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BAHA Attract to Osia conversion patients: comparison of the two systems and long-term outcomes

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Abstract

Objective. Osia is a new, transcutaneous, active bone-conduction implant. This study aimed to compare the BAHA Attract and the first-generation Osia system after BAHA Attract to Osia conversion surgery.

Method. Five patients who had previously used the BAHA Attract system were converted to the first generation of the Osia system. Surgical aspects of the two different systems, audiological performance and subjective opinions of the patients were investigated. Pure tone audiometry and speech audiometry in quiet was performed with each patient's BAHA 5 sound processor on Attract, and the test battery was repeated six weeks after the Attract to Osia conversion and at different time points after the first fitting. Details of the surgery and patients' feedback were analysed.

Results. Audiology tests showed significant improvement when using either system; however, the Osia system performance was better. Based on patient feedback, all the five implantees preferred the Osia system.

Conclusion. The study results suggest that the Osia system is a safe and powerful hearing implant that provides good clinical outcomes.

Main Article

Dr Z Bere takes responsibility for the integrity of the content of the paper

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Introduction

Bone conduction hearing implants are commonly used to treat conductive or mixed hearing loss as well as single-sided deafness, especially in cases where the patient is unable to use a conventional hearing aid.[1–5] Considering the need for a powerful and safe transcutaneous solution, Cochlear developed its first active, non-skin penetrating bone-conduction hearing implants, called the Osia® system.

The Osia system has a fitting range of up to 55 dB HL, making the indication range similar to using the bone-anchored hearing aid (BAHA®) 5 power sound processor on BAHA Attract®.[6,7] The Osia system is therefore recommended for use in patients with conductive hearing loss, mixed hearing loss or single-sided deafness, where average bone-conduction thresholds are equal to or less than 55 dB HL.[8]

Expected performance with the implanted device can be estimated using a similarly powered sound processor, such as the BAHA 5 or BAHA 5 power sound processor, on a headband called a Softband. The system is currently approved for use in adults and children over 12 years of age. In contrast to other active bone-conduction hearing implants with magnetic floating-mass transducers, signal amplification in the Osia system uses a piezoelectric transducer (piezo-power transducer), which is attached to the widely used BI300 titanium implant. The BI300 implant is anchored to the skull via the same surgical procedure used when fitting BAHA Attract and Connect® systems.

The aim of this study was to perform an in-patient comparison between the long-term audiological performance of the first-generation Osia system (Osia G1) with the BAHA Attract system. Therefore, five experienced BAHA Attract patients were enrolled, and their Attract systems were removed and replaced with the Osia system. We also collected information regarding the surgical procedure, post-operative care and patient satisfaction in terms of surgery and subjective opinion of Osia G1 performance.

Materials and methods

The patients who contributed to the study signed an informed consent form that was approved by the local institutional review board (Human Investigation Review Board, University of Szeged, Albert Szent-Györgyi Clinical Centre (number: 163/2020-SZTE).

Five adults (aged equal to or more than 18 years; 1 female, 4 male) with bilateral, mixed hearing loss who previously (more than 3 years prior to selection) underwent BAHA Attract implantation were enrolled. In terms of hearing performance, all patients met candidacy for BAHA Attract at the time of Attract implantation and were aided with a BAHA 5 sound processor. Each of the patients was informed about the new implant, the

necessity of repeated surgery with general anaesthesia and post-operative surgical and audiological care and follow up.

No post-operative wound healing complications were reported after the first implantation. In three cases, bone-conduction thresholds deteriorated gradually over time (by 10–20 dB HL); however, thresholds did not reach 55 dB HL. In the other two cases, recurrent issues with magnet compression and discomfort limited daily usage of the sound processor.

All patients underwent a general otolaryngological and anaesthesiological examination. We analysed patients' cranial computed tomography (CT) scans performed prior to Attract surgery.

