

ORIGINAL RESEARCH

The Hannover Coupler V2: Audiological outcomes of a round window coupler for the Vibrant Soundbridge

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Abstract

Introduction: The Hannover Coupler version 2 (HC2) was designed to (1) adapt the coupler geometry to the round window (RW) niche (2) to stabilize the floating mass transducer, and (3) to control static coupling forces to the RW. First audiological outcomes with a custom-made HC2 are reported here.

Material and Methods: Ten patients were enrolled in our site-initiated, prospective study. To assess audiological outcomes up to 6 months, preoperative and postoperative hearing thresholds, word recognition score (WRS) at 65 dB SPL and the speech recognition threshold in quiet and noise were performed. The effective gain (EG) and the coupling efficiency were calculated.

Results: One revision surgery had to be performed during the study period and a significant, but clinically not relevant bone conduction thresholds change was observed at 4 and 6 kHz at 6-month follow-up. At 6 months, the median WRS ($n = 10$) improved significantly from 0% to 80%. The median speech reception threshold in noise improved significantly from 11.6 to -2.4 dB SNR, and in quiet significantly from 79.6 to 44.4 dB SPL. The average EG of -1.3 dB indicated a closure of the air bone gap. The determined average coupling efficiency of 23.3 dB was within the acceptance range suggested by the manufacturer.

Conclusion: For patients with mixed hearing loss and multiple ear surgeries, the HC2 provided good and stable speech recognition results exceeding published results of RW coupling without a coupler or coupling with the RW soft coupler.

KEYWORDS

Hannover Coupler V2, mixed hearing loss, round window coupling, Vibrant Soundbridge

1 | INTRODUCTION

The Vibrant Soundbridge (VSB, MED-EL) is an active middle ear implant (AMEI) with a floating mass transducer (FMT) providing vibratory stimulation to the ossicles or directly to the cochlear windows

LOE Level I Ib.

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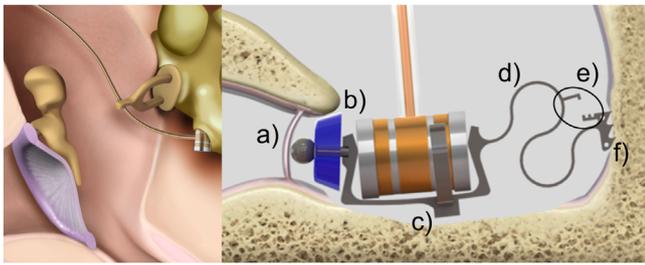


FIGURE 1 Left: Vibrant Soundbridge directly coupled to the inner ear. Right: The Hannover Coupler V2 with (a) ball tip with a diameter of 0.5 mm, (b) silicone shield (blue), (c) cage for the floating mass transducer, (d) spring, (e) indicator for the applied force, and (f) the anchor

(Figure 1, Left). For more than 25 years, the VSB is successfully used to treat patients with hearing loss, which do not benefit from conventional hearing aids.^{1,2} In patients with pure sensorineural hearing loss, the FMT is typically attached to the long process of the incus of the ossicular chain.³ In 2005, Colletti et al.⁴ successfully implanted the VSB with the FMT at the cochlear round window (RW). This milestone enables the treatment of patients with mixed and conductive hearing loss. Subsequently, other coupling sites like the stapes or oval window were investigated to expand treatment options.⁵⁻⁹

Regarding the RW coupling, clinical outcomes suffered from large variations.¹⁰⁻¹² Main reasons are the mismatch of the diameter of the FMT and the RW membrane¹³ and the surgically challenging placement of the FMT at the RW.¹⁴ The RW niche must be enlarged to fit the FMT, especially the bone close to the RW membrane, to improve the contact between RW membrane and FMT. Although drilling close to the RW membrane can cause cochlear noise trauma,¹⁵ studies confirmed stable bone conduction (BC) thresholds after RW coupling of the FMT.^{11,16,17}

One approach to improve the coupling of the FMT to the RW membrane was to use interposed materials like fascia.^{17,18} Additionally, couplers such as the hemispherical titanium RW-coupler¹⁹ or the conically shaped silicone soft coupler²⁰ were developed. Both couplers improved the audiological outcomes, but did not decrease their variation. It was demonstrated that the coupling quality depends on the static preload of the RW membrane with an optimal range of 5 to 20 mN.²¹⁻²⁴ However, the applied forces are usually unknown.

