

PURE TONE AUDIOMETRY OUTSIDE A SOUND BOOTH USING EARPHONE ATTENUATION, INTEGRATED NOISE MONITORING, AND AUTOMATION

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ABSTRACT

Objective: Accessibility of audiometry is hindered by the cost of sound booths and shortage of hearing health personnel. This study investigated the validity of an automated mobile diagnostic audiometer with increased attenuation and real-time noise monitoring for clinical testing outside a sound booth.

Design: Attenuation characteristics and reference ambient noise levels for the computer-based audiometer (KUDUwave) was evaluated alongside the validity of environmental noise monitoring. Clinical validity was determined by comparing air and

bone conduction thresholds obtained inside and outside the sound booth (23 subjects). Test-retest reliability was established for a sub-group of 11 subjects.

Results: Improved passive attenuation and valid environmental noise monitoring was demonstrated. Clinically, air conduction thresholds inside and outside the sound booth, corresponded within 5 dB or less >90% of instances (mean absolute difference 3.3 ± 3.2 SD). Bone conduction thresholds corresponded within 5 dB or less in 80% of comparisons between test environments, with a mean absolute difference of 4.6 dB (3.7SD). Threshold differences were not statistically significant. Mean absolute test-retest differences outside the sound booth was similar to those in the booth.

Conclusion: Diagnostic pure tone audiometry outside a sound booth using automated testing, improved passive attenuation, and real-time environmental noise monitoring demonstrated reliable hearing assessments.

Keywords:

Audiometry, Automated Audiometry, Attenuation, Diagnostic Hearing Assessment, Noise Monitoring, Maximum Permissible Ambient Noise Levels, Occupational Hearing Assessment

INTRODUCTION

Many attempts have been made to allow for diagnostic pure tone audiometry testing outside a sound booth (Berger & Killion, 1989; Frank et al, 1997; Berger et al, 2003; Bromwich et al, 2008; Buckey et al, 2013). When conducting diagnostic pure tone audiometry in occupational settings, a controlled test environment, with ambient noise levels that are sufficiently low to allow for threshold measurements down to 0 dB HL, is

required. In clinical settings, ambient noise levels need to be lower in order to allow for testing down to -10 dB HL. The presence of ambient noise may artificially elevate hearing thresholds due to masking. Several international and national institutions (e.g. International Organization for Standardization, American National Standards Institute and South African National Standards) have specified standards for maximum permissible ambient noise levels (MPANLs) at specific test frequencies. Although audiometric sound booths are traditionally used to attain a compliant test environment, there are a number of limitations and concerns regarding their use.

A major concern, especially in developing countries, is accessibility and expense related to sound booths (Maclennan-Smith et al, 2013). In many settings, such as schools, nursing homes and rural areas, sound booths are not readily available (Lankford & Hopkins, 2000; Swanepoel et al, 2010a; Maclennan-Smith et al, 2013; Swanepoel et al, 2013). Even when mobile booths are available, they rarely comply with standards due to inadequate attenuation of low-frequency ambient noise. Frank and Williams (1994) in a study of the noise levels of 490 single-walled prefabricated booths used for industrial testing found that only 33% met the ANSI/ASA S3.1-1991 (R2013) MPANLs for air conduction testing using supra-aural earphones. Similarly, Lankford et al. (1999) reported that only 38% of mobile audiometric booths complied with ANSI/ASA S3.1-1991 (R2013) MPANLs for air conduction testing.

Booths for diagnostic audiometry usually offer better attenuation than mobile booths, with noise levels closer to prescribed MPANLs. However, in developing countries,

diagnostic booths are generally restricted to larger cities because of cost and requirements for adequate space, architectural proficiency, and quiet ventilation (Glorig, 1965; Martin, 1991). Noise occurring during a typical workday must be taken into account when certifying diagnostic booths annually to ensure that MPANLs comply with standards put in place by regulating authorities (Occupational Noise Exposure, 1983; ANSI/ASA S3.1-1991 [R2013]). Annual certification of a sound booth is completed at a single point in time once a year which means that clinicians will usually be unaware when transient noise exceeds MPANLs inside a diagnostic sound booth during testing at other times. Frank and Williams (1993) studied the noise levels of 136 audiometric booths in various audiological facilities across the US. Compliance with ambient noise standards (ANSI S3.1-1991) was surprisingly poor, with 50% of booths meeting the standards for air conduction audiometry (ears covered) for test frequencies of 250 to 8000 Hz. Only 14% of booths had sufficiently low ambient noise levels for testing bone conduction (ears uncovered) at 250 to 4000 Hz.

Alternative approaches to reduce ambient noise during audiometric testing have been investigated. Passive and active noise reduction approaches in headphone sets have been proposed as a way to reduce the influence of background noise (Berger & Killion, 1989; Berger et al, 2003; Bromwich et al, 2008; Buckey et al, 2013). Noise-reducing enclosures covering supra-aural earphones provide little attenuation over and above the earphone's own attenuation (Berger & Killion, 1989) and are not sufficient for threshold estimation with intensity levels down to 0 dB HL (Frank et al., 1997). Noise-reducing enclosures may also invalidate the calibration of supra-aural earphones or may change

the required reference equivalent threshold sound pressure level (RETSPL) values for supra-aural earphones (Frank et al., 1997). Furthermore, attenuation provided by supra-aural earphones is frequency-dependant and varies with its contact with the listener's skull. This is also true for insert earphones, where insertion depth affects attenuation (Clark & Roeser, 1988). Insert earphones reduce ambient noise more effectively than supra-aural earphones for compliant testing (Berger & Killion, 1989). Deeply inserted insert earphones provide sufficient attenuation (between 30 - 40 dB) to permit estimation of air conduction thresholds as low as 0 dB HL for frequencies ranging from 125 to 8000 Hz within typical office noise environments (Berger & Killion, 1989).

Double attenuation, achieved by the simultaneous use of insert foam plugs and circumaural earcups, provides a further increase in attenuation (Berger, 1984; Berger et al, 2003). For instance, in a study by Bromwich et al. (2008) the combined use of inserts and active noise reduction (ANR) headphones allowed for compliant air conduction testing of frequencies 250 to 4000 Hz in the presence of 30 dB background noise. Nevertheless, background noise exceeding this level resulted in elevated hearing thresholds (Bromwich et al, 2008). Therefore, in addition to attaining adequate attenuation, it would be preferential to measure and monitor ambient noise levels continually during patient testing to ensure they are within permitted criteria to safeguard against false threshold shifts due to transient noise sources.

