Thomas Zahnert, Hubert Löwenheim, Dirk Beutner, Rudolf Hagen, Arneborg Ernst, Hans-Wilhelm Pau, Thorsten Zehlicke, Hilke Kühne, Natascha Friese, Anke Tropitzsch, Jan-Christoffer Lüers, Robert Mlynski, Ingo Todt, Karl-Bernd Hüttenbrink

Multicenter Clinical Trial of Vibroplasty Couplers to Treat Mixed/Conductive Hearing Loss: First Results

Erstveröffentlichung in / First published in:

Audiology & Neurotology. 2016, 21 (4), S. 212 – 222 [Zugriff am: 19.05.2020]. Karger. ISSN 1421-9700.

DOI: https://doi.org/10.1159/000444616

Original Paper

Audiology & Neurotology

Audiol Neurotol 2016;21:212–222
DOI: 10.1159/000444616

Received: July 26, 2015
Accepted: February 8, 2016
Published online: June 29, 2016

Multicenter Clinical Trial of Vibroplasty Couplers to Treat Mixed/Conductive Hearing Loss: First Results

Thomas Zahnert[a] Hubert Löwenheim[b] Dirk Beutner[c] Rudolf Hagen[d] Arneborg Ernst[e] Hans-Wilhelm Pau[f] Thorsten Zehlicke[f] Hilke Kühne[a] Natascha Friese[b] Anke Tropitzsch[b] Jan-Christoffer Lüers[c] Robert Mlynski[d, f] Ingo Todt[e] Karl-Bernd Hüttenbrink[c]

[a]Department of Medicine, Clinic of Otorhinolaryngology, Head and Neck Surgery, Technical University of Dresden, Dresden, [b]Department of Otorhinolaryngology, Head and Neck Surgery, Hearing Research Center, University of Tübingen Medical Center, Tübingen, [c]Department of Otorhinolaryngology, Head and Neck Surgery, Medical Faculty, University of Cologne, Cologne, [d]Department of Otorhinolaryngology, Plastic, Aesthetic and Reconstructive Head and Neck Surgery, Comprehensive Hearing Center, University of Würzburg, Würzburg, [e]Department of Otolaryngology at UKB, Hospital of the University of Berlin, Charité Medical School, Berlin, and [f]Department of Otorhinolaryngology, Head and Neck Surgery, Rostock University Medical Center, Rostock, Germany

Key Words

Conductive hearing loss · Mixed hearing loss · Vibroplasty · Couplers · Middle ear implant

Abstract

Objective: To evaluate the safety and effectiveness of round window (RW), oval window (OW), CliP and Bell couplers for use with an active middle ear implant. ***Methods:*** This is a multicenter, long-term, prospective trial with consecutive enrollment, involving 6 university hospitals in Germany. Bone conduction, air conduction, implant-aided warble-tone thresholds and Freiburger monosyllable word recognition scores were compared with unaided preimplantation results in 28 moderate-to-profound hearing-impaired patients after 12 months of follow-up. All patients had previously undergone failed reconstruction surgeries (up to 5 or more). In a subset of patients, additional speech tests at 12 months postoperatively were used to compare the aided with the unaided condition after implantation with the processor switched off. An established quality-of-life questionnaire for hearing aids was used to determine patient satisfaction. ***Results:*** Postoperative bone conduction remained stable. Mean functional gain for all couplers was 37 dB HL (RW = 42 dB, OW = 35 dB, Bell = 38 dB, CliP = 27 dB). The mean postoperative Freiburger monosyllable score was 71% at 65 dB SPL. The postimplantation mean SRT_{50} (speech reception in quiet for 50% understanding of words in sentences) improved on average by 23 dB over unaided testing and signal-to-noise ratios also improved in all patients. The International Outcome Inventory for Hearing Aids (IOI-HA) quality-of-life questionnaire was scored very positively by all patients. ***Conclusion:*** A significant improvement was seen with all couplers, and patients were satisfied with the device at 12 months postoperatively. These results demon-

T. Zahnert and H. Löwenheim are co-first authors and contributed equally to this work.

Prof. Dr. Karl-Bernd Hüttenbrink
Department of Otorhinolaryngology, Head and Neck Surgery
Medical Faculty, University of Cologne
DE–50923 Cologne (Germany)
E-Mail karl-bernd.huettenbrink@uk-koeln.de

strate that an active implant is an advantage in achieving good hearing benefit in patients with prior failed reconstruction surgery.

Introduction

To treat hearing loss with a conductive component, reconstruction using passive prostheses, bone, or other grafting material is standard treatment [Colletti et al., 1987]. For reconstruction, multiple surgeries are often necessary and results are highly variable. Some evaluations of long-term results have indicated rates of failure of up to 45–50% for passive reconstruction using various materials, including extrusion rates up to 16% [Kapur and Jayaramchandran, 1992; Shinohara et al., 2000]. Despite fairly successful ossiculoplasties, hearing loss interfering with speech intelligibility remains in a substantial number of reconstruction patients, who require hearing aids even after surgery. By then, an auditory canal widened by previous surgeries can be difficult to fit with an ear mold effectively enough to prevent feedback. For medical reasons like allergies against hearing aid materials or chronic external otitis a treatment with hearing aids might be contraindicated.

Another treatment option for hearing rehabilitation was provided by the development of active middle ear implants [Ball, 2010] and their approval for mixed and conductive hearing loss, providing new options for surgical intervention in difficult-to-treat middle ears [Huber et al., 2006]. Surgical implantation of an active or 'direct drive' device – with a transducer located in the middle ear – can provide vibratory stimulation closer to the cochlea while bypassing the outer ear canal and a damaged or partially missing ossicular chain. The floating mass transducer (FMT) of the Vibrant Soundbridge (VSB; MED-EL, Innsbruck, Austria) is designed to mimic the natural function of the middle ear while preserving residual cochlear function. In middle ears compromised by congenital/chronic disease and previous surgeries, however, the challenge is to find the most effective placement for the FMT. The surgery, or 'vibroplasty', has been studied extensively to evaluate which placements work best in conductive and mixed hearing loss. Techniques using couplers with various FMT placements have been summarized in detail by Lüers et al. [2013].

