VALIDITY OF DIAGNOSTIC PURE TONE AUDIOMETRY USING A PORTABLE COMPUTERISED AUDIOMETER WITHOUT A SOUND-TREATED ENVIRONMENT

FELICITY JANE MACLENNAN-SMITH

A dissertation submitted in fulfilment of the requirements for the degree

M.COMMUNICATION PATHOLOGY

In the Department of Communication Pathology at the

UNIVERSITY OF PRETORIA

FACULTY OF HUMANITIES

SUPERVISOR: PROFESSOR DE WET SWANEPOEL

CO-SUPERVISOR: PROFESSOR JAMES W. HALL III

JANUARY 2013

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LIST OF ABBREVIATIONS

AC – Air Conduction

ANSI – American National Standards Institute

ASHA – American Speech Hearing Association

BC – Bone Conduction

dB – Decibel

HL – Hearing Level

Hz – Hertz

IEC – International Equipment Calibration

ISO – International Standards Organisation

PT – Pure Tone

SANS – South African National Standards

UN – United Nations

WHO – World Health Organisation

ABSTRACT

It is estimated that 10% of the global population is impaired to a significant degree by a decrease in hearing sensitivity. With the greatest proportion of these persons residing in developing countries where communities are grossly underserved, it is incumbent on hearing healthcare professionals to seek means of offering equitable hearing health care services to these communities. The delivery of conventional diagnostic hearing services to these population groups is challenged by limitations in human resources, financial constraints and by the dearth of audiometric testing facilities that are compliant with permissible ambient noise levels for reliable testing. Valid diagnostic hearing assessment without an audiometric test booth will allow greater mobility of services and could extend hearing healthcare service delivery in underserved areas. The purpose of this study was to investigate the validity of diagnostic pure tone audiometry in a natural environment, outside a sound treated room, using a computer-operated audiometer with insert earphones covered by circumaural earcups incorporating real-time monitoring of environmental noise.

A within-subject repeated measures research design was employed to assess elderly adults with diagnostic air (250 to 8000 Hz) and bone (250 to 4000 Hz) conduction pure tone audiometry. The study was of a quantitative nature and the required data was collected by testing subjects initially in a natural environment and subsequently in a sound booth environment to compare the threshold measurements. One experienced audiologist used audiometric KUDUwave test equipment to evaluate subjects in both environments. A total of 147 adults with an average age of 76 (± 5.7) years were tested. Ears had pure tone averages (500, 1000, 2000 and 4000 Hz) of ≥ 25 dB in 59%, >40 dB in 23% and > 55 dB in 6% of cases.

Analysis of collected data showed air conduction thresholds (n = 2259) corresponding within 0 to 5 dB in 95% of all comparisons between testing in the natural and sound booth environments. Bone conduction thresholds (n = 1669) corresponded within 0 to 5 dB in 86% of comparisons and within 10 dB or less in 97% of cases. Average threshold differences (–0.6 to 1.1) and standard deviations (3.3 to 5.9) were within typical test-retest reliability limits. Recorded thresholds showed no statistically significant differences with a paired samples t-test (p > 0.01) except at 8000 Hz in the left ear. Overall the correlation between the air-conduction thresholds recorded in the sound booth environment and the natural environment was very high (> 0.92) across all frequencies while for bone conduction threshold correlation for the two environments fell between 0.63 and 0.97.

This study demonstrates that valid diagnostic pure tone audiometry in an elderly population can be performed in a natural environment using an audiometer employing insert earphones covered by circumaural earcups with real-time monitoring of ambient noise levels. Mobile diagnostic audiometry performed outside of an audiometric sound booth may extend current hearing healthcare services to remote underserved communities where booths are scarce or inaccessible. In combination with Telehealth applications this technology could offer a powerful and viable alternate diagnostic service to persons unable to attend conventional testing facilities for whatever reasons.

Key Words: Hearing tests; Air conduction; Bone conduction; Computer-operated audiometer; Ambient noise; Natural environment; Sound-treated booth; Hearing healthcare services; Underserved communities; Extended service delivery.

1. INTRODUCTION

Hearing loss has a mild to profound impact on communicative functioning depending on a host of factors including severity, age of identification and age of onset (Bess, Lichtenstein, Logan, Burger & Nelson, 1989; Yoshinaga-Itano, Sedey, Coulter & Mehl, 1998). The best strategy for optimal benefit from intervention is the early identification of hearing impairment regardless of age. This is the goal of audiologists (Hall & Mueller, 1997).

The prevalence of hearing loss is increasing in populations in general and particularly more so in certain age groups (Weinstein, 2009). Of all groups of individuals, those over the age of 65 are at the greatest risk for sensory-neural hearing loss (Cruickshanks et al., 1998). It is estimated that approximately one third of adults older than 65 years of age present with significant hearing loss, with a prevalence of 94% for high frequency impairment (Cruickshanks et al., 2003; Mitchell et al., 2011). Prevalence of hearing loss rises to approximately 63% in those 71+ years of age (Wilson et al., 1999) and to 90% in those over the age of 80 (Cruickshanks et al., 1998). Hearing loss in the older adult is neither trivial nor benign. The reduction in quality of life is proportionate to the increase in hearing impairment. As an individual's potential to interact with the environment diminishes, auditory-verbal communication that is vital to relationships is compromised relating to associated poorer quality of life and functional health (Bess, Lichtenstein, Logan, Burger & Nelson, 1989; Wilson et al., 1999).

1.1 Rationale

As science continues to contribute to the reduction of mortality, the group of older adults is growing significantly. The fastest growing segment of the population is that of the over 80 group (UN, 2001). This segment is currently increasing at 3.8 per cent per year and comprises more than one tenth of the total number of older persons. By the middle of the century, one fifth of older persons will be 80 years or older (UN, 2001). Despite this institutional barriers still limit services to the older adult population. The average adult with hearing impairment waits more than ten years before seeking audiological assistance and the average age of new hearing aid users is almost 70 years (Weinstein, 2009). The silent nature of hearing loss, diminishing physical mobility, limited access to transport and sound-treated diagnostic facilities, together with cost, all contribute to the lack of motivation and opportunity to address the impairment. Considering the prevalence of hearing loss in older population groups, and the far-reaching negative consequences of such impairment, audiologists should become part of preventative hearing health care and early intervention by means of screening and identification programmes. Screening procedures involve the examination of asymptomatic persons to determine whether they do or do not exhibit the disorder of interest (Gravel, Fischer & Chase, 2009).

Screening in places such as retirement homes or communities, presents the audiologist with a number of challenges. The first of these is the management of ambient noise. Test stimulus levels often need to be set above the 20dBHL recommended by the American Speech-Language-Hearing Association (ASHA, 1997). This particularly compromises the identification of minimal hearing loss. Secondly and in contrast to the first challenge, it is incumbent on audiologists to limit over-referrals that may arise from ineffective management of ambient noise (ASHA,

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1997). Thirdly a prerequisite of any screening programme is the follow-up accessibility and availability of diagnostic and treatment facilities for the individual, in addition to the likelihood of reasonable compliance (Gravel et al., 2009).

Diagnostic hearing tests are ideally performed in specially constructed sound-treated chambers with very low levels of background noise. Because pure tone (PT) stimuli presented close to normal thresholds may be masked by extraneous noise, there are strict guidelines for maximum permissible ambient noise levels in audiometric test booths (Schlauch & Nelson, 2009). Centres for diagnostic audiometry are constrained by the financial outlay for a test booth or sound-treated room and the lack of hearing health care professionals (Swanepoel, 2010; Swanepoel, Olusanya & Mars, 2010a). Most of these centres are therefore located in cities and large towns. For the rural population, attendance at a sound-treated facility is fraught by the practicalities of distance, the lack of suitable transportation and of funds for transportation. This is particularly significant in developing countries such as South Africa (Swanepoel, 2010; Swanepoel et al., 2010a).

1.2 Problem Statement

Notwithstanding the availability of diagnostic centres, attendance by some older adults may be impeded by their poor physical mobility and lack of suitable transportation. Thus non-compliance following screening procedures becomes relevant in service delivery to communities. It is incumbent on audiologists to seek effective alternate methods of identifying and diagnosing individuals in need of intervention by extending the availability of diagnostic procedures to these individuals in their area and community.

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A newly developed portable PC-based audiometer (KUDUwave by GeoAxon), which actively monitors environmental noise levels throughout testing and also utilizes double attenuation in the form of insert and circumaural earphones, may be one way of delivering diagnostic services to patients outside of conventional clinics (Swanepoel et al., 2010b). These features could potentially improve efficacy and efficiency of both screening and diagnostic service delivery to communities where attendance at a sound-treated facility is tenuous. This could contribute to improved hearing healthcare coverage for rural areas and remote patients where specialized audiology services are lacking. In addition, the following constraints of conventional screening programmes, namely the management of extraneous noise and non-compliance of follow-up succeeding screening would be effectively addressed.

Given the fact that South Africa has limited financial resources within the public sector, the delivery of responsible services is of paramount concern to the Health Care Sector (Kaltenbrunn, Louw & Hugo, 2005). The fact that KUDUwave equipment possibly offers a diagnostic procedure that does not necessitate the use of a sound-treated room, poses the question: *What is the validity of this system when used outside of a sound-treated environment compared to conventional diagnostic audiometry in an audiometric test booth?*

Establishing the efficacy of diagnostic audiometric equipment that can be used outside of a test booth may provide practitioners with an alternate validated service for delivering ear and hearing healthcare to underserved and rural communities. In addition this technology may offer the potential of bridging the gap that currently exists in the health care system by facilitating telemedicine applications for diagnostic audiometry conducted outside of a conventional audiometric test booth setting (Swanepoel, 2010).

2. METHODOLOGY

2.1 Research Objectives

Main Aim

The main aim of this study was to determine the validity of audiometric pure tone (PT) thresholds in older adults when measured outside an audiometric test booth using a portable computerised audiometer.

Sub-aims

The sub-aims that addressed the main aim were:

1. To compare PT air conduction (AC) thresholds, recorded in a natural environment using a portable computerised audiometer, to those obtained in an audiometric test booth, in a sample of older adults.

2. To compare PT bone conduction (BC) thresholds, recorded in a natural environment using a portable computerised audiometer, to those obtained in an audiometric test booth, in the same sample of older adults.

Results of sub aims 1 & 2 were processed and described in the article titled *Validity of Diagnostic Pure-Tone Audiometry without a Sound-treated Environment in Older Adults* (chapter 3), which was accepted for publication in the International Journal of Audiology on 1 October 2012 and is currently in press. Posted Early Online 11 November 2012 and available at

http://informahealthcare.com/doi/abs/10.3109/14992027.2012.736692.

2.2 Research Design

The goal of this study was to investigate and describe possible similarities and differences in measured PT thresholds using different audiometric procedures. The research design used was a repeated-measure within-subject design, where the results of two procedures were investigated in a systematic manner and compared within a group of subjects so that the differences or similarities between them could be described (Hofstee, 2006; Mouton, 2008). The data gathered yielded information that was summarized through statistical analyses thus qualifying this study as quantitative (Leedy & Ormrod, 2005). An evaluative dimension of this study is represented by the outcome-based appraisal of the validity of the portable computerised approach for audiometric pure tone evaluations in a natural environment as opposed to the gold standard of an audiometric test booth (Hofstee, 2006).

2.3 Ethical Considerations

Ethical clearance for this study was obtained from the Research Ethics Committee, Faculty Humanities, University of Pretoria, prior to the collection of any data (Leedy & Ormrod, 2005), (Appendix A). Neither the researcher nor the supervisors are affiliated in any way to the manufacturers of the equipment used in this study. Whenever human beings are the focus of investigation, the ethical implications of what is proposed needs to be carefully considered (Leedy & Ormrod, 2005). In order to protect the rights and welfare of the participants in this study the following aspects were essentially addressed:

Informed Consent

Participation in this study was entirely voluntary for all respondents. Hearing assessments were conducted on site at retirement facilities. Informed consent was obtained as follows: Appointments were arranged with the management of six retirement facilities. Letters of request (Appendix B) were personally delivered to each facility at which stage the researcher was available to answer questions concerning the proposed research. In three cases the researcher was referred to the Body Corporate of the facility. The management of two of the centres declined to participate in the research study. Three management groups and one Body Corporate agreed to give their residents who so wished, the opportunity to participate in the project (Appendix C). Letters informing residents of the aims of the study, the procedures to be followed and inviting participation were disseminated to all resident units, including those in frail care, at each facility (Appendix D, English and Afrikaans). In addition respondents were informed verbally of the test procedures and the protocol to be followed prior to inclusion in the study. It was brought to their attention both verbally and in written form that they may withdraw from the study at any time without negative consequences. Participants were required to complete and sign an informed consent form (Appendix E, English and Afrikaans).

Protection from Harm

Participation in a study should not increase the normal risks of day-to-day living, nor subject the participant to unusual stress, embarrassment or loss of self-esteem. Any possible discomfort that may accompany procedures should be explained to participants in advance of participation (Leedy & Ormrod, 2005). The collection procedures used for this study were non-invasive, standard and routine. Refer to

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informed consent procedural letter (Appendix D, English and Afrikaans) for respondents.

Privacy

A research study should respect a participant's right to privacy, anonymity and confidentiality (Leedy & Ormrod, 2005). Participants were guaranteed privacy both verbally and in written format. Allocating a specific alphanumeric code to each respondent ensured anonymity in the processing of data and reporting of findings.

