Critical Review: In the adult population receiving little benefit from hearing aids, would the Vibrant Soundbridge middle ear implant provide better outcomes on measures such as speech intelligibility and subjective questionnaires?

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This critical review examines the benefit of the Vibrant Soundbridge (VSB) middle ear implant for the adult population who receive little to no benefit from their hearing aids. Study designs include mixed (between and within) group studies and single-group (pre-post test) studies. Overall, the literature reviewed provides evidence that the VSB provides greater perceived benefit than conventional hearing aids, at least for those dissatisfied with their aids. In terms of speech intelligibility, the results are variable. Some studies show greater benefit using the VSB while others show no difference. These inconsistencies are worthy of further, more thorough investigation.

Introduction

It is estimated that approximately 20% of people with hearing loss use hearing aids. However, only 58% are fully satisfied with their aid(s). These individuals may complain of poor sound quality, occlusion effects, or feedback issues when using hearing aids. Consequently, these concerns have resulted in a significant number of hearing aid returns. In addition, there are individuals who have such a significant hearing loss that hearing aids may not improve speech intelligibility drastically yet who are not candidates for cochlear implants due to their relatively good residual hearing. With these considerations, middle ear implants were introduced. (Luetje et al., 2002)

Among the various middle ear implants available worldwide, the Vibrant Soundbridge (VSB) by Med El is the only FDA-approved middle ear implant and has grown significantly throughout the years. (Truy et al., 2008)

The VSB is a semi-implantable middle-ear device that offers an alternative treatment option for patients with sensorineural, conductive, or mixed hearing loss (Truy et al., 2008). The VSB is composed of an external microphone, sound processor and amplifier, an audio processor, and an internal vibrating ossicular prosthesis. Sound waves are detected by the microphone located behind the ear and then analysed and processed by the sound processor. The vibrating ossicular prosthesis sends the sound to a magnet surrounded by a coil called the floating mass transducer (FMT). This transducer is attached to the incus, stapes, or round window which causes it to vibrate. (Luetje et al., 2002)

There are several theoretical reasons a middle ear implant such as the VSB may produce better sound quality than conventional hearing aids. First, the VSB provides improved signal coupling since it bypasses the outer and most of the middle ear, yielding a potentially more efficient high-frequency sound transfer system. Secondly, there is a reduction in acoustic feedback since the signal is not delivered into the external auditory canal. Lastly, the occlusion effect is not an issue since the outer ear remains non-occluded. (Truy et al., 2008)

Several studies have compared hearing aid and VSB outcomes. Results obtained in these studies were mixed, some of them showing better outcomes with the VSB while others showed no differences between the devices. This ambiguity will be addressed in this review.

Objectives

The primary objective of this critical review is to determine if the Vibrant Soundbridge (VSB) can provide adults with greater benefit than conventional hearing aids. The secondary objective is to provide recommendations for clinical practice.

Methods

<u>Search Strategy</u>
Computerized databases including PubMed, MEDLINE and CINAHL were searched using the following strategy: ((mixed hearing loss) OR (sensorineural hearing loss) OR (conductive hearing loss)) AND (hearing aids) AND (Vibrant Soundbridge). The search was limited to articles written in English. Additional articles were obtained through reference lists of acquired articles.
<u>Selection Criteria</u>
Studies selected for inclusion in this critical review paper were required to investigate the comparison of the Vibrant Soundbridge to conventional hearing aids. With the exception of age (adults as opposed to children), no limits were set on the demographics of research participants.
<u>Data Collection</u>
Results of this literature search yielded 5 articles congruent with the selection criteria. Three of the studies employed a single-group (pre-post test) design. The level of evidence of this design is 3. Two of the studies employed a mixed (between and within) group design. The level of evidence of this design is 2a.

Results

Single-group (pre-post test) Study

Study #1: Beltrame, Martini, Prosser, Giarbini, and Steirtberger (2009) evaluated the effects of functional hearing when implanting the Vibrant Soundbridge (VSB) in patients with mixed hearing loss, varying from moderate to profound losses.

