

The Cochlear™ Osia® System

Clinical highlights from published evidence on the Osia System

The Cochlear Osia System (Fig 1.) is an active transcutaneous bone conduction device (BCD) designed to deliver powerful, high-quality sound through a small, under-the-skin implant and off-the-ear sound processor (SP).¹ Using piezoelectric technology, the system transmits sound vibrations directly to the inner ear, bypassing deficiencies in the outer or middle ear to offer clear and natural hearing.² The Osia System is designed to improve hearing outcomes for adults and children as young as five years old with conductive hearing loss (CHL), mixed hearing loss (MHL), and single-sided deafness (SSD).³

The Osia System offers a surgical approach with low complication rates⁴ and a comfortable, cosmetically appealing design.⁵ Patients and families consistently report excellent sound quality,⁵ improved speech understanding,^{5–9} and a notable enhancement in quality of life.^{9–11} Furthermore, as the only active system with high-resolution MRI compatibility^{12,13} and robust long-term outcomes,^{9,10} the Osia System represents an advanced and reliable solution in bone conduction hearing technology.

This clinical paper summarises recent evidence across paediatric research; clinical safety, functional hearing, and patient-reported outcomes; MRI compatibility, and economic benefit of the Osia System. These studies demonstrate how Osia System continues to extend the boundaries of bone conduction hearing care across diverse patient groups.



Fig. 1. The Osia System

Paediatric research

Outcomes Following Cochlear Osia 2 Implantation in Patients Ages 5-11 Years: A Multi-Center Trial (n=50)⁶ (Cochlear sponsored research)

Investigators and country: Shawn M Stevens, Abby Meyer, Alejandro Rivas, Sarah Mowry, Daniela Carvalho, Kay W Chang, John Germiller, Yi-Chun Carol Liu, and Viral Tejani; United States of America.

Inclusion criteria: Children with CHL, MHL (PTA4 ≤55 dB HL), or SSD (profound loss in implanted ear, normal PTA4 ≤20 dB HL contralaterally) were eligible, including those with prior chronic or congenital ear anomalies.

Methods: This prospective study collected pre-operative data (unaided and Cochlear Baha® System aided with an equivalent 55 dB fitting range (Baha 5 Power sound processor on a Softband)), and postoperative data (aided with Osia 2 SP) at activation and again at 3 and 6 months after implantation (Table 1). Parent-reported outcomes and daily device use were gathered at 3 and 6 months post operatively. The study evaluated audiometric measures, parental Speech, Spatial and Qualities of Hearing Scale (SSQ), and safety outcomes through 6 months, with surgery- or device-related adverse events (AEs) monitored for up to 12 months.

Outcomes: All patients were implanted with the Osia System (OSI200 Implant and the Osia 2 SP). Forty-nine completed the 12-month endpoint of the study (Table 2). Most had congenital ear disease, with 60% presenting with aural atresia.

Table 1.

Study variables	
Variable	Details
Demographics	Age/sex/race/ethnicity
Clinical variables	Surgical indications, operative data, implant-related AEs, and hearing outcomes.
Aided testing with Baha 5 Power SP on a Softband (pre-operatively) vs Osia 2 SP (post-operatively)	PTA4 for AC, BC, and soundfield thresholds (0.5–4 kHz). CNC word scores measured unaided and aided at 60 dBA. Speech-in-noise testing (BKB-SIN at 65 dBA), reported as SNR-50.
Parental-reported outcomes post-operatively at 3 and 6 months	SSQ questionnaire. Average daily use (hours/day) and device retention rated on a 0–10 scale (no retention - very good retention).

Table 2.

Outcomes following Osia implantation study patient demographics	
Age (mean/±SD/median)	7.4±2.0 years
Male/female	23/27
Type of hearing loss	CHL/MHL: 37
	SSD: 13

An anterior post-auricular S-shaped incision with inferior extension was most commonly used, with a mean surgical time of 58.4 minutes. Mean soft tissue thickness showed no significant difference between ages 5–6 and 7–11 years. Thirty-two AEs occurred in 17 children, mostly procedure- or device-related; three were serious but all resolved without long-term effects.

Device use showed a mean daily wear time of 9.8 hours at 6 months post-implantation. Median retention score was 8/10 overall and 7/10 during sports. Parent-reported SSQ-Total scores improved from a median of 7.1 preoperatively to 8.4 (p<0.0001) at all postoperative time points.

Mean PTA4, CNC word scores and BKB-SIN improved significantly from preoperative unaided levels to 6 months post-Osia implantation (p<0.0001) (Table 3) and was also significantly better than preoperative aided levels with the Baha 5 Power sound processor on a Softband (p<0.0001).

Table 3.

Outcomes following Osia implantation study audiological outcomes				
	Pre-op unaided	Pre-op Baha aided	3 months Osia aided	6 months Osia aided
Mean PTA4	55.2	27.6	-	23.1
Median CNC word score (%)	14	72	82	86
Mean BKB-SIN	13.8	5.7	3.9	3.5

“Osia is safe and effective for children aged 5–11 years, with consistent outcomes and no differences between the youngest and older children.”

Audiological outcomes of the Cochlear Osia 2 bone conduction system implanted under expanded indications in a pediatric population (n=50)⁷ (Cochlear sponsored research)

Investigators and country: Viral D Tejani, Shawn Stevens, Abby Meyer, Megan Bartoshuk, Stephanie Berry, Page Aubuchon, Marine Cismas, Shannon Doolittle, Jennifer Drob, Nancy Flores, Lindsay M. Hill, Erin M. Levy, Hannah Litton, Rebecca Maher, Amanda Marchegiani, Laurie Mauro, Catherine Moyer, Jessica L. S. Novak, Julie Purdy, Melissa Tribble, and Gail Murray; United States of America.

Inclusion criteria: Children aged 5–11 with CHL or MHL and a BC PTA ≤55 dB HL (500–3000 Hz), or SSD with profound sensorineural HL in the ear to be implanted and normal hearing (AC PTA ≤20 dB HL) (500–3000 Hz) in the other ear.

Methods: A prospective multicenter trial at seven sites followed children before surgery, at Osia activation, and at 3-, 6-, and 12-months post-surgery. Preoperative testing assessed unaided AC and BC thresholds, CNC words in quiet at 60 dBA, and BKB-SIN at 65 dBA in noise. A Baha 5 Power sound processor with an equivalent 55 dB fitting range on a Softband was used preoperatively for the aided testing and an Osia 2 sound processor postoperatively. Parents/guardians completed the SSQ before surgery and at 3- and 6-months post-surgery.

Outcomes: Demographics of children implanted with the Osia System are detailed in Table 4. Overall, the implantation procedure was well tolerated, and complications were minor.

Table 4. Audiological outcomes study demographics

	SSD (n=13)	CHL/MHL (n=37) (CHL: 35/MHL: 2)
Age (mean)	7.6 years	7.3 years
Aetiology of HL	Cochlear nerve aplasia: 2 Cochlear nerve hypoplasia: 2 Other: 9	Atresia: 25 Microtia: 3 Other: 9

CNC word recognition scores in SSD patients rose from unaided to pre-operatively aided to 3- and 6-months post-implant (p<0.001). In the CHL/MHL group, CNC scores improved similarly including a significant gain between 3 and 6 months (p=0.018) and a large improvement from pre-operatively aided to 6 months Osia aided (p<0.001) (Fig. 2).

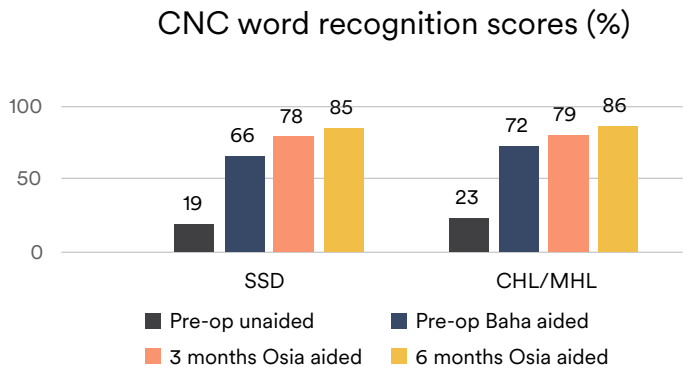
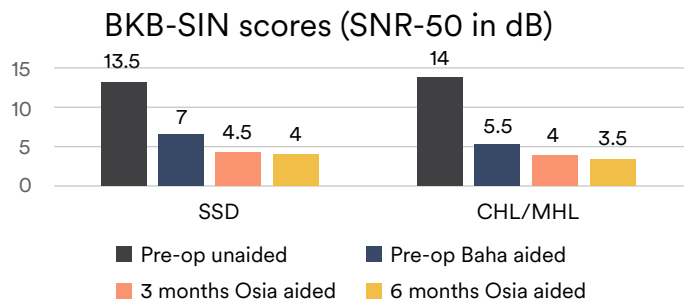


Fig. 2.

