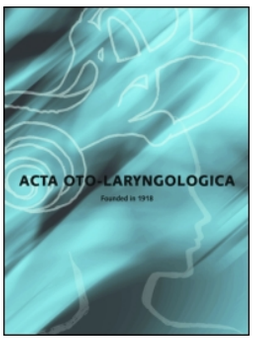

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RESEARCH ARTICLE

Clinical performance of the Osia™ system, a new active osseointegrated implant system. Results from a prospective clinical investigation

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ABSTRACT

Background: Bone-conduction hearing implants are standard of care devices.

Aims/Objectives: Evaluation of a new active magnetic bone-conduction hearing implant: Cochlear Osia™ system.

Material and methods: This device uses a transcutaneous connection between an external sound-processor and an osseointegrated implant that generates vibrations using a piezoelectricity-based internal bone-conduction system. Nine patients with conductive-hearing loss were implanted. Surgical efficacy, hearing performance and quality-of-life were evaluated. Hearing performance in quiet and in noise was compared with unaided hearing and hearing with the Baha 5 Power® Sound Processor on a softband.

Results: Surgery and healing were uneventful. Statistically significant improvements in audibility, speech-understanding, speech-recognition and quality-of-sound in noise and quiet were found for the Osia™ compared to preoperative unaided hearing and aided hearing with the Baha 5 Power® Sound Processor on a softband. The active vibration system provided improvement at low and high frequencies. At 6 months postoperatively, all patients continue to use the device.

Conclusions and significance: The Osia™ is safe and effective, improving speech-recognition in quiet and in noise, at low and high frequencies, thus delivering better quality-of-hearing than passive devices.

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KEYWORDS
Active bone-conduction hearing-implant; hearing improvement in high frequencies; quality-of-hearing; Bone anchored hearing aid; Baha

Introduction

Bone conduction hearing implants (BCHI) transform sound into vibrations that are transferred *via* an osseointegrated implant to the skull bones and through them to the cochlea, bypassing the external auditory canal and middle ear [1]. Passive bone conduction hearing devices consist of an external sound processor-vibrator (that transforms sound into vibrations) and an internal osseointegrated implant (e.g. titanium embedded in the skull) that receives the vibrations and transmits them passively to the cochlea through the skull bones. The connection between the processor and the implant can be percutaneous (through a skin penetrating abutment) or transcutaneous (magnetic connection through an intact skin). Both systems are safe and effective in providing hearing improvement in conductive and single sided hearing loss [2,3].

In passive devices the hearing improvement is largest in the lower speech frequency range. In the case of the passive device BAHA Attract, the performance drops gradually above 3000 Hz because of the soft tissue attenuation of the externally generated vibration, attenuation that affects mainly the high frequencies [4]. In an active bone conduction hearing device, although the processor is external, the vibrator itself is separated from de processor and is located under the skin. With this design, an internally placed vibrator that is in direct contact with the skull bone generates vibrations that are transmitted to the cochlea through the skull bones.

The Osia™ system (Cochlear) is a new active bone conduction hearing implant system with transcutaneous connection between the external processor and the implant. The vibrator (actuator) is piezoelectricity based and is connected directly to a titanium screw that is anchored and osseointegrated to the skull bone. Piezoelectric effect, or piezoelectricity is the ability of certain materials to generate an electric charge in response to applied mechanical stress (vibrations), or reversibly to generate mechanical stress (vibrations) in response to an external electric charge.

Thus, with this device one would expect to have: (A) a safe and efficient sound transmission by using the benefits of the Baha Attract device of a single point fixation in the bone [3]. (B) An improvement of hearing in higher frequencies with a better quality of sound by using an active internal vibration system that can overcome the attenuation of sound through soft tissue [4].

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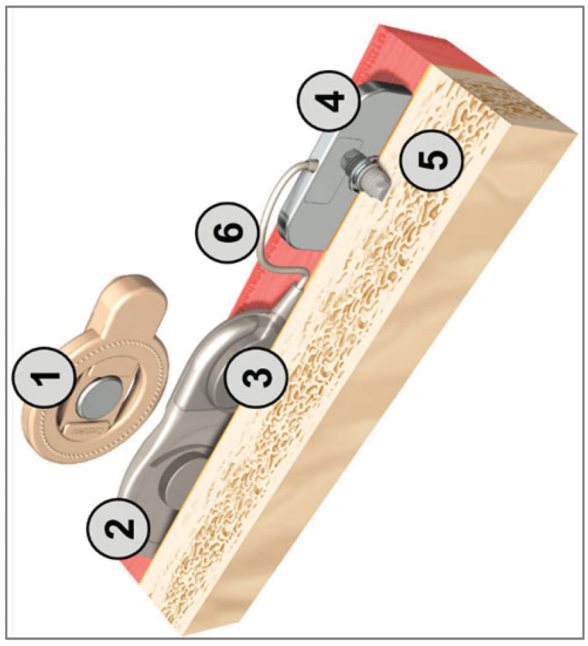


