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Long-Term Outcomes of Vibroplasty Coupler Implantations to Treat Mixed/Conductive Hearing Loss

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Keywords

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

Abstract

Objective: To evaluate the long-term safety and performance of four different vibroplasty couplers (round window, oval window, CliP and Bell coupler) in combination with an active middle ear implant. **Methods:** This was a multicentre, prospective, long-term study including 5 German hospitals. Thirty adult subjects suffering from conductive or mixed hearing loss were initially enrolled for the study, 24 of these were included in the final analysis with up to 36 months of postsurgical follow-up data. Bone conduction and air conduction were measured pre- and postoperatively to evaluate safety. Postoperative aided sound field thresholds and

Freiburger monosyllable word recognition scores were compared to unaided pre-implantation results to confirm performance. Additional speech tests compared postoperative unaided with aided results. To determine patient satisfaction, an established quality-of-life questionnaire developed for conventional hearing aid usage was administered to all subjects. **Results:** Mean postoperative bone conduction thresholds remained stable throughout the whole study period. Mean functional gain for all couplers investigated was 38.5 ± 11.4 dB HL (12 months) and 38.8 ± 12.5 dB HL (36 months). Mean word recognition scores at 65 dB SPL increased from 2.9% in the unaided by 64.2% to 67.1% in the aided situation. The mean postoperative speech reception in quiet (or 50%

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understanding of words in sentences) shows a speech intelligibility improvement at 36 months of 17.8 ± 12.4 dB SPL over the unaided condition. The signal-to-noise ratio (SNR) improved by 5.9 ± 7.2 dB SNR over the unaided condition. High subjective device satisfaction was reflected by the International Inventory for Hearing Aids scored very positively. **Conclusion:** A significant improvement was seen with all couplers, and audiological performance did not significantly differ between 12 and 36 months after surgery.

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Introduction

Pathologies that interrupt the ossicular chain are multifactorial and often result in conductive hearing loss [reviewed in Blom et al., 2015]. Reconstruction of the ossicular chain (ossiculoplasty) using passive prostheses of either biological or synthetic origin is standard treatment [Colletti et al., 1987]. Short-term and long-term ossiculoplasty results however can vary significantly [Yu et al., 2013], and poor long-term results are caused by various factors with extrusion and displacement being most common. Moreover, patients who underwent ossiculoplasty very often require a conventional hearing aid (cHA) even after surgery [Cox et al., 2017; De la Cruz and Teufert, 2003]. The additional use of cHAs may be suitable to treat the sensorineural component of the hearing loss. However, some patients may not benefit from cHAs due to medical reasons like allergies or chronic otitis externa.

In order to overcome the limitations of the ossiculoplasty and cHAs for the treatment of conductive or mixed hearing loss, the Vibrant Soundbridge (VSB) was combined with a further development of the Kurz middle ear prostheses, namely the vibroplasty couplers. These passive prostheses are made of the bioinert material titanium which is well tolerated [Meulemans et al., 2013]. The VSB is a transcutaneous, semi-implantable active middle ear implant. The core of the VSB is the floating mass transducer (FMT) which is designed in a way to mimic the natural function of the middle ear. The vibroplasty couplers facilitate the coupling between the FMT and the most suitable vibratory structure of the middle ear. Vibroplasty couplers are available in different designs and thus may be placed either on the stapes footplate (vibroplasty OW coupler), the stapes head (vibroplasty CliP coupler, vibroplasty Bell coupler) or the round window (vibroplasty RW coupler) [Hüttenbrink et al., 2008, 2011]. These vibroplasty couplers are summarized as vibroplasty couplers of the 2nd generation. A detailed de-

scription of the surgical method including illustrations of 2nd-generation coupler placement can be found in the preceding publication [Zahnert et al., 2016]. Recently 3rd-generation couplers which can be either placed on the short or the long process of the incus as well as the round window were developed to complement the range of vibroplasty couplers. The different types account for the anatomical variability in the middle ear compromised by congenital/chronic disease and previous surgeries.

There are several publications that report on vibroplasty coupler usage [Lee et al., 2017; Luers et al., 2013; Müller et al., 2017; Schraven et al., 2016; Schwab et al., 2014; Wang et al., 2016].

The mean study follow-up reporting period regarding vibroplasty coupler usage lies between 3 and 12 months. Consequently, there are only few reports on the long-term safety and performance of the VSB in combination with vibroplasty couplers. Leinung et al. [2016a] evaluated the audiological functional gain in 16 children with uni- and bilateral aural atresia implanted with the VSB in concert with different coupling modalities for up to 36 months after implantation. Schraven et al. [2016] examined the long-term results (up to 84 months) of 83 subjects implanted with a VSB in combination with different FMT positions either with or without the use of a vibroplasty coupler. The retrospective design is a limitation of this study. The duration of the follow-up of patients included in a VSB/coupler study published by Zhao et al. [2016] was between 3 and 41 months. A restriction of this study was the relatively small number of subjects included ($n = 9$). Moreover, only one coupler type, namely the RW vibroplasty coupler, was studied in 7 subjects. The present multicentre study aims to report, confirm and extend evidence of the long-term performance and safety of the VSB system in combination with vibroplasty couplers up to 36 months after VSB surgery. In addition, interim data of the same study collected up to 1 year after VSB [Zahnert et al., 2016] implantation should be substantiated by additional data provided in the present publication.

Material and Methods

Subjects and Materials

This prospective, single subject repeated measures study collected data between September 2010 (first subject in) and March 2016 (study close-out).

The analytic population of 24 subjects (10 males and 14 females) was followed up to 36 months after VSB implantation (VORP 502) originally at 5 university hospitals in Germany, after approval by the ethics committee (Freiburg, FEKI code 010/2050).

