
Abstract:

OBJECTIVES: Bone-conduction implants (BCI) are available for adults and children who are aged 5 years or more. Because a transcutaneous bone-conduction implant introduced in 2013 does not completely fit into all adult mastoids, we investigated mastoid dimensions and the possibility of fitting the implant in children.

DESIGN: Computed tomography scans of 151 mastoids from 80 children and young adolescents from the age of 5 months to 20 years and 52 control mastoids from 33 adults 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:

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 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.


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.


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.


No Abstract available


Abstract:
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.


Abstract:
OBJECTIVE: To establish whether preoperative assessment using a conventional, percutaneous bone conducting implant (pBCI) processor on a headband accurately 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 ≤ 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 ≤ 0.01). The siBCI performed better than both pBCI processors on a headband at 3 to 4 kHz, except 1 kHz (p ≥ 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:

OBJECTIVE: Patients with congenital unilateral conductive hearing loss (UCHL) can either be watchful monitored or treated surgically through the fitting of a percutaneous bone conduction device (BCD) or, in some cases, atresia repair. The current study evaluated the long-term compliance and satisfaction with a percutaneous BCD in this specific population.
STUDY DESIGN: Fifty-three consecutive patients with congenital UCHL treated with a percutaneous BCD in our tertiary referral center between 1998 and 2011 were identified. Clinical and audiological data were retrospectively gathered from the patients' files. The patients were interviewed by telephone about their current device usage status and were asked to complete the Speech, Spatial and Qualities of Hearing Scale (SSQ).

RESULTS: Compliance with the BCD was 56.6% after a mean follow-up of 7 years. The mean age at implantation of the users (22 years) was significantly higher than that of the nonusers (10 years). The mean time of device usage before the patients stopped using the BCD was 5 years. The primary reasons mentioned for quitting the BCD were experiencing excess background noise and/or subjectively not receiving enough benefit. Objectively measured features of binaural processing affected by the BCD were found to correlate with long-term BCD usage. The SSQ revealed significant improvement in the aided condition compared with the nonaided condition in the users, in contrast to the nonusers.

CONCLUSION: The current disappointing long-term compliance figures indicate the need for an even more careful and individualized approach with lifelong follow-up when fitting BCDs in this specific population, especially in children.


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.


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 \( \geq 18 \) 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 \( \leq 18 \) 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 occured 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 suit 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 positions.

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.


Abstract:

The surgical procedure for Bonebridge implantation cannot be done in some cases without exposing the dura mater or sigmoid sinus. Surgical simulation technology can help to identify such difficulties prior to surgery and be used to clarify the optimal location and orientation of the device to be implanted. However, there has not been a simple strategy to drill the temporal bone at exactly the same location as that simulated on the computer. Based on our previous development of the surface template-assisted marker positioning (STAMP) method for performing image-guided otologic surgery, we recently developed a noninvasive guiding method, the BB-STAMP method, for performing image-guided Bonebridge implantation. Three patients underwent Bonebridge implantation at our surgical center during the years of 2013-2014. The authors in the simulation center supported the surgery using the BB-STAMP method. The time and effort required to 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:

The Bonebridge (R) (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:
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 significant.

CONCLUSIONS: The proposed BB-STAMP is a promising method for replicating exactly what is performed during simulation without using a surgical navigation system.