Critical Review: Which verification method for Bone Anchored Hearing Systems and their removable Softband counterparts is best for use with adults?

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This critical review examines the methods commonly used to verify Bone Anchored Hearing Solutions (BAHS) and their removable Softband counterparts with adults. Study designs include two within group repeated measures and an expert opinion with two case studies. Overall, the research supports the use of electromechanical, audibility derived (in acceleration level) verification methods to verify BAHS but at this time, this verification method is not feasible for widespread clinical use.

Introduction

Providing a client with an appropriate hearing aid and ensuring an appropriate fit is a multistep process. This process includes assessment, prescription of hearing aids where necessary, verification of the hearing aids and outcome measures (College of Audiologists and Speech Pathologists of Ontario, 2000). The verification component of the process is crucial to ensuring that the hearing aids have the appropriate gain characteristics for the specific client's hearing loss. The College of Audiologists and Speech Language Pathologists of Ontario (CASLPO) state in their preferred practice guidelines that the preferred method of verifying hearing aids is through real ear measurements of the electroacoustic properties of the hearing aid (CASLPO, 2000). This method of verification has become standard practice with traditional air conduction hearing aids, but is not routinely used with BAHS in the clinic. This is due, in part, to the absence of an equivalent real ear measure for BAHS. As a result, most clinicians who prescribe BAHS use aided soundfield testing and different forms of speech testing to verify the fit of BAHS (Flynn, Sadeghi, Halvarsson, (2009), Lustig, Arts, Brackmann, Francis, Molony, Megerian, (2001)). As has been noted in previous papers, there are a number of problems with aided soundfield testing as a verification method. In 1992, Seewald, Hudson, Gagne and Zelisko (1992) compared the sound field aided audiogram with an electroacoustic method. They found that when the results from both methods were converted into sensation level (SL), the aided audiogram method generated higher SL estimates in 74% of the 13 participants. In some cases the increase was between 15-20 db above the electroacoustic method (Seewald, Hudson, Gagne, Zelisko, 1992). Although this research was conducted with air conduction hearing aids, the potential for over amplification remains a significant concern when using sound field audiograms to verify the response of a BAHS. Other limitations of the sound field aided audiogram include, but are not limited to sound field calibration issues, ambient room and hearing aid circuit noise and that the response of the aid is only measured with pure tones (hearing aids respond differently to complex stimuli than they do to pure tones). In addition, with the development of non-linear BAHS, the fact that the aided sound field audiograms only show gain at low input levels becomes a significant problem. The aided audiogram will therefore not be able to measure how the BAHS will function with mid or loud level inputs (Hawkins, 2004).

In 2006, Hodgetts, Scollie and Swain conducted a study that provided necessary information for the creation of an alternative verification method for BAHS. They examined whether the output force of the removable Softband BAHS was affected by the tension of the band used to secure the BAHS to the client's head. They also examined the required volume control setting to ensure audibility of speech. Finally, they examined whether there was a significant relationship between contact force, volume control and the preferred listening levels for each of the two BAHS they tested (the Classic 300 and the Compact). To complete the objective measures, they used an artificial mastoid and a Force Sensing Resistor to measure the output force and output voltage. They found that the output force level only increased slightly as the contact force (tension of the headband) increased. They also found that the two BAHS had different ranges of output intensity, which affected the amount of audibility each device provided. Their results showed that audibility was dependent on the volume control of the BAHS and the frequency range of each BAHS. Based on these objective results, the authors postulated that their participants would place the volume control at 2 (out of 3) to ensure audibility of sounds without peak clipping or maximizing the output limiting software. Results showed that the participants preferred listening levels were 2.7 for the Compact and 2.6 for the Classic 300 (Hodgetts, Scollie, & Swain, 2006). These results are significant for many reasons but for the purposes of this paper, the important conclusion was that the electromechanical measurement of output force and voltage was a reliable way to measure the output of the BAHS. This is significant as it indicates that an electromechanical verification technique is possible.

