

**Thursday, September 7<sup>th</sup>, 2023**

10:00-12:00 Surgical Outcomes and Considerations 1

**Evaluation of implant stability and audiological benefit of the Ponto BHX bone anchored hearing system following a one-stage surgical implantation procedure in a pediatric population.**

Anirvan Banerjee<sup>1</sup>, Kia Nøhr Iversen<sup>2</sup>, Maria Åberg Håkansson<sup>2</sup>

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**Abstract**

**Objectives:** Bone anchored hearing surgery is a well-recognized procedure in paediatric patients and has been shown to have successful surgical and audiological outcomes. Traditionally a two-stage approach has been employed for bone anchored hearing surgery in children, where the flange fixture with a cover screw is inserted and after allowing time for osseointegration (3-6 months), a hole is punched in the skin exactly over the flange fixture, cover screw removed, and the abutment is attached. Recently, one-stage surgery in which a pre-mounted abutment on an implant is inserted in the bone has been successful in paediatric patients and has been implemented into clinical practice. The purpose of the prospective study is to collect surgical and audiological data from paediatric patients and increase the knowledge on the long-term performance of one-stage bone anchored hearing surgery in the paediatric population.

**Methods:** Pediatric patients undergoing one-stage surgery using the Ponto BHX implant system at The James Cook University Hospital (Middlesbrough, UK) were recruited for a 24-month prospective follow-up study. Surgical and audiological outcomes were assessed prior to and during surgery, as well as at 6 follow-up visits throughout the 24-month follow-up period. The primary outcome of the study was implant stability, measured by Implant Stability Quotient (ISQ), after 6 months compared to at surgery.

**Results and conclusion:** In total, 17 implants were placed during the study (one bilateral and 15 unilateral patients). A sleeper implant was placed approximately 10mm from the centre of the primary implant and a cover screw placed as backup in case of implant failure. The patient cohort consisted of 6 girls and 10 boys aged 7-14 years. Preliminary 6-month data show good implant stability, with no implant losses and a 6-point increase in mean ISQ between surgery and 6-month follow-up. Soft tissue was reported to heal well, and no major complications or adverse events were reported. In conclusion, preliminary 6-month data from this cohort suggest safe and reliable outcomes with the one-stage surgery in a pediatric population.

**Long term outcomes of the Ponto BHX wide diameter implant system (Oticon Medical, Sweden) over a 7-year period.**

Ann-Louise McDermott BDS, MBChB, FRCS, FRCS(ORL-HNS), PhD<sup>1</sup>, Anne Child-Hymas<sup>2</sup>, Sadia Halema<sup>3</sup>, Channa Panagamuwa MBChB, FRCS (ORL-HNS)<sup>4</sup>, Konstance Tzifa MBChB, FRCS, MPhil, FRCS (ORL-HNS), DLO<sup>4</sup>

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## **Abstract**

**Objective:** To evaluate the clinical outcomes of Children treated with the bone anchored hearing system using the Ponto BHX wide diameter implant system (Oticon Medical, Sweden) over a 7-year period. (No surgeries performed between March 2020-October 2021 due to COVID-19)

**Methods:** A retrospective cohort study conducted at a tertiary paediatric centre. 156 consecutive paediatric patients aged 4-16 years were included in the study between January 2016 to January 2023. Main outcome measures recorded and analysed were clinical outcomes, implant failure rates, and peri-abutment reactions.

**Results:** 156 children, implanted with 255 implants, were included in the study. Nine implant failures were reported (3.5%) of which two were a result of trauma. Three children had an abutment removed. Adverse skin reactions (Holgers grade 2–4) were observed in 3.1% of all postoperative visits, occurring in 27 individuals (17%).

**Conclusions:** The wide diameter Ponto BHX bone anchored hearing implants continue to demonstrate superior survival rates and excellent clinical outcomes compared with previous implant systems used in our Institution over the past three decades.

## **Guidelines for deciding between cochlear implantation and bone anchored devices for adults with significant hearing in one ear**

Claire Iseli MBBS (hons), FRACS, MS<sup>1,2</sup>, Rodney Hollow Masters of Audiology<sup>1</sup>, Alex Rousset PhD<sup>1</sup>, Sylvia Tari Masters of Audiology<sup>1</sup>, Raoul Wills BA (Hons) MCIAud AAudA<sup>1</sup>

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## **Abstract**

**Objectives:** To develop clinical guidelines that assist in establishing if a cochlear implant (CI) or bone conduction device (BCD) is the more suitable option for adults who present with a severe to profound hearing loss in one ear and no worse than a moderate loss in the other ear.

Methods: Speech perception, localization and subjective feedback measures were obtained from a group of 50 adults following CI surgery. All adults had a PTA of <60dBHL in the contralateral ear. Outcome measures included: a speech in adaptive noise (SRT) test, a monosyllabic word test presented directly to the CI, a 13-speaker localization test and questionnaires (SSQ, Tinnitus Inventory and IOI-HA). Correlations between the outcome measures and factors such as level of hearing and duration of hearing loss were examined. These outcomes were then compared with our clinic's experience with BCD to develop clinical guidelines.

Results: There were significant improvements post CI on all measures in this group. There was an average improvement of 5dB on the SRT tests following implantation and the mean implant-alone monosyllabic word score was equivalent to that obtained by the clinic's standard CI recipient group. There was no correlation between speech perception measures and SSQ total score, indicating both types of measures were useful. While patients with a duration of hearing loss up to 20 years benefited from implantation, those with a duration of <5 years had higher satisfaction scores on IOI-HA. Subjects with more hearing in the contralateral ear scored better on some measures. If a patient had a duration of hearing loss < 20years and achieved an improvement in pre-CI SRT with CROS/BCD of <7dB (speech to bad ear, noise to good ear) then a CI could be considered, with appropriate counselling about expectations.

## **Preliminary outcomes of a multicenter study on the Minimally Invasive Ponto Surgery (MIPS) for bone-anchored hearing implants.**

Daniel Coelho MD, FACS<sup>1</sup>, Sam Daniel MDCM, FRCSC<sup>2</sup>, Walter Kutz MD<sup>3</sup>, Jack Wazen MD<sup>4</sup>, Harold Kim MD<sup>5</sup>, Benjamin Copeland MD<sup>6</sup>, Xabier Altuna MD, PhD, FEBEORL-HNS<sup>7</sup>, Albina Islam<sup>1</sup>, Nicole Amichetti PhD, MS<sup>8</sup>, [Aren Bezdjian PhD<sup>8</sup>](#), Maria Åberg Håkansson PhL, MSc<sup>9</sup>

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### **Abstract**

Objectives:

The success of a bone conduction hearing system (BAHS) depends on the performance of the bone-anchored implant, the corresponding abutment, and the sound processor. For the implant and abutment to be useful they need to provide reliable anchorage for the sound processor. This reliable anchorage can be impacted by varied intra- and postoperative factors. The primary objective is to

examine the rate of successful implant/abutment complexes providing a reliable anchor for the sound processor after placement using the Minimally Invasive Ponto Surgery (MIPS).

#### Method:

This prospective study (clinicaltrials.gov identifier NCT04279236) was conducted across seven centers in North America and Europe. Subjects participated in seven visits at predetermined timepoints over a follow-up period of 12 months. All patients underwent MIPS using implants and abutments from Oticon Medical AB (Askim, Sweden). The primary measure is the proportion of implant/abutment complexes that provide reliable anchorage for the sound processor three months after MIPS. Additional measures, such as intra- and postoperative complications, skin assessments, and patient reported outcomes such as the Abbreviated Profile of Hearing Aid Benefit (APHAB) are collected.

#### Results:

Preliminary data was obtained from 59 patients (19 males), mean age = 56 years (range: 23-88). Surgical duration was a mean of 10 minutes (SD  $\pm$  9) with the majority performed under local/monitored anesthesia care. The most commonly used implant (85 percent) was the 4mm BHX, and the most commonly used abutment was 9mm (51 percent). No severe intraoperative complications are reported, and postoperative follow-up suggests limited skin reactions with 97percent of assessments across visits classified as a Holger's Score 0 or 1. Patients fitted with their sound processor report, on average, 9-11 hours of daily use. Subjects also report a significant benefit from their BAHs as reflected in global APHAB scores (before BAHs= 55.05, after BAHs=25.98,  $p < 0.001$ ).

#### Conclusions:

Preliminary findings suggest that MIPS provides a stable and reliable implant/abutment complex with excellent surgical outcomes with no severe intra- or post operative complications. The relatively short procedure duration is well tolerated under local anesthesia suggesting that MIPS may be a feasible in a clinic or office setting.

## **MRI Considerations in Conversion to Active Bone Conduction Implants**

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University of Miami Miller School of Medicine, Miami, FL, USA

### **Abstract**

#### **Objectives:**

There is increased patient and provider interest in using active transcutaneous Bone Conduction Implants (BCIs) which offer the benefit of strong hearing performance with reduced soft tissue and skin complications. However, transcutaneous options often necessitate the use of a magnet to secure the processor which results in potential MRI compatibility issues along with increased imaging artifact. This

is an especially important consideration when considering conversion of an existing percutaneous BCI to a transcutaneous BCI. Here, we review MRI related complications over a 10 year period in both classes of implants. We also discuss MRI considerations in a case of a conversion from a percutaneous BCI to an active transcutaneous BCI.

### **Methods:**

The FDA Manufacturer and User Device Facility Experience (MAUDE) was searched using product codes “LXB” (for Bone Conduction Implants) and “PFO” (for Active Bone Conduction Implants). The medical device reports were searched for any language containing “MRI” or Magnetic resonance imaging. Patient events, reported symptoms, and any additional interventions were noted. Elective explants were excluded. MRI artifact dimensions (radii at the image level of maximal signal loss) were assessed in a patient implanted with active transcutaneous bone conduction implants at our institution (with and without metallic artifact reduction) and compared to MRI artifact with a transcutaneous BCI. Artifact dimensions were compared to the literature on auditory implant MRI artifacts (e.g. cochlear implants).

### **Results:**

6 MRI related events that met inclusion criteria were identified in the FDA MAUDA database from 2013-2023 for passive BCIs. 17 MRI related events that met inclusion criteria were reported for active transcutaneous BCIs (6 bone bridge, 11 OSIA). Events included auditory symptoms (6/17), magnet dislodgement (8/17), isolated pain at implant site (2/17) and device failure (1/17). Artifact size (measured as radii at the image level of maximal signal loss) was 9.3mm with a passive percutaneous BCI compared to 31.5mm for the active transcutaneous BCI.

### **Conclusion:**

Active transcutaneous BCIs offer the benefit of strong hearing performance with reduced soft tissue and skin complications when compared to percutaneous BCIs. MRI compatibility and artifacts are important considerations when considering conversion to an active transcutaneous BCI.

## **Preoperative planning and navigation for optimized placement of the Bonebridge**

Nils Kristian Prenzler PD Dr. med.<sup>1</sup>, Daniel Schurzig Dr.<sup>1,2</sup>, Thomas Lenarz Prof. Prof. h.c. Dr. med.<sup>1</sup>

<sup>1</sup>Hannover Medical School, Hannover, Germany. <sup>2</sup>Med-El Research Center, Hannover, Germany

### **Abstract**

Background: Transcutaneous bone conduction systems have proven themselves to be a reliable treatment option for patients with conductive or mixed hearing loss. The second generation of the MED-EL Bonebridge (BB) is such a device, and it could be shown that the system can even be implanted in young children. The only requirement is a sufficient bone thickness since the BB is fixated in the skull with 2 screws. Preoperative assessment of the bone thickness is hence essential especially in young

children. The most recent release of the preoperative planning software Otoplan enables the user to not only assess the bone thickness, but also to virtually implant the patient and export models of the implanted BB. Within this case series, these virtually implanted models were used to optimize implant placement during surgery.

**Materials & Methods:** Patients received 3 marker screws in the temporal bone prior to an intraoperative cone beam CT (CBCT) scan. Images were loaded into Otoplan to virtually define the optimal BB position and to export the corresponding model. Both the CBCT scan and the model were then loaded into an electromagnetic navigation system. The screws were used for exact registration of the system and the planned BB placement was projected onto the actual patient. BB implantation was then pursued accordingly and the marker screws were explanted.

**Results:** Good alignment of planned and actual BB position was achieved in all patients. The precise planning of the position of the device allowed safe placement even in pediatric cases where only small islands of sufficiently thick bone were present. The procedure simplified the implantation, particularly in cases of auditory canal atresia where relevant landmarks on the surface of the bone are missing.

**Conclusion:** Virtual BB implantations in Otoplan simplify optimal BB placement in comparison to assessments in standard DICOM viewers. The projection of the planned position onto the patient using navigation is a practical tool that can make the implantation more reliable and safer for the patients.

## **Subtemporalis Muscle Middle Cranial Fossa Bone-Island Craniotomy Technique for Placement for BONEBRIDGE Active Transcutaneous Bone-Conduction Implants**

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### **Abstract**

**Objective:** Placement of an active transcutaneous bone-conduction implant (BCI) requires drilling of a precise bone muscle middle cranial fossa bone-island craniotomy technique which simplifies the procedure and bed to accommodate the device and allow for fixation points to make appropriate contact with bone, which can be difficult even when lifts are used. We describe a subtemporalis obviates the need for lifts in securing the device.

**Study Design:** Prospective case series.

**Setting:** Tertiary academic medical center.

**Patients:** Seventeen patients underwent surgery for placement of 18 transcutaneous BCIs, 14 for conductive or mixed hearing loss (CMHL), and 4 for single-sided deafness (SSD).

**Interventions:** Surgical placement of a transcutaneous BCI with a bone-island craniotomy technique.

Main Outcome Measures: Functional gain in air-conduction thresholds, aided air-bone gap, frequency of need for lifts, minor and major complications.

Results: For the CMHL cohort, with the transcutaneous BCI in place there was a highly statistically significant mean functional gain of 35.4 dB HL (range 16.7 - 50.25, SD: 12.4) compared to the unaided condition ( $p < 0.0001$ , 95% CI: 36.6 - 51.6 dB HL). Lifts were not needed in any case. There was one minor complication requiring a second procedure in a patient who had previously received radiation and no major complications. There was no device loss or failure.

Conclusions: A subtemporalis muscle middle cranial fossa bone-island craniotomy technique eliminates the need for lifts and is a safe and effective method for placement of a transcutaneous BCI.

## **Clinical Performance, Audiological Outcomes, and Quality of Life of the Cochlear Osia<sup>®</sup> System**

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### **Abstract**

**Objective:** The Cochlear Osseointegrated Steady-State Implant Bone Anchored Hearing Device (Osia) is a surgically implanted titanium apparatus that utilizes a piezoelectric actuator under the skin to address conductive and mixed hearing loss as well as single-sided deafness. The purpose of this study is to examine the clinical, audiological, and quality-of-life outcomes in patients who underwent Osia implantation.

**Methods:** This is a retrospective study analyzing thirty adult patients (age 27-86) with conductive hearing loss (CHL), mixed hearing loss (MHL), or single-sided deafness (SSD) who were implanted with the Osia device from January 2020 to March 2023 at a single institution by the senior author. Preoperative speech score testing (CNC, AzBio in quiet, AzBio in noise) was performed in all subjects while unaided, wearing conventional air conduction hearing aids, and wearing a softband BAHA. These preoperative speech scores were then compared to post-implantation speech scores using paired t-test analysis to assess the degree of speech improvement. In order to analyze the quality of life after Osia implantation, each patient filled out the Glasgow Benefit Index (GBI) survey. The GBI is a series of 18 questions answered using a five-point Likert scale that addresses the changes in general health status, physical health status, psychosocial health status, and social support after a medical intervention.

**Results:** CHL, MHL, and SSD patients had significant improvement in hearing and speech recognition scores after Osia implantation compared to preoperative unaided hearing: CNC (14% vs 80%,  $p < 0.0001$ ), AzBio in Quiet (26% vs 94%,  $p < 0.0001$ ), and AzBio in Noise (36% vs 87%,  $p = 0.0001$ ). Preoperative speech scores using the softband BAHA were accurate predictors of post-implantation speech scores and can serve to determine surgical candidacy for the Osia. Post-implantation Glasgow Benefit Index patient

surveys demonstrated significant improvement in quality of life with patients scoring an average increase of +54.1 points in health satisfaction.

Conclusion: Adult patients with CHL, MHL, and SSD can receive significant improvement in speech recognition scores after implantation with the Osia device. This translates to improved quality of life, which was confirmed on the post-implantation Glasgow Benefit Index patient surveys.

## **Chronic Otitis Media: Treatment of Remnant Hearing Loss with Active Osseointegrated Implant.**

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### **Abstract**

Chronic otitis media (COM) is a long-term inflammation of the middle ear. Untreated COM leads to progressive degradation of the middle ear cavity and its structures, resulting in conductive and mixed hearing losses. Hearing impairment has a negative and significant impact on the health and quality of life of those affected and therefore it is important to treat it. Among the treatment strategies for optimal auditory rehabilitation in cases of COM, active bone conduction implants can be the most modern and effective solution. Objective: Description of the surgical process and audiological outcomes of the active bone conduction implant, the OSIA2 device, in patients with secondary hearing loss due to chronic otitis media. Method: This is a retrospective and descriptive study. Thirty-seven (37) subjects were enrolled in the investigation. All participants presented unilateral or bilateral COM. Demographic, surgical and audiological parameters were collected. Results: The mean age was 42.6 years, with 72% male. Mixed hearing loss was the most frequent type with 76% of the cases and in 54% the implants were on the right side. Two patients have received a bilateral implant, totalizing 39 surgeries. The mean surgery time was 47 minutes. The average skin thickness was 7 mm. Soft tissue thinning was performed in 4 subjects and (some degree of) bone polishing/removal in 11 subjects. A 4mm implant was used in 37 (95%) subjects and in 18% of these cases presented slight bleeding while the implant was being inserted. Inverted-J surgical incisions were used in 74%. In the postoperative period, 92% presented 0 or 1 on the TISA scale. One implant (2.5%) was removed after activation due to post-surgical infection. It was observed that pure tone audiometry in free field improved significantly after the implantation. The mean gain on PTA4 was 29.6dBHL and mean gain for 4000, 6000 and 8000 Hz was 16.7dBHL. Conclusion: The OSIA2 implantation in a representative group of patients with COM was feasible and demonstrated



great audiological outcomes and low complication rates. Advances in bone conduction technologies, may help reduce the negative impact of hearing loss caused by previous middle ear infections and surgeries.

## **Age-related changes in temporoparietal bone material properties influence stability of bone-anchored hearing implants**

Aren Bezdjian<sup>1,2</sup>, Bettina Willie<sup>3,1</sup>, Sam Daniel<sup>1</sup>, Nicholas Mikolajewicz<sup>1</sup>, Samer Salameh<sup>1</sup>

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### **Abstract**

The present study investigates the bio-mechanical properties of the calvaria acting as a host bone for implants for osseointegrated bone anchored hearing implants. The relationship between primary stability as determined by the Resonance Frequency Analysis tool, mechanical testing and calvaria characteristics in a human cadaveric model and in a prospective cohort series. 29 donated cadaveric skull bones were dissected to obtain the temporoparietal region where osseointegrated bone-anchored hearing implants (BAHIs) are placed. 29 BAHIs were placed in 13 pediatric (mean age: 10.6, range: 5 – 17 years) and 16 adult (mean age: 45.9, range: 18 – 70) patients. After placement, implant stability quotient was measured and repeated for precision testing. This stability quotient was correlated with mechanical testing outcomes (push-out test and fracture toughness tests). Finally, micro-CT imaging was performed in order to further investigate the properties of the host-bone receiving the implant. Donor characteristics indicate a relatively old average age of donor (mean = 76.8) as well as the presence of respiratory, cardiac, renal, neoplastic, and mixed comorbidities. Regression analysis of cadaveric implant properties showed a positive relationship between peak load and mean ISQ scores, between peak load and age of donor, and between crack growth toughness and age of donor. Furthermore, a negative relationship was found between crack initiation toughness and age of donor, and a non-linear relationship was observed between mean ISQ scores and age of donor. In our clinical cohort, an increase in stability quotient after implantation was seen similarly in pediatric and adult recipients. After 7 weeks of implantation, stability assessments regress to intra-operative scores in adults. However, a significant increase in stability quotients were found at the 3 to 6 weeks in the pediatric cohort. Our clinical data show that 1) for pediatric patients, a 6-week latency period prior to coupling the sound processor is warranted. 2) For adults, processor coupling could likely be performed as soon as skin around the abutment site has healed. Our cadaveric data demonstrate that the RFA system accurately predicts the force required to displace the implant, suggesting that the non-invasive ISQ method for measuring implant stability has clinical relevance.

## **An examination of microbiological and structural interactions between implants and tissues in a cohort of extracted bone-anchored hearing implants**

Marsel Ganeyev<sup>1,2</sup>, Furqan Ali Shah Prof. Dr.<sup>1</sup>, Margarita Trobos Prof. Dr.<sup>1</sup>, Tim Calon MD. Dr.<sup>3</sup>, Malou Hultcrantz Prof. Dr. MD.<sup>4</sup>, Howard Savage Jones MD.<sup>5</sup>, Peter Monksfield MD.<sup>6</sup>, Robert Stokroos MD.<sup>3</sup>, Peter Thomsen Prof. Dr.<sup>1</sup>, Anders Palmquist Prof. Dr.<sup>1</sup>, Martin Lars Johansson Dr.<sup>1,2</sup>

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## **Abstract**

### *Objectives*

Currently, most of the knowledge about bone conduction devices (BCDs) is based on subjective clinical measurements, while information about the biological events at the interface between tissues and the devices is inaccessible. Very few cases have analysed the implant and surrounding tissues, as controlled elective retrieval is rare. To gain a better understanding of the mechanisms for successful and unsuccessful outcomes, the present study has implemented multiple analytical and correlative strategies, allowing for a multiscale and multimodal investigation of the interface between tissue and BCDs in humans. Thus, the main objective of this study is to identify correlations between implant-tissue interactions and clinical patient data to further transfer it into translational research.

### *Methods*

We have previously concluded that systematic retrieval protocols can be implemented to efficiently preserve tissue for state-of-the-art analytical techniques, and by using a logistic scheme, we can correlate the clinical history of patients who have had their implants removed with the microbiological, cell biological, and morphological fingerprints obtained in the laboratory. Thus, in the established network, different sampling procedures and analytical tools were employed, including X-ray micro-computed tomography (micro-CT), histology/histomorphometry, fluorescence in situ hybridization (FISH), and microbiology.

### *Results*

To date, 13 electively retrieved BCDs have been investigated. Reasons for removal were chronic pain, recurrent infection and inflammation, or mechanical complications. Prior to retrieval, tissue samples were obtained for molecular and microbial analyses in some cases. After retrieval, tissue samples were subjected to micro-CT analysis and embedded for histological and ultrastructural analyses. In the present work, we combined the collected data for the biggest cohort of explanted BCDs, including their histological, microbiological, and structural profiles. Examples of the results from the different analyses will be presented, with an emphasis on correlating the clinical outcome with the analytical findings.

### *Conclusion*

By implementing a systematic retrieval network and a subsequent multi-scale analytical strategy, it is possible to improve the correlation between the clinical history of patients and the microbiology, cell

biology, and morphology of the tissues that interface with electively removed or failed bone conduction implants.

## **OSIA® 2 in conductive and mixed hearing loss: experience in a large number of patients.**

Francisco Gonzalez Eslait Dr.<sup>1,2</sup>, Leonardo Ordoñez Dr.<sup>3,4,5</sup>, José Agustin Caraballo Dr.<sup>6,7,8</sup>, Jorge Cabrera Dr.<sup>1,2</sup>, Rafael Jaramillo Dr.<sup>9</sup>

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### **Abstract**

Bone conduction hearing devices are widely used and indicated in cases of conductive or mixed hearing loss where the conventional hearing aids are not indicated or tolerated. The osseointegrated implant directly stimulates the bone with its piezoelectric transducer and is directed by an external sound processor. In June 2020, the Osia2 System was introduced in Colombia. Safety and effectiveness of the Osia-system have been proved by some research with small size sample (<100) but not in a large number of patients.

**Objective:** To describe the surgical results and clinical outcomes of an active osseointegrated implant system in a large sample (>500) of patients with conductive or mixed hearing loss.

**Method:** National multicenter, prospective, repeated measures study. Patients with conductive or mixed hearing loss were included. Surgical parameters, functional gain (GF) and self-perceived benefits (by COSI questionnaire) were evaluated. The GF was obtained by comparing the pre-surgical audiometric thresholds without assistance, with the postsurgical thresholds with the implanted system, in free-field.

**Results:** Between June 2020 and April 2023, 507 patients were included in the study with mean age of 28 years (min 5-max 82), being 60% adults (≥18 yrs). Most patients had a diagnosis of conductive hearing loss (67%) followed by mixed hearing loss (33%) and 59% devices were implanted in the right ear. Among the surgeries, 11% (58) corresponded to the conversion of other devices to piezoelectric. The surgeries lasted an average of 54 minutes and in 70% were used 4mm implant. Mean skin thickness was 5.5mm with only 4% soft tissue reduction. The mean GF in free field observed with 12 months from activation for conductive hearing loss, was 36dB and for mixed hearing loss, the observed GF was 43.6dB. Sixty-five percent referred would like to improve their ability to follow conversations in quiet or in background noise on COSI. Fifty-nine percent of this group stated that they could hear better or much better on these situations using the device.

**Thursday, September 7<sup>th</sup>, 2023**

**10:00-12:00 Bone Conduction Hearing Science 1**

**Middle Ear Optical Coherence Tomography (ME-OCT). What can this new modality add to our understanding of bone conducted sound?**

Robert Adamson PhD., Drew Hubley BSc, Cathy Creaser MSc. Aud C, Nael Shoman MD, David Peter Morris FRCS(ORLHNS)MD

Dalhousie University, Halifax, Nova Scotia, Canada

**Abstract**

Middle Ear Optical Coherence Tomography (ME-OCT) is an emerging, non-invasive imaging technology with an appealing set of capabilities for otological diagnostics. ME-OCT provides transtympanic 2D and 3D depth-resolved images of the middle ear space with high resolution and high contrast for both bone and soft tissues. At the same time, Doppler ME-OCT allows clinicians to transtympanically interrogate the frequency-resolved mobility of middle ear structures in response to a sound stimulus. ME-OCT has previously been shown to provide useful diagnostic information relevant to determining aetiology of conductive hearing loss, to assessing tympanic membrane pathologies, to detecting and differentiating various forms of otitis media and to assessing the results of middle ear surgery. To date, however, ME-OCT has not been applied to assessment of bone-conduction devices.

In this study we investigate the application of ME-OCT to the objective measurement of bone conduction-induced vibrations in the middle ear. In a population of N=10 healthy (normal-hearing) subjects we use ME-OCT to measure the vibratory response of the middle ear to contralateral bone stimulation at sites on the promontory, and along the ossicular chain at the lenticular process of the incus and at the umbo, reporting transfer function magnitudes and phases. In the same population we correlate objective measurements of bone-conduction induced middle ear vibrations to audiometric thresholds for the first time.

The implications of these results to the application of ME-OCT in the assessment of bone conduction implants is discussed.

**An fNIRS investigation of neuroplasticity following bone conduction amplification: A multiple single-case experimental approach.**

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## **Abstract**

**Objectives:** Percutaneous bone conduction device (BCD) users are an understudied group, with 1) unique etiologies (e.g., congenital ear malformation, chronic ear disease), and 2) complex medical pathways (i.e., other treatment pathways are sometimes attempted prior to BCD). Functional near infrared spectroscopy (fNIRS) is a particularly useful tool for studying brain activity of individuals with BCDs because 1) it is silent, 2) it has no contraindications for use, and 3) it is not distorted by the BCD implant(s). Here we implement a multiple single-case, longitudinal design to study the trajectory of neural reorganization following BCD fitting.

**Methods:** N = 8 participants (4 females; 5 new hearing aid users) having a mixed or conductive hearing loss were recruited to participate. Study design included 5 visits prior to receiving their BCD to establish a baseline; and 4 visits post fitting (i.e., seven days, one, three and six months). At one week post, measurements of 1) in-situ thresholds, 2) current fittings, and 3) verification of output with the skull simulator and surface microphone were taken. At seven days, one month, three months, and six months post-device delivery, participants completed speech-in-noise measures (with fNIRS) and patient-reported outcome questionnaires.

**Results:** We found changes in brain signal in the left and right superior temporal gyrus (STG) and dorsolateral prefrontal cortex (DLPFC) over the course of treatment, with marked changes particularly at seven days post treatment. In addition, we found increased connectivity between the left/right STG following treatment.

## **Relation between temporal bone 3D motion and intracochlear pressure under bone conduction**

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## **Abstract**

**Objectives:** The complex 3D motion pattern of the temporal bone, particularly the otic capsule, during bone conduction (BC) stimulation at different frequencies and its correlation with the intracochlear pressure difference across the cochlear partition are being investigated.

**Methods:** Measurements were conducted on six samples from three fresh frozen cadaver heads, with both medial and lateral surfaces of the temporal bone exposed. The skull bone was excited in the frequency range of 0.1-20 kHz using the actuator of a bone conduction hearing aid (BCHA), and stimulation was applied sequentially to the ipsilateral mastoid and classical BAHA location via transcutaneous and percutaneous coupling. The resulting 3D motions were monitored across various

areas, including the lateral and medial surfaces of the skull, the ipsilateral temporal bone, the skull base, and the promontory and stapes. Each test condition consisted of 130-200 measurement points with a pitch of approximately 5-10 mm. Additionally, intracochlear pressure in the scala tympani and scala vestibuli was measured using a custom-made intracochlear acoustic receiver.

Results: The area near (<1-2cm away) the otic capsule was mostly rigid up to 10 kHz, while the skull base deformed above 1-2 kHz, with an onset of deformation near the stimulation location already at 0.5 kHz. In addition, the 3D motion varied in direction and timing (phase) between regions of the skull. In contrast, the average motion magnitude across these regions was relatively similar (within 2-7dB). Above 1 kHz, the ratio between the differential intracochlear pressure and the promontory motion was relatively independent of coupling and stimulation location.

Conclusions: The bone around the otic capsule remains rigid up to significantly higher frequencies than the rest of the skull surface, resulting in primarily inertial loading of the cochlear fluid.

## **Music Perception in Bone Anchored Hearing Implant Users**

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### **Abstract**

**Objective:** Music is a highly complex acoustic stimulus in both spectral and temporal content. Accurate representation and delivery of high-fidelity information are essential for music perception. However, it is unclear how well bone-conducted hearing implants (BAHI) transmit music. The study objective is to establish music perception performance baselines for BAHI users and normal hearing (NH) listeners and compare outcomes between the cohorts.

**Methods:** A case-controlled, cross-sectional study was conducted among 18 BAHI users and 11 NH controls. Music perception was assessed via performance on seven major musical element tasks: pitch discrimination, melodic contour identification, rhythmic clocking, basic tempo discrimination, timbre identification, polyphonic pitch detection, and harmonic chord discrimination.

**Results:** BAHI users performed comparably well on all music perception tasks with their device compared to the unilateral condition with their better-hearing ear. BAHI performance was not statistically significantly different from NH listeners' performance. BAHI users performed just as well, if not better than NH listeners when using their control contralateral ear; there was no significant difference between the two groups except for the rhythmic timing (BAHI non-implanted ear 69% (95% CI: 62-75%); NH 56% (95% CI: 49-63%),  $p=0.02$ ) and basic tempo tasks (BAHI non-implanted ear 80% (95% CI: 65-95%); NH 75% (95% CI: 68-82%),  $p=0.03$ ).

Conclusions: This study represents the first comprehensive study of basic music perception performance in BAHl users. Our results demonstrate that BAHl users perform as well with their implanted ear as with their contralateral better-hearing ear and NH controls in the major elements of music perception.

## Correlation between promontory vibration and surface microphone measurement in bone conduction stimulation

Patrick Maas MSc<sup>1</sup>, Mohammad Ghoncheh PhD<sup>2</sup>, Stefan Stenfelt PhD<sup>3</sup>, [Hannes Maier PhD<sup>2,4</sup>](#)

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### Abstract

**Introduction:** Bone conduction (BC) hearing systems are used to treat patients with conductive and mixed hearing losses. A major challenge, however, is the objective determination of BC systems' output performance in transcutaneous BC systems. Surface microphone (SM) recordings offer a non-invasive alternative method for evaluation of BC vibrations. The objective of this study was to benchmark non-invasive SM recordings on the forehead against the gold standard of laser Doppler velocimetry (LDV) on the cochlear promontory (CP) for BC output evaluation in human cadaver heads.

**Materials and Methods:** A percutaneous bone anchored hearing systems (Ponto 3, Oticon Medical) was implanted on the intended placement at 55 mm superior-posterior to the ear canal opening in five (10 ears) human cadaveric heads. To determine the vibration response LDV (OFV 534, Polytec) measurements were performed on the ipsilateral cochlear promontory through a small triangular perforation of the ear drum. Radiating sound from the head was measured with the SM on the middle of the forehead. The SM has the structure of a stethoscope with a microphone placed in the apex of the cone and was calibrated before experiments against a probe microphone (ER7c, Etymotic) on the skin.

**Results:** The output performance of the bone conduction hearing system on the cochlear promontory and on the forehead could be determined at a minimum signal-to-noise-ratio of 12 dB. The average sound pressure levels recorded by the SM were between 40 and 100 dB SPL. A correlation and linear regression analysis suggests a linear relation between frequency compensated SPLs and velocity magnitudes on the ipsilateral cochlear promontory. An error distribution analysis indicates that CP vibration can be estimated non-invasively with an accuracy of ~10 dB standard deviation between 0,1 to 10 kHz by surface microphone measurements.

**Conclusions:** Our results suggest that CP vibrations measured invasively by LDV measurements can be estimated with non-invasive surface microphone measurements on the forehead with 10 dB accuracy for technical and diagnostic use in clinical settings.

# **Optical Coherence Tomography Vibrometry: Non-destructive intracochlear investigation of bone conduction in humans**

Lore Kerkhofs PhD Candidate, Alexander Geerardyn PhD Candidate, MD, Carmen Bartic Prof, Tristan Putzeys Postdoc, Nicolas Verhaert Prof, MD

KU Leuven, Leuven, Belgium

## **Abstract**

**Objective:** The objective was to investigate bone conduction (BC) in the human cochlea, for the first time, by using Optical Coherence Tomography (OCT) vibrometry. OCT vibrometry allows mapping of the velocity and phase of intra- and extracochlear structures in the cochlear proximate hook region. The aim is to overcome the limitations of previous methods, which either disrupt cochlear integrity or can only be applied to extracochlear structures, by providing non-destructive and detailed in-depth imaging through the round window membrane (RWM).

**Methods:** Bone-conduction stimulation was applied by placing a Radioear B71 at a superior-posterior position 4 cm away from the external ear canal of human cadaver heads. All heads displayed normal middle ear transfer function and underwent a mastoidectomy (N = 5 heads, 8 ears). OCT was used to investigate intracochlear anatomy through the RWM and subsequently, OCT vibrometry was used to record micro-anatomy displacements at frequencies 500, 750, 1000, 1500, 2000, 3000 & 4000 Hz.

**Results:** We were able to measure the velocity and phase of the extracochlear promontory, stapes, and RWM, but also on the intracochlear osseous spiral lamina (OSL) and basilar membrane (BM), without the need to alter the cochlear integrity (e.g. fenestration or blue lining). Using this technique, it should be emphasized that only measures in the proximate hook region could be performed, due to the thick otic capsule. The BC data of the visualized structures was comparable to the previously described results of e.g. Stenfelt et al. (2004), who investigated the velocity and phase of the RWM, OSL and BM using laser doppler vibrometry.

**Conclusion:** In this research, OCT vibrometry was used to investigate the displacements of both intra- and extracochlear structures stimulated by BC. By means of vOCT in human cadaver heads, we were able to measure velocity and phase without altering the cochlear integrity. Overall, the results suggest OCT vibrometry is a valuable tool for investigating BC stimulation on intracochlear structures of the human cochlea. Further studies are needed to confirm the accuracy of this method in a larger sample size and to compare it to other techniques used in BC mechanics.

## **Directionality and decomposition of the bone conduction mechanisms at the inner ear**

Simon Kersten<sup>1</sup>, Henning Taschke<sup>2</sup>, Michael Vorlaender<sup>1</sup>

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## Abstract

*Objectives:* The presented study aims at relating the different mechanisms at the inner ear during bone conduction hearing: the relative motion between the stapes footplate and the surrounding bone, inertial forces of the fluids due to a translation, and a pressure change due to a deformation of the inner ear.

*Methods:* Finite element simulations were conducted to characterize and compare the mechanisms. The model is based on an anatomical geometry within an osseous cuboid obtained from medical images that includes the three scalae, the vestibulum and the semicircular ducts. The model was validated against measured sound pressures, impedances, and velocity distributions of the cochlear partition reported in the literature. Sequentially, wave-like and translational excitations in three orthogonal directions were applied. These enable a decomposition of the responses for the wave-like motion into portions related to the fluid inertia and the deformation.

*Results:* The focus of the analysis is on the intracochlear sound pressures close to the cochlear base to investigate the macro-mechanical (fast-wave) effects. The decomposition exhibits a transition of the dominating mechanisms from the fluid inertia at lower frequencies to the deformation above. Both the pressure responses and the frequency range of the transition vary with the direction of the excitation. The inspection of the overall pressure distribution highlights this directionality to be related to the complex geometry of the inner ear.

*Conclusion:* The simulations add up to established considerations regarding the bone conduction mechanisms at the inner ear by giving insights into their frequency-dependent and directional relation. The observed directionality indicates that the variance found between bone conduction responses for different excitation positions and types (e.g., responses of bone conduction hearing aids, the perception of one's own voice) may partially be attributed to the inner ear mechanisms itself. A limitation of the study is the artificial excitation in three orthogonal directions. Therefore, it will be interesting to extend the investigations by applying the presented methods with the model integrated into a full head geometry.

## Vibration pattern of the cochlear bone with bone conduction stimulation

Stefan Stenfelt PhD<sup>1</sup>, Srdan Prodanovic PhD<sup>1</sup>, Mohammad Ghoncheh PhD<sup>2</sup>, Hannes Maier PhD<sup>2</sup>

<sup>1</sup>Linköping University, Linköping, Sweden. <sup>2</sup>Medical University Hannover, Hannover, Germany

## Abstract

**Objectives.** During bone conduction hearing, sound is transmitted through the structures of the head that ultimately results in a vibration of the basilar membrane in the cochlea. This basilar membrane vibration is believed to originate in the pressure difference between the cochlear scalae. Experimental, clinical, and numerical studies suggest that this pressure difference is mainly caused by the vibration of the cochlear bone. However, the contribution of the vibration modes to bone conduction hearing is not clarified.

**Methods.** The vibration of the bone surrounding the inner ear is categorized in three modes (translational, rotational, and compressional motion) with three spatial dimensions. The parameters were estimated from vibration measurements in five ears in human cadaver heads using a 3D laser Doppler vibrometer. The 3D vibrations at 15 to 20 positions on the bony surface of the cochlea were measured during bone conduction stimulation. The coordinates of the measurement points in relation to the cochlear geometry were obtained by high-resolution cone-beam CT. The nine parameters of the cochlear bony motion were estimated by a minimum square algorithm.

**Results.** The translational motion dominates for the entire frequency range investigated, 0.3 to 10 kHz. When the rotational and compressional components are computed as their magnitudes at the outer surface of the cochlea, they are approximately 20 dB below the translational motion at 0.3 kHz but increase with around 10 dB per decade. The rotation seems to be nearly 10 dB greater around the axis in-line with the internal auditory canal compared to the two other axes. The compression is significantly lower in the direction of the internal auditory canal compared to other directions. When the vibration parameters are converted to wave speed, the speed is around 100 m/s at 0.3 Hz increasing with frequency to 400 m/s at 2 kHz. At higher frequencies, the wave speed is around 500 m/s.

