University of Alberta

CONTRIBUTIONS TO A BETTER UNDERSTANDING OF FITTING PROCEDURES FOR BAHA

by

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Abstract

Current approaches to fitting Bone Anchored Hearing Aids (Baha) rely heavily on subjective patient feedback of "loudness" and "sound quality." Audiologists are limited to this approach for two reasons: (1) the technology in current models of Baha does not allow for much fine-tuning of frequency response or maximum output on an individual basis and (2) there has not been a valid approach to verifying the appropriateness of the fitting on an individual basis.

In this dissertation, a series of three studies contributes to a better understanding of fitting procedures for Baha. The first study explored the variability in mechanical point impedance for Baha users. Substantial variability from person to person suggested the need for individual or in-situ fitting procedures that would account for each person's unique bone conduction auditory system. The second study compared two in-situ fitting approaches (real-ear sound pressure level and real-head acceleration level) to the traditional aided soundfield approach currently used to verify most Baha fittings. It was determined that the real-head acceleration approach was the most accurate method of Baha verification. The third study used the real-head acceleration approach in conjunction with a modified prescriptive procedure to map aided speech onto each individual's dynamic range of hearing. Substantial performance improvements with this "audibility-derived" fitting were found when compared to subjects' performance with their original "patient-derived" and "technology-limited" Baha fittings.

Human heads vary considerably from one individual to another and accurate Baha fittings require careful consideration of the unique contribution of each person's bone conduction system. By measuring all auditory information (thresholds and upper limits of comfort) and all hearing aid information (aided Baha responses to speech) on each individual, one can compare directly the output of the Baha to the unique auditory needs of a given

patient. With more flexible processor technology and an accurate and reliable objective method for fitting the Baha, greater audibility of aided speech can be achieved in the most important frequency regions. Implications for engineers interested in developing more sophisticated and flexible Baha processors and implications for audiologists interested in more objective measures of Baha fitting are explored.

Epigraph

"The goals of hearing aid fitting do not change whether one is fitting conventional, programmable, or digital technology. Most audiologists can agree on the following set of goals for a hearing aid fitting: sounds are audible, comfortable but not uncomfortable; the hearing aids provide good sound quality and a safe listening environment; and amplification meets the patient's communication needs and expectations. The goals do not change depending on the technology chosen. How the goals are met may change slightly."

Palmer, C. V., Lindley G. A., & Mormer, E. (2000). Selection and Fitting of Conventional Hearing Aids. In: M. Valente, H. Hosford-Dunn, and R. Roeser (Eds.) *Audiology: Treatment.* Thieme: New York. Pg. 398.

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Chapter 1: Dissertation Introduction

1 Chapter 1

The overall goal of this dissertation is to increase our understanding of the fitting procedures for Baha. The studies conducted for this thesis were model-driven and parallel much of the discovery and validation work previously developed to evaluate air conduction hearing aids. Similar approaches to assess and verify Baha were intended to enhance knowledge transfer and encourage clinical application.

1.1 A General Overview

Some hearing impaired patients cannot wear air conduction hearing aids for a variety of reasons (e.g., aural atresia, chronic ear disease; Håkansson et al., 1990a; Snik, Mylanus & Cremers, 2001). Assuming there is sufficient residual cochlear function in at least one ear, the alternative mode of sound delivery for these patients is bone conduction amplification through skull vibration. One of the most common types of bone conduction hearing devices today is known as the Baha (formerly known as the Bone Anchored Hearing Aid). The Baha consists of a vibrational sound processor connected via an abutment to a surgically implanted titanium screw in the parietal-mastoid region of the patient's skull. Most Baha users do well with their devices; however, some patients fail to perform as well as might be expected based on current clinical Baha fitting procedures. Even for those patients who are performing well, the current procedures often shed little light on what aspects of their hearing abilities or the hearing aid fitting have led to their success. It is proposed that researchers and clinicians lack the techniques to accurately and reliably assess bone conduction hearing and verify the appropriateness of the Baha vibrational output for ***individual*** Baha users.

This dissertation is conceptualized in Figure 1-1. The left-hand side of Figure 1-1 shows a model of the hearing aid fitting process (Seewald et al, 1996). Accurate information obtained during the *assessment* phase is used to guide the *selection* of appropriate output characteristics for a given individual for a given device (in this case, the Baha). Next, the hearing aid output is determined to *verify* the appropriateness of the aided output to the parameters determined in the *selection* phase. Finally, if the hearing aid output has been *verified* to be acceptable, the individual's performance with the device is *validated* through outcome measurement. The current research provides information to improve our understanding of a number of these model parameters for Baha. Each of the 3 studies and their relationship to the model is depicted on the right-hand side of Figure 1-1.

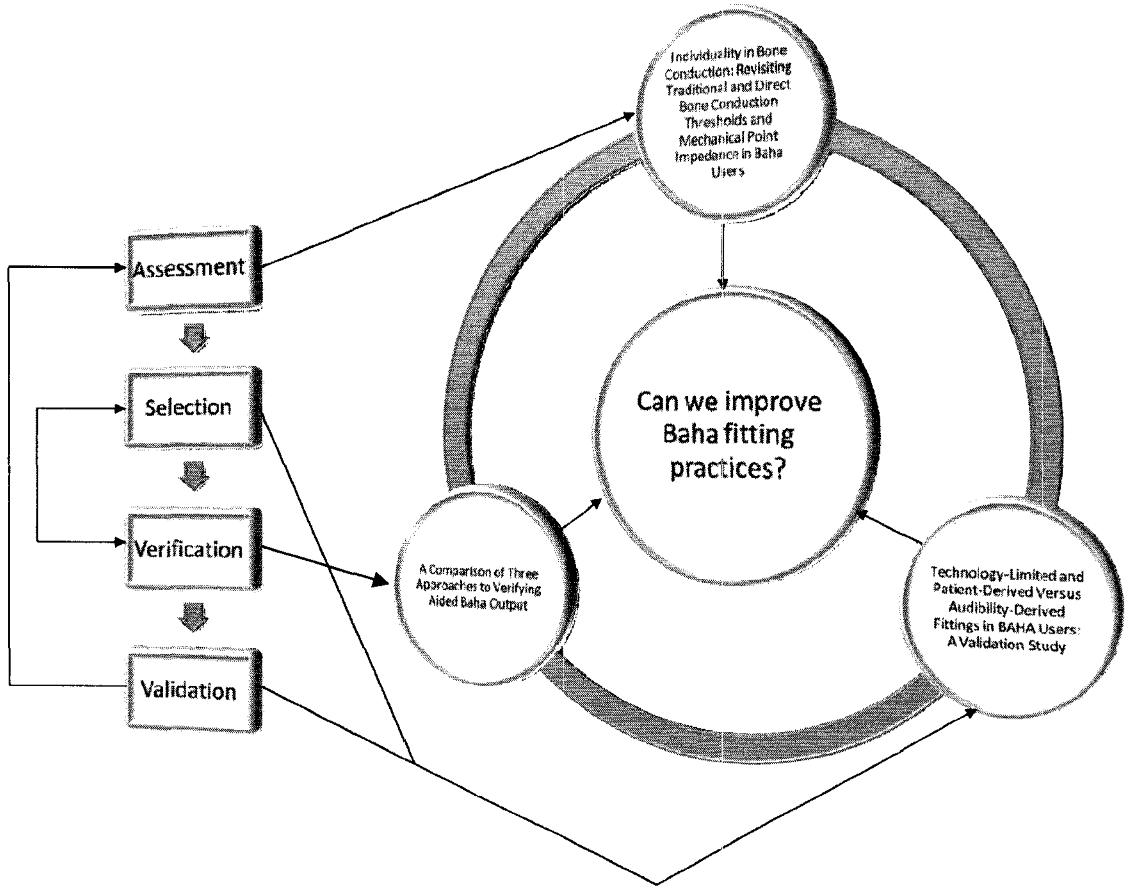

Figure 1-1. Conceptualization of the series of research projects.

1.2 Literature Review

1.2.1 Hearing in Perspective

Sound has both a physical sense, as in the case of "vibrations" originating from a source, and a perceptual sense, as in the case of how these vibrations are heard. Our hearing system presents us with a representation of the world of sound sources around us. When the hearing system functions reliably, this is, to say the least, a remarkable phenomenon.

Consider the world of sound sources to which we are exposed every day. Each source producing its own vibrations that are inextricably superimposed in the air before they reach us. Remarkably, listeners with normally functioning hearing systems are able to disentangle these vibrations so dependably that they are not aware of the fact that the sounds were ever mixed.

To be heard, the airborne (acoustic) vibrations must first be transduced into a mechanical vibration, then into hydrodynamic vibration and finally into an electro-chemical neural process. Typically, the tiny acoustic vibrations travel down the external auditory canal, inducing a displacement of the tympanic membrane that is proportional to the amplitude and spectral content of the acoustic vibration. The tympanic membrane is connected to the ossicular chain, within the air-containing space known as the middle ear. The primary function of the middle ear (with respect to hearing) is to act as an impedance matcher. Impedance is a structure's resistance to vibration when a force is applied (Håkansson, Carlsson & Tjellstrom, 1986). The tiny mechanical vibrations received at the tympanic membrane must eventually enter the fluid-filled cochlea. Since fluid has higher impedance than air (consider waving your arm in the air versus underwater), the mechanical vibrations will be attenuated before entering the cochlea. The area differential between the tympanic membrane and the other end of the ossicular chain, the stapes footplate, accounts for the majority of the impedance match between the mechanical vibration in the middle ear and the hydrodynamic vibration in the cochlea.

The vibration of the stapes footplate creates a complex traveling wave along the length of the basilar membrane inside the cochlea with peak displacements in accordance with the spectral content of the incoming vibrations. In the normally functioning cochlea, tiny outer hair cells actively amplify and finely tune the basilar membrane response. These outer hair cells allow for greater sensitivity to soft sounds and more accurate filtering of incoming frequency components. Sufficient displacement of the basilar membrane, either through an intense enough incoming sound source (approximately 50 dB SPL), or the assistance of the outer hair cells, results in a shearing of the stereocilia on the tops of the inner hair cells. The shearing motion opens chemical channels in the inner hair cells creating an electrical potential that results in the release of neurotransmitters, thereby generating the necessary action potentials to send the signals through the brainstem to the cortex where the sound is eventually interpreted.

Thorough description of the hearing processes, especially from the cochlea to the cortex including interpretation of complex speech sounds, is far more exigent than this brief overview permits. Tiny components of the top-down processes that facilitate the analysis of complex auditory scenes (Bregman, 1991), the perception of speech in the presence of complex background noise (Peters et al., 1998) and/or limited spectro-temporal information (Shannon et al., 1995) are dissertations unto themselves. However, the focus of this work will be on expanding our understanding of the influence of inputs to the auditory periphery with the expectation that top-down processes are easier to comprehend, if we first understand what is being delivered to patients from the bottom up.

1.2.2 Air and Bone Conduction Hearing

The path of sound waves from air to cochlea represents the predominant mode of hearing---air conduction hearing. However, another mode of hearing---bone conduction---is also available. To hear by bone conduction, no matter how complex the actual physiology, vibrations from some location on the skull need to be sufficiently intense to generate a traveling wave in the cochlea. If that traveling wave is of sufficient magnitude, the cochlea to cortex pathway will be stimulated and the perception of sound will occur.

At the cortical level, a 1000 Hz tone at a patient's threshold of hearing will have the same neural representation regardless of the mode of stimulation (air or bone). However, there will be tremendous differences between the input levels (air or bone) required to generate that same neural representation to the patient. Moreover, these differences in input requirements are not only important considerations ***between*** air and bone conduction, but also ***within*** each mode of stimulation from person to person.

Consider the case of air conduction hearing. Two patients with equivalent systems from the cochlea to the cortex require different input levels to obtain the same neural representation of a given sound. This is attributable to the combined effects of the size differences between their respective ear canals, interaction of the input signal with the tympanic membrane compliance, differing impedance levels in the canal walls or middle ear spaces and other peripheral variables. Failure to capture and understand the influence of as many of these variables as possible may lead to erroneous assumptions about the signal levels required by each patient to hear optimally. As an example of this, Saunders and Morgan (2003) measured the real ear output responses for a fixed level input in 1814 ears. They found that the same input can result in an ear canal output that varies by as much as 40 dB from person to person. Indeed, no two ears are necessarily alike.

The same is expected to be true for bone conduction. Two patients with the same neural representation of a given sound will require different inputs to generate that neural representation. Alternatively, the same input to the two patients may result in a different neural representation of the sound. For one patient, the same input may be easier to detect than for the other. It is logical to assume that understanding and accounting for these differences on an individual basis will be a necessary component in the fitting of Baha.

While much has been learned about the mechanical dynamics of direct bone conduction (Håkansson et al., 1985), the variability in bone conduction hearing (Dirks, 1964), the differences between transcutaneous and percutaneous bone conduction (Håkansson et al., 1984, 1990; Stenfelt & Håkansson, 1999) and the complex physical and physiological pathways (Stenfelt et al., 2000; Purcell, 2003), it has had little impact on the clinical practices of most audiologists. The clinical assessment procedure for Baha candidacy (the HL audiogram) has limitations as a reference quantity, because the measure includes the highly variable skin and subcutaneous tissue, while the Baha functions through direct bone conduction. This discrepancy makes comparisons of aided function to unaided function tenuous. Even if clinicians ignore the unaided function and choose to concern themselves only with aided Baha function, the verification procedure currently used by most audiologists---aided soundfield thresholds---is plagued with validity and reliability limitations (Seewald et al., 1992; Stelmachowicz et al., 2002; Hawkins, 2004). As mentioned before, these limitations to the fitting of Baha make it difficult to understand why a given patient is or is not doing well with a Baha.

1.2.3 Fitting Air Conduction and Bone Conduction Hearing Aids

The goal for selecting and fitting amplification should be to match, as closely as possible, the amplification characteristics of a hearing aid(s) to the unique auditory characteristics of the person with the hearing loss so that person can use his/her residual hearing to its maximum potential (Cornelisse et al., 1995). This *goal* should not change depending on what type of hearing aid is being fitted (air conduction vs. bone conduction). How one arrives at meeting the goal, however, may vary slightly.

Within the "aided" condition, there are two fundamental relationships to consider: (1) what is the level of amplified speech, relative to a listener's threshold of hearing, with both measures obtained at some common reference point on the patient?, and (2) what is the maximum hearing aid output relative to the levels a listener judges as being uncomfortably loud with both measures obtained at some common reference point on the patient (Seewald, 1995)? Consideration of these relationships with respect to air conduction and bone conduction amplification (i.e., Baha) will be explored. In particular, careful consideration will be given to various rules and practices used for fitting of air conduction hearing aids and how they may be applied to the fitting of Baha.

1.2.4 Hearing Aid Prescriptive Procedures (Fitting Rules)

A great number of fitting rules---known as prescriptive procedures---have been developed to address the fundamental relationships between hearing aid electroacoustics (gain, frequency response) and the hearing abilities of listeners (see Traynor, 2000 for a review). In an attempt to minimize the trivial application of important electroacoustic characteristics, prescriptive procedures use theoretical rationales to generate the prescription of specific corrective amplification for each listener. The advantage of the prescriptive approach is obvious. As Byrne (1992) points out "the theoretical basis on which the [prescription] is made has been explicitly stated and is therefore accessible to critical examination." Those prescriptive rationales for which sufficient validation data exist continue to be used and refined. Those without sufficient validation data tend to fall out of use. Without a theoretical (and validated) rationale for the prescription of electroacoustic characteristics, each listener may function as a unique experiment with potentially variable and unpredictable outcomes. This has been the case for fitting of Baha for many years.

Recent consensus documents have recommended that hearing aid fitting be done in a systematic way (AAA, 2003; ASHA, 1998; Pediatric Working Group, 1996). The recommended approach typically follows a series of stages from assessment to validation (see Figure 1-1 for an example of one such approach). Accurate information obtained during the *assessment* phase is used to guide the *selection or prescription* of appropriate output characteristics for a given individual with a given device. Next, the hearing aid output is determined to *verify* the appropriateness of the aided output to the electroacoustic parameters determined in the *selection* phase. Finally, if the hearing aid output has been *verified* to be acceptable, the individual's performance with the device is *validated* through outcome measurement (Seewald, 1995).

The same rules for validating a hearing aid fitting (e.g., aided speech recognition in noise, subjective benefit, satisfaction) are applicable to both air conduction hearing aids and Bahas. However, assessment procedures, selection or prescriptive methods and verification approaches between the two devices may have different rules that need to be considered. These will be outlined in separate sections. Special attention will be given to the concept of Baha gain in the selection or prescription section.

1.2.4.1 Assessment

During the assessment phase, information is gathered to help understand the type and degree of hearing loss as well as patient perceived handicap. The thresholds of hearing and thresholds of discomfort are two critical measures typically obtained (ASHA, 1998). The assessment information ultimately will be used to guide the prescription of electroacoustic parameters for the air conduction hearing aid. Since air conduction hearing aids ultimately amplify speech into the ear canals of patients in sound pressure level (dB SPL), it has long been established that determining the hearing levels of patients in dB SPL either directly (with a probe microphone) or through the use of some acoustic transforms (e.g., real ear to coupler difference; RECD) in the ear canal is highly important (Seewald, 1995, 1996; Stelmacowicz, 1988; ASHA, 1998; Hawkins, 1991). This approach captures the unique acoustic signature of each patient's ear canal on the incoming sound and positions the audiologist to make a direct comparison of amplified speech to the listener's thresholds at some common reference point (in this case, the ear canal).

Current assessment procedures for Baha users[1] involve testing the softest sound a person can hear by bone conduction in dB HL. A standard bone oscillator is coupled to the patient's mastoid via a steel-tension headband. For the Baha user, this coupling method is inherently unsatisfactory. The Baha operates through direct bone conduction, which invalidates hearing levels measured using an bone conduction transducer positioned over the skin-covered mastoid and held in place with a headband as a baseline for aided comparison. Moreover, unaided air conduction thresholds contain the patient's air-bone gap and, therefore, do not serve as a valid baseline for aided comparison either (see functional gain in the verification section). The thresholds of interest for Baha users are those obtained directly through the Baha abutment. What is needed is a means to measure both the hearing thresholds and the thresholds of discomfort (assessment data) by bone conduction as well as amplified speech at some common reference point.

1.2.4.2 Selection or Prescription

The goal of the selection or prescription stage of the fitting process is to generate electroacoustic targets of a desired hearing aid for a particular individual. The approach to prescribing electroacoustic parameters should facilitate verification and validation of the devices (ASHA, 1998). As mentioned earlier, there are several options available to generate prescriptive targets for amplified speech. As members of the ASHA Ad Hoc committee on hearing aid selection and fitting for adults noted: "although no universally accepted method exists for expressing the ideal electroacoustic characteristics of hearing aids, there is significant knowledge base for making rational and defensible decisions. It is the audiologist's responsibility to determine the requisite electroacoustic characteristics using methods that are based in current scientific knowledge."

For air conduction hearing aids, one well-validated approach to the prescription of hearing aid targets is the Desired Sensation Level (DSL i/o) prescriptive method (Seewald, 1995, Cornelisse et al, 1995; Jenstad et al., 1999). The DSL method is introduced here, because a

[1] An assumption is made here that we already know that the user is a Baha candidate. *Assessment* in this sense is not an issue of candidacy, but rather, an issue of what information about the user's hearing is most critical as the first stage of the Baha fitting process.

modified version of this approach was used in the third study in this series of projects. In essence, the threshold of hearing and the threshold of discomfort data obtained in the assessment phase (in patient-specific real ear SPL) define a user's residual auditory area (dynamic range). The DSL mathematical algorithm takes the information about the residual auditory area across frequencies and "maps" a wide range of inputs within this dynamic range (Cornelisse et al, 1995). The algorithm produces targets for amplified speech within the ear canal of the user. These real ear targets serve as a guide for subsequent real ear verification of hearing aid output on an individual basis.

1.2.4.2.1 Gain for Baha

Functional gain (unaided soundfield thresholds minus aided soundfield thresholds) has received a lot of attention in the Baha literature. However, actual prescription of gain for Baha has received almost no attention. There are several reasons for this. First, for the most part, traditional ear-level Bahas (e.g., Classic 300, Compact, & Divino) serve more of a bypass function than a compensation (or gain) function (Carlsson & Håkansson, 1997). That is, these hearing aids are often selected for patients with normal cochlear function who simply need to bypass a conductive hearing loss. However, in recent years it has become more common to include users with mixed hearing loss as potential candidates for Baha. As the degree of bone conduction (sensorineural) hearing loss increases, the demand for more output and device flexibility increases as does the demand for prescriptive considerations of how to appropriately shape the frequency response.

The second reason gain prescription with Baha has received little attention may reflect the confusion about what gain actually represents for a Baha. For air conduction hearing aids, gain is simply the difference between the output amplitude and the input amplitude in dB. For example if a hearing aid produces an output at 1000 Hz of 100 dB SPL with an input of 60 dB SPL, the gain would be 40 dB. Note that the quantity associated with both the output and the input is SPL. When this is the case, the gain (output SPL – input SPL) is reported as just a dB value (Carlsson & Håkansson, 1997). When discussing the Baha, the concept of gain is not so straightforward. Because the output of the Baha is a mechanical vibration (often expressed in dB output force level ref: 1 μN) while the input to the Baha is an acoustic vibration (expressed in dB SPL ref: 20 μPa), the reference for "gain" actually becomes 0.05 m^2. It is perhaps more sensible to talk about acousto-mechanical sensitivity level (AMSL) than it is to talk about gain---even though the AMSL is analogous to gain (Dillion, 2000).

A third concern regarding Baha gain is reflected in the following: knowledge of a Baha's AMSL does little to inform the clinician about how the device will function on a given patient with a given hearing loss, when the patient is listening to suprathreshold inputs such as speech. It is conceivable that one might have two different Bahas with the same gain (e.g., a Classic and a Compact) measured on a skull simulator (or in the soundfield for that matter) with a soft input that have vastly different responses on a given patient in response to average or loud speech (owing in this case to the difference in available output level). Moreover, it is likely that individual differences in the vibrational responses between patients make understanding the relationship between gain---as measured on a coupler---and the patient's hearing abilities tenuous.

Consequently, prescriptive rules for prescribing gain for Baha have not emerged. Prescribing sensation level estimates on an individual basis may be less confusing than prescribing gain. If a listener's residual auditory area (dynamic range) could be defined using some quantity (say SPL or acceleration level) at some common reference point, the DSL i/o algorithm could be used to generate targets for amplified speech within that dynamic range. Of course, the gain of the Baha is still important, as it will ultimately decide whether or not a given Baha is capable of providing a sufficient sensation level. However, the output of the Baha will contain the input and the gain plus any non-linearities that may exist in the processing. One of the most important advantages of the DSL mapping procedure is that it does not necessarily matter whether the inputs to the algorithm are in real ear SPL or some alternative (e.g., acceleration level in dB). So long as the algorithm is fed a reliable, individual residual auditory area, it can be programmed to generate "prescriptive" targets both for amplified speech and for maximum hearing aid output (Cornelisse et al., 1995; Scollie, personal communication). This prescriptive approach for Baha would parallel the prescription process for air conduction devices and would satisfy our goal of better understanding the relationship of aided Baha speech to the dynamic range of hearing on an individual basis.

1.2.4.3 Verification

During the verification stage, the actual hearing aid output characteristics are compared to the prescribed characteristics determined during the selection or prescription stage. In the case of air conduction aids, if the prescription yielded real ear SPL targets for amplified speech and maximum output, the verification procedure would require the audiologist to compare the real ear SPL of the hearing aid in the patient's ear to these targets. Of course, a major advantage of this approach is that, not only is it possible to compare the hearing aid output to the prescriptive target, but the output can be compared to the real ear hearing threshold data (for audibility assessment) and the real ear threshold of discomfort data all obtained with the same common reference point (Seewald, 1995). Other verification approaches, such as real ear insertion gain, do not allow for a direct comparison between hearing thresholds and thresholds of discomfort (Scollie & Seewald, 2002).

For the verification of Baha, traditional approaches have used either functional gain or aided soundfield thresholds to verify the in situ performance of the device (e.g., Snik et al., 1994). Functional gain is defined as the difference in dB between unaided thresholds obtained in the soundfield (dB HL) and aided thresholds obtained in the soundfield with the Baha connected (dB HL). The rationale for calculating functional gain reflects the idea that, so long as the Baha is functioning within the linear range, the gain estimate achieved at threshold will reflect the gain of the device for higher-level inputs (e.g., conversational speech). This is not necessarily a valid assumption. First, the functional gain will always overestimate the gain by the size of the air-bone gap (difference between air conduction and bone conduction thresholds). Second, gain estimated from threshold calculations will be incorrect because of non-linearity often associated with higher-level inputs. For example, the Baha Compact begins to compress even in response to conversational level inputs of 65 to 70 dB SPL. In study 2, the investigator will detail a number of other concerns regarding aided soundfield thresholds and propose two alternative approaches to verification for Baha.

1.2.4.4 Concluding Thoughts on Fitting Rules

The goal for fitting hearing aids is the same for both air conduction devices and Baha---match the hearing aid to the user's unique auditory needs. At first glance, it would appear that the rules for fitting Baha should differ in important ways from the rules for fitting air conduction hearing aids, owing to important differences such as location and mode of stimulation. However, by keeping the two fundamental considerations in mind --- (1) the level of amplified speech, relative to a listener's threshold of hearing, with both measures obtained at some common reference point on the patient, and (2) the maximum hearing aid output relative to the levels a listener judges as being uncomfortably loud, with both measures obtained at some common reference point on the patient --- it turns out the rules may not be that different after all.

1.2.5 **An Objection Anticipated**

The reader who is familiar with the Baha literature may be wondering what the point of all this discussion is regarding fitting guidelines and prescriptive rules for Baha. Do we really need to worry about all these stages of fitting like assessment, selection and verification? After all, is it not true that, when we look at validation data (outcome measures), Baha users are overwhelmingly satisfied with their devices (Dutt et al., 2002; Mylanus et al., 1995)? Is it not true that Baha users perform better with the Baha than they do with traditional bone conduction devices on a headband (Tjellstrom et al., 1985; Mylanus et. al., 1994)? Are Bahas not in many ways superior to air conduction hearing aids for these patients (Mylanus et al., 1998)?

A seemingly compelling argument may proceed as follows. "I have been fitting Baha for years now. For the most part I simply give the device to the patient and ask him/her to set the volume control to the point where it sounds best. The overwhelming majority of people I see are extremely pleased with the Baha. In fact, in my practice, Baha users seem to be the most satisfied patient group I've ever treated." Is it really necessary to put such a fine point on the fitting of Baha when the current fitting approaches, regardless of their potential limitations, seem to be, if not ideal, then at least sufficient?

Imagine that you were a baker and you discovered over the years that the overwhelming majority of the people that ate your cakes were pleased with the taste. However, to your dismay, some people just do not care for them[2]. Our hypothetical baker may be content with the knowledge that he cannot please everyone. Alternatively, he may be wondering what ingredients make his cakes taste so pleasing to most people but not to others. He may also wonder if simply asking his patrons if they are satisfied with the taste of his cakes provides enough insight into where his measurements may or may not need adjusting. What can he identify about the variability in his patrons taste buds? Is there a way for him to consistently measure the most important ingredients for each patron? If he tailors the recipe on an individual basis, does he please even more people than if he keeps the recipe that makes the majority of patrons happy?

[2] To the further dismay of our baker, he discovers that the least satisfied of his patrons also seem to be the most vocal about their distaste.

Indeed, the majority of Baha users are satisfied with their devices (Dutt et al., 2002). However, in the spirit of intellectual honesty, clinicians and researchers must admit that: (1) not everyone is satisfied with the Baha; (2) some people may report being satisfied, even though, if appropriate adjustments could be made, there may be room to increase their satisfaction, and (3) some people report being satisfied when, in fact, they are not. While satisfaction may be an important outcome measure, Ross and Levitt (1997) warn:

> *"It is important to recognize the limitations of this measure and how easily it can be misused. Not only is the measure ill defined (hearing-aid satisfaction means different things to different people) but the measure is too dependent upon situational variables and too influenced by a host of personal factors (such as expectations, communication demands, life style, etc.) to be the sole-measure of success."*

Satisfaction alone offers the clinician or researcher only limited insight into what makes a given Baha fitting a success or failure. Since the goal of this series of projects is to increase our understanding of key Baha fitting issues, the Baha clinician or researcher --- just like the hypothetical baker --- needs to know more than just whether or not the Baha user was satisfied. He seeks understanding with respect to variability in his patient population (Study 1); he aims to find valid and reliable measurement techniques so he can consistently determine how much of the most important ingredients (e.g., audibility of aided speech) to include in his fitting (Study 2); and finally, he tests whether or not providing the appropriate ingredients on an individual basis leads to better performance than simply keeping his generic recipe (Study 3).

1.3 Aim of this Dissertation

In chapters 2, 3 and 4, three studies will be presented that were designed to improve our understanding of a number of key Baha fitting issues. In the first study, the investigator explored the difficulty in predicting the relationship between transcutaneous and percutaneous thresholds. Additionally, the variability in direct bone conduction responses from patient to patient was explored. The second study compared 3 verification approaches to assessing speech audibility with a Baha. The third study was designed to compare the influence of different fitting approaches on the outcomes of Baha patients. Together, these studies address several components of the Baha fitting model outlined in Figure 1-1 and hopefully contribute to a growing body of knowledge related to the fitting of Baha.

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Chapter 2: Individuality in Bone Conduction: Revisiting Traditional and Direct Bone Conduction Thresholds and Mechanical Point Impedance in Baha Users

2 Chapter 2

2.1 Introduction

Developments in technology and in the mechanical and physiological sciences offer great promise to mitigate the effects of conductive, mixed and even single-sided hearing loss through the use of bone conduction amplification (i.e., the Baha). Unfortunately, much of what has been learned in the laboratories has had only limited impact on clinical protocols. Candidacy for Baha is still based largely on the traditional HL audiogram, and verification of Baha is still based largely on the aided soundfield audiogram. The second study of this dissertation explores the limits of the aided soundfield audiogram for the verification of Baha, and the third study validates a new approach to Baha fitting. Both the second and third studies were predicated on the notion that each Baha user's responses to bone conducted stimuli are highly individual. The first study revisited and extended two aspects known to contribute to this individuality in bone conduction responses: (1) the relationship between traditional bone conduction thresholds and thresholds obtained directly through the Baha abutment, and (2) the mechanical point impedance through the Baha abutment in live patients.

2.1.1 Context Scenario

A clinician receives a referral audiogram for consideration of Baha candidacy. The patient shows a mixed hearing loss secondary to chronic ear infections. The air conduction thresholds are in the severe to moderately-severe range, while the bone conduction thresholds slope gently from 30 dB at 250 Hz to 50 dB at 4000 Hz. This hypothetical audiogram is displayed in Figure 2-1. Since the audiologist knows that an air conduction hearing aid is contraindicated due to the ear infections, it is correctly assumed that bone conduction amplification, and the Baha in particular, is the best choice for this individual. However, the patient has just asked a difficult question, "How much better will I hear through the abutment compared to the headband?" Moreover, the patient has decided that he will not wear the Cordelle II (body aid), leaving the audiologist to wonder how confident to be that the current ear level Bahas will provide enough output given these audiometric bone conduction thresholds. Both of these questions require the audiologist to believe he or she has a good understanding of the relationship between the traditional HL thresholds and the direct bone conduction hearing abilities of the patient. Moreover, he or she must also have a good understanding about the direct bone conduction output capabilities of a given Baha when connected to a patient. This paper will show that both of these expectations are difficult to predict if the only information at your disposal is the HL audiogram.

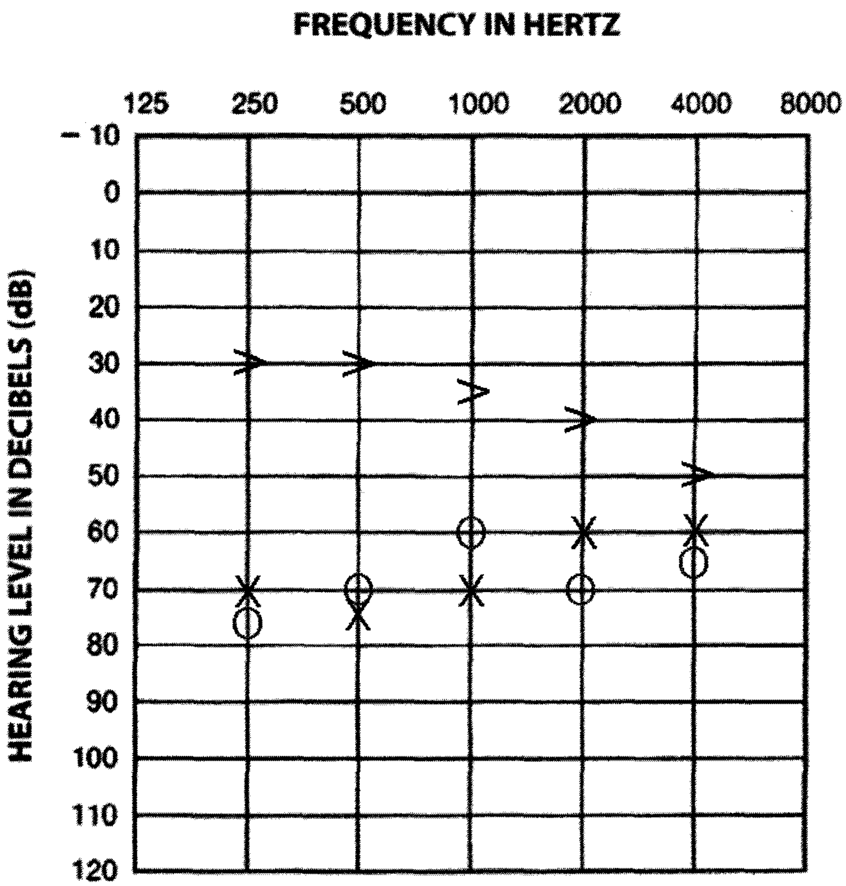

Figure 2-1. Audiogram from a hypothetical Baha candidate.

2.1.2 Bone Conduction Hearing

Bone conduction hearing is a highly intricate process involving contributions from: (1) air conducted sound radiated in the ear canal, (2) middle ear ossicular inertia, (3) inner ear cochlear fluid inertia, (4) compression of the cochlear walls, and (5) pressure transmission from the cerebrospinal fluid (Stenfelt & Goode, 2005). Stenfelt and colleagues have shown that it is difficult to separate and understand the contributions of each bone conduction hearing component, especially in the live patient (Stenfelt, Håkansson & Tjellstrom, 2000; Stenfelt, Håkansson,& Tjellstrom, 1998; Stenfelt, Hato, & Goode, 2002; Stenfelt, Hato, & Goode, 2004a; Stenfelt, Naohito, & Goode, 2004b; Stenfelt, Wild, Hato & Goode,2003). However, the problem can be defined more simply. To be heard (or to stimulate threshold), bone conduction vibrations, with a given bone conduction transducer, need to be of sufficient magnitude at a given frequency to result in a basilar membrane displacement large enough to begin the electro-chemical cascade of transmission from the inner hair cells to the auditory cortex. The success of bone conduction transmission depends on: (1) the coupling between the transducer and patient, (2) the mechanical impedance of the skull to which the bone conduction transducer is connected, (3) the transfer of energy along the five various bone conduction routes listed above, and (4) the status of the inner ear.

2.1.3 Traditional Bone Conduction vs. Direct Bone Conduction Thresholds

One of the main advantages to the Baha has always been the coupling. Traditional bone conduction hearing aids were held in place by a steel tension headband that, in addition to being aesthetically unappealing, often led to pressure sores. By contrast, the Baha is rigidly connected to an implant in the parietal-mastoid region of a patient's skull, thereby eliminating the need for a headband. In addition to the practical advantages of the Baha coupling, there is also no skin and subcutaneous tissue to interfere with the transmission of bone conducted sounds from transducer to the skull. So, how much of an advantage is there to delivering bone conduction sounds directly to the skull via the Baha abutment (percutaneously) compared to delivering bone conduction sounds through the skin and tissue (transcutaneously) via a steel tension headband?

A number of researchers have attempted to answer this question (Håkansson, Tjellstrom, & Rosenhall, 1984; Håkansson, Tjellstrom, & Rosenhall, 1985; Mylanus, Snik, & Cremers, 1994; Stenfelt, & Håkansson, 1999). There are 3 methods that have been used to estimate the differences between transcutaneous and percutaneous bone conduction. If a given subject's hearing thresholds are used, one can determine the difference (in dB) at threshold between: (1) the electrical voltage or current delivered to the bone conduction transducer, (2) the acceleration off of the skull, and (3) the force required to vibrate the skull. For example, Håkansson et al. (1984) used Bekesy audiometry to investigate the difference in voltage (dB) required to stimulate bone conduction thresholds with a conventional Oticon bone conduction transducer pressed against the skin or rigidly connected to a Baha abutment. On the 10 subjects tested, they found almost no difference in transcutaneous vs. percutaneous bone conduction thresholds in the low frequencies. However, they discovered a mean threshold improvement with the direct bone conduction of between 10 and 20 dB in the mid to high frequencies. Håkansson et al. (1985) found an even more dramatic improvement in thresholds by direct bone conduction when measuring the acceleration level at threshold. In that instance, the differences were large at all frequencies especially at 1000, 1500 and 2000 Hz, where the threshold improvements on the seven subjects averaged to 27, 25.5 and 27.5 dB respectively. Stenfelt and Hakansson (1999) measured the voltage to the transducer for trans- and percutaneous thresholds and then converted these voltages to force as a reference quantity on 9 subjects. They found that, at 250, 500 and 1500 Hz, the force level required to generate a threshold was actually lower through the skin than when measured directly through the abutment. At all other frequencies the direct bone conduction thresholds required a lower force level. However, this time the average differences were only 7 dB or less. The threshold level shifts (+/- 1 SD) for these three studies are graphed in Figure 2-2. Two things should be fairly obvious to the reader: (1) there are considerable differences in threshold shifts depending on the study you read and the method used to measure the threshold differences and (2) the variability in responses at a given frequency appears to be fairly large. In fact, Håkansson et al. (1985) noted that:

"The shapes and the absolute values of each threshold curve are highly individual and do not give any universally valid information."

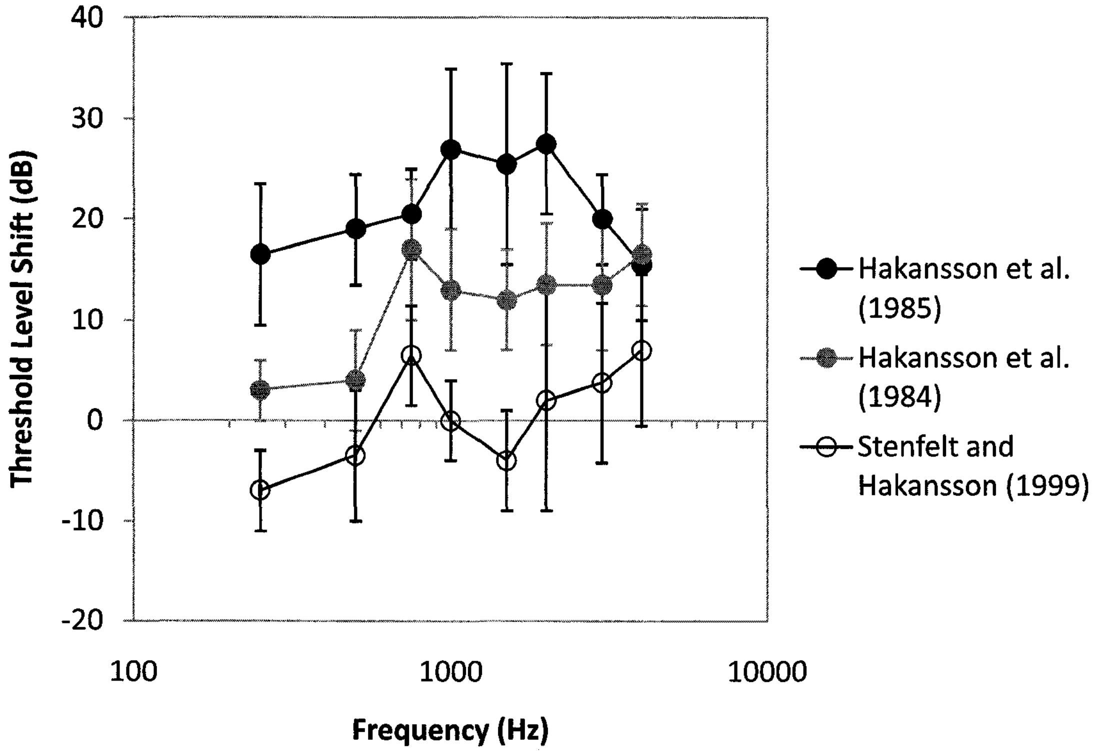

Figure 2-2. Difference in threshold level shifts measured three ways in three different studies (error bars = +/- 1 SD).

In spite of this conclusion, more than 20 years ago, it is often noted in journal articles, at conferences and symposia, in company literature and most likely in the Baha candidacy clinics, that a given user can expect an improvement of somewhere between 15 and 20 dB with the Baha compared to traditional bone conduction through the skin and subcutaneous tissue. It is not that this is necessarily an incorrect statement. However, given the differences between studies and the variability in subject responses, this conclusion may be somewhat misleading for a given individual.

To make matters worse, the differences in transcutaneous and percutaneous thresholds from subject to subject appear to be unrelated to what would seem to be an obvious variable. Using the voltage to transducer method of threshold shift estimation, Mylanus, et al., (1994) found no correlation between the thickness of the skin and subcutaneous tissue and the pure tone average (PTA) threshold shift. An individual was just as likely to display a threshold shift of 10 dB with only 2 mm of skin and tissue as was an individual with 9 mm of skin and tissue. Conversely, they found an individual with only 2 mm of thickness had a PTA threshold shift of 16 dB, while someone else had 13 mm of thickness but a PTA threshold shift of only 3 dB.

Stenfelt and Håkansson (1999) postulated that the teeth might provide a better estimate of direct bone conduction than thresholds measured through the skin covered mastoid, because they are coupled more directly to the skull bones. They found that, at some frequencies, the teeth provided a closer approximation to direct bone conduction thresholds than the skin-covered mastoid. At other frequencies the skin-covered mastoid provided a closer approximation. In either case, the differences were quite small. Additionally, measuring bone conduction through the teeth may introduce a new range of variability, because subjects are sure to vary with respect to the quality of their dentition (missing teeth, wearing dentures etc).

So, moving from a transcutaneous to a percutaneous coupling, in general, has been shown to lead to a lowering of thresholds. However, there is considerable variability from study to study and subject to subject. While the skin and tissue have an effect, the net difference appears to be unrelated to the thickness and cannot be used as a pre-operative predictor of likely improvements with direct bone conduction (Mylanus et al., 1994). Another likely source of variability from subject to subject is the mechanical point impedance measured through the Baha abutment. Even ignoring the variability from the skin and subcutaneous tissue by measuring the responses directly through the Baha abutment, one is still likely to see variability from subject to subject. How much variability, though?

2.1.4 Mechanical Point Impedance

When vibratory motion at a given point is compared to the force driving it, the "resistance to be set in motion" is defined as the mechanical impedance of the system under test. The expression is:

$$Z = F/v \qquad (1)$$

Where:

Z = mechanical impedance (Ns/m)
F = force applied (N)
v = vibration velocity (m/s)

When vibrating something as complex as a human skull, we are bound to identify inter-subject variability. This variability may have important implications for Baha users. For example, a skull with low impedance will be easier to vibrate than a skull with high impedance. Consequently, the same input to two different patients (i.e., the same Baha) may result in very different vibration magnitudes. Even if both patients had matched auditory systems from the inner ear to the cortex, the difference in mechanical impedance may result in dramatically different traveling waves at the basilar membrane and, ultimately, very different sound perception.

Several investigators have reported on the mechanical point impedance of human skulls. The majority of these studies describe the mechanical impedance of cadaver heads and/or dry skulls (Stenfelt, Håkansson & Tjellström, 2000; Stenfelt & Goode, 2005) or the mechanical impedance of the skin-covered skull in live subjects (Flottorp & Solberg, 1976). To date, the most comprehensive investigation of mechanical point impedance through a Baha abutment in living patients comes from Håkansson, Carlsson & Tjellström (1986). Using a Bruel and Kjaer 8001 impedance head, they were able to simultaneously measure the force and the acceleration in response to a Bruel and Kjaer mini-shaker (type 4810) directly from the Baha abutment in 7 patients. Mechanical impedance was derived by first converting the acceleration signal into velocity and then dividing the force by this derived value. They determined that there were fairly large differences between subjects due to a number of factors. For example, they noted that their subjects (like most Baha subjects) have skull anatomy that deviates from patient to patient due to surgical interventions, developmental malformations and/or inherent individual differences. Also, they noted that the "coupling" between the impedance head and the titanium screw (of the Baha abutment) was potentially influenced by the angle of the impedance head to the screw. In a study using cadaver heads, Stenfelt and Goode (2005) also identified that the angle of the impedance head can be a problem and noted that, to circumvent this, it is best to orient the impedance head vertically on the cadaver heads so that no shear or bending forces were acting on the force gauge and thereby influencing the results.

