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Percutaneous bone ancored hearing aid: hearing benefits

Prótese auditiva ancorada ao osso percutânea: benefícios auditivos

Brenda Catalani[1], *Tyuana Sandim da Silveira Sassi*[2], *Érika Cristina Bucuvic*[2], *Luiz Fernando Manzoni Lourençone*[3,4], *Kátia de Freitas Alvarenga*[5], *Rubens Vuono de Brito Neto*[3,4]

ABSTRACT

Purpose: To describe the benefits in hearing thresholds and sentence recognition performance in silence and noise, in users of the unilateral Ponto® system. **Methods**: An observational, retrospective, longitudinal study. The sample consisted of secondary data sources from 10 individuals with conductive or mixed hearing loss who underwent surgery with the Ponto® System. The results were analyzed in the following pre-surgical conditions (without hearing aids; with hearing aids by air or bone conduction; with the Ponto Pro® processor with a soft band) and post-surgical (on activation and after six months of use). **Results:** The thresholds of pure tone audiometry by air and bone conductions remained stable after surgery, while the auditory thresholds in free field and speech recognition in silence and in noise were statistically better when using the Ponto® system. There was no difference between the results obtained with the individuals using Ponto® with soft band and post-surgically. **Conclusion**: The Ponto® system provided benefits in hearing detection skills in all tested frequencies, as well as, in recognition of the sentence in silence and noise.

Keywords: Ossicular prosthesis; Speech audiometry; Bone conduction; Audiometry; Hearing aids

RESUMO

Objetivo: Descrever os benefícios nos limiares auditivos e no desempenho de reconhecimento de sentenças no silêncio e no ruído em indivíduos com a adaptação unilateral do Sistema Ponto®. **Métodos:** Estudo observacional, retrospectivo, de seguimento longitudinal. A casuística foi composta por fontes de dados secundários de dez indivíduos com perda auditiva condutiva ou mista, que foram submetidos à cirurgia com o Sistema Ponto®. Os resultados foram analisados nas seguintes condições: a) pré-cirúrgicas: sem AASI; com AASI por condução aérea ou óssea e com o processador Ponto Pro® acoplado a uma banda elástica; b) pós-cirúrgicas: na ativação e após seis meses de uso. **Resultados:** Os limiares da audiometria tonal por conduções aérea e óssea mantiveram-se estáveis após a cirurgia, enquanto os limiares auditivos em campo livre e o reconhecimento de fala no silêncio e no ruído foram estatisticamente melhores na ativação e após seis meses de uso do Sistema Ponto®. Não houve diferença nos resultados com os indivíduos utilizando o Sistema Ponto® com a banda elástica e após a cirurgia. **Conclusão:** O Sistema Ponto® propiciou benefício nas habilidades auditivas de detecção em todas as frequências testadas, assim como no reconhecimento de sentenças no silêncio e no ruído.

Palavras-chave: Prótese ossicular; Audiometria da fala; Condução óssea; Audiometria; Auxiliares de audição

Study carried out at Divisão de Saúde Auditiva, Hospital de Reabilitação de Anomalias Craniofaciais, Universidade de São Paulo – USP – Bauru (SP), Brasil.
[1]Programa de Pós-graduação em Fonoaudiologia, Faculdade de Odontologia de Bauru – FOB, Universidade de São Paulo – USP – Bauru (SP), Brasil.
[2]Divisão de Saúde Auditiva, Hospital de Reabilitação de Anomalias Craniofaciais – HRAC, Universidade de São Paulo – USP – Bauru (SP), Brasil.
[3]Hospital de Reabilitação de Anomalias Craniofaciais – HRAC, Universidade de São Paulo – USP – Bauru (SP), Brasil.
[4]Curso de Medicina, Faculdade de Odontologia de Bauru – FOB, Universidade de São Paulo – USP – Bauru (SP), Brasil.
[5]Departamento de Fonoaudiologia, Faculdade de Odontologia de Bauru – FOB, Universidade de São Paulo – USP – Bauru (SP), Brasil.
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Corresponding author: Brenda Catalani. E-mail: brenda.catalani@usp.br
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INTRODUCTION

Routinely, the rehabilitation of individuals with hearing loss is performed through the adaptation of hearing aids, associated with the Speech-Language Pathology therapeutic process. However, in individuals with hearing loss due to congenital or acquired malformations, middle ear, congenital atresia/microtia and chronic otitis media, these devices may not be adaptable[1].

