

## Systematic Review

# Safety and Effectiveness of the Vibrant Soundbridge in Treating Conductive and Mixed Hearing Loss: A Systematic Review

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**Objectives/Hypothesis:** For many years, the therapeutic approach for conductive and/or mixed hearing loss has consisted of middle ear surgery with replacement of defect ossicles, and if possible the application of a hearing aid. Advances in technology have led to the introduction of electromagnetic active implantable devices such as the Vibrant Soundbridge (VSB). With its various coupling techniques for different pathophysiological situations in the middle ear, the VSB offers greater improvement in the hearing performance of affected persons.

**Data Source:** PubMed, OvidSP (MEDLINE), EMBASE (DIMDI), the National Institute for Health research (NIHR) Centre for Reviews and Dissemination (including the National Health Service Economic Evaluation Database, Database of Abstracts of Reviews of Effects, and Health Technology Assessment), and the Cochrane Library were searched to identify articles published between January 2006 and April 2014 that evaluated the safety and effectiveness of the VSB in comparison to no intervention, bone conduction hearing implants (BCHI), and middle ear surgery plus hearing aids for adults and children with conductive or mixed hearing loss.

**Methods:** Study selection and data extraction was carried out by multiple reviewers. Study quality was assessed using the Oxford Centre for Evidence-Based Medicine levels of evidence (2011); and a checklist available from the Evidence Analysis Library, Academy of Nutrition and Diabetics.

**Results:** Thirty-six publications were identified: 19 on VSB outcomes in 294 individuals, 13 on BCHI outcomes in 666 individuals, and four on middle ear surgery plus hearing aid outcomes in 43 individuals. Two systematic reviews were also identified. Heterogeneous outcome measures made it difficult to summarize data. In general, the VSB proved to be safe and effective when compared to no intervention and BCHI, and provided more and consistent hearing gain compared to middle ear surgery plus conventional hearing aids.

**Conclusion:** As demonstrated in the literature, the VSB as an active device offers an effective alternative for patients with various middle ear pathologies, particularly with mixed hearing loss and failed previous tympanoplasties when classical ossiculoplasty could not provide enough functional gain. This new strategy in hearing rehabilitation has led to an improved quality of hearing and life.

**Key Words:** Vibrant Soundbridge, conductive, mixed, hearing loss.

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## INTRODUCTION

In Europe, the prevalence of mixed and conductive hearing impairment amounts to 5%. The improvement in hearing in those patients has changed greatly by the introduction of electronic, active, implantable devices. The previous treatment strategy consisted of middle ear surgery with replacement of defect ossicles, and if possible the fitting of a hearing aid. The introduction of the Vibrant Soundbridge (VSB) (MedEL, Innsbruck, Austria) in 1996 has led to a change in the therapeutic approach.

Since then, different coupling techniques (*vibroplasty*) have been developed to adapt middle ear implants (MEIs) to nearly every pathophysiological situation within the middle ear and to restore hearing by amplification of residual hearing. This has become particularly effective in patients with chronic otitis media. These patients typically undergo several surgical revisions to improve hearing; however, the inflammatory response of the middle ear leads to a sensorineural hearing loss over time. Ear surgeries often entail a change in the shape and condition of the skin of the outer ear canal (cutaneous lesions, keloid formation), resulting in hearing aids not always being applicable. The VSB poses an alternative for improving the hearing and communication skills of such patients.

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## MATERIALS AND METHODS

### Search Strategy

As part of this systematic review, PubMed and OvidSP (MEDLINE), EMBASE (DIMDI), the NIHR Centre for Reviews

and Dissemination (including NHS EED, DARE, and HTA), and the Cochrane Library were searched using a comprehensive search strategy to identify articles published between January 2006 and April 2014. These dates were set in accordance with the publication dates of the first known articles on the VSB and the Bonebridge (MedEL, Innsbruck, Austria). The search was extended to full texts of articles and included papers published in English or German. The list of study titles was supplemented with potentially relevant publications already known by the research team, and the bibliographic references of reviews were searched to locate additional relevant materials.

