



Assessment Protocol for Candidates for Bone-Anchored Hearing Devices

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Abstract

Introduction The technology regarding bone-anchored hearing devices has been advancing. Nevertheless, complications are still often reported, which can impair treatment adherence and lead to discontinuation of use. There is a lack of studies conducted in tropical countries, where complications can be even greater, as well as standardized protocols for selection, indication and evaluation.

Objective To characterize implanted patients from a Brazilian public institution and describe the medical and audiological assessment protocols to which they were submitted during the selection process and in the follow-up after surgery.

Method An observational, cross-sectional study evaluating the medical records of patients with hearing loss and ear malformations and describing the care protocol through which they were treated.

Results The medical records of 15 patients were reviewed: 6 received transcutaneous implants, and 9, percutaneous implants; 9 patients reported some type of skin lesion, 2 reported pain on the follow-up visit, and 3 had osseointegration failure. The time between surgery and activation ranged from 2 to 9 months. The median scores on the sentences, Sentences in Noise and Monosyllable tests were 100%, 60% and 80%, respectively.

Conclusion It was possible to characterize the patients who received implants at the institution. The patients performed well in silence and had greater difficulty in noise. Even patients who had complications did not complain about the audibility and sound quality. It is essential to develop a model and to standardize the assessment and follow-up methods aimed at the benefit of users of bone-anchored hearing devices, as well as to enable the technico-scientific development in this field.

Keywords

- ▶ hearing loss
- ▶ bone conduction
- ▶ hearing aids
- ▶ correction of hearing impairment

Introduction

Hearing loss can lead to a series of impairments in language development and speech changes, affecting the individual's communication and possibly causing other problems that involve cognitive, emotional, social and educational aspects.

Efficient diagnosis and early intervention, including the indication and fitting of suitable hearing devices, are needed to mitigate these impairments.

A bone-anchored hearing device (BAHD) is a hearing aid that amplifies sound through bone conduction and is fixed to the head by means of an elastic band or a surgically-

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implanted internal component. The external component captures background noise and makes its sound reach the cochlea through mechanical amplification.

Bone-anchored hearing devices have been used as a form of treatment for individuals with hearing loss who do not benefit from the use of conventional hearing aids (HAs) due to anatomical and physiological malformations of the external and middle ears, such as agenesis and atresia of the external auditory canal or infectious ear conditions. It can also be recommended for severe to profound unilateral hearing loss with no benefit in the perception of auditory speech with HA fitting, for transcranial stimulation of the contralateral ear.

There are two types of BAHDs: percutaneous devices, which consist of a titanium pin and a sound processor that are attached to a percutaneous fixation abutment; and transcutaneous devices, which are a system composed of two magnets, one internal and one external, that use the force of magnetic attraction to fix the sound processor to the implant, instead of the abutment. Currently, there are two commercially available percutaneous systems in the Brazilian public health system: Baha Connect (Cochlear Ltd., Sidney, Australia) and Ponto (Oticon Medical, Smørum, Denmark). In turn, there are also two commercially available transcutaneous models: Baha Attract (Cochlear Ltd.) and Bonebridge (MED-EL, Innsbruck, Austria).

It should be noted that the devices can be tested prior to surgery using an elastic band fitted to the patient's head, which includes a plastic disk to which the sound processor is attached. Thus, the elastic band presses this disc against the skin behind the ear. Despite the fact that the sound transmission is dampened and the amplification is less effective due to the presence of skin and subcutaneous tissue, the elastic band is considered the preoperative test with the result closest to that of the implant, with a difference of 1 dB to 13 dB.¹ In addition, since it can be used in patients who do not yet have sufficient skull thickness to undergo surgery, the use of an elastic band enables an effective auditory rehabilitation at increasingly younger ages.²

Although the literature shows good results with BAHDs, the technology is still very recent and has been undergoing several innovations and interventions. The many complications reported, such as those related to pain, infections, and osseointegration failure,³ do not always affect the audiological benefit,⁴ but they have a direct impact on treatment adherence.⁵ Furthermore, there are few studies conducted in large tropical countries, such as Brazil, where there are several variables involving climate and habits. It is also known that the benefit provided by hearing devices is directly related to a good and detailed preoperative evaluation of medical and audiological criteria and to the follow-up after surgery. Therefore, it is essential to standardize the pre- and postoperative procedures and carry out an analysis of patients who are already BAH users, in order to analyze the long-term results and, with the findings, improve the techniques that may optimize the need for follow-up visits and reduce the discontinuation of use and rate of complications resulting from this treatment.

