Bone-Anchored Hearing Aids in Infants and Children Younger Than 5 Years

Taryn Davids, MD; Karen A. Gordon, PhD; Doug Clutton, MClSc; Blake C. Papsin, MD, MSc

Objective: While bone-anchored hearing aids (BAHAs) are currently indicated for rehabilitation in children older than 5 years with bilateral maximal conductive hearing loss, our objective was to capitalize on potentially important stages of auditory and speech-language development by providing BAHAs to children younger than 5 years.

Design: A retrospective review of surgical data of children receiving BAHA implants over a 10-year period.

Setting: The Hospital for Sick Children, Toronto, Ontario.

Patients: Twenty children 5 years or younger (mean±SD age, 3.21±1.65 years) served as the study group, while 20 older children (mean±SD age, 7.63±1.55 years) served as the comparison group.

Interventions: All patients received BAHA implants. Children with cortical bone thickness less than 2.5 mm underwent a 2-stage procedure; children with cortical bone thickness greater than 4 mm underwent a single-stage procedure.

Main Outcome Measures: Traumatic and skin revision complication rates and implantation interstage intervals were compared between groups.

Results: The mean±SD interstage interval was 7.72±3.81 months for the younger children, which was significantly longer than for the older children (4.41±2.51 months) (P < .003). Two traumatic fixture losses occurred in the younger children, while 4 occurred in the older children. Skin site revision was required in 3 younger children. All children are currently wearing their BAHAs.

Conclusion: Two-stage BAHA implantation with a prolonged interval between stages yields surgical success in younger children comparable to that routinely observed in older children.


In the pediatric population, early and consistent stimulation of the cochlea is critical for the optimal development of speech and language. It is therefore important to provide early diagnosis and habilitation for patients with a mixed or conductive hearing loss (CHL). Aural rehabilitation for CHL initially relied on conventional bone-conduction (BC) hearing aids until the first successful osseointegration of a titanium implant into the temporal bone was achieved in the late 1970s. This was the start of a new alternative to BC hearing aids in the form of a bone-anchored hearing aid (BAHA). Now, over a quarter of a century later, more than 15,000 patients have been fitted with BAHAs worldwide.

One advantage of the BAHA over an air-conduction (AC) device is that it is not dependent on an ear mold. Therefore, it can directly stimulate the cochlea in children with bilateral microtia or atresia, avoiding the problems associated with an ill-fitting mold. A second advantage of the BAHA is that it can be used in children with chronic suppurative otitis media whose disease precludes the use of AC hearing aids.

The advantages of the BAHA over a conventional BC hearing aid stem from its ability to function without a tension headband. Eliminating the headband reduces complaints of pressure or tension headaches, decreases the frequency of pressure ulcers associated with the device, and improves aesthetic appeal and overall user compliance. Sound quality and reliability are better with the BAHA than with the conventional BC device due to the direct coupling of the hearing aid and the skull. This allows immediate transmission of sound to the cochlea without any soft tissue dampening or significant power loss.

Present criteria for implantation of a BAHA in children include bilateral CHL or mixed hearing loss due to congenital aural
The risk of implant failures in the pediatric population is estimated to be 5.8% to 15.0%. Failures tend to occur early and primarily involve direct trauma. Relative to the adult skull, the infant skull is lower in mineral and higher in water content. Osseointegration, therefore, runs a higher theoretical risk of failure in a younger population. Failure due to skin site infection or overgrowth can be minimized by careful regular hygiene, which reduces the chance of skin thickening and ulceration at the graft site. As patients assume some element of responsibility in maintaining their devices, one could expect that younger children will have more difficulty adequately caring for their fixture site and be at a higher risk of failure due to skin site infection and overgrowth. The ideal age for implantation suggested by the literature is 2 to 4 years, but this is not common practice. The US Food and Drug Administration, which does not govern practice in Canada, limits BAHA implantation to children older than 5 years. We report implantation in children as young as 14 months and compare outcomes of children who received BAHAS at age 5 years or younger with children receiving them after age 5 years.

**METHODS**

We identified children who received BAHAS at our institution between 1996 and 2006 (79 patients). Patients were ranked according to age at the time of the initial procedure, and 20 children had received their implants on or before their fifth birthday. This group was then compared with the next successive 20 children older than 5 years from our age-ordered database. Age at surgery, sex, selected ear (right or left), dates of surgical procedures, complications at the site of the implantation, additional surgical procedures, surgical indications, and associated syndromes were documented. Audiometric testing was performed on site before and after implantation; unaided (AC) and aided (BC hearing aid or BAHA) thresholds were measured. In infants, all measures were made in response to sound-field stimulus presentation, which provides data for at least the better ear. Implantations were performed by a staff surgeon in either a 1- or 2-staged procedure. The surgical decision to use a single stage as opposed to a 2-stage procedure was made at the time of surgery and was based on the thickness of the cortical bone. In bone thinner than 2.5 mm, a 2-stage procedure was always used. In bone thicker than 4 mm, a single-stage procedure was used. In children with bone thickness between 3 and 4 mm, additional factors such as patient age (<9 years), developmental delay, and greater distance from the hospital were accounted for and often swayed us to opt for the more conservative 2-stage procedure. All patients in this study received a 3-mm fixture placed flush with the calvarial surface, often slightly abutting or depressing the dura. Patients were seen 1 week after stage 1 of the implantation.

