

# VIBRANT SOUNDBRIDGE Bibliography

With  
abstracts



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- 297 Park YA, Kong TH, Chang JS, Seo Y. J. (2017) Importance of adhesiolysis in revision surgery for Vibrant Soundbridge device failures at the short incus process. *Eur Arch Otorhinolaryngol.* [Epub ahead of print].

Abstract:

The objectives of the study were to report a vibrant soundbridge (VSB) implant revision surgical method involving adhesiolysis at the short incus process under local anesthesia and demonstrate successful hearing performance after surgery. Three cases of VSB surgery, performed in 2016, were enrolled. All cases had diagnoses of device failure. This 'seven-incision line' exposed the floating mass transducer directly, after which the three steps (adhesiolysis, curettage, and hydrocortisone injection) were performed. Upon fitting the VSB, sound fields were evaluated immediately and at 3 months after the revision. During the revisions of surgery, all patients achieved immediate hearing gains and noticed differences in the outer devices with different amplifications. Satisfactory improvements in hearing thresholds and speech recognition abilities were confirmed by improvements of 20-30 dB in hearing loss 3 months after revision surgery. The VSB implant revision surgical method involving adhesiolysis is safe and efficient for patients who experience a VSB device failure. This method will reduce the requirement for surgery under general anesthesia, reduce the overall period of clinical therapy and, therefore, minimize patients' medical costs.

- 296 Jung J, Kim JW, Moon IS, Kim SH, Choi JY. (2017) Vibrant Soundbridge can improve the most comfortable listening level in sensorineural hearing loss: our experience of 61 patients. *Clin Otolaryngol.* [Epub ahead of print].

Abstract:

In auditory rehabilitation, the most comfortable listening level (MCL) is important because the conversation partners of patients with hearing impairment are often individuals with normal hearing. Thus, normalizing MCL can help patients with hearing loss to reduce the communication handicap with individuals with normal hearing. While active middle ear implants demonstrate comparable performance with conventional hearing aids (HA) with regard to functional hearing gain and speech intelligibility, little is known about the effect of middle ear implants on the MCL. Therefore, we evaluated the MCL of active middle-ear implants compared with that of conventional HA in patients with moderate and moderate-to-severe sensorineural hearing loss (SNHL). We found that the Vibrant Soundbridge (VSB) active middle-ear implant had a pure-tone threshold similar to conventional HA. However, the MCL in VSB-aided conditions was significantly lower (by ~10 dB) than for HA-aided conditions. In addition, the significant improvement in MCL was attributable to robust amplifications at 1 kHz and 2 kHz compared with conventional HA. VSB implantation nearly normalized MCL for patients with SNHL. In terms of normalizing MCL, VSB implantation is a good choice for hearing rehabilitation in patients with SNHL. This article is protected by copyright. All rights reserved.

- 295 Labassi, S. Beliaeff, M. Pean, V. Van de Heyning, P. (2017) The Vibrant Soundbridge(R) middle ear implant: A historical overview. *Cochlear Implants Int.* [Epub ahead of print].

**Abstract:**

OBJECTIVE: To present a historical overview of the Vibrant Soundbridge(R) (VSB) middle ear implant (MEI), since its beginning in the 1990s to date and to describe its course and contemplate what it might become in the future. HISTORY: MEIs started to take form in researchers' mind in the 1930s with the first experiment of Wilska. In the 1970s, several devices, such as the Goode and Perkins', the Maniglia's, or the Hough and Dormer's were created but remained prototypes. It is only in the 1990s the devices that emerged remained on the market. In 1994, Symphonix, Inc. was created and aimed to manufacture and commercialize its semi-implantable MEI, the VSB. The principle of the VSB lies on a direct drive of the sound to a vibratory structure of the middle ear through an electromagnetic transducer, the floating mass transducer (FMT). The particularity of the system VSB is the simplicity of the transducer which is made of both the magnet and the coil; thus, the FMT, fixed on a vibrating middle ear structure, mimics the natural movement of the ossicular chain by moving in the same direction. The goal of the VSB was to give an alternative to patients with mild-to-severe sensorineural hearing loss who could not wear hearing aids (HAs) or who were unsatisfied conventional HA users. Subsequent to Tjellstrom's experiment in 1997, implantations started to include etiologies such as otosclerosis, radical mastoidectomy, failed ossiculoplasty/tympanoplasty, and atresia. Nowadays, the VSB, with more than 20 years of experience, is the oldest and most used middle ear implant worldwide. It is well acknowledged that the straightforward design and reliability of the transducer have certainly contributed to the success of the device.

- 294 Chen T, Ren L-J, Yin D-M, Li J, Yang L, Dai P-D, Zhang T-Y. (2017) A comparative study of MED-EL FMT attachment to the long process of the incus in intact middle ears and its attachment to disarticulated stapes head. *Hearing Research.* [Epub ahead of print]

**Abstract:**

The Vibrant Soundbridge© (VSB) active middle-ear implant provides an effective treatment for mild-to severe sensorineural hearing loss in the case of normal middle ear anatomy and mixed hearing loss in middle ear malformation. The VSB floating mass transducer (FMT), with proper couplers, can be installed on various structures of the ossicular chain, e.g., the short and long process of the incus, the stapes head, and the stapes footplate. A long process (LP) coupler is most commonly used for FMT attachment to the long process of the incus with intact ossicular chain, while CliP and Bell couplers are two standardized and reliable methods for FMT attachment to the stapes head with missing incus and malleus. However, the difference and relationship of the vibration properties among these three FMT couplers remain unclear. In the present study, the stapes footplate velocity responses of the LP, CliP, and Bell couplers have been investigated in eight fresh temporal bones (TBs) to evaluate the vibration properties of these three couplers. Normal and reconstructed middle ear transfer functions (METFs) were determined from laser Doppler

vibrometer (LDV) measurements. A mastoidectomy and a posterior tympanotomy were performed to expose the ossicular chain. The METFs of the normal middle ear and middle ear with LP-FMTcoupler were compared under acoustic stimulation, thus the mass effect of the FMT with LP coupler was evaluated. Additional comparisons were made between the stapes footplate vibrations of the LP-FMT coupler (with the intact ossicular chain at the long process of the incus), CliP-FMT-coupler and Bell- FMT-coupler on the stapes head (after incus and malleus removed) under active electromechanical stimulation. After the installation of CliP-FMT-coupler and Bell-FMT-coupler to the middle ear, the average velocity amplitude of the stapes footplate, comparing to the LP-FMT-coupler, was about 15 dB higher between 1 and 6 kHz, and 10 dB lower at about 0.5 kHz. Quantitatively, there was no significant difference between the CliP-FMT-coupler and Bell-FMT-coupler. According to our study, installation of CliP-FMT-coupler or Bell-FMT-coupler on the stapes head provides considerable improvement of the middle ear mechanical and functional responses, comparing with the LP-FMT-coupler in the temporal bone experiments. Moreover, the installation of the Bell-FMTcoupler to the stapes head produces essentially the same footplate velocity responses in comparison to the CliP-FMT-coupler.

- 293 Lee HJ, Lee JM, Choi JY, Jung J. (2017) Evaluation of Maximal Speech Intelligibility With Vibrant Soundbridge in Patients With Sensorineural Hearing Loss. Otol Neurotol. [Epub ahead of print].

**Abstract:**

**OBJECTIVE:** The study investigated improvements in maximal speech intelligibility after Vibrant Soundbridge (VSB) implantation and analyzed the effect of the hearing loss pattern on maximal speech intelligibility represented by a phonetically balanced word score (PBmax). The effect of middle ear implants on PBmax has not been evaluated yet.

**STUDY DESIGN:** Study.

**SETTING:** Tertiary academic medical center.

**PATIENTS/INTERVENTIONS:** Sixty patients who underwent VSB from December 2011 to January 2016 were retrospectively reviewed. All the patients had hearing aids preoperatively.

**MAIN OUTCOME MEASURES:** Pure-tone and speech audiometry were checked with and without hearing aids and then with the VSB. The patients were divided into two groups: flat and down-sloping type of hearing loss. PBmax score was evaluated at the most comfortable listening level before and after VSB implantation and compared with scores with/without HA.

**RESULTS:** PBmax for both conventional HA and VSB were significantly higher compared with the unaided condition. The improvement in speech recognition was significantly better using VSB than using HA ( $p = 0.003$ ). However, there was no significant difference in the improvement provided by VSB and HA in patients with a flat hearing loss. Patients with a down-sloping audiogram showed significantly better improvement with VSB than with HA ( $p = 0.003$ ). Moreover, patients with greater preoperative high-frequency hearing loss had greater improvement in PBmax after VSB implantation.

**CONCLUSION:** Speech intelligibility can be significantly improved by VSB implantation, especially in patients with a down-sloping hearing loss. This finding can help select patients who will benefit most from VSB implantation.

- 292 Lee JM, Lee YH, Jung J, Kim SH, Moon IS, Choi JY. (2017) Audiologic Gain of Incus Short Process Vibroplasty With Conventional Incus Long Process Vibroplasty: A Retrospective Analysis of 36 Patients. *Otol Neurotol.* [Epub ahead of print].

Abstract:

OBJECTIVE: To compare the audiological and non-audiological benefits of incus short process (SP) vibroplasty with those of conventional incus long process (LP) vibroplasty. STUDY DESIGN: Retrospective analysis. SETTING: Tertiary referral center. PATIENTS: Thirty-six patients with sensorineural hearing loss were treated with the semi-implantable middle ear hearing device. Of these, 22 were treated with conventional LP vibroplasty, and 14 were treated with SP vibroplasty using SP couplers. INTERVENTIONS: Implantation with the semi-implantable middle ear hearing device by different methods. MAIN OUTCOME MEASURES: Pre- and postoperative hearing level, word recognition score, operation time, and duration of hospital stay were compared. We also surveyed a questionnaire to assess postoperative complications. RESULTS: The improvement in hearing gain was comparable between SP vibroplasty and conventional LP vibroplasty, except at 8 kHz, at which LP vibroplasty showed better hearing gain ( $p < 0.05$ ). Patients undergoing SP vibroplasty had shorter operation time ( $p < 0.01$ ) and duration of hospital stay ( $p < 0.01$ ). While four patients who underwent incus LP vibroplasty experienced taste changes, none who underwent incus SP vibroplasty experienced any complications. CONCLUSIONS: SP vibroplasty with the newly invented SP coupler could be a good alternative to conventional LP vibroplasty for treating patients with sensorineural hearing loss. Although both SP vibroplasty and LP vibroplasty produce good results, the former is associated with a shorter operation time and duration of hospital stay as well as fewer complications.

- 291 Muller M, Salcher R, Lenarz T, Maier H. (2017) The Hannover Coupler: Controlled Static Prestress in Round Window Stimulation With the Floating Mass Transducer. *Otol Neurotol.* [Epub ahead of print].

Abstract:

INTRODUCTION: Stimulation of the cochlear round window (RW) with the floating mass transducer (FMT) still suffers from large variation in clinical outcomes. Beside the geometric mismatch between RW and FMT diameter that is a known limiting factor in achieving optimal coupling between actuator and RW membrane, the applied static force between FMT and RW is usually undefined. In this study, the feasibility and efficacy of a specially designed FMT coupler permitting application of static preloads to the RW membrane to optimize FMT-RW coupling was investigated. METHODS: Experiments were performed in fresh human cadaveric temporal bones. The "Hannover Coupler" FMT-prosthesis has a spherical tip ( $d=0.5$  mm) at the front end and a spring at the prosthesis back that enables the application of static preloads and mobility of the FMT at the same time. Stapes footplate (SFP) displacements in response to acoustic stimulation of the tympanic membrane and to RW stimulation by the FMT were measured by a Laser-Doppler

vibrometer. RESULTS: Average SFP displacement responses of ASTM standard F2504-05 compliant temporal bones to RW stimulation by the "Hannover Coupler" were dependent on the applied force (approximately 0-100 mN) and increased by up to 25 dB at frequencies  $\geq$  1 kHz. When averaged at speech relevant frequencies (0.5, 1, 2, 4 kHz) SFP displacements showed a global maximum at RW preloads of approximately 4 mN. CONCLUSION: The coupling between FMT and RW membrane was improved by the application of static RW preloads as indicated by increased SFP amplitudes to RW stimulation.

- 290 Thomas JP, Voelter C, Neumann K, Dazert S. (2017) Vibroplasty in Severe Congenital or Acquired Meatal Stenosis by Coupling an Active Middle Ear Implant to the Short Process of the Incus. *Otol Neurotol Aug*; 38(7):996-1004.

Abstract:

OBJECTIVE: To evaluate the safety and effectiveness of coupling an active middle ear implant to the short process of the incus in subjects with meatal pathologies. STUDY DESIGN: Retrospective study. SETTING: Tertiary referral center. PATIENTS: Twelve patients suffering from either congenital aural atresia or acquired meatal fibrosis. INTERVENTION: Implantation of an active middle ear implant with coupling of the actuator to the short process of the incus. MAIN OUTCOME MEASURES: Evaluation of the air conduction and bone conduction hearing thresholds pre- and postoperatively, aided warble-tone hearing thresholds, unaided and aided speech recognition in quiet and noise. Questionnaires on subjective benefit and quality of life. RESULTS: Mean unaided postoperative air conduction and bone conduction thresholds did not vary significantly from preoperative values ( $p = 0.55$  and  $0.082$ , respectively). The mean functional gain amounted to  $42.1 \pm 8.8$  dB, the mean aided sound field threshold of the implanted ear was  $28.6 \pm 8.6$  dB. No significant difference in functional gain but a close to significant difference in postoperative aided thresholds ( $p = 0.053$ ) were found between subjects with congenital atresia and acquired fibrosis. Subjective benefit assessed by the global score of the Abbreviated Profile of Hearing Aid Benefit questionnaire revealed an improvement of 31 to 42%. CONCLUSION: Coupling of the actuator to the short process of the incus is a safe and clinically promising procedure in cases where the standard application to the long process is not feasible. In pure conductive hearing loss the benefit is comparable to long incus process coupling, whereas in mixed hearing loss slightly worse results were observed.

- 289 Kosaner Kliess M, Klubenschaedl M, Zoehrer R, Schlick B, Scandurra F, Urban M. (2017) Cost-Utility of Partially Implantable Active Middle Ear Implants for Sensorineural Hearing Loss: A Decision Analysis. *Value in Health [Epub ahead of print]*.

Abstract:

Background: Partially implantable active middle ear implants (aMEIs) offer a solution for individuals who have mild to severe sensorineural hearing loss and an outer ear medical

condition that precludes the use of hearing aids. When otherwise left untreated, individuals report a lower quality of life, which may further decrease with increasing disability. In the lack of cost-effectiveness studies and long-term data, there is a need for decision modeling. Objective: To explore individual-level variance in resource utilization patterns following aMEI implantation. Methods: A Markov model was developed and analyzed as microsimulation to estimate the incremental cost utility ratio (ICUR) of partially implantable aMEIs compared with no (surgical) intervention in individuals with sensorineural hearing loss and an outer ear medical condition in Australia. Cost data were derived mostly from the Medicare Benefit

Schedule and effectiveness data from published literature. A third-party payer perspective was adopted, and a 5% discount rate was applied over a 10-year time horizon. Results: Compared with baseline strategy, aMEIs yielded an incremental cost of Australian dollars (AUD) 13,339.18, incremental quality-adjusted life-year (QALY) of 1.35, and an ICUR of AUD 9,913.72/QALY. Of the respective number of simulated patients who visited each health state, 75.73% never had a minor adverse event, 99.82% did not experience device failure, and 97.75% did not cease to use their aMEIs. Probabilistic sensitivity analyses showed the ICUR to differ by only 0.95%. Conclusions: In the Australian setting, partially implantable aMEIs offer a safe and cost-effective solution compared with no intervention and are also well accepted by users

- 288 Wang D, Han D, Zhao S, Ren R, Dong J. (2017) Preoperative assessment of stapes implantations of the vibrant SoundBridge for congenital aural atresia patients. *Acta Otorhinolaryngol* 137(9):935-939.

Abstract:

OBJECTIVE: The objective of this study is to retrospectively analyze the imaging characteristics of patients with congenital aural atresia who underwent Vibrant Soundbridge implantation, and to investigate the importance of preoperative evaluation of vibroplasty. MATERIALS AND METHODS: The study included 16 patients with bilateral congenital aural atresia aged 6-25 years (mean age, 14.7 years). All patients underwent Vibrant Soundbridge implantations. RESULTS: Among the 16 patients, 15 successfully underwent stapes implantation. The average height of the stapes of these 15 patients was 2.93 mm, which was significantly different from that of the control group with normal hearing ( $p < .001$ ). The average distance between the tympanic segment of the facial nerve and the stapes was 1.41 mm in patients in whom the oval window was occluded by the displaced facial nerve. In the non-occluded group, the average distance was 2.00 mm. No significant difference was observed between the two groups ( $p = .08$ ). CONCLUSION: The distance between the facial nerve and stapes, as well as the height of the stapes, could be important predictors of successful stapes implantation of Vibrant Soundbridge.

- 287 Lee, J. M., Jeon, J. H., Moon, I. S., Choi, J. Y. (2017) Benefits of active middle ear implants over hearing aids in patients with sloping high tone hearing loss: comparison with hearing aids. *Acta Otorhinolaryngol Ital.* [Epub ahead of print]

**Abstract:**

In this retrospective chart review we compared the subjective and objective benefits of active middle ear implants (AMEIs) with conventional hearing aids (HAs) in patients with sloping high tone hearing loss. Thirty-four patients with sensorineural hearing loss were treated with AMEIs. Of these, six had sloping high tone hearing loss and had worn an HA for more than 6 months. Objective assessments, a pure-tone audiogram, as well as a word recognition test, and the Korean version of the Hearing in Noise Test (K-HINT), and a subjective assessment, the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire, were performed. Tests were conducted under three circumstances: 1) the unaided state before surgery; 2) the HA-aided state before surgery; and 3) the AMEI-aided state 3 months after surgery. The average high-frequency hearing gain ( $>/= 2$  kHz) was significantly better with AMEIs than with HAs. Although the result had no statistical significance, AMEIs showed a superior word recognition score (WRS) compared to HAs. However, the most comfortable hearing level at which the WRS was tested was significantly decreased with an AMEI compared to an HA. In the K-HINT, patients with an AMEI showed greater recognition than those fitted with an HA under both quiet and noisy conditions. The APHAB scores revealed that patients were more satisfied with an AMEI rather than an HA on all subscales. The use of vibroplasty in patients with sloping high tone loss resulted in positive hearing outcomes when compared to conventional HAs. Based on the data from this study, AMEIs provided better objective and subjective results and could, therefore, be a better alternative for the treatment of sloping hearing loss.

- 286 Iwasaki S, Usami SI, Takahashi H, Kanda Y, Tono T, Doi K, Kumakawa K, Gyo K, Naito Y, Kanzaki S, Yamanaka N, Kaga K. (2017) Round Window Application of an Active Middle Ear Implant: a Comparison With Hearing Aid Usage in Japan. *Otol Neurotol*. May 5. [Epub ahead of print]

**Abstract**

**OBJECTIVE:** To report on the safety and efficacy of an investigational active middle ear implant (AMEI) in Japan, and to compare results to preoperative results with a hearing aid. **DESIGN:** Prospective study conducted in Japan in which 23 Japanese-speaking adults suffering from conductive or mixed hearing loss received a VIBRANT SOUNDBRIDGE with implantation at the round window. Postoperative thresholds, speech perception results (word recognition scores, speech reception thresholds, signal-to-noise ratio [SNR]), and quality of life questionnaires at 20 weeks were compared with preoperative results with all patients receiving the same, best available hearing aid (HA). **RESULTS:** Statistically significant improvements in postoperative AMEI-aided thresholds (1, 2, 4, and 8kHz) and on the speech reception thresholds and word recognition scores tests, compared with preoperative HA-aided results, were observed. On the SNR, the subjects' mean values showed statistically significant improvement, with -5.7dB SNR for the AMEI-aided mean and -2.1dB SNR for the preoperative HA-assisted mean. The APHAB quality of life questionnaire also showed statistically significant improvement with the AMEI. **CONCLUSION:** Results with the AMEI applied to the round window exceeded those of the

best available hearing aid in speech perception as well as quality of life questionnaires. There were minimal adverse events or changes to patients' residual hearing. This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. <http://creativecommons.org/licenses/by-nc-nd/4.0/>.

- 285 Tisch M. (2017) [Implantable Hearing Devices]. Laryngorhinootologie. Apr; 96(S 01):S84-S102.

Abstract:

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

- 284 Müller A, Mir-Salim P, Zellhuber N, Helbig R, Bloching M, Schmidt T, Koscielny S, Dziemba OC, Plontke SK, Rahne T. (2017) Influence of Floating-mass Transducer Coupling Efficiency for Active Middle-ear Implants on Speech Recognition. Otol Neurotol. 2017 Apr 5. [Epub ahead of print].

Abstract:

**OBJECTIVE:** The efficiency of vibroplasty (coupler-floating mass transducer [FMT] assembly) can be monitored by direct stimulation of the inner ear through the active middle-ear implant system and comparison of the vibroplasty *in vivo* threshold and the postoperative bone-conduction pure-tone threshold. The aim of this study was to compare the vibroplasty *in vivo* threshold with the postoperative speech recognition in patients with a high preoperative maximum word recognition score. **STUDY DESIGN:** Retrospective cohort study of German-speaking patients implanted with a vibrating ossicular prosthesis (VORP) 502 or VORP 503 and high preoperative maximum word recognition score between the years of 2011 and 2015. **SETTING:** Multicenter study of four German centers. **PATIENTS:** Twenty-three active middle-ear implant users. **INTERVENTION:** Rehabilitative. **MAIN OUTCOME MEASURES:** Bone-conduction pure-tone and vibroplasty thresholds, postoperative aided word recognition score (WRS) at 65dB SPL (sound pressure level) and preoperative maximum WRS with Freiburg monosyllabic words. **RESULTS:** The mean postoperative aided WRS at 65dB SPL was 82%. An increasing difference between vibroplasty thresholds and bone-conduction thresholds was associated with a higher discrepancy between the unaided maximum WRS and the postoperative aided WRS. Only if this difference was less than 20dB, an articulation index of 0.5 (WRS=75%) or more was

achieved. CONCLUSIONS: Audiological outcome after vibroplasty depends on the coupling efficiency reflected by the vibroplasty threshold.

- 283 Mancheño M, Aristegui M, Sañudo JR. (2017) Round and Oval Window Anatomic Variability: Its Implication for the Vibroplasty Technique. *Otol Neurotol.* 2017 Mar 24. [Epub ahead of print]

Abstract:

**OBJECTIVE:** The objective of this study is to evaluate the anatomical variability of round and oval window regions and its relationship with their closest structures, to determine its implication on the fitting and stabilization of the middle ear implant Vibrant Soundbridge. **METHODS:** Variations of the anatomy of round and oval window regions were assessed in a total of 85 human dissected temporal bones. Afterward, we evaluated the adaptation and subsequent stabilization of the floating mass transducer (FMT) of the Vibrant Soundbridge in 67 cases in round window (RW) and in 22 cases in oval window (OW), and the influence that the variability of the different anatomical features examined had on this stabilization. We also assessed access and surgeon's view of the RW niche through the facial recess approach. **RESULTS:** Stabilization of the FMT in the RW was achieved in 53 (79%) of the 67 cases; we found that the less favorable anatomical conditions for stabilization were: membrane smaller than 1.5 mm, presence of a high jugular bulb and a narrow or very narrow RW niche. Frequently, two or more of these conditions happened simultaneously. In seven cases (22%) access to the RW through facial recess approach did not allow positioning the FMT in place. OW stabilization succeeded in 18 (82%) of the 22 cases. **CONCLUSION:** Round and oval window vibroplasty are difficult surgical techniques. To place the FMT directly on the OW may be easier as we do not have to drill the niche. In both regions there are some anatomical conditions that hinder fitting the FMT and even make it impossible. Once fitted, the main problem is to achieve good stabilization of the device.

- 282 Cebulla M, Geiger U, Hagen R, Radeloff A. (2017). Device optimised chirp stimulus for ABR measurements with an active middle ear implant. *Int J Audiol.* Apr 19:1-5.

Abstract:

**OBJECTIVE:** Active middle ear implants are widely used to treat adults and children with sensorineural, conductive, or mixed hearing loss. Currently, there is no adequate method to determine the performance of active middle ear implant systems. **DESIGN:** The proposed method is based on measuring the auditory brainstem response while stimulating the hearing system via the active middle ear implant (Vibrant SoundbridgeTM, VSB; MEDEL, Austria). The acoustic stimulation was achieved via an optimised chirp stimulus (CE-Chirp), implemented in the Eclipse system (Interacoustics, Denmark). To compensate for the frequency-specific delays in the VSB system, the underlying model function of the CE-Chirp was adjusted accordingly (VSB-CE-Chirp). **Study samples:** The study includes 12 subjects having mild to profound sensorineural, conductive or mixed

hearing loss. RESULTS: The use of an optimised VSB-CE-Chirp instead of the CE-Chirp increases significantly the ABR wave V amplitudes (1.63 times) and so also increases their identifiability (by 15.2%). On average, wave V could be identified at a 7.5 dB lower stimulation level. CONCLUSION: The constructed VSB-CE-Chirp stimulus, after it had been transmitted through the VSB system, follows well the shape of the original CE-Chirp. Preliminary measurements in VSB patients demonstrated a significantly improved ABR amplitude with the VSB-CE-Chirp.

- 281 Bruehhage KL, Leichtle A, Schönweiler R, Todt I, Baumgartner WD, Frenzel H, Wollenberg B. (2017). Systematic review to evaluate the safety, efficacy and economical outcomes of the Vibrant Soundbridge for the treatment of sensorineural hearing loss. *Eur Arch Otorhinolaryngol.* Apr; 274(4):1797-1806.

Abstract:

Introduced in the late 90s, the active middle ear implant Vibrant Soundbridge (VSB) is nowadays used for hearing rehabilitation in patients with mild to severe sensorineural hearing loss (SNHL) unable to tolerate conventional hearing aids. In experienced hands, the surgical implantation is fast done, safe and highly standardized. Here, we present a systematic review, after more than 15 years of application, to determine the efficacy/effectiveness and cost-effectiveness, as well as patient satisfaction with the VSB active middle ear implant in the treatment of mild to severe SNHL. A systematic search of electronic databases, investigating the safety and effectiveness of the VSB in SNHL plus medical condition resulted in a total of 1640 papers. After removing duplicates, unrelated articles, screening against inclusion criteria and after in-depth screening, the number decreased to 37 articles. 13 articles were further excluded due to insufficient outcome data. 24 studies remained to be systematically reviewed. Data was searched on safety, efficacy and economical outcomes with the VSB. Safety-oriented outcomes included complication/adverse event rates, damage to the middle/inner ear, revision surgery/explant rate/device failure and mortality. Efficacy outcomes were divided into audiological outcomes, including hearing thresholds, functional gain, speech perception in quiet and noise, speech recognition thresholds, real ear insertion gain and subjective outcomes determined by questionnaires and patient-oriented scales. Data related to quality of life (QALY, ICER) were considered under economical outcomes. The VSB turns out to be a highly reliable and a safe device which significantly improves perception of speech in noisy situations with a high sound quality. In addition, the subjective benefit of the VSB was found to be mostly significant in all studies. Finally, implantation with the VSB proved to be a cost-effective and justified health care intervention.

- 280 Djalilian H.R., Mahboubi H., Haidar Y.M., Paulick P., Merlo M.W., Bachman M. (2017). Development of a novel completely-in-the-canal direct-drive hearing device. *Laryngoscope.* Apr; 127(4): 932-938.

Abstract:

OBJECTIVES/HYPOTHESIS: To develop a novel completely-in-the-canal device capable of directly driving the tympanic membrane (TM) and ossicular chain from the ear canal.

STUDY DESIGN: Development and feasibility study.

METHODS: A voice coil actuator design was developed to drive the TM. Bench testing of the device using laser Doppler vibrometry (LDV) and sound recording was performed. Temporal bone studies using LDV were performed using different designs of the contact tip-TM interface to find the most efficient method of sound transmission. Two short-term clinical performance studies were performed using the latest 3-mm-wide device. Comparison was made to natural sound and to the Vibrant SoundBridge floating mass transducer simulator.

RESULTS: On bench testing, the device was found to have a low (<0.5%) total harmonic distortion in all frequencies above 400 Hz. Temporal bone studies revealed the device was capable of producing vibrations equivalent to 104 to 120 dB sound across most frequencies. The most efficient method of stimulation was when the device was coupled to the malleus. Short-term clinical performance studies indicated that pure tones and complex sound can be presented with the device. The sound quality of the experimental device was rated as better than the SoundBridge simulator device.

CONCLUSIONS: The direct-drive hearing device is capable of producing a wide range of sound frequencies and amplitudes. The device can transmit complex sound with low power requirements. Further work on the development of the device is needed for long-term and wider clinical use.

- 279 Grégoire A, Van Damme JP, Gilain C, Bihin B, Garin P. (2017) Our auditory results using the Vibrant Soundbridge on the long process of the incus: 20 years of data. *Auris Nasus Larynx*. Mar 9. pii: S0385-8146(16)30438-2.

#### Abstract

OBJECTIVE: After 20 years of experience with different types of middle ear implants, we analyzed our database about the Vibrant Soundbridge (VSB) to know the rate of complications, the effect on the residual hearing and the audiometric gain in our center.

METHOD: The study was retrospective and included all VSB implants bound to the long process of the incus in our tertiary medical center between january 1999 and february 2015. We observed the effect of surgery on residual hearing by comparing bone and air conduction thresholds before and after implantation. The functional results of the implant were quantified by measuring, at several post-operative intervals, the thresholds with the VSB in pure tone audiology and speech audiology, in quiet and in noise. RESULTS: 53 VSB were implanted in 46 patients aged between 22 and 81 years old (average 53.9). 48 patients (90%) suffered from a sensorineural hearing loss, and 5 patients from a mixed hearing loss due to an otosclerosis (but only 3 of them have undergone stapedotomy). There were no major complications (e.g. facial palsy, dead ear or postoperative infection). The placement of the implant created an insignificant deterioration of the air conduction thresholds (5,6 dB HL) and bone conduction thresholds (2.2 dB HL) at 6 weeks post-implantation. The bone conduction thresholds increased by 4.7 dB HL 2.5 years after

surgery in comparison with the preoperative results, which is also considered clinically insignificant. With the implant turned on, the pure tone audiometry thresholds in open field, in quiet, were significantly improved (gain of 13.9 dB on average on frequencies from 250 to 8000 Hz), particularly at frequencies of 1000, 2000 and 4000 Hz as the average gain on these frequencies amounted to 19.4 dB. The speech intelligibility in a cocktail party noise was also improved by 18.3% on average at 6, 52 and 104 weeks post-implantation. CONCLUSION: The Vibrant Soundbridge with the electromagnetic vibrator fixed to the long process of the incus is a safe active middle ear implant with no major complications; it has no significant impact on the residual hearing. The VSB is particularly suitable for patients who are unable to wear conventional hearing aids due to anatomical or infectious problems in the external ear canal, or in case of poor audiotometric results with conventional hearing aids. The VSB brings significant hearing gain, as it is particularly efficient in frequencies for the speech range and higher, resulting especially in better speech intelligibility in noisy environments.

- 278 Pirlich M, Dietz A, Meuret S, Hofer M. (2017) Implantierbare Knochenleitungs- und aktive Mittelohröhrengesysteme /Implantable Bone Conduction and Active Middle Ear Devices. Laryngo-Rhino-Otol, Feb; 96(02): 120-129.

Abstract

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.

- 277 Olszewski L, Jedrzejczak WW, Piotrowska A, Skarzynski H. (2017) Round window stimulation with the Vibrant Soundbridge: Comparison of direct and indirect coupling Laryngoscope. Feb 21.

Abstract

OBJECTIVES/HYPOTHESIS: The purpose of this study was to measure the degree of coupling between the floating mass transducer (FMT) and the round window membrane (RWM) in patients with conductive and mixed hearing loss implanted with the Vibrant Soundbridge (VSB) device. The efficiency of direct and indirect coupling of the FMT to the RWM was compared by measuring differences between the initial prescription targets and the final settings of the VSB audio processor after fine-tuning. STUDY DESIGN: Retrospective study. METHODS: Investigation of a group of subjects with either conductive or mixed hearing loss implanted with the VSB, a device that uses a FMT coupled

to the RWM. There were two subgroups: subjects in which coupling was direct (no interposed material) or indirect (interposed material). The functional gain, insertion gain, and compression characteristics of the device were measured to assess the efficiency of coupling and to investigate the proximity of the fitting to prescriptive targets. RESULTS: Coupling for the subgroup with indirect coupling of the RWM was higher (better) than for the subgroup with direct coupling. The gain deviation from prescriptive targets was smaller for the subgroup with indirect coupling. CONCLUSIONS: The coupling method can have an effect on the coupling efficiency and the final electroacoustic settings of the device. The prescription targets were not accurate for the majority of subjects from either subgroup. Indirect coupling appears to provide more effective stimulation of the cochlea.

- 276 Célérier C, Thierry B, Coudert C, Blanchard M, Loudon N, Garabédian EN, Denoyelle F. (2017) Results of VSB implantation at the short process of the incus in children with ear atresia. *Int J Pediatr Otorhinolaryngol*. Feb; 93:83-87.

Abstract:

OBJECTIVE(S): To describe a new and more simple surgical procedure for implanting the Vibrant Soundbridge (VSB) on the short process of the incus in children with ear atresia and atretic plate and present the audiometric results. METHODS: Since 2014, pre- and post-operative audiometric tests with tonal and vocal audiometry at the maximal follow up, respectively 33, 22 and 12 months were performed after VSB implantation at the ENT department, Necker Enfants Malades Hospital, Paris, France. 3 children aged 11, 9 and 15 years with conductive hearing loss due to high grade ear atresia and absent ear canal were implanted. The malformed and fused malleus-incus complex was found to be immobile in two of the subjects, who then underwent a superior tympanotomy to carefully remobilize the malleus. Stapes were mobile in all cases. The FMT clip was customized and crimped on the short process, stabilized by the metallic wire. RESULTS: At the maximum follow-up time, the bone conduction was unchanged, and the mean aided ACPA was 21 dB, 29 dB and 30 dB, compared to 66 dB, 63 dB and 68 dB unaided, respectively. The word recognition score (WRS) at 65 dB SPL increased from 10%, 10% and 70% (unaided) respectively to 100% (aided). CONCLUSIONS: The long process of the incus is usually very hypoplastic in patients with ear atresia with a fused malleus-incus complex lateral to the stapes. VSB coupling to the long process of the incus or the stapes may be challenging in small mastoids. Coupling to the short process of the incus is comparatively a simple procedure, since there is no need for posterior tympanotomy and has no proximity to the facial nerve. The results of this study are similar to other ear atresia cases in the literature with classic FMT placement on the stapes or long process of the incus. Outcomes should be confirmed in a larger number of patients.

- 275 Coordes A., Jahreiss L., Schönfeld U., Lenarz M. (2017). Active middle ear implant coupled bilaterally to the round window despite bilateral implanted stapes prostheses. *Laryngoscope*. Feb; 127(2): 500-503.

Abstract:

After stapes surgery, patients with mixed or moderate hearing loss have limited possibilities for hearing improvement. We are reporting on a patient who underwent stapedotomy bilaterally 20 years ago and had sensorineural and mixed hearing loss. Recurrent otitis externa prevented the use of hearing aids. This patient was treated bilaterally with the Vibrant Soundbridge (Med-El, Innsbruck, Austria) successively. The Schuknecht piston stapes prostheses remained in situ. The Floating Mass Transducer (FMT; Med-El) was coupled to the round window (RW) and provided good acoustic reinforcement bilaterally. In conclusion, for patients with otosclerosis and stapes surgery, the FMT-RW coupling (Bess AG, Berlin, DE) is a safe procedure with good acoustic amplification.

- 274 Busch S, Lenarz T, Maier H. (2017) Comparison of Alternative Coupling Methods of the Vibrant Soundbridge Floating Mass Transducer  
Audiol Neurotol. Jan 10;21(6): 347-355

**Abstract:**

The active middle ear implant Vibrant Soundbridge® provides a variety of coupling modalities of the floating mass transducer (FMT) to various structures of the ossicular chain and the round window. A retrospective analysis was performed on 125 subjects ( $n = 137$  ears) (1) to compare the efficacy of the different FMT coupling modalities with increasing degree of hearing loss, (2) to compare the performance in speech outcome and the effective gain between the coupling types, and (3) to evaluate the risk of additional hearing loss of each coupling procedure. The patients were grouped according to their type of FMT coupling into incus vibroplasty (incus group,  $n = 59$ ), round window vibroplasty with coupler (RWC group,  $n = 23$ ), round window vibroplasty without coupler (RW group,  $n = 22$ ), and oval window vibroplasty with coupler (OWC group,  $n = 33$ ). For each coupling group, pre- and postoperative thresholds, the results of the Freiburg monosyllable test at 65 dB SPL, and the effective gain across frequencies (0.5–6 kHz) were evaluated. A logistic regression function was used to describe the relationship between word recognition scores (WRS, in % correct) and the mean bone conduction (BC) hearing loss. The surgical procedure had no clinically relevant effect on BC thresholds of patients in each coupling group. The BC pure tone average (PTA4) for 50% WRS predicted by the model function was similar for the incus (48.2 dB nHL), RW (47.8 dB nHL), and OWC (49.0 dB nHL) groups, but higher for the RWC group (67.9 dB nHL). However, the median WRS was 80% or better with no significant differences in speech perception between coupling types (Kruskal-Wallis test,  $p = 0.229$ ). The effective gain shows an advantage for the incus coupling between 0.5 and 2 kHz over the other coupling types. The performance of the FMT coupling modalities is equally good for patients with a mild-to-moderate hearing loss, but the efficacy of coupling types differs for patients with greater hearing loss (>48 dB BC HL).

- 273 Leinung M., Zaretsky E., Lange B.P., Hoffmann V., Stöver T., Hey C. (2017). Vibrant Soundbridge (®) in preschool children with unilateral aural atresia: acceptance and benefit. Eur Arch Otorhinolaryngol. Jan; 274(19): 159-165.

**Abstract:**

The aim of this pilot study was to determine the acceptance and benefit from the middle ear implant system Vibrant Soundbridge® (VSB, MED-EL Corporation, Austria) by means of a questionnaire, compared to a previously used conventional bone conducting hearing device, in preschool children with unilateral congenital aural atresia. Prospective cohort study. All nine children with unilateral congenital aural atresia used the VSB and had previous experience with a bone conducting hearing device. The benefit from the VSB was evaluated by questionnaires concerning acceptance of hearing aids, handling, listening effort, behavior, quality of life, and the duration of daily use and compared to the experience with the bone conducting hearing device. In addition, to quantify the benefit from the VSB use, audiological assessment (pure-tone audiometry via free field testing, speech audiometry, and localization test) was performed with and without VSB. The questionnaires and audiological test results were compared pairwise. According to all questionnaire areas, children benefited significantly more from the VSB compared to bone conducting hearing device ( $p < .05$ ). The most important finding was a significant increase in daily use from 2 h for the bone conducting hearing device to 10 h for the VSB. Children performed significantly better with the VSB than without it in the audiological assessment. Children with unilateral aural atresia benefited significantly more from the VSB compared to a conventional bone conducting hearing device according to the parents' questionnaires and yielded better results in the audiometry and localization test with the VSB than without it.

- 272 De Brito R, Pozzobom Ventura LM, Jorge JC, Oliveira EB, Manzoni Lourencone LF. (2016) An Implantable Hearing System As Rehabilitation for Hearing Loss Due to Bilateral Aural Atresia: Surgical Technique and Audiological Results. *J Int Adv Otol.* Dec 12(3):241-246.

**Abstract:**

**OBJECTIVE:** To demonstrate the surgical technique and audiological results of a middle ear implant for restoring hearing in patients with bilateral aural atresia and microtia with conductive or mixed hearing loss. **MATERIALS AND METHODS:** In this prospective study, 12 subjects aged 12 years and older presenting with hearing loss and bilateral congenital aural atresia underwent surgical insertion of a middle ear implant. The patients underwent tympanomastoidectomy with a wide opening of the attic and preservation of the roof of the atresic tympanic bone to expose the middle ear and position the floating mass transducer of the implant. **RESULTS:** There were no intraoperative or postoperative complications. The hearing threshold averages in a free field were 53.5 dB preoperatively and 25.6 dB postoperatively. Monosyllabic word recognition averaged 61% preoperatively and 91.3% postoperatively. The average speech perception in quiet conditions during the hearing in noise test improved from 67.11 dB to 45.99 dB, and the signal-to-noise ratio improved from 5.64 to 1.31. **CONCLUSION:** The tested system is an excellent option for auditory rehabilitation of conductive hearing loss due to bilateral ear atresia. The surgery is well structured and safe and provides several alternatives to the surgeon, which is

valuable in difficult cases.

- 271 Monini S, Bianchi A, Talamonti R, Atturo F, Filippi C, Barbara M. (2016) Patient satisfaction after auditory implant surgery: ten-year experience from a single implanting unit center. *Acta Otolaryngol*. Dec 5:1-9.

#### Abstract

**CONCLUSIONS:** The satisfaction rate of the subjects with an auditory implant appears strictly related to the resulting auditory improvement, and the surgical variables would play a prevailing role in respect to the esthetic factors.

**OBJECTIVES:** To assess the rate of satisfaction in subjects who underwent the surgical application of an auditory device at a single Implanting Center Unit.

**METHOD:** A series of validated questionnaires has been administered to subjects who underwent the surgical application of different auditory devices. The Glasgow Benefit Inventory (GBI), the Visual Analog Scale (VAS), and the Abbreviated Profile of Hearing Aid Benefit (APHAB) have been used to compare the implanted situation with the hearing-aided one; a percutaneous bone conductive implant (pBCI) with an active middle ear implant (AMEI) on the round window in mixed hearing loss; and an invisible, fully-implantable device with a frankly and bulky semi-implantable device.

**RESULTS:** The mean GBI scores were higher in Vibrant Soundbridge (VSB)® and Bonebridge® subjects, without significant differences among the various devices. The mean VAS score increased for all the devices in comparison with the conventional hearing aid. The mean APHAB score was similarly better in the implanted condition as total and partial scores.

- 270 Schnabl J, Wolf-Magele A, Pok SM, Hirtler L, Heinz G, Sprinzl GM. (2016) Magnetic Resonance Imaging Compatibility of a New Generation of Active Middle Ear Implant: A Clinically Relevant Temporal Bone Laboratory Study. *Otol Neurotol*.

**Abstract:** **OBJECTIVE:** Magnetic resonance imaging (MRI) has become an essential tool of modern medical imaging and disease diagnosis. In November 2014, a new MRI-conditional (up to 1.5 T) generation of an active middle ear implant (AMEI) was released to the market. The aim of the study was to test the MRI compatibility of the new implant system in a clinical-anatomical study. **DESIGN:** Experimental cadaver head model. **SETTING:** Temporal bone laboratory. **PARTICIPANTS:** AMEIs were implanted in 28 fixed temporal bones at three different floating mass transducer (FMT)-coupling positions ( $N = 8$  short process of the incus,  $N = 16$  long process of the incus,  $N = 4$  round window). **MAIN OUTCOME MEASURES:** The position of the FMT and the integrity of the ossicular chain was monitored through microscopy, microendoscopy, and computed tomography (CT) scans before and after the MRI (1.5 T) was conducted. Proper function of the implant was tested with reverse transfer function (RTF) measurements. **RESULTS:** Neither positional nor functional changes after MRI were observed. **CONCLUSION:** The new generation of the AMEI is a MRI-compatible system, which features an easier and quicker implant fixation method. The option of MRI in patients with AMEI should be taken into consideration

during the preoperative discussion with potential candidates.

- 269 Shin DH, Seong KW, Puria S, Lee KY, Cho JH. (2016) A tri-coil bellows-type round window transducer with improved frequency characteristics for middle-ear implants. *Hear Res*, 341, 144-154.

**Abstract:**

A number of methods to drive the round window (RW) using a floating mass transducer (FMT) have been reported. This method has attracted attention because the FMT is relatively easy to implant in the RW niche. However, the use of an FMT to drive the RW has been proven to produce low outputs at frequencies below approximately 1 kHz. In this study, a new tri-coil bellows-type transducer (TCBT), which has excellent low frequency output and is easy to implant, is proposed. To design the frequency characteristics of the TCBT, mechanical and electrical simulations were performed, and then a comparative analysis was conducted between a floating mass type transducer (like the FMT) and a fixed type transducer (like the TCBT). The features of the proposed TCBT are as follows. First, the TCBT's housing is fixed to the RW niche so that it does not vibrate. Second, the internal end of a tiny bellows is connected to a vibrating three-pole permanent magnet located within three field coils. Finally, the rim of the bellows bottom is attached to the end of the housing that hermetically encloses the three field coils. In this design, the only vibrating element is the bellows itself, which efficiently drives the RW membrane. To evaluate the characteristics of this newly developed TCBT, the transducer was installed in the RW niche of temporal bones and the velocity of the stapes was measured using a laser Doppler vibrometer. The experimental results indicate that the TCBT can produce 100, 111, and 129 dB SPL equivalent pressure outputs at below 1 kHz, 1-3 kHz, and above 3 kHz, respectively. Thus, the TCBT with one side coupled to the RW via a bellows will be easy to implant and offer better performance than an FMT.

- 268 Lee J.M., Jung J., Moon I.S., Kim S.H., Choi J.Y. (2016). Benefits of active middle ear implants in mixed hearing loss: Stapes versus round window. *Laryngoscope*. [Epub ahead of print]. doi: 10.1002/lary.26244

**Abstract:**

**OBJECTIVES/HYPOTHESIS:** We compared the audiologic benefits of active middle ear implants with those of passive middle ear implants with hearing aids in mixed hearing loss, and also compared the outcomes of stapes vibroplasty with those of round window vibroplasty. **STUDY DESIGN:** Retrospective chart review.

**METHODS:** Thirty-four patients with mixed hearing loss due to chronic otitis media were treated with a middle ear implant. Of these, 15 were treated with a passive middle ear implant (conventional ossiculoplasty with a partial ossicular replacement prosthesis), nine with an active middle ear implant coupling to the stapes, and 10 with an active middle ear implant coupling to the round window. Patients underwent pure-tone/free-field

audiograms and speech discrimination tests before surgery and 6 months after surgery, and the results of these tests were compared.

**RESULTS:** The active middle ear implant resulted in better outcomes than the passive middle ear implant with hearing aids at mid to high frequencies ( $P < .05$ ). Patients who received either a stapes vibroplasty or a round window vibroplasty showed comparable hearing gain except at 8,000 Hz (48.9 dB vs. 31.0 dB,  $P < .05$ ). Patients who received a stapes vibroplasty showed an improvement even in bone conduction at 1,000 Hz and 2,000 Hz (both  $P < .05$ ).

**CONCLUSIONS:** Active middle ear implantation could be a better option than treatment with passive middle ear implants with hearing aids for achieving rehabilitation in patients with mixed hearing loss. Vibroplasty via either oval window or round window stimulation shares similar good results.

**LEVEL OF EVIDENCE:** 4 Laryngoscope, 2016.

- 267 Volkenstein S., Thomas J.P., Dazert S. (2016) Bone Conduction and Active Middle Ear Implants. *Laryngorhinootologie*, 95(5), 352-363.

**Abstract:**

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

- 266 Leinung M, Zaretsky E, Lange BP, Hoffmann V, Stöver T, Hey C. (2016) Die Vibrant Soundbridge: Ein alternatives Hörsystem bei Vorschulkindern mit Gehörgangsatresie. *Laryngorhinootologie*. 95(9), 627-633.

No Abstract available.

- 265 Koci V., Seebacher J., Weichbold V., Zorowka P., Wolf-Magele A., Sprinzl G., Stephan K. (2016). Improvement of sound source localization abilities in patients bilaterally supplied with active middle ear implants. *Acta Otolaryngol.* 136(7):692-8. doi:10.3109/00016489.2016.1155232.

**Abstract:**

**CONCLUSIONS:** Patients, who are bilaterally supplied with active middle ear implants, perform slightly better in sound localization tasks than when unilaterally aided or unaided.

**OBJECTIVES:** To investigate the impact of bilateral use of active middle ear implants on sound source localization in the horizontal plane in patients with a sloping moderate-to-severe hearing loss.

**METHODS:** Ten adults supplied with Med-EL Vibrant Soundbridge systems (VSB) in both ears participated in the study. Four listening conditions were tested: unaided, aided with VSB on left or right ear and on both sides. In each condition the subjects had to judge the direction of broadband noises delivered randomly across a semicircular array of 11 loudspeakers arranged in an anechoic chamber.

**RESULTS:** When unaided or bilaterally aided, the subjects localized on average 40% of the stimuli correct; when unilaterally aided (left or right), this rate dropped to 20-30% in either condition. Precision of sound localization was highest when bilaterally aided, i.e. the mean RMS angular error was 10°, and lowest when unilaterally aided, i.e. 15°. This is in line with bilateral hearing aid users, who show similar performance in sound.

- 264 Wang D, Zhao S, Zhang Q, Li Y, Ma X, Ren R. (2016) Vibrant SoundBridge combined with auricle reconstruction for bilateral congenital aural atresia. *Int J Pediatr Otorhinolaryngol.* Jul; 86:240-5.

#### Abstract

**OBJECTIVES:** To report an integrating surgical method of Vibrant SoundBridge (VSB) implant and auricle reconstruction. **METHODS:** 4 cases of congenital bilateral external/middle ear malformation were enrolled. All of them were diagnosed as bilateral bony atresia and grade III microtia. Stapes vibroplasty was performed for all subjects in one operation with auricle reconstruction stage 3. The clinical information and hearing outcomes were analyzed. **RESULTS:** Satisfied aesthetic outcomes were confirmed by sculptured outline and symmetric shape on both sides. Mean improvement in hearing threshold with VSB activation was 25.9 dB HL, while mean scores of speech recognition test were 21.8-46.3%.

**CONCLUSION:** Combined surgical method of VSB implant and aesthetic reconstruction is safe and efficient for congenital external/middle ear malformation case.

- 263 Zahnert T., Löwenheim H., Beutner D., Hagen R., Ernst A., Pau H.W., Zehlicke T., Kühne H., Friese N., Tropitzsch A., Lüers J.C., Mlynski R., Todt I., Hüttenbrink K.B. (2016). Multicenter Clinical Trial of Vibroplasty Couplers to Treat Mixed/Conductive Hearing Loss: First Results. *Audiol Neurotol.* 21(4):212-222. doi: 10.1159/000444616.

