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Main Article

Updated surgical experience with bone-anchored hearing aids in children

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Abstract

Background: We present the results of a retrospective review of children undergoing implantation with bone-anchored hearing aids (BAHAs) at the Great Ormond Street Hospital for Children.

Methods: The case notes of 71 children undergoing BAHA placement at the Great Ormond Street Hospital for Children between December 1990 and August 2002 were reviewed. Outcome measures included hearing thresholds, incidence of fixture loss, skin reaction and need for revision. Quality of life outcomes were also measured.

Results: Eighty-five ears had been implanted. Fifty-four per cent of children had experienced no complications, 42 per cent had required revision surgery and 26 per cent had experienced fixture loss at some point. Young age at implantation was associated with an adverse outcome. Trauma and failure of osseointegration had been the commonest reasons for failure. A skin reaction around the abutment had occurred at some point in 37 per cent of children but had persisted for longer than six months in only 9 per cent; this had been associated with fixture loss. The use of fixture site split skin grafts had reduced problems with skin hypertrophy and hair overgrowth. Hearing thresholds when using BAHAs had been comparable to those when using bone conduction hearing aids. However, BAHAs had significant additional benefits in terms of sound quality, ease of use and overall quality of life.

Conclusion: Bone-anchored hearing aids provide significant benefits over other types of hearing aid, both audiologically and in terms of quality of life. Careful selection of candidates and meticulous follow up are required in order to minimize complications.

Key words: Implants and Prostheses; Otological Surgical Procedures; Hearing Aids; Children

Introduction

It is now over 25 years since the introduction of extra-oral, osseointegrated implantation.[1] Over this period, the technique has become widely accepted as the 'gold standard' for management of conductive hearing loss in patients with microtia, using bone-anchored hearing aids (BAHAs). The technique may also be used to treat other forms of conductive hearing loss (for example, otosclerosis or active chronic otitis media) when more traditional methods of hearing rehabilitation have failed.[2] Similarly, placement of osseointegrated fixtures has become one of the techniques used for prosthetic reconstruction in a number of locations in the head and neck region, not least the external ear.

The technique relies upon the propensity of titanium to become firmly bonded to bone, as well as its resistance to corrosion and non-toxicity.[3] The presence of a stable cutaneous–implant interface is also important. In particular, a thin, firmly attached, hair-free skin border around the implant is vital for success.[4]

The benefits of BAHAs over traditional bone-conduction hearing aids have been well documented.[5,6] Benefits include improved sound quality, reduced discomfort and improved cosmesis.[7,8] These benefits are particularly pertinent to the paediatric population. It has become evident, however, that this particular group of patients has specific requirements regarding cochlear implantation if long-term success is to be achieved.[9–13]

In 1997, our centre published results for the first 32 children undergoing placement of BAHAs at the Great Ormond Street Hospital For Children.[9] Since then, many more children have undergone implantation. This paper presents the more recent experience of BAHA implantation at our centre, which has a purely paediatric caseload.

Materials and methods

Local ethical committee approval was obtained prior to commencement of this study.

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All children who had undergone BAHA fitting between December 1990 and August 2002 were identified from the databases of the departments of otolaryngology and audiology. This included those who had been involved in the previous study.

The case notes for each child were reviewed. The following background information was recorded: date of birth, sex, indications for BAHA, associated medical conditions, associated craniofacial abnormalities, previous hearing aid use and requirement for auricular reconstruction. The following information regarding surgical technique was recorded: side, dates at which each stage was performed, grade of surgeon, type of skin graft, number of holes drilled, number of fixtures inserted, length of screw, dural exposure and abutment type. The following audiological data were recorded: type of aid fitted, and pre- and post-operative bone- and air-conduction hearing thresholds at 0.5, 1, 2 and 4 kHz. The duration of follow up was also recorded, together with any relevant complications.

Subsequently, each child was mailed three validated questionnaires examining quality of life (QoL) issues following implantation. These were: the Glasgow children's benefit inventory (a general post-operative QoL instrument); the Glasgow hearing aid difference profile (which measures the change between two different types of hearing aid in terms of: hearing difficulty in certain situations, proportion of time that the hearing aids are used, benefit gained from the new aid compared with the old, and level of satisfaction with the new aid compared with the old); and the Nijmegen BAHA QoL instrument (which measures BAHA-specific QoL issues such as effectiveness of aiding, sound quality, visibility and ease of use). Each child (or parent) was asked to return the questionnaires to the Great Ormond Street Hospital for Children, together with a signed consent form, in a stamped addressed envelope.