MPANLs are significantly stricter whenever ears are not covered by an earphone, which typically occurs during bone conduction testing (ANSI/ASA S3.1-1991 [R2013]). Bone

conduction thresholds are usually obtained by placing a bone vibrator on the mastoid or on the forehead. During mastoid placement of the bone vibrator, the test ear must be unoccluded while masking is applied to the occluded non-test ear (Martin, 1991). Limited evidence is available on bone-conduction audiometry conducted outside a sound-treated booth (Maclennan-Smith et al, 2013) because ambient noise in natural environments often exceeds MPANLs for ears uncovered (ANSI/ASA S3.1-1991 [R2013]). By occluding both ears with insert earphones placed deep into the bony part of the ear canal whilst employing forehead placement of the bone vibrator, the occlusion effect can be minimized and achieve sufficient attenuation of background noise (Dean & Martin, 2000; Stenfelt & Goode, 2005). This also allows for automated diagnostic audiometry without having to move the bone transducer between ears during the test (Margolis et al. 2008). Automation also has the potential to be incorporated into telemedicine practices, increasing access to hearing tests in remote areas (Margolis & Morgan, 2008; Swanepoel et al, 2010c; Visagie, Swanepoel & Eikelboom, IN PRESS).

A novel diagnostic audiometer with automation, increased attenuation (using insert earphones with a circumaural headset incorporated into the unit) and real-time environmental noise monitoring has promise for diagnostic audiometry in underserved areas where sound booths and audiologists are typically unavailable (Fagan & Jacobs, 2009; Swanepoel et al, 2010a; Swanepoel et al, 2010b; Maclennan-Smith et al, 2013). This computer-based audiometer (KUDUwave, eMOYODotNET, Johannesburg, South Africa) has demonstrated equivalent audiometry thresholds compared to standard audiometers using manual and automated (Swanepoel et al, 2010c; Swanepoel &

Biagio, 2011; Storey et al, 2014) testing inside audiometric sound booths. Accurate air and bone conduction thresholds have also been determined manually outside sound-treated environments for adults and children (Maclennan-Smith et al, 2013; Swanepoel et al, 2013).

The attenuation advantage of the insert earphone and custom circumaural earcup for the KUDUwave in addition to the validity of its real-time noise monitoring feature has not, however, been quantified to date. Furthermore, no validation on automated air and bone conduction testing outside a sound booth has been reported using this device. As a result, the current investigation comprised two studies. The first investigated the validity of the combined insert earphone and circumaural earcup attenuation and real-time noise monitoring feature whilst the second determined the accuracy and test-retest reliability of automated air and bone conduction audiometry outside sound-treated environments using the KUDUwave audiometer.

STUDY 1 - TRANSDUCER ATTENUATION AND INTEGRATED AMBIENT NOISE MONITORING

Study 1 investigated the attenuation characteristics and live ambient noise-monitoring feature of the KUDUwave audiometer. Real-ear attenuation for transducers was determined along with reference ambient noise levels as recorded by the external earcup microphones of the audiometer. Approval for the study was obtained from the

institutional research ethics committee (Faculty of Humanities, University of Pretoria). All subjects provided informed consent prior to data collection.

Subjects

A sample of 15 normal hearing subjects (10 males and 5 females) was recruited in order to determine the attenuation of various transducers and transducer combinations in accordance with procedures described in ISO 8253-1 (ISO, 2010). Age ranged from 18-31 years with an average age of 22.5 years.

Equipment

Data collection was conducted in a double-walled IAC (Industrial Acoustic Company Inc., New York) audiometric booth adhering to ambient noise levels specified by ANSI/ASA S3.1-1991 (R2013) for evaluating hearing for air and unoccluded bone conduction down to 0 dB HL from 125 to 8000 Hz. A GSI-61 diagnostic Type 1 clinical audiometer (Grason-Stadler, Eden Prairie, MN) was used to obtain air conduction thresholds within a sound field for determining transducer attenuation, and was also used to obtain reference noise monitoring levels for the external earcup microphones of the KUDUwave on the developer version of the user interface software (eMOYO).

The GSI-61 audiometer was calibrated with an 824 Type 1 sound level meter (Larson Davis, Provo, Utah). Both GSI sound field speakers (Grason-Stadler, Eden Prairie, MN) were calibrated before testing commenced.

An 824 Type 1 Sound Level Meter (Larson Davis, Provo, Utah) was used to determine the intensity where narrow band noise (NBN) levels reached maximum permissible ambient noise levels (MPANLs) for insert earphones (ANSI/ASA S3.1-1991 [R2013]) during the first study.

Methods

The experimental setup involved presentation of warble tones (to minimize the effects of standing wave artifacts) at octave and inter-octave frequencies from 250 Hz to 8000 Hz through free field within a double-walled sound booth. The azimuth of the speakers was 45 degrees on the left and right, 1 m from the subject's ears. Tones were presented from both speakers simultaneously. Therefore, results were not ear-specific and represented the best hearing threshold, irrespective of ear. Subjects were instructed to respond to tones by pressing a button.

A modified Hughson-Westlake threshold seeking method was used to determine hearing thresholds starting at 1000 Hz and 30 dB hearing level (HL), moving on to lower octave frequencies down to 250 Hz, and then higher octave frequencies from 2000 to 8000 Hz. Thresholds were measured down to levels of -10 dB HL. Hearing thresholds were 15 dB or less in all cases. Additional free-field audiograms with three different configurations were conducted in a randomized order to measure transducer and combined transducer attenuation. These bilateral transducer conditions included a) ER-3A insert earphones; b) TDH-39 supra-aural transducers; c) insert earphones (see MacLennan-Smith et al. 2013 for technical detail of KUDUwave transducers) combined

with KUDUwave circumaural earcups functioning as attenuator. Despite being omitted during initial experiments, 125 Hz transducer attenuation (for condition a and c) was determined at a later stage using a sub-group of 5 of the original participants tested using a similar procedure but employing narrowband noise (NBN), which is specified as acceptable by ISO 8253-1 (ISO, 2010). The level of attenuation provided by the various transducers and transducer combinations was calculated as the difference in threshold at individual frequencies with and without transducers fitted. This allowed determination of MPANLs for the KUDUwave transducers taking into account the decibel attenuation advantage above insert earphones.