**Conclusion.** The measurement of bony vibrations at multiple points close to the cochlea revealed translational motion as dominant for frequencies up to 10 kHz. Estimates of wave speed and compression of the bone are similar to previous estimates in the literature.

## **Influence of the Skull Vault Contents on the Head Motion under Bone Conduction**

Christian von Mitzlaff MD<sup>1</sup>, Ivo Dobrev PhD<sup>2</sup>, Tahmine Farahmandi PhD<sup>2</sup>, Christof Roosli MD<sup>1</sup>

<sup>1</sup>Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Zurich, University of Zurich,, Zurich, Switzerland. <sup>2</sup>Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Zurich, University of Zurich,, Zürich, Switzerland

### **Abstract**

**Objectives:** Investigate the influence of the non-osseous intracranial contents (ICC) on the skull bone wave propagation, including dependence on stimulation location and coupling.

**Methods:** Three Thiel embalmed whole-head cadaver specimens were measured, while the skull contents were initially intact and later removed. The osseous pathways were activated sequentially via mastoid stimulation with a percutaneously implanted screw, a transcutaneous magnet, and a 5-Newton steel headband. The non-osseous pathways were activated through stimulation on the eye, neck, and dura using a 5-Newton steel headband. During each test condition, the skull bone response was monitored by a three-dimensional laser Doppler vibrometer system, which measured the 3D motions of the ipsi-, top, and contra-lateral skull surface at approximately 200 points with a pitch of about 15-20mm.

Results: The removal of the ICC had a limited effect on the average response of the skull surface, with only minor differences observed. The most significant changes were seen under dura stimulation. In a few cases, the sound wave modal pattern on the skull surface indicated a tendency towards sound wave elongation, resulting in an upshift ( $\sim 1/2$  octave) in the observed natural frequencies (4 - 10 kHz) with the removal of the ICC. This upshift in the transition frequency was also evident in the estimated deformation across the lateral surfaces of the temporal bones. These changes were consistent with the expected reduction in mass and damping due to the removal of ICC.

Conclusion: In general, the motion of the skull bone is only marginally influenced by intracranial contents, resulting in a limited reduction in its natural frequencies.

**Thursday, September 7<sup>th</sup>, 2023**

10:00-12:00 Audiologic Outcomes

## **Evaluation of a Super Powerful Bone-Anchored Hearing System and its users: A Retrospective Study**

Emma. M. Teunissen MD<sup>1</sup>, Herman J.W. Kok<sup>1</sup>, Arno M. Janssen PhD<sup>1</sup>, Myrthe K.S. Hol MD, PhD, Prof.<sup>1,2</sup>, Arjan J. Bosman PhD<sup>1</sup>

<sup>1</sup>Department of Otorhinolaryngology, Donders Center for Neurosciences, Radboud university medical centre, Nijmegen, Netherlands. <sup>2</sup>Department of Otorhinolaryngology/Head and Neck Surgery, Research School of Behavioural and Cognitive Neurosciences, Graduate School of Medical Sciences, University of Groningen, University Medical Center Groningen, Groningen, Netherlands

### **Abstract**

Title: Evaluation of a Super Powerful Bone-Anchored Hearing System and its users: A Retrospective Study

Objectives: To evaluate the Cochlear Baha 5 SuperPower (5SP) and its users.

Methods: All 82 adult patients with severe-to-profound hearing loss fitted with the Cochlear Baha 5SP as a percutaneous bone-anchored hearing system in our center between 2016 and 2019 were identified and included in this study for a general description. Patients with incomplete data or criteria known to influence the reliability of audiological tests (n=24) were excluded from the complete audiological analysis, resulting in 58 completely analyzed patients. Main outcome measures: Unaided and aided pure-tone thresholds and aided free-field speech perception in quiet.

Results: The median unaided air conduction (AC) PTA0.5-2kHz of the completely analyzed group was 75 dB; the median unaided AC PTA1-4kHz was 84 dB. For bone conduction and direct bone conduction (dBC), the median PTA0.5-2kHz was 52 and 47 dB, respectively. Based on the median dBC PTA0.5-2kHz,

one patient fell outside the 65 dB sensorineural hearing loss (SNHL) fitting range. When fitted with the superpower device, the median free-field speech reception threshold (SRT) shift was 34 dB, and the median speech perception score at 65 dB SPL was 80%.

## Conclusion

At least 25% of the studied patients has a cochlear implant indication based on (<70%) speech perception. Although this SNHL-severity, the superpower device provides them with a substantial benefit in hearing. Preferably, the device should be fitted body-worn to work optimally without too many feedback problems.

## 2-YEAR FOLLOW-UP WITH THE NEW BONEBRIDGE (BCI602)

Georg Sprinzl Prof.Dr., Philipp Schoerg MSc, Astrid Magele Phd Dr.

1University Clinic St. Poelten, Department of Otorhinolaryngology, Head & Neck Surgery, St. Poelten, Austria; and 2Karl Landsteiner Institute of Implantable Hearing Devices, St. Poelten, Austria., St.Poelten, Austria, Austria

### Abstract

**Background:** The Bonebridge (BCI601), is a remarkable prosthesis which has benefitted especially those with mild to moderate conductive and mixed hearing loss (C/MHL). Since it's market introduction in 2012, numerous studies with more than 500 patients have been published, pointing out the exceptionally good audiological results, high patient satisfaction and low complication rates. The latest generation, the BCI602 released in 2019/20, presented the same outcomes but is almost half the size of the previous generation.

**Objectives:** Our objective was to report our 24-months' follow-up (F/U) on audiological benefits and patient satisfaction with the new Bonebridge (BCI602).

**Results:** From the 12 implanted subjects aged between 2 and 63 years (mean 33.0±20.7) already completed their 24-months F/U. After 24-months of usage, the average daily wearing time ranged between 8 and 17 hours (mean 10.9±4.2). No complications were reported. The mean functional gain (FG) in the M/CHL cohort after 24-months was 25.1±9.7. The mean percentage of speech recognition in quiet for the M/CHL group at the 24-months F/U significantly improved from 10.0±17.61 to 82.5±8.8 after 24-months (P=0.0007). The mean speech reception threshold in quiet (SRT) and under various signal-to-noise ratios (SNR) improved significantly from 55.5±12.6 to 38.0±9.9 (P=0.0222) and from -0.6±3.8 to -3.8±1.7 (P=0.0160), respectively. The Quality-of-Life Questionnaires (AQoL8d) resulted in an improvement in health utility which was not significantly different compared to age- and sex matched normal hearing subjects (P=0.177). The hearing quality evaluated via the SSQ12, especially the dimension of spatial hearing improved significantly (P=0.0276).

**Conclusions:** These 24-months results of the new Bonebridge BCI602 showed significantly improved audiological performance (FG, WRS, SNR and SRT50). The new size and the introduction of self-drilling

screws resulted in no limitations during surgery. Objective audiological results were accompanied with high patient satisfaction, improved quality of life and increased wearing, hence hearing time. Therefore, the new device BCI602 can be highly recommended for the given indications and especially for difficult anatomical and surgical cases.

## **Objective measurement of audibility in patients using bone conduction devices – challenges and possible solutions.**

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### **Abstract**

**Objectives:** The purpose of this study is to evaluate and compare some different solutions of a skin microphone to objectively measure the audibility in order to the fitting of bone conduction (BC) devices.

**Methods:** First, different possibilities to obtain an objective and device independent method to estimate audibility of a specifically fitted BC device in a specific patient will be discussed. Also, the domain and unit in which audibility can be presented, such as force, SPL or other reference, will be discussed.

We have investigated different versions of a specially designed skin microphone and performed preclinical testing of prototypes including sensitivity, noise floor and by-pass of direct sound not passing the BC device. The audibility measured on the patients using the skin microphone was compared with the results obtained on a Skull simulator and on an artificial mastoid.

Some different methods of attachment of the skin microphone as well as sensitivity at different positions on the forehead will be discussed.

**Results:** It was found that by-pass of direct sound to the skin microphone, not passing the BC device, could be a limiting factor at low or higher frequencies. With sufficient direct sound shielding of the skin microphone, this limitation was considerably reduced and without influence on the accuracy of the audibility measurement.

Also, the noise floor of the skin microphone can be a limiting factor, but with proper choice of microphone this problem was reduced. The noise floor problem was further reduced and negligible when the signal level at hearing threshold, which is sometimes below the skin microphone noise floor, was measured after increasing the level to a supra threshold level at read-off and then calculating backwards.

The preferred skin microphone solution was tested and verified on a larger group of patients, and the results will be presented by Persson et al.

Conclusion: An appropriately shielded skin microphone placed in the center of the patient's forehead can be a valuable tool for verifying and optimizing the fitting of any type of BC device.

## **A Post-Market Interventional Cohort Study Evaluating The Clinical Efficacy Of The Osia™ 2 System In The US Market.**

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**Stephanie Bourn**

**Presenting Author Status (Student, Postdoc, etc.)**

Audiologist

### **Abstract**

**OBJECTIVE:** 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 piezoelectric actuator that is placed under the skin. A post-market interventional study demonstrated the clinical efficacy and safety of the Osia 2 System in a cohort of adult patient with conductive or mixed conductive hearing loss.

**METHODS:** Nationwide data obtained during a multi-center post-market interventional cohort study of the Cochlear™ Osia™ 2 System was reviewed. Twenty adult subjects were evaluated at 3 months post-operative between aided and unaided conditions. Audiometric testing included sound field pure tone average (PTA), speech in quiet with CNC monosyllabic words, and speech in noise testing with AzBio sentences in a fixed +5 signal-to-noise condition, and the adaptive QuickSIN. In addition to the hearing performance measures, subject reported outcomes on the Speech, Spatial and Qualities of Speech (SSQ 12) were obtained pre-treatment and again post treatment to measure subject reported improvement. Safety associated with implantation of the Osia 2 system was assessed by recording and summarizing device or procedure related adverse events.

**RESULTS:** Comparison of unaided to aided condition with the Osia 2 Implant system showed a positive treatment effect on measures of sound field thresholds, monosyllabic word scores, sentence scores in a fixed noise condition, and sentence scores in an adaptive noise condition. At the same time patient-reported questionnaires demonstrated 2 or more category points toward a more satisfied rating. This additional subject-reported self-assessment revealed a positive treatment effect consistent with results detailed above.

**CONCLUSION:** In a post-market interventional study, the Cochlear™ Osia™ 2 Implant System deployed in a cohort of 20 adult subjects revealed a safe and effective treatment of either conductive or mixed conductive hearing loss. The digital piezoelectric stimulation of this active auditory osseointegrated

implant delivers effective improvements in speech understanding necessary for engendering high-levels of subjective patient satisfaction.

## **Auditory implants anchored to bone: Increase of auditory benefits in users**

Francisco Gonzalez Dr.<sup>1,2</sup>, Juan Felipe Monroy Dr.<sup>3</sup>, Jose Agustin Caraballo Dr.<sup>4,5,6</sup>, Carlos Vélez Dr.<sup>7</sup>, Rodrigo Jacome Dr.<sup>8</sup>

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### **Abstract**

**Introduction:** Since the early 1980s the Baha® system has been available as a bone conduction device to rehabilitate patients with conductive, mixed hearing loss or unilateral deafness. The surgical technique used has remained substantially unchanged in recent years and has been shown to be safe and effective. A large range frequency of amplification and an improvement access to high-frequency hearing may be advantageous in impaired listeners who, generally, experience reduced access to high frequency speech cues and decreased speech perception abilities in competing noise. The most recent developments have focused on new technologies aimed at reducing size, improving signal processing, and optimizing patients' hearing performance.

**Objective:** To analyze the preliminary results of hearing benefit and expectations of patients using the Baha® 6 Max System.

**Method:** Prospective study with repeated measures. Patients who received a Baha® 6 max device are included. Collection of demographics, preoperative, surgical data, patient expectations and audiological follow-up at 3 and 12 months of use.

**Results:** Between September 2021 and April 2023, 120 participants were included, 61% adults, mean age of implantation 43.6 years (min 18 - max. 83) and 39% children mean age 10 years (min 4 - max. 18), 49% in right ear and 7.5% bilateral. 97% of the devices were Attract. The most frequent etiology is microtia-atresia in 58% of patients. 9% of patients were diagnosed with unilateral deafness, 54% conductive hearing loss and 37% mixed hearing loss. For conductive and mixed losses, the preoperative PTA4 was 74.2dB and postoperative with Baha 6 Max was 28.8dB ( $p < 0.001$ ), on average the discrimination of 100% pre-operative bisyllabics are obtained at 86.7dB and in the post-operative at 45.9% ( $p < 0.001$ ). Gain at high frequencies (4000Hz-8000Hz) was significantly higher than with other devices. The expectations of 59% patients before receiving the implant were focused on improving their conversations in noise and silence (36.4% and 22.7% respectively). One year after using the system, 81% report hearing better and 18% slightly better.

Conclusions: The Baha® 6 max technology provides patients with excellent auditory performance and allows them to achieve their expectations of improved speech comprehension in both silence and noise.

## **Benefits in speech understanding in noise with the Ponto 5 SuperPower and OpenSound Navigator in BCD recipients**

Thomas Wesarg Dr., Susan Arndt Prof. Dr.

Department of Otorhinolaryngology, Medical Center – University of Freiburg, Freiburg, Germany

### **Abstract**

Directional microphones have been shown to improve speech understanding when presenting speech from the front in spatially separated noise in bilaterally hearing-impaired BCD recipients. In 2022, the Ponto 5 SuperPower, a new BCD sound processor was launched. This processor features OpenSound Navigator, an adaptive and combined directionality and noise-reduction system that continuously analyzes and rebalances sound scenes to further improve speech understanding in noise. This study aims to compare speech understanding in noise in BCD recipients with bilateral hearing loss between the Ponto 5 SuperPower and the Ponto 3 SuperPower, and between their sound processing technologies Omnidirectional (Ponto 3 SP, Ponto 5 SP), Full Directional (Ponto 3 SP), and OpenSound Navigator (Ponto 5 SP).

Eight adult BCD recipients, four of them unilaterally and four bilaterally implanted with Ponto implants, who use the Ponto 3 SP, have been included. Seven recipients showed mixed and one recipient had sensorineural hearing loss. In each condition, the speech reception threshold (SRT) for OLSA sentences presented in speech-shaped noise was measured. Speech was presented from the front at an adaptive level, and noise from three loudspeakers at  $\pm 120$  and  $180$  degrees simultaneously at 65 dB SPL. Before testing, a Ponto 5 SP loaner device was fitted, and recipients were required to get used to listening with this device for 30 minutes.

There was a significant effect of sound processor and technology on SRT (Friedman's ANOVA:  $c2(3)=20.85$ ,  $p<0.001$ ). On group median, the BCD recipients showed a significantly lower (better) SRT with Ponto 5 SP compared to Ponto 3 SP both with Omnidirectional (Wilcoxon signed-rank test: DSRT=2.6 dB,  $p=0.008$ ), a better SRT with Ponto 5 SP with OpenSound Navigator versus Ponto 3 SP with Full Directional (DSRT=1.55 dB,  $p=0.148$ ), a significantly improved SRT with Ponto 5 SP with OpenSound Navigator versus Omnidirectional (DSRT=5.8 dB,  $p=0.008$ ), and a significantly better SRT with Ponto 3 SP with Full Directional versus Omnidirectional (DSRT=6.85 dB,  $p=0.008$ ).

In BCD recipients with mixed hearing loss, the application of the Ponto 5 SuperPower with the OpenSound Navigator improves speech understanding in spatially separated noise.



# Towards Determining Reference Equivalent Threshold Force Levels at Extended High Frequencies

Aaron Remenschneider MD, MPH, Jeffrey T Cheng PhD, John J Rosowski PhD, Barbara S Herrmann PhD  
Massachusetts Eye and Ear, Boston, MA, USA

## Abstract

**Objectives:** Measurement of bone conduction (BC) thresholds at extended high frequencies (EHF; above 8 kHz) is of clinical interest but is complicated by limitations in standard BC transducer output, a lack of calibration standards and sparse normative data. We used the Tascam HP-F200, a non-standard bone oscillator, and a new transducer calibration paradigm (Remenschneider et al, JASA 2022) to determine EHF force thresholds in dB re 1 $\mu$ N. We report BC thresholds in normal hearing volunteers and compare them to thresholds obtained using alternate BC transducers.

**Methods:** Volunteers with standard frequency (250-8kHz) air (AC) and bone (BC) conduction thresholds  $\leq 20$ dBHL were recruited for EHF AC and BC testing with Sennheiser HDA 200 earphones and a calibrated Tascam HP-F200, respectively. An audiologist obtained thresholds at EHF with AC in both ears and unilateral unmasked BC thresholds in the left or better hearing ear. Repeat testing of BC thresholds was performed following removal and replacement of the BC transducer in a subset of volunteers.

**Results:** Thirty-seven volunteers, mean age 31 years (range 18-47), met inclusion criteria. We identified the following median BC thresholds: 8kHz - 41 dB re 1 $\mu$ N, 9kHz - 40dB, 10kHz - 43dB, 11.2kHz - 40dB, 12.5kHz - 38 dB, 14kHz - 45dB, 16kHz - 61dB. The range of EHF BC thresholds between volunteers widened with frequency, but the  $\pm 25\%$  range around the median was generally 5-10dB. EHF thresholds were significantly lower in volunteers younger than 30 years of age compared with older volunteers. AC thresholds showed a similar increased variability with increasing frequency. In eleven volunteers, test-retest BC threshold variability was less than 2dB across EHF.

**Conclusions:** EHF BC thresholds can be consistently measured in dB re 1 $\mu$ N using the Tascam HP-F200. A range of EHF AC and BC thresholds are observed across individuals with normal standard frequency thresholds; these thresholds increase with age. Test-retest variability of EHF BC thresholds may be less than published reports of EHF AC threshold variability. Our EHF BC thresholds are consistent with historical reports in similar volunteers using an alternative BC transducer. Measurement of EHF BC thresholds may assist in differentiating etiologies of EHF hearing loss.

## Long-term follow-up in active transcutaneous bone conduction implants

Eleonor Koro MD<sup>1</sup>, Elenor Lundgren BSc<sup>1</sup>, Henrik Smeds MD, PhD<sup>2</sup>, Mimmi Werner MD, PhD<sup>1</sup>

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## **Abstract**

**Objective:** To evaluate long-term outcomes of active transcutaneous bone conduction implants (atBCIs) regarding safety, hearing and quality of life.

**Method:** It is a clinical study with retrospective medical record analysis combined with prospective audiometry and quality of life questionnaires, in three secondary to tertiary care hospitals. All subjects operated with an atBCI in three regions in Sweden were asked for informed consent. Indication for atBCI was single sided deafness (SSD) and conductive or mixed hearing loss (CMHL). The Main Outcome Measures were Pure tone and speech audiometry and Glasgow Benefit Inventory (GBI).

**Result:** Thirty-three subjects were included and 29 completed all parts. Total follow up-time was 124.1 subjects-years. Nineteen subjects had CMHL. In this group, the pure tone averages (PTA4) were 56.6 dB HL unaided and 29.6 dB HL aided, comparable with a functional gain of 26.0 dB HL. Effective gain (EG) was -12.7 dB HL. With bilateral hearing, the Word Recognition Scores in noise (WRS) were 36.5% unaided and 59.1% aided. Fourteen subjects had SSD or asymmetric hearing loss (AHL). In this group, the PTA4 were > 100 dB HL unaided, compared to 32.1 dB HL aided, with the contralateral ear blocked. EG was -9.1 dB HL. With bilateral hearing, the WRS were 53.2% unaided and 67.9% aided. The means of the total GBI scores were 31.7 for CMHL and 23.6 for SSD/AHL.

**Conclusion:** Few complications occurred during the study, and the atBCI is concluded to provide a safe and effective long-term hearing rehabilitation.

## **Moving beyond QALYs: A composite indicator to measure the benefit of hearing implants**

Michael Urban Dr. rer.nat, MBA, MSc, Annegret Hoch MSc, Thomas Dejaco PhD, Klaas Kiesewetter MA, Karin Rose-Eichberger Mag., Francesca Maria Scandurra PhD, Bettina Schlick PhD, Christina Schwarz Mag. MPH

MED-EL Medical Electronics, Innsbruck, Austria

## **Abstract**

**OBJECTIVES:** Generic measures of benefit such as quality-adjusted life years (QALYs) allow for an assessment of opportunity costs but fall short in adequately capturing all relevant dimensions of a specific technology's benefit. Looking at hearing implants, the goal of the presented study was to develop a new measure of benefit for hearing implants.

**METHODS:** The benefit of using a hearing implant encompasses multiple dimensions. In addition to improved hearing and speech understanding (audiological benefits), safety and reliability of the implant as well as subjective benefits such as wearing comfort are of relevance. Following methodical guidelines by OECD and JRC, this study aggregates empirical measures for these dimensions to a single composite indicator of hearing implant benefit. Different techniques for aggregation and imputation of missing data were used and compared.

**RESULTS:** As a starting point, transcutaneous bone conduction implants and two dimensions of benefit they bring for the patient are considered: audiological benefit and subjective benefit. Based on a systematic review of the literature and a meta-analysis, mean, and variation of aided speech understanding measured by word recognition score in quiet (audiological dimension) and daily wearing time in hours (subjective dimension) are computed. A multiplicative link between the two indicators is chosen, where both dimensions have the same weight. The indicator takes a value of 8,5 (aided WRS \* WT = 0,85 \* 10,0 hours) for piezoelectric implants and a value of 7,6 for electromagnetic implants (aided WRS \* WT = 0,86 \* 8,8 hours). The result can be interpreted as the “effective hours” a patient hears per day, where one effective hour equals one hour per day at perfect speech understanding (analogous to quality-adjusted life years where one QALY equals one year at perfect health). Due to this interpretation, the composite indicator is well suited to complement established measures of benefit in a cost-effectiveness analysis.

**CONCLUSIONS:** For hearing implants, composite indicators can be used to measure the multiple dimensions of benefit. Next, we will include more variables to measure subjective and audiological benefit and add safety (incidence adverse events) as a third dimension to measure patient benefit more comprehensively.

## **Active Transcutaneous Bone Conduction Implant in Children: Objective and Subjective Benefits**

Katarzyna Cywka PhD, Henryk Skarzynski Prof., PD, PhD, Bartłomiej Krol MD, Piotr Skarzynski Prof., MD, PhD

Institute of Physiology and Pathology of Hearing, Warsaw, Poland

### **Abstract**

The Bonebridge hearing implant is an active transcutaneous bone conduction implant suitable for various types of hearing loss. It was first launched in 2012 as the BCI 601, with a newer internal part (BCI 602) released in 2019. The BCI 602 can be used in patients previously excluded due to insufficient anatomical conditions, in patients with outer and middle ear congenital defects.

The purpose of this study is to evaluate the objective and subjective benefits of the new Bonebridge BCI 602 in children who have hearing impairment due to conductive or mixed hearing loss.

The study group included 22 children aged 8–18 years (mean age 14.7 years) with conductive or mixed hearing loss. All patients were implanted unilaterally with the new Bonebridge BCI 602 implant. PTA, speech recognition tests (in quiet and noise), and free-field audiometry were performed before and after implantation. Word recognition scores were evaluated using the Demenko and Pruszewicz Polish Monosyllabic Word Test, and speech reception thresholds in noise were assessed using the Polish Sentence Matrix Test. The subjective assessment of benefits was carried out using the APHAB (Abbreviated Profile of Hearing Aid Benefit) questionnaire.

After implantation of the BCI 602 all patients showed a statistically significant improvement in hearing and speech understanding. The mean word recognition score (WRS) changed from 12.1% before implantation to 87.3% after 6 months. Mean speech reception threshold (SRT) before implantation was +4.79 dB SNR and improved to -1.29 dB SNR after 6 months. All patients showed stable postoperative results. The APHAB questionnaire showed that difficulties in hearing decreased after implantation, with a statistically significant improvement in global score. Pre-operative scores (M = 35.7) were significantly worse than post-operative scores at 6 months (M = 25.7).

The present study confirms that the BCI 602 is an innovative and effective solution, especially for patients with conductive and mixed hearing loss due to anatomical ear defects. The BCI 602 system provides valuable and stable audiological and surgical benefits. Subjective assessment confirms the effectiveness of the BCI 602. The BCI 602 offers the same amplification as the BCI 601, but with a smaller size.

## **Objective measurement of audibility for patients with bone conduction devices using a new skin microphone.**

Ann-Charlotte Persson Certified Audiologist<sup>1,2</sup>, Bo Håkansson Professor<sup>3</sup>, Karl-Johan Fredén Jansson Postdoc<sup>3</sup>, Sabine Reinfeldt Associate professor<sup>3</sup>, Måns Eeg-Olofsson MD specialist in ENT and Audiology<sup>2</sup>

<sup>1</sup>Habilitation & Health, Hearing organization, Gothenburg, Västra Götalandsregionen, Sweden. <sup>2</sup>The Institute of Clinical Sciences, University of Gothenburg, Gothenburg, Västra Götalandsregionen, Sweden.

<sup>3</sup>Dept of Electrical Engineering, Chalmers University of Technology, Gothenburg, Västra Götalandsregionen, Sweden

### **Abstract**

**Objectives:** To evaluate a new method that can be used in a clinical setting to obtain an optimal hearing aid fitting for each individual with a bone conduction device.

**Methods:** In this study we have measured aided InSitu warble tone sound field thresholds and maximum power output (MPO) using an audiometer-driven loudspeaker, placed 1 meter in front of the patient, while simultaneously measuring the sound on the forehead using a skin microphone. A second loudspeaker, placed 30 cm from the hearing aid, provided a speech signal from a Callisto system which also was measured with the skin microphone. The patient's own bone conduction device was used in all tests and the spectrum of the skin microphone signal was measured with a signal analyser Agilent 35670.

The individual dynamic range was determined by subtracting the skin microphone signal at hearing thresholds from the corresponding signal at MPO level. Thereby, the dynamic range can be used to measure the audibility of the speech signal with the same skin microphone. Totally 29 subjects (15 males, 14 females) with different types and models of bone conduction devices (Baha, Ponto, BCI, Sentio, BoneBridge) were tested.

Results: The measurements show that the method with a skin microphone placed on the forehead can be used to measure the audibility of patients with bone conduction devices. The results have also been used to adjust the gain, so far, on one test subject to increase audibility. The increase in audibility in that subject was verified by speech tests, before and after the adjustment was carried out.

Conclusions: In conclusion, it was found that the proposed method with a skin microphone placed on the forehead can be used

- to determine the dynamic range of individual patients with any kind of bone conducted device,
- to measure the audibility of individually fitted bone conducted devices, and
- to detect and help to improve a poor fitting.

## **Auditory and Speech Performance in Patients following Cochlear™ Osia® System IMPLANTATION**

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<sup>1</sup>King Abdulaziz University Hospital, Jeddah, Saudi Arabia. <sup>2</sup>King Abdulaziz University Hospital, Jeddah, Saudi Arabia

### **Abstract**

Objective: The aim of the study was to evaluate the clinical audiological outcomes as well as patient satisfaction following implantation with Cochlear™ Osia® System .

Patients and Methods: This is a prospective clinical study. A total of 30 patients who underwent the Cochlear™ Osia® surgery were analyzed for audiological outcomes, surgical complications, and device-related postoperative follow-up. Speech recognition performance and hearing aided thresholds with and without device conditions were evaluated.

Results: The surgical procedure and healing were uneventful. Statistically significant improvements in audibility and speech understanding recorded for the test device compared with pre-operative unaided hearing. The overall mean for the gain in frequencies 0.5 to 4 kHz was 35 dB. On average, the speech discrimination scores improved by 36% post-operatively. Good soft tissue outcomes were reported, without major soft tissue related complications. At the end of the investigation, all patients continued to use and benefit from the device.

Conclusions: The Osia bone conduction device provides good outcomes in patients with conductive, mixed, or single-sided sensorineural hearing loss.

**Thursday, September 7<sup>th</sup>, 2023**

## 13:00-14:40 Plenary Session: Binaural Hearing

### **Functional benefits of bilateral bone anchored hearing devices (BAHD) for children and adults with conductive and mixed hearing losses**

René Gifford Ph.D., Hilary Davis Au.D.

Vanderbilt University Medical Center, Nashville, TN, USA

#### **Abstract**

Bilateral bone anchored hearing devices (BAHD) are not the standard recommendation for individuals with bilateral conductive and mixed hearing losses. One reason is that there is a misconception that transcranial attenuation for bone conduction is 0 dB; however, transcranial attenuation for bone conduction has been reported as high as 17 dB with considerable intersubject variability. Indeed, the high-frequency region is most affected by transcranial attenuation which holds the greatest potential for negatively impacting outcomes, especially for children acquiring speech and language. Thus, the purpose of this study was to investigate the impact of bilateral BAHD on speech recognition in complex environments, left/right discrimination, and subjective reports of speech, spatial, and qualities (SSQ) for children and adults with bilateral conductive and mixed hearing losses. Of the 11 study participants, 5 had bilaterally osseointegrated BAHD and 6 had unilateral BAHD for whom we fitted a BAHD on soft band for the non-implanted side. Speech recognition testing included an 8- loudspeaker surround system with restaurant noise originating from 7 loudspeakers and randomly roving target sentences in the frontal plane. We also assessed left/right discrimination in an anechoic chamber via adaptive minimum audible angle (MAA) with broadband noise bursts. For the roving speech condition, participants with bilateral osseointegrated BAHD exhibited similar speech recognition performance regardless of source azimuth whereas unilateral BAHD recipients using a second BAHD on soft band exhibited significantly better performance for speech directed to the osseointegrated BAHD, even in the “bilateral” BAHD condition. For left/right discrimination, we observed better spatial resolution with bilateral versus unilateral BAHD; however, bilateral benefit was noted for all participants. Finally, individuals with bilaterally osseointegrated BAHD rated all SSQ dimensions 1.8- to 2.4-points higher as compared to those with unilaterally osseointegrated BAHD. In summary, individuals with bilaterally osseointegrated BAHD exhibited 1) less impact of ear and source effects for randomly roving sentences in diffuse noise, 2) better left/right discrimination, and 3) higher SSQ scores as compared to unilateral BAHD conditions and participants. These preliminary results support a clinical recommendation of bilateral BAHD for adults and children with bilateral conductive and mixed hearing losses.

#### **Sound Localization with Bilateral Bone Conduction Devices**

Coosje J.I. Caspers MD, PhD<sup>1</sup>, Arno M. Janssen PhD<sup>1</sup>, Martijn J.H. Agterberg PhD<sup>1,2</sup>, Cor W.R.J. Cremers MD, PhD, Prof.<sup>1</sup>, Myrthe K.S. Hol MD, PhD, Prof.<sup>1,3</sup>

<sup>1</sup>Department of Otorhinolaryngology, Donders Center for Neurosciences, Radboud university medical center, Nijmegen, Netherlands. <sup>2</sup>Department of Biophysics, Donders Institute for Brain, Cognition and Behavior, Radboud University, Nijmegen, Netherlands. <sup>3</sup>Department of Otorhinolaryngology/Head and Neck Surgery, University Medical Center Groningen, Research School of Behavioral and Cognitive Neurosciences, Graduate School of Medical Sciences, University of Groningen, Groningen, Netherlands

## **Abstract**

Title: Sound localization with bilateral bone conduction devices

Objectives: To investigate sound localization in patients bilaterally fitted with bone conduction devices (BCDs). Additionally, clinically applicable methods to improve localization accuracy were explored.

Methods: Fifteen adults with bilaterally fitted percutaneous BCDs were included. At baseline, sound localization, (un)aided pure-tone thresholds, device use, speech, spatial and qualities of hearing scale (SSQ) and York hearing-related quality of life (YHRQL) questionnaire were measured. Settings to optimize sound localizing were added to the BCDs. At one month, sound localization was assessed again and localization was practiced with a series of sounds with visual feedback. At three months localization performance, device use and questionnaire scores were determined again.

Results: At baseline, one patient with congenital hearing loss demonstrated near excellent localization performance and four other patients (three with congenital hearing loss) localized sounds (quite) accurately. Seven patients with acquired hearing loss were able to lateralize sounds, i.e. identify whether sounds were coming from the left or right side, but could not localize sounds accurately. Three patients (one with congenital hearing loss) could not even lateralize sounds correctly. SSQ scores were significantly higher at three months. Localization performance, device use and YHRQL scores were not significantly different between visits.

Conclusion: In this study, the majority of experienced bilateral BCD users could lateralize sounds and one third was able to localize sounds (quite) accurately. The localization performance was robust and stable over time. Although SSQ scores were increased at the last visit, optimizing device settings and a short practice session did not improve sound localization.

## **Neural correlates of selective attention in adults with a simulated conductive hearing loss wearing BAHS**

Valentina Zapata-Rodriguez<sup>1</sup>, Emina Alickovic<sup>2</sup>, Lorenz Fiedler<sup>2</sup>, Mona El Hichou<sup>1</sup>, Marcus Holmberg<sup>3</sup>, Tove Rosenbom<sup>1</sup>, Federica Bianchi<sup>1</sup>

<sup>1</sup>Oticon Medical, Smørum, Denmark. <sup>2</sup>Eriksholm Research Centre, Snekkersten, Denmark. <sup>3</sup>Oticon Medical, Askim, Sweden

## **Abstract**

**Objectives:** Selective auditory attention involves actively listening to a desired sound source while ignoring unwanted sounds. It is a key aspect of successful speech understanding in complex sound environments. This study evaluates the feasibility of electroencephalography (EEG) measurements to reliably investigate neural correlates of selective attention for bone-anchored hearing system (BAHS) users. Additionally, this study evaluates listening effort during selective attention.

**Methods:** 24 normal hearing participants participated. A bilateral conductive hearing loss was simulated by blocking both ears with earplugs and earmuffs. Participants were fitted with a BAHS (Ponto 4, Oticon Medical AB) mounted on a softband.

EEG and pupil dilation were recorded during a task of selective attention. The participants were asked to attend to either a left or a right talker (male and female voice) that simultaneously presented newsclips in 16 talker babble noise.

Four conditions were tested: three aided conditions (bilateral BAHS, unilateral BAHS with attended speech at either the aided or unaided side), and one unaided normal hearing condition (no blocking).

**Results:** Artifacts induced by the BAHS sound processor in EEG were identified in 2 out of the 26 participants (7.7%). The neural representation of the attended speech was stronger in all the tested conditions compared to the unattended speech and background noise. The neural representations obtained for the bilateral and ipsilateral condition were not significantly different. In contrast, neural representations were significantly enhanced for the unaided condition, and significantly diminished for the contralateral condition.

Listening effort quantified via pupil dilation was significantly different between the bilateral and ipsilateral conditions, and the bilateral and contralateral conditions, while the bilateral and unaided conditions were not significantly different.

**Conclusion:** It is feasible to measure EEG in BAHS users and the artifacts produced by the sound processors do not have a significant effect on data quality. Neural representation of the attended speech was strongest for the unaided normal hearing condition, similar between bilateral and ipsilateral conditions, and weakest for the contralateral. This study is to our knowledge the first study objectively measuring selective attention in BAHS users, and it opens a whole new measurement approach to further optimizing outcomes.

## **Inter-aural separation during hearing by bilateral bone conduction stimulation**

Sudeep Surendran PhD, [Stefan Stenfelt Phd](#)

Linköping University, Linköping, Sweden

### **Abstract**

**Objectives.** Cross-head transmission inherent in bone conduction hearing is one of the most important factors that limit the performance of bone conducted binaural hearing. Even if the inter-aural level



difference with bone conduction stimulation has been well investigated, the inter-aural time delay, especially at low frequencies, is essentially unknown.

**Methods.** The inter-aural level, phase, and time differences were estimated in 20 participants with normal hearing using a cancellation procedure. A bone conducted tone or tone burst provided at one mastoid was cancelled by a second bone conducted sound at the opposite mastoid by adjusting the level and phase or time delay. This was done for one-third octave frequencies between 250 Hz and 4000 Hz.

**Results.** The contribution to hearing from contralateral stimulation was found to be the lowest around 2 kHz and the highest around 1 kHz. The inter-aural phase difference from stationary signal cancellation showed an overall increase with frequency starting at around no phase difference ( $35^\circ$ ) at 250 Hz to reach  $607^\circ$  at 4 kHz. The inter-aural time difference was very low ( $61 \mu\text{s}$ ) at 250 Hz and increased to 1.1 ms at 800 Hz before falling to 0.6 ms at 4 kHz.

**Conclusion.** The relatively short time difference at the lowest frequencies suggests that the auditory system has difficulties resolving the temporal cues at those frequencies important for correct binaural processing. At frequencies of 500 Hz and above, the time delays are longer or in the same range as the maximum inter-aural time delay with air conduction stimulation. This indicates that the auditory system should be able to use binaural cues with bilaterally applied bone conducted sound at frequencies of 500 Hz and above.

## **Superior sound localisation with bilateral middle ear implants**

Martijn Agterberg, Prof. Emmanuel Mylanus, Dr. Froukje Cals

Radboud University Medical Center, Nijmegen, Netherlands

### **Abstract**

Potentially bilateral application of hearing implants can result in optimal sound localization behavior. However, many studies demonstrate lateralization of sounds for patients with conductive/mixed hearing loss, implanted with bone-conduction devices (BCDs), and for patients with sensorineural hearing loss implanted with cochlear implants. We present an overview of localization abilities of patients with bilateral conductive hearing loss. We present typical individual examples and refer to the related papers. We demonstrate promising localization abilities of a patient implanted with bilateral middle-ear implants. We suggest that implantation with devices stimulating only the ipsilateral cochlea in patients with pure conductive hearing loss can result in optimal sound localization abilities and that this topic needs further investigation. When the cochlea is intact, isolated bilateral stimulation seems to result in accurate processing of binaural cues.

**Thursday, September 7<sup>th</sup>, 2023**

## 15:00-17:00 Surgical Outcomes and Considerations 2

### **Evaluation of osseointegration of percutaneous bone anchored hearing implants as a function of surgical technique**

Anne-Line MUTSCHLER MD<sup>1</sup>, Arnaud DEVEZE MD,PhD<sup>2</sup>, Cécile PARIETTI-WINKLER MD, PhD<sup>3</sup>, Anne CHARPIOT MD, PHD<sup>4</sup>, Caroline GUIGOU MD<sup>5</sup>, Xavier-Nicolas BONNE MD, PhD<sup>6</sup>, Xavier DUBERNARD MD, PhD<sup>7</sup>, Mary DAVAL MD<sup>8</sup>, Laurent TAVERNIER MD, PhD<sup>9</sup>

<sup>1</sup>Department of ORL, University Hospital Besançon, Besançon, France. <sup>2</sup>Ear Institute, Clairval Hospital, Ramsay Santé, Marseille, France. <sup>3</sup>Department of ORL, Nancy University Hospital, Nancy, France.

<sup>4</sup>Department of ORL, Hautepierre Academic Hospital, Strasbourg, France. <sup>5</sup>Department of ORL, Dijon University Hospital, Dijon, France. <sup>6</sup>Ear Institute, Le Bois Hospital, Ramsay Sante, Lille, France.

<sup>7</sup>Department of ORL, Reims University Hospital, Reims, France. <sup>8</sup>Department of ORL, Hopital Rotschild, Paris, France. <sup>9</sup>Department of ORL, Besançon University Hospital, Besançon, France

#### **Abstract**

**Introduction:** Osseointegration describes the phenomenon by which an implant is embedded in the structure of the bone during healing, so as to achieve strong and long-lasting stability of the implant in the bone. Several studies suggest that bone anchored hearing implants are less well osseointegrated with minimally invasive (MI) techniques compared to linear incision (LI) techniques without significant results. The main objective of our study is to compare osseointegration between these 2 techniques.

