1. INTRODUCTION, BACKGROUND AND RATIONALE

The aim of this chapter is to present the effects of hearing loss as rationale to hearing screening and the need to develop standardized procedures and criteria for differentiating middle ear effusion from sensorineural hearing loss in early infancy. A breakdown of all the chapters included will also be provided.

1.1 INTRODUCTION

> *"With the rapid implementation of universal newborn hearing screening (UNHS) programs, there is a need for a test of middle-ear function to distinguish sensori-neural hearing loss from middle ear pathology."* (Margolis, Bass-Ringdahl, Hanks, Holte & Zapala, 2003:384)

Hearing loss is often described as an invisible condition as it offers no obvious indications and is often asymptomatic. It may merely be overlooked or be mistaken for developmental delay or attention deficit disorder (Hogan, Stratford & Moore, 1997:350; Roush, 2001:3). Permanent hearing loss in infants almost always affects the development of speech and language and may leave them with deficits in the ability to communicate with an effective language system (Roush, 2001:3; Rossetti, 1996:35; Mauk & White, 1995:6). Furthermore, eighty percent of a child's ability to develop speech, language and related cognitive skills is established by the time the child is thirty-six months of age, with hearing being vitally important for the healthy development of such skills. Therefore hearing loss can result in impaired academic achievement and social-emotional development (Luterman 1999:41; JCIH, 2000:798,800; Northern & Downs, 2002:81). The degree of hearing loss, age of identification and intervention and each individual's unique characteristics interact to determine

the consequences of a hearing loss. In general, the greater the degree of hearing loss, the greater the implication for oral language development (Roush, 2001:18; Luterman, 1999:107).

The negative consequences of severe bilateral sensorineural hearing loss, have long been recognized, but it has only been in recent years that the damaging consequences of mild bilateral and unilateral sensorineural hearing loss, or *conductive* hearing loss have been realised (Mauk & White, 1995:6). Persistent conductive hearing loss, often caused by the presence of middle ear effusion, is common in infants. Untreated chronic middle ear effusion, although rare, can result in serious medical complications including cholesteatoma, meningitis, and sensorineural hearing loss (Roush, 2000:18). Conductive hearing loss secondary to middle ear effusion early in life, may impact on the development of auditory processing skills, and understanding of speech in the presence of competing noise. The relationship between middle ear effusion and communication skills has been well documented (Northern & Downs 2002:66). It is also recognized that persistent or recurrent middle ear effusion has potentially detrimental long-term consequences, especially for children already experiencing communicative disorders related to learning disabilities or developmental delays (Roush, 2001:19). Bearing this in mind, early detection, diagnosis, and habilitation of hearing loss, both sensorineural and conductive, is crucial to forestall delays in speech, language and general development (JCIH, 2000:798; Koivunen, Uhari, Laitakari, Alho and Luotonen, 2000:216; Luterman, 1999:35).

1.2 BACKGROUND

Research has shown that children who are identified with hearing loss, and given appropriate intervention before six months of age, maintain language development consistent with their cognitive abilities (Yoshinaga-Itano, 2001). The positive outcomes of early identification and management of hearing loss in infants, has lead to the development of Early Hearing Detection and Intervention Programs (EHDI) (JCIH, 2000:799; Northern & Downs, 2002:259).

In the USA, according to the Joint Committee on Infant Hearing (JCIH, 2000:798), all infant's hearing should be screened using objective, physiologic measures in order to identify those with congenital or neonatal onset hearing loss and such procedures should be in progress with identification of hearing loss by three months of age and intervention initiated by six months of age.

Newborn hearing screening protocols typically include the use of Otoacoustic Emmission (OAE) and Automated Auditory Brainstem Response (AABR) procedures to detect hearing loss (Kei, Allison-Levick, Dockray, Harrys, Kirkegard, Wong, Maurer, Hegarty, Young and Tudehope, 2003:21; Mencher *et al.* 2001:4; Roush, 2001:50; JCIH, 2000:802). OAEs (low-intensity sounds emitted by the ear that can be detected by a sensitive microphone placed in the ear canal) can be recorded reliably in response to auditory stimuli (Roush, 2001:49). The AABR reflect electrical activity of the VIIIth (auditory) nerve and brainstem, in response to auditory stimuli (Roush, 2001:60; Martin & Clark, 2000:165). ABR screenings are usually performed using automated instruments, reporting a pass or refer result after comparing acquired responses to normal ABR responses stored in computer memory (Roush, 2001:61).

However, successful recording of OAEs and AABR responses not only require a healthy cochlea and intact auditory nerve, but also *necessitates normal or near normal middle ear functioning* (Roush, 2001:50; Fowler and Shanks, 2002:202; Koivunen *et al.,* 2000:212; Sutton, Gleadle and Rowe, 1996:10; Thornton, Kimm, Kennedy and Cafarelli-Dees, 1993:319). The recording of OAEs from neonates and infants can also be influenced and affected by external and middle ear pathology leading to 'false positive' test results (Thornton *et al.,* 1993:322).

False positive test results refer to ears with normal underlying hearing but who do not have sufficiently strong OAE and / or ABR responses at the time of the newborn hearing screening test (Keefe, Zhao, Neely, Gorga and Vohr, 2003:389, Roush, 2000:19). OAE and ABR results are known to be sensitive to outer ear canal obstruction and middle ear effusion, causing temporary

conductive dysfunction. Transient middle ear dysfunction can cause high false-positive test outcomes in the presence of normal cochlear function (Keefe *et al.,* 2003:389; Doyle, Burggraaff, Fujikawa, Kim and MacArthur, 1997:598; Sutton *et al.,* 1996:9; Thornton *et al.*, 1993:319).

It is clear therefore that the results of OAE and auditory brainstem response testing depend, to a large extent, on the condition of the middle ear. Abnormal middle ear functioning can be a major reason for failure of neonatal hearing screening (Sutton *et al.,* 1996:9). As universal screening for hearing in infants develops, it becomes increasingly important to distinguish and separate middle-ear pathology from pathology of the cochlea and brainstem to ensure appropriate follow-up procedures are initiated (Fowler & Shanks, 2002:202). As transient middle ear dysfunction may be more prevalent in neonatal and infant ears than cochlear or sensori-neural hearing losses, there is a critical need for a better understanding of middle ear functioning in neonates and infants (Keefe, Folsom, Gorga, Vohr, Bulen & Norton, 2000:443).

A key contributing factor on the condition of the middle ear and in turn on the outcome of OAE and ABR test procedures is the presence of middle ear effusion (Yeo, Park, Park & Suh, 2002:798; El-Refaie, Parker & Bomford, 1996:3; Wada, Ohyama, Kobayashi, Koike and Noguchi, 1995:162; Thornton *et al.,* 1993:319; Trine, Hirsch & Margolis, 1993:401). MEE is characterized by fluid in the middle ear without evidence of infection. A number of synonyms are used to describe this condition, including serous otitis, secretory otitis, nonsuppurative otitis, fluid ear and middle ear effusion (MEE) (Northern & Downs, 2002:75). As OAEs are transmitted from the cochlea to the ear canal via the middle ear, the transmission properties of the middle ear directly influence the OAE characteristics (Yeo *et al.,* 2002:794). Middle ear effusion (MEE) has a very high prevalence, affecting nearly all children at least once during the early months or years of life (Northern & Downs, 2002:65; Roush, 2001:11; Hogan *et al.*, 1997:350). In contrast, sensorineural hearing loss occurs far less frequently with an incidence of approximately three per 1000 for all newborn infants (Roush, 2001:20).

MEE creates a mild to moderate conductive hearing loss that averages 20 dB, but can be as great as 50 dB (Hogan *et al.*, 1997:350; Northern & Downs, 2002:66). The fluctuating hearing loss caused by MEE, which is often recurrent, can lead to the inability to hear short unstressed words and low intensity speech sounds, distortion of sound and inconsistent auditory reception (Northern & Downs, 2002:66). Unlike acute episodes of middle ear disease, which are readily apparent from pain and other overt symptoms, non-infected middle ear fluid and hearing loss are often overlooked without appropriate screening procedures (Roush, 2001:14, Hogan *et al.,* 1997:350).

In the clinical setting MEE is generally identified and diagnosed by means of an array of examinations and electrophysiological test-procedures. These include otoscopic examination, pneumatic otoscopy, acoustic immittance measures, and Otoacoustic emissions (Casselbrant, Gravel, Margolis & Marchisio, 2002:95; Roush, 2001:35; Koivunen *et al.,* 2000:212). Acoustic immittance measures, specifically tympanometry, have proved over the years to be the best single audiologic procedure for assessing middle ear functioning (Hall & Mueller, 1997:177). Added advantages of acoustic immittance measures when acoustic reflexes are also recorded include the possibility for differential diagnosis between middle ear, cochlea, eighth nerve and lower auditory brainstem pathology (Hall & Mueller, 1997:177). Acoustic immittance measurements have evolved from a specialty procedure, to a fundamental and routine part of the audiological test battery (Wiley & Fowler, 1997:1). Its contribution to clinical diagnosis has become well accepted as an objective tool for diagnosing middle ear pathologies (Fowler & Shanks, 2002:175; Petrak, 2002:1; Palmu, Puhakka, Rahko & Takala, 1999:178). The high sensitivity of acoustic immittance measures in screening for middle ear disorders forms the basic rationale for the use of such measures in screening protocols (Roush, 2001:66; Wiley & Fowler, 1997:1).

Acoustic immittance refers to acoustic admittance or acoustic impedance of the middle ear structures, or both (Wiley & Stoppenbach, 2002:161; Wiley & Fowler, 1997:1). Acoustic impedance and admittance are reciprocal terms. Admittance

is the ease with which sound energy flows through the acoustic middle ear system, whereas impedance refers to the opposition to the flow of energy (Wiley & Stoppenbach, 2002:161; Hall & Mueller, 1997:178; Wiley & Fowler, 1997:22). An acoustic transmission system, such as the human ear, that offers high acoustic admittance to the flow of sound has low acoustic impedance. Although both terms have been used to describe acoustic measures of middle ear function, current commercially available acoustic immittance instruments typically provide measures of admittance (Wiley & Stoppenbach, 2002:161). Clinical admittance measures can be broadly separated into two general areas: tympanometry and acoustic reflex measures (Wiley & Stoppenbach, 2002:168). Tympanometry and recording stapedius reflexes for acoustic signals are the two procedures that form the primary set of acoustic immittance measurements used in most audiology clinics (Wiley & Fowler, 1997:1). As previously mentioned, acoustic immittance measures are sensitive to middle ear pathologies and require no behavioral response on the part of the patient. Thus, the measures can be obtained in clinical patients for whom behavioral response techniques are not always feasible, such as very young children.

Tympanometry involves measures of the acoustic admittance in a hermetically sealed ear canal as air pressure is varied above (+) and below (-) atmospheric level in the ear canal (Wiley & Fowler, 1997:2). In tympanometry the mobility of the tympanic membrane is measured while the membrane is exposed to an acoustic energy, commonly referred to as the probe tone (Gruber, 2002:1; GSI-TympStar Manual, 2002). In the ear, the tympanic membrane is mechanically coupled with the middle ear ossicles to the oval window; the interface between the middle and inner ear. It is this entire system (membrane, middle ear and oval window) that is forced into oscillation when tympanometric measurements are being performed (Gruber, 2002:1). The probe unit provides the acoustic signal (probe signal) that serves as the reference for acoustic immittance measures. For the vast majority of instruments, the probe signal is a tone of a specified frequency and sound pressure level. Since the sound pressure level of the probe tone within the ear canal varies as a function of mobility, it is possible to record these changes in mobility as a function of pressure (Wiley &

Fowler, 1997:8). Currently there are instruments that provide for multiple probe frequencies (i.e. 226 Hz, 678 Hz, 1000 Hz).

The most commonly used probe tone in conventional tympanometry has been a 226 Hz probe signal (Fowler & Shanks, 2002:175; Roush, 2001:67). This probe tone has some definitive advantages when testing the adult ear as the adult middle-ear system is stiffness-dominated (compliance) at this frequency and the effects of mass and friction are minor (Kei *et al.,* 2003:21; Fowler & Shanks, 2002:187; Petrak, 2002:1; Purdy & Williams, 2000:9). However when higher probe tone frequencies are used, the middle ear no longer acts as a mass-controlled system and mass components, particularly of the eardrum and ossicles, become more significant (Fowler & Shanks, 2002:187; Meyer *et al.*, 1997:192). It has been found that tympanograms collected from infant ears progress differently than those collected from adult ears especially when a low frequency probe tone is used (Keefe *et al.,* 2000:444; Purdy *et al.,* 2000:9; Palmu *et al.,* 1999:207; Meyer *et al.,* 1997:190; Sutton *et al.,* 1996:10; Holte, Margolis & Cavanaugh, 1991:20).

A review of the literature reveals that there is controversy and debate among professionals at which age tympanometry becomes reliable for detecting MEE in infants (Northern & Downs, 2002:80; Purdy & Williams, 2000:9; Meyer *et al.,* 1997:189). The choice of probe tone, most sensitive to the detection of MEE, is also not fully agreed on (Northern & Downs, 2002:80; Fowler & Shanks, 2002:187; Petrak, 2002:2; Purdy *et al.,* 2000:9; Meyer *et al.,* 1997:189). For some years it has been recognised that conventional low-frequency probe tone tympanometry is inappropriate for infants below 7 months of age, because of poor sensitivity and high false positive as well as false negative results (Petrak, 2002:1; Purdy & Williams, 2002:9; Sutton, 2000:1; Meyer *et al.,* 1997:189).

Studies have shown that infants below four months of age may demonstrate what appear to be normal 226 Hz tympanograms with confirmed MEE, and abnormal tympanograms in normal ears (Purdy & Williams, 2000:9; Paradise et al, 1976 in Meyer *et al.,* 1997:189; Keefe *et al.*, 1996:372). It was originally

believed that infant ear canal walls were so compliant that a movement of the entire wall occurred that imitated the type A-tympanograms (Holte *et al*., 1991:20). The reason for false positive and false negative results are unclear although it has been speculated that the anatomical differences of the adult and infant middle ear transmission system, may be contributory factors (Petrak, 2002:2; Keefe & Levi, 1996:362; Meyer *et el.,* 1997:190; Holte *et al.,* 1991:20). During development of the infant ear, several anatomical changes take place, which influence the mechanical properties of the ear canal. These changes in acoustic response have been attributed to these physical changes in the external and middle ear after birth by some researchers (Meyer *et al*, 1997:190; Keefe & Levi, 1996:362).

1.3 RATIONALE

A number of studies have shown that there may be a better correlation between the presence of middle ear effusion and the shape of the tympanogram when a high-frequency probe tone is used in young infants (Kei *et al.,* 2003:27; Keefe *et al.,* 2000:461; Meyer *et al.,* 1997:194; Sutton *et al.,* 1996:15). Thornton *et al.* (1993:320) found that the percentage of successful admittance measurements obtained using a 226 Hz probe frequency was 68%, but when a 1000 Hz probe tone was used, this figure rose to 87%. Meyer *et al.,* (1997:194) and Sutton *et al.,* (1996:10) supports the argument that a high frequency probe tone is able to identify the presence of pathology that is unrecognized by conventional 226 Hz tympanometry. In a study by LaRossa, Mitchell and Cardinal (1993:34) 226 Hz tympanometry results were not repeatable or reliable in identifying MEE in infants in the Neonatal Intensive Care Units. According to Petrak (2002:2) a higher frequency probe tone is needed to collect tympanograms that will be useful in identifying middle ear effusion in infants. Other research comparing high frequency tympanometry to OAE and/or auditory brainstem response results (Rhodes, Margolis, Hirsch & Napp, 1999:806; Hirsch, Margolis & Rykken, 1992:181) indicates better sensitivity to conductive pathology for 678 Hz and 1000 Hz tympanograms than conventional low frequency probe tone tympanometry.

Despite the advantages of high frequency tympanometry in identifying mass-related middle ear pathology, high frequency / multi-frequency probe tones are not commonly used. The major barrier to incorporating high-frequency tympanometry into the routine test battery is that the measures are more complex and not as easily understood as 226 Hz tympanograms (Fowler & Shanks, 2002:186). There are no accepted guidelines on classifying, interpreting high-frequency tympanograms or validated criteria for distinguishing normal from abnormal tympanograms in infants (Petrak, 2002:1; Purdy & Williams, 2000:9; Sutton *et al.,* 1996:11). According to Petrak (2002:2) and Sutton (2000:2), as further research continues to support high frequency tympanometry, the best choice for a tympanometric probe frequency in infants under four months of age is 1000 Hz. Currently there are still many questions regarding the sensitivity and specificity of 1000 Hz tympanometry to the presence of MEE in infants (Purdy & Williams, 2000:24). To date, there is no universal normative data classification system in place for high frequency probe tone measures, as for the 226 Hz probe tone in adults (Petrak, 2002:2). Normative values have mainly been determined for adults and children from three to sixteen years of age (Palmu *et al.*, 2001:178). Thus there is a dearth of research on tympanometry in infants, especially those with the highest risk and incidence of otitis media, i.e. those under 2 years of age (Sininger 2003:380; Northern & Downs, 2002:80; Palmu *et al.,* 2001:178). Fowler and Shanks (2002:202) emphasize the need for additional studies on infants with normal ears and confirmed middle ear pathology before guidelines can be established for the reliable use of high frequency tympanometry in distinguishing normal from pathologic ears in this population. In a recent study by Kei *et al.* (2003:20), characteristics of 1000 Hz tympanograms for neonates with normal Transient Evoked OAEs, and a single peaked admittance tympanogram, were described. This may serve as a guide for detecting middle ear effusion in infants.

As newborn hearing screening programs are rapidly expanding, a need exists for a simple and objective method to evaluate and interpret middle ear status in infants. As previously mentioned, the results of otoacoustic emissions and auditory brainstem responses depend on the condition of the middle ear.

Middle ear pathology must therefore be separated from pathology of the cochlea and brainstem for appropriate follow-up and referrals (Fowler and Shanks, 2002:202). According to Kei *et al.,* (2003:27) there is potential for high frequency tympanometry to be utilized in neonatal hearing screening programs to identify possible middle ear dysfunction. It may also serve to decrease the number of infants in which a definite audiological diagnosis is delayed due to chronic MEE.

1.4 PROBLEM STATEMENT

"Because transient middle-ear dysfunction may be more prevalent in neonatal ears than cochlear or sensorineural hearing losses, there is a critical need for a better understanding of middle-ear functioning in neonates" (Keefe *et al.,* 2000:443). Tympanometry is effective in identifying various forms of middle ear dysfunction, and can be used to help interpret OAE and ABR measurements in the same ear (Keefe *et al.,* 2000:444). It has been suggested that because middle ear effusion is likely to reduce or eradicate OAEs and elevate AABR thresholds, it may be a major reason for failure of neonatal hearing screening in infants and account for much of the false positive results (Sutton *et al.,* 1996:16).

