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Abstract:

The intraoperative and postoperative objective functional assessment of transcutaneous bone conduction implants is still a challenge. Here we compared intraoperative Laser-Doppler-vibrometry (LDV, Polytec Inc.) to measure vibration of the bone close to the implant to Outer Ear Canal Sound Pressure Level (OEC-SPL) measurements. Twelve single sided deafness (SSD) patients with contralateral intact ossicular chains and eight bilateral conductive hearing loss (CHL) patients were included in the study. SSD patients had a minor average air-bone-gap (ABG) of 0.4 ± 0.4 dB (0.5, 1, 2, 4 kHz mean value (MV) ± standard deviation (SD)) on the contralateral side where a normal transmission between cochlea and the tympanic membrane can be assumed. CHL patients had an impaired middle ear transmission with a mean ABG of 46.0 ± 7.9 dB (MV±SD). Vibration and OEC-SPL responses could reliably be recorded with a minimal signal-to-noise ratio of at least 12 dB. Average OEC-SPL on the contralateral side and intraoperative vibration measurements were strongly correlated in SSD ($r(2) = 0.75$) and CHL ($r(2) = 0.86$) patients. The correlation in individual results between OEC-SPL and vibration measurements was weak, indicating some underlying inter-individual variability. The high correlation of average responses showed that OEC-SPL are closely linked to bone vibration, although both cannot be equivalently used for intraoperative testing due to the high variability in individual results. On the other hand, OEC-SPL provides an easy and affordable measurement tool to monitor stability and functionality postoperatively using individual reference measurements. We observed no significant differences (t-test, $p < 0.05$) by comparing results from contralateral OEC-SPL in twelve SSD and eight CHL patients at frequencies between 0.5 and 8 kHz. This implies that the part of the measured sound pressure in the ear canal originating from the cochlea and emitted by the tympanic is not dominant and OEC-SPL is mainly due to vibration of the external ear-canal walls as the only other pathway of BC sound to reach the ear canal. In addition, the transcranial attenuation (contralateral outer ear canal sound pressure divided by ipsilateral) was compared to previous studies measuring vibration by LDV and accelerometer. The trend in the average transcranial attenuation in patients was similar to previous studies measuring the OEC-SPL with less than 5 dB difference.
Abstract:

BACKGROUND: Hearing aids and implants employing bone conduction stimulation have a long tradition in the treatment of conductive or mixed hearing loss, with their indications being extended in the 2000s to include single sided deafness. Existing percutaneous bone conduction implants (BCI) provide significant audiological gain but are associated with a high rate of complications. This has led to the development of passive transcutaneous BCIs, however audiological benefit may be compromised. An active transcutaneous BCI, the Bonebridge, was recently introduced and first implanted in 2011 as part of a clinical trial.

OBJECTIVE OF REVIEW: To introduce and assess the safety and effectiveness of the Bonebridge for individuals with conductive or mixed hearing loss, and single sided deafness.

TYPE OF REVIEW: Systematic review.

SEARCH STRATEGY: the Cochrane Library, PubMed and OVIDSP (MEDLINE) and EMBASE were searched to identify papers on the Bonebridge published as of June 2014. No exclusion criteria were set on publication language, study design or reported outcomes. The literature found was supplemented by presentations from relevant conferences.

EVALUATION METHOD: Study selection, data extraction and study quality assessment was carried out by a single reviewer with any uncertainties resolved with consulting a second reviewer. Studies were synthesized narratively and results were tabulated.

RESULTS: A total of 29 studies, 17 published and 12 presentations, were identified. The highest quality evidence was from three single arm trials. In those assessing the safety of implantation, 6 out of 117 patients experienced a minor adverse event with superficial revision surgery being required in one case. Studies demonstrated improved hearing thresholds and speech recognition with the Bonebridge when compared to no aiding in adults and children with either type of hearing loss. This was reflected in high device satisfaction rates. Data collected in the second year of device use further suggest the benefit to remain constant.

CONCLUSION: The transcutaneous bone conduction implant system Bonebridge provides a valuable and stable audiological benefit to patients suffering from conductive or mixed hearing loss and single sided deafness. With its active transcutaneous design the Bonebridge offers a lower complication rate to percutaneous systems and higher and more reliable hearing gain compared to other transcutaneous or percutaneous systems. Moreover the fast activation of the implant system enables the recipient of the system to benefit in a short time frame postoperatively from the intervention. This article is protected by copyright. All rights reserved.
BACKGROUND: Various different hearing systems are available for device-supported hearing rehabilitation of patients with mixed hearing loss. Using the recently introduced objective comparison criterion "maximum output" (i.e., the maximum output level of a hearing device), the indications for different hearing devices can be compared.