**Material and method:** We conducted a retrospective, multicentre study involving 4 centres. Two groups were constituted according to the surgical technique used, MI or IL. The primary endpoint was extrusion within 180 days of implant placement, excluding trauma. This extrusion rate was compared between the 2 groups.

**Results:** We included 54 patients in the MI group and 71 in the IL group. The rate of extrusion within 180 days of implant placement and outside the context of trauma was 30.6% in the MI group and 0% in the IL group ( $p < 0.001$ ). The survival curves compared between the 2 groups also showed a significantly lower implant survival rate in the MI group ( $p < 0.001$ ).

**Conclusion:** The extrusion rate in our study was significantly higher in the MI group compared to the IL group. We believe that for patients whose terrain suggests difficulties in osseointegration, IL techniques should be preferred to MI techniques. However, studies with a higher level of evidence are needed to corroborate our results.

### **Long-term follow-up of a wide diameter bone anchored hearing implant: 10-year experience on stability, survival and tolerability of an implant loaded at 3 weeks post-surgery**

Emma M. Teunissen MD<sup>1</sup>, Coosje J.I. Caspers MD, PhD<sup>1</sup>, Maarten A. Vijverberg MD<sup>1</sup>, Emmanuel A.M. Mylanus MD, PhD, Prof.<sup>1</sup>, Myrthe K.S. Hol MD, PhD, Prof.<sup>1,2</sup>

<sup>1</sup>Department of Otorhinolaryngology, Donders Center for Neurosciences, Radboud university medical centre, Nijmegen, Netherlands. <sup>2</sup>2. Department of Otorhinolaryngology/Head and Neck Surgery, Research School of Behavioural and Cognitive Neurosciences, Graduate School of Medical Sciences, University of Groningen, University Medical Center Groningen, Groningen, Netherlands

## **Abstract**

Title: Long-term follow-up of a wide diameter bone anchored hearing implant: 10-year experience on stability, survival and tolerability of an implant loaded at 3 weeks post-surgery

Objectives: To compare stability, survival, and soft tissue reactions between a wide-diameter (test) and previous generation small diameter (control) bone-anchored hearing implant and to ascertain the safety of loading the test implant three weeks post-surgery, at a long-term follow-up of 10 years.

Methods: This study is a continuation of two previously completed, multicenter, randomized, controlled trials and consisted of 1-2 additional follow-up visits until ten years post-surgery. Fifty-one of the 72 participants from the previous trials were included. Patients received a test or control implant. All control implants were loaded six weeks post-surgery (group A). Test implants were loaded three (group B) or six weeks (group C) post-surgery.

Results: The test implant showed significantly higher implant stability quotient (ISQ) values than the control implant throughout the 10-years follow-up. At ten years, the mean ISQ-high values for both implants were higher than at the first follow-up visit. No significant differences in change of ISQ-high from baseline to ten years were noticed between both implants and loading groups. Soft tissue reactions were rarely seen. At 10-years follow-up, no patients presented with adverse soft tissue reactions. Excluding explantations, the implant survival rate was 78.6% (group A), 100% (group B) and 90.0% (group C).

Conclusion: The test implant showed superior mean ISQ values and significantly better implant survival throughout 10-years follow-up. In addition, the current study concludes that it is safe to load the test implant at three weeks post-surgery, as long-term results show high ISQ values and good implant survival.

## **PETROSECTOMY AND BONE CONDUCTION IMPLANT, AN ALTERNATIVE FOR EARLY AUDITORY REHABILITATION IN PATIENTS WITH COM**

Rafael Jaramillo, Bertha Villegas Audiologist

Caldas Hospital SES, Manizales, Caldas, Colombia

**Rafael Jaramillo**

**Presenting Author Status (Student, Postdoc, etc.)**

Otologist from Department of Otorhinolaryngology Caldas Hospital, Manizales, Colombia.

## **Abstract**

Hearing loss greater than 30dB is expected to be found in 3 out of every 10 patients with chronic otitis media (COM), even after mastoidectomy and bone chain reconstruction. Sometimes multiple surgeries are performed before adequate hearing rehabilitation. Petrosectomy has been performed in multiple indications, this being a procedure reserved for patients with poor cochlear reserve. Probably due to the complexity of the surgical technique that requires complete drilling of the temporal bone, obliteration of the eustachian tube and the mastoid cavity with fat grafts, as well as blind sac closure of the external canal ear. Modifications in the surgical technique make this a less complex and shorter procedure. Mastoidectomy on demand with drilling only of diseased mastoid cells, obliteration of the tube without the need to leave grafts in the cavity and blind sac closure is performed in two layers to prevent skin migration.

**Objective:** To describe the surgical procedures and audiological results for the BCHD in a group of patients with COM who underwent a modified petrosectomy.

**Results:** Eighty-nine modified petrosectomy has been performed in patients with COM. Of the 89 patients with petrosectomy, 2 presented recanalization of the external auditory canal, 5 cholesteatomas detected at 6 months with magnetic resonance imaging (MRI), but of those 5 only two found residual cholesteatoma in the cavity during revision surgery, and two local infections controlled with intravenous antibiotics. Sixteen patients with bone threshold <30dB, were taken 6 months later to hearing rehabilitation with bone conduction implants. Ten patients were implanted with Osia System and six with Baha Attract. The Glasgow Benefit Inventory (GBI) and the Chronic Otitis Media Outcome Test (COMOT-15) were also performed, observing an improvement in quality of life.

**Conclusion:** Modified petrosectomy is a safe procedure, which allows early rehabilitation of patients with chronic otitis media in whom mastoidectomy with reconstruction of the chain and conventional hearing aids do not provide an acoustic solution.

## **Surgical site comparison of two active implantable transcutaneous bone conduction hearing aid generations**

Benjamin Loader MD

Klinik Landstraße, Vienna, Austria

**Benjamin Loader**

**Presenting Author Status (Student, Postdoc, etc.)**

Author, Professor

## **Abstract**

**Purpose:** The study aimed to evaluate surgical placement, audiological benefit and safety of two transcutaneous implantable bone conduction hearing aid generations.

**Introduction:** Bone conduction implants (BCIs) are indicated for people with conductive and mild to moderate combined hearing loss. The first active transcutaneous BCI, the BCI601 (MED-EL, Innsbruck, Austria 2012), utilizes a floating mass transducer (FMT) of 8.4mm depth. The BCI602 (2019), reduced the required depth to 4.5mm, with a slightly wider implant bed. Primarily, both fully implantable devices are implanted in the mastoid, yet anatomical considerations due to previous surgery or disease, may necessitate implantation at a secondary site, such the retrosigmoidal skull.

**Methods:** This retrospective dual center (Wiener Gesundheitsverbund, Vienna, Austria), chart review analyzed BCI601 and BCI602 surgeries respectively (03/2015 - 04/2023). Surgical site of implantation and complication data was recorded as mastoidal, retrosigmoidal and temporal. Audiological outcomes investigated were pre- and post-operative sound field audiometry and word recognition score.

**Results:** A total of 62 subjects were implanted. 26 received a BCI601 (13w, 13m, Mean Age: 43±19) and 36 a BCI602 (21w, 15m, Mean Age: 40±15 years). Two bilateral BCI601 users were implanted, and six patients received the BCI602 on both sides. Placement of the BCI601 was in the sinodural angle in 17 cases (65%), while 8 (31%) subjects required a retrosigmoidal placement. 1 BCI601 was placed above the temporal line. 24 (67%) BCI602 implants were placed in the mastoid, 11 retrosigmoidally (31%) and 1 above the temporal line. All subjects of both device generations reported a significantly improved speech perception ( $P<0.05$ ), with no statistical significance between the groups. Two BCI601 have been explanted since 2015 while 1 surgical wound revision was performed in the BCI602 cohort, without implant loss. No significant differences between the two device generations in any of the audiological outcomes nor in long-term safety aspects were found.

**Conclusion:** Both BCI601 and BCI602 significantly improve word recognition scores, with a low risk of major complications postoperatively. The BCI602 required a reduced drilling depth, which allowed mastoidal placement in thin cortical mastoids, however the distribution of implant location remained constant, with similarly low complication rates.

## **Long-term Clinical Outcomes of Percutaneous Implants for Bone Conduction Devices: Prospective Five Year Evaluation of Different Implant Designs and Surgical Techniques**

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## **Abstract**

**Title:** Long-term clinical outcomes of percutaneous implants for bone conduction devices: Prospective five year evaluation of different implant designs and surgical techniques

**Objectives:** To evaluate long-term outcomes on implant stability and soft tissue complications between a wide diameter 4.5-mm implant versus small diameter 3.75-mm implant and the linear incision technique with tissue preservation (LIT-TP) versus linear incision technique with tissue reduction (LIT-TR).

**Methods:** Single follow-up visit of two previously completed clinical studies. A total of 68 patients were included. These patients either received a 4.5-mm-wide or 3.75-mm-wide implant and were operated using either the LIT-TP or LIT-TR technique.

**Results:** No significant differences between the 4.5-mm-wide and 3.75-mm-wide implant were observed in implant- (97.4% versus 95.0%) or abutment survival (94.8% vs 95%). For the LIT-TP versus LIT-TR, no significant differences between implant (96.0% vs 100%) or abutment survival (92.0% vs 92.0%) were seen. Implant stability quotient (ISQ) from surgery increased significantly over time for both implants and both surgical techniques. During the 5-year follow-up of patients operated using LIT-TR, adverse Holgers scores (Holgers $\geq$  2) were observed in 15.2% of the 4.5-mm-wide implants and in 23.5% of the 3.75-mm-wide implants ( $p=0.72$ ). When comparing Holgers scores between LIT-TR and LIT-TP, adverse Holgers were reported in 10.5% versus 30.0% ( $p=0.27$ ).

**Conclusion:** At 5-year follow-up, high implant and abutment survival rates were observed for both implant designs. No significant differences were observed between surgical techniques. It can be concluded that both the 4.5-mm-wide implant and the LIT-TP procedure are safe in the long-term.

## **Removal of Prior Generation BAHAs and Staged Implantation with Active Transcutaneous Devices: Surgical Outcomes and Approach to Management**

Evan Tooker MS, Mana Espahbodi MD, Allison Durham MD, Richard Gurgel MD, MSCI, [Neil Patel MD](#)

University of Utah, Salt Lake City, UT, USA

## **Abstract**

**Objective:** To evaluate surgical and clinical outcomes of patients following prior generation bone-anchored hearing aid (BAHA) explantation and subsequent transcutaneous active bone conduction hearing device (BCHD) implantation and to provide guidance regarding staging of surgery and adjunctive procedures.

**Methods:** Data collection included demographics, hearing loss etiology, medical history, previous percutaneous BAHA complications, novel device implant complications, device revisions, and postoperative follow-up.

Results: A total of 6 subjects with older generation BAHA devices underwent explantation and subsequent implantation with a MED-EL BONEBRIDGE(TM) (67%, 4/6) or Cochlear(TM) Osia® (33%, 2/6) device as adults. The primary reason for BAHA explant was pain (83%, 5/6) secondary to infection and skin overgrowth and one obsolete device case, secondary to discontinuation of their processor. Mean time between BAHA removal and BCHD staged implant was 6.8 months (IQR, 2.2-11.4 months). Two subjects developed complications following their BCHD implantation which warrant discussion. The first subject underwent BAHA abutment removal in clinic. She had a persistent wound overlying the osseointegrated screw requiring removal and temporalis rotational flap. She underwent a staged Osia implantation, but ultimately developed partial dehiscence of the skin and soft tissue, necessitating further surgical intervention. The second subject experienced an infection after BONEBRIDGE implantation, necessitating washout and treatment with intravenous antibiotics. The patient subsequently developed device failure, requiring explantation and implantation of a new device. The authors hypothesize that the BONEBRIDGE infection case may have been due to the short time frame (32 days) between BAHA explant and BONEBRIDGE implantation. An algorithm for how to approach explantation and implantation of a novel BCHD is proposed. Ultimately, all patients who transitioned from BAHA to a novel device are active users with good hearing benefit.

Conclusion: The transition from a BAHA to a novel transcutaneous device is nuanced. Staged BAHA explantation and novel BCHD implantation with sufficient time for wound healing is vital. Adjunctive procedures to augment soft tissue in cases of prior skin attenuation either from passive magnetic devices or dermatome technique BAHA implantations may be required to avoid complications with larger internal devices.

## **Outcomes and experience of a new one-step drill system (MONO) for bone anchored hearing procedures – results from a multicentre study of 51 patients**

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### **Abstract**

Objectives: During the last 15 years, surgical techniques for installation of bone anchored hearing systems (BAHS) have continuously improved, both considering surgical invasiveness and clinical benefits for the patient. The latest advancement, MONO, was introduced in 2021. With a novel drill design, the osteotomy is created using only one single drill step, thus bypassing the risk of drill misalignment. This study aims to follow patients undergoing BAHS-treatment using the MONO procedure for 12 months, to confirm safeness and effectiveness of the procedure.

Methods: A prospective multicentre study at seven centres in the UK, the Netherlands, Denmark and Sweden included 51 adult patients (52 implants) implanted using the MONO procedure (clinicaltrials.gov identifier NCT04606823). Clinical outcomes, performance, and quality of life-improvement were monitored at 9 days, 5 weeks, 3 months (primary endpoint), 6- and 12 months.

Results: The patients had a mean age of 57 years (range: 19–81), with 49% being over 65 years. Surgical time was short;  $10 \pm 5$  minutes with local anaesthesia used in 69% of cases. After 3 months, 94.2% (CI: 84.4–98.0) of the implant/abutment complexes were stable and in use. There were no or minor skin reactions in 97.6% of all post-operative visits, with adverse skin reaction (Holgers = 2) seen in 4 patients. There were three implant failures; one traumatic failure at around 7 weeks and 2 spontaneous failures, one of which was surgery-related due to incomplete insertion of the fixture. Surgery was rated as quick and easy, with efficient bone removal. Firm initial pressure of the drill against the bone is recommended. Using the Glasgow Benefit Inventory (GBI), 96% of the patients experienced an overall improvement in quality of life 3 months after surgery.

Conclusion: The 3-month data confirms MONO as a safe and efficient procedure, resulting in excellent skin outcomes, largely improved quality-of-life for the patients, and an implant survival of 94%. Twelve-month results will be available in May 2023 for presentation at the OSSEO meeting.

## **Tissue classification following bone anchored hearing implant surgery: A machine learning approach to monitoring skin response**

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<sup>4</sup>Department of Computing Science, Edmonton, AB, Canada. <sup>5</sup>Institute for Reconstructive Sciences in Medicine, Edmonton, AB, Canada

### **Abstract**

Objectives. Here, we aim to 1) expand the available evidence for the use of machine learning techniques for soft tissue classification following bone-anchored implantation and 2) discuss the implications of such approaches towards the development of classification apps to aid in tissue monitoring.

The application of machine learning techniques in the soft tissue literature has become a large field of study. One of the most commonly reported outcomes following bone conduction abutment surgery is soft tissue health. Unfortunately, the classification of tissue around the abutment as healthy vs. not healthy is a subjective process even though such decisions can have significant implications for treatment (i.e., topical treatment vs. surgical revision).

Methods. We built and tested a Convolutional Neural Network (CNN) Model for the classification of tissues that were rated using the traffic light system, as 'green' (i.e., healthy), 'yellow' (i.e., not healthy)



minor), and 'red' (i.e., not healthy severe). Representative image samples were gathered from the Institute for Reconstructive Sciences in Medicine. The image samples were cropped, zoomed and normalized. Feature extraction was then implemented and used as the input to train an advanced CNN model.

Results: Image classification for the various models, namely, 1) healthy ('green') vs. not healthy ('yellow' and 'red') model, 2) healthy ('green') vs. not healthy ('yellow') model, 3) not healthy ('yellow') vs. not healthy ('red') model were all trained and tested. Validation accuracies and losses were all within reasonable ranges (ranging from 72% - 89%) and typical with the current literature. Details about the strengths and limits of each model will be discussed.

Conclusions: Tissue health and its assessment is an ongoing challenge for percutaneous bone conduction users. If machine learning can aid in the classification of tissue health, this would have significant implications for patients, clinicians and surgeons. Here we discuss how machine learning can be applied to tissue classification as a potential technological aid in the coming years.

## **EARLY SURGICAL AND AUDIOLOGIC OUTCOMES OF THE OSIA, TRANSCUTANEOUS BONE CONDUCTION HEARING DEVICE IN A PAEDIATRIC COHORT**

Rebecca Harrison, Anne Markey, Nathan Walker, Laura Strachan, Sujata De, [Sunil Sharma](#)

Alder Hey Children's Hospital, Liverpool, United Kingdom

### **Abstract**

Objectives: Traditional bone anchored hearings aids have been used successfully in paediatric patients since the 1990s. The Osia is a new transcutaneous bone conduction hearing device which has been accepted for use in children over the age of 5 years in the United Kingdom. Our aim was to review the early outcomes from implantation with the Osia device in our paediatric population.

Methods: A retrospective case review was performed investigating the audiological and surgical outcomes of Osia insertion amongst paediatric patients at our tertiary centre between March 2022 and January 2023. Notes were reviewed for age at insertion, co-morbidities, surgical placement, complications and audiological outcomes.

Results: Between March 2022 and January 2023 10 transcutaneous Osia devices were inserted in 7 patients, median age 10 years (range 7-12 years). Co-morbidities included Crouzon, Goldenhar and Down's syndrome. Preliminary audiological testing increased mean CHILD score from 5.43 (range 4.6-6.1) pre-operatively to 7.0 (range 6.5-7.4) post-operatively. Due to patient co-morbidities the Osia has been inserted into different sites within the skull with no complications. There were no post-operative complications in our cohort.

Conclusion: We have found the Osia to be safely inserted in paediatric patients with no long term complications. Preliminary tests have shown that it improves audiological outcomes and is comfortable to use.

## **Our Experience After A Decade Of Combining Hearing Implants With Autologous Auricular Reconstruction**

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### **Abstract**

Keywords: auricular reconstruction, microtia, hearing implants
Purpose/Aim: To describe how we combine hearing with autologous auricular reconstruction in children with Congenital Aural Atresia. To explain the clinical, audiological and radiological work-up and technical aspects of the procedure. To report the audiological and surgical outcomes
Materials and Methods: Demographics, indication, operative details, surgical and audiological outcomes including processor datalogging and Children's Home Inventory for Listening Difficulties (CHILD) questionnaire were collected on all children undergoing hearing implantation with / or as part of a planned autologous auricular reconstruction.
Results: 4 Osias, 4 BAHA Connects, 13 BAHA Attracts, 9 Bonebridges and 7 Vibrant Soundbridges were implanted in children aged 5 – 15 (average 6) between December 2014 and March 2023. Implantation performed before autologous reconstruction in 21, with first stage auricular reconstruction in 2 and with final stage in 7. One patient required conversion of BAHA Connects to Osias due to abutment site infections. One patient developed pressure necrosis following application of audio processor and conductor link damage at revision surgery. They were successfully converted to Attract. No drop in bone conduction hearing occurred following implantation. Datalogged use in bilateral microtia patients was 12 hours / day minimum. Datalogged usage in unilateral microtia patients was 1.1 to 12 hours / day. In unilateral patients average CHILD (in noise) improvement was from 4.79 to 6.89.
Conclusions: Combined implantation with the first stage of reconstruction abandoned as the Temporo-parietal vascular flap required to cover the newly constructed ear meant inadequate cover of the implant. Now implant either before auricular reconstruction (sited with plastic surgical input to avoid the eventual site of ear and damage to its potential blood supply) or with the final stage. We have demonstrated no significant deterioration in the inner ear function and improved hearing with the CHILD questionnaire. Objective measurement of device use with datalogging shows variable use in unilateral patients. Numbers too small to demonstrate benefit of one implant over another.

**Cortical measurement of the temporal bone with computed tomography in children from 2 to 4 years old in Mexico National Rehabilitation Institute as a**

## **planning method for active transcutaneous bone conduction hearing aids placement.**

Ivan Schobert, Daniella Monroy, Alan Botello , Ricardo González

National Institute of Rehabilitation, Mexico city, CDMX, Mexico

### **Abstract**

The main cause of hearing loss in children is predominantly conductive. Microtia atresia syndrome is a common cause for this type of auditory impairment for congenital causes. The best option for hearing rehabilitation in children with conductive hearing loss is amplification with bone conduction hearing aids with or without surgery. In children with CHL with moderate to severe congenital cause, as is observed in atresia or congenital EAC stenosis, surgical intervention with auditory bone conduction hearing implants is highly recommended in order to support regular development in speech and language. The FDA (Food and Drug Administration) recommends implanting bone conduction hearing aids starting at 5 years old, given that this is considered to be the minimum age necessary to have an adequate thickness of the bone cortex (3 mm) for the placement of the screws in the skull, in order to avoid inflicting damage upon the meninges.

Thanks to technological advances in the design of bone conduction implants, they can be implanted in children of a younger age, obtaining as a main benefit the early auditory rehabilitation of a higher quality compared to bone vibrator type hearing aids. Surgical planning is executed by reviewing the tomographic measurements to prevent damage and complications in surgery.

General Objective: We analyze thickness of bone cortex at retrosigmoid level of 72 ear and mastoid computed tomographies of children from 2 to 4 years and 11 months old. Thickness of more than 3mm for placement of screws were registered in 141 ears to determine the viability for implantation.

Methodology: Observational, descriptive, and transversal study. Patient tomographies of patients older than 2 years of age and younger than 4 years and 11 months of ears and mastoids that have the quality and cuts necessary to take the measurements in diverse areas of the retrosigmoid region. This was made through a DICOM image registered software.

Results: In the majority of ears analyzed by tomography there is an adequate thickness of the cortex bone (greater than 3 mm) for the placement of an active bone conduction implant that uses 2 screws at the retrosigmoid region.

## **Innovations to implanting the OSIA® 2 bone conduction hearing aid: new incision and flexible placement**

Jose Agustin Caraballo Dr.<sup>1,2,3</sup>, Valeria Lavado Lozano Dra.<sup>1</sup>

<sup>1</sup>Clínica Los Nogales, Bogotá, Colombia. <sup>2</sup>Compensar Entidad Promotora de Salud, Bogotá, Colombia.

<sup>3</sup>Sanitas Entidad Promotora de Salud, Bogotá, Colombia

## Abstract

**Introduction:** The OSIA® 2 bone conduction system is a device intended to rehabilitate patients with audiological indications of conductive or mixed hearing loss or with unilateral deafness. Among the challenges when positioning the Osia® 2 system is, on the one hand, the quality of the skin in patients who have previously undergone ear surgery or reconstruction of the pinna and, on the other hand, avoiding the area of the skull with the greatest irregularity or curve present towards the tip of the mastoid, this without affecting the audiological result despite the final positioning of the processor.

**Methodology:** Descriptive study of the modification in the surgical technique. Two groups are formed: 1. Technique recommended by the manufacturer 2. Modified surgical technique. Audiometric audiometry results (250Hz to 8000Hz) and discrimination of sentences in silence and in noise (HINT) with the Osia 2 processor, measurement of distance and angle of the Osia 2 microphones in relation to the EAC and measurement of subjective quality of life outcomes GBI questionnaire.

**Results:** A total of 30 patients (15 in each group) were included. When it come to the surgical technique, a modification to the manufacturer's recommendation is presented, the location of the piezoelectric transducer (BCI300) due to not having intact skin in the surgical area, especially in cases with skin disorders such as atrophy, fibrosis or previous infection. We present a simple surgical technique that offers a modified "C" incision with posterior flap, location of the BCI300 most posterior and higher with respect to the external auditory canal. Consequently, the BCI300 should be positioned towards the temporal squamous bone which offers a flatter surface. No statistically significant differences were found between the audiological results by frequency, nor in PTA. The tests in discrimination in silence and noise with the HINT have high performance without differences between the two groups. In the GBI they rate improvement in quality of life in all dimensions.

**Conclusions:** A new surgical technique is described, safe for the patient, with comparable audiological results and no statistically significant difference in quality of life, compared to the surgical technique recommended by the manufacturer.

**Thursday, September 7<sup>th</sup>, 2023**

**15:00-17:00 Verification and Outcome Measures**

## **How To Reduce Random Error (Noise) and Systematic Error (Bias) in Our Bone Conduction Fittings**

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<sup>1</sup>University of Alberta, Edmonton, AB, Canada. <sup>2</sup>Institute for Reconstructive Sciences in Medicine, Edmonton, AB, Canada

## Abstract

**Objectives:** New and even seasoned clinicians can be overwhelmed by the number of options available to treat conductive and/or mixed hearing loss with bone conduction devices (BCDs). There are devices retained by headbands, adhesives or implanted magnets. There are devices with implants that penetrate through the skin and somewhere the vibrator is implanted under the skin. With all these options, many questions emerge: which device is best for the person sitting in front of me? On which information do base my decisions? Setting aside a lot of practical and contextual information (e.g., age, healthcare context, device tendering processes), how do I determine the “best” choice for my patient?

**Methods:** Here we argue that there is too much reliance in the field on validation measures of performance (e.g., aided thresholds, speech in noise) with one device vs. another and too little attention paid to the fitting and verification of the two devices prior to measuring outcomes.

**Results:** We will demonstrate, using real life fittings, how the use of a generic prescriptive algorithm (e.g., DSL-BCD) can help to ensure that two comparison devices are set to comparable output targets prior to making any comparisons. The advantage of using a prescriptive approach with verification is it provides a reduction in the amount of random error (noise) and also provides clinicians a way of checking for systematic error (bias).

**Conclusion:** Just like all human decisions (radiologists examining x-rays, judges sentencing crimes), audiologists fitting BCDs can be inherently noisy and biased. 10 clinicians fitting the same person may prescribe different devices with differing outputs. There are methods available today, and more emerging, that allow us to reduce the noise and bias in our BCD fittings. Reducing noise and bias should allow for easier and more repeatable decision making in the field as it continues to grow.

## **A New Method to Determine Maximum Output of a Transcutaneous Active Bone Conduction Implant**

Mohammad Ghoncheh PhD, Susan Busch Dr. rer. agr., Lenarz Thomas Prof. Dr., Maier Hannes Prof. Dr.

Hannover Medical School, Hannover, Germany

### **Abstract**

**Introduction:** Determination of maximum output of bone conduction devices (BCD) to provide an evidence-based indication criterium when treating patients with conductive or mixed hearing loss is essential to ensure sufficient benefit. Here, we introduce a new method to determine the maximum output hearing level (MOHL) of a transcutaneous active BCD using patients’ audiological data from clinical routine examinations.

**Method:** The method uses the maximum force output of the device and the force threshold driven from the routine insitu threshold measurements of the patients to estimate the available dynamic range of the implanted device on an individual. We determine the maximum output in terms of hearing level MOHL [dB HL] of the Bonebridge using the estimated dynamic range and the bone conduction (BC) threshold of the patient as the base line. Ninety ears implanted with the Bonebridge between 2012 and 2020 (average age  $45 \pm 19$  yrs. ranging from 5 to 84 years) were included in this study. The analyses of

MOHLs were performed on both cochleae and the MOHLs were separated based on better or worse frequency-by-frequency specific BC thresholds on the ipsilateral (implanted) side.

Results: The average ipsilateral MOHLs were in the range between 51 and 73 dB HL for frequencies from 0.5 to 6 kHz in the group with better BC threshold on the ipsilateral ears. The average contralateral MOHLs in the group with better contralateral hearing were in the range from 43 to 68 dB HL. Average MOHLs were up to 8 dB higher across audiometric frequencies for ears with better BC threshold on the ipsilateral side and the difference between ipsi- and contralateral group were significant (t-test;  $p < 0.05$ ).

Conclusion: Our proposed method uses the direct and bone conduction threshold data of the patients from clinical routine to determine the frequency specific MOHL.

## **Assessing listening effort and speech intelligibility in users of bone- anchored hearing systems.**

William Brassington MSc<sup>1</sup>, Rosalyn Parker BSc<sup>1</sup>, Gwawr Jones BSc<sup>1</sup>, Federica Bianchi PhD<sup>2</sup>

<sup>1</sup>University Hospitals Birmingham, Birmingham, England, United Kingdom. <sup>2</sup>Oticon Medical, Smørum, Denmark

### **Abstract**

Objectives: In recent years there has been an increase in studies evaluating how different signal processing strategies in hearing assistive devices affect listening effort. Listening effort can be traditionally assessed via subjective questionnaires after a given task is performed. However, several studies in the last decade have shown that the pupil dilation can function as an objective indicator of listening effort during the execution of a task. The aim of this study is to investigate listening effort during a speech-in-noise task, where task demands are systematically varied, in bone-anchored hearing systems (BAHS) users.

Methods: 14 adult patients with a bilateral conductive or mixed hearing loss were included in the study and fitted with Ponto 4 (Oticon Medical, Askim, Sweden). The participants performed a speech-in-noise test at different signal-to-noise ratios (SNRs) and at different settings of the Ponto 4's OpenSound Navigator (OSN) feature (OSN ON, OSN OFF) while an eye-tracking camera recorded pupil dilation as an indicator of listening effort. After two laboratory visits, the participants underwent a field trial period of about 3 months, where Ponto 4 was used in everyday life. Self-reported performance was evaluated with the Speech, Spatial, and Qualities of Hearing scale (SSQ) questionnaire and overall preference was assessed between own device and Ponto 4 at the end of the study.

Results: Overall pupil dilation and peak pupil dilation were significantly reduced when OSN was ON vs. OFF at +4 dB SNR suggesting less listening effort was required when listening to speech in noise with OSN activated. Activating OSN also led to significantly higher speech intelligibility across the five tested SNRs. The SSQ scores were significantly better with Ponto 4 than with own device. Additionally, the

preference questionnaire showed a strong overall preference for the Ponto 4 over the participants own device.

Conclusions: Activating OSN led to significantly less listening effort at +4 dB SNR and significantly higher speech intelligibility across the five tested SNRs. Overall, there was a strong preference for the Ponto 4 over own device and all subjects chose to keep the Ponto 4 at the end of the study.

## **Auditory Conduction Equal-Loudness (ACE): A review of auditory equal-loudness methods.**

Rafael Patrick Ph.D. and Tomasz Letowski Ph.D.

Human IMPaC-T; Virginia Tech, Blacksburg, VA, USA

### **Abstract**

**Background & Objectives:** In most instances, equal-loudness curves (ELC) are established within a specific stimulation mode (intramodal). However, some studies seek to establish points of subjective equality (PSE) for a specific intensity of one mode of stimulation that matches with another mode of stimulation while all other stimulation entities remain equal (intermodal). Intermodal ELCs are classified based on the transmission medium of the reference and target stimulation. In recent years, the holistic investigation into human auditory perception has expanded to explore intermodal and bimodal or multimodal psychoacoustic phenomena. This work aims to provide a review of intramodal and intermodal equal-loudness studies and present a unified method for auditory conduction equal-loudness (ACE) exploration in normal hearing listeners.

**Methods:** First, air-to-air ELCs represent the traditional way PSEs have been captured. These measures allow for the equalization of air conduction (AC) presentation of sound across established frequencies. Next, air-to-bone ELC which have been marginally investigated and moderately represents intermodal PSE captured across frequencies and stimulation devices. Intermodal investigations provide evidence regarding the relationship between sound transmission speed to the inner ear via a traditional three-step process compared to direct stimulation of bone and tissue. Last, and still unclear, bone-to-bone ELCs represent the comparison of vibrotactile stimulation at one contact point – typically on the head – with another contact point – typically symmetrically located. Depending on the purpose, all ELCs can be established using a signal of the same or different frequencies, while bone-to-bone ELCs can be captured using a variety of contact point configurations.

**Results:** The intrinsic value of utilizing holistic approaches to establishing ELCs is that accurately measured PSE could be used to predict other PSEs while allowing for these predictions to be tested and retested across stimulation entities. Most importantly, unknown PSEs can be predicted once a wide variety of stimulation mode configurations have been established.

**Conclusion:** With combined intramodal and intermodal data collection methods, individualized equal-loudness contours may be better defined while reducing variability. Lastly, a research protocol including intramodal and intermodal PSE checkpoints may be beneficial in various equal-loudness-related studies.

## **Predicting In-Situ Bone Conduction Device Thresholds from Audiometric Thresholds**

Marlene Bagatto PhD, Rana El-Naji MCISc, Susan Scollie PhD

Western University, London, Ontario, Canada

### **Abstract**

**Purpose:** Bone conduction hearing devices (BCD) on soft headbands or adhesives are suitable for children who have conductive or mixed hearing losses and are too young to undergo surgical placement of similar devices. An important clinical step is to obtain in-situ behavioural thresholds using the BCD to account for skin transmission loss, which may not be possible in young children for whom early access to speech is critical.

We aimed to determine the difference between audiometric BC thresholds and in-situ BCD thresholds in adults and children. This will inform a correction to audiometric BC thresholds to predict in-situ BCD thresholds for young children.

**Method:** In-situ BCD and audiometric BC thresholds were obtained from 20 normal hearing adults. A retrospective file review was conducted to obtain similar data in a clinical sample of 26 children with conductive and mixed hearing losses. Across groups, the relationship between in-situ and audiometric BC thresholds was examined. Corrections to audiometric BC thresholds were considered and used to generate DSL BC targets.

**Results:** Differences between in-situ BCD and audiometric BC thresholds ranged from 7.5 to 23.0 dB at 250 and 4000 Hz in adults and 0.63 to 16.92 dB at 250 and 4000 Hz in children. Adding a correction to audiometric BC thresholds predicted in-situ BCD thresholds to within 3.9 dB on average (SD =7.44). Applying this correction, the average difference in simulated DSL targets was 1.5 dB across frequency.

**Conclusions:** This work provides a clinical correction for predicting in-situ thresholds from audiometric BC thresholds to generate DSL BC targets for young infants who are not developmentally ready to participate in behavioural audiometry. The suggested corrections have been applied to a clinical protocol for trial within an infant hearing program.

## **Head Simulator 2 - the development of a novel bone conduction measurement interface**



Henrik Fyrlund

Cochlear, Mölnlycke, Sweden

## **Abstract**

**Objectives:** Recent development in the field of bone conduction is towards active transcutaneous systems. These devices have new and different interfaces for connecting to the skull bone which are not compatible with a Skull simulator (e.g., TU-1000). Therefore, it is not possible to easily and objectively measure, compare or listen to the performance of these implant systems. Cadaver measurements are often used to evaluate output performance, however drawbacks include one practical handling, difficult acoustic environment, they are time consuming and costly etc.

Therefore, the Head Simulator was developed with the aim to have physical model which is anatomically correct with similar mechanical and acoustic properties compared to a real human head. The objective was to enable objective three directional measurements and sound quality assessment of any bone conduction system in a repeatable and accurate manner in the right acoustic environment.

**Methods:** The Head Simulator was developed by building an artificial head model by prototyping and testing different materials to find the right properties for bone, skin, soft tissue and brain. Verification was done by comparing the mechanical impedance, output performance, transcranial attenuation, skin attenuation and acoustic feedback data of the Head Simulator with live human or cadaver data as reference.

**Results:** The result is a physical anatomically correct plastic head with similar properties as a human head, with 3-axis vibration sensors build in in the cochlea positions. When comparing the Head Simulator properties with average human clinical data or cadaver data they show similar results within +/-3 dB from 100 to 10 kHz in terms of output transfer function, mechanical impedance and acoustic feedback response.

**Conclusion:** The performance of any bone conduction system(s) can be measured and compared with the uniquely designed Head Simulator, and it will show what a real patient would hear. The difference between real head and the Head Simulator are very small but comparing to the skull simulator the difference in output could be >15 dB at 10 kHz. It is therefore a reliable source of predicting actual clinical performance. It can also be used for live listening and compare different bone conduction systems simultaneously.

## **Assessing our Ability to Meet the DSL-BCD v1.1 Targets for Percutaneous Bone-Conduction Users: A Retrospective Review of our Last 100 Fittings**

Alex Gascon MPA<sup>1,2</sup>, Cassandra Cowan B.Sc.<sup>1,2</sup>, William Hodgetts PhD<sup>1,2,3</sup>

<sup>1</sup>Institute for Reconstructive Sciences in Medicine, Misericordia Community Hospital, Edmonton, AB, Canada. <sup>2</sup>Faculty of Rehabilitation Medicine, University of Alberta, Edmonton, AB, Canada.

<sup>3</sup>Communication Sciences and Disorders, University of Alberta, Edmonton, AB, Canada

## Abstract

**Objectives:** The DSL-BCD v1.1 formula (Hodgetts & Scollie, 2017) provides target output-force-level for percutaneous bone-conduction hearing devices worn on a skin-penetrating abutment (BCD). The DSL-BCD v1.1 targets can be used in clinical settings to guide BCD fitting practices. This verification framework is a recent development in bone-conduction amplification. In clinical settings, BCD's output may deviate from the DSL-BCD targets due to the user's preferred listening level, feedback or BCD's output limits. Since its inception, how the DSL-BCD v1.1 targets compare to BCD fittings in clinical settings has not been investigated with a large sample of participants using a variety of BCD models.

A better understanding of target achievability for various types of hearing losses and BCD models is needed to assess whether the DSL-BCD v1.1 targets require modifications. Furthermore, a description of the characteristics of BCD fittings measured with in clinic with skull-simulator may be valuable to clinicians.

**Methods:** This retrospective study investigates the characteristics of BCD fittings obtained in clinic. Data collection is ongoing. The data from 100 BCD users from the Institute for Reconstructive Science in Medicine (iRSM, Edmonton, Canada) with conductive or mixed hearing loss as well as single-sided deafness is being collected. Skull-simulator measurements obtained during routine audiology appointments will be reviewed. The aided speech intelligibility index (SII) and output-to-targets deviations across frequency will be analyzed. How the BCD model, user's hearing thresholds and age relate to the SII and the output-to-target deviations will also be explored.

## On the dynamic properties of the non-invasive bone-conduction device ADHEAR™

Michael Lauxmann Dr.-Ing., Dmitrii Burovikhin MSc.

Reutlingen University, Reutlingen, Germany

## Abstract

**Objectives:** The ADHEAR™ system (MED-EL, Innsbruck, Austria) is a non-invasive bone conduction device to treat conductive hearing loss and single-sided deafness. In contrast to the nonsurgical alternatives on headbands or spectacle frames, the audio processor of ADHEAR is placed retroauricularly on an adhesive adapter without any preload. Surprisingly, that does not result in worse audiological outcomes than the alternatives with significant preload. The objective of this study is therefore to investigate the influence of preload on the dynamic transmission characteristics of the ADHEAR™ system.

**Methods:** It is postulated that the force applied to the cranial skin is the decisive mechanical input variable for that hearing system. To investigate cause-effect relationships between the force applied to the skull and the electrically induced vibrations of the electro-magnetic transducer, the overall system is decomposed into subsystems. First, the motion of the free transducer without the adhesive adapter, secondly the transfer properties of the adhesive adapter (plastic plate, adhesive film) and thirdly, the

complete system including the skull skin are investigated in static and dynamic measurements and simulations depending on different mass and force loading.

**Results :** The transducer dynamics itself does not depend on preload. The coupling of the actuator to the skull also has hardly any influence on the actuator dynamics. However, the adhesive adapter is relatively compliant and reduces the output force above 2 kHz, especially because the connection to the mastoid is often not widely spread due to the highly variable shape (strong/weak curvature). Preload increases the coupling stiffness and thus the transmissible force above 1.5 kHz by 8 -10 dB. This was found both in tests on test subjects as well as in the laboratory on an artificial skull bone.

**Conclusion:** The basic excitation principle of the ADHEAR™ system uses the inertia of the transducer without the need of any preload and thus enables a comfortable fit. An optimized, more widely spread contact of the adhesive adapter with the mastoid, being tailored to the individual shape of the mastoid, would increase contact stiffness and thus flank the pleasant wearing comfort with a better hearing performance, especially in higher frequencies.

