First results with the active osseointegrated implant system Osia in patients with single-sided deafness

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Objective(s): The Osia® System (Cochlear™) is an active osseointegrated system intended for the treatment of patients with conductive and mixed hearing loss. It can be also used in cases of single-sided deafness (SSD) for contralateral routing of signal (CROS) for bone conduction thresholds ≤ 25 dB HL on the contralateral side. The Osia® implant is placed subcutaneously under the intact skin behind the ear with the piezoelectric actuator attached to an osseointegrated BI300 implant on the mastoid. The external processor is magnetically attached to the head. As the Osia® was recently CE certified, and new on the market, with limited patient outcome data for SSD available, the objective of this study was the evaluation of audiological results and patient satisfaction for the Osia system in SSD patients.

Methods: Six patients (age 53.2 ± 5.2) with long-term SSD since birth or early childhood (five cases) or short-term SSD with insufficient treatment with a cochlear implant (one case) were implanted with an Osia in clinical routine to benefit from CROS hearing. A retrospective, monocentric clinical observation study was performed. Audiological measurements included hearing thresholds, sound field audiograms (S_0) with the contralateral ear muffled and plugged and word recognition score (in %) in quiet using the Freiburg monosyllable test. Speech intelligibility was determined with the Oldenburg sentence test (OLSA) in quiet (S_{90Osia}; in %) and in noise ($S_0N_{90contra}$ and $S_{90Osia}N_{90contra}$; in dB SNR) with an adaptive speech level. All tests were performed unaided and aided with the Osia System. Subjective benefit with the Osia system for SSD patients was determined by using two questionnaires; the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Bern Benefit in Single Sided Deafness (BBSSD).

Results: Two months after activation, audiological results with the Osia system showed an improvement in speech perception in quiet and in as noisy environments. Patient confirmed a significant benefit with the Osia system compared to the unaided situation by reporting of less problems and easier conversations in everyday listening situations.

Conclusion: The Osia system is a good alternative for Patients with SSD who cannot benefit from cochlear implants.

Effect of ambient pressure changes on coupling efficiency of a middle ear implant actuator

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Introduction: One of the options to treat moderate to severe sensorineural (SNHL) and mixed hearing loss (MHL) is the implantation of an active middle ear implant like the Cochlear™ Carina® System. The actuator of the implant is fixed firmly to the skull and stimulates the ossicular chain through vibration. Clinicians and recipients need assurance that the coupling will be stable over time, even under slow movements of the ossicular chain caused by changes in barometric pressure. Therefore we designed a study to test whether pressure fluctuations to the middle ear expected from events of daily life could potentially move the ossicular chain enough to change coupling efficiency of the actuator.

Methods: Experiments were performed on 10 ASTM compliant human temporal bones. Two daily-life pressure events were simulated; Valsalva's manoeuvres (500 cycles of -40 hPa - +60 hPa) and jumping into a swimming pool and diving 3 meters deep (a step change of 300 hPa). Actuator coupling efficiency was measured before and after the pressure events through Laser Doppler vibrometric measurement of stapes motion for a frequency range between 100 Hz and 10 kHz. The actuator coupling efficiency was expressed as equivalent sound pressure levels at 1 V_{rms} actuator input. Three different coupling configurations were tested; coupling to the incus body, coupling to a small hole to the incus body made by a surgical laser (standard procedure at Hannover Medical School) and coupling to the long process of the incus via an áWengen clip.

Results: After the 500 pressure cycles as well as the larger pressure event of 300 hPa, no reduction in coupling efficiency of > 6 dB was observed in any of the TB in the frequency range 100-1000 Hz. Larger changes of 13-24 dB were seen in 2 temporal bones at frequencies >1000 Hz, which may be due to the well-known rocking vs piston motion at higher frequencies.

Conclusion: All 3 coupling configurations connected the actuator securely to the ossicular chain, under variations of barometric pressure that can be expected in daily life.

Improvement of speech perception of Carina implanted patients by an external speech processor

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Introduction: The totally-implantable Carina system is intended for sensorineural hearing losses and, with coupling elements, for combined hearing losses. The Carina is the most powerful acoustic implant in terms of output available on the market. In this observational study we investigated the additional benefit of the external Button Audio Processor 2.2 (BAP2.2).

Methods: Eleven patients implanted with a Carina were acutely supplied with an external audio processor BAP2.2 and tested. In all patients direct threshold were determined with the Carina software. In sound field, aided pure-tone thresholds, a speech recognition in quiet (Freiburg monosyllables test) and in noise (Oldenburg sentence test) were determined with and without the Button Audio Processor BAP2.2. The APHAB was used to compare the benefit of the Carina with and without the BAP2.2.

Results: First results showed a mean word recognition score at 65 dB SPL of 21% with the Carina only and 59% with the external BAP. That is a benefit of 38 % at 80 dB SPL, scores improved from 55% with the Carina only to 85 % with the external BAP2.2. That is an additional benefit with the BAP of 38 and 30%points, respectively. Speech in noise, results from eight subjects was 2.96 dB SNR with the Carina only and -0, 23 dB SNR with the BAP2.2. That is an additional benefit of 3.19 dB SNR with the BAP.

Conclusions: The benefit with the fully-implantable Carina can be further improved by using an additional external BAP. The additional BAP is a non-surgical solution for Carina implanted patients with progressing hearing loss and insufficient speech understanding.

Single-Scala Intracochlear Pressure Recordings for Determining Performance of Middle Ear Actuators

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Active middle ear implants (AMEI) are used for the treatment of sensorineural or mixed hearing loss. The performance of middle ear actuators can be calculated by comparing stapes velocities or intracochlear pressure differences (P_{Diff}) recorded in response to acoustic stimulation versus actuator stimulation. However, there are scenarios where measuring the stapes velocity and/or P_{Diff} may not be feasible, for example when access to the stapes or one of the scalae is obscured or impractical. Another motivation for single-scala measurements lies in reducing resources and simplifying measurement protocols that have previously relied on pressure measurements in both scalae. This study investigates whether pressure measurements in one cochlear scala, either in scala tympani or in scala vestibuli, are sufficient as reference to determine the output of an AMEI or to estimate the sound pressure level elicited by other vibratory sources in forward stimulation. To this end, we re-analyzed data from a previous study that investigated the performance of a commercial middle ear actuator coupled to the incus in ten fresh temporal bones (Grossöhmichen et al. 2017). We calculated the "equivalent sound pressure level" (eqSPL) at 1 V_{rms} actuator voltage, which is defined as the sound pressure level necessary to elicit the same stapes or intracochlear magnitude response as ossicular stimulation with the actuator driven at 1 V_{rms}. The actuator performance was calculated based on stapes velocities and intracochlear pressure measurements in scala vestibuli, scala tympani, and P_{Diff}. Our results show that the actuator produced equivalent sound pressure levels of ~100-120 dB at 1 V_{rms}, in line with our earlier findings. No significant differences were found between results when intracochlear pressure differences (P_{Diff}) or measurements in scala vestibuli or scala tympani alone were used as reference. The actuator performance calculated from stapes displacement predicted slightly higher equivalent sounds pressure levels at frequencies above 1000 Hz, but these results were not statistically significant. Our findings show that pressure measurements in one scala can be sufficient to evaluate the performance of an AMEI coupled to the incus. The method may be extended to other stimulation modalities of the middle ear or cochlea when access to the stapes or one of the scalae is impractical, or when artifacts in pressure measurements in one scala are expected.