
**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.


**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 imaging appearance of FMT connected to these couplers, however, is not well known. 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.


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.


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.


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.


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.

**Abstract:**
Objective: To present results for the auditory rehabilitation of patients with Treacher Collins syndrome with bilateral osseous atresia, using middle-ear implantation 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 ± standard deviation decreased to 22.8 ± 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.


**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.

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 audiometry. 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.


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 audiologic 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 cares 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.


**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.


**Abstract:**
Conclusions: 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.


**Abstract:**

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. Prospective cohort study. Tertiary, referral centerThree patients with previous middle ear surgery and moderate-to-severe ipsilateral, mixed hearing loss. 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. Audiologic assessment involving pure-tone audiometry, aided and unaided free-field audiometry, Freiburg monosyllabic word test, and registration of any complications. 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. 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.


**Abstract:**

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. 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. Tertiary referral center. Thirteen experienced unilateral German-speaking active middle ear implant users with either
mixed or conductive hearing loss were enrolled. Directional audio processor. SNR50 obtained from 4 different noise conditions. 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 S0N0 condition of 1.3 dB, in S0NVS 2.3 dB, in S0Ncont 3.1 dB, and in S0N180 4.5 dB. As expected, the largest DA was found in the S0N180 condition. No DA was expected in the S0N0 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. The directional AP yields immediately improved speech understanding in noise.


Abstract:
To investigate the effect of vibrant sound bridge implantation in microtia whose reconstructive external auditory canal occurred atresia. Three cases (2 males and 1 female) of microtia had undergone 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. 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. Through vibrant sound bridge implantation, the hearing level of microtia whose reconstructive external auditory canal occurred atresia was improved effectively.


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 tympanosclerosis.


Abstract:
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. 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. Evaluating the safety and efficacy of the VSB in combination with a PORP or TORP to treat conductive and mixed hearing loss. 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. 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.


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


Abstract:

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. A retrospective analysis. University-affiliated medical center. Six patients with severe mixed hearing loss and a mean sensorineural hearing loss component between 40 and 70 dB. 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. 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. There is large variance in functional gain between the patients suggesting high variability in the effectivity of the FMT coupling. The speech recognition results for the experimental group were not systematically better than in either control group. There is large variability in results that might be ascribed to coupling effectivity. 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.


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.


**Abstract:**
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. Prospective cohort study. Tertiary referral center, Otolaryngology Department, University of Verona, Verona, Italy. 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. 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 ± 8.9 and 41.7 ± 11.1 dB HL, respectively, in the monitored and unmonitored cohorts (P = .0032). 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.


**Abstract:**
To illustrate the pre- and postoperative imaging features of patients affected by congenital aural atresia (CAA) treated with the Floating Mass Transducer (FMT) of the Med-El Vibrant Soundbridge (VSB) fitted on the Round Window (RW). Case series with chart review. Tertiary referral center. Fifteen patients, 8 males and 7 females, ranging in age from 3 months to 54 years (mean [SD] 22.1 [5.1] years), treated with the FMT on the RW for bilateral (11 patients) and unilateral (4 patients) CAA, underwent high-resolution computed tomography (HRCT) scans with oblique reconstruction planes.
preoperatively to assess radiological landmarks useful for diagnosis and surgery, as well as cone-beam computed tomography (CBCT) scans postoperatively to visualize early complications and evaluate the correct positioning of FMT on the RW at follow-up times ranging from 12 to 60 months. Ossicular chain abnormalities were present in all ears. These consisted most frequently of a malleus to incus fusion (15 ears). The facial nerve had an abnormal course and/or caliber in 15 ears. The RW was stenotic in 1 patient. High-resolution computed tomography with oblique reconstruction planes affords a complete understanding of CAA anatomy and surgical balance for Vibroplasty. The CBCT permits a precise postoperative determination of the location of the FMT on the RW. The CBCT in the patients’ follow-up is preferable to HRCT because it is less expensive and has a lower administered radiation dose. This is a very important feature in view of the fact that the FMT is also fitted on the RW in infancy.


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.


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.


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


**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.


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.


Abstract:
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). Single subject, repeated measures. Two university hospital ENT departments. 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. Measuring the efficacy and safety of OW- and CliP-Coupler-Vibroplasty as a method to treat mixed hearing loss. 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. OW- or Clip-Coupler-Vibroplasty
using couplers was found to be a straightforward procedure, which produced good results in this group of patients.


**Abstract:**
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 electrocochleography (ECoG) for optimal fitting of the Floating Mass Transducer (FMT) on the Round Window (RW) membrane. Tertiary referral medical center; retrospective case series. 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 (≥ 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. RW implantation. 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. 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. 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.


**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 perfor-
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.


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.


Abstract:
To review the current knowledge on magnetic resonance imaging (MRI) safety of the Vibrant Soundbridge (VSB) system, an implantable, active middle ear implant. National Library of Medicine’s online database and clinical reports. All available articles from 1995 to 2010 on MRI compatibility of the VSB and other active middle ear implants. 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). 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.