### Study Selection and Data Extraction

After removing duplicates, titles and abstracts were screened against the set interface to conic and integer programming solvers (PICOS). Unrelated titles were removed, and the full texts of the remaining were obtained for further screening. Studies were excluded if they still did not fulfill the eligibility criteria or if appointed a negative quality rating. Screening of titles and abstracts was conducted by two reviewers, with discrepancies resolved by discussion or consultation with a third reviewer. Inter-rater reliability calculated using Cohen's kappa ( $k$ )<sup>1</sup> statistic was  $k = .8031$ . Full texts were then screened by three reviewers working independently, with discrepancies resolved by discussion. Using the arithmetic mean of  $k$ ,<sup>2</sup> inter-rater reliability was found to be  $k = .7566$ .

Data was extracted using the template from the Cochrane Consumers and Communication Review Group (<http://www.latrobe.edu.au/chcp/cochrane/resources.html>). Data were only extracted if reported in the text or tables, or if it could be accurately calculated from graphs, figures, or raw data sets. Information was extracted from each article on sample characteristics, type of intervention and outcome measures, and outcome data. Study quality was assessed using the levels of evidence of the Oxford Centre for Evidence-based Medicine (CEBM) (<http://www.cebm.net/ocebml-levels-of-evidence/>) and a checklist available from the Evidence Analysis Library, Academy of Nutrition and Diabetics (<http://andevidencelibrary.com/topic.cfm?cat=1317&a>)

### RESULTS

The electronic database search yielded 184 citations, which decreased to 130 after removing duplicates. Thirty-eight articles were further identified from study bibliographies. Overall, 168 titles were screened against inclusion criteria. Ninety-six titles were removed, and the full texts of the remaining 72 articles were obtained. Of these, 38 were removed due to their being published in foreign languages or having a poor quality or the wrong study design. As seen in Figure 1, 34 studies were finally included in the systematic review.

#### Study Characteristics and Results

**Vibrant Soundbridge Versus Unaided.** Nineteen articles<sup>3-21</sup> were identified that investigated the effectiveness of the VSB. These included 16 single cohort before-after studies, two concurrent cohort studies, and one non-randomized clinical trial. The studies covered a total of 294 adults and children with various etiologies. Four studies reported specifically on patients with atresia. Seven studies reported outcomes collected after 12 months of implantation, with follow-ups ranging up to 65 months. Eleven studies were designated as providing level 4 evi-

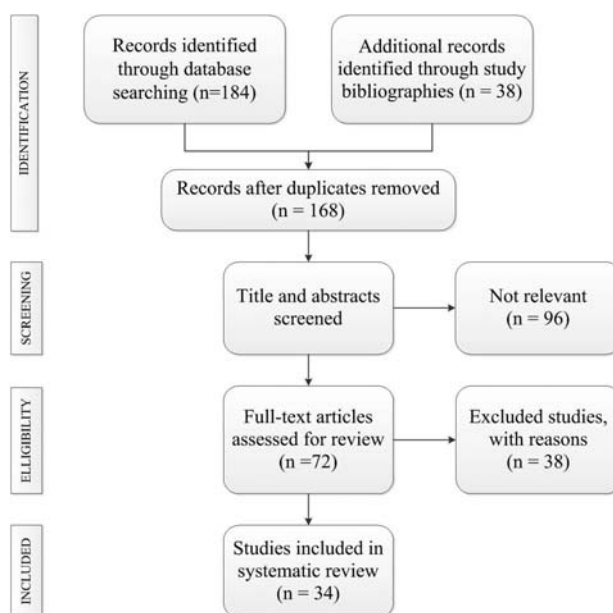


Fig. 1. Flowchart of study selection.

dence and the remaining as providing level 3 evidence. The quality assessment is tabulated in Figure 2a.

**Adverse Events.** Thirteen studies covering 196 patients reported on postoperative complications. Across all studies, 32 participants were affected by an adverse event, leading to an occurrence rate of 16.3%. The most common complication was floating mass transducer (FMT) extrusion, with an occurrence of 6.63%. This was followed by wound dehiscence (2.04%) and dizziness (1.53%). Device failure was observed in three patients (1.53%). Revision surgery was required in 20 patients (10.2%).

**Bone Conduction Thresholds.** Twelve studies reported the bone conduction pure-tone thresholds (PTA4), calculated over .5, 1, 2, 3, or 4 kHz. No significant shift in thresholds was observed, regardless of the testing interval.