The equipment needed to measure mechanical point impedance is not readily available. Earlier work in this area has revealed that the previous coupling of the impedance head to the old bayonet style coupling may introduce small errors into the measurements (Håkansson et al., 1986). Given the limited number of studies using live patients, the small sample sizes and the complexities of the measurement procedures used, a new method for estimating the mechanical point impedance directly through the new snap coupling Baha abutment in live patients is proposed. Magnitude data from this new procedure can be compared to existing data from live patients to update our understanding of mechanical impedance in live Baha patients (especially those with the new snap coupling).

2.1.5 The Present Study

The goal of this study was to explore the individuality in bone conduction responses from two perspectives on a group of Baha subjects. First, the investigator illustrates the variability in mechanical point impedance from subject to subject measured directly through the Baha abutment using a novel technique. Next, the variability in acceleration thresholds possible through the Baha abutment at discreet audiometric frequencies for a given HL value measured with a traditional bone conduction transducer is explored. The following questions were of interest:

a. What is the range of mechanical impedance responses across frequencies on a group of Baha subjects?
b. What is the average mechanical impedance across frequencies measured directly through the Baha abutment?
c. How do the average magnitude values from Baha subjects in this study compare to the average magnitude values and the model of mechanical impedance found in Håkansson et al. (1986)?
d. For a given traditional HL threshold value at a given frequency, what is the range of acceleration responses in direct bone conduction measured at threshold in a group of Baha users?

Most of these questions are relevant to the hypothetical context scenario above. The audiologist needs to know, when the patient gets the Baha abutment, how much this particular patient's vibratory system behaves like the next patient's. He also needs to know how much variability he can expect in direct bone conduction thresholds given the HL audiogram he has for his patient. If the skin and tissue introduce unpredictable variability from person to person and the mechanical impedance varies from person to person, he may be wondering how much the audiogram he has in front of him informs the likelihood of success for this patient with a given Baha.

2.2 Methods

2.2.1 Subjects

32 Baha users (19 men, 13 women) were enrolled in this study. All 32 subjects completed both the traditional and direct acceleration threshold estimations. Data for the point impedance measures were lost for 3 subjects (corrupted data transfer). The average age was 54.1 years with a standard deviation of 16.2 years. All users had the snap coupling and had owned their Baha for a minimum of 6 months prior to testing. Subjects formed a diverse sample of Baha candidates. The majority of patients had chronic ear disease, many of whom had undergone previous mastoid surgeries. One user had single-sided deafness and had undergone tumor removal, and several users had aural atresia. As Håkansson et al (1986) pointed out, mechanical impedance may differ depending on underlying etiology. Therefore, a diverse sample was necessary. Figure 2-3 shows the unmasked bone conduction thresholds +/- 1 standard deviation for the subjects in this study.

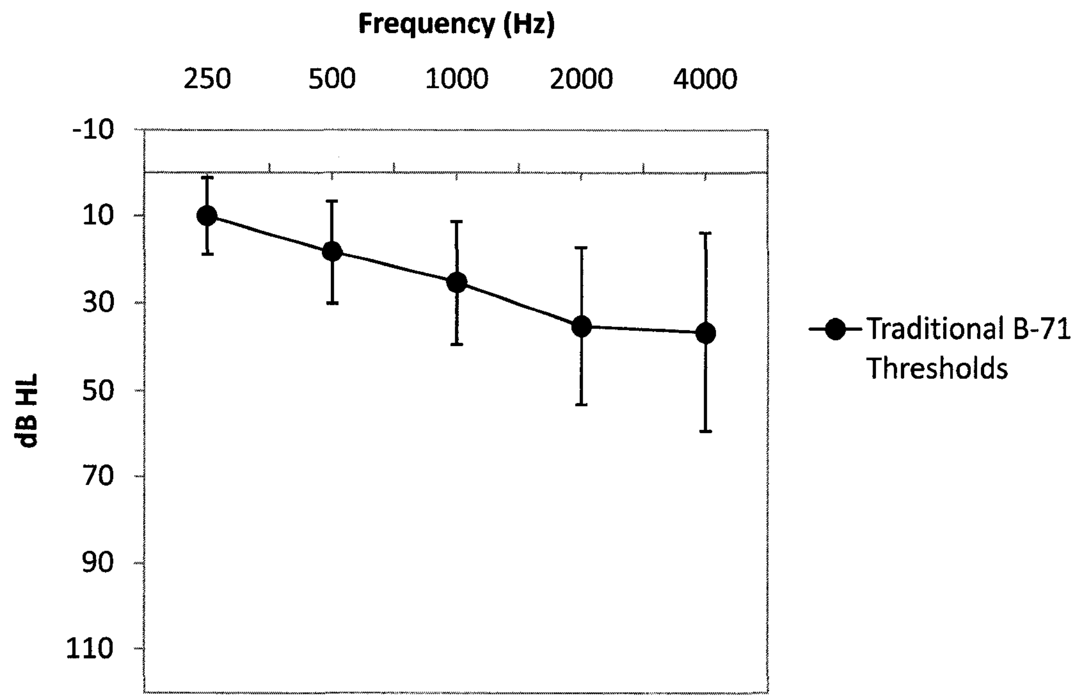

Figure 2-3. Unmasked bone conduction thresholds (+/- 1 SD) for the subjects used in this study.

2.2.2 Overview of the Instrumentation

Several components were required for the assessment of direct bone conduction thresholds and mechanical impedance. Before introducing the components, Figure 2-4 shows how these components were connected to each other to obtain the measures.

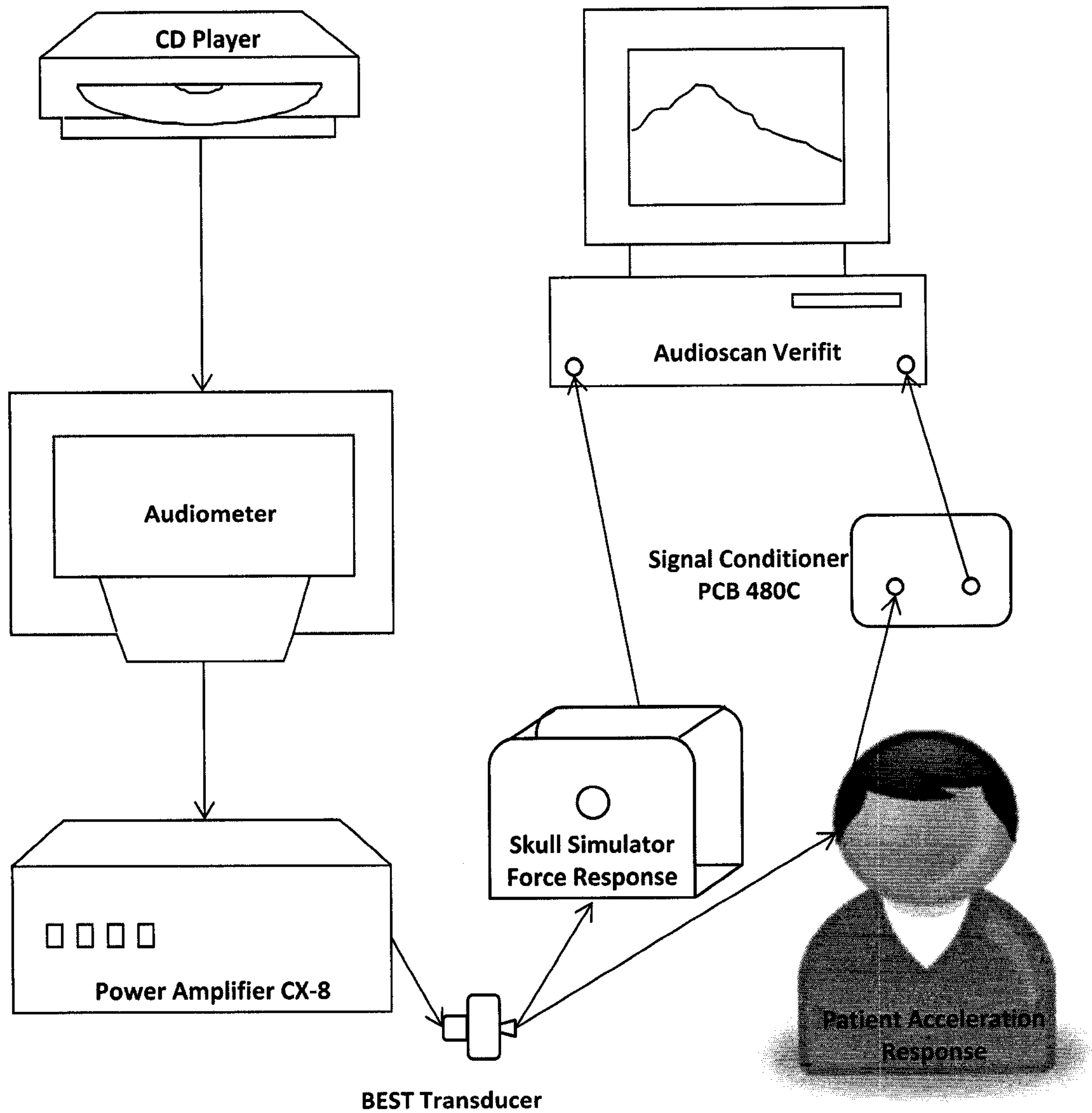

Figure 2-4. Overview of the experimental set-up.

2.2.3 Transducer

Transducers convert one form of energy to another. In the case of the Baha, a bone conduction transducer converts an electrical signal from a delivery source (e.g., the audiometer) to a mechanical vibration that can be delivered to the patient. The recently-developed Balanced Electromagnetic Separation Transducer (BEST) (Håkansson, 2003) is highly linear, small in size, and capable of spanning a wide range of outputs with low distortion. Additionally, the design of the BEST is such that it is completely stiff through the entire vibrating central portion. Consequently, it is conceivable that a vibration sensor could be placed on the backside of the transducer to measure the vibrations delivered to the patient (see Figure 2-5A and 2-5B). A special version of this transducer was produced with 150 µm air gaps, an output impedance of 4 ohm direct current and a resonance peak between 350-400 Hz. The transducer could be driven by a variety of signal generators. The BEST transducer was used in this study in 2 ways: (1) to test thresholds through the abutment and (2) to deliver a constant force level broadband signal for the impedance measures.

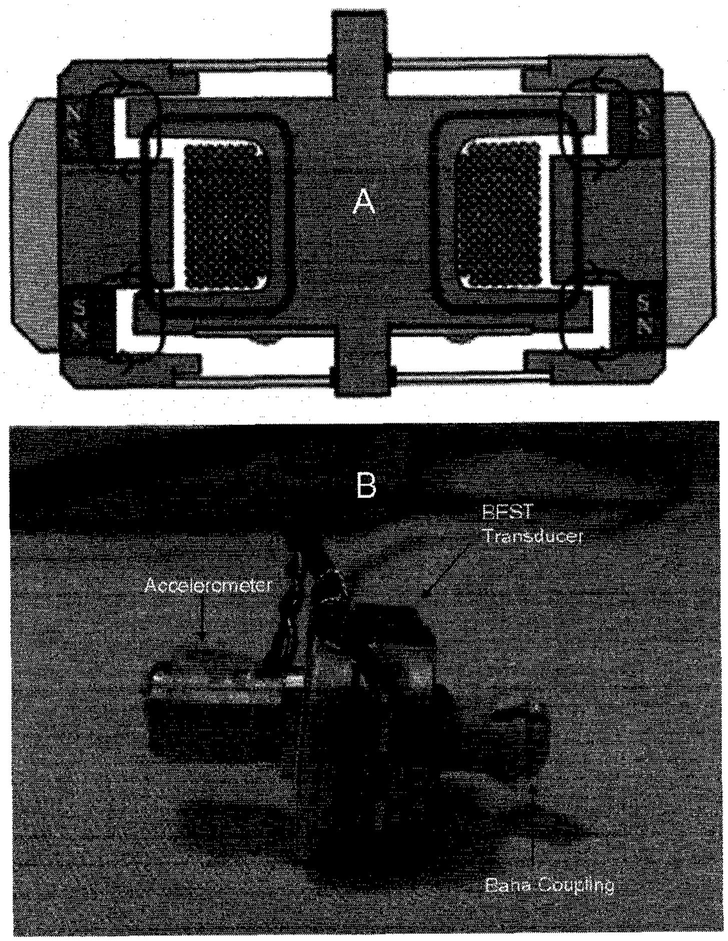

Figure 2-5A/B. Side profile of the BEST transducer showing the mechanical stiffness through the central core (A). The actual BEST transducer used in this study is pictured below (B).

2.2.4 Sensor and Signal Conditioner

An accelerometer produces a voltage at its output terminals proportional to the acceleration to which it is subjected. A PCB piezoelectric accelerometer (Model 352B10) was chosen for this study (see Figure 2-4B). This accelerometer has a sensitivity of 10 mV/g and low weight (0.7 g). The voltages at the output terminals of the accelerometer were extremely small so the signal was fed through a preamplifier (signal conditioner), before it reached the signal analyzer. A PCB model 480C signal conditioner (with 10 times gain) was used to condition the low level acceleration signal.

2.2.5 Signal Analysis

For all acceleration measures, analysis of the conditioned output voltage was performed by an Audioscan Verifit VF-1 Real-Ear Hearing Aid Analyzer (subsequently referred to as the Verifit; Audioscan, Dorchester, Ontario). The Verifit is a real-time, real-ear, dual-channel audio measurement system (FFT spectrum analyzer) that is typically used for the real ear assessment of hearing abilities and the real-ear verification of air conduction hearing aid output. It is calibrated to display a specific sound pressure level (SPL) value for a given electrical signal level. In the case of an air conduction hearing aid or a real-ear measurement, the displayed SPL will be the SPL associated with the voltage at the entrance to the measurement microphone (either coupler or real-ear microphone).

For this study, the Verifit was calibrated for two different purposes. First, it was calibrated to measure the signal from the accelerometer (acceleration response) at the entrance to the real-ear microphone. It was also calibrated to accept the signal from the TU-1000 skull simulator (force response) at the entrance to the coupler microphone. For the acceleration response, a 200 mV 1000 Hz signal was equivalent to a display of 120 dB SPL. For the force response, the coupler microphone of the Verifit received an electrical signal from the accelerometer inside the TU-1000. However, because the skull simulator has a known load (50 g mass) with an impedance much greater than the output impedance of the transducers used to drive it, the electrical signal level from the accelerometer in the skull simulator will be indicative of the force level, since Force = Load Mass * Acceleration (Håkansson & Carlsson, 1989). For the current test system, a 1000 Hz tone of 120 dB SPL was equal to .2 Volts/N. Figure 3-4 shows the BEST attached to the TU-1000 skull simulator and connected to the Verifit.

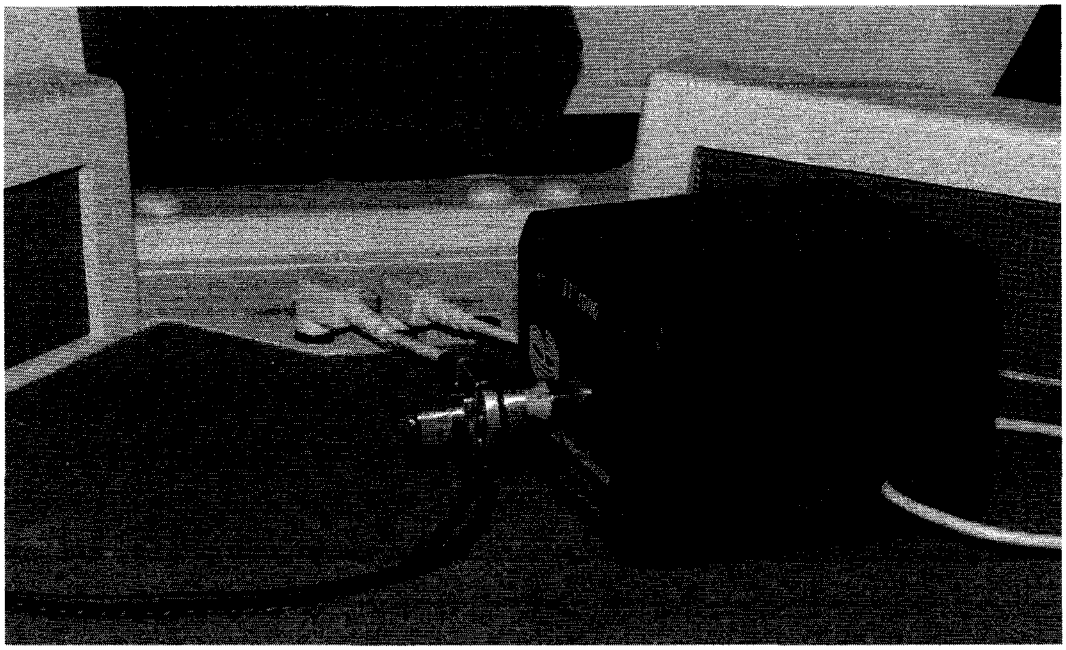

Figure 2-6. The BEST transducer connected to the TU-1000 skull simulator that is connected to the Verifit coupler microphone input.

The Verifit can be set to function as a spectrum analyzer in either the real-ear mode or the coupler mode. By selecting the pink noise input and changing the input level to 0 dB SPL, the system will function as an FFT analyzer calculating the level in $1/12^{th}$ octave bands for signals delivered from external sources (Audioscan, 2005). For threshold measurements the manual control function was used to measure the acceleration levels associated with pure tones at specific audiometric frequencies.

2.2.6 Signal Delivery

For the traditional bone conduction thresholds testing, an interacoustics audiometer was used to deliver pure tones to a calibrated B-71 bone conduction transducer. For the direct bone conduction threshold testing, pure tones were routed from the right headphone jack of an Interacoustics AC-40 audiometer to one channel of a QSC eight-channel power amplifier (model CX-8; Costa Mesa, USA). The BEST transducer was connected to the output of the CX-8 and could subsequently be connected to either a Baha patient or the skull simulator. For each patient we first needed to determine an HL to acceleration transform (essentially a real ear to dial difference using the accelerometer instead of a real ear microphone). With the BEST transducer connected to a patient and a constant level tone (60 dB HL dial setting) being generated from the audiometer, we measured the acceleration, in-situ, off the back of the BEST transducer. Pilot testing had revealed that 60 dB HL produced an acceleration that exceeded the noise floor of the measurement system at all frequencies. Additionally, pilot testing revealed that, so long as we were above the noise floor of the system, changes in dB HL resulted in linear changes in dB acceleration level (dB AL).

Mechanical impedance is frequency dependent. Therefore, the signal used to calculate the acceleration needed to span a broad range of frequencies (i.e., those relevant to the speech spectrum). The speech-shaped broadband noise track from the Connected Sentences Test (CST; Cox, Alexander & Gilmore (1987)) was used for all measures. The compact disk track was routed from a CD player through the Interacoustics AC-40 Audiometer. The output from the right headphone jack was routed to the CX-8 amplifier.

2.2.7 Procedures

For this study, only 4 pieces of information were required from the subject: (1) thresholds in dB HL with a standard bone conduction transducer, (2) thresholds directly through the Baha abutment with the BEST transducer, (3) the fixed level (60 dB HL audiometric dial reading) acceleration transform value at each audiometric frequency, and (4) the fixed-level broadband acceleration response to the CST noise. The order in which these data were gathered for each subject was randomized.

2.2.8 Data Analyses

All data presented in this study are descriptive in nature with one exception. For the comparison between the average impedance data in the current study and the average impedance data from Håkansson et al. (1986), a one-way ANOVA with a Bonferonni adjusted alpha level was used to determine if there were any significant differences between the two studies at the following frequencies: 250, 500, 1000, 2000 and 4000 Hz.

2.3 Results

2.3.1 Preliminary Mechanical Impedance Testing

Before addressing the variability in mechanical impedance in all subjects, the writer presents some preliminary test results comparing the novel technique for measuring mechanical impedance magnitude to a Bruel and Kjaer 8001 impedance head. Figures 2-6 and 2-7 show the methods of comparison testing. A BEST transducer was connected to the B & K impedance head, which was connected to either the TU-1000 skull simulator (Figure 2-6) or a Baha patient (Figure 2-7).

Figure 2-7. BEST transducer in series with a B & K impedance head connected to a TU-1000 skull simulator. Measures were not taken in this manner. The setup was displayed this way so that all equipment could fit easily in one Figure.

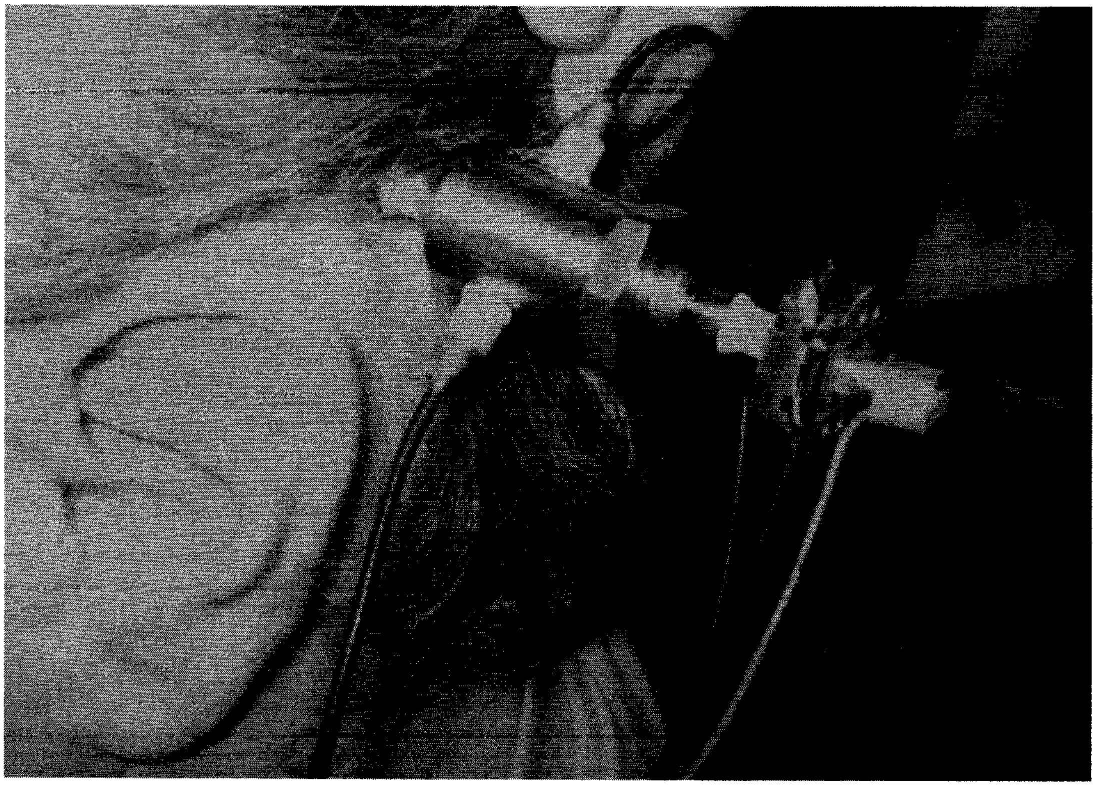

Figure 2-8. BEST transducer and B & K impedance head connected to a patient.

Figure 2-8 shows the magnitude responses for one subject using both impedance techniques. The BEST transducer shows comparable results for the B & K impedance head in the frequency range from approximately 300 to 6000 Hz. Differences at the low and high frequencies between approaches are likely a consequence of the force response measured on the skull simulator utilized with the BEST approach (described below).

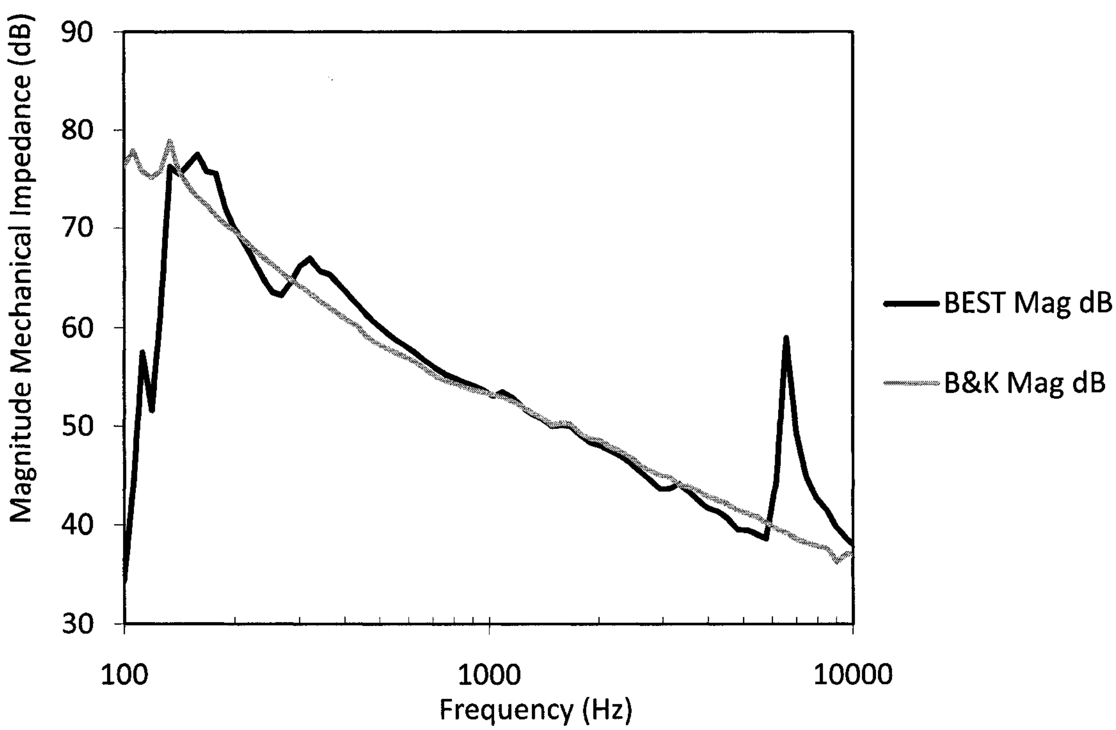

Figure 2-9. Comparison of two approaches to measuring mechanical impedance in 1 subject.

2.3.2 Mechanical Impedance Calculations

Calculation of the mechanical impedance in this study required 2 measures: (1) the force response of the input signal delivered to each patient and (2) the velocity response associated with that given force level. The second measure, velocity, can be derived from the acceleration response of the BEST transducer. Since the BEST transducer is rigid through the entire vibrating portion, the acceleration at the back side of the transducer should be sensitive to the load to which it is connected. Differences in patient's skulls will alter the load, thereby altering the acceleration.

2.3.2.1 Force response of Skull Simulator

The force response (in dB) of the BEST transducer is displayed in Figure 2-9. There is a resonance between 300 and 400 Hz. Above 5500 Hz there appears to be another resonance that is likely due to the snap coupling compliance between the BEST transducer and the TU-1000. This force response will be the same for each patient and therefore only needed to be obtained once. However, the measure was obtained on 5 occasions and the responses were found to be within 1 dB each time.

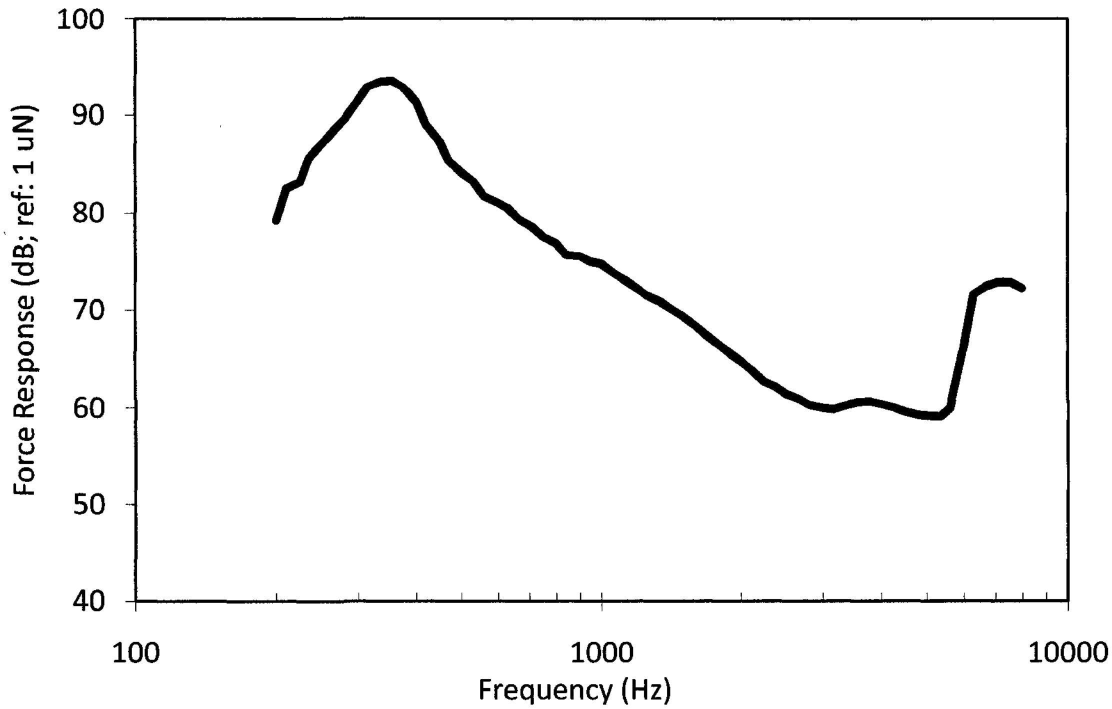

Figure 2-10. Force response for the BEST transducer connected to a TU-1000 skull simulator.

2.3.2.2 Acceleration Responses

Acceleration responses for all patients are shown in Figure 2-10. There is a greater range of acceleration responses in the lower frequencies. There appears to be a collapsing of acceleration differences in patients between 3000 and 4000 Hz. The range then increases again above 4000 Hz.

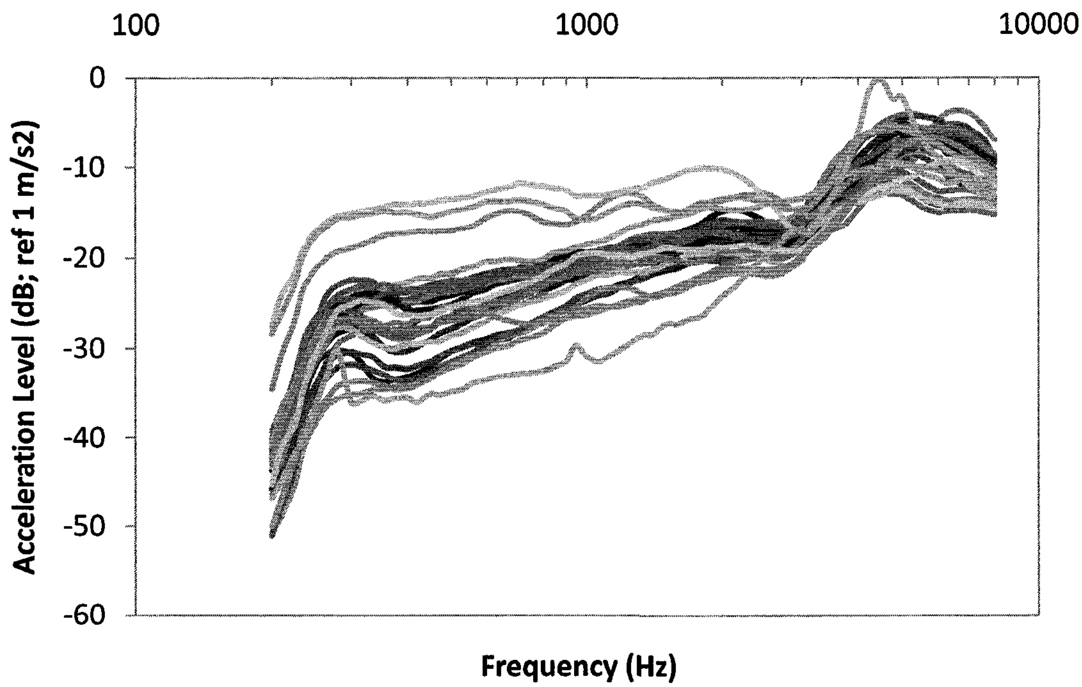

Figure 2-11. Acceleration response for the 28 Baha subjects measured off the back of the BEST transducer.

2.3.2.3 Velocity Calculations

At each frequency, the linear acceleration level was converted to a velocity measurement to calculate the mechanical impedance. This was accomplished using the following equation (Håkansson, 1986):

$v = a/j\,\omega$ (2)

Where:

v = velocity (m/s)
a = acceleration (m/s^2)
j = the complex constant and
$\omega = 2\pi f$. (angular frequency in radians/second)

2.3.3 **Mechanical Impedance**

The mechanical impedance was derived at each 1/12th octave frequency using the force response from the skull simulator and the derived velocity response from the in-situ acceleration data from each Baha patient (from equation 2). Figure 2-11 displays the mechanical impedance in dB (20 * log[Z]) across frequencies for all 28 Baha patients. The dotted black line shows the average mechanical impedance.

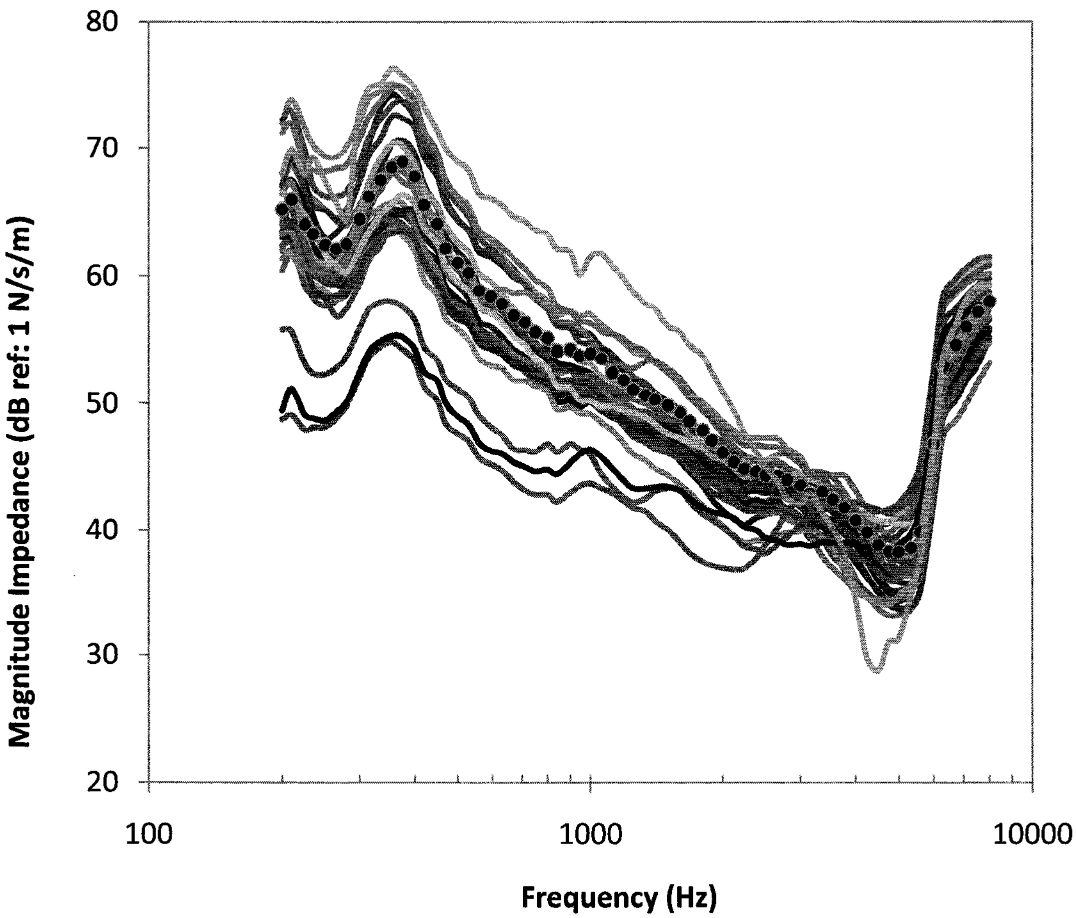

Figure 2-12. Mechanical impedance data for 28 Baha subjects. Average impedance is shown with the dotted black line.

In general, the mechanical impedance is higher in magnitude and more varied for low frequency inputs. At some frequencies, the range of impedance responses exceeded 25 dB. This implies that a given bone conduction input to the Baha abutment may be impeded by 75 dB on one person but only 50 dB on another. Clearly, a Baha producing a fixed output may vibrate differently depending on the patient to which it is connected.

In Figure 2-12, the average data at discreet audiometric frequencies are plotted with the average data from the 7 subjects in Håkansson et al. (1986). The one-way ANOVA revealed that differences at 2000 Hz (Mean difference = 4.8 dB; $F_{(1,34)} = 17.05$, $p < 0.001$) and 4000 Hz (Mean difference = 6.2 dB; $F_{(1,34)} = 24.84$, $p < 0.001$) were significant. These are marked with stars in Figure 2-12.

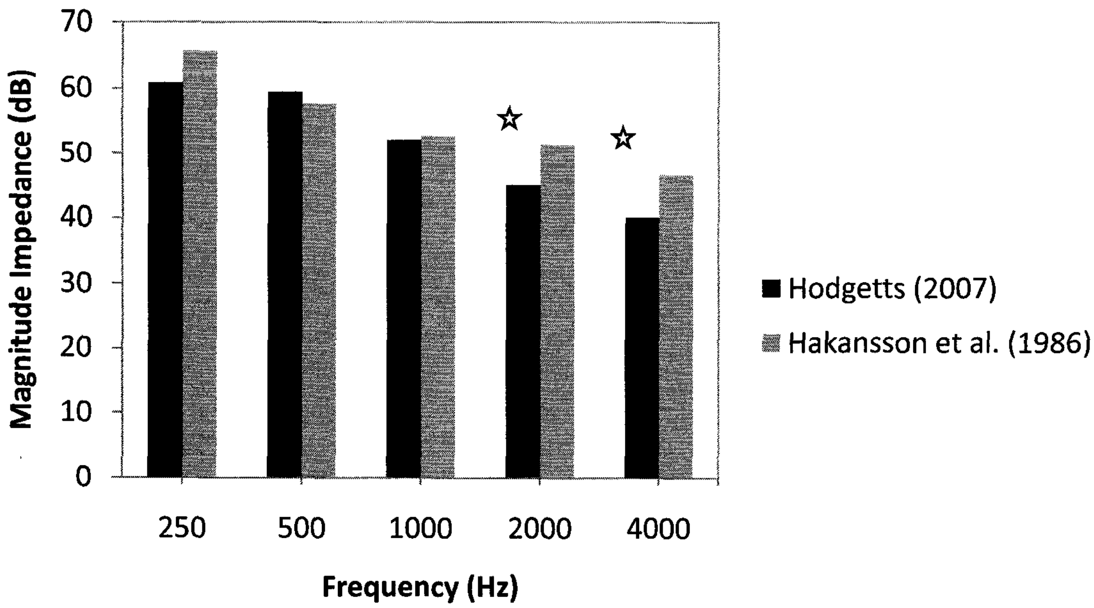

Figure 2-13. Mechanical impedance at audiometric frequencies comparing the current study to that of Håkansson et al. (1986).

2.3.4 Traditional HL Thresholds vs. Direct Acceleration Thresholds

Figures 2-13 to 2-17 show the relationship between HL thresholds (in 5 dB steps) on the x-axis and AL thresholds on the y-axis for 250, 500, 1000, 2000 and 4000 Hz. Each graph also shows the linear trend line and the associated linear equation. These graphs are intended to aid understanding of the problem facing the clinician in the context scenario outlined in the introduction. What they show are the ranges of thresholds in dB AL associated with a given HL audiogram threshold value for the 32 subjects. For example, at 250 Hz, 8 of the 32 subjects had an HL threshold of 0 dB measured through the skin and tissue with the traditional B-71 bone conduction transducer. However, the range of AL thresholds for these 8 subjects spanned almost 40 dB (36.5 to 76 dB). Similarly, at 500 Hz, 9 of the 32 subjects had a threshold of 25 dB. However, the AL thresholds ranged from 53 dB to 81.5 dB (range = 28.5 dB). Consider also the fact that a subject may present with 30 dB HL thresholds at 250 Hz, but show lower acceleration thresholds than another subject who had 0 or 5 dB HL thresholds. It may be reasonable for the reader to assume that 250 Hz is notoriously unreliable by bone conduction. That may be the case. However, even though the slopes of the regression lines become steeper at 1000, 2000 and 4000 Hz, the same unpredictable outcomes emerge. At 2000 Hz, an HL threshold of 20 dB shows a range from 45 to 61.5 dB in acceleration. Similarly comparison of the 2 grey dots at 2000 Hz show that a difference of 30 dB in HL may only result in a difference of 5 dB in acceleration level. These same within and across HL differences are represented in Figure 2-17 with the ellipses.

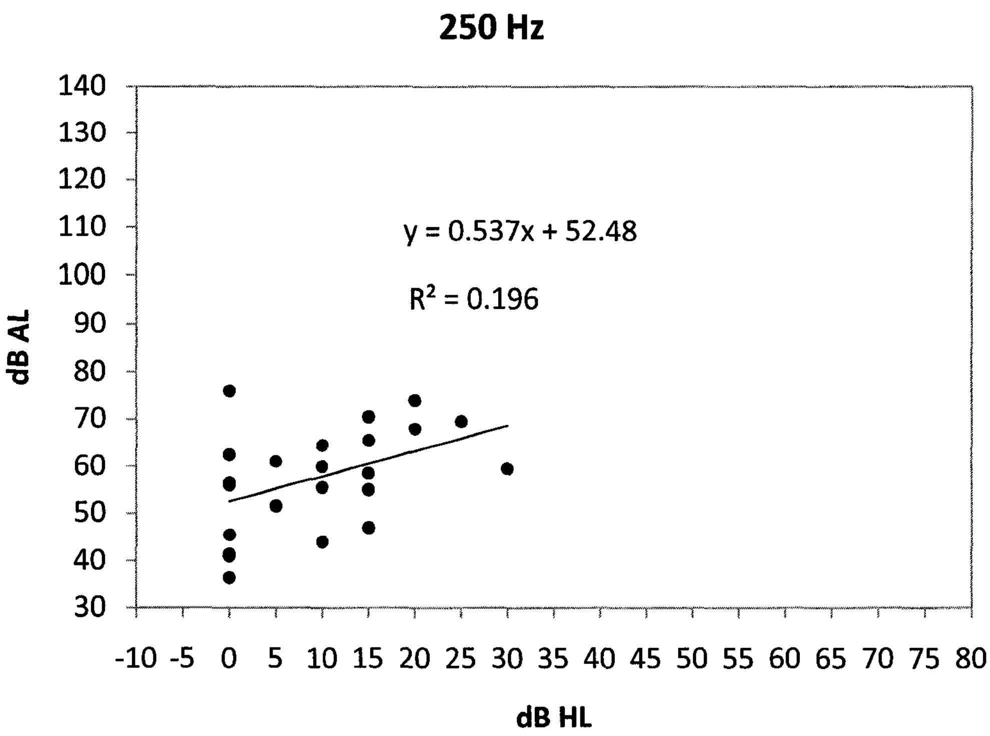

Figure 2-14. Range of acceleration thresholds for a given threshold in dB HL at 250 Hz. Not all subjects had both HL and AL thresholds at 250 Hz. Also, some dots are superimposed.

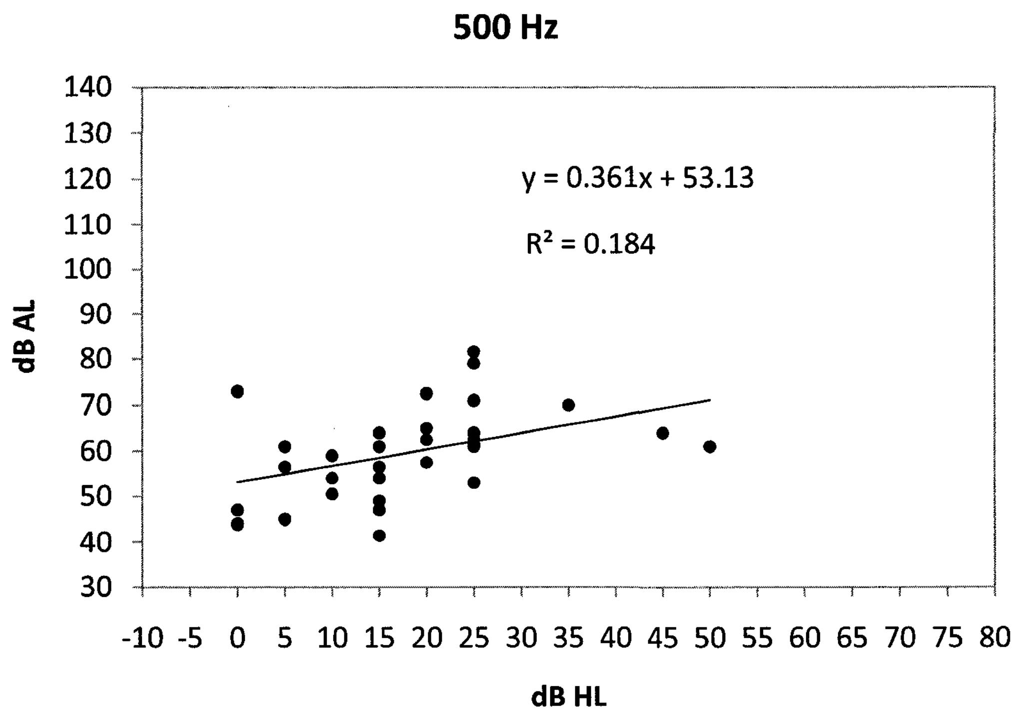

Figure 2-15. Range of acceleration thresholds for a given threshold in dB HL at 500 Hz.