The multicenter clinical study reported here was designed to provide long-term clinical data to supplement surgical experience and document the development of FMT placement techniques. These couplers (Kurz Medizintechnik, Dusslingen, Germany) were developed to standardize and stabilize the placement of the FMT, situating it between a 3-pronged clasp at one end and a prosthesis section at the other end. The CliP and Bell couplers have either an 8-pronged clip or a notched bell that fits onto the stapes capitulum. These are similar to standard Kurz PORPs (partial ossicular replacement prosthesis, Dresden and Tübingen types, respectively) [Beleites et al., 2011; Hüttenbrink et al., 2011]. The oval window (OW) coupler is similar to a TORP (total ossicular replacement prosthesis) that can be placed at the stapes footplate if the footplate is mobile and the suprastructure of the stapes is absent or unusable [Hüttenbrink et al., 2008, 2010; Zahnert et al., 2010]. This provides an option for direct coupling of the FMT to a cochlear window, but does not require as much drilling as placement at the round window (RW).

In cases where the RW is large enough, the FMT can be affixed to it directly [Colletti et al., 2006]. This 'RW vibroplasty' – which bypasses a missing or severely damaged ossicular chain entirely and relies solely on the vibrational energy passed through the FMT – has been shown to be safe and effective, with stable results in long-term studies [Baumgartner et al., 2010; Bernardeschi et al., 2011; Böheim et al., 2012; Skarzynski et al., 2014]. However, placing the FMT at the RW often requires drilling and may be complicated by individual differences in RW size, depth of recession, or in cases of RW sclerosis. In order to resolve these and other surgical issues, the RW coupler was developed with a rounded tip and smaller contact point. An example of this application was reported by Iwasaki et al. [2012], showing good results using the coupler in a 68-year-old woman with severe bilateral mixed hearing loss, tympanosclerosis with plaques on the RW and a small RW (0.9 mm compared with a mean of 1.78 mm in control cases).

A recently published consensus paper on RW vibroplasty also provides guidelines on best practices for RW implantation to ensure optimal coupling and placement [Beltrame et al., 2014].

Materials and Methods

This prospective study was conducted at 6 university hospitals in Germany, after approval by an ethics committee (Freiburg, FEKI code 010/2050). It was designed and conducted in accordance with the principles of the Declaration of Helsinki. Adults with mixed or conductive hearing loss, in whom other treatments such as bone conduction (BC) devices or hearing aids were con-

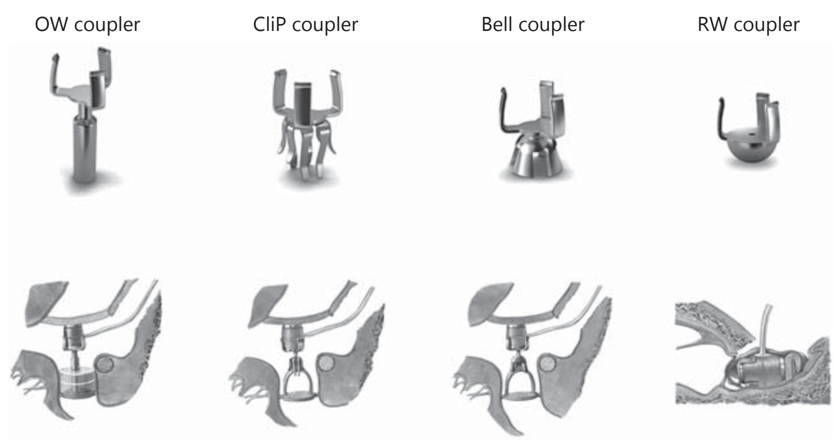

Fig. 1. Coupler types and placement.

traindicated, and/or in whom passive reconstruction surgery had failed, were enrolled. All patients had dry ears with intact eardrums, without the Eustachian tube orifice plugged at the time of surgery (with the exception of 1 patient). The coupler and FMT placement were chosen intraoperatively based on surgical findings and could not be randomized. Additionally, different surgical methods, such as reinforcing the eardrum with cartilage, placing cartilage over the implant, the use of Silastic sheeting and placing tissue between the RW membrane and the FMT [Beltrame et al., 2014] were used, based on the individual patient pathologies and anatomical preconditions. Coupling of middle ear implants is very important for proper sound transfer following middle ear reconstruction. Passive implants are often designed with a clip mechanism or centering modules like the Omega connector (Kurz) in order to improve the coupling quality to the stapes head and footplate. It can be assumed that proper coupling is also important for active middle ear implants. The diameter of the RW membrane is about the same size as the VSB, but in many cases it is impossible to completely explore the RW membrane. Drilling work at the promontory is necessary to expose the membrane, carrying the risk of noise or membrane trauma. A coupler can reduce this risk and improve the contact to the membrane as well. Since the diameter of the VSB is bigger than that of the oval niche, a coupler to the footplate is absolutely necessary in order to ensure contact between the transducer and the footplate.

The idea behind the use of the Bell coupler and the CliP coupler is to provide better mechanical stability at the stapes head. Both couplers are designed to work together with the shape of the stapes head. The clip coupler is thought to realize an additional force coupling to the bone of the stapes head and thus better sound transmission in the higher frequencies and better stability against static pressure changes. However, the CliP coupler cannot be used in all cases. If the patient has an atrophic stapes head or narrow relation to the promontory, the Bell coupler is an alternative option. The 4 couplers and their recommended placements are shown in figure 1.

