

Bone-anchored hearing aid (BAHA): indications, functional results, and comparison with reconstructive surgery of the ear

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SUMMARY

Introduction: The bone-anchored hearing aid (BAHA) is a bone conduction hearing device that transmits sound directly into the inner ear. It is mainly used in patients with conductive hearing loss associated with aural atresia, but it is also used in those with mixed and sensorineural hearing loss.

Goals: To review the main indications for BAHA, to analyze the audiometric results and its benefits for patients and compare them with other treatment modalities, and to compare the literature data with our sample of 13 patients.

Method: The research was performed using a database covering works in English, Spanish, and Portuguese, with no limitations in the years when the procedures were performed. We compared the literature data with our results for the 13 patients who underwent BAHA implantation between the years 2000 and 2009.

Results: Most of the studies showed that BAHA has great advantages over reconstructive surgery in terms of hearing results, complications, and disease recurrence. The postoperative results for our 13 patients were satisfactory and comparable with the results from the literature, with closure of the air-bone gap in 7 patients and achieving an air-bone gap of 10 dB in 6 patients. No postoperative complications were observed.

Conclusion: BAHA is a better treatment option than reconstructive surgery for patients with bilateral deafness. It is a relatively simple surgical procedure with few complications and good hearing results. Recent studies have examined its use in conductive and unilateral sensorineural hearing loss.

Keywords: ear, middle, hearing, hearing loss, conductive.

INTRODUCTION

The bone-anchored hearing aid (BAHA) is a bone-integrated implant that was introduced in clinical practice in Sweden in the 1970s (1). It is a bone conduction hearing device that transmits sound directly into the inner ear, bypassing skin impedance and subcutaneous tissue. It has been used in patients with mixed or conductive hearing loss who do not benefit from conventional amplification devices. It is indicated mostly for patients with conductive hearing loss resulting from the closure of the external ear canal and other malformations of the middle and external ear; however, it can also be performed in patients with surgical mastoid cavities or those who do not adapt to conventional hearing aids. Several publications have shown the benefits of BAHA on improved hearing.

GOALS

The goals of this manuscript were to review the main indications for BAHA, analyze the audiometric results and benefits provided to patients compared with other treatment modalities (e.g., concomitant reconstructive surgery and cosmetic surgery), and compare the data from the literature with our sample of 13 patients who underwent this procedure between 2000 and 2009. Electronic databases (PubMed, MEDLINE, Ovid, and Cochrane) were searched for works in English, Spanish and Portuguese, with no limitations for year in which procedures were performed. The following search terms were used: (hearing loss *or* deafness *or* congenital aural *or* CAA *or* external auditory canal *or* EAC *or* Ear canal *or* Ear auricle) *and* (atresia *or* abnormalities *or* congenital) *and* (prosthesis implantation *or* prosthesis design *or* bone conduction *or* osteo-integrated

bone-conduction device *or* BAHA *or* BAHA system *or* bone-anchored *or* hearing aid *or* hearing aids *or* prosthesis fitting) *and* ((epidemiologic methods) *or* (comparative study) *or* (Prognosis/Narrow [filter]) *or* (Therapy/Broad [filter])).

DISCUSSION

Malformations of the external and middle ear can be associated with sensorineural or conductive hearing loss. Conductive hearing loss is common when there is atresia external auditory canal (EAC) stenosis, or malformation of the ossicular chain. Many authors have reported favorable outcomes of BAHA surgery and ear reconstruction.

BAHA surgery is a relatively simple procedure that was approved by the FDA in 1996 for adults and in 1999 for children above 5 years of age (2,10) (if a 3-mm fixer is installed, a bone density of at least 2.5 mm is necessary; this occurs at approximately 5 to 7 years of age³) and can be completed in a single session or over 2 sessions. Before the age of 5 years, patients can be rehabilitated with a bone vibrator attached to an elastic band (*soft band*). VERHAGEN et al. (4) evaluated 12 children with congenital atresia of the EAC. The children had an average age of 2 years and 3 months (1 month to 5.5 years), with hearing thresholds below 60 dB that reached approximately 27 ± 6 dB with the use of the bone vibrator, suggesting that this amplified sound as well as the BAHA. HOL et al. (5) also supported the use of the band with bone vibrator in small children after following 2 children (1 of whom had a BAHA bilateral *soft band*, which provides a binaural summation of approximately 3 to 5 dB).