Conventional tympanometric measurement in neonatal ears has been found to be unreliable due to anatomical differences between the adult and infant ear (Petrak, 2002:2; Purdy & Williams, 2000:9; Palmu *et al.,* 1999:207; Meyer *et al.,* 1997:190; La Rossa, Mitchell & Cardinal, 1993:32). Tympanometry using a higher frequency probe tone appears to overcome this problem. However validation of high frequency probe tone tympanometry for measuring middle ear status in neonates and young infants has not yet been established (Fowler & Shanks, 2002:175; Sutton *et al.,* 1996:10).

1.5 DIVISION OF CHAPTERS

A description of the sections included in this study is provided in Table 1.1.

TABLE 1.1 Outline and description of chapters

CHAPTER 1	**INTRODUCTION, BACKGROUND AND RATIONALE**
	Chapter one provides a background and rationale for the present study and highlights the need for a clinical tool to differentiate between conductive and sensori-neural hearing loss in early infancy.
CHAPTER 2	**CRITICAL REVIEW OF MIDDLE EAR ASSESSMENT IN INFANTS**
	Chapter two provides an overview of the structures involved in the assessment of the middle ear system. Knowledge thereof, and a thorough understanding of the principles of immittance measures, is essential to critically evaluate the procedures currently used for the assessment of the infant middle ear. Included is a comparison of the advantages and disadvantages of these methods.
CHAPTER 3	**RESEARCH METHODOLOGY**
	A detailed description of the methodological approach and research design followed during this study will be given. A description of the sample, materials and apparatus used, procedures used for assembling and analysing data will be discussed.
CHAPTER 4	**RESULTS AND DISCUSSION**
	The results obtained from the empirical research will be presented in accordance with the main- and sub-aims formulated for the study. The findings of this study will be discussed within the broader framework outlined in the first three chapters. Present results will be compared to other studies.
CHAPTER 5	**CONCLUSIONS AND RECOMMENDATIONS**
	The study will be concluded by a summary of the significant findings. This chapter will also include a critical evaluation, the clinical implications and recommendations of this study.

1.6 DEFINITION OF TERMS

A definition of the most important terms relevant to the context of this study is provided in Table 1.2.

TABLE 1.2 Terminology list

IMMITTANCE	Measures of acoustic impedance (opposition to flow of energy) or acoustic admittance (ease with which energy flows) within the middle ear system. Refers to both tympanometry and recording of stapedial reflexes.
TYMPANOMETRY	Measures of a) opposition to energy flow or b) ease of energy flow in the ear canal as a function of changes in air pressure. Performed by introduction of an acoustic signal and measurement of sound pressure level of the signal in the ear canal as pressure is varied above (+) and below (-) atmospheric pressure.
ACOUSTIC REFLEX	Stapedial muscle reflex, elicited in response to an acoustic signal of sufficient intensity, which causes an increase in acoustic impedance measured at the eardrum.
PROBE TONE	A continuously delivered signal into the ear by the probe speaker. Acoustic immittance in analysed by monitoring of probe-tone sound pressure level in the ear canal by means of the probe microphone. Low (226 Hz) or high (678 / 1000 Hz) tones can be used to measure middle ear mobility. *A 1000 Hz probe tone was utilized for tympanometry and acoustic reflex measurements during this study.*
PEAK ADMITTANCE	The point of maximum mobility on a tympanogram which indicates the degree of energy flow within the middle ear system. In the current study this was measured at the point of maximum positive deflection on the tympanogram.
TYMPANOMETRIC PEAK PRESSURE	The pressure value where maximum mobility occurs (peak of the tympanogram) and which approximates pressure within the middle ear space. In the current study this was measured at the corresponding peak admittance point.

TABLE 1.2 continued…

ACOUSTIC SUSCEPTANCE (B_a)	Interaction between compliance elements and mass elements of a system. Susceptance is positive at lower frequencies when a system is stiffness-controlled and negative when it is controlled by mass at higher frequencies. Recorded simultaneously as G_a tympanograms in the current study and analysed in terms of peak admittance and tympanometric peak pressure. Number of extrema also determined and shape classified as mass or stiffness dominated.
ACOUSTIC CONDUCTANCE (G_a)	Relates to the impact of friction elements on susceptance and refers to the resistance to energy flow. Recorded simultaneously as B_a tympanograms in the current study and analysed in terms of peak admittance and tympanometric peak pressure. Number of extrema also determined and shape classified as mass or stiffness dominated.
ACOUSTIC ADMITTANCE (Y_a)	Represent ease of flow of acoustic energy and is determined by susceptance (B) and conductance (G) components of the middle ear system. Peak admittance and tympanometric peak pressure values obtained from Y_a tympanograms used for compilation of normative values.

1.7 SUMMARY

Chapter one has provided an orientation and rationale for the current study by presenting relevant information on the effect of middle ear effusion on general development and the necessity for inclusion of a test for middle ear function as part of a screening protocol. The lack of research in the literature in the area of high frequency immittance in infants has been highlighted and considered in the formulation of the rationale and problem statement for the study. An outline of the chapters to follow has been included.

2. CRITICAL REVIEW OF MIDDLE EAR ASSESSMENT IN INFANTS

The main aim of this chapter is to provide an overview of the controversies surrounding the assessment of the infant middle ear. An outline of the structures involved in the assessment of middle ear functioning, the physics underlying middle ear measurements, and the developmental changes that occur in the infant middle ear will be reviewed. Based on this theoretical foundation, current methods for assessment of middle ear functioning in infants will be critically reviewed in support of the search for an accurate, objective test method.

2.1 INTRODUCTION

The accurate assessment of middle-ear status in newborns and young infants is becoming increasingly important due to the widespread implementation of universal newborn hearing screening (UNHS) programs. Newborn hearing screening initiatives and legislation for implementation thereof has received extensive attention in research and in practice over the past ten years. In the 1994 Position Statement, the Joint Commission on Infant Hearing endorsed the goal of universal detection of infants with hearing loss and encouraged continuing research to develop and to improve methodologies for identification and intervention of hearing loss (JCIH, 1994:3). This was extended by the Year 2000 Position Statement, which stated that all infants' hearing should be screened using *objective, physiologic measures* in order to identify those with congenital or neonatal onset hearing loss (JCIH, 2000:6). The targeted hearing loss for UNHS programs was defined by the JCIH as, "permanent bilateral or unilateral, sensory or conductive hearing loss, averaging 30 – 40 dB or more in the frequency region important for speech recognition (approximately 500 through 4000 Hz)" (JCIH, 2000:7). Current newborn hearing screening protocols typically include the use of Otoacoustic Emissions (OAE) and

Automated Auditory Brainstem Response (AABR) procedures to detect hearing loss in infants (Keefe *et al.,* 2003:389; Kei *et al.,* 2003:21; Mencher *et al.* 2001:5; Roush, 2001:58,63; JCIH, 2000:7; Koivunen *et al.,* 2000:212). However, successful recording of these measures *necessitates normal or near normal middle ear functioning* and can therefore be affected by middle ear pathologies or temporary conductive dysfunction, not otherwise detected (Fowler & Shanks, 2002:122; Roush, 2002:19; Yeo *et al.,* 2002:797; Koivunen *et al.,* 2000:212; Sutton, *et al.,* 1996:9; Thornton *et al.,* 1993:319). Hence, a significant issue in newborn hearing screening programs is the problem of false positive test results, referring to ears with normal hearing that do not have sufficiently strong OAE and/or ABR responses at the time of the newborn screening test.

A widely held view is that middle ear dysfunction, most often transient in nature during the neonatal and perinatal periods, is responsible for such false-positive outcomes (Keefe *et al.,* 2003:389). False-positive test results can have costly financial implications due to unnecessary follow-up and re-testing expenses. For developing countries this may have a significant impact on sustaining newborn screening programs. Margolis, Bass-Ringdahl, Hanks, Holte and Zapala (2003:384), also highlight this point, stating that there is an urgent need for a test of middle ear function in infants to distinguish sensorineural hearing loss from middle ear pathology in order to (a) identify screening fails caused by transient external- or middle ear conditions, (b) to determine the need for medical management of middle ear disease and (c) to determine the need and timing of follow-up procedures such as auditory brainstem response testing.

As acoustic immittance measurements can objectively identify, and are sensitive to, middle ear disorders, it is widely used in audiologic assessment procedures (Palmu *et al.,* 1999:207; Wiley & Fowler, 1997:116). Since acoustic immittance measurement is not a behavioural test, is not time consuming, is non-invasive, and is relatively easy to administer, it can be used to assess middle ear functioning in the difficult-to-test and paediatric population (Wiley & Fowler, 1997:2; Silman & Silverman, 1991:71). However, the clinical utility of

tympanometry to assess middle ear functioning has been clearly established for all populations except infants less than 6 months of age (Fowler & Shanks, 2002:186; Meyer *et al.,* 1997:190; Holte, Margolis & Cavanaugh, 1991:1). More recent research has aimed to provide clarification on the issue of middle ear assessment in infants (Kei *et al.,* 2003:27, Margolis *et al.,* 2003:391, Meyer *et al.,* 1997:193, Sutton *et al.,* 1996:15). However, due to the underlying difficulties in assessment of the infant ear, there are still no clear guidelines and generally accepted standards or norms for assessment of the infant middle ear. These issues and underlying fundamentals of the assessment of the infant middle ear will be reviewed in the following sections.

2.2 CURRENT ISSUES IN THE ASSESSMENT OF MIDDLE EAR FUNCTIONING IN INFANTS

Objective measurement of middle ear function continues to be refined and currently technology offers the opportunity for improved diagnosis of middle ear disorders by using multi-frequency and multi-component tympanometry (Lilly, 2005:6). Can tympanometry however be used reliably in the assessment of the infant middle ear? This has been questioned extensively in literature dating back from the 1970's, when Paradise, Smith and Bluestone (1976, in Meyer *et al.,* 1996:189) were the first to cast suspicion over tympanometric use with infants younger than seven months. These authors found that normal tympanograms could co-exist with confirmed middle ear effusion when a conventional low frequency probe tone is used.

Research has consistently demonstrated that tympanograms collected from infant ears progress differently than those collected from adult ears and that the acoustic response of the external and middle ear systems vary significantly over the first years after birth (De Chicchis, Wendell Todd & Nozza, 2000:101; Holte *et al.,* 1991:2; Keefe & Levi, 1996:363; Meyer *et al.,* 1997:194; Petrak, 2002:2). As an answer to the question of the most suitable probe tone for infant middle ear measures, contradictory results were reported in earlier research. Holte *et al.,* (1991:23) concluded that the probe tone frequency of choice for infants

below four months of age is 226 Hz because it is least affected by individual maturational differences and tympanometric patterns are more interpretable than at higher frequencies. In contrast, Meyer *et al*., (1997:194) reported that the use of a high frequency probe tone may have greater diagnostic sensitivity to middle ear pathology than conventional 226 Hz tympanometry.

Attempts to explain contradicting and varying results have been made, as is seen in Keefe and Levi, (1996:367) and Keefe *et al.,* (2000:444) who noted that a confounding factor in neonatal tympanometry is that the introduction of positive or negative pressure into the neonatal ear canal, increases or decreases the ear-canal volume, respectively, and due to extremely compliant ear canal walls in the infant ear, this in turn affects acoustic immittance measurements. Similar results were obtained by Holte *et al.,* (1991:21) who indicated that prior to one month of age, many tympanograms recorded in the negative to positive (- / +) direction of air pressure change resulted in ear canal collapse and subsequent uninterpretable tympanograms. This was overcome and avoided by the use of a positive to negative (+ / -) direction of air pressure change. As a result, recording in the + / - direction was recommended as an important procedural step in tympanometry in infants (Holte *et al.,* 1991:21).

It is evident therefore, that the choice of probe tone for performing tympanometry in neonates was not fully agreed on. However, a number of studies have shown that there may be a better correlation between the presence of middle ear effusion and the shape of the tympanogram when a high-frequency probe tone is used in young infants (Kei *et al.,* 2003:27; Keefe *et al.,* 2000; Purdy & Williams, 2000:10; Meyer *et al.,* 1997:194; Marchant *et al*., 1984:593), and in recent year it has become widely accepted that conventional tympanometry is not an effective test for middle ear function in young infants (Kei *et al.,* 2003:21; Lantz, Petrak & Prigge, 2004:3; Marchant, McMillan, Shurin, Johnson, Turczyk, Feinstein & Panek, 1984:594; Margolis *et al.,* 2003:384; Sutton *et al.,* 1996:9,10).

Evidence of this is seen in Thornton *et al.* (1993:320) who found that the percentage of successful admittance measurements obtained using a 226 Hz probe frequency was 68%, but when a 1000 Hz probe tone was used, this figure rose to 87%. Meyer *et al.,* (1997:194) and Sutton *et al.,* (1996:10) support the argument that a high frequency probe tone is able to identify the presence of pathology that is unrecognized by conventional 226 Hz tympanometry.

There is increasing interest in high frequency tympanometry, motivated by the need to have an objective test of middle ear function in newborn hearing screening programs. More research is however needed to establish the reliability and validity of high frequency tympanometry for assessment of the infant middle ear system, and to establish guidelines and norms for accurate interpretation of results (Purdy & Williams, 2000:22). In order to understand this controversy and the respective effects of low versus high frequency probe tone immittance measures on infant middle ear assessment, knowledge of the fundamental underlying physics and anatomical background of the infant ear is required. The anatomical structures and developmental changes, relevant to the assessment of the infant middle ear, will therefore be reviewed in the following sections.

Knowledge of the underlying structures and physical principles involved in acoustic measures of middle ear functioning is fundamental to understand the assessment of the infant middle ear and the questions surrounding it. The following section provides this information.

2.3 ANATOMICAL STRUCTURE AND PHYSIOLOGY RELEVANT TO THE ASSESSMENT OF THE INFANT MIDDLE EAR

Anatomical differences between the infant and adult middle ear transmission system have been regarded as the reason for the varying acoustic responses, and this has also been regarded as the reason for high false positive and false negative results when using conventional tympanometry in the infant population

(Petrak, 2002:2; Meyer *et al.,* 1997:190; Keefe and Levi, 1996:361; Holte, *et al.,* 1991:1).

2.3.1 Middle ear structure and function

The middle ear is part of an interrelated system including the nose, nasopharynx, Eustachian tube and mastoid cavities. The close communication of the middle ear with these surrounding structures impacts on both the cause of middle ear disease and the assessment thereof (Silman & Silverman, 1991:128). The middle ear itself consists essentially of the tympanic membrane and the middle ear cavity, which contains the three middle ear ossicles and is essential in the clinical diagnosis of middle ear pathologies (Martin & Clark, 2000:251).

The middle ear, or tympanic cavity, is a small air-filled, mucosa-lined cavity within the petrous portion of the temporal bone. It is flanked laterally by the tympanic membrane and medially by a bony wall with two openings, the superior oval (vestibular) window and the inferior round (cochlear) window. The superior boundary of the epitympanic recess forms the 'roof' of the middle ear cavity. The middle ear space contains a mechanical system composed of three ossicles, the *malleus, incus and stapes*, which collectively transmit the mechanical energy of sound from the tympanic membrane to the fluid-filled inner ear via the oval window (Marieb, 1995:527; Martin & Clark, 2000:251). During development of the infant ear, several physical changes take place, which influence the mechanical properties of the ear canal. Various authors regard these as contributory factors to tympanometry outcome differentials in adult and infant populations (Petrak, 2002:2; Holte *et al.,* 1991:2; Silman & Silverman, 1991:121). The factors include

- An increase in size of the external ear, middle ear cavity and mastoid. A typical ear-canal diameter for a one month old infant is 4,4 mm compared with 8mm for an adult (Keefe & Levi, 1996:362). The stiffness component of the middle ear is largely determined by the

tympanic cavity volume and it is postulated that there is an overall decrease in stiffness with an increase in cavity size and maturation (Meyer *et al.,* 1997:190).

- Decrease in the overall mass due to changes in bone density and gradual loss of mesenchyme clinging to middle ear ossicles (Meyer *et al.,* 1997:190). The osseous portion of the ear canal is not completely formed until about 1 year of age. As previously mentioned pressurising the ear canal may result not only in movement of the tympanic membrane, but also in distension of the ear canal walls (Holte *et al.,* 1991:2).

- Change in the orientation of the tympanic membrane. The eardrum in the infant ear canal is orientated at a flatter angle with respect to the ear-canal axis (Keefe & Levi, 1996:362).

- Tightening of the ossicular joints and close coupling of the stapes to the annular ligament results in changes in resistance (Meyer *et al.,* 1997:190).

- Early changes include the fusing of the tympanic ring. This process involves mechanical changes, which influence the tympanogram shape in neonates.

2.3.2 Tympanic membrane

The tympanic membrane forms the boundary between the external auditory canal and middle ear cavity and is therefore the most visible structure of the middle ear. The membrane is a thin, translucent, connective tissue membrane, covered by skin on its external face and by a mucosa lining internally. It is shaped like a flattened cone, with its apex protruding medially into the middle ear. It has both a tense portion *(pars tensa)* as well as a smaller, more flaccid portion known as *pars flaccida* (Roush, 2001:5; Marieb, 1995:527). The

orientation of the structures of the tympanic membrane and middle ear changes from infancy to adulthood. The infant tympanic membrane is almost horizontal, the lateral process of the malleus is most prominent and the pars flaccida is thicker and more vascular. Conversely the adult membrane is more vertical, has a less prominent lateral process of the malleus, and the pars flaccida appears more vascular (Roush, 2001:36). When sound waves enter the external meatus, the tympanic membrane moves in response to incoming sound waves and transmit the vibratory patterns to the middle ear ossicles (Marieb, 1995:528). Pathological conditions, such as middle ear effusion, affect the movement of the ossicles and in turn that of the tympanic membrane, causing a decrease in the transmission capability.

2.3.3 Eustachian tube and its relation to middle ear function

The middle ear space behind the tympanic membrane in a healthy ear is normally filled with air. This air space connects to the nasopharynx (the superior-most part of the throat), by the Eustachian tube running obliquely downward to link the middle ear cavity with the nasopharynx. In an adult, the tube is between 30mm and 40mm in length and comprises one-third bone at the middle ear end and two-thirds cartilage. The adult Eustachian tube lies in a relatively vertical position providing protection for the middle ear. (Marieb, 1995:528). In contrast, an infant Eustachian tube is short, horizontal and composed of relatively flaccid cartilage. The nearly horizontal position for the infant's Eustachian tube allows for retrograde reflux of bacteria from the nasopharynx into the middle ear (Northern & Downs, 2002:65). Because transient middle ear dysfunction is more prevalent in neonatal ears than cochlear or sensorineural hearing losses, there is a need for a better understanding of the middle ear functioning in neonates. In the following section a brief review of the functioning of the Eustachian tube will be given.