The surgical methods used for implantation have been described elsewhere.[1] Each child had undergone a two stage procedure. The first stage had involved insertion of the flange fixture screw. The second stage, several months later, had involved application of a skin graft and insertion of the abutment (which attaches to the screw and allows attachment of an appropriate hearing aid). Entific Medical Systems (Cochlear, Weybridge, UK; previously Nobelpharma Auditory System) hearing aids had been used in all cases. Children had been reviewed at three weeks, three months, six months and every six months thereafter. At follow up, skin reaction around the abutment had been recorded according to Holgers' classification (Table I).[10]

Statistical analysis was carried out when appropriate. The Student *t*-test was used for quantitative data. The chi-square test was used for categorical data.

TABLE I

CLASSIFICATION OF SKIN REACTION[10]

Score	Description
0	No irritation
1	Slight redness
2	Red and moist tissue, no granulation tissue
3	Red and moist tissue with granulation tissue
4	Revision of skin penetration necessary

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Results

During the study period, 41 boys and 30 girls had undergone primary implantation. Fourteen children had also had the opposite ear implanted (secondary implantation) at some point, making a total of 85 ears implanted. Figure 1 illustrates the age distribution of children undergoing primary implantation. The mean age at primary implantation had been 8.7 years (standard deviation (SD) 3.7 years) with a range of 3.6–17.2 years. The mean age at secondary implantation had been 12.1 years (SD 3.0 years). The mean follow-up duration had been 4.5 years (SD 3.4 years). Seventy-nine per cent of stage one and stage two procedures had been performed by the senior authors (DMA and CMB), 19 per cent of stage one and stage two procedures had been performed by senior trainees, and in 2 per cent of cases the operating surgeon had not been documented.

The indications for implantation are shown in Table II. Sixty-one children had had microtia. The majority of these children had had an associated craniofacial abnormality, the most common being Treacher Collins syndrome (mandibulofacial dysostosis). Nine of these children had undergone attempted middle-ear reconstruction prior to receiving their implant. Four of these had suffered on-going, active chronic otitis media. A further eight children had suffered primary, active chronic otitis media.

Fifty-two and 17 ears had had 3 mm and 4 mm fixtures inserted, respectively. The length of the screw had not been recorded for 11 ears. Five ears had had a 3 mm and a 4 mm fixture implanted. In 55 per cent of cases, dura had been exposed at the base of the drill hole. After 1995, each child had undergone insertion of an additional 'sleeper' fixture during the primary procedure. The mean interval between the first and second stages had been 6.8 months (SD 14.1 months). Figure 2

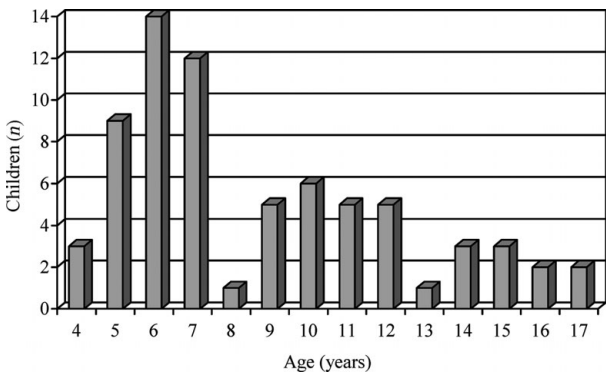

FIG. 1

Distribution of age at primary bone-anchored hearing aid implantation.

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TABLE II

INDICATIONS FOR BAHA INSERTION

Diagnosis	Patients (*n*)
Microtia	
Treacher Collins	24
Isolated bilateral atresia	22
Cleft lip and palate	4
Goldenhars	4
Pfeiffers	3
Cloverleaf skull	1
Downs	1
Nager	1
18q	1
Active chronic otitis media	
Non-syndromic	2
Klippel Fiel	1
Treacher Collins	1
Branchio-oto-renal	1
Russel–Silver	1
Downs	1
Sticklers	1
Other	
Recurrent otitis externa	1
Ossicular chain fixation	1
Total	71

BAHA = bone-anchored hearing aid

illustrates the types of skin graft used. In latter years, the graft had invariably been obtained by raising a split skin graft from the skin overlying the fixture site.

Table III lists the complications and outcomes experienced. Fifty-four per cent of children had not developed any complications. Forty-two per cent of children had required revision surgery at some point (25 per cent had required a single revision).

