RAPID HTA REVIEW		
N° richiesta	**Data richiesta**	**Richiedente**
224	26 Gennaio 2022	Otorinolaringoiatria AOUP

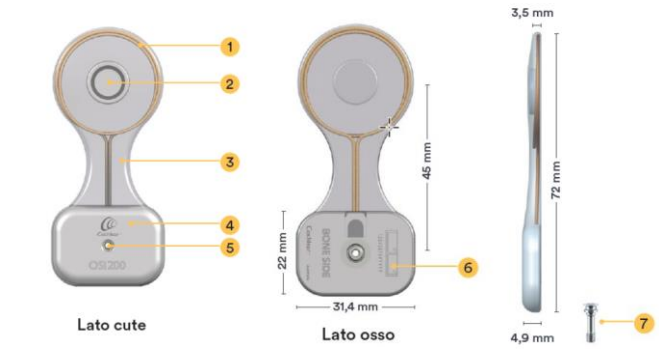
Dati generali della tecnologia in valutazione			
Nome commerciale			
Sistema Cochlear Osia			
Nome generico			
Sistema di impianto attivo osteointegrato			
Nome fabbricante			
Cochlear			
Nome fornitore			
Cochlear			
RDM	**REF**		
DM processore del suono Cochlear: 2141203; RDM impianto OSI 200: 2137719	Non applicabile		
Tipo	**Marchio CE (data)**	**Classe di rischio**	**Approvazione FDA**
assemblato	2021	Impiantabile attivo	
CND			
J03 (riferita ai due componenti del kit)			
Campo di applicazione			
Deficit uditivi			
Paziente target			
1) Perdita dell'udito mista o trasmissiva. Soglie di conduzione ossea con media del tono puro (PTA4; media di 0,5, 1, 2 e 4 kHz) ≤ 55 dB HL; 2) Sordità neurosensoriale monolaterale (SSD). Soglie di conduzione aerea con media del tono puro (PTA4; media di 0,5, 1, 2 e 3 kHz) ≤ 20 dB HL nell'orecchio sano. Viene utilizzato per trattamenti di patologie dell'orecchio medio (otite media cronica, colesteatoma, otosclerosi, esiti non soddifacenti di chirurgie ricostruttive dell'orecchio medio come stapedotomia, timpanoplastica, ecc.). Il dispositivo, oltre a garantire una maggiore amplificazione del suono, permette di intervenire su pazienti non altrimenti protesizzabili; in tal modo si dà risposta ad unmet clinical need.			
Indicazione d'uso da scheda tecnica			
Il sistema Cochlear Osia utilizza la conduzione ossea per trasmettere i suoni alla coclea (orecchio interno), in modo da migliorare l'udito. L'impianto OSI200 deve essere utilizzato come parte del sistema Cochlear Osia per convertire le informazioni provenienti dal processore del suono esterno in vibrazioni meccaniche. Il sistema Cochlear Osia è concepito per i pazienti che presentano le seguenti patologie: a) Perdita dell'udito mista o trasmissiva. Soglie di conduzione ossea con media del tono puro (PTA4; media di 0,5, 1, 2 e 4 kHz) ≤ 55 dB HL; b) Sordità neurosensoriale monolaterale (SSD). Soglie di conduzione aerea con media del tono puro (PTA4; media di 0,5, 1, 2 e 3 kHz) ≤ 20 dB HL nell'orecchio sano.			

Figura 1: impianto Cochlear™ Osia® OSI200

Principali competitor
Chirurgie ricostruttive dell'orecchio medio oppure uso di sistemi acustici convenzionali o ancorati all'osso percutanei e transcutanei

Dettagli tecnologici
Descrizione
Il sistema richiesto utilizza la conduzione ossea per trasmettere i suoni alla coclea (orecchio interno), in modo da migliorare l'udito. L'impianto osteointegrato converte le informazioni provenienti dal processore del suono esterno in vibrazioni meccaniche. Il processore del suono capta il suono circostante e lo trasferisce all'impianto attraverso un collegamento induttivo digitale. Il trasduttore piezoelettrico non contiene alcun elemento magnetico e pertanto l'impianto risulta compatibile con RM condizionata a 1,5T con il magnete in posizione, e a 3 T quando il magnete viene rimosso. Inoltre, il processore esterno presenta un design molto sottile (10,4 mm) e risulta ben accettabile da parte dei pazienti portatori.
Elementi di innovazione
Sono legati al miglioramento della performance uditiva nei pazienti sottoposti all'impianto.

