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Clinical Performance Assessment of a New Active Osseointegrated Implant System in Mixed Hearing Loss: Results From a Prospective Clinical Investigation

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Objective: Evaluation of a new active osseointegrated bone-conduction hearing implant in moderate to severe mixed-hearing loss.
Study Design: Prospective observational study of a series of cases.
Setting: Tertial referral center.
Patients: Twenty patients with moderate mixed-hearing loss were evaluated (10 Cochlear Osia group and 10 Baha 5 Power Connect -control group).
Intervention: Rehabilitative.
Main Outcome Measures: Hearing performance in quiet and in noise and quality-of-life were evaluated.
Results: Improvements in audibility, speech-understanding, speech-recognition, and quality-of-sound in noise and quiet were found for the Osia System compared with preoperative unaided hearing and performance was similar to that obtained with Baha 5 Power Connect.
Conclusions: The new active transcutaneous bone conduction system provided a tonal improvement in free-field at middle and high frequencies. The performance in speech recognition in quiet and in noise was similar to control group outcomes. **Key Words:** Audiometry—Bone conduction hearing—Mixed hearing loss—Pure-tone—Quality of life—Speech perception.

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Moderate-to-severe mixed hearing loss has classically presented a difficult auditory rehabilitation, with hearing aid fitting or percutaneous osseointegrated hearing devices being the only solution for many years.

The use of bone conduction hearing implants (BCHI) began more than 40 years ago and these devices are now the chosen alternative in some cases of conductive and mixed hearing loss. However, in their initial versions and models their indications were limited to BC thresholds close to 40 dB. In recent years, as a result of technological advancement (1), the output characteristics of bone conduction transducers have improved and various models are available that can compensate for higher degrees of hearing loss (2). In cases of mixed hearing loss, BCHI require gains capable of compensating for the loss of the sensorineural component (3). BCHI are the preferred treatment in patients with mixed hearing loss who cannot be rehabilitated with conventional hearing aids due to low tolerance or a poor performance obtained from them, or because of medical reasons such as anatomical or pathological changes in the middle/external ear. These circumstances demand an individual assessment.

There are different BCHI models for treating mixed hearing losses. For mild cases, with BC thresholds under 45 dB, fitting can be performed using an active transcutaneous BCHI, such as the Bonebrige (ME-DEL, Austria), or with a percutaneous BCHI, which include the Baha (Cochlear, Australia), and Ponto systems (Oticon Medical, Denmark). The transcutaneous BCHI Sophono or Baha Attract System are also an option in cases of mixed losses, but they must be carefully considered as

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they present a lower hearing gain due to tissue attenuation, especially in higher frequencies (4). Baha Power and Ponto SuperPower models can be used to treat hearing losses of up to 55 and 65 dB, respectively, which makes them a good option in mixed hearing loss because of their wider indication threshold (5). The latter devices are percutaneous, and therefore are not exempt from skin complications that may appear around the implant and they are also less aesthetically pleasing compared with transcutaneous systems. An active transcutaneous BCHI offers the advantages of passive transcutaneous BCHI, such as less skin complications and better aesthetics, and higher power output compared with comparable percutaneous systems. So far, only Bonebridge is in the market, with BC threshold indications under 45 dB.

In this observational study we will present the preliminary results of the new active transcutaneous piezoelectric osseointegrated hearing implant system, Osia (Cochlear, Sydney, Australia) (6,7). We will proceed to evaluate the subjective and functional gain of this device in patients with moderate hearing loss with BC thresholds between 45 and 55 dB and we will compare the results with a similar group of users of Baha 5 Power Connect.

METHODS

We performed a prospective observational study on a series of cases gathered between December 15, 2018 and April 1, 2019. During this period, 10 patients were implanted with the new active piezoelectric transcutaneous osseointegrated hearing implant system, Osia (Cochlear, Sydney, Australia). The study was approved by the CEIC (ethics committee) of the hospital and by the General Office of Pharmaceuticals and Health Products (CAEPRO).

