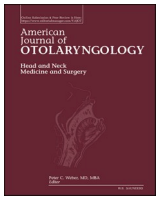
American Journal of Otolaryngology–Head and Neck Medicine and Surgery 42 (2021) 102818

Contents lists available at ScienceDirect

American Journal of Otolaryngology–Head and Neck Medicine and Surgery

journal homepage: www.elsevier.com/locate/amjoto



Early Osia® 2 bone conduction hearing implant experience: Nationwide controlled-market release data and single-center outcomes

Mary Rose Goldstein *, Stephanie Bourn, Abraham Jacob

Ear & Hearing, Center for Neurosciences, Tucson, AZ, United States of America

ARTICLE INFO

Keywords:
Osia
Audiology
Otology
Aural rehabilitation
Bone-anchored hearing devices
Baha
Bone conduction hearing implant

ABSTRACT

Purpose: Bone conduction hearing devices are a well-established treatment option for conductive or mixed hearing losses as well as single-sided deafness. The Osia® 2 System is an active osseointegrated device where a surgically implanted titanium fixture supports a newly developed piezoelectric actuator that is placed under the skin.

Methods: Nationwide data collected during a controlled-market release (CMR) of the Cochlear™ Osia® 2 System as well as outcomes at single, tertiary-level private practice Otology/Neurotology center were retrospectively reviewed. Key learnings from surgeons and audiologists are discussed.

Results: During the CMR period, 23 surgeons performed 44 operations on 43 recipients. The mean age of recipients was 44 years and mean surgery duration was 52 min. The most commonly used incision was postauricular but anterior to the device (78%). Five complications were observed during the CMR, none of which were device related. Twenty-one audiologists performed 33 Osia® 2 activations during the CMR. The mean age of this group was 47 years, and the mean duration of each activation appointment was 55 min. Single-center data at the authors' institution demonstrated an average additional PTA4 gain with the Osia® 2 patients of 9.6 dB compared to Baha Attract and 10.2 dB compared to Baha Connect.

Conclusion: The Cochlear™ Osia® 2 System represents a significant advance in auditory osseointegrated implant technology. Digital piezoelectric stimulation delivers high power outputs, improves high frequency gain for optimal speech perception, and maintains safety while providing excellent patient satisfaction.

1. Introduction

Early designs for bone conduction devices required a vibrating transducer to be mounted on a headband assembly. While effective in providing hearing benefit, the combined complexity of the head band and the associated pressure needed to produce a stable and effective stimulation was neither cosmetically pleasing nor comfortable for long term use. The main breakthrough came with percutaneous, direct-connect bone conduction implants that eliminated the negative effects of skin or tissue damping on the vibrational system. Dr. Per-Ingvar Branemark's seminal work during the 1950's and 60's establishing titanium's ability to osseointegrate into bone provided the foundation for development of such implants [1]. Anders Tjellstrom described a two-stage procedure to insert a titanium fixture into postauricular bone followed by placement of a percutaneous abutment at a 2nd stage; soon-thereafter, he published results on a single stage operation for implantation of fixture and abutment at the same setting [2–5]. These systems, which utilized principles of osseointegration for transcranial stimulation of the inner ears, were first approved by the U.S. Food and Drug Administration (FDA) in 1997. Lustig and colleagues, reviewing data from the first 40 patients implanted in the U.S. at 12 tertiary centers, found favorable outcomes and validated bone conduction as an effective means of rehabilitating conductive and mixed hearing loss [6]. By 2002, these implants became available to patients with unilateral sensorineural hearing loss, also termed Single-Sided-Deafness (SSD) [7].

First generation implant abutments were short, requiring significant reduction of subcutaneous tissue to ensure that the external sound processor did not inadvertently contact adjacent skin. Subsequent abutments of varying lengths cleared both thin and thick scalps, decreased surgical times, improved infection rates and decreased the incidence of skin overgrowth. Sound engineers continued to improve upon the profile and footprint of the external sound processor, materials science refined the skin-to-abutment interface, and a vigorous post-operative hygiene regimen was found to further minimize skin

* Corresponding author at: Ear & Hearing, Center for Neurosciences, 2450 E River Rd, Tucson, AZ 85718, United States of America.
E-mail addresses: mgoldstein@neurotucson.com (M.R. Goldstein), sbourn@neurotucson.com (S. Bourn), ajacob@neurotucson.com (A. Jacob).

https://doi.org/10.1016/j.amjoto.2020.102818
Received 5 August 2020;
Available online 28 October 2020

complications. None-the-less, an external abutment was still present, visible, and required lifelong care.

Further evolution of bone conduction technologies led to development of transcutaneous (non-skin penetrating) systems such as the Cochlear™ Baha® Attract and the Sophono Alpha™. Here, the skin remained intact and the external sound processor, with its vibrating actuator, was connected magnetically [8]. Therefore, abutment related skin complications were eliminated and cosmesis was improved. Proper candidate selection, magnet strength and the use of a soft pad to distribute pressure across the magnetic connection area were found to maximize benefit [9]; however, the main drawback to these systems was limitation in gain (especially in high frequencies) from attenuation of vibratory energy passing through hair, skin and other soft tissues [10]. To maintain the cosmetic benefits of magnetic coupling while improving output levels to overcome skin dampening, MedEL (Innsbruck, Austria) developed BONEBRIDGE™, a transcutaneous bone conduction system that utilizes an active electromagnetic implant coupled with an externally worn processor. This device received FDA approval in July 2018.

