Wideband Acoustic Immittance for Assessing Middle Ear Functioning

for at-risk neonates in the NICU

By

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LIST OF ABBREVIATIONS

AABR   **Automated Auditory Brainstem Response**

ANSD   **Auditory Neuropathy Spectrum Disorder**

ASHA   **American Speech-Language-Hearing Association**

DPOAE   **Distortion Product Otoacoustic Emission**

EHDI   **Early Hearing Detection and Intervention**

HFT   **High Frequency Tympanometry**

HPCSA   **Health Professions Counsel of South Africa**

JCIH   **Joint Committee on Infant Hearing**

NICU   **Neonatal Intensive Care Unit**

OAE   **Otoacoustic Emission**

OME   **Otitis Media with Effusion**

PCHL   **Permanent Congenital Hearing Loss**

RAI   **Reflective Area Index**

TEOAE   **Transient Evoked Otoacoustic Emission**

WAI   **Wideband Acoustic Immittance**

ABSTRACT

Hearing loss in early childhood and infancy often goes undetected because it exhibits no obvious indication and symptoms. The primary aim of newborn hearing screening is to detect permanent hearing loss. Since otoacoustic emissions (OAE) and automated auditory brainstem response (AABR) are sensitive to hearing loss, they are often used as screening tools. On the other hand, these screening tests can be affected by transient outer ear and middle ear conditions that are often present at birth. This is an especially characteristic state of affairs for NICU neonates. These false positive results may render screening programmes inefficient and can lead to increased parental anxiety. Wideband acoustic immittance (WAI) has shown potential for accurate assessment of middle ear function in neonates, and is therefore recommended as an adjunct tool for newborn hearing screening programmes. The main aim of the study was to determine the feasibility of using WAI in NICU neonates in terms of tone and click stimuli.

Testing was conducted in the NICU units of three private hospitals in Pretoria. As part of the selection criteria all the neonates had to pass both DPOAE and AABR screenings before they were included in the study. In total, 56 NICU infants (106 ears) with a gestation age of between 32 and 37 weeks and a mean gestational age of 35.6 weeks who passed both DPOAE and AABR hearing screens in one or both ears were selected. For WAI measurements there were two measurements, one for each channel in the probe (chirp and tone stimuli). Normative regions were defined across the wideband reflective spectrum for both tone and chirp stimuli and for integrated frequency ranges. The chirps and tone stimuli compared relatively well with each other at the

90th percentile with the same amount of reflectance across all frequencies. The median reflectance reached a minimum of 0.67 at 1-2 kHz but increased to 0.7 below 1 kHz and 0.72 above 2 kHz for the tone stimuli. For chirp stimuli the median reflectance reached a minimum of 0.51 at 1-2 kHz but increased to 0.68 below 1 kHz and decreased to 0.5 above 2 kHz.

Results of this study identified WAI patterns that had not previously been reported in the literature. High reflective values were obtained across all frequency ranges, especially in the frequency ranges below 3 kHz and above 4 kHz. The age of the neonates when tested (mean gestational age 35.6 weeks, with a standard deviation of 1.6) might have influenced the results. The neonates in this study were of a very young age compared to the ages of the infants in previous studies on WAI. Environmental noise in NICU might have influenced the results. Additional research is required to investigate WAI testing in ears with and without dysfunction.

1 INTRODUCTION

1.1 Background

Congenital hearing loss has been described as the most common sensory birth defect and it is estimated that it affects one to six in every 1,000 newborns. (Wrightson, 2007). Early hearing detection and intervention (EHDI) can provide access to essential sensory experience in the critical developmental periods for language acquisition during the first year of life, offering hearing impaired children developmental outcomes comparable to those of their normal hearing peers (Joint Committee on Infant Hearing [JCIH], 2007). Considering the negative consequences and increased societal costs of undetected infant hearing loss, the importance of universal infant hearing screening cannot be over-emphasized (Swanepoel, 2009). If congenital hearing loss is not recognized and managed, a child's speech, language, and cognitive development are often severely delayed. Early-identified children (hearing loss identified prior to six months of age) have better outcomes in all areas of their development (Yoshinaga-Itano, 1999). Universal newborn hearing screening is a way to identify hearing impaired newborns with or without risk factors and has become routine and even mandated in many countries around the world (Hunter, 2010). A known risk factor for congenital hearing loss is premature birth necessitating a stay in the neonatal intensive care unit (Wrightson, 2007). Admission to the neonatal intensive care unit (NICU) for a period of more than two days increases the likelihood of the presence of hearing impairment 10 fold (Wrightson, 2007).

1.2 Technologies used in Newborn Hearing Screening

Two screening methods are currently used to identify possible hearing impairment in well babies as well as at-risk infants. These screening methods are Automated Auditory Brainstem Response (AABR) and Otoacoustic Emissions (OAE). OAEs provide a measure of outer hair cell functioning in the cochlea and are recommended for screening in well-baby nurseries and community-based immunization programmes (HPCSA, 2007). It utilizes basic probe placement and 'pass/refer' criteria and can therefore be used by non-specialist screeners (Swanepoel, 2009; Swanepoel, Hugo & Louw, 2006). The OAE test evaluates the function of the peripheral auditory system, primarily the cochlea (Wrightson, 2007). AABR tests the auditory pathway from the external ear to the lower brainstem by presenting a series of soft clicks through earphones. Electrodes on the infant's forehead measure brain wave activity in response to the clicks (Wrightson, 2007). The AABR is a measure of neural synchrony in the eighth cranial nerve and is the technology of choice in neonatal intensive care units (Shahnaz, 2008). This is due to the high prevalence of auditory neuropathy, which is only detectable with a neural-based screening test such as the AABR (HPCSA, 2007). Both AABR and distortion product otoacoustic emissions (DPOAE) screening may produce false-positive test results and can be influenced by motion artefacts and transient outer and middle ear conditions such as Otitis Media with effusion (OME; Hunter, 2008). Although AABR is the method of choice in NICUs it is considered less sensitive than DPOAE to OME (Hunter, 2010).

For the purpose of distinguishing middle ear problems from sensorineural hearing loss, a brief and accurate, non-invasive middle ear functioning diagnostic tool may be useful in combination with screening technologies like DPOAE and AABR. Conventional tympanometry is effective in evaluating middle ear functioning accurately and in detecting other middle ear conditions such as Otitis Media with effusion (OME) in children older than seven months, but its efficacy in infants six months and younger is debatable due to the immaturity of infant outer and middle ears (Holte, 1991; Hunter & Morgolis, 1992). Tympanometry using a higher probe-tone frequency (1 kHz) is recommended for diagnostic testing in infants younger than four months because it is more sensitive to middle ear dysfunction than conventional tympanometry (Hunter, 2010). The sensitivity and specificity of 1 kHz tympanometry has been compared with that of wideband acoustic immittance tests in newborns and shown to produce poorer results (Sanford, 2009). Thus, the need remains for effective validated tools for middle ear assessment in newborn hearing screening.

Wideband acoustic immitance (WAI) is the most frequently used way to display wideband acoustic impedance measurements (Hunter, 2010). In the 1920's, ear canal wideband acoustic impedance was made popular in research with the development of the Zwislocki acoustic bridge (Hunter, 2010). WAI is a method of middle ear analysis that may provide improved diagnostic capability over single frequency tympanometry (Hunter, 2008). WAI provides important information about middle ear function and can explain variations in how the middle ear receives, absorbs, and transmits sound

energy across a wide range of frequencies (Shahnaz, 2008). WAI has been measured more extensively in well babies than in neonatal intensive care unit neonates, who have a significantly higher incidence of OME (Shahnaz, 2008). WAI is a technique that uses a broad range of frequencies from 62 Hz to 13000 Hz. It includes power reflectance as well as admittance and impedance quantities and has the potential to increase the accuracy of diagnosing middle ear pathologies in infants failing newborn hearing screening (Keefe, 2003). Middle ear assessment is recommended for newborns referred from well-baby nurseries and NICUs as part of the diagnostic assessment (Joint Committee on Infant Hearing, 2007). Other methods of middle ear assessment such as pneumatic otoscopy are useful but require specialized expertise to perform and interpret in newborns (Margolis, 2003; Baldwin, 2006; Calandruccio, 2006; Alaerts, 2007). In summary WAI may be useful for detecting those neonates who are more likely to obtain a "refer" result on a DPOAE-based hearing screen due to middle ear dysfunction. A possible advantage of WAI is the fact that ear canal pressurization is not needed, allowing for easier probe fits. The testing can be combined with OAE testing in a single probe and unit.

1.3   Rationale

A critical period exists for the development of optimal language skills and for optimal intervention outcomes. Middle ear conditions such as poor pneumatization of the middle ear, residual amniotic fluid, and OME constitute a major reason for unsuccessful neonatal hearing screening, especially in NICU populations that are already at an increased risk of permanent hearing loss (Boudewyns, 2011). Any false positive results may render screening programmes inefficient due to high referral numbers which might lead to

increasing expenses and increased parental anxiety. Distinguishing middle ear conditions from sensorineural hearing loss is a key factor to improve screening programme efficacy and for appropriate referrals (Boudewyns, Declau, Van den Ende, 2011). Alternative tools such as WAI have shown potential for identifying conductive contributors to screen failures and for promoting timely diagnosis and subsequent intervention. Although initial reports on WAI have been promising, it is still not widely used in clinical contexts (Hunter, 2008). WAI in full term neonates has been measured in studies by Hunter (2010) and Aithal, Kei, Driscoll, Khan and Swanston (2015). Since hearing screening is typically performed prior to discharge from the NICU, premature neonates are likely to be screened when they are still preterm. One concern is the shortage of normative data for WAI in comparison to existing techniques used with young infants, especially at-risk populations like the NICU neonates (Hunter, 2010). The NICU population has a high prevalence of hearing loss and also has high referral rates due to a higher incidence of middle ear conditions such as OME.

1.4   Contribution

According to the HPCSA position statement on infant hearing screening (2007), evidence-based research is needed to guide the development of infant hearing screening programmes in different contexts in South Africa. A most significant aspect would be to determine whether screen referrals on DPOAE and AABR in at-risk preterm neonates are due to transient middle ear problems as opposed to sensorineural hearing loss. WAI is a tool that may offer an accurate and non-invasive middle ear diagnostic outcome that could be used in adjunct with DPOAE and AABR screening to differentiate screen

referrals at an earlier stage. This would make referrals for medical and audiological follow-ups possible and ensure earlier diagnosis, allowing early intervention services to be most effective especially in preterm neonates in NICUs who already have an increased risk for hearing loss.

The aim of the study is therefore to determine the feasibility of wideband acoustic immittance for assessing middle ear functioning in at-risk neonates in the NICU.

2 METHODOLOGY

2.1 Research objectives

The study made use of infant hearing screening technologies which comprised DPOAE, AABR, and middle ear evaluation technology WAI, particularly wideband reflectance (WBR). These technologies were used in testing preterm neonates in NICUs, in order to assess middle ear functioning of at-risk neonates in the NICU. Upon completion of the data collection and analyses an article was drafted and submitted to an accredited peer-reviewed journal. Table 1 provides the proposed title, a summary of objectives, and the name of the journal for this submission.

Table 1: Proposed title, objective and journal for submission

Proposed title	Wideband Acoustic Immittance for Assessing Middle Ear Functioning for preterm neonates in the NICU.
Objective	The main objective of this study was to determine the feasibility of wideband acoustic immittance for assessing middle ear functioning in at-risk neonates in the NICU. A further objective was to indicate the difference between the reflectance values of tones and click stimuli.
Journal for submission	South African Journal of Communication Disorders

2.2 Research context

The research was conducted on preterm neonates with a mean age at testing of 35.6 weeks (range: 32-37 weeks, standard deviation 1.6), who passed both DPOAE and AABR. The neonates were from NICUs at three private hospitals in Pretoria, Gauteng. WAI was measured using chirp and tone stimuli. In addition to reflectance, the reflectance area index (RAI) values were calculated. Neonates who presented with abnormal DPOAE and AABR results were excluded from the study. The research coincided with a regular screening service offered at these hospitals by a private audiology practice based at two of the three hospitals. Permission was granted by the private practice for this research project to coincide with the regular screening practice (Appendix D). Possible participants who were discharged prior to screening were tested as a follow-up appointment on an outpatient basis at the private audiology practice that served the hospitals.