The inclusion criteria included patients over 18 with mixed hearing loss and BC thresholds between 45 and 55 dB and with no surgical contraindications. Patients with diseases such as osteoporosis or Paget's disease or who had undergone radiotherapy in head and neck or who could not undergo follow-up tests were excluded from participating.

Following inclusion, all patients underwent a subjective hearing evaluation 1 month before their preoperative test. Follow-up testing was conducted 6 months after activation of the sound processor. Every patient underwent the following tests in free-field with the loudspeaker positioned al 0 degree azimuth of the patient:

- Hearing thresholds were measured by pure-tone audiogram at 0.5, 1, 2, 3, and 4 kHz.
- Speech audiometry in quiet consisting of lists of 25 two-syllable words emitted at 55, 60, 65, and 70 dB SPL.
- Speech audiometry with background noise and lists of two-syllable words following the signal-to-noise ratio (SNR), where narrow band noise was emitted at a fixed intensity of 65 dB and the signal was modified in three intensities: SNR +0; at 70 dB achieving an SNR +5, and finally 75 dB achieving an SNR +10.
- Speech perception in noise was also assessed using the Oldenburg Speech test (Matrix test, Auritec) using a background noise level of 65 dB and 50% correct answers.

Additionally, we selected a control group of 10 patients with similar audiological characteristics to the intervention group. The control group were fitted with a Baha 5 Power sound processor on an abutment for at least 6 months and the same audiological tests and questionnaires were performed on both groups.

Regarding the material used for the performance of the different audiometric tests, a 25 m3 soundproof room with all the necessary equipment was arranged, soundproof certificates and requirements UNE-EN ISO 11957, UNE-EN ISO 717-1 and compliance with the European Directive 93/42/EEC of Medical Supplies. The hearing evaluation was done with an AC40 clinical audiometer (Interacoustics AS, Assens, Denmark) properly calibrated. The verbal tests in open context were conducted using the list of two-syllable words of Marrero and Cárdenas. The background noise used was a narrow bandwidth sound.

To analyze the subjective benefit, patients were asked to answer two different quality-of-life questionnaires, the *Glasgow Benefit Inventory* (GBI) and the *Abbreviated Profile of hearing Aid Benefit* (APHAB), 6-months postoperatively.

The GBI contains 18 questions which measures the impact a medical intervention has on a patient's quality of life. Outcomes are scored between −100 (the worst possible situation) and +100 (the best possible situation) and the questionnaire is divided into three subscales: general, social support, and physical health (8).

The APHAB quantifies the hearing burden experienced by patients and is comprised of 24 questions that are answered before and after aiding. The instrument is stratified into subscales covering ease of communication, reverberation, background noise (BN), and aversiveness and the final score is calculated as a percentage (9). Once the percentage of problems resulting from both situations is evaluated, the benefit of using the hearing aid can be calculated.

Data collection and analysis was performed in Microsoft Excel. To determine the performance of the Osia System compared with Baha 5 Power on an abutment, mean comparison analyses were performed. Before the comparison, the following data were found to be normally distributed as determined by Shapiro–Wilk test: functional gain thresholds, speech perception, and QoL scores. One-way ANOVA analyses were therefore performed for each condition on intervals (preoperative and 6 mo postactivation). In all cases, a significance level of 0.05 ($p < 0.05$) was used to determine significance for analysis and Eta-squared (η^2) to report effect size.

RESULTS

The study was completed on 20 patients, 10 test, and 10 controls, with an average age of 62 years (mean age of test group was 63.3 ± 7.7 yrs; mean age of control group was 61.8 ± 6.9 yrs). All the patients presented with secondary mixed hearing loss due to chronic otitis media with several years of development. The activation of the device in all the patients was done 1 month after the surgical intervention. Verbal and tonal results in the preoperative test and 6 months after the implantation of the device are shown in Table 1.