#### Abstract:

**OBJECTIVE:** To evaluate the safety and effectiveness of round window (RW), oval window (OW), CliP and Bell couplers for use with an active middle ear implant.

**METHODS:** This is a multicenter, long-term, prospective trial with consecutive enrollment, involving 6 university hospitals in Germany. Bone conduction, air conduction, implant-aided warble-tone thresholds and Freiburger monosyllable word recognition scores were

compared with unaided preimplantation results in 28 moderate-to-profound hearing-impaired patients after 12 months of follow-up. All patients had previously undergone failed reconstruction surgeries (up to 5 or more). In a subset of patients, additional speech tests at 12 months postoperatively were used to compare the aided with the unaided condition after implantation with the processor switched off. An established quality-of-life questionnaire for hearing aids was used to determine patient satisfaction.

**RESULTS:** Postoperative bone conduction remained stable. Mean functional gain for all couplers was 37 dB HL (RW = 42 dB, OW = 35 dB, Bell = 38 dB, CliP = 27 dB). The mean postoperative Freiburger monosyllable score was 71% at 65 dB SPL. The postimplantation mean SRT50 (speech reception in quiet for 50% understanding of words in sentences) improved on average by 23 dB over unaided testing and signal-to-noise ratios also improved in all patients. The International Outcome Inventory for Hearing Aids (IOI-HA)quality-of-life questionnaire was scored very positively by all patients.

**CONCLUSION:** A significant improvement was seen with all couplers, and patients were satisfied with the device at 12 months postoperatively. These results demonstrate that an active implant is an advantage in achieving good hearing benefit in patients with prior failed reconstruction surgery.

- 262 Gostian A.O., Pazen D., Ortmann M., Anagiotos A., Schwarz D., Hüttenbrink K.B., Beutner D. (2016). Loads and Coupling Modalities Influence the Performance of the Floating Mass Transducer as a Round Window Driver. *Otol Neurotol.* Jun; 37(5):524-32.

**Abstract:**

**HYPOTHESIS:** High loads forcing the floating mass transducer (FMT) of a single active middle ear implant toward the round window membrane (RWM) affect the backward stimulation of the cochlea.

**BACKGROUND:** Various factors influence the backward stimulation of the cochlea. We investigated the effects of various loads applied to the FMT together with different coupling techniques at the fully exposed RWM on the vibration transmission. **METHODS:** Experimental study on temporal bones with the FMT linked to a load cell mounted on a translation stage moving it against the fully exposed RWM with increasing loads up to 200 mN by itself, with interposed perichondrium, cartilage or connected to the round window coupler. Cochlear stimulation is measured by the volume velocities of the stapes footplate using LASER-Doppler-vibrometry. **RESULTS:** Loads ranging from 5 to 20 mN induce the highest volume velocities of the stapes footplate. Increasing loads decrease the transmission of vibration in the low-frequency range but enhance the transmission of high frequencies. The interposition of perichondrium and cartilage proved to be advantageous.

**CONCLUSION:** The load applied to the FMT distinctly affects the backward stimulation of the cochlea. Although increasing loads have inverse effects on the transmission of low and high frequencies, high loads lead to an overall decrease of cochlear stimulation. Out of the applied coupling techniques interposed perichondrium and cartilage allow for the most efficient stimulation.

- 261 Zwartekot J.W., Mulder J.J., Snik A.F., Cremers C.W., Mylanus E.A. (2016). Active Middle Ear Implantation: Long-term Medical and Technical Follow-up, Implant Survival, and Complications. *Otol Neurotol.* 2016 Jun; 37(5):513-9.

Abstract:

**OBJECTIVE:** To evaluate the long-term medical and technical results, implant survival, and complications of the semi-implantable vibrant soundbridge (VSB), otologics middle ear transducer (MET), and the otologics fully implantable ossicular stimulator (FIMOS). **STUDY DESIGN:** Retrospective cohort study. **PATIENTS:** Patients with chronic external otitis and either moderate to severe sensorineural or conductive/mixed hearing loss. **SETTING:** Tertiary referral center.

**INTERVENTION:** Implantation with the VSB, MET, or FIMOS. **MAIN OUTCOME MEASURES:** Medical complications, number of reimplantations, and explantations. **RESULTS:** Ninety-four patients were implanted, 12 patients with a round window or stapes application. 28 patients were lost to follow-up. The average follow-up duration was 4.4 years (range, 1 month-15 years). 128 devices were evaluated: (92 VSB, 32 MET, 4 FIMOS). 36 devices (28%) have been explanted or replaced (18 VSB, 14 MET, 4 FIMOS). Device failure was 7% for VSB, 28% for MET, and 100% for FIMOS. In 16 patients (17%) revision surgery (n=20) was performed. Twenty patients (21%) suffered any medical complication. **CONCLUSION:** Medical and technical complications and device failures have mostly occurred in the initial period of active middle ear implants (AMEI) implementation and during clinical trials or experimental procedures. All four FIMOS had technical difficulties. An important decrease in the occurrence of both medical and technical complications was observed. Application in more recent years did not show any complications and the recent device failure rates are acceptable. Magnetic resonance imaging (MRI) incompatibility should be taken into account when indicating AMEI.

- 260 Chen K., Yin D., Lyu H., Yang L., Zhang T., Dai P. (2016). Anatomic measurements of the posterior tympanum related to the round window vibroplasty in congenital aural atresia and stenosis patients. *Acta Otolaryngol.* May; 136(5):470-4. Epub 2016 Jan 12.

Abstract:

**Conclusions:** With the aggravation of the external auditory canal malformation, the size of extra-niche fossa became smaller, providing concrete data and valuable information for the better design, selecting and safer implantation of the transducer in the area of round window niche. Three-dimensional measurements and assessments before surgery might be helpful for a safer surgical approach and implantation of a vibrant soundbridge. **Objectives:** The aim of this study was to investigate whether differences exist in the morphology of the posterior tympanum related to the round window vibroplasty among congenital aural atresia (CAA), congenital aural stenosis (CAS), and a normal control group, and to analyze its effect on the round window implantation of vibrant soundbridge. **Methods:** CT images of 10 normal subjects (20 ears), 27 CAS patients (30 ears), and 25 CAA patients (30 ears) were analyzed. The depth and the size of outside fossa of round

window niche related to the round window vibroplasty (extra-niche fossa)and the distances between the center of round window niche and extra-niche fossa were calculated based on three-dimensional reconstruction using mimics software. Finally, the data were analyzed statistically. Results: The size of extra-niche fossa in the atresia group was smaller than in the stenosis group ( $p < 0.05$ ); furthermore, the size of extra-niche fossa in the stenosis group was smaller than that of the control group ( $p < 0.05$ ). There was no statistically significant difference of the depth of extra-niche fossa among different groups.

- 259 Doi K., Kanzaki S., Kumakawa K., Usami S., Iwasaki S., Yamanaka N., Naito Y., Gyo K., Tono T., Takahashi H., Kanda Y. (2016). Evaluation of the Effectiveness and Safety in a Multi-center Clinical Trial of VIBRANT SOUNDBRIDGE in Japan. *Nihon Jibiinkoka Gakkai Kaiho*; 118(12):1449-58. [Article in Japanese]

Abstract:

Middle ear implants (MEIs) such as the Vibrant Soundbridge (VSB) are attractive and alternative treatments for patients with conductive, sensorineural, and mixed hearing loss who do not benefit from, or who choose not to wear, conventional hearing aids (HAs). Recent studies suggest that MEIs can provide better improvements in functional gain, speech perception, and quality of life than HAs, although there are certain risks associated with the surgery which should be taken into consideration, including facial nerve or chorda tympanic nerve damage, dysfunctions of the middle and inner ears, and future device failure/explantation. In Japan, a multi-center clinical trial of VSB was conducted between 2011-2014. A round window vibroplasty via the transmastoid approach was adopted in the protocol. The bony lip overhanging the round window membrane (RWM) was extensively but very carefully drilled to introduce the Floating Mass Transducer (FMT). Perichondrium sheets were used to stabilize the FMT onto the RWM. According to the audiological criteria, the upper limit of bone conduction should be 45 dB, 50 dB, and 65 dB from 500 Hz to 4, 000 Hz. Twenty-five patients underwent the surgery so far at 13 different medical centers. The age at the surgery was between 26-79 years old, and there were 15 males and 10 females. The cause of conductive or mixed hearing loss was middle ear diseases in 23 cases and congenital aural atresia in two cases. The data concerning on the effectiveness and safety of VSB was collected before the surgery and 20 weeks after the surgery. Significant improvements of free-field Pure Tone Audiogram (PTA) from 250 Hz to 8, 000 Hz were confirmed ( $p < 0.001$ ). Hearing gain up to 40 dB was achieved in the 1, 000 Hz to 4, 000 Hz range. No deterioration in either air conduction or bone conduction at PTA was noted at 20 weeks after the surgery. Monosyllable speech perception in both quiet and noisy conditions improved significantly ( $p < 0.001$ ). The speech discrimination score in both quiet and noisy conditions improved significantly too ( $p < 0.001$ ). In the future, it is likely that there will be an increasing population even in Japan that will meet the criteria for MEIs such as VSB. However, the long-term efficacy and safety of these devices should be established.

- 258 Schraven S.P., Mlynški R., Dalhoff E., Heyd A., Wildenstein D., Rak K., Radeloff A., Hagen R., Gummer A.W. (2016). Coupling of an active middle-ear implant to the long process of the incus using an elastic clip attachment. *Hear Res.* Apr 13.

Abstract:

The active middle-ear implant Vibrant Soundbridge(©) (VSB) is used to treat mild-to-severe sensorineural hearing losses. The standard surgical approach for incus vibroplasty is a mastoidectomy and a posterior tympanotomy, crimping the Floating Mass Transducer (FMT) to the long process of the incus (LPI) (standard crimped application). However, tight crimping increases the risk of necrosis of the LPI, resulting in reduction of energy transfer and loss of amplification. The aim of this study was to develop a new coupling device for the LPI, that does not require crimping, and to test its vibrational transfer properties in temporal-bone preparations. An extended antrotomy and a posterior tympanotomy were performed in ten fresh human temporal bones. As a control for normal middle-ear function, the tympanic membrane was stimulated acoustically and the vibration of the stapes footplate was measured by laser Doppler vibrometry (LDV). FMT-induced vibration responses of the stapes were then measured for the standard crimped application at the LPI and for the newly designed elastic long process coupler (LP coupler). For the LP coupler, velocity-amplitude responses in temporal-bone preparations showed increased mean amplitudes at around 1 kHz (~10 dB) and a reduction between 1.8 and 6 kHz (13 dB on average for  $2 \leq f \leq 5$  kHz). In conclusion, attachment of the FMT to the LPI with the LP coupler leads to generally good mechanical and functional coupling in temporal-bone preparations with a notable disadvantage between 1.8 and 6 kHz. Due to its elastic clip attachment it is expected that the LP coupler will reduce the risk of necrosis of the incus long process, which has to be shown in further studies. Clinical results of the LP coupler are pending.

- 257 Polanski J.F., Soares A.D., Dos Santos Z.M., Mendonça Cruz O.L. (2016). Active middle-ear implant fixation in an unusual place: clinical and audiological outcomes. *J Laryngol Otol.* Apr;130 (4):404-7.

Abstract:

**OBJECTIVE:** The Vibrant Soundbridge is an active middle-ear implant for hearing rehabilitation that is usually placed in the long process of the incus or round window. This study reports on the unusual implant attachment to the short process of the incus in a patient with ear malformation, and describes their audiological and clinical outcomes.

**METHODS:** Case report and literature review.

**RESULTS:** Audiological evaluation with the Vibrant Soundbridge implant showed a pure tone average of 31 dB. The speech test, at 65 dB HL, revealed correct recognition of 92 per cent of disyllabic words. The Glasgow Hearing Aid Benefit Profile showed high levels of satisfaction, hearing aid use and benefit. **CONCLUSION:** Fixation of the Vibrant Soundbridge implant on the short process of the incus is a feasible option, with good clinical and audiological outcomes.

Coupling the floating mass transducer to the short process of the incus is a good surgical option, especially when the long process and the oval or round window are inaccessible.

- 256 Gostian A.O., Schwarz D., Mandt P., Anagiotos A., Ortmann M., Pazan D., Beutner D., Hüttenbrink K.B. (2016). Performance of the round window soft coupler for the backward stimulation of the cochlea in a temporal bone model. *Eur Arch Otorhinolaryngol*. Mar 28. [Epub ahead of print]

Abstract:

The round window vibroplasty is a feasible option for the treatment of conductive, sensorineural and mixed hearing loss. Although clinical data suggest a satisfying clinical outcome with various coupling methods, the most efficient coupling technique of the floating mass transducer to the round window is still a matter of debate. For this, a soft silicone-made coupler has been developed recently that aims to ease and optimize the stimulation of the round window membrane of this middle ear implant. We performed a temporal bone study evaluating the performance of the soft coupler compared to the coupling with individually shaped cartilage, perichondrium and the titanium round window coupler with loads up to 20 mN at the unaltered and fully exposed round window niche. The stimulation of the cochlea was measured by the volume velocities of the stapes footplate detected by a laser Doppler vibrometer. The coupling method was computed as significant factor with cartilage and perichondrium allowing for the highest volume velocities followed by the soft and titanium coupler. Exposure of the round window niche allowed for higher volume velocities while the applied load did not significantly affect the results. The soft coupler allows for a good contact to the round window membrane and an effective backward stimulation of the cochlea. Clinical data are mandatory to evaluate performance of this novel coupling method *in vivo*.

- 255 Lassaletta L., Calvino M., Zernotti M., Gavilán J. (2016). Postoperative pain in patients undergoing a transcutaneous active bone conduction implant (Bonebridge). *Eur Arch Otorhinolaryngol*. Mar 11. [Epub ahead of print]

Abstract:

The objective of the study was to evaluate postoperative pain following a transcutaneous active conductive hearing implant. 27 patients undergoing Bonebridge (BB) bone conduction implantation were evaluated with two pain-related questionnaires. The Headache Impact Test (HIT-6) was used to measure the degree of disability including none or little impact ( $\leq 49$ ), mild (50-55), moderate (56-59), and severe ( $\geq 60$ ). 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  $\geq 3$ . 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.

- 254 Schraven S.P., Großmann W., Rak K., Shehata-Dieler W., Hagen R., Mlynki R. (2016). Long-term Stability of the Active Middle-ear Implant with Floating-mass Transducer Technology: A Single-center Study. *Otol Neurotol.* Mar; 37(3):252-66.

**Abstract:**

**OBJECTIVE:** To examine the long-term results of an active middle-ear implant (AMEI) with floating-mass transducer (FMT) technology. **STUDY DESIGN:** Prospective cohort study of German-speaking patients implanted with an AMEI between 2006 and 2013. **SETTING:** Single-center study. **PATIENTS:** Eighty-three patients. **INTERVENTION:** AMEI with FMT technology implantation. **MAIN OUTCOME MEASURES:** Long-term outcome (27 mo; range, 12-84 mo) for FMT position in correlation with pure-tone audiometry, auditory thresholds for frequency-modulated (warble) tones, vibroplasty thresholds for pure tones, and speech audiometry in quiet and noise. **RESULTS:** In 15.6% of patients, a revision surgery was necessary to improve functional performance of the AMEI, and the highest revision rate was found with FMT coupling to the round window not using couplers. A peak number of revision surgeries were observed 3 years after the initial surgery. Stable audiological results (pure-tone audiometry and speech audiometry in quiet and noise) were observed up to 84-month post-surgery. Incus vibroplasty (classic indication) showed a significantly lower functional gain compared with oval and round window vibroplasty. Vibroplasty in combined or conductive hearing loss showed no functional difference between forward and reverse stimulation of the cochlea; however, significantly lower vibroplasty thresholds were detected when using a coupler. **CONCLUSIONS:** The AMEI with FMT technology can be safely used in treatment of patients with mild-to-severe sensorineural, conductive, or mixed hearing loss. Optimized coupling, especially in incus vibroplasty, has to be developed to achieve enhanced audiological results.

- 253 Mondelli M.F., Mariano T.C., Honório H.M., Brito R.V. (2016). Vibrant Soundbridge and Bone Conduction Hearing Aid in Patients with Bilateral Malformation of External Ear. *Int Arch Otorhinolaryngol.* 20(1):34-8.

**Abstract:**

**INTRODUCTION:** Hearing loss is the most common clinical finding in patients with malformation of the external ear canal. Among the possibilities of treatment, there is the adaptation of hearing aids by bone conduction and the adaptation of implantable hearing aids. Objective To assess speech perception with the use of Vibrant Soundbridge (VBS -

MED-EL, Innsbruck, Austria) associated with additional amplification in patients with bilateral craniofacial malformation. **METHOD:** We evaluated 11 patients with bilateral malformation over 12 years with mixed hearing loss or bilateral conductive. They were using the Softband (Oticon Medical, Sweden) and bone conduction hearing aid in the ear opposite the one with the VSB. We performed the evaluation of speech perception using the Hearing in Noise Test. **RESULTS:** Participants were eight men and three women with a mean of 19.5 years. The signal / noise ratio presented significant results in patients fitted with VSB and bone conduction hearing aid. **CONCLUSION:** The results of speech perception were significantly better with use of VBS combined with bone conduction hearing aids.

- 252 Jung J., Roh K.J., Moon I.S., Kim S.H., Hwang K.R., Lee J.M., Hou J.H., Choi J.Y. (2016). Audiologic limitations of Vibrant Soundbridge device: Is the contralateral hearing aid fitting indispensable? Laryngoscope. [Epub ahead of print]

**Abstract:**

**OBJECTIVES/HYPOTHESIS:** The purpose of this study was to evaluate the audiologic limitations of the Vibrant Soundbridge (VSB) implant and the benefits of contralateral hearing aid (HA) fitting in VSB recipients. **STUDY DESIGN:** Retrospective study. **METHODS:** Twenty-three patients with symmetrical sensorineural or mixed hearing loss were enrolled in this study. The patients underwent VSB implantation in one ear and HA fitting in the other. Aided pure-tone audiometry was performed to measure the functional gains of each device. The Korean version of the Hearing in Noise Test (K-HINT) was used to determine the sentence speech perception in a quiet environment and the signal-to-noise ratio (SNR) in a noisy environment. **RESULTS:** VSB implantation resulted in hearing gains comparable to that of conventional HAs at high frequencies, whereas the functional gains at low frequencies were not satisfactory in the mixed hearing loss group. In these patients, the contralateral HA sufficiently amplified the low frequencies. The results of the K-HINT of the SNR in the VSB-aided ear were not significantly improved when compared to HA-aided contralateral ear. However, binaural fitting of a VSB and HA resulted in substantially improved SNR when compared to the unaided condition. This improvement of the SNR strongly correlated with functional gains at low frequencies in the contralateral HA-aided ear. **CONCLUSIONS:** Although unilateral VSB implantation is limited in terms of low-tone enhancement and speech perception in noisy environments, contralateral HA fitting can overcome these limitations and increase the efficacy of hearing rehabilitation.

- 251 Roh K.J., Lee E.J., Choi B.I. & Son, E.J. (2015). A case of Incus Vibroplasty: Postoperative changes in residual hearing. *J Audiol Otol.* 19(1), 54–57.

**Abstract:**

In patients with mild to severe hearing loss, conventional hearing aids offer limited benefits and several problems with feedback and cosmesis. Middle ear implants are a feasible option for patients with moderate to severe hearing loss who are unable to

achieve adequate benefit from or cannot tolerate hearing aids for various reasons. Here we present a case of middle ear implant surgery using Vibrant Soundbridge with incus vibroplasty technique, and describe the hearing changes during postoperative follow-up.

- 250 Kaulitz S., Großmann W., Steinbach J., Hackenberg S., Kraus F., Köhler C., Mlynki R., Radeloff A., Rak K., Schraven SP., Hagen R. (2015) Direct Drive Simulation - Sound-Simulation of the Vibrant Soundbridge®. Laryngorhinootologie. [Epub ahead of print].

**Abstract:**

**BACKGROUND:** The Direct-Drive-Simulation (DDS) tends to simulate the sound quality of hearing with the active middle ear implant Vibrant Soundbridge® (VSB). Up to now a scientific evaluation of the validity is missing. Furthermore, the test procedure has not been described yet. Aim of this study was to evaluate the test validity and to describe the test realization in detail. **MATERIAL AND METHODS:** 10 patients evaluated their sound impression on scales from 1 to 10 concerning sound quality during DDS, postoperative free field testing at least 3 month after the first fitting of the VSB and in the everyday life situation. 3 patients were implanted bilaterally. Together, 36 data sets could be analyzed. **RESULTS:** Coupling of the Floating Mass Transducer (FMT), which was placed inside of a silicone probe during DDS was successful in all cases. In 11 out of 13 cases the coupling quality was judged as "good" and only in 2 cases as "medium". None of the patients needed local anesthesia. Comparing the evaluation of the sound impression during DDS preoperatively, and with the implanted VSB in free field testing and in everyday life no significant differences were found. **CONCLUSION:** The DDS offers the possibility of a realistic preoperative sound simulation of the "VSB-hearing" in case of sensorineural hearing loss. Thus, the test is supposed to facilitate the patient's decision towards possible treatment options. The specialist gets additional information regarding the indication especially when audiologic indication criteria are critical. The DDS should be a basic part of the preoperative diagnostic prior to VSB-implantation.

- 249 Dazert S., Thomas JP., Volkenstein S. (2015) Surgical and Technical Modalities for Hearing Restoration in Ear Malformations. Facial Plast Surg. 31(6):581-6.

**Abstract:**

Malformations of the external and middle ear often go along with an aesthetic and functional handicap. Independent of additional aesthetic procedures, a successful functional hearing restoration leads to a tremendous gain in quality of life for affected patients. The introduction of implantable hearing systems (bone conduction and middle ear devices) offers new therapeutic options in this field. We focus on functional rehabilitation of patients with malformations, either by surgical reconstruction or the use of different implantable hearing devices, depending on the disease itself and the severity of malformation as well as hearing impairment. Patients with an open ear canal and minor malformations are good candidates for surgical hearing restoration of middle ear structures with passive titanium or autologous implants. In cases with complete fibrous or

bony atresia of the ear canal, the most promising functional outcome and gain in quality of life can be expected with an active middle ear implant or a bone conduction device combined with a surgical aesthetic rehabilitation in a single or multi-step procedure. Although the surgical procedure for bone conduction devices is straightforward and safe, more sophisticated operations for active middle ear implants (e.g., Vibrant Soundbridge, MED-EL, Innsbruck, Austria) provide an improved speech discrimination in noise and the ability of sound localization compared with bone conduction devices where the stimulation reaches both cochleae.

- 248 Kumakawa K., Kanzaki S., Usami S., Iwasaki S., Yamanaka N., Doi K., Naito Y., Gyo K., Tono T., Takahashi H., Kanda Y. (2015). Multicenter Clinical Study of Vibrant Soundbridge in Japan: Analysis of Subjective Questionnaires. *Nihon Jibiinkoka Gakkai Kaiho*. 118(11):1309-18. [Article in Japanese].

Abstract:

The Vibrant Soundbridge (VSB) is an active middle ear implant with the Floating Mass Transducer (FMT). We performed a multicenter study to study the efficacy of the VSB by means of "the 10 Questionnaire on Hearing 2002" and "the APHAB questionnaire" at 13 hospitals between 2011 and 2013. In all, 23 patients with mixed or conductive hearing loss received VSB implantation by the round window placement technique. These individuals were generally unable to use, or gained little from conventional hearing aids or bone conduction hearing aids. Two questionnaires were administrated before the surgery and 20 weeks after the VSB implantation. Scores on every item of "the 10 Questionnaire on Hearing 2002" showed significant improvement under noise after VSB implantation. On the APHAB, the scores for Ease of Communication, Reverberation, and Background subscales improved significantly after the VSB implantation, while the score for the Aversiveness subscale alone failed to show a positive improvement from the in experience to the new sound. Analysis of the responses to these subjective questionnaires revealed better results after VSB implantation as compared to the preoperative data. In conclusion, RW vibroplasty with the use of VSB provided subjective benefit in patients with conductive and mixed hearing loss.

- 247 Renninger D., Ernst A., Todt I. (2015). MRI scanning in patients implanted with a round window or stapes coupled floating mass transducer of the Vibrant Soundbridge. *Acta Otolaryngol*. 136(3):241-4.

Abstract:

**CONCLUSION:** MRI examinations in patients with an alternatively coupled VSB can lead to unpleasant side-effects. However, the residual hearing was not impaired, whereas the hearing performance with the VSB was decreased in one patient which could be fixed by a surgical revision. Different experiences for the VSB 503 can be expected. **OBJECTIVE:** To investigate the *in vivo* effects of MRI scanning on the Vibrant Soundbridge system (VSB) with an alternatively coupled Floating Mass Transducer (FMT). **METHOD:** Sixty-five VSB (502) implantees were included in this study. Of them, 42 questionnaires could be

evaluated with the patients' statements about their medical, otological, and general condition before, during, and after an MRI scan which was indicated for different medical reasons, despite the previous implantation of an alternatively coupled Vibrant Soundbridge System. RESULTS: In four patients (9.5%), five MRI examinations were performed. These were done for different indications (e.g. knee and shoulder joint diagnostics). During the scanning, noise and subjectively perceived distortion of the implant were described. A deterioration of the hearing gain with the VSB in place was found in one patient. A decrease of the hearing threshold was not observed.

- 246 Ernst A., Todt I., Wagner J. (2015). Safety and effectiveness of the Vibrant Soundbridge in treating conductive and mixed hearing loss: A systematic review. *Laryngoscope*.

[Epub ahead of print]

Abstract:

OBJECTIVES/HYPOTHESIS: For many years, the therapeutic approach for conductive and/or mixed hearing loss has consisted of middle ear surgery with replacement of defect ossicles, and if possible the application of a hearing aid. Advances in technology have led to the introduction of electron magnetic active implantable devices such as the Vibrant Soundbridge (VSB). With its various coupling techniques for different pathophysiological situations in the middle ear, the VSB offers greater improvement in the hearing performance of affected persons. DATA SOURCE: PubMed, OvidSP (MEDLINE), EMBASE (DIMDI), the National Institute for Health Research (NIHR) Centre for Reviews and Dissemination (including the National Health Service Economic Evaluation Database, Database of Abstracts of Reviews of Effects, and Health Technology Assessment), and the Cochrane Library were searched to identify articles published between January 2006 and April 2014 that evaluated the safety and effectiveness of the VSB in comparison to no intervention, bone conduction hearing implants (BCHI), and middle ear surgery plus hearing aids for adults and children with conductive or mixed hearing loss. METHODS: Study selection and data extraction was carried out by multiple reviewers. Study quality was assessed using the Oxford Centre for Evidence-Based Medicine levels of evidence (2011); and a checklist available from the Evidence Analysis Library, Academy of Nutrition and Diabetics. RESULTS: Thirty-six publications were identified: 19 on VSB outcomes in 294 individuals, 13 on BCHI outcomes in 666 individuals, and four on middle ear surgery plus hearing aid outcomes in 43 individuals. Two systematic reviews were also identified. Heterogeneous outcome measures made it difficult to summarize data. In general, the VSB proved to be safe and effective when compared to no intervention and BCHI, and provided more and consistent hearing gain compared to middle ear surgery plus conventional hearing aids. CONCLUSION: As demonstrated in the literature, the VSB as an active device offers an effective alternative for patients with various middle ear pathologies, particularly with mixed hearing loss and failed previous tympanoplasties when classical ossiculoplasty could not provide enough functional gain. This new strategy in hearing rehabilitation has led to an improved quality of hearing and life.

- 245 Wolf-Magele A., Koci V., Schnabl J., Zorowka P., Riechelmann H., Sprinzl GM. (2015). Bilateral use of active middle ear implants: speech discrimination results in noise. *Eur Arch Otorhinolaryngol.* [Epub ahead of print].

Abstract:

Binaural sound reception has advantages over unilateral perception, including better localization and sound quality as well as speech and tone reception in both quiet and noisy environments. Up to now, most active middle ear implant (AMEI) users have been unilaterally implanted, but patient demand for an implant on the other side is increasing. Ten bilaterally-AMEI implanted native German-speaking adults were included in the study. The Oldenburg sentence test was used to measure speech reception thresholds in noise. The subject's signal-to-noise ratio (SNR) at a speech reception score of 50 % was calculated for different noise conditions. SRT was measured as a function of noise condition (nc) and listening condition (lc)-for example, SRT (lc, nc), with nc from SON0, SON-90, or SON90 and lc from left, right or both. For each noise condition, the squelch effect and the binaural summation effect were calculated. Patients in this study demonstrated improvement with bilateral AMEIs compared to right or left AMEI only in all three tested listening conditions. Statistical significance was found in the SON0 condition to favor usage of bilateral AMI versus either the right or left side only. The benefits of binaural hearing are well known, also in normal-hearing individuals. In the future every bilateral implantation should be a part of the clinical routine. Bilateral implantation can help to reduce problems in background noise and restore directional hearing.

- 244 Mueller M., Salcher R., Majdani O., Lenarz T., Maier H. (2015). Electro-Mechanical Stimulation of the Cochlea by Vibrating Cochlear Implant Electrodes. *Otol Neurotol.* 36(10):1753-8.

Abstract:

**INTRODUCTION:** Electro-acoustic stimulation (EAS) of the cochlea uses the preserved residual low-frequency hearing for acoustic stimulation in combination with electrical stimulation. The acoustic low-frequency component is amplified and high-frequency hearing is enhanced by a cochlear implant (CI). In this work, the feasibility of EAS by the floating mass transducers (FMTs) firmly attached to the implanted electrode was investigated and the achieved stapes displacement was compared with sound stimulation. **METHODS:** Experiments were performed in eight fresh human temporal bones compliant to the ASTM standard (F2504-5). Four EAS custom-made prototypes (EAS-CMP) were tested, consisting of standard MED-EL CI electrodes with Vibrant Soundbridge (VSB) FMTs or a Bonebridge (BB) FMT tightly molded to the electrode in different orientations. The stapes footplate (SFP) response to EAS-CMP stimulation and sound stimulation was measured using a Laser Doppler Vibrometer (LDV). **RESULTS:** The SFP displacement amplitudes achieved by EAS-CMP stimulation were calculated to 1 VRMS FMT input and were pair-wise statistically compared between prototypes yielding no significant differences at frequencies  $\leq 1\text{kHz}$ . At frequencies  $\leq 1\text{kHz}$  stimulation by the BB FMT resulted in a flat and

potentially highest SFP displacement amplitude of approximately -40dB re  $\mu\text{m}$  at 1VRMS input voltage. Estimated equivalent sound pressure levels achieved by the BB FMT prototype were approximately 83-90 eq. dB SPL at frequencies  $\leq 1\text{kHz}$ . CONCLUSION: The feasibility of cochlear stimulation by vibrating electrodes was shown although the achieved output level at frequencies  $\leq 1\text{kHz}$  was too low for EAS applications.

- 243 Bianchin G., Tribi L., Reverzani A., Formigoni P., Polizzi V. (2015). Original Solution for Middle Ear Implant and Anesthetic/Surgical Management in a Child with Severe Craniofacial Dysmorphism. *Case Rep Otolaryngol.* 2015:205972.

Abstract:

We describe the novel solution adopted in positioning middle ear implant in a child with bilateral congenital aural atresia and craniofacial dysmorphism that have posed a significant challenge for the safe and correct management of deafness. A five-year-old child, affected by a rare congenital disease (Van Maldergem Syndrome), suffered from conductive hearing loss. Conventional skin-drive bone-conduction device, attached with a steel spring headband, has been applied but auditory restoration was not optimal. The decision made was to position Vibrant Soundbridge, a middle ear implant, with an original surgical application due to hypoplasia of the tympanic cavity. Intubation procedure was complicated due to child craniofacial deformities. Postoperative hearing rehabilitation involved a multidisciplinary team, showing improved social skills and language development.

- 242 Zhao S., Gong S., Han D., Zhang H., Ma X., Li Y., Chen X., Ren R., Li Y. (2015). Round window application of an active middle ear implant (AMEI) system in congenital oval window atresia. *Acta Otolaryngol.* 23:1-11.

Abstract:

CONCLUSION: Application of the Vibrant Soundbridge to the round window (RW) membrane can be utilized as an efficient therapy for congenital oval window (OW) atresia. OBJECTIVE: To report the surgical technique and auditory outcome of an active middle ear implant (AMEI) system used in patients with congenital OW atresia. METHODS: Nine subjects with congenital OW atresia (six males and three females, ranging in age from 5.5 to 25 years, average 12.5 years) were implanted with an AMEI (Vibrant Soundbridge) at the round window (RW-Vibroplasty). Five cases were diagnosed as having isolated congenital OW atresia while four patients presented with combined external / middle ear malformation. RESULTS: An improvement of 30 dB in average pure-tone air conduction thresholds (0.5-4 kHz) was achieved, with the high frequencies showing greater results. The subjects achieved postoperative speech recognition scores of 80-100% on the Computerized Mandarin Speech Test System (CMSTS) sentence test. Bone conduction thresholds were confirmed as stable in all subjects postoperatively. Decline in auditory benefit was noticed in two subjects, who then underwent revision surgery. One of these revision surgery patients then experienced stable hearing recovery, while the other

patient's hearing declined.

- 241 Mlynški, R., Dalhoff, E., Heyd, A., Wildenstein, D., Rak, K., Radloff, A., Hagen, R., Gummer, A.W. & Schraven, S.P. (2015). Standardized active middle-ear implant coupling to the short incus process. *Otol Neurotol.* 36(8), 1390-8.

Abstract:

**INTRODUCTION:** Active middle-ear implants with floating-mass transducer (FMT) technology are used to treat mild-to-severe sensorineural hearing losses. The standard surgical approach for incus vibroplasty is a mastoidectomy and a posterior tympanotomy, crimping the FMT to the long incus process. An alternative fixation side with less surgical trauma might be the short incus process and incus body. The aim of this study was to develop and test a short incus process coupling device for its functional properties in temporal bone preparations and clinical practice. **MATERIALS AND METHODS:** An extended antrotomy and a posterior tympanotomy were performed in 10 fresh human temporal bones. As a control for normal middle-ear function, the tympanic membrane was stimulated acoustically, and the vibration of the stapes footplate was measured using laser Doppler vibrometry. FMT-induced vibration responses of the stapes were then measured for standard attachment at the long process and for 2 types of couplers designed for attachment at the short process of the incus (SP1 and SP2 coupler). Additionally, the functional outcome in 2 patients provided with an SP2 coupler was assessed postoperatively at 2 weeks, 3 months, and then 11 months, using pure-tone audiometry, auditory thresholds for frequency-modulated (warble) tones, vibroplasty thresholds, and speech audiometry in quiet and noise. **RESULTS:** For the SP2 coupler, velocity-amplitude responses in temporal-bone preparations showed generally similar mean amplitudes as compared with the standard coupling of the FMT to the long process but with clearly increased mean amplitudes between 0.7 and 1.5 kHz and with reduced interindividual variation between 0.5 and 3 kHz. The clinical data of 2 patients with mild-to-severe sensory hearing loss showed good vibroplasty thresholds and convincing results for speech audiometry in quiet (Freiburger monosyllables at 65 dB SPL,  $23 \pm 31\%$  unaided versus  $83 \pm 4\%$  aided) and noise (Hochmair-Schulz-Moser-test at 65 dB SPL at 10 dB SNR,  $32 \pm 45\%$  unaided and  $42 \pm 29\%$  aided).

**CONCLUSION:** The attachment of the FMT to the short incus process with the SP2 coupler leads to good mechanical and functional coupling in an experimental setup and clinical practice.

- 240 Frenzel H., Sprinzl G., Streitberger C., Stark T., Wollenberg B., Wolf-Magele A., Giarbini N., Strenger T., Müller J. & Hempel, J.M. (2015). The Vibrant SOUNDBRIDGE in children and adolescents: Preliminary European multicentre results. *Otol Neurotol.* 36(7), 1216-22.

Abstract:

**OBJECTIVE:** Evaluation of safety and efficacy of the Vibrant Soundbridge in the treatment of hearing loss in children and adolescents with primary focus on improvement in speech

discrimination. STUDY DESIGN: Prospective, single-subject repeated-measures design in which each subject serves as his/her own control. SETTING: Tertiary referral center. PATIENTS: Nineteen patients aged 5 to 17 years. INTERVENTION: Implantation of an active middle ear implant. MAIN OUTCOME MEASURE: Improvement in word recognition scores, speech reception thresholds, and signal-to-noise ratios (SNRs) were evaluated, in addition to air and bone conduction. Oldenburger Kids Satztest/Oldenburger Satztest sentences and Göttinger/Freiburger monosyllables at 65-dB hearing level were tested in two age groups. RESULTS: Significant speech discrimination improvement was seen in all patients after 6 months. In children 5 to 9 years old, mean monosyllable recognition improved from 28.9% (unaided) to 95.5% (Soundbridge-aided). Aided 50% sentence discrimination at 44.1 dB and SNR of -4.9 dB were measured. In patients 10 to 17 years old, mean word recognition improved from 18.5% to 89.0%, sentence reception threshold improved to 40.2 dB, and SNR to -3.6 dB. Comparison between age groups indicated a slight trend toward quicker adaptation by older subjects. However, after initial adjustment, a higher level of overall benefit was seen at 6 months in younger children. CONCLUSIONS: Currently, the only middle ear implant approved for pediatric patients, the Vibrant Soundbridge, provides an option in cases of congenital aural atresia or disease-induced defects, when surgical intervention and reconstruction is indicated. The 6-month results in this comparatively large study population validated conclusions found in previous trials.

- 239 Marino R., Lampacher P., Dittrich G., Tavora-Vieira D., Kuthubutheen J. & Rajan G.P. (2015). Does coupling and positioning in Vibroplasty matter? A prospective cohort study. Otol Neurotol. 36(7), 1223-30.

**Abstract:**

OBJECTIVE: Vibroplasty has offered a new modality of hearing rehabilitation in patients with mixed, conductive, and sensorineural hearing loss who cannot wear hearing aids. Potentially, the positioning of the floating mass transducer (FMT) in vibroplasty surgery has a critical effect on hearing outputs. In this study, the impact on hearing outputs and coupling efficiency are evaluated by comparing various vibroplasty applications in the middle ear. No other study to date has examined the coupling efficiency of round window (RW) versus an ossicular vibroplasty application. STUDY DESIGN: Prospective cohort study of patients with underlying ear pathologies who were not able to wear hearing aids. METHODS: This is an ongoing prospective study of 16 patients. All patients had a standard audiological test battery. Direct drive transfer function analysis results were correlated with bone conduction thresholds to assess the efficiency of the FMT coupling. Speech perception in quiet and quality of life measure questionnaires were used to assess outcomes. Nine patients had round window vibroplasty, six patients had stapes vibroplasty, and one patient had traditional incus vibroplasty. RESULTS: Patients with a soft tissue coupler between the FMT and the RW had significantly reduced coupling efficiency. Patients who had direct RW contact had significantly improved coupling efficiency. Patients who underwent stapes or incus vibroplasty had the greatest coupling efficiency. CONCLUSION: This study demonstrates that attachment to the stapes or incus provides the best coupling when compared to round window vibroplasty. When applicable,

stapes or incus coupling should be the first choice when implementing vibroplasty.

- 238 Chen K., Lyu H., Xie Y., Yang L., Zhang T. & Dai, P. (2015). Morphological characteristics of Round Window Niche in Congenital Aural Atresia and Stenosis patients. *J Comput Assist Tomogr.* 39(4), 547-51.

Abstract:

**OBJECTIVE:** The aim of this study was to measure the round window niche (RWN) among congenital aural atresia (CAA), congenital aural stenosis (CAS) and control groups and to analyze whether differences exist between them.

**METHODS:** Computed tomography images of 10 normal subjects (20 ears), 27 CAS patients (30 ears) and 25 CAA patients (30 ears) were analyzed. We measured RWN on the basis of 3-dimensional reconstruction. **RESULTS:** The anterior wall length and the depth of RWN were smaller in control group than those in the CAS group; furthermore, the anterior wall length and the depth of RWN in CAS group were smaller than those in CAA group ( $P < 0.05$ ). The posterior wall length of RWN was found smaller in the control group than that in both hCAS and CAA groups ( $P < 0.05$ ). The superior and inferior wall lengths of RWN were found smaller in control group than those in the CAA group ( $P < 0.05$ ). There were no statistically significant differences in the sizes of the round window membrane and niche opening or the angle between the plane of the RWN opening and the round window membrane plane among all groups. **CONCLUSIONS:** The RWN walls lengths and its depth tended to be longer with the aggravation of the aural malformations. Our calculation results may provide some information for a better design and a safer implantation of the floating mass transducer in the area of RWN.

- 237 Seo Y.J., Kim H.J., Moon I.S. & Choi, J.Y. (2015). Changes in tinnitus after Middle Ear Implant Surgery: Comparisons with the Cochlear Implant. *Ear Hear.* 36(6):705-9.

Abstract:

**OBJECTIVES:** Tinnitus is a very common symptom in patients with hearing loss. Several studies have confirmed that hearing restoration using hearing aids or cochlear implants (CIs) has a suppressive effect on tinnitus in users. The aim of this study was to analyze the effect of other hearing restoration devices, specifically the middle ear implant (MEI), on changes in tinnitus severity. **DESIGN:** From 2012 to October 2014, 11 adults with tinnitus and hearing loss underwent MEI surgery. Pure-tone audiometry, tinnitus handicap inventory (THI), and visual analog scale scores for loudness, awareness, and annoyance and psychosocial instruments were measured before, immediately after, and 6 months after surgery. Changes in hearing thresholds and THI scores were analyzed and compared with those of 16 CI recipients. **RESULTS:** In both MEI and CI groups, significant improvements in tinnitus were found after the surgery. The THI scores improved in 91% of patients in the MEI group and in 56% of those in the CI group. Visual analog scale scores and psychosocial scale scores also decreased after surgery, but there were no statistical differences between the groups. **CONCLUSIONS:** The results indicate that the MEI may be

as beneficial as the CI in relieving tinnitus in subjects with unilateral tinnitus accompanying hearing loss. Furthermore, this improvement may manifest as hearing restoration or habituation rather than a direct electrical nerve stimulation, which was previously considered as the main mechanism underlying tinnitus suppression by auditory implants. This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivatives 3.0 License, where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially.

- 236 Braun K., Zenner H.P., Friese N. & Tropitzsch, A. (2015). [Differential indication of active middle ear implants]. *HNO*. 63(6), 402-18.

**Abstract:**

**INTRODUCTION:** Hearing aids (HA) provide adequate support for many patients with hearing loss, but not all. Around one third of 10.000 patients provided with hearing aids in the Abbreviated Profile of Hearing Aid Benefit felt no actual benefit when using the hearing aid, although they demonstrated the necessary hearing improvement on speech audiometry. Epidemiological data show bad compliance, especially in older people. Only one in three hearing aid owners wears their device regularly. For this subpopulation of patients active middle ear implants (AMEIs) have been used since 1998. In the present review, the current indications for AMEIs are presented. **MATERIAL AND METHODS:** A selective literature search in PubMed, as well as a guideline search at the Arbeitsgemeinschaft der Wissenschaftlichen Fachgesellschaften e. V. (German Association of Scientific Societies), was carried out. **RESULTS:** The present review shows that when there is an adequate indication the hearing capacity of patients can be thoroughly rehabilitated and thus their quality of life improved with the help of AMEIs. Although most commercially available systems have a satisfactory risk profile, increased extrusion rates, malfunctioning and facial paresis have been reported in older implant series. The advantages of AMEIs include increased hearing gain, reduced feedback, increased hearing quality, increased speech discrimination in the presence of background noise, and an absence of occlusion. **CONCLUSIONS:** The audiological indication for AMEIs in primary care is usually controversial, since the functional hearing gain and increase in speech discrimination may be small compared with modern conventional hearing aids. AMEIs thus play a main role in the secondary care of patients who do not have sufficient benefit or who have side effects after having a conventional hearing aid fitted.

- 235 Barbara M, Volpini L, Ciotti M, Filippi C, Covelli E, Monini S, D'Ambrosio F. (2015). Cone beam computed tomography after round window vibroplasty: do the radiological findings match the auditory outcome? *Acta Otolaryngol*. 135(4), 369-75.

**Abstract:**

**CONCLUSION:** The cone beam computed tomography (CBCT) imaging technique has proved to be reliable for assessing the appropriate positioning of the floating mass transducer (FMT) in the round window (RW) niche, although some parameters do not seem to be

essential for achieving a satisfactory functional outcome. OBJECTIVES: To evaluate the role that specific imaging parameters derived from CBCT of the temporal bone have for predicting the functional outcome after RW vibroplasty (RW-VP). METHODS: CBCT imaging was carried out in a homogeneous group of patients who presented with a mixed type of hearing loss after open tympanoplasty. Three arbitrary radiological parameters were taken into account: the FMT/RW membrane contact, bony contacts of the FMT margins, and the inferior FMT tissue support. The audiological assessment took into consideration the PTA4 (500-4000 Hz), the PTA2 (125-250 Hz), and the word recognition score (WRS) in quiet and in noise. RESULTS: One subject presented with all positive CBCT parameters and showed a good, but not the best auditory performance among the study group. In the majority of the subjects, with a satisfactory postoperative hearing improvement, at least two of the three radiological parameters were present. In comparison with the unaided condition, an improvement in both the PTA4 and PTA2 was found in all the subjects.

- 234 Jovankovicová A, Staník R, Kunzo S, Majáková L, 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), 975-79.

**Abstract:**

OBJECTIVES: Congenital aural atresia and ear deformities have been the subject of serious discussions for centuries. These malformations are associated with significant aesthetic and functional problems. Outcome of the surgical solution is rarely optimal. Despite the gradual improvement of surgical techniques the surgery still remains associated with very limited short-term and mainly long-term functional outcome. Therefore, the priority treatment in modern otology becomes implantable devices-BAHA, Bonebridge and active middle ear implants. METHODS: The functional and aesthetic outcomes of aural atresia reconstruction performed at Pediatric ENT Department of Children's University Hospital were retrospectively evaluated and compared with the results prospectively obtained from implantable hearing devices (BAHA, Vibrant Soundbridge, Bonebridge), which have been implanted in patients with aural atresia at Department of ORL HNS, University Hospital Bratislava. RESULTS: Aural atresia reconstruction has been performed in 34 patients during last 25 years. Results of the surgery could be viewed as excellent only in three patients (gain above 30dB). Air conduction threshold has decreased after the surgery in seven patients, and in two cases total deafness occurred after the surgery. Patients gain on average 12dB in auditory threshold after surgery. Hearing devices were implanted to the group of 11 children in order to improve their hearing. All of them were the patients with bilateral aural atresia. After implantation a significant improvement in hearing threshold occurred in all children (30-35dB on average). Together with results of air conduction threshold in patient with aural atresia before and after surgery and implantation we also present a standard deviation. CONCLUSION: The functional outcome of implantable hearing devices in patients with bilateral aural atresia clearly dominates over the traditional reconstructive surgery. Aesthetic results in pinna deformity management remain a major concern for patients and parents. Implantable epiphysis 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.

- 233 Chen K., Lyu H., Xie Y., Yang L., Zhang T. & Dai P. (2015). The positional relationship between facial nerve and round window niche in patients with congenital aural atresia and stenosis. *Eur Arch Otorhinolaryngol.* 273(3):587-91.

**Abstract:**

To investigate whether differences existing in the distance between facial nerve (FN) and round window niche opening among congenital aural atresia (CAA), congenital aural stenosis (CAS) and a normal control group and to assess its effect on the round window implantation of vibrant soundbridge, CT images of 10 normal subjects (20 ears), 27 CAS patients (30 ears) and 25 CAA patients (30 ears) were analyzed. The distances from the central point of round window niche opening to the terminal point of the horizontal segment, the salient point of pyramidal segment, the beginning point of the vertical segment, and the vertical segment of the facial nerve (abbreviate as OA, OB, OC, OE, respectively) were calculated based on three-dimensional reconstruction using mimics software. The results suggested that the pyramidal segment of the FN was positioned more closely to round window niche opening in patients with both CAA and CAS groups than that in control group, whereas there was no significant difference between CAA and CAS group ( $P < 0.05$ ). The vertical portion of the FN was positioned more closely to round window niche opening in the CAA group than those in both the CAS and control groups with statistical significance ( $P < 0.05$ ). Furthermore, the vertical portion of the FN was positioned more closely to round window niche opening in the CAS group than that in control group ( $P < 0.05$ ). In conclusion, the dislocation between facial nerve and round window niche in patients with congenital auditory canal malformations could have significant effects on the round window implantation of vibrant soundbridge. Moreover, three-dimensional measurements and assessments before surgery might be helpful for a safer surgical approach and implantation of vibrant soundbridge.

- 232 Mojallal H, Schwab B, Hinze AL, Giere T, Lenarz T. (2015). Retrospective audiological analysis of bone conduction versus round window vibratory stimulation in patients with mixed hearing loss. *Int J Audiol.* 54(6), 391-400.

**Abstract:**

**OBJECTIVE:** To compare audiological outcomes in mild-to-moderate mixed hearing loss patients treated with a bone-anchored hearing aid or an active middle-ear implant. **Analysis:** aimed to refine criteria used in preoperative selection of implant type. **DESIGN:** Retrospective comparative analysis of audiological data. Follow-up time ranged between 0.55 and 8.8 years. **STUDY SAMPLE:** For detailed comparative analysis, 12 patients (six in

each group) with comparable bone conduction thresholds and similar clinical characteristics were selected. A larger cohort of 48 patient files were used to evaluate overall audiological indication criteria (24 per group). RESULTS: In free-field tone audiometry, Baha patients showed mean aided thresholds between 40-48 dB, whereas hearing thresholds for VSB patients were 25-43 dB. Baha and VSB users had mean WRS of 56% and 82%, respectively, at 65 dB. Better speech understanding in noise was seen with the VSB. CONCLUSION: Analysis of the main cohort ( $n = 48$ ) showed that treatment with round window vibroplasty leads to better hearing performance than treatment with a bone-anchored hearing device, if the bone conduction pure-tone average (0.5 to 4 kHz) is poorer than 35 dB HL. Audiological analysis in the smaller comparative analysis showed similar findings.

- 231 Gostian A.O., Hüttenbrink K.B., Luers J.C., Anagiotos A., Beutner D. (2015). Long-term Results of TORP-Vibroplasty. *Otol Neurotol*, 36(6), 1054-60.

