The Journal of Laryngology and Otology
June 1993, Vol. **107**, pp. 502–509

Osseointegrated implants in the management of childhood ear abnormalities: the initial Birmingham experience

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Abstract

Over a four-year period 72 children with ear abnormalities have been referred for assessment by the extraoral osseointegrated implant team at The Queen Elizabeth Hospital, Birmingham. Thirty-two children have been judged suitable for rehabilitation. Twelve children have completed rehabilitation using bone-anchored hearing aids and/or auricular prostheses. Two fixtures (seven per cent of those loaded) have dislodged and required replacement. Audiological assessment of the bone-anchored hearing aid users shows only small improvements in their aided thresholds, compared to thresholds obtained with their previous aid. However all now have thresholds of 30 dB(A) or better and report a marked improvement in sound quality. When surveyed, hearing aid and prosthesis users report high levels of satisfaction with this form of rehabilitation. The technique adds a new dimension to the management of children with aural anomalies. The approach and results of a multidisciplinary programme are reported.

Key words: Implants; Titanium; Bone conduction; Hearing aid, Prosthesis; Congenital defects

Introduction

The use of osseointegrated implants to retain auricular prostheses and/or a bone-anchored hearing aid (BAHA) has introduced a new dimension to the management of patients with congenital and acquired ear abnormalities. Osseointegrated titanium fixtures (with percutaneous abutments to which a prosthesis or hearing aid is attached) allow secure fixation of these appliances. This permits more accurate construction of a prosthesis, with improved marginal adaptation which allows camouflage of the junction between prosthesis and skin. Similarly, hearing aids anchored in this fashion can offer advantages in hearing rehabilitation, comfort, cosmesis and security, when compared to other types of rehabilitation.

Although there is considerable international interest in osseointegrated implants and their extraoral applications, most centres have limited experience with extraoral implants. This unit currently has the largest experience with this technique in the United Kingdom. Apart from Branemark, Tjellstrom, and their colleagues in Gotenburg, Sweden, who pioneered the use of osseointegrated implants, few units have published their results of using extraoral implants (Branemark and Albrektsson, 1982; Tjellstrom *et al.*, 1985; Tjellstrom *et al.*, 1988; Hakansson *et al.*, 1990; Parel *et al.*, 1986; Cremers *et al.*, 1992). To the best of our knowledge, only Tjellstrom has commented in detail on using osseointegrated implants to treat children (Tjellstrom, 1989).

We present our preliminary results of using this technique to rehabilitate children with abnormalities of their external and/or middle ears.

Patients and methods

An extraoral osseointegrated implant programme has been underway at The Queen Elizabeth Hospital, Birmingham, since mid-1988. A multi-disciplinary team was established at the outset, involving otolaryngologists, maxillofacial surgeons, maxillofacial prosthetic technicians and audiologists. Over 100 patients have had extraoral implants placed for the retention of bone-anchored hearing aids, auricular prostheses and facial prostheses. In the paediatic arm of the programme (Fig. 1), 72 children have been referred for assessment.

Assessment

Patients being considered for a bone-anchored hearing aid undergo a battery of tests including pure tone audiometry, speech audiometry, and assessment of loudness

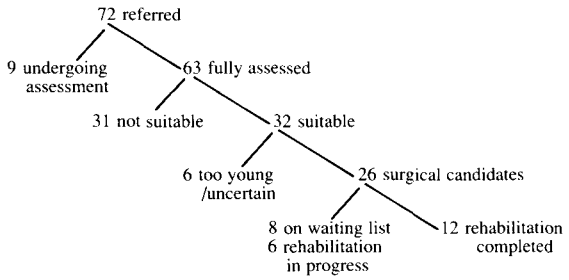

FIG. 1

Distribution of 72 paediatric patients with ear abnormalities referred for consideration of rehabilitation using osseointegrated implants, July 1988 to June 1992.

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Accepted for publication: 6 March 1993.