The Eustachian tube is thought to have a number of functions of which the most important is that of equalizing the pressure between the middle ear and the external air pressure, and to ventilate the middle ear system (Wiley & Fowler,

1997:67). The mucosa of the middle ear absorbs oxygen from the contained air thereby reducing the middle ear pressure. The Eustachian tube facilitates the passage of air from the nasopharynx to replace the absorbed oxygen. The Eustachian tube opens momentarily during swallowing, yawning or jaw movements (active opening) or if the pressure gradient existing between the aural and pharyngeal cavities overcome the closing forces of the tube (passive opening). If, due to obstruction or dysfunction, the Eustachian tube is unable to open, air in the middle ear will be absorbed by the blood vessels in the lining of the middle ear (Northern & Downs, 2002:65). As no air is able to go up the Eustachian tube to replace the decreasing air in the middle ear, a vacuum develops. A non-functioning Eustachian tube may therefore lead to negative middle ear pressure resulting in retraction of the tympanic membrane. This will in turn cause fluid, which is normally secreted by the mucous membrane lining, to be sucked into the middle ear space resulting in the formation of middle ear effusion (Martin & Clark, 2000:255). This is known as serous otitis media and is often associated with middle ear disorders and conductive loss of hearing (Wiley & Fowler, 1997:68). As equalizing pressure changes in the middle ear cavity is the primary role of the Eustachian tube, the development of negative middle ear pressure can be viewed as a marker of Eustachian tube dysfunction (Palmu *et al.,* 2001:62).

The ability to equilibrate over- and under-pressure by swallowing or jaw movement has been shown to be poorer in children than adults and markedly poorer in infants. Poorer muscle control has been suggested as the reason for the reduced occurrence of opening of the Eustachian tube resulting in reduced pressure equalisation in children (Northern & Downs, 2002:65). Furthermore, due to the anatomical differences between the adult and infant Eustachian tube, as previously discussed, the higher incidence of middle ear disorders in the early years of life implies that Eustachian tube immaturity can be linked to the development of these disorders (Northern & Downs, 2002:65). A more detailed review of pathological conditions of the middle ear, linked to Eustachian tube dysfunction, will therefore be provided.

2.4 FACTORS AFFECTING MIDDLE EAR STATUS IN INFANTS

Middle ear effusion (MEE), otherwise known as otitis media with effusion (OME), is a common condition infants experience at some time during the early years of life (Northern & Downs, 2002:65; Roush, Drake & Sexton, 1992:63). The presence of middle ear effusion can cause persistent conductive hearing loss and although rare, untreated chronic otitis media can result in serious medical conditions such as cholesteatoma, meningitis, and sensorineural hearing loss (Martin & Clark, 2000:258).

As previously mentioned, the Eustachian tube plays an important role in the ventilation of the middle ear, and is often associated with the development of otitis media, when dysfunctional (Northern & Downs, 2002:71). *Otitis media*, or inflammation of the middle ear, is highly prevalent in young children, especially during the first two years of life (Northern & Downs, 2001:65; Roush, 2001:11). Although it has been classified in many ways, Roush (2001:11) describes two basic forms: *Acute otitis media* and *serous otitis media.* Other authors have included terms such as secretory, suppurative and non-suppurative otitis media (Northern & Downs, 2002:66; Martin & Clark, 2000:258; Hogan *et al.,* 1997:1).

Acute otitis media usually presents with sudden onset as the result of viral or bacterial agents invading the middle ear tissues, causing otalgia, fever and general discomfort. Acute otitis media often occurs during upper respiratory tract infections, as the mucous lining of the middle ear is continuous with that of the pharynx. Acute upper respiratory tract illnesses are frequently treated with prescription antimicrobials, and over use is known to occur, which is associated with the development and spread of bacteria with antimicrobal resistance. In the United States evidence-based guidelines to improve the judicious use of antimicrobial agents in children have been developed by the Centres for Disease Control and Prevention (Garbutt, Jeffe and Shackelford, 2003:143). In a study to assess compliance with the judicious use of antimicrobials in children with acute otitis media, Garbutt *et al.,* (2003:144) hypothesized that as acute otitis media accounts for 30% of all pediatric antimicrobial prescriptions, over

diagnosis of acute otitis media and over treatment with antimicrobials is thought to occur (Garbut *et al.,* 2003:143).

The second form, *Serous otitis media* or *otitis media with effusion (OME),* involves secretion of fluid from the mucous membrane lining of the middle ear. In contrast to acute otitis media, OME is generally characterized by non-infected (serous) effusion drawn into the middle ear cavity as a result of poor Eustachian tube function. Thus, OME is defined as inflammation of the middle ear with fluid present, but without obvious signs of ear infection (Roush, 2001:12). It is important to note that OME is more likely to escape detection than acute otitis media as it is usually asymptomatic, except for the temporary hearing loss caused by the middle ear effusion (Roush 2001:12).

The nature and prevalence of middle ear disorders is also of specific relevance to the implementation of newborn hearing screening programs, as these are among the most common diseases affecting young children (Roush *et al.,* 1992:63). As previously noted, objective measures used in newborn hearing screening (such as evoked otoacoustic emission or ABR testing) can be adversely affected by the presence of MEE (Kei *et al.,* 2003:384, Sininger, 2003:380, Thornton *et al.,* 1993:319) and can result in false positive referrals due to transient middle ear conditions (Margolis *et al.,* 2003:384. As noted by Trine, Hisrch and Margolis (1993:401), the middle ear is involved in the delivery of the evoking stimulus to the cochlea and in the transmission of the OAE to the ear canal. The recording of an otoacoustic emission therefore has a twofold dependence upon the transmission characteristics of the middle ear.

Estimates of prevalence of MEE in infants vary, but many studies substantiate that most children experience at least one episode of otitis media in early childhood with peaking in prevalence between 6 and 12 months of age (Northern & Downs, 2002:65; Gliddon & Sutton, 2001:77; Roush *et al.,* 1992:63). Gliddon and Sutton (2001:84) reported a rise in the prevalence of abnormal tympanometry from 2% neonatally to 39% at eight months of age. In view of the context of the current study it is important to note that race, birth

history and home environment has been identified as increased risk factors for otitis media (Woods, 2003:687; Gliddon & Sutton, 2001:78). There is also evidence that higher numbers of siblings, male sex and lower maternal socio-economic status are associated with more persistent MEE (Gliddon & Sutton, 2001:78). A study to determine prevalence of middle ear disorders in black children in a specific South African context has shown a prevalence of 13% among four to five year old children (Bhoola & Hugo, 1995:19); however as prevalence is known to be higher in the first years of life, an elevated incidence can be predicted in the infant population generally.

Identification of children with OME should therefore be one of the primary objectives of screening procedures to identify screening failures caused by transient external- or middle ear conditions, to establish the need for medical management and to determine the need and timing of follow-up procedures (Margolis *et al.,* 2003:384). As correct diagnosis dictates treatment, the Centres for Disease Control and Prevention (Garbut *et al.,* 2003:143) recommend the use of specific diagnostic criteria to prevent the over diagnosis and treatment of otitis media. These criteria include the presence of otorrhea of middle ear origin, or the presence of middle ear effusion and signs or symptoms of acute local or systematic illness. Pneumatic otoscopy is recommended to confirm the presence of middle ear effusion (Dowell, Marcy, Phillips, Gerber & Schwartz, 1998 in Garbutt *et al.,* 2003:143). Various other methods have also been employed to assess middle ear functioning and to aid in the diagnosis of otitis media. Questions regarding the reliability, suitability and merit of performing different methods of middle ear assessment on the infant ear have been raised in various reports (Casselbrant, Gravel, Margolis & Marchisio, 2002:95; Holte & Margolis, 2002:387; Kei *et al.,* 2003:21; Palmu *et al.,* 1999:207; Sininger, 2003:378). A critical review of methods of middle ear assessment, with specific relevance to assessment of the infant middle ear, will be given in the following section.

2.5 CRITICAL REVIEW OF MIDDLE EAR ASSESSMENT METHODS FOR INFANTS

"There is still no better, quicker, or less expensive single audiologic procedure for assessing the status of the middle ear, cochlea, eighth nerve, and lower auditory brainstem than performing a complete immittance test battery." Hall and Mueller (1997:177)

This classic quote by Hall and Mueller (1997:177) clearly points out that the most commonly used and reliable tool in the identification and diagnosis of middle ear pathology, is *acoustic immittance measures* (Holte & Margolis, 2002:387; Northern & Downs, 2002:210). Immittance measurement has widespread clinical use and has an established role in the audiological assessment of hearing and in the diagnosis of middle ear pathology (Palmu *et al.,* 1999:207).

In infant testing, however, use has been controversial as previously described. Alternative test methods and procedures have been investigated in an attempt to identify a test protocol with both high sensitivity (rate of correct classification for *affected* individuals) and specificity (rate of correct classification for *unaffected* individuals) in the diagnosis of middle ear effusion in infants. Factors, such as age and developmental status, state of alertness and available instrumentation also influence the selection of methods to assess middle ear functioning (Roush, 2001:33). Prior to a review of immittance measures, an overview of two other methods to establish middle ear status in infants, *otoscopy and Otoacoustic emission testing* will be described. Practical implications for their application in neonatal and infant populations are included.

2.5.1 Otoscopy

Visualisation of the major landmarks of the tympanic membrane and middle ear signs of external ear disease and canal obstruction can aid in the diagnosis of middle ear dysfunction (Roush, 2001:36). The tympanic membrane is the most visible structure of the middle ear, and is consequently the most important in making clinical judgements about middle ear disease via otoscopy (Govender,

1998:33). Sutton *et al.,* (2002:3), recommend that otoscopy should be carried out on all infants prior to tympanometry to rule out occlusion of the external auditory canal by wax, vernix or debris. However, otoscopic investigation is very difficult to perform in newborns and infants because the tympanic membrane is often obscured from view by vernix, the neonatal ear canal is very narrow, and the tympanic membrane has a different orientation and appearance (Gliddon & Sutton, 2001:78). Difficulty in visualizing the infant tympanic membrane is often also increased by lack of infant co-operation (Palmu *et al.,* 1999:208).

Assessment of otoscopic results relies purely on subjective evaluation, skill, and experience of the examiner (Govender, 1998:39). While disorders of the ear canal are often visible through otoscopic inspection, disorders of the middle ear are often not apparent based on otoscopic inspection of the tympanic membrane and thus, require more advanced evaluation techniques (Casselbrant *et al.,* 2002:388, Wiley and Fowler, 1997:11).

Pneumatic otoscopy allows application of positive and negative pressures in the ear canal to visually assess the movements of the tympanic membrane (Casselbrant *et al.,* 2002:95). In a study to determine the usefulness of pneumatic otoscopy in predicting middle ear effusion in children, Govender (1998:101), compared the sensitivity and specificity of pneumatic otoscopy and tympanometry as compared to myringotomy to confirm the presence of middle ear effusion. Results indicated that, when compared to myringotomy, pneumatic otoscopy showed good sensitivity (80%) and moderate specificity (60%) while tympanometry showed excellent sensitivity (96%) and good specificity (80%) (Govender, 1998:103). This finding is consistent with the reports of others who noted that tympanometry was more accurate than pneumatic otoscopy in detection of middle ear effusion (Casselbrant *et al.,* 2002:95; Govender, 1998:103; Holte & Margolis, 2002:388). Nozza *et al.,* (1994:310) also found that otoscopy alone had good sensitivity but only fair specificity. Roberts *et al.,* 1995 (in Gliddon & Sutton, 2001:78) found that inter-observer agreement was poor for pneumatic otoscopy during the first three

days of life, but that by 2 weeks it had returned to acceptable levels, suggesting that this test is not valid for use on very young infants.

Otoscopy therefore does not prove to be a sufficient single diagnostic indicator, which is both sensitive and specific, for the identification of middle ear effusion in infants and should be used as an adjunct to other screening procedures (DeConde Johnson, 2001:485). Furthermore, as middle ear effusion is most difficult to detect with otoscopy in the paediatric population (Pellet, Cox & MacDonald, 1997:181) and is a technique that requires significant experience for reliable interpretation of results, it is not always routinely performed on neonates (Northern & Downs, 2002:79). Therefore it is necessary to turn to other procedures for the assessment of middle ear functioning in the infant population. As OAEs are frequently used in newborn hearing screening programs, this proves a viable option to be reviewed as a method of middle ear assessment in addition to the assessment of hearing.

2.5.2 Otoacoustic Emissions (OAEs)

Successful recording of OAEs not only requires a normal functioning cochlea, but also necessitates normal or near-normal middle ear function (Koivunen *et al.,* 2000:212). Consequently present OAEs are a useful indication of normal middle ear function and transmission, whilst absent OAEs can be an indication of either a middle ear or a sensory pathology. When used in conjunction with ABR screening, the OAE becomes very useful, since the OAE is more sensitive to middle ear effusion than the ABR screening (El-Refaie *et al.,* 1996:7). Before being measured in the external auditory canal, all OAEs must pass through the middle ear and hence changes in sound conduction of the middle ear, such as middle ear effusion and negative pressure within the middle ear, affect the detection of otoacoustic emissions in the external auditory canal. This is due to the fact that the presence of middle ear effusion and negative pressure within the middle ear, changes elasticity and suppresses conduction of sounds through the middle ear (Yeo *et al.,* 2002:794). OAE measurement relies on the middle ear conductive mechanism first to transmit the stimuli to the inner ear

and then to convey the cochlear emissions, by way of reverse transmission, back into the ear canal where recording takes place (Yeo *et al.,* 2002:797, Sutton *et al.,* 1996:10). Middle ear effusion therefore affects OAEs both by reducing their transmission from the cochlea through the middle ear and by attenuating the stimulus reaching the cochlea.

Results of recent studies have confirmed that middle ear effusion affects the expression rate of Spontaneous OAEs, Transient evoked OAEs and Distortion Product OAEs and would aid in evaluating the middle ear condition. (Yeo *et al.,* 2002:798). Strong statistical significance has been found between abnormal tympanometry results and OAE failure (Thornton *et al.,* 1993:322; Sutton *et al.,* 1996:10). Casselbrant *et al.,* (2002:96) also pointed out that since some ears with MEE have minimal hearing loss, the presence of MEE reduces the specificity of OAEs as a screening technique for detection of significant hearing impairment. However, OAEs may be effective as a combined screen for middle ear disease and sensori-neural hearing loss.

Using OAEs as a combined test for middle ear functioning and cochlear integrity appears promising, yet, passing an OAE test cannot serve as a "gold-standard" (Kei *et al.,* 2003:26) for normal middle ear function as OAEs have been found to be present in ears with middle ear dysfunction in children and adults (Margolis *et al.,* 2003:385, Thornton *et al.,* 1993:320). Furthermore an absent recording of OAEs does not provide exact information regarding the degree or configuration of the hearing loss and is unable to differentiate between a pure sensory-neural hearing loss, and conductive hearing loss with underlying middle ear conditions, and consequently it is of limited value in the diagnosis of middle ear function when no OAEs are recorded (Koivunen *et al.,* 2000:216, Northern & Downs, 2002:234; Sininger 2003:380). Because transient middle-ear dysfunction may be more prevalent in neonatal ears than cochlear or sensori-neural hearing losses, there is a critical need for a better understanding of middle ear functioning in infants (Keefe *et al.,* 2000:443).

Although AABR and OAE testing are widely used in newborn hearing screening programs, they do not provide diagnostic information in their screening mode. ABR and OAE screening does not effectively distinguish between mild sensorineural hearing loss and conductive hearing loss. More complicated diagnostic ABR procedures that compare air-and-bone conduction can be used effectively to differentiate conductive hearing loss from sensorineural hearing impairment. However, the analysis time and level of expertise that this type of instrumentation demands of the user makes it too difficult, costly, and therefore inappropriate as a screening tool (Shahnaz, 2002:1). Furthermore, as previously mentioned passing an OAE test in the strictest sense, cannot guarantee normal middle ear function as OAEs have been found to be present in some ears with middle ear effusion (Kei *et al.,*2003:26; Thornton *et al.,* 1993:323). Therefore an objective method for middle ear assessment is essential for use in conjunction with OAE and AABR screening procedures for correct diagnosis and identification of otitis media.

As a test of middle ear function, immittance measurements have proven to be the best single diagnostic indicator for the identification of middle ear pathology Hall and Mueller (1997:177). Immittance measures have widespread clinical use and are established to accurately identify middle ear pathology in adults and older children (Palmu *et al.,* 1999:207). A review of immittance measurements, as a technique for middle ear assessment, will therefore be provided in the following section.

2.5.3 Immittance measurement

Immittance is a generic term that encompasses tympanometry and acoustic reflex measurements. Current commercially available immittance instrumentation measures acoustic admittance and / or its components, acoustic susceptance and acoustic conductance (Lilly, 2005:24). Tympanometry, as currently defined, refers to measures of acoustic admittance that are taken at various pressure points, and is an objective procedure used to evaluate the mechanical characteristics of the tympanic membrane and middle

ear as pressure changes are created in the ear canal (Roush, 2001:67). All determinations of middle ear function are indirectly made by measurements made in the plane of the tympanic membrane (Martin & Clark, 2000:152). These values are graphed to form a tympanogram (Fowler & Shanks, 2002:175).

Tympanometry and recording of acoustic reflexes are objective tests of tympanic membrane mobility, middle ear pressure and of brainstem auditory activation (Sininger 2003:37) and the primary rationale for the clinical use of immittance measures is that they are sensitive to middle ear disorders. Additionally an acoustic immittance procedure requires no behavioural response from the patient and is a feasible method of middle ear assessment in the infant population (Wiley & Fowler, 1997:2). Immittance measures have potential for improving diagnostic accuracy of otitis media in clinical practice, and have long been accepted as a reliable and valid method of assessing middle ear function in children above the age of approximately seven months of age, however, suspicion has been cast over the usefulness thereof for infants below this age in earlier reports (Gliddon & Sutton, 2001:78; Palmu et al., 2001:178; Purdy & Williams, 2000:9; Meyer et al., 1997:189, 190).

The following sections will expand on the current outlook, as found in recent literature, on the use of immittance measurements. The implications for the infant population will be reviewed with renewed interest in high frequency tympanometry. An in-depth discussion of the fundamentals of immittance is however necessary to evaluate its application in infants critically and this will follow in section 2.6.1. A discussion of the underlying physical and acoustic principles of acoustic immittance will also be included. Knowledge of the underlying structures and physical principles involved in acoustic measures of middle ear functioning is important to understand the assessment of the infant middle ear and the controversies surrounding it. These aspects are therefore reviewed in the following section.

2.6 CRITICAL REVIEW OF IMMITTANCE MEASUREMENTS: PRINCIPLES AND APPLICATION IN INFANTS

Developmental changes in the infant middle ear influence reliable and valid use of immittance measures in this population. In order to understand the effects of these developmental changes and other influencing factors, a discussion of the underlying physical and acoustic principles of acoustic immittance is provided in the subsequent sections.