In a sub-study of study 1, the circumaural earcup (left and right) microphones of five KUDUwave devices (10 microphones) were assessed to determine the variability across microphones when monitoring noise at prescribed MPANLs. A sound field configuration was utilized with NBN presented through speakers at MPANLs for insert earphones (ANSI/ASA S3.1-1991 [R2013]) to test down to 0 dB HL across octave frequencies. This was achieved by setting up a Type 1 Sound Level Meter (824 Larson Davis Type 1 SLM, Provo, Utah) in a double-walled sound booth at 0° azimuth 1 m from the sound field speaker (midpoint 87.5 cm above the floor). A fast time weighted average (125 milliseconds) response setting and octave band filtering was used. The NBN intensity, determined on the audiometer using 1 dB increments, at the MPANL for insert earphone testing at 0 dB HL (ANSI/ASA S3.1-1991 [R2013]) was recorded. Subsequently the KUDUwave earcup was set up to ensure the earcup microphone was positioned in exactly the same place as the Type 1 SLM microphone (see figure 1). The



Figure 1. KUDUwave and Sound Level Meter setup during MPANL [ANSI S3.1 (1999(R2013))] measurements

NBN intensity levels at the MPANLs across frequencies for insert earphone testing at 0 dB HL (ANSI/ASA S3.1-1991 [R2013]) was subsequently presented. These ambient noise levels, as recorded by the KUDUwave earcup microphones, were recorded as relative dB levels on the developer version of the software (eMOYO). This was repeated for the 10 microphones on the earcups of the five KUDUwave audiometers used.

The KUDUwave earcup microphone measuring ambient noise was subsequently calibrated to compensate for variability in microphone sensitivity by ensuring

environmental noise monitoring was conservative. This was achieved by equating the minimum noise level measured across octave frequencies tested across the 10 KUDUwave microphones (5 devices) using NBN equal to the MPANL for insert earphone testing down to 0 dB HL (ANSI/ASA S3.1-1991 [R2013]) as reference level. The KUDUwave noise-monitoring feature compensates for the variability between earcup microphones by monitoring at most aggressive levels across each of the 10 microphones evaluated. In addition to this, the monitoring represents the average maximum noise levels over a 100-millisecond time period ensuring that noise levels indicated on the software represent the highest levels.

Data analysis

Descriptive statistics were applied to determine attenuation levels for the various transducer conditions and also for representing the differences for sound levels across the 10 microphones evaluated in regards to the KUDUwave audiometers' noise monitoring. A Wilcoxon signed ranks test (significance $p < 0.01$) was used to compare transducer attenuation.

Results

Attenuation levels for the various transducers demonstrate the slight advantage of a combination of insert earphones and circumaural earcups (Figure 2 and Table 1). External earcup microphones measured the MPANLs for insert earphones (as presented by NBN) (Table 2). Across the 10 microphones assessed there was a small difference in levels measured with a standard deviation of 1.4 to 2.1 dB across

frequencies. MPANLs for insert earphones (based on ANSI 3.1 1999(R2013) standards) and those calculated for the insert earphone and KUDUwave circumaural

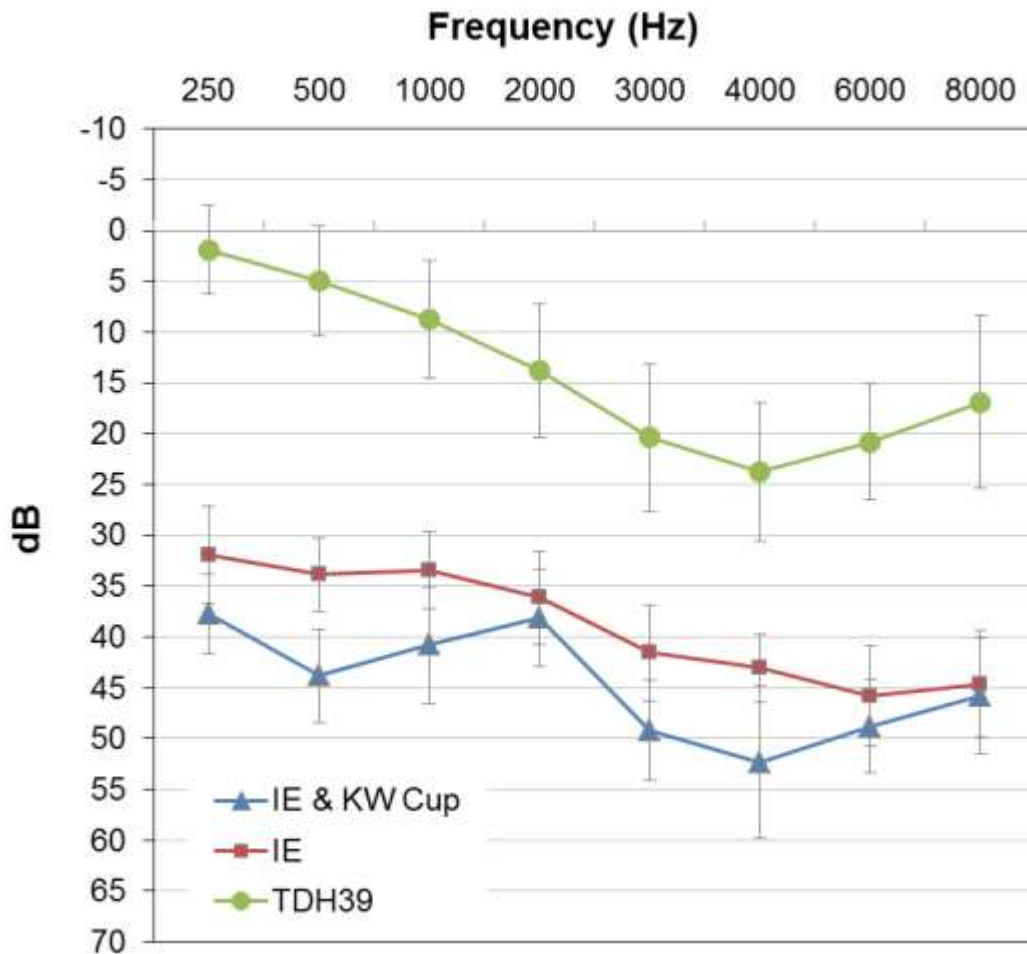


Figure 2. Comparison of sound field attenuation of different transducers and transducer combinations (n=15)
(IE, insert earphone; KW, KUDUwave; Error bars = 1 Standard Deviation)