The second stage of the procedure was planned based on the bone thickness found during stage 1. The thinner the bone, the longer the delay between stages 1 and 2 (Figure). Patients were again seen 1 week after stage 2 of the procedure. Subsequent follow-up visits were planned for 3-month intervals until the 9-month mark, at which time visits were scheduled biannually (earlier if parental or patient concerns or complications arose).

**RESULTS**

Patient characteristics are listed in Table 1. Audiometric testing was performed on all children before implantation; unaided (AC), BC-aided, and BAHA-aided
thresholds were measured. Both groups, on average, had normal BC thresholds, indicative of primary CHL. In addition, there was an improvement in audibility using a BAHA or hearing aid, and thresholds appeared to be better for the BAHA in both groups.

All children (20/20) in the younger group and 18 of 20 children older than 5 years received BAHA implants in a 2-stage procedure. The remaining older children (2/20) underwent a single-stage procedure. The mean±SD interval between stages 1 and 2 for the younger group (7.72±3.81 months; range, 3.4-15.9 months) was significantly longer than for the older children (4.41±2.51 months; range, 2.8-9.7 months) (*t18,02=3.24; P<.003). As illustrated in the Figure, there is a moderate correlation (r²=0.48; P<.001) between the interstage interval and the age of the child. Four children (2 in each group) had longer delays between stages than the 95% confidence intervals of the sample would predict.

Of the 2 children in the younger group who had longer-than-predicted interstage intervals, the first had a delay of 14.7 months. After her initial BAHA assessment, she underwent a bicoronal incision for an unrelated intracranial procedure, after which she had significant areas of her cranium that failed to ossify. At stage 1 of her BAHA implantation procedure, the fixture was placed in thin bone approximately 4 mm from an area of deficiency. This necessitated a longer delay before stage 2 was undertaken. The second of these 2 children had a delay of 15.9 months owing to thin bone and developmental delay related to his craniofacial anomaly (cat eye syndrome). In the younger group, the 2 children who required a longer-than-predicted delay both had a combination of thin bone and craniofacial anomalies with associated developmental delays; the delay for these children was 10.6 and 9.6 months.

The BAHA fitting was typically done approximately 6 to 8 weeks after stage 2 of the procedure. This allowed for the younger group to use their devices by mean±SD age 4.07±1.49 years (Table 1). This means that despite the prolonged interstage interval required owing to the thinner bone encountered in younger children, patients were still able to use their BAHAs at an earlier age.

As listed in Table 2, there were 2 children who had traumatic fixture loss at 6 and 18 months after the stage 2 procedure. Both were as a result of bumps or falls at home or school. Three children returned to the operating room for skin revisions at 32, 33, and 90 months after the stage 2 procedure. For all 3 cases, this was related to poor hygiene and less-than-adequate upkeep of the surgical site. For 2 of the 3, there was an associated global development delay that may have contributed to poor wound hygiene and surgical site irritation.

As summarized in Table 3, for the remaining patients, there were a total of 3 other traumatic fixture losses requiring revision in the operating room. The first patient was hit by a basketball at school 50 months after stage 2 was completed. The second and fourth patients' fixture losses occurred during play at home or in school at 18 and 12 months after stage 2 implantation, respectively. The statistical comparisons of revision rates are listed in Table 4; no statistically significant difference between rates of revision between groups were found; however, there was a significant difference in the rates of skin revisions between the younger and older groups.

Successful osseointegration occurred in all children in the younger group. There was a single failure of osseointegration in the older group (patient 3, nontraumatic loss). This child was presumed to have unexplained organic predisposition to fixture failure and required 3 revision procedures at 3, 15, and 52 months after initial implantation. It was only after various other pathologic skeletal fractures occurred that endocrinologic, metabolic, and genetic investigations were initiated. The same child received both a BAHA and bilateral bone-anchored auricular...
encounter thin bone, we insert a 3-mm fixture flush with the calvarial surface and lengthen the interstage interval accordingly. As shown in the Figure, there may be individual cases in which the delay between surgical stages must be further lengthened: in our sample, 4 children had delays longer than predicted owing to additional concerns including developmental delay and slow osseointegration.