As a therapeutic alternative for these individuals, there is a diversity of electronic devices that differ not only in the way the sound is transmitted to the cochlea, but also in the clinical procedures involved in its adaptation, which can be outpatient or outpatient and surgical.

In the outpatient context, the individual sound amplification device by bone conduction (BAHA), composed of a metal arch and a vibrator that, in contact with the mastoid, promotes cochlear stimulation, without the need for the passage of the sound through the outer and middle ears, consecutively[2]. However, this type of hearing aid can cause irritation or headache since the transmitter is pressed firmly against the mastoid skin. In addition, there are reports of some people referring to interference in sound quality and speech recognition, as the transmitter's position changes[3].

For the group of prostheses that require the surgical procedure, there are the middle ear prostheses with two parts: the internal one, composed of the surgically implanted receiver/modulator and the external audio processor, which is placed on the scalp and remains on its scalp. position by magnetic attraction between the two parts. At the end of the conductive wire, there is a mass fluctuation transducer that can be inserted into the anvil, oval window, or round window[4].

Finally, there are bone-anchored hearing aids (BAHA), implanted for the first time in 1977[5] and, in Brazil, in 1997, in a hospital, in syndromic individuals with conductive and mixed hearing loss. Initially, these prostheses, designed to contemplate some specific clinical situations, started, with technological evolution, to have the criteria for indication expanded, including, currently, individuals with profound unilateral sensorineural hearing loss[6].

BAHA comprise two parts: one surgically positioned and the other, external, which constitutes the sound processor. BAHA, whose coupling with the external unit occurs using a titanium pin implanted to the bone is called percutaneous, and prostheses that the coupling with the external unit occurs using a magnet are called transcutaneous. BAHA that vibrates bone through the skin (skin drive) are called passive transcutaneous, with magnets implanted under the skin, commercially available as Baha® Attract and Sophono®. BAHA that directly stimulate bone (direct drive) are called percutaneous (Baha® Connect and Ponto®) and active transcutaneous (Bonebridge® and Osia)[7].

Concomitant with the advancement of therapeutic alternatives, companies are constantly concerned that new technologies improve the processing of the sound signal received by the user of the BAHA, with consequent benefit in speech perception and greater comfort in a noisy environment[8]. In this perspective, the company Oticon Medical developed and launched, in 2009, the Ponto® System, a percutaneous BAHA that provide advanced aspects of signal processing, such as adaptive directionality, suppression of wind noise, reduction of environmental noise, among others, features also present in aerial conduction sound amplification devices[9].

Recent research has been carried out with the Ponto® System, comparing different models and strengths[10], implant stability[11], or even assessing hearing discrimination after using this device[12], however, nationwide, there are no records of the benefit obtained by the individual with hearing impairment after surgery for BAHA with the Ponto® System.

Thus, this research aimed to describe the benefits in hearing thresholds and sentence recognition performance in silence and noise in individuals with conductive or mixed hearing impairment, in pre- and post-surgical conditions with the BAHA Ponto® System.

METHODS

This is a study with primary, observational, and retrospective design, with longitudinal follow-up, approved by the Research Ethics Committee of "Hospital de Reabilitação de Anomalias Craniofaciais" (HRAC / USP), under report 3.417.010. As this is a retrospective study through the collection of data already present in the medical records, without the need for additional information or disclosure of patients' images, the Informed Consent Form (ICF) was dispensed with.

Data collection was performed through documentary analysis of medical records of patients enrolled in the Hearing Health Division of the Hospital for Rehabilitation of Craniofacial Anomalies of the University of São Paulo - HRAC / USP. The program has a standardized clinical protocol for the evaluation and monitoring of candidates and users of BAHA. Secondary data were collected using the Tasy hospital management software system, from July to August 2019.