Beneficence

Where excessive cerumen was present respondents were offered the option of having it removed prior to participation in this study (Informed consent letter – Appendix D and Informed consent form – Appendix E). Participants were required to attend a professional practice for a second evaluation. Not all residents, in particular those in assisted living and frail care units, had ready access to transport facilities. The Rotary Club of Hermanus was approached for their co-operation in the transportation of participants. The Club agreed to make motor vehicle transport available for those who wished to make use thereof (Appendix F). Results of audiometric findings were communicated to participants for appropriate management of pathologies or hearing loss, so providing an identification and referral service. This information was provided verbally to respondents in a feedback session. A copy of the air and bone conduction audiogram was made available to each respondent irrespective of whether the data could be used for this study. Use was made of the 'Familiar Sounds' audiogram to illustrate hearing thresholds and provide a copy of the audiometric results (Appendix G).

2.4 Research Participants

Research Population

This study sampled subjects from an adult population group of 65 years and older who resided in retirement facilities in the Western Cape.

Sampling Method

Non-probability purposive sampling was used as the researcher could not predict or guarantee that each element of the population would be represented in the sample by including participants the researcher deemed as 'typical' of a certain age group (Leedy & Ormrod, 2005). Once initial consent (Appendix C) from each of four retirement facilities was obtained, letters describing the research project requirements for participation, procedures to be followed, guarantee of confidentiality and the option of termination of participation, were disseminated to residents (Appendix D). This was accompanied by a document of informed consent for completion by each respondent (Appendix E). Initially an approach of stratified sampling was to be used to ensure that equal opportunities existed for each respondent to participate in the study (Leedy & Ormrod, 2005). The researcher found however, that it was possible to accommodate all respondents after the selection criteria had been applied.

Selection Criteria

The diagnostic pure tone evaluation was firstly conducted at the retirement centre in a room provided by the facility and then followed by the same evaluation at an audiology clinic in an audiometric booth. Individual ears were included in the study when at both evaluations an intact tympanic membrane was otoscopically visible in combination with a normal Type A tympanogram. These criteria excluded from the

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study six ears with possible transitory middle ear pathology. In cases of excessive cerumen this was removed by the audiologist before testing. One of the participants elected to seek the services of another professional for the removal of cerumen prior to the first evaluation. The selection criteria are set out in Table 2.1

Table 2.1 Selection criteria for research participants

Criteria	Description	Justification
Age	Participants were required to be over the age of sixty five (65)	Hearing loss in the aged contributes to deterioration of quality of life (Bess, et al., 1989). The prevalence of hearing loss was found to be 45.9 % in a group of participants whose average age was 65.8 years (Range 45 - 92) (Cruickshanks, et al., 1998).
Conductive component	Absence of conductive component/Type A tympanogram on both test occasions	Screening procedures recognize the effects of fluctuating conductive hearing loss. The two hearing tests required from each participant were ideally to be performed within two weeks between procedures. Possible fluctuations in hearing acuity had to be excluded.
Language	English, Afrikaans first or second-language speakers	The researcher is proficient in English and Afrikaans.
Transport	Access to transport.	Participants were required to visit a professional practice for conventional PT audiometry. Hermanus Rotary Club made motor vehicle transport available for those who wished to make use thereof (Appendix F). In the event that an applicant did not have access to transport and was physically unable to make use of the supplied alternative, he/she was not considered for participation in this study.

Description of participants

A sample of 147 elderly subjects (57% female), with an average age of 75.8 years (SD 5.7; Range 65 – 94) were recruited from the four retirement homes for diagnostic pure tone audiometry evaluations. In total, 59% of the ears included in the study

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(n=288) from the 147 subjects demonstrated pure tone average (0.5, 1, 2 and 4 kHz) thresholds of 25 dB or greater. Slightly under a quarter of ears (23%) had pure tone averages of greater than 40 dB and 6% had pure tone averages of greater than 55 dB.

2.5 Data Collection Equipment

Audiometric equipment and apparatus used for data collection are described individually. A succinct comment on the function of each instrument is included.

Immittance Meter

Tympanometry was conducted as part of the selection criteria. An Interacoustics MT 10 handheld impedance audiometer/middle ear analyser employing a 226 Hz +/– 3% probe tone and a pressure range of +200 to –300 daPa was used for this measurement. A positive to negative sweep was employed with a pump speed of 250-350 daPa/second. Compliance range was 0.0-5 ml.

Audiometer

The audiometer used for diagnostic pure tone air and bone conduction was a KUDUwave 5000 (GeoAxon, Pretoria, South Africa), a Type 2 Clinical Audiometer (IEC 60645-1/2). The software-controlled audiometer was operated via an Acer Travelmate 2492 Notebook running Windows XP. The audiometer hardware is encased in each circumaural earcup and is powered by a USB cable that is plugged into the Notebook. The transducers are custom insert earphones with circumaural cups that cover the insert earphones after insertion, and a B-71 bone oscillator (Kimmetrics, Smithsburg, Md.) that is placed on the forehead with a standard adjustable spring headband. The headband is held in place on the centre of the

circumaural headband with a screw fitting (Figure 2.1). The audiometer is equipped with two microphones on each circumaural earcup. These monitor the environmental noise in octave bands during testing. The ambient noise levels are visually represented in real-time on the software throughout the evaluation (Figure 2.2). The noise monitoring function of the KUDUwave uses a low-pass (< 125 Hz), seven single octave band-pass (125, 250, 500, 1000, 2000, 4000 and 8000 Hz) and a high-pass (> 8000 Hz) filter to separate the incoming sound. The output of these filters is monitored in real-time and the peak value calculated and compared to a proprietary volume unit ballistic profile and the higher of the two passed to the user interface software (eMOYO) every 100 ms. The filters have a stop-band attenuation of 90 dB and pass-band ripple of 0.003 dB.

The environment-monitoring microphones incorporated in the headset were verified using an input signal of 1000 Hz at 94 dB SPL to show a maximum variation of 3.6 dB across microphones. Calibration of the microphones was based on an effective attenuation level which was determined using expert subjects with normal hearing sensitivity. This required the deep placement of insert earphones under the circumaural earcups of the KUDUwave audiometer. Pure tone stimuli were then presented at irregular intervals to the test subjects, at an intensity level 10 dB higher than their threshold for the test frequency, for each octave band and inter-octave band frequency (125 to 8000 Hz). Continuous narrowband noise was presented through free field speakers situated at 45 degrees 1 meter in front of each subject. The intensity of the noise was slowly increased until the pure tones could no longer be detected. The average of these levels at each frequency and per ear was used as the effective attenuation level for each frequency.

A response button is connected to the KUDUwave device to record subject responses to stimuli and to document response times. The audiometer was calibrated prior to commencement of the study using an 824 Type 1 sound level meter (Larson Davis, Provo, Utah) with a 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. Insert earphones were calibrated in accordance with ISO 389-2 and the bone oscillator according to ISO 389-3.

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Figure 2.1 KUDUwave audiometer showing insert earphones, circumaural earcups housing audiometers and forehead bone conductor mounted centrally on headband

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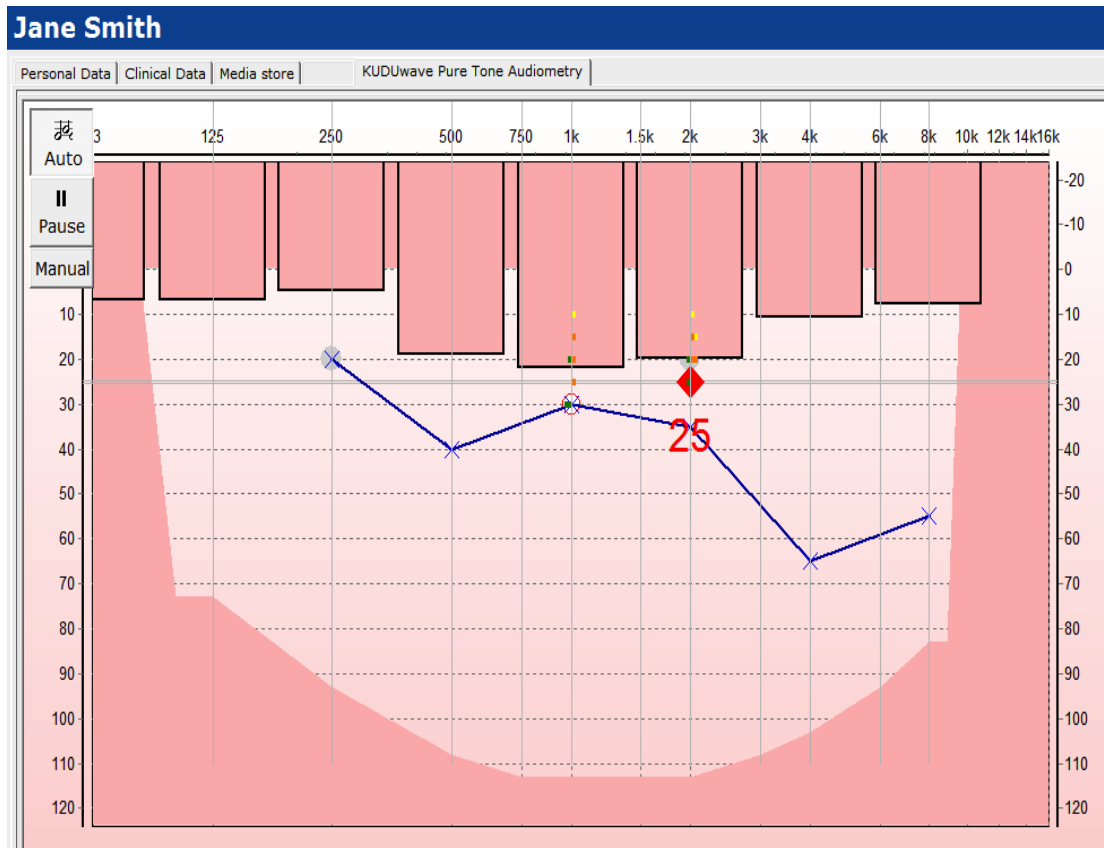
Figure 2.2 Screenshot of KUDUwave software demonstrating real-time monitoring of ambient noise levels while establishing thresholds

Audiometric Test Booth

Testing in the audiometric booth was conducted in a certified single-walled audiometric booth adhering to the maximum permissible ambient noise levels specified by ANSI (ANSI S3.1-1999(R2008)) for evaluating hearing to 0 dB HL from 250 to 8000 Hz. (Appendix H).

Sound Level Meter

A SVAN 957 Sound and Vibration Analyser, a Type 1 sound level analyser meeting the IEC 61672:2002 standard was used to record average noise levels over a 30

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minute period in two of the natural test environments and in the audiometric test booth for comparison of the ambient noise levels in each environment.

Otoscope

A Heine otoscope was used for otoscopic examinations and cerumen management.

Cerumen Management Equipment

Curette by Jobson-Horne, Ear loop by Billeau, Crocodile tweezers, light source (head torch) and standard sterilization equipment.

2.6 Data Collection and Analysis Procedures

2.6.1 Data Collection Procedures

Subject Assessments

An otoscopic examination and tympanometry was conducted prior to each evaluation for the purpose of identifying any transient middle ear pathology that would have excluded a subject from participation in the study. Each subject was tested twice, by the same experienced audiologist, with diagnostic air (250, 500, 1000, 2000, 3000, 4000, 6000, and 8000 kHz) and bone conduction (250, 500, 1000, 2000, 3000, and 4000 Hz) pure tone audiometry. The same KUDUwave audiometer was utilised for all diagnostic threshold measurements. The initial evaluation took place at the retirement facility, where the suitability for inclusion of the respondent in this study was established by applying the criteria requirements. Testing sequence was held constant, to limit procedure variability for the optimum comparison between the two test environments. By conducting the initial test in the natural retirement facility environment potential travelling costs and inconvenience were limited in the event

that a respondent proved not to meet the selection criteria. The natural environment provided by the retirement facility constituted a quiet furnished or semi-furnished room. An attempt was made to ensure that the test environment be free of distractions by placing a request for silence sign on the door of the room where the tests were conducted (Franks, 2001). The presenter sat in front of the subject but the wall behind her was kept blank.

The second evaluation was conducted with the subject in a certified audiometric test booth at an audiology clinic. Initial test results were not visible to the audiologist during the second evaluation, nor were they accessed prior to the test in the booth. The average time interval between tests was 6.4 (± 6.2 SD) days with the longest period being 42 days.

For air conduction pure tone threshold measurements insert foam tips of 12mm in length were fully inserted in the ear canal and then covered by the circumaural earcups of the audiometer for additional attenuation (insert earphone and circumaural earcup attenuation). Berger, Kieper and Gauger (2003) reported average attenuation for deeply inserted insert foam plugs covered by circumaural earphones, which is similar to the current study's double attenuation, of 57, 62, 49, 40, 50 and 50 dB for 250, 500, 1000, 2000, 4000 and 8000 Hz, respectively. These attenuation values exceed that of typical transportable sound-treated booths (Franks, 2001). Exceptions for full 12 mm depth of insertion were made in a small number of cases where stenosis was present. In these instances the inserts were placed as deeply as possible into the ear canals without causing discomfort.

