

Development of a Novel Bone Conduction Verification Tool Using a Surface Microphone: Validation With Percutaneous Bone Conduction Users

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Objectives: To determine if a newly-designed, forehead-mounted surface microphone would yield equivalent estimates of audibility when compared to audibility measured with a skull simulator for adult bone conduction users.

Design: Data was analyzed using a within subjects, repeated measures design. There were two different sensors (skull simulator and surface microphone) measuring the same hearing aid programmed to the same settings for all subjects. We were looking for equivalent results.

Patients: Twenty-one adult percutaneous bone conduction users (12 females and 9 males) were recruited for this study. Mean age was 54.32 years with a standard deviation of 14.51 years. Nineteen of the subjects had conductive/mixed hearing loss and two had single-sided deafness.

Methods: To define audibility, we needed to establish two things: (1) in situ-level thresholds at each audiometric frequency in force (skull simulator) and in sound pressure level (SPL; surface microphone). Next, we measured the responses of the preprogrammed test device in force on the skull simulator and in SPL on the surface mic in response to pink noise at three input levels: 55, 65, and 75 dB SPL. The skull simulator responses were converted to real head force responses by means of an individual real head to coupler difference transform. Subtracting the real head force level thresholds from the real head force output of the test aid yielded the audibility for each audiometric frequency for the skull simulator. Subtracting the SPL thresholds from the surface microphone from the SPL output of the test aid yielded the audibility for each audiometric frequency for the surface microphone. The surface microphone was removed and retested to establish the test-retest reliability of the tool.

Results: We ran a 2 (sensor) \times 3 (input level) \times 10 (frequency) mixed analysis of variance to determine if there were any significant main effects and interactions. There was a significant three-way interaction, so we proceeded to explore our planned comparisons. There were 90 planned comparisons of interest, three at each frequency (3 \times 10) for the three input levels (30 \times 3). Therefore, to minimize a type 1 error associated with multiple comparisons, we adjusted alpha using the Holm-Bonferroni method. There were five comparisons that yielded significant differences between the skull simulator and surface microphone (test and retest) in the estimation of audibility. However, the mean difference in these effects was small at 3.3 dB. Both sensors yielded equivalent results for the majority of comparisons.

Conclusions: Models of bone conduction devices that have intact skin cannot be measured with the skull simulator. This study is the first to present and evaluate a new tool for bone conduction verification. The surface microphone is capable of yielding equivalent audibility

measurements as the skull simulator for percutaneous bone conduction users at multiple input levels. This device holds potential for measuring other bone conduction devices (Sentio, BoneBridge, Attract, Soft head-band devices) that do not have a percutaneous implant.

Key Words: Audibility, Bone conduction amplification, Force, Sensation level, Sound pressure level, Verification.

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INTRODUCTION

Objective assessment of audibility provided to an individual patient by bone conduction devices (BCDs) has remained an elusive challenge for many years (Hodgetts et al. 2010, 2011; Dillon 2012). Unlike the fitting of air conduction hearing aids, where individual real ear measures have validated, understood, and well-defined processes where both the targets for amplification and the actual output of the device can be assessed on the same SPLogram or SpeechMap, clinicians working with bone conduction still often resort to the use of aided soundfield thresholds to assess the fitting of the BCD. Unfortunately, aided thresholds are known to provide limited information regarding: (1) the output of the BCD with respect to speech or a speech-like input, (2) the dynamic range (DR) of the device, or (3) the input/output characteristics of the device under test. Moreover, the poor test-retest reliability of aided thresholds limits their usefulness significantly (Hawkins 2004). Objective alternatives to aided soundfield thresholds for BCDs have been investigated. For example, Hodgetts et al. (2010) assessed the sensation level of aided speech by bone conduction using three methods: aided thresholds, real ear sound pressure level (SPL), and an accelerometer on the moving mass of the bone conduction transducer. The authors found that all three approaches to estimating sensation level lead to different answers even though the output of the bone conduction study device did not actually vary. The aided thresholds overestimated the aided speech. The ear-canal SPL was contaminated in the low frequencies by soundfield speech entering the ear canal and adding to the measurement and by the limited sensitivity of the microphone in the high frequencies. The accelerometer approach provided an accurate representation of the bone conduction output but remained an impractical measurement tool for individual patients because there is no access to the moving mass of the transducer in the clinic.

SPLogram

Broadly, verification requires a method that allows the clinician to define the DR of hearing in some common metric at some common location. In the case of air conduction hearing aids, this method involves transforms and steps that allow for the definition of threshold and loudness discomfort levels in dB SPL at the common reference point of the ear canal. Once the DR of hearing is defined, prescriptive algorithms such as DSL v5 or NAL NL2

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(Seewald et al. 2005; Keidser et al. 2011) can be used to map targets for aided speech at multiple inputs into that individual DR of hearing. Real ear probe microphones or transform-corrected coupler-based measures are used to assess the actual output of the device against the targets for multiple input levels (Hodgetts & Scollie 2017). Finally, the clinician assesses with the patient (assuming it is not a young child) the adequacy of the fitting based on their subjective feedback, and further adjustments are made, or a period of acclimatization is recommended.

