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BONEBRIDGE Bibliography

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171 Sprinzl, G., Lenarz, T., Hagen, R., Baumgartner, W. D., Keintzel, T., Keck, T., Riechelmann, H., Magele, A., Salcher, R., Maier, H., Mlynski, R., Radeloff, A., Rak, K., Riss, D., Liepins, R., Hamzavi, S., Rasse, T., Potzinger, P., Schmutzhard, J., Zorowka, P., Mittmann, P., Boheim, K. and Todt, I. (2021). "Long-Term, Multicenter Results With the First Transcutaneous Bone Conduction Implant." Otol Neurotol.

OBJECTIVE: Investigation of long-term safety and performance of an active, transcutaneous bone conduction implant in adults and children up to 36 months post-implantation. STUDY DESIGN: Prospective, single-subject repeated-measures design. SETTING: Otolaryngology departments of eight German and Austrian hospitals.*daggerdouble dagger section sign|| paragraph sign#**daggerdagger Affiliations listed above that did not participate in the study.double daggerdouble dagger section sign section sign|||| paragraph sign paragraph sign. PATIENTS: Fifty seven German-speaking patients (49 adults and eight children) suffering from conductive or mixed hearing loss, with an upper bone conduction threshold limit of 45 dB HL at frequencies between 500 and 3000 Hz. INTERVENTION: Implantation of the Bonebridge transcutaneous bone conduction hearing implant (tBCI). MAIN OUTCOME MEASURES: Patients' audiometric pure tone averages (PTA4) (0.5, 1, 2, 4 kHz) thresholds (air conduction, bone conduction, and sound field) and speech perception (word recognition scores [WRS] and speech reception thresholds [SRT50%]) were tested preoperatively and up to 36 months postoperatively. Patients were also monitored for adverse events and administered quality-of-life questionnaires. RESULTS: Speech perception (WRS: pre-op: 17.60%, initial activation [IA]: 74.23%, 3M: 83.65%, 12M: 83.46%, 24M: 84.23%, 36M: 84.42%; SRT50%: pre-op: 65.56 dB SPL, IA: 47.67 dB SPL, 3M: 42.61 dB SPL, 12M: 41.11 dB SPL, 24M: 41.74 dB SPL, 36M: 42.43 dB SPL) and sound field thresholds (pre-op: 57.66 dB HL, IA: 33.82 dB HL, 3M: 29.86 dB HL, 12M: 28.40 dB HL, 24M: 28.22 dB HL, 36M: 28.52 dB HL) improved significantly at all aided postoperative visits. Air and bone conduction thresholds showed no significant changes, confirming preservation of patients' residual unaided hearing. All adverse events were resolved by the end of the study. CONCLUSIONS: Safety and performance of the tBCI was demonstrated in children and adults 36 months postoperatively.

170 Król, B., Cywka, K. B., Skarżyńska, M. B. and Skarżyński, P. H. (2021). "Implantation of the Bonebridge BCI 602 after Mastoid Obliteration with S53P4 Bioactive Glass: A Safe Method of Treating Difficult Anatomical Conditions-Preliminary Results." Life (Basel) 11(5).

This study presents the preliminary results of a new otosurgical method in patients after canal wall down (CWD) surgery; it involves the implantation of the Bonebridge BCI 602 implant after obliteration of the mastoid cavity with S53P4 bioactive glass. The study involved eight adult patients who had a history of chronic otitis media with cholesteatoma in one or both ears and who had had prior radical surgery. The mean follow-up period was 12 months, with routine follow-up visits according to the schedule. The analysis had two aspects: a surgical aspect in terms of healing, development of bacterial flora, the impact on the inner ear or labyrinth, recurrence of cholesteatoma, and possible postoperative complications (firstly, after obliteration of the mastoid cavity with S53P4 bioactive glass, then after implantation). The second was an audiological aspect which assessed audiometric results and the patient's satisfaction based on questionnaires. During the follow-up period, we did not notice any serious postoperative complications. Studies demonstrated significantly improved hearing thresholds and speech recognition in quiet and noise using the Bonebridge BCI 602. Data collected after six months of use showed improved audiological thresholds

and patient satisfaction. Based on the preliminary results, we believe that the proposed two-stage surgical method using bioactive glass S53P4 is a safe and effective way of implanting the Bonebridge BCI 602 in difficult anatomical conditions. This makes it possible to treat a larger group of patients with the device.

169 Ellsperman, S. E., Zwolan, T. A. and Telian, S. A. (2021). "Rehabilitation for unilateral deafness - Narrative review comparing a novel bone conduction solution with existing options." Am J Otolaryngol 42(6): 103060.

Patients with single sided deafness (SSD) struggle with sound localization and speech in noise. Existing treatment options include contralateral routing of signal (CROS) systems, percutaneous bone conduction hearing devices (BCHDs), passive transcutaneous BCHDs, active BCHDs, and cochlear implants. Implanted devices provide benefits in speech in noise compared to CROS devices. Percutaneous BCHDs transmit sound efficiently but have aesthetic drawbacks and skin complications. Scalp attenuation impacts passive transcutaneous BCHD performance. Active BCHDs overcome these issues and provide benefits for speech in noise. Cochlear implantation is the only existing option that restores binaural input but introduces electrical rather than acoustic stimuli to the deaf ear. Active BCHDs have been designed to maintain efficient sound transmission and avoid chronic skin irritation and cosmetic concerns that may occur with percutaneous BCHDs. Cochlear implantation may be a superior option for recently deafened SSD patients, though this requires further study. The duration of deafness, patient age and comorbidities, and a shared decision-making model among patients, surgeons, and audiologists should be considered in device selection. The aim of this manuscript is to review available devices, discuss surgical considerations for implantable devices, review available published results for speech in noise and sound quality with each device, and provide an overview to guide shared decision making for patients and providers. This review consolidates available literature and reviews experience with a newer active transcutaneous active BCHD available for use in the SSD population.

168 Canzi, P., Avato, I., Beltrame, M., Bianchin, G., Perotti, M., Tribi, L., Gioia, B., Aprile, F., Malpede, S., Scribante, A., Manfrin, M. and Benazzo, M. (2021). "Retrosigmoidal placement of an active transcutaneous bone conduction implant: surgical and audiological perspectives in a multicentre study." Acta Otorhinolaryngol Ital 41(1): 91-99.

INTRODUCTION: The retrosigmoidal (RS) placement of the Bonebridge system (BB) has been advocated for cases of unfavourable anatomical or clinical conditions which contraindicate transmastoid-presigmoidal positioning. However, these disadvantageous conditions, combined with the considerable dimensions of the implant, may represent a challenge, especially for surgeons with no skull base experience. Moreover, the literature reports only limited experience concerning RS implantation of the BB system. METHODS: A multicentre, retrospective study was conducted to analyse the surgical and functional outcomes of a wide population of patients undergoing RS placement of the BB system by means of a surgical technique specifically developed to overcome the intraoperative issues related to this surgery. Twenty patients with conductive or mixed hearing loss and single sided deafness were submitted to RS implantation of the BB system. RESULTS: Audiological assessment concerning the measurement of the functional and effective gain by pure-tone audiometry (28 dB HL and -12.25 dB HL, respectively) and speech audiometry (24.7 dB HL and -21 dB HL, respectively) was conducted. A high overall subjective improvement of quality of life was

recorded with the Glasgow Benefit Inventory questionnaire. No major complications, such as device extrusions or other conditions requiring revision surgery, were reported during the follow-up period (median: 42 months). CONCLUSIONS: In our study, which has one of the largest cohort of patients reported in the literature, RS placement of the BB system was safe and effective. Our functional results showed comparable hearing outcomes with presigmoidal placement. The effective gain, rarely investigated in this field, may be the object of further research to improve our understanding of bone conduction mechanisms exploited by bone conduction hearing implants.

167 Sikolova, S., Hosnova, D., Perceova, K., Bartos, M., Kruntorad, V. and Urik, M. (2021). "Retroauricular Emphysema as a Late Complication After Bonebridge Implantation: Case Report." Ear Nose Throat J 100(4): 233-236.

Bonebridge (BB) is the first active implantation system for bone conduction that is placed fully under the skin. Experience suggests that BB is characterized by low incidence of postoperative complications. This case report presents a rare case of a 16-year-old girl with incidence of emphysema occurring over the implant 1 year after operation. We performed a computed tomography scan that showed pockets of gas above the floating mass transducer so we provided the revision surgery and sealed the artificial opening with fat from the earlobe and fibrin glue. Since that time, no air has collected in the retroauricular area and the implant has been fully functional.

166 Vogt, K., Desmet, J., Janssen, A. M., Agterberg, M. J. H. and Snik, A. F. M. (2021). "Unexplained Variation in Benefit of Treatment of Congenital Unilateral Aural Atresia: A Review of the Literature." Audiol Neurootol: 1-8.

OBJECTIVE: A review of published data regarding binaural hearing after treatment of congenital unilateral conductive hearing loss (UCHL) due to aural atresia. Treatment options concern atresia surgery (reconstructive surgery), application of a bone conduction device (BCD), or application of a middle ear implant (MEI). DATA SOURCES: Database PubMed was searched for articles published in English and German between January 1, 1994, and January 1, 2019. STUDY SELECTION: The initial search identified 52 studies, of which 9 met the inclusion criteria. DATA SYNTHESIS: Comparison of studies was based on a structured review. Meta-analysis was not feasible because of the heterogeneity of outcome measures, the limited number of relevant papers (9), and diverse types of treatment (5). CONCLUSIONS: Treatment of UCHL results in bilateral hearing instead of binaural hearing. The large intersubject variability in benefit of treatment is unexplained with a clear improvement in the minority of listeners and a limited improvement or binaural interference in most listeners after atresia repair or amplification with a BCD or MEI.

165 Seiwerth, I., Frohlich, L., Schilde, S., Gotze, G., Plontke, S. K. and Rahne, T. (2021). "Clinical and functional results after implantation of the bonebridge, a semi-implantable, active transcutaneous bone conduction device, in children and adults." Eur Arch Otorhinolaryngol.

PURPOSE: Aim of the study was to evaluate the surgical, clinical and audiological outcome of 32 implantations of the Bonebridge, a semi-implantable transcutaneous active bone conduction implant. METHODS: In a retrospective cohort study, we analyzed data for 32 implantations in 31 patients (one bilateral case; seven age < 16 years) with conductive or mixed hearing loss, malformations, after multiple ear surgery, or with single-sided deafness as contralateral routing of

signal (CROS). RESULTS: Four implantations were done as CROS. Five cases were simultaneously planned with ear prosthesis anchors, and 23 implantations (72%) were planned through three-dimensional (3D) "virtual surgery." In all 3D-planned cases, the implant could be placed as expected. For implant-related complications, rates were 12.5% for minor and 3.1% for major complications. Implantation significantly improved mean sound field thresholds from a preoperative 60 dB HL (SD 12) to 33 dB HL (SD 6) at 3 postoperative months and 34 dB HL (SD 6) at > 11 postoperative months ($p < 0.0001$). Word recognition score in quiet at 65 dB SPL improved from 11% (SD 20) preoperatively to 74% (SD 19) at 3 months and 83% (SD 15) at > 11 months ($p < 0.0001$). The speech reception threshold in noise improved from - 1.01 dB unaided to - 2.69 dB best-aided ($p = 0.0018$). CONCLUSION: We found a clinically relevant audiological benefit with Bonebridge. To overcome anatomical challenges, we recommend preoperative 3D planning in small and hypoplastic mastoids, children, ear malformation, and simultaneous implantation of ear prosthesis anchors and after multiple ear surgery.

164 Garcier, M., Lavedrine, A., Gagneux, C., Eluecque, T. and Bozorg Grayeli, A. (2021). "Bone-Anchored and Closed Skin Bonebridge Implant in Adults: Hearing Performances and Quality of Life." Audiol Neurootol: 1-7.

INTRODUCTION: Bonebridge(R) is a novel active bone-anchored hearing implant. The purpose of this study was to evaluate the ease of implantation, the hearing performances, and the patient-reported benefit. MATERIALS AND METHODS: This is a prospective cross-sectional study of 24 consecutive adult patients implanted for a mixed hearing loss (13 chronic otitis media (COM) and 11 other aetiologies). Twenty-one implants were placed in the retrosigmoid position and 3 in the mastoid. Audiometry, Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire, as well as 5 implant-specific questions (analogue visual scale [AVS] 0-10 score), was administered. RESULTS: Surgery lasted 73 +/- 29.7 min on average. No major complication occurred. All patients were users at the last follow-up visit (median: 9-month range: 3-25). The average prosthetic gain was similar in COM and other aetiologies (43 +/- 4.8 dB and 50 +/- 7.2, respectively, not significant, Wilcoxon test). Bone-conduction thresholds were not deteriorated by surgery (Kruskal-Wallis test, not significant). APHAB scores improved in all categories except aversiveness (global score 45 +/- 7.0% in COM and 32 +/- 10.2% in others, not significant, and Wilcoxon test). Local pain (AVS: 3.23 +/- 3.2, n = 16) and manipulation difficulties (3.1 +/- 3.69) were low. The device was considered aesthetic (8.3 +/- 2.49). Perfectible autonomy (5.0 +/- 2.8) and difficulties wearing the implant during sport or at work (5.1 +/- 3.47) were the weakest points. CONCLUSIONS: BoneBridge(R) implant provides reproducible results for the rehabilitation of mixed hearing losses and unilateral hearing loss.

163 Seiwerth, I., Schilde, S., Wenzel, C., Rahne, T. and Plontke, S. K. (2021). "Planning tools and indications for "virtual surgery" for the Bonebridge bone conduction system." HNO.

BACKGROUND: Implantation of the Bonebridge (MED-EL, Innsbruck, Austria), an active semi-implantable transcutaneous bone conduction hearing system, involves the risk of impression or a lesion in intracranial structures, such as the dura or sigmoid sinus. Therefore, determining the optimal implant position requires careful preoperative radiological planning. OBJECTIVE: The aim of this study was to provide an overview of the possibilities for preoperative radiological planning for the Bonebridge implantation and to evaluate their indications and feasibility. MATERIALS AND METHODS: A systematic literature search was conducted in the PubMed/MEDLINE database for all

studies with preoperative planning or implant placement as the primary endpoint or that secondarily mention preoperative planning. RESULTS: Of 558 studies, 49 fulfilled the inclusion criteria. In 18 studies, preoperative planning and floating mass transducer (FMT) placement were the primary endpoints, whereas in 31 studies, preoperative planning was described secondarily. CONCLUSION: There are both freely available and commercial tools involving different time commitments for preoperative three-dimensional (3D) planning and intraoperative transfer. Preoperative 3D planning can increase the safety of Bonebridge implantation.

162 Carnevale, C., Til-Perez, G., Arancibia-Tagle, D., Tomas-Barberan, M. and Sarria-Echegaray, P. (2021). "Cervicofacial surgery and implantable hearing device extrusion: management of challenging cases." J Laryngol Otol 135(3): 212-216.

OBJECTIVE: To describe our management of implantable hearing device extrusion in cases of previous cervicofacial surgery. METHODS: A review was conducted of a retrospectively acquired database of surgical procedures for implantable hearing devices performed at our department between January 2011 and December 2019. Cases of device extrusion and previous cervicofacial surgery are included. Medical and surgical management is discussed. RESULTS: Four cases of implant extrusion following cervicofacial surgery were identified: one involving a Bonebridge system and three involving cochlear implants. In all cases, antibiotic treatment was administered and surgical debridement performed. The same Bonebridge system was implanted in the middle fossa. The three cochlear implants were removed, and new devices were implanted in a more posterior region. CONCLUSION: Previous cervicofacial surgery is a risk factor for hearing implant extrusion. The middle fossa approach is the best option for the Bonebridge system. Regarding the cochlear implant, it is always suitable to place it in a more posterior area. An inferiorly based fascio-muscular flap may be a good option to reduce the risk of extrusion.

161 Crowder, H. R., Bestourous, D. E. and Reilly, B. K. (2021). "Adverse events associated with Bonebridge and Osia bone conduction implant devices." Am J Otolaryngol 42(4): 102968.

PURPOSE: Active transcutaneous Bone Conduction Implants (BCIs) are relatively new to the market and may offer improved outcomes while reducing skin-related complications associated with previous models. The purpose of this study is to examine medical device reports (MDRs) submitted to the Food and Drug Administration's (FDA) Manufacturer and User Device Facility Experience (MAUDE) database to identify adverse events with the active, transcutaneous BCIs, Bonebridge and Osia. METHODS: A search of the FDA MAUDE database was conducted using product code "PFO" (for Active Implantable Bone Conduction Hearing System), brand names "Bonebridge" and "Osia." Data was collected on device malfunction, patient injury, inciting events, and subsequent interventions between July 1, 2018 and November 1, 2020. RESULTS: The search query yielded 83 reports that met inclusion criteria, 56 regarding Bonebridge and 27 regarding Osia. A total of 91 adverse events were reported, including 45 device malfunctions and 46 patient injuries. Of all adverse events, 15 (32.6%) patient injuries were reported with Bonebridge use compared to 31 (67.4%) patient injuries with Osia use, whereas 42 (93.3%) of the device malfunctions were reported for Bonebridge and 3 (6.7%) were reported for Osia. The most commonly reported adverse events included lack of conduction or hearing (n = 26, 28.6%), infection (n = 14, 15.4%), and intermittent or reduced conduction or hearing (n = 12, 13.2%). We estimate patient injuries to occur in 2.1% of patients implanted with Osia over a 28 month period. CONCLUSION: There are limitations to the database which make systemic analysis

challenging. This study suggests that patients with transcutaneous, active BCIs may be experiencing fewer soft tissue injuries, but similar device malfunctions as those with previous models.

160 Wickert, E., Kurz, A., Voelker, J., Hagen, R., Kaulitz, S. and Rak, K. (2021). "[Simultaneous implantation of epithesis anchors and Bonebridge to treat severe ear malformations]." Laryngorhinootologie.

OBJECTIVE: Surgical treatment with bone conduction hearing implants and epitheses for ear malformations offer the right combination of hearing rehabilitation and cosmetic reconstruction. The surgical procedure is often performed in two-stage surgical steps. This project aimed to gain experience with a procedure in which the hearing implant and the epithesis anchors are inserted simultaneously. MATERIAL AND METHODS: Four ears of three patients (nf = 1, nm = 2) with severe ear malformations (type III, according to Weerda) received a Bonebridge and an epithesis anchor with three base posts in one operation each. Previously, the indication for the use of a bone conduction implant using the active middle ear implant (aMEI) score, according to Frenzel (2013), had been established. RESULTS: All patients scored 4 points each in the aMEI score, indicating an unfavorable prognosis for successful implantation of an active middle ear implant. The treatment with a Bonebridge and an epithesis anchor was performed without complications. Postoperatively, the initial audiological fitting and the application of the magnetic abutment were performed after 4 weeks. Audiometry showed a functional gain of up to 30 dB and an improved speech comprehension. The epithesis was shaped like the contralateral ear. After treatment, patients were satisfied with the audiological and cosmetic results. CONCLUSIONS: The simultaneous surgical procedure with a bone conduction hearing implant and epithesis anchor is a good option for the treatment of ear malformations. The aMEI-score was a helpful instrument for the indication. The procedure reduced the surgical risk and the time and effort required for treatment.

159 Seiwerth, I., Schilde, S., Wenzel, C., Rahne, T. and Plontke, S. K. (2021). "[Planning tools and indications for "virtual surgery" for the Bonebridge bone conduction system. German version]." HNO.

BACKGROUND: Implantation of the Bonebridge (MED-EL, Innsbruck, Austria), an active semi-implantable transcutaneous bone conduction hearing system, involves the risk of impression or a lesion in intracranial structures, such as the dura or sigmoid sinus. Therefore, determining the optimal implant position requires careful preoperative radiological planning. OBJECTIVE: The aim of this study was to provide an overview of the possibilities for preoperative radiological planning for the Bonebridge implantation and to evaluate their indications and feasibility. MATERIALS AND METHODS: A systematic literature search was conducted in the PubMed/MEDLINE database for all studies with preoperative planning or implant placement as the primary endpoint or that secondarily mention preoperative planning. RESULTS: Of 558 studies, 49 fulfilled the inclusion criteria. In 18 studies, preoperative planning and floating mass transducer (FMT) placement were the primary endpoints, whereas in 31 studies, preoperative planning was described secondarily. CONCLUSION: There are both freely available and commercial tools involving different time commitments for preoperative three-dimensional (3D) planning and intraoperative transfer. Preoperative 3D planning can increase the safety of Bonebridge implantation.

158 Gao, M., Zhao, C., Yang, J., Chen, P., Liu, Y., Wang, D. and Zhao, S. (2021). "Bone-conduction hearing aid is effective in congenital oval window atresia." Acta Otolaryngol 141(4): 321-327.

BACKGROUND: Implantable bone-conduction hearing aids (BCHA) are effective in patients with congenital ear malformations.However, there is no large sample study to verify the efficacy of Bonebridge in patients with congenital oval window atresia. OBJECTIVES: To investigate efficiency of implantable bone-conduction hearing aids in Mandarin-speaking patients with congenital oval window atresia. MATERIAL AND METHODS: We retrospectively analyzed 15 patients, who were confirmed with either unilateral or bilateral congenital oval window atresia by temporal bone CT. All patients were implanted with a bone-conduction hearing device between July 2016 and July 2019 at Beijing Tongren Hospital, Capital Medical University. Pure tone audiometry (PTA), air-bone gap (ABG), speech discrimination scores (SDSs), and hearing thresholds were performed. RESULTS: Postoperative complications including facial paralysis were particularly rare. Unaided mean sound field threshold was 62.2 +/- 10.5 dBHL and that with implantable bone-conduction hearing aids was 39.1 +/- 13.2 dBHL ($p < 0.01$). The mean speech discrimination scores improved greatly ($p < 0.01$), specifically with regard to sentence and disyllabic words. CONCLUSIONS: Patients with congenital oval window atresia often show moderate to severe conductive hearing loss. Implantable bone-conduction hearing aids are considerably safe and stable for hearing rehabilitation. It is a novel treatment modality for Mandarin-speaking patients with congenital oval window atresia.

157 Della Volpe, A., De Lucia, A., Ippolito, V., Pastore, V., Iuppariello, L., Formisano, M., Clemente, F. and Di Stadio, A. (2021). "Use of a 3D reconstruction model in a patient with severe atresia auris for optimal placement of Bonebridge transcutaneous bone conduction implant." Eur Arch Otorhinolaryngol.