Forehead placement bone conduction audiometry was conducted with both ears occluded by the deep insertion of the earphone and the circumaural earcup. This was done to increase the attenuation of ambient noise levels (Berger, 1983; Berger &

Killion, 1989; Berger et al., 2003) and to minimize the occlusion effect. By placing insert earphones down to the bony part of the ear canal the occlusion effect is reduced allowing for bone conduction evaluation with occluded ears (Dean & Martin, 2000; Stenfelt & Goode, 2005; Swanepoel & Biagio, 2011). Deep insertion required removal of cerumen by the audiologist in 24.5% of the subjects prior to their being included in this study.

Verbal instructions were given in either English or Afrikaans and the participant was required to demonstrate an understanding of the test procedures before commencement of the evaluation. Subject responses with a patient response button allowed for recording reaction times for true positive responses within 1.5 seconds after stimulus presentation. Thresholds were measured using a routine modified 10 dB down and 5 dB up bracketing method (modified Hughson-Westlake method) and commenced at 1000 Hz and 40 dB HL in the left ear, proceeding to the lower frequencies before recording thresholds at high frequencies. In the absence of a response at 40 dB HL the intensity of the tone was increased in steps of 10 dB until a response was noted, from where the bracketing method recommenced. When the AC thresholds in test and non-test ears differed by 75 dB or more at frequencies of 1000 Hz and below and 50 dB or more at frequencies above 1000 Hz, effective masking of 30 dB above the air conduction threshold of the non-test ear was employed and a plateau sought. A continuous contralateral effective masking level of 20 dB above the air conduction threshold of the non-test ear was used for the forehead bone conduction audiometry (ASHA, 2005). Thresholds were evaluated down to a minimum of 0 dB HL.

Ambient noise levels were actively monitored across octave bands throughout the test procedures in both test environments. When the noise exceeded the maximum

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ambient noise level allowed for establishing a threshold, as based on the effective attenuation level of the KUDUwave software, the audiologist waited for the transient noise to abate or continued testing at other frequencies.

All information and data was collected and documented on the KUDUwave software. The age, gender, dates, time lapse in days between test procedures, otoscopic findings, tympanogram type and notes were recorded on the software. Audiometric threshold findings were documented, and described for the experimental (natural environment) and controlled (sound-treated booth) conditions. The research process used four sets of data from each participant as follows:

- Audiometric measurement of AC thresholds using the KUDUwave audiometer in a quiet room (natural environment) at a retirement facility.

- Audiometric measurement of AC thresholds using the KUDUwave in an audiometric test booth.

- Audiometric measurement of BC thresholds using the KUDUwave audiometer in a quiet room (natural environment) at a retirement facility.

- Audiometric measurement of BC thresholds using the KUDUwave in an audiometric test booth.

All data was collected bilaterally from each participant although data from six ears necessitated exclusion due to possible transitory middle ear pathology. Subjects were made aware of the fact that the test could be terminated at any time should he/she feel unable or unwilling to continue with any of the procedures. Verbal and written feedback of hearing thresholds was given to each participant following the second hearing test (Appendix G).

Ambient Noise Measurements

Average noise levels were recorded over a 30 minute period with a Type 1 sound level meter in two of the retirement homes and in the certified audiometric test booth environment for comparison.

2.6.2 Data Processing and Analysis Procedures

As the data of this study is of a quantitative nature it was entered into a Microsoft Excel data sheet before exporting to SPSS (v.19). The threshold data for air- and bone conduction testing in the two environments was analysed descriptively with average differences and absolute average differences presented with respective distributions. Correspondence of thresholds between the natural and clinical environment was described in percentages and with 95% Confidence Intervals. Inferential statistics using a Paired Samples t-Test with the significance level at 1% determined whether hearing thresholds differed significantly, statistically and clinically, between natural and clinical environments. Pearson correlation coefficients for air and bone conduction thresholds recorded in the natural and audiometric booth environment described the correlation between the thresholds measured in the two environments.

3. VALIDITY OF DIAGNOSTIC PURE-TONE AUDIOMETRY WITHOUT A SOUND-TREATED ENVIRONMENT IN OLDER ADULTS

Authors: Felicity Maclennan-Smith, De Wet Swanepoel and James W Hall III

Note: This article was edited in accordance with the editorial specifications of the journal and may differ from the editorial style of the rest of this document.

3.1 ABSTRACT

Objective: To investigate the validity of diagnostic pure-tone audiometry in a natural environment using a computer-operated audiometer with insert earphones covered by circumaural earcups incorporating real-time monitoring of environmental noise. *Design*: A within-subject repeated measures design was employed to compare air (250 to 8000 Hz) and bone (250 to 4000 Hz) conduction pure-tone thresholds measured in retirement facilities with thresholds measured in a sound-treated booth. *Study sample*: 147 adults (average age 76 ± 5.7 years) were evaluated. Pure-tone averages were ≥ in 59%, mildly (>40 dB) elevated in 23% and moderately (>55 dB) elevated in 6% of ears. *Results*: Air-conduction thresholds (n=2259) corresponded within 0 to 5 dB in 95% of all comparisons between the two test environments. Bone-conduction thresholds (n=1669) corresponded within 0 to 5 dB in 86% of

comparisons. Average threshold differences (-0.6 to 1.1) and standard deviations (3.3 to 5.9) were within typical test-retest reliability limits. Thresholds recorded showed no statistically significant differences (Paired Samples T-test: p>0.01) except at 8000 Hz in the left ear. *Conclusion*: Valid diagnostic pure-tone audiometry can be performed in a natural environment with recently developed technology, offering the possibility of access to diagnostic audiometry in communities where sound-treated booths are unavailable.

Key Words: Audiometry; air conduction; bone conduction; computer-operated audiometer; ambient noise; natural environment; sound booth

Abbreviations

AC Air conduction

BC Bone conduction

3.2 INTRODUCTION

Pure-tone audiometry has remained the unequivocal gold standard for assessment of hearing since its widespread inception as a clinical tool more than six decades ago. A prerequisite for reliable audiometry measures is a controlled test environment with sufficiently low level of ambient noise to ensure background noise does not mask hearing thresholds as low as 0 dB HL. An adequate test environment is typically achieved by employing audiometric test booths or sound-treated rooms that are specially constructed to provide a sound-isolated environment for testing. Standards

of international and national bodies such as the American National Standards Institute (ANSI) and the South African National Standards (SANS) require that ambient noise levels in audiometric test rooms be sufficiently low so as to ensure that hearing thresholds are not artificially elevated.

The compliance of audiometric booths with permissible ambient noise levels specified by ANSI (ANSI S3.1-1999(R2008)) has however been surprisingly poor. A study by Frank and Williams (1993) measured noise levels in 136 audiometric test rooms in various audiological facilities. For air-conduction testing using supra-aural earphones only 50% of booths had sufficiently low ambient noise levels for testing 250 to 8000 Hz (ANSI S3.1-1999). For bone-conduction testing with ears uncovered, permissible ambient noise levels were sufficient in only 14% of booths for testing 250 to 8000 Hz. In a similar study conducted on 490 single-walled prefabricated audiometric booths used for industrial testing only 33% met the ANSI (ANSI S3.1-1999) minimum permissible noise levels (Frank & Williams, 1994).

Another compliance concern related to audiometric booths is that they are to be certified annually during a "typical" working day to ensure compliance with permissible ambient noise levels standards (ANSI, 1999; OSHA, 1983). Transient sources of noise can however vary during a "typical" or "atypical" day or days and may affect test results without the clinician's knowledge (Frank & Williams, 1993; Frank & Williams, 1994).

Apart from compliance concerns, audiometric sound booths and sound-treated rooms have other limitations related to expense and mobility. The booths appropriate for diagnostic audiometry are usually more costly than the audiometer, especially for double-walled rooms. Furthermore because of their size and weight, sound-treated booths almost always remain in one location, and cannot be transported to test sites.

Mobile booths are used for occupational screening purposes and require calibration after each relocation for compliance with specified standards (ANSI, 1999; OSHA, 1983). The use of mobile booths is cumbersome and often not financially viable for servicing patients, who, in need of diagnostic audiometry, are unable to attend audiological centres (e.g. bed ridden patients or patients in retirement homes). The expense of sound-treated booths and their lack of mobility hinder the delivery of diagnostic audiometry services in lower-income developing countries where they are often unavailable or restricted to large cities (Swanepoel, Clark et al, 2010; Swanepoel, Olusanya & Mars, 2010). The challenge of accessing a proper sound environment is also particularly pertinent for the growing field of telemedicine applications in audiometry which demonstrates the potential to provide services in remote and underserved regions (Swanepoel, Clark et al, 2010; Swanepoel, Olusanya & Mars, 2010).

Owing to the above limitations and challenges related to sound-booths, alternate passive and active noise reduction approaches in headphone sets have been investigated to allow for sufficient attenuation for reliable testing down to 0 dB HL. Supra-aural earphones by themselves provide limited attenuation of ambient noise, especially in lower frequencies (Berger & Killion, 1989; Arlinger, 1986; Frank & Wright, 1990). The use of supra-aural earphones within noise-reducing enclosures has been evaluated in an attempt to improve attenuation to allow for compliant testing in environments with high ambient noise levels. Although these provide additional attenuation, they are insufficient for diagnostic testing down to 0 dB, especially at lower frequencies (Frank, Greer & Magistro, 1997). In addition, thresholds are further elevated with poorer test-retest reliability than regular supra-aural earphones (Frank, Greer & Magistro, 1997).

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Insert earphones are recommended as a more effective way of reducing ambient noise levels for compliant testing (Frank, Greer & Magistro, 1997; Berger & Killion, 1989). According to Berger and Killion (1989), insert earphones that are properly placed within the external ear canal can provide 30 to 40 dB of attenuation of ambient noise which is sufficient to allow for testing down to audiometric zero across the frequency range of 125 to 8000 Hz in typical office noise environments. The attenuation with insert earphones may be prone to some variability owing to insertion depth even though hearing thresholds measured with insert earphones are consistent (Berger & Killion, 1989; Clark & Roeser, 1988). Adding earmuffs or circumaural earcups over the insert earphones provides a further increase in attenuation (Berger, 1983; Berger, Kieper & Gauger, 2003). Active noise reduction headphone technology may also be included in these circumaural earcups covering insert earphones. Bromwich et al (2008) used a combination of circumaural active noise cancellation earphones covering insert earphones and demonstrated that with 30 dB SPL ambient noise levels in the sound field no shifts in hearing thresholds were noticed across frequencies (250 – 4000 Hz). Ambient noise exceeding this level can however result in threshold elevations (Bromwich et al, 2008) and the active circuitry may raise the noise floor to unacceptable levels.

The benefit of increased attenuation using insert earphones covered with circumaural earcups is therefore negated if the ambient environmental noise is not monitored continually to ensure compliance while each threshold is measured. The current study investigated the validity of hearing threshold estimation in a natural environment with a recently validated audiometer (Swanepoel & Biagio, 2011) utilizing insert earphones covered by circumaural earcups that incorporate external microphones monitoring environmental noise levels during testing.

3.3 METHOD

This repeated-measure within-subject study was approved by the institutional Ethics Committee of the University of Pretoria in South Africa and all subjects provided informed consent prior to participation.

3.3.1 Subjects

A sample of 147 elderly subjects (57% female) with an average age of 75.8 years (SD 5.7; Range 65 – 94) was recruited from four retirement homes in the Western Cape, South Africa, for diagnostic pure-tone audiometry evaluations conducted first at the retirement home in a room provided by the facility and followed by the same evaluation at an audiology clinic in an audiometric booth. Individual ears were included in the study when at both evaluations an intact tympanic membrane was otoscopically visible in combination with a normal Type A tympanogram. These criteria excluded from the study six ears with possible transitory middle ear pathology. In cases of excessive cerumen this was removed by the audiologist before testing. In total, 59% of the ears included in the study (n=288) from the 147 subjects demonstrated pure-tone average (500, 1000, 2000 and 4000 Hz) thresholds of 25 dB or greater. Nearly a quarter (23 %) of ears had pure-tone averages of greater than 40 dB and 6% had pure-tone averages of greater than 55 dB.

3.3.2 Equipment

Tympanometry was conducted as part of the screening procedure using an Interacoustics MT 10 handheld impedance audiometer/middle ear analyser employing a 226 Hz probe tone. The audiometer used was a KUDUwave 5000 (GeoAxon, Pretoria, South Africa), a Type 2 Clinical Audiometer (IEC 60645-1/2) that

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was software controlled and operated via a Notebook (Acer Travelmate 2492 running Windows XP). The audiometer hardware was encased in each circumaural earcup and was powered by a USB cable plugged into the Notebook. The transducers included embedded custom insert earphones, which were covered by the circumaural cups after insertion. The insert earphone frequency response approximated that of the ER3A within 1 dB across test frequencies allowing for the use of the international insert earphone standard (ISO 389-2, 1994) for calibration. A B-71 bone oscillator (Kimmetrics, Smithsburg, Md.) was placed on the forehead with a standard adjustable spring headband held in place on the centre of the circumaural headband with a screw fitting (Figure 3.1).