In the SSD group, CNC phoneme scores improved from unaided to Baha aided, 3, and 6 months Osia aided (all p<0.001). CNC phoneme scores in the SSD group improved significantly from unaided to Baha-aided and at 3 and 6 months with Osia (all p<0.001). Scores also improved from Baha-aided to 6 months Osia aided (p=0.03). In the CHL/MHL group, CNC phoneme scores improved from unaided to Baha aided, and 3 months, and 6 months Osia aided (all p<0.001) (Fig 3.).

BKB-SIN (SNR-50) scores improved significantly from unaided to Baha-aided and at 3 and 6 months with Osia in both the SSD (p<0.01) and CHL/MHL groups (p<0.001) (Fig. 3).



*Lower BKB-SIN scores indicate better performance, reflecting the ability to understand speech at lower signal-to-noise ratios.

Fig. 3.

For both SSD and CHL/MHL patients, soundfield thresholds improved significantly across all frequencies compared with unaided hearing. In SSD, 500 Hz thresholds improved from 57.31 to 25.39 dB HL with Osia at 6 months, with similar gains at 1000–2000 Hz and 4000 Hz from 35.00 Baha-aided to 24.23 dB HL with Osia. In CHL/MHL, 500 Hz thresholds improved from 54.85 unaided to 25.20 dB HL at 6 months Osia aided, and 2000 Hz threshold from 32.97 Baha-aided to 23.92 dB HL with Osia. Overall, Osia provided sustained improvements, with extra high-frequency gains in CHL/MHL over Baha.

In the SSD group, SSQ scores for all domains improved significantly from uniaded to 6 months, with spatial gains at 3 months, and speech scores remained stable over time. In the CHL/MHL group, all SSQ domains improved significantly by 3 months and were maintained at 6 months. Parent-reported datalogging showed consistent device use, increasing from ~8 to 10 hours/day in SSD children and averaging ~10 hours/day at both time points in the CHL/MHL group.

“Osia provides children aged 5–11 with superior hearing, speech, and daily-life benefits, outperforming unaided hearing and non-surgical BCDs.”

Impact of Early Intervention on Children with Congenital Conductive Hearing Loss: Role of Active Transcutaneous Bone Conduction Implants (n=57)⁵ (Independent research)

Investigators and country: Faisal Zawawi , Afnan F Bukhari , Sara A Khairy , and Mohamed Garrada; Saudi Arabia.

Inclusion criteria: Children under 12 years with unilateral or bilateral microtia and canal atresia, excluding those with comorbidities or craniofacial syndromes.

Methods: This prospective cohort study followed children for at least 2 years, comparing unaided children, Softband BCD users, and Osia System recipients. Analyses examined early (<3 years) versus later implantation and assessed school performance and quality of life (QoL) before and after Osia implantation. Study variables can be seen in Table 5.

Table 5.

Study variables	
Variable	Details
Socio demographics and device specific data	Patient demographics and BCD information e.g. OSI200 or OSI300.
Surgical data	Surgery time and outcomes.
Hearing test results	Unaided and aided PTA, speech discrimination scores
School performance records across the first 6 years of schooling (grades 1–6)	1) Academic performance (grades A–F), 2) grade repetition, 3) involvement in extracurricular activities.
Arabic Hearing Environments and Reflection on Quality-of-Life Measurement for Children Survey (HEAR-QL-AR) 26 (completed at enrollment AND the last month of the study*	26-item questionnaire assessing QoL in children with hearing loss across hearing, social, academic, and emotional domains.
Preference between the non-surgical option and the Osia, as well as their reasoning.	Post-operative survey at 6-months for Osia

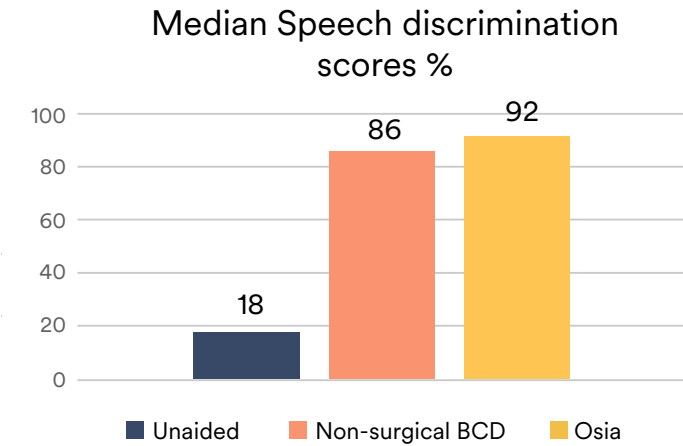
*Participants who were younger than 6 were excluded from completing the questionnaire, as the questionnaire is not validated for children under 6 years of age.

Outcomes: Fifty-seven children with canal atresia (eight bilateral) were included (Table 6), with school performance and HEAR-QL-AR data for 45 of them. Children aged 3–9 years received the Osia (OSI200 or OSI300) implant (median surgery time 38 minutes) with no complications. Four children later had auricular reconstruction, also without complications.

Table 6.

Early intervention study patient demographics	Age (median)
Unaided (n=14)	9.25 years
Nonsurgical BCD users (n=17)	7.5 years
Osia implant recipients (n=27) (implanted before 9 years of age)	7 years

Both non-surgical BCDs and Osia (OSI200 or OSI300) significantly improved hearing, lowering median PTAs from ~65 dB unaided to 32.5 dB and 27.5 dB, respectively, with Osia showing a significant advantage in speech discrimination (Fig. 4).



*Statistically significant differences between unaided, non-surgical BCD, and Osia conditions (p = 0.001)

Fig. 4.

Unaided children had lower QoL scores than BCD users, and earlier BCD use was linked to better outcomes. After ≥6 months, Osia users had the highest median QoL (76), exceeding non-surgical BCDs (64) and unaided children (p < 0.001).

Repeat-year rates were highest in the unaided group (4/14), lower with non-surgical BCDs (1/13) and Osia (0/18; p=0.027). Academically, the BCD groups outperformed the unaided group, earning median grades of “A” vs. “B” (p=0.004). Osia recipients participated in more extracurricular activities (median 1.5 vs. 1; p=0.041). Earlier access to BCDs strongly correlated with greater extracurricular involvement.

Families of Osia recipients reported the greatest hearing improvements and described improved speech, better sound detection and understanding, enhanced overall mood, and stronger school performance. All 27 Osia recipients preferred Osia over non-surgical BCDs. Users reported clearer hearing, improved speech and music perception, better sound quality, and appreciated the discreet design. No patients reported cutaneous issues, chronic pain, or headaches post-implantation, and children used their sound processors for a median of 10.1 hours per day.

“Early access to the Osia System improves hearing outcomes, academic performance, and QoL in children with CHL.”

Surgical and audiometric outcomes of active osseointegrated bone-conduction hearing device (Cochlear™ Osia® 2 system) placement from a tertiary paediatric centre (n=49)¹⁴
(Independent research)

Investigators and country: Mona Mozaffari, Nicola Guderley, Anita Wong, Sevasti Konstantinidou, Nikul Amin and Robert Nash; United Kingdom

Inclusion criteria: Children who underwent Osia implantation.

Methods: A retrospective review of Osia implantations which included data on demographics, aetiology, audiometry, and operative details.

Outcomes: During the study, 66 Osia 2 devices were implanted in 49 patients (Table 7), including 25 with bilateral hearing loss (15 received simultaneous bilateral implants). Before implantation, 48 patients used hearing amplification (Baha 5 on a softband, Ponto 3 on a softband, behind-the-ear hearing aid, Baha Attract and Adhear (adhesive bone conduction aid)).

Table 7.

Surgical and audiometric outcomes study patient demographics	
Age at implantation (median)	9.6 years (range 5.2-18.8)
Male/Female	26/23
Type of hearing loss	CHL: 42
	Sensorineural HL: 5
Aetiology of HL	MHL: 2
	Congenital aural atresia: 31
	Middle ear dysplasia: 7 (4 with microtia)
	Ear canal stenosis: 5 (2 with microtia)
	SSD: 5
	COM with failed ossiculoplasty: 1

Incisions were curvilinear and compatible with future auricular reconstruction, successfully done in three patients. Postoperative complications occurred in 32.6% of patients (mostly minor), with two major events. All patients received intraoperative antibiotics.

Postoperative PTA (excluding SSD) improved significantly over preoperative unaided thresholds ($p<0.001$), with further improvement over pre-operative aided thresholds reaching significance only at 4 kHz ($p<0.001$). Speech-in-noise performance also improved, with scores significantly better than unaided at 0, 5, and 15 dB SNR ($p<0.001$) and better than pre-operative aided at 0 dB SNR ($p=0.042$).