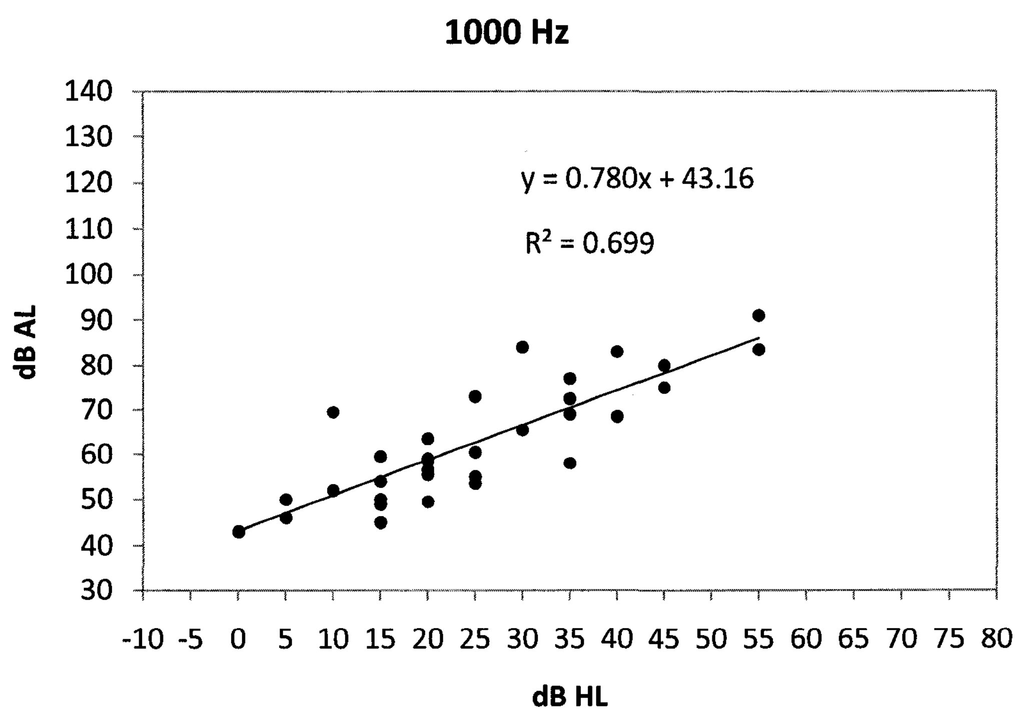

Figure 2-16. Range of acceleration thresholds for a given threshold in dB HL at 1000 Hz.

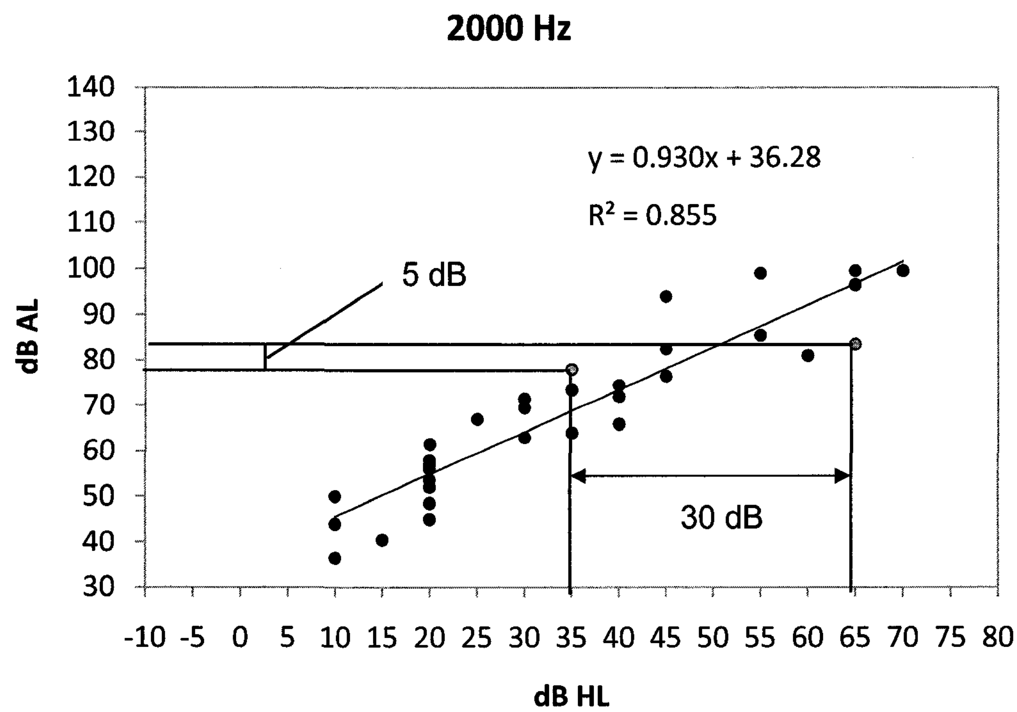

Figure 2-17. Range of acceleration thresholds for a given threshold in dB HL at 2000 Hz.

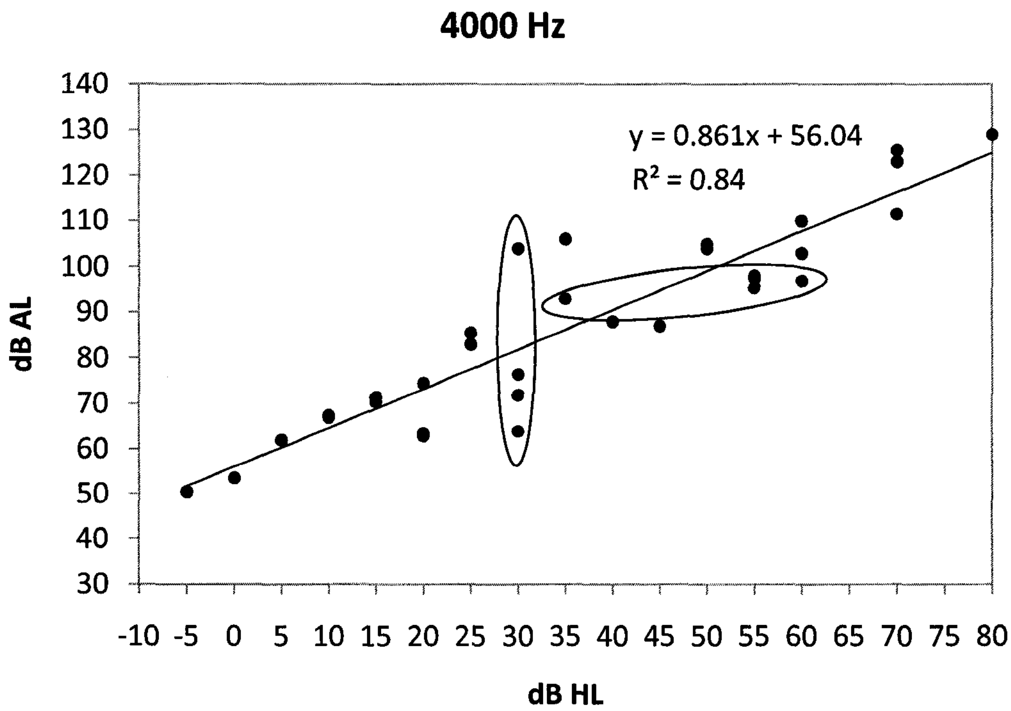

Figure 2-18. Range of acceleration thresholds for a given threshold in dB HL at 4000 Hz.

2.4 Discussion

The goals of this study were to: (1) gain further insight into the individuality of bone conduction responses via the direct bone conduction route (the mechanical point impedance) and (2) expand our understanding of the relationship between a given HL threshold value and the direct bone conduction acceleration threshold. A clinician faced with a question such as, "How much better will I hear going directly to the bone?" needs to know not only what the "average" benefit of direct bone conduction might be, but also how much variability there is from person to person. Similarly, the clinician may be familiar with the output capabilities (i.e., frequency response) of a given Baha on a skull simulator (Håkansson & Carlsson, 1989), however the skull simulator has the same "average" impedance for all measures. Given the real life variability from person to person, it may be difficult for the clinician to "estimate" the relationship between a given response on a skull simulator and the real life response on a patient.

2.4.1 Mechanical Point Impedance

The reader may have noticed that, as far as the clinical questions regarding individuality of bone conduction responses are concerned, the acceleration curves for a fixed input would have been sufficient. However, mechanical impedance was calculated to facilitate comparisons with existing data from live skulls (Håkansson et. al, 1986).

The mechanical impedance responses in Figure 2-11 were quite varied. At several frequencies, the range exceeded 20 to 25 dB. In other words, a fixed input to the Baha patient may meet with relatively limited impedance on one person, but considerably more on another. Impedance is influenced by the load to which a transducer is connected. The "load" in this case is not only the human skull but the entire transmission pathway. Skulls differ in mass, density, geometry, resonant frequencies and damping characteristics, all of which can influence the mechanical impedance of bone conducted stimuli (Stenfelt & Goode, 2005). However, even the quality of the snap coupling is likely to have an effect on impedance from person to person. The better coupled the vibration transducer is to the load (the Baha abutment), the greater the impedance. Consider a case in which a patient presents with a poor quality snap connection. Perhaps the device is 5 years old and the plastic coupling has rounded off from the repeated snapping into and out of the abutment. As the quality of the coupling decreases, the accelerometer on the backside of the BEST transducer should measure increased acceleration (because the transducer is more free to vibrate), which would indicate a lowering of mechanical impedance. Fewer vibrations would actually be delivered to the patient. A change to a new snap coupling should alter the mechanical impedance. Whether or not this change in impedance would result in a perceptual change in bone conduction hearing for the subject needs to be investigated.

The average impedance data from the current study were comparable to the average data from Håkansson et al. (1986) for 250, 500 and 1000 Hz. At 2000 and 4000 Hz, the average impedance from the current study was significantly lower. However, data from the present study below 250 Hz and above 6000 Hz were not felt to be reliable. For the B & K impedance head both the force and acceleration are measured simultaneously on the patient. For the BEST approach, only the acceleration response was obtained directly on the patient. The one-time force response measurement from the skull simulator (Figure 2-9) will differ from that of the patient in the low frequencies because of a difference in mass between the human skull and the skull simulator. In the high frequencies, the force response will differ between the human skull and the skull simulator because of differences in coupling compliance. Therefore, the impedance data with the novel approach are really most relevant between 250 and 6000 Hz. Differences between the studies at 2000 and 4000 Hz are not surprising, given the much larger sample size and greater diversity of subjects in the current study. While the updated average data may be useful for standards or the development of new bone conduction transducers or measurement couplers, the main goal of this study was to explore the range of responses possible and to relate that range of responses to the real-life challenges facing a Baha clinician.

2.4.2 Traditional HL Thresholds vs. Direct Acceleration Thresholds

The unpredictable responses associated with the skin and subcutaneous tissue added even more variability from person to person. Figures 2-13 to 2-17 showed that direct acceleration thresholds for a given HL threshold can vary by as much as 40 dB. Similarly, a change of 30 dB on the HL scale between 2 subjects may only result in an acceleration threshold difference of 5 dB or less.

It is important to remember that the current study involved only adult Baha subjects. It is probable that overall impedance variability and differences in skin and tissue would increase even more, if pediatric heads were included in this study. Because of this large variability, it is perhaps a bit misleading for the Baha clinician to consider the average "skull" in the same way it has always been a bit misleading for the clinician fitting air conduction hearing aids to consider the average "ear."

In fact, close parallels can be drawn between the testing of thresholds and fitting of air conduction hearing aids and the comparable aspects of fitting Baha devices discussed in this study. For air conduction hearing tests, the dB HL (audiometer dial) values can be transformed to sound pressure level (SPL re: 20 µPa) in a coupler (typically 2-cc's) by adding the reference equivalent threshold sound pressure level (RETSPL) values for whatever transducer was used to measure the hearing levels (e.g., Insert earphones, TDH headphones, soundfield speaker; American National Standards Institute (ANSI), 1996). Since hearing aid output can be measured in SPL in a coupler, the conversion of hearing thresholds from dB HL to dB SPL is logical. However, referencing hearing thresholds and hearing aid output to a 2-cc coupler incorrectly assumes that all ears are created equally--- like a 2-cc coupler (Sanders & Morgan, 2003; Scollie et al., 1998).

Saunders and Morgan (2003) convincingly demonstrated the danger in referencing everything to an average coupler. They found that for a fixed signal level in a coupler, the sound pressure level measured in the ear canals of 1814 ears can vary by as much as 40 dB. Of course, the real ears of patients have an average response curve (ear canals have an "average" impedance), however it often looks nothing like the response curve of a 2-cc coupler, and it has repeatedly been shown that the variability from person to person is so large that it is imperative that each ear be measured directly using in-situ real ear measurement procedures (Zelisko et al., 1992; Scollie et al., 1998; Gagne et al., 1991a, 1991b; Gauthier & Rapisardi, 1992a; Hawkins et al., 1991).

In the same way, findings related to the variability in bone conduction responses should give clinicians who are routinely basing candidacy decisions for Baha on traditional bone conduction thresholds considerable pause. A given HL threshold value may, in fact, provide very little information regarding the direct bone conduction acceleration threshold level. Similarly, knowledge of the gain/frequency response of a given Baha on a skull simulator (Baha coupler) may offer only limited insight about how that device will perform on the patient (in-situ), given each patient's unique bone conduction system.

2.4.3 **Looking Forward**

If the above statements are true, it creates a conundrum for the Baha clinician. He may not really know how good a candidate a given patient is until the Baha implant is in place and direct bone conduction thresholds and Baha responses are measured in-situ. However, as most experienced Baha clinicians already know, whenever we are dealing with borderline Baha candidates (i.e., moderately-severe mixed hearing loss), it is wise to: (1) offer them a trial with a Baha on a headband (in spite of limited predictability, seldom do people do worse with direct bone conduction hearing), (2) ensure that the device choice is conservative (convince the patient that he/she may need to wear the Cordelle), and (3) provide the candidate with realistic expectations.

Perhaps most importantly, this study indicated that it would be prudent for clinicians to wait until they have had a chance to measure direct bone conduction thresholds in-situ and have a method of measuring direct Baha responses in-situ before they order the Baha. The next study compared two in-situ approaches to measuring direct bone conduction thresholds and output responses for Baha verification. These new in-situ approaches are contrasted with the traditional aided soundfield threshold approach to Baha verification.

2.5 References

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Chapter 3: A Comparison of Three Approaches to Verifying Aided Baha Output

3 Chapter 3

3.1 Introduction

In the audiological literature, a great deal of attention has been given to the prescription and subsequent verification of frequency response characteristics for hearing aids (Traynor, 2000). While there appears to be no agreed upon formula for the exact level of amplified speech, it is generally accepted that speech needs to be audible to be perceived.

Assessing speech audibility requires the use of valid and reliable verification procedures (AAA, 2003; ASHA, 1998; Seewald et al., 1996). For years, aided soundfield thresholds were used to verify the audibility of both air and bone conduction hearing aids. While these measures can be seen to serve a purpose in audiology by validating the softest sound a person can hear with the hearing aid on, significant limitations preclude their use as a method for verifying the audibility of aided speech. Alternatives to aided soundfield thresholds have emerged for verifying air conduction hearing aids. To date, valid and reliable approaches for verifying Baha are lacking.

3.1.1 Context Scenario

Imagine a Bone Anchored Hearing Aid (Baha) user who comes to your clinic for an annual evaluation. He/she reports that speech understanding in background noise has become more difficult over the past year and wonders if there is an adjustment you can make to the hearing aid to mitigate this. You make an adjustment to the Baha that theoretically decreases the low frequency output of the device. How do you know that you actually changed the hearing aid output? Do you ask the patient if the Baha sounds different? Perhaps, you decide to measure aided soundfield thresholds before and after the adjustment. This paper explores the validity and reliability of this approach to verifying speech audibility with Baha and proposes two alternative approaches that might be used instead. Before exploring the new approaches, we begin with a treatment of the broad limitations known to plague the use of aided soundfield thresholds.

3.1.2 Limitations of the Aided Soundfield Threshold

The limitations of the aided soundfield threshold for verifying speech audibility have been identified by many authors (e.g., Stelmachowicz & Lewis, 1988; Seewald et al., 1996; Hawkins et al., 1987) and will not be reproduced in their entirety here. See Hawkins (2004) for an excellent review. However, the limitations most critical to verifying bone conduction hearing aids (with a special emphasis on the Baha) will be examined.

3.1.2.1 Calibration and Masking

Aided soundfield thresholds are often determined so that the softest sound a person can hear with the hearing aid can be expressed in dB HL. There is an important difference between aided soundfield thresholds and functional gain. Functional gain (unaided threshold minus aided threshold) will result in a dimensionless dB value, since it is the relative difference between the two thresholds that is important (i.e., it does not matter if your booth is accurately calibrated in dB HL). Aided soundfield thresholds are not dimensionless. The reference for these measures is dB HL. Therefore, the soundfield in which the aided threshold is measured needs to be accurately calibrated according to some standard (e.g., ANSI, 1996)[3].

Not only does the soundfield need to be calibrated on a regular basis, but the clinician needs to know the azimuth assumed for that calibration. ANSI (1996) provides calibration data for 3 azimuths. Failure to properly seat the patient according to how the booth was calibrated (e.g., 0º vs. 90º to the soundfield speaker) can result in errors of 5 to nearly 10 dB at some frequencies. The accuracy of the aided soundfield threshold depends greatly on the clinician's knowledge of the calibration of the soundfield in which the testing occurred.

Hearing aid circuit noise and ambient room noise may also be problematic for bone conduction hearing aid users. Patients who require bone conduction hearing aids often have normal or near-normal bone conduction hearing, especially in the low frequencies. Figure 3-1 shows the unaided bone conduction thresholds (measured through a standard bone oscillator) and the aided thresholds of a Baha user. The circuit noise and the ambient room noise may combine to mask the low frequency aided thresholds. It can often appear to the clinician, quite alarmingly, that the aided hearing with the Baha is much worse than the unaided hearing.[4] Because of this limitation aided thresholds obtained at low frequencies are often invalid (Macrae & Frazer, 1980).

[3] For all bone conduction hearing aids (including the BAHA), functional gain is not meaningful, because the unaided thresholds include the conductive loss and thus overestimate the functional gain by the size of the air-bone gap.
[4] This may also be exacerbated by the poor low frequency response of the Baha through the skull.

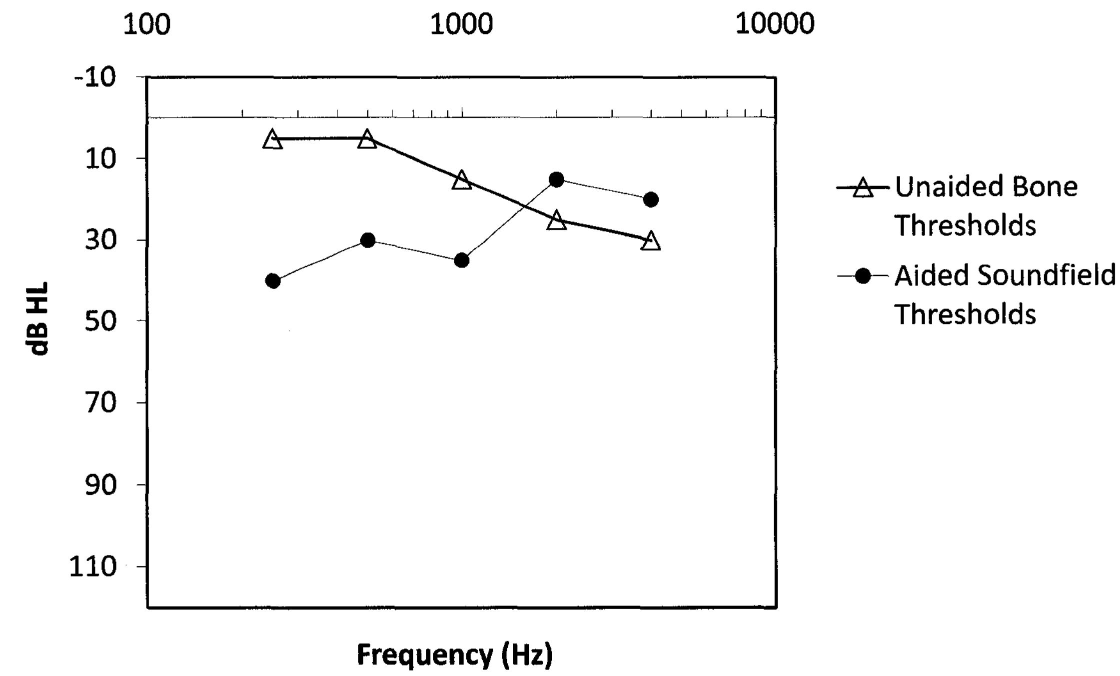

Figure 3-1. Audiogram for an adult Baha user showing unaided bone conduction thresholds measured through a standard bone oscillator and aided soundfield thresholds with the Baha in place at use setting. Low frequency aided thresholds are significantly impaired due to the effective masking of the circuit noise and ambient room noise.

3.1.2.2 Practical Issues

For all hearing aid users, there are a number of practical limitations to measuring aided soundfield thresholds. First, the results are always dependent upon accurate and consistent behavioural data. A clinician interested the effects of a change to the frequency response of the hearing aid would need to re-measure the aided soundfield thresholds every time an adjustment was made. Not only is this method time-consuming for the audiologist, it demands a great deal of the patient. In certain hard-to-test populations (e.g., young children, developmentally-delayed children, and mentally-handicapped adults), obtaining even one behavioural audiogram can be challenging (Seewald et al., 1996).

Second, in most cases, aided soundfield thresholds are not sensitive enough to differentiate adjustments to the hearing aid under two or more conditions. Imagine that the clinician made an adjustment to the tone control of a hearing aid, which theoretically resulted in a 5 dB increase in the high frequency gain. If he/she re-measures the aided audiogram to determine if the change resulted in a significant improvement, the inherent variability in the test procedure requires that the aided thresholds (obtained at the same frequency) change by more than 15 dB to be considered significantly different from one another (Hawkins et al., 1987). Therefore, the aided soundfield thresholds would be insensitive to the change that was made to the frequency response of the hearing aid (despite it being perceptually relevant to the listener), since adjustments of more than 15 dB are unlikely from trial to trial.

Third, when assessing hearing aids with aided thresholds obtained at discrete audiometric frequencies, a major consequence is that the measurement resolution is in 5 dB increments at half-octave intervals. Given the relatively crude representation of the frequency by intensity response curve provided by aided soundfield thresholds, it is entirely possible that two hearing aids with quite different frequency response curves (measured on a coupler) could yield nearly identical aided thresholds. Figure 3-2 and Figure 3-3 show an example of this from my lab. This subject was wearing a baha Intenso at his preferred user setting (MCL). We tested him to determine his aided soundfield thresholds and also measured the frequency response of his hearing aid on a skull simulator (Figure 3-3). We then adjusted the frequency response and returned the volume control to his previous setting. We tested his aided soundfield thresholds a second time. Notice how the aided soundfield thresholds are virtually the same in spite of the fairly large differences in frequency response. At 250 Hz the difference on the coupler was almost 25 dB. However, due to hearing aid circuit noise and ambient booth noise, the aided soundfield thresholds at 250 Hz are identical. Also plotted on Figure 3-2 are the critical differences from Hawkins et al.(1987) required to consider a change in aided soundfield from test 1 to test 2 significantly different at 0.05 level.

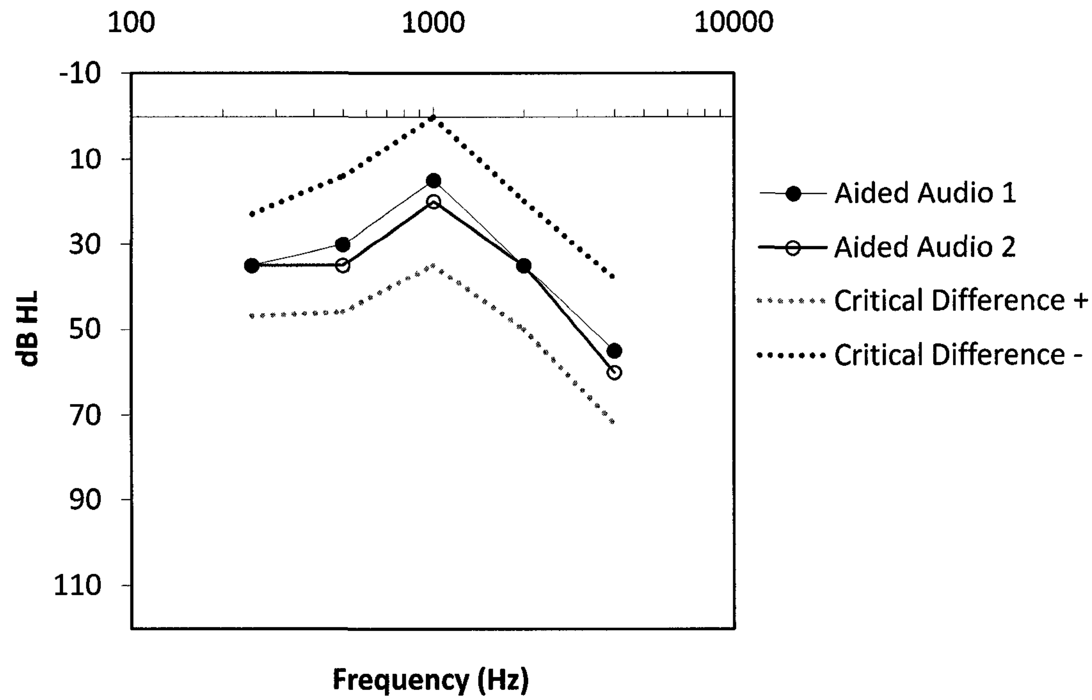

Figure 3-2. Aided soundfield thresholds determined for two different frequency response settings on one Baha user. Also plotted are the test-retest critical differences for aided soundfield thresholds from Hawkins (1987).

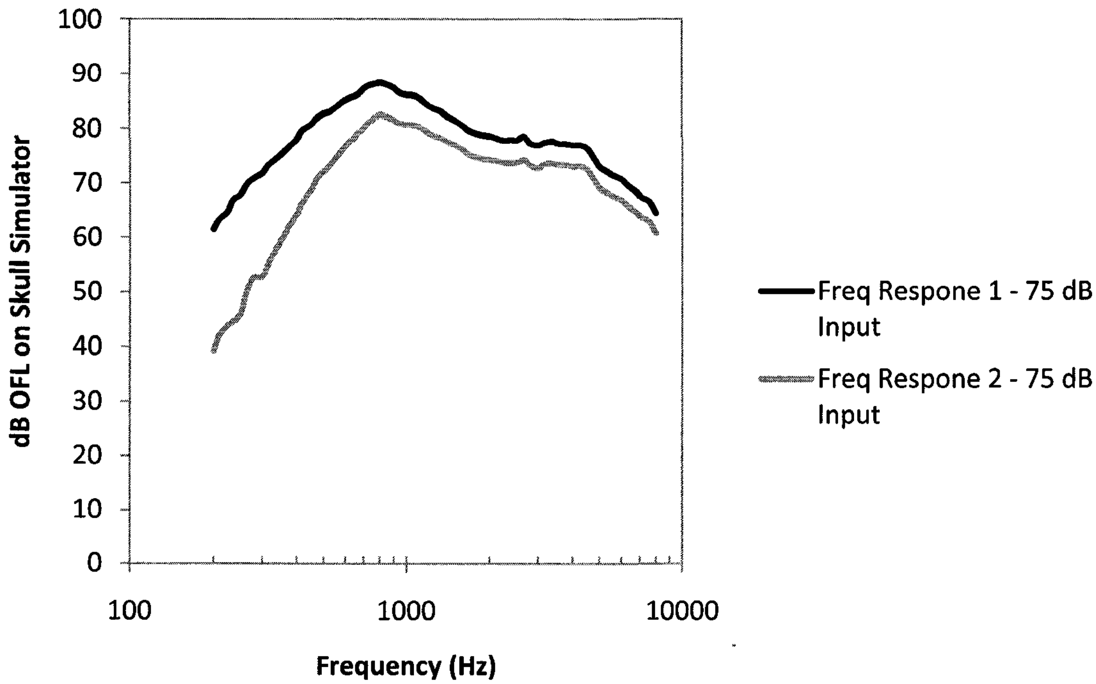

Figure 3-3. Different frequency responses for the two aided soundfield tests in Figure 3-2 measured through a skull simulator (Baha coupler).

Fourth, aided soundfield thresholds only tell you about the gain of the hearing aid in response to low level inputs. Most bone conduction hearing aids are linear. At the time of writing, there were 3 models of Baha available: The Divino, Intenso (ear level devices) and Cordelle (body aid). The Divino and Intenso are both linear devices (at low input levels), while the Cordelle can be programmed to be a linear or a WDRC hearing aid. One might assume that, if all devices were programmed to function linearly, the gain at threshold could be applied to suprathreshold levels (e.g., speech) to obtain an estimate of aided output capabilities. This may be true of moderately-low level inputs (soft speech). However, the aided soundfield threshold approach does not inform the clinician at all about the gain for higher level inputs such as loud speech or the output limiting characteristics of each device. In the case of Bahas, the devices all contain some form of output compression. Two devices (i.e., the Divino and Intenso) may yield similar aided thresholds, however the audibility of conversational or loud speech can diverge because of the differences in output capabilities (non-linearities) between the two devices.

3.1.2.3 The Speech Spectrum in dB HL

Aided soundfield thresholds represent the softest sounds the Baha user can hear across frequencies with the hearing aid on. The assumption is that the higher these aided thresholds are on the audiogram, the better the hearing. This may be true---and sufficient--- if all we were interested in was the softest sounds a user can hear in the aided condition. However, clinicians are usually much more interested in how the Baha user will perceive speech, not soft warble tones. A reasonable question at this point is, "How do the aided soundfield thresholds relate to the audibility of speech?"

One approach to answering this question is to plot the unaided speech spectrum on the audiogram in dB HL. If the aided soundfield thresholds are better than the majority of the unaided speech spectrum, it is assumed that most of the speech will be audible to the Baha user. Many researchers have attempted to plot the speech spectrum in dB HL. Unfortunately, the unaided spectra often differ from one another in significant ways (Olsen, Hawkins & Van Tassel, 1987). As Hawkins (2004) notes, this is not surprising "given the various transformations that must be made to construct a long-term speech spectrum in dB HL." (p. 57). In other words, there is no universally understood speech banana that clinicians can use to evaluate the audibility of speech with respect to aided soundfield thresholds for a given individual.

When you consider all of these limitations to aided soundfield thresholds as a verification tool, it is somewhat surprising to discover how commonly they are still used today (Hedley-Williams, Tharpe & Bess, 1996; Tharpe, Fino-Szumski & Bess, 2001), especially when valid and reliable alternatives are available as is the case for air conduction hearing aids. To date, a viable alternative to aided soundfield thresholds for Baha verification has not been demonstrated. In this study we propose 2 new alternatives to assessing audibility of aided speech with the Baha. These alternatives will be compared to an estimate of aided speech audibility with soundfield aided thresholds. Before introducing the 2 alternatives for Baha, an alternative for verifying air conduction hearing aids will be presented first.

3.1.3 Real Ear Verification of Air Conduction Hearing Aids

Scollie and Seewald (2002) recommended the following characteristics for a good verification protocol: (1) it tells the clinician how the hearing aid processes speech; (2) it tells the clinician the levels at which output is limited; (3) it is an efficient, reliable and valid procedure; (4) it can be used with infants and difficult-to-test patients; and (5) it is meaningful.

For air conduction hearing aids, electroacoustic in-situ protocols that satisfy these characteristics have been available for many years (Cox & Alexander, 1990; Seewald et al., 1996; Moodie et al., 1994). One approach, known commonly today as the real ear in-situ approach (also known as the SPLogram), was originally described by Erber (1973) and has since been expanded and validated (e.g., Scollie & Seewald, 2002). The goal of this approach is to define a person's residual dynamic range of hearing with some common reference. This is accomplished by using a probe microphone to determine the softest sound a person can hear and the loudest sound a person will tolerate across frequencies in dB SPL near the tympanic membrane. The hearing aid is then worn and the level of the hearing aid in response to speech or "speech-like" inputs is measured across frequencies in dB SPL near the tympanic membrane. The audibility of speech and the maximum output of the hearing aid can be directly compared to the auditory dynamic range of hearing, since both the auditory information and hearing aid responses were measured with the same units (dB SPL) at the same reference point (the tympanic membrane).[5]

[5] This "in-situ" approach has been simplified through the use of couplers and patient real-ear-to-coupler difference (RECD) measures. These are not presented here, as we draw closer parallels in the current study to the true in-situ approach for air conduction aids. Another approach to verifying air conduction hearing aids is available (i.e., insertion gain). However, this approach fails to satisfy all 5 characteristics listed above and is, therefore, not discussed in this study.

Figure 3-4 shows an unaided display of a SPLogram. Thresholds and loudness discomfort levels are plotted in SPL at the tympanic membrane. The unaided Long Term Average Speech Spectrum (LTASS) associated with a 65 dB SPL speech input is also plotted (plus the peaks and valleys of speech). Figure 3-5 shows an aided SPLogram display. The unaided input spectrum has been amplified by an air conduction hearing aid. The level and shape of the aided signal in relation to the user's thresholds of hearing at the tympanic membrane is depicted. Also plotted in Figure 3-5 is a line depicting the level and shape of the hearing aid's maximum power output (MPO) in relation to the user's loudness discomfort levels.

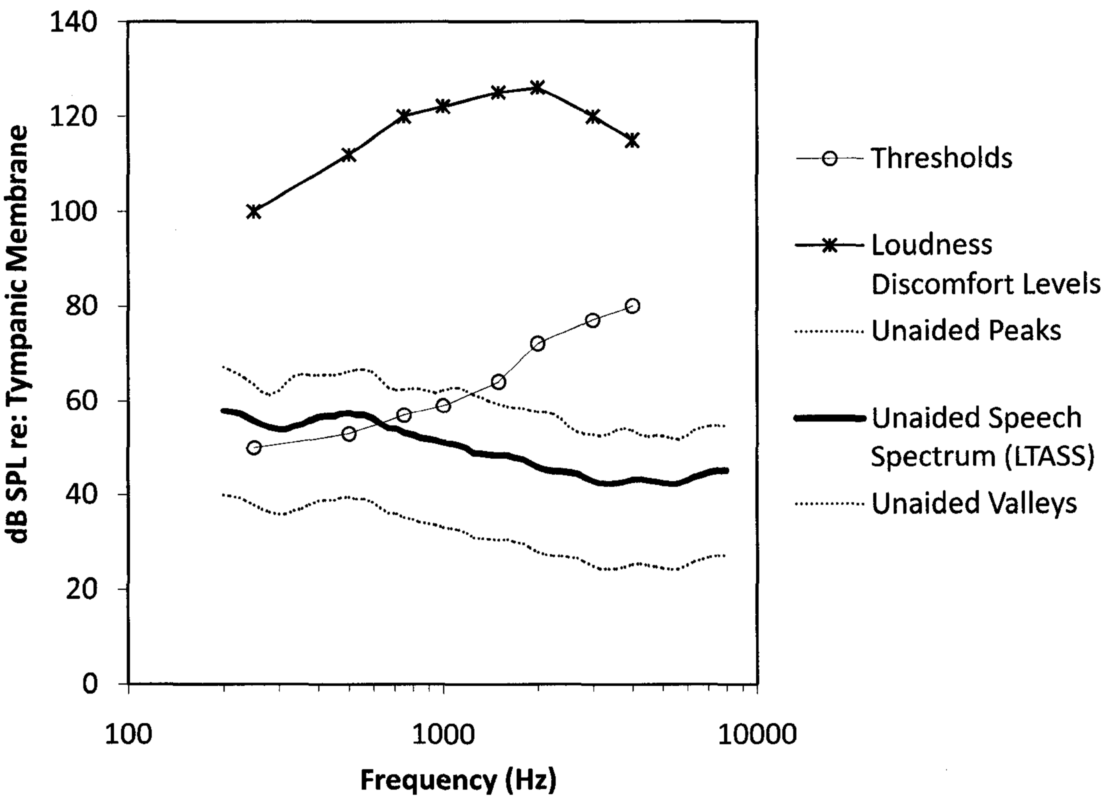

Figure 3-4. Example of an Unaided SPLogram

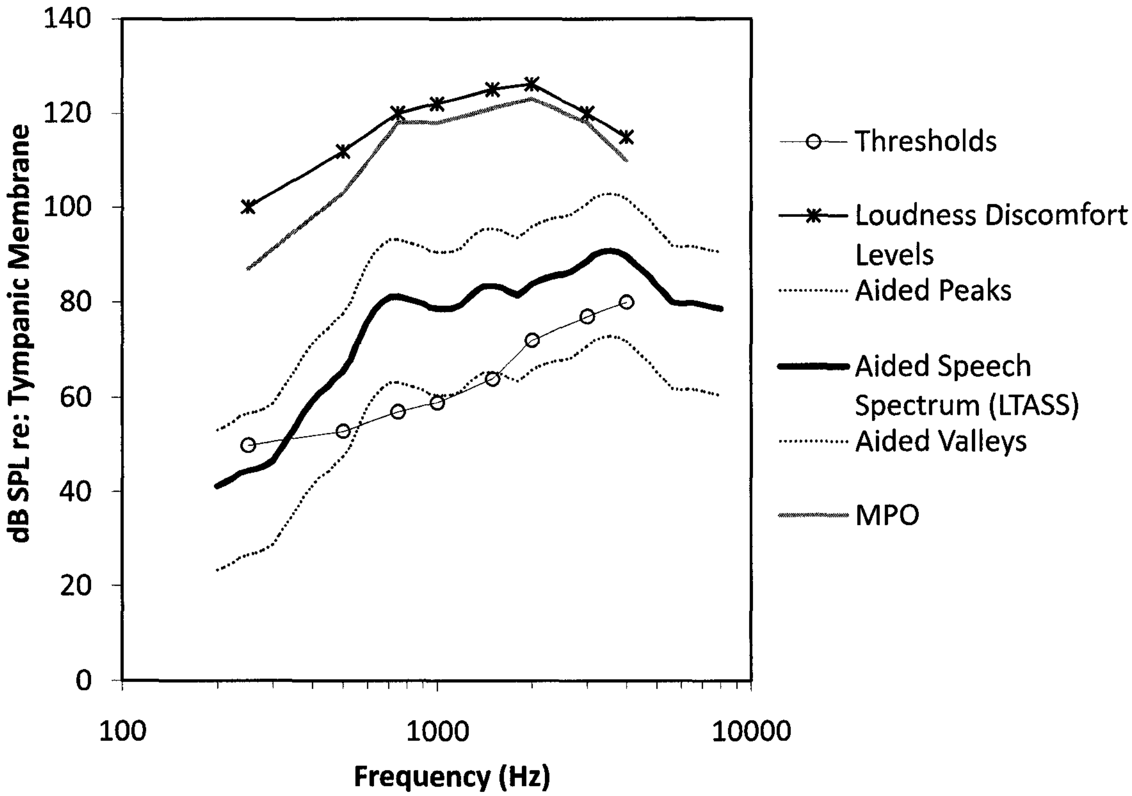

Figure 3-5. Example of an aided SPLogram display.

From a display perspective, SPLograms are more helpful to clinicians and patients than aided soundfield thresholds, as they allow for direct comparison of the output of the hearing aid directly to each user's unique auditory needs with real speech inputs (rather than soft warble tones). But is this approach more efficient, reliable and valid than the aided soundfield approach?

Efficiency is determined by the time and effort taken to complete a procedure. Thresholds are always measured and loudness discomfort levels are often measured for most patients. Therefore, including them in the in-situ verification protocol does not add time. Electro-acoustic real ear measures take from about 1 to 15 seconds to complete. Compare this time to the amount of time required to obtain aided soundfield thresholds each time an adjustment is made to the hearing aid. Repeated behavioural measurements are extremely time-consuming. Four adjustments to the frequency response characteristics of a given hearing aid may take 20 minutes to verify with the aided soundfield approach, whereas the in-situ electroacoustic adjustments may take at most 1 minute to verify (assuming 15 seconds each).

Reliability can be determined by the differences that are expected on two consecutive tests of the same type (Scollie & Seewald, 2002). As mentioned before, the test-retest reliability of the aided soundfield approach is approximately 15 dB across frequencies (Hawkins et al., 1987). Real-ear measures, such as those being advocated here, show a test-retest reliability of about 2 dB from infants to adults when measured by an experienced clinician (Sinclair et al., 1996).

Validity addresses whether or not the measurement procedure accurately determines the hearing instrument performance without errors due to signal processing, signal type, or noise (Scollie & Seewald, 2002). As mentioned earlier, the aided soundfield approach contains validity problems with respect to all three. The aided soundfield threshold approach does not inform the clinician about input-output characteristics of the signal processing, uses signal types that do not reflect real inputs to the hearing aid and is plagued by room and microphone noise effects. Conversely, the real-ear electroacoustic approach allows for the accurate characterization of signal processing (e.g., input/output) characteristics through the use of multiple input types and levels. However, the in-situ measurement of real ear thresholds can be plagued by noise floor problems when attempting to measure thresholds at levels below 40 to 50 dB SPL. For air conduction hearing aids, this noise floor problem can be easily avoided through the use of transforms such as the Real Ear to Coupler Difference (RECD) or Real Ear to Dial Difference (REDD; Moodie et al., 1994; Scollie et al., 1999).

3.1.4 **Two In-Situ Approaches to Verifying Baha**

3.1.4.1 Real Ear (Electroacoustic)

The real ear in-situ approach to verifying Baha is the same as the real ear in-situ approach to verifying air conduction hearing aids, save one difference. Instead of delivering signals directly into the ear canal via an earphone (for thresholds and LDLs) or an air conduction hearing aid (for the hearing aid response measures), all signal delivery comes through the Baha abutment. It has been known for many years that, whenever the skull is vibrated, the bony and cartilaginous portions of the canal radiate air conducted sound into the external ear (Tonndorf, 1966). This radiated SPL is not thought to contribute a great deal to the sensation of hearing by bone conduction (Stenfelt & Goode, 2005a). Indeed, much of the SPL actually escapes the ear canal, because there is less impedance to the outside air than there is to the tympanic membrane (Tonndorf, 1966). If, however, the ear canal is occluded, SPLs associated with bone conducted stimuli increase, especially below 1000 Hz. This increase in ear canal SPL is known as the occlusion effect (Huizing, 1960; Elpern & Naunton, 1963).

It may be possible to use this canal-radiated SPL as a reference quantity for in-situ Baha verification. A probe microphone could be placed in the ear canal to measure the real-ear SPL associated with bone conduction thresholds and loudness discomfort levels. Additionally, the real ear microphone could be used to measure the aided response of the Baha. Assuming freedom from non-linearities and noise floor effects, this approach should satisfy the above criteria for a good verification protocol (Scollie & Seewald, 2002).

3.1.4.2 Accelerometer (Electromechanical)

A second in-situ approach to verifying Baha is proposed. As mentioned in the first study of this dissertation, a special transducer (Balanced Electromagnetic Separation Transducer (BEST) (Hakansson, 2003) that is mechanically stiff through the entire vibrating central core can be used to deliver sound to the patient from the audiometer for thresholds and LDL testing. The same transducer can be driven by a Baha for the aided Baha responses. In both cases, an accelerometer mounted to the backside of the transducer measures the in-situ accelerations (in dB) associated with the audiometric and aided Baha data. Instead of the ear canal SPL as a reference, the backside of the transducer (in dB acceleration level (AL)) becomes the reference. Again, by defining all hearing and hearing aid characteristics in the same units (dB AL) at the same reference point (backside of the transducer connected to the Baha abutment), it may be possible to satisfy the characteristics of a good verification protocol outlined above.

3.1.5 A Comparison of Three Approaches

To this point, we have introduced three possible methods for verifying the output of Baha: aided soundfield thresholds, real ear and accelerometer. The primary goal of this study is to compare the three approaches for determining the sensation level of the long term average speech spectrum (LTASS) for Baha users. The author proposed the SL of the LTASS (as opposed to the SL of speech peaks or valleys), because this is the value for which targets are generated with most prescriptive procedures. Audiologists who routinely fit hearing aids according to a SPLogram approach will be familiar with assessing the SL of the LTASS in relation to the thresholds of hearing. With both the real ear and accelerometer approaches, a secondary outcome of interest will be possible. By measuring the loudness discomfort levels and the maximum power output (MPO) of the Baha, we can compare the output capabilities of the Baha directly with the levels Baha users deem to be uncomfortable. This outcome measure is not possible with the aided soundfield approach.

For the SL estimates, if the three verification procedures all measure the same thing, using the same hearing aid with the same settings for all three estimates, should result in comparable results.

