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OTOLOGY

A comparative study of audiological outcomes and compliance between the Osia system and other bone conduction hearing implants

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Abstract

Purpose To examine the subjective and objective audiological benefits of the Osia system compared to devices commonly implanted prior to the introduction of this system.

Methods Osia recipients with either conductive hearing loss (CHL/MHL) ($n=9$) or single-sided deafness (SSD) ($n=8$) who underwent surgery from February 2021 to March 2022 were prospectively recruited. The audiological outcomes and usage rate of Osia implantees were compared with those of retrospectively recruited patients implanted with other devices ($n=50$). The subjective satisfaction of the Osia implantees was also evaluated through questionnaires.

Results All users of the Osia system were classified as regular users. In the CHL/MHL group, the effective gain of the Osia system (11.1 ± 14.9 dB) surpassed that of the Baha and Bonebridge (− 2.7 ± 12.6 dB) at 2 kHz ($p=0.01$, Mann–Whitney U test). Among the devices, the Osia system tended to tolerate the worst bone conduction thresholds, up to the level of 61 dB. In the SSD group, the functional gain of Osia at 4 kHz (37.5 ± 3.1 dB) was higher than that of the Baha and Bonebridge group (26.9 ± 3.0 dB) ($p=0.05$, Mann–Whitney U test).

Conclusion The Osia system yielded larger audiological gain than the Baha Attract and Bonebridge devices, especially at high frequencies, leading to substantially higher compliance. The Osia system tended to have the strongest tolerance to aggravated bone conduction thresholds among the available transcutaneous bone conduction hearing implants. Therefore, the Osia system could potentially be a good option for CHL/MHL patients with bone conduction thresholds of 50 dB HL or more, as well as patients with SSD.

Keywords Osia · Bone conduction hearing implants · High frequency gain · Usage rate · Bonebridge · Baha

Introduction

Bone conduction hearing implants (BCHIs) induce vibration of the temporal bone, which directly stimulates the cochlea, enabling the auditory rehabilitation of patients with conductive or mixed hearing loss (CHL/MHL) and single-sided deafness (SSD) [1, 2]. The Osia (Cochlear, Sydney, Australia) is an active transcutaneous BCHI. The implant (OSI200) is unique in that it utilizes a piezoelectric actuator anchored to the mastoid bone through an osseointegrated screw (BI300 implant). This piezoelectric actuator generates mechanical forces in response to electrical signals delivered by the external sound processor.

Early experiences with the Osia system have shown favorable results [3–5]. With the new implant, a maximum average hearing loss of up to 55 dB in bone conduction (BC) at frequencies of 0.5, 1, 2, and 4 kHz can be rehabilitated. Considering that the first generation of BCHIs could only tolerate a BC threshold of 35–40 dB [5–7], this represents a large increase in the maximum average BC threshold, potentially allowing benefits to be received by a wider population of patients with worse degrees of hearing loss.

The Osia system has been reported to have the advantage of larger gain at higher frequencies than passive BCHIs [8, 9]. Therefore, we wanted to examine the functional and effective gain of Osia treatment in both CHL/MHL and SSD

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patients. Previously we reported our experience with BCHIs [10], comparing the audiological outcomes between various kinds of devices. The current study aimed to examine the benefits of the higher maximal power output and the larger higher frequency gain of the new device as compared to the devices commonly implanted prior to the introduction of the Osia system—the Baha and the Bonebridge. We also analyzed whether this audiological factor led to 1) tolerance in patients with worse BC and 2) better usage rate among Osia implantees in comparison to the usage rate reported for other BCHIs in our previous study.

Materials and methods

Participants and ethical considerations

The recipients of the Osia system who underwent surgery from February 2021 to March 2022 were prospectively recruited. Patients with either CHL/MHL or SSD whose ages ranged from 18 to 80 years were eligible for the study. In total, 17 patients (7 men, 10 women) were recruited during the study period: nine had CHL/MHL and eight had SSD. The mean age at operation was 58.9 ± 16.0 years in the CHL/MHL group and 41.8 ± 17.8 years in the SSD group.

