

Osseointegrated implants in the management of childhood ear abnormalities: with particular emphasis on complications

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Abstract

Little has been published about the difficulties encountered during the insertion of osseointegrated implants for the attachment of bone anchored hearing aids (BAHA) and auricular prostheses in children. This study examines this issue in the first 51 children implanted at our centre. During surgery, the most common problem encountered was the presence of thin bone resulting in incomplete insertion of fixtures. Five fixtures had failed to integrate and six fixtures were lost in the long-term, however, only five children required revision surgery. The reason why few patients require revision was due to the judicious insertion of 'sleeper' fixtures. At follow-up, seven children required counselling for psychological problems. It is apparent from this study that osseointegrated implants in children are associated with difficulties, re-emphasizing that a paediatric osseointegration programme requires significant investment, and should only be undertaken by institutions that are committed to its success.

Key words: Child; Hearing Aids; Osseointegration; Post-Operative Complications; Intra-Operative Complications

Introduction

Traditionally children with significant deformities of the external and middle ears were provided with conventional bone-conduction hearing aids at an early age in an attempt to ensure satisfactory speech development.¹ These hearing aids are known for their poor cosmetic result, inferior sound quality and discomfort resulting from the persistent pressure of the aid on the soft tissue over the mastoid.^{2,3} Later in life these children underwent reconstructive surgery in an attempt to restore a cosmetically acceptable auricle and/or a functioning ossicular chain. Although these surgical techniques were widely used, the results were less than satisfactory except for treatment of minor deformities.⁴

Osseointegrated implants have been used successfully in adults for the attachment of bone anchored hearing aids (BAHA) and auricular prostheses.⁵⁻⁷ This initiated their use in children, therefore offering a revolutionary form of rehabilitation in the management of conductive hearing loss and auricular deformities.^{4,8,9}

Many centres have reported the results of osseointegration in paediatric patients confirming high integration rates.⁸⁻¹² However the literature has barely addressed difficulties and complications that

are encountered in this age group even though they are a unique population with specific needs. The aim of this study is to report on these particular issues.

Materials and methods

This study is a retrospective case note review of all patients (below the age of 17 years) who have been fitted with a BAHA and/or auricular prosthesis at our centre since the start of the programme in 1989. Details of each child's medical condition, surgical-history and post-operative course were collected and analysed, with particular emphasis on surgical difficulties and complications.

All patients underwent osseointegrated implantation by a two-staged procedure as originally described by Tjellström, consisting of implantation (Stage 1) followed by skin penetration (Stage 2).¹³ The senior author has previously described the specific details of techniques used in this study.¹⁴ The Nobelpharma auditory system (Nobelpharma AB, Goteborg, Sweden) has been used exclusively for the purposes of this series, incorporating the HC-200, HC-220, and HC-300 sound processor units.

A protocol for the post-operative care of these children was followed, which consisted of the routine review of implanted children at one month, six

TABLE I
THE DIAGNOSIS OF CHILDREN WHO UNDERWENT IMPLANTATION FOR A BAHA, AURICULAR PROSTHESIS (AP) OR BOTH

Diagnosis	Patients for BAHA	Patients for AP	Patients for both	Number of patients
Congenital				
Treacher-Collins syndrome ²¹	13		1	14
Oculoauricularvertebral (Goldenhar) syndrome ²¹	5			5
Hemifacial Microsomia ²¹		4		4
First arch syndrome ²¹		2		2
Okiihiro syndrome ²¹			1	1
Bixler-Antley syndrome ²¹	1			1
Trisomy 18 syndrome (Edwards) syndrome ²¹	1			1
VACTERL ²²	1			1
DeGrouchyII-del (18q) ²¹	1			1
Branchio-oto-renal-syndrome ²¹	1			1
Un-identified congenital anomalies	5	9	1	15
Acquired				
Burn		2		2
Road traffic accident		2		2
Unspecified acquired trauma		1		1
Total number of patients	28	20	3	51

months, and 12 months post-fitting of the BAHA and/or auricular prosthesis, and twice yearly thereafter. At each of these appointments the stability of the implants were checked and the skin penetration site cleaned. Skin reactions around the implant were graded according to the classification of Holgers *et al.*: 0 = no irritation, 1 = slight redness, 2 = red and moist but with no granulation formation noted, 3 = as in two, but with granulation tissue noted, and 4 = revision of skin-penetration necessary.¹⁵