Twelve individuals with mixed hearing loss were selected. All subjects had either chronic otitis media or otosclerosis, in which case the coupling of a traditional hearing aid would be problematic and bone-conduction (BC) hearing aid would be insufficient.

All 12 subjects were surgically implanted with the VSB in close proximity to the round window (RW) in order to directly drive the inner ear fluids. Each patient underwent a preoperative comprehensive audiological assessment including cerebral and brainstem magnetic resonance imaging. Hearing was evaluated by pure-tone and speech audiometry, as well as bone conduction masked thresholds.

Audiologic outcomes were obtained before surgery and 7 to 9 months after surgery. Testing consisted of: 1) preoperative air-conduction pure-tone thresholds under earphones and bone-conduction thresholds; 2) free-field, warble tone threshold, with VSB off and then on; 3) speech reception threshold (SRT) for sentences in quiet with VSB off and then on; 4) SRT for sentences in noise at 55 and 70 dB sound pressure level (SPL) with VSB on. These results were then compared to those of conventional hearing aids (Siemens Signia) using the NAL/NL1 prescriptive algorithm.

The authors suspected that should the coupling of the device onto the RW be perfect, the air-bone gap for all individuals would be closed. Therefore, a rough estimate of the coupling can be made by the comparison of bone-conduction and aided thresholds across the frequencies. Results, however, showed that the air-bone gap between 0.25 and 0.5 kHz could not be completely closed for most patients.

To evaluate the VSB gain in relation to the patients' hearing needs, thresholds were obtained with the VSB on and off. Results showed the hearing aid PTA gains predicted by NAL/NL1 were between one half and two thirds of the hearing loss, whereas most patients showed VSB gains worse than that prescribed by NAL/NL1. However, the difference in gain between the VSB and Siemens Signia was highly variable (between +15 and -39 dB).

On average, the VSB implant improved the SRT in quiet from 85 (VSB off) to 61 dB SPL (VSB on), thus providing a 24 dB gain (±12.5 standard deviation). The measurements of aided SRT in background noise showed only a slight, insignificant increase for both the VSB and hearing aids at both noise levels (55 and 70 dB SPL).

The authors discussed many plausible factors explaining the variability in the results. These included the individual anatomy of the round window, stapes mobility on the oval window, degree of cochlear impairment, and the coupling of the VSB to the round window membrane. The authors also mentioned that compared to the potential maximum gain of the VSB audio processor, their results were somewhat less than the theoretical expectancy. They then concluded that bypassing the middle ear ossicles can provide a reliable strategy for hearing restoration in purely conductive and less severe mixed hearing loss.

As a result of the variable results, the information provided may be taken with a mild degree of confidence. Due to the limited number of subjects, the authors were unable to look for a significant correlation between the VSB gain and middle ear conditions. In addition, there were no statistical analyses conducted. Therefore, it may be questionable to recommend the middle ear implant to a patient with mixed hearing loss as the benefits the patient will receive over their conventional hearing aids is unknown.

Single-group (pre-post test) Study

Study #2: Sziklai and Szilvassy (2011) assessed the difference in speech recognition using the Vibrant Soundbridge (VSB) and open-fit hearing aids in patients with sloping high-frequency sensorineural hearing loss.

Seven patients aged 21 to 62 years with sloping high-frequency sensorineural hearing loss were selected in the study. Each patient was implanted with a VSB implant with the floating mass transducer, which delivers the vibrations, coupled to the incus. All patients had used the implant daily over a period of at least 2 years before participating in the study. In addition, the patients all had experience with conventional hearing aids before implantation for at least 3 months. Both devices were fitted with specific fitting strategies recommended by the manufacturers.

The procedures involved routine unaided thresholds and aided thresholds in sound field with the middle ear implant and then with the open fit hearing aids. Speech recognition testing was performed in Hungarian.

There were two separate sessions examined. In the first session, unaided pure tone thresholds were measured preoperatively and postoperatively in order to account for any change in hearing. In the second session, the aided sound field thresholds, speech understanding scores, and functional gain obtained using the middle ear implant and open-fit hearing aid were determined and compared.