Unaided and aided pure tone audiometry was performed; unaided air conduction thresholds with supra-aural headphone and bone conduction thresholds over the mastoid process were measured at 250, 500, 1000, 2000 and 4000 Hz. Speech audiometry in quiet was also measured, including speech recognition thresholds and word recognition testing in quiet, using a loudspeaker in the S0 position (loudspeaker placed in front of the patient). Aided free-field pure tone audiometry, speech recognition threshold and word recognition test were first measured with each patient's BAHA 5 sound processor on Attract. After replacing the Attract system with Osia G1, the test battery was repeated 6 weeks after the implantation (i.e. at first fitting and at 3, 6, 12 and 24 months after the first fitting).

A short surgical questionnaire was administered to all patients who underwent BAHA Attract implantation and Osia implantation. The questionnaire was designed to capture the following data: type of anaesthesia, surgical time, soft tissue reduction, intra-operative complications, healing problems, aesthetic outcome, pain and numbness. Questionnaire data were collected following each implantation surgery, and questions related to patient-reported data (i.e. healing problems, aesthetic outcome, pain and numbness) were repeated at first fitting (six weeks after surgery). Patients scored the questions about pain and numbness from 1 to 5 with the help of a visual analogue scale. The results of the Attract and Osia systems were compared.

Subjective opinion about comfort, daily use, sound quality and speech understanding were systematically collected from BAHA Attract patients via a questionnaire. These questionnaires were completed after Attract implantation and following Osia implantation at each visit after initial fitting. Sound quality and speech understanding was scored from 1 (bad) to 5 (very good).

Osia system implantation was carried out following the manufacturer's guidelines. Figure 1 outlines the surgical steps. After planning the implant position, an approximately 4-cm incision was performed in the posterior-superior region of the temporal area, close to that of the previous Attract surgery. The incision line halved the distance between the coil magnet and the posterior superior edge of the transducer. From this approach, the Attract magnet could be easily reached and was removed. The BI300 implant was also removed in cases where it obstructed the Osia system transducer (three cases). Soft tissue and periosteum were separated carefully from the bone above and under the incision, until the Osia G1 template could be comfortably positioned. In all cases, a new BI300 implant was fixed at the level of the ear canal, far enough from the pinna, as recommended by the guidelines. Bone surface was smoothed to avoid transducer–bone contact, and the magnet was positioned under the skin. After the coil was positioned, intra-operative functionality testing was performed, and the transducer was fixed to the BI300 implant. After closure, mild compression was created with bandages for 48 hours, and patients left the department on the third post-operative day.

Results

Figure 2 displays the average unaided and aided pure tone thresholds with the BAHA Attract and Osia G1 systems. The black line represents mean unaided bone-conduction hearing thresholds across individual test frequencies, and the red line represents the mean unaided air-conduction hearing thresholds across the individual test frequencies. The mean unaided bone-conduction and air-conduction hearing thresholds across the frequency range were 24 ± 9.2 dB HL and 72 ±

