Received: 24 February 2022 | Accepted: 23 March 2022

DOI: 10.1002/lio2.839

ORIGINAL RESEARCH

Laryngoscope Investigative Otolaryngology

Clinical feasibility of a novel test setup for objective measurements using the VIBRANT SOUNDBRIDGE

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Abstract

Objectives: The VIBRANT SOUNDBRIDGE is a widely used active middle ear implant to treat hearing loss. The floating mass transducer is surgically coupled to the ossicles, the round or oval window. A reliable method to monitor the coupling efficiency intraoperatively is highly desired. Research groups have developed several methods, but limitations remain. This study aims to evaluate the clinical feasibility of a new research setup for auditory brainstem response measurement to evaluate the coupling efficiency.

Method: In 14 subjects, the new tool was used to record VSB-evoked ABR thresholds during surgery. The intra-op ABR thresholds were compared to pre-op bone conduction (BC) thresholds and post-op vibrogram thresholds to evaluate the feasibility of the method as a tool to monitor coupling efficiency.

Results: The mean pre-op BC threshold average at 1, 2, and 4 kHz (PTA3) was 47 dB HL, the mean intra-op ABR threshold was 54 dB nHL, and the mean post-op vibrogram PTA3 was 60 dB HLeq. ABR was measurable in all subjects using the new tool. Correlation between pre-op BC thresholds and intra-op ABR thresholds was statistically significant; however, one outlier was present.

Conclusion: Intra-op hearing threshold detection through ABR and direct stimulation of the VSB implant was reliable using this new tool. Despite some individual variability, first results correlate well with pre-op BC and post-op vibrogram thresholds.

KEYWORDS

ABR, active middle ear implant, intraoperative measurement, objective measurement

1 | INTRODUCTION

For patients with mild to severe sensorineural, conductive, or mixed hearing loss, where conventional hearing aids show limitations like feedback, sound distortion or patient-related problems such as recurrent infections or insufficient stimulation, active middle ear implants represent an alternative to conventional hearing aids. The VIBRANT SOUNDBRIDGE (VSB, MED-EL, Innsbruck, Austria) was introduced in 1996, reviews of clinical experience conclude safe and effective device performance.[1,2] This semi-implantable device consists of an internal part comprising of a receiver coil, a conductor link, and an electromagnetic floating mass transducer (FMT) and an external part,

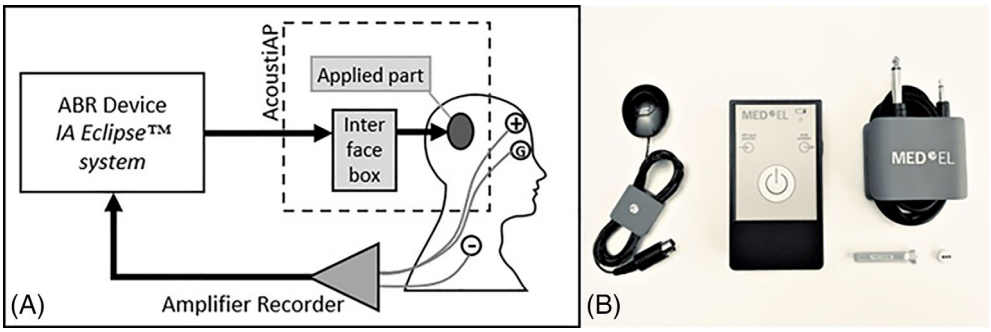

FIGURE 1 The measurement setup and the AcoustiAP device. The measurement setup (A) shows the ABR system, the AcoustiAP consisting of the interface box and the applied part. The subject with positive (+), negative (−) and ground (G) electrode, connected to the amplifier recorder. A photo of the AcoustiAP device parts (B; image provided by manufacturer). Left to right: The applied part, interface box, cable, magnet door opening tool and a strength three magnet.

the audio processor (AP) held on the skin via an implanted magnet. The FMT transforms airborne sound to mechanical vibrations. With structure specific couplers, the FMT can be placed during vibroplasty onto a variety of anatomical structures within the middle ear: the short process (SP) of the incus, the long process (LP) of the incus, the stapes head (SH-, Bell- or CLiP-coupler), the round window (RW) membrane, or the oval window (OW). Energy transfer from the FMT to the inner ear depends on the coupling efficiency. A measure of coupling efficiency is the comparison of bone conduction (BC) thresholds and vibrogram (VIB) thresholds. The vibrogram is an in-situ threshold measurement and is performed through the implant itself. Deteriorating coupling efficiency is indicated by increasing difference between BC and VIB thresholds.[3] The VIB is routinely used postoperatively (post-op), however during vibroplasty the surgeon has to rely on visual and tactile observations. Therefore, a reliable method to monitor the coupling efficiency intraoperatively (intra-op) is highly desired.

