

REMOTE TELEHEALTH HEARING ASSESSMENT IN A RURAL COMMUNITY- A VALIDATION STUDY

By

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TABLE OF CONTENTS

| | |
|---|-----------|
| FIGURES | 4 |
| TABLES | 4 |
| LIST OF ABBREVIATIONS | 5 |
| ABSTRACT | 6 |
| | |
| 1. RESEARCH PROPOSAL | |
| | |
| 1.1. Motivation, background and research problem | 8 |
| | |
| 1.2. RESEARCH METHODS | 12 |
| 1.2.1. Research Aim | 12 |
| 1.2.2. Research design | 13 |
| 1.2.3. Ethical considerations | 13 |
| 1.2.4. Research subjects | 14 |
| 1.2.4.1. Selection criteria | 15 |
| 1.2.4.2. Subject selection procedure | 16 |
| 1.2.5. Material and Apparatus | 17 |
| 1.2.5.1. Data collection apparatus | 17 |
| 1.2.5.2. Audiometric assessment | 17 |
| 1.2.5.3. Analysis of data | 19 |
| 1.2.6. Procedures for data collections, recording and analysis | 19 |
| 1.2.6.1. Data collection | 19 |
| 1.2.6.2. Procedures for recording data | 24 |
| 1.2.6.3. Procedure for data analysis | 24 |
| 1.2.7. Validation and Reliability | 25 |

| | |
|---|-----------|
| 1.2.7.1. Validity | 25 |
| 1.2.7.2. Reliability | 25 |
| 1.2.8. Expected findings and hypothesis | 25 |
| 1.2.8.1. Expected findings | 25 |
| 1.2.8.2. Hypothesis | 25 |
| 1.2.9. Expected contributions to the field of audiology | 26 |
| 1.2.10. Budget | 26 |
| | |
| 2. RESEARCH ARTICLE | 28 |
| | |
| 2.1. Abstract | 28 |
| | |
| 2.2. Introduction | 29 |
| | |
| 2.3. Materials and Methods | 31 |
| 2.3.1. Participants | 31 |
| 2.3.2. Equipment | 32 |
| 2.3.3. Test Environment | 33 |
| 2.3.4. Test Procedures | 34 |
| | |
| 2.4. Data Analysis | 35 |
| | |
| 2.5. Results | 35 |
| | |
| 2.6. Discussion | 39 |
| | |
| 2.7. Conclusion | 42 |
| | |
| 2.8. Acknowledgement | 43 |
| | |
| 2.9. Disclosure Statement | 43 |
| | |
| 3. DISCUSSION AND CONCLUSION | 44 |

| | |
|---|-----------|
| 3.1. Discussion of Results | 44 |
| 3.2. Clinical implications and recommendations | 47 |
| 3.3 Critical evaluation | 48 |
| 3.4. Suggestions for future research | 49 |
| 3.5. Conclusion | 50 |
| | |
| 4. REFERENCES | 52 |
| | |
| 5. APPENDICES | 57 |
| APPENDIX A: Cover letter for Informed Consent | 59 |
| APPENDIX B: Letter to Executive of LA Visagie en Seun Pty | 63 |
| APPENDIX C: Letter of Consent-from the Employer | 66 |
| APPENDIX D: Form for data collection | 68 |
| APPENDIX E: Acceptance of Proposal and ethical clearance letters | 71 |

FIGURES

| | |
|--|-----------|
| Figure 1. Quantitative data collection phases | 20 |
|--|-----------|

TABLES

| | |
|--|-----------|
| Table 1. Ethical considerations | 13 |
|--|-----------|

| | |
|--|-----------|
| Table 2. Test-retest differences in AC thresholds recorded in the natural and booth environments and correspondence | 36 |
|--|-----------|

| | |
|--|-----------|
| Table 3. Average absolute differences | 37 |
|--|-----------|

| | |
|--|-----------|
| Table 4. Average ambient noise levels in the natural environment for test (n=20) and retest (n=20) audiometry measurements combined | 37 |
|--|-----------|

| | |
|--|-----------|
| Table 5. Difference in AC thresholds recorded in the booth and natural environments | 38 |
|--|-----------|

| | |
|--|-----------|
| Table 6. Difference in AC thresholds recorded in the natural compared to tele-audiology environment; as well as booth compared to tele-audiology environments | 39 |
|--|-----------|

LIST OF ABBREVIATIONS

WHO - World Health Organization

HPCSA –Health Professions Council of South Africa

ASHA - American Speech and Hearing Association

AC - Air conduction

TYMP – Tympanometer

UK – United Kingdom

SLM - Sound level meter

BC - Bone conduction

Hz-Hertz

dB - Decibel

ABSTRACT

The global need for increased hearing health care currently far exceeds the capacity for delivering these services, especially in developing countries where the ratio of audiologists to the population is often less than one per every million. The imbalance is further compounded by the requirement for diagnostic assessments to be conducted in an audiometric (sound proof) booth, as a large proportion of the population has limited access to centres where these booths can be found. A tele-audiology approach utilising a portable diagnostic audiometer could provide the solution, enabling hearing assessments to be conducted remotely and without an audiometric booth. This would obviate the necessity for people from rural communities having to travel long distances, often with great difficulty and at great expense, to the nearest sound (audiometric) booth. An additional advantage would be that an audiologist could service a range of remote communities at the same time.

The purpose of this study was to determine the accuracy of pure tone air conduction (AC) thresholds obtained using a synchronous telehealth approach without a sound booth in a rural South African community.

Hearing thresholds in a sound booth and in a natural environment were obtained from an initial sample of 20 adults (range 19 to 63 years; mean age 50 ± 13 years; 55% female), recruited from a rural agricultural community. A subgroup of ten adults (20 ears) volunteered for the tele-audiology threshold testing. AC thresholds (250-8000 Hz) were determined and subsequently compared in these environments. Typical threshold variability was determined using test-retest correspondence as a reference for the threshold correspondence using a telehealth mode.

Test-retest threshold correspondence in the booth and natural environments were within ± 5 dB in 96.7% and 97.5% of comparisons respectively. No significant differences were noted when AC hearing thresholds determined in the telehealth configuration were compared to those recorded in the gold standard booth environment. Threshold correspondence between the telehealth environment on the one hand and booth and natural environments on the other hand were within ± 5 dB in 82% and 85% of comparisons, respectively.

The current study is the first of its kind to report synchronous telehealth hearing assessments conducted in a natural environment in a rural community. It demonstrates the validity of using synchronous tele-audiology for conducting hearing assessments in a remote rural agricultural community without a sound booth. It also highlights the potential for using non-clinical facilitators in remote locations, which could reduce the burden on the limited number of audiologists. These technologies make it possible for diagnostic hearing assessments to be included as part of a remote telemedicine kit and open up new possibilities in telehealth and tele-audiology support.

Keywords: Rural community, remote testing, air conduction audiometry, natural environment, telehealth, tele-audiology, portable computerised equipment, sound booth, interpreter, facilitator.

1. RESEARCH PROPOSAL

1.1. MOTIVATION, BACKGROUND AND RESEARCH PROBLEM

As mortalities have dropped and life expectancies have risen worldwide, the focus in global health care systems has shifted to the reduction of disabilities and handicaps such as hearing impairment and deafness (WHO, 2008a).

The World Health Organization (WHO) has, on the basis of statistical data, estimated that there are 360 million people with bilateral moderate to profound hearing loss in the world (WHO, 2013) - a number which is likely to double if one includes mild hearing losses. Accordingly, the WHO estimates that hearing loss is the most prevalent disabling condition globally (WHO, 2008a). Developing countries such as South Africa harbour two-thirds of the population of people with hearing loss and half of them have a hearing loss that may have been avoided.

Hearing loss is a serious disability which has a significant impact on families' and individuals' social and economic situations as well as on the resources of communities and countries (WHO, 2006a). As a result there has been a global increase in the perceived need for hearing health care.

The need, however, far exceeds the current capacity to deliver services to all those who require them (Swanepoel, 2006). Globally, the majority of persons with hearing loss are neither identified early nor able to access diagnostic services, and have no intervention option available to them (WHO, 2008a). Global health care efforts are manifestly inadequate in reaching the majority of people in need of hearing health care. More than 80% of people with hearing loss reside in developing countries and underserved poorer communities where services are either totally absent or very limited, which makes a striking statement regarding global inequality in hearing health care (WHO, 2006b; Fagan and Jacobs, 2009). In these underserved poorer communities the risk of hearing loss is higher due to disease outbreaks, unhygienic living conditions, lack of access to health care and poorer knowledge about prevention (Olusanya, Ruben and Parving, 2006).

In South Africa, where 38% of the population live in underserved poorer rural communities (Internet World Statistics, 2013), almost a third of the population may have a high risk for hearing loss that goes unidentified and untreated due to a lack of audiological services.

Goulios and Patuzzi (2008) identified this shortage of professional audiological resources and services in South Africa, estimating that there are 1000 Audiologists/Speech Therapists practising in South Africa, making the ratio of therapists in the population to be 1:45,000.

The low percentage of audiologists in the population makes service delivery to all communities in South Africa even more challenging. The rest of Africa, where ratios are even higher at 1:4.1million presents an even greater problem. This supports the statement that hearing health care services in South Africa and globally are totally inadequate.

In their review of the profile of health care services Goulios and Patuzzi (2008) concluded that the scarcity of both services and hearing health care professionals can be ascribed to three factors: a reported lack of professional and public awareness; lack of government funding; and, most significantly, lack of available training programmes. A factor compounding the lack of access of people living in remote rural areas to audiological services is the great distances they need to travel to access these services, coupled with unaffordable travel costs (Krumm, Ribera and Froelich, 2002; Fagan and Jacobs, 2009).

Thus the challenge for health care providers lies in reaching all people in need of hearing health care including those living in the remote underserved rural areas so characteristic of the majority of Africa. All resources and newly developed modern approaches in hearing health care need to be considered and reviewed critically to determine the most effective ways to bring services to people (Swanepoel et al., 2010a). This includes developments in computerised technology, which are becoming more accessible and make it possible to deliver hearing health care services to remote rural communities globally.

Currently the gold standard for diagnostic assessment of hearing is utilising a clinical pure tone audiometer with the patient in a sound booth (Bexelius et al., 2008). In

traditional clinical audiology, assessments are conducted in private practice rooms, private hospitals, government hospitals, tertiary institutions, schools, industries, and community environments (HPCSA, 2007). In these settings it is only possible to assess hearing ability diagnostically if the assessment takes place in a sound booth or room where environmental noise levels can be controlled and ambient noise levels are low enough to ensure that hearing thresholds as low as 0 dB HL can be assessed. Without a sound proof room or booth, ambient noise levels can affect the hearing assessment. If the ambient noise levels rise above a particular threshold the assessment will be described as “hearing screening” (Bexelius et al., 2008).

The requirement of a sound booth limits the provision of hearing health care primarily to tertiary hearing care institutions or specialised centres, since the equipment is expensive and not portable. The sound booths suitable for diagnostic audiometry are usually more costly than the audiometer and because of their size and weight, sound booths remain in one location. This seriously limits the delivery of diagnostic audiometry in developing countries with large rural remote populations, as many people may not have access to these centres and institutions which are typically situated in the larger cities (Swanepoel et al., 2010a; Swanepoel et al., 2010b).

