Percutaneous bone-anchored hearing aids at a pediatric institution

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OBJECTIVES: **The goals were to evaluate hearing, complications, and patient satisfaction with the percutaneous bone-anchored hearing aid (BAHA) and to monitor long-term successful use achieved by careful patient selection.**

METHODS: **This prospective longitudinal study included participants with inoperable congenital bilateral aural atresia, pure-tone average (PTA) bone conduction less than 45 dB HL, prior use of a conventional bone-conduction hearing aid (CBCA), and adequate intelligence, integration, and personal hygiene. Surgery for BAHA implantation was performed in two stages. Evaluation consisted of skin reactions, audiologic results with CBCA and BAHA, and patient satisfaction. Follow-up was at least 24 months.**

RESULTS: **In 11 participants aged 5 to 17 years, the PTA free-field air conduction improved 37%, and free-field speech discrimination improved 23%. Successful integration and implant use were achieved in 10 cases but were lost in 1 case as a result of head trauma. All patients preferred the BAHA as opposed to the CBCA.**

CONCLUSIONS: **The BAHA is a valuable device that can improve hearing and provide significant parent and patient satisfaction. Careful selection appears to correlate with successful long-term use.** (Otolaryngol Head Neck Surg 2000;122:887-91.)

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Despite advances in aural atresia reconstruction surgery, it is not possible to provide all patients with dry ears and good hearing. There is a group of patients whose only choice is to use a conventional bone-conduction hearing aid (CBCA), although there are disadvantages to the device. The sound quality is poor, traveling through soft tissue and losing energy in the process.[1,2] Sound reaching the skull bone is transmitted with fairly low attenuation and distortion; the greatest losses to attenuation are in the important high-frequency range. Poor sound quality is of great concern in the rehabilitation of children because often their conductive hearing loss is present when they are developing speech and language.[3] A direct coupling between the transducer and the skull is of great acoustic advantage. There are other advantages to such a system: there is no discomfort due to the pressure of the transducer, the position of the hearing aid is stable, and there is no steel spring over the head to apply pressure when wearing a headband or heavy eyeglass frames.[4]

Titanium implants in bone have been used for more than 25 years. In Sweden, Branemark et al[5] discovered that direct contact between living bone and an implant made of commercially pure titanium (99.75%) results in osseointegration, a stable bond that can sustain biomechanical loads. This principle was first successfully applied in edentulous patients for attaching dental implants. In 1977 the Branemark implant system was used outside the oral cavity for the first time. Three patients using CBCAs underwent implantation with the percutaneous bone-anchored hearing aid system (BAHA; Nobel Biocare AB, Göteborg, Sweden). The BAHA system is formed by a titanium implant (fixture) with minor irregularities in its surface, drilled in place in the mastoid process, and a transducer attached to a skin-penetrating abutment fixed in place by a gold screw[6] (Fig 1).

At this time, more than 3000 patients worldwide use the BAHA system.[4,6] At the Hospital Infantil de México "Federico Gómez," a tertiary referral center for patients of low socioeconomic status, we designed a prospective longitudinal study to evaluate audiologic benefit, complications, and patient satisfaction with the BAHA, attempting to achieve long-term successful use based on careful patient selection.