Results indicated that with respect to speech recognition scores, there were no statistically significant differences between the two devices (84.0 ± 14.7 for VSB and 90.6 ± 12.5 for open-fit).

With respect to functional gain, the results for the VSB were on average 48.2 ± 11.6 dB and 41.7 ± 9.2 dB for the open-fit hearing device, at 1-3 kHz. The difference was not seen to be significant. However, at 4-8 kHz, the results for the VSB were on average 26.4 ± 7.0 dB and 13.2 ± 5.1 dB with the open-fit hearing aid. The difference was found to be significant.

The authors concluded that there was no statistically significant difference between results obtained from the VSB middle ear implant and the open-fit hearing aids with respect to speech recognition. They also indicated that the results do, nonetheless, support the use of the VSB, especially for high frequency losses in the 4-8 kHz range.

A limitation of this study is the lack of information on the characteristics of the speech words being used. Since the only statistically significant difference was observed at high frequencies, it would be beneficial to evaluate words with high frequency emphasis, such as the monosyllabic word recognition scores used in Canada. In addition, speech recognition in noise was not evaluated. As a result of the significant increase in high frequency gain with the VSB, speech recognition in noise scores may have proven to be better for VSB users. The low number of subjects was also an issue. Not only were there only six subjects, the age range was quite large and the hearing losses were variable. All these variables should be taken into account, especially with such a small group of applicants. Therefore, the conclusion made in this study seems to be weak and therefore has less value clinically.

Single-group (pre-post test) Study

Study #3: Luetje, Brackman, Balkany, Maw, Baker, Kelsall, Backous, Miyamoto, Parisier, and Arts (2002) evaluated the performance of the Vibrant Soundbridge (VSB) on 50 adult subjects with moderate to severe sensorineural hearing loss.

Subjects were required to be over the age of 18 with English as their first language. The subjects were also required to be users of conventional hearing aids for a period of at least 3 months before initial evaluation. Only subjects with a sensorineural hearing loss were enrolled.

Measures included functional gain, speech recognition, acoustic feedback, occlusion, and patient self-assessment in order to determine satisfaction, perceived performance, and device preference compared to an appropriately fit conventional hearing aid.

Each subject was fitted with the VSB and the entire hearing device was activated and programmed to meet each patient's needs. An evaluation period was conducted 6 weeks post surgery.

Aided Thresholds: For the 50 subjects who wore the Vibrant Soundbridge, mean improvement in functional gain measured from 500 through 6000 Hz was significant ($P < 0.001$, Wilcoxon signed-rank test).

Speech Recognition: No statistical difference was observed for aided word recognition in quiet using the NU-6 word lists ($P = 0.12$, Wilcoxon signed-rank test). The Revised Speech Perception in Noise (R-SPIN) was administered using low pass (LP) sentences. The mean change in LP word scores between the pre-surgical aided conditions and 3 months after activation was not significant ($P = 0.59$, paired *t test:* $P = 0.55$, Wilcoxon signed rank test).

Self-Assessment Questionnaires: The Profile of Hearing Aid Performance (PHAP) inventory was used to assess subject-perceived improvements. The number of individuals who reported improvement in scores was significant compared with the pre-surgical aided conditions.

Hearing Device Satisfaction Scale (HDSS) was administered on all 50 subjects. Ninety four percent reported an improvement in satisfaction rating when the Soundbridge was compared with their aided pre-surgical condition. Eighty six expressed satisfaction with "clearness of sound and tone" of the Soundbridge compared to only 31% who used the acoustic hearing aid. Eighty-eight percent reported improvement in sound quality of own voice and effectiveness in background noise. Three percent of those using the Soundbridge reported acoustic feedback while sixty percent reported the issue using the acoustic hearing aid. Ninety-eight percent expressed satisfaction with overall fit and comfort as well as ease of cleaning and maintenance.

The SHACQ was also administered at the three-month follow-up with the use of the Vibrant Soundbridge. The majority of subjects reported being better able to understand speech in all situations except "on the telephone," compared to using the acoustic hearing aid. In terms of performance, the strongest preference for the device was found in "one-to-one conversations" (76%) and the lowest was found at "live performance at theatres" (53%).

