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Auditory Rehabilitation in Mixed Hearing Loss Due to Chronic Otitis Media Sequelae: Passive versus Active Transcutaneous Bone Conduction Implant

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Auditory Rehabilitation in Mixed Hearing Loss Due to Chronic Otitis Media Sequelae: Passive versus Active Transcutaneous Bone Conduction Implant

Short running head: Active Vs Passive BCI in MHL due to COM

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Author contributions

Study conception and design: Cagnacci Buzo B, Rincón Nossa LA. **Data collection:** Ordóñez Ordóñez LE, Caraballo Arias JA, González Eslait FJ, Monroy Barreneche JF, Guzmán Durán JE, Jaramillo R, Izquierdo JC. **Data analysis:** Ordóñez Ordóñez LE, Angulo Martínez ES, Cagnacci Buzo B, Rincón Nossa LA, Rojas Serrano ML**. Material preparation and first draft writing:** Ordóñez Ordóñez LE, Angulo Martínez ES, Rojas Serrano ML. **Writing, reviewing and editing of the manuscript:** Ordóñez Ordóñez LE, Angulo Martínez ES, Rojas Serrano ML, Caraballo Arias JA, González Eslait FJ, Monroy Barreneche JF, Guzmán Durán JE, Jaramillo R, Izquierdo JC. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Abstract

Purpose: To compare audiological outcomes and self-perceived benefits in patients with sequelae of chronic otitis media (COM) and mixed hearing loss (MHL) undergoing rehabilitation with either a passive transcutaneous bone conduction implant (PT-BCI) or an active transcutaneous bone conduction implant (AT-BCI).

Methods

A multicenter, prospective and observational analytical study in Colombia included patients receiving PT-BCI or AT-BCI. Main outcomes were pure-tone average (PTA=0.5-4Khz), high-frequency PTA (HF-PTA=4–8 kHz), and Client Oriented Scale of Improvement (COSI). Comparative analyses used two-way repeated-measures ANOVA (complete-case) followed by linear mixed-effects models for repeated measures (LMMs-RM) to address group imbalance and missing postoperative data, thereby optimizing statistical power.

Results

A total of 211 AT-BCI and 50 PT-BCI patients were included. Baseline characteristics were comparable, except for soft-tissue thickness. Both devices achieved significant improvements in PTA and HF-PTA at 3 and 12 months ($p<0.010$). LMMs-RM confirming significant effects of device type and time for both outcomes: for PTA (Type of device: $F_{(1,321)}=5.317$, $p=0.022$; Time: $F_{(2,321)}=201.179$, $p<0.001$) and for HF-PTA (Type of device: $F_{(1,320)}=5.665$, $p=0.018$; Time: $F_{(2,320)}=116.934$, $p<0.001$).

82 patients (88.2%) reported that their performance with the device was “Better”/“Much better” on the COSI scale, no statistically significant differences observed between the AT-BCI and PT-BCI groups ($p=0.283$).

Conclusions

AT-BCI provides a clinically meaningful auditory gain in both PTA and HF-PTA in patients with MHL secondary to COM. This level of audiological performance is achieved as early as the 3-month follow-up and is maintained over time, while remaining superior for HF-PTA to that obtained with PT-BCI.

Key words: Chronic Otitis Media; Auditory Rehabilitation; Mixed Hearing Loss; Bone Conduction Implant; Client Satisfaction Questionnaire

Introduction

Chronic otitis media (COM) is a persistent inflammatory disorder of the middle ear and mastoid cavity, typically presenting with recurrent otorrhea through a tympanic membrane perforation and associated hearing loss [1]. The World Health Organization estimates an incidence of approximately 4.8%, with 22.6% of cases occurring in children under five years of age [2]. More recent data indicate a global prevalence of around 3.8%, corresponding to nearly 297 million affected individuals worldwide [3]. The burden is disproportionately concentrated in low- and middle-income countries, which account for approximately 85% of cases; among these patients, 62% exhibit disabling hearing loss and 21.5% present with bilateral disease [3,4]. COM is a well-recognized cause of psychosocial, educational, and cognitive impairment [2,3].

COM most commonly leads to conductive hearing loss (CHL), primarily due to tympanic membrane perforation and/or ossicular chain (OC) disruption. In addition, sensorineural hearing loss (SNHL) may occur because of bacterial toxins and inflammatory mediators affecting the inner ear. Mixed hearing loss (MHL) reflects the coexistence of conductive and sensorineural components arising from combined impairment of sound transmission and cochlear function [5–7]. Longer disease duration, repeated surgical interventions, and advancing age have been associated with a greater SNHL component [6–9]. For instance, a study conducted in Bangladesh reported bone-conduction thresholds exceeding 20 dB HL in patients with disease duration longer than 15 years [6].

Management of COM sequelae is primarily surgical and includes tympanoplasty for restoration of the tympanic membrane and ossicular continuity, as well as mastoidectomy to re-establish ventilation of the middle ear and mastoid system [2,4]. Several factors have been proposed to influence surgical outcomes, including the presence of cholesteatoma, perforation size, OC status, revision procedures, middle ear volume, and surgeon experience [4,10,11].

Conversely, other studies suggest that tailoring the surgical approach to disease severity may yield comparable outcomes across a wide spectrum of presentations [12]. Reported anatomical success rates for tympanoplasty, defined by tympanic membrane integrity and infection control, range from 60% to 95% [11]. Functional success following ossiculoplasty has been described at 53–61%, using an air–bone gap (ABG) cutoff of less than 20 dB [10,13]. With respect to prosthetic reconstruction, success rates of approximately 70% have been reported for partial ossicular reconstruction prostheses (PORP) and 57% for total ossicular reconstruction prostheses (TORP) [14].

In patients who do not achieve adequate audiological outcomes after tympanomastoid surgery or OC reconstruction, conventional hearing aids are considered first-line rehabilitation. However, their effectiveness may be limited in cases with ABG greater than 30 dB, in canal wall-down mastoidectomy cavities where device use may compromise aeration and perpetuate otorrhea, and in patients with single-sided deafness (SSD) [15,16]. For this subset of patients, bone conduction implants (BCIs), which transmit sound via bone-conducted vibrations to the inner ear, represent an effective alternative for CHL, MHL, and SSD [16–18].

BCIs are classified as percutaneous or transcutaneous, depending on whether the sound processor is connected through a skin-penetrating abutment or via magnetic coupling across intact skin [16]. They may also be categorized as passive or active systems according to the location of the vibrating transducer: passive BCIs rely on an external transducer, whereas active BCIs incorporate an internal vibrating component [16,19].

