

Summary

Clinical evidence on the Osia[®] System



The Cochlear[™] Osia[®] System is a new active osseointegrated steady-state implant (OSI) indicated for patients with mixed (MHL), conductive (CHL) hearing loss and single-sided deafness (SSD).

The system uses an implantable Piezo Power[™] transducer that is fixed to the bone via an osseointegrated implant. Power to drive the transducer and digital sound signal are transferred from the sound processor to the implant through a digital radiofrequency (RF) link.

Two versions of the Osia System have been developed. The first generation of the Osia System consists of the OSI100 implant, with a flexible lead between the transducer and coil, as well as the Osia Sound Processor utilized externally, *Fig. 1*. The second generation consists of the OSI200 implant, which is monolithic with a fixed distance between the transducer and coil to further reduce the risk of feedback and simplify the surgery. This system uses the Osia 2 Sound Processor, which is smaller, has updated signal processing, wireless connectivity and more efficient power management than the previous generation, *Fig. 2*.

The Osia 2 Sound Processor is also compatible with the first generation implant OSI100.

A multitude of clinical research has been performed on the Cochlear Osia System, both through sponsored international multicenter studies and as investigator initiated and independent research. The objective of this whitepaper is to summarize the current clinical evidence on the Osia System, and help new clinics to make an informed choice regarding when to use the Osia System and what outcomes to expect.

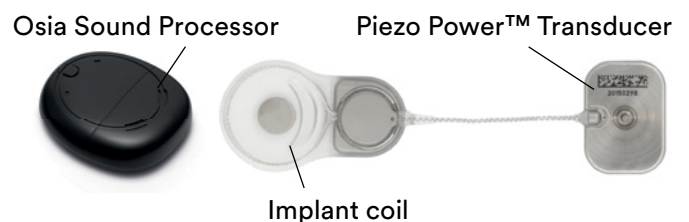


Fig 1: The Osia System with the OSI100 implant and the Osia Sound Processor

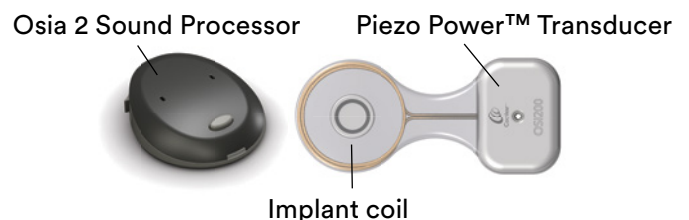


Fig 2: The Osia System with the OSI200 implant and the Osia 2 Sound Processor

CLINICAL RESULTS IN SPONSORED RESEARCH – ADULTS (GEN 1)

Clinical outcomes

- Significantly improved aided thresholds above 250 Hz compared to a Baha® Power Sound Processor on Baha Softband
- Hearing in noise improved by 7.5 dB SNR over a Baha Power Sound Processor on Softband
- Average daily use of 11.3 hours/day across all patient groups

Clinical performance of the Osia System – Results from a prospective, international, multicenter clinical investigation (N=51)¹

Investigators and study sites: Emmanuel Mylanus, Radboud University Medical Center, Nijmegen, The Netherlands; Robert Briggs, The Royal Victorian Eye and Ear Hospital, Melbourne, Australia; Susan Arndt, Universitätsklinikum Freiburg, Germany; Piotr Skarżyński, World Hearing Center Institute of Physiology and Pathology of Hearing, Kajetany, Poland; Steven Telian, University of Michigan, Ann Arbor, United States.

Inclusion criteria: Adults with bone conduction thresholds of up to 55 dB HL in the implanted ear, or SSD were included.

Method: This was an open, prospective, international, multicenter clinical investigation conducted at five centers in Europe, the United States and Australia. Subjects were implanted with the first generation Osia System and followed for 12 months. Demographic patient data are summarized in *Table 1*.

Table 1: Patient demographics

Osia System multicenter study patient demographics	
Patient age	Average 47.4 years old (19-77)
CHL	14 patients
MHL	23 patients
SSD	14 patients

Audiological evaluations included audiometric thresholds, speech recognition in noise and speech recognition in quiet. Results were compared with unaided hearing and preoperative tests with a Baha® BP110 Power Sound Processor on Softband. Patient health-related quality of life outcomes were assessed with the Health Utility Index 3 (HUI3), and audiological subjective evaluation with Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Speech, Spatial and Qualities of Hearing Scale (SSQ12).

Outcomes: At the 12-month follow-up, the patients demonstrated statistically significant improvements in aided thresholds at all measured frequencies compared to the unaided condition. More importantly, they also showed statistically significant improvements in hearing thresholds above 250 Hz compared to the Baha BP110 Power Sound Processor on Softband, *Fig. 3*.