Another factor limiting the provision of hearing care is the availability of audiological services. A recent approach to expanding hearing health care services is the use of telehealth applications in audiology that could facilitate the remote assessment of hearing (Krumm, Ribera and Froelich, 2002). Telehealth is the delivery of health services from one location to another using a telecommunication medium (Krumm and Ferrari, 2008). Telehealth services are typically provided by clinicians to underserved populations through the internet, computer networks, dial-up and satellite technology (Krumm and Ferrari, 2008).

The development of new compliant portable audiometers may obviate the need for a sound booth by providing double attenuation (i.e., insert and circumaural earphones); live continual monitoring of environmental noise for compliance; and also the implementation of active noise cancellation features (Swanepoel, 2010). A recent computer-based audiometer, the KUDUwave, utilises insert earphones covered by circumaural earcups with a built in sound blocking feature known as the ambidome. There are microphones on the outside and inside of the circumaural

earcup to monitor environmental noise and to alert the user when this noise exceeds the acceptable limits.

Telehealth can be employed in three different manners: synchronous (real-time via interactive videoconferencing), asynchronous (store and forward manner), or as a hybrid model consisting of both synchronous and asynchronous aspects (Krumm, 2007). This allows the provision of health care services to individuals virtually anywhere in the world, as connectivity can be achieved in a variety of ways (Krumm and Ferrari, 2008). The improvement of internet connectivity and distribution (Swanepoel et al., 2010b) leads the way for implementation of telehealth in clinical environments. Over the past 8 years Africa's internet usage has shown exceptional growth, exceeding 1000% (Internet World Statistic, 2009). This fast growth is accompanied by the availability of satellite services and extensive roll-out of cellular networks which have opened the door to telehealth in the most remote and underserved areas (Swanepoel et al., 2010b).

Telehealth could therefore, according to ASHA'S position statement (ASHA, 2005), serve as an approach to meet patients' needs, where face-to-face services are not feasible (e.g., in remote rural communities). It serves to augment and not to replace face-to-face service interaction between the clinician and the patient. It also offers the potential to extend clinical services to rural, remote, and underserved populations (Polovoy, 2008). Several medical disciplines have already adopted this model, including cardiology, radiology, otology, paediatrics, pharmacology, psychology, psychiatry, and speech language and pathology (Krumm and Ferrari, 2008), paving the way for its use in audiology.

The recent significant improvements in telecommunications have enabled the use of telehealth in hearing health care in Africa. This promises important applications that could benefit society by allowing remote rural communities access to hearing health care. These communities will probably experience the greatest benefit from tele-audiology. Although this is a new and exciting field of practice, audiologists still need to determine the boundaries of tele-audiology application in service delivery, and also to validate the use of remote services to ensure they are comparable to face-to-face services (Krumm, Ribera and Froelich, 2002). If tele-audiology is found to be comparable then it is the ethical duty of hearing health care providers to attempt a

comprehensive service delivery to all of South Africa's communities by the optimum utilisation of resources.

This study will investigate the validity of utilising tele-audiology for determining hearing impairment in underserved communities. This will be done by investigating the reliability and accuracy of a test conducted via a portable computerised tele-audiology compliant diagnostic audiometer without a sound booth compared to the reliability and accuracy of tests done with the same portable computerised audiometer in a sound booth. After reliability and accuracy have been established a smaller sample of the same population will be tested through tele-audiology in a natural environment with the same portable computerised audiometer.

The research question this study will address is:

Can valid and reliable synchronous telehealth hearing assessments be conducted in a rural location, without a sound booth, using a portable computerised diagnostic audiometer?

1.2. RESEARCH METHODS

1.2.1. Research Aim

To describe the reliability and accuracy of synchronous telehealth hearing assessments in a rural location without a sound booth using a portable computerised diagnostic audiometer.

Sub aims

- To determine test-retest reliability of diagnostic pure tone AC thresholds obtained in a natural environment and to compare them to thresholds obtained in a sound booth.
- To compare diagnostic pure tone AC thresholds obtained in a natural environment using a synchronous telehealth configuration to thresholds obtained face-to-face in both natural and sound booth environments.

1.2.2. Research design

As the same research group will be used across the various test situations, this study follows a within subject comparative quasi-experimental design (Leedy and Ormrod, 2005; Mouton, 2002). The ‘gold standard’ (utilising a portable computerised audiometer in the sound booth) will be used as a control to give a comparative baseline. The portable computerised audiometry conducted in a natural environment and using tele-audiology in the natural environment will be the experimental condition.

1.2.3. Ethical considerations

The ethical considerations listed in Table 1 will be adhered to.

An exemplar letter of consent to the subjects, as well as to the employer, is attached in appendix A and B respectively. The letter of permission from the employer, which was obtained prior to the initiation of the research, is attached in appendix C.

Table 1. Ethical considerations

| 1.2.3.1. RESPECT FOR PERSONS |
|--|
| <p>Informed consent (Appendix A): An informed consent letter will be provided to all possible participants explaining the following:</p> <ul style="list-style-type: none"> • purpose of the research project • a short description of procedures • that no risks or discomfort will be associated with participating • benefits of participating for the subjects and future research and implementation • that it is voluntary and they may withdraw at any time (Leedy and Ormrod, 2005) • that confidentiality will be maintained (Neuman, 1997) • inducement of participating through stating that there will be no costs involved <p>The contents of the letter will be explained by the interpreter/research assistant as most of the participants’ primary languages are Zulu/Swazi and Portuguese. The interpreter/research assistant is competent in Afrikaans, English, Zulu/Swazi and Portuguese.</p> <p>Debriefing of respondents: After each study the researcher will give the subjects an opportunity to work through their experience and its aftermath. The researcher will assist subjects and try to minimise any possible harm. Thus through debriefing, problems generated by the research experience can be corrected (Babbie, 2001 as cited in de Vos, 2002).</p> |

1.2.3.2. BENEFICENCE AND NON-MALFEASANCE

Good research design: This study utilises a descriptive quantitative, quasi-experimental design (Leedy and Ormrod, 2005). Although part of the design is quasi-experimental, participants will not be experimented on; therefore no ethical issues should arise surrounding the research design.

Favourable risk-benefit balance: This study has a favourable risk-benefit balance for participants. There will be no physical, psychological, social, or any other risk involved in participating in this research project (Leedy and Ormrod, 2005). This research project will strive to be well structured and participants will be well-informed so that there will be no misunderstanding or feeling of deception. The hearing tests will be free of charge and an inducement (sponsored lunch) will be used for rewarding participants for their time and effort. Benefits of participating in this study will be designed to override any risks, without undue inducement of participation.

Relevance of research: This research project will have high relevance in a country such as South Africa. Basic audiological services are not yet widespread in remote rural areas due to the lack of audiologists, financial and human resources, implementation of new technology and the scarcity of contextually relevant research and skills in this matter. Therefore these services are limited and not reachable. These factors vindicate the relevance of this research project, and it can therefore be said to be ethical to conduct this study.

Safeguards for vulnerable populations: Due to social inequalities, in this case poverty, low literacy skills and language barriers, selected participants may feel vulnerable. The research assistant/translator will help the researcher to inform and translate all important information in the participant's language so that every aspect of the project will be understood by each participant. If in any case a participant does not feel assured or comfortable they are free to withdraw without any further consequences.

1.2.3.3. DISTRIBUTIVE JUSTICE

Actions and competence of researchers: "Researchers are ethically obliged to ensure that they are competent and adequately skilled to undertake the proposed investigation" (Strydom as cited in de Vos, 2002). The researcher has 8 years of clinical experience of hearing assessment and intends to perform a planned research project. The researcher intends to be sensitive across all cultural boundaries and no value judgements are to be made.

1.2.4. Research subjects

Non-probability purposive sampling (Neuman, 1997) will be used to identify the population for conducting the research. Purposive sampling will enable the researcher to select individuals that are representative of a pre-determined subpopulation of interest. As the aim of the study is to investigate the validity of utilising the new technology to determine hearing impairment in underserved communities, a sample group that is representative of an underserved community will be selected.

The sample group will be drawn from a remote agricultural community, situated in Karino (Mpumalanga, South Africa) where the research will be based. Subjects will volunteer from an initial population of 80 individuals.

1.2.4.1. Selection criteria

Participation in the research study will be voluntary and will only commence once informed consent has been provided (Appendix A). Subjects will be selected according to the following selection criteria:

Geographical area of research

For the sake of convenience and based on time and financial constraints, research will be conducted on a farm that is geographically accessible to the researcher. With consent from LA Visagie & Seun (Edms) Bpk, an agricultural company in Karino, Mpumalanga, South Africa (Appendix C), employees will be requested to voluntarily take part as subjects in the research project.

The members of the agricultural community of LA Visagie & Seun are drawn predominantly from the neighbouring rural communities of Kanyamazane, Kabokweni, and Bosbokrand. These communities are typical of underserved communities across South Africa when it comes to the provision of health care. Therefore these communities will provide this study with a representative population.

Age

Audiological services have to accommodate every demographic group and for that reason the decision has been made to draw the sample population from across all age groups. There will be one exception, the exclusion of subjects below the legal age of consent in South Africa, viz. 18 years.

Language

English is not the first language for the majority of the sample population. A translator from the community will be made available to translate and explain the informed consent letter as well as the research procedures in the subjects' preferred language.

Normal external and middle ear functioning

Certain middle ear pathologies can cause temporary conductive hearing loss. As a result hearing may fluctuate and the true clinical picture will be masked (Bess and Humes, 1995). This may influence the accuracy of the pure tone thresholds (Hall and Mueller, 1997). An otoscopic examination of the external meatus and immittance measurement of the middle ear will be performed, bilaterally for each subject.

Only subjects with Type A tympanograms will be included in the study. Type A tympanograms are best described as representing middle ear pressure between -100 and +100 daPa, ear canal volumes between 0,65 ml and 1,75 ml, and static admittance between 0,3 and 1,9 ml (Katz, 1994). If impacted cerumen, any abnormalities in the meatus, redness of the tympanic membrane, or possible middle ear pathologies is observed, the subjects will be excluded from the study and referred for medical management.

As middle ear functions may fluctuate, a time limit of no more than a week between the tests done in a natural environment and tests done in the sound booth will be set. This will be to ensure consistent middle ear function across the sample population.

1.2.4.2. Subject selection procedure

In order to identify the sample population from the agricultural community a meeting will be held with the farm manager, all employees, and the sections managers. At this meeting an interpreter will explain the purpose of the research and how participation will be free of charge, voluntary, not harmful and at all times confidential. From this initial meeting a list of willing volunteers (25) will be drawn up, from which the sample population will be selected.

Consent will be obtained from the identified test subjects through the interpreter, who will use the consent form to explain the test procedure and study aims. All questions regarding the project and testing procedure will be answered by the researcher through the interpreter. Those subjects willing to participate in the study will confirm their participation by signing an informed letter of consent. To ensure confidentiality once the participants have signed the consent forms and passed the middle ear function test they will be assigned numbers and no recordings of their names will be made.