FLogram

Hodgetts and Scollie (2017) have put forward a method that allows for a similar verification approach to a coupler-based SPL approach for percutaneous BCDs. They used in situ thresholds from the manufacturer's software and the patient's own device to determine the force response at threshold using a skull simulator. Again a series of transforms (reference equivalent threshold force levels in direct bone conduction and Real Head to Coupler Difference [RHCD]) are required to move the thresholds to real head force level to serve as the bottom of the DR of hearing (see Hodgetts & Scollie 2017 for more detail). Unlike air conduction hearing, where the hearing aid has only a small mass, low-impedance eardrum to vibrate, BCDs are coupled to a large head with high impedance. At the time of writing, the maximum power output (MPO) of BCDs remains lower than the loudness discomfort levels (LDLs) of most bone conduction users. Hodgetts (2008) found that a power device with MPO similar to those of today's transducers was, depending on frequency, approximately 10 to 15 dB lower than measured LDLs. This implies that, when dealing with a BCD, the upper limit of the DR of hearing is more likely to be the MPO of the device under test and not the actual LDL of the patient. The DR of the FLogram is, thus, defined at the bottom end by the individual's sensorineural thresholds and at the upper end by the limited MPO of the device.

Skull Simulator and Skin Involvement

The verification methods proposed by Hodgetts and Scollie (2017) are currently valid only for percutaneous BCDs. Since we can easily move the processor between the patient's head (for thresholds) and the skull simulator (for device output measurements), so long as the appropriate transforms are applied, we can directly compare the force-level targets generated by DSL-BCD v1.1 to the actual output of Ponto or Baha devices.

While percutaneous solutions remain very common in the field of bone conduction, a number of technologies have been released in recent years that leave intact skin in the vibration pathway (see Reinfeldt et al. 2015 for a thorough review). When this is the case, the correspondence between the in situ threshold measures on the patient and the subsequent output of the device on a skull simulator cannot be easily compared since components in the vibration pathway are either under the skin (e.g., BoneBridge or Sentio) or in the case of Baha Attract, Medtronic Sophono, or a Ponto/Baha on a Soft Headband, the vibrations have to travel through skin, which is well known to be highly variable from person to person and cannot be replicated with a simulator (Håkansson et al. 1984; Mylanus et al. 1994).

One way to get around the challenges of implanted vibrators or skin transmission is to measure thresholds and device output directly on the patient. In this case, there would be no need to remove the vibrator to assess its output, and the highly variable

skin component would be included in the measures, therefore, negating its influence on an individual basis as it is included and accounted for in the measures of threshold and aided output.

Current Objective

In this article, we present a novel verification tool for BCDs that utilizes a sensitive microphone worn on the forehead of patients and show how this device can yield equivalent results to the current skull simulator approach for percutaneous BCDs.

MATERIALS AND METHODS

Study Participants

Twenty-one adult percutaneous bone conduction users (12 females and 9 males) were recruited for this study. Mean age was 54.32 years with a standard deviation of 14.51 years. Nineteen of the subjects had conductive/mixed hearing loss and two had single-sided deafness. All participants consented to participation in accordance with the health research ethics boards at the University of Alberta and the Institute for Reconstructive Sciences in Medicine. All subjects had a percutaneous abutment with a snap coupling that was compatible with the test device (Oticon Ponto Plus Power).

Experimental Setup

Surface Microphone • The novel forehead-mounted measurement tool discussed herein is a custom system comprising three primary elements: (1) an off-the-shelf Sonion model 66BB30 electret condenser microphone, (2) an analog amplifier circuit utilizing a Texas Instruments model OPA172 operational amplifier designed to provide 20× gain, and (3) a custom-designed and machined polymer housing. The circuit in question utilizes passive components for gain setting and power stage decoupling. Together, these elements create an acoustic measurement tool suitable for measuring low-level, skin-based acoustic emissions from a bone conduction user's forehead. The device is pictured in Figure 1.

Force Probe for In Situ Thresholds • To directly measure force-level in situ thresholds (dBN), a standard BCD Oticon Ponto Plus Power was modified. This modification involved adhering a small, light-weight MEMS accelerometer to the moving mass of the bone conduction transducer, facilitating real-time measurement of the acceleration of the force-producing moving mass. Using Newton's Second Law, the measured acceleration, and the fact that the mass of the device is a known quantity, the force produced by the BCD was calculated. Care was taken during this modification to ensure that the internal circuitry and overall mechanical characteristics of the device went unaltered. This was verified by measuring force-level performance before and after the addition of the accelerometer.