The current work introduces a new category of active osseointegrated devices, the Cochlear™ Osia® 2 System (Cochlear Bone Anchored Solutions, Sweden). Here, a surgically implanted titanium fixture (BI300) now supports a newly developed piezoelectric actuator (OSI200), including a receiver stimulator, receiving coil and retention magnet, that is placed under the skin. Piezoelectric technology has been used in various forms for many years and is based on the unique property of certain materials whereby applied force or vibration generates an electrical current. This effect is reversed in the OSI200 such that when an electrical current is applied, a mechanical change is rendered. Layers of the piezoelectric material bend; cause counterweights to generate and augment vibrations; and this vibrational energy is sent into bone through the actuator's connection with the BI300 implant. The Cochlear™ Osia® 2 System's external sound processor houses a corresponding retention magnet, which keeps the sound processor in place and aligns the transmitting and receiving coils. This processor uses complementary technology developed for cochlear implants in the form of a digital link that transmits both power and digital amplified signals to the internal receiver stimulator package. The Osia® 2 System was U.S. FDA approved in 2019 and is indicated for treatment of single-sided deafness as well as mixed/conductive hearing losses. For single-sided deafness, this system is cleared for use in patients with air conduction PTA $\leq$ 20 dB at 0.5, 1, 2 and 3 kHz in the contralateral ear, and for patients with conductive or mixed hearing losses, bone conduction PTA must be less than or equal to 55 dB at 0.5, 1, 2, and 3 kHz in the ipsilateral ear.

Following regulatory clearance of Osia® 2 System by the United States Food and Drug Administration, Cochlear Americas conducted a Controlled Market Release (CMR) from December 9, 2019 to February 14, 2020. *Importantly*, a CMR is *not* equivalent to a Clinical Trial. The purpose of the CMR was to train a small group of experienced ear surgeons & audiologists on the new Osia® 2 System; provide guidance regarding surgical technique as well as device programming; discuss possible best practices based on research and pre-approval studies; and then observe real-world surgical and audiological first experiences. While Cochlear Americas field staff were present to provide support and passively collect anonymized data where appropriate, surgeons and audiologists were not bound to sponsor-specified methodologies and prospective/rigorous data collection as they would be in a formal Clinical Trial. Furthermore, the CMR timeframe was predetermined and unlike a Clinical Trial, its duration was not subject to patient accrual. Therefore, Cochlear Americas field staff were not present for device activations that fell outside the months allocated to the CMR even if surgery was performed within the CMR dates. No patient-specific audiological data were collected as part of the CMR. The purpose of the Osia® 2 System CMR was to provide Cochlear Americas with early insights that could be used to refine training, adjust internal operations, and change company logistics prior to full commercial launch in February 2020. Those data are presented here. In addition, this paper presents surgical experiences and audiological performance data for six recipients implanted by the senior author; comparisons are made with recently implanted Baha Connect and Baha Attract patients. Key learnings at the national level as well as outcomes and performance of the system within a single practice are described.

2. Materials and methods

2.1. Cochlear™ Americas Osia® 2 System controlled market release

FDA clearance of the Cochlear™ Osia® 2 System was obtained on November 15, 2019. A Controlled Market Release (CMR) was conducted by Cochlear Americas in the United States during the period of December 9, 2019 through February 14, 2020. The surgical CMR timeframe ran from December 9, 2019 to January 24, 2020. Since device activation typically occurred about 4 weeks after surgery, the activation CMR timeframe ran from January 10, 2020 to February 14, 2020. Eleven activations for Osia® 2 implants operated between December 9, 2019 and January 24, 2020 occurred after closure of the audiology part of the CMR on February 14, 2020 and are not included in the CMR data. Recall, a CMR is not equivalent to a Clinical Trial. While a clinical trial seeks to prospectively accrue a predetermined number of patients, a CMR retrospectively reviews patients who underwent said intervention during a specific timeframe.

Clinics invited by Cochlear Americas to participate in the CMR had at least 5 years' experience implanting and fitting Cochlear™ Baha® and/or Cochlear™ Nucleus® devices, willingness to complete surveys and share feedback with Cochlear, and surgical volumes of at least 15 Baha and/or cochlear implant systems per year. All participating clinics had previous experience with Baha. While these criteria were broad and discretionary, the company's primary goal was to invite clinics with adequate experience in implantable device surgery. Surgeons and audiologists attended training prior to their first Osia® 2 case and committed to having Cochlear Americas personnel present for surgery as well as subsequent device activation during the CMR timeframe. CMR sites were trained to the recommended surgical and audiological parameters which included candidacy and indications, surgical instrumentation and procedures (BI300 and OSI200), surgical troubleshooting, post-operative management, the Osia® 2 sound processor, and the fitting software. For surgeons and audiologists, the training included a practical component as appropriate for their disciplines; surgeons implanted the Osia® 2 System on a model and the audiologists programmed sound processors in the fitting software.

Bone anchored hearing implant surgery has evolved over the past several decades, with the most significant change being a transition from percutaneous to transcutaneous stimulation. The OSI200 (Osia® System) implant location is identified using an implant template and the projected incision is measured 10–15 mm away from the edge of the template. The site of the BI300 fixture is also identified at this time. The incision is taken down to the periosteum and retracted to visualize the marking created for the BI300 and also to create a pocket for the coil of the OSI200. The drilling of the BI300 site is identical to other systems utilizing this implant (i.e. Baha Connect and Attract). A Bone Bed Indicator is then attached to the BI300 implant to ensure there is enough clearance of bone for the OSI200 to engage with the BI300. If the Bone Bed Indicator is impeded by bone, that area is polished to allow for clearance. Once that is established, the OSI200 is connected to the BI300 implant with a fixation screw, the incision is closed, and a dressing of choice is applied.

After approval by the Western Institutional Review Board (IRB), anonymized first experience data from the controlled market release was collected and collated. Cochlear Americas field personnel described their observations from surgery as well as device activations using SurveyMonkey® [11]. Product related problems were reported using Cochlear's standard operating procedure - Global Complaint Handling.

Table 1
Center for Neurosciences demographic information.

	Age (years)	Gender	Laterality	Type of hearing loss
Patient 1	66	Female	Right	SSD
Patient 2	72	Female	Left	SSD
Patient 3	71	Male	Right	MCHL*
Patient 4	47	Male	Right	SSD
Patient 5	74	Male	Left	MCHL
Patient 6	62	Male	Right	MCHL

* Patient has mixed conductive hearing loss; however, the Osia stimulates the contralateral cochlea.