TABLE I
AGE, INDICATION AND REHABILITATION NEEDS OF TREATED PATIENTS

Patient	Age	Indication	Rehabilitation needs
1	15	Unilateral external ear atresia	R prosthesis
2	14	Treacher Collins Syndrome	L prosthesis + BAHA
3	13	Unilateral external ear atresia	R prosthesis
4	11	Treacher Collins Syndrome	R BAHA
5	13	Bilateral external ear atresia	L prosthesis + BAHA
6	15	Treacher Collins Syndrome	L prosthesis + BAHA
7	10	Unilateral external ear atresia	L prosthesis
8	14	Unilateral external ear atresia	L prosthesis
9	10	Craniofacial microsomia	R prosthesis
10	9	Craniofacial microsomia	L prosthesis + BAHA
11	6	Treacher Collins Syndrome	R BAHA
12	8	Treacher Collins Syndrome	R BAHA

BAHA = Bone-anchored hearing aid.

discomfort levels. Free-field testing (warble tones and speech audiometry) is undertaken with and without the patients' current hearing aid.

Assessment for prosthetic rehabilitation is undertaken jointly by the surgeons and maxillofacial technicians in the team. Following establishment of the programme, all patients judged suitable for rehabilitation have met patients who have undergone similar treatment, before any decisions about surgery are made. Fifty-three children have had their audiological and clinical assessment completed. Of these, 32 have been judged suitable for rehabilitation using osseointegrated implants. Twelve children have had their rehabilitation completed. All the children treated so far have congenital anomalies – one child who lost his pinna through trauma is too young to rehabilitate at present. Rehabilitation is in progress for seven children who will not be discussed further in this paper. Children have undergone prosthetic rehabilitation of orbital defects are also excluded from this discussion.

Rehabilitation

Of the 12 children (six male, six female; age range six to 15 years, median 13 years) whose rehabilitation has been completed, five have Treacher Collins Syndrome (mandibulofacial dysostosis). The remainder have varying degrees of craniofacial microsomia (hemifacial microsomia, first arch syndrome) or isolated ear anomalies. Their presentations and requirements for rehabilitation are summarized in Table I. Patients 11 and 12 are siblings. Children requiring fixtures for fitting of bone-anchored hearing aids undergo surgery at as early an age as possible. The youngest child in this series was six years old at the time of surgery. All the children fitted with bone-anchored hearing aids have a bilateral conductive hearing loss. Surgery to allow fitting of auricular prostheses is delayed until the children are older. The youngest child to undergo surgery for an auricular prosthesis was aged nine years at the time of surgery.

TABLE II
BONE-ANCHORED HEARING AID USERS

Patient no. (as in Table I)	Unaided PTA threshold (average 0.5–4.0 kHz, dB HL) AC	BC	A–B gap	Previous aid
2	63	18	45	BC
4	73	11	62	BC
5	55	20	35	BC
6	70	3	67	AC
10	69	16	53	AC
11	51	15	36	BC
12	52	15	37	BC

Pure tone thresholds i.e. PTA (mean of 0.5, 1, 2, 3, 4 kHz) in decibels, hearing level, best hearing ear (and implanted side). AC = air conduction thresholds; BC = bone conduction thresholds; A–B gap = difference between mean air conduction and mean bone conduction thresholds.

All paediatric procedures are performed under general anaesthesia, using the surgical technique recommended by Nobelpharma AB and previously described by Tjellstrom (1989). The surgery is staged, with a minimum interval of three months between the first stage (the placement of the titanium fixtures in the temporal bone) and the second stage (when the skin and soft tissues are thinned and titanium abutments placed on the fixtures). A hearing aid or a bar to stabilize a prosthesis are fitted several weeks later, once the skin and subcutaneous tissues are stable.

Results

Three children required a bone-anchored hearing aid alone, four required a bone-anchored hearing aid and a prosthesis, while five required a prosthesis alone (Table I). The results of this programme can be assessed in terms of hearing rehabilitation, cosmetic rehabilitation and problems associated with the osseointegrated technique of fixation.

Hearing rehabilitation

Seven children have been fitted with bone-anchored hearing aids. All use the HC-200 (earlevel) Nobelpharma aid, and have used their aids for a minimum period of seven months (range seven to 27 months, median 14 months). Their pre-operative and post-operative audiological assessments are summarized in Table II, Table III and Fig. 2.