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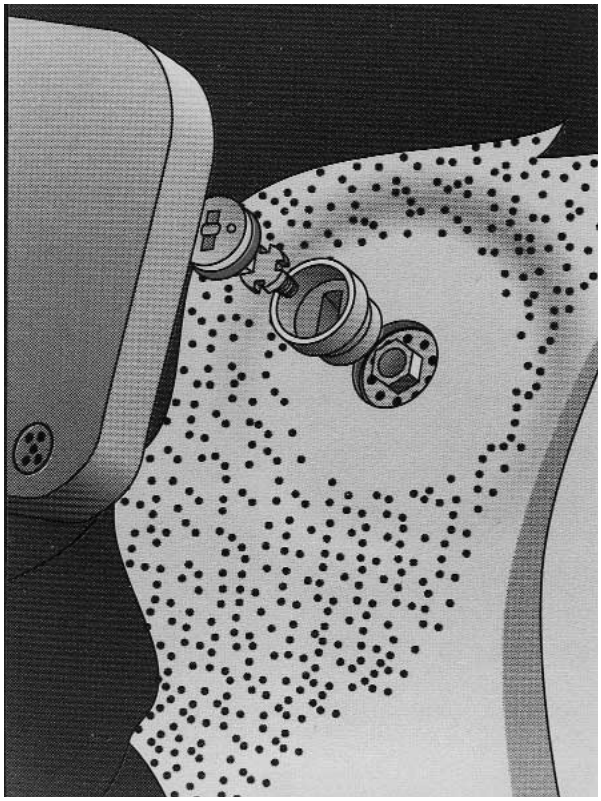

Fig 1. BAHA system. *From left to right:* Electronic transducer, coupling, gold screw, percutaneous titanium abutment, and titanium implant fixture in mastoid cortex. (From Nobel Biocare AB, Göteborg, Sweden.)

METHODS AND MATERIAL

The research protocol was reviewed and approved by the appropriate local institutional review board. All candidates for the BAHA and their parents were counseled before starting the multidisciplinary evaluation protocol, and informed consent was obtained before implantation. The BAHA classic 300 was used in all cases.

Eligibility Criteria

Inclusion criteria were as follows: (1) bone-conduction pure-tone average (PTA) 45 dB HL or better with 100% speech discrimination; (2) high-resolution CT demonstrating inoperable bilateral congenital microtia atresia[7,8]; (3) age at least 5 years, to allow the minimal bone thickness necessary for implantation in the mastoid area (3 mm thickness is optimal); and (4) current use of a CBCA. Exclusion criteria were as follows: (1) sensorineural hearing loss with a bone-conduction PTA lower than 45 dB HL, (2) lack of hygiene facilities to properly clean the skin around the implant, (3) insufficient score on the psychological evaluation (minimal standards for intelligence and family support), (4) economic capability to purchase batteries (approximate cost $1 US), and (5) accessibility to the hospital for follow-up visits.

Preimplantation Evaluation

Full otolaryngologic history and physical examination were performed. The anatomy of the ear was independently evaluated by 2 otolaryngologists on the basis of high-resolution CT findings.[7,8]

The preoperative audiologic evaluation consisted of measuring PTA (125-3000 Hz) in both air and bone conduction, free-field PTA with and without CBCA, 100% speech audiometry discrimination in decibels hearing level, and 100% speech audiometry discrimination with background noise at 65 dB HL with CBCA.[9] The test, originally described by Hakansson et al, was adapted to our group; we used sentences with a high degree of difficulty, using colloquial language common to Mexico City. The patient's socioeconomic background was taken into account when selecting the words. The patient, wearing a CBCA, was also asked to pinpoint the position of natural vocal speech in an area with high background noise (at a distance of 3 m), and the patient's ability to do so was evaluated.

Every patient underwent psychological assessment that included the full history, intelligence, and personality evaluation (Weschler age-specific tests); exclusion of incapacitating psychopathology; and exploration of psychological needs and intellectual resources (Minnesota multiphase personality, Frost's auto-descriptive test, and House-Tree-Person test). Finally, the patient and family were informed in detail about the BAHA, to establish realistic expectations. A social worker intervened to evaluate personal hygiene habits, infrastructure (running water, electricity), family dynamics and support, and economical ability to cover expenses such as cost of surgery and replacement batteries. The ability to contact patients for follow-up was also taken into consideration.

All the information gathered was reviewed by the authors, and the their decision had to be unanimous for a patient to be accepted in the study.