Although percutaneous BCIs provide excellent audiological outcomes, they are associated with skin-related complications that may require medical or surgical management, and occasionally revision or device replacement [20]. To mitigate these limitations, transcutaneous systems have been developed, including passive transcutaneous BCIs (PT-BCIs) such as BAHA

Attract® (Cochlear, Sydney, Australia), and active transcutaneous BCIs (AT-BCIs) such as Bonebridge® (MED-EL, Innsbruck, Austria) and Osia® Cochlear System (Cochlear, Sydney, Australia) [18,19]. Both PT-BCIs and AT-BCIs have demonstrated significant improvements in audiological thresholds, speech reception, sound localization, and quality of life [15–21]. However, because AT-BCIs bypass attenuation by the skin and subcutaneous tissues, they are expected to provide superior performance, particularly at higher frequencies [19,21], which may be especially relevant in patients with MHL.

Notably, most available studies predominantly include patients with CHL from heterogeneous etiologies, among which microtia is often the most frequently represented condition [16–21]. Consequently, comparative evidence specifically addressing audiological outcomes between AT-BCI and PT-BCI in patients with MHL secondary to COM remains limited. This population typically exhibits a more pronounced sensorineural component at higher frequencies, underscoring the clinical relevance of high-frequency performance.

Although AT-BCIs may be considered most logical contemporary option, device selection in clinical practice is often constrained by regulatory frameworks, economic factors, and variability in healthcare coverage. As a result, patients may be offered percutaneous devices, PT-BCIs, or AT-BCIs. Further robust clinical evidence is therefore required to inform policymakers and healthcare stakeholders and to support evidence-based decision-making in the selection of BCI systems for patients with sequelae of COM.

The aim of this study was to compare audiological outcomes and self-perceived benefits in patients with sequelae of COM and MHL who underwent auditory rehabilitation with PT-BCI (BAHA Attract®) versus piezoelectric AT-BCI (Osia®). Additionally, the study sought to determine whether AT-BCI provide superior auditory performance, particularly at high frequencies.

Materials and Methods

Study design

We conducted a national, multicenter, prospective and analytical observational study in Colombia, including patients with sequelae of COM who received auditory rehabilitation for MHL using a transcutaneous BCI, either passive (BAHA Attract®) or active (Osia® Cochlear System), **Figure 1**. Surgical procedures were conducted between August 13, 2021, and March 15, 2025. Reporting of the study adhered to the STROBE recommendations for observational studies [22].

Selection of participants

Patients with sequels of COM were eligible for inclusion if they were scheduled to undergo implantation with either an active or a passive transcutaneous BCI as part of their clinical treatment. Both pediatric and adult patients were included. Audiological inclusion criteria required the presence of MHL in the affected ear, defined by a pure-tone average (PTA) bone-conduction threshold at 0.5, 1, 2, and 4 kHz greater than 20 dB HL, together with an air-conduction PTA greater than 40 dB HL.

Exclusion criteria comprised patients with CHL, SSD, or neurological and/or cognitive impairments that could preclude reliable audiological assessment.

Data collection and outcome variables

Demographic, audiological, clinical, and surgical data were prospectively collected using the electronic platform MAIA (by its acronym in Spanish: Monitoreo Anual de Implantes Auditivos). The primary outcomes were device-assisted audiological performance and patient-reported benefit.

Audiological performance was assessed by postoperative free-field audiometry with the device processors in situ. The conversational pure-tone average (PTA; 0.5, 1, 2, and 4 kHz) and high-frequency PTA (HF-PTA; 4, 6, and 8 kHz) were calculated as the principal outcome measures. Preoperative behavioral thresholds were obtained within 1–3 months before surgery. Postoperative evaluation was conducted at 3 and 12 months (±1 month) after device activation, using free-field testing with the loudspeaker positioned at 0° azimuth and 1 m from the participant's head.

Self-perceived benefit at 12 months was evaluated using the Client Oriented Scale of Improvement (COSI) questionnaire [23], which measures perceived benefit in everyday listening situations. For children aged 10 years or younger, pediatric response categories were applied, with proxy responses (typically from a parent) provided in consultation with the child. For participants older than 10 years and adults, adult response categories were used, with responses completed either by the child (with proxy support) or directly by the adult.

Prior to activation, participants identified specific daily listening situations targeted for improvement from a predefined list of 16 items. At 12 months after transcutaneous BCI activation, perceived improvement in these selected situations was rated on a 5-point scale (1=worse, 2=same, 3=slightly better, 4=better, 5=much better). For analysis, the 16 situations were grouped into five categories: Emotional, Speech in Quiet, Speech in Noise, and Social Activities and Environmental Perception (common to both age groups), and a fifth category defined as Telephone Use in participants older than 10 years and Communication Skills in those aged 10 years or younger.

Statistical Analysis

Descriptive analyses were performed using measures of central tendency and dispersion for quantitative variables (interval, proportional, and ordinal), while nominal variables were summarized using frequencies. For proportional and interval variables, normality of distribution was assessed using the Shapiro–Wilk test. Variables with a normal distribution were analyzed using parametric tests; otherwise, nonparametric tests were applied.

To evaluate audiological performance— PTA and HF-PTA with the device at three and 12 months postoperatively—over time according to the type of implanted device (AT-BCI vs PT-BCI), a multilevel modeling approach was applied. Initially, a two-way repeated-measures ANOVA was performed, with time as the within-subject factor and device type as the between-subject factor, as an exploratory complete-case analysis to obtain an overall view of the behavior of the audiological outcome measures. However, given the clinical nature of the study, which exhibited imbalance in group sizes (n=211 vs n=50) and missing data at postoperative follow-up visits, a linear mixed-effects model for repeated measures (LMM-RM) was subsequently implemented. The LMMs-RM were specified using a scaled-identity covariance structure and estimated by restricted maximum likelihood. The model focused on the fixed effects of time, group, and their interaction, and the random intercept was omitted to ensure convergence and stability of the Hessian matrix, thereby functioning as a robust general linear model. This approach allowed inclusion of all subjects with at least one valid measurement in the follow-up, optimizing statistical power and mitigating the case-loss bias inherent to traditional ANOVA methods. COSI scores were analyzed separately and comparisons performed according to BCI type. Statistical significance was set at $p<0.05$. All statistical analyses were conducted using IBM SPSS Statistics, version 26.0 (IBM Corp., Armonk, NY, USA).

