



Hearing Rehabilitation with Osia[®] 2 in Patients with Bonebridge[®] Failure

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Purpose: This study aimed to compare the clinical performance and patient satisfaction of the Osia[®] 2 system with the Bonebridge[®] system in patients requiring reimplantation owing to Bonebridge[®] device malfunction.

Materials and Methods: A retrospective chart review was conducted on seven patients who initially received Bonebridge[®] and subsequently underwent reimplantation with Osia[®] 2 following device failure. Audiological outcomes were evaluated using pure tone audiometry and the Korean Hearing in Noise Test. Subjective outcomes were assessed with the Abbreviated Profile of Hearing Aid Benefit (APHAB) and Speech, Spatial and Qualities of Hearing Scale (SSQ).

Results: Osia[®] 2 provided greater low-frequency gain and comparable high-frequency gain compared to Bonebridge[®]. The median hearing gain with Osia[®] 2 was 60.0 dB (interquartile range, 48.75–83.0), consistent with previous findings for this model and higher than those reported for the earlier Osia[®] model. Patient questionnaires indicated significant improvements in APHAB and SSQ scores with Osia[®] 2 compared to both unaided and Bonebridge[®]-aided conditions.

Conclusion: The Osia[®] 2 system demonstrated audiological outcomes and patient satisfaction comparable to the Bonebridge[®] system in this reimplantation cohort. Osia[®] 2 may be a favorable option for patients with conductive or mixed hearing loss or single-sided deafness, pending further studies on long-term device reliability.

Key Words: Bone conduction; hearing aids; hearing loss, unilateral; hearing loss, conductive; bone-anchored prosthesis

INTRODUCTION

Bone-conducting hearing implants (BCHIs) transfer sound to the inner ear via skull vibrations, bypassing the external and middle ears, to enable auditory rehabilitation in patients with conductive hearing loss and single-sided deafness (SSD). The first generation of these implants were percutaneous, direct-connect bone conduction implants, which used osseointegra-

tion to stimulate the inner ears transcranially.¹ In percutaneous implants, the abutments penetrate the skin, leading to potential skin complications and cosmetic concerns. This prompted the development of transcutaneous systems such as Cochlear[™] Baha[®] Attract (Cochlear Bone Anchored Solutions, Sydney, Australia) and Sophono Alpha[™] (Medtronic, Minneapolis, MN, USA). In these systems, the skin remained intact, and the external sound processor, with a vibrating actuator, was connected magnetically to the internal fixture.^{2,3} However, these systems also had limitations, such as reduced gain due to the attenuation of vibratory energy as it passed through the skin and soft tissues.⁴ To address this issue, Bonebridge[®] (MED-EL Corp, Innsbruck, Austria), a transcutaneous system utilizing an active electromagnetic implant, was developed. Unlike the passive (skin-drive) transcutaneous system, where the vibrating actuator is external, this active (direct-drive) system transfers sound to an internal implant, converting it to an electrical signal. The electrical signal is then transmitted to the actuator, which generates vibrations. This system minimizes

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transmission loss and has demonstrated superior high-frequency gain compared to passive devices.^{5,6} Bonebridge® was the only available active transcutaneous bone conduction hearing device until the release of the Osia® system in 2018.⁷

The Osia®2 system (Cochlear BAS, Molnlycke, Sweden) is a new active transcutaneous bone conduction implant system that utilizes piezoelectric stimulation, connecting transcutaneously to an external processor. Piezoelectric technology generates vibratory energy when an electrical current is applied, transmitting the vibration to the bone through the actuator's connection to the implanted titanium fixture. This system provides high output and improvements in speech recognition.⁸

The Osia® system received the United States Food and Drug Administration (FDA) approval in November 2019, with studies demonstrating its safety and favorable results.⁹⁻¹² In South Korea, two studies investigated auditory habilitation using the Osia® system.^{13,14} The Osia® system reportedly provides greater gain than passive BCHIs, especially at higher frequencies, delivering better sound quality due to its active internal vibration system, which overcomes the attenuation of sound through soft tissue.^{8,15} The Osia®2 system, the latest generation of the Osia® series, is expected to offer hearing improvement effects that are comparable to, or better than, those of the Bonebridge®, another active transcutaneous implantation device. Some studies comparing audiologic outcomes between the Osia® and Bonebridge® systems suggest that the Osia® offers superior gain.^{14,15} However, it is important to note that these comparisons were not based on studies conducted in identical patient groups, making direct comparisons challenging.