“Osia is a safe, increasingly preferred pediatric hearing solution delivering excellent audiometric outcomes with minimal surgical complications.”

Single-Stage Ear Reconstruction Simultaneous With Piezoelectric Osia® Bone Conduction Implantation (n=8)¹⁵
(Independent research)

Investigators and country: Courtney Leonard, Michelle Oberoi, Caitlyn Belza, Daniela Carvalho, Amanda Gosman, and Samuel Lance; United States of America.

Inclusion criteria: Children who passed conductive hearing tests and were qualified to receive Osia implantation with alloplastic ear reconstruction.

Methods: Suitability for combined reconstruction and Osia placement was assessed. Preoperative planning included temporoparietal fascial (TPF) or occipital fascial (OF) flaps when the TPF or its blood supply was compromised.

Standard TPF Flap Technique: Position the Osia near the posterior periauricular incision to ensure coverage and minimize incision extension; extend intraoperatively if needed to reach adequate mastoid bone for secure anchoring (Fig. 5).

OF Flap Technique: The Osia is positioned more anteriorly or posteriorly based on the incision. Unlike the TPF flap, incision extension is mandatory to access and elevate the occipital fascial flap. Avoid placing the implant beneath the incision, as the scalp does not advance forward with this flap (Fig. 6).

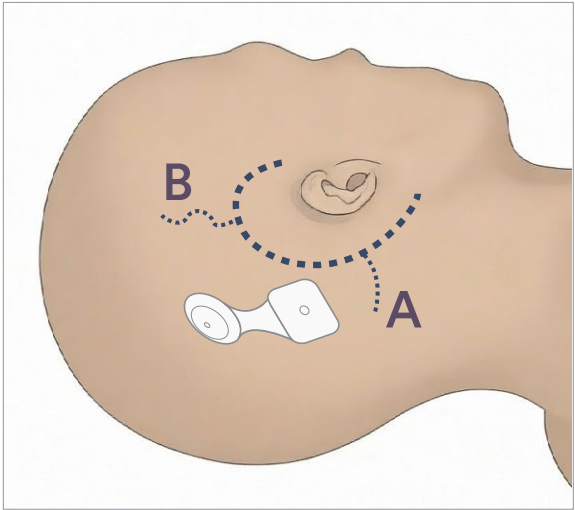


Fig. 5. TPF flap technique

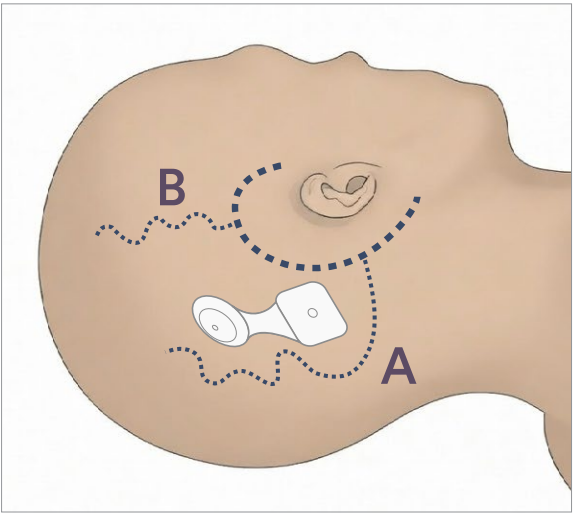


Fig. 6. OF flap technique

Outcomes: A total of 8 patients were included (Table 8). The TPF flap technique was used in seven cases, and an OF flap technique in one case. Periauricular incisions were used for TPF cases, with extension into a coronal incision for the OF case. The pericranium was preserved as an inferiorly based flap in all cases to cover the Osia implant while maintaining venous outflow. Mean total surgery time was 9.3 hours, with Osia placement averaging 53 minutes. During the follow-up period of 26 months, one minor revision from trauma occurred; there were no flap failures, delayed healing, or implant exposures. All Osia implants provided functional hearing.

Table 8.

Single-stage ear reconstruction study patient demographics	
Age (median)	8 years
Grade 3 microtia	7 patients
Revision cases	1 patient

“Osia enables safe, effective, single-stage ear reconstruction in children, delivering reliable hearing outcomes with minimal complications”

Clinical safety, functional hearing, and patient-reported outcomes

Active Osseointegrated Steady-State Implant System: Surgical and Clinical Performance (n= 580)⁸ (Cochlear sponsored research)

Investigators and country: Leonardo Ordoñez-Ordoñez, José Agustín Caraballo, Jorge Guillermo Cabrera Ortiz, Francisco Gonzalez Eslait, Rafael Jaramillo Saffon, José Gabriel Lora, Santiago Hernandez, Jose Guzman, Luz Adriana Rincon, Byanka Cagnacci Buzo; Colombia

Inclusion criteria: Patients with CHL or MHL with BC thresholds ≤55 dB PTA (0.5–3 kHz) in the affected ear, or SSD, who were candidates for Osia implantation.

Methods: This prospective study compared preoperative AC and BC thresholds with postoperative Osia outcomes. Functional gain and effective gain were calculated. The Client Oriented Scale of Improvement (COSI) measured benefits from Osia in six areas: Speech in Noise, Speech in Quiet, Telephone Use, Work, Social, and Emotional.

Outcomes: Between 2020 and 2023, 580 patients received an Osia 2 implant. See Table 9 for patient demographics.

Table 10.

Functional and effective gain by frequency, PTA, and high-frequency PTA (HF PTA)											
		0.25	0.5	1	2	3	4	6	8	PTA*	HF PTA**
Functional gain	CHL	41.4	39.5	40.0	36.1	39.1	32.7	36.2	35.8	38.6	34.9
	MHL	40.1	43.1	47.9	42.3	38.8	39.9	48.5	48.4	44.4	45.6
	SSD	76.5	58.6	67.8	71.7	66.4	64.5	67.4	54.5	66.1	62.1
Effective gain	CHL	14.5	12.3	8.5	7.1	12.3	13.9	-	-	9.3	-
	MHL	14.5	4.9	-3.9	-8.8	-2.1	1.1	-	-	-2.6	-

*PTA=average of 0.5, 1, and 2 kHz; **HF PTA=average of 4, 6, and 8 kHz.
**Functional gain = real-world hearing improvement.; Effective gain = improvement in thresholds.

Table 9.

Active Osseointegrated Steady-State study demographics	
Age (years)	Children (<18): 223 Adults (>18): 357
Sex	Male: 304 Female: 276
Type of hearing loss	CHL: 341 MHL: 167 SSD: 72

Mean surgery time was 54 minutes, with most incisions anterior to the implant and no significant intraoperative complications. Sixty-six surgeries converted from other BC devices, mainly due to Holgers-3 skin issues; Holgers-4 cases were implanted after infection resolution in a separate surgical field.

Thirteen medical AEs (2.2%) occurred, mostly mild, with six more severe cases including three explants and three extrusions managed surgically. Eleven device related AEs (1.9%), internal noise, connection issues, one broken screw, were resolved via component replacement or SP upgrade.

Audiometric thresholds evaluated after 3–6 months of Osia use, showed significant improvement in postoperative thresholds compared to preoperative unaided AC thresholds (p<0.05) across all hearing loss types. Functional and Effective gains can be seen in Table 10.

The COSI showed mean improvement across all areas ranging from “better” to “much better” compared with preoperative conditions. Approximately half of the patients completing COSI prioritized improvements in speech perception in noise.

“The Osia System delivers strong functional and effective hearing gains with improved speech understanding.”

Active piezoelectric bone conduction implant Osia® 2 - evaluation of surgery and one-year audiological and quality of life benefits (n=20)⁹ (Independent research)

Investigators and country: Wojciech Gawęcki, Renata Gibasiewicz, Magdalena Błaszczyk, Małgorzata Wierzbicka, Ewelina Bartkowiak; Poland.

Inclusion criteria: Adult patients with unilateral or bilateral MHL or CHL who met the criteria for BCD implantation were implanted with the Osia 2 System (OSI200).

Methods: This prospective study followed Osia-implanted patients for at least one year, assessing surgical outcomes, audiological performance (unaided, Baha 6 Max on Softband, and Osia-aided), in situ bone-conduction thresholds, and quality of life using the Abbreviated Profile of Hearing Aid Benefit (APHAB) and SSQ.

Outcomes: The study included 20 patients, their sociodemographic details can be seen in Table 11.

Table 11.