## **Safety of Bonebridge - Comparison of patient-relevant events**

Burkard Schwab MD, PhD

ENT-Department, Helios-Clinic, Hildesheim, Lower Saxonia, Germany

### **Abstract**

#### **Purpose**

To review types and frequencies of adverse events (AE) associated with bone-conduction hearing implants (BCHIs)

#### **Methods**

Cochrane, PubMed, and EMBASE libraries were searched for primary articles in English or German language that reported on adverse events following BCHI implantation, included at least five patients and were published between 1996 and 2016. Study characteristics, demographics, and counts of adverse events were tabulated and analyzed within the R statistical programming environment.

#### **Results**

Following assessment of the reporting quality of adverse events, we present a brief guideline that potentially improves AE reporting in this field of research. For the full dataset, we summarize study-level adverse event frequencies in terms of ratio of events to ears (REE) by AE groups and by device. For a subset of studies, we also report cumulative incidence (risk) for minor- and major adverse-events by device and by device groups.

#### **Conclusions**

Data analyzed in this review show that: (1) the reporting quality of adverse events associated with BCHI is often very low; (2) adverse events associated with BCHI are qualitatively different and not equally

frequent among devices; (3) state-of-the-art implantable BChIs are a safe treatment option for hearing loss.

## **Electroacoustic evaluation of the bone conduction transducer B250 for vestibular and hearing diagnostics in comparison with Radioear B71 and B81**

Karl-Johan Fredén Jansson PhD<sup>1</sup>, Bo Håkansson PhD<sup>1</sup>, Ann-Charlotte Persson PhD student<sup>2</sup>, Luca Verrecchia MD, PhD<sup>3</sup>, Sabine Reinfeldt PhD<sup>1</sup>

<sup>1</sup>Dept of Electrical Engineering, Chalmers University of Technology, Gothenburg, Sweden. <sup>2</sup>Habilitation & Health, Hearing organization, Region Västra Götaland, Gothenburg, Sweden. <sup>3</sup>Dept of Clinical Science, Intervention and Technology, Karolinska Institutet, Stockholm, Sweden

### **Abstract**

**Objectives:** The B250 transducer was originally designed to generate high bone conduction (BC) sound at 250 Hz for efficient stimulation of the audio-vestibular system in clinical settings. The objective of this study is to evaluate its electroacoustic performance and to compare it with the two most widely used audiometric transducers B71 and B81.

**Methods:** A sample of six B250 prototype transducers were evaluated based on measurements of frequency response, total harmonic distortion (THD), maximum hearing level and electrical impedance. For comparison with B71 and B81, already published data from six samples of each device were analyzed together with complementary measurements of maximum hearing level at 125 Hz using seven samples of each device. For absolute measurements in terms of decibel hearing level (dB HL), the difference in reference equivalent threshold force levels (RETFLs) between B81 and B250 were estimated by comparing pure tone threshold measurements of 60 healthy ears with normal hearing (15 males and 15 females, 20–37 years) using both devices.

**Results:** The B250 has approximately 27-28 dB higher frequency response magnitude than both B71 and B81 at 250 Hz and can generate higher maximum hearing level than both devices at low frequencies: 11.8 to 35.8 dB (125-1000 Hz) higher than B71, and 1.4 to 18.6 dB (125-750 Hz) higher than B81. The maximum difference in RETFLs were found to be on the average  $13.5 \pm 8.7$  dB higher for B250 at 250 Hz.

**Conclusion:** The B250 produces higher output force with less distortion than both B71 and B81, especially at 125 and 250 Hz, which could possibly improve low frequency investigations of the audio-vestibular system.

**Thursday, September 7<sup>th</sup>, 2023**

## 15:00-17:00 Bone Conduction Hearing Science 2

### **Assessing the Accuracy of Preclinical Evaluation Techniques for Bone Conduction Devices**

Irina Wils MSE<sup>1</sup>, Alexander Geerardyn MD<sup>1,2</sup>, Tristan Putzeys PhD<sup>1</sup>, Guy Fierens PhD MSE<sup>3,1</sup>, Katleen Denis PhD MSE<sup>1</sup>, Nicolas Verhaert PhD MD<sup>1,2</sup>

<sup>1</sup>KU Leuven, Leuven, Belgium. <sup>2</sup>University Hospitals Leuven, Leuven, Belgium. <sup>3</sup>Cochlear Technology Center, Mechelen, Belgium

#### **Abstract**

**Objectives:** The effectiveness of new bone conduction devices is usually assessed by experimentally measuring the promontory velocity (VProm) or the intracochlear differential pressure (ICDP). Unlike air conduction, bone conduction involves multiple pathways with varying contributions between structures depending on the stimulation location. Therefore, ICDP, the measurement closest to the cochlear nerve, is considered the most accurate prediction of the perceived loudness. However, measuring VProm is less invasive and more precise. This study aims to evaluate the accuracy of VProm to predict ICDP while also assessing ear canal pressure (ECP), which is measured with a non-invasive technique.

**Methods:** A percutaneous bone conduction device was implanted in six human ears from four cadaveric heads. ICDP, VProm, and ECP were simultaneously measured while varying the intensity, frequency, and position of stimulation. All data were normalized to a measurement at 70 dB HL, at the standard Baha position, at the same frequency, and in the same specimen. The best linear fit was determined between ECP, VProm, and ICDP.

**Results:** The ICDP varied between 70 and 130 dB SPL. The best linear fit between ECP and ICDP resulted in a Pearson correlation coefficient of 0.64 ( $p < 0.0001$ ) and a root mean square error (RMSE) of 7.31 dB. In comparison, the fit between VProm, and ICDP resulted in a correlation coefficient of 0.75 ( $p < 0.0001$ ) and an RMSE of 6.32 dB. Normalizing to the same position instead of the standard Baha increased the correlation coefficient to 0.94 for both ECP and VProm, with RMSE decreasing to 2.77 and 2.71 dB, respectively. This indicates that part of the variability in the data is caused by changing the position of the bone conduction device.

**Conclusion:** Both the ECP and VProm can predict the ICDP with an average error of 6 to 7 dB. Thus, both measurement techniques could be used to evaluate bone conduction devices. However, due to this error, the sample and effect size should be large enough to use the prediction. Furthermore, the study was conducted in normal hearing ears and should be validated for conductive hearing loss.

**RETFL for active transcutaneous devices – beware of the A/B effect**

Marcus Holmberg<sup>1</sup>, Simon Simon Ziska Krogholt<sup>2</sup>, Patrick Maas<sup>2</sup>, Tove Rosenbom<sup>2</sup>

<sup>1</sup>Oticon Medical, Askim, Sweden. <sup>2</sup>Oticon Medical, Smørum, Denmark

**Marcus Holmberg**

## **Abstract**

**Objectives:** The RETFL (Reference Equivalent Threshold Force Level) is the vibration force level corresponding to the threshold of hearing of young normal hearing persons. This is the very fundament of bone conduction audiology, and influences everything from device development to prescription quality.

The RETFL differs between various applications, and depends on e.g., the effect of skin dampening if applying vibrations outside of the skin, distance to the cochlea, etc. The percutaneous RETFL is well-described and used throughout many years in prescription of gain and output in percutaneous devices. The RETFL for active transcutaneous devices is not conclusively discussed and described, and might not be the same across different systems. The general assumption in the field is that the percutaneous RETFL should be corrected for the so-called A/B position effect, with reduced vibrations needed to make sounds audible in the high frequencies for positions close to the cochlear. The purpose of this review was the revisit this assumption.

**Methods:** Data from all studies performed by Oticon Medical (Askim, Sweden) where the correctness of the assumed RETFL could be verified by clinical data were revisited. In addition, a review of available, published data on RETFL for active transcutaneous devices, or clinical data where the RETFL for an active transcutaneous device could be deducted based on in-situ and regular BC threshold data was performed. Further, data sets including 1D and 3D laser doppler measurement data were reviewed.

**Results:** The results as expected confirms that the use of the percutaneous RETFL is supported by a wealth of clinical data. The available clinical data on active transcutaneous RETFL is scarce. The available data indicates no or limited benefit of close proximity to the cochlear. This is further supported by published data comparing 1D and 3D laser doppler measurements.

**Conclusion:** We conclude that bone conduction field does not currently have a RETFL for active transcutaneous devices. We further conclude that the so-called A/B effect needs to be revisited. A clear suggestion for how the field of bone conduction research can resolve and conclude on this issue will be presented.

## **Static and dynamic computational modeling and analysis of the bone-implant interface of the bone-anchored hearing implant-abutment system**

Boyu Pan Master of Science degree<sup>1</sup>, Marsel Ganeyev Master of Science degree<sup>2,3</sup>, Anders Palmquist Ph.D.<sup>2</sup>, Martin Johansson Ph.D.<sup>2,3</sup>, Lindsey Westover Ph.D.<sup>1</sup>

<sup>1</sup>University of Alberta, Edmonton, Alberta, Canada. <sup>2</sup>University of Gothenburg, Gothenburg, Sweden.

<sup>3</sup>Oticon Medical AB, Askim, Sweden

**Boyu Pan**

## **Abstract**

**Objectives:** The objective of this study is to investigate the stress-strain distribution and magnitude at the bone-implant interface after the torsional insertion of the implant into the temporal bone in bone-anchored hearing system applications using finite element analysis.

**Methods:** Commercially available 3mm and 4 mm implant with different lengths of abutments (Wide Ponto implant, Oticon Medical, Sweden) was modeled using finite element analysis (FEA). The implant is threaded and the temporal bone is osteotomized with a geometric notch. A dynamic finite element analysis is performed by applying the clinically adopted insertion torque to the implant, allowing the peri-implant stress and strain distribution and magnitude to be investigated.

**Results:** The finite element analysis provided a detailed evaluation of the stress and strain distribution in the bone for the bone-anchored hearing system at various conditions.

**Conclusion:** This study demonstrated the use of FEA in understanding the stress-strain distribution at the bone-implant interface for various implant-abutment systems. Future work will focus on extending the model to understand the stress-strain environment with different abutment lengths under physiological loading conditions such as installing and removing the sound processor as well as understanding differences in the stress-strain environment with different implant system designs.

## **Speech in noise with bilateral active bone conduction implant for conductive and mixed hearing loss**

Andrea Canale MD PhD, Andrea Albera MD

AOU Città della Salute e della Scienza di Torino, Torino, Italy, Italy

## **Abstract**

**Objective:** To evaluate speech in noise results and subjective benefit in bilateral active bone conduction implant for bilateral mixed hearing loss.

**Study Design:** Prospective, comparative **Setting:** ENT Unit, Department of Surgical Sciences, University of Turin.

**Patients:** 7 patients with conductive / mixed hearing loss **Intervention(s):** Patients underwent simultaneous or sequential bilateral surgery for active bone conduction implant (ABCI). **Main Outcome Measure(s):** The speech intelligibility in noise was assessed with the Ita Matrix test in summation, squelch and head shadow settings. First, the tests were performed with one device activated in the ear

with lower speech recognition score (SRS), then with both devices. Patients filled in an Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire to investigate the hearing aid benefit.

Results: When bilateral devices were activated, an improvement of signal- to-noise ratio (SNR) was observed in all settings. The difference between bilateral and unilateral stimulation is 4.66 dB ( $p=0.016$ ) in the summation, 2.24 dB ( $p=0.047$ ) in the squelch, 7.50 dB ( $p=0.016$ ) in the head shadow setting.

Looking at the APHAB Global Score (GS), patients report lower mean scores, hence less difficulties, when using two devices (GS: 21.9%; SD: 8.28) rather than one (GS: 33.0%; SD: 10.24) ( $p$  value = 0.018)

Conclusions: In symmetric mixed bilateral hearing loss, rehabilitation with an ABCI fitted bilaterally shows audiological advantages in speech perception in noise, not only thanks to the summation effect and by reducing head shadow, but also by improving the binaural unmasking based on the squelch effect. Audiometric outcomes are confirmed by the Global Scores obtained in the APHAB questionnaire.

## **Comfort and safety of a novel device for attaching bone-anchored hearing aid processors**

Jonathan Reid MD, Allan Ho MBBS, MSc

University of Alberta, Edmonton, Alberta, Canada

### **Abstract**

Introduction: Bone conduction hearing devices (BCDs) are an alternative to conventional hearing aids. A percutaneous BCD consists of a processor attached to an abutment traversing the skin, fixed to an osseointegrated implant. Day-to-day attachment and removal of the processor has been associated with scalp reactions in 21% of patients, and the consequences may escalate to complete implant removal. We sought to develop a BCD barrier device and evaluate whether it improved comfort and ease of attaching the processor and reduced adverse events.

Methods: We conducted a prospective cohort study. A prototype hair-barrier device was designed using SolidWorks software. Devices were fabricated using a 3D printer with polylactic-co-glycolic acid. Adult patients with a BCD implanted more than 30 days prior were recruited from a tertiary otology practice. Patients received a device and watched a brief instructional video, then could use it freely at home. After 2 weeks, patients completed a questionnaire. Likert scales, free text questions, and the System Usability Scale (SUS) were included.

Data were analyzed as proportions and frequencies. Descriptive analysis was used to interpret free text responses.

Results: Ten devices have been printed to distribute to ten patients. Patients complete a questionnaire upon follow-up to evaluate satisfaction, usability, safety, and subjective feedback. The mean SUS score is recorded, with a SUS > 68 indicating above average usability. Adverse events include hair pulling and skin irritation.



Conclusion: A simple 3D-printed device can safely and effectively clear hair from the abutment when attaching a BCD, improving comfort with BCD use.

#### Learning Objectives

1. Describe common minor adverse events associated with daily BCD usage.
2. Describe the process of developing a simple device concept into a prototype and finished version.
3. Understand the domains of and how to utilize and interpret the validated System Usability Scale in evaluating usability of a device or system.

## **Temporal bone 3D motion and intracochlear pressure under bone conduction: a hybrid FEM and experimental study**

Ivo Dobrev PhD<sup>1</sup>, Jongwoo Lim PhD<sup>2</sup>, Flurin Pfiffner PhD<sup>1</sup>, Christof Rösli Prof.<sup>1</sup>, Namkeun Kim Prof.<sup>3</sup>

<sup>1</sup>Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Zurich, University of Zurich, Zurich, Switzerland. <sup>2</sup>Department of Mechanical Engineering, Sogang University, Seoul, Korea, Republic of. <sup>3</sup>Department of Mechanical Engineering, Sogang University, Zurich, Korea, Republic of

### **Abstract**

**Objectives:** The complex 3D motion pattern of the temporal bone, particularly the otic capsule, during bone conduction (BC) stimulation at different frequencies, and its correlation with the intracochlear pressure difference across the cochlear partition are being investigated experimentally and numerically.

**Methods:** Data has been collected from six samples from three fresh frozen cadaver heads, including: 3D velocity at 130-200 points across the lateral and medial surfaces of the ipsilateral temporal bone and skull base; 3D motion of a single point at the promontory and stapes; differential intracochlear pressure. Excitation was provided sequentially to the ipsilateral mastoid and classical BAHA location via a percutaneous coupling, in the 0.1-20 kHz frequency range. The experiment was digitally recreated by a custom finite element model (FEM), based on the LiUHead, with the addition of a middle ear and cochlea. The Young modulus of the bone domain within the FEM was varied between 4, 8, and 20 GPa.

**Results:** Overall, there was a good agreement on the raw data between experimental data and FEM, in the range of 1-5 kHz. Predicted differential intracochlear pressure, normalized by the promontory motion, was within the confidence intervals of the experimental data for most frequencies. The spatial variation of the amount of deformation across the skull base, and the otic capsule in particular, was dependent on the material properties of the FEM and closely matched the experimental data.

**Conclusion:** Both methods indicated that the otic capsule acted as a rigid accelerometer within the temporal bone, namely, inertially actuated by the surrounding skull bone, while remaining primarily rigid even above 10kHz.

## **In-vivo investigation of the Skull Bone Sound Waves under Bone Conduction**

Aikaterini Dimitrakopoulou MD, Ivo Dobrev PhD, Christof Roosli MD

Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Zurich, University of Zurich,, Zurich, Switzerland

### **Abstract**

**Objectives:** The aim is to quantify the surface waves speeds across the skin-covered skull in live humans with previous data in cadaver heads.

**Methods:** Preliminary tests are being conducted on volunteers (awake, no sedation), where the skull is being excited transcutaneously via an actuator from a BCHA, held by a 5N-steel-band at a location posterior to the forehead. The resultant motion was monitored at ~100 points via a single-sensitivity-axis scanning laser Doppler vibrometer (SWIR Scan-Sense, Optomet, Germany) in the area of the forehead, where the skin was covered with a flexible retroreflective tape. Stimulation was provided at 3-5 kHz, in order to evoke wave motion with at least half a wavelength within the measurement area (~10-12cm wide), while having sufficiently high output from the BCHA. Signal processing methods have been implemented in order to reduce the effect of motion artifacts from random body movements. In-vivo data is compared with equivalent surface wave measurements of cadaver heads with and without skin.

**Results:** Measurements on the cadaver heads, with and without skin, indicate no major change in the spatial distribution (wavelengths) of the wave patterns across the superior skull. This was regardless of reduced skin vibration, relative to the skull, due to soft tissue damping. In-vivo skull vibration data indicated wave speeds comparable to cadaver head data.

**Conclusion:** The skull wave motion observed in patients is similar to previous experimental data in cadaver heads.

## **Influence of the head boundary conditions on the skull bone motion under bone conduction**

Yves Hottiger, Ivo Dobrev PhD, Flurin Pfiffner PhD, Christof Rösli Prof.

Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Zurich, University of Zurich, Zurich, Switzerland

### **Abstract**

**Objectives:** Investigate the influence of the head support and boundary conditions on the skull bone motion, including dependence on stimulation location.

**Methods:** One Thiel embalmed whole-head cadaver specimen was measured, while the skull neck support was varied by adjusting the stiffness of a custom head support holder. The osseous pathways

were activated percutaneously via stimulation of the mastoid, BAHA location, or forehead. For each head support condition, the head stiffness, relative to its support, was evaluated by measuring the 3D deflection of the skull's vertex at several force levels (1-10N) in the anterior-posterior and left-right direction sequentially. For each stimulus and neck support condition, the skull bone response was monitored by a three-dimensional laser Doppler vibrometer system, which measured the 3D motions of the ipsi-, top, and contra-lateral skull surface at approximately 40-50 points with a pitch of about 50 mm. Stimulation was provided from 0.1-2 kHz to observe the skull's low-frequency behavior and its transition from rigid-body to deformation.

Results: Moving the head support points from neck vertebrae to neck muscle attachment points changed the head stiffness 3-5 times. The low-frequency vibrational response of the skull changed in magnitude, spatial composition, and frequency dependence with changing the boundary conditions of the skull. Stimulation further away from the head support location resulted in a more pronounced directionality of the primarily rigid body motion of the skull at low frequencies.

Conclusion: In general, the motion of the skull bone is influenced by the neck support, but only at low frequencies.

## **Basilar membrane and organ of Corti vibration in guinea pigs measured with OCT during bone conduction stimulation**

Srdan Prodanovic PhD, Mingduo Zhao MSc, Anders Fridberger PhD, [Stefan Stenfelt PhD](#)

Linköping University, Linköping, Sweden

### **Abstract**

**Objectives.** The vibration pattern of the structures inside the living ear when stimulation is by bone conduction (BC) has not been presented in detail. The differences and similarities of the vibrations between air conduction (AC) and BC stimulation are therefore unknown. These are here investigated in sedated guinea pigs.

**Methods.** The inner ear vibrations are measured with an optical coherence tomography system (OCT). The bulla of the guinea pig is opened enabling optical access to the inner ear through the round window. First, hearing thresholds at frequencies between 2 and 12 kHz are obtained in the guinea pig with AC and BC stimulation using measurements of the compound action potential. This facilitates comparison of AC and BC stimulation at the same hearing level. The vibration measurements with the OCT are conducted at 30 and 40 dB HL for both AC and BC stimulation. The measurements are done both across and along the basilar membrane.

**Results.** With AC stimulation, the maximum vibration is seen at the organ of Corti with only small vibration levels visible at the spiral lamina. With BC stimulation, the entire cochlea vibrates but the maximum vibration is found at the organ of Corti. When the BC vibration is analyzed in relation to bony vibrations at the cochlear boundary, the vibration at the organ of Corti is enhanced. However, the vibration of the spiral lamina is significantly greater than with AC stimulation, especially at lower

frequencies. At higher frequencies, the vibration pattern of the inner ear structures become more complex with BC stimulation.

Conclusion. The OCT system is well suited for inner ear vibration measurement with both AC and BC stimulation. The threshold estimation enabled AC-BC comparisons at the same stimulation levels inside the cochlea. Overall, AC and BC stimulation seem to generate the same relative vibration at the organ of Corti when stimulated at the same hearing level, but BC stimulation tend to result in greater vibration levels of the spiral lamina and spiral ligament compared to AC stimulation.

## Investigation of bone conduction efficiency at various positions

Alexander du Puits<sup>1,2</sup>, Kristian Åsnes<sup>3</sup>, Thomas Lenarz<sup>2,4</sup>, Hannes Maier<sup>2,4</sup>

<sup>1</sup>Cochlear Deutschland GmbH & Co. KG, Hannover, Germany. <sup>2</sup>Department of Otolaryngology, Hannover Medical School, Hannover, Germany. <sup>3</sup>Cochlear Bone Anchored Solutions AB, Mölnlycke, Sweden.

<sup>4</sup>Cluster of Excellence "Hearing4all", Hannover, Germany

### Abstract

#### Objectives

Previous studies have shown, that a reduced distance between the stimulation site and the cochlea leads to higher outputs for bone conduction devices (BCD). This would result in reduced energy consumption and Maximum Output (MO). Therefore, the aim of this study was to identify alternative coupling sites closer to the ear canal (EC) and quantify the influence on bone conduction efficiency.

#### Methods

To determine the influence of various positions on the efficiency, ipsi- and contralateral cochlear promontory (CP) velocity was measured in medial-lateral direction by 1D Laser Doppler vibrometry (LDV). Measurements were performed on 5 freshly frozen (10 ears) whole human cadaver heads, approved by the ethics committee of the Hannover Medical School (10658\_BO\_K\_2022). A bone anchor, with a 12 mm abutment and driven by a Cochlear™ Baha® 5 (Cochlear Ltd., Australia) actuator, was implanted at seven different positions: five on the surface (25 to 55 mm posterior to EC) and two in a recessed position (depth: 5 to 8 mm, 20 mm posterior to EC). Stimulation was performed with 78 frequencies, ranging from 0.1 to 10 kHz.

#### Results

The ipsilateral CP vibrational velocities (medial-lateral) showed minor sample and inter-individual variability, for  $f < 500$  Hz. In comparison to the designated Cochlear™ Baha® position, average CP vibration results showed a significant increase for frequencies  $> 500$  Hz. The highest improvements were observed for the positions on the skull surface closest to the EC (25 mm posterior to EC) and the recessed positions (depth: 5 to 8 mm, 20 mm posterior to EC). In contrast, the contralateral results showed similar differences for lower frequencies ( $f < 500$  Hz) but smaller improvements in efficiency for

higher frequencies ( $f > 500$  Hz). Simultaneously, the amplitude was significantly smaller for frequencies  $> 1$  kHz.

### Conclusion

The presented results showed a significant increase of CP vibrational velocities in medial-lateral direction, with decreasing distance of the stimulation site to the cochlea. Implanting the bone anchor in greater proximity and a recessed position led to similar or even higher MO when compared to positions on the skull surface.

## **Pilot Study of Patients who do or could Utilize a Bone Anchored Hearing Implant (BAHI): Preliminary Review of Cognition & Hearing Performance**

Marsadi Layne Parliament Au.D., Jordan Lamanna B.S, Morgan Oktela Fuentes Au.D., Michelle Anrold Au.D., Ph.D, Victoria Sanchez Au.D., Ph.D

University of South Florida, Tampa, FL, USA

### **Abstract**

#### **Objective**

Untreated hearing loss is independently associated with cognitive decline and dementia. Currently, there is one large-scale randomized controlled trial evaluating cognition among older adults with typical sensorineural hearing loss that received traditional hearing intervention including (ACHIEVE Study; Clinicaltrials.gov identifier: NCT03243422). There remains a significant gap in the literature on other types and configurations of hearing loss and how other forms of auditory rehabilitative treatment, such as a BAHI, may influence cognition, hearing performance, and other functional measures.

Primary objective of this pilot study is to evaluate the cognitive and hearing effects of BAHI intervention between patients who could versus do utilize a BAHI. This patient-preference unblinded clinical trial utilizes most procedures conducted in the large-scale ACHIEVE Study in hopes of having comparative pilot data.

#### **Methods**

BAHI candidates are recruited from the USF Health Department of Otolaryngology. Baseline and follow-up assessments (collected every 6-months for 3 years) include a standardized neurocognitive test battery, objective hearing performance (e.g., Words in Noise Test) and completion of self-reported questionnaires. Data collection is ongoing, but we are comparing change in cognitive and hearing performance from baseline to follow-up between BAHI users (intervention group) to those who opted not to uptake BAHI intervention (control group).

#### **Results**

To date, 11 participants have been enrolled (6 BAHI, 5 Non-BAHI). At Baseline, the mean age of all participants was 41 years, majority are white (91%), cognitively intact ( $\bar{X}$  MMSE =29.8), 6 had a mixed hearing loss, 3 conductive, 1 single-sided deafness, with an average difficulty hearing in noise threshold

of 5.95 dB SNR on the WIN. Comparing Baseline to follow-up (12 month or 18 month), BAHI users improved on WIN (1.82 dB SNR) and self-reported hearing abilities. Descriptively, both groups have remained stable on neurocognitive assessments.

### **Conclusion**

Our Pilot Study is generating evidence to evaluate BAHI influence on cognitive and hearing performance. Preliminary data suggests a greater improvement on speech-in-noise performance among BAHI users, as would be expected with a hearing intervention. At the present follow-up assessments, cognitive performance remains equivalent and stable across both intervention and control groups.

## **Sound lateralization under bilateral bone conducted stimulus by a virtual acoustical system**

Liu-Jie Ren PhD<sup>1</sup>, Yi Yu PhD<sup>2</sup>, Tian-Yu Zhang PhD<sup>1</sup>, Chen-Long Li PhD<sup>1</sup>, You-Zhou Xie PhD<sup>1</sup>

<sup>1</sup>Eye&ENT Hospital of Fudan University, Shanghai, China. <sup>2</sup>Shanghai University of Medicine and Health Sciences, Shanghai, China

### **Abstract**

**Purpose:** Sound localization is an essential need for patients with bilateral fitting of BCDs, but the performance may be influenced by the bone conduction pathways, especially the crosstalk. This study compares the sound lateralization in healthy people under bilateral air/bone conducted (AC/BC) stimulus.

**Methods:** A virtual acoustical system was developed and was controlled by a house-made MATLAB software. The stimulation sound can be either made with headphones or two paired B71 bone vibrators. Sixteen healthy volunteers were adopted for the following tests. (1) Comparing the sound localization ability between bilateral AC and BC – Tone bursts of 500, 1k, and 2k Hz sound were used, the sound level is about 50 dB above the hearing threshold of the volunteer. Then two-channel sound was generated according to the HRTF of the standard Kamear head, mimicking the sound from 12 different directions from -82.5 to 82.5 degrees (15 degrees interval). Twenty-four randomly ordered presentations were given to the volunteers for response. (2) The sound lateralization with different combinations of ILDs and IPDs. Two-channel tone bursts were generated for AC/BC stimulus, and the volunteers were forced to choose from 'left', 'right' or 'middle/dont know'. The sounds vary in ILD (-20 to 20 dB) and IPD (-PI to PI). (3) We recording the objective feeling of a sequence of tone-bursts with gradually varying IPDs from -6PI to 6PI, lasting about 30 seconds. We asked the trained volunteer to report the lateralization (left or right) using a computer mouse.

**Results and conclusions:** (1) the sound localization MAE bilateral BC is significantly larger than that of bilateral air conduction, which means that bone conduction sound localization ability is somehow naturally weakened. (2) The sound lateralization under bilateral air conduction follows simple rules related with the ILDs and IPDs, e.g. the precedence effect. However, the bone conduction sound lateralization under pure tone stimulus seems more complicated. and does not follow the precedence

effect exactly. It seems that due to the cross-talk (or superposition) of BC pure-tones, the IPD modulates the ILD in the cochlea level, and influence the sound lateralization.

**Friday, September 8<sup>th</sup>, 2023**

**08:45- 10:45 Plenary Session: Pediatrics**

**Implantation of the second generation of the Bonebridge in children under 5 years**

Kerstin Willenborg, Busch Susan, Schurzig Daniel, Thomas Lenarz

Dept. of Otolaryngology, Hannover Medical School, Hannover, Germany

**Abstract**

**Objectives:** The MedEl Bonebridge system is an active transcutaneous bone conduction implant system for patients with conductive and mixed hearing loss or single-sided deafness. Younger children with a lesser bone thickness were previously treated with a percutaneous osseointegrated bone-anchored hearing aid (BAHA) due to its low depth of insertion into the bone or an active middle-ear implant, but the BAHA with its percutaneous screw increases the risk of implant infections or involvement of the implant in head trauma and middle-ear implant surgery involves manipulation of the ossicles with possible risk of surgical trauma and post-operative implant displacement. Transcutaneous bone conduction implant systems omit complications. The second generation of the Bonebridge (BCI 602) features a decreased thickness with reduced drilling depth and can thus be implanted in younger children.

**Methods:** In this study children under 5 years with unilateral aural atresia were implanted with the second generation of the Bonebridge. Because children under 5 years often have a low bone thickness, computed tomography was performed to measure bone thickness and to determine the consistency of the temporal bone using the Otoplan software in order to find the optimal location for the implant.

**Results:** All patients were successfully implanted and no severe adverse effects were observed. All showed a good postoperative hearing performance.

**Conclusion:** With adequate preoperative workup, the second generation of the Bonebridge can be safely implanted in children under 5 years with a good postoperative audiological outcome and without adverse effects.

## **Advancement of patient care in a pediatric microtia and aural atresia multidisciplinary clinic**

Adkisson Kirsten AuD<sup>1</sup>, Hedman Megan AuD<sup>2</sup>

<sup>1</sup>Children's Hospital Colorado, Aurora, CO, USA. <sup>2</sup>Children's Hospital Colorado, Aurora, CO, USA

### **Abstract**

Children's Hospital Colorado holds a monthly pediatric multidisciplinary clinic for patients with microtia and aural atresia. Microtia and aural atresia are birth abnormalities of the ear. The advancement of patient care in this clinic has been reviewed over fifteen years via a culmination of research. The current Joint Commission on Infant Hearing (JCIH) guidelines indicate audiologic evaluation before three months of age and early intervention (EI) before six months of age. A five-year retrospective review of the electronic medical record (2012-2017) of 55 patient charts in the Children's Hospital Colorado multidisciplinary clinic revealed the age of diagnostic hearing evaluation, early intervention referral, and the fitting of amplification significantly decreased to align within the JCIH guidelines. To identify additional clinical data and socioeconomic information affecting this patient population, a larger group of patients totaling 373, were included in a retrospective review (2008-2018). Results indicated socioeconomic factors do not appear to influence patient treatment selection for microtia and aural atresia. Additionally, fitting a nonsurgical bone conduction hearing device (BCHD) at a younger age is associated with higher likelihood of nonsurgical BCHD compliance, that is in turn associated with patients and families proceeding with surgical BCHD and framework surgery. Most recently, a ten-year (2013-2023) analysis was completed with approximately 80 patients who proceeded with surgical BCHD intervention. Results indicated half of the patients were seven years old and younger. The results of this review will promote early identification and intervention allowing for patients to take advantage of advancements in technology.

## **Subjective Fatigue in Children with Unaided and Aided Unilateral Hearing Loss**

Kim. H.E. Bakkum MD<sup>1</sup>, Emma M. Teunissen MD<sup>1</sup>, Arno M. Janssen PhD<sup>1</sup>, Judith E.C. Lieu MD, PhD<sup>2</sup>, Myrthe K.S. Hol MD, PhD, Prof.<sup>1,3</sup>

<sup>1</sup>Department of Otorhinolaryngology, Donders Center for Neurosciences, Radboud university medical centre, Nijmegen, Netherlands. <sup>2</sup>Department of Otolaryngology – Head and Neck Surgery, Washington University School of Medicine, St. Louis, Missouri, USA. <sup>3</sup>Department of Otorhinolaryngology/Head and Neck Surgery, Research School of Behavioural and Cognitive Neurosciences, Graduate School of Medical Sciences, University of Groningen, University Medical Center Groningen, Groningen, Netherlands

### **Abstract**

Title

Subjective fatigue in children with unaided and aided unilateral hearing loss



**Objectives:** This study investigates subjective fatigue and hearing-related QoL in children with unaided and aided UHL. Furthermore, this study evaluates the influence of different hearing aids, subject-specific factors and respondent-type (parent-proxy versus child-report) on subjective fatigue.

**Methods:** A cross-sectional study was conducted from June 2020 until September 2020 at the department of otorhinolaryngology in the (tertiary) Radboud University Medical Center.

**Participants:** 90 children 8-18 years and 123 parents were asked to participate, of whom 72 (80%) children and 106 (86%) parents completed the questionnaires. Potential participants with UHL were identified via patient databases. Healthy siblings were asked to participate as controls. Inclusion criteria were age 2-18 years and Dutch as primary language. Children were excluded based on criteria known to affect fatigue or to influence reliable/unreliable completion of questionnaires. **Main outcomes and measures:** The main study outcome was the difference in subjective fatigue and hearing-related QoL between children with unaided UHL, aided UHL and children with normal hearing. Subjective fatigue and hearing-related QoL were measured using the PedsQLTM-MFS and HEAR-QL questionnaires respectively.

**Results:** 34 children with unaided UHL, 36 with aided UHL and 36 healthy children were included for data-analysis. Child-reports revealed significantly more cognitive fatigue in children with aided UHL compared to children with normal hearing. Parents reported more fatigue on several domains in children with UHL compared to normal-hearing siblings. Especially children with aided UHL were seemed at increased risk for fatigue. Children with UHL scored lower on hearing-related QoL than children with normal hearing. No clear differences were found in fatigue and QoL between children with unaided and aided UHL.

**Conclusion:** Children with unaided and aided UHL seem to experience more subjective fatigue and lower hearing-related QoL than children with normal hearing. Prospective longitudinal studies are required to investigate the influence of hearing aids on fatigue and QoL in individual patients.

## **Osia<sup>®</sup> 2 Implantation in Age < 12 Years**

Lauren Pinzás

*Yi-Chin Liu*

Texas Children's Hospital, Houston, TX, USA

### **Abstract**

**Objective:** To describe the outcomes of the Cochlear Osia<sup>®</sup>2 system in children of < 12 years with conductive or mixed hearing loss or single-sided deafness.

**Methods:** A four-year (October 2018-May 2023) mixed cohort study of children implanted with the Osia<sup>®</sup>2 at a tertiary pediatric hospital was performed. Inclusion criteria were completion of pre-operative unaided audiometry and Osia<sup>®</sup>2 implantation prior to age 12. Mean preoperative unaided pure-tone

average air conduction (PTA AC), bone conduction (PTA BC), and air-bone gap (ABG) were compared to aided metrics at 1, 3, 6, and >12 months postoperatively. Functional gain (FG), effective gain (EG), and complication rates were calculated.

**Results:** Twenty-two children (26 implants; 5 bilateral, 16 unilateral), median age: 10.2 years (IQR 7.60-11.0), were included. Unaided PTA AC, PTA BC, and ABG were 70.9 (SD 20.7), 14.4 (SD 6.3), and 56.7 dB HL (SD 20.6). Aided thresholds at 1 month (20.4 dB HL, SD 5.8;  $P < .01$ ), 3 months (24.7 dB HL, SD 6.7;  $P < .001$ ), 6 months (19.5 dB HL, SD 6.6;  $P < .001$ ) and > 12 months (24.4 dB HL, SD 4.2;  $P < .001$ ) improved significantly. Average FGs were 53.7 dB HL (SD 17.6), 55.9 dB HL (SD 6.0), 61.1 dB HL (SD 9.1), 47.7 dB HL (SD 26.1), and average EGs were -13.5 dB HL (SD 8.1), -8.4 dB HL (SD 7.7), -11.8 dB HL (SD 6.3), -12.2 dB HL (SD 11.5). Average difference in unaided versus aided PTA BC was 1.4 dB HL (SD 3.0), with one patient with a PTA BC > 5 dB HL at 1 month postoperatively. Intraoperative events were 7 dural exposures (27%), 5 re-drilling sites (19%), and 1 subdural injury (4%). Over 11.1 months (IQR 5.6-27.8), major and minor complication rates were 15.4% (4/26 implants) and 35% (9/26 implants).

**Conclusions:** Osia<sup>®</sup> 2 implantation in 5- to 11-year-olds demonstrate significant audiologic gain and excellent safety profile over a range of 1 month to 3 years postoperatively. Limitations of this study include a partially retrospective design and disruptions in scheduled audiometric testing due to the COVID-19 pandemic.

## **BONEBRIDGE Implantation in Pediatric Patients Age 11 Years and Younger: Is it Safe and Effective?**

Kaitlyn Brooks MD<sup>1</sup>, Anastasia Kolousek BS, MA<sup>2</sup>, Erin Holman AuD<sup>3</sup>, Sean Evans MD<sup>1</sup>, Nandini Govil MD, MPH<sup>1</sup>, Kristan Alfonso MD<sup>1</sup>

<sup>1</sup>Department of Otolaryngology- Head and Neck Surgery, Children's Healthcare of Atlanta, Emory University School of Medicine, Atlanta, GA, USA. <sup>2</sup>Morehouse School of Medicine, Atlanta, GA, USA.

<sup>3</sup>Department of Audiology, Children's Healthcare of Atlanta, Atlanta, GA, USA

### **Abstract**

**Objective:** To compare audiometric outcomes and safety of off-label BONEBRIDGE implantation in children younger than 12 years to FDA-approved implantation in children 12 years and older.

**Methods:** Patients who underwent BONEBRIDGE implantation were included in a retrospective cohort study and were categorized by off-label use (<12 years) and  $\geq 12$  years of age at time of bone conduction hearing device (BCHD) implantation. Hearing outcomes reported are first available after BCHD fitting. Primary audiometric outcomes were post-implantation monaural speech recognition threshold (SRT) and binaural Speech-In-Noise Testing (SINT). SINT used age-appropriate wordlists in soundfield with 0-degree and 90-degree Azimuth configurations presented at 50 dB + 5 signal-to-noise ratio. Mann-Whitney U tests were performed to assess for statistical significance between audiometric outcomes. Significance was set at  $p < 0.05$ .

Results: Nineteen patients (25 implants) <12 years of age and 17 patients (23 implants) ≥12 years of age underwent BCHD implantation. Median age for off-label BCHD implantation was 6 years; median age for patients 12 and older was 16.2 years. Pre-BCHD speech recognition threshold (SRT) was better ( $p < 0.01$ ,  $Z = -2.9$ ) for the older patient group (median 50 dB, IQR 40 – 50) than the younger patient group (median 60 dB, IQR 55 – 90). Post-BCHD SRT, however, was significantly improved in the younger patient group (median 25 dB, IQR 20 – 25) versus the older patient group (median 35 dB, IQR 29 – 36), which was significant ( $p = 0.001$ ,  $Z = 3.1$ ). The two groups performed similarly on aided SINT in all testing configurations ( $p > 0.05$ ,  $-1 < Z < 1$ ). Post-operative complication rate was low for both age groups (9% vs 8%), as was re-presentation rate (9% vs 8%). Median follow-up times for the two groups were similar: 3.9 months (IQR 1.5 – 9.3 months) for patients younger than 12 and 3.4 months (IQR 1.3 – 9.6 months) for patients 12 years and older.