In the CHL/MHL group, all participants had previously undergone tympanomastoidectomy due to chronic otitis media on the implanted side prior to BCHI, with insufficiently satisfactory hearing outcomes (i.e., an air–bone gap of 25 dB or larger postoperatively). Notably, in the CHL/MHL group, two patients had normal contralateral hearing, while seven patients had bilateral hearing loss. In the SSD group, all patients had severe to profound sensorineural hearing loss at the implanted site, and the hearing level at opposite site was within 30 dB HL. All candidates went through a rigorous headband trial of Baha5 to minimize the postoperative non-use rate. One experienced surgeon (B.Y.C) performed surgery in all cases using routine procedures, in accordance with the manufacturer's recommendation.

To compare the audiological gain between the Osia system and other devices, all BCHI recipients from 2015 to 2020 ($n = 50$) were retrospectively recruited. The choice of device was mainly based on the time of surgery. Specifically, the Bonebridge (MED-EL, Innsbruck, Austria) was the device mainly implanted at our center between 2015 and 2018. After the introduction of the Baha5 power speech processor in 2018, the Baha Attract (Cochlear, Australia) became the most commonly implanted device. Within this group of Baha and Bonebridge implantees, 24 patients were classified as SSD, while 26 manifested CHL/MHL. The mean age at operation was 52.9 ± 16.7 years in the CHL/MHL group and 48.1 ± 17.4 years in the SSD group among Baha and Bonebridge implantees. There were no perioperative complications. The applied sound processors were Baha5 for Baha Attract and Amadé BB for Bonebridge. The Baha and Bonebridge implantation were also carried out at the same center by the same surgeon (B.Y.C).

The fitting of the devices was performed in accordance with the manufacturers' guidelines. The initial activation of the sound processor was performed 4 weeks after implantation. All participants were followed-up for 3–12 months after surgery, and the postoperative audiological results, presence of complication, and usage time of BCHIs were evaluated.

All participants voluntarily participated in the study and provided written informed consent after a full explanation of the risks and benefits of the procedure. The study protocol conformed to the guidelines of the Declaration of Helsinki and Korean Good Clinical Practice. This study was reviewed and approved by the Institutional Review Board of Seoul National University Bundang Hospital (IRB-B-2010-642-004).

Evaluation of subjective satisfaction

Usage rate of BCHIs

The daily average time of BCHI use was assessed using data logging. Participants who used BCHIs for at least 2 h per day were classified as regular users, and others were categorized as irregular users, as previously described [11].

Questionnaires on hearing-related quality of life among the Osia system implantees

The subjects implanted with the Osia system were asked to complete the Speech, Spatial and Quality of Hearing Scale (SSQ) and the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaires preoperatively and postoperatively at 1 month, 3 months, and 6 months.

Evaluation of audiological benefits

We aimed to compare the audiological outcomes of Osia system implantees with those implanted with Baha Attract or Bonebridge, the two most commonly implanted devices before the introduction of Osia. Pure tone audiometry and speech audiometry were performed preoperatively and postoperatively. The BC threshold, air conduction (AC) threshold, and aided threshold level were measured at frequencies of 0.25, 0.5, 1, 2, 3 and 4 Hz. The pure tone average was calculated across the frequencies of 0.5, 1, 2, and 4 kHz. The speech discrimination score was determined using monosyllabic phonetically balanced words to be presented at the level of 30 dB above the speech recognition threshold. The examiner presented 50 words, and the intensity of the examiner's voice was balanced at 0 dB on a volume unit meter. The percentage

of words repeated correctly by the patient was recorded. Free-field audiometry was performed in an adapted, soundproof room, with the signal presented from a loudspeaker placed at the height of the subject's ears, at a distance of 1 m and angle of 45° or −45°. The aided hearing thresholds with BCHIs were determined using warble tones over the range 500–4000 Hz at octave intervals. A preoperative audiological evaluation was performed within 1 month before surgery, and the postoperative BC threshold, AC threshold, and aided level with BCHIs were evaluated at around 12 months after surgery.