Verhaegen et al. (2010) recorded auditory steady state response (ASSR) during VSB implantation.[4] Radeloff et al. (2011) used sinusoidal tone bursts to record compound action potentials.[5] Colletti et al. (2011) used the electrocochleography (ECochG) measurement during VSB RW-surgery.[6] Mandalà et al. (2011) recorded ECochG in children.[7] However, due to its complexity and invasiveness this method did not find extended usage. Verhaert et al. (2015) performed auditory brainstem response (ABR) and ASSR measurements using click stimuli.[8]

In 2017, Cebulla et al. introduced a wireless method. The streaming device miniTek™ (Sivantos, Erlangen, Germany) was used, connected to an ABR system, to transfer the signal to the AP of the VSB with wireless approach. Cebulla et al. (2017) generated an optimized chirp stimulus to record ABR thresholds via the VSB to overcome frequency-specific time delays of the VSB system.[9] Geiger et al. (2019) concluded a feasibility study with this setup.[10] Several limitations remained. As a standard AP was used, the stimulus was subject to signal processing. Thus, the AP had to be programmed with a flat amplitude transfer function and a pre-processed stimulus had to be used to overcome signal deformation caused by the AP. Furthermore, the wireless transmission range was limited and unstable connection causing measurement failure could occur.

Fröhlich et al. in 2020 and 2021 published data of a multi-centric clinical study of objective measurement with VSB via a customized setup similar to the one from Verhaegen et al. (2010).[11] Despite reliable results, this setup showed limitations like influence of the AP signal processing, the need for individual adjustment of the gain settings and special preparation of an outdated AP (e. g. AP404, Vibrant MED-EL).

To address the limitations from both previous methods, the manufacturer developed a wired research tool called AcoustiAP (MED-EL, Innsbruck, Austria). This tool can be connected to any kind of ABR system and is placed onto the receiver coil of the implant directly (Figure 1). The AcoustiAP thereby provides a direct signal transmission from the ABR system to the FMT without signal deformation, as there is no digital signal processing integrated in the applied part (APP).

The aim of this study was to evaluate the feasibility of this new method to record intra-op ABR thresholds using the AcoustiAP tool. Furthermore, the goal was to test the correlation between the recorded ABR thresholds, pre-op BC and vibrogram thresholds to evaluate the usability of the ABR to analyze the coupling efficiency.

2 | MATERIAL AND METHODS

2.1 | Subjects

Patients that were planned for VSB implantation were asked to participate in this study. 14 subjects (6 female, 8 male) older than 18 years were enrolled. The mean age was 50 ± 20 years, ranging from 25 to 89 years. The subjects had conductive- (CHL; $n = 1$), mixed- (MHL; $n = 10$) or sensorineural hearing loss (SNHL; $n = 3$). All subjects received the VORP503 implant (9 left, 5 right) with different vibroplasty techniques (8 round window without coupler, 3 incus long process, 2 Clip couplers on stapes head, 1 incus short process), see Table 1. The local ethics committee reviewed and approved the study

TABLE 1 Subject characteristics

ID	Sex	Age	Hearing loss	Side	Pathologies	Coupling location	Coupler type
1	F	29	SNHL	R	Dermatitis, psoriasis	LP	LP coupler
2	M	39	MHL	R	Tympanoplasty, stapedoplasty	RW	Direct
3	M	66	MHL	L	Cholesteatoma, COM	RW	Direct
4	M	53	MHL	L	Previous 5 surgeries	RW	Direct
5	F	71	MHL	L	Recurrent cholesteatoma	RW	Direct
6	F	48	MHL	R	Cholesteatoma resection	RW	Direct
7	M	63	MHL	R	Cholesteatoma recurrence	RW	Direct
8	F	25	CHL	L	Multiple cholesteatoma surgery	RW	Direct
9	F	35	MHL	L	Cholesteatoma	SH	Clip coupler
10	F	29	MHL	L	COM, tympanoplasty and drainage	SH	Clip coupler
11	M	70	SNHL	L	SNHL	SP	SP coupler
12	M	57	MHL	L	Acute otitis and mastoiditis	RW	Direct
13	M	89	SNHL	L	SNHL	LP	LP coupler
14	M	28	MHL	R	Cholesteatoma resection	LP	LP coupler