Functional Gain

The average hearing thresholds across participants in free field for unaided condition, Baha 5 Power, and Osia System and mean gain per frequency are shown in Table 1 and Figure 1A. It is interesting to note that the largest and significant differences between functional gain results in the Osia System and de Baha group were obtained at higher frequencies where the Osia System provided more gain (shown in detail in Fig. 1B). Regarding the tonal results with the use of the Osia System we

TABLE 1. *Mean of hearing thresholds (dB HL) per frequency, speech recognition in quiet and in noise, and quality-of-life questionnaires*

		Mean Thresholds Implanted Ear (dB HL)						
		0.5	1	2	3	4 kHz	Mean	Gain
No aid	AC	77.5	78.3	71.6	74.16	75	75.31	—
	BC	45.8	44.2	46.7	47.5	47.5	46.34	—
Osia		34.5	35.5	37.5*	46.1*	49.5*	40.62	35.89*
5 Power		30.5	40	44*	50*	65*	45.9	30.61*

	Speech Recognition							
	Speech in Quiet (%)				Speech in Noise -*S/R*- (%)			Matrix
	55 dB	60 dB	65 dB	70 dB	S/R + 0	S/R + 5	S/R + 10	SRT(dB)
No aid	9.5	31.33	50.33	61.5	8	30.7	45.33	−9.6
Osia	65.83*	82	92.33	99.33	16.3	60.41	77.24	−1.26
5 Power	52.44*	73.89	93.56	99.67	20.5	65.17	83.17	−2.7

	QoL Questionnaires							
	GBI				APHAB			
	Total	General	Social	Physical	EC	RV	BN	AV
Osia	44.44	54.16	28.44	21.67	53	55	53	−8
5 Power	36.33	44.92	29.17	13.34	56.22	57.34	51.58	−16.52

*Significant differences indicated by *asterisks* (one-way ANOVA analyses; $p < 0.05$).

AC indicates air conduction; APHAB, abbreviated profile hearing aid benefit; BC, bone conduction; GBI, Glasgow benefit inventory; S/R, signal-to-noise ratio; SRT, speech reception threshold. Ease of communication (EC), reverberation (RV), background noise (BN), aversiveness (AV).