The most common adverse events associated with active transcutaneous BCHIs are device malfunctions, accounting for 28.6% of all reported adverse events. These malfunctions are primarily caused by idiopathic factors, exposure to 1.5-Tesla magnetic resonance imaging (MRI), or trauma.¹⁶ In such cases, device removal and replacement are necessary, and reimplantation with a different device is often considered to prevent recurrence. These situations provide an opportunity for a direct comparison of the efficacy and safety of different devices. In this context, the authors observed cases in which patients were reimplanted with the Osia®2 system following Bonebridge® device malfunction, allowing for a direct comparison of the auditory rehabilitation outcomes between the two devices.

MATERIALS AND METHODS

Study population

Recipients of the Bonebridge® system who underwent surgery from February 2014 to August 2024 were retrospectively reviewed. The implantation surgeries were performed by two otologic surgeons with 32 and 25 years of experience in BCHI surgery, respectively, as of 2024. A total of 130 surgeries were performed, with 18 device malfunctions reported. Device mal-

functions occurred between 30 and 49 months post-implantation. Two patients experienced device malfunctions following MRI, one patient experienced malfunction following external trauma, and the remaining patients experienced idiopathic device failures. Among these cases, 10 patients underwent reimplantation surgery, seven became non-users, and one patient was lost to follow-up. Patients who decided on reimplantation were presented with two options: reimplantation with the same Bonebridge® system or with the Osia®2. They were informed of the potential for device failure with both systems and the limited long-term data on Osia®2, as well as its status as the most recent model. The final choice was made through shared decision-making between the patient and medical team. Among the 10 patients who underwent reimplantation, three received the same Bonebridge® device, while seven underwent reimplantation with the Osia®2 system. A retrospective chart review was conducted on seven patients who underwent reimplantation with Osia®2.

This study was approved by the Institutional Review Board of our center (IRB No.1-2023-0020) and conducted in accordance with the Declaration of Helsinki. The same institution waived the requirement for written consent owing to the retrospective design of this study.

Surgical procedure

All reimplantation surgeries were performed by a single experienced surgeon (I.S.M). Removal of the previous Bonebridge® device and reimplantation of the Osia®2 device were completed in a single procedure under local anesthesia. An incision was made along the existing scar line, and soft tissue overlying the Bonebridge® floating mass transducer (FMT) was dissected to expose the implant and surrounding bone. The anchoring screws were removed, and the entire device was easily extracted, as it had not integrated with the bone. The BI300, a titanium screw designed for osseointegration and vibration transmission, was positioned 5–10 mm posterior to the previous FMT well using the manufacturer's drill guide (Fig. 1A).¹⁷ The OSI200, a piezoelectric transducer with a magnet, was placed and secured through the actuator to the BI300 screw. Since the optimal position of the OSI200 implant was slightly superior to the ear canal without touching the pinna and positioning it too far posteriorly could risk damaging the sigmoid sinus or dura, the previous FMT well and the new OSI200 placement could not be fully separated. As a result, the anterior part of the OSI200 floated above the previous FMT well, preventing full contact with the bone (Fig. 1B).

Device fitting was performed according to the manufacturer's guidelines, and the initial activation of the sound processor took place 4 weeks post-implantation. All patients were followed up for at least 12 months post-surgery.