Audiological assessment was undertaken prior to implantation and at each follow-up visit, the results of which have been previously described.⁸

Results

Over a period of seven years, 51 children (M:F ratio = 29:22) were implanted primarily to fit 31 BAHA and 23 auricular prostheses. Seven of these children required re-implantation during the period of the study, thus a total of 58 implantations were reviewed. At the time of surgery the mean age was 7.6 years (range = two to 10 years; SD = \pm 3.2) for fitting a BAHA, and 9.2 years (range = seven to 15.5 years; SD = \pm 3.7) for fitting an auricular prosthesis.

Thirty-one of the implantees had bilateral conductive hearing losses and were rehabilitated with a BAHA. Fifteen children had bilateral auricular atresia and 21 children had unilateral auricular deformities. Of these 36 children with auricular abnormalities, 23 received an auricular prosthesis. The causes of deafness and auricular deformities are presented in Table

I, which demonstrates that the commonest indication for implantation was congenital anomalies of the external and middle ears. Mandibulofacial dysostosis (Treacher-Collins' syndrome) was by far the most common syndrome encountered in this population.

A total of 107 fixtures were fitted at Stage 1, 56 were implanted for BAHA, and 51 for auricular prostheses. Table II shows the number and length of fixture used, in the different subgroups of children. Twelve of the fixtures were intended as 'sleepers' (a sleeper is a second fixture inserted at Stage 1 as a spare for future use, if the main fixture is lost).

The most common difficulty encountered during the insertion of the titanium fixtures was related to inadequate calvarial thickness (Table III). In two children the Stage 1 was abandoned, as it was not possible to insert a minimum of 2.5 mm of the fixture length. These children were successfully implanted six months later. The lateral sinus or dura-mater were exposed during the insertion of 33 fixtures without any complications. Fifteen of these fixtures were incompletely inserted (remaining proud of the skull surface) despite several attempts to find a suitable site with bone of appropriate thickness (Table III). Multiple attempts to seat a fixture were necessary in at least 23 children, prior to accomplishing a satisfactory fit. Significant bleeding was encountered during the insertion of three fixtures, all from large emissary veins. Of all the fixtures that were difficult to insert only three failed to integrate, all of which had been incompletely inserted.

TABLE II
THE LENGTHS OF FIXTURES IMPLANTED AND THEIR INTENDED USE IN THE THREE MAIN SUBGROUPS OF CHILDREN

	Implanted for BAHA		Implanted for auricular prostheses		Implanted for both		Total number of fixtures
	3 mm	4 mm	3 mm	4 mm	3 mm	4 mm	
Intended for use	40	1	25	19	8	2	95
Intended as a sleeper	10				2		12
Total number of fixtures	50	1	25	19	10	2	107

TABLE III

THE DIFFICULTIES ENCOUNTERED DURING STAGE 1 IN CHILDREN WHO UNDERWENT IMPLANTATION FOR A BAHA, AURICULAR PROSTHESIS (AP) OR BOTH

Difficulty	Implanted for BAHA 16/51*	Implanted for AP 9/44*	Implanted for both 3/12*	Total number of fixtures 39/107*
Exposed lateral sinus	3	2	2	7
Exposed dura	18	6	2	26
Incomplete insertion	9	4	2	15**
Loose fitting	1	2	1	4
Soft bone	0	3†	0	3†
Bleeding	3	0	0	3
Total number of fixtures	34	17	7	58

*Number of patients/number of fixtures.