earcup combination are displayed in Table 3. NBN was presented at the MPANLs for the KUDUwave and the monitoring bars for each octave frequency indicated the intensity to be within 1 dB of the expected measured intensity based on the microphones dB value for each MPANL.

Table 1. Sound field attenuation of different transducers and transducer combinations (n=15). IE = Insert earphone; KW = KUDUwave

| | FREQUENCIES | | | | | | | | |
|-------------|-------------|------------|------------|------------|------------|------------|------------|------------|------------|
| | 125Hz* | 250Hz | 500 Hz | 1000Hz | 2000Hz | 3000Hz | 4000Hz | 6000Hz | 8000Hz |
| IE & KW Cup | | | | | | | | | |
| Mean (SD) | 31.0 (5.5) | 37.7 (3.9) | 43.8 (4.6) | 40.8 (5.7) | 38.1 (4.8) | 49.2 (4.9) | 52.3 (7.5) | 48.8 (4.6) | 45.8 (5.7) |
| Minimum | 25 | 30 | 35 | 30 | 30 | 40 | 40 | 40 | 35 |
| Maximum | 40 | 45 | 50 | 55 | 45 | 55 | 60 | 55 | 55 |
| 3A IE | | | | | | | | | |
| Mean (SD) | 23.0 (2.7) | 31.9 (4.8) | 33.8 (3.6) | 33.5 (3.8) | 36.2 (4.6) | 41.5 (4.7) | 43.1 (3.3) | 45.8 (4.9) | 44.6 (5.2) |
| Minimum | 20 | 20 | 25 | 25 | 30 | 35 | 35 | 40 | 40 |
| Maximum | 25 | 40 | 40 | 40 | 45 | 50 | 45 | 60 | 55 |
| TDH39 | | | | | | | | | |
| Mean (SD) | | 1.9 (4.3) | 5.0 (5.4) | 8.8 (5.8) | 13.8 (6.5) | 20.4 (7.2) | 23.8 (6.8) | 20.8 (5.7) | 16.9 (8.5) |
| Minimum | | -5 | 0 | 0 | 5 | 10 | 10 | 10 | 5 |
| Maximum | | 10 | 15 | 15 | 25 | 30 | 35 | 30 | 35 |

*Measured on a sub-group (n=5) using NBN.

Table 2. Measurement variability across 10 KW external earcup microphones at MPANLs [ANSI S3.1 (1999(R2013))] for insert earphones

| | FREQUENCY | | | | | | |
|---|-----------|--------|--------|---------|---------|---------|---------|
| | 125 Hz | 250 Hz | 500 Hz | 1000 Hz | 2000 Hz | 4000 Hz | 8000 Hz |
| Maximum variability (dB) between microphones (n=10) | 4 | 4 | 5 | 5 | 4 | 5 | 5 |
| Mean difference (dB) between L & R microphones (n=5 pairs) | 1 | 0.6 | 1 | 0.4 | 0.4 | 0.8 | 1.4 |
| SD of difference (dB) between L & R microphones (n=5 pairs) | 0.7 | 0.5 | 0.7 | 0.5 | 0.9 | 0.8 | 1.7 |

L, left; SD, standard deviation; R, Right.

Table 3. MPANLs [ANSI S3.1 (1999(R2013))] in dB re: 20 µPa for insert earphones and determined for the KUDUwave insert earphone and circumaural earcup combination

| | FREQUENCY | | | | | | |
|---|-----------|--------|--------|---------|---------|---------|--------|
| | 125 Hz | 250 Hz | 500 Hz | 1000 Hz | 2000 Hz | 4000 Hz | 8000Hz |
| MPANL ANSI S3.1 (1999(R2013)) for inserts | 59 | 53 | 50 | 47 | 49 | 50 | 56 |
| KW attenuation* advantage above inserts | 8** | 6 | 10 | 7 | 2 | 9 | 1 |
| MPANL for KW* according to ANSI S3.1(1999(R2013)) for inserts | 67 | 59 | 60 | 54 | 51 | 59 | 57 |

KW, KUDUwave; MPANL, maximum permissible ambient noise level.

**Insert earphones covered by custom circumaural earcups*

***Attenuation for 125 Hz was determined on a sub-group (n=5) using NBN*

Discussion

Insert earphones combined with circumaural earcups (as utilized by the audiometer used in this study) provided maximum attenuation at all frequencies and significant ($p < 0.01$; Wilcoxon) improvement across frequencies compared to other transducers.

The limited attenuation advantage at 2 kHz compared to insert earphones alone is attributed to sound transmission via bone-conduction pathways (Berger et al, 2003).

The combined transducer attenuation levels are similar to those for a mini 5-cm panel booth (Frank, 2001) and exceed those of typical transportable sound-treated booths (Frank, 2001). Berger et al. (2003) reported slightly higher attenuation for deeply inserted insert foam plugs covered by circumaural earcups compared to the current study's double attenuation. This might be due to the way the insert foam plugs were fitted, and because foam plugs intended for hearing protection provide slightly better

attenuation than insert earphones used for hearing testing. The foam plugs used in the Berger et al. (2003) study were fitted optimally and even uncomfortably in some cases, which is not practical when fitting insert earphones during occupational hearing testing (Berger et al, 2003). Deep insertion of insert earphones is, however, necessary to minimize the occlusion effect during bone conduction testing if ears remain occluded (Dean & Martin, 2000; Stenfelt & Goode, 2005). The setup of the KUDUwave audiometer therefore offers maximum attenuation of ambient noise whilst allowing for bone conduction testing with occluded ears.