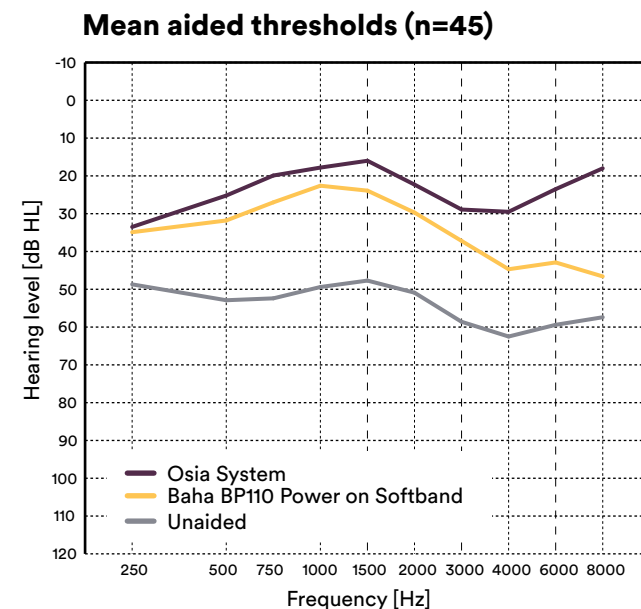


Fig 3: Aided thresholds with the Osia System at 12 months compared to unaided and pre-operative test with a Baha BP110 Power Sound Processor fitted on a Softband.

For speech recognition, study participants showed improvements in speech recognition in quiet, especially at the lower presentation levels, *Fig. 4*.

When it came to improvement in speech recognition in noise, the Osia System clearly outperformed the unaided condition and the non-surgical solution by an average of 13.4 dB and 7.4 dB respectively, *Fig. 5*.

Mean speech recognition in quiet (n=45)

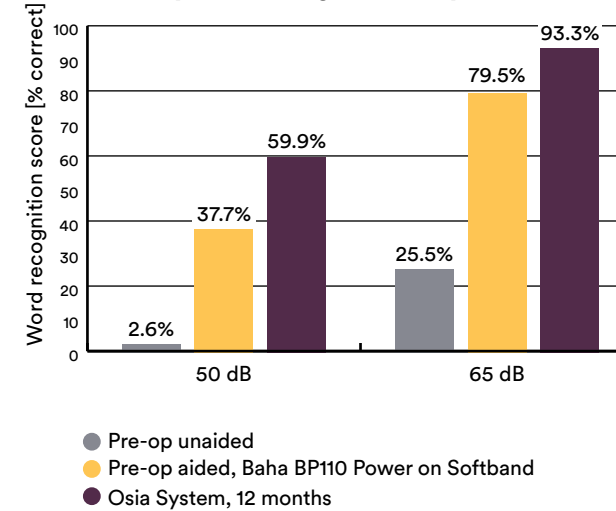


Fig 4: Speech recognition in quiet with the Osia System at 12 months compared to unaided and pre-operative test with a Baha BP110 Power Sound Processor fitted on a Softband.

Adaptive speech recognition in noise

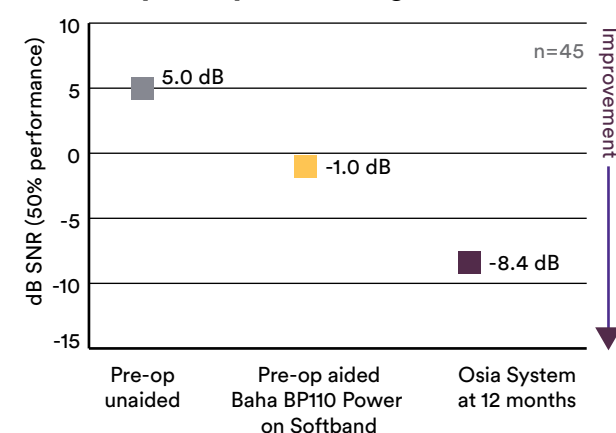


Fig 5: Adaptive speech recognition in noise, 50% performance, Speech from front, noise from behind. With the Osia System at 12 months compared to unaided and pre-operative test with a Baha BP110 Power Sound Processor fitted on a Softband.

Statistically significant improvements were observed compared to the unaided condition on all questionnaires, including the hearing and speech attributes of HUI-3. Additionally, patients reported significant improvements in ease of communication, reverberation and background noise in APHAB and statistically significant improvements across all measures presented in the SSQ12.

The benefit of the Osia System was also reflected in a high ratings of wearing comfort and an average daily use of the system of 11.3 hours/day across the whole group. The highest daily use was seen in the group of MHL/CHL patients with an average of 12.2 hours/day, in the group of SSD patients the average was 9.3 hours/day. Importantly, subjects in the Osia study used the system 33% longer than a similar group of patients in a multicenter study on the Baha Attract System where the daily average use was 8.5 hours/day².

The primary safety evaluation concluded that postoperative healing was satisfactory, and few complications were reported. One implant was removed before activation due to post-surgical infection deemed not to be related to the device but to the procedure.

