
   **Abstract:**

   **Objectives:** To assess the functional performance of the Bonebridge (BB, MED-EL), a newly-designed transcutaneous bone conduction implant that allows the skin to remain intact and to compare it with the current clinical model of choice, a percutaneous bone conduction implant (BAHA BP100, Cochlear Bone Anchored Solutions AG). **MATERIALS AND METHODS:** The devices were compared using two methods: (1) Measurements of cochlear promontory acceleration in five cadaver heads: Accelerations of the cochlear promontories on both ipsilateral and contralateral sides were measured using a Laser Doppler system, with free-field sound stimuli of 90 dB SPL in the frequency range of 0.3-10 kHz (2) Measurements of pure-tone sound field thresholds in 5 normally hearing human adult subjects under a condition of simulated hearing loss. For the latter measurements, the devices were applied to the head using a Softband, and measurements were performed in the frequency range of 0.25-8 kHz. Within investigation comparisons (i.e., in cadavers or listeners) and a cross-comparison analysis of the cadaver and human results were done. **RESULTS:** Results from the cadaver heads showed that the cochlear promontory acceleration with the BB was higher within 10 dB on the ipsilateral side and lower within 5 dB on the contralateral side than the acceleration with the BAHA, in the frequency range of 0.7-10 kHz. The transcranial attenuation of the acceleration for the BB was greater than for the BAHA within 20 dB. For the sound-field threshold assessments with human subjects, the BB and BAHA showed similar threshold improvements of more than 10 dB HL for the ipsilateral side. For the contralateral side, the threshold improvement with the BB was less than with the BAHA, indicating better separation between ipsilateral and contralateral sides. **CONCLUSIONS:** Preclinical results imply that the BB has functional performance similar to the BAHA and could be beneficial to patients suffering with conductive and mixed hearing losses as well as for those with unilateral impairment. Based on these preliminary results, a carefully designed clinical trial with conservative inclusion criteria can be recommended. This article is part of a Special Issue entitled “MEMRO 2012”.


   **Abstract:**

   The Bonebridge is an active bone conduction implant (BCI) that is primarily indicated in patients with conductive and combined hearing loss. However, many of these patients present with a radical cavity as a result of previous surgery. In these cases, the implant
should not be introduced into the mastoid region, but rather via a retrosigmoid approach to maintain separation from the pathological alteration. To ensure the best possible acoustic transduction, the Bone Conduction-Floating Mass Transducer (BC-FMT) should be positioned near to the cochlea. This requires precise identification of the sigmoid sinus, which cannot be achieved accurately enough using external anatomical landmarks. We thus report on two patients in whom the Bonebridge was implanted via a retrosigmoid approach using CT-guided navigation.


Abstract:

Objective: To investigate safety and efficacy of a new transcutaneous bone conduction hearing implant, over a 3-month follow-up period. STUDY DESIGN: Prospective, single-subject repeated-measures design in which each subject serves as his/her own control. SETTING: Departments of Otolaryngology at 4 hospitals in Germany and Austria. PATIENTS: Subjects were 12 German-speaking adults who suffered from conductive or mixed hearing loss. The upper bone conduction threshold limit was set to 45 dB HL at frequencies between 500 Hz and 4 kHz. INTERVENTION: Implantation of a transcutaneous bone conduction hearing implant. MAIN OUTCOME MEASURES: Subjects’ speech perception (word recognition scores and SRT50%) and audiometric thresholds (air conduction, bone conduction and sound field at frequencies 500 Hz to 8 kHz) were assessed preoperatively, 1 month postoperatively and 3 months postoperatively. The subjects were monitored for adverse events and given a questionnaire to assess their satisfaction levels. RESULTS: Speech perception as measured by word recognition scores and SRT50% improved on average about 78.8% and 25 dB HL, respectively, 3 months after implantation. Aided thresholds also improved postoperatively at all tested frequencies and continued to improve from 1 to 3 months postoperatively. Air conduction and bone conduction thresholds showed no significant changes, confirming that subjects’ residual unaided hearing was not deteriorated by the treatment. Only minor adverse events were reported and resolved by the end of the study. CONCLUSION: The new transcutaneous bone conduction implant was demonstrated to be safe and effective in adults up to 3 months of device use.

Abstract:

Percutaneous bone conduction implants are widely used in patients with conductive and mixed hearing loss with no benefit from conventional air conduction hearing aids. These devices have several complications including skin reaction, wound infection, growth of skin over the abutment, and implant extrusion. We describe a case of a transcutaneous bone conduction implantation (Bonebridge, Med-el) in a patient with conductive hearing loss due to chronic otitis media. Surgical planification was performed with the software 3D slicer 4.1. According to this program, the implant transductor was positioned in the retrosigmoid area. Aided thresholds demonstrate a significant benefit, with an improvement from 68dB to 25dB. Speech discrimination scores improved 35dB. The patient is very happy and uses her device daily. The Bonebridge implant is a promising transcutaneous bone conduction implant for patients with conductive hearing loss. Retrosigmoid implantation may be useful in cases with mastoid pathology or previous surgery.


Abstract:

Conclusions: The Bonebridge® (BB) transcutaneous bone conductive implant (BCI) may overcome some of the issues related to a percutaneous BCI, such as management of the external screw, delayed activation or possible skin complications. Moreover, it has been shown to enable a functional outcome similar to percutaneous BCI in both conductive and mixed types of hearing loss. Objectives: To obtain clinical data from a preliminary series of patients implanted with a new transcutaneous BCI. Methods: Four subjects affected by conductive/mixed hearing loss underwent implantation of the BB by two approaches: the transmastoid, presigmoid approach and the retrosigmoid approach. Soundfield thresholds were assessed with warble tones in a soundproof audiometric booth, and word recognition scores (WRss) as speech reception thresholds (SRTs) were used to compare the unaided versus the post-implantation condition. Results: The surgical procedure was completed in all cases, with only minor intraoperative divergence from the CT-based planning and no postoperative complications. The average improvement of the SRT in quiet with the BB in comparison to the unaided condition was 36.25 dB. All the implanted subjects reached SRT values below 65 dB, indicating a better understanding in quiet, with 100% word recognition.