PURPOSE: Patients affected by severe atresia auris (AA) can be a challenge during hearing restoration surgery due to the abnormal position of vascular and nervous structures in the bone. A 3D reconstruction model of malformed temporal bones can be helpful for planning surgery and optimizing intra-, peri-, and post-operative results. METHOD: A 5-year-old girl with severe AA on the right side was implanted with a Bonebridge transcutaneous bone conduction implant (tBCI). 3D printing was used to reproduce the malformed temporal bone, find a good position for the tBCI and plan out the surgical details in advance. Hearing tests were performed before and after surgery and information about intra-, peri-, and post-operative outcomes were collected. RESULTS: The patient did not show any negative outcomes and, thanks to the Bonebridge, completely recovered hearing on the right side. CONCLUSIONS: 3D printing is a useful tool for planning surgery in AA patients and for preventing possible risks related to the unknown malformed anatomy.

156 Liu, Y., Ren, R. and Zhao, S. (2020). "Successive ipsilateral surgery of Vibrant Soundbridge and Bonebridge devices for congenital bilateral conductive hearing loss: a case report." J Int Med Res 48(12): 300060520972280.

The Bonebridge and Vibrant Soundbridge systems are semi-implanted hearing devices, which have been widely applied in patients with congenital conductive hearing loss. However, comparison between these two hearing devices is rare, especially in the same patient. We report a 23-year-old man who underwent successive implantation of Vibrant Soundbridge and Bonebridge devices in the same ear because of dysfunction of the Vibrant Soundbridge. We provide insight on the patient's experience and compare the audiological and subjective outcomes of satisfaction.

155 Scotta, G., Allam, A., Dimitriadis, P. A., Wright, K., Yardley, M. and Ray, J. (2020). "Surgical and functional outcomes of two types of transcutaneous bone conduction implants." J Laryngol Otol 134(12): 1065-1068.

OBJECTIVE: This study aimed to evaluate surgical and functional outcomes, in a tertiary referral centre, of two different types of semi-implantable transcutaneous bone conduction devices. METHOD: This study involved prospective data collection and review of patients implanted between November 2014 and December 2016. Glasgow Hearing Aid Inventory (Glasgow Hearing Aid Benefit Profile or Glasgow Hearing Aid Difference Profile) and Client Oriented Scale of Improvement were completed where appropriate. Surgical and audiological outcomes were recorded in the surgical notes. RESULTS: Glasgow Hearing Aid Difference Profile and Glasgow Hearing Aid Benefit Profile showed similar mean score in the active and the passive transcutaneous bone conduction devices. Client Oriented Scale of Improvement showed improvements in listening situations. Post-operative speech reception threshold showed better mean threshold in the active transcutaneous bone conduction devices group when compared with the passive transcutaneous bone conduction devices group. No device failures or surgical complications existed in either group, with the surgical time being less in the passive transcutaneous bone conduction devices group. CONCLUSION: Both devices are reliable semi-implantable transcutaneous bone conduction devices with excellent surgical and functional outcomes and patient satisfaction. Overall surgical time was much less in the passive transcutaneous bone conduction devices group with no necessity for pre-planning. This is much easier to remove with the possibility of conversion to other devices in the manufacturer's portfolio and wide-ranging wireless accessories. Further studies are needed to assess the longer-term results in a bigger population.

154 Wang, D., Ren, R., Chen, P., Yang, J., Gao, M., Liu, Y. and Zhao, S. (2021). "Application of retrosigmoid sinus approach in Bonebridge implantation." Acta Otolaryngol 141(2): 129-134.

BACKGROUND: Bonebridge is an suitable option for conductive hearing loss, however, the traditional approach cannot accomplished a satisfying implantation for patients with congenital malformation or radical mastoidectomy. OBJECTIVES: To evaluate the clinical application of retrosigmoid sinus approach in Bonebridge implantation and postoperative evaluation. MATERIALS AND METHODS: 11 patients who underwent retrosigmoid sinus approach Bonebridge implantation from March 2016 to September 2019 were retrospectively analyzed, including 6 males and 5 females, aged 12-54 years old (30.6 in average). Among them, 4 cases had undergone bilateral radical mastoidectomy, 6 cases had bilateral congenital aural atresia or stenosis, and 1 case had unilateral congenital aural atresia. RESULTS: All patients underwent Bonebridge implantation through retrosigmoid sinus approach according to the preoperative image reconstruction and plan. There was no surgical injury of sigmoid sinus or cerebrospinal fluid leakage during the operation. The aided threshold obtained an increase of 32.32 dB HL; the speech recognition rates of bisyllabic words, monosyllabic words and sentence were 79.6%, 67.8% and 75.0%, respectively. After 11-53 months of follow-up, the hearing effect was stable and no long-term complications occurred. CONCLUSION: The retrosigmoid sinus approach is an effective surgical approach for patients with congenital ear deformities or radical cavity after mastoidectomy.

153 Hundertpfund, J., Meyer, J. E. and Óvári, A. (2020). "Patient-reported long-term benefit with an active transcutaneous bone-conduction device." PLoS One 15(11): e0241247.

PURPOSE: To evaluate the long-term benefits in hearing-related quality of life, patient satisfaction and wearing time of patients rehabilitated with an active transcutaneous bone-conduction device. Adverse events and audiological outcomes are reported as secondary outcomes. METHODS: This retrospective, mono-centric cohort analysis involves 16 adults with conductive or mixed hearing loss with a mean device experience of 51.25 months. Patient-reported outcome measures were assessed using the short version of the Speech, Spatial and Qualities of Hearing Scale (SSQ12-B) and the German version of the Audio Processor Satisfaction Questionnaire (APSQ). Audiological outcomes as well as incidence of adverse events were obtained from patients´ charts. RESULTS: The hearing-related quality of life improved significantly within all subscales of the SSQ12-B scoring a mean overall of 2.95 points. Patient satisfaction measured with the APSQ scored 8.8 points on average. Wearing times differed considerably and patients with lower levels of education seemed to use their device longer compared to patients with academic education. Eight minor adverse events were documented, all of which resolved during follow-up. The mean gain in word recognition score at the last follow-up measured at 65 dB was 75.9%, while speech reception threshold was lowered by 35.1 dB. CONCLUSION: Even after several years, patients report significant benefits in hearing-related quality of life and device satisfaction. In combination with a low rate of minor adverse events and significantly improved audiological outcomes, the device is considered as a comfortable and effective option in hearing rehabilitation.

152 Jones, S. and Spielmann, P. (2020). "Device profile of the Bonebridge bone conduction implant system in hearing loss: an overview of its safety and efficacy." Expert Rev Med Devices 17(10): 983-992.

INTRODUCTION: The Bonebridge is an active transcutaneous semi-implantable bone conduction hearing device suitable for several types of hearing loss. It has unique benefits over some more established technologies. It consists of an internal active implant and an external sound processor. It was first launched in 2012, with a newer model released in late 2019. AREAS COVERED: The structure and features of the device are described. Indications, audiological criteria, and contraindications to implantation are discussed. The planning and procedure of implantation surgery are also described. Research outlining the outcomes of implant use and risk of adverse events is highlighted. EXPERT OPINION: The evidence included in this article demonstrates the successful audiological outcomes and patient satisfaction with Bonebridge implantation. The rate of adverse events following surgery is low and compares well with other devices which may be considered for Bonebridge candidates. The device should be considered as an option for suitable candidates and in many cases may be the better option available, given the low incidence of skin complications and the absence of a skin penetrating abutment. Future advances are likely to affect sound processor technology, connectivity, and possibly further reduction in implant size and gain.

151 Amin, N., Soulby, A. J., Borsetto, D. and Pai, I. (2021). "Longitudinal economic analysis of Bonebridge 601 versus percutaneous bone-anchored hearing devices over a 5-year follow-up period." Clin Otolaryngol 46(1): 263-272.

OBJECTIVES: Percutaneous bone-anchored hearing devices (pBAHDs) are the most commonly used bone conduction implants (BCI). Concerns surround the long-term complications, notably skin-related, in patients with percutaneous abutments. The active transcutaneous BCI Bonebridge system

can help avoid some of these pitfalls but is often considered a second-line option due to various factors including perceived increased overall costs. DESIGN: Longitudinal economic analysis of Bonebridge BCI 601 versus pBAHD over a 5-year follow-up period. SETTING: A specialist hearing implant centre. PARTICIPANTS: Adult patients (>/=16 years) with conductive hearing loss, mixed hearing loss or single-sided deafness, who received a Bonebridge or pBAHD implant between 1/7/2013 and 1/12/2018 with a minimum 12-month follow-up. MAIN OUTCOME MEASURES: We compared the mean costs per implanted patient for both implants at 1, 3 and 5 years postoperative time points. Clinical effectiveness was evaluated using objective and patient-reported outcome measures. RESULTS: The mean total cost per patient of Bonebridge was significantly higher than pBAHD at 1-year post-implantation (pound8512 standard deviation [SD] pound715 vs pound5590 SD pound1394, P < .001); however, by 5-years post-implantation this difference was no longer statistically significant (pound12 453 SD pound2159 vs pound12 575 SD pound3854, P > .05). The overall cost convergence was mainly accounted for by the increased long-term complications, revision surgery rates and higher cost of the pBAHD external processor compared to Bonebridge. CONCLUSIONS: Long-term costs of Bonebridge to healthcare providers are comparable to pBAHDs, whilst offering lower complication rates, comparable audiological benefit and patient satisfaction. Bonebridge should be considered as a first-line BCI option in appropriate cases.

150 Shih, M., Gitomer, S. A., Barton, G. and Liu, Y. C. (2020). "Image-guided surgical navigation for bone-conduction hearing device implant placement." Int J Pediatr Otorhinolaryngol 139: 110392.

INTRODUCTION: For pediatric patients, bone-conduction hearing devices (BCHD) have demonstrated excellent outcomes. Unique to this population, BCHD implant surgeries can be technically challenging in children due to thinner, developing bone and syndromes with atypical anatomy. Image-guided surgical navigation (IGSN) clarifies underlying skull structure, potentially improving outcomes. IGSN is commonly used in otorhinolaryngologic surgeries, but current use in BCHD placement surgeries remains unprecedented. We report favorable results of IGSN in BCHD implantation for three children with complex otologic anatomy: two syndromic patients with variable temporal bone thickness, and one with prior mastoidectomies. The three patients each underwent a successful hearing implant surgery without significant intra- or post-surgical complications. All patients had good audiologic outcomes. METHODS AND MATERIALS: We report using IGSN to assist in BAHA or BONEBRIDGE implant surgery for three medically complicated patients. For stereotactic imaging, the patients each received pre-operative high-resolution CT scans using the paranasal sinus fusion protocol without contrast. The first patient was a 6-year-old male with CHARGE-associated abnormal temporal bone anatomy, atretic left auditory nerve, and bilateral chronic tympanic membrane perforation and otorrhea resulting in bilateral mixed conductive and sensorineural hearing loss. The patient thus was unable to consistently tolerate hearing aids. The second patient was an 18-year-old male with Rosai-Dorfman disease, history of bilateral chronic mastoiditis and middle ear infections, bilateral mastoidectomies, and bilateral malleus and incus removal resulting in mixed conductive and sensorineural hearing loss. The third patient was an 11-year-old male with Treacher Collins Syndrome, bilateral microtia, and bilateral atresia of the external auditory canals resulting in bilateral conductive hearing loss. RESULTS: The patients each underwent a successful hearing implant surgery without significant intra- or post-surgical complications. All patients had good audiologic outcomes. CONCLUSION: Intraoperative IGSN can be a beneficial adjunct to BCHD implant placement surgeries for pediatric patients with abnormal temporal bone anatomy. IGSN can help identify the optimal surgical implantation sites, thereby reducing the risk for major morbidities

associated with BCHD implantations. Furthermore, our findings expand application of IGSN use to placement of both BAHA and BONEBRIDGE.

149 Lee, H. J., Kahinga, A. A. and Moon, I. S. (2021). "Clinical effect of an active transcutaneous bone-conduction implant on tinnitus in patients with ipsilateral sensorineural hearing loss." Auris Nasus Larynx 48(3): 394-399.

OBJECTIVES: This study investigated the effect of an active transcutaneous bone conduction implant (BoneBridge()) in the management of tinnitus in patients with unilateral sensorineural hearing loss. METHODS: From October 2016 to July 2018, 15 patients with unilateral tinnitus accompanied by ipsilateral sensorineural hearing loss received BoneBridge() implants. Pure-tone average, tinnitus handicap inventory (THI), and a visual analogue scale (VAS) for awareness, loudness, and annoyance were measured before and 6 months after surgery. We defined improvement as a reduction of more than 20% between preoperative and postoperative VAS and THI scores, and changes in the THI of over 7 points were also assessed. RESULTS: Mean THI scores before surgery (72.8 +/- 16.1) had significantly improved by 6 months postoperatively (50.9 +/- 18.9) (p = 0.003). VAS scores for loudness and annoyance also statistically significantly improved (p = 0.011 and 0.002). The amount of functional hearing gain correlated with changes in VAS scores for annoyance. This correlation was stronger with the improvement of high frequency hearing. CONCLUSION: BoneBridge() is beneficial in patients with tinnitus accompanied by sensorineural hearing loss. This finding can help select patients who will benefit most from bone conduction implants.

148 Utrilla, C., Gavilan, J., Garcia-Raya, P., Calvino, M. and Lassaletta, L. (2020). "MRI after Bonebridge implantation: a comparison of two implant generations." Eur Arch Otorhinolaryngol.

PURPOSE: Analysis of head magnetic resonance images (MRI) of patients with active bone conduction implants (BCIs) is challenging. Currently, there are two generations of the transcutaneous Bonebridge system (BCI601 and BCI602), the main difference between them being the transducer design and thickness. The aim was to compare the effect of transducer placement and artifact reduction sequences on legibility of MRI scans. METHODS: Four Thiel-fixed human head specimens were used: BCI601 was implanted in sinodural and middle fossa placement, and BCI602 in middle fossa and retrosigmoid approach. Images were obtained with a Signa((R)) 1.5T MR. A metal artifact reduction sequence known as MAVRIC (multiacquisition variable-resonance image combination) was used. Each specimen was scanned using standard axial T2 SE and compared with axial MAVRIC artifact reduction sequences. RESULTS: Qualitatively, limits of the artifact produced by the implant were better defined with MAVRIC than with standard T2 sequences. Assessment of contralateral internal auditory canal (IAC) was possible in all cases. Placement of the BCI602 in the middle fossa allowed the view of the ipsilateral IAC using MAVRIC sequence. Quantitatively, the artifact was reduced with MAVRIC sequence from 6.3 to 59.7%, depending on the position of implant and model; the middle fossa placement and the BCI602 being those generating shorter artifact radio. CONCLUSION: Artifact optimized sequences as MAVRIC reduce the artifact caused by the Bonebridge system. The middle fossa approach allows a better visualization of IAC canal in the ipsilateral ear with both implant versions, but the effect is more prominent with the BCI602.

147 Richards, J. P., Symms, J. T., Beasley, K. and Coffman, H. M. S. (2020). "Bone conduction implants." Curr Opin Otolaryngol Head Neck Surg 28(5): 308-313.

PURPOSE OF REVIEW: To discuss the different types of bone conduction implants available today and describe the types of hearing loss that could benefit from bone conduction implants. RECENT FINDINGS: Bone conduction implants have been used successfully for over two decades. However, there have been barriers to their use because of skin complications and limited high-frequency hearing gains. Recently developed technologies, such as active bone conduction implants may overcome some of these limitations, potentially opening the door for improved aided benefit and increased patient satisfaction from bone conduction amplification. SUMMARY: A variety of bone conduction implants currently exist, with suitable amplification options available for many different types and severities of hearing loss and patient preferences.

146 Zhao, C., Yang, J., Liu, Y., Gao, M., Chen, P., Zheng, J. and Zhao, S. (2020). "Horizontal sound localisation and speech perception in Bonebridge-implanted single-sided deafness patients." J Laryngol Otol: 1-8.

OBJECTIVE: This study aimed to investigate the benefit of Bonebridge devices in patients with single-sided deafness. METHOD: Five patients with single-sided deafness who were implanted with Bonebridge devices were recruited in a single-centre study. Participants' speech perception and horizontal sound localisation abilities were assessed at 6 and 12 months post-operatively. Speech intelligibility in noisy environments was measured in three different testing conditions (speech and noise presented from the front, speech and noise presented from the front and contralateral (normal ear) side separately, and speech presented from the ipsilateral (implanted Bonebridge) side and noise from the contralateral side). Sound localisation was evaluated in Bonebridge-aided and Bonebridge-unaided conditions at different stimuli levels (65, 70 and 75 dB SPL). RESULTS: All participants showed a better capacity for speech intelligibility in quiet environments with the Bonebridge device. The speech recognition threshold with the Bonebridge device was significantly decreased at both short- and long-term follow up in the speech presented from the ipsilateral (implanted Bonebridge) side and noise from the contralateral side condition ($p < 0.05$). Additionally, participants maintained similar levels of sound localisation between the Bonebridge-aided and unaided conditions ($p > 0.05$). However, the accuracy of localisation showed some improvement at 70 dB SPL and 75 dB SPL post-operatively. CONCLUSION: The Bonebridge device provides the benefit of improved speech perception performance in patients with single-sided deafness. Sound localisation abilities were neither improved nor worsened with Bonebridge implantation at the follow-up assessments.

145 Pepe, G., Negri, M., Falcioni, M., Di Lella, F. and Vincenti, V. (2020). "Bonebridge implantation for mixed hearing loss in a patient with Kabuki syndrome." Acta Biomed 91(3): e2020079.

The high prevalence of middle ear disease with related hearing loss in Kabuki syndrome requires the diagnostic and treatment expertise of otologists. This case report describes outcomes and changes in the quality of life of a patient affected by Kabuki syndrome with a history of recalcitrant chronic otitis media and mixed hearing loss who had undergone several unsuccessful surgical procedures before solving his problems by means of subtotal petrosectomy and active middle ear implant.

144 Rohani, S. A., Bartling, M. L., Ladak, H. M. and Agrawal, S. K. (2020). "The BONEBRIDGE active transcutaneous bone conduction implant: effects of location, lifts and screws on sound transmission." J Otolaryngol Head Neck Surg 49(1): 58.

BACKGROUND: The BONEBRIDGE (MED-EL, Innsbruck, Austria) is a bone-conduction implant used in the treatment of conductive and mixed hearing loss. The BONEBRIDGE consists of an external audio processor and a bone-conduction floating mass transducer that is surgically implanted into the skull in either the transmastoid, retrosigmoid or middle fossa regions. The manufacturer includes self-tapping screws to secure the transducer; however, self-drilling screws have also been used with success. In cases where the skull is not thick enough to house the transducer, lifts are available in a variety of sizes to elevate the transducer away from the skull. The objective of the present study was to investigate the effects of screw type, lift thickness, and implant location on the sound transmission of the BONEBRIDGE. METHOD: Six cadaveric temporal bones were embalmed and dried for use in this study. In each sample, a hole was drilled in each of the three implant locations to house the implant transducer. At the middle fossa, six pairs of screw holes were pre-drilled; four pairs to be used with self-tapping screws and lifts (1, 2, 3, and 4 mm thick lifts, respectively), one pair with self-tapping screws and no lifts, and one pair with self-drilling screws and no lifts. At the transmastoid and retrosigmoid locations, one pair of screw holes were pre-drilled in each for the use of the self-tapping screws. The vibration of transmitted sound to the cochlea was measured using a laser Doppler vibrometry technique. The measurements were performed on the cochlear promontory at eight discrete frequencies (0.5, 0.75, 1, 1.5, 2, 3, 4 and 6 kHz). Vibration velocity of the cochlear wall was measured in all samples. Measurements were analyzed using a single-factor ANOVA to investigate the effect of each modification. RESULTS: No significant differences were found related to either screw type, lift thickness, or implant location. CONCLUSIONS: This is the first known study to evaluate the effect of screw type, lift thickness, and implant location on the sound transmission produced by the BONEBRIDGE bone-conduction implant. Further studies may benefit from analysis using fresh cadaveric samples or in-vivo measurements.

143 Yang, J., Zhao, C., Liu, Y., Gao, M., Ren, R., Wang, D., Huang, Z. and Zhao, S. (2020). "The effect of anatomical variables and use of the Lifts system on hearing outcomes after implantation of an active transcutaneous bone conduction device in bilateral congenital conductive hearing loss." J Otolaryngol Head Neck Surg 49(1): 57.

BACKGROUND: Malformations of the temporal bone present different challenges to the implantation of a transcutaneous active bone conduction device, such as Bonebridge (Med-el, Innsbruck, Austria). This study aims to describe the benefits of high-resolution computed tomography (HRCT) in preoperative assessment and to analyze whether characteristics of the mastoid process, intraoperative compression of the dura or sigmoid sinus, and the use of the Lifts system, lead to differences in audiological performance after implantation. METHODS: We examined 110 cases of congenital microtia. The structure of the temporal bone was examined using HRCT and a 3D simulation software program. The mean anteroposterior mastoid bone thickness from the external auditory canal to the sigmoid sinus was measured (a measurement referred to as "AP", hereafter). Sound field threshold (SFT), speech reception threshold (SRT) in noise, and word recognition score (WRS) in quiet, before and after implantation, were also measured. Independent variables were recorded in all patients: mastoid type (well pneumatized or poorly pneumatized), the presence of dural or sigmoid sinus compression, and the use of the Lifts system. RESULTS: We found

that the mean AP in the non-compression group was 16.2 ± 2.3 mm and in the compression group, 13.1 ± 2.9 mm ($p < 0.001$). We analyzed the hearing improvement of patients grouped by mastoid development, dural or sigmoid sinus compression, and use of the Lifts system, and found that these factors did not interact and that they had no influence on the hearing outcomes ($p > 0.05$). CONCLUSIONS: The AP dimension in the non-compression group was significantly larger than that in the compression group. This finding combined with the ROC curve analysis revealed the AP dimension was a high-accuracy predictor of potential surgical complications involving the dura and sigmoid sinus compression. Further analysis revealed that there was no interaction between the chosen variables: mastoid type, dural or sigmoid sinus compression, and the use of the Lifts system, and that all of these factors had no significant impact on hearing performance. Bonebridge was shown to produce effective and stable bone conduction and to improve patients' hearing performance.

142 Wenzel, C., Schilde, S., Plontke, S. K. and Rahne, T. (2020). "Changes in Bone Conduction Implant Geometry Improve the Bone Fit in Mastoids of Children and Young Adults." Otol Neurotol 41(10): 1406-1412.