Figure 1. Schematic representation of the Osia™ Device. External components (over the skin): 1. External processor with magnet. Internal components (under the skin): 2. Receiver with magnet. 3. Stimulator. 4. Vibrator (actuator). 5. Titanium screw (BI300 implant inserted in the bone of the skull). 6. Coil that transports electrical stimulation from the stimulator to the vibrator.

The aim of the present investigation was to evaluate the clinical performance of this new active magnetic bone conduction hearing implant system in 9 patients with conductive and mixed hearing loss.

Material and methods

Test device

The Osia™ System consists of external (over the skin) and internal (under the skin) components (Figures 1–3) External components: Externally (over the skin) is the sound processor (Figures 1 and 2). It has a processing unit, a magnet and two battery cells. It has a microphone that picks up the sound which is processed by the processing unit and is sent transcutaneously to the implant located under the skin. Internal components: Under the skin (Figures 1–3) is the receiver that has a magnet (that maintains contact and allows correct alignment with the magnet of the external sound processor) and a stimulator that sends the electric stimulus to the vibrator (actuator). The actuator is piezoelectricity based and is connected directly to a titanium screw termed BI300 (Baha Implant 300 series) that is anchored and osseointegrated to the skull bone.

Investigational site and patient selection

This is a prospective, longitudinal, descriptive and single-subject design comparative study, in which each subject serves as his or her own control. It is being conducted in a clinic, in Santiago de Chile from May 2018 to present. This report includes data from May 2018 to May 2019, and the data that were collected are part of clinical follow up of recipients that were implanted with the Osia™ System. The Osia™ device was registered and is certified in the European Commission under number I7180178611070. The Ethics and Research Committee of the investigational site approved this investigation in accordance with the Declaration of Helsinski and international guidelines of Good Clinical Practice.

All subjects invited to participate in this study were informed about their free and spontaneous participation and signed an Informed Consent form containing all procedures to be performed. Nine patients with conductive hearing loss that met the inclusion criteria participated in this study. Patients were included if they were (A) post-lingual individuals (children or adults) whose temporal bone cap was $\geq$4 mm; (B) patients with conductive or mixed hearing loss in the ear to receive the implant; (C) pure tone averages in 4 thresholds (PTA4bone) (average thresholds of 500, 1000, 2000 and 4000 Hz) for sounds *via* bone conduction equal or less than 55 dB and (D) patients who had been tested with the Baha 5 Power® Sound Processor on a softband before the implant of the device and who completed all the procedures further described. They were excluded if they (a) were unable to perform speech test, (B) had evident or perceivable cognitive or neurological alteration that made it impossible to perform the study procedures described ahead and (C) had health issues or conditions that contraindicate surgery such as uncontrolled diabetes, and/or conditions that could affect osseointegration and/or wound healing. Table 1 summarizes the patient data.

Surgical procedure

The surgical technique used to implant the Osia™ system combines the surgical procedures employed for the conventional devices Baha Attract and cochlear implants. The location of the device is shown in Figure 4.

Audiological testing

All audiological and speech tests were conducted in a sound-attenuating audiological booth. Both speech and noise were presented from a single loudspeaker located at 0^a azimuth at one meter directly in front of the subject. When the contralateral hearing was good enough like normal hearing or mild hearing loss, the contralateral ear was occluded with ear insert protector and masking *via* earphone with Narrow Band Noise for pure tones and Speech Shaped Noise por speech recognition tests. The room and the audiological equipment were calibrated in accordance with ISO 8253.

