THE CLINICAL VALUE OF THE AUDITORY STEADY STATE RESPONSE FOR EARLY DIAGNOSIS AND AMPLIFICATION FOR INFANTS (0 – 8 months) WITH HEARING LOSS

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For Frederick, Nell and Mieke

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SUMMARY

TITLE	:	THE CLINICAL VALUE OF THE AUDITORY STEADY STATE RESPONSE FOR EARLY DIAGNOSIS AND AMPLIFICATION FOR INFANTS (0 – 8 months) WITH HEARING LOSS
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There has always been a need for objective tests that assess auditory function in infants, young children, and/or any patient whose development level precludes the use of behavioral audiometric techniques. Although the Auditory Brainstem Response (ABR) is seen as the 'gold standard' in the field of objective audiometry, it presents with its own set of limitations. The Auditory Steady State Response (ASSR) has gained considerable attention and is seen as a promising addition to the AEP 'family' to address some of the limitations of the ABR. The ASSR promises to estimate all categories of hearing loss (mild to profound) in a frequency specific manner. It also indicates to the possibility to validate hearing aid fittings by determining functional gain of hearing aids by determining unaided and aided ASSR thresholds.

An exploratory research design was selected in order to compare unaided thresholds, obtained through the use of three different procedures – ABR, ASSR and behavioral thresholds. Aided thresholds were also obtained and compared with two procedures – the aided ASSR (measured and predicted) and aided behavioral threshold. The results indicated that both the ABR (tone burst and click) and ASSR provided a reasonable estimation of the subsequently obtained behavioral audiograms. The ASSR, however, approximated the behavioral thresholds closer than the ABR and were furthermore able to quantify hearing thresholds accurately for subjects with severe and profound hearing losses. The result indicated further that the ASSR can be instrumental in the validation process of hearing aid fittings in infants. These results demonstrated however, that the ASSR measured thresholds underestimate the aided behavioral thresholds and the aided ASSR predicted thresholds overestimate the aided behavioral thresholds.

The research concluded that the ASSR is useful in estimating frequency-specific behavioral thresholds accurately in infants and validating hearing aid fittings. Until evidence is sufficient to recommend the ASSR as primary electrophysiological measure of hearing in infants, the ASSR should be used in conjunction with the ABR – following a test battery approach in the diagnostic process of hearing loss in infants. The ASSR further shows great promise in validating hearing aid fittings, but this specific application of the ASSR needs further research evidence on large groups to validate the procedure.

Key terms: Objective tests, estimate behavioral thresholds, auditory brainstem response, auditory steady state response, frequency specific, test battery, validation of hearing aids, ASSR measured thresholds, ASSR predicted thresholds, auditory evoked potentials.

OPSOMMING

TITEL	**:**	**DIE KLINIESE WAARDE VAN DIE OUDITIEF STANDHOUDENDE RESPONS VIR VROEË IDENTIFIKASIE VAN GEHOORVERLIES EN VROEË PASSING VAN GEHOORAPPARATE IN DIE JONG BABA (0 – 8 maande)**
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In die veld van Oudiologie is daar ‘n voortdurende behoefte na objektiewe oudiometriese prosedures om ouditiewe sensitiwiteit in babas, jong kinders en/of enige pasiënte wie se ontwikkelingsvlak hul uitskakel van gedragsoudiometrie, te bepaal. Die Ouditiewe Breinstam Respons (OBR) word gesien as die “goue standaard” in die veld van objektiewe oudiometrie, alhoewel die tegniek sy eie beperkinge voorhou. Die Ouditiewe Standhoudende Respons (OSR), het aansienlike aandag begin geniet en word gesien as ‘n belowende toevoeging tot die ‘familie’ van Ouditief Ontlokte Potensiale (OOP), wat gevolglik sekere van die OBR se tekortkominge kan aanspreek. Die OSR blyk ‘n ouditief ontlokte respons te wees wat spesifiek geskik is om alle kategorieë van gehoorverlies frekwensie-spesifiek te voorspel. Daar is ook aanduidings dat die OSR geskik mag wees om passings van gehoorapparate by jong babs te bevestig, deur beide onversterkte en versterkte OSR drempels te bepaal.

‘n Ondersoekende navorsingsontwerp is gebruik om onversterkte drempels, soos bepaal deur drie verskillende prosedures – OBR, OSR en gedragsoudiometrie – te bepaal en te vergelyk. Versterkte drempels is ook bepaal en vergelyk deur middel van twee prosedures, naamlik die versterkte OSR (meting en voorspelling) en versterkte gedragsoudiometrie. Die resultate het getoon dat beide die OBR (toonbreuk en klik) en die OSR ‘n redelike beraming van suiwertoon gedragsoudiometrie vertoon. Die OSR het egter die suiwertoondrempels meer akkuraat beraam en was daartoe instaat om die erge en uitermatige gehoorverliese te kwantifiseer. Die resultate het verder daarop gedui dat die OSR ‘n rol kan speel in die bevestiging/validasie van gehoorapparaatpassings in babas. Die resultate het gedui daarop dat die OSR meting die versterkte gedragsoudiometrie drempels onderskat, terwyl die OSR voorspelde drempels die versterkte gedragsoudiometrie drempels oorskat.

Die navorsing het bevind dat die OSR nuttig is om frekwensie-spesifieke suiwertoondrempels akkuraat vir babas te voorspel. Die OSR toon ook waarde in die validasie-proses wanneer gehoorapparate gepas word. Verdere navorsing is egter nodig alvorens die OSR as primêre elektrofisiologiese prosedure aanbeveel kan word om gehoor van babas te evalueer. Dit is duidelik dat die OSR deel van ‘n toets-battery benadering moet wees om gehoorsensitiwiteit van babas te evalueer. Die OSR dui verder daarop dat dit ‘n rol kan speel in die validasie-proses wanneer gehoorapparate gepas word, maar dat hierdie toepassing van die tegniek verdere navorsing benodig. Validasie daarvan op groot groepe is nodig.

Sleutelwoorde: Objektiewe oudiometrie, beraming van suiwertoondrempels, ouditiewe breinstam respons, ouditiewe

standhoudende respons, frekwensie-spesifiek, toetsbattery, validasie van gehoorapparate, OSR meting, OSR voorspelling, ouditief ontlokte potensiale.