Preoperative BC thresholds were compared to short-term postoperative thresholds measured at clinical visits up to 3 months after surgery and to long-term results up to 12 months postoperatively. According to the literature [Böheim et al., 2012; Skarzynski et al., 2014], audiometric thresholds have been reported to be stable 12 months postoperatively, with aided performance significantly improved over preoperative measurements. Additionally, basic audiological tests showed that the air and BC thresholds of the patients were not altered by the operation. Therefore, a 12-month postoperative follow-up time is deemed to be sufficient to assess long-term performance and safety. Safety was further monitored with otoscopy, medical examination and surgical reports. Preoperative air conduction (AC) and BC thresholds under headphones, free-field warble-tone thresholds, and free-field Freiburger monosyllables (at 65 dB SPL in quiet) were compared with postoperative VSB-aided results. In a few patients, testing took place at 3, 6 or 10 months postoperatively, but as patients tend to improve with increased experience using the VSB, any bias would have been negligible and actually weighted against the treatment rather than in favor of it. Data were divided into groups by coupler type for subanalysis. In a subset of patients, speech testing with the Oldenburger sentence test (OLSA) was available for analysis at 12 months postoperatively. In these patients, SRT_{50} (speech reception in quiet for 50% understanding of words in sentences) and signal-to-noise ratios (SNR) in constant 65-dB SPL spectrally matched background noise were tested. Unaided results obtained with the processor switched off were compared with aided results. Speech and noise signals were delivered from the same speaker placed at 1 m/0° azimuth in front of the subject. Patient satisfaction was measured with the German translation of the International Outcome Inventory for Hearing Aids (IOI-HA) questionnaire. The most relevant results are depicted graphically, with full data presented in text.

SPSS Statistics 19 (IBM, Armonk, N.W., USA) was used (statistical significance set to $p < 0.05$). Repeated-measures ANOVAs were used to evaluate BC and AC over time, Kolmogorov-Smirnov tests to check for normal distribution, and parametric paired-sample t tests to evaluate audiometric and speech testing. For analyses by coupler group, Wilcoxon signed-rank tests were applied due to

Table 1. Enrolled patients: presurgical condition and characteristics

Primary pathology			Degree of hearing loss (PTA 4)			Surgical history		
etiology	n	%	severity	n	%	prior surgeries	n	%
Chronic otitis media	12	40.0	Moderate	1	3.3	One	5	16.7
Cholesteatoma	11	36.7	Moderate/severe	12	40.0	Two	10	33.3
Chronic otitis media/cholesteatoma	4	13.3	Severe	13	43.3	Three	5	16.7
			Profound	4	13.3	Four	4	13.3
Atresia	1	3.3				Five or more	2	6.7
Microtia	1	3.3				Multiple/unspecified	4	13.3
Otosclerosis	1	3.3						

PTA = Pure-tone audiology.

the small sample sizes. Graphs and figures were created using Microsoft Excel and GraphPad Prism 6.0. MED-EL employees designed and monitored this multicenter study and patients will be followed up long-term for 36 months. The statistical analysis plan set out in the study protocol included the handling of missing data using last observation carried forward for missing values from the initial fitting at the following interval if necessary. Single missing values in a test data set were not substituted. In case individuals were not able to elicit a response at the maximal audiometer output intensity at a given frequency, a threshold 5 dB above the maximum audiometer output limit was used to provide a conservative estimated value for the absent response.

Results

Patients

Patients were consecutively enrolled over a period of 14 months from September 2010 to December 2011, and followed up until the final evaluation time point or exclusion. Only adult patients 18 years or older who were either native German speakers or possessed a very good knowledge of the German language were enrolled. Further inclusion criteria included psychological stability and medical and audiological indication criteria for the VSB. Patients with inner ear disorders, ongoing middle ear infections, chronic pain in or around the head, and skin or scalp conditions that may preclude attachment of the audio processor were not included in the study.

The distribution of patients initially recruited at participating clinics was as follows: Berlin (n = 8), Dresden (n = 4), Cologne (n = 5), Rostock (n = 1), Tübingen (n = 7) and Würzburg (n = 5). The demographic characteristics of the enrolled patients were as follows: 17 were female and 13 were male, 2 had purely conductive impairment, and the remainder had mixed hearing loss with an additional sensorineural component. Patients ranged in age from 34 to 77 years (mean age = 58) at surgery. Presurgical conditions and characteristics are provided in table 1. All patients had undergone at least 1 previous surgery in the implanted ear, with most having had multiple prior surgeries. A high percentage of patients had moderately severe to severe hearing loss. Most had had a history of chronic otitis media (40%) or cholesteatoma (36.7%), or a combination of both (13.3%). There was no sign of active disease at the time of implant surgery.

Safety Results

At 12 months postoperatively, data were available for 24 patients. BC results are presented in figure 2. Stable thresholds demonstrated that implantation had no negative effect on residual sensorineural hearing. Mean thresholds remained unchanged between pre- and postoperative testing (p values at frequencies of 0.25–4 kHz ranged from 0.339–0.985).

A total of 6 patients were excluded from the analysis. Preoperative CT scans in 2 patients did not provide sufficient information about accessibility/mobility of the remaining ossicular chain elements, and it was therefore determined during surgery; however, after study enrollment implantation with a coupler was not feasible in these patients. One further patient was dropped from the paired-samples BC and all further data analyses due to deterioration in hearing and resulting concomitant treatment outside the study protocol criteria. In this patient there had been no surgical complications, although the patient's footplate had been found at surgery to be hypermobile. In further clinical follow-up, no indication of underlying disease, in particular Ménière's disease, was