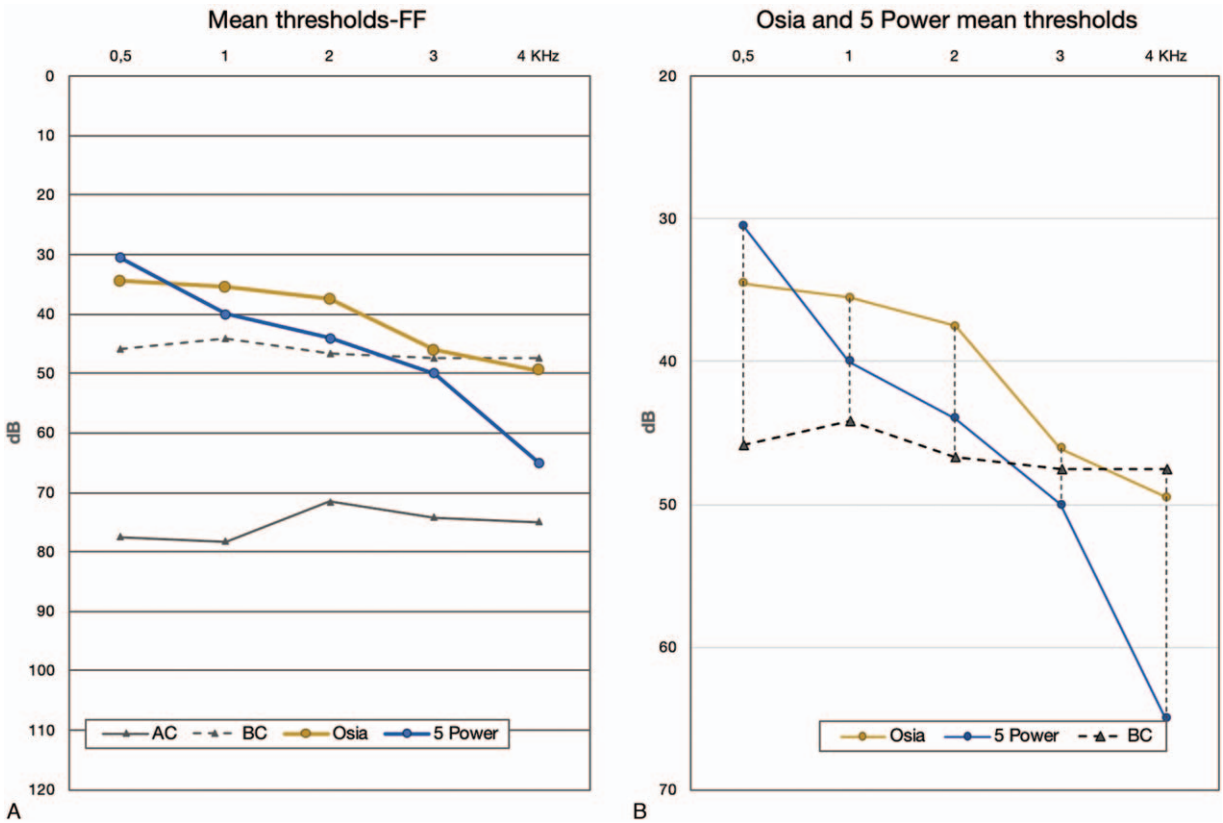

FIG. 1. *A*, Mean of free field thresholds for unaided condition (AC, air conduction; BC, bone conduction), Baha 5 Power Connect and Osia (post-6 mo) per frequency. *B*, Difference (gain) between threshold for Baha 5 Power Connect and Osia System. Overclosure: when the aided threshold overcomes the preoperative bone conduction threshold.

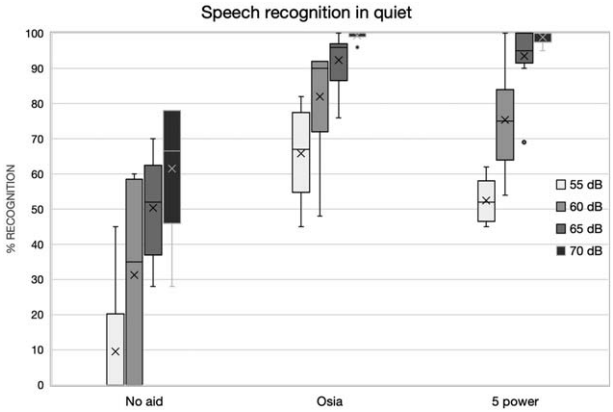

FIG. 2. Score of correct words in Speech in quiet fixed at 55, 60, 65, and 70 dB HL, for unaided, Osia, and Baha 5 Power Connect.

observed overclosure, when the Osia threshold overcomes the preoperative bone conduction thresholds, at 0.5, 1, 2, 3, and 4 kHz. Using Baha 5 Power Connect, there was an overclosure at 0.5, 1, and 2 kHz, and at 3 and 4 kHz the aided thresholds were below the bone conduction thresholds. The average functional gain for all frequencies was 35.9 dB for the Osia group and of 30.6 dB for the Baha 5 Power Connect group.

Speech Recognition

Speech recognition in quiet results is presented at four different intensities (55, 60, 65, and 70 dB SPL) (Table 1 and Fig. 2). In the unaided situation speech intelligibility scores of 9.5, 31.3, 50.3, and 61.5% were obtained, respectively. Using Baha 5 Power Connect, speech recognition improved to 52.4, 73.9, 92.6, and 99.7% and also improved significantly reaching intelligibilities of 65.8, 82, 92.3, and 99.3% with the Osia System.