Active piezoelectric bone conduction implant study demographics	
Age (mean)	50 years (range 24-73)
Sex	Male: 7 Female: 13
Type of hearing loss	Bilateral: 16 (MHL: 10, MHL and sensorineural: 4, CHL and mixed:1, CHL and sensorineural: 1) Unilateral n=4 (CHL: 3, MHL: 1)
Aetiology of hearing loss	Chronic otitis media: 14 Otosclerosis: 3 Atresia: 3
PTA4 (0.5, 1, 2, 4 kHz) (mean)	AC: 71 dB HL (range 46-95) BC: 31 dB HL (range 13-48)

Surgeries were completed without major complications, with a mean operative time of 64.5 minutes. The BI300 implant was placed as planned in most cases, with seven repositioned for anatomical reasons. Minor postoperative issues, two small hematomas and transient pain or numbness, resolved within weeks, and no soft tissue complications occurred over one year.

One year after implantation, Osia-aided thresholds improved significantly over unaided hearing, with a mean functional gain of 47.4 dB HL, 8.6 dB higher than Baha 6 Max on Softband (38.8 dB HL), showing a significant additional benefit.

Speech understanding in quiet and noise improved substantially with Osia versus unaided hearing, with one-year gains of 13–60% in quiet and 37–62% in noise (all p<0.05) (Fig. 7). The Osia 2 System outperformed the Baha 6 Max on Softband, with SNR improving from +3.43 dB unaided to –5.35 dB (gain 8.8 dB, p <0.001). Direct BC thresholds rose 7.7 dB across 0.5–4 kHz (p<0.001), with 13.8 dB gain at 6 kHz (p<0.001).

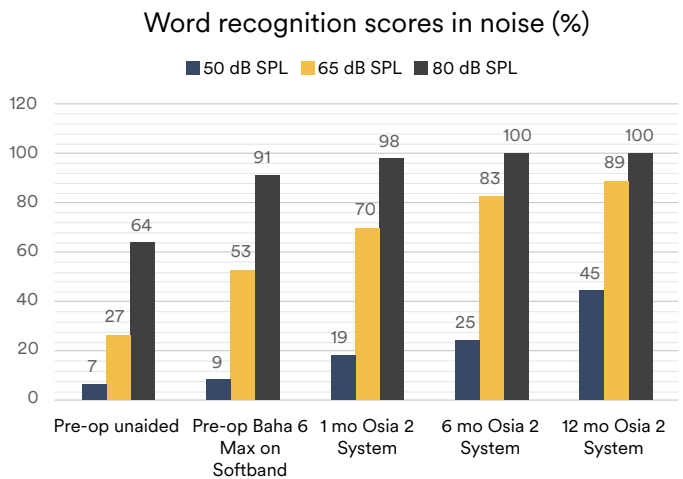


Fig. 7.

APHAB scores improved significantly in overall hearing and subscales (except aversiveness), with mean gains of 31% overall, 30% ease of communication, 37% background noise, and 26% reverberation (all p<0.001). SSQ scores also rose across all domains (speech, spatial, quality; all p<0.001).

“The Osia System delivers safe, powerful speech-in-noise performance with communication gains in MHL and CHL.”

A Systematic Review of Surgical Characteristics and Adverse Events of an Active, Transcutaneous Bone Conduction Device (n=18 studies/ n=336)¹⁷ (Independent research)

Investigators and country: Alma Jukic, Christopher C Munhall, and Shawn M Stevens; the United States of America

Inclusion criteria: Human clinical studies on the Osia implant reporting surgical outcomes, audiometry, or adverse events; non-English, non-human, cadaveric studies, reviews, and meta-analyses were excluded.

Methods: A systematic search (January 2019–April 2023) on bone conduction and the Osia System (OSI200) was conducted. Two reviewers screened studies, extracted data (demographics, clinical history, surgery, adverse events, audiometry), and assessed evidence levels. Results were summarised; meta-analysis was not done due to heterogeneity.

Outcomes: Eighteen studies of 336 patients (mean age 38.7 years) were analysed. Most had MHL/ CHL (79.5%) and 19.5% SSD, commonly due to aural atresia or COM. Over half used prior hearing aids, and many had previous ear surgery. Twelve studies detailed Osia procedures, including operative time, incisions, soft tissue thickness, and intraoperative techniques (Table 12). Sixteen studies (303 patients) reported 61 postoperative complications (Table 13).

Table 12.

Summary of key surgical findings					
Operative Time (12 studies)	Incision Type (4 studies)	Incision Location* (7 studies)	Soft Tissue Thickness (4 studies)	Tissue Reduction (10 studies)	Bone Polishing (9 studies)
71.6 min (mean)	C: 54.8% S: 36.9% Other: 6.0%	Post-auricular anterior: 73.6%	6.0±1.5mm	6.4%	43.7%

*Location reported relative to bone implant site.

Table 13.

Summary of postoperative complications		
Complication	% of Patients	Comments
Infection	5.0%	Resolved with oral antibiotics
Excessive pain	3.3%	–
Magnet-related issues	2.0%	Retention or tissue complications
Hematoma	1.7%	–
Surgical re-exploration	0.3%	Rare
Explantation	1.0%	~1/3 later reimplanted

Sixteen studies reported audiometric results, though differences in reporting limited pooled analysis. Weighted mean improvements with Osia included a 35.4 dB gain in PTA, 16.1 dB gain at high frequencies (>6 kHz), SRT improvements of 19.1 dB (unaided) and 9.4 dB (preoperative aided), and a 59.7% increase in SRS.

“Systematic evidence confirms Osia as safe, efficient, and highly effective with minimal complications”

A key study evaluating the hearing outcomes of the new Osia 3 sound processor compared with the current Osia 2 sound processor in adult Osia Implant recipients (n=29)¹⁶ (Cochlear sponsored research)

Investigators and country: Robert Cowan, Karyn Galvin, Christiane D’hondt, Bailey Harmon, Esti Nel and Håkan Hua; Australia and the United States of America.

Inclusion criteria: Adults with an Osia implant (OSI100/200/300) CHL, MHL with bone-conduction thresholds up to 65 dB HL, or SSD with profound SNHL in the implanted ear and normal hearing in the other ear (PTA≤20 dB HL), and at least one month of Osia 2/2(l) SP use.

Methods: In this prospective, repeated-measures study, participants were randomised to wear either the Osia 2/2(l) or investigational Osia 3/3(l) SP for 2–4 weeks. Baseline testing included AC/ BC audiometry, and speech perception in quiet at 50 and 65 dB SPL and noise (SON0; SON180). During each period, participants underwent fitting, performed aided hearing thresholds measurements in sound field and speech recognition testing and, and completed SSQ-12 and device questionnaires regarding sound quality, satisfaction and preference. Primary outcome was speech recognition in noise with Osia 3 sound processors compared to unaided condition. Secondary outcomes included device-to-device comparisons across measurements.

Outcomes: Twenty-nine patients were included (demographic and clinical data are shown in Table 14). Most participants used the Osia 2 or Osia 3 sound processor (65%), while 35% used the Osia 2(l) or Osia 3(l) sound processor during the study.

Table 14.

Evaluating the hearing outcomes of the new Osia 3 SP patient demographics	
Age (mean)	61.5 years
Male/Female	23/6
Country	Australia: 18 patients United States of America: 11 patients
Type of hearing loss	MHL: 24 CHL: 3 Sensorineural HL: 2
Aetiology of HL	Unknown: 7 Other: 9 Atresia: 3 Cholesteatoma: 4 Chronic otitis media: 3 Radical mastoidectomy: 2 Tumor: 1
Osia implant	OSI100: 2 patients OSI200: 17 patients OSI300: 10 patients

The Osia 3 Sound Processor improved hearing, with an average SRT in noise (SON0) improvement of 7.28 dB SNR, from 6.48 dB unaided to –0.80 dB; word recognition at 65 dB SPL increased by 59.1%, from 29.0% unaided to 88.1%; and PTA4 improved by 31.98 dB, from 60.73 dB HL unaided to 28.75 dB HL aided with Osia 3 (all p<0.025). SSQ-12 scores showed Osia 3 matched or exceeded Osia 2, with smaller gains in speech (+0.87), spatial (+0.38), and quality (+0.55) subscales. Aided WRS at 50 and 65 dB SPL were similar between devices, with Osia 3 showing significant gains versus unaided. SRT in noise and PTA4 demonstrated equivalent performance to Osia 2, with Osia 3 providing better hearing thresholds from 2 kHz and above.