Ethical considerations

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki [24] and the Colombian Resolution 8430 of 1993 for research involving human subjects [25]. The study protocol was approved by the Ethics Committee under opinion CEISH 0559-2019. No personally identifiable patient data were collected, and confidentiality and privacy were maintained in compliance with national regulations.

Results

During the study period, 359 ears (hereafter referred to as cases) in patients with sequelae of COM were scheduled for surgery involving transcutaneous BCI implantation. Of these, 261 cases—including three bilateral implantations—in 258 patients were included in the final analysis. **Figure 2** illustrates the study flowchart and the distribution of cases according to the type of transcutaneous BCI.

Baseline data and bivariate analyses

Baseline data and bivariate analyses comparing the AT-BCI and PT-BCI groups for the study population are summarized in **Table 1**. The mean age of the study cohort was 51.9 years (SD±16.4; range, 8.8–84.3 years). Sex distribution was comparable between groups, and most participants were adults, accounting for 95.7% of the sample (247/258). Most cases corresponded to primary surgeries; however, 24 cases (9.19%) involved conversion from a previous BCI. The most used implant length was 4 mm, applied in 85.06% of cases (222/261), and mean soft-tissue thickness was 5.86 ± 1.37mm. Soft-tissue reduction was not required in 87.70% of cases (229/261). Among cases in which soft-tissue reduction was performed, it was more frequently required in PT-BCI group (30.0%; 15/50) than in AT-BCI group (4.74%; 10/211); Fisher's exact test, $p < 0.001$.

In the bivariate analysis, also presented in **Table 1**, comparing baseline variables according to device type, no significant differences were observed between the two groups with respect to age, sex, distribution of adults and children, side of surgery, primary versus conversion surgery, reasons for conversion surgery, or implant length. A statistically significant difference was identified in soft-tissue thickness, which was greater in patients receiving an AT-BCI (5.99 ±1.40mm) compared with those receiving a PT-BCI (5.34±1.12mm).

With respect to the preoperative audiological profile, the AT-BCI group exhibited a mean air-conduction PTA of 69.6dB (SD=14.0) and an HF-PTA of 80.4dB (SD=18.5), whereas the PT-BCI group showed a mean air-conduction PTA of 72.7dB (SD=14.7) and an HF-PTA of 80.1dB (SD=18.9). Given that all patients presented with MHL, bone-conduction thresholds were also elevated. In the AT-BCI group, mean bone-conduction PTA was 31.2dB (SD=10.4) with an HF-PTA of 34.4dB (SD=15.9), while in the PT-BCI group the corresponding values were 38.4dB (SD=14.1) and 42.4dB (SD=16.5), respectively. Overall, this profile characterizes a typical patient with severe hearing loss, a mild neurosensory component, and an air–bone gap of approximately 40dB.

Comparative audiological outcomes between AT-BCI and PT-BCI

To evaluate comparative audiological outcomes between the two device types over time (longitudinal analyses), initial exploratory analyses were conducted using a repeated-measures analyses of variance with a between-subject factor (two-way repeated-measures ANOVAs). Building upon these findings, confirmatory analyses were subsequently performed using a more robust LMMs-RM. Separate models were constructed for PTA and HF-PTA to minimize potential bias due to collinearity and redundancy between outcome measures.

In **Table 2** are presented the baseline audiological data obtained by pure-tone audiometry, as well as postoperative free-field audiometric outcomes with device use at 3 and 12 months.

Tests of normality (Shapiro–Wilk) applied to preoperative air-conduction thresholds and to free-field measurements at 3 and 12 months indicated that these variables followed a normal distribution in 5 of the 6 comparisons performed ($p>0.05$), except for HF-PTA at the 12-month follow-up ($p=0.020$).

a. Exploratory longitudinal analyses using two-way repeated-measures ANOVA (complete-case analysis)

For these analyses, device type (AT-BCI vs. PT-BCI) was included as a between-subject factor in the models for both PTA and HF-PTA. In addition to the assumption of normality, the assumptions of homogeneity of variances were verified using Levene's tests ($p>0.05$), as well as homogeneity of the variance–covariance matrices using Box's M test (PTA: $p=0.101$; HF-PTA: $p=0.203$). As the assumption of sphericity was violated (Mauchly's test, <0.001; both for PTA and HF-PTA), the Greenhouse–Geisser correction was applied (Greenhouse–Geisser tests, PTA=0.669 and HF-PTA=0.692). These analyses demonstrated that the interaction between device type and audiometric outcomes at the postoperative follow-up time points (3 and 12 months) were not statistically significant for PTA ($F_{(1.339)}=1.560$, $p=0.218$, $\eta^2=0.019$, $\beta\text{-}1=0.269$; Greenhouse–Geisser correction) or HF-PTA ($F_{(1.383)}=1.036$, $p=0.335$, $\eta^2=0.014$, $\beta\text{-}1=0.194$; Greenhouse–Geisser correction). With respect to the main treatment effect—namely, implantation with any BCI—on audiometric outcomes over time, the results are presented in **Table 2**. Postoperative free-field audiometric assessments at 3 and 12 months demonstrated a highly significant improvement in auditory performance with both AT-BCI and PT-BCI devices, for both PTA ($F_{(1.339)}=330.3$, $p<0.001$, $\eta^2=0.807$, $\beta\text{-}1=1$; Greenhouse–Geisser correction) and HF-PTA ($F_{(1.383)}=120.3$, $p<0.001$, $\eta^2=0.616$, $\beta\text{-}1=1$; Greenhouse–Geisser correction). In the AT-BCI group, postoperative auditory outcomes were approximately 30 dB HL for PTA and 36 dB HL for HF-PTA. Although patients in the PT-BCI group also demonstrated clinically

meaningful postoperative improvement, their auditory outcomes were generally inferior and exhibited greater variability compared with those observed in the AT-BCI group. Specifically, PTA values ranged from 30.9 to 37.1 dB HL, while HF-PTA values ranged from 41.3 to 49.8 dB HL.