OBJECTIVE: This article reviews important terms such as gain, dynamic range, and maximum output level—all of which are relevant for the selection of a hearing device. The experimental part of this study compares all currently available hearing devices and determines the range of their indication with respect to the maximum bone-conduction hearing threshold.

MATERIALS AND METHODS: The maximum frequency-specific output levels reported in the literature for the Baha Cordelle 2, the Sophono Alpha 2, and the Bonebridge (measured at the skull simulator), as well as those of the Codacs and the Soundbridge (in-vivo measurements) are compared to the maximum output levels given in the datasheets of the BP110 Power, the Baha Cordelle 2, the Bonebridge, the Codacs, the Ponto Pro Power, and the Sophono Alpha 2. Using appropriate correction factors, the maximum dynamic range and thus the maximum indication based on the bone-conduction hearing threshold was determined.

RESULTS: In patients with mild sensorineural hearing loss, passive transcutaneous hearing or Bonebridge implants can achieve good audiological results. In the transition region to moderate hearing loss, percutaneous devices are applicable. Combined hearing loss with more pronounced sensorineural hearing loss is best treated with a Soundbridge or Codacs implant. In the latter case, the cochlear potential for speech recognition has to be explored and, where appropriate, cochlear implants considered as an alternative.
were retrospectively analyzed. After three-dimensional reconstruction, mastoid volume was measured. The chances of fitting the Bonebridge or a novel BCI were determined as a function of age. Implant diameter and implantation depths were virtually varied to identify the most advantageous dimensions for reducing the minimum age for implantation.

RESULTS: Mastoid volume increased to 13.8 ml in female and 16.4 ml in male adult mastoids at ages 18.9 years (male) and 19.0 years (female). Without compromising the middle fossa dura or the sinus and without lifts, the Bonebridge implant fit in 81% of male adult mastoids and 77% of the female adult mastoids. For children, the 50% chance of fitting a Bonebridge in the mastoids was reached at age 12 years; with a protrusion of 4 mm (4-mm lifts), this age was reduced to >6 years. The novel BCI fit in 100% of male and 94% of female adult mastoids.

CONCLUSIONS: Casing diameter is the most limiting factor for Bonebridge implantation in children. A modified implant casing with a truncated cone and reduced diameter and volume would increase the number of hearing impaired children who can be rehabilitated with a Bonebridge implant. Radiological planning for Bonebridge implantation is necessary in all children.


Abstract:
The occurrence of oval window atresia is a rare anomaly with conductive hearing loss. Traditional atresia surgeries involve challenging surgical techniques with risks of irreversible inner ear damage. Recent reports on Bonebridge (Medel, Innsbruck, Austria), a novel implantable bone conduction hearing aid system, assert that the device is safe and effective for conductive hearing loss. We present a case of Bonebridge implantation in an eight-year-old girl with bilateral oval window atresia.


Abstract:
PURPOSE: Accommodating a novel semi-implantable bone conduction hearing device within the temporal bone presents challenges for surgical planning. This study describes the utility of CT in pre-operative assessment of such an implant.

METHODS: Retrospective review of pre-operative CT, clinical and surgical records of 16 adults considered for device implantation. Radiological suitability was assessed on CT using 3D simulation software. Antero-posterior (AP) dimensions of the mastoid bone and minimum skull thickness were measured. CT planning results were correlated with
operative records.

RESULTS: Eight and five candidates were suitable for device placement in the transmastoid and retrosigmoid positions, respectively, and three were radiologically unsuitable. The mean AP diameter of the mastoid cavity was 14.6 mm for the transmastoid group and 4.6 mm for the retrosigmoid group (p < 0.05). Contracted mastoid and/or prior surgery were predisposing factors for unsuitability. Four transmastoid and five retrosigmoid positions required sigmoid sinus/dural depression and/or use of lifts due to insufficient bone capacity.

CONCLUSION: A high proportion of patients being considered have contracted or operated mastoids, which reduces the feasibility of the transmastoid approach. This finding combined with the complex temporal bone geometry illustrates the importance of careful CT evaluation using 3D software for precise device simulation.


Abstract:

INTRODUCTION: Electro-acoustic stimulation (EAS) of the cochlea uses the preserved residual low-frequency hearing for acoustic stimulation in combination with electrical stimulation. The acoustic low-frequency component is amplified and high-frequency hearing is enhanced by a cochlear implant (CI). In this work, the feasibility of EAS by the floating mass transducers (FMTs) firmly attached to the implanted electrode was investigated and the achieved stapes displacement was compared with sound stimulation.