Note: "Direct" without coupler.
Abbreviations: CHL, conductive hearing loss; LP, incus long process; MHL, mixed hearing loss; RW, round window; SH, stapes head; SNHL, sensorineural hearing loss; SP, incus short process.

(EK number: GS4-EK-4/685–2020). Written informed consent was obtained from all patients before enrolment.

2.2 | AcoustiAP

The AcoustiAP consists of an audio cable to connect to the ABR device, an interface box housing two AAA batteries enabling to turn the device on and off and to monitor the battery status. The interface box is connected to the APP, an AP housing, without any signal processing circuit. The applied part holds a magnet for appropriate positioning over the implant and the coil for signal transmission (Figure 1 B). The device was calibrated by the manufacturer to stimulate the implant with the same intensity level as it would with an insert earphone of 50 Ohms, which are used in the case of the IA Eclipse™ (Interacoustics) system (information provided by the manufacturer).

2.3 | Procedure

Preoperative AC and BC thresholds were measured using an Equinox 2.0 AC440 audiometer (Interacoustics). The intra-op ABR measurement was performed directly after final positioning of the FMT in the operating room. The post-op ABR measurement was performed after activation of the implant. At both time points the same electrodes (Ambu® Neuroline 720) and electrode placement was used: The active electrode (+) was placed on the top of the forehead, the ground electrode (G) below this position, and the reference electrode (−) was placed ipsilateral on the neck. The vibrogram was recorded at two timepoints post-op (T1 at implant activation and T2 3 month after activation). Instead of the widely used PTA4 (0.5, 1, 2 and 4 kHz average) we report here the PTA3 (1, 2 and 4 kHz average), for comparison between pre-op BC, ABR, and VIB results. The reason for choosing PTA3 instead of PTA4 was to avoid misleading results caused by elevated deviation between BC and vibrogram thresholds at 500 Hz.[4,5] The PTA4 was still used to report the mean basic audiological AC and BC results.

2.4 | Auditory brainstem response measurement

The ABR measurements were performed with the IA Eclipse™ system (EP25 version 4.4, Interacoustics). The ABR Eclipse device generated the stimulus and measured the ABR outcome. The acoustic signal chosen for the measurement was the CE CHIRP as described by Elberling et al. (2007).[6] The standard procedure for ABR was used. 2000 single stimuli with alternating polarity were presented. The stimulation rate was set at 49.1 Hz and the artifact threshold was set to 40 μV if the electric noise was not higher, to ensure artifact free recordings. In certain cases, the threshold had to be set to 80 μV to allow recording of the signal. The filter setting was 30 Hz to 1500 Hz (digital, FFT filter). The average time for one measurement session was approximately 10 min comprising of 4 to 7 recordings.

2.5 | Intraoperative measurement

After positioning of the FMT, the AcoustiAP was positioned to transmit the stimuli. The first stimulation was performed at high intensity below the uncomfortable loudness level of the patient, to ensure a positive response defined by clear identification of wave V. Once a positive response was identified, if surgical time allowed, the stimulus decreased in 10 dB steps, until disappearance of wave V. If the