In most cases, information regarding age of the recipient, skin flap thickness measurements, incision type, and length of the surgical procedure. Activation data collected when possible included: software skin flap estimates, software suggested magnet strength, and length of the activation appointment.

2.2. Center for Neurosciences (CNS) Osia® 2 surgical and audiological experience

Western Institutional Review Board (IRB) approval was obtained at Center for Neurosciences (CNS) in Tucson, Arizona for retrospective review of internal clinical data for patients receiving bone conduction technologies between April 2017 and April 2020. Six patients between ages 47–74 years underwent implantation of the Cochlear™ Osia® 2 System December 17, 2019–January 27, 2020 by the senior author. No single surgeon in the CMR did more than 6 implants.

Of the six recipients, three had SSD hearing profiles and three had mixed/conductive hearing loss (MCHL); however, one of the MCHL patients actually received stimulation to his better hearing contralateral cochlea, thus, his hearing profile was more representative of SSD. For each Osia® 2 patient, preoperative Phonetically Balanced Maximum (PB max) scores were obtained via insert earphones using recorded Consonant-Nucleus-Consonant (CNC) 50-word lists. Postoperatively, CNC word scores were re-assessed using recorded 50-word lists at a presentation level of 60 dBA via sound-field speaker at 0-degree azimuth with and without the Osia® 2 processor. Lastly, functional gain was measured in sound-field to determine threshold of audibility with use of the device. The contralateral ear was plugged and muffed during all sound-field testing procedures. Functional gain measures for 40 Baha Connect recipients and 17 Baha Attract recipients operated by the senior author between April 2017 and April 2020 were queried for comparison. Functional gain (versus PB Max and speech testing) was utilized as it was the most reliably reported metric during our retrospective chart review.

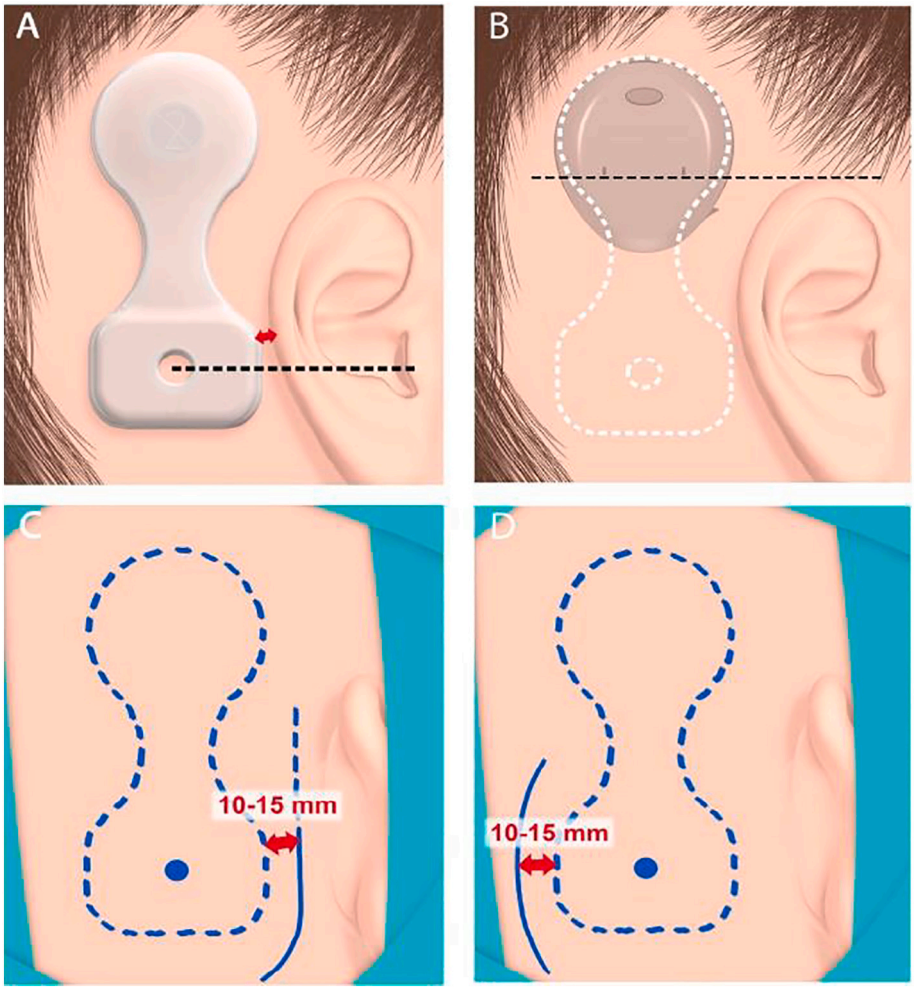


Fig. 1. A–D. Implant template and projected incision. Panel A: positioning of the OSI200 template prior to marking incision; panel B: importance of OSI200 placement for optimal microphone orientation of the Osia® 2 processor; panel C: marking and positioning of anterior incision; panel D: marking and positioning of posterior incision.