CLINICAL RESULTS IN SPONSORED RESEARCH – SOUND PROCESSOR UPGRADE (GEN 1)

Key outcomes

- Up to four times less battery consumption using the Osia 2 Sound Processor compared to the Osia Sound Processor
- 100% of patients prefer the Osia 2 Sound Processor over the Osia Sound Processor

Comparison between the Osia Sound Processor and the Osia 2 Sound Processor (N=11)³

Investigators and study site: Robert Cowan, Robert Briggs, Royal Victorian Eye and Ear Hospital, Melbourne, Australia

Inclusion criteria: Adult patients with at least one year experience of the Osia Sound Processor.

Method: Single-center, prospective comparison between the Osia Sound Processor and the Osia 2 Sound Processor. Eleven Osia users were included at the clinic in Melbourne, see further patient demographics in *Table 2*. Comparisons between the sound processors were made after six weeks of use. Both hearing outcomes and self-reported outcomes were collected.

Table 2: Patient demographics.

Osia upgrade study patient demographics	
Patient age	Average 48.7 years old Range: 32-73
Conductive hearing loss	2 patients
Mixed hearing loss	3 patients
Single sided deafness	6 patients

Outcomes: Using the Osia 2 Sound Processor, aided thresholds from 500-8000 Hz were improved by 3.4 dB on average. Speech recognition in quiet and noise were statistically equivalent between the two sound processors.

For the self-reported outcomes, the APHAB questionnaire reflected an improvement across all subscales, Fig. 6.

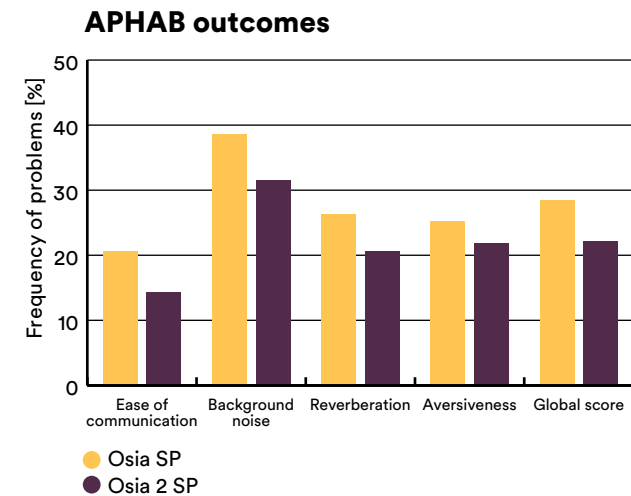


Fig. 6: Outcomes from APHAB questionnaire comparing first and second generation Osia Sound Processor (N=11).

Small improvements were also noted in the SSQ questionnaire, mainly in the Speech and Spatial domain. The evaluation also employed the Quebec User Evaluation with Assistive Technology questionnaire (QUEST) to evaluate the user satisfaction from a device. Overall, the subjects were “more or less satisfied” to “very satisfied” with all variables for both sound processors. When the subjects specified the three most important items for their satisfaction with the Osia 2 Sound Processor, most subjects chose effectiveness, comfort and durability. Importantly, battery consumption was significantly decreased with some patients using up to four times less batteries with the Osia 2 Sound Processor.

Notably, when asked about their preference, all 11 subjects chose the Osia 2 Sound Processor. It was an even distribution between the factors influencing the choice, but the “Possibility to use wireless accessories” was important for 10 of the 11 subjects and sound quality was an important deciding factor for eight of the subjects.

CLINICAL RESULTS IN SPONSORED RESEARCH – ADULTS (GEN 2)

Key outcomes

- Significant improvement in aided thresholds, speech recognition in quiet and in noise compared to the unaided situation.
- Similar hearing outcomes as the first generation Osia System.
- Significantly improved battery lifetime with the second generation system.

Clinical performance, safety and patient reported outcomes of the OSI200 implant (N=29)⁴

Investigators and study site: Robert Briggs, The Royal Victorian Eye and Ear Hospital, Melbourne, Australia; Catherine Birman, Sydney Cochlear Implant Center, Sydney, Australia; Michael CF Tong, The Chinese University of Hong Kong, Hong Kong, SAR.

Inclusion criteria: Adults with CHL, MHL with a pure tone average (PTA) of ≤ 55 dB SNHL in the implanted ear, or SSD.

Method: This was an open, prospective, international, multicenter clinical investigation conducted at three centers, two in Australia and one in Hong Kong with 6-month follow-up. 29 subjects were implanted with the second generation Osia System. At the primary endpoint (3 months follow-up), which is presented below, 17 patients completed the follow-up visit, the remaining 12 patients could not travel to the clinic due to the COVID-19 pandemic.