Master Device Description • While everyone in the study had different thresholds, we decided to fix the master hearing aid to one prescription so that the only thing that varied with respect to audibility would be the individual's thresholds. While this does not make sense in clinical practice, this simplified our data collection and comparisons. Therefore, the master device used in this study for all soundfield-based measurements was an unaltered, preprogrammed, Oticon Ponto Plus Power. Programming was done using Oticon's Genie Medical software, with the device programmed to have a 20 dB HL hearing loss



Fig. 1. Renderings of the surface microphone. Green elements represent the circuit board and the led “on light” indicator.

across all audiometric frequencies (250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, and 8000 Hz), all automatic features switched off, and the microphones set to omnidirectional mode.

Testing System Description • All soundfield signals were generated, and all sensory data were measured using an Audioscan Verifit. Generated acoustic signals were routed through an externally connected Audioscan speaker, with level and frequency response being tuned in real time via the connected On-Ear reference microphone. The Verifit’s On-Ear system was calibrated using a custom cable so as to provide a flat 0 dB frequency response rather than the expected real ear probe tube frequency response. This ensured that measured sensory data does not have to be corrected by post-processing. All skull simulator measures were accomplished using a TU-1000 skull simulator modified and calibrated to be used with the Audioscan Verifit system.

Experimental Protocol

Force Probe Suprathreshold Correction • At each audiometric frequency, the force probe correction values were determined by placing the force probe on the skull simulator and measuring the response from the accelerometer on the backside of the device.

Master Device Characterization • To calculate sensation level estimates in the force domain, an understanding of the master device’s force output response was required. The characterization of the master device was accomplished using an Audioscan Verifit, the On-Ear reference microphone, and a connected skull simulator. The master device was coupled to the skull simulator, and the reference microphone was placed at the same level and in the same plane, as near as possible to the master device’s microphone ports, thus, ensuring calibrated and controlled pink noise stimuli. The force level output of the test device is shown in Figure 2 for pink noise stimulation at 55, 65, and 75 dB.

In Situ Audiometry • For each patient, individual in situ-level thresholds were determined at each audiometric frequency using the Genie Medical software program. The force probe was used for signal delivery through the patient’s abutment, and

thresholds were determined using the modified Hughson–Westlake procedure (Carhart & Jerger 1959). The in situ threshold measurements were done in a sound-treated booth.

Correcting Hearing Loss Thresholds to Force Thresholds

The experimental setup to determine the real head force-level thresholds for each patient is shown in Figure 3. The Genie Medical software program was used to deliver signals to the force probe at each audiometric frequency with a presentation level of 30 dB HL. The On Ear Measurements (Manual Control) option on the Audioscan Verifit was used to determine the force probe response values (dBN) at each frequency. The force probe threshold values were then corrected to 0 dB HL by subtracting the difference between the presentation level (30 dB) and the in situ patient threshold at each frequency.

$$F_{TH} = RH - (30 - IS_{TH})$$

where F_{TH} is the corrected force probe threshold value (corrected to 0 dB HL); RH is the real head force probe response (dBN); and IS_{TH} is the in situ patient threshold value.

Surface Microphone Thresholds • The experimental setup to determine the surface microphone response for each patient is shown in Figure 4. Again, the force probe was used for signal

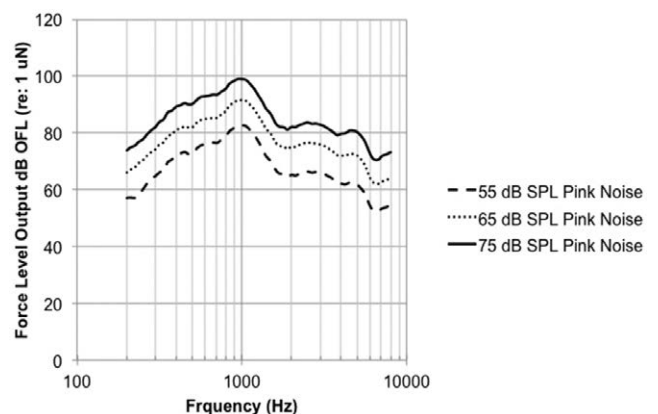


Fig. 2. Force level output of the test device.