Functional gain data were recorded in patients obtained with the Baha 5 Power Sound Processor on a softband as well as the patient's postoperative experience with the Osia™ system. Free-field measurements were used to assess functional gain, with the loudspeaker positioned at O^a azimuth of the patient. Hearing thresholds were measured at 250, 500, 1000, 2000, 3000, 4000, and 6000 Hz. Functional gain results were further recorded after adaptation of the

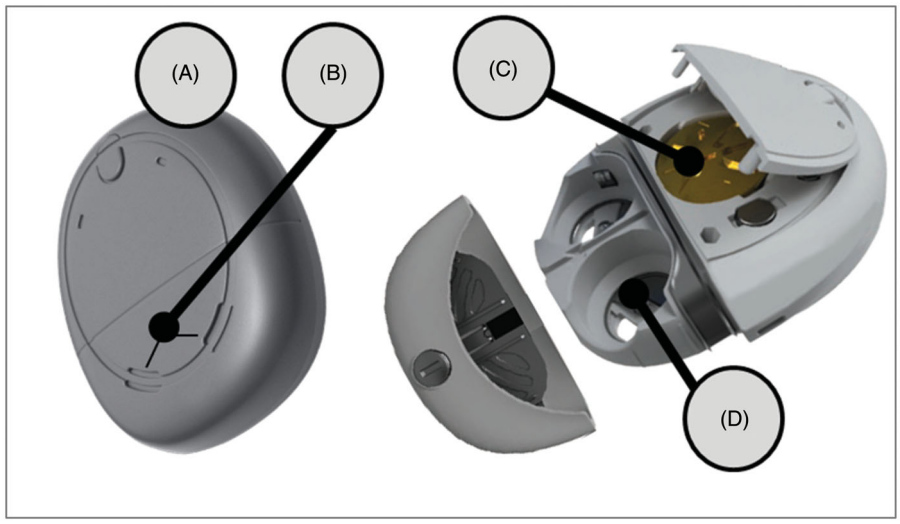


Figure 2. Osia™ external sound processor: (A) External Sound Processor of the Osia™ System (Release 1 – Based on Sound Processor CP930™). (B) Microphone. (C) Magnet. (D) Battery compartment.

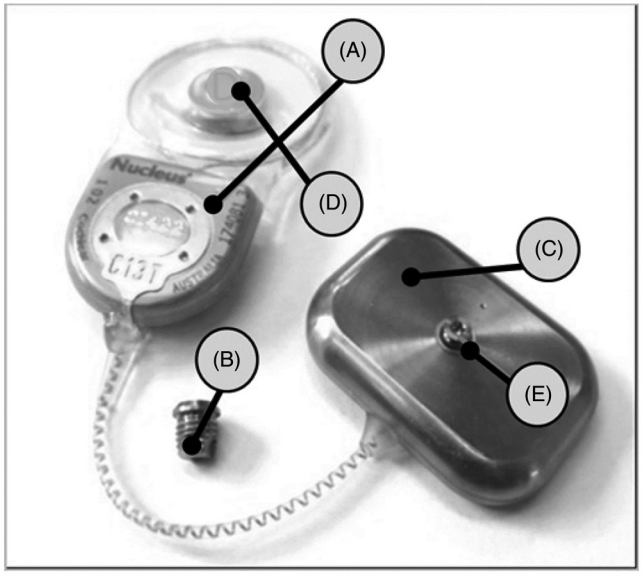


Figure 3. Internal (under the skin) components of the device: (A) Stimulator. (B) Titanium implant osseointegrated (BI300) to be inserted in the bone of the skull. (C) Vibrator (actuator). (D) Magnet. (E) Screw placed through the vibrator that is screwed to the titanium implant (BI300) thus allowing transmission of vibrations through the skull bone to the cochlea.

test devices and subsequently, after activation of the Osia™ system, according to the schedule described in Scheme 1.

Speech Recognition Performance was assessed with Hearing in Noise Test (HINT), that consists of lists containing 20 digitally recorded sentences that were presented in quiet and in noise. In this study, they were free-field.

Four test conditions were performed with Baha5 Power in the preoperative and Osia™ System in the two postoperative times: (i) Speech in noise fixed level at ratio signal/noise (S/N) = 0 dB ($S_{65}N_{65}$), (ii) Speech in noise fixed level at S/N = 5 dB ($S_{65}N_{60}$), (iii) Speech adaptative in noise fixed level (S_{adapt} N_{55}) and (iv) Speech in adaptative mode (S_{adapt}) in order to identify the speech reception threshold (SRT) associated with 50% recognition score (i.e. SRT in silence and in noise). Sentences were administered at 65 dB SPL, except in adaptative condition, which represented a conversational speech level for everyday environments. Each participant was tested first in a silence fixed condition to guarantee the knowledge and training with the test. The SRT conditions (iii and iv) were performed three times and the final considered in the analysis was the average of three trials per each subject.