Audiol Neurotol 2016;21:212–222
DOI: 10.1159/000444616

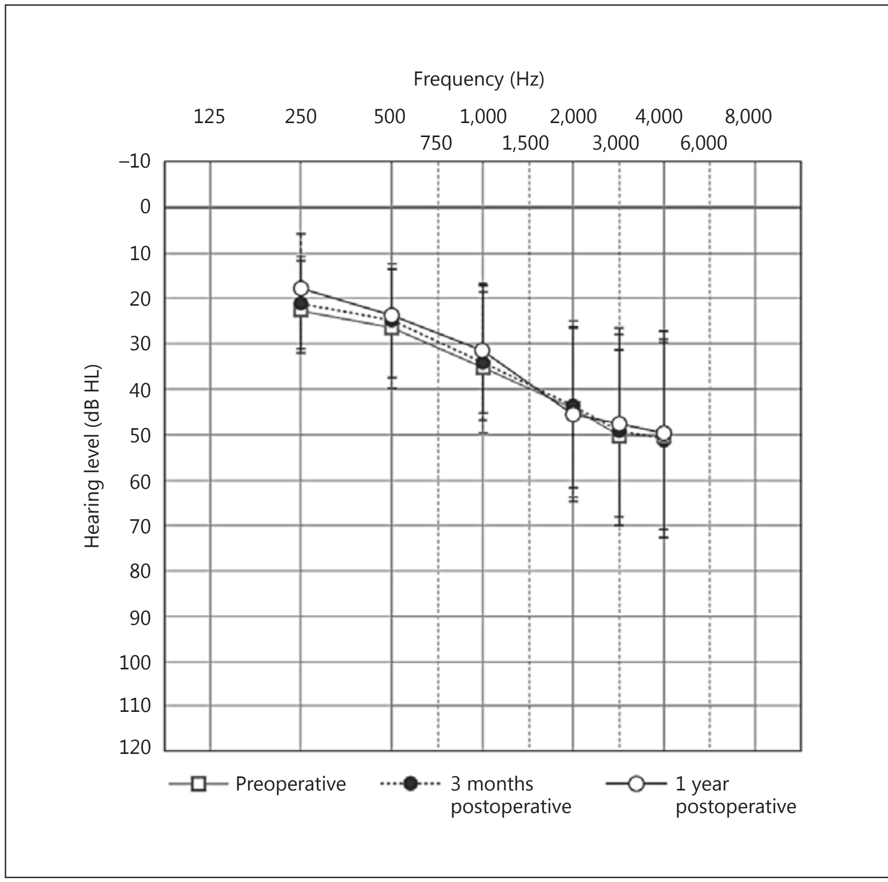

Fig. 2. Mean BC thresholds for all data available at 3 months (n = 27) and 12 months (n = 24) postoperatively. Error bars reflect ± SD.

found. However, the extent of hearing fluctuation already present preoperatively was outside the study parameters and the data had to be excluded. Subjectively, the patient was very satisfied with the VSB and later had the contralateral ear implanted as well.

One patient had been included in short-term postoperative BC analysis, although it turned out postoperatively that the patient was not in sufficient command of the German language. As speech testing results might therefore not have been comparable to the rest of the cohort, the patient was excluded from further analyses.

As is often the case with multiple prior surgeries and chronic or debilitating middle ear conditions, 2 patients could not be evaluated for the entire study period, but their removal from the analyses for the reasons detailed below was not device- or surgery-related and did not introduce bias to the results.

After short-term BC testing, a 77-year-old patient was hospitalized due to a fracture of the femoral bone followed by inflammation-induced acute hearing impairment requiring cortisone therapy on the implanted side and facial palsy on the nonimplanted side. The patient recovered from the facial palsy. The overall medical condition of the patient was not good, and she missed appointments and did not use the audio processor regularly. It was decided, in conjunction with the clinic, to exclude the patient. There is no device relation for the acute hearing impairment and the comorbid occurrences.

One patient's hearing, which was at the edge of the indication criteria before the operation, deteriorated beyond these criteria during the course of the study, and the VSB was replaced with a cochlear implant.

Detailed surgical reporting and follow-up showed the treatment to be safe in this large study cohort. No cases of vertigo or tinnitus were reported. One patient had mild pruritus on the skin under the audio processor, which was resolved by using a weaker attachment magnet in the processor. One patient reported disturbing noises during certain head movements, which was corrected with repositioning surgery in which the Bell coupler was changed to a CliP coupler. In 1 patient in this study (VSB placement at the head of the stapes) tympanoplasty itself was effective.

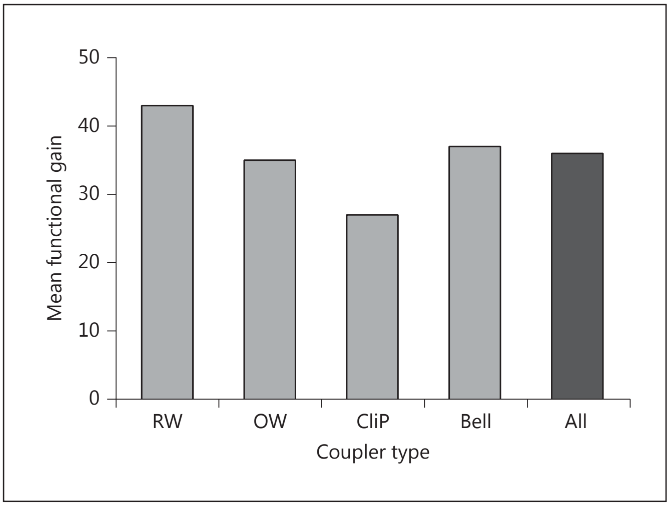

Fig. 3. Functional gain for whole group and each coupler type, calculated using mean free-field warble-tone thresholds for frequencies 0.5, 1, 2 and 4 kHz in the VSB/coupler-implanted ear: preoperative unaided compared with 1-year postoperative aided thresholds.

Audiometric Results

AC audiometry was missing for 1 patient postoperatively, and 1 had to be excluded from warble-tone analysis because the patient's preoperative hearing was so poor that hearing aids had been used to aid preoperative testing, leading to data that were not comparable with the postoperative results of the rest of the cohort. No significant change in AC thresholds was found. Patients were divided according to which coupler they had received, and no statistically significant difference was found between pre- and postoperative mean measurements in any of the coupler groups ($p = 0.23$ to $p = 0.49$ across different frequencies and coupler groups). However, enrollment in some coupler groups was smaller than originally expected. Additionally, patient anatomy in these indications is extremely diverse, and therefore in these smaller samples, conclusions could not be drawn about whether one particular coupler provided better conductive assistance over another.