2.3 Research design and methods

Table 2 presents an overview of the study design, participant selection criteria, sampling method, expected sample size, equipment and apparatus, data collection material, and procedures.

Table 2: Research design and methods

Study design	A cross sectional exploratory design yielding quantitative data was used for the study. Preterm neonates were screened by means of DPOAE, AABR, and Wideband acoustic immittance (WAI) with subsequent diagnostic testing for infants who registered a "refer" score on their hearing screening.
Participant selection criteria	• A private audiology practice offered a regular hearing screening service to all preterm neonates in the NICU. This service included DPOAE and AABR testing. The parents/caregivers were asked if their neonate's hearing screening results could be used for the study and whether the researcher would be allowed

	to conduct an additional test on their neonate. Once the parent/caregiver had given the informed consent, the additional test (the WAI test) was performed. • Participants had to be admitted as preterm neonates in the NICU. Participants had to be classified as medically stable by NICU personnel. A gestation age of between 32 and 37 weeks was required. • Both male and female participants were included. • Parents or the caregiver of participants were required to have signed the Informed Consent Form (Appendix B). • Parents or the caregiver had to be able to read or understand English or Afrikaans. • Only neonates who presented with normal DPOAE and AABR results were considered for the study.
Participant sampling	Non-probability sampling was used (Hussey, 2010).
Expected sample size	The proposed sample comprised 70 NICU neonates assessed at three different institutions. It was calculated that it would be possible to screen 70 NICU neonates in the time frame that was allocated for data collection. The sample size was not based on the number of neonates expected in the NICUs during the time of the study.
Equipment and apparatus	• The Natus Algo 3i AABR Newborn Hearing Screening System screens both ears simultaneously. It is fully automated with objective "pass/refer" results that require no interpretation. It is completely standardized with pre-set screening parameters. • Automated Biologic (AuDx) OAE equipment. The stimulus parameters for the Biologic (AuDX) automatically determine the stimulus level, stopping rules, and "pass/refer" result based on pre-set criteria. • Mimosa Acoustics - Wideband acoustic immittance equipment. Each system was used with the disposables specifically designed for use with that system, in order to ensure validity and accuracy.
Data collection material	The parents or caregivers of possible participants were given a letter of informed consent (Appendix A) and an informed consent form to complete (Appendix B). Results from all tests performed were documented on a data collection sheet/test form (Appendix C) as well as printed and documented in a computer programme. The informed consent form (Appendix B) and a data sheet/test form (Appendix C) were completed for every participant screened in the NICU – it contained the informed consent, short hearing loss high-risk register, and the screening details and results.
Data collection procedures	▪ All preterm neonates admitted to the NICU had access to the regular hearing screening services provided by the private audiology practice. The parents/caregivers of all possible participants were granted the opportunity to take part in the study. The parents/caregivers were informed that if they gave consent for their neonate to take part in the study, an additional test (WAI) would be conducted if the results on the DPOAE and AABR tests were normal. . ▪ The researcher explained the details pertaining to the informed consent to the neonate's parent/caregiver. The information was made available in English and Afrikaans (Appendix A). ▪ The researcher asked the parent/caregiver if they would like their neonate to be screened as part of an official research programme and to participate in the study. The parent/caregiver was asked to sign the informed consent form to demonstrate her/his willingness to participate (Appendix B). ▪ The researcher took down a short medical case history and completed a high-risk register for hearing loss which was part of

	the data collection sheet/test form (Appendix C).
	▪ A bilateral screening with DPOAE and AABR was performed as part of the regular screening service. The DPOAE entailed a small probe placed in the neonate's ear and took less than a minute to complete. With the AABR test three electrodes were placed on the neonate's forehead in order to measure brain wave activity. This test took between five and 20 minutes to complete. Both of these methods did not harm or hurt the neonate and were not invasive procedures. After the regular screening service an additional test was added if the parent/caregiver gave written consent and the results on the DPOAE and AABR tests were normal (Appendix B). With the WAI test a small probe was once again placed in the neonate's ear. This test measured the status of the middle ear and took less than one minute per test to complete. The test was non-invasive and did not have any negative effect on the infant. The results of all mentioned screening methods were noted on the data collection sheet (Appendix C).
	▪ Neonates who obtained a bilateral "refer" result were given an appointment for a second screening. The second screening was always done with the same screening technology as the first screening. If a second bilateral "refer" result was obtained, the infant was referred directly for diagnostic audiology and ENT services.
	▪ If the researcher was unable to test a neonate due to restlessness, irritability, or a technical fault, the parent or caregiver was notified that the screening could not be done and that the testing would take place on the following day in the NICU if possible.
	▪ Counselling with language-appropriate pamphlets regarding normal speech, language, and hearing development within the first two years of a child's life was given to all parents/caregivers of participants – regardless of screening outcome.
	▪ The researcher kept a log of all costs pertaining to the hearing screening service and separated the AABR, DPOAE, and WAI costs.
Statistical analysis	Descriptive statistics: Mean age at time of testing, mean birth weight, and the number of male and female neonates who took part in the study were documented. Coverage rates, referral rates, and follow-up rates of DPOAE, AABR and WAI (%) were noted. Mean number of DPOAE, AABR and WAI screening tests done per ear was calculated.

2.4 Ethical considerations

According to the South African National Health Act (2007) and the American Speech-Language-Hearing Association (ASHA) guidelines for the responsible conduct of research (2009), medical and health care research is subject to ethical standards that promote respect for all human beings and protect their health and rights. In keeping with this statement, the study was initiated and conducted within the framework of the ethical guidelines set out in the Guidelines of Practice in the Conduct of Clinical Trials in Human Subjects in South Africa (South African Department of Health, 2000), in the South African National Health Act (2007) and the ASHA Guidelines for the responsible conduct of research (2009).

Table 3: Ethical principles applicable to research design, participant selection, data collection and analysis procedures (South African Department of Health, 2000; South African National Health, 2007 & ASHA Guidelines for the responsible conduct of research, 2009).

Principle	Application to study
The right, safety, and wellbeing of the participants are the most important considerations and should prevail over interest of science and society. Foreseeable risks and inconveniences should be weighed against the anticipated benefit for participants and society. A study should only be initiated and continued if the anticipated benefits justify the risks. Investigators have special responsibilities to ensure confidentiality, informed consent, avoidance of coercion, ability to withdraw without penalty, and a risk–benefit analysis.	Universal Newborn Hearing Screening is a regular service provided by a private audiology practice to all NICU neonates in the designated hospitals. The hearing screening technologies that were used are DPOAE and AABR. If the parent/caregiver gave consent that their neonate's hearing screening results may be used as part of the study and if the neonate passed both the DPOAE and AABR tests, an additional component WAI was added to the process. There were no risks involved for the participants of this study with the only inconvenience being the time that was spent by the neonates' parents or caregiver to complete the necessary documents giving informed consent that the neonate be screened using the screening methods discussed and that the results obtained be used for research purposes. The study offered an indirect benefit to each participant in the sense that they had access to early hearing detection services and, if necessary, to early intervention services. Considering the high prevalence of hearing loss (3-6/1000 live births), it is essential to make this service available to all neonates born in South Africa. There were no risks involved for the participants of this study as the hearing screening tests (AABR, DPOAE and WAI) were non-intrusive and did not hurt or harm the neonate.
Research or experimentation on an individual may only be conducted after the participant has been informed of the objectives of the research or experimentation and any possible positive or negative consequences on his or her health.	There were no direct benefits to the neonates taking part in the study but neither were any risks involved. Information was supplied to all parents or caregivers of potential participants in the study. The information form (Appendix A) included the purpose and rationale of the study as well as participant rights.
The health care provider must also, where possible, inform the individual in a language that the individual understands, and in a manner which takes into account the individual's level of literacy.	Information was given in the language of the participants' choice (Appendix A). The researcher is fluent in English and Afrikaans. If information was required in another language, a competent healthcare worker in the NICU was asked to act as translator and to assist in answering any questions that the potential participants had.

Freely given informed consent should be obtained from every participant prior to clinical trial participation.	Informed consent was obtained from every participant through the use of the informed consent form (Appendix B). Written consent was acquired from the parent or caregiver prior to the assessment.
The participant should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal.	This principle is stated in the information form (Appendix A). the information was reiterated verbally to parents and caregivers of potential participants in their preferred language prior to commencement of the assessment session. If the parent/caregiver decided not to participate, their neonate's hearing was still screened – their data were just not included in the research study. Their decision did not have negative consequences for their infant or prevent their infant from still receiving the service.
The confidentiality of records that could identify participants should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).	Participant confidentiality was ensured as results for each individual were reported using a coding system. By using this method the identity of the participant was known only to the researcher. This was also explained in the information form (Appendix A).
A preliminary study should be conducted in compliance with the protocol that has received prior institutional review board/ independent ethics committee approval. All investigators planning to include humans in experiments should submit research proposals to an independent, objective review panel to ensure that the rights of participants, researchers, and institutions are protected.	The proposal was submitted to the Research Ethics Committee of the Faculty of Humanities of the University of Pretoria for approval. No data collection commenced prior to approval of the study.

3 RESEARCH ARTICLE

TITLE: Wideband Acoustic Immittance for assessing middle ear functioning for preterm neonates in the NICU

Authors: Nandel Gouws, De Wet Swanepoel and Leigh Biagio de Jager

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

3.1 Abstract

3.1.1 Background

The primary aim of newborn hearing screening is to detect permanent hearing loss. Since otoacoustic emissions (OAE) and automated auditory brainstem response (AABR) are sensitive to hearing loss, they are often used as screening tools. On the other hand, false-positive results are most often due to transient outer and middle ear conditions. Wideband acoustic immittance (WAI) which includes physical measures known as reflectance and absorbance has shown potential for accurate assessment of middle ear function in young infants.

3.1.2 Objective

The main objective of this study was to determine the feasibility of wideband acoustic immittance (WAI) as a diagnostic tool for assessing middle ear

functioning in preterm neonates in the neonatal intensive care unit (NICU) designed for premature and ill neonates. A further objective was to indicate the difference between the reflectance values of tones and click stimuli.

3.1.3 Method

Fifty six at-risk neonates (30 male and 26 female), with a mean age at testing of 35.6 weeks (range: 32-37 weeks, standard deviation 1.6), from three private hospitals, who passed both the DPOAE and AABR tests, were evaluated prior to discharge from NICU. Neonates who presented with abnormal DPOAE and AABR results were excluded from the study. WAI was measured using chirp and tone stimuli. In addition to reflectance, the reflectance area index (RAI) values were calculated.

3.1.4 Results

Both Tone and Chirp Stimuli indicate high power reflectance values below a frequency of 1.5 kHz.   Median reflectance reached a minimum of 0.67 at 1-2 kHz but increased to 0.7 below 1 kHz and 0.72 above 2 kHz for the tone stimuli. For chirp stimuli the median reflectance reached a minimum of 0.51 at 1-2 kHz but increased to 0.68 below 1 kHz and decreased to 0.5 above 2 kHz. A comparison between the present study and previous studies on WAI indicated substantial variability across all frequency ranges.

3.1.5 Conclusion

These WAI measurements conducted on at-risk preterm NICU neonates (mean age at testing - 35.6 weeks, range: 32-37 weeks) identified WAI patterns not previously reported in the literature. High reflective values were obtained across all frequency ranges. The age of the neonates when tested

might have influenced the results. The neonates in the present study were very young preterm neonates compared to the ages of neonates in previous studies. WAI measured in at-risk preterm neonates in the NICU was variable with environmental and internal noise influences. Transient conditions affecting the sound-conduction pathway might have influenced the results. Additional research is required to investigate WAI testing in ears with and without middle ear dysfunction. The findings of the current study imply that in preterm neonates it was not possible to determine the feasibility of WAI as a diagnostic tool to differentiate between ears with and without middle ear pathology.