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LIST OF ABBREVIATIONS

AABR	-	Automated Auditory Brainstem Response
ABG	-	Air Bone Gap
ABR(s)	-	Auditory Brainstem Response(s)
AC	-	Air Conduction
AEP(s)	-	Auditory Evoked Potential(s)
AER	-	Auditory Evoked Response
AM	-	Amplitude Modulation
ASSR(s)	-	Auditory Steady State Response (s)
BC	-	Bone conduction
BT	-	Behavioral Threshold
CF(s)	-	Carrier Frequency (s)
CNS	-	Central Nervous System
dB	-	Decibel
eCochG	-	Electrocochleography
EEG	-	Electro-Encephalo-Gram
EOAE	-	Evoked Oto-acoustic Emissions
FFR	-	Frequency Following Response
FFT	-	Fast Fourier Transform
FM	-	Frequency Modulation
HL	-	Hearing Level
Hz	-	Hertz
IAFM	-	Independent Amplitude and Frequency Modulation
JCIH	-	Joint Committee on Infant Hearing
Kg	-	kilogram
kHz	-	Kilo Hertz
kOhms	-	Kilo Ohm

L	-	Left
L-I	-	Latency Intensity
LLR	-	Late Latency Response
MASTER	-	Multiple auditory steady-state response
MF(s)	-	Modulation Frequency (s)
mg	-	milligram
MLR	-	Middle Latency Response
ms	-	Millisecond
n	-	Number
nHL	-	Normal Hearing Level
NICU	-	Neonatal Intensive Care Unit
NR	-	No Response
OAE(s)	-	Oto-Acoustic Emission (s)
PC	-	Phase Coherence
R	-	Right
s	-	Second
sec	-	Second
SD	-	Standard Deviation
SLR	-	Short Latency Responses
SN_{10}	-	Slow-negative Potential
SNHL	-	Sensory Neural Hearing Loss
SPL	-	Sound Pressure Level
SSP	-	Steady State Potential
SSEP		Steady State Evoked Potential
TB	-	Tone Burst
UNHS	-	Universal Newborn Hearing Screening
USA	-	United States of America
WRS	-	Word Recognition Scores

Chapter 1

INTRODUCTION

Chapter one introduces the problem this study confronts; the rationale therefore, describes the terminology used, and presents an overview of the content and organization of the study.

1.1 ORIENTATION TO THE STUDY

The practice of pediatric audiology is based on the principle that the best outcomes for a child with hearing loss are achieved when his or her hearing status is determined as early as possible, followed by timely intervention (Cone-Wesson, 2003:253). Hearing loss in newborn infants can go undetected until as late as three years of age without specialized testing (Hayes & Northern, 1997:4). When hearing loss is detected in the newborn period, infants can benefit maximally from amplification (hearing aids) and intervention to facilitate speech and language development (Sininger, Doyle & Moore, 1999:11). Evidence regarding neural development strongly supports such early intervention for optimal outcomes of communication ability and hearing in infants (Sininger, Doyle & Moore, 1999:11). Pediatric audiologists, therefore, should facilitate early detection of hearing loss and intervention through screening programs and in-depth hearing assessments, determining which technologies and habilitation programs are best suited to the needs of both the infant and the family.

In order to capitalize on the positive aspects of early identification, the Year 2000 Position Statement on Infant Hearing Screening produced by the Joint Committee on Infant Hearing (JCIH), recommend that all infants' hearing should be screened using **objective, physiologic** measures in order to identify hearing loss (JCIH, 2000:10). Audiologic and medical evaluations should be conducted before three months of age. Infants with confirmed hearing loss should receive intervention before six months of age from health care and education professionals with expertise in hearing loss and deafness in infants and young children (JCIH, 2000:10).

Infants identified according to these recommendations are too young for the use of traditional audiometric procedures to determine an audiogram (Cone-Wesson, 2003: 254). Instead, electrophysiologic methods such as Auditory Evoked Potentials (AEP) must be used to estimate hearing thresholds. Ongoing evaluation of hearing function is furthermore needed to monitor the effects of early intervention and AEP tests may also form an important part in this process (Cone-Wesson, 2003:270).

According to Diefendorf and Weber (1994:56), four criteria need to be addressed before amplification of a hearing loss can occur. The degree, the configuration, the symmetry and the type of hearing loss must be determined. Amplification and habilitation strategies, such as choice of hearing aids, cochlear implants and choice of mode of communication, are based on the above criteria – usually revealed by the audiogram (Ross, 2001:3). Electrophysiological tests can assist in the process of characterizing hearing loss for infants, since these tests can measure auditory function objectively - giving frequency-specific information needed to fit appropriate amplification in this young population.

Apart from assisting in the process of diagnosing the hearing loss, it is important to verify that a specific hearing aid provides adequate amplification (Picton, Dimitrijevic, Van Roon, Sasha-John, Reed & Finkelstein, 2002:63). According to Picton et al. (2002:64), verification of a hearing aid fitting provides some indication of how well sounds are heard when the aid is used at its prescribed settings. Electrophysiological tests can assist in this process of verification in infants and young children. Studies have indicated that both the Auditory Brainstem Response (ABR) and the Auditory Steady State Response (ASSR) can be used to estimate threshold when the stimuli is transduced by a hearing aid (Garnham, Cope, Durst, McCormick, & Mason, 2000:268; Picton, Durieux-Smith, Champagne, Whittingham, Moran, Gigueve & Beauregard, 1998:315). Since the early identification of hearing loss through newborn hearing screening has resulted in a younger population being served by the audiologist, electrophysiological tests are becoming a more essential part of the required test-battery.

1.2 BACKGROUND

The audiologist serves as the professional primarily responsible for the assessment and non-medical diagnosis of auditory impairment. Assessment includes, but is not limited to, the administration and interpretation of behavioral, electroacoustic, and electrophysiologic measures of the status of **peripheral** and **central auditory nervous systems** (Stach, 1998:3). The main purpose of a hearing evaluation is to define the nature and extent of hearing impairment. A comprehensive description of hearing ability serves as a first step in the rehabilitation of a hearing handicap that result from an impairment. An individual with a hearing disorder must therefore rely on an assessment of auditory function as the foundation of the rehabilitation process (Swanepoel, 2001:1).

Pure tone audiometry represents the first and, arguably, the most fundamental measure of hearing acuity (Harrell, 2002: 71). The behavioral pure tone audiogram is a measure of auditory threshold as a function of frequency. The audiogram configuration provides fundamental baseline information for the selection of a suitable amplification system (Stach, 1998:68). It is understandable then that pure tone audiometry has remained the audiometric procedure of choice. It embodies the gold standard for frequency-specific threshold establishment against which all other audiometric measures are compared (Swanepoel, 2001:3).

