions should perform at least ten reconstructions each year in order to maintain there expertise, as lack of experience is the main factor leading to patients having to undergo further restorative procedures.

Complications at donor cartilage sites

Complications are also possible at the donor cartilage site and are likely to be more significant in a paediatric patient than in an adult. This is particularly the case because it is necessary to create an adult-size ear from a child's proportionally smaller rib cartilage. Eavey and Ryan (1996) reported on what they regarded as the three main problems:

- the incision site for cartilage harvesting can result in excessive scar length and postoperative discomfort for children;
- the skin graft donor site, which is usually taken from the hip, can result in discomfort and an unaesthetic appearance; and
- in occasional patients, there may be insufficient rib length to create a curled helix.

Ohara et al (1997) reported on donor-site complications, specifically chest wall deformities and thoracic scoliosis occurring after harvest of coastal cartilage grafts. The mean age of patients was 7.9 years and the follow-up ranged from 2 to 19 years, averaging 8 years. The cases were reviewed for donor-site complications using radiography and physical examination. Ribs from which costal cartilage had been harvested showed increased inward bowing on radiographs in 16 of the 32 donor sites. The frequency of rib deformities was 20% when cartilages were harvested from patients older than 10 years of age, and 63% in patients younger than 10 years old. The authors pointed out that, while early operation is recommended to reduce the adverse psychological impact on both patients and their parents, early surgery increases the risk of thoracic deformity. They recommended delaying costal cartilage grafts for as long as possible, leaving the costochondrial junction intact to minimise chest wall deformity and thoracic scoliosis.

Another long-term study reported on residual problems in chest donor sites (Thomson et al 1995). The study reported on rib cartilage removal for microtia reconstruction in which the process was usually initiated between the ages of two and three years. In this procedure an axial half of the sixth rib was harvested along with all of the seventh and eighth rib cartilages with their attached perichondrium. A total of 88 chest donor sites in 80 patients were evaluated. During the procedures there were 19 uneventful pleural perforations (22%) and two patients required a chest drain for treatment of operative pneumothorax. Postoperative atelectasis without evidence of pneumothorax occurred in

seven patients. One year following removal of the rib cartilage, chest scars were classified as excellent in 25% of cases, good in 33%, acceptable in 28% and poor in 14%. Chest topography deformities were rated as normal in 75% of cases, mild retrusion in 19% and severe retrusion in 6%.

In summary, the harvesting of costal cartilages for total ear reconstruction is associated with various functional problems, including pneumothorax, atelectasis, pain, unsatisfactory scars and chest deformities. Whilst the ideal age for rib cartilage harvesting is generally accepted to be 6 years, variations in the factors exist. Tanzer (1959) preferred children to be slightly younger at 5–6 years; Brent preferred patients to be 7–10 years; and Fukuda (1974) reported that better results in shape or size could be obtained in patients older than 10 years of age.

Is it effective?

Ear reconstruction

The appearance (shape, curve and size) of the reconstructed ear compared with the normal ear has been frequently used to indicate the success of the procedure. The reported results are summarised in Table 2. Some cases reported by Nagata (1994a,b,c,d, 1995) may be duplicated. As it was not possible to confirm this, results reported in each of his publications are presented in the Table 2.

Table 2 Clinical outcomes — total ear reconstruction

Study	Subjects/procedures	Outcome
Brent (1992)	*n*=546 with microtia Age: 5–62 Subgrouping based on the level of emotional impact: (A) severely affected (B) moderately affected (C) mildly affected 4-stage procedure	Average follow-up: 5.3 years (range: 1–17 years) Satisfactory: 83.3–100% (questionnaire survey of all subgroups) Durability at mean 5.3 years: 98.5% (*n*=273) Emotional benefit in subgroups: A B C significant: 80% 59% 46% some 20% 39% 58% unchanged 0% 9.1% 25%
Nagata (1993)	*n*=5 with microtia Mean age: 11.8 (range: 8–16) 2-stage procedure	Average follow-up: 2.8 years Satisfactory: 5
Nagata (1994a)	*n*=6 with lobule-type microtia Mean age: 8.5 (8–9) 2-stage procedure	Average follow-up: 9 months Satisfactory: 2
Nagata (1994b)	*n*=5 with concha-type microtia Mean age: 8.8 (range: 8–10) 2-stage procedure	Average follow-up: 8.4 months Satisfactory: 1
Nagata (1994c)	*n*=3 with small concha-type microtia Mean age: 10 (range: 10) 2-stage technique	Average follow-up: 6 months Satisfactory: 2