3.2 Introduction

3.2.1 Background

Congenital hearing loss has been described as the most common sensory birth defect and is estimated to affect one to six in every 1000 newborns (Wrightson, 2007). Universal newborn hearing screening is a way to detect permanent hearing loss in newborns, whether they present with known risk factors or not (Miller, Hunter, Feeney, Jeng, & Bohning, 2010). A known risk factor for congenital hearing loss is premature birth necessitating a stay in the neonatal intensive care unit (NICU; Wrightson, 2007). Currently automated auditory brainstem response (AABR) and otoacoustic emission (OAE) hearing screening methods are used to identify possible hearing loss in well-babies as well as at-risk premature neonates. Both these screening procedures may be influenced by middle ear conditions. OAEs in particular are affected by middle ear pathology (Hunter, Prieve, Kei, & Sanford, 2013). While AABR appears to

be less affected, air conduction thresholds for diagnostic auditory brainstem response (ABR) may be elevated in the presence of middle ear effusion (MEE; Hunter *et al.*, 2013). Due to the high prevalence of middle ear effusion in neonates (Boudewyns, Declau, Van den Ende *et al.*, 2011), effective and efficient diagnostic tools that can be used in combination with hearing screening technologies like OAE and AABR are necessary to help detect middle ear dysfunction. Wideband acoustic immittance (WAI) is a method of middle ear analysis that may provide diagnostic capability in diagnosing middle ear conditions in neonates (Hunter, Tubaugh, Jackson, & Propes, 2008). While tympanometry uses a single frequency stimulus, WAI measures function across a range of frequencies (Hunter *et al.*, 2008). Wideband acoustic immittance (WAI) includes measures such as wideband reflectance (WBR) and wideband absorbance (WBA).

Keefe, Folsom, Gorga *et al.* (2000) found that the addition of a WAI test improved the prediction of hearing status when 2638 newborns were tested with distortion product otoacoustic emissions (DPOAE), transient evoked otoacoustic emissions (TEOAE), and automated auditory brainstem response (AABR). Information on middle ear status was thus shown to improve the ability to predict hearing status (Hunter *et al.*, 2008). WAI tests have also demonstrated better identification of middle ear pathology in neonates than either 226 or 1 kHz probe tone tympanometry (Hunter *et al.*, 2008); WAI is therefore a tool that may offer an accurate and non-invasive diagnosis of middle ear function and could be used to differentiate between a "refer" on neonatal hearing screening due to outer and middle ear pathology, and a

"refer" due to permanent congenital or early onset hearing loss in at-risk neonates residing in the NICU.

3.2.2 Literature Review

Hearing loss in early childhood and infancy often goes undetected because it exhibits no obvious indication and symptoms. The primary aim of newborn hearing screening is to detect permanent hearing loss, a condition to which OAE and AABR are sensitive (Hunter *et al.*, 2010). These screening tests can be affected by transient outer ear and middle ear conditions that are often present at birth (Hall, Smith, & Popelka, 2004). This may lead to false positive results. Neonates in NICU typically represent 10% of the newborn population and the prevalence for permanent congenital or early onset hearing loss (PCHL) is higher than any other condition screened for in the newborn period (Joint Committee on Infant Hearing (JCIH), 2007). Admission for a period of longer than two days in the NICU is associated with a higher incidence of PCHL (JCIH, 2007).

Accurate early identification of PCHL is especially problematic in the neonatal population because of the high prevalence of otitis media with effusion (Hunter *et al.*, 2008). Distinguishing middle ear conditions from sensorineural hearing loss is important to improve hearing screening programme efficacy and for appropriate referrals (Boudewyns *et al.*, 2011). In addition, Vartiainen (2000) reported delayed diagnosis in infants with PCHL due to coexistent transient middle ear pathology. Measures of middle ear dysfunction are therefore essential for audiological diagnosis of PCHL (JCIH, 2007) and

should be routinely incorporated in hearing screening protocols (Hunter *et al.*, 2013).

Assessing conductive disorders in young infants (aged 0-6 months) is a challenge (Kei & Zhao, 2012). Conventional 226 Hz tympanometry is effective in evaluating middle ear functioning accurately in children older than seven months, but its efficacy in infants six months and younger is limited due to the immaturity of infant outer and middle ears (Holte, Margolis, & Cavanaugh, 1991; Hunter & Morgolis, 1992). During the development of the infant ear, several anatomic changes take place that influence the mechanical properties of the ear canal and middle ear (Shahnaz, Cai, & Qi, 2014). Immittance testing using a higher probe tone frequency (1 kHz) is recommended for diagnostic testing in infants younger than four months because it is more sensitive to middle ear dysfunction than conventional 226 Hz tympanometry (Hunter *et al.*, 2010).

In addition to high probe tone immittance testing, WAI has been recommended as a test of middle ear function for young infants (Aithal, Kei, Driscoll, & Khan, 2013). WAI measurements of the middle ear can provide information about how well the middle ear functions across the traditional audiometric frequency range, instead of at a single frequency, as is the case with tympanometry (Feeney, Stover, Keefe, Garinis, Day, & Seixas, 2014). The technique uses a broad range of frequencies from 62 Hz to 13 000 Hz, and includes a measure of power reflectance as well as admittance and impedance quantities. According to Hunter *et al* (2008), WAI provides more detailed information on the status of the middle ear than tympanometry, and does not require pressurization of the ear canal that might cause discomfort to

the infant, making it less difficult to obtain results (Keefe *et al.*, 1993). Power reflectance is the ratio of reflected energy to incident energy (Voss & Allen, 1994) and ranges from zero (representing complete transfer of sound into the middle ear) up to one (representing no sound transferred into the middle ear). Power reflectance is highest at frequencies below 1000 Hz and above 4000 Hz (Hunter *et al.*, 2010), which corresponds to the middle ear transfer function with the most compliant frequencies in the mid-frequency range. WAI has the potential to increase the accuracy of diagnosing middle ear pathologies in infants failing newborn hearing screening (Keefe *et al.*, 2003).

Keefe *et al.* (2003) demonstrated that inclusion of the WAI test in universal newborn hearing screening (UNHS) programmes decreased the false positive rates from 5% to 1%. This finding suggests that information on middle ear status improves the ability to correctly refer neonates for diagnostic hearing assessments, and improves the ability to predict hearing status. WAI is therefore recommended as an adjunct tool within newborn hearing screening programmes.

The effect of anatomic differences on WAI patterns in healthy infants have been investigated by several researchers. Keefe *et al.* (1993) measured WAI patterns in 78 healthy infants aged one to 24 months. They reported that infants have lower middle ear compliance and higher resistance compared to adults, which was attributed to ear canal wall movement at lower frequencies. This results in a clear separation in energy reflectance values between one month old infants and adults for responses of less than 0.7 kHz, with infants having lower energy reflectance values than adults. Keefe, Folsom and Gorga *et al.* (2000) measured energy reflectance (ER) in 4031 ears of NICU

neonates, healthy neonates, and healthy neonates with one or more risk factors for hearing loss. Shahnaz *et al.* (2014) stated that maturation of the middle ear occurs after birth and continues as infants become older. Results showed that power reflectance values increased (closer to 1) at low frequencies (<400 Hz) and decreased (closer to 0) at high frequencies (>2000 Hz) as a function of age.

Hunter *et al.* (2010) demonstrated an increase in energy reflectance at 2 kHz and greater when middle ear dysfunction was suspected in newborns. Hunter *et al.* (2010) used DPOAEs to predict middle ear status at birth and at four days thereafter. A few days after birth, when these newborns passed DPOAE screening, reflectance values improved (decreased) with normalization of middle ear function in frequency ranges involving 2 kHz and greater. The DPOAE test is therefore often used as the reference standard to determine normal middle ear function in infants. However, the DPOAE alone may not accurately identify minor or sub-clinical middle ear pathologies (Kemp, 2002) and hence may not serve as an ideal reference standard (Hunter *et al.*, 2010; Stanford *et al.*, 2009). According to Aithal *et al.* (2015), combining DPOAE with high frequency tympanometry, TEOAE, and AABR may provide more stringent control for middle ear pathology in the neonatal population.

WAI patterns were measured by Shahnaz (2008) in 31 NICU neonates that passed both AABR and TEOAE screening protocols, and compared these to WAI measurements of 56 adults with normal hearing. Results showed a clear separation in reflectance between NICU neonates and adults for responses of less than 0.727 kHz. NICU neonates had lower reflectance values than adults at the low frequencies (Shahnaz, 2008). Shahnaz (2008) reported a mean

gestation age of 37.8 weeks of the neonates tested. It is unclear; however, whether this was the gestation age at birth or the gestation age at time of testing. Newborn hearing screening routinely takes place prior to discharge from NICU, which may mean that preterm neonates undergo hearing screening at a younger age than that of the infants tested by Shahnaz (2008). The current study therefore aimed to determine the feasibility of using WAI for assessing middle ear functioning of preterm neonates in the NICU.

3.3   Ethical considerations

The study was approved by the Institutional Review Board before data collection commenced. Neonates enrolled in the study were born at any one of three specified private hospitals and were admitted to the NICU after birth. Parents of NICU neonates were informed of the study and given the opportunity to participate. Written parental consent was obtained prior to data collection. It was communicated to the parents that there are no risks involved for the participants of this study as the screening tests are non-intrusive and not harmful to the neonate.

3.4   Research method and design

A cross sectional exploratory design yielding quantitative data was used for the study. At-risk preterm neonates with a gestation age of 32 to 37 weeks (mean age at testing 35.6 weeks, SD= 1.6) admitted to the neonatal intensive care unit (NICU) who passed hearing screening by means of both DPOAE and AABR were evaluated using WAI prior to discharge. Neonates who presented with abnormal DPOAE and AABR results were excluded from the

study.The study coincided with a routine hearing screening service offered at these hospitals by a private audiology practice.

3.4.1 Participant selection criteria

A purposive sampling technique was used (Etikan, Musa, & Alkassim, 2016). The caregivers for preterm neonates with a gestation age of 32 to 37 weeks who were admitted to the NICU were given the opportunity to participate in the study. All neonates had to be considered medically stable by NICU personnel and had to have passed both DPOAE and AABR screenings before they were included in the study. AABR and DPOAE testing was done for selection of participants and not for data gathering. Male and female neonates were accepted as participants in the study. In total, the caregivers for 56 preterm neonates (106 ears) who passed both DPOAE and AABR hearing screening in both ears provided written informed consent for participation. Six ears were referred for further testing from either DPOAE or AABR, or both, and were excluded from the study. WAI measurements could be obtained in 75 ears using a chirp stimulus, in 82 ears by applying a tone stimulus, and in 59 ears using both chirp and tone stimuli. Mean gestational age at the time of testing was 35.6 weeks (range: 32-37 weeks; SD=1.6) with a mean birth weight of 2.1kg (range: 1.1–3.45 kg; SD = 0.5) Fifty infants (89.3%) were asleep during testing, four (7.2%) were awake but quiet and two (3.6%) were awake and restless. Twenty six neonates were female and thirty neonates were male.

3.5 Materials and methodology used for data gathering

WAI using either a tone or a chirp stimulus or both, was performed on the neonates who passed their hearing screens and for whom informed consent was obtained.

3.5.1 Automated Auditory Brainstem Response (AABR)

AABR was conducted with the Natus Algo 3i AABR Newborn Hearing Screening System. This system screens both ears simultaneously at an intensity of 35 dBnHL and 37 clicks per second. It is fully automated with objective "pass/refer" results that require no interpretation (Natus Algo 3i User Manual, 2013).

3.5.2 Distortion Product Otoacoustic Emissions (DPOAE)

The Automated Biologic (AuDx) OAE screener was used to conduct the DPOAE measurements. DPOAEs were measured in response to pairs of primary tones, with f2 set at 2, 3, 4, and 5 kHz. The f2/f1 ratio was 1.2 for each primary pair. The stimulus level of f1 was 65 dB SPL, and the stimulus level of f2 was 55dB SPL. For an overall "pass" result of the DPOAE test, three of the four test frequencies had to meet the response conditions defined for a "pass". A "pass" at each f2 frequency is implemented in the default setup parameters of the AuDx with reference to absolute DPOAE amplitude and the difference between DPOAE amplitude and noise floor (AuDx Service and User's Manual, 2002).

