BONEBRIDGE
Bibliography

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Abstract:

Combined hearing loss is an essential indication for implantable hearing systems. Depending on the bone conduction threshold, various options are available: Patients with mild sensorineural deafness usually benefit from transcutaneous BCI, while percutaneous BCI systems are recommended also for moderate hearing loss. For combined hearing loss with moderate and high-grade cochlear hearing loss, active middle ear implants are recommended. For patients with incompatibilities or middle ear surgery, implants are a valuable and proven addition to the therapeutic options.

Abstract:

OBJECTIVE: One option for patients with single sided deafness (SSD) who experience problems with insufficient hearing in different surroundings is the treatment with percutaneous bone-anchored hearing aids. Common medical problems associated to a skin penetrating abutment can be avoided by active transcutaneous bone conduction hearing implants. The purpose of our study was to evaluate the benefit of an active transcutaneous bone conduction hearing implant in patients with SSD. PATIENTS AND METHODS: Patients suffering from SSD who are implanted with an active transcutaneous bone conduction hearing implant in retrosigmoidal position were audiologically analyzed. The audiological test battery included air and bone conduction thresholds, word recognition score (WRS) in quiet and speech intelligibility (Oldenburg Sentence Test [OLSA]) in noise. Patient satisfaction was evaluated with the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Bern-Benefit in Single-Sided Deafness (BBSS) questionnaire. RESULTS: The monosyllable WRS and the signal-to-noise ratio (SNR) assessed by the OLSA was significantly better in all aided conditions. Also, the APHAB categories ease of communication and reverberation and the average benefit in the BBSS improved significantly if using the device. CONCLUSION: The Bonebridge is a transcutaneous alternative to the well-established percutaneous bone conducting devices in patients with single sided deafness. An improvement in hearing in noise and quiet as well as a decrease of the head shadow effect can be expected.
alternative. These hearing systems are divided according to their mode of action into active middle ear implants when stimulating the auditory ossicles or the round window, into bone conduction devices while stimulating the skull directly, into cochlear implants with direct acoustic stimulation to the cochlea with its auditory nerve and finally into auditory brainstem implants by bridging the peripheral auditory structures. Taking careful criteria of indications and anatomical specificities into account, significant improvements can be achieved in comfort, speech understanding and thus quality of life for a large number of patients.


Abstract:

OBJECTIVES: In 2016, NHS England published the commissioning policy on Bone Conducting Hearing Devices (BCHDs). This policy was informed by updated evidence on the clinical and cost-effectiveness of BCHDs as well as by the 2013 Bone Anchored Hearing Aid (BAHA) policy. Commissioning policies set the criteria for service delivery and therefore have a major impact on the care received by patients. It is important that stakeholders have a good appreciation of the available evidence informing policy, as this will promote engagement both with the policy and with future research leading on from the policy. In this article, we provide stakeholders with a transparent and pragmatic assessment of the quality of the body of evidence available to inform current BCHD national policy. METHOD: (i) A systematic review of the literature on BCHDs published since the development of the 2013 policy was performed in September 2016, adhering to PRISMA recommendations. The search terms used were as follows bone conduction; bone conducting; bone anchor; BAHA; Bone Anchored Hearing Aid; Bone Conducting Hearing Device; BCHD; Bone Conducting Hearing Implant; BCHI; Sophono; Bonebridge; Soundbite; Ponto; Hearing aid; implant; device; hearing device. Publications that could inform current BCHD policy were included. The quality of included articles was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. (ii) The quality of evidence referenced by the 2013 BAHA policy was assessed using the GRADE system. RESULTS: (i) Of the 2576 publications on BCHDs identified by the systematic search, 39 met the inclusion criteria for further analysis. Using the GRADE criteria, the quality of evidence was classified as of ‘very low quality’. (ii) The 2013 BAHA policy was informed by 14 references. The GRADE system classifies the quality of evidence that informed the policy as of ‘very low quality’. CONCLUSIONS: The GRADE system defines the body of evidence available to inform current national BCHD policy as of ‘very low quality’. There is an urgent need for high-quality research to help make informed policy decisions about the care of patients with hearing loss. An (inter)national registry of BCHDs could address this need.

