■ BRIEF COMMUNICATION

First 2 Years of Experience With BAHA: Results in 12 Patients

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Objective: To describe our first 2 years' experience following implementation of the BAHA program at our hospitals with special emphasis on the benefits and complications of use in each patient.
Material and Method: Retrospective review since the beginning of the programme at 2 Teaching Hospitals in 2004. Twelve patients were implanted with BAHA, and their complications are described, along with hearing loss and their audiological gain with the hearing aid.
Results: Eleven patients with BAHA completed the follow-up. The average age was 31.6 (18.9) years, and their average conductive hearing loss of was 45.5 dB with an audiological gain of 33.6 dB. We had one patient with a minor complication (mild infection of the skin flap) and another with a major one (loss of the titanium implant).
Conclusions: The BAHA programme started in 2004 has generated good results in terms of positive audiological data, patient acceptance and low complication rates.

Key words: BAHA. Titanium implants. Skin flap.

Primeros 2 años de experiencia en BAHA: resultados en 12 pacientes
Objetivo: Describir la experiencia durante los primeros 2 años de implementación del programa de BAHA en nuestras instituciones, puntualizando los beneficios en cada paciente y las complicaciones con su uso.
Material y método: Estudio retrospectivo desde el inicio del programa en el 2004 en 2 hospitales universitarios sobre 12 pacientes implantados con BAHA; se describe las complicaciones, su déficit auditivo y su ganancia audiológica con el audífono.
Resultados: Once pacientes con BAHA completaron el seguimiento, con un promedio de edad de 31,6 ± 18,9 años, con un déficit auditivo conductivo de 45,5 dB en promedio y una ganancia de 33,6 dB, una complicación menor (infección menor del colgajo) y una mayor (pérdida del implante de titanio).
Conclusiones: Adelantamos un programa de BAHA con buenos resultados audiológicos, buena aceptación de los pacientes y baja tasa de complicaciones.

Palabras clave: BAHA. Colgajo de piel. Implante de titanio.

INTRODUCTION

The use of titanium implants began when it was found that titanium integrates into bone, when Branemark (Sweden), during the sixties, discovered that osteocytes grew in apposition to the titanium surface and developed a strong bond; hence, it began to be used in oral and craniofacial reconstructive surgeries.[1] With Tjellstrom and Granstrom's introduction in 1977 of a hearing aid fitted to a titanium implant in the temporal bone, the bone-anchored hearing aid (BAHA), a device to amplify and restore hearing, began to be used in certain conditions in which conventional amplification was not suitable.[2] The BAHA is indicated in patients with unilateral conductive, mixed or sensorineural hearing loss that cannot be surgically corrected or who do not tolerate fitting of traditional hearing aids, in cases such as: aural atresia, otosclerosis, moist or large cavities, chronic external otitis, narrow canals, and single ears.

Compact and Divino processors are indicated in hearing losses with average pure tone thresholds of ≥45 dB HL for the bony pathway; for the Cordelle II model, the losses can be of up to 70 dB HL with 2-syllable discrimination >60% in the better ear.[3]

MATERIAL AND METHOD

Retrospective follow-up of 12 patients from January 2004 to January 2006. Subjects underwent BAHA implantation for different indications (Table 1).

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The surgeries were performed under general anaesthesia by the same surgical team at 2 institutions. Surgical steps:

– The implant area is drawn and the area is shaved and infiltrated
– An inferiorly pedicled skin flap is raised using a dermatome
– Subcutaneous cellular tissue is resected
– A 5-mm cross-shaped incision is made on the mastoid periostium
– Milling and insertion of the titanium implant following Branemark's standard technique. In children under the age of 14 years a second screw is implanted[4]
– Absorbable sutures are placed from the subcutaneous edges to the periostium
– The flap is sutured to the surrounding skin using non-absorbable material
– Exteriorization in adults. In children, exteriorization takes place at a later stage
– The amplifier is turned on 3 months after surgery in adults and 4-6 months following surgery in children

Preoperative audiometric data were collected: pure tone audiometry (PTA) for air and bone conduction thresholds at frequencies of 500, 1000, 2000, and 4000 Hz, in addition to the speech reception threshold (SRT) for 2-syllable words in each ear. The free field PTA and SRT with the BAHA device were carried out at the same frequencies.

Likewise, both major and minor complications were recorded as was the treatment and daily time in use in hours.

Results were analyzed using the SPSS version 11.5 software package (SPSS Inc., Chicago, Illinois, United States).

The threshold for statistical significance was $P<.05$.

RESULTS

Patient follow-up lasted for a mean of 10.9 (4.5) months. Two patients with BAHA implants did not undergo proper audiological follow-up and were therefore excluded from the results. The mean age was 31.6 (18.9) years. In the 8 female and 2 male patients, the implanted ear and aetiology presented similar frequencies (Table 1).

The air and bone PTA of the implanted and contralateral ear are presented in Table 2. All patients presented some kind of hearing loss and PTA was seen to be in similar ranges. The gap varied between 45.5 and 40.3 dB in the implanted ear and contralateral ear, respectively ($P=.392$).