Subjective listening benefits and satisfaction with their bone implants were assessed using the Speech, Spatial and Auditory Quality Scale (SSQ-12) and Glasgow Benefit Inventory (GBI) questionnaire. SSQ-12 [5] is a questionnaire that aims to evaluate a qualified experience and quantify as inability to hear in realistic communication situations. From this premise, three general domains were created: Part 1 – hearing for speech; Part 2 – spatial hearing and Part 3 – hearing qualities. The SSQ-12 was administered to patients with both devices, Osia™ and Baha®5 Power for comparative purposes, in pre and postoperative conditions, according to the schedule provided in Scheme 1.

The aim of GBI is to quantify a large deterioration in health status or a large improvement in health status [6]. The original 18 question GBl was first scored into a total score then scored into the three subscales: (a) General factors (b) Social (c) Physical GBI has been validated for ear, nose and throat interventions and was also systematically reviewed in 2016 [7]. GBI was only administered to patients after the surgery and it was simply used to establish the effect of Osia™ implantation on patient health status.

Statistical analysis

To determine the performance of Osia™ System compared to Baha5 Power, paired comparison analyses were performed, where each participant served as their own control. Before the comparison, data were tested with Shapiro-Wilk test and was confirmed a normal distribution in all data: functional gain thresholds, speech perception and SSQ scores. So paired T-test were performed for each condition on intervals (pre, post-2, and post-6 months). In all cases, a

Table 1. Recipients biographic and disease information.

Patient	Gender	Age (yrs)	PTA4bone (dB)	Osia Ear	Etiology implanted ear	Implanted ear	Contralateral ear	Occlusion during Audiological test
1	M	19	8.75	R	Atresia /microtia	Moderate Conductive HL	Normal	X
2	F	28	22.5	R	Previous ear reconstruction Congenital Atresia	Moderate Conductive HL	Normal	X
3	F	42	21	R	Previous mastoidectomy Congenital partial atresia	Severe Conductive HL	Mild Conductive HL	X
4	F	6	15	L	Congenital Atresia	Moderate Conductive HL	Normal	X
5	F	29	8.7	L	Congenital atresia. Pinna reconstructed	Severe Conductive HL	Normal	X
6	F	55	32.5	L	Bilateral Congenital atresia	Moderate Mixed HL	Moderate Mixed HL	X
7	M	54	25	R	Atresia/microtia	Severe MixedHL	Severe Mixed HL	X
8	F	64	45	R	Previous mastoidectomy	Severe Conductive HL	Mild Sensorioneural HL	X
9	F	21	12.5	R	Congenital fixation of stapes	Moderate Conductive HL	Normal	X

yrs: years; 4FPTAbone: Average of bone conduction threshold in 500, 1000, 2000 and 4000 Hz; HL: Hearing Loss; R: right ear; L: Left ear; M: male; F: Female.

significance level of .05 was used to determine significance for analysis.

Results

Surgery was performed under general anesthesia and was uneventful in all patients. Sound processor fitting was performed at 6 weeks after surgery in all patients. No skin or retention issues were observed. Overall pain scores were low indicating no or very limited pain at the initial fitting in the majority of cases. There was no pain at 6 months. All patients noticed a small post auricular bulk when touching the skin over the receptor but considered it as part of the procedure and not an adverse effect. All patients use their devices all day during their daily activities.

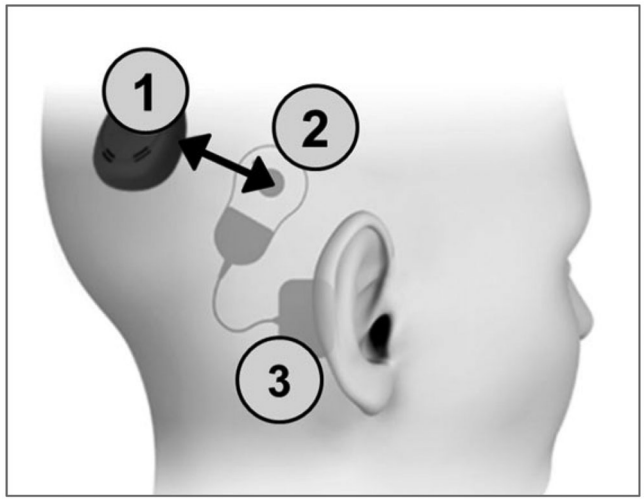


Figure 4. Location of the device relative to ear. Over the skin: 1. Sound Processor. Under the skin: 2. Stimulator. 3. Vibrator (actuator).