OBJECTIVES: In 2012 the first active bone conduction implant was introduced, but did not fit into the mastoids of some adults and many children. Thus, a geometry change of the transducer was proposed (BCI 602). In this study, we aimed to determine whether these changes improved the mastoid cavity fit of the implant in children and young adults. DESIGN: We retrospectively analyzed computed tomography scans of 151 mastoids from 81 children and adolescents (age range, 5 mo to 20 yr) and 52 control mastoids from 33 adults. After three-dimensional reconstruction of the temporal bone from computed tomography, we virtually implanted the BCI 602 into the mastoids, and compared the bone fit with that of the BCI 601. RESULTS: The BCI 602 could be virtually implanted in 100% of patients >/=12 years old, while the BCI 601 transducer could be completely embedded in the bone of only 70% of these mastoids. Moreover, virtual implantation of the BCI 602 was possible in 75% of children 3 to 5 years of age, while the BCI 601 did not fit in the mastoids of any patients under 5 years old without the use of lifts. CONCLUSIONS: Compared to the BCI 601, placement of the BCI 602 allegedly requires less bone removal. The newer BCI 602 transducer is more likely than its predecessor to be completely accommodated in the mastoid bone among all age groups and indications. Preoperative planning is still recommended to avoid exposure of delicate structures.

141 Plontke, S. K., Götze, G., Wenzel, C., Rahne, T. and Mlynski, R. (2020). "Implantation of a new active bone conduction hearing device with optimized geometry." HNO 68(Suppl 2): 106-115.

Here, we describe the surgical technique for implanting a new, active, transcutaneous bone conduction hearing aid. The implant technology is based on a system that has been in use reliably since 2012. The geometry of the new implant has been adapted based on experience with previously introduced implants. The surgery was feasible, standardized, and safe. Due to the optimized geometric design that improved the bone fit, it is not necessary to use specialized, detailed preoperative planning, except in challenging anatomical conditions; e.g., in young children, malformations, poor pneumatization, or after a canal wall down mastoidectomy.

140 Dobrev, I., Farahmandi, T. S. and Röösli, C. (2020). "Experimental investigation of the effect of middle ear in bone conduction." Hear Res 395: 108041.

OBJECTIVES: Experimental investigation of the contribution of the middle ear to bone conduction (BC) hearing sensation. METHODS: Experiments were conducted on 6 fresh cadaver whole head specimens. The electromagnetic actuators from a commercial bone conduction hearing aid (BCHA), Baha(R) 5 SuperPower and BoneBridge (BB), were used to provide stepped sine stimulus in the range of 0.1-10 kHz. The middle ear transfer function (METF) of each cadaver head was checked against the ASTM F2504-05 standard. In a first step, the stapes stimulus into the cochlea, under BC, was estimated based on the differential velocity between the stapes footplate and the promontory. This was based on sequential measurements of the 3D velocity of the stapes footplate and the promontory. In parallel, the differential tympanic membrane (TM) pressure was recorded by measuring sound pressure in the middle ear and in the external auditory canal each measured 1-2 mm from the TM. The measurement procedure was then sequentially repeated, after: a) opening the middle ear cavity; b) ISJ interruption; c) closing the middle ear cavity. At the end, the velocity at each actuator is measured for comparison purposes. Stapes footplate and promontory motion was quantified as the 3D motion at a single measurement point via a three-dimensional laser Doppler vibrometer (3D LDV) system. The combined motion was used for all motion parameters. RESULTS: The METF, based on the combined motion, matches better to the ASTM standard, making the measurements resilient to oblique measurement directions. The Baha actuator produced approximately 10 dB SPL more output than the BB above 2 kHz. This resulted in 2-5 dB increase in the differential pressure across the TM, after middle ear cavity opening, for Baha stimulation, and up to 9 dB drop (around 2 kHz) for BB stimulation. The differential stapes motion follows linearly the level of motion of the stimulation area, however, it is affected by actuator resonances in a more complex way. Interruption of the ISJ, reduces the differential motion of the stapes with 1-5 dB, only at 1-3 kHz. CONCLUSION: Combined velocity more objectively describes the stapes and skull motion, than any individual motion component. The state of the ME cavity and the ISJ affect the cochlear input of the stapes, however, the effect is limited in frequency and magnitude.

139 Stravrakas, M., Metherall, P. and Ray, J. (2020). "Preoperative 3D Virtual Preplanning for Bonebridge Implantation: Our Experience." Ear Nose Throat J: 145561320940075.

138 Van Deun, L., De Voecht, K., Desloovere, C. and Verhaert, N. (2020). "Safety and efficacy of the Bonebridge bone conduction implant: a comparative study." B-ENT 16(1): 9-14.

Objective: We prospectively evaluated safety and clinical efficacy of an active bone conduction implant, named Bonebridge, in patients with conductive hearing loss (CHL). Performance was compared with the preoperative aided condition. Methods: Nine Dutch-speaking patients were implanted with Bonebridge in a single tertiary referral center and were followed up for 4 years and 11 months (mean). Six patients had CHL, one had mixed hearing loss (MHL), and two had single-sided deafness. Preoperatively, patients were fitted with a conventional air conduction hearing aid (HA) and/or a bone-anchored HA processor worn on a headband. Intra- and postoperative complication rates were assessed for all patients. Five patients with CHL/MHL participated in an extensive audiological evaluation, including regular measurements of hearing thresholds (air and bone conduction), speech reception in quiet (consonant vowel consonant or CVC words) and noise

(sentences), and subjective satisfaction (Abbreviated Profile of Hearing Aid Benefit questionnaire and the Speech, Spatial and Qualities of Hearing Scale). Results: Patients' residual hearing was not deteriorated by the implantation, and no adverse events were reported. For CHL and MHL cases (n=5), the median functional gain was 20 dB at activation and remained stable thereafter. After 3 months, the median word recognition score in quiet at 40 dB A was 80%. The median speech reception threshold in noise was 4.8 dB signal to noise ratio 1 year postoperatively. Comparison with preoperative scores with a bone conduction device on a headband revealed no significant differences. Questionnaires demonstrated subjective satisfaction. Stable performance was observed along the entire follow-up period. Conclusion: Bonebridge can be considered a safe and effective treatment option for patients with CHL.

137 Alves, F., Ribeiro, J. C., Alves, M. and Goncalo, M. (2020). "Titanium allergy as a possible cause of extrusion of a bone conduction ear implant." Contact Dermatitis 83(2): 148-149.

136 Plontke, S. K., Götze, G., Wenzel, C., Rahne, T. and Mlynski, R. (2020). "[Implantation of a new active bone conduction hearing device with optimized geometry. German version]." HNO.

Here, we describe the surgical technique for implanting a new, active, transcutaneous bone conduction hearing aid. The implant technology is based on a system that has been in use reliably since 2012. The geometry of the new implant has been adapted based on experience with previously introduced implants. The surgery was feasible, standardized, and safe. Due to the optimized geometric design that improved the bone fit, it is not necessary to use specialized, detailed preoperative planning, except in challenging anatomical conditions; e.g., in young children, malformations, poor pneumatization, or after a canal wall down mastoidectomy.

135 Yang, J., Chen, P., Zhao, C., Liu, Y., Gao, M., Huang, Z. and Zhao, S. (2020). "Audiological and subjective outcomes of 100 implanted transcutaneous bone conduction devices and preoperative bone conduction hearing aids in patients with bilateral microtia-atresia." Acta Otolaryngol 140(8): 675-681.

Background: Bonebridge (BB) and bone conduction hearing aid (BCHA) are effective in patients with bilateral congenital microtia-atresia (CMA).Objectives: To investigate and compare the outcomes of these devices in a large sample size.Materials and methods: This single center prospective study involved 100 patients with bilateral CMA who were implanted with BBs and used BCHAs before implantation. Sound field threshold (SFT), speech reception thresholds (SRTs) and word recognition scores (WRSs) were compared between unaided, BCHA used and implanted patients. The Abbreviated Profile of Hearing Aid Benefit (APHAB) was used to evaluate subjective satisfaction.Results: Compared to unaided condition, the SFT, WRS and SRT of BCHA and BB were significantly improved. With BCHA or BB, the three subscale scores of the APHAB (ease of communication, background noise and reverberation) significantly reduced. However, the aversiveness subscale scored significantly higher than unaided condition. All outcomes were better in BB condition than BCHA.Conclusions: BB or BCHA use can be considered as effective methods to improve audiological outcomes and subjective satisfaction. Although not as good as BB, BCHA use is critical for improving hearing in the early period of language and auditory pathway development before the skull is suitable for BB implantation.

134 Han, J. J., Park, H. R., Song, J. J., Koo, J. W. and Choi, B. Y. (2020). "A comparison study of audiological outcome and compliance of bone conduction implantable hearing implants." Eur Arch Otorhinolaryngol 277(11): 3003-3012.

PURPOSE: The present study aimed to evaluate and compare the outcome of different bone conduction hearing implants (BCHIs) in subjects with mixed hearing loss (MHL) and single-sided deafness (SSD) in terms of audiometric results and compliance. METHODS: Twenty-one subjects with MHL and 18 subjects with SSD undergoing implantation of Baha connect, Baha attract, or Bonebridge were enrolled. Functional gain, effective gain, and usage rate of BCHIs were retrospectively reviewed. RESULTS: As for MHL, the functional gain of three devices was not significantly different (p = 0.477), while the effective gain of Bonebridge was higher (- 8.8 [- 15.0, - 3.5] dB) than that of Baha connect (- 20.0 [- 26.3, - 11.3] dB, p = 0.037), especially at 0.5 kHz (p = 0.010) and 1 kHz (p = 0.014). In SSD subjects, the effective gain of Bonebridge was significantly higher than that of Baha attract (- 11.3 [- 15.0, - 7.5] vs - 21.3 [- 21.3, - 16.3] dB, p = 0.012), while the functional gain of Bonebridge and Baha attract was not different. The constant usage rate of BCHIs tends to be higher in MHL subjects [17/21 (82%)] than that in SSD subjects [10/18 (56%)]. In SSD subjects, the constant user group showed higher functional gain than the non-constant user group, with a significant difference at 3 kHz (35.0 [33.8, 45.0] vs 17.5 [10.0, 27.5] dB, p = 0.006). CONCLUSION: Bonebridge shows a higher effective gain than Baha connect in the MHL group and Baha attract in the SSD group. The usage rate of BCHIs is lower in SSD than that in MHL. In SSD subjects, the constant user group tended to show higher functional gain than the non-constant user group. Irrespective of the device type, the tendency of higher functional gain of BCHIs, especially at mid frequencies, may potentially lead to yield good compliance in SSD, mandating a meticulous fitting strategy ensuring a sufficient mid-frequency functional gain in SSD.

133 Fan, X., Ping, L., Yang, T., Niu, X., Chen, Y., Xia, X., Gao, R., Fan, Y. and Chen, X. (2020). "Comparative effects of unilateral and bilateral bone conduction hearing devices on functional hearing and sound localization abilities in patients with bilateral microtia-atresia." Acta Otolaryngol 140(7): 575-582.

Background: Various amplification options are available for patients with congenital bilateral conductive hearing loss. Unilateral bone conduction hearing device (BCHD) is widely used for these patients, whereas benefits of bilateral BCHDs in certain subgroups of patients require further exploration.Objectives: To evaluate functional and directional hearing in patients with unilateral Bonebridge (MEDEL) and contralateral ADHEAR (MEDEL) devices.Materials and methods: This study included 32 patients (20 males, 12 females), of mean age 11.8 years (range 7-27 years). Hearing thresholds, speech perception and sound localization were tested three months after activation of the Bonebridge under three conditions: unaided, unilateral BHCD (Bonebridge) and bilateral BHCDs (Bonebridge plus contralateral ADHEAR). Patient acceptance of these devices in daily life was evaluated by questionnaire.Results: Compared with unaided, the mean hearing thresholds (0.5, 1, 2, and 4 kHz) and speech perception with unilateral BCHD and bilateral BCHDs were improved significantly ($p < .05$ each). Markers of directional hearing ability, including percentages of accurate responses, bias angles and RMS errors, were significantly better with bilateral BCHDs than unilateral BHCD ($p < .05$ each). Questionnaire revealed high patient satisfaction with both unilateral and

bilateral devices.Conclusions: Functional hearing and sound localization abilities were better with bilateral BCHDs than unilateral BCHD.

132 Siegel, L., You, P., Zimmerman, K., Parnes, L. and Agrawal, S. K. (2020). "Active Transcutaneous Bone Conduction Implant: Audiometric Outcomes Following a Novel Middle Fossa Approach With Self-Drilling Screws." Otol Neurotol 41(5): 605-613.

OBJECTIVE: To present surgical and audiometric outcomes of patients implanted with an active transcutaneous bone conduction implant following the novel middle fossa surgical approach with self-drilling screws. STUDY DESIGN: Retrospective review. SETTING: Tertiary care center. PATIENTS: Thirty-seven adults with either conductive or mixed hearing loss that met indications for an active transcutaneous bone conduction implant were consecutively implanted from April, 2013 to May, 2018. INTERVENTION: Unilateral middle fossa implantation of an active transcutaneous bone conduction implant. MAIN OUTCOME MEASURES: Patient charts were reviewed for surgical outcomes and complications over the 6-year period. Preoperative air conduction, preoperative bone conduction, and 3-month postoperative aided thresholds were recorded. Speech perception was assessed using CNC words and AzBio sentences. Pure-tone averages (PTAs; measured at 0.5, 1.0, 2.0 and 3.0 kHz), air-bone gap, and functional gain were calculated. RESULTS: Mean air conduction and bone conduction PTAs (+/-standard deviation) of the implanted ear were 66.8 dB (+/-14.9 dB) and 21.9 dB (+/-14.0 dB), respectively. Mean aided PTA was 26.5 dB (+/- 8.5 dB). The average functional gain was 40.3 dB (+/-19.0 dB). Favorable speech perception outcomes were observed. No complications or instances of revision surgery were reported, with a mean follow-up time of 32 months (range, 9-71 mo). CONCLUSIONS: This is the first paper to describe outcomes of patients implanted with an active transcutaneous bone conduction implant via the middle fossa with self-drilling screws. Favorable surgical outcomes were observed with a follow-up of up to 6 years.

131 Curca, I. A., Parsa, V., Macpherson, E. A., Scollie, S., Vansevenant, K., Zimmerman, K., Lewis-Teeter, J., Allen, P., Parnes, L. and Agrawal, S. (2020). "Audiological outcome measures with the BONEBRIDGE transcutaneous bone conduction hearing implant: impact of noise, reverberation and signal processing features." Int J Audiol 59(7): 556-565.

Objective: To assess the performance of an active transcutaneous implantable-bone conduction device (TI-BCD), and to evaluate the benefit of device digital signal processing (DSP) features in challenging listening environments.Design: Participants were tested at 1- and 3-month post-activation of the TI-BCD. At each session, aided and unaided phoneme perception was assessed using the Ling-6 test. Speech reception thresholds (SRTs) and quality ratings of speech and music samples were collected in noisy and reverberant environments, with and without the DSP features. Self-assessment of the device performance was obtained using the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire.Study sample: Six adults with conductive or mixed hearing loss.Results: Average SRTs were 2.9 and 12.3 dB in low and high reverberation environments, respectively, which improved to -1.7 and 8.7 dB, respectively with the DSP features. In addition, speech quality ratings improved by 23 points with the DSP features when averaged across all environmental conditions. Improvement scores on APHAB scales revealed a statistically significant aided benefit.Conclusions: Noise and reverberation significantly impacted speech recognition performance and perceived sound quality. DSP features (directional microphone processing and

adaptive noise reduction) significantly enhanced subjects' performance in these challenging listening environments.

130 Ghoncheh, M., Lenarz, T. and Maier, H. (2020). "A Precision Driver Device for Intraoperative Stimulation of a Bone Conduction Implant." Sci Rep 10(1): 1797.

Semi-implantable bone conduction implants (BCI) and active middle ear implants (AMEI) for patients with sensorineural, conductive or mixed hearing loss commonly use an amplitude modulation technology to transmit power and sound signals from an external audio processor to the implant. In patients, the distance dependence of the signal amplitude is of minor importance as the skin thickness is constant and only varies between 3-7 mm. In this range, critical coupling transmission technique sufficiently reduces the variability in amplitude, but fails to provide well-defined amplitudes in many research and clinical applications such as intraoperative integrity tests where the distance range is exceeded by using sterile covers. Here we used the BCI Bonebridge (BB, Med-El, Austria) as an example to develop and demonstrate a system that synthesizes the transmission signal, determines the distance between the transmitter and the receiver implant coil and compensates transmission losses. When compared to an external audio processor (AP304) on an artificial mastoid, our system mainly decreased amplitude variability from over 11 dB to less than 3 dB for audio frequencies (0.1-10 kHz) at distances up to 15 mm, making it adequate for intraoperative and audiometric tests.

129 Ray, J., Lau, K., Moraleda, J., Yardley, M., Dawoud, M. and Dimitriadis, P. A. (2019). "Soft-tissue outcomes following implantation of different types of bone conduction hearing devices in a single centre." J Laryngol Otol 133(12): 1079-1082.

OBJECTIVE: To compare soft-tissue complications following implantation of different bone conduction hearing devices. METHODS: Adults who underwent implantation of different bone conduction hearing devices, between January 2008 and December 2016, were included in the study. Five groups were identified depending on the soft-tissue approach: (1) split-thickness skin flap with use of dermatome; (2) Sheffield 'S'-shaped incision with skin thinning; (3) linear incision without skin thinning (hydroxyapatite-coated abutment); (4) 'C'-shaped full-thickness incision for passive transcutaneous bone conduction hearing devices; and (5) post-aural incision for active transcutaneous bone conduction hearing devices. The main outcome measures were different soft-tissue complications. RESULTS: The study comprised 120 patients (group 1 = 20 patients, group 2 = 35, group 3 = 35, group 4 = 20, and group 5 = 10). Soft tissue related problems were encountered in 55 per cent of patients from group 1, 26 per cent in group 2, 3 per cent in group 3, and 0 per cent in groups 4 and 5. CONCLUSION: There was a reduction in soft tissue related complications with reduced soft-tissue handling. In addition, there was a shift from an initial skin-penetrating (percutaneous) approach to a non-skin-penetrating (transcutaneous) approach.

128 Cheon, J. H., Lee, H. C., Im, G. J., Park, J. Y. and Park, C. (2019). "Safety and efficacy of transcutaneous bone conduction implant surgery for hearing improvement in microtia patients with bilateral hearing impairment." Arch Plast Surg 46(6): 525-534.

BACKGROUND: In microtia patients with bilateral hearing impairment, hearing improvement is crucial for language development and performance. External auditory canal reconstruction (EACR)

has been performed to improve hearing, but often result in complications. We performed transcutaneous bone conduction implant (TBCI) surgery in these patients. This study aimed to evaluate the safety and efficacy of TBCI surgery. METHODS: A retrospective review was performed of five patients who underwent auricular reconstruction and TBCI surgery and 12 patients who underwent EACR between March 2007 and August 2018. Hearing improvement was measured based on the air-bone gap values using pure-tone audiometry over a 6-week postoperative period. We reviewed other studies on hearing improvement using EACR and compared the findings with our result. The surgical techniques for TBCI were reviewed through case analyses. RESULTS: Postoperative hearing outcomes showed a significant improvement, with a mean gain of 34.1 dB in the TBCI cohort and 14.1 dB in the EACR cohort. Both gains were statistically significant; however, the TBCI cohort showed much larger gains. Only three of the 12 patients who underwent EACR achieved hearing gains of more than 20 dB, which is consistent with previous studies. All patients who underwent TBCI surgery demonstrated hearing gains of more than 20 dB and experienced no device-related complications. CONCLUSIONS: TBCI is a safe and effective method of promoting hearing gains in microtia patients with bilateral hearing impairment. TBCI surgery provided better hearing outcomes than EACR and could be performed along with various auricular reconstruction techniques using virgin mastoid skin.

127 Schwab, B., Wimmer, W., Severens, J. L. and Caversaccio, M. D. (2020). "Adverse events associated with bone-conduction and middle-ear implants: a systematic review." Eur Arch Otorhinolaryngol 277(2): 423-438.

PURPOSE: To review types and frequencies of adverse events (AE) associated with bone-conduction hearing implants (BCHIs) and active middle-ear implants (aMEIs) as reported in the literature. METHODS: Cochrane, PubMed, and EMBASE libraries were searched for primary articles in English or German language that reported on adverse events following BCHI or aMEI implantation, included at least five patients and were published between 1996 and 2016. Study characteristics, demographics, and counts of adverse events were tabulated and analyzed within the R statistical programming environment. RESULTS: Following assessment of the reporting quality of adverse events, we present a brief guideline that potentially improves AE reporting in this field of research. For the full dataset, we summarize study-level adverse event frequencies in terms of ratio of events to ears (REE) by AE groups and by device. For a subset of studies, we also report cumulative incidence (risk) for minor- and major adverse-events by device and by device groups. CONCLUSIONS: Data analyzed in this review show that: (1) the reporting quality of adverse events associated with BCHI and aMEIs is often very low; (2) adverse events associated with BCHI and aMEIs are qualitatively different and not equally frequent among devices; (3) state-of-the-art implantable BCHIs and aMEIs are a safe treatment option for hearing loss.

126 Ryberg, A. C., West, N., Sass, H. C. R. and Caye-Thomasen, P. (2019). "[Bone-anchored hearing aids and active middle ear implants]." Ugeskr Laeger 181(36).

This review is concerned with hearing implants, which are used in patients with hearing loss, who cannot be treated successfully with a conventional hearing aid. Among these implants, bone-anchored hearing systems (BAHS) can be used for conductive or mixed hearing loss, while active middle ear implants primarily are reserved for sensorineural hearing loss. For BAHS, active transcutaneous implants may replace percutaneous implants as a future first choice.

125 Svrakic, M. and Vambutas, A. (2019). "Medical and Audiological Indications for Implantable Auditory Devices." Otolaryngol Clin North Am 52(2): 195-210.

Implantable auditory devices (IADs) are a viable hearing restoration option for patients with hearing loss. Conditions such as chronic otitis externa, congenital aural atresia, and chronic otitis media can be treated with a variety of implants. Progressive disease are also amenable to restoration with IADs, providing stabilized hearing. When considering the best rehabilitative options, the patient's preference, ease of surgery, ease of device use, quality of life, and the traditional alternatives (such as ossiculoplasty, hearing aids, and cochlear implants) need to be considered. Patients with conductive, mixed, and sensorineural losses, mild to severe in nature, can be candidates for IADs.

124 Lailach, S., Müller, C., Lasurashvili, N., Seidler, H. and Zahnert, T. (2019). "[Active hearing implants in chronic otitis media]." HNO.