The audiological gain of the CHL/MHL group was evaluated by calculating the effective gain. The effective gain was evaluated as the difference between the mean BC thresholds at the side with better BC level and the mean aided levels in the MHL group and between the BC thresholds at the opposite site and aided level in the SSD group at 0.5, 1, 2, and 4 Hz [13, 14].

The audiological gain of SSD was evaluated by calculating the functional gain. The functional gain was calculated as a difference between the mean AC thresholds and aided thresholds for 0.5, 1, 2, and 4 Hz. When the hearing level of the non-implanted site was better than that of the implanted site, such as in patients with SSD, the aided thresholds were evaluated with the non-test ear blocked. The blocking of the non-test ear was performed with an earmold impression of a hearing aid and covered with an earmuff, and the attenuation of the non-test ear blocking was about 40 dB SPL [12].

Statistical analysis

All results are presented as mean and standard deviation. Statistical analyses were performed using SPSS version 24.0 (IBM Corp., Armonk, NY, USA). p values < 0.05 were considered to indicate statistical significance. Comparisons of audiological outcomes between the devices were performed with a non-parametric test because of the limited number of subjects. In patients with SSD, the aided hearing thresholds, functional gain, and effective gain were compared using the Mann–Whitney U test. For Osia implantees, improvements in the two aforementioned questionnaires at 1 month, 3 months, and 6 months after surgery were examined using the Wilcoxon signed-rank test.

Results

Subjective satisfaction with BCHIs

Device usage rates of BCHIs

Our prior report found different usage rates among subjects with SSD and CHL/MHL [10]. Therefore, we also compared the regular usage rate of Osia users with that of Baha and Bonebridge users separately for CHL/MHL and SSD patients in this study. For the CHL/MHL participants, all 9 Osia system users became regular users who used the Osia system for at least 2 h per day. However, this figure turned out not to reflect a statistically significant difference from that of the Baha and Bonebridge users (76.2%, 21 of 26 were regular users) ($p = 0.30$. Fisher exact test). In contrast, the usage rate of the Osia system for SSD participants (100%, all 8 patients were regular users) was significantly higher than that of the Baha and Bonebridge users (58.3%, 14 of 24 were regular users) ($p = 0.04$, Fisher exact test).

Questionnaires on hearing-related quality of life in the Osia system implantees

The participants showed a significant subjective benefit from the Osia system compared to their preoperative status as assessed using the APHAB and SSQ questionnaires (Supplementary Information 1 and 2). Overall, the SSQ questionnaire better reflected the subjective benefits in both SSD and CHL/MHL patients implanted with Osia, and the CHL/MHL patients implanted with Osia showed better subjective benefits, especially in the SSQ, than did the SSD patients (Supplementary Information 1 and 2).

Audiological benefits of BCHIs in CHL/MHL

Effective gain in BCHIs (Osia system versus other bone conduction devices)

Among the entire BCHI cohort with CHL/MHL ($n = 35$), the average BC threshold was 39.5 ± 14.5 dB HL at the implanted side and 37.8 ± 29.0 dB HL at the opposite side, revealing no obvious difference. The average AC thresholds were 77.4 ± 13.9 dB HL on the implanted side and 55.4 ± 27.8 dB HL on the opposite side, showing that the devices were implanted on the side with the worse AC threshold (Fig. 1a). All participants showed significant improvement in the hearing level with BCHIs, and the average aided level was 38.3 ± 10.1 dB HL, similar to the better BC threshold among both ears.

The effective gain, which is the difference between the better ear BC threshold and the aided level, was − 6.8 ± 10.5 dB. The effective gain of the Osia group (11.1 ± 14.9 dB, $n = 9$) was significantly higher than that of the Baha and Bonebridge group (-2.7 ± 12.6 dB, $n = 26$) at 2 kHz ($p = 0.01$, Mann–Whitney U test, Fig. 1b).