In recent years, a new coupler for the RW was designed, termed “Hannover Coupler” (HC1),²⁴ addressing all previously mentioned challenges. The custom-made design has a small ball tip on a rod allowing an automatic centering of the coupling point and overcoming the diameter mismatch, reducing the drilling of the bony overhang.^{13,25} The FMT is held in the cage of the coupler, and a spring at the rear end ensures a stable positioning with controlled force on the RW membrane. One case of a patient provided with the HC1 was published and showed good audiological results.²⁶ Based on the experiences with the HC1, a new improved version was designed.

In this subsequent study presented here, we observed the performance of the redesigned and optimized custom-made device (CMD)

version of the HC termed “Hannover Coupler V2” (HC2) in a series of clinical application.

2 | MATERIAL AND METHODS

2.1 | The Hannover Coupler V2

The redesigned coupler has a movable silicone shield between ball tip and FMT cage to avoid bone contact of the FMT and long-term migration into the RW (Figure 1, Right). This coupler has an s-shaped spring, including an anchor at the rear end to stabilize positioning in the RW niche and a visual indicator for the applied force close to the anchor. The indicator has two indication pins next to the anchor. The correspondence of the upper pin with one of the lower pins indicates forces of 5 mN (first pin) and 20 mN (second pin), respectively. The range of 5 to 20 mN is the suggested range of applied forces for successful RW coupling with the VSB.^{24,27}

2.2 | Study design

This prospective, investigator-initiated, study was designed to observe and monitor the use of the custom-made HC2 during clinical routine at the Department of Otorhinolaryngology, Hannover Medical School in a systematic framework. Patients intended for implantation with a VSB with RW application were screened for the treatment with the HC2, supplied as CMD by the manufacturer (MED-EL) for each individual, according to the medical device directive.^{28,29} Criteria for study participation was a BC threshold within the indication range (± 5 dB) for the VSB coupled to the RW and a written consent to participate in the study. The study was approved by the local ethics committee (EC approval 3593-2017) and comprised four appointments with audiometric testing, including a preoperative appointment to assess the unaided baseline (PreOP), the initial activation (IA) with fitting of the processor 6–8 weeks after surgery and a 3- and 6-month follow-up (3M, 6M).

2.3 | Subjects

Between May 2017 and April 2021, 13 patients were treated with the HC2 in conjunction with the VSB, and the first 10 patients who agreed to participate and gave their informed consent were enrolled. The cohort included five female and five male patients with a mean age of 58.6 ± 10.1 years (min. 47.1–max. 75.7 years) at surgery. All patients suffered from mixed hearing loss, most of them with a pronounced air-bone gap (ABG >30 dB, $n = 9$), and underwent multiple ear surgeries prior to implantation and participation in this study. During the observational period, one revision (ID09) was performed, despite unproblematic performance of the device, and good speech perception of the patient, due to an occurring dysacusis. In this case, the date of the re-implantation with a new implant was considered as the onset of participation in the study. Until May 1st, 2021, all subjects completed the 6M