Some authors recommend BAHA before 5 years of age, as this period is crucial for speech development. DAVIDS et al. (6) performed BAHA surgeries between 1996 and 2006 and divided the patients into 2 groups: below 5 years of age (20 patients) and above 5 years of age (20 patients). In 38 patients, the surgery was performed in 2 stages. The main difference between the age groups was a longer gap between the first and second stages of the procedure in the below-5-year-olds to ensure osteointegration. Complications included a higher incidence of skin growth or infection among the younger patients (3 in the younger group and 0 in the older group), while the incidence of traumatic loss was similar (2 in the younger group and 4 in the older group). There were no osteointegration flaws in any of the patients below 5 years of age. MAZITA et al. (7) performed BAHA surgery in a single session only in patients older than 12 years. Of the 16 patients in their study who underwent the procedure (11 of them in 2 stages), there was an average airway conduction threshold improvement from 64.9 dB

preoperatively to 29.7 dB postoperatively, with an average functional gain of 35.2 dB. The authors noted that percutaneous BAHA transmission is more efficient by 10 to 15 dB than transcutaneous transmission, and they also advocate the use of the elastic band in children younger than 3 months old (7).

ROTENBERG et al. (8) describe the experience of establishing a BAHA program, including treatment algorithms, protocols, methodology, complications, and patient satisfaction. In their program, the initial assessment occurs between birth and 4 years of age, when the parents are contacted and informed of treatment options. When there is atresia or malformation of the middle ear, hearing is also evaluated. Once the patient is 5 years old, the parents are called for a discussion about the treatment and receive information about postoperative care and follow-up. The authors quoted their data from a retrospective analysis of 11 cases. The complications included only 1 case with excessive growth of soft tissues, which can be avoided during the initial skin preparation with circumferential debridement of the tissues and application of a thin, hairless skin graft. Bone growth around the fixer can be avoided by removing the surrounding periosteum. This is highly satisfying to the patients and their parents, and the major complaints involve esthetics and the necessary care for the device required during physical activities.

The conventional procedure usually requires 2 surgical sessions, and the literature suggests a gap of 3 to 6 months between the procedures. During the first session, a titanium pin is fixed in the bone. The second session involves the removal of fat, excess subcutaneous tissue, and hair follicles, along with a skin puncture to expose the fixer. The BAHA is finally adapted 6 to 8 weeks after the second procedure. ALI et al. (9) performed a study with 30 children who underwent surgery between 1997 and 2005. Surgery conducted in a single session was associated with few complications (2 infections of the surgical site, 1 skin hypertrophy, 1 chronic infection, and 2 losses of implant after local trauma) and had the advantage of avoiding a second exposure to anesthesia.

BENTO RF conducted unilateral BAHA implants in 13 patients between 2000 and 2009. The causes of hearing loss were Treacher Collins syndrome (3), EAC atresia (9 total, 6 of which were bilateral), and mastoid cavity (1). The age of the patients ranged from 3 to 34 years (average 14.3). In preoperative audiometry, 10 patients had a gap of 30 to 40 dB and 2 had mixed loss with a gap of 30 dB (audiometry was not possible for 1 patient). Seven patients exhibited closure of the air-bone gap (4 with bilateral EAC atresia, 2 with Treacher Collins syndrome, and 1 with mastoid cavity), there were 2 whose sensorineural loss persisted (they had mixed loss

before the surgery), and 6 patients had a persistent 10 dB gap postoperatively (3 EAC atresia, 2 bilateral EAC atresia, and 1 Treacher Collins syndrome). There were no significant differences between the audiometric results according to the cause of the hearing loss, and 1 patient who underwent a previous mastoidectomy surgery with a preoperative gap of 40 dB had an excellent outcome (closure of the air-bone gap). The surgery was performed in a single procedure in all patients, except in 1 with Treacher Collins Syndrome, and there were no postoperative complications.