Table 1. Patients' demographics

| ID | Age, years | Gender | Implant side | Coupler | AC PTA ₄ | BC PTA ₄ | HL type | Severity | Aetiology | Previous ear surgeries |
|----|------------|--------|--------------|---------|---------------------|---------------------|---------|-------------------|-------------------------|------------------------|
| 01 | 66 | F | R | RW | 85 | 38 | MHL | severe | COM | 2 |
| 02 | 54 | F | L | RW | 81 | 44 | MHL | severe | COM | 1 |
| 03 | 72 | F | R | RW | 81 | 58 | MHL | severe | COM/ cholesteatoma | 2 min. |
| 04 | 73 | F | L | RW | 96 | 51 | MHL | profound | COM | 1 min. |
| 05 | 52 | M | L | RW | 68 | 25 | MHL | moderately severe | COM | unknown |
| 06 | 66 | F | R | RW | 84 | 50 | MHL | severe | cholesteatoma | multiple |
| 07 | 68 | F | R | RW | 76 | 60 | MHL | severe | COM | 3 min. |
| 08 | 46 | M | R | RW | 56 | 15 | CHL | moderately severe | COM/ cholesteatoma | multiple |
| 09 | 49 | M | L | RW | 77 | 29 | MHL | severe | microtia | 2 |
| 10 | 46 | F | L | OW | 89 | 49 | MHL | severe | cholesteatoma | 5 min. |
| 11 | 54 | M | R | OW | 78 | 50 | MHL | severe | cholesteatoma | 2 min. |
| 12 | 44 | F | R | OW | 73 | 47 | MHL | severe | COM | 3 |
| 13 | 34 | M | R | OW | 88 | 59 | MHL | severe | cholesteatoma | 5 min. |
| 14 | 55 | M | R | OW | 64 | 30 | MHL | moderately severe | cholesteatoma | 4 min. |
| 15 | 61 | F | R | OW | 56 | 16 | CHL | moderately severe | cholesteatoma | 3 min. |
| 16 | 60 | F | L | OW | 60 | 27 | MHL | moderately severe | COM/ cholesteatoma | multiple |
| 17 | 71 | M | R | CliP | 89 | 33 | MHL | severe | cholesteatoma | 4 |
| 18 | 66 | M | R | CliP | 63 | 25 | MHL | moderately severe | COM/L, cholesteatoma | 2 min. |
| 19 | 51 | F | L | CliP | 100 | 53 | MHL | profound | COM | 4 min. |
| 20 | 56 | F | L | Bell | 68 | 30 | MHL | moderately severe | COM | 2 min. |
| 21 | 68 | M | L | Bell | 94 | 49 | MHL | profound | cholesteatoma | 1 min. |
| 22 | 64 | M | L | Bell | 69 | 48 | MHL | moderately severe | COM | 1 |
| 23 | 75 | F | L | Bell | 71 | 47 | MHL | severe | COM | 3 |
| 24 | 69 | F | R | Bell | 62 | 27 | MHL | moderately severe | cholesteatoma | 2 |

AC, air conduction; BC, bone conduction; HL, hearing loss; PTA₄, pure-tone average at 0.5, 1, 2 and 4 kHz; min., minimum; MHL, mixed hearing loss; CHL, conductive hearing loss; COM, chronic otitis media; L, left; R, right; RW, round window; OW, oval window.

One centre in Rostock included only 1 subject with insufficient knowledge of the German language, and thus the centre was excluded from the final analysis. Another 5 subjects were not part of the final analysis of the study for the following reasons: 2 subjects were not implanted with a vibroplasty coupler due to anatomical/pathological conditions found during surgery; a deterioration of the general health status was the reason for study exclusion of another subject; 2 other subjects were excluded due to ageing-related deterioration of the remaining hearing threshold beyond indication criteria. One subject was pre-operatively already out of indication and inclusion criteria for bone conduction (BC) at 3 kHz (75 dB HL) and at 4 kHz (85 dB HL). The other subject had pre-existing unstable BC thresholds. No surgical complications were reported for this subject. In a further safety clinical follow-up, no indication of an underlying disease was found. Subjectively, the patient was very satisfied with the device and underwent a second VSB implantation on the contralateral ear.

A VSB in combination with a vibroplasty coupler of the 2nd generation was implanted in all included subjects. All subjects suffered from either conductive ($n = 2$) or mixed hearing loss ($n = 22$) and did either not benefit from cHAs or underwent failed recon-

struction surgeries. Pre-operative mean air conduction (AC) and BC pure-tone average (PTA₄) thresholds were at 76.1 ± 12.8 and 39.8 ± 13.63 dB HL, respectively. Subjects suffered from moderately severe ($n = 9$) over severe ($n = 12$) to profound ($n = 3$) hearing loss. Additional study inclusion and exclusion criteria are reported elsewhere [Zahnert et al., 2016]. The FMT was connected to the stapes (CliP coupler $n = 3$ or Bell coupler $n = 5$), the oval window (OW coupler $n = 7$) or the round window (RW coupler $n = 9$). Based on the medical findings and the anatomical conditions, the responsible surgeon decided on the respective coupler usage.

The mean age of the 24 analysed subjects was 59 years (range: 34–75 years). All included subjects had undergone at least one previous ear surgery in the implanted ear. For most subjects the aetiology of the hearing impairment was chronic otitis media ($n = 10$) or cholesteatoma ($n = 9$), or a combination of both ($n = 4$). One subject suffered from microtia. For demographic details please refer to Table 1.

Audiological Assessments

Audiometric testing was conducted in an audiometric sound-attenuated room, using calibrated signals and equipment accord-

ing to accepted ISO standards. All included subjects were evaluated at regular intervals to include 1 pre-operative evaluation and 6 postoperative evaluations (initial activation (IA), 3, 6, 12, 24 and 36 months postoperatively). The IA of the audioprocessor took place 6–8 weeks after surgery.

Pure-Tone Audiometry

AC (0.5–8 kHz) and BC (0.5–4 kHz) pure-tone thresholds were tested for both ears using insert earphones, headphones or a calibrated BC vibrator, as appropriate, on each ear individually. Pre-operative unaided PTA₄ (0.5, 1, 2 and 4 kHz) thresholds were compared to postoperative VSB unaided thresholds.