In addition, the models demonstrated that, in the AT-BCI group, no significant differences were observed in pairwise comparisons (Bonferroni correction) between the 3- and 12-month postoperative measurements (p=0.601 for PTA and p=0.535 for HF-PTA). Similarly, in the PT-BCI group, pairwise comparisons between the 3- and 12-month postoperative assessments did not reveal statistically significant differences (p=0.147 for PTA and p=0.141 for HF-PTA). Finally, with respect to the main effect of the between-subject factor (AT-BCI vs PT-BCI), the effect of device type on PTA approached the threshold of statistical significance ($F_{(1)}$=3.827, p=0.054, η^2=0.046, β-1=0.489). AT-BCI showed significantly better outcomes at the 3-month follow-up (p=0.014), whereas performance did not differ between devices at 12 months. Similar results were observed for HF-PTA, with the effect of device type again approaching statistical significance ($F_{(1)}$=3.957, p=0.050, η^2=0.050, β-1=0.502). As with PTA, AT-BCI recipients achieved significantly better HF-PTA outcomes at 3 months (p=0.014), while results were comparable between AT-BCI and PT-BCI at the 12-month follow-up, **Figure 3**.

b. Longitudinal comparative analysis of audiological outcomes using linear mixed-effects models for repeated measures

To further explore comparative postoperative outcomes between the two device types, LMMs-RM were employed. In addition to effectively addressing imbalances arising from differences in sample size between the two groups, this approach makes use of all available data and avoids the exclusion of paired observations due to missing values at specific time points—as

may occur with two-way repeated-measures ANOVA. Consequently, the models allowed inclusion of all patients with at least one postoperative evaluation.

LMMs-RM (n=242), for the PTA outcome revealed a significant main effect of device type ($F_{(1, 443)}$=4.035, p=0.045), indicating overall differences in audiological performance between groups. A significant main effect of time was also observed ($F_{(2, 443)}$=328.445, p<0.001), reflecting a substantial improvement in hearing performance following surgery across the entire cohort. In contrast, the interaction between device type and time did not reach statistical significance ($F_{(2, 443)}$=0.565, p=0.569), suggesting that the rate of audiological improvement over the follow-up period was comparable between AT-BCI and PT-BCI recipients. For the HF-PTA outcome, the analyses demonstrated significant main effects for both device type ($F_{(1, 439)}$=4.335, p=0.038) and time ($F_{(2, 439)}$=187.021, p<0.001), as well as a statistically significant interaction between device type and time ($F_{(2, 439)}$=3.056, p=0.048), demonstrating superior audiological performance of AT-BCI compared with PT-BCI.

To assess the potential confounding effect of tissue thickness—which was the only variable showing a statistically significant difference between implant groups in the bivariate analyses—LMMs-RM were performed with tissue thickness included as a covariate (n=181). The results indicated that tissue thickness was a significant predictor of audiological performance in the PTA model ($F_{(1, 321)}$=3.959, p=0.047), but not in the HF-PTA model ($F_{(1, 320)}$=1.118, p=0.291). After adjustment for this covariable, significant main effects of device type and time were maintained for both outcomes: for PTA (Type of device: $F_{(1, 321)}$=5.317, p=0.022; Time: $F_{(2, 321)}$=201.179, p<0.001) and for HF-PTA (Type of device: $F_{(1, 320)}$=5.665, p=0.018; Time: $F_{(2, 320)}$ =116.934, p<0.001).

Overall evaluation of these findings indicates that, when considering results derived from the LMMs-RM together with the two-way repeated-measures ANOVA data presented in **Table 2**

and **Figure 3**, AT-BCI provided statistically significant superior audiological outcomes at the 3-month follow-up and demonstrated superior HF-PTA performance throughout the entire follow-up period, even after controlling for the confounding variable identified in the bivariate analysis.

Self-perceived benefits outcomes (COSI)

As only two patients were aged ≤10 years, results from the COSI questionnaire applicable to individuals >10 years of age (adults) are reported. In the COSI survey administered prior to device activation, valid COSI responses were obtained from 172 patients (AT-BCI=145; PT-BCI =27). The domain most frequently prioritized by participants in the overall cohort was "Speech in Noise", selected in 86 cases (50.0%), followed by "Speech in Quiet" in 38 cases (22.1%) and "Social Activities and Environmental Perception" in 26 cases (15.1%). No statistically significant differences were observed between the two groups (AT-BCI vs PT-BCI) with respect to the type of domain prioritized in the COSI questionnaire, as assessed by Fisher's exact test (p=0.864).

With respect to the survey results obtained 12 months after device activation, data were available for 93 patients, including 78 AT-BCI users and 15 PT-BCI users. In the overall cohort, 82 patients (88.2%) reported that their performance with the device was "Better" or "Much better" in the situations they had individually prioritized. For comparisons between device types, the nonparametric Mann–Whitney U test was applied, given the ordinal nature of the scale and the non-normal distribution of the data. No statistically significant differences were observed in COSI scores between the AT-BCI group (average rank=46.80) and the PT-BCI group (average rank=54.40), p=0.283; **Figure 4**.

Discussion

Clinical studies on auditory rehabilitation using BCIs are predominantly composed of individuals with CHL, accounting for approximately 60% to 80% of reported cases [18,19,]. It is also noteworthy that outcomes are frequently analyzed without differentiating between the CHL and MHL subgroups [18]. Consequently, it is desirable to present data specifically on patients with sequelae of COM who exhibit MHL, and to provide direct comparisons between AT-BCIs and PT-BCIs within this population. Such evidence may contribute to a more precise understanding of device performance in the presence of a clinically relevant sensorineural component. This information may support government authorities and healthcare system stakeholders in making informed, evidence-based decisions regarding BCI device selection in patients with sequelae of COM, particularly in cases with long-standing disease.

With a follow-up period of one year, and accounting for missing data and imbalance in group sizes using robust covariate-adjusted models (LMMs-RM), it was possible to include all subjects with at least one valid measurement at either the 3- or 12-month follow-up, thereby optimizing statistical power. Within this analytical framework, AT-BCI provided statistically significant superior audiological outcomes at the 3-month follow-up and demonstrated superior HF-PTA performance throughout the entire follow-up period, even after controlling for the confounding variable identified in the bivariate analysis.

In the bivariate analysis, no statistically significant differences were observed between the two groups (PT-BCI vs AT-BCI) with respect to age, sex, side of surgery, primary versus conversion surgery, indications for conversion surgery, or implant length. A statistically significant difference was identified in soft-tissue thickness, which was greater in patients receiving AT-BCI (5.99±1.40mm) compared with those receiving PT-BCI (5.34±1.12mm). This finding may be explained by the higher frequency of soft-tissue reduction procedures in the PT-BCI group (30.0%; 15/50) compared with the AT-BCI group (4.74%; 10/211).