The following primary questions were of interest:

a. Are there differences in SL estimates of the aided LTASS for each of the three approaches?
b. Are the SL estimates dependent upon the input level used to derive the aided LTASS?
c. Are the SL estimates comparable at some frequencies, but not others?

The following secondary questions were of interest:

d. What is the maximum "ideal" dynamic range of hearing by direct bone conduction?
e. What is the maximum "functional" dynamic range of hearing by direct bone conduction?

3.2 Methods

3.2.1 Subjects

Twenty-three subjects (8 females, 15 males) with a mean age of 53.1 years (22.9 years to 79.8 years; SD = 15.8) were recruited from the Bone Conduction Amplification program at COMPRU. All subjects were Baha users for at least 3 months and all had snap coupling abutments. The average bone conduction PTA for all 23 subjects was 23.9 dB (SD = 13.6). Nineteen of the subjects had bilateral conductive or mixed hearing loss. One of the subjects had the Baha for single sided deafness, and three had unilateral conductive or mixed hearing loss. For the 4 subjects with unilateral hearing loss, the better hearing ear was occluded with a foam earplug with a noise reduction rating of 29 dB for all the testing.

3.2.2 Instrumentation

3.2.2.1 Overview of the Instrumentation

Several components were required for the assessment of sensation level estimates. Before introducing the components, Figure 3-6 shows how these components were connected to each other to obtain the measures.

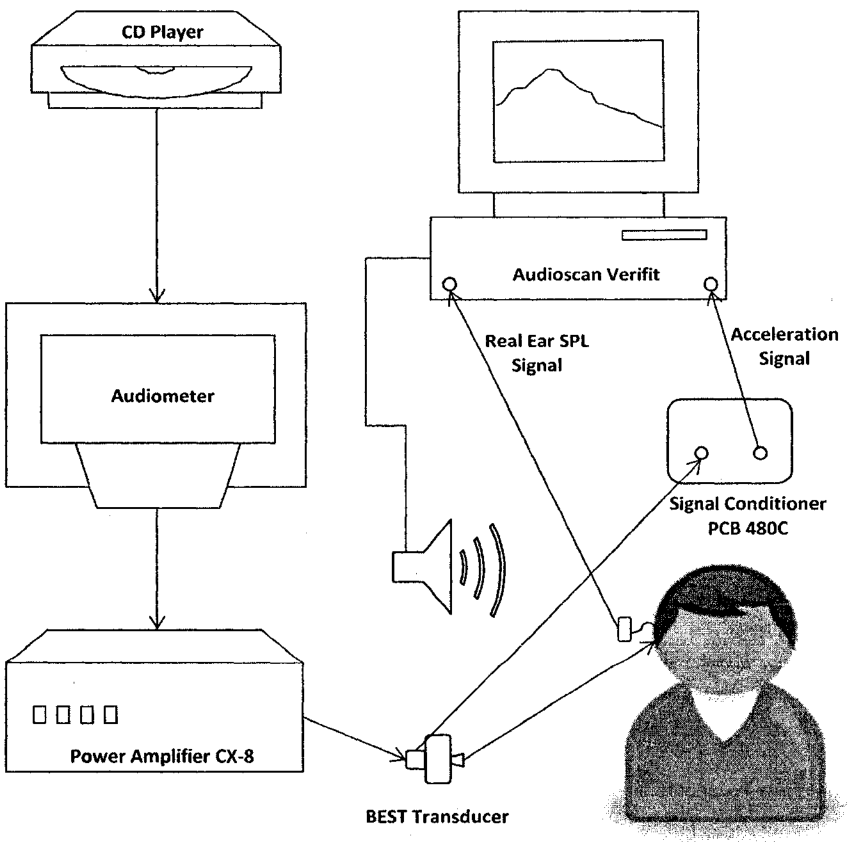

Figure 3-6. Overview of the experimental set-up.

3.2.2.2 Aided Soundfield Approach

For the aided soundfield approach, the following 2 quantities were needed to assess the SL of the LTASS for each subject: (1) what is the level (in SPL) at the Baha microphone associated with the aided soundfield threshold?, and (2) what is the level of the unaided LTASS (in SPL) at the Baha microphone associated with 55, 65 and 75 dB SPL real speech inputs.

An Audioscan Verifit VF-1 Real-Ear Hearing Aid Analyzer (subsequently referred to as the Verifit (Dorchester, Ontario, 2005) was used to derive both of these quantities. First, the Verifit was set to function as a sound level meter using the manual control feature. This allowed the author to use the probe microphone to assess the SPL at the Baha microphone (in $1/12^{th}$ octave intervals) of the warble tones used to test aided soundfield thresholds at each audiometric frequency. The real ear measurement unit of the Verifit contains both a probe microphone and a reference microphone. The reference microphone ensures that the expected level presented to a patient (e.g., an overall RMS level of 65 dB SPL) is actually being delivered. The probe microphone is typically placed in the ear canal to measure the output of the hearing aid in the ear. For the aided soundfield approach we were interested in the level of the LTASS associated with different speech inputs at the Baha microphone. The probe microphone was placed at the entrance to the Baha microphone and the Verifit was set to deliver real speech samples at overall RMS levels of 55, 65 and 75 dB SPL. The calibrated real speech was a 15 second passage, spoken by a male talker, originally from the Connected Sentences Test (Cox et al., 1987). By selecting Speechmap® on the Verifit, the probe microphone sampled the incoming speech signal every 128 ms in $1/12^{th}$ octave intervals at the Baha microphone. The ear is approximately 10 to 20 dB less sensitive to sounds which last only a few milliseconds compared to sounds which last more than 100 milliseconds (Cole, 2005). This is an important point. We are ultimately interested in comparing the SL of the LTASS to thresholds. Thresholds are obtained with signals that are at least several hundred milliseconds in length, therefore the sampling time for the speech signal cannot be too short. Otherwise the estimate of speech sensation level would be erroneous. The Speechmap system also measures the peaks of speech (the level exceeded only 1% of the time) and the valleys of speech (the level exceeded 70% of the time). The unaided LTASS plus the peaks and valleys of speech for a 65 dB SPL input are displayed in Figure 3-4.

3.2.2.3 Real Ear Approach

For the real ear approach, the following 2 quantities were needed to assess the SL of the LTASS for each subject: (1) with a special Baha transducer being driven by the audiometer, what is the level (in SPL) in the ear canal of each patient associated with the threshold of hearing obtained directly through the Baha abutment?, and (2) with the Baha connected to the abutment and a probe microphone in the ear canal, what is the level of the aided LTASS (in SPL) associated with 55, 65 and 75 dB SPL real speech inputs?

The real ear manual control setting of the Verifit was used to assess the ear canal SPL associated with direct bone conduction thresholds. The Speechmap® setting was used to deliver 55, 65 and 75 dB SPL real speech inputs to the Baha. The probe microphone was used to measure the aided LTASS in the ear canal generated by the Baha vibrations at each speech input level.

3.2.2.4 *Accelerometer Approach*

For the accelerometer approach, the following 2 quantities were needed to assess the SL of the LTASS for each subject: (1) with a special Baha transducer being driven by the audiometer (described below), what is the level (in acceleration level (AL) on the backside of the transducer) of each patient associated with the threshold of hearing obtained directly through the Baha abutment?, and (2) with a special transducer driven by a Baha and connected to the abutment, what is the level of the aided LTASS (in AL off the backside of the transducer) associated with 55, 65 and 75 dB SPL real speech inputs?

As with the real ear approach above, the manual control setting of the Verifit was used to assess the acceleration level associated with direct bone conduction thresholds. The Speechmap® setting was used to deliver 55, 65 and 75 dB SPL real speech inputs to the Baha. The accelerometer signal was delivered to the probe microphone input to measure the aided LTASS off the backside of the transducer generated by the Baha vibrations at each speech input level (more on this below).

3.2.2.5 *Special Transducers*

For both the real ear and accelerometer approaches, special bone conduction transducers were used. Two versions of the Balanced Electromagnetic Separation Transducer (BEST) (Håkansson, 2003) with Baha snap couplings were designed specifically for this study. The first version was designed to test the dynamic range of hearing by direct bone conduction. This "audiometric version" of the BEST transducer had a larger mass, lower resonant peak, greater output capabilities and could be driven directly by an audiometer. The second version of the BEST transducer was wired directly to a Baha Divino. The Baha version of the BEST transducer is similar in size and output properties to the current Baha Divino transducers. Figure 3-7 shows both of these transducers. On the left is the Baha Divino used to drive the "Baha version" of the BEST transducer shown in the middle of the Figure. The audiometric version is shown on the right. The main advantage of using the BEST transducers for this study is that they are rigid through their entire vibrating central core. See Study 1 of this dissertation for a more thorough description of the BEST transducer. By placing an accelerometer on the backside of the transducers we can measure the accelerations indicative of those being delivered on the front side of the transducer to the patient.

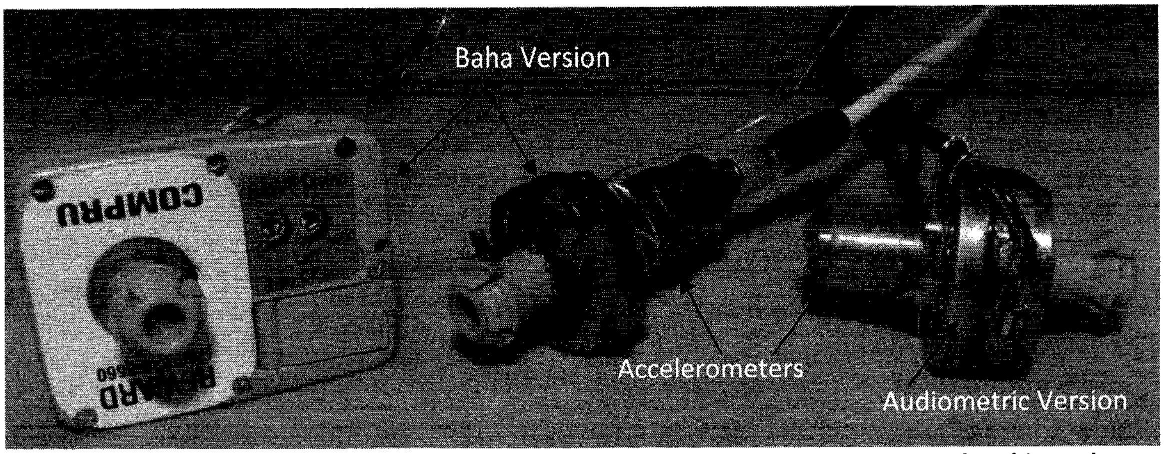

Figure 3-7. The Baha (left) and Audiometric (right) versions of the BEST transducer used in this study. Also depicted are the accelerometers used to measure the accelerations off the backside of the transducers.

3.2.2.6 Accelerometers and Signal Conditioning

Accelerometers produce voltages at their output terminals proportional to the acceleration to which they are subjected. Two PCB piezoelectric accelerometers (PCB Piezotronics, Depew, New York, USA; Models 352B10 and 352C66) were chosen for this study. For the audiometric data (threshold and dynamic range assessment), model 352B10 with a sensitivity of 10 mV/g was connected to the back of a BEST transducer and was used exclusively for audiometric testing. Model 352C66, with a sensitivity of 100 mV/g was connected to the back of the BEST transducer that was driven by the Divino. The voltages at the output terminals of the accelerometers were quite small. Therefore, it was necessary to feed the signals for both accelerometer models through a preamplifier (signal conditioner), before they reached the signal analyzer. A PCB model 480C signal conditioner was used to condition the low level acceleration signals. For the model 352B10 accelerometer (10 mV/g), the signal conditioner was set to 10 times gain. For the model 352C66 accelerometer (100 mV/g), the gain on the signal conditioner was set to unity. Since there was a 10 times difference in accelerometer sensitivity (20 dB difference), the measured accelerations after signal conditioning from the audiometric and Baha accelerometers were directly comparable.

3.2.2.7 Signal Analysis and Calibration

For all acceleration measures, analysis of the conditioned output voltage was performed by the Verifit. The Verifit is typically calibrated to display a specific sound pressure level (SPL) value for a given electrical signal level. In the case of an air conduction hearing aid or a real-ear measurement, the displayed SPL will be the SPL associated with the voltage at the measurement microphone input which may be either a coupler or real-ear microphone.

For this study, the Verifit was calibrated for two additional purposes. First, it was calibrated to measure the signal from both BEST accelerometers (acceleration response) at the entrance to the real-ear microphone. The accelerometer responses were used to determine the acceleration (in dB AL) associated with the in-situ thresholds and loudness discomfort levels and the acceleration responses (in dB AL) of the aided Baha output[6]. The Verifit was also calibrated to accept the electrical signal from a TU-1000 Baha skull simulator (force response) at the entrance to the coupler microphone. For the aided testing, we used 1 Baha Divino test aid that had the wires jumped to the "Baha version" of the BEST transducer. The TU-1000 was used to match each Baha subject's current device (as closely as possible) to the test aid.

For the acceleration response, a 200 mV 1000 Hz signal was equivalent to 120 dB SPL displayed on the Verifit screen. For the force response, the coupler microphone of the Verifit received an electrical signal from the accelerometer inside the TU-1000. However, because the skull simulator has a known load (50 g mass) with an impedance much greater than the output impedance of the transducers used to drive it, the electrical signal level from the accelerometer in the skull simulator is indicative of the force level, since Force = Load Mass * Acceleration (Håkansson & Carlsson, 1989). For the current test system, a 1000 Hz tone of 120 dB SPL was equal to .2 V/N. Figure 3-8 shows the audiometric BEST transducer attached to the TU-1000 skull simulator and connected to the Verifit. Since the conversion factors are known for both the accelerometers and the skull simulator, the SPLs displayed by the Verifit were easily converted to either acceleration or force measures.[7]

[6] The real ear reference microphone on the Verifit is typically calibrated with a probe microphone in place. The probe microphone has resonances associated with its shape and length that---once known---are automatically subtracted by the Verifit. When the author was not using the probe microphone (i.e., using the accelerometer), it was necessary to calibrate the Verifit real-ear microphone to have a flat response so that tube resonances were not automatically subtracted from our acceleration responses. A y-splitter was used so the hearing aid coupler microphone (which has a flat spectrum) could be calibrated against the real ear reference microphone. Once the Verifit stored the flat calibration curve, the conditioned acceleration signal could be plugged into the y-splitter in place of the coupler microphone. Thus, the reference microphone would monitor the input signal level and adjust the speaker output accordingly, while the "probe" microphone would measure the acceleration signal without subtracting the tube resonances.

[7] Many thanks to Bill Cole for his assistance in setting up the Verifit to function as an accelerometer signal analyzer.

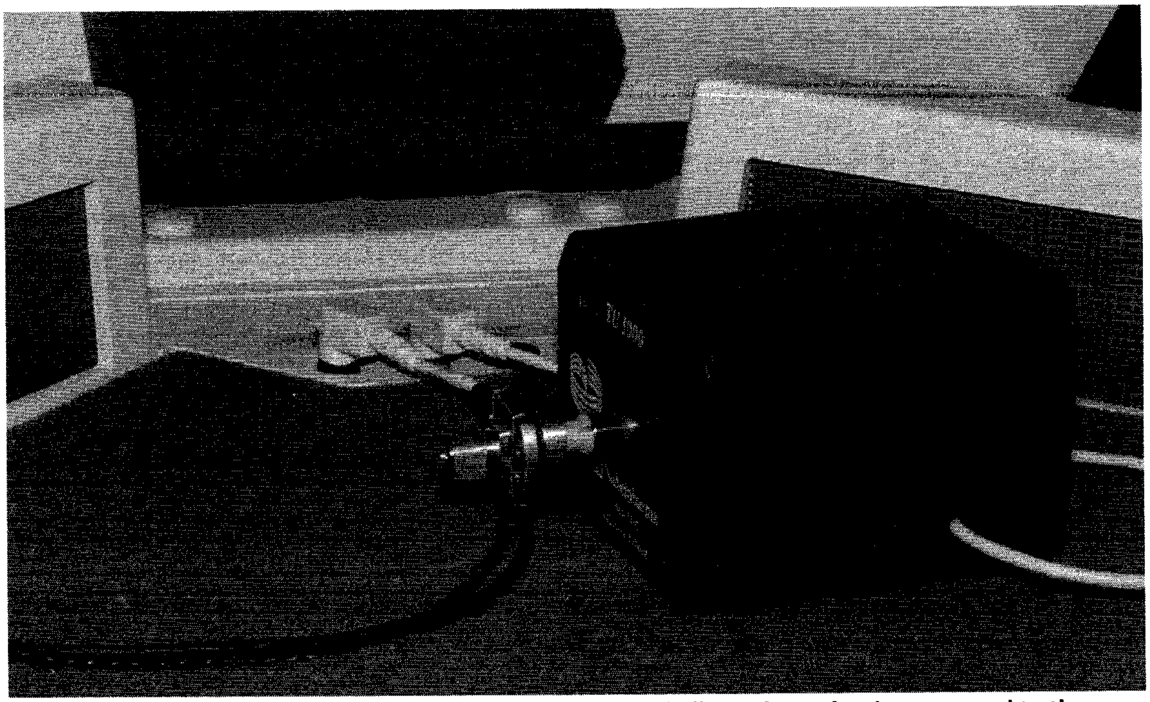

Figure 3-8. The BEST transducer connected to the TU-1000 skull simulator that is connected to the Verifit coupler microphone input. This set-up was used to match the Divino test aid to each subject's Baha use setting.

The following Verifit functions were used in this study: (1) "Real Ear Manual Control" was used to determine the HL to acceleration transform for audiometric testing (see below for description), (2) "Coupler Multicurve" was used to match the Divino test aid to the user's current Baha settings (see below for description), and (3) "Real Ear Speechmap®" was used to measure the in-situ aided responses. Data from the Verifit were exported to a text file for each subject, then the text file was converted to an Excel spreadsheet for subsequent data analysis.

3.2.2.8 In-Situ Audiometry Set-up

The Baha will ultimately amplify and deliver speech through the Baha abutment, therefore it is logical to determine threshold and loudness discomfort levels (LDLs) through the abutment so all variables related to each subject's hearing and hearing aid are all relative to the same signal delivery point. This is true for both the real ear and accelerometer approaches. The only differences between the two approaches are the location (ear canal vs. backside of BEST transducer) and metric (dB SPL vs. dB AL) for referencing these thresholds and LDLs. Figure 3-9 shows the set up for both the real ear and accelerometer approaches. The audiometric version of the BEST transducer was used for all signal delivery. A probe microphone was placed in the occluded ear canal for the SPL measures and an accelerometer was placed on the backside of the BEST transducer for the acceleration measures.

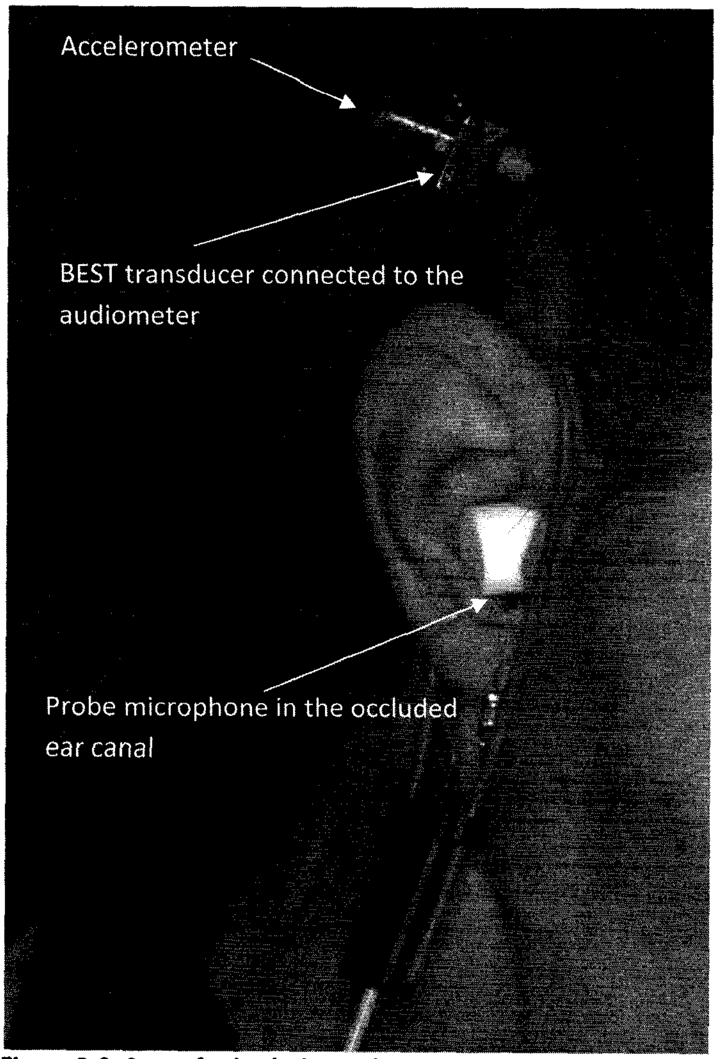

Figure 3-9. Setup for both the probe microphone and acceleration in-situ audiometry. The BEST transducer was connected to the audiometer for all signal delivery.

Output signals from the right headphone channel of an Interacoustics AC-40 audiometer (Interacoustics; Assens, Denmark) were routed to one channel of a model CX 8, eight-channel power amplifier (QSC; Costa Mesa, USA). The audiometric version of the BEST transducer was connected to the output of the CX-8 and was subsequently connected to the BAHA subject. With this set-up, the audiometer dial was set to 60 dB HL to ensure a stable signal that consistently exceeded the noise floor of the measurement system. For the real ear approach, at 250, 500, 1000, 2000 and 4000 Hz an HL-to-SPL (real-ear-to-dial-difference) transform was measured with the real ear manual control mode of the Verifit. For the acceleration approach, at the same audiometric frequencies, an HL-to-AL transform was measured. Once these 2 transforms were known, testing of threshold and loudness discomfort level (LDL) could proceed using the audiometer and the BEST transducer.

3.2.3 Procedure

3.2.3.1 In-Situ Audiometry

With the audiometric version of the BEST transducer connected to the patient's Baha abutment, thresholds were established at 250, 500, 1000, 2000 and 4000 Hz using a modified Hughson-Westlake procedure. Both the SPL and acceleration transforms for 60 dB HL dial setting on the audiometer were known, therefore the actual SPL and acceleration values at threshold were easily obtained. For example, if the transform SPL value for 1000 Hz at 60 dB HL on the audiometer dial for a given subject was 80 dB and the actual threshold value for that subject was 50 dB, the true in-situ SPL for that subject at threshold would be 70 dB (80 dB – 10 dB).The same approach was used for the threshold conversions to AL.

For the LDL testing, a modified version of the procedure outlined by Hawkins (1980) was used. The same instructions were given to each subject and, as Hawkins (1980) suggests, would be categorized as instructions seeking the criterion of "definite discomfort." The instructions were modified slightly from the original instructions used by Morgan, Wilson and Dirks, (1974):

This is a test in which you will hear sounds through your Baha abutment. I want you to decide when the sound is at a level that you think is uncomfortably loud or unpleasantly loud. By "uncomfortably loud" I mean when the sound is so loud that you would choose not to listen to it for any period of time. Push the button when the loudness of the sound attains a level to which you would not listen. I will lower the level and then repeat the procedure. Are there any questions?

The LDL values in dB HL dial settings were converted to in-situ SPL and acceleration values using the 60 dB HL transform. If the same subject's LDL at 1000 Hz was 110 dB HL on the audiometer dial, the actual LDL in SPL was 130 dB (80 dB + 50 dB).

3.2.3.2 Matching the Test Aid to Each User's Preferred Baha Settings

Since the method of measuring the in-situ Baha responses in this study required the use of a test Baha Divino coupled to a BEST transducer, we first needed to simulate their current Baha by matching the test aid to the subject's user settings. To do this, the subject's Baha, with its typical use settings was placed on the skull simulator and routed through the hearing instrument test coupler microphone of the Verifit. A 60 dB pink noise stimulus was used to measure the frequency response of the current Baha in response to an average level input. Additionally, a 90 dB pure tone sweep was used to measure the current Baha's MPO. The dial settings of the test Baha were then adjusted to match both the 60 dB pink noise curve and the 90 dB MPO curve for each user's current Baha as closely as possible. The majority of patients in this study were using either the Baha Compact, Classic or Divino. Therefore, it was relatively easy to match the settings with the test Divino, because it can be set to behave much like a Classic or a Compact by adjusting the low-cut and output compression settings,

3.2.4 **Outcome Measures**

As mentioned in the introduction, the primary outcome measure of interest was the estimate of sensation level of the LTASS for each of the 3 approaches at multiple input levels and at multiple frequencies. The secondary outcome of interest was the difference between "ideal" or maximum dynamic range of hearing (without the Baha) and the "functional" or device-limited dynamic range of hearing with the Baha. Each outcome measure is detailed below.

3.2.4.1 Sensation Level Estimates:

3.2.4.1.1 Aided Soundfield Threshold Approach (AS)

In the introduction, it was mentioned that there were no standardized plots of the speech spectrum in dB HL. Even if the details of a transformation from SPL to HL were known, the plots usually assume only 1 input level in the derivation (e.g., 65 dB SPL). We are interested in the SL estimates at multiple *frequencies* and at multiple *levels*. Gengel, Pascoe and Shore (1971) described an alternative approach to estimating SL that does not rely on the HL audiogram. Essentially, if you know the softest SPL a person can hear with the hearing aid on at each frequency (aided soundfield threshold in SPL) and you know the SPL associated with the LTASS at each of those frequencies, the sensation level can be derived by subtracting the aided soundfield threshold from the unaided LTASS (Seewald et al., 1992; Ling & Ling, 1978).

All measurements were made in a sound treated-booth. Again, HL dial settings to SPL transforms were required. This time, instead of placing the probe microphone into the ear canal, the HL to SPL transform was measured at the locations of a Baha microphone on a patient seated in the centre of the room (1.8 meters) and 90 degrees azimuth to a Bose (model 151; Framingham MA, USA) loudspeaker mounted 1.15 meters from the floor in the corner of the room. The HL-to-SPL transform was measured on both sides of a subject's head to ensure that we know the transform when the Baha was worn on either side of the head. A 70 dB warble tone was delivered from the audiometer to the loudspeaker at each of the following frequencies: 250, 500, 1000, 2000, and 4000 Hz. The SPL transform for a given HL dial setting could thus be used to convert aided soundfield thresholds measured in HL to SPL at the Baha microphone. The HL to SPL transform was checked on 3 people who differed in height. The SPL at the Baha microphone did not differ by more than 2 dB at any frequency for all three subjects.

A second calibration procedure was needed for the aided soundfield approach. To obtain the required LTASS in SPL at the entrance to the Baha microphone for the same frequencies as the aided soundfield thresholds, a subject was seated in the same chair as for the HL to SPL calibration. This time, separate runs of real speech were delivered from the Verifit soundfield speaker at 0 degree azimuth with overall RMS levels of 55, 65 and 75 dB SPL respectively. These overall RMS levels were controlled by the real ear reference microphone. The probe microphone measured the unaided LTASS (plus the peaks and valleys) for each input level. The RMS levels (in SPL) were obtained in 1/12th octaves for all frequencies between 200 and 8000 Hz. However, we only needed the RMS levels for 250, 500, 1000, 2000 and 4000 Hz to derive our SL estimates. The width of a warble tone is roughly 1/12th of an octave, which allowed for a fairly direct comparison of the LTASS in 1/12 octaves to the warble tones in 1/12th

octaves. Again the unaided LTASS was calibrated on the same three people used to check the aided soundfield threshold calibration. Equivalent results were obtained for all three subjects.

Once both the aided soundfield and the LTASS calibrations were known, the only information required to estimate SL of the LTASS was the actual aided soundfield thresholds of individual Baha patients. With the test Baha set to match each patient's user setting, aided soundfield thresholds were obtained at 250, 500, 1000, 2000 and 4000 Hz using warble tones from the interacoustics AC-40 audiometer. SL estimates were derived as follows: (a) if, at 1000 Hz, the aided soundfield threshold was 25 dB HL and the transform value associated with a 70 dB HL dial setting was 76 dB SPL, the actual SPL associated with the aided threshold would be 31 dB SPL (76-45 dB) and (b) if the SPL of the 1000 Hz region of the 65 dB overall RMS LTASS was 51 dB SPL, the SL would be 20 dB (51 – 31 dB SPL). This derivation of SL was repeated for all frequencies and all input levels.

3.2.4.1.2 Real Ear Approach (SPL)

Once in-situ real ear thresholds were known (see above), we needed to determine the aided LTASS for each input level in the ear canal of each patient. Again, the test Baha, matched to each patient's use setting, was worn. The test aid was connected to a headband and the wires from the Divino were jumped to the Baha BEST transducer that was connected to the Baha abutment (see Figure 3-10). The calibrated real speech from the Verifit was delivered to the Baha (with the level controlled by the reference microphone) and the ear canal SPL was measured in 1/12th octaves. We also measured the noise floor of the aided condition with the hearing aid on and no input to the patient. This time, instead of comparing the unaided LTASS to the softest audible warble tone, the comparison was between the aided LTASS and the unaided thresholds of hearing. If the aided LTASS value at for the 1/12th octave interval centred at 1000 Hz for a 65 dB overall RMS input was 48 dB SPL and the threshold of hearing at 1000 Hz was 38 dB SPL, the sensation level would be 10 dB (38 – 28 dB SPL).

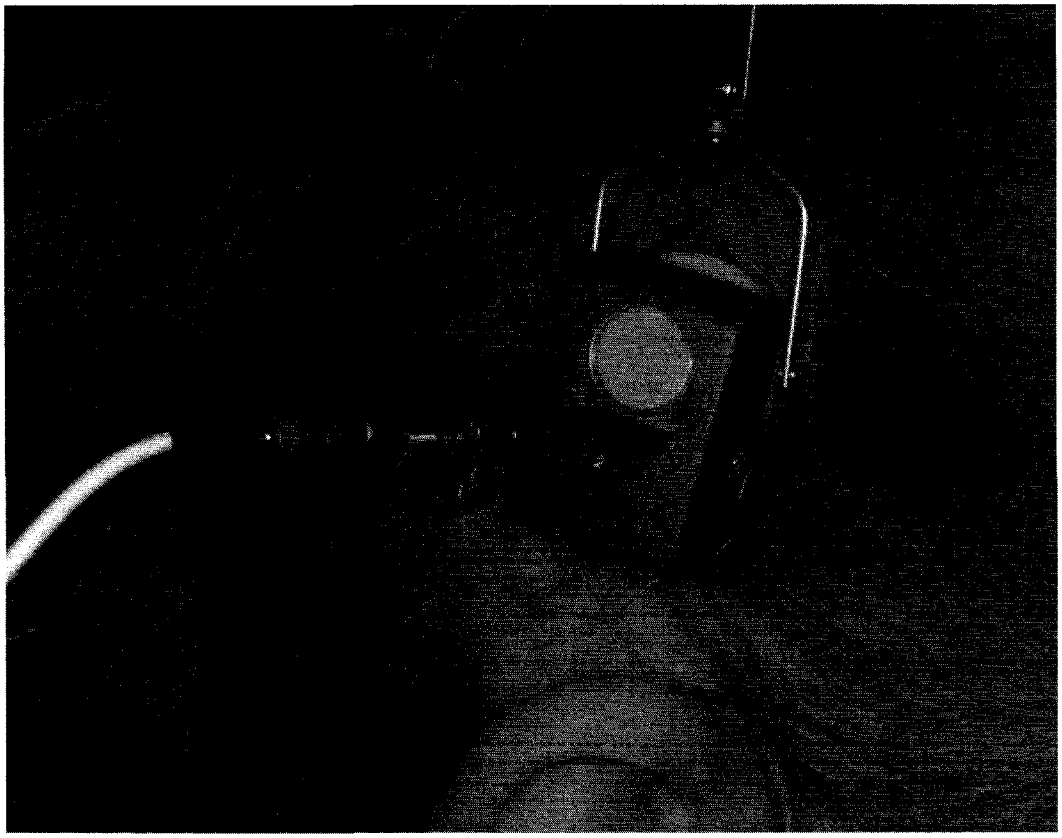

Figure 3-10. Test Divino coupled to a steel headband. The wires from the internal processor are used to drive the BEST transducer for the aided LTASS assessments. For the real ear approach, a probe microphone in the ear canal measured the aided LTASS. For the accelerometer approach, the accelerometer on the backside of the BEST transducer measured the LTASS.

3.2.4.1.3 Accelerometer Approach (AL)

As with the real ear in-situ response, the SL of the accelerometer approach was derived by comparing the aided LTASS to the unaided thresholds. Instead of the ear canal, the accelerations measured on the back of the Baha best transducer were compared to the acceleration thresholds measured on the back of the audiometric BEST transducer. We also measured the noise floor of the measuring approach with the hearing aid on and no input to the patient.

3.2.4.2 Dynamic Range Estimates:

As mentioned earlier, a secondary objective of this study was to determine, using the new in-situ approaches, the relationship between what might be considered an "ideal" or maximum dynamic range by direct bone conduction, versus the "functional" or device-limited dynamic range offered with the current ear level Divino processor.

Procedures for obtaining the ideal dynamic range of hearing estimates were described above. To compare ideal dynamic range to the device limited dynamic range, we needed to measure the maximum power output (MPO) of the Baha on each patient. The Speechmap® system on the Verifit generates a 90 dB pure tone sweep, and the output of the Baha was measured with either the probe microphone in the ear canal or with the accelerometer.

3.2.5 Statistical Design and Analyses

The primary objective was to assess if there were differences in SL estimates between the 3 approaches. The dependent variable (DV) was sensation level (in dB). There were 3 independent variables (IV). The first IV was Approach with 3 levels (aided soundfield threshold (AS), real ear (SPL), and acceleration level (AL)). The second IV was Input with three levels (55 dB SPL, 65 dB SPL, and 75 dB SPL). The third IV was Frequency with 5 levels (250, 500, 1000, 2000, 4000 Hz). Consequently, a 3 x 3 x 5 repeated measures ANOVA was performed to check for main effects and interactions between the IVs. Assuming significance for the interaction in the repeated measures ANOVA a great many mean comparisons (990) would be required in full post hoc analyses. However, many of the mean comparisons were not of interest in this study. Consider that the frequency response of the Baha is not flat. If we compared the mean response of a Baha at 250 Hz and at 4000 Hz within one approach (e.g., AL) at a fixed input level (e.g., 55 dB SPL) we would most likely find that the differences were significant. In this case, the difference would be attributed to the fixed frequency response of the Baha and not necessarily the manipulation of the independent variables. Consequently, we planned our contrasts to maximize statistical power. Paired-samples t-tests were proposed for the individual planned comparisons. To minimize the likelihood of a type-1 error for multiple contrasts, a Bonferonni correction was applied to the experiment-wise p-value. The desired experiment-wise error rate (.05) was divided by the number of planned comparisons (45), This meant that for any one pairwise t-test of means to be significantly different, the p-value associated with the contrast had to be lower than 0.0011. All statistical analyses were performed using SPSS (Version 15, 2006).

The dependent variable for the secondary objective was dynamic range (in dB). Again, there were 3 IVs: Approach with 2 levels (SPL and AL), Type with 2 levels (ideal and functional) and Frequency with 5 levels (250, 500, 1000, 2000, 4000 Hz). A 2 X 2 X 5 repeated measures ANOVA was used with Bonferonni-adjusted planned paired-samples t-tests to explore the individual comparisons.

3.2.6 Effect Size Calculations

Determining the strength of an effect by statistical significance testing alone is difficult. Consequently effect size calculations were included for each of the planned comparisons. As t-tests of means were used, Cohen's d was considered the most appropriate effect size equation (Cohen, 1988). Where,

$$d = \frac{\mathrm{mean}_1 - \mathrm{mean}_2}{\sqrt{(\mathrm{SD}_1^2 + \mathrm{SD}_2^2)/2}} \quad (1)$$

Interpreting the strength of the effect is not universally agreed upon (Huberty, 2002), however a widely accepted opinion is that of Cohen (1992) where 0.2 is indicative of a small effect, 0.5 a medium effect, and 0.8 a large effect size.

3.3 Results

3.3.1 Sensation level Estimates

Figures 3-11, 3-12, and 3-13 show the relationships between thresholds of hearing and the LTASS averaged across all 23 subjects for the AS, SPL, and AL approaches respectively. Sensation level estimates were derived by subtracting the threshold values from the LTASS values at 250, 500, 1000, 2000, and 4000 Hz for each input level (55 dB SPL, 65 dB SPL and 75 dB SPL). Arrows at 500, 1000, and 2000 Hz illustrate the calculations of SL. At 500 Hz, the arrow shows the calculations for a 55 dB SPL input. The arrow at 1000 Hz shows the SL calculation for that frequency with a 65 dB SPL input. Finally, the arrow at 2000 Hz shows the SL calculation at that frequency for a 75 dB SPL input. Similar calculations were performed for 250 and 4000 Hz at all input levels as well.

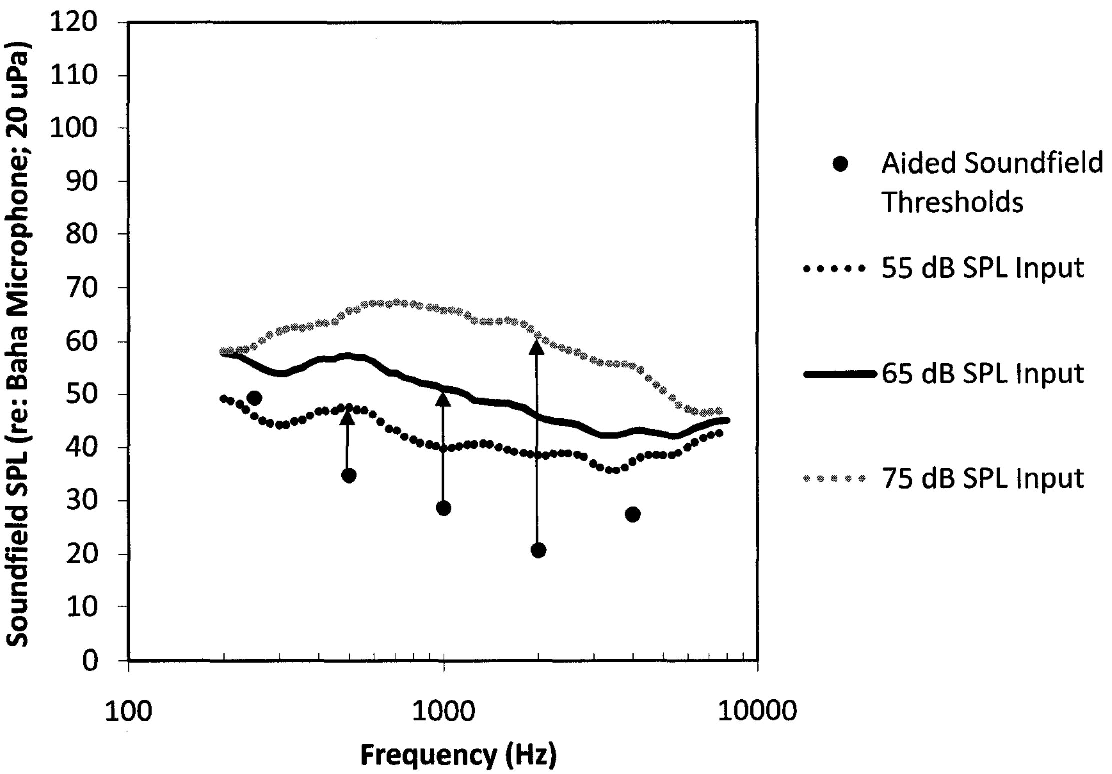

Figure 3-11. The relationship between aided soundfield thresholds and the unaided LTASS across frequencies for 55, 65 and 75 dB SPL speech inputs. SL calculations are depicted by the arrows.

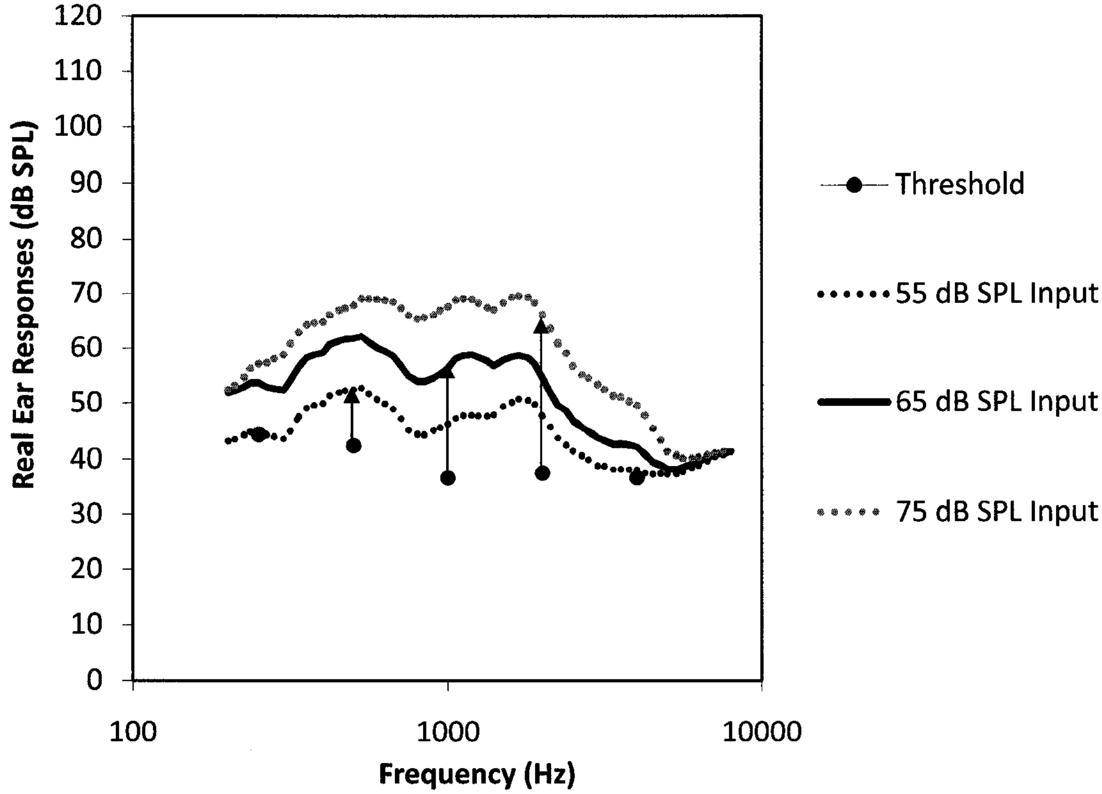

Figure 3-12. The relationship between unaided bone conduction thresholds (referenced to ear canal SPL) and the aided LTASS by bone conduction across frequencies for 55, 65 and 75 dB SPL speech inputs. SL calculations are depicted by the arrows.

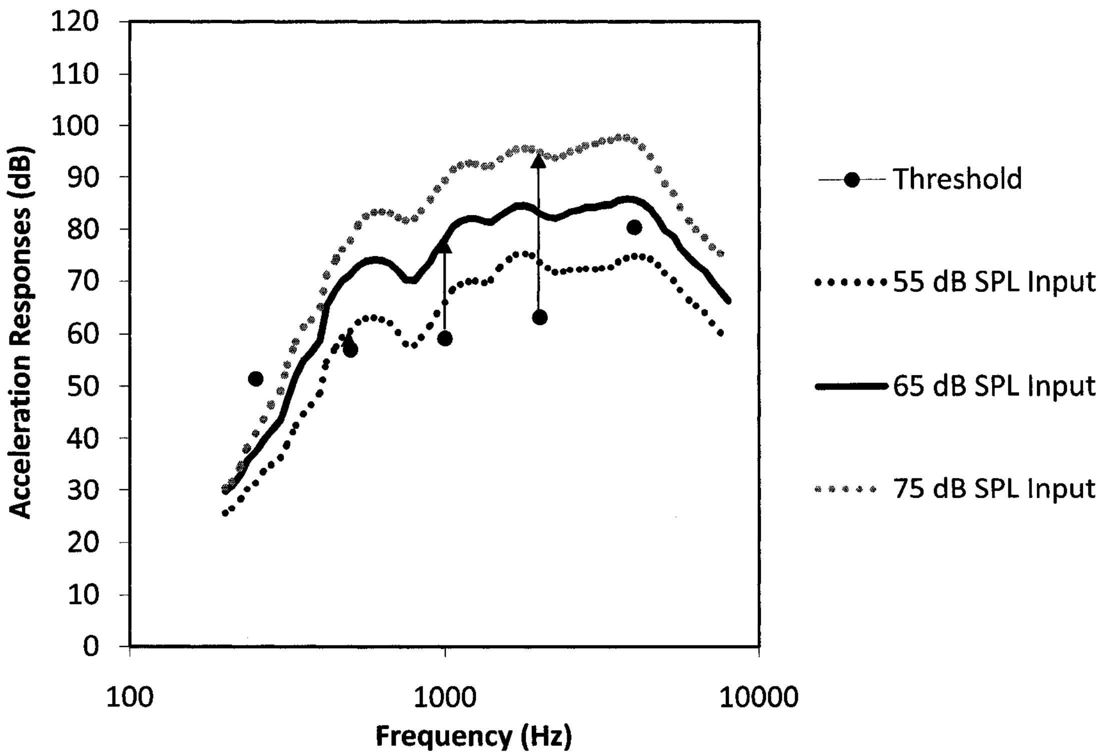

Figure 3-13. The relationship between unaided bone conduction thresholds (referenced to the backside of the BEST transducer) and the aided LTASS by bone conduction across frequencies for 55, 65 and 75 dB SPL speech inputs. SL calculations are depicted by the arrows.