Five children previously used a bone-conducting hearing aid, two previously used an air-conduction aid. All continue to use their bone-anchored aid and use no other aids. Assessing their free-field results (warble tones, mean improvement in thresholds at 500 Hz and 1, 2, and 4 kHz), four children have thresholds improved by 5 dB(A) or more, when compared to their thresholds with their previous aid. Three children have changes in their thresholds of less than 5dB(A). All now have a mean aided threshold of 30 dB(A) or better, whereas only one child

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TABLE III
BONE-ANCHORED HEARING AID USERS, FREE-FIELD ASSESSMENTS

Patient no. (as in Table I)	Warble tone thresholds (average 0.5–4.0 kHz, dB(A)) No aid	Old aid	BAHA	Speech discrimination scores (at 63 dB(A)) No aid	Old aid	BAHA
2	62	43	29	0	100	100
4	63	32	25	0	100	100
5	54	26	25	0	100	95
6	64	49	19	0	75	90
10	80	33	26	0	85	90
11	65	37	30	0	75	70
12	56	32	29	n/a	n/a	n/a

Warble tone thresholds, dB(A) (mean of 0.5, 1, 2, 4 kHz). Speech discrimination score at 63 dB(A) (conversational level). No aid = unaided; old aid = previous AC or BC aid; BAHA = bone-anchored hearing aid; n/a = not available.

had a mean-aided threshold of this level using her previous aid.

Speech discrimination scores (AB word lists at a conversational level of 63 dB(A), free-field testing) have been obtained for the six eldest children in three situations – unaided, with their previous aid and with their bone-anchored hearing aid. One patient (patient 4) had a marked improvement in his speech discrimination score, compared to his result with his previous aid. The remainder had little change in their scores.

A postal survey has been developed to assess the opinions of the children and their parents about this form of hearing rehabilitation. All seven children (or their parents) have completed the survey. All the children use their aid every day, for more than eight hours per day. They all report high degrees of satisfaction with the aid in most hearing situations and feel the aid amplifies sound adequately. All feel the aid is easy to use, with a pleasing improvement in the quality of sound obtained, compared to their previous aid.

Hearing conservation in background noise remains less than satisfactory for the majority (four out of seven) of the children. An increase in 'wind hiss', compared with the previous aid is reported by most children (five out of seven), regardless of the type of aid used previously. All feel the aid is cosmetically more acceptable and more stable than their previous aid. Children who previously used bone-conducting hearing aids consider freedom

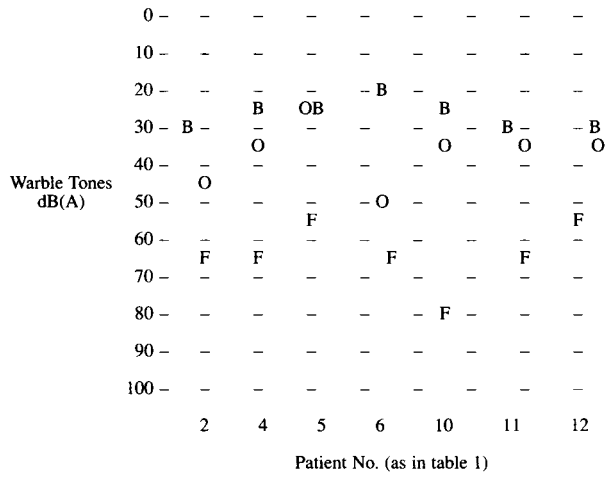

FIG. 2

Schematic representation of mean free-field warble tone thresholds tabulated in Table III. F = unaided thresholds; O = thresholds with 'old aid': (previous aid); B = thresholds with BAHA.

from the pressure symptoms and skin inflammation that arise from using a bone-conducting hearing aid are major benefits of this system. Fig. 3 shows the abutment position and BAHA fitted.

Overall satisfaction with the aiding system, graded on a scale of 1 to 10 (1 = dissatisfied, 10 = very satisfied), was assessed as 10 by for children, as 9 by two children and as 7 by one child. All graded the aid as more satisfactory than their previous aid. Two children have had their fixtures dislodged, requiring replacement, as outlined below.

Prosthetic rehabilitation

Nine children have auricular prostheses. All were aged nine years or older before the first stage procedure. All have used their prosthesis for a minimum of 10 months (range 10 to 44 months; median 14 months).