...contd

Table 2 (contd)

Study	Subjects/procedures	Outcome
Nagata (1994d)	*n*=3 with ear elevation for constructed auricle Mean age: 9 (range: 8–10) 2-stage procedure	Average follow-up: 8.7 months Satisfactory: 3
Nagata (1995)	*n*=6 with microtia Mean age: 11.2 (range: 9–16) 2-stage procedure	Average follow-up: 2 years Satisfactory: 5
Aguilar (1996)	*n*=31 5-stage procedure[a]	No follow-up details provided
Okajima et al (1996)	*n*=495 3-stage procedure[b] 219 completed 1st stage 176 completed 2nd stage 100 completed 3rd stage 2 had corrective surgery Average age=10	Satisfaction survey: 1st stage = 76.7% satisfied 2nd stage = 88.6% satisfied 3rd stage = 99% satisfied
Firmin (1998)	*n*=352 with microtia (primary and secondary reconstruction) Age: not stated 2-stage procedure:184 4-stage procedure: 144 (1-stage procedure: 24)[c]	Average follow-up: 1 year Very good*: 17% (60/352) Good*: 40% (140/352) Fair**: 20% (70/352) Undecided: 9% (30/352) * no definition given; **cases with complications or those of secondary cases (Results of the remaining 52 patients were not mentioned)
Gates et al (1998)	*n*=19 with microtia Age: not stated 2-stage procedure	Postoperative results were good (no details given)
Bhandari (1998)	*n*=76 with post-burn deformity Age: not stated Different techniques were used in patient groups based on skin availability etc	Average follow-up: 4.25 years (range: 0.8–6 years) Satisfactory results without complications: Group I (healthy auricular region skin): 86% (19/22) Group II (auricular region skin can be used): 89% (8/9) Group III (require temporoparietal flaps): 93% (38/41) Group IV (require free flaps) 100% (4/4)
Brent (1999)	*n*=1094 with microtia (500 were from previous report in 1992) Age: 5–62 (47% were 6–7) 4-stage procedure	Follow-up range: 1 to 18 years Average of 7.7 years Survey sent to 500 patients. 50.8% response rate received No further details provided

[a] Aguilar 5-stage protocol: 1 = framework construction and placement; 2 = lobule creation; 3 = atresia repair; 4 = tragal creation; 5 = aurical elevation

[b] Okajima 3-stage protocol: 1 = formation of ear lobe, construction and placement of framework; 2 = transplanted costal cartilage is elevated with the skin; 3 = tragus and conchol cavity are formed

[c] 1-stage protocol not typical (details not given)

NOTE: All studies were NHMRC level IV (case series)

Branemark implant

Nine reports were reviewed for information on the Branemark implant technique. Five of the reports discussed the clinical experience with the techniques and the implants over a period of years (Holgers et al 1989, Lundgren et al 1993, Berg et al 1994, Burton et al 1996, Wazen et al 1999). The studies involved only a few subjects and the reported information was not consistent between studies making effective comparison difficult. Studies reported on the number of fixtures and observations, the stability of implants, skin conditions and levels of patient satisfaction. Four of these studies referred to clinical application in craniofacial deformities, with only one study reporting solely on ears. It was not always possible from the published results to separate the results relating to the ears from those relating to other regions in the head and neck. A summary of the information obtained is given in Table 3.