The audiometer had two microphones on the circumaural earcup that monitored the environmental noise in octave bands during testing and was visually represented in real-time on the software (Figure 3.2). The noise-monitoring function of the KUDUwave used 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 output of these filters was monitored in real-time and the peak value calculated and compared to a proprietary volume unit ballistic profile and the higher of the two passed to the user interface software (eMOYO) every 100ms. The filters had a stop-band attenuation of 90 dB and pass-band ripple of 0.003 dB. The environment-monitoring microphones incorporated in the headset were verified using an input signal of 1 kHz at 94 dB SPL to show a maximum variation of 3.6 dB across microphones. Calibration of the microphones was based on an effective attenuation level which was determined using expert subjects with normal hearing sensitivity. Pure tones were presented at irregular intervals to the test subjects at an intensity level 10 dB higher than the threshold of the test ear for frequencies in each octave

band as well as the inter-octave frequencies (125 to 8000 Hz). The insert earphones were placed in the ear canals with the 12mm foam tip completely fitted into the canal and covered by the circumaural cups of the KUDUwave audiometer. Continuous narrowband noise was presented through free-field speakers situated at 45 degrees 1 meter in front of the subject. The intensity of the noise was slowly increased until the pure tones could not be detected. The average of these levels at each frequency and per ear was used as the effective attenuation level for each frequency.

A response button was connected to the KUDUwave device to record patient responses to stimuli and to document response times. The audiometer was calibrated prior to commencement of the study using an 824 Type 1 sound level meter (Larson Davis, Provo, Utah) with a G.R.A.S. (Holte, Denmark) IEC 711 coupler for insert earphones and an AMC493 Artificial Mastoid on an AEC101 coupler (Larson Davis) with 2559 ½ inch microphone for the Radioear B-71 bone oscillator. Insert earphones were calibrated in accordance with ISO 389-2 and the bone oscillator according to ISO 389-3. Testing in the audiometric booth was conducted in a single-walled audiometric booth adhering to ambient noise levels specified by ANSI (ANSI S3.1-1999(R2008)) for evaluating hearing down to 0 dB HL from 250 to 8000 Hz.

Figure 3.1 KUDUwave audiometer showing insert earphones, circumaural earcups housing audiometers and forehead bone conductor mounted centrally on headband
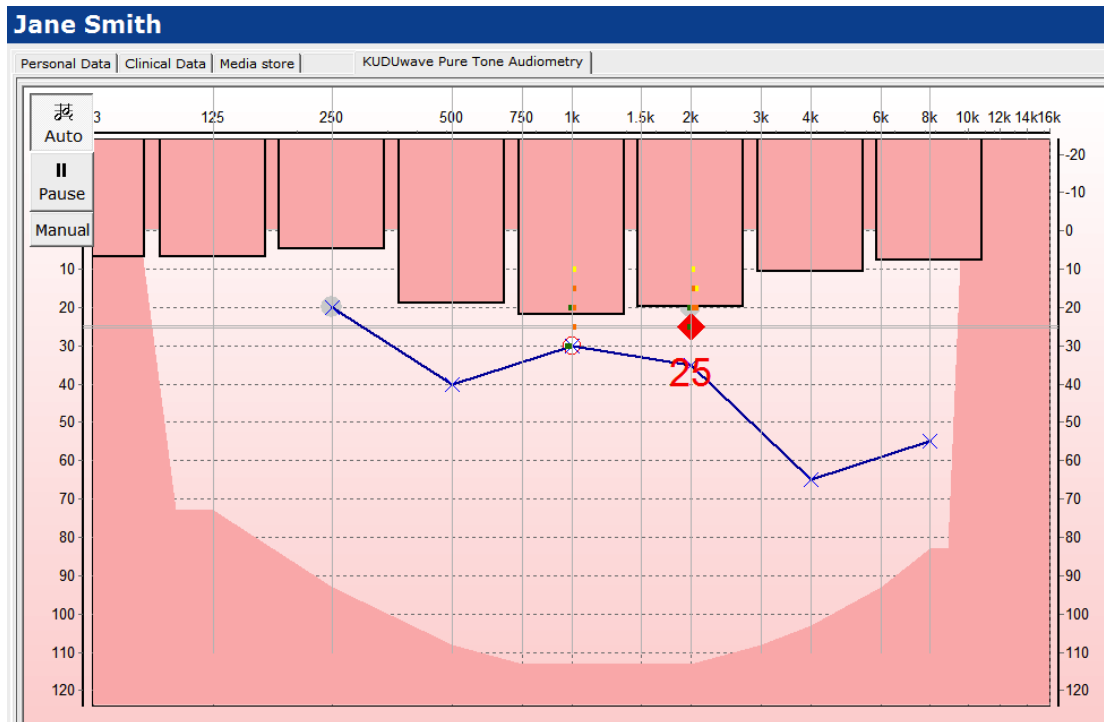
Figure 3.2 Screenshot of KUDUwave software demonstrating real-time monitoring of ambient noise levels while establishing thresholds

3.3.3 Procedures

Subjects were tested twice with diagnostic air (250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz) and bone-conduction (250, 500, 1000, 2000, 3000, 4000 Hz) pure-tone audiometry by the same experienced audiologist using the same audiometer. Testing sequence was held constant, intentionally confining procedure variability for the best comparison between the two test environments. In all cases, the initial test was conducted in a natural environment provided by the retirement home facility, and constituted a quiet furnished room. Conducting the initial test in the natural environment limited travelling costs and inconvenience in the event that a respondent proved not to meet the selection criteria. The second evaluation was conducted with the subject in a certified audiometric booth at an audiology clinic. Initial test results were not visible to the audiologist during the second evaluation, nor were they

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accessed prior to the test in the booth. The average time interval between tests was 6.4 (± 6.2 SD) days with the longest period being 42 days. An otoscopic examination and tympanometry were conducted prior to each evaluation to confirm the absence of any transient middle ear influences before inclusion in the study.

Air-conduction pure tones were delivered via deeply inserted insert foam tips covered by the circumaural earcups of the audiometer for additional attenuation (insert earphone and circumaural earcup attenuation). In the small number of cases where the 12mm foam tips could not be fully inserted, such as in the presence of stenosis, they were placed as deeply as possible into the ear canals. Berger et al, (2003) reported average attenuation for deeply inserted insert foam plugs covered by circumaural earphones. This is similar to the current study's double attenuation of 57, 62, 49, 40, 50 and 50 dB for 250, 500, 1000, 2000, 4000 and 8000 Hz, respectively. These attenuation values exceed those of typical transportable sound-treated booths (Franks, 2001). Forehead placement bone-conduction audiometry was conducted with both ears occluded by the deep insertion of the earphones. Placement of the insert earphones was deep with the foam tip inserted completely into the canal to improve the attenuation of ambient noise (Berger & Killion, 1989; Berger, 1983; Berger, Kieper & Gauger, 2003) and to minimize the occlusion effect. Placing insert earphones down to the bony part of the ear canal reduces the occlusion effect allowing for bone-conduction evaluation with occluded ears (Dean & Martin, 2000; Stenfelt & Goode, 2005; Swanepoel & Biagio, 2011). Deep insertion required removal of cerumen by the audiologist in 24.5% of the subjects prior to their inclusion in this study.

Verbal instructions were provided in either English or Afrikaans to ensure that the participant demonstrated an understanding of the test procedures. Subject responses

with a patient response button allowed for recording reaction times for true positive responses within 1.5 seconds after stimulus presentation. Thresholds were measured using a routine modified 10 dB descending and 5 dB ascending method (modified Hughson-Westlake method) commencing at 1000 Hz at 40 dB HL in the left ear and proceeding to the lower frequencies before recording thresholds at high frequencies. In the absence of a response at 40 dB HL, the intensity was increased in steps of 10 dB until a response was noted from where the bracketing method recommenced. Masking of 30 dB above the air-conduction threshold of the non-test ear commenced for air-conduction audiometry when the thresholds in test and non-test ears differed by 75 dB or more at frequencies of 1000 Hz and less and 50 dB or more at frequencies above 1000 Hz. A continuous contralateral effective masking level of 20 dB above the air-conduction threshold of the non-test ear was used for the forehead bone-conduction audiometry (ASHA, 2005).

Average noise levels recorded (over a 30 minute period) with a Type 1 sound level meter in two of the retirement homes showed average noise levels of 46.5 and 53.6 dBA as opposed to 21.2 dBA in the sound-booth environment. The KUDUwave software actively monitored ambient noise levels across octave bands throughout the test procedures in both test environments. Whenever the noise exceeded the maximum ambient noise level allowed for establishing a threshold as indicated by the effective attenuation level in the KUDUwave software, the audiologist waited for the transient noise to abate or continued testing at other frequencies. Thresholds were evaluated down to a minimum of 0 dB HL.

3.3.4 Analysis

The threshold data for air-conduction and bone-conduction testing in the two environments were analysed descriptively with average differences and absolute

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average differences presented with respective distributions. Correspondence of thresholds between the natural and clinical environment was described in percentages and with 95% Confidence Intervals. A Paired Samples T-test with the significance level at 1% was used to determine whether hearing thresholds differed significantly between natural and clinical environments.

3.4 RESULTS

Average air-conduction threshold differences between the natural environment and audiometric booth testing (Table 3.1) were between -0.6 and 1.1 dB with standard deviations of between 3.3 and 5.9 dB across frequencies and left and right ears. Average bone-conduction threshold differences between the natural environment and audiometric booth testing (Table 3.2) were between -0.6 and 1.3 dB with standard deviations of between 4.0 and 7.5 dB across frequencies and left and right ears. Differences in the natural and audiometric booth environments across ears and frequencies were within ± 5 dB for 95% of air-conduction thresholds (n=2259) and 86% of bone-conduction thresholds (n=1669). Bone-conduction thresholds corresponded within 0 to 10 dB in 97% of cases. Approximately half of the air-conduction (53%) and bone- conduction (51%) thresholds showed no change between test environments.

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Table 3.1 Difference in air conduction thresholds recorded in the natural and audiometric booth environment (Thresholds recorded in the booth subtracted from those recorded in the natural environment)

Freq (Hz)	250	500	1000	2000	3000	4000	6000	8000
Left AC Difference (Natural & Booth)								
n	143	143	143	143	143	143	139	126
Average	0.0	0.1	0.2	0.1	-0.6	-0.4	0.0	1.1
SD	5.4	4.3	3.6	3.5	3.3	3.4	3.6	4.6
95% CI	-0.8;0.9	-0.5;0.9	-0.3;0.9	-0.4;0.7	-1.2;0.1	-1.0;0.1	-0.7;0.5	0.3;1.9
±5dB %	87	92	97	98	99	97	97	94
±10dB %	97	99	100	100	100	100	100	98
Right AC Difference (Natural & Booth)								
n	145	145	145	144	143	143	140	131
Average	-0.3	0.1	-0.3	0.1	-0.3	-0.3	-0.2	0.6
SD	5.9	3.9	3.6	4.0	3.9	3.5	3.9	4.7
95% CI	-1.3;0.6	-0.6;0.7	-0.9;0.3	-0.6;0.8	-1.0;0.3	-0.8;0.3	-0.8;0.5	-0.2;1.5
±5dB %	86	96	97	96	95	99	97	88
±10dB %	96	100	99	99	100	100	99	100

Table 3.2 Difference in bone conduction thresholds recorded in the natural and audiometric booth environment (Thresholds recorded in the booth subtracted from those recorded in the natural environment)

Freq (Hz)	250	500	1000	2000	3000	4000
Left BC Difference (Natural & Booth)						
n	140	139	142	141	135	132
Average	0.7	0.8	0.1	0.6	-0.6	-0.3
SD	5.9	5.7	7.5	4.1	4.0	4.4
95% CI	-0.3;1.7	-0.2;1.7	-1.2;1.3	-0.1;1.2	-1.3;0.1	-1.1;0.5
±5dB %	86	85	73	93	93	92
±10dB %	94	97	90	99	100	99
Right BC Difference (Natural & Booth)						
n	142	141	143	142	136	136
Average	-0.2	1.3	0.4	0.2	-0.1	-0.3
SD	6.3	6.0	6.2	4.1	4.7	5.1
95% CI	-1.2;0.9	0.3;2.3	-0.6;1.4	-0.5;0.9	-0.9;0.7	-1.2;0.5
±5dB %	86	77	78	94	91	88
±10dB %	94	96	95	99	99	99

Normal hearing thresholds (≤25 dBHL) and elevated thresholds (>25 dBHL) as shown in Table 3.3, demonstrated similar average threshold differences and standard deviations. The average absolute difference for air-conduction thresholds was 2.7 dB (± 3.2 SD) and 2.7 dB (± 3.1 SD) for normal (≤25 dBHL) compared to elevated (>25 dBHL) threshold comparisons respectively. Air-conduction thresholds in the natural and audiometric booth corresponded within 5 dB or less of each other in 94.1% of cases for normal hearing thresholds (≤25 dBHL) compared to 94.9% for

elevated thresholds (>25 dBHL). The average absolute difference for bone-conduction thresholds was 3.4 dB (± 4.2 SD) and 3.4 dB (± 4.3 SD) for normal (≤25 dBHL) compared to elevated (>25 dBHL) threshold comparisons respectively. Bone-conduction thresholds in the natural environment and audiometric booth corresponded within 10 dB or less of each other in 96.7% of cases for normal hearing thresholds (≤25 dBHL) compared to 96.9% for elevated thresholds (>25 dBHL).