METHODS: Experiments were performed in eight fresh human temporal bones compliant to the ASTM standard (F2504-5). Four EAS custom-made prototypes (EAS-CMP) were tested, consisting of standard MED-EL CI electrodes with Vibrant Soundbridge (VSB) FMTs or a Bonebridge (BB) FMT tightly molded to the electrode in different orientations. The stapes footplate (SFP) response to EAS-CMP stimulation and sound stimulation was measured using a Laser Doppler Vibrometer (LDV).

RESULTS: The SFP displacement amplitudes achieved by EAS-CMP stimulation were calculated to 1 VRMS FMT input and were pair-wise statistically compared between prototypes yielding no significant differences at frequencies ≤1kHz. At frequencies ≤1kHz stimulation by the BB FMT resulted in a flat and potentially highest SFP displacement amplitude of approximately -40dB re μm at 1VRMS input voltage. Estimated equivalent sound pressure levels achieved by the BB FMT prototype were approximately 83-90 eq. dB SPL at frequencies ≤1kHz.

CONCLUSION: The feasibility of cochlear stimulation by vibrating electrodes was shown although the achieved output level at frequencies ≤1kHz was too low for EAS applications.
INTRODUCTION: Bone conduction implants are indicated for patients with conductive and
mixed hearing loss, as well as for patients with single-sided deafness (SSD). The
transcutaneous technology avoids several complications of the percutaneous bone
conduction implants including skin reaction, skin growth over the abutment, and wound
infection. The Bonebridge (MED-EL, Austria) prosthesis is a semi-implantable hearing
system: the BCI (Bone Conduction Implant) is the implantable part that contains the Bone
Conduction-Floating Mass Transducer (BC-FMT), which applies the vibrations directly to the
bone; the external component is the audio processor Amadé BB (MED-EL, Austria), which
digitally processes the sound and sends the information through the coil to the internal
part. Bonebridge may be implanted through three different approaches: the transmastoid,
the retrosigmoid, or the middle fossa approach.

OBJECTIVE: This systematic review aims to describe the world’s first active bone conduction
implant system, Bonebridge, as well as describe the surgical techniques in the three
possible approaches, showing results from implant centers in the world in terms of
functional gain, speech reception thresholds and word recognition scores.

DATA SYNTHESIS: The authors searched the MEDLINE database using the key term
Bonebridge. They selected only five publications to include in this systematic review. The
review analyzes 20 patients that received Bonebridge implants with different approaches
and pathologies.

CONCLUSION: Bonebridge is a solution for patients with conductive/mixed hearing loss
and SSD with different surgical approaches, depending on their anatomy. The system
imparts fewer complications than percutaneous bone conduction implants and shows
proven benefits in speech discrimination and functional gain.

OBJECTIVE: To establish whether preoperative assessment using a conventional,
percutaneous bone conducting implant (pBCI) processor on a headband accurately

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Abstract:
represents postoperative performance of a semi-implantable BCI (siBCI).

STUDY DESIGN: Retrospective case series.

SETTING: Tertiary otology unit.

PATIENTS: Five patients with chronic otitis media (implanted unilaterally) and one with bilateral congenital ossicular fixation (implanted bilaterally).

INTERVENTION(S): Semi-implantable bone conduction hearing implant.

MAIN OUTCOME MEASURE(S): Functional hearing gain; preoperative (headband) versus postoperative (aided) speech discrimination; unaided bone conduction (BC) versus postoperative (aided) soundfield threshold.

RESULTS: Significant functional gain was seen at all frequencies (one-tailed t test p G 0.01; n = 7). There was a 50 dB improvement in median speech reception threshold (SRT) from 70 dB unaided to 20 dB aided. Compared to the preoperative BC, aided siBCI thresholds were worse at 0.5 kHz, but at frequencies from 1 to 6 kHz, the siBCI closely matched the bone curve ( p G 0.01). The siBCI performed better than both pBCI processors on a headband at 3 to 4 kHz, except 1 kHz ( p G 0.01).

CONCLUSIONS: BC thresholds may be a better indicator of implant performance than headband assessment. Candidacy assessment for siBCI implantation that relies on headband testing with pBCI processors should be interpreted with caution because the headband may under-represent the implanted device. This seems to be especially true at 3 kHz and above and may make it difficult for surgeons to conduct accurate informed consent discussions with patients about the realistic anticipated outcomes and benefits of the procedure.


Abstract:

STUDY DESIGN: Prospective cohort study.

SETTING: Tertiary referral center.

PATIENTS: Nine adults with SSD for more than 1 year and normal hearing on the contralateral side (PTA <30 dB HL) were implanted with a tBCD.

INTERVENTIONS: Transmastoidal implantation of a Bonebridge (BB, MED-EL) tBCD.