Abstract:

OBJECTIVE: There is no consensus regarding the benefit of implantable hearing aids in congenital unilateral conductive hearing loss (UCHL). This study aimed to measure sound source localization performance in patients with congenital UCHL and contralateral normal hearing who received a new bone conduction implant. STUDY DESIGN: Evaluation of within-subject performance differences for sound source localization in a horizontal plane. SETTING: Tertiary referral center. PATIENTS: Five patients with atresia of the external auditory canal and contralateral normal hearing implanted with transcutaneous bone conduction implant at the Medical University of Vienna were tested. INTERVENTION: Activated/deactivated implant. MAIN OUTCOME MEASURE: Sound source localization test; localization performance quantified using the root mean square (RMS) error. RESULTS: Sound source localization ability was highly variable among individual subjects, with RMS errors ranging from 21 to 40 degrees. Horizontal plane localization performance in aided conditions showed statistically significant improvement compared with the unaided conditions, with RMS errors ranging from 17 to 27 degrees. The mean RMS error decreased by a factor of 0.71 ($p<0.001$). CONCLUSION: Analysis revealed improved sound localization performance in a horizontal plane with the activated transcutaneous bone conduction implant. Some patients with congenital UCHL might be capable of developing improved horizontal plane localization abilities with the binaural cues provided by this device.


Abstract:

The aim of this study was to examine the functional hearing results regarding speech perception and auditory sound localization in a high-resolution directional hearing setup following implantation with a new bone conduction device (MED-EL Bonebridge, Innsbruck, Austria). In addition, we assessed the patient acceptance of the Bonebridge system using a questionnaire. The study design is retrospective study. The setting is University Hospital Frankfurt. 18 patients implanted with a Bonebridge device from May 2012 to January 2015 were participated in this study. Speech perception in quiet was tested with the Freiburg monosyllable test at a presentation level of 65 dB SPL. Speech perception in noise was tested post-operatively with the Oldenburg sentence test (OLSA) in best-aided condition. We assessed auditory sound localization with a high-resolution directional hearing setup. To evaluate the acceptance by patients using the Bonebridge in daily life, we used a modified questionnaire. The overall average of functional hearing gain ($n = 18$) was 29.3 dB ($\pm 20.7$ dB). Speech perception of monosyllabic words in quiet improved by 20.7% on average, compared with the pre-operative aided condition. Mean speech reception thresholds (SRTs) of the Oldenburg sentence test (OLSA) improved significantly from -3.8
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dB SNR (range -5.7 to 5.8 dB SNR) to -5.2 dB SNR (range -6.3 to -0.6 dB SNR) after implantation. Regarding localization abilities, no significant difference was found between the unaided and aided conditions following Bonebridge implantation. A survey of patients' acceptance and handling of the Bonebridge implant in daily life revealed high patient satisfaction. All patients accepted and benefited from the implanted system. No infections or adverse surgical effects occurred. Speech perception significantly improved in quiet and in noise. No significant difference in sound localization was observed. Acceptance of the Bonebridge implant, tested with a modified questionnaire, was high.


Abstract:

OBJECTIVE: To access a method of fitting a designated location on the patient's temporal bone by surgically navigating to the Bonebridge implantation. STUDY DESIGN: A patient with unilateral profound hearing loss received early intervention with the Bonebridge implant for binaural hearing. The optimal implant site was determined from computed tomography (CT) images using a three-dimensional (3D) simulation software program before the surgery. The pre-calculated coordinates from the 3D simulation software program were moved to the Scopis Hybrid Navigation System. After using the surgical navigation system for the surgery, we evaluated the degree of mismatch of the center of the bone conduction-floating mass transducer (BC-FMT) between the computer simulation and the actual drilling. RESULTS: The time required to determine the implant location on the surface of the patient's temporal bone was shortened, and the accuracy of the implantation was high. The coordinates on the 3D simulation system were comparable to the surgical navigation system. The predicted coordinates were replicated exactly upon actual drilling during the surgery, and we could confirm this in preoperative and postoperative images. CONCLUSIONS: Using an image-guided surgical navigation system to aid in the placement of the BC-FMT on the simulated location is a simple procedure and is more effective that finding the exact coordinates. It also shortens the decision time for applying the implant.