TABLE 1 Demographics of enrolled patients

Pat ID	Age [years]	Etiology	Known previous surgeries	Known number of surgeries	4PTA _{AC} [dB HL]	4PTA _{BC} [dB HL]	4PTA _{SF} [dB HL]
ID01	70.5	Otosclerosis	Multiple tympanoplasties	2	73.8	36.3	56.3
ID02	51.8	COE	Subtotal petrosectomy, obliteration, VSB-OW (explanted)	17	66.3	18.8	68.8
ID03	75.7	COM, PIMMF	Subtotal petrosectomy, obliteration	4	86.3	25.0	86.3
ID04	47.1	COM, Cholesteatoma	Subtotal petrosectomy, obliteration, mastoidectomy	4	86.3	36.3	80.0
ID05	70.4	PIMMF, COE, COM	Mastoidectomy, multiple tympanoplasties	2	43.8	27.5	36.3
ID06	54.7	Cholesteatoma	Subtotal petrosectomy, Obliteration	3	108.8	55.0	100.0
ID07	57.2	COM, Cholesteatoma	Subtotal petrosectomy, obliteration	4	81.3	17.5	60.0
ID08	52.4	COM - epitympanic	Subtotal petrosectomy, obliteration	4	105.0	26.3	77.5
ID09	48.5	Unknown	Multiple tympanoplasties	2	47.5	15.0	51.3
ID10	57.3	COE, Ossicle chain disruption	Multiple tympanoplasties	Unknown	95.0	17.5	62.5

Abbreviations: AC, air conduction; BC, bone conduction; COE, chronic otitis externa; COM, chronic otitis media; PIMMF, post-inflammatory medial meatal fibrosis; PTA4, average at 0.5, 1, 2, 3, 4 kHz; SF, sound field threshold; VSB-OW, VSB coupled to the oval window.

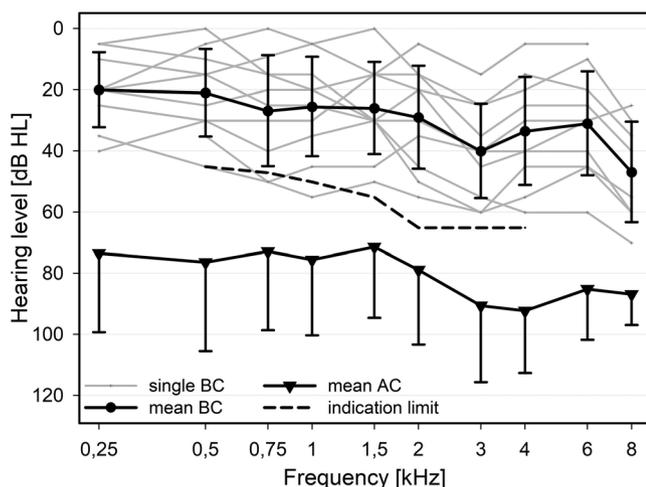


FIGURE 2 Preoperative mean (\pm standard deviation) BC (black circles) and AC (black triangles) thresholds ($n = 10$). Individual BC thresholds for each patient are depicted as light gray lines. The lower indication limit of the VSB for round window application is indicated by the dashed black line. AC, air conduction; BC, bone conduction; VSB, Vibrant Soundbridge

appointment and their data were analyzed. Demographic details, etiologies, known previous surgeries and the preoperative average air conduction (4PTA_{AC}), BC (4PTA_{BC}), and unaided sound field (SF) thresholds (4PTA_{SF}) are shown in Table 1 and Figure 2.

2.4 | Audiometric testing

Audiometric tests were performed in sound proof rooms with calibrated audiometers. They included pure tone air (AC) and BC