**Air Conduction Thresholds.** Eleven studies reported the PTA4, calculated over .5, 1, 2, and 4 kHz. In a total of 144 patients, preoperative air conduction thresholds ranged from 64.9 to 82 dB hectoliters (HL), with a mean of 72 dB HL. Aided AC threshold values were measured at 3 and >12 months by four and six studies, respectively. The mean thresholds were 34.2 dB HL (range 28.7 –38.5 dB HL) and 30 dB HL (22–37.2 dB HL). Five studies also reported the PTA4 calculated over .5 to 3 kHz. The PTA ranged from 69 to 77 dB, also averaging at 72 dB HL. Aided AC threshold values measured after 6 months of use in three studies and averaged 26 dB HL (range 24–29 dB HL). Regardless of which PTA method was used, hearing thresholds improved substantially in all studies.

**Functional Gain.** Six studies reported the functional gain measured over .5, 1, 2, and 4 kHz; and two reported the gain measured over .5 to 3 kHz. Results measured at 3, ~9, and average 18 months using the prior PTA4. The functional gain of the VSB at 3 months ranged from 12.5 dB to 43.4 dB HL, averaging at 29.6 dB. Studies

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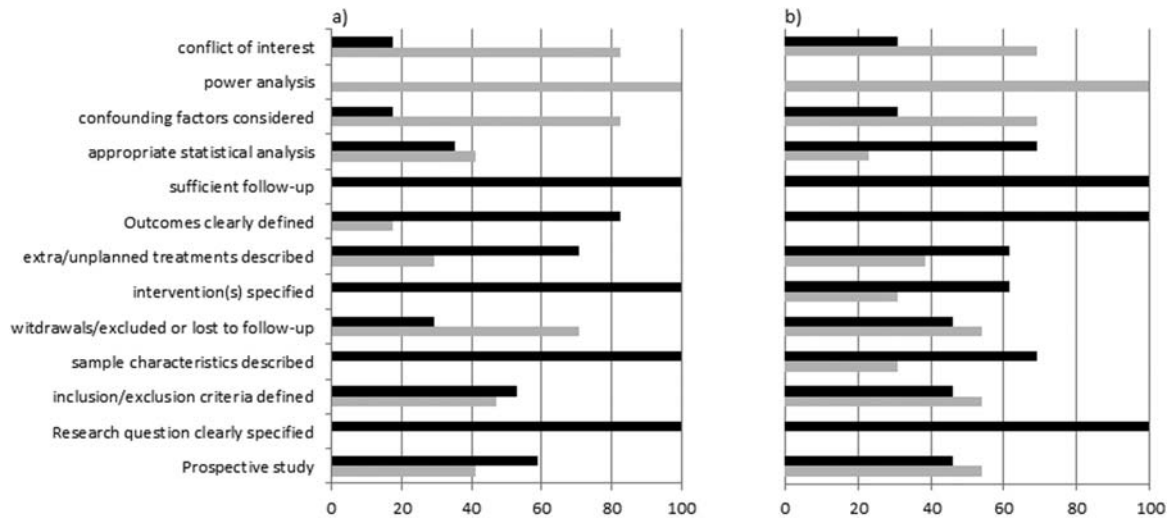


Fig. 2. Quality assessment of the different studies selected.

evaluating gain over time showed no change between 3 and 6 months<sup>14</sup> and between 3 and 40 months.<sup>4</sup>

**Speech Recognition.** Speech in quiet was measured by various speech tests, the most frequently used ones being Italian disyllabic word lists and Freiburger monosyllabic word lists. Speech recognition was shown to improve by 63% to 99% after at least 3 months of use (Italian disyllabic words), and by 52% to 81% after at least 6 months of use (Freiburger monosyllabic words). A meta-analysis of these results is presented in Figure 3. The test of heterogeneity was significant for Italian disyllabic scores ( $I^2 = 90\%$ ,  $P < .000001$ ) and not significant for Freiburger monosyllable scores ( $I^2 = 0\%$ ,  $P = .062$ ), leading to a random-effect model for the prior and a fixed-effect model for the latter. A significant improvement in speech was found with a combined mean improvement of 71.5% and 69% for each test, respectively. The 50% speech recog-

inition threshold (SRT50) was investigated in five studies and was shown to improve by 33 dB to 41 dB after at least 3 months of use.