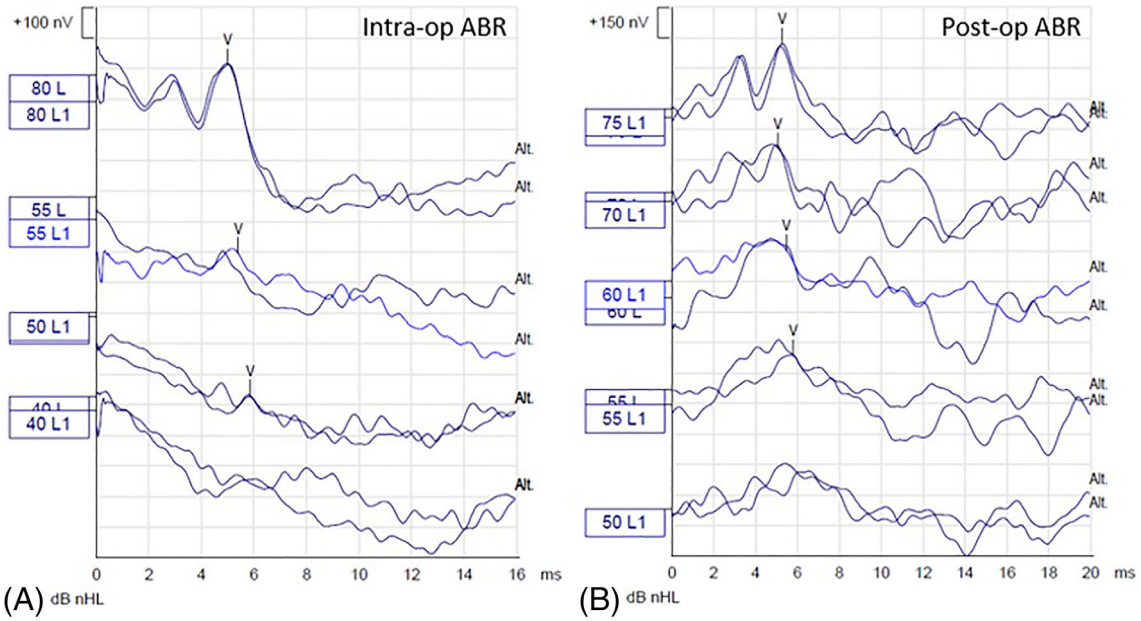

FIGURE 2 ABR response curves of the intra-op (A) and post-op measurement (B) from subject number 12, as an example for illustration. The x-axis shows the latency (ms), and the y-axis shows the presentation level in dB nHL. The wave V was marked by the experimenter (V). Wave V was identified at the lowest stimulation level of 50 dB nHL intra-op and at 55 dB nHL post-op.

surgical time was limited, after first detection of wave V, the following stimuli was presented 10 dB above the pre-op BC threshold. As an example, in case of patient 12 (Figure 2), the pre-op BC PTA3 was 33 dB HL. Thus, the second ABR was performed at 40 dB nHL. If wave V detection was unsure, an additional measurement was performed elevating the stimulus by 5 dB. The ABR threshold was defined as the lowest stimulation level at which identification of wave V was achieved in two consecutive recordings. After visual and tactile observation of proper coupling, the wave V was recorded without consecutive manipulation of the coupling.

2.6 | Postoperative measurement

For the post-op ABR measurement the subjects were seated in a comfortable chair with a head rest. The ABR measurement was with short and increasing stimuli level. The subjects were asked to indicate the most comfortable level (MCL) as first stimulation level for the following ABR measurement.

For the ABR measurement, the subjects were instructed not to actively respond to any signal heard, instead they were asked to close their eyes and relax for the measurement session of approximately 15 minutes. Starting at MCL the ABR recoding was performed as described for intra-op measurements.

2.7 | Statistics

Quantitative data were presented as mean ± standard deviation. The Pearson correlation coefficient was calculated to evaluate the relation between intra-op ABR and pre-op BC thresholds, and between intra-op ABR and vibrogram thresholds. The nonparametric Mann Whitney test was used to compare the difference between the round window and ossicular chain group regarding the deviation between pre-op BC and intra-op ABR thresholds. Statistical significance was set to $p < .05$. GraphPad Prism 7.04 software was used for statistical analysis.

3 | RESULTS

Individual audiological results of AC and BC thresholds are provided in the Table S1.

The average PTA4 AC threshold of all 14 subjects was 65 ± 15 dB HL and the average PTA4 BC was 41 ± 17 dB HL.

ABR thresholds, as wave V response, could be measured in all 14 subjects. Electrode impedance (Z) was below 2 kΩ for nine patients, below 3 kΩ for four patients and below 5 kΩ for subject number 8. Wave V was measured as main indicator for the intra-op measurement. The average amplitude was between 0.024 and 0.188 μV and the latency was between 5.87 and 9.27 ms.