Table 3: Patient demographics

Indication	Total no of patients	Patients with 3-month follow-up
CHL/MHL	24	15
SSD	5	2

Audiological evaluations included audiometric thresholds, speech recognition in noise and in quiet. 3-month results with the Osia System were compared with unaided hearing outcomes. The patients reported outcomes will be summarized in the publication of 6-month results.

Outcomes: The patients demonstrated statistically significant improvements in aided thresholds at all measured frequencies compared to the unaided condition, Fig. 7.

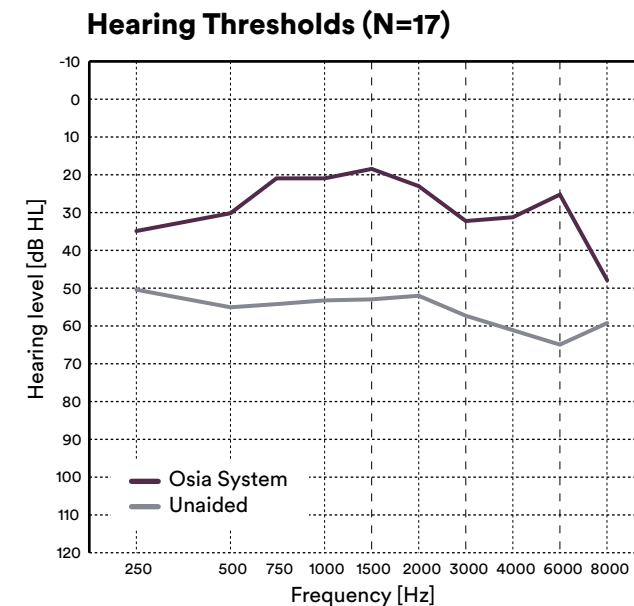


Fig. 7: Aided thresholds with the Osia System at 3 months compared to unaided.

For speech recognition, study participants showed significant improvements in speech recognition in quiet, especially at the lower presentation levels, Fig. 8.

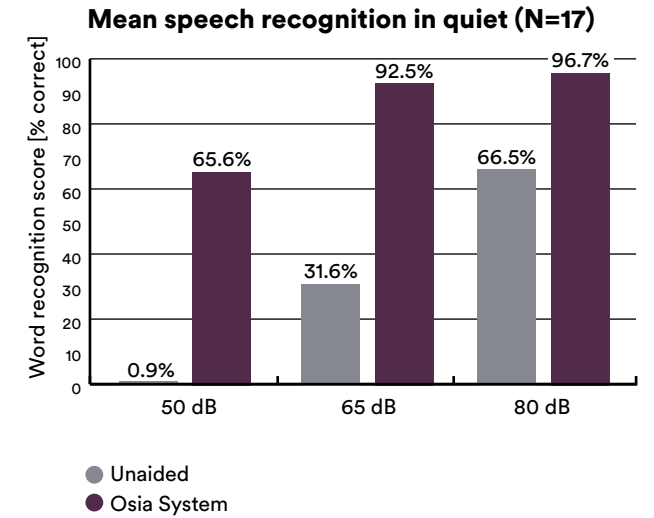


Fig. 8: Speech recognition in quiet with the Osia System at 3-months compared to unaided.

When it came to improvement in speech recognition in noise, the Osia System clearly outperformed the unaided condition by an average of 9.5 dB, Fig. 9.

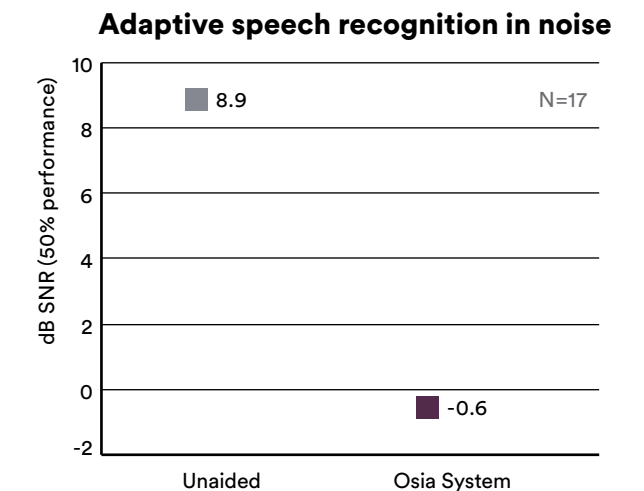


Fig. 9: Speech recognition in noise with the Osia System at 3 months compared to unaided.

This study replicates the outcomes seen with the first generation Osia System, demonstrating excellent improvements in aided audiometric thresholds, as well as speech recognition in quiet and in noise with the second-generation implant. Similar to what was seen in the sound processor upgrade study (page 3), the battery lifetime was increased using the second generation system with an average of two days, and patients reporting up to four days of battery lifetime.