Abstract:

OBJECTIVE: Assessing long-term results of patients treated with total ossicular replacement prosthesis (TORP)-vibroplasty. DESIGN: Retrospective analysis. SETTING: Tertiary referral center. PATIENTS: A total of five patients (two women, three men; mean age, 66 yr) were eligible for evaluation after an average follow-up period of 5.1 years after TORP-vibroplasty. INTERVENTIONS: Implantation of an active middle ear device in conjunction with a titanium coupler for oval window placement in patients with chronic middle ear disease with missing stapes suprastructure. MAIN OUTCOME MEASURES: Audiometric outcomes and satisfaction of the patients. RESULTS: The functional gain was 45.2 and 45.6 dB HL at 6 months and 5.1 years after implantation, respectively. The speech recognition using the Freiburg monosyllabic word test and speech intelligibility showed postoperatively a distinct improvement and revealed no statistically significant change across time for the entire follow-up period. According to the International Outcome Inventory for Hearing Aids questionnaire, the patients stated considerable subjective benefits and satisfaction with the device. CONCLUSION: The good outcomes of TORP-vibroplasty in chronic disabled ears are stable. They provide long-term and long-lasting satisfying audiology results combined with a high satisfaction of the patient. Prerequisite is the stable attachment to the cochlear windows.

- 230 Maier H, Hinze AL, Gerdes T, Busch S, Salcher R, Schwab B, Lenarz T. (2015). Long-Term Results of Incus Vibroplasty in Patients with Moderate-to-Severe Sensorineural Hearing Loss. *Audiology & Neurotology*, 20, 136-146.

Abstract:

OBJECTIVES: The principal aim of this study was to assess the safety and effectiveness of the middle ear implant Vibrant Soundbridge (VSB) in patients with moderate-to-severe sensorineural hearing loss up to a mean ( $\pm$  standard deviation) duration of  $11.1 \pm 2.1$  years (min. = 8.2, max. = 13.9,  $n = 16$ ) after the intervention. DESIGN: This was a retrospective, single-subject repeated-measurements study over a long-term period. A

total of 104 German-speaking adults (for 122 implants) were included in this study (54 male, 50 female). The mean age at implantation was 54.5 years (min. = 19.0, max. = 80.4). Audiological outcome and speech intelligibility were assessed in all VSB patients at different time points in non-overlapping groups. RESULTS: Bone conduction (BC) thresholds were preserved after the implantation and no indication was found of an increase over time of the small air-bone gaps introduced by the implantation. BC and air conduction thresholds worsened similarly in both implanted and non-implanted ears over time. The decrease in audiological benefit provided by the VSB was moderate and the Word Recognition Score in quiet conditions at 65 dB SPL was still largely improved with the VSB in the longest observed group. CONCLUSIONS: These results confirm that the VSB does not affect the integrity of the inner/middle ear and is still beneficial in long-term follow-up.

- 229 Lassaletta L, Calvino M, Sánchez-Cuadrado I, Pérez-Mora RM, Muñoz E, Gavilán. (2015). Pros and Cons of Round Window Vibroplasty in Open Cavities: Audiological, Surgical, and Quality of Life Outcomes. *Otol Neurotol.* 36(6), 944-952.

**Abstract:**

OBJECTIVE: To evaluate the audiological, surgical, quality of life, and quality of sound outcomes in adults with open cavities implanted with the Vibrant Soundbridge (VSB) implant using round window (RW) vibroplasty approach. STUDY DESIGN: Retrospective study. SETTING: Otolaryngology department, tertiary referral hospital. SUBJECTS AND METHODS: Twelve adult patients with conductive or mixed hearing loss, all with previous middle ear surgery, underwent RW vibroplasty in an open cavity. Compound action potential thresholds were assessed during surgery. Surgical complications were recorded. Subjective benefit was evaluated using the Nijmegen Cochlear Implant Questionnaire (NCIQ), Glasgow Benefit Inventory (GBI), and Hearing Implant Sound Quality Index (HISQUI29) tests. RESULTS: Mean follow-up was 42 months (range 12-76). There was no significant change in bone conduction thresholds after surgery. Mean functional gain was 34.3 dB and speech discrimination score at 65 dB significantly improved from 14 to 83%. Extrusion of the wire link was the main surgical complication in four patients. All NCIQ domains improved after surgery. All patients had a positive overall GBI score (mean 35.0). Mean HISQUI29 score was 152.8, on average the quality of sound being defined as "very good." CONCLUSION: VSB is an effective method of hearing restoration for adults with open cavities suffering from conductive or mixed hearing loss. Intraoperative electrocochleography may be considered of significant help to check the coupling to the inner ear. The high rate of extrusion suggests that middle ear obliteration may be considered in these patients.

- 228 Mlynksi R, Dalhoff E, Heyd A, Wildenstein D, Hagen R, Gummer AW, Schraven SP. (2015). [Reinforced active middle ear implant fixation in incus vibroplasty]. *Ear Hear.* 36(1), 72-81.

**Abstract:**

OBJECTIVES: The active middle ear implant Vibrant Soundbridge was originally designed to

treat mild-to-severe sensorineural hearing losses. The floating mass transducer (FMT) is crimped onto the long incus process. The procedure is termed incus vibroplasty to distinguish from other attachment sites or stimulus modi for treating conductive and mixed hearing losses. Rare but possible complications are difficult incus anatomy, necrosis of the long incus process, secondary detachment, and loosening of the FMT with concomitant amplification loss. The aim of this study was to functionally evaluate reinforcement of the standard attachment of the FMT to the long incus process. The head of a Soft Clip stapes prosthesis was used for reinforcement. Functional evaluation was performed in temporal-bone preparations and in clinical practice.

**DESIGN:** A subtotal mastoidectomy and a posterior tympanotomy were performed in ten fresh human temporal bones. As a control for normal middle-ear function, the tympanic membrane was stimulated acoustically and the vibration of the stapes footplate and the round-window (RW) membrane, respectively, were measured by laser Doppler vibrometer (LDV). FMT-induced vibration responses of the stapes and RW were then measured for standard attachment and attachment reinforced with the head of a Soft Clip stapes prosthesis. Additionally, the outcome in two groups of patients with incus vibroplasty using standard and the reinforced FMT attachment were compared. Eleven patients were treated by standard coupling; nine patients obtained reinforcement with the head of the Soft Clip stapes prosthesis. Three to six months postoperatively, auditory thresholds for frequency-modulated (warble) tones and vibroplasty thresholds for pure tones were measured. **RESULTS:** In temporal bone, laser Doppler vibrometer measurements showed significantly enhanced vibration amplitudes of the stapes footplate and the RW membrane for the reinforced attachment compared with those for the standard attachment (on average, 5-10 dB at frequencies below 1 kHz and above 4 kHz). Interindividual amplitude variations were also smaller for reinforced attachment (on average, the standard deviation was 4-7 dB smaller). The clinical data showed lower vibroplasty thresholds for reinforced attachment compared with standard attachment, which amounted to, on average, 16 dB at 500 Hz and 12 dB at 4 kHz. **CONCLUSION:** Auxiliary fixation of the FMT by reinforcing the attachment to the long incus process, in these experiments with the head of a Soft Clip stapes prosthesis, leads to enhanced mechanical and functional coupling, evidenced by lower vibroplasty thresholds and increased bandwidth together with reduced variability of the vibrational frequency responses of the stapes footplate and RW membrane.

- 227 Carlson ML, Pelosi S, Haynes DS.(2014) Historical development of active middle ear implants. Otolaryngol Clin North Am. Dec;47(6):893-914.

#### Abstract

Active middle ear implants (AMEIs) are sophisticated technologies designed to overcome many of the shortcomings of conventional hearing aids, including feedback, distortion, and occlusion effect. Three AMEIs are currently approved by the US Food and Drug Administration for implantation in patients with sensorineural hearing loss. In this article, the history of AMEI technologies is reviewed, individual component development is outlined, past and current implant systems are described, and design and implementation successes and dead ends are highlighted. Past and ongoing challenges facing AMEI

development are reviewed.

- 226 Minovi A, Dazert S. (2014). Diseases of the middle ear in childhood. GMS Curr Top Otorhinolaryngol Head Neck Surg. 13, 1865-75.

Abstract:

Middle ear diseases in childhood play an important role in daily ENT practice due to their high incidence. Some of these like acute otitis media or otitis media with effusion have been studied extensively within the last decades. In this article, we present a selection of important childhood middle ear diseases and discuss the actual literature concerning their treatment, management of complications and outcome. Another main topic of this paper deals with the possibilities of surgical hearing rehabilitation in childhood. The bone-anchored hearing aid BAHA® and the active partially implantable device Vibrant Soundbridge® could successfully be applied for children. In this manuscript, we discuss the actual literature concerning clinical outcomes of these implantable hearing aids.

- 225 Kahue Ch.N., Carlson ML, Daugherty JA, Haynes DS, Glasscock ME III. (2014). Middle Ear Implants for Rehabilitation of Sensorineural Hearing Loss: A Systematic Review of FDA Approved Devices. Otology & Neurotology. 35(7), 1228-1237.

Abstract:

**OBJECTIVE:** To systematically review the safety and efficacy of the 3 Food and Drug Administration-approved middle ear implant (MEI) systems currently in use for the rehabilitation of sensorineural hearing loss. **DATA SOURCES:** MEDLINE and Cochrane Library databases were systematically searched by 2 independent reviewers. **STUDY SELECTION:** An initial search yielded 3,020 articles that were screened based on title and Abstract. A full manuscript review of the remaining 80 articles was performed, of which 17 unique studies satisfied inclusion criteria and were evaluated. **DATA EXTRACTION:** Variables including functional gain, speech recognition score improvement, audiometric threshold shift following surgery, adverse events, and patient reported outcome measures were recorded. Study quality was appraised according to author conflict of interest, prospective or retrospective study design, inclusion criteria, number of patients, proper use of study controls, outcome measures reported, length of follow-up, and level of evidence. **DATA SYNTHESIS:** Heterogeneous outcome reporting precluded meta-analysis; instead a structured review was performed using best available data. **CONCLUSION:** The majority of studies evaluating the safety and efficacy of MEIs are retrospective in nature with limited follow-up. To date, no prospective randomized controlled trial exists comparing contemporary air conduction hearing aid performance and MEI outcomes. Based on available data for patients with sensorineural hearing loss, functional gain and word recognition improvement seems similar between conventional hearing aids and MEIs, whereas patient-perceived outcome measures suggest that MEIs provide enhanced sound quality and eliminate occlusion effect.

- 224 Schraven S.P., Mlynski R., Dalhoff E., Wildenstein D., Alkonyi B., Gummer A.W., Hagen R. (2014). [Vibro-EAS: A Proposal for Electroacoustic Stimulation]. *Otol Neurotol.* 36(1), 22-27.

Abstract:

**HYPOTHESIS:** In situ evaluation of the vibration performance of a hybrid system for intracochlear fluid stimulation, constructed from a floating mass transducer (FMT) coupled to an electric acoustic stimulation (EAS) cochlea implant (CI) electrode. **BACKGROUND:** EAS uses both CI technology to restore severe-to-profound hearing loss at high frequencies and acoustic amplification for mild-to-moderate hearing loss in the low-to-mid frequency range. More patients with residual hearing are becoming candidates for EAS surgery because of the improved techniques for hearing preservation. Most patients with partial deafness fulfill the audiological criteria at low and mid-frequencies for the active middle-ear implant with FMT (VSB). The FMT of the VSB is a potential device for acoustical stimulation in EAS. **METHODS:** In seven fresh human temporal bones, stapes amplitude responses for fixation of a FMT to the long incus process (standard coupling) was compared with those for FMT fixation to a 20-mm inserted standard cochlea electrode array (31.5 mm) via the round window (Vibro-EAS). Vibration of the stapes footplate was measured by laser Doppler vibrometry. **RESULTS:** For 0.316 Vrms drive voltage, stimulation of the intracochlear fluid using a FMT-driven CI electrode (Vibro-EAS) yielded stapes amplitude responses comparable to those for acoustic stimulation with 84 dB SPL. These amplitude responses are 30 to 42 dB lower at frequencies up to 4 kHz than those for VSB standard coupling. **CONCLUSION:** Intracochlear combined electrical and mechanical stimulation may be a viable technique for electroacoustic stimulation. A reliable technique for attachment or integration of the FMT to the cochlea electrode array has yet to be developed.

- 223 Gostian A.O., Pazen D., Ortmann M., Luers J. Ch., Anagiotos A., Huttenbrink K.B., Beutner D. (2014). [Impact of Coupling Techniques of an Active Middle Ear Device to the Round Window Membrane for the Backward Stimulation of the Cochlea]. *Otol Neurotol.* 36(1), 111-7.

Abstract:

**HYPOTHESIS:** Interposed cartilage and the round window coupler (RWC) increase the efficiency of cochlea stimulation with the floating mass transducer (FMT) of a single active middle ear implant (AMEI) placed against the round window membrane. **BACKGROUND:** Treatment of mixed and conductive hearing loss with an AMEI attached to the round window is effective, yet the best placement technique of its FMT for the most efficient stimulation of the cochlea remains to be determined. **METHODS:** Experimental study on human temporal bones with the FMT placed against firstly the unaltered round window niche and then subsequently against the fully exposed round window membrane with and without interposed cartilage and the RWC. Cochlea stimulation is measured by the volume velocities of the stapes footplate using LASER vibrometry. **RESULTS:** At the undrilled round window niche, placement of the FMT by itself and with the RWC resulted in similar volume

velocities. The response was significantly raised by interposing cartilage into the undrilled round window niche. Complete exposure of the round window membrane allowed for significantly increased volume velocities. Among these, coupling of the FMT with interposed cartilage yielded responses of similar magnitude compared with the RWC but significantly higher compared with the FMT by itself. CONCLUSION: Good contact to the round window membrane is essential for efficient stimulation of the cochlea. Therefore, interposing cartilage into the undrilled round window niche is a viable option. At the drilled round window membrane, the FMT with interposed cartilage and attached to the RWC are similarly effective.

- 222 Schwab B., Salcher R., Teschner M. (2014). Comparison of two different titanium couplers for an active middle ear implant. *Otol Neurotol.* 35(9), 1615-1620.

Abstract:

OBJECTIVE: To compare surgical methods, functional gain, and speech discrimination using two different coupling methods for an active middle ear implant. Of several couplers enabling placement of the active element at various locations, two function directly at a cochlear membrane, bypassing a missing or malformed ossicular chain. This study evaluates whether either of these methods is more beneficial. STUDY DESIGN: Retrospective case review. SETTING: ENT surgical clinic. PATIENTS: Forty-seven German-speaking patients with moderate to severe mixed hearing loss. INTERVENTIONS: Records of patients implanted with either a round window (RW) or oval window (OW) coupler and active implant were examined. Preoperative and postoperative bone and air-conduction thresholds, auditory gain, and speech perception were compared. MAIN OUTCOME MEASURES: Functional gain, Freiburger monosyllables in quiet. RESULTS: The range of hearing benefit shown by functional gain in patients implanted with the RW coupler (median) was between 22.5 dB (at 0.25 kHz) and 52.5 dB (2 and 3 kHz). In the OW group, improvement was similar, ranging from 21 dB (at 8 kHz) to 50 dB (1 and 2 kHz). Patients in both groups showed a similar improvement in speech recognition. Median preoperative unaided word recognition was 0% at 60 dB HL for both patient groups, improved postoperatively in both groups to median 85% correct at 65 dB HL and 95% at 80 dB HL. CONCLUSION: Placement of an active middle ear implant using the RW and the OW coupler was found to be safe, although the surgical methods differ. Safety and efficacy of both couplers present no significant differences.

- 221 Park A.Y., Jeon J.H., Moon I.S., Choi J.Y. (2014). A case of the vibrant soundbridge stapes coupler in patients with mixed hearing loss. *Korean J Audiol.* 18(2), 93-96.

Abstract:

The Vibrant Soundbridge (VSB) with stapes clip coupler placement at the stapes head has been used successfully to treat mixed hearing loss. Coupling between the floating mass transducer of the VSB and the stapes head is technically less demanding than incus vibroplasty and is more likely to generate a positive outcome without significantly changing residual hearing or resulting in medical or surgical complications. A 65-year-old

man with bilateral mixed hearing loss and chronic otitis media underwent vibroplasty with a stapes clip coupler. Speech discrimination scores in both quiet and noise environments showed better functional gain with the VSB than with the use of a conventional hearing aid. The results of the present case show the feasibility of implanting a VSB with a stapes coupler in patients with mixed hearing loss due to chronic otitis media.

- 220 Lüers J.C., Hüttenbrink K.B. (2014). Vibrant Soundbridge Rehabilitation of Conductive and Mixed Hearing Loss. *Otolaryngol Clin North Am.* 47(6), 915-26.

Abstract:

The Vibrant Soundbridge is the world's most often implanted active middle ear implant or hearing aid. During the last few years, the device indications have expanded from sensorineural hearing loss to conductive and mixed hearing loss. Titanium couplers have led to improved contact of the floating mass transducer with the middle ear structures. The resulting hearing gain is satisfying for most patients, but so far, there is no clear audiologic advantage over conventional hearing aids. Currently, the indications are mainly related to intolerance of conventional hearing aids (eg, chronic otitis externa), severe mixed hearing loss with a destructed middle ear and certain medical diagnosis (eg, congenital atresia).

- 219 Beltrame A.M., Todt I., Sprinzl G., Profant M., Schwab B. (2014). Consensus statement on round window vibroplasty. *Ann Otol Rhinol Laryngol.* 123(10):734-40.

Abstract:

**OBJECTIVE:** This study aimed to review current knowledge regarding implantation of the Vibrant Soundbridge floating mass transducer (FMT) at the round window (round window vibroplasty) as well as to form a consensus on steps for a reliable, stable surgical procedure. **DATA SOURCES:** Review of the literature and experimental observations by the authors. **CONCLUSION:** Round window (RW) vibroplasty has been established as a reliable procedure that produces good and stable results for patients with conductive or mixed hearing loss. The experience gained over the past few years of the authors' more than 200 implantations has led to consensus on several key points: (1) a wide and bloodless access to the middle ear with facial nerve monitoring, (2) the careful and correct identification and exposure of the round window membrane, (3) a good setup for efficient energy transition of the FMT, namely, perpendicular placement of the FMT with no contact to bone and the placement of cartilage behind the FMT to create a preloaded "spring" function, and (4) 4 points of FMT fixation: a rim of the round window bony overhang left intact both anterior and posterior to the FMT, conductor link stabilization, and cartilage behind the FMT. In addition, the FMT should be covered with soft tissue.

- 218 Dillon M.T., Tubbs R.S., Adunka M.C., King E.R., Hillman T.A., Adunka O.F., Chen D.A., Buchman C.A. (2014). Round window stimulation for conductive and mixed hearing loss. *Otol Neurotol.* 35(9), 1601-1608.

**Abstract:**

OBJECTIVE: Assess surgical complications, postoperative residual hearing, and speech perception outcomes of placement of a middle ear implant on the round window in conductive and mixed hearing loss cases. STUDY DESIGN: Single-subject, repeated-measures design where each subject served as his or her own control. SETTING: Tertiary referral medical systems. SUBJECTS: Eighteen subjects with either conductive or mixed hearing loss who could not benefit from conventional amplification were enrolled in a clinical trial investigating vibratory stimulation of the round window. Intervention: The floating mass transducer (FMT) was positioned in the round window niche. MAIN OUTCOME MEASURES: Unaided residual hearing, and aided sound field thresholds and speech perception abilities were evaluated preoperatively, and at 1, 3, 6, and 10 months post-activation of the external speech processor. RESULTS: Six subjects experienced complications that either required further medical management or resolved on their own. There was no difference in residual bone conduction thresholds or unaided word discrimination over time. All subjects experienced a significant improvement in aided speech perception abilities as compared to preoperative performance. CONCLUSION: Subjects with conductive and mixed hearing loss with placement of the FMT in the round window niche experienced improved sound field thresholds and speech perception, without compromising residual hearing thresholds. Vibratory stimulation of the round window via a middle ear implant may be an appropriate treatment option for patients with conductive and mixed hearing loss. Additional research is needed on the preferred placement of the FMT, improvement of functional gain, and methods to limit postoperative complications and need for revision surgery.

- 217 Canale A., Dagna F., Cassandro C., Giordano P., Caranzano F., Lacilla M., Albera R. (2014). Oval and round window vibroplasty: a comparison of hearing results, risks and failures. Eur Arch Otorhinolaryngol. 271(10), 2637-40.

**Abstract:**

The aim of this study was to compare oval and round window vibroplasty. Eighteen (18) patients implanted with Vibrant Soundbridge (VSB) were enrolled. Two groups were formed depending on FMT placement: on round window in ten cases (RW group) and on oval window in eight (OW group). Pre and postoperative audiological tests were performed both under headphones and free-field settings, VSB on and off. One (1) RW patient experienced sudden hearing loss at the operated side after 4 months from surgery and was excluded from the analysis. Both groups showed good hearing results. Significant differences were measured at free-field pure-tone test with VSB on at 0.5 kHz (RW better than OW,  $p = 0.026$ ) and 4 kHz (OW better than RW,  $p = 0.043$ ). Both techniques share similar good results and are considered safe. However, we had one failure with deep and sudden hearing threshold worsening after some months of good results. From a surgical point of view OW vibroplasty is easier and safer to perform, when the stapes suprastructure is absent, as it does not require any drilling and should be preferred in such cases. More reports are needed to explain if RW vibroplasty is risky in a mid to long term.

- 216 Khan A., Hillman T., Chen D. (2014). Vibrant Soundbridge Rehabilitation of Sensorineural Hearing Loss. *Otolaryngol Clin North Am.*; 47(6), 927-39.

Abstract:

The Vibrant Soundbridge is a means to rehabilitate patients with sensorineural hearing loss. It differs from hearing aids in that it uses mechanical energy rather than acoustic sound to deliver better sound quality to the inner ear. The implant's crucial component is a floating mass transducer that is directly fixed to the incus to drive it, which is introduced into the middle ear through a facial recess approach. Although this is a newer technology, studies thus far have demonstrated better hearing results compared with hearing aids in terms of functional gain and speech intelligibility, and better outcomes on subjective assessments.

- 215 Beleites T., Bornitz M., Neudert M. & Zahnert, T. (2014). [The Vibrant Soundbridge as an active implant in middle ear surgery]. *HNO*, 62(7), 509-519.

Abstract:

Implantable hearing aids are not only gaining importance for the treatment of sensorineural hearing loss, but also for treatment of mixed hearing loss. The most frequently used active middle ear implant is the Vibrant Soundbridge (VSB) system (Fa. MED-EL, Innsbruck, Österreich). Following widening of the spectrum of indications for the VSB, various new coupling systems have been established. Based on the literature, available petrosal bone investigations and finite element model (FEM) calculations, this article summarizes the current knowledge concerning mechanical excitation by the VSB. Important concomitant aspects related to coupling, transmission and measurement are also discussed.

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

Abstract:

**BACKGROUND:** Patients with unilateral atresia and microtia encounter problems in sound localization and speech understanding in noise. Although there are four implantable hearing devices available, there is little discussion and evidence on the application of these devices on patients with unilateral atresia and microtia problems. **OBJECTIVE:** This paper will review the details of these four implantable hearing devices for the treatment of unilateral atresia. They are percutaneous osseointegrated bone anchored hearing aid, Vibrant Soundbridge middle ear implant, Bonebridge bone conduction system, and Carina fully implantable hearing device. **METHODS:** Four implantable hearing devices were reviewed and compared. The clinical decision process that led to the recommendation of a device was illustrated by using a case study. **CONCLUSIONS:** The selection of appropriate implantable hearing devices should be based on various factors, including radiological

findings and patient preferences, possible surgical complications, whether the device is Food and Drug Administration- (FDA-)/CE-approved, and the finances. To ensure the accurate evaluation of candidacy and outcomes, the evaluation methods should be adapted to suite the type of hearing device

- 213 Lee J., Seong K., Lee S.H., Lee K.Y. & Cho, J.H.(2014). Comparison of auditory responses determined by acoustic stimulation and by mechanical round window stimulation at equivalent stapes velocities. Hear Res. 314, 65-71.

**Abstract:**

Active middle ear implants (AMEIs) have been studied to overcome the limitations of conventional hearing aids such as howling, occlusion, and social discrimination. AMEIs usually drive the oval window (OW) by means of transmitting vibrational force through the ossicles and the vibrational force corresponding to sound is generated from a mechanical actuator. Recently, round window (RW) stimulation using an AMEI such as a floating mass transducer (FMT) to deliver sound to the cochlea has been introduced and hearing improvement in clinical use has been reported. Although previous studies demonstrated that the auditory response to RW stimulation was comparable to a sound-evoked auditory response, few studies have investigated the quantification of the physiologic performance of an AMEI through RW stimulation on the inner ear *in vivo*. There is no established relationship between the cochlear responses and mechanical stimulation to RW. The aim of this study is to assess the physiologic response in RW stimulation by an AMEI. The transferred energy through the RW to the inner ear could estimate the response corresponding to acoustic stimulation in order to quantify the AMEI output in the ossicular chain or OW stimulation. The parameters of the auditory brainstem responses (ABRs) were measured and compared based on stapes velocities similar enough to be regarded as the same for acoustic stimulation to the external auditory canal (EAC) and mechanical stimulation to the RW in an *in vivo* system. In conclusion, this study showed that the amplitudes and latencies of the ABRs of acoustic and RW stimulation showed significant differences at comparable stapes velocities in an *in vivo* system. These differences in the ABR amplitudes and latencies reflect different output functions of the cochlea in response to different stimulation pathways. Therefore, it is necessary to develop a new method for quantifying the output of the cochlea in the case of RW stimulation.

- 212 Lo J.F., Tsang W.S., Yu J.Y., Ho O.Y., Ku P.K. & Tong, M.C. (2014). Contemporary hearing rehabilitation options in patients with aural atresia. BioMed research international; VOL: 2014; 761579 /2014/

**Abstract:**

Congenital aural atresia is the failure of development of the external auditory canal. It usually occurs in conjunction with microtia, which is the malformation of the auricle due to a failure of development of the external ear. Aural atresia, with or without microtia, may significantly affect the hearing and social life of the patients. It is important for every medical practitioner to be aware of the possible treatment options for hearing

rehabilitation in this group of patients. In the era of modern technology, new choices, including Bone-Anchored Hearing Aid (BAHA) (Cochlear Ltd. and Oticon Medical), Vibrant Soundbridge (VSB) (MED-EL, Innsbruck, Austria), and Bonebridge system (BB) (MED-EL, Innsbruck, Austria), provide high-end alternatives to traditional Bone Conduction Hearing Aid and Auditory Canal Reconstruction. All these options have advantages and disadvantages, and they are appropriate for different patients and/or at different ages. This paper aims to provide an overview of the management of hearing rehabilitation in congenital aural atresia patients and a discussion of each treatment option.

- 211 Fu Y., Dai P. & Zhang, T. (2014). The location of the mastoid portion of the facial nerve in patients with congenital aural atresia. *Eur Arch Otorhinolaryngol.* 271(6), 1451-5.

**Abstract:**

In order to investigate the location of the mastoid portion of the facial nerve in patients with congenital aural atresia and to assess its effect on the round window middle ear implant (MEI) transducer implantation approach, 70 patients with unilateral congenital aural atresia were examined by computer tomography (CT). The patients were divided into two groups based on their ages: 44 patients in Group A (2-12 years) and 26 patients in Group B (13-29 years). CT scans were reviewed for each patient. Based on the CT findings, the mastoid portion of the facial nerve's spatial configuration with respect to the oval and round windows was qualitatively recorded. Additionally, the exact location of the facial nerve was measured quantitatively. The results suggested that of the 70 deformed ears, 57 had facial nerves located at the round window, six at the oval window, and seven at the normal site. Of the 70 normal opposite ears, 63 had facial nerves located at the normal site, and the other seven had facial nerves located at the round window. Based on the quantitative measurements, the mastoid portion of the facial nerve was more anteriorly positioned in the deformed ears: 3.44-6.09 mm more anteriorly located in Group A and 4.35-7.41 mm more anteriorly located in Group B. In conclusion, in patients with congenital aural atresia, the dislocation of the facial nerve could have significant effects on the surgical approach to round window MEI transducer implantation.

- 210 Loney E.L. (2014). The role of radiology in active middle ear implantation. *Clin Radiol.* 69(8), 323-330.

**Abstract:**

Active middle ear implants (AMEIs) have been available for a number of years and yet most radiologists have never heard of them. Some bear a striking resemblance to cochlear implants whereas others are more similar to conventional hearing aids. The aims of this review are to provide an introduction as to the types of implants available, how they work and when they are indicated. Also, to highlight important pre-operative imaging features that can influence surgery and to consider the role of imaging in the post-operative setting. As patient choice increases, it becomes more likely that radiologists will encounter these devices in daily practice and knowledge of them may prove useful.

- 209 Saylisoy S., Incesulu A., Kaya E., Pinarbasli O. & Adapinar, B. (2014). The round window diameter in congenital aural atresia and comparison with sensorineural hearing loss and control group. *J Comput Assist Tomogr.* 38, 461-3.

Abstract:

OBJECTIVE: The aim of this study was to measure round window (RW) diameters in patients with congenital aural atresia (CAA) or sensorineural hearing loss (SNHL) and a normal control group and to analyze whether differences exist between these groups. METHODS: Temporal bone computed tomographic scans of 12 patients with CAA (5 males, 7 females) aged 1 to 50 years (median age, 6 years), 12 patients with SNHL (8 males, 4 females) aged 2 to 32 years (median age, 5 years), and 11 patients (3 males, 7 females) aged 2 months to 53 years (median age, 8 years) randomly selected from a pool of patients with unilateral chronic otitis media or cholesteatoma were reviewed. We measured RW diameter on oblique reconstruction planes. To prevent possible individual differences, skull width was measured. RESULTS: There were no statistically significant differences between all groups for skull width. Both RW diameter and RW membrane width were found smaller in the CAA group than both SNHL group and control group with statistical significance, whereas there were no statistically significant differences between the SNHL group and the control group. CONCLUSIONS: We found that both the RW diameter and RW membrane width in CAA were smaller than those in the control group. If this finding is supported in future studies, the production of floating mass transducer with different sizes may be useful. We suggest that RW diameter should be measured in each patient before operation and thus a floating mass transducer with the appropriate caliber should be chosen.

- 208 Liu H., Ge S., Cheng G., Yang J., Rao Z. & Huang, X. (2014). Transducer type and design influence on the hearing loss compensation behaviour of the electromagnetic Middle Ear Implant in a finite element analysis. *Adv Mechanic Eng.* ID: 867108.

Abstract:

Several types of electromagnetic transducer for the middle ear implants (MEIs) have been developed as an alternative to conventional hearing aids for the rehabilitation of sensorineural hearing loss. Electromagnetic transducer type and design are thought to have a significant influence on their hearing compensation performance. To investigate these effects, a middle ear computational model was constructed based on a complete set of microcomputerized tomography section images of a human ear. Its validity was confirmed by comparing the model predicted motions with published experimental measurements. The result shows that the eardrum driving transducer (EDT) is superior to the floating mass transducer (FMT) in hearing compensation when the transducer mass is small but inferior to the FMT when the mass gets bigger. The incus body driving transducer (IBDT) is the most ineffective type of transducer for hearing compensation. Moreover, the masses of the EDT and the FMT decrease the transducer performance mainly at higher frequencies: the greater the transducer mass, the lower the displacement of the stapes excited by these transducers. On the other hand, the IBDT driving rod stiffness decreases

transducer's performance severely at low frequencies and its adverse effect on transducer performance increases with the decrease of the stiffness of the IBDT driving rod.

- 207 Lupo J.E., Koka K., Jenkins H.A. & Tollin D.J. (2014). Vibromechanical assessment of active middle ear implant stimulation in simulated middle ear effusion: a temporal bone study. *Otol Neurotol.* 35(3), 470-75.

Abstract:

**HYPOTHESIS:** Active middle ear implant (AMEI) generated vibromechanical stimulation of the ossicular chain (ossicular chain vibroplasty [OCV]) or the round window (round window vibroplasty [RWV]) is not significantly affected by simulated middle ear effusion in a human temporal bone model. **BACKGROUND:** OCV and RWV may be employed for sensorineural, mixed, and conductive hearing losses. Although middle ear effusions may be encountered across patient populations, little is known about how effusions may affect AMEI vibromechanical efficiency. **METHODS:** Laser Doppler vibrometry of stapes velocities (SVs) were performed in a human temporal bone model of simulated effusion (N = 5). Baseline measurements to acoustic sinusoidal stimuli, OCV, and RWV (0.25-8 kHz) were made without effusion. The measurements were repeated with simulated middle ear effusion and compared with baseline measurements. Data were analyzed across 3 frequency bands: low (0.25-1 kHz), medium (1-3 kHz), and high (3-8 kHz). **RESULTS:** Acoustic stimulation with simulated middle ear effusion resulted in a significant ( $p < 0.001$ ) frequency-dependent attenuation of SVs of 4, 10, and 7 dB (low, medium, and high ranges, respectively). OCV in simulated effusion resulted in attenuated SVs of 1, 5, and 14 dB (low, medium, and high) compared to without effusion; however, this attenuation was not significant ( $p = 0.07$ ). Interestingly, in the setting of RWV, simulated effusion resulted in significantly ( $p = 0.001$ ) increased SVs of 16, 11, and 8 dB (low, medium, and high). A 3-dB variance in AMEI efficiency was observed in repeated measurements in a single temporal bone. **CONCLUSION:** The efficiency of OCV was not significantly affected by the presence of a middle ear effusion. Improved efficiency, however, was observed with RWV.

- 206 Bittencourt, G.A., Rademaker Burke, P., de Souza Jardim, I., de Brito, R., Tsuji, R.K., de Oliveira Fonseca, A.C. & Ferreira Bento, R. (2014). Implantable and semi-implantable hearing aids: A review of history, indications, and surgery. *Int Arch Otolaryngol.* 18(3), 303-310.

Abstract:

**INTRODUCTION:** The complaints associated with the use of conventional amplifying hearing aids prompted research at several centers worldwide that ultimately led to the development of implantable devices for aural rehabilitation. **OBJECTIVES:** To review the history, indications, and surgical aspects of the implantable middle ear hearing devices. **DATA SYNTHESIS:** Implantable hearing aids, such as the Vibrant Soundbridge system (Med-El Corporation, Innsbruck, Austria), the Maxum system (Ototronix LLC, Houston, Texas, United States), the fourth-generation of Carina prosthesis (Otologics LLC, Boulder, Colorado, United States), and the Esteem device (Envoy Medical Corporation - Minnesota,

United States), have their own peculiarities on candidacy and surgical procedure. CONCLUSION: Implantable hearing aids, which are currently in the early stages of development, will unquestionably be the major drivers of advancement in otologic practice in the 21st century, improving the quality of life of an increasingly aged population, which will consequently require increased levels of hearing support

- 205 McKinnon B.J., Dumon T., Hagen R., Lesinskas E., Mlynski R., Profant M., Spindel J., Van Beek-King J. & Zernotti M. (2014). Vibrant Soundbridge in aural atresia: Does severity matter? *Eur Arch Otorhinolaryngol.* 271(7):1917-21.

Abstract:

Congenital aural atresia (CAA) poses significant challenges to surgical remediation. Both bone anchored hearing aids (BAHA) and the Vibrant Soundbridge (VSB) have been considered as alternatives or adjuncts to conventional atresiaplasty. A consensus statement on VSB implantation in children and adolescents recommended against implantation when the Jahrsdoerfer score was less than 8. More recent publications suggest that patients with Jahrsdoerfer scores between three and seven may benefit from VSB implantation. The purpose of this study was to further investigate the outcomes of VSB implantation in CAA. The study was a multi-center, retrospective review. A retrospective review of data (patient's demographic, clinical, implant and audiological information) from four collaborating centers that have performed VSB implantation in CAA was performed. Outcomes based on severity of the atresia using the Jahrsdoerfer and Yellon-Branstetter scoring systems were also evaluated. Data from 28 patients from the four centers revealed no iatrogenic facial nerve injuries or change in bone thresholds. Post-operative speech threshold and speech recognition was, respectively, 39 dB and 94 %. Jahrsdoerfer and Yellon scores ranged from 4 to 9 and 4 to 12, respectively. The scores did not correlate to or predict outcomes. Three individual elements of the scores did correlate to initial, but not long-term outcomes. Atresiaplasty and BAHA in the management of CAA are not complete solutions. VSB may offer an alternative in these surgically complex patients for achieving amplification, though better metrics for patient selection need to be developed.

- 204 Azadarmaki R., Tubbs R., Chen D.A. & Shellock, F.G. (2014). MRI Information for commonly used Otologic Implants: Review and update. *Otolaryngol Head Neck Surg.* 150(4), 512-519.

Abstract:

OBJECTIVE: To review information on magnetic resonance imaging (MRI) issues for commonly used otologic implants. DATA SOURCES: Manufacturing companies, National Library of Medicine's online database, and an additional online database ([www.MRIsafety.com](http://www.MRIsafety.com)). REVIEW METHODS: A literature review of the National Library of Medicine's online database with focus on MRI issues for otologic implants was performed. The MRI information on implants provided by manufacturers was reviewed. RESULTS: Baha and Ponto Pro osseointegrated implants' abutment and fixture and the implanted magnet

of the Sophono Alpha 1 and 2 abutment-free systems are approved for 3-Tesla magnetic resonance (MR) systems. The external processors of these devices are MR Unsafe. Of the implants tested, middle ear ossicular prostheses, including stapes prostheses, except for the 1987 McGee prosthesis, are MR Conditional for 1.5-Tesla (and many are approved for 3-Tesla) MR systems. Cochlear implants with removable magnets are approved for patients undergoing MRI at 1.5 Tesla after magnet removal. The MED-EL PULSAR, SONATA, CONCERT, and CONCERT PIN cochlear implants can be used in patients undergoing MRI at 1.5 Tesla with application of a protective bandage. The MED-EL COMBI 40+ can be used in 0.2-Tesla MR systems. Implants made from nonmagnetic and nonconducting materials are MR Safe. CONCLUSION: Knowledge of MRI guidelines for commonly used otologic implants is important. Guidelines on MRI issues approved by the US Food and Drug Administration are not always the same compared with other parts of the world. IMPLICATIONS FOR PRACTICE: This monograph provides a current reference for physicians on MRI issues for commonly used otologic implants.

- 203 Eze N., Miro'n A., Rogers G., Jeronimidis G., O'Connor A.F. & Jiang, D. (2014). The effect of angulation of the vibrating Floating Mass Transducer on stapes velocity. *Otol Neurotol.* 35(7):1223-7.

Abstract:

HYPOTHESIS: Changes to the angular position of the vibrating floating mass transducer (FMT) coupled to the long process of the incus will not affect stapes velocity. OBJECTIVE: The MED-EL Vibrant Soundbridge is an active middle ear implantable device, which constitutes an effective alternative to acoustic hearing aids for the rehabilitation of patients with sensorineural and mixed hearing loss. Because of varied anatomy, it is not always possible to position the FMT in line with the vibrating axis of the stapes. Changes in stapes velocity after angulation of the FMT are measured using laser Doppler vibrometry (LDV). METHODS: The study was performed on 7 human cadaveric temporal bones. The FMT was attached to the incus and angled at the recommended 0 degree or at 45 degrees relative to the vibrating axis of the stapes, and the stapes velocity measured using LDV. RESULTS: In comparison to the 0-degree position, angulating the FMT to 45 degrees reduced cochlea input as measured by stapes velocity, although there was no statistical significance to this difference. Placing the FMT at 45 degrees did not compromise the peak output of the device but resulted in a phase lag which was more marked compared with the 0-degree position. CONCLUSION: If it is not anatomically possible to position the FMT in line with the vibrating axis of the stapes, then placement at up to 45 degrees does not significantly alter the performance of the implant particularly in the midfrequencies that are crucial to the understanding of speech.

- 202 Henseler M.A., Polanski J.F., Schlegel C. & Linder, T. (2014). Active Middle Ear Implants in patients undergoing subtotal petrosectomy: Long-term follow-up. *Otol Neurotol.* 35(3), 43.

Abstract:

**OBJECTIVE:** In 2009, we had introduced the active middle ear implant (aMEI) round window coupling in patients undergoing a subtotal petrosectomy and reported our first results. In the current study, we evaluated the long-term firmness of the vibrating floating mass transducer (FMT) within the round window niche, the long-term audiologic results and the patient's perspective of wearing the speech processor over time.

**PATIENTS AND INTERVENTION:** Of 10 patients, 6 female and 1 male patients (age range from 30 to 71 yr) had undergone subtotal petrosectomy with aMEI round window vibroplasty and were available for a long-term follow-up. Indications were recurrent or chronic ear infections with preserved inner ear function and inability for ossicular chain reconstruction. A thin piece of fascia was placed between the FMT and the round window membrane once the round window niche had been enlarged by drilling. The operative cavity was filled with fat and a muscle flap in all cases.

**MAIN OUTCOME MEASURES:** Audiologic evaluations included pre- and postoperative pure-tone audiometry, Freiburger syllable and numeric tests. All patients underwent preoperative computed tomographic (CT) scans and magnetic resonance imaging (MRI) examination. Postoperative follow-up included CT scans at 1 and preferentially 3 to 5 years to confirm the correct positioning of the FMT and the complete removal of the underlying pathology. Subjective benefit was rated by the Glasgow Hearing Aid Benefit Profile.

**RESULTS:** There were no immediate postoperative complications. CT scans confirmed the correct and durable positioning of the FMT. Audiometric tests revealed a stable and adequate functional gain in all patients with limited adjustments over time. Subjective rating reached a high satisfaction score, and all patients remained long-term implant users. One patient developed a skin necrosis over the implant because of excessive pressure exerted by the retaining magnet of the headpiece. Revision was performed using local skin flaps with preservation of the functioning implant.

**CONCLUSION:** Our radiologic, audiometric, and subjective data show stable long-term results of round window vibroplasty in patients undergoing subtotal petrosectomy, and we continue to recommend this treatment option instead of another mastoid revision procedure.

- 201 Salcher R., Schwab B., Lenarz T. & Maier H. (2014). Round window stimulation with the Floating Mass Transducer at constant pretension. *Hear Res.* 314, 1-9.

**Abstract:**

**OBJECTIVE:** Mechanical stimulation of the round window (RW) of the cochlea is successfully done with the Vibrant Soundbridge (Med-El), but clinical outcomes show a substantial degree of variability. One source of variability is variation in the static force applied by the stimulator to the round window (Maier et al., 2013). In this study we investigated other sources of variability by maintaining a constant pre-load testing the effect of a coupler device and the interposition of soft tissue between the stimulator and the RW.

**STUDY DESIGN:** Experimental. **METHODS:** The stapes footplate displacement produced by stimulation of the round window was determined in fresh human temporal bones. The response to sound and actuator stimulation was measured with a Laser Doppler Velocimeter at the stapes footplate. The RW was stimulated by a Floating Mass Transducer (FMT) with/without (1) an additional RW coupler (supplied by the manufacturer), and (2)

the interposition of TUTOPATCH® between the stimulator and the RW, while maintaining a pre-load of ~1.96 mN. RESULTS: In 8 temporal bones with normal stapes footplate response to sound, we found an average 11.9 dB increase (500 Hz-2 kHz) under controlled conditions by using the coupler together with the interposition. The increase was statistically significant at 500 Hz ( $p < 0.01$ ). Additionally, the coupler/interposition combination reduced the variability between experiments (FMT alone SD = 10.9 dB; FMT with TUTOPATCH® & coupler: SD = 3.4 dB @ 500 Hz) and increased the repeatability. CONCLUSION: At controlled static force an improved output level, inter-subject variability and repeatability were found by using a coupler/TUTOPATCH combination in RW stimulation with the FMT. The high variability found in clinical experience is not solely due to inter-subject variability, but to coupling conditions and can be optimized further.

- 200 Sargsyan S., Rahne T., Kösling S., Eichler, G. & Plontke S.K. (2014). Hearing rehabilitation with single-stage bilateral vibroplasty in a child with Franceschetti syndrome. Eur Arch Otorhinolaryngol. 271(5), 1339-43.

Abstract:

Hearing is of utmost importance for normal speech and social development. Even children who have mild or unilateral permanent hearing loss may experience difficulties with understanding speech, as well as problems with educational and psycho-social development. The increasing advantages of middle-ear implant technologies are opening new perspectives for restoring hearing. Active middle-ear implants can be used in children and adolescents with hearing loss. In addition to the well-documented results for improving speech intelligibility and quality of hearing in sensorineural hearing loss active middle-ear implants are now successfully used in patients with conductive and mixed hearing loss. In this article we present a case of successful, single-stage vibroplasty, on the right side with the fixation of the FMT on the stapes and PORG CLIP vibroplasty on the left side in a 6-year-old girl with bilateral mixed hearing loss and multiple dyslalia associated with Franceschetti syndrome (mandibulofacial dysostosis). CT revealed bilateral middle-ear malformations as well as an atretic right and stenotic left external auditory canal. Due to craniofacial dysmorphia airway and (post)operative, management is significantly more difficult in patients with a Franceschetti syndrome which in this case favoured a single-stage bilateral procedure. No intra- or postoperative surgical complications were reported. The middle-ear implants were activated 4 weeks after surgery. In the audiological examination 6 months after surgery, the child showed 100% speech intelligibility with activated implants on each side.

- 199 Zwartsenpot J.W., Snik A.F., Mylanus E.A. & Mulder, J.J. (2014). Amplification options for patients with mixed hearing loss. Otol Neurotol. 35(2), 221-226.

Abstract:

OBJECTIVES: To compare amplification options for patients with mixed hearing loss. Devices tested include percutaneous and transcutaneous bone conductors (BCDs) and middle ear implants with their actuator directly coupled to the cochlea. SETTING: Tertiary academic

medical center. **METHOD AND PARTICIPANTS:** Maximum output was studied with simulators. As simulators are lacking for the middle ear implants (the Vibrant Soundbridge [VSB] and the Cochlear's Direct Acoustic Cochlear Stimulator [Codacs]), the maximum output had to be measured in patients (4 and 5 patients, respectively). **MAIN OUTCOME MEASURE:** The maximum output averaged at 0.5, 1, and 2 kHz was the main outcome measure, which was expressed in dB HL, using appropriate transformation tables. **RESULTS:** The maximum output was the highest for the Codacs device and was above the patients' uncomfortable loudness levels. The maximum output of the VSB varied between 65 and 85 dB HL, and that of percutaneous BCD varied between 68 and 80 dB HL depending on the type of device. The transcutaneous BCD, the Sophono device, had the lowest output. **CONCLUSION:** Only with the Codacs device can the complete dynamic range be used. The maximum output of the VSB is lower and variable owing to the coupling to the cochlea. For patients with a sensorineural hearing loss component up to 50 dB HL, a percutaneous BCD forms a good treatment option that is completely independent of the middle ear status. The transcutaneous Sophono BCD is suitable for patients with a (sub-)normal sensorineural hearing loss component of 20 dB or less.

- 198 Colletti L., Mandala M., Colletti G. & Colletti, V. (2014). Vestibulotomy with Ossiculoplasty versus Round Window Vibroplasty procedure in children with oval window aplasia. *Otol Neurotol.* 35(5), 831-837.

**Abstract:**

**OBJECTIVE:** To review the surgical procedures and outcomes in children with bilateral oval window aplasia (OWA). **STUDY DESIGN:** Retrospective cohort review. **SETTING:** Tertiary referral center. **PATIENTS:** Children suffering from OWA between 1990 and 2010. **INTERVENTION:** Vestibulotomy with ossiculoplasty (V-OPL) or round window vibroplasty (RWV). **MAIN OUTCOME MEASURES:** Findings at radiology and surgery, preoperative and postoperative bone conduction (BC), air conduction (AC), and RWV-air conduction (RWV-AC) thresholds and speech discrimination scores (SDSs). **RESULTS:** Among 23 children, 11 underwent V-OPL and 8 RWV. Four children in the V-OPL group had aborted surgery and were excluded from the study. In all the remaining 19 children, the 6-month follow-up time showed postoperative AC and SDS values significantly better than the preoperative thresholds in both groups. At the 36-month long-term follow-up, AC and SDS were stable in the RWV group but showed a significant worsening in the V-OPL children compared with the 6-month follow-up results. Preoperative versus postoperative BC values showed a significant difference between the 2 groups at 36 months; 5 of the V-OPL group underwent revision following the same surgical principles, which did not result in improved outcome. **CONCLUSION:** In children with OWA, V-OPL provides modest long-term results and carries higher risks of BC degradation compared to RWV. Both procedures are technically challenging but considering the respective hearing results and morbidity of primary and revision surgery, we have abandoned the V-OPL procedure in favor of RWV. In infants and children younger than 5 years with OWA previously not considered candidates for hearing restoration, we consider RWV as the first-choice surgery. It has shown to provide significantly better hearing outcomes than traditional atresia surgery with minimal

complication rate.

- 197 Edfeldt L., Stromback K., Grendin J., Bunne M., Harder H., Peebo M., Eeg-Olofsson M., Petersson C.M. & Konradsson, K. (2014). Evaluation of cost-utility in middle ear implantation in the 'Nordic School': A multicenter study in Sweden and Norway. *Acta Otolaryngol.* 134(1), 19-25.

Abstract:

**CONCLUSION:** Hearing restoration using an active middle ear implant (AMEI) is a highly cost-effective treatment for a selected group of patients with no other possibilities for auditory rehabilitation. **OBJECTIVES:** To evaluate the cost-utility of using an AMEI for hearing rehabilitation. **METHODS:** This was a prospective, multicenter, single-subject repeated study in six tertiary referral centers. Twenty-four patients with sensorineural (SNHL), conductive (CHL), and mixed hearing loss (MHL) were implanted with the AMEI Vibrant Soundbridge(R) (VSB) for medical reasons. All patients were previously rehabilitated with conventional hearing aids. Multiple validated quality of life patient questionnaires, Health Utilities Index (HUI 2 and 3), and Glasgow Hearing Aid Benefit Profile (GHABP) were used to determine the utility gain and quality adjusted life years (QALY). Directly related treatment costs for the implantation were calculated and related to utility gain and QALY. **RESULTS:** The cost/QALY for patients with SNHL was estimated at euro7260/QALY, and for patients with C/MHL at euro12 503/QALY.

- 196 Cristalli G., Sprinzl G., Wolf-Magele A., Marchesi P., Mercante G. & Spriano G. (2014). Active middle ear implant after lateral petrosectomy and radiotherapy for ear cancer. *Otol Neurotol.* 35(4), 146-152.