Methods for assessing speech recognition in noise also varied. German Oldenburger sentence test (OLSA) sentences were used in two studies to establish the signal-to-noise ratio (SNR) for 50% correct recognition in noise. In a group of 12 patients, the SNR improved from 12 dB sound pressure level (SPL) to 3 dB SPL after 3 months of use.<sup>10</sup> After 40 months of use, the SNR was measured to be 5 dB SPL, reflecting a 7 dB SPL improvement from baseline and no significant change over time.<sup>4</sup>

**Subjective Benefit.** Three research groups (four studies) assessed the subjective benefit of the VSB using the Abbreviated Profile of Hearing Aid Benefit (APHAB), Hearing Device Satisfaction Scale (HDSS), and Glasgow

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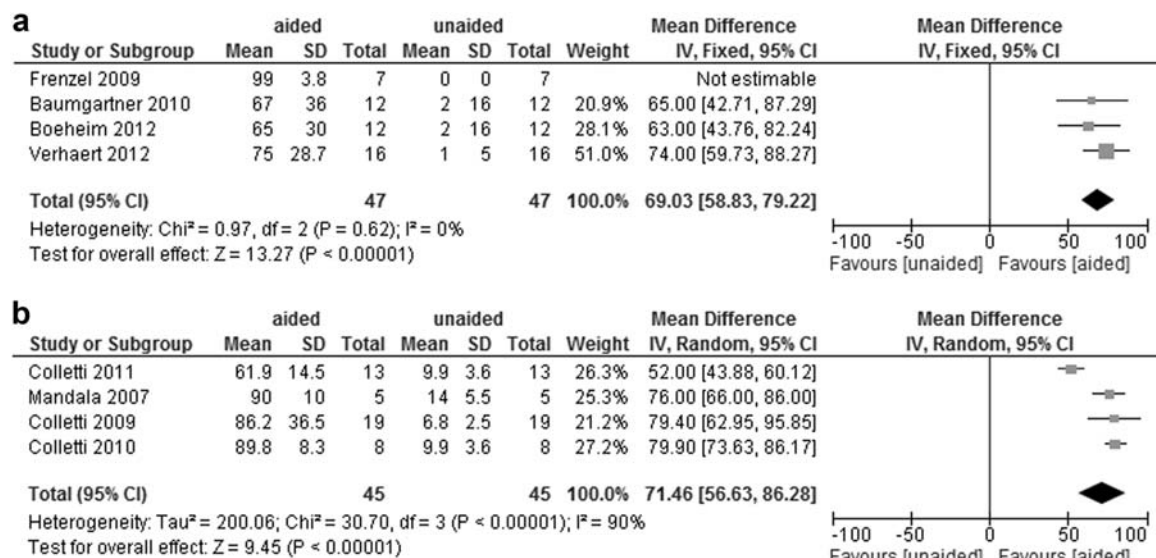


Fig. 3. Meta-analyses of speech outcomes with the Vibrant Soundbridge. (a) and in direct comparison with tympanoplasty (b) CI = confidence interval; SD = standard deviation.

Benefit Inventory (GBI). A significant benefit of the VSB can be seen on most subscales of the APHAB at 3 months and over time. Overall device satisfaction measured by the HDSS showed a similar trend with scores improving at 3 months and remaining constant at 40 months. Glasgow Benefit Inventory scores indicated that general health is improved with the VSB and that social support and physical health is not as much affected. Interestingly there was a slight improvement over time in social support and a slight decrease in physical health, which was suggested by the authors to be related to ageing.

**Cost Effectiveness.** No studies were identified that investigated the cost-effectiveness of the VSB in the conductive/mixed hearing loss population.

### ***Vibrant Soundbridge Versus Bone Conduction Hearing Implants***

There were no primary research studies comparing the efficacy of the VSB and bone conduction hearing implants (BCHI). However, one systematic review conducted by the Medical Services Advisory Committee (MSAC),<sup>22</sup> which evaluated the safety and effectiveness of MEIs, was identified. Data regarding BCHI outcomes was obtained from 13 primary research papers<sup>23–35</sup> and one other systematic review.<sup>36</sup> This second review was conducted under the commissioning of the National Institute of Health Research (NIHR) to evaluate the effectiveness of bone-anchored hearing aids (BAHAs) in treating bilateral hearing loss.