1.2.5. Apparatus and materials

1.2.5.1. Data collection apparatus

Data Sheet

The data sheet (Appendix D) will include biographical data (subjects' age, gender, and language and literacy skills) as well as otoscopic and immittance measurements. Background of the subjects is relevant for description of the research sample.

Apparatus and materials for otoscopic and immittance measurements

A Heine Minilux 2000 handheld otoscope will be manually used to examine the external meatus bilaterally, to determine if any impacted cerumen, growths in the external meatus or redness of the tympanic membrane can be observed. As this is part of the selection criteria, subjects with any of these listed conditions will be excluded from the study and referred for medical management.

A GSI 38 Auto (TYMP) tympanometer employing a 226 Hz probe tone with standard adult probe tips will be used to determine the middle ear functioning. A type A tympanogram is required for subjects to participate further in the study.

Each speculum and probe tip will be sterilised in Milton's sterilising solution before use.

1.2.5.2. Audiometric assessment

For determining the audiometric thresholds, assessment will consist of different sets of test equipment, instruments, assessment environments, and phases. The first test situation will be in a natural environment (in an office at the workplace on the farm) without a sound booth and will include the following new developed technology equipment.

KUDUwave (eMoyo, South Africa). This is a portable diagnostic type 2 audiometer (IEC 60645-1/2) that allows audiologists/hearing health care professionals to conduct diagnostic hearing tests, without a sound booth. This audiometer consists of a transducer with built-in insert earphones which are covered by the circumaural earcups (with a built in sound blocking feature, the ambidome™). After insertion the

ambidome™ attenuates noise similarly to a sound booth. A Bone oscillator can also be fitted to the circumaural headband with a screw fitting. The audiometer has two microphones on the circumaural earcups that monitor environmental noise in octave bands during testing. This is visually symbolized in real time on the software. The noise-monitoring function of the KUDUwave uses low pass (<125 Hz), seven single octave band pass (125, 250, 500, 1000, 2000, 4000 and 8000 Hz) and high-pass (>8000 Hz) filters to separate the incoming sound. The audiometer hardware is encased in each circumaural earcup and is powered by a USB cable and will be plugged into a Notebook computer (HP Probook 4530 S-series PC, Windows 7).

The KUDUwave will be operated via a HP Probook (S series) through a USB cable. Software loaded on the notebook is used to control all audiometry function e.g. the production of sounds, and record the responses of the participant. Data generated in the form of test scores will be safely stored during the duration of the research as audiograms on a separate external hard drive.

A SVAN959 digital type 1 (SVANTEK Spz.o.o, Warsaw 2007) sound and vibration level meter and analyser (SLM) will be used to record average noise levels in the natural environment. This instrument is intended for general acoustic and vibration measurements, environmental monitoring, and occupational health and safety monitoring.

The second test situation will comply with conventional audiometric assessment in a clinical environment in Nelspruit, at the Nelspruit Medi-clinic:

- Testing will be conducted in a single-walled audiometric booth adhering to ambient noise levels specified by ANSI (ANSI S3.1-1999(R2008)). The KUDUwave will be used as the audiometer for evaluating hearing down to 0 dB HL.

The third test situation will use a subgroup of 10 subjects from the test population in the previous test environments. This subgroup will be used to determine the accuracy of a portable computerised audiometry using a telehealth configuration.

The following equipment will be used for the third test situation:

- KUDUwave (portable computerised audiometer)

- Two HP Probooks (S-series) with built-in web cameras.
- Wireless 3G connection.
- A facilitator who will help as an instructor and translator to perform the test through videoconferencing (telehealth setup).

There will be a distance of 1.2 km between the researcher and facilitator, to simulate the physical separation in situations where the equipment and the telehealth approach are intended to be used. Physical separation could have been simulated in the same building, with the researcher and facilitator occupying separate rooms. However, this would not have allowed issues like varying internet connectivity to be taken into consideration as both the researcher and facilitator would be subject to the same connectivity. A clear and structured plan will be discussed and put into place before executing the last assessment.

All test equipment will be sterilised before use by each patient through Milton sterilising solution or an alcohol swab.

1.2.5.3. Analysis of data

All the data, both biographical data and audiometric test results, will be entered onto an Excel spreadsheet in preparation for statistical analysis. Statistical analysis procedures that will be used include the use of descriptive statistics such as measurements of central tendency (mean, median, and mode), measures of variability (standard deviation, range), and correlation coefficients.

1.2.6. Procedures for data collection, recording and analysis

1.2.6.1. Data collection

The group of subjects will undergo an identical battery of audiometric assessments. The audiometric assessments will take place in three different test environments and in two different phases as illustrated in the following diagram (Figure 1).

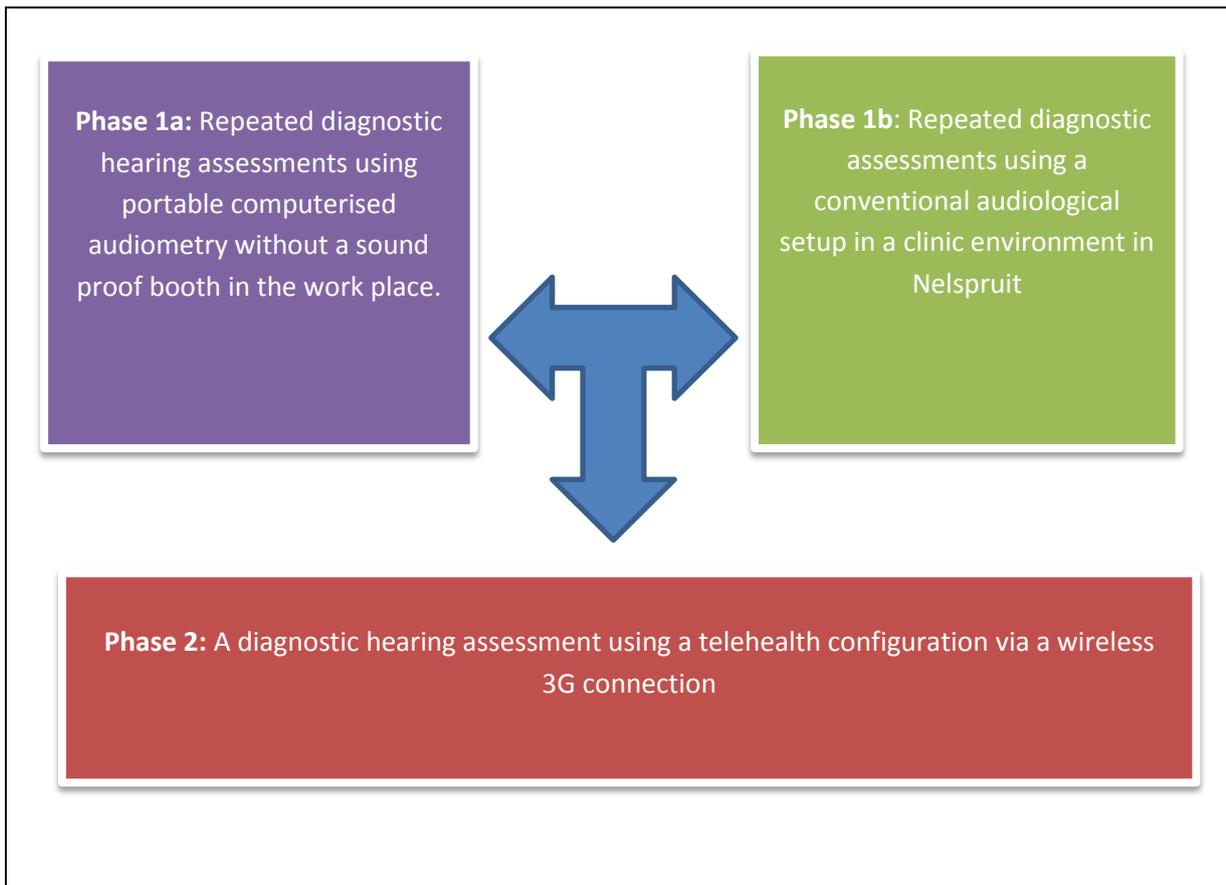


FIGURE 1. Quantitative data collection phases

Data Collection

Phase 1a & b testing will be done simultaneously, commencing in a counter-balance way (half of the participant tested firstly in the natural environment and other half tested firstly in the booth environment) to exclude an order effect.

Phase 1a

This test phase will take place in an available office at the workplace on the farm as this is identified as the natural environment. The office that will be provided is a comparable test location to the spaces that would be available in rural communities, (rooms in clinics, school buildings, or community centres) should this equipment be utilised to provide audiological services to underserved communities.

A timetable will be devised with the section managers to ensure that the research does not disturb the day-to-day running of the farm. Subjects will be assigned to turn up in groups of five for testing.

Each subject will undergo two pure tone AC assessments bilaterally. (Right and left ears of each subject will be tested twice in the initial two environments to determine test-retest reliability outside and inside the booth.)

- Test-retest will not be done consecutively (other participants will be tested between a single individual's test and retest) but will take place on the same day.
- The hearing test will be performed by the researcher (who is a qualified audiologist) with the help of the facilitator (who will serve as the research assistant) explaining the test procedures. Clear instructions will be given to each subject.
- Any uncertainty exhibited by any participant at that time will be addressed and issues clarified by the researcher through the help of the facilitator.
- The KUDUwave connected to an HP Probook with a USB cable will be used to obtain the diagnostic AC thresholds.
- The subject will be seated looking away from the researcher, as body movements and facial expressions may give visual clues to the subject when to respond.
- The circumaural ear cups with the built in insert earphones will be placed over the subject's head and correct ear canal size insert tips (12 mm) will be placed on the insert earphone in the ear canal.
- A response button will be connected to the KUDUwave device to record patients' responses to stimuli and to document response time.
- To obtain pure tone AC thresholds the following frequencies will be tested: 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, and 8000 Hz. According to Stach (1998) clinical diagnostic pure tone audiometry thresholds are usually measured over the range of 250 Hz at the low end up to 8000 Hz at the high end.
- A conventional 10 dB down and 5 dB up bracketing method (modified Hughson-Westlake method) will be used to determine AC hearing thresholds. Testing will commence with the right ear at 1000 Hz and proceeded to lower frequencies (250-500 Hz), before increasing to higher frequencies (2000-8000 Hz) for all subjects.

- Pure tone signals across the above mentioned frequency range will be presented through the insert earphones.
- A threshold for each frequency will be determined by the response from the subject for the right and left ear respectively through the response button.
- Results of the recordings will be saved on the audiogram in the audiometer software.
- All equipment used (insert tips and ear cups) will be sterilised before each hearing assessment with Milton sterilising solution and alcohol swabs.

Phase 1b

Test phase two will consist of AC audiometry in a conventional clinical environment with a sound booth. The test subjects will be transported 25 km from the farm to Nelspruit Medi-clinic at the researchers' expense. To ensure the reliability of the results no more than a week will be allowed to lapse between phase one and two.

- Hearing assessment will take place in an audiology assessment room using a sound booth.
- The KUDUwave will be used as the audiometer plugged into the HP Probook via a USB cable. Insert earphones covered with circumaural earcups will be used to assess the hearing ability of each subject.
- The researcher and instructor will explain the same test procedures and give clear instructions.
- The subject will be seated in the sound booth.
- Pure tone signals through the insert earphones will be presented over the frequency range (250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz and 8000 Hz).
- A threshold for each frequency will be determined by the response from the response button from the subject for the right and left ear respectively.
- Each test will be performed twice to determine test-retest reliability.
- The results will be saved on the computer software on an audiogram.