A 3 (fitting approach) x 3 (input level) x 5 (frequency) repeated measures ANOVA was used to test for differences among estimates of sensation level of the LTASS. The 3-way interaction was significant ($F_{(4.5, 99.3)} = 15.70$, $p < 0.0001$), allowing us to proceed to the planned comparisons of interest using paired-samples t-tests and a Bonferonni-adjusted p-value. Table 3-1 shows all 45 t-test contrasts, the mean differences, 95% confidence intervals of the difference and the significance of each. Grey rows indicate differences that were significant at the 0.0011 level. Table 3-2 shows the effect size calculations for all 45 contrasts. Grey rows indicate effect sizes of 0.8 or greater. Figures 3-14, 3-15 and 3-16 show the average sensation level estimates at all 5 frequencies and all 3 input levels. It is perhaps helpful to consider the relationship between the effect size of a given contrast and the difference in dB associated with that contrast. We can see in Table 3-2 that a large effect of 0.8 corresponds to a difference of 5.7 to 7.8 dB, depending on the size of the pooled standard deviation term. In other words, a difference of approximately 6 to 8 dB can be considered a large effect.

Table 3-1. Significance testing for all 45 planned comparisons. P-values needed to be less than 0.0011 to be considered statistically significant. Shaded contrasts are significant.

		Comparison	Mean1 – Mean2	95% CI Lower Bound	Upper Bound	t	p-value
55 dB Input	250	AL - SPL	-19.55	-25.15	-13.94	-7.23	0.0000
	250	AL - AS	-15.24	-20.20	-10.27	-6.37	0.0000
	250	SPL - AS	4.31	-1.88	10.50	1.44	0.1626
	500	AL - SPL	-5.18	-9.34	-1.03	-2.59	0.0168
	500	AL - AS	-8.90	-13.32	-4.47	-4.17	0.0004
	500	SPL - AS	-3.71	-7.88	0.45	-1.85	0.0781
	1000	AL - SPL	-0.24	-2.77	2.28	-0.20	0.8448
	1000	AL - AS	-5.74	-9.48	-2.01	-3.19	0.0042
	1000	SPL - AS	-5.50	-8.15	-2.86	-4.32	0.0003
	2000	AL - SPL	1.84	-1.74	5.43	1.07	0.2975
	2000	AL - AS	-10.15	-15.65	-4.66	-3.83	0.0009
	2000	SPL - AS	-12.00	-16.79	-7.21	-5.20	0.0000
	4000	AL - SPL	-4.13	-9.18	0.91	-1.70	0.1033
	4000	AL - AS	-15.57	-19.80	-11.34	-7.64	0.0000
	4000	SPL - AS	-11.44	-15.84	-7.04	-5.39	0.0000
65 dB Input	250	AL - SPL	-21.92	-27.56	-16.27	-8.05	0.0000
	250	AL - AS	-18.77	-23.71	-13.84	-7.90	0.0000
	250	SPL - AS	3.14	-3.10	9.39	1.04	0.3079
	500	AL - SPL	-3.86	-7.53	-0.19	-2.18	0.0402
	500	AL - AS	-8.07	-11.52	-4.61	-4.85	0.0001
	500	SPL - AS	-4.21	-8.31	-0.10	-2.13	0.0450
	1000	AL - SPL	1.82	-0.66	4.29	1.52	0.1422
	1000	AL - AS	-4.85	-8.47	-1.22	-2.77	0.0111
	1000	SPL - AS	-6.66	-9.64	-3.69	-4.65	0.0001
	2000	AL - SPL	4.57	0.71	8.42	2.46	0.0224
	2000	AL - AS	-7.81	-12.81	-2.80	-3.23	0.0038
	2000	SPL - AS	-12.37	-17.40	-7.35	-5.10	0.0000
	4000	AL - SPL	2.64	-2.55	7.83	1.06	0.3028
	4000	AL - AS	-10.50	-14.83	-6.17	-5.03	0.0000
	4000	SPL - AS	-13.14	-17.98	-8.30	-5.63	0.0000
75 dB Input	250	AL - SPL	-21.86	-27.62	-16.10	-7.87	0.0000
	250	AL - AS	-18.61	-23.30	-13.91	-8.22	0.0000
	250	SPL - AS	3.26	-3.14	9.65	1.06	0.3028
	500	AL - SPL	-3.25	-6.51	0.01	-2.07	0.0508
	500	AL - AS	-9.70	-13.37	-6.02	-5.47	0.0000
	500	SPL - AS	-6.45	-10.74	-2.15	-3.11	0.0051
	1000	AL - SPL	1.97	-0.36	4.31	1.75	0.0940
	1000	AL - AS	-8.28	-11.90	-4.66	-4.75	0.0001
	1000	SPL - AS	-10.26	-13.23	-7.28	-7.14	0.0000
	2000	AL - SPL	4.79	1.16	8.43	2.73	0.0121
	2000	AL - AS	-11.57	-15.99	-7.15	-5.43	0.0000
	2000	SPL - AS	-16.36	-21.15	-11.58	-7.09	0.0000
	4000	AL - SPL	6.73	1.56	11.90	2.70	0.0130
	4000	AL - AS	-11.33	-15.32	-7.33	-5.88	0.0000
	4000	SPL - AS	-18.06	-23.48	-12.64	-6.91	0.0000

Table 3-2. Effect size calculations for all 45 planned comparisons. Calculations are based on Cohen (1992). Large effect sizes of 0.8 or greater are highlighted.

Input Level	*Planned Comparison*		*Mean1 - Mean2*	*(SD1)2*	*(SD2)2*	*Pooled SD*	*Effect Size*
55 dB Input	250	AL - SPL	-19.5487	149.3	122.3693	8.241197	2.37207
	250	AL - AS	-15.2357	149.3	154.3281	8.712463	1.748719
	250	SPL - AS	4.313043	122.3693	154.3281	8.317112	-0.51857
	500	AL - SPL	-5.18348	180.6546	92.11327	8.257843	0.627704
	500	AL - AS	-8.89652	180.6546	110.1779	8.526905	1.043347
	500	SPL - AS	-3.71304	92.11327	110.1779	7.111454	0.522122
	1000	AL - SPL	-0.2413	132.0462	74.87382	7.192357	0.03355
	1000	AL - AS	-5.74391	132.0462	76.14625	7.214437	0.796169
	1000	SPL - AS	-5.50261	74.87382	76.14625	6.144511	0.895532
	2000	AL - SPL	1.843478	208.9474	85.49174	8.579614	-0.21487
	2000	AL - AS	-10.1543	208.9474	196.996	10.07402	1.007974
	2000	SPL - AS	-11.9978	85.49174	196.996	8.403687	1.427686
	4000	AL - SPL	-4.13304	190.6615	42.10497	7.628342	0.541801
	4000	AL - AS	-15.5709	190.6615	149.8024	9.225831	1.687747
	4000	SPL - AS	-11.4378	42.10497	149.8024	6.926531	1.651307
65 dB Input	250	AL - SPL	-21.9178	191.4852	123.667	8.876264	2.469263
	250	AL - AS	-18.7748	191.4852	154.3281	9.298028	2.019222
	250	SPL - AS	3.143043	123.667	154.3281	8.336592	-0.37702
	500	AL - SPL	-3.86043	139.5879	96.49867	7.682555	0.502494
	500	AL - AS	-8.06739	139.5879	110.1779	7.90199	1.020932
	500	SPL - AS	-4.20696	96.49867	110.1779	7.188124	0.585265
	1000	AL - SPL	1.817391	126.5423	100.5387	7.534603	-0.24121
	1000	AL - AS	-4.84565	126.5423	76.14625	7.118436	0.680719
	1000	SPL - AS	-6.66304	100.5387	76.14625	6.646145	1.002543
	2000	AL - SPL	4.566522	194.9845	128.2211	8.988959	-0.50801
	2000	AL - AS	-7.80609	194.9845	196.996	9.899249	0.788553
	2000	SPL - AS	-12.3726	128.2211	196.996	9.016888	1.372159
	4000	AL - SPL	2.64	215.5159	53.18573	8.19606	-0.32211
	4000	AL - AS	-10.5017	215.5159	149.8024	9.55665	1.098893
	4000	SPL - AS	-13.1417	53.18573	149.8024	7.123695	1.844793
75 dB Input	250	AL - SPL	-21.8622	168.3706	126.9374	8.592265	2.544402
	250	AL - AS	-18.6065	168.3706	154.3281	8.981908	2.071556
	250	SPL - AS	3.255652	126.9374	154.3281	8.385486	-0.38825
	500	AL - SPL	-3.2487	118.7082	82.25517	7.088078	0.458332
	500	AL - AS	-9.69826	118.7082	110.1779	7.564491	1.282077
	500	SPL - AS	-6.44957	82.25517	110.1779	6.936012	0.929867
	1000	AL - SPL	1.972174	108.0356	91.80723	7.068288	-0.27902
	1000	AL - AS	-8.28304	108.0356	76.14625	6.78568	1.220665
	1000	SPL - AS	-10.2552	91.80723	76.14625	6.479843	1.582634
	2000	AL - SPL	4.792609	180.0518	125.8918	8.745622	-0.548
	2000	AL - AS	-11.57	180.0518	196.996	9.70886	1.191695
	2000	SPL - AS	-16.3626	125.8918	196.996	8.984541	1.821196
	4000	AL - SPL	6.732609	209.1607	72.3886	8.389716	-0.80248
	4000	AL - AS	-11.3252	209.1607	149.8024	9.473161	1.195506
	4000	SPL - AS	-18.0578	72.3886	149.8024	7.453036	2.422882

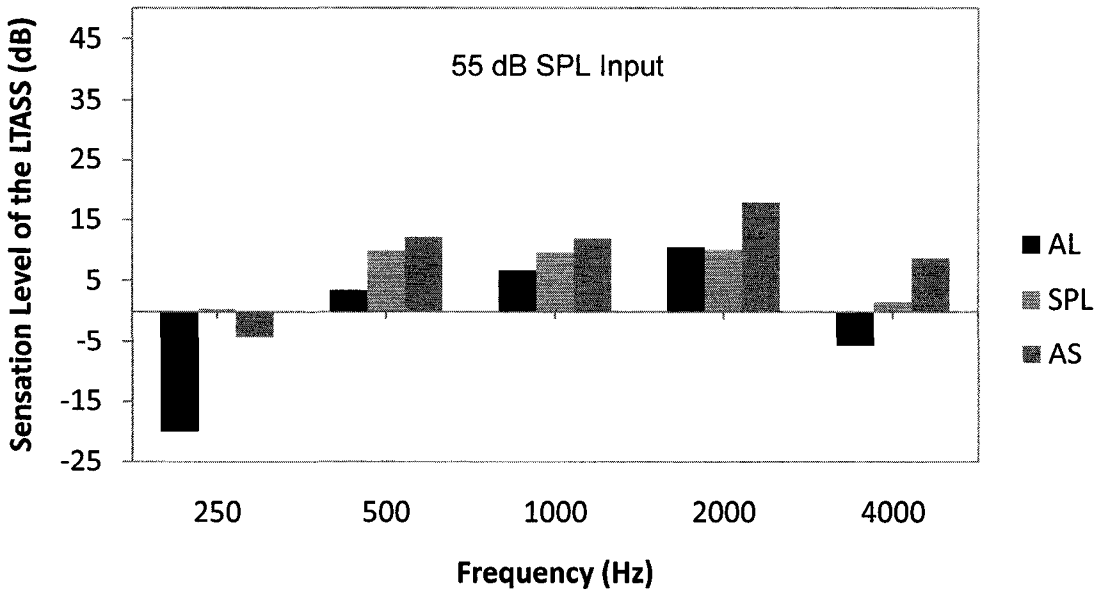

Figure 3-14. Sensation level estimates for all three approaches calculated with a 55 dB SPL input.

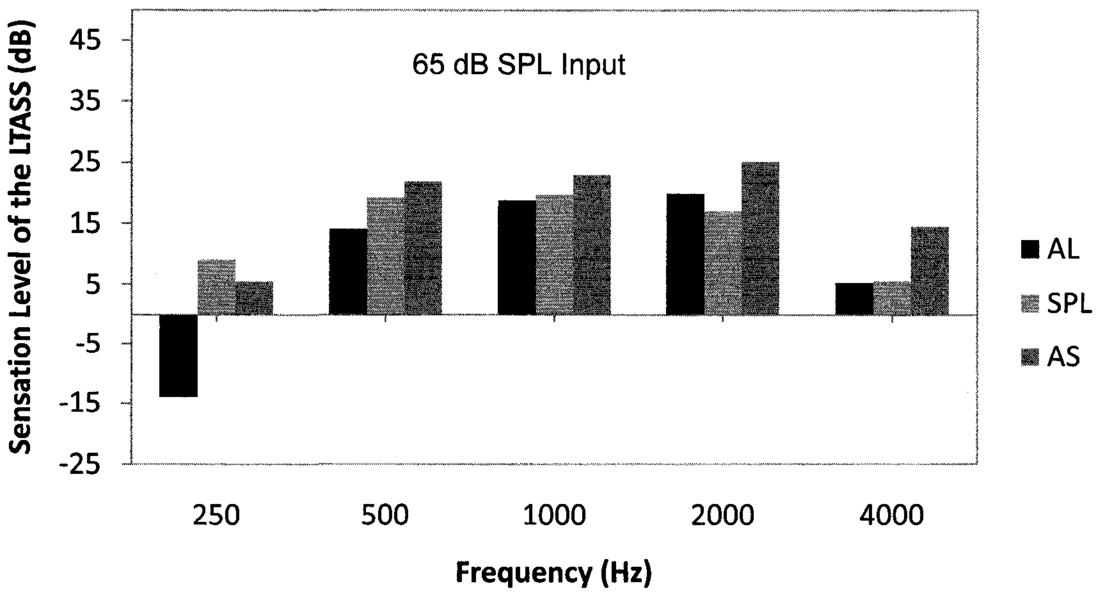

Figure 3-15. Sensation level estimates for all three approaches calculated with a 65 dB SPL input.

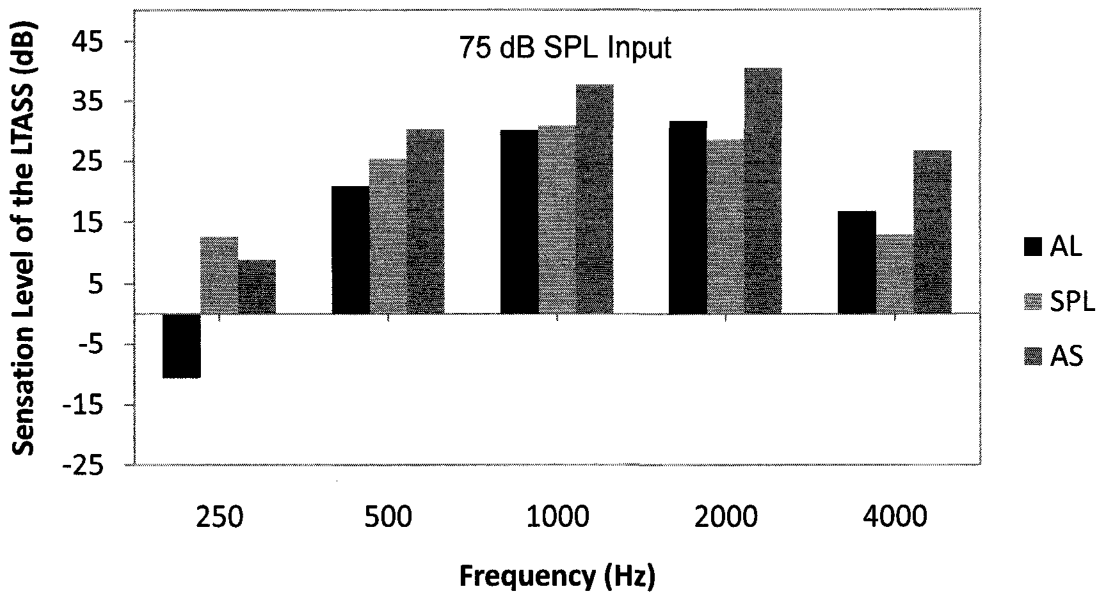

Figure 3-16. Sensation level estimates for all three approaches calculated with a 75 dB SPL input.

The values plotted in Figures 3-17 to 3-25 illustrate the extent to which the SL estimates derived from the two methods under comparison agreed at each frequency. Values of zero on the y-axis represent perfect agreement between the two methods used to estimate SL of aided speech. As opposed to the aggregate plots in Figure 3-14 to 3-16, each point in these graphs represents one subject.

There appears to be little agreement between any of the approaches at 250 Hz. In general, the AL and SPL approach appear to agree more closely with each other than they do with the AS approach. It is expected that, if the mean difference between approaches was close to 0, then all values should be near the 0 line with roughly 50% of the values above the 0 line and 50% of the values below. The three AL minus SPL contrasts showed differences of 61%, 53% and 46% at 55, 65 and 75 dB SPL respectively. Compare these differences to the AL minus AS contrasts of 84%, 84% and 90% at 55, 65 and 75 dB SPL respectively. This means that, with loud speech (75 dB SPL), the aided soundfield approach estimated higher SL values 90% of the time when compared to the AL approach.

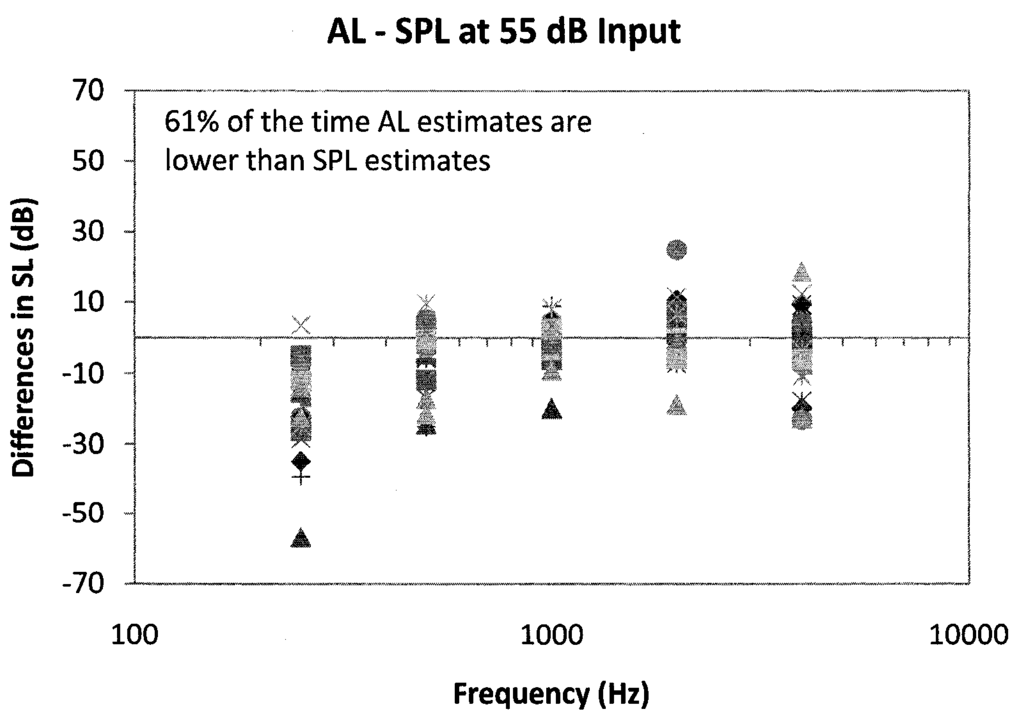

Figure 3-17. SL difference values as a function of frequency. Each value was calculated by subtracting the SPL estimate from the AL estimate for the same subject.

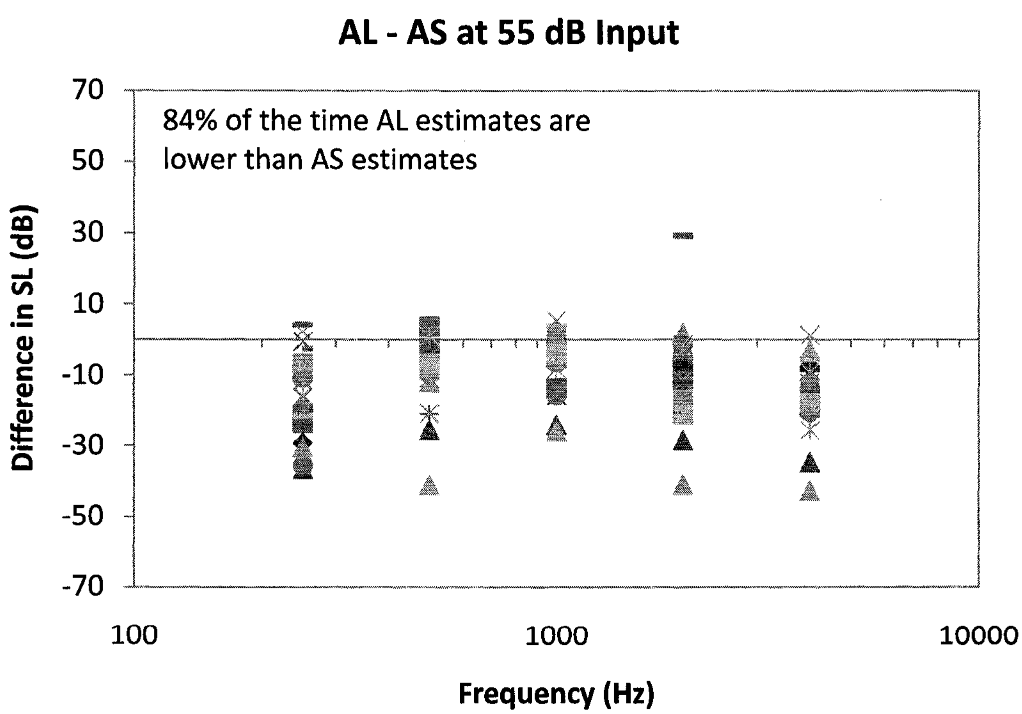

Figure 3-18. SL difference values as a function of frequency. Each value was calculated by subtracting the AS estimate from the AL estimate for the same subject.

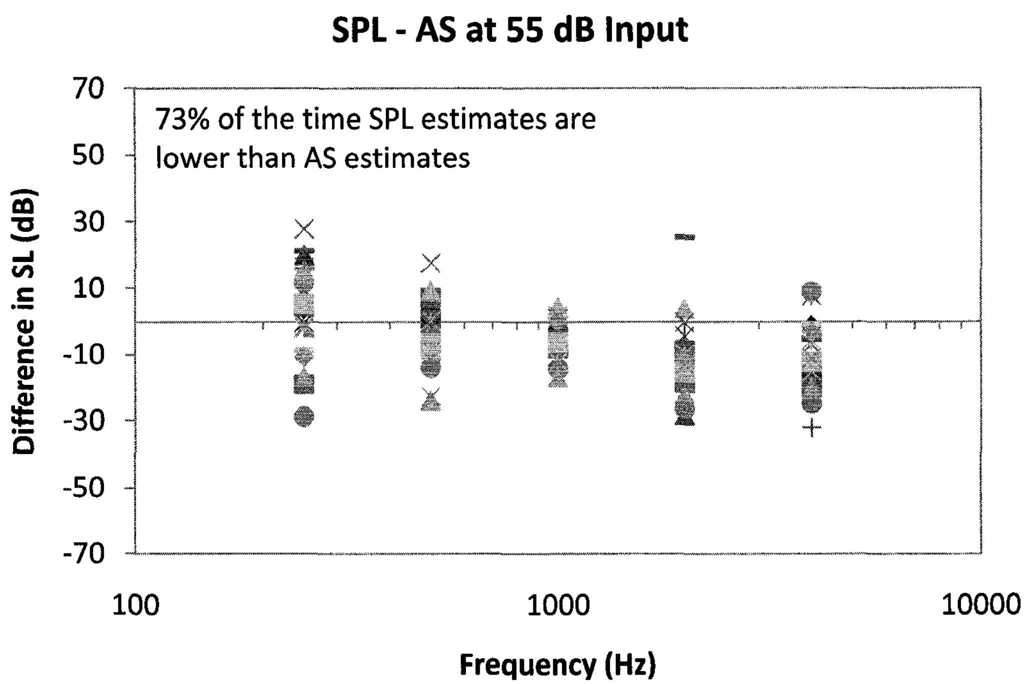

Figure 3-19. SL difference values as a function of frequency. Each value was calculated by subtracting the AS estimate from the SPL estimate for the same subject.

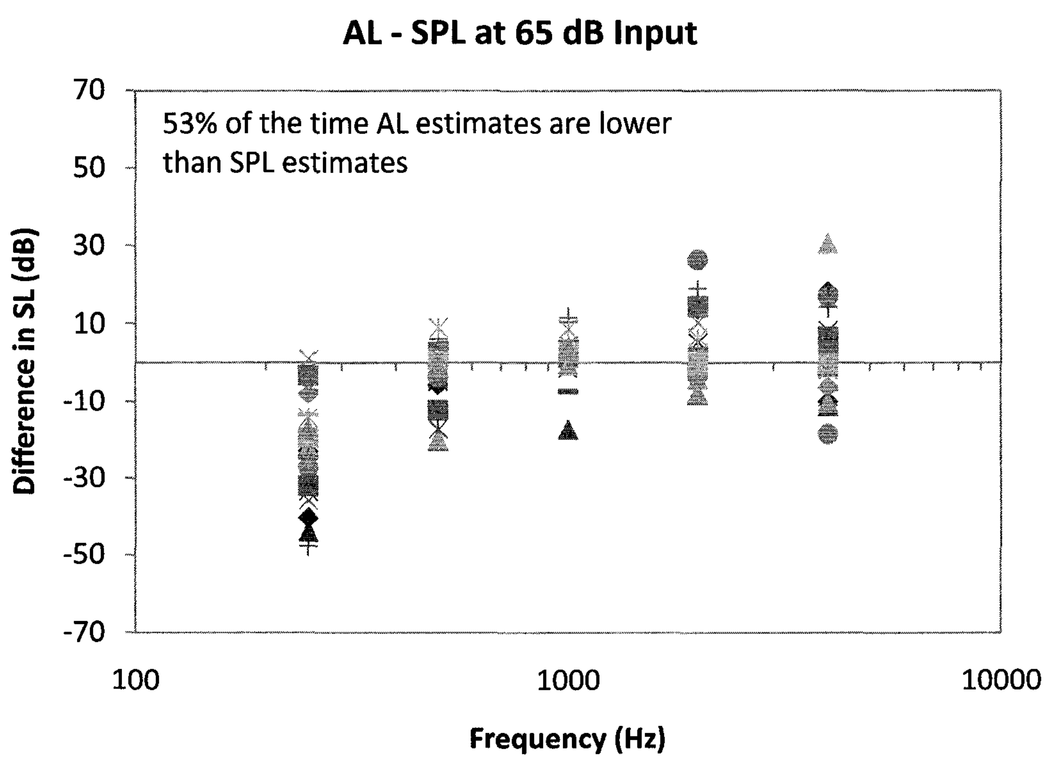

Figure 3-20. SL difference values as a function of frequency. Each value was calculated by subtracting the SPL estimate from the AL estimate for the same subject.

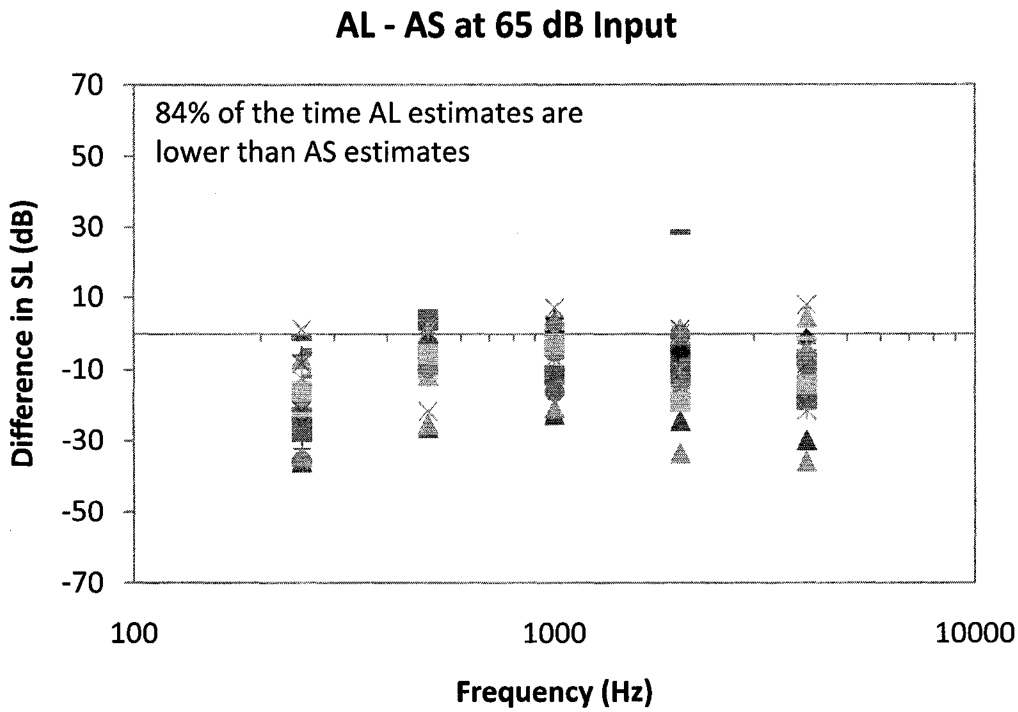

Figure 3-21. SL difference values as a function of frequency. Each value was calculated by subtracting the AS estimate from the AL estimate for the same subject.

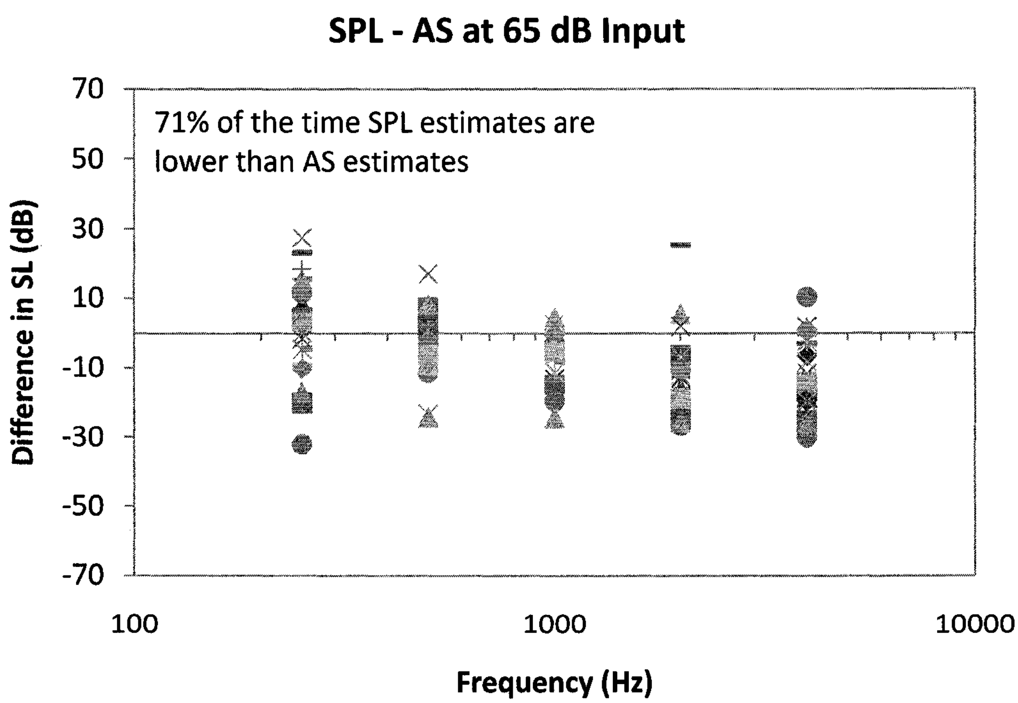

Figure 3-22. SL difference values as a function of frequency. Each value was calculated by subtracting the AS estimate from the SPL estimate for the same subject.

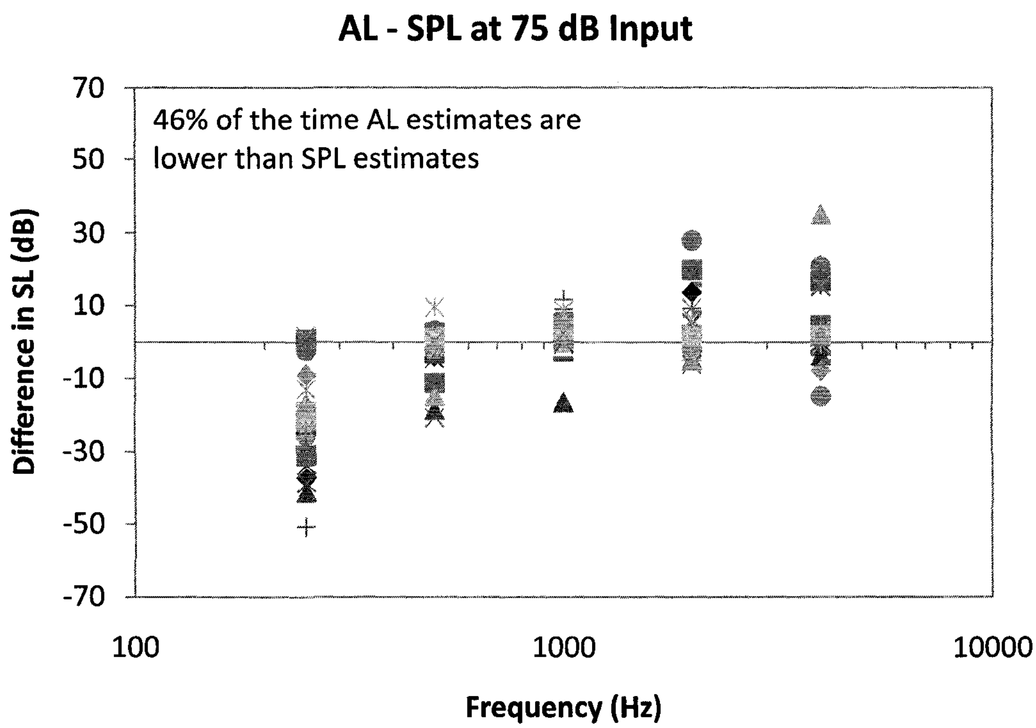

Figure 3-23. SL difference values as a function of frequency. Each value was calculated by subtracting the SPL estimate from the AL estimate for the same subject.

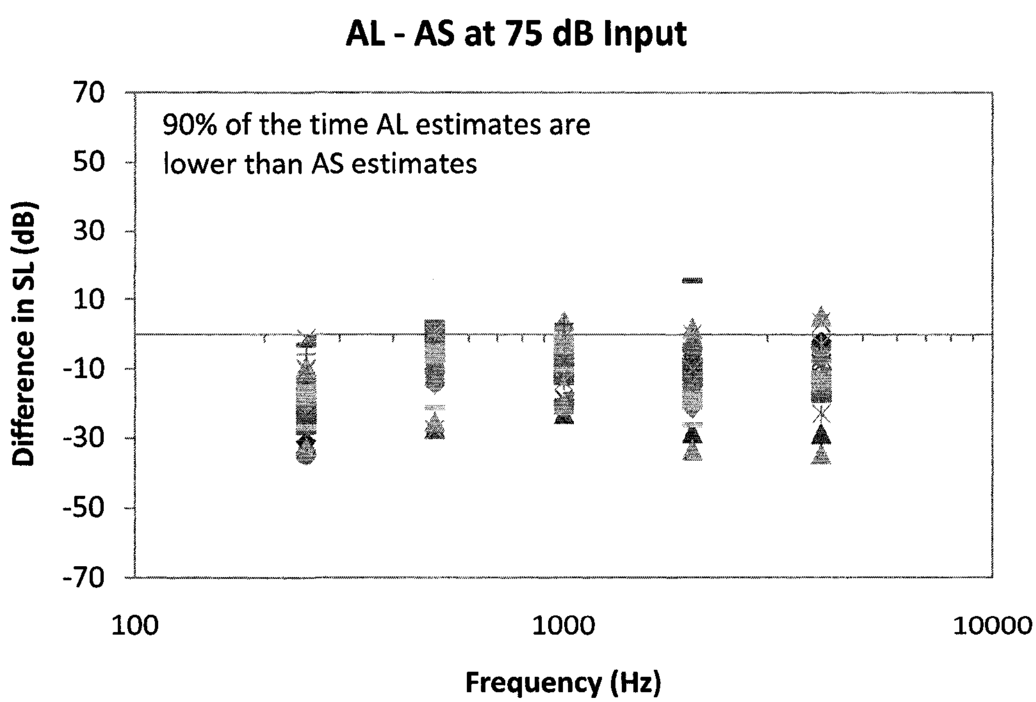

Figure 3-24. SL difference values as a function of frequency. Each value was calculated by subtracting the AS estimate from the AL estimate for the same subject.

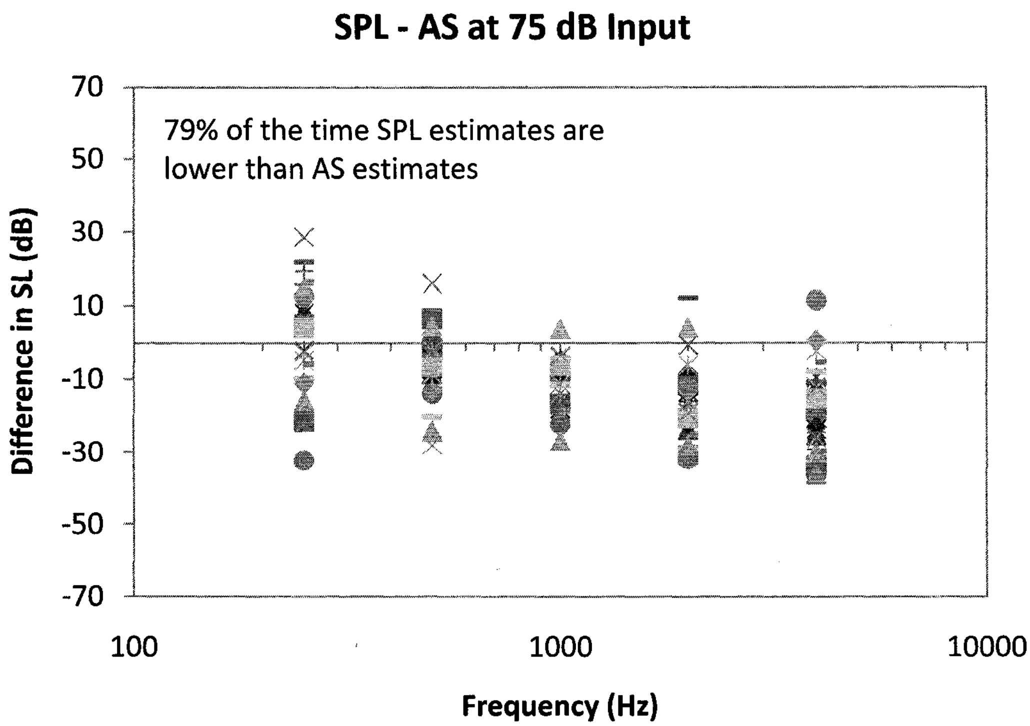

Figure 3-25. SL difference values as a function of frequency. Each value was calculated by subtracting the AS estimate from the SPL estimate for the same subject.

3.3.2 Dynamic Range

To analyze the secondary objective, which was to compare the maximum dynamic range by direct bone conduction to the device-limited dynamic range of the current ear level Divino processor, the investigators used a 2 x 2 x 5 repeated measures ANOVA. Since this was the second repeated measures ANOVA in this study, the experiment-wise p value was adjusted in the same way as for the first ANOVA. A significant 3-way interaction of approach x type of DR x frequency was found ($F_{(2.55, 56.11)} = 28.29$, $p < 0.001$). Planned comparisons were carried out on the 20 contrasts of interest. There were no differences at any frequency for the ideal dynamic range calculation between the AL and SPL approaches. Significant differences emerged when comparing the functional dynamic range estimates to ideal dynamic range estimates at all frequencies for both approaches. Figures 3-26 and 3-27 show the in-situ relationships between noise floor, thresholds, aided speech LTASS, MPO and UCL for the AL and SPL approaches respectively. Estimates of functional dynamic range also were compared between the two approaches. Clearly the MPO of the Baha was a limiting factor to the functional dynamic range in both approaches. However, the functional DR for the AL approach was significantly lower at 250 Hz due to the poor output response measured at that frequency with the accelerometer. Also, though not significantly different, it can be seen in Figure 3-27 that, for 2000 and 4000 Hz, the bottom of the functional dynamic range is no longer the thresholds, but the noise floor of the system.

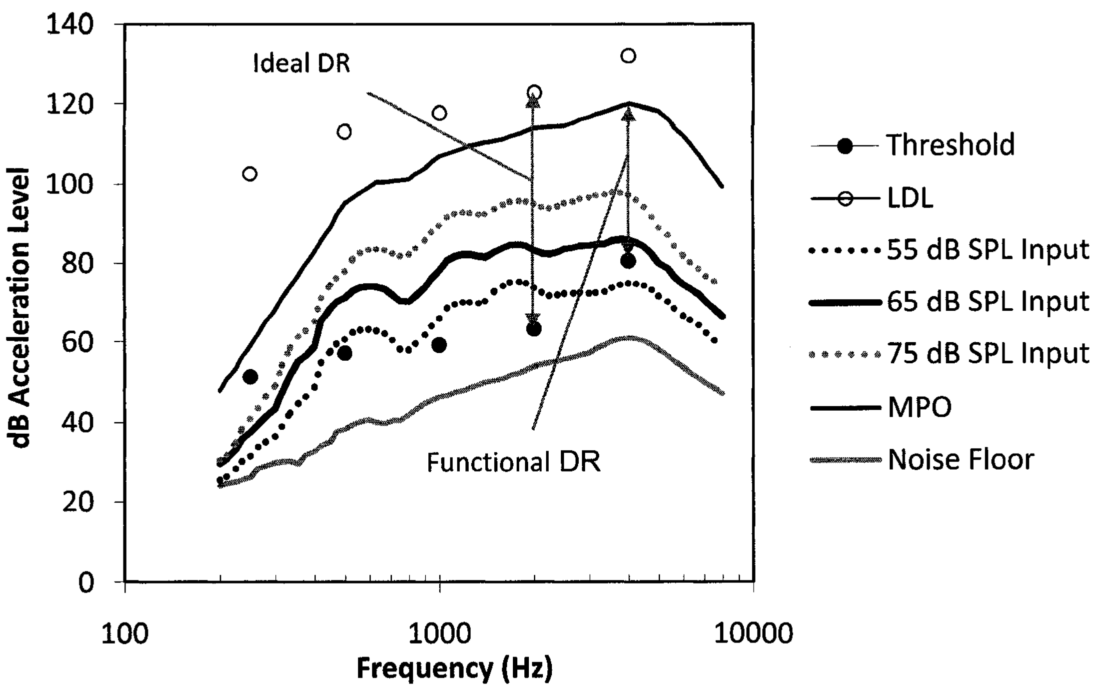

Figure 3-26. In-situ acceleration responses. The derivation of Ideal and functional dynamic range estimates are shown with the grey arrows.

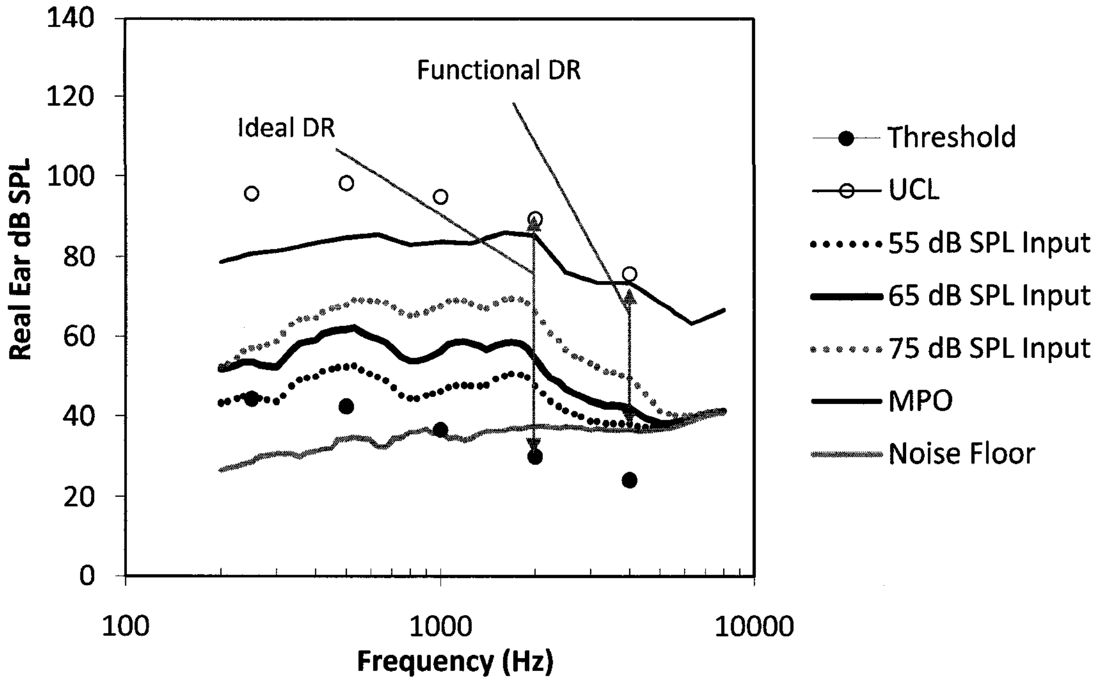

Figure 3-27. In-situ SPL responses. The derivation of Ideal and functional dynamic range estimates are shown with the grey arrows.