It is clear that the standard clinical pure tone technique will not be effective for all clinical populations. The most obvious is the pediatric population. This is also true of the developmentally delayed and, in some cases, the severely physically impaired (Harrell, 2002:73). Conditioned audiometric test techniques (such as visual reinforcement audiometry), that can provide increasingly accurate information in older children (>6 months), are not suitable for quantifying hearing loss in very young infants or for those with visual or developmental disabilities (Rance & Briggs, 2002:237) as suprathreshold stimulation is required to elicit reflexive responses. These conditioned audiometric methods are limited to the detection of hearing loss greater than 50 dB HL (Diefendorf & Weber, 1994:57).

Therefore, as the age of identification is reduced the need for accurate, reliable, **objective** methods for determining hearing thresholds, is becoming more urgent. When an infant is identified as having a hearing loss, there is an immediate need to characterize the degree, the configuration, and the type of loss, since appropriate recommendations regarding the selection and fitting of devices such as hearing aids and cochlear implants, can only be made with an understanding of both the degree and configuration of a child's hearing loss (Rance & Briggs, 2002:237; Vander Werff, Brown, Gienapp, & Schmidt Clay, 2002:228).

Different techniques have therefore been developed over the years in order to address the problem of quantifying hearing loss in young infants. One such a measure, that was received positively for diagnostic purposes in the pediatric field, was otoacoustic emissions – discovered in 1978 by David Kemp. Otoacoustic emissions (OAE's) are sounds that originate in the cochlea and propagate through the middle ear and into the ear canal, where they can be measured using a sensitive microphone (Prieve & Fitzgerald, 2002:440). It has been known for the last 20 years that individuals with significant cochlear hearing loss have no measurable Evoked Otoacoustic Emissions (EOAE's). Hall (1997:265) has indicated that EOAE's are either not measurable from subjects with hearing loss or are substantially reduced in amplitude compared to normal hearing individuals. The minimum level required for measurable EOAE's ranges from 25 – 40 dB HL (Prieve & Fitzgerald, 2002:452).

Given this specific population and the need for specific information, with regard to degree, configuration, symmetry and type of hearing loss, work in the area of OAE's does not provide compelling evidence to indicate that EOAE's could be used to predict the nature of an infant's hearing loss (Prieve & Fitzgerald, 2002:456). This procedure is, however, a powerful tool for newborn hearing screening and should form an integral part of the differential diagnosis test battery in the diagnosis of hearing loss in infants (Hall, 2000:391).

The ABR is a far field evoked potential that is used frequently to estimate auditory sensitivity in children too young to be tested using standard behavioral methods. The ABR to click stimuli is the most commonly used clinical procedure in predicting hearing sensitivity (Vander Werff, Brown, Gienapp, & Schmidt Clay, 2002:228). Although the abrupt onset of the click stimulus is ideal for generating the ABR, the drawback is that the click is a broad-spectrum signal, containing energy across a wide range of frequencies. Owing to this frequency spread, clicks cannot be used to assess sensitivity in specific frequency regions, but rather to provide a gross estimate of hearing sensitivity (Arnold, 2000:454).

ABR to brief tones can be used to obtain more frequency-specific threshold information than available from the click ABR. Stapells (2000a:13) has shown across studies that tone-ABR thresholds have been found to be a reliable method in obtaining frequency specific information in this young population. Stapells (2004: conference presentation) maintains that the tone-evoked auditory brainstem response (tone-ABR) is currently the only measure that can reliably provide information with regard to severity, configuration and nature of hearing loss in infants. Some studies have however questioned the frequency-specificity and reliability of threshold estimation with low frequency tone-evoked ABR (Cone-Wesson et al., 2002:174). In addition, toneburst ABR waveforms, especially to low-frequency stimuli, tend to be less distinct and more difficult to identify than the click ABR (Arnold, 2000:459). Output limitations are also a concern with tone burst stimuli, particularly for low-frequency tone bursts for which thresholds are elevated relative to behavioral thresholds. These concerns may limit the implementation of toneburst ABR protocols (Vander Werff et al., 2002:229).

1.3 RATIONALE

In the past two decades, the Auditory Steady State Response (ASSR) has been developed as an alternative frequency specific Auditory Evoked Potential (AEP) approach to quantify hearing loss (Rance et al., 1998:499). Vander Werff et al. (2002:228) define the ASSR as "*an alternative evoked potential technique that uses continuous rather than transient stimuli to elicit a response from the auditory system".* Unlike the ABR, the ASSR use stimuli that is continuous. The stimuli used to evoke ASSR, are modulated tones, which are frequency specific due to the fact that spectral energy is contained only at the frequency of the carrier tone and the frequency of the modulation (Hood, 1998:117). Responses from the neural system that responds to the changes or modulations in the stimuli are recorded. The ASSR appears to be generated by the same neural anatomical regions from which the ABR evoked by clicks or tone-bursts is produced (Cone-Wesson, 2003:267).

The ASSR shows potential to address some of the limitations associated with ABR testing in the early diagnosis and amplification of infants. One of the limitations of ABR is the lack of frequency specificity. The nature of the ASSR stimuli offers advantages over other short duration stimuli (Rance et al, 1998:499). Because the threshold estimates obtained from ASSR testing are frequency specific, it allows for testing across the audiometric range and for the generation of evoked potential audiograms (Rance et al., 1998:499). This feature will address the problem of determining the configuration of hearing loss in infants.

Due to the limitations in maximum output with the ABR, the absence of wave V in ABR test results does not inevitably imply the absence of hearing (Arnold, 200:457). Rance et al. (1998:506) demonstrated the advantages of using ASSR's to determine residual hearing thresholds in infants and children for whom ABR's could not be evoked at 100 dBnHL. The continuously modulated tone used to elicit the ASSR can be presented at levels as high as 120 dB HL. Absence of a click- or tone-burst ABR does not inevitably indicate profound deafness, and ASSR tests may reveal enough residual hearing to consider the use of amplification or help determine the preferred ear for cochlear implantation (Rance et al., 1998:506). The advantages offered by the ASSR in this regard are most beneficial for infants and children as the severity of the hearing loss can be determined in a more accurate manner.

Cone-Wesson et al. (2002:270) mentions a third limitation of the ABR for audiologic application as the subjective nature of response detection. Although methods for "automatic detection" of ABR exist, these algorithms have been successfully applied for click-evoked ABR. There are no published data on the use of automatic detection criteria for detecting the response to tonal stimuli. In contrast, there has been extensive research on the efficacy for detecting a steady-state response automatically (Cone-Wesson et al., 2002:175; Rance et al., 1995:499). The objective nature of response detection in the ASSR measures may lead to more accurate diagnosis of hearing loss in infants.