Evidenze cliniche ed economiche
Studi clinici
Gli studi clinici su questo dispositivo, pur se caratterizzati dall'esiguità del numero di pazienti arruolati, mostrano evidenze convincenti riguardo all'efficacia di OSIA (vedasi Appendice). L'Appendice riporta l'abstract degli studi di Pla-Gil et al. (2021), Rauch et al. (2021), Willenborg et al. (2022), Goldstein et al. (2021), Lau et al. (2020), Goycoolea et al. (2020) e Mylanus et al (2020). Altrettanto importanti sono le informazioni che da tali studi emergono riguardo alla sicurezza di questa procedura, la quale risulta sufficientemente dimostrata.
Sperimentazioni cliniche
Sono presenti ulteriori studi in corso.
Linee guida
Non disponibile
Analisi di costo-efficacia
Non disponibile
Report HTA
Nessuno
Benefici attesi
Deciso miglioramento delle prestazioni in situazioni di quiete e di rumore, e conseguente incremento della qualità della vita. Alto livello di accettazione. Dal punto di vista chirurgico tempistiche ridotte ed efficace alternativa alle chirurgie ricostruttive dell'orecchio medio.

Prezzo e costo terapia per paziente		
Prodotto (Fabbricante)	**Prezzo unitario (euro)**	**Costo terapia per paziente (euro)**
Cochlear	10mila	Informazione non disponibile

Prezzo e costo terapia per paziente con le alternative terapeutiche già in uso		
Prodotto (Fabbricante)	**Prezzo unitario (euro)**	**Costo terapia per paziente (euro)**
Sistema acustico	10mila	Informazione non disponibile

Rimborso procedura legata all'uso del dispositivo medico richiesto			
Codice ICD9-CM di diagnosi principale (descrizione)	**Codice ICD9-CM di intervento (descrizione)**	**Codice DRG (descrizione)**	**Tariffa (euro)**
389.00	20.95, 20.21	55 €1.485 + €8.568 (tariffa aggiuntiva, Deliberazione della Giunta regionale 27.09.2016, n. 947)	

Dati riassuntivi		
Numero richiesta	**Data richiesta**	**Richiedente**
224	Non riportata	ORL AOUP
Tecnologia in valutazione		
Si		
Eventuali esperti esterni coinvolti		
No		
Status di dispositivo innovativo		
Sì		
Nel caso di dispositivo innovativo indicare i criteri usati per la definizione del carattere di innovatività		
/__/ "Unmet clinical need" ossia bisogno terapeutico non soddisfatto o non sufficientemente soddisfatto /x / Documentato vantaggio di natura clinica rispetto al comparator già in uso /__/ Documentato vantaggio di natura economica e/o organizzativa. Questo criterio viene preso in considerazione solo se il dispositivo dimostra di essere clinicamente sovrapponibile alle tecnologie di riferimento.		
Conclusioni e parere del Gruppo di lavoro Regionale permanente sui Dispositivi Medici (GRDM)		
Parere favorevole Si sottolinea che questo dispositivo inteso nell'ambito di questa sua indicazione clinica è caratterizzato da elementi rilevanti di innovazione e pertanto rappresenta uno dei casi in cui si rende necessaria una valutazione HTA riferita al singolo dispositivo. Risulta altresì inopportuno che la decisione su questo dispositivo venga demandata alle future valutazioni espresse da un collegio tecnico di gara perché ciò determinerebbe un ritardato accesso al dispositivo da parte delle strutture del nostro SSR.		
Data di redazione della scheda		
31 Gennaio 2022		

Estensore della scheda
Andrea Messori
Farmacista aziendale referente per la richiesta
Domenica Mamone
Decisione della Commissione per la valutazione delle tecnologie e degli investimenti sanitari (C-HTA)
Parere favorevole condizionato al costo che dovrà essere lo stesso di quello di aggiudicazione della gara.
Data della decisione della C-HTA
10 Febbraio 2022

BIBLIOGRAFIA

Vedi Appendice

APPENDICE

1. PMID: 33710155

Otol Neurotol . 2021 Aug 1;42(7):e905-e910.
doi: 10.1097/MAO.0000000000003116.