2.6.1 Fundamentals and principles of acoustic immittance measurements

Acoustic immittance is a collective term that is used to describe the transfer of acoustic energy, whether measured in terms of acoustic admittance (flow of energy, Y_a) or acoustic impedance (opposition to the flow of acoustic energy, Z_a) or both terms (Ferekidis, 2003:59; Roush, 2001:66; Wiley & Fowler, 1997:1,8; Silman & Silverman,1991:71,77). The character of the energy system under measurement is signified by the associated term, *acoustic*, and is indicated by the subscript, *a*, appended to each abbreviation *(*Wiley & Stoppenbach, 2002:161; Wiley & Fowler, 1997:8). Acoustic admittance (Y_a) refers to the *ease* with which sound energy flows through an acoustic system, while acoustic impedance (Z_a) refers to the *opposition* to the flow of sound. Acoustic admittance and impedance are direct reciprocals and therefore if an acoustic transmission system, such as the human middle ear, has a high acoustic admittance, it has low acoustic impedance. Conversely if the middle ear has a low acoustic admittance, it has high acoustic impedance (Wiley & Stoppenbach, 2002:161; Wiley & Fowler, 1997:1). Both terms have been used to describe acoustic measurements of middle ear function, although current commercially available acoustic immittance instruments typically provide measures in terms of acoustic admittance (Wiley & Stoppenbach, 2002:161; Shahnaz, 2002:1; Roush, 2001:66; Wiley & Fowler, 1997:7; Jerger & Northern, 1980:1). An example of how impedance and admittance tympanograms are graphically recorded and illustrated by current commercially available

tympanometers is given in Figure 2.1. Note that because impedance and admittance are reciprocal quantities, the phase relations are reversed, and therefore a mirror image is obtained (Fowler & Shanks 2002:163).

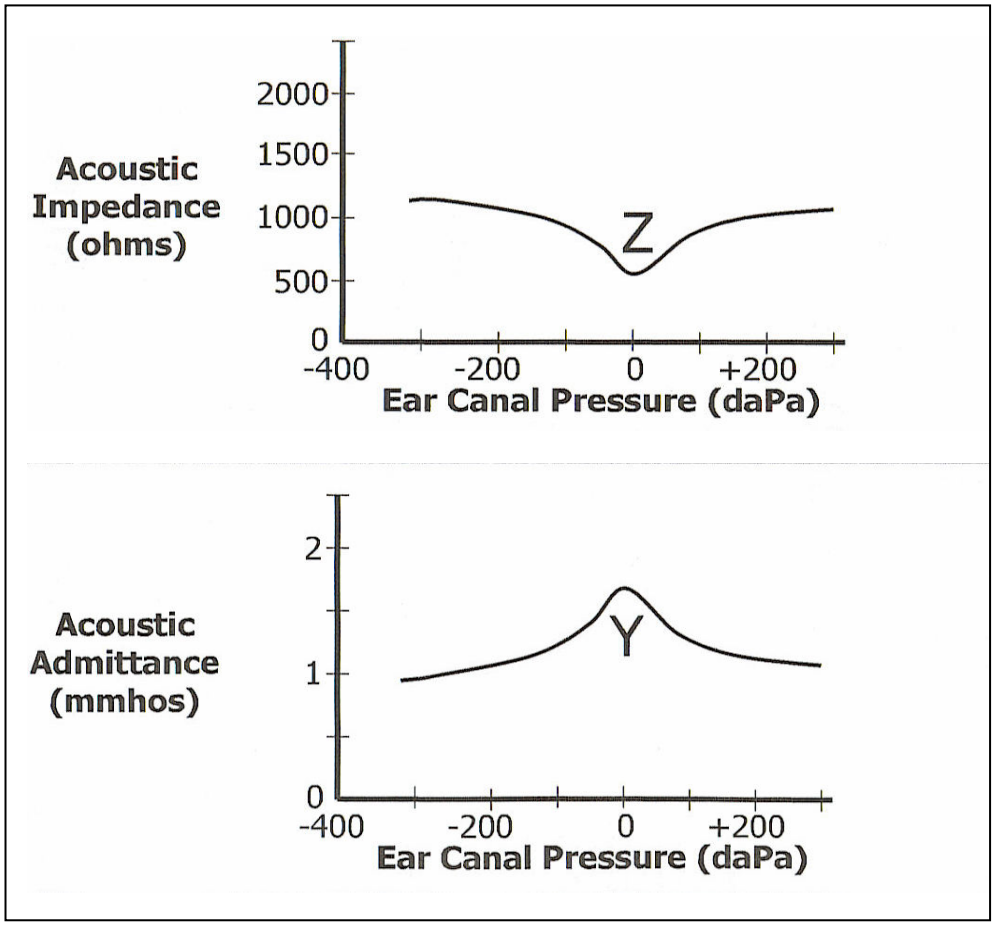

Figure 2.1 Graphic illustration of impedance (Z) vs. admittance (Y) tympanograms (Adapted from Wiley & Fowler, 1997:3)

In order to effectively understand and use acoustic immittance measures, knowledge of the fundamental physical and acoustic principles, coupled with knowledge of the basic anatomy and physiology of the middle ear structures involved in these measures, is essential.

Regardless of the specific instrument used to assess acoustic admittance or impedance, the basics of measurements are the same and require at least three primary subsystems as illustrated in Figure 2.2: a) a sound pressure source, b) a means of varying and monitoring air pressure changes in the ear

canal and c) an analysis system for monitoring the SPL of the probe signal (Wiley & Fowler, 1997:8). If acoustic reflex measures are performed, a fourth subsystem (d) providing a test signal source for eliciting of the acoustic reflex would be included in the measurement system.

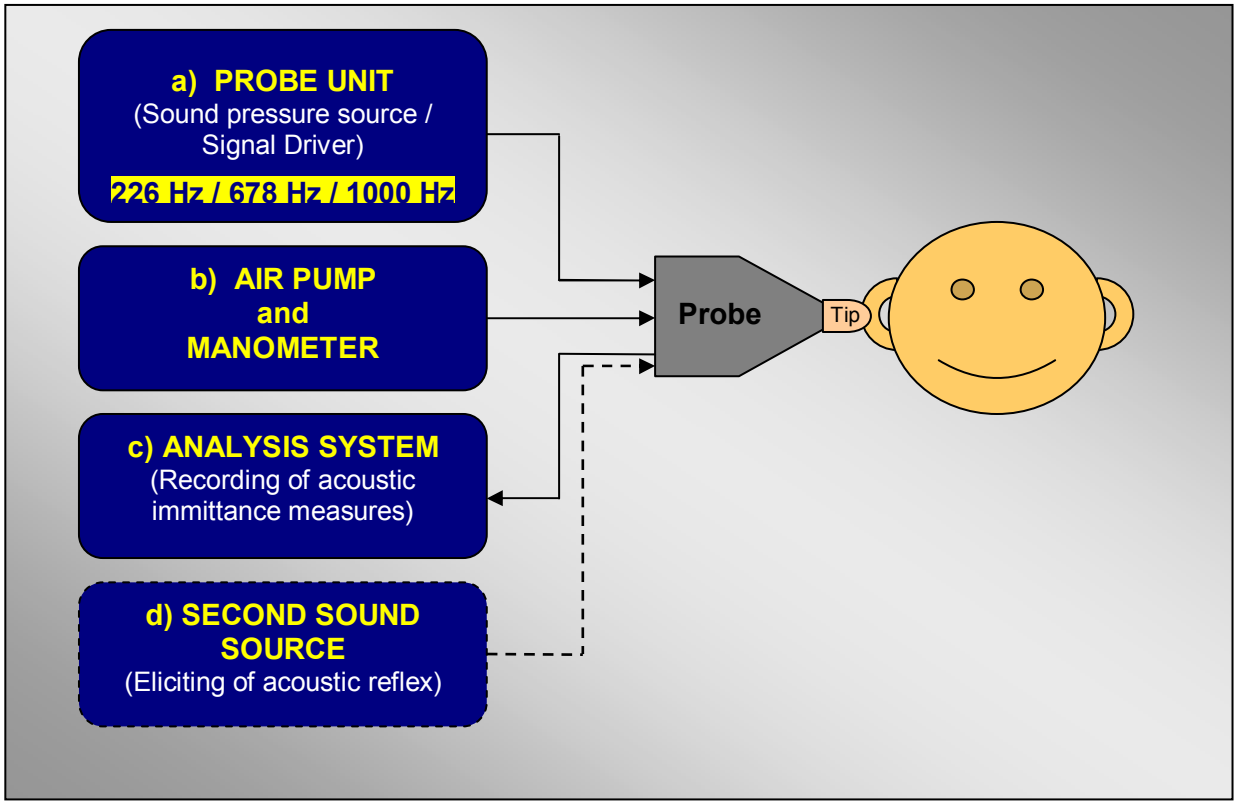

Figure 2.2 Diagram of electroacoustic immittance instrumentation
(Adapted from Wiley & Fowler 1997:9 and Wiley & Stoppenbach, 2002:168)

The measurements of acoustic immittance is performed by introducing an acoustic signal (probe tone) to the ear and measuring the sound pressure level (SPL) of the signal in the ear canal as air pressure changes are varied and monitored (Wiley & Fowler, 1997:8). The SPL of the probe tone, measured at the probe tip, serves as an indirect index of acoustic admittance or impedance as it is directly proportional to the acoustic impedance offered by the ear at the point of measure (Wiley & Fowler, 1997:8). Higher SPL measurements of the probe tone indicate higher levels of acoustic impedance or conversely lower levels of acoustic admittance, offered by the ear under measurement.

Although the ideal point of measure is the tympanic membrane, it is not feasible to place a probe tip next to the eardrum using commercially available instruments. Hence, the tip of the probe unit is the point at which the acoustic immittance analysis system receives input and implies plane of measurement (Wiley & Fowler, 1997:11). Measures are therefore termed compensated acoustic measure, referring to the extraction of ear canal effects (Wiley & Fowler, 1997:12).

Acoustic immittance measures in the human ear can be explained on the bases of mechanical, electrical, and mathematical principles. In the human ear, a specified peak compensated acoustic *impedance* value would represent the total opposition to sound flow offered by the ear under test at the lateral surface of the tympanic membrane. This measure represents the acoustic impedance at the input to the middle ear (Wiley & Fowler, 1997:13).

The middle ear system is composed of different mechanical structures. These react to sound and pressure waves in a variety of ways, transferring energy and causing changes in state of the mechanical structures of the middle ear system. These do not always occur instantaneously when a force is applied. An acoustic impedance measure is determined by the complex relation of the applied force (sound pressure) to the velocity (or sound flow) (Wiley & Fowler, 1997:13). The way in which different structures oppose sound flow is complex across middle ear components. The overall acoustic impedance or admittance measured at the probe tip is determined by the multifaceted contributions of the volume of the external ear canal, the tympanic membrane, the interconnected cavities of the middle ear, the ossicular chain, and the coupling of the stapes footplate to the oval window of the cochlea. For example, the introduction of substantial (positive or negative) ear canal pressure effectively stiffens the tympanic membrane and middle ear transmission system which affects immittance measures proportionately (Wiley & Fowler, 1997:14). It is clear therefore that a number of mechanical variables within the middle ear affect immittance measurements. A brief discussion of the mechanical variables within the middle ear is presented below.

2.6.2 The middle ear as a mechanical system

In the ear, the tympanic membrane is mechanically coupled with the middle ear ossicles to the oval window – the interface between the middle and inner ear. It is this entire system (membrane, middle ear and oval window) that is forced into oscillation when sound waves enter the ear canal (Gruber, 2002:1). Under normal circumstances, when a sound wave enters the ear canal, it progresses inward until it reaches the tympanic membrane where some of its energy sets the membrane into vibration and some is reflected. The tympanic membrane is stimulated by sound energy, which in turn, sets the ossicular chain into motion. Movement of the malleus, which is attached to the tympanic membrane, sets the incus into motion, which in turn triggers the stapes to move. The stapes is set in the opening of the inner ear, the oval window. Sound is then conducted via the stapes through the oval window into the cochlea. The mobility of the ossicular chain therefore dictates to a great extent, the quantity of sound perceived by an individual. If the middle ear system is stiffened or disturbed for any reason, the amount of energy transmitted to the oval window will be altered (Martin & Clark, 2000:253).

The tympanic membrane and ossicular chain also act as an impedance-matching device to bring sound from the air into the cochlea. Since the cochlea is fluid-filled, it presents a reflective barrier to airborne sound. The impedance-matching capability of the middle ear is primarily related to the ratio of the area of the tympanic membrane to that of the stapes of the footplate (Martin & Clark, 2000:254). There are three factors that determine how much energy is accepted or reflected and in what frequency ranges. These factors are the *mass* of the system, the *stiffness* of the system, and its *resistance* (Jerger and Northern, 1980:3).

2.6.3 Mass, stiffness and resistance components of the middle ear

The acoustic impedance measured at the tympanic membrane is controlled by the mass of the middle ear ossicles, the stiffness of the ossicular ligaments and

muscles, the stiffness of the tympanic membrane and round window membrane, the stiffness of the air contained in the tympanum, the mass and friction that result from air movement within the tympanum, and, finally, the impedance, primarily resistance, offered by the coupling of the stapes footplate to the cochlea at the oval window (Lilly, 1993 and Zwislocki, 1976 in Wiley & Fowler, 1997:14).

In terms of the relative contributions of the mass, stiffness and resistance components to the overall opposition to energy flow, the components may be categorized as *in-phase* (those that occur simultaneously with the applied force) and *out-of-phase* (those that precede or lag behind the applied force). The in-phase component of impedance is known as *resistance* (R) and the out-of-phase component is known as *reactance (X)*. The complex relations between resistive and reactive components determine the total acoustic impedance (Fowler and Shanks, 2002:162).

In the human ear energy transfer is initiated when sound waves are presented to the ear canal and sound pressure is applied to the tympanic membrane (Fowler and Shanks, 2002:162). The effects of each of the mechanical components are determined by the frequency of the sound entering into the ear canal. Sound waves, entering the ear canal and impinging upon the tympanic membrane, have both inward and outward motions that exert forces on the middle ear structures. Consequently we have to consider the incoming force not only in the positive direction, but also in the negative direction, and all points in time between maximum positive and maximum negative deflection. The acceptance or reflection of energy in the middle ear is, largely, *frequency dependent* (Jerger & Northern, 1980:3). Mathematically, the impedance equation can be expressed as follows, indicating the effect of frequency (Jerger and Northern 1980:3):

$$Z = \sqrt{R^2 + 6.28\,fM - \frac{k^2}{6.28f}}$$

Resistance Mass Stiffness

Z= impedance
R = Resistance
f = frequency M = Mass k = stiffness

An admittance Cartesian plot is presented in Figure 2.3 to illustrate the effect of frequency of measurement tone on the resultant acoustic admittance.

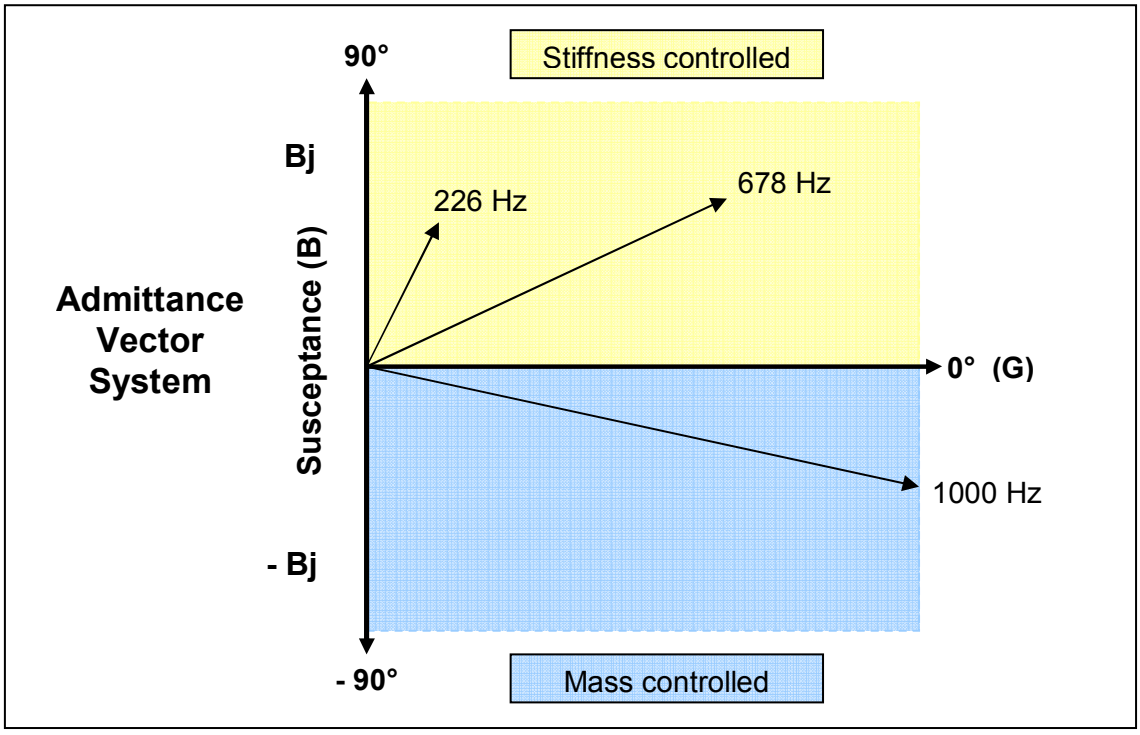

Figure 2.3 Influence of frequency on admittance vector system (adapted from Wiley & Stoppenbach, 2002:166, 189)

If the stiffness of a given system increases, the effect of the increased stiffness will be to weaken transmission in the low frequencies. If we increase the mass of the system, the effect will be to weaken transmission in the high frequencies. Thus measures made using low frequency probe tone provide information on the stiffness (reciprocal = compliance) characteristics of the middle ear, while measures made with high frequency probe tones provide information regarding the mass characteristics of the middle ear, particularly of the eardrum and ossicles (Fowler & Shanks, 2002:187). This proves to be especially useful in testing of the infant middle ear, which is a **mass-dominated system** (Holte *et al.*, 1991:20). Meyer *et al.,* (1997:193) found the use of a 226 Hz probe tone in the neonate and infant to be less sensitive to measuring the acoustic characteristics of the middle ear as it is more sensitive to measuring the stiffness-dominated system of the adult-ear. Further findings indicated that the use of a high frequency probe tone was more suitable for use in infants as it is

more sensitive to changes in mass-dominated systems (Meyer *et al.,* 1997:194). Despite the advantages of high frequency tympanometry in identifying mass-related middle ear pathology, high frequency and multi frequency tympanometry probe tones are not commonly used. The major barrier to incorporating high frequency tympanometry into the routine test battery is that the measures are more complex and not as easily understood as 226 Hz tympanometry (Fowler & Shanks, 2002:187).