All prosthesis users (adults and children) treated in the unit have received a detailed questionnaire by post. The questionnaire was developed in the unit, but is distributed by university staff not involved in the osseointegrated implant programme, allowing anonymous replies. It assesses patient attitudes towards their disability and rehabilitation, including their opinions about their current prosthesis and the method of fixation. Seven of nine children (78 per cent) have completed and returned the questionnaire. Their responses to relevant questions are summarized in Table V.

Careful cleaning of the abutments and surrounding skin is necessary to prevent infections. The majority of the children find this difficult, enlisting the help of a parent in this daily routine. One child reported an abutment-related infection which required outpatient dressings. All the children wear their prosthesis every day, for at least seven hours per day. This suggests a high degree of satisfaction with this method of rehabilitation, which is confirmed on direct enquiry. Six of the seven children (86 per cent) feel the overall result of their implant retained prosthesis is totally acceptable, the remaining child rating the result as acceptable. All would recommend an implant retained prosthesis to other patients. Fig. 4 illustrates rehabilitation with an implant-retained prosthesis.

Problems relating to the osseointegrated method of fixation

To rehabiliate the twelve children, a total of twenty-eight fixtures have been 'loaded', following confirmation of 'osseointegration' at the second stage surgery. The

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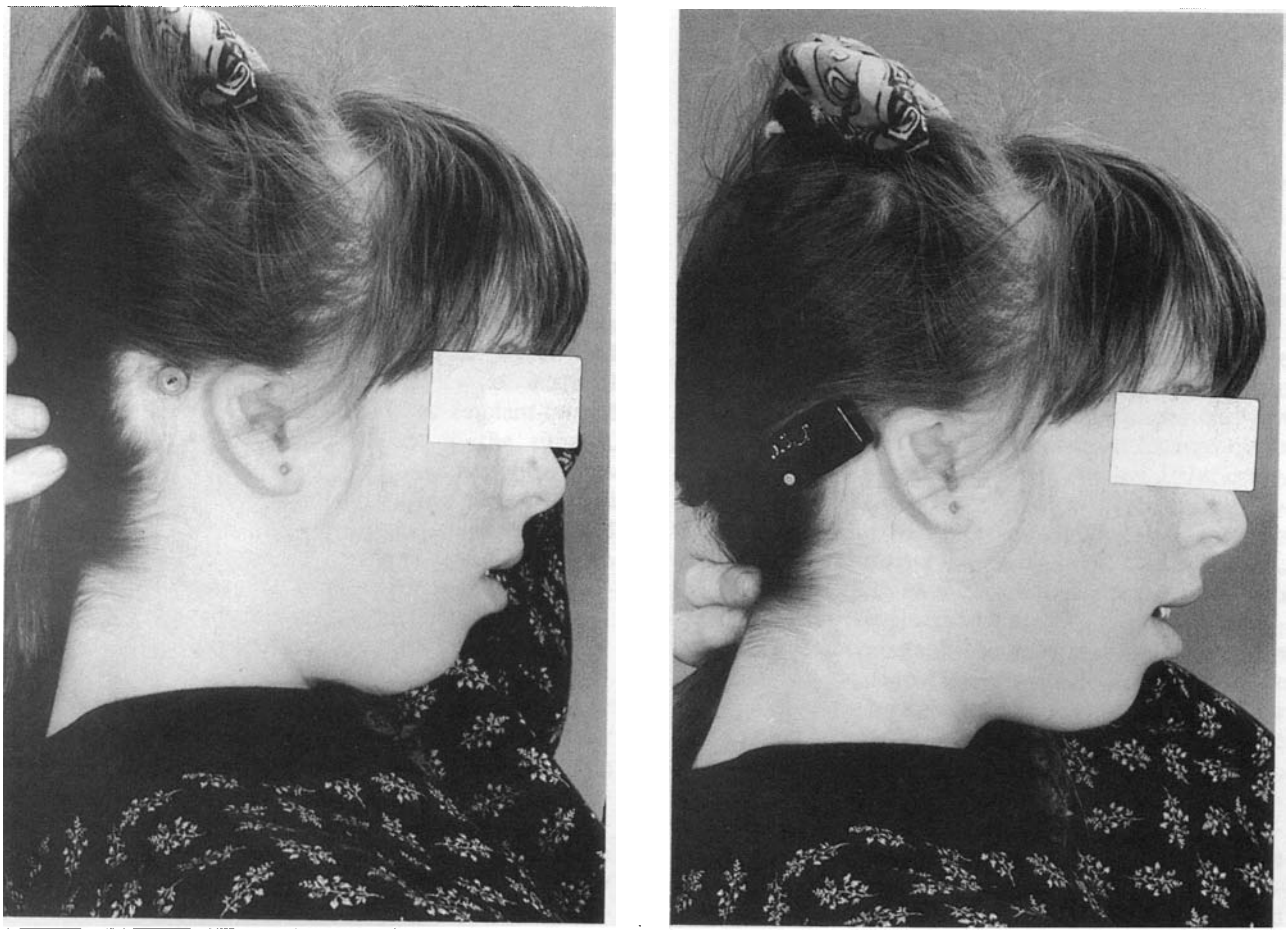