Soft-tissue reduction in BAHA Attract® and Osia® surgeries was historically recommended by the manufacturer when soft-tissue thickness exceeded 6–9mm, to ensure adequate magnetic coupling and optimal device performance. Notably, as PT-BCIs were introduced prior to active devices, early surgical approaches tended to favor thinner soft-tissue flaps. This tendency is reflected in the present study, where soft-tissue reduction was significantly more frequent in the PT-BCI group than in the AT-BCI group ($p<0.001$). Over time, in an effort to reduce complications such as chronic postoperative pain and alterations in skin trophic status secondary to aggressive subcutaneous tissue reduction, surgical techniques evolved toward the use of supraperiosteal flaps, in which the implant is positioned in a pocket above the muscle–periosteum and beneath the skin. This shift in surgical approach coincided with the introduction and wider adoption of AT-BCIs. These factors likely explain the observed statistically significant differences in flap thickness, with thinner soft tissues more commonly seen in PT-BCI recipients compared with AT-BCI recipients. Importantly, in the context of this study, this variable was specifically analyzed to determine its potential impact on audiological outcomes. The findings indicate that soft-tissue thickness itself did not independently influence audiological performance, which was instead primarily associated with the type of device used.

When interpreting these findings, it is important to consider that separate models were constructed for PTA and HF-PTA in order to minimize potential bias related to collinearity and redundancy between outcome measures, as 4kHz is included in both calculations. Preoperatively, the AT-BCI and PT-BCI groups exhibited comparable levels of hearing impairment. Postoperatively, both device types were associated with substantial improvements in auditory performance at 3 and 12 months. However, although both devices achieved clinically meaningful gains, PT-BCI outcomes tended to be slightly poorer and more variable compared with those observed in the AT-BCI group. This pattern is consistent with the expected attenuation of

446 acoustic energy across the skin and soft tissues inherent to passive transcutaneous systems. In
447 contrast, the more consistent performance observed with AT-BCI may reflect the direct
448 transmission of vibratory energy to the bone, which could be particularly relevant in patients with
449 a mixed component of hearing loss. Overall, these findings suggest that while both technologies
450 provide effective auditory rehabilitation, active systems may offer a more stable and predictable
451 audiological performance profile, particularly when considering outcomes across different
452 frequency ranges.

453 When comparing the results of the present study with the published literature, similar
454 findings for PTA have been reported. Park et al. (2024) [26] described mean preoperative PTA
455 values of 67.4±17.2 dB in the AT-BCI group (Osia®) and 76.7±16.8 dB in the PT-BCI group
456 (BAHA Attract®), with postoperative PTA at 6 months of 34.3±15.3 dB and 41.8±18.6 dB,
457 respectively. In that study, statistically significant improvements were observed across all PTA
458 frequencies, with greater audiological gain in the AT-BCI group, particularly at 2kHz and 4kHz
459 [26]. Comparable results were reported by Szabó et al. (2023) [27] in a cohort of five patients
460 who underwent conversion from PT-BCI (BAHA Attract®) to AT-BCI (Osia®). Audiological
461 assessment across frequencies from 250 to 4000Hz demonstrated improvement from a
462 preoperative PTA of 72±10.4dB to postoperative PTA values of 43±8.6dB with PT-BCI and
463 28±4.3dB with AT-BCI. Although both systems provided significant hearing improvement
464 compared with the unaided condition, AT-BCI consistently showed superior performance across
465 frequencies, particularly above 2000Hz [27]. Similarly, Goldstein et al. (2021) reported superior
466 functional gain with AT-BCI, with a mean difference of 9.6dB in PTA compared with PT-BCI
467 [28]. In the present study, a comparable trend was observed, with AT-BCI demonstrating a 3.1dB
468 greater improvement in PTA than PT-BCI.

Regarding high-frequency performance, the AT-BCI group exhibited a preoperative HF-PTA of 80.4±18.5dB, while the PT-BCI group showed a comparable value of 80.1±18.9dB. At postoperative assessments performed at 3 and 12 months, HF-PTA improved to approximately 36dB in the AT-BCI group, whereas in the PT-BCI group values ranged from 41.3 to 49.8dB HL. As observed for PTA, auditory outcomes with PT-BCI were generally inferior and exhibited greater variability compared with those obtained with AT-BCI; however, both devices achieved highly significant improvements in HF-PTA. These findings are consistent with previous reports. Park et al. (2024) observed that PT-BCI (Baha Attract®) did not demonstrate significant gain at 8000Hz [26], while Goldstein et al. (2021) reported superior high-frequency performance with AT-BCI, with gains exceeding those of PT-BCI by 5.8dB at 4000 Hz and 19.4dB at 6000Hz [28]. Similarly, Nevoux et al. (2023) found that amplification with PT-BCI (Baha Attract®) was effective primarily up to 2kHz, whereas AT-BCI (Osia®) demonstrated sustained gain across higher frequencies, with amplification maintained up to 8kHz [29].

Improved high-frequency auditory performance represents a clinically relevant advantage, particularly for speech perception, including speech understanding in noise. Moreover, high-frequency audibility is essential in pediatric populations, as accurate detection and identification of fricative sounds are critical for morphological and phonological development [30].

Additionally, it should be emphasized that audiological performance in both AT-BCI and PT-BCI groups remained stable between the 3-month and 12-month postoperative assessments, although the magnitude of improvement was more pronounced in the AT-BCI group (see **Figure 3** for a detailed visual representation). These findings are consistent with those reported by Park et al. (2024), who observed no meaningful differences in outcomes between 1, 3, and 6 months following implantation [26]. Furthermore, studies with longer follow-up durations of 12 and 24

493 months have demonstrated sustained stability of audiological outcomes, with most gains
494 occurring within the first 3 to 6 months after surgery [31,32]. This pattern may be considered
495 clinically relevant, as it suggests that final device programming and optimization can be achieved
496 relatively early in the postoperative course, particularly in AT-BCI systems for this type of
497 hearing loss. Such early stabilization of hearing outcomes may offer advantages for both patients
498 and healthcare systems by facilitating more efficient use of clinical resources and accelerating the
499 rehabilitation process.

500 In the present study, patient-perceived benefit was assessed using the COSI questionnaire,
501 demonstrating significant improvement across all evaluated domains, particularly in speech in
502 noise, speech in quiet, social activities, and environmental perception. Similar findings were
503 reported by Ray et al. (2023), who observed favorable COSI outcomes following rehabilitation
504 with both percutaneous and transcutaneous BCIs; however, transcutaneous devices showed
505 superior performance in speaking over the phone ($p<0.001$) and feeling of embarrassment
506 ($p=0.043$) [33]. Consistent with prior literature, comparative evaluations of quality of life
507 following implantation with AT-BCI and PT-BCI—using instruments such as the Abbreviated
508 Profile of Hearing Aid Benefit (APHAB), the Speech, Spatial, and Qualities of Hearing Scale
509 (SSQ), and the International Outcome Inventory for Hearing Aids (K-IOI-HA)—have generally
510 demonstrated overall benefit without significant differences related to device type [27,29,31].
511 Notwithstanding these similarities in patient-reported outcomes, recent studies have suggested
512 that AT-BCI sound processors may offer improved comfort, with patients tending to wear them
513 for longer daily durations compared with PT-BCI systems. This finding may be explained by the
514 absence of vibratory transmission at the skin level and the reduced requirement for high magnetic
515 retention forces in AT-BCI devices [27,28].