Table 3.3 Difference in air and bone conduction thresholds ≤25 dB and >25 dB recorded in the natural and audiometric booth environment (Thresholds recorded in the booth subtracted from those recorded in the natural environment)

Freq (Hz)	250	500	1000	2000	3000	4000	6000	8000
AC Thresholds ≤ 25 dB difference (Natural & Booth)								
n	209	208	177	133	96	72	45	15
Average	0.3	0.5	0.0	0.3	-0.1	-0.5	0.4	3.0
SD	5.3	4.0	3.6	3.7	3.4	3.9	3.2	4.1
±5dB %	88	94	95	97	99	96	100	87
AC Thresholds > 25 dB difference (Natural & Booth)								
n	79	80	111	154	190	214	234	242
Average	-1.2	-0.8	0.0	-0.1	-0.7	-0.3	-0.3	0.7
SD	6.1	4.3	3.5	3.8	3.7	3.3	3.8	4.7
±5dB %	84	93	98	97	96	99	97	91
BC Thresholds ≤ 25 dB difference (Natural & Booth)								
n	273	243	212	146	111	100		
Average	0.5	1.4	1.2	0.7	-0.3	-0.2		
SD	5.7	5.9	6.4	3.8	4.3	4.3		
±5dB %	86	79	75	95	95	91		
BC Thresholds > 25 dB difference (Natural & Booth)								
n	9	37	73	137	160	168		
Average	-6.7	-1.8	-2.6	0.0	-0.4	-0.4		
SD	13.2	4.3	7.6	4.4	4.5	5.1		
±5dB %	78	92	74	92	91	89		

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The average absolute difference between thresholds recorded in the natural and audiometric booth environments for air conduction (Figure 3.3) was 2.7 ± 3.1 dB and for bone conduction (Figure 3.4) was 3.4 ± 4.3 dB, across all frequencies. The average absolute differences (Table 3.4) in air-conduction thresholds varied between 2.0 and 3.6 dB across frequencies with standard deviations between 2.6 and 4.0 dB. Bone-conduction average absolute differences varied between 2.6 and 5.2 with standard deviations between 3.2 and 5.3.
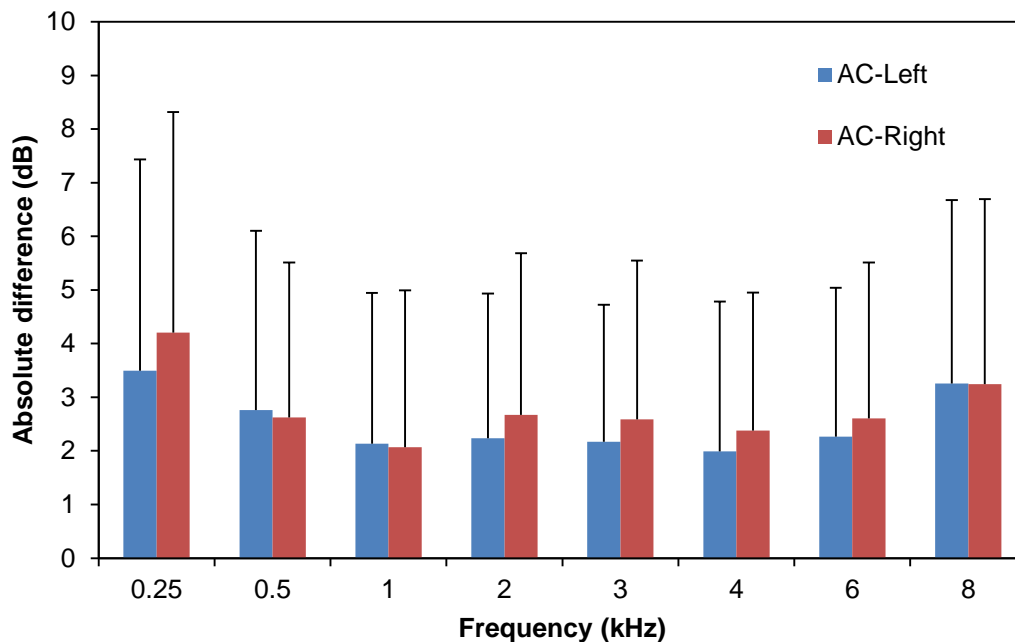
Figure 3.3 Average absolute difference between air conduction thresholds recorded in the natural and audiometric booth environment (error bars = 1 SD)
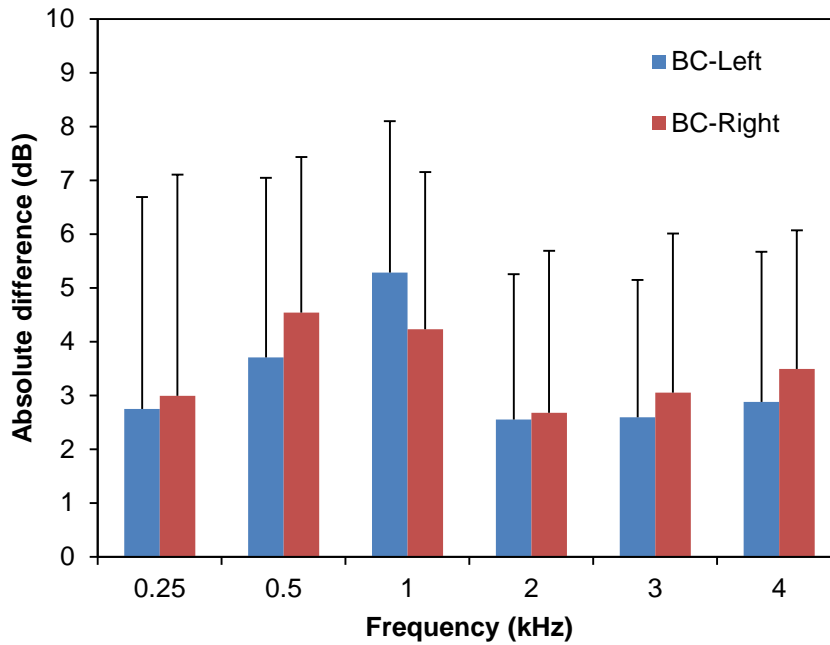
Figure 3.4 Average absolute difference between bone conduction thresholds recorded in the natural and audiometric booth environment (error bars = 1 SD)

Table 3.4 Absolute difference in air and bone conduction dB thresholds recorded in the natural and audiometric booth environment (Left & Right ears combined)

Freq (Hz)	250	500	1000	2000	3000	4000	6000	8000
AC Threshold Correlation (Natural & Booth)								
Ave (Abs)	3.6	2.7	2.2	2.2	2.1	2.0	2.3	3.2
SD	4.0	3.3	2.9	2.7	2.6	2.8	2.8	3.4
n	294	294	294	293	292	292	284	262
BC Threshold Correlation (Natural & Booth)								
Ave (Abs)	2.8	3.8	5.2	2.6	2.7	2.9		
SD	5.3	4.3	5.3	3.2	3.3	3.3		
n	288	286	291	289	276	273		

Comparison of air- and bone-conduction thresholds obtained in the natural and audiometric booth environments revealed no statistically significant differences (Paired Samples T-test; p>0.01) except at 8000 Hz in the left ear for air conduction (p=0.006). That one exception was not clinically significant. Differences were within 0 to 5 dB of each other for 94% of thresholds. Table 3.5 shows threshold correlation coefficients between 0.92 and 0.99 for air conduction and 0.63 and 0.97 for bone conduction in the natural and audiometric booth test environments.

The number of subject responses to pure-tone presentations and the average reaction time and standard deviation of these were also compared between the natural and audiometric booth environments and showed no significant difference (Paired Samples T-test; p>0.01).

Table 3.5 Pearson correlation coefficients for air and bone conduction thresholds recorded in the natural and audiometric booth environment

Freq (Hz)	250	500	1000	2000	3000	4000	6000	8000
AC Threshold Correlation (Natural & Booth)								
Left	.93	.96	.97	.98	.99	.99	.98	.97
Right	.92	.97	.98	.98	.98	.98	.98	.96
BC Threshold Correlation (Natural & Booth)								
Left	.73	.90	.89	.97	.97	.97		
Right	.63	.87	.92	.97	.96	.96		

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3.5 DISCUSSION

Ambient noise may reduce the specificity of audiometric testing (Bromwich et al, 2008). In the absence of an audiometric booth, the management and the monitoring of background noise are essential for accurate evaluation of hearing thresholds (Swanepoel, Clark et al, 2010; Swanepoel, Olusanya & Mars, 2010). We evaluated the performance of an audiometer employing passive attenuation using insert earphones covered by circumaural earcups coupled with real-time monitoring of environmental noise for air-conduction and bone-conduction threshold measurement in a natural environment. Double transducer attenuation using insert foam plugs and circumaural earcups produces a significant increase in ambient noise attenuation that may actually exceed typical attenuation for transportable sound booths (Berger, Kieper & Gauger, 2003; Franks, 2001). Results of the current study confirmed statistically and clinically equivalent hearing thresholds as measured in a natural environment versus a sound-treated booth.

Air-conduction thresholds measured in the natural and standard audiometric booth corresponded within typical 5dB or less test-retest limits for thresholds measured in a sound booth (Stuart et al, 1991; Smith-Olinde et al, 2006; Margolis, Glasberg, Creeke & Moore 2010; Swanepoel, Mngemane et al, 2010; Swanepoel & Biagio, 2011). Average absolute air-conduction threshold differences for the current study (2.7 ± 3.1 dB) were within previously reported average test-retest absolute difference values (3.6 ± 3.9 dB and 3.5 ± 3.8 dB) for the same audiometer (Swanepoel, Mngemane et al, 2010; Swanepoel & Biagio, 2011).

In the current study, 95% of threshold comparisons were within 5 dB or better compared to 88% for test-retest measures in a sound booth environment previously reported for this audiometer (Swanepoel, Mngemane et al, 2010). The slightly better

correspondence between air-conduction thresholds recorded in the natural and sound booth environments compared with the test-retest differences reported by Swanepoel, Mngemane et al (2010) may partly be attributed to the omission of 125 Hz as a test frequency in the current study. This low test frequency showed a larger test-retest discrepancy than the other frequencies in the Swanepoel, Mngemane et al (2010) study. Overall the correlation between air-conduction thresholds recorded in a sound booth environment and a natural environment was very high (>.92) across all frequencies.

The average absolute difference in bone-conduction thresholds recorded in the natural and audiometric booth (3.4 ± 4.3 dB) was within previously reported bone-conduction test-retest differences (Laukli & Fjermedal, 1990; Margolis et al, 2010; Swanepoel & Biagio, 2011). The average absolute test-retest variability for this same audiometer previously reported in a small group of 10 normal-hearing subjects was 7.1 ± 6.4 dB. Laukli and Fjermedal (1990) reported bone-conduction test-retest standard deviation variability between 3.2 and 4.8 dB across 250 to 4000 Hz in a small sample of normal-hearing adults. Similarly, Margolis et al (2010) reported an average absolute test-retest difference for bone-conduction thresholds of 4.1 ± 3.8 dB across frequencies. Overall, 97% of bone-conduction thresholds corresponded within 10dB between the two environments, which is within accepted bone-conduction test-retest variability (Roeser & Clark, 2007). Bone-conduction test-retest thresholds are more susceptible to variability compared with air-conduction thresholds owing to several factors including differences in static force applied, location of the bone vibrator, functional state of the middle ear, position of the lower jaw, and distortion of bone vibrators at lower frequencies (Stenfelt & Goode, 2005; Stuart et al, 1991).

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Owing to the advancing age of the population assessed, hearing loss greater than 25 dB (average of 500, 1000, 2000 and 4000 Hz) was present in 59% of ears. Since ambient noise would be more likely to affect threshold determination in the normal ranges (0 – 25 dB HL) the validity of thresholds in the natural and sound booth environments was compared for normal and abnormal hearing categories (Table 3.3). Similar threshold correspondence and absolute threshold differences were however obtained from the two environments for air- and bone-conduction testing. Thresholds for air conduction corresponded within 5 dB in 94.1% compared with 94.9% for normal and elevated hearing thresholds respectively. For bone-conduction thresholds, correspondence was within 10 dB in 96.7% compared with 96.9% for normal and elevated hearing thresholds respectively.

This study provides evidence that valid diagnostic air-conduction and bone-conduction pure-tone hearing thresholds can be recorded using a mobile audiometer without a sound booth or sound-treated room. Using insert earphone and circumaural earcup attenuation, with real-time monitoring of noise, provides passive control of environmental noise and offers on-going active evaluation of transient extraneous interference. Our data support the possibility of conducting valid diagnostic pure-tone audiometry outside a regular clinic setup. Active noise monitoring provides a measure of quality control. Furthermore, the system can be set to monitor noise levels according to the average attenuation provided by the test setup in a typical group of subjects as opposed to double attenuation values previously reported (Berger, Kieper & Gauger, 2003). By employing these attenuation levels, the software can be programmed to monitor ambient noise levels across octave or inter-octave levels, according to standards for audiometric test environments (e.g. ANSI S3.1-1999(R2008)). This allows the clinician to monitor the noise that may be

influencing threshold testing at specific frequencies and intensities. For valid bone-conduction testing outside an audiometric booth, occlusion of the non-test ear is required. Deeply inserted insert earphones can minimize the occlusion effect at low frequencies (250 – 1000 Hz) to a clinically insignificant level (Stenfelt & Goode, 2005). Achieving deep insertion of the insert earphone may however be challenging and in the present study 24.5% of subjects required removal of cerumen by the clinician before testing.