MAIN OUTCOME MEASURES: Aided and unaided speech discrimination scores in three different spatial settings were measured using the Oldenburg sentence test (OLSA).
Quality of life was assessed by two questionnaires, the Bern Benefit in Single Sided Deafness Questionnaire (BBSS) and the Speech, Spatial and Qualities of Hearing scale for benefit questionnaire (SSQ-B).

RESULTS: Speech discrimination scores measured by OLSA showed a mean signal-to-noise ratio improvement of 1.7 dB SPL for the aided condition compared with the unaided condition in the setting where the sound signal is presented on the side of the implanted ear and the noise is coming from the front (p < 0.05). In the other two settings (signal and noise from front; signal from normal hearing ear and noise from front), the signal-to-noise ratio did not change significantly. This benefit became manifest after 6 months. Good satisfaction was indicated by positive results on the questionnaires.

CONCLUSION: Speech discrimination in noise for patients implanted with the BB is comparable with patients with other bone conduction hearing aids. A learning curve is clearly detectable. The subjective benefit was rated positively by the patients. With the advantage of intact skin conditions after implantation, the BB is an adequate option for patients with SSD.


Abstract:

The Bonebridge (®) (BB, Med-El) is a newly designed transcutaneous active bone conductive implant with functional outcome similar to percutaneous bone-anchored hearing systems (BAHS). It is currently approved only for patients ≥ 18 years. Since the BB allows the skin to remain intact and therefore should be able to overcome some of the issues related to percutaneous BAHS including skin reactions, wound infection and implant extrusion, it would be especially attractive for use in children. We present a preliminary series of the first three cases of BB implantation in children/adolescents (10-16 years). Two subjects were affected by conductive hearing loss (CHL) and one subject by single-sided deafness (SSD). The surgical procedure with transmastoid approach was completed in all cases without complications. Both subjects with CHL showed an increase in speech perception thresholds in quiet from preoperative unaided to 6 months postoperatively with BB of 37 dB, respectively, of 12 dB. The adolescent with SSD attained -3.1 dB unaided vs. -5.6 dB with the BB in the "speech and noise from the front" presentation and +0.5 unaided vs. -5.0 dB with the BB in the "speech from the unilateral deaf side/noise from the normal hearing side" presentation using the adaptive Oldenburg Sentence Test. The results show a straightforward surgical procedure and satisfactory functional gain after BB implantation also in children/adolescents. BB implantation in patients ≤ 18 years is currently an "off-label use" so that detailed information about alternative treatment options, operation risks and the lack of approval for use in children is essential.

Abstract:

Bonebridge (BB) implantation relies on optimal anchoring of the bone-conduction implant in the temporal bone. Preoperative position planning has to account for the available bone thickness minimizing unwanted interference with underlying anatomical structures. This study describes the first clinical experience with a planning method based on topographic bone thickness maps (TBTM) for presigmoid BB implantations. The temporal bone was segmented enabling three-dimensional surface generation. Distances between the external and internal surface were color encoded and mapped to a TBTM. Suitable implant positions were planned with reference to the TBTM. Surgery was performed according to the standard procedure \((n = 7)\). Computation of the TBTM and consecutive implant position planning took 70 min on average for a trained technician. Surgical time for implantations under passive TBTM image guidance was 60 min, on average. The sigmoid sinus \((n = 5)\) and dura mater \((n = 1)\) were exposed, as predicted with the TBTM. Feasibility of the TBTM method was shown for standard presigmoid BB implantations. The projection of three-dimensional bone thickness information into a single topographic map provides the surgeon with an intuitive display of the anatomical situation prior to implantation. Nevertheless, TBTM generation time has to be significantly reduced to simplify integration in clinical routine.


Abstract:

The different kinds of bone-conduction devices (BCDs) available for hearing rehabilitation are growing. In this paper, all BCDs currently available or in clinical trials will be described in categories according to their principles. BCDs that vibrate the bone via the skin are referred to as skin-drive devices, and are divided into conventional devices, which are attached with softbands, for example, and passive transcutaneous devices, which have implanted magnets. BCDs that directly stimulate the bone are referred to as direct-drive devices, and are further divided into percutaneous and active transcutaneous devices; the latter have implanted transducers directly stimulating the bone under intact skin. The percutaneous direct-drive device is known as a bone-anchored hearing aid, which is the BCD that has the largest part of the market today. Because of some issues associated with the percutaneous implant, and to some extent because of esthetics, more transcutaneous solutions with intact skin are being developed today, both in the skin-drive and in the direct-drive category. Challenges in developing transcutaneous BCDs are mostly to do with power, attachment, invasiveness, and magnetic resonance imaging compatibility. In the future, the authors assume that the existing percutaneous direct-drive BCD will be retained as an important rehabilitation alternative, while the transcutaneous solutions will increase their part of the market, especially for patients with bone-
conduction thresholds better than 35 dB HL (hearing level). Furthermore, the active transcutaneous direct-drive BCDs appear to be the most promising systems, but to establish more detailed inclusion criteria, and potential benefits and drawbacks, more extensive clinical studies are needed.