The eligibility criteria were individuals with bilateral conductive or mixed hearing impairment, who underwent surgery for the BAHA Sistema Ponto® in the period, and who presented the following data in the medical record: pure tone audiometry for air and bone conduction in pre- and post-surgical conditions, being considered the evaluation performed immediately before the surgery; thresholds in free field tonal audiometry and sentence recognition in silence and noise under the following conditions:

- Pre-surgical (considered the last evaluation performed next to the surgery): without electronic device; with hearing aids by air or bone conduction; with the Ponto Pro® processor attached to an elastic band;
- Post-surgical: activation of the BAHA Ponto® System, which occurs 12 weeks after surgery; six months of use of the BAHA Ponto® System.

Exclusion criteria were the lack of any data among those required, thus excluding medical records that did not present enough information for the study in question.

The data collected according to the applied procedure are described below:

- Pure tone audiometry: tonal thresholds for air conduction obtained at frequencies from 0.25 to 8 kHz and thresholds for bone conduction obtained at frequencies from 0.5 to 4 kHz for the pure tone stimulus, presented through the supra-aural headset TDH49 - Telephonics and bone vibrator B71 - Radioear, respectively;

- Free field tonal audiometry: tonal thresholds obtained at frequencies of 0.5; 1; two; 3 and 4 kHz for the modulated tone stimulus (Warble) with the speaker positioned at 0º azimuth one meter from the individual, in an acoustic booth. For the realization of pure tone and free field audiometry, the Astera 2 Madsen - Otometrics audiometer was used;
- Recognition of sentences in silence and noise: the six lists of 10 sentences proposed by Costa et al.[13] were recorded and presented in silence and noise, using the same Astera 2 Madsen - Otometrics audiometer, connected to an amplifier in the field free and to a loudspeaker positioned at 0º azimuth, one meter from the individual, in an acoustically treated room.

The speech recognition threshold was investigated in conditions without and with the hearing aid and the Ponto® System, in silence and noise. For this, the ascending-descending technique (strategy proposed by Levitt and Rabiner[14], called adaptive sequence) was used, for the presentation of the ten sentences. Thus, the first sentence was presented at an intensity of 65 dBHL (hearing level decibel) and, in the face of correct repetition by the individual, the intensity was decreased in steps of 4 dBHL, until the occurrence of an error made by the individual, in the repetition. From that intensity, steps of 2 dBHL were used in the intensity, that is, 2 dBHL increased in the presentation of the sentence in case of error or decreased by 2 dBHL in the event of a correct answer until finalizing the used list. To calculate the speech recognition threshold, the intensity at which the first error was obtained was considered, adding it to the intensity of presentation of subsequent sentences. The value obtained was divided by the total sentences used in the sum, thus establishing the threshold for recognition of sentences in silence.

The same technique was used, but with the presentation of competitive noise at an intensity of 60 dBHL, i.e., an initial signal/noise ratio of +5 dB (decibel), to determine the threshold of recognition of the sentences in noise. The signal/noise ratio was determined by subtracting the sentence recognition threshold in the noise of the fixed noise intensity of 60 dBHL.

Analysis of results

The results were presented in the form of tables and graphs. Initially, the data were submitted to descriptive statistical analysis, with the percentage of occurrence being determined for each nominal qualitative variable and the values of mean, SD (standard deviation), median, 25th and 75th percentiles determined.

For inferential statistics, according to the Kolmogorov-Smirnov test, the auditory thresholds obtained in pure and air conduction pure tone audiometry did not present a normal distribution ($p \geq 0.05$), which determined the use of tests non-parametric. To compare the tonal thresholds for air and bone conductions obtained without a device and those in different conditions, the Wilcoxon Test was used, while for those obtained in the free field, the Friedman Test and, subsequently, the Tukey Test were applied. On the other hand, the analysis of the data referring to the recognition of sentences in silence and noise, found a normal distribution, thus using the parametric test Variance with Repeated Measures and, later, the Tukey Test.