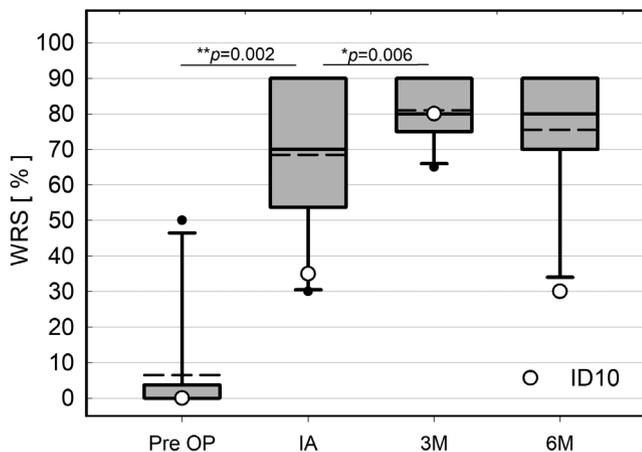
thresholds (via headphones), SF thresholds with warble tones and speech perception in quiet and noise, with the contralateral side plugged and muffled. The vibrogram threshold (V_{thr}) was determined by direct stimulation of the implant via the processor (also known as in situ measurement) at each postoperative appointment (IA, 3M, 6M). When the audiometer limit was reached, the threshold was estimated as the audiometer limit plus 5 dB as best-case estimate. This estimation was needed for five subjects for preoperative AC and unaided SF threshold (ID03, ID04, ID06, ID08, and ID10) for 0.5, 2, 3, 4, and 6 kHz. The pure tone average was taken as the mean value at 0.5, 1.0, 2.0, 4.0 kHz. The word recognition score (WRS) was assessed with the Freiburg monosyllable test at 65 dB SPL presentation level. For patients with a preoperative WRS of 0% at 80 dB SPL, a WRS of 0% at 65 dB SPL was assumed (ID01, ID02, ID03, ID06). The German matrix test (Oldenburg sentence test [OLSA]) was performed in quiet (speech reception threshold; SRT_{50%} [dB SPL]) and noise (signal-to-noise ratio; SRT_{50%} [dB SNR]) with the Oldenburg Measurement Application (OMA, Hörtech GmbH). The OLSA measurements of the unaided baseline situation were performed in two cases postoperatively before the IA (ID02, ID07) with the device switched off. Patients with a 4PTA_{AC} \geq 47 dB HL are not able to hear the noise of 65 dB SPL.³⁰ As in these cases the measured SNR reflects the SRT, we limited the SNR results to a maximum of 12 dB SNR.

The effective gain (EG), defined as the aided SF threshold deducted from the postoperative BC threshold, was calculated for each frequency at 6M. A positive EG indicates an overclosure of the air-bone gap. The coupling efficiency was determined as the BC threshold deducted from the in situ threshold V_{thr} . For thresholds, EG, and the coupling efficiency, the mean was calculated across four frequencies (0.5, 1, 2, and 4 kHz). At IA, patients were provided with SAMBA sound processors. Furthermore, the mean daily wearing time of the processor was assessed.

TABLE 2 Changes in bone conduction thresholds preoperatively versus 6M appointment ($n = 10$)

Frequency [kHz]	0.5	1	1.5	2	3	4	6
Mean [dB]	3.0	2.5	1.5	1.5	-2.0	5.5	9.0
SD [dB]	6.3	8.9	10.3	6.3	6.3	7.6	9.9
Min [dB]	-5.0	-10.0	-10.0	-5.0	-10.0	-5.0	-5.0
Max [dB]	15.0	20.0	25.0	15.0	10.0	20.0	25.0
<i>p</i>	.168	.397	.656	.309	.343	.037	.019

Abbreviations: *p*, significance of paired *t*-test; SD, standard deviation.

**FIGURE 3** Freiburg monosyllable test results ($n = 10$). Solid lines depict the median, dashed lines, the mean, and whiskers, the 5th/95th percentile. Significant differences are indicated above the box plots (Wilcoxon signed rank test). Results of subject ID10 are highlighted (white circles).

2.5 | Statistical analysis

Data analysis was performed using SigmaPlot 14 (Systat Software Inc.). Data were checked for normal distribution (Shapiro–Wilk test). The paired *t*-test was used in case of parametric data distribution, and the paired Wilcoxon signed-rank test was used for nonparametric data. Mean values are always given with the standard deviation (mean \pm SD) throughout the text. Results of nonparametric data are given with median and additionally with (mean \pm SD) to establish comparability with other studies. If data were missing, the corresponding results were not considered in the analysis.