Bone conduction thresholds among regular users of each BCHI

Of note, the average BC threshold of the better ear of the CHL/MHL patients implanted with the Osia system was

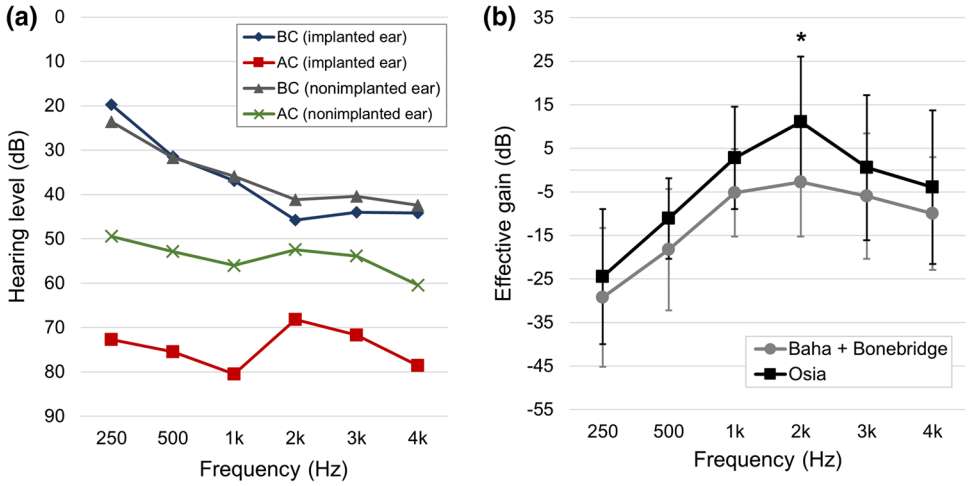

Fig. 1 Preoperative audiological profile of implantees with conductive or mixed hearing loss (CHL/MHL) (**a**) and comparison of effective gain (**b**). *BC* bone conduction, *AC* air conduction

36.5 ± 14.7 dB HL, which was slightly higher than that of the Baha (27.8 ± 15.2 dB HL, $p = 0.22$, Mann–Whitney U test) and Bonebridge (28.1 ± 12.8 dB HL, $p = 0.17$, Mann–Whitney *U* test) groups, although the difference was not statistically significant. When comparing the BC thresholds exclusively of the regular users of Osia, Bonebridge, and Baha Attract, the results were 36.5 ± 14.7 dB HL, 27.3 ± 12.4 dB HL, and 31.4 ± 13.6 dB HL, respectively (Table 1).

The BC thresholds of the regular users with the worst hearing in the Osia, Bonebridge, and Baha Attract groups were 61.3 dB HL, 56.3 dB HL, and 46.3 dB HL, respectively. Additionally, the average values of the worst 30% of bone conduction thresholds from regular users of each BCHI were 52.9 ± 6.0 dB HL ($n = 3$), 40.3 ± 9.0 dB HL ($n = 5$), and 43.4 ± 3.3 dB HL ($n = 3$), respectively. These data suggest that the Osia system could tolerate the worst BC threshold among the various BCHIs.

Correlation of audiological gain and subjective benefits in the Osia system with CHL/MHL

Next, to see the relationship, if any, between audiological gains and subjective benefits, the correlations between the effective gain at 2 kHz and the changes in the SSQ and the EC and BN domains of the APHAB (the domains in which statistically significant improvements were documented in the CHL/MHL group) were analyzed. A significant correlation between the higher effective gain at 2 kHz at 1 month and changes in subjective satisfaction was seen in the speech (rho = −0.9, $p = 0.004$) and spatial (rho = −0.8, $p = 0.004$) domains of the SSQ (Fig. 2).

Next, we further analyzed whether the worse BC threshold of the better ear among the Osia system implantees contributed to the worse subjective satisfaction. We could not identify any hint of a significant correlation between a BC threshold up to 61.3 dB HL and changes in the SSQ and the EC and BN domains of the APHAB (Fig. 3).