Table 3 Summary of studies of clinical experience using Branemark ear implants

Author	Subjects/procedures	Outcome
Holgers et al (1989)	*n*=85, no diagnosis given, not known if microtia	2 of 280 fixtures not integrated in the bone. Total of 1863 observations.
	280 fixtures inserted	No adverse reaction in 89.6%; slightly reddish in 6.8%; red and moist in 2.5%; 0.9% granulation and 0.2% extensive tissue reaction.
Lundgren et al (1993)	*n*=28 craniofacial patients (3 with congenital microtia = 6 ears)	2 of the 3 patients with microtia needed reoperation due to infection of hair follicles and granulation tissue ingrowth. No other data reported.
	Ages: 16, 22 and 27 years	
Berg et al (1994)	*n*=22 (11 with microtia = 18 ears)	Average follow-up 36 months (3-30 months)
	Mean age: 35.4 (range: 15–73)	The 11 microtia patients not distinguishable from others in study.
		14 patients very satisfied; 6 patients satisfied; 2 considerably dissatisfied.
Burton et al (1996)	Two case series: No diagnosis noted and no other details reported	Follow-up 1–3.5 years with 143 implant observations.
	Case series #1 = patients with 30 titanium implants	2.8% noted symptomatic skin reactions; 1.4% noted significant tissue reaction.
	Case series #2 = 94 patients	98% success rate reported – no details provided.
Wazen et al (1999)	*n*=6 (2 with congenital microtia)	Study reported that all 6 patients using prostheses were greatly satisfied – no other details provided.

NOTE: All studies were NHMRC level IV (case series)

In reviewing their clinical experience and patient feedback, the authors of the studies shown in Table 3 noted some advantages in using the Branemark bone-anchored technique over adhesive retention (an alternative of the Branemark technique in which the prothesis is fixed by adhesive (and is removed on a regular basis). These were lack of dermatitis, lack of allergic reactions to adhesives, more secure and predictable placement of prosthesis, rehabilitation complete with minimal surgery; enhanced patient security and improved longevity of the prosthesis; and colour transition that reduces detectability.

Parel et al (1986) reported that, although technology had advanced the type of adhesives on the market, each type of adhesive had its own limitations. The paste or liquid aromatic cements require daily removal, which can frictionally damage the extrinsic coloration of

the facial surface. The silicone-based adhesives are extremely retentive but tend to damage fine margins with daily prosthesis use, and also require a silicone solvent for cleaning away adhesive residue, which may deteriorate the base material.

The remaining three reports (Wilkes et al 1994, Granstrom et al 1993, Somers et al 1998) outlined the authors views on comparisons between surgical ear reconstructions and titanium implants and reported on their clinical experience in this area. This data is summarised in Table 4.

Table 4 Comparisons between ear reconstructions and the Branemark implant

Author	Number of patients	Ear reconstruction comments	Branemark implant comments
Wilkes et al (1994)	55 ear reconstruction 14 Branemark	Indications for ear reconstructions: • classic microtia • lower third intact • patient preference • less compliant patient	Indications for comparator: • major cancer resection • radiotherapy • absence of lower half ear • severely compromised tissue • patient preference • failed autogenous reconstruction • potential craniofacial anomaly • poor operative risk
Granstrom et al (1993)	47 ear reconstructions (in 37 patients) 73 Branemark	Classified by aesthetic outcome: • only 8/37 patients satisfied • 35/47 ears as neither patient nor surgeon satisfied • 2/47 as surgeon satisfied • 10/47 as both patient and surgeon satisfied	Classified by aesthetic outcome: • 72 as both patient and surgeon satisfied • 1 as surgeon satisfied
Somers et al (1998)	27 ear reconstructions (6 four-stage/21 two-stage) Av age: 16 (range: 6–52) 35 Branemark Av age: 39 (range: 9–82) Average follow-up: 39 months	Cases rated as: • 9 — very good • 12 — good • 4 — fair • 2 — deceiving Advantages listed as 'owned new ear', no daily care, no maintenance and no renewal	Questionnaire reported satisfaction with prosthesis. Inconspicuous and stable. Disadvantage listed as daily care, occasional loss, colour difference and gradual discoloring and brittleness over time. Advantages are good reproduction with minimal surgery.

Note: All studies were NHMRC level IV (case series)

Wilkes et al (1994) pointed out that while the results of ear reconstructions continue to improve and become more consistent, it is still a technique that is technically demanding, not always applicable to all types of ear deformities and not available everywhere. In order for a prosthesis to be successful, it must meet the criteria of aesthetic acceptability, functional performance, biocompatability and desired retention. Parel et al (1986) defined the criteria for a successful prosthesis as longevity, morbidity, retrievability and function. With regards to longevity, the implant is considered successful if it is still functioning satisfactorily after five years. This occurred in 75% of patients treated.