## Clinical Consensus Document for Fitting Non-Surgical Transcutaneous Bone Conduction Hearing Devices to Children

Laurie Mauro Au.D.<sup>1</sup>, Marlene Bagatto Ph.D., Au.D.<sup>2</sup>, Dave Gordey Ph.D.<sup>3</sup>

<sup>1</sup>Children's Hospital of Philadelphia, Philadelphia, PA, USA. <sup>2</sup>Western University, London, Ontario, Canada. <sup>3</sup>Oticon A/S, Toronto, Ontario, Canada

### Abstract

**Objective:** Historically, fitting protocols for bone conduction hearing devices (BCHDs) for infants and children were not well established, often leaving gaps in clinical practice. The purpose of this work was to provide evidence- and consensus-based clinical direction for evaluating and fitting non-surgical transcutaneous (i.e., soft band) BCHDs to young children. The document addresses the assessment, selection, fitting considerations, verification, and validation for non-surgical BCHDs for children under five years of age who have permanent unilateral or bilateral conductive or mixed hearing losses.

**Methods:** The document was developed through a consensus meeting of the Clinical Outcomes in Pediatric Audiology (COPA) Working Group. A review of literature combined with a nominal group technique to achieve consensus from the experienced members of the group informed the content. The COPA group includes clinical and research pediatric audiologists throughout North America with expertise in BCHDs. This document does not address the management of children with profound unilateral sensorineural hearing loss or single-sided deafness (SSD).

**Results:**

- **Candidacy:**
  - Determined by bone conduction (BC) pure tone average (PTA) that includes 500, 1000, 2000, and 4000 Hz
  - Low and high frequency BC information is necessary to fit the indicated ear
- **Fitting:**
  - The goal for fitting is within four weeks of diagnosis
  - Soft bands fitted to infants younger than two months of age can be challenging

- Fitting of binaural BCHDs for symmetrical bilateral hearing loss is recommended; however, sequential fittings may be necessary for young infants
- In-Situ Audiometry/Verification:
  - Performing in-situ BCHD threshold measurements is recommended to individualize the fitting
  - Desired Sensation Level (DSL) BC prescriptive targets are available for adult percutaneous fittings; DSL targets for children and non-surgical BCHD are not available

Conclusion: The consensus document provides clinical direction for an area of pediatric audiology that has previously lacked clinical guidelines and protocols. The work serves as a basis for future research (e.g., BCHDs for children with SSD) and clinical contributions to support this pediatric audiology population. As evidence and new technology evolve, so will this document.

**Friday, September 8<sup>th</sup>, 2023**

11:00- 12:30 Pediatrics 2

## **OSIA IMPLANTATION IN THE PAEDIATRIC POPULATION: SURGICAL APPROACH AND BESPOKE SURGICAL PLANNING**

Hanneke Bruijnzeel Bachelor (Medicine) Universiteit van Amsterdam, PhD (Otolaryngology) UMC Utrecht Brain Center Rudolf Magnus<sup>1</sup>, Ramtin Pir-Siahbazy Bachelor of Medicine, Bachelor of Surgery (University of Nottingham)<sup>1</sup>, Elizabeth Whittle Audiology<sup>2</sup>, Rachel Boyd Audiology<sup>2</sup>, Simone Schaefer Consultant Paediatric Otolaryngologist<sup>1</sup>, Iain Bruce Consultant Paediatric Otolaryngologist<sup>1</sup>, Jaya Nichani Consultant Paediatric Otolaryngologist<sup>1</sup>

<sup>1</sup>Department of Paediatric Otolaryngology and Head and Neck Surgery, Royal Manchester Children's Hospital,, Manchester, United Kingdom. <sup>2</sup>Department of Paediatric Audiology, Royal Manchester Children's Hospital, Manchester, United Kingdom

### **Abstract**

Objectives: Traditional bone-conduction hearing devices (BCHDs) are used to treat unilateral and bilateral conductive and/or mixed hearing loss - either as a sequelae of middle ear disease e.g. cholesteatoma; a congenital abnormality e.g. aural atresia/microtia; or acquired from trauma. However, their applications have been limited by cutaneous infections (percutaneous devices) and suboptimal hearing rehabilitation (transcutaneous devices). An active, transcutaneous osseointegrated BCHD system aims to attenuate these limitations. We report our experience with the Cochlear™ Osia® OS1200 Implant in terms of surgical approach in children implanted between September 2021 and to date, and outline anatomical and co-morbid instances which necessitated a deviation from the standard surgical approach.

Methods: In our prospective database, maintained by the audiology team, we documented the standard surgical approach, and any alterations in bespoke cases - outlining the motivation behind the deviation from standard.

We looked at the standard approach recommended by the company and evaluated the modifications to the approach required in our patient population to facilitate implantation alongside ensuring approach to current, previous and future surgical considerations.

Results: Twenty children received either a unilateral (n=15) or bilateral (n=5) Cochlear™ Osia® OSI200 Implant. Age at implantation ranged between 7 and 19 years. Surgical approach was divided into 3 groups: previous cholesteatoma/middle ear disease and its retro-auricular scar (n=11), microtia/syndromic (and its need for reconstruction) (n=6), and unilateral sensorineural hearing loss without anatomical abnormalities (n=3).

Conclusions: We report on paediatric Cochlear™ Osia® OSI200 implantation in children and its amendments in surgical approach. Our experience shows that in this specific population, bespoke surgical planning is essential to establish optimal therapeutic outcomes.

## **Candidacy and surgical considerations in the application of Osia2® in large cohort of children as young as 5 years of age.**

Sharon Cushing MD, Samantha Goh MD, Vicky Papaioannou Aud, Blake Papsin MD, Karen Gordon Aud PhD

Hospital for Sick Children, University of Toronto, Toronto, ON, Canada

### **Abstract**

Objectives: To review the clinical and hearing characteristics of Osia2® candidates as well as their surgical outcomes and complications in children as young as 5 years of age.

Methods: A retrospective review of patients (<18 years of age) receiving Osia2® in our centre from 2018-2023 was conducted. Operative time was measured and adverse events were assessed.

Results: 102 patients received unilateral (n=94) or bilateral (n=8) Osia2® for a total of 110 implants. Age-at-implantation was mean(SD)=11.3(4.1), range=4.9-17.7 years. Genetic or syndromic comorbidities were present in 27%. 89%(91/102) of children had prior experience with BCDs; 53% wore non-surgical devices such as the softband BCD and 36% had a prior surgical BCD (e.g. BAHA®Connect).

Mean(SD) operative time was 76(23) minutes. Bilateral Osia® were implanted sequentially with mean(SD) interval of 388(259) days.

Six adverse events required re-operation in four patients (4/102, 3.9%) who were 9 years of age or older. Two experienced surgical-site haematoma and infection, leading to device-exposure and explantation; one received re-implantation and required an additional return to OR for skin flap

reduction and is now successfully wearing their device. A third patient also required re-operation for skin flap reduction. A fourth patient experienced device exposure at the level of the magnet receiver stimulator and required explantation. Three of the children had significant comorbidities; one had had prior microtia repair and two of the patients with device-loss had significant developmental delay.

Conclusion: Rehabilitation of hearing is feasible with a surgical bone conduction aid (Osia2®) in children as young as 5. Complications occur at low rates and are often clustered in individual patients with medical and surgical complexities.

## **Auditory Outcomes and Safety Assessment of Bonebridge Implantation in Patients with Bilateral Microtia Aged 5 Years and Younger**

Yin-Yi Qiu, Yi-Fan Wang, Sui-Jun Chen

Department of Otolaryngology, Sun Yat-sen Memorial Hospital of Sun Yat-sen University, Guangzhou, China

### **Abstract**

**Objective:** Facing the urgent need to improve hearing, the available hearing aids for preschool children with bilateral microtia are limited. Currently, Bonebridge is one of the safe and effective bone-conduction auditory implant devices, and previous studies suggest that children aged 5 years above are more suitable for implant. In our retrospective study, we intend to confirm the hearing effect and surgical safety of Bonebridge implantation on bilateral microtia patients aged 5 years and younger by following-up and analyzing the clinical and audiological data of different ages children, and widening the age range for Bonebridge implantation with risk of complications under control.

**Methods:** This study used a retrospective data collection method to gather clinical and audiological information of 2 to 12-year-old bilateral microtia patients who underwent Bonebridge implantation surgery in our hospital from September 2016 to September 2022. Patients were divided into a 5-year-old and younger age group (experimental group) and a 6-12-year-old age group (control group) to compare their differences in postoperative hearing gain, surgical conditions, and post-surgical complications.

**Results:** After the surgery, the improvement of air conduction audibility thresholds in the both group was statistically significant ( $P < 0.01$ ). The improvement in the experimental group was even significantly higher compared to the control group ( $P < 0.05$ ). One case in each group experienced subcutaneous hematoma after the surgery, but no other serious surgery or implant-related complications were observed. There was no statistical significant differences in operation time and sigmoid sinus or endocranium exposure between the two groups ( $P > 0.05$ ).

**Conclusion:** Through retrospective analysis, this study confirms that Bonebridge implantation surgery can achieve satisfactory hearing recovery with a low incidence of complications for children under the age of 5 with bilateral microtia. Age cannot be used as a restriction for the performance of Bonebridge

implantation. This study provides a good foundation for expanding the age range of Bonebridge implantation surgery and further conducting large-scale prospective studies.

## **Pediatric Limited Usable Hearing Unilaterally (LUHU): A scoping review of treatment and management considerations**

Christine Brown M.Cl.Sc, Krystal Beh M.Cl.Sc, Marlene Bagatto PhD

Western University, London, Ontario, Canada

### **Abstract**

**Objectives:** Limited usable hearing unilaterally (LUHU), historically referred to as single sided deafness, is a term used to describe a unilateral sensorineural hearing loss, often of profound degree on the affected side, characterized by the apparent or predicted lack of benefit from an air conduction hearing aid (Picou et al., 2020). For infants and young children with LUHU, functional benefit cannot be formally assessed. Early intervention for identified hearing loss is considered standard practice (JCIH, 2019). This juxtaposition results in management challenges. Treatment options for the pediatric population evolve with new evidence. This changing landscape can be summarized and operationalized to support effective and timely intervention.

**Methods:** A scoping review was completed using search terms such as: children, unilateral hearing loss, hearing aid, cochlear implant, and others. The Scopus, PubMed, and Embase databases were searched as they house health care publications.

**Results:** 425 publications were identified for review and three reviewers screened their abstracts. 299 publications will undergo full review by independent reviewers. Early results indicate that LUHU management decisions hinge on imaging results. Children with LUHU and an intact auditory nerve should be considered candidates for cochlear implantation (CI). In contrast, evidence for bone conduction device fitting for children with LUHU is lacking. Speech in noise performance arose as an additional management challenge for children with LUHU.

**Conclusion:** Through this scoping review, evidence for the management of children with LUHU supports consideration of multiple factors. For children with an intact auditory nerve, a CI is an option for interested families. When the auditory nerve is insufficient, management decisions are further complicated. Hearing care professionals and parents could consider a remote microphone (RM) system, a contralateral routing of signal (CROS) fitting, or a bone conduction device (BCD). These and other conclusions will be further described during the presentation. There continues to be a need for research outlining outcomes for children with LUHU and auditory nerve insufficiency.

## **The Safety and Audiologic Benefit of Replacing Sophono Bone Conduction Hearing Devices with BONEBRIDGE or Osia in Pediatric Patients**

Anastasia Kolousek BS, MA<sup>1</sup>, Kaitlyn Brooks MD<sup>2</sup>, Erin Holman AuD<sup>3</sup>, Nandini Govil MD, MPH<sup>2</sup>, Kristan Alfanso MD<sup>2</sup>

<sup>1</sup>Morehouse School of Medicine, Atlanta, GA, USA. <sup>2</sup>Department of Otolaryngology - Head and Neck Surgery, Children's Healthcare of Atlanta, Emory University School of Medicine, Atlanta, GA, USA.

<sup>3</sup>Department of Audiology, Children's Healthcare of Atlanta, Atlanta, GA, USA

## **Abstract**

**Objective:** To evaluate the surgical outcomes and audiologic benefit of replacing Sophono passive transcutaneous bone conduction hearing devices (BCHD) with active transcutaneous devices in pediatric patients.

**Methods:** A retrospective cohort study (IRB STUDY00001551) examined pediatric patients under the age of 21 who underwent Sophono BCHD explantation and replacement with BONEBRIDGE or Osia implants from 2019-2023. Outcomes included minor and major complication rate and audiologic outcomes. Major complications were classified as requiring surgical intervention. Audiologic comparisons between the two devices were done with speech recognition threshold (SRT) and speech-in-noise testing (SINT) with sound presented at 50 dB + 5 SNR. Speech in noise testing was performed in soundfield at 0 degree Azimuth positioning.

**Results:** Eight patients with a median age of 17 years (IQR 16.1-19.5) were included. Two patients (25%) received Osia implants while six patients (75%) received BONEBRIDGE implants. One patient (12.5%) experienced a headache and returned to the emergency department, which was classified as a minor adverse event. There were no instances of device exposure or soft tissue infection. Patients had a baseline pure tone average (PTA) of 65.00 dB (IQR 41.88- 65.94) and air-bone gap of 40.63 dB (IQR 32.50- 48.75). Aided audiologic testing with the Sophono BCHD revealed a median SRT of 20.00 dB (IQR 20-57.50) and median SINT score of 91% (IQR 91.00%-94.00%). Following BONEBRIDGE or Osia implantation, aided audiometry revealed a median SRT of 35.00 dB (IQR 31.25-35.00), and a median SINT of 97.00% (IQR 96.00-97.50%). The median change in SRT was -20 (IQR -30 - 5) and the median change in SINT was +5.50% (IQR 3.25%-7.75%). Seven patients (87.5%) preferred their new device while one (12.5%) felt their Sophono BCHD was superior.

**Conclusion:** Replacing Sophono BCHDs with updated active transcutaneous BCHD has few complications. Even though patients had worse SRT with active transcutaneous devices, SINT was better for active transcutaneous devices when compared to the Sophono. All but one patient reported subjective benefit of the new device. These results indicate that patients who desire device replacement should expect similar or improved audiologic outcomes with little complications.

## **INITIAL EXPERIENCE WITH THE COCHLEARTM OSIA®2 OSSEOINTEGRATED IMPLANT TO TREAT CONDUCTIVE HEARING LOSS IN CHILDREN**



Mark Felton MBChB, BSc, MSc, MD, FRCS<sup>1,2</sup>, Jason Powell MD, PhD, FRCS<sup>3,1</sup>, Amjad Tobia MD, FRCS<sup>1,3</sup>, Wang Annie<sup>4</sup>, Beers Alison<sup>4</sup>, Neil Chadha MBChB(Hons) MPHe BSc(Hons) FRCS<sup>1,3</sup>

<sup>1</sup>University British Columbia, Vancouver, BC, Canada. <sup>2</sup>BC Children's Hospital, Vancouver, BC, Canada. <sup>3</sup>BC Children's Hospital Division Pediatric Otolaryngology, Vancouver, BC, Canada. <sup>4</sup>BC Children's Hospital, Audiology, Vancouver, BC, Canada

## Abstract

**Objectives:** The Cochlear™ Osia®2 is an active osseointegrated steady-state implant system developed to provide bone conduction hearing while avoiding complications of percutaneous devices, such as infection, skin overgrowth and displacement. To our knowledge, outcomes have not been extensively described in children. We aim to describe our initial experience with the device and determine the surgical, hearing and patient reported outcomes in a series of children/young adults undergoing implantation.

**Methods:** A retrospective chart review of children/young adults (≤19 years of age) who underwent implantation of the Osia system at BC Children's Hospital, Vancouver, Canada. We collected outcomes including; indications, surgical techniques, comprehensive hearing outcomes, qualitative patient reported outcome measures and surgical/post operative complications.

**Results:** 12 implants were placed in 10 children (5 males, 5 females) age range 8 – 19 years. Implant activation and implant processor programming occurred at approximately 6 weeks post-operatively. We describe our surgical techniques (including various incisions used) and challenges. Also audiological outcomes pre and post implant activation, including air/bone conduction thresholds, speech perception and datalogging (implant device wear time). Quality of life questionnaires were completed prior to surgery and again 6 months post activation, including, HEAR QL for Children and for Adolescents, The Speech, Spatial, and Qualities of Hearing, and Screening Instrument for Targeting Educational Risk (completed by teachers).

**Conclusions:** The Cochlear™ Osia® system is a safe and effective bone conduction device in children and young adults with no significant intra/post operative complication.

## OSIA - IMPLANT PLACEMENT DEPENDING ON AGE GROUP IN CHILDREN

Zsolia Bere MD<sup>1</sup>, Adam Perenyi MD<sup>1</sup>, Balint Posta MD<sup>1</sup>, Roland Nagy PhD<sup>1</sup>, Gabor Katona Prof<sup>2</sup>, Jozsef Geza Kiss Prof<sup>1</sup>, Laszlo Rovo Prof<sup>1</sup>

<sup>1</sup>University of Szeged, Department of Otolaryngology, Head and Neck Surgery, Szeged, Hungary. <sup>2</sup>Heim Pal National Pediatric Institute, Ear Nose Throat Department, Budapest, Hungary

## Abstract

**Purpose:** Continuous technological advances result in the availability of new bone conduction hearing implants, and their suitability for pediatric patients need to be investigated. The Cochlear™ Osia® 2

system is a new powerful active osseointegrated steady-state implant system that uses digital piezoelectric stimulation to treat hearing loss. The implant is currently approved for patients aged 12 years and above in the United States, and  $\geq 7$  kg body weight in the European Union. Therefore, further clinical studies are required to assess device characteristics in younger patients. The aim of our study was to perform a morphometric study among 5-12-year-old children, and to develop a surgical protocol for Osia 2 system implantation based on these findings.

**Methods:** We examined retrospectively collected cranial CT scans of 5-12-year-old patients from our clinical database (40 cases in total, 4 age groups, 10 patients/group). We measured the bone and soft tissue thickness as well as the position of the sigmoid sinus in the implantation region,. 3D printed temporal bones were also used for hands-on planning.

**Results:** Soft tissue thickness varied between  $3.2 \pm 0.5$  mm and  $3.6 \pm 0.6$  mm and bone thickness varied between  $3.5 \pm 1.1$  mm and  $4.7 \pm 0.3$  mm in the different age groups. The sigmoid sinus was located  $1.3 \pm 0.2$  cm posterior to the ear canal, and the anterior distance was  $4.8 \pm 0.9$  to  $7.1 \pm 1.1$  mm.

**Conclusion:** Our morphometric study showed that patients aged 5-12 have different anatomical dimensions compared to adults, but that implantation of the Osia 2 system is feasible in these patients using an altered implant positioning recommended by our data. The Cochlear Osia 2 system is therefore an option for hearing rehabilitation in younger children.

## **The Transition from Abutment to Active Transcutaneous Bone Conduction Hearing Devices in Pediatric Patients**

Kaitlyn Brooks MD<sup>1</sup>, Anastasia Kolousek BS, MA<sup>2</sup>, Erin Holman AuD<sup>3</sup>, Nandini Govil MD, MPH<sup>1</sup>, Kristan Alfonso MD<sup>1</sup>

<sup>1</sup>Department of Otolaryngology - Head and Neck Surgery, Children's Healthcare of Atlanta, Emory University School of Medicine, Atlanta, GA, USA. <sup>2</sup>Morehouse School of Medicine, Atlanta, GA, USA.

<sup>3</sup>Department of Audiology, Children's Healthcare of Atlanta, Atlanta, GA, USA

### **Abstract**

**Objective:** To assess patient motivation, speech-in-noise testing (SINT) outcomes, and complication rates in pediatric patients who transitioned to active transcutaneous bone conduction hearing devices (BCHD) after using an abutment-style BCHD.

**Methods:** A retrospective cohort study (IRB STUDY00001551) included patients who had a history of BCHD with an external abutment and underwent implantation with an active transcutaneous BCHD (BONEBRIDGE or Osia implants) from 2019 – 2023 at a tertiary care pediatric center. All patients were prescribed antibiotics at time of active transcutaneous BCHD implantation. Complications were divided into minor and major; major complications were defined by operative intervention or device explantation. SINT results with age-appropriate wordlists were collected for the patients using both abutment-style and active transcutaneous BCHD.

Results: Five patients aged 11 – 14 years (median age 13.8 years) underwent implantation with 8 active transcutaneous BCHD after previously using an abutment-style device. The abutment-style BCHD were placed between 2011 – 2017 (aged 4 – 7 years). Three patients who previously used the Ponto 3 (6 implants, 75%) chose the Cochlear Osia implant (6 implants, all bilateral); two patients who previously used the BAHA Connect (2 implants, 25%) chose the BONEBRIDGE implant (2 implants, both unilateral). All patients previously endorsed intermittent infection, discomfort, or dislike for their abutment-style device and voiced satisfaction in regards to their decision to change technology. Complications occurred in 3 implant sites (37.5%). One patient with Treacher Collins Syndrome suffered persistent device exposure and infection despite advancement flap revision surgery, long courses of oral antibiotics, and local wound care; this implant was eventually removed. Minor and major complication rates were 25% and 12.5%, respectively. Speech-in-noise-testing (SINT) with abutment-style devices (n=4) ranged from 90 – 100% (median 98%) with signal presented from 40 – 50 dB + 5-10 signal-to-noise ratio (SNR). SINT for active transcutaneous devices (n=5) ranged from 84 – 100% (median 98%) for signal presented at 50 dB + 5 SNR.

Conclusion: While functional outcomes with abutment-style and active transcutaneous BCHD were relatively similar, pediatric patients expressed happiness after transitioning to the lifestyle-friendly active transcutaneous devices. Post-operative complications are not uncommon when abutment BCHD are replaced with active transcutaneous BCHD.

## Management of Single Sided Deafness in a Pediatric Population

Annemarie Wollet AuD

Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, USA

### Abstract

**Objectives:** Infants and young children with single sided deafness (SSD) present challenges in audiologic management due to the lack of evidence-based protocols. Cincinnati Children's Hospital Medical Center (CCHMC) has an established team of providers who specialize in the assessment and management of this population. In the absence of evidence-based protocols, it has been necessary to draw from evidence-led and consensus-based treatment recommendations. The management approach at CCHMC focuses on educating the patient and family about the challenges associated with SSD and the current technology options available to empower the family in the decision-making process. Additionally, audiologists at CCHMC are participating members of the Clinical Outcomes in Pediatric Audiology (COPA) working group. The group's current efforts are focusing on developing a consensus document and education materials for providers managing young children with SSD.

**Methods:** Current practice at CCHMC for managing patients with SSD has evolved based on emerging evidence, clinician experiences, advances in technology options, and patient outcomes. Participating in the COPA working group supports collaboration among pediatric audiologists and researchers across North America to improve patient management and practice consensus for young patients with SSD.

**Results:** The family education and evaluation approach taken by CCHMC clinicians for this population will be reviewed including fitting, and counseling considerations for pediatric patients. Supportive cases will be used to illustrate this process. An update on the COPA working group's current project as it relates to this population will be shared.

**Conclusion:** Patient and family education for children who have SSD is an important clinical practice area that requires further guidance for audiologists. The review of the CCHMC's current clinical practices has contributed to the efforts of the COPA Working Group's efforts to develop a consensus document and education materials for working with young children who have SSD.

**Friday, September 8<sup>th</sup>, 2023**

11:00- 12:30 SSD

## **Cochlear implants for single sided deafness: improved sound-localization performance without processing of binaural cues**

Martijn Agterberg<sup>1</sup>, Adriana Smit MD, PhD<sup>2</sup>, Prof. Emmanuel Mylanus<sup>1</sup>, Dr. Froukje Cals<sup>1</sup>

<sup>1</sup>Radboud University, Nijmegen, Netherlands. <sup>2</sup>University Medical Center Utrecht, Utrecht, Netherlands

### **Abstract**

**Objectives:** Patients with single-sided deafness (SSD) experience difficulties with speech perception in noise and sound localization. Potentially they can benefit from fitting a cochlear implant (CI), in particular when they are suffering from tinnitus. The literature reports improved subjective benefits and improved sound localization abilities when listening with a CI. However, patients rather "lateralize" sounds instead of localizing sounds. The term "lateralization" is used to describe that the patient reports that the sound appears from the left or right, rather than from any position.

**Methods:** Sound localization in both the horizontal (-70° to 70° azimuth) and vertical (-35° to 40° elevation) plane is measured in a sophisticated setup by measuring the natural head-pointing response towards perceived sound locations. In this setup loudspeakers are not visible so subjects can only rely on auditory information enabling to test binaural hearing.

**Results:** We demonstrate that on average CI listeners benefit from the CI. However, the inter-subject variability in sound localization abilities varies significantly in both the aided and unaided condition and is related to high-frequency hearing loss in the hearing ear. Binaural hearing is not restored. In the unaided condition patients can localize sounds in the horizontal plane by using monaural spectral pinna cues, loudness and timbre.

**Conclusion:** We conclude that it is important to improve counseling and discuss the expectations of implantation in detail with the patients. We advise to share the information that there is no consensus

on how to treat single sided deafness, that speech understanding in complex listening situations will remain difficult and that non-invasive options to improve speech understanding in specific situations are available.

## **Sound Localization in Active Transcutaneous Bone Conduction Implant Users with Single-Sided Deafness**

Madison Epperson MD, Gerily Jones AuD, Chioma Anidi BA, Nadine Ibrahim MD, Renee Banakis Hartl MD, AuD

University of Michigan, Ann Arbor, MI, USA

### **Abstract**

**Title:** Sound Localization in Active Transcutaneous Bone Conduction Implant Users with Single-Sided Deafness

**Objectives:** To evaluate sound localization accuracy of subjects with single-sided deafness (SSD) with active transcutaneous bone conduction implants (atBCI) compared to the unaided condition and normal hearing controls.

**Methods:** Prospective case-control study in tertiary referral center including 6 patients with moderate to profound unilateral sensorineural hearing loss implanted with an atBCI and 11 normal hearing controls. Frequency-specific localization was assessed in a semi-anechoic chamber using a 24-speaker array. Stimuli included broadband (BBN) and narrowband noise (NBN) with center frequencies of 500, 1000, and 4000 Hz. Perceived stimulus angle was recorded and compared with presented stimulus location. Statistical analyses were performed using ANOVA and Wilcoxon rank-sum tests. Main outcome measures included:

- (1) Root-mean-square (RMS) error (degrees) and regression slope.
- (2) Subjective assessment of localization ability (Speech Spatial Qualities questionnaire).

**Results:** Normal hearing controls localized with excellent precision and accuracy. Subjects with SSD demonstrated worse localization by RMS error and regression slope compared to controls for both BBN ( $p < 0.0001$ ) and NBN at 500 Hz and 1000 kHz ( $p < 0.0001$ ). There was no statistically significant difference ( $p = 0.3979$ ) in slope between all groups at 4000 Hz, likely due to the relatively preserved unaided high frequency localization of some SSD individuals in the unaided and aided condition. Unaided performance was poorest at 500 Hz. There was significant improvement of 5.2o RMS error at 500 Hz with the atBCI over unaided. Individual localization varied widely within the SSD cohort, with some individuals showing significant improvement in RMS error with the atBCI, particularly at 4000 Hz. Though SSQ confirmed particular difficulty in the spatial hearing domain, all domains improved with device use.

**Conclusion:** Localization ability for individuals with SSD falls into a somewhat bimodal distribution. Some have fair localization, particularly at high frequencies, that is preserved or slightly improved with the atBCI. Others have minimal localization ability, with no apparent device benefit. Localization performance was frequency-specific, worse at 500 Hz. For better performers, atBCI may slightly improve localization at low frequency stimuli.

## **OSIA in Single-Side Deafness: Surgical and audiological outcomes**

Jose Eduardo Guzmán Dr.<sup>1,2</sup>, Luis Fernando Rincón Dr.<sup>3,4</sup>, Fernando Silva Dr.<sup>3,4</sup>, Jorge Cabrera Dr.<sup>3,4</sup>, Francisco Gonzalez Dr.<sup>3,4</sup>, Santiago Hernandez Dr.<sup>5,6</sup>

<sup>1</sup>Hospital Militar Central, Bogotá, Colombia. <sup>2</sup>Clínica Infantil de Colsubsidio, Bogotá, Colombia. <sup>3</sup>Clínica Visual y Auditiva, Cali, Colombia. <sup>4</sup>Instituto para niños ciegos y sordos del Valle del Cauca, Cali, Colombia. <sup>5</sup>Clínica de Marly, Bogotá, Colombia. <sup>6</sup>Hospital Universitario San Ignacio, Bogotá, Colombia

### **Abstract**

The Osia2<sup>®</sup> is an active transcutaneous bone conduction implant indicated for patients with conductive and mixed hearing loss but can also be used in cases of single-sided deafness (SSD). Bone conduction hearing devices can be used to reroute signals directed at the impaired ear transcranially using bone conduction to the functioning cochlea on the contralateral side. Limited outcome data for SSD is still available. To investigate the surgical procedures and audiological results for the Osia<sup>®</sup>2 in SSD patients.

**Method:** Multicenter, retrospective, and descriptive study. Patients with SSD and bone conduction PTA4 ≤25dBHL on the contralateral side were included. Data analysis of surgical technique, audiological measurement and subjective benefit for SSD patients was conducted. Functional gain measurements were performed comparing unaided to aided condition with the Osia<sup>®</sup>2. To determine subjective benefit and self-perception of disability with the Osia<sup>®</sup>2, participants also completed the COSI and the SSQ-B version, respectively.

**Results:** Seventy-two patients were included in the study with mean age of 36.3 years, being 76% younger than 18 years. Fifty-nine percent of the implants were on the right side and 7 cases were transitions of previous implant to Osia<sup>®</sup>2. The mean surgery time was 51 minutes. The average skin thickness was 5.9mm. Soft tissue thinning was performed in 2 subjects and a 4mm implant was used in 63 patients. The mean gain on PTA4 was 78.9dB, comparing unaided pre-surgical threshold to aided threshold in free field with the contralateral ear properly masked. Seventy-eight percent referred would like to improve their ability to follow conversations in quiet or in background noise on COSI. Eighty-seven percent of this group stated that they could hear better or much better on these situations using the device. In the SSQ-B, the average was 2.6 in the language domain, 2.1 spatial hearing, and 2.3 sound qualities, indicating an improvement with the Osia<sup>®</sup>2 in daily-life-situations.

**Conclusion:** The OSIA2 implantation in a group of patients with SSD was feasible and demonstrated great audiological outcomes and low complication rates. Advances in bone conduction technologies, may help reduce the negative impact of SSD mainly in noise environments.

## **Guidelines for deciding between cochlear implantation and bone anchored devices for adults with significant hearing in one ear**

Claire Iseli MBBS (hons), FRACS, MS<sup>1,2</sup>, Rodney Hollow Masters of Audiology<sup>1</sup>, Alex Rousset PhD<sup>1</sup>, Sylvia Tari Masters of Audiology<sup>1</sup>, Raoul Wills BA (Hons) MClAud AAudA<sup>1</sup>

<sup>1</sup>Royal Victorian Eye and Ear Hospital, Melbourne, Victoria, Australia. <sup>2</sup>Melbourne University, Melbourne, Victoria, Australia

### **Abstract**

**Objectives:** To develop clinical guidelines that assist in establishing if a cochlear implant (CI) or bone conduction device (BCD) is the more suitable option for adults who present with a severe to profound hearing loss in one ear and no worse than a moderate loss in the other ear.

**Methods:** Speech perception, localization and subjective feedback measures were obtained from a group of 50 adults following CI surgery. All adults had a PTA of <60dBHL in the contralateral ear. Outcome measures included: a speech in adaptive noise (SRT) test, a monosyllabic word test presented directly to the CI, a 13-speaker localization test and questionnaires (SSQ, Tinnitus Inventory and IOI-HA). Correlations between the outcome measures and factors such as level of hearing and duration of hearing loss were examined. These outcomes were then compared with our clinic's experience with BCD to develop clinical guidelines.

**Results:** There were significant improvements post CI on all measures in this group. There was an average improvement of 5dB on the SRT tests following implantation and the mean implant-alone monosyllable word score was equivalent to that obtained by the clinic's standard CI recipient group. There was no correlation between speech perception measures and SSQ total score, indicating both types of measures were useful. While patients with a duration of hearing loss up to 20 years benefited from implantation, those with a duration of <5 years had higher satisfaction scores on IOI-HA. Subjects with more hearing in the contralateral ear scored better on some measures. If a patient had a duration of hearing loss < 20years and achieved an improvement in pre-CI SRT with CROS/BCD of <7dB (speech to bad ear, noise to good ear) then a CI could be considered, with appropriate counselling about expectations.

**Conclusion:** Clinical guidelines for counselling and recommending CI versus BCD for adults who present with significant levels of hearing in one ear and a severe to profound loss in the other have been established based upon measured outcomes data.

# **PERFORMANCE IN SPEECH DISCRIMINATION IN NOISE IN PATIENTS WITH UNILATERAL PROFOUND HEARING LOSS USERS OF AN ACTIVE PIEZOELECTRIC BONE CONDUCTION AUDITORY PROSTHESIS**

Francisco Gonzalez Eslait Prof., Julia Maria Fernandez Aud., Emelina Ruiz Tejada Dra.

Universidad del Valle, Cali, Colombia

## **Abstract**

Unilateral profound hearing loss (PAPU) is a hearing problem affecting only one ear with severe or deep hearing thresholds with poor language discrimination not amenable to amplification and contralateral unrestricted hearing. It causes hearing impairment by losing the ability to localize sound and understand speech in noisy environments. Each year, about 60,000 people in the United States acquire single-sided deafness. The use of bone-implantable additive devices is one of the treatment options available. This paper reports hearing performance and satisfaction with a new piezoelectric active implantable hearing prosthesis (IASO 2) used in the rehabilitation of patients with PAPU.

**OBJECTIVE:** To evaluate the audiological performance and satisfaction of users with PAPU of the Osia® 2 piezoelectric osseointegration active bone conduction device (Cochlear Corp., Sydney, Australia), especially under noise conditions.

**METHODS:** Patients with PAPU implanted with a piezoelectric active bone conduction system were audiotically analyzed with several tests: bone and air conduction thresholds, percentages of silent word discrimination and adaptive and non-adaptive noise conditions. Satisfaction with the device was also assessed using the BBSS (Bern benefit in single sided deafness questionnaire) for PAPU.

**RESULTS:** The PTA with OSIA 2 was 24,375 dB (free-field thresholds) and the percentage of discrimination for words was significantly better in terms of the use of the system in non-adaptive noise conditions (15% better than without the use of the device). The device's BBSS showed a wide degree of satisfaction especially in mitigating the problems associated with PAPU in reverberant environments and in group conversations.

**CONCLUSION:** The Osia 2 system is a transcutaneous alternative of active bone conduction in the rehabilitation of patients with PAPU that helps auditory performance in noise with a consistent degree of satisfaction.

**Friday, September 8<sup>th</sup>, 2023**

11:00- 12:30 Surgical Outcomes and Considerations



## Medical and device related adverse events in Osia® 2

Jose Agustin Caraballo Dr.<sup>1,2,3</sup>, Jorge Cabrera Dr.<sup>4,5</sup>, Leonardo Ordoñez Dr.<sup>6,7,8</sup>, Rafael Jaramillo Dr.<sup>9</sup>, Jorge Almarío Dr.<sup>10</sup>

<sup>1</sup>Clínicas Los Nogales, Bogotá, Colombia. <sup>2</sup>Compensar Entidad Promotora de Salud, Bogotá, Colombia. <sup>3</sup>Sanitas Entidad Promotora de Salud, Bogotá, Colombia. <sup>4</sup>Clínica visual y auditiva, Bogotá, Colombia. <sup>5</sup>Instituto para niños ciegos y sordos del Valle del Cauca, Cali, Colombia. <sup>6</sup>Clínica Universitaria Colombia, Bogotá, Colombia. <sup>7</sup>Unisanitas, Bogotá, Colombia. <sup>8</sup>Hospital Militar Central - Universidad Militar Nueva Granada, Bogotá, Colombia. <sup>9</sup>Hospital de Caldas SES, Manizales, Colombia. <sup>10</sup>Hospital Universitario mayor Méderi, Bogotá, Colombia

### Abstract

**INTRODUCTION:** Percutaneous Bone Conduction Implant (BCI) required a abutment that penetrates through the skin, predisposing patients to potential complications. Though reported numbers have varied widely, skin complication rates for percutaneous BCIs have been shown to occur in 22% of patients. Transcutaneous BCIs, as Osia System, are implanted under the skin without a persistent opening in the skin and may offer improved outcomes while reducing skin-related complications associated with previous models. Hence, there are limited studies documenting complications with Osia System postoperatively, though research suggests there are fewer complications when compared to previous models.

**AIM:** To review all medical/device-related adverse events (MDRAEs) associated with the Osia System.

**METHOD:** In Colombia, Cochlear follow closely and ask that all MDRAE be reported to them. A search of the Cochlear's database was conducted looking for MDRAE submitted between June 2020 to April 2023. Adverse events (AE) were separated into two categories: patient injuries and device malfunctions. For patient injuries, TISA criteria were applied. Device malfunctions (DM) were stratified.

**RESULTS:** Out of 580 implants, a total of 13 (2.2%) AE related to patient's injuries were reported. Two AE were classified as TISA 1 who patients complained about local pain, discomfort, and heat sensation. One patient needed to make a MRI and referred heat sensations and pain, even with the MRI kit use. Four cases were classified as TISA 2 with reports of discharge, hematomas, and skin problems. TISA 3 was assigned to 6 cases: three explants due to ear infection not related with Osia; and three extrusions also due to site infections with posterior repositioned device. Out of 580 implants, a total of 11 (1.9%) adverse events related to device malfunctions were reported, including internal noise (n=3) and lack of connection between internal and external components (n=7). One screw broken during implant placement to the BI300 was reported and the last cases.

**CONCLUSION:** This study suggests that OSIA complication rate is low in comparison with other BCI devices. Besides improved treatment outcomes and implant functionality with recent BCI device innovations, the complication rate seems to be rare as well the device malfunctions.

# Feasibility of a novel, one-stage, drill system for bone-anchored hearing implants

Marsel Ganayev MSc<sup>1</sup>, Ruben Strijbos PhD<sup>2,3</sup>, Loïse Straatman<sup>2,3</sup>, Robert Stokroos Prof, MD<sup>2,3</sup>, Peter Thomsen Prof, MD<sup>1</sup>, Anders Palmquist Prof, PhD<sup>4</sup>, Martin L Johansson PhD<sup>1,5</sup>

<sup>1</sup>Department of Biomaterials, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden. <sup>2</sup>Department of Otorhinolaryngology, Head and Neck Surgery, University Medical Centre Utrecht, Utrecht, Netherlands. <sup>3</sup>University Medical Centre Utrecht Brain Centre, University of Utrecht, Utrecht, Netherlands. <sup>4</sup>Department of Biomaterials, Institute of Clinical Sciences, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Netherlands. <sup>5</sup>Research & Technology, Oticon Medical, Askim, Sweden

## Abstract

**Objectives:** The use of a minimally invasive surgical procedure, such as MIPS, for installing the bone anchored hearing system (BAHS) has resulted in important advantages compared with previously available surgical techniques. Here a novel minimally invasive procedure (MONO), where the final osteotomy is created in one single drilling step, is compared with MIPS, in which a three-step drilling sequence is employed, in terms of cutting performance and heat generation. Further, the feasibility of the MONO procedure is evaluated in terms of the dura response to drill trauma in comparison with MIPS.