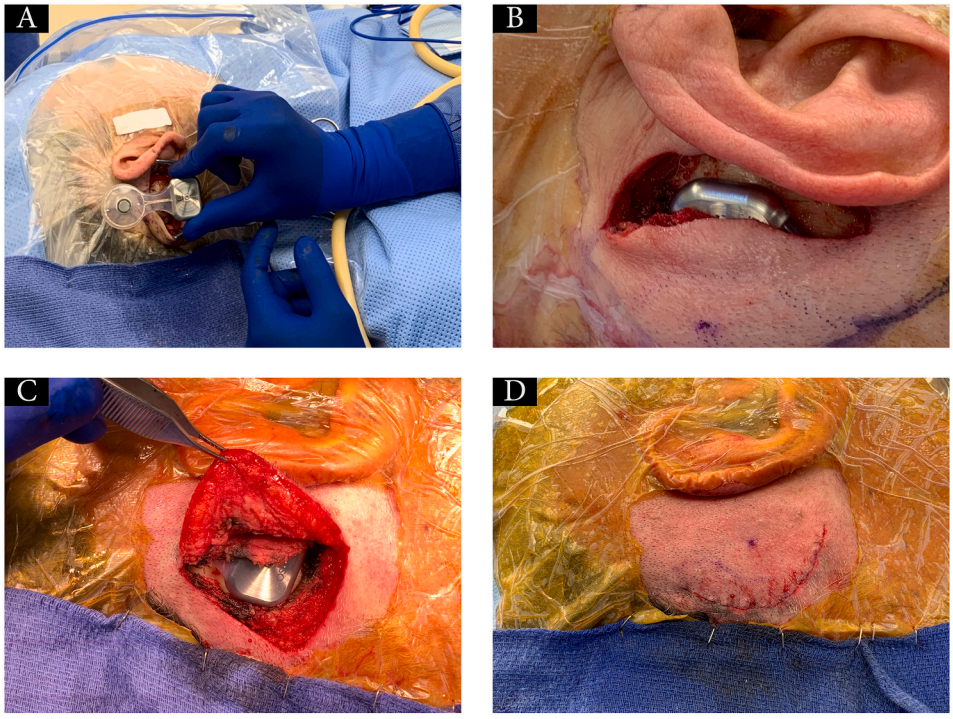


Fig. 2. A–D. Photos of surgical procedure. Panel A: OSI200 prior to implantation; panel B: anterior incision with OSI200 in place; panel C: posterior incision with OSI200 in place, panel D: closed posterior incision.

3. Results

3.1. Center for Neurosciences: surgical experience

Six patients between ages 47–74 years underwent implantation of the Cochlear™ Osia® 2 System December 17, 2019–January 27, 2020 by the senior author (Table 1). All six patients were operated under general anesthesia with the bed rotated 180-degrees. The OSI200 implant's position was determined by using a silicone template to outline the proposed incision 10–15 mm anterior or posterior to the edge of the template. Two sterile templates are provided in the implant kit. One was used to make these markings prior to incision while the other was used later in the operation under sterile conditions. Having the sound processor posterior to pinna just above the temporal line is important; therefore, the OSI200 template was positioned in this manner prior to marking the incision (Figs. 1A, B, and 2A). Since skin and soft tissues are typically thinner just behind the pinna, staying 15 mm away from the implant's anterior edge is advised when using an anterior incision (Fig. 1C). Posteriorly, soft tissue is more robust, and a 10 mm separation between incision and template markings is adequate (Fig. 1D). The incision does not need to be as long as the device itself; in most patients, it begins at about the midpoint of the implant and extends caudally (Fig. 1C and D). The inferior limb of the incision is then carried around the bottom of the template, again staying 10–15 mm away. Flap thickness at the sound processor site should be measured using a 25- or 27-gauge needle; ideally, the flap should be $\leq$9 mm. Lastly, the BI300 fixture's location should also be marked on skin.

The anterior incision can be used in most patients (Figs. 1C, 2B); however, those with prior history of ear or lateral skull base surgery will need a posterior incision (Figs. 1D, 2C) in order to avoid violating the previous surgery site. After infiltration of lidocaine/epinephrine, the incision is made with a #15 blade. Soft tissues are then elevated while using either monopolar or bipolar cautery for hemostasis. With the anterior incision, a single flap can be lifted while the posterior incision may require elevation of skin and musculoperiosteal tissues separately. Bone is exposed with a periosteal elevator, and the precise location for BI300 fixture is then marked by passing a needle from the previously made skin marking to underlying bone. Bleeding from emissary veins may require use of bone wax, and either cautery or methylene blue can be used for marking the BI300 fixture placement site. A subperiosteal pocket is then fashioned for the OSI200 silicone template, making sure that its placement lines up with skin markings. Drilling for placement of the BI300 fixture is identical to Baha Connect and Attract Systems where a Guide Drill is initially engaged to create a depth in the bone for either a 3 mm or 4 mm. Once the depth is confirmed, the appropriate Widening Drill creates the final diameter for the implant, and the BI300 is placed to the recommended torque according to bone quality (Fig. 3A). A Bone Bed Indicator (modified version of the one used in Baha Attract surgery) is then attached to the BI300 implant and rotated 360-degrees to ensure there is enough clearance of bone for the OSI200 to engage with the BI300 (Fig. 3B). If the Bone Bed Indicator is impeded by bone, that area would need to be polished to allow for the clearance. The OSI200 is then connected to the BI300 implant with a fixation screw (Fig. 3C and D), the incision is closed (Fig. 2D), and a mastoid dressing of choice is placed. None of the patients operated at Center for Neurosciences had any postoperative surgical complications.

3.2. Cochlear™ Americas Osia® 2 System controlled market release: surgical experience

Ninety-two surgeons and 115 audiologists from 35 clinics were trained during the Osia® CMR. Osia® surgeries were only performed by trained surgeons, and Osia® activations were only performed by trained audiologists. During the CMR period, 23 surgeons performed 44 surgeries on 43 recipients (1 bilateral) from December 9, 2019 through January 24, 2020 (Table 2). The mean age of recipients was 44 years old with a range between 10 and 85 years old. The mean length of surgery was 52 min (median 50 min, range 24–130 min, SD = 19). Skin flap thickness at the magnet site was measured by 83% of the surgeons in 32 recipients. While measuring skin flap thickness is suggested best-practice, it was measured at the discretion of the surgeon. Recall again that this was a CMR, not a Clinical Trial. When measured, mean skin