In patients with inadequate hearing improvement after tympanoplasty and failure of conventional hearing aid fitting, active hearing implants provide an alternative treatment option. Active middle ear implants function as a vibromechanical bypass of the stiffness and damping effect of a poorly oscillating tympanic membrane and the (reconstructed) ossicular chain. The selection of the hearing system depends on the maximum output levels of the hearing system and the anatomical conditions in mostly multiply operated ears. The development of variable coupling elements for active middle ear implants led to an extension of the indications to include not only purely sensorineural hearing loss but also mixed and conductive hearing loss in patients, as the transducer can now be coupled to the (mobile) stapes or the round window membrane. The article provides an overview of current clinical study results and recommendations on the indications for active hearing implants in patients with chronic otitis media.

123 Chang, Y. and Stenfelt, S. (2019). "Characteristics of Bone-Conduction Devices Simulated in a Finite-Element Model of a Whole Human Head." Trends Hear 23: 2331216519836053.

Nowadays, many different kinds of bone-conduction devices (BCDs) are available for hearing rehabilitation. Most studies of these devices fail to compare the different types of BCDs under the same conditions. Moreover, most results are between two BCDs in the same subject, or two BCDs in different subjects failing to provide an overview of the results between several of the BCDs. Another issue is that some BCDs require surgical procedures that prevent comparison of the BCDs in the same persons. In this study, four types of skin-drive BCDs, three direct-drive BCDs, and one oral device were evaluated in a finite-element model of the human head that was able to simulate all BCDs under the same conditions. The evaluation was conducted using both a dynamic force as input and an electric voltage to a model of a BCD vibrator unit. The results showed that the direct-drive BCDs and the oral device gave vibration responses within 10 dB at the cochlea. The skin-drive BCDs had similar or even better cochlear vibration responses than the direct-drive BCDs at low frequencies, but the direct-drive BCDs gave up to 30 dB higher cochlear vibration responses at high frequencies. The study also investigated the mechanical point impedance at the interface between the BCD and the head, providing information that explains some of the differences seen in the results. For example,

when the skin-drive BCD attachment area becomes too small, the transducer cannot provide an output force similar to the devices with larger attachment surfaces.

122 Koro, E. and Werner, M. (2019). "Outcomes after Application of Active Bone Conducting Implants." Audiol Neurootol 24(4): 197-205.

BACKGROUND: A bone conducting implant is a treatment option for individuals with conductive or mixed hearing loss (CHL, MHL) who do not tolerate regular hearing aids, and for individuals with single-sided deafness (SSD). An active bone conducting implant (ABCI) was introduced in 2012 with indication in CHL, MHL, and SSD, and it is still the only ABCI available. With complete implantation of the active transducer and consequent intact skin, a decrease in infections, skin overgrowth, and implant losses, all common disadvantages with earlier passive bone conducting implants, could be expected. Our Ear, Nose and Throat Department, a secondary care center for otosurgery that covers a population of approximately 365,000 inhabitants, was approved to implant ABCIs in 2012. OBJECTIVES: Our aim was to conduct an evaluation of audiological and subjective outcomes after ABCIs. METHOD: A cohort study with retrospective and prospective data collection was performed.The first 20 consecutive patients operated with an ABCI were asked for informed consent. The main outcome measures werepure tone and speech audiometry and the Glasgow Benefit Inventory (GBI). RESULTS: Seventeen patients accepted to participate and 15 were able to complete all parts. Six patients had CHL or MHL. In this group the pure tone audiometry tests are comparable with an average functional hearing gain of 29.8 dB HL. With bilateral hearing, the mean Word Recognition Score (WRS) in noise was 35.7% unaided and 62.7% aided. Ten patients had the indication SSD. With the hearing ear blocked, the pure tone average was >101 dB HL, compared to 29.3 dB HL in sound field aided. With bilateral hearing, the mean WRS in noise was 59.7% unaided and 72.8% aided. The mean of the total GBI score was 42.1 in the group with CHL or MHL and 20.6 in the group with SSD. CONCLUSIONS: The patients benefit from their implants in terms of quality of life, and there is a substantial hearing gain from the implant for patients with conductive or MHL. Patients with SSD benefit less from the implant than other diagnoses but the positive outcomes are comparable to other options for this group.

121 Fan, X., Wang, Y., Fan, Y., Du, H., Luo, N., Zhang, S. and Chen, X. (2019). "TCOF1 pathogenic variants identified by Whole-exome sequencing in Chinese Treacher Collins syndrome families and hearing rehabilitation effect." Orphanet J Rare Dis 14(1): 178.

BACKGROUND: Treacher Collins syndrome (TCS, OMIM 154500) is an autosomal disorder of craniofacial development with an incidence rate of 1/50,000 live births. Although TCOF1, POLR1D, and POLR1C, have been identified as the pathogenic genes for about 90% TCS patients, the pathogenic variants of about 8-11% cases remain unknown. The object of this study is to describe the molecular basis of 14 clinically diagnosed TCS patients from four families using Whole-exome sequencing (WES) followed by Sanger sequencing confirmation, and to analyze the effect of bone conduction hearing rehabilitation in TCS patients with bilateral conductive hearing loss. RESULTS: Four previously unreported heterozygous pathogenic variants (c.3047-2A > G, c.2478 + 5G > A, c.489delC, c.648delC) were identified in the TCOF1 gene, one in each of the four families. Sanger sequencing in family members confirmed co-segregation of the identified TCOF1 variants with the phenotype. The mean pure-tone threshold improvements measured 3 months after hearing intervention were 28.8 dB for soft-band BAHA, 36.6 +/- 2.0 dB for Ponto implantation, and 27.5 dB

SPL for Bonebridge implantation. The mean speech discrimination improvements measured 3 months after hearing intervention in a sound field with a presentation level of 65 dB SPL were 44%, 51.25 +/- 5.06, and 58%, respectively. All six patients undergoing hearing rehabilitation in this study got a satisfied hearing improvement. CONCLUSIONS: WES combined with Sanger sequencing enables the molecular diagnosis of TCS and may detect other unknown causative genes. Bone conduction hearing rehabilitation may be an optimal option for TCS patients with bilateral conductive hearing loss.

120 Guignard, J., Arnold, A., Weisstanner, C., Caversaccio, M. and Stieger, C. (2013). "A Bone-Thickness Map as a Guide for Bone-Anchored Port Implantation Surgery in the Temporal Bone." Materials (Basel) 6(11): 5291-5301.

The bone-anchored port (BAP) is an investigational implant, which is intended to be fixed on the temporal bone and provide vascular access. There are a number of implants taking advantage of the stability and available room in the temporal bone. These devices range from implantable hearing aids to percutaneous ports. During temporal bone surgery, injuring critical anatomical structures must be avoided. Several methods for computer-assisted temporal bone surgery are reported, which typically add an additional procedure for the patient. We propose a surgical guide in the form of a bone-thickness map displaying anatomical landmarks that can be used for planning of the surgery, and for the intra-operative decision of the implant's location. The retro-auricular region of the temporal and parietal bone was marked on cone-beam computed tomography scans and tridimensional surfaces displaying the bone thickness were created from this space. We compared this method using a thickness map (n = 10) with conventional surgery without assistance (n = 5) in isolated human anatomical whole head specimens. The use of the thickness map reduced the rate of Dura Mater exposition from 100% to 20% and suppressed sigmoid sinus exposures. The study shows that a bone-thickness map can be used as a low-complexity method to improve patient's safety during BAP surgery in the temporal bone.

119 Zradzinski, P., Karpowicz, J. and Gryz, K. (2019). "Electromagnetic Energy Absorption in a Head Approaching a Radiofrequency Identification (RFID) Reader Operating at 13.56 MHz in Users of Hearing Implants Versus Non-Users." Sensors (Basel) 19(17).

The aim of this study was to model the absorption in the head of an electromagnetic field (EMF) emitted by a radiofrequency identification reader operating at a frequency of 13.56 MHz (recognized as an RFID HF reader), with respect to the direct biophysical effects evaluated by the specific absorption rate (SAR), averaged over the entire head or locally, over any 10 g of tissues. The exposure effects were compared between the head of a user of a hearing implant with an acoustic sensor and a person without such an implant, used as a referenced case. The RFID HF reader, such as is used in shops or libraries, was modeled as a loop antenna (35 x 35 cm). SAR was calculated in a multi-layer ellipsoidal model of the head-with or without models of hearing implants of two types: Bonebridge (MED-EL, Austria) or bone anchored hearing aid attract (BAHA) (Cochlear, Sweden). Relative SAR values were calculated as the ratio between the SAR in the head of the implant user and the non-user. It was found that the use of BAHA hearing implants increased the effects of 13.56 MHz EMF exposure in the head in comparison to non-user-up to 2.1 times higher localized SAR in the worst case exposure scenario, and it is statistically significant higher than when Bonebridge implants are used (Kruscal-Wallis test with Bonferroni correction, $p < 0.017$). The evaluation of EMF exposure

from an RFID reader with respect to limits established for the implant non-user population may be insufficient to protect an implant user when exposure approaches these limits, but the significant difference between exposure effects in users of various types of implants need to be considered.

118 Brkic, F. F., Riss, D., Scheuba, K., Arnoldner, C., Gstottner, W., Baumgartner, W. D. and Vyskocil, E. (2019). "Medical, Technical and Audiological Outcomes of Hearing Rehabilitation with the Bonebridge Transcutaneous Bone-Conduction Implant: A Single-Center Experience." J Clin Med 8(10).

Bone-conduction implants are a standard therapeutic option for patients with conductive, unilateral, or mixed hearing loss who either do not tolerate conventional hearing aids or can benefit from surgery. The aim of this study was to evaluate long-term medical and technical outcomes, and audiological results with the Bonebridge transcutaneous bone-conduction implant. This retrospective study included all patients implanted with a bone-conduction hearing implant at a tertiary medical referral center between March 2012 and October 2018. Medical and technical outcomes included the mean length of implant usage, medical and technical complications (skin and wound infection, lack of benefit, technical failure), explantations and revisions, coupling approaches, implant failure rate, implant survival and the implant loss for added follow-up years. Auditory results were measured by functional hearing gain and the Freiburger monosyllabic test at 65 dB sound pressure level. Sixty-four patients were included in the study; five of these were implanted bilaterally (69 devices). Five unilaterally implanted patients were lost to follow-up. The mean follow-up was 27.1 months (range: 0.2 months-6.3 years). The mean implant usage was 25.9 months (range: 0.2 months-6.3 years). Fifty-seven implants (89.1%) were in use at the end of the follow-up period. Complications occurred in six ears (9.4%). Five implants (7.8%) were explanted without reimplantation. Device failure occurred in one implant (1.6%), which was possibly caused by recurrent head trauma. The rate of implant loss due to technical device failure (damage to device) was 1 per 72 follow-up years. The mean improvement on the Freiburger monosyllabic test (52.1%, $p = 0.0001$), and in functional hearing gain across frequencies (26.5 dB, $p = 0.0001$) was significant. This single-center follow-up reveals the medical and technical reliability of a transcutaneous bone-conduction implant for hearing rehabilitation because complication and revision rates were low. The majority of patients still used the device at the end of the observation period. Implantation resulted in favorable hearing outcomes in comparison to that of unaided conditions. Cautious patient selection mainly regarding co-morbidities, the history of chronic otologic diseases and proper surgical technique seems to be crucial in reducing complications.

117 Magele, A., Schoerg, P., Stanek, B., Gradl, B. and Sprinzl, G. M. (2019). "Active transcutaneous bone conduction hearing implants: Systematic review and meta-analysis." PLoS One 14(9): e0221484.

BACKGROUND: In July 2018 the active transcutaneous bone conduction hearing implant received FDA approval in the US (for patients 12 years and older with conductive and/or mixed hearing loss or single-sided deafness), reflecting the current trend of moving away from percutaneous hearing solutions towards intact skin systems. OBJECTIVES: To critically assess the current literature on safety, efficacy and subjective benefit after implantation with an active transcutaneous bone conduction hearing device. DATA SOURCES: Literature investigation was performed by electronic database search including PubMed and Cochrane Central Register of Controlled Trials, and manual search of relevant journals and reference lists of included studies. STUDY ELIGIBILITY CRITERIA: Randomized controlled trials, clinical controlled trials and cohort

studies, case series and case reports investigating subjective and objective outcomes. STUDY APPRAISAL AND SYNTHESIS METHODS: Retrieved literature was screened and extracted by two reviewers independently. Subgroup analysis of indications (conductive and/or mixed hearing loss, single-sided deafness) and participant ages (pediatric vs. adults) was conducted on patients with active transcutaneous bone conduction devices. Sensitivity analysis was performed to test the stability of the results in meta-analysis. RESULTS: 39 citations reporting on pre- and postoperative audiological results, speech performance in quiet and in noise, localization testing as well as subjective outcomes were included in this systematic review. Functional gain as well as word recognition score outcomes could be further investigated via meta-analysis. All outcomes reported and summarized here reflect beneficial audiological performance and high patient satisfaction, accompanied with a low complications rate (minor event incidence rate: 9.9 person-years; major incidence rate: 148.9 person-years) for the indications of conductive and mixed hearing loss as well as in individuals suffering from single-sided deafness for all age groups of subjects who underwent active transcutaneous bone conduction hearing device implantation. LIMITATIONS: A limiting factor of this systematic review was the Level of Evidence of the reviewed literature, comprising 2a/3a studies (cohort studies and case-control studies). Furthermore, the reporting standards, especially in outcomes such as word recognition scores in quiet and in noise, vary across study cites from various countries, which impedes comparisons. Last but not least, no other comparable other device was retrieved as the active transcutaneous bone conduction hearing device is the only available at the moment. CONCLUSION: The device's transcutaneous technology results in a minor event incidence rate of one in 9.9 person-years and a major incidence rate of one in 148.9 person-years. Based on the audiological outcomes, high patient satisfaction as well as the low complication rate, the authors recommend the active transcutaneous bone conduction hearing device as a safe and effective treatment for patients suffering from hearing loss within the device's indication criteria (conductive and/or mixed hearing loss or single-sided deafness).

116 Spielmann, P. M., Roplekar, R., Rae, C., Ahmed, F. and Jones, S. E. M. (2018). "Is the use of a bone conduction hearing device on a softband a useful tool in the pre-operative assessment of suitability for other hearing implants?" J Laryngol Otol 132(6): 505-508.

OBJECTIVE: To assess whether pre-operative assessment with a bone conduction hearing device on a softband is an accurate predictor of performance with one of two transcutaneous hearing implants.Study designCohort study comparing pre-and post-operative speech audiometry using correlation analysis. METHODS: Pre-operative pure tone audiometry and aided half optimum speech recognition thresholds were compared with post-operative aided results for each ear that had undergone implantation. Data were collected prospectively. RESULTS: Full data were available in 24 ears. In 19 out of 24 ears (79 per cent), the difference between pre- and post-operative speech scores was less than 10 dB, demonstrating a good clinical correlation. The Pearson correlation coefficient was calculated at 0.66 (95 per cent confidence interval = 0.357-0.842), indicating a strong statistical correlation. CONCLUSION: Pre-operative softband testing shows good clinical correlation and strong statistical correlation with hearing implant performance. The findings suggest there is value in using the test to predict performance and guide patients' expectations.

115 Schilde, S., Plontke, S. K. and Rahne, T. (2017). "A Three-Dimensional Geometric-Morphometric Study to Quantify Temporal Bone Growth and its Consequences for the Success of Implanting Bone Anchored Hearing Devices." Otol Neurotol 38(5): 721-729.

OBJECTIVE: A computed tomography (CT)-based morphological-investigation to describe temporal bone growth and to devise a predictive test of the likely success of Bonebridge implantation into the growing mastoid region of the temporal bone in young patients. STUDY DESIGN: Retrospective cross-sectional study. SETTING: University Hospital Halle (Saale), Germany. PATIENTS: Two cohorts participated. This first, of patients aged less than 21 years, comprised 42 men, and 33 women patients. The second cohort, for those aged more than or equal to 21 years, comprised 17 men, and 20 women patients. INTERVENTION: One hundred eighty three three-dimensional (3-D) reconstructions of the mastoid portion of the temporal bone without malformations or chronic middle ear disease were created on the base of high resolution computer tomography. The 3-D-reconstructions were analyzed using 13 linear measurements and volumetry. PRIMARY OUTCOME MEASURE: A CT/3-D model derived metric with which to best estimate the likely success of fitting a Bonebridge. RESULTS: Volume increase stagnated at, on average, 15.6 years of age (men), or 17.5 years (women). The most obvious extent of growth was observed in the craniocaudal direction from the middle cranial fossa to the tip of the mastoid process (total height). This growth is highly correlated with the increase of the mastoid volume ($r = 0.938$) and thus represents the most influential factor on mastoid volume increase. The total height of the mastoid portion can be used to usefully predict the chance of successful Bonebridge implantation.The depth of the mastoid almost doubled its size from birth (8.93 mm) to adulthood (16.34 mm) and also strongly affects the mastoid volume ($r = 0.912$). That portion between the external auditory canal (EAC) and the sigmoid sinus showed a lower growth capacity. CONCLUSIONS: The highly significant correlations between CT derived linear parameters and Bonebridge fitting ($p < 0.001$) can be used to estimate the success of Bonebridge implantation. The remarkable inter-individual variation of mastoid shape underlines the necessity of radiological preoperative planning.

114 Sim, J. H., Dobrev, I., Gerig, R., Pfiffner, F., Stenfelt, S., Huber, A. M. and Roosli, C. (2016). "Interaction between osseous and non-osseous vibratory stimulation of the human cadaveric head." Hear Res 340: 153-160.

Bone conduction (BC) stimulation can be applied by vibration to the bony or skin covered skull (osseous BC), or on soft tissue such as the neck (non-osseous BC). The interaction between osseous and non-osseous bone conduction pathways is assessed in this study. The relation between bone vibrations measured at the cochlear promontory and the intracranial sound pressure for stimulation directly on the dura and for stimulation at the mastoid between 0.2 and 10 kHz was compared. First, for stimulation on the dura, varying the static coupling force of the BC transducer on the dura had only a small effect on promontory vibration. Second, the presence or absence of intracranial fluid did not affect promontory vibration for stimulation on the dura. Third, stimulation on the mastoid elicited both promontory vibration and intracranial sound pressure. Stimulation on the dura caused intracranial sound pressure to a similar extent above 0.5 kHz compared to stimulation on the mastoid, while promontory vibration was less by 20-40 dB. From these findings, we conclude that intracranial sound pressure (non-osseous BC) only marginally affects bone vibrations measured on the promontory (osseous BC), whereas skull vibrations affect intracranial sound pressure.

113 Todt, I., Lamecker, H., Ramm, H., Frenzel, H., Wollenberg, B., Beleites, T., Zahnert, T., Thomas, J. P., Dazert, S. and Ernst, A. (2014). "[Development of a computed tomography data-based Vibrant Bonebridge viewer]." Hno 62(6): 439-442.

BACKGROUND: Because of the anatomy of the mastoid and the size of the actuator, positioning of the Vibrant Bonebridge B-FMT can be difficult without prior evaluation of the individual computed tomography (CT) scan of the temporal bone. Development of a user-friendly CT data viewer to enable positioning of the B-FMT in the temporal bone model, whilst identifying individual, potential anatomic conflicts and offering possible solutions could provide a useful tool for preoperative positioning. OBJECTIVES: Aim of the study was to define the requirements of a Vibrant Bonebridge viewer and construct a prototype. MATERIALS AND METHODS: Based on a ZIBAmira software version and inclusion of a B-FMT model upon creation of a model of the temporal bone-which allows the intuitive estimation of individual, anatomic conflicts-a Vibrant Bonebridge viewer was constructed. RESULTS: The segmentation time of the individual digital imaging and communications in medicine (DICOM) data set is about 5 min. Positioning within the individual three-dimensional temporal bone model allows quantitative and qualitative estimation of conflicts (sigmoid sinus, middle cranial fossa) and determination of a preferred position for the B-FMT. Lifting of the B-FMT can be simulated with the help of a virtual washer. CONCLUSION: The Vibrant Bonebridge viewer reliably allows simulation of B-FMT positioning. The clinical value of the viewer still has to be evaluated.

112 Jung, J., Kim, H. J., Lee, Y. H., Moon, I. S. and Choi, J. Y. (2019). "Extended-duration deafness is correlated with better subjective satisfaction in CROS-tBAHI recipients." Clin Otolaryngol 44(4): 688-692.

Key points
This study aimed to assess subjective satisfaction regarding CROS-tBAHI and identify positive predictive factors for successful fitting of tBAHI devices after surgery. CROS-tBAHI showed better hearing threshold in the aided ears and improved the SNR in speech perception in noise; nevertheless, the increased signal-to-ratio was not associated with better subjective satisfaction regarding CROS-tBAHI. Duration of deafness was a positive predictive factor for better subjective satisfaction regarding CROS-tBAHIs, probably explained by relatively lower expectation about the surgery in patients with extended duration deafness. Patients with longer durations of single-sided deafness or asymmetric hearing loss would be good candidates for CROS-tBAHI implantation.

111 Oh, S. J., Goh, E. K., Choi, S. W., Lee, S., Lee, H. M., Lee, I. W. and Kong, S. K. (2019). "Audiologic, surgical and subjective outcomes of active transcutaneous bone conduction implant system (Bonebridge)." Int J Audiol 58(12): 956-963.

Objective: Our objective was to evaluate the surgical restrictions, audiologic benefits and satisfaction from using an active transcutaneous bone conduction device (BCD), Bonebridge((R)) (BB) in patients with mixed/conductive hearing loss (MCHL) or single-sided deafness (SSD).Design: A retrospective review from all patients who underwent BB surgery at the Pusan National University Hospital from 2015 to 2017 for SSD or MCHL was performed.Study sample: Twenty-two patients with SSD and five with MCHL had a BB implanted and analysed.Results: Complete transmastoid implantation of the device was possible for all patients with an intact canal wall (ICW), using lifts if

necessary. The overall functional hearing gain (FHG) in SSD and MCHL was 31.4 and 37.6 dB, respectively. The mean percentage of speech recognition in a quiet was 81% (vs. 11% unaided) for MCHL group and 82% (vs. 29% unaided) for SSD group. Mean speech recognition scores in noise improved significantly under various signal-to-noise ratio (SNR) for both groups. Questionnaires showed overall improvement, and there was no significant difference between the two groups.Conclusions: The BB provides improved functional gain, and there were no limitations during surgery despite the large device. Both MCHL and SSD group had benefit and improved quality of life with BB.

110 Alzhrani, F. (2019). "Objective and subjective results of the Bonebridge transcutaneous active direct-drive bone conduction hearing implant." Saudi Med J 40(8): 797-801.