Sound Field Audiometry

Sound field tests were conducted under the S₀N₀ configuration with the contralateral ear plugged with deeply inserted foam earplugs (3M Earplugs 1100 or similar; signal-to-noise ratio, SNR = 37 dB) and covered with ear muffs (3M Peltor ×5 or similar; SNR = 37 dB). To calculate the functional gain (FG), pre-operative unaided sound field thresholds (SF) were compared to postoperative aided SF thresholds. Speech intelligibility was tested by word recognition scores (WRS), speech reception thresholds in quiet (SRT) and in noise as an SNR. The WRS measured by the Freiburger Monosyllables at 65 dB SPL in quiet compared pre-operative unaided to postoperative aided scores. SRT and SNR measured by the Oldenburger Sentence (OLSA) test compared postoperative unaided with aided thresholds in quiet and in noise. The SRT₅₀ was defined as the level needed to understand 50% of words in a list. The SRT₅₀ was tested in quiet (SRT) and with a fixed background noise level at 65 dB SPL and varying speech levels (SNR).

Subjective Device Satisfaction

Subjective satisfaction with the VSB was measured with the German translation (IIEH) of the International Outcome Inventory for Hearing Aids (IOI-HA) questionnaire. The questionnaire was administered pre-operatively only to subjects who had used a CHA before middle ear implantation.

Safety Measures

Pre-operative BC PTA₄ thresholds were compared to those measured at 12 and 36 months after surgery. Safety was further monitored with otoscopy, medical examination and surgical reports. Adverse events (AE) were recorded and if possible followed up until the events were resolved.

Statistical Analyses

IBM SPSS Statistics 19.0 (IBM, Armonk, New York, NY, USA) was used for all analyses reported in the work. Graphs, figures and tables were created using Microsoft Excel and Graphpad Prism 6.0. A confidence level of 95% and above ($p < 0.05$) indicated statistical significance.

Inferential statistics was applied to AC, BC, SF, WRS, SRT and SNR outcomes for the whole group as well as for the 3 separate coupler groups. Subjects were divided into 3 different coupler groups depending on the FMT's position in the middle ear: stapes group including Bell and CliP coupler (stapes), round window group (RW) and the oval window group (OW). A Kolmogorov-Smirnov test showed that data are not normally distributed, therefore the Friedman test was applied to test for a significant change over the tested intervals pre-operatively, at IA, 12 months and 36

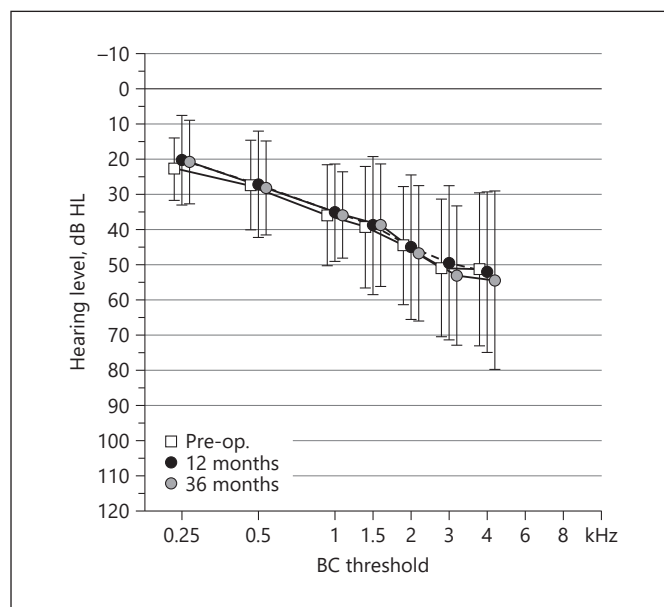


Fig. 1. Mean BC thresholds for all subjects comparing pre-operative with 12-month ($n = 27$) and 36-month ($n = 24$) postoperative thresholds. Error bars reflect \pm SD.

months postoperatively. The Wilcoxon signed-rank test was used for post hoc pairwise comparisons, i.e. to test for a significant difference between the tested intervals. For SRT and SNR the Wilcoxon signed-rank test compared unaided and aided SRT/SNR at IA, 12 months and 36 months. p values for the Wilcoxon signed-rank test were adjusted with the Bonferroni correction ($p < 0.017$). Improvements reported here result from the population of the pairwise analysis. To avoid repetitions, the IA time point is not shown in the present work; however, the Bonferroni-corrected p value of $p < 0.017$ must still be applied.

Results

Safety Results

AC PTA₄ thresholds remained stable throughout the tested intervals ($p = 0.145$), and no change greater than ± 5 dB in residual hearing was observed for the whole subject group. Also, no statistically significant difference was found between pre- and postoperative mean AC PTA₄ measurements in any of the coupler groups (RW: $p = 0.495$; OW: $p = 0.231$; stapes: $p = 0.507$).

As indicated in Figure 1b and c, thresholds remained stable throughout the whole study period. The post hoc Wilcoxon signed-rank test found no statistically significant difference between pre- and postoperative BC PTA₄ values (12 months: $p = 0.841$ and 36 months: $p = 0.235$) for the whole group. Again, no statistically significant dif-

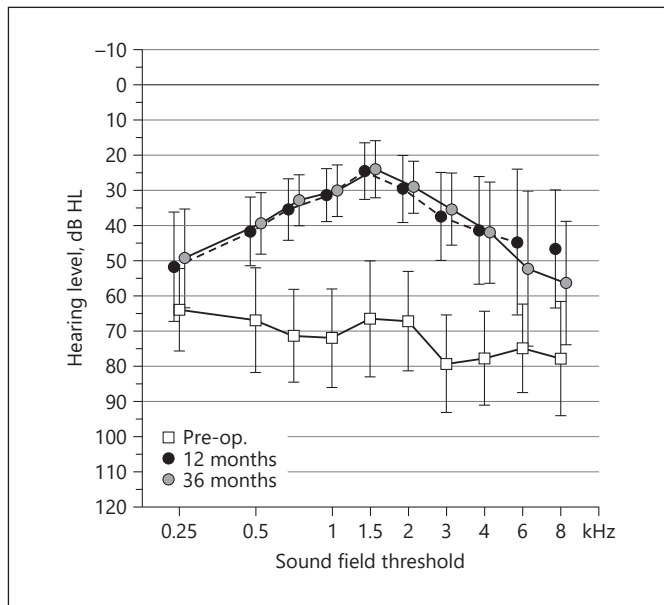


Fig. 2. Mean sound field thresholds measured with warble tones for the VSB/coupler-implanted ear ($n = 23$): pre-operative unaided compared with 12- and 36-month postoperative aided thresholds. Error bars reflect \pm SD.