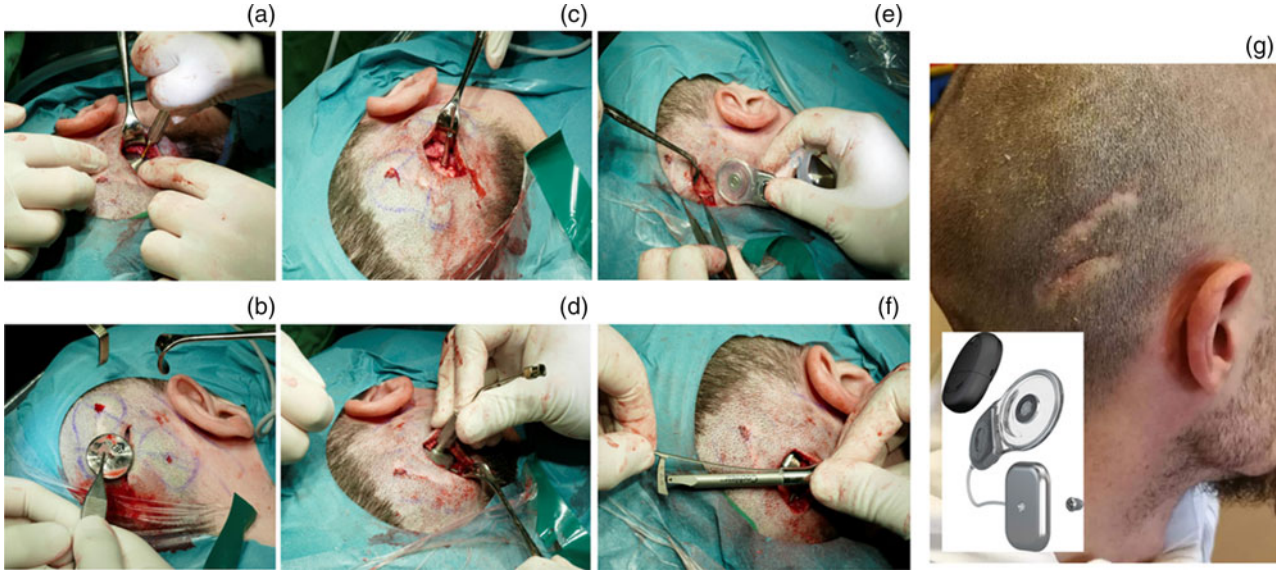

Figure 1. Steps of Attract removal and Osia G1 implantation surgery. (a and b) Removal of Attract magnet; (c and d) determination of the position of the Osia actuator after implantation of a new BI300 titanium implant; (e) coil insertion; (f) fixation of the actuator after intra-operative test and (g) patient at sixth post-operative week, showing upper incision used for the previous Attract surgery and lower incision made for the Osia implantation.

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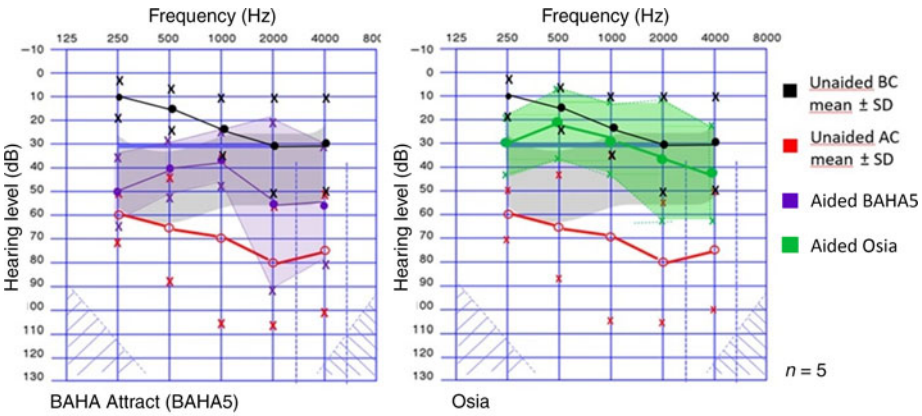

Frequency	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
ABG gain Attract (dB HL)	13	30	40	30	26
ABG gain Osia (dB HL)	30	47	47	50	43

Figure 2. Graphs showing unaided and aided hearing threshold for (a) bone-anchored hearing aid (BAHA; with BAHA 5 sound processor) Attract and (b) Osia G1 systems. Table shows air–bone gap (ABG) gain with each system compared with the unaided situation. BC = bone conduction; AC = air conduction; SD = standard deviation

10.4 dB HL, respectively. In the left panel, the purple line represents the mean aided hearing thresholds obtained when aided with a BAHA 5 sound processor on Attract, with a mean aided threshold across the frequency range of 43 ± 8.6 dB HL. In the right panel, the green line represents the mean aided threshold across the frequency range when aided with the Osia system. Mean aided hearing threshold with the Osia system was 28 ± 4.3 dB HL. When comparing the aided results, the Osia G1 system performs better in all test frequencies; however, both systems provided significant hearing improvement compared with the unaided situation. As shown in Figure 2, air–bone gap gain with Attract and Osia G1 were calculated with an aided and unaided formula and compared between each test frequency. Osia G1 performance was better at each frequency, especially over 2000 Hz. In speech testing, the average gain was 43.3 ± 7.9 dB with Osia and 27.8 ± 9.8 dB with Attract (Figure 3).