3.5.3 Wideband Acoustic Immittance (WAI)

Power reflectance, which is part of WAI, is the square of pressure reflectance and the ratio of reflected power over incident power (Shahnaz *et al*., 2014).

Therefore, a power reflectance value of one will indicate that 100% of the energy has been reflected, whereas a power reflectance value of zero will indicate that 100% of the energy has been absorbed and transmitted through the middle ear. Power reflectance values greater than one will indicate that more energy has been received than was used as stimulus, which might be attributed to a noisy test environment and/or restless neonate.

Hunter *et al.* (2010) proposed the use of a reflectance area index (RAI), wherein, instead of individual reflectance values, the reflectance values are averaged over a specified frequency range (e.g., 1-2 kHz, 1-4 kHz, 2-6 kHz). RAI can be applied to both the continuous chirp stimulus reflectance function and the discrete tone stimulus function. The RAI has the same unit (percentage) as reflectance (Hunter *et al.*, 2010).

The commercial HearID system model 3.5.0.5 (Mimosa Acoustics, Inc.) was used for the WAI (module 4.5.0.0). The system consists of a laptop-hosted PC-card, connected to an ER-10C probe (Etymotic Research, Elk Grove Village, IL) with a probe adaptor cable and a calibration cavity set of four cavities.

Probe tubes were covered with a silicone rubber tip size ER10C-03 (4.3mm). The same rubber tip size was used for all the neonates tested. This specific probe tip was used due to its easy and stable insertion in the ear canal. The silicone rubber tips were relatively incompressible in the neonate's ear, but still provided a better fit than the foam tips which are more suitable for larger ear canals. The rubber tips were considered more appropriate in size for the neonate ear (Hunter *et al.*, 2010). The probe was calibrated daily (every 24

hours) in a quiet room with HearID before testing commenced in the NICU. The Mimosa Acoustics Calibration Cavity Set (Voss & Allen, 1994) was used during probe calibration.

Each test session for all the neonates tested consisted of two WAI measurements in each ear - one for each stimulus type, namely chirp and tone stimuli. The wideband chirp stimulus was presented at a volume of 60 dB sound pressure level (SPL) repeatedly for an average of 1 sec. The chirp stimulus data consisted of a frequency range from 0.21 to 6 kHz with 248 measurements within this range. The 9-tone series (250, 500, 750, 1000, 1500, 2000, 3000, 4000 and 6000 Hz) was presented simultaneously at a volume of 60 dB SPL. The grouping of frequencies which were averaged to determine the RAI, was determined by the software for each individual measurement completed in accordance to similar reflectance values at adjacent frequencies (e.g.: 250 & 300 Hz, 400 – 800 Hz, etc.) for each of the neonates. The same method was described and followed by Hunter *et al.* (2010).

3.6 Procedure

Testing was conducted in the NICU. The same audiologist conducted all the procedures. Neonates were first tested by DPOAE and AABR. To test the reliability of the results from the DPOAE and the AABR tests, a rescreen was conducted once if a "refer" result was obtained during the DPOAE test and the same principle was applied for the AABR test. These tests were performed as the initial hearing screening (stage 1) as part of a universal newborn hearing screening programme. The relevant protocol specifies that testing should

consist of no more than two attempts using the same screening technique on each ear (JCIH, 2007).The AABR and DPOAE testing was done for the selection of subjects and not for the purpose of data gathering. WAI was conducted once the neonate passed both the DPOAE and the AABR screening. For WAI measurements at least two measurements were completed per ear, one for each channel in the probe (chirp and tone stimuli). The ear that was most accessible was tested first.

Test time for each neonate varied between 20 and 45 minutes to assess both ears with DPOAE, AABR and WAI. Test time depended on various factors including the neonate's wakefulness and fussiness, as well as difficulties maintaining probe insertion and noisy environments. In certain cases, the probe had to be refitted between measurements due to noisy conditions and inaccurate probe placement. Since NICU ambient noise levels are typically high, a major difficulty during the testing was to keep the noise levels low. It was important to make sure that the neonate was as quiet as possible and in a restful state before testing commenced. To achieve this, neonates were tested after feeding, while in natural sleep, or in an awake and quiet state. Pacifiers were used if needed to sooth the neonates, as well as swaddling. The HearID system made it possible to repeat tests. This was done if it was possible to settle down the neonate sufficiently.

3.6.1 Data screening, cleaning, and reduction

An expected challenge was to keep noise levels as low as possible while conducting the tests. The aim of data screening was to find one WAI measurement, using either a chirp stimulus or a tone stimulus or both, per ear

and one DPOAE and AABR measurement in the same test session (Hunter *et al.,* 2010).

In the current study, the best chirp stimulus and tone stimulus measurements were automatically selected within a test session using a default algorithm in the software. This algorithm is described by Hunter *et al.* (2010) as follows: (a) the signal to noise ratio (SNR) at frequencies lower than 1 kHz had to be > 10 dB for over half the tested frequencies; (b) reflectance for each channel within a measurements could not be separated by > 5 percentage points for frequencies > 1 kHz; and (c) for measurements meeting these criteria, the measurement with the highest SNR between 1 and 6 kHz was chosen. The software that was used during the screening process did not provide warnings to the tester as to whether noise levels were unacceptable. To remove high noise and off-target stimulus levels, therefore, the data were post hoc screened. This screening process consisted of identifying measured data with a reflectance value greater than 100% and adjusting the value to 100% (Hunter *et al.*, 2010).

Table 4 presents the number of times that out of range reflectance values of greater than 100% had to be adjusted to 100%. From 961 Hz to 2016 Hz there are a total number of 1665 samples, and 322 of these samples were corrected to a reflectance value of a 100 – therefore 19.3% of the data in this range was corrected.

Table 4: Number of corrected WBR samples using chirp and tone stimuli

Chirp Stimuli (n =75 ears)		
Frequency Range (Hz)	**Total Samples**	**Number Corrected (%)**
210 – 961	1184	522 (44)
961 – 2016	1165	322 (19)
2016 – 3000	1554	316 (20)
3000 – 4008	1591	310 (19)
4008 – 5016	1591	303 (19)
5016 – 6000	1591	302 (19)
Tone Stimuli (n = 82 ears)		
Frequency Range (Hz)	**Total Samples**	**Number Corrected (%)**
258 - 750	246	71 (29)
750 - 1992	246	42 (17)
1992 - 6000	249	29 (12)

3.7 Results

After data correction was applied, percentiles were calculated at individual frequencies for both chirp and tone stimuli. RAI values were subsequently calculated for the frequency ranges as indicated in **Table 5** and **Table 6**. This process involved evaluation of individual frequencies between 0.25 and 8 kHz (Aithal *et al.,* 2013). As stated by Aithal *et al.* (2013) and Hunter *et al.* (2010), an alternative method would be to evaluate the RAI's obtained, by grouping adjacent frequencies with similar reflectance. The RAI estimation would involve fewer variables and facilitate accurate interpretation of the results.

WAI measurements were recorded across the wideband reflective spectrum for both tone and chirp stimuli and for integrated frequency ranges in 106 ears. In some cases the neonate was restless and only one of the stimuli could be applied. Individual tests were absent for various reasons such as distress or nonperformance on the part of the neonate and inadequate signal level for DPOAE testing. For the neonates in the present study, **Table 5** and **Table 6** present the reflectance values for the 0, 5th, 10th, 50th, 90th, 95th

and 100th percentiles at the individual frequencies and RAI frequency ranges

for tone stimuli and chirp stimuli respectively.

Table 5: Mean reflectance and reflectance area index (RAI) values for 0.26 to 6 kHz for NICU neonates using tone stimuli (n=82 ears).

| | Percentiles | | | | | | | | |
Frequency (kHz)	0	5	10	25	50	75	90	95	100
0.26	0.06	0.18	0.28	0.62	0.85	1.00	1.00	1.00	1.00
0.49	0.17	0.24	0.54	0.67	0.85	1.00	1.00	1.00	1.00
0.75	0.14	0.29	0.34	0.64	0.84	1.00	1.00	1.00	1.00
1.01	0.11	0.23	0.33	0.49	0.70	0.96	1.00	1.00	1.00
1.50	0.07	0.14	0.18	0.39	0.67	0.91	1.00	1.00	1.00
1.99	0.02	0.11	0.22	0.38	0.72	0.98	1.00	1.00	1.00
3.00	0.04	0.08	0.13	0.34	0.72	0.95	1.00	1.00	1.00
4.01	0.01	0.09	0.15	0.41	0.75	0.97	1.00	1.00	1.00
6.00	0.02	0.05	0.10	0.31	0.76	0.96	1.00	1.00	1.00
RAI									
0.26-0.49	0.11	0.21	0.41	0.64	0.80	0.83	0.83	0.83	0.83
0.75-1	0.12	0.26	0.34	0.57	0.74	0.79	0.79	0.79	0.79
1.5-2	0.04	0.12	0.20	0.39	0.65	0.69	0.69	0.69	0.69
3-6	0.02	0.07	0.13	0.35	0.69	0.72	0.72	0.72	0.72

Table 5 indicates high reflectance values from the 75th percentile onwards.

A similar trend is seen from the chirp stimuli data in **Table 6**. Reflectance values of 56% are already evident at the 10th percentile for a frequency range between 210 and 400 Hz. When the RAI values are compared for the 0th to 75th percentiles, it is apparent that the low frequency range below 1 kHz has the highest reflectance values. For the 90th to 100th percentiles reflectance values of 100% were obtained across the complete frequency band.

Table 6: Mean reflectance and reflectance area index (RAI) values for 0.26 to 6 kHz NICU neonates using chirp stimuli (n = 75 ears)