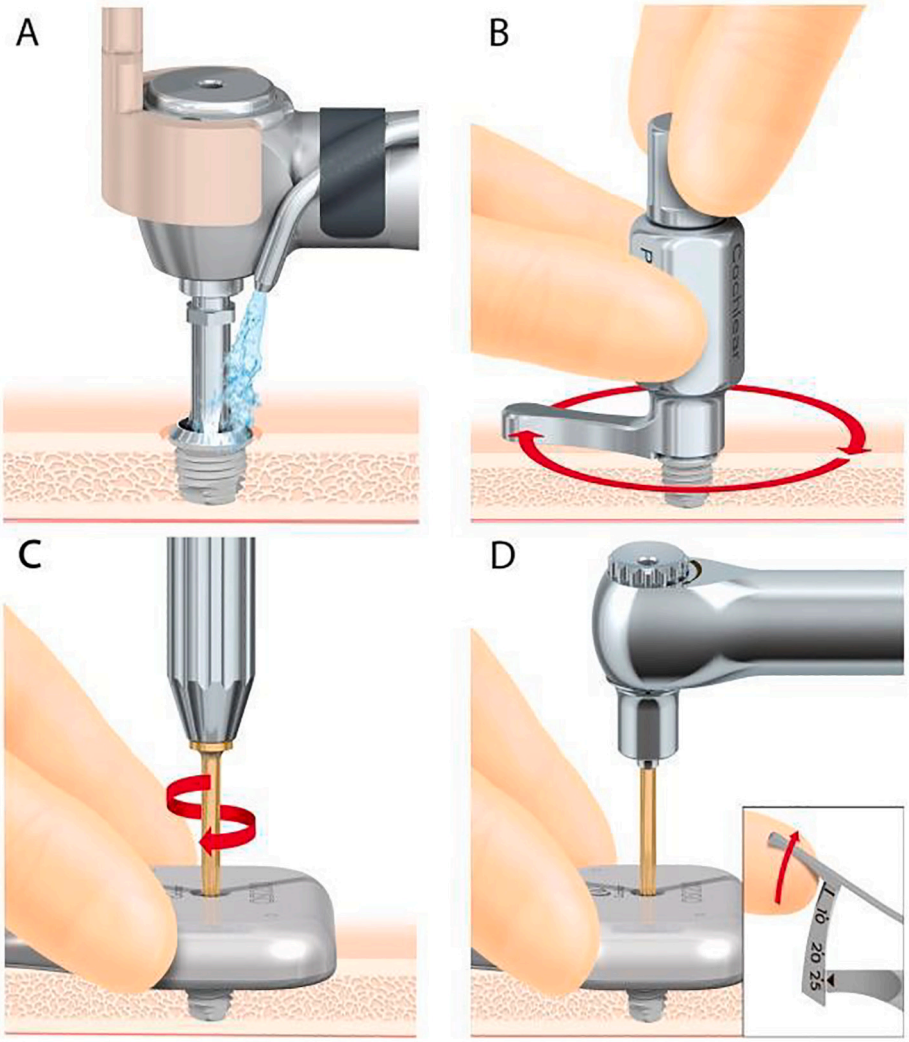


Fig. 3. A–D. Drilling of the BI300 site. Panel A: Insertion of the BI300 implant into bone, of which the OSI200 will attach with a Fixation Screw. Panel B: The Bone Bed Indicator fixates to the BI300 Implant and is rotated in a 360 degree motion to assure clearance of bone and tissue under the OSI200. Panel C: The OSI200 is fastened to the BI300 with the Fixation Screw, initially hand tightened gently with a manual screwdriver. Panel D: The Fixation Screw is then tightened to 25 Ncm with the Multi Wrench, which is a torque wrench.

thickness measured was 6 mm (range 3–8 mm, SD = 1.3). Flap thinning is advised when thickness is >9 mm. None of the recipients underwent primary skin reduction at surgery. The most commonly used incision (78%) was post auricular but anterior to the device, 17% were posterior to the device, and the remaining 5% were classified as "other". Those classified as "other" may apply to situations where patients with prior BAHA Connect or mastoid ear surgery required further modifications of the incision. After use of the Bone Bed Indicator, bone polishing was performed in 19 recipients (44%). Cochlear Americas field personnel did not record whether prophylactic antibiotics were used. This was left to the discretion of the surgeon.

Five complications were observed during the CMR, none of which were device related. The most serious complication involved exposure of dura with bleeding from the transverse sinus. Despite this, the BI300 implant fixture was successfully placed in this patient. There were two postoperative wound infections, both treated successfully with antibiotics. One of those patients had Type 1 Diabetes and was a smoker. Lastly, there were two postoperative hematomas. One resolved via application of cold compresses, and the other was treated by needle aspiration.

3.3. Cochlear™ Americas Osia® 2 System controlled market release: audiologic experience

Twenty-one audiologists performed 33 Osia® 2 sound processor activations from January 10, 2020 through February 14, 2020 (Table 2). The mean age of this subgroup was 47 years old with a range of 10–85 years old. The mean length of the activation appointment was 55 min (range 30–75 min, SD = 10.82). Time was measured for the entirety of the appointment, which may include programming, counseling, and testing. Components of the appointment varied by clinic and were not captured in the field report. No audiological outcomes data were collected in the CMR by Cochlear Americas. At the fitting, the programming software conducts a measurement to estimate the skin flap thickness and provides suggested magnet strength. Out of the 33 activations, 31 field reports contained the skin flap estimation. Mean skin flap estimate was 6 mm (range < 2–10 mm, SD = 2.0). Twenty-nine reported the magnet strength: 35% for strength 1, 23% for strength 2, 19% for strength 3, 23% for strength 4.

3.4. Center for Neurosciences: audiologic experience

The Osia® 2 sound processor was activated about 4–5-weeks postoperatively in all 6 patients. Average appointment time for initial activation was 57.5 min. Per our practice, all bone conduction hearing implant patients are typically scheduled for an hour-long visit, inclusive of programming, orientation, counseling, and validation measures. Therefore, despite being new technology, no additional appointment time is necessary for programming the Osia® 2 System. Programming the Osia® 2 sound processor was similar to programming of the Cochlear™ Baha Connect or Attract sound processors, with one additional step being digital link calibration. This measures the implant's

Table 2
Number of participating clinics, professionals trained, and completed Osia® surgeries and activations per professional during the controlled market release. Where there are multiple professionals from one clinic who performed surgeries or activations, they are denoted as a, b, and c where applicable (ex. 3 (a, b, c)). The appropriate number of surgeries or activations completed are then attributed to each professional (ex. a = 1, b = 1, c = 1).