Speech audiometry also confirmed significant improvement in aided thresholds. Figure 3 summarises the individual speech recognition thresholds and word recognition testing scores (upper panels) as well as average results (lower panels). Unaided thresholds (mean speech recognition threshold: 62 ± 25 dB HL; mean word recognition testing: 76 ± 25 dB HL) were significantly higher compared with aided ones (mean speech recognition threshold, Attract: 36.3 ± 10 dB HL and Osia: 28.8 ± 8 dB HL; word recognition testing, Attract: 55 ± 10 dB HL and Osia: 43 ± 10 dB HL). However, no significant difference was detected between BAHA Attract and Osia results, although mean thresholds with the Osia system were better. During the follow up, no change was determined.

Table 1 shows the surgical questionnaire summary, designed originally for BAHA candidates. Previous results from the participants, which were collected after their Attract implantation, were compared with the results after Osia G1 implantation. All Osia G1 surgical procedures were performed under general anaesthesia, except in one case because of patient preference. Compared with Attract implantation, Osia G1 surgery, which was performed with a similar posterior-superior linear or arc-shaped incision in the temporal area, required more time. However, Osia G1 surgical time reduced significantly with the number of cases. In all of the cases, soft tissue thickness was less than 5 mm at the

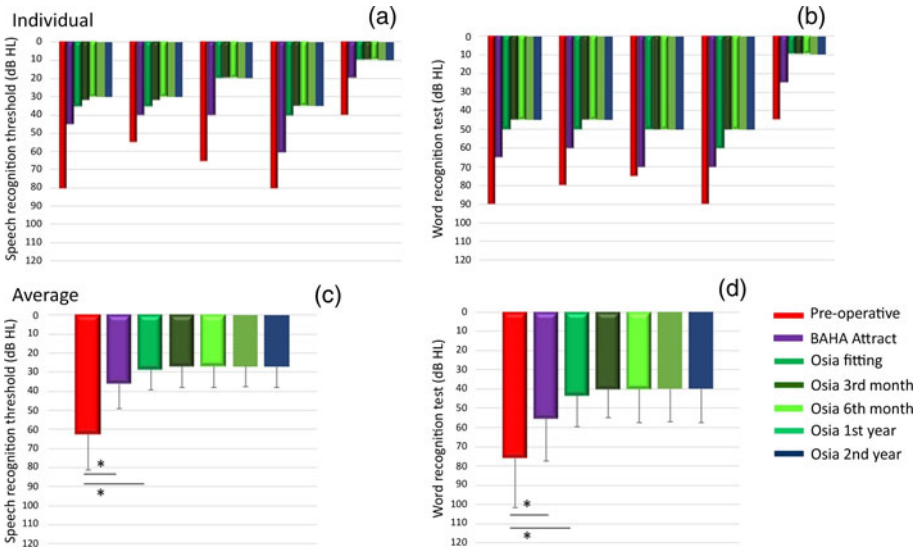

Figure 3. Speech audiometry results. (a) Speech recognition threshold and (b) word recognition test scores for each individual, and (c) speech recognition threshold and (d) word recognition test scores on average. Average of thresholds were statistically analysed with the analysis of variance test. *$p \leq 0.001$

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Table 1. Surgical questionnaire for bone-anchored hearing aid patients*

Parameter	Attract system	Osia system
Anaesthesia (*n*)	Local, 5	Local, 1; general, 4
Surgical time (mean ± SD (maximum, minimum); minutes)	12 ± 1; 13, 10	80 ± 30; 110, 53
Surgical approach	Posterior-superior	Posterior-superior
Soft tissue reduction	No	No
Intra-operative complication	No	No
Wound healing problem	No	No
Pain (score)†	VAS 2 → 0–1 (6 week)	VAS 3 → 0–1
Numbness (score)†	VAS 3–4 → 1–2 (6 week)	VAS 4–5 → 2
Aesthetic outcome‡	Very good	Very good

*$n = 5$; †visual analogue scale (VAS) was used. For the VAS, 5 = debilitating pain and 0 = no pain. ‡Possible answers were: bad, poor, good, very good, excellent. SD = standard deviation

level of the coil, and therefore no soft tissue reduction was performed. No intra-operative complication, such as dura or sigmoid sinus injury, bleeding or liquorrhoea was detected. No haematoma, seroma, infection or other wound healing problem was detected during the follow up. Evaluation of pain and numbness relied on a visual analogue scale, where 0 represented no pain or numbness and 5 represented the worst pain and numbness. Pain was negligible with the use of both systems, and numbness reduced with time. All patients reported very good aesthetic outcomes after both Attract and Osia implantation.