3.4 Discussion

3.4.1 A Comparison of Three Approaches

The primary goal of this study was to compare three approaches to verifying Baha. We developed and tested two new in-situ approaches (one electroacoustic, one electromechanical) and then compared these new approaches to the traditional aided soundfield approach. Since all three approaches were supposed to estimate the same thing (the sensation level of the long-term average speech spectrum) with the same hearing aid, equivalent results would have indicated that no one approach is necessarily better than the next. However, significant differences were found between approaches, illustrating how different procedures can provide different answers to the same clinical question (Seewald et al., 1992). So, which is the best approach to use for Baha?

3.4.1.1 Limitations of the Aided Soundfield Approach

With the exception of 250 Hz, the aided soundfield approach produced the highest estimates of speech sensation level. Averaged across frequencies and input levels, the AS approach estimated SLs 11 dB higher than the AL approach and 7 dB higher than the SPL approach. The discrepancy between the AL and SPL approaches occurred mostly at 250 Hz. That the AS approach provided higher estimates than either in-situ approach is not surprising given the limitations known to be associated with aided soundfield thresholds. For the present study, the most important limitations were: (1) the measurement of aided responses to low level inputs only, (2) the low frequency noise floor of the Baha, and (3) the limited frequency resolution of the aided response.

First, several investigations have found that the estimates of aided speech audibility (sensation level of the LTASS in this study) are higher with functional gain or aided soundfield measures compared to electroacoustic approaches such as real ear probe measures (Stelmachowicz et al., 2002; Gengel et al.,1971 Seewald et al.1992). Even with a linear hearing aid such as the one used in this study, low level inputs (soft warble tones) fail to account for the output–limiting characteristics and the interaction that these characteristics can have with the gain of the hearing aid in response to suprathreshold inputs such as speech. If a Baha with non-linear processing had been used throughout the input range (wide dynamic range compression; WDRC), the estimates for SL with AS approach undoubtedly would have been even higher, as WDRC provides more gain for soft sounds relative to linear processing (Stelmachowicz et al., 2002). Furthermore, when the SL estimates were inferred from the different input speech spectra, the effects on the processor were not actually measured. Given the known input/output function of this particular test Baha, for the 75 dB SPL input, some components of speech could reach the output compression threshold for some individuals (depending on MPO and volume control settings); however, with the current AS approach, the different speech inputs from 55 to 75 dB SPL always resulted in a linear increase in SL estimates precisely because the estimates were derived from speech that was never processed by the Baha. Additionally, this onetime low-level input measurement did little to inform the clinician about MPO of the Baha.

Second, the low frequency noise floor of the Baha can also limit the usefulness of the aided soundfield approach. Essentially, the noise floor masks the aided thresholds, especially at 250 and 500 Hz, making the aided thresholds at those frequencies look worse than the unaided thresholds (Macrae & Frasier, 1980). The implications of this are not immediately obvious in the present study, because the aided thresholds were not explicitly compared to the unaided bone conduction thresholds. Instead, they were simply converted to SPL for comparison with the SPL of the unaided LTASS. However, to illustrate the point, the data are presented here. The average unaided HL thresholds at 250 and 500 Hz were 8 and 16 dB HL, while the average aided thresholds at those frequencies were 36 and 32 dB HL, respectively. While estimating exactly how much better the aided thresholds should be compared to the unaided thresholds is highly problematic (see study 1 in this series), it would seem logical that, if the noise floor was not present, they should be better than the levels found in this study. Consider the sensation level estimates in Figure 3-14 to 3-16. At 250 Hz and 500 Hz, the AS approach provided significantly higher estimates of SL than the AL approach for all input levels. If the aided thresholds at the low frequencies were not limited by the noise floor problem, then estimates of SL with this approach would have been even higher. In other words, the noise floor actually protected the aided soundfield approach at these frequencies from providing even higher estimates of SL than were found in this study.

Finally, the only frequencies tested in the present study for the aided soundfield thresholds were 250, 500, 1000, 2000, and 4000 Hz. The actual frequency response of a given Baha may show sharp peaks or dips due to resonant characteristics and/or impedance differences from subject to subject. A given frequency response on a coupler may take a different shape when connected to a patient. In this study, the same device was used for all subjects. However, given the unique bone conduction systems of the individuals studied, this one device showed vastly different frequency responses depending on the person to whom it was connected. Even the average data in Figures 3-26 and 3-27 show a fairly obvious dip in the frequency response around 750 to 800 Hz for both the AL and SPL approaches that would not have been detected using the crude frequency resolution of the aided soundfield approach.

3.4.1.2 Advantages of the Real Ear and Accelerometer Approaches Relative to Aided Soundfield

There were a number of generic advantages to both the real ear and accelerometer approaches over the aided soundfield approach in this study. First, and perhaps most importantly, both approaches actually measured the output responses to real-life speech at multiple input levels *after* the processing of the Baha. Whatever unique interactions occurred between the input to the Baha and the gain (e.g., low output compression threshold), the output of the Baha, measured in-situ, captured them. Second, both approaches facilitated direct comparisons of aided output to the dynamic range of hearing at some common reference point measured directly through the Baha abutment. The aided soundfield approach did not have a valid reference for dynamic range comparisons. Third, both approaches permitted amplitude by frequency measurements in 65 bands ($1/12^{th}$ octaves), a significant improvement in resolution compared to the 5 (1-octave) bands considered with the AS approach. Finally, unlike the AS approach, both in-situ approaches were highly repeatable and sensitive to small adjustments in frequency response.

3.4.1.3 Advantages of the Real Ear over the Accelerometer Approach

The real ear approach also had some unique advantages compared to the accelerometer approach. The approach required no special equipment or calibration and used technology and protocols that are familiar to most clinicians routinely fitting air conduction hearing aids. It is conceivable that a clinician could connect a Baha Cordelle transducer to an audiometer for dynamic range assessment by direct bone conduction[8]. Once the HL to SPL transform was known (see methods section) and dynamic range of hearing determined, the patient's actual Baha could be connected and the ear canal SPL measured in-situ. With the accelerometer approach, special BEST transducers with mounted accelerometers (one for audiometric assessment and one for a test Baha) were needed both for the dynamic range assessment and the aided responses. The same features of the Verifit (or whatever real ear analyzer the clinician uses) could be used to measure the responses. However, the accelerometer signals would need to be conditioned and calibrated so that a known electrical signal from the accelerometer corresponded to a given SPL reading on the analyzer.

3.4.1.4 Advantages of the Accelerometer over the Real Ear Approach

Of course, there are some practical limitations to using the real ear approach too. For example, many Baha patients either do not have ear canals (atresias) or have chronic drainage or wax problems, which can plug probe microphones. Even if the probe microphone can be inserted in the ear canal, the placement in relation to the reflection of sound off the tympanic membrane can have a measurable effect in the high frequencies (Caldwell, Souza & Tremblay, 2006). Also, the noise floor of most clinical probe microphone equipment, in the high frequencies, makes it difficult to measure SPLs below about 40 dB (Scollie & Seewald, 2002). In Figure 3-26 it can be seen that the noise floor of the probe microphone in this study interfered with the aided speech outputs of the Baha at 2000 and 4000 Hz for the 55 dB SPL speech input and at 4000 Hz for the 65 dB SPL speech input. It may be possible to use a more sensitive microphone with signal averaging to minimize the noise floor problem; however, this requirement would necessarily eliminate many of the "currently available" advantages associated with the real ear approach.

3.4.1.5 Discrepancies at 250 Hz

For the real ear approach, a foam earplug was required to measure the tiny amplitude signals generated in the ear canal. This, no doubt had the potential to create an occlusion effect at low frequencies for some individuals (Stenfelt & Goode, 2005; Reinfeldt et al., 2006). In theory, since all measures (thresholds, UCL and aided responses) were obtained with the earplug in place, the relationship between threshold and aided speech (the sensation level estimates) should have been insensitive to the occlusion effect. An increase in ear canal SPL for

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[8] The Cordelle transducer is a variable reluctance transducer and has inherently non-linear characteristics, especially at low frequencies and high levels, making the accurate assessment of dynamic range at low frequencies unlikely with this type of transducer (Stenfelt & Håkansson, 2002).

pure tones at low frequencies should have been comparable to the increase in ear canal SPL for speech sounds at low frequencies assuming freedom from noise floor effects and non-linearities in the ear canal. This should have held true even though many of the patients had ear canals and middle ears that were "non-normal." Figure 3-26 and 3-27 show that the dynamic range estimates for the AL and SPL approaches looked identical. However, the low frequency response of the aided speech for the SPL approach was significantly higher than aided speech response for the accelerometer approach. So, why the discrepancy for aided speech output between approaches at low frequencies?

Since we know that the bone conduction transducers have a poor low frequency response (greater force is required to move the skull at low frequencies), it seems unlikely that the extra SPL in the ear canal is coming from the bone conduction route. This is confirmed by the equivalent ideal dynamic range estimates. Thresholds and LDLs were tested directly from the audiometer by bone conduction. For the aided responses, the speech was delivered from a speaker in the soundfield. In the case of the accelerometer, the soundfield SPL would have no influence. However, in spite of the foam plug, the low frequencies of speech appear to have entered the ear canal and been included in the probe microphone measures. One can see that there was some attenuation by the foam plug; the 90 dB pure tone sweep input used to measure MPO resulted in only 80 dB in the ear canal. However, the results for 250 Hz and perhaps even 500 Hz for the SPL approach have to be considered invalid as a reference for aided Baha responses as the majority of measured output does not appear to come from bone conduction.

3.4.1.6 Accelerometer or Real Ear Approach

Unlike the SPL approach, the AL approach is always above the noise floor of the measuring system and is not affected by the soundfield SPL for the aided measures. For the fitting of hearing aids, sacrificing accuracy at 250 Hz as a consequence of SPL entering the ear canal through the foam plug may not be altogether problematic. However, the SPL approach also sacrifices accuracy at 2000 and 4000 Hz, especially for softer inputs, because of the noise floor problem. With real ear measurement of air conduction hearing aids, the noise floor problem is easily avoided by using a 2-cc coupler and a onetime real-ear to coupler difference (RECD) transform. A similar approach for Baha is not currently available.

3.4.2 **Ideal vs. Functional Dynamic Range of Hearing**

The secondary analysis of interest from this study related to the ideal vs. functional dynamic range data. If one ignores the data from the SPL approach, the AL data indicate 2 things of interest: (1) the ideal dynamic range of hearing by direct bone conduction is narrower than would perhaps be expected given the relatively normal bone conduction thresholds of the patients in this study, and (2) in spite of this narrow dynamic range of hearing, the average MPO of the Divino used in this study was still considerably lower than the LDLs of the patients.

There is some evidence that bone conduction dynamic range may be smaller than expected by air conduction. Stenfelt and Håkansson (2002) found that the loudness growth for air conduction (AC) and bone conduction (BC) stimulation was not equivalent. At 250 Hz every

10 dB increase in air conduction loudness was equal to only an 8 dB increase in bone conduction loudness. The slopes of the loudness function increased for higher frequencies to a maximum of 9.3 dB of BC for every 10 dB of AC increase at 2000 Hz. Certainly at low frequencies and high intensities, people may respond to vibrotactile stimulation rather than the loudness of the signal, but the loudness growth was shallower by bone conduction even with lower intensity signals (those that did not cause vibrotactile stimulation). Also, as with all investigations into loudness, the responses were highly individual.

In this study, subjects used their Bahas at user chosen settings. It appears that the MPO of the Baha does not exceed the patient LDLs at any frequency. Since most Bahas operate linearly up to the MPO[9] with a relatively fixed frequency response, users likely set the volume control to the point where they perceive the device to provide the optimum balance of loudness and sound quality in most situations (Cox, 1991). However, is this approach to fitting the Baha optimal? Is it possible that greater flexibility in frequency response shaping, more sophisticated signal processing (i.e., WDRC) and greater maximum output could lead to improved performance over the technology and fitting practices used with today's Bahas? The importance of these questions surely increases for patients with increasing bone conduction hearing loss and they form the basis for the next study in this series.

3.5 Conclusions

Despite the many limitations to aided soundfield thresholds as a verification tool, many authors still consider their use appropriate for verification of Baha and cochlear implants (Stelmachowicz et al., 2002; Hawkins, 2004). It is the opinion of the investigators that the reasons for this continued endorsement simply reflects the fact that a more accurate and viable alternative to this approach for Baha has not been proposed.

In this study, the investigator demonstrated 2 possible alternatives to aided soundfield thresholds. Both alternatives used protocols familiar to most audiologists fitting air conduction hearing aids, in-situ dynamic range and aided response assessment. It was discovered that the accelerometer approach provided the most accurate characterization of in-situ Baha performance. Indeed, the accelerometer approach can be used to address our two fundamental verification questions outlined in Chapter 1 of this dissertation: (1) what is the level of amplified speech, relative to a listener's threshold of hearing, with both measures obtained at some common reference point on the patient?, and (2) what is the maximum hearing aid output relative to the levels a listener judges as being uncomfortably loud with both measures obtained at some common reference point on the patient (Seewald, 1995)?

For the accelerometer approach to be adopted clinically, BEST transducers with mounted accelerometers would be required (one transducer for threshold testing and one for a master Baha). The accelerometers would also need to be calibrated for whatever hearing aid analyzer the audiologist used. Also, a skull simulator would be needed to measure the response of a given patient's Baha in comparison to the response determined to be appropriate with the master Baha. It is conceivable that a kit or module could be produced that would provide

[9] The Cordelle can be set to operate like a WDRC hearing aid (K-amp).

clinicians with this special equipment and instructions for calibrating it for each hearing aid analyzer on the market.

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Chapter 4: Technology-Limited and Patient-Derived Versus Audibility-Derived Fittings in Baha Users: A Validation Study

4 Chapter 4

4.1 Introduction

The goals of any hearing aid fitting should be to: (1) provide audibility and comfort for important environmental sounds, especially speech and (2) ensure that loud sounds are not uncomfortable (Sinclair, Cole & Pumford, 2001; Palmer, Lindley, & Mormer, 2000). These goals do not change depending on the type of technology chosen. They are just as important when fitting a Baha, as they are when fitting an air conduction hearing aid.

4.1.1 Fitting Baha

Current approaches to fitting Baha rely heavily on patient feedback of "loudness" and "sound quality." This approach, referred to as patient-derived (PD), assumes that the individual will choose settings that will maximize speech intelligibility while ensuring that sounds are of good quality and not uncomfortable. Baha audiologists are limited to this approach for two reasons: (1) the technology in current models of Baha does not allow for much fine-tuning of frequency response or maximum output on an individual basis and (2) there has not been a valid approach to verifying the frequency response or maximum output of Baha on an individual basis. Is it possible that, if audiologists had more advanced and programmable signal processing technology from which to choose, and if they had better methods of verifying aided audibility of speech, they would fit the Baha using a more systematic approach that would be audibility-, rather than patient-derived, and if so, would an audibility-derived approach lead to better outcomes?

Audiological consensus documents assert that hearing aid fitting should be done in a systematic way (AAA, 2003; ASHA, 1998; Pediatric Working Group, 1996). The recommended approach typically follows a series of stages from assessment to validation (see Figure 4-1 for one such approach; Seewald, 1995). Accurate information obtained during the *assessment* phase is used to guide the *selection or prescription* of appropriate output characteristics for a given individual with a given device. Next, the hearing aid output is determined to *verify* the appropriateness of the aided output to the electroacoustic parameters determined in the *selection* phase. Finally, if the hearing aid output has been *verified* to be acceptable, the individual's performance with the device is *validated* through outcome measurements (Seewald, 1995).

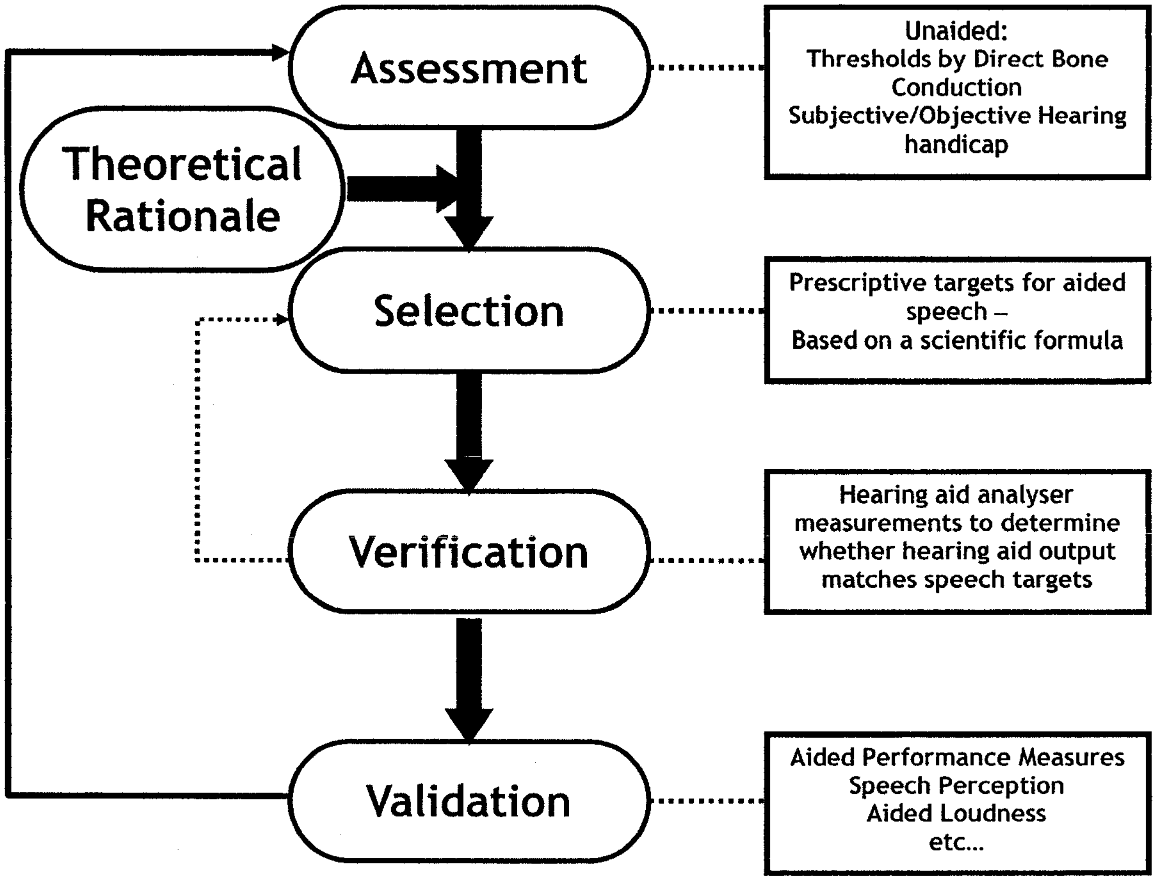

Figure 4-1. Model of the hearing aid fitting process. Adapted from Seewald (1995).

At the core of all these stages, lies the "theoretical rationale" or prescription through which the audiologist attempts to match, as closely as possible, the electroacoustic characteristics of a given device to the unique auditory needs of a patient in an effort to optimize detection, loudness and intelligibility of speech (Scollie, 2005).

Study 1 in this series of studies informed the *assessment* phase of Baha fitting by demonstrating that no two heads are alike and suggesting that thresholds should be measured directly through the Baha abutment. Study 2 in this series of studies informed the *verification* phase of Baha fitting by developing an in-situ method of verifying speech output that defined all hearing assessment parameters (auditory dynamic range) and hearing aid parameters (aided output, MPO) in the same units at the same reference point: acceleration levels at the Baha abutment. This new in-situ approach was essentially a "real ear" verification approach for Baha using acceleration instead of sound pressure level. In this final study of the series, the author aims to inform both the *selection* and the *validation* phases of Baha fitting by comparing the outcomes of a modified prescriptive procedure, one that utilizes an audibility-derived (AD) prescriptive approach, to the current patient-derived (PD) approach.

4.1.2 An Audibility-Derived Prescriptive Procedure for Baha

Historically, there have been several prescriptive procedures for fitting hearing aids (see Traynor, 2005 for a thorough review). Not all procedures lead to the same electroacoustic prescription and not all prescriptions lead to the same outcomes (Seewald et al., 2005). However, like all ideas submitted to the intellectual marketplace, those prescriptive procedures that have scientific validity and clinical support continue to be used and refined, while those that do not, tend to fall out of favor.

One well-validated and clinically-utilized procedure for prescribing electroacoustic parameters for air conduction hearing aids is the Desired Sensation Level (DSL) method (Scollie, Seewald, Cornelisse, Moodie, Bagatto, Laurnagaray et al., 2005). The DSL method has been continuously adapted to accommodate the changes in modern technology. Originally the mathematical formula for prescribing real-ear output targets was intended only for linear hearing aids. Today, most modern hearing aids incorporate some form of automatic gain control or non-linear compression such as wide dynamic range compression (WDRC). The newest version of DSL (DSL m[i/o], version 5) prescribes output targets for aided speech at multiple input levels, for hearing aids with multiple channels, expansion and multi-memory capabilities (Scollie et al., 2005).

The DSL algorithm is a series of mathematical equations that describe the relationship between the input level of a signal delivered to a hearing aid and the output level produced by the hearing aid (Cornelisse, Seewald & Jamieson, 1995). Essentially, the goal of the DSL procedure is to map (compress) the input spectrum that a hearing aid user is likely to experience into his or her residual dynamic range of hearing in order to ensure that speech is audible and not uncomfortable across as broad a frequency range as possible. The formula is frequency dependent and, therefore, provides different targets for different frequencies, depending on the size of the dynamic range in a given frequency region.

Though the DSL algorithm was developed for, and has only been tested on, air conduction hearing aids, it may be possible to use a modified version of the formulae to prescribe output targets for alternative devices such as the Baha. In study 2, the investigators described an approach to assessing dynamic range directly through the Baha abutment in terms of acceleration level (dB). So long as a reliable dynamic range is entered into the DSL algorithm, it can be programmed to map the input range of signals (e.g., soft, average and loud speech) into that dynamic range. It is now possible to verify the aided Baha response in acceleration level, facilitating direct comparison between the actual aided output and the targets for that output. This option raises several interesting questions. How do the frequency/output responses of current Bahas compare to the prescribed targets on a group of listeners? If they are dissimilar, what types of changes to the responses of the current Baha would be required to meet the targets? If changes to the Baha response could be made to meet the targets, would that lead to improved performance?

4.1.3 Technology limitations of Current Bahas

Sensation level estimates from the previous study indicated two things: (1) the high frequency (4000 Hz) aided LTASS for soft speech was, on average, below threshold and (2) the maximum power output capabilities were significantly limited (i.e., due to limitations in the Baha MPO, it cannot utilize the full dynamic range of the listener). Recall, also, that the pure tone average bone conduction thresholds in this study were only 23 dB HL. It is probable that, as the degree of bone conduction (sensorineural) hearing loss increases for a Baha user, the need for greater flexibility in processing strategies (e.g., multi-channel compression) and frequency response shaping may be required in order to ensure audibility across all frequencies.

Three models of Baha are currently available: the Divino, Intenso, and Cordelle. A fourth model (the Baha Classic) which is no longer marketed by the Baha manufacturer was used by some of our subjects in this study (though not in the actual testing). The Classic, Divino and Intenso are all linear hearing aids. The Classic uses peak clipping to limit output, while the Divino and Intenso both use output compression. The Cordelle (body aid) can be programmed to behave as a linear or a WDRC hearing aid. For the Cordelle, regardless of whether it is used as a linear or WDRC aid, output compression is used to limit loud sounds. All of these Bahas are equipped with a potentiometer that can be used to decrease the low frequencies from the factory default settings. Unfortunately, none of the Bahas have a potentiometer for increasing the high frequency output. The Divino also has a potentiometer for controlling the amount of output compression that is applied (it can be set to lower the MPO from the factory default settings). None of our subjects used the Intenso in this study, however there are only minor differences between the Intenso and the Cordelle when both are set to their maximum settings. Other than the resonant peak and potential microphone location effects, the Intenso functions very much like a Cordelle set to linear mode. The skull simulator responses for both the MPO and soft aided speech LTASS (55 dB SPL input) for the Intenso and Cordelle set to their default factory settings and full-on volume are shown in Figure 4-2.

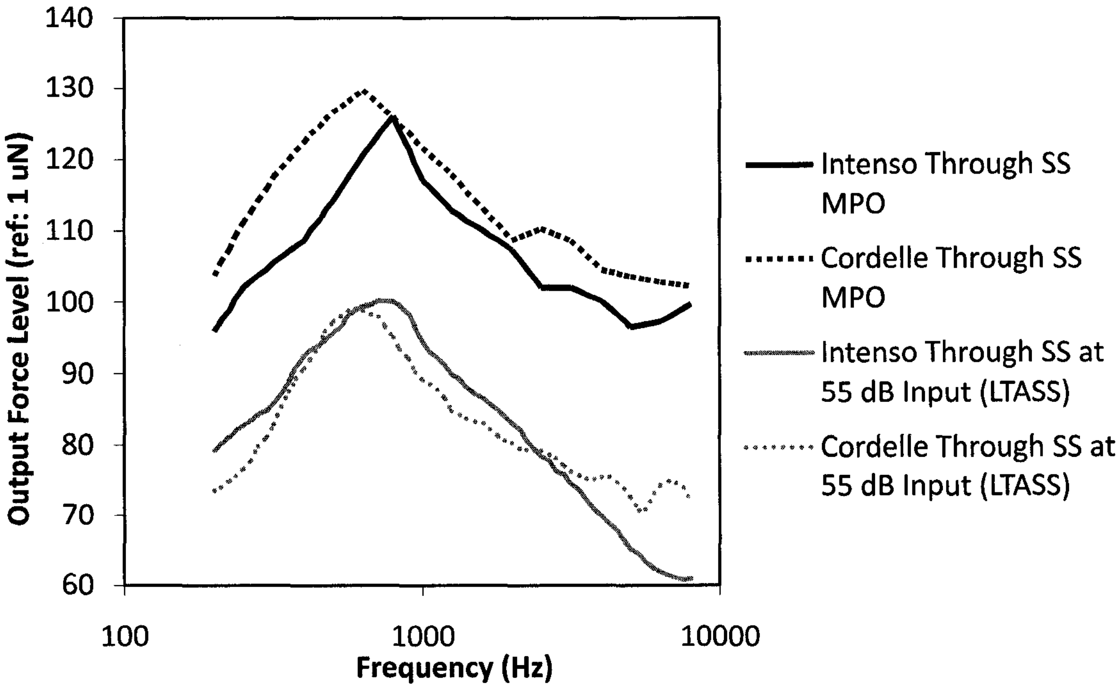

Figure 4-2. Skull simulator responses for both the MPO and soft aided speech LTASS (55 dB SPL input) for the Intenso and Cordelle set to their default factory settings and full-on volume.

4.1.4 Advanced Signal Processing for Baha

From an audiological perspective, all Bahas are extremely limited in terms of programmability, especially for high frequency sounds. Audiologists are accustomed to having more diverse signal processing technologies at their disposal. They are also accustomed to having the flexibility to shape the frequency responses of the hearing aid to maximize audibility on an individual basis. While there may not be absolute agreement about the value of all high frequency information (Hogan & Turner, 1998; Ching, Dillon & Katsch, 2002), so long as there are no expected cochlear dead regions, amplification of the high frequencies, so as to restore audibility, usually leads to improved intelligibility (Moore, 2002). There is also a growing body of evidence to suggest that compression, in combination with audibility-derived frequency responses is beneficial for both adults (Laurence, Moore & Glasberg, 1983; Moore, Johnson, Clarke & Pluvinage, 1992; Hickson, 1994, Dillon, 1996; Moore, 1998; Scollie et al., 2005) and children (Stelmachowicz, Kopun, Mace, Lewis & Nittrouer, 1995; Jenstad, Seewald, Cornelisse & Shantz, 1999; Stelmachowicz, 2002; Scollie et al., 2005).

4.1.5 The Current Study

This study was designed to test the efficacy of two different Baha fitting approaches: (1) patient-derived (PD) fittings based on current Baha technology and (2) audibility-derived (AD) fittings based on more advanced signal processing and prescriptive targets for speech audibility. A computer-controlled master Baha was used to derive both fittings. For the PD fitting, the user's current Baha settings were matched with the master Baha. Additionally, the master Baha settings were limited to those available with the current models of Baha (i.e., linear with output compression). For the AD fitting, a modified DSL m[i/o] fitting strategy was used (Scollie et al, 2005) to map all hearing aid output levels (in acceleration) into each user's dynamic range (in acceleration). For the AD fitting, the following parameters were controlled on the Master Baha: frequency shaping (3 bands), compression (3 channels), overall gain and MPO.

The following research questions were of interest: When the Baha is adjusted to an AD protocol versus a PD protocol,

a. are there significant differences in estimates of aided sensation level?
b. are there significant differences in sentence recognition in quiet and in noise?
c. are there significant differences in consonant recognition in noise?
d. is there a significant difference in aided loudness for speech?
e. is there a significant difference in subjective percentage of word understood?

4.2 Methods

4.2.1 Subjects

Sixteen subjects (8 males, 8 females) with a mean age of 61.0 years (36.5 years to 81.0 years) were recruited from the Bone Conduction Amplification program at COMPRU. The following inclusion criteria were used. All subjects: 1) were Baha users for at least 3 months, 2) had snap coupling abutments, and 3) had mixed high frequency hearing loss with pure tone average bone conduction hearing thresholds greater than 20 dB HL at 500, 1000, 2000 and 4000 Hz. The bone conduction pure tone average (PTA) for all sixteen subjects was 39.1 dB (SD = 10.6) (Figure 4-3). Three of the sixteen subjects had one ear that was better than the other by air conduction. For these subjects, the better hearing ear was occluded with a foam earplug with a noise reduction rating of 29 dB for all the testing.

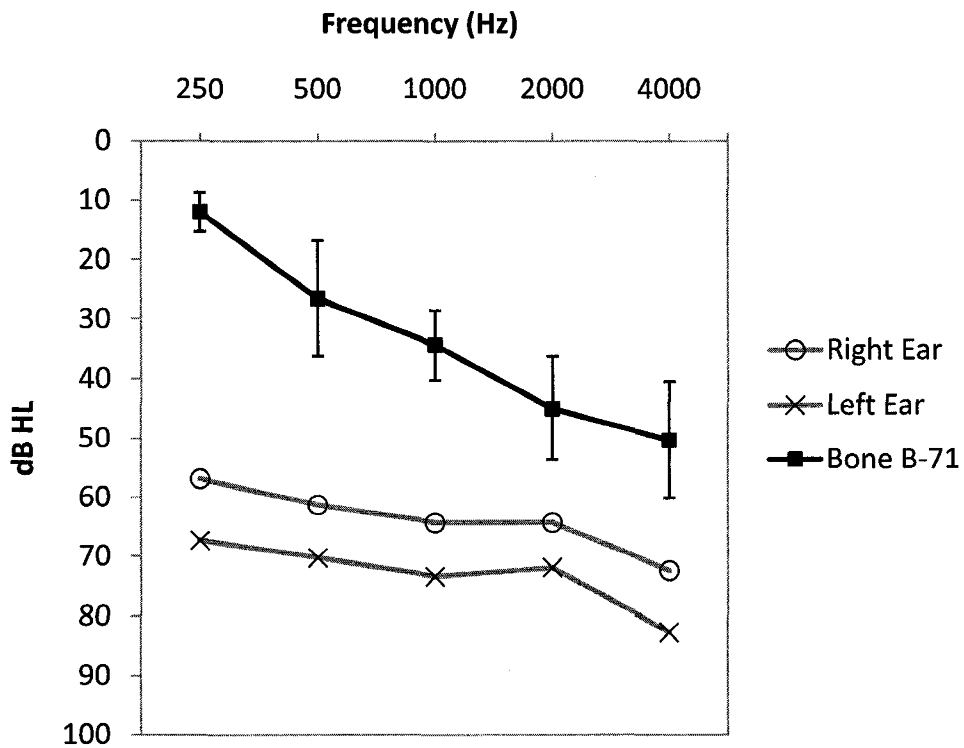

Figure 4-3. Average pure tone air and bone conduction hearing thresholds for 16 subjects expressed in dB HL with 95% CIs displayed for bone conduction thresholds.

4.2.2 Instrumentation

4.2.2.1 *Overview of the Instrumentation*

Several components were required for the completion of this study. Before introducing the components, Figure 4-4 shows how these components were connected to each other to obtain the measures.

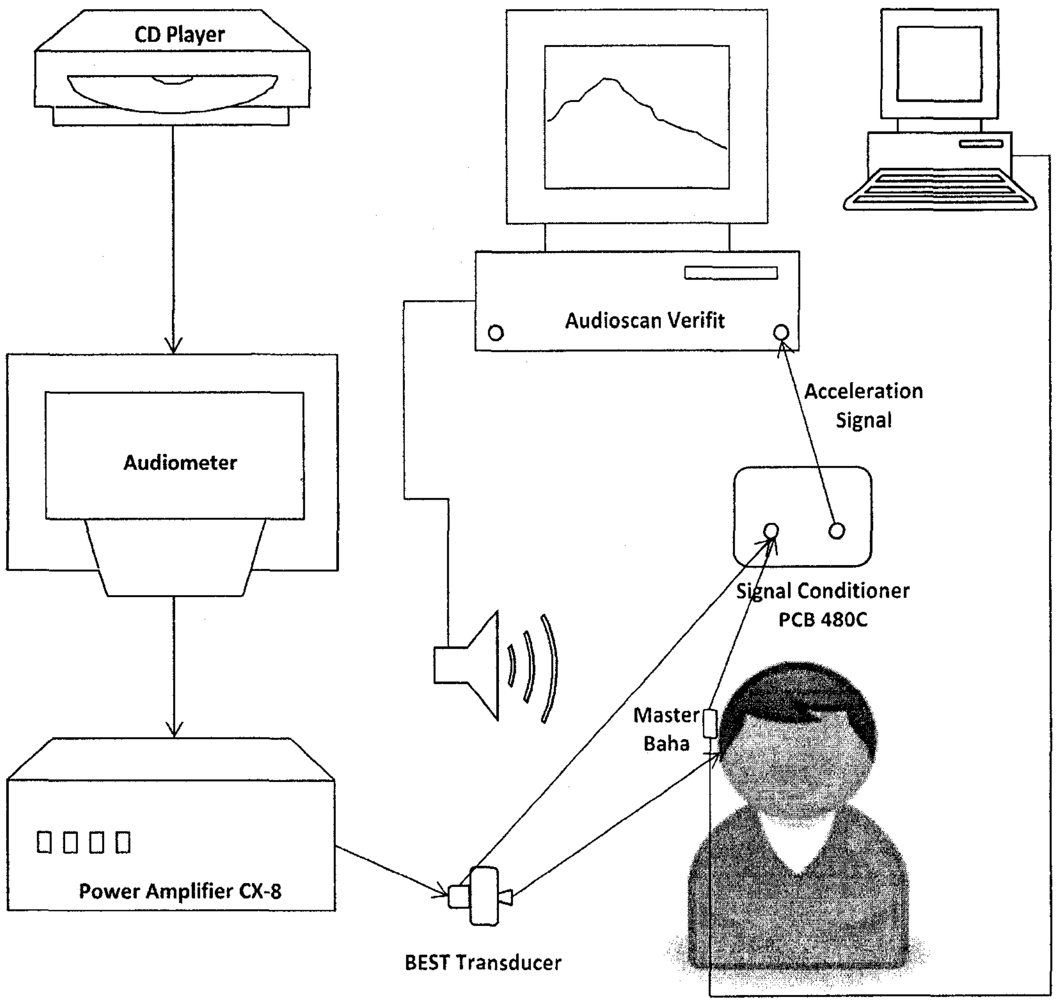

Figure 4-4. Overview of the experimental set-up.

4.2.2.2 *Master Baha*

Testing for both the patient-derived (PD) and the audibility-derived (AD) fittings was accomplished through the use of a computer-controlled DSP board that functioned as a master Baha hearing aid. This DSP board was originally designed by Texas Instruments (Dallas, Texas, USA) under the name DHP100[10]. A newer version of the device is now sold by Spectrum Digital (Stafford, Texas, USA) under the name Portable Evaluation Platform (PEP5416). The DHP100 platform used in this study was based on the TMS320C5402 16-bit fixed-point DSP chip from Texas Instruments.

The DHP100 has 2 input channels and 1 output channel. For the input channel, a Knowles Electronics (Itasca, Illinois, USA) FG Series omni-directional microphone was used. For the output channel, a Balanced Electromagnetic Separation Transducer (BEST; Håkansson, 2003) with a Baha snap coupling was designed specifically for this study. Figure 4-5 shows both the input FG microphone and the output BEST transducer connected to a patient. The BEST transducer has a mass and resonant frequency very similar to the transducers used in the Classic, Compact and Divino. The main advantage of using the BEST transducer for this study is that it is rigid through its entire vibrating central core. By placing an accelerometer on the backside of the transducer, the accelerations delivered to the patient on the front side of the transducer can be measured. On the DHP100, the input and output channel potentiometers were carefully calibrated to ensure that the highest input levels (e.g., 90 dB pure tone sweeps) did not result in DSP clipping on the input side and that the BEST output transducer did not result in levels that were either too intense for the subjects (based on previous work in this series of projects) and/or too intense for the transducer (based on technological limitations of the transducer provided by Håkansson, 2003).

The DHP100 was connected to the parallel port of a laptop computer via a Spectrum Digital JTAG emulator. Texas Instruments' Code Composer Studio software was required to interact with the DSP chip. Additionally, proprietary hearing aid programming software (Freed & Soli, 2006) was used to set the parameters of the DSP chip. The following parameters were used in this study: 1) frequency shaping in 3 bands (<1 KHz, 1 to 3 KHz, > 3 KHz), 2) compression ranging from 1:1 to 8:1 in the same 3 channels, 3) overall gain control (a digital volume control), 4) maximum output control.

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[10] Many Thanks To Dan Freed and Dr. Sigfrid Soli for their assistance with the set-up and use of the DHP100 Master Baha.

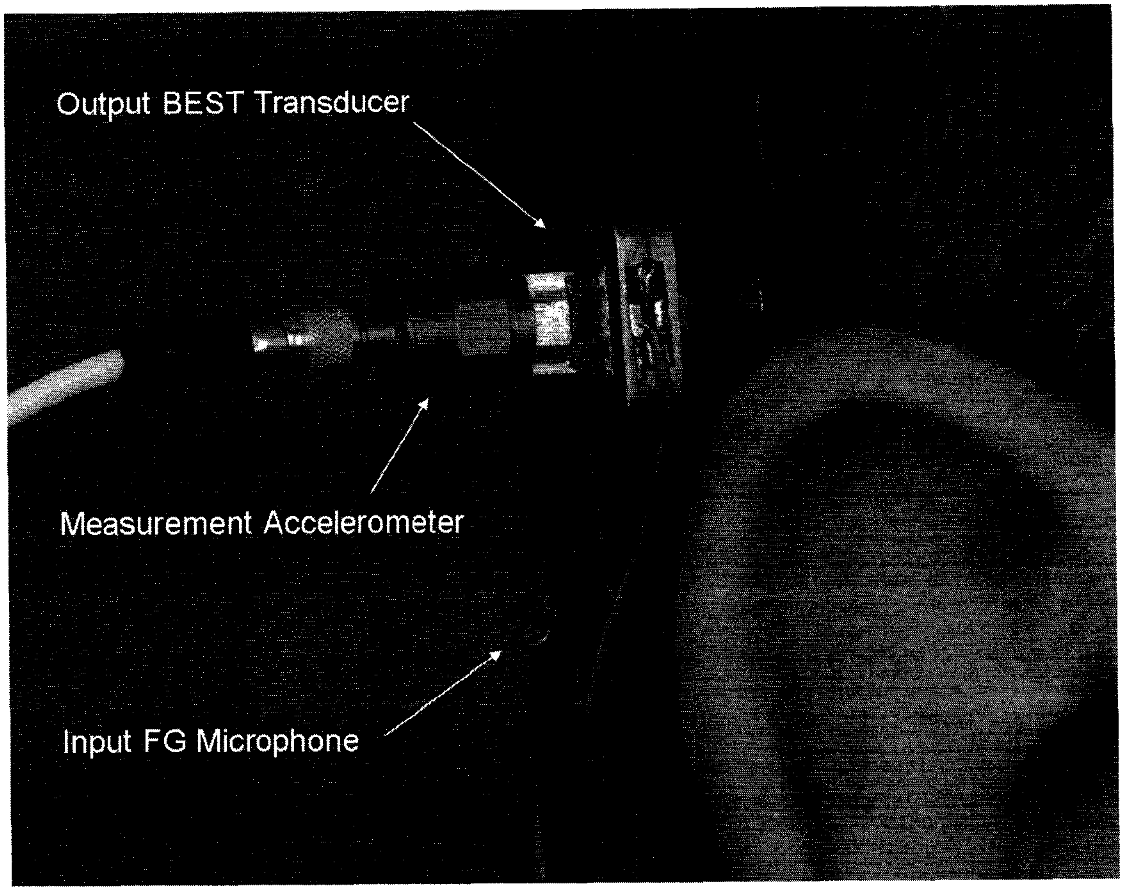

Figure 4-5. Input to and output from the DHP100 Master Baha platform connected to a subject. Also shown is the measurement accelerometer connected to the back of the BEST transducer.

4.2.2.3 Accelerometers and Signal Conditioning

The Baha functions by vibration, so an alternative to sound pressure level is required for signal analysis. Accelerometers produce voltages at their output terminals proportional to the acceleration to which they are subjected. Two PCB piezoelectric accelerometers (PCB Piezotronics, Depew, New York, USA; Models 352B10 and 352C66) were chosen for this study. For the audiometric data (threshold and dynamic range assessment), model 352B10 with a sensitivity of 10 mV/g was connected to the back of a BEST transducer and was used exclusively for audiometric testing. Model 352C66, with a sensitivity of 100 mV/g was connected to the back of the BEST transducer that was used with the master Baha. The voltages at the output terminals of the accelerometers were quite small. Therefore, the signals for both accelerometer models were fed through a preamplifier (signal conditioner), before they reached the signal analyzer. A PCB model 480C signal conditioner was used to condition the low level acceleration signals. For the model 352B10 accelerometer (10 mV/g), the signal conditioner was set to 10 times gain. For the model 352C66 accelerometer (100 mV/g), the gain on the signal conditioner was set to unity. Since there was a 10 times difference in accelerometer sensitivity (20 dB difference), the measured accelerations after signal conditioning from the audiometric and master Baha were directly comparable.

4.2.2.4 Signal Analysis

For all acceleration measures, analysis of the conditioned output voltage was performed by an Audioscan Verifit VF-1 Real-Ear Hearing Aid Analyzer (subsequently referred to as the Verifit; Dorchester, Ontario, 2005). The Verifit is a real-time, dual-channel audio measurement system (FFT spectrum analyzer) that is typically used for the real ear assessment of hearing abilities and the real-ear verification of air conduction hearing aid output. It is calibrated to display a specific sound pressure level (SPL) value for a given electrical signal level. In the case of an air conduction hearing aid or a real-ear measurement, the displayed SPL will be the SPL associated with the voltage at the measurement microphone input which may be either a coupler or a real-ear microphone.

For this study, the Verifit was calibrated for two different purposes. First, it was calibrated to measure the signal from the accelerometer (acceleration response) at the entrance to the real-ear microphone. It was also calibrated to accept the signal from the TU-1000 Baha skull simulator (force response) at the entrance to the coupler microphone. For the acceleration response, a 200 mV 1000 Hz signal was equivalent to 120 dB SPL displayed on the Verifit screen. For the force response, the coupler microphone of the Verifit received an electrical signal from the accelerometer inside the TU-1000. However, because the skull simulator has a known load (50 g mass) with an impedance much greater than the output impedance of the transducers used to drive it, the electrical signal level from the accelerometer in the skull simulator is indicative of the force level, since Force = Load Mass * Acceleration (Håkansson & Carlsson, 1989). For the current test system, a 1000 Hz tone of 120 dB SPL was equal to .2 V/N. Figure 4-6 shows the BEST attached to the TU-1000 skull simulator and connected to the Verifit. The conversion factors are known for both the accelerometers and the skull simulator, so the SPLs measured by the Verifit were easily converted to either acceleration or force measures.

