BONEBRIDGE Bibliography

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**Abstract:**
For over three decades, bone conduction hearing aids have been changing the lives of patients with impaired hearing. The size, appearance and fitting discomfort of early generations of bone conduction hearing aids made them unpopular. The advent of bone-anchored hearing aids in the 1970s offered patients improved sound quality and fitting comfort, due to the application of osseointegration. However, the issue of post-operative peri-abutment pin tract wound infection persisted. The Bonebridge system incorporates the first active bone conduction device, and aims to resolve peri-abutment issues. Implantation of this system in an Asian patient is presented.


**Abstract:**
**BACKGROUND:** Every year in Germany approximately 3,500 patients receive a cochlear implant or other hearing implants with an implantable magnet. At the same time more and more patients are examined by magnetic resonance imaging (MRI). For the indications and execution of this imaging modality a number of restrictions and safety measures have to be considered. **METHODS:** This article is based on the restrictions of the manufacturers and a selective literature search in PubMed using the following keywords: MRI compatibility/MRI safety + cochlea implant/auditory brainstem implant/Bonebridge/Carina/Esteem/Otomag/Sophono alpha/Vibrand Soundbridge. We included all 20 publications of this search concerning the MRI compatibility of the hearing implants complemented by papers cited in the primary articles. **RESULTS:** High electromagnetic field intensities as used in MRI can cause malfunction and dislocation of the implant or the magnet in the device. Older cochlear implants (CI) and the current CIs produced by Advanced bionics without explantation of the magnet, some CI models produced by the company Cochlear and the middle ear implants Carina(R)/Esteem(R) (older models) and Vibrant-Soundbridge(R) are not approved for MRI examinations. Other hearing prostheses are approved for 0.2 T, 1.0 T or 1.5 T MRI and in exceptional circumstances 3 T MRI. Recommendations of the manufacturers have to be followed, notably wearing a head bandage during the imaging procedure. The longitudinal axis of the patient's head has to be positioned parallel to the main magnetic field of the scanner. The patient may not move the head laterally during the examination. Possible artefacts and the reduced validity of the results of skull MRI have to be considered when evaluating the indications for the examination. **CONCLUSION:** For patients wearing hearing implants with an implantable magnet the indications for MRI in devices with MRI certification should be rigorously restricted. Possible defects/dislocation of the implants may occur and the quality of the skull MRI images is reduced. A close contact between
the radiologist and the implanting team is required. Other diagnostic procedure options should be exhausted before employing MRI.


**Abstract:**

**BACKGROUND:** With the Bonebridge, a new bone-anchored hearing aid has been available since March 2012. The objective of the study was to analyse the visualisation of the implant itself as well as its impact on the representation of the bony structures of the petrosal bone in CT, MRI and cone beam CT (CBCT). **METHODS:** The Bonebridge was implanted unilaterally in two completely prepared human heads. The radiological imaging by means of CBCT, 64-slice CT, 1.5-T and 3.0-T MRI was conducted both preoperatively and postoperatively. The images were subsequently evaluated from both the ENT medical and radiological perspectives. **RESULTS:** As anticipated, no visualisation of the implant or of the petrosal bones could be realised on MRI because of the interactive technology and the magnet artefact. In contrast, an excellent evaluability of the implant itself as well as of the surrounding neurovascular structures (sinus sigmoideus, skull base, middle ear, inner ear, inner auditory canal) was exhibited in both the CT and in the CBCT. **CONCLUSION:** The Bonebridge can be excellently imaged with the radiological imaging technologies of CT and CBCT. In the process, CBCT shows discrete advantages in comparison with CT. No relevant restrictions in image quality in the evaluation of the bony structures of the petrosal bones could be seen.


**Abstract:**

Hearing rehabilitation after bilateral radical mastoidectomy has different options. The Bonebridge is a new type of middle ear implant bone conduction. It leaves the external ear canal opened and offers acoustic and aesthetic advantages that make it a new alternative of choice. We report our first case of Bonebridge implanted on a 17 years old patient. He had bilateral conductive hearing loss secondary to a bilateral radical mastoidectomy with open technique and meatooplasty for a bilateral cholesteatoma. The surgical technique is described. After 8 months of use the hearing gain is stable without cutaneous adverse effect.

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.


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:
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.

M. Canis; F. Ihler; J. Blum, and C. Matthias. [CT-assisted navigation for retrosigmoidal implantation of the Bonebridge.]. HNO, Mar 2013.

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:
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”.