Most of the patients complained about discomfort caused by magnet compression when using the Attract system. In 2 of 5 Attract cases, magnet strength reduction was successful in eliminating issues related to magnet compression. In contrast, the Osia sound processor proved to be very comfortable, and patients wore it continuously for an average of 11 hours per day, which was around 3 hours longer per day than when using the Attract system. Battery life was significantly shorter with the Osia G1 sound processor. However, the audiological performance of the Osia system was better, especially at higher frequencies and in noisy environments when compared with the Attract system (Table 2).

Table 2. Patient feedback

Parameter	Attract system	Osia system
Comfort	Problem: magnet compression, numbness, itching, redness	Comfortable, lightweight sound processor
Daily use (hours/day)	~8	11
Battery life (days)	5–7	1
Sound quality, low frequencies (score)*	4	4
Sound quality, high frequencies (score)*	3	4
Speech understanding (score)*	3	4–5

*Patient feedback via questionnaire about subjective opinion, sound quality and speech understanding: 1 (bad) to 5 (very good)

Discussion

The novelty of our study was that a direct comparison between the performance of both the Attract and Osia systems could be performed in the same individual; therefore, audibility, wearing comfort and, in particular, the patients' subjective experience, could be judged more accurately than in separate test groups. Our results are well correlated with the results of other comparative studies.[6] Since we also investigated surgery, post-operative status and patient satisfaction or feedback, our results are also potentially helpful in improving the surgery for bone-conduction hearing implants in general.

- The Osia system is a new, safe and powerful transcutaneous active bone-conduction hearing implant
- This study directly compared the performance of the BAHA Attract and Osia systems in the same individual
- From an audiological perspective, the Osia system provides better outcomes compared with the passive transcutaneous Attract system, especially at higher frequencies
- The difference between the first- and second-generation Osia system is only the structural design of the implant
- Therefore, the long-term results with the first generation likely reflect the performance of both systems

Previously, our department developed a minimally invasive surgical technique based on a multimodal morphometric study of the temporal soft tissue area.[9] In that particular study, we demonstrated that when the incision is placed superior-posterior to the Attract position it does not compromise the macrocirculation of the peri-implant area, which contributed to fewer post-operative healing problems. When implanting the Osia system, we positioned the incision similarly (i.e. the posterior-superior temporal area, close to the previous incision). The length of the incision line is also comparable with the Attract approach (i.e. approximately 4 cm). We found that with extended undermining and retraction of soft tissue, large dissection and extended flap creation can be avoided, which potentially contributes to fewer post-operative complications. Moreover, preservation of the integrity of the retroauricular area does not compromise the opportunity for reconstructive ear surgery. Based on previous data presented on the Attract system, we also believe that a similar incision technique can contribute to better healing when implanting the second-generation Osia system. Moreover, this surgical approach preserves large vessels, which are necessary for reconstructive techniques in patients with external ear malformation.

For Osia system implantation, the position of the BI300 implant was recommended to be level with the ear canal, as opposed to BAHA Attract where the superior edge of the processor should be placed in line with the top of the pinna, 50–60 mm from the ear canal.[10] Since we strictly followed the Osia system surgical guidelines in terms of implant, transducer and coil arrangement, we did not use the previously placed BI300 implant for the fixation of the transducer. Regardless of the stable position of the previously implanted BI300 in the bone, the implant was removed when it obstructed the transducer. Although these old implants underwent complete osseo-integration, they were not difficult to remove with the manufacturer's tools, and the bone was not harmed. Nonetheless, we recommend using the original BI300 in conversion cases in the future, except in cases where the original implant position decreases optimal placement of the coil and sound processor. Pre-operative cranial