ference was found between pre- and postoperative mean BC PTA_4 measurements in any of the coupler groups (RW: 12 months: $p = 0.141$ and 36 months: $p = 0.833$; OW: 12 months: $p = 0.31$ and 36 months: $p = 0.933$; stapes: 12 months: $p = 0.128$ and 36 months: $p = 0.327$). On average no more than a ± 5 dB change in BC PTA_4 was observed indicating that the implantation had no negative effect on residual hearing. Considering however individual BC PTA_4 thresholds at 36 months postoperatively a decrease by more than 10 dB (commonly accepted test/retest range; Acoustical Society of America: ANSI-S3.21.2004) in 1 subject (see Table 1: ID 20) was observed. This subject experienced a BC PTA_4 decrease of 20 dB after undergoing two revision surgeries.

Thirty-six months postoperatively a total of 33 AE was reported for 24 subjects. 28 of these 33 AE were neither related to the device nor to the procedure. 5 AE were assessed as procedure related, 3 thereof were serious AE. The 2 non-serious AE affected 2 subjects. One subject (ID 23) had mild pruritus on the skin under the audioprocessor. This event was resolved by using a weaker attachment magnet in the processor. The other subject (ID 19) had cephalalgia and otalgia but this condition was resolved without any treatment. The 3 reported serious AE concerned 3 subjects. One subject (ID 01) experienced a perforation of the eardrum on the VSB-implanted side

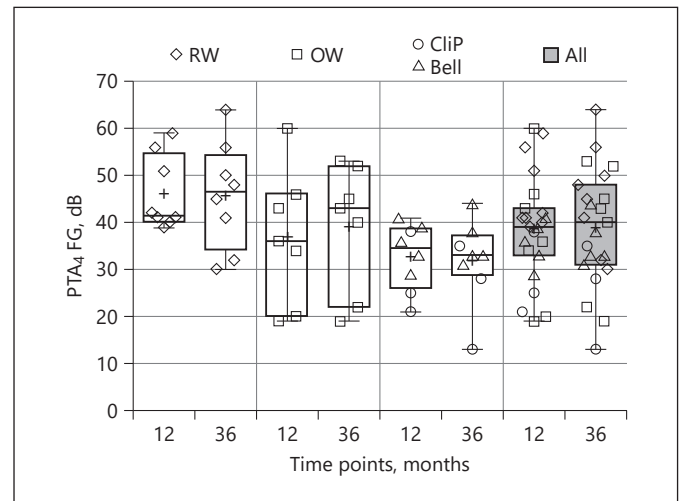


Fig. 3. PTA_4 functional gain (FG) for 12 and 36 months postoperatively for the whole group and each coupler subgroup. The different coupler groups are shown as separate boxes and are marked differently (the diamond refers to the RW coupler group, the hexagon refers to the OW coupler group, the circle refers to the CliP stapes coupler group and the pyramid refers to the Bell stapes coupler group); the grey box refers to the overall study population including all coupler types. Boxes extend from the 25th to the 75th percentiles. The line in the middle represents the median, the + is the mean and the circles are individual values.

3 months after surgery. A myringoplasty resolved this event. Due to decreased hearing a subject (ID 03) underwent reposition surgery. Still another subject (ID 20) reported disturbing noises during certain head movements and had to undergo two revision surgeries (the same subject experienced the BC PTA_4 decrease of 20 dB). The originally implanted Bell coupler was exchanged by a CliP coupler and finally also this coupler was removed and the FMT was directly coupled to the round window.

Sound Field Thresholds and Functional Gain

As indicated in Figure 2 SF measured with warble tones improved at 12 and 36 months over pre-operative unaided measurements at all frequencies, and hearing thresholds were best at 1.5 kHz. The PTA_4 of these thresholds significantly ($n = 23$, $p < 0.001$) improved from 74 ± 12.9 dB HL pre-operatively unaided to 36.0 ± 8.2 dB HL at 12 months and 35.1 ± 6.7 dB HL at 36 months postoperatively aided. SF remained stable without significant change between 12 and 36 months ($p = 0.509$).

The FG calculated as the difference between unaided pre-operative and 12- as well 36-month postoperative aided SF PTA_4 thresholds yielded an FG for the whole group of 38.5 ± 11.4 dB FG at 12 months and of $38.8 \pm$

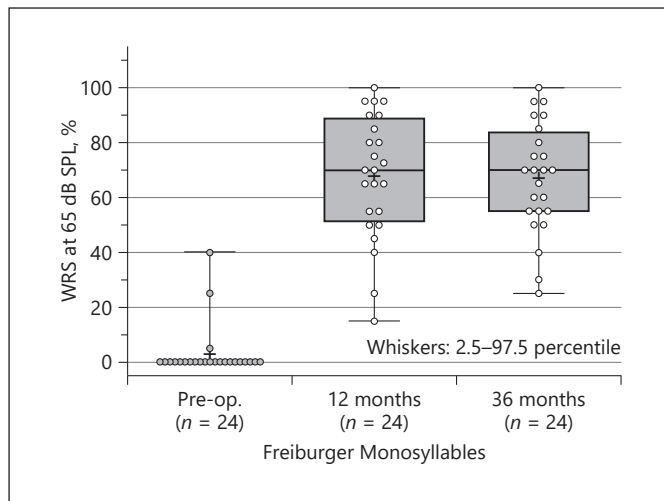


Fig. 4. Word recognition score (WRS) as measured by the Freiburg Monosyllable test presented at 65 dB SPL. Pre-operative unaided WRS (%) compared to postoperative VSB-aided 12-month and 36-month data. Boxes extend from the 25th to the 75th percentiles. The line in the middle represents the median, the + is the mean and the circles are individual values.