Developmental changes that occur in the infant ear canal (see section 2.3.1) are postulated to contribute and have an effect on the stiffness, mass and resistance components of the infant middle ear (Petrak, 2002:1; Meyer *et al.,* 1997:190; Holte *et al.,* 1991:20). As previously described s*tiffness* of the middle ear controls the low frequency responses and is largely determined by the tympanic volume and to a lesser extent the fibrous nature of the tympanic membrane (Meyer *et al.,* 1997:190). It is postulated that there is an overall decrease in the stiffness with an increase in cavity size and maturation. The orientation of the neonatal tympanic membrane also changes post-natally due to inward displacement of the tympanic ring to the more vertical position of the adult tympanic membrane. The ossicles predominately determine the *mass* of the middle ear and controls high frequency responses. Developmentally there is a net overall decrease in the mass components in the middle ear due to the decreased density of the stapes through internal bone erosion, and the gradual loss of mesenchyme clinging to the ossicles. The *resistive* component of admittance comprises mainly the frictional forces opposing motion. There is a change in resistance during maturation due to tightening of the ossicular joints, closer coupling of the stapes to the annular ligament and a resultant change in the reactive force exerted by the cochlear fluids (Meyer *et al.,* 1997:190). The developmental changes result in a *mass-governed* middle ear transmission system gradually changing to the more adult-like stiffness-dominated system.

The preceding overview of the mechanical properties of the middle ear, which included the effects of mass and stiffness elements in the adult and infant

middle ear, serves as background to a review of the clinical application of tympanometry as a method of middle ear function in infants.

2.6.4 Clinical application of tympanometry

The primary rationale for performing tympanometry on a patient is to assess the functioning of the middle ear system and to determine the existence and potential causes of middle ear disorders (Petrak, 2002:1; Palmu *et al.,* 1999:207; Gaihede & Ovesen, 1997:215; Wiley & Fowler, 1997:1,39; LaRossa *et al.,* 1993:32). Consequently tympanometry has an established role in the audiological assessment of hearing and in otological studies as an objective tool for diagnosing middle ear pathologies (Palmu *et al.,* 1999:207; Wiley & Fowler, 1997:2). There are several tympanometric methods ranging from ***vector*** (single-frequency, single component) tympanometry to ***multi-component and multi-frequency tympanometry.*** A brief description of these methods will follow.

2.6.4.1 Vector tympanometry

Vector (single frequency, single component) tympanometry involves the measurement of one component, generally the acoustic admittance vector. Conventionally a single, low frequency probe tone (typically 226 Hz) has been used. By using only one probe-tone frequency, the view of the middle ear is restricted, almost as if you were to try to estimate hearing sensitivity by testing thresholds at only one frequency. Disorders that exert an influence on middle ear mechanics only at the high frequencies, such as those adding mass to the system, will not be evident using only the low-frequency probe tone (Wiley & Fowler, 1997:40).

Measurement of vector tympanograms involves the application of pressure, which is varied from a positive pressure to a negative pressure. The resulting changes in acoustic admittance are measured and plotted as a tympanogram. At the extremes of pressure, the tympanic membrane and middle ear system

stiffen and the ear canal effectively becomes a hard-walled cavity. This necessitates specific consideration when testing the infant ear, as ear canal wall distensibility has been held responsible for unusual tympanometric shapes (Holte *et al.,* 1991:19). The infant ear canal and tympanic membrane are more vulnerable to changes in middle ear pressure and therefore a high negative pressure could cause a collapse of the canal whilst a high positive pressure could result in distension of the ear canal walls (Holte *et al.,* 1991:21). Wiley and Fowler (1997:59) supported this notion stating that as the infant ear canal is cartilaginous, it cannot be modeled as a hard-walled cavity as it is in adults. Little acoustic energy passes through the tympanic membrane and the majority of acoustic energy is reflected into the ear canal. At the pressure extremes, therefore, the acoustic admittance of the middle ear is minimal. As the ear canal pressure approaches atmospheric pressure (0 daPa) less energy is reflected and more pass into the middle ear. Near atmospheric pressure, the normal tympanic membrane passes most of the acoustic energy into the middle ear; therefore, the acoustic admittance is at its highest value.

The normal vector tympanogram, therefore, has a single, positive peak near atmospheric pressure. Because the normal middle ear system is dominated by compliant acoustic susceptance, manufacturers commonly call the single component *compliance*, although in reality the single component is the vector component, *acoustic admittance.* (Wiley & Fowler, 1997:40,41). The susceptance (B) and conductance (G) components fully determine the admittance (Y) of the middle ear system. The conductance component is in phase with the delivered probe tone, whereas the susceptance is an out-of-phase component. Consequently the susceptance and conductance elements can be separated by analysis of the phase of the reflected probe tone (Lantz, Petrak & Prigge, 2004:38). This is used by middle ear analysers to plot B/G tympanograms and simultaneous recording of B and G components is known as multi-component tympanometry. An overview of multi-component tympanometry is provided in the following section.

2.6.4.2 Multi-Component tympanometry

Multi-component tympanometry refers to measurement of the two components, susceptance (B_a) and conductance (G_a), which provide an adequate view of the magnitude and direction of the admittance. Evaluation of these two components is more important for the interpretation of tympanograms measured with high frequency probe tones than for tympanograms measured with a 226 Hz probe tone because of the variety of tympanometric shapes that occur in normal as well as abnormal ears at higher probe frequencies (Wiley & Fowler, 1997:56). The various shapes indicate the relative contribution of mass and stiffness to the admittance tympanogram and are used to separate normal from pathological tympanograms and to determine the cause of the abnormalities reflected in the tympanogram. Knowing whether a tympanogram has increased mass or stiffness allows the clinician to identify the probable cause of the middle ear disorder that has resulted in the changes in the tympanogram (Wiley & Fowler, 1997:56). Holte *et al.*, (1991:23), suggesting that the complex components of admittance must be measured to calculate the meaningful values of static admittance magnitude, also noted the importance of performing multi-component tympanometry.

Pathologic conditions alter the shape of tympanograms and therefore the goal of the diagnostic use of tympanometry is to separate the changes that are caused by pathologic conditions from the changes that are associated with normal variability (Wiley & Fowler, 1997:44). Infant testing, however, has been a controversial issue because of ambiguous results. Mass effects are better evaluated with the component tympanometry and at high probe tone frequencies.

2.6.4.3 Tympanometric peak pressure (TPP)

A rough estimate of the resting pressure within the middle ear is indicated from the pressure location of the tympanograms peak (Wiley & Fowler, 1997:2). Acoustic admittance is at its highest value when the pressures on both sides of

the tympanic membrane are equal. The diagnostic value of measuring TPP is that it can detect the presence of negative pressure in the middle ear. If the Eustachian tube becomes blocked by disease, negative pressure develops in the middle ear before the development of effusion as the liquids from the tissues surrounding the middle ear are drawn into the middle ear. The presence of negative middle ear pressure can therefore indirectly indicate a problem with Eustachian tube function, often associated with the initial stages of otitis media (Wiley & Fowler, 1997:2). Tympanometric peak pressure is considered to have little clinical value for screening purposes, due to amount of normal pressure variation, which may lead to over-referral rates in screening programs (Wiley & Fowler, 1997:49). This is in contrast to studies by Thornton *et al.,* (1993:320) who suggested that in assessment of infant middle ear function by high frequency tympanometry, positive middle ear pressure was the best indicator of middle ear dysfunction as correlated to OAE pass / fails results. Further limitations are the fact that an unique tympanometric pattern does not exist for every possible middle ear disorder, and thus clinical expertise and classification systems for different tympanometric shapes are necessary for correct diagnosis.

2.6.5 Classification systems in tympanometry

Various classification systems have been developed for conventional low frequency tympanometry. However, due to the complex notching patterns that can occur when the infant middle ear is assessed at different probe frequencies, no universal classification system exists at present. According to the Vanhuyse classification system (Vanhuyse *et al.* 1975 in Fowler & Shanks, 2002:191), tympanometric shapes can be classified according to the number of extrema in the susceptance and conductance tympanograms and assumptions can be made about the contributions of mass and stiffness elements. As notching is a more prevalent in neonatal and infant ears compared to adult ears at similar frequencies (Holte *et al.,* 1991:12), this classification system appears useful for application in the infant population. Figure 2.4 provides a graphic illustration of the Vanhuyse classification system and how mass and stiffness dominancy can

be derived from tympanograms shape. As the infant middle ear is a mass-dominated system with a lower resonant frequency, tympanograms will progress differently compared to tympanograms collected from an adult middle ear, which is stiffness controlled (Lantz *et al.,* 2004:3, Purdy & Williams, 2000:12). Therefore the Vanhuyse model is a useful classification scheme at higher probe frequencies close to middle ear resonance where complex multi-peaked tympanograms are normal.

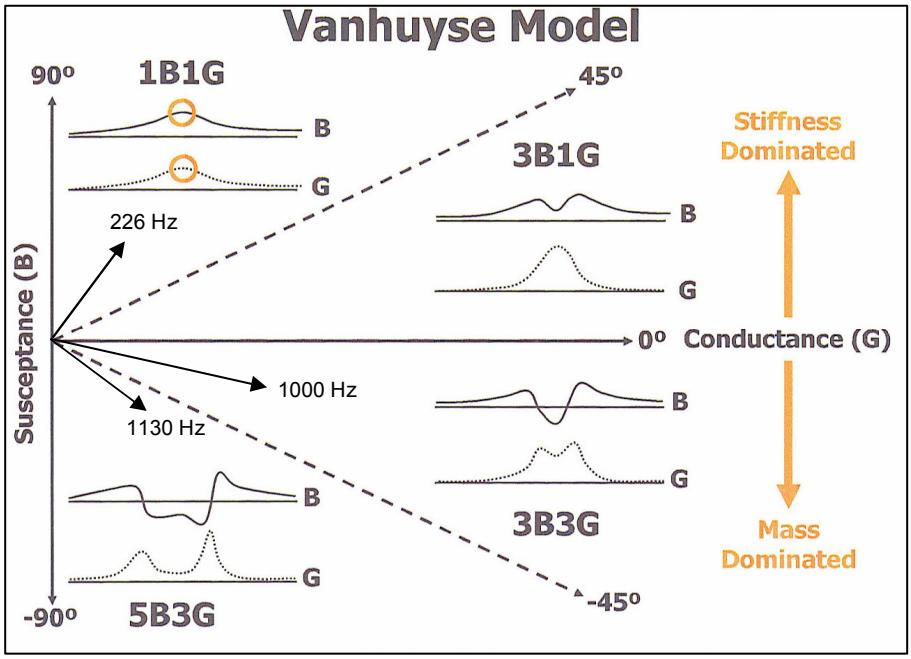

Figure 2.4 Vanhuyse classification model (Adapted from Fowler & Shanks, 2002:189,191)

Figure 2.4 illustrates that as frequency increases, the shapes of component tympanograms progress from single peaked to notched tympanograms. Vanhuyse *et al.,* (in Fowler & Shanks, 2002:191) developed a model to explain the variety of shapes for susceptance and conductance tympanograms. Between 90° and 45° both susceptance and conductance tympanograms are single peaked and this pattern is designated 1B1G. As the acoustic admittance vector rotates between 45° and 0°, the susceptance (B_a) tympanogram notches, but conductance (G_a) remains single peaked and this pattern is designated 3B1G. When the admittance vector rotates between 0° and -45°, both the

susceptance and conductance tympanograms notch; this forms the 3B3G pattern (Fowler & Shanks, 2002:191).

As the tympanometry probe tone frequency is increased and approaches the point of middle ear resonance (where mass and stiffness are equal) the shape of the tympanogram becomes more complex and notching occurs (Purdy & Williams, 2000:10). The resonant frequency is the probe tone frequency where the mass and stiffness components are in balance, and susceptance becomes zero due to the counteractive forces of its components (Ferekidis, 2003:60). A normal value for resonant frequency for adult ear is around 900 – 1000 Hz (Ferekidis, 2003:60; Purdy & Williams, 2000:11). Below this value the middle ear system is stiffness-controlled and above the normal value mass-controlled according to the more prominent component of susceptance (Petrak, 2002:1). Another method of middle ear assessment that therefore merits investigation is multi-frequency tympanometry. This is an advanced, sweep frequency method of acoustic impedance measurement and provides values for the resonant frequency of the middle ear.

2.6.6 Multi-frequency tympanometry

Multi-frequency tympanometry allows for middle ear function to be tested over a wide frequency range (226 – 2000 Hz) to determine the resonant characteristics of the middle ear. By means of multi-frequency tympanometry it is possible to directly assess the resonant frequency of the middle ear system where mass and stiffness elements are in balance (Ferekidis, 2003:60). Meyer *et al.,* (1997:194) hypothesized that the initial use of multiple frequency tympanometry to determine the middle ear resonance frequency may enable the audiologist to make appropriate probe frequency selection depending on the characteristics of each individual middle ear. Changes in resonant frequency are used to assess the pathology of the middle ear system, especially those of the ossicular chain as any ossicular chain discontinuity lowers the resonant point and any stiffness (for example otosclerosis) makes it higher (Ferekidis, 2003:60, Holte & Margolis, 2002:389). Multi-frequency tympanometry has been shown to

improve test sensitivity in some cases of otitis media (Holte & Margolis, 2003:389), however due to increased testing time and required duration of infant co-operation and the need for enhanced operation and interpretation skills, it does appear favourable as a screening tool for middle ear function in infants. However, acoustic reflexes measured with a high frequency probe tone, appear a more valuable adjunct to high frequency tympanometry in infants as part of a the assessment of middle ear functioning.

2.6.7 Acoustic reflex testing

Gelfand (2002:205) defines the acoustic reflex as the reflexive contraction of the middle ear muscles as a result of sound stimulation. The stapedial muscle is attached to the stapes. When contracted, this muscle pulls the stapes posteriorly, thus impeding its movement into the oval window (Martin & Clark, 2000:215). The most important parameter of the acoustic reflex is the acoustic reflex threshold (ART). This is referred to as the lowest stimulus intensity at which a contraction of the stapedius muscle can reliably be recorded. Acoustic reflex measurement also has a high sensitivity for the detection of middle ear pathology (Neumann, Uppenkamp & Kollmeier, 1996:359).

The acoustic reflex is detected as a change of middle ear compliance. Two stimuli are presented to the subject: typically a low frequency tone of 226 Hz is used to measure the compliance of the middle ear, and an additional high level tone of limited duration is used to elicit the acoustic reflex (Neumann *et al.,* 1996:360). If the level of the additional sound is high enough to elicit the acoustic reflex, the acoustic compliance decreases and the level of the measurement tone increases. The increase of the measurement tone level can be detected with a microphone placed in the ear canal. The acoustic reflex can be a very useful part of the audiologic evaluation in infants as a present acoustic reflex is added support for normal middle ear function in infants (Sininger, 2003:380).

Studies with newborns have demonstrated that the acoustic reflex is typically not reliably detectable when a low frequency (226Hz) probe tone is used (McMillan, Marchant & Shurin, 1985:145; Purdy *et al.,* 2000:21). Reflexes have however been recorded with reasonable reliability in infants when a high frequency probe tone and an ipsilateral stimulus in the mid-frequency range is used to activate the reflex (Rhodes, Margolis, Hirsch & Napp, 1999:802). Marchant *et al.,* (1984:593) have also demonstrated that when a 660 Hz probe tone is used for acoustic reflex measurements, absent or elevated ipsi-lateral reflexes were closely associated with middle ear effusion.

Sutton *et al.,* (1996:12) reported that acoustic reflexes were absent in over half of the ears tested in their study-population of 84 special care neonates. Although they found OAE failure to be highly associated with acoustic reflex absence, they found that reflexes were also absent in most of the ears with normal tympanograms and in most of the ears passing OAEs. Thus they concluded that acoustic reflex absence alone is not a very specific indicator of middle ear effusion (Sutton *et al.,* 1996:12). Hirsch, Margolis and Rykken (1992:186) found that the high correspondence between elevated reflex thresholds and delayed ABR wave V latencies suggests that the combined information from acoustic reflex thresholds and ABR-testing may be valuable in the early detection of abnormal middle ear dysfunction.

It is apparent therefore that the ability to measure acoustic reflexes in infants depends to a large extent on the probe tone frequency that is utilized. Similarly, as previously mentioned, the outcome of tympanometric measures in the infant population depends largely on the choice of probe tone frequency. A discussion of the conventional (226 Hz) probe tone tympanometry in comparison to high frequency (1000 Hz) probe tone tympanometry and the implications for infant testing follows in the next section.

2.6.8 Conventional tympanometry versus high frequency tympanometry

The diagnosis of middle ear effusion in neonates and infants presents specific problems and the age at which tympanometry becomes reliable for the detection of middle ear effusion is not fully agreed on (Meyer *et al.,* 1997:190). In infants under 7 months of age, the interpretation of tympanometry is controversial, and for some years it has been recognised that conventional low-frequency probe tone tympanometry is inappropriate because of poor sensitivity to middle ear disease in young infants (Purdy & Williams, 2000:9; Fowler & Shanks, 2002:187). Paradise, Smith and Bluestone (1976, in Meyer *et al.,* 1997:189), were the first to cast suspicion over the use of tympanometry with infants younger than 7 months of age. They demonstrated that normal tympanograms could coexist with confirmed middle ear effusion in that age group. Results reported by Holte *et al.,* (1991:388) also reported that low frequency; single-component tympanometry can produce spurious patterns in neonates.

Questionable results and reasons for the high false negative rate when using low frequency 226 Hz tympanometry in the infant population are unclear, although it has been speculated that the anatomical differences and significant variations in the acoustic response properties, between the infant and adult middle ear transmission system may be a contributory factor (Meyer *et al.,* 1997:190; Keefe *et al.,* 1996:361; Holte *et al.,* 1991:1).

Anatomical development of the external ear canal has been suggested as a contributor to tympanometric shape in neonates (Holte *et al.,* 1991:1; Meyer *et al.,* 1997:190; Purdy & Williams, 2000:9). The osseous portion of the ear canal is not completely formed until about 1 year of age. Thus, in the first few months of life, pressurizing the ear canal during tympanometry may result not only in movement of the tympanic membrane, but also in the distention of the ear canal walls.

Thornton *et al.,* (1993:320) reported that the percentage of successful recordings using a 220 Hz probe tone was 68%, but when a 1000Hz probe tone was used, the figure rose to 87%, supporting the notion that high frequency tympanometry is more effective in infants. Sutton *et al.,* (1996:16) found OAE screening results strongly related to tympanometry when a high frequency probe tone is used. Similar results were found by Meyer *et al.,* (1997:193), suggesting that the use of a high frequency probe tone is more sensitive to the identification of middle ear effusion in the infant population. The high frequency probe tone was found to be able to identify the presence of pathology that was unrecognised by conventional 226 Hz tympanometry (Meyer *et al.,* 1997:194). As a result it was concluded that high frequency tympanometry is a useful indicator of middle ear status, and that middle ear effusion strongly affects OAEs in neonatal years. Negative middle ear pressure also has a significant effect on OAE results. Therefore, as middle ear effusion has a confirmed impact on the successful recording of OAEs, an objective measure, such as high frequency tympanometry, is necessary to differentiate between true cochlear and middle ear pathology. The high degree of association between high frequency tympanometry and presence or absence of OAEs as reported by Sutton *et al.,* (1996:15), supports the validity of high-frequency tympanometry as an indicator of middle-ear status in neonates.