Outcome measurements

The main outcome measures were divided into audiological

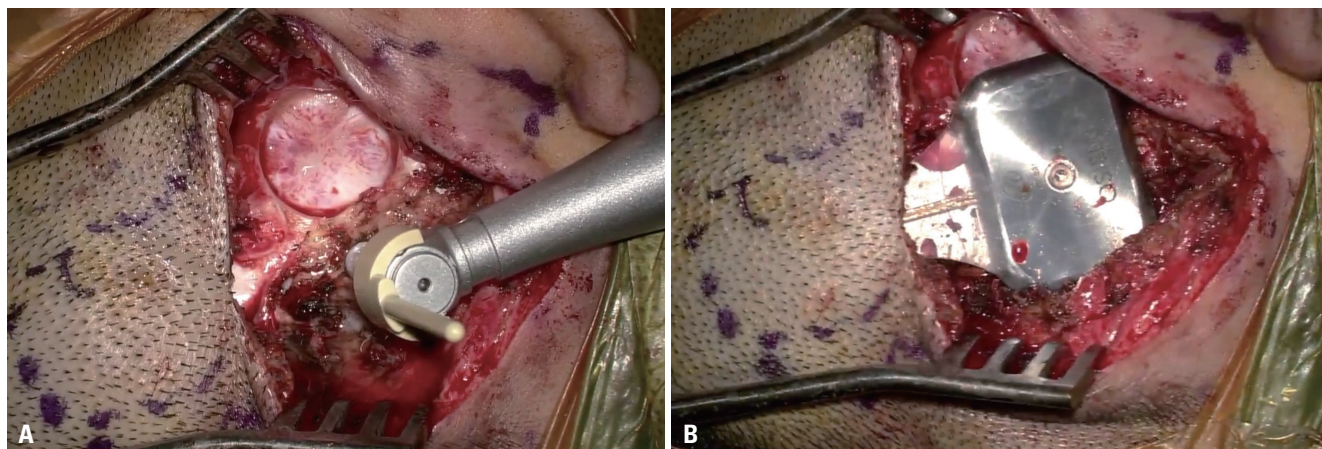


Fig. 1. Surgical procedure of Osia®2 implantation. (A) After removal of the Bonebridge® floating mass transducer (FMT), the drill for the BI300, an osseointegrated titanium screw, is positioned 5–10 mm posterior to the FMT well. (B) The OSI200, a piezoelectric transducer, is fixed with BI300. The anterior portion of the OSI200, overlapping with the previous FMT well, could not fully contact the bone.

and patient-reported outcomes. Audiological outcome measures included aided hearing performance with Osia®2 at 4–6 months post-surgery, assessed using pure tone audiometry (PTA) and the Korean Hearing in Noise test (K-HINT).¹⁸ These results were compared with the unaided hearing performance of the patients and with their aided performance when using the Bonebridge® device. Audiological tests conducted 4–6 months after Bonebridge® surgery were collected and compared to ensure consistency. Aided PTA was performed after device activation via sound field testing through speakers with contralateral masking noise. Average hearing gain was calculated across 500, 1000, 2000, and 4000 Hz as the difference between the pre- and post-operative air conduction (AC) thresholds. K-HINT was performed to evaluate speech performance in noise with target sentences and speech-shaped noise delivered through the loudspeaker at a constant level of 65 dBA. The signal-to-noise ratio was adjusted to determine the level at which the participant could accurately recognize 50% of the sentences. The speech originated from the front, with noise generated from the front, left (90°), and right of the patients. Four conditions (quiet, noise from the front, noise from the right, and noise from the left) were tested. Composite scores, representing the average performance in noisy environments, were calculated using the formula: $([2 \times \text{noise front} + \text{noise right} + \text{noise left}] / 4)$.¹⁹

Additionally, patients who underwent reimplantation with Osia®2 were asked to complete the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Korean version of Speech, Spatial and Quality of Hearing Scale (SSQ) questionnaires preoperatively and postoperatively. The APHAB includes 24 questions across four subscales that assess the impact of hearing loss in various everyday situations. The ease of communication (EC) subscale examines hearing in a quiet environment without background noise (BN), while the BN subscale assesses hearing situations with BN. The reverberation (RV) subscale evaluates hearing in large spaces with echoes, and the aversiveness (AV)

subscale measures the discomfort caused by loud sounds.²⁰ Higher scores indicate a greater degree of difficulty or more frequent problems in the assessed areas. The SSQ questionnaires assess self-reported hearing abilities in various situations within the three domains: speech perception, spatial hearing, and qualities of hearing.²¹ The questionnaire results were compared at three time points: without any device, 1 month before the Osia®2 surgery while using Bonebridge®, and 6 months after the Osia®2 surgery. Since routine questionnaire collection for hearing-aided patients was not implemented at our institution before 2020, results 6 months post-Bonebridge® surgery were not available.

Statistical analysis

Statistical analysis was made using IBM SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Given the small sample size, continuous variables were analyzed using non-parametric tests. Continuous and ordinal variables across three repeated measures (unaided, Bonebridge-aided, and Osia-aided) were analyzed using the Friedman test, followed by Wilcoxon signed-rank tests for post-hoc pairwise comparisons when a significant difference was detected. All statistical tests were two-sided, and a p -value of <0.05 indicated statistical significance. For the three predefined pairwise comparisons (unaided vs. Bonebridge, unaided vs. Osia, and Bonebridge vs. Osia), unadjusted p -values were reported without formal correction for multiple testing, given the exploratory nature of the study and the limited sample size.

