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A Sound Foundation Through Early Amplification

Proceedings of the 7th International Conference 2016

Prescription and verification considerations for bone conduction device users

Bill Hodgetts, Ph.D.

Abstract

The last 10 years has seen tremendous expansion in the field of bone conduction devices (BCDs). From a time when there was only one company offering technology to a small group of patients, clinicians, and researchers, there are now several new companies and many new clinicians and researchers helping patients with ever-expanding candidacy criteria and treatment options. However, unlike air conduction hearing aids, there is still a relatively underdeveloped body of literature with respect to how BCDs are verified and prescribed. This is particularly true for the pediatric populations that have devices that include skin in the bone conduction pathway.

In this chapter, I will review the challenges of prescription and verification procedures for percutaneous devices (e.g., Baha® and Ponto® device. I will also review an approach to developing and implementing a BCD prescription (based on Desired Sensation Level v5) with the use of a skull simulator for verification.

Finally, I will discuss the new BCD technologies with skin in the measurement pathway and explore the challenges and potential solutions under evaluation for verifying and prescribing output for these new devices.

Introduction

For the last many years, our research and clinical teams have been working on solving two primary knowledge-to-action gaps in the field of bone conduction devices (BCDs):

1. Clinicians are concerned that they do not have sufficient tools or knowledge on how to verify the output of BCDs (verification); and
2. Clinicians are concerned that they are relying on manufacturers' settings rather than independently validated prescriptive approaches and procedures for fitting the BCDs (prescription).

At the core of any hearing aid fitting is a very basic idea that has been with us for many years. For a hearing aid fitting to be successful, there should be a "good match" between all of the known auditory needs of the individual seeking hearing help and the acoustic or (in the case of BCDs) mechanical characteristics of the device (Seewald et al., 1995). Although this notion might seem straightforward, a glance at Figure 1 shows only some of the many considerations that need to be taken into account on both the individual and the hearing aid side of this "match." For example, in BCD users, the thresholds by bone conduction matter a great deal more than in air conduction fittings because they reveal the type of hearing loss that is relevant for BCDs. These devices were originally designed and intended for use on individuals with conductive or mixed hearing loss due to chronic middle ear disease or for those born without ear canals. Over the years, candidacy has expanded to include individuals with single-sided deafness (SSD; Wazen et al., 2003; Hol et al., 2010). Obviously, thresholds are not enough. We need to consider lifestyle, perceived handicap, expectations, and more. And, in the case of bone conduction devices, we need to consider additional factors such as the transmission from skull to the cochlea, the method of connecting the device and whether it includes skin or not in the transmission pathway (more below). Additionally, the interaural attenuation is especially important for SSD patients and needs to be considered carefully (Eeg-Olofsson et al., 2011). There are also significant differences in the impedance properties with which a BCD interacts (a skull) compared to the impedance properties with which an air conduction hearing aid (ACHA) interacts (an eardrum). These differences in impedance and coupling have an influence on the frequencies that can be transmitted effectively by bone conduction compared to air conduction. Bone conduction transducers (at the time of writing) transmit best in the 500 to 3000 Hz regions but are capable (at least to some degree) of a bandwidth between approximately 250 and 8000 Hz.

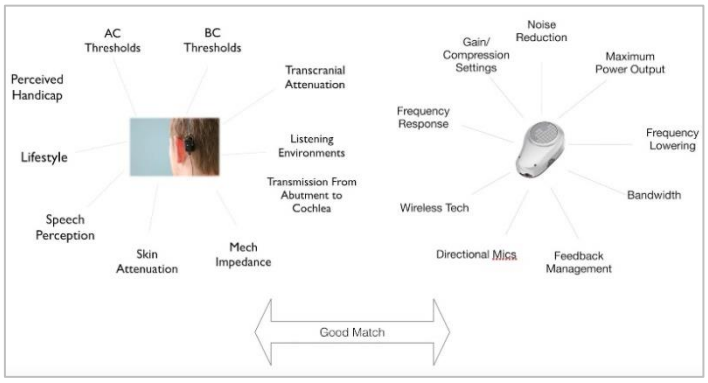

Figure 1. Some of the many considerations that are necessary to find a "good match" between the auditory needs of an individual and the mechanical properties of a bone conduction device.