FIG. 3

Patient no. 4 (hearing loss secondary to Treacher Collins Syndrome): (a) showing the BAHA abutment; (b) the BAHA in place. The aid normally lies in a more vertical plane, covered by her hair.

bone-anchored hearing aids are held by a single fixture (nine in number, including two replacements). The auricular prostheses (nine) are stabilized by two fixtures (three fixtures in one case), contributing nineteen fixtures to the total number 'loaded'. In some cases, more fixtures have been placed but not 'loaded'. Seventeen of the 'loaded' fixtures were 3 mm in length, the remainder (11) 4 mm. Three fixtures could not be placed to their full depth because of contact with the underlying sigmoid sinus or dura. In all cases a minimum of 2 mm of cortical bone was sought to anchor the implant. At the second stage operation all abutments were found to have 'integrated', with no detectable movement when the abutment was fitted. Often new bone had grown over the fixture flange between

TABLE IV

SURVEY OF AURICULAR PROSTHESIS USERS

How easy is it to clean your abutments and the skin surrounding them?				
	very easy	simple	difficult	very difficult
	2	1	4	–
Who cleans your abutments?				
	self	self/parent	parent	sibling
	2	1	4	–
Do you wear your prosthesis every day?				
	yes	no		
	7	–		
For how long do you wear your prosthesis each day?				
1–3 hours	4–6 hours	7–9 hours	10–13 hours	>13 hours
–	–	2	3	2
Overall, how do you feel about the results of the implant retained prosthesis?				
totally unacceptable	unacceptable	tolerable	acceptable	totally acceptable
–	–	–	1	6
Would you recommend to other patients to have an implant retained prosthesis?				
	yes	no		
	7	–		

N.B. Seven out of nine children responded.