Functional gain was calculated as the difference between unaided preoperative and 12-month postoperative aided free-field warble-tone testing, with the processor set to each patient's preference and adjusted as necessary during follow-up. As shown in figure 3, the average of the frequencies 0.5, 1, 2 and 4 kHz yielded a functional gain of 36 dB HL for all couplers combined. Individual results of each coupler group were as follows: RW = 43 dB, OW = 35 dB, Bell = 37 dB, CliP = 27 dB. These values exceed clinically significant improvement, measured at 15 dB HL [Maier et al., 2015]. The average preoperative unaided and postoperative aided free-field thresholds, respectively, at the frequencies 0.5, 1, 2 and 4 kHz for each coupler group in dB HL were as follows: RW = 75.44 and 32.06, OW = 76.79 and 41.60, CliP = 60.00 and 32.90, Bell = 73.40 and 36.60. All couplers yielded the expected benefit in the range of a mild hearing loss (30 ± 10 dB HL). The aided free-field threshold for the OW coupler does not fall out of this category as the standard deviation (SD) is ±6.6 dB HL. As seen in figure 4, overall warble-tone thresholds showed a significant improvement over preoperative unaided measurements at all frequencies, and hearing thresholds were best (lowest) at 1.5 kHz.

Word Recognition Scores

Freiburger monosyllables in quiet in the preoperative unaided condition were compared with aided 12-month postoperative results (fig. 5). The mean unaided preoperative word recognition score (WRS) was 2.9% (range 0–40%, SD 9.4) and the VSB-aided mean for all patients was 71% (15–100%, SD 22.4).

However, true effectiveness in individual patients was more applicable to analysis of benefit. All but 3 of the patients had hearing loss causing substantial impairment in speech intelligibility, as shown by preoperative WRS scores of 0%. A significant improvement in the group was shown with the parametric paired-sample t test after approximately normal distribution was demonstrated by the Kolmogorov-Smirnov test ($p < 0.001$).

The Wilcoxon signed-rank test was used for analyses of coupler groups due to the small sample sizes. RW-implanted patients ($n = 9$) improved from unaided preoperative WRS of 0% in all patients to aided mean scores of 73.3% (15–100%, SD 25.9). Significant improvement ($p = 0.008$) was shown. OW-implanted patients ($n = 7$) improved from a mean of 3.6% (0–25%, SD 9.4) to 68.2% (40–95%, SD 19.8). A significant total improvement of 64.6% ($p = 0.018$) was shown.

In 5 patients with the Bell coupler, the preoperative WRS was 0% in all patients and the VSB-aided mean WRS improved to 69% (25–95%, SD 28.8) postoperatively. A significant improvement was shown ($p = 0.041$). In the 3 patients with available data for the CliP coupler, the preoperative unaided WRS was 15% (0–40%, SD 21.8) and the VSB-aided mean was 70% (55–80%, SD 13.2). The mean improvement over preoperative scores was 55%. A significant difference between preoperative unaided testing and 1-year postoperative aided values was

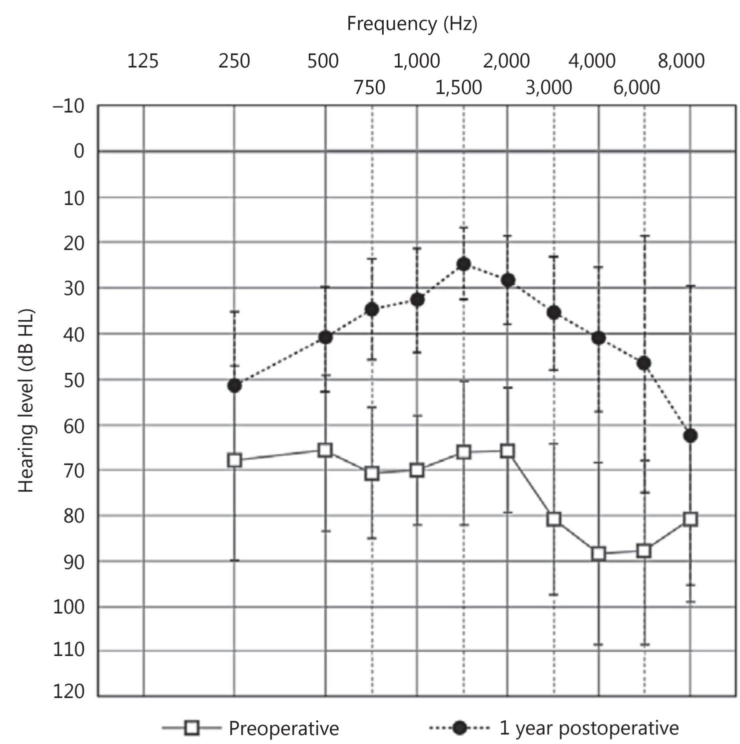

Fig. 4. Mean free-field warble-tone thresholds for the VSB/coupler-implanted ear (n = 23): preoperative unaided compared with 1-year postoperative aided thresholds. Error bars reflect ± SD.