Abstract:
To observe the in vivo effects of MRI scanning on the Vibrant Soundbridge system. Retrospective questionnaire. 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. 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. MRI scanning with an implanted Vibrant Soundbridge has possible major side effects, but did not affect cochlear function in this serie.


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.


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.


Abstract:
To investigate the effect of Vibrant Soundbridge (VSB) implantation. 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. 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. Patients with a sensorineural or conductive hearing loss may benefit from VSB implantation.
Abstract:

To evaluate the outcomes of younger (<60 yr) and older (≥60 yr) patients implanted with the Vibrant Soundbridge (VSB). The aim was to determine if there were differences between groups. 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. 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. 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.

Abstract:

To describe an active auditory rehabilitation method (clip Vibroplasty) for conductive or mixed hearing loss in cases of a preserved stapes superstructure. After temporal bone experiments, the new clip Vibroplasty was clinically used in 4 patients with chronic otitis media. 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. Transfer characteristics of laser Doppler vibrometry experiments;audiologic outcomes of the 4 patients. 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. 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.


Abstract:
To describe our surgical and audiometric experience using different active middle ear implant strategies facing various anatomic situations in aural atresia. Retrospective case review. Tertiary academic referral center. 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. Active middle ear implant on stapes capitulum. 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. 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. 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.


Abstract:
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). Retrospective case series. Tertiary referral ear center. 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. 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. 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. 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.


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.

*Abstract:* No abstract available


*Abstract:*

To report a surgical implantation of the Vibrant Soundbridge (VSB) middle ear implant in dogs. Pilot study. Dogs (n=3). 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. No intraoperative complications occurred and CT images confirmed correct placement of the VSB. A VSB can be safely implanted in the middle of dogs.


*Abstract:* No abstract available


*Abstract:*

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). 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). 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 Gőtze'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. 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.


Abstract:
To evaluate the transcanal surgical implantation of the semi-implantable Vibrant Soundbridge (VSB) device in patients with severe external otitis. Retrospective analysis. 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. 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. The transcanal approach for the implantation of the VSB has led to postoperative complications different from those reported after the transmastoidal posterior tympanotomy approach.


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.


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 ± 3.0 dB, and the average bone conduction threshold was 42 ± 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 ± 3.9 dB (n = 24) and with VSB in free-field condition 24 ± 2.1 dB (n = 22). VSB is safe and efficacious for auditory rehabilitation in conductive and mixed hearing losses.


Abstract:

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 with sensorineural or mixed hearing loss subjected to revision surgery of an active middle ear implant. Recording of Compound Action Potentials (CAPs) of the auditory nerve in response to stimulation via an active middle ear implant during revision surgery. CAP thresholds as a measure of mechanical coupling and system integrity. 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.


**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.


**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

Magnetic resonance imaging safety of the Floating Mass Transducer. *Otol Neurotol*,

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.

VJ. Verhaegen, JJ. Mulder, JF. Noten, BM. Luijten, CW. Cremers, and AF. Snik.
Intraoperative auditory steady state response measurements during Vibrant Soundbridge middle ear

Abstract:
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. Intraoperative measurement of objective hearing thresholds
using auditory steady state responses (ASSRs). Radboud University Nijmegen Medical
Centre, tertiary referral hospital. Four individuals with mixed hearing loss and, at least no
incus, in need for a middle ear implant. 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. Differences in ASSR thresholds between different FMT coupling options within patients. 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. 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.


Abstract:
The results support bilateral sequential implantation for patients who are not completely satisfied after implantation of one side. To evaluate the benefit of bilateral Vibrant Soundbridge middle ear implantation as compared with unilateral implantation in quiet and noisy environments. 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. Both qualitative and quantitative assessments demonstrated improvement in speech intelligibility, especially in background noise, but also for low voice intensity in quiet.


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.


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 audiometry (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.

**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.


**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.1 Several studies have proven the effectiveness and safety of the VSB in patients with conductive and mixed hearing loss.2–7 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.

**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.


**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.


**Abstract:**

To assess the relation between cost and effectiveness of implantable middle ear hearing devices in patients with pure sensorineural hearing loss. Literature review. 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. 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.

**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, AMEI patients 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.


**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.

**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 audiologic 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.


**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.


**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.


**Abstract:**

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. Six fresh human cadaveric temporal bones were used. After mastoidectomy, posterior tympanotomy 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). 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. 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.


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.


Abstract:

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. 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. 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. 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.


Abstract:
Is the human ossicular chain stabile 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? 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. 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. 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. 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.


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 RW FMT was perpendicularly placed in the Round Window and underlayed with connective tissue. Fixation of the RW FMT 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 RW FMT does not act as a small bone anchored hearing aid, but instead, acts as a direct vibratory stimulator of the Round Window membrane.


**Abstract:**

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). Within-subjects prospective design. Tertiary referral hospital. 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. 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. 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. 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.


**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.


Abstract:
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). 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. 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). 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.


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 audiometry (PTA) was unchanged by the surgical procedure. After 18 months of implant use, the mean PTA loss in free-field warble tone audiometry 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.


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.