- All equipment used for each subject's assessment will be sterilised before testing.

Phase 2

The final phase of the audiometric assessment will be completed by a subgroup of the subjects of the same research population. The facilitator from the local community, with no formal audiology training or tertiary education, will act as the research facilitator, setting the environment up and assisting the researcher as the assessments will be performed over a distance. Throughout the test the facilitator and the researcher will communicate through videoconferencing to ensure that there will be no misunderstandings and that the results will be reliable.

- The subject and the facilitator will be stationed in Karino on the farm in the same office used in phase 1a (the natural environment). The researcher will be located in the main office building on the farm 1.2 km away.
- Testing will take place through a wireless 3G internet connection using two HP Probooks with web cameras and "Skype" to communicate through videoconferencing.
- The facilitator will explain the same test procedure.
- The KUDUwave is plugged into the HP Probook and connected to the HP notebook of the researcher via a wireless 3G connection. The connected apparatus will be used to obtain the diagnostic hearing test scores and store it on an audiogram included in the eMoyo software programme.
- The subject will be seated looking away from the interpreter, as body movements and facial expressions may give visual clues to the subject when to respond.
- The ear cups with the built in insert earphones will be placed over the subject's head and the precise ear canal size insert tips must be placed in the ear canal.
- The researcher at the remote site office will test the subject through the wireless connection using an HP notebook as the audiometer.
- Recordings will be stored on an audiogram included in the eMoyo software programme.

- Before assessments commence the internet connection will be checked by the researcher.
- All equipment used for each subject's assessment will be sterilised by the interpreter/ research assistant.

1.2.6.2. Procedure for the recording of data

Subjects' biographical information will be recorded on the data sheet against their assigned number, as will the results of the otoscopic examination and the tympanogram. The audiometric results will be stored on the software programme on the HP Probook. The information and raw test scores will then be coded and recorded on an Excel spread sheet.

1.2.6.3. Procedure for data analysis

Normal ranges and distributions will be employed to demonstrate test-retest reliability in natural and booth environments and differences as well as absolute differences in AC thresholds obtained between: 1) the natural and conventional booth environments; 2) the booth and tele-audiology environments; 3) the natural and tele-audiology environments.

Accuracy of hearing thresholds determined outside a sound booth and remotely will be ascertained via a comparison against the gold standard (differences in the booth environment). Average differences between corresponding thresholds in the different environments and their distributions (SD and range) will be established. The percentage correspondences of threshold difference within specified ranges will also be calculated.

The distribution of threshold values will determine whether parametric, or non-parametric, statistics will be applied. A match-pairs statistical test will allow differences in threshold values to be compared across the testing environments. Statistical significance will be indicated by $p < 0.01$.

1.2.7. Validity and Reliability

1.2.7.1. Validity

Validity is the degree to which a measurement does what it is intended to do (Bostwick and Kyte, 1981 as cited in de Vos 2002:166). The measure of validity will be particularly pertinent to this research project.

Criteria related validity refers to the extent to which the results of a measurement instrument are comparable to another independently valid criterion. In this scenario the KUDUwave maximum permissible ambient sound pressure levels was compared to existing theoretical criteria such as SANS 10182 standards.

1.2.7.2. Reliability

Reliability measures an instrument's ability to yield the same results on repeated trials. If a measure is unreliable it cannot be valid (Durheim, 2002).

To test the reliability of the findings the subjects will rest during each phase of data collection, enabling the reliability of the data being collected and the techniques being used to be tested through the internal consistency method (Durheim, 2002) Internal consistency will be obtained by determining the degree to which each item in the results correlates with the other items.

1.2.8. EXPECTED FINDINGS AND HYPOTHESIS

1.2.8.1 Expected findings

It is expected that using the KUDUwave with its external noise attenuation, thresholds measured in a natural environment without a sound booth will be comparable to those recorded in a sound booth. Furthermore, when utilised in a telehealth scenario the thresholds recorded will be comparable to those in a face-to-face setting, as the procedure has been designed with this in mind.

1.2.8.2 Hypothesis

1. There will be no significant difference between threshold values obtained in the booth and natural environments.

2. There will be no significant difference between the threshold values obtained in the tele-health application in the natural environment and the face-to-face applications in both the booth and natural environments.

1.2.9. EXPECTED CONTRIBUTIONS TO THE FIELD OF AUDIOLOGY

The following possible outcomes and contributions will be discussed:

- ❖ As part of the study is exploratory, the results/findings will lay the cornerstones for incorporating newly developed technology into the basic hearing assessment battery e.g. for the mining industry, industrial hearing screening, and assessing hearing in remote underserved communities of South Africa.
- ❖ The results may motivate audiologists to make a mind shift towards practicing outside the typical clinical environment by using newly developed technology such as tele-audiology to serve the whole community of South Africa.
- ❖ The results may create interest in further research possibilities and opportunities in this specific field of research.
- ❖ If there is a positive response towards tele-audiology, then in the future hearing aid fitting could be possible through this method of using portable computerised technology.

1.2.10. BUDGET

BUDGET FOR PLANNING AND CONDUCTING MASTERS RESEARCH PROJECT

| DESCRIPTION | COST |
|--|-------------|
| Application fees 2009 | R 200.00 |
| Registration fees 2009 | R 1 830.00 |
| Annual study fees 2009/2010 for M.Communication Pathology. | R 17 570.00 |
| Departmental administration fees 2009 | R 150.00 |
| Minolta photo copy fees 2009 | R 200.00 |
| Petrol fee for attending the Masters programme week | |

| | | |
|---|---|-----------|
| to and from Nelspruit | R | 340.00 |
| Toll gate fees to and from Nelspruit | R | 350.00 |
| Research text book | R | 540.00 |
| Paper for printing research proposal and dissertation | R | 200.00 |
| Language editor | R | 1 700.00 |
| Technical editor | R | 1 500.00 |
| <u>Research costs:</u> | | |
| Lunch incentives for subjects participating in lunch and after hours at R20.00 per subject | R | 1 800.00 |
| Sterilising material | R | 160.00 |
| Information sheets | R | 180.00 |
| Stationery | R | 150.00 |
| Petrol and transport for subjects | R | 400.00 |
| Letters of consent (70 x 20 c) | R | 140.00 |
| Binding and printing of examiner drafts 3x R 270.00 | R | 810.00 |
| Binding of dissertation 2x copies at R 500.00 per copy | R | 1 000.00 |
| | R | 11 650.00 |

2. RESEARCH ARTICLE

TITLE: ACCURACY OF REMOTE HEARING ASSESSMENT IN A RURAL COMMUNITY

Authors: Ansophi Visagie, De Wet Swanepoel and Robert H. Eikelboom

Journal: Journal of Telemedicine and E-Health

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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.

2.1. Abstract

Background: This study determined the accuracy of pure tone air conduction (AC) thresholds obtained using a synchronous telemedicine approach without a sound booth in a rural South African community.

Introduction: The global need for increased hearing health care currently far exceeds the capacity for delivering these services, especially in developing countries. A tele-audiology approach utilising a portable diagnostic audiometer could provide the solution, enabling hearing assessments to be conducted remotely and without a sound booth.

Material and Methods: Hearing thresholds in a sound booth and natural environment were obtained from an initial sample of 20 adults (range 19 to 63 years; mean age 50 ± 13 years; 55% female), recruited from a rural agricultural community. A subgroup of ten adults (20 ears) volunteered for the telemedicine threshold testing. AC thresholds (250-8000 Hz) were determined and subsequently compared in these environments. Typical threshold variability was determined using test-retest correspondence as a reference for the threshold correspondence using a telemedicine mode.

Results: Test-retest threshold correspondence in the booth and natural environments were within ± 5 dB in 96.7% and 97.5% of comparisons respectively. No significant differences were obtained in AC hearing thresholds determined in the telemedicine configuration compared to those recorded in the gold standard booth environment. Threshold correspondence between the telemedicine compared to booth and natural environments were within ± 5 dB in 82% and 85% of comparisons, respectively.

Conclusion: The current study demonstrates the validity of using synchronous telemedicine for conducting hearing assessments in a remote rural agricultural community without a sound booth.

2.2. Introduction

Increased access to hearing health care through telemedicine is an area of growing interest due to the global occurrence of hearing loss and limited access to care. With an estimated global prevalence of 5.3%, hearing loss is considered by the World Health Organization (WHO) as the most prevalent disabling condition globally (WHO, 2013a). Worldwide 360 million people suffer from permanent bilateral disabling hearing, more than two-thirds of whom live in developing countries with severely limited access to care (WHO, 2013a).

While the global need for increased hearing health care is recognised, in reality the need far exceeds the current capacity to deliver these services (Goulios and Patuzzi 2008; Fagan and Jacobs 2009; Swanepoel and Hall 2010). According to a recent survey by the WHO the majority of developing countries have less than one audiologist to serve every million people (WHO, 2013b).

In South Africa for example the ratio of audiologists per capita is one to every 100 000 people (Fagan and Jacobs, 2009). Whilst far better than most sub-Saharan African countries the ratio is still five times worse than in a typical developed country like the UK (Fagan and Jacobs, 2009). The shortage of audiologists, mostly urban distribution of professionals and limited resources mean access to services for most, especially those in rural areas, are limited (Goulios and Patuzzi 2008; Fagan and Jacobs 2009; Swanepoel, 2006).

Access to audiological services is further compounded by the requirement for diagnostic assessments to be conducted in a sound booth (Maclennan-Smith et al., 2013; Swanepoel, Maclennan-Smith and Hall, 2013; Bexelius et al., 2009). This restricts the provision of hearing health care primarily to tertiary hospital-based institutions or specialised centres found in larger towns and cities.

As in many other developing countries, a large proportion (38%) of South Africans live in rural areas with limited access to health care services (WHO 2013a; Internet World Statistics, 2013). These communities face barriers such as large traveling distances at high costs and the inconvenience of being away from home or work for a day or two to visit a health care facility, especially one that may have some form of ear and hearing health care provider (Fagan and Jacobs, 2009).

Consequently, innovative means of bringing hearing health services to people utilising telemedicine holds promise for reaching remote communities with audiological care (Storey et al., 2014; Clark and Swanepoel, 2014), especially as the global revolution in internet connectivity and the extensive roll out of cellular networks, are making it increasingly possible to provide access to underserved rural areas with tele-audiology (Swanepoel et al., 2010a).

A recent mobile diagnostic audiometer utilising increased ambient noise attenuation (covering insert earphones with circumaural earcups) combined with continuous environmental noise monitoring enables compliant hearing testing to be done outside conventional sound booths (Storey et al., 2014). Studies using this diagnostic device on children (Swanepoel et al., 2013) and elderly participants (Maclennan-Smith et al., 2013) have reported accurate threshold determination outside of conventional sound booth environments. The requirement for sound booths for diagnostic hearing assessments has limited access because these booths are usually not mobile and are prohibitively expensive (Maclennan-Smith et al., 2013). A diagnostic computer-operated mobile audiometry system that provides a way to conduct hearing assessments without the requirement for a sound booth could increase access to services, especially if combined with a telemedicine model. This could enable audiologists to conduct hearing assessments remotely (Swanepoel et al., 2010c) and facilitate numerous locations simultaneously.