Objective

- 1) The present study aims to characterize patients who received implants through a Brazilian benchmark public institution, according to the hearing loss, the implanted side, the implanted device, the time between surgery and activation, and the auditory performance in speech in silence and noise recognition tests.
- 2) In addition, the study also aimed to describe the medical and audiological evaluation to which these patients were submitted during the selection process, as well as the follow-up after surgery.

The protocol described in the present study is already adopted by the staff of the outpatient clinic of the Department of Otorhinolaryngology at a Brazilian public hospital, and it may vary according to the different research and care centers.

Method

The present study is part of a project approved by the institutional Ethics in Research Committee under opinion no. 4.254.874. This is an observational, cross-sectional study including a retrospective assessment of medical records of patients who received implants at the hospital.

The researchers evaluated the medical records of 51 patients examined at the clinic between 2011 and 2019, 28 of whom had already been implanted with a BAH. In this context, the study included 15 individuals for whom there was complete data on speech recognition tests. In turn, patients who had not yet completed the assessment process were excluded.

All of these patients were treated using the same medical and audiological protocols described below.

Assessment Protocol

Preoperative Evaluation

Otorhinolaryngological Evaluation

The otorhinolaryngologist gathered the patients' history, considering their otological and surgical history.

In addition, imaging tests such as computed tomography (CT) and magnetic resonance imaging (MRI) were also requested, which are important to visualize and investigate the condition of the middle and inner ears and the thickness of the skullcap.

Then, the eligible patients were referred for an audiological evaluation after the medical opinion.

Audiological Evaluation

- Anamnesis: it covers the patient's clinical history, etiology and hearing loss in each ear, the results of the previously-performed tests and treatments, as well as a record of the previous experience with hearing devices.
- Pure-tone audiometry by air conduction (AC) and bone conduction (BC).

- Vocal audiometry by AC and BC, with speech recognition threshold (SRT) and word recognition testing (WRT) of monosyllable and/or disyllable words.
- Acoustic immittance with tympanometry and acoustic reflex thresholds (whenever possible).
- Loudness discomfort levels: their assessment infrequencies from 250 Hz to 8,000 Hz was used to regulate the maximum output of the sound processor.
- Assessment and guidance on expectations: the patients and their families were instructed on the evaluation, surgery and follow-up process, as well as on the functioning of the devices and their benefits and limitations. Furthermore, the expectations of the patient and their families were evaluated and discussed so that adjustments could be made.

Indications

Based on Directive GM/MS no. 2776⁶ of the Brazilian Ministry of Health, patients over 5 years of age who have conductive or mixed bilateral hearing loss and who meet all the following criteria are candidates to receive the device through the Brazilian Unified Health System (Sistema Único de Saúde, SUS, in Portuguese):

- 1) Congenital bilateral ear malformation that makes it impossible to adapt to conventional HAs;
- 2) Air-bone gap greater than 30 dB in the average of frequencies of 500 Hz, 1,000 Hz, 2,000 Hz, and 3,000 Hz;
- 3) Mean threshold higher than 60 dB for bone conduction at the frequencies of 500 Hz, 1,000 Hz, 2,000 Hz, and 3,000 Hz in the ear to receive the implant;
- 4) Percentage of open-set word recognition test greater than 60% in monosyllables without the use of conventional HAs.

Side to Receive the Implant

In order to decide the side of the implant, the speech processor was adapted with an elastic band, and the patient was submitted to an assessment, which included speech recognition tests, performed in each ear separately. From an audiological perspective, the largest air-bone gap is selected for the implant, either based on conventional audiometry or AC/BC auditory brainstem response (ABR) and greater correctness in the WRT for monosyllabic words.

Although previous audiological results were decisive for the final decision for surgery, assessments of the anatomical condition and skullcap thickness were mandatory for the decisions regarding the side to receive the implant and the type of implantation.

Finally, BAHD potency was selected based on BC hearing thresholds and audiological results.

Postoperative Evaluation

Otorhinolaryngological Evaluation

The otorhinolaryngologist monitored the healing process at the implant site to avoid possible complications, such as pain, skin lesions, tissue growth around the abutment, infections, and failure in osseointegration.

The release for activation of the sound processor occurred at intervals ranging from 4 to 12 weeks, depending on each case.

Audiological Evaluation

Activation

On the day of activation of the sound processor, the professionals reinforced the guidelines and advice on possible benefits and limitations. In addition, the patients also received information on the daily care and handling of their BAHD, specifically for each implant.

Device fittings were performed using the software of each brand after in-situ audiometry aiming at audibility, speech comprehension, and comfort.