Twenty children had experienced fixture loss (22 episodes in total). Nine children in this group had been syndromic, compared with 11 who were non-syndromic. The mean age at implantation in those children experiencing fixture loss had been 7.8 years (SD 4.0 years), compared with a mean age of 9.6 years (SD 3.5 years) in those who had not lost fixtures ($p = 0.05$). Boys made up 70 per cent of those patients experiencing fixture loss, compared with 57 per cent of those who had not lost their fixture. This difference was not statistically significant ($p < 0.1$). Fixture loss had occurred within one year of implantation in 65 per cent of cases. Delayed fixture loss had predominantly resulted from trauma. There was no significant difference in fixture loss rates between children with 3 mm implants and those with 4 mm implants ($p < 0.5$).

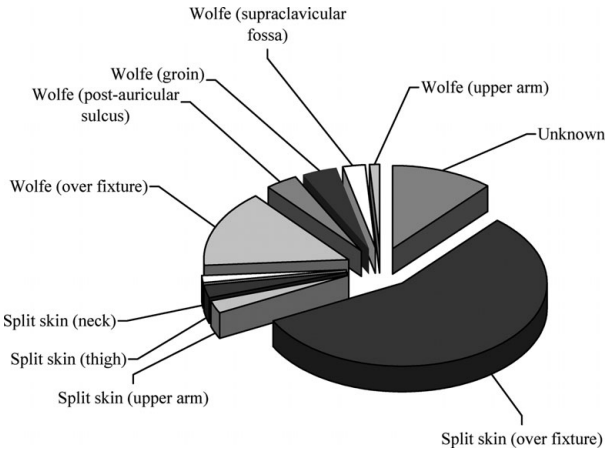

FIG. 2

Types of graft used for stage II bone-anchored hearing aid implantation.

Thirty-seven per cent of children had suffered a skin inflammation scoring two or more at some point during the follow-up period, but 91 per cent of these had settled by the next appointment. There was no significant difference in skin reaction between the different types of skin graft used. However, those children who had had split skin grafts taken from the fixture site were less likely to develop hypertrophy of the graft than those who had had full thickness Wolfe grafts or split skin grafts taken from other areas (11 *vs* 36 per cent, respectively; $p < 0.01$). For both groups, 80 per cent of the children who had developed thickening of the skin graft required revision surgery.

Of those children who had undergone contralateral BAHA insertion after the initial implant: five had been due to the initial BAHA being in an inappropriate position to allow auricular reconstruction or bone-anchored auricular prosthesis placement; two had experienced failed osseointegration on the initial side; three had developed chronic infection around the abutment; two had developed skin and bony overgrowth around the abutment; and one had developed bony overgrowth alone. In one child, the reason for contralateral implantation was not documented.

Three children had subsequently stopped wearing their BAHA. The first child had developed a progressive sensorineural hearing loss which became unaidable with a BAHA. The second child played sport frequently and had found the BAHA a hindrance; he had also undergone two stage two revisions because of skin overgrowth. The third child had been accepted into the programme in its early stages, but, after implantation, he temporarily went back to his air conduction aids and realized that he heard better with them. A single child had undergone implantation but never used an aid because of failed osseointegration.

The children's mean aided thresholds had been 33 dBA before and after implantation. This is higher than one would expect for a population with predominantly conductive hearing loss. The reasons for this are twofold. Firstly, normal or near normal aided thresholds had been recorded as 'threshold < 30 dBA', and these were taken as 30 dBA for this calculation in the majority of notes. Secondly, there had been a number of patients with a mixed hearing loss.

The number of QoL questionnaires returned was extremely low. Thirteen Glasgow children's benefit inventory questionnaires and 12 Glasgow hearing aid difference profile questionnaires were returned. Eleven Nijmegen BAHA QoL questionnaires were returned. This represented a response rate of 16.9 per cent.