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CT scans were analysed to determine the bone thickness and the ideal position of the implant. In cases where mastoidectomy was performed earlier, the position of the sigmoid sinus and bone thickness over the sinus had to be considered. In these cases, a 3-mm implant was used in the retrosigmoid approach ($n = 2$). Beyond this, overall difficulty of Osia surgery was negligible, although the surgical time was significantly longer compared with Attract surgery. Surgery time decreased gradually, on a case-by-case basis, which indicates a learning curve. In our latest series, the surgical time was 56 and 52 minutes for Osia to Attract systems, which is consistent with times reported by other groups.[11] The monolithic design of the second-generation Osia implant, in which the transducer is connected to the coil, may also reduce intra-operative time. Surgery under local anaesthesia ($n = 1$) was well tolerated based on the patient's report.

Compared with unaided thresholds, aided pure tone audiometry showed significant improvement when using either of the bone-conduction hearing implants. Functional gain in our study was comparable with the results of other groups that tested the Attract and Osia systems.[11–13] Although the indication range of the Osia system was similar to Attract, audiological output with the Osia system exceeded that of other bone-conduction hearing implants[11–15] and provided more high-frequency benefit compared with the Attract system. Speech tests also confirmed the free-field pure tone audiometry results. Although both Attract and Osia systems provided improved speech and word recognition compared with the unaided situation, there was a tendency towards better amplification with the Osia system. However, the low number of patients was not sufficient to conduct statistical analyses.

Overall feedback on the Osia system was very good. Although the implantable portion of the Osia G1 is larger and more complex than the Attract system, and the surgical time is longer, post-operative complaints such as pain and numbness were lower. In terms of comfort and daily use, the Osia system performed significantly better than the Attract system. None of the patients complained about pain, numbness or a feeling of heat when using the Osia sound processor, which are the most frequent problems associated with the Attract system.[16,17] Even with the application of the Softpad, which distributes the pressure of Attract magnet over the contact area to decrease sensitivity, most of the patients needed to rest the contact site between long periods of usage. In the worst cases, even a reduction of magnet strength does not solve the problem, and prolonged compression of soft tissue can result in skin complications, such as atrophy and necrosis.[18] In contrast with the passive transcutaneous system, where soft tissue is exposed to the direct force of the magnet, vibration and heat, the Osia sound processor transfers the signal across the soft tissue via a digital link, where the sound is then converted to vibrations by the implanted transducer. Therefore, there is no mechanical transfer of vibration across the soft tissue, promoting better soft tissue health. Although battery life of the Osia G1 sound processor was lower than using a sound processor on the Attract system, we believe that the improved audiological performance and comfort of the Osia system would encourage patients to opt for the system.

Our study results suggest that the Osia system is a safe and powerful transcutaneous active bone-conduction hearing implant that provides good clinical outcomes for patients with conductive hearing loss and mixed hearing loss. Since the difference between the first- and second-generation Osia system is only the structural design of the implant, our long-term results likely reflect the performance of both systems. The surgical steps are easy and straightforward, and based on our previous morphometric study, the posterior-superior approach is recommended in primary implantation and in transition cases. Pre-operative CT scans are useful and may be necessary in paediatric cases and cases of cranial malformation, where the anatomy and bone thickness in the implant area should be more carefully considered. The intra-operative complication rate with the Osia system is very low because the implant is small, and in contrast to other active transcutaneous bone-conduction hearing aids, the transducer does not have to be fully recessed; only the bone surface must be smoothed to avoid direct contact. From an audiological perspective, the performance of the Osia system was better compared with the passive transcutaneous Attract system, especially at higher frequencies. Moreover, the functional gain surpasses the performance of direct percutaneous and other active bone-conduction hearing implants. Based on patient feedback, the main advantages of the Osia system were captured when listening in noisy environments. Moreover, the Osia sound processor was more comfortable, and provided the opportunity of daylong use without the need to rest the sound processor site.

Competing interests. None declared

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