Audiological benefits of BCHIs in single-sided deafness

Among the entire BCHI cohort with SSD ($n = 32$), the average BC threshold was 93.8 ± 20.2 dB HL on the implanted side and 17.8 ± 12.2 dB HL on the opposite side. To evaluate the hearing level with BCHIs in the SSD group, the unaided level (M-level) and the aided level were evaluated in the free

Table 1 Comparison of bone conduction thresholds of CHL/MHL patients implanted with Osia, Bonebridge, or Baha Attract

Device	Total implantees	Regular users	Irregular users	Threshold of the patient with the worst hearing from regular users of each BCHI	Average of the worst 30% of bone conduction thresholds from regular users of each BCHI
Osia	36.5 ± 14.7	36.5 ± 14.7	–	61.3	52.9 ± 6.0
Bonebridge	28.1 ± 12.8	27.3 ± 12.4	33.8 ± 19.4	56.3	40.3 ± 9.0
Baha Attract	27.8 ± 15.2	31.4 ± 13.6	19.2 ± 18.1	46.3	43.4 ± 3.3

The numbers are in dB HL

CHL/MHL conductive hearing loss/mixed-type hearing loss, *BCHI* bone conduction hearing implant

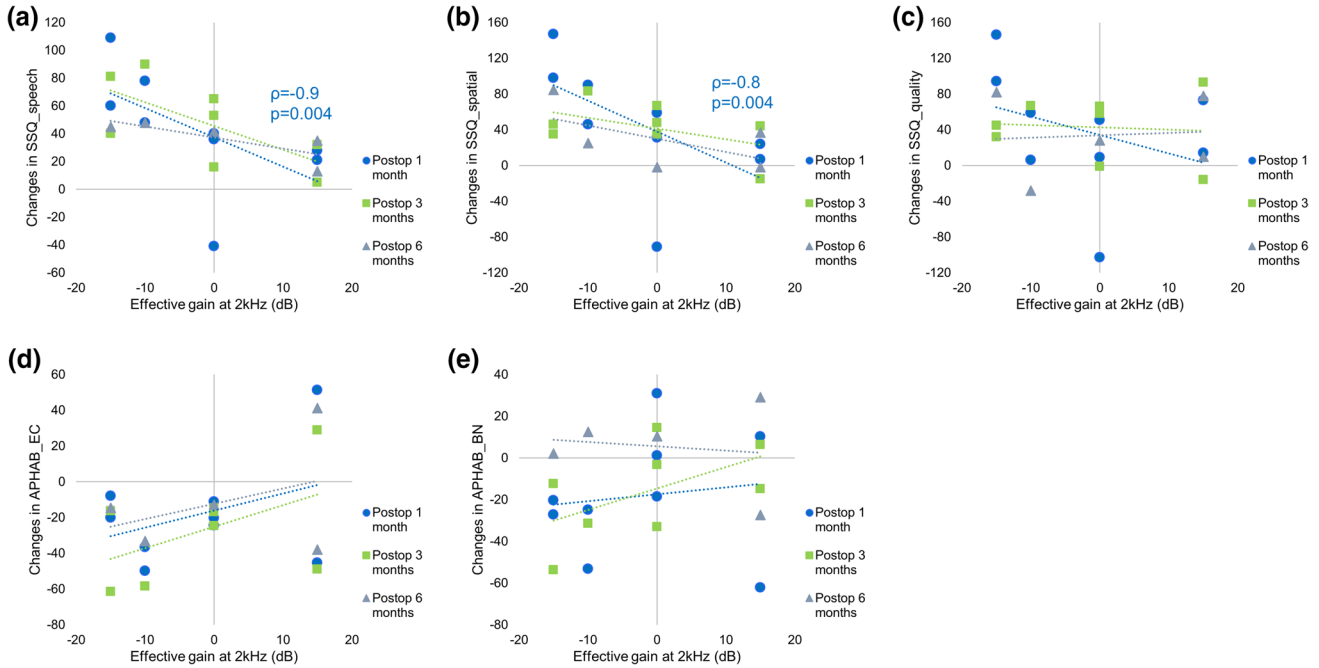

Fig. 2 Correlations between effective gain at 2 kHz and changes in the SSQ and the EC and BN domains of the APHAB for conductive or mixed hearing loss patients implanted with the Osia system. *SSQ* Speech, Spatial and Quality of Hearing Scale, *APHAB* Abbreviated Profile of Hearing Aid Benefit, *EC* ease of communication, *BN* background noise