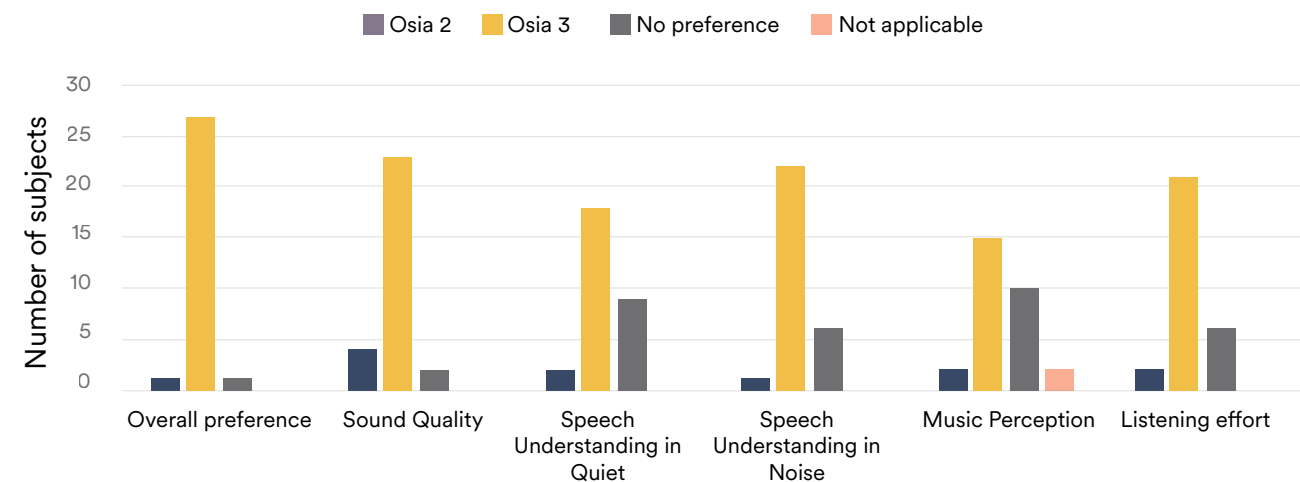


Fig. 8. Subjective Ratings of Sound Perception and Satisfaction with Osia 3 versus Osia 2 SPs

Daily use was similar between SPs (12.36 h for Osia 2 vs. 12.62 h for Osia 3). All participants (100%) would recommend the Osia 3 SP, satisfaction with the Osia 3 Charger was high (82.8% very satisfied), and overall device preference strongly favoured Osia 3 SP (93.1%), with higher preference across sound quality, speech in quiet and noise, music perception, and listening effort (Fig. 8).

“Osia 3 SP delivers clearer speech and improved hearing performance, supported by high user confidence and preference”

Clinical performance, safety, and outcomes of an active osseointegrated bone conduction hearing implant system at 24-month follow-up (n=20)¹⁰ *(Cochlear sponsored research)*

Investigators and country: Robert Cowan, Aaran T Lewis, Carina Hallberg, Michael C F Tong, Catherine S Birman, Iris H Y Ng, and Robert Briggs, Australia and Hong Kong

Inclusion criteria: This study collected 12- and 24-month follow-up data from Osia System (OSI200) recipients who had existing data from a previous study (at pre-implantation and 6 months post-implantation).

Methods: This prospective, multicenter, study compared safety, patient-reported outcomes Health Utilities Index Mark 3 (HUI3), APHAB, and SSQ-12), change in free-field hearing thresholds (PTA4), and speech reception threshold (SRT) in noise (dB SNR) with the Osia System at 6 months and 12- and 24-months post-implantation.

Outcomes: Twenty patients participated in this extended follow-up study (Table 14). The majority had CHL or MHL. Patient demographics can be seen in Table 15.

Table 15.

Clinical performance, safety, and patient reported outcomes demographics	
Age (mean)	44.9 years
Sex (Male/Female)	9/11
Type of hearing loss	SSD: 3 CHL; 11 MHL: 6
Aetiology	COM: 4 Tumor: 1 Malformation; 7 Unknown/other: 8

Nine device- or procedure-related adverse events occurred in six participants (6–24 months), mostly mild and within the first three months; all but three resolved by study end.

Hearing outcomes showed stable, sustained benefits from 6 to 24 months, with consistent improvements in PTA4 and speech-in-noise performance and no significant changes over time or compared with earlier aided results.

Quality-of-life outcomes remained stable from 6 to 24 months, with HUI3 and APHAB unchanged and SSQ maintaining pre-implantation gains (all $p>0.05$).

At 12 and 24 months, patients who completed the questionnaire (n=19) reported high satisfaction with the Osia System, with 18/19 satisfied or very satisfied overall at 24 months. Battery life (6 months 24.7 h vs. 24 months 23.3 h), daily usage (8.2 h vs. 8.5 h), retention (75.7 vs. 82.8/100), and comfort (86.7 vs. 87.8/100) remained stable, reflecting sustained usability and user experience.

“The Osia System delivers safe, long-term hearing, quality-of-life, and satisfaction for patients”

Long-term data of the new transcutaneous partially implantable bone conduction hearing system Osia® (n=22)¹⁸ *(Independent research)*

Investigators and country: Ann-Kathrin Rauch, Thomas Wesarg, Antje Aschendorff, Iva Speck, and Susan Arndt; Germany

Inclusion criteria: Adult patients implanted with the Osia system (OSI100 implant, Osia 1 SP) and later had a sound processor upgraded to Osia 2.

Methods: Patients were assessed preoperatively (unaided and Baha/Ponto sound processors on Softband-aided) and at 6 and 12 months post-operatively (Osia-aided), including before/after Osia 2 upgrade. AC/BC thresholds, PTA4, speech recognition in quiet, and QoL (SSQ, HUI2/3, APHAB) were measured pre-operative and at 12, 24, and 36 months.

Outcomes: Data from 22 patients were available (Table 16). Mean surgery time was 64.4 minutes for unilateral and 160 minues for bilateral Osia implantation. Two serious adverse events, one explantation and one reimplantation due to infection, occurred, with both patients achieving stable postoperative hearing.

Table 16.

Long-term data of the new transcutaneous partially implantable bone conduction hearing system demographics	
Age (mean)	44.32 years
Sex (Male/Female)	13/9
Type of hearing loss	MHL/CHL: 19 SSD: 3

In CHL/MHL patients, Osia significantly improved aided AC thresholds versus unaided hearing, with the largest gains at higher frequencies. In SSD, Osia significantly lowered aided PTA4 and improved thresholds across all frequencies, with a trend toward greater high-frequency benefit. Improvements were similar between Osia 1 and 2 sound processors.

Speech scores improved significantly with Osia 1/2 sound processors compared with unaided hearing ($p<0.001$). In SSD patients, Osia also outperformed the Softband, with higher absolute speech recognition scores. Pure-tone and speech audiometry confirmed clear functional gains with Osia implantation, with both Osia 1 and 2 sound processors performing better than the Softband-aided condition.

All patients demonstrated sustained improvements in hearing-related quality of life with Osia, maintained up to 36 months. SSQ (Fig. 9) and APHAB scores improved across key domains, particularly background noise, with stable loudness tolerance. Overall QoL (HUI2/3) improved significantly at 36 months, while hearing-specific HUI3 scores remained stable. Greater benefits were associated with longer device use. CHL/MHL patients showed greater improvements in APHAB background noise and overall HUI3 scores than SSD patients. Mean daily use exceeded 8 hours.

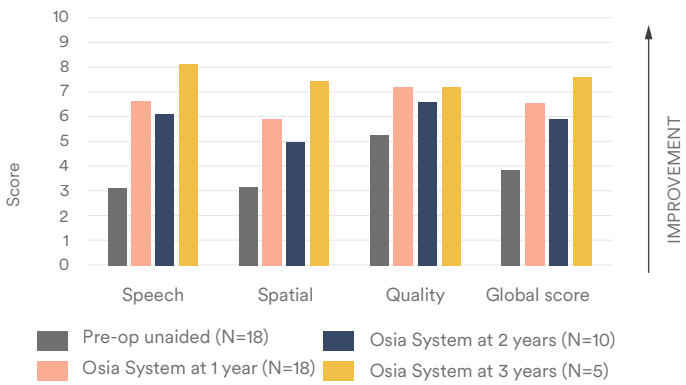


Fig. 9. SSQ outcomes

Upgrading from Osia 1 to Osia 2 sound processors did not change objective audiometric outcomes, but all patients preferred Osia 2 sound processors, reporting better sound quality, loudness, and overall hearing experience. Age was the only predictor of speech understanding, with younger patients achieving better speech scores. In contrast, older patients reported greater perceived benefit on SSQ and APHAB.

“Long-term evidence shows the Osia System delivers safe, durable hearing improvements and sustained QoL, with high patient satisfaction and preference for Osia sound quality.”

Clinical Outcomes of an Active, Transcutaneous, Bone Conduction Hearing Device: A Retrospective Study (n=60)¹⁹ (Independent research)

Investigators and country: Alma Jukic, Marine Cismas, Nancy Flores, and Shawn M Stevens; United States of America.

Inclusion criteria: Patients with MHL, CHL (BC PTA <55 dB), or SSD (hearing ear AC PTA ≤30 dB HL) aged ≥12 years who received an Osia 2 implant. Inclusion required completed surgery and at least one postoperative follow-up ≥4 weeks.