A 0.05 significance level was set for inferential analysis. The statistical analysis software used was SPSS, version 21.

RESULTS

Given the previously established criteria, the medical records of 10 individuals were analyzed, 5 male and 5 female, with an average age of 27 years old, minimum of 15 years old and maximum of 49 years old, unilaterally adapted with the Ponto Pro System®. Of these individuals, 6 had bilateral ear malformations and 4 had sequelae of bilateral chronic otitis media and used hearing aids by air or bone conduction, prior to surgery. The characterization of the sample is presented in Chart 1.

The thresholds of pure tone audiometry by air and bone conduction for the frequencies tested in the pre-surgical and post-surgical stages, with individuals without electronic devices, did not present significant differences ($p > 0.05$) (Figure 1).

Chart 1. Characterization of the series

n	Gender	Activation age (years old)	Type and degree of hearing loss	Implanted side
1	F	32	RE: severe conductive LE: moderate conductive	R
2	M	27	Bilateral: severe mixed	L
3	F	25	RE: moderate conductive LE: severe conductive	L
4	M	21	Bilateral: severe conductive	L
5	M	30	RE: moderate conductive LE: moderate mixed	R
6	F	24	Bilateral: moderate conductive	R
7	F	15	Bilateral: moderate mixed	R
8	M	49	RE: profound mixed LE: moderate mixed	R
9	M	27	RE: profound sensorineural LE: moderate mixed	L
10	F	20	RE: moderate mixed LE: profound sensorineural	R

Subtitle: n = subject number; F = female; M = male; RE = right ear; LE = left ear; R= right; L= left

Regarding tonal thresholds of free field audiometry in the three pre-surgical conditions (without electronic device; with hearing aids by air or bone conduction and with the Ponto Pro® processor attached to an elastic band) and the two post-surgical conditions (activation of the BAHA Ponto® System and 6 months after activation), it was possible to verify significant improvement of the thresholds, when comparing those found in the free field audiometry without the use of the electronic device with the other evaluation conditions, except for the condition of the individual with hearing aid, in which the difference occurred only for the frequencies of 2, 3 and 4 kHz. There was no significant difference between the thresholds obtained with the individual using the Ponto Pro® System attached to an elastic band (pre-surgical moment) and in the post-surgical moments (Figure 2).

As for the performance in the recognition of sentences in silence, the same pre- and post-surgical conditions mentioned above were compared, with a difference between the results, when compared to those found in free field audiometry without the use of the electronic device and to all other conditions of assessment in which the individual was using the hearing aid or Ponto Pro® (pre- and post-surgery). There was no significant difference between the thresholds obtained with the individual using the Ponto System coupled to an elastic band (pre-surgical) and the conditions of post-surgical evaluation (Table 1).

In the data referring to the performance in the recognition of sentences in noise, also compared between all the pre- and post-surgical conditions already described, a difference was found between the condition without an electronic device, when compared to the conditions with the Ponto Pro® processor coupled to an elastic band, on activation and 6 months after activation, but not with the individual using the hearing aid. No differences were observed between the other test conditions (Figure 3).

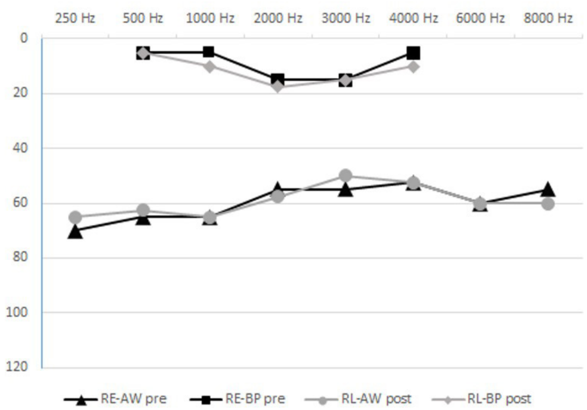

Figure 1. Median of pure tone thresholds (dBHL) obtained in pure tone audiometry, by air and bone conduction, in pre- and post-surgical conditions