Clinic	Number of surgeons trained	Number of surgeons who performed surgeries	Number of surgeries per surgeon	Number of audiologists trained	Number of audiologists who performed activations	Number of activations per audiologist
1	1	0	0	1	0	0
2	2	1	6	3	2 (a, b)	a = 1, b = 1
3	1	0	0	1	0	0
4	1	1	1	2	1	2
5	1	1	4	2	1	4
6	0	0	0	1	0	0
7	0	0	0	1	0	0
8	2	0	0	0	0	0
9	1	0	0	2	0	0
10	1	1	2	6	1	2
11	2	0	0	2	0	0
12	1	0	0	1	0	0
13	8	1	1	11	1	1
14	3	2 (a, b)	a = 2, b = 1	11	3 (a, b, c)	a = 1, b = 1, c = 1
15	1	0	0	1	0	0
16	10	2 (a, b)	a = 2, b = 1	14	2 (a, b)	a = 2, b = 1
17	4	3 (a, b, c)	a = 1, b = 1, c = 1	3	2	a = 1, b = 1
18	5	1	2	2	1	1
19	5	0	0	9	0	0
20	3	0	0	1	0	0
21	4	1	1	4	0	0
22	1	1	4	2	2	a = 3, b = 1
23	2	0	0	1	0	0
24	1	0	0	2	0	0
25	1	1	5	2	2 (a, b)	a = 1, b = 1
26	6	0	0	6	0	0
27	2	0	0	4	0	0
28	2	1	1	3	0	0
29	1	1	1	1	1	1
30	1	0	0	3	0	0
31	3	0	0	4	0	0
32	4	3 (a, b, c)	a = 1, b = 3, c = 1	2	1	5
33	2	0	0	2	0	0
34	9	2 (a, b)	a = 1, b = 1	1	1	1
35	1	0	0	4	0	0
35	92	23	44	115	21	33

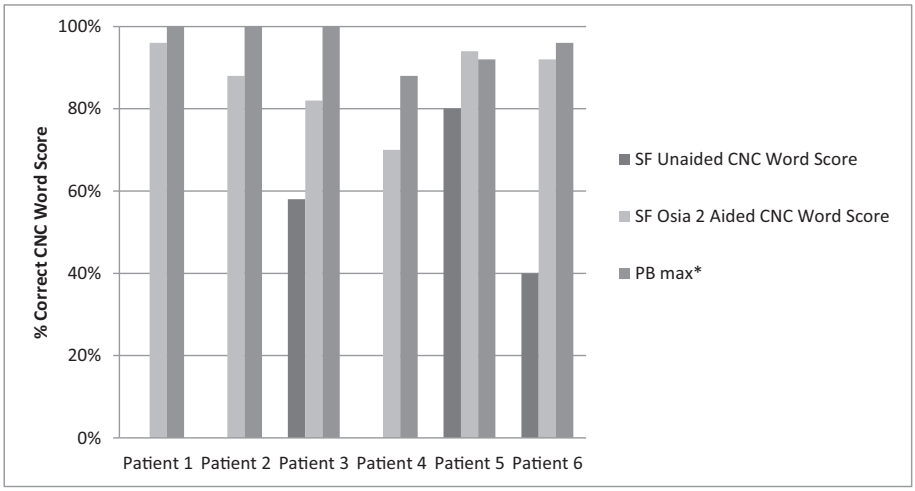


Fig. 4. Center for Neurosciences monosyllabic word performance data in the unaided, aided, and PB max listening conditions for Osia® 2 patients. *For mixed and conductive hearing loss, the PB max score of the implanted ear is presented. For SSD patients, the PB max score of the ear contralateral to the implant is presented.

characteristics in-situ in order to appropriately set the notch filter for output levels as well as estimate skin flap thickness and recommended magnet strength. Anecdotally, the presence of feedback was greatly reduced in the fitting of the Osia® 2 System in comparison to the fitting of the Baha Connect or Attract. Average time of active programming in our clinic was approximately 10 min with the remaining 47.5 min spent on orientation, counseling, and validation measures.

Speech perception outcomes are demonstrated in Fig. 4, indicating that speech perception was maintained when comparing aided Osia® 2 responses to pre-operative PB max scores. Additionally, functional gain in speech perception was calculated by comparing aided versus unaided sound-field CNC word scores, yielding an average improvement of 57%.

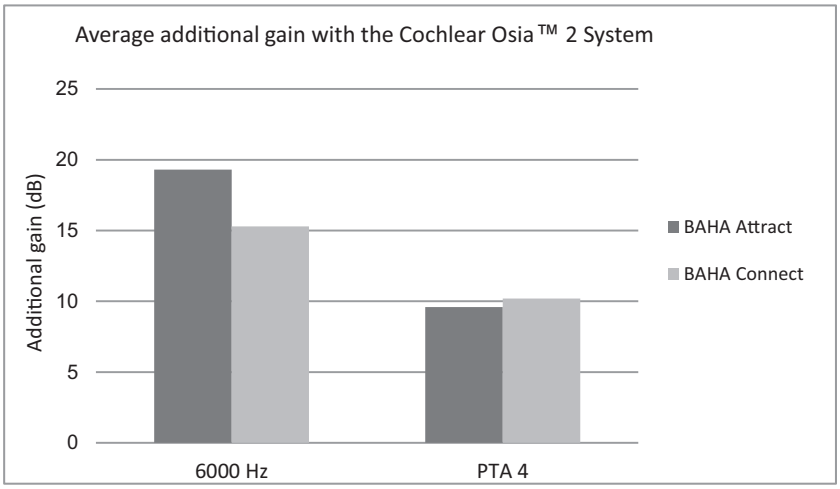


Fig. 5. Center for Neurosciences: average additional gain with the Osia® 2 System compared to Attract and Connect.