Subject 8 had average PTA3 BC thresholds of 7 dB HL pre-op, 13 dB HL post-op and stable vibrogram thresholds of 30 dB HLeq. However, we recorded an intra-op wave V ABR response of 60 dB nHL for this subject. Due to the high impedance and questionable ABR result, data from subject 8 is shown in graphs but was not included in statistical analysis for calculation of mean thresholds and correlations.

Analyzing the data of the remaining 13 subjects, the mean pre-op BC PTA3 was 47 ± 14 dB HL, the mean intra-op ABR threshold was

TABLE 2 Individual data

ID	Pre-op BC PTA3 dB HL	intra-op ABRdB nHL	Impedance kΩ	Rejection limit µV	Post-op Vibrogram T1 PTA3 dB HLeq
1	62	70	<2	40	57
2	37	55	<2	80	60
3	62	65	<2	80	75
4	57	50	<3	80	nt
5	62	55	<3	80	82
6	33	40	<2	40	43
7	52	60	<2	40	67
8	7	60	<5	40	30
9	32	30	<3	80	28
10	22	50	<3	40	28
11	57	70	<2	40	73
12	33	50	<2	40	47
13	60	60	<2	40	82
14	45	50	<2	40	80

Note: Bone conduction (BC), auditory brainstem response (ABR), PTA3 (1, 2, and 4 kHz), not tested (nt).

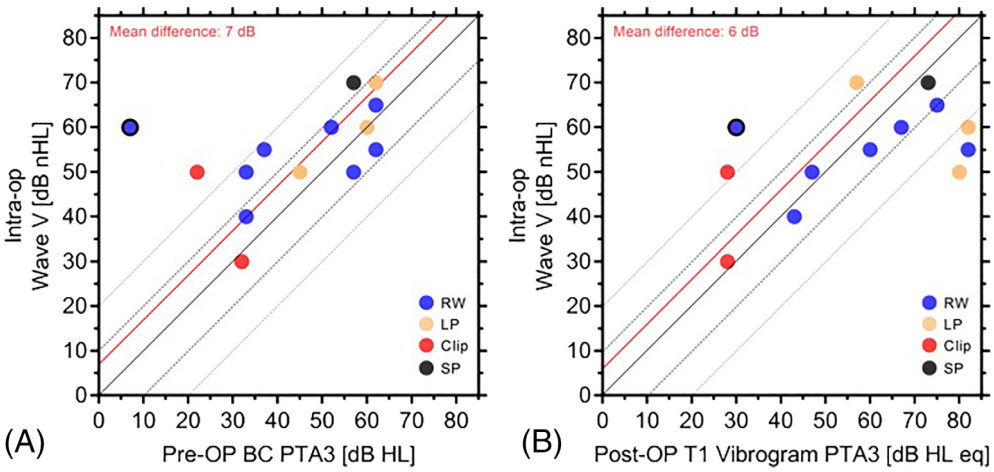

FIGURE 3 Comparison of intra-op ABR (wave V in dB nHL) and pre-op BC results (A; $n = 14$). Comparison of intra-op ABR and post-op vibrogram results (B; $n = 13$). The blue circle with the black border represents the outlier subject number 8, which was excluded from calculation of the mean difference, which is represented by the red line and text. The solid black diagonal is the line of equal thresholds and the dashed lines represent the ±10 and ± 20 dB deviation range.

54 ± 11 dB nHL and the mean post-op vibrogram PTA3 was 60 ± 20 dB HLeq, individual data are shown in Table 2.

The mean difference between pre-op BC and intra-op ABR thresholds was 7 ± 10 dB (Figure 3). On average ABR thresholds were 7 dB higher compared with the pre-op BC thresholds. Out of the 13 subjects within the analytical population, nine (69%) were within the ±10 dB limit, three (23%) were within the ±20 dB limit. With a difference of 28 dB subject 10 was outside this range (Figure 3). The analysis revealed a statistically significant positive correlation between the pre-op BC and intra-op ABR results ($r = .7034$, $p = .0037^{**}$). As well the correlation between intra-op ABR thresholds and post-op vibrogram thresholds was statistically significant ($r = 0.6334$, $p = .0270^{*}$). The vibrogram thresholds were on average 6 ± 15 dB higher than the ABR threshold. Within the study, post-op data of 5 patients was acquired at one additional timepoint. The post-op BC thresholds, post-op ABR thresholds and an additional vibrogram measurement (T2) were gathered. Due to the pandemic situation post-op data from all subjects could not be collected.