With regard to the Glasgow hearing aid difference profile, nine children had noticed a reduction in

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TABLE III

COMPLICATIONS OF BAHA IMPLANTATION*

	Loose abutment	Loss of abutment	Loss of fixture	Bony overgrowth	Skin overgrowth	Hair growth
n	25	15	22	12	22	2
Mean onset (months)	22.6	11.3	25.5	62.5	45.1	22.0
Median onset (months)	12.0	10.0	6.0	56.5	35.0	1
Range of onset (months)	2–99	2–27	2–62	4–96	2–104	1–38
SD (months)	25.9	9.2	31.9	40.9	37.9	26.2
Reason						
Unknown	1	0	5	NA	NA	NA
None	19	1	3	NA	NA	NA
Trauma	2	8	5	NA	NA	NA
Infection	3	6	3	NA	NA	NA
Failed OI	NA	NA	6	NA	NA	NA
Outcome						
Abutment tightened	25	NA	NA	NA	NA	NA
Revision stage II	0	15	NA	6	13	2
BAHA resited	NA	0	13	0	1	0
BAHA opposite ear	NA	0	3	4	3	0
Awaiting revision	0	0	5	1	3	0
No intervention	0	0	1	1	2	0

*$n = 85$. SD = standard deviation; OI = osseointegration; NA = not applicable; BAHA = bone-anchored hearing aid

hearing difficulty, comparing their BAHA with a bone conduction hearing aid (significant at the 0.01 level). There had also been an increase in the amount of time the BAHA was used, compared with the bone conduction hearing aid (significant at the 0.01 level). Nine of the children wore their BAHA all the time, compared with six children who wore their bone conduction hearing aid constantly. The other three children used their BAHA more than three-quarters of the time. Two children who had worn their bone conduction hearing aid less than a quarter of the time went on to wear their BAHA constantly. Ten of the children reported an overall benefit from the BAHA compared with the bone conduction hearing aid. Similarly, 10 children reported that they were more satisfied with the BAHA than with the bone conduction hearing aid.

Of the 10 children returning the Nijmegan questionnaire, almost all reported that their BAHA was more effective in quiet and noisy environments than their bone conduction hearing aid. The BAHAs also provided better sound quality, were less visible and were easier to handle than bone conduction hearing aids. The improvement in sound quality was regarded as the most important benefit. Four children with chronically discharging ears noticed an improvement in the amount of discharge. Only four of the children regarded cleaning the BAHA abutment site as a burden.

Regarding the Glasgow children's benefit inventory, almost none of the children reported a worsening of QoL following BAHA insertion. Many of the children reported that their QoL was much better following BAHA insertion. This was particularly true for the following domains: overall QoL, progress and development, and learning.

Discussion

The majority of children in this series had undergone successful insertion of their BAHA. Fifty-four per cent had experienced no difficulties during the post-implantation follow-up period. The vast majority of those who had developed complications required revision surgery at some point.

Twenty-eight per cent of children required re-implantation because of fixture loss. This figure is higher than that reported by most other published paediatric series (Table IV), despite the staged insertion process.[10–16] A number of series included children who had both BAHA and bone-anchored auricular prostheses, and it was not possible to separate the data for these two groups in some. However, in those series in which the BAHA data were presented separately, the overall trend was towards a lower fixture loss rate in the bone-anchored auricular prosthesis patients compared with the BAHA patients. The overall fixture loss rates were therefore skewed. Once this was taken into account, a number of series had results that were broadly similar to those of the present series.

The lower fixture loss rates in the bone-anchored auricular prosthesis population may be because these devices are not subject to the severe vibratory loading that the BAHA fixtures are subject to.

TABLE IV

COMPARISON OF BAHA FIXTURE LOSS IN PUBLISHED PAEDIATRIC POPULATIONS

Author	Year	Fixture loss (%)	Population (*n*)
Jacobsson *et al.*[15]	1992	6	16
Stevenson *et al.*[16]	1993	29	7
Papsin *et al.*[9]	1997	15	32
Béjar-Solar *et al.*[11]	2000	9	11
Tietze & Papsin[12]	2001	5	19
Granstrom *et al.*[13]	2001	10*	100
Zeitoun *et al.*[14]	2002	20	31

*Bone-anchored hearing aids (BAHAs) and bone-anchored auricular prostheses; no specific BAHA figures.

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Fixture loss did not appear to be related to syndromic status or to the sex of the child. However, the age of the child at primary implantation was important, with those implanted at a younger age being more likely to lose their implant than older children.

The age distribution of the present study population was similar to that of other published paediatric BAHA populations.[10–16] However, a number of units implant children as young as two years. This department does not implant children younger than four years of age because of the increased risk of fixture loss in younger children.