Abstract:

OBJECTIVES: Congenital aural atresia and ear deformities have been the subject of serious discussions for centuries. These malformations are associated with significant aesthetic and functional problems. Outcome of the surgical solution is rarely optimal. Despite the gradual improvement of surgical techniques the surgery still remains associated with very limited short-term and mainly long-term functional outcome. Therefore, the priority treatment in modern otology becomes implantable devices-BAHA, Bonebridge and active middle ear implants.

METHODS: The functional and aesthetic outcomes of aural atresia reconstruction performed at Pediatric ENT Department of Children's University Hospital were retrospectively evaluated and compared with the results prospectively obtained from implantable hearing devices (BAHA, Vibrant Soundbridge, Bonebridge), which have been implanted in patients with aural atresia at Department of ORL HNS, University Hospital Bratislava.

RESULTS: Aural atresia reconstruction has been performed in 34 patients during last 25 years. Results of the surgery could be viewed as excellent only in three patients (gain above 30dB). Air conduction threshold has decreased after the surgery in seven patients, and in two cases total deafness occurred after the surgery. Patients gain on average 12dB in auditory threshold after surgery. Hearing devices were implanted to the group of 11 children in order to improve their hearing. All of them were the patients with bilateral aural atresia. After implantation a significant improvement in hearing threshold occurred in all children (30-35dB on average). Together with results of air conduction threshold in patient with aural atresia before and after surgery and implantation we also present a standard deviation.

CONCLUSION: The functional outcome of implantable hearing devices in patients with bilateral aural atresia clearly dominates over the traditional reconstructive surgery. Aesthetic results in pinna deformity management remain a major concern for patients and parents. Implantable epithesis bring promising results. Since there is no universal solution to this disorder, the final selection of the treatment is upon the patient. Patients should opt for the most suitable solution through consultation with the surgeon, after clarifying the advantages and disadvantages of each option.

Abstract:

Bone-anchored hearing devices have evolved over recent years. This article provides an overview of the device history, indications, evolution of surgical technique, evidence for benefit and focuses on the challenges that are faced in the pediatric population.


Abstract:

OBJECTIVE: To describe our experience with positioning the Bonebridge (BB) device, a semi-implantable transcutaneous bone conduction implant for patients with conductive and mixed hearing loss as well as for those suffering from single-sided deafness.

METHODS: The following is a retrospective case review of 4 adults suffering from conductive or mixed hearing loss and single-sided deafness. The BB device was implanted unilaterally via 2 different approaches selected case by case: the presigmoid transmastoid and the retrosigmoid approach. An audiological evaluation in the free field was conducted to observe the functional benefit with this device. The Glasgow Health Status Inventory (GHSI) and the Glasgow Benefit Inventory (GBI) questionnaires were filled out to evaluate patients’ quality of life in relationship to the intervention.

RESULTS: No intra- or postoperative complications were observed. The performance in the speech test in all 4 cases reached 100% in the aided condition at 65 dB, while in the unaided condition at 65 dB, it was less than 10%. The GHSI and GBI questionnaires showed an improvement in quality of life after implantation.

CONCLUSIONS: The BB device is a safe and effective solution for individuals with pathologies such as chronic otitis media, atresia auris and otosclerosis with inadequate benefit from conventional surgery or bone conduction hearing aids.


Abstract:

BACKGROUND: Patients with unilateral atresia and microtia encounter problems in sound localization and speech understanding in noise. Although there are four implantable hearing devices available, there is little discussion and evidence on the application of these devices on patients with unilateral atresia and microtia problems.
OBJECTIVE: This paper will review the details of these four implantable hearing devices for the treatment of unilateral atresia. They are percutaneous osseointegrated bone anchored hearing aid, Vibrant Soundbridge middle ear implant, Bonebridge bone conduction system, and Carina fully implantable hearing device.

METHODS: Four implantable hearing devices were reviewed and compared. The clinical decision process that led to the recommendation of a device was illustrated by using a case study.

CONCLUSIONS: The selection of appropriate implantable hearing devices should be based on various factors, including radiological findings and patient preferences, possible surgical complications, whether the device is Food and Drug Administration (FDA)/CE-approved, and the finances. To ensure the accurate evaluation of candidacy and outcomes, the evaluation methods should be adapted to suite the type of hearing device.