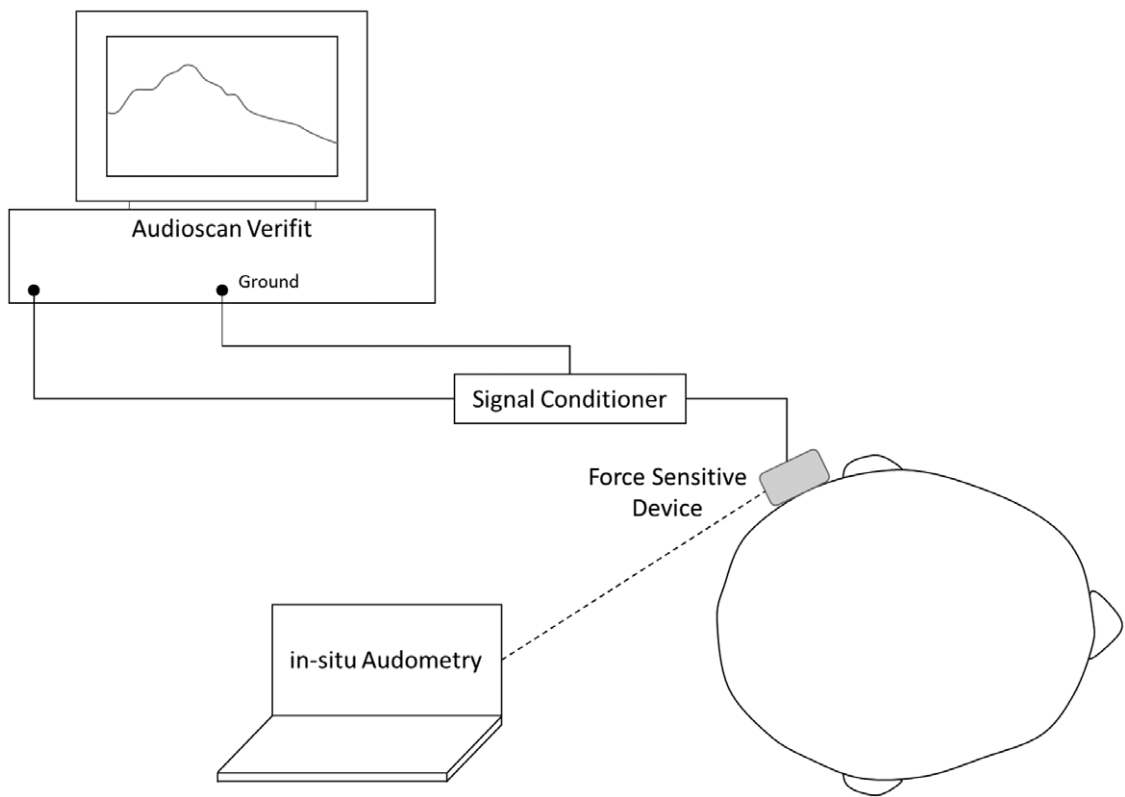


Fig. 3. Experimental setup for real head force probe response (RH) measurement.

delivery at each audiometric frequency with a presentation level of 30 dB. The surface microphone was mounted on the patient's forehead using a soft elastic strap to ensure a good connection with the skin. The On Ear Measurements (Manual Control) option on the Audioscan Verifit was used to determine

the surface microphone response at each frequency. The surface microphone SPL threshold values were then corrected to 0 dB HL by subtracting the difference between the presentation level (30 dB) and the in situ patient threshold at each frequency, similar to the force probe threshold correction described earlier.