Functional gain

The mean thresholds in free field for unaided condition, Baha®5 Power and Osia™ System and mean gain per frequency are shown in Figure 5(A). It is interesting to note that the largest and significant differences between functional gain results were obtained at higher frequencies (show in detail in Figure 5(B)). It was also calculated a single number to express the entire gain that was obtained from average of the gains per each frequency. So, when comparing pre-surgical results of Baha®5 Power with softband to postoperative surgical procedures with the Osia™ system at 2 months after activation, the average functional gain for all frequencies was statistically higher ($p < .05$) for Osia™ System (36.88 dB) than for Baha®5 Power (30.57 dB).

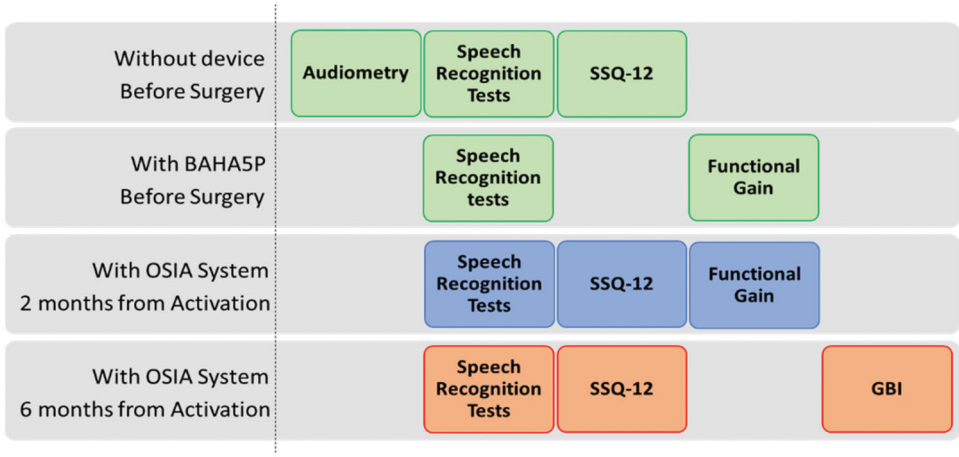
Speech recognition

The group mean for the four speech test conditions are displayed in Figure 6. They were compared the results of pre-surgical Baha®5 Power with softband and postoperative with the Osia™ system were compared at 2 and 6 months after activation. For Speech in noise fixed level condition S/$N = 0$ (i) the average of correct words was significantly better with the Osia™ system, being 78.1% for Osia™-2 months, 89.5% for Osia™-6 months and 68.5% for Baha®5 Power. In an easier condition, noise fixed level S/$N = 5$ (ii) the average of correct words was also significantly better with the Osia™ system, being 96.2% for Osia™-2 months, 97.4% for Osia™-6 months and 92.3% for Baha®5 Power.

Osia™ superiority has also observed at adaptative conditions. The mean of speech reception threshold (SRT) (ii) was significantly higher with Baha5Power than Osia™, 36.4 dB with Baha versus 26.9 dB for Osia™-2 months and 26.8 dB for Osia™-6 months. For noise condition, the average signal-to-noise (S/N) threshold was also significantly. higher, being −0.7 dB with Baha5Power and −1.6 dB with Osia™-2 months and -2.2 with Osia™-6 months. The results of the speech performance were also significantly better at 6 than at 2 months.

Questionnaires

The SSQ-12 was completed at all intervals (pre, post-2 and post-6 months). Statistically significant improvements ($p < .05$) were observed in the SSQ-12 Speech and Qualities scales when comparing pre to 2 months and pre to 6 months conditions, which may indicate that the reported benefit can be even greater after one year of use. This is shown in Figure 7.



Scheme 1. Scheme of evaluation program.