Surgery

A detailed description of the technique can be found elsewhere.[4] Implantation is done in 2 stages. In the first surgery, a skin flap is elevated in the mastoid area, a small circle of periosteum is elevated, the implant is drilled in place with a cover screw, and the skin is closed; a standard mastoid dressing is then placed.[4,6]

A period of 3 months must elapse before the second stage, to allow osseointegration to take place. If a mechanical load is placed before this process, a fibrous capsule could form around the implant, preventing solid attachment and interfering with ideal sound conduction. In the second stage subcutaneous tissue and hair follicles are eliminated around the

Table 1. Types of skin reactions around percutaneous abutment

Types of skin reactions	n	%
No irritation	71	87
Slight erythema	7	8
Erythema and moisture	3	4
Red and moist with granulation tissue	1	1
Infection leading to loss of implant	0	0
TOTAL	82	100

implant site (a partial-thickness skin graft is an alternative), skin is perforated, and the abutment is screwed in place. Although some authors have reported performing the procedure as a single stage,[10] we believe that a conservative approach is warranted in children. After the skin has healed (usually after 2 weeks), the transducer can be put in place.

Postimplantation Protocol

The follow-up time was 24 months. Visits were scheduled at 1, 2, 4, 6, 12, 18, and 24 months.

The patient and family were fully instructed in caring for their BAHA. Daily hygiene included cleaning around the skin-penetrating abutment with unwaxed dental floss and regular soap, If any erythema developed around the implant area, the patients were instructed to come to the hospital. A topical antibiotic ointment with a mild steroid was used to treat this condition.

At each visit, the condition of the skin was evaluated on a scale from 0 to 4: 0, normal; 1, slight erythema; 2, red and moist; 3, red and moist with granulation tissue; and 4, infection leading to removal or loss of implant.[11]

At 6 months, complete evaluations were scheduled. The above-mentioned audiologic tests performed with the CBCA were repeated with the BAHA, and PTA (125-3000 Hz) in both air and bone conduction was measured for use as a control.

A subjective patient-satisfaction questionnaire was given out, and a quality-of-life psychological test evaluating emotional condition, impact on daily chores and social activities, social support, and pain was applied (Coop/Dartmouth test).[12]

RESULTS

Eleven patients (4 female, 7 male) aged 5 to 17 years with bilateral congenital microtia atresia were included. Four patients had mandibulofacial dysostosis (Treacher-Collins syndrome). The mean age at implantation was 10 years.

A 3-mm implant fixture was used in 64% of cases (n = 7), and a 4-mm fixture was used in 36% (n = 4). The sigmoid sinus was exposed in 3 patients. Multiple attempts to seat the implant were necessary in 27% of the cases (n = 3); in 1 patient, 8 attempts were necessary to properly seat the fixture because air cells were repeatedly exposed at the first stage. In all patients, thinned full-thickness depilated grafts were used at the second-stage surgery.

Table 2. Audiologic results (dB HL)

	Before surgery	After surgery	Difference in thresholds
Air-conduction PTA (RE)	69	71	±2
Air-conduction PTA (LE)	69	68	±1
Bone-conduction PTA (RE)	20	18	±2
Bone-conduction PTA (LE)	14	15	±1
Free-field PTA	64	63	±1
Level at which RE 100% speech audiometry discrimination was achieved	87	90	±3
Level at which LE 100% speech audiometry discrimination was achieved	84	83	±1
Free-field PTA (CBCA/BAHA)	30	19	–11
Free-field 100% speech audiometry, background noise at 65 dB (CBCA/BAHA)	62	48	–14

RE, Right ear; *LE,* left ear.

Ten patients had attained successful use of their BAHAs at the 2-year follow-up visit. One patient was unable to obtain osseointegration. Less than 24 hours after discharge from the first stage, during rough play she received an impact to the mastoid area, with immediate formation of a hematoma. Her mother did not report this injury until 6 days later. At that point 10 mL of sanguineous fluid was drained, a mastoid dressing was applied, and oral antibiotics were administered as indicated. We decided to proceed with the second stage 4 months later. During the second stage, the implant appeared to be well integrated, and she began use of her BAHA. After 6 weeks she came in for an unscheduled visit and reported mobility of the implant. The implant was rejected without any sign of infection, which indicated a lack of osseointegration. There were no major complications.