OBJECTIVES: To investigate the effectiveness of a bone-anchored hearing implant system (Bonebridge implant technology) as a rehabilitation treatment for individuals with conductive or mixed hearing losses. Methods: This is a retrospective cohort study. Twelve implanted ears with conductive or mixed hearing losses were implanted with this device at a tertiary university hospital between 2012 and 2016. Audiological tests included pure tone air conduction (AC) and bone conduction (BC) measurements and unaided and aided sound-field thresholds. To evaluate the speech intelligibility in a quiet environment, the speech discrimination score (SDS) was tested using Arabic monosyllabic words, and the speech reception threshold (SRT) was measured using Arabic disyllabic words spoken in front of them. The subjective sound quality was assessed with the Hearing Implant Sound Quality Index (HISQUI). Results: In comparison with the unaided condition, there was a significant improvement in the aided thresholds, SDS, and SRT. Comparing the aided and unaided thresholds, the average AC threshold improved with an average functional gain of 40+/-6.3dB. The unaided SRT improved from 72.5 dB hearing levels (HL)(median) to 27.5 dB HL (median) when aided, and patients performed 71% better, on average, based on the SDS with the help of the device. The HISQUI questionnaire revealed high satisfaction with the device sound quality. Conclusion: Patients with conductive and mixed hearing loss substantially benefit from the Bonebridge active transcutaneous BC hearing implant.

109 You, P., Siegel, L. H., Kassam, Z., Hebb, M., Parnes, L., Ladak, H. M. and Agrawal, S. K. (2019). "The middle fossa approach with self-drilling screws: a novel technique for BONEBRIDGE implantation." J Otolaryngol Head Neck Surg 48(1): 35.

BACKGROUND: Bone conduction implants can be used in the treatment of conductive or mixed hearing loss. The BONEBRIDGE bone conduction implant (BB-BCI) is an active, transcutaneous device. BB-BCI implantation can be performed through either the transmastoid or retrosigmoid approach with their respective limitations. Here, we present a third, novel approach for BB-BCI implantation. OBJECTIVE: Describe the detailed surgical technique of BB-BCI implantation through a middle fossa approach with self-drilling screws and present preliminary audiometric outcome data following this approach. METHODS: A single institution, retrospective chart review was completed for patients implanted with the BB-BCI via the middle fossa approach. Preoperative planning and modelling were performed using 3D Slicer. Audiological testing was performed pre- and post-operatively following standard audiometric techniques. RESULTS: Forty patients underwent BB-BCI implantation using the middle fossa approach. Modelling techniques allowed for implantation through the use of external landmarks, obviating the need for intraoperative image guidance. The

surgical technique was refined over time through experience and adaptation. Mean follow-up was 29 months (range 3-71 months) with no surgical complications, favourable cosmesis, and expected audiometric outcomes. An average functional gain of 39.6 dB (+/- 14.7 SD) was found. CONCLUSION: The middle fossa technique with self-drilling screws is a safe and effective option for BONEBRIDGE implantation. As a reference for other groups considering this approach, an annotated video has been included as a supplement to the study.

108 Fan, X., Yang, T., Niu, X., Wang, Y., Fan, Y. and Chen, X. (2019). "Long-term Outcomes of Bone Conduction Hearing Implants in Patients With Bilateral Microtia-atresia." Otol Neurotol 40(8): 998-1005.

OBJECTIVES: To evaluate the long-term outcomes of three different types of bone conduction hearing implants (BCHI)-BAHA, Ponto, and Bonebridge-in Mandarin-speaking patients with bilateral microtia-atresia. METHODS: This cohort study enrolled 59 patients affected by bilateral microtia-atresia, with an upper bone conduction threshold limit of 30 dB HL at frequencies of 0.5 to 4 kHz. All subjects underwent unilateral BCHI surgery, including 26 (18 males, 8 females, of mean age 8.7 +/- 1.9 yr) implanted with BAHA devices; 10 (7 males, 3 females, of mean age 11.7 +/- 2.8 yr) implanted with Ponto devices; and 23 (14 males, 9 females, of mean age 9.0 +/- 1.8 yr) implanted with Bonebridge devices. The main outcome measures included long-term audiological benefits, patient satisfaction, and complications. Each subject acted as his or her own control. RESULTS: Two years after BCHI surgery, the mean hearing thresholds in the BAHA, Ponto, and Bonebridge groups had improved to 22.6 +/- 1.6 dB HL, 21.6 +/- 1.2 dB HL, and 22.5 +/- 1.5 dB HL, respectively. The mean percentages of subjects in these three groups recognizing speech at 65 dB SPL under quiet conditions were 97.7 +/- 4.2%, 96.3 +/- 1.1%, and 94.4 +/- 9.4%, respectively, whereas the mean percentages recognizing speech under noise conditions (signal:noise ratio +5) were 87.0 +/- 1.8%, 89.3 +/- 9.3%, and 85.3 +/- 4.7%, respectively. Questionnaires revealed patients' benefits and satisfaction with this surgery. Three (11.5%) of 26 patients in the BAHA group and 1 (10%) of 10 in the Ponto group experienced skin irritation, but all recovered after local treatment. Five (19.2%) patients in the BAHA group and two (20%) in the Ponto experienced abutment extrusion about 6 months postoperatively, with all achieving good results after revision surgery to replace the abutment. One (3.8%) patient in the BAHA group experienced local chronic inflammation and underwent surgery to replace the BAHA with a Bonebridge implant. One (4.3%) patient in the Bonebridge group developed a local infection 3 months postoperatively and underwent implant removal. CONCLUSIONS: All three BCHIs were well tolerated after long-term follow-up, and all improved audiometric thresholds and the intelligibility of speech in the presence of both quiet and noise. These implants should be considered valid and safe options for the functional rehabilitation of patients with bilateral microtia-atresia.

107 Ren, R., Zhao, S., Wang, D., Li, Y., Ma, X., Li, Y., Fu, X., Chen, P. and Dou, J. (2019). "Audiological effectiveness of Bonebridge implantation for bilateral congenital malformation of the external and middle ear." Eur Arch Otorhinolaryngol 276(10): 2755-2762.

PURPOSE: To evaluate the audiological effectiveness of Bonebridge implantation in patients with bilateral congenital malformation of the external and middle ear. METHODS: Twenty-eight cases [17 boys and 11 girls; median age, 12 years (range 8-36 years)] had unilateral Bonebridge implantation. Audiological tests were performed preoperatively and postoperatively, and included

the pure-tone audiometry test, speech discrimination score (SDS), and evaluation of the unaided and aided hearing thresholds in sound fields. For the group of patients aged > 12 years, Mandarin Speech Test Materials were used to determine the SDS. For the other cases, the Mandarin Lexical Neighborhood Test was used. The daily life efficacy was assessed using the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire postoperatively. The t and t' tests were used in the statistical analyses. RESULTS: The hearing threshold with the Bonebridge improved by 25-35 dB HL, compared to that of the unaided condition. The SDS of patients aged > 12 years improved by about 50%; the SDS also improved by 10-20% in the three patients aged < 12 years. According to the APHAB, the mean Bonebridge scores of ease of communication, background noise, and reverberation decreased by 60.3 +/- 15.7, 50.2 +/- 11.1, and 59.4 +/- 7.8, respectively, compared to the preoperative scores, and the Bonebridge score of aversiveness was higher (69.8 +/- 10.8) than the unaided score. CONCLUSIONS: The audiological effectiveness of the Bonebridge was significant and noticeable in bilateral congenital malformation of the external and middle ear. The Bonebridge can be an alternative and effective solution for those patients to improve hearing.

106 Dusu, K., Walsh, M. and Eze, N. (2019). "Paediatric Bonebridge: bilateral simultaneous asymmetrical implantation." J Laryngol Otol 133(8): 719-722.

BACKGROUND: The Bonebridge is an active transcutaneous bone conduction implant recommended as a surgical option for adults and children (aged 5-18 years). Successful implantation of the Bonebridge is often restricted by an insufficient amount of temporal bone to house the transducer in the paediatric patient. METHOD AND RESULTS: In this unique paediatric case, bilateral Bonebridge devices were implanted simultaneously in the right sinodural angle and the left middle cranial fossa. CONCLUSION: The simultaneous implantation of bilateral Bonebridge devices was well tolerated in this paediatric patient, with significant improvement in her hearing. The middle cranial fossa is a viable option for housing the transducer.

105 Skarzynski, P. H., Ratuszniak, A., Krol, B., Koziel, M., Osinska, K., Cywka, K. B., Sztabnicka, A. and Skarzynski, H. (2019). "The Bonebridge in Adults with Mixed and Conductive Hearing Loss: Audiological and Quality of Life Outcomes." Audiol Neurootol 24(2): 90-99.

BACKGROUND: Considering that hearing loss has a significant impact on social functioning, everyday activity and a person's emotional state, one of the most important goals of hearing rehabilitation with bone conduction devices is improvement in a patient's quality of life. OBJECTIVES: To measure self-assessed quality of life in patients implanted with the Bonebridge, a bone conduction device. METHOD: Prospective, observational, longitudinal study with one treatment group. Twenty-one patients with mixed or conductive hearing loss were included, and each individual served as its own control. The Abbreviated Profile of Hearing Aid Benefit (APHAB) was used to measure patient-reported quality of life before intervention and at 3 and 6 months after activation of the device. At the same time frames, pure-tone audiometry and speech understanding in quiet and in noise were tested. RESULTS: Hearing-specific quality of life increased significantly after intervention and remained stable up to 6 months. Both word recognition in quiet and speech reception threshold in noise were significantly better after 6 months compared to before surgery. Outcomes of aided speech understanding were independent of initial bone conduction thresholds and equally high (word recognition score >75%) across the device's indication range. CONCLUSIONS: The Bonebridge provides not only significant audiological benefit in both speech understanding in

quiet and in noise, but also increases self-perceived quality of life in patients suffering from mixed and conductive hearing loss. Together with a very low rate and minor nature of adverse events, it is the state-of-the-art solution for hearing rehabilitation in patients with mixed or conductive hearing loss up to a bone conduction threshold of 45 dB HL.

104 Canale, A., Boggio, V., Albera, A., Ravera, M., Caranzano, F., Lacilla, M. and Albera, R. (2019). "A new bone conduction hearing aid to predict hearing outcome with an active implanted device." Eur Arch Otorhinolaryngol 276(8): 2165-2170.

PURPOSE: We compared our historical medium-term data obtained with an active semi-implanted bone conduction device and the hearing results of a new passive bone conduction hearing device to determine its predictive value for the hearing results with the semi-implanted device. METHODS: The study sample was 15 patients with an active bone conduction implant (mean follow-up 26 months). Pure tone audiometry was performed with headphones, sound field speech audiometry was conducted unaided, and free-field speech audiometry was carried out with both the active bone conduction system and the passive device switched off. RESULTS: As compared with the unaided condition, speech reception was significantly improved with both devices. Comparison of speech reception threshold at 100% of word recognition showed no difference between the active and the passive device. At lower intensity the difference in speech perception was significant in the patients with monaural fitting (group A) and was non-statistically significant in those with binaural fitting (group B); the speech reception threshold at 50% of word recognition was 26.00 dB (+/- 10.22) with the active implant and 30.50 dB (+/- 7.98) with the passive device in group A ($p = 0.047$) and 24.00 dB (+/- 5.48) and 29.00 dB (+/- 2.24) in group B ($p = 0.052$), respectively. CONCLUSIONS: The hearing outcome after active bone conduction implant was comparable to published data. Compared with the unaided condition, speech recognition was significantly improved with the passive device. The device may also provide value to predict the hearing outcome with the implanted device, especially at higher intensities. LEVEL OF EVIDENCE: IV.

103 Wimmer, W., Hakim, A., Kiefer, C., Pastore-Wapp, M., Anschuetz, L., Caversaccio, M. D. and Wagner, F. (2019). "MRI Metal Artifact Reduction Sequence for Auditory Implants: First Results with a Transcutaneous Bone Conduction Implant." Audiol Neurootol 24(2): 56-64.

OBJECTIVE: Magnetic resonance imaging (MRI) is often limited in patients with auditory implants because of the presence of metallic components and magnets. The aim of this study was to evaluate the clinical usefulness of a customized MRI sequence for metal artifact suppression for patients with implants in the temporal bone region, specifically patients with a transcutaneous bone conduction implant. METHODS: Two whole head specimens were unilaterally implanted with a transcutaneous bone conduction implant. MRI examinations with and without a primarily self-build sequence (SEMAC-VAT WARP) for metal artifact suppression were performed. The diagnostic usefulness of the acquired MRI scans was rated independently by two neuroradiologists. The sequence was also used to acquire postimplantation follow-up MRI in a patient with a transcutaneous bone conduction implant. RESULTS: The customized SEMAC-VAT WARP sequence significantly improved the diagnostic usefulness of the postimplantation MRIs. The image acquisition time was 12 min and 20 s for the T1-weighted and 12 min and 12 s for the T2-weighted MRI. There was good agreement between the two blinded raters (Cohen's kappa = 0.61, $p < 0.001$). CONCLUSION: The sequence for metal artifact reduction optimized in Bern enables MRI at 1.5 T in

patients with active transcutaneous bone conduction implants without sacrificing diagnostic imaging quality. Particularly on the implanted side, imaging of intracranial and supra- and infratentorial brain pathologies is clinically more valuable than standard diagnostic MRI without any artifact reduction sequences.

102 Barbara, M., Covelli, E., Filippi, C., Margani, V., De Luca, A. and Monini, S. (2019). "Transitions in auditory rehabilitation with bone conduction implants (BCI)." Acta Otolaryngol 139(4): 379-382.

BACKGROUND: The bone conductive implants (BCI) are nowadays a reliable alternative for rehabilitation of specific forms of hearing loss, i.e. conductive, mixed or single sided deafness (SSD). Aims/Objective: To analyse the various factors in play when considering an auditory rehabilitation with a bone-conductive device (BCI). MATERIALS AND METHODS: The clinical charts of subjects who underwent BCI application at the same Implanting Center from 2005 to 2018 were retrieved analysing also the reason for eventual explantation and the alternative option (transition) for hearing rehabilitation. RESULTS: Nine BAHA Compact, 4 BAHA Intenso, 21 BAHA Divino, 3 BAHA BP100, 4 Ponto, 2 Sophono, 5 Bonebridge, 5 BAHA5 Attract; 11 BAHA5 Connect were used in 12 unilateral COM; 16 bilateral COM; 3 unilateral cholesteatoma; 6 bilateral cholesteatoma; 2 unilateral otosclerosis; 5 bilateral otosclerosis; 9 congenital malformations; 6 major otoneurosurgical procedures; 5 sudden deafness. Explantation was necessary for five subjects. CONCLUSIONS: Middle ear pathology and sequels from surgery represent the most common reason for BCI implantation, both in unilateral and in bilateral cases. Transition from one implantable device to another one can be predictable, mostly when explantation is necessary. SIGNIFICANCE: The role of BCI for rehabilitation in middle ear pathology may be extremely important.

101 Carnevale, C., Tomas-Barberan, M., Til-Perez, G. and Sarria-Echegaray, P. (2019). "The Bonebridge active bone conduction system: a fast and safe technique for a middle fossa approach." J Laryngol Otol 133(4): 344-347.

BACKGROUND: The transmastoid pre-sigmoid approach is always the preferred choice for implantation of the Bonebridge active bone conduction system in patients with a normal anatomy. When an anatomical variant exists or a previous surgery has been performed, a retrosigmoid approach or middle fossa approach can be performed. METHODS: The preferred surgical technique for a middle fossa approach is described. A 14 mm drill head (Neuro Drill) was used to create the bed at the squamous portion of the temporal bone. Surgical time and complication rate were analysed. RESULTS: The surgical time was shorter than 30 minutes in all cases, and only 14 seconds were needed to create a 14 mm bone bed. No complications were observed during the follow-up period (6-45 months). CONCLUSION: Use of the Neuro Drill for the middle fossa approach is an easy technique. It significantly decreases the surgical time, without increasing the complication rate.

100 Skarzynski, H., Ratuszniak, A., Osinska, K. and Skarzynski, P. H. (2018). "Anterior Course Of The Sigmoid Sinus And Use Of A Lift With The Bonebridge Implant: Case Report." J Hear Sci 8(4): 56-61.

Background: The Bonebridge bone conduction implant (BCI) is used in cases of conductive, mixed hearing loss and single-sided deafness. The system can be implanted in the mastoid process pre- or retrosigmoidally. Presigmoid placement tends to reduce the number of subsequent

implantations. The use of new refinements – such as spacers called BCI lifts, which facilitate adjustment during surgery – broadens the applicability of Bonebridge to a larger group of patients. Conclusions: The Bonebridge system is an effective treatment for hearing loss caused by chronic otitis media in cases where classic otosurgery cannot be performed. Difficult conditions during surgery, as caused by an anterior sigmoid sinus, can limit the use of the Bonebridge. In such cases use of a lift can widen implantation options. Case report: This case study presents a 58-year-old female patient with bilateral chronic otitis media who had undergone several operations in the past and who qualified for a Bonebridge implant. During surgery, a lift for the lower screw of the bone-conduction floating mass transducer (BC-FMT) was used because of an anterior course of the sigmoid sinus. We analysed hearing results before and 3 months after the surgery. The results indicated stable bone conduction thresholds and improved hearing and speech recognition after implantation.

99 Snik, A., Maier, H., Hodgetts, B., Kompis, M., Mertens, G., van de Heyning, P., Lenarz, T. and Bosman, A. (2019). "Efficacy of Auditory Implants for Patients With Conductive and Mixed Hearing Loss Depends on Implant Center." Otol Neurotol 40(4): 430-435.

INTRODUCTION: Although from a technological point of view, progress is impressive, most implantable hearing devices for conductive or mixed hearing loss have a limited capacity. These devices all bypass the impaired middle ear; therefore, the desired amplification (gain) should be based on the cochlear hearing loss (component) only. The aim of the study is to review the literature with regard to accomplished gain with current implantable devices. METHOD: Thirty-one articles could be included. Aided thresholds were compared with prescribed values, based on cochlear hearing loss (bone-conduction thresholds), according to the well-validated NAL rule. RESULTS: For the majority of the studies, NAL targets were not met. Variation in accomplished gain between implant teams was unacceptably large, largely independent of the type of device that was used. NAL targets were best met at 2 kHz, with worse results at the other frequencies. CONCLUSION: Large variations in reported results were found, which primarily depended on implant center. Based on the analyses, a pragmatic fitting procedure is proposed which should minimize the differences between implant centres.

98 Chan, K. C., Wallace, C. G., Wai-Yee Ho, V., Wu, C. M., Chen, H. Y. and Chen, Z. C. (2019). "Simultaneous auricular reconstruction and transcutaneous bone conduction device implantation in patients with microtia." J Formos Med Assoc 118(8): 1202-1210.

BACKGROUND/PURPOSE: The Bonebridge (BB) is a newly designed transcutaneous bone conduction hearing implant. We describe, for the first time, simultaneous BB implantation and different surgical techniques of auricular reconstruction for microtia patients with aural atresia/stenosis. METHODS: Ten patients with unilateral or bilateral microtia underwent BB implantation combined simultaneously with either total auricular reconstruction using bespoke hand-carved Medpor framework or second stage auricular projection using autologous costal cartilage framework. Auditory aided and unaided sound fields were evaluated using (1) a pure-tone average (PTA4), (2) a speech reception threshold (SRT), and (3) a Speech Discrimination Score (SDS) at a sound level of 65 dB SPL. RESULTS: All patients and their families were satisfied with the aesthetic outcome of their constructed ears with no requests for further revision. No major complications were encountered. One patient developed minor partial skin graft epidermolysis that healed uneventfully, and another patient had a three month period of auditory acclimatization to the

BB device that resolved. Postoperatively, the mean aided PTA4 decreased by 35.35 dB, while the SRT was 54.5 dB HL unaided and 28 dB HL with use of a BB sound processor. The SDS increased by 16.4%-65 dB SPL. CONCLUSION: Simultaneous BB implantation during either total auricular reconstruction or framework projection for microtia patients who have aural atresia/stenosis is feasible and safe. This approach reduces operative stages, thereby minimizing schooling/occupational disruption and time to total microtia reconstruction and auditory rehabilitation.

97 Lin, J., Chen, S., Zhang, H., Xiong, H., Zhang, Z., Liang, M., Zhang, X., Ye, H. and Zheng, Y. (2019). "Application of Implantable Hearing Aids and Bone Conduction Implant System in patients with bilateral congenital deformation of the external and middle ear." Int J Pediatr Otorhinolaryngol 119: 89-95.

OBJECTIVE: To determine the efficacy of the application of the Implantable Hearing Aids and Bone Conduction Implant System in patients with bilateral congenital deformation of the external and middle ear. METHODS: twenty patients with bilateral congenital malformation of the external and middle ear were included in the study. Implantable Hearing Aids implantation was performed in ten patients, and Bone Conduction Implant System implantation was performed in ten patients. Audiometric tests, including pure-tone audiometry and speech discrimination in the free field were performed pre-operatively and post-operatively. RESULTS: Implantable Hearing Aids and Bone Conduction Implant System implantation were performed successfully in all patients. The mean pure-tone threshold improvement with Implantable Hearing Aids or Bone Conduction Implant System activation in the free filed pure tone audiometry was 25dB and ranged from 0.25 to 4kHz. Mean free field speech discrimination in quiet was 80% at 65dB compared to 18% pre-operatively. The mean pure-tone threshold improvement with Bone Conduction Implant System was 25.5dB better than 18.2dB with Implantable Hearing Aids. The mean free filed speech discrimination in quite improvement with Bone Conduction Implant System was 66% better than 58% with Implantable Hearing Aids. CONCLUSION: Implantable Hearing Aids or Bone Conduction Implant System are effective options for improving hearing in patients with bilateral congenital deformation of the external and middle ear. The procedure is safe and effective, and its indications are wider than those of tympanoplasty for such cases. Furthermore, the Bone Conduction Implant System is better than Implantable Hearing Aids, tympanoplasty and hearing aids.

96 Zernotti, M. E., Chiaraviglio, M. M., Mauricio, S. B., Tabernero, P. A., Zernotti, M. and Di Gregorio, M. F. (2019). "Audiological outcomes in patients with congenital aural atresia implanted with transcutaneous active bone conduction hearing implant." Int J Pediatr Otorhinolaryngol 119: 54-58.