CLINICAL RESULTS IN SPONSORED RESEARCH - PEDIATRIC (GEN 1)

Key outcomes

- Excellent improvement in hearing thresholds, speech recognition in quiet and in noise in children with the Osia System compared to unaided.

Osia System pediatric study (N=14)⁵

Investigators and study site: Blake Papsin, Sharon Cushing, Marylynn Fenness, Jaina Neghandi, Karen Gordon. SickKids Hospital, Toronto, Canada

Inclusion criteria: Children (under 18 years old) with single-sided or bilateral conductive or mixed hearing loss who are possible candidates for a percutaneous bone anchored system.

Method: Prospective study, 14 children with an average age of 14.2 years (range:10.3-17.7), were implanted with 15 Osia Systems. Five had unilateral CHL, 5 had bilateral CHL, and 4 had SSD and did not meet CI candidacy criteria.

Initial results: At initial activation, comfortable audibility was achieved immediately in 7/14 children. Six requested decreases in loudness. A follow-up revealed overall ease of use and good device retention. Post-operative hearing thresholds were improved by 30 dB on average compared to unaided thresholds, Fig. 10.

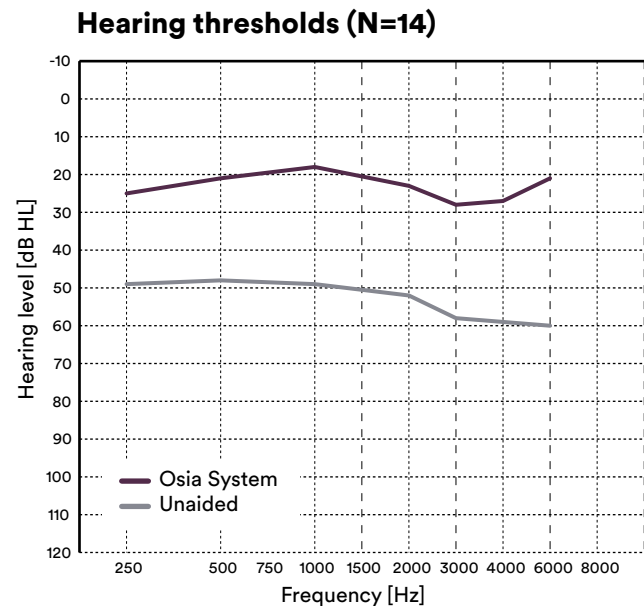


Fig. 10: Comparison of aided and unaided hearing thresholds with the Osia System

Additionally, post-operative speech testing revealed excellent improvement in speech recognition in quiet and noise with the Osia System compared to unaided. Skin irritation at the magnet site was observed in two children and resolved after reduction of magnet strength and subsequent use of the Baha SoftWear™ pad.

Current assessment of the Osia clinical trial suggests this device has the potential to benefit children across a wide range of hearing loss configurations and etiologies.

INVESTIGATOR INITIATED AND INDEPENDENT RESEARCH (GEN 1)

Initial outcomes

- Good outcomes in adult and pediatric patients
- Speech recognition in quiet and in noise with the Osia System outperforms comparators
- Initial results show superior outcomes with the Osia System when transitioning from the Baha Attract System

Osia System compared to Baha 5 Power on Softband (N=9)⁶

Investigators and study site: Goycoolea JM, Ribalta G, Tocornal FJ, Levy R, Alarcon P, Bryman M, Cagnacci B, Catenacci C, Oyanguren V, Vilches I, Briones V, García R. Clinica de Las Condes, Santiago, Chile

Inclusion criteria: Post lingual adults and children with sufficient bone depth and bone conduction thresholds up to 55 dB HL.

Method: Prospective investigation with pre-surgical evaluation using Baha 5 Power Sound Processor fitted on the Baha Softband. Post-operative evaluations performed measuring functional gain as well as speech recognition using hearing in noise test (HINT). Subjective evaluation using the SSQ, APHAB, and Glasgow Inventory questionnaires. All assessments were done at 2 and 6-months.

Outcomes: At 6 months the speech reception threshold in quiet had improved by 9.5 dB with the Osia System compared to Baha 5 Power on Softband. Adaptive speech recognition in noise

was -2.2 dB SNR with the Osia System compared to -0.7 dB SNR using the Softband, Fig. 11. Statistically significant improvements were seen in the Speech and Qualities scales of the SSQ.