12.5 dB FG at 36 months (Fig. 3). The clinically significant end point of 10 dB FG at one or more frequencies was reached for all subjects. For 1 subject implanted with the RW coupler no pre-operative values were available but postoperative aided SF thresholds were at 46.5 dB HL at 12 months and 31.5 dB HL at 36 months.

Individual results for each coupling group were as follows: RW coupler ($n = 8$; $p = 0.002$) 46.2 ± 8.1 dB FG (12 months) and 45.8 ± 11.5 dB FG (36 months); OW coupler ($n = 7$; $p = 0.002$) 36.6 ± 14.6 dB FG (12 months) and 38.9 ± 13.6 dB FG (36 months); stapes coupler (includes Bell and CliP; $n = 8$; $p = 0.002$) 32.5 ± 7.0 dB FG (12 months) and 31.7 ± 9.1 dB FG (36 months).

Word Recognition Scores

Considering pooled coupler groups, the mean unaided pre-operative WRS at 65 dB SPL was $2.9 \pm 9.4\%$, the aided mean WRS at the 12-month evaluation was $67.8 \pm 20.2\%$ and the mean aided WRS at 36 months was $67.1 \pm 20.2\%$ (Fig. 4). WRS improvement was significant ($n = 24$, $p < 0.001$). No significant difference was calculated when comparing 12-month postoperative data with 36-month postoperative data ($p = 0.852$), indicating that the benefit provided by the VSB in combination with any coupler is stable throughout 36 months. All individual subjects implanted with the VSB independent of the couplers used, demonstrated improved speech recognition

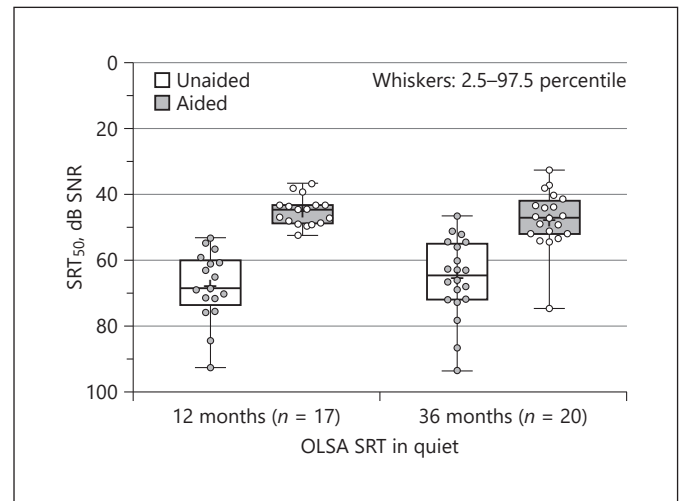


Fig. 5. SRT_{50} in quiet as measured by OLSA sentences for the VSB-implanted ears. Postoperative unaided conditions at 12 and 36 months were compared with the corresponding aided conditions. Boxes extend from the 25th to the 75th percentiles. The line in the middle represents the median, the + is the mean and the circles are individual values.

by far more than 10% which was regarded as clinically significant value.

Eight subjects implanted with a stapes coupler (Bell or CliP) significantly ($p = 0.002$) improved from an average unaided pre-operative WRS of $5.6 \pm 14.0\%$ to $61.3 \pm 22.2\%$ at 12 months postoperatively and $57.5 \pm 20.9\%$ at 36 months. The WRS remained stable between 12 and 36 months ($p = 0.526$). Nine subjects received an RW coupler and significantly ($p < 0.001$) improved from 0% WRS pre-operatively to $73.3 \pm 26.0\%$ at 12 and $72.2 \pm 15.6\%$ at 36 months postoperatively. The WRS remained significantly stable between 12 and 36 months ($p = 0.752$). Seven OW implanted subjects significantly ($p = 0.002$) improved from a mean pre-operative WRS of $3.6 \pm 9.5\%$ to $68.2 \pm 19.8\%$ at 12 and $71.4 \pm 23.2\%$ at 36 months postoperatively. Like for all other coupler types the WRS did not change from 12 to 36 months postoperatively ($p = 0.752$).

Speech Intelligibility in Quiet and in Noise

The OLSA compared speech reception thresholds in quiet (SRT) and in noise (SNR) with and without the VSB activated at postoperative clinical assessments up to 36 months after implantation. At the 12-month evaluation the SRT_{50} improved from 67.8 ± 10.5 dB SPL in the unaided to 45.2 ± 4.4 dB SPL in the aided condition (mean improvement: 22.7 ± 11 dB SPL; $n = 17$). Similarly, at 36

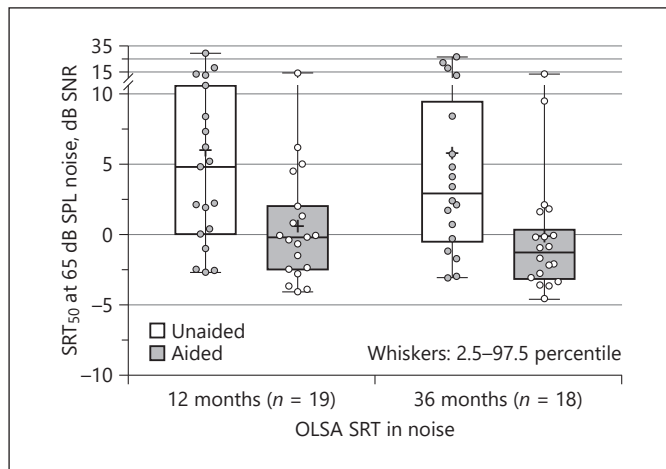


Fig. 6. SNR measured by SRT_{50} at a fixed noise level of 65 dB SPL with varying speech levels. Postoperative unaided testing at 12 and 36 months was compared to the respective VSB-aided condition. Boxes extend from the 25th to the 75th percentiles. The line in the middle represents the median, the + is the mean and the circles are individual values.

months the SRT_{50} improved from 65.4 ± 11.9 dB SPL in the unaided to 47.6 ± 8.8 dB SPL in the aided condition (mean improvement: 17.8 ± 12.4 dB SPL; $n = 20$) (Fig. 5). Both SRT differences between unaided and aided are significant with a p value of ≤ 0.001 . No significant difference between aided 12- and 36-month data was found ($p = 0.825$).