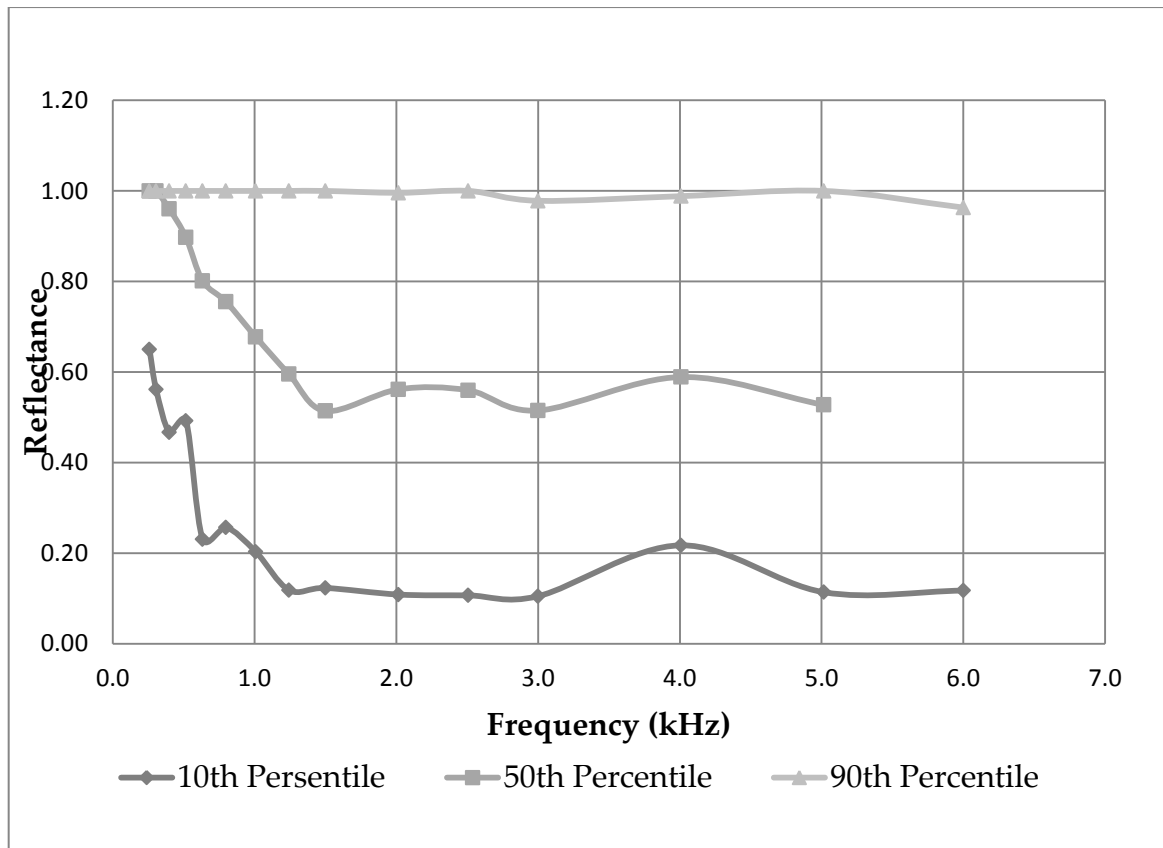|	Percentiles								
Frequency (kHz)	**0**	**5**	**10**	**25**	**50**	**75**	**90**	**95**	**100**
0.26	0.00	0.41	0.65	0.92	1.00	1.00	1.00	1.00	1.00
0.30	0.00	0.44	0.56	0.82	1.00	1.00	1.00	1.00	1.00
0.40	0.00	0.34	0.47	0.77	0.96	1.00	1.00	1.00	1.00
0.52	0.00	0.31	0.49	0.64	0.90	1.00	1.00	1.00	1.00
0.63	0.00	0.15	0.23	0.56	0.80	1.00	1.00	1.00	1.00
0.80	0.00	0.18	0.26	0.44	0.76	0.99	1.00	1.00	1.00
1.01	0.00	0.14	0.20	0.40	0.68	1.00	1.00	1.00	1.00
1.24	0.00	0.08	0.12	0.30	0.60	0.92	1.00	1.00	1.00
1.50	0.00	0.10	0.12	0.24	0.51	0.90	1.00	1.00	1.00
2.02	0.00	0.08	0.11	0.28	0.56	0.90	1.00	1.00	1.00
2.51	0.00	0.06	0.11	0.27	0.56	0.90	1.00	1.00	1.00
3.00	0.00	0.06	0.11	0.27	0.52	0.78	0.98	1.00	1.00
4.01	0.00	0.11	0.22	0.35	0.59	0.87	0.99	1.00	1.00
5.02	0.00	0.03	0.11	0.30	0.53	0.90	1.00	1.00	1.00
6.00	0.00	0.06	0.12	0.26	0.50	0.83	0.96	1.00	1.00
RAI									
0.211-0.4	0.00	0.35	0.56	0.83	0.93	0.94	0.94	0.94	0.94
0.4-0.89	0.00	0.17	0.32	0.53	0.70	0.77	0.77	0.77	0.77
0.9-1.24	0.00	0.13	0.19	0.34	0.54	0.64	0.64	0.65	0.65
1.26-2	0.00	0.08	0.12	0.27	0.43	0.52	0.52	0.52	0.52
2-2.5	0.00	0.04	0.10	0.24	0.52	0.57	0.57	0.57	0.57
2.5-3.0	0.00	0.05	0.12	0.26	0.52	0.54	0.54	0.54	0.54
3.0-4.0	0.00	0.10	0.17	0.32	0.51	0.54	0.54	0.54	0.54
4.0-6.0	0.00	0.07	0.13	0.31	0.46	0.53	0.53	0.53	0.53

The 10th, 50th, and 90th percentile values measured for reflectance for tone and chirp stimuli, at individual frequencies, are presented in Figure 1 and Figure 2 respectively.
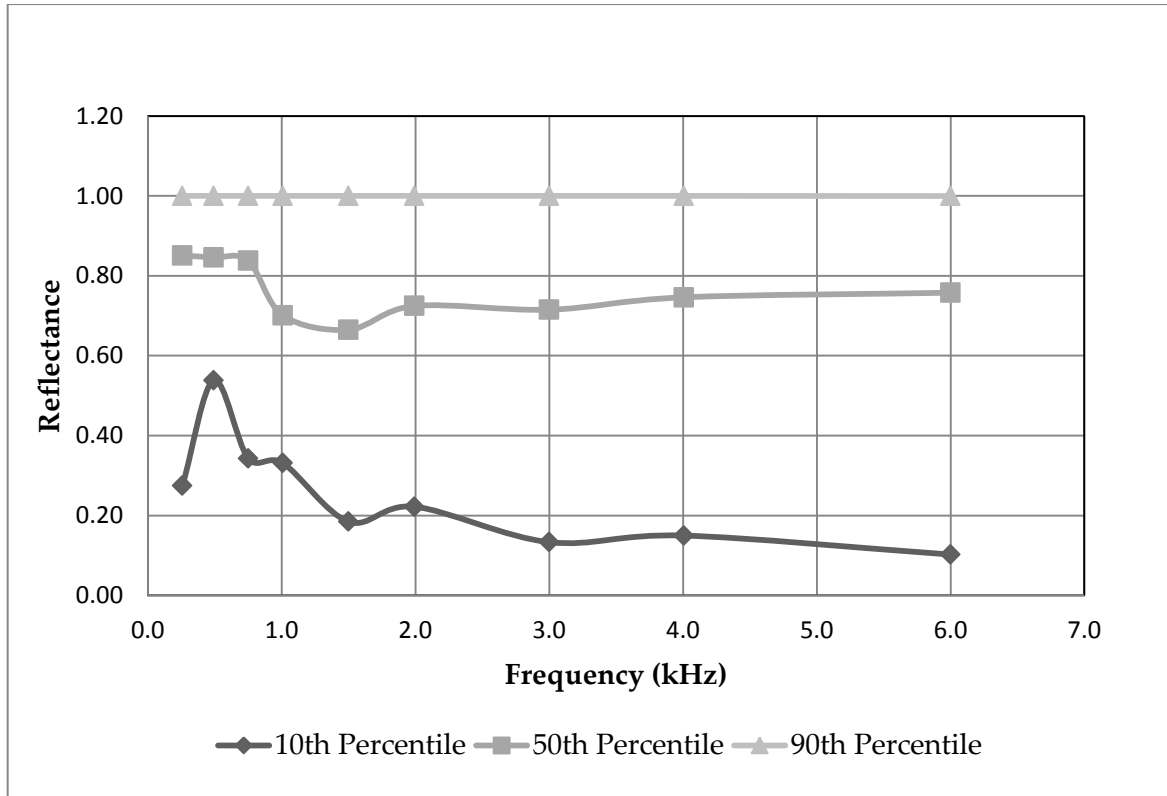
Figure 1: Reflectance data for tone stimuli at individual frequencies (n=8 ears)

Figure 1 indicates the reflectance data for tone stimuli at individual frequencies. The 90th percentile shows a reflectance value of 1 throughout the frequency range. For the 50th percentile higher reflectance values are visible in the low frequency range compared to the reflectance values of the mid and high frequency ranges. Higher reflectance values are also visible in the low frequency ranges for the 10th percentile, compared to the reflectance values of the mid and high frequency ranges.

Figure 2: Reflectance data for chirp stimulus at individual frequencies (n=75 ears)

The 10th and 50th percentile reflectance values decrease between 0.2 and 1.5 kHz after which the reflectance value data remain relatively constant. The 90th percentile reflectance values for tone and chirp stimuli remained one throughout the frequency range. The median reflectance reached a minimum of 0.67 at 1 to 2 kHz, but increased to 0.7 below 1 kHz and 0, 72 above 2 kHz for tone stimuli. For chirp stimuli the median reflectance reached a minimum of 0.51 at 1 to 2 kHz, but increased to 0.68 below 1 kHz and decreased to 0.5 above 2 kHz.

3.8   Discussion

WAI measures, using chirp and tone stimuli, were obtained for individual frequencies from 0.26 to 6 kHz, as well as RAIs that were averaged over different frequency regions (**Table 5** and **Table 6**). High reflectance values were obtained below 1.5 kHz for both tone and chirp stimuli (range of reflectance values: 0.26 – 6 kHz) compared to the frequency range above 1.5 kHz when considering the 0th to 75th percentiles. The high reflectance values measured in the current study below 1.5 kHz are in agreement with several other studies that also showed that, for infants, reflectance is the highest at frequencies below 1 kHz and above 4 kHz, and lowest in the frequency region between 1 and 4 kHz (Aithal *et al.*, 2013; Hunter, Tubaugh, Jackson, & Propes, 2008). In comparison with previous research on WAI in infants (Aithal *et al.*, 2013; Hunter *et al.*, 2010; Shahnaz *et al.*, 2014), the reflectance values measured in the current study were lower at 1.25 – 2 kHz, and between 3 – 4 kHz. The 50th percentile was higher in the current study than in the study of Aithal *et al.* (2013).

The WAI results of the present study are compared to the study of Aithal *et al.* (2013) in Figure 3. If the median reflectance of the two studies are compared, similar reflectance values are present in the mid frequency range of 3 - 4 kHz. In the study of Aithal *et al.* (2013), the reflectance values obtained at 3 kHz are similar to the reflectance values obtained at 3 kHz for the present study. In the low frequency ranges below 3 kHz and in the high frequency range above 4 kHz, however, the present study shows much higher reflectance values if compared to those of Aithal *et al.* (2013). The difference between the WAI of the current study and that of Aithal *et al.* (2013) may be due to the fact that the

current study was conducted on NICU neonates, while that of Aithal *et al.* (2013) was conducted on full term infants.
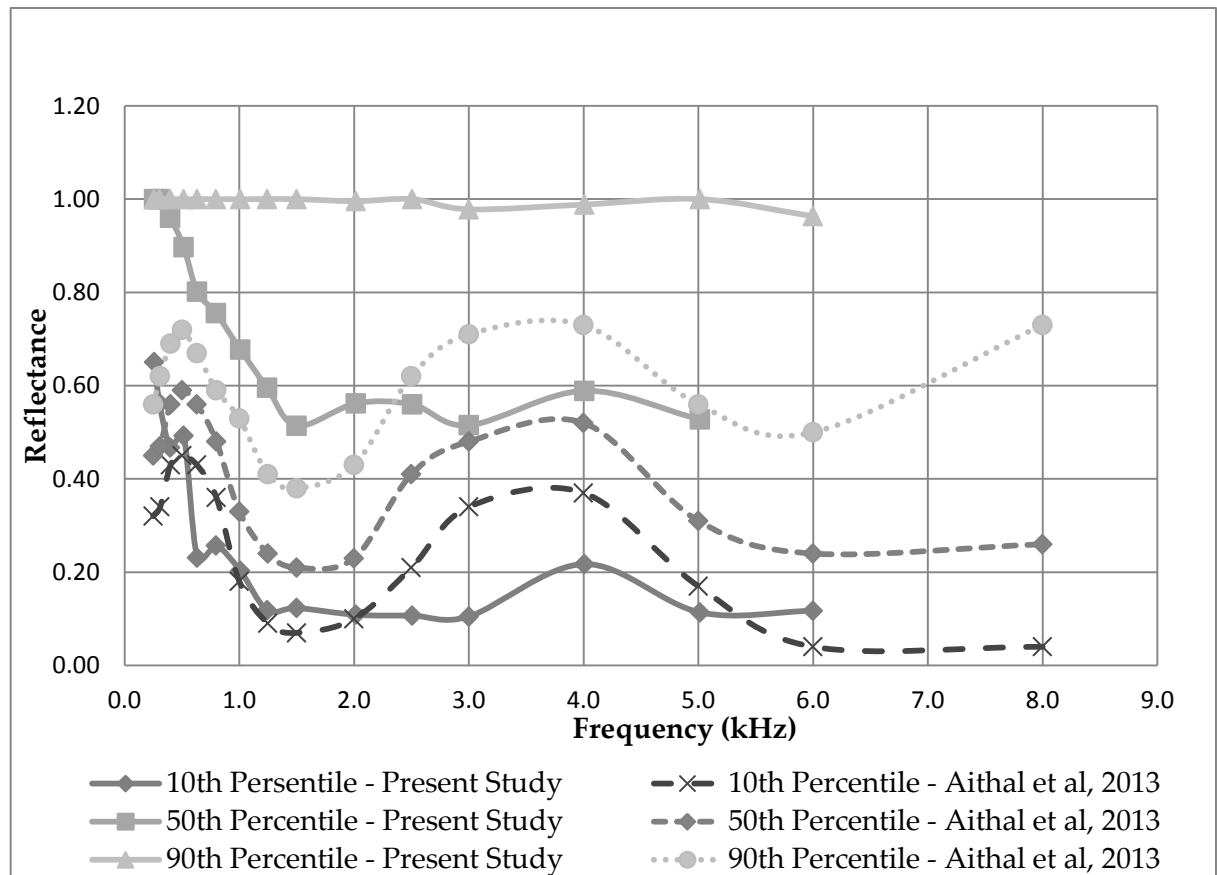
Figure 3: A comparison of the reflectance values measured in the present study and by Aithal *et al.* (2013).