Subtitle: HZ = hertz; RE-AW = right ear-airway; RE-BP = right ear-bone pathway; RL-AW = left ear-airway; RL-BP = left ear bone-pathway; Wilcoxon test p> 0.05

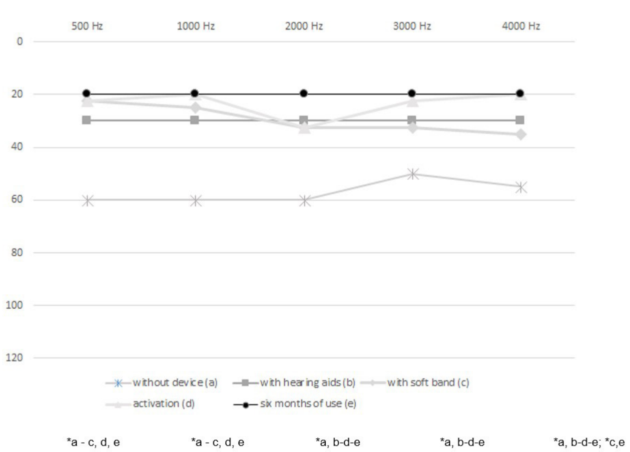

Figure 2. Median of pure tone thresholds (dBHL) obtained in free field audiometry, in pre- and post-surgical conditions

Subtitle: Hz = hertz; HA = individual hearing aid; Friedman test (p <0.001); Different letters (a, b, c, d, e) on the line indicate significant differences (p ≤ 0.05) between the conditions evaluated (Tukey test)

DISCUSSION

For decades, the Speech-Language Pathologist, in clinical practice, when faced with an individual with unilateral or bilateral middle and/or middle ear malformation, with consequent conductive hearing loss, felt his therapeutic performance restricted, given the scarcity of technological options for stimulation hearing. Bone

Table 1. Sentence recognition threshold in silence and signal/noise ratio, according to the evaluation conditions

Conditions	Silence (dBHL)		Signal to noise ratio (dB)	
	Average	SD	Average	SD
Without device	56.8^{a}	5.6	3.6^{a}	1.7
With hearing aids	$31.4^{b,a}$	8.3	0.5^{b}	3.5
With soft band	$33.2^{c,a}$	9.2	$-1.4^{c,a}$	3.7
Activation	$29.5^{d,a}$	11.4	$-2.6^{d,a}$	2.9
Six months of use	$25.9^{e,a}$	8.9	$-3.4^{e,a}$	3.6

Variance Test with Repeated Measures. Different letters (a, b, c, d, e) on the line indicate significant differences (p≤ 0.05) between the conditions evaluated (Tukey test)

Subtitle: dBHL = decibel hearing level; dB = decibel; SD = standard deviation

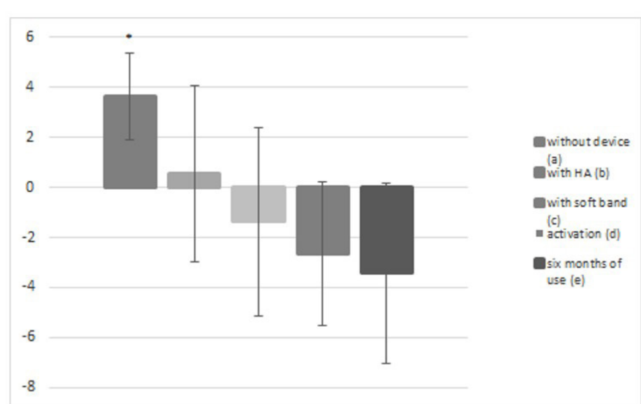

Figure 3. Signal to noise ratio (dB) obtained, according to the evaluation conditions

Subtitle: HA = hearing aids; *a - c, d, e; Different letters (a, b, c, d, e) in the column indicate significant differences (p ≤ 0.05) between the conditions evaluated conduction hearing aids were the most accessible possibility, not because they are easily adapted and accepted, but because they do not require surgery. The literature in the area describes the unfavorable aspects of this electronic device, ranging from uncomfortable sensations to the user to the difficulty of maintaining it in the correct position to achieve adequate and quality stimulation, especially in children.