Attenuation of sound booths and their respective noise levels may differ substantially depending on transient noise sources (Storey et al, 2014) and often do not comply with recommended MPANLs specified by existing standards (Frank & Williams, 1994; Lankford et al, 1999; Frank & Williams, 1993). Therefore, real-time monitoring of ambient noise has the potential to make the clinician aware of non-compliance during testing in the presence of high noise levels. The audiometer used in the current study employs live monitoring of background noise based on reference noise monitoring levels. Reference noise monitoring levels for the KUDUwave external earcups were established taking into consideration the variability between external microphones and the relative attenuation advantage provided by the insert earphone and circumaural earcup combination. Using the lowest sensitivity level across the 10 microphones assessed, to reference MPANLs on the software means the noise monitoring is aggressive. In other words microphones with maximum variability from the most conservative one (across the 10 assessed) will indicate higher noise levels (by up to 4

or 5 dB) across octave frequencies. This is a conservative compensation for the variability that may be encountered across different KUDUwave external earcup microphones. In addition to this, monitoring using the average peak noise levels over a 100-millisecond time period ensures that noise levels represent the highest levels. This type of noise monitoring may prove advantageous above conventional diagnostic audiometry within sound booths, where transient noise may interfere with threshold testing without the tester's knowledge.

STUDY 2 - ACCURACY AND RELIABILITY OF AUDIOMETRY OUTSIDE A SOUND BOOTH

Study 2 determined the accuracy and test-retest reliability of frequency specific threshold measurements using the KUDUwave audiometer in a control and experimental condition. During the control condition, air and bone conduction thresholds were acquired manually within a double-walled sound booth, The experimental condition also acquired thresholds outside a sound booth in a natural environment using an automated test sequence. Test-retest reliability was determined by repeating the experimental and control condition in a sub-group (n=11) of subjects.

Approval for the study was obtained from the institutional ethics committee. All subjects provided informed consent prior to data collection.

Subjects

Twenty-three normal-hearing subjects (age range, 20-75 years; average age 35.5) participated in the first phase of this study to determine accuracy. From the initial 23 subjects a sub-group of 11 randomly selected subjects were subsequently retested in the control and experimental conditions to determine test-retest reliability.

Equipment

The KUDUwave (eMOYOdotNET, Johannesburg, South Africa), a mobile Type 2B screening, diagnostic and clinical audiometer (IEC 60645-1/2) operated from a computer software interface was used to measure pure tone air and bone conduction thresholds in both settings. The system comprised custom insert earphones (similar to ER-3A) positioned inside noise-excluding circumaural earphones, and a B-71 bone oscillator (Kimmetrics, Smithsburg, MD) held in place on the forehead with a standard adjustable spring headband attached to the circumaural headband. Patient responses to stimuli and response times are recorded via a response button connected to the device. The audiometer is powered by a USB cable connected to the laptop. The device enables real-time monitoring of ambient noise levels in octave bands through an external microphone on each circumaural earcup. The noise monitoring function of the KUDUwave uses low-pass (< 125 Hz), seven single octave band-pass (125, 250, 500, 1000, 2000, 4000 and 8000 Hz) and high-pass (>8000 Hz) filters to separate the incoming sound. The filters have a stop-band attenuation of 90 dB and pass-band ripple of 0.003 dB. The outputs of these filters are monitored in real-time and the peak value passes to the user interface software (eMOYO) every 100-milliseconds, which is

visually represented within the software. By representing the peak and not the average ambient noise values averaged over each 100-millisecond period, the device provides an aggressive monitoring function. The noise level indicated also represents the peak value for the microphone at the ear undergoing testing. The noise monitoring function utilised was based on results of the study 1, where reference equivalent threshold (RET) attenuation levels were obtained and incorporated in the user interface software, alongside reference ambient noise levels for the KUDUwave external earcup microphones. Noise monitoring provides real-time visual feedback of ambient noise levels and notes when a “no-response” was recorded when noise exceeded MPANL’s at that intensity.

Prior to the commencement of the study, the KUDUwave was calibrated using a 824 Type 1 sound level meter (Larson Davis, Provo, Utah) with G.R.A.S. (Holte, Denmark) IEC 711 coupler for insert earphones and an AMC493 Artificial Mastoid (Larson Davis) on an AEC101 coupler (Larson Davis) with 2559 ½ inch microphone for the Radioear B-71 bone oscillator. The insert earphone frequency response approximates that of the ER-3A within 1 dB across test frequencies allowing for the use of the international insert earphone standard (ISO 389-2, 1994) for calibration. The bone oscillator was calibrated in accordance with ISO 389-3. Ambient noise levels during the experimental condition were monitored with a 824 Type 1 Sound Level Meter (Larson Davis, Provo, Utah).

Methods

Pure tone audiometry was conducted at octave and inter-octave frequencies from 250 Hz to 8000 Hz for air conducted stimuli and from 250 Hz to 4000 Hz for bone conducted

stimuli using the KUDUwave audiometer. All subjects were tested once inside a double-walled sound booth (control condition) and outside the booth in a natural office environment (experimental condition). The clinician conducting manual audiometry was blinded to the results of the initial test for this sub-group. Thresholds for the same condition were compared to establish test-retest reliability.

The bone conduction vibrator was placed on the forehead, with insert earphones deeply inserted in the ear canals to minimize the occlusion effect (Dean & Martin, 2000; Stenfelt & Goode, 2005). Air and bone conduction thresholds could therefore be obtained without moving the transducers, and the device automatically administered masking when appropriate. Masking of 20 dB above the air conduction threshold of the non-test ear was applied for bone conduction audiometry (ASHA, 2005). Verbal instructions were provided and subjects were required to respond to tones by pressing a button. A modified Hughson-Westlake threshold seeking method was used during both conditions. Testing commenced at 1000 Hz and 30 dB HL. Then lower octave frequencies were tested. After testing at 250 Hz, higher octave frequencies were evaluated starting at 2000 Hz and through to 8000 Hz. The order of the tests for the control vs. experimental setting was randomized and all tests were conducted on the same day. All subjects were tested with conventional manual audiometry inside the sound booth and with an automated test sequence outside the booth. Thresholds were measured down to a minimum of 0 dB HL. Ambient noise levels were measured using a SLM during testing in the experimental condition for octave frequencies 250 Hz to

8000 Hz. Measurements were made at the same height as the test subjects' head, positioned behind them.

Data analysis

The paired-sample Wilcoxon Signed Rank Test for non-parametric data was used to compare within-subject hearing thresholds across control and experimental conditions (accuracy) and within control and experimental conditions (test-retest reliability). Left and right ears were analyzed separately and a Bonferroni correction was applied to adjust for multiple comparisons.