Abstract:
AIM: Information about the temporal bone size and variations of anatomical structures are crucial for a safe positioning of the Vibrant Bonebridge B-FMT. A radiological based preoperative planning of the surgical procedure decreases the surgical time and minimizes the risk of complications.

MATERIALS AND METHODS: We developed a software tool, which allows a catch up of foreign DICOM data based CT temporal bone scans. The individual CT scan is transmitted into a 3D reconstructed pattern of the temporal bone. In this 3D reconstruction the individually favored position of the B-FMT should be found.

RESULTS: The software allows a determination of a safe B-FMT position by identifying the individual relation of middle fossa, jugular bulb and external auditory canal. Skull thickness and screw length are contained parameters for the surgical planning.

CONCLUSION: An easy to handle software tool allows a radiologically data based safe and fast surgical positioning of the B-FMT.


Abstract:
CONCLUSION: The surface template-assisted marker positioning (STAMP) method is useful for successful Bonebridge (BB) implantation on a planned site while avoiding dangerous
OBJECTIVES: To confirm the usefulness of the STAMP method for the safe operation of BB.

METHODS: From a patient’s temporal bone CT data, a guide plate and confirmation plate were generated by the STAMP method. The guide plate is used to mark the correct place for implantation, while the confirmation plate lets us know the correct angle and depth of the hole.

RESULTS: With the guide plate, the correct place for BB implantation was easily found. The hole was made to be an appropriate size with the confirmation plate while exposing only a small part of sigmoid sinus as simulated. Finally, the BB implant was successfully placed exactly at the planned site.

Abstract:

The new transcutaneous bone conduction implant (BCI) Bonebridge (BB, MED-EL) allows the skin to remain intact and therefore overcomes some issues related to percutaneous systems, such as skin reaction around the external screw and cosmetic complaints. According to manufacturer, BB is MRI conditional up to 1.5 Tesla (T). The artefact of the neurocranium after BB implantation is extensive as shown in the present report. This has to be taken into account when patients suffering conductive, mixed or single-sided hearing loss with candidacy for a BCI are counselled. In patients with comorbid intracranial tumour or other diseases of the brain that require imaging control scans with MRI percutaneous, BCI should be the implant of choice considering the very small artefact of the percutaneous screw in MRI.

Abstract:

OBJECTIVE: To investigate the possibility of using a modified reverse transfer function (RTF) measurement intraoperatively during surgery of a new transcutaneous bone conduction hearing implant to evaluate the status of the device.

METHODS: Tests were performed on a cadaver skull (preclinically) and two conductive hearing loss patients implanted with a new transcutaneous bone conduction implant. During intraoperative activation, the RTF was measured using a microphone attached perpendicularly and directly to the skin in the middle section of the forehead.
RESULTS: The RTF could be measured for all frequencies from 500 to 6,000 Hz.

CONCLUSION: The usage of an intraoperative RTF measurement may be a good method to verify the mechanical coupling of the bone conduction floating mass transducer and to test the functional integrity of the implant in an objective way.


Abstract:

OBJECTIVES/HYPOTHESIS: The aim of this study was to evaluate functional hearing gain, speech understanding, and preoperative bone-conduction thresholds with the bone-conduction implant Bonebridge.

STUDY DESIGN: Retrospective study at a tertiary referral center.

METHODS: Twenty-four consecutive Bonebridge patients were identified. Nine patients suffered from combined hearing loss (HL), 12 from atresia of the external auditory canal and three from single-sided deafness. One patient was lost to follow-up. Twenty-three patients were therefore analyzed.

RESULTS: The overall average functional hearing gain of all patients (n = 23) was 28.8 dB (+/-16.1 standard deviation [SD]). Monosyllabic word scores at 65 dB sound pressure level in quiet increased statistically significantly from 4.6 (+/-7.4 SD) percentage points to 53.7 (+/-23.0 SD) percentage points. Evaluation of preoperative bone-conduction thresholds revealed three patients with thresholds higher than 45 dB HL in the high frequencies starting at 2 kHz. These three patients had a very limited benefit of their bone-conduction implants.

CONCLUSIONS: The Bonebridge bone-conduction implant provides satisfactory results concerning functional gain and speech perception if preoperative bone conduction lies within 45 dB HL.

LEVEL OF EVIDENCE: 4.