OBJECTIVES: The objective of this study is to evaluate the safety and efficacy of the transcutaneous Bone Conduction Implant, the Bonebridge, in patients with congenital aural atresia. METHODS: Audiometry, speech recognition test and free field audiometry were performed. Word recognition scores and speech perception was evaluated using Spanish phonetically-balanced disyllables word list. RESULTS: Fourteen subjects were implanted with the Bonebridge (seven bilateral placements). The study cohort comprised seven males and seven females aged from 3 to 17 years (mean age 9.76yrs). All patients accepted and benefited from the implanted Bonebridge system. The pre-operative PTA4 was 66.4dB (64.2-68.6, 95-%CI) and improved after activation to 19.2dB (16.9-21.5, 95%CI), resulting in a mean functional gain of 47,2dB. Regarding speech

discrimination, the pre-operative outcomes of the disyllabic measurements were 34.3% and for monosyllables 27.4%. Following activation the speech discrimination improved to 98.6% and 97.9%, respectively. No infections or adverse device related effects occurred in patient group. CONCLUSION: We have concluded that the Bonebridge implant is an innovative solution for patients with conductive or mixed hearing loss and unilateral loss suffering from congenital atresia. Different surgical techniques may be used for implant placement, based on the patient's anatomy. Studies show improved functional gain, better speech perception, and lower rates of percutaneous complications associated with this implant.

95 Yang, J., Wang, Z., Huang, M., Chai, Y., Jia, H., Wu, Y., Dai, Y., Li, Y. and Wu, H. (2018). "BoneBridge implantation in patients with single-sided deafness resulting from vestibular schwannoma resection: objective and subjective benefit evaluations." Acta Otolaryngol 138(10): 877-885.

BACKGROUND: The BoneBridge could rehabilitate hearing for patients with single-sided deafness (SSD). OBJECTIVES: To evaluate the objective and subjective benefits of BoneBridge implantation in patients after vestibular Schwannoma resection and to explore the factors affecting the benefits. MATERIAL AND METHODS: We prospectively enrolled all 15 patients implanted with BoneBridge after VS resection from January to June 2017. The primary outcome was the ability to hear in noisy conditions. The secondary outcomes were the soft-band BoneBridge try-on rate, the frequency of BB use, the sound source localization test result, and questionnaire measures of quality of life (QoL). RESULTS: Patients showed better speech recognition ability in the presence of noise with the BoneBridge. The BoneBridge provided no help in sound localization, although most patients reported subjective sound localization benefits. The results of QoL questionnaires showed significant satisfaction with BoneBridge implantation. The unilateral hearing deprivation duration and high education levels had significant impacts on the subjective benefits of patients. CONCLUSIONS: The BoneBridge could improve speech recognition performance in complex auditory backgrounds, as well as QoL, especially in patients with short unilateral hearing deprivation durations and high education levels. SIGNIFICANCE: The BoneBridge is an effective hearing aid for single-sided deafness patients after VS removal.

94 Wimmer, W., von Werdt, M., Mantokoudis, G., Anschuetz, L., Kompis, M. and Caversaccio, M. (2019). "Outcome prediction for Bonebridge candidates based on audiological indication criteria." Auris Nasus Larynx 46(5): 681-686.

OBJECTIVE: To re-evaluate current indication criteria and to estimate the audiological outcomes of patients with Bonebridge bone conduction implants based on preoperative bone conduction thresholds. METHODS: We assessed the outcome of 28 subjects with either conductive or mixed hearing loss (CMHL) or single-sided deafness (SSD) who were undergoing a Bonebridge implantation. We used linear regression to evaluate the influence of preoperative bone conduction thresholds of the better/poorer ear, indication group, and language (German- and French-speaking patients) on aided sound field thresholds. In addition, aided word recognition scores at 65dB sound pressure level were fit with a logistic model that included preoperative bone conduction thresholds of the better/poorer ear, indication group, and language as effects. RESULTS: We found that both aided sound field thresholds and word recognition were correlated with the preoperative bone conduction thresholds of the better hearing ear. No correlation between audiological outcomes and

the preoperative bone conduction thresholds of the poorer ear, language, or indication group was found. CONCLUSION: Bone conduction thresholds of the better hearing ear should be used to estimate the outcome of patients undergoing Bonebridge implantation. We suggest the indication criteria for Bonebridge candidates considering maximal bone conduction thresholds of the better ear at 38dB HL to achieve an aided sound field threshold of at least 30dB hearing level and an aided word recognition score of at least 75% for monosyllabic words.

93 Miller, M. E. (2019). "Osseointegrated Auditory Devices: Bonebridge." Otolaryngol Clin North Am 52(2): 265-272.

Bonebridge is an active bone conduction device that consists of a bone conduction-floating mass transducer (BC-FMT) and magnet internally and an audio processor externally. Surgery for implantation can be performed under local anesthesia but requires surgical planning for adequate bone depth for the BC-FMT well. Bonebridge does not require osseointegration to function, so the device can be activated early. One disadvantage of Bonebridge is the sizable artifact on MRI created by the internal magnet. Studies of Bonebridge implantation demonstrate few complications, and hearing outcomes are audiologically equivalent to other bone conduction devices.

92 Ratuszniak, A., Skarzynski, P. H., Gos, E. and Skarzynski, H. (2019). "The Bonebridge implant in older children and adolescents with mixed or conductive hearing loss: Audiological outcomes." Int J Pediatr Otorhinolaryngol 118: 97-102.

INTRODUCTION: For children with conductive or mixed hearing loss, in whom use of conventional hearing aids is impossible or limited, use of bone conduction devices is recommended. The choice between the available types of devices depends mostly on the degree of hearing loss, age, and anatomical conditions. One device application in children older than 5 years is the Bonebridge implant. The aim of this study is to assess the benefits and safety of this device in children. METHODS: The material was a group of 11 older children and adolescents aged 10-17 years (mean=14.7, SD=2.45) with single-sided or bilateral conductive or mixed hearing loss, implanted unilaterally with the Bonebridge system at the World Hearing Center in Kajetany near Warsaw between 2014 and 2016. Benefits of the Bonebridge were assessed with warble tone audiometry and word audiometry in free field, as well as an APHAB (Abbreviated Profile of Hearing Aid Benefit) questionnaire before and after implantation. RESULTS: Hearing tests showed a statistically significant improvement in hearing sensitivity and speech discrimination. Results of the questionnaire confirm the benefits of Bonebridge implantation to the older children in terms of their auditory performance under various acoustic conditions. CONCLUSIONS: At a one-year follow up the Bonebridge system was found to be a safe, efficient, and effective tool for compensating for conductive or mixed hearing loss in older children and adolescents. For good anatomical conditions the Bonebridge implant provides a safe alternative to other popular bone conduction systems.

91 Georgescu, M., Baumgartner, W. D., Modan, A. and Vrinceanu, D. (2018). "The First Active Transcutaneous Bone Conduction Implant in Romania-Case Report of Permanent Conductive Hearing Loss Due to Cleft Palate." Trends Telemed E-Health (TTEH) 1(2): 1-7.

Since the introduction of bone conduction hearing implants in 1977, quality of life of the implantees have improved substantially. The first available option were bone-anchored hearing

devices, which improved sound quality, but had the major disadvantage of post-operative skin and wound infections. Therefore, new technologies seeking intact skin solution have emerged lately. The BONEBRIDGE system (MED-EL, Medical Electronics, Innsbruck, Austria) incorporates the first active bone conduction device, which especially aims to resolve abutment issues and still offers excellent audiological benefit. The successful implantation of this system in the first Romanian patient suffering from congenital lip and hard palate cleft with recurrent suppurative otitis media is presented. The authors report their experience with implantation, in terms of indications, selection assessment as well as functional results with a critical review of advantages and disadvantages in comparison with classical methods.

90 Tang, I. P., Ngui, L. X. and Prepageran, N. (2018). "A review of surgical and audiological outcomes of bonebridge at tertiary centres in Malaysia." Med J Malaysia 73(5): 276-280.

OBJECTIVES: To investigate the surgical and audiological outcome of Bonebridge (BB) at tertiary centres in Malaysia. STUDY DESIGN: Prospective, intra-subject repeated measurements of which each subject is his/her own control, from year 2012 to 2016 at two tertiary referral centres. METHODS: Twenty patients with hearing loss who fulfilled criteria for BB and showed good response to bone conduction hearing aid trial were included. Implantations of BB were carried out under general anaesthesia with preoperative computed tomography (CT) planning. Complications were monitored up to six months postoperatively. Subjects' audiometric thresholds for air conduction, bone conduction and sound field at frequencies of 250Hz to 8kHz were assessed preoperatively and at six months postoperatively. Subjects' satisfaction was evaluated at 6 months post operatively with Hearing Device Satisfaction Scale (HDSS) questionnaire. RESULTS: There was no major complication reported. Mean aided sound field thresholds showed significant improvement for more than 30dB from 500 to 4000kHz ($p<0.05$). There was no significant change in mean unaided air conduction and bone conduction thresholds pre and post operatively from 500 to 4000kHz, with a difference of less than 5dB ($p>0.05$). All the patients were very satisfied (>80%) with the implant, attributing to the promising functional outcome and acceptable cosmetic appearance. CONCLUSIONS: BB implantation surgery is safe and is effective in restoring hearing deficits among patients aged five and above with conductive or mixed hearing loss and single-sided hearing loss.

89 Wang, Y., Xing, W., Liu, T., Zhou, X., Qian, J., Wang, B., Zhao, S. and Zhang, Q. (2018). "Simultaneous auricular reconstruction combined with bone bridge implantation-optimal surgical techniques in bilateral microtia with severe hearing impairment." Int J Pediatr Otorhinolaryngol 113: 82-87.

BACKGROUND: Congenital bilateral microtia with external ear canal (EAC)/middle ear malformation lead to severe appearance defects, hearing impairment and language barrier. Here we report an optimal integrated surgical technique for BoneBridge implantation and auricular reconstruction, which reduce time span of operation, total cost and patients' suffering as well. METHOD: Seven patients with bilateral external and middle ear malformation received 2-stage auricular reconstruction (age from 7 to 11 years old). In the 1st stage, 6th, 7th, and part of 8th autologous costal cartilage were used to make main body and C-shaped base part of the framework. In 2nd stage of the operation, dissect and lift the framework, isolate postauricular fascia and periosteum, put the BoneBridge subperiosteally and fixed with titanium screw. The C-shaped cartilage base was further attached to the framework and retroauricular fascial flaps and a full-

thickness skin graft obtained from the donor site was used to cover posterior raw surface. RESULTS: Patients were followed up for about 8 months post operation, all of them satisfied with the outcomes and symmetric shape on both sides about desirable 3D detail without adverse complications. Hearing test indicated the mean improvement of auditory threshold of 34.8dB HL 3 weeks after BoneBridge implantation, with mean scores of speech recognition test ranging from 26% to 62%. CONCLUSION: The combined 2-stage surgical techniques of simultaneous auricular reconstruction and BoneBridge implantation is safe and efficient for bilateral microtia with significant advantages in decreasing operation difficulties, shortening treatment span and relieving suffering for patients.

88 Vogt, K., Frenzel, H., Ausili, S. A., Hollfelder, D., Wollenberg, B., Snik, A. F. M. and Agterberg, M. J. H. (2018). "Improved directional hearing of children with congenital unilateral conductive hearing loss implanted with an active bone-conduction implant or an active middle ear implant." Hear Res 370: 238-247.

Different amplification options are available for listeners with congenital unilateral conductive hearing loss (UCHL). For example, bone-conduction devices (BCDs) and middle ear implants. The present study investigated whether intervention with an active BCD, the Bonebridge, or a middle ear implant, the Vibrant Soundbridge (VSB), affected sound-localization performance of listeners with congenital UCHL. Listening with a Bonebridge or VSB might provide access to binaural cues. However, when fitted with the Bonebridge, but not with a VSB, binaural processing might be affected through cross stimulation of the contralateral normal hearing ear, and could interfere with processing of binaural cues. In the present study twenty-three listeners with congenital UCHL were included. To assess processing of binaural cues, we investigated localization abilities of broadband (BB, 0.5-20kHz) filtered noise presented at varying sound levels. Sound localization abilities were analyzed separately for stimuli presented at the side of the normal-hearing ear, and for stimuli presented at the side of the hearing-impaired ear. Twenty-six normal hearing children and young adults were tested as control listeners. Sound localization abilities were measured under open-loop conditions by recording head-movement responses. We demonstrate improved sound localization abilities of children with congenital UCHL, when listening with a Bonebridge or VSB, predominantly for stimuli presented at the impaired (aided) side. Our results suggest that the improvement is not related to accurate processing of binaural cues. When listening with the Bonebridge, despite cross stimulation of the contralateral cochlea, localization performance was not deteriorated compared to listening with a VSB.

87 McLeod, R. W. J., Culling, J. F. and Jiang, D. (2018). "Advances in the Field of Bone Conduction Hearing Implants." Adv Otorhinolaryngol 81: 24-31.

The number of marketed bone-conduction hearing implants (BCHIs) has been steadily growing, with multiple percutaneous devices and transcutaneous devices now available. However, studies assessing efficacy often have small sample sizes and employ different assessment methodologies. Thus, there is a paucity of evidence to guide clinicians to the most appropriate device for each patient. This paper outlines audiological guidelines for the latest devices, as well as research from the most up-to-date clinical trials. We also outline the evidence base for some potentially contentious issues in the field of bone conduction, including bilateral fitting of BCHIs in those with bilateral conductive hearing loss as well as the use of BCHIs in single-sided deafness (SSD). Bilateral

fitting of BCHIs have been found to significantly increase the hearing thresholds in quiet and improve sound localization, but to give limited benefits in background noise. Studies conducted via multiple assessment questionnaires have found strong evidence of subjective benefits for the use of BCHIs in SSD. However, there is little objective evidence of benefit for SSD patients from sound localization and speech in noise tests.

86 Vickers, D., Canas, A., Degun, A., Briggs, J., Bingham, M., Toner, J., Cooper, H., Rogers, S., Cooper, S., Irving, R., Spielman, P., Batty, S., Jones, S., Asher, A., Chung, M., Donnelly, N., Skibinska, A., Gardner, R., Raine, C., Andrew, R., Green, K., Ghulam, H., Nunn, T., Jiang, D., Furhapter, S., Urban, M., Hanvey, K., Flynn, S., Lovegrove, D. and Saeed, S. (2018). "Evaluating the effectiveness and reliability of the Vibrant Soundbridge and Bonebridge auditory implants in clinical practice: Study design and methods for a multi-centre longitudinal observational study." Contemp Clin Trials Commun 10: 137-140.

Background: The Vibrant Soundbridge middle ear implant and the Bonebridge bone conducting hearing device are hearing implants that use radio frequency transmission to send information from the sound processor to the internal transducer. This reduces the risk of skin problems and infection but requires a more involved surgical procedure than competitor skin penetrating devices. It is not known whether more complex surgery will lead to additional complications. There is little information available on the reliability of these systems and adverse medical or surgical events. The primary research question is to determine the reliability and complication rate for the Vibrant Soundbridge and Bonebridge. The secondary research question explores changes in quality of life following implantation of the devices. The tertiary research question looks at effectiveness via changes in auditory performance. Method: The study was designed based on a combination of a literature search, two clinician focus groups and expert review.A multi-centre longitudinal observational study was designed. There are three study groups, two will have been implanted prior to the start of the study and one group, the prospective group, will be implanted after initiation of the study. Outcomes are surgical questionnaires, measures of quality of life, user satisfaction and speech perception tests in quiet and in noise. Conclusion: This is the first multi-centre study to look at these interventions and includes follow up over time to understand effectiveness, reliability, quality of life and complications.

85 Ngui, L. X. and Tang, I. P. (2018). "Bonebridge transcutaneous bone conduction implant in children with congenital aural atresia: surgical and audiological outcomes." J Laryngol Otol 132(8): 693-697.

OBJECTIVES: To investigate the surgical and audiological outcomes of the Bonebridge transcutaneous bone conduction hearing implant among children with congenital aural atresia. METHODS: Six children were recruited and underwent Bonebridge transcutaneous bone conduction implant surgery. The patients' audiometric thresholds for air conduction, bone conduction and sound-field tests were assessed pre-operatively and at six months post-operatively. Patients' satisfaction was assessed at six months post-operatively with the Hearing Device Satisfaction Scale. RESULTS: No major complications were reported. Mean aided sound-field thresholds improved post-operatively by more than 30 dB for 0.5-4 kHz (p 0.05). All patients were satisfied (scores were over 90 per cent) with the implant in terms of functional outcome and cosmetic appearance. CONCLUSION:

Bonebridge transcutaneous bone conduction implant surgery is safe and effective among children with congenital aural atresia with conductive hearing loss.

84 Loader, B., Sterrer, E., Reichmayr, C., Kaider, A., Gstottner, W., Baumgartner, W. D. and Vyskocil, E. (2018). "Direct comparison of mastoidal and retrosigmoidal placement of a transcutaneous bone conduction device after canal wall down tympanoplasty." Clin Otolaryngol 43(6): 1603-1606.

Cholesteatoma and chronic otitis media are common and regularly treated in surgical otology centers. Repeated surgeries are often required in order to eliminate residual disease and reconstruct functional hearing. Frequently, the posterior wall of the auditory canal has to be resected resulting in a canal wall down (CWD) technique with variable hearing outcome. This article is protected by copyright. All rights reserved.

83 Roesch, S., Kugler, A., Schlattau, A. and Rasp, G. (2018). "Temporary Explant of a Transcutaneous Bone Conduction Hearing Implant for Imaging of the Pituitary Gland." Otol Neurotol 39(7): e557-e560.

OBJECTIVE: Clinical report on feasibility and outcome of a surgical procedure. PATIENT: Nine-year-old child, supplied with a transcutaneous bone conduction hearing implant, requiring magnetic resonance imaging of the head to exclude a tumor of the pituitary gland. INTERVENTION: Temporal removal and subsequent reimplantation of the implant in a single surgical procedure. MAIN OUTCOME MEASURE: Postoperative audiometric results. CONCLUSION: Under specific clinical circumstances, temporary removal of the transcutaneous bone conduction implant described, is technically accomplishable.

82 Carnevale, C., Til-Perez, G., Arancibia-Tagle, D. J., Tomas-Barberan, M. D. and Sarria-Echegaray, P. L. (2018). "Hearing outcomes of the active bone conduction system Bonebridge((R)) in conductive or mixed hearing loss." Acta Otorrinolaringol Esp.

OBJECTIVE: The active transcutaneous bone conduction implant Bonebridge((R)), is indicated for patients affected by bilateral conductive/mixed hearing loss or unilateral sensorineural hearing loss, showing hearing outcomes similar to other percutaneous bone conduction implants, but with a lower rate of complications. The aim of this study was to analyze the hearing outcomes in a series of 26 patients affected by conductive or mixed hearing loss and treated with Bonebridge((R)). METHODS: 26 of 30 patients implanted with Bonebridge((R)) between October 2012 and May 2017, were included in the study. We compared the air conduction thresholds at the frequencies 500, 1000, 2000, 3000, 4000Hz, the SRT50% and the percentage of correct answers at an intensity of 50dB with and without the implant. RESULTS: "Pure tone average" with the implant was 34.91dB showing an average gain of 33.46dB. Average SRT 50% with the implant was 34.33dB, whereas before the surgery no patient achieved 50% of correct answers at a sound intensity of 50dB. The percentage of correct answers at 50dB changed from 11% without the implant to 85% with it. We only observed one complication consisting of an extrusion of the implant in a patient with a history of 2 previous rhytidectomies. CONCLUSIONS: The hearing outcomes obtained in our study are similar to those published in the literature. Bonebridge((R)) represents an excellent alternative in the treatment of conductive or mixed hearing loss, and with a lower rate of complications.

81 Frenzel, H. (2018). "Hearing Rehabilitation in Congenital Middle Ear Malformation." Adv Otorhinolaryngol 81: 32-42.

Microtia and atresia cause significant conductive hearing loss of up to 60 dB HL. The bilateral cases suffer from severely restricted communication abilities and require immediate acoustic stimulation. There is also growing evidence that unilateral cases benefit from an early and selective stimulation of the affected side. Hearing restoration can be performed in selected cases of minor malformation by classic middle ear reconstruction. However, the majority of patients presumably benefit better from a hearing aid. There are 3 main types: active middle ear implants, active bone conduction implants and passive bone conduction implants. All implants improve speech perception, speech recognition, the signal-to-noise ratio and directional hearing. The extent varies among implants and requires further studies. Decision making on the implant type depends on the extent of malformation and hence the preoperative imaging. New scoring systems provide reliable risk stratification. Second it depends on the age of the patient. The active middle ear implants provide a selective stimulation of the affected side and are beneficial if implanted in the first years of life during the maturation period of the auditory system. In conclusion, hearing rehabilitation of congenital atresia should be performed as early as possible. This includes not only the bilateral but also the unilateral affected patients.

80 Rader, T., Stover, T., Lenarz, T., Maier, H., Zahnert, T., Beleites, T., Hagen, R., Mlynski, R. and Baumgartner, W. D. (2018). "Retrospective Analysis of Hearing-Impaired Adult Patients Treated With an Active Transcutaneous Bone Conduction Implant." Otol Neurotol 39(7): 874-881.

OBJECTIVE: To determine the therapeutic success and safety of an active transcutaneous bone conduction implant (tBCI) in adult patients with conductive or mixed hearing loss. STUDY DESIGN: Retrospective case review. SETTING: Five university hospitals in Frankfurt, Hannover, Dresden, Wurzburg, and Vienna. PATIENTS: Data were analyzed from 61 patients (31 women, 30 men) with a mean age of 50 years (min. 26, max. 80). Forty patients had mixed, and 21 conductive hearing loss. Typical etiologies were history of otitis media (n = 20) and cholesteatoma (n = 17). INTERVENTIONS: Implantation of the active tBCI. MAIN OUTCOME MEASURES: Data were analyzed for the following time points: up to 6 months postoperatively ("short-term"), 6 to 37 months postoperatively ("long-term"), and the last available measurement per patient ("most recent"). Pure-tone audiometry (air and bone conduction, AC and BC) and sound field thresholds with warble tones (WT), word recognition scores with Freiburger monosyllables (WRS), as well as speech reception thresholds (SRT) using the Oldenburg sentence test (OLSA) in quiet (SRT) and in noise (signal-to-noise ratio, SNR) were collected. RESULTS: No significant changes in air- and bone-conduction thresholds were observed after implantation. A mean WRS improvement of 54% using the active tBCI was shown at the short-term assessment, i.e., a mean score of 79% compared with 25% in the unaided condition. Results remained stable, with a mean score of 75% at the long-term assessment. SRT in noise improved by 3.6 dB SNR in the implanted ear at the short-term assessment. Overall six adverse events and four serious adverse events were reported, resulting in a rate of 9.84 and 6.56%, respectively. CONCLUSION: The tBCI clearly improves speech intelligibility in patients with conductive or mixed hearing loss, showing stable results up to 1 year post-implantation.