Results

Threshold accuracy

Real mean air conduction threshold differences were between -2.0 and 1.5 dB (standard deviation range between 3.3 and 8.5 dB) for the left and right ears across frequencies. Absolute mean air conduction threshold differences varied between 1.7 to 5.9 dB (standard deviation range between 2.6 and 6.3 dB) across frequencies and left and right ears. Real mean bone conduction threshold differences between conditions ranged from 0.2 and 3.9 dB (standard deviations of between 4.7 and 10.4 dB) and 1.7 to 3.5 dB (standard deviations between 2.9 and 6.7 dB) for absolute mean bone conduction threshold differences.

Almost all (91%) air conduction thresholds across left and right ears, and 80% of bone conduction thresholds corresponded within 5 dB or less of each other between the two

Table 4. Mean (real and absolute) threshold differences between the sound booth (B) and the natural (N) office environment (n=23) and test-retest condition (n=11)

| | FREQUENCY | | | | | | |
|--|------------|------------|------------|------------|------------|------------|------------|
| | 250 Hz | 500 Hz | 1000 Hz | 2000 Hz | 4000 Hz | 8000 Hz | All |
| B and N Mean difference (SD) | | | | | | | |
| AC left | -1.1 (3.6) | -0.9 (3.9) | -0.9 (5.8) | -0.4 (5.2) | -0.4 (3.3) | -2.0 (8.5) | -0.7 (2.4) |
| AC right | 1.5 (6.3) | 0.0 (5.0) | 0.9 (5.0) | -0.2 (5.3) | -0.2 (5.5) | -1.5 (7.1) | -2.5 (2.9) |
| BC | 2.2 (4.7) | 2.0 (7.2) | 0.4 (5.0) | 0.2 (10.4) | 3.9 (8.3) | | -0.1 (2.8) |
| B and N Mean Abs difference (SD) | | | | | | | |
| AC left | 2.4 (2.6) | 2.6 (3.0) | 3.9 (4.3) | 3.5 (3.8) | 1.7 (2.9) | 5.9 (6.3) | 3.3 (2.2) |
| AC right | 3.7 (5.3) | 3.0 (3.9) | 1.7 (4.7) | 2.8 (4.5) | 3.3 (4.4) | 4.6 (5.6) | 3.2 (4.1) |
| BC | 3.0 (4.2) | 3.3 (6.7) | 3.0 (3.9) | 3.5 (3.8) | 1.7 (2.9) | | 4.6 (3.7) |
| Test-Retest B Mean difference (SD) | | | | | | | |
| AC left | 0.0 (5.9) | 0.5 (4.7) | 0.0 (5.5) | -0.5 (4.7) | 2.3 (2.6) | 4.1 (6.3) | 1.1 (2.8) |
| AC right | 0.9 (3.8) | 0.9 (3.0) | 0.9 (2.0) | 1.4 (3.2) | 0.0 (3.2) | 0.9 (4.9) | 0.8 (1.7) |
| BC | 0.0 (3.9) | 0.9 (2.0) | 3.2 (9.0) | 1.8 (5.6) | 2.3 (6.5) | | 1.6 (2.7) |
| Test-Retest B Mean Abs difference (SD) | | | | | | | |
| AC left | 4.6 (3.5) | 3.2 (3.4) | 3.6 (3.9) | 3.2 (3.4) | 2.3 (2.6) | 5.0 (5.5) | 3.6 (2.2) |
| AC right | 2.7 (2.6) | 1.8 (2.5) | 0.9 (2.0) | 2.3 (2.6) | 1.8 (2.5) | 2.7 (4.1) | 2.0 (1.4) |
| BC | 1.8 (3.4) | 0.9 (2.0) | 7.7 (5.2) | 3.6 (4.5) | 3.2 (6.0) | | 3.5 (2.6) |
| Test-Retest N Mean difference (SD) | | | | | | | |
| AC left | 1.8 (6.0) | 0.5 (4.2) | 0.0 (3.9) | 0.9 (4.4) | 1.4 (3.9) | -1.8 (2.5) | 1.2 (3.7) |
| AC right | 0.0 (3.2) | -1.8 (4.6) | 0.0 (2.2) | 1.8 (4.0) | 0.0 (3.2) | 5.5 (5.9) | 0.9 (2.8) |
| BC | 0.0 (8.1) | -0.5 (6.9) | 1.8 (6.4) | 0.5 (6.5) | 1.4 (4.5) | | 1.6 (4.3) |
| Test-Retest N Mean Abs difference (SD) | | | | | | | |
| AC left | 3.6 (5.0) | 3.2 (2.5) | 2.7 (2.6) | 2.7 (3.4) | 2.3 (3.4) | 1.8 (2.5) | 2.7 (1.9) |
| AC right | 1.8 (2.5) | 3.6 (3.2) | 0.9 (2.0) | 2.7 (3.4) | 1.8 (2.5) | 6.5 (4.7) | 2.9 (2.0) |
| BC | 3.6 (7.1) | 3.2 (6.0) | 4.6 (4.7) | 4.1 (4.9) | 3.2 (3.4) | | 3.7 (2.8) |

B, booth; N, natural office environment; SD, standard deviation; AC, air conduction; BC, bone conduction; Abs, absolute.

conditions (Table 4). There were no statistically significant differences between the thresholds determined in the two conditions for air and bone conduction ($p>0.05$; Wilcoxon Signed Ranks Test).

During pure tone testing in the natural environment, maximum ambient noise levels (Figure 3) ranged between 33.7 and 46.3 dB SPL across frequencies, with the highest average ambient noise levels measured at 250 Hz.