Methods: This retrospective review analysed demographic, clinical and surgical data from Osia recipients. Outcomes included complications, daily use and retention, as well as pre- and postoperative audiometry (AC, BC, SRT, WRS in quiet and noise). Functional gain and PTA4 were calculated, and preoperative BC thresholds were compared with postoperative Osia-aided results.

Outcomes: Sixty patients (67 implants) were included (Table 17), of whom 12 (20%) were aged 12–18 years. Prior hearing rehabilitation was reported in 33 patients (55%), most commonly Baha implants (57.6%) or conventional hearing aids (30.3%). Thirty-nine patients (65%) had previous otologic surgery. Mean follow-up was 13.7 months.

Table 17.

Clinical Outcomes of an Active, Transcutaneous, Bone Conduction Hearing Device demographics	
Age (median)	51 years
Sex Male/Female	25/35
Type of hearing loss	MHL: 33 SSD: 18 CHL: 9
Aetiology of HL	Chronic ear disease: 31 Congenital ear malformations: 25 Other: 18

Mean implantation time was 53.9 minutes (anaesthesia to extubation), 79.9 minutes with concurrent procedures and 43.7 minutes for Osia-only surgery. An S-shaped incision was most common. Bone polishing, tissue thinning and poor bone quality were infrequent and managed intraoperatively. Occasional partial dural exposure occurred without CSF leak, and bleeding was rare and well controlled.

High-frequency hearing showed marked gains, with mean improvements of 35.4 dB at 6 kHz and 40.7 dB at 8 kHz from unaided conditions. Speech recognition thresholds and word recognition scores improved in both quiet and noise (Fig. 10). Device use was high (mean 9.6 h/day), with 100% retention. All observed improvements were statistically significant.

Adverse events occurred in 10.4% of patients and included early infections treated with antibiotics, mild postoperative pain (3%), and reoperations (5.9%). One device extrusion was managed by removing the processor and repairing the soft tissue, allowing implant preservation for later reimplantation.

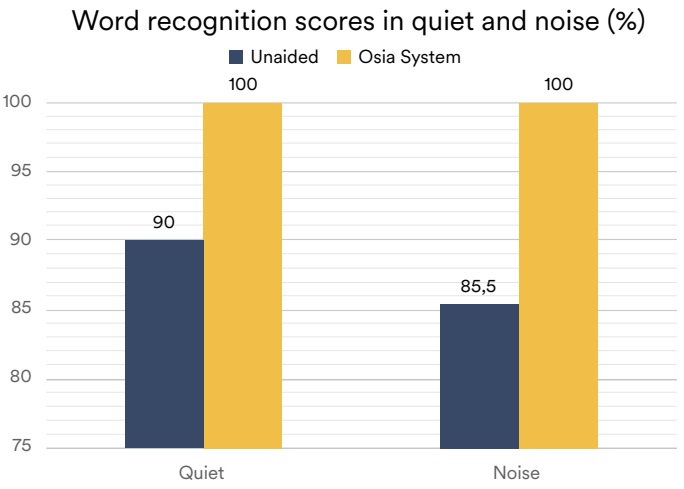


Fig. 10.

“Osia provides reliable hearing improvements, particularly in high frequencies, with a low complication rate.”

MRI compatibility

MRI evaluation of the Osia® 2 hearing implant with OSI300 actuator: insights from a full-head cadaver model¹³ (Independent research)

Investigators and country: Beata Diosi, Fiona Anna Molnar, Zsofia Bere, Angela Csomor, Imre Kaszas, Zoltan Toth, Balint Posta, Antal Nogradi, Zsigmond Tamas Kincses, Laszlo Rovo, and Adam Perenyi; Hungary

Testing: A human cadaveric head preserved in ethanol was used. The Osia implant (BI300 and OSI300) was positioned at the audilogically optimal site.

Methods: Imaging was performed on GE Signa Artist 1.5 T and GE Discovery 750 w 3 T MRI scanners using 16-channel (1.5 T) and 24-channel (3 T) head–neck coils, following standard head and inner ear protocols with full-head and temporal bone sequences (Table 18).

The cadaver head was first scanned on 1.5 T and 3 T MRI without the implant. After Osia implantation, it was rescanned supine, adding T1 and T2 MAVRIC SL sequences. Scans were repeated after magnet removal, with and without the non-magnetic plug. Three radiologists independently graded anatomical structures (0–3) for visibility and diagnostic utility on ipsilateral and contralateral sides for both scanners.

The cadaver head was first scanned on 1.5 T and 3 T MRI without the implant. After implantation, it was repositioned supine, and the protocol was repeated with additional T1 and T2 MAVRIC SL sequences on both scanners. The full measurement series was then repeated after magnet removal, both without and with the Osia non-magnetic Plug. Three radiologists independently scored all MRI scans for diagnostic quality. Anatomical structures were evaluated using a grading system (0–3), based on structure visibility and sequence diagnostic utility. Assessments were performed separately for ipsilateral and contralateral sides on both 1.5 T and 3 T scanners.

Outcomes: MRI with the Osia implant caused artefacts, mainly near the ipsilateral implant on conventional sequences, but high-resolution and MAVRIC SL sequences minimized them, keeping most structures clearly visible. After magnet removal, nearly all 1.5 T and 3 T scans were fully diagnostic (Table 19). Across 1.5 T and 3 T, the Osia implant permitted reliable MRI assessment. Artefacts were localized as expected, but MAVRIC SL sequences and magnet removal in many cases restored diagnostic quality.

Table 18.

Full-head and temporal bone sequences		
	1.5 T Scanner	3 T Scanner
Full-Head Sequences	3D T1 FSPGR T2 PROPELLER 3D SWAN EPI DWI 3D T2 FLAIR Cube T1 MAVRIC SL (5 mm slices)	Axial 3D T1 FSPGR T2 PROPELLER 3D SWAN EPI DWI 3D T2 FLAIR Cube T1 MAVRIC SL
High resolution Temporal Bone Sequences (Pars Petrosa)	3D T2 Cube (0.8 mm) FIESTA-C (0.8 mm) T2 MAVRIC SL (2 mm)	Axial 3D T2 Cube (0.4 mm) 3D FIESTA-C (0.4 mm) T2 MAVRIC SL (2 mm) Axial DWI (non-EPI) PROPELLER (3 mm)

Table 19.

MRI Visibility Index (VI) with Osia Implant 1.5 T and 3 T	
Sequence (Scanner)	Outcome
SWAN (1.5 T/3 T)	Magnet in place: non-diagnostic; After removal: mostly diagnostic ipsilateral structures
DWI (EPI) (1.5 T/3 T)	Magnet in place: non-diagnostic; After removal: limited ipsilateral structures visible
DWI (non-EPI PROPELLER) (3 T)	Magnet in place: non-diagnostic; After removal: diagnostic
DWI (non-EPI PROPELLER) (3 T)	Magnet in place: non-diagnostic; After removal: diagnostic
3D T1 FSPGR (1.5 T/3 T)	Magnet in place: ipsilateral non-diagnostic; After removal: fully diagnostic except minor cerebellar artefact
3D T2 FLAIR Cube (1.5 T/3 T)	Magnet in place: moderate artefacts; After removal: some ipsilateral cerebellar/lobar structures partially obscured
T2 PROPELLER (1.5 T/3 T)	Magnet in place: some artefacts; After removal: mostly diagnostic
3D T2 Cube (1.5 T/3 T)	Magnet in place: some ipsilateral cerebellar obscuration; After removal: evaluable except cerebellar hemisphere
FIESTA-C (1.5 T/3 T)	Magnet in place: streak artefacts; After removal: mostly diagnostic
T1 MAVRIC SL (1.5 T/3 T)	Magnet in place: reduced artefacts, minor streaking; After removal: fully diagnostic except minor ipsilateral cerebellar artefact
T2 MAVRIC SL (1.5 T/3 T)	Magnet in place: minimally affected; After removal: fully diagnostic

“The Osia System supports clear, high-quality MRI imaging with minimal artifact, allowing reliable visualization of most brain and inner ear structures at both 1.5 T and 3 T.”

The Safety of Active Hearing Implants in the Ultra-high Field Magnetic Resonance Environment: A Pilot Study²⁰
(Cochlear sponsored research)

Investigators and countries: Guy Fierens, Matthew Clemence, Nicolas Verhaert, Richard Bowtell, Rebecca S Dewey; United Kingdom and Belgium.

Testing: This study evaluated how OSI200 and OSI300 behave under extreme 7-Tesla MRI conditions to test safety and performance beyond routine clinical use.