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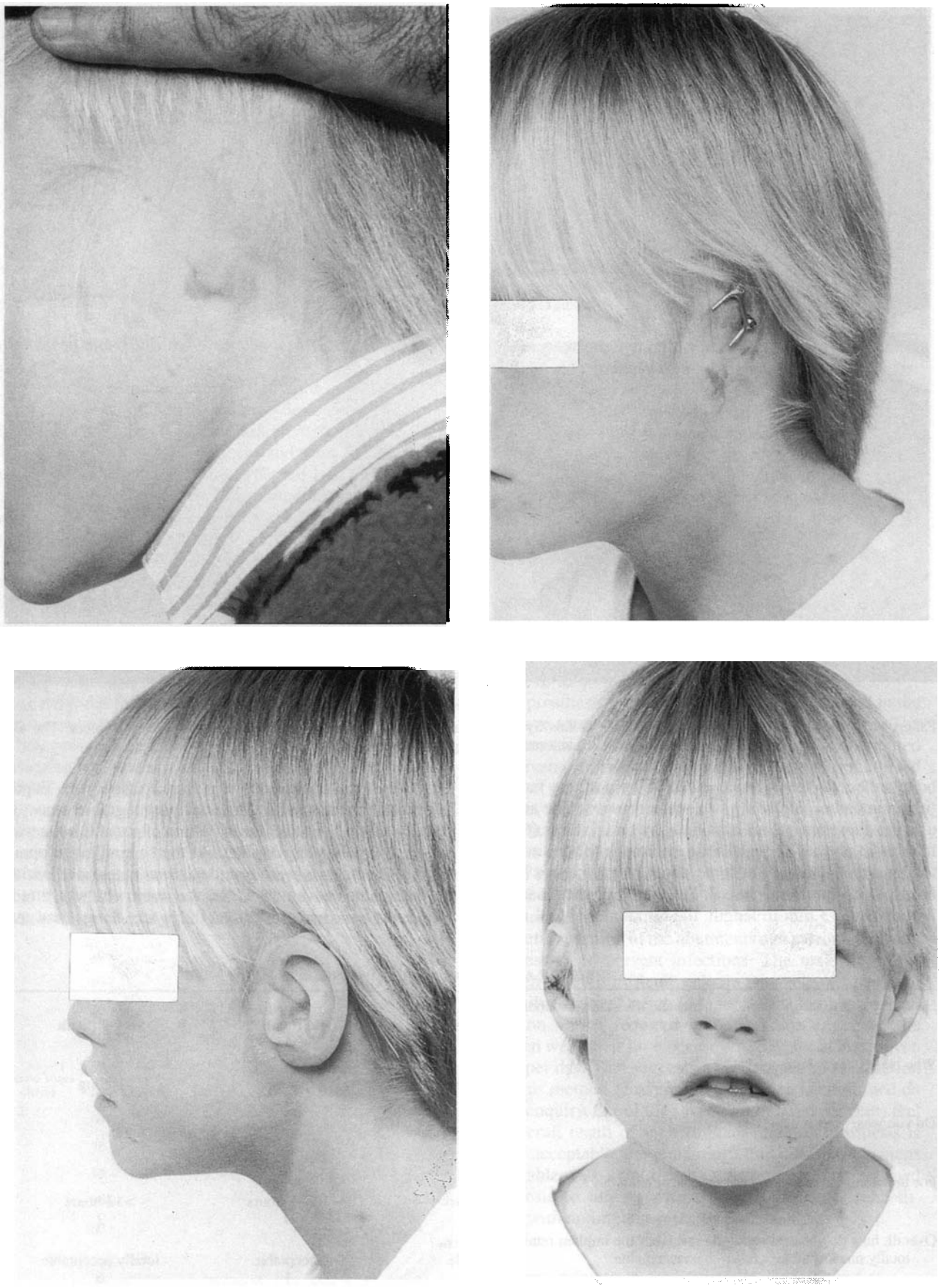

FIG. 4

Patient no. 9 (craniofacial microsomia with left aural atresia), showing (a) vestigal pinna, removed at second stage procedure; (b) abutments and bar to anchor prosthesis; (c) prosthesis in place; (d) frontal view showing left prosthesis and right ear (recently traumatized!). Note facial asymmetry and incomplete left facial palsy.

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the procedures, sometimes requiring removal to allow fitting of the abutment.

Two implants (1 × 3 mm and 1 × 4 mm; 7 per cent of those loaded) have loosened and been lost. Both were anchoring a hearing aid and failed within three months of loading, with no clinical evidence of implant-related inflammation or infection. It is of interest that the shorter fixture had not been placed to its full depth when implanted, because of limited bone thickness. Both implants have been replaced, with successful resumption of hearing aid use.

As outlined above, one of the survey respondents reported an infection around his implant which had required outpatient dressings. A review of hospital records revealed one other episode of implant-related infection (affecting a nonrespondent to the survey), treated by outpatient dressings and oral antibiotics. Thus two patients (17 per cent of this series) have suffered minor implant-related skin infections which responded readily to simple measures. Apart from replacing the two dislodged implants, no revision surgery has been undertaken. No abutments have needed to be removed.

Discussion

Abnormalities of the external ear and middle ear encountered in children are some of the most challenging disorders treated by otolaryngologists and plastic surgeons. In general these are congenital anomalies, occurring in isolation or as part of a craniofacial syndrome. The abnormalities may be unilateral or bilateral, with any combination of abnormalities of the auricle, external auditory meatus and middle ear being encountered. Several authors have developed systems to classify congenital conductive hearing disorders, which emphasise that the severity of the hearing loss and any middle ear anomaly tends to correlate with the degree of aural atresia and severity of any associated auricular anomaly (Gill, 1969; Pracy, 1987).