RESULTS

Among seven patients who underwent reimplantation with Osia®2, two had mixed hearing loss (MHL), and five had SSD. All patients had severe to profound hearing loss in AC at the implanted site, while the hearing levels in the opposite ear

were within 40 dB HL. The mean age at the time of the first Bonebridge® surgery was 46.71 ± 22.30 years, and at the time of Osia®2 reimplantation was 52.43 ± 21.90 years. The group included two males and five females. No adverse event occurred during or after surgery (Table 1).

Audiometric outcomes

Both Bonebridge®-aided (BB-aided) and Osia®2-aided (Osia-aided) conditions demonstrated improved hearing thresholds compared to the unaided condition across all frequencies, with stable performance across the tested frequency range (Fig. 2A). Although both devices provided significant benefits over unaided hearing, the Osia-aided condition generally showed slightly better thresholds across most frequencies compared to the BB-aided condition, particularly at lower frequencies (500–1000 Hz, $p=0.039$ and $p=0.017$, respectively). At higher frequencies (2000–4000 Hz), the performance of both devices was more comparable ($p>0.05$). The average hearing gain at 500, 1000, 2000, and 4000 Hz also showed significant improvement with both devices [median BB-aided hearing gain:

58.75 dB, interquartile range (IQR), 45.0–72.50 dB; Osia-aided hearing gain: 60.0 dB, IQR, 48.75–83.0 dB]. However, there were no significant differences between the BB-aid and Osia-aided conditions ($p=0.207$) (Fig. 2B).

The Osia-aided K-HINT results were available for all seven patients; however, unaided and BB-aided results were available for only six and four patients, respectively. One patient had only Osia-aided K-HINT results and was therefore excluded from the statistical analysis. The Osia-aided K-HINT composite scores showed a significant reduction compared to the unaided score ($p=0.028$), with a median unaided score of 2.25 (IQR, 0.54–4.20) and a median Osia-aided score of -0.15 (IQR, -1.90–0.63) (Fig. 3). However, there was no statistically significant difference between the unaided and BB-aided results ($p=0.068$), with a median BB-aided score of -1.0 (IQR: -2.8–0.43). Additionally, no significant change was observed between BB-aided and Osia-aided scores ($p=0.850$).

Questionnaires

The APHAB and SSQ results for all patients in unaided, BB-aid-

Table 1. Demographics of Patients Who Underwent Osia®2 Implantation after Bonebridge Failure

No.	Sex	Age at implant (year)		Laterality	Indication
		Bonebridge®	Osia®2		
1	M	45	53	Left	SSD
2	F	14	20	Right	SSD
3	M	52	56	Right	MHL-chronic otitis media
4	F	63	70	Right	SSD
5	F	13	20	Right	MHL-congenital aural atresia
6	F	68	75	Right	SSD
7	F	68	73	Right	SSD

SSD, single-sided deafness; MHL, mixed hearing loss.