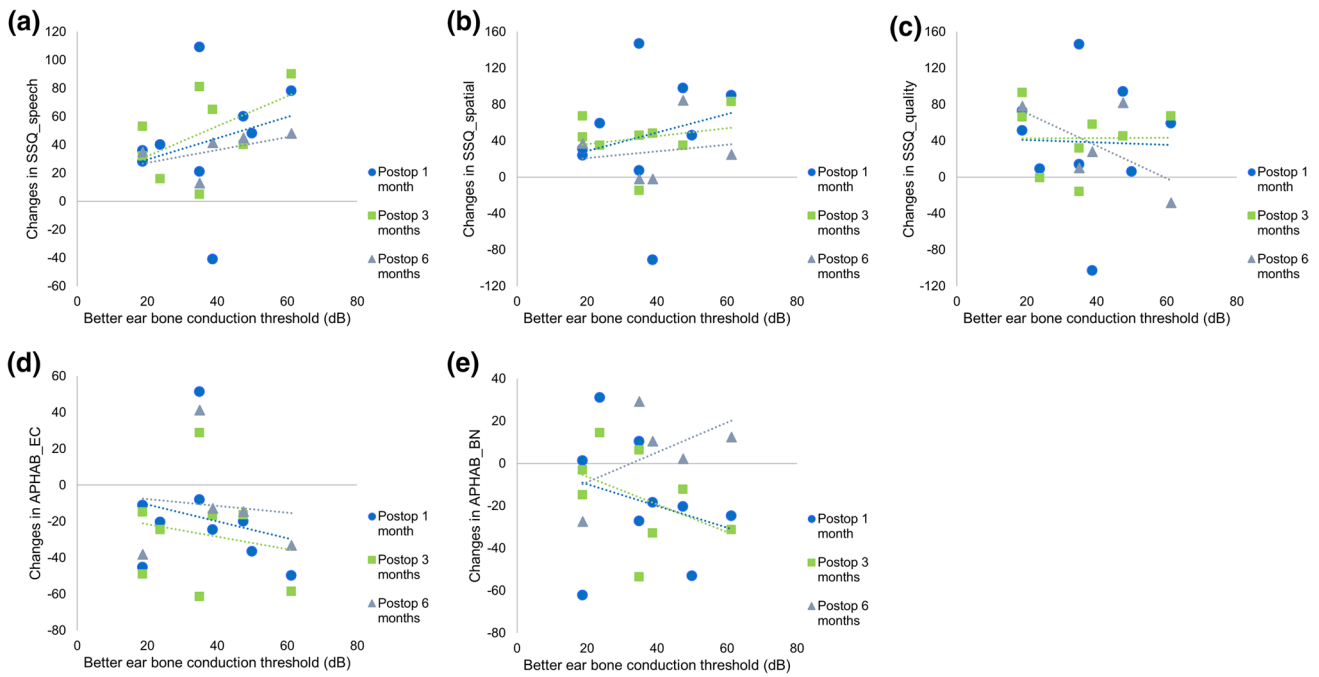

Fig. 3 Correlations between bone conduction threshold and the changes in the SSQ and the EC and BN domains of the APHAB. *SSQ* Speech, Spatial and Quality of Hearing Scale, *APHAB* Abbreviated Profile of Hearing Aid Benefit, *EC* ease of communication, *BN* background noise

field with the opposite ear muffled. The average M-level and aided level across all frequencies were 50.6 ± 13.0 dB HL and 26.8 ± 7.7 dB HL, respectively (Fig. 4a).