According to Rance et al. (1998:506) a further advantage of the ASSR as opposed to the ABR, is the speed with which a response can be detected. Although Hall (2005:conference presentation) disputes the speed of the ASSR to be faster than the ABR, several researchers have concluded that ASSR offers the possibility of estimating frequency-specific hearing thresholds in babies in a more time-efficient way (Luts, Desloovere, Kumar, Vandermeersch & Wouters, 2004:995; Swanepoel, 2001:112; Rance et al., 1998:506). A constant unpredictable factor in testing infants is that they may awake at any moment during the procedure. The fast detection speed of the ASSR thus reduces the need to have the infant asleep or under sedation for long periods of time.

It is techniques such as the ASSR that underlie successful early amplification of hearing necessary to preclude or limit the auditory sensory deprivation effects (Ross, 1996:13). The amplification process begins directly after the diagnosis of a hearing loss has been made. Functional evaluation of a hearing aid seeks to determine whether the child benefits from such amplification. The functional evaluation of hearing aids is as essential as an electroacoustic evaluation thereof. The aided audiogram can evaluate whether the child is able to hear soft sounds within expectations, based on the electroacoustic fitting of the hearing aid. Kuk (2004:1) also maintains that using the levels obtained through functional gain must be a reassurance to the parent to ensure that the optimal opportunity is given to develop a child's potential. Although ABR measures have been used in the past to assist in the fitting of hearing aids in children, the clinical use of these procedures are technically challenging (Garnham et al., 2000:268; Mahoney, 1985:351).

ASSR's have been used to demonstrate the gain provided by amplification (Picton et al., 1998:315). ASSR's can be obtained in the sound-field condition – measuring an unaided response as well as the aided response. The difference in ASSR threshold obtained in the aided condition is then used to predict the functional gain of the hearing aid (Cone-Wesson, 2003:272). According to Glockner in Cone-Wesson (2003:272), hearing aids appear to transduce the modulated tones with good fidelity; the spectral characteristics of the modulated tones played through an analog hearing aid with no compression are well preserved. The fact that the stimuli are much more stable over time than brief transients means that they are more reliably transferred through the free field speakers and hearing aids – even when the hearing aids are non-linear (Picton et al., 2002:66). After being diagnosed with a hearing loss and fitted appropriately with hearing aids, the adequacy of the fitting needs to be validated. Validation is an ongoing process designed to ensure that the infant is receiving optimal speech input from others and that his or her own speech is adequately perceived (Pediatric Amplification Protocol, 2003:15).

1.4 PROBLEM STATEMENT

The dawn of an era of early identification of hearing loss in newborns and infants confronts audiologists with new challenges and opportunities. The advent of universal newborn hearing screening has made it all the more common for audiologists to see infants less than two to three months of age who have been identified as being at risk of having a hearing loss. The process of fitting a hearing aid or determining the candidacy for cochlear implantation requires detailed knowledge of these infants' residual hearing abilities (Vander Werff et al., 2002:228). For newborns and infants, evoked potential estimates of audiometric thresholds may be the only information about hearing status that is available at the time when these critical decisions need to be made.

The transformation of new discoveries into practical clinical procedures has been a frequent occurrence in audiological test development over the past three decades (Gorga, 1999:29). Several recent studies have therefore explored the relationship between ASSR electrophysiological thresholds and audiometric behavioral thresholds for normal-hearing and hearing impaired listeners (Dimitrijevic et al., 2002:205; Herdman & Stapells, 2001:41; Lins et al., 1996:81; Rance et al., 1995:499). These investigators have reported finding significant correlations between ASSR thresholds and behavioral audiometric thresholds for individuals with a range of hearing losses. Other studies have focused on the correlations between the ASSR and ABR as threshold prediction technique (Cone-Wesson et al., 2002:173, Vander Werff et al., 2002:227). Although these results appear promising, it is difficult to make definite conclusions about the application of ASSR to the infant population, as these studies were based on the responses of adults or older children rather than infants to evaluate the efficacy of the ASSR as a threshold estimation tool.

Stapells (2002a:14 & 2004: conference presentation) cautions that too few studies are available concerning the infant population to recommend the ASSR method for clinical use. However, the potential advantages of the ASSR that come from continuous rather than transient stimuli, including potentially better frequency-specificity and the ability to obtain higher output levels, warrant further investigation of the clinical application of the ASSR in the infant population.

In addition to the need of a tool for frequency specific estimations of hearing in infants the validation of amplification early on is also an essential component. Seewald (2001:70) emphasizes the need for improving the quality of pediatric hearing aid fitting, as the consequences of decisions made will be with a child forever. Yet, after fitting hearing aids on infants, validation of the fitting in most cases occurs through the use of subjective questionnaires and variables being evaluated such as auditory awareness, speech-production abilities, rate of language acquisition and social development (Scollie & Seewald, 2002:702) Aided thresholds are generally done only when the infant is mature enough to complete behavioral audiometry which may be several months after the initial fitting. In the age of early identification, this needs to be addressed. A limited number of studies on ASSR and functional gain have been performed (Glockner in Cone-Wesson, 2003:272; Picton et al., 2002:63; Picton et al., 1998:315). These studies focused on adults and older children and although the results are promising, the application possibilities of the ASSR in addressing the specific needs of the infant population need further investigation.

Bess (2000:250) and Gravel (2005:19) urge audiologist to collect, evaluate and integrate evidence about procedures in order to become evidence-based practitioners[1]. This implies that as new procedures become available, clinicians must be willing to continually evaluate and modify their clinical protocols. Therefore, with the advent of the ASSR in clinical practice and in light of the crucial importance of early identification of hearing loss and of the intervention process that follows, the question that arises is:

What is the clinical value of Auditory Steady State Response for early diagnosis and for evaluation of amplification in infants with hearing loss?

It was the purpose of this research endeavor to find answers to this particular question.

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[1] Evidence Based Practice is an approach to clinical service delivery that has become increasingly advocated in the past decade. EBP is defined as the 'conscientious, explicit, and judicious use of current best evidence in making decisions about the care of patients (Oxford-Centre for Evidence Based Medicine, 2004: online).

1.5 DEFINITION OF TERMS

For the purposes of this study, the following terms will be defined and discussed in order to promote a mutual understanding of the basic and primary concepts dealt with in it. The terms provided are adapted from the work of Mendel, Danhauer & Singh (1999) in the *Illustrated Dictionary of Audiology,* unless otherwise stated.

Amplification of a hearing loss – amplification refers to an increase in the intensity of sounds. This is a collective term used for devices such as hearing aids. When referring to hearing aid assessment, the term functional gain is often used when validating a hearing aid fitting. Functional gain refers to the difference in performance between aided and unaided thresholds measures.