Abstract:

In 2011 a bone conduction implant that utilizes electromagnetic signals transmitted through the skin instead of vibrations was introduced onto the market. The implantable portion (the bone conduction floating mass transducer, or BC-FMT) is an electromagnetic transducer that is fixed to the skull bone with screws and delivers mechanical vibrations to the inner ear. It is often not possible to place the relatively large BC-FMT (15.8 mm in
diameter and 8.7 mm in height) exclusively in the bone of the mastoid. The surgeon might be confronted with (1) a dura mater in the middle cranial fossa which is too low, (2) a more anteriorly situated sigmoid sinus, (3) a patient who has previously undergone a radical mastoidectomy or (4) children who have smaller temporal bones. In these cases the surgeon might select a retrosigmoid 2 or middle fossa approach 3. Even if the ideal position of the implant has been determined with computed tomography 4 prior to surgery, it might be necessary to gain space by compressing the dura and/or sinus to accurately attach the BC-FMT's screws. To date, there have been no studies that systematically evaluate the safety and hearing outcomes following compression of the dura and the sinus with a bone conduction device. Furthermore, it is unclear if potential interactions between osseous and non-osseous pathways simultaneously activated by this mode of stimulation might change hearing outcomes 5. Therefore, the aim of this study was to review a consecutive series of implantations in which the device released vibrations not only to the skull but also directly to the dura or the sigmoid sinus.


Abstract:
CONCLUSIONS: The satisfaction rate of the subjects with an auditory implant appears strictly related to the resulting auditory improvement, and the surgical variables would play a prevailing role in respect to the esthetic factors. OBJECTIVES: To assess the rate of satisfaction in subjects who underwent the surgical application of an auditory device at a single Implanting Center Unit. METHOD: A series of validated questionnaires has been administered to subjects who underwent the surgical application of different auditory devices. The Glasgow Benefit Inventory (GBI), the Visual Analog Scale (VAS), and the Abbreviated Profile of Hearing Aid Benefit (APHAB) have been used to compare the implanted situation with the hearing-aided one; a percutaneous bone conductive implant (pBCI) with an active middle ear implant (AMEI) on the round window in mixed hearing loss; and an invisible, fully-implantable device with a frankly and bulky semi-implantable device. RESULTS: The mean GBI scores were higher in Vibrant Soundbridge (VSB)® and Bonebridge® subjects, without significant differences among the various devices. The mean VAS score increased for all the devices in comparison with the conventional hearing aid. The mean APHAB score was similarly better in the implanted condition as total and partial scores.


Abstract:
Semi-implantable transcutaneous bone conduction devices are treatment options for
conductive and mixed hearing loss (CHL/MHL). For counseling of patients, realistic simulation of the functional result is desirable. This study compared speech recognition in noise with a semi-implantable transcutaneous bone conduction device to external stimulation with a bone conduction device fixed by a headband. Eight German-language adult patients were enrolled after a semi-implantable transcutaneous bone conduction device (Bonebridge, Med-El) was implanted and fitted. Patients received a bone conduction device for external stimulation (Baha BP110, Cochlear) fixed by a headband for comparison. The main outcome measure was speech recognition in noise (Oldenburg Sentence Test). Pure-tone audiometry was performed and subjective benefit was assessed using the Glasgow Benefit Inventory and Abbreviated Profile of Hearing Aid Benefit questionnaires. Unaided, patients showed a mean signal-to-noise ratio threshold of 4.6±4.2 dB S/N for speech recognition. The aided results were -3.3±7.2 dB S/N by external bone conduction stimulation and -1.2±4.0 dB S/N by the semi-implantable bone conduction device. The difference between the two devices was not statistically significant, while the difference was significant between unaided and aided situation for both devices. Both questionnaires for subjective benefit favored the semi-implantable device over external stimulation. We conclude that it is possible to simulate the result of speech recognition in noise with a semi-implantable transcutaneous bone conduction device by external stimulation. This should be part of preoperative counseling of patients with CHL/MHL before implantation of a bone conduction device.