**At least 2.5 mm of fixtures were inserted, of these three failed to integrate.

†All implanted in a 14-year-old boy with first arch syndrome who is a successful auricular prosthesis user.

The period between Stage 1 and Stage 2 was influenced by the findings at initial surgery, and a longer period was preferred when difficulties were encountered during insertion. The mean was 15.9 weeks (range eight to 26 weeks; SD + 5.7).

At Stage 2, it was noted that four fixtures had failed to osseointegrate (all inserted for BAHA), and new-bone formation had occurred around another fixture. It was possible in this last case to drill away the excess bone and successfully apply a BAHA.

In order to compensate for the four fixtures that had failed to osseointegrate, it was necessary to use three sleepers (one child did not have a sleeper inserted). Two were used successfully, while the third sleeper had failed to integrate. Therefore this child and the one without a sleeper had to undergo revision of the Stage 1.

After loading of the BAHA auricular prosthesis i.e. during follow-up (mean = 3.2 years; range = 0.5–seven years; SD = ± 1.6) six fixtures were dislodged, three with no apparent cause at five, eight and nine months respectively whilst the remaining three were dislodged secondary to trauma. All six lost fixtures had been fitted with BAHA. Of these six patients, two had sleepers which were exposed in an attempt to replace two of these lost fixtures, one of which was successfully loaded while the other was surrounded with new bone that precluded its use. In an attempt to drill the excess bone the fixture was lost. Therefore re-implantation was necessary for five children.

Table IV, presents the total number of fixtures lost in this study and the reason for their loss. Although a total of 12 fixtures were lost (two of these were sleepers) only seven re-implantations were necessary because sleepers could be utilized for some of the losses. Of the 12 fixtures intended as sleepers only

five were used. Three were required at the Stage 2, of which two were used successfully while the third failed to integrate. In addition two sleepers were required at a later date (eight and nine months) of which one was used successfully and the other separated during an attempt to clear new bone formation. Soft tissue reactions during the follow-up period are shown in Table V.

A considerable number of the adolescent children required psychiatric support during or following implantation. Table VI shows the difficulties encountered with these children, all of which were overcome after suitable counselling.

Traumatic damage of BAHA or auricular prostheses was encountered frequently, at least three fixtures were dislodged as a result of trauma, five abutments were irreversibly damaged, retaining bars were bent, two BAHA were damaged, and prosthetic auricles were burned, split and lost.

Discussion

In this study the outcomes of 107 titanium fixtures for fitting 31 BAHA and 23 auricular prostheses in 51 patients has been reviewed. These children underwent 58 implantations and were followed-up for a mean period of 3.2 years.

The main difficulty encountered at the Stage 1 was inadequate skull thickness. The reason for the thinness is not simply dependent on patients' age, but also on the fact that the majority of these children have significant craniofacial abnormalities. Thin bone was encountered in some older children too. Underdevelopment of the skull and the mastoid bones has been clearly documented in Treacher-Collins' syndrome, the most common condition implanted in this study and in other series.^{10,12,16,17} In other craniofacial syndromes with normal calvar-

TABLE IV
THE TOTAL NUMBER OF LOST FIXTURES

Reason for loss	Fixtures number (%)
<i>Early loss</i>	
Failed to integrate	5 (4.7%) (All BAHA)
<i>Post-loading</i>	
Trauma	3 (2.8%) (All BAHA)
New bone formation	1 (0.9%) (AP)
No obvious cause	3 (2.8%) (All BAHA)
Total	12 (11.2%)

TABLE V
DISTRIBUTION OF SKIN REACTIONS FROM 214 OBSERVATIONS AT THE IMPLANT SITE

Description	Type	Number of observations	Percent
Normal	0	197	92
Reddish	1	9	4.2
Red and moist	2	4	1.9
Granulation	3	4	1.9