Abstract:

**BACKGROUND:** Tumor of the temporal bone is a rare disease with a very poor prognosis. Surgery and postoperative radiotherapy are usually the recommended treatments for squamous cell carcinoma (SCC) of the external and middle ear, which may cause conductive hearing loss. The purpose of this study was to evaluate the audiologic results and compliance of active middle ear implant (AMEI) and establish the feasibility of the procedure in a patient treated for middle ear cancer. **METHODS:** A 73-year-old patient treated with lateral petrosectomy, neck dissection, reconstruction/obliteration by pedicled pectoralis major myocutaneous flap, and postoperative full dose radiotherapy for external and middle ear SCC was selected for AMEI. Preoperative audiometric and speech audiometry tests were performed on both ears before and after the activation. **MAIN OUTCOME MEASURES:** Pure tone free field audiometry. Binaural free field speech audiogram. **RESULTS:** Aided pure tone free field audiometry AMEI results show an increase in air conduction. Speech audiogram showed better discrimination scores in AMEI-aided situations. No complications were observed. **CONCLUSION:** AMEI after surgery followed by radiotherapy for middle ear cancer is feasible. Acoustic results in obliterated ear are satisfactory.

- 195 Yang S.M., Zou Y.H., Li J.N., Jiao Q.S., Yi H.J. & Han, D.Y. (2014). Vibrant Soundbridge implantation via the third window in two Chinese patients with severe bilateral congenital aural atresia. *Acta Otolaryngol.* 134(1), 1-6.

Abstract:

**CONCLUSION:** In patients with undeveloped vestibular/oval windows and inaccessible round windows, Vibrant Soundbridge (VSB) implantation performed by placing the transducer into a reconstructed window on the inner tympanum wall demonstrated significant improvement in hearing and verbal communication ability. **OBJECTIVE:** To report our surgical experience with new placement of the VSB in pediatric patients with undeveloped vestibular windows, inaccessible round windows, and severe bilateral congenital aural atresia (CAA). **METHODS:** In two patients with bilateral CAA selected for middle ear implantation, CT scans revealed severe middle ear malformation including inaccessible round windows, absence of vestibular/oval windows, and abnormal facial nerve anatomy. The transducer of the VSB was implanted into a 'window' drilled at the inner tympanum wall in both patients. **RESULTS:** The surgery was successful. Pure-tone air conduction thresholds across the frequencies of 0.25-8 Hz were improved by 35 dB (preoperation, 69.2 dB; postactivation, 34 dB) in patient 1 and 46.6 dB (preoperation, 75.8 dB; postactivation, 24.2 dB) in patient 2. Normal hearing thresholds were achieved in the range of 1-8 kHz in both patients. A sentence recognition rate of up to 100% (65 dB SPL in a quiet room) was attained by both patients after surgery and VSB activation at 3 months postoperatively.

- 194 Agterberg M.J., Frenzel H., Wollenberg B., Somers T., Cremers C.W. & Snik A.F. (2014). Amplification options in unilateral aural atresia: An active middle ear implant or a bone conduction device? *Otol Neurotol.* 35(1), 129-135.

Abstract:

**BACKGROUND:** There is no consensus on treatment of patients with congenital unilateral aural atresia. Currently, 3 intervention options are available, namely, surgical reconstruction, application of a bone-conduction device (BCD), or application of a middle ear implant. **OBJECTIVE:** The present study aims to compare the BCD with the application of a middle ear implant. We hypothesized that cross-hearing (stimulating the cochlea by means of bone conduction contralateral to the implanted side) would cause BCD users to have difficulty performing localization tasks. **METHODS:** Audiologic data of 4 adult patients with a middle ear implant coupled directly to the cochlea were compared with data of 4 adult patients fitted with an osseointegrated BCD. All patients were fitted during adulthood. The emphasis of this study is on directional hearing. **RESULTS:** The middle ear implant and the BCD improved sound localization of patients with congenital unilateral aural atresia. Unaided scores demonstrate a large variation. **CONCLUSION:** Our results demonstrate that there was no advantage of the middle ear implant over the BCD for directional hearing in patients who had no amplification in childhood. The BCD users had the best bandwidth.

- 193 Ihler F., Kohler S., Meyer A.C., Blum J., Strenzke N., Matthias C. & Canis M. (2014). Mastoid cavity obliteration and Vibrant Soundbridge implantation for patients with mixed hearing loss. *Laryngoscope*, 124(2), 531-537.

Abstract:

**OBJECTIVES/HYPOTHESIS:** To review the results of obliteration of a preexisting mastoid cavity with abdominal fat and Vibrant Soundbridge implantation in patients with mixed hearing loss (MHL) and to compare the data with results of Vibrant Soundbridge implantation in patients with MHL without mastoid cavity and with pure sensorineural hearing loss (SNHL). **STUDY DESIGN:** Retrospective chart analysis of 10 patients (10 ears) with MHL and preexisting mastoid cavity, 18 patients (19 ears) with MHL alone and nine patients (10 ears) with SNHL treated in one tertiary referral center. **METHODS:** Vibrant Soundbridge implantation and obliteration in case a mastoid cavity existed previously. Pure tone audiometry (average air-bone gap, average functional gain), speech audiometry (Freiburg Monosyllabic Test) and complication rate were main outcome measures. **RESULTS:** Postoperative average air-bone gap was  $-15.1 \pm 21.2$  dB in patients with MHL with mastoid cavity obliteration,  $-7.2 \pm 11.4$  dB in patients with MHL without mastoid cavity, and  $-5.7 \pm 11.2$  dB in patients with SNHL. Average functional gain was  $40.0 \pm 23.5$  dB,  $39.7 \pm 12.1$  dB, and  $9.5 \pm 10.6$  dB. Postoperative speech discrimination rate was  $77.9 \pm 20.8\%$ ,  $83.3 \pm 13.6\%$ , and  $83.6 \pm 6.3\%$ . No severe intraoperative or postoperative complications were noted. **CONCLUSIONS:** Mastoid cavity obliteration during Vibrant Soundbridge implantation in patients with MHL and preexisting mastoid cavity is a safe procedure. The audiometric results are satisfying and comparable to those of other patient groups implanted with the same device. **LEVEL OF EVIDENCE:** 4.

- 192 Mlynški R., Nguyen T.D., Plontke S.K. & Kosling S. (2014). Presentation of Floating Mass Transducer and Vibroplasty couplers on CT and cone beam CT. *Eur Arch Otorhinolaryngol*. 271(4), 665-672.

Abstract:

Various titanium coupling elements, Vibroplasty Couplers, maintaining the attachment of the Floating Mass Transducer (FMT) of the active middle ear implant Vibrant Soundbridge (VSB) to the round window, the stapes suprastructure or the stapes footplate are in use to optimally transfer energy from the FMT to the inner ear fluids. In certain cases it is of interest to radiologically verify the correct position of the FMT coupler assembly. The aim of this study was to present the radiological appearance of correctly positioned Vibroplasty Couplers together with the FMT using two different imaging techniques. Vibroplasty Couplers were attached to the FMT of a Vibrant Soundbridge and implanted in formalin fixed human temporal bones. Five FMT coupler assemblies were implanted in different positions: conventionally to the incus, a Bell-Coupler, a CliP-Coupler, a Round Window-Coupler and an Oval Window-Coupler. High spatial resolution imaging with Multi-Detector CT (MDCT) and Cone Beam CT (CBCT) was performed in each specimen. Images were blind evaluated by two radiologists on a visual basis. Middle ear details, identification

of FMT and coupler, position of FMT coupler assembly and artefacts were assessed. CBCT showed a better spatial resolution and a higher visual image quality than MDCT, but there was no significant advantage over MDCT in delineating the structures or the temporal bone of the FMT Coupler assemblies. The FMT with its coupler element could be clearly identified in the two imaging techniques. The correct positioning of the FMT and all types of couplers could be demonstrated. Both methods, MDCT and CBCT, are appropriate methods for postoperative localization of FMT in combination with Vibroplasty Couplers and for verifying their correct position. If CBCT is available, this method is recommended due to the better spatial resolution and less metal artifacts.

- 191 Vyskocil E., Riss D., Honeder C., Arnoldner C., Hamzavi J.S., Baumgartner W.D., Flak S. & Gstoettner W. (2014). Vibroplasty in mixed and conductive hearing loss: Comparison of different coupling methods. *Laryngoscope*, 124(6), 1436-43.

Abstract:

**OBJECTIVES/HYPOTHESIS:** To evaluate modified coupling techniques of the Vibrant Soundbridge system in patients with mixed and conductive hearing loss and to compare it with conventional vibroplasty. **STUDY DESIGN:** Retrospective study. **METHODS:** Two different groups were evaluated: 1) nine cases of conventional incus vibroplasty in comparison with 2) nine patients with modified coupling of the floating mass transducer. In the modified coupling approach, the vibrant floating mass transducer was attached to 1) the stapes/oval window, 2) the round window, or 3) the drilled promontory bone (promontory fenestration window). In three patients, an additional ossiculoplasty was performed. Preoperative and postoperative aided and unaided pure-tone and free-field audiology and Freiburg monosyllabic word test were used to assess hearing outcome. **RESULTS:** Functional hearing gain obtained in patients with mixed and conductive hearing loss who underwent modified coupling was 39 dB. Patients with pure sensorineural hearing loss who received conventional incus coupling showed a functional hearing gain of 25 dB. Average functional gain was 41 dB in the oval window group, 45 dB in the round window group, and 30 dB in the promontory fenestration window group. Word recognition test revealed an average improvement of 51% and 21% in the modified and in the conventional approach, respectively. **CONCLUSIONS:** Modified vibroplasty is a safe and effective treatment for patients with conductive and mixed hearing loss. Coupling the floating mass transducer to the promontory bone (promontory fenestration window) is a viable option in chronically disabled ears if oval and round window coupling is not possible.

- 190 McKinnon B. & Watts, T. (2013). Subcutaneous emphysema and pneumolabyrinth plus pneumocephalus as complications of middle ear implant and cochlear implant surgery. *Ear Nose Throat*. 92(7), 298-300.

Abstract:

We conducted a retrospective case review at a tertiary academic medical center for the complications of pneumolabyrinth with pneumocephalus and subcutaneous emphysema after surgery for middle ear and cochlear implants. Charts of 76 cochlear implant and 2

middle ear implant patients from January 2001 through June 2009 were reviewed. We identified 1 cochlear implant recipient with pneumolabyrinth and pneumocephalus, and 1 middle ear implant recipient with subcutaneous emphysema. Surgical exploration was performed for the pneumolabyrinth with pneumocephalus; the subcutaneous emphysema was managed conservatively. The patient with the cochlear implant, who had had a ventriculoperitoneal shunt placed, experienced pneumolabyrinth with pneumocephalus 6 years after uneventful surgery. Middle ear exploration revealed no residual fibrous tissue seal at the cochleostomy. The middle ear and cochleostomy were obliterated with muscle, fat, and fibrin glue. The ventriculoperitoneal shunt was deactivated, with clinical and radiographic resolution. On postoperative day 5, the patient who had undergone the middle ear implant reported crepitance over the mastoid and implant device site after repeated Valsalva maneuvers. Computed tomography showed air surrounding the internal processor. A mastoid pressure dressing was applied and the subcutaneous emphysema resolved. These 2 cases support the importance of recognizing the clinical presentation of pneumolabyrinth with associated pneumocephalus, as well as subcutaneous emphysema. Securing the internal processor, adequately sealing the cochleostomy, and providing preoperative counseling regarding Valsalva maneuvers and the potential risk of cochlear implantation in the presence of a ventriculoperitoneal shunt may prevent adverse sequelae.

- 189 Hempel J.M., Braun T. & Berghaus A. (2013). Funktionelle und ästhetische Rehabilitation der Mikrotie bei Kindern und Jugendlichen. *HNO*, 61(8), 655-661.

**Abstract:**

**BACKGROUND:** Microtia leads to a severe functional and aesthetic handicap. Traditionally, the auricle is often reconstructed with cartilage transplants, which is, however, associated with some partially substantial disadvantages. The authors have instead used implants of porous polyethylene for successful ear reconstruction for years, thus, avoiding some of these disadvantages. A significant benefit for the patient is achieved by simultaneous hearing rehabilitation by the implantation of active middle ear prostheses. **METHODS:** The authors present their surgical concept which allows functional and aesthetic rehabilitation of microtia in children and adolescents in a single operation. In the respective patient collective, audiometric measurements in quiet and noisy environments were conducted pre- and postoperatively, and health-related quality of life was determined using a validated questionnaire. **RESULTS:** All patients experienced a substantial hearing gain both in quiet and noisy environments. The evaluation of health-related quality of life showed a significant benefit from the intervention. **CONCLUSION:** Functional and aesthetic rehabilitation of microtia with active middle ear implants and ear reconstruction using porous polyethylene leads to good and reliable long-term results and can increase the health-related quality of life of affected children and adolescents. The main advantage of this concept is the possibility of a single procedure.

- 188 Klein K., Nardelli A. & Stafinski T. (2013). A systematic review of the safety and effectiveness of the Vibrant Soundbridge. *J Otol Rhinol*. 2(3).

**Abstract:**

OBJECTIVE: To examine the current state of the science related to the safety and effectiveness of the Vibrant Soundbridge middle ear implant in the treatment of hearing loss. DATA SOURCES: MEDLINE, EMBASE, The Cochrane Library, Web of Science, CINAHL, PsycINFO and the Centre for Reviews and Dissemination were searched without date or language limits. STUDY SELECTION: Titles and Abstracts of 7700 citations were screened and 69 articles selected for full review, of which 44 studies involving a total 832 patients met the study's eligibility criteria. DATA EXTRACTION: Information was extracted using a pre-tested data Abstract:ion form and study quality was assessed using the Oxford Centre for Evidence-Based Medicine Levels of Evidence. DATA SYNTHESIS: Due to heterogeneity across studies, metaanalysis was not performed and comparisons were made by structured review. CONCLUSION: Of the studies that compared the VSB to conventional hearing aids, the majority reported statistically significant improvements in functional gain, speech reception, and quality of life with the VSB. Regarding speech recognition, the findings were mixed. Among studies that compared the VSB to the unaided condition, there was clinical benefit observed in all categories with the device. Adverse event rates were reasonably low, although VSB implantation poses a significant risk compared to non-invasive treatment with conventional hearing aids. The Vibrant Soundbridge middle ear implant appears to offer a safe and effective alternative for patients able and unable to wear conventional hearing aids.

- 187 Todt I., Rademacher G., Wagner J., Mittmann P., Basta D. & Ernst A. (2013). Radiological control of the floating mass transducer attached to the round window. *Sci World J.*, ID 902945.

**Abstract:**

The surgical rehabilitation of mixed hearing losses can be performed by coupling the floating mass transducer of the Vibrant Soundbridge to the round window. The quality of coupling the floating mass transducer to the round window is crucial for the audiological outcome. It was the aim of this study to further observe the different patterns of floating mass transducer position at the round window. We compared twenty patients with mixed hearing loss implanted with a floating mass transducer attached to the round window and 24 surgeries between 5/2007 and 6/2010. An evaluation of the chronological observation of the flat panel angiography-controlled position of the floating mass transducer at the round window with relation to the surgical report and the audiological outcome was done. We observed no changes in the mean pre- and postbone conduction thresholds. The floating mass transducer position was variable and could be radiologically classified and correlated with the audiological outcome. A learning curve was observed from the earlier to later implantations. Postoperative, radiological evaluation of the location and angle of the floating mass transducer by means of flat panel tomography allowed us to classify the floating mass transducer position at the round window into 4 groups.

- 186 Wu H. & Huang Q. (2013). Indications of vibrant soundbridge implantation. *Lin Chung Er Bi*

Yan Hou Tou Jing Wai Ke Za Zhi, 27 (16), 871-873. [Article in Chinese]

No Abstract available

- 185 Wu P. & Huang H. Clinical application of vibrant soundbridge. Lin Chung Er Bi Yan Hou Tou Jing Wai Ke Za Zhi, 27 (16), 868-871. [Article in Chinese]

No Abstract available

- 184 Ihler F., Bewarder J., Blum J., Matthias C. & Canis M. (2013). Long-term functional outcome and satisfaction of patients with an active middle ear implant for sensorineural hearing loss compared to a matched population with conventional hearing aids. Eur Arch Otorhinolaryngol. 271(12):3161-9.

Abstract:

The objectives of the study were to review the results of an active middle ear implant for sensorineural hearing loss in patients who were unable to wear or did not benefit from conventional hearing aids in comparison to patients with a matched degree of hearing loss successfully fitted with a conventional hearing aid. A retrospective chart review of 10 patients (10 ears) after implantation of an active middle ear implant and 12 patients (13 ears) with conventional hearing aids in one tertiary referral center was performed. Intervention for sensorineural hearing loss was the implantation of an active middle ear implant in one group or fitting of conventional hearing aids in the other group. Outcome measures were pure-tone audiometry (auditory thresholds, functional gain), speech audiometry (Freiburg Monosyllabic Test in quiet and in noise) and a quality-of-life questionnaire (Glasgow Benefit Inventory). Average functional gain was 25.2 +/- 8.6 and 14.6 +/- 10.8 dB, speech recognition score in noise was 36.6 +/- 18.4 and 31.2 +/- 19.2 % and in quiet was 66.0 +/- 23.2 and 61.5 +/- 23.8 %, Glasgow Benefit Inventory total score was 38.3 +/- 32.3 and 24.8 +/- 22.2 in patients with active middle ear implants and conventional hearing aids, respectively. In two patient groups matched for degree of sensorineural hearing loss, active middle ear implants provided comparable speech recognition and superior functional gain and quality of life compared to conventional hearing aids. Level of evidence: 4

- 183 Schraven S.P., Dalhoff E., Wildenstein D., Hagen R., Gummer A.W. & Mlynki R. (2013). Alternative fixation of an active middle ear implant at the short incus process. Audiol Neurotol. 19 (1), 1-11.

Abstract:

INTRODUCTION: Since 1996, the preferred approach for positioning the active middle-ear implant Vibrant Soundbridge(c) is a mastoidectomy and a posterior tympanotomy. With this device, placement of the floating mass transducer (FMT) on the long incus process is the standard method for treatment of mild-to-severe sensorineural hearing loss in the case of normal middle-ear anatomy. The aim of this study was to determine the

vibrational effectiveness of FMT placement at the short incus process. Materials and METHODS: An extended antrotomy and a posterior tympanotomy were performed in 5 fresh human temporal bones. As a control for normal middle-ear function, the tympanic membrane was stimulated acoustically and the vibration of the stapes footplate and the round-window (RW) membrane were (sequentially) measured by laser Doppler vibrometry. Vibration responses for coupling of an FMT to the long incus process (standard coupling) were compared to those for coupling to the short incus process. RESULTS: Apart from narrow frequency bands near 3 and 9 kHz for the stapes footplate and RW membrane, respectively, the velocity responses presented no significant differences between standard coupling of the FMT and coupling to the short incus process. CONCLUSION: Coupling the FMT to the short incus process may be a viable alternative in cases where the surgical approach is limited to an extended antrotomy. A reliable technique for attachment to the short incus process has yet to be developed. (c) 2013 S.

- 182 Nospes S., Mann W. & Keilmann A. (2013). [Magnetic resonance imaging in patients with magnetic hearing implants: Overview and procedural management.]. Radiologe, 53(11), 1026-32.

**Abstract:**

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

radiologist and the implanting team is required. Other diagnostic procedure options should be exhausted before employing MRI.

- 181 DeAbajo J., Sanhueza I., Giron L. & Manrique M. (2013). Experience with the active middle ear implant in patients with moderate-to-severe mixed hearing loss: Indications and results. *Otol Neurotol.* 34 (8), 1373-79.

Abstract:

OBJECTIVE: Quantify the improvement and impact of the active middle ear implants (AMEIs) on a moderate-to-severe mixed hearing loss population. STUDY DESIGN: Retrospective study on the indications and results obtained by individuals implanted with the AMEI. SETTINGS: Tertiary referral center. PATIENTS: Thirteen adult patients with moderate-to-severe hearing loss were evaluated. Air and bone conductive pure tone audiometry and disyllabic word discrimination was performed before and after surgery. The follow-up period was from 5 to 64 months. INTERVENTION: Surgical implantation of the AMEI. MAIN OUTCOME MEASUREMENT: Auditory performance analyzed using pure tone and speech audiometry with AMEI off and on. RESULTS: The average auditory gain in the frequency range 0.5 of 6 kHz was 44.07 dB. The average AC audiometric performance after activating the device is significantly better than the preoperative BC performance in 10 of 13 patients, with an average gain of 11.3 dB. Speech audiometry performance using disyllabic words showed a significant improvement. The detection threshold reduced significantly, from 65 to 24 dB ( $p = 0.012$ ) with the AMEI. The speech recognition score at 65 dB SPL also showed a significant improvement from 28% to 90% post surgery ( $p = 0.004$ ). The maximum speech recognition score also improved post surgery, from 56% to 93% with the AMEI ( $p = 0.023$ ). CONCLUSION: The AMEI is considered an appropriate device to be used by patients with BC losses up to 70 dB, provided that hearing levels are present in all frequencies between 0.5 and 4 kHz, and the speech recognition percentage is above 60% in the ear chosen for implantation.

- 180 Schwab B., Grigoleit S. & Teschner M. (2013). Do we really need a coupler for the round window application of an AMEI? *Otol Neurotol.* 34, 1181-85.

Abstact:

OBJECTIVE: Implanting active middle ear implants (AMEI) at the round window has become a standard procedure to restore hearing for patients with moderate inner ear or mixed hearing loss. The round window (RW)-Coupler was developed as an alternative coupling aid to fit smaller RW diameters and require less drilling in the RW niche. The question arises whether using the RW-Coupler is useful and a safe procedure compared with the nonuse of the RW-Coupler MATERIALS AND METHODS: Forty-nine German-speaking patients were implanted with either a RW-Coupler attached to an AMEI floating mass transducer (FMT) or without coupler. They were evaluated preoperatively and postoperatively for bone and air conduction thresholds with and without the implant, as well as speech perception tests. RESULTS: Bone conduction thresholds remained stable preoperatively and postoperatively. The patient's functional gain was slightly better with the RW-Coupler. Focusing on the

average speech perception performances, both groups presented an improvement of speech perception above 80% at 65 dB HL. CONCLUSION: RW-Coupler-Vibroplasty was found to be a safe procedure, which produced good results in this group of patients with mixed hearing loss.

- 179 Verhaert N., Desloovere C. & Wouters, J. (2013). Acoustic hearing implants for mixed hearing loss: A systematic review. *Otol Neurotol.* 34: 1201-09.

Abstract:

OBJECTIVE: A systematic review of literature to determine the clinical outcome and safety of the range of acoustic hearing implants (AHIs) in adults with mixed hearing loss (MHL). DATA SOURCES: Databases MEDLINE, Embase, and Cochrane were searched with no language restrictions between 1950, or the start date of each database, up to March 1, 2013. STUDY SELECTION: Initial search found 1,794 studies, of which, 19 met the inclusion criteria of AHI for adults with MHL where safety, coupling strategies to the inner ear, hearing outcome, and patient-reported outcome measures (PROMs) were analyzed, preferably compared with a conventional hearing aid or a bone-conduction implant. DATA EXTRACTION: A study quality assessment based on different parameters was included: specification of eligibility criteria, prospective study, ethical approval gained, appropriate controls, power calculation, outcome measures, and analysis performed. DATA SYNTHESIS: Comparisons between studies were made based on structured review as meta-analysis was not feasible because of the heterogeneity of outcome measures and reports. CONCLUSION: The current systematic review shows that AHI and their different coupling strategies in the treatment of MHL were beneficial in terms of speech in quiet, PROM, and safety regarding residual hearing. Overall, the level of evidence and the quality of the included studies were judged to be moderate to low. More comprehensive data on coupling to the inner ear and the comparison with conventional hearing aids or alternatives for speech in noise is mandatory. Long-term follow-up data are also needed.

- 178 Monini S., Filippi C., Atturo F. & Barbara M. (2013). Is the bone-conduction headband test useful for predicting the functional outcome of a round window active middle ear implant? *Otol Neurotol.* 34, 1329-35.

Abstract:

OBJECTIVE: To estimate the reliability of the Bone Conduction-HeadBand (BC-HB) test for predicting the postoperative functional outcome of a round-window (RW) vibroplasty. STUDY DESIGN: Within-subject comparison of the functional results of the BC-HB test, which is routinely used for the preoperative evaluation of a bone-conduction transducer, with an active middle ear implant (AMEI) placed onto the round window. SETTING: Tertiary referral university hospital center. PATIENTS: Seven patients with similar anatomic (absent stapes superstructure) and functional (moderate, mixed hearing loss) sequelae from open tympanoplasty technique. INTERVENTION: All subjects underwent preoperative audiologic assessment with the BC-HB. Subsequently, all subjects underwent surgical placement of an AMEI onto the round window. MAIN OUTCOME MEASURE: Pure tone and speech

audiometry in quiet and noise were assessed. Additionally, evaluation of specific satisfactory targets was performed using the Client Oriented Scale of Improvement. RESULTS: Pure tone and speech audiometry in quiet established that both devices had very similar performance and provided remarkable improvement compared with the unaided condition. However, high-frequency gain and speech audiometry in noise demonstrated better performance with RW-AMEI. CONCLUSION: In patients presenting with mixed hearing loss as a sequela from middle ear surgery, the preoperative BC-HB test may be helpful in predicting the final functional outcome and patient satisfaction with RW-AMEI.

- 177 Butler C.L., Thavaneswaran P. & Lee I.H. (2013). Efficacy of the active middle-ear implant in patients with sensorineural hearing loss. *J Laryngol Otol.* 127(S2), S8-S16.

Abstract:

INTRODUCTION: This systematic review aims to advise on the effectiveness of the active middle-ear implant in patients with sensorineural hearing loss, compared with external hearing aids. METHODS: A systematic search of several electronic databases, including PubMed and Embase, was used to identify relevant studies for inclusion. RESULTS: Fourteen comparative studies were included. Nine studies reported on the primary outcome of functional gain: one found that the middle-ear implant was significantly better than external hearing aids ( $p < 0.001$ ), while another found that external hearing aids were generally significantly better than middle-ear implants ( $p < 0.05$ ). Six of the seven remaining studies found that middle-ear implants were better than external hearing aids, although generally no clinically significant difference (i.e.  $\geq 10$  dB) was seen. CONCLUSION: Generally, the active middle-ear implant appears to be as effective as the external hearing aid in improving hearing outcomes in patients with sensorineural hearing loss.

- 176 Luers J.C., Huttenbrink K.B., Zahnert T., Bornitz M. & Beutner D. (2013). Vibroplasty for mixed and conductive hearing loss. *Otol Neurotol.* 34(6), 1005-12.

Abstract:

OBJECTIVE: To summarize new application methods of an active middle ear implant (Vibrant Soundbridge) in patients with conductive or mixed hearing loss. DATA SOURCES: Publications listed in the Medline/PubMed database. STUDY SELECTION: All publications published in English language; search term Vibrant Soundbridge AND floating mass transducer in all fields. DATA EXTRACTION: Structured analysis of all publications. DATA SYNTHESIS: Extraction of significant findings and conclusions and audiometric data. CONCLUSION: Modern application methods of an active middle ear implant (VSB) open new therapeutic options for patients with various outer and middle ear diseases resulting in conductive or mixed hearing loss. Titanium couplers can help to couple the active middle ear implant in a standardized way to remnants of the ossicular chain or to the round window. Thus, the active middle ear implant has been established as an alternative treatment option for patients with mixed and conductive hearing. However, the heterogeneity of the studies published so far complicates the analysis of the audiometric

results, and thus, the functional hearing gain after VSB implantation varies a lot.

- 175 Zwartekot J.W., Hashemi J., Cremers C.W., Mulder J.J. & Snik A.F. (2013). Active middle ear implantation for patients with sensorineural hearing loss and external otitis: Long-term outcome in patient satisfaction. *Otol Neurotol.* 34, 855-861.

Abstract:

**OBJECTIVE:** To study long-term subjective benefit of patients with sensorineural hearing loss and chronic external otitis who use active middle ear implants. **DESIGN:** Single-subject repeated measures in a preintervention and postintervention design with multiple postintervention measurements (questionnaires). **SETTING:** Tertiary academic center. **PATIENTS:** Moderate-to-severe sensorineural hearing loss ( $n = 56$ ) with severe chronic external otitis who use the Vibrant Soundbridge (VSB) or Otologics MET middle ear implant systems. **MAIN OUTCOME MEASURE:** Changes in hearing disability and handicap as evaluated using the Abbreviated Profile of Hearing Aid Benefit (APHAB), the Nijmegen Cochlear Implant Questionnaire (NCIQ), and the Glasgow Benefit Inventory (GBI). **RESULTS:** Data of 33 patients (mean postoperative duration of 7.5 yr) were available. No difference in subjective results was found between the VSB and Otologics MET patient groups. Total percentage of nonuse was 13%. Long-term APHAB results show a significant decrease in disability for 43% of the patients compared with 54% at 1-year postoperative. NCIQ results show a significant benefit for all subdomains with a negative trend over time. The GBI results show a significant long-term increase in quality of life with positive scores for 82% of the assessed patients. **CONCLUSION:** Long-term postoperative patient satisfaction and quality of life results show a significant difference compared with preoperative measurements, with conventional hearing aids. A negative trend over time is found on all questionnaires, which might reflect patient aging (increase of hearing loss) or habituation to a situation with fewer concerns regarding a patient's external otitis.

- 174 Just T., Specht O., Punke C., Schmidt W. & Pau H.W. (2013). [Effect of fenestration of the cochlea on the vibration of the round window membrane]. *Laryngorhinootologie*, 92 (6), 394-399.

Abstract:

Drilling a promontory window and coupling an FMT into the scala tympani may be a surgical alternative to stapes surgery in obliterate tympanosclerosis. Aim of this experimental study on human temporal bones was to measure changes of the acoustic transfer function from the tympanic membrane to the round window membrane after drilling a promontory window and insertion of a floating mass transducer. Laser vibrometry and acoustic measurements were performed on 11 temporal bone preparations equipped with a microphone attached to the round window. Calibrations were carried out to allow determination of SPLs affecting the cochlea after drilling a promontory window leaving the membranous inner ear intact and after insertion of an FMT into the cavity (with or without slight pressure). Drilling a promontory window does influence the transfer function. Insertion of the FMT with additional slight pressure further changes the transfer function.

The presence of a promontory window changes the acoustic transfer function to the round window. Further investigations are needed to correlate the qualitative results with the audiological results after "third window vibroplasty" (inserted floating mass transducer without stimulation).

- 173 Claros P. & Pujol, M.C. (2013). Active middle ear implants: Vibroplasty in children and adolescents with acquired or congenital middle ear disorders. *Acta Otolaryngol.* 133 612-619.

**Abstract:**

**CONCLUSION:** Active middle ear implant (AMEI) implantation in children and adolescents is safe and provides improved hearing results. No statistical difference in hearing outcomes was shown in the group of patients affected by chronic middle ear diseases versus aural atresia. Also, the transducer location (round window versus oval window placement) did not lead to different outcomes in hearing abilities. **OBJECTIVES:** (1) To assess the hearing outcomes with the active implant Vibrant Soundbridge (VSB) in children and adolescents. (2) To evaluate whether functional results of the subjects in the study could depend on the hearing loss etiology (chronic middle ear diseases versus aural atresia) or on transducer location (round window versus oval window placement). **METHODS:** The study was carried out with a retrospective, single-subject, repeated measures design, and included 22 children and adolescents with conductive or mixed hearing loss due to aural atresia or chronic middle ear diseases. Preoperative and postoperative pure tone air conduction (AC) and bone conduction (BC) thresholds were measured to demonstrate implantation safety. Free-field warble tone and speech audiometry were performed to assess postoperative hearing abilities with and without the VSB. **RESULTS:** No significant changes in mean BC or AC thresholds between preoperative and postoperative conditions were seen in the 22 patients. Mean PTA4 functional gain was 30.7 dB. Averaged over all 22 patients, word recognition at 65 dB SPL changed from an average of 19% in the unaided postoperative condition to 97% in the VSB-aided condition. Functional results were independent of hearing loss etiology and transducer location.

- 172 Colletti L., Mandala M. & Colletti V. (2013). Long-term outcome of round window Vibrant Soundbridge implantation in extensive ossicular chain defects. *Otolaryngol Head Neck Surg.* 149(1), 134-141.

**Abstract:**

**OBJECTIVE:** To evaluate retrospectively the long-term safety and efficacy of the first 50 patients, all suffering from severe ossicular chain defects and with moderate to severe mixed hearing loss, who received the Vibrant SoundBridge with the floating mass transducer located on the round window membrane. To evaluate differences in outcome versus etiology and age of the patient population. **STUDY DESIGN:** Case series with planned data collection. **SETTING:** Tertiary referral medical center. **SUBJECTS AND METHODS:** Patients eligible for implantation of the floating mass transducer on the round window membrane ranged in age from 2 months to 74 years with a moderate to severe

conductive or mixed hearing loss from different etiologies. For each adult patient, preoperative versus postoperative bone and air conduction thresholds, air-bone gaps, and speech understanding scores were evaluated at 24-month follow-up. At 60-month follow-up, data were available from 33 patients. Preoperative and postoperative free-field auditory brainstem responses were studied in infants and children. Intraoperative and short- and long-term postoperative complications are presented. RESULTS: There were significant improvements in speech perception and pure-tone audiometry in adults and auditory brainstem response thresholds in infants immediately after surgery and at follow-up examinations (12 to 71 months). No significant complications or device extrusions were observed in the present series. CONCLUSIONS: Infants, children, and adults with moderate to severe conductive or mixed hearing loss obtained substantial benefit from implantation of the floating mass transducer on the round window membrane regardless of the etiology of hearing loss and previous surgery.

- 171 Edfeldt L. & Rask-Andersen, H. (2013). Round window vibroplasty in chronic ear surgery: Comparison with conventional hearing rehabilitation. *Acta Otolaryngol.* 133(8) 814-825.

Abstract:

CONCLUSION: Functional hearing results with round window vibroplasty in chronically disabled middle ears were comparable and, at high frequencies, superior to the results achieved with previously used conventional hearing aids even after extended surgery. Soft tissue transfer appears to be more important than floating mass transducer (FMT) alignment with the round window membrane (RWM) for efficient coupling or sonoinversion. OBJECTIVES: To evaluate the functional hearing results of an active middle ear implant (AMEI) to the round window niche (RWN). The results were compared with previously used conventional hearing aids. The position of the FMT was determined by cone-beam computed tomography (CBCT). METHODS: This was a prospective cohort study carried out in a tertiary referral center. Seven patients with severe middle ear disease were implanted with an AMEI with round window application. The postoperative hearing outcome was compared with preoperative hearing using unaided and conventionally aided conditions. The results were correlated with the physical/geometric relation of the FMT to the RWM as determined with CBCT. RESULTS: Dislocation of the FMT was not observed. One patient was re-implanted due to accidental damage to the electrode. In all patients, the pertinent functional hearing results were achieved and were comparable to previous rehabilitation results.

- 170 Frenzel H., Sprinzl G., Widmann G., Petersen D., Wollenberg B. & Mohr C. (2013). Grading system for the selection of patients with congenital aural atresia for active middle ear implants. *Neuroradiol.* 55(7), 895-911.

Abstract:

INTRODUCTION: Active middle ear implants (aMEI) are being increasingly used for hearing restoration in congenital aural atresia. The existing gradings used for CT findings do not meet the requirements for these implants. Some items are expendable, whereas other

important imaging factors are missing. We aimed to create a new grading system that could describe the extent of the malformation and predict the viability and challenges of implanting an aMEI. METHODS: One hundred three malformed ears were evaluated using HRCT of the temporal bone. The qualitative items middle ear and mastoid pneumatization, oval window, stapes, round window, tegmen mastoideum displacement and facial nerve displacement were included. An anterior- and posterior round window corridor, oval window and stapes corridor were quantified and novelly included. They describe the size of the surgical field and the sight towards the windows. RESULTS: The ears were graded on a 16-point scale (16-13 easy, 12-9 moderate, 8-5 difficult, 4-0 high risk). The strength of agreement between the calculated score and the performed implantations was good. The comparison of the new 16-point scale with the Jahrsdoerfer score showed that both were able to conclusively detect the high-risk group; however, the new 16-point scale was able to further determine which malformed ears were favorable for aMEI, which the Jahrsdoerfer score could not do. CONCLUSION: The Active Middle Ear Implant Score for aural atresia (aMEI score) allows more precise risk stratification and decision making regarding the implantation. The use of operative corridors seems to have significantly better prognostic accuracy than the Jahrsdoerfer score.

- 169 Guldner C., Heinrichs J., Weiss R., Eivazi B., Bien S., Teymoortash A., Werner J.A. & Diogo I. (2013). Prospective evaluation of reliability of cone beam computed tomography in detecting different position of vibroplasty middle ear implants. Clin Otolaryngol. 38(3), 217-224.

**Abstract:**

**OBJECTIVES:** This study had the following objectives: (i) To determine the accuracy of determination of Vibrant Soundbridge position in the spectrum of typically implanted sites in the middle ear. (ii) To assess inter-observer agreement between 3 observers with different levels of radiology experience. (iii) To determine the suitability of cone-beam computed tomography (CT) to be used as the baseline radiological assessment post implantation, confirm ferromagnetic transducer (FMT) position. **DESIGN:** Prospective research study. Using 4 fresh human cadaveric heads, different types of vibroplasty were performed. After each step, cone-beam CT was performed for each of the 4 cadaveric heads. **SETTING:** University hospital (ENT and Neuroradiology). **PARTICIPANTS:** Four fresh cadaveric heads of human donors were operated and analyzed by radiological imaging. **MAIN OUTCOME MEASURES:** There are different ways of coupling an FMT to the anatomical structures of the middle and inner ear. Possibilities of differentiation between these coupling variants should be presented. **RESULTS:** The individual reconstruction view was significantly different from a standardized view for each observer (observer 1:  $p = 0.003$ ; observer 2:  $p = 0.001$ ; observer 3:  $p = 0.002$ ) for all coupling variants combined as well as for each individual coupling variant (overall correct diagnosis: 100% vs. 60%). Regarding the frequency of correct diagnosis, no significant differences were found between the 3 observers ( $p > 0.500$ ) for each individual coupling variant as well as for all coupling variants combined. The worst rates of correct diagnosis were found in the standardized view for incus (42%), stapes (0%), and TORP (17%) vibroplasty. **CONCLUSION:** Cone-beam

CT as a radiological control for Vibrant Soundbridge is safe and adequately sensitive and reliable and is therefore suitable for clinical investigation. The position of the FMT in the middle ear and the presence or absence of an additional coupler could be determined in this study. Therefore, cone-beam-CT is useful for the assessment of device failure when there has been gross displacement of the FMT (or smaller displacements in case of a baseline postoperative cone-beam CT). Regarding the quality of imaging, cone-beam CT produced accurate results with different observers with widely varying radiological experience.

- 168 Marino R., Linton N., Eikelboom R.H., Statham E. & Rajan G.P. (2013). A comparative study of hearing aids and round window application of the Vibrant Soundbridge (VSB) for patients with mixed or conductive hearing loss. *Int J Audiol.* 52(4), 209-218.

Abstract:

OBJECTIVE: This study was undertaken to determine the efficacy of the round window (RW) application of the vibrant soundbridge (VSB) in patients with mixed or conductive hearing loss. DESIGN: Speech in quiet and in noise were compared to preoperative data attained with conventional hearing aids so that each subject served as his or her own control in a single test protocol. STUDY SAMPLE: Eighteen adults implanted monaurally with the VSB in the poorer hearing ear. Experience with the VSB ranged from nine to 25 months. RESULTS: Sixteen of the 18 subjects were successful VSB users, wearing their device all waking hours. There was no significant deterioration in the averaged bone conduction results preoperatively versus post-operatively ( $p > 0.05$ ). Speech recognition in quiet results were not significantly different to performance attained whilst wearing hearing aids ( $p > 0.05$ ). Speech recognition in noise performance was substantially improved with use of the VSB in most test conditions. CONCLUSIONS: For the majority of the subjects, the VSB was an effective method of hearing restoration for their mixed and conductive hearing loss.

- 167 Atas A., Tutar H., Gunduz B. & Bayazit Y.A. (2013). Vibrant Soundbridge application to middle ear windows versus conventional hearing aids: A comparative study based on international outcome inventory for hearing aids. *Eur Arch Otorhinolaryngol.* 271(1), 35-40.

Abstract:

In this study, we aimed to compare the outcomes of satisfaction of the patients who used hearing aids preceding the vibrant sound bridge (VSB) application on middle ear windows (14 oval window and 5 round window). Nineteen adult patients with conductive or mixed hearing loss were included in the study. All patients used behind the ear hearing aids on the site which was selected for VSB application. The patients used hearing aids for at least 3 months before the VSB operation. The floating mass transducer (FMT) was placed on one of the middle ear windows (oval or round) in VSB operation. The patients were evaluated with International Outcome Inventory for Hearing Aids (IOI-HA) preoperatively after at least 3 months trial of conventional hearing aid and postoperatively after 3

months use of VSB. No perioperative problem was encountered. The total score of IOI-HA was significantly higher with VSB compared with conventional hearing aids ( $p < 0.05$ ). No statistically significant difference was found between the daily use, residual activity limitations, satisfaction, impact on others, quality of life between middle ear implant and hearing aid ( $p > 0.05$ ). The IOI-HA scores were significantly higher with the middle ear implant than the conventional hearing aid regarding benefit and residual participation restrictions ( $p < 0.05$ ). Although the scores for quality of life assessment was similar between VSB and hearing aid use, there was a superiority of VSB in terms of benefit and residual participation restrictions as well as overall IOI-HA scores as the FMT was placed on one of the middle ear windows.

- 166 Skarzynski H., Olszewski L., Skarzynski P.H., Lorens A., Piotrowska A., Porowski M., Mrowka M. & Pilka A. (2013). Direct round window stimulation with the Med-El Vibrant Soundbridge: 5 years of experience using a technique without interposed fascia. Eur Arch Otorhinolaryngol. 271, 477-482.

**Abstract:**

The objective of this study was to present 5 years of surgical experience, and the extended results of hearing preservation (based on 3-year follow-up), with the Med-El Vibrant Soundbridge (VSB) in which the floating mass transducer (FMT) is placed directly against the round window membrane, and the fascia is used only as covering tissue to keep it in position. A retrospective survey of surgical and audiological data was conducted to evaluate the performance and stability of patient hearing, with audiometric measurements performed over fixed time intervals up to 36 months. 21 patients, aged 19-62 years (mean 48.4), with mixed or conductive, bilateral or unilateral hearing loss were included in this study. Surgical intervention involved monaural implantation of the Med-El VSB between 2006 and 2009. The results were assessed using pure tone audiometry. In 5 years of experience with the technique, no significant complications or device extrusion were observed except for two revision surgeries requiring FMT repositioning. In the 3-year follow-up, we observed stable hearing in the implanted ear. It is concluded that direct round window stimulation without interposed fascia is an alternative for patients with hearing impairment caused by chronic otitis media and/or lack of ossicles, especially after modified radical mastoidectomy. It allows good results in a selected group of patients, although further observation on a larger population is needed to confirm long-term validity and effectiveness.

- 165 Zernotti M.E., Arauz S.L., Di Gregorio M.F., Arauz S.A., Taberner P. & Romero M.C. (2013). Vibrant Soundbridge in congenital osseous atresia: Multicenter study of 12 patients with osseous atresia. Acta Otolaryngol. 133(6), 569-573.

**Abstract:**

**CONCLUSION:** The study suggests that the Vibrant Soundbridge (VSB) middle ear implant could be a valid alternative for patients with congenital aural atresia to compensate for their hearing loss. **OBJECTIVE:** To determine the audiologic benefit the VSB provides in

patients with congenital aural atresia. METHODS: Twelve patients with congenital aural atresia were implanted with VSB: eight patients were unilaterally atretic (67%) and 4 (33%) were bilaterally atretic. In five cases the implant was placed onto the round window, in another five cases the implant was placed on the stapes, in only one case a prosthesis (coupler) was used to fix the implant into the oval window, and in one case a fenestration on the cochlear endostium was performed. RESULTS: The mean functional gain obtained for all patients evaluated was 62 dB at 0.5 kHz, 60 dB at 1 kHz, 48.3 dB at 2 kHz, and 50.8 dB at 4 kHz. The mean functional gain for all frequencies evaluated was 55.1 dB.

- 164 Tsang W.S., Yu J.K., Wong T.K. & Tong M.C.J. (2013). Vibrant Soundbridge system: Application of the stapes coupling technique. *Laryngol Otol.* 127(1), 58-62.

Abstract:

INTRODUCTION: The use of the stapes coupling technique, employed in the Vibrant Soundbridge system, is technically less demanding than the vibroplasty technique, and is more likely to generate a positive outcome without significantly changing residual hearing or resulting in medical or surgical complication. METHOD: We report a patient with repeated left ossiculoplasty failure, who was successfully implanted with a Vibrant Soundbridge. CONCLUSION: We believe that the stapes coupling technique can provide natural stimulation to the inner ear, resulting in a better perceived sound quality.

- 163 Lesinskas E., Stankeviciute V. & Petrusonis M. (2012). Application of the Vibrant Soundbridge middle-ear implant for aural atresia in patients with Treacher Collins syndrome. *J Laryngol Otol.* 126(12), 1216-23.

Abstract:

OBJECTIVE: To present results for the auditory rehabilitation of patients with Treacher Collins syndrome with bilateral osseous atresia, using middle-earimplantation with a Vibrant Soundbridge. METHODS: Three patients underwent vibroplasty for aural atresia with moderate to severe conductive hearing loss. The pre-operative Jahrsdoerfer radiological score was 4 for all patients. Patients underwent active middle-ear implantation of a Vibrant Soundbridge implant (coupling the floating mass transducer to the rudimentary stapes or footplate distally, and positioning it adjacent to the round window membrane proximally), with audiological analysis as follow up. RESULTS: After implant activation, the mean air conduction threshold  $\pm$  standard deviation decreased to 22.8  $\pm$  5.5 dB HL, representing a mean functional gain of 44.5 dB. The mean word recognition score (for bisyllabic words at 65 dB SPL) increased from 0 to 97 per cent. CONCLUSION: Vibrant Soundbridge implantation is an effective hearing rehabilitation procedure in patients with Treacher Collins syndrome with bilateral osseous atresia. This is a versatile implant which can achieve coupling even in cases of severe middle-ear malformation.

- 162 Gunduz B., Atas A., Bayazit Y., Goksu N., Gokdogan C. & Tutar H. (2012). Functional outcomes of Vibrant Soundbridge applied on the middle ear windows in comparison with

conventional hearing aids. *Acta Otolaryngol.* 132(12), 1306-10.

**Abstract:**

**CONCLUSION:** Vibrant Soundbridge (VSB) application to the middle ear windows yields better functional outcomes than conventional hearing aids. However, speech discrimination scores obtained with VSB and conventional hearing aids are similar. **OBJECTIVE:** To assess audiological outcomes of round and oval window applications of VSB in comparison with conventional hearing aids. **METHODS:** Nineteen adult patients were included in the study. The patients had mild to moderate, moderate or moderate to profound conductive or mixed hearing loss. During surgery the floating mass transducer (FMT) was placed on the round ( $n = 14$ ) or oval ( $n = 5$ ) window. After the surgery, audiometric evaluation and free field audiometric evaluation of both ears was carried out. **RESULTS:** The hearing thresholds in the low frequencies were not significantly different between the conventional hearing aids and VSB. The functional gains obtained with oval and round window approaches were similar except for 500 Hz. The hearing thresholds in the mid and high frequencies were significantly better with VSB than the conventional hearing aids. The functional gain in the low frequencies was not significantly different between VSB and conventional hearing aids. The functional gain in the other frequencies was significantly better with VSB than conventional hearing aids.

- 161 Frenzel H., Schönweiler R., Hanke F., Steffen A. & Wollenberg B. (2012). The Lübeck flowchart for functional and aesthetic rehabilitation of aural atresia and microtia. *Otol Neurotol.* 33(8), 1363-7.

**Abstract:**

Current strategies for functional rehabilitation of microtia-atresia patients with bone-anchored implants or surgical atresia repair have been extended by the feasibility of active middle ear implants. The aim of the present research is to evaluate a new flowchart of the treatment of these patients that considers active middle ear implants. Congenital aural atresia and microtia. Bilateral cases are provided with a conductive hearing aid after birth and implanted with an active middle ear implant within the second year. Unilateral cases are provided with a conductive hearing aid and implanted with a middle ear or bone-conduction device in early childhood. Unilateral cases without amplification in the vulnerable time after birth are carefully selected for late implantation. At age 8 to 10, the auricular reconstruction is completed. Feasibility of implantation irrespective of age, functional gain in audiology. The results of early implantation are as good as those previously published for adolescents. Mean reaction threshold with the Vibrant Soundbridge was 21 dB. Mean functional gain was 48 dB. The local tissues are unaltered and ready for auricular reconstruction. Active middle ear implants allow early and selective stimulation of the auditory pathway in children with congenital conductive hearing loss and are expected to lead to the normal development of the binaural hearing functions. To date, it is the only option if the stimulation is to be started at the age of 12 to 18 months. This was implemented into a new flowchart for aural atresia-microtia.

- 160 Roman S., Denoyelle F., Farinetti A., Garabedian E.-N. & Triglia J.-M. (2012). Middle ear implant in conductive and mixed congenital hearing loss in children. *Int J Pediatr Otorhinolaryngol.* 76(12), 1775-8.

Abstract:

PURPOSE: Active middle ear implant can be used in children and adolescents with congenital hearing loss. The authors report their experience with the semi implantable Medel Vibrant Soundbridge® (VSB) in the audiological rehabilitation of such patients. METHODS: In this retrospective study, audiological and surgical data of 10 children (10.5±4 years) implanted with 12 VSB in 2 tertiary care ENT Departments were analysed. RESULTS: Two children with bilateral external auditory canal (EAC) atresia and mixed hearing loss (mean air conduction (AC) thresholds=65dB HL) were bilaterally implanted. Eight children presented with microtia associated with EAC atresia bilaterally (n=3) and unilaterally (n=5). All of them had a conductive hearing loss in the implanted ear (mean (AC) thresholds were 58.75dB HL preoperatively). The Floating Mass Transducer was crimped on the long process of the incus (n=8) or on the suprastructure of the stapes (n=4). There were no intra- or postoperative surgical complications. All the children wore their implants after 5 weeks. Postoperative mean bone conduction (BC) thresholds were unchanged. The mean aided thresholds with VSB (four frequencies warble tones at 0.5, 1, 2 and 4kHz) were 28dB HL (±10). Word discrimination threshold in quiet conditions in free field with the VSB unilaterally activated was 50% at 38dB SPL (±9). CONCLUSION: The results indicate that satisfaction of the children and their parents is very encouraging but surgeons should be cautious with this new approach in relation to the pinna reconstruction and to possible risks to inner ear and facial nerve.