Speech recognition in noise data is presented at SNR0, SNR+5, and SNR+10 dB in Table 1 and Figure 3, and improvements were observed for both BCHI. Unaided scores of 8, 30, and 45%, improved to 20, 65, and 83% with Baha 5 Power Connect and to 16, 60, and 77% when

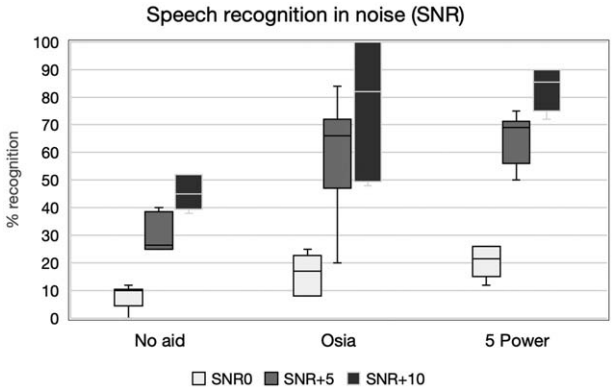

FIG. 3. Score of correct words in speech in noise fixed level at S/N + 0 dB, speech in noise fixed level at S/N + 5 dB (70/65), and speech in noise fixed level at S/N + 10 dB (75/65) for unaided, Osia and Baha 5 Power Connect.

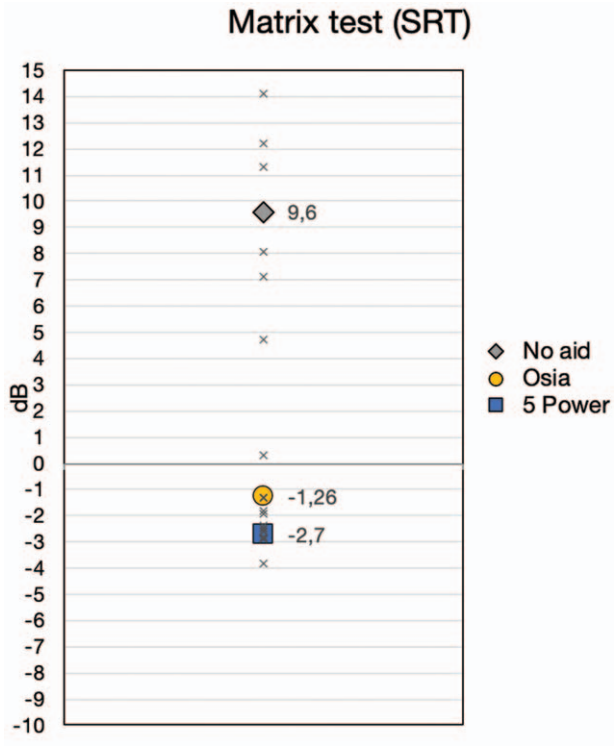

FIG. 4. Mean SRT scores in speech adaptative in noise fixed level (65 dB) Oldenburguer speech test for unaided, Osia and Baha 5 Power Connect. SRT indicates speech reception threshold.

patients were aided with the Osia System but the findings were not statistically significant.

Speech reception thresholds obtained with the *Oldenburguer speech test* (Table 1 and Fig. 4) demonstrated that patients needed +9.6 dB over background noise to reach 50% of intelligibility. With the use of the devices the speech recognition threshold improved to 1.3 dB with the Osia System and −2.7 in the Baha 5 Power Connect group were not statistically significant.

Quality-of-Life (QoL) Questionnaires

The results to the APHAB and GBI questionnaires with both devices are shown in Table 1 and Figure 5 A and B, respectively.