The SNR changed from 6.0 ± 8.2 dB SNR at the unaided 12-month evaluation to -0.2 ± 4.5 dB SNR in the aided condition (mean improvement: 5.4 ± 5.2 dB SNR; $n = 19$). At the 36-month evaluation the SNR improved from 5.8 ± 8.7 dB SNR in the unaided to -0.2 ± 4.7 dB SNR in the aided condition (mean improvement: 5.9 ± 7.2 dB SNR; $n = 18$). Mean SNR differences between unaided and aided conditions 12 and 36 months postoperatively were significant ($p \leq 0.001$) (Fig. 6). Again, no change in SNR was observed between 12 and 36 months ($p = 0.082$). This result clearly demonstrates that speech intelligibility in noise improved.

IOI-HA, Patient Satisfaction

Subjective device satisfaction/benefit was evaluated by the IOI-HA consisting of 7 answer categories on a 5-point rating system (1 = worst to 5 = best) [Cox and Alexander, 2002]. The IOI was answered by 10 subjects before VSB implantation who were using cHAs and by 23 subjects 12 and 36 months after VSB implantation.

All participants who answered the IOI-HA were very satisfied with the VSB in all categories.

The responses to all categories given resulted in a score above 4 and a mean score of 4.61 ± 0.8 at 12 and of 4.5 ± 0.8 at 36 months postoperatively. In contrast, the mean satisfaction for 10 subjects wearing cHAs pre-operatively ranged between 2 and 2.9 (mean = 2.39 ± 1.23).

Discussion

The main objectives of the vibroplasty coupler development were the following: (1) standardizing the different FMT attachment possibilities, (2) providing additional options to install the VSB in patients with mixed and conductive hearing loss and (3) improving stability of the transducer at the respective anatomical structure of the middle ear in order to enable long-term performance and safety of the VSB.

The 4 different couplers assessed in this study facilitate the placement of the FMT at 3 different structures (stapes, OW, RW) of the middle ear. In contrast to the other vibroplasty techniques that couple the FMT to parts or remnants of the ossicular chain, the RW vibroplasty directly couples the FMT to an inner ear window, sometimes using fascia or cartilage between FMT and inner ear membrane. The advantage of coupler usage in RW vibroplasty is obvious as unstable or insufficient FMT attachment to the RW membrane may be ineffective in transferring vibratory energy supplied by the audioprocessor [Lassaletta et al., 2015]. This finding is supported by Olzowski et al. [2017], who reported that better FMT coupling can be achieved by using interposed material such as tissue or RW coupler especially for cases where the RW niche is smaller than the diameter of the FMT. The RW coupler provides a more stable FMT connection compared to fascia fixation, which may become atrophic over time and affects coupling efficacy. FMT migration encountered in RW vibroplasty without coupler usage is an undesired side effect and is reported by different authors [Baumgartner et al., 2010; Marino et al., 2015]. Schraven et al. [2016] report on high revision surgery numbers of up to 71% in RW vibroplasty without coupler usage. We observed a revision surgery rate of 11% in the RW coupler group (1/9) which is in agreement with previous works [Skarzynski et al., 2014; Zhao et al., 2016]. Although an ossicular attachment point for the FMT is surgically less challenging than RW vibroplasty which requires drilling of the RW niche, RW vibroplasty using the RW coupler is the best alternative for cases where no ossicular chain is present. The present study however showed that the use of the RW coupler did not pose any additional risks com-

pared to the vibroplasty techniques that couple to structures of the ossicular chain (Bell and CliP coupler, OW coupler). One subject allocated to the stapes coupling group had to undergo two revision surgeries, thus the revision rate (2 out of 8) of this group is comparable to that of the RW coupler group. Overall, medical as well as surgical complications did not exceed the expected ranges for middle ear surgeries [Fiedler et al., 2013; Govil et al., 2017]. All serious AE were either not or probably not device related.

Moreover BC and AC PTA₄ thresholds remained stable up to 36 months after surgery for the whole subject collective, indicating that the VSB implantation is an atraumatic procedure which preserves residual hearing over a long term. According to the Acoustical Society of America (ANSI-S3.21 2004), a difference of 10 dB between 2 PTA assessments does not represent a significant difference for the subject in terms of hearing perception. One subject experienced a BC PTA₄ decrease of more than 10 dB. This finding may be attributed to the two revision surgeries that were performed in this subject. In general, it can be expected that deteriorations of BC thresholds in the long term may be reflected by physiological alterations due to ageing or other, physiological or pathological effects [Gates et al., 2008] and are therefore unlikely to be related to VSB in combination with vibroplasty couplers.

Subjects included in the present study experienced at least one previous middle ear surgery. Thus, the enrolment of subjects with similar middle ear impairments in each coupler category was difficult. Nevertheless, in this fairly heterogeneous subject group suffering from moderate, profound or severe hearing loss all subjects experienced a hearing improvement up to 36 months postoperatively as investigated by FG and speech intelligibility. Consequently, each coupler type may be chosen according to the anatomical condition as the coupler type did not affect safety or benefit from the VSB. The FG calculated as the difference between unaided pre-operative and 12-month as well as 36-month postoperative aided sound field thresholds yielded an FG of 38.5 ± 11.4 (12 months) and of 38.8 ± 12.5 dB HL (36 months) for the whole subject group. All coupler types performed similarly without a significant difference between coupler groups. Analysis of published studies demonstrated hearing gains of 28–55 dB for FMT coupling to the oval window, the stapes and the round window without any coupler. These values are not significantly different than those measured in the present study; however, couplers offer a standardized coupling procedure compared with non-established