While telemedicine offers unique opportunities for providing access to hearing health care services to underserved populations worldwide (Swanepoel et al., 2010a; Swanepoel et al., 2010b; Swanepoel et al., 2010c), tele-audiology has been surprisingly slow to be incorporated into existing services. This is partly due to a limited number of studies investigating the applications and validity of tele-audiology services (Swanepoel and Hall, 2010). More evidence from clinical validation studies comparing tele-audiology applications to conventional face-to-face services are still left wanting (Swanepoel et al., 2010a). In light of the pressing need to improve hearing health care access for underserved and rural communities it is important to validate the potential benefit that mobile diagnostic audiometers combined with telemedicine models could have to increase access. Most studies in tele-audiology for hearing assessment have been proof of concept studies (Swanepoel et al., 2010c) conducted in clinical and laboratory environments. This study will therefore investigate the reliability and accuracy of synchronous diagnostic audiometry in a rural agricultural community where there is limited access to audiological services.

2.3. Materials and Methods

2.3.1. Participants

Approval from the institutional ethics committee of the University of Pretoria, South Africa was granted, and all participants provided informed consent prior to participation.

This study was conducted in a remote agricultural community in Karino (Mpumalanga, South Africa). Twenty-five of 80 individuals working at a local farm volunteered to partake in the study. Since English was not the first language for the majority of the participants a translator from the same community was made available to facilitate both the informed consent and explain the research procedures in the participant's preferred language.

Participants provided biographical data, including age, gender, language and literacy levels. This was followed by an otoscopic examination and immittance measurements of middle ear functioning done by an audiologist to determine middle ear pathology. Middle-ear pathology can cause temporary conductive hearing loss

that may influence pure tone audiometry thresholds from one test session to another. Five participants with possible middle ear pathologies were excluded from the study and referred for medical management, reducing the final sample size to 20 individuals (40 ears, 55% female). The average age was 40 years (SD 13; range 19 to 63).

2.3.2. Equipment

A Heine minilux 2000 handheld otoscope was used to examine the external meatus bilaterally to detect any abnormalities in the ear canal. Tympanometry was conducted as part of the screening procedure using a GSI 38 Auto (Tymp) tympanometer employing a 226 Hz probe tone with standard adult probe tips. The KUDUwave (eMoyoDotNet, Johannesburg, South Africa), a portable diagnostic type 2 audiometer (IEC 60645-1/2), was used to conduct the AC hearing assessment. The KUDUwave utilises insert earphones covered by circumaural earcups (with a built in sound blocking feature called the Ambidome™) after insertion. The Ambidome™ provides noise attenuation similar to a single-walled sound booth. It has a microphone on each circumaural earcup that monitors environmental noise in octave bands during testing. This is visually represented in real time by the audiometer's software. The noise-monitoring function of the KUDUwave uses low pass (<125 Hz), seven single octave band pass (125, 250, 500, 1000, 2000, 4000 and 8000 Hz) and high-pass (>8000 Hz) filters to separate the incoming sound. The audiometer hardware is encased in each circumaural ear cup and is powered by a USB cable plugged into laptop computer.

A SVAN959 digital type 1 (SVANTEK Spz.o.o, Warsaw 2007) sound and vibration level meter and analyser (SLM) was used to record average noise levels in the natural environment during testing.

Two HP Probook (S-series) laptops were utilised. The one in the patient site was running the eMoyo software (eMoyoDotNet, Johannesburg, South Africa). The other laptop was located at the remote clinician site.

Control of the audiometer software by the laptop at the remote clinician site was performed through application sharing software (TeamViewer 4, Goppingen, Germany). The remote clinician was in audio-visual contact with the patient through

videoconferencing software (Skype Video call version 4, Luxemburg), and the laptops' built in microphones and HD webcams. A 3G cellular network was used to connect to the internet at both sites.

2.3.3. Test Environments

Three test environments were utilised in validating the synchronous telemedicine use of the KUDUwave in a natural environment:

1) *Booth environment* - conducted in a clinical environment at a hospital, where the test was conducted face-to-face in a single-walled audiometric booth adhering to ambient noise levels required by ANSI (ANSI S3.1-1999 R2008) for AC testing.

2) *Natural environment (without a sound booth)* – conducted face-to-face in an office at participants' workplace on a farm.

3) *Tele-audiology configurations in a natural environment (without a sound booth)* - A subgroup of 10 participants (20 ears) from the test population volunteered for further testing. Participants were tested in the same office used for the natural test environment (2), while the clinician was located at a remote office 1.2 kilometres from the test site. A tele-audiology facilitator from the local community and with no formal audiology training or tertiary education facilitated the participants during the test, while an audiologist (clinician) conducted the AC hearing assessment through videoconferencing and the wireless 3G internet connection. The tele-audiology facilitator was selected on a voluntary basis, based upon his language abilities and willingness to participate. He was able to communicate with participants in a number of different home languages (i.e. Swazi, Portuguese, Shangaan, Zulu and Sotho).

Onsite training of the tele-audiology facilitator was conducted by the audiologist, and included guidance on earphone insertion, headset positioning and usage of the response button. A clear structured plan for conducting the tele-audiology assessment was developed and put in place before any remote testing was undertaken. The plan laid out testing procedures in a step-by-step manner for the facilitator to follow.

2.3.4. Test Procedures

Right and left ear hearing thresholds of participants were assessed in each of the environments. To determine test-retest reliability, the face-to-face tests in the booth and in the natural environment were repeated. Test-retest was not done consecutively, but took place on the same day and testing was done in a counter-balance manner to avoid an order effect. The same audiologist conducted the hearing tests in all three environments.

In order to determine the validity of synchronous hearing assessments hearing thresholds determined in a face-to-face setup with the KUDUwave audiometer at the remote site (natural environment) was first compared to thresholds determined inside a sound booth (gold standard test environment). Subsequently synchronous hearing assessments using a tele-audiology setup was conducted at the remote site (natural environment) and compared to the face-to-face testing determined in the sound booth (gold standard test environment) and the natural environment.

All pure-tone AC audiometry tests were conducted across octave-interval frequencies from 250 to 8000 Hz and were identical between all the environments. A conventional 10 dB down and 5 dB up bracketing method (modified Hughson-Westlake method) was used to determine AC hearing thresholds. Testing commenced with the right ear at 1000 Hz and proceeded to lower frequencies (250 and 500 Hz), before increasing to higher frequencies (2000, 4000 and 8000 Hz) for all participants. Threshold testing was not done lower than 0 dB HL.

The eMoyo software controlling the Kuduwave audiometer actively monitored ambient noise levels across octave bands throughout the test procedures. Whenever the noise exceeded the maximum permissible ambient noise level for establishing a threshold the test was paused while the audiologist waited for the noise to subside back to a permissible level (Maclennan-Smith et al., 2013).

To assess the ambient office noise levels during face-to-face testing in the natural environment the SLM was positioned 30 cm behind the participants head to record the average environmental noise for each of the 20 participants over the duration of their hearing assessment.

Recording time was also documented for conducting the test in the natural environment and the booth environment, and in the tele-audiology environment. Time recording was initiated with the first stimulus presentation to the first ear tested and was terminated after the last patient response recorded for the last ear tested.

2.4 Data analysis

Normal ranges and distributions were employed to demonstrate test-retest reliability in natural and booth environment and differences as well as absolute differences in AC thresholds obtained between: 1) the natural and conventional booth environment; 2) the booth and tele-audiology environment; 3) the natural and tele-audiology environment.

Accuracy of hearing thresholds determined outside a sound booth and remotely was ascertained via a comparison against the gold standard (in the booth environment). Average differences between corresponding thresholds in the different environments and their distributions (SD and range) were established. The percentage correspondences of threshold difference within specified ranges were also calculated.

Due to a non-parametric distribution of threshold values the Wilcoxon matched-pairs tests was used to investigate the difference in thresholds between test environments at each frequency, with ($p < 0.01$) indicating a significant difference.

2.5 Results

Hearing thresholds recorded in the gold standard sound booth environment ranged between 0 and 40 dB across frequencies tested (250-8000 Hz). The average threshold level was 11.4 dB, (SD 7.1 dB; Range 9.1 dB to 14.6 dB) with 10% of thresholds recorded at 0 dB.

Test-retest reliability for hearing thresholds

In the booth environment the average test-retest AC threshold differences varied between 0.8 and 1.6 dB, with standard deviations between 2.7 and 4.9 dB across the

frequencies (Table 2). Test-retest correspondence was within ± 5 dB for 96.7% of cases.

Average test-retest AC threshold differences in the natural environment varied between -0.3 and 1.3 dB, with standard deviations between 2.4 and 3.6 dB across the frequencies (Table 2). Test-retest correspondence was within ± 5 dB in 97.5% of cases.

Table 2. Test-retest differences in AC thresholds recorded in the natural and booth environments and correspondence (Retest thresholds subtracted from initial thresholds). n = Number of ears; SD = Standard deviation; CI = Confidence interval; dB = Decibel.

| Frequency (Hz) | 250 | 500 | 1000 | 2000 | 4000 | 8000 | Average |
|----------------------------|----------|----------|----------|----------|----------|----------|----------|
| Natural environment | | | | | | | |
| <i>N</i> | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| <i>Average diff</i> | 0.3 | 0.4 | 1.0 | -0.3 | 1.3 | 0.1 | 0.4 |
| <i>SD</i> | 3.6 | 2.9 | 3.6 | 2.5 | 3.5 | 2.4 | 3.1 |
| <i>95% CI</i> | -0.9:1.4 | -0.5:1.3 | -0.2:2.2 | -1.1:0.6 | 0.1:2.4 | -0.6:0.9 | -0.5:1.5 |
| ± 5 dB % | 95 | 100 | 95 | 100 | 95 | 100 | 97.5 |
| ± 10 dB% | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| Booth environment | | | | | | | |
| <i>N</i> | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| <i>Average diff</i> | 0.9 | 1.6 | 1.5 | 1.3 | 0.8 | 0.9 | 1.2 |
| <i>SD</i> | 4.2 | 3.5 | 4.6 | 3.2 | 2.7 | 4.9 | 3.9 |
| <i>95% CI</i> | -0.5:2.2 | 0.5:2.7 | 0.04:2.9 | 0.2:2.3 | -0.1:1.6 | -0.7:2.5 | -0.1:2.4 |
| ± 5 dB % | 95 | 97.5 | 95 | 100 | 100 | 92.5 | 96.7 |
| ± 10 dB% | 100 | 100 | 97.5 | 100 | 100 | 97.5 | 99 |

The absolute average difference was slightly higher in the booth environment (2.6 \pm 2.9 dB) than the natural environment (1.8 \pm 2.6 dB) (Table 3).

A comparisons of test-retest thresholds in both booth and natural environment revealed no statistically significant differences ($p < 0.01$) except at 500 Hz in the booth environment.