Clinical Performance Assessment of a New Active Osseointegrated Implant System in Mixed Hearing Loss: Results From a Prospective Clinical Investigation

Ignacio Pla-Gil[1], María Aragonés Redó, Tomàs Pérez-Carbonell, Paz Martínez-Beneyto, Miguel Orts Alborch, Antonio Morant Ventura, Emilia Latorre Monteagudo, Ignacia Pitarch Ribas, Jaime Marco Algarra
Affiliations expand

Abstract

Objective: Evaluation of a new active osseointegrated bone-conduction hearing implant in moderate to severe mixed-hearing loss.

Study design: Prospective observational study of a series of cases.

Setting: Tertial referral center.

Patients: Twenty patients with moderate mixed-hearing loss were evaluated (10 Cochlear Osia group and 10 Baha 5 Power Connect -control group).

Intervention: Rehabilitative.

Main outcome measures: Hearing performance in quiet and in noise and quality-of-life were evaluated.

Results: Improvements in audibility, speech-understanding, speech-recognition, and quality-of-sound in noise and quiet were found for the Osia System compared with preoperative unaided hearing and performance was similar to that obtained with Baha 5 Power Connect.

Conclusions: The new active transcutaneous bone conduction system provided a tonal improvement in free-field at middle and high frequencies. The performance in speech recognition in quiet and in noise was similar to control group outcomes.

2. PMID: 34792628
Eur Arch Otorhinolaryngol
. 2021 Nov 18.
doi: 10.1007/s00405-021-07167-9. Online ahead of print.

Long-term data of the new transcutaneous partially implantable bone conduction hearing system Osia®

Ann-Kathrin Rauch[1], Thomas Wesarg[2], Antje Aschendorff[2], Iva Speck[2], Susan Arndt[2]
Affiliations expand

Abstract

Purpose: The new active transcutaneous partially implantable osseointegrated system Cochlear™ Osia® System is indicated in case of conductive or mixed hearing loss (CHL/MHL) with a maximum average bone conduction hearing loss of 55 dB, or in single-sided deafness (SSD). The implant directly stimulates the bone via a piezoelectric transducer and is directed by an external sound processor. We conducted a monocentric retrospective longitudinal within-subject clinical study at our tertiary academic referral center. The aim was to investigate long-term data (2017-2021) on audiological outcomes and hearing-related quality of life for the Osia system.

Methods: Between 2017 and 2020, 22 adults (18: CHL/MHL; 3: SSD) were implanted with the Osia100 implant; seven received bilateral implants. As of 10/2020, the sound processor was upgraded to Osia 2.

Results: Mean Osia system use by 04/2021 was 30.9 ± 8.6 months (range 17-40 months). Unaided bone conduction thresholds were unchanged postoperatively. One patient had to be explanted because of prolonged wound infection. Aided hearing thresholds were significantly lower compared to the unaided thresholds preoperatively, along with a marked increase in speech recognition in quiet. Speech processor upgrade resulted in a stable benefit. Patients with CHL/MHL and SSD showed a similar improvement in self-rated hearing performance revealed by SSQ, APHAB, and HUI questionnaires.

Conclusion: The Osia system is a safe, effective and sustainable option for treatment of conductive and mixed hearing loss or single-sided deafness.

3. PMID: 33902037
Audiol Neurootol
. 2022;27(1):83-92.
doi: 10.1159/000515489. Epub 2021 Apr 26.

A New Active Osseointegrated Implant System in Patients with Single-Sided Deafness

Kerstin Willenborg[1], Emilio Avallone[1], Hannes Maier[1,2], Thomas Lenarz[1,2], Susan Busch[1,2]
Affiliations expand

Abstract

Objective: The Cochlear™ Osia® System (Osia) is an active transcutaneous bone conduction implant system intended for patients with conductive and mixed hearing loss but can also be used in cases of single-sided deafness (SSD) for the contralateral routing of signal (CROS). The Osia implant is placed subcutaneously under

the intact skin behind the ear with the piezoelectric actuator connected to an osseointegrated BI300 implant - a titanium screw used for a 2-stage Baha surgery - on the mastoid. The external processor is magnetically attached to the subcutaneous implant receiver coil. As the Osia has recently been CE certified and is new on the market, with limited patient outcome data for SSD available, the objective of this study was the evaluation of surgical procedure, audiological results, and patient satisfaction for the Osia in SSD patients.