Abstract:

In patients with conductive hearing loss caused by middle ear disorders or atresia of the ear canal, a Bonebridge implantation can improve hearing by providing vibratory input to the temporal bone. The expected results are improved puretone thresholds and speech recognition. In the European Union, approval of the Bonebridge implantation was recently
extended to children. We evaluated the functional outcome of a Bonebridge implantation for eight adults and three children. We found significant improvement in the puretone thresholds, with improvement in the air-bone gap. Speech recognition after surgery was significantly higher than in the best-aided situation before surgery. The Bonebridge significantly improved speech recognition in noisy environments and sound localization. In situations relevant to daily life, hearing deficits were nearly completely restored with the Bonebridge implantation in both adults and children.


Abstract:

OBJECTIVE: To evaluate the benefit of a preoperative three-dimensional (3D) planning tool for surgically placing the bone conduction floating mass transducer (BC-FMT) of the Bonebridge (BB) bone conduction implant.

PATIENTS: Adult patients (n = 5) and one pediatric patient (n = 1) with conductive or mixed hearing loss caused by chronic ear disease, malformation, or single-sided deafness.

INTERVENTION(S): Development of a preoperative planning tool that allowed free adjustment of the implant in an individual 3D model of the skull to evaluate completely fitting the BC-FMT into a bony bed and to identify an optimal implant position. Implantation of the BB with mastoid or retrosigmoid placement after individual preoperative planning and “virtual surgery”.

MAIN OUTCOME MEASURES: Feasibility of the preoperative 3D planning process, transfer into the intraoperative situation, and audiologic results after BB implantation.

RESULTS: Individual preoperative planning was considered beneficial especially in cases of small mastoid bone volume, for example, because of previous canal wall down mastoidectomies, and in the case with malformation.

CONCLUSION: For optimal placement of the BC-FMT of the BB, preoperative 3D planning is recommended especially in primarily small poorly pneumatized mastoids, hypoplastic mastoids in malformations, reduced bone volume after canal wall down mastoidectomy, or the small mastoids in children. Effort should be made to reduce segmentation and surgical planning time by means of automation.

Abstract:

INTRODUCTION: Recently, a new active bone conduction implant, the Bonebridge, was introduced. This transcutaneous device is proposed as an alternative to previous percutaneous systems. The current study aims to determine the maximum output (MO) of the Bonebridge by making use of Bonebridge-generated sound pressure levels in the occluded ear canal of the unaided ear.

METHODOLOGY: The test setup consisted of audiometry and input-output measurements. These tests were performed on 3 Bonebridge users with conductive or mixed hearing loss (bone-conduction thresholds, \( \leq 45 \) dB HL) at least 3 months after implantation surgery. All the patients were implanted and were evaluated in the Antwerp University Hospital. The MO of the device was determined by measuring input-output functions with a microphone placed in the occluded contralateral ear canal using the Aurical REM system. During testing, the sound processor was fitted in linear amplification mode and with unlimited output to determine the MO and the input dynamic range of the Bonebridge. This experimental setup intends to evaluate the device in a fitting program without compression.

RESULTS: The mean MO of the device was 55 dB HL (SD, 6 dB HL) at 0.5 kHz, 61 dB HL (SD, 18 dB HL), 71 dB HL (SD, 10 dB HL) at 2 kHz, and 60 dB HL (SD, 10 dB HL) at 4 kHz. The mean dynamic range of the Bonebridge was 41 (SD, 5) dB HL, 46 (SD, 10) dB HL, 46 (SD, 5) dB HL, and 37 (SD, 16) dB HL for 0.5, 1, 2, and 4 kHz, respectively.

CONCLUSION: In summary, ear canal measures can effectively be used to assess input-output behavior of the Bonebridge. The present study indicates that the MO of the Bonebridge ranges from 55 to 71 dB HL, depending on frequency. Accepting a minimum dynamic range of 35 dB with the Bonebridge, fitting of the Bonebridge in a linear program is advocated in patients with a sensorineural hearing loss component of up to 30 dB HL.

prepare for the surgery were evaluated. In addition, a postoperative analysis was performed to assess the accuracy of placing the device in the planned location. The BB-STAMP method enabled the surgeon to precisely replicate the computer simulation in the real patient with submillimetric accuracy without complexity. Thus, the use of experienced and elaborative simulation coupled with the creation of a tailor-made three-dimensional template (BB-STAMP) enables surgeons to perform quick, precise and safe surgical procedures at distant institutions.


Abstract:

OBJECTIVE: To describe the surgical technique under local or general anesthesia of 5 cases that have undergone this procedure and the audiologic results obtained with this new device.

PATIENTS: Four patients with mixed hearing loss and 1 patient with single-sided deafness.

INTERVENTION: Therapeutic.

MAIN OUTCOME MEASURES: The surgery was planned beforehand with a 3D reconstruction of a CT scan. The procedure was documented and timed in every case. Air and bone conductive pure tone audiometry and disyllabic words discrimination were tested after and before the procedure. Results were statistically analyzed.