3 | RESULTS

3.1 | Pure tone audiometry

Preoperative and postoperative (6M) BC thresholds were compared and statistically analyzed for each frequency between 0.5 and 6 kHz. Up to 3 kHz, changes in residual hearing were not significant (Table 2). However, a significant decrease of 7.6 and 9.0 dB was found at 4 kHz (*t*-test, $p = .037$) and 6 kHz (*t*-test, $p = .019$), respectively.

Comparing BC and the AC thresholds, the preoperative mean (0.5, 1, 2, 4 kHz) air-bone gap (4PTA_{ABG}) was at least 51.6 dB \pm 19.3 dB ($n = 10$, best estimate). An average EG (0.5, 1, 2, 4 kHz) of -1.3 ± 14.1 dB at 6M was achieved. The highest mean EG was found at 1 kHz with 4.0 ± 16.8 dB, and the lowest mean EG was found at 0.5 kHz with -8.5 ± 16.3 dB.

The lowest coupling efficiency was found at 0.5 kHz with a mean of 35.5 ± 19.8 dB HL (ranging from 10 dB to 75 dB). The highest coupling efficiency was achieved at 3 kHz with a mean of 14.5 ± 13.4 dB (ranging from -5 to 35 dB).

3.2 | Speech recognition

The median WRS in quiet improved significantly from preoperative 0% to 70% ($66.5\% \pm 23.1\%$) at IA (Wilcoxon signed Rank test, $p = .002$). In addition, the median WRS increased significantly from IA to 3M to 80% ($81.0\% \pm 8.1\%$) (Wilcoxon signed rank test, $p = .006$). Results remained stable at 6M, with a median of 80% ($75.0\% \pm 17.8\%$) and 9 out of 10 subjects achieving a WRS $\geq 70\%$. Results of the Freiburg monosyllable test in quiet are shown in Figure 3. Subject ID10 experienced a pronounced decline in WRS from 80% at 3M follow-up to 30% at 6M.

Speech recognition thresholds were available for eight subjects, since two subjects declined to participate. The median speech recognition threshold in quiet (SRT_{50%} [dB SPL], Figure 4, Left) significantly improved from 79.6 dB SPL (75.0 ± 20.2 dB SPL) preoperative to 44.4 dB SPL (45.8 ± 4.6 dB SPL) at 6M (Wilcoxon signed rank test, $p = .016$). Also, the median speech recognition threshold in noise (SRT_{50%} [dB SNR], Figure 4, Right) significantly improved from a median of 11.6 dB SNR (7.5 ± 6.9 dB SNR) preoperative to -2.4 dB SNR (-1.4 ± 3.3 dB SNR) at 6M appointment (Wilcoxon signed rank test, $p = .023$).

4 | DISCUSSION

The coupling efficiency, synonymous with the efficiency of the vibration transmission between FMT and RW membrane, is reduced by the diameter mismatch of the FMT and the RW membrane as well as by coupling forces that are outside the optimal range.^{13,20–22,24} The HC2 was designed to enable standardized coupling and optimize the coupling efficiency, and thereby to reduce the variability in clinical outcomes.