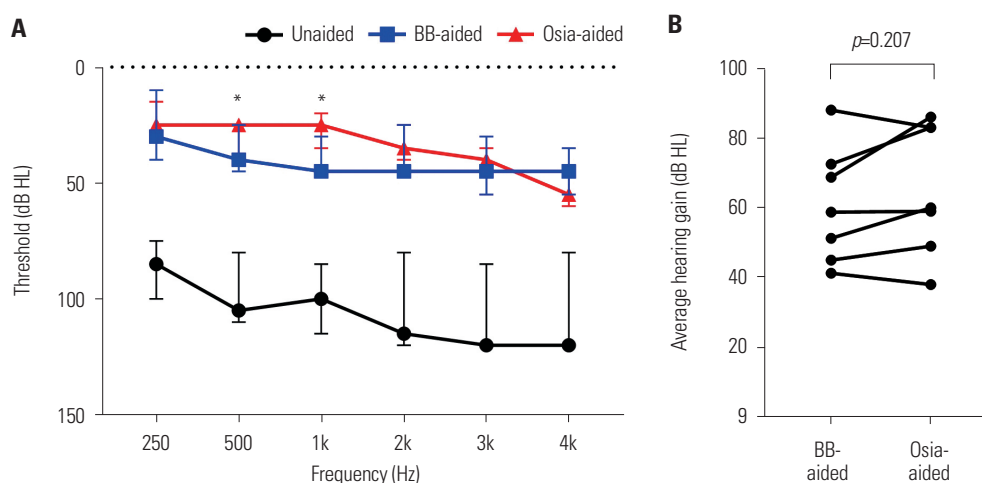


Fig. 2. Comparison of hearing thresholds for unaided, Bonebridge®-aided (BB-aided), and Osia®2-aided (Osia-aided) conditions. (A) Black circles represent unaided air-conduction (AC) hearing thresholds, the blue squares represent AC thresholds with BB-aided hearing, and the red triangles represent AC thresholds with Osia-aided hearing. The values were presented as averages, and error bars indicate the standard deviation. Both devices showed significant improvement across all frequencies, including high frequencies, compared to the unaided condition. Asterisks (*) indicate frequencies where Osia®2 provided significantly greater gain than Bonebridge® (500–1000 Hz, $p=0.039$ and $p=0.017$, respectively). (B) Average hearing gain at 500, 1000, 2000, and 4000 Hz also showed no significant difference between the BB-aided and Osia-aided conditions ($p=0.207$).

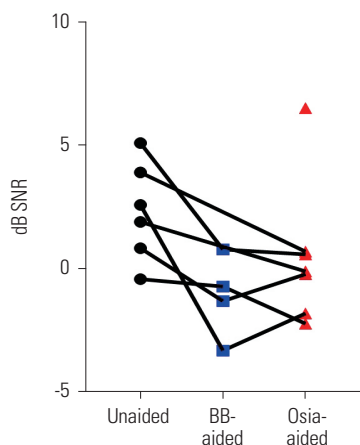


Fig. 3. Korean Hearing in Noise test (K-HINT) composite scores under unaided (black circles), Bonebridge®-aided (BB-aided; blue squares), and Osia®2-aided (Osia-aided; red triangles) conditions. A significant improvement was observed in the Osia-aided condition compared to the unaided condition ($p=0.028$). No statistically significant difference was found between the unaided and BB-aided scores ($p=0.068$), or between BB-aided and Osia-aided scores ($p=0.850$). One unconnected red triangle in the top-right corner represents a patient for whom only Osia-aided K-HINT data were available; this case was excluded from the statistical analysis.

ed, and Osia-aided conditions are shown in Table 2 and Fig. 4 as median values with IQRs. For the APHAB, all subscales showed significant improvement with both BB and Osia. When comparing BB-aided and Osia-aided conditions, most subscales, except for BN, showed significant improvement following reimplantation with Osia. For the SSQ, all subscales improved after Osia reimplantation compared to both unaided and BB-aided conditions. Unlike the APHAB results, the BB-aided condition did not show significant improvement over the unaided condition in the SSQ.

DISCUSSION

The primary indication for BCHIs has traditionally been conductive hearing loss due to chronic inflammatory ear disease or congenital aural atresia. However, since the FDA approved their use in 2002 in patients with unilateral sensorineural hearing loss, their application has expanded to include cases of SSD.^{22,23} Recent advancements, including high-output sound processors and active transcutaneous devices, have positioned

Table 2. Abbreviated Profile of Hearing Aid Benefit (APHAB) and Speech, Spatial, and Qualities of Hearing Scale (SSQ) Results

Questionnaires	Median	Quartile	<i>p</i>			
			Friedman test	Unaided vs. BB-aided	Unaided vs. Osia-aided	BB-aided vs. Osia-aided
APHAB						
BN			0.026	0.042	0.034	0.058
Unaided	60	46–70				
BB-aided	46	42–54				
Osia-aided	40	30–41				
RV			0.001	0.043	0.018	0.018
Unaided	62	54–70				
BB-aided	56	48–62				
Osia-aided	37	32–43				
EC			0.001	0.043	0.018	0.018
Unaided	71	60–75				
BB-aided	42	31–48				
Osia-aided	5	5–6				
AV			0.001	0.039	0.018	0.018
Unaided	73	70–89				
BB-aided	63	60–73				
Osia-aided	39	27–45				
SSQ						
Speech			0.001	0.068	0.018	0.018
Unaided	28	23–42				
BB-aided	40	28–53				
Osia-aided	104	100–110				
Spatial			0.001	0.068	0.018	0.018
Unaided	38	18–61				
BB-aided	50	28–71				
Osia-aided	110	106–111				
Quality of hearing			0.002	0.655	0.018	0.018
Unaided	40	29–46				
BB-aided	42	29–42				
Osia-aided	72	69–90				

Osia-aided, Osia®2-aided; BB-aided, Bonebridge®-aided; EC, ease of communication; RV, reverberation; BN, background noise; AV, aversiveness.

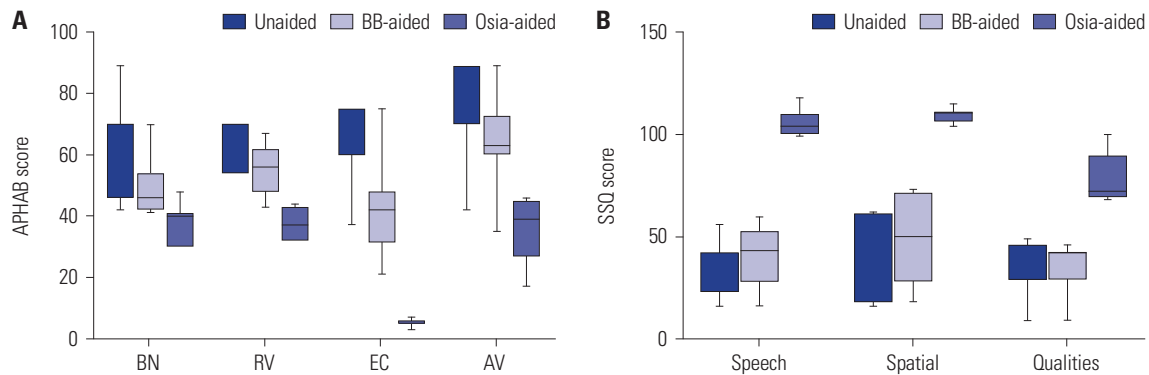


Fig. 4. Box plot comparison of Abbreviated Profile of Hearing Aid Benefit (APHAB) and Speech, Spatial, and Qualities of Hearing Scale (SSQ) scores across three conditions: unaided, Bonebridge[®]-aided (BB-aided), and Osia[®]2-aided (Osia-aided). Boxes represent interquartile ranges, and horizontal lines within boxes represent median values. (A) For the APHAB, significant improvements were observed in all subscales [ease of communication (EC), reverberation (RV), background noise (BN), and aversiveness (AV)] with both BB and Osia. When comparing BB-aided to Osia-aided conditions, most APHAB subscales, except for BN, showed significant improvement with Osia. (B) In the SSQ scores, all subscales demonstrated improvement following Osia reimplantation compared to both unaided and BB-aided conditions. Unlike the APHAB results, the BB-aided condition did not show significant benefit over the unaided condition in SSQ scores.

these aids as a primary treatment option for patients with unilateral hearing loss.

According to previous studies, the Osia[®] system demonstrated additional hearing gains of up to 10.2 dB compared to passive BCHIs, particularly at higher frequencies, due to reduced soft tissue impedance.^{14,15,24} The Osia[®] system is expected to deliver effective and comparable hearing outcomes to the Bonebridge[®] system, as both utilize active vibration mechanisms that can overcome soft tissue sound attenuation. Previous studies have reported similar or greater hearing gains with the Osia[®] system compared to the Bonebridge[®] system.^{15,24}

This study evaluated the clinical performance of the Osia[®]2 system, a new generation of active transcutaneous BCHI system, in seven patients who had previously used the Bonebridge[®] system. This study design enabled a direct comparison between the two systems within each patient, thereby eliminating individual variability. The hearing gain with the Osia[®]2 system was 60.0 dB, consistent with previous reports on Osia[®]2.¹⁰ However, as functional gain reflects the fitting to individual hearing thresholds rather than the intrinsic performance of the devices, these results should be interpreted with caution. The hearing gains in this study exceeded those reported in previous studies with the earlier Osia[®] model, which ranged from 36.88 dB to 42.8 dB.^{8,15,25} This difference may be attributed to advancements in sound processing technology, feedback management in the new generation device, and differences in enrolled patient characteristics. This study predominantly included patients with SSD, whereas other studies focused on patients with MHL. Compared to Bonebridge[®], Osia[®]2 provided greater gain at low frequencies and similar gains at higher frequencies. Since reimplantation of Osia[®]2 involved partial floating above the previous FMT well, preventing full contact with bone, implantation in fresh, undamaged bone may further enhance hearing gains at high frequencies.

The questionnaires indicated a high level of subjective satisfaction with the Osia[®]2 system, with both APHAB and SSQ scores showing improvement after Osia[®]2 reimplantation compared to both unaided and BB-aided conditions. However, the BB-aided questionnaire responses were obtained 1 month prior to Osia[®]2 reimplantation, during which time all patients had malfunctioning devices. Therefore, the differences between BB-aided and Osia-aided scores should be interpreted with caution. If the BB-aided questionnaires had been collected 6 months post-implantation, scores might have been more favorable.

Potential advantages of the new Osia[®]2 system over the Bonebridge[®] may be attributed to its osseointegrated component (BI300 screw), which allows for more effective transmission of vibrations through the skull bones to the inner ear. Additionally, the piezoelectric actuator may contribute to improved performance, as it has been reported to generate higher sound pressure levels at higher frequencies than electromagnetic methods.²⁶ In addition to these technical features, the potential reasons for higher subjective satisfaction associated with Osia[®]2 may be attributed to several external factors. First, the Osia[®]2 sound processor is smaller, lighter, and more cosmetically discreet compared to the older Bonebridge[®] processors that were available at the time of initial implantation in these patients.²⁷ These physical improvements likely enhanced daily comfort and patient acceptance. Second, the reimplantation surgery for Osia[®]2 was performed under local anesthesia without hospitalization, in contrast to the original Bonebridge[®] surgeries, which typically required general anesthesia and inpatient care. The reduced surgical burden, combined with comparable hearing outcomes, may have positively influenced patient perceptions and satisfaction.

According to the FDA database, the most common adverse events for both Bonebridge[®] and Osia[®] were device malfunctions, including issues such as lack of hearing or intermittent or reduced hearing.¹⁶ Osia[®] implant malfunctions were reported in only three out of the 1500 implants, with an estimated

prevalence of 0.2%. In contrast, the prevalence of Bonebridge[®] malfunction could not be determined from the FDA database due to insufficient data. However, several single-center studies have reported malfunction rates ranging from 1.9%²⁸ to 7.8%,²⁹ indicating variability across institutions and follow-up periods. Similarly, recent review suggests a trend toward a higher rate of device malfunctions associated with Bonebridge[®], although precise incidence rates remain uncertain.³⁰ In the present study, the Bonebridge[®] malfunction rate was 13.8%, occurring between 30 and 49 months post-implantation. While Bonebridge[®] has provided significant hearing improvement, its high malfunction rate raises concerns. Since Osia[®]2 demonstrated a comparable level of hearing improvement in this study, it is anticipated that it may address these malfunction issues. However, long-term follow-up data were not available, so extended follow-up is needed to determine the malfunction rate for Osia[®]2. If the malfunction rate remains low over several years, Osia[®]2 could be considered superior in terms of both safety and effectiveness.

This study has several limitations, including the small sample size. Although multiple pairwise comparisons were conducted, we reported unadjusted *p*-values to avoid overly conservative corrections that might mask clinically relevant differences. This approach increases the risk of type I error; therefore, the findings should be interpreted with caution. Future studies with larger sample sizes are needed to confirm these results with appropriate statistical corrections. In addition, this study did not include a comparative analysis between patients who underwent Osia[®]2 reimplantation and those who received a second Bonebridge[®] implant, which may have provided further insight into outcome differences between reimplantation strategies.

The findings of this study suggest that the Osia[®]2 system offers audiological outcomes and patient satisfaction that are comparable to, or potentially better than, those of the Bonebridge[®] system. While the small sample size limits definitive conclusions, the Osia[®]2 system may be a promising alternative to Bonebridge[®]—the primary active transcutaneous bone conduction device to date—for patients with conductive or MHL or SSD.

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AUTHOR CONTRIBUTIONS

Conceptualization: In Seok Moon. **Data curation:** In Seok Moon. **Formal analysis:** Ji Min Yun and Yunbin Nam. **Funding acquisition:** In Seok Moon. **Investigation:** Ji Min Yun and Gerard Lapina. **Methodology:** In Seok Moon. **Project administration:** Ji Min Yun. **Resources:** In Seok Moon and Gerard Lapina. **Software:** Ji Min Yun. **Supervision:** In Seok Moon. **Validation:** Ji Min Yun and In Seok Moon. **Visualization:** Yunbin Nam. **Writing—original draft:** Ji Min Yun and Yunbin Nam.

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