RESULTS: All patients tolerated well the procedure. Four patients were intervened under local anesthesia and 1 under general anesthesia because of an associated procedure. All patients showed statistically significant difference between the presurgery and postsurgery audiologic tests.

CONCLUSION: Implantation of the Bonebridge with local or general anesthesia is a safe and feasible procedure, with audiometric results that can come close with the ones provided by BAHD users.


Abstract:

Congenital aural atresia is the failure of development of the external auditory canal. It usually occurs in conjunction with microtia, which is the malformation of the auricle due to a failure of development of the external ear. Aural atresia, with or without microtia, may significantly affect the hearing and social life of the patients. It is important for every
medical practitioner to be aware of the possible treatment options for hearing rehabilitation in this group of patients. In the era of modern technology, new choices, including Bone-Anchored Hearing Aid (BAHA) (Cochlear Ltd. and Oticon Medical), Vibrant Soundbridge (VSB) (MED-EL, Innsbruck, Austria), and Bonebridge system (BB) (MED-EL, Innsbruck, Austria), provide high-end alternatives to traditional Bone Conduction Hearing Aid and Auditory Canal Reconstruction. All these options have advantages and disadvantages, and they are appropriate for different patients and/or at different ages. This paper aims to provide an overview of the management of hearing rehabilitation in congenital aural atresia patients and a discussion of each treatment option.


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 review functional results and quality of life of the first patients implanted with a newly introduced bone conduction implant system.

STUDY DESIGN: Retrospective chart analysis of 6 patients (6 ears) implanted for conductive hearing loss (CHL) and mixed hearing loss (MHL) in 1 tertiary referral center between July 2012 and February 2013.

METHODS: Implantation of a new bone conduction hearing device. Pure tone audiometry (air conduction and bone conduction thresholds, pure tone average, air-bone gap, and
functional gain), speech audiometry (Freiburg Monosyllabic Test), intraoperative and postoperative complication rate, and patient satisfaction (Glasgow benefit inventory [GBI]) were assessed.

RESULTS: Air-conduction pure tone average (PTA) was 58.8 +/- 8.2 dB HL. Unaided average air-bone gap (ABG) was 33.3 +/- 6.2 dB. Aided air-conduction PTA in sound field was 25.2 +/- 5.1 dB HL. Aided average ABG was -0.3 +/- 7.3 dB. Average functional gain was 33.6 +/- 7.2 dB. Mean improvement of GBI was +36.1. No intraoperative complications occurred. During a follow-up period of 8.5 +/- 2.2 months, no device failure and no need for revision surgery occurred.

CONCLUSION: Audiometric results of the new bone conduction hearing system are satisfying and comparable to the results of devices that have been applied previously for CHL and MHL. Intraoperatively and postoperatively, no complications were noted.


Abstract:

PURPOSE: Most of the current Bonebridge surgeries undergo preoperative simulation planning in a computer. However, surgeons usually use the landmarks on the bone surface to determine the location where to implant the device, using the simulation image in the computer only as a reference (conventional method). We developed an image-guided method for precisely replicating simulation surgery upon performing Bonebridge implantation.

METHODS: Based on our previous development of the surface template-assisted marker positioning (STAMP) method for performing image-guided otologic surgery, we fabricated templates that fit only at the designated location on the patient’s temporal bone surface. The Bonebridge STAMP (BB-STAMP) plate shows the exact location where to start drilling. The BB-STAMP was also combined with a perforator-guiding sleeve, so that the location, direction and depth of the cylindrical well could be precisely replicated as simulated. We also created a STAMP plate for confirmation that fits only after sufficient drilling at the correct location is finished. To evaluate the proposed methods, we performed simulation surgery on four cadaveric temporal bones and their 12 replicas (three each for four bones). The time used and the degree of mismatch between the simulated location and the drilled location were compared.

RESULTS: A feasibility study was successfully conducted using the proposed BB-STAMP methods and the conventional method. The amount of time required for the procedure did not differ significantly between the surgical methods, although using the BB-STAMP and perforator guide was always quicker. The degree of mismatch between the simulation and resected models had tendency to be smaller when the surgery was guided by the BB-STAMP with or without a perforator guide, although the difference was not statistically
CONCLUSIONS: The proposed BB-STAMP is a promising method for replicating exactly what is performed during simulation without using a surgical navigation system.


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:

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 SRT 50%) 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 SRT 50% 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:

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:

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.


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:

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:

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.

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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 meatoplasty for a bilateral cholesteatoma. The surgical technique is described. After 8 months of use the hearing gain is stable without cutaneous adverse effect.