If we consider the right side of Figure 1, we see many familiar factors to consider from ACHA, like gain by frequency response and compression. However, much of what we know about gain by frequency response and compression comes from research into ACHAs. Many BCD users (those with purely conductive losses) have mostly normal bone conduction thresholds. One might think that compression would be unnecessary for these individuals because the cochlea is likely to have a fairly normal dynamic range. However, the maximum power output of BCDs is often quite limited. This is because the head is a very difficult object to vibrate compared to a tiny eardrum. Whereas air conduction hearing aids can potentially exceed an individual's upper limit of comfort, BCDs often cannot (Hodgetts, 2008). For example, Figure 2 shows the "ideal" versus "functional" dynamic range of hearing in BCD users. Hodgetts (2008) measured the loudness discomfort level (LDL) for bone conduction pure tones using a special high-power vibrator connected to an audiometer. The open circles show the average loudness discomfort levels (LDL) results from 16 BCD users. Also plotted on this figure with the top solid line is the maximum power output (MPO) of the BCDs used at the time of the study (Baha Intenso™). It is unimportant that the y-axis is displaying acceleration instead of the more commonly used force for BCDs. It is the relationship difference in decibels that is important. The upper ceiling of a BCD user's dynamic range of hearing is limited by the device instead of their LDL. That is why the dynamic range is referred to as "functional" versus "ideal". Although many new processors have been released, only recently are we starting to see MPOs that are higher than older models. However, they are still not likely, in most cases, to exceed the LDL of BCD patients. Therefore, to return to our consideration of gain and compression for the individual with conductive hearing loss, we need to do more investigating about the value and need for compression in the case of a patient using a BCD device when the dynamic range is limited by the functional capabilities of the BCDs' MPO versus the loudness discomfort level of patients. As seen below, this has important

consequences for the prescription of targets for an individual's dynamic range of hearing.

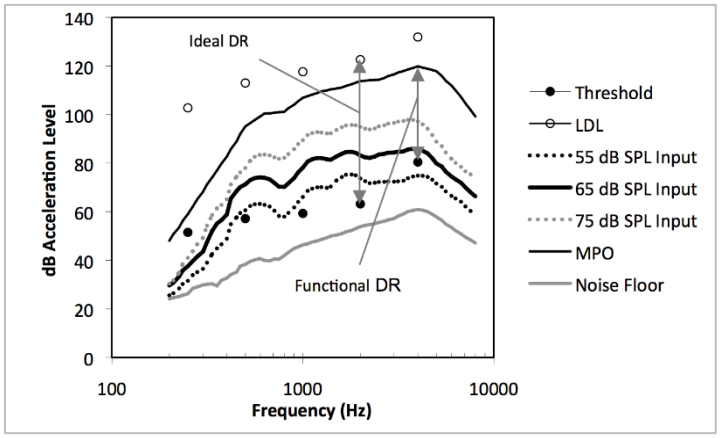

Figure 2. Demonstration of "ideal" versus "functional" dynamic range of hearing in bone conduction device users. The MPO of BCDs is almost always lower than the LDL of BCD users. DR = dynamic range; LDL = loudness discomfort level; MPO = maximum power output; SPL = sound pressure level.

Choices, choices, choices

In the past, there were few bone conduction options for individuals with conductive or mixed hearing loss. Most devices were on a headband or occasionally attached to the arms of eye glasses. However, in 1977, Tjellström and Granström implanted the first patient with a bone anchored hearing aid (BAHA; 1994). The basic principle was to take a titanium dental implant and place it behind the ear in the parietal-mastoid region of the skull until it integrated into the bone. There was then an abutment (connector) that would protrude through the skin allowing for the direct connection of a vibrator to the skull rather than to the skin (see Figure 3). This approach had several key advantages over the old headband style BCDs including: 1) better sound transmission; 2) improved comfort; and 3) better aesthetics. For many years, the BAHA was the primary option for individuals needing BCDs. The field had generally agreed that better sound transmission by direct bone conduction was worth the trade-offs for the possibilities of implant losses (i.e., extrusions) and skin reactions around the abutment (Reyes et al., 2000; Snik, Mylanus, Proops & Wolfaardt, 2005).

Figure 3. Example of a current percutaneous bone conduction device (Baha® 5) that connects through the skin via an implant and abutment. Image courtesy of Cochlear Corporation.