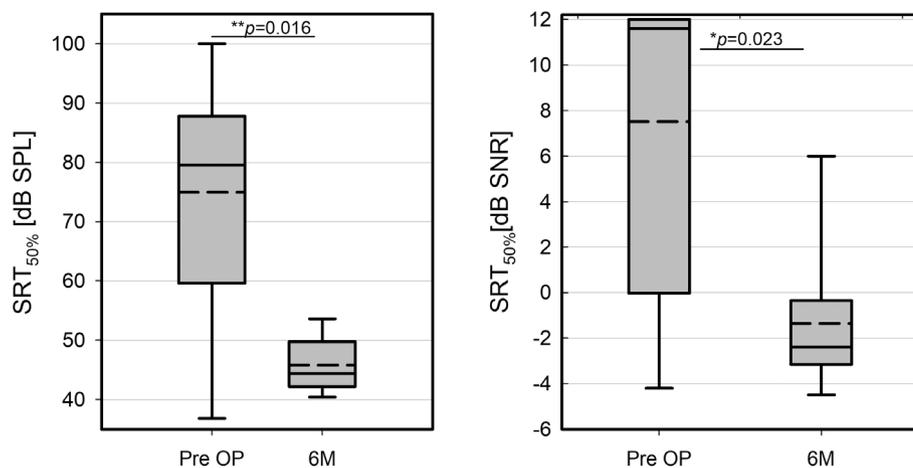


FIGURE 4 Results of speech perception (OLSA). Left: Speech reception threshold in quiet. Right: In noise preoperative and at 6M appointment ($n = 8$). Significant differences are indicated above the box plots (Wilcoxon signed rank test). Solid lines depict the median, dashed lines, the mean, and whiskers, the 5th/95th percentile.

This study intended to investigate the audiological outcome of the new RW coupler HC2 as a custom-made device. Although all subjects had a long history of ear surgeries (up to 17 known surgeries on the treated ear) and a mixed hearing loss, good audiological outcomes 6 months after implantation were achieved.

Our study showed a statistically significant, although clinically not relevant, increase in BC threshold at 4 and 6 kHz at 6M. Examination of threshold data identified three subjects (ID03, ID06, and ID07) with a pronounced decrease in BC threshold of up to 20 dB at 4 or 6 kHz between first and last appointments. For two subjects, the decrease (ID03 20 dB at 4 kHz, ID04 25 dB at 6 kHz) only occurred at 6M. Both subjects had suffered from intermittent tinnitus, which can have a masking effect on threshold measurements. In subsequent measurements the thresholds were comparable to the preoperative ones. For subject ID07, fluctuating BC thresholds were found across all frequencies, and at every preoperative and postoperative threshold measurement, with a 4PTA_{BC} varying from 15 to 28.8 dB. The observed increase of BC thresholds in these three cases were not permanent and possibly not related to the surgery or the device. The observation of transient hearing loss in higher frequencies accords with other studies.^{17,31} Skarzynski et al.¹⁷ suggest that the short-term increase in BC thresholds can be caused by healing effects after surgery like swelling and tissue growth. Furthermore, Maier et al.³¹ show that slow, age-related hearing loss can be compensated to a certain degree with refitting of the audio processor.

The average EG of $-1.3 \text{ dB} \pm 14.1 \text{ dB}$ indicates the closure of the air-bone gap. At 0.5 kHz, the minimum EG of $-8.5 \text{ dB} \pm 16.3 \text{ dB}$ and the minimum coupling efficiency of $35 \text{ dB} \pm 19.8 \text{ dB}$ may be caused by two different reasons. On the one hand, vibration transmission at 0.5 kHz is generally lower than for other frequencies.³²⁻³⁴ On the other hand, the low EG at 0.5 kHz can be caused by a too high preload between FMT and RW membrane.²⁴ Nevertheless, a certain amount of preload is required to ensure efficient transmission at higher frequencies. Speech recognition in quiet and noise increased significantly after IA. With a maximum increase between IA and 3M appointment, results were stable at the 6M appointment, when subjects achieved an aided median WRS in quiet of 80% ($75.0\% \pm 17.8\%$). This exceeded

the results of patients with RW coupling in other publications, for example in Zahnert et al.³⁵ ($73.3\% \pm 26.0\%$, $n = 9$, RW Titan Coupler), Sprinzl et al.³⁶ ($51.8\% \pm 26.6\%$, $n = 31$, without coupler) and Rahne et al.¹² ($62.9\% \pm 24\%$, $n = 9$, RW soft coupler). Even with a BC threshold exceeding the indication limit, good audiological results were achieved (ID01 90% WRS, ID06 70% WRS).