**Materials:** The cutting characteristics of the drill bits were determined by measuring the torque and force while drilling in cadaveric bone at different feed rates. The heat generation was determined by measuring the temperature increase around the osteotomies. Fresh frozen temporal bone was subjected to penetration by the drills beyond the base of the mastoid bone to different depths. The sites were evaluated, and the damage to and possible penetration of the dura were determined.

**Results:** The study demonstrated a significantly superior cutting performance for MONO drill compared with the MIPS drill system. Significantly less heat was generated during drilling with MONO compared with MIPS for all variations of drilling procedure (drilling time, feed rate and amount of irrigation). The *ex vivo* evaluation showed that for a drill depth exceeding the mastoid bone thickness by less than 1 mm, damage to the dura was limited or nonexistent, whereas for a drill depth exceeding bone thickness by 2 mm, damage increased, or the dura was penetrated. There was a trend toward more damage and penetration using the MIPS guide drill bit compared with the MONO drill bit.

**Conclusion:** The MONO procedure is the first one drill step procedure for BAHS. Importantly, less heat was generated using MONO, despite the entire bone volume being removed in one sequence. If the dura is encountered, MONO is not more inclined to penetrate the dura than the MIPS system. In conclusion, the new MONO procedure provides a minimally invasive, safe, streamlined and efficient procedure for installation of the BAHS implant system.

## **Alternative Skin Incision for Baha Attract System: Personal Experience**

Aleksandra Slezak M.D., Ph.D, Maciej Wrobel M.D., Ph.D.

Department of Otolaryngology and Laryngological Oncology, Collegium Medicum of the Nicolaus Copernicus University, University Hospital No. 1, Bydgoszcz, Poland

### **Abstract**

**Objectives:** Evaluation of the usefulness of the simplified vertical incision in the Baha Attract System operation

**Methods:** A retrospective analysis was conducted on patients treated with the BAHA Attract system, where surgical access to the operative field was achieved using a vertical incision.

The cosmetic aspects of the skin incision, technique of the surgery, the course of wound healing, complaints reported by patients and the hearing results of the prosthesis were assessed.

**Results:** The study included 5 patients, the follow-up ranged from 3 to 6 months. During the observation period, no adverse effects or complications resulting from the performed surgical incision and the use of processors via magnetic coupling were observed.

**Conclusions:** The longitudinally placed incision line results in minimal bleeding from the scalp and enables quick achievement of hemostasis. It helps avoid conflicts with existing scars in the preauricular area in patients previously treated with percutaneous access.

## **A comparative study of chronic pain between the new Osia system, percutaneous Bone-anchored hearing aids and Cochlear implants.**

Mridul Rana MBBS, James Ramsden

Oxford University Hospitals, Oxford, United Kingdom

### **Abstract**

**Introduction:** Chronic pain is reported as a rare but challenging problem with hearing implants. Our aim is to assess how the new piezoelectric osseointegrated implant, Osia, compares to percutaneous Bone-anchored hearing aids (BAHA) and Cochlear implants with regards to pain.

**Methods:** 30 patients meeting criteria for hearing implants in a tertiary centre were evaluated; 10 percutaneous BAHA users, 10 Cochlear Implant users and 10 Osia users. Follow up was for a minimum of 6 months after initiating device use. Participants answered a questionnaire focusing on pain. The Brief Pain Inventory score (BPI) was used to assess pain severity (0 = no pain to 10 = worst pain). Additional data was collected on localised skin changes, headaches and medical or surgical interventions required for pain management.

Results: 0 Osia users (0%) reported pain as a significant side effect of their device compared with 3 BAHA users (30%) and 1 (10%) Cochlear user. Pain after 6 months of device use was lowest in the Osia group; only 1 patient reporting a score other than 0. BPI ranges on follow up were 0-1 in the Osia group, 0-5 in the BAHA group and 0-7 in the Cochlear group. None of the Osia users required medical management of pain, reduced their device use or were considering removal unlike BAHA and Cochlear users.

Conclusion: Osia Implant users have less pain in comparison with percutaneous BAHA and Cochlear users, allowing them to maximise the use of their device, preventing failure and the need for removal.

## **Preliminary investigations on MRI-induced artifacts from the Osia 2 System**

Adam Perenyi<sup>1,2</sup>, Beata Diosi<sup>2</sup>, Zsofia Bere<sup>1</sup>, Angela Csomor<sup>2</sup>, Linda Szabo<sup>1</sup>, Balint Posta<sup>1</sup>, Mikos Csanady<sup>1</sup>, Antal Nogradi<sup>3</sup>, Antal Nogradi<sup>3</sup>, Zsigmond Tamas Kincses<sup>2</sup>, Laszlo Rovo<sup>1</sup>

<sup>1</sup>Department of Otorhinolaryngology, Head and Neck Surgery University of Szeged, Szeged, Hungary.

<sup>2</sup>Department of Radiology, University of Szeged, Szeged, Hungary. <sup>3</sup>Department of Anatomy, Histology and Embriology, University of Szeged, Szeged, Hungary

### **Abstract**

Purposes: Hearing implants, especially those containing magnets, often limit the assessment of head MRI examinations due to susceptibility artifacts, which potentially lead to inconclusive reports. Our primary aim is to evaluate MRI-induced effects attributed to the Osia 2 System in terms of utility in assessment of selected intracranial structures in order to provide an anatomy-based guide for clinicians. The utility of sequences with metal-artifact reduction is also assessed.

Methods: MRI scanning with adherence to the institutional “inner ear” protocol with a General Electric Signa Artist 1.5 Tesla scanner. Wholebrain and focused T1 and T2 weighted sequences with metal-artifact reduction (MAVRIC SL) with the Implant magnet in place and removed. After scanning, image quality independently assessed by three head and neck radiologists on a 4-point scale with regards to diagnostic value in the radiological assessment of 14 intracranial structures.

Results: The Osia 2 System produces image artifacts of varying degrees in the series of standard imaging sequences, predominantly on the ipsilateral, but also on the contralateral side of the head, relative to the implant. The overwhelming majority of the susceptibility artifacts are caused by the implant magnet. However, with the magnet in place, metal artifact reduction provides significantly better image quality that is comparable with the Osia 2 Implant after magnet removal.

Conclusions: This is the first investigation published on the effect of the Osia 2 Implant on image evaluation potential in a 1.5 Tesla MRI scanner. Metallic artifact reduction sequences are effective tools in tackling the diagnostic difficulties attributed to metal artifacts produced by the Osia 2 Implant with implant magnet in place, which potentially allows for sufficiently good quality images without surgical intervention to remove the magnet or the implant.

## Evaluating risk factors and comorbidities associated with OSIA2 implantation

Pavel Kipnis BS<sup>1</sup>, De'Andre Warren MD<sup>2,1</sup>, Alejandro Rivas MD<sup>2,1</sup>, Viral Tejani AuD, PhD<sup>3,1</sup>, Sarah Mowry MD, FACS<sup>2,1</sup>

<sup>1</sup>Case Western Reserve University School of Medicine, Cleveland, OH, USA. <sup>2</sup>Department of Otolaryngology - Head and Neck Surgery, University Hospitals Cleveland Medical Center, Cleveland, OH, USA. <sup>3</sup>Department of Audiology, University Hospitals Cleveland Medical Center, Cleveland, OH, USA

### Abstract

**Objectives:** The aim of this study was to identify and evaluate risk factors and comorbidities associated with OSIA2 implantation at a tertiary academic care center.

**Methods:** A retrospective review of all patients >12 years of age who underwent OSIA implantation surgery from October 2020 through March 2023 was performed. Demographic information, surgical history, past medical history, and follow-up information was collected for each patient. Complications due to OSIA implantation were defined as poor audiologic performance of implant, intractable pain, auricular proptosis, surgical site infection, wound dehiscence, or implant extrusion which resulted in subsequent implant removal.

**Results:** 55 patients underwent OSIA implantation at our institution in the time range defined for this study. 44 patients met the criteria for inclusion.

7 of 44 patients were identified as having a complication due to OSIA implantation. 5 were female, and 2 were male. Of the 7 patients with complications, 3 patients had a history of hypertension, 2 had coronary artery disease, and 2 had a history of type II diabetes mellitus. 2 of the 7 patients had a history of a chronic pain syndrome; one patient had a history of rheumatoid arthritis, and one had a history of neuropathic pain. 5 of the 7 patients reported poor audiologic performance of implant, 3 reported pain which was poorly controlled pharmacologically, 2 experienced wound dehiscence, 2 experienced surgical site infection, and 2 reported implant extrusion. In one patient with implant extrusion, damage of the implant silicon housing was evident. Every patient that experienced bone-anchored hearing aid (BAHA) complications as an indication for conversion to OSIA (n=3) later experienced complications with OSIA implantation.

**Conclusion:** Patients with a history of previous BAHA complication, type II diabetes mellitus, and microvascular disease may be at higher risk to experience complications with OSIA placement. Additionally, the surgical technique necessary for OSIA implantation may be more nuanced than previously reported, with incision and implant placement possibly contributing to postoperative pain. Despite providing enhanced performance in hearing rehabilitation, further research is needed to better elucidate complication rates and predisposing risk factors for poor outcomes.

## Ten years and 228 surgeries later; we suggest that minimally invasive surgery for bone anchored hearing implants is here to stay.

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### Abstract

**Objectives:** The overall objective of this study was to compare surgical and postoperative outcomes between different clinical practice for bone-anchored hearing implant installations. As the surgical techniques have evolved significantly in recent years, particular focus is on exploring differences between linear incision and minimally invasive surgical techniques for bone-anchored implants.

**Method:** The study utilized a retrospective design and collected data from 228 bone-anchored hearing implants in 200 patients, performed over a 10-year period between 2012 and 2022 in a university hospital in São Paulo, Brazil. The setting of the study was the referral hospital from the Ribeirão Preto Medical School, University of São Paulo, involving approximately 35 otologic surgeons, fellows, and other trainees during this period. To reflect a real-world life setting, eligibility criteria from clinical practice were applied. Information on demography, etiology, surgical setup, complications, and audiological outcomes were collected.

**Results:** The minimally invasive technique is associated with shorter surgery duration, 19.5 (SD=9.6) versus 43.9 (SD=22.2) minutes ( $p<0.0001$ ) as compared to a linear incision technique. The minimally invasive technique was also associated with a lower occurrence of complications when compared to linear incision techniques (intraoperative; 1.8% versus 4.9% ( $p = 0.39$ ), postoperative; 49% versus 66% ( $p=0.039$ ). Most differences were seen in complications relating to skin and wound healing. For example, for the Holgers score, 70% of the minimally invasive cases reported no skin reaction (Holgers = 0) during follow-up compared with 48% of the linear incision cases ( $p=0.010$ ).

**Conclusion:** Adoption of a minimally invasive surgical technique for installation of bone-anchored hearing implants can reduce surgical complexity without compromising safety aspects or clinical benefits. Shorter surgery time and fewer complications, especially those associated with the skin and wound healing, could be expected when going from a linear incision to a minimally invasive technique. The findings in the current study support using the minimally invasive techniques in an in-office setting, outside the main operating room.

# **Magnetic Resonance Imaging Artifact Associated with Transcutaneous Bone Conduction Implants: Cholesteatoma and Vestibular Schwannoma Surveillance**

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## **Abstract**

**Objective:** To evaluate the MR image artifact and image distortion associated with the two transcutaneous bone conduction implants currently available in the United States.

**Study Design:** Cadaveric study

**Methods:** Two cadaveric head specimens (one male, one female) were unilaterally implanted according to manufacturer guidelines and underwent MR imaging (General Electric and Siemens 1.5T scanners) under the following device conditions: 1) no device, 2) Cochlear Osia with magnet and headwrap, 3) Cochlear Osia without magnet, 4) MED-EL Bonebridge with magnet. Maximum metal mitigation techniques were employed in all conditions, and identical sequences were obtained. Blinded image scoring (diagnostic vs nondiagnostic image) was performed by experienced neuroradiologists according to anatomical subsite.

**Results:** All device conditions produced artifact and image distortion. The Osia with magnet produced diagnostic T1- and T2-weighted images of the ipsilateral temporal bone, however, non-EPI DWI was nondiagnostic. The Osia without magnet scanned on the Siemens MR imaging demonstrated the least amount of artifact and was the only condition that allowed for diagnostic imaging of the ipsilateral temporal bone on DWI. The Bonebridge produced a large area of artifact and distortion with involvement of the ipsilateral and contralateral temporal bones.

**Conclusions:** In summary, of the three device conditions (Osia with magnet, Osia without magnet, and Bonebridge), Osia without magnet offered the least amount of artifact and distortion and was the only condition in which diagnostic DWI was available for the middle ear and mastoid regions on the Siemens MR imaging scanner.

## **Performance outcomes with laser-ablated BHX implants for bone-anchored hearing procedures – 3-month data from a multi centre study of 50 patients**

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## Abstract

**Objectives:** Bone-anchored hearing system (BAHS) implants have improved over time. The latest improvement is the Ponto BHX implant (Oticon Medical, Sweden). With its partly laser-ablated surface, creating micro and nano level surface structure in the thread valleys of the screws, the implant has shown to increase the bone bonding with 153% compared with standard implants. The overall objective of this study was to prospectively study the rate of successful BAHS use after implantation of the Ponto BHX implant.

**Methods:** The study used a prospective, multi centre design including 50 adult patients and six European hospitals. Ponto BHX implant installations were performed using either the linear incision or the Minimally Invasive Ponto Surgery (MIPS) technique. Clinical follow-up, complication rates, and patient benefit were monitored at 9 days, 5 weeks, 3 months (primary endpoint), 6 and 12 months.

**Results:** In a total of 50 patients (51 implants), the median age at surgery was 59 years (range: 20–80) and 56% of the participants were female. According to surgeon preference, 65% of all surgeries were performed using linear incision, 33% using MIPS, and 2% converting from MIPS to linear incision due to excessive bleeding. All patients received the 4mm implant except one that instead had a 3mm implant placed. No major intra or postoperative complications have been reported. Preliminary data show that the patients are highly satisfied with their hearing solution with an average of 12 hours sound processor usage per day and improved quality of life 3 months after surgery. Two spontaneous implant losses occurred 5–6 weeks after surgery, resulting in 96% implant survival. Pain and numbness, often transient, were experienced by few patients, and skin reactions were few with only three patients (6%) having an adverse skin reaction (Holgers $\geq$ 2) up until 3 months.

**Conclusion:** Installation of Ponto BHX implants is safe and provide excellent clinical outcome regardless of the technique used (linear incision or MIPS). Preliminary data indicate no unexpected findings or safety issues, high patient satisfaction, and an implant usability of 96% three months after surgery.

**Friday, September 8<sup>th</sup>, 2023**

13:30- 15:00 Pediatrics 3



# **Paediatric Percutaneous Bone Anchored Hearing Aid Implant Failures: Comparing the Experience of a Tertiary Center with a Systematic Review of the Literature and Meta-Analysis.**

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## **Abstract**

**Background:** Percutaneous Bone Anchored Hearing Aids (BAHAs) first came into use in the 1980s. They have been widely shown to be effective from an audiological standpoint in treating paediatric patients with conductive or mixed hearing loss. Despite this, uptake has been restricted due to the significant rates of implant failure and extrusion. This abstract presents a systematic review and meta-analysis of the literature combined with a case-series of device failures from a paediatric tertiary centre.

**Methods:** Four databases were searched, yielding 562 articles for screening. Two reviewers screened independently for title and abstract, and full text. Data extraction was conducted to identify the number of failures within the included papers. Random-effects meta-analysis was used to produce a summary effect size for the proportion of failures across the literature. The risk of bias was assessed using the Joanna Briggs Institute critical appraisal tools. Subsequently, our retrospective case-series included consecutive paediatric patients who underwent percutaneous BAHA surgery for the period 2003-to 2019. The primary outcome was implant failure with extrusion of the fixture from the cranium.

**Results:** In total, 34 papers were included in this review detailing 1599 implants across 1285 patients. There were 198 reported failures in the literature, giving an overall implant failure rate of 11% following random-effects analysis. The most common reason for failure was traumatic extrusion. The risk of bias was deemed to be low. In our case-series, we recorded a total of 104 implantations across 76 patients. The median age was 11 years. Five implants (in four children) failed (4.8%), two due to trauma, and three due to infection.

**Discussion:** We postulate that the explanation for our lower-than-expected failure rates includes exclusively using 4mm fixtures from a single manufacturer and older age at first implantation. Our implant survival results are more reassuring when considering that the latest generation of active transcutaneous devices from the same manufacturer utilizes the same 4mm implant. Limitations of the systematic review findings relate to the heterogeneity of study designs. Future work to develop a minimum data set and standardized reporting format for bone conduction implants (BCI) would be beneficial.

# The outcome of children after OSIA-2 implantation: safety, auditory outcome, and quality of life

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## Abstract

**Objective:** Advancements in technology have resulted in the production of new bone conduction hearing implants, with their suitability for pediatric patients being a major concern. The Cochlear Osia<sup>®</sup> 2 (OSIA-2) is a new active osseointegrated steady-state implant system that utilizes digital piezoelectric stimulation to treat hearing loss. The aim of this is to assess the safety and auditory performance of OSIA-2 in children with hearing loss

**Method:** Prospective cohort study on children (18 years and younger) who have received OSIA-2 implantation from January 2021 to January 2023. Demographics, comorbidities, radiological imaging, operative details, pre and post operative audiological testing (including audiometric measurements, speech discrimination and sound localization), surgical outcome and complication were recorded. Children older than 7 were given HEARQL questionnaire preoperatively and 3 months postoperatively to determine the impact of OSIA on their quality of life.

**Results:** Twenty children (21 implants) were included in this study with a median age of implantation was 7 years (range 3.1 - 17.5 years). Most patients had conductive hearing loss & mixed hearing loss (CHL/MHL) due microtia and canal atresia (14/20), chronic ear disease (1/20) and single sided deafness (SSD) (5/20). Only one patient had bilateral simultaneous OSIA implantation. None of the patients had any postoperative complications. For children with conductive hearing loss, the median air-bone-gap was reduced from 50dB to 10dB ( $p$  value 0.01). At 6kHz the median aided threshold was 15dB. All the patients were wearing the device regularly with median usage duration of 9.5h per day.

There also a significant improvement in specific sound localization in children with CHL/MHL (26% to 90%  $p$  value < 0.001). Furthermore, children with SSD had an improved sound localization from 15% to 50% ( $p$  value 0.01). This was mostly notable in determining the general sound location (right or left).

Finally, the HEARQL score increased from 68% to 87% ( $p$  value 0.01)

**Conclusion:** OSIA-2 is a safe procedure to be performed on children. It yielded a significant audiological gain especially in high frequencies, speech discrimination and sound localization. This resulted in a high patients' compliance and usage hours as well as improved quality of life.

## Best Practices and Clinical Experience in Children with Bone Conduction Hearing Devices (BCHDs)

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<sup>1</sup>Children's Healthcare of Atlanta, Atlanta, GA, USA. <sup>2</sup>Emory University, Atlanta, Ga, USA. <sup>3</sup>Morehouse School of Medicine, Atlanta, GA, USA

## **Abstract**

**Objectives:** Transcutaneous bone conduction implants have created a need for new clinical protocols. From candidacy to verification, transcutaneous implants have changed how we test and treat children with BCHDs. We have studied and adapted best practice guidelines for patient management in children with BCHDs. We hypothesized that these well-defined instructions could identify trends in patient outcomes.

**Methods:** Our population included children under 21 years old fit with BCHDs in approximately 100 ears. We used relevant literature to develop best practice guidelines for management in children with BCHDs. Clinical experience further informed and refined these guidelines. We established specific instructions for determining candidacy, discussing device options, and assessing device benefit. Candidates for BCHDs included children with conductive and mixed hearing loss in one or both ears and children with single-sided deafness. Device selection varied based on patient age and hearing loss. We used aided testing to assess device benefit. With the introduction of transcutaneous bone conduction implants, we focused more on speech stimuli. Speech testing ranged from Ling 6 Sound audiograms to sentence recognition in noise. When possible, we used speech in noise testing to assess three noise conditions, with noise presented to the front, the impaired ear, and the better ear. Without prescriptive targets for any transcutaneous implant, we also relied on speech testing to verify device fitting. We only used soundfield thresholds to make programming decisions if we observed trends in speech perception.

**Results:** Our best practice guidelines provided a systematic approach for observing trends in patient outcomes. Active transcutaneous implants yielded poorer soundfield thresholds and better speech perception scores compared to other bone conduction implants. Speech testing was more predictive than soundfield thresholds for assessing real-world benefits.

**Conclusion:** Our experience shows that best practice guidelines can help identify trends in patient outcomes. Best practices should include speech perception testing to assess device benefit and to verify device fitting in children with BCHDs.

## **A comparative study between audiological and speech outcomes of a non-implantable wearing options for BAHA in pediatric population**

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## **Abstract**

**Objectives:** To determine the audiological benefit of the current BAHAS sound processor worn on a SoundArc and to compare it to the known Softband in terms of soundfield hearing thresholds and speech understanding in patients who have purely conductive, mixed and SSD hearing loss.

**Methods:** A cross sectional study looking at children with Conductive, mixed or SSD hearing loss who are not candidates for middle ear surgery, canaloplasty, or standard hearing aids. At the baseline visit, pure-tone audiograms, including masked/unmasked air- and bone conduction thresholds with speech recognition scores were obtained. After a two-week experiment, each patient had an aided free field hearing threshold measurement with a BAHA sound processor on the Softband and SoundArc. Unrestricted area at the frequency range 250-4000 Hz in octave intervals, warble tone thresholds were computed. A speech discrimination test of monosyllabic words was conducted based on behavioral maps.

**Results:** A total of 32 children were identified. Twelve patients received right-side processors, eight received left-side processors, and six received bilateral processors. Sixteen of the patients were diagnosed with MHL, Twelve with CHL, and four with SSD. After two weeks of using programmed processors with Softband and SoundArc, all children were examined. The threshold for aided pure-tone audiometry was tested twice through each of the two transmission paths: first with the BAHA Softband and again with the SoundArc. The aided pure-tone audiometry threshold demonstrated a statistically significant improvement in PTA. The mean air-conduction thresholds for frequencies (0.5 to 4 kHz) were 63 dB, while the aided mean thresholds with the device (with Softband and SoundArc) was 35dB. When compared to the unaided scenario, a statistically significant improvement of 98 percent (SoundArc) to 96 percent (Softband) was found at 65 dB SPL. There were no statistically significant differences between any of the ensembles ( $p > 0.261$ ).

**Conclusion:** the tendency of BCHIs to have higher functional gain, especially at mid frequencies, could potentially contribute to good SSD compliance.

## **Demography of the Cochlear™ Osia® 2 System pediatric study: diversity in clinical trials**

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## **Abstract**

**Objectives:** The FDA has issued several guidance documents in recent years regarding the importance of enhancing participant diversity in clinical trials, specifically ways for Sponsors to promote diversity in their clinical trials to better represent the populations who will be utilizing the drug/ device. Obtaining

data from a diverse participant population will better increase access and representation when developing new technologies and/or drug applications.

**Methods:** In developing the protocol for CAM5766 “A pivotal, prospective, multi-center, geographically diverse, open-label study evaluating the safety and effectiveness of the Cochlear Osia® 2 System in a pediatric population” Cochlear™ Americas carefully considered the eligibility criteria to allow for recruitment of a more diverse population [e.g., fewer exclusions related to concomitant medications or comorbidities; race/ethnicity; financial burden]. The study population [N=50] consisted of children aged 5 to 11 years of age who presented with conductive or mixed hearing loss (up to 55 dB HL) or single-sided deafness (SSD). Additionally, Cochlear provided devices free of charge to mitigate restrictions based on insurance non-coverage or financial burden. Consent documentation was provided in both English and Spanish.

**Results:** 50 participants were implanted with the Osia 2 device (N=37 Mixed/Conductive loss / N=13 SSD). Enrolled patients were more likely to identify as non-white (28%) than the general US population (24%). Patients were also more likely to report identifying as Hispanic/Latinx (38%) than the US population (18.7%). 8% of participants’ parents utilized a Spanish consent form.

In addition to having a racially diverse participant population, the study also enrolled 38% of participants with one or more comorbidity, rare disease, or disorder. 4 participants enrolled have been diagnosed with ADHD and 2 participants are reported to be on the autism spectrum.

**Conclusion:** While outcome data from the study is not yet complete or available, Cochlear intends to show that geographic, racial and ethnic diversity and/or participant comorbidities do not have a significant impact on the outcomes of clinical trial conduction and outcomes. Additionally, as patients were not recruited based on ethnicity or race, factors contributing to this more ethnically/racially diverse study population will be discussed.

## **Mapping the standard of care and health outcomes in patients with chronic otitis media**

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### **Abstract**

**Study Purpose:** Management of patients with chronic otitis media is multidimensional and requires an array of surgical and non-surgical interventions to treat the infection and the associated hearing loss.

The current treatment pathway is poorly characterized and limited reporting of outcomes data act as a barrier to delivering evidence-based, patient-centred care in this patient group, especially when it comes to hearing rehabilitation. To overcome these barriers, we are currently mapping healthcare utilization in these patients as part of a multicentre, retrospective chart review and an international patient register.

**Materials and Methods:** An ongoing retrospective multicentre clinical investigation with a minor prospective element conducted at seven clinics across Germany, France and Spain. The medical chart review will provide health care data on around 100 patients with chronic otitis media and a PTA4 air bone gap of  $\geq 30$  dB or a PTA4 air-bone gap between 25-30 dB with PTA4 air conduction thresholds  $\geq 40$  dB HL within 12 months after primary tympanoplasty in the operated ear. Pre- and post-operative audiograms will also be extracted from the medical records. Quality of life and hearing disability data will be collected via the Health Utilities Index Mark III, the Chronic Otitis Media Outcome Test-15 and the Speech, Spatial and Qualities of Hearing Scale 12, respectively.

**Results:** Episodes of care from the time of initial surgery to study inclusion will be presented and stratified by etiology and intervention type. Post-operative free-field PTA4 hearing thresholds following middle ear surgery, plus additional interventions, will be compared to those measured pre-operatively for the unaided condition. Hearing and quality of life outcomes will be stratified by intervention type. Productivity losses due to hearing impairment will be calculated. The ability of the middle ear risk index to predict tympanoplasty success will be investigated.

**Conclusion:** This study is a first step towards comprehensively mapping standard of care and its effectiveness in terms of hearing outcomes and quality of life in patients with chronic otitis media. These data can be used to direct evidence-based care and support more effective and cost-effective methods of hearing rehabilitation.

## **Active bone conduction device programming trends in pediatric patients with conductive hearing loss: A single center experience**

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### **Abstract**

**Objectives:** At our pediatric tertiary care center, active bone conduction devices—such as the Cochlear Osia 2 and MED-EL Bonebridge—have become the default bone conduction implant option for patients with permanent conductive hearing loss. Unlike passive bone conduction devices, there is no verification system to objectively assess the function or output of the device. As such, active bone conduction devices rely on subjective patient report to evaluate sound quality. The purpose of this study was to assess trends in programming based on patient report of sound quality at the time of device activation.

**Methods:** A retrospective chart review was conducted for 85 children 5 to 18 years of age with permanent conductive hearing loss and received an active bone conduction device in at least one ear. Active bone conduction devices used included the Cochlear Americas Osia 2 and MED-EL Bonebridge. Reports of sound quality issues, such as “static” and “echo”, were common at the time of activation requiring additional programming. Information regarding programming changes made was obtained from clinical documentation.

**Results:** Preliminary results suggest a majority of patients required additional programming outside of the typical workflow to resolve sound quality issues at the time of activation. Common programmatic changes included activating the low pass filter setting, decreasing gain at specific frequencies, and readministering the digital link calibration. Resolution of sound quality issues was reached by the end of nearly all activation visits. A small subset of patients required additional programming during subsequent appointments.

**Conclusion:** Sound quality issues are commonly reported during initial activation of active bone conduction devices in pediatric patients at our center. We have found these issues can typically be resolved within the activation appointment with additional programming. These results will be further discussed within the context of how a patient’s ability to provide reliable reports of sound quality may influence clinical recommendations regarding active bone conduction devices in the pediatric population.

## **Adhesive Bone Conduction Device Long Term Result and Subjective Benefit In Children With Aural Atresia**

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<sup>3</sup>Catholic University of Cordoba, Cordoba, Argentina

### **Abstract**

**Objectives:** Congenital aural atresia (CAA) produces profound conductive hearing loss (CHL). There are options for the treatment of CHL caused by CAA, surgical as well as non-surgical ones such as headbands, soft-bands or spectacle frames. The ADHEAR system (MED-EL, Austria) is a non-surgical transcutaneous passive bone conduction system. The audio processor is placed retro-auricularly on an adhesive adapter. The aim is evaluating the hearing outcomes, speech discrimination and subjective satisfaction in children aided with the ADHEAR over a period of one year.

**Methods:** 15 children (5-16 years) with CHL diagnosed with CAA were included in this prospective, observational, repeated-measures study. Each subject used an adhesive device for one year and served as his/her own control. Baseline, free field audiometry and speech discrimination tests were performed. To quantify the subjective satisfaction, the MAIS, MUSS and KIDSCREEN questionnaires were used. Also, APSQ questionnaire was used.

Results: The unaided sound field threshold improved from an average PTA4 of  $63.6 \pm 3.4$  dB HL to an aided average PTA4 of  $29.3 \pm 3.0$  dB HL after 1 month of device use. The unaided word recognition score (WRS) improved from an average of  $27.9 \pm 15.9$  % to an aided average WRS of  $91.3 \pm 4.4$  % ( $p = .0003$ ) after 1 month using the ADHEAR system. The average aided WRS was  $92.0 \pm 4.1$  % ( $p = .0002$ ) after 6 months and  $92.7 \pm 5.3$  % ( $p < .0001$ ) after 12 months with the ADHEAR. The test at the signal to noise ratio of +5 dB SNR revealed an unaided average WRS of  $22.3 \pm 13.1$  %. After 1 month of device use, the aided average WRS was  $80.0 \pm 6.5$  % ( $p < .0001$ ),  $81.3 \pm 6.4$  % ( $p < .0001$ ) after 6 months and  $78.7 \pm 5.5$  % ( $p = .0014$ ) after 12 months using the ADHEAR subjective evaluation using questionnaires showed improvements and better results over time.

Conclusion: CAA patients using the new adhesive bone conduction hearing aid ADHEAR had good functional gain (34 dB) and high satisfaction rates, as measured with the MAIS, MUSS and KIDSCREEN questionnaires.

## **Datalogging in a Cohort of Children Receiving Osia2®**

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### **Abstract**

Objectives: To determine the effectiveness of datalogging in the Osia2® device, a surgical bone conduction device, to measure consistency of daily device use in a group of children with unilateral or bilateral hearing loss.

Methods: A retrospective chart review of children receiving Osia2® in our centre from 2018-2023 was conducted. Datalogs from the Osia2 processor were used as a proxy for device use. Osia2® dataloggs were reported in specific categories of daily hours: 0-4, 4-8, 8-12, 12-16, 16-20 and 20+ hours of daily use. Limited Osia2® use was defined as >50% of time in the 0-4 daily hour category with good Osia2® use as a lower percentage in this category with the remainder of use in the higher categories of daily use.

Results: 102 children ranging in age from 4.9-17.7 years received unilateral (n=94) or bilateral (n=8) Osia2® (total of 110 implants). Datalogs were available in only 18 children (9 left, 7 right, and 2 bilateral) as it was not a default setting for all Osia2® processors. Mixed model analyses revealed no significant effect of date or ear implanted across repeated measures. Data in 5 children showing a percentage of daily use in the 20+ hours category was not consistent with clinical reports. Ten children showed low use (>50% in 0-4 hours category) and 8 children had data suggesting more consistent Osia2® use.

Conclusions: Accurate and available datalogging has become a standard of care in hearing rehabilitation. Datalogs from the Osia2® in children provide an approximation of daily use, revealing that ~50% of



children who received this implant were using the device consistently. Refinement of the datalogging algorithm to systems that are more similar to those in current hearing aids or cochlear implants would likely be of benefit to more accurately quantify daily device use. Recordings of 20+ hours in several children calls into question the accuracy of the measures in those individuals. Future iterations of the Osia2® datalogging system could provide an important clinical tool to verify use and to understand non-use in patient populations in a manner that can influence future candidacy selection.

**Friday, September 8<sup>th</sup>, 2023**

13:30- 15:00 Middle Ear

## **What can we learn for bone conduction devices from active middle ear implants? The role of maximum output and necessary dynamic range**

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### **Abstract**

**Introduction:** The frequency specific maximum output (MO) of acoustic devices, such as conventional hearing aids as well as bone conduction devices and active middle ear implants, belongs to the most important parameters that are crucial for speech intelligibility and patient benefit. However, in many cases technical limitations prevent the use of the patients' entire residual input range due to too low MO. Here, we present a method to determine individual MO from clinical routine data with the Vibrant Soundbridge (VSB) and an MO-based analysis of how much coverage of the dynamic range is required for sufficient speech intelligibility.

**Materials and Methods:** For our retrospective analysis, 69 patients, implanted with the VSB at the round window (RW) at the Medical School Hannover (Germany), were analyzed. Firstly, individual frequency-dependent MO was determined and secondly, the dynamic range (DR) was calculated for each patient and frequency. Finally the word recognition score (WRS) in quiet was correlated to the absolute and weighted DR across the frequencies 0.5, 1.0, 2.0 and 4.0 kHz.

**Results:** The MO was similar for different coupling types with a maximum at 1.5 kHz. The average MO over speech relevant frequencies (0.5, 1.0, 2.0, 4.0 kHz) was between  $71.6 \pm 13.8$  dB HL to  $82.6 \pm 7.3$  dB HL for different coupling modalities to the RW. Despite minor differences in avg. MO, the variability between coupling modalities was pronounced. Word recognition scores in quiet (n=67) improved with

increasing dynamic range and were strongly correlated between predictor and outcome variable ( $r = 0.962 - 0.964$ ). A significant shift in performance was detected above a DR of 20 dB with a mean WRS of  $\geq 77.3\%$  ( $\pm 16.1\%$  standard deviation) and a mean WRS of  $\leq 51.7\%$  ( $\pm 29.6$  dB standard deviation) below.

**Conclusion:** The individual MO and DR can be successfully determined from patients' clinical data only, permitting an in-depth analysis of patient outcomes. Our approach equally applies to bone conduction devices for the prediction of necessary dynamic range and for the definition of evidence based frequency-specific indication limits.

## Is age a limitation for middle ear and bone conduction implants? Hearing and quality of life outcomes

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### Abstract

**Introduction:** The aims were to determine if there were differences between Vibrant Soundbridge (VSB) and BoneBridge (BB) devices, and age groups (<55y and  $\geq 55y$ ) in terms of audiological and quality of life outcomes.

**Methods:** Retrospective study to evaluate patients who were implanted with VSB and BB during 2008-2022. Postoperative tests included free-field warble tone threshold, and speech discrimination score (SDS) @65 dB for disyllabic in quiet with devices on and off. Subjective benefit was evaluated using Nijmegen Cochlear Implant Questionnaire (NCIQ) both pre- and post-operatively, and the scores of Glasgow Benefit Inventory (GBI) and Hearing Implant Sound Quality Index (HISQUI19) after surgery.

**Results:** 48 adult patients using daily VSB (n=22) and BB (n=26) were included. They were divided into two groups: <55 and  $\geq 55y$ .

Mean functional gain was  $32 \pm 11$  and  $22 \pm 15$  dB in the VSB and BB group, respectively ( $p=0.015$ ). No difference was observed between the younger and older groups.

SDS with the device on was higher in the younger VSB group:  $99 \pm 3\%$  vs  $86 \pm 16\%$  ( $p=0.049$ ). No differences were observed either between younger and older groups in BB sample, and between all VSB and BB patients.

All NCIQ domains improved following surgery in VSB and BB users, both in younger and older implantees. All VSB and BB users had a positive overall GBI score ( $36 \pm 23$  vs  $37 \pm 13$ , respectively), except one VSB  $\geq 55y$  whose score was 0. Moreover, younger VSB users rated better all GBI responses ( $45 \pm 23$  vs

22±18, p=0.020). Mean HISQUI19 score was 98±18 and 101±15 in VSB and BB, respectively, defined as “good” the quality of sound. No differences were found between the age groups either.

Conclusion: All patients had, regardless of age, good audiological benefit from both VSB and BB use. Additionally, VSB users experienced a better gain than BB users, although speech test outcomes were similar in both groups.

Because of these good audiological results, along with their good outcomes in quality of life, VSB and BB hearing solutions should be regularly offered to adults with hearing loss that meet their indication criteria, independently of their age range.

## **Hearing rehabilitation and microbial shift after middle ear surgery with Vibrant Soundbridge in patients with chronic otitis media**

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### **Abstract**

Introduction: Patients with otitis media (OM) encounter significant functional hearing impairment with conductive, or a combined hearing loss and long-term sequelae involving impaired speech/language development in children, reduced academic achievement and irreversible disorders of middle and inner ear requiring a long time therapy and/or multiple surgeries. In its persistent chronic form, Otitis media (COM) can often only be treated by undergoing ear surgery for hearing restoration. The persistent inflammatory reaction plays a major role, often caused by multi-resistant pathogens in the ear. Herein, we present outcomes of patients implanted with currently the only FDA approved active Middle Ear Implant Vibrant Soundbridge (VSB), suffering from persistent COM.

Methods: The study enrolled 42 patients, treated by performing middle ear (ME) surgery to different extents and implanted with the VSB to various structures in the ME. Included were 17 children and 25 adults that had recurrent and/or persisting OM and significant hearing loss. Preoperative and postoperative patients' audiometric data were evaluated and the benefit with VSB assessed using the Glasgow Benefit Inventory for adults and pediatric cohorts. The microbial spectrum of pathogens was assessed before and after surgery, exploring the colonization of the otopathogens, as well as the intestinal microbiome from individually burdened patients.

Results: The mean functional gain is 29.7 dB HL (range from 10 to 56.2 dB HL) with a significant improvement in speech intelligibility in quiet. Following VSB implantation, no significant differences in coupling were observed at low complication rates. Postoperatively patients showed significantly

increased benefit with VSB compared to the untreated situation, including less otorrhea, pain, medical visits, and medication intake, with no recurrent OM and significant bacterial shift in otopathogens. The analysis of the intestinal microbiome displayed a high abundance of bacterial strains that might be linked to chronic and persistent inflammation.

Conclusions: Functional ear surgery including rehabilitation with a VSB in patients suffering from COM present to be safe and effective. The successful acceptance accompanied by the improved audiological performance resulted in significant benefit with VSB, with a shift in the ear pathogens and altered microbiome, thus is a great opportunity to be treated.

## **Intraoperative Estimation of the Coupling Efficiency of Active Middle Ear Implant for Different Types of Couplers Using Frequency-Specific Auditory Steady-State Responses**

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### **Abstract**

**Objectives:** The Vibrant Soundbridge (VSB) is an active middle ear implant for the treatment of adults and children with sensorineural, conductive, or mixed hearing loss. Depending on hearing loss and middle ear physiology, the actuator of the VSB can be coupled to different structures in the middle ear. The quality of the coupling has a major influence on the subsequent hearing success. In recent years, a method based on auditory steady-state responses (ASSR) has been shown to be well suited for intraoperative estimation of hearing thresholds to verify coupling efficiency of the implant actuator. This article presents results using frequency-specific ASSR in relation to the coupler types used.

**Method:** ASSRs were measured intraoperatively via the VSB. For this purpose, a standard ASSR system was used to stimulate the implant's actuator coupled to the middle ear structures and to register ASSRs via scalp electrodes. Frequency-specific thresholds were determined simultaneously at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz.