Table 3. Average absolute differences (SD) between thresholds in natural, booth, and telemedicine (tele) environments SD = Standard deviation

| Frequency (Hz) | 250 | 500 | 1000 | 2000 | 4000 | 8000 | Ave |
|------------------------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| Test-retest - natural | 2.0 (2.9) | 1.6 (2.4) | 2.3 (2.9) | 1.3 (2.2) | 2.3 (2.9) | 1.3 (2.1) | 1.8 (2.6) |
| Test-retest – booth | 3.1 (2.9) | 2.6 (2.8) | 3.5 (3.2) | 2.2 (2.5) | 1.5 (2.3) | 2.9 (4.1) | 2.6 (2.9) |
| Natural vs booth | 5.3 (5.1) | 3.6 (4.7) | 2.8 (4.1) | 3.5 (3.0) | 2.1 (2.5) | 4.0 (4.7) | 3.5 (4.0) |
| Natural vs tele | 4.3 (3.4) | 5.5 (4.6) | 5.3 (5.3) | 4.0 (3.9) | 3.0 (2.9) | 6.0 (6.6) | 4.7 (4.4) |
| Booth vs tele | 6.5 (6.3) | 6.3 (4.2) | 2.8 (3.8) | 3.5 (4.0) | 2.8 (3.8) | 4.8 (4.9) | 4.5 (4.5) |

The ambient noise levels across 20 measurements for the test-retest natural office environment indicated average levels between 37.4 and 60.1 dBA (Table 4).

Table 4. Average ambient noise levels in the natural environment for test (n=20) and retest (n=20) audiometry measurements combined. LEQ = Time Averaged Noise Level

| | PEAK (dB C) | MAX (dB A) | MIN (dB A) | LEQ (dB A) |
|----------------|-------------|-------------|-------------|-------------|
| Average | 80.4 | 65.5 | 31.6 | 45.1 |
| SD | 6.6 | 5.4 | 7.2 | 4.5 |
| Range | 70.8 - 97.6 | 56.8 – 77.4 | 22.2 – 43.4 | 37.4 – 60.1 |

Accuracy of hearing thresholds in the natural environment

Average AC threshold differences between the booth and natural environment (Table 5) varied between -2.9 and 1.0 dB, with standard deviations between 3.3 and 6.9 dB across the frequencies (Table 5). Correspondence between the natural and booth environment was within ± 5 dB for 88% of thresholds.

A comparison of thresholds in the natural and booth environment revealed no statistically significant differences ($p < 0.01$) except at 500 Hz.

Table 5. Difference in AC thresholds recorded in the booth and natural environments (Booth thresholds were subtracted from the natural thresholds). n = Number of ears; SD = Standard deviation; CI = Confidence interval; dB = Decibels.

| Frequency (Hz) | 250 | 500 | 1000 | 2000 | 4000 | 8000 | Average |
|--------------------------------|-----------|-----------|-----------|-----------|----------|----------|-----------|
| Initial Test | | | | | | | |
| N | 40 | 40 | 40 | 40 | 40 | 40 | 40 |
| Average diff | -2.5 | -2.9 | -1.8 | -1.8 | 0.4 | 1.0 | -1.3 |
| SD | 6.9 | 5.2 | 4.2 | 4.3 | 3.3 | 6.1 | 5.0 |
| 95% CI | -4.7:-0.3 | -4.5:-1.2 | -3.2:-0.3 | -3.1:-0.4 | -0.7:1.4 | -1.0:3.0 | -2.9:0.36 |
| ± 5 dB % | 75 | 85 | 85 | 92.5 | 100 | 90 | 88 |
| ± 10 dB% | 90 | 95 | 97.5 | 100 | 100 | 95 | 96.25 |

Accuracy of hearing thresholds determined using telemedicine

Average threshold differences between the booth and tele-audiology environments varied between -1.5 dB and 1.0 dB, with standard deviations between 5.6 and 8.3 dB across the frequencies for the initial test (Table 6). Average correspondence between the two environments was within ± 5 dB for 82% of thresholds.

Average threshold differences between the natural and tele-audiology environments were between -6.0 and 1.3 dB, with standard deviations between 3.6 and 5.8 dB across the frequencies (Table 6). Average thresholds correspondence between the two environments was within ± 5 dB for 85% of thresholds.

The only statistically significant difference between thresholds was at 250 Hz in the natural compared to the tele-audiology environments ($p < 0.01$).

Table 6. Difference in AC thresholds recorded in the natural compared to tele-audiology environment; as well as booth compared to tele-audiology environments (tele-audiology thresholds were subtracted from thresholds in the natural and booth environments). n = Number of ears; SD = Standard deviation; CI = Confidence interval; dB = Decibels.

| Frequency (Hz) | 250 | 500 | 1000 | 2000 | 4000 | 8000 | Average |
|---------------------|-----------|-----------|----------|----------|----------|----------|-----------|
| Natural | | | | | | | |
| N | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| Average diff | -6.0 | -3.3 | -1.3 | -1.5 | -0.5 | 1.3 | -1.9 |
| SD | 5.8 | 5.7 | 5.4 | 5.4 | 4.3 | 3.6 | 5.0 |
| 95% CI | -8.7:-3.3 | -5.9:-0.6 | -3.7:1.3 | -4.0:1.0 | -2.5:1.5 | -0.4:2.9 | -4.2:-0.5 |
| ± 5 dB % | 70 | 75 | 90 | 80 | 95 | 100 | 85 |
| ± 10 dB% | 80 | 100 | 95 | 100 | 100 | 100 | 96 |
| Booth | | | | | | | |
| N | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| Average diff | -1.5 | 0.7 | 0.7 | 1.0 | -0.7 | -1.5 | -0.22 |
| SD | 5.9 | 7.2 | 5.6 | 8.3 | 6.2 | 8.2 | 6.9 |
| 95% CI | -2.7:5.7 | -4.3:2.8 | -2.9:1.4 | -3.4:1.4 | -1.4:2.9 | -1.9:4.5 | -2.8;3.1 |
| ± 5 dB % | 70 | 70 | 95 | 90 | 85 | 80 | 82 |
| ± 10 dB% | 75 | 90 | 95 | 95 | 100 | 95 | 92 |

2.6. Discussion

Remote hearing assessment through tele-audiology has the potential to provide access to previously underserved populations. An important barrier to the provision of valid tele-audiology hearing assessments is finding a suitable test environment

since audiometric sound booths are unavailable in rural and remote areas (Swanepoel et al., 2010a; Swanepoel, 2012). This study utilised a mobile audiometer that provides attenuation and monitoring of environmental noise to allow for testing outside a booth as has been demonstrated recently (Maclennan-Smith et al., 2013). Test-retest reliability and accuracy of AC threshold testing outside a sound booth was determined against the gold standard of face-to-face testing in an audiometric sound booth as reference variability against which the accuracy of synchronous telemedicine hearing assessment in the natural environment can be compared. It should be noted that the average ambient noise level recorded in the natural environment (37.4 - 60.1 dBA) was representative of a typical office environment (Hemp and Glowatz, 1995).

Results from the current study demonstrated that hearing thresholds determined in a natural environment through a synchronous telemedicine setup provides clinically equivalent thresholds compared to the gold standard of testing inside a sound booth.

Test-retest reliability of AC thresholds in the booth and natural environment showed no statistically significant difference across frequencies (except at 500 Hz in the booth), with 96.7% and 97.5% of thresholds corresponding within ± 5 dB in the booth and natural environment. Average differences and standard deviations were within expected ranges compared to results from a recent meta-analysis reporting test-retest differences across studies (Mahomed et al., 2013). The absolute AC threshold difference in the natural environment (1.8 ± 2.6 dB) was also within the range of previously reported average test-retest absolute difference values 3.2 ± 3.9 dB (Mohamed et al., 2013), 3.5 ± 3.8 dB (Swanepoel and Biagio, 2011).

When compared directly to the booth environment 88% of the threshold correspondences obtained in the natural environment was within ± 5 dB. This finding is lower than the 95% reported by Maclennan-Smith et al. (2013). However, the average absolute difference 2.7 ± 2.9 dB was similar to their findings of Maclennan-Smith et al. (2013) (2.7 ± 3.1 dB). This confirms the findings of Maclennan-Smith et al. (2013) that valid air-conduction audiometry can be conducted in a natural environment without a booth, using insert earphones covered by circumaural earcups with integrated active monitoring of ambient noise levels.

There was no statistically significant difference in AC hearing thresholds determined in the synchronous telemedicine configuration in the natural environment compared to those recorded in the booth environment. Results of the current study are in close agreement with previous studies that compare pure tone audiometry thresholds obtained remotely and face-to-face (Swanepoel et al., 2010c; Choi et al., 2007; Givens and Elangovan, 2003).

Comparing AC threshold determined in the tele-audiology configuration and the natural environment showed a significant difference ($p < 0.01$) at 250 Hz only. Whether this translates to a clinical significance is questionable as the average absolute difference at this frequency (4.3 ± 3.4 dB) was actually lower than the average absolute difference between the natural and booth environments (5.3 ± 5.1 dB).

Thresholds correspondence within ± 5 dB between the tele-audiology configuration and the booth and natural environments were 82% and 85% respectively. This is slightly lower than the correspondence between the booth and natural environment (88%) and also compared to the findings of Choi et al. (2007) (89%) and Swanepoel et al. (2010c) (96%). There are a number of differences between the current study and those of Choi et al. (2007) and Swanepoel et al. (2010c) which could explain the slight differences. Firstly, tele-audiology was conducted a natural environment in the current study, whereas in the other two it was conducted in a booth environment. By conducting the tele-audiology assessment in a natural environment an additional a layer of potential variability was added to the current study that could explain this lower correspondence. Secondly, both Choi et al. (2007) and Swanepoel et al. (2010c) used clinicians to facilitate the tele-audiology, whereas the current study utilised a facilitator with no formal clinical or audiological training. A trained clinician would have minimised the possibility of any incorrectly inserted earphone that might have contributed to a lower correspondence at (± 5 dB). The fact that there was no significant differences in the data obtained in the tele-audiology environment, where a facilitator was utilised, and the booth environment, which was solely under the clinician's control, suggests the facilitator training and structural plan was adequate. Finally sample sizes in both Choi et al. (2007) ($n=37$; 74 ears) and Swanepoel et al. (2010c) ($n=30$; 60 ears) were larger than that of the current study (20 ears) -

reducing the significance each data value has on the sample population as a whole and diluting any error values.

Some limitations to the current study include the relatively limited sample size for the tele-audiology component and the fact it was drawn from a single rural community. A follow-up study utilising several larger sample populations drawn from rural communities in different provinces and working in different environment (agricultural, industrial and mining) would allow for investigation in terms of replication of the current findings in different demographic, social and environmental situations. In addition to this the inclusion of children, the elderly and those with different degrees of hearing loss would ensure that tele-audiology approaches were suitable for assessing hearing health for the whole community. Finally, due to time constraints with the subjects the current study only measured AC thresholds and not bone conduction (BC) thresholds. As both are important in accessing hearing health any future studies should investigate AC and BC thresholds in order to evaluate the appropriateness of tele-audiology in assessing hearing health.