APHAB showed a positive benefit in the subscales of ease of communication, reverberation, and background noise both for the Osia System and the Baha 5 Power Connect groups but not statistically significant ($p > 0.05$), with percentages of 53 versus 56.2% for FC, 55 versus 57.3% and 53 versus 51.6% for RF. No benefit was recorded for the aided situations in aversiveness subscale; in fact with the use of BCHI, the problems in this area increased, resulting in a decrease in score of −8 versus −16.5%.

The GBI questionnaire was positive for both BCHI but not statistically significant ($p > 0.05$). A score of 44.4 was obtained with the Osia System and 36.3 for the Baha 5 Power Connect system. In the general subscale, the average score was 54.2 for the Osia System versus 44.9 for Baha 5 Power Connect. Scores in the social support

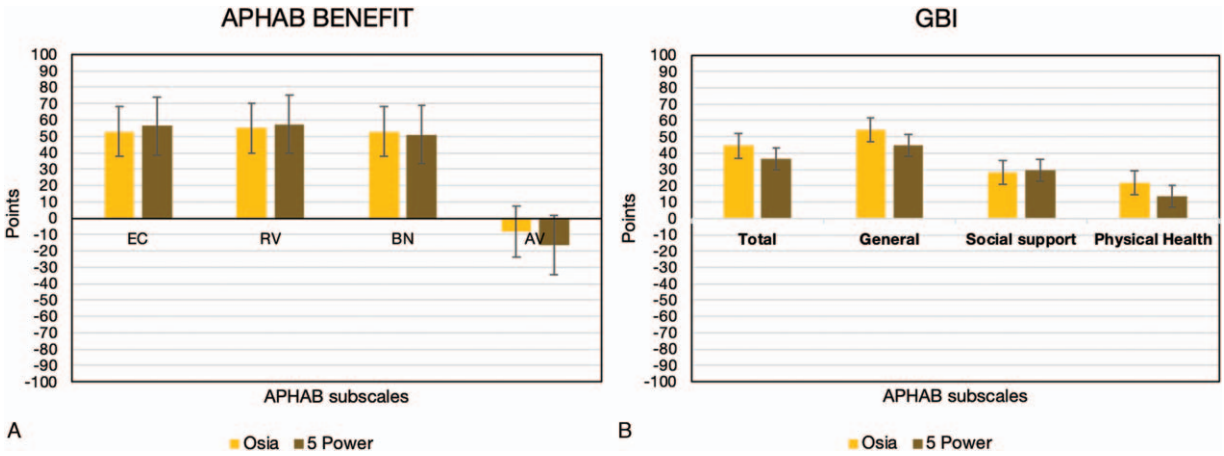

FIG. 5. *A*, Abbreviated profile hearing aid benefit. (APHAB) scores for the four subscales with error bars for both devices (Osia and Baha 5 Power Connect) (AV indicates aversiveness; BN, background noise; EC, ease of communication; RV, reverberation). *B*, Glasgow Benefit Inventory (GBI) scores for total and for the three subscales with error bars for both devices (Osia and Baha 5 Power Connect).

subscale were 28.4 versus 29.2 and in the physical health subscale scores were 21.7 versus 13.3.

DISCUSSION

This study evaluated the clinical performance of the Osia system, a new active transcutaneous osseointegrated implant system, in 10 patients with moderate, mixed hearing loss. Our preliminary exploratory study on 10 patients implanted with the Osia system allowed us to assess the effectiveness and variability of these implants compared with a comparative percutaneous solution. This study will facilitate the design of future confirmatory studies that aim to investigate the effectiveness of the new Osia system versus percutaneous systems.

All patients had a mixed hearing loss with average BC thresholds between 45 and 55 dB HL and air conduction threshold between 70 and 80 dB HL, which severely compromised the speech recognition of all the patients. A diagnosis of chronic otitis media also made the patients good candidates for our study. The postimplant results presented both speech and tonal improvements in all the patients.