Both systematic reviews were of high quality with full disclosure of the search strategy, inclusion criteria, and included studies. Unfortunately, a meta-analysis was not possible due to heterogeneous outcome measures. No definite conclusions could be drawn due to the lack of comparative studies. However, the MSAC review specified that MEIs were at least as safe as BAHAs, but that in general BAHA patients reported more wound healing difficulties. In patients with any degree of conductive/mixed hearing loss (C/MHL), MEI implantation and activation was indicated as leading to improvements. The NIHR review indicated that hearing can be improved with BAHAs, but outcomes were debatable when compared to bone or air conduction hearing aids.

Twelve primary research papers evaluating the effectiveness of the BAHA, and one evaluating the effectiveness of the Alpha (Sophono Inc, Boulder, CO),<sup>23</sup> were included in the current review. Further articles were found as a result of the database search but were later excluded due to data being available only for the aided conditions. The included studies comprised of five case series, seven single cohort before-after studies, and one randomized clinical trial. According to the CEBM levels of evidence, seven studies provided level 4 evidence, five provided level 3 evidence, and the clinical trial provided level 2 evidence. The BAHA studies covered 660 adults and children with various etiologies. Four studies reported specifically on patients with atresia. Studies including patients with single-sided deafness were kept in the review when reporting surgical outcomes. The length of follow-up ranged from 3 months up to 6.5

years. Effectiveness of the Alpha device was investigated in six children with atresia evaluated at a follow-up of 6 months. The quality assessment is tabulated in Figure 2b.

**Adverse Events.** Eight studies reported on postoperative complications, with the BAHA in a total of 543 patients who received 609 implants. The most common implant-related complications were failure of osseointegration and fixture loss, with occurrence rates of 7.2% and 6.4%, respectively. The occurrence of adverse skin reactions was as high as 29.4%, which was according to Holger's grading, mainly grade 1 or 2 reactions. The next most common adverse event was thickening or overgrowth of skin, with a rate of 9.4% across all studies. Revision surgery was required in 29.9%.

No major complications were observed with the Alpha device. In two patients, a slight redness was seen on the skin covering the implant. This was managed successfully by reducing the strength of the external magnet. No pain was reported by any patient over a period of 18 months.

**Bone Conduction Thresholds.** Four studies reported on the bone conduction PTA4 calculated over .5, 1, 2, and 4 kHz. In 46 patients with normal preoperative bone conduction (BC) thresholds, no significant difference was observed 3 to 6 months after surgery.

**Air Conduction Thresholds.** Five studies reported on the air conduction PTA4 calculated over .5, 1, 2, and 4 kHz. In 56 patients, preoperative AC thresholds ranged from 58 dB to 71.5 dB HL and averaged at 64dB HL. The mean aided thresholds ranged from 14 dB to 28.5 dB HL, regardless of the amount of follow-up. One study that collected data at 6 and 12 months demonstrated no significant change over time.<sup>25</sup> There were no studies that calculated the PTA over .5 to 3 kHz.

**Functional Gain.** Two studies reported the functional gain in 17 patients. One study measured a gain of 31.4 dB at 3 months,<sup>35</sup> and the other measured a gain of 46 dB over a long-term follow-up.<sup>27</sup> The prior study was carried out in patients with various etiologies, whereas the latter focused only on patients with atresia.

**Speech Recognition.** Speech recognition in quiet was evaluated using different methods. Two studies measured SRT50 in a total of 19 patients with atresia. The SRT improved by 31.7 dB with the BAHA<sup>33</sup> and by 33.3 dB with the Alpha device.<sup>23</sup> Another study measuring word recognition scores (WRS), found patients with atresia to perform high preoperatively (88%) and showed no significant improvement over a 12-month period.<sup>25</sup> In patients with various etiologies, the WRS improved substantially from a mean of 14% to 89% with the BAHA.<sup>35</sup>

**Subjective Outcomes.** Six studies of low-reporting quality investigated the subjective benefit of receiving a BCHI. Three studies used a custom BAHA questionnaire together with the APHAB or Coping Behaviour Inventory (G(C)BI). Regardless of the methods used, postoperative improvements were seen in all patients, and most were satisfied with their device. Results were reported for the APHAB over a long-term follow-up.