3.6 CONCLUSION

Environmental noise has historically been controlled during diagnostic audiometry by using audiometric booths that are certified annually. Advances in technology may however offer alternate ways of performing diagnostic audiometry while simultaneously extending testing sites beyond the confines of the conventional audiometric booth setting. The current study demonstrated that valid diagnostic air-conduction and bone-conduction audiometry can be conducted on elderly patients at their retirement facilities without the use of a sound booth or sound-treated room using insert earphones covered by circumaural earcups with integrated active monitoring of ambient noise levels. Continual monitoring of ambient noise during testing provides an effective measure of quality control. The possibility of performing diagnostic audiometry with patients unable to attend clinics for any number of reasons extends access to valid evaluations outside of a conventional clinic. Of greater significance and with further-reaching implications, this type of technology permits the delivery of diagnostic audiometry services to low- and middle-income countries where sound booths are a scarce luxury and diagnostic testing is impossible as a result (Swanepoel, Clark et al, 2010; Swanepoel, Olusanya & Mars,

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2010). With more than 80% of people with hearing loss globally residing in developing countries, these new advances in technology may lead to a broadening of access to diagnostic hearing health care services in these communities (WHO, 2006; Swanepoel, Clark et al, 2010; Swanepoel, Olusanya & Mars, 2010). Access to audiometry is a global concern (Margolis & Morgan 2008; Swanepoel, Clark et al, 2010, Swanepoel & Hall, 2010) for which the continued advances in technology must be harnessed to ensure that people with hearing loss everywhere have access to services.

3.7 ACKNOWLEDGEMENTS

None

3.8 DECLARATION OF INTEREST

The authors report no conflicts of interest and state that they alone are responsible for the content and writing of this article. Data from this study were presented at the XXXI World Congress of Audiology on May 3, 2012 in Moscow and at the Coalition for Global Hearing Health Conference on May 30, 2012 in Pretoria, South Africa.

4. DISCUSSION AND CONCLUSION

Initial studies have demonstrated the consistency of air conduction thresholds measured with PC-based audiometry and conventional audiometry in adults with normal hearing (Choi, Lee, Park, Oh & Park, 2007; Swanepoel & Biagio, 2011). These data were recorded from tests done in an audiometric test booth that attenuated environmental noise to levels that complied with the ANSI standard (ANSI S3.1-1999(R2008)) for maximum ambient noise levels required for testing to 0 dB Hearing Threshold Level (Choi et al., 2007; Swanepoel & Biagio, 2011). Obstacles to the use of audiometric test booths, particularly in developing countries, include their limited availability, when available their stationary nature that usually confines them to large cities and the requisite annual compliance check or calibration after re-location. These add to the financial burden of servicing rural communities and may limit service delivery in such areas (Swanepoel et al., 2010b; Swanepoel, Olusanya & Mars, 2010a).

Telemedicine applications in audiometry have demonstrated potential to provide access to underserved and remote regions (Swanepoel, 2010; Nemes, 2010). In the absence of a suitable audiometric booth, adequate management and monitoring of background noise becomes essential for accurate evaluation of hearing thresholds (Swanepoel et al., 2010b; Swanepoel et al., 2010a). Supra-aural earphones have demonstrated limited attenuation properties particularly in the lower frequencies (Frank, Greer & Magistro, 1997; Berger & Killion, 1989). Using supra-aural earphones together with passive noise-reducing ear enclosures can offer additional attenuation. These plastic domed enclosures such as the Audiocup, Auraldome 11, AudioMate, and Madsen ME 70, fit over and around the ear much like an earmuff and can provide a further 7-10 dB attenuation as in the case of the ME 70 (Poulsen,

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1988). However the attenuation achieved by these enclosures remains insufficient for diagnostic testing down to an audiometric zero, particularly in the lower frequency range (Frank et al., 1997).

Insert earphones have been recommended as a more effective alternative to reducing ambient noise levels for compliant testing, realising 30 to 40 dB of attenuation of ambient noise which is sufficient for testing down to 0 dB across the speech frequency range (Frank et al., 1997; Berger & Killion, 1989; Wright & Frank, 1992). A prerequisite for this is that these earphones be inserted deeply into the ear canal. The level of attenuation is a function of the insertion depth in the ear canal whereas the hearing thresholds are not (Berger & Killion, 1989; Clark & Roeser, 1988). By covering the insert earphones with circumaural earcups a further increase in attenuation can be provided (Berger, 1983; Berger, Kieper & Gauger, 2003). Double transducer attenuation using deeply inserted foam plugs and circumaural earcups produces a significant increase in ambient noise attenuation that may actually exceed typical attenuation for transportable sound booths (Berger et al., 2003). Active noise reduction technology used in conjunction with insert earphones and circumaural earcups has been demonstrated to provide accurate hearing threshold measurement in levels of up to 30 dB ambient noise between 250 and 4000 Hz (Bromwich et al., 2008). However, exceeding this level of ambient noise can result in threshold shifts (Bromwich et al., 2008) effectively nullifying the double attenuation of insert earphones used with circumaural earcups. Consequently the continual monitoring of ambient noise levels becomes requisite to ensure that diagnostic thresholds are established solely when ambient environmental noise levels are compliant.

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A mobile computer-based audiometer with real-time monitoring of ambient noise levels and incorporating telehealth applications has recently been validated in an audiometric test booth setting by Swanepoel and Biagio (2011). In the present study the performance of this audiometer that additionally employs passive attenuation using insert earphones covered by circumaural earcups was evaluated for validity of air and bone conduction threshold measurement in a natural environment.

4.1 *Discussion of results*

4.1.1 *Ambient noise levels*

Measurements of noise levels were recorded over a 30 minute period with a Type 1 Sound level meter in two of the retirement homes (natural environment) and in the acoustic test booth. Average noise levels of 46.5 and 53.6 dBA were measured in the natural environments compared to 21.2 dBA in the sound-booth environment where ambient noise levels did not exceed the permissible maximal noise levels specified by ANSI (ANSI S3.1- 1999(R2008); Appendix H) for testing down to 0dB. The average noise levels measured in the natural environments unsurprisingly exceeded these standards. The software in the audiometric equiment actively monitored ambient noise levels across octave bands and displayed these measurements in real-time throughout the test procedures in both test environments (Figure 2.2). Whenever the noise exceeded the maximum ambient noise level allowed for establishing a threshold, as indicated by the effective attenuation level in the software, the audiologist waited for the transient noise to abate or continued testing at other frequencies. Thresholds were evaluated down to a minimum of 0 dB HL.

4.1.2 *Hearing threshold comparisons*

All participants demonstrated a clear understanding of the instructions as given prior to testing. In total 2259 air conduction and 1669 bone conduction threshold data were collected for comparative analysis.

Air conduction thresholds

Of the 2259 air conduction thresholds measured in the natural and standard audiometric booth, 95% corresponded within 5 dB, with 53% of thresholds exhibiting no change. This falls within typical test-retest limits for thresholds measured in an audiometric test booth (Stuart, Stenstrom, Tompkins & Vandenhoff, 1991; Smith-Olinde, Nicholson**,** Chivers**,** Highley & Williams, 2006; Margolis et al., 2010; Swanepoel, Mngemane, Molemong, Mkwanazi & Tutshini, 2010c; Swanepoel & Biagio, 2011) and compares well with test-retest measures of 88% previously reported by Swanepoel et al. (2010c) for the same audiometer. The finding of a slightly lower correspondence by Swanepoel et al. (2010c) may be ascribed in part to their inclusion of the test frequency 125 Hz, where a larger test-retest inconsistency was recorded when compared to the other frequencies (Swanepoel et al., 2010c). The average absolute air conduction threshold difference of 2.7 (± 3.1) dB for the present study accords with formerly reported average test-retest absolute differences of 3.6 (± 3.9) dB and 3.5 (± 3.8) dB for the same audiometer (Swanepoel et al., 2010c; Swanepoel & Biagio, 2011) establishing validity. Comparison of air conduction thresholds recorded in the natural and audiometric booth settings showed no statistically significant differences illustrated by a paired samples t-test ($p > 0.01$) with the exception of 8000 Hz in the left ear where $p = 0.006$. This one exception did not however translate to a clinically significant difference. The overall high correlation coefficients of between 0.92 and 0.99 across all frequencies for thresholds recorded

in the natural and audiometric sound booth environment reiterate the evidence of reliability and accuracy of air conduction threshold testing using this type of technology.

Bone conduction threshold results

For the 1669 bone conduction thresholds measured in the natural and audiometric booth environments, across ears and frequencies, thresholds differed within ± 5 dB in 86% and within 10 dB in 97% of cases which corresponds well with clinically accepted bone conduction test-retest parameters (Roeser & Clark, 2007). Similarly the average bone conduction threshold differences of – 0.6 to 1.3 dB (4.0 – 7.5 dB), and average absolute threshold difference of 3.4 (± 4.3) dB, between the natural and audiometric booth testing environments, were within formerly reported bone conduction test-retest differences (Laukli & Fjermedal, 1990; Margolis et al., 2010; Swanepoel & Biagio, 2011). In addition these findings compare favourably with the average absolute test-retest variability of 7.1 (± 6.4) dB measured for this same audiometer in a small group of 10 normal hearing subjects by Swanepoel and Biagio (2011). For the frequencies 500 to 4000 Hz the correlation coefficient for bone conduction thresholds measured in a natural environment compared to those recorded in an audiometric test room was high (> 0.87). At 250 Hz, however, correlation was between 0.63 and 0.73. This low frequency showed the largest test-retest variance of all the frequencies. This may be attributed to the fact that bone conduction test-retest thresholds are more susceptible to variability compared to air conduction thresholds owing to several factors including differences in static force applied by the bone oscillator to the forehead, location of the bone vibrator, functional state of the middle ear, position of the lower jaw, and distortion of bone vibrators at lower frequencies (Stenfelt & Goode, 2005).

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4.2 *Clinical implications and recommendations*

The identification and diagnosis of hearing loss is the essential initial component to the successful management of hearing loss and the subsequent improvement in quality of life that is attainable with appropriate intervention. This study demonstrates that valid air and bone conduction audiometry can be performed on elderly patients in their own environment outside of an audiometric booth. The establishment of the accuracy and reliability of thresholds recorded with this type of equipment suggests that the use of double attenuation coupled with real-time monitoring of ambient noise as a strategy for managing environmental noise may be a valid option for accurately assessing hearing thresholds. Validation of this novel technology advances an alternate approach to providing effective mobile diagnostic audiometric services to population groups that have not had access to audiology services in the past. These groups include rural communities, those without transport facilities and those unable to be transported. The portability of this type of system which can be powered by a battery in the absence of electricity may extend hearing health care services to underserved communities in all parts of South Africa and other developing countries.

Telehealth applications

Where electricity and access to the internet are available the telehealth application of this type of technology may make diagnostic air and bone conduction pure tone tele-audiology possible. This could have highly significant and widespread implications for low and middle income countries where sound booths and human resources are insufficient to meet the needs of communities. More than 80% of people with hearing loss reside in developing countries (WHO, 2006; Swanepoel et al., 2010b; Swanepoel et al., 2010a). The benefit of providing audiometric services without expenditure on an audiometric test booth, its transportation or maintenance, in

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combination with tele-audiology that effectively negates patients' transport needs and costs may make a valuable contribution to the extension of cost effective diagnostic hearing healthcare service delivery in these communities. Augmenting tele-audiology with recently validated automated audiometric paradigms for diagnostic hearing testing (Margolis et al., 2010; Swanepoel et al., 2010c; Swanepoel & Hall, 2010) would not only exploit the mobility of this technology without an audiometric booth but would furthermore facilitate testing where hearing healthcare professionals are not available. Merging these applications may significantly broaden access to audiometric healthcare assistance to underserved communities.

Recommendations

Insert earphones require deep insertion to offer the most effective attenuation of environmental noise (Frank et al., 1997; Berger & Killion, 1989; Clark & Roeser, 1988) and for occlusion of the non-test ear when performing bone conduction testing outside of an audiometric test booth (Berger, 1983; Stenfelt & Goode, 2005). Margolis and Moore (2011) reported the smallest occurrence of the occlusion effect using circumaural earphones followed by fully inserted insert earphones when establishing bone conduction thresholds with both ears occluded. Stenfelt and Reinfeldt (2007) observed a 10 dB effect at frequencies below 1000 Hz with deeply inserted insert earphones. It is suggested that one way of addressing the limitation of this technique may be to use a correction factor for occlusion effects at the lower frequencies.

Deep insertion of the insert earphone to a depth of 12mm proved to be challenging in the present study as 24.5% of subjects required removal of cerumen before the evaluation could proceed. Training in cerumen management would be to the

advantage of the audiologist. Alternate arrangements may also be sought prior to audiometric evaluations.

The findings of this research project demonstrating a novel approach to diagnostic audiometry, may be regarded by Health Departments and professionals responsible for the hearing welfare of populations as presenting an opportunity to broaden diagnostic hearing health care service delivery to citizens in all areas of the country. Hearing healthcare that takes advantage of the tele-audiology applications of this type of technology might however require the assistance of suitably qualified personnel for otoscopy, the insertion of insert earphones, circumaural earcup placement and the giving of appropriate instructions for the realisation of online diagnostic audiometric service delivery.

The scarcity of human resources contributes to the challenges of providing a credible hearing healthcare service in South Africa and other developing countries (Swanepoel, Olusanya & Mars, 2010a). The South African National Department of Health has recognised this fact and has recently requested that the training of mid-level workers in the profession be considered by the Professional Board for Speech, Language and Hearing Professions (Singh, 2012). Mid-level workers may contribute to the expansion of hearing healthcare services in the country. It is suggested that in its deliberations the Professional Board consider the inclusion of tele-audiology support in the mid-level workers' scope of practice. Alternately, or in addition, primary healthcare workers may be trained to provide the appropriate support to professionals in the implementation of tele-audiology.