**Abstract:**
To describe a new technique in surgical treatment of obliterative tympanosclerosis by applying a Floating Mass Transducer (FMT) to a Third Window. A 64-year-old woman with a severe combined hearing loss due to tympanosclerosis received a Third Window Vibroplasty. 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. 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. 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.


**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.


**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.


**Abstract:**

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. Retrospective study. Tertiary referral center. University hospital. 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. Hearing rehabilitation. Postoperative surgical and anatomic results. Anatomic results and functional results in patients operated with the FMT on the Round Window. 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.


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.


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.


**Abstract:**

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. Prospective noncontrolled study. Audiologic and surgical records analysis. 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. 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. 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.

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.


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.

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.


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.


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.


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.


Abstract: Abstract not available


Abstract:
To assess the functional results of the Vibrant Soundbridge (VBS) placed on the Round Window (RW) in patients with mixed hearing loss. Retrospective evaluation of functional hearing, with measurements performed 7 to 9 months postoperatively. Two tertiary referral hospital centers. Twelve individuals with mixed severe hearing loss associated with chronic suppurative otitis media and otosclerosis. Surgical placement of the VBS mechanical effector in close contact with the RW membrane to directly drive the inner ear fluids. Functional hearing gain as analyzed via pure-tone audiometry and speech audiometry with VBS off and on in quiet and in noise. 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. 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.

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.


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.


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.

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.


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.


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 electromagnetic transduction.


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 tympanoplastoric 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.


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.


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 patient’s 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.


Abstract:
To define audiological application criteria for different implantable hearing aid devices. Retrospective study. 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). 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. 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 been 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.

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 audiologic 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.


Abstract:

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. 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. 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. 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.


**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 the 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.


**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.

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 be perform extremely well especially in the high frequencies. It offers a new solution for rehabilitation of high frequency hearing loss.


Abstract: No abstract available


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.


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.


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.


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.


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.

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.


Abstract:
To assess the feasibility of a new, active middle ear device in temporal bones (TB). 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. 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. 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. Bell-Vibroplasty is feasible in TBs. Bell-Vibroplasty performance in TBs is sufficient to allow for a clinical trial as a next step.

**Abstract:**

To determine the cost-effectiveness of middle-ear implantations in hearing-impaired patients with severe external otitis in the Netherlands. Cost-effectiveness analysis, using single-subject repeated measures of quality of life and total cost determinations. 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. 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. Based on the cost per QALY, middle-ear implantation proved to be a cost-effective and justified health care intervention in the Netherlands.


**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.

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.


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.


Abstract:
To present long-term results with a semi-implantable middle ear implant, the Vibrant Soundbridge (VSB), and analyze pre- and post-operative results of audiologic tests. Retrospective chart review with additional patient interview and audiologic testing. One tertiary referral center. Twenty patients who met the selection criteria of the manufacturer were evaluated at least two years after implantation. Monaural Implantation of the VSB in 20 patients, in two of these 20 patients implantation of the second ear in a second stage. 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 audiologic 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. 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.


Abstract:
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. 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. Private neurotology clinic and tertiary
care teaching hospital. 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. 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.

121 S. Labassi and M. Beliaeff. Retrospective of 1000 patients implanted with a Vibrant
Abstract: No abstract available

122 P. Garin, M. Debaty, and C. Galle. Hearing in noise with the Vibrant Soundbridge middle-
Abstract: No abstract available

123 I. Todt, RO. Seidl, and A. Ernst. Hearing benefit of patients after Vibrant Soundbridge
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.


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 aid did not significantly improve hearing in noise.


**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.


**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.


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 hyperacuity 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.

**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.


**Abstract:** no abstract available no paper available


**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.

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.


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.


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.


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.


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.

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.


Abstract:
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. 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. Tertiary referral center. 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. 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. 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.


Abstract:
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. Retrospective chart review with additional clinical and audiologic testing and extensive interview of the patients. The study was conducted at two referral centers. 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. 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. 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. 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.

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.


Abstract: English abstract not available


Abstract: English abstract not available, Editorial and articles


Abstract:
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. Prospective clinical study. Basic functions were measured, including gain as a function of input level and speech perception in quiet.
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. 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. 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.


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.
Abstract:

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. Single-subject study with each subject serving as his or her own control. SETTING: Multicenter clinical study conducted at 10 centers in Europe. 47 patients who met the selection criteria for participation in the study. Implantation of the VSB direct-drive middle ear hearing device. 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. 47 patients had successful surgery for implantation and fitting with the VSB device. 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.

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.


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.

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.


Abstract: no Abstract available


Abstract: no Abstract available


Abstract: no Abstract available


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 questionnaire 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.


Abstract:
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. Longitudinal case reports. Tertiary referral center. Subjects. The subjects had bilateral sensorineural hearing loss with an average hearing loss of 40 to 70 dB HL. 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. 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.


Abstract: no Abstract available


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
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.

Abstract: no Abstract available

Abstract: no Abstract available

Abstract: To present the technical background of implantable hearing aids and to consider biomechanical problems and selective criteria for candidates. Publications and evidence on biomechanical aspects of middle ear function. 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.

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.

Abstract: no abstract available

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.

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.


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.