Regarding the tonal audiometric gain, we observed that with both BCHI we achieved air-bone gap closures and overclosure at most measured frequencies. An interesting fact is that with the use of the Osia System we obtained a greater mid- and high-frequency gain compared with Baha 5 Power Connect and this was statistically significant at low frequencies. Bravo et al. (10) as well as Baumgartner et al. (11) have also reported better audiological performance using active transcutaneous hearing devices at 4 kHz. A comparative study between active and passive devices done by Zernotti and Sarasty (12) also showed that active devices provide better performance at mid and high frequencies. Goycoolea et al. (6) and Mylanus et al. (7), also in an exploratory study comparing the Osia System to Baha 5 Power on softband, reported the biggest and most significant differences in functional gain at higher frequencies. These studies, as well as our own, support the concept of better functional results for high frequencies with piezoelectric stimulation.

Speech recognition in quiet scores were better at 55 and 60 dB in the Osia group compared with the control group; 65.8 versus 52% and 82 versus 73.9%, respectively. Although at higher intensities (65 and 70 dB) the hit percentage exceeded 90% in both groups and was slightly better with Baha 5 Power Connect (92.3 versus 93.5% and 99.3 versus 99.7%, respectively).

In contrast, the Osia group, despite having a priori better tonal thresholds in middle and high frequencies, as well as better intelligibility in silence at low intensities, obtained slightly worse results in speech perception with background noise. However, we obtained an improvement in the three situations with the use of both BCHI and the discrimination scores between both systems were not statistically significant. Goycoolea et al. (6) obtained better results with the use of the Osia System than with Baha 5 Power, but it must be pointed out that they used different hearing tests and the comparator system was used on a softband where soft tissue attenuation can diminish the performance.

Furthermore, it is worth noting that both groups obtained large improvements in speech reception thresholds in noise when implementing the Matrix test. In both groups, the results were excellent and we did not detect a statistically significant difference between the Baha 5 Power Connect and Osia System group. These results also differ from the Goycoolea et al. study (6) in which they obtained a Speech Reception Threshold −0.7 dB with Baha 5 Power and −2.2 dB with the Osia System after the first 6 months and also differ from the Mylanus et al. study (7) in which they obtained at 12 month a Speech Reception Threshold −7.9 dB.

The APHAB and GBI tests both reflect the tonal and speech results obtained as all patients demonstrated similar audiological benefits and improvements in their quality of life. Our study indicates that patients implanted

with the Osia System experience a positive improvement in their quality of life. The measured improvement in quality of life was similar to that observed in other studies conducted on patients with mixed hearing loss (13,14). The highest score was observed in the general health condition, followed by the social condition and then the physical condition.

Despite differing in the type of BCHI analyzed, subjective results on our patients present better results than those provided by the Lekue et al. study (15), in which the results for the GBI questionnaire are presented for 54 patients after aiding with a BCHI. Their results were the following: an overall score of 38, while in the general, social, and physical subscales scores were 51, 15, and 7, respectively. The fact that our patients present higher scores may be related to the degree of hearing loss experienced before the surgery and, therefore, the hearing gain obtained after the adaptation. Patients in the Lekue et al. study presented with conductive hearing loss and BC thresholds under 40 dB, or unilateral SNH, whereas our sample is composed of patients with moderate, mixed hearing loss with involvement of the contralateral ear. Because our patients experience greater hearing isolation, when adapted, it would be expected that they present a better evaluation in the subjective tests even though the tonal gains were similar.

Our work, despite studying a small sample that does not permit a strong statistical analysis, shows preliminary results for a new osseointegrated device barely studied and referred to in literature to date. Based on our preliminary data, we think that the Osia System may be a good therapeutic option for patients presenting with mixed hearing loss and BC thresholds between 45 and 55 dB because of its good speech and tonal functional results and due to the closure or overclosure in bone conduction threshold. Additionally, the Osia System also provides similar outcomes to the percutaneous Baha 5 Power Connect.

Future trials should study a larger sample size to determine statistical inference and evaluate and verify the audiological results of this device with greater accuracy and certainty.

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