Over time, new technologies emerged and there has been an increasing interest in the bone conduction market. We have seen new companies, clinicians, and researchers enter the field and introduce new ideas and sometimes updated old ideas. There are now many more options available to people who might benefit from a BCD. Figure 4 shows a classification structure based on Reinfeldt et al.'s study (2015) that can be helpful when considering all the BCD options. In broad terms, there are two methods of delivering sound to the skull. One method involves a direct connection between the *vibrator* and the skull (direct drive) and the other method involves a connection to the skull that includes the skin in the vibration pathway (skin drive). Skin drive devices are similar (in principle) to the old headband style of hearing aid. The vibrator is coupled to the patient either via an elastic headband (softband) or by magnets (one implanted and one on the skin). In all cases, the vibrator will lose some energy to the skin before it reaches the skull. The amount of energy lost to the skin depends on the frequency and is highly individual and variable. Figure 5 shows results from Verstraeten, Zarowski, Somers, Riff and Offeciers (2009) and our own lab results for an unpublished replication study we performed. Skin drive has the largest loss in the high frequencies, but it is the inherent individual variability that is most challenging. We have trouble predicting from skin drive thresholds how much an individual will benefit from a direct drive device. Audiologically, it does not make sense to keep the skin in the vibration pathway. However, there are many reasons why skin drive is still recommended. Firstly, many patients are too young for the surgery and have skulls that are too thin to accommodate the implant (Priwin & Granström, 2005). In the United States, the Food and Drug Administration (FDA) mandates that children need to be at least five years old before having an implant. Additionally, the highest number of implant problems and skin problems occur in children, which makes the skin drive appealing as it mostly removes potential site infection as a barrier to hearing. Finally, many people live far away from specialty centres that offer BCDs and routine checkups on the skin can be difficult. Therefore, they might choose skin drive devices as an option.

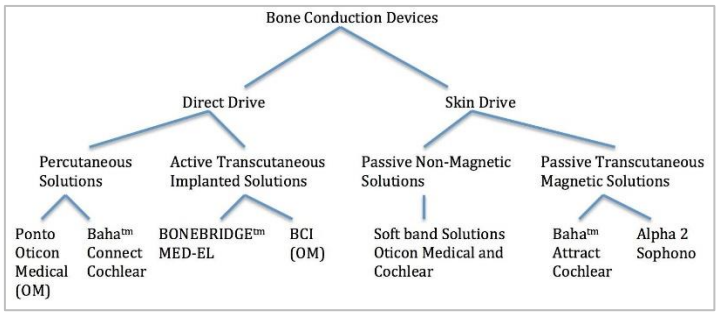

Figure 4. Classification scheme for current bone conduction devices.

On the direct drive side, there are percutaneous options that were introduced above in Figure 3 and these are still the most common types of BCD. Here there are two primary families of devices: the Baha® (Cochlear) and the Ponto® (Oticon Medical). We will discuss the prescription and verification approaches for these devices below. Two other options are presented on the direct drive side: the BCI® and BONEBRIDGE®. For both of these devices, the active vibrator is implanted under the skin and the signal from the processor is passed to the vibrator via an inductive link (similar to a cochlear implant). In theory, these devices have all the benefits of direct drive (no loss of energy to the skin) and all the benefits of skin drive (limited infections and implant loss). However, at present, neither device is approved in the United States. The BONEBRIDGE® has been approved in Canada and Europe for some time for both adults and children (Huber et al., 2013) while the BCI® is still undergoing clinical trials in Europe (Reinfeldt, Håkansson, Taghavi, & Eeg-Olofsson,, 2015). From a pediatric perspective, in some countries the BONEBRIDGE® can be implanted in young children and adolescents. However, very careful consideration and surgical planning must be undertaken in these cases because the skull is so much thinner and the vibrator is quite large (Hessepass et al., 2015).