Study design: In a prospective, monocentric clinical observation study, 6 patients (18 years of age or older) with SSD and bone conduction thresholds pure tone average 0.5, 1, 2, and 4 kHz ≤25 dB HL on the contralateral side were implanted with an Osia. Analysis of clinical outcome data with respect to surgical technique, adverse events, audiological measurement, and subjective benefit for SSD patients was conducted. Audiological measurements performed included hearing thresholds, sound field thresholds, word recognition scores (WRS; in %) in quiet, and speech recognition thresholds in noise (in dB SNR). All tests were performed unaided and aided with the Osia. The subjective benefit with the Osia was determined by using 2 questionnaires; the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Bern Benefit in Single-Sided Deafness (BBSSD).

Results: Preliminary results indicate a straightforward surgical procedure with a low rate of complications and an improvement in speech perception in quiet, listening performance in everyday situations and patient satisfaction. However, in one of 6 subjects, a revision surgery had to be performed.

Conclusion: Provided that SSD patients are open for CROS hearing, they can benefit from the Osia by reduced head shadow effects and better speech recognition. Special caution should be given to the skin at the site of implantation to avoid complications.

4. PMID: 33166860
Am J Otolaryngol
. Jan-Feb 2021;42(1):102818.
doi: 10.1016/j.amjoto.2020.102818. Epub 2020 Oct 28.

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

Mary Rose Goldstein [1], Stephanie Bourn [2], Abraham Jacob [3]
Affiliations expand

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.

5. PMID: 32405815
Eur Arch Otorhinolaryngol
. 2020 Nov;277(11):2995-3002.
doi: 10.1007/s00405-020-06022-7. Epub 2020 May 13.

First United Kingdom experience of the novel Osia active transcutaneous piezoelectric bone conduction implant

Kimberley Lau[1,2], Gianluca Scotta[3,4], Kay Wright[5], Vicki Proctor[5], Larissa Greenwood[5], Moustafa Dawoud[3,4], Jaydip Ray[3,4]
Affiliations expand

Abstract

Purpose: Bone conduction hearing devices are widely used and indicated in cases of conductive, mixed or single-sided deafness where the conventional hearing aids are not indicated or tolerated. This prospective study aims to investigate the surgical and hearing outcomes of a novel active piezoelectric transcutaneous bone conduction device (t-BCD).

Methods: Prospective data were collected from the first 10 patients who underwent implantation with the t-BCD Osia (Cochlear, Australia) (between Dec 2018 and March 2019) in a tertiary referral centre. The main outcome measures include: surgical outcome, free field speech testing with speech recognition thresholds, audiological gain and patient-reported outcomes including the 'Glasgow Benefit Inventory' (GBI) and the 'Client Oriented Scale of Improvement (COSI).

Results: The mean length of surgery was 70.6 min (range 50-87, SD = 9.5). Mean skin thickness measured was 5.6 mm (range 4-8, SD = 1.1). There were two post-operative wound infections which settled conservatively. One required revision surgery to thin skin. The average gain in hearing with the implant was + 39.4 dB. Pre-implantation mean unaided SRT was 38.1 dB (SD = 7.8) and the post-implantation mean-aided SRT was 22.7 dB (SD = 4.6) (p = 0.000078). There was improvement in COSI domains. The mean Glasgow disability score dropped from 52% pre-implantation to 20% post-implantation (p = 0.001).

Conclusions: This new active t-BCHD provides excellent audiological gain and improvement in speech recognition. Patient-reported outcomes have also been very positive. The surgery was straightforward with no major surgical complications reported. Further studies will be required to examine long-term outcomes in larger number of patients.