- 159 Verhaert N., Mojallal H. & Schwab B. (2012). Indications and outcome of subtotal petrosectomy for active middle ear implants. *Eur Arch Otorhinolaryngol.* 270(4), 1243-8.

Abstract:

The aim of this study was to describe the outcome and possible complications of subtotal petrosectomy (SP) for Vibrant Soundbridge (VSB) device surgery in a tertiary referral center. A secondary objective was the evaluation of hearing results in a subgroup of subjects who received the VSB device. Between 2009 and early 2011, 22 adult subjects with chronic otitis media (COM) underwent a SP, blind sac closure of the external auditory canal and abdominal fat obliteration to facilitate the application of an active middle ear implant (AMEI) in a staged procedure. Indications consisted of mixed hearing loss after previous tympanomastoplasty and failure of hearing rehabilitation with a hearing aid or bone conduction device in COM. Pre- and postoperative pure-tone audiograms were analyzed in respect to deterioration of inner ear function, unaided and aided (hearing aid, bone-anchored hearing aid and VSB) speech audiograms were compared to verify improvements in communications skills and functional gains. Incidence and type of complications were reviewed. No significant change was observed regarding mean bone conduction thresholds after the first stage procedure. Some minor wound healing problems were noted. Speech perception using the VSB (n = 16) showed a mean aided

speech discrimination at 65-dB SPL of 75 \% [standard deviation (SD) 28.7], at 80-dB SPL of 90 \% (SD 25.1). Our results suggest that for selected patients with open mastoid cavities and chronic middle ear disease, SP with abdominal fat obliteration is an effective and safe technique to facilitate safe AMEI placement.

- 158 Böheim K., Mlynki R., Lenarz T., Schlägel M. & Hagen R. (2012). Round window vibroplasty: Long-term results. *Acta Otolaryngol.* 132(10), 1042-8.

Abstract:

**CONCLUSION:** The round window (RW) approach in the use of the Vibrant Soundbridge® (VSB) is a safe and effective treatment of conductive and mixed hearing losses for a period of more than 3 years of device use. **OBJECTIVE:** To investigate the long-term safety and efficacy as well as user satisfaction of patients with conductive and mixed hearing losses implanted with the VSB using RW vibroplasty. **METHODS:** Twelve patients with conductive and mixed hearing losses were evaluated after 40 months of daily VSB use. Safety was assessed by evaluating reports of postoperative medical and surgical complications as well as by changes in bone conduction hearing thresholds. Efficacy outcome measures included aided and unaided hearing thresholds, speech recognition in quiet and in noise and subjective benefit questionnaires. **RESULTS:** The safety results revealed no significant medical complications. One subject experienced sudden hearing loss after 18-24 months of device use, but still continues to wear the device to her satisfaction. With regard to efficacy, there were no significant changes from short- to long-term results in aided word understanding, functional gain or speech recognition threshold, suggesting that the outcomes are stable over time. Subjective questionnaires revealed either the same or better results compared with the short-term data.

- 157 Schwab B., Salcher R.B., Maier H. & Kontorinis G. (2012). Oval window membrane vibroplasty for direct acoustic cochlear stimulation: Treating severe mixed hearing loss in challenging middle ears. *Otol Neurotol.* 33(5), 804-809.

Abstract:

**OBJECTIVE:** To date, all the Vibrant Soundbridge (VSB) applications have managed to stimulate the inner ear indirectly. Our objective was to present a new VSB application for direct inner ear stimulation. **STUDY DESIGN:** Prospective cohort study. **SETTINGS:** Tertiary, referral center. **PATIENTS:** Three patients with previous middle ear surgery and moderate-to-severe ipsilateral, mixed hearing loss. **INTERVENTIONS:** Oval Window Membrane Vibroplasty (OWMV) for direct acoustic cochlear stimulation. A Total Ossicular Replacement Prosthesis (TORP) was attached to the Floating Mass Transducer (FMT). Then, the stapes footplate was perforated, and the tip of the FMT-TORP assembly was advanced approximately 1 mm into the inner ear. A silicon ring was placed around the TORP's tip to prevent it from slipping deeper into the inner ear. **MAIN OUTCOME MEASURE:** Audiologic assessment involving pure-tone audiometry, aided and unaided free-field audiometry, Freiburg monosyllabic word test, and registration of any complications. **RESULTS:** OWMV resulted in an average functional hearing gain of 36.1 dB (range, 24.2-47.5 dB). Although

the greatest amplification was observed in the higher frequencies, there also was a significant improvement in the lower frequencies. The surgery was not related to any difficulties; vertigo, inner ear trauma, or further complications did not occur.

**CONCLUSION:** We present a new method for direct acoustic cochlear stimulation using an active middle ear implant. The preliminary results show that OWMV is a promising and safe option for treating moderate and severe hearing loss, even in challenging cases with previous middle ear operations or fixed stapes footplate.

- 156 Wolfram M.D., Giarbini N. & Streitberger C. (2012). Speech-in-noise and subjective benefit with active middle ear implant omnidirectional and directional microphones: A within-subjects comparison. *Otol Neurotol.* 33(4), 618–622.

**Abstract:**

**OBJECTIVES:** To evaluate speech understanding in noise by comparing signal-to-noise ratios for 50% correct word understanding (SNR50) using an omnidirectional and a directional microphone audio processor (AP) in 4 different noise conditions. 2) To compare subjective speech understanding abilities, spatial hearing abilities, and qualitative hearing performance with the 2 processors. **STUDY DESIGN:** A prospective, single-subjects repeated-measures study design was used to compare speech understanding performance with the 2 APs acutely and after 6 weeks' acclimatization time. **SETTING:** Tertiary referral center. **PATIENTS:** Thirteen experienced unilateral German-speaking active middle ear implant users with either mixed or conductive hearing loss were enrolled. **INTERVENTION:** Directional audio processor. **MAIN OUTCOME MEASURES:** SNR50 obtained from 4 different noise conditions. **RESULTS:** SNR50s with the directional AP were lower (better) than with the omnidirectional AP in all noise conditions, although there were no changes in aided PTA thresholds. In acute testing, the mean SNR50 showed a significant directional advantage (DA) for the directional AP in the SON0 condition of 1.3 dB, in SONVS 2.3 dB, in SONcont 3.1 dB, and in SON180 4.5 dB. As expected, the largest DA was found in the SON180 condition. No DA was expected in the SON0 condition but was present. After 6 weeks of acclimatization time, no significant change from the acute testing was found, suggesting that patients experienced improved performance with the directional AP, even without acclimatization time. There was no significant change in subjective questionnaire outcomes. **CONCLUSION:** The directional AP yields immediately improved speech understanding in noise.

- 155 Zhao S., Gong S., Han D., Chen S., Li Y., Ma X. & Liu H. (2012). [The application of Vibrant Soundbridge in microtia whose reconstructive external auditory canal occurred atresia] Lin Chung Er Bi Yan Hou Tou Jing Wai Ke Za Zhi, 26(10), 433-435.

**Abstract:**

**OBJECTIVE:** To investigate the effect of vibrant sound bridge implantation in microtia whose reconstructive external auditory canal occurred atresia. **METHOD:** Three cases (2 males and 1 female) of microtia had underwent hearing reconstruction operation (Include

the external ear canal reconstructive surgery and tympanoplasty). The age ranged from 15 to 18 years and the average age was 17 years. All the 3 cases suffered from conductive hearing loss with the air-bone gap ranging from 51.6 to 65.0 dB HL and the average value being 56.3 dB HL. All the 3 cases underwent vibrant sound bridge implantation, including the floating mass transducer implanted in the head of stapes in 2 cases and in the niche of round window in 1 case. RESULTS: The postoperative hearing level improved from 21.6 to 52.5 dB HL with an average of 32.2 dB HL. There were no complications such as vertigo, tinnitus and facial paralysis. CONCLUSION: Through vibrant sound bridge implantation, the hearing level of microtia whose reconstructive external auditory canal occurred atresia was improved effectively.

- 154 Iwasaki, S., Suzuki, H., Moteki, H., Miyagawa, M., Takumi, Y. & Usami, S. (2012). Experience with the Vibrant Soundbridge RW-Coupler for Round Window Vibroplasty with tympanosclerosis. *Acta Otolaryngol.* 132(6), 676–682.

**Abstract:**

Usage of the Vibrant Soundbridge (VSB) with Round Window (RW)-Coupler placement at the RW has been shown to successfully treat mixed hearing loss. Coupling between the VSB's Floating Mass Transducer (FMT) and the RW membrane is difficult in the case of sclerosis in the RW and drilling down the bony lip until the RW membrane can be seen completely can possibly induce a perilymphatic fistula. A 68-year-old woman who had bilateral mixed hearing loss with sclerosis in the RW due to tympanosclerosis underwent a RW-Vibroplasty with a RW-Coupler. Speech discrimination scores in quiet and noise and functional gain with the VSB with RW-Coupler were better than those using a conventional hearing aid. The results of the present case have shown the feasibility of implanting a VSB with RW-Coupler in patients with mixed hearing loss due to tympano-sclerosis.

- 153 Huber A.M., Mlynški R., Müller J., Dillier N., Holzmann D., Wolfram M.D. & Hagen R. (2012). A new Vibroplasty coupling technique as a treatment for conductive and mixed hearing losses: A report of 4 cases. *Otol Neurotol.* 33(4), 613–617.

**Abstract:**

**OBJECTIVE:** The primary objective was to report on experiences regarding the safety and efficacy of the Vibrant Soundbridge (VSB) using a Floating Mass Transducer (FMT)-Partial/Total Ossicular Replacement Prosthesis (PORP/TORP) assembly as a treatment for conductive and mixed hearing losses of mild-to-moderate/severe degree. The secondary objective was to gather information regarding device fitting, as well as to refine surgical procedures. **PATIENTS:** Five German-speaking adults from 2 European study sites were implanted with a VSB using an FMT-PORP/TORP assembly and evaluated before and after surgery for air-and bone-conduction thresholds and speech recognition performance. **MAIN OUTCOME MEASURES:** Evaluating the safety and efficacy of the VSB in combination with a PORP or TORP to treat conductive and mixed hearing loss. **RESULTS:** Residual cochlear hearing was unaffected by implantation with the device. Functional gain (measured as the difference between preoperative unaided and postoperative VSB-aided

thresholds) could be calculated in 2 of 5 subjects, demonstrating that the VSB is effective in treating bone-conduction hearing losses of moderate/severe degree. Word recognition tests in quiet and noise showed good improvement in 3 of the cases. One patient experienced several other medical problems, making her audiological outcomes limited. One patient was excluded from the study owing to insufficient benefit and subsequently underwent revision surgery with FMT placement at the Round Window. CONCLUSION: The use of the VSB, implanted using the FMT-PORP/TORP assembly, was safe in all and efficacious in 3 of the 5 cases in this study. These are patients who may have few, if any, other options to manage their hearing loss.

- 152 Marino R., Tavora Viera D. & Rajan G.P. (2012). Tinnitus and quality of life after Round Window Vibroplasty. *Intern Tinnitus J.* 17(2), 134-139.

Abstract:

OBJECTIVE: To measure the Quality of Life outcomes and impact on tinnitus perception in a group of patients after Round Window Vibroplasty (RW-VSB) for mixed or conductive hearing loss. STUDY DESIGN: A single-subject, repeated measures design was employed. All VSB fittings were based on hearing thresholds results and were not set to mask tinnitus. METHODS: Ten Round Window-Vibroplasty patients were assessed with the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Tinnitus Reaction Questionnaire (TRQ). RESULTS: Subjects reported less hearing difficulties in 3 of 4 APHAB subscales. Tinnitus perception was decreased in all subjects with tinnitus pre-operatively. CONCLUSION: Round window vibroplasty in our cohort of patients with mixed or conductive hearing improved quality of life outcomes. There was significant improvement on APHAB scores and a significant decrease in tinnitus perception in subjects experiencing tinnitus prior to implantation.

- 151 Yu J.K.Y., Tsang W.S.S., Wong T.K.C. & Tong M.C.F. (2012). Outcome of Vibrant Soundbridge middle ear implant in Cantonese-speaking mixed hearing loss adults. *Clin Exp Otorhinolaryngol.* 5(S1), S82-S88.

Abstract:

OBJECTIVES: To investigate the aided benefits, speech recognition in quiet and in noise, change in hearing and subjective report of satisfaction on mixed hearing loss adults implanted with Vibrant Soundbridge (VSB) middle ear implant. METHODS: Eight Cantonese speaking adult patients with mixed hearing loss were enrolled in a single-subject, repeated measures prospective study design. Audiometric testing, including air and bone conduction and word recognition under sound-field were conducted before surgery. Device activation was arranged 8 weeks after operation. Audiometric testing was taken to evaluate the change in hearing. Patients were asked to wear the device and come back for fine tuning as needed. Outcome measurements were undertaken at 3 and 6 months after device activation. The outcome measures included sound-field thresholds, Cantonese Hearing in Noise Test (CHINT), Abbreviated Profile of Hearing Aid Benefit (APHAB) and International Outcome Inventory for Hearing Aids (IOI-HA). RESULTS: The application of the VSB

improved the aided thresholds and improved speech intelligibility in quiet and noise without significant changes in hearing thresholds. CONCLUSION: VSB is considered as a safe, effective and reliable auditory rehabilitation option for Cantonese speaking adults with mixed hearing loss.

- 150 Verhaegen V.J., Mulder J.J., Cremers C.W. & Snik A.F. (2012). Application of active middle ear implants in patients with severe mixed hearing loss. *Otol Neurotol.* 33(3), 297–301.

Abstract:

OBJECTIVE: To determine the long-term benefit of the Vibrant Soundbridge (VSB) middle ear implant in patients with severe mixed hearing loss and to compare it with other hearing devices. DESIGN: A retrospective analysis. SETTING: University-affiliated medical center. PATIENTS: Six patients with severe mixed hearing loss and a mean sensorineural hearing loss component between 40 and 70 dB. INTERVENTIONS: Patients received a VSB with the Floating Mass Transducer (FMT) coupled to the Round Window or to the Oval Window via a residual stapes structure. MAIN OUTCOME MEASURES: Functional gain and speech recognition results. Results are compared with 2 control groups matched for mean sensorineural hearing loss: 1) patients with mixed hearing loss and a bone-anchored hearing device, and 2) patients with sensorineural hearing loss and traditional implantation of the VSB. RESULTS: There is large variance in functional gain between the patients suggesting high variability in the effectiveness of the FMT coupling. The speech recognition results for the experimental group were not systematically better than in either control group. CONCLUSION: There is large variability in results that might be ascribed to coupling effectiveness. On the average, speech recognition results were not better or worse than those found in patients with similar hearing loss fitted with bone-anchored hearing devices.

- 149 Barillari M., Cerini R., Carner M., Cacciatori C., Spagnolli F., Cardobi N., Mandalà M., Colletti L., Colletti V. & Pozzi Mucelli R. (2012). Congenital aural atresia treated with Floating Mass Transducer on the round window: 5 years of imaging experience. *Radiol Med.* 117(3), 488–499.

Abstract:

The aim of this paper is to illustrate imaging features of patients affected by congenital aural atresia (CAA) before and after treatment with a Vibrant Soundbridge (VSB) device implanted on the Round Window. Ten patients (5 males and 5 females; mean age 22.1 years) with CAA underwent preoperative high-resolution computed tomography (HRCT) to estimate the degree of involvement of the middle- and inner-ear structures and highlight radiological landmarks useful for surgical planning. Bilateral CAA, mostly of the mixed type, was present in 7 patients and ossicular chain abnormalities in 16 ears (94% of cases). The Round Window region was normal in all patients, whereas facial-nerve course and/or caliber abnormalities were present in 6 ears (35.3%). The tympanic cavity was small in 13 ears (76.5%), whereas the mastoid was well pneumatized in 8/17 (47%). HRCT provides accurate information about anatomy and malformations of the middle and inner ear and

can thus assist the surgeon in planning the procedure.

- 148 Colletti V., Mandalà M. & Colletti L. (2012). Electrocochleography in round window Vibrant Soundbridge implantation. *Otolaryngol Head Neck Surg.* 146(4), 633–640.

Abstract:

**OBJECTIVE:** To determine the role of intraoperative electrocochleography to optimize the fitting of the Floating Mass Transducer of the Vibrant Soundbridge on the Round Window membrane in patients with conductive and mixed hearing loss. **STUDY DESIGN:** Prospective cohort study. **SETTING:** Tertiary referral center, Otolaryngology Department, University of Verona, Verona, Italy. **SUBJECTS AND METHODS:** Twenty-six adult patients suffering from chronic otitis media with moderate to severe conductive and mixed hearing loss, all with previous unsuccessful functional surgery, underwent Round Window Vibroplasty. Thirteen subjects had intraoperative compound cochlear action potentials measured to assess Vibroplasty coupling during and after surgery. In these patients, surgery was modified according to electrocochleographic feedback. The other 13 had Vibroplasty without electrocochleography monitoring. **RESULTS:** The average preoperative air conduction and bone conduction thresholds (0.5-4 kHz) were not statistically significantly different between the 2 cohorts ( $P > .05$ ). Compound action potential recordings indicated specific surgical modalities to optimize coupling of the Floating Mass Transducer with the Round Window membrane. The average postoperative Vibrant Soundbridge-aided air conduction threshold improvements (0.5-4 kHz) were  $54.6 \pm 8.9$  and  $41.7 \pm 11.1$  dB HL, respectively, in the monitored and unmonitored cohorts ( $P = .0032$ ). **CONCLUSION:** Improved Round Window Vibroplasty outcomes are observed when the surgeon is promptly informed of the compound action potential changes induced by the Floating Mass Transducer Round Window membrane Vibroplasty and alters surgery accordingly. The key point for optimal coupling is a Floating Mass Transducer in full contact with the Round Window membrane, free to vibrate without any contact with the surrounding bony structures and mobile footplate.

- 147 Carner M., Cerini R., Colletti L., Barillari M., Spagnolli F., Cardobi N., Pozzi Mucelli R. & Colletti V. (2012). Computed tomography in 15 congenital aural atresia patients and Floating Mass Transducer on the round window. *Otolaryngol Head Neck Surg.* 147(1), 184-191. *[This manuscript has been retracted as an OnlineFirst submission because it contains substantial similar content to an earlier article published by the authors, in contradiction to the Journal's publishing policy]*
- 146 Lim L.H., Del Prado J., Xiang L., Yusof A.R. & Loo J.H. (2012). Vibrant Soundbridge middle ear implantations: Experience at National University Hospital Singapore. *Eur Arch Otorhinolaryngol.* 269(9), 2137-43.

Abstract:

Vibrant Soundbridge (VSB) has been recommended for both adults and children with all types of hearing loss. The aim of this study was to evaluate the objective and subjective

benefits with VSB and the difference in benefits for patients with different types of hearing loss. A retrospective case review was conducted on seven consecutive patients who had received VSB implantations at the National University Hospital of Singapore from March 2006 to November 2009. Patients were divided into the Sensorineural Hearing Loss (SNHL) Group and Conductive Hearing Loss (CHL)/Mixed Hearing Loss (MHL) Group. Surgical complications were evaluated, and objective and subjective results were compared between the two groups. No major complications were observed during the follow-up of up to 4 years. Greater objective and subjective benefits were observed in the CHL/MHL Group. Subjective benefits were consistent with objective improvements. Pre-operative counseling for realistic expectations is important, especially for patients with SNHL.

- 145 Sia K.J., Chai C.K., Tang I.P. & Prepageran N. (2012). Vibrant Soundbridge: A new implantable alternative to conventional hearing aids in children. *Med J Malaysia*, 67, 625-626.

**Abstract:**

The Vibrant Soundbridge is a new middle ear implantable hearing device. It was first introduced for adult patients with moderate to severe sensorineural hearing loss. With the innovation of the surgical techniques, its usage had been broadened for children and those patients with conductive and mixed hearing loss. We report first two cases of monoaural Vibrant Soundbridge implantation in Malaysia. They were children with bilateral conductive hearing loss who had failed to benefit from previous hearing aids. Floating mass transducers were attached in oval window and long process of incus respectively. Remarkable hearing yield was observed without surgical complication.

- 144 Strenger T. & Stark T. (2012). The application of implantable hearing aids using the Vibrant Soundbridge as an example. *HNO*, 60(2), 169-176.

**Abstract:**

Over the last decade, bone conducting hearing aids, cochlear implants and implantable hearing aids have come to represent additional treatment options in clinical routine-alongside conventional hearing aids-for hearing impaired patients. Thanks to experience gained in recent years with implantable hearing aids and the consistent evaluation of functional results, the original spectrum of indications has been progressively extended. Today, implantable hearing aids are available for the hearing (re)habilitation of various forms of middle ear pathology as well as sensorineural hearing loss within the audiological criteria. With CE certification for children, the treatment of younger patients with implantable hearing aids has also become possible. Using the Vibrant Soundbridge as an example, the function, indications and contraindications of implantable hearing aids are described and the surgical procedure and post-operative care discussed.

- 143 Zernotti M.E., Gregorio M.F. & Sarasty A.C. (2012). Middle ear implants: Functional gain in mixed hearing loss. *Braz J Otorhinolaryngol*. 78(1), 109-112.

**Abstract:**

Osseous atresia and chronic otitis media are diseases benefit with middle ear implants. Surgery for atresia is technically complicated, has significant number of complications and functional results are often poor. The osseointegrated hearing aids are an alternative. They provide a very good functional gain, but have many problems with the skin and osseointegration. In chronic otitis media, the ossiculoplasty solved partially the hearing problem. Unfortunately in some cases of otitis media and in open cavities fitted with conventional hearing aids the gain is unsatisfactory. AIM: To determine the usefulness of an active middle ear implant.

**MATERIALS AND METHOD:** Longitudinal Study. Vibrant-Soundbridge was implanted in eight patients with severe mixed hearing loss. Four patients had chronic otitis media and four had unilateral atresia. The placement of the stimulator (FMT or Floating Mass Transducer) was in five patients on Round Window, two in stapes and one in the Oval Window.

**RESULTS:** Functional gain was 35 dB, 40 dB, 48.7 dB and 50 dB for the frequencies 500, 1000, 2000 and 4000 Hz, respectively.

**CONCLUSION:** Vibrant-Soundbridge is an excellent option in hearing recovery in severe and profound mixed hearing loss. It also provides an excellent functional gain in diseases difficult to treat with conventional hearing aids.

- 142 Karkas A., Chahine K. & Schmerber S. (2012). The benefit of the reverse transfer function in the fitting process of the Vibrant Soundbridge middle ear implant. *Acta Otolaryngol.* 132(2), 173–178.

**Abstract:**

Reverse transfer function (RTF) measurement of the Vibrant Soundbridge (VSB) middle ear implant (MEI) is an objective method to evaluate the function of the VSB and can be used to adjust the Connexx value required to reach the optimal VSB gain during fitting sessions. To investigate the sound transfer of the VSB with the RTF in implanted patients and evaluate the role of RTF in the fitting process of the VSB. This was a prospective study including patients undergoing VSB implantation and RTF recording from March 2007 to October 2010. Three parameters were analyzed. 1) RTF: energy transmitted in dB SPL to ear canal by retrograde vibration of malleus and tympanic membrane. 2) Connexx value: level of amplification in dB delivered by the audioprocessor to the Floating Mass Transducer (FMT). 3) VSB gain: difference in dB HL in free field between aided and unaided conditions. Ten patients fitted the criteria. RTF measurements revealed a significant inter-patient disparity. We adjusted the Connexx value according to the RTF value to obtain an optimal VSB gain within comfort levels. The VSB gain and RTF with Connexx value were closely correlated together. The mean VSB gain and RTF value converted to dB HL had comparable values.

- 141 Klingmann C., Klingmann A. & Skevas T. (2011). Suitability of the partially implantable active middle-ear amplifier Vibrant Soundbridge® to hyperbaric exposure. Diving Hyperb Med. 41(4), 239–232.

Abstract:

Active middle ear amplifiers represent a modern possibility to treat sensorineural, conductive and combined hearing loss. They can be in use in divers and patients who need hyperbaric oxygen therapy. Therefore, active middle-ear amplifiers have to be tested to determine whether or not they are prone to implosion or function loss in hyperbaric conditions. We asked three of the companies registered by the German health authorities as manufacturers of active middle ear amplifiers to test their devices in hyperbaric conditions. Med-El agreed to support the study; Envoy stated that their devices were unable to withstand a pressure of 608 kPa; Otologics had no capacity to take part in this study. Twelve Vibrant Soundbridge® (Med-El) middle-ear amplifiers were tested in a water bath in a hyperbaric chamber. Four devices were pressurised to a maximum of 284 kPa, four devices to 405 kPa and four devices to 608 kPa, each for a maximum dive time of 78 minutes. The functions of the 12 devices were tested by the manufacturer pre- and post-hyperbaric exposure. Visual inspections as well as laboratory function tests were normal in all 12 devices after hyperbaric exposure. Hyperbaric exposure to more than one bar pressure difference can result in structure damage, implosion or loss of function of the mechanical device. The Vibrant Soundbridge® middle-ear amplifier tolerated a single hyperbaric exposure to pressures of up to 608 kPa for 78 minutes with no loss of performance.

- 140 Beleites T., Neudert M., Beutner D., Hüttenbrink K.B. & Zahnert T. (2011). Experience with Vibroplasty Couplers at the stapes head and footplate. Otol Neurotol. 32(9), 1468–1472.

Abstract:

**OBJECTIVE:** To report on experiences with implanting the Vibrant Soundbridge (VSB) coupled to the stapes head using a new Clip-Coupler or to the stapes footplate using a new OW-Coupler (Clip- or OW-Coupler Vibroplasty). **STUDY DESIGN:** Single subject, repeated measures. **SETTING:** Two university hospital ENT departments. **PATIENTS:** Fourteen German-speaking patients from 2 European study sites were implanted with either a Clip-Coupler or OW-Coupler attached to a VSB Floating Mass Transducer (FMT). They were evaluated preoperatively and postoperatively for bone and air conduction thresholds with and without the implant, as well as speech perception tests. **MAIN OUTCOME MEASURES:** Measuring the efficacy and safety of OW- and Clip-Coupler-Vibroplasty as a method to treat mixed hearing loss. **RESULTS:** Bone conduction thresholds remained stable preoperatively and postoperatively. The patients' average speech perception performances at 65/80 dB (HL) increased from 0.8/13.8% to 63/82%. The pure tone audiograms showed an average improvement in air conduction thresholds after implantation with the VSB of 25 dB at 0.5 kHz to 50 dB at 4 kHz. **CONCLUSION:** OW- or Clip-Coupler-Vibroplasty using couplers was found to be a straightforward procedure, which produced

good results in this group of patients.

- 139 Mandalà M., Colletti L. & Colletti V. (2011). Treatment of the atretic ear with Round Window Vibrant Soundbridge implantation in infants and children: Electrocotchleography and audiologic outcomes. *Otol Neurotol.* 32(8), 1250–55.

Abstract:

**OBJECTIVE:** To evaluate the long-term outcomes of the first 5 infants and 9 children with congenital aural atresia (CAA) who had undergone hearing rehabilitation using the MED-EL Vibrant Soundbridge with intraoperative assistance of electrocotchleography (ECoG) for optimal fitting of the Floating Mass Transducer (FMT) on the Round Window (RW) membrane. **STUDY DESIGN:** Tertiary referral medical center; Retrospective case series. **PATIENTS:** Infants and children ranging in age from 2 months to 16 years with a moderate-to-severe conductive or mixed hearing loss with CAA. For comparison, the study population was divided into 2 groups: older children ( $\geq 5$  yr of age; 5 patients) and younger children/infants ( $< 5$  yr of age; 9 subjects) who were submitted to different audiologic tests appropriate for their age and general condition. **INTERVENTION:** RW implantation. **MAIN OUTCOME MEASURES:** Compound action potential threshold and amplitude were assessed as a function of different methods for stabilizing the FMT on the RW. Pure tone audiogram at 0.5, 1, 2, and 4 kHz, free-field speech testing (older children), bone conduction and free-field auditory brainstem response (ABR; younger children and infants), intraoperative and postoperative complications, and FMT displacement or extrusion rate. **RESULTS:** Statistically significant differences were observed with ECoG recordings between pre- and post-FMT-RW membrane optimization with fascia and cartilage ( $p < 0.001$ ). Significant improvements were observed in speech perception and pure-tone and ABR threshold, immediately after surgery and at follow-up intervals (12–65 mo) in children and infants ( $p < 0.01$ ). No complications or instances of device extrusion were observed. **CONCLUSIONS:** Infants and children with moderate-to-severe conductive or mixed hearing loss, not suitable or unwilling to accept Bone-Anchored Hearing Aids and who would not tolerate traditional bone and air conduction hearing aids, obtain substantial benefit with the FMT-RW implantation procedure. Intraoperative ECoG is of significant help in achieving the best FMT-RW fitting.

- 138 Wang X., Hu Y., Wang Z. & Shi H. (2011). Finite element analysis of the coupling between ossicular chain and mass loading for evaluation of implantable hearing device. *Hear Res.* 280(1-2), 48–57.

Abstract:

Finite element (FE) model is used to analyze the coupling effects between ossicular chain and transducer of implantable middle-ear hearing devices. The mass loading of the transducer is attached to the long process of the incus in the form of Floating Mass Transducer (FMT) or applied near the incus-stapes joint by a magnet of contactless electromagnetic transducer (CLT). By changing placement of the transducer, crimping connection and damping parameter of the crimping mechanism, theoretical performances

of the transducers were investigated on mechanical characteristics in two aspects: (1) displacement change at the stapes footplate, which describes the change in hearing due to placement of the transducer; (2) the equivalent pressure output of the transducer, which relates the footplate displacement driven by transducer to the sound pressure applied to a normal ear to produce that displacement. For the FMT with a less tight crimping connection or low supporting rigidity, a large drop of the sound-induced stapes displacement occurs at a specific frequency, with a peak reduction about 25.8 dB. A tight connection or high supporting rigidity shifts the drop of the stapes displacement to higher frequency. For the CLT, an electromagnetic transducer of 25 mg placed near the incus-stapes joint produces a maximum decrease of the stapes displacement around 16.5 dB. The equivalent sound pressure output and electromagnetic force requirement are proposed to produce the stapes displacement equivalent to that ear canal sound stimulus. The drop of the footplate displacement caused by mass loading effect can be recovered by the transducer stimulation over frequency range from 1500 Hz to 4000 Hz. The FE analysis reveals that enhancing the coupling stiffness between the clip and the ossicular chain is much helpful for maximizing the efficiency of the transducer stimulation.

- 137 Luers J.C., Beutner D. & Hüttenbrink K.B. (2011). Implantable hearing aids. *HNO*, 59(10), 980–987.

**Abstract:**

Strictly speaking, implantable hearing aids are technical systems that process audiological signals and convey these by direct mechanical stimulation of the ossicular chain or cochlea. They have certain benefits over conventional hearing aids in terms of wearing comfort and general acceptance. As current studies lack convincing audiological results, the indications for implantable hearing aids are primarily of medical or cosmetic nature. To date, three systems are available in Germany: Vibrant Soundbridge®, Carina®, and Esteem®. Because the performance of the different implantable and nonimplantable hearing systems together with various surgical procedures are currently undergoing major changes, audiological indications may also develop in the future.

- 136 Wagner J.H., Ernst A. & Todt I. (2011). Magnet resonance imaging safety of the Vibrant Soundbridge system: A review. *Otol Neurotol.* 32(7), 1040–46.

**Abstract:**

**OBJECTIVE:** To review the current knowledge on magnetic resonance imaging (MRI) safety of the Vibrant Soundbridge (VSB) system, an implantable, active middle ear implant. **DATA SOURCES:** National Library of Medicine's online database and clinical reports. **STUDY SELECTION:** All available articles from 1995 to 2010 on MRI compatibility of the VSB and other active middle ear implants. **RESULTS:** Minor demagnetization was found for alignments of the magnets antiparallel to the magnetic field of the scanner, which played no clinically important role. In some cases, the torque forces upon MRI scanning can lead to pain and/or dislocation of the implant or dislocation of the Floating Mass Transducer (FMT) depending on its type of positioning and attachment in the middle ear. Consecutive

need of revision surgery is possible. Voltage induction may cause loud audible sounds; however, there were no reports for cochlear hearing loss. No significant heating effects upon MRI scanning were reported. Image artifacts occur especially because of the large magnet. In none of the patient or temporal bone studies, the ossicles, round or Oval Window, or other middle ear structures were injured, and there was no functional loss of the implant performance (i.e., demagnetization of the FMT). CONCLUSION: MRI examinations of up to 1.5T may be of crucial diagnostic importance to the patients implanted with a VSB, but there seems no serious risk of harm to the patient or damage to the VSB. A dislocation of the FMT can be possible during MRI, and this does depend on transducer position and the security of the transducer to the vibratory structure and the coupling mode used. The next generation of VSB systems should consider those possible changes in its design.

- 135 Todt I., Wagner J., Goetze R., Scholz S., Seidl R. & Ernst A. (2011). MRI scanning in patients implanted with a Vibrant Soundbridge. *Laryngoscope*, 121(7), 1532–35.

Abstract:

OBJECTIVE: To observe the in vivo effects of MRI scanning on the Vibrant Soundbridge system. STUDY DESIGN: Retrospective questionnaire. METHOD: Sixty-three implantees answered a retrospective questionnaire covering their medical/otological and physical conditions pre-, intra-, and post-magnetic resonance imaging scanning (MRI). Bone conduction (BC) thresholds were measured after MRI scanning and compared with the prescan BC. RESULTS: Thirteen implantees (20.6%) underwent 19 MRI scans (1; 1.5 T) for different medical indications (e.g., exclusion of a brain tumour, lumbar disc herniation etc.). Scanner-related impulse noise, pain in the middle ear, or pressure at the receiver bed, as well as changes of the transfer function of the Floating Mass Transducer (FMT) are observed frequent effects of MRI scanning. Two patients required transtympanal repositioning of the FMT. A subjectively reported or objectively documented sensorineural hearing loss was not found in any of our patients in this series. CONCLUSION: MRI scanning with an implanted Vibrant Soundbridge has possible major side effects, but did not affect cochlear function in this serie.

- 134 Sprinzl G.M., Wolf-Magele A., Schnabl J. & Koci V. (2011). The active middle ear implant for the rehabilitation of sensorineural, mixed and conductive hearing losses. *Laryngorhinootologie*. 90(9), 560–572.

Abstract:

Active middle ear implants, such as the Vibrant Soundbridge, are used as an important part in the rehabilitation of sensorineural, conductive hearing, or mixed hearing loss. The attachment of the Vibrant Soundbridge at the Round Window and the usage of the Vibroplasty couplers strongly expanded the application of the Vibrant Soundbridge. The Vibrant Soundbridge is developed for patients who have an intolerance to hearing aids and a moderate to profound sensorineural hearing loss. The VSB also provides an optimal solution for patients with failed middle ear reconstructions or patients with atresia. To

capture the improvement with the VSB Implant with different hearing losses a literature analysis was conducted. The functional gain was analyzed for 107 patients with conductive hearing loss and for 214 patients with sensorineural hearing loss out of 14 studies. Patients with conductive and mixed hearing loss resulted in a functional gain from 30 to 58 dB with the VSB. Patients with a pure sensorineural hearing loss showed a functional gain of 23-30 dB. The VSB bone conduction threshold shift was analyzed for all studies conducted in the years between 2000 and 2009. In 11 of the 16 studies there was no significant ( $p=0.05$ ) change found. In 5 studies, the pre- to post-surgical bone conduction threshold shift was less than 10 dB. None of these studies measured a threshold shift of more than 10 dB. The flexible attachment at either the long process of the incus with sensorineural hearing loss, with an conductive hearing loss at the Round Window or the use of Vibroplasty couplers at the Oval Window, head of the stapes or Round Window makes the VSB an extremely versatile instrument. If patients can't wear conventional hearing aids, had failed middle ear reconstructions or atresia the VSB presents, due to the significant hearing improvement in any type of hearing loss, an ideal solution.

- 133 Green K. (2011). The role of active middle-ear implants in the rehabilitation of hearing loss. *Expert Rev Med Devices*. 8(4), 441–447.

**Abstract:**

The surgical implantation of auditory devices to improve or restore the sensation of hearing in affected individuals is a rapidly growing area of modern ear, nose and throat, and audiological practice. Following the enormous success of cochlear implantation and set to take an increasing role in the rehabilitation of deafness is the active middle-ear implant. They should be viewed as an alternative to conventional hearing aids for individuals who are either unable to wear hearing aids or reject them for a variety of reasons. This article discusses the different types of middle-ear implant that are currently in use and examines the significant challenges that remain to be overcome to further advance this field.

- 132 Zhao S., Gong S., Han D., Chen X., Liu B., Ma X., Mo L., Liu H., Chen J. & Zhang N. (2011). Vibrant Soundbridge implantation (two cases report). *Zhonghua Er Bi Yan Hou Tou Jing Wai Ke Za Zhi*, 46(7), 576–579.

**Abstract:**

**OBJECTIVE:** To investigate the effect of Vibrant Soundbridge (VSB) implantation. **METHODS:** In accordance with the indications for VSB implantation, surgeries were done for two patients who suffered from either a sensorineural or conductive hearing loss (microtia). Their preoperative auditory thresholds (0.5, 1, 2 and 4 kHz) were 56 dB HL and 61 dB HL. The VSB was turned on and adjusted seven weeks after surgery. **RESULTS:** Postoperative auditory thresholds of the two patients were improved. Their pure tone thresholds were 32 dB HL and 40 dB HL, and the respective improvement was 24 dB HL and 21 dB HL. There was no facial paralysis, vertigo and tinnitus. **CONCLUSION:** Patients with a

sensorineural or conductive hearing loss may benefit from VSB implantation

- 131 Wolf-Magele A., Schnabl J., Woellner T., Koci V., Riechelmann H. & Sprinzl G.M. (2011). Active middle ear implantation in elderly people: A retrospective study. *Otol Neurotol.* 32(5), 805–811.

Abstract:

**OBJECTIVE:** To evaluate the outcomes of younger (<60 yr) and older ( $\geq 60$  yr) patients implanted with the Vibrant Soundbridge (VSB). The aim was to determine if there were differences between groups. **METHOD:** A retrospective study was used to evaluate all patients who were implanted and fit with a VSB during 2008 and 2009 at the Department of Otorhinolaryngology-Head and Neck Surgery, Medical University Innsbruck. Differences in audiologic, medical, and surgical outcomes between younger and older patients were evaluated. **RESULTS:** No patients had major complications during or after the surgical procedure. All patients had a good hearing benefit as supported by improvements in hearing thresholds from the preoperative to the postoperative condition in the sound field. There were differences between groups in speech understanding postoperatively; however, the differences were not statistically significant. **CONCLUSION:** All patients had, independent of age, good audiologic benefit from VSB use. Based on the low risk of medical or surgical complications, the easy use of the hearing implant, audiologic improvements, and potential social benefits, we think that the VSB should be regularly offered to adults with hearing loss, whether they are young or old.

- 130 Hüttenbrink K.B., Beutner D., Bornitz M., Luers J.C. & Zahnert T. (2011). Clip Vibroplasty: Experimental evaluation and first clinical results. *Otol Neurotol.* 32(4), 650–653.

Abstract:

**OBJECTIVE:** To describe an active auditory rehabilitation method (clip Vibroplasty) for conductive or mixed hearing loss in cases of a preserved stapes superstructure. **PATIENTS:** After temporal bone experiments, the new clip Vibroplasty was clinically used in 4 patients with chronic otitis media. **INTERVENTIONS:** A new titanium double clip device (clip Vibroplasty) was developed for a standardized and effective coupling of the Floating Mass Transducer of the Vibrant Soundbridge to the intact stapes. Temporal bone experiments using Laser Doppler Vibrometry were performed to evaluate the device's acoustic efficiency. The audiologic outcomes of the first 4 patients were analyzed. The subjective benefits and satisfaction were assessed using the standardized International Outcome Inventory for Hearing Aids in all patients. **MAIN OUTCOME MEASURES:** Transfer characteristics of laser Doppler vibrometry experiments; audiologic outcomes of the 4 patients. **RESULTS:** In the temporal bone experiment, coupling of the FMT using the titanium double clip support produced transfer characteristics across all tested frequencies comparable to our former total ossicular reconstruction prosthesis or an optimal Round Window application. The intraoperative application of the clip Vibroplasty was uneventful in all cases. No signs of prosthesis dislocation were noted within the follow-up period of approximately 12 months. The audiologic outcome of the first patients showed good

hearing gain in pure-tone and speech audiometry, with results that are unobtainable using a conventional air conduction hearing aid. CONCLUSION: The concept of a partial ossicular reconstruction prosthesis Vibroplasty using a titanium clip support entails a straightforward procedure similar to a classic partial ossicular reconstruction prosthesis tympanoplasty. The unoccluded ear canal and the superior auditory performance offer an advantageous application of this "power clip" in cases of chronic middle ear dysfunction.

- 129 Verhaert N., Fuchsmann C., Tringali S., Lina-Granade G. & Truy E. Strategies of active middle ear implants for hearing rehabilitation in congenital aural atresia. *Otol Neurotol.* 32(4), 639–645.

Abstract:

OBJECTIVE: To describe our surgical and audiometric experience using different active middle ear implant strategies facing various anatomic situations in aural atresia. STUDY DESIGN: Retrospective case review. SETTING: Tertiary academic referral center. PATIENTS: Five patients with congenital aural atresia, (3 unilateral and 2 bilateral), with mean age of 22.4 years (range, 12-44 yr), referred for hearing rehabilitation. INTERVENTION: Active middle ear implant on stapes capitulum. MAIN OUTCOME MEASURES: Description of surgical implantation with different active middle ear implants. Preoperative and postoperative air conduction, bone conduction, and aided and unaided thresholds and speech scores were measured, at mid to long term. Subjective benefit analysis was determined through the Abbreviated Profile of Hearing Aid Benefit questionnaire. RESULTS: After activation and fitting of the devices, a mean functional gain of 32.5 dB hearing level was measured. Speech tests in quiet showed a mean functional gain of 20.2 dB. Patients had a mean follow-up period of 12 months. No intraoperative or postoperative complications were noted. Furthermore, we reflected on new coupling possibilities, especially in a difficult case with stapes-footplate fixation where no approach of the Round Window was feasible because of aberrant facial nerve course.

CONCLUSION: Facing anatomic variations in congenital aural atresia, active middle ear implants can provide substantial hearing improvement in safe conditions and open new strategies for hearing rehabilitation.

- 128 Kontorinis G., Lenarz T., Mojallal H., Hinze A.L. & Schwab B. (2011). Power stapes: An alternative method for treating hearing loss in osteogenesis imperfecta? *Otol Neurotol.* 32(4), 589–595.

Abstract:

OBJECTIVE: To present power stapes, stapedotomy, and middle ear implantation with Vibrant Soundbridge (VSB) performed in a one-step surgery as an alternative option for hearing rehabilitation in patients with osteogenesis imperfecta (OI). STUDY DESIGN: Retrospective case series. SETTING: Tertiary referral ear center. PATIENTS: A family with genetically proven OI Type I. Two patients, mother and son, with severe to profound mixed hearing loss underwent 3 power stapes, 1 unilateral and 1 bilateral sequential. MAIN

**OUTCOME MEASURES:** Thorough audiological diagnostic batteries including aided and unaided pure-tone and free-field audiometry and Freiburger monosyllabic word test were used to assess the preoperative status and the postoperative hearing outcome. High-resolution computed tomography of the temporal bones was performed as well. Surgical procedure and any special considerations were analyzed in detail.

**RESULTS:** The hearing outcome was favorable in all cases, showing in comparison to the preoperative values an average improvement of 36.8 dB. Severe intraoperative bleeding of the middle ear mucosa was the only complication and could be easily controlled by allowing short time intervals. Inner ear trauma did not occur in any case.

**CONCLUSION:** Power stapes represents a safe and promising procedure for treating hearing loss in selected patients with OI. Furthermore, it introduces a new, advantageous VSB application in cases of mixed hearing loss with severe otosclerosis and increased bone-conduction thresholds.

- 127 Todt I., Rademacher G., Wagner F., Schedlbauer E., Wagner J., Basta D. & Ernst A. MRI safety of the Floating Mass Transducer. *Cochlear Implants Int.* 12(S1), S133–S135.

**Abstract:**

The goals of this study are to observe 1.5-T Magnetic Resonance Imaging (MRI)-related changes to the Vibrant Soundbridge Floating Mass Transducer (FMT) magnetization, function, and position in different coupling modes within the middle ear; changes to middle ear structures; and effects on the transfer function to the inner ear. The MRI safety of implantable hearing devices is important in daily routine clinical care as well as in urgent care. Nine FMTs were repeatedly investigated before and after MRI scanning. Changes in the position of the FMT (Round Window, incus, and stapes) and in the ossicular chain in temporal bones were estimated by microscopy, microendoscopy, and flat panel angiography. Functional investigations of the FMT in different coupling modes were done using laser Doppler vibrometry. Qualitative demagnetization could be ruled out in all specimens after up to 11 MRI scans. In FMT couplings to the long process of the incus ( $n = 18$ ), positional changes were found in 5 temporal bones. A disarticulation or exarticulation of the ossicles was not observed. Mean laser Doppler vibrometry measurements showed MRI-related changes in the stapes velocity. In FMT couplings to the Round Window ( $n = 23$ ), we observed a fixation-dependent influence of MRI scanning on the FMT position and mean transfer function. The functional integrity of the FMT was not significantly influenced after multiple MRI scans. Positional changes of the FMT within the middle ear are possible, but we observed no structural damage to middle ear structures. Effects on the transfer function are possible.

- 126 Côté M., Deguine O., Calmels M.N., Iversenc G. & Fraysse B. (2011). Baha or Medel Vibrant Soundbridge: Results and criteria of decision. *Cochlear Implants Int.* 12(S1), S130–S132.

No Abstract available

- 125 Ter Haar G., Mulder J.J., Venker-van Haagen A.J., van Sluijs F.J. & Smoorenburg G.F. (2011). A surgical technique for implantation of the Vibrant Soundbridge middle ear implant in dogs. *Vet Surg.* 40(3), 340-346.

Abstract:

OBJECTIVE: To report a surgical implantation of the Vibrant Soundbridge (VSB) middle ear implant in dogs. STUDY DESIGN: Pilot study. ANIMALS: Dogs (n=3). METHODS: A lateral approach to the tympanic bulla was used to insert the Floating Mass Transducer of the VSB into the tympanic bulla. Using microscopic guidance the transducer was moved to and inserted into the Round Window niche by manipulation through the acoustic bony meatus, after reflection of the tympanic membrane. VSB position was confirmed by computed tomography (CT) imaging. RESULTS: No intraoperative complications occurred and CT images confirmed correct placement of the VSB. CONCLUSION: A VSB can be safely implanted in the middle of dogs.

- 124 Tsang W.S., Wong T.K. & Tong M.C. (2011). Vibrant Soundbridge system: Round Window stimulation with the Vibroplasty technique. *Ear Nose Throat J.* 90(4), E39.

No Abstract available

- 123 Sziklai I. & Szilvássy J. (2011). Functional gain and speech understanding obtained by Vibrant Soundbridge or by open-fit hearing aid. *Acta Otolaryngol.* 131(4), 428-433.

Abstract:

CONCLUSION: There is no significant difference in speech recognition scores obtained with the Vibrant Soundbridge and the open-fit hearing aid. However, the Vibrant Soundbridge may be superior to open-fit hearing aids in improving hearing at high frequencies (4-8 kHz). OBJECTIVES: To assess whether an improvement in speech recognition conferred by Vibrant Soundbridge is more marked than that afforded by open-fit hearing aids in patients with sloping high frequency sensorineural hearing loss (SNHL).METHODS: This study had a self-control prospective design. Seven patients aged 21-62 years with sloping high frequency SNHL were recruited into the study. Each patient received a Vibrant Soundbridge middle ear implant (Vibrant MED-EL) and wore an open-fit hearing aid (Danavox, DOT 10). Speech recognition tests were performed according to protocols suggested by árpád Götze's speech definition test in Hungarian language. In the first session, conventional hearing thresholds (unaided pure tone thresholds) were measured. In the second session, the aided sound-field threshold, speech understanding score and functional gain obtained using middle ear implants and open-fit hearing aids were determined after programming of the devices. RESULTS: Regarding speech recognition scores, there were no significant differences between data obtained with the middle ear implant and those with the open-fit hearing aid.

- 122 Zwartekot J.W., Mulder J.J., Snik A.F. & Cremers C.W. (2011). Vibrant Soundbridge surgery in patients with severe external otitis: Complications of a transcanal approach. *Otol*

Neurotol. 32(3), 398–402.

Abstract:

OBJECTIVE: To evaluate the transcanal surgical implantation of the semi-implantable Vibrant Soundbridge (VSB) device in patients with severe external otitis. STUDY DESIGN: Retrospective analysis. METHODS: Long-term postoperative complications and postoperative hearing thresholds were evaluated in 13 adults with bilateral sensorineural hearing loss (average of between 40 and 55 dB HL) and therapy-resistant external otitis after implantation of the VSB by a transcanal surgical method. RESULTS: Postoperative audiometry findings were comparable with those reported after the transmastoidal posterior tympanotomy approach. In 2 patients, the chorda tympani was intentionally sacrificed to maximize the size of the facial recess. Seven postoperative complications occurred in 6 patients (46%) during a mean follow-up period of 51 months: extrusion of the conducting wire into the ear canal (n=5), collapse of the cartilaginous part of the ear canal (n=1), and tympanic membrane perforation (n=1). In the revision operations that added additional layers of fascia for the patients with wire extrusions, repeated extrusion occurred in 3 of 4 cases. CONCLUSION: The transcanal approach for the implantation of the VSB has led to postoperative complications different from those reported after the transmastoidal posterior tympanotomy approach.

- 121 Rajan G.P., Lampacher P., Ambett R., Dittrich G., Kuthubutheen J., Wood B., McArthur A. & Marino R. (2011). Impact of Floating Mass Transducer coupling and positioning in Round Window Vibroplasty. Otol Neurotol. 32(2), 271–277.