As regards audiological follow-up of the implanted ear, we found a significant improvement with the use of the BAHA hearing aid; PTA improved by 34.5 dB; SRT improved by 37.7 dB on average, and the gap closed at 11.9 dB (Table 3).

In adults, a single-step surgery was performed and the implant was switched on 3.8 months later. In children, the implant was turned on at 8 months. Patient number 3 presented extrusion of the active implant after 2 months, resulting in the rescue implant having to be used and a 12-month wait to turn it on. The patients reported using the hearing aid 12.1 h/day.

Table 1. Baseline[a]

Age, mean (SD) (interval), y	31.6 (18.9) (6-51)
Gender, males:females	2:8
CMH:SRUH	4:6
RE:LE	5:6
Indication CM:CSNOE	5:6

[a]SD indicates standard deviation; CMH, Central Military Hospital; SRUH, "San Rafael" University Hospital; CM, congenital malformation; RE, right ear; LE, left ear; CSNOE, chronic suppuration in non-operable ear.
Eleven surgeries were performed in 10 patients.

Table 2. Pre-Operative Audiological Performance[a]

	Mean (SD)
Airborne PTA in IE	68.6 (13)
Bone PTA in IE	22.2 (8.9)
Gap in IE	45.5 (9)
SRT in IE	78.6 (13.8)
Airborne PTA in CE	61.8 (20.3)
Bone PTA in CE	21.5 (13.5)
Gap in CE	40.3 (13.4)
SRT in CE	71.8 (16.3)

[a]CE indicates contralateral ear; IE, implanted ear; PTA, pure tone audiometric thresholds; SRT, speech reception threshold.
Eleven surgeries were performed in 10 patients.

Table 3. Audiological Performance in the Implanted Ear[a]

	Pre-Operative	*Post-Operative*	*Difference*[b]	*P*[c]
PTA LE	68.6 (8.9)	34.1 (11.3)	34.5 (12.2)	<.001
SRT LE	78.6 (13.8)	40.1 (8.6)	37.7 (13.7)	<.001
Gap	45.5 (9)	11.9 (6.7)	33.6 (12.8)	<.001

[a]PTA LE indicates pure tone audiometric thresholds in left ear; SRT LE, speech reception threshold in left ear.
[b]Corresponds to closure of the gap.
[c]Paired Student *t* test.
Eleven surgeries were performed in 10 patients. The data are expressed as mean (standard deviation).

There were 3 complications. The complication reported in case 3 was due to the spontaneous, untriggered loss of the implant, with subsequent appropriate response when the rescue screw was applied. Case 6 presented a late infection in the area of the skin flap around the pedestal that was treated with oral and topical antibiotics, with complete resolution of the infection and return to use of the hearing aid. Case 9 presented a free skin flap during the operation with the dermatome; it was repositioned to ensure apposition of the free flap over the periostium and with compressive dressing it showed good integration at the 3-month follow-up.

DISCUSSION

Patients with conductive or mixed hearing loss who are not good candidates for surgery or who do not tolerate fitting of conventional hearing aids for hearing rehabilitation may benefit from BAHA implants.[4]

Percutaneous transmission amplifiers have typically been used; however, there have been conflicting outcomes, as well as reports of user dissatisfaction, because of the variability in positioning and poor fitting, or because they are uncomfortable to wear and sound energy is lost through the skin, resulting in sound fidelity loss of up to 10-20 dB.[4-7] Connecting the sound processor directly to the bone-anchored implant resolves many of the issues described[5] and has demonstrated additional advantages such as bilateral stimulation of the cochleae and lack of feedback.[8]

Another alternative is reconstructive surgery in the case of congenital or functional malformations with poor audiological performance in severe malformations scoring <7 on Jahrsdoerfer's scale.[9]

The most common reasons for implanting the BAHA system in our study were draining mastoid cavities and congenital malformations not amenable to surgical correction. All of our patients had some degree of hearing improvement, with closure of the air-bone gap <10 dB in 27%, <15 dB in 72%, and <20 dB in 10/11 patients (90.9%).

The average gap closure in our group was 12 dB, with an average audiological gain of 34.5 dB. Similar studies, such as the one carried out by Lustig et al, report a gap closure of 18 dB and hearing improvement of 28 dB. In contrast, discrimination measured in the SRT improved by 37.7 dB; Liepert and DiToppa, in their 15-patient experience, report a 30 dB gain.

Reports of studies with BAHA reveal a low complication rate, the most common ones being partial or complete loss of the flap, skin growth around the pedestal, flap irritation or infection, and extrusion of the implant.[10] Other less common causes and isolated reports refer to loss of implant due to trauma, mental illness, or intracerebral abscess.[11,12] Among the complications, a free graft appeared intraoperatively in 1 patient but was integrated satisfactorily into the underlying periostium, despite reports of losses of up to 46.7% of the graft surrounding the implant.[13]

It is worth mentioning that we followed the international recommendations of leaving a rescue screw in place for children, in the light of the high extrusion rate, as occurred in patient number 3 of 6 years of age.[14]

Bone-anchored hearing aids provide otorhinolaryngologists with a good alternative for the rehabilitation of patients with hearing loss who are not candidates for using traditional hearing aids.

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