Methods: Experiments measured magnetic forces, torque, magnet stability, heating, and imaging artifacts using standardized methods and tissue-mimicking phantoms. Device function was repeatedly assessed to ensure MR exposure caused no damage. Testing used a T Philips Achieva scanner with a single-channel transmit and 32-channel receive coil.

Only the OSI300 was tested with its magnet because its rotating design can safely align in MRI. Magnetic force was compared to device weight: A force ratio <1 indicates forces weaker than gravity (safe). Ratios >1 may still be acceptable if the device is well secured. As with magnetically induced force, a torque ratio <1 is generally considered a conservative safety threshold. Higher ratios may be acceptable if the device is securely fixated. Magnetization was measured before and after exposure using a magnetic field camera. Details of measurements can be seen in Table 20.

Table 20.

The Safety of Active Hearing Implants in the Ultra-high Field Magnetic Resonance Environment testing procedures		
Testing	Method of testing	Outcome measures
Device Functionality	Verified before/after each exposure, and after 10 exposures, using a digital link calibration (DLC) test.	Confirmed implants still communicate and operate normally. Ensures 7T exposure does not harm electronics.
Magnetic Force	Device hung from a string at the point of strongest magnetic pull; deflection measured.	Measures magnetic attraction during MRI; excessive force could displace the implant.
Magnetic Torque	Device rotated on a low-friction turntable (ASTM standard).	Measures twisting force trying to rotate the device. High torque could cause discomfort or implant rotation.
Magnetization Change	Magnets heated to body temperature, repeatedly exposed to 7T, magnet strength measured.	Assesses if magnetic field alters magnet strength and confirms secure processor retention.
Gradient-Induced Heating	Phantom scanned 15 min with rapidly switching gradients; 5 temperature sensors.	Measures heating from gradient coils. Prevents tissue injury from gradient heating.
RF Heating	Phantom scanned 15 min at high SAR (3.2 W/kg).	Measures heating from RF energy absorption. Ensures implant does not create hotspots.
Imaging Artifacts	Implants placed on head phantom; artifacts measured using 7T clinical sequences.	Measures the extent of signal void around the device and its impact on anatomic visibility.
Testing With/Without Magnet	The OSI300 was tested under all three conditions, OSI200 was evaluated only after magnet removal with a non-magnetic plug.	Reflects real-world MRI configurations. Important for safety and artifact reduction.

Implants were fixed to the right side of a head phantom and scanned using standard 7 T clinical sequences within 3 T safety limits, all in the coronal plane. The OSI300 was imaged with the magnet in place, with a non-magnetic plug, and with the cassette removed. The OSI200 was scanned only without the magnet.

Each scan was compared to a reference image without an implant. Regions with >80% signal loss were defined as artefact, and the slice showing the largest artefact was used to measure its maximum width and height.

Outcomes: The devices remained fully functional after testing, supporting 7T scanning of implanted patients. With magnets in place, force ratios exceeded 1, indicating forces greater than gravity; after magnet removal, ratios fell below 1, indicating forces lower than gravity (safe). Device magnetization rose on average 7% then slightly fell 1% after repeated exposures. Gradient-induced heating was minimal, with the highest rise of 0.24°C near the OSI300 non-magnetic cassette.

“Osia implants remained fully functional and safe in 7T MRI, demonstrating strong reliability (7T MRI is off-label; standard clinical MRI conditions still apply*.”

**Osia OSI200 and OSI300 implants are MRI conditional at 1.5T and 3T, with OSI200 requiring magnet removal at 3T; see MRI guidelines for details. In 7T testing, devices remained functional with minimal heating, while magnetic forces, torque, and magnetization changes were observed.*

Magnetic Resonance Imaging Artifact Associated With Transcutaneous Bone Conduction Implants: Cholesteatoma and Vestibular Schwannoma Surveillance²¹ *(Independent research)*

Investigators and countries: Ashley M. Nassiri, Steven A Messina, John C Benson, John I Lane, Kiaran P McGee, Joshua D Trzasko, and Matthew L. Carlson; United States of America.

Testing: Two cadaver heads were used for implantation and imaging of Osia 2 System with magnet, Osia 2 System without the magnet, and Bonebridge (BCI 602).

Methods: Images were done for four conditions: 1) pre-implantation, 2) Osia with magnet and headwrap, 3) Osia without magnet, and 4) Bonebridge with magnet. Devices were implanted at the same location, and identical MR scanners were used.

Imaging was performed on Siemens Magnetom Aera and GE Optima 450w 1.5 T scanners using standard and metal artifact–reduction sequences (Table 21). Three neuroradiologists independently evaluated the ipsilateral temporal bone, mastoid, middle ear (including epitympanum), and otic capsule (cochlea and semicircular canals), images scoring each region and sequence as diagnostic or non-diagnostic if obscured by artifact.

Table 21.

Full-head and temporal bone sequences		
	1.5 T Siemens imaging	1.5 T GE imaging
MR imaging sequences	T1 SPACE T2 SPACE Non-EPI DWI HASTE T1 SEMAC T2 SEMAC T1 VAT-WARP T2 VAT-WARP	T1 CUBE T2 CUBE Non-EPI DWI Propeller T1 MAVRIC T2 MAVRIC

Outcomes: All implanted devices caused substantial ipsilateral temporal bone artifact, whereas scans without implants were fully diagnostic (Table 22). Metal artifact–reduction sequences improved visualization for Osia and Bonebridge, though diffusion-weighted imaging remained largely non-diagnostic. Removing the Osia magnet reduced artifact, permitting limited assessment, while Bonebridge produced the largest overall artifact. No device allowed diagnostic mastoid imaging on diffusion-weighted sequences.

Table 22

	Osia with magnet			Bonebridge			Osia without magnet		
	Mastoid	Middle ear	Otic capsule	Mastoid	Middle ear	Otic capsule	Mastoid	Middle ear	Otic capsule
Siemens									
T1 SPACE	0	0	0	0	0	0	0	1	1
T1 VAT-WARP	1	1	1	0	0	0	1	1	1
T1 SEMAC	1	1	1	0	0	0	1	1	1
T2 SPACE	0	0	0	0	0	0	0	1	1
T2 VAT-WARP	1	1	1	0	0	0	1	1	1
T2 SEMAC	1	1	1	0	0	0	1	1	1
Non-EPI DWI HASTE	0	0	0	0	0	0	0	1	1
GE									
T1 CUBE	0	0	0	0	0	0	0	1	1
T1 MAVRIC	1	1	1	0	0	0	1	1	1
T2 CUBE	0	0	0	0	0	0	0	1	1
T2 MAVRIC	1	1	1	0	0	0	1	1	1
Non-EPI DWI Propeller	0	0	0	0	0	0	0	0	0

*1=diagnostic image, 0=non-diagnostic.

“Osia without a magnet was the only BCD that enabled diagnostic DWI imaging of the otic capsule and middle ear.”

Economic benefit

Comparative Clinical Effectiveness and Cost-Effectiveness of the Cochlear Osia System and Baha Attract System in Patients with Conductive or Mixed Hearing Loss or Single-Sided Deafness²² *(Cochlear sponsored research)*

Investigators and country: Matthias Brunner, Manjula Schou, Robert J Briggs, Dell Kingsford Smith; Australia

Testing: Evaluate the comparative clinical effectiveness and cost-utility of the Osia System versus the passive transcutaneous Baha Attract System for patients with CHL, MHL or SSD in an Australian healthcare setting.

Methods: This study comprised a literature review with Markov modelling. Costs and outcomes were discounted at 5% per year over a 10-year horizon, reflecting the Osia implant warranty. HUI3 utilities were used to calculate quality adjusted life years (QALYs), and cost-effectiveness was expressed as the incremental cost-effectiveness ratio (ICER), showing the extra cost per QALY gained for Osia versus the Baha Attract system.

Outcomes: Three studies were included in the review. While none directly compared Osia with Baha Attract, all evaluated outcomes versus unaided hearing and non-surgical BCDs, enabling indirect comparison.

The economic model showed that the Osia System was cost-effective for patients with CHL, MHL, and SSD over a 10-year horizon (Table 23). Compared with the Baha Attract System, the ICER was \$29,301 per QALY, well below the commonly cited Australian willingness-to-pay threshold of \$50,000. per QALY.

Table 23.

Cost-utility model results				
Deterministic Results	Osia System	Baha Attract System	Incremental Change	ICER
Undiscounted				
Total costs (AUD)	\$35,084	\$28,630	\$6453	\$24,301/ QALY
Total QALYs	7.50	7.24	0.27	
Discounted				
Total costs (AUD)	\$31,605	\$25,257	\$6348	\$29,301/ QALY
Total QALYs	6.09	5.88	0.22	

*AUD=Australian dollars

Sensitivity analyses showed the ICER was most influenced by the time horizon. A 5-year horizon increased the ICER to \$50,895/QALY, while a lifetime horizon reduced it to \$16,004/QALY, indicating greater long-term value. Cost-effectiveness was strongest in patients with CHL/MHL (\$14,161/QALY). All other parameter variations had minimal impact, with ICERs remaining below \$50,000/QALY.