2.7. Conclusion

The current study demonstrates the validity of hearing thresholds determined through synchronous tele-audiology in a non-clinical environment. It also highlights the potential for using non-clinical facilitators in remote locations, which could reduce the burden on the limited number of clinical human resources. There was no significant difference in pure tone hearing thresholds determined in the conventional face-to-face clinical environment and a telemedicine setup. The study is the first of its kind to report synchronous telemedicine hearing assessments conducted in a natural environment in a rural community. Results demonstrate telemedicine hearing assessments to be comparable to the current 'gold standard'. These technologies make it possible for diagnostic hearing assessments to be included as part of remote telemedicine kit and can give new opportunities in telemedicine support. Tele-audiology has the potential to expand hearing health care provision to enable remote rural populations to access services.

2.8 Acknowledgement

Authors gratefully acknowledge all the participants and the facilitator for their participation in the research project.

2.9. Disclosure Statement

No competing financial interests exist.

3. DISCUSSION AND CONCLUSION

3.1. Discussion of results

Telehealth offers unique opportunities for providing access to hearing health care services to underserved populations worldwide (Swanepoel et al., 2010a). The term refers to the utilisation of information and communication technology in health care provision and the field to which it is applied is often prefixed with “Tele”, such as tele-audiology. The possible benefits of this technology are far reaching and range from facilitating medical education and research to improving access to health care and addressing the current imbalance in the distribution of healthcare professionals globally (Wootton et al., 2009). In terms of hearing health care provision, telehealth approaches could enabled clinicians to penetrate previously underserved rural and remote location, providing hearing health care to those identified by the WHO as the most in need (WHO, 2013a). Telehealth care has been gaining momentum over recent years across many fields (Lancaster et al., 2008; Swanepoel et al., 2010a; Clark and Swanepoel, 2014), and will continue to do so as communication networks and global internet access improve.

While telehealth offers unique opportunities for proving access to hearing health care services to underserved populations worldwide (Swanepoel et al., 2010a; Swanepoel et al., 2010b; Swanepoel et al., 2010c), tele-audiology has been surprisingly slow to be incorporated into existing services. This is in part due to the limited number of studies investigating the applications and validity of tele-audiology (Swanepoel and Hall, 2010). However, another important barrier to the provision of valid tele-audiology hearing assessments is finding a suitable test environment, since audiometric sound booths are unavailable in rural and remote areas (Swanepoel et al., 2010a; Swanepoel, 2012). The latest mobile diagnostic audiometers that provide monitoring and attenuation of environment noise do allow for testing outside a sound booth, as has been recently demonstrated (Maclennan-Smith et al., 2013; Swanepoel et al., 2013). Using this technology in combination with a tele-audiology approach has the potential to revolutionise hearing health care provision in developing countries (Swanepoel et al., 2010a; Storey et al., 2014), as it addresses two of the key limiting factors. Firstly, the telehealth approach addresses the

availability of audiologists (WHO, 2013a) and secondly, the new diagnostic audiometers minimise the need for the diagnostic assessment to be conducted in a sound booth (MacLennan-Smith et al., 2013; Swanepoel et al., 2013). In light of the WHO estimate that hearing loss is the most prevalent disabling condition, affecting 360 million people globally (WHO, 2013a), the potential that tele-audiology has as a means of bringing hearing health services to currently underserved communities needs to be investigated. Currently, the few tele-audiology studies that have been undertaken are proof of concept studies (Swanepoel et al., 2010c; Choi et al., 2007) in clinical environments that are not necessarily representative of the remote rural communities that this technology has the potential of benefiting.

This study is the first to evaluate the reliability and accuracy of synchronous tele-audiology using mobile diagnostic audiometers outside of a conventional clinical environment, in a natural environment that replicates the remote communities in which it is hoped that this technology can be utilized. The results from the current study demonstrated that hearing thresholds determined in a natural environment through a synchronous tele-audiology setup provides clinically equivalent thresholds compared to the gold standard of testing inside a sound booth.

Test-retest reliability of AC thresholds in the booth and natural environment showed no statistically significant difference across frequencies (except at 500 Hz in the booth), with 96.7% and 97.5% of thresholds corresponding within ± 5 dB in the booth and natural environment. Average differences and standard deviations were within expected ranges compared to results from a recent meta-analysis reporting test-retest difference across studies (Mahomed et al., 2013). The absolute AC threshold difference (1.8 ± 2.6 dB) was within previously reported average test-retest absolute difference values of 3.5 ± 3.8 dB (Swanepoel and Biagio, 2011), and 3.2 ± 3.9 dB (Mahomed et al., 2013) for the same audiometer. This study therefore supports the findings of the above authors that reliable AC audiometry can be conducted in a non-clinical environment without sound booth when using insert earphones covered by circumaural earcups with integrated active monitoring of ambient noise levels.

When compared directly to the booth environment 88% of the threshold correspondences obtained in the natural environment was within ± 5 dB. This finding is lower than the 95% reported by MacLennan-Smith et al. (2013). The average

absolute difference of 2.7 ± 2.9 dB, however, was similar to the findings of MacLennan-Smith et al. (2013) (2.7 ± 3.1 dB). This confirms the findings of MacLennan-Smith et al. (2013), that valid air-conduction audiometry can be conducted in a natural environment without a booth, using insert earphones covered by circumaural earcups with integrated active monitoring of ambient noise levels.

There was no statistically significant difference in AC hearing thresholds determined in the synchronous telehealth configuration in the natural environment compared to those recorded in the booth environment. Results of the current study are in close agreement with previous studies that compare pure tone audiometry thresholds obtained remotely and face-to-face (Swanepoel et al., 2010c; Choi et al., 2007; Givens and Elangovan, 2003).

Comparing AC threshold determined in the tele-audiology configuration and the natural environment showed a significant difference ($p < 0.01$) at 250 Hz only. Whether this translates to clinical significance is questionable, as the average absolute difference at this frequency (4.3 ± 3.4 dB) was actually lower than the average absolute difference between the natural and booth environments (5.3 ± 5.1 dB). In a clinical setting, decreases in hearing of 5dB would not be adjusted for or considered a hearing loss, so while the differences at 250Hz were considered statistically significant they would not be considered clinically significant and therefore would not impact on the feasibility of using tele-audiology in a rural setting.

Thresholds correspondence within ± 5 dB between the tele-audiology configuration and the booth and natural environments were 82% and 85% respectively. This is slightly lower than the correspondence between the booth and natural environment (88%) and also compared to the findings of Choi et al. (2007) (89%) and Swanepoel et al. (2010c) (96%). There are a number of differences between the current study and those of Choi et al. (2007) and Swanepoel et al. (2010c) which could explain the slight differences. Firstly, tele-audiology was conducted in a natural environment in the current study, whereas in the other two it was conducted in a booth environment. By conducting the tele-audiology assessment in a natural environment an additional layer of potential variability was added to the current study that could explain this lower correspondence. Secondly, both Choi et al. (2007) and Swanepoel et al. (2010c) used clinicians to facilitate the tele-audiology, whereas the current study

utilised a facilitator with no formal clinical or audiological training. A trained clinician would have reduced the risk of any incorrectly inserted earphone that may have contributed to a lower correspondence at ± 5 dB. Finally, sample sizes utilised by both Choi et al. (2007) (n=37; 74 ears) and Swanepoel et al. (2010c) (n=30; 60 ears) were larger than that of the current study (n=10; 20 ears). The larger populations in their studies reduced the significance of the impact of each data value on the whole and diluted any error values.

Even with the difference in correspondence, the fact that there were no significant differences across the frequencies when comparing tele-audiology thresholds with the gold standard in the booth validates the use of mobile diagnostic audiometers in tele-audiology configurations. Building on the findings of Choi et al. (2007) and Swanepoel et al. (2010c), the findings of the current study represent a strong argument that tele-audiology is a viable option for improving hearing health care provision in remote rural communities and in non-clinical environments.

3.2. Clinical implications and recommendations

Tele-audiology applications have the potential to address the current deficient in hearing health care service provision in developing countries (Swanepoel et al., 2010a; MacLennan-Smith et al., 2013).

The current study is the first of its kind to report synchronous telemedicine hearing assessments conducted in a natural environment in a rural community and it demonstrates the validity of hearing thresholds determined through synchronous tele-audiology in a non-clinical environment.

The capacity to produce thresholds in a natural environment comparable to those obtained in a booth environment, minimises the need for a sound booth. This has been one of the key barriers towards addressing the global need for increased hearing health care provision (MacLennan-Smith et al., 2013; Swanepoel et al., 2013). The stationary and expensive nature of sound booths traditionally confines diagnostic assessments to tertiary hospital based institutions or specialised centres found primarily in larger towns or cities. This has made hearing health care inaccessible to those living in remote rural communities (Fagan and Jacobs, 2009).

The findings of this study supports those of Swanepoel et al. (2013) and MacLennan-Smith et al. (2013) who reported that the AC thresholds obtained using the same mobile diagnostic audiometer in natural environment without a sound booth were comparable to those obtained in a sound booth.

Additionally, this study found using the KUDUwave mobile diagnostic audiometer in a tele-audiology configuration to be equivalent to the standard face-to-face AC threshold testing. While two previous studies (Choi et al., 2007; Swanepoel et al., 2010c) drew similar conclusions, these were both undertaken in clinical or laboratory settings. By conducting the assessment in a non-clinical environment that is representative of the remote rural locations which it is hoped this technology will one day service, this study has advanced our understanding about the capabilities of this technology. The findings demonstrate that synchronous tele-audiological testing can be used in combination with the KUDUwave to accurately test AC hearing thresholds of adults in remote rural areas. This validates a tele-audiological approach for providing hearing health care to previously underserved communities. This approach would also address the shortage of audiologists in developing countries by allowing hearing assessments to be conducted remotely, enabling audiologists anywhere in the world to conduct the assessment.

3.3. Critical evaluation

The current study is the first of its kind to report synchronous telemedicine hearing assessments conducted in a non-clinical, natural environment that replicated the remote communities in which it is hoped that this technology can be utilised. In so doing it has advanced our understanding of the technology's capability to provide hearing health care to currently underserved rural communities.

There were, however, some limitations to this study.

The initial sample population (80 individuals) was small. With just under a third of this population (25 individuals =50 ears) volunteering to take part in the study and 5 of these being ruled out with middle ear or hearing issues, the final sample size of 20 individuals (=40 ears) for the threshold assessments in the natural environment and booth environment was lower than had been hoped, especially as only half of them

(10 individuals = 20 ears) volunteered to be part of the tele-audiology assessment. The small sample size meant that any error factors would have a large impact. A follow up study, using the same methodological approach but with a larger initial population, is recommended. Ideally the sample population would be no smaller than 30 individuals (60 ears) for the best statistical strength. The small sample size was, however, unavoidable for this study and as such should be kept in consideration when discussing or applying the findings of this study.

The study was confined to one rural location. Ideally, it would have been replicated in several rural locations across South Africa, as this would have improved demographical representation as well as increased the population of the study. However, time and financial constraints did not allow for this.

In any follow on studies bone conduction (BC) as well as AC thresholds should be measured. Constraints on the amount of time subjects could have away from work meant only AC thresholds were tested in this study. To have been able to include BC thresholds would have given a more accurate evaluation of the individuals' hearing level. It would also have reduced the impact which issues like the possible occlusion effect of insert earphone placement had on the results, which in turn would assist in the interpretation of the findings. Furthermore, BC is an important aspect of the standard hearing assessment. To properly evaluate the validity of tele-audiology applications and remote diagnostic audiometers BC should be included.