**Results:** Intraoperative measurements were performed in more than 40 patients. In these patients, 6 different coupler types (i.e. Clip, short head (SH), short progress (SP), oval window (OW), Bell, round window soft (RWS)), were used to place the actuator of the implant. Frequency-specific hearing thresholds could be determined intraoperatively in all patients. There was a high correlation between intraoperatively determined ASSR thresholds and preoperative bone conduction thresholds at 1000 Hz and very high correlations of thresholds at 2000 Hz and 4000 Hz. Very good coupling quality was observed for the with Clip, SH, SP and OW coupler followed by the RWS and Bell coupler.

**Conclusion:** The presented results shows that frequency-specific ASSR can be measured intraoperatively in patients implanted with a VSB. These measurements allow a reliable estimation of the coupling efficiency between the actuator of the implant and the middle ear structure during surgery.

# Comparison of Auditory Brainstem Response (ABR) and Electrocochleography (ECochG) Measurements for Evaluating Coupling Efficiency in Active Middle Ear Implants

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## Abstract

**Objective:** To compare the coupling efficiency of the Vibrant Soundbridge (VSB) implant using ABR and ECochG in different coupling modalities, and evaluate the feasibility and postoperative outcomes.

**Methods:** Intraoperative monitoring was performed on 15 patients (mean age  $58.5 \pm 19.4$  years) with conductive or moderate mixed hearing loss who underwent VSB implantation. The coupling efficiency of the VSB was assessed using ECochG responses (wave-I) and ABR thresholds (wave-V) in two different coupling modalities: round window coupling (eight cases) and ossicular chain coupling (six stapes coupling and one incus coupling). During intraoperative monitoring, ABR measurements were performed using a Chirp LS, while ECochG measurements were carried out using a 1.5 kHz tone burst. Stimulation intensity was gradually decreased until no responses were observed. In situ threshold measurements with the implant (vibrogram) and bone conduction thresholds were measured four weeks post-surgery.

**Results:** ABR testing successfully determined coupling efficiency in all 15 patients, while ECochG was successful in only eight patients. The average ABR threshold was  $64 \pm 11.8$  dB nHL, and the ECochG threshold was  $67.5 \pm 11.6$  dB nHL. The ABR threshold was on average 21.9 dB nHL higher than the preoperative bone conduction threshold ( $42.1 \pm 12.4$  dB HL), whereas the ECochG threshold was 30.4 dB nHL higher. There was a significant correlation between ABR and preoperative bone conduction thresholds ( $p = 0.03$ ,  $R^2 = 0.32$ ), but not between ECochG and preoperative bone conduction thresholds ( $p = 0.054$ ,  $R^2 = 0.49$ ). No significant difference was found in coupling modalities (OC or RW) using either method (OC:  $p = 0.099$ , RW:  $p > .99$ ).

**Conclusions:** Monitoring coupling efficiency through ABR and ECochG testing is clinically relevant. ABR testing is more reliable and feasible than ECochG for intraoperative threshold testing with the implant.

# Hearing improving surgery or middle ear implant? Lifetime costs of the Vibrant Soundbridge (VSB) compared to alternative treatment options

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## Abstract

**Objectives:** When considering different treatment options, economic aspects play an important role in the decision-making process from a payer's perspective. Often, high initial (implantation) cost is a barrier to access state of the art medical devices. However, knowledge of the patient's lifetime cost is limited. The present analysis addresses this question by using the example of the VSB and its comparators.

**Methods:** The study determines the costs for three patient groups. Group A patients receive a VSB without having received any prior intervention. Group B includes patients who underwent at least one hearing-improving surgery prior to VSB implantation. Group C includes patients who will be treated with hearing-improving surgeries throughout their lives. A Monte Carlo simulation was applied to estimate lifetime cost. Data on demographics, case revenues, time intervals between surgeries and failure rates are used as inputs. Relevant cost components were based on data from a maximum care hospital and from the hospital financing system in Germany.

**Results:** We simulated over the entire remaining lengths of live. During this period of 26.71 [±13.86] years the cost for patients in group A amounted to 19,558 € [±4,504]. The result in group B was 25,508 € [±5,620] including 2.46 [±1.70] hearing-improving surgeries within the first 4.05 [±6.09] years. The treatment during the remaining 22.66 [+14.56] years corresponds to group A. For group C, the cost amounted to 28,363 € [±10,367]. In group C, however, more than 26% cannot be successfully treated until the end of their lives, which is based upon a model assumption that a maximum of 15 surgeries can be performed. However, this means that the cost for a longer treatment is still higher than the value shown.

**Conclusion:** It turns out that after high implantation cost in group A, only low follow-up cost is incurred - which leads to the lowest mean value. The costs in groups B and C are higher because the recurring need for follow-up surgery has a significant impact. From an economic perspective, the option of treatment with a VSB should be considered earlier - especially for patients with a high remaining life expectancy.

**Friday, September 8<sup>th</sup>, 2023**

**13:30- 15:00 Audiologic and Surgical Considerations**

## **Active bone conduction device implantation: OSIA® under local anesthesia and sedation**

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### **Abstract**

**Abstract:** Purpose To report the outcomes and the patients' subjective experience of OSIA implantation performed under local anesthesia. To describe an useful technique for those patients with complex comorbidities or personal choice eligible for local anesthesia.

**Methods:** Descriptive study. 9 adult patients made that made the choice for local anesthesia for Osia® device surgery were included. Review of medical records is performed to identify sociodemographic characteristics, clinical history, and intraoperative information. Subjective information is collected through a non-standardized questionnaire to quantify pain sensation during and after surgery, recovery time, and postoperative symptoms.

**Results:** We present an alternative technique under local anesthesia and sedation for the newest generation OSIA 2 (Cochlear Americas, Englewood, CO) active bone conduction device in the context of the SARS-COV 2 virus pandemic. The anesthetic and surgical technique is presented with satisfactory results in terms of excellent nerve block, none or minor pain sensation, rapid postop recovery, fewer post-anesthetic side effects compared to general anesthesia, shorter surgical time and the absence of intra-surgical and early post-surgical complications,. An additional positive impact consists of more eligible patients for surgery whom for some reason have contraindication to general anesthesia due to their complex comorbidities, elderly patients, heart disease conditions, pulmonary disease, or even those with complex airways. We also found an improved cost- effectiveness profile for the hospitals.

**Effectiveness and stability of audiological, functional and surgical outcomes after implantation of an active bone conduction device**

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## **Abstract**

**Purpose:** to assess the effectiveness and safety of a bone-conduction implant, the Bonebridge BCI 602, in adults with conductive or mixed hearing loss.

**Methods:** the study group included 42 adults who had either conductive or mixed hearing loss. All patients underwent Bonebridge BCI 602 implant surgery. Before and after implantation, pure-tone audiometry, speech recognition tests (in quiet and noise), and free-field audiometry were performed. Word recognition scores were evaluated using the Polish Monosyllabic Word Test. Speech reception thresholds in noise were assessed using the Polish Sentence Matrix Test. Subjective assessment of benefits was done using the APHAB (Abbreviated Profile of Hearing Aid Benefit) questionnaire.

**Results:** the APHAB questionnaire showed that difficulties in hearing decreased after BCI 602 implantation. Both word recognition in quiet and speech reception threshold in noise were significantly better after BCI 602 implantation and remained stable for at least 12 months. A significant advantage of the device is a reduced time for surgery while maintaining safety. In this study, the mean time for BCI 602 implantation was 28.3 min ± 9.4.

**Conclusions:** Bonebridge BCI 602 implant is an effective hearing rehabilitation device for patients with conductive or mixed hearing loss. Patient satisfaction and audiological results confirm its efficacy and safety. Its new shape and dimensions allow it to be used in patients previously excluded due to insufficient or difficult anatomical conditions.

## **A Retrospective Cost Analysis of Soft Tissue Complications of Percutaneous Bone Anchored Hearing Aids (BAHA) – A Series of 137 Consecutive Patients**

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## **Abstract**

**Introduction:** Percutaneous bone conduction devices are an option for the management of patients with mixed/conductive hearing loss and single sided deafness. A departmental audit has shown 40% of



patients require intervention to manage a soft tissue complication with a significant increase in post operative clinic appointments (1).

**Aim:** Our aim was to examine the frequency and cost of soft tissue complications in a cohort of patients with a passive percutaneous bone conduction device from the West Coast of Scotland as part of a service review.

**Method:** A retrospective case notes review of 137 consecutive adult and paediatric patients who received a percutaneous bone conduction device (Oticon Ponto) from February 2016 to March 2023 was conducted. Complications were classified as level 1 (requiring clinic review and topical medication), level 2 (requiring healing cap and ribbon gauze or silver nitrate cautery) or level 3 (soft tissue debridement/revision or replacement of the device). The cumulative cost of the clinical encounters was analysed. In response to the findings a pathway for managing soft tissue complications has been introduced. This ensures patients with recurrent infections are reassessed for an active transcutaneous device.

**Results:** The mean follow up time in our cohort is 44.7 months with on average 4.1 clinic appointments. 40.1% (55/137) of patients had soft tissue complications. The majority, 65.4% of patients required level 1 management, 7.2% level 2 and 18.1% level 3. 4.4% (6/55) patients had soft tissue complications leading to loss of implant with 1 patient converted to a transcutaneous device. 4/55 (7.2%) of patients required a longer abutment. 5 patients in our cohort were non-users (3.7%).

**Conclusions:** Findings show a high rate of soft tissue complications in patients with percutaneous devices. Transcutaneous bone conduction devices have been shown to be associated with less soft tissue complications (2). These findings have implications for those planning the prioritisation of services in a public healthcare setting. The additional morbidity and cost of managing soft tissue complications of percutaneous devices should be factored into decision making when offering bone conduction hearing devices.

## **Hearing performance of the Osia®2 System in patients with microtia-atresia**

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### **Abstract**

**Introduction:** Currently, a bone conduction technology is available for the treatment of patients with conductive and mixed hearing loss due to anatomical alterations of the external ear as microtia-atresia. The most recent device is the Osia®2 System consists of a piezoelectric transducer and a sound processor. Audiological and quality of life benefits have already been reported in patients with microtia-atresia using other bone conduction devices.

**Aim:** To describe the surgical information, audiological outcomes and patients expectations with the Osia®2 in patients with microtia-atresia.

**Method:** Observational and prospective study. Patients who met the selection and implantation criteria for the Osia®2 System were included. Audiometry (pre and postoperative), speech discrimination in quiet, and fixed noise were performed. Patients completed the COSI before and 12 months after receiving the implant and sound quality was measured using the HISQUI-19 index.

**Results:** Sixteen patients were included, 10 children and 6 adults with, an average age of 9.6+4.7 and 42.17+19.9 years, respectively. One patient underwent transition from Baha percutaneous system, by Holgers 4. Flap reduction was necessary in 12.5% and the mean of final measurement was 4.3+1.3mm (min 2-max 6). In the preoperative tests, PTA4 for air conduction was 65.9dB and for bone conduction was 18.8dB and speech discrimination in quiet was 100% at 85dB. With Osia 2 device, mean of air conduction PTA4 was 20.4dB and speech discrimination in quiet was also 100% at 58.3dB (p=0.001, Value T=6.64). Mean of speech recognition in noise (signal-to-noise ratio = 0dB/ speech at 60dB) was 95.6+6.9% (min 82%-max 100%). In the COSI, 50% of the patients have reported expectations to improve on the emotional area, such as stopping feeling ashamed or stopping feeling excluded. 12 months after using the system, they report feeling much better. In the HISQUI, on average, 110 points were obtained, which represents very good sound quality.

**Conclusion:** In patients with microtia-atresia, the Osia®2 System can be considered an excellent rehabilitation option, offering audiological benefits both in quiet and in noise situation. In addition, Osia2 fully met the expectations of patients, who reported very good sound quality when using the device.

## **BILATERAL OSIA® BONE CONDUCTION DEVICE: EVALUATION OF HEARING PERFORMANCE IN NOISE**

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### **Abstract**

**INTRODUCTION:** When it comes to auditory conduction through bone, multiple debates have been found regarding the bilateral use of implantable devices. Some authors state that this benefit will be perceived only by those patients whose bone pathway is symmetrical and otherwise patients will choose to use only the processor they perceive with greater benefit. The discussion continues and clinical evidence is necessary for correct decision making.

**OBJECTIVE:** To evaluate the audiological performance in patients with conductive or mixed hearing loss, bilaterally implanted with Osia® System bone conduction device.

**METHODS:** Prospective study. Audiological evaluation that included free-field audiometry, speech recognition with fixed and adaptive noise (S0°/R0°). All conditions were evaluated unaided and aided, bilaterally and separately per ear. Quality of life was evaluated with GBI and self-perception of disability with SSQ-12.

**RESULTS:** We included 13 patients diagnosed with conductive or mixed hearing loss. Free-field PTA in unaided condition was 59.9dB. Free-field PTA with Osia aided conditions were on the right side: 26.2dB, on the left side: 27.6dB, and with bilateral OSIA: 24.2dB. The speech recognition in fixed noise (S/R=0dB) was 62% to unaided condition. For Osia aided conditions: in the right ear was 73.7%, in the left ear was 75.1%, and bilaterally was 79%. Speech recognition with adaptive noise was +4.4dB for unaided condition while for Osia aided conditions: in the right ear was -2.7dB, in the left ear was -3.1, and bilaterally was -3.5dB. Statistically significant differences were obtained when comparing the performance in adaptive noise with bilaterally aided with unaided condition ( $p < 0.001$ ) and when comparing unilateral with bilateral use ( $p = 0.026$ ). The total average in the GBI was 52.5 which represents a significant improvement in their quality of life and the total in the SSQ-12 was 4.6.

**CONCLUSION:** Patients using bilaterally Osia System demonstrate a significant improvement in speech recognition in noise, which leads us to conclude that whenever it is possible for the patient to access bilateral adaptation should be performed. The benefits of bilateral implant will drive a better quality of life and an improvement in their self-perception of disability.

## **Bone conduction threshold measurements in patients with bone conduction devices – a comparison of available methods**

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### **Abstract**

**Objectives:** The semi-implantable bone conduction devices connect the skull to the hearing device by means of an implant. The presence of this implant provides three possible methods for conducting bone conduction evaluation, which may yield different results for the same patient. Comparisons of results from different centers may therefore be interpreted incorrectly.

**Methods:** The study compares the results of audiological measurements in a group of 53 adult patients implanted with bone conduction devices. Measurements were conducted in three modes, depending on

oscillator position (over the implant or over the bone) and its type (oscillator integrated in the BCD or audiometric oscillator), defined as BC-direct, BC-PTA (classic), and BC-indirect.

**Results:** Differences between the obtained results can reach up to 21.48 dB with a mean of 10 dB across all frequencies. The lowest values, regardless of the type of implant connection, were recorded for BC-indirect mode, whereas the highest mean all-frequency thresholds were recorded in BC-direct. A comparison of the results for single frequencies revealed significant statistical differences except for 2 and 4 kHz in selected comparisons.

**Conclusions:** The most comparable thresholds were obtained when the oscillator is positioned on the mastoid, aside from an implant. The results of alternative measuring modes, while obtainable, should be avoided as a substitute for "classic" audiometry, as they can vary considerably. Furthermore, the "classic" mode of bone conduction threshold measurement is conducted with standardized equipment, and pre-operative data obtained with the same method are available for future comparison.

## **Skull Simulator: Verification of prescribed force levels by the DSL-BC rule in percutaneous bone anchored hearing devices users.**

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### **Abstract**

**Objectives:** To verify the difference between the real force level and the prescribed by the DSL-BC rule of percutaneous bone anchored hearing devices (BAHD), through the skull simulator and the need to make adjustments to ensure adequate amplification for users of these devices.

**Methods:** This is a cross-sectional study, in which 12 patients using percutaneous BAHD, aged between 10 and 39 years, with conductive and/or mixed hearing loss of mild to severe degree, with bone thresholds of up to 25dB. Participants had been users for an average of 17 months. The research protocol included the intra-subject evaluation, in two steps: Step 1 - the actual force level (dB  $\mu$ N) of the BAHD was measured in the participants' current use and comfort settings; then, a tolerance of  $\pm$  5dB  $\mu$ N was adopted between the force level obtained and the prescribed values by the DSL-BC rule for decision making to adjust or not the force level of the device; Step 2 - performed the adjustment of the force level (dB  $\mu$ N) of all frequencies in which the tolerance was extrapolated (for more or for less) and performed a new measurement of the real force level of each participant.

**Results:** A statistical analysis of the data was carried out, in order to verify the difference values in the frequencies of 500 Hz, 1kHz, 2kHz, 3kHz and 4kHz. Thus, for Step 1, the frequency with the greatest difference between the actual and prescribed force levels was 4,000 Hz for a sound input of 90dB

(Average = 10.57 dB; standard deviation = +/- 22.80 dB). The other frequencies in which the tolerance level +/- 5dB  $\mu$ N was extrapolated were 1,000 Hz (90dB input), 2,000 Hz (50, 70 and 90 dB input) and 4,000 Hz (50 and 70dB input). After adjustments made in Step 2, the values of this difference were homogeneous for all frequencies (Average= 3.23 dB, standard deviation= +/- 2.80).

**Conclusion:** The skull simulator is effective in demonstrating the real force levels, making it possible to prescribe relevant adjustments to be performed on these devices, guaranteeing adequate amplification for users and avoiding over or under amplification.

## **10 years' experience with the Bonebridge: the old and new generation in comparison BCI601 and BCI602**

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### **Abstract**

**Introduction:** For people with mild to moderate conductive or mixed hearing loss bone conduction implants (BCI) are indicated. The first available device of this kind was the Bonebridge (BCI 601), presenting with exceptional results in audiological performance, safety, and patient satisfaction. Ten years on, a new generation was released: the BCI 602. The aim of this study was to compare the two device generations to evaluate their equality.

**Methods:** A retrospective chart review of 26 patients BCI 602 patients was performed and compared to 6 subjects implanted in 2011 with the BCI 601.

**Results:** Twenty-three adults (23 ears) aged between 6 and 63 years of age (mean  $35.2 \pm 17.0$ ) and three children (4 ears) aged five years or younger were implanted (mean  $3.3 \pm 1.2$ ). Twelve patients with M/CHL (7 with a normal contralateral ear), five subjects with atresia (4 with a normal contralateral ear) and six subjects suffering from SSD received the BCI 602 implant. No surgical nor post-surgical complications occurred. Complete transmastoid implantation was possible in all cases, including the children below the age of five, without the use of lifts or exploration of the dura and sinus. The mean percentage of word recognition in quiet for the M/CHL group after 12 months improved significantly to  $86.67 \pm 7.53$  ( $p < .0001$ ). The mean speech reception threshold in quiet and under various signal-to-noise ratios significantly improved (from  $54.76 \pm 10.04$  to  $38.00 \pm 9.89$ ,  $p = .0222$ ; and from  $-0.14 \pm 3.27$  to  $-4.01 \pm 2.14$ ,  $p = .0004$ ; respectively). The subjects reported high satisfaction with the device accompanied with a mean wearing time of 9.5 hours per day.

**Conclusions:** These one-year results of the BCI 602 showed significantly improved audiological performance, accompanied with high patient satisfaction, and improved quality of life comparable to

our 10 years of experience with the previous generation, with the additional benefit of reduced size, making prior surgical planning redundant. Based on these results; the BCI 602 can be highly recommended for the given indications and especially for difficult anatomical and surgical cases and a re-evaluation of the given indication for children 5 years or older is highly recommended.

## Long-term follow-up of the Bone Conduction Implant

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### Abstract

**Objectives:** The Bone Conduction Implant (BCI) is an active transcutaneous bone conduction device developed in collaboration between Chalmers University of Technology and Sahlgrenska University Hospital, in Gothenburg, Sweden. It has been under clinical investigation since 2012 and the objective of this study is to evaluate the 5 year results of 13 patients.

**Methods:** A total of 16 patients have been implanted with the BCI, 13 in Gothenburg (followed for 5 years) and 3 in Stockholm (followed for 1 year). The follow-up of these patients has included audiological performance investigations, questionnaires, safety evaluation and objective functionality testing of the device. The audiological measurements included sound field warble tone thresholds, speech recognition threshold (SRT), speech recognition score (SRS) and signal to noise ratio threshold (SNR-threshold). The questionnaires are Abbreviated Profile of Hearing Aid Benefit (APHAB), Glasgow Benefit Inventory (GBI) and International Outcome Inventory of Hearing Aids (IOI-HA). For comparison, a Ponto Pro Power on softband was used as reference device for a period of four weeks prior to the BCI surgery, and was evaluated with the same protocol.

**Results:** The accumulated implant time for all 16 patients was 131 years (range 6.4-10.4 years) in April 2023. During this time, no serious adverse events have occurred. However, one explantation was necessary after an implant failure in January 2023 – this happened 9.3 years after implantation but was then successfully reoperated 3 months later. The functional improvement for the 13 patients after 5 years was on average 29.5 dB (average over 0.5, 1, 2 and 4 kHz), the SRT improvement was 24.5 dB and the SRS improvement was 38.1%, and the aided SNR-threshold was on average -6.4 dB. The patients experience a statistically significant benefit, using the BCI, shown with APHAB, GBI and IOI-HA. All results show similar or better performance with the BCI compared to the reference device.

**Conclusion:** The long-term audiometric measurements showed statistically significantly improved hearing ability over the unaided situation, and similar or better results compared to the reference device. The BCI has shown to be safe and effective for patients with conductive and mild-to-moderate mixed hearing loss.

**Saturday, September 9<sup>th</sup>, 2023**

11:30- 13:20 Quality of Life / Access to Care

## **Does Social Deprivation Affect Uptake of Auditory Implantation in Eastern Scotland?**

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### **Abstract**

**Objectives:** Patients' access to medical care is a critical aspect of healthcare delivery in Scotland. The relationship between accessing medical services and deprivation is complex: Individuals living in deprived areas typically require greater medical care but access it less frequently and effectively. This 'inverse care law' is well recognized but the relationship between social deprivation and auditory implantation has not been studied in the UK population. The SIMD (Scottish index of multiple deprivation) is a measure of relative deprivation across postal codes. SIMD looks at the extent to which an area is deprived across seven domains: income, employment, education, health, access to services, crime and housing. We proposed to identify the pattern of uptake of auditory implantation (bone conduction and middle ear implants) across our population with respect to SIMD.

**Methods:** SIMD decile groups were used to measure the degree of deprivation and allow for data analysis. The most deprived cohorts were in decile 1 and the least deprived in decile 10. We analyzed the above data using 'R environment'.

**Results:** Our department primarily provides auditory implants for Fife and Tayside, as well as a tertiary service to other areas of Scotland. Our patient population was 792,380 in 2021. 233 patients with bone conduction and middle ear implants were identified. Eleven patients were identified from other health boards and were excluded from analysis (n=224). There was no significant difference in implantation rate across decile groups: CHI2 test for goodness of fit with  $p=0.9817$  suggested that the observed distribution of implants was not significantly different from the expected distribution based on the population density in each decile. The Kruskal-Wallis test also suggested that there was no significant difference in distribution of the implants across SIMD deciles. Pearson's correlation coefficient of 0.9298 indicated a strong positive correlation between the number of implants and population density in each SIMD decile.

Conclusion: There were more implant recipients in less deprived groups but there were similar rates of implantation across all decile groups. We conclude that there was no evidence that deprivation was an obstruction to accessing auditory implantation in our population.

## **Job satisfaction and quality of life in adult users of bone conduction hearing devices pre- and post-implantation: a 1-year follow-up study**

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### **Abstract**

**Objectives:** To date, studies examining the effect of hearing impairment on working life in adults with bone conduction hearing devices are limited. This study examines how hearing rehabilitation with bone conduction hearing implants affects health-related quality of life and working life for hearing-impaired adults of working age. A second aim was to examine the subjective assessment of functional hearing pre- and post-implantation in the same population.

**Methods:** This study used data from the Cochlear Implant Recipient Observational Study to assess hearing disabilities and work satisfaction in 18–65-year-old recipients of bone conduction hearing implants. Baseline data were collected pre-implantation and patients were followed-up at 12-months post-implantation. Extracted data included patient demographics, Health Utilities Index-Mark III (HUI-3), the Speech Spatial and Qualities of Hearing Scale-49 (SSQ), and self-reported employment data on job satisfaction and work amenability.

**Results:** Data are presented for 43 patients, pre-implantation and at 12-months follow-up following implantation with a bone conduction hearing implant. Improvements in hearing and speech attribute, and overall health-related quality of life were observed between pre-and post-implantation. Overall hearing disability decreased post-implantation, job satisfaction and work amenability improved significantly. Spearman rank order correlation (Rs) uncovered a moderate, positive correlation between SSQ Qualities scores and job satisfaction scores, which was statistically significant (Rs = .500, p = .008).

**Conclusions:** Data supports the use of bone conduction hearing implants for hearing rehabilitation since these devices were shown to improve health-related quality of life, reduce hearing disability, and improve work performance and job satisfaction in healthy, actively working individuals.



## **Bone anchored hearing aids (BAHA): Life changing surgery. A quality-of-life (QoL) study reporting the impact of BAHA surgery on patient's general, physical, psychological, and social wellbeing.**

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### **Abstract**

**Objectives:** This study aims to review the impact of Bone Anchored Hearing Aid (BAHA) surgery on patients' QoL. There have been numerous studies reporting the QoL benefits of elective surgical procedures, however there is limited research regarding the impact of BAHAs. Where studies do exist their sample sizes are limited by patient number and timescale.

**Methods:** The Glasgow Benefit Inventory Scale (GHIS) was used to assess patients' quality of life pre and post BAHA surgery. A total of 168 patients over ten years of practice from a single UK site were included.

**Results;** BAHA surgery showed statistically significant improvements across all the wellbeing domains; general, physical, psychological, and social.

**Conclusion:** The largest of its kind, this study argues that BAHAs should be considered in the leagues of joint arthroplasty and cataract surgery as a highly effective, life-improving, surgical procedure.

## **From Percutaneous to Transcutaneous: Hearing Outcomes and Quality of Life in transitions between Bone Conduction Implant.**

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### **Abstract**

**Introduction:** Percutaneous bone conduction hearing implants have been used with very good hearing results; however, in some patients, there is limitation or impossibility in its use due to skin reactions. Transcutaneous bone conduction implants are an alternative that has good hearing results and has a lower potential risk of skin problems. In this study we want to describe the audiological and quality of life results in patients who required a transition from the percutaneous to the transcutaneous system.

Methods: This is an observational, descriptive, cross-sectional study that included patients who required a transition from the percutaneous system to the active transcutaneous system. Hearing performance was assessed using a hearing in noise test and quality of life using the Glasgow Benefit Inventory (GBI) scale.

Results: A total of 11 ears (9 patients) transitioned from the passive percutaneous to the active transcutaneous system were included. The percutaneous implant was used for an average of  $10.15 \pm 4.4$  years before transition surgery. In 100% of the cases the reason for the transition was repetitive skin reactions (Hollers 2 to 4). Preoperative speech recognition in fixed noise with the percutaneous system was  $88.5 \pm 6.8\%$  (min 72.6%; max 94.2%) and with the active transcutaneous system it was  $91.3 \pm 2.58\%$  (min 87.9; max 94.6); differences that were not statistically significant ( $p=0.83$ ). In adaptive noise, the signal/noise ratio (SNR) with the percutaneous system was  $-4.0 \pm 1.32\text{dB}$  (min  $-5.3\text{dB}$ ; max  $-1.8\text{dB}$ ) and with the active transcutaneous implant  $-4.84 \pm 1.0\text{dB}$  (min  $-6.3$ ; max  $-3.5$ ); statistically significant difference ( $p=0.05$ ). The results of the GBI scale showed a positive change both in the global result  $+42.8 \pm 19.14$ ; as in the three subscales (general health status  $+44.26 \pm 18.33$ , social relationships  $+45.67 \pm 26.52$  and physical health  $+38.50 \pm 27.39$ ).

Conclusion: The transition from a percutaneous bone conduction device to an active transcutaneous one can be carried out effectively, maintaining good performance in language recognition. In postoperative tests with the active transcutaneous system, they have a significant better SNR. A positive change in quality of life was observed with transition surgery.

## **Long-term speech perception and quality of life outcomes in adults with the active transcutaneous osseointegrated bone-conduction implant system Osia**

Thomas Wesarg Dr., Ann-Kathrin Rauch Dr., Antje Aschendorff Prof. Dr., Iva Speck Dr., Susan Arndt Prof. Dr.

Department of Otorhinolaryngology, Medical Center – University of Freiburg, Freiburg, Germany

### **Abstract**

The Osia System (Osia) is a partially implantable, active transcutaneous bone-conduction implant system. It comprises an osseointegrated implant and an external sound processor. The implant uses a piezoelectric transducer for direct bone-conduction stimulation. Its fitting range is up to 55 dB HL BC in case of conductive or mixed hearing loss (CHL/MHL), or single-sided deafness. The aim of our retrospective longitudinal clinical study was to investigate long-term outcomes in speech perception and hearing-related quality of life in adult Osia recipients who were implanted between 2017 and 2020 at our tertiary academic referral center.

Eighteen adults with CHL/MHL received Osia100 implant(s) between 2017 and 2020. Seven subjects were implanted bilaterally. Starting in October, 2020, the recipients' sound processors were upgraded from Osia 1 to Osia 2. Long-term data were collected after 12, 24, and 36 months of device use. Speech

perception was assessed as word recognition for monosyllables presented at 65 dB SPL. To evaluate the hearing-related quality of life, the Speech, Spatial and Qualities of Hearing Scale (SSQ) was administered.

On group average, there was no change in unaided bone conduction thresholds in the implanted ear postoperatively. Compared to the preoperatively unaided condition (baseline), the subjects obtained a significant improvement in speech recognition with both Osia 1 and Osia 2 at 12 months. Pooled across the three sections of the SSQ, the subjects showed significantly better overall scores of 6.6 at 12 months, 5.9 at 24 months, and 7.6 at 36 months after device activation compared to baseline.

Adult subjects with CHL/MHL benefit from Osia implantation and auditory rehabilitation in both speech perception and hearing-related quality of life.

## Exploring the Influence of Price Anchoring and Emphasis Framing on Willingness to Purchase Hearing Aids

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### Abstract

**Objective:** The majority of people experiencing hearing loss turn to the internet as the first response to their symptoms [1], where they may encounter more widely-ranging perspectives and prices for hearing aids (HAs) than those purveyed in clinics. This study investigates whether exposure to various types of information online can influence adults aged 40 and above in their willingness to purchase HAs. Specifically, we examined the effects of price anchoring, through high or low HA prices in advertisements, and emphasis framing that focuses on either lifestyle appeal or technological capabilities of HAs.

**Methods:** In a 2x2 experimental design, 271 participants browsed a website simulating an online search for hearing health information. Participants were randomized to view banner ads featuring either high or low HA prices (anchoring condition) and read about three differently-priced fictitious HAs with varied technology levels, whose descriptions emphasized either lifestyle appeal or technological capabilities (framing condition). Using visual analog scales, participants rated their willingness to purchase each device as well as their likelihood of not purchasing any device.

**Results:** After correcting for multiple comparisons and controlling for self-rated hearing ability, trust in online health information, and HA knowledge and personal importance, two-way ANCOVAs revealed no significant interaction effects and no significant main effects of anchoring or framing on purchase willingness for the three fictitious devices. However, self-rated knowledge was a significant covariate in the model for all three devices ( $p < 0.001$ ), and was significantly positively correlated with purchase willingness for all three. Exploratory testing showed that participants with above-median self-rated

knowledge expressed significantly higher purchase willingness for all devices ( $p < .001$ ,  $d \geq .743$  for all comparisons).

**Conclusions:** Price anchoring and messaging manipulations did not result in meaningful differences in participants' willingness to purchase HAs, suggesting that HA clinics and manufacturers may not benefit from rethinking their online communication strategies in these areas. Future research should explore strategies to increase subjective HA knowledge among potential buyers.

## **Need for Action: The Costs of unaddressed Hearing Loss in Brazilian Children and Cost-Effectiveness of Interventions**

Michael Urban Dr. rer.nat, MBA, MSc, Thomas Dejaco PhD, Annegret Hoch MSc, Klaas Kieseewetter MA, Karin Rose-Eichberger Mag., Francesca Maria Scandurra PhD, Bettina Schlick PhD, Christina Schwarz Mag. MPH

MED-EL Medical Electronics, Innsbruck, Austria

### **Abstract**

**Objective:** Brazil, with a prevalence of self-reported hearing loss (HL) of 5.1 %, ranges among the top-10 countries worldwide regarding costs of unaddressed HL. Since HL imposes high long-term costs on society, particularly in children, cost-effective interventions are needed. This study aims to determine healthcare costs of untreated HL for children in Brazil, and whether hearing implants are a cost-effective intervention.

**Methods:** Healthcare costs for children with HL were assessed based on the Global Burden of Disease database and findings from the World Health Organization. Cost-effectiveness of interventions was investigated by applying a Markov modelling technique, adopting a life-cycle cost perspective over 10 years. Sensitivity analyses were conducted to identify the factors with the greatest impact on the results.

**Results:** Prevalence of HL in children (5-14 years, at least moderate HL) in Brazil is 341,593 individuals. For those healthcare costs are significantly higher than for children with normal hearing. The additional yearly healthcare costs (excluding hearing aids and implants) amount to R\$ 1,721 (moderate HL), R\$ 3,583 (severe HL), R\$ 4,177 (profound HL) per child. Overall, the estimated yearly HL-related healthcare costs for Brazilian children (5-14 years; at least moderate HL) add up to R\$ 780.4 Mio.

Over a 10-year time horizon, the costs for an intervention with a bone-conduction device or middle ear implant sum up to R\$ 40,451 per child, while the costs of leaving the HL untreated amount to R\$ 13,250 (moderate HL) and R\$ 27,300 (severe HL, all costs discounted at a rate of 3 %). Both interventions can be considered cost-effective, given a willingness-to-pay threshold of 1xGDP (R\$ 40,500) or lower: The ICER of treatment with an implant compared with no intervention is R\$ 31,280 for moderate HL and R\$

15,125 for severe HL. Sensitivity of these results is high: the cost of untreated HL is the variable with greatest impact on cost-effectiveness of an intervention with an implant.

Conclusion: Unaddressed HL poses substantial costs to the Brazilian healthcare system. Further research is needed whether and to what extent the costs of untreated HL should be taken into account in the Brazilian health care setting.

## **Assessment of Clinical Performance, Audiological Outcomes, and Quality of Life with the Oticon Minimally Invasive Ponto Surgery (MIPS)**

Allen Young MD MPH, Carolyn Brennan AuD, Sharon Rende AuD, Jack Wazen MD FACS

Silverstein Institute, Sarasota, FL, USA

### **Abstract**

**Objective:** The Oticon Minimally Invasive Ponto Surgery (MIPS) is a safe, quick, and cosmetically-optimal way to surgically insert a titanium implant to address conductive and mixed hearing loss as well as single-sided deafness. The purpose of this study is to examine the clinical, audiologic, and quality-of-life outcomes in patients who underwent MIPS implantation.

**Methods:** This is a retrospective study analyzing 40 adult patients with conductive hearing loss (CHL), mixed hearing loss (MHL), or single-sided deafness (SSD) who were implanted with the MIPS device from January 2017 to April 2023 at a single institution by the senior author. The surgery is performed under local anesthesia with intravenous sedation and its minimal 5-mm punch incision shortens the healing period and reduces operating time, ranging from 4 to 7 minutes. Preoperative speech score testing (CNC, AzBio in quiet, AzBio in noise) was performed in all subjects while unaided and wearing a soft band BAHA. These preoperative speech scores were then compared to post-implantation speech scores using paired t-test analysis to assess the degree of speech improvement. Patients were monitored postoperatively and their surgical sites were graded on the Holger's scale. In order to analyze the quality of life after MIPS implantation, patients filled out the Glasgow Benefit Index (GBI) survey. The GBI is a series of 18 questions that address the changes in general, physical, and social health status after a medical intervention.

**Results:** CHL, MHL, and SSD patients had significant improvement in hearing and speech recognition scores after MIPS implantation compared to preoperative unaided hearing: CNC (7.1% vs. 79.6%,  $p < 0.00001$ ), AzBio in Quiet (13.7% vs. 89.2%,  $p < 0.00001$ ), and AzBio in Noise (18% vs. 80.2%,  $p < 0.0002$ ). Postoperatively, all the patients demonstrated good healing with Holger's score 0-1 at the 3-, 6-, and 12-month mark with no complications. There were zero incidences of implant loss. Post-implantation GBI patient surveys demonstrated significant improvement in quality of life.

Conclusion: MIPS is a safe, efficient, and effective procedure for adult patients with CHL, MHL, and SSD. Patients receive significant improvement in speech recognition scores after implantation which further translates to improved quality of life.

## The Birmingham 'high-throughput' system for local anaesthetic percutaneous bone-anchored hearing implantations

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### Abstract

**Objectives:** Being one of the pioneering centres in the bone-anchored hearing research field, our ENT-centre has gained lots of experience over the past 40 years. As bone-anchored hearing system (BAHS) surgeries are elective, non-cancer cases, they are often not a clinical priority. To help as many patients as possible, we have developed a time and cost-efficient approach for BAHS surgeries. Here, we aim to share our experience.

**Methods:** In Birmingham BAHS surgery has been performed under local anaesthesia (LA) for the last 10 years and batched for the last 5 years. At present, we allocate one day per month doing batched BAHS surgeries. We use a procedure room and a set-up using conventional or minimally invasive surgery and LA. This provides an efficient use of staffing and excludes the need for an anaesthetist. Patients are observed for 30 minutes before discharge with follow-up in our specialist nurse clinic.

**Results:** We can efficiently manage eight BAHS cases a day and patients stay in the hospital approximately 2 hours. The hospital benefits include freeing up space in the main operating room and also cost savings from staffing and efficiency.

Over the last decade the presenting author has operated on approximately 400 BAHS cases of which 87% were under LA. Our centre is also involved in two implant investigations, one evaluating the Ponto BHX implant (using the linear incision technique) and one evaluating the minimally invasive MONO procedure (using Ponto Wide implants). In these patients (n=25) all but one surgery was performed under LA and surgery was on average short, 7 and 5 minutes, respectively. During the 1-year trial, no severe intra-operative complications or implant losses have been reported. There is one adverse 1-week post-operative skin reaction (Holgers 2) reported and patients are experiencing an improved quality of life.

**Conclusion:** Percutaneous BAHS procedures are typically short, non-prioritised elective surgeries that result in great benefit for patients. Using the approach described here, more patients can get access to surgery in a time and cost-efficient way and hence, significantly improve their quality-of-life. This has been well accepted by patients and staff alike.

# Cost-Utility of Bone Conduction Implants for Conductive or Mixed Hearing Loss or Single-Sided Deafness: A Decision Analysis

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## Abstract

**Objectives:** Bone Conduction Implants (BCIs) are a safe and effective treatment solution for adults and children suffering from a Conductive or Mixed Hearing Loss or Single-Sided Deafness. The aim of this study was to assess and compare the cost effectiveness of different BCI systems for adults and children in Argentina, to determine the most cost-effective treatment strategy.

**Methods:** A cost utility analysis was used to compare the cost-effectiveness of different BCI systems. The incremental cost effectiveness ratio (ICER) was examined by both costs (direct healthcare costs) and health outcomes, using the Health Utility Index (HUI-3) to measure the utility gain and derive for quality adjusted life years (QALYs). A Markov Model, with a third-party payer perspective was applied to the Argentinian setting. A 5% discount rate was applied over a 10-year time horizon.