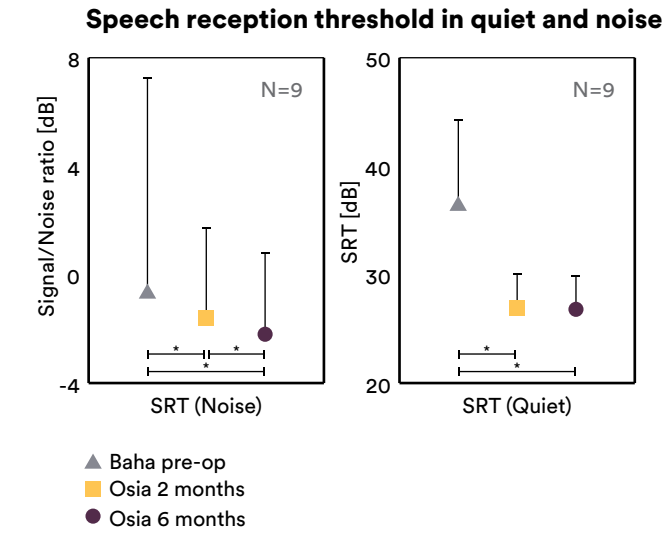


Fig. 11: Mean speech reception threshold in quiet and in noise with the Osia System compared to Baha 5 Power on Softband.

In conclusion, this study demonstrated significant improvement in speech recognition in quiet and noise with the Osia System as well as improved aided thresholds in the low and high frequencies, thus delivering better quality of hearing than passive devices.

Outcomes of the new Osia System compared to Baha Attract System (N=7)⁷

Investigators and study site: Nevoux J, Pronost N, Boulet M, Papon J-F. APHP - Paris Saclay, Bicêtre University Hospital, Le Kremlin-Bicêtre, France.

Inclusion criteria: Adult patients with MHL currently fitted with a Baha Attract System that were initially successful cases, but due to degrading hearing are in need of a more powerful solution.

Method: Prospective study where existing Baha Attract System patients were switched to the Osia System. Evaluation of surgical outcomes, aided thresholds, speech recognition thresholds, hearing in noise and sound localization. Subjective evaluation using the APHAB, the Glasgow Health Status Inventory (GHSI), the Glasgow Benefit Inventory (GBI) and the HUI3. Comparison of pre-operative results with the Baha Attract System using the Baha 5 Power and the Baha 5 SuperPower Sound Processors to the post-surgical outcomes with the Osia System.

Initial results: With the Osia System hearing thresholds above 2000 Hz improved by 37 dB on average compared to the Baha 5 Power Sound Processor on Baha Attract System, and by 17 dB on average compared to the Baha 5 SuperPower Sound Processor on Baha Attract System. Patients also noted considerable improvement of speech recognition in noise with the Osia System.

Osia System, a new active transcutaneous bone conduction device: Preliminary results (N=14)⁸

Investigators and study site: Marco J, Gil IP, Latorre E, Pitarch I, Marco A. Hospital Clinico Universitario De Valencia, Valencia, Spain

Inclusion criteria: Adult patients with MHL and a sensorineural hearing loss of 45-55 dB. No previous bone conduction implant. Showing good performance with Baha 5 Power Sound Processor on Softband.

Method: Prospective study assessing aided thresholds, speech recognition in quiet, speech recognition in noise and the GBI and SSQ questionnaires pre and post-surgery. Additionally, patients with the Osia System will be compared to a similar group of patients using the Baha Connect System with the Baha 5 Power.

Initial results: Preliminary results demonstrate improved aided hearing thresholds in the high frequencies with the Osia System compared to Baha 5 Power on abutment, Fig. 12.

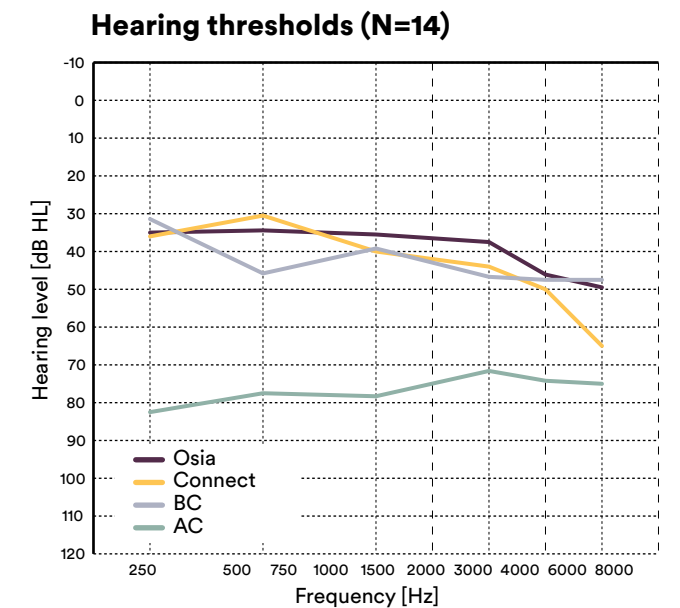


Fig. 12: Aided and unaided hearing thresholds with the Osia System compared to matched group of Baha Connect System patients fitted with the Baha 5 Power Sound Processor

Additionally, initial results show equal performance in terms of speech recognition in quiet and in noise with the Osia System compared to Baha 5 Power on abutment.