Trauma and neoplasia are common causes of auricular abnormalities in adults, but rare causes of auricular abnormalities in childhood. All except one of the children we have assessed so far have congenital anomalies. It is apparent that, even in the best hands, the results of hearing and cosmetic rehabilitation for children with these abnormalities have been variable in quality and normally require multiple procedures. The wide variety of procedures proposed for both areas of rehabilitation suggests that the optimal solutions have not yet been found. Poor liaison between the surgeons caring for these children can create further problems.

In recent years the use of osseointegrated titanium implants to retain prostheses and bone-conduction hearing aids has been added to the techniques available to treat this group of patients. Titanium implants were first proposed by Branemark and his colleagues (1969). As a consequence, implants to retain intraoral prostheses were developed, with low implant failure rates confirmed by careful long-term follow-up (Adell, 1985). Tjellstrom and his colleagues in the ENT Department, The Sahlgrenska Hospital, University of Gotenburg, began placing titanium implants extraorally in 1977. They initially placed implants to retain bone-anchored hearing aids, then expanded their programme to use implants to retain auricular prostheses and prostheses for other craniofacial defects. Their paediatric programme started in 1984. Traditionally, plastic surgeons attempt auricular reconstruction for children with microtia, while otolaryngologists attempt to correct any atresia of the external auditory meatus and the associated conductive hearing loss. Auricular reconstruction usually requires multiple procedures over several years, even when undertaken by experienced surgeons (Brent, 1980a,b).

Otologists have previously concentrated on creating a dry, stable external auditory meatus, with or without attempts at middle ear reconstruction. This approach usually involved multiple procedures to create a wide meatus, often through the creation of a mastoid cavity. The success rate for this type of procedure varies between authors, but restenosis and/or chronic discharge occur commonly in most reported series (Coleman, 1974; Pracy, 1987; Federspil and Delb, 1992). Most authors report disappointing hearing results from operating on cases with congenital aural atresia (Bellucci, 1981; Cremers *et al.*, 1988). Almost all children still require a hearing aid, with long-term use of an air-conduction aid often proving difficult because of chronic discharge or inability to retain an aid in the constructed meatus (Pracy, 1977 and 1987). The extraoral osseointegrated system relies on three factors for long-term stability. Firstly, the titanium implants are stabilized by being intimately surrounded by living bone, the process Branemark titles 'osseointegration' (Branemark, 1985). Secondly, vigorous thinning of the subcutaneous tissues and skin prevents skin movement around the abutments, allowing them to penetrate the skin permanently, without major problems with abutment-associated infections. The risk of infection is reduced further by ensuring the surrounding skin is not hair-bearing skin (Tjellstrom, 1989).

The craniofacial implant system and bone-anchored hearing aid system, titled the 'Branemark System' and 'Nobelpharma Auditory System' respectively, are manufactured and marketed by Nobelpharma AB, Gotenburg, Sweden.

Children with ear anomalies constitute 15 per cent of the osseointegrated implant workload in this unit, while adults with congenital ear anomalies constitute a further 33 per cent of the workload. Fifteen per cent of the patients in the osseointegrated programme have Treacher Collins Syndrome, the remainder a variety of congenital and acquired craniofacial abnormalities or an acquired conductive hearing loss. All patients are managed by a multidisciplinary team during their assessment, surgery and rehabilitation. A maxillofacial technician attends theatre with patients requiring prostheses, to ensure the fixture positions will allow optimal rehabilitation. We would discourage surgeons from undertaking the surgical aspects of the technique, if their unit lacks maxillofacial technicians and audiologists with the expertise and enthusiasm required for this type of rehabilitation.