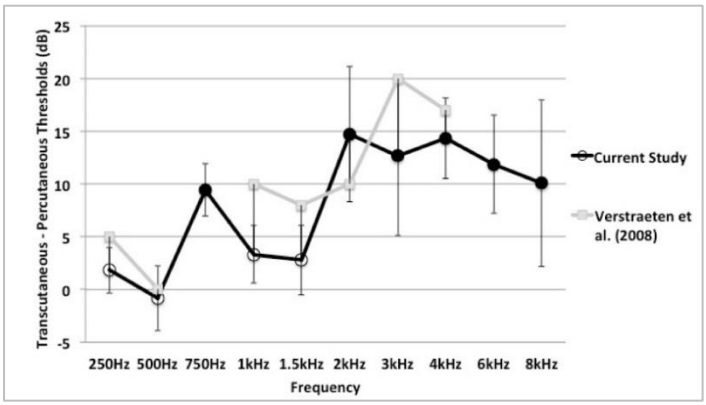

Figure 5. Threshold differences between skin drive and direct drive from two experiments. Errors bars represent +/- 95% confidence intervals.

Which device?

How does one go about choosing a device? It is important to put this choice into context. Whenever possible, decisions about which device is best for a patient should be based on the available evidence with respect to device and surgical outcomes and should be determined jointly with the interdisciplinary team overseeing the patient. At a minimum, this should include the audiologist and surgeon but might also include many other healthcare and support professionals. As many of these new devices and approaches are still in their early phases of testing and evaluation, it is likely that not all decisions will be based solely on the "best outcomes", but more on factors related to surgical interest in a particular device or the patient's ability to maintain a clean implant site (in the case of percutaneous BCDs), or an audiologist's persistence that too much signal would be "lost to the skin". Maybe the distance the patient has to travel matters or perhaps the health care payers only cover a certain device. The deciding factors are far from trivial.

For children under the age of five years, we are really left with one approach. As stated earlier, the FDA mandates that children cannot have surgery for a BCD until they are five years old. Therefore, we must use a soft headband with either the Oticon Ponto® family of processors or the Cochlear Baha® family of processors. Soft headbands are elastic headbands with a hard plastic coupling that can be adjusted on the head of a child to deliver vibrations to the skull. Ideally, the device should be worn on the mastoid, but with infants, who are often in car seats or other chairs/strollers, mastoid placement is less convenient. We usually recommend that the devices be brought to the temple region when in a car seat. Also, we recommend that the tension of the headband not be too tight. There is not a large gain in output by increasing the tension much beyond two Newtons (the approximate tension that keeps the band securely in contact but also allows you to slide one finger under the band; Hodgetts, Scollie & Swain, 2006). As mentioned above, there is little likelihood that the BCD will produce so much output that it could cause hearing damage, but it is usually recommended to set the volume near either the manufacturer's recommended setting or (as we will see below) a DSL v5 recommended target and then deactivate the volume control.

Verification and prescription for BCDs

Despite all of the known challenges and limitations, one of the primary outcome measures still used to document gain of BCDs is aided soundfield thresholds (Hawkins, 2004; Hodgetts et al., 2010). One might present the higher aided soundfield thresholds of one device versus another as evidence that it is the better device. Often there will be no comparison group at all or the aided thresholds will be compared to the unaided thresholds only. Although such measures provide audiologists with validation that the device is working and that the patient is hearing soft warble tones in quiet, it is not a valuable verification measure with respect to aided speech (Hodgetts et al., 2010). Little about the results of a person hearing a soft warble tone can be used to inform an audiologist how to adjust the processor and make changes to improve performance. Unfortunately, for all the devices that have intact skin in the pathway (both skin drive and active transcutaneous), what is presented below is not yet available for prescription and verification.

Skull simulator prescription and verification

The approach for prescribing and verifying percutaneous BCDs follows a very similar approach to real ear verification for air conduction hearing aids. It defines an individual's dynamic range of hearing in some common metric at some common point, and then provides targets for aided speech within that dynamic range of hearing. For ACHAs, the common metric is sound pressure level (SPL) and the common point is the ear canal. In the case of BCDs, the common metric is force level (FL) and the common point is the percutaneous abutment. Figure 6 shows how we define these two common metrics and points for ACHAs and BCDs.