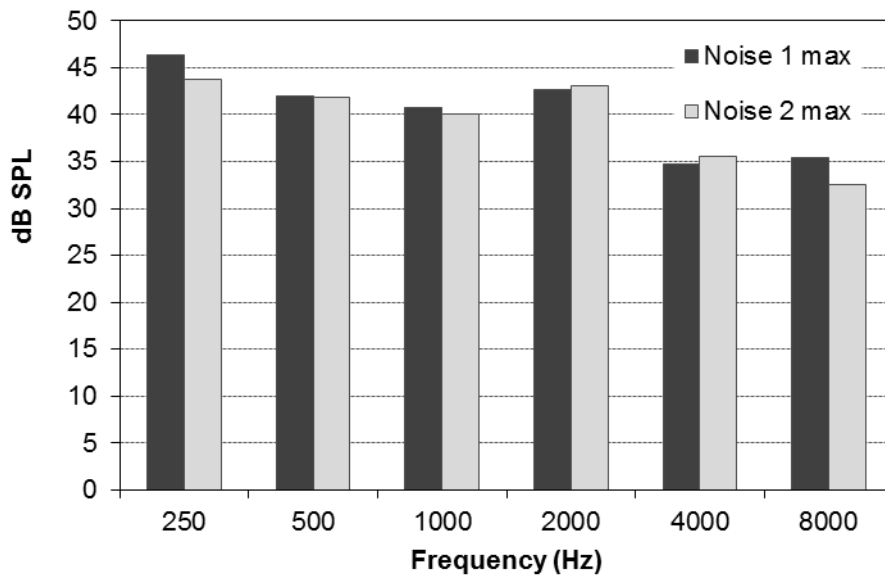


Figure 3. Maximum ambient noise levels recorded in the experimental condition for study 2 to determine accuracy (noise 1 condition) and reliability (noise 2 retest condition) of audiometry

Test-retest reliability

Test-retest threshold differences for air and bone conduction demonstrated similar mean differences (real and absolute) and standard deviations for both conditions as seen in Table 4. The real mean test-retest difference for air conduction thresholds in

the sound booth ranged between -0.5 to 4.1 dB (standard deviations between 2.0 and 6.3 dB), and between -1.8 and 5.5 dB (standard deviations between 2.2 and 6.0 dB) in the natural environment for left and right ears. Real mean bone conduction threshold differences for test-retest data in the sound booth ranged between 0.0 to 3.2 dB (standard deviations between 2.0 and 9.0), and between -0.5 to 1.8 dB (standard deviation range of 4.5 to 8.1) in the natural environment.

The absolute mean test-retest threshold differences (Table 4) for air conduction thresholds obtained in the booth were between 0.9 and 5.0 dB (standard deviation between 2.0 to 5.5 dB), and between 0.9 to 6.5 dB (standard deviations between 2.0 and 5.0 dB) in the natural environment.

For bone conduction thresholds obtained in the control condition, absolute mean test-retest differences ranged from 0.9 to 7.7 dB (standard deviation between 2.0 and 6.0 dB) and 3.2 to 4.6 dB (standard deviation between 3.4 and 7.1 dB) in the natural environment. There was no statistically significant difference between the test-retest threshold differences for air and bone conduction audiometry in the experimental and control conditions ($p>0.05$; Wilcoxon Signed Ranks Test).

Comparing test-retest thresholds for air conduction revealed 92.5% of thresholds obtained in left and right ears corresponded within 5 dB in the sound booth condition, and 92.3% of thresholds obtained in left and right ears corresponded within 5 dB in the natural environment (Table 5). For bone conduction, 80% of test-retest threshold

Table 5. Percentage correspondence of Air Conduction Thresholds for Left and Right Ears in the Booth and the Natural Office Environment (n=23) and Test-Retest condition (n=11)

| | <i>FREQUENCY</i> | | | | | | |
|--------------------------------------|------------------|--------|---------|---------|---------|---------|------|
| | 250 Hz | 500 Hz | 1000 Hz | 2000 Hz | 4000 Hz | 8000 Hz | All |
| Air Conduction Correspondence | | | | | | | |
| 0 to ± 5 dB | | | | | | | |
| B and N | 97.9 | 93.6 | 82.7 | 93.5 | 93.6 | 87 | 91.4 |
| Test-Retest B | 90.9 | 95.5 | 90.9 | 95.5 | 100 | 81.8 | 92.5 |
| Test-Retest N | 90.9 | 95.5 | 100 | 90.9 | 95.5 | 81.0 | 92.3 |
| ±10 dB | | | | | | | |
| B and N | 0.0 | 4.3 | 15.2 | 2.2 | 2.1 | 4.4 | 4.7 |
| Test-Retest B | 9.1 | 4.5 | 9.1 | 4.5 | 0.0 | 9.1 | 6 |
| Test-Retest N | 4.6 | 4.5 | 0.0 | 9.1 | 4.5 | 14.3 | 6.2 |
| ±15 dB | | | | | | | |
| B and N | 0.0 | 2.1 | 0.0 | 2.1 | 4.3 | 4.3 | 2.1 |
| Test-Retest B | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 9.1 | 1.5 |
| Test-Retest N | 4.5 | 0.0 | 0.0 | 0.0 | 0.0 | 4.8 | 1.6 |
| >±15dB | | | | | | | |
| B and N | 2.1 | 0.0 | 2.1 | 2.2 | 0.0 | 4.3 | 1.8 |
| Test-Retest B | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Test-Retest N | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

B, booth; N, natural office environment.

comparisons in the sound booth corresponded within 5dB compared to 85.4% of thresholds in the natural environment (Table 6).