Table 7 presents reflectance area indices (RAI) obtained from neonates in the present study compared to those reported by Aithal *et al.* (2013). When comparing the RAI values obtained by Aithal *et al.* (2013) with those of the present study, the RAI values for the mid frequencies range (2-4 kHz) at the 10th percentile are found to be comparable, but for the 90th percentile much higher RAI values were obtained. Considering the complete frequency range (0.2-6 kHz), the difference in RAI values between the present study and that of Aithal *et al.* (2013) at the 10th and 90th percentile was 23.4% and 41.7% respectively. Similarly, the mean difference in RAI values across the

frequency range of 1 - 6 kHz at the 10th and 90th percentile was 4.1% and 44.8% respectively. For the lower percentile values, it seems as if the difference is lower for the higher frequency range (1-6 kHz), indicating that the low frequency values, less than 1 kHz, contribute to the relatively high RAI values. Reflectance values for both studies tend to increase at a frequency less than 1.5 kHz and between 2 - 4 kHz. RAI values reported by Hunter *et al.* (2010) in a study on healthy full term infants demonstrated similar WAI values to those reported by Aithal *et al.* (2013). However, the 90th and 100th percentile WAI values measured by Hunter *et al.* (2010) were higher than those presented by Aithal *et al.* (2013). In the study by Hunter *et al.* (2010) reflectance values were defined over various frequency regions for both tone and chirp stimuli, which was also done in the present study. The results obtained by Hunter *et al.* (2010) indicated that tone and chirp stimuli reflectance values were essentially indistinguishable. In the present study, both tone and chirp stimuli indicate high power reflectance values below a frequency of 1.5 kHz. Median reflectance reached a minimum of 0.67 at 1-2 kHz but increased to 0.7 below 1 kHz and 0.72 above 2 kHz for the tone stimuli. For chirp stimuli the median reflectance reached a minimum of 0.51 at 1-2 kHz but increased to 0.68 below 1 kHz and decreased to 0.5 above 2 kHz.

According to the report of Shahnaz *et al.* (2014), the WAI results for newborns tested at one month intervals up to six months of age show that power reflectance increased at low frequencies (<400Hz) and decreased at high frequencies (>2000 Hz) as a function of age. If the results of the present study are compared to the results from Shahnaz *et al.* (2014), power reflectance decreases at high frequencies (>2000 Hz) for the 50th and 10th percentile. In

the present study, high reflectance values were obtained at low frequencies (<800 Hz) at the 50th percentile, but values decreased at the 25th and 10th percentile.

Table 7: Reflectance area indices (RAI) of infants in the present study (n=75) compared to those reported by Aithal *et al.* (2013) (n=66)

Frequency (kHz)	0 Percentile		10th Percentile		90th Percentile		100th Percentile	
	Aithal	Present study	Aithal	Present study	Aithal	Present study	Aithal	Present study
0.2 – 6	16.4	0	25.9	49.3	58.3	100.0	74.9	100.0
1 – 2	3.8	0	10.8	13.9	44	100.0	61.1	100.0
1 – 4	8.1	0	19.3	13.8	54.7	99.6	69.7	100.0
1 - 6	7.2	0	17.4	13.3	54.3	99.1	72.7	100.0
2 – 4	10.7	0	25.5	13.8	62.5	99.3	73.6	100.0
2 – 6	8.5	0	20.6	13.2	59.4	98.9	76.8	100.0
4 – 6	8.2	0	19.7	12.5	59.9	98.4	85.9	100.0
2	1.4	0	9.8	10.7	43.1	99.7	50.7	100.0

Methodological differences between the studies of Hunter *et al.* (2010), Aithal *et al.* (2013), Shahnaz *et al.* (2014), and the present study could be contributing to the differences in reflectance measures reported. Differences between the studies include: reference standard used, age of infant sample, mass element control of the middle ear, instrumentation used, and probe fit.

Firstly, the reference standard used to determine middle ear status was different. The present study used DPOAE measurements to confirm the absence of outer and middle ear pathology whereas previous studies by Aithal *et al.* (2013), Hunter *et al.* (2010) and Shahnaz *et al.* (2014) used a combination of DPOAE, TEOAE, and low frequency and high frequency tympanometry as a reference standard. Middle ear pathology may have been overlooked by using DPOAE only. Although a "pass" on a test battery which includes DPOAE provides some assurance of an unobstructed conductive pathway, it should not be regarded as a gold standard for detecting ears with

a satisfactory conductive condition, in view of the limitations of the test battery when used with young infants (Aithal *et al.*, 2014).

It is possible, therefore, that conductive pathology may have been overlooked due to the protocol that was used in the current study compared to other studies such as those by Aithal et al. (2014), Hunter *et al.* (2010), and Shahnaz *et al.* (2014), who included additional measures to ensure normal outer and middle ear function.

The second possible reason for the discrepancy in WAI measures between the current and previous WAI studies is the age of the infant sample. Aithal *et al.* (2013) conducted their research on full-term neonates with a mean gestational age of 38.7 weeks (SD= 5.01, range: 36-42 weeks). Shahnaz (2008) also conducted research on NICU neonates, as did the present study, but with a mean gestational age of 37.8 weeks (range: 32-51 weeks) and not earlier than three weeks before discharge, compared to the premature neonates tested in the present study (mean age at testing 35.6 weeks, range: 32-37 weeks), who were younger.

According to a study by Keefe and Levi (1996), one month old infants have smaller energy reflectance values than NICU infants at lower frequencies. The present study indicated high reflectance values in the low frequency range. Shahnaz *et al.* (2014) stated that if the overall mass of the middle ear is higher for NICU infants than for one month old infants, more incident energy will be reflected and less will be absorbed at higher frequencies. Although the presence of amniotic fluid in the ear canal and middle ear is not unique to premature neonates, it is possible that the amount of mesenchyme in the

middle ear is greater in premature than in full term neonates due to the normal middle ear developmental changes that take place towards the end of the third trimester. This may be the reason why the reflectance value data obtained in the premature neonates of the current study was higher than those recorded in previous studies.

Aithal *et al.* (2014) reported that a developmental trend was evident in the normal development of the infant ear canal and middle ear. Reflectance results obtained from zero and six months old infants differed significantly from those of other age groups in the study. WAI results exhibited a multipeaked pattern for infants aged zero to two months, while a single broad peaked pattern was observed for four and six month old infants, indicating that developmental effects of WAI were evident for infants during the first six months of life. Participants in the study by Hunter *et al.* (2010) were healthy full term neonates and tests were conducted between three and 102 hours after birth. The mean age at time of testing was 29 hours after birth. Hunter *et al.* (2010) reported that with normalization of middle ear function, reflectance values decreased during the first four days after birth, and proposed that high reflectance values in neonates are indicative of conductive pathology.

Infants were included in the current study if they passed DPOAE screening, which implies an absence of significant conductive pathology. However, it is possible that neonates may have passed DPOAE testing while presenting with minimal conductive pathology (Baldwin, 2006). Minimal outer and middle ear pathology may therefore have played a role in the higher reflectance values reported in the present study. It is for this reason that Aithal *et al.* (2014) and Shahnaz *et al.* (2014) added more stringent measures of middle

ear function, namely 1 kHz tympanometry and TEOAE. Hunter *et al.* (2010) attributed high reflectance values at regions involving 2 kHz to middle ear pathology.

Shahnaz (2008) reported mass element control conduction of the high-frequency response of the middle ear. Therefore, if the mass of the middle ear is higher for neonates than for one month old infants, more incident energy will be reflected and less will be absorbed at high frequencies (Shahnaz, 2008). The overall maturation of the middle ear might result in an increase in mass at birth, which gradually decreases as infants become older. If the middle ear is mass dominated in early infancy and in preterm neonates, it can affect the conduction of higher frequencies to the cochlea. The impedance of the neonatal middle ear is dominated more by mass than by stiffness (Holte *et al.*, 1991). It is possible that the mass dominated middle ear systems of the preterm neonates in the current study resulted in higher reflectance values compared to full term infants tested by Hunter *et al.* (2010) from birth to four months.

Thirdly, the instruments used in the various studies differed. Both the equipment and calibration procedures for the WAI measurements in the present study differed from that used by Aithal *et al.* (2013). Aithal *et al.* (2013) used Reflwin, developed by Interacoustics A/S in Denmark. However, the Mimosa WAI system used in the present study was also used by Hunter *et al.* (2010) and by Shahnaz *et al.* (2008). Equipment choice is therefore unlikely to have played a contributing role in the difference in WAI results. Calibration methods and different ear tips used for the two systems could

have contributed to the observed differences between the studies (Merchant *et al.*, 2010).

Lastly, a tight probe fit should be ensured for accuracy of WAI measurements. The reflectance response is sensitive to the quality of probe fit which, in turn, affects the energy being reflected or absorbed (Aithal *et al.*, 2012). Keefe *et al.* (2000) used negative equivalent volume to verify the seal only during the recording of results. This method reported that 13% of neonates had a poor acoustic seal. A hermetic seal was often difficult to obtain because of the small size of the ear-canal opening Keefe *et al.* (2000) and Feeney and Sanford (2005) noted that a poor probe tip seal allows for loss of energy in the low frequency portion of the stimulus and decreases reflectance measured in the ear canal (Hunter *et al.*, 2008). This is in contrast to the present study, since very high reflectance values were present at frequencies below 1 kHz. This suggests that poor probe fit was not the cause of high reflectance values at low frequencies. Nevertheless, probe fit should be checked during data acquisition using either visual display of results or equivalent volume to determine adequate seal.

Finally, concerning inherent background noise in the NICUs, it is possible that the noise levels influenced WAI test results, as was reported by Shahnaz (2008). The overall A-weighted noise level in the NICU was measured as 65 dB SPL by Shahnaz (2008). WAI values below 450 Hz were therefore excluded in their study. The present study did not measure noise levels in the NICUs, which can be regarded as a shortcoming. It is therefore possible that external noise levels present during WAI testing might have resulted in the elevated reflectance values. However, this is only likely to have been the case

for the low frequency reflectance values measured in the current study and does not account for the high reflectance levels between 0.5 and 3 kHz and above 4 kHz. WAI results obtained from the present study are similar to results from participants reported as possibly presenting with conductive pathology in a study by Sanford *et al.* (2009). This may indicate that WAI measurements in preterm neonates cannot be used to effectively differentiate between ears with conductive pathology and those without. WAI measurements may provide data to suggest that many newborn hearing screening referrals are a consequence of transient conditions affecting the sound conduction pathway. However, further research on preterm neonates with confirmed conductive pathology is required.

3.9　Conclusion

The data from the current study identified WAI patterns that had not previously been reported in the literature.　High reflective values were obtained across all frequency ranges especially in the low frequency ranges below 3 kHz and in the high frequency range above 4 kHz. The age of the neonates when tested might have influenced the results. The neonates of the present study were very young preterm neonates compared to the ages of neonates in previous studies. WAI measurements on at-risk preterm neonates in the NICU were variable with environmental and internal noise influences. Transient and/or maturational conditions affecting the sound conduction pathway may have influenced the results. Additional research is required to investigate WAI testing in ears with and without confirmed outer and/or middle ear dysfunction.