The authors concluded that the study demonstrates the safety (residual hearing) and efficacy (functional gain, word recognition, and self-assessment) of the Vibrant Soundbridge. The authors also stated that all subjects preferred the Vibrant Soundbridge over the acoustic hearing aids.

This article gives a variety of assessments to examine the efficacy of the Vibrant Soundbridge. The subjective measures help understand what situations the implant will help most and what situations it may not. There are also a significant number of patients in this study which improves the strength of the results. Clinically, this article is quite relevant when examining patients with sensorineural hearing loss and determining treatment recommendations.

Retrospective, mixed (between and within) group study
Study #4: Truy, Philibert, Vesson, Labassi, and Collet (2008) compared gain and speech intelligibility measured in quiet and in noise between the Signia hearing aid and the Vibrant Soundbrdige (VSB) which both used the same 8-channel digital signal processing technology from Siemens Audiologische Technik GmbH.

Six people (2 men, 4 women, aged between 42 and 59 years) with a steeply sloping hearing loss were selected to complete the whole study: 3 months of Signia hearing aid use, VSB implantation, and 3 months of VSB use.

Patients were first fitted with the Signia hearing aid. At the end of this period, a test battery was performed to evaluate their hearing performances with the hearing aid. Patients were then implanted with the VSB. The first fitting of the VSB was performed 2 months later, and after 3 months of VSB use, the same test battery was performed to evaluate patients' hearing performances with the VSB. Performance measures with the two devices were then compared.

The test batteries performed at each session consisted of; 1) free-field aided and unaided hearing thresholds; 2) aided and unaided word recognition score at 3 different intensity levels; and 3) aided and unaided intelligibility at 5 signal-to-noise ratios.

The difference in preoperative versus postoperative thresholds was not significant (2-way repeated measurement analysis of variance; $F(1,5) = 7.3$; $p = 0.04$).

Larger gains (aided minus unaided thresholds) were found with the VSB than with the hearing aid, particularly at 0.5, 2, and 4kHz (device x frequency: $F(4,20) = 13.2$; $p < 0.05$).

Word recognition performances were best with the VSB only at the lowest intensity level (40 dB SPL). At higher intensity levels (50 and 60 dB SPL) performances reached 100% and no differences among these 3 conditions (unaided, VSB, and hearing aids) could be observed.
Speech intelligibility in noise showed better scores measured with the VSB than with the hearing aid or unaided (post hoc tests; $p < 0.01$) at all 5 signal-to-noise ratios.

The authors concluded that it is likely that direct-drive amplification can provide more high-frequency gain than hearing aids, leading to better performance.

The article provided the necessary information in order to compare the effects of the hearing aids versus the VSB. Limitations with this study include the small amount of individuals that were evaluated.

Mixed (between and within) group study
Study #5: Wolf-Magele, Schnabl, Woellner, Koci, Riechelmann, Sprinzl (2011) evaluated the outcomes of younger (<60 yr) and older (≥60 yr) patients implanted with the Vibrant Soundbridge (VSB) during 2008 and 2009. The aim was also to determine if there were differences between the two groups.

The 26 patients evaluated consisted of adults 18 years of age or older with conductive, mixed, or sensorineural hearing loss. They also needed to have at least three months experience with conventional hearing aids and to have disliked the devices due to poor speech intelligibility or medical reasons such as chronic otitis externa.

Aided and unaided thresholds were compared by averaging the sound-field thresholds at 0.5, 1, 2, and 3 kHz preoperatively without hearing aids and postoperatively with the VSB. Preoperative and postoperative pure-tone averages were also compared and grouped by the site of placement of the floating mass transducer (FMT). Depending on the patient's middle ear anatomy and type of hearing loss, the FMT was positioned on the stapes, the incus, or on the round window.

Results indicated that under aided conditions, thresholds improved by approximately 26 dB. The amount of hearing improvement did not differ significantly between the 2 age groups and there was no significant difference in improvement between the 3 different surgical techniques.