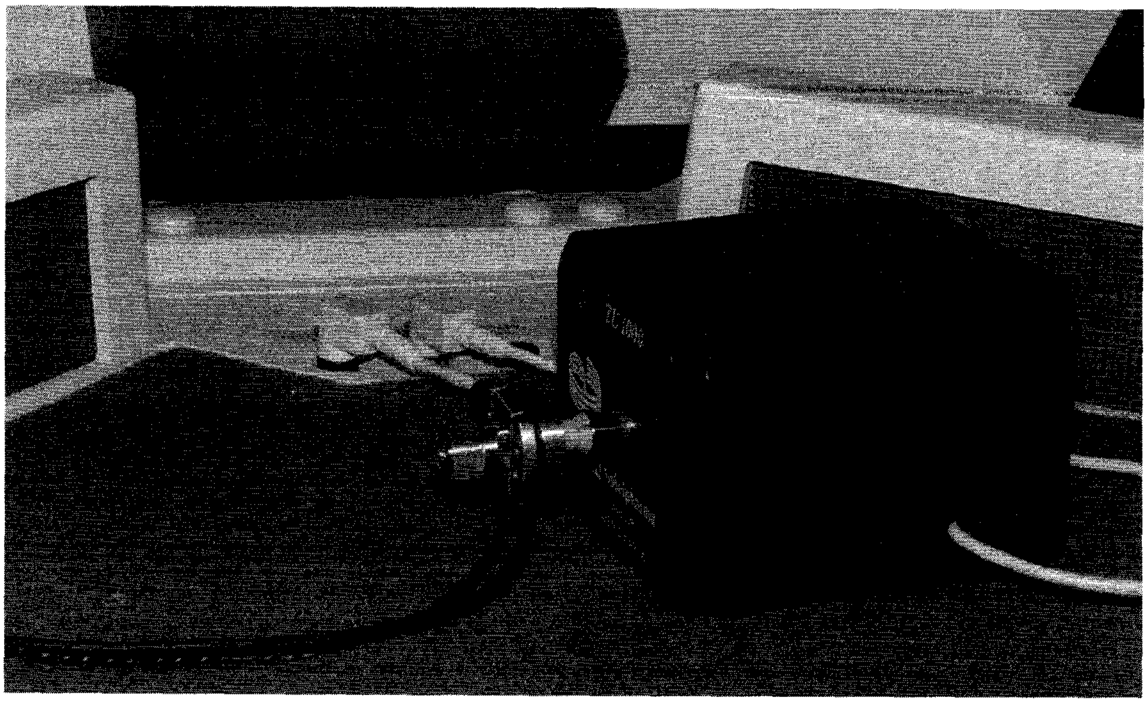

Figure 4-6. The BEST transducer connected to the TU-1000 skull simulator that is connected to the Verifit coupler microphone input. This set-up was used to match the Master Baha to each subject's Baha use setting (PD fitting).

The following Verifit functions were used in this study: 1) "Real Ear Manual Control" was used to determine the HL to acceleration transform for audiometric testing (see below for description), 2) "Coupler Multicurve" was used to match the master Baha to the user's current Baha settings (see below for description of PD fitting), and 3) "Real Ear SpeechMap" was used to measure the in-situ aided responses for both the PD and the AD fittings. Data from the Verifit were exported to a text file for each subject that was then converted to an Excel spreadsheet for subsequent data analysis.

4.2.2.5 In-Situ Audiometry Set-up

Previous work in this series of projects focused extensively on in-situ determination of dynamic range of hearing directly through the Baha abutment. Since the Baha will ultimately amplify and deliver speech through the Baha abutment, it is logical to determine threshold and loudness discomfort levels through the abutment to ensure that all variables related to each subject's hearing and hearing aid are relative to the same reference point.

Output signals from the right headphone channel of an Interacoustics AC-40 audiometer (Interacoustics; Assens, Denmark) were routed to one channel of a model CX-8 eight-channel power amplifier (QSC; Costa Mesa, USA). The audiometric version of the BEST transducer was connected to the output of the CX-8 and was subsequently connected to the BAHA subject. With this set-up, the audiometer dial was set to 60 dB HL to ensure a stable signal that consistently exceeded the noise floor of the measurement system. At 250, 500, 1000, 2000 and 4000 Hz, an

HL-to-acceleration-level (AL) transform (equivalent to a real-ear-to-dial difference measure) was determined for each subject by measuring the in-situ acceleration level at each frequency with the real ear manual control mode of the Verifit. Once this transform was known, testing of threshold and loudness discomfort level (LDL) could proceed using the audiometer and the BEST transducer

4.2.3 **Procedure**

4.2.3.1 In-Situ Audiometry

With the audiometric version of the BEST transducer connected to the patient's Baha abutment, thresholds in dB AL were established at 250, 500, 1000, 2000 and 4000 Hz using a modified Hughson-Westlake procedure. With a known acceleration transform for 60 dB HL dial setting on the audiometer, the actual acceleration value at threshold was easily obtained. For example, if the transform acceleration value for 1000 Hz at 60 dB HL on the audiometer dial for a given subject was 80 dB and the actual threshold value for that subject was 50 dB, the true in-situ acceleration for that subject would be 70 dB (80 dB – 10 dB). For the LDL test, the procedures outlined by Hawkins (1980) were used. Again the LDL values in dB HL dial settings were converted to in-situ acceleration values using the 60 dB HL transform. If the same subject's LDL at 1000 Hz was 110 dB HL on the audiometer dial, the actual acceleration LDL was 130 dB (80 dB + 50 dB). The in-situ threshold and LDL values in acceleration were subsequently used to derive aided speech targets for each subject using a modified DSL m[i/o] approach (Scollie et al., 2005).

4.2.3.2 Patient-Derived Fitting

As mentioned earlier, the PD fittings were the Baha patients' use settings with their current Baha devices. Subjects in this study used three models of Bahas (8 Divinos, 2 Cordelles and 6 Classics). Each PD fitting was derived from patient-driven perception of overall loudness (volume control or gain adjustment), perception of voice "echo" (low cut control) and perceived distortion in response to loud sounds (output compression; available on the Divino only). The audiologist had adjusted each user's Baha at time of delivery and again (if deemed necessary) at a 3 month follow-up visit. Some patients also chose to have their Baha adjusted several times during this 3 month period. For each adjustment, it was the patient's opinion of the sound that was used to guide the fitting. For example, if a patient complained of the perception of "talking in a barrel," the low cut was increased until the patient no longer perceived this to be a problem. This fitting approach was consistent with the manufacturer's recommendations. For example,

> *"Test which [low cut] setting the patient prefers by letting the patient listen to a couple of different settings. Make sure that the patient adjusts the volume control to their [most comfortable listening level] after every alteration." (Baha Audiological Manual, 2005).*

As the method of measuring the in-situ Baha response in this study required the use of the BEST transducer and an accelerometer, it was necessary to first simulate the subject's current Baha by matching the Master Baha to the subject's user settings. To do this, the subject's Baha with its typical use settings was placed on the skull simulator and routed through the hearing instrument test coupler microphone of the Verifit. A 60 dB pink noise stimulus was used to measure the frequency response of the current Baha in response to an average level input. Additionally, a 90 dB pure tone sweep was used to measure the current Baha's MPO. The software settings of the Master Baha then were adjusted to match both the 60 dB pink noise curve and the 90 dB MPO curve for each user's current Baha. Figure 4-7 shows the match of these 4 curves averaged across all 16 subjects. Whenever there was a failure to match the frequency response exactly, the higher output from the Master Baha was taken.

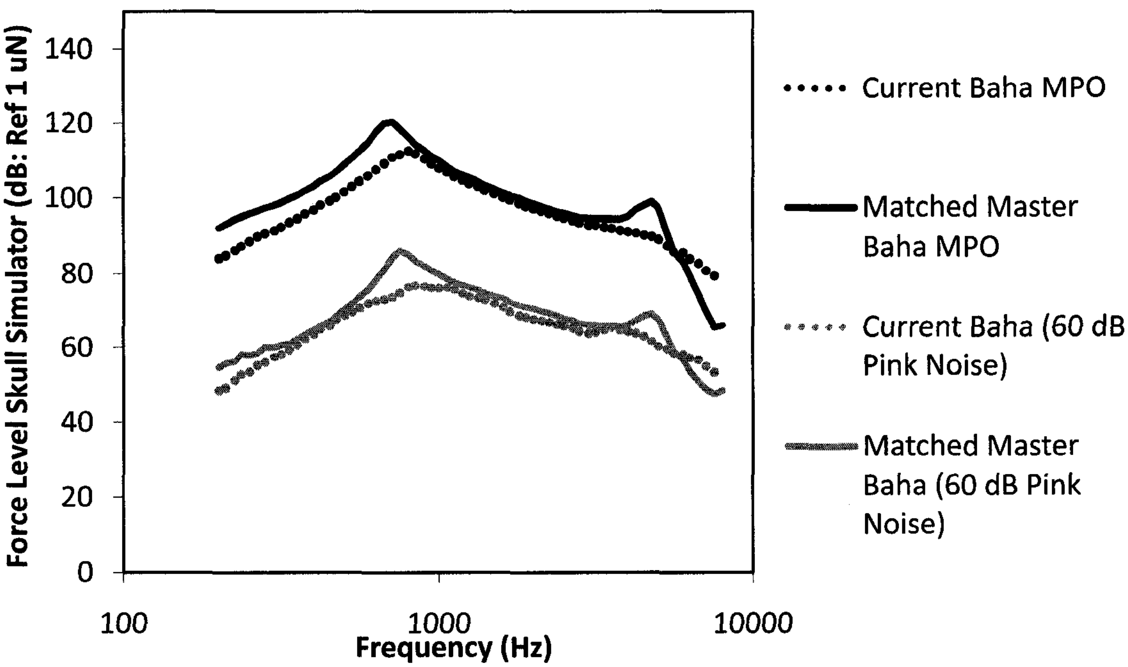

Figure 4-7. Average match of the Master Baha to the current Baha settings for 2 input levels.

4.2.3.3 Audibility-Derived Fittings

The AD fitting was a theoretical fitting approach based on a modified version of the Desired Sensation Level (DSL) method of hearing aid fitting. In its broadest terms, the DSL method seeks to ensure that amplified speech is audible across as broad a range of frequencies and as broad a range of input levels as possible (Seewald et al., 1996; Scollie et al., 2005). It does this by mapping the full range of input intensities into the hearing aid user's residual dynamic range of hearing. For this study, an Excel version of the DSL m[i/o] formula was used[11]. After

[11] The author wishes to acknowledge Dr. Susan Scollie for her assistance in setting up and testing the modified version of DSL m[i/o].

entering each subject's threshold and LDL information, the spreadsheet was used to generate targets (in acceleration level) for amplified speech. An average level input of 65 dB SPL was used to generate the targets. The spreadsheet was also used to calculate the target levels for the peaks and valleys of average speech and the compression ratio at each 1/3[rd] octave frequency. We used the subjects' LDLs in acceleration level for the MPO target. The relationship between the auditory characteristics of our Baha subjects (thresholds and LDL) and the targets (with peaks and valleys) for amplified speech are depicted in Figure 4-8.

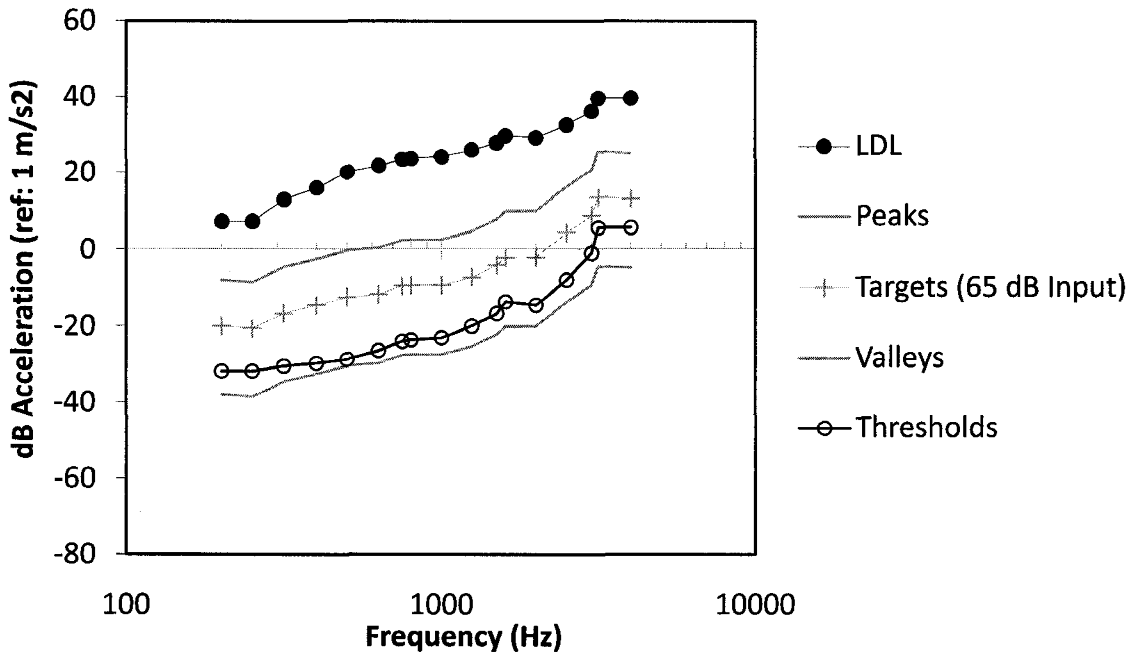

Figure 4-8. Average acceleration level hearing thresholds and LDLs for the 16 subjects used in this study. The modified DSL m[i/o] targets plus the peaks and valleys for an average level (65 dB SPL) speech input are also shown.

The in-situ acceleration responses of the master Baha, when connected to a subject, can be measured directly with the Verifit. However, thresholds, LDLs and speech targets in acceleration level cannot be displayed on the same screen, because currently there is no way to enter these data into the Verifit. To circumvent this problem, a screen capture of the Verifit monitor was used to generate an acetate copy that could be taped directly over the screen being used to display the in-situ Baha responses on the Verifit. This made it possible to use a marker to plot the threshold, LDL and speech level targets from the Excel spreadsheet onto the acetate and still easily see the real-time acceleration responses of the Baha on the monitor behind.

To match the targets, a reference microphone was connected to each subject's ear to ensure that the incoming real speech signal generated by the Verifit was 65 dB SPL[12]. Next, the master Baha was connected to each subject as in Figure 4-5 above.

Using the master Baha fitting software, the average compression ratio targets for each of the three channels under our control (< 1 KHz, 1 to 3 KHz, and > 3KHz) were entered. Table 4-1 shows the average compression ratios and standard deviations for each of these channels. With real speech being delivered to the patient, the frequency response shape was approximated by adjusting the gain for the same three frequency bands. The overall gain was then adjusted to match, as closely as possible, the DSL targets marked on the acetate. Finally, the maximum output level was adjusted to ensure that the Master Baha MPO approximated, but did not exceed, each subject's LDL. The time constants for attack and release were fixed at 15 ms (attack) and 130 ms (release). Figure 4-9 shows the differences in input/output response characteristics for the PD and AD fittings for one subject at 4000 Hz. The effects of the compression settings and MPO capabilities of the AD fitting can be seen.

Table 4-1. Average compression ratios and standard deviations for the 3 channels used on the master Baha in the AD fittings.

	< 1 KHz	*1 to 3 KHz*	*> 3 KHz*
Compression Ratio	1.98 : 1	2.19 : 1	2.22 : 1
Standard Deviation	0.57	0.65	0.65

[12] Typically the real ear reference microphone on the Verifit is calibrated with a probe microphone in place. The probe microphone has resonances associated with its shape and length that---once known---are automatically subtracted by the Verifit. Since the probe microphone was not used, it was necessary to calibrate the Verifit real-ear microphone to have a flat response so that tube resonances were not automatically subtracted from the obtained acceleration responses. A y-splitter was used so that a hearing aid coupler microphone (which has a flat spectrum) could be calibrated against the real ear reference microphone. Once the Verifit stored the flat calibration curve, the conditioned acceleration signal could be plugged into the y-splitter in place of the coupler microphone. Thus, the reference microphone monitored the input signal level and adjusted the speaker output accordingly, while the "probe" microphone measured the acceleration signal without subtracting the tube resonances.

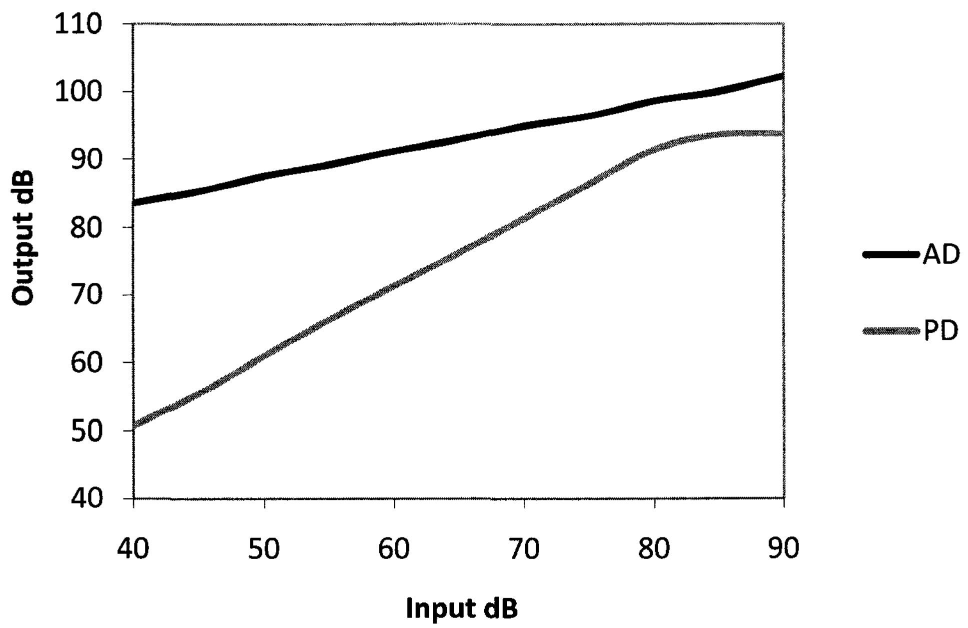

Figure 4-9. Example of Input/Output curves at 4000 Hz for both the PD and AD fitting approaches.

4.2.4 Outcome Measures

The following outcome measures were used to compare the PD and AD fitting approaches: (1) sensation level of aided speech, (2) sentence recognition in quiet and in noise, 3) consonant recognition in noise, (4) aided loudness, and (5) subjective percentage of words understood. Each will be described in detail below. The order in which the outcome measures were obtained was consistent across subjects and occurred in the order in which the tests are introduced below. However, within a given outcome measure, the order of the condition under test (PD or AD) was counterbalanced across all subjects.

4.2.4.1 Sensation Level of Aided Speech

To assess sensation level (SL) of the PD fitting, subjects were connected to the master Baha that had been matched to their current Baha. Real speech signals were delivered from the Verifit speaker (and monitored by the reference microphone) at 55 dB SPL, 65 dB SPL and 75 dB SPL. The output acceleration response of the master Baha for each input was analyzed over the 15-second passage from the Verifit (long term average speech spectrum; aided LTASS). Additionally, a 90 dB swept signal was used to measure the MPO of the Master Baha. To assess sensation level of the AD fitting, the only variable that changed was the master Baha settings. Acceleration responses from both PD and AD fittings were exported to Excel for subsequent graphing and analysis.

To derive sensation level estimates, we subtracted the thresholds from the average aided (LTASS) response levels at 250, 500, 1000, 2000, and 4000 Hz. These SL values were then compared at each frequency to determine if there were significant differences between the PD and AD approaches.

4.2.4.2 Sentence Recognition in Quiet and in Noise

Sentence recognition in quiet and sentence recognition in noise were assessed for both fittings using the Hearing in Noise Test (HINT). The HINT consists of lists of 20 sentences that have been equated for length and difficulty. The HINT is an adaptive tracking procedure that determines the level required for the subject to get 50% of the sentences correct. In the quiet condition, the 50%-correct level is presented as an absolute level in dB A. For the noise condition, a spectrally matched noise signal fixed to 65 dB A was presented in the soundfield to the non-Baha side. The speech level was adaptively adjusted until the subject achieved 50% correct. For the noise condition, the signal-to-noise ratio (level of signal – level of noise in dB) is reported.

4.2.4.3 Consonant Recognition in Noise

For the consonant recognition in noise testing, stimuli were twenty-one English consonants (b, ch, d, f, g, h, j, k, l, m, n, p, r, s, sh, t, th, v, w, y, z) spoken in an "aCil" context by a female speaker. The stimuli were from the University of Western Ontario Distinctive Features Differences test (UWODFD; Cheesman & Jamieson, 1996). To minimize the likelihood of ceiling effects, the stimuli were presented in the presence of background noise. However, rather than fix the background noise at a pre-determined signal-to-noise (SNR) ratio, the SNR required to get 50% correct on the HINT noise condition during the PD fitting was used. For example, if a subject's score in the HINT noise condition was +2 dB, the background noise was presented at a level 2 dB lower than the signal.

4.2.4.3.1 Consonant and Noise Level Calibration

The consonants were concatenated using Matlab. Using ECoS experiment generator software (Avaaz Innovations; London, Canada), the concatenated stimuli were delivered through an RP2.1 real-time processor (Tucker-Davis Technologies; Alachua, USA) and then through channel 2 of the QSC amplifier. With a subject seated at 1 meter and 0 degrees azimuth from a soundfield speaker, the level of the QSC amplifier was adjusted until the Verifit real ear microphone (acting as an averaging sound level meter) measured an RMS average of 65 dB SPL. The noise signal was the speech-shaped multitalker babble track from the Connected Speech Test (CST; Cox, Alexander & Gilmore, 1987). The track was routed from a CD player through channel 1 of the Interacoustics audiometer and then delivered from a soundfield speaker 1.5 meters and 180 degrees azimuth to the listener. Again the Verifit reference microphone coupled to a seated subject was used as an averaging sound level meter to calibrate the noise signal. When the audiometer dial was set to 58 dB HL, an RMS level of 65 dB SPL was measured at the subject's ear. To return to the previous example of +2 dB SNR, channel 1 of the audiometer would need to be set to 56 dB HL to ensure that the consonants were 2 dB more intense than the noise (65 dB SPL consonant and 63 dB SPL noise).

Subjects were given a sheet that showed them all the consonant stimuli arranged in alphabetical order. Prior to beginning the actual testing, a practice run of 21 stimuli in quiet was completed to familiarize each subject to the task and the stimulus choices. Subjects were allowed to ask for repetition only during the practice runs. For testing in both the PD and AD conditions, the CST noise track was played continuously. Subjects listened to each stimulus and verbally repeated what they heard. A research assistant who was blind to the condition under test recorded the subject's responses. The ECoS software automatically scored whether the response was correct or not. Subjects who were unsure of what they heard, were asked to make a guess. A higher percentage of consonants correct (out of 21) would be indicative of better performance. However, for statistical analyses, percent correct scores themselves were not used, because their variances are often correlated with their means, the data are not normally distributed and the scale values are not linear in relation to the test variability (Studebaker, 1985). Consequently the raw percent correct scores were transformed into rationalized arcsine units (RAU) for data analysis.

4.2.4.4 Aided Loudness

Aided loudness Judgments were assessed using the Contour Test of Loudness Perception (Cox et al., 1997). Continuous speech passages from the CST test were presented in the soundfield at 1 meter and 0 degrees azimuth at 52 dB A, 65 dB A and 75.5 dB A to simulate casual, raised and loud speech according to Pearsons et al. (1977). The levels were calibrated in the same way as the noise signal was calibrated for the consonant recognition test (CD routed through audiometer and measured with Verifit). The individual was asked to judge the loudness of the speech using one of seven loudness categories from Table 4-2. Each had to judge 6 conditions in total (3 levels each for the PD and AD fittings). To understand how aided loudness judgments compared to normal hearing listeners' judgments under the same conditions, norms were gathered for this booth under the same condition using 10 normal hearing listeners.

Table 4-2. Rating Scale for the Contour Test of Loudness Perception.

Rating	*Descriptor*
7	Uncomfortably loud
6	Loud, but okay
5	Comfortable, but slightly loud
4	Comfortable
3	Comfortable, but slightly soft
2	Soft
1	Very soft

4.2.4.5 *Subjective Percentage of Words Understood*

The final outcome measure asked the subjects to estimate the percentage of words they felt they understood in each of the 6 conditions of the aided loudness test. After listening to each passage of connected speech, subjects were asked to generate a rating proportional to its intelligibility using an equal appearing interval scale from 0 to 100%. The approach was a modified version of the speech intelligibility rating (SIR) test (Cox & McDaniel, 1989).

4.2.5 **Statistical Design and Analyses**

There were 6 dependent variables (DVs):

1. Sensation Level (20)
2. HINT quiet (1)
3. HINT noise (1)
4. Consonant recognition in noise (1)
5. Aided loudness (3)
6. Subjective percentage of words understood (3)

The values in parentheses behind each dependent variable indicate the number of contrasts of interest (planned comparisons) within that DV. For the DVs HINT quiet, HINT noise and Consonant recognition in noise, there was only one independent variable (IV), Fitting with 2 levels (PD and AD). For the SL dependent variable there were 3 IVs. The first IV was Fitting with 2 levels (PD and AD). The second IV, was Input with 4 levels (55 dB, 65 dB 75 dB and MPO) and the third IV was Frequency with 5 levels (250, 500, 1000, 2000 and 4000 Hz). Normally a 2 x 4 x 5 design would yield 40 possible contrasts. However, the investigator was only interested in contrasts between AD and PD fittings within a given frequency at a given level. For example, the contrast of PD vs AD fitting at 4000 Hz with soft speech (55 dB). The contrast of PD at 250 Hz with a 65 dB input with the AD at 2000 Hz with a 75 dB input was not of interest in this study. For the aided loudness and subjective percentage of words understood DVs, there were 2 IVs: Fitting with 2 levels (PD and AD) and Input Speech Level with 3 levels (52, 65 and 75.5 dB A). Thus the grand total of planned comparisons for all dependent variables was 29.

A one-way, repeated measures MANOVA was considered. However, there are many assumptions underlying that approach. For example, the dependent variables should be linearly-related to one another, and there should be homogeneity of variance-covariance matrices and normality of distributions. In addition, this particular analysis is sensitive to outliers (Brace, Kemp & Snelgar, 2003) which were anticipated in these data. A more conservative approach using paired-samples t-tests for the outcome measures with only 2 levels and repeated measures ANOVAs for the outcome measures with more than 2 levels was chosen. To minimize the likelihood of a type-1 error for multiple contrasts, a Bonferonni correction was applied to the experiment-wise p-value. The desired experiment-wise error rate (.05) was divided by the number of planned comparisons (29), This meant that for any one pair-wise t-test of means to show a significant difference, the p-value associated with the contrast had to be lower than 0.0017. All statistical analyses were performed using SPSS (Version 15, 2006).

4.2.6 **Effect Size Calculations**

Determining the strength of an effect by statistical significance testing alone is difficult. Consequently effect size calculations were included for each of the planned comparisons. As t-tests of means were used, Cohen's d was considered the most appropriate effect size equation (Cohen, 1988). Where,

$$d = \frac{\mathrm{mean}_1 - \mathrm{mean}_2}{\sqrt{(\mathrm{SD}_1^2 + \mathrm{SD}_2^2)/2}} \quad (1)$$

Interpreting the strength of the effect is not universally agreed upon (Huberty, 2002), however a widely accepted opinion is that of Cohen (1992) where 0.2 is indicative of a small effect, 0.5 a medium effect and 0.8 a large effect size.

4.3 Results

4.3.1 Sensation Level of Aided Speech

A 2 (fitting approach) x 4 (input level) x 5 (frequency) repeated measures (completely within-subjects) ANOVA was used to investigate differences in SL estimates. All main effects and interactions were significant ($p < 0.0001$), allowing the investigator to proceed to the individual planned comparisons of interest using paired-samples t-tests and a Bonferonni-adjusted p-value (See Appendix 4-A for all 20 contrasts). Figure 4-10 shows the differences in SL between the AD and PD fitting approaches at each frequency for each level of input. These values were derived by subtracting the SL values for the PD fitting from the SL values for the AD fitting. Positive values indicate increased SL for the AD fitting. Significant differences are indicated with an asterisk. The AD fitting approach, in general, resulted in higher sensation levels, especially for the important high frequency information. The effect was most pronounced when soft speech (55 dB SPL) was used as an input. The mean difference in SL at 4000 Hz and 55 dB speech input was 25.44 dB (95% CI = 22.97 to 27.92) and the resulting effect size of this contrast was 1.71 (See Appendix 4-B for all 29 effect size calculations).

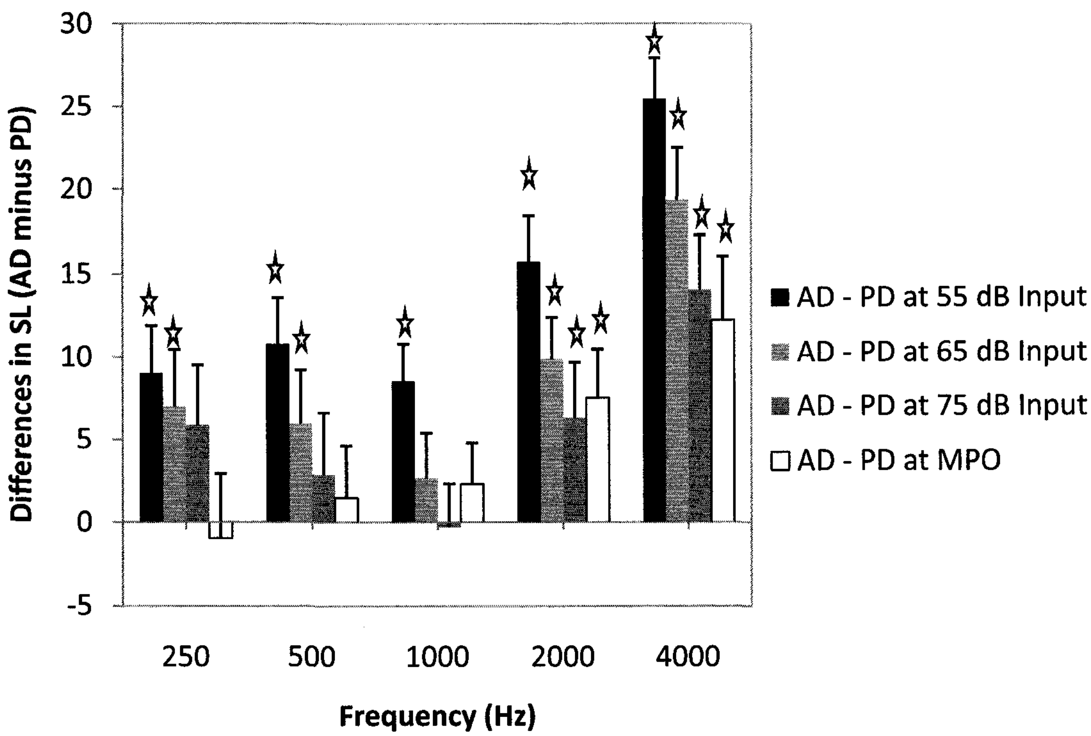

Figure 4-10. Differences in aided SL between the AD and PD fitting approaches at each input level. Differences were derived by subtracting SL with the PD approach from SL with the AD approach. Positive values indicate increased SL with the AD Approach. Significant differences are starred.

Figures 4-11 (PD) and 4-12 (AD) show the average aided acceleration responses for all 4 input levels on the same graph as the auditory dynamic range and speech target information. Aided acceleration responses that are above the threshold curve would be audible, while aided responses below the threshold curve would not be. It is important to recognize that the three speech curves were derived from the aided Long Term Average Speech Spectrum (LTASS). The peaks and valleys of speech would fall above and below these average aided LTASS lines. Again, speech, especially in the high frequencies and for all input levels, is made more audible with the AD approach. Additionally, the MPO of the AD approach is much closer to the subjects' LDL. The wide dynamic range compression used in the AD approach is providing much more gain for soft inputs, while ensuring that gain for loud inputs does not exceed LDL.

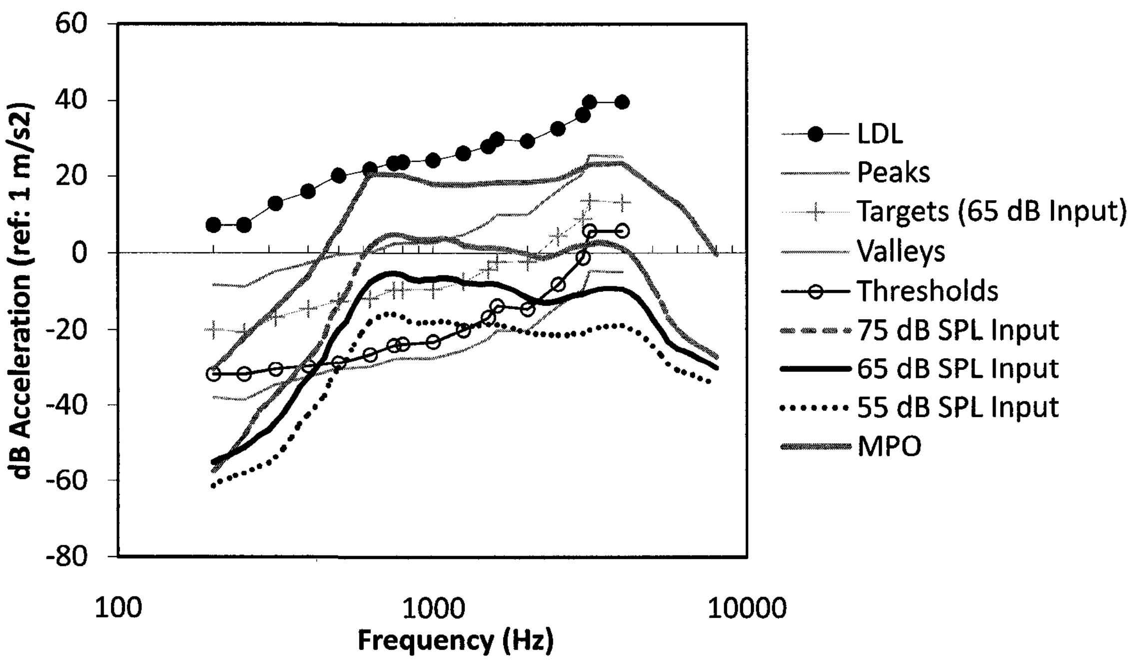

Figure 4-11. Average LTASS associated with 55, 65 and 75 dB SPL speech inputs using the PD fitting protocol. Also shown is the aided MPO. Aided audibility of the LTASS can be assessed by comparing the aided outputs to the threshold curve.

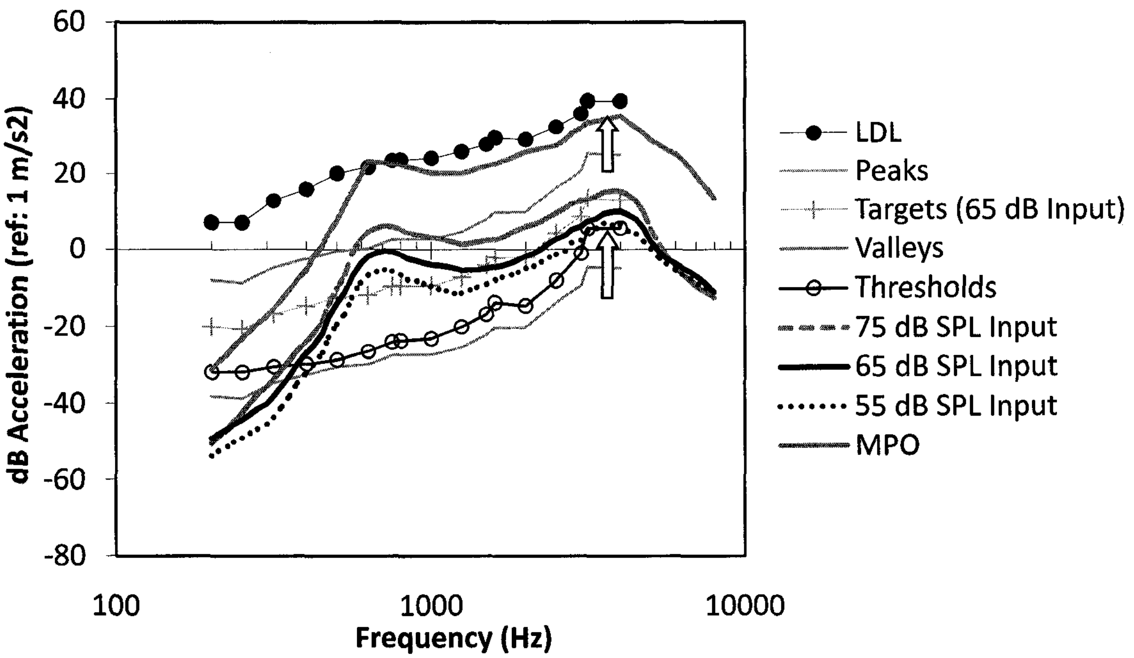

Figure 4-12. Average LTASS associated with 55, 65 and 75 dB SPL speech inputs using the AD fitting protocol. Also shown is the aided MPO. Aided audibility of the LTASS can be assessed by comparing the aided outputs to the threshold curve.

4.3.2 Sentence Recognition in Quiet and In Noise

Mean HINT scores (+/- 95% CI) in quiet for both the PD (M = 53.11, SD = 7.95) and AD (M = 46.44, SD = 7.22) fittings are shown in Figure 4-13. As expected, the AD fitting resulted in a significantly lower HINT threshold in quiet (t(15) = 5.28, p < 0.001; effect size = 0.88). Figure 4-14 shows the mean HINT scores (+/- 95% CI) with noise at the non-Baha side. The AD fitting (M = -0.09, SD = 4.70) was significantly better (t(15) = -4.19, p < 0.001; effect size = 0.59) than the PD fitting (M = 2.59, SD = 4.39). A difference of 1 dB on the HINT is equal to a change of 8.9% in sentence intelligibility (Koch, Nilsson & Soli, 1994; Nilsson, Soli & Sullivan, 1994). For the noise condition, the average improvement for the AD fitting was 23.86%.

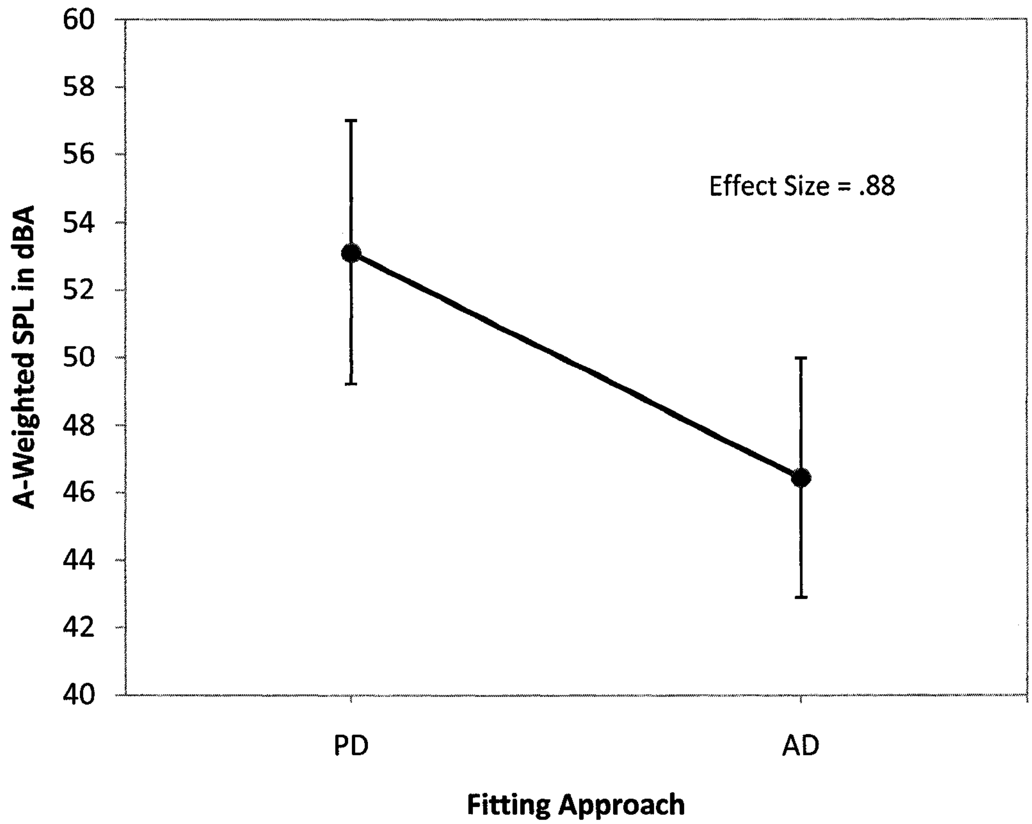

Figure 4-13. HINT scores in quiet (dBA) for each fitting approach. 95% confidence intervals are also displayed.

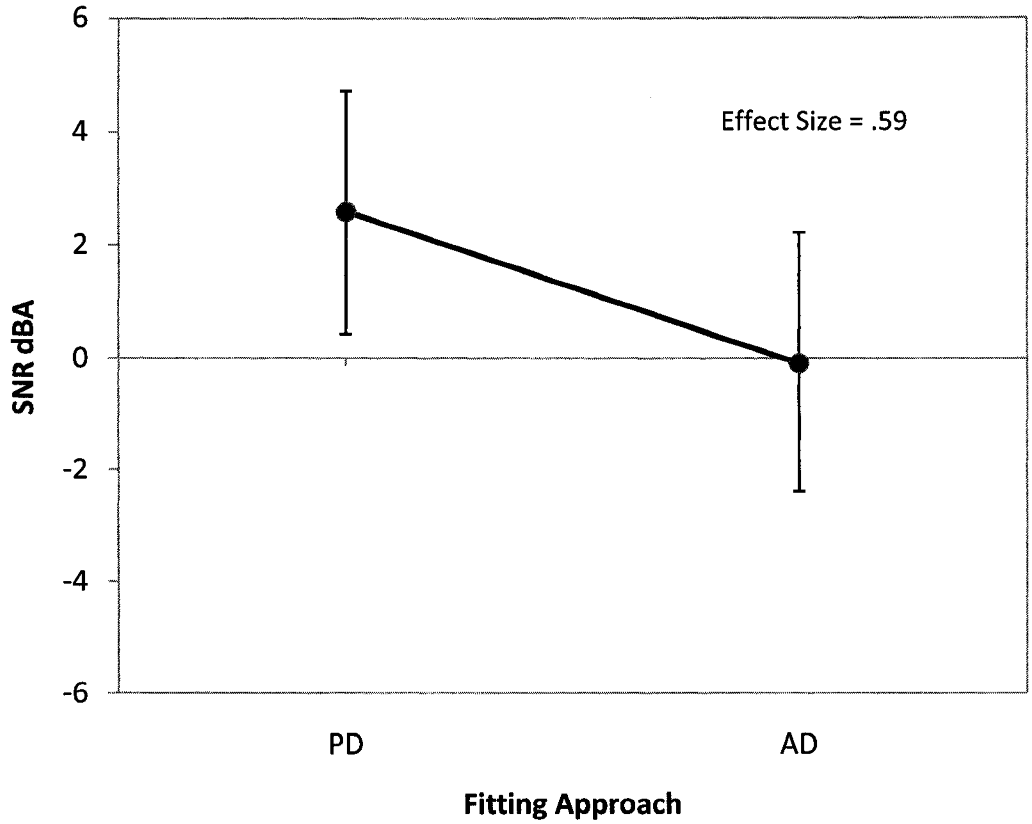

Figure 4-14. HINT scores in noise (SNR dBA) for each fitting approach. 95% confidence intervals are also displayed.

The 95% confidence limits for repeated measures are known for both HINT conditions and can be used to estimate significance on an individual basis. For example, in the quiet condition, if performance differences from one condition to the next exceed +/- 1.48 dB, then one can reasonably estimate that the change was significant. For the HINT noise condition, the test-retest confidence interval is +/- 1.42 (Koch, Nilsson & Soli, 1994). Figure 4-15 shows the HINT scores in quiet on an individual basis with the 95% confidence intervals. Differences between conditions can be found by tracing lines from each score to the x- (AD) and y- (PD) axes. Scores falling within the 95% CI are not different. However, scores that fall above the 95% CI indicate better performance with the AD fitting, while scores below the 95% CI indicate better performance with the PD fitting. No subjects performed better in quiet with the PD fitting. Subjects 1, 5 and 10 did not differ significantly in quiet with either fitting approach. Figure 4-16 shows the same type of graph for the HINT scores in noise. Again, the majority of subjects performed better in the AD condition. However, subjects 14, 9, 10 and 7 did not differ between conditions and subject 6 actually performed better with the PD fitting.