Validation

- Effective gain: it was assessed in terms of the difference (in dB) between the hearing thresholds obtained in open field, with and without the device, under the same speech recognition test conditions.
- Speech recognition test in open field, in silence and noise, and in open or closed presentation: this test assessed the individual's auditory performance through a list of 25 monosyllabic words and a list of sentences, both phonetically balanced in Brazilian Portuguese.⁷ The number of words varies from 4 to 7 per sentence in the List of Sentences in Portuguese (LSP).⁸ It should be noted that sentences represent the characteristics of conversational situations better than single words. However, patients must repeat all the words correctly to get a correct answer.

The lists were presented in a situation of silence and competing background noise, as a speech-shaped noise, in the contralateral acoustic stimulation. In addition, the test was carried out inside the acoustic booth, with the individual at a distance of 60 cm, at 0° azimuth in relation to the acoustic stimulation and at 180° from the contralateral acoustic stimulation.

Thus, the test was performed in 4 different situations: 1) monosyllables at 65 dB SPL in silence; 2) LSP at 50 dB SPL in silence; 3) LSP at 65 dB SPL in silence; and 4) LSP at 65 dB SPL with competing background noise at 55 dB SPL (signal-to-noise ratio +10 dB) in the contralateral acoustic stimulation.

- Subjective evaluation: patients were asked to assess their satisfaction with the use of the devices through questionnaires.

Guidance

The patients and their families were instructed and advised on the functioning, handling and maintenance of the external component of the device, as well as on hygiene and care regarding the location of the abutment, as percutaneous devices require daily cleaning in that region.

Follow-Up

Patients were then monitored at follow-up visits at 1, 3, 6 and 12 months after surgery. After this period, follow-up visits were carried out once a year or at the patient's discretion, in case of need for medical and/or audiological evaluation.

Telemonitoring of implant users was recently implemented in the protocol of our clinic. These patients were contacted by the audiologist on staff by phone call and asked if they were well adapted to the use of the devices or if they reported any physical or auditory discomfort. Patients were also asked to send a photo of the abutment or magnet region via the messaging app, which was analyzed by otorhinolaryngologists, who could call the patient for a face-to-face follow-up visit if an evaluation was needed.

Results

The study group consisted of 15 patients, 9 male (60%) and 6 female (40%), aged between 7 and 69 years, with a mean age of 19.6 years and median age of 15 years, as shown in ►Table 1.

Among these participants, 14 patients (93.3%) received unilateral implants, while 1 (6.7%) received bilateral implants due to significant visual impairment. As for the

type of implant, 6 patients (40%) received transcutaneous implants and 9 (60%), percutaneous implants.

The time between surgery and activation ranged from 2 to 9 months, with a mean of 4 months and a median of 3 months. It should be noted that the patient in whom activation took 9 months reported difficulty in going to the follow-up visit, as she lives in another state and, therefore, the longer time recorded is not due to clinical complications.

The duration of use of the BAHD ranged from 2 to 84 months, with an average of 16.2 months and a median of 8 months. The time was counted from the date of activation to the date the speech recognition tests were performed.

Regarding complications, 9 patients (60%) had some type of skin lesion, such as edema or hyperemia (1 transcutaneous user and 8 percutaneous users). In the follow-up visits, 2 adult patients (13.33%) with transcutaneous implants reported pain. In addition, 3 patients (20%) who had percutaneous devices had complications in osseointegration

Table 1 Characterization of the study sample

Variable	Category	N (%)
Age at activation (years)	Median (range)	15 (7–69)
Time between surgery and activation (months)	Median (range)	3 (3–9)
Gender	Female	6 (40%)
	Male	9 (60%)
Amplification	Bilateral	1 (6%)
	Unilateral	14 (94%)
Etiology	Bilateral atresia	1 (6.5%)
	Ectrodactyly ectodermal dysplasia	1 (6.5%)
	Malformation	6 (40%)
	Bilateral microtia	5 (34%)
	Frasier syndrome	1 (6.5%)
	Treacher Collins syndrome	1 (6.5%)
Hearing loss in the ear with the device	Conductive	13 (86.7%)
	Mixed	2 (13.3%)
Hearing loss in the contralateral ear	Conductive	13 (87%)
	Mixed	1 (6.5%)
	Anacusis	1 (6.5%)
Processor	Amade Bonebridge (MED-EL, Innsbruck, Austria)	2 (12.5%)
	Baha 4 (Attract, Cochlear Ltd., Sidney, Australia)	1 (6.25%)
	Baha 4 (Connect, Cochlear Ltd.)	1 (6.25%)
	Baha 5 (Connect, Cochlear Ltd.)	2 (12.5%)
	Ponto Plus Power (Oticon Medical, Smørum, Denmark)	7 (44%)
	Samba Bonebridge (MED-EL)	3 (18.5%)
Implanted side	Right	5 (31%)
	Left	11 (69%)
Postoperative pain	Yes	2 (13%)
	No	13 (87%)