methods for the single point attachment of the FMT [reviewed in Luers et al., 2013]. Besides long-term safety, proven by stable residual hearing and improved hearing thresholds, improvement in speech intelligibility is one of the crucial outcome measures in the evaluation of a treatment success in hearing rehabilitation. Mean postoperative, VSB-aided word recognition scores at 12 and 36 months resulted in 67.8 and 67.1%, respectively. Our findings are in good agreement with those from previous studies including vibroplasty couplers in which WRS at 65 dB SPL of around 70% were reported [Brito et al., 2016; Busch et al., 2016; Hüttenbrink et al., 2004; Müller et al., 2017; Schraven et al., 2016; Schwab et al., 2014; Wang et al., 2016; Zhao et al., 2016]. The treatment success in speech intelligibility is further supported by a mean SRT improvement of 22.7 dB SPL at 12 months and of 17.8 dB SPL at 36 months postoperatively. Similar findings are published by Frenzel et al. [2015], who reported on VSB implantations using couplers in children.

To understand speech in background noise may be the most challenging situation for every hearing device user. In the present study the SNR significantly improved from +5.75 dB SNR in the unaided to -0.17 dB SNR in the aided condition 36 months after implantation (improvement: -5.5 dB SNR). This result goes in line with an SNR improvement of -4.33 dB SNR reported by Brito et al. [2016].

Interestingly, between 12 and 36 months neither a further improvement nor a deterioration regarding audiological and speech intelligibility performance was detected indicating that the plateau was reached already earlier than 12 months postoperatively. Encouragingly, subjects are still benefitting from the device to the same extent as observed in the interim analysis.

Although Leinung et al. [2016b] did not report on any FMT dislocation during the follow-up period of up to 36 months, one revision surgery reported here was necessary 20 months after surgery. Overall a revision surgery rate of 8.3% can be reported for this study. Similar rates were found for other studies using vibroplasty couplers for FMT positioning (4.4–22%) [Busch et al., 2016; Ihler et al., 2014; Zhao et al., 2016]. In addition, VSB implantation with conventional incus or round window vibroplasty concluded revision rates between 3.8 and 18.8% [Gregoire et al., 2018; Maier et al., 2015; Marino et al., 2015].

Health-related quality of life is often considered to be an important end point of health care interventions. Improvement in health-related quality of life is highly subjective and does not necessarily correlate with objectively measurable clinical benefits. This work however clearly

shows that clinically measurable outcomes like PTA and sound field audiometry correlate with the results of the IOI-HA questionnaire over an assessment period of 36 months after VSB implantation. For the IOI-HA, Cox and Alexander [2002] defined scores of 1 or 2 on an item as non-beneficial outcomes. All subjects implanted with the VSB, regardless of the coupler used, showed scores for each of the 7 items higher than 4. The results show a substantial amount of benefit, satisfaction and improvement in quality of life for patients implanted with a VSB during a 3-year usage period.

Conclusion

This is the first prospective study that shows in a large cohort of subjects that the VSB in combination with different vibroplasty couplers provides a stable and long-term solution for patients suffering from mixed or con-

ductive hearing loss. No significant deterioration in audiological benefit was detected across the study period of 36 months. In comparison to conventional vibroplasty coupling the FMT to the long process of the incus or the round window, vibroplasty couplers allow on the one hand more surgical flexibility in a variety of challenging anatomies combined with a higher degree of standardization on the other hand. Audiological benefit reported in this study was comparable to data of other studies on the VSB in combination with vibroplasty couplers. Safety concerns were outweighed as the VSB regardless of the coupler type used was beneficial for each study participant.