From the perspective of the individual and/or family, as the resulting hearing loss is commonly conductive, mild, or moderate and, at first, with little impact on language development and oral communication, the individual's and/or family's adherence to treatment generally it was not effective, because the interest, most of the time, was in plastic surgery for anatomical correction, sustained, mainly, by the fear of prejudices observed in social life.

However, greater knowledge about the impact of conductive hearing loss on auditory processing, with possible academic difficulties, associated with advances in bone conduction hearing aid technology, has been observed in recent years, greater interest by professionals in research with users BAHA, in order to sustain the clinical practice.

In this context, the present study analyzed the benefits obtained from the unilateral indication of the Ponto Pro® System in individuals with bilateral hearing loss (Chart 1).

The Ponto® System is a BAHA, that is, a device capable of producing a sound sensation, independent of the function of the external and middle ear[15,16], as it transmits energy through the vibration of the skull. It is a percutaneous implantable device, that is, the coupling with the external unit occurs through a titanium pin implanted in the mastoid bone.

The surgical procedure is not considered complex by the specialist, as the structures of the ear are not manipulated during the intervention. Thus, no change in the thresholds obtained in pure tone audiometry by air and bone conduction after surgery is expected, as was observed in the present study (Figure 1) and consistent with the previously described[12].

In addition, studies with different percutaneous prostheses have already demonstrated their effectiveness, with significant improvement in tonal thresholds at all frequencies in free field audiometry[15-18], when comparing conditions without and with the electronic device. However, the greatest gain has been described for the highest[19] or medium[20] frequencies, which differs from the results obtained in this study, which maintained a similar gain between all frequencies surveyed, 0.5 to 4 kHz (Figure 2).

Speech perception was analyzed in previous studies through the recognition of monosyllabic and disyllabic words, with significant improvement in the post-adaptation moment of the device, both in silence[15,17,19,21] and in silence and noise[21]. A similar finding was obtained in the speech perception of sentences in silence (Table 1).

It should be noted, however, that it was found that the performance in speech perception in silence, at the time of activation and after six months of using the Ponto® System, did not show a significant difference (Table 1), which suggests that the benefit obtained by bone conduction amplification is immediate in individuals using hearing aids by air or bone conduction prior to surgery. Future studies should be carried out to verify whether this result is maintained, even in individuals who are not previous users of hearing aids, whether by air or bone conduction.

For the perception of speech with competitive noise, a better performance was found in the situation of difficult listening in conditions with the use of the Ponto® System, a result not observed for hearing aids by air or bone conduction (Table 1), a finding consistent with previous studies[22,23].

Contrary to what was previously described[12], the benefit of the Ponto® System for speech perception in noise was observed, even though it is a unilateral adaptation, a finding that allows us to question how much the stimulation by bone conduction also provides the stimulation of the contralateral cochlea, which it would simulate bilateral stimulation, an aspect that should be explored in future studies.

As with the auditory detection ability, there was no significant difference in performance for speech perception in noise at activation and after six months, despite the mean of the most negative signal/noise ratio after six months (Figure 3), a result similar to that of a study with one year of use of the device[24].

In general, the results obtained with the Ponto Pro® processor attached to an elastic band did not differ significantly from the post-surgical results (activation and six months of use), both in pure field audiometry and in speech perception in silence and noise. Therefore, this device allows the individual to make a more conscious decision regarding the surgery, with realistic expectations regarding the post-surgical benefits.

It is noteworthy that, despite the limitations of the present study regarding the number of participants and the heterogeneity of the casuistry, we can state that the use of percutaneous BAHA promotes significant improvement in the audiological data and speech recognition of the user.

CONCLUSION

The Ponto® System provided a benefit in hearing detection skills at all frequencies tested, demonstrated by the thresholds obtained in the free field, as well as in the recognition of sentences in silence and noise.

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