Auditory Evoked Potential – electrical activity evoked by sounds arising from auditory portions of the peripheral or central nervous system traveling from cranial nerve VII to the cortex, recorded with electrodes and also known as auditory evoked response. In this study the focus will be on the following evoked potentials:

- *Auditory Brainstem Response* (ABR) – an objective test that measures the electrical potential produced in response to sound stimuli by the synchronous discharge of the first- through sixth- order neurons in the auditory nerve and brainstem; also known as brainstem auditory evoked potential (BAEP) and brainstem auditory evoked response (BAER).
- *Auditory Steady State Response* (ASSR) – an auditory evoked potential in which the response wave-form approximates the rate

of stimulation; also referred to as steady-state evoked potential (SSEP).

Clinical value – Audiology is the health-care profession devoted to hearing. It is a clinical profession that has as its unique mission the evaluation of hearing ability and the amelioration of impairment that results from hearing disorders (Stach, 1998:2). Pediatric audiologists play a crucial role in early identification of hearing impairment in infants and evaluation of their hearing abilities. In addition, pediatric audiologists evaluate the need for hearing aid amplification in the pediatric population and monitor the success of these fittings. This study focuses on the potential value of the ASSR as an assessment tool that could aid the pediatric audiologist in fulfilling his/her clinical responsibilities.

The ASSR have been used in audiology research centers around the world. The results from the clinical studies have shown that ASSR thresholds can be used to predict pure-tone thresholds in sleeping infants and young children. It has also shown success in evaluating hearing aid fittings by determining functional gain. As with other discoveries in the field of audiology where transformation of new discoveries into clinical procedures has occurred, this study investigates the adoption of the ASSR into the clinical setting, comparing this promising technique with the traditional approaches used in the difficult-to-test populations.

Early diagnosis – The Healthy People 2000 initiative established the goal to reduce the average age at which children with significant hearing impairment are identified to no more than 12 months of age by the year 2000 (Diefendorf, 2002:469). With the implementation of universal hearing screening programs, the Joint Committee on Infant Hearing (1994) recommendations were that all infants with hearing loss should be identified by three months of age, and receive intervention by six months of age. In this study the time of identification varied between three months of age and 6 months of age. Intervention (amplification) was implemented immediately after diagnosis – trying to conform to the guidelines of the JCIH.

Infant - refers to a child during earliest period of life – before age 1 after the neonatal period (The concise Oxford dictionary, 1982:512).

1.6 DIVISION OF CHAPTERS

A research endeavor, consisting of both an empirical and theoretical component was conducted, in order to answer the research question stated above. The following section delineates the division of chapters and provides a short summary of the contents of each chapter.

Chapter one: *Background and rationale*

This chapter provides an overview of the importance of the need of electrophysiological procedures in the diagnostic process of hearing loss in young infants and the difficult-to-test population. The ABR is contrasted with the ASSR technique with regard to its potential for estimating pure tone behavioral thresholds. The use of ASSR in estimating functional gain in the young population is discussed. The rationale for the study and the problem statement is provided. Definitions of the terms and concepts fundamental to this study are provided and clarified.

Chapter two: ***Clinical application of Auditory Evoked Potentials in infants: Comparing the auditory brainstem response and auditory steady state response***

The current procedures of choice for early intervention for infants are discussed – considering early identification and diagnosis of hearing loss and amplification for infants with hearing loss. Attention is given to the diagnostic process and hearing aid fitting in the young infant population - focusing on the problems and challenges. A critical discussion of AEP's in pediatric audiology will follow thereafter – comparing the ABR method with the ASSR method.

Chapter three: ***Research Methodology***

This chapter describes the operational framework implemented to conduct this study. The aims of this present study are outlined. The research design and method are discussed. The ethical issues related to this study are considered. The subjects, material and apparatus used in the study are described as well as the procedure that was followed to conduct this study.

Chapter four: ***Results and Discussion***

The results are presented according to the sub-aims stipulated in chapter three in order to address the main aim of the study. The results are presented – utilizing the results from each individual subject. Thereafter the collective results of the six subjects will be considered. Interpretation and discussion of the results are performed. The value and meaning of the research findings in relation to other studies and literature in this regard is discussed.

Chapter five: ***Conclusions and Implications***

The results from this study are summarized. This chapter provides an outline of the significant results and the way they contribute to current literature. Using *critical appraisal* methods, the research evidence are assessed – considering the value, validity, reliability and relevance thereof. Future research recommendations are provided and a conclusion regarding the study is formulated.

1.7 SUMMARY

This chapter aimed to provide relevant background information in order to focus on the research endeavor and to provide a broad perspective of the rationale underlying the study. Attention was drawn to the infant population as a difficult-to-test population and the special need for objective audiometric measures in this population at a time when critical decisions need to be made about intervention strategies.

Chapter 2

CLINICAL APPLICATION OF AUDITORY EVOKED POTENTIALS IN INFANTS: COMPARING THE AUDITORY BRAINSTEM RESPONSE AND AUDITORY STEADY STATE RESPONSE

This chapter aims to provide a theoretical background to the empirical research and provides a critical evaluation and interpretation of the relevant literature pertaining to the scope of this study

2.1 INTRODUCTION

'*From the moment that Auditory Evoked Potentials (AEP) were first recorded, audiologists sought to exploit the responses in order to evaluate the hearing status of persons difficult to test'* (Jerger, 1998: editorial). The use of AEP's for estimation of hearing sensitivity and infant hearing screening has had a major impact on the ability to identify hearing impairment in children, as this provides an objective means of assessing the integrity of the peripheral and central auditory systems (Stach, 1998:293). The Auditory Brainstem Response (ABR) has become the most widely clinically used AEP in estimating hearing thresholds, but for the past few decades an evoked potential, particularly suited for frequency-specific measurements, the Auditory Steady State Response (ASSR), has come under close scrutiny (Hood, 1998:117). In addition to estimating hearing sensitivity in infants, the ASSR promises to provide a better evaluation of hearing aid performance (Swanepoel, Schmulian & Hugo, 2002:52), which is an important component in the validation of hearing aid fittings.

This chapter therefore explores the clinical application of Auditory Evoked Potentials – comparing the ABR and ASSR as an objective procedure in the diagnosis of hearing loss and validation of hearing aid fitting in infants.

In the first section, the current procedures of choice for early intervention for infants will be discussed under the following two sub-headings: **Early identification and diagnosis of hearing loss** and **amplification for infants with hearing loss**. After laying this foundation, a critical discussion of **AEP's in pediatric audiology** will follow**.**

2.2 EARLY INTERVENTION FOR INFANTS WITH HEARING LOSS

Audiologists are entering a particularly optimistic era for the provision of early intervention services. There are technological advances resulting in much earlier identification of childhood hearing loss, improved amplification devices providing enhanced audibility, and increased opportunities for families to receive interventions that are responsive to family-identified needs (Moeller, 2001:109).