Abstract:
Objective: To examine the objective and subjective outcome of a new transcutaneous bone conduction hearing device. Study Design: Prospective, consecutive case series. Patients: Twelve patients were implanted. Eight patients had a conductive/mixed (con/mix) hearing loss. Four had single sided deafness. Main Outcome Measures: At half-year follow-up, aided and unaided sound field hearing was evaluated by 1) warble tone thresholds, 2) pure-tone average (PTA4), 3) speech discrimination score (SDS) in quiet, and 4) speech reception threshold 50% at 70 dB SPL noise level (SRT50%). Subjective outcome was evaluated by three questionnaires: 1) International Outcome Inventory for Hearing Aids, 2) Speech, Spatial and Qualities of Hearing Scale 12, and 3) a questionnaire on frequency and duration of use. Results: No major complications occurred. The mean aided PTA4 was lowered by 23 dB. SDS was increased by 40% at 50 dB, by 34% at 65 dB, and by 12% at 80 dB SPL. SRT50% in noise improved 5.2 dB. 58% of the patients used the device daily and 83% at least 5 days a week. 50% used the device >8 hours and 75% >4 hours a day. Mean International Outcome Inventory for Hearing Aids score was 3.7, corresponding to beneficial outcome. In Speech, Spatial and Qualities of Hearing Scale 12, “quality of hearing” scored especially high. The con/mix hearing loss group showed larger benefit especially in SDS, SRT50% in noise and the subjective evaluations, whereas frequency and duration of use were similar. Conclusion: This study on the first 12 Nordic patients implanted with a new transcutaneous bone conduction hearing device demonstrates
significant objective, as well as subjective hearing benefit. Patient satisfaction was high, as was the frequency of use.


Abstract:

The majority of patients with moderate to severe hearing loss can be supplied with conventional hearing aids depending on severity and cause for hearing loss in a satisfying way. However, some patients either do not benefit enough from conventional hearing aids or cannot wear them due to inflammatory reactions and chronic infections of the external auditory canal or due to anatomical reasons. For these patients there are fully- and semi-implantable middle ear and bone conduction implants available. These devices either directly stimulate the skull (bone conduction devices), middle ear structures (active middle ear implants) or the cochlea itself (direct acoustic stimulation). Patients who failed surgical hearing rehabilitation or do not benefit from conventional hearing aids may achieve a significant better speech understanding and tremendous improvement in quality of life by implantable hearing devices with careful attention to the audiological and anatomical indication criteria.


Abstract:

Patients with neurofibromatosis type II will eventually succumb to bilateral deafness. For patients with hearing loss, modern medical science technology can provide efficient hearing restoration through a number of various methods. In this article, several hearing restoration methods for patients with neurofibromatosis type II are introduced.


Abstract:

The objective of this study is to evaluate the safety and efficacy of a new transcutaneous bone-conduction implant (BCI BB) in patients with conductive and mixed hearing loss or with single-sided deafness (SSD), 1 year after surgical implantation. The study design is multicentric prospective, intra-subject measurements. Each subject is his/her own control. The setting is nine university hospitals: 7 French and 2 Belgian. Sixteen subjects with conductive or mixed hearing loss with bone-conduction hearing thresholds under the
upper limit of 45 dB HL for each frequency from 500 to 4000 Hz, and 12 subjects with SSD (contralateral hearing within normal range) were enrolled in the study. All subjects were older than 18 years. The intervention is rehabilitative. The main outcome measure is the evaluation of skin safety, audiological measurements, benefit, and satisfaction questionnaires with a 1-year follow up. Skin safety was rated as good or very good. For the mixed or conductive hearing loss groups, the average functional gain (at 500 Hz, 1, 2, 4 kHz) was 26.1 dB HL (SD 13.7), and mean percentage of speech recognition in quiet at 65 dB was 95 % (vs 74 % unaided). In 5/6 SSD subjects, values of SRT in noise were lower with BB. Questionnaires revealed patient benefit and satisfaction. The transcutaneous BCI is very well tolerated at 1-year follow up, improves audiometric thresholds and intelligibility for speech in quiet and noise, and gives satisfaction to both patients with mixed and conductive hearing loss and patients with SSD.