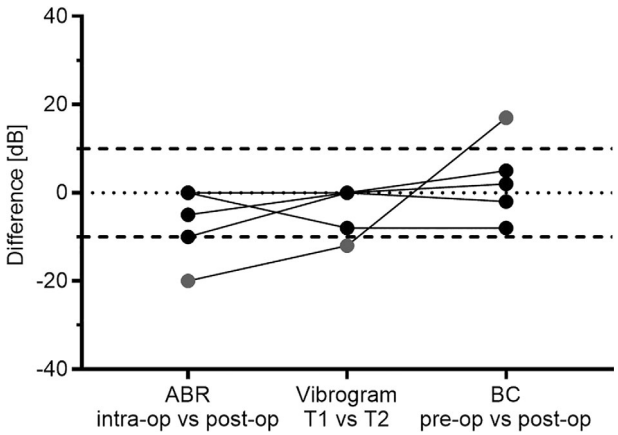

FIGURE 4 Difference between intra-op and post-op ABR thresholds, between the vibrogram at T1 and T2, and between pre- and post-op BC thresholds. Dashed lines represent the ±10 range. Solid lines connect the data points of subjects. Gray circles show results from subject number 9.

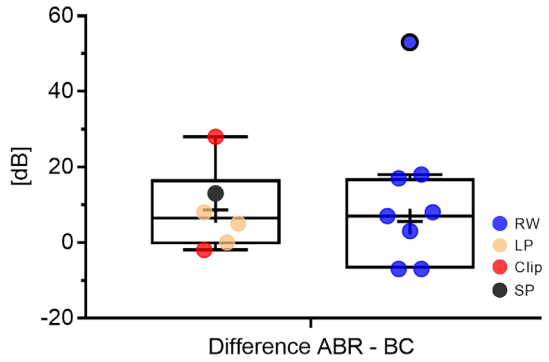

FIGURE 5 Differences between pre-op BC and intra-op ABR thresholds, comparing the group of patients with ossicular chain coupling (OC group: LP, Clip or SP) against the group with round window coupling (RW group). The blue circle with the black border represents the outlier subject number 8, which was excluded from the analysis. No statistical significance was found ($p = .7558$), comparing both groups.

Besides the results from subject 9, the difference between pre- and post-op BC thresholds, between intra-op and post-op ABR thresholds and between the vibrogram at T1 and T2, were within the ±10 dB limit (Figure 4). In most subjects ($n = 8$), vibroplasty was performed by positioning the FMT directly onto the RW membrane without any coupler (RW group). In the remaining six subjects the FMT was attached onto the ossicular chain (OC group) via different couplers (for details see Table 1). The deviation of differences between pre-op BC and intra-op ABR thresholds was independent of the type of coupling. No significant difference was found comparing the RW and OC group (Figure 5).

4 | DISCUSSION

The first aim of this clinical study was to evaluate the feasibility of a novel research setup for testing the auditory evoked potentials via the VSB hearing system during surgery. In second line, we aimed to compare the intraoperative results with pre-op BC and post-op vibrogram thresholds to evaluate the coupling efficiency.

The ABR as the objective measure was chosen because of its non-invasive approach and common usage in all professional centers. Moreover, this method can be applied postoperatively without any additional effort for clinicians and patients. Thus, comparing to previous introduced methods that are complex to perform post-op like ECochG,[7] ABR presents considerable benefits and less risks for patients. However, the condition for post-op ABR measurements can be less favorable compared with the intra-op measurement condition under anesthesia. In awaked condition, the ABR responses can be affected by movement or restlessness of the patient. Second, sources of electromagnetic disturbances are usually more frequent in places outside the operating room. For successful post-op ABR measurements these factors must be controlled.