Currently there are no universally accepted guidelines or normative data system on classifying or interpreting high-frequency tympanograms in neonates and young infants (Petrak, 2002:2; Sutton *et al.,* 1995:10). Recent studies by Kei *et al.* (2003:25) and Margolis *et al.,* (2003:385) have provided preliminary normative values for 1000 Hz tympanometry performed on infants. Though this provides eminent guidelines for clinical practise in high frequency tympanometry, more results and normative values are imperative for the development of a standardised classification or interpretation system. Normative values from 1000 Hz tympanograms reported by Margolis *et al.,* (2003:385, 386) and Kei *et al.,* (2003:25) are presented in tables 2.1 and 2.2.

TABLE 2.1 Normative tympanometric values from 1kHz tympanograms by Margolis *et al.,* (2003:385)

	Birth GA (wks)	Test CA (wks)	Test CA (wks)	TPP (daPa)	Y +200	Y -200	Y Peak	Comp Y (+200)	Comp Y (-400)
Mean	32.8	3.9	36.7	-9	1.4	0.6	2.2	0.8	1.5
SD	4.2	3.8	2.7	48	0.3	0.2	0.7	0.5	0.7
Max	41.0	20.1	44.7	145	2.9	1.4	5.4	3.4	4.7
Min	23.0	0.1	31.3	-188	0.8	0.4	1.0	0.1	0.3
5^{th} Percentile	26.0	0.4	32.6	-93	0.9	0.4	1.3	0.2	0.6
50^{th} Percentile	32.4	2.1	36.6	-5	1.3	0.6	2.1	0.8	1.5
95^{th} Percentile	40.0	10.9	41.0	53	1.9	1.0	3.4	1.6	2.7

Margolis *et al.,* (2003:386) reported descriptive statistics for characteristics and tympanometric measures of 1000 Hz probe tone tympanometry measurements. In contrast to previous reports of complex high frequency tympanometry patterns, Margolis *et al.,* (2003:388) reported that tympanograms recorded in their study were almost always single peaked and free of irregular patterns. Margolis *et al.,* (2003:388) found static admittance values to be substantially higher for infants who passed OAE screening and suggested that due to the strong relationship between OAE pass-fail status on static admittance, many screening failures may result from middle ear rather than inner-ear factors. Therefore, as previously discussed, passing OAE screening suggests normal middle ear function and given the invasive constraint of using surgical procedures to confirm middle ear function, OAEs can be used as a control variable in studies investigating normative immittance measures. This method was applied in both studies by Margolis *et al.,* (2003:387) and Kei *et al.,* (2003:22).

TABLE 2.2 Normative Data for 1000 Hz tympanometry by Kei *et al.*, (2003:25)

Variable	N (ears)	Mean	SD	5th Percentile	95th Percentile
Peak Compensated Static Admittance Ypc (mmho)					
(Left ear)	106	1.04	0.51	0.39	1.95
(Right ear)	106	1.16	0.58	0.39	2.28
Admittance at +200 daPa, Y200 (mmho)					
(Left ear)	106	3.20	1.11	1.54	5.09
(Right ear)	106	3.06	1.07	1.40	5.01
Gradient					
(Left ear)	57	0.51	0.13	0.33	0.71
(Right ear)	62	0.48	0.13	0.27	0.75
Tympanometric width, TW (daPa)					
(Left ear)	57	97.7	30.1	46.1	144.2
(Right ear)	62	107.6	28.0	56.6	154.0
Ear Canal Pressure, Pec (daPa)					
(Ears combined)	212	18.3	41.6	-58.0	86.6
Downward Admittance, Yd (mmho)					
(Ears combined)	212	2.13	0.77	0.13	3.54

Kei *et al.,* (2003:27) reported that single-peaked 1000 Hz tympanograms were recorded in 92.2% of neonatal ears. Normative data reported by Margolis *et al.,* (2003:386) and Kei *et al.,* (2003:25) (Tables 2.1 and 2.2) provide criterion for identifying middle ear dysfunction in newborns and infants and may be helpful for distinguishing between screening fails caused by sensorineural hearing loss and those caused by transient external or middle ear conditions. However, as these studies were limited in sample size (170 neonates participated in the study by Kei *et al.,* (2003:22) and normative values from 65 NICU and 30 full-term babies respectively, were reported by Margolis *et al.,* 2003:385), results cannot be applied universally and large scales studies are necessary for the compilation of representative normative data.

Despite the advantages of high frequency tympanometry in identifying mass-related middle ear pathology, high frequency / multi-frequency probe tones are not commonly used. The major barrier to incorporating high-frequency tympanometry into the routine test battery is that the measures are more complex and not as easily understood as low frequency 226 Hz tympanometry (Fowler & Shanks, 2002:187).

2.7 IMPLICATIONS FOR INFANT TESTING

The preceding sections commenced with a discussion of otoscopy, OAEs and immittance measures as tests of middle ear function. As otoscopy is often very difficult to perform in newborns and infants, and has several other disadvantages, it does not appear advantageous as a specific diagnostic indicator for the identification of OME in infants (Holte & Margolis, 2002:388). OAE testing is sensitive to MEE and is often abolished by it (Yeo *et al.,* 2002:797) and therefore may serve a secondary role for the identification of potential middle ear pathology. However, as no discrimination between middle ear pathology and sensory hearing impairment can be made with absent OAE results in isolation it is clearly an imperfect isolated test of middle ear function.

Immittance measures therefore prove to be the best single diagnostic technique for the assessment of middle ear function in infants. Supported by current literature it is recommended that high frequency (1000 Hz) immittance measurements should be included in a battery of tests to identify any abnormality in an infant's hearing system (Lantz, Petrak & Prigge, 2004:4). Research has indicated that there may be a better correlation between the presence of middle ear effusion and the shape of the tympanogram when a high frequency probe tone is used (Marchant *et al.,* 1984:593). Acoustic reflex measurements complement tympanometry in the identification of middle ear effusion and acoustic reflexes should be present in healthy infant ears when using a 1000 Hz probe tone and ipsilateral stimulus (Sininger 2003:380).

A summary of the advantages and disadvantages of the methods typically used for middle ear assessment in infants, as discussed in the preceding sections, is provided in Table 2.3.

TABLE 2.3 Comparison of methods for middle ear assessment in infants

METHOD	ADVANTAGES	DISADVANTAGES	REFERENCES
OTOSCOPY	✓ Useful in identifying complete occlusion of ear canals and foreign bodies ✓ Inexpensive	× Skill and experience is valuable adjunct × Subjective – variability among otoscopists × Difficult to perform, particularly in young neonates × No golden standard – actual verification only by myringotomy × Low sensitivity × No objective record – must be manually documented	~ Sutton et al., 1996:9 ~ Roush *et al.,* 1992: 66 ~ Pellet *et al.,* 1997: 181,187 ~ Govender, 1998:68
OAEs	✓ Dependent on middle ear state – useful in detecting middle ear effusion ✓ Sensitive to middle ear pathology ✓ Objective ✓ Quick administration ✓ Permanent record is available to print out for record and comparison	× Does not distinguish cochlear from middle ear pathology × Have been found to be present in ears with middle ear pathology × Expensive cost involved	~ Thornton et al., 1993:319 ~ Koivunen *et al.,* 2000:212
IMMITTANCE • **Tympanometry** • **Acoustic reflexes**	✓ Fairly quickly and easily performed ✓ Objective ✓ Easy to obtain ✓ High sensitivity ✓ Permanent record is available to print out for record and comparison	× No accepted guidelines on classifying or interpreting high frequency tympanograms in young infants × Low specificity × Criteria developed for one group / population may not be suitable for use with another × Cost involved	~ Sutton et al., 1996:11 ~ Roush et al., 1992:63, 64 ~ Nozza *et al.,* 311 ~ Govender, 1998:68 ~ Palmu *et al.,* 1999:210; 2000:264; 2002:141

Advantages and disadvantages of different methods used in the assessment of the infant middle ear are summarized in Table 2.3. Lack of objectivity and intricacy to perform otoscopy makes this the least resilient method of middle ear assessment. Though OAEs are objective and sensitive to middle ear pathology it cannot distinguish cochlear from middle ear pathology and therefore are an imperfect test of middle ear function. It is therefore clear from Table 2.3 and the above discussion that immittance measurements currently appears to the best

single diagnostic indicator for the assessment of middle ear function in neonates and infants. High frequency immittance measurement indicates significant promise and requires further investigation in the infant population.

2.8 SUMMARY

This chapter provided a critical discussion on the current issues in the assessment of the infant middle ear in terms of the physical properties and the use of different instrumentation and test protocols. Procedures were compared with regards to their effectiveness and utility in the identification of middle ear effusion in the infant population. There is evidence in the literature supporting the use of high frequency tympanometry, though various limitations currently confine clinical use. High frequency tympanometry currently indicates significant promise in the infant population and there is potential for it to be utilized in neonatal hearing screening programs to screen for middle ear dysfunction (Kei *et al.,* 2003:27).

Preliminary normative values may be helpful to differentiate between screening failures caused by sensorineural hearing loss and those caused by transient external and middle ear conditions (Margolis *et al.,* 2003:389). However in light of Newborn Hearing Screening Programs and the number of false positive failures that can occur due to middle ear effusion, more detailed and large scale investigations of high frequency immittance, as a test of middle ear function in young infants are necessary.

The need for normative value classification systems for 1000 Hz probe tone immittance, serve as the primary rationale and motivation for conduction of the present study. The theoretical aspects covered in this chapter, serve as background to the development of the research methodology, which will be discussed in the subsequent chapter.

The literature supports the use of high frequency probe tone immittance measures in infants in identifying middle ear effusion. However, to be a reliable

tool for clinical use it is necessary to have knowledge of the characteristics and normative values for 1000 Hz immittance measures. That raises the question:

"What characterizes normal high frequency (1000 Hz) probe tone tympanometry and acoustic reflexes in infants and what are the variables that need to be taken into account when interpreting these results?"

3 RESEARCH METHODOLOGY

Chapter 3 describes the main and sub-aims formulated for this study. The methodological approach is discussed and a description of research subjects provided. Procedures for data-collection and analysis are included.

3.1 INTRODUCTION

In its simplest form research can be defined as the collection of methods used to systematically produce knowledge (Neuman, 1997:6). The research methodology is the strategic framework for action that serves as a bridge between the research questions and the execution of the research. It is the precisely designed and planned nature of observation that distinguishes research from other forms of everyday observation (Durrheim, 1999:29). When the ultimate goal of the research is to generalise findings to a specific context in order to assist decision-making, this "knowledge" is developed to convert existing knowledge into products, processes and technologies (Durrheim, 1999:41).

It is generally recognised that conventional low frequency tympanometry is not a reliable measure of middle ear functioning in infants and higher frequency probe tones are advocated when assessing the infant middle ear (Sutton *et al.,* 2002:2; Purdy & Williams, 2000:9). However, there is currently no universal criterion or classification system for identification of middle ear disorders in infants and neonates when high frequency immittance is employed (Fowler & Shanks, 2002:186). To aid the classification and use of high frequency immittance in clinical practice, the need for further research have recently been highlighted by authors (Kei *et al.,* 2003:27; Margolis *et al.,* 2003:384; Purdy & Williams, 2000:23).

Founded on the dearth in current literature, this study aimed to describe the characteristics of high frequency (1000 Hz) acoustic immittance results in normal neonates and infants to establish normative data for this population. The normative data, derived from the sample of infants with normal middle ear functioning, may serve as a guide for identifying middle ear dysfunction in infants and neonates.

This chapter outlines the research question and design and describes the methodological approach to obtaining, recording and analysing of data.

3.2 HYPOTHESIS

As successful recording of OAEs are known to be sensitive to middle ear pathology, it is hypothesized that infants who pass DPOAE hearing screening have normal middle ear functioning, and will show a peaked 1000 Hz tympanogram. The hypothesis was tested by comparing results obtained from OAE testing to results of 1000 Hz tympanometry and acoustic reflex measurement. Since this hypothesis was confirmed, results from 1000 Hz immittance measures could be used to derive normative data.

3.3 AIMS OF RESEARCH

The aims of the current research study are as follows:

3.3.1 Main aim

The main aim of the study is to determine and describe the characteristics and normative values of high frequency (1000 Hz) acoustic immittance measures in a sample of infants between the ages of 0 – 12 months.

3.3.2 Sub-aims

The following sub-aims were formulated to achieve the main aim of the study:

1. To describe the shape and characteristics of high frequency **admittance (Y_a)** tympanograms within subgroups A and B and to determine associations between OAE results and measured tympanometric variables.

2. To describe examples and characteristics of **susceptance (B_a)** and **conductance (G_a)** tympanograms within subgroups A and B.

3. To describe results of 1000 Hz probe tone acoustic reflexes, measured with an ipsilateral 1000 Hz stimulus, for all test ears and to compare results with OAE and tympanometry results.

4. To describe high frequency immittance norms for the subgroup of infants demonstrating both OAE pass results in addition to peaked 1000 Hz admittance tympanograms.

3.4 RESEARCH APPROACH

The nature of the present research study and the type of data that was obtained primarily necessitated a *quantitative research approach* (Terre Blanche & Durrheim 1999:42). Quantitative research is objective and aims to classify features, count them, and construct statistical models in an attempt to explain what is observed and therefore a qualitative approach involves analysis of numerical data (Durrheim 1999:96). The results obtained from immittance measurements performed during this study provided a range of variables that were statistically analysed to describe and interpret the data (Leedy & Ormrod, 2001:252).

In contrast, qualitative research is more subjective and the aim of *qualitative analysis* is to obtain a complete, detailed description of data not represented by

numerical values (Leedy & Ormrod, 2001:147). For the purpose of this study a secondary qualitative approach was used to lesser degree for the purpose of subjective description and analysis of tympanogram shapes.

3.4.1 Research design

The research design addresses the planning of scientific inquiry and the formulation of a strategy for obtaining information to answer the research questions (Goddard & Melville, 2005:32; Leedy & Ormrod, 2001:91). Terre Blanche & Durrheim (1999:29) describes the research design as a bridge between the research questions and the execution or implementation of the research.

The research design that was implemented in the present study comprised of analytical, descriptive, and exploratory research (Leedy & Ormrod, 2001:148, Neuman 1997:19). Terre Blanche and Durrheim (1999:29) describes the advantages of employing multiple research methods as a way of addressing different, but complimentary questions within a study. It can also be used to enhance interpretability of statistical analysis of a primarily quantitative study, by a qualitative narrative account. A graphical illustration of the primary research design and methods utilized in the present study are presented in Figure 3.1 (compiled from Durrheim, 1999:39, 40).

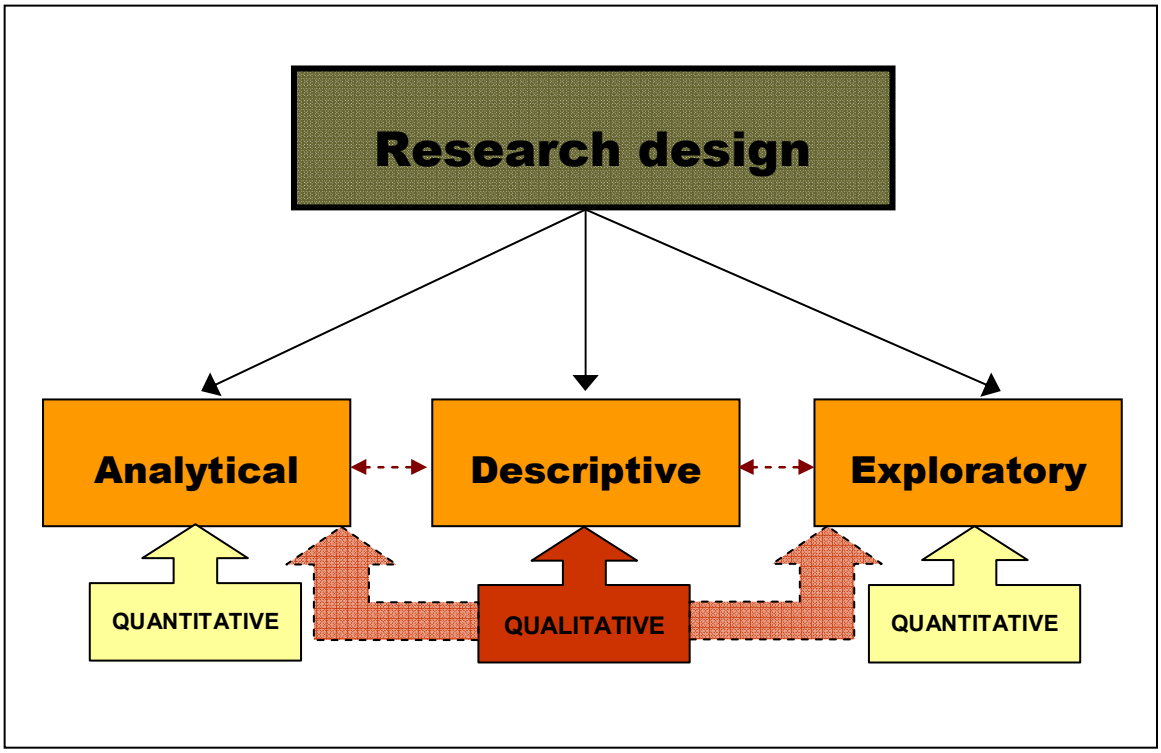

Figure 3.1 Research methods representing the research design of the current study

As illustrated in Figure 3.1 the research design utilised in this study consisted of analytical, descriptive and exploratory elements. The rationales for following these designs are as follows:

1) The research design is ***analytical*** due to the quantitative nature of the data, which were obtained from results of physical audiologic measurements. Inferential statistics was used to analyze the data to obtain a representation of which immittance values can be classified as normal for infants.

2) The research design is ***descriptive*** in nature due to the fact that certain aspects of the data (e.g. the shape of the tympanogram-forms) will be described in terms of similarities and differences. A descriptive approach will also be followed in the description of values and ranges of normative values (Leedy & Ormrod, 2001:259).

3) The research design can also be classified as ***exploratory***. Exploratory studies are used to make preliminary investigations into relatively unknown areas of research and when new knowledge is sought (Neuman 1997:19; Terre Blanche & Durrheim, 1999:39). Literature on high frequency immittance measurements is limited and universal normative values for 1000 Hz probe tone measurements have been specified.

As the findings derived from the current research have the potential for practical application, and aims to contribute towards the resolving of practical issues and difficulties in decision making when utilizing and interpreting high frequency tympanometry results in infants, the current study can be defined as *applied research* (Durrheim, 1999:41).

3.5 ETHICAL CONSIDERATIONS

Whenever the focus of investigation is human beings, ethical implications of what is proposed must be carefully considered (Leedy & Ormrod, 2001:107). Ethical clearance for conducting the current study was obtained from the Research Proposal and Ethics Committee, Faculty of Humanities, University of Pretoria (Appendix B) and the Ethical Committee of the District Health Department of North West Province. Specific ethical issues that were considered during the execution of the current study are as follows:

3.5.1 Potential harm to research subjects

The collection procedures utilised for the current study were non-invasive and mothers or caregivers were informed verbally and in written format about the full bearing of the investigation.