TABLE VI
THE PSYCHOLOGICAL DIFFICULTIES ENCOUNTERED WITH SOME
ADOLESCENT PATIENTS

Difficulties encountered	Number of patients
Refused Stage 2 (phobia)	1
Refused the use of BAHA	1
Poor care (phobia)	4
Difficulties coping at school	1
Total	7 (13.7%)

ial thickness, there may be variations in the skull contour that make implantation and alignment difficult. A child (14 years old), in this series, had an extremely soft mastoid bone of sufficient thickness to allow complete insertion. This child became a successful auricular prosthesis user.

It was previously suggested that pre-operative imaging with computerized tomography may be useful in ensuring adequate thickness of the skull in the under five age group.¹² However, the position and alignment of the BAHA is determined by the skull contour, which is unappreciated through 2D imaging. In addition, early intervention is essential to ensure adequate auditory input for speech development in the congenitally deaf child. In cases where unfavourable conditions are encountered during implantation, it is possible to leave the fixture unloaded for a longer period. Using this policy, all children in this series, including two patients (two years old) became successful BAHA users within a period of one year of implantation. Those who experienced late failure had a minimal period of 5.9 months of auditory input at a very early stage that is thought to have contributed to their development.

In this study, the only factors recognized to contribute to fixture loss were trauma and incomplete insertion. All fixtures, which exposed the dura or the lateral sinus, were successfully loaded except the three, which were incompletely inserted. Surprisingly the four loosely fitting fixtures had all integrated well. These findings reinforce previous reports.¹⁰⁻¹²

The implantation of sleepers proved to be a useful policy. Although five fixtures did not integrate only three patients required re-implantation. However, it was not always advantageous to use a sleeper, as factors that lead to failure of integration of the main fixture may contribute to the loss of the sleeper as demonstrated in one of our patients. In addition, new bone formation, a phenomena encountered exclusively in paediatric implantees can make fitting an abutment impossible.¹⁰⁻¹² Attempts to re-expose the fixture using a diamond drill were not always successful. Although the higher rate of bone healing observed in younger patients may cause difficulties in some children it may be beneficial in cases of incomplete insertion.

This study shows that osseointegrated implants in children are only marginally less successful than in adults. Tjellström's group reported success rates of 90 to 95 per cent in predominantly adult series of BAHA.^{11,18-20} However, direct comparison with

published results is difficult due to the variations in the studied populations. An obvious difference between our series and that of the Great Ormond Street hospital may be related to their policy of not implanting children younger than five years.¹² We agree with their conclusions that the success of a programme is related to the number of children who wear their aids. In our study all children including the youngest are successful BAHA or auricular prostheses users.

Trauma appears to be a challenge unique for the paediatric age group; it resulted in the damage of several fixtures, abutments, retaining bars, BAHA and auricular prostheses.

The observation that a considerable number of adolescents had psychological problems that required psychiatric input confirms that managing these difficult children requires a multi-disciplinary team approach. It also re-emphasizes that a paediatric osseointegration programme requires significant investment in terms of resources and time, and should only be undertaken by institutions that are committed to its success.

It appears that implanting for BAHA is a different entity to implanting for auricular prostheses. For each auricular prosthesis two or more fixtures are used per prosthesis compared to one for each BAHA. In addition the aim of implantation is different, for auricular prostheses it is purely cosmetic whilst for BAHA it is for speech acquisition. This difference necessitates surgeons to implant younger children for BAHA than for auricular prostheses, and permits the use of a large number of 4 mm fixtures for auricular prostheses. These differences may explain the considerably larger number of difficulties encountered whilst implanting for BAHA rather than auricular prostheses and may be the reasons for the greater risk of fixture loss with BAHA.

Conclusion

It is apparent from this study that osseointegrated implants in children are associated with difficulties, however the benefits from their use particularly for BAHA far outweigh their disadvantages.

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