As the tele-audiology component of this study was done after the initial assessments in natural and clinical environments, participant familiarity could potentially mask the effect of using an inexperienced test facilitator. In any follow up studies, running the tele-audiology component of the study simultaneously with the conventional face-to-face methodology and utilizing a counter-balanced methodology would negate any issues regarding participant familiarity.

3.4. Suggestions for future research

As this study was the first of its kind to test the tele-audiological approach in a non-clinical environment, further studies are needed to ratify the findings.

Similar studies should be conducted in different rural areas of South Africa in order to see if these results can be replicated under different demographical conditions and with different populations, for example children, elderly people, and people working in different occupational health settings (mining and industrial). This will enable a determination of the range of environments that can reliably accommodate this type of testing.

In designing these studies a bigger sample population should be sought as it would enable researchers to assess the accuracy of the technology more confidently, especially at the lower frequencies where the occlusion effect appears to be playing a role.

Another interesting research opportunity would be to select individuals with moderate to severe hearing loss (>25 dB). This would enable researchers to investigate whether the mobile diagnostic audiometers and tele-health approaches are comparable to the 'Gold Standard' in a sound booth for individuals with known hearing loss.

Testing BC thresholds along with AC threshold would also be a suggested direction for future research. BC thresholds give a better clinical picture of the ear pathology and are particularly important for identifying the type of hearing loss. Validation of the BC thresholds recorded remotely will need to be done if tele-audiology is to be adopted for assessing hearing health in rural communities in a non-clinical situation.

Finally, automated testing for asynchronous purposes is another possibility for future research. Asynchronous use would enable a facilitator to conduct a series of hearing assessments in a rural location, and the information could be stored and subsequently forwarded to an audiologist working remotely who would not need to do the assessment in real time. This approach has many potential merits. It would eliminate any potential connectivity issues that can effect real-time examinations and could help address the problem of having too few audiologists, as non-clinical facilitators could be trained to conduct the assessments. It would, however, need to be tested in a non-clinical environment and the approach validated.

3.5. Conclusion

The possibility of remotely testing hearing accurately over long distances and potentially across the globe is an exciting one. It could revolutionise hearing health care, providing services to those who currently have no access, and address the global hearing health care crisis. Advances in hearing care technology with the development of mobile diagnostic audiometers like the KUDUwave along with improved internet access and coverage make this more of a possibility than ever before. Currently there are too few studies investigating tele-audiology's potential, feasibility, or validity when compared to the current 'Gold Standard'. These studies need to be conducted in order for the potential of tele-audiology to be realised and for it to be adopted into hearing health care provision.

This study has gone some way toward addressing this research deficiency. It is the first to report synchronous tele-audiology hearing assessments conducted in a natural environment in a rural community. However, more remote testing studies in natural environments rather than clinical or laboratory settings will be required before tele-audiology is accepted as an alternative to the current gold standard diagnostic testing in a sound booth.

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APPENDICES:

APPENDIX A: Letter of Informed Consent.

100
1908 - 2008UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Department of Communication Pathology

Date:

Dear Participant

As part of my M. Communication Pathology studies at the University of Pretoria I am conducting a research project. ***This research aims to determine the accuracy of new technology existing out of new test equipment to test your hearing ability (portable computerised diagnostic audiometry).*** If you agree to participate in this study you will undergo two hearing test in two different locations. One will be on site at your workplace with this new portable computerised audiometer. The other will be in a clinical setting through conventional diagnostic hearing testing in Nelspruit. Each test will approximately take 10 minutes. A third small subgroup will be tested remotely (over a distance) through a wireless computerised connection.

By participating in this study you can provide important information to help ensure the best possible service delivery to South African citizens in need of audiological services in all geographical areas. The research will be done with approval of your employer LA Visagie & Seun. If you are interested to participate please note the following:

- You will participate voluntary and you may withdraw from participation at any time and without negative consequences.
- Only your gender, age, language, nationality and education level will be used for statistical information.
- All the participants will be given a number and no names will be used in the research. This is to ensure confidentiality.
- Results will be made available after testing, if you wish to know the outcome.
- If necessary or required, referrals will be made to the local provincial Hospital for further medical management.
- All equipment used will be sterilised after each participant to comply with health care requirements.
- There will be no costs involved.
- Transport to and from Nelspruit will be arranged outside working hours.
- A free lunch will be sponsored for your time and effort.
- The researcher will be present while signing the informed consent for support and to answer any questions if you require more information.

All data will be considered confidential and it will be stored at the University of Pretoria for 15 years for archiving purposes.

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Your honest and reliable responses during performing this study will be appreciated.

I sincerely thank you for your time and effort.

Yours sincerely,



Ansophi Visagie
Postgraduate student

Prof De Wet Swanepoel
Research Supervisor

Dr Maggi Soer
Acting Head: Communication Pathology

PORTABLE COMPUTERISED DIAGNOSTIC AUDIOMETRY: A STUDY IN COMPLIANCE & TELEHEALTH

Researcher: Ms Ansophi Visagie

Supervisor: Prof De Wet Swanepoel

Please complete the following in order to grant permission for your participation in this research project.

I, _____ hereby give my informed consent that I am willing to voluntarily participate in the above mentioned research project. I understand that I can withdraw at anytime without any negative consequences to myself.

Date: _____

Signed: _____

APPENDIX B: Letter to the employer (Informed consent).



Department of Communication Pathology

15 January 2010

Dear LA Visagie & Seun

**PERMISSION FOR RESEARCH PROJECT: PORTABLE COMPUTERISED DIAGNOSTIC
AUDIOMETRY: A STUDY IN COMPLIANCE & TELEHEALTH**

For the majority of our South Africans staying in remote rural areas the availability and possibility of specialised health care services like diagnostic hearing assessments are very restricted and sometimes not even reachable. As you know due to various circumstances and factors it is almost impossible for people staying in remote rural areas to access these health services. Regarding this situation it is clear that a need arises to develop and bring these health services to the people through new technology. New developments in telehealth and audiology now make it possible to assess hearing in a natural setting such as the work place. This information will be used to validate the possibility of bringing health care services to remote rural areas using new technology.

As part of my M. Communication Pathology studies at the University of Pretoria I am conducting a research project to validate such technologies. ***This research will aim to determine the reliability and accuracy of computerised portable audiometry without a sound proof booth using a synchronous telehealth configuration.*** This implies assessing peoples hearing ability outside the conventional clinical setup as well as over a distance.

I would like to ask your permission to assess the hearing of approximately thirty (30) of the farm workers employed by LA Visagie & Seun. They will undergo two hearing assessments in two different locations. One will be on site at your workplace with this new portable audiometer. The other will be in a clinical setting through conventional diagnostic hearing assessment in Nelspruit. A third small subgroup of 10 subjects will be tested through a telehealth system over a distance. Assessment times will be scheduled in their lunch hour and after hours and as inducement they will be sponsored a free lunch. The test battery will consist of the following:

- Otoscopic examination of the external ear canal
- A tympanogram measuring the middle ear functioning
- Pure tone air conduction assessing their hearing ability
- An information sheet requiring; Gender, age, nationality, language and education level.

An informed consent letter will be conveyed to each participant explaining the content and research project procedures. Participation will be strictly voluntary by signing the informed

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Pretoria, 0002
South Africa

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Facsimile : 00 27 12 420-3517

dmv@swansport@up.ac.za
www.up.ac.za

consent and there will be no costs involved. Results will be available for participants if they wish to know the outcome. If necessary or required, referrals will be made for further medical management. All information will be confidential and your farm and industry will not be reported in any of the findings.

By participating in this study you can provide important information to help ensure the best possible service delivery to South African citizens in need of audiological services in all geographical areas.

We look forward to hear from you.

Yours sincerely,

Ansophi Visagie
Postgraduate student

Prof De Wet Swanepoel
Research Supervisor

Dr Maggi Soer
Acting Head: Communication Pathology

APPENDIX C: Consent letter from the employer.



27 January 2010

Mrs A Visagie
13 Bataleur Street
Shandon Estate
Nelspruit

Dear Mrs visagie

LA Visagie & Seun (Edms) Bpk hereby grants you permission to conduct your research on the Farm Neroli (owned by LA Visagie). We acknowledge the fact that 30 of our employees will willingly and confidentially take part in your research project. We also are aware of the fact that it will take place in lunch time and after hours whereby an incentive (sponsored lunch) will be given to each employee.

Good luck with your studies.

Regards

A handwritten signature in black ink, appearing to be 'A. Visagie', is written over a faint, larger version of the company logo.

MANAGING DIRECTOR
LA VISAGIE & SEUN (EDMS) BPK

☎ 013 747 2700 📠 013 747 2800 📍 57 Karino 1204 📧 info@visagiegroupp.com 🌐 www.visagiegroupp.com

Direkteure E.M.Visagie N.Visagie L.A.Visagie A.Visagie J.G.Smit
Visagie Beherende Trust Nakalela Beleggings (Edms) Bpk Andeon Visagie (Edms) Bpk

EUREPGAP Certified

APPENDIX D: Data collection form.

University of Pretoria
Faculty of Humanities
Department of Communication Pathology
Masters research project 2010.

Reliability and accuracy of portable computerised audiometry.
DATA COLLECTION SHEET

Subject number:

| | |
|--|--|
| | |
|--|--|

Date of testing:

| | | | | | | | |
|---|---|---|---|--|--|--|--|
| 2 | 0 | 1 | 0 | | | | |
|---|---|---|---|--|--|--|--|

Gender:

| | |
|---|---|
| M | F |
|---|---|

Age:

| | |
|--|--|
| | |
|--|--|

Language:

Literacy skills:

| | |
|------|-------|
| Read | Write |
|------|-------|

Otосcopy:

| Right ear | Left ear |
|-----------|----------|
| | |

Tympanogram:

| Right ear | Left ear |
|-----------|----------|
| | |

APPENDIX E: Letters of acceptance for research proposal and ethical clearance.



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Office of the Deputy Dean

30 March 2010

Dear Prof Swanepoel

Project: Reliability and accuracy of portable computerised diagnostic audiometry
Researcher: A Visagie
Supervisor: Prof DCD Swanepoel
Department: Communication Pathology
Reference number: 9809763

I am pleased to be able to tell you that the above application was **approved** by the **Postgraduate Committee** on 16 March 2010 and the **Research Ethics Committee** on 16 March 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

**FACULTY OF HUMANITIES
POSTGRADUATE COMMITTEE**

COMMENTS/ SUGGESTIONS FROM THE POSTGRADUATE COMMITTEE

VISAGIE A(9809763)

The study is very technical but in my appraisal well thought through
The potential development stemming from this study is well argued –
especially taking into account the dire need for service delivery in primary
health care

This is an innovative study

I have weighed up the apparent accessibility provided by the specific farm and
the potential link to being associate with the researcher I have also
considered that the stance portrayed is professional and has taken that into
account

Furthermore the candidate is doing a technically very challenging study and
understandably would want to secure the research context as
comprehensively as possible

I therefore think that the structured approach and practical considerations has
taken into account all the potential dilemmas