Among the limitations of the present study, it should be acknowledged that, despite the use of robust analytical approaches—including two-way repeated-measures ANOVA and LMMs-RM—the imbalance in sample sizes between device groups, as well as losses to follow-up, introduced a degree of uncertainty in the interpretation of the results. This limitation is further reflected in the statistical power estimates obtained from the repeated-measures ANOVA analyses, particularly for the interaction between device type and audiological outcomes over time, as well as for the main effect of device type, which ranged from 0.194 to 0.502. Given the ethical constraints inherent to conducting randomized controlled trials in this clinical context, particularly when comparing AT-BCI and PT-BCI, future research should aim to include more balanced sample sizes across treatment groups. Moreover, prospective studies should incorporate standardized and simultaneous assessment of audiological thresholds both in the unaided condition and with the device in use under free-field conditions. Such an approach would allow for a more accurate characterization of device-specific performance and facilitate clearer comparisons between implant types.

In conclusion, the findings of the present study show that AT-BCI provides clear and clinically meaningful auditory gain in both PTA and HF-PTA in patients with MHL secondary to COM. This level of audiological performance is achieved as early as the 3-month follow-up and is maintained over time, while remaining superior to that obtained with PT-BCI. The early achievement of stable auditory outcomes may facilitate the implementation of more cost-effective device programming strategies, thereby offering potential benefits not only for patients in terms of timely rehabilitation, but also for healthcare systems by improving the efficiency of resource utilization.

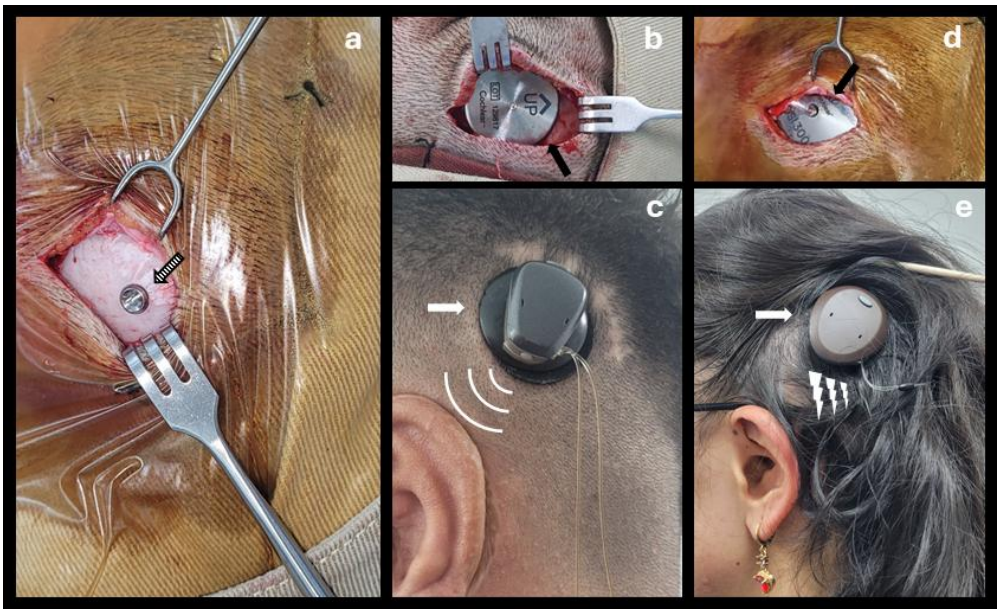
Statements and Declarations

Conflicts of Interest and Source of Funding: LEOO has consultant agreements and research projects with Advanced Bionics LLC and Cochlear Limited. JACA, FJGE, JFMB, JEGD, RF and JCI have consultant agreements and research projects with Cochlear Limited. BCB and LARN are currently employed by Cochlear Limited, a company that manufactures and supplies bone conduction hearing devices. The remaining authors have no conflicts of interest to declare.

Partial financial funding was received from Fundación Universitaria Sanitas (Unisanitas, Bogotá, Colombia), specifically for statistical analysis.

Ethics approval: The study protocol was approved by the Ethics Committee under opinion CEISH 0559-2019. This study complies with the ethical standards established by the Declaration of Helsinki and the resolution 8430 of 1993 of Colombia for studies in human beings.