The Joint Committee on Infants Hearing (JCIH) therefore endorses early detection of and intervention for infants with hearing loss through integrated, interdisciplinary systems of universal hearing screening, evaluation, and family-centered intervention (Northern & Downs, 2002:269). This very early intervention maximizes the prospects that these patients will acquire the communication skills necessary to achieve their full potential (Kirkwood, 2002: editorial).

2.2.1 Early identification and diagnosis of hearing loss

Hearing loss is an important health problem in childhood that severely impacts on quality of life. The identification of permanent hearing impairment is the first step in a lifelong process for each infant (Seewald, 2000: vii). Early identification of hearing loss in children has always been a longstanding clinical priority in audiology, as hearing loss that goes undetected in infants and young children compromises optimal development and personal achievement (Diefendorf, 2002:469). Language and communication serve as a foundation for normal child development, and delays in the acquisition of these skills affect literacy, academic achievement, and social and personal development (Hayes & Northern, 1997:4). Identification of a child's hearing loss at an early age is therefore the first step in a comprehensive plan that allows for early medical management, consideration of acoustic amplification, and placement in an early intervention program (Diefendorf & Weber, 1994:43).

With the positive effect of early identification, the Joint Committee on Infant Hearing (2000) in the USA recommends that, whenever possible, diagnostic testing should be completed and habilitation should begin by the time an infant with a congenital hearing impairment reaches the age of six months. The effectiveness of the early intervention process hinges on the audiologist's ability to accurately predict hearing thresholds in the first months of life. The primary objective in assessing the hearing of an infant or young child is to obtain reliable, ear-specific and frequency-specific information on auditory function as soon after birth as possible (Bachmann & Hall, 1998:4). This objective can currently only be met through the use of auditory evoked potentials (AEP) (Sininger & Cone-Wesson, 2002:298).

AEP's have been used in diagnostic audiology for more than three decades and is becoming increasingly prominent as the age of hearing loss identification is being reduced significantly due to Universal Newborn Hearing Screening (UNHS) programs (Roeser, Valente & Hosford-Dunn, 2000:10).

The challenge of accurately determining the hearing status of an infant or young child is reliant on specialized training and extensive clinical experience (Hayes & Northern, 1997:234). No single auditory test is precise enough to be a perfect and complete assessment tool. Defining the nature and degree of an infant's hearing loss requires the use of multiple tests and techniques. The need for a test-battery approach in pediatric assessment can therefore not be overstated (Diefendorf, 2002:473). The basic pediatric hearing evaluation includes a thorough developmental history, followed by behavioral frequency-specific threshold tests, acoustic immittance measurements, otoacoustic emission tests (OAE) and ABR as necessary (Hayes & Northern, 1997:234). The pediatric hearing evaluation typically is an ongoing activity and should be adaptable to different circumstances (Hayes & Northern, 1997:234).

With the age of identification decreasing, behavioral conditioning of neonates and very young infants to sound field auditory stimuli is not feasible (Diefendorf & Weber, 1994:56). An acoustic immittance test battery can be used to categorize the nature of the hearing loss into conductive, cochlear, or brainstem pathology (Northern & Downs, 2002:211; Hayes & Northern, 1997:251). Although immittance can provide valuable information, it cannot predict the degree, configuration, type and symmetry of the hearing loss.

With the introduction of clinical devices in 1988 for measuring evoked otoacoustic emissions, this technique has become a relatively recent adjunct to nonbehavioral physiologic-based auditory response measurements (Hall, 2000:2). The presence of EOAE's has proven to be evidence of a normal functioning cochlea and peripheral hearing system. However, Robinette & Glattke (2000:506) cautions that OAE's cannot be used to estimate the amount of hearing loss. The application of OAE's include the screening for hearing loss in the newborn and pediatric population, augmenting behavioral test results in difficult-to-test patients, developing a true differential diagnosis in terms of separating hearing loss into "sensory" and "neural" components and identifying individuals with subtle abnormalities of CNS function (Robinette & Glattke, 2000:506).

In order to objectively measure the neural responses beyond the sensory response of the cochlea, AEP's must be employed. Mendel, Danhauer & Singh (1999:7) defines AEP's as electrical activity evoked by sounds arising from auditory portions of the peripheral or central nervous system traveling from cranial nerve VIII to the cortex – also known as auditory evoked responses (AER). Although inferences can be made about hearing from the evoked potential data, it should be emphasized that it is not a test of hearing, but rather a test of synchronous neural function – the ability of the central nervous system to respond to external stimulation in a synchronous manner (Hood, 1998:95).

The current most common classification of AEP according to the latency epoch of the response to be examined, was adapted from the work of Picton et al. in 1974 and 1977 and Picton and Fitzgerald in 1983 (Ferraro & Durrant, 1994:318). The *late latency response* (LLR) is the electrical potentials emanating from the surface of the scalp in response to an auditory signal. These responses are generated by the cortex at time intervals of 100 to 200 msec after presentation of an auditory stimulus (Hood, 1998:4). These include the N_1 complex and the P_{300} (Ferraro & Durrant, 1994:318). The *middle latency response* (MLR) occurs between 10 and 80 msec following signal onset and are thought to arise from thalamic and primary cortical projection areas (Hood, 1998:4). The most prominent of these is the 40 Hz steady state potential (SSP) (Ferraro & Durrant, 1994:318).

Those AEP's occurring within the first 10 -15 msec following stimulus onset are generally referred to as the "early" or *short latency responses* (SLR). The SLR includes the ABR and also several components preceding the ABR that are recorded via electrocochleography (ECochG) (Burkard & Secor, 2002:233). Other SLR include the slow-negative potential (SN_{10}) and the frequency following response (FFR). The clinical use of both these SLR's has been overshadowed by that of other AEP's like the ABR.

The late latency responses are present in infants and children, but are unreliable for threshold estimates in sleeping individuals and the recording and interpretation in children require considerable experience (Stapells, 2000a:13; Hall, 1992:107). The middle latency responses are not reliably obtained in infants and young children, and their absence in an otherwise normal sleeping infant may be completely normal (Stapells, 2000a:13).