4 DISCUSSION AND CONCLUSION

4.1 Summary of Results

Normative WAI regions were defined across the wideband reflective spectrum for both tone and chirp stimuli and for integrated frequency ranges. The chirps and tone stimuli compared relatively well with each other at the 90th percentile with the same amount of reflectance across all frequencies. However, when comparing it to data from well babies large deviations were visible in the low frequency range. The median reflectance reached a minimum of 0.67 at 1-2 kHz but increased to 0.7 below 1 kHz and 0.72 above 2 kHz for the tone stimuli. For chirp stimuli the median reflectance reached a minimum of 0.51 at 1-2 kHz but increased to 0.68 below 1 kHz and decreased to 0.5 above 2 kHz. If the data on median reflectance of the present study are compared to those from the study of Aithal *et al.* (2013), similar reflectance values are found to be present in the mid frequency range of 3-4 kHz. In the low frequency ranges below 3 kHz and in the high frequency range above 4 kHz, however, the present study shows much higher reflectance values if compared to those reported by Aithal *et al.* (2013).

In the study by Hunter *et al.* (2010) reflectance values were defined over various frequency regions for both tone and chirp stimuli, which was also done in the present study. The results obtained by Hunter *et al.* (2010) indicated that tone and chirp stimuli reflectance values are essentially indistinguishable. In the present study, both tone and chirp stimuli indicated high power reflectance values below a frequency of 1.5 kHz.   Median reflectance

reached a minimum of 0.67 at 1-2 kHz but increased to 0.7 below 1 kHz and 0.72 above 2 kHz for the tone stimuli. For chirp stimuli the median reflectance reached a minimum of 0.51 at 1-2 kHz but increased to 0.68 below 1 kHz and decreased to 0.5 above 2 kHz.

According to the study by Shahnaz *et al.* (2014), the WAI results for newborns tested at one month intervals up to six months of age indicated that power reflectance increased at low frequencies (<400Hz) and decreased at high frequencies (>2000 Hz) as a function of age. If the results of the present study are compared to the results from Shahnaz *et al.* (2014), power reflectance decreases at high frequencies (>2000 Hz) for the 50th and 10th percentile. In the present study, high reflectance values were obtained at low frequencies (<800 Hz) at the 50th percentile, but decreased at low frequencies (<800 Hz) at the 25th and 10th percentile, indicating that age does play a significant role in results obtained from wideband acoustic immittance measurements.

4.2   Clinical implications and recommendations

The findings of the current study imply that in preterm neonates it was not possible to differentiate between ears with and without middle ear pathology using WAI. WAI has the potential to be a feasible measure of outer and middle ear function if conducted in the proper environment. It is a measure that shows great promise as an adjunct test for middle ear assessment in newborn hearing screening programmes. It could be a useful tool in prioritising neonates for further diagnostic evaluation (Aithal, 2015). WAI using ambient pressure may be advantageous because the highly compliant ear canal in newborns could lead to inaccurate results when pressurized for

standard immittance testing (Holte, 1991). Newborns with high reflectance hearing screening scores should be rescreened because most middle ear problems are transient and resolve spontaneously.

4.3   Critical evaluation

The reference standard used to determine middle ear status might have been a limitation of the present study. The present study used DPOAE measurements to determine the presence/absence of outer and middle ear pathology whereas previous studies by Aithal *et al.* (2013), Hunter *et al.* (2010) and Shahnaz *et al.* (2014) used a combination of DPOAE, TEOAE, and low frequency and high frequency tympanometry as a reference standard. Middle ear pathology may have been overlooked by using DPOAE only.

Further possible limitations might have been the age of the infant sample as well as the size of the infant sample. In a study by Hunter (2010), nearly 500 ears were included in the statistical analysis. Only 106 ears were included in the present study. Aithal *et al.* (2013) conducted their research on full-term neonates with a mean gestational age of 38.7 weeks (SD= 5.01, range: 36-42 weeks). Shahnaz (2008) also conducted research on NICU neonates as did the present study, but with a mean gestational age of 37.8 weeks (range: 32-51 weeks) and not earlier than three weeks before discharge, compared to the premature neonates of the present study (mean age at testing 35.6 weeks, range: 32-37 weeks) who were much younger.

It was not always possible to obtain a tight probe seal in the infants. In some circumstances, the probe had to be removed and reinserted more than once

to achieve a good seal during the test. This process had the potential to disturb the well settled neonate. Thus, the equipment used can be seen as a possible limitation affecting the results of the study as well as the test order in which the tests were conducted. Test order was kept constant with DPOAE done first, followed by AABR and then WAI. Because test order was not counter-balanced, this could potentially affect results if the probe location moved between tests. The environment in which the measurements were conducted was not optimal. Noise levels in NICU environments are typically high.

4.4 Suggestions for further research

Further research is recommended using equipment that allows all tests (e.g. DPOAE and WAI) to be performed using a single probe. It is suggested that further research be conducted on larger sample sizes and in a quiet room or once the neonate has been discharged. Future studies that collect normative data should aim to break down results by age by randomly assigning neonates to be tested at particular times or repeat testing over time in different environments. Objective measures such as air and bone conduction ABR should be incorporated to further refine the application of WAI (Shahnaz, 2008). The addition of a cost analysis would provide additional information regarding the feasibility of WAI use in NICU. In addition, future studies could explore the predictive value of WAI measures in NICU neonates.

4.5 Conclusion

The results of this study revealed WAI patterns that had not been previously reported in the literature.   High reflective values were obtained across all

frequency ranges especially in the low frequency ranges below 3 kHz and in the high frequency range above 4 kHz. Age of the neonates when tested might have influenced the results. The preterm neonates of the present study were very young compared to the ages of neonates in previous studies. WAI measured in at-risk preterm neonates in the NICU was variable with likely environmental and internal noise influences. Transient and/or maturational conditions affecting the sound conduction pathway may have influenced the results. Additional research is required to explore WAI testing in ears with and without confirmed outer and/or middle ear dysfunction.

Wideband acoustic immittance might be an appropriate measure for investigating conductive conditions in neonates. Finally, there is no gold standard for evaluating outer/middle ear function in neonates.

5   ACKNOWLEDGEMENTS

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APPENDIX A

Cover Letter for Informed Consent:

English and Afrikaans

Date:

Dear Parent/Caregiver,

RE: Neonatal Hearing Screening in the Neonatal Intensive Care Unit (NICU) as part of a Research project.

We are researchers at the Department of Communication Pathology at the University of Pretoria and are conducting research in Neonatal Intensive Care Units (NICUs) to identify middle ear pathology in premature neonates by using different hearing screening technologies. Hearing loss is estimated to affect one in every 1,000 newborns. Various causes for hearing loss can be identified but a known risk factor for hearing loss includes premature birth necessitating a stay in the neonatal intensive care unit. Universal newborn hearing screening is a way to identify hearing impaired newborns with or without risk factors and have become routine and even mandated in many countries around the world. If hearing loss is not recognized and managed, a child's speech, language and cognitive development are often severely delayed. According to various researches early-identified children (prior to 6 months) have better outcomes in all areas of their development. An admission to the neonatal intensive care unit (NICU) for more than two days may increases the likelihood of the presence of hearing impairment 10 fold.

How will my child's hearing be screened?

Currently two screening methods are used in NICUs to identify possible hearing impairment in at-risk neonates. These screening methods are automated auditory brainstem response (AABR) and distortion product otoacoustic emissions (DPOAE) tests. Both of these methods are totally objective and physiological meaning that no response is required from the infant. Both tests are approved by the Health Professions Council of South Africa (HPCSA). With both tests a soft sound is presented into your baby's ear but different responses are measured to give an indication of the functioning of your baby's hearing system. These tests will not hurt or harm your baby. Although AABR and DPOAE screening methods are most widely used, false-positive test results do occur. Both AABR and DPOAE can be influenced by outer- and middle-ear conditions like amniotic fluid, vernix, debris and motion artefacts. Otitis Media with effusion (OME) is one of the major reasons for failure of neonatal hearing screening especially in neonatal intensive care unit (NICU) populations that are already at an increased risk of permanent hearing loss. In conjunction with AABR en DPOAE an alternative test such as wideband acoustic immittance (WAI) used together with DPOAE and AABR have shown promise to identify conductive contributors to screen failures to promote timely diagnosis and subsequent intervention.

How long is the test?

The test session which will include all tests (three tests) mentioned above will vary between 15 and 30 minutes depending on your baby's state and the noise levels in the unit. It is best if your baby is asleep or in a quiet state while the screening test is being done. Both ears will be tested.

When will the results be available?

The results will be available immediately and you are welcome to ask any questions regarding the test results or your baby's hearing if you wish. You are also welcome to be present while the tests are conducted.

What happens if my baby does not pass the test?

If your baby does not pass the hearing screening test in both ears, you will be informed and an appointment will be made to repeat the screening. If your baby does not pass the second hearing screening in both ears, he/she will be referred to a reputable Audiology practice were intensive diagnostic testing will be done in order to identify the degree and nature of the possible hearing loss as well as referral to an Ear, Nose and Throat (ENT) specialist if needed. Based on these diagnostic results appropriate intervention plans will be established.

What happens if my baby passes the test?

Even if your baby passes the hearing screening test it is important to continue monitoring him/her as hearing loss may sometimes develop over time. Certain conditions like, mumps, measles, rubella and even recurrent middle-ear infections may influence your child's hearing.

As soon as you become aware of your child having difficulty hearing in the future please have his/her hearing assessed at your nearest clinic, hospital or audiology practice.

Confidentiality

A record of your baby's hearing screening results will be stored on a computer database. This information will only be made available to the audiologists who may be involved in testing your child's hearing (if applicable) and to the researchers. All information will be treated as confidential and your baby's name will not be used since each participant will be assigned an identifying code which will be used for all data processing. Results may be published in a journal article and thesis report but no identifying information will be used at any time.
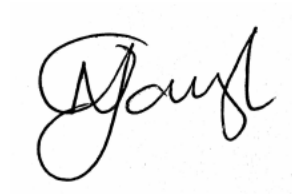
Voluntary participation

We would like to invite you to participate in this study. You may withdraw at any time after the study has begun and you do not have to provide an explanation for withdrawing from the study. If you withdraw, your baby's treatment will not be affected in any way. Your baby's hearing will still be screened if you wish, but the results will not be used in this study.

If you agree to have your baby's hearing screened as part of this study, please sign the informed consent area on your child's test form. Please note that all data will be stored for 15 years at the University of Pretoria for research and archiving purposes.

For any further information, you can contact me at: 083 653 8285

Sincerely,

Ms. Nandel Gouws

Audiologist

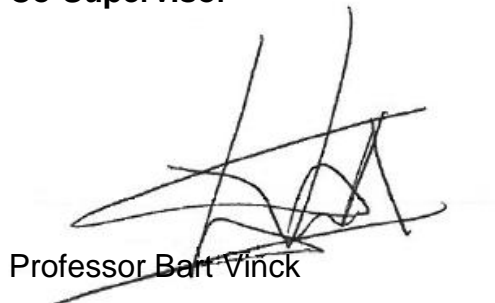**M.Communication Pathology Student**

Professor De Wet Swanepoel

Project Supervisor

Dr. Leigh Biagio de Jager, PhD

Co-Supervisor

Professor Bart Vinck

HEAD: Department of Speech-Language Pathology and Audiology

Datum:

Geagte Ouer/Versorger,

INSAKE: Neonatale gehoorsifting in die Neonatale Intensiewe Sorgeenheid as deel van 'n navorsings projek

Ons is navorsers by die Departement Kommunikasiepatologie, Universiteit van Pretoria, en gaan navorsing doen in Neonatale Intensiewe Sorgeenhede. Ons wil graag die uitkomste van resultate vergelyk wanneer ons babas se gehoor met verskillende tegnologieë sif .Gehoorverlies affekteer bykans een in elke 1,000 pasgebore babas wêreldwyd. Verskeie redes vir gehoorverlies kan geidentifiseer word maar 'n bekende risiko faktor vir gehoorverlies sluit in premature geboorte wat opname in die Neonatale Intensiewe Sorgeenheid vereis. Universele Neonatale gehoorsifting is 'n manier om gehoor gestremde pasgebore babas met of sonder risikos vir gehoorverlies te identifiseer. Indien gehoorverlies nie vroegtydig geidentifiseer word nie, kan aspekte soos u baba se spraak, taal en kognitiewe ontwikkeling erg benadeel word. Verskeie navorsing het bewys dat indien 'n baba met 'n gehoorverlies vroeg geidentifiseer word (voor 6 maande) die uitkomste beter is in alle areas van hul ontwikkeling. Die opname in die Neonatale Intesiewe Sorgeenheid vir meer as twee dae kan die voorkoms van 'n moontlike gehoorverlies tot tien keer verhoog.