Disclosure Statement

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

References

- Baumgartner WD, Böheim K, Hagen R, Müller J, Lenarz T, Reiss S, et al. The Vibrant Soundbridge for conductive and mixed hearing losses: European multicenter study results. *Adv Otorhinolaryngol*. 2010;69:38–50.
- Blom EF, Gunning MN, Kleinrensink NJ, Lokin AS, Bruijnzeel H, Smit AL, et al. Influence of Ossicular Chain Damage on Hearing After Chronic Otitis Media and Cholesteatoma Surgery: A Systematic Review and Meta-analysis. *JAMA Otolaryngol Head Neck Surg*. 2015 Nov;141(11):974–82.
- Brito R, Pozzobom Ventura LM, Jorge JC, Oliveira EB, Manzoni Lourencone LF. An Implantable Hearing System As Rehabilitation for Hearing Loss Due to Bilateral Aural Atresia: Surgical Technique and Audiological Results. *J Int Adv Otol*. 2016 Dec;12(3):241–6.
- Busch S, Lenarz T, Maier H. Comparison of alternative coupling methods of the Vibrant Soundbridge floating mass transducer. *Audiol Neurotol*. 2016;21(6):347–55.
- Colletti V, Fiorino FG, Sittoni V. Minisculptured ossicle grafts versus implants: long-term results. *Am J Otol*. 1987 Nov;8(6):553–9.
- Cox MD, Trinidad A, Russell JS, Dornhoffer JL. Long-Term Hearing Results After Ossiculoplasty. *Otol Neurotol*. 2017 Apr;38(4):510–5.
- Cox RM, Alexander GC. The International Outcome Inventory for Hearing Aids (IOI-HA): psychometric properties of the English version. *Int J Audiol*. 2002 Jan;41(1):30–5.
- De la Cruz A, Teufert KB. Congenital aural atresia surgery: long-term results. *Otolaryngol Head Neck Surg*. 2003 Jul;129(1):121–7.
- Fiedler T, Boeger D, Buentzel J, Esser D, Hoffmann K, Jecker P, et al. Middle ear surgery in Thuringia, Germany: a population-based regional study on epidemiology and outcome. *Otol Neurotol*. 2013 Jul;34(5):890–7.
- Frenzel H, Sprinzl G, Streitberger C, Stark T, Woltenberg B, Wolf-Magele A, et al. The Vibrant Soundbridge in Children and Adolescents: Preliminary European Multicenter Results. *Otol Neurotol*. 2015 Aug;36(7):1216–22.
- Gates GA, Feeney MP, Mills D. Cross-sectional age-changes of hearing in the elderly. *Ear Hear*. 2008 Dec;29(6):865–74.
- Govil N, Kaffenberger TM, Shaffer AD, Chi DH. Factors influencing hearing outcomes in pediatric patients undergoing ossicular chain reconstruction. *Int J Pediatr Otorhinolaryngol*. 2017 Aug;99:60–5.
- Gregoire A, Van Damme JP, Gilain C, Bihin B, Garin P. Our auditory results using the Vibrant Soundbridge on the long process of the incus: 20 years of data. *Auris Nasus Larynx*. 2018 Feb;45(1):66–72.
- Hüttenbrink KB, Beutner D, Bornitz M, Luers JC, Zahnert T. Clip vibroplasty: experimental evaluation and first clinical results. *Otol Neurotol*. 2011 Jun;32(4):650–3.
- Hüttenbrink KB, Zahnert T, Bornitz M, Beutner D. TORP-vibroplasty: a new alternative for the chronically disabled middle ear. *Otol Neurotol*. 2008 Oct;29(7):965–71.
- Hüttenbrink KB, Zahnert T, Wüstenberg EG, Hofmann G. Titanium clip prosthesis. *Otol Neurotol*. 2004 Jul;25(4):436–42.
- Ihler F, Bewarder J, Blum J, Matthias C, Canis M. Long-term functional outcome and satisfaction of patients with an active middle ear implant for sensorineural hearing loss compared to a matched population with conventional hearing aids. *Eur Arch Otorhinolaryngol*. 2014;271:3161–9.
- Lassaletta L, Calvino M, Sánchez-Cuadrado I, Pérez-Mora RM, Muñoz E, Gavilán J. Pros and Cons of Round Window Vibroplasty in Open Cavities: Audiological, Surgical, and Quality of Life Outcomes. *Otol Neurotol*. 2015 Jul;36(6):944–52.
- Lee JM, Jung J, Moon IS, Kim SH, Choi JY. Benefits of active middle ear implants in mixed hearing loss: stapes versus round window. *Laryngoscope*. 2017 Jun;127(6):1435–41.
- Leinung M, Zaretsky E, Ernst BP, Trier B, Stover T, Hey C. [Vibrant Soundbridge(R): An alternative hearing system for preschool children with aural atresia]. *Laryngorhinootologie*. 2016a Sep;95(9):E1. German.
- Leinung M, Zaretsky Y, Ernst B, Vaerst B, Stöver T, Hey C. [Vibrant Soundbridge®: An Alternative Hearing System for Preschool Children with Aural Atresia]. *Laryngorhinootologie*. 2016b Sep;95(9):627–33.
- Luers JC, Hüttenbrink KB, Zahnert T, Bornitz M, Beutner D. Vibroplasty for mixed and conductive hearing loss. *Otol Neurotol*. 2013 Aug;34(6):1005–12.
- Maier H, Hinze AL, Gerdes T, Busch S, Salcher R, Schwab B, et al. Long-term results of incus vibroplasty in patients with moderate-to-severe sensorineural hearing loss. *Audiol Neurotol*. 2015;20(2):136–46.

- Marino R, Lampacher P, Dittrich G, Tavora-Vieira D, Kuthubutheen J, Rajan GP. Does coupling and positioning in vibroplasty matter? A prospective cohort study. *Otol Neurotol*. 2015;36(7):1223–30.
- Meulemans J, Wuyts FL, Forton GE. Middle ear reconstruction using the titanium Kurz Variac partial ossicular replacement prosthesis: functional results. *JAMA Otolaryngol Head Neck Surg*. 2013 Oct;139(10):1017–25.
- Müller A, Mir-Salim P, Zellhuber N, Helbig R, Bloching M, Schmidt T, et al. Influence of Floating-Mass Transducer Coupling Efficiency for Active Middle-Ear Implants on Speech Recognition. *Otol Neurotol*. 2017 Jul;38(6):809–14.
- Olszewski L, Jedrzejczak WW, Piotrowska A, Skarzynski H. Round window stimulation with the Vibrant Soundbridge: comparison of direct and indirect coupling. *Laryngoscope*. 2017 Dec;127(12):2843–9.
- Schraven SP, Gromann W, Rak K, Shehata-Dieler W, Hagen R, Mlynski R. Long-term stability of the active middle-ear implant with floating-mass transducer technology: A single-center study. *Otol Neurotol*. 2016;37(3):252–66.
- Schwab B, Salcher R, Teschner M. Comparison of two different titanium couplers for an active middle ear implant. *Otol Neurotol*. 2014 Oct;35(9):1615–20.
- Skarzynski H, Olszewski L, Skarzynski PH, Lorens A, Piotrowska A, Porowski M, et al. Direct round window stimulation with the Med-El Vibrant Soundbridge: 5 years of experience using a technique without interposed fascia. *Eur Arch Otorhinolaryngol*. 2014;271:477–82.
- Wang D, Zhao S, Zhang Q, Li Y, Ma X, Ren R. Vibrant SoundBridge combined with auricle reconstruction for bilateral congenital aural atresia. *Int J Pediatr Otorhinolaryngol*. 2016 Jul;86:240–5.
- Yu H, He Y, Ni Y, Wang Y, Lu N, Li H. PORP vs. TORP: a meta-analysis. *Eur Arch Otorhinolaryngol*. 2013;270:3005–17.
- Zahnert T, Löwenheim H, Beutner D, Hagen R, Ernst A, Pau HW, et al. Multicenter Clinical Trial of Vibroplasty Couplers to Treat Mixed/Conductive Hearing Loss: first Results. *Audiol Neurotol*. 2016;21(4):212–22.
- Zhao S, Gong S, Han D, Zhang H, Ma X, Li Y, et al. Round window application of an active middle ear implant (AMEI) system in congenital oval window atresia. *Acta Otolaryngol*. 2016;136(1):23–33.