Table 6. Percentage correspondence of Bone Conduction Thresholds for Left and Right Ears in the Booth and the Natural Office Environment (n=23) and Test-Retest condition (n=11)

| | FREQUENCY | | | | | |
|---------------------------------------|-----------|--------|---------|---------|---------|------|
| | 250 Hz | 500 Hz | 1000 Hz | 2000 Hz | 4000 Hz | All |
| Bone Conduction Correspondence | | | | | | |
| 0 to \pm 5 dB | | | | | | |
| B and N | 87.0 | 87.0 | 91.3 | 52.2 | 82.6 | 80.0 |
| Test-Retest B | 90.9 | 100 | 45.5 | 72.7 | 90.9 | 80.0 |
| Test-Retest N | 81.8 | 90.9 | 81.8 | 81.8 | 90.9 | 85.4 |
| \pm 10 dB | | | | | | |
| B and N | 8.7 | 8.7 | 4.3 | 30.4 | 4.4 | 11.3 |
| Test-Retest B | 9.1 | 0.0 | 36.3 | 27.3 | 0.0 | 14.5 |
| Test-Retest N | 0.0 | 0.0 | 9.1 | 9.1 | 9.1 | 5.5 |
| \pm 15 dB | | | | | | |
| B and N | 4.3 | 0.0 | 4.3 | 8.8 | 4.3 | 4.3 |
| Test-Retest B | 0.0 | 0.0 | 18.2 | 0.0 | 0.0 | 3.6 |
| Test-Retest N | 9.1 | 0.0 | 9.1 | 9.1 | 0.0 | 5.5 |
| $>$ \pm 15 dB | | | | | | |
| B and N | 0.0 | 4.3 | 0.0 | 8.6 | 8.7 | 4.3 |
| Test-Retest B | 0.0 | 0.0 | 0.0 | 0.0 | 9.1 | 1.8 |
| Test-Retest N | 9.1 | 9.1 | 0.0 | 0.0 | 0.0 | 3.6 |

B, booth; N, natural office environment.

Discussion

Study 2 revealed the accuracy and reliability of pure tone audiometry using automated test sequences in a natural environment using the KUDUwave audiometer. There were no statistically significant threshold differences between the experimental and control conditions (91% within 5 dB for air conduction and 91% within 10 dB for bone conduction), as well as, test-retest correspondence for the control condition (93% within

5 dB for air conduction and 95% within 10 dB for bone conduction). These results for air conduction compare favorably to typical test-retest limits of 5 dB or less for thresholds measured in a sound booth (Stuart et al, 1991; Smith-Olinde et al, 2006; Margolis et al, 2010; Swanepoel et al, 2010c; Swanepoel & Biagio, 2011; Storey, 2014).

Averaged across left and right ears, mean absolute threshold differences for air conduction (3.3 ± 3.2) corresponded with mean test-retest absolute difference values previously reported for the same audiometer in a sound booth (Swanepoel et al, 2010c; Swanepoel & Biagio, 2011). Similarly, MacLennan-Smith et al. (2013) reported mean absolute threshold differences of 2.7 ± 3.1 dB between measurements in a natural environment and sound booth on a sample of elderly subjects. In a more recent study Storey et al. (2014) also reported absolute threshold differences of between 2.5 and 5.73 dB across frequencies comparing thresholds of the KUDUwave audiometer in 40 dB of noise compared to a clinical audiometer in a booth.

During pure tone testing in the experimental condition, ambient noise levels (Figure 3) were on average lower across all frequencies than the MPANL requirements for ears covered as set out by ANSI/ASA S3.1-1991 (R2013), but much higher than the requirements for ears uncovered. Noise levels were representative of that of a typical office environment. Compliant bone conduction audiometry would not have been allowed in the presence of these levels of background noise. Results of this study, however, show that the bone conduction threshold differences between the two conditions were within typical test-retest variability of 10 dB for bone conduction

audiometry conducted in a sound booth (Roeser & Clark, 2007; Margolis et al, 2007). Mean absolute differences in bone conduction thresholds recorded in the two conditions (4.6 ± 3.7) compares to 3.4 ± 4.3 dB reported by MacLennan-Smith et al. (2013) between recordings in a natural environment and sound booth. These are similar to, and slightly better than, the test-retest difference for bone conduction (7.1 ± 6.4) obtained in a sound-treated booth with the same audiometer in a recent study (Swanepoel & Biagio, 2011). Increased test-retest variability in bone compared to air conduction thresholds is attributed to factors such as the static force applied, location of the bone vibrator, the position of the lower jaw, functional state of the middle ear, and distortion of bone vibrators at lower frequencies (Stenfelt & Goode, 2005).

The mean absolute test-retest differences in the sound booth (2.8 ± 1.8 and 3.5 ± 2.6 for air and bone conduction, respectively) are virtually the same as those recorded in the natural environment (2.8 ± 2.0 and 3.7 ± 2.8 for air and bone conduction, respectively). The mean absolute test-retest threshold differences across air conduction and bone conduction frequencies in the sample reported by Swanepoel and Biagio (2011) was slightly higher than in the current study.

In light of previous reports demonstrating the validity of automation using this computer-based audiometer in a sound booth (Swanepoel et al, 2010c; Storey et al, 2014), and other reports validating manual audiometry with this device outside a sound booth (MacLennan-Smith et al, 2013; Swanepoel et al, 2013), this study demonstrates the validity of automated audiometry outside a sound booth with this device when used in a

typical office environment. No significant differences were found when comparing test-retest reliability between thresholds obtained manually inside a sound booth and automated thresholds obtained in a natural environment. These data are in line with the findings of a recent meta-analysis and systematic review of automated threshold audiometry (Mahomed et al, 2013).

Limitations to the study include the low levels of background noise present in the office environment during pure tone testing. A similar study conducted in higher levels of background noise across all frequencies than the MPANL requirements for ears covered, as set out by ANSI/ASA S3.1-1991 (R2013) would be an important future research priority. Another limitation is the fact that only normal hearing subjects were included and not clinically representative cases with hearing loss. One may however argue that those with hearing loss are less affected by ambient noise and as a result findings illustrate performance characteristics for the most adverse situation - testing down to normal hearing levels.

CONCLUSION

This study investigated a novel audiometry solution for provision of hearing related services outside the confines of conventional clinics and for addressing the limitations of sound booths. With advancements in technology, it has become possible for a mobile computer-based audiometer with double ear level attenuation to be coupled with live monitoring of ambient noise levels. This means that diagnostic audiometry services could be extended to locations with suboptimal acoustic environments with the

integrated quality control of monitoring noise. This study demonstrated that accurate and reliable testing in a natural environment using automated testing comparable to that of manual audiometry conducted within a sound booth is possible when using sufficient earphone attenuation in combination with real-time monitoring of ambient noise.

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