Abstract:

The Round Window application of the Vibrant Sound bridge, the so-called Round Window Vibroplasty, is gaining increasing popularity for hearing rehabilitation of patients with mixed hearing loss or conductive hearing loss. In these patients, conventional hearing amplification and/or surgical restoration is either not possible or has failed because of chronic ear disease, extensive otosclerosis, or malformations. The exact mechanisms of direct cochlear stimulation via the Round Window membrane are not yet completely understood. It is unclear what kind and what degree of contact is required between the Floating Mass Transducer (FMT) and the Round Window membrane (RWM) to elicit a functional hearing perception with the implant. We investigated the coupling efficiency between the FMT and the RWM and how the efficiency is altered by the FMT position, the degree of FMT-RWM contact, and the use of a soft tissue coupler. Prospective cohort study. Tertiary referral center in Western Australia. Patients undergoing Round Window Vibroplasty for a mixed or conductive hearing loss otherwise not aidable. Patients underwent Round Window Vibroplasty and received audiological and coupling analysis in the follow-up. These data were then correlated with FMT positioning and the extent of FMT-RWM interface as determined by postoperative high-resolution temporal bone computed tomography. Coupling and hearing levels in relation to FMT positioning and degree of FMT-RWM contact. Of 10 patients, 8 were available for Vibroplasty behavioral threshold testing. In 2 patients, testing could not be done because of wound breakdown

requiring device explantation in 1 case, and in the other case, the bone conduction thresholds dropped 2 months after implantation, thus falling out of the performance range of the device. Postoperative FMT migration occurred in 50% of the patients (3/6) with recurrent chronic ear disease and status after multiple previous ear operations. All patients, including the 3 patients requiring surgical repositioning of the FMT, attained significantly improved speech in quiet and speech in noise when compared with the preoperatively best aided performance. All patients showed significantly improved average Abbreviated Profile of Hearing Benefit scores with the use of the FMT. Direct (partial or complete) contact with the RWM resulted in good coupling efficiency; soft tissue coupling resulted in a reduced coupling efficiency.

- 120 Bernardeschi D., Hoffman C., Benchaâ T., Labassi S., Beliaeff M., Sterkers O. & Grayeli A.B. (2011). Functional results of Vibrant Soundbridge middle ear implants in conductive and mixed hearing losses. *Audiol Neurotol.* 16(6), 381–387.

**Abstract:**

Our purpose was to evaluate the results of Vibrant Soundbridge (VSB) in conductive or mixed hearing loss. Twenty-five adult patients (29 ears) with a mixed or conductive hearing loss and various etiologies were included in this retrospective study. The preoperative ipsilateral pure tone average was  $71 \pm 3.0$  dB, and the average bone conduction threshold was  $42 \pm 2.8$  dB ( $n = 29$ ). The transducer was placed on the long apophysis of the incus ( $n = 16$ ), in the Round Window ( $n = 10$ ) or on the stapes ( $n = 3$ ). No complications were noted. The bone conduction threshold remained unchanged. VSB was activated in all cases. The postoperative pure tone average without VSB was  $63 \pm 3.9$  dB ( $n = 24$ ) and with VSB in free-field condition  $24 \pm 2.1$  dB ( $n = 22$ ). VSB is safe and efficacious for auditory rehabilitation in conductive and mixed hearing losses.

- 119 Radeloff A., Shehata-Dieler W., Rak K., Scherzed A., Tolsdorff B., Hagen R., Mueller J. & Mlynški R. (2011). Intraoperative monitoring of active middle ear implant function in patients with normal and pathologic middle ears. *Otol Neurotol.* 32(1), 104–107.

**Abstract:**

**OBJECTIVE:** To describe a technique enabling the intraoperative assessment of the mechanical coupling of active middle ear implants in patients with normal or dysfunctional middle ears. **PATIENTS:** Patients with sensorineural or mixed hearing loss subjected to revision surgery of an active middle ear implant. **INTERVENTION:** Recording of Compound Action Potentials (CAPs) of the auditory nerve in response to stimulation via an active middle ear implant during revision surgery. **MAIN OUTCOME MEASURES:** CAP thresholds as a measure of mechanical coupling and system integrity. **CONCLUSION:** Determining CAP thresholds may be suitable for identifying a proper mechanical coupling of active middle ear implants in patients with a dysfunctional middle ear, even if the ossicular chain is disrupted.

- 118 Colletti L., Carner M., Mandalà M., Veronese S. & Colletti V. (2011). The Floating Mass Transducer for external auditory canal and middle ear malformations. *Otol Neurotol.* 32(1), 108–115.

Abstract:

The indications for the Med-El Vibrant Soundbridge, currently limited to patients with sensorineural hearing loss and normal middle ear function, have been extended to include patients with conductive or mixed hearing loss because of severe acquired or congenital ossicular chain defects. Patients with congenital aural atresia have combined malformations of the external auditory canal and the middle ear, often accompanied by severe mixed hearing impairment. Long-term results of traditional surgical techniques for treatment of congenital aural atresia show a persistent air-bone gap in most patients, suggesting that new and better techniques for hearing rehabilitation in these patients would be of value. This study demonstrates that placement of the Floating Mass Transducer of the Med-El Vibrant Soundbridge on the Round Window (RW) allows optimal amplification and enables the restoration of good hearing in these patients. Retrospective case review. Tertiary referral center. The study population comprised 12 patients-5 adults and 7 children-with severe external auditory canal and middle ear malformations. The patients were either judged not to be candidates for air conduction hearing aids or declined bone conduction and Bone-Anchored Hearing Aids. RW implantation. Pure-tone threshold and speech understanding. Significant improvements were observed in pure-tone threshold and speech understanding immediately after surgery and at follow-up intervals ranging from 12 to 48 months. No complications or instances of device extrusion were observed in these patients. The results suggest that RW implantation offers a viable and improved treatment option for patients with severe mixed hearing loss and congenital malformation of the outer and middle ear.

- 117 Shimizu Y., Puria S. & Goode, R.L. (2011). The Floating Mass Transducer on the Round Window versus attachment to an ossicular replacement prosthesis. *Otol Neurotol.* 32(1), 98–103.

Abstract:

The Vibrant Soundbridge Floating Mass Transducer (FMT) is part of a commercially available implantable hearing device in which the FMT can be placed in the Round Window (RW) niche or attached to a partial (V-PORP) or total ossicular replacement prosthesis (V-TORP) contacting the stapes head or footplate. The goal is to provide efficient transfer of sound vibration into the cochlea. The hypothesis is that the FMT location on the prosthesis is superior to the RW location. No direct comparisons of the 3 FMT sites have been performed using the same measurement location. A new measurement method called the Third Window method was used in eleven fresh human temporal bones to compare the sites. A small hole was made into the scala tympani of the temporal bones preserving the endosteum. A reflective target was placed on the Third Window endosteum and displacement of the cochlear fluid was measured using a Polytec HLV-1000 laser Doppler vibrometer. The input to the FMT at all locations was a constant 316 millivolts (mV); the

frequency range was 0.5 to 8.0 kHz. The V-PORP and V-TORP FMT locations both provided statistically significant better performance above 1.0 kHz than the RW site but not below that frequency. The V-PORP and V-TORP responses were similar at all test frequencies. In this temporal bone model, the FMT provided better higher frequency performance when attached to a PORP or TORP than in the RW niche.

- 116 Lim LH, Xiang L, Del Prado J, Ee Chin L, Beltrame MA. (2011) Simultaneous Vibrant Soundbridge Implantation and 2nd Stage Auricular Reconstruction for Microtia with Aural Atresia. *Audiol Res.* Sep 23;1(2):e28.

#### Abstract

Aural atresia and severe microtia are associated malformations that result in problems with hearing and cosmesis, associated speech and language difficulties and diminished self-esteem. In cases where middle ear ossiculoplasty and aural atresia canalplasty are expected to give poor hearing outcomes that would eventually require the use of hearing aids, bone anchored hearing aids or active middle ear implants may be better options. This case report describes a simultaneous Vibrant Soundbridge implantation and 2(nd) stage auricular reconstruction with rib graft cartilage for an 11-year-old boy with grade III microtia and aural atresia 8 months after the 1(st) stage reconstruction. Audiometric results of the Vibrant Soundbridge aided ear were comparable to that of the contralateral hearing aid aided ear.

- 115 Olze H, Zahnert T, Hesse G. (2010) Hearing aids, implantable hearing aids and cochlear implants in chronic tinnitus therapy. *HNO.* Oct; 58(10):1004-12.

#### Abstract

Chronic tinnitus can be influenced positively by plastic cortical changes of tinnitus assignment and auditory perception. Acoustic stimulation plays an important role, either through active hearing therapy or through a hearing device. The positive effect of hearing aids regarding tinnitus loudness and severity has been shown in many studies with large numbers of patients and amounts to up to 70%. Implantable hearing systems and their effect on tinnitus have not been examined sufficiently yet; there are reports about positive as well as negative effects on tinnitus perception. There is a strong indication, however, when pathological processes in the middle ear need direct coupling of the implantable hearing aid with the stapes or the round window and there is no possibility of providing a conventional hearing aid due to high-grade combined hearing loss. Cochlear implants (CI) for profoundly deaf patients influence tinnitus loudness and severity in 34-93% of the patients; the large deviation is due to inhomogeneous parameters in the studies that are not always based on validated questionnaires. Existing tinnitus, however, influences the outcome of CI patients. There are studies and discussions about the effect of CI for unilateral deafness with tinnitus.

- 114 Todt I., Rademacher G., Wagner F., Schedlbauer E., Wagner J., Basta D. & Ernst A. (2010). Magnetic resonance imaging safety of the Floating Mass Transducer. *Otol Neurotol.* 31(9),

1435–40.

**Abstract:**

The goals of this study are to observe 1.5-T magnetic resonance imaging (MRI)-related different coupling modes within the middle ear; changes to middle ear structures; and effects on the transfer function to the inner ear. The MRI safety of implantable hearing devices is important in daily routine clinical care as well as in urgent care. Nine FMTs were repeatedly investigated before and after MRI scanning. Changes in the position of the FMT (Round Window, incus, and stapes) and in the ossicular chain in temporal bones were estimated by microscopy, microendoscopy, and flat panel angiography. Functional investigations of the FMT in different coupling modes were done using laser Doppler vibrometry. Qualitative demagnetization could be ruled out in all specimens after up to 11 MRI scans. In FMT couplings to the long process of the incus ( $n = 18$ ), positional changes were found in 5 temporal bones. A disarticulation or exarticulation of the ossicles was not observed. Mean laser Doppler vibrometry measurements showed MRI-related changes in the stapes velocity. In FMT couplings to the Round Window ( $n = 23$ ), we observed a fixation-dependent influence of MRI scanning on the FMT position and mean transfer function. The functional integrity of the FMT was not significantly influenced after multiple MRI scans. Positional changes of the FMT within the middle ear are possible, but we observed no structural damage to middle ear structures. Effects on the transfer function are possible.

- 113 Verhaegen V.J., Mulder J.J., Noten J.F., Luijten B.M., Cremers C.W. & Snik A.F. (2010). Intraoperative auditory steady state response measurements during Vibrant Soundbridge middle ear implantation in patients with mixed hearing loss: Preliminary results. *Otol Neurotol.* 31(9), 1365–68.

**Abstract:**

**OBJECTIVE:** To optimize intraoperatively the coupling of the Floating Mass Transducer (FMT) of the Vibrant Soundbridge middle ear implant to the round or oval cochlear window in patients with mixed hearing loss. **STUDY DESIGN:** Intraoperative measurement of objective hearing thresholds using auditory steady state responses (ASSRs). **SETTING:** Radboud University Nijmegen Medical Centre, tertiary referral hospital. **PATIENTS:** Four individuals with mixed hearing loss and, at least no incus, in need for a middle ear implant. **INTERVENTION:** Surgical placement of the Vibrant Soundbridge. ASSR thresholds were measured intraoperatively, whereas FMT coupling to the cochlea was manipulated to find the most effective coupling of the FMT. **MAIN OUTCOME MEASURE:** Differences in ASSR thresholds between different FMT coupling options within patients. **RESULTS:** With ASSR, we assessed placement of the FMT in the Round Window niche, loosely or tightly packed in the niche; creation of a mobile window in case of a fixed stapes footplate; and FMT position coupled to the stapes that afforded vibration in the natural vibration direction or perpendicular to it. Furthermore, test-retest variations in ASSR thresholds were studied. It was shown that differences in ASSR thresholds could be detected, while manipulating the FMT couplings, which were statistically significant. **CONCLUSION:** Intraoperative ASSR

measurement is a good method to study different positions of the FMT and to determine the best position of the FMT for a patient.

- 112 Garin P., Schmerber S., Magnan J., Truy E., Uziel A., Triglia J.M., Bebear J.P., Labassi S. & Lavieille J.P. (2010). Bilateral Vibrant Soundbridge implantation: Audiologic and subjective benefits in quiet and noisy environments. *Acta Otolaryngol.* 130(12), 1370-78.

Abstract:

**CONCLUSIONS:** The results support bilateral sequential implantation for patients who are not completely satisfied after implantation of one side. **OBJECTIVE:** To evaluate the benefit of bilateral Vibrant Soundbridge middle ear implantation as compared with unilateral implantation in quiet and noisy environments. **METHODS:** This was a multicentric and retrospective study of 15 patients with symmetrical sensorineural hearing loss who were implanted sequentially in both ears. The performance of each subject was compared under three conditions: with the right implant activated, with the left implant activated, and with both implants activated. Audiometric tests were compared with self-assessment subjective evaluation by questionnaire. **RESULTS:** Both qualitative and quantitative assessments demonstrated improvement in speech intelligibility, especially in background noise, but also for low voice intensity in quiet.

- 111 Cremers C.W., O'Connor A.F., Helms J., Roberson J., Clarós P., Frenzel H., Profant M., Schmerber S., Streitberger C., Baumgartner W.D., Orfila D., Pringle M., Cenjor C., Giarbini N., Jiang D. & Snik A.F. (2010). International consensus on Vibrant Soundbridge® implantation in children and adolescents. *Int J Pediatr Otorhinolaryngol.* 74(11), 1267-69.

Abstract:

Active middle ear implants augment hearing in patients with sensorineural, conductive, and mixed hearing losses with great success. However, the application of active middle ear implants has been restricted to compromised ears in adults only. Recently, active middle ear implants have been successfully implanted in patients younger than 18 years of age with all types of hearing losses. The Vibrant Soundbridge (VSB) active middle ear implant has been implanted in more than 60 children and adolescents worldwide by the end of 2008. In October 2008, experts from the field with experience in this population met to discuss VSB implantation in patients below the age of 18. A consensus meeting was organized including a presentation session of cases from worldwide centers and a discussion session in which implantation, precautions, and alternative means of hearing augmentation were discussed. At the end of the meeting, a consensus statement was written by the participating experts. The present consensus paper describes the outcomes and medical/surgical complications: the outcomes are favourable in terms of hearing thresholds, speech intelligibility in quiet and in noise, with a low incidence of intra- and postoperative complications. Taken together, the VSB offers another viable treatment for children and adolescents with compromised hearing. However, other treatment options should also be taken into consideration. The advantages and disadvantages of all possible treatment options should be weighed against each other in the light of each individual

case to provide the best solution; counseling should include a.o. surgical issues and MRI compatibility.

- 110 Luetje C.M., Brown S.A. & Cullen R.D. (2010). Vibrant Soundbridge implantable hearing device: Critical review and single-surgeon short- and long-term results. Ear Nose Throat J. 89(9), E9–E14.

Abstract:

We conducted a retrospective descriptive study of a series of 31 consecutively presenting patients who had been implanted with the Vibrant Soundbridge middle ear hearing device. All implantations had been performed by the senior author. Three of these patients had undergone bilateral implantation, and 4 others had undergone subsequent explantation and reimplantation in response to known or suspected device failure, giving us a total of 34 ears and 38 implants. Our goal was to ascertain short- and long-term outcomes as measured by conventional audiology (pure-tone average at 1 to 6 kHz) and long-term benefit as defined by the use or nonuse of the device. We found that at the initial activation session 2 months postoperatively, the average hearing thresholds were within 3 dB of the preoperative thresholds in all 34 ears and all 38 implants. The mean short-term gain at activation in the 38 implants was 28.1 dB. Nineteen patients (20 ears) were available for long-term evaluation, with the length of follow-up ranging from less than 1 year to 11 years (mean: 7.3). Of these 20 ears, 9 demonstrated further gain (mean: 10.8 dB) despite any natural hearing deterioration; of the remaining 11 ears, gain was unchanged in 2, diminished in 7 (mean: -3.6 dB), and gain data were unavailable in 2. In the final analysis, there were 20 user ears and 10 nonuser ears; 4 ears were lost to all follow-up. We conclude that direct-drive hearing with the Vibrant Soundbridge middle ear hearing device is beneficial and provides sustained audiometric gain. Factors that have a significant impact on patient use or nonuse include difficulty in obtaining audiologic support and the direct and indirect costs of the device. Without audiologic or financial support, some patients may choose to become nonusers and to either switch to conventional hearing aid amplification or become apathetic about hearing improvement.

- 109 Kiefer J. & Staudenmaier R. (2010). Combined aesthetic and functional reconstruction of ear malformations. Adv Otorhinolaryngol. 68, 81–94.

Abstract:

Surgery for major malformations of the outer and middle ear involves aesthetic as well as functional aspects. Whereas reconstruction of the auricle with autogenous rib cartilage is well established and has shown favorable results, functional repair using classic reconstructive techniques is possible only in a limited group of patients and the outcome is often unsatisfactory. Active middle ear implants (MEI) offer a promising alternative to reconstructive surgery. Fifteen patients with ear malformations underwent implantation of an active middle ear implant (Soundbridge), with or without concomitant reconstruction of the auricle. The vibrating element, the Floating Mass Transducer (FMT), was coupled either to the Round Window, stapes, Oval Window or incus, according to each individual's

anatomical middle ear situation. Aesthetic as well as functional outcomes were evaluated. Implantation could be integrated into aesthetic reconstruction of the auricle without complications. In 14/15 patients, a satisfactory functional result could be achieved (< 30 dB pure-tone audiometry). Neither facial nerve palsy nor inner ear hearing loss was observed after implantation. The versatile form of the FMT of the Soundbridge allows for adaptation of the coupling procedure to the individual anatomical situations. Implantation of a Soundbridge MEI is a valuable option for functional reconstruction of the malformed ear, which may offer more consistent and reliable results than classic reconstructive surgery.

- 108 Mlynški R., Müller J. & Hagen R. (2010). Surgical approaches to position the Vibrant Soundbridge in conductive and mixed hearing loss. *Oper Techniq Otolaryngol.* 21, 272–277.

**Abstract:**

Although tympanoplasty yields excellent results in the treatment of infectious middle ear diseases, postsurgical rehabilitation of mixed hearing loss is a challenge for ear, nose, and throat (ENT) specialists. Radical cavities, malformations of the pinna, and auditory canals that are too wide or too narrow may preclude rehabilitation with conventional hearing aids. To achieve sufficient amplification, hearing aids must be tightly sealed in the auditory canal. Tight sealing may lead to radical cavity infections or may cause recurrent myringitis. For many patients, frequent care of the ear is required, thus significantly reducing the patient's quality of life. The Vibrant Soundbridge (VSB) is a commercially available, partially implantable hearing system classically used to treat sensorineural hearing loss. Patient satisfaction and performance with the device have been very good, as reported in numerous publications.<sup>1</sup> Several studies have proven the effectiveness and safety of the VSB in patients with conductive and mixed hearing loss.<sup>2-7</sup> The combination of tympanoplasty procedures with the implantation of a VSB has been termed "Vibroplasty." The surgical techniques to approach these cases are explained in this article.

- 107 Service G.J. & Roberson J.B. (2010). Alternative placement of the Floating Mass Transducer in implanting the med-el Vibrant Soundbridge. *Oper Techniq Otolaryngol.* 21, 194–196.

**Abstract:**

Implantable hearing devices, such as the Vibrant Soundbridge, were originally developed to be an alternative to traditional external auditory canal hearing devices. Recent modifications in surgical technique have allowed this implantable device to find a unique new niche in the treatment of mixed hearing loss. The primary design of the Vibrant Soundbridge marries a Floating Mass Transducer to the incus to deliver mechanical energy through the native conductive mechanism. Variants to this theme have been developed to address specific issues. In this work we review the alternative placements of the Floating Mass Transducer with different ossicular reconstruction configurations and placement at the Round Window.

- 106 Ball G.R. (2010). The Vibrant Soundbridge: design and development. *Adv Otorhinolaryngol.* 69, 1–13.

Abstract:

This chapter is a condensed history of the design and development of the Vibrant Soundbridge that introduces and discusses the origins of the Floating Mass Transducer and the Vibrant Soundbridge and the design philosophy that led to the invention and realization of the system. The Vibrant Soundbridge has been worked on and studied by a large group of engineers, researchers, physicians and formal advisory boards whose combined efforts have led to approval for the system as it stands today. The system and operation as well as the possible future applications for middle ear implant technology are discussed. The author also thanks the many people that have contributed to the use and increasing adoption of the Vibrant Soundbridge to date.

- 105 Snik A.F., Verhaegen V., Mulder J. & Cremers C. Cost-effectiveness of implantable middle ear hearing devices. *Adv Otorhinolaryngol.* 69, 14–19.

Abstract:

OBJECTIVE: To assess the relation between cost and effectiveness of implantable middle ear hearing devices in patients with pure sensorineural hearing loss. DESIGN: Literature review. RESULTS: Four studies were identified that described the effect of middle ear implantation on quality of life in groups of at least 20 patients. Several different quality of life questionnaires were used. CONCLUSIONS: Our review demonstrated that middle ear implantation is a cost-effective health care intervention in patients with sensorineural hearing loss who suffered an additional therapy-resistant chronic external otitis.

- 104 Wagner F., Todt I., Wagner J. & Ernst, A. (2010). Indications and candidacy for active middle ear implants. *Adv Otorhinolaryngol.* 69, 20–26.

Abstract:

Currently, there are two active middle ear implants available commercially: the Vibrant Soundbridge system and the Carina system. A third active middle ear implant, the Esteem, is under clinical evaluation. All devices are indicated for patients with moderate-to-severe hearing loss. Because active middle ear implants are directly coupled to middle ear structures, many of the problems that patients with conventional hearing aids report, such as acoustic feedback, occlusion, and irritation of the outer ear canal, are avoided. In addition, AMEIs perform well in background noise. However, indications for AMEIs are selective and candidates should be carefully evaluated before surgery. Before considering an AMEI, patients should be provided with conventional hearing aids. Only when benefit is insufficient and audiological selection criteria are met is further candidacy evaluation indicated. Since Colletti described coupling the Vibrant Soundbridge directly onto the Round Window membrane in 2006, the indications for the Vibrant Soundbridge have expanded and the VSB is implanted in patients with conductive and mixed hearing

losses. Patients have often undergone middle ear surgery before. Especially mixed hearing loss cases with 30-60 dB HL sensorineural hearing impairment and 30-40 dB HL air-bone gaps may be helped by this new application.

- 103 Hüttenbrink K.B., Beutner D. & Zahnert, T. (2010). Clinical results with an active middle ear implant in the Oval Window. *Adv Otorhinolaryngol*, 69, 27–31.

Abstract:

Some patients with chronic middle ear disease and multiple failed revisions, who also need a hearing aid, may benefit from an active middle ear implant. An advantage of an active middle ear implant is that the ear canal is unoccluded. Following extensive experimental development in temporal bones and investigations of various locations and attachments of a Vibrant Soundbridge transducer, a new titanium clip holder for the vibrant Floating Mass Transducer was developed. This assembly is a total ossicular replacement prosthesis (TORP) that is placed on the stapes footplate. Six patients were implanted with this device. Acoustic results demonstrate significantly improved gain, especially in the high frequencies, which is typically unobtainable by conventional hearing aids. The simple procedure of placing an active TORP assembly on the stapes footplate, similar to the implantation of a passive TORP prosthesis during tympanoplasty, offers promising treatment for cases of incurable middle ear disease.

- 102 Rameh C., Meller R., Lavieille J.P., Deveze A. & Magnan, J. (2010). Long-term patient satisfaction with different middle ear hearing implants in sensorineural hearing loss. *Otol Neurotol*. 31, 883–892.

Abstract:

Implantable hearing devices are a viable option for patients with moderate-to-severe sensorineural hearing loss who cannot benefit from the conventional hearing aids. In this study, we focus on the patients' satisfaction with 3 different middle ear implants, the Vibrant Soundbridge (VSB), the semiimplantable Otologics MET implant, and the fully implantable Carina implant. Between 1998 and 2008, we have implanted 112 patients with these devices. Hereby, we gathered preimplantation and postimplantation audiology data to evaluate the functional gains. To assess patient satisfaction, we have used a specific questionnaire focusing on implant dysfunction, audiologic satisfaction in different scenarios, and common daily life practical applications. Our final population included 19 semiimplantable Otologics, 10 Carina, and 45 VSB patients. Free-field functional gain and speech reception threshold improvement were undeniable for all implants. However, this was not reflected in real-life patient satisfaction. Only 20% to 42% of the patients were more satisfied with their implants compared with their contralateral conventional hearing aids. Satisfaction dropped from 70% to 90% during conversations in quiescence to 0% to 20% in crowded situations. Depending on the type of implant, 29% to 67% of patients were satisfied enough to repeat the procedure again. Audiologic results with middle ear implants are encouraging and stable on the long term, but they do not correlate with the patients' index of satisfaction. The implants have to be further improved to offer more

patient satisfaction in real-life situations, especially in noisy environments and for multimedia use.

- 101 Zahnert T., Bornitz M. & Hüttenbrink K.B. (2010). Experiments on the coupling of an active middle ear implant to the stapes footplate. *Adv Otorhinolaryngol.* 69 32–37.

Abstract:

Although the function of active middle ear implants in cases of intact ossicular chains and ventilated middle ears is well known, information about sound transfer function to the inner ear in cases of chronic middle ear effusion and defective middle ear structures is needed. A temporal bone model was developed to measure (1) the coupling of the active middle ear implant Vibrant Soundbridge in cases of nonventilated radical cavities, and (2) the effect of effusion and cartilage shielding. Three fresh human temporal bone specimens were studied. After preparation of a radical cavity, the Floating Mass Transducer was coupled to the stapes footplate. The transducer was stimulated with 50 mV multisinus signals and inner ear fluid vibration was measured using a microphone in the Round Window niche. Several coupling conditions were simulated with mass and stiffness variations and cartilage shielding. Coupling modality and prestress have the most influence on the sound transfer function to the inner ear. Cartilage shielding may ensure better coupling of the FMT to the footplate. The effect of middle ear effusion is negligible. The Vibrant Soundbridge provides good sound transfer to the inner ear not only in cases of coupling onto an intact ossicular chain in a ventilated middle ear but also in cases of coupling to the stapes footplate in non-ventilated radical cavities.

- 100 Baumgartner W.D., Böheim K., Hagen R., Müller J., Lenarz T., Reiss S., Schlögel M., Mlynški R., Mojallal H., Colletti V. & Opie J. (2010). The Vibrant Soundbridge for conductive and mixed hearing losses: European multicenter study results. *Adv Otorhinolaryngol.* 69, 38–50.

Abstract:

The Vibrant Soundbridge (VSB) is an active middle ear implant, 'direct-drive' hearing system for the treatment of hearing loss. Recently, the VSB has been applied to conductive and mixed hearing losses. The aim of this study is to evaluate aided benefit, speech recognition in quiet and noise, subjective benefits, changes in residual hearing, and medical and surgical complications in adults with conductive or mixed hearing losses implanted with the VSB using Round Window (RW) Vibroplasty. Twelve German-speaking adults participated in a single-subject, repeated measures study design comparing their performance using the VSB with their own unaided preoperative performance. Hearing performance and changes in residual hearing were assessed using routine audiometric measures, sound field thresholds, and word and sentence recognition in quiet and in noise. Subjective benefits, including subjective hearing performance, device satisfaction, and quality of life were evaluated using the Abbreviated Profile of Hearing Aid Benefit, the Hearing Device Satisfaction Scale, and the Glasgow Benefit Inventory, respectively. Aided hearing thresholds, word recognition at conversational levels, and sentence recognition in

quiet and noise were significantly improved without significant changes in residual cochlear hearing and without major medical and surgical complications. One subject required repositioning surgery to improve transducer coupling with the RW membrane. Subjective benefit and device satisfaction were good, as were overall and general quality of life. The VSB, implanted using RW Vibroplasty, is a safe and effective treatment for adults with conductive and mixed hearing losses who may have few, if any, other options.

- 99 Pennings R., Ho A., Brown J., van Wijhe R.G. & Bance M. (2010). Analysis of Vibrant Soundbridge placement against the Round Window membrane in a human cadaveric temporal bone model. *Otol Neurotol.* 31(6), 998–1003.

Abstract:

**OBJECTIVE:** To evaluate optimal placement of the Floating Mass Transducer of the Vibrant Soundbridge (Med-El, Innsbruck, Austria) against the Round Window membrane, particularly the impact of interposed coupling fascia and of covering materials. **METHOD:** Six fresh human cadaveric temporal bones were used. After mastoidectomy, posterior tympano-tomy and removal of the Round Window niche, the Floating Mass Transducer (FMT) of the Vibrant Soundbridge (VSB) was placed against the Round Window membrane (RWM) in the following ways: in direct contact, or with interposed fascia. Both conditions were combined with a second parameter: no cover over the FMT or covered with fascia, fat or cartilage. The inner ear was stimulated through the VSB with a frequency sweep from 0.1 to 8 kHz at 1 V RMS. Stapedial footplate vibrations were recorded with a PSV-400 Scanning Laser Doppler Vibrometer (Polytec, Waldbronn, Germany). **RESULTS:** A learning curve exists for optimal placement of the VSB. Sufficient removal of bone around the Round Window is essential. Without covering materials, there is increased transmission of vibrations if fascia is interposed between the RWM and the FMT. If there is no interposed fascia, vibration transmission is increased with a fascia or fat (but not cartilage) cover. There is no added advantage of cover and interposed fascia, either is as good as the other. **COCNCLUSION:** Optimal placement of the VSB against the Round Window relies heavily on surgical precision in placement. There is improved transmission of vibrations with either interposed fascia, or with a covering material.

- 98 Frenzel H., Hanke F., Beltrame M. & Wollenberg B. Application of the Vibrant Soundbridge in bilateral congenital atresia in toddlers. *Acta Otolaryngol.* 130(8), 966–970.

Abstract:

The Vibrant Soundbridge offers an excellent audiologic rehabilitation for toddlers with microtia and atresia. It provides direct stimulation of the cochlea and straightforward adaption to the given anatomical structures. The 'posterior atresia incision' preserves the physical integrity of the tissue layers around the ear remnant, which is essential for an aesthetic auricular reconstruction. Patients with bilateral aural atresia require immediate auditory stimulation to ensure normal speech development. We present an operative technique that allows safe restoration of hearing before aesthetic reconstruction. A 6-year-old boy presented with bilateral microtia and osseous atresia. A hairline incision was

performed through all layers and was followed by a subperiostal preparation towards the atresia plane. The fused malleus-incus-complex was removed and the transducer was crimped to the stapes suprastructure on both sides. Speech performance is nearly normal in both quiet and noise conditions. The surgery did not affect the tissues that are important for the later ear reconstruction.

- 97 Zehlicke T., Dahl R., Just T. & Pau HW. (2010). Vibroplasty involving direct coupling of the Floating Mass Transducer to the Oval Window niche. *J Laryngol Otol.* 124(7), 716–719.

**Abstract:**

**OBJECTIVE:** To demonstrate the technique and clinical application of Vibroplasty in which the Floating Mass Transducer component of the Vibrant Soundbridge implant is coupled directly to the Oval Window niche, in patients with a mobile stapes footplate but a malformed or destroyed stapes suprastructure. **METHOD:** The underlying concept was to create a soft tissue casing for the Floating Mass Transducer, while also firmly connecting the transducer to a small, solid cartilage 'plunger' attached to the stapes footplate. This was realised by removing almost all the cartilage from a larger piece of cartilage-perichondrium, leaving only a tiny cartilage island about half a millimeter in diameter, attached to a much wider 'blanket' of perichondrium. **RESULTS:** By coupling the Floating Mass Transducer directly to the Oval Window niche, patients' speech understanding was improved. Post-operative aided thresholds of 30-40 dB HL were achieved by all patients. **CONCLUSION:** In patients with mixed hearing loss combined with a destroyed stapes suprastructure but a mobile stapes footplate, we describe the coupling of the Floating Mass Transducer component of a Vibrant Soundbridge to the stapes footplate, as an alternative to coupling to the Round Window.

- 96 Jesacher M.O., Kiefer J., Zierhofer C. & Fauser C. (2010). Torque measurements of the ossicular chain: Implication on the MRI safety of the hearing implant Vibrant Soundbridge. *Otol Neurotol.* 31(4), 676–680.

**Abstract:**

**HYPOTHESES:** Is the human ossicular chain stable enough to withstand the torque of a Vibrant Soundbridge middle ear hearing implant in the magnetic field of a 1.5 T magnetic resonance imaging (MRI) system? **BACKGROUND:** The Vibrant Soundbridge is a semi-implantable hearing device in which a tiny electromechanical transducer, called Floating Mass Transducer (FMT), is clipped to the ossicular chain within the middle ear. The FMT contains a permanent magnet, which can generate a torque when exposed to a static magnetic field of MRI systems. Since the transducer is routinely attached to the long process of the incus, this torque could affect or even disrupt the ossicular chain. This study investigates the likelihood of a middle ear injury by an FMT in an MRI system. **METHODS:** Torque measurements were performed on 10 unpreserved human temporal bones. A brass fork was attached to the long process of the incus via a posterior tympanotomy, and a defined torque was applied by a calibrated torque meter. The torque was increased stepwise until an injury of the middle ear was observed. **RESULTS:** The mean

torque at which the middle ear was injured was 4.3 mN.m +/- 1.7 mN.m. The lowest value measured was 1.5 mN.m, and the highest was 6.5 mN.m. CONCLUSION: Even the lowest torque measured is more than 1.5 times higher than the "worst-case" torque affecting the FMT during a 1.5 T MRI examination. The torque on an FMT crimped to the long process of the incus should therefore not harm the human middle ear.

- 95 Arnold A., Kompis M., Candreia C., Pfiffner F., Häusler R. & Stieger C. (2010). The Floating Mass Transducer at the Round Window: Direct transmission or bone conduction? Hear Res. 263(1-2), 120–127.

Abstract:

The Round Window placement of a Floating Mass Transducer (FMT) is a new approach for coupling an implantable hearing system to the cochlea. We evaluated the vibration transfer to the cochlear fluids of an FMT placed at the Round Window (RWFMT) with special attention to the role of bone conduction. A posterior tympanotomy was performed on eleven ears of seven human whole head specimens. Several RWFMT setups were examined using laser Doppler vibrometry measurements at the stapes and the promontory. In three ears, the vibrations of a bone anchored hearing aid (BAHA) and an FMT fixed to the promontory (pFMT) were compared to explore the role of bone conduction. Vibration transmission to the measuring point at the stapes was best when the RWFMT was perpendicularly placed in the Round Window and underlaid with connective tissue. Fixation of the RWFMT to the Round Window exhibited significantly lower vibration transmission. Although measurable, bone conduction from the pFMT was much lower than that of the BAHA. Our results suggest that the RWFMT does not act as a small bone anchored hearing aid, but instead, acts as a direct vibratory stimulator of the Round Window membrane.

- 94 Boeheim K., Pok S.M., Schloegl M. & Filzmoser P. (2010). Active middle ear implant compared with open-fit hearing aid in sloping high-frequency sensorineural hearing loss. Otol Neurotol. 31(3), 424–429.

Abstract:

OBJECTIVE: To compare 2 open-ear hearing solutions for sloping high-frequency sensorineural hearing loss: open-fit hearing aid (HA) and active middle ear implant (AMEI). STUDY DESIGN: Within-subjects prospective design. SETTING: Tertiary referral hospital. PATIENTS AND DEVICES: Fourteen patients with sloping, high-frequency sensorineural hearing loss were recruited from 39 patients previously implanted with an AMEI and 10 agreed to participate, ranging in age from 44 to 73 years (mean, 59 yr). Patients were selected because their hearing thresholds (500-3,000 Hz) qualified them for both AMEI and open-fit HA use. All patients received a Vibrant Soundbridge (Vibrant MED-EL) for an average of 25.1 months before data collection and used their AMEI on a daily basis. The open-fit HA used in this study was the Delta 8000 (Oticon). Both study devices have been fit with the specific fitting strategies as recommended by the manufacturer. MAIN OUTCOME MEASURES: Sound-field hearing thresholds, Freiburger monosyllabic words in

quiet, speech reception thresholds for 50% correct recognition for Freiburger numbers and for Oldenburg sentences in quiet, and speech reception thresholds for 50% correct recognition for Oldenburg sentences in noise. RESULTS: Both HA and AMEI conditions showed significantly better sound-field thresholds and speech recognition on monosyllabic word and sentence tests in quiet and in noise than in the unaided condition. A comparison of aided conditions revealed that, in the AMEI-aided condition, high-frequency audibility and speech discrimination scores in quiet and in noise were significantly better than those in the open-fit HA. CONCLUSION: Both open-fit HAs and AMEIs provided audiologic benefit to patients with sloping high-frequency sensorineural hearing loss. However, despite overlapping indication criteria for the 2 devices, performance with the AMEI was significantly better for the AMEI than for the open-fit HA.

- 93 Nakajima H.H., Dong W., Olson E.S., Rosowski J.J., Ravicz M.E. & Merchant S.N. (2010). Evaluation of Round Window stimulation using the Floating Mass Transducer by intracochlear sound pressure measurements in human temporal bones. *Otol Neurotol.* 31(3), 506–511.

**Abstract:**

Round Window (RW) stimulation with a Floating Mass Transducer (FMT) can be studied experimentally and optimized to enhance auditory transduction. The FMT (MED-EL Vibrant Soundbridge) has been recently implanted in patients with refractory conductive or mixed hearing loss to stimulate the RW with varying degrees of success. The mechanics of RW stimulation with the FMT have not been studied in a systematic manner. In cadaveric human temporal bones, measurements of stapes velocity with laser vibrometry in response to FMT-RW stimulation were used to optimize FMT insertion. The effect of RW stimulation on hearing was estimated using simultaneous measurements of intracochlear pressures in both perilymphatic scalae with micro-optical pressure transducers. This enabled calculation of the differential pressure across the cochlear partition, which is directly tied to auditory transduction. The best coupling between the FMT and RW was achieved with a piece of fascia placed between the RW and the FMT, and by "bracing" the free end of the FMT against the hypotympanic wall with dental impression material. FMT-RW stimulation provided differential pressures comparable with sound-induced Oval Window stimulation greater than 1 kHz. However, less than 1 kHz, the FMT was less capable. Measurements of stapes velocity and intracochlear sound pressures in scala vestibuli and scala tympani enabled experimental evaluation of FMT stimulation of the RW. The efficacy of FMT-RW coupling was influenced significantly by technical and surgical factors, which can be optimized. This temporal bone preparation also lays the foundation for future studies to investigate multiple issues of relevance to both basic and clinical science such as RW stimulation in stapes fixation, nonaerated middle ears, and third-window lesions, and to answer basic questions regarding bone conduction.

- 92 Pok S.M., Schlägel M. & Böheim K. (2010). Clinical experience with the active middle ear implant Vibrant Soundbridge in sensorineural hearing loss. *Adv Otorhinolaryngol.* 69, 51–58.

**Abstract:**

**BACKGROUND/AIMS:** To evaluate gain at threshold level and speech recognition performance of 54 subjects with mild-to-severe symmetrical sensorineural hearing loss (SNHL) that received the active middle ear implant system Vibrant Soundbridge (VSB). **METHODS:** Pre- and postoperative assessments of hearing thresholds and monosyllabic word discrimination were performed in a homogeneous group of 54 adults who received a VSB system (VORP 502/AP 404) in an active middle ear implant (AMEI) program in a tertiary referral hospital. All subjects included in this study had mild-to-severe, predominately sloping SNHL. Gain at threshold level and speech recognition results were assessed for unaided and aided conditions using the patient's walk-in hearing aid (HA) and the VSB in a retrospective study design. **RESULTS:** A comparison of pre- and postoperative unaided air conduction thresholds revealed a mean decrease in pure tone averages of 3.9 dB (0.25-8 kHz). Gain at threshold level (unaided thresholds minus AMEI-aided thresholds) was, on average, 20.9 dB at 0.5 kHz, 20.5 dB at 1 kHz, 23.8 dB at 2 kHz, 30.2 dB at 3 kHz, 36.1 dB at 4 kHz, 37.6 dB at 6 kHz and 37.9 dB at 8 kHz. Monosyllabic word discrimination at 65 dB SPL improved from a mean of 30% in the unaided condition to 44% for the HA-aided condition ( $p<0.05$ ), with a further increase to 57% for the VSB-aided condition ( $p<0.05$ , compared to the HA). **CONCLUSION:** The AMEI system VSB can be considered as an effective rehabilitation alternative in subjects with mild-to-severe SNHL and unsatisfying benefit from conventional hearing aids.

- 91 Roman S., Nicollas R. & Triglia J.M. (2010). Middle ear implant for mixed hearing loss with malformation in a 9-year-old child. Eur Ann Otorhinolaryngol Head Neck Dis. 127(1), 11-14.

**Abstract:**

The aim was to report the results of the first case in France of pediatric auditory rehabilitation with a middle ear implant and to discuss the putative indications with this new therapeutic option in children. A prospective study over 18 months on clinical and audiometric results after a middle ear implantation with a Vibrant Med-El® implant in a 9-year-old child with mixed hearing loss. Postoperative unaided pure tone audiology (PTA) was unchanged by the surgical procedure. After 18 months of implant use, the mean PTA loss in free-field warble tone audiology was 33.75 dB and the intelligibility threshold was 30 dB. After 18 months of follow-up, the intelligibility threshold was improved by 25 dB in comparison with the preoperative results with two hearing aids. The implant worked perfectly well and the child did not show any complication during this period. The reliability of the implant and the quality of the auditory results obtained in this case and in a limited number of cases in the world make the Vibrant Med-El® a new therapeutic option in hearing loss in children with bilateral auricular atresia.

- 90 Ter Haar G., Mulder J.J., Venker-van Haagen A.J., van Sluijs F.J., Snik A.F. & Smoorenburg G.F. (2010). Treatment of age-related hearing loss in dogs with the Vibrant Soundbridge middle ear implant: Short-term results in 3 dogs. J Vet Intern Med. 24(3), 557-564.

**Abstract:**

Age-related hearing loss (ARHL), or presbycusis, is the most common form of acquired hearing loss in dogs. Middle ear implants have been used successfully in people with ARHL who cannot benefit from conventional hearing aids. Audibility improves in dogs with ARHL after implantation of the Vibrant Soundbridge (VSB) middle ear implant. Three Beagle dogs with ARHL, mean age 11.1 years. The dogs were assessed pre- and postoperatively by brainstem-evoked response audiometry (BERA), otoscopy, and computed tomography scans of the ears. A VSB middle ear implant was implanted unilaterally. Three months later the functionality of the implants was assessed by auditory steady-state responses (ASSRs), after which the dogs were euthanized for histopathological examination. The VSB was implanted successfully in all dogs. Recovery from surgery was uneventful, except for transient facial nerve paralysis in 2 dogs. ASSRs showed that hearing improved after activation of the implants with a mean of 20.7, 13, and 16.3 dB at 1, 2, and 4 kHz, respectively. The implantation procedure did not affect residual hearing (with inactive implants) as measured by BERA. Implantation of the VSB resulted in lower ASSR thresholds, but only at the higher gain settings of the audioprocessor. As in humans, a more powerful audioprocessor is required to treat sensorineural hearing loss exceeding 20 dB in dogs. A substantial improvement in patient-owner communication will have to be demonstrated in future studies before the procedure can be recommended in clinical practice.

- 89 Pau H.W. & Just T. (2010). Third Window Vibroplasty: An alternative in surgical treatment of tympanosclerotic obliteration of the Oval and Round Window niche. *Otol Neurotol.* 31(2), 225-227.

**Abstract:**

**OBJECTIVE:** To describe a new technique in surgical treatment of obliterative tympanosclerosis by applying a Floating Mass Transducer (FMT) to a Third Window. **PATIENT:** A 64-year-old woman with a severe combined hearing loss due to tympanosclerosis received a Third Window Vibroplasty. **INTERVENTION:** A mastoidectomy and a posterior tympanotomy via the large facial recess were performed. The promontory was exposed by a transcanal approach. The Third Window was performed anterior inferior to the Round Window. The membranous cochlea was left intact. The FMT was gently pushed into the perichondrium-coated cochlear window. All other surgical steps were the same as in conventional FMT application. **RESULTS:** Preliminary data of this report reveal that Vibroplasty with coupling of the FMT directly to a Third Window leads to similar audiological results compared with the conventional coupling of the FMT on the Round Window niche. **CONCLUSION:** The presented case demonstrates the applicability of a Third Window Vibroplasty in obliterative tympanosclerosis. Further studies will show if our assumption of a reduced risk for inner ear trauma is justified or not.

- 88 Arnold A., Stieger C., Candreia C., Pfiffner F. & Kompis M. (2010). Factors improving the vibration transfer of the Floating Mass Transducer at the Round Window. *Otol Neurotol.* 31(1), 122-128.

**Abstract:**

With the placement of a Floating Mass Transducer (FMT) at the Round Window, a new approach of coupling an implantable hearing system to the cochlea has been introduced. The aim of the present experimental study is to examine the influence of different ways of FMT placement at the Round Window on the vibration energy transfer to the cochlea. Experiments were performed on 8 ears of human whole head specimens. A mastoidectomy and facial recess approach were performed to access the middle ear structures. Seven different conditions were compared, that is, a perpendicular or 90-degree rotated position of the FMT in the Round Window niche, overlaid or underlaid with connective tissue or with tight fixation and disrupted ossicular chain. The FMT was stimulated electrically and the movements at the FMT, the stapes head, and the promontory were measured using laser Doppler vibrometry. Vibration transmission to the cochlear fluids was best with the FMT placed perpendicular to the Round Window membrane and underlaid with connective tissue. The energy transfer to the inner ear was up to 45 dB higher compared with tight fixation condition, where the poorest energy transfer was found. Underlaying the FMT with connective tissue improved energy transfer even for a suboptimal orientation of the FMT. The way of coupling of the FMT to the Round Window has a substantial influence on the vibration transmission. Energy transfer to the inner ear is highest with the FMT placed in the Round Window and underlaid with tissue.

- 87 Faccioli N., Barillari M., Guariglia S., Zivellonghi E., Rizzotti A., Cerini R. & Mucelli R.P. (2009). Radiation dose saving through the use of cone-beam CT in hearing-impaired patients. Radiol Med. 114(8),1308-18.

**Abstract:**

Bionic ear implants provide a solution for deafness. Patients treated with these hearing devices are often children who require close follow-up with frequent functional and radiological examinations; in particular, multislice computed tomography (MSCT). Dental volumetric cone-beam CT (CBCT) has been reported as a reliable technique for acquiring images of the temporal bone while delivering low radiation doses and containing costs. The aim of this study was to assess, in terms of radiation dose and image quality, the possibility of using CBCT as an alternative to MSCT in patients with bionic ear implants. One hundred patients (mean age 26 years, range 7-43) with Vibrant Soundbridge implants on the Round Window underwent follow-up: 85 with CBCT and 15 with MSCT. We measured the average tissue-absorbed doses during both MSCT and CBCT scans. Each scan was focused on the temporal bone with the smallest field of view and a low-dose protocol. In order to estimate image quality, we obtained data about slice thickness, high- and low-contrast resolution, uniformity and noise by using an AAPM CT performance phantom. Although the CBCT images were qualitatively inferior to those of MSCT, they were sufficiently diagnostic to allow evaluation of the position of the implants. The effective dose of MSCT was almost three times higher than that of CBCT. Owing to low radiation dose and sufficient image quality, CBCT could be considered an adequate

technique for postoperative imaging and follow-up of patients with bionic ear implants.

- 86 Bruschini L., Forli F., Giannarelli M., Bruschini P. & Berrettini S. (2009). Exclusive transcanal surgical approach for Vibrant Soundbridge implantation: Surgical and functional results. *Otol Neurotol.* 30(7), 950–955.

Abstract:

**OBJECTIVE:** An alternative transcanal surgical technique named "exclusive transcanal approach" for Vibrant Soundbridge (VSB) implantation is presented. The surgical steps and our experience in a series of 12 patients are reported. **STUDY DESIGN:** Retrospective study. **SETTING:** Tertiary referral center. University hospital. **PATIENTS:** Twelve patients, 8 women and 4 men, mean age 50 years (range, 41-71 yr), were implanted with the VSB through the exclusive transcanal approach. In 7 patients with moderate sensorineural hearing loss, the Floating Mass Transducer (FMT) was placed on the incus, whereas in 5 patients with a mixed hearing loss for chronic otitis media and/or previous middle ear surgeries, the FMT was placed on the Round Window. **INTERVENTION:** Hearing rehabilitation. **MAIN OUTCOME MEASURES:** Postoperative surgical and anatomic results. **RESULTS:** Anatomic results and functional results in patients operated with the FMT on the Round Window. **COCONLUSION:** The exclusive transcanal approach proved to be faster, simpler, and safer in comparison to the classic surgical technique through the facial recess, reducing the risk of chorda tympani and facial nerve lesions. All the patients and, in particular, those operated placing the FMT on the Round Window achieved improvements in hearing thresholds and speech perception tests from the use of the VSB. Moreover, after a mean 21-month follow-up (range, 15-32 mo), we did not observe any complication such as tympanic membrane perforations, external ear canal skin lesions, or extrusion of the coil in the external ear canal.

- 85 Canale A., Lacilla M., Perotti M., Pallavicino F., De Siena L. & Albera R. (2009). Monitored anesthesia care with target-controlled infusion in Vibroplasty. *Ann Otol Rhinol Laryngol.* 118(9), 625–629.