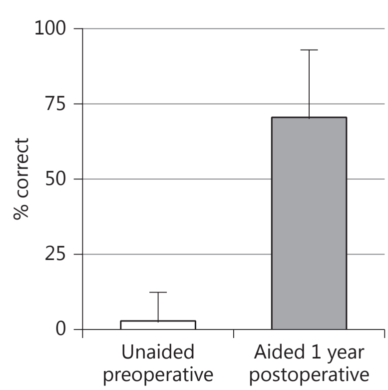

Fig. 5. WRS. Freiburger monosyllables presented at 65 dB SPL. Bars show the SD; top of the column shows the mean (n = 24).

not found (p = 0.109) in this group, probably due to the very small sample size and 1 patient with a high preoperative WRS. However, all individual patients implanted with the CliP coupler demonstrated improved speech recognition (improvements over preoperative scores were 75, 35 and 55% respectively, with total postoperative scores of 80, 75 and 55%). Additionally, the postoperative aided mean in the CliP coupler group (70%) was comparable with the other groups (RW 73.3%, OW 68%, Bell 69%).

OLSA Sentences

The OLSA tested in quiet was used to compare speech perception thresholds with and without the VSB activated at postoperative clinic visits up to 12 months after surgery. SRT_{50} was defined as the dB SPL needed to understand 50% of words in one test list. As shown in figure 6, SRT_{50} improved on average by 23 dB with the VSB activated. The OLSA was also used for SNR, using a test protocol with a fixed background noise level of 65 dB and varied speech signal (fig. 7). All individual test results

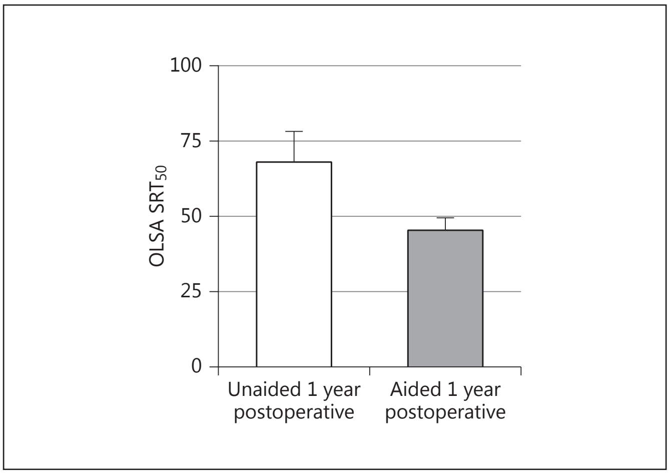

Fig. 6. SRT_{50} in quiet (OLSA sentences) for the implanted ear: postoperative unaided condition compared with VSB/coupler-aided condition. Bars show the SD; top of the column shows the mean (n = 17).

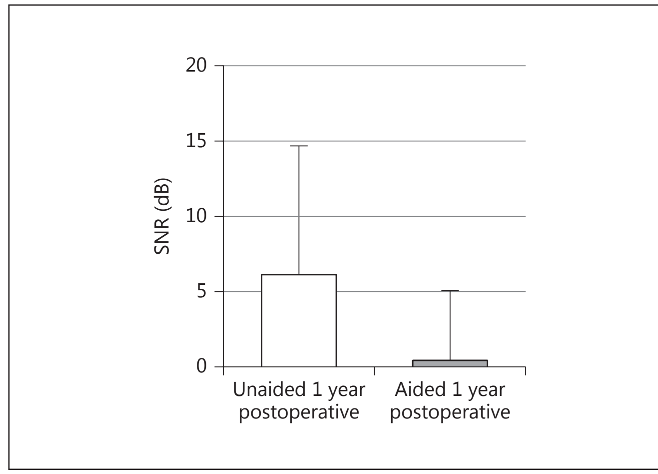

Fig. 7. SNR (OLSA sentences) for the implanted ear (noise level 65 dB SPL, speech level varied): postoperative unaided testing compared with postoperative testing with activated VSB. Bars show the SD; top of the column shows the mean (n = 16).

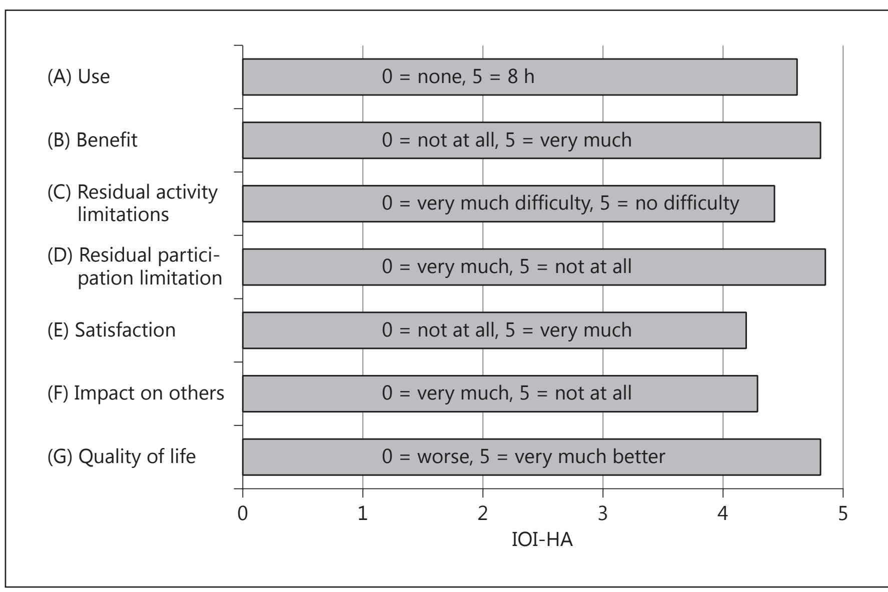

Fig. 8. Patient satisfaction: IOI-HA questionnaire responses from 21 patients, rated from 1 (worst) to 5 (best).

showed improvements in SNR with the VSB activated, demonstrating that speech comprehension in background noise improved for each patient.

Patient Satisfaction: IOI-HA

A German translation of a questionnaire designed to evaluate external hearing aids, the IOI-HA (IIEH in German) [Cox et al. 2002], was answered by 21 patients. This translation carefully follows the design principles of the original version. Heuermann et al. [2005] showed that the psychometric properties of this German translation are to a large extent similar to the English version, and that the German version is a valid self-reporting instrument for evaluating patient satisfaction. Validation of the German translation included a mailing campaign in 2,000 patients (Cronbach's alpha of 0.91) and field tests in 80 patients (Cronbach's alpha of 0.83).