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4.3 Critical evaluation and contribution to the field of audiology

Advancing and clarifying of arguments, reasons and evidence for reaching certain conclusions requires appraisal to demonstrate that data does logically support research findings (Mouton, 2008). Subsequently this project is critically evaluated in terms of its strengths and limitations to complement the perspectives presented by the conclusions.

Strengths of the study

This was the first study to establish the validity of dianostic air and bone conduction threshold measurement outside of a conventional test booth, using a novel approach, and has immediate relevance and value (Mouton, 2008) for expanding hearing healthcare services.

The audiometer used in this research project was validated by Swanepoel and Biagio (2011) using 30 subjects and compared diagnostic results to a standard type 1 audiometer. In another study 38 subjects were recruited by Swanepoel et al. (2010c) to establish the accuracy of the automated hearing assessment feature of this equipment. The present study employed a large sample of 147 subjects affirming and lending credence to its findings of validity of threshold determination outside of an audiometric booth with this technology.

A third strength of this study is the ecological validity of the research which was increased by collecting data at four different sites with varying natural environmental parameters, representative of typical test environments in retirement facilities, where this type of technology may be utilised.

Although the majority of ears (n=173) had hearing loss of >25 dB there was a sufficiently large contingent of ears with normal pure tone averages of ≤25 dB

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(n=121) for establishing the validity of this type of technology used outside of an audiometric booth environment for ears without hearing loss. This is relevant as ambient noise would be most likely to affect threshold determination in the normal ranges of 0-25 dB HL and implies that this technology may be appropriate for use as a diagnostic tool in population groups where it is anticipated that the majority of the population group have normal hearing thresholds.

A further strength of this project is that test protocol variables were limited by employing one audiologist for all the data collection. On-site cerumen management assisted with consistent deep placement of insert earphones for both tests, confining the influence that varying depths of insertion may have had on the occlusion effect and ultimately threshold measurements.

For the protection of collected data, precautionary measures in the programme software prohibited any amendments of threshold data once documented. Coupled with this the audiologist was automatically blinded to prior audiometric results. Although first test results could voluntarily be accessed, they never were until both audiograms had been determined and audiometric findings were discussed with the participant.

Finally the short average time interval of 6.4 days between the two tests reduced the likelihood of transient conductive components that may have excluded the data from a participating subject, while simultaneously ensuring that possible adaptation from one test to the next did not require consideration.

Limitations of the study

The salient limitation of this research project is the non-randomisation of test sequence between the two environments where threshold data was collected. Test

sequence was held constant with the initial test always being performed in the natural environment at a retirement facility. This was done to accommodate the older adult respondents who may not have met the selection criteria. In this way traveling costs and the inconvenience of having to leave their environment were considered. The results of the study would, however, have been strengthened had test sequence been randomised to negate any test-retest effect that may have been present when thresholds were re-assessed.

Secondly, the selection criteria required that subjects be over the age of 65 years of age partly to facilitate availability for retest appointments within a short space of time. In 41% of the subjects pure tone thresholds were ≤ 25 dB. Although no significant difference was found in a comparison of the validity of thresholds in the natural and sound booth environments for normal and abnormal hearing categories, a larger contingent of normal hearing subjects would have provided further credence to the use of this type of technology outside of an audiometric booth. The second motivation for recruiting older adults as subjects for this study anticipated their tolerance of the double attenuation of insert and circumaural earcups that also housed the audiometer hardware. Including younger subjects such as school entry-level learners in this project may have presented challenges for the researcher. However, the validation of this type of technology for this population group would have significantly added to the value of the present findings. Similar validated findings for children may lead to the extension of valuable diagnostic services to learners.

Thirdly, average noise levels were recorded post facto in two of the four natural test environments, each for a period of 30 minutes. Measurement and recording of ambient noise levels during all threshold determination would have augmented the

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findings of this study demonstrating the efficacy of the double attenuation system and the real-time monitoring of ambient noise levels as a means of environmental noise management in this type of technology.

4.4 *Future research*

This research study demonstrated that valid diagnostic air and bone conduction audiometry can be performed on an older adult community outside an audiometric booth environment using passive double transducer attenuation with real-time monitoring of ambient noise. The use of this technology which may be used without a conventional test booth under specific conditions does nonetheless raise additional questions requiring further research.

Other population groups, in particular young children where the impact of hearing loss on the development of verbal communication function is mild to profound (Yoshinaga-Itano et al., 1998), may benefit from this technology. Anticipated challenges to the testing of children with a double transducer attenuation system may include the necessity of cerumen management prior to testing and the tolerance of deep insertion of the insert earphones (Berger et al., 2003) in combination with the size and the 480g weight of the circumaural earcups, that house the audiometers, on a child's head. Despite these considerations validating diagnostic air and bone conduction on this population group would serve to clarify its applicability to children.

Should a study demonstrate validity of this type of technology for use with children in a typical school environment, it may result in the valuable extension of diagnostic services to this population group. A diagnostic service in a school setting may address some of the challenges experienced with present screening programmes

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such as over-referrals, that may arise from ineffectual management of ambient noise, the accessibility and availability of diagnostic facilities for follow-up in addition to the likelihood of reasonable compliance with referrals subsequent to the screening (Gravel et al., 2009). Although diagnostic services without an audiometric booth may be made available to children in schools, follow-up services for management of identified hearing loss would still be required. Much validation research would be needed before such services may be made available to children in their school environment. Notwithstanding this, the possibility of extending services using this novel type of technology holds great promise for those groups of our population in the greatest need.

Of the participants in this study 41% presented with normal pure tone averages of ≤ 25 dB. Similar average threshold differences and standard deviations were demonstrated in normal and elevated thresholds. However, few of the subjects had thresholds of 0 dB. Test duration may be prolonged in subjects with a high percentage of thresholds between 0 and 10 dB as ambient noise would be more likely to affect threshold determination in this range. Protracted testing in combination with the discomfort of a deeply inserted insert earphone may prove a stumbling block in the application of this technology with young children. Validating this equipment with a group of normal hearing children may satisfy both this and the prior consideration.

The realisation of a tele-audiology programme will require the assistance of suitably qualified personnel. Identifying and establishing a model of service delivery including relevant training modules for assistants will contribute to ensuring that access to diagnostic hearing healthcare services may become a reality for all communities.

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4.5 *Conclusion*

Historically diagnostic air and bone conduction audiometry has been conducted in conventional annually certified audiometric test booths that allow for testing of hearing thresholds down to 0 dB. Advances in technology with double transducer attenuation incorporating insert earphones with circumaural earcups and real-time on-screen monitoring of noise provide both passive control and active quantification of transient extraneous interference for testing outside of a booth. This study presents evidence that valid diagnostic air and bone conduction pure tone hearing thresholds can be recorded using a mobile computerised audiometer without an audiometric booth or sound-treated environment. The potential to take diagnostic audiometry beyond the regular clinical establishment may extend hearing healthcare services to patients unable to attend clinics for any number of reasons. The possibility of coupling the extension of diagnostic hearing tests outside of a sound booth with tele-audiology applications may empower hearing healthcare professionals to reach remote communities in low and middle income countries where audiometric booths and human resources are a scarce luxury and diagnostic evaluations improbable as a result (Swanepoel et al., 2010a; Swanepoel et al., 2010b). It is a global concern that communities everywhere have access to hearing healthcare services (Margolis et al., 2008; Swanepoel et al., 2010b) and for this cause the continued advances in technology need to be garnered and developed for the benefit of all people.

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6. APPENDICIES

APPENDIX A

79

ETHICAL CLEARANCE

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Office of the Deputy Dean

31 August 2010

Dear Prof Swanepoel,

Project:	**Validity of pure tone audiometry using a portable computerised audiometer outside an audiometric test booth**
Researcher:	FJ Maclennan-Smith
Supervisor:	Prof DCD Swanepoel
Department:	Communication Pathology
Reference number:	70142875

I am pleased to be able to tell you that the above application was **approved** (with comment) by the **Postgraduate Committee** on 17 August 2010 and **approved** by the **Research Ethics Committee** on 26 August 2010. Data collection may therefore commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it would be necessary to apply for a new research approval and ethical clearance.

The Committee requests you to convey this approval to the researcher.

We wish you success with the project.

Sincerely

Prof John Sharp
**Chair: Postgraduate Committee &
Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA**
e-mail: john.sharp@up.ac.za

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APPENDIX B

LETTER TO MANAGEMENT/BODY CORPORATE

OF RETIREMENT FACILITY

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Department of Communication Pathology

Date:

Dear Sir/Madam

RE: PARTICIPATION OF RESIDENTS AT YOUR RETIREMENT CENTRE IN HEARING TESTS AS PART OF A POSTGRADUATE RESEARCH PROJECT

I am a postgraduate master's degree student, registered in the Department of Communication Pathology, University of Pretoria. I am undertaking a study, comparing the test results of new equipment for the evaluation of hearing with results obtained in a conventional manner. Findings of this study will indicate the suitability of making use of this equipment in areas where a soundproof booth is not available. This is the case in many rural areas, schools, and in situations where transportation to a conventional testing site is not possible.

Data collection will only commence once the study is approved by the research Ethics Committee, Faculty of Humanities, University of Pretoria. All data collection will also only commence once a resident has provided consent to participation in the study.

I would like to request that you consider the following:

- To allow me the opportunity to test the hearing of residents in a quiet room on the centre's premises. This would be arranged at times suitable to the centre. Alternately, hearing tests will be done in each home/room.
- Should the management make available a venue for testing but at a later stage wish to terminate the arrangement, the centre will be entitled to withdraw its co-operation without any negative consequences.
- A letter of informed consent will be given to each resident. This will supply them with a list of the procedures that will be followed, including the fact that participation in the study will require that two hearing tests be done. Transportation for the second test will be made available by Rotary Hermanus. A copy of the letter addressed to residents is attached for your perusal.
- Every participant will have to provide consent to have his/her hearing assessed twice.

All information of the centre and residents will be treated as confidential. Participants in the study will be required to be over the age of 65 years. Each will be assigned an identifying code for the processing of data and to ensure anonymity.

Further information may be obtained from me. My contact numbers are: 028 3131437 / 0834430221

Sincerely

Ms Felicity Maclennan-Smith
Postgraduate Researcher / Audiologist

Communication Pathology Bldg R3-5	Tel: +27 12 4202304	dewet.swanepoel@up.ac.za
University of Pretoria	Fax: +27 12 4203517	www.up.ac.za
PRETORIA 0002		
Republic of South Africa		

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Professor De Wet Swanepoel
Research Supervisor

Dr Maggi Soer
ACTING HEAD: Dept of Communication Pathology

Communication Pathology Bldg R3-5
University of Pretoria
PRETORIA 0002
Republic of South Africa

Tel: +27 12 4202304
Fax: +27 12 4203517

dewet.swanepoel@up.ac.za
www.up.ac.za

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APPENDIX C

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PERMISSION FROM RETIREMENT FACILITIES

ONRUS MANOR BODY CORPORATE

Private Bag X12 HERMANUS 7200
Ph 028 3163000; Fax 028 3163001

"PAVETE EMERITUS"

1st June 2010

Me Felicity Maclennan-Smith

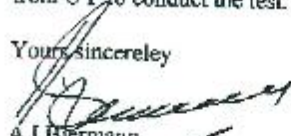Email to : felicityjanems @ gmail . com

PARTICIPATION OF RESIDENTS AT ONRUS MANOR RETIREMENT VILLAGE IN HEARING TESTS FOR THE COLLECTION OF DATA FOR REASEARCH PURPOSES:

You are hereby authorised to perform your test at our village.
We understand from management that a suitable venue will be made available .

The letter of informed consent handed to us for our perusal ,is acceptable,and may be distributed amongst our residents,Our admin office will assist you in this.

Thank you in anticipation and trust that you will receive authorisation from U P to conduct the test.

Yours sincereley

A I Biermann
Chairman Board of Trustees
ONRUS MANOR BODY CORPORATE

BERG 'N SEE

Telefoon (02831) 21155
Telephone

Private Bag X06
HERMANUS. 7200
Fax : (028)3123966

Dear Felicity

Re: Hearing Tests for research data

The Board of Trustees at Berg 'n See are happy to inform you that consent is given to commence the research project as discussed with Management and Dr Rush.

Many thanks
Carol Rush

Dw. macouba
Manager.

Board of Trustees, Medical

Felicity Maclenan-Smith

From: Quintus Investments [cbd@intekom.co.za]
Sent: Wednesday, June 09, 2010 10:03 AM
To: felicityjanema@gmail.com
Subject: Data for research

Hallo Felicity,

Jammer ek kom nou eers terug na jou oor jou navorsings projek.
Ons ondersteun jou graag en sal jou help waar ons kan.
Laat weet asseblief as ons moet voortgaan om inwoners bo 65 te werf vir jou navorsing.

Groete
Henk Oostenbrink
Village of Golden Harvest

6/9/2010

APPENDIX D

LETTER TO RESIDENT OF RETIREMENT FACILITY

ENGLISH AND AFRIKAANS

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Department of Communication Pathology

Date:

Dear Resident

RE: **INFORMED CONSENT FOR YOUR PARTICIPATION IN A HEARING TEST AS PART OF A POSTGRADUATE RESEARCH PROJECT**

I am a postgraduate master's degree student, registered in the Department of Communication Pathology, University of Pretoria. I am undertaking a study, comparing the test results of new equipment for the evaluation of hearing with results obtained in a conventional manner. Findings of this study will indicate its suitability in areas where a sound-treated booth is not available. This is the case in many rural areas, schools and in situations where transportation to a conventional testing site is not possible.