A four-frequency pure tone average of 500, 1000, 2000, and 4000 Hz (PTA4) was utilized for analysis of pure-tone thresholds. Average unaided PTA4 for air-conduction thresholds was 85.8 dB HL preoperatively on the side of implantation. The average sound-field Osia® 2 aided PTA4 was 27.3 dB HL, indicating a postoperative mean hearing gain of 58.5 dB. For comparison, the PTA4 was calculated for 40 Baha Connect recipients and 17 Baha Attract recipients sequentially operated by the senior author between April 2017 and April 2020. The average unaided PTA4 air-conduction thresholds for Connect patients was 77.6 dB HL on the side of implantation pre-operatively. The sound-field aided mean was 29.3 dB HL, indicating a postoperative mean hearing gain of 48.3 dB. Unaided PTA4 air-conduction thresholds for Attract patients were 86.6 dB HL on the side of implantation pre-operatively. The sound-field aided mean was 38.0 dB HL, indicating a postoperative mean hearing gain of 48.6 dB. Overall, the average additional PTA4 gain in Osia® 2 patients was 9.6 dB over Attract and 10.2 dB over Connect. We were also interested in whether the Osia® 2 patients had improved high frequency performance. At 6000 Hz, Osia® 2 outperformed Baha Attract by 19.3 dB and Baha Connect by 15.3 dB. For 4000 Hz, average additional gain was 5.8 dB over Attract and 4.6 dB over Connect (Figs. 5 and 6).

Three patients implanted with the Osia® 2 device at the Center for Neurosciences had SSD. In addition, one patient had a MCHL but the Osia® 2 stimulated the better hearing (contralateral) cochlea. Therefore, this patient behaved more like an SSD patient than someone with MCHL. In these four patients, the head shadow effect was assessed for both unaided and aided conditions using recorded AzBio sentences at 60 dBA in a +5 dB SNR. The patients were placed between two loudspeakers with the speech signal presented to the poorer ear and the noise signal presented to the contralateral (better) ear. This was assessed in the unaided and Osia® 2 aided conditions. Results indicated a mean unaided score of 34% and a mean aided score of 63%, indicating a mean head shadow improvement of 29%.

Lastly, post-activation patient reported outcomes were recorded in half our patients. For 3 of the 6 patients, the Hearing Handicap Inventory for the Elderly - Screening version (HHIE-S) was assayed pre and post-activation [12]. Average pre-activation HHIE-S was 24, suggesting a mild-moderate hearing handicap. Average post -activation HHIE-S using the Osia® 2 System was 7, suggesting no hearing handicap based on self-assessment. Two patients were younger than 65 years old so the HHIE-S is not an appropriate measure due to age. One patient did not complete the HHIE-S entirely, thus the scores were not reported.

4. Discussion

This study is the first to report multi-center data from the controlled-market release of the Cochlear™ Osia® 2 System in the United States as well as early more detailed audiometric and surgical results of the first six patients implanted in a single-center. The Osia® 2 System is FDA approved for the treatment of mixed and conductive hearing loss as well as single-sided deafness and is the world's first device in a new category of "Active Osseointegrated Implants" (OSI), where digital piezoelectric stimulation is utilized instead of electromagnetic stimulation. Findings from the national controlled-market release indicate that the Osia® 2 has comparable safety outcomes to other available bone anchored hearing systems. While a larger incision and more soft tissue dissection is required for surgery, the basic steps of bone fenestration, widening, polishing adjacent bone, and placing the fixture are all familiar to anyone having performed traditional Baha surgery. Nationally, average surgical time from incision to closed was 52 min with the shortest operation being 24 min. As the learning curve improves with experience, surgeon time is likely to decrease.

Using the Osia® 2 System, our single-center findings demonstrate an average additional 500, 1000, 2000, and 4000 Hz (PTA4) gain of 9.6 dB compared to Cochlear™ Baha® Attract and 10.2 dB compared to Cochlear™ Baha® Connect systems. Even more compelling is the additional high-frequency gain with the Osia® 2. We found an average additional gain of 19.3 dB at 6000 Hz when compared to the Baha® Attract and 15.3 dB of additional gain over the Baha® Connect. This improved high-frequency gain may result from absence of skin attenuation or damping seen in passive bone-anchored solutions, more optimum positioning of the osseointegrated point of stimulation, and the effectiveness of using a piezoelectric transducer [13,14]. In addition, feedback commonly observed with traditional Baha devices is greatly reduced, which allows for more gain and headroom with the Osia® 2 System.

Being able to hear better in daily listening conditions is the ultimate goal of any device, and in line with this goal, we found that patient self-reported satisfaction was high with the Osia® 2 System. Self-perceived hearing handicap on the Hearing Handicap Inventory for the Elderly - Screening version (HHIE-S) was obtained pre and post implantation for three of our patients implanted at Center for Neurosciences. There were two patients who were younger than 65 years old, where the HHIE-S was not appropriate, and one patient did not complete the HHIE-S entirely, thus the scores were not used. The average pre-activation HHIE-S was 24, suggesting a mild-moderate hearing handicap compared to average post-activation HHIE-S of 7, suggesting no hearing handicap [12]. Consistent with our results, early Osia® outcomes in the United Kingdom also found a decrease in hearing disability and improved hearing in a variety of daily listening conditions [13].