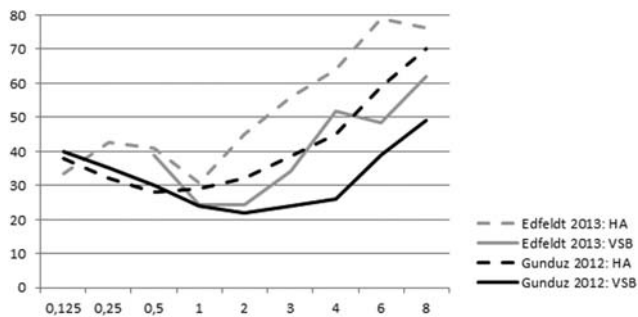


Fig. 4. Audiometric outcome with hearing aids versus middle ear implants (American Academy of Otolaryngology–Head and Neck Surgery standardized reporting format). HA = hearing aids; VSB = Vibrant Soundbridge.

**Cost-Effectiveness.** A cost utility analysis was carried out by Monksfield et al.<sup>26</sup> using the Health Utilities Index (HUI) in 70 patients diagnosed with C/MHL and single-sided deafness. Baseline utility data were obtained in reference to preoperatively worn hearing aids. The HUI scores improved from 0.59 (95% confidence interval [CI]: 0.53–0.65) preoperatively to 0.66 (95% CI: 0.60–0.72) at 6 months postfitting. Based on these values and life expectancy tables from 2008, the mean gain associated with receiving a BAHA was 1.89 quality-adjusted life years (QALYs) (95% CI: 0.71–3.23). Discounting the utility change gave 1.17 additional QALYs (95% CI: 0.50–1.91). The mean total cost for provision of a BAHD with continuing annual maintenance contract for the duration of the life expectancy of each patient and including discounting was found to be £21,430 (95% CI: £20,263–£22,535). Applying these costs and outcome results to the incremental cost-effectiveness ratio (ICER) equation gives an ICER of £16,565/QALY for the base case of receiving a BAHD rather than standard care when using undiscounted costs and QALYs.

### Vibrant Soundbridge Versus Ear Reconstruction Surgery Plus Hearing Aids

Four studies were identified which compared the outcomes of VSB application (*vibroplasty*) against middle ear reconstruction surgery plus hearing aids in patients with mixed or conductive hearing loss.<sup>6,15,20,21</sup> These studies which were included in the above section VSB versus unaided, comprised of single cohort before/after trials with comparisons drawn to preoperatively worn hearing aids in 43 adults. The audiological and subjective outcomes of these studies are summarized below.

**Air Conduction Thresholds and Functional Gain.** Two studies assessed AC thresholds across all frequencies in 25 individuals. The mean thresholds are depicted in Figure 4. One study (Gunduz et al.<sup>6</sup>) did not report the threshold at 3 kHz and was thus calculated as the average of 2 kHz and 4 kHz. Both studies demonstrate better AC thresholds with the VSB in the mid- to high frequencies. Gunduz et al.<sup>6</sup> have found this difference to be significant ( $P < .05$ ). The functional gain with the VSB was also found to be significantly better, with a

mean FG of 37.3 dB ( $\pm$  10.1 dB) compared to 29.2 dB ( $\pm$  7.2 dB) with hearing aids.

**Speech Recognition.** Two studies have assessed WRSs and have demonstrated no significant differences between hearing aids and the VSB. Using monosyllabic AB words presented at 65 dB SPL, Marino et al.<sup>15</sup> found WRSs to be 85.3%  $\pm$  11.8% with hearing aids and 83.8%  $\pm$  24.5% with the VSB. Similar values were obtained by Gunduz et al.<sup>6</sup>; however, the presentation level was not specified.