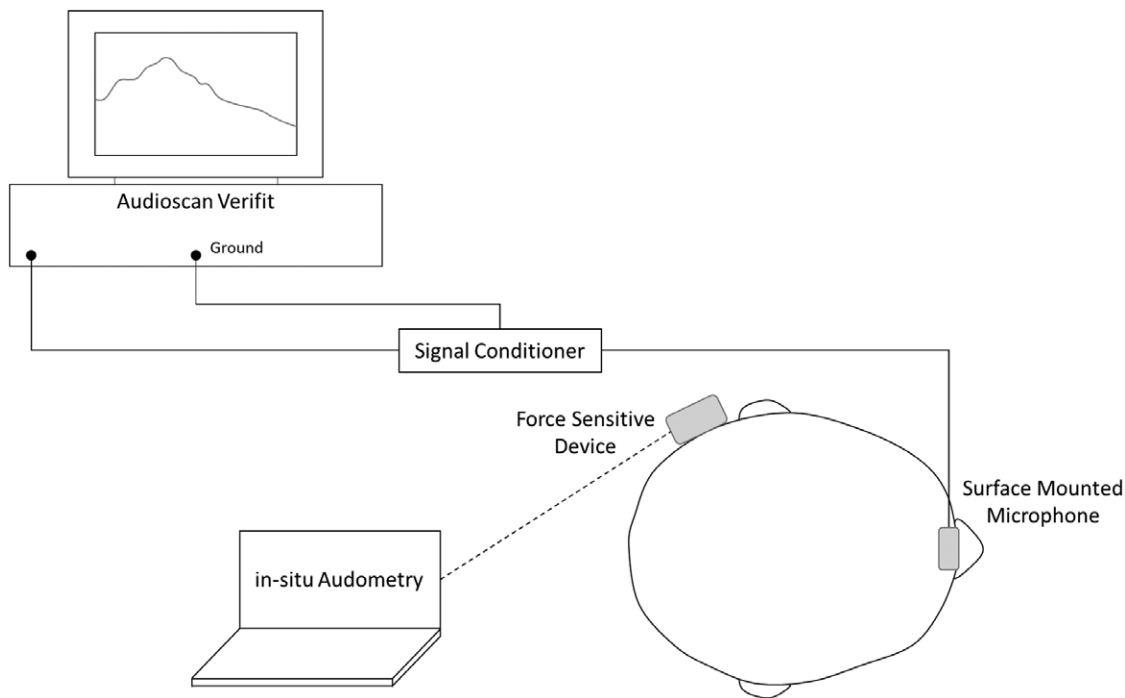


Fig. 4. Experimental setup for surface microphone response measurement.

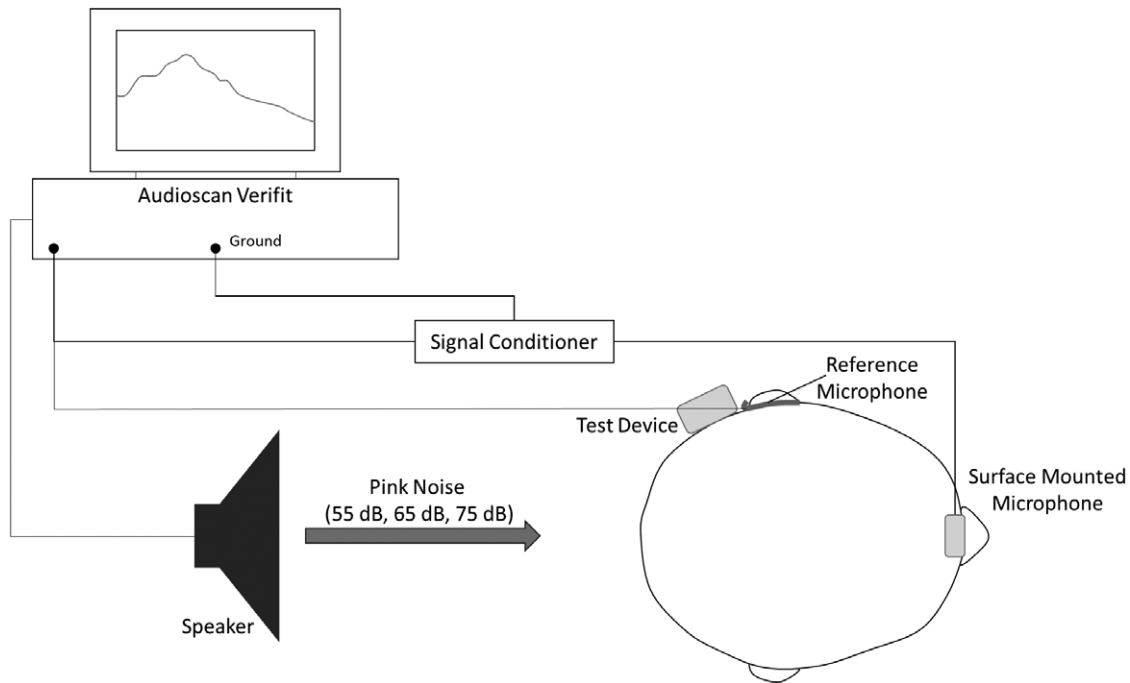


Fig. 5. Experimental setup for the surface microphone pink noise tests.

Surface Microphone Pink Noise Tests • The surface microphone audibility was ultimately determined by capturing the vibration of the forehead surface in response to pink noise presented at 55, 65, and 75 dB. The experimental setup for these tests is shown in Figure 5. The On Ear Measurements (Speech Map) option on the Audioscan Verifit was used to present the pink noise stimulation from a speaker located behind the patient. The master test device (Oticon Ponto Plus Power) was connected to the patient's abutment, and a reference microphone was placed on the ear next to the test device. The three levels of pink noise stimulation were presented under two conditions: (1) with the test device muted to establish the artificial noise floor of the surface microphone, and (2) with test device turned on to capture the aided response through the surface microphone. The response curves for each test were exported to a text file for further analysis.

Test–Retest • The surface microphone was removed from the patient and replaced to determine the test–retest reliability of the device. The surface microphone thresholds (Fig. 4) and the pink noise stimulation tests (Fig. 5) were repeated.

Data Analysis

Audibility: Skull Simulator • The skull simulator response values were converted to real head force responses at each stimulation level (55 dB, 65 dB, and 75 dB SPL) by means of an individual RHCD transform. The skull simulator audibility was determined by subtracting the corrected real head force probe threshold value from the real head force output of the test aid.

$$\text{Audibility}_{(\text{Skull Simulator})} = \text{MD} + \text{RHCD} - F_{\text{TH}}$$

where MD is the master device characterization at each stimulation level; RHCD is the individual real head to coupler difference which is equal to the real head force probe response minus

the force probe super threshold correction; and F_{TH} is the corrected force probe threshold value.