Figure 1. Type of transcutaneous BCIs used in the study population



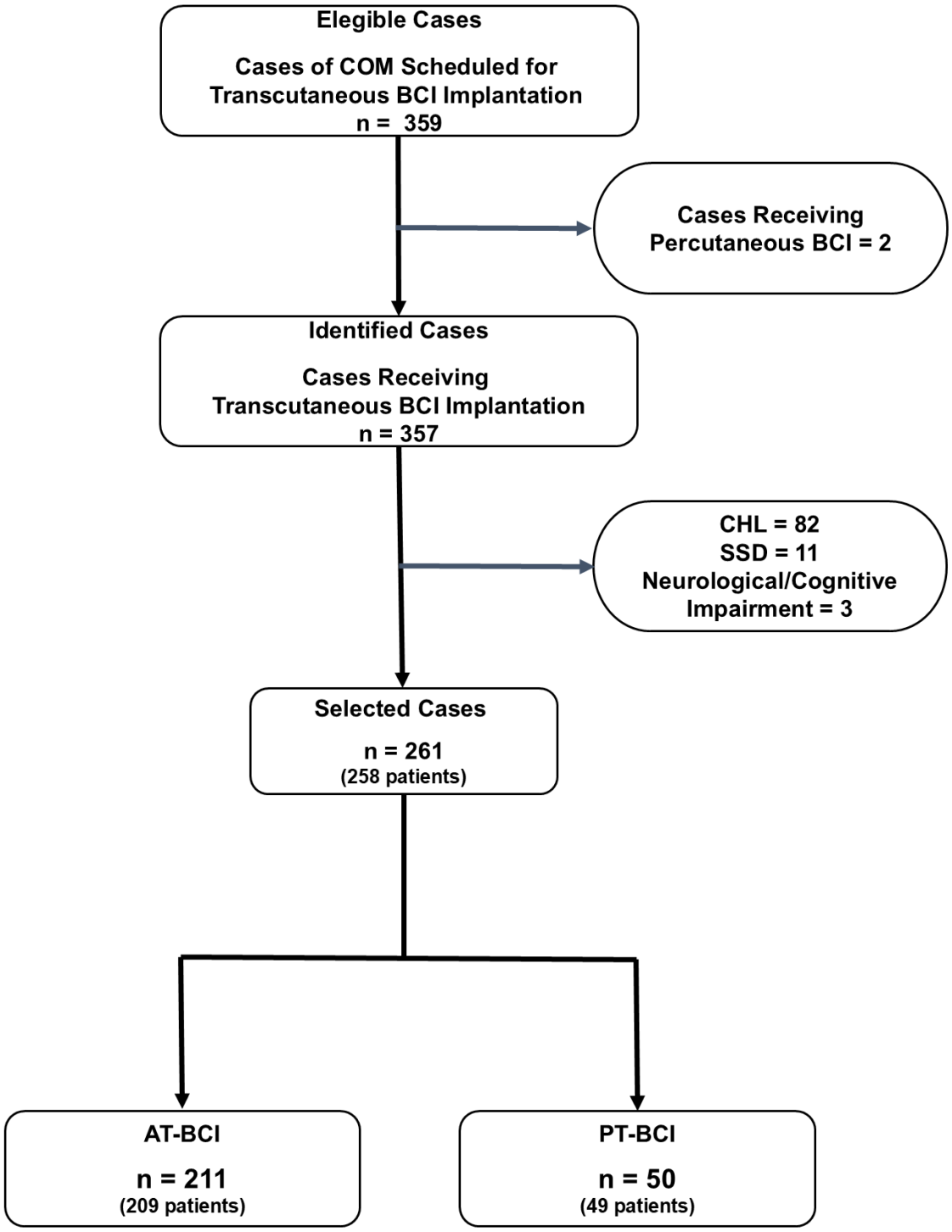
The images illustrate the transcutaneous BCIs used in the study population. Panel **a** show the osseointegrated BI300® implant (striped arrow), which serves as the cranial anchoring system and vibratory energy transmission pathway for both PT-BCI and AT-BCI. Panels **b** and **c** correspond to the PT-BCI, whereas panels **d** and **e** depict the AT-BCI. Black arrows indicate the internal component of each BCI, while white arrows indicate the sound processors.

In the PT-BCI, the internal component consists of a magnetic coupling system attached to the osseointegrated implant (**a**). In this BCI, the sound processor (white arrow in panel **c**) receives the acoustic signal and generates vibrations that are transmitted transcutaneously through the scalp to the internal component (black arrow in panel **b**), which then conveys the vibrations to the skull via the osseointegrated implant, thereby stimulating the inner ear.

In contrast, in the AT-BCI, the sound processor (white arrow in panel **e**) captures the acoustic information, encodes it, and transmits it via radiofrequency to the internal component (black arrow in panel **d**). The internal component decodes the signal and directly generates vibrations that are transmitted to the skull through the osseointegrated implant (**a**), resulting in stimulation of the inner ear.

PT-BCIs are subject to attenuation of vibratory energy during transcutaneous transmission through the scalp, which is more pronounced at higher frequencies. By contrast, AT-BCIs generate vibrations at the internal component beneath the skin and therefore do not experience this attenuation.

583 **Figure 2. Flowchart of study patients**

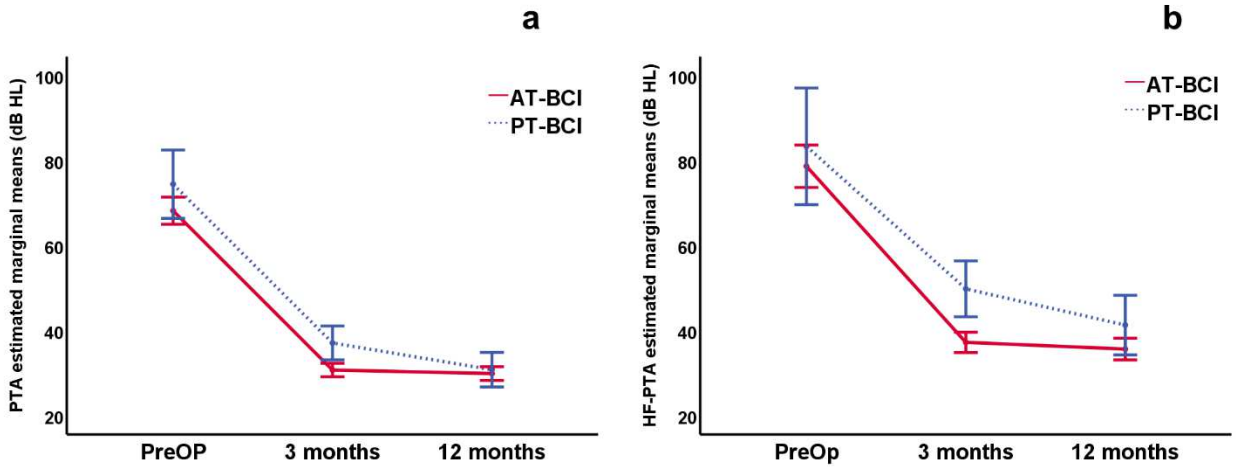


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585 COM: Chronic otitis media. BCI: Bone conduction implant. CHL: Conductive hearing loss. SSD:

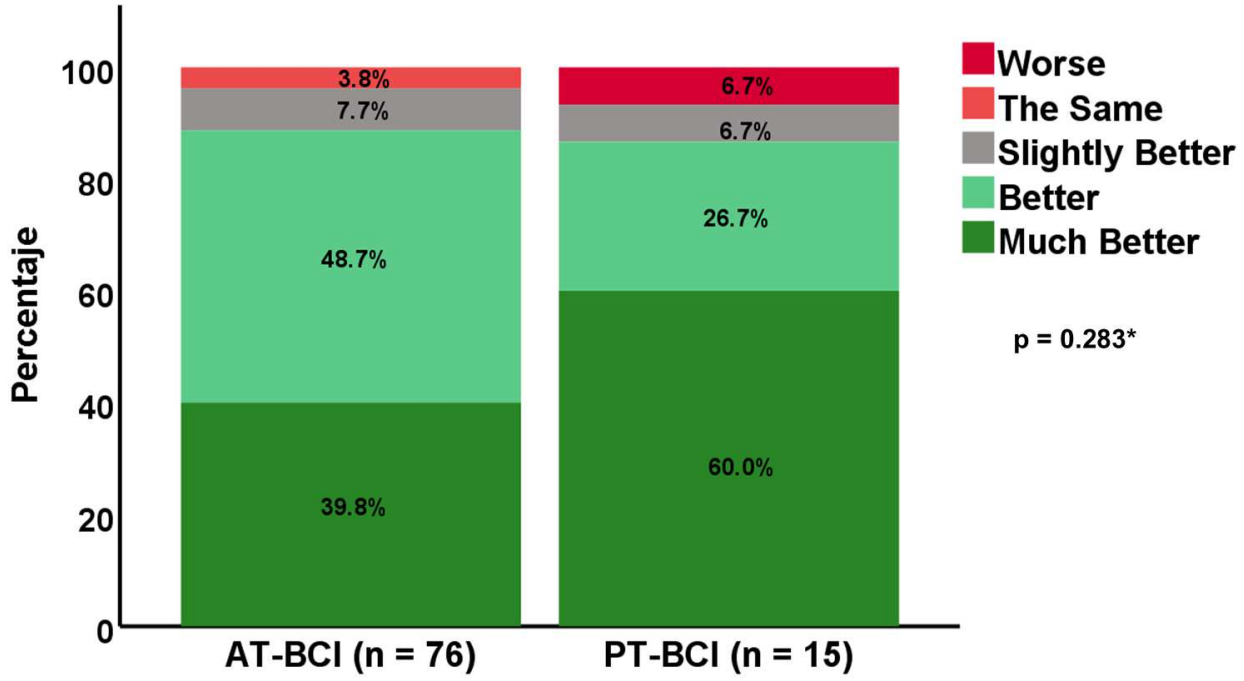
586 Sigle sided deafness. AT-BCI: Active transcutaneous BCI. PT-BCI: Passive transcutaneous BCI

Figure 3. Comparison of the effect type of device (AT-BCI vs PT-BCI) on auditory outcome measures (PTA and HF-PTA) at postoperative follow-up intervals of 3 and 12 months.



Graphical representations are provided for both device types, based on estimated marginal means derived from two-way repeated-measures ANOVA models. Error bars indicate the 95% confidence intervals of the estimated means. Outcomes are shown for PTA (panel **a**) and HF-PTA (panel **b**).

Figure 4. COSI outcomes by device group



* Mann-Whitney U test.

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Table 1. Baseline characteristics and bivariate analyses of the study population

Variables	AT-BCI n = 211 cases (209 patients)	PT-BCI n = 50 cases (49 patients)	*p*	Total group n = 261 cases (258 patients)
Demographics*				
Age (years), mean ± SD	51.72 ± 15.88	52.64 ± 18.50	0.723†	51.89 ± 16.37
Age group, n (%)				
Adults	202	45	0.229‡	247 (95.74%)
Children (< 18 y)	7	4		11 (4.26%)
Sex, n (%)				
Male	93	24	0.568††	117
Female	116	25		141
Clinical and surgical data**				
Side of surgery				
Right	113	25	0.651††	138 (52.87%)
Left	98	25		123 (47.13%)
Conversion				
No	191	46	0.797‡	237 (90.81%)
Yes	20	4		24 (9.19%)
Sophono	10	0	NA	10 (41.67%)
Baha Connect	7	0		7 (29.17%)
BAHA Attract	3	0		3 (12.50%)
Not reported	0	4		4 (16.66%)
Reason for conversion (n = 24)				
Patient preference	10	2	0.952‡	12 (50%)
Holgers 3	3	0		3 (12.50%)
Holgers 4	7	2		9 (37.50%)
Implant length				
3 mm	33	6	0.516††	39 (14.94%)
4 mm	178	44		222 (85.06%)
Tissue thickness (mm), mean ± SD (n = 191)	5.99 ± 1.40	5.34 ± 1.12	**0.009**†	5.86 ± 1.37

SD: Standard deviation. AT-BCI: Active transcutaneous bone conduction implant. PT-BCI: Passive transcutaneous bone conduction implant.
* Considering the number of subjects, n = 258. ** Considering the number of cases (ears), n = 261: a variable retains its default n value unless explicitly assigned a different value
† Student's t test. ‡ Fisher's exact test. †† Chi-square test.

Table 2. Baseline audiological characteristics and postoperative free-field outcomes (dB HL) across device groups.

Group	Preoperative (Pure tone audiometry) mean ± SD				Postoperative* (Free field audiometry) mean ± SD p			
	Air conduction				3 months		12 months	
	PTA		HF-PTA		PTA	HF-PTA	PTA	HF-PTA
AT-BCI	69.6 ± 14.0	p = 0.195†	80.4 ± 18.5	p = 0.920†	30.7 ± 6.4 **< 0.001**‡	37.2 ± 10.0 **< 0.001**‡	29.9 ± 6.6 **< 0.001**‡	35.7 ± 10.3 **< 0.001**‡
PT-BCI	72.7 ± 14.7		80.1 ± 18.9		37.1 ± 8.2 **< 0.001**‡	49.8 ± 9.6 **0.010**‡	30.9 ± 7.7 **< 0.001**‡	41.3 ± 12.6 **0.011**‡

dB HL: decibels hearing level. SD: standard deviation. AT-BCI: Active transcutaneous bone conduction implant. PT-BCI: Passive transcutaneous bone conduction implant. PTA: pure-tone average (0.5, 1, 2, and 4 kHz). HF-PTA: high-frequency PTA (4, 6, and 8 kHz). ANOVA: analysis of variance. LMM: linear mixed-effects models.

* The sample size with available audiometric measurements at both the 3- and 12-month follow-up time points was 81 patients (AT-BCI=70; PT-BCI=11), and these data were used in the two-way repeated-measures ANOVA models. For the linear mixed-effects models, the sample size comprised 242 cases; this was 181 cases when the potential confounding factor identified in the bivariate analysis was included in the LMMs. Detailed methodological aspects and results of these analyses are presented in the main text.

† Student's t test.

‡ Two-way repeated-measures ANOVA models with device type (AT-BCI vs. PT-BCI) included as a between-subject factor, with separate models constructed for PTA and HF-PTA. Postoperative free-field audiometric measurements obtained at 3 and 12 months were compared with preoperative air-conduction thresholds, while accounting for the device type used. The statistical results presented here correspond to pairwise comparisons between postoperative and preoperative values. Additional analyses and results are reported in the main text.

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