The incidence of aural atresia is estimated to be 1 per 10,000 births; in 25% of cases, the atresia is bilateral (10). FUCHSMANN et al. (10) evaluated BAHA results in 16 patients with an average postoperative threshold of 25.4 ± 5.7 dB (average gain of 33 ± 7 dB). The average postoperative air-bone gap was 10.5 ± 5.9 dB, and there was closure of the gap in 10 patients. The free-field speech recognition threshold improved from 63 dB to 30 dB. For most surgeons, a pure-tone air threshold of 30 dB or less represents a good result, and 85% of the patients in this study exhibited such thresholds.

RICCI et al. (2) evaluated the audiometric results in 47 patients who underwent BAHA. In this group, 31 had bilateral congenital atresia, 9 had chronic otitis media or history of ear surgery, and 7 had osteosclerosis. The average preoperative air-bone gap was 33.2 ± 16.5 dB. There was a closing of the gap in 40 patients, and 14 had overclosure, when the BAHA threshold overcomes the preoperative bone conduction threshold. CARLSSON and HAKANSSON (11) related this phenomenon and stated that when the BAHA reaches its maximum potential, the air-bone gap can virtually close, with an additional maximum sensory compensation of 5 to 10 dB at frequencies between 700 and 3000 Hz. Speech perception also improved in approximately 31 patients by $64 \pm 31\%$ at 60 dB HL. Of the 9 patients with chronic otitis media, 7 exhibited improvement in the infection. MacNamara and Mylanus reported similar results (quoted in Ricci et al. 2). Forty-five patients in their study answered a questionnaire and reported an improvement in quality of life after BAHA surgery. The authors reported 3 cases with complications, 2 with skin growth around the implant, and 1 with extrusion due to osteointegration failure. McDERMOTT et al. (11) in a retrospective study of 182 children who underwent BAHA implantation surgery, had success in 97% of the patients who used the implant daily. KUNST et al. (13,14) implanted BAHAs in 20 patients with unilateral conductive hearing loss. The bone-conduction thresholds were normal in both ears, with a gap in the affected ear of 50 dB. All the patients presented speech recognition and free-field thresholds better than 25 dB with BAHA use. Patients with acquired conductive loss (2)

showed the greatest improvements in sound localization after BAHA. One unexpected finding was a good result in the ear without the BAHA with improvements in speech comprehension, particularly in cases of congenital hearing loss. The authors stated that further studies are needed to explain this finding. Consistent use of the device is highly predictive of the benefit to the patient, and even in cases for which the exams did not show significant gain, patients who used the device were satisfied (10,14). The authors also evaluated subjective improvement through questionnaires and concluded that most patients seemed to benefit from BAHA use (12).

In the largest series, the best hearing results with BAHA were achieved when the cochlear reserve (bone threshold) was better than 45 dB. LUSTING et al. (1) confirmed this finding when they evaluated the first 40 patients rehabilitated with BAHA in the United States. Twenty-one patients had hearing loss due to chronic otitis media, 9 due to EAC atresia/stenosis, 5 due to osteosclerosis or congenital hearing loss, 3 after skull base surgery, 1 for keratosis obliterans, and 1 for conductive hearing loss of unknown cause. The preoperative gap was 38 ± 16 dB. Eighty percent of patients obtained a 10 dB gap reduction, 60% achieved a 5 dB reduction, and 30% presented overclosure. The best audiometric results were achieved in patients with osteosclerosis or congenital hearing loss who presented a 42 dB increase with BAHA. The chronic otitis media patients had an average of 33 dB gain, and the EAC stenosis/atresia patients had an average of 22 dB gain. Patients with hearing loss due to surgery at the base of the skull had the worst outcomes. Complications included a flaw in osteointegration in 1 patient and local skin reaction in 3 patients. One patient was not satisfied with the sound quality achieved by the anchored prosthesis.

