A NEW BONE CONDUCTION IMPLANT (BCI) SYSTEM USED IN A FIRST CLINICAL STUDY

Hamidreza Taghavi1, Bo Håkansson1, Sabine Reinfeldt1, Karl-Johan Fredén Jansson1, Mårten Eeg-Olofsson2

1 Department of Signals and Systems, Chalmers University of Technology, Gothenburg, Sweden. 2 ENT Department, Sahlgrenska University Hospital, Department of Otorhinolaryngology, University of Gothenburg, Gothenburg, Sweden

1. Introduction
Patients with conductive and mixed hearing loss can be rehabilitated by percutaneous bone-anchored hearing aids (BAHA). Even though the BAHA has been successful and more than 100,000 patients have been implanted, the skin-penetrating implant site needs life-long daily care and some skin complications may occur. A new Bone Conduction Implant (BCI) system has been designed and developed as an alternative to the percutaneous BAHA and recently implanted for long-term use in four patients. In a BCI the skin and subcutaneous tissue is kept intact and the sound is transmitted via an inductive link [1,2].

2. Method
The study was done on four patients in the clinical study phase. Two patients had bilateral conductive loss and two had unilateral conductive loss. The BCI consists of an externally worn sound processor and an implanted unit called the Bridging Bone Conductor (BBC), which is permanently implanted in the mastoid portion of the temporal bone. The BBC contains a transducer, a tuned demodulator and uses an inductive link for communication with the external sound processor similar to cochlear implants, see Figure 1. The BCI sound processor has been implemented in a very efficient ultra-low power Application Specific Integrated Circuit (ASIC) that optimizes the power and sound transmission through the inductive link. The inductive link gain has been designed to be fairly robust for skin flap thickness variations of 2-8 mm. The output force level and total harmonic distortion of the BCI devices were measured on Skull simulator in an acoustic measurement set-up. To measure the efficiency of the BCI, the battery current consumption of the BCI was also measured based on American National Standards Institute standards. In addition, a nasal sound pressure (NSP) measurement was used as an intraoperative method to verify that the implant operates properly before closing the incision.

3. Results
It was found that the BCI can generate high enough output force for the candidate patients with unilateral and bilateral conductive hearing loss. The output force level of the BCI measured on Skull simulator is fairly robust for skin flap thickness range of 2-8 mm. It was found that the battery current consumption of the BCI is in a range that can be used with a single hearing aid battery for 5-7 days based on patients’ use. Moreover, it was shown that the NSP measurement on the patients was a proper method for verification of the implant functionality during surgery and in follow-up sessions.

4. Conclusion
The Bone Conduction Implant has been developed and implanted in four patients and the performance and verification methods show that the implant performs as expected after surgery. The NSP will be used as the verification method during coming BCI surgeries.

References

Figure 1: The BCI system with an implanted and capsuled transducer with a flat surface contact to the temporal bone. The vibrations are received to the cochlea by means of bone conduction. (BEST: Balanced Electromagnetic Separation Transducer)