Despite the need for a prolonged interstage interval in younger patients with thin cortical bone, the mean±SD age (4.07±1.49 years) of patients fitted with an active BAHA is still lower than that of patients older than 5 years who undergo implantation (8.18±1.44 years). Earlier implantation of BAHAs allows the younger children who receive them to benefit from earlier speech and language habilitation.

Pediatric patients rely greatly on their caregivers to provide maintenance and hygiene of the skin around their fixtures. As the child grows, the fixture occasionally becomes buried by new cortical bone. The skin around the graft can thicken circumferentially around the abutment in response to local infection, making it more difficult to maintain. In our series, 3 children in the younger group required revision of skin grafts in the operating room, owing to either poor hygiene or improper care of the implant site. Skin revisions for all patients occurred no earlier than 30 months after the stage 2 procedure, reinforcing the notion that this is typically a late complication. The rate of skin overgrowth in the literature suggests that it occurs with equal frequency among adults and children; therefore, age should not predispose a child to increased risk of skin revision. On the other hand, children in the younger age groups are more dependent on caregivers for proper care and hygiene of their implant sites, which possibly puts them at greater risk for complications. Two of the 3 younger children requiring skin revision at our institution also had an associated developmental delay, which may have increased the challenge associated with fixture care and maintenance. It should be noted that children in the older group did not require revisions for skin overgrowth.

Traumatic revision of fixture loss is greater in the pediatric population than the adult population. It is important for parents to be educated on the need for their children to wear helmets during sporting activities to minimize traumatic events, particularly in patients with underlying developmental delay. Unfortunately, all events are not foreseeable and traumatic losses can still occur across all age groups. Our data demonstrate no signifi-

### Table 3. Postoperative Complications in Children Older Than 5 Years

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Diagnosis</th>
<th>Age at Time of Procedure, y</th>
<th>Postoperative Complication (Cause)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Syndromic microtia</td>
<td>5.8</td>
<td>BAHA 1</td>
<td>8.8 (Trauma)</td>
</tr>
<tr>
<td>2</td>
<td>Syndromic microtia</td>
<td>6.5</td>
<td>BAHA 2</td>
<td>11.0 (Trauma)</td>
</tr>
<tr>
<td>3</td>
<td>Syndromic microtia</td>
<td>8.0</td>
<td></td>
<td>3 Revisions for traumatic loss, bone disorder NYD</td>
</tr>
<tr>
<td>4</td>
<td>Syndromic microtia</td>
<td>9.5</td>
<td></td>
<td>No comment</td>
</tr>
</tbody>
</table>

**Abbreviations:** BAHA, bone-anchored hearing aid implantation procedure; NYD, not yet diagnosed.

### Table 4. Statistical Analysis of Postoperative Complications in Pediatric Patients With BAHAs

<table>
<thead>
<tr>
<th>Patient Age, y</th>
<th>Postoperative Revision Needed, No.</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤5</td>
<td>Trauma 2, Skin 3</td>
<td>.39</td>
</tr>
<tr>
<td>&gt;5</td>
<td>Trauma 4, Skin 0</td>
<td>.08</td>
</tr>
</tbody>
</table>
cant difference in the rate of trauma between the younger and older groups. Two children in the younger group required traumatic revisions, both owing to head trauma at school or at play. Four children in the older group group required traumatic revisions, 3 owing to head trauma, 1 (requiring multiple revisions) owing to bone abnormality not yet diagnosed. These findings support the use of a sleeper fixture in young children so that the BAHA can be reapplied and activated as quickly as possible after traumatic loss.

Certainly the earlier a patient receives a BAHA device, the greater the duration of wear, and the greater the opportunity for complication. Similarly, the earlier the use of the device, the earlier and greater the benefit the BAHA may have on speech and language acquisition.

In conclusion, 2-stage BAHA implantation yields surgical success in younger children that is comparable in audiologic outcomes and traumatic device failures and/or revisions with that achieved in older children when there is an appropriate (ie, lengthened) delay between surgical stages to allow for osseointegration.

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Correspondence: Blake C. Papsin, MD, MSc, Department of Otolaryngology, Sixth Floor, Elm Wing, The Hospital for Sick Children, 555 University Ave, Toronto, Ontario, Canada M5G 1X8 (blake.papsin@utoronto.ca).

Author Contributions: Dr Davids had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Papsin. Acquisition of data: Davids, Clutton, and Papsin. Analysis and interpretation of data: Davids, Gordon, and Papsin. Drafting of the manuscript: Davids, Gordon, and Papsin. Critical revision of the manuscript for important intellectual content: Gordon, Clutton, and Papsin. Statistical analysis: Davids and Gordon. Obtained funding: Papsin. Administrative, technical, and material support: Clutton and Papsin. Study supervision: Gordon and Papsin.

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Additional Information: The primary investigator had secure access to all patient files and data included in this study. Collected data were secured on a secure, password-entry-only computer on the hospital premises.

REFERENCES