Another modality for treating hearing loss in cases of atresia and ear malformation is reconstructive surgery, particularly canaloplasty, tympanoplasty, and stapes and ossiculoplasty, whether including or not including associated aesthetic reconstruction of the hearing pavilion. EVANS and KAZAHAYA (15) compared the results of reconstructive surgery in 29 patients versus BAHA in 6 patients in a pediatric population. The average hearing gain in dB was 17.7 after the reconstructive surgery and 31.8 dB after BAHA. In this study, 93% of patients required sound amplification postoperatively, even after reconstructive surgery, and there were 18 cases of late complications, most commonly recurrent EAC stenosis (8 patients) and recurrent otitis externa (7 patients). In the BAHA group, there was only 1 complication (hypertrophic scar). These findings encompass the main reasons why reconstructive surgery is currently discouraged in most centers.

In 1993, GRANSTROM et al. (16) published a study of 111 patients, 45 with bilateral modification (156 ears total) who underwent a total of 134 reconstructive surgeries. The most common causes of malformation were Treacher Collins syndrome (21 patients) and hemifacial microsomia (18 patients). In 73 ears, aesthetic surgery was performed with placement of an auricular prosthesis. Severity of hearing loss was found to be proportional to the severity of the malformation, while the hearing gain with the reconstructive surgery was lower for the more severe malformations. The hearing improvements for 44 ears after more than 2 years of follow-up were poor (0 to 10 dB) in 24 patients, moderate (10 to 30 dB) in 19, and good (above 30 dB) in only 5 patients. Twenty-four ears required reoperation, mainly due to restenosis (10) and continuous otorrhea (3). BAHA surgery was performed in 39 patients. In all cases, both the patients and their surgeons were satisfied with the results. The results for the aesthetic auricular prostheses were also good, as 72 of the 73 patients were satisfied with the surgery. In this study, the authors agreed with the general consensus in the literature that ear reconstruction surgery is one of the most difficult of the otological procedures, and disappointing results for both aesthetics and hearing (in this study, only 34% of patients reached the social level of hearing), along with the increase in experimental BAHA use, have led to a more conservative approach toward reconstructive surgery. CHANG et al. (2006) (17) also correlated severe microtia and surgical revisions with lower audiometric gains after reconstructive surgery (15.3 dB in revision surgeries versus 20 dB in primary surgery, after 3 years) concluding that in these cases, BAHA must be offered as an alternative, as it can provide more secure and stable results. MAZITA et al. (7) recommend canaloplasty in patients with normal pneumatization of the middle ear and mastoid in whom the facial nerve, the ossicular chain, and middle and inner ear are normal or minimally affected.

The placement of a prosthetic hearing pavilion with aesthetic finality is another alternative to reconstructive surgery. In these cases, the functional portion can be complemented with BAHA placement. In the study mentioned above, GRANSTROM et al. (16) compared the results of reconstructive surgery with those of BAHA and the pavilion prosthesis coupled to the bone in 111 patients and 134 reconstructive surgeries, including 73 surgeries for placement of the pavilion prosthesis and 39 BAHA insertions. All of the patients in the BAHA group considered the BAHA superior to conventional amplification devices, and 72 of 73 pavilion prosthesis patients were satisfied with their prosthesis, while only 8 of the 37 reconstructive surgery patients were satisfied, and only 34% achieved a social level of hearing. The authors suggested that reconstructive surgery should be

contraindicated for unilateral congenital atresia and took the same conservative approach to bilateral atresia in light of their disappointing results and the increasing experience with BAHA. In 2001, the same authors published data from the 100 patients who first underwent the surgery, 76 of whom had BAHAs or aesthetic anchored prostheses implanted (3). Complications included adverse skin reactions in 9.1% and implant failure in 5.8%. Revision surgery was necessary in 22% because their temporal bones were still growing. Most of the revisions occurred in patients between 5 and 11 years of age, a period during which the bone grows considerably. The authors did not indicate aesthetic surgery for patients younger than 5 years of age.