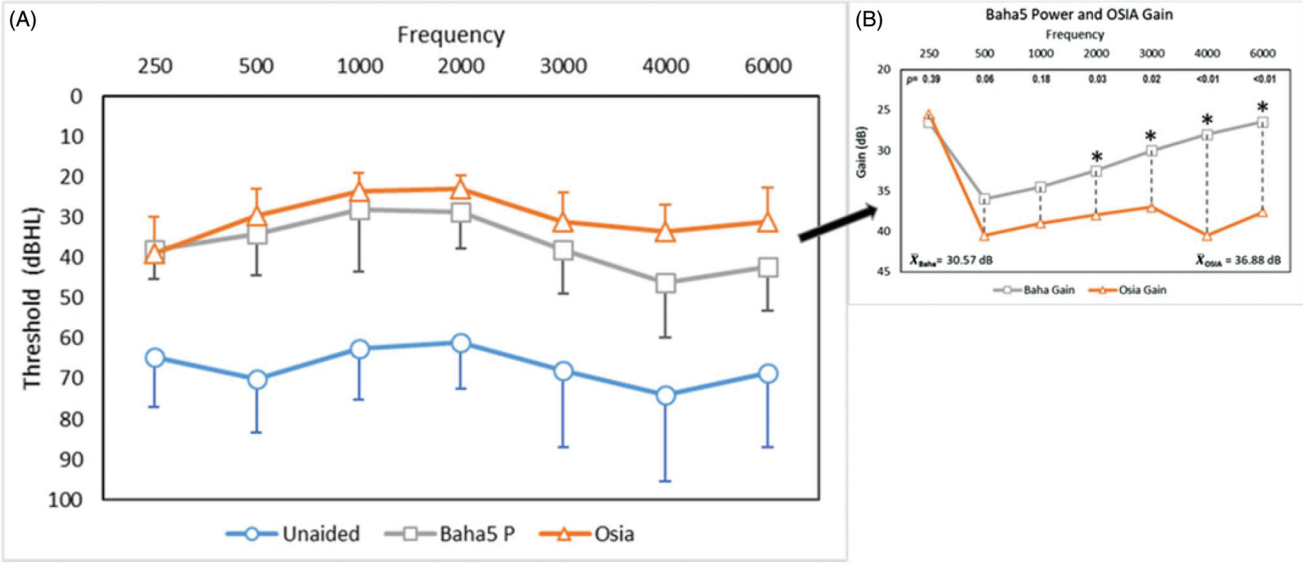


Figure 5. (A) Mean of free field thresholds and Standard Deviation for unaided condition, Baha5 Power with softband and Osia™ (post-2months) per frequency. (B) Difference (gain) between threshold for Baha5 Power and Osia™ System. $\bar{x}$ indicate a total gain per device. It is an average of gain per frequency. Significant improvements are shown by bars below the conditions with significant differences indicated by asterisks (pared T-test; $p < 0.05$). Error bars show standard error for each condition.

The GBI was the only applied at post-surgical-2 months. The GBI analysis was performed as purposed by the original analysis (8,9), the total score for each patient was calculated and then averaged to give equal weight to each question 3 (no change) was subtracted from the total and the result multiplied by 50 to produce a benefit score. All these scores ranged from −100 to +100. The same analysis was used for each of the subscales. Positive scores denote benefits and negative scores denote some deterioration. Figure 8 shows the results of the questionnaire. Patient benefit was found following implantation with an Osia™ implant for total scores (27.2) and for the three subscales. In no situation did provision of the bone implant result in a deterioration of health.

Discussion

This study evaluated the clinical performance of the Osia™ system, a new generation of active magnetic bone conduction hearing implant (BCHI) system in 9 patients with conductive or mixed hearing loss. BCHIs are used to treat patients with conductive, mixed or single sided hearing loss. Patients wearing these devices experience good performance and high satisfaction [8]. In the present study, the surgical procedures were uneventful and there were no instances of skin irritation, pressure-related skin necrosis or significant tissue reactions. This represents significantly less adverse soft tissue reactions than implants involving a skin-penetrating abutment [9], and/or electromagnetic such as BAHA Attract [2]. Although the soft tissue reactions in percutaneous devices are not significant, one would obviously expect that they should be higher than those of a transcutaneous electromagnetic device.

Overall pain scores were very low indicating no or limited pain in the majority of cases. There were no other local effects. When asked, patients noticed a small postauricular when touching the skin over the receptor but considered it as part of the procedure with no inconvenience. All patients use their device during the whole day.