Assessment of Tissue Around Abutment

The total number of skin observations was 82. Of these, 71 were scheduled follow-up visits, and 11 were unscheduled. Results are summarized in Table 1. In 87% of the observations, there was no skin reaction around the abutment. In 8% of the observations, a type 1 reaction was noted. On investigation, the reaction was a product of overzealous cleaning. A topical antibiotic

Fig 2. Close-up look of BAHA in use by a 6-year-old girl.

Fig 3. BAHA in a 14-year-old boy with Treacher-Collins syndrome.

with a mild steroid was prescribed for 5 days, with less forceful cleaning. The only observation with formation of granulation tissue was attributed to improper cleaning technique, leaving significant debris to accumulate around the abutment for several weeks.

Audiologic Results

The audiologic evaluation was based on comparison of the CBCA with the BAHA. There were no differences between PTA bone- or air-conduction thresholds before and after implantation. The mean PTA thresholds are summarized in Table 2. The free-field PTA comparing the CBCA to the BAHA improved 37% (11 dB HL), discrimination with background noise at 65 dB HL improved 23% (14 dB HL), and accurate directional identification of location of a sound source was demonstrated in 80% of cases; no patients were able to identify the position of the sound source with the CBCA.

Psychological Results

In the subjective questionnaire comparing the CBCA to BAHA, all patients preferred the BAHA, believed there had been an excellent improvement in aesthetic appearance, and would choose to have it done again (scale: excellent, good, fair, poor, very poor). Quality-of-life tests results uniformly showed the response "hardly could have done better" (options: hardly could have done better, pretty good, indifferent, pretty bad, hardly could have done worse). Physical and emotional condition was reported as very improved. Positive family support was confirmed in all cases.

DISCUSSION

Our group of BAHA patients represents the current experience at our institution. In the literature, it is the first socially challenged pediatric group studied in a multidisciplinary analysis, with detailed documentation of psychological and social work issues.

The BAHA system has proved to be a well-established and low-risk procedure. It does not compromise the child's hearing.[2,3,6,16] The BAHA offers advantages over the CBCA, most important of which is the up to 37% improvement in hearing. The original audiometric measurements specifically adapted for BAHA users were described,[1,9] with monosyllabic words competing with background noise. This test was adapted to our group; we decided to use sentences with a high degree of difficulty, using colloquial language common to Mexico City. The socioeconomic background was taken into account when selecting the words. The improvement in aesthetic appearance noted should not be underestimated (Figs 2 and 3), especially in children with malformations who are entering adolescence. Children learn quite easily to manage the BAHA, removing and attaching it without trouble. Ideally, parents should be given full support and should be able to discuss the options for a child with microtia atresia with an otolaryngologist, audiologist, auricular surgeon, prosthetics specialist, and psychologist.

The development of a BAHA program must be seen as a multidisciplinary effort that goes far beyond the surgery itself. Inflammation with erythema around the abutment has been reported to be as high as 80%.[3] We believe that our low rate of inflammation was achieved by strict inclusion criteria and close follow-up. To establish a successful program, surgeons need considerable time and resources. Although the BAHA is solid, in 4 patients we found it was damaged by abuse: in 1 case the patient took a shower wearing the transducer, and in the other 3 cases the BAHA was dropped on a hard surface during play. Precautions should be taken to have a spare BAHA to loan because in our experience children

become quite dependent on the device and do not like to use a CBCA even for a short period.

Most BAHA failures can be traced to poor candidate selection, resulting in deficient hygiene, and leading to infection, or to an inadequate surgical technique that results in thick, mobile skin or contamination of the titanium surface.[6,10,11,16] In a few patients the cause of loss of integration resulting in failure may not be clear. Success with the BAHA in the pediatric age group ranges from 85% to 94%,[3,14-16] demonstrating results that are predictable if full commitment is dedicated to the program.

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