“The Osia System is a cost-effective hearing solution that delivers superior clinical outcomes and greater value than passive transcutaneous systems.”

Cost-effectiveness Analysis Comparing Osia System to Percutaneous Bone Conduction Devices in Sweden²³ (Cochlear sponsored research)

Investigators and country: Federico Ghinelli, Carolyn Steeds, Laura Wells, Jeremy Wales, Mimmi Werner, Daniela D’Ostilio,Hlíf Sigurgeirsdóttir Liljenberg; Sweden.

Testing: Evaluate cost-effectiveness of the Osia System compared with percutaneous solutions to treat adult patients in Sweden.

Methods: A Markov model with a lifetime horizon was used in adults, comprising three health states: with implant, without implant, and death. QALYs were estimated using HUI3, with costs and outcomes discounted at 3% annually. Cost-effectiveness was assessed via ICER (cost/QALY) using multiple thresholds, as no formal Swedish WTP exists.

Outcomes: Osia was cost-effective versus percutaneous devices, with an incremental cost of 79,293 SEK and 0.73 QALYs gained (ICER 108,318 SEK/QALY; Table 24), improving slightly when accounting for complication-related disutility. Key drivers were baseline age, surgical cost, and health utility differences.

Table 24.

Cost-effectiveness results		
	Osia	Percutaneous Devices
Total costs per patient	336,642 SEK	257,349 SEK
Total QALYs per patient	15.28	14.55
Incremental cost per patient	79,293 SEK	
Incremental QALYs per patient	0.73	
ICER	108,318 SEK/QALY	

Abbreviations: ICER = incremental cost-effectiveness ratio; QALY = quality-adjusted life year; SEK = Swedish krona.

The results indicated that Osia is more effective but also more costly than percutaneous BCDs. Cost-effectiveness acceptability curves showed Osia’s probability of being cost-effective ranged from 43% at 100,000 SEK/QALY to 100% at 500,000 SEK/QALY.

“With long-term cost-efficiency and lasting benefits, Osia supports superior hearing outcomes for patients and healthcare systems compared with percutaneous alternatives.”

Summary

The Osia System is a safe, reliable, and effective BC solution, providing lasting improvements in hearing, speech understanding, and QoL for patients with CHL, MHL or SSD. Clinical evidence shows consistent audiological gains, low complication rates, high patient satisfaction, validated MRI compatibility, and cost-effectiveness. In children, early implantation supports auditory development, academic performance, and social participation, while enabling efficient surgical approaches. Collectively, these findings establish the Osia System as a clinically robust, patient-centered, and economically sustainable solution that advances hearing care across diverse populations and settings.

Hear now. And always

Cochlear is dedicated to helping people with moderate to profound hearing loss experience a world full of hearing. As the global leader in implantable hearing solutions, we have provided more than 750,000 devices and helped people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to next generation technologies. We collaborate with leading clinical, research and support networks to advance hearing science and improve care.

That's why more people choose Cochlear than any other hearing implant company.

REFERENCES

1. Cochlear Limited. Cochlear™ Osia® System [Internet]. 2026 [cited 14 February 2026]. Available from: <https://www.cochlear.com/us/en/home/products-and-accessories/cochlear-osia-system>.
2. Cochlear Limited. Osia® Implant [Internet]. 2026 [cited 14 February 2026]. Available from: <https://www.cochlear.com/us/en/home/products-and-accessories/cochlear-osia-system/osia-implants>.
3. Cochlear Limited. Cochlear™ Osia® System [Internet]. 2026 [cited 14 February 2026]. Available from: <https://www.cochlear.com/us/en/professionals/products-and-candidacy/osia>
4. Key, S., Mohamed, N., Da Cruz, M., Kong, K. & Hasan, Z. Systematic Review and Meta-Analysis of a New Active Transcutaneous Bone Conduction Implant. *The Laryngoscope* 134, 1531–1539 (2024).
5. Zawawi, F., Bukhari, A. F., Khairy, S. A. & Garrada, M. Impact of Early Intervention on Children with Congenital Conductive Hearing Loss: Role of Active Transcutaneous Bone Conduction Implants. *Audiol Neurotol* 1–10 (2025) doi:10.1159/000547943.
6. Stevens, S. M. et al. Outcomes Following Cochlear Osia 2 Implantation in Patients Ages 5–11 Years: A Multi-Center Trial. *The Laryngoscope* lary.32159 (2025) doi:10.1002/lary.32159.
7. Tejani, V. D. et al. Audiological outcomes of the Cochlear Osia 2 bone conduction system implanted under expanded indications in a pediatric population. *International Journal of Audiology* 1–10 (2025) doi:10.1080/14992027.2025.2550530.
8. Ordoñez-Ordoñez, L. et al. Active Osseointegrated Steady-State Implant System: Surgical and Clinical Performance. *Otol Neurotol* 46, e109–e116 (2025).
9. Gawęcki, W., Gibasiewicz, R., Błaszczyk, M., Wierzbicka, M. & Bartkowiak, E. Active piezoelectric bone conduction implant Osia® 2 - evaluation of surgery and one-year audiological and quality of life benefits. *Eur Arch Otorhinolaryngol* 282, 1757–1768 (2025).
10. Cowan, R. et al. Clinical performance, safety, and patient-reported outcomes of an active osseointegrated bone-conduction hearing implant system at 24-month follow-up. *Eur Arch Otorhinolaryngol* 281, 683–691 (2024).
11. Young, A., Fechtner, L., Brennan, C., Rende, S. & Wazen, J. Clinical performance, audiological outcomes, and quality of life of the Cochlear Osia® system. *American Journal of Otolaryngology* 44, 103951 (2023).
12. Diosi, B. et al. Artefacts on magnetic resonance imaging with Osia®2 bone conduction hearing aid: A cadaver study. *Cochlear Implants International* 25, 434–444 (2024).
13. Diosi, B. et al. MRI evaluation of the Osia® 2 hearing implant with OSI300 actuator: insights from a full-head cadaver model. *Cochlear Implants International* 26, 287–303 (2025).
14. Mozaffari, M. et al. Surgical and audiometric outcomes of active osseointegrated bone-conduction hearing device (Cochlear™ Osia® 2 system) placement from a tertiary paediatric centre. *International Journal of Pediatric Otorhinolaryngology* 190, 112272 (2025).
15. Leonard, C. et al. Single-Stage Ear Reconstruction Simultaneous With Piezoelectric Osia® Bone Conduction Implantation. *Ann Plast Surg* 94, S441–S445 (2025).
16. Cochlear Limited. CLTD5861 Clinical Investigation Report. Cochlear Limited, Sweden. 2026; D2367205.
17. Jukic, A., Munhall, C. C. & Stevens, S. M. A Systematic Review of Surgical Characteristics and Adverse Events of an Active, Transcutaneous Bone Conduction Device. *Ann Otol Rhinol Laryngol* 133, 956–966 (2024).
18. Rauch, A.-K., Wesarg, T., Aschendorff, A., Speck, I. & Arndt, S. Long-term data of the new transcutaneous partially implantable bone conduction hearing system Osia®. *Eur Arch Otorhinolaryngol* 279, 4279–4288 (2022).
19. Jukic, A., Cismas, M., Flores, N. & Stevens, S. M. Clinical Outcomes of an Active, Transcutaneous, Bone Conduction Hearing Device: A Retrospective Study. *Otolaryngol.--head neck surg.* 171, 833–840 (2024).
20. Fierens, G., Clemence, M., Verhaert, N., Bowtell, R. & Dewey, R. S. The Safety of Active Hearing Implants in the Ultra-high Field Magnetic Resonance Environment: A Pilot Study. *Otology & Neurotology* 46, 1338–1345 (2025).
21. Nassiri, A. M. et al. Magnetic Resonance Imaging Artifact Associated With Transcutaneous Bone Conduction Implants: Cholesteatoma and Vestibular Schwannoma Surveillance. *Otolaryngol.--head neck surg.* 170, 187–194 (2024).
22. Brunner, M., Schou, M., Briggs, R. J. & Kingsford Smith, D. Comparative Clinical Effectiveness and Cost-Effectiveness of the Cochlear Osia System and Baha Attract System in Patients with Conductive or Mixed Hearing Loss or Single-Sided Deafness. *JMAHP* 12, 5–20 (2024).
23. Ghinelli, F. et al. Cost-effectiveness Analysis Comparing Osia System to Percutaneous Bone Conduction Devices in Sweden. *Otology & Neurotology* 47, 255–261 (2026).

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