Discussion

All the information regarding the effectiveness and complications of total ear reconstruction surgery is based on data from case series (NHMRC level IV evidence). The data suggests that total ear reconstruction using autologous costal cartilage has the following advantages:

- near-normal cosmetic appearance and function;
- long-lasting without ongoing maintenance;
- satisfactory success rate; and
- benefits to patient's emotional well-being.

The disadvantages are:

- the complexity of the surgical procedure; and
- the risk of complications at both the graft and donor sites.

The success of reconstruction depends on the following factors:

- refinement of technique;
- surgical experience; and
- the presenting deformity of external ear.

What are the economic considerations?

Because there was insufficient clinical data available to provide reliable information on clinical success and complication rates, a lack of data on direct and indirect costs incurred and a very low volume of expected utilisation of the procedure, an economic analysis was not conducted. Very few of the studies discussed any economic considerations or associated issues of relevance. Patients with a failed ear reconstruction are often referred for a subsequent Branemark procedure.

Conclusions

Safety

Although the number of complications associated with the technique can be quite high, particularly at the donor cartilage site, this is considered acceptable considering the overall benefits of the procedure.

Effectiveness

The procedure is complex and requires a considerable degree of training and experience to achieve acceptable results.

The procedure, if successful, is able to accomplish a near-normal ear in terms of cosmetic appearance and function. Because of this, some patients (or parents of patients) may accept the slightly higher apparent complication rate compared with the alternative Branemark implant procedure.

Cost-effectiveness

Insufficient data were available to assess the cost-effectiveness of the procedure.

Recommendation

MSAC noted that there is only level IV evidence on total ear reconstruction. As clinical trials are unlikely ever to be conducted, higher level evidence is unlikely to become available in the future. However, it acknowledged that given the small size of the patient population and their special needs, special considerations of access and equity should be taken into account in the assessment of this application. It also noted that the procedure should only be undertaken by suitably trained and experienced surgeons.

MSAC recommended that, on the basis of the available evidence on total ear reconstruction and considerations of access and equity, public funding should be supported for this procedure.

The Minister for Health and Aged Care accepted this recommendation on 6 March 2000

Appendix A MSAC terms of reference and membership

The terms of reference of MSAC are to advise the Commonwealth Minister for Health and Aged Care on:

- the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported;
- which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness;
- references related either to new and/or existing medical technologies and procedures; and
- undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC), and report its findings to AHMAC.

The membership of MSAC comprises a mix of clinical expertise covering pathology, nuclear medicine, surgery, specialist medicine and general practice, plus clinical epidemiology and clinical trials, health economics, consumers, and health administration and planning:

Member	Expertise
Professor David Weedon (Chair)	pathology
Ms Hilda Bastian	consumer health issues
Dr Ross Blair	vascular surgery (New Zealand)
Mr Stephen Blamey	general surgery
Dr Paul Hemming	general practice
Dr Terri Jackson	health economics
Professor Brendon Kearney	health administration and planning
Mr Alan Keith	Assistant Secretary, Diagnostics and Technology Branch, Commonwealth Department of Health and Aged Care
Dr Richard King	gastroenterology
Dr Michael Kitchener	nuclear medicine
Professor Peter Phelan	paediatrics
Dr David Robinson	plastic surgery
Associate Professor John Simes	clinical epidemiology and clinical trials
Dr Bryant Stokes	neurological surgery, representing the Australian Health Ministers' Advisory Council

Appendix B Supporting committee

Supporting committee for MSAC application 1024 — Total ear reconstruction

Dr David Robinson (Chair) MBBS, FRCS, FRACS, President of Seniro Medical Staff Association, Princess Alexandra Hospital, Brisbane	member of MSAC
Dr Richard Barnett MBBS, FRACS, FACS Visiting Reconstructive and Cosmetic Surgeon, Department of Plastic and Facio-maxillary Surgery Royal North Shore Hospital, Sydney	nominated by the Australian Society of Plastic Surgeons
Dr Robert Black MBBS, FRACS, FRCS, FACS Visiting Ear, Nose and Throat Surgeon, Mater Misericordiae Hospital, Brisbane Associate Professor of Surgery, University of Queensland	nominated by the Royal Australian College of Surgeons
Ms Merinda Northrup Member of Health Issues Centre with a particular interest in child health	consumer representative

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