The ABR has none of these limitations and has become the procedure of choice in the diagnostic assessment of the difficult-to-test populations (Stapells, 2002:14; Bachmann & Hall, 1998:41; Hall & Mueller, 1997:321). Several recording methods have been proposed in which the ABR can be used to predict the degree, configuration, type and symmetry of the hearing loss (Hood, 1998:98). Many reports exist demonstrating the usefulness of these techniques in the diagnostic process of hearing loss in infants (Gorga, 2002:49; Stapells, 2000a:16; Gorga, 1999:31; Bachman & Hall, 1998:41; Stapells & Oates, 1997:261). The ASSR have recently gained considerable attention and caused excitement among audiologists, especially those involved in the assessment and subsequent hearing aid fitting of infants with hearing loss (Stapells et al., 2005:43).

2.2.2 Early amplification for infants with hearing loss

Once a hearing impairment has been identified, a complete assessment must be performed in a valid and timely manner. The findings from the assessment are used to develop the initial components of the intervention for the infant's entire life (Seewald, 2000: vii). Although many guidelines, such as the Joint Committee on Infant Hearing (JCIH, 2000:10), call for application of intervention procedures to begin no later than six months of age, the challenge of meeting such an obligation is daunting. The fitting of hearing aids on infants has always presented problems due to the limited capability to utilize standard behavioral testing techniques. With infants, hearing aids are fitted on the basis of only a few thresholds per ear, with no suprathreshold auditory perception (Pediatric Working Group, 1996:53). Even with the more recent advances in infant assessment, the threshold predictions are useful, but do not replace behavioral audiometry (Scollie & Seewald, 2002:687). The hearing aid selection, fitting, verification and validation process is therefore an ongoing challenge in this young population.

2.2.2.1 Approaches to pediatric hearing aid fitting

The immediate goal of sensory assistance to hearing impaired children is to provide as much sensory information as possible with regards to the sound patterns of speech (Boothroyd, 1997:17). The long term goal of enhancing sensory capacity is to increase the speed and quality of development of spoken language skills – to employ a *developmental* rather than *remedial* approach (Ross, 1996:13). Success in meeting this long-term goal depends not only on aided sensory capacity, but also on communicative experience, combined with appropriate clinical and educational management (Boothroyd, 1997:17).

Once hearing loss has been characterized, the next step is to determine whether amplification should be worn (Lewis, 2000:150). According to The Pediatric Working Group (1996:54), "thresholds equal to or poorer than 25 dB HL would indicate candidacy for amplification in some form." As stated before, the goal of amplification is to ensure audibility of the speech input, verify that sounds are not uncomfortably loud and to ensure consistent audibility and hearing aid performance over time (Palmer, 2005:10; Kuk & Marcoux, 2002:504).

Although similar decisions about amplification characteristics must be made for the infant as for the adult, the information on which these decisions are based and the needs of these two groups are quite different (Palmer, 2005:11; Beauchine & Donaghy, 1996:145). At the simplest level, infants' ears are smaller than those of adults: a difference that significantly impacts amplification-fitting decisions, such as choice of moulds and choice of prescriptive targets (Palmer, 2005:11; Scollie & Seewald, 2002:687; Dillon, 2001:410; Lewis, 2000:150; Beauchine & Donaghy, 1996:145).

Moreover, audiological information available at the time of hearing instrument fitting may be limited in the case of infants. The pediatric audiologist needs to rely on threshold estimates at the time when the hearing instruments are selected. Delaying amplification until complete audiological information is available, may mean that the infant is without amplification during critical periods of language development (Scollie & Seewald, 2002:685; Beauchine & Donaghy, 1996:145).

Furthermore, the communication needs of an infant who has a congenital hearing loss are also distinct from those of an adult who has progressive, late-onset hearing loss. Infants differ from adults in how they *use* amplification. They listen to speech from different distances and heights and amplification should account for these input differences. Infants also differ from adults in that they use amplification to *acquire* spoken language. They do not have the same knowledge base that adults have when attempting to make sense of auditory signals that may be distorted, incomplete, or affected by noise (Scollie & Seewald, 2002:685; Lewis, 2000:150; Beauchaine & Donaghy, 1996:145).

Pediatric amplification fitting procedures should therefore provide objective, valid, and reliable measures of hearing aid performance for speech-level and high-level inputs for the infant/child (Palmer, 2005:12; Scollie & Seewald, 2002:689, Dillon 2001:404). These measures should take into account the needs of infants and children for auditory self-monitoring and the acquisition of auditory processing abilities through aided sound.

The hearing aid fitting process for infants can be described as five sequential stages (Pediatric Amplification Protocol, 2003:15; Scollie & Seewald, 2002:685; Pediatric Working Group, 1996:53). These stages are summarized in Table 2.1.

Table 2.1 Stages of hearing aid fitting process

Stage	Process
• Assessment	➢ The hearing loss is measured, and candidacy for amplification is determined
• Selection	➢ Numeric target for hearing aid electroacoustic performance are calculated, and appropriate hearing aids are chosen
• Verification	➢ The hearing aids are adjusted to provide the desired electroacoustic performance
• Validation	➢ Aided auditory function is evaluated and compared with habilitative goals
• Informational Counseling and follow-up	➢ Orientation to hearing aids are provided and hearing aid usage is monitored

A short discussion of each of these stages will follow:

- *Assessment*

The efficacy of hearing aid fitting is predicated on the validity of the audiological assessment. An essential goal of the comprehensive audiological assessment is to obtain ear- and frequency- specific estimates of hearing threshold for use as a starting point in hearing instrument fitting at the earliest opportunity (Roush, 2005:105; Pediatric Working Group, 1996:54). Complete audiological data is seldom obtained when testing the very young child. In the absence of an audiogram, hearing aid fitting should proceed on the basis of frequency-specific ABR threshold estimations unless neurological status contra-indicates such action (Roush, 2005:105; Scollie & Seewald, 2002:689; Ross, 1996:16; Diefendorf, Reitz, Escobar & Wynne, 1996:125).

- *Selection*

The Pediatric Working Group (1996:54) recommended that infants/children with thresholds poorer than 25 dB HL between 1000 and 4000 Hz should be seen as candidates for amplification – either through the use of personal hearing aids or some other form of amplification (Lewis, 2000:150). Once the decision to provide amplification has been made, selection of hearing aids is a complex process (Scollie & Seewald, 2002:691; Beauchaine & Donaghy, 1996:145). Recent advancements in hearing instrument technology offer the potential for significant improvement in the language and communication abilities and overall quality of life of infants with hearing loss (Buerkli-Halevy & Checkley, 2000:77). It is important to select amplification based on the full range of unique characteristics of each infant, including the hearing loss, the family, the educational and home environment, and available hearing aid technology (Buerkli-Halevy & Checkley, 2000:77; Beauchaine & Donaghy, 1996:145).