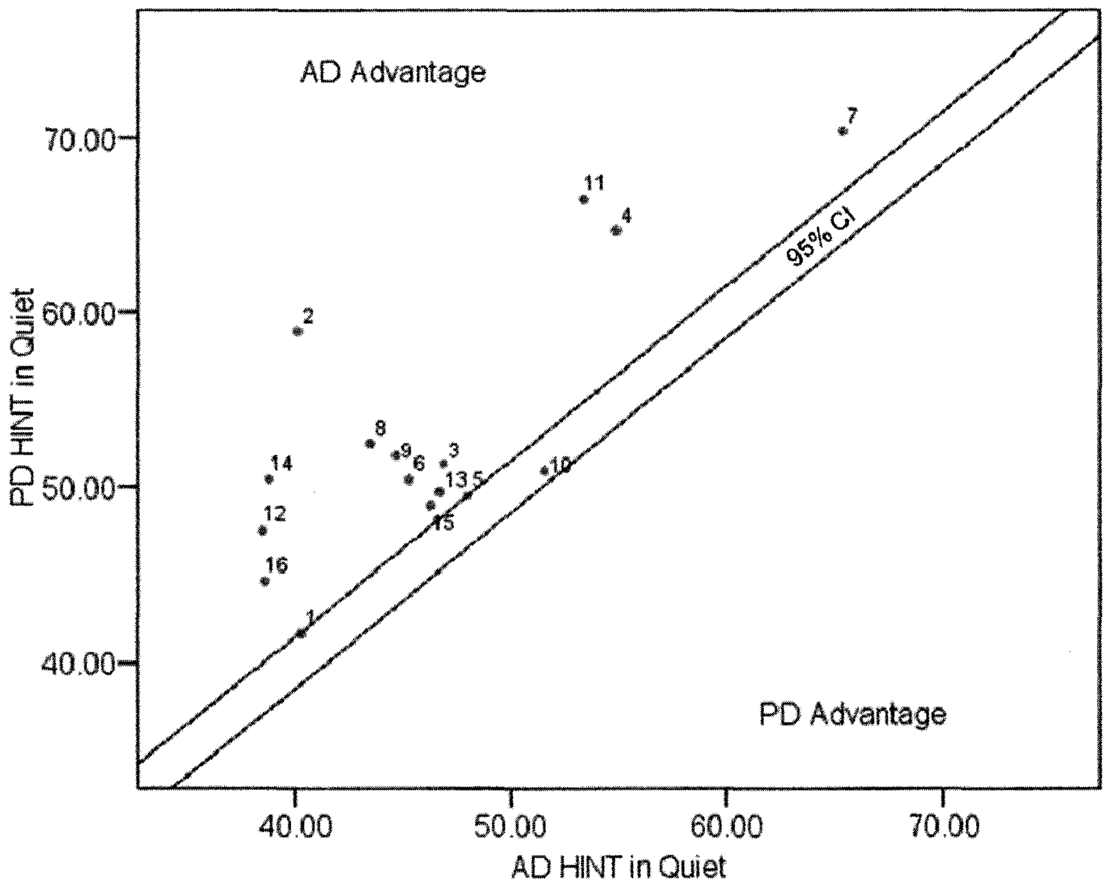

Figure 4-15. Individual HINT scores in quiet. The numbers represent each subject in the study. A comparison of each subject's score in the AD and PD conditions can be derived by tracing a line to both the x and y axes. The test-retest 95% confidence interval is shown about the origin. If a score falls within this CI, it is not significantly different. Scores above this CI indicate an advantage for the AD fitting, while scores below indicate an advantage for the PD fitting.

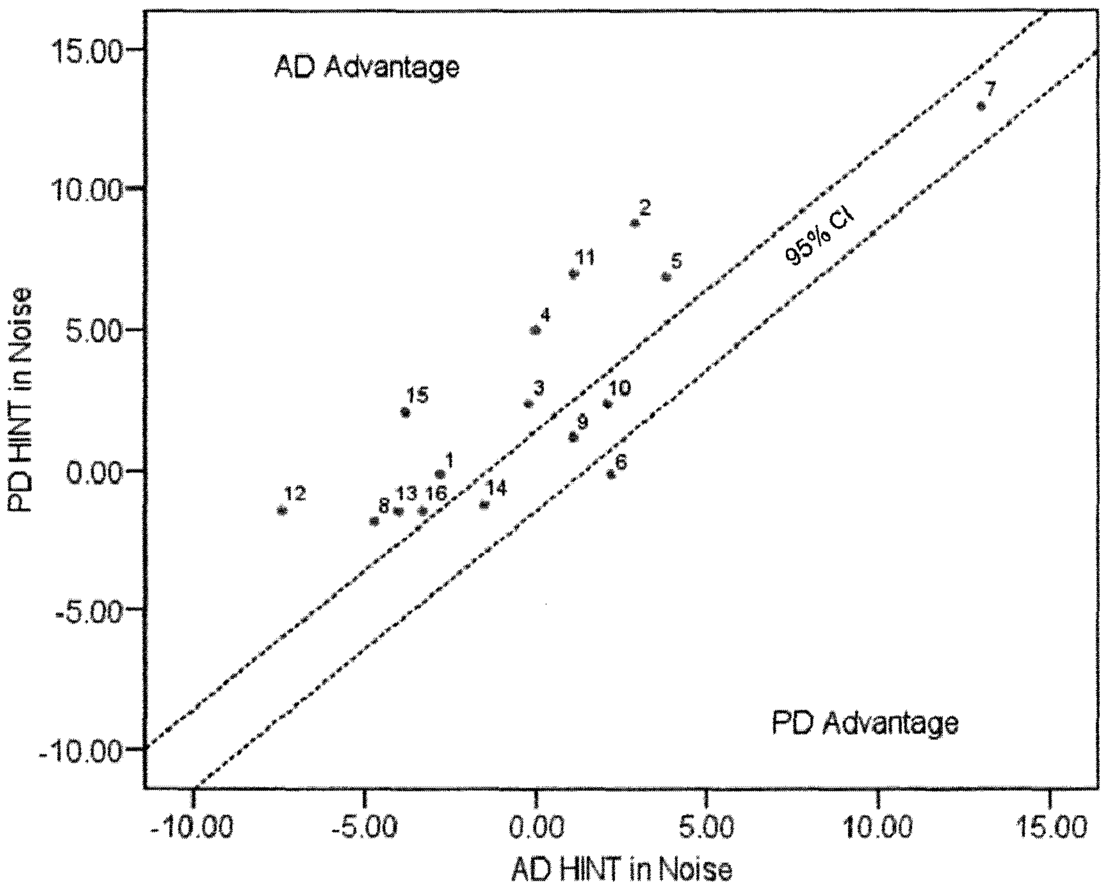

Figure 4-16. Individual HINT scores in noise. The numbers represent each subject in the study. A comparison of each subject's score in the AD and PD conditions can be derived by tracing a line to both the x and y axes. The test-retest 95% confidence interval is shown about the origin. If a score falls within this CI, it is not significantly different. Scores above this CI indicate an advantage for the AD fitting, while scores below indicate an advantage for the PD fitting.

4.3.3 Consonant Recognition in Noise

Rationalized arcsine units (RAU) for the AD fitting (M = 69.11, SD = 16.27) were found to be significantly higher than for the PD fitting (M = 52.93, SD = 19.06; $t(15) = 5.92$, $p < 0.001$). Figure 4-17 shows the means (+/- 95% CI) for the RAU scores. While RAU scores are not directly equivalent to percent correct, the RAU scores displayed were on average less than 0.3% different from the raw percent correct scores. This small difference between RAU and raw score is largely due to the fact that the majority of percent correct scores for both PD and AD fitting were in the range of 15% to 85%. RAUs calculated from raw scores outside of this range are known to show much larger differences (Studebaker, 1985). In other words, these scores can be "intuitively" interpreted as percent correct consonant scores in spite of the transformation.

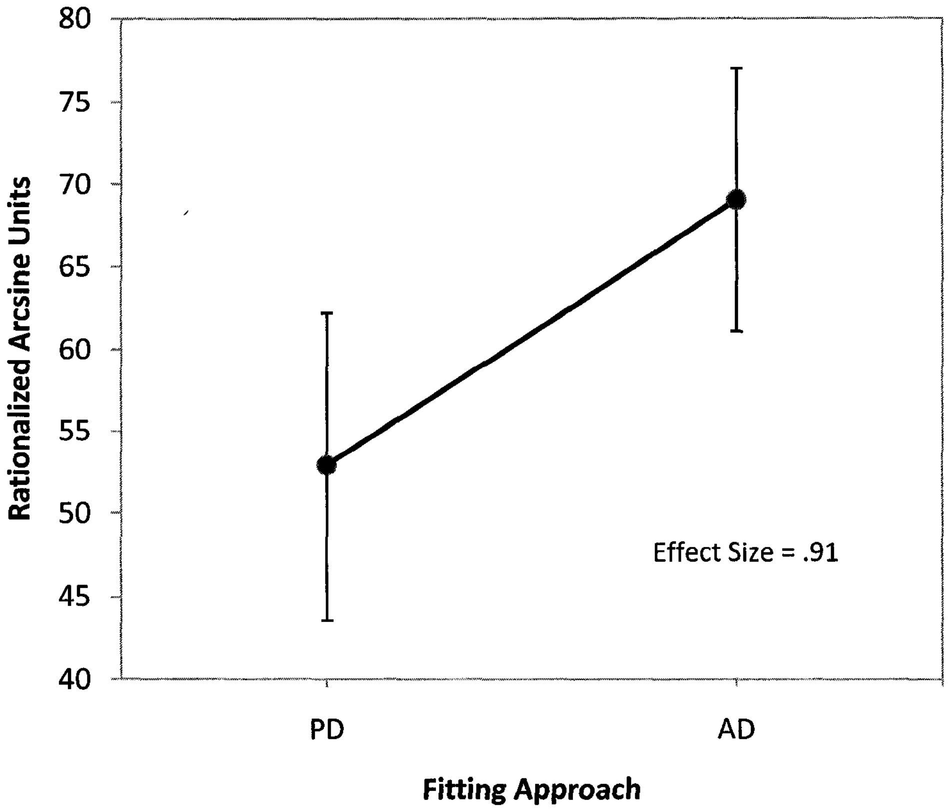

Figure 4-17. Rationalized arcsine units for the consonant recognition task (+/- 95% CI).

4.3.4 Aided Loudness

Figure 4-18 shows the results of the aided loudness testing at all 3 levels for both the PD and AD fitting approaches. The loudness norms (+/- 1 SD) for 10 normal hearing listeners are also plotted. No significant differences were found between fitting approaches at any level. The casual (52 dB A) input was approaching significance ($p = 0.013$), with the subjects tending to find soft speech louder with the AD approach. Interestingly, for loudness to be "normalized" one would expect the loudness judgments to be nearer to the normal hearing listeners' judgments. It appears that neither fitting approach resulted in normalized loudness with the master Baha.

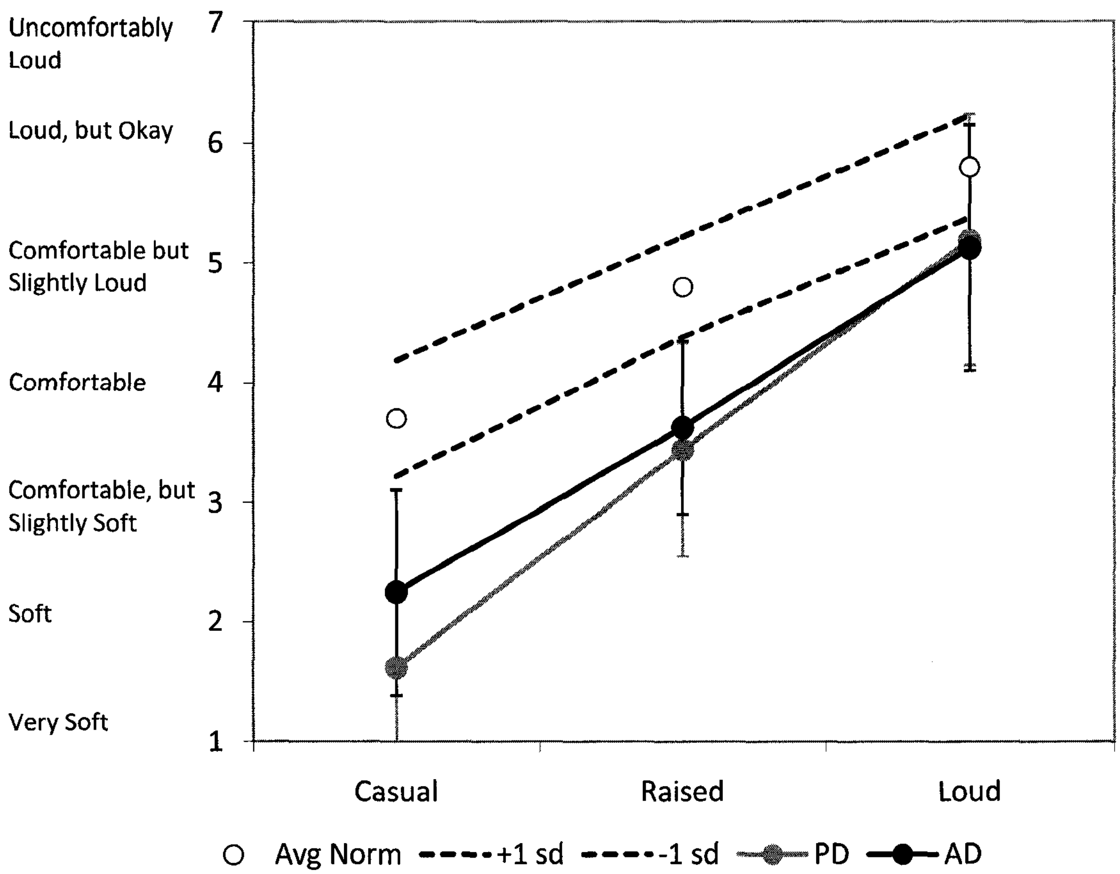

Figure 4-18. Aided loudness for the PD and AD fitting approaches at 3 different speech input levels (+/- 95% CI). Also plotted are the norms for (+/- 1 SD) for normal hearing listeners in the test booth.

4.3.5 Subjective Percentage of Words Understood

During each of the loudness conditions, subjects were asked to estimate the percentage of words understood. The data for these judgments are presented in Figure 4-19. The difference between the percentage of words understood with PD and Ad fitting approaches, when the input was casual speech, approached significance (p = 0.020), however none of the planned contrasts were found to be significantly different.

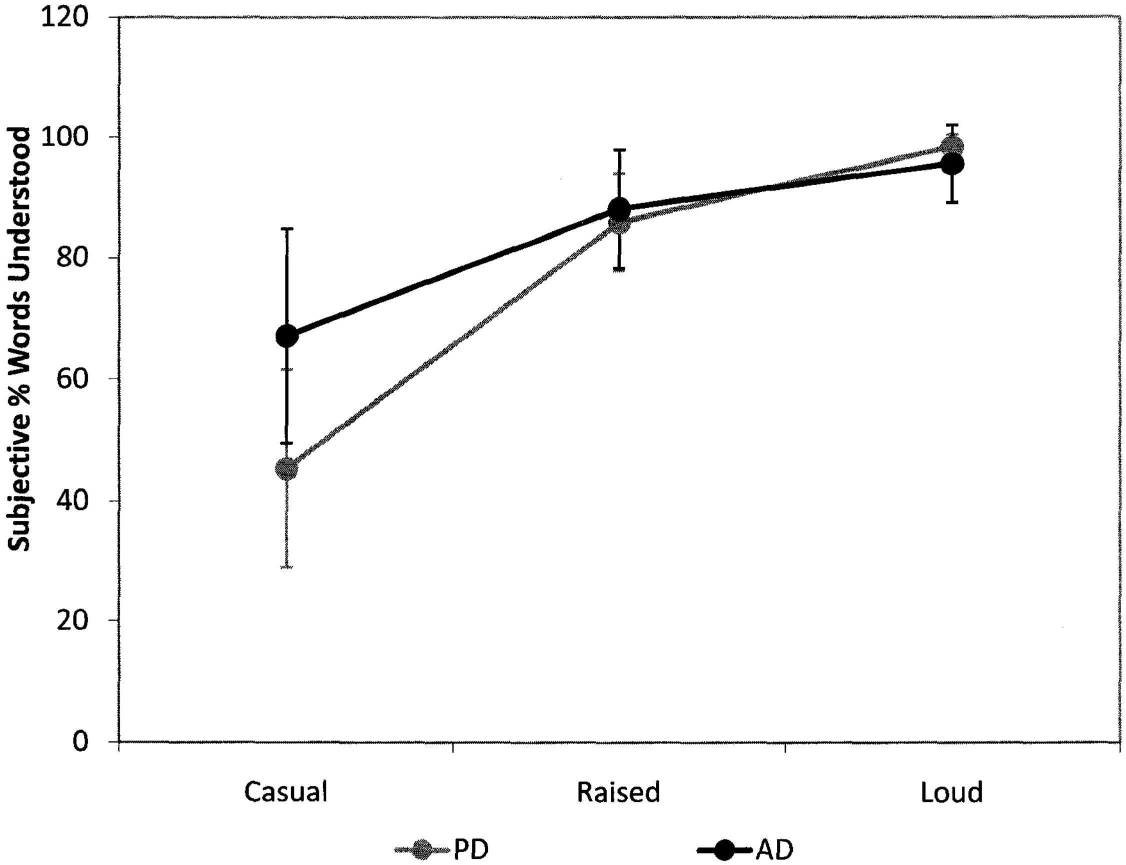

Figure 4-19. Subjective percentage of words understood by speech input level and fitting approach (+/-95% CI).

4.4 Discussion

This study was designed to test whether an audibility-derived (AD) Baha fitting produced better outcomes than the patient-derived (PD) fitting approach commonly used to fit Bahas today. It was hypothesized that the AD fitting would yield better outcomes compared to the PD fitting for two reasons: (1) the frequency shaping of the Baha for each individual was altered to ensure a greater degree of audibility could be achieved, especially for the high frequencies of speech, and (2) the signal processing technology for the AD protocol was not limited to the technology currently available in today's Bahas. Results from this efficacy study validate this assumption.

The following sections discuss the implications of these results in terms of each of the outcomes measures.

4.4.1 Sensation Level of Aided Speech

Several studies have shown that predicted speech intelligibility increases with increased audibility for high frequencies (Ricketts, 1996; Stelmachowicz et al., 1998). The current models of Baha have no high frequency shaping options. Consequently, it is not feasible with today's technology for the Baha audiologist to increase the high frequency gain of the Baha for a particular individual. Thus, in the context of the current efficacy study, the computer-controlled master Baha was set to the frequency shape and technological processing limitations of current Bahas for the PD fitting. These limitations were lifted for the AD fitting so that it was possible to shape the Baha response according to a modified DSL prescriptive procedure.

Sensation level differences between the two approaches were quite large and the differences were largest at higher frequencies. This indicated that there is a large difference, especially at the high frequencies, between the current use output of today's Bahas and the prescribed output from a modified audibility-driven prescriptive procedure. In Figure 4-11, it is apparent that the majority of speech, regardless of input level, would be inaudible above 3000 Hz for the subjects in this study using the current PD approach with today's technology limitations. When one considers soft speech inputs (55 dB SPL), the aided LTASS was below threshold at approximately 1200 or 1300 Hz and above. In contrast, the shapes of the aided frequency response for the AD protocol ensured that the majority of the aided LTASS was above threshold for almost all frequencies (see Figure 4-12). Additionally, owing to the wide dynamic range compression, the range of speech outputs for all three inputs (55, 65 and 75 dB SPL) was compressed to fit within the dynamic range of hearing for the subjects in this study. Finally, the high frequency MPO was increased for the AD approach, thereby maximizing the available headroom into which amplified speech could be mapped. Given these differences in sensation level, it is easy to predict superior performance with the AD fitting. But was it better?

4.4.2 Sentence Recognition in Quiet and in Noise

Significant improvements in HINT scores in both quiet and noise were found with the AD fitting protocol. Effect size calculations revealed a large effect in quiet and a medium to large effect in noise. The medium to large effect in noise was equivalent to a 24% improvement in sentence recognition in noise with the AD protocol over the PD fitting. Statistical significance testing, while critical to the analysis of a difference (probability that it occurred by chance alone), does little to inform the clinician or researcher about the importance of the difference. Audiologists are typically interested in the clinical significance of a treatment (in this case the fitting protocol). Effect size calculations are a common currency that can help researchers answer the question "Is the difference between treatments meaningful (large enough to be worth achieving)?" As mentioned before, there is debate about exactly what labels to use (or whether labels should be used at all) for the interpretation of effect sizes (e.g., Glass, McGaw, & Smith, 1981). However, it is well-established that larger effect sizes (like those achieved in the current study) are associated with more meaningful clinical differences.

A second meaningful approach to looking at the differences between the PD and AD fitting protocols was shown in Figures 4-15 and 4-16. These figures illustrated the individual scores for both the PD and AD fitting in the context of the 95% confidence limits for repeated measures on the HINT (Koch, Nilsson, & Soli, 1994). Not all subjects showed differences that were outside of the 95% confidence limits. However in quiet, none of the subjects performed better with the PD fitting, and only 1 subject performed better in noise with the PD fitting.

A third approach that can be used to assess the clinical importance of a difference involves the comparison of the treatment groups to the norms for a given standardized test. How did the aided performance of the Baha patients with both the PD and AD fitting protocols compare to the norms for the Hearing in Noise Test (HINT) gathered in the same soundfield? Average, normally-hearing adults can typically understand 50% of sentences in quiet with speech presented 15 dBA and in the noise condition used in this study at a signal-to-noise (SNR) ratio of -10 dBA. The average level for our subjects for the PD fitting was 53 dBA, while the AD fitting improved to 46 dBA. For the noise condition, performance improved from 2.6 dB SNR with the PD fitting to -0.1 dB SNR for the AD fitting. While the improvement from 53 to 46 dBA represents a large and significant effect, 46 dBA is considerably worse than normal performance. It seems likely that targets for aided speech that provided even greater audibility than those prescribed in this study may have the potential to improve aided speech recognition in noise and in quiet. More work is needed to determine appropriate targets for Baha users.

4.4.3 Consonant Recognition in Noise

Consonant recognition in noise was sensitive to differences between the PD and AD fitting approaches. Similar findings were reported by Jenstad et al. (1999). This outcome offers additional support to the findings for sentence level material. However, the real value of consonant recognition testing usually involves calculation of confusion matrices for error analysis (e.g., place, manner and voicing errors) (Miller & Nicely, 1955). Unfortunately, to do this reliably in this study, many more blocks of data would have been required. Future studies addressing the fitting of Bahas should include more blocks of data, so an analysis of consonant confusions can be made for Baha users.

4.4.4 Aided Loudness

No significant differences were found between the PD and AD fitting approaches on the aided loudness test. The Baha subjects' loudness ratings were also compared to norms gathered on the same test in the current soundfield set-up. Most prescriptive procedures for WDRC hearing aids, including the one used in this study, have the goal of normalizing loudness (Smeds, 2004). Somewhat surprisingly, neither approach resulted in aided loudness perception that would be considered "normalized." It is not entirely clear why this was the case. In gathering the norms, the normal hearing subjects used both ears and the predominant route for sound delivery was air conduction. Stenfelt and Håkansson (2001) showed that the growth of loudness is shallower by bone conduction than by air conduction. Moreover, when using the Baha, there is really only 1 microphone and 1 transducer. The normal hearing subjects would have based their loudness judgments, in part, on binaural summation cues that would not necessarily have been available to the Baha users. Based on the dynamic range results from this and the previous study and the results for aided loudness, it seems clear that more research is needed to fully understand loudness with direct bone conduction.

4.4.5 Subjective Percentage of Words Understood

The outcome using subjective percentage of words understood failed to show any significant differences in this study. Subjective ratings for soft speech showed the expected trend of higher intelligibility, owing mostly to the WDRC processing (more gain for soft inputs). However, given the inherent subjectivity in this measure, it is perhaps not surprising that it failed to tease out meaningful statistical or clinical differences. Anecdotally, it did provide the subjects with an opportunity to provide some feedback to the researchers about their subjective perception of the sound. In some cases, subjects reported things like, "it is much clearer with this setting compared to the other setting, but I can still understand most of the words with both settings."

4.4.6 What is the Source of the Difference between Fitting Approaches?

One of the limitations to the design of this study is that it did not allow for separate comparisons between the effects of audibility as a consequence of frequency response changes and audibility as a consequence of compression, on their own, in comparison to the PD fitting. Since the AD fitting altered both the shape of the output response and the compression characteristics simultaneously, the relative importance of each can only be inferred from what is known in the air conduction hearing aid literature.

4.4.6.1 Effects of Compression Alone

In general, WDRC amplification provides the most benefit, in comparison to linear amplification, for low level speech in quiet (Souza, 2002). If a linear hearing aid is prescribed with a volume control and a comparable frequency response, there is little evidence to suggest that WDRC alone will offer superior speech intelligibility in quiet or in noise (Dillon, 1996). It is expected that whatever benefit may have resulted from the additional low level gain in the AD fitting used in this efficacy study would likely have less influence in a clinical trial (effectiveness study), because all Bahas come with a volume control (Souza & Kitch, 2001). In our study, we found significant improvements in quiet and in noise. An additional condition, in which the frequency response remained the same as the current PD frequency response but the processing was changed from linear to WDRC, may have provided more insight into the exact effects of compression on the Baha patients. This may be an area for future research. However, it is unlikely that, given what is known in the literature, that compression alone would explain the majority of the improvements, especially in the noise conditions of the speech tests.

4.4.6.2 Effects of Compression and Frequency Shaping on Audibility

WDRC processing can make soft components of speech more audible. In Figure 4-12 providing more gain for the soft speech (WDRC) would allow for more of it to be fitted within the dynamic range of hearing. However, the WDRC advantage would likely have only been minor. The majority of the benefit must be a consequence of the altered frequency response shape. By providing compression to a signal that has also been shaped to fit within the users' dynamic range, significantly greater audibility was achieved in the most important frequency regions. It is probable that, even if the fitting was linear, there would have been a significant advantage for the AD fitting simply because of the better audibility derived from the frequency shaping.

4.4.7 **Is the Current Prescriptive Procedure Ideal?**

One of the underlying assumptions for using the modified DSL prescriptive procedure for Baha was that dynamic range for air conduction hearing aids was an appropriate metric for the derivation of output targets by bone conduction. As such, there were no corrections applied to the targets to compensate for the degree of conductive loss. The direct bone conduction dynamic range of hearing was assumed to be proportional to the air conduction dynamic range used in the calculation of targets. Again, given the potential differences in loudness growth between air and bone conduction and the limited correspondence between the Baha fittings and the normative loudness growth data in Figure 4-18, more research is needed to determine if normal or less than normal overall loudness is preferred or ideal for Baha users (Smeds, 2004). Additionally, the low frequency response of the Baha appears to be considerably below prescriptive targets. It is well known that the low frequency response by bone conduction is limited. The skull impedance is highest for low frequencies (see study 1). It is not likely feasible, nor necessary, to amplify low frequencies for Baha users. Many of the low frequency sounds contribute little to intelligibility, unless the listener has profound sensornineural hearing loss.

The intention of this study was not to prove that the targets for DSL were necessarily the best targets for Baha. The modified DSL targets that were used simply provided an initial approximation of targets that might be appropriate for a Baha user. Further research is required to determine if there are better targets for the fitting of Baha, especially in light of the fact that the valleys for the 65 dB SPL speech targets were all below thresholds. It may be that the investigator failed to provide sufficient targets for the majority of users in this study. That said, the value of the DSL method extends beyond simply the output targets it provides. The DSL method represents a structured and comprehensive series of stages that allow the clinician an opportunity to assess, prescribe, verify and validate a given hearing aid fitting. For the present study, the fact that performance improved dramatically for some outcome measures, offers support for more careful consideration of the output capabilities of a given Baha in relation to the dynamic range of hearing for a given individual.

4.5 Conclusions

Considerations for Baha fitting have received only limited attention in the literature. It is broadly assumed that, so long as the bone conduction thresholds of a potential candidate are better than some agreed-upon cut-off (e.g., 45 dB HL), they will perform adequately with the Baha set to its factory defaults. Depending on the patient-derived feedback regarding loudness and sound quality, small adjustments might be made to the low cut potentiometer. However, this study revealed that, when a Baha user's dynamic range is used to develop targets for aided speech that place the Baha's aided response within a given user's dynamic range of hearing (audibility-derived), performance improves considerably over the more traditional patient-derived fitting. The implications of this finding hold genuine clinical significance in two respects. Audiologists fitting Bahas should consider adopting a more systematic approach to prescribing and verifying output characteristics for Baha users. Engineers responsible for the design and technology in Bahas should consider providing patients and their audiologists with more flexible devices that can be programmed and verified using the most up-to-date scientifically-based methods. These considerations for Baha fitting surely will increase in importance with the degree of bone conduction hearing loss.

4.6 References

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Appendix 4-1. Significance testing for all 29 planned contrasts. P-values less than 0.0017 were considered statistically significant. Shaded contrasts are significant.

			95% CI			
Input Level	*Planned Comparison*	*Mean2 - Mean1*	*Lower Bound*	*Upper Bound*	*t*	*p-value*
55 dB	AD - PD (250 Hz)	9.06	6.25	11.86	6.88	0.0000
	AD - PD (500 Hz)	10.78	7.96	13.59	8.17	0.0000
	AD - PD (1000 Hz)	8.54	6.28	10.79	8.07	0.0000
	AD - PD (2000 Hz)	15.74	13.03	18.44	12.41	0.0000
	AD - PD (4000 Hz)	25.44	22.97	27.92	21.91	0.0000
65 dB	AD - PD (250 Hz)	6.99	3.53	10.46	4.30	0.0006
	AD - PD (500 Hz)	5.98	2.72	9.24	3.91	0.0014
	AD - PD (1000 Hz)	2.71	0.04	5.37	2.17	0.0469
	AD - PD (2000 Hz)	9.86	7.33	12.40	8.29	0.0000
	AD - PD (4000 Hz)	19.37	16.25	22.48	13.24	0.0000
75 dB	AD - PD (250 Hz)	5.90	2.26	9.53	3.46	0.0035
	AD - PD (500 Hz)	2.91	-0.79	6.61	1.68	0.1146
	AD - PD (1000 Hz)	-0.32	-2.99	2.36	-0.25	0.8039
	AD - PD (2000 Hz)	6.32	2.96	9.67	4.01	0.0011
	AD - PD (4000 Hz)	14.03	10.77	17.29	9.17	0.0000
MPO	AD - PD (250 Hz)	-0.94	-4.85	2.96	-0.52	0.6138
	AD - PD (500 Hz)	1.49	-1.63	4.62	1.02	0.3240
	AD - PD (1000 Hz)	2.34	-0.12	4.80	2.03	0.0608
	AD - PD (2000 Hz)	7.50	4.52	10.48	5.36	0.0001
	AD - PD (4000 Hz)	12.22	8.40	16.05	6.81	0.0000
	AD - PD HINT Quiet	-6.67	-9.36	-3.97	-5.28	0.0000
	AD - PD HINT Noise	-2.68	-4.05	-1.32	-4.19	0.0010
	AD - PD Consonant Recognition	16.17	10.35	21.99	5.92	0.0000
Casual	AD - PD Aided Loudness	0.63	0.15	1.10	2.82	0.0130
Raised	AD - PD Aided Loudness	0.19	-0.26	0.63	0.90	0.3830
Loud	AD - PD Aided Loudness	-0.06	-0.52	0.39	-0.29	0.7740
Casual	AD - PD Subjective % Words	21.88	3.78	39.97	2.58	0.0210
Raised	AD - PD Subjective % Words	2.25	-5.51	10.01	0.62	0.5460
Loud	AD - PD Subjective % Words	-2.81	-9.12	3.49	-0.95	0.3570

Appendix 4-2. Effect Size Calculations for all planned comparisons in this study. Calculations based on Cohen (1992).

Input Level	*Planned Comparison*	*Mean2 - Mean1*	*(SD2)²*	*(SD1)²*	*Pooled SD*	*Effect Size*
55 dB	AD - PD (250 Hz)	9.06	156.61	181.71	13.01	***0.70***
	AD - PD (500 Hz)	10.78	92.12	114.65	10.17	***1.06***
	AD - PD (1000 Hz)	8.54	109.73	133.22	11.02	***0.77***
	AD - PD (2000 Hz)	15.74	149.60	185.57	12.95	***1.22***
	AD - PD (4000 Hz)	25.44	209.47	232.63	14.87	***1.71***
65 dB	AD - PD (250 Hz)	6.99	168.94	186.86	13.34	***0.52***
	AD - PD (500 Hz)	5.98	100.56	107.99	10.21	***0.59***
	AD - PD (1000 Hz)	2.71	130.79	136.89	11.57	***0.23***
	AD - PD (2000 Hz)	9.86	153.43	193.83	13.18	***0.75***
	AD - PD (4000 Hz)	19.37	271.57	237.85	15.96	***1.21***
75 dB	AD - PD (250 Hz)	5.90	185.22	197.82	13.84	***0.43***
	AD - PD (500 Hz)	2.91	120.28	106.92	10.66	***0.27***
	AD - PD (1000 Hz)	-0.32	135.37	174.01	12.44	***-0.03***
	AD - PD (2000 Hz)	6.32	165.52	218.32	13.85	***0.46***
	AD - PD (4000 Hz)	14.03	337.12	233.68	16.89	***0.83***
MPO	AD - PD (250 Hz)	-0.94	172.79	192.47	13.51	***-0.07***
	AD - PD (500 Hz)	1.49	69.40	105.19	9.34	***0.16***
	AD - PD (1000 Hz)	2.34	183.65	187.35	13.62	***0.17***
	AD - PD (2000 Hz)	7.50	237.67	240.32	15.46	***0.49***
	AD - PD (4000 Hz)	12.22	377.90	316.80	18.64	***0.66***
	AD - PD HINT Quiet	6.67	63.17	52.17	7.59	***0.88***
	AD - PD HINT Noise	2.68	19.26	22.11	4.55	***0.59***
	AD - PD Consonant Recognition	16.37	253.59	405.80	18.16	***0.90***
Casual	AD - PD Aided Loudness	0.63	0.73	0.38	0.75	***0.84***
Raised	AD - PD Aided Loudness	0.19	0.52	0.80	0.81	***0.23***
Loud	AD - PD Aided Loudness	-0.06	1.05	1.10	1.04	***-0.06***
Casual	AD - PD Subjective % Words	21.88	1289.90	1114.90	34.68	***0.63***
Raised	AD - PD Subjective % Words	2.25	399.58	268.25	18.27	***0.12***
Loud	AD - PD Subjective % Words	-2.81	172.92	19.06	9.80	***-0.29***

Chapter 5: Summary and Conclusions

5 Chapter 5

The overall goal of this dissertation was to improve Baha fitting practices. To achieve this goal, a model of the hearing aid fitting process was used to guide the selection of appropriate research topics (see Figures 1-1 and 4-1 for review of the hearing aid fitting model). Each study was designed with the hope that it would not only contribute to one or more components of the model, but also combine with the other studies to help address the overall goal of the dissertation.

It was the investigators' belief that there were several weaknesses in the current Baha fitting practices that, if they could be improved upon, may provide clinicians an approach that would ensure a better match between the auditory needs of the patients they treat and the electromechanical output capabilities of the Bahas they fit. The technology and procedures audiologists currently use to assess hearing and the technology and procedures they currently use to assess the hearing aids are outdated and can yield inaccurate or insufficient information. As signal processing technologies march on inexorably, these failings are becoming increasing problematic. Audiologists are not unaware of the limitations of some of the current Baha fitting approaches (e.g., aided soundfield thresholds). However, viable alternatives such as those that have been proposed for air conduction hearing aids (e.g., real ear measures) have not been proposed and tested for Baha. The next section briefly summarizes the studies in this dissertation that proposed and tested new fitting practices for Baha users.

5.1.1 Study 1: Individuality in Bone Conduction: Revisiting Traditional and Direct Bone Conduction Thresholds and Mechanical Point Impedance in Baha Users

5.1.1.1 Summary

A number of studies have addressed the important differences between thresholds obtained transcutaneously (through the skin) and percutaneously (directly through the Baha abutment). Unfortunately, the size of these differences between the two threshold measurements varies considerably from study to study depending on what reference was used for thresholds (electrical, acceleration or force). Moreover, at any given frequency the variability from subject to subject appears to be substantial. In this study, the problem was revisited from a slightly different perspective. It was hypothesized that, owing to the highly individual transcutaneous to percutaneous transform, thresholds from a standard audiometric bone conduction audiogram in dB HL would provide only limited information with respect to how a person would eventually hear by direct bone conduction. In support of this notion, it was discovered that, at some frequencies, the same dB HL thresholds could be associated with a range of direct bone conduction acceleration thresholds as large as 40 dB.

A secondary goal of this study dealt with mechanical impedance directly through the Baha abutment. Previous research has revealed a great deal about the complex transmission properties and mechanical impedance of the human skull. Much of that work was done on cadaver heads and/or dry skulls. Only a few studies have investigated the acceleration responses or mechanical impedance on individual Baha patients in vivo. A novel technique was developed for assessing the mechanical impedance and acceleration responses on live Baha patients directly through the Baha abutment. A new transducer that was mechanically stiff through the vibrating central core was used (Håkansson, 2003). An accelerometer was mounted to the backside of the transducer and used to measure the acceleration response to a fixed level input, when the transducer was connected to 28 adult Baha patients. Changes to the load (Baha user) side of the transducer resulted in considerable differences in acceleration responses. The acceleration data also were used in combination with a force response from a skull simulator to derive the mechanical impedance responses.

5.1.1.2 Conclusions

- Direct bone conduction thresholds are difficult to predict from the HL audiogram.
- The range of acceleration or impedance responses can vary substantially from subject to subject.
- The mechanical impedance and the skin and tissue likely combine to ensure that the transform from transcutaneous to percutaneous bone conduction remains relatively unpredictable from subject to subject.
- Audiologists should be aware that the borderline Baha candidates according to manufacturer specifications using a traditional bone conduction oscillator may provide reasonable estimates in some cases, and may be off by a considerable margin in others.
- It is potentially problematic to rely too heavily on manufacturer specifications or average coupler responses when attempting to understand how the Baha will function on a given user. The same device measured on a skull simulator may have very different vibratory characteristics when connected to a patient, depending on the mechanical impedance of the patient's skull and tissue.
- It would be beneficial to continue to gather trans- and percutaneous threshold data to determine if the predictive relationship improves with sample size. However, from a clinical perspective the findings presented in this series of studies are quite compelling.
- To capture the unique auditory characteristics of each Baha user, audiologists should consider measuring all hearing information and hearing aid information in-situ in direct mechanical quantities (e.g., acceleration level or perhaps force level).

5.1.2 Study 2: A Comparison of Three Approaches to Verifying Aided Baha Output

5.1.2.1 Summary

The primary goal of this study was to understand and characterize (as accurately as possible) the relationship between an individual's hearing and the aided response of the Baha (the audibility of amplified speech). The first study in this series of studies suggested that an in-situ approach to understanding this relationship likely would be necessary, given the variability from person to person or system to system. Two new in-situ methods of measuring the audibility of amplified speech in 24 Baha users have been proposed: Real Ear and Accelerometer. For the Real Ear approach, a probe microphone in the ear canal was used to measure the sound pressure level of all auditory and hearing aid responses delivered through the Baha abutment. For the Accelerometer approach, an accelerometer mounted to the back of a special transducer was used to measure the acceleration of all auditory and hearing aid responses delivered through the Baha abutment. We contrasted the estimates of aided sensation level derived with these 2 new methods with a more traditional aided soundfield threshold approach.

A secondary interest in this study was the determination of "ideal" vs. "functional" dynamic range of hearing. Ideal dynamic range of hearing was determined with the audiometer and represented the range, in dB, between the thresholds and LDLs for the Baha users. Functional dynamic range for most users was represented by the range, in dB, between thresholds and the MPO of the Baha.

5.1.2.2 Conclusions

- For the most part, the aided soundfield approach overestimated speech audibility compared to the real ear and accelerometer approaches. This was mostly due to the fact that low-level warble tones were used to derive the aided response. When measuring the aided Baha response directly on a patient, non-linearities in the aided response occurred with average-to-loud inputs reducing the actual aided output of the Baha.

- In aggregate form, the real ear and acceleration approaches provide fairly similar estimates of sensation level for the mid-frequencies (500 to 2000 Hz). However:

    - The low frequencies (250 Hz) for the real ear approach are potentially invalid, because much of the low frequency speech appears to have been able to enter the ear canal through the earplug where it was picked up by the probe microphone

    - The high frequencies (4000 Hz) for the real ear approach are potentially invalid because the noise floor of the probe microphone interferes with measurement of the soft high frequency components of speech in the ear canal.

- Ideal dynamic range is potentially smaller than would be expected, and functional dynamic range is significantly limited by the MPO of the Baha. There was considerable headroom available for most of the patients. However, the test Baha used in this study did not have sufficient output to reach the users LDLs.

- More research is needed to determine loudness scaling by direct bone conduction. It may be helpful to use patients with normal bone conduction hearing at all frequencies (e.g., individuals with implant-retained auricular prostheses secondary to traumatic loss) to determine whether their ideal dynamic range by bone conduction differs from their air conduction dynamic range and the dynamic range of a series of Baha patients with normal cochleas.

5.1.3 Study 3: Technology-Limited and Patient-Derived Versus Audibility-Derived Fittings in BAHA Users: A Validation Study

The goal of the final study in this series was to determine if fitting (and verifying) the Baha according to an audibility-derived (AD) approach resulted in improved outcomes compared to the traditional patient-derived (PD) fitting approach commonly-used today. The audibility derived fitting was based on each Baha user's dynamic range of hearing directly through the Baha in acceleration. A modified prescriptive procedure used for air conduction hearing aids (DSL m[i/o]) was used to map the aided Baha responses of a master Baha (measured in acceleration) onto each patient's dynamic range of hearing, also in acceleration. For the patient-derived fitting, the Baha user's current settings were matched with the master Baha.

Several outcomes were investigated including: aided sensation level of speech, sentence recognition in quiet and in noise, consonant recognition in noise, aided loudness and subjective intelligibility of speech.

5.1.3.1 Conclusions

- Sensation level estimates of aided speech were considerably higher with the AD approach. The estimates increased with increasing frequency. Also, the largest difference occurred with the softest speech inputs, owing to the WDRC compression used in the AD fitting.

- Significant improvements on both the HINT in quiet and in noise were found with the AD protocol. Although, the effects were large, it may have been the case that insufficient targets were used to derive the AD fitting. More work is needed to determine if performance can be improved to levels near normal with different fitting targets.

- Consonant recognition in noise also improved significantly, which lent support to the HINT findings with sentence level materials.

- Aided loudness measures indicated that there were no significant differences in perceived loudness between the AD and PD fitting protocols. There was a trend for soft speech to be considered louder with the AD approach, though this did not reach statistical significance. As with study 2, there appears to be an opportunity for additional research regarding loudness perception by direct bone conduction.

- Subjective percentage of words understood showed no significant differences between approaches.

- This study provided important validation support of the acceleration verification procedure described in study 2. The approach allowed for an accurate characterization of dynamic range and direct comparison of aided speech within that dynamic range.

- The fitting was based on a well-validated air conduction procedure. However, it remains to be seen whether the targets used in the current study were ideal or if even better performance could be obtained with a different set of targets.

5.2 Final Thoughts

There are a few final points to consider. What if the MPO of the Baha cannot be raised to the levels used in Study 3? In reality, the battery consumption required to drive the Baha at levels such as those in Study 3 may result in unacceptable battery life, which raises doubts about the benefits of increased headroom and whether it outweighs a shortened battery life. Related to that, will increasing the gain and MPO to "audibility-derived" levels result in unacceptable amounts of feedback? Feedback was not a problem in this series of studies. However, these studies were all done in a controlled laboratory setting and the results may not reflect the environments and situations in which feedback may become problematic in the real world. As the algorithms for feedback cancellation continue to improve, this may be only a marginal concern. Finally, perhaps the most important question is, "How will this dissertation affect an audiologist's practice in a busy clinic on Monday morning?"

In this series of studies, the investigator's efforts were focused on acceleration responses. Acceleration represents the most direct measure of skull vibrations. However, short of having a considerable amount of specialized equipment, audiologists may be wondering how to include this information in their practices. No doubt audiologists felt the same way in the 1980's and early 1990's when probe microphone measures began to replace behavioural measures as the most accurate, valid and reliable method of measuring the responses of air conduction hearing aids. Clinician's may justifiably take the view, "It's fine for you with all your research equipment, but I don't have the money or the time for all these extra measures." The answer to this complaint is two-fold. First, acceleration is not necessarily the only method that can be used to assess direct bone conduction hearing and hearing aid responses. It may be possible to obtain force level results that are equivalent to acceleration level results. The advantage of the force level approach would be its ability to map and measure all hearing and hearing aid information to a skull simulator or coupler. A new series of studies will address the accuracy of this force level approach, but if it proves viable, only a small amount of special equipment would be required and the processes would directly parallel coupler-based measures of air conduction hearing aids. Second, in light of the promising findings related to acceleration level information from this series of studies, clinical audiologists need greater support from companies that manufacture Bahas and from companies that manufacturer hearing aid analyzers to provide them with integrated and seamless clinical solutions. There were no measures done for Baha output responses in this series of studies that were any more complicated or time-consuming than similar measures for air conduction hearing aids, if properly integrated equipment were to become available.

The findings from this series of studies justify the following general statements related to the fitting and verification of Baha:

1. Whenever possible, all hearing aid selection and prescription decisions should be based not on the HL audiogram, but rather, on the direct bone conduction dynamic range determined in-situ with direct mechanical quantities (e.g., acceleration or force).
2. Whenever possible, all hearing aid verification should be done in direct bone conduction mechanical quantities, so actual Baha-aided output can be compared directly to each user's unique auditory needs.
3. Engineers developing Baha are strongly urged to consider creating devices that are more flexible in terms of their frequency shaping abilities and processing (compression) technology to give audiologists greater control over the programmability of the Baha to meet individual patients' needs.