The average functional gain, which is calculated as the M-level minus the aided level, was 17.6 ± 20.5 dB across all frequencies from all devices. It was more pronounced

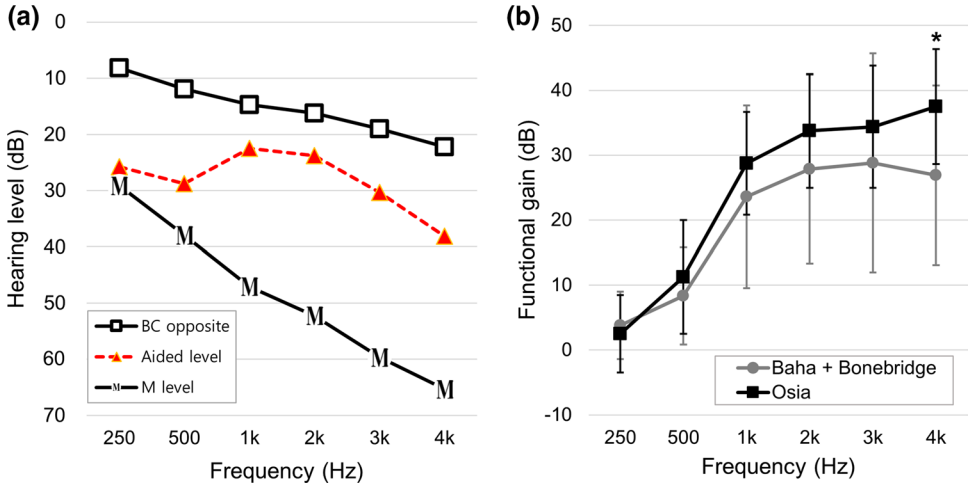

Fig. 4 Hearing level (red) with bone conduction hearing implants in the single-sided deafness group (**a**) and comparison of functional gain (**b**) according to devices. *BC* bone conduction

towards higher frequencies and the functional gain of the Osia system ($n=8$) tended to be larger than that of the composite group of the Baha Attract and Bonebridge users ($n=24$) in mid to high frequencies. Notably, at 4 kHz, the functional gain in the Osia group (37.5 ± 8.9 dB) was significantly higher than in the composite group of Baha Attract and Bonebridge users (26.9 ± 13.8 dB) ($p=0.05$, Mann–Whitney *U* test, Fig. 4b). The functional gain of the Baha Attract and Bonebridge users at 4 kHz was 21.7 ± 15.7 dB and 29.0 ± 13.0 dB, respectively.

Discussion

The current study demonstrated that the piezoelectric transcutaneous Osia system can be implanted safely in patients with CHL/MHL and SSD, with obvious subjective and objective benefits. Importantly, this study demonstrated significantly larger audiological gains of the Osia system than other BCHIs in both SSD and MHL patients. Further, we displayed preliminary data suggesting a correlation between subjective (usage rate or satisfaction as revealed by the SSQ and the APHAB) and objective benefit (audiological gain) for the Osia system both in CHL/MHL and SSD patients.

Unlike bilateral symmetric sensorineural hearing loss, the hearing difficulty perceived by SSD patients like those included in this study differ from person to person, and the need for intervention depends on the individual's daily sound environment. Therefore, the best mode of rehabilitation is not uniform among patients, and the rehabilitation options should be individualized. For successful auditory rehabilitation, the proper selection of devices, with consideration of patients' hearing level/type, characteristics, and personal needs, is mandatory. There are several options, including BCHIs, which is why we need comparative studies among the different devices.

Through this study, we were able to verify statistically significantly larger audiological gain for Osia, especially at high frequencies (significant at 2 kHz for CHL/MHL patients and 4 kHz for SSD patients) than in other BCHIs, which to the best of our knowledge is the first finding of this type in the literature. In prior reports, the Osia system has consistently shown significant improvements, especially at higher frequencies. For example, Goldstein et al. in 2020 reported an average additional gain of around 10 dB of Osia compared with Baha Attract/Connect in 40 operations [3]. Regarding amplification at higher frequencies, which is important for speech perception, Goycoolea et al. found the Osia system to be superior to even Baha5 SuperPower on a Softband, especially at 2–6 kHz [4]. Rauch et al. also found larger amplification power at higher frequencies (increased four frequency pure tone average of around 7 dB), for both CHL (unilateral and bilateral) and SSD Osia recipients, who had a significant advantage at frequencies above 1 kHz in comparison with other bone amplification devices, such as BAHS on a Softband.