Abstract:

Correct positioning of a Floating Mass Transducer during middle ear implant surgery is often problematic. With the use of monitored anesthesia care (MAC), however, deep sedation is maintained during surgery, followed by conscious sedation in which the patient can respond to test questions that investigate correct device position and function. The main aim of this study was to determine whether intraoperative audiometric assessment was feasible with MAC with target-controlled infusion in Vibroplasty. An additional aim was to determine whether MAC was sufficiently comfortable for patients during the procedure. The study group comprised 8 patients who underwent Vibroplasty under sedation. Before suturing, audiometric assessment was done by stimulating the external auditory processor with pure tones at 0.5, 1,2, and 4 kHz. Blood pressure, arterial oxygen saturation level, heart rate, and end tidal carbon dioxide level were monitored during the procedure and at awakening. Audiometric assessment was successfully completed in all 8 patients. The

selected parameters indicated that no patient experienced pain or discomfort during surgery; the absence of discomfort was confirmed 1 to 2 hours after the operation by simple questioning. We found MAC to be an efficient and relatively safe technique for verifying the correct coupling of the Floating Mass Transducer with the middle ear during Vibroplasty. The patients were able to respond appropriately to questions and commands; moreover, none reported having experienced pain or discomfort during the operation.

- 84 Haynes D.S., Young J.A., Wanna G.B. & Glasscock M.E. (2009). Middle ear implantable hearing devices: an overview. *Trends Amplif.* 13(3), 206–214.

Abstract:

Hearing loss affects approximately 30 million people in the United States. It has been estimated that only approximately 20% of people with hearing loss significant enough to warrant amplification actually seek assistance for amplification. A significant interest in middle ear implants has emerged over the years to facilitate patients who are noncompliant with conventional hearing aides, do not receive significant benefit from conventional aides, or are not candidates for cochlear implants. From the initial studies in the 1930s, the technology has greatly evolved over the years with a wide array of devices and mechanisms employed in the development of implantable middle ear hearing devices. Currently, these devices are generally available in two broad categories: partially or totally implantable using either piezoelectric or electromagnetic systems. The authors present an up-to-date overview of the major implantable middle ear devices. Although the current devices are largely in their infancy, indications for middle ear implants are ever evolving as promising studies show good results. The totally implantable devices provide the user freedom from the social and practical difficulties of using conventional amplification.

- 83 Cuda D., Murri A. & Tinelli N. (2009). Piezoelectric Round Window osteoplasty for Vibrant Soundbridge implant. *Otol Neurotol.* 30(6), 782–786.

Abstract:

**OBJECTIVE:** To evaluate the Piezosurgery (PZS) ultrasonic bone dissector as an alternative to conventional drilling to implant the Vibrant Soundbridge transducer in the Round Window (RW) niche. **STUDY DESIGN:** Prospective noncontrolled study. Audiologic and surgical records analysis. **METHODS:** Eight patients with mixed hearing loss and previous unsuccessful otologic surgeries were recruited. A transcanal or transmastoid approach was used. Round Window osteoplasty was performed with the PZS device to implant the VBS Floating Mass Transducer for cochlear stimulation. **RESULTS:** The osteoplasty was performed safely with PZS, and all patients were successfully implanted. No sensorineural hearing deterioration occurred in all but 1 patient. The postoperative air conduction threshold was slightly higher than preoperatively because of minor middle ear transfer function changes. After fitting, patients continue to wear their speech processors full-time. The aided speech discrimination scores at conversational level ranged from 65 to 100%. Aided hearing threshold was 32.2 dB HL (preoperative threshold under earphones, 62.8 dB HL). One patient affected by congenital aural atresia had a posterior canalithiosis

on the operated side that was successfully treated by the repositioning maneuver.

**CONCLUSION:** The PZS device proved to be effective for RW osteoplasty; Floating Mass Transducer was successfully implanted in all patients. Audiologic results are comparable to those obtained from traditionally operated patients. Relative to conventional drilling, the PZS allows a safer osteoplasty because it does not produce any rotation or torque that reduces the risk of RW membrane injury. Although hearing was preserved in our sample, the potential inner ear risks need to be further evaluated in both experimental and clinical fields.

- 82 Stieve M., Winter M., Battmer R., Lenarz M. & Lenarz T. (2009). The influence of the coupling of actuation drivers of implantable hearing systems on the mechanics of the middle ear. *Cochlear Implants Int.* 10(3), 160–165.

**Abstract:**

We used multifrequency tympanometry to provide middle ear mechanics after implantation of different implantable hearing aids. A total of 34 patients were included in the investigation; 19 of them were fitted with the Otologics system and 15 with the MED-EL Vibrant Soundbridge system. With the Otologics recipients, measurements were made preoperatively and both two months and at least 12 months postoperatively. Measurements involving the MED-EL patients were taken at least 12 months postoperatively. For all measurements, the non-implanted contralateral side was used as a control. Preoperatively, the resonance frequency of the Otologics patients was 904.3 +/- 218.2 Hz for the implanted side and 907.1 +/- 161.8 Hz for the non-implanted side. Postoperatively, a significant increase ( $p < 0.01$ ) compared with the preoperative value and the control side was observed after two months: 1111.3 +/- 234.7 Hz, as opposed to 823.8 +/- 274.5 Hz on the contralateral side. After 12 months, the resonance point was restored to approximately the preoperatively measured values: 975 +/- 55.3 Hz (implanted side) and 901.3 +/- 207.1 (control side). The resonance frequency in the Symphonix patients, as measured after at least 12 months (on average, 35 months), was 1006.3 +/- 269.5 Hz on the non-implanted side and 900.1 +/- 249.3 Hz on the implanted side. It is apparent that the resonance frequency on the implanted side was higher than on the control side, although the difference was not significant ( $p = 0.496$ ). Monitoring following the implantation of active hearing systems is therefore recommended in order that conclusions can be drawn regarding the adequacy of the coupling of the actuation driver to the ossicular chain.

- 81 Beutner D. & Hüttnerbrink K.B. (2009). Passive and active middle ear implants. *Laryngorhinootologie*, 88(S1), S32–S47.

**Abstract:**

Besides eradication of chronic middle ear disease, the reconstruction of the sound conduction apparatus is a major goal of modern ear microsurgery. The material of choice in cases of partial ossicular replacement prosthesis is the autogenous ossicle. In the event of more extensive destruction of the ossicular chain diverse alloplastic materials, e.g.

metals, ceramics, plastics or composites are used for total reconstruction. Their specialised role in conducting sound energy within a half-open implant bed sets high demands on the biocompatibility as well as the acoustic-mechanic properties of the prosthesis. Recently, sophisticated titanium middle ear implants allowing individual adaptation to anatomical variations are widely used for this procedure. However, despite modern developments, hearing restoration with passive implants often faces its limitations due to tubal-middle-ear dysfunction. Here, implantable hearing aids, successfully used in cases of sensorineural hearing loss, offer a promising alternative. This article reviews the actual state of affairs of passive and active middle ear implants.

- 80 Streitberger C., Perotti M., Beltrame MA. & Giarbini, N. (2009). Vibrant Soundbridge for hearing restoration after chronic ear surgery. Rev Laryngol Otol Rhinol (Bord). 130(2), 83–88.

**Abstract:**

Middle ear surgery is primarily concerned with resolving the discharging pathology, in the case of chronic otitis media (COM), or with complete eradication, in case of cholesteatoma. Either of these procedures may require repeated surgeries, often resulting in severe mixed hearing impairment. A middle ear implant may be indicated in these cases instead of a hearing aid because the anatomical conditions in such cases often impede an adequate acoustic coupling. The objective of this study was to evaluate MED-EL Vibrant Soundbridge (VSB) implantation in patients with severe conductive and mixed hearing loss occurring after middle ear surgery for cholesteatoma or chronic otitis media (COM). Over a 2-years period, the VSB system was implanted in 40 patients between 35 and 81 year old (mean: 59.5). Surgery was performed with comparable technique in 3 regional hospitals in Italy: Rovereto (n=16), Meran (n=12) and Tortona (n=12). The 40 candidates for implantation had a history of 1-5 previous surgeries. Of those, 20 patients suffered from COM and 20 from cholesteatomas. The Floating Mass Transducer (FMT) of the VSB was placed and stabilized on the Round Window niche in 32 cases; alternative positioning was necessary in 8 cases. Bone conduction (BC) was tested 1 day post-operatively. At 1 month post-surgery and between 6-9 months, open-field warble tones threshold in VSB-off and VSB-on conditions and open-field speech audiometry for words in quiet were conducted. Results of BC audiometry one day post-operatively showed no significant changes in hearing. Unaided mean pure tone average (PTA4) was 82.38 dB SPL with a mean speech recognition threshold (SRT) of 94.28 dB SPL. Results obtained after a minimum of three months post-operatively were evaluated in terms of aided thresholds and functional gain. At VSB activation, the mean PTA4 was 50.63 dB SPL with a mean SRT of 61.68 dB. After 6-9 months, the group had a mean PTA4 of 47.89 dB SPL and a mean SRT of 53.33 dB SPL. Implantation of the VSB with its direct driver of the inner ear fluids appears promising for auditory rehabilitation of severe mixed hearing loss associated with sequelae of cholesteatoma surgery. Patients' results improved over time, allowing us to assume a positive effect of consolidation of the coupling related to fibrosis. Results reported here refer to 6-9 months of observation and do not provide evidence of long term stability.

- 79 Dumon T., Gratacap B., Firmin F., Vincent R., Pialoux R., Casse B. & Firmin B. (2009). Vibrant Soundbridge middle ear implant in mixed hearing loss: Indications, techniques, results. *Rev Laryngol Otol Rhinol (Bord)*. 130(2), 75–81.

Abstract:

The aim of this article is to illustrate the aetiologies of mixed hearing loss that can benefit from a Vibrant Soundbridge (VSB) middle ear implant, the techniques performed and the first results. The authors report their experience of 13 implantations in mixed hearing loss due to otosclerosis, sequelae of chronic otitis media and congenital aural atresia. The VSB implant was implanted alone or in association with another middle ear surgical procedure, on the ossicular chain or on the Round Window membrane. The average auditory gain for all patients is 32 dB for pure tone thresholds, and 25 dB for speech recognition. It results from the addition of a gain on the conductive hearing loss by direct stimulation of the inner ear, to a gain on the sensorineural hearing loss by amplification. Middle ear implants are the only hearing aids affording a gain in both the conductive and sensorineural components of mixed hearing losses.

- 78 Colletti V., Carner M. & Colletti L. (2009). TORP vs Round Window implant for hearing restoration of patients with extensive ossicular chain defect. *Acta Otolaryngol*. 129(4), 449–452.

Abstract:

Round Window Implant (RWI) with a Floating Mass Transducer (FMT) may be suggested as the first choice in hearing rehabilitation for patients with chronic otitis media (COM) and extensive destruction of the ossicular chain. To investigate the pros and cons of the total ossicular replacement prosthesis (TORP) vs the RWI in restoration of hearing in patients with COM. Thirty-eight patients with bilateral moderate to severe mixed or conductive hearing loss from COM without cholesteatoma and bilateral ossicular chain erosion (footplate residual) were alternately assigned to a titanium-TORP (T-TORP) and to RWI with the FMT of the Medel Vibrant Soundbridge (MVBS) located onto the RW niche. The therapeutic efficiency, preoperative vs postoperative air-conduction gain and speech recognition were investigated for the two groups and statistically analyzed at 36 months postoperatively. The following postoperative anatomic conditions were also evaluated for the two groups: 1) recurrence of infection, 2) retraction pocket, 3) extrusion rate, and 4) displacement of the prosthesis. Good functional results and stability at 36 months were obtained with both procedures. The extrusion rates for T-TORP were low. So far no extrusion has been observed for RWI. Hearing results were statistically much better for RWI vs T-TORP for all investigated parameters.

- 77 Tisch M. & Maier H. (2009). Semi-implantable hearing aids for sensorineural hearing loss and combined hearing loss: Experiences at the German armed forces hospital in Ulm. *HNO*, 57(3), 208–215.

**Abstract:**

In recent years semi-implantable hearing aids have become an established option in the treatment of sensorineural hearing loss. In Germany two semi-implantable systems are available, namely the MedEl Soundbridge system and the Otologics MET system, both of which are active middle ear implants. Since 1996 almost 3,500 Soundbridge systems and 300 MET systems have been implanted worldwide. The majority of patients who have received semi-implantable hearing aids consider them to be superior to conventional hearing aids in many respects. Reported benefits include improved speech intelligibility (especially in noise), better sound quality, a more natural sounding own voice and the general advantages of an open ear canal. Implantable hearing systems can be used for a wider range of indications than conventional hearing aids. They are particularly useful in the treatment of patients with high-frequency hearing loss and patients with combined hearing loss. An analysis of the hearing outcomes that have thus far been reported for all patients with a hearing implant shows an average improvement in the hearing threshold by 15 dB, which corresponds to an improvement in hearing of more than 30%. As a consequence semi-implantable hearing systems are an excellent addition to the existing range of conventional hearing aids.

- 76 Vent J., Luers J.C. & Beutner D. Half-open bony channel technique for fixation of the Vibrant Soundbridge. *Clin Otolaryngol.* 34(1), 87–88.

No abstract available

- 75 Beltrame A.M., Martini A., Prosser S., Giarbini N. & Streitberger C. (2009). Coupling the Vibrant Soundbridge to cochlea Round Window: auditory results in patients with mixed hearing loss. *Otol Neurotol.* 30(2), 194–201.

**Abstract:**

**OBJECTIVE:** To assess the functional results of the Vibrant Soundbridge (VBS) placed on the Round Window (RW) in patients with mixed hearing loss. **STUDY DESIGN:** Retrospective evaluation of functional hearing, with measurements performed 7 to 9 months postoperatively. **SETTING:** Two tertiary referral hospital centers. **SUBJECTS:** Twelve individuals with mixed severe hearing loss associated with chronic suppurative otitis media and otosclerosis. **INTERVENTION:** Surgical placement of the VBS mechanical effector in close contact with the RW membrane to directly drive the inner ear fluids. **MAIN OUTCOME MEASUREMENT:** Functional hearing gain as analyzed via pure-tone audiometry and speech audiometry with VBS off and on in quiet and in noise. **RESULTS:** We observed a mean gain of 37.5 dB (0.5–4 kHz) with wide individual differences. The overall gain is mainly due to the air-bone gap recovery, whereas a further 12-dB mean improvement of air-conducted threshold is evident at 2 kHz. The speech reception threshold in quiet shows a mean gain of 24 dB, whereas in noise, it requires a signal-to-noise ratio 7 to 13 dB greater than normal-hearing controls. All patients are daily users of their VBS device. **CONCLUSION:** A middle ear implant capable of directly driving the cochlear fluids seems to be a promising alternative for individuals with a severe to profound mixed hearing loss. However,

variability in hearing recovery is great, likely reflecting variability in responsiveness of the cochlea associated with chronic pathologic findings and, possibly, variability in how the VBS effector interfaces with the RW. Modifying the shape of the VBS effector can improve the mechanical coupling to the RW to better exploit the device's amplification power.

- 74 Frenzel H., Hanke F., Beltrame M., Steffen A., Schönweiler R. & Wollenberg B. (2009). Application of the Vibrant Soundbridge to unilateral osseous atresia cases. *Laryngoscope*, 119(1), 67–74.

**Abstract:**

Patients with high-grade atresia-microtia suffer from a combined malformation of the outer and middle ears, typically leading to a severe hearing impairment. Long-term results of middle ear reconstruction with tympanoplasty are often insufficient due to persistent air-bone gaps, and new techniques in hearing rehabilitation are required. The objective of this research is to evaluate the active middle ear implant, the Vibrant Soundbridge (VSB), for hearing rehabilitation of patients with unilateral osseous aural atresia. Prospective analysis of a consecutive cohort of seven atresia patients (mean age = 15 years). During plastic auricular reconstruction of unilateral atresia-microtia cases, an access through the bony atresia plate was drilled. The Floating Mass Transducer was coupled to the stapes (or remaining stapes suprastructure), ossicular chain, or Round Window, depending on the anatomic needs of the patient. Audiometric testing, including pure-tone thresholds, and speech testing in quiet and noise were performed. The mean threshold with the VSB activated in the free field warble tone audiometry was 23.8 dB hearing level (HL). Mean functional gain was 45.5 dB HL. Mean aided free field speech discrimination in quiet was 64% at 50 dB, 99% at 65 dB, and 100% at 80 dB. By circumventing the malformed middle ear and directly stimulating the cochlea, the VSB provides a new rehabilitation option for atresia patients. We conclude that the procedure is safe and effective and can be implemented in combination with outer ear reconstruction.

- 73 Linder T., Schlegel C., DeMin N. & van der Westhuizen S. (2009). Active middle ear implants in patients undergoing subtotal petrosectomy: New application for the Vibrant Soundbridge device and its implication for lateral cranium base surgery. *Otol Neurotol.* 30(1), 41–47.

**Abstract:**

The functional outcome of ossiculoplasties in chronic ear and lateral cranium base surgery depends on the presence of a ventilated middle ear space and is guided by the existence or absence of ossicular remnants. In patients with poorly ventilated middle ears, after multiple previous operations, missing stapes suprastructure, or after partial temporal bone resection for tumor removal, restoration of conductive hearing is not possible. The direct placement of a vibrating Floating Mass Transducer (FMT) onto the Round Window membrane with obliteration of the surgical cavity is a new option. Starting in January 2006, five patients underwent a subtotal petrosectomy to control their chronically discharging ear, to remove residual cholesteatoma, or to revise previous incompletely

exenterated cavities. Four patients underwent a simultaneous placement of a Vibrant Soundbridge (VSB) onto the Round Window membrane; one patient had a staged reconstruction after initial Bone-Anchored Hearing Aid rehabilitation. In all operations, the external ear canal and the eustachian tube were closed, and the cavity was obliterated using abdominal fat. Preoperative and postoperative pure tone audiograms were analyzed in respect to deterioration of inner ear function, aided and unaided (hearing aid, VSB, and Bone-Anchored Hearing Aid) speech audiograms were compared to verify improvements in communication skills, functional gains were calculated at comfortable level settings, and postoperative computed tomographic scans were used to exclude recurrent disease and to confirm the position of the FMT onto the Round Window membrane. Patient's satisfaction was measured using a standardized questionnaire. All patients were very satisfied daily users of their middle ear implant and had complete eradication of their middle ear pathology. Bone conduction worsened at 2 kHz, with preservation of inner ear function in the other frequencies. Whereas none of the patients had any unaided speech discrimination before the surgery at conversational levels, all patients obtained 95 to 100% correct monosyllabic scores at 70 to 80 dB using the VSB. The functional gain was highest at higher frequencies. Patients with combined hearing loss undergoing subtotal petrosectomy with complete fat obliteration of the middle ear and mastoid area can be safely rehabilitated, placing the FMT of a VSB onto the Round Window membrane, either at the time of primary surgery, or as a staged secondary procedure.

- 72 Cremers C.W., Verhaegen V.J. & Snik A.F. (2009). The Floating Mass Transducer of the Vibrant Soundbridge interposed between the stapes and tympanic membrane after incus necrosis. *Otol Neurotol.* 30(1), 76–78.

**Abstract:**

The Floating Mass Transducer (FMT) of the Vibrant Soundbridge (VSB) can be interposed in the middle ear in case of an absent incus. The VSB is a middle ear implant in which the FMT is attached to the long process of the incus to directly drive the ossicular chain. In this case report, there was gradual deterioration in speech perception after VSB fitting and deterioration in hearing thresholds. During exploratory resurgery, it became clear that the ossicular chain was interrupted due to necrosis of the long process of the incus. The VSB could no longer function because there was no connection between the incus and stapes. Reconnection of the FMT to the anterior crus of the stapes on 1 side and the tympanic membrane on the other side. Reconnection of the FMT to the stapes head led to obvious improvement in audiometric results. The air-bone gap was reduced from approximately 35 to approximately 25 dB, which indicated that the construction with the FMT was working like a partial ossicular replacement prosthesis. At 1.5 years' follow-up, the aided hearing thresholds of approximately 45 dB hearing level were slightly poorer than those measured after the first procedure with classical positioning of the FMT. However, the speech recognition score in quiet at 65 dB sound pressure level was 70% with the classical FMT application and with the FMT connected between the stapes and tympanic membrane. It could be concluded that when the incus is absent, placement of the FMT directly on to the stapes is an acceptable solution.

- 71 Cenjor Español C., Morera Pérez C. & Ramos Macías A. (2008). How middle-ear implants work. *Acta Otorrinolaringol Esp.* 59 (S1), 7–9.

Abstract:

Middle-ear implants consist of a microphone, an audioprocessor, a battery, a receiver and a transducer. Transducers can be classified in three groups: piezoelectric, electromagnetic, and electromechanical. The middle ear transducer (MET) system (Otologics) is composed of an outer part that uses a multichannel digital acoustic signal processing system that transforms this acoustic signal into an electromagnetic stimulus. This system has fully implantable devices. The Vibrant Med El Soundbridge uses an electromagnetic design in which a Floating Mass Transducer is crimped around the long process of the incus by a titanium strap, transmitting vibration to the ossicular chain.

- 70 Ramos Macías A. (2008). Surgical implantation of the med-el Vibrant Soundbridge. *Acta Otorrinolaringol Esp.* 59 (S1), 17–20.

Abstract:

Surgical implantation of the Med-El Vibrant Soundbridge is, in the initial phases, similar to that of other otologic processes but differs in certain aspects that should be known. The surgical steps are as follows: incision, mastoidectomy, posterior tympanotomy, preparation of the implant bed, and placement of the device. The present article also describes the surgical procedure for placement of the device in the Round Window.

- 69 Manrique R. M., Girón L. & Huarte Irujo A. (2008). Active middle-ear implants. *Acta Otorrinolaringol Esp.* 59 (S1), 10–13.

Abstract:

Active middle ear implants are classified as piezoelectric implants, which use the properties of piezoelectric materials. There are two types of piezoelectric implants: monomorphic and dimorphic; electromagnetic transduction uses a magnet, usually a rare earth magnet (e.g. samarium cobalt) and an energizing coil. This magnetic field causes the magnet to vibrate, which in turn, through the tympanic-ossicular chain, causes movement of the cochlear fluids. Electromechanical transduction is a variation of electro-magnetic transduction.

- 68 Olgun L., Balaban M., Özüer M.Z., Gültekin G. & Uckan B. (2008). Round Window Application of Implantable Hearing Aids in Radical Cavities. *Med J Otol.* 4(3), 191–196.

Abstract:

INTRODUCTION: Electromagnetic middle ear implants which had been originally used in patients with high frequency hearing losses with normal middle ear conductive mechanism, recently were begun to be used on patients with defective or absent ossicles.

Round window application of transducer of electromagnetic implant, first used by Colletti seems to be promising in such patients. OBJECTIVES: In this study indications and a modified technique of round window attachment of an electromagnetic implant (Vibrant Sound Bridge) are presented, and results obtained on 5 patients are discussed. MATERIALS AND METHODS: All patients had been implanted at Izmir Teaching and Research Hospital on 2007 - 2008. All cases were formerly operated in various centers because of cholesteatoma and all but one found to be free of residual or recurrent cholesteatoma during surgery. In all cases floating mass transducer has been applied onto the round window membrane in a perichondrial envelope. Patients were switched on 4-6 weeks after surgery. RESULTS: Pre-op AC levels were between 65-85 db (median 69.3) and BC levels were between 10.1-60db (median 33.7). SDS scores were between 46-95 % (median 77.3) In all patients we have not seen any deterioration in these values after surgery. After switch on hearing thresholds with implant were elevated near to BC levels. SDS scores were considerably better in all patients (median 83) after surgery.

- 67 Osaki Y., Sasaki T., Kondoh K., Iwaki T. & Kubo T. Implantation of a vibratory mass transducer on the Round Window: A report of two cases. Nihon Jibiinkoka Gakkai Kaiho, 111(10), 668-671.

Abstract:

The Vibrant Soundbridge (VSB, Med-El, Austria) is a semiimplantable hearing aid usually attached to the long process of the incus to vibrate the ossicular chain in patients with moderate to severe mixed hearing loss. We implanted a VSB vibratory transducer on the Round Window membrane of the left ear in two cases not treated effectively by tympanoplasty surgeries. Pure tone audiography did not differ significantly in the two cases pre- or postoperatively, indicating that the small mass transducer does not adversely affect middle-ear vibration. Postoperative hearing thresholds with VSBs were similar to those when patient 1 wore an air-conductive hearing aid and patient 2 wore a bone-anchored hearing aid (BAHA). VSB implantation on the Round Window could thus potentially benefit many patients with mixed hearing loss.

- 66 Hüttenbrink K.B., Zahnert T., Bornitz M. & Beutner D. (2008). Torp-Vibroplasty: A new alternative for the chronically disabled middle ear. Otol Neurotol. 29(7), 965-971.

Abstract:

Surgery can often eradicate chronic middle ear disease in patients with recurrent cholesteatoma, tubal dysfunction, and others; however, in many cases, social hearing cannot be restored even after multiple revision tympanoplasties. A hearing aid is then recommended. Placement of an implantable hearing aid with its advantage of an unoccluded ear canal, irrespective of middle ear function, seems to be a promising alternative. After establishing the biomechanics of the ear in our temporal bone laboratory, various locations and attachments of a Vibrant transducer were investigated. These experiments resulted in the development of a new titanium clip holder for a Vibrant integrated total ossicular replacement prosthesis assembly with placement on the

footplate. Four patients with permanent severe combined hearing loss were implanted with this device after multiple revision tympanoplasties. The first case is described in detail. Placing a transducer directly on the footplate via a rod transmission gave a better gain for the high frequencies than in the Round Window location. The acoustic results of the patients showed an improved gain in speech understanding, unobtainable by a conventional hearing aid. The concept of a total ossicular replacement prosthesis-Vibroplasty establishes a straightforward procedure in the tympanic cavity similar to a normal tympanoplasty. The open ear canal and its superior acoustic performance offer a promising perspective for revision operations in cases of incurable middle ear dysfunction.

- 65 Skarzynski H., Obrycka A., Piotrowska A. & Lorens A. (2008). Application of the middle ear implant in case of high frequency hearing loss-case study. *Otolaryngol Pol.* 62(5), 606–612.

**Abstract:**

People who suffer from hearing impairment complain mainly of a problem with communication. Wearing hearing aids can often compensate some problems related with moderate to severe sensorineural hearing loss. Many of hearing aids users complain of some problems associated with plugging the ear canal, such as feedback, unpleasant sound while eating, unnatural sound of their own voice, physical discomfort. The alternative method for some group of patients with sensorineural loss is the middle ear implant. In the middle ear implant the sound is converted into mechanical vibrations that directly drive the ossicular chain inside the middle ear. It leaves the ear canal open and ear drum undisturbed. The sound quality is improved and residual hearing is preserved. Additionally feedback is reduced while comfort improved. 53-year-old man with bilateral sensorineural hearing loss (mild at low frequencies up to 1000 Hz in combination with severe degree at high frequencies) was implanted with Vibrant Soundbridge system. Tests of speech comprehension in quiet were performed using monosyllabic word lists. Improvement in patients score was observed while testing with Vibrant Soundbridge. Patient also reports significant improvement in subjective assessment. Application of the Floating Mass Transducer for sound processing results in significant improvement in sound quality. Results obtained indicate a high level of benefits with the Vibrant Soundbridge.

- 64 Verhaegen V.J., Mylanus E.A., Cremers C.W., & Snik A.F. (2008). Audiological application criteria for implantable hearing aid devices: A clinical experience at the Nijmegen Orl Clinic. *Laryngoscope*, 118(9), 1645–49.

**Abstract:**

**OBJECTIVE:** To define audiological application criteria for different implantable hearing aid devices.

**STUDY DESIGN:** Retrospective study.

**METHODS:** Comparisons were made between aided speech recognition scores obtained at

conversational level (65 dB) in patients with the Vibrant Soundbridge (VSB) ( $n = 22$ ), the Otologics middle ear transducer (MET) ( $n = 10$ ), conventional hearing aids (behind-the-ears) ( $n = 47$ ), and cochlear implants (CIs) ( $n = 123$ ).

**RESULTS:** In relation to hearing loss, only for mild hearing loss, speech recognition scores with VSB were comparable to that with conventional hearing aids. In the Otologics MET users, speech recognition scores were comparable with those of the conventional hearing aid users until a mean hearing loss of about 75 dB HL. At a sensorineural hearing loss of about 65 dB HL or more, the Otologics MET users have better speech recognition scores than the VSB users. For comparison with CI users, we followed a more conservative approach. In 90% of the users of a CI, speech recognition scores were better than those in: 1) patients with a conventional hearing aid and a mean hearing loss of about 95 dB HL or worse; 2) patients with an Otologics MET and a mean hearing loss of 85 dB HL or worse.

**CONCLUSION:** Patients fitted with a VSB or an Otologics MET middle ear implant do not demonstrate better speech recognition scores than patients fitted with today's conventional hearing aids. Results might even be worse. However, the VSB and Otologics MET are a good option in patients with moderate (VSB) to severe (Otologics MET) sensorineural hearing loss and external otitis.

- 63 Truy E., Philibert B., Vesson J.F., Labassi S. & Collet L. (2008). Vibrant Soundbridge versus conventional hearing aid in sensorineural high-frequency hearing loss: a prospective study. *Otol Neurotol.* 29(5), 684–687.

**Abstract:**

The present study was aimed to compare gain and speech intelligibility measured in quiet and in noise between the Signia hearing aid and the Vibrant Soundbridge (VSB), both devices using the same sound processing technology. A prospective longitudinal study was performed. Six patients with a steeply sloping high-frequency hearing loss were selected. The protocol comprised 3 months' hearing aid use, VSB implantation, and 3 months' VSB use. Patient performances were evaluated unaided and aided by audiology assessments, including free-field thresholds and word recognition tasks in quiet and in noise. Statistical analysis revealed a slight decrease in overall frequencies in pure-tone audiometry after surgery; however, this decrease did not exceed 5 dB and was not different from the changes that occurred in the contralateral non implanted ear. The measures of aided and unaided hearing thresholds showed statistically significant larger gains with the VSB than with the hearing aid. In quiet, speech performances were poorer unaided than with either device. Because of ceiling effects, statistically significant higher scores with the VSB than with the hearing aid were only observed at the lowest intensity level. In noise, speech intelligibility was reported to be better with the VSB compared with both unaided and with the hearing aid at 5 signal-to-noise ratios. This prospective study demonstrated that direct-drive stimulation provided by the VSB allows better speech performances than acoustic stimulation for rehabilitation of patients with steeply sloping high-frequency

hearing losses.

- 62 Mosnier I., Sterkers O., Bouccara D., Labassi S., Bebear J.P., Bordure P., Dubreuil C., Dumon T., Frachet B., Fraysse B., Lavieille J.P., Magnan J., Martin C., Meyer B., Mondain M., Portmann D., Robier A., Schmerber S., Thomassin J.M., Truy E., Uziel A., Vanecloo F.M., Vincent C. & Ferry E. (2008). Benefit of the Vibrant Soundbridge device in patients implanted for 5 to 8 years. *Ear Hear.* 29(2), 281–284.

Abstract:

**OBJECTIVES:** To assess audiological performance, satisfaction rate, and side effects of 100 patients who have been using the middle ear implant Vibrant Soundbridge (VSB) for 5 to 8 yr when compared with data collected from 3 to 18 mo postsurgery.

**DESIGN:** Audiological testing and subjective evaluation using self-assessment scales were performed in 77 out of the 100 patients using the VSB for 5 to 8 years. The results were compared to data collected 3 months (audiological testing) and 18 months (self-assessment scales) after surgery. Twenty-three patients have not been evaluated for different reported reasons.

**RESULTS:** Pure-tone hearing thresholds decreased similarly in both implanted and contralateral ears. The satisfaction ratings and the functional gain provided by the VSB remained stable. Speech comprehension in quiet conditions without the VSB decreased from 56 to 37% in 5 to 8 yr, but an 81% score was achieved with the VSB.

**CONCLUSION:** This study demonstrates that the performance of the VSB does not deteriorate for more than 5 yr, without adverse effect. These results confirm the safety and the effectiveness of the VSB with a long-term follow-up.

- 61 Cerini R., Faccioli N., Barillari M., De Iorio M., Carner M., Colletti V. & Pozzi Mucelli R. (2008). Bionic ear imaging. *Radiol Med.* 113(2), 265–277.

Abstract:

The aim of this study was to illustrate the different imaging features of middle and inner ear implants, brainstem implants and inferior colliculus implants. We retrospectively reviewed the computed tomography (CT) images of 468 patients with congenital or acquired transmissive or neurosensory hearing loss who underwent surgery. The implants examined were: 22 Vibrant Soundbridge implants, 5 at the long limb of the incus and 17 at the Round Window, 350 cochlear implants, 95 brainstem implants and 1 implant at the inferior colliculus. All patients underwent a postoperative CT scan (single or multislice scanner) and/or a Dentomaxillofacial cone-beam CT scan (CBCT) (axial and multiplanar reconstruction), and/or a plain-film radiography to visualise the correct position of the implant. The CBCT scan depicts Vibrant site of implant better than plain-film radiography, with a lower radiation dose compared to CT. For cochlear implants, a single plain radiograph in the Stenvers projection can directly visualise the electrodes in the cochlea.

All patients with brainstem or inferior colliculus implants underwent postoperative CT to exclude complications and to assess correct implantation, but the follow-up of these implants can be performed by plain radiography alone. CT and CBCT scans are reliable and relatively fast methods for precisely determining the location of middle ear implants. CBCT is preferable to CT because of the lower radiation dose administered; a single plain-film radiograph is enough to visualise and follow-up cochlear, brainstem and inferior colliculus implants.

- 60 Arauz L., Mercandino E., Arauz A. & Campo E. (2007). Vibrant Soundbridge-ubicación en Ventana Oval utilizando prótesis ad-hoc. Otolaringológica, XXIX, 10–14.

Abstract:

The Vibrant Soundbridge (VSB) device is a vibratory system which generates the necessary energy to transmit the sound waves to the inner ear, with the adequate amplification to compensate the patient's hearing loss. The device started being applied in sensorineural hearing losses, being adjusted by clip to the large process of the incus. Afterwards Dr. Colletti developed a technique for the application of the VSB in the Round Window, extending criteria to mixed and conductive hearing losses. This paper has the aim to show a new prosthesis to adapt the VSB to the Oval Window niche, intending that the mechanical energy travel through its natural pathway.

- 59 Batman C., Sari M., Baylancicek S. & Yumusakhuylu A.C. (2007). First use of the Vibrant Soundbridge middle ear implant in Turkish patients: A Report of 2 cases. The Mediterranean J Otol. 3, 167-172.

No abstract available

- 58 Böheim K., Nahler A. & Schlägel M. (2007). Rehabilitation of high frequency hearing loss: use of an active middle ear implant. HNO, 55(9), 690–695.

Abstract:

In spite of modern technology conventional hearing aids are only helpful in a limited number of patients with sensorineural hearing loss. In particular, patients presenting with moderate to severe high frequency hearing loss but only mild hearing loss in the low frequencies suffer from problems associated with conventional hearing aids such as occlusion of the ear canal and feedback. The aim of the study was the evaluation of rehabilitation of patients with high frequency hearing loss with the active middle ear implant Vibrant Soundbridge. The Vibrant Soundbridge was surgically implanted into 30 patients, and the Floating Mass Transducer was clipped onto the long process of the incus. Out of the 30 patients 9 presented with a ski slope audiogram of high frequency hearing loss of 25 dB within 1 octave in the frequency range 1000-8000 Hz. Main outcome measures were pure tone audiometry, speech audiometry in quiet and in noise. Residual hearing was preserved in all cases. Functional hearing gain was in proportion to the individual hearing losses and was remarkably high in the high frequencies up to 8000 Hz.

Mean functional gain was 34 dB in the frequencies between 2000-8000 Hz. Speech recognition scores in quiet and in noise were significantly higher with the implant compared to the unaided situation. The middle ear implant Vibrant Soundbridge has been shown to perform extremely well especially in the high frequencies. It offers a new solution for rehabilitation of high frequency hearing loss.

- 57 Foyt D., Steiniger E. & Rende S. (2007). Bone island tunnel for cochlear and Vibrant Soundbridge implantation. *Laryngoscope*, 117(8), 1395–96.

No abstract available

- 56 Snik A.F., van Duijnhoven N.T., Mulder J.J. & Cremers C.W. (2007). Evaluation of the subjective effect of middle ear implantation in hearing-impaired patients with severe external otitis. *J Am Acad Audiol.* 18(6), 496–503.

Abstract:

The subjective benefit of middle ear implantation was studied in a group of 23 hearing-impaired patients who could not use conventional hearing aids owing to severe chronic external otitis. Changes in hearing disability (Abbreviated Profile of Hearing Aid Benefit [APHAB]) and changes in quality of life (Glasgow Benefit Inventory [GBI]) were determined. Mean benefit value on the APHAB for the subscale Ease of Communication was close to the mean reference value for conventional hearing aids. For the subscales Reverberation and Background Noise, a poorer result was found. Individual analysis of the APHAB scores showed significant benefit in 12 out of the 23 patients. According to the GBI, 16 out of 17 patients reported that middle ear implantation had made a positive impact on their quality of life. It is concluded that middle ear implantation has a positive effect on hearing difficulties and quality of life in hearing-impaired subjects who cannot use conventional devices. The APHAB outcomes were not better than those reported for conventional devices.

- 55 Wollenberg B., Beltrame M., Schönweiler R., Gehrking E., Nitsch S., Steffen A. & Frenzel H. (2007). Integration of the active middle ear implant Vibrant Soundbridge in total auricular reconstruction. *HNO*, 55(5), 349–356.

Abstract:

Patients with high-grade microtia and atresia require a sophisticated and specific treatment. Apart from the plastic reconstruction of the auricle, in some cases hearing rehabilitation is medically indicated or is desired by the patients. The long-term results of simultaneous middle ear reconstruction with tympanoplasty are often inadequate owing to a persisting air-bone gap, and new techniques in hearing rehabilitation are needed for these patients. We present three cases of unilateral atresia to illustrate a combined approach integrating hearing rehabilitation using the active middle ear implant Vibrant Soundbridge (VSB) into plastic auricular reconstruction. The VSB was attached to the stapes suprastructure via the titanium clip in two of these cases and in the third case a

subfacial approach was used to attach it directly to the membrane of the Round Window. The air-bone gap was reduced to 17 dB, 14 dB and 0.25 dB HL. In free-field speech recognition tests at 65 dB SPL the patients achieved 100%, 90% and 100% recognition with the activated implant. No postoperative complications such as facial nerve paresis, vertigo or inner ear damage were found. The integration of active middle ear implants in auricular reconstruction opens up a new approach in complete hearing rehabilitation. The additional implantation of the VSB does not have any negative effect on the healing process or the cosmetic outcome of the auricular reconstruction.

- 54 Offergeld C., Kromeier J., Aschendorff A., Maier W., Klenzner T., Beleites T., Zahnert T., Schipper J. & Laszig R. (2007). Rotational tomography of the normal and reconstructed middle ear in temporal bones: An experimental study. *Eur Arch Otorhinolaryngol.* 264(4), 345–351.

Abstract:

Imaging is an essential diagnostic tool in reconstructive middle ear surgery, especially in pre-operative planning. Due to ongoing improvement of imaging quality and development of new imaging techniques like e.g. rotational tomography (RT) post-operative follow-up and immediate evaluation of surgical results may become more important. The aim of this experimental study was to evaluate RT as a new tool for postoperative determination of middle ear anatomy and implant position in temporal bones. RT was performed in ten temporal bone specimen after insertion of different middle ear prostheses concerning material, shape and length (PORP; TORP; Stapes piston). An implantable hearing device (Symphonix Soundbridge) was also implanted and visualized. For comparison some specimen additionally underwent conventional computed tomography (CT), including the newest technology. Characterization of anatomical structures of the temporal bone using RT was of comparable quality to conventional CT-scans in all investigated specimen while requiring approximately 30% of the CT's irradiation exposure. Unlike CT the RT showed almost no problems due to metallic artefacts of the implanted prostheses. Furthermore RT enabled a 3-dimensional view of the temporal bone and angle determination of inserted prostheses towards the tympanic membrane and/or the malleus handle. Detailed imaging of the prostheses allowed determination of shape, material and localization within the specimen's reconstructed middle ear. The new imaging technique of RT allows precise presentation of anatomical structures and middle ear implants in temporal bones. Following these experimental results it will be our future work to evaluate this method in clinical practise.

- 53 Venail F., Lavieille J.P., Meller R., Deveze A., Tardivet L. & Magnan J. (2007). New perspectives for middle ear implants: first results in otosclerosis with mixed hearing loss. *Laryngoscope*, 117(3), 552–555.

Abstract:

Middle ear implantation is an efficient procedure to restore moderate to severe sensorineural hearing loss (HL) in selected patients. Implantation of such devices requires

ossicular chain integrity. Patients suffering from otosclerosis with mixed HL should be eligible for this treatment after stapes surgery with air-bone gap closure. To address this issue, we report four cases of middle ear implantation after or during stapes surgery. Results and complications obtained with Vibrant Soundbridge, MedEl and Middle Ear Transducer, Otologics are reported. Audiologic results were similar to those obtained in cases of sensorineural HL. One case of postoperative labyrinthitis was observed.

- 52 Dumon T. (2007). Vibrant Soundbridge middle ear implant in otosclerosis: technique - indication. *Adv Otorhinolaryngol.* 65, 320–322.

Abstract:

With our growing experience with the Vibrant Soundbridge (VSB) middle ear implant, the question emerged of its indication in mixed hearing loss due to advanced otosclerosis. We describe the VSB implantation technique in primary otosclerosis performed together with a stapedotomy piston procedure. Hearing results under headphone and free-field conditions show that the stapedotomy piston procedure closes the air-bone gap as expected and that the VSB provides comparable gain to that usually recorded for pure sensorineural hearing loss. The gains of the two procedures add up. These results open the field of mixed hearing loss to the VSB middle ear implant.

- 51 Steiger C., Bernhard H., Waeckerlin D., Kompis M., Burger J. & Haeusler R. (2007). Human temporal bones versus mechanical model to evaluate three middle ear transducers. *J Rehabil Res Dev.* 44(3), 407–415.

Abstract:

A life-size mechanical middle ear model and human temporal bones were used to evaluate three different middle ear transducers for implantable hearing aids: the driving rod transducer (DRT), the Floating Mass Transducer (FMT) or vibrant sound bridge, and the contactless transducer (CLT). Results of the experiments with the mechanical model were within the range of the results for human temporal bones. However, results with the mechanical model showed better reproducibility. The handling of the mechanical model was considerably simpler and less time-consuming. Systematic variations of mounting parameters showed that the angle of the rod has virtually no effect on the output of the DRT, the mass loading on the cable of the FMT has a larger impact on the output than does the tightness of crimping, and the output level of the CLT can be increased by 10 dB by optimizing the mounting parameters.

- 50 Huber A.M., Ball G.R., Veraguth D., Dillier N., Bodmer D. & Sequeira D. (2006). A new implantable middle ear hearing device for mixed hearing loss: A feasibility study in human temporal bones. *Otol Neurotol.* 27(8), 1104–09.

Abstract:

HYPOTHESES: To assess the feasibility of a new, active middle ear device in temporal

bones (TB).

**BACKGROUND:** This device is designed for patients with mixed hearing loss subsequent to chronic middle ear infection, surgery, or trauma. This Bell-Vibroplasty is built from a VIBRANT MED-EL Vibrant Soundbridge and a Kurz Bell titanium partial ossicular replacement prosthesis.

**METHODS:** In three fresh TBs, healthy and reconstructed middle ears were analyzed by means of laser Doppler interferometry. The sound transmission properties of a partial ossicular replacement prosthesis and a passive and an active Bell-Vibroplasty were compared with healthy middle ear function.

**RESULTS:** The measurements provided reliable results with small standard deviations and good signal-to-noise ratios. The performance levels of the partial ossicular replacement prosthesis and of the passive Bell-Vibroplasty were comparable with that of healthy middle ear function. The activated Bell-Vibroplasty provided linear function and a flat frequency response within the measured frequency range (500 Hz-8 kHz), with peak deviations of less than 10 dB. The maximum output of the Bell-Vibroplasty was equivalent to 125-dB sound pressure level.

**CONCLUSION:** Bell-Vibroplasty is feasible in TBs. Bell-Vibroplasty performance in TBs is sufficient to allow for a clinical trial as a next step.

- 49 Snik A.F., van Duijnhoven N.T., Mylanus E.A. & Cremers C.W. (2006). Estimated cost-effectiveness of active middle-ear implantation in hearing-impaired patients with severe external otitis. *Arch Otolaryngol Head Neck Surg.* 132(11), 1210-15.

**Abstract:**

**OBJECTIVE:** To determine the cost-effectiveness of middle-ear implantations in hearing-impaired patients with severe external otitis in the Netherlands.

**DESIGN:** Cost-effectiveness analysis, using single-subject repeated measures of quality of life and total cost determinations.

**SETTING:** Hospital based. Patients Moderately to severely sensorineurally hearing-impaired patients ( $n = 21$ ) with severe chronic external otitis, eligible to receive a middle-ear implant. Main Outcome Measure Cost per quality-adjusted life-year (QALY), based on scores of the Medical Outcomes Study Short-Form Health Survey (SF-36) generic quality of life questionnaire. Only direct costs were included in cost calculation of middle-ear implantation.

**RESULTS:** Mean health utility gain was 0.046 (0.012-0.079) ( $P = .01$ ) measured at the mental component of the SF-36. With a mean profitable time of 19.4 years and an overall cost of euro 14,354, minimal cost-effectiveness of middle-ear implantation was euro

16,085/QALY.

**CONCLUSION:** Based on the cost per QALY, middle-ear implantation proved to be a cost-effective and justified health care intervention in the Netherlands.

- 48 Kiefer J., Arnold W. & Staudenmaier R. (2006). Round Window stimulation with an implantable hearing aid (Soundbridge) combined with autogenous reconstruction of the auricle - A new approach. ORL J Otorhinolaryngol Relat Spec. 68(6), 378-385.

**Abstract:**

Congenital malformations of the auricle are often combined with atresia of the outer ear canal and malformations of the ossicles, representing aesthetic as well as functional deficits. Optimal treatment should therefore address both aspects equally. This report describes a new approach, combining the reconstruction of the auricle with implantation of an active middle ear hearing aid, stimulating the Round Window membrane. A 33-year-old male patient, with bilateral ear microtia, fibrous atresia of the external ear canals and malformation of the ossicles due to Treacher Collins-Franceschetti syndrome was included in the study. In stage one, the cartilage framework of the new auricle, made of autogenous rib cartilage, was fabricated and implanted. During stage two, the auricle was elevated, a retro-auricular sulcus was formed and a Vibrant MED-EL Soundbridge device was implanted. The transducer was coupled to the Round Window membrane. Both functional and aesthetical results were favourable. Aided thresholds were between 15 and 30 dB in the frequency range of 0.75-6 kHz, monosyllabic word understanding at 65 dB SPL increased from 0 to 80%. Combining aesthetic and functional rehabilitation, autogenous reconstruction of a new auricle together with the implantation of an active middle ear hearing aid, coupled to the Round Window membrane, is a promising new approach.

- 47 Colletti V., Soli S.D., Carner M. & Colletti L. (2006). Treatment of mixed hearing losses via implantation of a vibratory transducer on the Round Window. Int J Audiol, 45(10), 600-608.

**Abstract:**

Early clinical findings are reported for subjects implanted with the Vibrant Med-El Soundbridge (VSB) device. The present criteria for the VSB, limiting its application to patients with normal middle ear function, have been extended to include patients with ossicular chain defects. Seven patients with severe mixed hearing loss were implanted with the transducer placed onto the Round Window. All had undergone previous surgery: six had multiple ossiculoplasties, and one had the VSB crimped on the incus with unsuccessful results. Round Window implantation bypasses the normal conductive path and provides amplified input to the cochlea. Post-operative aided thresholds of 30 dB HL were achieved for most subjects, as compared with unaided thresholds ranging from 60-80 dB HL. Aided speech reception thresholds at 50% intelligibility were 50 dB HL, with most subjects reaching 100% intelligibility at conversational levels, while unaided

thresholds averaged 80 dB HL, with only one subject reaching 100% intelligibility. These results suggest that Round Window implantation may offer a viable treatment option for individuals with severe mixed hearing losses who have undergone unsuccessful ossiculoplasties.

- 46 Truy E., Eshraghi A.A., Balkany T.J., Telishi F.F., Van De Water T.R. & Lavieille J.P. (2006). Vibrant Soundbridge surgery: Evaluation of transcanal surgical approaches. *Otol Neurotol.* 27(6), 887–895.

**Abstract:**

Since its introduction, surgery for the placement of the Vibrant Soundbridge (VSB) device has been performed using a facial recess approach. Because of the size of the VSB device, this approach requires a large facial recess that can lead to complications, i.e., facial palsy and/or taste disturbance. The purpose of this study is to develop and compare transcanal surgical approaches for leading the VSB into the middle ear. Cadaver temporal bones in a university temporal bone laboratory. First, two experienced senior surgeons validated the three possible approaches in human temporal bone: 1) the classical facial recess approach; 2) a small mastoidectomy, elevation of a tympanomeatal flap, small atticotomy, 0.5-mm cutting of the bony external auditory canal (EAC) from the cortical plane on its approximately two-thirds to three-fourths and then a trough to pass the electrode array into the middle ear; and 3) similar to the second approach but with replacing the cutting of the bony EAC with a tunnel from the mastoid cavity to the EAC. Both the second and third approaches were transcanal. Next, five residents and six attending surgeons performed the three operations and evaluate these different approaches by using analog visual scales (VAS) for each procedure. They assess the following: 1) the ease of passing the electrode array and the Floating Mass Transducer (FMT) into the middle ear, 2) the ease for FMT clipping, and 3) their self-confidence using each approach. Time required for the three operations was measured. Measurements of landmarks were obtained on all temporal bones. Two patient cases illustrate the clinical application of this new surgical approach. The two transcanal approaches were assessed to be easier, faster, and safer methods for VSB surgery than the classic facial recess approach. VSB surgery has been performed using a facial recess approach with risk for facial nerve and taste disturbance. Transcanal approaches are good alternative for this surgery. Three major limitations are to be assessed in future patient studies: the pathologic findings of the EAC, the design of the FMT regarding the axis of the ossicular chain, the long-term evaluation of the skin of the external ear canal.

- 45 Schmuziger N., Schimmann F., àWengen D., Patscheke J. & Probst R. (2006). Long-term assessment after implantation of the Vibrant Soundbridge device. *Otol Neurotol.* 27(2), 183–188.

**Abstract:**

**OBJECTIVE:** To present long-term results with a semi-implantable middle ear implant, the

Vibrant Soundbridge (VSB), and analyze pre- and post-operative results of audiology tests.

**STUDY DESIGN:** Retrospective chart review with additional patient interview and audiology testing. **SETTING:** One tertiary referral center. **SUBJECTS:** Twenty patients who met the selection criteria of the manufacturer were evaluated at least two years after implantation.