Postoperatively, free field warble tone thresholds were measured in noise with the VSB switched on, and the SNR for 50% correct speech recognition was assessed. There was no statistical difference between the two groups ($p = 0.076$, Mann-Whitney U test).

In summary, all patients had significantly improved VSB aided hearing thresholds as compared with their preoperative unaided hearing. The authors concluded that the VSB provides very good improvement in speech understanding outcomes, especially in patients with presbyscusis, for whom conventional hearing aids often were dissatisfactory or unsuccessful. However, the authors failed to include any evidence that the VSB device is more favourable over conventional hearing aids in this population. Therefore, we can only assume that the patients were generally more satisfied with the VSB over the conventional hearing aids. In addition, speech tests were only performed postoperatively and with the VSB device switched on. Therefore, it is unclear whether patients' speech intelligibility scores were better than with hearing aids or unaided.

Since this is a retrospective study, there may have been some selection bias. There may have been many who decided not to participate because of poor performance using the VSB device.

Nonetheless, the article does provide useful information on the performances of younger and older adults with the VBS device which is clinically relevant when determining candidacy.

Discussion

Overall, the examined research provides sufficient evidence to support the usage of the Vibrant Soundbridge (VSB) for adult patients with little success using conventional hearing aids.

There is, however, a significant amount of variability in terms of performance in speech intelligibility tests. Beltrame et al. (2009), Sziklai & Szilvassy (2011), and Luetje et al. (2002) showed no significant improvement on speech in quiet scores for the VSB device over conventional hearing aids. The only study to show better speech intelligibility results in favour of the VSB was the study done by Truy et al. (2008) and only at low intensity levels. However, the low number of subjects used in the article reduces the confidence in the results. Wolf-Magele et al. (2011) mentions that speech is improved using the VSB but fails to provide any evidence supporting that claim.

More variability was seen on speech intelligibility in noise tests. Truy et al. (2008) found a significant improvement using the VSB over hearing aids. Sziklai & Szilvasy (2011) also found that all subjects had better sensitivity scores using the VSB at higher frequencies. However, they did not test speech intelligibility in noise. Therefore, it may be that patient performance in noisy situations would have been greater when using the VSB because of the extended bandwidth provided. In contrast, Beltrame et al. (2009) and Luethe et al. (2002) found no statistical significance in improvement with regards to speech intelligibility in noise using the VSB device over hearing aids.

Performance and satisfaction questionnaires were only performed in one study. Luetje et al. (2002) showed that all 50 subjects in the study had preferred the VSB device over their conventional hearing aids on both questionnaires. This study provided the necessary statistical analyses as well as sufficient amount of subjects to be reliable. However, there seemed to be some discrepancy in the results. Subjects perceived greater performance and satisfaction while their objective tests showed otherwise. More detailed research is needed with regards to subjective questionnaires to understand why these discrepancies may exist.

With regards to hearing loss, the VSB device seems to be most effective for patients with sensorineural loss (Luetje et al (2002); Sziklai & Szilvassy (2011)). Beltame et al (2009) found results to be variable in the mixed hearing loss population.

Conclusion and Clinical Implications

In summary, there seems to be a lot of promise in recommending middle ear implants such as the Vibrant Soundbridge (VSB) for patients coming into clinic who dislike hearing aids due to discomfort or medical contraindications. In cases of speech intelligibility, there does not seem to be sufficient evidence in recommending the VSB device for those whose primary concern is speech understanding in quiet or in noise.

Recommendations

1. It is recommended that further research be conducted for patients with mixed or conductive hearing losses where the coupling of the floating mass transducer (FMT) has not been completely successful.

2. Further research is also needed in the effectiveness of the Vibrant Soundbridge with regards to speech intelligibility, especially in noise.

3. Most subjective measures (satisfaction or performance questionnaires) are also recommended in order to further understand what patients are satisfied or dissatisfied with in daily listening situations when wearing the Vibrant Soundbridge.

4. Larger sample sizes are also necessary in order to be more confident when making clinical recommendations.

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