All procedures will be non-invasive and results will be made available to you. If you agree to participate in this study the procedures to be followed will be as follows:

- **Examination** of ear canals using an otoscope.
- **Removal of wax**, should this be required.
- Measurement of **middle ear pressure** using a soft tip in the ear canal.
- **Testing of hearing**, which will require that you respond to sounds presented through earphones. Your hearing will be tested twice.
- **Results of the hearing tests** will be communicated to you verbally after the test using the conventional equipment. In addition a **written report** and recommendations will be available on request.

Relevant information:
- Participants will be required to be over the age of 65 years
- All tests will be done free of charge
- Your hearing will be evaluated twice;
    1. at the retirement centre. Dates and times will be arranged with both you and the centre.
    2. at consulting rooms in Hermanus. In the event that you are without transport, Rotary Hermanus, have agreed to assist with the transportation of small groups of participants. Appointments will be telephonically confirmed at a time which is convenient for you.
- Each test should not exceed 30 minutes.
- You have the right to withdraw from the study at any time.
- All information will be treated as confidential. Data processing will be done using a code and not by name.
- None of the procedures are invasive or painful
- Coded data will be stored for 15 years as required by the University of Pretoria.

Should you wish to be considered for participation in this project, please complete the 'Informed Consent' section provided.

Further information may be obtained from me. My contact numbers are: 028 3131437 / 0834430221

Communication Pathology Bldg R3-5   Tel: +27 12 4202304   dewet.swanepoel@up.ac.za
University of Pretoria   Fax: +27 12 4203517   www.up.ac.za
PRETORIA 0002
Republic of South Africa

Sincerely,

Felicity Maclennan-Smith
Postgraduate Researcher / Audiologist

Professor De Wet Swanepoel
Research Supervisor

Dr Maggi Soer
ACTING HEAD: Department of Communication Pathology

Communication Pathology Bldg R3-5
University of Pretoria
PRETORIA 0002
Republic of South Africa

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Fax: +27 12 4203517

dewet.swanepoel@up.ac.za
www.up.ac.za

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UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Departement Kommunikasiepatologie

Datum: 14/09/2010

Geagte Inwoner

TOESTEMMING TOT DEELNAME IN 'N GEHOORTOETS WAT DEEL VORM VAN 'N NAGRAADSE NAVORSINGSPROJEK

Ek is 'n nagraadse meestersgraad student, geregistreer in die Departement Kommunikasiepatologie aan die Universiteit van Pretoria. Ek onderneem 'n studie wat die toetsresultate van nuwe toerusting vergelyk met resultate van konvensionele toetsing. Met die navorsing kan ons vasstel of hierdie toerusting gebruik kan word wanneer 'n klankdigtekamer nie beskikbaar is nie. Dit is die geval in baie plattelandse areas, in skole en in omstandighede waar vervoer na 'n konvensionele toetslokaal nie moontlik is nie.

Die roetiene toetse is nie pynlik of traumaties nie. Die uitslae van die gehoortoetse, asook aanbevelings, sal aan u bekend gemaak word. Indien u aan hierdie projek wil deelneem sal die volgende prosedures gevolg word:

- **Ondersoek** van oorkanale met 'n otoskoop.
- **Verwydering van oormatige was** indien nodig.
- Die meting van **middeloordruk** met 'n sagte proppie wat in die oorkanaal geplaas word.
- **Gehoortoetse**: U sal versoek word om op verskeie klanke, wat deur oorfone aangebied word, te reageer. Hierdie toets sal twee keer uitgevoer word.
- Die **uitslae van die gehoortoetse** sal mondelings aan u bekend gemaak word na die toets in die konvensionele toetslokaal. 'n **Skriftelike verslag** met aanbevelings sal beskikbaar wees op versoek.

Relevante inligting:
- Respondente moet 65 jaar of ouer wees.
- Die gehoortoetse is gratis.
- U gehoor sal twee keer getoets word:
    1. by die aftreeoord. Afsprake sal gereël word om u, en die oord, te pas.
    2. by konsultasiekamers in Hermanus. Afspraaktye sal telefonies gemaak word. Reëlings is getref met die Rotariers van Hermanus om vervoer te voorsien aan klein groepe indien nodig.
- Gehoortoetse behoort nie langer as 30 minute te duur nie.
- U kan enige tyd onttrek van die studie, sonder gevolge.
- Alle inligting is vertroulik. 'n Kode word aan elke persoon toegeken. Geen name word in die verwerking van data gebruik nie.
- Die toetse is nie traumaties of pynlik nie
- Gekodeerde navorsingsdata sal vir 15 jaar geberg word soos vereis deur die Universiteit van Pretoria. .

Indien u oorweeg wil word vir deelname aan hierdie navorsingsprojek, voltooi asseblief die toestemmingsbrief voorsien. Besorg dit by die kantoor voor of op Donderdag 23 September 2010. Indien u verdere inligting verlang, kontak my gerus by een van hierdie nommers:
028 3131437 / 0834430221

Kommunikasiepatologie Gebou R3-6   Tel: +27 12 4202304   dewet.swanepoel@up.ac.za
Universiteit van Pretoria   Faks: +27 12 4203517   www.up.ac.za
PRETORIA 0002
Republiek van Suid Afrika

Sincerely,

Felicity Maclennan-Smith
Postgraduate Researcher / Audiologist

Professor De Wet Swanepoel
Research Supervisor

Dr Maggi Soer
ACTING HEAD: Department of Communication Pathology

APPENDIX E

INFORMED CONSENT FORM FOR RESPONDENT

ENGLISH AND AFRIKAANS

INFORMED CONSENT:

MY PARTICIPATION IN A HEARING TEST PROJECT

<u>Please complete the following:</u>

I _____, hereby confirm that I have read
the above-stated information on this hearing test project.

I hereby consent to participation in this study. I understand that the data will be
used for research purposes, in accordance with the requirements of the University of Pretoria
and the Guidelines on Research Protocol of The Health Professions Council of South Africa.

_____
Signature

_____
Date

_____
Contact number/s

INGELIGTE TOESTEMMING:

MY DEELNAME AAN 'N GEHOORTOETSPROJEK

Voltooi asseblief die volgende:

Ek, _____ bevestig dat ek die inligting verskaf oor

hierdie gehoortoetsprojek gelees en verstaan het.

Ek gee hiermee toestemming tot my deelname aan hierdie studie. Ek verstaan dat die data vir navorsingsdoeleindes gebruik gaan word. Dit word gedoen in ooreenstemming met die vereistes van die Universiteit van Pretoria en die riglyne vir navorsingsprotokol van die Raad vir Gesondheidsberoepe van Suid Afrika.

_____

Handtekening

_____

Datum

_____

Kontaknommer/s

APPENDIX F

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AGREEMENT FROM ROTARY CLUB HERMANUS

Rotary Club of Hermanus - Rotary International District 9350

President: Colin Adams

Dear Felicity,

Transportation of Research Participants.

The above project was adopted at the Hermanus Rotary Club Board Meeting of 29th June 2010.
Transportation will be carried out by individual Rotarians on a voluntary basis.
A roster will have to be drawn up and we will require some notice of the times etc in order to do this.

Good Luck with your project.

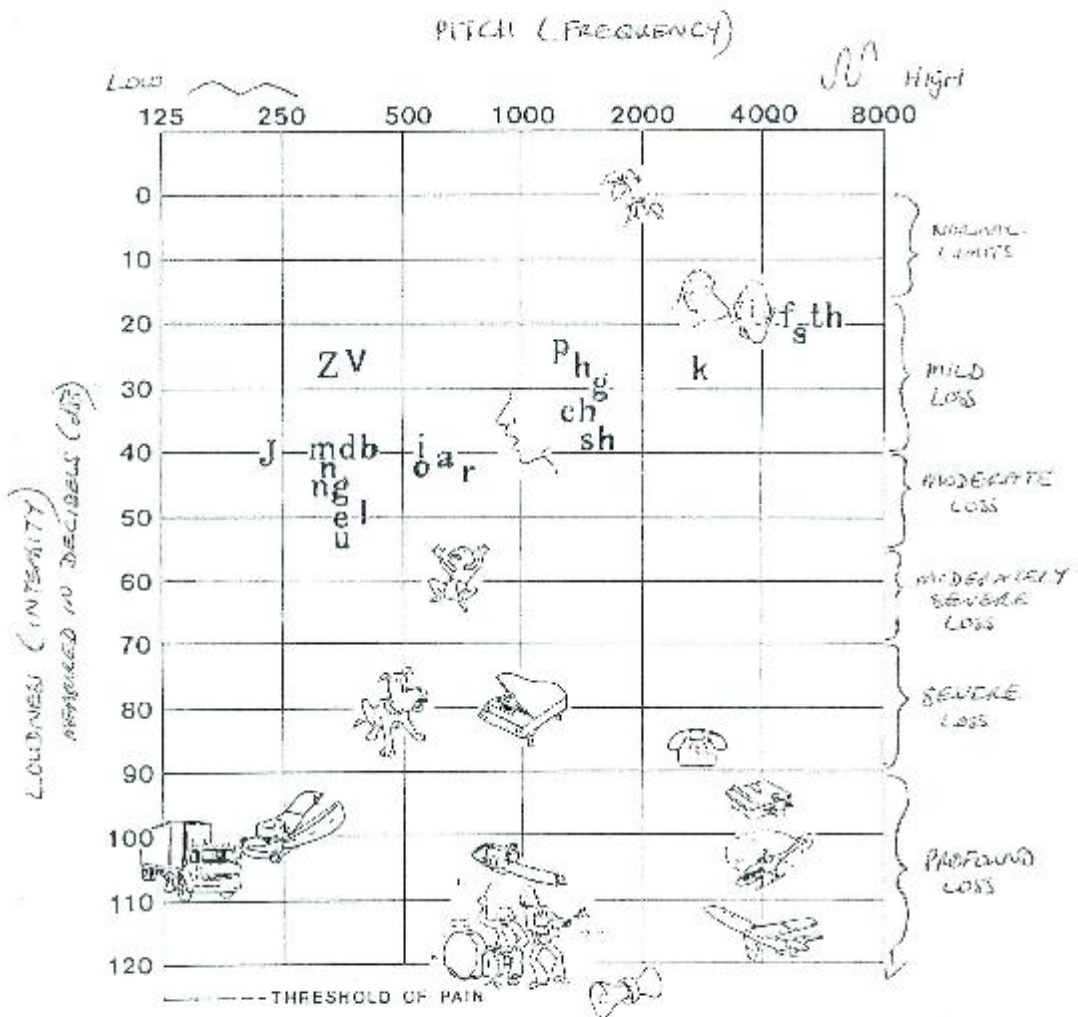**Yours in Service,**

Ian Wallace.

APPENDIX G

THE 'FAMILIAR SOUNDS' AUDIOGRAM

FOR FEEDBACK TO PARTICIPANTS

APPENDIX G

AUDIOGRAM / OUDIOGRAM

Date / Datum:

O = Right / Regs

X = Left / Left

THE FAMILIAR SOUNDS AUDIOGRAM

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APPENDIX H

CALIBRATION CERTIFICATE OF

SOUND-TREATED BOOTH

Techno Hear

P.O. Box 32360	1395 Cunningham Avenue
Totiusdal	Waverley
Pretoria	Pretoria
South Africa	South Africa
0134	0186

Cell : +27 (0)82 458 4515
Fax : +27 (0)86 212 2141

19 October 2010

Attention : *Felicity Maclennan-Smith*

P.O. BOX 113
HERMANUS
7200

EVALUATION OF AUDIOMETRIC TEST SITE

1. Purpose of Test

To determine if the proposed site would meet the requirements of *SANS 10182:2004* "Obtaining an Acoustic Environment suitable for Audiometric Testing".

2. Test Site

The sound level measurements were performed by Mr W de Klerk on 19 October 2010 at *8 Magnolia Street in Hermanus*. The sound level measurements were performed inside the Audiometric Test Enclosure.

3. Test Equipment

1.	Sound Level Meter:	Quest 1800	#HP 8110015
2.	Sound Level Calibrator:	Quest QC-20	#QO 9090053
3.	Octave Band Filter:	Quest OB300	#HV 8120023
4.	Microphone:	Bruel and Kjaer	#1743885

The equipment was certified as accurate by M & N Acoustic Services cc in December 2009. The calibration certificate number for the above mentioned equipment is 2009-1107/1108.

Calibration Signal: Before: 114,0dB   After: 114,0dB.

4. Test Procedure

The test procedure outlined in SANS 10182:2004 paragraph 4.2 was followed to obtain the readings noted in table 1.

CC Reg. No. : 2010/022795/23   **Member : William de Klerk**

5. Test Results

Octave Band Frequencies (Hz)	Maximum Sound Pressure Level Allowed in dB (SANS 10182)	Sound Pressure Levels Obtained at Test Site (dB)
125	29.0	27.9
250	21.0	20.3
500	20.5	19.8
1000	24.0	15.5
2000	31.0	12.9
4000	37.0	12.9
8000	35.5	13.7

Table 1

6. Conclusion

As can be seen from the above results the measured sound pressure levels are all below the recommended sound pressure levels for diagnostic audiometry according to SANS 10182:2004. The audiometric booth is therefore suitable for diagnostic audiometry, at the site mentioned in point 2 of this report.

Best Regards

William de Klerk

William de Klerk

TechnoHear cc