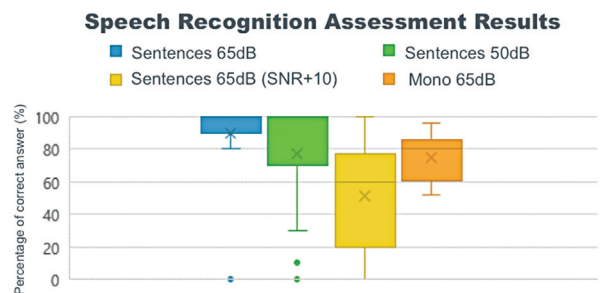


Fig. 1 Results of the speech recognition assessment.

leading to abutment extrusion and underwent reimplantation surgery.

As for the performance in speech recognition, **Figure 1** shows the results of the Speech Recognition Tests as follows:

- List of Sentences at 65 dB SPL in silence: the average score was 89.33%, while the median score was 100%.
- List of Sentences at 50 dB SPL in silence: the average score was 78%, while the median score was 100%.
- List of Sentences at 65 dB SPL in noise at 55 dB SPL: the average score was 50.66%, while the median score was 60%.
- List of Monosyllables at 65 dB SPL: the average score was 74.66%, while the median score was 80%.

Table 2 shows the results of each patient and the time using the device. In total, 1 (6.7%) patient scored 0 on the sentence tests, but obtained 64% of correct answers in monosyllables, which is due to the fact that an answer is only considered correct if the patient repeats the sentence exactly as it was presented, so they cannot make mistakes or omit any of the words.

Table 2 Results of the speech recognition assessment of users of the bone-anchored hearing device

PATIENT	TIME OF USE OF THE DEVICE (MONTHS)	SENTENCES AT 65 DB (%)	SENTENCES AT 50 DB (%)	SENTENCES AT 65 DB (SNR + 10) (%)	MONO 65 DB (%)
1	24	100	100	60	96
2	48	100	100	70	92
3	2	100	100	80	96
4	8	100	100	60	68
5	11	100	70	20	80
6	10	0	0	0	64
7	5	100	100	100	64
8	3	100	100	80	52
9	6	80	10	10	60
10	84	90	100	20	80
11	9	90	90	30	80
12	4	100	30	60	60
13	2	100	100	60	88
14	2	80	70	10	60
15	24	100	100	100	80

Discussion

A good evaluation to select the best device for each patient is essential in the rehabilitation of individuals with hearing loss. When BAHDs are an alternative, teamwork aims to obtain the best prognosis. Together, the medical and audiological evaluations are important to define the side to receive the implant and the best type of device for each case.

As the institution was accredited by the SUS as a BAHD center only in March 2017, in the present study, we only had the medical records of 15 patients to evaluate. Before this accreditation in 2017, surgeries were performed sporadically at this institution.

Among the patients evaluated, 14 (93.3%) received unilateral implants, and only 1 (6.7%) patient received bilateral implants. Currently, the SUS only authorizes the performance of unilateral surgeries; bilateral procedures can only be authorized in special cases, as occurred with the patient in the present study who had Frasier syndrome with significant visual impairment.

Since both cochleae receive stimulation with the adaptation of a single BC device, the bilateral fitting of BAHDs in patients with conductive or mixed bilateral hearing loss is still a controversial topic. However, as some studies show that the interaural attenuation of BC is not always null and can vary between 5 to 10dB,⁹ it cannot be said that the cochleae are receiving the same stimulation of a unilateral bone stimulus. Gürses et al. (2020)¹⁰ found that users of unilateral BAHD do not show improvement in sound localization and still have difficulty in temporal auditory processing skills with the use of the device.

Studies¹¹⁻¹⁴ show advances in hearing and language with the bilateral use of BAHDs when compared to the unilateral

device. In turn, a Janssen et al. (2012)¹⁴ carried out a systematic review of studies published from 1977 to 2011 in order to raise evidence that the bilateral fitting of BAHDs is better than the unilateral fitting. As for the subjective results, the questionnaire applied to the patients showed better scores in the learning and emotional aspects of children with bilateral fitting, in addition to improvement in all items in adults with bilateral fitting. Thus, the authors¹⁴ found many benefits of the bilateral fitting of BAHD when compared to the unilateral fitting, such as: improved detection in silence; improved speech perception in silence; improved speech perception in noise under most noisy conditions; improved location and sound lateralization; better sound detection; and better self-perception of quality of life.