Objectives

The primary objective of this paper is to critically evaluate the research behind the various verification methods used for BAHS. The secondary objective is to determine whether one verification method is superior to the others and should be adopted for widespread clinical use.

Methods

Search Strategy
Computerized databases, including CINAHL, PubMed, and Google Scholar were searched using the following search terms: (bone anchored hearing aid), (bone anchored hearing aid) AND (verification), BAHA, BAHS, (bone conduction), Hodgetts, (Hodgetts) AND (bone anchored hearing aid). Citation searches were also used. No search limits were placed on the articles.

Selection Criteria
Studies selected for inclusion in this critical review were required to describe the development of a verification method and or recommend a verification method for BAHS with use with adults in a non-research clinical setting. No papers were excluded based on low ratings of validity or level of evidence or a reduced population (for example a verification method addressing one particular etiology).

Data Collection
The literature search yielded three articles that met the selection criteria. These papers included (1) expert opinion, and (2) within group studies.

Results

Speech-in-noise Verification
In 2008 Snapp and Telischi proposed an assessment and verification protocol for those with single sided deafness using BAHS. The assessment portion of their protocol will not be discussed in detail in this paper. Their verification protocol recommends repeated speech-in-noise measures coupled with benefit questionnaires. The authors state in their paper that speech-in-noise tests are appropriate for assessment, pre-fitting and verification of amplification (Snapp & Telischi, 2008). They also note that based on "it's speech stimuli, background noise component, measuring strategy, sensitivity and efficiency" the QuickSIN is an appropriate speech-in-noise test for this population. The QuickSIN measures the signal to noise ratio (SNR) required to correctly identify 50% of the sentences presented during multi-talker babble. Test results are divided into levels of impairment (normal to severe). This allows the clinician to determine the needed increase in decibels for an appropriate SNR to be achieved. Therefore, if the patient shows improvement in the level of impairment with the BAHS implant, then the BAHS is deemed to be functioning appropriately.

The authors did not provide any statistics or data to support their protocol as this was not an experimental study, but an expert opinion paper. The authors cited references to support their claims that the protocol is appropriate, but did not review the literature. For example, although the authors report that the QuickSIN is a sensitive measure, the do not report levels of sensitivity or specificity. At the end of the paper, they included two cases studies which primarily addressed the assessment phase of their protocol. The first case study reported improved results on the QuickSIN when the patient was wearing a demonstration version of the BAHS as compared with the unaided condition. The second case study documented a person who showed no improvement on the QuickSIN with the demonstration device. Both patients were implanted with BAHSs, and a benefit questionnaire was admistered at least 6 weeks post-operatively. The first patient reported increased benefit with the BAHS while the second patient did not report any benefit. It should be noted that the authors did not report that the QuickSIN was used to verify their speech-in-noise performance post-operatively although it is part of their recomendation, and "benefit" was based soley on the patients' responses on a questionnaire which was not included in the paper. The level of evidence associated with this paper was a 4.5, the validity was equivocal and the importance was suggestive.

Electromechanical Verification
Hodgetts, Hakansson, Hagler and Soli (2008) compared three different methods of verifying BAHS. The three methods that were comparied were an aided soundfield audiogram, an electroacoustic approach based on the verification used with traditional air conduction hearing aids, and an electromechanical verification method using acceleration levels. The authors wanted to know (1) whether all three methods produced similar SL estimates for the long term average speech spectrum (LTASS), (2) whether these SL estimates were dependent on the input level of the signal, and (3) whether the SL estimates were comparable at some or all frequencies. All twenty-three participants had been

BAHS users for at least three months, had snap coupling abutments and had a mean age of 53.1 years. For the purposes of the study, two bone conduction transducers called Balanced Electromagnetic Separation Transducers (BEST), one for audiometric testing and one for BAHS verification, were developed and used. The BEST transducers were preferred over existing bone conduction transducers because their rigid core allowed an accelerometer to be attached to the back of both transducers to measure the acceleration levels associated with each stimulus. The BEST transducers were connected to a Verifit, which allowed the researchers to measure the output of the BAHS in acceleration level (AL) as well as sound pressure level (SPL).

Each participant had their unaided thresholds and loudness discomfort levels (LDLs) established at 250, 500, 1000, 2000 and 4000 Hz through their abutment using the audiometric version of the BEST transducer. During the audiometric assessment, a probe tube was placed in the occluded ear canal to measure real ear dB SPL while acceleration levels were measured through the BEST transducer.

At this point, the aided soundfield thresholds were measured for each patient. An HL to SPL transform for the sound booth was measured to ensure accurate SPL values at the BAHS microphone, regardless of which side the participant wore the BAHS. For the aided soundfield approach, the authors also needed calibrated RMS levels for the test frequencies for unaided LTASS at 55, 65, 75 dB SPL in order to convert the aided audiogram into SL as described by Gengel, Pascoe and Shore (1971), and used by Seewald, Hudson, Gagne and Zelisko (1992). After the calibration measurements were completed on three participants, the aided soundfield thresholds were measured for each participant.

For the real ear measures, a real-ear-to-dial difference (REDD) was established for the real ear measures (HL to SPL) and acceleration (HL to AL). The audiometric dial readings to SPL transforms at 250, 500, 1000, 2000, 4000 Hz were established so that the actual threshold values in SPL or acceleration level could be obtained. The authors therefore had all the information necessary to accurately calculate the participants' thresholds.

At this point, the aided LTASS was measured in the ear using a probe microphone. The LTASS values for each input at each frequency were compared to the unaided thresholds and the SL values were derived. Finally, the acceleration levels from the back of the BEST transducer for the aided LTASS were compared to the unaided thresholds to derive the SL values for the acceleration condition.

The authors completed a 3(fitting approach)x 3(input level) x5(frequency) repeated measures ANOVA and paired-sample t tests using Bonferonni-adjusted p-values to evaluate their data. The author's used Cohen's d to determine that a 6-8 decibel difference could be considered a significant effect. They concluded that the aided soundfield condition produced the highest estimates of SL at all frequencies except 250 Hz, which is consistent with research from air conduction hearing aids. These estimates of SL were 11 dB higher than those derived from the acceleration level method and 7 dB higher than the estimates derived from the real-ear method. According to Cohen's d, these differences in dB were both considered significant.

After examining the statistics and different elements affected by the measurement choice, including noise floor interference, frequency resolution, ability to measure the actual output of the BAHS, and ability to perform the measure on most patients with BAHS, the authors concluded that although the acceleration level measure and real ear measure shared many advantages over the aided sound field method, the acceleration method should be adopted.

The authors completed a thorough study, with an appropriate number of participants who represented a wide variety of hearing losses. Their conclusions were based not only on their statistical results, but also practicality of applying the methods in the clinic. The most notable problem in the study was that although they provided a logical argument for why the BEST tranducers were more accurate for their measurments, they provided no data to substantiate that claim. The level of evidence of this study was rated as a 2, and the validity and importance were both rated as compelling.

A Validation Study

In 2010, the same authors completed a validation study comparing the acceleration level verification method (AD) described in their 2008 study to a traditional patient derived verification method (PD), which relied on patient reports of loudness and sound quality. The authors wanted to determine whether the two verification methods produced differences in BAHS output, sentence recognition in quiet and noise, consonant recognition in noise, aided loudness for speech and subjective percentage of words understood. Sixteen participants were recruited for the study, where a master BAHS and BEST transducers were used to collect the data. As before, thresholds and LDLs and appropriate dial differences were established through the abutment using the audiometric BEST transducer. For the patient derived fitting, the settings from the participants' own BAHS were used, as the settings were set to suit the participants' desires for listening. For the audibility derived fitting, a modified Desired Sensation Level (DSL) algorithm was developed so that the BAHS output could be compared to acceleration level dB targets as is standard with air conduction hearing aids.

The authors used multiple outcome measures to determine whether there were differences between the two verification methods. Output levels of aided speech were measured by presenting real speech from the Verifit at 55, 65, 75 dB as well as a 90 dB signal to measure the maximum power output of the BAHS. The results were then compared to the DSL targets. Sentence recognition in quiet and noise were measured by using the Hearing In Noise Test (HINT). Consonant Recognition in noise was measured by using the Distinctive Features Differences test (DFD). Aided loudness was judged though the Contour Test of Loudness Perception. Finally, subjective percentage of words understood was measured by a subjective percentage of words the participants felt they understood from a paragraph of speech.

To analyze their data, the authors used a series of paired-samples t tests as the most conservative analysis for outcome variables with two levels and repeated measures analysis of variance for the outcome variables with more than two levels. A Bonferroni correction of p-values was used in order to minimize type 1 errors. Their results indicate that: 1) the output of the BAHS set to the PD fittings would be inaudible, regardless of input level, above 3000 Hz whereas the majority of inputs are audible for the AD fitting; 2) HINT scores were significantly better (lower) for the AD fittings than for the PD fittings ($p<0.001$) and the results relate to a 24% improvement in sentence recognition in noise for the AD fit; 3) Consonant recognition in noise was significantly better with the AD fit ($p<0.001$); 4) There was no significant difference between the two verification methods on the aided loudness measure although the casual input (52 dBA) approached significance ($p=0.013$) with participants tending to find soft speech louder in the AD condition; and 5) Subjective percentage of words understood approached significance for casual speech ($p=0.020$), but none of the planned contrasts revealed significant differences.

As with the previous study, this study was comprehensive and complete in its analysis. The level of evidence was rated as a 2 while the validity and importance were both compelling. The authors did not note whether this was a double or single blinded study, which would have been preferable. The authors conclude, again, that the AD fitting and verification method is preferable, but it is not clinically feasible at this time.

Discussion

The results of the studies will be addressed in two groups, the study recommending speech testing and the two studies comparing different verification methods. The study advocating the use of speech in noise testing had a number of flaws, primarily the lack of data included in the study. The inclusion of two case studies at the end of the paper suggests that some data was collected. If that was the case, the data should have been reported. The rational for using a speech-in-noise test, specifically the QuickSIN, was compelling so a more thorough examination of the protocol should be completed before it is proposed for clinical use.

The studies comparing multiple verification methods were conducted well given the limitations of the population. Given how few people wear BAHS, participant groups of twenty-three and seventeen are certainly appropriate. In addition, the use of repeated measures with the different BAHS settings on a master BAHS allowed the authors to compare the different verification methods directly from person to person without the confound of multiple devices.

Conclusion

The electromechanical method of verifying BAHS using acceleration level should be adopted, as it has been shown to be the most reliable verification method that ensures an appropriate fit to target that is comparable to the verification method used with air conduction hearing aids. In addition, this method can be used on all clients who require a BAHS, not just a subset.

Clinical Implications

At this time, the most appropriate verification method, the electromechanical method, is not actually clinically viable. The BEST transducers used in the studies are not widely available and are expensive enough to limit their use in most clinics. Having said that, this method is certainly preferable to the other verification methods reviewed currently in use in the clinic, as it directly measures the output of the BAHS. In the meantime, while we wait for technology to catch up with the evidence, we are forced to use non-evidence based methods to verify BAHS in the clinic. Until that time, the sound field audiogram will hopefully be supplemented with suprathreshold testing such as the

QuickSIN or HINT as well as other subjective tests used in these studies in order to combat some of the well-known drawbacks with the sound field audiogram.

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