79 Lavilla Martin de Valmaseda, M. J., Cavalle Garrido, L., Huarte Irujo, A., Nunez Batalla, F., Manrique Rodriguez, M., Ramos Macias, A., de Paula Vernetta, C., Gil-Carcedo Sanudo, E., Lassaletta, L., Sanchez-Cuadrado, I., Espinosa Sanchez, J. M., Batuecas Caletrio, A. and Cenjor Espanol, C. (2018). "Clinical guideline on bone conduction implants." Acta Otorrinolaringol Esp.

INTRODUCTION AND GOALS: During the last decade there have been multiple and relevant advances in conduction and mixed hearing loss treatment. These advances and the appearance of new devices have extended the indications for bone-conduction implants. The Scientific Committee of Audiology of the Sociedad Espanola de Otorrinolaringologia y Cirugia de Cabeza y Cuello SEORL-CCC (Spanish Society of Otolaryngology and Head and Neck Surgery), together with the Otology and Otoneurology Committees, have undertaken a review of the current state of bone-conduction devices with updated information, to provide a clinical guideline on bone-conduction implants for otorhinolaryngology specialists, health professionals, health authorities and society in general. METHODS: This clinical guideline on bone-conduction implants contains information on the following: 1) Definition and description of bone-conduction devices; 2) Current and upcoming indications for bone conduction devices: Magnetic resonance compatibility; 3) Organization requirements for a bone-conduction implant programme. RESULTS AND CONCLUSIONS: The purpose of this guideline is to describe the different bone-conduction implants, their characteristics and their indications, and to provide coordinated instructions for all the above-mentioned agents for decision making within their specific work areas.

78 Der, C., Bravo-Torres, S. and Pons, N. (2018). "Active Transcutaneous Bone Conduction Implant: Middle Fossa Placement Technique in Children With Bilateral Microtia and External Auditory Canal Atresia." Otol Neurotol 39(5): e342-e348.

AIM: The aim of this study is to present the middle fossa technique (MFT) as an alternative for patients who cannot undergo traditional surgery for active transcutaneous bone conduction implants (ATBCI) due to their altered anatomy or desire for future aesthetic reconstruction. DESIGN: A case series descriptive study was designed. The MFT was developed. Preoperative and postoperative information from 24 patients with external auditory canal atresia (EACA) and implanted with ATBCI was reviewed. RESULTS: A total of 24 children with bilateral EACA received implants in the middle cranial fossa. Their average age was 12. Of these patients, eight had an associated congenital disorder: Goldenhar Syndrome, Treacher Collins Syndrome or the Pierre Robin Sequence. The average follow-up was at 17 months (ranging from between 2- and 36 mo) and there were no major complications. Four patients showed skin erythema at the processor site after turn on, which was solved by lowering the magnet strength. One patient had a scalp hematoma that required puncture drainage. The hearing thresholds went down on average from 66.5 to 25.2 dB 1 month after turn on. Speech recognition improved respectively from 29.4% without and 78.9% with a bone conduction hearing aid to 96.4%. CONCLUSION: MFT placement of the ATBCI was proven to be safe and effective and a viable option for treating pediatric patients with EACA who cannot receive implants at the sinodural angle or in the retrosigmoidal position because of their altered anatomy and/or desire for future aesthetic reconstruction.

77 Kulasegarah, J., Burgess, H., Neeff, M. and Brown, C. R. S. (2018). "Comparing audiological outcomes between the Bonebridge and bone conduction hearing aid on a hard test band: Our experience in children with atresia and microtia." Int J Pediatr Otorhinolaryngol 107: 176-182.

INTRODUCTION: To compare the audiological results of Bone Conduction Hearing Aid (BCHA) on hard test band and Bonebridge (BB) implant among children with microtia and atresia. METHODS: This is a retrospective review of patients with microtia and atresia who underwent BB implant insertion from September 2014 to February 2017 in Starship Children's Hospital. Preoperative audiological testing using a powered BCHA (Oticon Medical Ponto Pro Power) on a hard test band was used to compare post-operative hearing assessments with the BB. RESULTS: Ten microtia and atresia patients were treated with a BB of whom three were treated bilaterally The children were aged between 5 and 15 and all had moderate to moderately severe conductive hearing loss. For each ear tested and subsequently implanted, BB aided speech scores were equivalent to that obtained by a BCHA. The mean improvement of speech reception threshold level between unaided and BB was statistically significant ($p>0.0001$). Subjective questionnaire data indicated that BB implanted patients were performing within the norms of overall listening, both in quiet and in noise. Aided Speech In Noise (SIN) testing values were found to range from 0.8-6.5 for BCHA and 0.2-1.2 for BB and the difference was not statistically significant with a p value of 0.143. CONCLUSION: In audiologic assessments BB performs comparably to BCHA among children with microtia and atresia.

76 Arnold, H., Schulze, M., Wolpert, S., Hirt, B., Tropitzsch, A., Zimmermann, R., Radeloff, A., Lowenheim, H. and Reimann, K. (2018). "Positioning a Novel Transcutaneous Bone Conduction Hearing Implant: a Systematic Anatomical and Radiological Study to Standardize the Retrosigmoid Approach, Correlating Navigation-guided, and Landmark-based Surgery." Otol Neurotol 39(4): 458-466.

HYPOTHESIS: Anatomical and radiological evaluation improves safety and accuracy of the retrosigmoid approach for positioning a transcutaneous bone conduction implant and provides anatomical reference data for standardized, landmark-based implantation at this alternative site. BACKGROUND: The primary implantation site for the floating mass transducer of a novel bone conduction hearing implant is the mastoid. However, anatomical limitations or previous mastoid surgery may prevent mastoid implantation. Therefore, the retrosigmoid approach has been introduced as an alternative. METHODS: Mastoid and retrosigmoid implantation sites were radiologically identified and evaluated in preoperative computed tomography scans of anatomical head specimens. Navigation-guided implantation was then performed in the retrosigmoid site (n = 20). The optimal retrosigmoid position was determined in relation to both the asterion and the mastoid notch as surgical landmarks in an anatomical coordinate system. RESULTS: Preoperative radiological analysis revealed spatial limitations in the mastoid in 45% of the specimens. Navigation-guided retrosigmoid implantation was possible without affecting the sigmoid sinus in all the specimens. The optimal implantation site was located 1.9 +/- 0.1 cm posterior/1.7 +/- 0.1 cm inferior to the asterion and 3.3 +/- 0.2 cm posterior/2.1 +/- 0.1 cm superior to the mastoid notch.Retrosigmoid skull thickness was 6.6 +/- 0.4 mm, measured anatomically, 7.0 +/- 0.4 mm, measured radiologically and 6.7 +/- 0.5 mm, measured with the navigation software. CONCLUSION: The navigation-guided retrosigmoid approach seemed to be a reliable procedure in all the specimens. Measurements of bone thickness revealed the need for spacers in 95% of the specimens. Reference coordinates of the optimal implantation site are provided and can confirm image-guided surgery or facilitate orientation if a navigation system is not available.

75 Thomas, J. P., van Ackeren, K., Dazert, S., Todt, I., Prescher, A. and Voelter, C. (2018). "Transmastoid implantability of an active transcutaneous bone conduction implant in adults with regard to the underlying pathology: a radiological simulation study." Acta Otolaryngol 138(6): 530-536.

OBJECTIVES: To compare the feasibility of transmastoid implantation of an active transcutaneous bone conduction device (BCD) in the most important pathologies of the temporal bone and the impact of implant lifts in adulthood. METHODS: First, clinical predominant pathologies for implantation of this BCD were evaluated by a literature review. Then, high-resolution CT of 240 temporal bones with neuro-otologic diseases (NOD), chronic otitis media (COM), or cholesteatoma, respectively, were investigated regarding their implantability, using a radiological simulation program. RESULTS: Chronic inflammatory diseases (CID) of the temporal bone with or without cholesteatoma account for most adults scheduled for an active BCD. Complete implantation was possible in almost all cases with NOD as well as COM, requiring an implant lift in 50% of COM and 20% of NOD (p = .025) cases. In contrast, in subjects with cholesteatoma, implantation required an additional tool in 92% of cases, leading to 59% implantability rate in these temporal bones. CONCLUSION: Adult subjects with CID of the temporal bone show more limiting anatomical conditions for transmastoid placement of an active transcutaneous BCD than those with single-sided deafness. Implant lifts increase the implantability significantly in subjects with COM and particularly in those with cholesteatoma.

74 van Barneveld, D., Kok, H. J. W., Noten, J. F. P., Bosman, A. J. and Snik, A. F. M. (2018). "Determining fitting ranges of various bone conduction hearing aids." Clin Otolaryngol 43(1): 68-75.

OBJECTIVES: To define fitting ranges for nine bone conduction devices (BCDs) over different frequencies based on the device's maximum power output (MPO) and to validate the assessment of MPO of BCDs in the ear canal. BACKGROUND: Maximum power output (MPO) is an important characteristic when fitting BCDs. It is the highest output level a device can deliver and is one of the major determinants of a device's fitting range. A skull simulator can be used to verify MPO of percutaneous BCDs. No such simulator is available for active and passive transcutaneous devices. DESIGN: The MPO of nine different BCDs was assessed either by real-ear measurements and/or with skull simulator measurements. MAIN OUTCOME MEASURES: MPO and cross-validation of the methods using the Bland-Altman method. RESULTS: Percutaneous BCDs have higher MPO levels compared to active and passive transcutaneous devices. This results in a wide dynamic range of hearing for percutaneous devices. Moreover, the assessment of MPO by real-ear measurements was validated. CONCLUSION: Based on MPO data, fitting ranges were defined for nine BCDs over seven frequencies.

73 Nevoux, J., Coez, A. and Truy, E. (2017). "[Medical devices correcting the deafness: Hearing aids and auditory implants]." Presse Med 46(11): 1043-1054.

The management of deafness has become a major public health issue as their lack of detection has a deleterious effect in children and increases the risk factors for aggravation of other pathologies in adults. The detection of deafness remains a real challenge: in the newborn, systematic screening at birth is a good strategy, in adults, much remains to be done. The functional rehabilitation of deafness is based on the use of hearing aids by aerial or bone conduction or of

auditory implants. There are three types of auditory implants available: bone anchored hearing implants, middle ear implants and cochlear implants. Many actors, in particular social organizations, can intervene in the financial management of these medical devices.

72 Tisch, M. (2017). "Implantable hearing devices." GMS Curr Top Otorhinolaryngol Head Neck Surg 16: Doc06.

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 bone conduction implants (BCI), while percutaneous BCI systems are recommended also for moderate hearing loss. For combined hearing losses 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.

71 Zanetti, D. and Di Berardino, F. (2018). "A Bone Conduction Implantable Device as a Functional Treatment Option in Unilateral Microtia with Bilateral Stapes Ankylosis: A Report of Two Cases." Am J Case Rep 19: 82-89.

BACKGROUND Implantable devices have been proposed as an alternative to hearing aids and auditory canal reconstruction in patients with microtia (congenital aural atresia), which includes a malformation of the external and middle ear. This report is of two rare cases of microtia associated with congenital stapes ankylosis treated with an implantable device and describes the treatment outcomes. CASE REPORT Two siblings from Ecuador, a 29-year-old woman, and her 35-year-old brother, were born with unilateral type II microtia with bilateral external auditory canal atresia and conductive hearing loss. Pre-operatively, high-resolution computed tomography (HRCT) imaging was performed using FastView software to allow placement of a bone conduction-floating mass transducer (BC-FMT) to couple a Bonebridge bone conduction implant (BCI) system in both patients. Pure-tone audiometry (PTA) testing and speech audiology were performed. The Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Speech, Spatial and Qualities (SSQ) of hearing scale questionnaires and scoring systems were used. Following activation of the implantable device, both patients achieved improved bilateral conductive hearing with sound-field (field-free) thresholds >25 dB, and speech recognition scores >90%. In both cases, hearing improvement remained at three years following surgery. CONCLUSIONS To our knowledge, these are the first reported cases of microtia with congenital stapes ankylosis successfully treated with a bone conduction implantable device. Patients with microtia and stapes ankylosis who are reluctant to undergo surgery may benefit from unilateral or bilateral, short-term or long-term use of a Bonebridge bone conduction implantable device.

70 Canzi, P., Marconi, S., Manfrin, M., Magnetto, M., Carelli, C., Simoncelli, A. M., Fresa, D., Beltrame, M., Auricchio, F. and Benazzo, M. (2017). "From CT scanning to 3D printing technology: a new method for the preoperative planning of a transcutaneous bone-conduction hearing device." Acta Otorhinolaryngol Ital 38(3): 251-256.

SUMMARY: The aim of the present study was to assess the feasibility and utility of 3D printing technology in surgical planning of a transcutaneous bone-conduction hearing device

(Bonebridge((R))) (BB), focusing on the identification of the proper location and placement of the transducer. 3D printed (3DP) models of three human cadaveric temporal bones, previously submitted to CT scan, were created with the representation of a topographic bone thickness map and the sinus pathway on the outer surface. The 3DP model was used to detect the most suitable location for the BB. A 3DP transparent mask that faithfully reproduced the surface of both the temporal bone and the 3DP model was also developed to correctly transfer the designated BB area. The accuracy of the procedure was verified by CT scan: a radiological marker was used to evaluate the degree of correspondence of the transducer site between the 3DP model and the human temporal bone. The BB positioning was successfully performed on all human temporal bones, with no difficulties in finding the proper location of the transducer. A mean error of 0.13 mm was found when the transducer site of the 3DP model was compared to that of the human temporal bone. The employment of 3D printing technology in surgical planning of BB positioning showed feasible results. Further studies will be required to evaluate its clinical applicability.

69 Fan, X., Wang, Y., Wang, P., Fan, Y., Chen, Y., Zhu, Y. and Chen, X. (2017). "Aesthetic and hearing rehabilitation in patients with bilateral microtia-atresia." Int J Pediatr Otorhinolaryngol 101: 150-157.

OBJECTIVES: To evaluate the safety and efficacy of auricle reconstruction and active transcutaneous bone-conduction implantation in patients with bilateral microtia-atresia. DESIGN: Patients were chosen prospectively, with each being his/her own control. SETTING: The setting was a tertiary referral center. PARTICIPANTS: Twelve patients, aged 6-18 years, with bilateral microtia-atresia suffering from bilateral conductive hearing loss. All had an upper bone conduction threshold limit of 45 dB HL at frequencies of 0.5-4 kHz. MAIN OUTCOME MEASURES: Patient satisfaction with the reconstructed auricle was rated as highly satisfactory, basically satisfactory, or unsatisfactory. Mean pure-tone thresholds and speech audiometry test results were compared among patients unaided, with a soft-band Bonebridge, and with an implanted Bonebridge. Subjective satisfaction was analyzed using three questionnaires: the Abbreviated Profile of Hearing Aid Benefit (APHAB), the Glasgow children's benefit inventory (GCBI), and the International Outcome Inventory for Hearing Aids (IOI-HA). RESULTS: All patients who underwent auricle reconstruction expressed satisfaction with their appearance. The mean pure-tone thresholds of unaided patients and those with soft-band and implanted Bonebridge were 55.25 +/- 3.43 dBHL, 31.37 +/- 3.03 dBHL, and 21.25 +/- 2.16 dBHL, respectively. The mean speech discrimination scores measured in a sound field with a presentation level of 65 dB SPL under these three conditions were 46.0 +/- 0.11%, 80.0 +/- 0.09%, and 94.0 +/- 0.02%, respectively. Questionnaires demonstrated patients' benefits and satisfaction with this surgery. CONCLUSIONS: The surgical procedure involving auricle reconstruction and Bonebridge implantation was safe and effective for patients with bilateral microtia-atresia, solving both appearance and hearing problems.

68 Bravo-Torres, S., Der-Mussa, C. and Fuentes-Lopez, E. (2018). "Active transcutaneous bone conduction implant: audiological results in paediatric patients with bilateral microtia associated with external auditory canal atresia." Int J Audiol 57(1): 53-60.

OBJECTIVE: To describe, in terms of functional gain and word recognition, the audiological results of patients under 18 years of age implanted with the active bone conduction implant, Bonebridge. DESIGN: Retrospective case studies conducted by reviewing the medical records of

patients receiving implants between 2014 and 2016 in the public health sector in Chile. STUDY SAMPLE: All patients implanted with the Bonebridge were included (N = 15). Individuals who had bilateral conductive hearing loss, secondary to external ear malformations, were considered as candidates. RESULTS: The average hearing threshold one month after switch on was 25.2 dB (95%CI 23.5-26.9). Hearing thresholds between 0.5 and 4 kHz were better when compared with bone conduction hearing aids. Best performance was observed at 4 kHz, where improvements to hearing were observed throughout the adaptation process. There was evidence of a significant increase in the recognition of monosyllables. CONCLUSIONS: The Bonebridge implant showed improvements to hearing thresholds and word recognition in paediatric patients with congenital conductive hearing loss.

67 Weiss, B. G., Bertlich, M., Scheele, R., Canis, M., Jakob, M., Sohns, J. M. and Ihler, F. (2017). "Systematic radiographic evaluation of three potential implantation sites for a semi-implantable bone conduction device in 52 patients after previous mastoid surgery." Eur Arch Otorhinolaryngol 274(8): 3001-3009.

The aim of this study was the evaluation of three localizations for the implantation of a semi-implantable transcutaneous bone conduction device after previous mastoid surgery. This is a retrospective review of electronic datasets of cranial computed tomography studies. The study setting is one tertiary referral center and included 52 consecutive adult patients (60 temporal bones) with a history of mastoid surgery. The intervention was virtual placement of the device with a planning software within the remaining mastoid as well as dorsal of the sigmoid sinus and caudal of the transverse sinus (retrosigmoidal localization) and dorsocranial of the parietomastoid suture and cranial of the transverse sinus (parietal localization). The main outcome measure included dimensions of the bone for the reception of implant and screws, relative localization of dura mater or sinus sigmoideus, distance to the cochlea, thickness of the epicranium and classification of implantation as possible or impossible. Implantation within the remaining mastoid was deemed possible in 35 mastoid bones (58.3%). The best-suited alternative localization was retrosigmoidal in 22 (42.3%) and parietal in 29 patients (55.8%). The mean distance from the implantation site to the cochlea was lowest with on average 41.2 +/- 3.1 mm from within the remaining mastoid. The differences in distance from the cochlea to the alternative localizations were each statistically significant ($p < 0.01$, ANOVA/Bonferroni t test). The retrosigmoidal and parietal localizations are suitable alternative implantation sites. The application of spacers may prevent contact to the sinuses or dura. Preoperative CT-based planning is recommended in cases of previous mastoid surgery. LEVEL OF EVIDENCE: 4 (case series).

66 Zradzinski, P., Karpowicz, J., Gryz, K. and Leszko, W. (2017). "[Evaluation of hazards caused by magnetic field emitted from magnetotherapy applicator to the users of bone conduction hearing prostheses]." Med Pr 68(4): 469-477.

BACKGROUND: Low frequency magnetic field, inducing electrical field (E_{in}) inside conductive structures may directly affect the human body, e.g., by electrostimulation in the nervous system. In addition, the spatial distribution and level of E_{in} are disturbed in tissues neighbouring the medical implant. MATERIAL AND METHODS: Numerical models of magneto-therapeutic applicator (emitting sinusoidal magnetic field of frequency 100 Hz) and the user of hearing implant (based on bone conduction: Bonebridge type - IS-BB or BAHA (bone anchorde

hearing aid) type - IS-BAHA) were worked out. Values of E_{in} were analyzed in the model of the implant user's head, e.g., physiotherapist, placed next to the applicator. RESULTS: It was demonstrated that the use of IS-BB or IS-BAHA makes electromagnetic hazards significantly higher (up to 4-fold) compared to the person without implant exposed to magnetic field heterogeneous in space. Hazards for IS-BAHA users are higher than those for IS-BB users. It was found that applying the principles of directive 2013/35/EU, at exposure to magnetic field below exposure limits the direct biophysical effects of exposure in hearing prosthesis users may exceed relevant limits. Whereas applying principles and limits set up by Polish labor law or the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines, the compliance with the exposure limits also ensures the compliance with relevant limits of electric field induced in the body of hearing implant user. CONCLUSIONS: It is necessary to assess individually electromagnetic hazard concerning hearing implant users bearing in mind significantly higher hazards to them compared to person without implant or differences between levels of hazards faced by users of implants of various structural or technological solutions. Med Pr 2017;68(4):469-477.

65 Zhao, S. Q., Ren, R., Han, D. M., Li, Y., Ma, X. B., Wang, D. N. and Li, Y. L. (2017). "[The implantation of Bonebridge in bilateral congenital malformation of external and middle ear]." Zhonghua Er Bi Yan Hou Tou Jing Wai Ke Za Zhi 52(7): 512-516.

Objective: To evaluate the auditory efficacy of Bonebridge implantation in patients with bilateral congenital malformation of external and middle ear. Methods: Eleven cases (6 males and 5 females) had unilateral Bonebridge implantation. The age ranged from 8 to 26 and the average age was 16.9. Seven to ten days after operation, the first fitting was undergone. In acoustic sound field, the average auditory thresholds were respectively measured for unaided ears and Bonebridge implanted ears by pure tone auditory (PTA, 0.25, 0.5, 1, 2 and 4 kHz). For the group over 12-year-old, MSTM was applied to evaluate speech discrimination score (SDS). For the other cases, MLNT was used as the test material. The auditory efficacy post Bonebridge implantation would be analyzed and evaluated by comparing the differences between unaided ears and Bonebridge implanted ears. Results: The bone conduction audibility threshold after Bonebridge implantation was as well as the preoperative. The auditory threshold with Bonebridge aided was improved to 25-35 dB HL, when compared to that of the unaided ears in the sound field. The SDS in the group over 12-year-old was improved about 50%; the efficacy was slightly limited for the other two cases (both less than 12 years old). Statistical analysis showed that there were significant differences between unaided ears and Bonebridge implanted ears in the sound field and SDS($P<0.05$). Conclusions: The auditory efficacy of Bonebridge is significant and noticeable in patients with bilateral congenital malformation of external and middle ear. Bonebridge provides a new and effective way for patient with congenital malformation of external and middle ear to reconstruct hearing.

64 Mukherjee, P., Cheng, K., Flanagan, S. and Greenberg, S. (2017). "Utility of 3D printed temporal bones in pre-surgical planning for complex BoneBridge cases." Eur Arch Otorhinolaryngol 274(8): 3021-3028.