Audibility: Surface Microphone • The audibility of the surface microphone was determined by subtracting the corrected surface microphone SPL threshold values from the SPL output of the test device at each stimulation level (55, 65, and 75 dB).

Statistical Analysis

We ran a 2 (sensor) \times 3 (input level) \times 10 (frequency) mixed analysis of variance to test for significant main effects and interactions and to ultimately test for equivalence in audibility between the skull simulator and surface microphone sensors. There were 90 planned comparisons of interest with three at each frequency (3×10) for the three input levels (30×3). The Holm–Bonferroni method was used to minimize type 1 error associated with

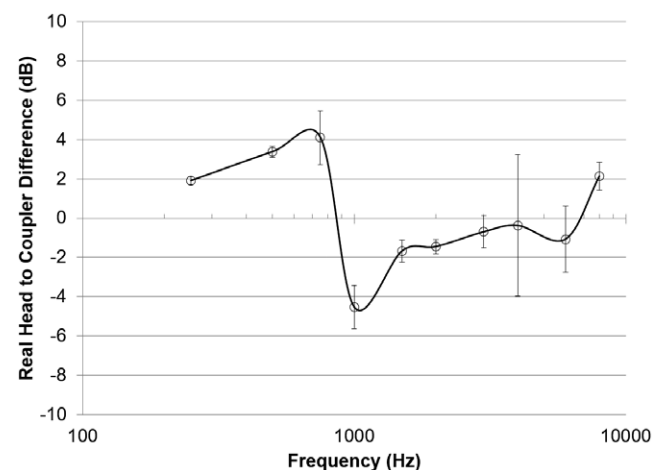


Fig. 6. Real Head to Coupler Difference (RHCD). Average values over all patients. Error bars indicate 1 SD.

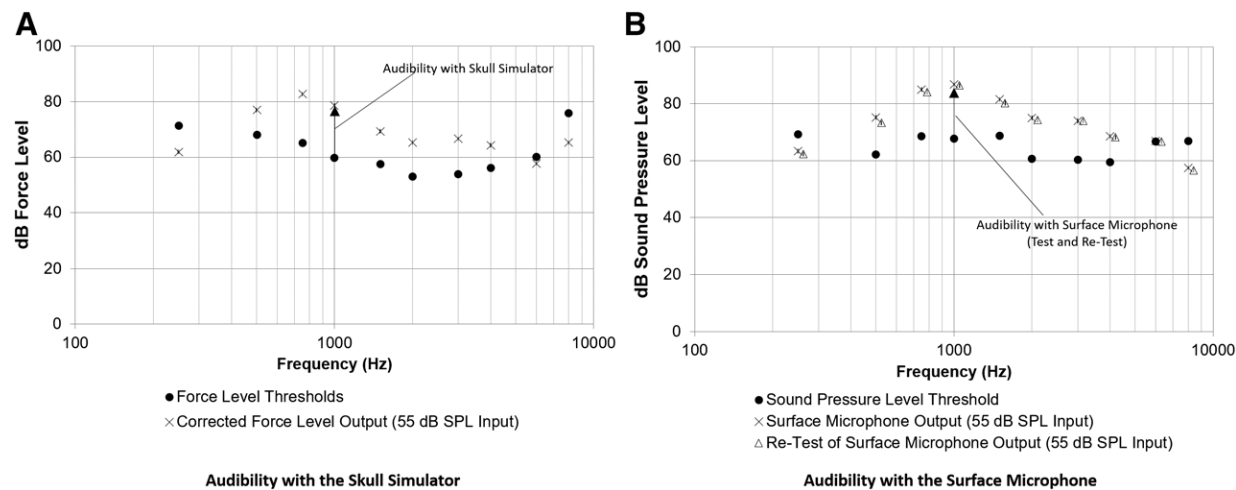


Fig. 7. Threshold values and measured output at 55 dB SPL presentation level. (A) shows the values for the skull simulator. (B) shows the values for the surface microphone (test and retest). Arrows indicate calculation of audibility for both devices.

multiple comparisons. Intraclass correlation coefficients (ICCs) were also used to test for agreement between the skull simulator and surface microphone sensors (test and retest).