**Results:** Within this study, four different bone conduction implants systems were compared to each other: percutaneous bone conduction implants (pBCIs), active transcutaneous bone conduction implant (atBCI), passive transcutaneous bone conduction implants (ptBCIs) and an active osseointegrated steady-state implant (OSI). Following a 10-year time horizon, total incremental costs (USD) and incremental QALYs yielded up to: (pBCIs: \$ 30,080 / 1.76 QALYs); (atBCI: \$ 27,977 / 1.93 QALYs); (ptBCIs: \$ 29,424 / 1.77 QALYs) and (OSI: \$ 32,097 / 1.66 QALYs). Compared to the atBCI, the other BCIs yielded an incremental cost utility ratio (ICUR) of (pBCI: \$ -12,196/QALY), (ptBCIs: \$ -8,760/QALY) and (OSI: \$ -15,333/QALY). Considering a willingness-to-pay (WTP) threshold of 1 GDP per Capita, as attributed by the WHO, the atBCI is both clinically superior and cost saving, compared to the other BCIs and can therefore be referred to, as the economically “dominant” treatment strategy. Probabilistic Sensitivity Analysis (PSA) showed that the probability of being cost-effective was approximately 60.0% for the atBCI.

**Conclusion:** All BCIs analyzed within this Argentinian setting had a positive treatment effect on adult’s and children’s QoL, when suffering from a conductive or mixed hearing loss or single-sided deafness. The atBCI had the highest impact on patients QoL with lowest overall costs, and can therefore be considered the most cost-effective treatment strategy.

## **The Healthy Hearing Ears Initiative COM Research Platform: A new online research tool for gathering data on patients with chronic otitis media related hearing loss**

Myrthe Hol, Thomas Lenarz on behalf of the Healthy Hearing Ears Initiative

### **Abstract**

**Objectives:** Chronic otitis media is a leading cause of acquired hearing loss and hearing rehabilitation strategies must accompany infection control in surgical planning. However, there is limited clinical evidence to inform surgeons on what treatment alternative is the best method to restore hearing based on the middle ear status of the patient. These uncertainties hinder the development and acceptance of best practice guidelines. How to manage surgical failures and revision surgeries, when to rehabilitate patients using hearing devices, and how to treat patients with mixed hearing loss are key areas that require targeted evidence generation.

**Materials and Methods:** The Healthy Hearing Ears Initiative ([www.healthyhearingears.org](http://www.healthyhearingears.org)), established by eight otologists from across the globe, have supported the development of an online research platform to support standardized data collection for patients with chronic otitis media who have experienced a failed primary tympanoplasty. The platform can be used to gather diagnostic and intervention codes based on ICD-11 standards and standardized audiometry data, as well as Quality of life and hearing disability data using the Chronic Otitis Media Outcome Test-15 and the Speech, Spatial and Qualities of Hearing Scale 12 questionnaires. The platform also compiles middle ear status variables using the Middle Ear Risk Index aiming at identifying prognostic indicators of surgical success.

The platform provides easy data entry for both clinician and patient while also facilitating collaboration and data pooling between clinics using the platform.

**Results:** The platform will deliver pre- and post-intervention free field PTA4 hearing thresholds, speech audiometry outcomes, quality of life and hearing disability scores stratified by diagnostic and intervention code. Middle ear status variables will be gathered with the objective of correlating these with the treatment outcomes, identifying useful prognostic factors to determine what treatment option is suitable for which patient.

**Conclusions:** The online research platform will enable targeted data collection that can be used to facilitate evidence-based treatment practice for aural rehabilitation of patients with chronic otitis media related hearing loss.



**Saturday, September 9<sup>th</sup>, 2023**

**11:30- 13:20 New Technologies**

## **Preclinical output performance evaluation of the novel active transcutaneous bone conduction implant Sentio**

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### **Abstract**

**Objectives:** The output performance of the novel semi-implantable transcutaneous bone conduction device Sentio (Oticon Medical) was compared to the established percutaneous bone-anchored hearing device Ponto 3 (Oticon Medical) using fresh cadaver heads. The impact of actuator position, tissue growth below the actuator and the depth of the bone bed on performance was investigated.

**Methods:** The percutaneous and the transcutaneous device were sequentially bilaterally implanted at two sites in 5 human cadaver heads: 55 mm superior-posterior to the ear canal opening (position A) and, 20 mm inferior-posterior to the ear canal opening behind the pinna on the mastoid (position B). The ipsi- and contralateral cochlear promontory (CP) velocity magnitude responses to percutaneous and transcutaneous stimulation were measured using 1-D laser Doppler velocimetry. Moreover, the CP vibration of the transcutaneous device placed directly on the skull bone surface was compared with the placement in a 3 mm deep bone bed. Finally, the influence of placing a 0.3 mm silicone interposition layer below the implanted transducer was also explored.

**Results:** The percutaneous device provided about 11 dB higher average CP vibration level than the transcutaneous device at frequencies between 0.5 and 10 kHz. The ipsilateral CP vibration responses with stimulation at position B were on average 13 dB higher compared to stimulation at position A. The placement of the transcutaneous transducer at position B provided similar or higher average vibration magnitudes than the percutaneous transducer at position A. Neither the 3 mm deep bone bed nor placement of the silicone layer under the transducer had a significant effects on the output performance of the transcutaneous device.

**Conclusions:** Our results using the CP vibration responses show that at frequencies above 500 Hz the new transcutaneous device at position B provides similar output levels as the percutaneous device at position A. The results also indicated that neither a bone bed nor a simulated tissue growth between the actuator and the bone affect the output performance of the device.

## **Sentio the new transcutaneous bone conduction hearing implant from Oticon Medical: The UK surgical experience and early clinical results**

Peter Monksfield<sup>1</sup>, Rupan Banga<sup>1</sup>, Mihalache Marwa<sup>1</sup>, William Brassington<sup>1</sup>, Manohar Bance<sup>2</sup>, Abi Asher<sup>3</sup>, James Tysome<sup>3</sup>

<sup>1</sup>University Hospitals Birmingham, Birmingham, United Kingdom. <sup>2</sup>University of Cambridge, Cambridge, United Kingdom. <sup>3</sup>Cambridge University Hospitals, Cambridge, United Kingdom

### **Abstract**

**Objectives:** The Sentio bone conduction system is a new transcutaneous device produced by Oticon Medical, Askim, Sweden. The first in human use of this device in its final design is now being investigated in a multicentre European study.

This project has developed from the earlier work of Bo Hakansson and the Gothenburg group<sup>1-3</sup>. The objective of this trial is to investigate the performance and safety of the final system.

**Methods:** This trial is a prospective, multi-centre, single-arm, clinical investigation of the safety and performance of the Sentio system in users with mixed/conductive hearing losses and single sided deafness. The surgical procedure will be demonstrated and the early clinical results will be presented from the two United Kingdom participating centres.

**Results:** Patient characteristics, intra-operative results and experiences will be shared. In addition, short-term audiological outcomes will be presented.

**Conclusion:** Surgical experience and a preliminary conclusion from the United Kingdom on the Sentio system will be discussed.

## **Shielding of the B250 transducer to reduce the artifact in auditory brainstem response investigations**

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Dept of Electrical Engineering, Chalmers University of Technology, Gothenburg, Sweden

### **Abstract**

**Objectives:** Bone conduction (BC) stimulation in auditory brainstem response (ABR) investigations are needed for objective hearing evaluation of patients suffering from conductive hearing loss. However, at

low frequencies, large currents in the transducer will generate magnetic fields causing artifacts being picked up by ABR electrodes attached to the patient's head. Recently, a shielding apparatus for the BC transducer B250 was developed at the Chalmers University of Technology, Gothenburg, with the intention to reduce this artifact. The aim of this study is to evaluate its shielding ability to reduce the electromagnetic artifact arising from the transducer during BC stimulated ABR.

Methods: The magnetic flux density surrounding the transducer was measured using a Lake Shore 425 Gaussmeter, both with and without shielding. Both active and passive shielding were evaluated for tone bursts and pure tones at the audiometric frequencies 250, 500, 750 and 1000 Hz on a phantom head. Also, a constant input current of 100 mARMS was swept between 100 and 1000 Hz. Furthermore, the electrical properties of the shielding apparatus were evaluated by electrical measurements.

Results: At a fixed hearing level of 50 dB HL, the artifact was in average reduced by  $51.5 \pm 1.2\%$  for all four test frequencies with a maximum artifact observed at 500 Hz. Due to its resonance peak at 250 Hz, the B250 required less current at 250 Hz than at 500 Hz to generate the same hearing level, resulting in lower artifact at that frequency. At frequencies above 500 Hz, the artifact rapidly decayed below the noise floor. For the constant input current measurements, the maximum artifact was observed at 131 Hz but it decayed for higher frequencies.

Conclusion: The proposed passive shielding apparatus for the B250 is reducing the artifact by approximately 50% and possibly further with active shielding. Due to the inherent frequency response of the transducer, the artifact at 250 Hz will be lower than at 500 Hz for the same hearing level. In the next phase, the method will be applied on healthy subjects as well as patients with conductive hearing loss to determine the clinical significance.

## Is hearing through bone conduction headsets bone conduction?

Sudeep Surendran PhD, Srdan Prodanovic PhD, [Stefan Stenfelt PhD](#)

Linköping University, Linköping, Sweden

### Abstract

Objectives: Recently, bone conduction headsets for communication have become popular. Common for most of these devices is that they have the transducers placed in front of the ear close to the ear canal opening. However, it is not clear if the sound perceived from these devices stem from the bony vibrations as in classic bone conduction theory, is transmitted to the inner ear by other means, or is primarily airborne sound emitted from the transducers themselves.

Methods: Hearing thresholds and ear canal sound pressures were obtained in twenty-one participants with normal hearing with BC transducers placed at either the mastoid or in front of the ear canal. In addition, a skull-bone vibration analysis was done in the computation model LiUHead with stimulation provided at the two positions.

Results: The hearing thresholds in terms of stimulation force levels were 20 to 40 dB lower (better) when the stimulation was in front of the ear compared to at the mastoid. The inter-aural separation was around 30 dB higher with stimulation at the front compared to at the mastoid. It was found that the sound pressure in the ear canal dominated the hearing when the stimulation was applied at the frontal position, and that this ear canal component was 25 to 30 dB higher than other components contributing to bone conduction hearing.

Conclusion: When bone conducted sound is applied close to the ear canal, as in several bone conduction headsets for communication, the sound transmission is primarily caused by sound radiated into the ear canal. This means that the sound transmission to the inner ear is similar to that with air conduction stimulation. Consequently, these devices are unsuitable for audiological measurements as they are affected by the middle ear status and would not be able to differentiate conductive from sensorineural hearing losses.

## **Evaluating and optimizing the performance and design of new bone conduction systems.**

Patrik Westerkull M.Sc. Eng. Ph., Carl Hultcrantz PhD

Otorix, Askim, VGR, Sweden

### **Abstract**

Objectives: The objective was to investigate and develop a new type of bone conduction (BC) hearing system. There is a significant need for a new flexible well-functioning bone conduction system in both surgical and non-surgical applications. A key to develop a new system is the optimization of the electromagnetic vibrator technology.

Method: Different compositions of advanced technologies are required to increase efficiency and reduce size of a bone conduction vibrator. Electromagnetic circuits are highly multidisciplinary where for example material choice, geometry, electronic and the magnetic field physics in terms of both static and dynamic behaviour is vital. Vibrator technology and performance optimization may also be depending on whether the application is in non-surgical, percutaneous or transcutaneous bone conduction solutions. The performance was evaluated in comparison with current bone conduction systems available on the market.

Results: The results showed that significant gains in vibrator performance could be reached to support new types of bone conduction systems that are more efficient considering the overall parameters related to efficiency in the clinic and for the patients. The audiological performance shows that it is well in-line with the market leading existing direct bone conduction solutions. The result of this development is to be implemented new bone conduction concepts to become available on the market in the future.

Conclusions: Multiple factors had to be considered in the development of the new BC concept. Vibrator technology is one of the cornerstones. Based on these new findings new BC systems with excellent performance can be further implemented both in the shape of existing bone conduction concepts as well as new type of bone conduction concepts which may offer a valuable clinical alternative to existing bone conduction solutions.

## **Liminal Spaces – A multimodal immersive auditory experience**

Rafael Patrick Ph.D.<sup>1</sup>, Tanner Upthegrove MFA<sup>2</sup>

<sup>1</sup>Human IMPaC-T; Virginia Tech, Blacksburg, VA, USA. <sup>2</sup>ICAT; Virginia Tech, Blacksburg, VA, USA

### **Abstract**

**Background & Objectives:** Liminal Spaces is a 15-minute fixed-media composition that uses the one-of-a-kind capabilities of the Virginia Tech ICAT CUBE to completely immerse listeners in an artificial soundscape. In collaboration with the artists, the authors conducted a pilot study aimed at investigating whether an artist's depiction of a story, Liminal Spaces, is experienced by an observer as expected through the exploration of a listener's ability to identify artistic artifacts of interest.

**Methods:** During a performance of Liminal Spaces, groups of four listeners (n=20) were asked to subjectively respond to specific auditory stimuli (i.e., artistic points of interest) presented through both air conduction (AC) and bone conduction (BC) pathways using a graphical user interface (GUI) displayed on an iPad. Listeners were asked to indicate – using a touch screen – when they heard a predetermined event (i.e., I heard the bird through the bone conduction headset; It was moving). The protocol sought to explore a listener's ability to accurately detect, recognize, identify, and localize auditory stimuli of interest while determining the extent to which a listener can distinguish perception between auditory pathways: air and bone conduction.

**Results:** Data analysis and results are forthcoming; however, preliminary reviews indicate that listeners could experience the performance in a way that satisfied the artist's intent and allowed attendees to depict the story being told in Liminal Spaces sonically.

**Conclusion:** In the near future, expectations for personalized immersive experiences will motivate the development of advanced auditory interfaces that utilize both modes of human audition. Furthermore, entertainment-based BC interfaces are growing in popularity and so will the value of being acoustically aware of one's immediate surrounding while being entertained. This study establishes a necessary precedent for understanding the role of BC in the future of immersive audio.

## **First Clinical Experience from a Novel Active Transcutaneous Bone Conduction Implant System**

Tierk W. Aukema MD<sup>1,2</sup>, Sander W.J. Ubbink ir<sup>1</sup>, Rutger Hofman MD, PhD<sup>1</sup>, Herman J.W. Kok<sup>2</sup>, Froukje L.J. Cals MD, PhD<sup>2</sup>, Emmanuel A.M. Mylanus MD, PhD, Prof.<sup>2</sup>, Myrthe K.S. Hol MD, PhD, Prof.<sup>1,2</sup>

<sup>1</sup>Department of Otorhinolaryngology/Head and Neck Surgery, Graduate School of Medical Sciences, University of Groningen, University Medical Center Groningen, Groningen, Netherlands. <sup>2</sup>Department of Otorhinolaryngology, Donders Center for Neurosciences, Radboud university medical centre, Nijmegen, Netherlands

### **Abstract**

Title: First clinical experience from a novel active transcutaneous bone conduction implant system.

Objectives: To share the first clinical experience from a novel active transcutaneous bone conduction implant system in users with mixed/conductive hearing losses and single sided deafness.

Methods: There is an ongoing long-term clinical investigation on the first version of the novel active transcutaneous bone conduction implant system (Sentio, Oticon Medical AB, Sweden) where so far 20 out of 50 planned patients have been implanted by 2 out of the 6 participating clinics (clinicaltrials.gov identifier NCT05166265). This report includes the first observations and clinical reflections on the surgical installation and clinical follow-up for these patients.

Results: The first implanted 20 patients had a mean age of 47 years and with the type of hearing loss being either conductive (n = 14), mixed (n = 4), or single sided deafness (n = 2) on the implanted side. Surgery duration from incision to last suture varied between 45 and 85 minutes, being of influence on the surgical learning curve. Implant installations could be done without any specific preoperative planning. The small size and the design of the implant enabled a smooth surgery installation with minimal bone preparation and with limited impact on surrounding tissue. Implant performance outcomes and safety profile follow expected patterns after the initial observed follow-up period of 12 months, currently. The overall patient satisfaction is positive.

Conclusion: These initial clinical observations indicate that the implant is indeed small and less invasive to install without compromising clinical outcomes. This may indicate opportunity for treatment with an active transcutaneous implant system also in younger ages where bone quantity may be limited.

## **Relieving Vertigo with Bone-Conducted Vibration: Preliminary Results from Clinical Trials**

Didier Depireux, Daniel Stolzberg, Alesia Robinson, Jonathan Akers, Samuel Owen

Otolith Labs, Washington, DC, USA

## **Abstract**

**Objectives:** Vertigo, the false sensation of motion, is a symptom of vestibular dysfunction that has a significant impact on the quality of life of those with chronic conditions. Pharmacological treatments have well known and unavoidable undesirable side-effects, including delayed activation.

Over the past few years, Otolith Labs has sought to create the bone conduction equivalent of a masker for the vestibular system, akin to the tinnitus maskers that provide relief in some proportion of tinnitus sufferers.

**Method:** We have developed a novel bone-conduction system that interacts with the peripheral vestibular system, through transmission of a low frequency (~50 Hz) vibration to the inner ear with an external stimulation device. This system is externally worn against the mastoid with a headband, and the force level imparted to the head can be adjusted within a narrow range by the user. We have conducted several clinical trials to measure dosing effect, form factor and efficacy vs a sham, mostly in a telehealth setting.

**Results:** This wearable device has an unexpectedly narrow therapeutic vibratory force level range, is powered by a small battery and is held against the mastoid with a comfortable headband. We will detail results from recent and ongoing clinical trials suggesting that the bone-conduction system is safe and effective at reducing the severity of vertigo episodes in patients with chronic vestibular disorder, including vestibular migraines and Ménière's disease.

**Saturday, September 9<sup>th</sup>, 2023**

11:30- 13:20 Atresia

## **The Costs of Unaddressed Hearing Loss in Chilean Children with Bilateral Microtia and External Auditory Canal Atresia and Cost Effectiveness of Different Treatment Interventions**

Klaas Kiesewetter Ing. MA<sup>1</sup>, Carolina Der MD, PhD<sup>2</sup>, Sofía Bravo Torres MSc<sup>2</sup>, Christina Schwarz Mag. MPH<sup>1</sup>, Annegret Hoch MSc<sup>1</sup>, Bettina Schlick PhD<sup>1</sup>, Francesca Scandurra PhD<sup>1</sup>, Karin Rose-Eichberger Mag.<sup>1</sup>, Thomas Dejaco PhD<sup>1</sup>, Michael Urban Dr. rer. nat. MBA MSc<sup>1</sup>

<sup>1</sup>MED-EL Medical Electronics, Innsbruck, Tyrol, Austria. <sup>2</sup>Dr Luis Calvo Mackenna Hospital; Universidad del Desarrollo; Clinica Alemana de Santiago, Santiago, Providencia, Región Metropolitana, Chile

## **Abstract**

**Objectives:** The aim of this study is to present the costs of untreated hearing loss (HL) in Chilean Children with Bilateral Microtia and External Auditory Canal Atresia (EACA) and to determine whether the current treatment interventions can provide a cost-effective treatment solution in Chile.

**Methods:** Costs from the perspective of the healthcare and educational sector were assessed for children with microtia or atresia in Chile. The cost-effectiveness of possible interventions was investigated and compared to children remaining untreated, but receiving a special educational subsidy, in addition to recurring speech therapies. A probabilistic Markov Model with a time horizon of 10 years was developed and applied to the Chilean setting.

**Results:** Hispanic countries have a significantly higher prevalence of microtia and external auditory canal atresia, compared to non-Hispanic countries. The incidence of microtia was 8.7 per 10,000 live births in Chile. Bilateral EACA affects only one in every 10,000 to 20,000 live births in Chile whereas unilateral atresia is seven times more common. Giving these numbers, the annually estimated costs (educational and healthcare) for children with bilateral microtia or EACA who remain untreated add up to approximately \$ 600,000.

Following a 10-year time horizon, incremental costs of an intervention with a bone conduction implant yield up to \$ 20,600 with an incremental QALY of 1.80 per child implanted, while healthcare and educational costs of leaving a child untreated yield up to \$ 14,000 with an incremental QALY of 0.58, resulting in an incremental cost-effectiveness ratio (ICER) of \$ 5,409 per QALY gained, considering a willingness-to-pay (WTP) threshold of 1 GDP per Capita, as attributed by the World Health Organization (WHO).

**Conclusion:** Unaddressed hearing loss in Chilean Children with Bilateral Microtia and External Auditory Canal Atresia imposes annual national costs of more than \$ 600,000. Bone Conduction Hearing implants are a cost-effective treatment strategy for children in Chile.

## **Audiological and plastic rehabilitation of atresia patients**

Anke Leichtle PD Dr. med., Daniela Hollfelder Dr. med., Armin Steffen Prof. Dr. med., Karl-Ludwig Bruchhage PD Dr. med.

Department of Otorhinolaryngology, Head and Neck Surgery, University Hospital Schleswig-Holstein, Lübeck, Schleswig-Holstein, Germany

## **Abstract**

**Introduction:** Patients with auricular atresia suffer from an aesthetic impairment due to the microtia, as well as from a functional hearing loss in the form of conductive or combined hearing loss. For aesthetic rehabilitation, auricular reconstruction in Lübeck is usually performed with autologous rib cartilage.



Audiological rehabilitation can be performed with partially implantable passive hearing systems or active transcutaneous bone conduction systems, such as the Bonebridge (BB) and the Vibrant Soundbridge (VSB) middle ear implant.

**Methods:** We present 19 patients with microtia of varying degrees of severity who were surgically treated using BB or VSB and auricular reconstruction. Auricular reconstruction was traditionally performed using autologous rib cartilage, and 3 patients were treated with epitheses. Audiological data were evaluated and quality of life was assessed using the Glasgow Benefit Inventory (GBI) and the Glasgow Benefit Inventory for Children (GBCI), particularly with regard to aesthetic benefit.

**Results:** Plastic aesthetic rehabilitation using autologous rib graft showed significantly higher quality of life compared to aesthetically unprovided microtia ( $p < 0.05$ ). In addition, we obtained significant functional hearing gain after BB or VSB implantation ( $p < 0.05$ ) and significant improvement in speech understanding in quiet and noise ( $p < 0.05$ ), with no significant differences in stapes or round window coupling after VSB implantation.

**Conclusion:** The combination of aesthetic and functional rehabilitation leads to a significant increase in the quality of life of atresia patients.

## **Audiological performance and subjective satisfaction between surgical and non-surgical bone conduction hearing aids in patients with aural atresia.**

Mario Zernotti<sup>1,2</sup>, Carolina Der<sup>3</sup>, Sofia Bravo-Torres<sup>3</sup>, Fernanda Di Gregorio<sup>2</sup>

<sup>1</sup>Universidad Nacional de Cordoba, Cordoba, Argentina. <sup>2</sup>Sanatorium Allende, Cordoba, Argentina. <sup>3</sup>Luis Calvo Mackenna Hospital, Santiago de Chile, Chile

### **Abstract**

**Objectives:** Atresia auris affects 1/10,000-20,000 live births, with the highest prevalence in Latin America at 5 to 21 of every 10,000 newborns. It produces an important conductive hearing loss conditioning the development and learning of children.

Comprehensive approach includes the aesthetic and functional treatment. To hearing loss there are surgical and non-surgical alternatives like rigid and softband systems. The disadvantages of these, include limited functional gain, cosmetic unattractiveness, and pain due to pressure on skin. Active transcutaneous bone conduction implants (BCI) achieve better sound transmission stimulating the bone directly. In 2016, an adhesive bone conduction device (aBCD) was introduced. The main objective of study was to assess the audiological performance and subjective satisfaction of children implanted with an active transcutaneous BCI over one year and to compare the outcomes with a non-surgical aBCD in the same users.

Methods: Prospective, multicentric study. Audiological performance and subjective satisfaction were evaluated at 1, 6 and 12 months post-implant activation, and after a 1-month trial with the non-surgical device. Tests: sound field audiometry; sound field speech in quiet and in noise; hearing-specific and audio processor-specific questionnaires.

Results: 10 patients completed all tests. The average PTA4 in the unaided condition was 65 dB HL and improved significantly to 20 dB HL after using the BCI for 12 months; with the aBCD an average PTA4 of 33 dB HL was measured. The speech recognition in quiet in the unaided condition was on average 33 %, which improved significantly using the BCI or aBCD. A mean WRS of 99 % with the BCI and 91 % with the aBCD could be achieved. The daily wearing time was 11 hours per day with the BCI and 9 hours using the aBCD. Overall, the BCI showed better results than the aBCD regarding subjective satisfaction.

Conclusions: The aBCD provide sufficient hearing improvement and subjective satisfaction and thus is a good solution for hearing rehabilitation if surgery is not desired or not possible. If surgery is an option, the bone conduction implant is better device in terms of hearing outcomes, and subjective satisfaction.

## **An Adhesive Bone Conduction Hearing Aid for Mandarin-Speaking Children with Unilateral Congenital Aural Atresia**

Yujie Liu MD, Danni Wang MD; PhD, Shouqin Zhao MD; PhD

Department of Otolaryngology Head and Neck Surgery, Beijing Tongren Hospital, Capital Medical University, Beijing, Beijing, China

### **Abstract**

Purpose: This study aimed to assess the objective and subjective satisfaction levels of an adhesive bone conduction hearing aid (BCHA) among Mandarin-speaking children with congenital unilateral microtia and atresia (UMA), as well as its impact on their sound localisation abilities.

Methods: Ten children (mean age:  $8.3 \pm 2.87$  years, follow-up period:  $10.9 \pm 6.21$  weeks) with UMA and unilateral conductive hearing loss were included. The hearing benefits of the device were evaluated using sound field hearing threshold (SFHT) and speech reception threshold (SRT) under noise. Subjective satisfaction was measured by the International Outcome Inventory for Hearing Aids (IOI-HA), the Speech, Spatial, and Qualities of Hearing Test for Parents (SSQ-P), and the Self-designed Use and Satisfaction Questionnaire. The sound localization ability was tested with broadband noise stimuli randomly played from seven loudspeakers at 3 different stimulus levels, and the mean absolute error (MAE) was calculated.

Results: Participants reported an average daily usage time of  $7.1 \pm 3$  hours. The mean SFHT significantly improved with a gain of  $21.9 \pm 4.38$  dB HL ( $p < 0.05$ ). Speech reception abilities were generally improved

under noise ( $p < 0.05$ ); however, when analyzing the binaural summation, squelch, and head shadow effects separately, the binaural squelch effect did not show a statistically significant improvement ( $p > 0.05$ ), while the other effects were improved with the use of the BCHA ( $p < 0.05$ ). Moreover, patients expressed high levels of satisfaction across three subjective questionnaires, with six patients rating the aesthetics of the BCHA highly. Additionally, seven individuals reported minor redness of the local retroauricular skin after removing the adhesive adapter, which resolved overnight after removal, and no painful feelings were reported. In the sound localisation test, there was no significant difference between the MAE in the unaided and aided situations ( $p > 0.05$ ).

Conclusion: The adhesive BCHA provides a concealed and aesthetical method to enhance hearing in children with congenital UMA during their early years. Furthermore, the device offers high subjective satisfaction without deteriorating their sound localisation abilities.

## **Microtia And Atresia in Latin America**

Luis Serrano DR MD Audiologist, Cenaudi, Cuenca, Ecuador

### **Abstract**

Objectives: To present our experience in Diagnosis and Adaptation of Bone Conduction System in children in Latin America

Methods: Follow-up of documented cases from 2009 to 2023, especially children with studies of auditory electrophysiology and tonal audiometry, with a focus on early neonatal hearing screening program

Results: from 2009 to the present, we have documented more than 5000 cases of Microtia with Atresia in Latin America, we have personally attended more than 3500 patients and we have adapted bone vibration systems in more than 2000 cases.

Our experience begins much earlier, with documented cases since 1995, however, the lack of adequate technologies in studies and above all, the lack of bone amplification devices suitable for our environment and economic reality of patients, delayed a lot the proper management in cases of Microtia

It is not until 2009, when we started working with the German company Bruckhoff, that the possibility of adapting more children became a reality, with surface bone vibration systems, which allowed us to give the answer we have been waiting for a long time.

Bruckhoff presented to the market 2 devices, one adapted in elastic band and another adapted in glasses, with excellent sound quality and above all, economically very accessible, but with a problem for us, the lack of exclusivity of the company did not allow us a further expansion of our program,

The situation changes drastically in 2021, when we signed with BHM Tech, an Austrian company with more than 20 years in the market, an exclusivity agreement to represent them in practically all of Latin America; allowing in this way to realize projects in a private and public way, which allows us to ensure that, in the coming years, many children who currently cannot be adapted for economic reasons, will have an option that comes through them by the public health systems

Conclusions: Project MICROTIA LATINOAMERICA, has shown in a few years, that we can organize and educate the population in a better way, from the initial issue diagnosis, adaptation, even in the aesthetic issue.

## **ADHEAR versus passive bone conduction implants in children with aural atresia**

Javier Gavilan<sup>1</sup>, Fernanda Pedrero<sup>1</sup>, Laura Cavalle<sup>2</sup>, Jose Manuel Morales<sup>1</sup>, Luis Lassaletta<sup>1</sup>

<sup>1</sup>La Paz University Hospital, Madrid, Spain. <sup>2</sup>La Fe University Hospital, Valencia, Spain

### **Abstract**

**Introduction:** The first adhesive bone conduction device was introduced in 2017. We compare the auditory outcomes and patient satisfaction between adhesive and passive transcutaneous bone-conduction implants.

**Methods:** We include 16 pediatric patients with bone conduction threshold  $\leq 25$ dB who were users of passive transcutaneous implants for at least one year, and gave them an adhesive system for one week. Pure tone thresholds and word recognition with bisyllables at 65dB with and without noise were measured for each of the two devices. A specific satisfaction questionnaire, SSQ life questionnaire and the Kindler quality of life questionnaire adjusted to the patient's age were also passed.

**Results:** The age of the patients was between 5 and 16 years. All of them had congenital aural atresia, 9 unilateral and 7 bilateral. The pure tone average in the studied ear recorded a mean threshold of 52 dB unaided. The mean passive transcutaneous-aided threshold was 27 dB and 29 dB with the adhesive-aided. The average word recognition score was 96% for the passive transcutaneous and 95% for the adhesive system in quiet. The word recognition score in noise at 5 dB SNR was 70% for the passive transcutaneous and 77% with the adhesive device and at 0 dB SNR 50% for the passive transcutaneous and 48% with adhesive implant.

**Conclusion:** The new adhesive bone conduction system provides comparable auditory results with passive transcutaneous bone conduction implants in free field, in word discrimination in quiet, and word recognition with background noise. The overall satisfaction of the new adhesive device is good.

## **Parent & Patient Perspectives about Intervention Options for Microtia Atresia**

Chrisanda Sanchez AuD, Jennifer Coto PhD, Hillary Snapp AuD, PhD, Ivette Cejas PhD

University of Miami, Miami, FL, USA

### **Abstract**

Microtia/atresia is a rare condition affecting the anatomical structure and development of the outer and/or middle ear, predominantly occurring in the Hispanic population. This condition is often associated with hearing loss, physical facial malformations, and subsequent psychosocial issues. Additionally, it commonly co-exists with craniofacial anomalies, secondary to conditions such as Goldenhaar syndrome (Hemifacial Microsomia) and Treacher Collins syndrome. While several advancements in treatment options have been made in the hearing and plastic surgery fields, there still is no consensus on the management of microtia/atresia or cross specialty guidelines on the overall management of these patients. Further, given that this condition primarily affects racial and ethnic minorities, there is great concern for health disparities. Specifically, individuals from minority backgrounds are at-risk due to limited access to qualified specialists, cultural stigma regarding physical malformations, lower health literacy, limited English proficiency, and socioeconomic status. To date, while each specialty may have their own individual practice guidelines, there is no unified approach to managing all aspects of the patients care even in the presence of craniofacial teams.

The current study will assess parent and patient perspectives related to treatment options for microtia/atresia and the primary concerns that drive their decisions related to intervention. We expect that parent perspectives will differ by child age, with parents of younger children being more concerned with physical appearance. In addition, we will assess parent and child agreement related to treatment decisions. Parents of children with unilateral or bilateral microtia atresia will be recruited from a comprehensive pediatric otology/audiology practice. Children ages ten and older will also be recruited. All participants will complete an electronic survey (in English or Spanish), including demographics, audiological and medical history, and questions related to microtia atresia treatment options and decision-making. This study is an important first step to identify gaps in parent and child knowledge related to both audiological and surgical options for individuals with microtia atresia. This not only has the potential to change counseling practices for this population, but also may help bridge the health disparity gap that exists in this population.

## **More than just ears: Psychology's contribution to microtia teams**

Deborah Mood PhD

University of Colorado Anschutz, Aurora, CO, USA

### **Abstract**

## Objectives:

1. Describe the role of psychologists on pediatric microtia teams
2. Review literature regarding developmental and psychosocial concerns reported among children and adolescents with microtia/atresia
3. Describe developmental and psychosocial screening within a pediatric microtia clinic

**Abstract:** Microtia teams often consist of ENT, audiology, and surgeons. Psychology is less often represented on these teams. However, several research based findings support the role of psychology on multidisciplinary microtia teams including: increased rates of co-occurring developmental disabilities among children who are D/HH generally (Mitchell & Karchmer, 2006; Syzmanski et al., 2012) and particularly among children with Goldenhar syndrome and other syndromes associated with craniofacial differences (Junaid et al., 2022); high rates of bullying and mood disorders such as depression and anxiety experienced by children with microtia (Du et al., 2007); and parent reported need for increased psychosocial support (Johns et al, 2018; Johns et al., 2022). Screening by psychologists on microtia teams improves early identification of developmental and psychosocial concerns and referral to appropriate intervention. Developmentally informed counseling is also critical for young children and adolescents making ear reconstruction and hearing technology decisions. Utilizing literature review as well as data from the past two years of psychology representation on a pediatric multidisciplinary microtia team, this presentation will describe co-occurring developmental, academic, and psychosocial concerns presented by pediatric microtia patients in order to highlight the role and value of psychology in improving patient outcomes. Developmental and psychosocial screeners as well as resources used in clinic will be shared.

## **Agensis of external auditory canal and aural atresia in children with complex anatomy: Active transcutaneous bone conduction implants or not implantable devises? Surgical considerations and quality of life impact.**

Carolina Der<sup>1,2,3</sup>, Sofia Bravo<sup>1</sup>, Nicolas Pons<sup>1</sup>, MariaJose Herrera<sup>1</sup>, Magdalena Cornejo<sup>1</sup>

<sup>1</sup>Dr Luis Calvo Mackenna Hospital, Santiago, Chile. <sup>2</sup>Universidad del Desarrollo, Santiago, Chile. <sup>3</sup>Clínica Alemana de Santiago, Santiago, Chile

### **Abstract**

**Introduction:** Agensis of external auditory canal is often associated with microtia. Conductive hearing loss is the most common audiological finding. It affects 1 in every 10.000 births worldwide. According to prevalence studies, in Chile this condition is 3 to 8 times more frequent.

Treatment options include functional and aesthetic approach. The functional options include implantable and not implantable devices. Two active transcutaneous bone conduction implants are available nowadays and both are suggested to be located in a retroarticular position.

Since a retro auricular incision and location is not always possible in children with complex anatomy and is a limitation to the aesthetic pinna reconstruction, the aim of this study is to describe the middle fossa location of both active bone conduction implants available and compare the audiological and quality of life results with an adhesive not implantable bone conduction device in a pediatric population with agenesis of external auditory canal.

Methods: Children who had unilateral or bilateral conductive hearing loss, secondary to agenesis of external auditory canal receiving implants between 2014 and 2023 were included. Sixty-two 5 to 18 y/o children were implanted with Bonebridge and 4 children were implanted with OSIA. All surgeries for both devices were performed with a middle fossa location technique. The audiological and quality of life results were compared with users of ADHEAR.

Results: For Bonebridge the follow-up was 9 years to 6 months. For OSIA 6 months. The surgery in this location was easier and faster than the retroauricular location for both devices. The PTA was similar for both devices but with differences in low frequencies (28 dB on average) with better results for Bonebridge. ADHEAR users had a higher PTA, 35 dB on average. The audiological and QoL results were according to the expected for these devices with a better result for the implantable ones.

Conclusions: Both Bonebridge and OSIA can be implanted in a middle fossa location with good results. OSIA patients had only 6 months follow-up, is necessary to see long term audiological and surgical results. ADHEAR is a good option of rehabilitation if the surgery is not a possibility.

## **Audiometric patterns and progression among children with congenital aural atresia or external auditory canal stenosis**

Brandon Abell BA<sup>1</sup>, Gabriela Heslop MD<sup>1,2</sup>, Megan Hedman AuD, CCC-A<sup>3</sup>, Kirsten Adkisson AuD, CCC-A<sup>3</sup>, Brian Herrmann MD<sup>2</sup>, Sarah Gitomer MD<sup>2</sup>

<sup>1</sup>University of Colorado Anschutz Medical Campus, Aurora, CO, USA. <sup>2</sup>Department of Otolaryngology – Head and Neck Surgery, Children’s Hospital Colorado, Aurora, CO, USA. <sup>3</sup>Children’s Hospital Colorado, Aurora, CO, USA

### **Abstract**

Objectives: Congenital aural atresia (CAA) and external auditory canal stenosis (EACS) are associated with significant conductive hearing loss, but hearing severity and patterns have not been compared between these groups previously. Hearing is thought to improve with ear canal growth in other populations with EACS, but it is unknown whether this is the case in patients with congenital EACS. Distinguishing complete atresia from narrow stenosis on physical exam is difficult in newborns—If

hearing improves with time, a marker on initial audiometric testing may be useful in differentiating EACS vs CAA. We aim to determine whether the severity and patterns of conductive hearing loss differ between patients with EACS and CAA.

**Methods:** Retrospective chart review was performed to evaluate 508 children treated for microtia, CAA, or congenital EACS at a tertiary referral children's hospital. Patients were categorized as having CAA or EACS through physical exam documentation, with confirmation by CT temporal bones when available. Patients with bilateral deformity, mixed or sensorineural hearing loss were excluded. Clinical audiologists performed age-appropriate audiometric testing. Hearing change was evaluated between first and last documented audiograms, prior to any canal or middle ear surgery, and was categorized using hearing loss pattern (flat, gradually rising, etc.) and the most severe hearing frequency. Statistical analysis was performed using R Studio.

**Results:** 214 children with unilateral deformity were included: 180 children with CAA (92 males, 51.1%; 128 right-sided, 71.1%); 34 children with EACS (17 males, 50%; 23 right-sided, 67.6%). There were no demographic differences between groups. Patients with atresia had worse initial hearing loss (58.9% severe, compared to 38.2% of patients with EACS;  $p=0.012$ ) and worse final hearing loss levels (77.2% severe vs. 58.8% for EACS patients;  $p<0.001$ ). There was no difference in the pattern of initial or final hearing loss between groups ( $p=0.092$ ).

**Conclusions:** Our results indicate patients with CAA have worse conductive hearing loss on initial and final audiograms than those with EACS. Hearing loss patterns did not differ between groups. These results offer important considerations for counseling families of infants with these conditions.

## **How we do it: Simultaneous Bilateral Osia implantation in children with microtia**

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### **Abstract**

**Purpose/Aim:** To describe the technical aspects of the procedure in cases of primary implantation and conversion from previous percutaneous implants. To report the audiological and surgical outcomes.

**Materials and Methods:** Clinical photographs and drawings to demonstrate how we do it and why. This includes where to place the implants in children with small and asymmetric temporal bones, how to ensure the implants are symmetrical, where to place the incisions and periosteal flaps in primary and revision cases to ensure excellent cosmesis, wound healing and no disruption of blood supply for future autologous auricular reconstruction.

**Results:** Audiological and clinical photographs of surgical outcomes are presented.



Conclusions: Our adaptation of the standard operative technique advocated for Osia implantation presented here is a simple, safe, effective solution to managing hearing problems in children with bilateral microtia.