The study cohort of Zahnert et al.³⁵ included 24 subjects with coupling to the RW ($n = 9$), oval window, ($n = 7$) and stapes ($n = 8$). The achieved mean SRT_{50%} in quiet of $45.2 \pm 4.5 \text{ dB SPL}$ ($n = 17$) is comparable to our findings. However, in noise, our results were slightly better ($-0.2 \pm 4.5 \text{ dB SNR}$ vs. $-1.4 \pm 3.3 \text{ dB SNR}$).

The daily wearing time of 14 to 18 h per day ($15.4 \pm 1.3 \text{ h/day}$) indicates a high satisfaction with the implanted system.

In our cohort of 10 participants, one subject (ID09) needed a revision surgery of the VSB during the study period. This subject suffered from dysacusis with an intermittent improvement after endonasal pansinusitis surgery. As the dysacusis continued, an adenotomy and a revision were performed. The subject had a good coupling efficiency and a WRS of 80% to 100% during all appointments before and after revision. During the study period, no device (implant and coupler) or surgery related revision was necessary in the investigated group.

However, for subject ID10, the WRS increased from 35% (IA) to 80% at the 3M appointment and decreased again to 30% at the 6M appointment. A revision surgery was intended and then postponed, after the patient achieved a WRS of 65% and a SRT_{50%} in noise of -3.2 dB SNR 2 months later. A computer tomography suggested a possible bone contact of the FMT. The changes of WRS scores and in situ measurements over the observation period also make an instable coupling in this subject likely.

The RW coupling is appropriate for patients with dysfunctional or missing ossicular chain, often caused by diseases like cholesteatoma or chronic otitis media, and the subsequent necessary surgeries. Furthermore, patients with a fixed ossicular chain due to otosclerosis, if a satisfactory hearing improvement cannot be achieved with passive prostheses.^{10,37} For this reason, it is common for the patients to have a long history of ear surgeries. For example, the study cohort in Zahnert et al.³⁵ underwent two previous ear surgeries on average

with two subjects that underwent at least five previous ear surgeries. In our study, subjects underwent 4–6 ear surgeries prior to the implantation of the VSB. One subject (ID02) had at least 17 ear surgeries and achieved finally 90% WRS with the HC2.

High revision rates for RW coupling can occur for three reasons: recurrent cholesteatoma, cable extrusion or insufficient audiological rehabilitation. For recurrent cholesteatoma, obliteration of open cavities is a favorable treatment.^{38,39} Cable extrusion occurs in patients with open cavities, often due to recurrent cholesteatoma and can also be prevented by obliteration.^{36,40} At our clinic, obliteration of open cavities and cholesteatoma is a standard procedure prior to the implantation of an AMEI. One criterion for revision surgery is a WRS of less than 50% at 65 dB SPL.³³ This strict policy is often not used for clinical studies, considering the published speech perception results of a WRS <50%.^{11,36,41} In our study, we followed this revision policy, which only would have led to one (postponed) revision (ID10). No further adverse events were reported.

An alternative treatment option for patients with CHL and MHL is the percutaneous bone anchored hearing aid (BAHA).^{42–44} However, a BAHA is only indicated for ipsilateral stimulation if the BC threshold of the ipsilateral ear is equal or better than the threshold on the contralateral side to avoid an unwanted CROS hearing effect. A BAHA could have been applied to five subjects of our cohort, but the subjects opted for the VSB due to reasons like unsatisfactory BAHA trials, cosmetics, or medical aspects like the higher risk of skin infection and loss of implant with a BAHA.⁴⁵

In conclusion, patients with mixed hearing loss, chronic inflammations, and numerous previous ear surgeries, were successfully treated and benefitted from good audiological results. Changes in the BC threshold at high frequencies were clinical not relevant (<10 dB). Albeit a long history of ear surgeries and their revisions in the investigated group, results demonstrated a high success rate of the HC2 for the RW coupling.

CONFLICT OF INTEREST

Nicole Knölke, Dawid Murawski, Nina Wardenga, Hannes Maier, and Thomas Lenarz received travel support by Med-El to conferences. The authors disclose no other conflicts of interest.

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