3.5.2 Informed consent

According to Leedy and Ormrod (2001:107) research subjects must be informed about the nature of the study to be conducted and must be given a choice of

whether they want to participate in the study or not. Furthermore they must be aware that they have the right to withdraw from the study at any time. A verbal explanation of the nature of the research project and the involvement required from the participants were provided to all possible research subjects. As two of the fieldworkers were fluent in more than three of the national languages, this information was conveyed in a language native to the subjects and ensured comprehension of the investigation. Parents and/or caregivers brought their infants for the assessment on a voluntary basis.

3.5.3 Research fieldworkers

The researcher and three other fieldworkers who had previous experience in the research context and with the research material performed data collection. All of the fieldworkers were qualified audiologists, apart from one fieldworker, who was a final year audiology student.

3.6 RESEARCH SUBJECTS

Wisker (2001:23) describes a sample as a selected group upon which research is conducted to indicate the larger whole. For this study, infants between the ages of 0 and 12 months were selected. This age group was selected firstly as the current study formed part of a PhD study investigating the feasibility of infant hearing screening at maternal and child health clinics in a developing South African community for infants 0 – 12 months of age (Swanepoel, 2004) and secondly as this provided the opportunity to describe age specific normative data over an extensive age range as there is discrepancy in the literature at which age conventional 226 Hz tympanometry can be successfully used to asses the infant middle ear .

The subjects used for the description of normal immittance values were required to have normal middle ear functioning. Subjects were recruited from the patients visiting the specified health clinics during the course of the data collection period.

3.6.1 Selection criteria

Selection of subjects in the study fulfilled the following criterion:

- **Health clinic**

All infants who attended the Refentse or the Eersterust health clinic in the Hammanskraal region during the specified data collection period were possible subjects for inclusion in the current study. The researcher and fieldworkers visited these clinics and data were obtained by performing an audiometric test protocol, developed for the purpose of this study, on infants at the clinic.

- **Age**

For the purpose of this study all subjects had to be between the ages of 0 and 12 months.

- **Co-operation**

Subjects had to preferably be in natural sleep or demonstrate a low state of alertness at the time of testing. In infants that were awake, general co-operation was required to the extent that the probe or electrode placement was tolerated for the full duration of the test. Lack of infant co-operation complicated testing, as movement and crying resulted in the recording of artifacts. Due to the importance of obtaining reliable data, only infants, who were co-operative and not resistant to testing, were included in the study sample.

- **Mothers or caregivers**

Subjects had to be accompanied by their mothers or caregivers to provide biographical information and a case file had to be available for each subject to ensure that the medical history and other important information on the subject, which the mother or caregiver was unable to supply, was available. The health clinic files also served as a means to record when an infant had been included in the study, to ensure that subjects were not included in the study more than once.

3.6.2 Inclusion and exclusion criteria for compilation of norms

For the compilation of normative values only ears displaying a clearly discernable peaked admittance tympanogram, in combination with an OAE pass result were included. If a subject failed OAE screening, displayed a flat tympanogram response curve or if it was not possible to complete both OAE and tympanometry procedures for the same ear, the data were excluded from the statistical analysis and were only used for a descriptive analysis.

As a result of the data exclusions, tympanometry and OAE results were statistically analysed for rendering of normative values from 809 (79%) of infants (424 males and 385 females). Data of infants included in the final analysis passed OAE testing in one or both ears, maintained an acceptable probe seal for tympanometric measurement in the corresponding ear or ears, and displayed a peaked tympanogram response curve in the same ear.

3.6.3 Subject selection procedures

Non-probability sampling (Leedy & Ormrod, 2001:218) was used in selecting research subjects. This method of subject-selection is also often referred to as random sampling Wisker (2001:23) and is motivated as a means of sampling as it ensures that all possible candidates have an equal chance of being selected. Subjects were selected according to the selection criteria set out for the purpose of this research project.

Subjects were recruited from the patient toll visiting the 6 week-immunization clinics at the specified locations selected for sampling. These locations were selected because of the large number of infants receiving services on a daily basis at these centres. Parents or caregivers of infants were informed about the research study and the opportunity to have their infant's hearing and middle ear status assessed, and infants were brought for assessment on a voluntary basis. All infants who were brought for assessment and who fulfilled the selection criteria were included in the research study. As previously mentioned

lack of infant co-operation complicated testing and had the potential to impair reliable recording of results, therefore infants who were in natural sleep or in a low state of alertness enjoyed preference in the selection of subjects over infants who were awake and crying.

3.6.4 Description of subjects

Due to the geographical representation of the research subjects, the majority of infants were of black ethnic origin, except for two infants. 510 infants, ranging in age from 0 – 52 weeks participated in the study. A distribution of the ages of the infants is presented in Figure 3.2.

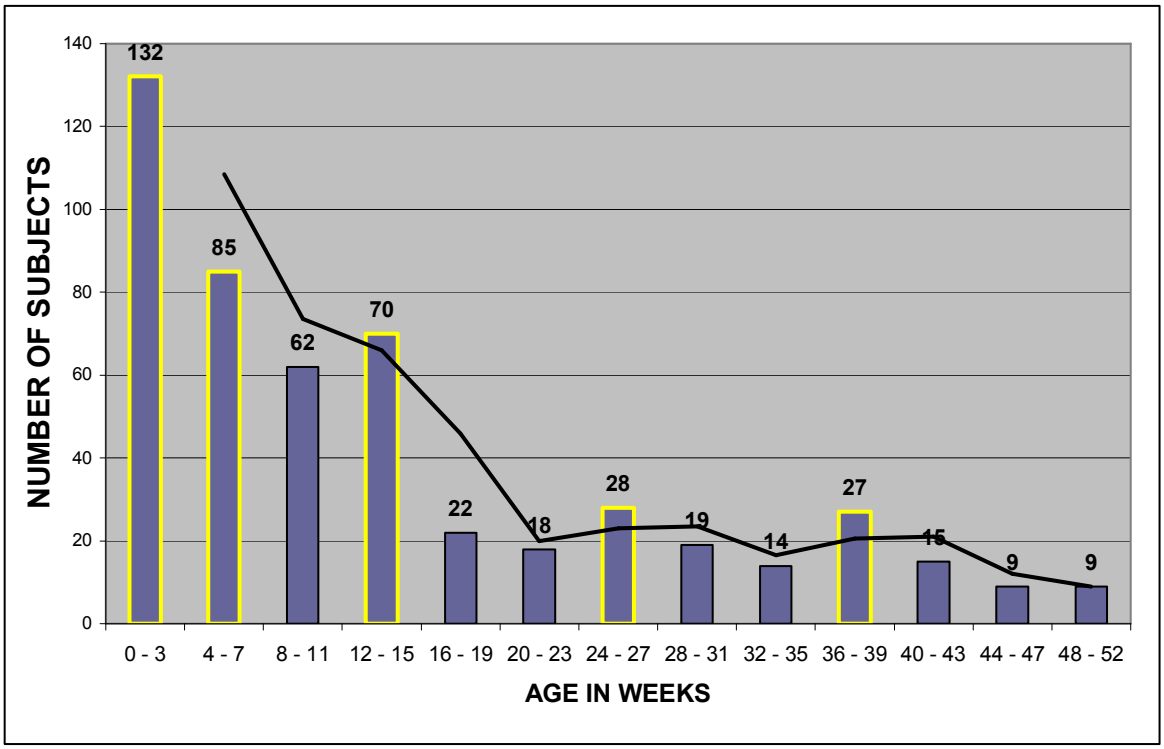

Figure 3.2 Age distribution of infants (n = 510)

A greater number of infants were found to attend at the age-groups of zero to three weeks, four to seven weeks, twelve to fifteen weeks, twenty four to twenty seven weeks, and thirty six to thirty nine weeks. This can be attributed to the fact that infants are generally brought to the maternal health care clinics for check-up and immunization procedures at 6 week time intervals. 26 % (132) of

infants were between the ages of zero to three weeks. The mean chronological age of infants that participated in the study was 12.8 weeks, with a standard deviation of 12.58 weeks. The gender distribution of the subjects was approximately equal with 248 (49%) female infants and 262 (51%) male infants included in the study. Statistical analysis indicated that no statistically significant gender-effect ($p > 0.5$) was evident in results obtained from 1000 Hz tympanometry.

3.7 MATERIAL AND APPARATUS

The material and apparatus used for the collection of data in this current study included apparatus for the recording of quantitative audiologic measures (dual OAE and AABR screening device and a GSI® Tympstar middle ear analyzer), in addition to a recording sheet (Appendix A) that was compiled on which all these variables were documented.

The material and apparatus are listed and discussed below:

- ***Data recording sheet***

A recording sheet (see Appendix A) was compiled to record all variable acoustic immittance and OAE measurement values, and biographical information obtained from a short structured interview with the mother or caregiver who accompanied the infants.

- ***Middle-Ear Analyzer***

A GSI® TympStar Version 2 Middle-Ear Analyzer was used to perform acoustic immittance measurements. The GSI® TympStar was calibrated in January 2003 before research commenced and re-calibrated after 300 infants were tested. As the middle ear analyzer was transported to the specified health clinics for recording of data, calibration checks were performed according to specifications provided by the manufacturer in the hard-walled test cavities prior to commencement of testing each day. Data from immittance measurements, performed with the GSI® TympStar, were recorded on the recording sheet

(Appendix A, section C) and a printout of all tympanograms and reflexes were made.

Test parameters for tympanometry and acoustic reflex measurements made with the GSI® TympStar were as follows:

Tympanometry

~ For recording of tympanograms the probe tone frequency of the tympanometer was set to 1000 Hz with a positive to negative pressure sweep of 200daPa per second as recommended for infants (Holte *et al.,* 1991:23) and to reduce recording time.

~ For each infant a Y_a (admittance) tympanogram, and a simultaneous B_a (susceptance) and G_a (conductance) tympanogram, was recorded in the left and right ear.

~ The point of maximum deflection was marked on each tympanogram to obtain the uncompensated peak admittance value with the corresponding pressure value at this point.

Reflexes

~ Acoustic reflexes were recorded with a 1000 Hz ipsilateral stimulus using a 1000 Hz probe tone. Present reflex thresholds were defined as the lowest intensity eliciting a reflex response with a deviation greater than 0.02. To be accepted as a true, the deviation had to be repeatable and had to indicate reflex growth with increase in intensity and a decrease in amplitude at lower intensities.

❒ ***OAE and AABR screener***

A handheld dual OAE and AABR GSI AUDIOscreener™ was used for hearing screening measurements. This device does not require the use of a computer and uses a single probe tone to conduct OAE and ABR measurements. The system uses 'real-ear' calibration to allow calibration within the test ear. Distortion Product (DP) OAE and click evoked ABR measurements were made

with this device. OAE measurements were used as the first screening step and AABR as the second screening step for those subjects who failed the first OAE screen. As OAEs are also known to be sensitive to middle ear functioning, the OAE pass / fail results was used as a cross-validation to identify infants with normal middle ear functioning.

The test parameters that were used for OAE testing with the GSI AUDIOscreener™ were as follows:

The default screening protocol, setting 'DPOAE 2', was selected on the GSI AUDIOscreener™ for screening neonates and infants in this study. Five frequencies were assessed for each ear and a pass criterion was based on passing at least four of the five frequencies evaluated. The stimulus parameters are in agreement with the guidelines by the American Speech-Language and Hearing Association (ASHA, 1997) and are presented in Table 3.1.

TABLE 3.1 OAE stimulus parameters (DPOAE 2)

	2000 Hz	3000 Hz	4000 Hz	5000 Hz	6000 Hz
L1/L2 ratio	65/55	65/55	65/55	65/55	65/55
F1 (Hz)	1750	2550	3250	4250	4950
F2 (Hz)	2100	3100	3950	4950	6000
Fdp (Hz)	1400	2000	2550	3550	3900
F1/F2	1.2	1.2	1.2	1.2	1.2

The recordings of OAEs were based on a F2 centre method and the frequencies were measured in a downward order starting with the highest and ending with the lowest using a linear averaging method of analysis.

3.8 DATA COLLECTION PROCEDURES

Research subjects were recruited from the specified health clinics. The health clinics were visited by the researcher and a three-stage procedure was performed to obtain data. The three stages are illustrated in Figure 3.3:

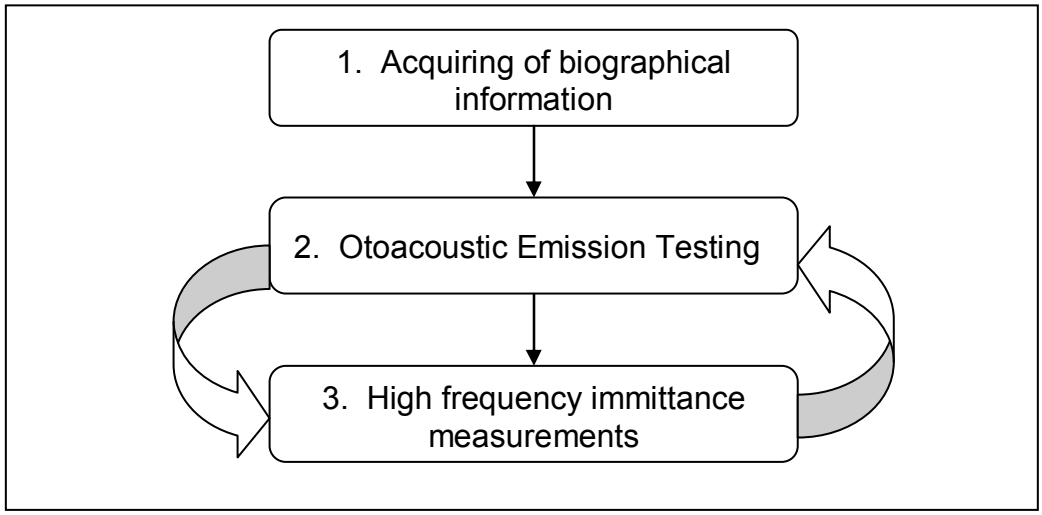

Figure 3.3 Three-stage data collection procedure

As two infants were occasionally tested simultaneously with the OAE and immittance equipment, OAE and immittance testing was performed in randomized order with immittance measures conducted first in certain cases and OAE testing first in other cases.

Stage 1: Biographical information

Mothers or caregivers of infants were informed that a voluntary hearing screening service was available to test their infant's hearing sensitivity and middle ear functioning and that the information would form part of a research project. If the mother/caregiver did not fully understand English or Afrikaans, this information and further explanation of procedures was provided by one of the two fieldworkers able to speak other African languages.

The following procedure was followed to obtain biographical information:

- ✓ Mothers who wished to have their infant's hearing screened brought their infants to the test rooms for a hearing screening.
- ✓ Caregivers were requested to bring their infants preferably if he / she was asleep or quiet and settled.

- ✓ The testing procedures were explained to mothers / caregivers and testing only commenced if consent was obtained.
- ✓ In a short structured interview with the mother or caregiver, biographical information and a medical case history was obtained from the mother/caregiver, supplemented by the infant's medical file. Data were recorded on the data sheet (Appendix A, sections A & B).

Stage 2: Otoacoustic emission (OAE) testing

The subsequent procedures were followed during OAE testing:

- ✓ The infant was placed in a comfortable position.
- ✓ After investigation of the infant's ear an appropriate sized disposable probe tip was selected and inserted into the infant's ear.
- ✓ The OAE screening module on the GSI AUDIOSCREENER™ was selected and testing commenced for the test ear. This procedure was repeated for the other ear.
- ✓ If an infant did not pass the initial DPOAE-hearing screening, an Automated Auditory Brainstem Response Test was performed as a second phase hearing screening (not included in analysis and description of results for this study).
- ✓ Results were recorded on the data recording sheet (Appendix A) and also in the infant's medical file.

Stage 3: High frequency immittance measures

Immittance measurements were performed according to the following procedures:

- ✓ An appropriate sized probe tip was selected and inserted into the infant's ear to ensure a good seal was obtained

- ✓ The probe tone frequency of the tympanometer was set to 1000 Hz with a positive to negative pressure sweep of 200 daPa per second to reduce recording time.
- ✓ For each infant a Y_a (admittance) tympanogram, and a simultaneous B_a (susceptance) and G_a (conductance) tympanogram was recorded in the left and right ear.
- ✓ The cursor option on the GSI® TympStar was used to mark the peak (measured at point of maximum positive deflection) of every tympanogram to provide the points of maximum peak admittance (mmho) and corresponding peak pressure (daPa) in each tympanogram.
- ✓ In the case of double peaked tympanograms measures were taken form the highest peak.
- ✓ If no peak was present, this was recorded as a "flat" tympanogram response curve.
- ✓ Recording of acoustic reflexes followed successful recording of tympanograms. Reflexes were recorded with a high frequency probe tone of 1000 Hz and at an ipsilateral test frequency of 1000 Hz.
- ✓ Reflex testing commenced at 70 dB HL and reflex threshold seeking was conducted by a 10 dB increase and 5 dB decrease in intensity level. Maximum testing level was 110 dB.
- ✓ Tympanometry and reflex results were printed for each subject.

Cross-infection precautions were maintained and all equipment was frequently cleaned with a sterilising solution. Sterile gloves were worn by all examiners during testing procedures.

The different procedures that were successfully performed within the total case sample, in addition to procedures that were not successfully completed are presented in Figure 3.4.