In general, we see some additional benefits by using the AcoustiAP compared with current solutions.[8,9,12,13] The first one is the user friendliness and simple application for any kind of ABR system. Using the direct and safe wired connection to the implant enables a stable and straight forward measurement, with less influence of electrical or acoustical distortions. In addition, as the AcoustiAP does not need to be fitted as a regular AP, there are no influences of signal processing and no risk for patients regarding high output stimuli during the measurement. This also facilitates a direct comparison to the pre-op BC thresholds.

In eight surgeries with MHL and CHL pathologies, the FMT was placed directly onto the RW-membrane without any coupler and only with an interposed fascia between RW and the FMT. Cartilage was used on the back side of the FMT to stabilize its position.

To avoid misleading results caused by elevated deviation between BC and vibrogram thresholds at 500 Hz, for data evaluation we considered the average of three main frequencies (1, 2, and 4 kHz) as PTA3 as previously described by Fröhlich et al. (2021).[12] The pre-op BC threshold was considered as the target magnitude and as an essential indicator for coupling efficiency. This is in line with the study of Geiger et al. (2019).[11] The pre-op BC and intra-op ABR results showed significant correlation and in the majority of cases (69%) the difference between both thresholds was within the 10 dB range. Fröhlich et al. (2021) defined ±10 dB as a maximum acceptable (clinically not relevant) difference.[13] One outlier (subject 8) was present. The patient presented normal hearing BC thresholds, visual and tactile observation of proper coupling was present intraoperatively and stable vibrogram thresholds confirmed this post-op. However, a questionably high ABR threshold was recorded. The high skin thickness of this subject and thus high impedance (Z > 3 kΩ) might have corrupted the sensitivity to measure a low ABR threshold in this subject. Although in 69% of cases threshold differences were within the 10 dB range, the remaining individual results differed by 13, 17, 18, and 28 dB. Reasons for this variation are not jet clear and should be further investigated. For five subjects the ABR outcome could be recorded at one additional timepoint post-op, in 4 out of these 5 subjects the change over time was within the 10 dB range. These are first results on the reproducibility and feasibility of the post-op ABR recording using the AcoustiAP, more data is needed to draw conclusions.

Geiger et al. (2019) found a difference between the median ABR threshold and median BC PTA4 of about 4 dB.[11] The difference between ABR and vibrogram PTA4 was about 20 dB. Although there is an acceptable agreement between our and their findings regarding coupling efficiency, due to the differences in setup, a direct comparison is not possible. For example, the AP in their study was fitted to a flat amplitude transfer function whereas the AcoustiAP does not use signal processing. The reason for a larger difference between ABR and vibrogram threshold in their study could be due to averaging results using PTA4 instead of PTA3.

Fröhlich et al. (2021) followed a fundamentally different approach to evaluate the coupling quality.[13] As coupling quality, they defined the difference between VIB PTA3 and post-op BC PTA3 and in a next step they compared these values with intra-op ABR responses. Additionally, it should be mentioned that the APs for intra-op

measurements were fitted to pre-op BC thresholds. Therefore, a direct comparison here is also not possible. However, in about 78% of cases, the difference was within the 10 dB range.[12,13]

Because of the small number of cases in this feasibility study, it was not possible to conclude any definite statement regarding the coupling efficiency of different couplers at the moment. However, our first results showed that the deviation of differences between pre-op BC and intra-op ABR thresholds was independent of the type of coupling.

5 | CONCLUSION

The ABR threshold measurement with the new AcoustiAP device is feasible and reproducible. It enables a straightforward measurement of the VSB device intra- and post-operatively. Despite some variability, good correlation between pre-op BC and intra-op ABR thresholds enables evaluation of coupling efficiency. We believe that the AcoustiAP could be a good tool to support surgeons performing vibroplasty and that rough coupling failures are detectable intra-operatively.

ACKNOWLEDGMENT

The authors would like to thank all participants in this study. For technical support of this study, the authors would like to express their special thanks to Lia Bicego and Samuel Blanc (MED-EL HQ).

FUNDING INFORMATION

All authors declare that no external funding was received during the preparation of this article.

CONFLICT OF INTEREST

All authors declare that there was no conflict of interest.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Sprinzl GM, Schörg P, Edlinger S, Ploder M, Magele A. Clinical feasibility of a novel test setup for objective measurements using the VIBRANT SOUNDBRIDGE. *Laryngoscope Investigative Otolaryngology*. 2022;7(4):1113-1119. doi:10.1002/lio2.839