For patients with CHL/MHL, effective gain is thought to be a better parameter to analyze auditory benefits than functional gain [10, 15], because the improvement of hearing with BCHIs is related to the BC hearing level of the better ear. Notably, the effective gain of the Osia group was significantly superior to that of the composite cohort of Baha Attract and Bonebridge group across all frequencies, although statistical significance was observed only at 2 kHz. The high usage rate of the Osia system, reaching 100% among CHL/MHL subjects, could be attributed to this high effective gain at 2 kHz. This hypothesis is well supported by the correlation of the subjective benefits, as documented by the SSQ and APHABL questionnaires, and the effective gain at 2 kHz among the Osia system users.

Furthermore, this study suggests that the Osia system, as a piezoelectric device, could be the only transcutaneous

BCHI that can reliably provide satisfaction in patients with MHL whose BC threshold is significantly elevated. For patients with MHL, the Osia system appears to tolerate the worst BC threshold among BCHI devices. First, the average BC threshold of the better ear of the CHL/MHL patients who were implanted and satisfied with the Osia system (36.5 ± 14.7 dB HL) was slightly worse than that of the CHL/MHL patients implanted with Baha (27.8 ± 15.2 dB HL) or Bonebridge (28.1 ± 12.8 dB HL), albeit with no statistical significance due to the small numbers. Second, the average of the worst 30% of BC thresholds from regular users of the three BCHI devices clearly showed that the Osia system had the best tolerance, with subjective satisfaction and increased BC thresholds. Lastly, there was no decrease in satisfaction of MHL subjects with the Osia system even as the BC threshold worsened up to 61.3 dB HL. Collectively, the Osia system could be considered as the only reliable transcutaneous BCHI for MHL subjects with a BC threshold between 50 and 60 dB HL.

Subjects with SSD suffer mainly from impairment of speech recognition in noise and sound localization. Several treatment options for SSD have been introduced, and BCHIs were reported as one of the effective treatment options for SSD. BCHIs showed a significant improvement in speech discrimination in noise circumstances [16]. In patients with SSD, BCHIs exert benefits by transmitting sound waves intercepted on the deaf side as vibrations to the contralateral cochlea, thereby eliminating or overcoming the head shadow effect [17–19]. The aided thresholds that one would expect to compensate for the head shadow effect are approximately 5 dB at 1 and 2 kHz and 25 dB at 4 kHz [14, 20]. This indicates that the gain at high frequencies is mainly related to overcoming the head shadow effect, providing an audiological basis for the higher compliance with the Osia system in this current study, since Osia generated significantly greater audiological gain at 4 kHz in SSD patients. In our previous comparative analyses between regular and irregular users among SSD patients, regular users displayed obviously higher functional gain from BCHIs than did irregular users [10]. In this regard, the remarkably high usage rate of the Osia group in SSD subjects could be substantially accounted for by the larger functional gain at high frequencies in the Osia system.

This study is an early outcome analysis including patients with 1 to 12 months of experience (average follow-up, 6.9 months) of the Osia system; therefore, a bias towards favorable outcomes of Osia might have existed. However, 15 out of the 17 implantees in this current study used the device for longer than 6 months.

This study had several limitations. The number of Osia patients included in the study was not large enough to draw definitive conclusions. The device was only recently introduced to our country, so we were unable to report long-term experiences. Furthermore, the quality-of-life questionnaires were only acquired from Osia implantees, so a comparative study of subjective satisfaction between devices was not undertaken.

Conclusion

The Osia system yielded larger audiological gain than were observed in the Baha Attract and Bonebridge cohort, especially at high frequencies, with significant differences at 4 kHz for SSD patients and 2 kHz for CHL/MHL patients, leading to significantly higher compliance among Osia users with SSD. A correlation was also found between subjective satisfaction and the auditory gain at 2 kHz among Osia implantees with CHL/MHL. Further, the Osia system offers the strongest tolerance to aggravated BC thresholds among the available transcutaneous BCHIs. Taken together, the Osia system could be positioned as a better fit for SSD patients for whom compliance can be an issue or for MHL patients with BC thresholds of 50 dB HL or more.

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Author contributions YK, and BYC designed the study, analyzed data, and wrote the paper; GC, HJO, collected and analyzed data. All authors read and approved the final manuscript.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

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