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Complications and audiological results of percutaneous bone-anchored hearing devices

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Abstract

Objective. To describe the post-operative complications and audiological results related to percutaneous bone-anchored hearing devices.

Methods. A retrospective review was conducted of 44 patients with bilateral conductive or mixed hearing loss who were implanted with unilateral Baha Connect or Ponto devices. A generalised linear model for repeated measurements was used.

Results. Twenty patients were Baha Connect users, and 24 were implanted with Ponto devices. Twenty-seven patients experienced complications. No fewer complications were found in the group of patients using longer abutments. When we compared the frequency of complications between Ponto and Baha Connect users, there was no statistically significant difference ($p = 0.90$). Free-field hearing thresholds were statistically significantly improved when we compared pre- and post-operative results ($p < 0.001$). Average speech perception also improved ($p < 0.001$).

Conclusion. Despite percutaneous bone-anchored hearing devices having a high rate of complications, they provide significant audiological benefits.

Main Article

Luiz Fernando Manzoni Lourençone takes responsibility for the integrity of the content of the paper

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Introduction

Bone conduction implants are osseo-integrated implants that transmit sound energy from vibrations in the skull, allowing patients with hearing loss to receive acoustic signals directly into the inner ear.[1] Bone-anchored hearing devices can be percutaneous or transcutaneous, depending on the presence or absence of a skin penetration abutment. Percutaneous implants can be active or passive.[2]

There are two percutaneous systems available: Baha® Connect system, developed by Cochlear Nordic company (Mölnlycke, Sweden), and Ponto®, created by Oticon Medical company (Askim, Sweden). Both systems comprise: an implant anchored in the temporal bone, a skin-penetrating abutment and an external sound processor.[3] The signal transmission is efficient at all frequencies because of the direct connection of the percutaneous systems.

In 1996, the Food and Drug Administration approved the use of Baha® bone-anchored hearing aids in the USA. The Baha Connect implant is made of titanium, and nowadays is available in 3 or 4 mm lengths. The abutment is covered with hydroxyapatite to prevent the problem of incompatibility between the skin and the titanium.[4] The abutment is available in 6, 8, 10, 12 and 14 mm lengths.[2] The Ponto system appeared in 2005; the implant is made of titanium, and the dimensions are 4.5 mm wide and 3–4 mm long. The abutment is available in 6 mm, 9 mm, 12 mm and 14 mm lengths, chosen according to skin thickness.[5]

Initially, the indications for these devices were conductive and mixed hearing loss, especially in cases where conventional hearing aids were contraindicated.[6] Later, there was expansion to adults and children with other ear pathologies, including congenital anomalies, patients who had undergone previous otological surgery and those with single-sided deafness.[7]

The degree of hearing loss accepted for rehabilitation with this type of prosthesis depends on the power of the processor. Patients with single-sided deafness must have a pure tone average of better than or equal to 20 dB HL in the contralateral, normal-hearing ear.[2]

Over time, several open surgical techniques have been described. Most of them included removing a significant amount of soft tissue in order to maintain thin skin thickness at the implant site. Later, there was a shift to reduce soft tissue resection and simplified linear incisions.[8] Hultcrantz[9] described minimally invasive Ponto surgery, using a 5 mm punch to remove a small fragment of soft tissue, sufficient to accommodate the Ponto system.

The Holgers[10] classification is used to describe post-operative skin reactions that occur around the abutment. The classification ranges from grade 0, when there is no irritation,

to grade 4, which corresponds to extensive soft tissue reaction when removal of the implant is necessary.

Percutaneous bone-anchored hearing devices can provide excellent audiological results. Patients who use the systems daily experience great satisfaction, reporting an important improvement in their quality of life.[11] It is possible that patients who experience a higher number of more severe skin complications indicate proportionally lower audiological benefits or, even, a reduction in quality of life. Better pre-operative counselling by the multidisciplinary team regarding the expected benefits of percutaneous bone-anchored hearing devices, as well as broad clarification of possible complications, may reduce the number of non-users in the future.[12]

This study was undertaken to describe the post-operative complications and audiological results related to percutaneous bone-anchored hearing devices.

Materials and methods

Study design

This is an observational and retrospective study, with longitudinal follow up. It was approved by the Research Ethics Committee of the Hospital for Rehabilitation of Craniofacial Anomalies of the University of São Paulo (Universidade de São Paulo). Data from patients followed up at the Hearing Health Division of the Hospital for Rehabilitation of Craniofacial Anomalies were retrospectively collected from their medical records. Written informed consent was obtained from patients.

Participant eligibility

Patients (adults and children) with bilateral conductive or mixed hearing loss, who underwent percutaneous bone-anchored hearing device surgery at our institution, were included if the following data were available: operation notes; medical records of out-patient follow up in the otorhinolaryngology department; and pure tone audiometry air and bone conduction values, free-field hearing thresholds, and average speech perception in silence and in noise conditions, in pre- and post-operative periods.

Patients whose medical records did not have enough information for the study, and patients who underwent the minimally invasive Ponto surgery technique, were excluded from the study.

Data collection

The data collected for the study of audiological results were: pure tone audiometry air and bone conduction values, free-field hearing thresholds, and average speech perception, in silence and in noise conditions. The applied procedures are described below.

For pure tone audiometry, tonal thresholds for air conduction were obtained at frequencies from 0.25 to 8 kHz, and thresholds for bone conduction were 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).

For free-field tonal audiometry, tonal thresholds were obtained at frequencies of 0.5–4 kHz for the modulated tone stimulus (warble), with the speaker positioned at 0° azimuth, 1 m from the individual, in an acoustic booth. For the realisation of pure tone and free-field audiometry, the Astera 2 Madsen (Otometrics) audiometer was used.

The speech reception threshold was measured aided and unaided,[13] in silence and in noise conditions. To this end, the method proposed by Costa *et al.*[14] was used, following the precepts of the Hearing in Noise Test.[15] In noise conditions, the noise level was fixed at 60 dB HL and the sentences were presented by a loudspeaker at an intensity of 65 dB HL, positioned at 0° azimuth, 1 m from the individual, in an acoustically treated room. The results are expressed as signal-to-noise ratio thresholds (in decibels).

All surgical procedures were performed by the same team, in a single stage, in an operating theatre and under general anaesthesia. Patients who underwent the linear surgical technique without reduction in skin thickness were included, as described below.

Step 1 involves measuring skin thickness. Step 2 concerns the surgical access incision. Specifically, an incision was made approximately 5–5.5 cm posteriorly and slightly superior to the external auditory canal on a line, with a 45-degree angle to the horizontal axis of the external auditory canal, after marking the skin with a surgical pen. Step 3 concerns the preparation of a quadrangular flap with an anterior pedicle: the skin was raised in the form of a flap, going deeper into the subcutaneous layer, but without removing the periosteum. Step 4 entails an incision in the central region of the periosteum and slight lateral divulsion of this periosteum. Step 5 involves drilling with a 3 mm deep drill, perpendicular to the bone, under continuous irrigation with saline solution. Step 6 concerns verification of the drilling depth and possible contact with the dura mater. Step 7 entails enlargement of the drilling diameter to the exact diameter of the implant. Step 8 involves positioning of the device in the prepared hole, outside the incision line. Step 9 concerns repositioning. Specifically, the flap was repositioned and then punched, and the abutment was connected to the implant. Step 10 concerns the suture: the flap was sutured with mononylon size 4.0. Step 11 concerns the dressing; specifically, a silicone button and Vaseline gauze were fixed around the abutment.

Patient age at the time of the processor activation, gender, congenital anomalies, hearing loss diagnosis, bone-anchored hearing device model used, characteristics of the implant and abutment used, date of surgery, date of activation, and post-operative complications were studied.

For standardisation purposes, complications were divided into two groups:[16] major and minor. Major complications were defined as those that required hospital care or those associated with significant morbidity, such as meningitis, brain abscess, osteitis or acute mastoiditis. Minor complications were divided into those requiring minimal out-patient treatment and out-patient revision surgery.

The Holgers classification[10] was used to classify skin complications: grade 0 reflects no skin complications, grade 1 represents a slightly reddish skin, grade 2 corresponds with reddish and moist skin, grade 3 reflects granulation tissue, and grade 4 represents an extensive soft tissue reaction with removal of the implant being necessary.

Statistical analysis

Results for continuous variables were expressed as mean and standard deviation (SD) values. Categorical variables were represented using absolute (n) and percentage frequencies. The distribution of data normality was observed using the Kolmogorov–Smirnov test. The Z score was used for non-normal distributions. Comparison of continuous data was

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Table 1. Associated syndromes

Syndrome	Patients (*n*)
Oculo-auriculo-vertebral spectrum	8
Pierre Robin sequence	1
Cornelia de Lange syndrome	1
Treacher Collins syndrome	20

performed using the generalised linear model for repeated measures.[17] Comparison of categorical data was performed using the Pearson's chi-square test and Fisher's exact test. A test result of $p \leq 0.05$ was considered statistically significant. The statistical analysis software used was SPSS, version 24.0.

Results

Based on the previously established criteria, the medical records of 49 patients were analysed. Five patients were excluded for the following reasons: four patients underwent the minimally invasive Ponto surgery technique and one patient missed the follow-up appointment after device activation. Thus, the final sample consisted of 44 patients, 26 females (59.1 per cent) and 18 males (40.9 per cent). The mean patient age at the moment of device activation was 21.9 years (SD, 8.30).

All patients were diagnosed with bilateral conductive or mixed hearing loss, and underwent unilateral Ponto or Baha Connect device surgery. All the patients used air or bone conduction hearing aids before the surgery. All of them had the external processor activated 12 weeks after the surgery. Thirty-eight of the patients had bilateral ear malformations and six had bilateral chronic otitis media sequelae. Associated syndromes are shown in Table 1.

Total devices

Twenty Baha Connect and 24 Ponto devices were used in 44 patients between July 2015 and April 2021. The characteristics of the implants and abutments used are described in Table 2.

Complications

During the average follow-up period of seven years, complications were recorded in 27 patients; no complications were reported for 17 patients. The total number of complications was 61, as some patients presented with complications more than once (Table 2). The median time between the date of the surgery and the occurrence of the first complication was 133 days. The 25th percentile was 80 days and the 75th percentile was 281 days.

When we compared the frequency of complications between Ponto and Baha Connect users, there was no statistically significant difference ($p = 0.90$).

In addition, no fewer complications were found when we studied the group of patients using longer abutments. For such an analysis, the 44 patients were divided into two groups: Ponto or Baha Connect System with 6 mm abutment users versus 9 mm or 12 mm abutment users. There was no statistical difference in this comparison ($p = 0.53$).

Severity of complications

Of the 61 complications, 2 were major complications: one patient had a skin infection around the implant, with extrusion of the device; the other had skin infection around the implant with associated myiasis. Both patients required hospitalisation. A total of 59 complications were classified as minor.

Severity of skin complications

Of the 61 skin complications recorded, 1 was Holgers grade 0, 22 were grade 1, 3 were grade 2, 18 were grade 3, and 17 were grade 4. The complication characterised as grade 0 occurred as spontaneous extrusion of the implant, without any associated skin complications. An overview of the skin reaction observations in the different subgroups is provided in Figure 1.

Eleven patients (25 per cent) had soft tissue overgrowth; all these patients required revision surgery. In three patients, soft tissue overgrowth occurred more than once. It was seen most frequently in one patient who was a Baha Connect (4 mm implant and 6 mm abutment) user. He experienced the complication four times in a period of nine months of implant use.

Implant extrusion

A total of five implants were lost or removed electively. The average time between the surgery and the implant loss was 345.60 days (SD, 272.73).

Audiological results

Figure 2 shows the mean pure tone thresholds (in decibel hearing level) obtained on pure tone audiometry, for air and bone conduction of the implanted ear. Comparison of the tested frequencies, in the pre- and post-operative periods, with

Table 2. Summary of percutaneous bone-anchored hearing devices used and complications recorded

Model & size of prostheses & abutments used	Number of patients per device	Patients with no complications recorded (*n*)	Patients with complications recorded (*n*)	Number of complications recorded
4 mm Baha with 6 mm abutment	20	8	12	35
3 mm Ponto with 6 mm abutment	4	1	3	11
4 mm Ponto with 6 mm abutment	1	0	1	1
3 mm Ponto with 9 mm abutment	7	3	4	4
4 mm Ponto with 9 mm abutment	9	4	5	8
4 mm Ponto with 12 mm abutment	3	1	2	2

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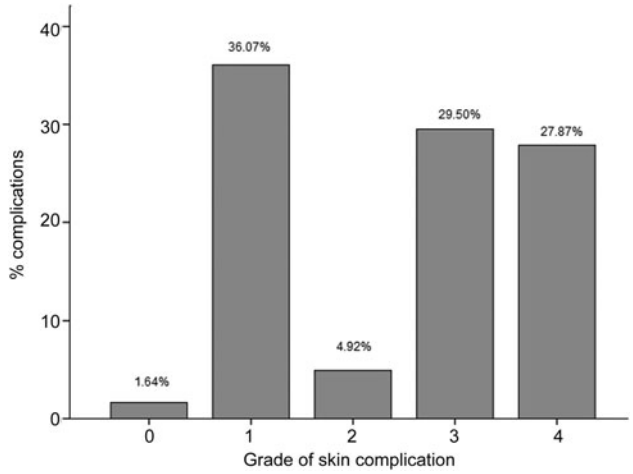

Figure 1. Holgers classification grades of skin complications.

individuals without percutaneous bone-anchored hearing devices did not reveal a statistically significant finding ($p > 0.05$).

Free-field hearing thresholds, based on the analysis of each frequency tested, improved when comparing the pre- and post-operative periods; this difference was statistically significant ($p < 0.001$) according to the generalised linear model for repeated measures (Table 3). In Figure 3, there was a significant reduction in the measurements of all frequencies when comparing the data from the time of device activation, or following six months of use, with the pre-operative period.

Regarding the recognition of sentences task performed in silence conditions, the same pre- and post-operative conditions mentioned above were compared. The analysis showed that the difference was statistically significant ($p < 0.001$), according to the generalised linear model for repeated measures. The average speech perception in quiet conditions in the Hearing in Noise Test improved from 56.86 dB HL (SD, 5.60) to 26.65 dB HL (SD, 6.60) after surgery. The same result was obtained in the noise condition, wherein the signal-to-noise ratio improved from 2.50 dB HL (SD, 3.10) to −2.73 dB HL (SD, 2.83) ($p < 0.001$); the details of these results are presented in Table 4. (Note that a lower signal-to-noise ratio indicates better performance.)

We divided the 44 patients into two groups to study whether patients who had complications throughout their use of bone-anchored hearing devices had a worse audiological result. One group consisted of patients diagnosed with Holgers grade 1–4 complications; the other group comprised patients who had not been diagnosed with any complication. We compared free-field hearing thresholds (mean per frequency) from the pre-operative period with those obtained after six months of bone-anchored hearing device use. No statistically significant difference was observed in this comparison at any frequency studied (Table 5).

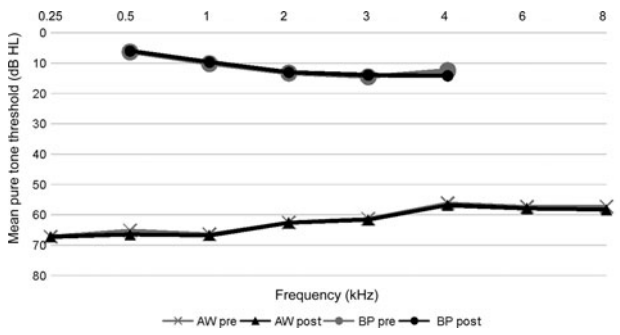

Figure 2. Mean pure tone thresholds on pure tone audiometry, for air and bone conduction of the implanted ear, in pre- and post-operative periods (at the time of device activation). AW pre = air conduction pathway pre-operative; AW post = air conduction pathway post-operative; BP pre = bone conduction pathway pre-operative; BP post = bone conduction pathway post-operative

Discussion

Bone-anchored hearing devices are effective solutions for the treatment of patients with unilateral or bilateral mixed and conductive hearing loss as well as single-sided deafness.[13]

Once a foreign body is placed through the skin into the bone, local skin reactions are possible. These reactions are usually initially managed with local treatment, without severe sequelae. However, a percentage of patients tend to have more significant problems, including skin overgrowth around the abutment, extrusion of the implant or more severe local infections.[18]

Mohamad *et al.*[19] published a systematic review of 30 articles, and recorded an overall incidence of skin complications of 9.4–84 per cent. Most of the patients in our study (61.36 per cent) had some complication after the surgery. These included: failure of osseointegration, skin reactions or infection, soft tissue hypertrophy, and overgrowth of the abutment.

Based on the existing literature, bone-anchored hearing aid surgery is considered a safe procedure for both adult and paediatric populations, with most complications being considered minor.[12] In agreement with what has been previously described in the literature, most of the complications reported in this study were classified as minor (96.7 per cent), but required medical follow up to guarantee successful treatment.

Regarding the Holgers classification of skin complications, 36.07 per cent of the complications in this study were Holgers grade 1, 4.92 per cent were grade 2, 29.50 per cent grade 3 and 27.87 per cent grade 4. This is in line with the findings of a meta-analysis by Kiringoda and Lustig[12] that included 2310 implants, which cited a grade 2 or higher skin complication rate ranging from 2.4 to 38.1 per cent. However, the study published by de Wolf *et al.*[20] showed skin reactions in a total of 172 cases; 61 per cent were classified as grade 1, 30.8 per cent as grade 2, 6.5 per cent as grade 3 and only 1.8 per cent as grade 4. When we compare only the most severe grades (3 and 4) between our study and that reported by de Wolf *et al.*,[20] we have a higher rate. This difference can be explained by a possible selection bias, as patients who have complications are more likely to come to the hospital for follow-up visits.

The incidence of skin overgrowth requiring revision surgery was 22.7 per cent in our patients, but in three patients this complication occurred more than once. Lloyd *et al.*[21] reported similar findings to ours in regard to skin overgrowth and revision surgery rates, which occurred in 31 per cent of their patients.

Complications can result in a loss of the implant, whether due to osseointegration failure, trauma, infection or lack of benefit to the patient. The implant loss rate reported in the review by Kiringoda and Lustig[12] ranged from 1.6 per cent to 17.4 per cent in adult and mixed populations. In our study, implant loss occurred in 11.4 per cent of the population.

The percutaneous device surgical procedures do not involve manipulation of the inner ear. Thus, no change in the thresholds obtained on pure tone audiometry, for air and bone conduction, after surgery is expected, as was observed in the

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Table 3. Summary and analysis of free-field thresholds on pure tone audiometry

Frequency & assessment time	Free-field thresholds (mean ± SD; dB HL)	*P*-values		
		Pre-operative *vs* at activation	At activation *vs* after 6 months of use	Pre-operative *vs* after 6 months of use
0.5 kHz				
– Pre-operative	60.37 ± 8.70	<0.001*	0.003*	<0.001*
– At activation	25.85 ± 8.30			
– After 6 months of use	23.17 ± 5.70			
0.75 kHz				
– Pre-operative	60.12 ± 9.65	<0.001*	0.32	<0.001*
– At activation	22.44 ± 5.50			
– After 6 months of use	21.71 ± 4.00			
1 kHz				
– Pre-operative	60.24 ± 10.95	<0.001*	1.0	<0.001*
– At activation	22.56 ± 5.30			
– After 6 months of use	22.07 ± 4.33			
1.5 kHz				
– Pre-operative	57.93 ± 11.30	<0.001*	0.15	<0.001*
– At activation	25.73 ± 8.20			
– After 6 months of use	24.27 ± 6.30			
2 kHz				
– Pre-operative	57.93 ± 10.50	<0.001*	0.15	<0.001*
– At activation	26.22 ± 7.75			
– After 6 months of use	24.15 ± 6.40			
3 kHz				
– Pre-operative	55.25 ± 10.45	<0.001*	0.17	<0.001*
– At activation	23.25 ± 6.95			
– After 6 months of use	22.25 ± 4.95			
4 kHz				
– Pre-operative	55.13 ± 10.60	<0.001*	1.0	<0.001*
– At activation	23.50 ± 7.90			
– After 6 months of use	23.75 ± 6.80			

*Indicates significant difference ($p \leq 0.05$). SD = standard deviation

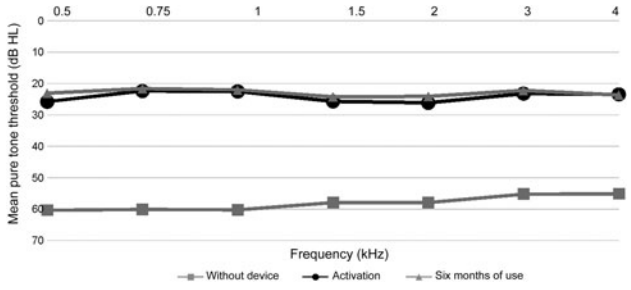

Figure 3. Mean pure tone thresholds on free-field audiometry, at pre- and post-operative periods (at the time of device activation and after six months of using bone-anchored hearing devices), in the implanted ear.

present study (Figure 2). The same was described previously by Celikgun and Kalcioglu.[22]

Studies of different percutaneous prostheses have demonstrated their effectiveness. Boleas-Aguirre *et al.*[23] described significant improvements in thresholds at all frequencies on free-field tonal audiometry with a bone-anchored hearing device. The same was evidenced in our study (Table 3 and Figure 3).

When we compared the audiological results at the time of device activation and after six months of using bone-anchored hearing devices, there was no significant difference (Table 3 and Table 4). This finding was observed in all audiological tests studied, with the exception of the 0.5 kHz frequency on free-field tonal audiometry. This suggests that the patient benefits from the device immediately, from the time of device activation, and this is maintained after six months of use. A similar result was recorded by Saliba *et al.*[24]

Speech perception was analysed through the recognition of sentences, with significant improvements following activation of the device, both in silence and in noise conditions (Table 4). A similar finding was obtained in a previous study.[3]

Although all the patients in our study were fitted with a percutaneous bone-anchored hearing device unilaterally, benefit was recorded for speech perception in noise (Table 4). This raises the question of how much the bone conduction stimulation also provides stimulation of the contralateral cochlea.