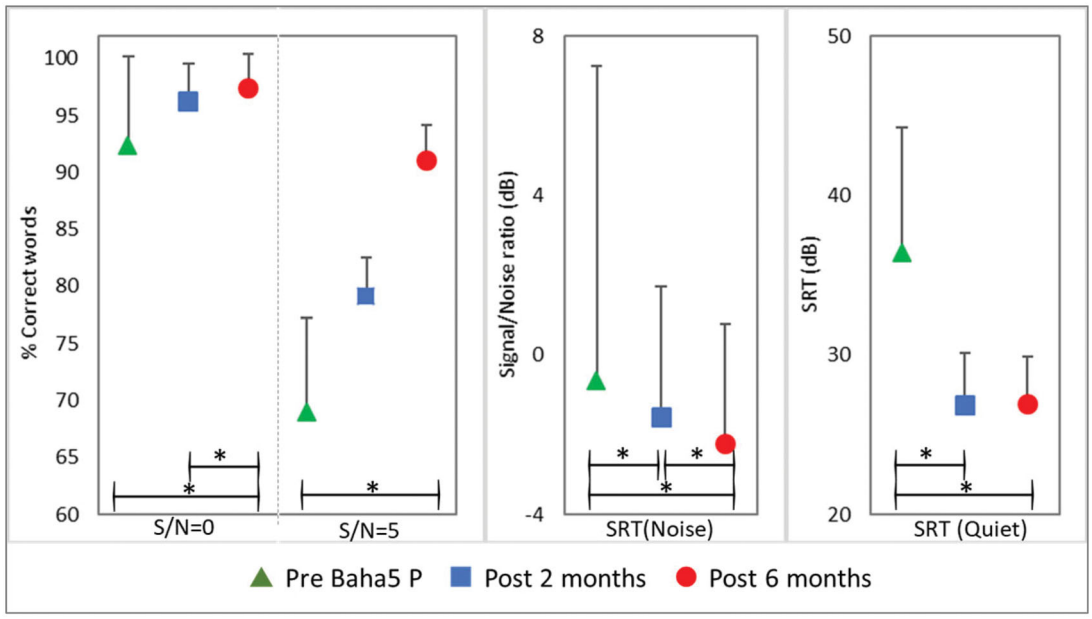


Figure 6. Two left images: Mean of correct words in (i) Speech in noise fixed level at S/*N* = 0 dB (65/65) and (ii) Speech in noise fixed level at S/*N* = 5 dB (65/60). Two right images: Mean SRT scores in (iii) Speech adaptative in noise fixed level (55 dB) (iv) Speech in adaptive mode. Significant improvements are shown by bars below the conditions with significant differences indicated by asterisks (paired T-test; $p < 0.05$). Error bars show standard error for each condition.

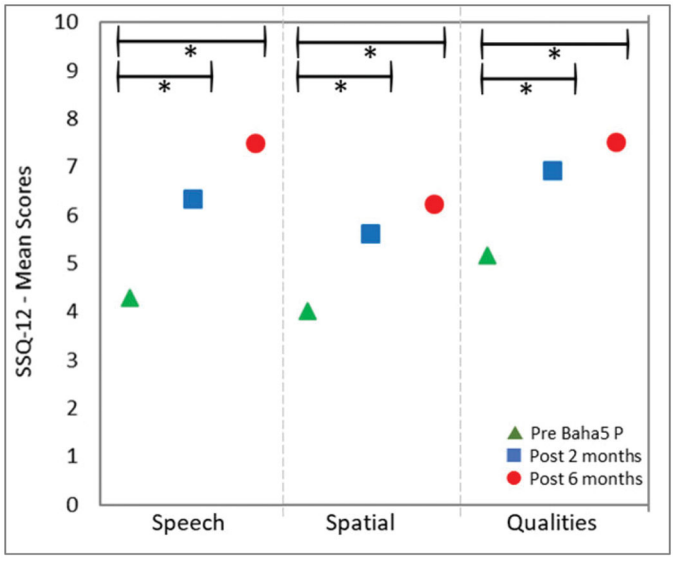


Figure 7. (A) Mean scores of SSQ-12 by categories in the three intervals: pre op with Baha5P and with Osia™ Post-2months and Post-6months. Significant improvements are shown by bars up the conditions with significant differences indicated by asterisks (paired T-test; $p < 0.05$).

In the Osia™, speech recognition in quiet and in noise was significantly better compared to either unaided situation, transcutaneous BAHA Attract and softband. This is also true for other active bone conduction implants [10]. However, although the results from Osia™ are very exciting, it is important to consider the fact that in this study Baha performance was tested with a softband and the devices were not implanted. Therefore, the differences between Baha and Osia™ could be smaller if both devices were implanted.

Audiometric threshold showed that the test device provides significant gain at all frequencies (36.88 dB). The total gain of Osia™ System was higher in comparison with another active device (28.02 dB) [11]. Moreover, it is interesting to note that the largest differences in functional gain results were obtained at higher frequencies.

In the BAHA Attract (passive device) the improvement is largest in the lower speech frequency range [2]. Above 3000 HZ in the case of the BAHA Attract the performance drops gradually as expected because of the soft tissue attenuation, which is known mainly to affect the high frequencies [4]. In pediatric patients with congenital conductive hearing loss implanted with an active bone conduction implant, Bravo et al. [12] as well as Baumgartner et al. [10] have reported best audiological performance at 4 kHz. A comparative study of active and passive devices by Zernotti et al. [13] also showed that active devices had a better performance at medium and high frequencies. These and our report are supportive of the concept of functional gain results at higher frequencies with active bone conduction devices.