Abstract:

OBJECTIVE: To investigate the safety and efficacy of a new bone conduction hearing implant in children, during 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: Otolaryngology departments of four Austrian hospitals. PATIENTS: Twelve German-speaking children aged 5 to 17 suffering from conductive or mixed hearing loss, with an upper bone conduction threshold limit of 45 dB HL at frequencies between 500 and 4000Hz. INTERVENTION: Implantation of the Bonebridge transcutaneous bone conduction hearing implant (tBCI). MAIN OUTCOME MEASURES: The subjects' audiometric thresholds (air conduction, bone conduction, and sound field at frequencies 500 Hz to 8kHz) and speech perception (word recognition scores [WRS] and 50% word intelligibility in sentences [SRT50%]) were tested preoperatively and at 1 and 3 months postoperatively. The patients were also monitored for adverse events and they or their parents filled out questionnaires to analyze satisfaction levels. RESULTS: Speech perception as measured by WRS and SRT50% improved on average approximately 67.6% and 27.5 dB, respectively, 3 months after implantation. Aided thresholds also improved postoperatively, showing statistical significance at all tested frequencies. Air conduction and bone conduction thresholds showed no significant changes, confirming that subjects' residual unaided hearing was not damaged by the treatment. Only minor adverse events were reported and resolved by the end of the study. CONCLUSION: Safety and efficacy of the new bone conduction implant was demonstrated in children followed up to 3 months postoperatively.

Abstract:

OBJECTIVES: In conductive, mixed hearing losses and single-sided-deafness bone-anchored hearing aids are a well-established treatment. The transcutaneous transmission across the intact skin avoids the percutaneous abutment of a bone-anchored device with the usual risk of infections and requires less care. In this study, the audiological results of the Bonebridge transcutaneous bone conduction implant (MED-EL) are compared to the generally used percutaneous device BP100 (Cochlear Ltd., Sydney, Australia).

METHODS: Ten patients implanted with the transcutaneous hearing implant were compared to 10 matched patients implanted with a percutaneous device. Tests included pure-tone AC and BC thresholds and unaided and aided sound field thresholds. Speech intelligibility was determined in quiet using the Freiburg monosyllable test and in noise with the Oldenburg sentence test (QLSA) in sound field with speech from the front (S0). The subjective benefit was assessed with the Abbreviated Profile of Hearing Aid Benefit.

RESULTS: In comparison with the unaided condition there was a significant improvement in aided thresholds, word recognition scores (WRS), and speech reception thresholds (SRT) in noise, measured in sound field, for both devices. The comparison of the two devices revealed a minor but not significant difference in functional gain (Bonebridge: PTA = 27.5 dB [mean]; BAHA: PTA = 26.3 dB [mean]). No significant difference between the two devices was found when comparing the improvement in WRSs and SRTs (Bonebridge: improvement WRS = 80% [median], improvement SRT = 6.5 dB SNR [median]; BAHA: improvement WRS = 77.5% [median], BAHA: improvement SRT = 6.9 dB SNR [median]).

CONCLUSION: Our data show that the transcutaneous bone conduction hearing implant is an audiologically equivalent alternative to percutaneous bone-anchored devices in conductive hearing loss with a minor sensorineural hearing loss component.


Abstract:

Conclusion Bonebridge (BB) and Sophono (SP) devices improved hearing; with the BB implant showing a better performance at medium and high frequencies. Furthermore, the BB, as an active implant, showed higher functional gain and increased time of use, when compared to the SP, a passive system. Objectives This study aims to compare surgical and audiological outcomes of SP and BB devices in order to assess and further differentiate the indication criteria. Methods Fourteen patients with conductive and mixed hearing loss were evaluated pre- and post-operatively (BB or SP) (period 2013-2014). Age, gender, surgical history, cause and type of hearing loss, implant use per day, levels of bone and air conduction, and functional gain were recorded. Data was analysed by Wilcoxon singed-rank and Wilcoxon rank-sum tests. Results Fourteen patients (BB; n = 10 and SP; n = 4) with an average age = 25.42 years (CI95 = 12.41-38.43) were evaluated. The gender relation was equal (1:1), with pre-implantation osseous thresholds of 20.42 dB
(CI95 = 11.15-29.69), and pre-implantation aerial thresholds of 70.83 dB (CI95 = 62.52-79.14). The SP wearing time was significantly lower than that of the BB (SP = 7-10 h/day, BB = 8-12 h/day; p = 0.0323). The functional gain did not differ significantly between the two devices (BB = 40.00 ± 13.19 dB, SP = 34.06 ± 15.63 dB; p = 0.3434), but a significant improvement from pre- to post-implantation was observed (p < 0.05). BB and SP decreased auditory thresholds at 1 and 2 kHz (< 0.01), respectively. The BB even significantly decreased thresholds at 0.5 kHz (p = 0.0140) and 4 kHz (p < 0.0001). No relevant surgical complications were found.