6. PMID: 32068449
Acta Otolaryngol
. 2020 Mar;140(3):212-219.
doi: 10.1080/00016489.2019.1691744. Epub 2020 Feb 18.

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

Marcos Goycoolea [1,2], Gloria Ribalta [1], Francisco Tocornal [1], Raquel Levy [1], Pilar Alarcón [1], Martin Bryman [3], Byanka Cagnacci [4], Catherine Catenacci [2], Valeria Oyanguren [4], Ignacia Vilches [1], Verónica Briones [1,2], Raimundo García [2]
Affiliations expand

Abstract

Background: Bone-conduction hearing implants are standard of care devices.**Aims/Objectives:** Evaluation of a new active magnetic bone-conduction hearing implant: Cochlear Osia™ system.**Material and methods:** This device uses a transcutaneous connection between an external sound-processor and an osseointegrated implant that generates vibrations using a piezoelectricity-based internal bone-conduction system. Nine patients with conductive-hearing loss were implanted. Surgical efficacy, hearing performance and quality-of-life were evaluated. Hearing performance in quiet and in noise was compared with unaided hearing and hearing with the Baha 5 Power® Sound Processor on a softband.**Results:** Surgery and healing were uneventful. Statistically significant improvements in audibility, speech-understanding, speech-recognition and quality-of-sound in noise and quiet were found for the Osia™ compared to preoperative unaided hearing and aided hearing with the Baha 5 Power® Sound Processor on a softband. The active vibration system provided improvement at low and high frequencies. At 6 months postoperatively, all patients continue to use the device.**Conclusions and significance:** The Osia™ is safe and effective, improving speech-recognition in quiet and in noise, at low and high frequencies, thus delivering better quality-of-hearing than passive devices.

7. PMID: 34855683
Otol Neurotol
. 2022 Feb 1;43(2):212-218.
doi: 10.1097/MAO.0000000000003426.

Early Outcomes of a New Active Transcutaneous Bone Conduction Implant in Pediatric Patients

Peng You[1,2], Alexander Choi[1], Jennifer Drob[3], Sabrina Marciante Hunsaker[3], Yi-Chun Carol Liu[1,2], Rodrigo Silva[1,2]
Affiliations expand

Abstract

Objective: To describe the early surgical and audiometric outcomes in pediatric patients implanted with a new active transcutaneous bone conduction implant system.

Study design: Retrospective case review.

Setting: Tertiary pediatric hospital.

Patients: Pediatric patients (18 or younger) with conductive or mixed hearing loss that completed postoperative aided testing following implantation with the Cochlear Osia system from December 2019 to December 2020.

Intervention: Rehabilitative.

Main outcome measure: Preoperative air conduction (AC), preoperative bone conduction (BC), and postoperative aided thresholds were compared. Pure-tone averages (PTA), air-bone gap (ABG), and functional gain were calculated. Surgical complications and patient satisfaction were summarized from the chart review.

Results: Sixteen patients (20 implants) met the inclusion criteria. The average age at the time of implantation was 12.9 ± 2.4 years. The preoperative AC and BC thresholds were 64.4 dB (±11.9 dB) and 7.9 dB (±4.90 dB), respectively, with an average ABG of 56.5 dB (±12.8 dB). The average postoperative aided threshold was 21.2 dB (± 4.25 dB) with a mean functional gain of 43.1 dB (±10.2 dB). One patient developed seroma postoperatively, which was treated conservatively. No other complications were reported over a mean follow-up time of 7.1 ± 4 months. For 13 patients with previous passive bone conduction implants or devices, the Osia system was universally favored.

Conclusions: The new active transcutaneous bone conduction system showed favorable early clinical and audiometric outcomes. Repeated processor connectivity issues represent a potential area for future device development. This is the largest pediatric case series to date.Level of Evidence: Level 4-Retrospective Review.

8. PMID: 34155570
Eur Arch Otorhinolaryngol
. 2021 Oct;278(10):4119-4122.
doi: 10.1007/s00405-021-06946-8. Epub 2021 Jun 21.

Active transcutaneous bone-anchored hearing implant: how I do it

S Arndt [1], A K Rauch [1], I Speck [2]
Affiliations expand

Abstract

Background: The Cochlear™ Osia® System leaves a retroauricular bump that can cause discomfort and poor aesthetic outcome.

Method: To reduce the retroauricular bump, we introduced an implant well in the bone behind the ear for the transducer. We used cutting and diamond drills to create the implant well with an average depth of 4-5 mm. The surgical time including the implant well (40 min) was within the range of reported average surgical time (52 min).

Conclusion: Introduction of an implant well resulted in a better aesthetic outcome and improved patients' comfort. The reduced distance between BI300 and ear canal might improve audiological outcome.