Baha Attract System – Osia System Conversion Patients: Comparison of the Two Systems (N=5)⁹

Investigators and study site: Rovo L, Bere S, Perenyi A, Jarabin J, Kiss JG. University of Szeged, Szeged, Hungary.

Inclusion criteria: Adult and pediatric patients with poor performance on the Baha Attract System due to degrading hearing.

Method: Prospective study where the pre-operative performance was assessed measuring aided thresholds, speech recognition in quiet and in noise with the Baha Attract System. Outcomes were compared to the post-surgical results with the Osia System.

Outcomes: The Osia System accomplished significant improvement in pure tone and speech audiometry results compared to the Baha Attract System, Fig 13.

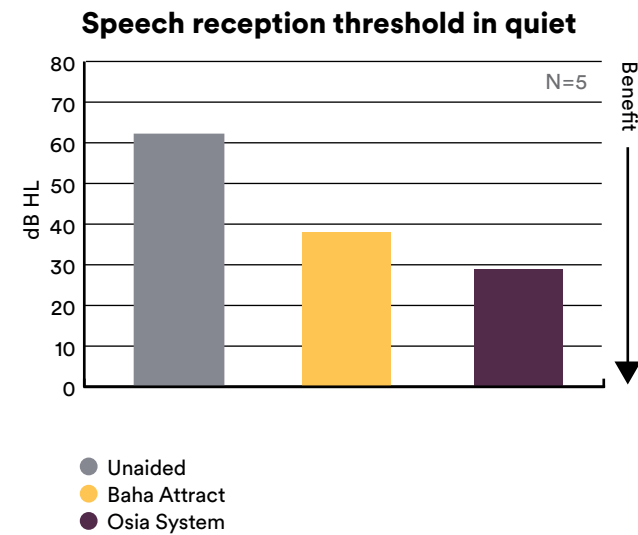


Fig. 13: Average SRT in quiet in the unaided situation, aided with Baha Attract System and with the Osia System for the five patients.

Additionally, patients rated the high frequency sound and hearing perception in noise as better with the Osia System compared to the Baha Attract System.

Surgical and functional outcomes of the new Osia implant (N=10)¹⁰

Investigators and study site: Lau K, Scotta G, Wright K, Proctor V, Greenwood L, Dawoud M, Ray J. Sheffield teaching Hospital, Sheffield, United Kingdom

Inclusion criteria: Adult patients with CHL, MHL and SSD with good benefit from pre-operative Softband test.

Method: Prospective study where patients were assessed using pure tone audiometry and speech testing. Additionally, their reasons for choosing the Osia System, initial patient reactions and views on aesthetic outcomes were noted.

Outcomes: The Osia System provided significant improvement of aided thresholds across 500, 1000, 2000 & 4000 Hz (PTA4) compared to the unaided situation, Fig. 14.

The Osia System yielded good subjective improvement as measured by the Client Oriented Scale of Improvement (COSI) and GHABP questionnaires. The researchers conclude that the Osia System requires less monitoring and reviews and it has a higher and wider range of amplification compared to other transcutaneous devices. They conclude it is well-suited for rehabilitation of moderate mixed and conductive hearing losses.

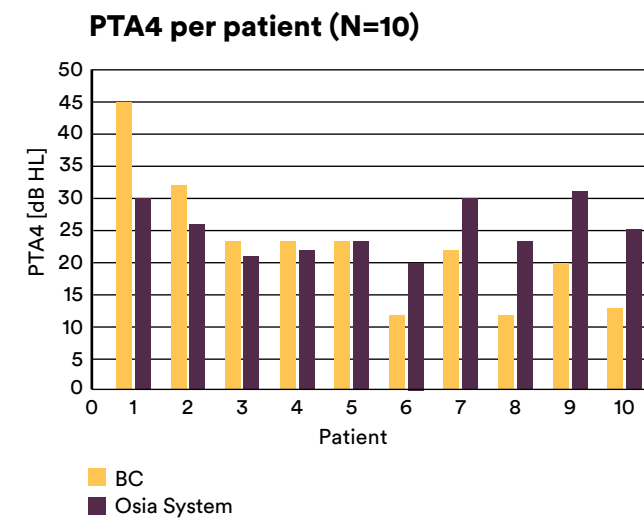


Fig. 14: PTA4 in the 10 patients fitted with the Osia System compared with AC and BC thresholds.

The evaluation of a surgery and the short term benefits of a new active bone conduction hearing implant - the Osia (N=8)¹¹

Investigators and study site: Gawecki M, Gibasiewicz R, Marszal J, Blaszczyk M, Gawlowska M, Wierzbicka M. Poznan University of Medical Sciences, Poznan, Poland

Inclusion criteria: Eight adult patients with mixed hearing loss.

Method: Patients were randomly divided into two groups, group 1 was implanted with the Osia System and group 2 was implanted with the Baha Attract System and fitted with the Baha 5 Power Sound Processor. The surgery, audiological and functional outcomes were analyzed and compared between the two groups. Patient demographics are shown in Table 4.