Both of these studies have further evaluated speech recognition in noise. For this purpose, Marino et al.<sup>15</sup> have used BKB sentences in multitalker babble noise. Speech was always presented from the front, whereas noise was presented in order from 0°, 90°, and 270° azimuth. Significantly better WRS were obtained in all conditions with the VSB. In contrast, when presenting speech at an SNR of 5 dB, Gunduz et al.<sup>6</sup> have found WRS not to significantly differ between the two devices.

**Subjective Outcomes.** Individuals who participated in the study by Gunduz et al.<sup>6</sup> have also responded to the International Outcome Inventory for Hearing Aids.<sup>20</sup> Significant differences in favor of the VSB were seen on the questions of benefit and residual participation restriction, as well as in the total score. More people indicated a subjective benefit and no effect of their hearing disability with the VSB. A subjective improvement in health status was also indicated in four out of five individuals who responded to the GBI at a longer follow-up.

## DISCUSSION

Thirty-four studies were included in this systematic review, which aimed to investigate the effectiveness of the VSB versus unaided conditions and conventional middle ear surgery with best-fitted hearing aids, respectively. Nineteen articles that investigated the VSB effectiveness against unaided conditions covered 294 adults and children, including atresia patients. Few adverse events were reported, with extrusion of the FMT (6.63%) being the most frequent one. This is not surprising because the underlying middle ear pathology is highly variable due to the ventilation conditions of the middle ear. Bone conduction thresholds were stable pre-/post-surgery, demonstrating that the VSB does not harm inner ear function and that it leads to a functional gain of 29.6 dB on average at 3 months. This effect was stable at 6 months<sup>14</sup> and 40 months<sup>4</sup> in the respective series and is reflected in the corresponding speech recognition test scores (monosyllables, sentence tests), which yielded statistically significant improvements from unaided conditions. The subjective benefit of the patients was reported by different scales: the APHAB developed for identifying the amount of difficulties experienced with hearing devices and the GBI pointing to changes in health status. Both showed an improvement that also remained stable over time. In our review, no cost-effectiveness studies were identified because the only one published on conductive and mixed hearing loss<sup>37</sup> just became available recently. Using the HUI mark 3 after 6 months of device use, the gain in receiving a VSB compared to no treatment was equal to

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1.62 QALYs, with undiscounted costs/QALY of €12 503, which was found to be highly cost-effective.

One systematic review conducted by the Australian MSAC<sup>22</sup> evaluated the safety and effectiveness of active MEI in comparison to BAHA; and another<sup>36</sup> evaluated the effectiveness of BAHA in bilateral HL. Both reviews were of a high-quality standard, with full disclosure of the search strategy, inclusion criteria, and included studies. A meta-analysis was not possible due to heterogeneous outcome measures, and no definite conclusions could be drawn due to the lack of comparative studies. Nevertheless, the MSAC demonstrated that the MEI is at least as safe as the BAHA, with the latter having significantly more wound complications. This raises the question if a more reliable and safer technological solution should be considered as an alternative medical approach in those patients to improve their hearing (i.e., VSB or Bonebridge applications).

The most remarkable progress in hearing improvement achieved with the VSB technology was reported to occur in patients with mixed hearing loss and previously failed conventional middle ear surgery (e.g., tympanoplasty, tympanorevisions). Those patients are largely at risk of being unaided for longer periods of time due to chronic inflammations affecting the outer ear canal/radical cavity. This in turn prevents the efficient use of hearing aids, as shown by Colletti et al.<sup>12</sup>

When comparing the data of conventional middle ear surgery plus hearing aids<sup>6,15</sup> against VSB (*vibroplasty*) in the same patients, the overclosure of the air-bone gap (ABG) provides a more favorable outcome in the latter.

## CONCLUSION

In general, the applications of the VSB in mixed and conductive hearing loss have widened the therapeutic spectrum to improve hearing in those patients who could not be treated effectively enough as yet. Adverse events are below the range for conventional tympanoplasty surgery and BCHI implantation; and the audiological outcomes demonstrate a long-term effectiveness (i.e., postoperative follow-up between 36–48 months in four studies covering 90 patients<sup>4,8,12,16</sup>). As shown very recently by Edfeldt et al.,<sup>37</sup> it is also a very cost-effective solution, with costs being below a willingness-to-pay thresholds of €20 000. However, this was a single study; it did not meet the criteria of multiple studies.

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