With the advent of single-sided hearing loss increasingly being treated with cochlear implantation, bone conduction implants are reserved for cases of conductive and mixed hearing loss with greater complexity. The BoneBridge (BB, MED-EL, Innsbruck, Austria) is an active fully implantable device with no attenuation of sound energy through soft tissue. However, the floating

mass transducer (FMT) part of the device is very bulky, which limits insertion in complicated ears. In this study, 3D printed temporal bones of patients were used to study its utility in preoperative planning on complicated cases. Computed tomography (CT) scans of 16 ears were used to 3D print their temporal bones. Three otologists graded the use of routine preoperative planning provided by MED-EL and that of operating on the 3D printed bone of the patient. Data were collated to assess the advantage and disadvantage of the technology. There was a statistically significant benefit in using 3D printed temporal bones to plan surgery for difficult cases of BoneBridge surgery compared to the current standard. Surgeons preferred to have the printed bones in theatre to plan their drill sites and make the transition of the planning to the patient's operation more precise. 3D printing is an innovative use of technology in the use of preoperative planning for complex ear surgery. Surgical planning can be done on the patient's own anatomy which may help to decrease operating time, reduce cost, increase surgical precision and thus reduce complications.

63 Tisch, M. (2017). "[Implantable Hearing Devices]." Laryngorhinootologie 96(S 01): S84-S102.

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.

62 Salcher, R., Zimmermann, D., Giere, T., Lenarz, T. and Maier, H. (2017). "Audiological Results in SSD With an Active Transcutaneous Bone Conduction Implant at a Retrosigmoidal Position." Otol Neurotol 38(5): 642-647.

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.

61 Pirlich, M., Dietz, A., Meuret, S. and Hofer, M. (2017). "[Implantable Bone Conduction and Active Middle Ear Devices]." Laryngorhinootologie 96(2): 120-129.

In case of audiological and/or anatomical limitations in the provision of conventional hearing aids, semi- or fully-implantable hearing systems represent a modern therapy 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.

60 Mandavia, R., Carter, A. W., Haram, N., Mossialos, E. and Schilder, A. G. M. (2017). "An evaluation of the quality of evidence available to inform current bone conducting hearing device national policy." Clin Otolaryngol 42(5): 1000-1024.

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.

59 Vyskocil, E., Liepins, R., Kaider, A., Blineder, M. and Hamzavi, S. (2017). "Sound Localization in Patients With Congenital Unilateral Conductive Hearing Loss With a Transcutaneous Bone Conduction Implant." Otol Neurotol 38(3): 318-324.

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.

58 Weiss, R., Leinung, M., Baumann, U., Weissgerber, T., Rader, T. and Stover, T. (2017). "Improvement of speech perception in quiet and in noise without decreasing localization abilities with the bone conduction device Bonebridge." Eur Arch Otorhinolaryngol 274(5): 2107-2115.

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 (+/-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 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.

57 Kong, T. H., Park, Y. A. and Seo, Y. J. (2017). "Image-guided implantation of the Bonebridge with a surgical navigation: A feasibility study." Int J Surg Case Rep 30: 112-117.

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.

56 Vyskocil, E., Riss, D., Arnoldner, C., Hamzavi, J. S., Liepins, R., Kaider, A., Honeder, C., Fumicz, J., Gstoettner, W. and Baumgartner, W. D. (2017). "Dura and sinus compression with a transcutaneous bone conduction device - hearing outcomes and safety in 38 patients." Clin Otolaryngol 42(5): 1033-1038.

55 Monini, S., Bianchi, A., Talamonti, R., Atturo, F., Filippi, C. and Barbara, M. (2017). "Patient satisfaction after auditory implant surgery: ten-year experience from a single implanting unit center." Acta Otolaryngol 137(4): 389-397.

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)((R)) and Bonebridge((R)) 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.

54 Ihler, F., Blum, J., Berger, M. U., Weiss, B. G., Welz, C. and Canis, M. (2016). "The Prediction of Speech Recognition in Noise With a Semi-Implantable Bone Conduction Hearing System by External Bone Conduction Stimulation With Headband: A Prospective Study." Trends Hear 20.

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.

53 Eberhard, K. E., Olsen, S. O., Miyazaki, H., Bille, M. and Caye-Thomasen, P. (2016). "Objective and Subjective Outcome of a New Transcutaneous Bone Conduction Hearing Device: Half-year Follow-up of the First 12 Nordic Implantations." Otol Neurotol 37(3): 267-275.

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 23dB. SDS was increased by 40% at 50dB, by 34% at 65dB, 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.

52 Volkenstein, S., Thomas, J. P. and Dazert, S. (2016). "[Bone Conduction and Active Middle Ear Implants]." Laryngorhinootologie 95(5): 352-363.

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.

51 Lee, J. M., Chang, J. W., Choi, J. Y., Chang, W. S. and Moon, I. S. (2016). "Hearing Restoration in Neurofibromatosis Type II Patients." Yonsei Med J 57(4): 817-823.

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.

50 Schmerber, S., Deguine, O., Marx, M., Van de Heyning, P., Sterkers, O., Mosnier, I., Garin, P., Godey, B., Vincent, C., Venail, F., Mondain, M., Deveze, A., Lavieille, J. P. and Karkas, A. (2017). "Safety and effectiveness of the Bonebridge transcutaneous active direct-drive bone-conduction hearing implant at 1-year device use." Eur Arch Otorhinolaryngol 274(4): 1835-1851.

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.

49 Baumgartner, W. D., Hamzavi, J. S., Boheim, K., Wolf-Magele, A., Schlogel, M., Riechelmann, H., Zorowka, P., Koci, V., Keck, T., Potzinger, P. and Sprinzl, G. (2016). "A New Transcutaneous Bone Conduction Hearing Implant: Short-term Safety and Efficacy in Children." Otol Neurotol 37(6): 713-720.

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 4000 Hz. 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 8 kHz) 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.

48 Gerdes, T., Salcher, R. B., Schwab, B., Lenarz, T. and Maier, H. (2016). "Comparison of Audiological Results Between a Transcutaneous and a Percutaneous Bone Conduction Instrument in Conductive Hearing Loss." Otol Neurotol 37(6): 685-691.

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 (OLSA) 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.

47 Zernotti, M. E., Di Gregorio, M. F., Galeazzi, P. and Tabernero, P. (2016). "Comparative outcomes of active and passive hearing devices by transcutaneous bone conduction." Acta Otolaryngol 136(6): 556-558.

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.

46 Wang, P., Fan, X. and Fan, Y. (2016). "[The research progress of Treacher Collins syndrome]." Lin Chung Er Bi Yan Hou Tou Jing Wai Ke Za Zhi 30(4): 333-338.

Treacher Collins syndrome (TCS, OMIM 154500), also known as Franceschetti-Klein syndrome, is a rare disorder that affects the first and second branchial arches. The estimated incidence is 1/50 000 live births. Mutations in TCOF1 (78%-93%) and POLR1C or POLR1D (8%) cause the disease. Most of TCS cases are inherited in a dominant pattern, while a small proportion are inherited in a recessive pattern. TCS has a variable phenotype with typical clinical characteristics including downward-slant of palpebral fissure, malar hypoplasia, mandibular hypoplasia and microtia. TCS management is a multidisciplinary affair, as interventions range from reconstructive to psychosocial. For hearing rehabilitation, TCS patients may have the choices of BAHA, ponto, vibrant soundbridge or bonebridge implantation. In this review, we summarize the TCS clinical malformations, diagnosis, genetics, management and auditory rehabilitation.

45 Lassaletta, L., Calvino, M., Zernotti, M. and Gavilan, J. (2016). "Postoperative pain in patients undergoing a transcutaneous active bone conduction implant (Bonebridge)." Eur Arch Otorhinolaryngol 273(12): 4103-4110.

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.

44 Pai, I., Rojas, P., Jiang, D., Obholzer, R. and Coward, T. (2017). "The use of 3D printed external and internal templates for Bonebridge implantation - technical note." Clin Otolaryngol 42(5): 1118-1120.

43 Ghoncheh, M., Lilli, G., Lenarz, T. and Maier, H. (2016). "Outer ear canal sound pressure and bone vibration measurement in SSD and CHL patients using a transcutaneous bone conduction instrument." Hear Res 340: 161-168.

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.

42 Sprinzl, G. M. and Wolf-Magele, A. (2016). "The Bonebridge Bone Conduction Hearing Implant: indication criteria, surgery and a systematic review of the literature." Clin Otolaryngol 41(2): 131-143.

BACKGROUND: Hearing aids and implants employing bone conduction (BC) 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 (SSD). 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 SSD. 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 were carried out by a single reviewer with any uncertainties resolved with consulting a second reviewer. Studies were synthesised 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 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 BCI system Bonebridge provides a valuable and stable audiological benefit to patients suffering from conductive or mixed hearing loss and SSD. 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.

41 Rahne, T., Schilde, S., Seiwerth, I., Radetzki, F., Stoevesandt, D. and Plontke, S. K. (2016). "Mastoid Dimensions in Children and Young Adults: Consequences for the Geometry of Transcutaneous Bone-Conduction Implants." Otol Neurotol 37(1): 57-61.

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.

40 Rahne, T. and Plontke, S. K. (2016). "[Device-based treatment of mixed hearing loss: An audiological comparison of current hearing systems]." HNO 64(2): 91-100.

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.

39 Kim, M. (2015). "Bonebridge Implantation for Conductive Hearing Loss in a Patient with Oval Window Atresia." J Int Adv Otol 11(2): 163-166.

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.

38 Law, E. K., Bhatia, K. S., Tsang, W. S., Tong, M. C. and Shi, L. (2016). "CT pre-operative planning of a new semi-implantable bone conduction hearing device." Eur Radiol 26(6): 1686-1695.

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. KEY POINTS: * Preoperative temporal bone CT is essential for determining Bonebridge device suitability. * Mastoid under-pneumatisation and prior mastoidectomy predict a retrosigmoid Bonebridge position. * 3D simulation software is recommended for precise device positioning.

37 Mueller, M., Salcher, R., Majdani, O., Lenarz, T. and Maier, H. (2015). "Electro-Mechanical Stimulation of the Cochlea by Vibrating Cochlear Implant Electrodes." Otol Neurotol 36(10): 1753-1758.

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 </=1 kHz. At frequencies </=1 kHz stimulation by the BB FMT resulted in a flat and potentially highest SFP displacement amplitude of approximately -40 dB re mum at 1 VRMS input voltage. Estimated equivalent sound pressure levels achieved by the BB FMT prototype were approximately 83-90 eq. dB SPL at frequencies </=1 kHz. CONCLUSION: The feasibility of cochlear stimulation by vibrating electrodes was shown although the achieved output level at frequencies </=1 kHz was too low for EAS applications.

36 Bento, R. F., Lopes, P. T. and Cabral Junior Fda, C. (2015). "Bonebridge Bone Conduction Implant." Int Arch Otorhinolaryngol 19(4): 277-278.

35 Zernotti, M. E. and Sarasty, A. B. (2015). "Active Bone Conduction Prosthesis: Bonebridge(TM)." Int Arch Otorhinolaryngol 19(4): 343-348.

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 Amade 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.

34 Gavilan, J., Adunka, O., Agrawal, S., Atlas, M., Baumgartner, W. D., Brill, S., Bruce, I., Buchman, C., Caversaccio, M., De Bodt, M. T., Dillon, M., Godey, B., Green, K., Gstoettner, W., Hagen, R., Hagr, A., Han, D., Kameswaran, M., Karltorp, E., Kompis, M., Kuzovkov, V., Lassaletta, L., Li, Y., Lorens, A., Martin, J., Manoj, M., Mertens, G., Mlynski, R., Mueller, J., O'Driscoll, M., Parnes, L., Pulibalathingal, S., Radeloff, A., Raine, C. H., Rajan, G., Rajeswaran, R., Schmutzhard, J., Skarzynski, H., Skarzynski, P., Sprinzl, G., Staecker, H., Stephan, K., Sugarova, S., Tavora, D., Usami, S., Yanov, Y., Zernotti, M., Zorowka, P. and de Heyning, P. V. (2015). "Quality standards for bone conduction implants." Acta Otolaryngol 135(12): 1277-1285.

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 HEARRING 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.

33 Rainsbury, J. W., Williams, B. A., Gulliver, M. and Morris, D. P. (2015). "Preoperative headband assessment for semi-implantable bone conduction hearing devices in conductive hearing loss: is it useful or misleading?" Otol Neurotol 36(2): e58-62.

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.

32 Laske, R. D., Roosli, C., Pfiffner, F., Veraguth, D. and Huber, A. M. (2015). "Functional Results and Subjective Benefit of a Transcutaneous Bone Conduction Device in Patients With Single-Sided Deafness." Otol Neurotol 36(7): 1151-1156.

OBJECTIVE: To analyze speech discrimination scores and subjective benefit of a transcutaneous bone conduction device (tBCD) in adults with single-sided deafness (SSD). 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.

31 Hassepass, F., Bulla, S., Aschendorff, A., Maier, W., Traser, L., Steinmetz, C., Wesarg, T. and Arndt, S. (2015). "The bonebridge as a transcutaneous bone conduction hearing system: preliminary surgical and audiological results in children and adolescents." Eur Arch Otorhinolaryngol 272(9): 2235-2241.

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.

30 Wimmer, W., Gerber, N., Guignard, J., Dubach, P., Kompis, M., Weber, S. and Caversaccio, M. (2015). "Topographic bone thickness maps for Bonebridge implantations." Eur Arch Otorhinolaryngol 272(7): 1651-1658.

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.

29 Reinfeldt, S., Hakansson, B., Taghavi, H. and Eeg-Olofsson, M. (2015). "New developments in bone-conduction hearing implants: a review." Med Devices (Auckl) 8: 79-93.

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.

28 Jovankovicova, A., Stanik, R., Kunzo, S., Majakova, L. and Profant, M. (2015). "Surgery or implantable hearing devices in children with congenital aural atresia: 25 years of our experience." Int J Pediatr Otorhinolaryngol 79(7): 975-979.

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 30 dB). 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 12 dB 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 (30-35 dB 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.

27 Doshi, J. and McDermott, A. L. (2015). "Bone anchored hearing aids in children." Expert Rev Med Devices 12(1): 73-82.

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.

26 Da Silva, V. A. R., Guimares, A. C., Cathilho, A. M. and Crespo, A. N. (2015). "Bonebridge a New Alternative of Hearing Rehabilitation for Patients with Single Sided Deafness or with Conductive or Mixed Hearing Loss." Austin J Otolaryngol. 2(3): 1032.

For many years patients with unilateral profound sensorineural hearing loss, who underwent radical mastoidectomy or had middle ear malformations, had few auditory rehabilitation options. Only the BAHA (Bone Anchored Hearing Aid) was a viable hearing aid for the treatment of all these diseases. In recent years, some new implantable prostheses anchored to the temporal bone were developed to treat these diseases: BAHA (CochlearTM), PONTO (Oticon MedicalTM), Alpha Hearing System (SophonoTM), Bonebridge (MED TLE) and BAHA Attract (CochlearTM). We can divide them into percutaneous bone transmission hearing aids (BAHA and PONTO) and subcutaneous (Alpha Hearing System, Bonebridge and BAHA Attract. The percutaneous transmission devices consist of a fixed element of titanium, screw and a sound processor. Titanium device is implanted in the patient's skull bone and connected to a percutaneous pillar and the sound processor. The sound processor converts acoustic energy into vibration that is transmitted through the piece of titanium to the skull, and then directly to the cochlea. These devices are widely used in the world, but there are risks of complications related to the device and the surgery

25 Bianchin, G., Bonali, M., Russo, M. and Tribi, L. (2015). "Active bone conduction system: outcomes with the Bonebridge transcutaneous device." ORL J Otorhinolaryngol Relat Spec 77(1): 17-26.

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.

24 Wolf, M., Agterberg, M., Snik, A., Mylanus, E., Hol, M. and Hempel, J. (2015). "Vibrant Soundbridge and Bonebridge: Bilateral Application in a Child with Bilateral Congenital Ear Canal Atresia." British Journal of Medicine and Medical Research 5(5): 705-710.

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.

23 Yu, J. K., Wong, L. L., Tsang, W. S. and Tong, M. C. (2014). "A tutorial on implantable hearing amplification options for adults with unilateral microtia and atresia." Biomed Res Int 2014: 703256.

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 percuteaneous 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.

22 Todt, I., Lamecker, H., Ramm, H. and Ernst, A. (2014). "A computed tomographic data-based vibrant bonebridge visualization tool." Cochlear Implants Int 15 Suppl 1: S72-74.

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.

21 Takumi, Y., Matsumoto, N., Cho, B., Ono, H., Mori, K., Tsukada, K., Ichinose, A., Yoshimura, H., Iwasaki, S., Komune, S. and Usami, S. (2014). "A clinical experience of 'STAMP' plate-guided Bonebridge implantation." Acta Otolaryngol 134(10): 1042-1046.

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.

20 Steinmetz, C., Mader, I., Arndt, S., Aschendorff, A., Laszig, R. and Hassepass, F. (2014). "MRI artefacts after Bonebridge implantation." Eur Arch Otorhinolaryngol 271(7): 2079-2082.

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.

19 Schnabl, J., Wolf-Magele, A., Pok, S. M., Schoerg, P., Hirtler, L., Schloegel, M. and Sprinzl, G. (2014). "Intraoperative measurement for a new transcutaneous bone conduction hearing implant." Otol Neurotol 35(7): 1242-1247.

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.

18 Riss, D., Arnoldner, C., Baumgartner, W. D., Blineder, M., Flak, S., Bachner, A., Gstoettner, W. and Hamzavi, J. S. (2014). "Indication criteria and outcomes with the Bonebridge transcutaneous bone-conduction implant." Laryngoscope 124(12): 2802-2806.

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.

17 Rahne, T., Seiwerth, I., Gotze, G., Heider, C., Radetzki, F., Herzog, M. and Plontke, S. K. (2015). "Functional results after Bonebridge implantation in adults and children with conductive and mixed hearing loss." Eur Arch Otorhinolaryngol 272(11): 3263-3269.

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.

16 Plontke, S. K., Radetzki, F., Seiwerth, I., Herzog, M., Brandt, S., Delank, K. S. and Rahne, T. (2014). "Individual computer-assisted 3D planning for surgical placement of a new bone conduction hearing device." Otol Neurotol 35(7): 1251-1257.

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.

15 Mertens, G., Desmet, J., Snik, A. F. and Van de Heyning, P. (2014). "An experimental objective method to determine maximum output and dynamic range of an active bone conduction implant: the Bonebridge." Otol Neurotol 35(7): 1126-1130.

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.

14 Matsumoto, N., Takumi, Y., Cho, B., Mori, K., Usami, S., Yamashita, M., Hashizume, M. and Komune, S. (2015). "Template-guided implantation of the Bonebridge: clinical experience." Eur Arch Otorhinolaryngol 272(12): 3669-3675.

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.

13 Manrique, M., Sanhueza, I., Manrique, R. and de Abajo, J. (2014). "A new bone conduction implant: surgical technique and results." Otol Neurotol 35(2): 216-220.

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.

12 Lo, J. F., Tsang, W. S., Yu, J. Y., Ho, O. Y., Ku, P. K. and Tong, M. C. (2014). "Contemporary hearing rehabilitation options in patients with aural atresia." Biomed Res Int 2014: 761579.

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.

11 Lassaletta, L., Sanchez-Cuadrado, I., Munoz, E. and Gavilan, J. (2014). "Retrosigmoid implantation of an active bone conduction stimulator in a patient with chronic otitis media." Auris Nasus Larynx 41(1): 84-87.

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.

10 Ihler, F., Volbers, L., Blum, J., Matthias, C. and Canis, M. (2014). "Preliminary functional results and quality of life after implantation of a new bone conduction hearing device in patients with conductive and mixed hearing loss." Otol Neurotol 35(2): 211-215.

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.

9 Cho, B., Matsumoto, N., Mori, M., Komune, S. and Hashizume, M. (2014). "Image-guided placement of the Bonebridge without surgical navigation equipment." Int J Comput Assist Radiol Surg 9(5): 845-855.

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.

8 Tsang, W. S., Yu, J. K., Bhatia, K. S., Wong, T. K. and Tong, M. C. (2013). "The Bonebridge semi-implantable bone conduction hearing device: experience in an Asian patient." J Laryngol Otol 127(12): 1214-1221.

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.

7 Sprinzl, G., Lenarz, T., Ernst, A., Hagen, R., Wolf-Magele, A., Mojallal, H., Todt, I., Mlynski, R. and Wolframm, M. D. (2013). "First European multicenter results with a new transcutaneous bone conduction hearing implant system: short-term safety and efficacy." Otol Neurotol 34(6): 1076-1083.

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.

6 Nospes, S., Mann, W. and Keilmann, A. (2013). "[Magnetic resonance imaging in patients with magnetic hearing implants: overview and procedural management]." Radiologe 53(11): 1026-1032.

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 to 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.

5 Huber, A. M., Sim, J. H., Xie, Y. Z., Chatzimichalis, M., Ullrich, O. and Röösli, C. (2013). "The Bonebridge: preclinical evaluation of a new transcutaneously-activated bone anchored hearing device." Hear Res 301: 93-99.

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

4 Güldner, C., Heinrichs, J., Weiss, R., Zimmermann, A. P., Dassinger, B., Bien, S., Werner, J. A. and Diogo, I. (2013). "Visualisation of the Bonebridge by means of CT and CBCT." Eur J Med Res 18: 30.

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

inner ear, inner auditory canal) was exhibited in both the CT and in the CBCT. CONCLUSION: The Bonebridge can be excellently imaged with the radiological imaging technologies of CT and CBCT. In the process, CBCT shows discrete advantages in comparison with CT. No relevant restrictions in image quality in the evaluation of the bony structures of the petrosal bones could be seen.

3 Canis, M., Ihler, F., Blum, J. and Matthias, C. (2013). "[CT-assisted navigation for retrosigmoidal implantation of the Bonebridge]." HNO 61(12): 1038-1044.

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.

2 Barbara, M., Perotti, M., Gioia, B., Volpini, L. and Monini, S. (2013). "Transcutaneous bone-conduction hearing device: audiological and surgical aspects in a first series of patients with mixed hearing loss." Acta Otolaryngol 133(10): 1058-1064.

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

1 Claros, P., Diouf, M. S. and Claros, A. (2012). "[Setting up a "Bonebridge"]." Rev Laryngol Otol Rhinol (Bord) 133(4-5): 217-220.

Hearing rehabilitation after bilateral radical mastoidectomy has different options. The Bonebridge is a new type of middle ear implant bone conduction. It leaves the external ear canal opened and offers acoustic and aesthetic advantages that make it a new alternative of choice. We report our first case of Bonebridge implanted on a 17 years old patient. He had bilateral conductive hearing loss secondary to a bilateral radical mastoidectomy with open technique and meatoplasty for

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

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