Hoe sal my baba se gehoor gesif word?

Die toetse wat gebruik word om babas se gehoor te sif word distorsie produk oto-akoestiese emissies (DPOAEs) en ouditiewe breinstamresponse (OBR) genoem. Beide toetse word aanvaar en aanbeveel deur die HPCSA (Health Professions Council of South Africa). Met beide toetse word 'n sagte klank in u baba se oor gespeel maar die respons word op verskillende maniere gemeet om 'n aanduiding te gee van die funksionering van u baba se gehoorsisteem. Die toetse is nie seer nie en sal nie enige ongemak veroorsaak nie. Alhoewel (OBR) en (DPOAE) siftingsmetodes mees algemeen gebruik word, is daar die risiko vir vals-positiewe resultate. Beide OBR en DPOAE kan beinvloed word deur buitenste en middel-oor toestande soos vrugwater, vernix en bewegings artifarkte. Otitis Media met effusie is een van die hoof redes waarom babas nie die neonatale gehoorsifting slaag nie, veral die populasie in die Neonatale Intensiewe Sorgeenheid wat reeds 'n verhoogde risiko het vir permanente gehoorverlies. In samewerking met (OBR) en (DPOAE) word een alternatiewe toetse naamlik "wideband acoustic immittance" (WAI) gebruik om konduktiewe faktore te elimineer en moontlik 'n meer akkurate diagnose so gou as moontlik te bepaal en die slaagsyfer van neonatale gehoorsifting te verhoog.

Hoe lank neem die toets?

Die toets sessie wat alle bogenoemde toetse (drie toetse) en administrasie insluit sal wissel tussen 15 en 30 minute afhangend van u baba se toestand. Dit sal die beste wees indien u baba slaap of in 'n baie rustige toestand is tydens die toetsing. Beide ore sal getoets word.

Wanneer sal die resultate beskikbaar wees?

Die resultate sal dadelik aan u bekend gemaak word en u is welkom om die persoon wat die toets uitvoer enige vrae te vra rakende die resultate.

Wat sal gebeur indien my baba nie die gehoorsifting slaag nie?

U sal ingelig word indien u baba nie die gehoorsifting in albei ore slaag nie. Dit is dan belangrik om so gou as moontlik 'n afspraak te maak sodat die siftingstoets herhaal kan word. As u baba die tweede sifting in albei ore nie slaag nie, sal hy/sy verwys word vir na 'n betroubare Oudiologie praktyk vir 'n volledige diagnostiese gehoorevaluasie om te bepaal of u kind 'n gehoorverlies het, asook na n Oor, Neus en Keel arts (ONK) indien nodig. Sou daar 'n gehoorverlies bestaan, sal toepaslike besluite geneem word om u baba se gehoorverlies en taalontwikkeling aan te spreek.

Wat beteken dit as my baba die gehoorsifting slaag?

Indien u baba die gehoorsifting slaag is dit steeds belangrik om sy/haar gehoor te monitor aangesien gehoorverlies kan ontwikkel soos wat kinders ouer word. Sekere siekte toestande soos masels, duitse masels, pampoentjies en selfs herhaalde middel oor ontsteking kan u kind se gehoor beinvloed. Sou u in die toekoms bewus word daarvan dat u kind gehoorprobleme ervaar moet u dadelik 'n afspraak maak by u naaste hospitaal, kliniek of oudiologie praktyk sodat u kind se gehoor weer getoets kan word. Dit is belangrik om gehoorverlies so gou moontlik te identifiseer sodat hulp verskaf kan word en u kind se taal kan ontwikkel.

Vertroulikheid/Konfidensialiteit

Rekord van u baba se gehoorsifting sal bewaar word op 'n rekenaardatabasis. Hierdie inligting sal slegs beskikbaar gemaak word aan die oudioloë wat moontlik betrokke kan wees by toekomstige gehoortoetse (indien van toepassing) en aan die navorsers. 'n Unieke kode word aan elke deelnemer toegeken vir dataverwerking en u baba se naam sal nie bekend gemaak word nie - alle inligting sal as streng vertroulik hanteer word. Die resultate van die studie kan moontlik in 'n finale verslag en/of joernaalartikel gepubliseer word maar geen identifiseerbare inligting sal daarin bevat word nie.
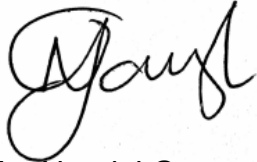
Vrywillige deelname

Ons wil u uitnooi om deel te neem aan die studie. U kan op enige stadium besluit om te onttrek van die studie en hoef nie 'n rede te verskaf nie. Sou u onttrek, sal dit nie u baba negatief affekteer nie. U baba se gehoor sal steeds gesif kan word, sou u dit so verkies, maar die resultate sal dan nie vir die studie gebruik word nie.

Indien u instem om u baba se gehoor te sif as deel van hierdie studie, moet u asseblief die "ingeligte toestemming" vorm teken. Neem asb kennis dat alle data vir 'n periode van 15 jaar by die Universiteit van Pretoria gestoor sal word vir navorsings- en argiefdoeleindes.

Vir enige verdere navrae kan u my gerus skakel by 083 653 8285

Byvoorbaat dankie,

Me. Nandel Gouws

Oudioloog

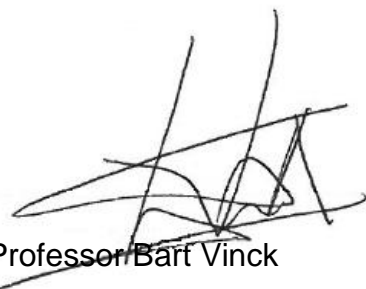**M.Kommunikasiepatologie Student**

Professor De Wet Swanepoel

Studieleier

Dr. Leigh Biagio de Jager, PhD

Mede studieleier

Professor Bart Vinck

HOOF: Departement Spraak-Taal Patologie en Oudiologie

APPENDIX B

Informed Consent Form: English and Afrikaans

Faculty of Humanities

Department of Speech, Language Pathology and Audiology

UNIVERSITY OF PRETORIA

Department Communication Pathology

INFORMED CONCENT FORM

Wideband Acoustic Immittance for Assessing Middle Ear Functioning for preterm neonates in the NICU	

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

Name of Infant	
Age of Infant	
Gender: Male/Female	
Test date	

I have received information about the study and have also had the opportunity to ask questions regarding the project and also received answers to any questions I may have asked. I hereby agree to have my baby participate in this project and acknowledge that the data will be used for research purposes. I am aware that I can withdraw my baby from this project at any time, should I wish. No harm will be done to my baby and his/her hearing will not be damaged in any way.

_____

Signature

Department of Speech, Language Pathology and Audiology

UNIVERSITEIT VAN PRETORIA

Departement Kommunikasie Patologie

INGELIGTE TOESTEMMING VORM

"Wideband Acoustic Immittance for Assessing Middle Ear Functioning for preterm neonates in the NICU"

Voltooi asseblief die volgende:

Naam van baba	
Ouderdom van baba	
Geslag: Manlik/Vroulik	
Toets datum	

Ek het inligting ontvang oor die studie en het ook die geleentheid gehad om vrae te vra rakende die projek. Ek het antwoorde ontvang op my moontlike vra. Ek gee hiermee toestemming dat my baba mag deelneem aan die projek en besef dat die resultate gebruik gaan word as deel van 'n navorsingsprojek. Ek is bewus dat ek enige tyd my baba kan onttrek van die projek indien ek dit so sou verkies. My baba se gehoor sal op geen manier beskadig word nie en hy/sy sal geen pyn of ongemak verduur nie.

_____

Handtekening

APPENDIX C

Data Collection Sheet / Test Form

Faculty of Humanities

Department of Speech, Language Pathology and Audiology

DATA COLLECTION SHEET/TEST FORM

Infant's details:

Patient ID:	
D.O.B	
Gender:	Male/Female
Screening date:	
Audiologist	

High Risk register for hearing loss:

Family History	y/n	Prematurity (weeks)	y/n
Retinitus Pigmentosa	y/n	Low birth weight ( )	y/n
Prenatal Health	y/n	Hyperbilirubinea	y/n
Mechanical Ventilation	y/n	Feeding disorder	y/n
Central Nervous System Disorder	y/n	Congenital infection	y/n

Other:_____

Results:

DPOAE		AABR		WAI	
Left	Right	Left	Right	Left	Right

Recommendations:

Follow-up Screening ASAP	y/n
Diagnostic Testing	y/n
Follow-up at 6 months	y/n
Follow-up at 1 year	y/n

APPENDIX D

Letter from Private Audiology Practice

Mariet du Plooy Oudioloë/Audiologists
Sedert / Since '89

diagnostiese
oudioloë

diagnostic
audiologists

◆ e-pos/e-mail:
audiology@lantic.net
hearinginbalance@gmail.com

**Praktyke –
Practices**

◆ 501 (5de vloer - 5th floor)
MEDFORUM HOSP.
hv/co Schoemanstr &
Nelson Mandelaweg / dr
Arcadia, Pretoria
(T) 012 320 8460
(T) 012 320 0258/9
(F) 012 322 0342

◆ Suite 16 (grond / ground)
PRETORIA OOS / EAST
HOSPITAAL / HOSP.
Garsfonteinryln / dr
Moreletapark, Pretoria
(T) 012 422 2696/606
(F) 012 993 4194

◆ G10 (grond / ground)
CURAMED KLOOF HOSP.
Jochemusstr. 511
(Rigel afrit/offramp, N1)
Erasmuskloof X3, Pretoria
(T) 012 367 4280
(F) 012 367 4319

◆ Suite 6 (vloer 1 - floor 1)
BROOKLYN CHIRURG.
SENTR. / SURG. CNTR.
Brooklyn Sirkel, Pretoria
(T) 012 320 8460
(F) 012 322 0342

**Dienste –
Services**

◆ Diagnostiese Oudiologie
Diagnostic Audiology
◆ Pediatriese Oudiologie
Pediatric Audiology
◆ Elektrofisiologiese toetsing
Electrophysiological testing
◆ Neonatale gehoorsifting
Neonatal hearing screening
◆ Medies geregt. Oudiologie
Medical legal Audiology
◆ Industriële Oudiologie
Industrial Audiology
◆ Balans funksie toetse (VNG)
Balance function tests (VNG)
◆ Stemterapie
Voice therapy
◆ Gehoorapparate
Hearing Aids

Date: October 2012

To whom it may concern,

Ms. Nandel Gouws has been an Audiologist at this practice since September 2009. She is currently enrolled as a Masters Postgraduate student in Audiology at the University of Pretoria. I hereby give permission that she may use results obtained from the Neonatal Hearing Screening program that my practice conducts at three private hospitals in Pretoria, Gauteng for her research purposes, if prior informed consent is received from all relevant parties.

Yours sincerely,

Mariet

Mariet du Plooy

Audiologist

Mariet du Plooy Oudioloë/Audiologists Ing./Inc. Reg. Nr./No: 1998/10305/21   PR. Nr./No: 8207011   HPCSA Reg. Nr./No: STA 0010227

APPENDIX E

Ethical Clearance Letter

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

1 October 2012

Dear Prof Swanepoel

Project:	**Wideband reflectance and high frequency tympanometry in at-risk infants – a comparative study**
Researcher:	**N Gouws**
Supervisor:	**Prof DCD Swanepoel**
Department:	**Sociology**
Reference number:	**10433920**

Thank you for your response to the Committee's letter of 5 September 2012.

I have pleasure in informing you that the Research Ethics Committee formally **approved** the above study at an *ad hoc* meeting held on 1 October 2012. 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 your actual research depart significantly from the proposed research, it will 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: Research Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: john.sharp@up.ac.za

Research Ethics Committee Members: Dr L Blokland; Prof M-H Coetzee; Dr JEH Grobler; Prof KL Harris; Ms H Klopper; Prof A Mlambo, Dr C Panebianco-Warrens; Prof J Sharp (Chair); Prof GM Spies; Prof E Taljard ; Dr FG Wolmarans, Dr P Wood