Abstract:

The objective of the study was to evaluate postoperative pain following a transcutaneous active conductive hearing implant. 27 patients undergoing Bonebridge (BB) bone conduction implantation were evaluated with two pain-related questionnaires. The Headache Impact Test (HIT-6) was used to measure the degree of disability including none or little impact (≤49), mild (50-55), moderate (56-59), and severe (≥60). The Brief Pain Inventory (BPI) was used to assess pain severity score and function interference (0 = no pain to 10 = worst pain); meaningful pain was considered to be ≥3. The impact of surgical factors on postoperative pain was analyzed. Postoperative BB pain results were compared with 11 Vibrant Soundbridge™ (VSB) and 103 cochlear implant (CI) users. The mean pre- and postoperative HIT-6 scores for BB implantation were 42.6 and 41.8, respectively and the mean preoperative BPI pain severity score changed from 0.6 to 0.9 postoperatively, whereas the preoperative interference score changed from 0.1 to 0.3. None of the mean postoperative values revealed significant pain. The retrosigmoid approach, the need for dural or sinus compression, and the use of bone conduction implant lifts had no significant impact on pain scores. The mean postoperative HIT-6 pain scores for patients with BB, VSB, and CI were 41.8, 46.4, and 42.8, respectively, with the differences not being significant. BB implantation causes no significant postoperative pain irrespective of sinus or dura compression. Pain scores were similar to those experienced by patients with other transcutaneous auditory implants such as middle ear or CIs.


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.
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:

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:

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 $\leq 1$ kHz. At frequencies $\leq 1$ kHz stimulation by the BB FMT resulted in a flat and potentially highest SFP displacement amplitude of approximately $-40$ dB re $\mu$m at 1VRMS input voltage. Estimated equivalent sound pressure levels achieved by the BB FMT prototype were approximately 83-90 eq. dB SPL at frequencies $\leq 1$ kHz.

CONCLUSION: The feasibility of cochlear stimulation by vibrating electrodes was shown although the achieved output level at frequencies $\leq 1$ kHz 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 worlds 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

Conclusion: Bone conduction implants are useful in patients with conductive and mixed hearing loss for whom conventional surgery or hearing aids are no longer an option. They may also be used in patients affected by single-sided deafness. Objectives: To establish a consensus on the quality standards required for centers willing to create a bone conduction implant program. Method: To ensure a consistently high level of service and to provide patients with the best possible solution the members of the HEARING network have established a set of quality standards for bone conduction implants. These standards constitute a realistic minimum attainable by all implant clinics and should be employed alongside current best practice guidelines. Results: Fifteen items are thoroughly analyzed. They include team structure, accommodation and clinical facilities, selection criteria, evaluation process, complete preoperative and surgical information, postoperative fitting and assessment, follow-up, device failure, clinical management, transfer of care and patient complaints.


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 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.


No Abstract available


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:

A 12-year-old child with bilateral congenital microtia and ear canal atresia was bilaterally implanted with a Vibrant Soundbridge (VSB) on the right side and a Bonebridge on the left side. Prior to these surgeries the child was using percutaneous bone conduction devices (BCDs) on a headband for more than 9 years. No complications occurred during the surgeries. Sound field audiological testing showed cumulative benefit when both devices were used simultaneously. Directional hearing was tested in a sound-attenuated room. To ensure that the subject could only use acoustic information to localize sounds, the test was performed in complete darkness. The ability to localize sounds was poor when listening with either the VSB or Bonebridge, but increased significantly when both devices were used simultaneously. To our knowledge this is the first case report about the bilateral implantation of a VSB and Bonebridge.


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 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, ≤ 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:

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.


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.


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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.

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