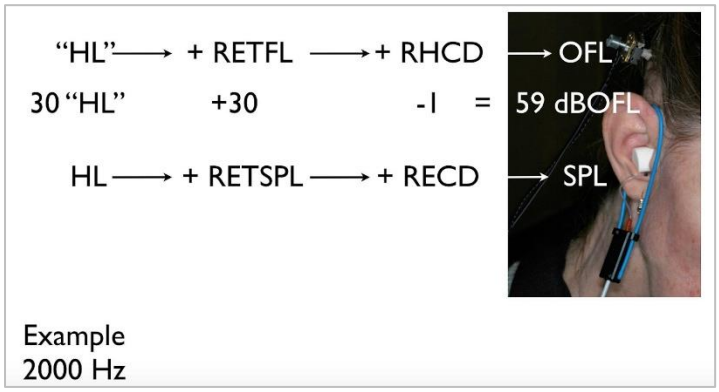

Figure 6. Defining common metrics and common reference points for ACHAs and BCDs. RETSPL = Reference equivalent threshold sound pressure level; RECD = Real ear to coupler difference; RETFL = Reference equivalent threshold force level; RHCD = Real head to coupler difference; OFL = Output force level

Figure 7 shows the functional dynamic range of a patient defined in FL at the percutaneous abutment. The bottom line represents the "0 dB HL" normal hearing curve in direct bone conduction. This is the reference equivalent threshold sound pressure level (RETFL). The middle line represents the softest sounds in FL that this particular patient can hear. The upper line represents the MPO of the device under consideration for this patient. Recall that the upper limit of the dynamic range in this case is the MPO of the device and not necessarily the LDL of the patient. Once the dynamic range is defined, we can use a prescriptive method such as DSL v5 to map targets for aided speech into that dynamic range. Recently, Oticon Medical has included prescription and verification formulae into their latest version of their fitting software. Now, clinicians can measure thresholds directly through the abutment with the patient's Ponto device. The corrections from Figure 6 will be automatically applied and the software will plot the dynamic range in force level.

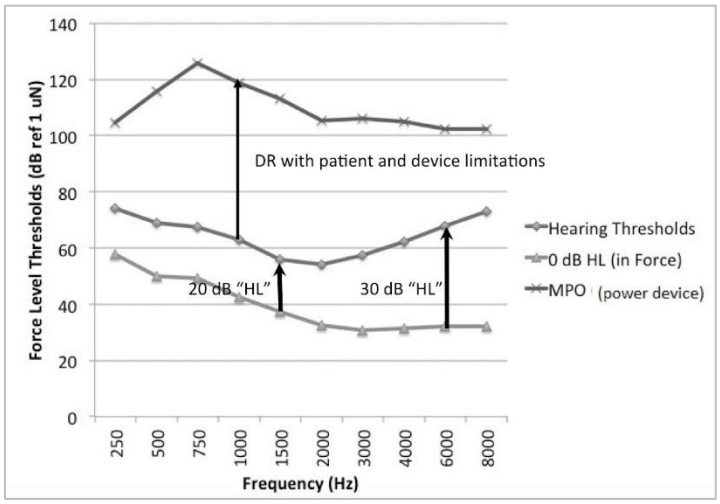

Figure 7. Force level dynamic range of hearing.

The Genie Medical software shows everything in force and it is often a very good representation of reality. However, to truly verify a BCD one must use some objective measure either on the head of the patient or by means of a coupler. For percutaneous BCDs, a Skull Simulator is recommended as they are used to measure the actual force response from a BCD, which allows for the FL responses of the hearing aid to be measured directly and compared to the expected targets within the software. We now have a direct method of comparing output force of the BCD to the targets and thresholds of an individual patient that is logically equivalent to the familiar real ear measures for ACHAs.

Conclusion

We still have much to learn with respect to fully closing the knowledge-to-action gaps listed above, especially with pediatric patients and for those individuals who choose a BCD that has skin in the transition pathway. Additional work is needed to solve these problems and move bone conduction prescription and verification procedures closer to the well-established and valid procedures we use in ACHAs.

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Author

Bill Hodgetts, Ph.D.
Associate Professor
University of Alberta and the Institute for Reconstructive Sciences in Medicine
Edmonton, Alberta, Canada
bill.hodgetts@ualberta.ca

Editors

Anne Marie Tharpe, Ph.D.
Chair, Phonak Research Advisory Board
Professor and Chair
Department of Hearing & Speech Sciences
Vanderbilt University School of Medicine
Nashville, Tennessee, United States

Marlene Bagatto, Ph.D.
Research Associate and Adjunct Research Professor
National Centre for Audiology
Western University
London, Ontario, Canada