Participants who answered the IOI-HA/IIEH indicated that they were very satisfied with the VSB in all categories. The IOI-HA uses a 5-point rating system (1 = worst to 5 = best) for each of 7 categories (see y-axis in fig. 8). Responses in all categories were well over 4. Almost all patients wore their processor more than 8 h per day (question A). They found the VSB helped either 'quite a lot' or 'very much' in situations where they most wanted to hear better (question B) and that they were able to hear in such situations either with 'no difficulty' at all or with only 'slight difficulty' (question C).

Additionally, patients responded that the VSB was either 'quite a lot' or 'very much' worth the effort of having it implanted and fitted, and wearing it (question D). They answered that it had mitigated their hearing loss so much that the impairment now had minimal, if any, effect on the things they wanted to do in life (question E). They scored questions evaluating 'impact on others' (question F) and 'quality of life' (question G) quite positively as well, with question G 'quality of life' receiving the highest overall score, equal in positive significance with the scoring of question D about whether the implanted device was 'worth the effort'.

Discussion

The development of FMT couplers was driven by the following goals: (1) simplifying vibroplasty by standardizing the different attachment possibilities and (2) improving stability with long-term effectiveness, for which good coupling of the transducer is a critical element [Beleites et al., 2011; Böheim et al., 2012; Zahnert et al., 2010]. Techniques for vibroplasty have expanded to keep pace with treatment indications and are now quite varied in the placement options offered for the FMT. RW vibroplasty differs from other types in that it connects the FMT directly to an inner ear window and not to (remnants of) the ossicular chain. Cartilage or fascia 'packing' can be placed between the FMT and the RW membrane, but fascia may atrophy over time, causing shrinkage and reducing contact between the FMT and the membrane. Careful drilling to widen the RW niche is often required, which could be one drawback to this approach. In comparison with this technique [Colletti et al., 2013; Skarzynski et al., 2014], the RW coupler may improve vibroplasty by adding a more stable substance to the fascia or cartilage (or eliminating the need for it), while also reducing the amount of drilling at the RW niche [Lüers and Hüttenbrink, 2014]. Schwab et al. [2013] state that using the RW coupler is a safer and more effective surgical procedure. It should be noted that the addition of the RW coupler increases the length of the FMT; however, we felt that this did not cause problems during surgery in inserting the FMT in front of the RW niche. It was necessary to carefully drill to remove some bone in the hypotympanic region to use the RW coupler, but this was not much more extensive than the amount removed when not using the RW coupler. This could become a surgical problem if the patient has a high-standing jugular bulb, in which case changing to stapes coupling could be a better option.

Vibroplasty at the stapes or stapes footplate/OW is more similar to standard ossiculoplasty in the surgical approach used. The natural interface between the ossicular chain remnant and OW remains intact, which may be a theoretically more 'natural' or stable construction [Lüers et al., 2013]. Surgical VSB placement poses challenges similar to reconstruction with passive prostheses in needing to achieve a balance between flexibility and stable, minimally invasive attachment to fragile middle ear elements. The advantage of coupler/transducer combinations is a standardized fixation of the FMT to the middle ear, irrespective of the passive sound conduction properties of the coupler/transducer/middle ear remnant combination. Additionally, in contrast to reconstruction using passive prostheses (which are solely driven by the comparatively low energy of airborne sound and must be surrounded by air for optimal function), attenuation caused by a more stable fixation does not play such a decisive role with an active coupler-transducer prosthesis. Therefore, a more stable attachment of the FMT using thick cartilage embedded with fibrin glue can be used, ensuring the long-term stability of the treatment [Lüers and Hüttenbrink, 2014].

Despite the satisfactory overall enrollment of patients with specialized needs examined in this study, a limitation of the study was the difficulty in recruiting a sufficient number of patients with a similar middle ear impairment in each coupler category to make a reliable comparison between groups. This is a common problem in patients with severely impaired middle ears, in which individually tailored surgical solutions are often required. Even in this fairly heterogeneous patient group, however, results showed beneficial stability of all vibroplasty types.

As warble-tone and speech testing demonstrate, all patients showed a substantial improvement in hearing benefit. A less dramatic AC improvement under headphones compared to free-field warble-tone and speech testing may indicate that, in most of these patients, the active transducer is more crucial for auditory rehabilitation than conductive repair. A similar interpretation can be drawn from the postoperative comparisons between unaided and aided SRT_{50} and SNR testing conducted at 12 months postoperatively. An improvement in OLSA testing indicated that activation of the 'direct drive' FMT is beneficial for patients with a high degree of conductive impairment. Particularly in cases when prior reconstruction has failed and the middle ear structure is severely damaged, the additional gain provided by an active transducer in close proximity to the inner ear is an advantage.

In terms of patient satisfaction, an unexpected result was seen with IOI-HA survey results. This survey was chosen because it is a commonly used test for externally worn hearing aids, and could be expected to provide general equivalence for comparison of patient satisfaction with the VSB. The IOI-HA questionnaire was originally developed to score responses of patients after 2 weeks of use with new externally worn hearing aids. As external hearing aid fitting requires no surgery, and the process is much simpler and less invasive than VSB implantation, responses to questions such as whether or not a hearing aid is 'worth the effort' (question D) might be weighted differently when the same questionnaire is used by patients who have just undergone surgery. Question G asks: 'Considering everything, how much has your present hearing aid changed your enjoyment of life?' Again, it might have been expected that the effort and investment involved in vibroplasty (including surgery and multiple clinic visits) detracted from patient satisfaction.