In contrast with other series, the length of the fixture screw did not appear to affect the rate of fixture loss.[17] However, shallow cortical bone thickness has previously been shown to result in a higher probability of fixture loss. In this population, the high proportion of patients with exposed dura at the base of the drill hole reflected the high number of children with thin cortical bone. This may have contributed to the high rate of fixture loss. Occasionally, a child may have undergone prior computerized tomography of the skull, and, in these cases, the imaging can be used to assess cortical bone thickness. However, bone thickness measured by this technique is a poor reflection of actual bone thickness encountered intra-operatively. A bone augmentation technique has been described by Granström and Tjellström.[18] In this procedure, an Expanded-polytetrafluoroethylene (e-PTFE) membrane is placed under the flange of the fixture in order to stimulate bone growth.

All but one of the children whose fixtures had failed to osseointegrate had had stage one of their surgery performed by the senior authors.

This study did not examine the behavioural aspects of the population, but these may play a significant role in fixture survival.

Further research to produce more robust aids and implants may reduce the number of fixtures lost due to trauma. In this series, this was a significant cause of delayed fixture loss.

The high rate of fixture loss in this population highlights the importance of inserting a reserve ('sleeper') fixture during the first stage of BAHA insertion.

It should be noted that some series in the literature do not show any benefit from staged implantation.[17] In view of this, and in view of the lower failure rate in the older age group, there is an argument for single-stage implantation in older children who would accept a 4 mm fixture.

The rates of peri-abutment skin reactions seen in this series compare favourably with those in other published series.[10–16] The development of such a reaction does not appear to be related to the type of graft used. However, children who had split skin grafts from the fixture site, as described by Woolford *et al.*,[19] showed a lower propensity for skin hypertrophy compared with children who had other graft types. This may relate to difficulties in the thinning or depilation of Wolfe grafts. Local split skin grafts also have the clear advantage of no donor site morbidity.

The hearing thresholds obtained with the BAHA were not significantly different to those obtained with a bone conduction hearing aid, but this may reflect the method of documentation used in our department. However, the literature has shown a 10–20 dB additional benefit with BAHAs compared with bone conduction hearing aids.[5,20] In addition, there is strong evidence that the hearing threshold itself is only one of several aspects important in hearing rehabilitation. For example, improved sound quality, comfort, ease of use and aesthetics are all proven benefits of BAHAs compared with bone conduction hearing aids.[7,8] They also have an impact on overall quality of life.[21]

The broader benefits of BAHAs over more traditional aids, particularly quality of life issues, were addressed by this study, although the poor response rate to the questionnaires makes it difficult to draw useful conclusions regarding these issues. However, for those children returning questionnaires, it is clear that BAHAs have significant hearing benefits over bone conduction hearing aids. Bone-anchored hearing aids not only produced more effective amplification but also improved speech recognition, sound quality and ease of use.

- **This paper presents the results of a retrospective review of children undergoing implantation with bone-anchored hearing aids at the Great Ormond Street Hospital for Children**
- **Outcome measures included hearing thresholds, incidence of fixture loss, skin reaction and need for revision**
- **Young age at implantation was associated with an adverse outcome. Trauma and failure of osseointegration were the commonest reasons for failure**
- **Bone-anchored hearing aids provide significant benefits, compared with other types of hearing aid, both audiologically and in terms of quality of life. Careful selection of candidates and meticulous follow up are required to minimize complications**

Importantly, respondents universally preferred the BAHA to the bone conduction hearing aid, and this was reflected in an increase in the amount of time the children wore their BAHA. Some useful suggestions were made by respondents, including production of a waterproof version of the BAHA and of a smaller, slimmer aid which would be less prone to knocks. Further prospective data collection would be useful in the assessment of these issues. Despite the poor questionnaire response rate, it was clear from the follow-up data that almost all respondents continued to use their aids even following revision surgery, and this is undoubtedly a reflection of the benefits obtained from BAHAs.

Bone-anchored hearing aid surgery clearly benefits children with certain types of conductive

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hearing loss, but careful patient selection is vital, as is the age at which implantation is performed. Similarly, recent modifications to the surgical technique and to the implants themselves have led to better outcomes and greater ease of use. In particular, the use of split skin grafts from the fixture site and the change from the bayonet to the snap coupling abutment have been particularly beneficial. However, regular and on-going care of BAHAs is of the utmost importance, not only by hospital staff but by the children and their parents. Similarly, rigorous follow up of patients is paramount to enable early identification and correction of problems.

Conclusions

Bone-anchored hearing aids are a safe and effective way of rehabilitating hearing for patients who are unable to use traditional hearing aids. However, implantation in the paediatric population requires careful consideration if results are to be optimized.

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