The questionnaires administered to patients provided another perspective on the advantages of Osia™ in treating patients. In our study, the average scores in patients implanted with Osia™ devices were consistent with previous results with BCHI [8,10,14]. In the SSQ-12, all patients in the present study reported that the Osia™ improved the three scenarios evaluated reducing hearing difficulties under different listening conditions (Figure 7). The scores improved with time and this it could be observed at the three points that were measured (pre, post-2months and post-6 months). The progressive improvement could indicate that the benefit perception could keep improving in time.

GBI was only administered to patients after the surgery and it was simply used to establish the effect of Osia™ implantation on patient health status. GBI measures the change in health status produced by an intervention, and it

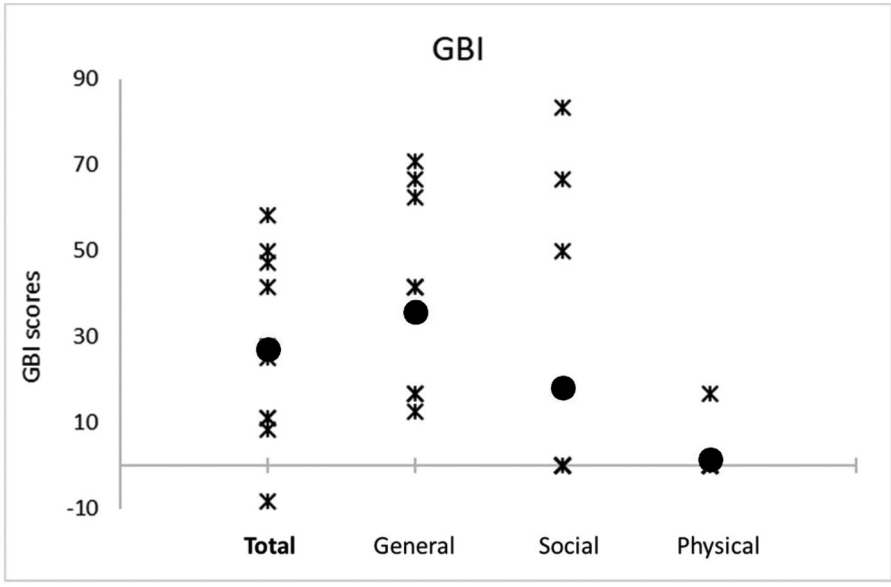


Figure 8. GBI scores for total and for the three subscales. (●) Mean for total score and for each subscale (ж) individual score.

is developed specifically for otorhinolaryngological interventions. The GBI questionnaire showed that device implantation was perceived as beneficial to health conditions, including physical health status. Our study showed that patients experience a positive quality of life outcome after implantation with the Osia™. All the individuals in this study chose to use their bone device, and the audiological evaluation showed that they benefited from their implant. The proportion of an improvement in quality of life was similar to other studies with conductive and mixed hearing loss patients [15,16]. The higher score was observed at general health status, followed by social status and the lower was physical status as shown in Figure 8.

Regarding possible advantages of this new active implant Osia™ System compared with currently existing active devices, the Osia™ allows to have improvements for hearing loss up to 55 dB which is higher than for currently existing active devices. On the other hand, the osseointegrated component (BI300 screw) of the Osia™ System should allow a better transmission of the stimulus through the bones of the skull to the internal ear. And last, the efficiency of the piezoelectric actuator is a factor to be considered.

It is interesting to mention that possibly because the active vibration system provides improvement at high frequencies, all patients consistently describe a significant improvement in the quality of hearing itself compared with the softband and unaided condition. Interestingly, all patients describe not only an improved hearing in terms of quality but also in terms of loudness.

Finally, it is important to mention that although our Osia™ surgery was successfully performed and the audiological and subjective benefits provided satisfactory outcomes in all nine patients, the number of subjects is small ($n = 9$). In addition to a longer term follow up of our patients, studies with Larger number of patients are required to confirm or deny our observations.

Conclusions

The clinical performance of this new active magnetic bone conduction hearing implant system in nine patients with conductive and mixed hearing loss was safe and effective. Audiometric and quality-of-life results were extremely satisfying. Improvement in speech recognition in quiet and in noise was significant compared to passive devices. The active vibration system provided improvement at low and high frequencies delivering a better quality of hearing than passive devices.

Disclosure statement

Cochlear Corporation provided the devices free of charge for the patients. All members of the team did the surgical and audiological procedures free of charge to the patients and did not receive any compensation (direct or indirect) from Cochlear Corporation.

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