**INTERVENTIONS:** Monaural Implantation of the VSB in 20 patients, in two of these 20 patients implantation of the second ear in a second stage.

**RESULTS:** Assessment of benefit and satisfaction using the standardized International Outcome Inventory for Hearing Aids, the Glasgow Benefit Inventory, and Visual Analogue Scales in all patients. Fifteen patients agreed to undergo audiology testing at follow-up including pure-tone- and speech audiometry in silence and noise. The majority of patients (13/20) reported to be satisfied or very satisfied with the VSB. Aided speech perception was comparable between the VSB and the hearing aid preoperatively. When compared to the preoperative audiograms, residual hearing from 0.5-4 kHz was significantly worse in the operated ear with 8 dB (Wilcoxon signed rank test  $p < 0.001$ ) but only 2.6 dB in the non-operated ear (Wilcoxon signed rank test,  $p > 0.05$ ). Major surgical complications did not occur. Permanent alteration in taste occurred in three patients and revision surgery was necessary in another three patients.

**CONCLUSION:** Satisfaction with the VSB was not superior to conventional hearing aids in subjective and in audiometric terms. Because of its impact on residual hearing and the requirement of implantation middle ear surgery, implantation of the VSB should be limited to patients with relevant side effects of hearing aids, e.g., severe chronic otitis externa.

- 44 Foyt D. & Carfara M. (2006). Minimal access surgery for the Symphonix/Med-El Vibrant Soundbridge middle ear hearing implant. *Otol Neurotol.* 27(2), 167-171.

#### Abstract:

**OBJECTIVE:** To develop a minimal access approach for implantation of the Vibrant Soundbridge middle ear hearing implant. This approach ideally uses the smallest skin incision possible, minimal or no hair shave, and the least possible amount of tissue and bone manipulation. This will facilitate the acceptability of the procedure to the general community and reduce the flap-related complication rate. The procedure is similar to the minimal access approach described for cochlear implantation.

**STUDY DESIGN:** Eight patients with various degrees of sensorineural hearing loss and one with a mixed hearing loss who met implant criteria for the Vibrant Soundbridge middle ear hearing implant received the device over a 42-month period. The first two patients underwent the traditional implant procedure with postauricular hair shave, postauricular S-shaped incision, and implant receiver suture fixation to the temporal bone. The following seven consecutive patients received a progressively smaller C-shaped postauricular skin incision, no hair shave, retrograde skull drilling for the implant seat, and no implant suture

fixation until the technique closely approximated the minimal access cochlear implant procedure. Postoperative performance of the Soundbridge/Vibrant Med-El was evaluated through audiology testing and subjective patient reports.

SETTING: Private neurotology clinic and tertiary care teaching hospital.

RESULTS: The technique was feasible in all patients. Follow-up for the minimal access group ranged from 3 years to 5 months. There were no complications related to the approach, and all patients were satisfied users of the implant. The lack of hair shave and small incision size was greatly appreciated and warmly endorsed by the patients.

CONCLUSION: The Vibrant Soundbridge/Vibrant Med-El can be safely implanted using the minimal access method that has been popularized for cochlear implant surgery. A large incision, extensive hair shave, risk of flap necrosis, and possibility of unsightly scar may deter patients from pursuing the potential benefits of implanted hearing technology. The technique may make the device more accessible to individuals who have concerns regarding cosmetics and potential flap complications.

- 43 Labassi S. & Beliaeff M. Retrospective of 1000 patients implanted with a Vibrant Soundbridge middle-ear implant. *Cochlear Implants Int.* 6(S1), 74–77.

No abstract available

- 42 Garin P., Debay M. & Galle C. (2005). Hearing in noise with the Vibrant Soundbridge middle-ear implant. *Cochlear Implants Int.* 6(S1), 72–74.

No abstract available

- 41 Todt I., Seidl R.O. & Ernst A. (2005). Hearing benefit of patients after Vibrant Soundbridge implantation. *ORL J Otorhinolaryngol Relat Spec*, 67(4), 203–206.

Abstract:

The present paper compares the audiometric results of different digital Vibrant Soundbridge audio processors (D and Signia) of patients with mild to severe sensorineural hearing loss. In a retrospective study, the audiometric results were evaluated and compared in terms of functional gain of warble tone measurements and speech audiometric data. 23 patients implanted between 1998 and 2003 with the Vibrant Soundbridge were included. At the time of implantation, they fulfilled the indication criteria for an implantation (7 patients with a D type, 16 with a Signia type while 3 patients changed from the D to the Signia type). The mean functional gain was increased from 22.8 dB (+/-6.5 dB SD) in the D type to 29.8 dB (+/-2.9) in the Signia type group. The speech-in-noise understanding was better in the Signia compared to the D type (59.3 +/- 11.5 dB and 65.7 +/- 10.1 dB, respectively). The latest upgrade of the external processor from the 3-channel, digital D type to the 8-channel, digital Signia type led in our data to

an auditory benefit in all patients.

- 40 Saliba I., Calmels M.N., Wanna G., Iversenc G., James C., Deguine O. & Fraysse B. (2005). Binaurality in middle ear implant recipients using contralateral digital hearing aids. *Otol Neurotol.* 26(4), 680-685.

**Abstract:**

For some patients, conventional hearing aids might have disadvantages that clearly limit the benefit of using them. The middle ear implant, Vibrant Soundbridge hearing prosthesis offers an approach to help such patients. Our study's objective was to identify the binaurality in a well-fitted digital hearing aid worn in the contralateral ear in recipients experienced with use of the Vibrant Soundbridge middle ear implant device. In a prospective study, warble-tone thresholds and stereophony were evaluated for the following conditions: (1) binaural unaided-with the middle ear implant inactive and the behind-the-ear hearing aid removed; (2) middle ear implant alone-middle ear implant active, behind-the-ear hearing aid removed; (3) middle ear implant plus behind-the-ear omnidirectional-middle ear implant active, behind-the-ear active; and (4) behind-the-ear omnidirectional alone-middle ear implant inactive, behind-the-ear omnidirectional active. Behind-the-ear omnidirectional and behind-the-ear is defined as the behind-the-ear active in the omnidirectional or directional response, respectively. Behind-the-ear is a contralateral digital hearing aid to the middle ear implant. Benefits such as improved sound detection, speech perception in quiet and in noise, and sound quality were investigated. The evaluation of subjective hearing benefit was based on the Abbreviated Profile of Hearing Aid Benefit (APHAB) test. Paired t tests (subject) were used to analyze the differences between mean thresholds for the different test conditions. Tertiary referral center. Eight adults (aged 45-68 yr) had undergone implantation with a single Vibrant Soundbridge at least 12 months before starting the study. These eight subjects presented no contraindication for contralateral hearing aid use. Patients were fitted 5 weeks before testing with a Siemens Signia digital behind-the-ear hearing aid in the side contralateral to the Vibrant Soundbridge. Five weeks after use of the contralateral hearing aid together with the middle ear implant, mean differences in warble-tone thresholds between Conditions 2 and 3 and between Conditions 3 and 4 were both statistically significant. The mean differences in speech reception thresholds were in line with the mean differences in average warble-tone thresholds. The mean speech reception threshold for the middle ear implant plus behind-the-ear omnidirectional condition was slightly worse (3 dB) than that for the middle ear implant alone condition; however, this difference was not statistically significant. Whereas speech reception threshold difference between Condition 1 and Condition 4 was not statistically significant (60 dB and 61 dB, respectively). The mean difference for the 0-degree azimuth alone was statistically significant ( $p < 0.05$ ) for the conditions middle ear implant alone and middle ear implant plus behind-the-ear omnidirectional. The middle ear implant alone appears to give good sensitivity at 2 kHz for any direction. Increasing scores indicate greater percentages of problems. Percentages of problems were on average lower for the middle ear implant when used with the contralateral digital hearing aid based on the global score. The use of

a middle ear implant Vibrant Soundbridge together with a contralateral digital hearing aid improved functional gain and speech perception thresholds in quiet, especially for the sound coming from the front of the patient. The use of a middle ear implant together with a contralateral digital hearing did not significantly improve hearing in noise.

- 39 Needham A.J., Jiang D., Bibas A., Jeronimidis G. & O'Connor A.F. (2005). The effects of mass loading the ossicles with a Floating Mass Transducer on middle ear transfer function. *Otol Neurotol.* 26(2), 218–224.

**Abstract:**

The aim of this study was to measure the mass loading effect of an active middle-ear implant (the Vibrant Soundbridge) in cadaver temporal bones. Implantable middle ear hearing devices such as Vibrant Soundbridge have been used as an alternative to conventional hearing aids for the rehabilitation of sensorineural hearing loss. Other than the obvious disadvantage of requiring implantation middle ear surgery, it also applies a direct weight on the ossicular chain which, in turn, may have an impact on residual hearing. Previous studies have shown that applying a mass directly on the ossicular chain has a damping effect on its response to sound. However, little has been done to investigate the magnitude and the frequency characteristics of the mass loading effect in devices such as the Vibrant Soundbridge. Five fresh cadaver temporal bones were used. The stapes displacement was measured using laser Doppler vibrometry before and after the placement of a Vibrant Soundbridge Floating Mass Transducer. The effects of mass and attachment site were compared with the unloaded response. Measurements were obtained at frequencies between 0.1 and 10 kHz and at acoustic input levels of 100 dB sound pressure level. Each temporal bone acted as its own control. Placement of the Floating Mass Transducer caused a reduction of the stapes displacement. There were variations between the bones. The change of the stapes displacement varied from 0 dB to 28 dB. The effect was more prominent at frequencies above 1,000 Hz. Placing the Floating Mass Transducer close to the incudostapedial joint reduced the mass loading effect. The Floating Mass Transducer produces a measurable reduction of the stapes displacement in the temporal bone model. The effect is more prominent at high frequencies.

- 38 à Wengen, D.F. (2004). [Implantable middle ear hearing aids]. *Therapeutische Umschau. Revue therapeutique* 61, 47-52.

**Abstract not available.**

- 37 Jiang D., Bibas A. & O'Connor A.F. (2004). Minimally invasive approach and fixation of cochlear and middle ear implants. *Clin Otolaryngol Allied Sci.* 29(6), 618–620.

**Abstract:**

One of the conventional surgical approaches for cochlear implantation is a retro-auricular incision with a posterior-inferiorly based skin and subcutaneous tissue flap and a superiorly based periosteal flap. The obvious advantage is an open operating field but the

disadvantages are a large wound and a lengthy operating time. It may also result in more wound-related complications. To overcome these disadvantages, we have developed a minimally invasive technique that includes a small retro-auricular single layer incision. We have used a metal bridge beneath the posterior flap to increase accessibility when creating a recess for the implant. A novel technique is used to place the securing suture deep to the flap. This technique has been used in 49 paediatric and adult patients, and there have been no wound-related complications. Although this technique was initially designed for the CLARION CII implant, it has been used to place and secure the new CLARION HiRes 90 K, the Nucleus device, the MEDEL device and the Vibrant Soundbridge.

- 36 Todt I., Seidl R.O., Mutze S. & Ernst A. (2004). MRI scanning and incus fixation in Vibrant Soundbridge implantation. *Otol Neurotol.* 25(6), 969–972.

Abstract:

Presentation of patient data after Vibrant Sound-bridge (VS) implantation/explantation with respect to magnetic resonance imaging (MRI) compatibility and stability of incus fixation of the implant. In a retrospective case review, we report on two patients who had to be diagnosed by cranial MRI scans after previous implantation of a VS. Moreover, in one of these cases, the incus was removed after explantation of the VS because of a peripheral hearing loss. This enabled a microscopic evaluation of the incus. At the long process of the incus, the floating mass transmitter (FMT) has been fixed for 4 years. Tertiary referral center. Two patients who fulfilled, at the time of implantation, the criteria for implantation of a VS. In both cases, no demagnetization of the external magnet nor of the FMT were found. Device function after the MRI scans were normal. Pure-tone audiometric thresholds remained unchanged after the MRI scanning and the scanning-related magnetic forces. In both cases, the FMT fixation of the incus was found to be regular. In one case, the fixation was checked by an additional tympanoscopy 1 year after the implantation, and in the other case it was assessed by recording the functional gain of the VS (which was normal) after the MRI scanning. One patient complained about a transient hyperacusis due to the loudness during the MRI scanning procedure. MRI scans showed a blackening of the implant area with spherical distortions of the picture. Although MRI scanning (at 1.5 tesla [T]) with the FMT in place did not lead to adverse effects in the two patients, systematic in vitro studies are required to determine a possible magnetization threshold that could impair the VS function when MRI scans are applied in those patients. The microscopically observed erosions of the long process of the incus after 4 years of FMT clamp fixation show similarities to findings after stapes revision surgery. However, this limited experience in one case does not allow us to make conclusions on the long-term stability of the incus fixation.

- 35 Vincent C., Fraysse B., Lavieille J-P., Truy E. Sterkers O. & Vaneecloo F.M. (2004). A longitudinal study on postoperative hearing thresholds with the Vibrant Soundbridge device. *Eur Arch Otorhinolaryngol.* 261(9), 493–496.

Abstract:

The Vibrant Soundbridge is a semi-implantable middle ear hearing device used in the rehabilitation of adults with sensorineural hearing loss. In order to evaluate the long-term effects of the implanted part of the device, audiological data from 39 patients implanted over several implant sites across France were collected and analyzed retrospectively. The mean follow-up time was 16 months; 25 patients had a follow-up period of over 1 year. Surgery was uneventful in all cases. The present study of the 39 implanted patients with a mid- to long-term follow-up found a statistically significant modification of hearing thresholds (pre- versus postoperative) for frequencies of 0.5 and 4 kHz. However, the shift of threshold was rather limited (2.79 and 3.34 dB, respectively), and this variation was not statistically different from the evolution of the opposite non-operated ear.

- 34 Langevin S. (2004). Surdité, neurosensorielle: Les implants d'oreille moyenne. Cahier Biomédical. 165, 25–30.

No abstract available

- 33 Snik A., Noten J. & Cremers C. (2004). Gain and maximum output of two electromagnetic middle ear implants: Are real ear measurements helpful? *J Am Acad Audiol.* 15(3), 249–257.

Abstract:

We compared the output of two electronic middle ear implants: the Otologics MET device and the Vibrant Soundbridge device. Both devices were programmed in the linear amplification mode. Aided minus unaided sound pressure levels recorded in the ear canal (objective gain) were compared to unaided minus aided soundfield thresholds (functional gain) in 13 patients with severe sensorineural hearing loss. In addition, input/output characteristics were studied with the help of ear canal measurements. Objective gain was consistently lower than functional gain, with wide variation between patients and frequencies. Using input/output data measured in the ear canal in combination with functional gain data, the mean maximum output of the two devices was estimated, expressed in dB SPL. In comparison to NAL-R target values, (functional) gain was adequate; however, the maximum output was low, especially for the Vibrant Soundbridge device.

- 32 Snik A. & Cremers C. (2004). Audiometric evaluation of an attempt to optimize the fixation of the transducer of a middle-ear implant to the ossicular chain with bone cement. *Clin Otolaryngol Allied Sci.* 29(1), 5–9.

Abstract:

Typically, an implantable hearing device consists of a transducer that is coupled to the ossicular chain and electronics. The coupling is of major importance. The Vibrant Soundbridge (VSB) is such an implantable device; normally, the VSB transducer is fixed to the ossicular chain by means of a special clip that is crimped around the long process of the incus. In addition to crimping, bone cement was used to optimize the fixation in six

patients. Long-term results were compared to those of five controls with crimp fixation alone. To assess the effect of bone cement (SerenoCem, Corinthian Medical Ltd, Nottingham, UK) on hearing thresholds, long-term post-surgery thresholds were compared to pre-surgery thresholds. Bone cement did not have any negative effect. Next, to test the hypothesis that aided thresholds might be better with the use of bone cement, aided thresholds were studied. After correction for the severity of hearing loss, only a small difference was found between the two groups at one frequency, viz. 2 kHz. It was concluded that there was no negative effect of using bone cement; however, there is also no reason to use bone cement in VSB users on a regular basis.

- 31 Uziel A., Mondain M., Hagen P., Dejean F. & Doucet G. (2003). Rehabilitation for high-frequency sensorineural hearing impairment in adults with the symphonix Vibrant Soundbridge: A comparative study. *Otol Neurotol.* 24(5), 775–783.

**Abstract:**

To assess and compare the benefits for patients with high-frequency hearing loss obtained from an implantable middle ear implant, the Symphonix Vibrant Soundbridge using the SIGNIA processing circuitry, to those derived from conventional amplification using the same integrated circuitry and to those derived from a variety of preoperatively worn hearing aids. A single-subject, repeated-measures study design was used for a comparative evaluation of the benefits derived from the Symphonix Vibrant Soundbridge and conventional amplification. Objective audiometric measures were performed postoperatively to compare the Symphonix Vibrant Soundbridge (404) and SIGNIA hearing aid, both using the SIGNIA processing chip. Tests were performed under three conditions: unaided, aided Symphonix Vibrant Soundbridge (404), and aided SIGNIA hearing aid. Subjective self-assessment scales, standardized and nonstandardized, were completed for the Symphonix Vibrant Soundbridge (404) and the preoperative hearing aid to compare the personally perceived benefits. Statistical comparison of the data sets with each device type was performed using the nonparametric Wilcoxon test. One tertiary teaching hospital and one hearing aid specialist fitting office. Six patients displaying a high-frequency hearing loss who had the Symphonix Vibrant Soundbridge implanted for an average of 17 months. Rehabilitative. Aided thresholds with the Symphonix Vibrant Soundbridge (404) and the SIGNIA hearing aid showed no significant difference. Speech comprehension scores in quiet and in noise were significantly improved with each device type over the unaided condition scores. Individual performance on speech test measures was equivalent or superior with the Symphonix Vibrant Soundbridge (404) in comparison with that with the SIGNIA hearing aid. When using the Symphonix Vibrant Soundbridge (404) in quiet, the group achieved 50% speech comprehension at significantly softer presentation levels ( $p = 0.027$ ) than when wearing the SIGNIA hearing aid. Similarly, in noise, 50% speech comprehension was achieved at significantly lower (more difficult) signal-to-noise ratios ( $p = 0.028$ ) with the Symphonix Vibrant Soundbridge (404) than with the SIGNIA hearing aid. The level of satisfaction for various aspects of the device and performance and listening ease, particularly in the presence of aversive sounds and in reverberant conditions, was reported as significantly better with the Symphonix Vibrant Soundbridge (404) than with

the preoperative hearing aid. Despite similar gain with each device type using the same SIGNIA processing technology, the patient group demonstrated significant advantages for speech comprehension in quiet and in noise when using the Symphonix Vibrant Soundbridge (404). Such an effect may be attributed to higher fidelity sound transmission by means of the direct-drive mechanism used by the implant. Subjective reports support the results from the objective assessments, both being in favor of the implant over conventional amplification. In conclusion, the Symphonix Vibrant Soundbridge (404) is a suitable treatment option offering advantages over conventional amplification to the hearing-impaired person with a high-frequency hearing loss.

- 30 Sterkers O., Boucarra D., Labassi S., Bebear J.P., Dubreuil C., Frachet B., Fraysse B., Lavieille J.P., Magnan J., Martin C., Truy E., Uziel A. & Vaneecloo F.M. (2003). A middle ear implant, the Symphonix Vibrant Soundbridge: Retrospective study of the first 125 patients implanted in France. *Otol Neurotol.* 24(3), 427–436.

**Abstract:**

The Vibrant Soundbridge is an active semi-implantable middle ear implant for the rehabilitation of patients with a sensorineural hearing loss who are not able to derive adequate benefit from conventional hearing aids. A retrospective study was performed to assess the overall level of satisfaction of implanted patients and to investigate the potential determinants of postoperative success. A retrospective survey of audiological data from repeated measures and subjective data from self-assessment scales administered postoperatively was conducted to determine the degree of benefit and satisfaction for Vibrant Soundbridge implantees. Twenty-one tertiary referral and teaching hospitals. The first 125 VSB implantees implanted in France between August 1997 and May 2001 were included in the study. No clinically significant change was observed for residual hearing postoperatively. Most patients (83%) reported they were either satisfied or very satisfied with the Vibrant Soundbridge. Analysis of correlation revealed a moderate correlation (Pearson coefficient  $r = 0.59$ ) between the degree of benefit reported via the patient survey and the degree of benefit reported via the Glasgow Benefit Inventory. A moderate correlation (Pearson coefficient  $r = 0.66$ ) was observed between speech comprehension scores in quiet for the preoperative unaided condition and the postoperative aided Vibrant Soundbridge condition. No correlation was observed between subjective reports of satisfaction postoperatively and performance on preoperative objective tests or patient characteristics. The results indicate a high level of satisfaction with the VSB as a treatment of sensorineural hearing impairment in patients with a wide range of characteristics. Preoperative scores for unaided speech comprehension tests in quiet may be a potential indicator of success on aided Vibrant Soundbridge speech comprehension tests postoperatively but do not reflect patient satisfaction with the device reported on self-assessment scales.

- 29 Garin P., Thill M., Gerard J., Galle C. & Gersdorff M. (2002). Speech discrimination in background noise with the Vibrant Soundbridge middle ear implant. *Otorhinolaryngol.* 3(12), 119–123.

**Abstract:**

Evaluate speech intelligibility in competing background noise for monaural users of the Vibrant® Soundbridge™ (VSB) middle ear implant (Symphonix). Nine adults with moderate to severe bilateral sensorineural hearing loss, and implanted with a unilateral VSB, were included in the study. The patients' experience of the implant ranged from 9 to 24 months. Retrospective single-subject repeated measures of speech intelligibility in background noise were performed using 2 different test procedures, the Elbaz test and the Garin and Galle test. The patients were tested VSB aided and VSB unaided in a variety of signal-to-noise ratios. The correct-score percentage for each ratio for each condition was averaged for the group of patients and compared with normative data for each test method. The VSB-aided condition showed results approaching normative data for both test methods. At a signal-to-noise ratio of zero, the Elbaz test showed a mean correct score of 55% for the VSB-unaided condition versus 85% for the VSB-aided condition. The Garin and Galle test showed a mean score of 34% for the VSB-unaided condition versus 94% for the VSB-aided condition. Although the unilateral VSB middle ear implant does not restore stereophony, it does improve speech intelligibility in background noise.

- 28 Thill M.P., Gérard J.M., Garin P. & Offeciers E. (2002). Belgian experience with the Vibrant Soundbridge prosthesis. *Acta Otorhinolaryngol Belg.* 56(4), 375–378.

**Abstract:**

The Belgian Experience with the Vibrant Soundbridge Prosthesis. The authors present the first results obtained with 13 patients implanted with the Vibrant Soundbridge, a semi-implantable electromagnetic hearing device. The first patient was implanted in October 1998. The results show that there were no significant modifications of the hearing thresholds after implantation. The average functional gain was 30 dB in tonal audiometry and 25.6 dB in vocal audiometry. All the patients are satisfied with the device and wear it daily.

- 27 Winter M., Weber B.P. & Lenarz T. (2002). Measurement method for the assessment of transmission properties of implantable hearing aids. *Biomed Tech.* 47(S1), 726–727.

**Abstract:**

Over the last five years the Symphonix Vibrant Soundbridge (VSB), an implantable hearing device, has proven an effective alternative treatment modality for patients suffering from moderate to severe sensorineural hearing loss. The results from the majority of our 40 patients are very encouraging but reveal clinical variations in benefit influenced by the coupling of the transducer to the ossicular chain. This study describes a set-up for measuring the sound pressure level in the external auditory canal when the middle ear implant is activated. The reverse transfer function allows the transducer performance to be determined both intra- and postoperatively. The sound pressure level shows a strong correlation with the stapes footplate displacement and free-field audiometry.

- 26 Todt I., Seidl R.O., Gross M. & Ernst A. (2002). Comparison of different Vibrant Soundbridge audio processors with conventional hearing aids. *Otol Neurotol.* 23(5), 669–673.

Abstract:

OBJECTIVE: To compare the functional gain of different Symphonix Soundbridge audioprocessors (HF-processor and D-processor) to preoperatively fitted conventional hearing aids of patients with mild to severe sensorineural hearing loss in the high-frequency range. STUDY DESIGN: In a prospective study, the Symphonix Soundbridge (HF-processor and D-processor) fitting results were evaluated and compared with conventional hearing aids. Postoperative air and bone conductances, the functional gain of warble-tone measurements, speech audiometric, and subjective outcome testing (Abbreviated Profile of Hearing Aid Benefit questionnaire) were studied. SETTING: Tertiary referral center. PATIENTS: Five patients (ages, 54-69 yr) with mild to severe sensorineural deafness in the high-frequency range, but no progression of hearing loss during the last two years, were initially fitted with the so-called HF-processor, then subsequently fitted with the D-processor, which was a fully digital one. RESULTS: One year after implantation of the Symphonix Soundbridge device, unchanged, stable air and bone conductances were found (except for one minor change). Over the whole frequency range (0.5-8.0 kHz), a mean gain of 16.1 dB (HF-processor), 27.1 dB (D-processor), and 15.2 dB (hearing aid) was found. CONCLUSION: The Symphonix Soundbridge device with different audioprocessors led to improved hearing in speech audiometric testing. The data show a significant improvement of hearing compared with conventional hearing aids in quiet, and a better functional gain in noise for the Symphonix Soundbridge system. The Abbreviated Profile of Hearing Aid Benefit questionnaire also revealed that the implant resulted in significant differences compared with conventional hearing aids in almost all subcategories. The Symphonix Soundbridge device can improve the hearing benefit of moderately to severely hearing handicapped patients—particularly in those with a high-frequency hearing loss—when compared with the conventional hearing aids of these patients, as evidenced by objective and subjective measurements. The Symphonix Soundbridge D-processor showed further improvements and resulted in an additional hearing benefit that was superior to that of the previously fitted HF-audioprocessor. This is owing to the refinements and upgrades in audioprocessor technology.

- 25 Junker R., Gross M., Todt I. & Ernst A. (2002). Functional gain of already implanted hearing devices in patients with sensorineural hearing loss of varied origin and extent: Berlin experience. *Otol Neurotol.* 23(4), 452–456.

Abstract:

OBJECTIVE: The evaluation process of patients with sensorineural hearing loss (SNHL) as candidates for an implantable hearing device is a complex matter. Different criteria have to be considered, such as audiologic, psychological, and socioeconomic issues, presently fitted hearing aids, and the patient's satisfaction with hearing aids. The objective of this study was to describe the evaluation process to select candidates for implantation of the

Vibrant Soundbridge system (Symphonix Devices, Inc., San Jose, CA, U.S.A.) in a capital area such as Berlin, where approximately 4 million people live. STUDY DESIGN: Retrospective chart review with additional clinical and audiologic testing and extensive interview of the patients. SETTING: The study was conducted at two referral centers. PATIENTS: A total of 45,350 pure-tone audiograms (PTAs) and speech audiograms (samples from 1987 to 1999) of patients with different extents and types of SNHL were screened. MAIN OUTCOME MEASURES: The PTA, speech audiograms, Abbreviated Profile of Hearing Aid Benefit questionnaire, and a telephone interview served as major criteria. However, several additional criteria in the evaluation and in the decision-making process were included and are described in detail. RESULTS: Of 45,350 patients' charts with their PTA, 346 patients appeared to be possible implant candidates (0.76%) because of their hearing loss. At the time of the hearing screening, 255 patients (0.56%) were possible candidates for the P-type Soundbridge audio processor, and 91 patients (0.2%) were possible candidates for the HF-type processor. Out of the initial 346 patients, 84 (24.3%) were not interested in being further tested or interviewed and declared their lack of interest in the implant technology for several reasons (e.g., satisfaction with their present hearing aid fitting, anxiety to be operated on). A total of 126 patients (36.4%) could be contacted neither by mail nor by telephone. A total of 61 patients (0.13%) declared that they were basically interested, but wanted to wait for further technological refinements (e.g., fully implantable devices). The remaining 75 patients (i.e., 0.16% of the total population screened) could be clinically reevaluated with regard to our standardized protocol. Because of clinical and other reasons, another 33 patients (0.07%) had to be excluded from this study. The resulting 42 patients (0.09%) were undergoing the final ABHAB interview and were ready to be implanted. CONCLUSION: The number of patients in a stochastic population who are realistic implant candidates for an implantable hearing device is limited. Although there are many more patients suffering from SNHL who meet the requirements of the implant system because of their audiograms, the complexity of a careful evaluation process extremely limits the number of implant candidates. Moreover, reimbursement restrictions in the present health economy worldwide have to be considered.

- 24 Luetje C.M., Brackman D., Balkany T.J., Maw J., Baker R.S., Kelsall D., Backous D., Miyamoto R., Parisier S. & Arts A. (2002). Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: a prospective controlled multicenter study. *Otolaryngol Head Neck Surg.* 126(2), 97–107.

**Abstract:**

The goal of the study was to evaluate the performance of a semi-implantable middle ear hearing device (Vibrant Soundbridge System [VSB]; Symphonix Devices, Inc.). A prospective, single-subject, repeated-measures multicenter study was conducted to determine the safety and efficacy of the VSB using analog and digital external processors. Measures included residual hearing, functional gain, speech recognition, acoustic feedback, occlusion, and patient self-assessment to determine satisfaction, perceived performance, and device preference compared with an appropriately fit acoustic hearing aid. Fifty-three

adult subjects with moderate to severe sensorineural hearing loss were evaluated at 4 or more intervals after implantation. Improvements in satisfaction, performance, and preference were statistically significant with the VSB, as was functional gain across all test frequencies ( $P < 0.001$ ). Occlusion and feedback were virtually eliminated. Aided speech recognition was comparable between VSB and the hearing aid. Residual hearing was unchanged. The VSB is a safe and effective treatment option for adults with moderate to severe sensorineural hearing loss.

- 23 Dubreuil C. (2002). Indication limits for middle ear vibrating Symphonix Soundbridge implant and Cochlear implant. *J Fr Otorhinolaryngol Audiophonol Chir Maxillofac.* 51(4), 159–161.

No abstract available

- 22 Chasin M. & Spindel J. (2001). Middle ear implants: A new technology. *Hear J.* 54(8), 33–48.

No abstract available

- 21 Snik A.F. & Cremers C.W. (2001). Vibrant semi-implantable hearing device with digital sound processing: effective gain and speech perception. *Arch Otolaryngol Head Neck Surg.* 127(12), 1433–1437.

Abstract:

**BACKGROUND:** The Vibrant Soundbridge (Symphonix Devices, San Jose, Calif) is a semi-implantable hearing device. The transducer is attached directly to the incus and is linked by telemetry to the externally worn audioprocessor. A major advantage of this semi-implantable setup, especially during its experimental phase, is that the audioprocessor can be updated. Recently, we replaced the previous 2-channel analog audioprocessor in 14 patients with a 3-channel digital device. **DESIGN:** Prospective clinical study. Basic functions were measured, including gain as a function of input level and speech perception in quiet. **PATIENTS:** Patients ( $n = 14$ ) had moderate to severe sensorineural hearing impairment (average hearing threshold at 0.5, 1.0, 2.0, and 4.0 kHz of 40- to 76-dB hearing level [HL]) and chronic external otitis, which contraindicated use of an ear mold. **RESULTS:** Gain of the 3-channel audioprocessor for comfortable listening levels and for conversational levels varied from approximately 15- to 30-dB HL, suggesting that the device is suitable for patients with hearing loss of up to 60- to 70-dB HL. In 5 patients, identical measurements were performed using their conventional hearing aids. The other 9 patients did not use a conventional hearing device because of severe external otitis. On average, results obtained with the Vibrant Soundbridge were not as good as those obtained with the conventional device. Nevertheless, patients were satisfied with the Vibrant Soundbridge because they could use it all day without pain or itching. **CONCLUSION:** The Vibrant Soundbridge is suitable for patients with hearing loss of up to 70-dB HL. Compared with conventional devices, in audiometric terms, a surplus value of the Vibrant

Soundbridge was not found.

- 20 Fraysse B., Lavieille J.P., Schmerber S., Enée V., Truy E., Vincent C., Vaneeckoo F.M. & Sterkers O. (2001). A multicenter study of the Vibrant Soundbridge middle ear implant: Early clinical results and experience. *Otol Neurotol.* 22(6), 952–961.

Abstract:

The Vibrant Soundbridge (VBS; Symphonix Devices, Inc., San Jose, CA, U.S.A.) is an active, semi-implantable, middle ear hearing device that directly drives the ossicular chain and is used in the treatment of patients with mild to severe sensorineural hearing loss. The benefits of the VBS and the effects of surgery were examined and compared with the preoperative aided condition in 25 patients with implants. Single-subject repeated-measures evaluations were performed with each patient acting as his or her own control. Objective audiologic measures and subjective questionnaires also were used. Five tertiary referral and teaching hospitals. Adult patients had bilateral sensorineural hearing loss (average hearing loss, 56 dB; range, 33-80 dB). Twenty-one patients had worn a conventional hearing aid before surgery (11 binaurally, 10 monaurally). Four patients had not used a conventional hearing aid before surgery. Rehabilitative. No significant change in residual hearing after surgery was observed. Functional gain was significantly superior with the VBS. No significant differences were observed for aided speech recognition in quiet. A significant improvement in communication in various listening conditions was reported with the VBS as compared with conventional hearing aids. The VBS surgical implantation procedure does not affect the residual hearing level in the implanted ear, nor does it present any unacceptable risk. Measurable benefit from the VBS in comparison with conventional amplification was demonstrated with regard to the provision of superior usable amplification and greater ease in communication in daily listening environments for the majority of patients.

- 19 Fisch U., Cremers C.W., Lenarz T., Weber B., Babighian G., Uziel A.D., Proops D.W., O'Connor A.F., Charachon R., Helms J. & Fraysse B. Clinical experience with the Vibrant Soundbridge implant device. *Otol Neurotol.* 22(6), 962–972.

Abstract:

**OBJECTIVE:** To evaluate the full degree and range of benefits provided by the Vibrant Soundbridge (VSB; Symphonix Devices, Inc., San Jose, CA, U.S.A.) and analyze pre-and postoperative results of audiologic tests. **STUDY DESIGN:** Single-subject study with each subject serving as his or her own control. **SETTING:** Multicenter clinical study conducted at 10 centers in Europe. **PATIENTS:** 47 patients who met the selection criteria for participation in the study. **INTERVENTIONS:** Implantation of the VSB direct-drive middle ear hearing device. **MAIN OUTCOME MEASURES:** Average change in unaided thresholds with the patient wearing headphones at each frequency pre-and postsurgery was measured. A mean threshold change less than 5 dB across all frequencies was considered clinically nonsignificant. **RESULTS:** 47 patients had successful surgery for implantation and fitting with the VSB device. **CONCLUSION:** The VSB is a new middle ear implant device that can be

used safely in the treatment of patients with moderate to severe sensorineural hearing loss.

- 18 Lenarz T., Weber B.P., Issing P.R., Gnadeberg D., Ambjørnsen K., Mack K.F., & Winter M. (2001). Vibrant Soundbridge system. A new kind hearing prosthesis for patients with sensorineural hearing loss. 2. Audiological results. *Laryngorhinootologie*, 80(7), 370–380.

**Abstract:**

Implantable hearing aids present a new treatment modality for patients suffering from sensorineural hearing loss. The functional gain obtained with the partially implantable Symphonix soundbridge system was evaluated in a clinical study. The audiological results achieved with n = 34 patients over a period of up to three years are presented in this second part of the publication. 34 patients have received the Symphonix Vibrant Soundbridge system since February 1997. The average age at implantation was 47.2 years (minimum: 18.9 years; maximum: 80.3 years). All patients have had several years of experience with hearing aids, which, however, provided insufficient functional gain or could not be fitted with a conventional hearing aid for medical reasons (such as auditory ear canal problems). All patients fulfilled the audiological selection criteria as they had bilateral moderate to severe sensorineural hearing loss. As a rule, the ear with poorer performance was implanted. All patients were fitted with the audio processor eight weeks after the implantation. The pure tone thresholds, the functional gain, the monosyllable and sentence understanding (Göttinger Sentence Test in quiet and noise) were preoperatively and postoperatively assessed. Standardized self-assessment questionnaires were used to evaluate the subjective benefit (PHAB) and the quality of hearing (HDSS) as compared to the preoperative situation. Further hearing tests were performed after four weeks, three, six, nine, twelve, eighteen, twenty-four and thirty-six months postoperatively. During the observation period of up to three years the audioprocessor was updated several times, most recently with the fully digital three-channel-system Vibrant D. The results obtained were documented. Postoperatively, the pure tone threshold with the soundbridge system switched off did not change significantly in the implanted ear. All patients had a functional gain that was either comparable to the gain achieved with hearing aids or better. In particular speech-related frequencies showed improved amplification. The free field speech recognition tests revealed higher scores in quiet and in noise. The patients commended the natural sound quality, the lack of feedback, the absence of occlusion and distortion, the improved speech understanding in noise and the favourable cosmetic appeal. Only two patients failed to achieve better results as compared to their performance with conventional hearing aids. No complications, such as a deterioration of hearing due to inner ear damage or a conductive hearing loss, were observed in the long-term. The Symphonix Vibrant Soundbridge is a new and promising treatment modality for patients suffering from moderate to severe sensorineural hearing loss. Further improvement of the good results can be expected with improved coupling of the transducer to the ossicular chain and further development of signal processing.

- 17 Ashburn-Reed S. (2001). The first FDA approved middle ear implant. The Vibrant Soundbridge. Hear J. 54(8), 47–48.

Abstract:

For many years, hearing aids have undoubtedly been the best treatment option for people diagnosed with mild-to-severe sensorineural hearing loss. However, despite significant advances in signal processing and device miniaturization which have made these devices more effective and attractive treatment options, many patients continue to reject acoustic hearing aids for myriad reasons, including, among others, occlusion, discomfort, and acoustic feedback. Irrespective of the cause for rejection, there is demand for a new classification of devices to help those adults for whom conventional acoustic amplification is inadequate. Until recently, discussions of middle ear implants (MEIs) for treatment of sensorineural hearing loss centered primarily around laboratory data and preliminary clinical trial data from small patient pools. But, on August 31, 2000, following a multi-center clinical trial (N=54 in the United States), the Food and Drug Administration (FDA) approved for commercial distribution the Vibrant® Soundbridge™, a semi-implantable middle ear device, making it the first MEI commercially available in the United States and Canada. Currently, more than 500 patients are using this device worldwide and long-term data are becoming available. MEIs typically utilize direct-drive technology, imparting mechanical vibrations directly to a vibratory structure of the ear, thereby improving signal coupling and bypassing the tympanic membrane. Patient reports of improved sound clarity are generally accompanied by the absence of insertion loss and the occlusion effect, common byproducts of acoustic amplification and frequent sources of patient dissatisfaction.

- 16 Snik A.F., Mylanus E.A., Cremers C.W., Dillier N., Fisch U., Gnaediger D., Lenarz T., Mazolli M., Babighian G., Uziel A.S., Cooper H.R., O'Connor A.F., Fraysse B., Charachon R. & Shehata-Dieler W.E. (2001). Multicenter audiometric results with the Vibrant Soundbridge, a semi-implantable hearing device for sensorineural hearing impairment. Otolaryngol Clin North Am. 34(2), 373–388.

Abstract:

The Vibrant Soundbridge, a semi-implantable hearing device for subjects with moderate to severe sensorineural hearing impairment was introduced commercially. First audiologic results are presented on 63 patients from 10 European implant centers. Hearing loss was at 0.5, 1, 2, and 4 kHz varying between 43 and 81 dB HL. The patients used the analogue audio processor, type 302. Measured sound-field gain was compared with NAL-R target values. For most patients an acceptable agreement was found. There was a subgroup of patients, however, with relatively low gain. The results suggest that this was related to the suboptimal positioning and fixation of the transducer to the incus.

- 15 Dieler R., Dazert S., Shehata-Dieler W. & Helms J. (2001). Evaluierung der funktionellen ergebnisse mit dem aktiven mittelohrimplantat Vibrant Sounbridge. HNO, 2, 75.

No abstract available

- 14 Ernst A. (2001). Implantierbare hoersysteme. HNO. 9(1), 13–15.

No abstract available

- 13 Babighian G. & Mazolli M. (2000). Prothese implantable d'oreille moyenne. Resultats cliniques. Les Cahiers D'ORL. 15(8), 322–330.

No abstract available

- 12 Dazert S., Shehata-Dieler W.E., Dieler R. & Helms J. (2000). "Vibrant Soundbridge" middle ear implant for auditory rehabilitation in sensory hearing loss. I. Clinical aspects, indications and initial results. Laryngorhinootologie, 79(8), 459–464.

Abstract:

The adequate therapy for patients suffering from a sensory hearing loss consists of fitting electronic hearing devices. Conventional hearing aids, however, present with significant inherent drawbacks such as insufficient amplification in the high frequency range, problems with the ear mold (feedback, occlusion, external otitis), or distortion of sound with an "unnatural" hearing impression. The partially implantable middle ear device Vibrant Soundbridge provides a sound wave conversion into mechanical vibrations at the middle ear ossicles using the Floating Mass Transducer (FMT). The audiological advantages are due to a direct moving force to the perilymph via incus and stapes. The Vibrant Soundbridge system is indicated in patients with a medium to severe symmetrical sensory hearing loss and a normal middle ear. Candidates need previous experience with conventional hearing aids without satisfactory results. The eight operated patients report a "natural" quality of sound and speech, a better hearing perception at high frequencies and the absence of feedback phenomena. Audiological evaluation and questionair results support the patients subjective hearing impression. The Vibrant Soundbridge improves hearing quality in patients with sensory hearing loss. The hearing implant is indicated in particular in patients that are unable to wear conventional hearing aids.

- 11 Snik A.F. & Cremers C.W. (2000). The effect of the "Floating Mass Transducer" in the middle ear on hearing sensitivity. Am J Otol. 21(1), 42–48.

Abstract:

OBJECTIVE: The Vibrant Soundbridge is a semi-implantable hearing device; the transducer is implanted, coupled directly to the incus. The influence of the implant surgery and the presence of the transducer on hearing sensitivity was studied in six implanted subjects. STUDY DESIGN: Longitudinal case reports. SETTING: Tertiary referral center. SUBJECTS: The subjects had bilateral sensorineural hearing loss with an average hearing loss of 40 to 70 dB HL. RESULTS: In five of the six subjects, no long-term effect of the surgery or the presence of the transducer on hearing thresholds was found. In the remaining subject, a

deterioration in hearing thresholds was found of 20 dB, with a high and low frequency component. In the 2-kHz region, hearing sensitivity was not deteriorated. In addition, chronic negative middle ear pressure occurred after surgery. CONCLUSION: Hearing thresholds did not change significantly in five of the six patients after placement of the "Floating Mass Transducer." It was speculated that the high frequency component of the hearing deterioration in the remaining patient was caused by cochlear damage caused by the surgery and that the low frequency component was caused by the chronic aeration problems indirectly related to the surgery.

- 10 Cremers C.W. & Snik A.F. (1999). De Vibrant Soundbridge, een semi-implanteerbaar hooroestel voor perceptieve lechthorendheid. Ned Tijdschr KNO-Heelkunde. 5,158–161.

No abstract available

- 9 Snik A.F. & Cremers C.W. (1999). First audiometric results with the Vibrant Soundbridge, a semi-implantable hearing device for sensorineural hearing loss. Audiol. 38(6), 335–338.

Abstract:

The Vibrant Soundbridge is a semi-implantable hearing device. The implanted electromagnetic transducer is attached to the incus and it is linked by telemetry to the externally worn audio processor. In Nijmegen, this device has been applied to seven patients with moderate or severe sensorineural hearing loss (PTA between 43 and 71 dB HL) who could not tolerate ear moulds. As the amplification of the device depends on the input level (amplifier with wide dynamic range compression), loudness scaling measurements were performed. The gain as a function of input level was determined from aided and unaided loudness growth curves. The mean gain was 21 dB at an input level of 40 dB SPL. The mean gain decreased to 5 dB at an input level of 90 dB SPL. Measured gain values were lower than target values prescribed by the FIG6 method, mainly however for the low-frequency range and for low-level sounds. It was concluded that this device is very promising for patients who cannot tolerate an ear mould.

- 8 Richards A. & Gleeson M. (1999). Clinical review, recent advantages. Brit Med J. 319, 1110–13.

Abstract:

OBJECTIVE: To present the technical background of implantable hearing aids and to consider biomechanical problems and selective criteria for candidates. DATA SOURCES: Publications and evidence on biomechanical aspects of middle ear function. CONCLUSIONS: Implantable hearing aids represent a technically attractive and clinically promising challenge. Yet, the mechanical complexity of biotechnical interfaces in the middle ear and technical problems are immense and perhaps not even fully understood. Currently available devices still leave many biomechanical questions unanswered. Therefore candidates should be carefully selected to avoid unsuccessful implantations, in order to

prevent a premature discredit of this fascinating technique.

- 7 Boucarra D. (1999). Nouvelle modalité de réhabilitation de l'audition: Prothèse Vibrant Soundbridge symphonix. La Lettre d'oto-rhino-laryngologie et de chirurgie cervico-faciale, 241, 29–30.

No abstract available

- 6 Hüttenbrink K.B. (1999). Current status and critical reflections on implantable hearing aids. Am J Otolaryngol. 20, 409–415.

Abstract:

OBJECTIVE: To present the technical background of implantable hearing aids and to consider biomechanical problems and selective criteria for candidates. DATA SOURCES: Publications and evidence on biomechanical aspects of middle ear function. CONCLUSIONS: Implantable hearing aids represent a technically attractive and clinically promising challenge. Yet, the mechanical complexity of biotechnical interfaces in the middle ear and technical problems are immense and perhaps not even fully understood. Currently available devices still leave many biomechanical questions unanswered. Therefore candidates should be carefully selected to avoid unsuccessful implantations, in order to prevent a premature discredit of this fascinating technique.

- 5 Lenarz T., Weber B.P., Mack K.F., Battmer R.D. & Gnadeberg D. (1998). The Vibrant Soundbridge system: A new kind of hearing aid for sensorineural hearing loss. 1: Function and initial clinical experiences. Laryngorhinootologie, 77(5), 247–255.

Abstract:

Patients suffering from moderate to severe cochlear hearing impairment cannot be considered for cochlear implantation on account of their relatively good residual hearing. Conventional hearing aids, on the other hand, have considerable disadvantages which clearly limit the benefit for these patients, e.g. feedback, sound distortion, unfavorable conditions for frequency transfer, occlusion, and recurrent infections of the auditory canal. In addition, many patients complain about a poor speech intelligibility in noise. Implantable hearing aids offer a new approach for improved auditory rehabilitation. The Vibrant Soundbridge system is based on an electromagnetic system, which is linked directly to the intact ossicular chain. Due to the high sound quality and the high frequency characteristic this system is ideally suited for the above-mentioned patient group. The usual disadvantages of conventional hearing aids can be avoided. Externally visible is merely the audio processor, which is worn in the retroauricular area and covered by hair. This processor transfers data and power via magnetic attachment transcutaneously. During a European multicenter clinical study, 19 patients were implanted at MHH since February 1997. No significant complications occurred. In all patients, postoperative unaided pure tone threshold was unaltered in comparison with the preoperative recordings. The use of the audio processor leads to a significant functional gain,

particularly in the high frequencies. The patients report about undistorted hearing resulting in a better speech understanding even in situations with loud background noise. The preliminary results show a promising new approach to the use of hearing prostheses for patients suffering from moderate to severe sensorineural hearing loss.

- 4 Snik A.F., Mylanus E. & Cremers C.W. (1998). Implantable hearing devices for sensorineural hearing loss: A review of the audiometric data. *Clin Otolaryngol.* 23, 414–419.

No abstract available

- 3 Gan R.Z., Wood M.W., Ball G.R., Dietz T.G. & Dormer K.J. (1997). Implantable hearing device performance measured by Laser Doppler Interferometry. *Ear Nose Throat.* 76(5), 297–309.

Abstract:

Recent application of the Doppler principle laser interferometry to audiology, acoustics and otology has facilitated the development of implantable hearing devices (IHDs). During the design and testing of two different electromagnetic middle ear implants for sensorineural hearing loss, we used single-point laser Doppler interferometry (LDI). A commercially available interferometer, internally calibrated and validated against a National Institute for Standards and Technology (NIST) standard, was used with both mechanical fixtures and fresh temporal bones to evaluate implant mass, shape and orientation, attachment, electromagnetic coupling and acoustic properties. At both Hough Ear Institute and Symphonix Devices, Inc., we have shown that high fidelity and amplitudes can be recorded *in vitro* over a frequency range of 500 Hz to 10 kHz. These data can provide greater assurance of safety and efficacy to regulatory agencies before entering clinical trials. We propose that LDI be considered as an international standard for accurate, consistent comparison of performances of all IHDs during development. Furthermore, the future availability of human IHD data will allow for the extrapolation of a mechanical bench model of the middle ear transfer function for use in quality control during manufacturing and diagnosis of failure in IHDs.

- 2 Ball G.R., Huber A. & Goode R.L. (1997). Scanning Laser Doppler Vibrometry of the middle ear ossicles. *Ear Nose Throat.* 76(4), 213–8, 220, 222.

Abstract:

This paper describes measurements of the vibratory modes of the middle ear ossicles made with a scanning laser Doppler vibrometer. Previous studies of the middle ear ossicles with single-point laser Doppler measurements have raised questions regarding the vibrational modes of the ossicular chain. Single-point analysis methods do not have the ability to measure multiple points on the ossicles and, consequently, have limited ability to simultaneously record relative phase information at these points. Using a Polytec Model PSV-100, detailed measurements of the ossicular chain have been completed in the human temporal bone model. This model, when driven with a middle ear transducer, provides detailed three-dimensional data of the vibrational patterns of the middle ear

ossicles. Implications for middle ear implantable devices are discussed.

- 1 Tjellström A., Luetje C.M., Hough J.V., Arthur B., Hertzmann P., Katz B. & Wallace P. (1997). Acute human trial of the Floating Mass Transducer. *Ear Nose Throat*. 76(4), 204–6, 209–10.

Abstract:

Five patients underwent acute implantation of the Floating Mass Transducer (FMT) to evaluate the ability of the FMT to produce measurable auditory thresholds when temporarily placed in the middle ears of patients undergoing routine stapedotomy procedures. The FMT was placed on the long process of the incus in an inferior position, as is planned for clinical application, and in two additional positions. The ability of the FMT to produce measurable auditory thresholds was demonstrated in all patients. Results were affected by the lack of a healing period, the presence of a fixed stapes and an open middle ear space, and patient sedation.

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