SOMERS et al. (18) compared the results of reconstructive plastic surgery with attachment of a prosthesis anchored to the bone. They studied 62 patients, among whom 35 had prosthesis placement and 27 had reconstruction. The reasons for surgery were anotia/microtia (26), trauma (6), and oncological (3). The rate of satisfaction among the prosthesis patients was high, with 34 patients who reported using the prosthesis every day. The complications included skin growth in 1 patient, skin reaction in 9 patients, and excessive subcutaneous tissue required reduction in 2 patients. The disadvantages of the prosthesis included the daily care requirements, occasional loss, and color change over time. Among the reconstructive surgeries, 21 were performed using the Nagata technique (preferred by the authors, conducted in 2 surgery sessions). The authors indicated this procedure for patients up to 6 years old, which is when the ear reaches about 85% of its adult size. The results were considered very good for 9 patients, good for 12, acceptable for 5, and bad for 2. The greatest failure rate occurred during the initial period. In cases of anotia and microtia, the authors only indicated prosthesis placement when the patient refused reconstruction, when reconstruction had already failed, when the cause was trauma or cancer, and for patients with multiple comorbidities. The authors indicate BAHA for patients who are undergoing reconstructive plastic surgery while awaiting functional surgery.

The hearing gain from BAHA can change over time, as SALIBA et al. (19) demonstrated. The authors evaluated the hearing of 17 patients preoperatively, on the day of insertion, and 6 and 12 months post-insertion. They found that the gain in speech discrimination at 1 year was better than immediately after the insertion (21.9% versus 11.7%), suggesting a learning process over time. The greater gain occurred in the presence of background noises. When speech intelligibility is measured binaurally with spatial separation of the sources of speech and noise, the threshold can vary up to 10 dB in individuals with normal hearing; in this study, the worst thresholds

occurred when speech and noise came from the same source, while the best thresholds occurred when speech and noise sources were 90° apart. The pure-tone average after 1 year was comparable to the results immediately after the insertion.

The indications for BAHA are not limited to conductive loss. CHRISTENSEN et al. (20), in a pilot study, implanted BAHAs in 23 children with deep unilateral sensorineural hearing loss. These children usually display poor school performance in noisy environments because of their hearing disability. The procedure was performed in 2 sessions, and hearing gains were demonstrated by improved scores on the *Hearing in Noise Test* (HINT) and the *Children's Home Inventory for Listening Difficulties* (CHILD) questionnaire. Among the study patients, there was an improvement of 40%, 21%, and 4% in 0, 5, and 10 dB, respectively, on the HINT and improvements of 2.41 for the patients and 2.5 for the parents as shown by the CHILD questionnaire scores.

More recent studies have supported the use of BAHA for patients with unilateral sensorineural deafness. Between 2006 and 2008, WAZEN et al. (21) studied 21 patients with air-conduction thresholds worse than 90 dB or speech discrimination lower than 15% for the most affected side and light-to-moderate contralateral deafness. The BAHA was implanted on the side with the worst hearing. The average age of the patients was 75 years. Hearing was measured with and without the BAHA and with 2 kinds of processor, Intense® and Divine®. There was a statistically significant postoperative improvement in both hearing thresholds and speech recognition scores versus pre-operation, and 91% of the patients reported improved quality of life on the Glasgow questionnaire. A significant difference in the HINT test scores favored the Intense® processor, which also provided a higher average functional gain (>55 dB versus ≤45 dB). The authors concluded that the BAHA is effective in the rehabilitation of patients with unilateral sensorineural deafness. HOL et al. (22) studied 27 patients with unilateral sensorineural hearing loss (25 acquired and 2 congenital) and evaluated the gain with BAHA CROS (transcranial routing of sound). They found poor results for sound localization, but improved scores for speech in noise, subjective benefit, and client satisfaction among those who answered the appropriate questionnaire.

CONCLUSION

The present review indicated that BAHA can be an excellent treatment option for patients with bilateral conductive deafness, as the literature has already established, due to its good hearing results, relative simplicity, and low

rate of complications. Recent studies have addressed its use for conductive deafness and unilateral sensorineural loss. The postoperative findings for our patients were compatible with the major published works sampled herein.

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