Table. 4: Patient demographics.

	Osia group	Baha Attract group
Age (mean)	58	51
Air conduction threshold PTA (dB HL)*	80	67.5
Bone conduction threshold PTA (dB HL)*	43.5	38.8

* At the side of implantation

Outcomes: Surgeries were successful in all cases and healing uneventful. Both groups significantly improved their audiometric thresholds and speech audiometry compared to unaided. Similarly, both groups demonstrated evident subjective improvements using APHAB and SSQ. Mean functional gain in pure tone audiometry was 42.8 dB for the Osia group and 38.8 dB for the Baha Attract group. The patients in the Osia group evaluated their quality of hearing as superior to patients in the Baha Attract group, Fig. 15.

Patient rating - quality of hearing (N=8)

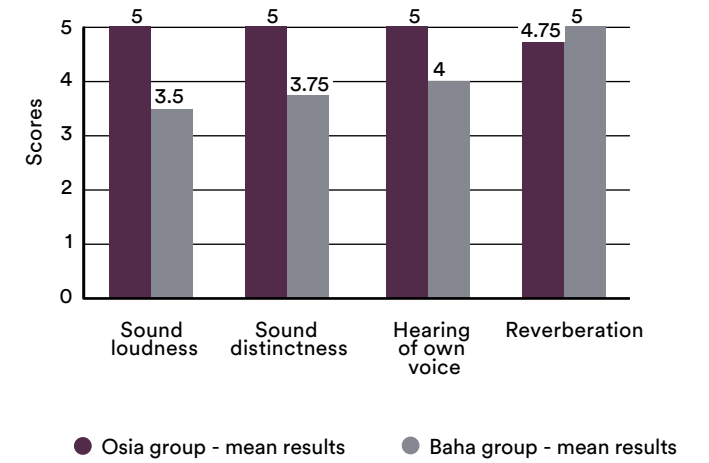


Fig. 15: Patient rating of quality of hearing using the Baha Attract and Osia System.

A new active osseointegrated implant system in patients with single sided deafness. (N=6)¹²

Investigators and study site: Willenborg K, Avallone E, Maier H, Lenarz T, Busch S. Medical University Hannover, Hannover, Germany.

Inclusion criteria: Six adult patients with single sided sensorineural deafness not indicated for a cochlear implant.

Method: Patients were implanted with the Osia System. The surgery, audiological and functional outcomes were recorded. One patient with a history of several explanted hearing implants had to be explanted due to wound dehiscence.

Outcomes: Preliminary results indicate a straightforward surgical procedure with a low rate of complications and improvement of speech recognition in quiet and in noise. Subjective benefit was noted both in questionnaires and in the wearing time of the device where recipients used the system up to 16 hours per day.

Osia System in children with conductive or mixed hearing loss (N=6)¹³

Investigators and study site: Smeds H et.al. Karolinska University Hospital, Stockholm, Sweden

Inclusion criteria: Children with CHL or MHL indicated for the Osia System.

Method: Prospective study where six children were implanted with the Osia System. Two children were implanted bilaterally, the other four unilaterally. Patient demographics are shown in *Table 5*.

Outcomes: All children had good hearing outcomes with less feedback than other bone conduction systems. It was possible to position the Osia System also in atretic temporal bones of children from eight years old.

Table 5: Patient demographics.

Gender	Age	Fitting
M	8	Bilateral
F	8	Bilateral
M	12	Unilateral
M	9	Unilateral
F	10	Unilateral
M	11	Unilateral

SUMMARY

The Osia System provides hearing care professionals with a new powerful solution to help adults and children with conductive and mixed hearing loss as well as those with single sided sensorineural deafness. Some of the unique benefits of the Osia System over existing technologies include the proven high frequency amplification, good speech understanding in quiet and in noise, the implantable piezoelectric transducer without any moving parts or magnetic material, and patient-preferred aesthetics. The clinical evidence is starting to build as demonstrated in the clinical outcomes outlined above. Clinical results to date show excellent outcomes and a low rate of complications, of which the majority were mild and transient.

The active osseointegrated steady-state implant system will be an important addition to the available range of implantable hearing solutions. The Osia System will be of benefit to patients that until today either did not accept a bone conduction solution due to lack of benefit, or due to aesthetic concerns, as well as those patient groups where current bone conduction systems have demonstrated a higher risk of soft tissue complications.

Hear now. And always

As the global leader in implantable hearing solutions, Cochlear is dedicated to helping people with moderate to profound hearing loss experience a life full of hearing. We have provided more than 600,000 implantable devices, helping 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 innovative future technologies. We collaborate with leading clinical, research and support networks.

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

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Please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

In the United States, the Osia System is indicated for patients 12 years of age or older. In Canada, the Osia System is indicated for patients 5 years of age or older.

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