For children with congenital conductive hearing losses, we still use conventional air conduction or bone-conduction aids until they are four or five years old, when bone-anchored hearing aids can be considered, depending on the audiological findings. While some children's hearing thresholds can be adequately improved with air conduction aids, abnormal canal and auricular anatomy can mean retaining a hearing aid is a problem. One child in

this series had undergone formation of a mastoid cavity and ear canal, with no improvement in her hearing thresholds. She was unable to retain an air-conduction aid in the operated ear. Bone-conducting hearing aids frequently provide the best conventional hearing rehabilitation for children with congenital conductive hearing losses. Unfortunately children often find the necessary headband uncomfortable, difficult to retain and unsightly. Pressure from the vibrator can lead to skin irritation and pain, preventing long periods of use. Freedom from these problems is perceived as a major benefit of a bone-anchored hearing aid by the children in this series. Placing fixtures in the temporal bone in preschool children can be difficult, because of limited cortical bone thickness. Tjellstrom has successfully placed fixtures in children as young as three years old (personal communication). We aim to place fixtures in cortical bone with a minimum thickness of 2 mm, with the intention of reducing the likelihood of failed 'osseointegration' or subsequent fixture loss. In some recent cases we have implanted two fixtures in a site suitable for anchoring a bone-anchored hearing aid, leaving the second fixture 'parked', with no abutment being fitted at the second stage operation. This precaution has been taken to minimize the period these patients would be without their boneconducting hearing aid, should their 'loaded' fixture fail. At this time none of these 'parked' fixtures have needed to be used.

All of the children using bone-anchored hearing aids prefer them to their previous aid, both for hearing rehabilitation and cosmesis. Their enthusiastic preference for their bone-anchored aids is somewhat at odds with our audiological assessments, which show only minor improvements in their free field pure tone and speech thresholds (Table III). However all seven now have mean aided free-field thresholds of 30 dB(A) or better, while only one child had thresholds of this level with her previous aid (Fig. 2). Children with auricular anomalies often present with skin tags, malformed pinnae or the unsatisfactory results of prior attempts at auricular reconstruction. For optimal prosthetic rehabilitation, these appendages need to be excised, giving a flat surface, covered in thin skin. This 'bare canvas' is the best foundation for prosthetic rehabilitation. The excision of unnecessary skin and soft tissues is the only irreversible step in the use of bone-anchored prostheses. It is a step many patients hesitate to take. Parents of children with craniofacial anomalies often feel very guilty about their children's disabilities, and seek their correction at as early an age as possible. Our policy is to delay the rehabilitation of auricular abnormalities until the children are old enough to be involved in making this decision. We review children at an early age, to assess them, to provide support and to advise their parents of the options for rehabilitation (Proops, 1992). Those families that wish to explore auricular reconstruction can then do so. One of the children in this series had previously undergone auricular reconstruction, with an unsatisfactory result.

When surveyed, all of the patients in this series reported a high degree of satisfaction with this method of rehabilitation. We feel it is noteworthy that all would recommend this form of rehabilitation to other patients. The technique does require motivated patients, as daily cleaning around the percutaneous abutments is necessary to avoid infections. Two patients in this series (17 per cent) have suffered minor implant-related skin infections. Hakansson *et al.* (1990) have reported in detail the frequency and severity of infections in a series of 167 people with bone-anchored hearing aids, followed for 10 years. Fifteen per cent of their patients suffered at least one skin 'reaction' requiring outpatient dressings or more intensive treatment. Seventy per cent of their patients never suffered any implant-related skin inflammation.

We have encountered an eight per cent fixture failure rate in this group – the loss of two implants that anchored hearing aids. This is a higher failure rate than that encountered by Tjellstrom and his colleagues, who report a two per cent failure rate in their programme overall, with the same failure rate in children as in adults (Tjellstrom, personal communication). The implant failure rate in our programme overall (adults and children) is three per cent (6 of 210 implants loaded). At this time, the number of children treated is too small to assess whether implant failure will be more of a problem in children than adults. Finding cortical bone of sufficient thickness to anchor fixtures appears to be a problem in children with craniofacial anomalies, who have abnormal temporal bones.

Summary

We are enthusiastic about the use of osseointegrated implants in the rehabilitation of children with ear abnormalities. Our initial results suggest this technique is a significant advance in the management of this group of patients. With a multidisciplinary team approach and appropriate case selection, successful cosmetic and hearing rehabilitation can be achieved, with a high degree of patient satisfaction. At this stage we are concerned that fixture loss may be more common in children than in adults. We will assess this factor carefully as our number of cases increases and their duration of follow-up increases.

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