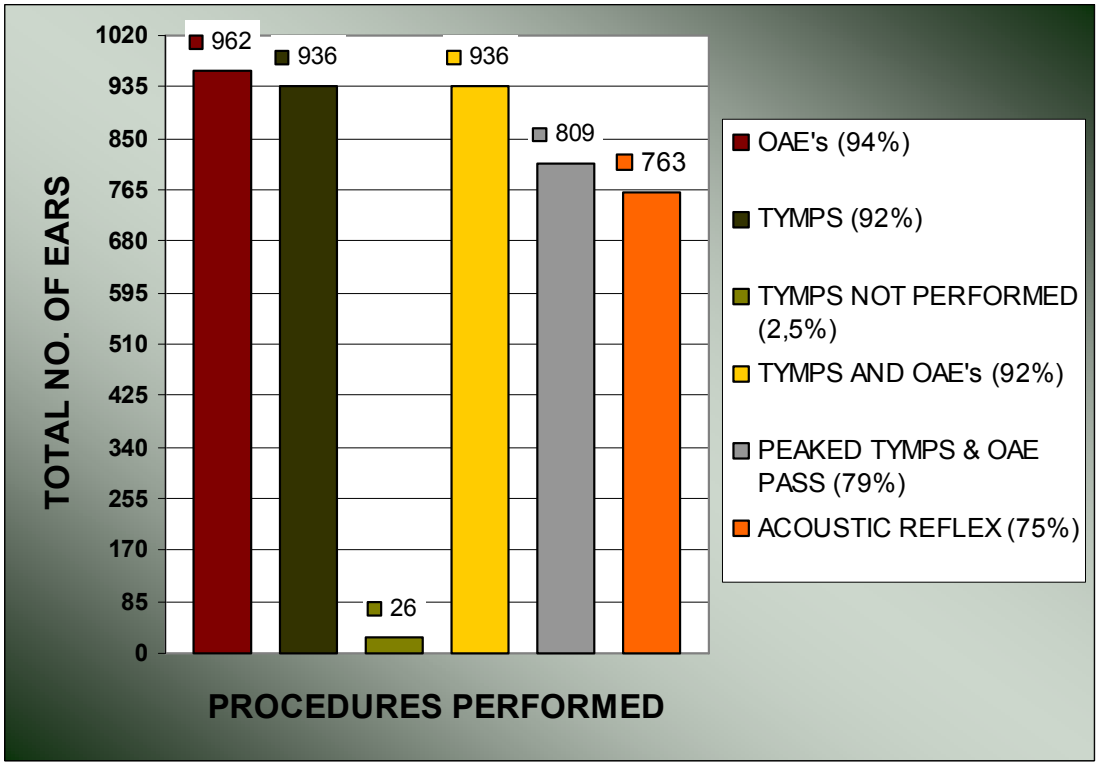

Figure 3.4 Procedures performed (n = 1020 ears)

As illustrated in Figure 3.4, OAEs were performed in 962 out of the total number of 1020 ears (94%). OAE and tympanometry testing were performed in randomised order, but due to state of alertness or lack of co-operation, it was not possible to obtain tympanometric measures from all infants. OAE testing and tympanometry was performed on 936 (92%) ears. Within this group an OAE pass result, in combination with a peaked tympanogram, was recorded from **809** (79%) of ears. Data derived from the last mentioned group was analyzed for the compilation of normative tympanometric values. Acoustic reflex measurement was performed in 763 (75%) ears.

3.9 DATA PREPARATION AND ORGANISATION PROCEDURES

Data obtained from OAE and immittance measures, in addition to biographical information, was recorded onto a data recording sheet (Appendix A). This raw quantitative data was coded to organise data into a suitable format which could be transformed into a data set in machine-readable format (Durrheim, 1999:98). This data capturing allowed for computerised analysis of data. The coded data

was entered into a statistical computer program (SAS statistical package) for statistical analysis.

3.9.1 Division of case sample into two subgroups based on middle ear function

The main aim of the study was addressed by an initial process of differentiating the sample of infants into two subgroups, based on judgment of immittance- and OAE measurement results. As discussed in Chapter 2, the recording of evoked otoacoustic emissions is dependent on the status of the middle ear and can be adversely affected by the presence of middle-ear effusion and negative middle ear pressure (Roush, 2001:50). As a screening tool, the technology consequently also appears to be useful for the detection of middle ear effusion in the infant population (Koivunen *et al.,* 2000:212; Thornton *et al.,* 1993:319). For the purpose of this study, results yielded from a DPOAE screening were acclaimed to differentiate the sample of infants into a group with normal middle ear functioning (OAE pass result) and a group with postulated middle ear effusion (OAE refer result). It was beyond the purpose of this study to clinically confirm the presence of middle ear effusion by invasive methods such as myringotomy, however as successful recording of OAEs are known to be sensitive to middle ear pathology, it was hypothesized that infants who pass DPOAE screening had ***normal middle ear functioning*** and infants who failed DPOAE screening had possible ***middle ear pathology*** (not excluding the possibility of sensory loss).

The validity of this method is supported by results by Sutton *et al.* (1996:10), in which the relationship between OAEs and tympanometry was investigated. Results indicated that OAEs are sensitive to middle ear effusion and are usually abolished by it, and it was concluded that abnormal tympanometry is strongly associated with OAE failure (Sutton *et al.,* 1996:13,14). A similar classification method was used by Margolis *et al.,* (2003:387).

OAEs were successfully recorded from 964 ears, signifying that it was not possible for OAE measurement in 56 (5,5%) of infant ears. A combination of OAE measurement and successful recording of 1000 Hz admittance tympanograms was achieved in **936 ears** of 510 healthy infants between the age of 0 and 52 weeks (Mean CA = 12.8 weeks). Lack of infant co-operation and state of alertness was the foremost reason that deterred the recording of OAEs in addition to tympanometry measurements in all infant ears. Only cases, in which a combination of an OAE and tympanometry result could be obtained in the same ear or in both ears, were included in the analysis of results.

A graphic representation of the procedure followed for the division of the groups is given in Figure 3.5

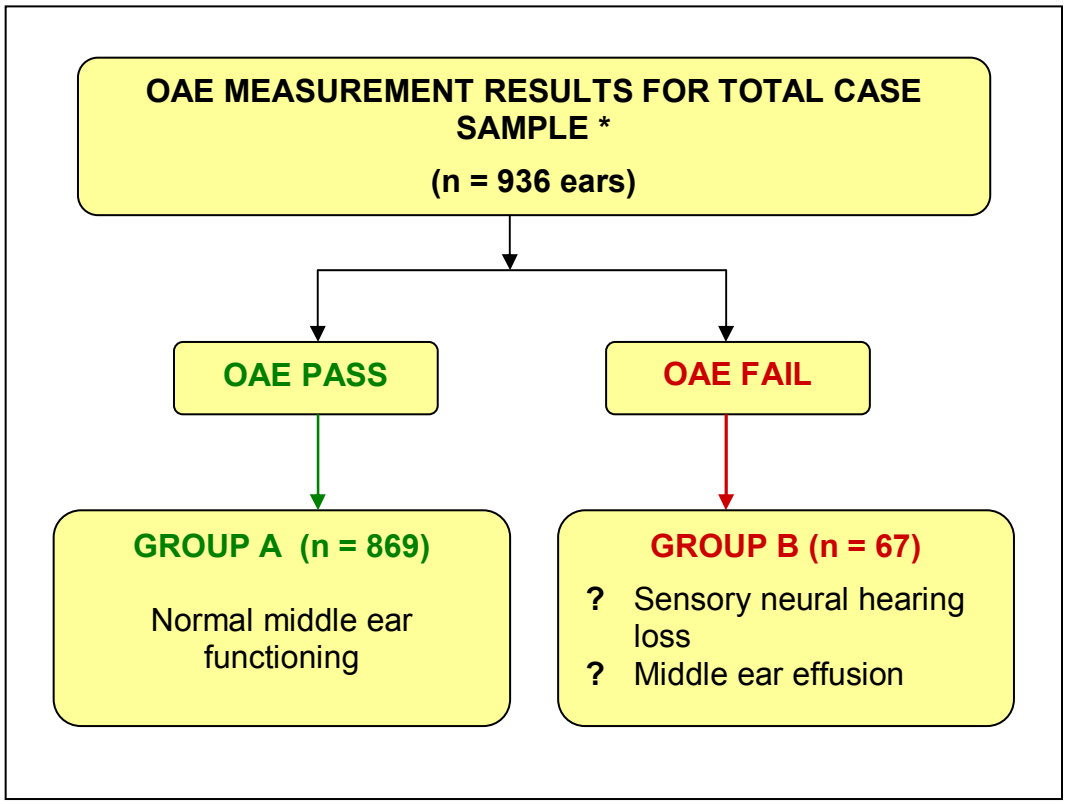

Figure 3.5 OAE results acclaimed for division of groups
(* OAEs and tympanograms recorded)

For the purpose of discussion of results in the subsequent chapters, the group with normal middle ear functioning is referred to as Group A, and the group with postulated middle ear effusion is referred to as Group B.

In summary, as the main aim of the current study was to determine and describe characteristics and normative values for 1000 Hz probe tone immittance measures, it was essential for infants used in the compilation of normative values to have normal middle ear functioning. A screening OAE procedure was used in conjunction with immittance measurements to identify infants with normal middle ear functioning. As the recording of an OAE is dependent on middle ear state, it also appears to be useful for detecting MEE in infants. The first phase of the study therefore set out to differentiate the sample into a group of infants with normal and abnormal middle ear functioning, as correlated with an OAE pass or fail result. The total case sample of 936 ears was divided into two groups, depending on outcome of OAE testing. Group A (869 ears) was classified as cases with normal middle ear functioning corresponding to an OAE pass result. Group B (67 ears) was classified as infants with postulated middle ear effusion, corresponding to an OAE fail result. Discussion of subsequent results will be based on results obtained within these subgroups. An initial comparison between results of OAE testing and tympanogram shape will be pursued to determine associations between OAE results and tympanogram shape.

3.9.2 Procedures for classification of tympanograms

Comparable to the procedure used for the division of the case sample according to OAE results, a similar process was used to differentiate the sample into a group with normal and a group with abnormal tympanograms. Recorded tympanograms were classified in terms of their shape and configuration. Results were subsequently compared to results of OAE testing to determine the relationship and agreement between results of the two procedures.

A visual inspection of the configuration of admittance (Y_a) tympanograms was applied as assessment for pass-fail differentiation of tympanograms. As there are still no generally accepted guidelines on the classification or interpretation of high frequency tympanograms in neonates (Kei *et al.,* 2003:27; Sutton *et al.,* 1996:11) classification of admittance (Y_a) tympanograms was based on whether

a discernable peak was present or not. The presence of a single peak or notching (double peak) was accepted as normal, while tympanograms with flat, even traces were considered to be suggestive of effusion (Purdy & Williams, 2000:16; Sutton *et al.,* 1996:11).

The characteristics of normal 1000 Hz probe tone Y-admittance tympanograms were determined and described in terms of peak admittance and corresponding tympanometric peak pressure values. Only ears displaying both a pass OAE result in addition to a peaked 1000 Hz probe tone admittance tympanogram in the same ear, were included in the compilation of normative values.

A flowchart to illustrate the research process is provided in Figure 3.6. This is supplemented by a graphic illustration of the research process and use of data categorized according to the main and sub-aims in Figure 3.7.

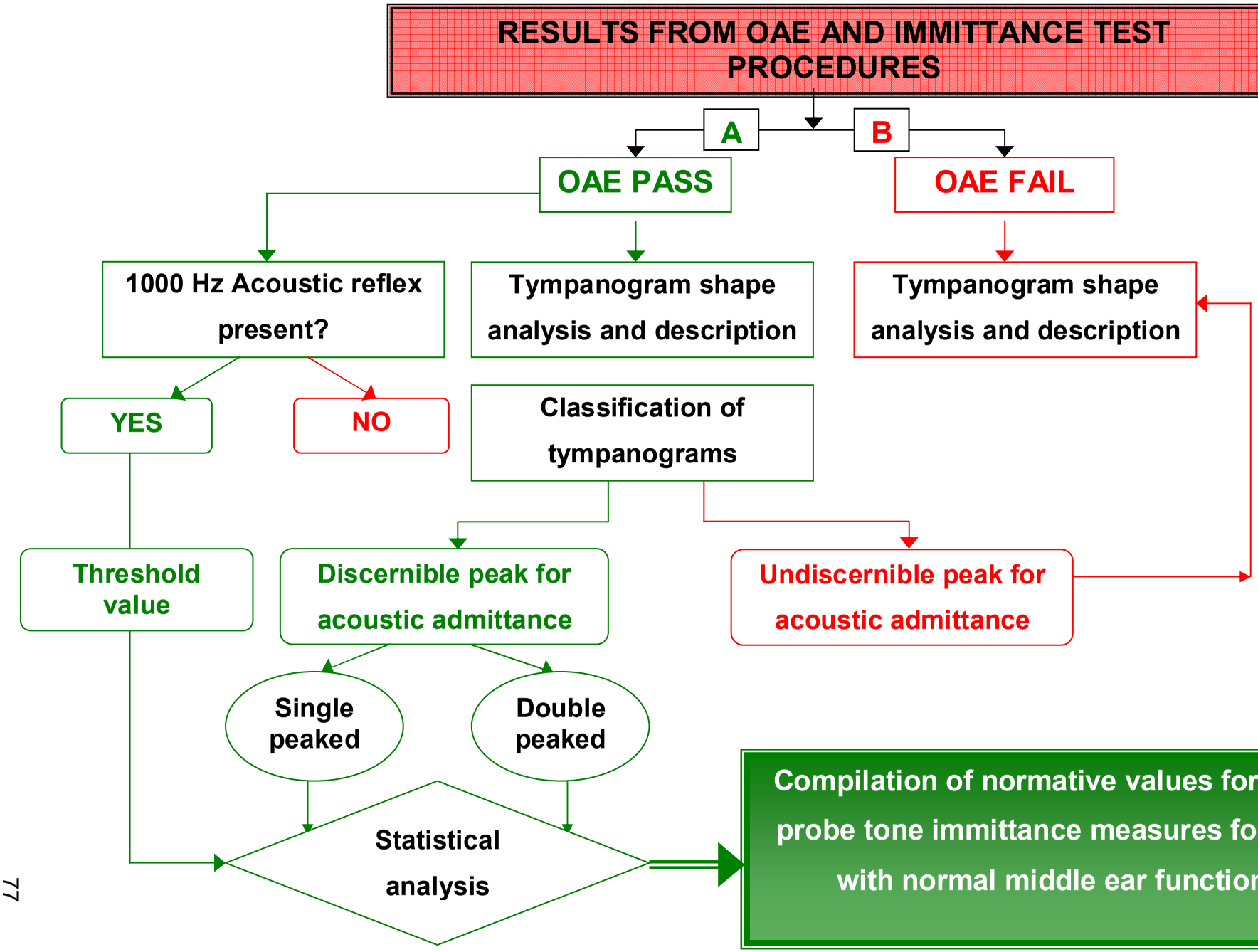

Figure 3.6 Flowchart of research process

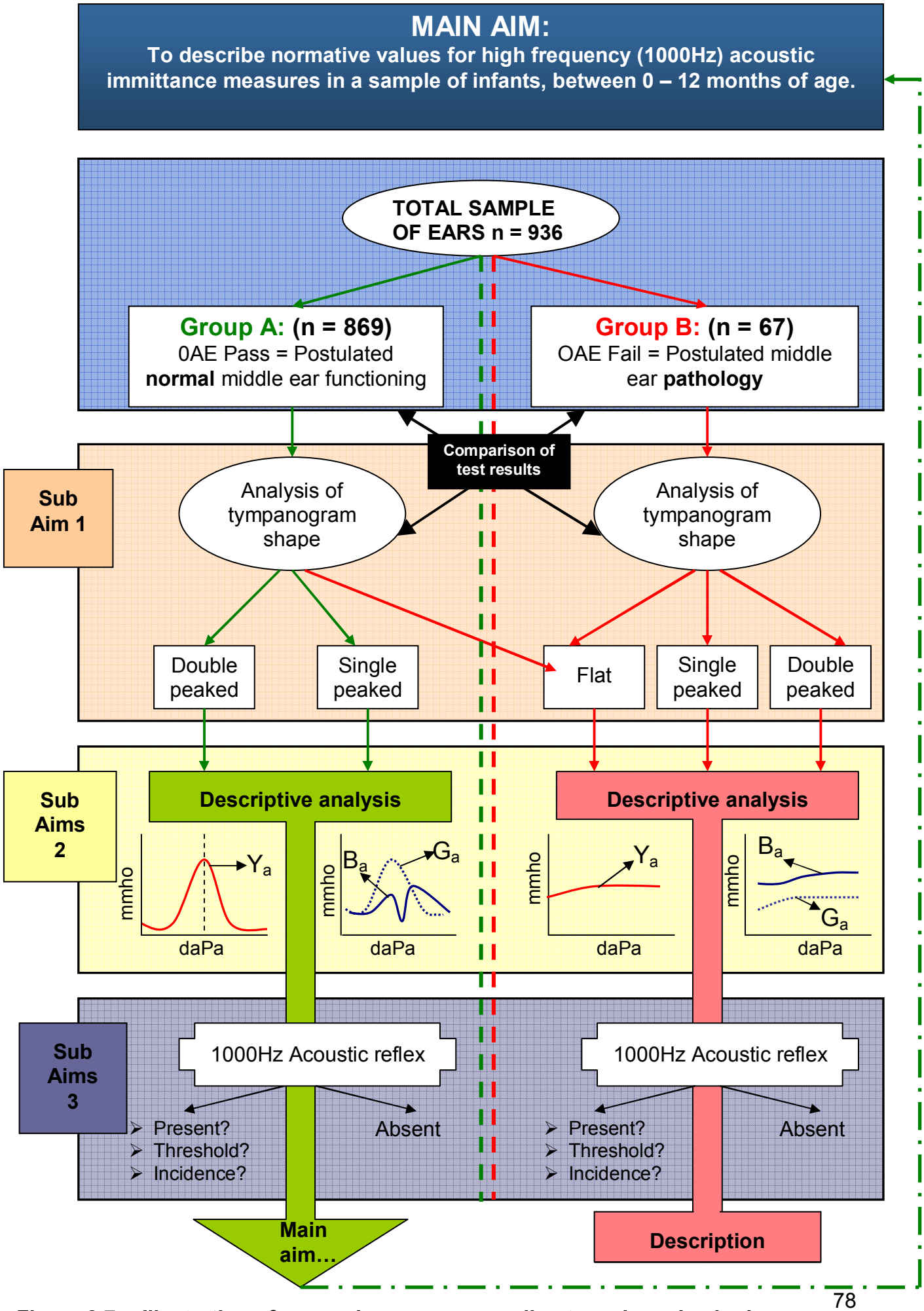

Figure 3.7 Illustration of research process according to main and sub-aims

3.10 DATA ANALYSIS

According to Leedy and Ormrod (2001:252) data analysis is a process of attempts to answer the question "What do the data mean?" Statistical procedures are used to analyse quantitative data allows for extraction of meaning and inferences about the characteristics of the data (Leedy & Ormrod, 2001: 258; Durrheim, 1999:96). This process involves various ways of organising data. The quantitative data obtained in the study were analysed by statistical methods to provide a means through which numerical data could be made more meaningful.

Descriptive and inferential statistics (Leedy & Ormrod, 2001:259) were used to describe the data and allowed for the drawing of conclusions about the sample population. Statistical methods that were utilised to test for differences between the mean values of variables, (i.e. gender, left and right ears, age effects and differences in measures between subgroup A and group B) included *t-test analysis* (Durrheim, 1999:119), ANOVA and Mann-Whitney analysis (Leedy & Ormrod, 2001:278). Descriptive statistics in the form of measures of variation, dispersion and standard deviations (Leedy & Ormrod, 2001:268) were used to determine and describe normative values for 1000 Hz probe tone tympanograms and acoustic reflexes.

3.11 SUMMARY

This chapter provided a description of the methodological approach implemented for the collection and analysis of the data to realise the main and sub-aims of this study. The research design and ethical considerations were described, followed by a description of the context where the research was conducted. Details of the selection criteria and research subjects included in the study were provided. A delineation of the material and apparatus, including specific test parameters was given and procedures for data-collection and analysis were included.