9. PMID: 33676070
Am J Otolaryngol
. Jul-Aug 2021;42(4):102968.
doi: 10.1016/j.amjoto.2021.102968. Epub 2021 Feb 26.

Adverse events associated with Bonebridge and Osia bone conduction implant devices

Hannah R Crowder [1], Daniel E Bestourous [2], Brian K Reilly [3]
Affiliations expand

Abstract

Purpose: Active transcutaneous Bone Conduction Implants (BCIs) are relatively new to the market and may offer improved outcomes while reducing skin-related complications associated with previous models. The purpose of this study is to examine medical device reports (MDRs) submitted to the Food and Drug Administration's (FDA) Manufacturer and User Device Facility Experience (MAUDE) database to identify adverse events with the active, transcutaneous BCIs, Bonebridge and Osia.

Methods: A search of the FDA MAUDE database was conducted using product code "PFO" (for Active Implantable Bone Conduction Hearing System), brand names "Bonebridge" and "Osia." Data was collected on device malfunction, patient injury, inciting events, and subsequent interventions between July 1, 2018 and November 1, 2020.

Results: The search query yielded 83 reports that met inclusion criteria, 56 regarding Bonebridge and 27 regarding Osia. A total of 91 adverse events were reported, including 45 device malfunctions and 46 patient injuries. Of all adverse events reported for Bonebridge, 15 (26.3%, 15/57) documented patient injuries, while the

majority (73.7%, 42/57) documented device malfunctions. Of all adverse events reported for Osia, 3 (8.8%, 3/34) were reported concerning malfunctions, while 31 (91.2%, 31/34) were reported for patient injuries. The most commonly reported adverse events included lack of conduction or hearing (n = 26, 28.6%), infection (n = 14, 15.4%), and intermittent or reduced conduction or hearing (n = 12, 13.2%). From the MAUDE database reported adverse events and the total number of Osia implants given to us from Cochlear over this 28 month period, we estimate patient injuries to occur in roughly 2.1% of patients.

Conclusion: There are limitations to the database which make systemic analysis challenging. This study suggests that patients with transcutaneous, active BCIs may be experiencing fewer soft tissue injuries, but similar device malfunctions as those with previous models.

10. PMID: 32925852

Otol Neurotol 2020 Oct;41(9):1249-1257, doi: 10.1097/MAO.0000000000002794.

Multicenter Clinical Investigation of a New Active Osseointegrated Steady-State Implant System

Emmanuel A M Mylanus [1], Håkan Hua [2], Stina Wigren [2], Susan Arndt [3], Piotr Henryk Skarzynski [4], Steven A Telian [5], Robert J S Briggs [6]
Affiliations expand

Abstract

Objective: A new active transcutaneous bone conduction hearing implant system that uses piezoelectric technology has been developed: an active osseointegrated steady-state implant system (OSI). This was the first clinical investigation undertaken to demonstrate clinical performance, safety, and benefit of the new implant system.
Study design and setting: A multicenter prospective within-subject clinical investigation was conducted.
Patients: Fifty-one adult subjects with mixed and conductive hearing loss (MHL/CHL, n = 37) and single-sided sensorineural deafness (SSD, n = 14) were included.
Main outcome measure: Audiological evaluations included audiometric thresholds, speech recognition in noise, and quiet. Hearing and health-related patient-reported outcomes (PROs; health utilities index [HUI], abbreviated profile of hearing aid benefit [APHAB], and speech, spatial of qualities of hearing scale [SSQ]), daily use, surgical and safety parameters were collected.
Results: Intra- and postoperative complications were few. One implant was removed before activation due to post-surgical infection. Compared with the preoperative softband tests, a significant improvement in speech recognition-in-noise was observed in the MHL/CHL group (-7.3 dB, $p \leq 0.0001$) and the SSD group (-8.1 dB, $p = 0.0008$). In quiet, word recognition improved in the MHL/CHL group, most markedly at lower intensity input of 50 dB SPL (26.7%, $p \leq 0.0001$). The results of all PROs showed a significant improvement with the new device compared with preoperative softband in the MHL/CHL group. In the SSD group significant improvements were observed in the APHAB and SSQ questionnaires.
Discussion: The results confirmed the clinical safety, performance, and benefit of this new treatment modality for subjects with CHL, MHL, and SSD.