- *Verification*

In the context of early intervention, infants will wear their hearing aids at fixed, clinician- determined settings for a long period of time (Scollie, 2005:91). Recent consensus statements have recommended that hearing aid prescription should be done in an *objective* manner

(Pediatric Working Group, 1996; Pediatric Amplification Protocol, 2003). At the verification stage, objective hearing aid prescriptions are used to prescribe specific amplification characteristics (Scollie, 2005:91). The hearing aids are adjusted until they provide the electroacoustic performance that is deemed appropriate for each infant/child (Scollie & Seewald, 2002:698; Beauchaine, 2002:106). The output of the instrument is measured objectively across frequency and input ranges. This procedure must confirm that the real-ear performance of the instrument provides output levels that are comfortable, safe, and without feedback. The use of this objective approach results in consistent treatment across infants and children (Scollie, 2005:91).

- *Validation*

Once the prescriptive procedure is complete, and the settings of the hearing aids have been verified, the validation process begins (Pediatric Amplification Protocol, 2003:15). Validation of aided auditory function is a critical component of the pediatric amplification provision process. The purpose of validating aided auditory function is to demonstrate the benefits/limitations of an infant's/child's aided listening abilities for perceiving speech of others as well as his/her own speech (Pediatric Amplification Protocol, 200315; Dillon, 2001:106; The Pediatric Working Group, 1996:56). Validation is accomplished, over time, using information derived through the aural habilitation process, as well as the direct measurement of the infant's/child's aided auditory performance.

- *Informational counseling and follow-up*

  Thorough and suitable counseling, monitoring and follow-up are essential in a pediatric hearing aid fitting process. Hearing aid orientation programs should include all members who will be assisting the infant (Beauchine, 2002:111). Typical audiological follow-up schedules for infants and young children are at least every three months to the age of three years. More frequent visits may be required when fitting infants younger than six months of age, (Beauchaine, 2002:111).

In the past audiologists have relied on aided audiograms (also known as functional gain measurements) as the primary **verification** tool for hearing aid fittings in infants and young children (Stelmachowicz, Hoover, Lewis & Brenman, 2002:38; Seewald, Moodie, Sinclair & Cornelisse, 1996:165; Hedley-Williams, Thorpe & Bess, 1996:107). Technically, functional gain is defined as the difference in dB between aided and unaided sound-field thresholds as a function of frequency. (Stelmachowicz et al., 2002:38). Typically, the goal has been to "shift" thresholds into the range of 20-25 dBHL.

Over the years, it has been acknowledged that several limitations are associated with the use of functional gain approaches for hearing aid **verification** (Seewald, Moodie, Sinclair & Cornelisse, 1996:178).

One serious limitation of this procedure is related to the form in which the performance criteria are specified (Stelmachowicz et al., 2002:38; Seewald et al., 1996:178). When a purely audiometric-based approach is taken to the selection process, it is not possible to verify that the desired electroacoustic characteristics have been provided to the infant without valid behavioral test results. Consequently, for infants, this approach will be of limited use when important selection-related decisions need to be made (Pediatric Amplification Protocol, 2003:13; Dillon, 2001:106). Another criticism of this procedure is the poor test-retest reliability (Stelmachowicz et al., 2002:13).

Functional gain measurements indicate only the frequency/gain characteristics of a hearing aid (Seewald et al., 1996:178). There are additional electroacoustic characteristics of hearing aids that should be considered within the selection process. Consideration should be given to aspects such as output limiting, compression thresholds, compression ratios and cross-over frequencies. Functional gain also does not supply frequency specific information. It gives information across the frequency spectrum at octave frequencies, but the inter octave frequencies and troughs are overlooked. The frequency resolution is therefore poor (Dillon, 2001:106). Small changes in electro-acoustic output of the hearing aid, or acoustic modifications may create alterations in the frequency response and gain characteristics of the hearing aid. This will not necessarily be noted in the functional gain measurement.

Aided audiograms describe hearing aid function for very soft sounds only, and then only at a few frequencies. In cases of severe to profound hearing loss, minimal or mild loss, or when non-linear signal processing, digital noise reduction, or automatic feedback reduction circuitry is used, misleading information may be obtained (Scollie & Seewald, 2002:688).

Due to the above limitations, computerized real-ear probe microphone measurements have become the preferred procedure to fit and adjust hearing aids with infants. But functional gain measures do however play a role in the ongoing process of **validation.** Dillon (2001:419) emphasizes that these measurements should be a supplement to the electroacoustic measurements. Functional gain measures have the following uses:

- It demonstrates to the parents that the child is capable of reacting to sound (Dillon, 2001:419). Aided and unaided speech reception or speech awareness thresholds can demonstrate the benefit of amplification to parents of infants. It may also rule out the possibility of non-organic hearing loss, neurological conditions, or auditory neuropathy (Stelmachowicz et al., 2002:39).
- It demonstrates that the hearing aid maximum output exceeds the child's hearing threshold at each frequency tested (Dillon, 2001:419).
- An aided threshold at the level expected, given the hearing aid coupler gain and unaided hearing threshold, provides further confirmation of the child's unaided thresholds (Dillon, 2001:419).
- In the case of profound hearing loss, aided thresholds at the expected levels confirm that the unaided thresholds were not based solely on vibratory sensations (Dillon, 2001:419). Aided thresholds are also the best way to document performance for bone-conduction instruments, frequency-transposition devices and cochlear implants (Stelmachowicz et al., 2002:42).

Validation of aided auditory function is a demonstration of the benefits and limitations of aided hearing abilities and begins immediately after the fitting and objective electroacoustic verification of amplification (Pediatric Amplification Protocol, 2003:15). Validation is an ongoing process designed to ensure that the child is receiving optimal speech input from others and that his or her own speech is adequately perceived (Pediatric Working Group, 1996:56; Pediatric Amplification Protocol, 2003:14). Functional gain is measured by finding the hearing thresholds in a sound field while a person is unaided and again while aided – through the use of behavioral audiometric procedures (Dillon, 2001:106).

Infants are however unable to provide conclusive behavioral information. It may therefore be necessary to incorporate subjective non-traditional evaluations, such as parent questionnaires, to gain behavioral information about the fitting outcome (Scollie & Seewald, 2002:701). Without the data derived from behavioral assessments, it is difficult to assess the performance of hearing aids even when the theoretical amplification specification is known (Garnham et al., 2000:267). Objective measures – using AEP's - to assess hearing aid performance would potentially aid the management of these difficult-to-test subjects as the behavioral functional gain measurements may only be performed after the infant has reached an appropriate developmental age where a response such as the head turn response may be utilized to measure functional gain. