UNIVERSIDADE DE SÃO PAULO
HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAS

ANA CAROLINA SOARES SUCCAR

# Complications and audiological results of percutaneous bone-anchored hearing devices

# Complicações e resultados audiológicos de próteses auditivas percutâneas ancoradas ao osso

BAURU
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Dissertação constituída por artigo apresentada ao Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo para obtenção do título de Mestre em Ciências da Reabilitação, na área de concentração Fissuras Orofaciais e Anomalias Relacionadas.

Orientador: Prof. Dr. Luiz Fernando Manzoni Lourençone

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Ana Carolina Soares Succar

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## DEDICATÓRIA

À minha família, base da pessoa que me tornei, por todo amor, incentivo e apoio. Em especial aos meus pais, responsáveis pelos ensinamentos necessários para minha construção pessoal, profissional e acadêmica.

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*“Educar é realizar a mais bela e complexa arte da inteligência. Educar é acreditar na vida e ter esperança no futuro”.*

***Augusto Cury***

## RESUMO

Objetivo: Descrever as complicações pós-operatórias e resultados audiológicos dos pacientes submetidos à cirurgia para colocação de próteses auditivas ancoradas ao osso (PAAO) percutâneas. Método: Análise retrospectiva dos prontuários de 44 pacientes com deficiência auditiva condutiva ou mista bilateral, que realizaram cirurgia para colocação da PAAO sistema Baha Connect® ou Ponto® unilateral, com análise pelo Modelo Linear Generalizado (GLM) para medidas repetidas. Resultados: Foram utilizados 20 Baha® Connect e 24 Ponto® e identificadas complicações em 27 pacientes. Ao compararmos usuários do sistema Ponto® e Baha® Connect, não houve diferença estatística entre as marcas no que se refere à frequência das complicações ($p=0,90$). Os limiares auditivos obtidos em campo livre melhoraram quando comparamos os dados pré e pós operatórios ($p<0,001$). No que se refere à percepção da fala, as análises mostraram melhora estatisticamente significante ($p<0,001$). Conclusão: Foi destacada a alta frequência de complicações associadas às PAAO percutâneas. Entretanto, demonstrou benefício audiológico em todos os testes estudados.



Palavras-chave: prótese osteoancorada; osteointegração; complicações pós-operatórias; aparelhos auditivos; audiologia.

## ABSTRACT

### Complications and audiological results of percutaneous bone-anchored hearing devices

Background: To describe the postoperative complications and audiological results related to percutaneous bone-anchored hearing devices (BAHDs). Methods: A retrospective review of 44 patients with bilateral conductive or mixed hearing loss who were implanted with unilateral Baha Connect® or Ponto®. Generalized Linear Model (GLM) for repeated measurements was used. Results: Twenty patients were Baha® Connect users, and twenty-four were implanted with Ponto®. Twenty-seven patients had experienced complications. When we compared the frequency of complications between Ponto® and Baha® Connect users, there was no statistical significance ($p=0.90$). Free-field hearing thresholds were statistically significantly improved when we compared preoperative and postoperative results ($p<0,001$). The average speech perception also improved ($p<0,001$). Conclusion: In spite of percutaneous BAHDs having a high rate of complications, they provide significant audiological benefits.



Keywords: bone-anchored prosthesis; osseointegration; postoperative complications; hearing aids; audiology.

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## LIST OF ACRONYMS

| | |
|---|---|
| BAHDs | Bone-anchored hearing devices |
| FDA | Food and Drug Administration |
| GLM | Modelo Linear Generalizado |
| HINT | Hearing in noise test |
| HL | hearing level |
| HRAC | Hospital de Reabilitação de Anomalias Craniofaciais |
| MIPS | Minimally Invasive Ponto Surgery |
| OAVS | Oculo-auriculo-vertebral spectrum |
| PAAO | Próteses auditivas ancoradas ao osso |
| PTA | Pure tone average |
| SD | Standard deviation |
| SNR | Signal-to-noise ratio |
| SSD | Single side deafness |
| USP | Universidade de São Paulo |

**SUMMARY**

# 1 Introduction

# 1 INTRODUCTION

Bone conduction implants are osseointegrated systems 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 (BAHDs) can be percutaneous or transcutaneous, depending on the presence or not 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 AB company, located in Mölnlycke, Västra Götaland, Sweden and Ponto®, created by Oticon Medical AB company, located in Askim, also in Sweden.

Both systems were built with the same principle: 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 (FDA) approved the use of Baha® in the United States of America. The Baha® Connect implant is made of titanium and nowadays is available in 3 or 4mm lengths. The abutment is covered with hydroxyapatite in order to prevent the problem of incompatibility between the skin and the titanium.[4] The abutment is available in 6, 8, 10, 12 e 14mm lengths.[2]

The Ponto® system appeared in 2005; the implant is made of titanium, and the dimensions are: 4.5-mm-wide and 3 or 4mm long. The abutment is available in 6mm, 9mm, 12mm e 14mm lengths, chosen according to skin thickness.[5]

Initially, the indications for these devices were for conductive and mixed hearing loss, especially when conventional hearing aids were contraindicated.[6] Later, there was expansion to adults and children with other pathologies of the ears, including congenital anomalies, patients with previous otological surgery and single side deafness (SSD).[7]

The degree of hearing loss accepted for rehabilitation with this type of prosthesis depends on the power of the processor. Patients with SSD must have a pure tone average (PTA) of better than or equal to 20 dB hearing level (HL) in the contralateral, normal hearing ear.[8]

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] in 2011, described Minimally Invasive Ponto Surgery (MIPS), using a 5mm punch to remove a small fragment of soft tissue, sufficient to accommodate the Ponto® system.[9]

The Holgers classification is used to describe postoperative skin reactions that occur around the abutment. The classification ranges from grade 0 (zero), when there is no irritation, to grade 4 (four), which corresponds to extensive soft tissue reaction when removal of the implant is necessary.[10]

Percutaneous BAHDs 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 experienced a higher number of more severe skin complications indicate proportionally lower audiological benefits or, even, a reduction in the levels of quality of life. Better preoperative counseling by the multidisciplinary team regarding the expected benefits of percutaneous BAHDs, as well as broad clarification of possible complications, may reduce the number of non-users in the future.[12]

# 2 Objectives

## 2 OBJECTIVES

This study was undertaken to describe the postoperative complications and audiological results related to percutaneous bone-anchored hearing devices (BAHDs).

# 3 Article

## 3 ARTICLE

The article presented in this Dissertation was written according to the The Journal of Laryngology and Otology instructions and guidelines for article submission.

# Complications and audiological results of percutaneous bone-anchored hearing devices

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## Abstract

**Background**: To describe the postoperative complications and audiological results related to percutaneous bone-anchored hearing devices (BAHDs).
**Methods**: A retrospective review of 44 patients with bilateral conductive or mixed hearing loss who were implanted with unilateral Baha Connect® or Ponto®. Generalized Linear Model (GLM) for repeated measurements was used.
**Results**: Twenty patients were Baha® Connect users, and twenty-four were implanted with Ponto®. Twenty-seven patients had experienced complications. When we compared the frequency of complications between Ponto® and Baha® Connect users, there was no statistical significance (p=0.90). Free-field hearing thresholds were statistically significantly improved when we compared preoperative and postoperative results (p<0,001). The average speech perception also improved (p<0,001).
**Conclusion**: In spite of percutaneous BAHDs having a high rate of complications, they provide significant audiological benefits.

## Keywords
Bone-Anchored Prosthesis; Osseointegration; Postoperative Complications; Hearing Aids; Audiology.

## Introduction

Bone conduction implants are osseointegrated systems that transmit sound energy from vibrations in the skull, allowing patients with hearing loss to receive acoustic signals directly into the inner ear.[1]

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Initially, the indications for these devices were for conductive and mixed hearing loss, especially when conventional hearing aids were contraindicated.[6] Later, there was expansion to adults and children with other pathologies of the ears, including congenital anomalies, patients with previous otological surgery and single side deafness (SSD).[7]

The degree of hearing loss accepted for rehabilitation with this type of prosthesis depends on the power of the processor. Patients with SSD must have a pure tone average (PTA) of better than or equal to 20 dB hearing level (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 (MIPS), using a 5mm punch to remove a small fragment of soft tissue, sufficient to accommodate the Ponto® system.

The Holgers[10] classification is used to describe postoperative skin reactions that occur around the abutment. The classification ranges from grade 0 (zero), when there is no irritation, to grade 4 (four), which corresponds to extensive soft tissue reaction when removal of the implant is necessary.

Percutaneous BAHDs 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 experienced a higher number of more severe skin complications indicate proportionally lower audiological benefits or, even, a reduction in the levels of quality of life. Better preoperative counseling by the multidisciplinary team regarding the expected benefits of percutaneous BAHDs, 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 postoperative complications and audiological results related to percutaneous BAHDs.

## 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). This is a retrospective study. Data from the patients followed up at Hearing Health Division of Hospital for Rehabilitation of Craniofacial Anomalies (HRAC) were retrospectively collected from their medical records. At the time of submission of the research project to the ethics committee, written informed consent was dispensed.

### *Participant eligibility*

Patients (adults and children) with bilateral conductive or mixed hearing loss, who underwent percutaneous bone-anchored hearing device surgery at our institution and who present the following data in the medical record: the operation note, medical record of outpatient follow-up in the otorhinolaryngology department, pure-tone audiometry air and bone conduction, free field hearing thresholds and average speech perception in silence and in noise conditions in pre and postoperative periods.

Patients whose medical records did not have enough information for the study and patients who underwent MIPS 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, free-field hearing thresholds and average speech perception, in silence and in noise conditions. The applied procedures 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 to 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.

The speech reception threshold was measured aided and unaided,[13] in silence and in noise. To this end, the method proposed by Costa[14] was used, following the precepts of the hearing in noise test (HINT).[15] In noise conditions, the noise level was fixed at 60 dB HL and the sentences were presented by a loudspeaker intensity of 65 dB HL positioned at 0º azimuth, one meter from the individual, in an acoustically treated room. The result was expressed as the signal-to-noise ratio (SNR) threshold in dB.

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

- Step 1- Measuring skin thickness;
- Step 2 - Surgical access incision: An incision was made approximately 5 to 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 and marking the skin with a surgical pen.

- Step 3 - 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 - Incision in the central region of the periosteum and slight lateral divulsion of this periosteum.
- Step 5 - Drilling with a 3mm deep drill, perpendicular to the bone and under continuous irrigation with saline solution.
- Step 6 - Verification of the drilling depth and possible contact with the dura mater.
- Step 7 - Enlargement of the drilling diameter to the exact diameter of the implant.
- Step 8 - Positioning of the device in the prepared hole, outside the incision line.
- Step 9 - Retail repositioning: The flap was repositioned and then punched and the abutment was connected to the implant.
- Step 10 - Suture: The flap was sutured with mononylon 4.0.
- Step 11 - Dressing: A silicone button and vaseline gauze were fixed around the abutment.

Age at the time of the processor activation, gender, congenital anomalies, hearing loss diagnosis, BAHD model used, characteristics of the implant and abutment used, date of surgery, date of activation and postoperative complications were studied.

For standardization purposes, complications were divided into two groups:[16] major and minor complications. Major was defined as those who required hospital care or with significant associated morbidity, such as meningitis, brain abscess, osteitis or acute mastoiditis, while minor complications were divided into those requiring minimal outpatient treatment and outpatient revision surgery.

To classify skin complications, the Holgers classification[10] was used: Grade 0 (zero) being compatible with no complications, Grade 1 (one) slightly reddish, Grade 2 (two), reddish and moist, Grade 3 (three), granulation tissue and Grade 4 (four), extensive soft tissue reaction when removal of the implant is necessary.

### *Statistical analysis*

Results for continuous variables were expressed as mean and standard deviation (SD). Categorical variables were represented using absolute (n) and percentage (%) frequencies. The distribution of data normality was observed using the Kolmogorov-Smirnov test. Z score was used for non normal distributions. Comparison of continuous data was performed using the Generalized Linear Model (GLM) for repeated measures.[17] Comparison of categorical data was performed using Pearson's chi-squared test and Fisher's exact test. A test result $p \leq 0.05$ was considered statistically significant. The statistical analysis software used was SPSS, version 24.0.

## Results

Given the previously established criteria, the medical records of 49 patients were analyzed; five were excluded due to the following reasons: four patients underwent the MIPS surgical technique and one patient missed the follow-up after activation. Thus, the final sample consisted of 44 patients, 26 (59.1%) female and 18 (40.9%) male. The mean age at the moment of 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®. All the patients used air or bone conduction hearing aids before the surgery. All of them had the external processor activated twelve weeks after the surgery.

Of these individuals, 38 had bilateral ear malformations and 6 had bilateral chronic otitis media sequelae. Associated syndromes are shown in Table 1.

**Table 1.** Associated syndromes

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

## *Total devices*

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

**Table 2.** Characteristics of percutaneous BAHDs used, number of patients per devices, number of complications recorded

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

## *Complications*

During the average follow-up period of 7 years, complications were recorded in 27 patients while in 17 patients it was not shown. The total number of complications was 61, since there were patients who presented 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 and the 75th percentile was 281 days.

When we compared the frequency of complications between Ponto® and Baha® Connect users there was no statistical significance (p=0.90).

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 2 groups: one group was composed of Ponto® or Baha® Connect System with 6mm abutments users versus 9 or 12mm abutments 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 skin infection around the implant, with extrusion of the device, and the other had skin infection around the implant with associated myiasis. Both patients required hospitalization. A total of 59 complications were classified as minor.

## *Severity of skin complications*

Of the 61 complications recorded, 1 was Holgers grade 0, 22 grade 1, 3 grade 2, 18 grade 3, and 17 were grade 4. The complication characterized as grade 0 occurred 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.

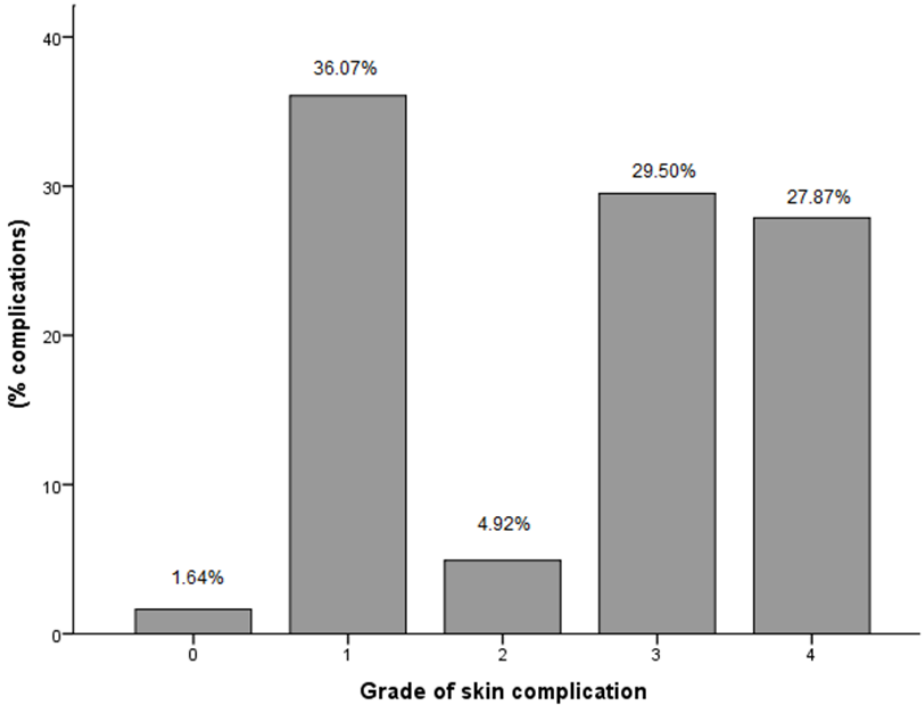


**Fig. 1.** Holgers classification

Eleven patients (25%) had soft tissue overgrowth; all 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 9 months of implant use.

## *Extrusion of the implant*

A total of 5 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 of pure tone thresholds (dB HL) obtained in pure tone audiometry, by air and bone conduction of the implanted ear. Comparing the tested frequencies in the

preoperative and postoperative periods, with individuals without electronic devices, was not considered statistically significant (p> 0.05).

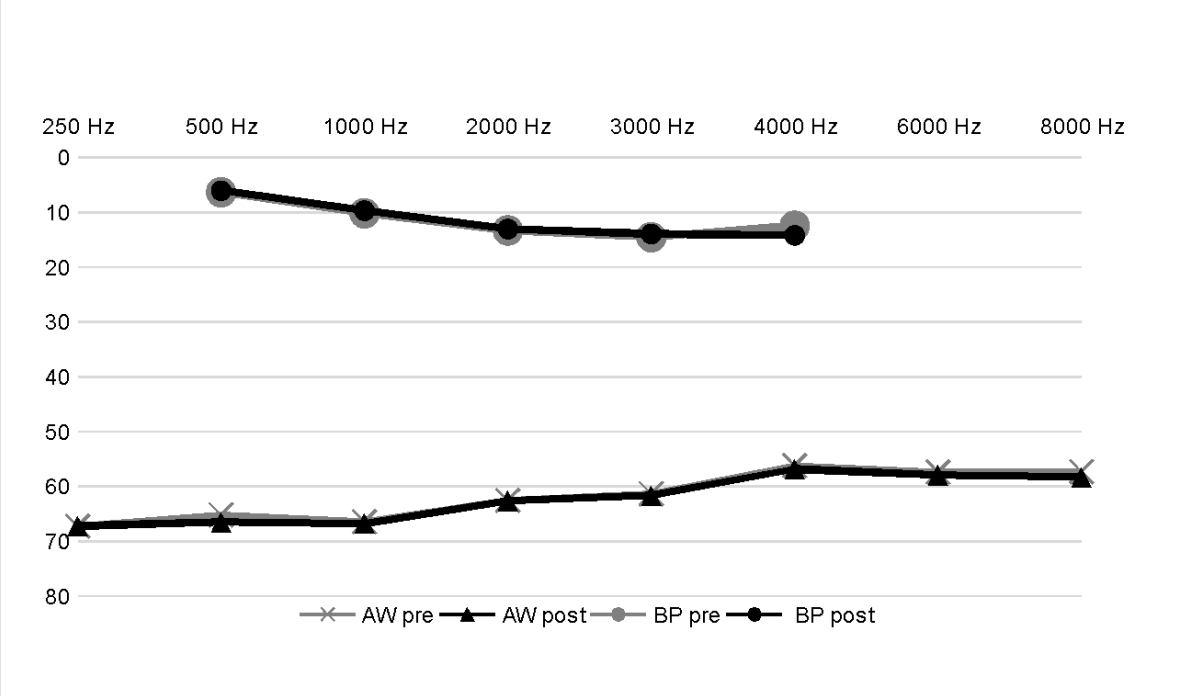


**Fig. 2.** Mean of pure tone thresholds (dB HL) obtained in pure tone audiometry, by air and bone conduction of the implanted ear, in preoperative and postoperative periods (at the time of activation)
**Subtitle**: Hz = hertz; AW pre = airway preoperative; AW post = airway postoperative; BP pre = bone-pathway preoperative; BP post = bone-pathway postoperative.

Free-field hearing thresholds, the analysis of each frequency tested, improved when comparing the preoperative and postoperative periods, this difference was statistically significant (p<0.001) (Table 3), generalized linear model (GLM) for repeated measures. In Figure 3 it was highlighted that there was a significant reduction in the measurements of all frequencies when comparing the data from the activation of the device or six months of use with the preoperative period.

**Table 3.** Mean of pure tone thresholds (dB HL) obtained in free-field hearing thresholds, the analysis of each frequency tested, according to the evaluation conditions

| **Frequencies** | **Mean (dBHL ± SD)** | **P valor** | | |
|---|---|---|---|---|
| | | **Preoperative vs activation** | **Activation vs six months of use** | **Preoperative vs six months of use** |
| **500 Hz** | | | | |
| Preoperative | 60.37 ± 8.70 | <0.001* | 0.003* | <0.001* |
| Activation | 25.85 ± 8.30 | | | |
| Six months of use | 23.17 ± 5.70 | | | |
| **750 Hz** | | | | |
| Preoperative | 60.12 ± 9.65 | <0.001* | 0.32 | <0.001* |
| Activation | 22.44 ± 5.50 | | | |
| Six months of use | 21.71 ± 4.00 | | | |

| | | | | |
|---|---|---|---|---|
| **1000Hz** | | | | |
| Preoperative | 60.24 ± 10.95 | <0.001* | 1.0 | <0,001* |
| Activation | 22.56 ± 5.30 | | | |
| Six months of use | 22.07 ± 4.33 | | | |
| **1500Hz** | | | | |
| Preoperative | 57.93 ± 11.30 | <0.001* | 0.15 | <0,001* |
| Activation | 25.73 ± 8.20 | | | |
| Six months of use | 24.27 ± 6.30 | | | |
| **2000Hz** | | | | |
| Preoperative | 57.93 ± 10.50 | <0.001* | 0.15 | <0,001* |
| Activation | 26.22 ± 7.75 | | | |
| Six months of use | 24.15 ± 6.40 | | | |
| **3000Hz** | | | | |
| Preoperative | 55.25 ± 10.45 | <0.001* | 0.17 | <0,001* |
| Activation | 23.25 ± 6.95 | | | |
| Six months of use | 22.25 ± 4.95 | | | |
| **4000Hz** | | | | |
| Preoperative | 55.13 ± 10.60 | <0.001* | 1.0 | <0,001* |
| Activation | 23.50 ± 7.90 | | | |
| Six months of use | 23.75 ± 6.80 | | | |

*indicate significant differences ($p \leq 0.05$)
**Subtitle**: dBHL = decibel hearing level; dB = decibel; SD = standard deviation

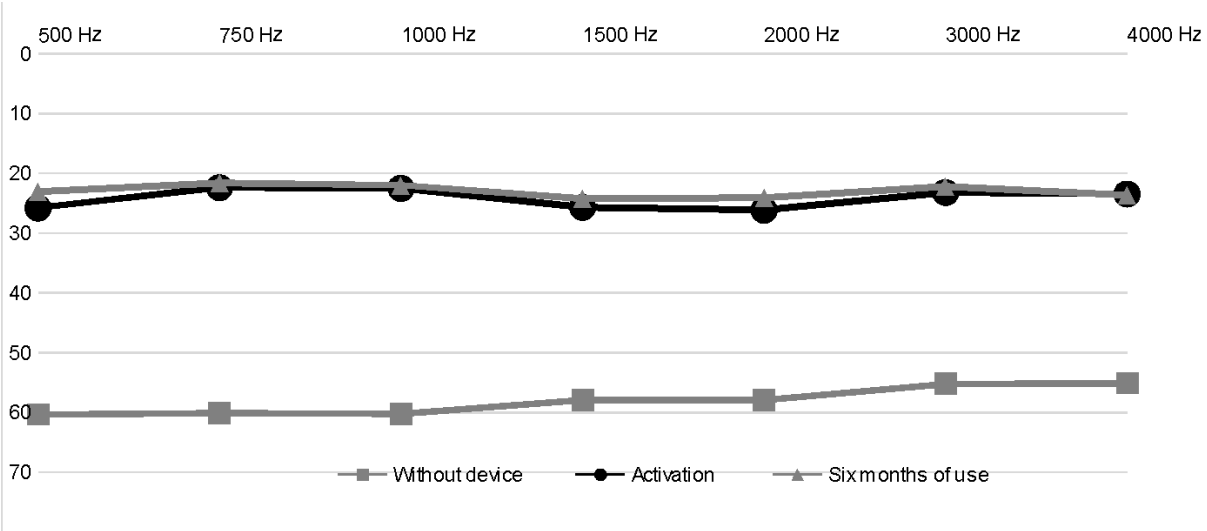


**Fig. 3.** Mean of pure tone thresholds (dB HL) obtained in free field audiometry, in preoperative and postoperative periods (at the time of activation and after six months of using BAHDs) of the implanted ear
**Subtitle**: Hz = hertz.

As for the performance in the recognition of sentences in silence, the same pre and postoperative conditions mentioned above were compared. The analysis showed that difference was statistically significant (p<0.001), GLM for repeated measures. The average speech perception in quiet conditions in the HINT 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, SNR 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 and Figures 4, 5. It is important to emphasize that when signal-to-noise ratio is lower, better is the patient's performance.

**Table 4.** Sentence recognition threshold in silence and signal-to-noise ratio, according to the evaluation conditions

| **Group** | **Silence (dB HL)** | **Signal-to-noise ratio (dB HL))** | **p-value** |
|---|---|---|---|
| | **Mean ± SD** | **Mean ± SD** | |
| Without device | 56.86 ± 5.60 | 2.50 ± 3.10 | <0.001 |
| Activation | 26.65 ± 6.60 a | -2.73 ± 2.83 d | <0.001 |
| Six months of use | 24.25 ± 7.10 bc | -2.95 ± 3.10 e | <0.001 |

a (significant differences between preoperative and activation), p<0.001.
b (significant differences between preoperative and six months of use), p<0.001.
c (no significant differences between activation and six months of use), p=0.026
d (significant differences between preoperative and activation), p<0.001.
e (significant differences between preoperative and six months of use), p<0.001.

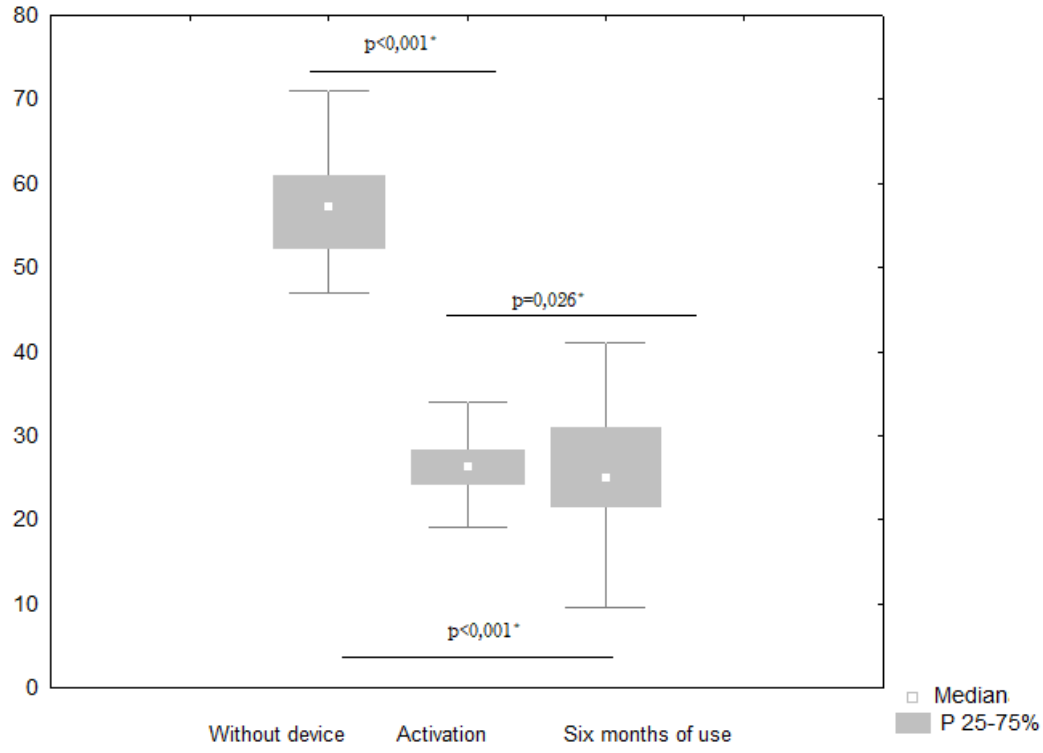


**Fig. 4.** Comparison between preoperative and postoperative (at the time of activation and after six months of using BAHDs) speech perception in quiet condition

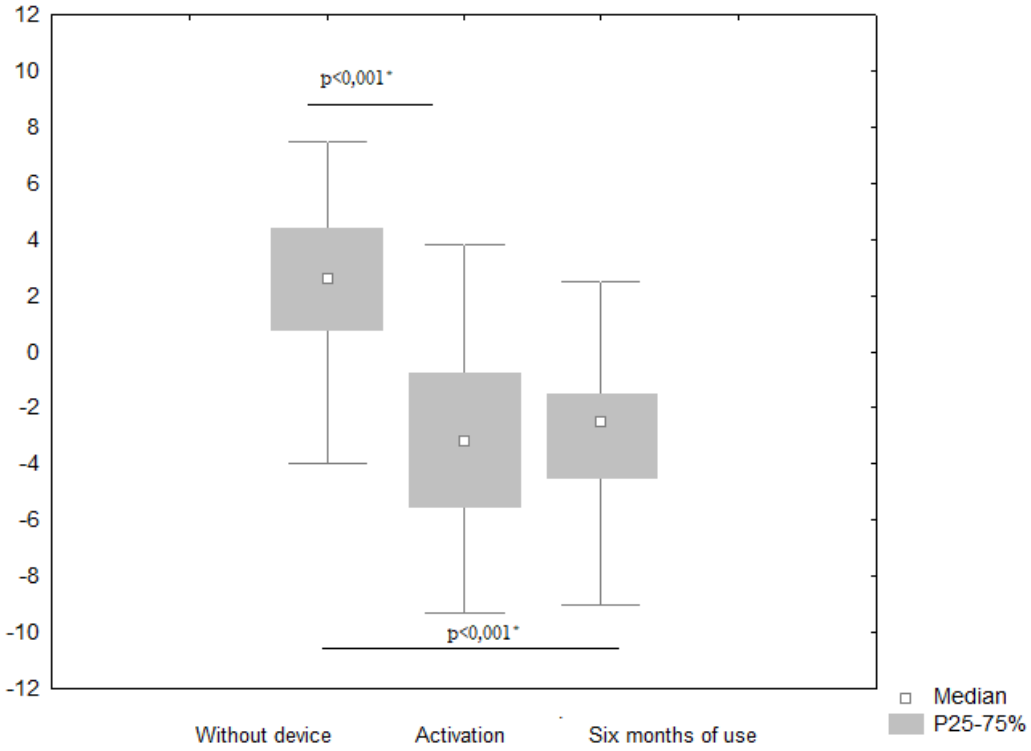


**Fig. 5.** Comparison of preoperative and postoperative (at the time of activation and after six months of using BAHDs) signal-to-noise ratios in the hearing in noise test

In order to study if patients who had complications throughout the use of BAHDs had a worse audiological result, we divided the 44 patients into 2 groups: Group 1, composed of patients who were diagnosed with Holgers complications from grade 1 to 4; and Group 0, composed of patients who have not been diagnosed with any complication. We compared free-field hearing thresholds (mean per frequency) between preoperative period and after six months of BAHD use. No statistical significance was observed in this comparison at any frequency studied (Table 5).

**Table 5.** Mean of pure tone thresholds (dB HL) obtained in free field audiometry, in preoperative and after six months of using BAHDs of the implanted ear, according to complications

| Frequencies | Groups | Pré | | Six months of use | |
|---|---|---|---|---|---|
| | | Mean (dBHL ± SD) | p-value | Mean (dBHL ±SD) | p-value |
| 500 Hz | 0 | 58.33 ±7.30 | 0.25 | 21.17±2.20 | 0.06 |
| | 1 | 61.40±9.40 | | 24.58±6.90 | |
| 750Hz | 0 | 59.11±9.70 | 0.73 | 20.60±1.70 | 0.13 |
| | 1 | 60.20±10.00 | | 22.50 ±4.90 | |
| 1000Hz | 0 | 58.33±10.43 | 0.51 | 21.47±4.25 | 0.46 |
| | 1 | 60.60±11.60 | | 22.50±4.42 | |
| 1500Hz | 0 | 56.50±10.70 | 0.68 | 22.64±4.00 | 0.16 |
| | 1 | 58.00±12.50 | | 25.40±7.35 | |
| 2000Hz | 0 | 57.35±10.00 | 0.98 | 24.10±7.10 | 0.98 |
| | 1 | 57.40±11.70 | | 24.20±6.00 | |

| | | | | | |
|---|---|---|---|---|---|
| 3000Hz | 0 | 53.75±7.20 | 0.68 | 25.60±16.85 | 0.44 |
| | 1 | 55.20±13.00 | | 22.70±5.90 | |
| 4000Hz | 0 | 54.00±5.85 | 0.69 | 26.50±18.10 | 0.68 |
| | 1 | 55.40±12.82 | | 24.780±8.00 | |

(group 0: composed of patients who have not been diagnosed with any complication; group 1: composed of patients who were diagnosed with Holgers complications from grade 1 to 4)

## Discussion

BAHDs are currently effective solutions for the treatment of patients with unilateral or bilateral mixed and conductive hearing loss, as well as SSD.[13]
Once a foreign body is placed through the skin into the bone, local skin reactions are possible. These reactions are usually treated at the beginning 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 that studied 30 articles and recorded that overall, skin complications ranged from 9.4 to 84%. Most of the patients in our study (61.36%) had some complication after the surgery, among them: failure of osseointegration, skin reactions or infection, soft tissue hypertrophy and overgrowth of the abutment.

Based on the existing literature, it is possible to say that bone-anchored aids surgery is a safe procedure for both adult and pediatric 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%), but required medical follow-up to guarantee a successful treatment.

Looking at the Holgers classification, 36.07% of the complications in this study were Holgers grade 1, 4.92% were grade 2, 29.50% grade 3 and 27.87% grade 4. This goes in the same line as a meta-analysis published by Kiringoda and Lustig[12] that included 2,310 implants and cited a grade 2 or higher skin complication rate ranging from 2.4 to 38.1%. However, the study published by de Wolf *et al.*[20] showed skin reactions in a total of 172 cases; 61% were classified as grade 1, 30.8% grade 2, 6.5% grade 3, and only 1.8% were grade 4. When we compare only the most severe grades (3 and 4) between our study and what was reported by de Wolf *et al.*[20], we have a higher rate. This difference can be explained by a possible selection bias, since patients who have complications are more likely to come to the hospital for follow-up visits.

The incidence of skin overgrowth requiring revision surgery occurred in 22.7% of our patients, but in three patients this complication occurred more than once. The experience published by Lloyd *et al.*[21] was similar to ours in regards to skin overgrowth and revision surgery rates, it occurred in 31% 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. Implant loss rate reported in the review by Kiringoda and Lustig[12] ranged from 1.6% to 17.4% in adult and mixed populations. In our study, implant loss occurred in 11.4% of the population.

The percutaneous systems surgeries do not involve manipulation of the inner ear. 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 2). The same was described earlier by Celikgun *et al.*[22]

Studies with different percutaneous prostheses have already demonstrated their effectiveness. Boleas-Aguirre *et al.*[23] described significant improvement in thresholds at all

frequencies in free field tonal audiometry with BAHD. The same was evidenced in our study (Table 3, Figure 3).

When we compared the audiological results at the time of activation and after six months of using BAHDs, it did not show a significant difference (Table 3, Table 4). It was observed in all audiological tests studied, with the exception of the 500 Hz frequency in the free-field tonal audiometry. It suggests that right at the moment of activation the patient already has access to the audibility of sounds, which was maintained after six months of use. A similar result was recorded by Saliba *et al*.[24]

Speech perception was analyzed through the recognition of sentences, with significant improvement in the post-adaptation moment of the device, both in silence and in noise. A similar finding was obtained in a previous study[3] (Table 4).

Although all the patients in our study were adapted with percutaneous BAHD unilaterally, benefit was recorded for speech perception in noise (Figure 5). This finding allows us to question how much the stimulation by bone conduction also provides the stimulation of the contralateral cochlea.

## Limitations and improvements

There is an evident scarcity of articles encompassing both brands of percutaneous BAHDs, 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 depends 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 the user, even though it may present some complications.

A prospective cohort study with a larger number of patients could provide more reliable results regarding the occurrence of postoperative complications, especially those classified as Holgers grade 1 and 2, data that can be lost in a retrospective study. Since there are minor complications, patients may not come to the service where the surgery was performed due to these complications, and they are not recorded on the medical record.

## Conclusion

The current study highlights the high frequency of complications associated with percutaneous BAHDs, regardless of whether Ponto® or Baha® Connect. However, it 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 the follow-up with the attending physician can be important to reduce complications.

### Acknowledgement

The authors would especially like to thank the entire team of professionals at the Hospital for Rehabilitation of Craniofacial Anomalies who collaborated to carry out this study.

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**Competing interests**

The authors report there are no competing interests to declare.

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# 4 Final Considerations

## 4 FINAL CONSIDERATIONS

1. When we compared the frequency of complications between Ponto® and Baha® Connect users there was no statistical significance.
2. No fewer complications have been found when we studied the group of patients using longer abutments.
3. Most complications were considered minor.
4. Free-field hearing thresholds, the analysis of each frequency tested, improved when comparing the preoperative and postoperative periods; these differences were statistically significant.
5. Speech perception was analyzed through the recognition of sentences, with significant improvement both in silence and in noise.
6. It was not possible to say that who had complications throughout the use of BAHDs had a worse audiological result.

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# Appendix

## APPENDIX A – Declaration of exclusive use of the article in dissertation/thesis

**DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN DISSERTATION/THESIS**

We hereby declare that we are aware of the article (Complications and audiological results of percutaneous bone-anchored hearing devices) will be included in Dissertation of the student Ana Carolina Soares Succar was not used and may not be used in other works of Graduate Programs at the Bauru School of Dentistry/University of São Paulo.

Bauru, march 3rd 2023

Ana Carolina Soares Succar — Author — Signature

Tyuana Sandim da Silveira Sassi — Author — Signature

Rubens Vuono de Brito Neto — Author — Signature

Luiz Fernando Manzoni Lourençone — Author — Signature

# Annexes

# ANNEX A – Proof of approval of the Ethics Committee in Research

USP - HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS DA UNIVERSIDADE DE SÃO PAULO -HRAC/USP

## PARECER CONSUBSTANCIADO DO CEP

**DADOS DO PROJETO DE PESQUISA**

**Título da Pesquisa:** Resultados audiológicos e complicações de próteses auditivas percutâneas ancoradas ao osso

**Pesquisador:** ANA CAROLINA SOARES SUCCAR

**Área Temática:**

**Versão:** 1

**CAAE:** 46627421.4.0000.5441

**Instituição Proponente:** Hospital de Reabilitação de Anomalias Craniofaciais da USP

**Patrocinador Principal:** Financiamento Próprio

**DADOS DO PARECER**

**Número do Parecer:** 4.741.479

**Apresentação do Projeto:**

Dados obtidos PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1742310.pdf 10/05/2021 13:50:08 e Ana_Carolina_Projeto.pdf 30/04/2021 16:26:49. Pesquisa de atualização da Ana Carolina Soares Succar, sob orientação de Prof. Dr. Luiz Fernando Manzoni Lourençone. Os implantes de condução óssea consistem em sistemas osteointegrados que transmitem o som através dos ossos do crânio, permitindo que os pacientes com perda auditiva possam receber sinais acústicos diretamente na orelha interna. As próteses auditivas ancoradas no osso (PAAO) se apresentam como soluções eficazes para o tratamento dos pacientes com perda auditiva mista e condutiva, unilateral ou bilateral, bem como para a deficiência auditiva neurossensorial unilateral. Os componentes do sistema percutâneo incluem um implante de titânio e um áudio processador, com ou sem pilar, sendo os referidos sistemas representados, em âmbito nacional, pelos seguintes: Baha (®) e Ponto (®). Como um corpo estranho é inserido no osso e através da pele, reações cutâneas locais são possíveis. As reações, via de regra, são tratadas com o simples cuidado local da ferida, sem sequelas significativas. No entanto, uma percentagem de pacientes tende a desenvolver problemas mais severos, incluindo crescimento excessivo da pele sobre o abutment, extrusão do implante e infecções locais mais graves da ferida operatória. O objetivo deste estudo é revisar a nossa experiência com os dispositivos de condução óssea percutâneo e descrever os resultados

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audiológicos e as complicações pós operatórias, por meio da análise retrospectiva dos prontuários de pacientes implantados com as prótese Baha (®) e Ponto (®)

**Objetivo da Pesquisa:**

Dados obtidos PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1742310.pdf 10/05/2021 13:50:08 e Ana_Carolina_Projeto.pdf 30/04/2021 16:26:49.

Segundo os autores os objetivos do estudo são: descrever os resultados audiológicos e as complicações pós operatórias dos pacientes submetidos à cirurgia para colocação de próteses auditivas percutâneas ancoradas ao osso, no Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo - USP, por meio da análise

retrospectiva dos prontuários.

**Avaliação dos Riscos e Benefícios:**

Dados obtidos PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1742310.pdf 10/05/2021 13:50:08 e Ana_Carolina_Projeto.pdf 30/04/2021 16:26:49

Riscos:

Os riscos são mínimos por se tratar de uma pesquisa com fontes secundárias de dados, o possível risco, seria a quebra de sigilo dos usuários submetidos à análise de prontuário. Em caso de riscos não previstos, a pesquisa será suspensa e a equipe de pesquisa assumirá as responsabilidades.

Benefícios:

A descrição das possíveis complicações e dos resultados audiológicos das próteses auditivas ancoradas no osso percutâneas representa a possibilidade de maior conhecimento do assunto, permitindo que os pacientes sejam conduzidos e adaptados da melhor maneira possível.

**Comentários e Considerações sobre a Pesquisa:**

Pesquisa com mérito científico. Trata-se de análise retrospectiva e descritiva de prontuários de todos os pacientes submetidos à cirurgia para colocação de próteses auditivas percutâneas ancoradas ao osso no Hospital de Reabilitação de Anomalias Craniofaciais da USP (HRAC/USP), na cidade de Bauru/SP, Brasil. Todos os procedimentos cirúrgicos foram realizados pela mesma equipe, em um único estágio, em centro cirúrgico e sob anestesia geral. A avaliação audiológica será realizada a partir da obtenção de dados dos seguintes testes: audiometria tonal liminar por conduções aérea e óssea , audiometria em campo livre e reconhecimento de sentenças no silêncio e no ruído. Todos os testes mencionados foram aplicados no período pré e pós operatório, o que permitirá a comparação dos resultados com e sem o processador de fala e se a prótese auditiva

percutânea ancorada ao osso contribuiu para a melhora da fala.
Critério de Exclusão:
Será considerado como critério de exclusão a falta de algum dado dentre aqueles requeridos, sendo assim, excluídos os prontuários que não apresentarem as informações suficientes para o estudo em questão.
Os autores esperam agregar conhecimento a respeito das possíveis complicações com a colocação das próteses auditivas percutâneas ancoradas ao osso e prever os resultados audiológicos com a utilização do sistema.

**Considerações sobre os Termos de apresentação obrigatória:**
Carta de encaminhamento; (Ana_Carolina_Carta.pdf 30/04/2021 16:12:19)
Formulário HRAC; (Ana_Carolina_Formulario.pdf 30/04/2021 16:13:11
Folha de Rosto da Plataforma Brasil;(Ana_Carolina_FR.pdf 30/04/2021 16:10:26)
Justificativa de Dispensa de TCLE;(Ana_Carolina_Dispensa.pdf 30/04/2021 16:14:42)
Termo de Compromisso, Confidencialidade e Autorização de Utilização de Dados em Projetos de Pesquisa (Ana_Carolina_Termo_Termo_Conf.pdf 30/04/2021 16:17:08)
Termo de Compromisso de Tornar Públicos os Resultados da Pesquisa e Destinação de Materiais ou Dados Coletados; (Ana_Carolina_Termo_Divulg.pdf 30/04/2021 16:16:29)
Termo de Compromisso do Pesquisador Responsável (Ana_Carolina_Termo_Pesq.pdf 30/04/2021 16:15:45)

**Recomendações:**
Não se aplica.

**Conclusões ou Pendências e Lista de Inadequações:**
Como o projeto não fere aspectos éticos, sugiro sua aprovação.

**Considerações Finais a critério do CEP:**
O pesquisador deve atentar que o projeto de pesquisa aprovado por este CEP refere-se ao protocolo submetido para avaliação. Portanto, conforme a Resolução CNS 466/12, o pesquisador é responsável por "desenvolver o projeto conforme delineado", se caso houver alterações nesse projeto, este CEP deverá ser comunicado em emenda via Plataforma Brasil, para nova avaliação.
Cabe ao pesquisador notificar via Plataforma Brasil o relatório final para avaliação. Os Termos de

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Consentimento Livre e Esclarecidos e/ou outros Termos obrigatórios assinados pelos participantes da pesquisa deverão ser entregues ao CEP. Os relatórios semestrais devem ser notificados quando solicitados no parecer.

**Este parecer foi elaborado baseado nos documentos abaixo relacionados:**

| Tipo Documento | Arquivo | Postagem | Autor | Situação |
|---|---|---|---|---|
| Informações Básicas do Projeto | PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1742310.pdf | 10/05/2021 13:50:08 | | Aceito |
| Projeto Detalhado / Brochura Investigador | Ana_Carolina_Projeto.pdf | 30/04/2021 16:26:49 | ANA CAROLINA SOARES SUCCAR | Aceito |
| Outros | Ana_Carolina_Termo_Termo_Conf.pdf | 30/04/2021 16:17:08 | ANA CAROLINA SOARES SUCCAR | Aceito |
| Outros | Ana_Carolina_Termo_Divulg.pdf | 30/04/2021 16:16:29 | ANA CAROLINA SOARES SUCCAR | Aceito |
| Outros | Ana_Carolina_Termo_Pesq.pdf | 30/04/2021 16:15:45 | ANA CAROLINA SOARES SUCCAR | Aceito |
| TCLE / Termos de Assentimento / Justificativa de Ausência | Ana_Carolina_Dispensa.pdf | 30/04/2021 16:14:42 | ANA CAROLINA SOARES SUCCAR | Aceito |
| Declaração de Instituição e Infraestrutura | Ana_Carolina_Formulario.pdf | 30/04/2021 16:13:11 | ANA CAROLINA SOARES SUCCAR | Aceito |
| Outros | Ana_Carolina_Carta.pdf | 30/04/2021 16:12:19 | ANA CAROLINA SOARES SUCCAR | Aceito |
| Folha de Rosto | Ana_Carolina_FR.pdf | 30/04/2021 16:10:26 | ANA CAROLINA SOARES SUCCAR | Aceito |

**Situação do Parecer:**
Aprovado

**Necessita Apreciação da CONEP:**
Não

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Continuação do Parecer: 4.741.479

BAURU, 28 de Maio de 2021

**Assinado por:**
**Renata Paciello Yamashita**
**(Coordenador(a))**

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