RESULTS

The average RHCD is shown in Figure 6 (averaged over all patients; error bars indicate 1 SD). The 2 (sensor) × 3 (input level) × 10 (frequency) mixed analysis of variance yielded a significant three-way interaction, and so we proceeded with the 90 planned comparisons. There were five comparisons that yielded significant differences between the skull simulator and surface microphone (test and retest) in the estimation of audibility. Four of these comparisons occurred at 250 Hz, and one occurred at 1500 Hz with a presentation level of 55 dB. However, the mean difference of these effects was small at 3.3 dB. As an example, the threshold levels and the output measurements at 55 dB SPL presentation level are shown in Figure 7 for the skull simulator (panel A) and surface microphone (panel B). The arrows in the figures indicate the calculation of audibility for both devices. The audibility results for both devices (including test–retest for the surface microphone) are shown in Figures 8–10 for input levels of 55, 65, and 75 dB, respectively.

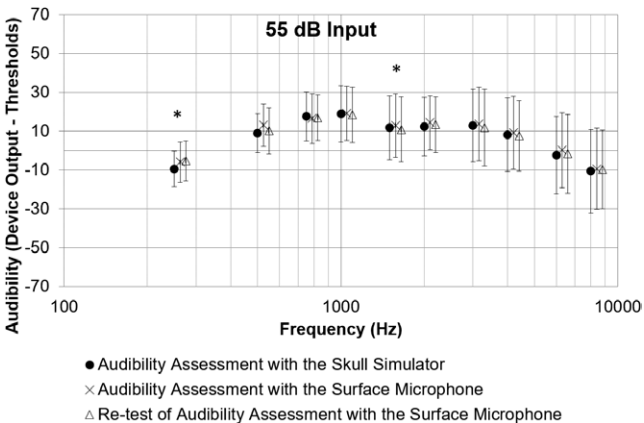


Fig. 8. Audibility for the skull simulator and surface microphone (test–retest) at 55 dB input. Average values over all patients. Error bars indicate 1 SD.

The plots show average values across all patients; error bars indicate 1 SD; and the significant differences are indicated with asterisks. It can be seen from the figures that both sensors yield equivalent results, and the surface microphone shows good test–retest reliability. This agreement is also supported with an

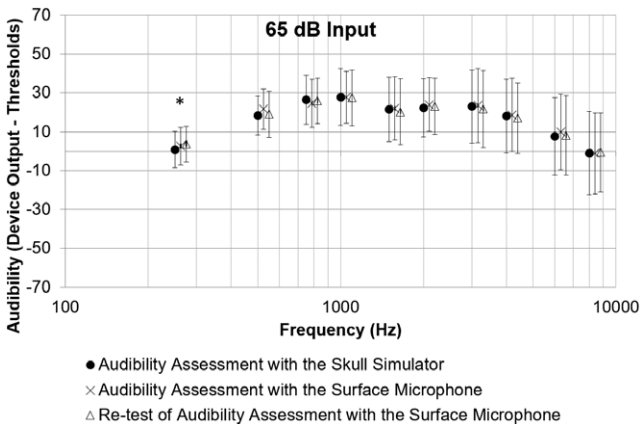


Fig. 9. Audibility for the skull simulator and surface microphone (test–retest) at 65 dB input. Average values over all patients. Error bars indicate 1 SD.

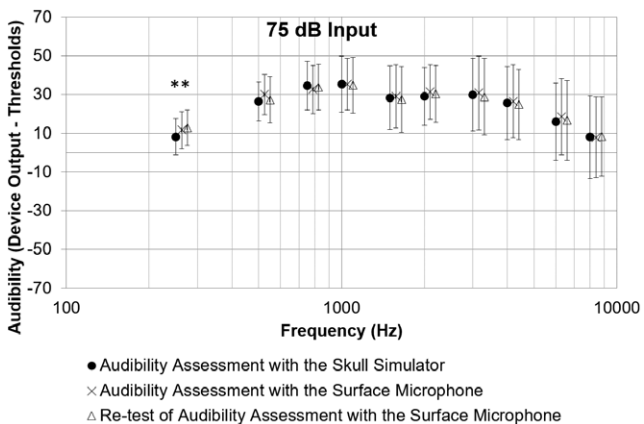


Fig. 10. Audibility for the skull simulator and surface microphone (test–retest) at 75 dB input. Average values over all patients. Error bars indicate 1 SD.

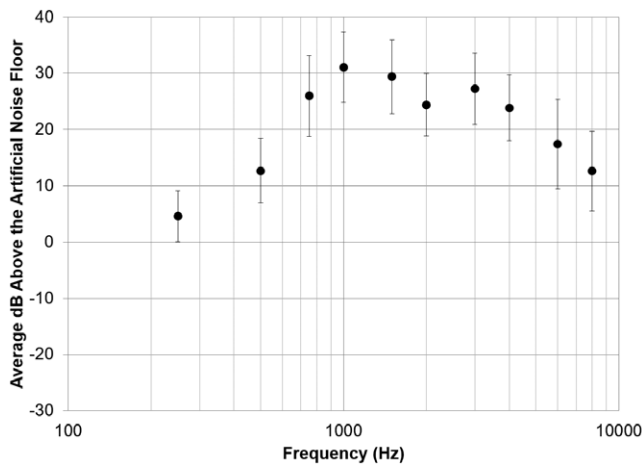


Fig. 11. Average decibel level above the surface microphone artificial noise floor at each audiometric frequency. Average over all patients and all stimulation input levels. Error bars indicate 1 SD.