Comfort and cosmesis are also important to patients considering

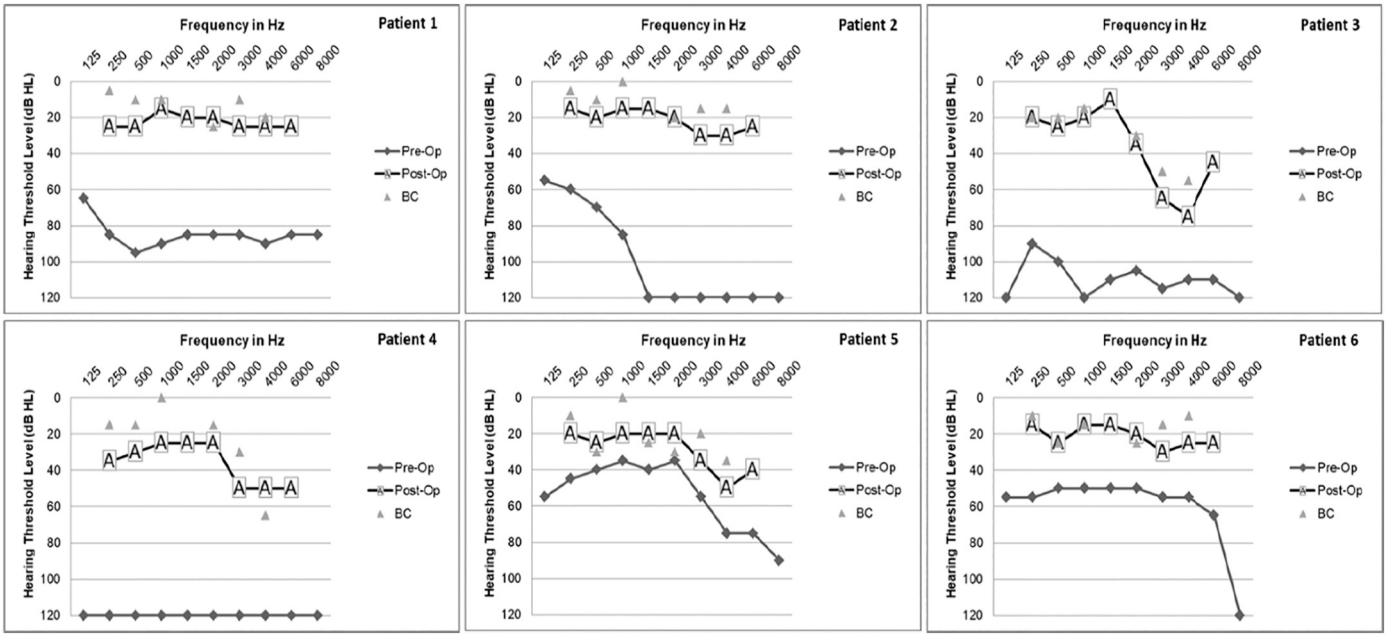


Fig. 6. Center for Neurosciences individual pre to post-operative audiometric thresholds using Osia® 2. For SSD patients, the bone conduction thresholds reported below are for the contralateral ear (ear of stimulation).

surgical hearing rehabilitation. The Osia® 2 sound processor has a very thin profile and is very light weight. It weighs just 9.4 g in comparison to the Baha 5 at 10.3 g and Baha 5 Power at 15.6 g. Since it couples to the internal device via magnets, no abutment is required and absolves patients of their need for lifelong aftercare. Unlike Baha Attract, which has an actively vibrating sound processor and requires a strong magnetic connection between the internal and external magnets for effective transmission, the Osia® 2 sound processor does not vibrate and typically does not require extreme magnet strength for sound transmission. This adds to comfort when using the Osia® 2 for extended periods of time.

5. Conclusion

The Osia® 2 System from Cochlear represents an important advance in hearing implant technology. Utilizing innovative digital piezoelectric stimulation, this active auditory osseointegrated implant (OSI) delivers high-power output and delivers improved high frequency gain for optimizing speech perception while maintaining safety and engendering high patient satisfaction.

Funding

This research did not receive external funding from agencies in the public, commercial, or not for profit sectors. Cochlear Americas (Denver, CO) completed their controlled-market release and incurred any associated financial costs, including data collection. Single-center data and analysis was not financially supported by Cochlear Americas.

CRediT authorship contribution statement

Mary Rose Goldstein: Conceptualization, Formal Analysis, Investigation, Data Curation, Writing – Original Draft Preparation, Writing Review & Editing, Visualization.

Stephanie Bourn: Conceptualization, Investigation, Data Curation, Writing Review & Editing, Visualization.

Abraham Jacob: Conceptualization, Investigation, Writing Review & Editing,

Declaration of competing interest

In accordance with Taylor & Francis policy, we are reporting that Abraham Jacob has consulted for Olympus, Medtronic, Cochlear Americas, and Advanced Bionics. Mary Rose Goldstein and Stephanie Bourn have consulted for Cochlear Americas.

Acknowledgements

We thank the Osia® recipients that participated in the Controlled Market Release (CMR) and in the study, together with all the colleagues at the participating CMR centers (Arizona Hearing Center, Phoenix, AZ; Arizona Ear Institute, Phoenix, AZ; Baylor College of Medicine, Houston, TX; Center for Hearing and Balance Disorders, Chesterfield, MO; Center for Neurosciences, Tucson, AZ; Children's Mercy Hospital, Kansas City, MO; Cochlear Hearing Center, San Antonio, TX; Ear Medical Group, San Antonio, TX; ENT Surgeons of Western New England, Springfield, MA; Ear, Nose, and Throat Associates at the Greater Baltimore Medical Center, Baltimore, MD; House Ear Institute, Los Angeles, CA; Idaho Ear Clinic, Boise, ID; Johns Hopkins Health System, Baltimore, MD; Loyola University Medical Center, Maywood, IL; Macias Otology, Phoenix, AZ; Massachusetts Eye and Ear Infirmary, Boston, MA; Michigan Ear Institute, Farmington Hills, MI; NYU Langone Health, New York, NY; Ohio State Eye and Ear Institute, Columbus, OH; Otologic Center, Inc., Kansas City, MO; Hospital of the University of Pennsylvania, Philadelphia, PA; Prevea Health, Green Bay, WI; Rush University Medical Center, Chicago, IL; Silverstein Institute, Sarasota, FL; Texas Children's Hospital, Houston, TX; The New York Eye and Ear Infirmary of Mount Sinai, New York, NY; University of Colorado, Aurora, CO; University of Iowa, Iowa City, IA; University of Massachusetts Medical Center, Worcester, MA; University of Miami Ear Institute, Miami, FL; University of Michigan, Cochlear Implant Program, Ann Arbor, MI; UT Southwestern Medical Center, Dallas, TX; Vanderbilt, Nashville, TN; Washington University, St. Louis, MO; West Virginia University Hospital, Morgantown, WV).

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