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Table 4. Sentence recognition thresholds in silence and signal-to-noise ratios, at each assessment time

Assessment time	Sentence recognition threshold in silence (mean ± SD; dB HL)	Signal-to-noise ratio (mean ± SD; dB HL)	*P*-value
Pre-operative	56.86 ± 5.60	2.50 ± 3.10	<0.001
At activation	26.65 ± 6.60*	−2.73 ± 2.83*	<0.001
After 6 months of use	24.25 ± 7.10†‡	−2.95 ± 3.10†	<0.001

*Significant difference between pre-operative and activation, $p < 0.001$; †significant difference between pre-operative and six months of use, $p < 0.001$; ‡no significant difference between activation and six months of use, $p = 0.026$. SD = standard deviation

Table 5. Summary and analysis of free-field thresholds on pure tone audiometry according to complications

		Free-field thresholds (mean ± SD; dB HL)			
Frequency	Post-operative skin complications	Pre-operative	*P*-value	After 6 months of use	*P*-value
0.5 kHz	No complications	58.33 ± 7.30	0.25	21.17 ± 2.20	0.06
	Holgers grade 1–4	61.40 ± 9.40		24.58 ± 6.90	
0.75 kHz	No complications	59.11 ± 9.70	0.73	20.60 ± 1.70	0.13
	Holgers grade 1–4	60.20 ± 10.00		22.50 ± 4.90	
1 kHz	No complications	58.33 ± 10.43	0.51	21.47 ± 4.25	0.46
	Holgers grade 1–4	60.60 ± 11.60		22.50 ± 4.42	
1.5 kHz	No complications	56.50 ± 10.70	0.68	22.64 ± 4.00	0.16
	Holgers grade 1–4	58.00 ± 12.50		25.40 ± 7.35	
2 kHz	No complications	57.35 ± 10.00	0.98	24.10 ± 7.10	0.98
	Holgers grade 1–4	57.40 ± 11.70		24.20 ± 6.00	
3 kHz	No complications	53.75 ± 7.20	0.68	25.60 ± 16.85	0.44
	Holgers grade 1–4	55.20 ± 13.00		22.70 ± 5.90	
4 kHz	No complications	54.00 ± 5.85	0.69	26.50 ± 18.10	0.68
	Holgers grade 1–4	55.40 ± 12.82		24.780 ± 8.00	

SD = standard deviation

Limitations and improvements

There is an evident scarcity of articles encompassing both brands of percutaneous bone-anchored hearing devices studied, which, while representing a limiting factor for the present study, highlights its innovative character. This study has limitations, most notably: the retrospective nature of data collection, which relies on good clinical documentation and appropriate follow up; the small sample size; and the heterogeneity of the study population. Nevertheless, it is possible to affirm that this auditory rehabilitation promotes significant improvement in the audiological results and speech recognition of device users, although it may present some complications.

- This is the first research article to compare the frequency of complications between Ponto and Baha Connect device users
- The occurrence of post-operative complications is well established; however, most complications were considered minor
- No fewer complications were found when patients using longer abutments were studied
- Free-field hearing thresholds, based on analysis of each frequency tested, significantly improved post-operatively compared with pre-operative findings
- Speech perception was analysed through sentence recognition, with significant improvement both in silence and in noise conditions
- It is not possible to determine whether patients who had complications throughout their use of bone-anchored hearing devices had a worse audiological result

A prospective cohort study with a larger number of patients could provide more reliable results regarding the occurrence of post-operative complications, especially those classified as Holgers grade 1 and 2, data that can be lost in a retrospective study. Patients may not attend the follow-up service because complications are only minor, and these complications are then not recorded on the medical record.

Conclusion

The current study highlights the high frequency of complications associated with percutaneous bone-anchored hearing devices, regardless of whether Ponto or Baha Connect devices were used. However, these devices showed audiological benefit in all frequencies tested, both in the free-field hearing thresholds and in the speech perception in silence and in noise conditions. Therefore, informing the patient about potential adverse effects and the need for continued care of the devices is necessary. Skin care around the abutment and follow up with the attending physician can be important to reduce complications.

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Competing interests. None declared

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