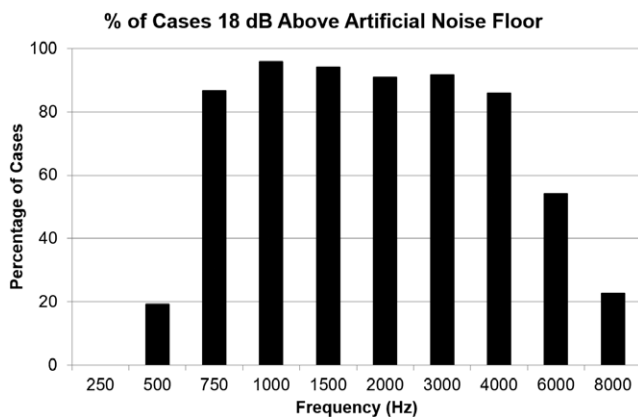


Fig. 12. Percentage of cases (all patients and all stimulation input levels) 18 dB above the surface microphone artificial noise floor at each audiometric frequency.

ICC of 0.990 at the group level and an average ICC of 0.949 (range: 0.895–0.898) at the individual level.

The surface microphone has some leakage of noise through the microphone casing, which causes an artificial noise floor in the device. Thus, it is important that the sensitivity at the microphone input (i.e., the vibrations off of the patient's forehead) exceed this artificial noise floor. Figure 11 shows the average level in decibel of the surface microphone response above the artificial noise floor. The plot shows the average values over all patients and all stimulation input levels (55, 65, and 75 dB). Figure 12 shows the percentage of cases (all patients and all input stimulation levels) at each audiometric frequency that exceed the artificial noise floor by at least 18 dB. In the long-term average speech spectrum, the valleys of speech are typically 18 dB below the average. We were

interested in the percentage of case that cleared 18 dB above the artificial noise floor at each frequency as this potentially represents full clearance of the entire spectrum above the artificial noise floor. Clearly from 750 to 4000 Hz, there is more than 80% clearance. As expected, the percentage of cases drops at the low- and high-frequency range. For comparison between the devices, Table 1 shows the absolute noise floor of the surface microphone in dB SPL along with the noise floor of the skull simulator in dB FL re: 1 μ N.

DISCUSSION

In many jurisdictions across the globe, it is recommended, if not imperative, that Audiologists verify their device fitting using validated tools (e.g., College of Audiologist and Speech-Language Pathologists of Ontario 2016). The area of bone conduction fitting has been lagging air conduction verification considerably, with insufficient tools and lack of knowledge about how to proceed.

Here we demonstrate initial validation data for a new verification tool to measure BCDs. This tool is not a replacement for the skull simulator but, instead, serves a novel purpose in allowing for the direct measurement of BCDs that have skin in the vibration pathway or have the vibrator placed underneath the skin. While there are still some development improvements to be made to the tool, especially with the low-frequency leakage and the high-frequency microphone sensitivity, this initial study revealed promising results.

One limitation of the study has to do with the use of pink noise as a surrogate for real speech signals. The reason we chose pink noise was that we wanted to be sure that patient movements and incidental sounds (e.g., breathing) would not contaminate our results. The pink noise measures could be gathered in a very short 1- to 2-second window, whereas the ≈ 15 seconds typically used to gather real speech data may last long enough for movement or breathing sounds to be included in the measure. We are currently investigating this in another study.

There are several other limitations to this study that should be discussed. The measurement sensitivity of the surface microphone is limited by the noise floor of the device and leakage and potentially the bandwidth of the device. We used a fixed frequency response in this study as an initial validation of the surface microphone approach. However, other fittings may be more at risk to fall below the measurement noise floor, which should be investigated in future studies. Finally, this initial validation was performed only with percutaneous bone conduction users. Thus, the use of the tools presented here for fully implantable devices and headband-worn devices would require further validation, which will be the topic of future research.

In this study, we showed that we could achieve equivalent audibility results (of a single master device) using two different tools. This new surface microphone, thus, holds potential to be of significant value for verification of BCDs, especially those that have the active vibrator under the skin and those that have skin in the vibration pathway.

TABLE 1. Noise floor measurements for the surface microphone and skull simulator

Frequency (Hz)	250	500	750	1000	1500	2000	3000	4000	6000	8000
Surface microphone absolute noise floor (dB SPL)	14.0	12.5	10.5	18.0	21.0	18.5	15.5	11.5	5.5	8.0
Skull simulator noise floor (dB FL re: 1 μ N)	33	33	28	26	27	26	26	27	29	30

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