Interestingly though, this group of VSB-implanted respondents scored these questions higher than any others on the IOI-HA. Findings should be balanced against the 3 patients who underwent AC, warble-tone and Freiburger testing but did not answer the IOI-HA, but overall the available results of the IOI-HA indicate that patients were very pleased with the implanted device, and preferred it, regardless of surgical risk and time needed for fitting, to any hearing aids (where possible) or other surgical treatment they had tried prior to VSB implantation. Such data probably indicate the degree to which this patient cohort, all with previous surgeries (up to 5 or more), had been dissatisfied with earlier treatments, including classic ossiculoplasty reconstruction, passive prosthetics and externally worn hearing aids.

This study, therefore, substantiated trends shown in earlier studies, as well as the general direction of current research, and confirmed that the VSB combined with a coupler has been a valuable addition to the toolkit available for the surgical treatment of conductive and mixed hearing loss. The release of the CE-approved 3rd-generation couplers in November 2014 points to the constant development in vibroplasty.

Disclosure Statement

Vibrant MED-EL, Innsbruck, Austria, initiated, organized and monitored this study and gave support for statistical analysis and manuscript preparation.

References

Ball GR: The Vibrant Soundbridge: design and development. Adv Otorhinolaryngol 2010;69:1–13.

Baumgartner WD, Böheim K, Hagen R, Muller J, Lenarz T, Reiss S, Schlogel M, Mlynski R, Mojallal H, Colletti V, Opie J: The Vibrant Soundbridge for conductive and mixed hearing losses: European multicenter study results. Adv Otorhinolaryngol 2010;69:38–50.

Beleites T, Neudert M, Beutner D, Hüttenbrink KB, Zahnert T: Experience with vibroplasty couplers at the stapes head and footplate. Otol Neurotol 2011;32:1468–1472.

Beltrame AM, Todt I, Sprinzl G, Profant M, Schwab B: consensus statement on round window vibroplasty. Ann Otol Rhinol Laryngol 2014;123(10):734.

Bernardeschi D, Hoffman C, Benchaa T, Labassi S, Beliaeff M, Sterkers O, Grayeli AB: Functional results of Vibrant Soundbridge middle ear implants in conductive and mixed hearing losses. Audiol Neurotol 2011;16:381–387.

Böheim K, Mlynski R, Lenarz T, Schlogel M, Hagen R: Round window vibroplasty: long-term results. Acta Otolaryngol 2012;132:1042–1048.

Colletti L, Mandala M, Colletti V: Long-term outcome of round window Vibrant Soundbridge implantation in extensive ossicular chain defects. Otolaryngol Head Neck Surg 2013;149:134–141.

Colletti V, Fiorino FG, Sittoni V: Minisculptured ossicle grafts versus implants: long-term results. Am J Otol 1987;8:553–559.

Colletti V, Soli SD, Carner M, Colletti L: Treatment of mixed hearing losses via implantation of a vibratory transducer on the round window. Int J Audiol 2006;45:600–608.

Cox R, Stephens D, Kramer S: Translations of the International Outcome Inventory for Hearing Aids (IOI-HA). Int J Audiol 2002;41:3–26.

Heuermann H, Kinkel M, Tchorz J: Comparison of psychometric properties of the International Outcome Inventory for Hearing Aids (IOI-HA) in various studies. Int J Audiol 2005;44:102–109.

Huber AM, Ball GR, Veraguth D, Dillier N, Bodmer D, Sequeira D: A new implantable middle ear hearing device for mixed hearing loss: a feasibility study in human temporal bones. Otol Neurotol 2006;27:1104–1109.

Hüttenbrink KB, Beutner D, Bornitz M, Luers JC, Zahnert T: Clip vibroplasty: experimental evaluation and first clinical results. Otol Neurotol 2011;32:650–653.

Hüttenbrink KB, Beutner D, Zahnert T: Clinical results with an active middle ear implant in the oval window. Adv Otorhinolaryngol 2010;69:27–31.

Hüttenbrink KB, Zahnert T, Bornitz M, Beutner D: TORP-vibroplasty: a new alternative for the chronically disabled middle ear. Otol Neurotol 2008;29:965–971.

Iwasaki S, Suzuki H, Moteki H, Miyagawa M, Takumi Y, Usami S: Experience with the Vibrant Soundbridge RW-coupler for round window vibroplasty with tympanosclerosis. Acta Otolaryngol 2012;132:676–682.

Kapur TR, Jayaramchandran S: Long-term results of total ossicular chain reconstruction using autografts. J Laryngol Otol 1992;106:688–691.

Lüers JC, Hüttenbrink KB: Vibrant Soundbridge rehabilitation of conductive and mixed hearing loss. Otolaryngol Clin North Am 2014;47: 915–926.

Lüers JC, Hüttenbrink KB, Zahnert T, Bornitz M, Beutner D: Vibroplasty for mixed and conductive hearing loss. Otol Neurotol 2013;34: 1005–1012.

Maier H, Hinze AL, Gerdes T, Busch S, Salcher R, Schwab B, Lenarz T: Long-term results of incus vibroplasty in patients with moderate-to-severe sensorineural hearing loss. Audiol Neurotol 2015;20:136–146.

Schwab B, Grigoleit S, Teschner M: Do we really need a coupler for the round window application of an AMEI? Otol Neurotol 2013;34: 1181–1185.

Shinohara T, Gyo K, Saiki T, Yanagihara N: Ossiculoplasty using hydroxyapatite prostheses: long-term results. Clin Otolaryngol Allied Sci 2000;25:287–292.

Skarzynski H, Olszewski L, Skarzynski PH, Lorens A, Piotrowska A, Porowski M, Mrowka M, Pilka A: Direct round window stimulation with the MED-EL Vibrant Soundbridge: 5 years of experience using a technique without interposed fascia. Eur Arch Otorhinolaryngol 2014;271:477–482.

Zahnert T, Bornitz M, Hüttenbrink KB: Experiments on the coupling of an active middle ear implant to the stapes footplate. Adv Otorhinolaryngol 2010;69:32–37.