Regarding the type of implant, it is already known that the sound transmission power of transcutaneous devices is lower than that of percutaneous devices.¹⁵ This loss of energy occurs through the barrier formed by the skin, hair and the layer of fat, increasing resistance and impairing sound transmission through the processors. However, transcutaneous devices have a lower rate of complications, which are resolved only with the adjustment in magnet strength in most cases.¹⁶

Although the surgical procedure to implant percutaneous devices is safe and easy to perform,¹⁷⁻¹⁹ these types of devices require daily cleaning in the abutment region, which, if neglected, can lead to complications such as: infections, skin irritation, and loss of abutment fixation.³ These complications are even more recurrent in the pediatric population, and directly impact treatment adherence.⁵

In the present study, patients with transcutaneous implants had fewer episodes of pain and skin lesions than those with percutaneous implants. A total of 9 patients (60%) had some type of skin lesion, and 3 patients (20%) with percutaneous devices had complications in osseointegration leading to abutment extrusion, and they underwent reimplantation surgery. The recurrence rates were higher than those suggested in a meta-analysis by Kiringoda and Lustig²⁰ (2013), who reported skin lesions ranging from 2.4% to 38.1%, and osseointegration failure ranging from 0% to 18% in adult and mixed populations and from 0% to 14.3% in pediatric populations.

In addition, the rates found were also higher than those reported in a systematic review by Kruyt et al.²¹ in 2020, which evaluated the effectiveness of BAHD in the pediatric population in 20 studies published between 2000 and 2017, covering 952 implants. Thus, this systematic review reported soft-tissue adverse reactions in 26.4% of the cases, revision surgery performed in 16.8% of the cases, and osseointegration failure in 6.4% of the cases.

Regarding the discontinuation rate, the results of the meta-analysis by Kiringoda and Lustig²⁰ ranged from 1.6% to 17.4% in the adult and mixed population, and from 0.0% to 25% in pediatric patients. In turn, Kruyt et al.²¹ reported discontinuation of the use of the device in 13.3% of the cases, whether due to failure in osseointegration, esthetic reasons, lack of benefit observed, trauma or recurrent infection. It should be noted that none of the patients discontinued the

use of the device in the present study. Thus, even individuals with skin complications did not report any impact on the audiological benefit but reported satisfaction with the use of the devices.⁴

Both guidance on care and hygiene with the abutment site and advice on the functioning, handling and maintenance of the device's external component for the patient and their families are essential for a successful fitting. Although all patients were instructed about the handling and hygiene of the abutment, the highest recurrence rates may be due to the tropical climate of Brazil. Therefore, patients implanted in the country are exposed to higher temperatures and humidity, which cause greater chances of developing skin lesions. In this sense, it is important to assess not only the etiological and audiological aspects of the individual to select the type of device, but also the region and climate of the place where the individual lives.

In addition, the audiological evaluation carried out in the follow-up visits is crucial to assess the benefit that BAHDs provide to the patient. The results of the speech tests show that patients achieved a good recognition rate with the use of BAHDs. Furthermore, the literature^{17,22,23} also shows good audiological results and a high level of patient satisfaction. The results also show that the time of use on the date the speech tests were performed varied greatly among the individuals in the sample, and even patients with little use time already had good performance in the tests, demonstrating that the results with HAs are quickly noticed.

As a reference center in BAHD fitting, the hospital serves patients from all over Brazil. However, transportation barriers such as long travel distance and transportation costs increase, leading to the need of new ways to manage and improve health care practices. The telemonitoring that was recently incorporated into the center's protocol is another possibility of providing assistance to patients using BAHDs. Therefore, further studies must be carried out to assess the effectiveness of this new tool.

Conclusion

The present study aimed to characterize BAHD users of a Brazilian public institution, who received implants and underwent audiological evaluations. Patients with ear malformation implanted with BAHD had good audiological performance in silence and greater difficulty in the presence of noise. In addition, no patients discontinued the use of the device. Even patients who had skin complications reported satisfaction and did not complain about the audibility and sound quality of the devices. Future studies should include larger samples and longer follow-up.

In addition, the present study described the protocol for the otorhinolaryngological and audiological evaluations of candidates for BAHDs, as well as the follow-up of patients implanted at a Brazilian public hospital. It is essential to develop a model and standardize the assessment and follow-up methods aimed at the benefit of BAHD users and enabling the technico-scientific development in this field.

Conflict of Interests

The authors have no conflict of interests to declare.

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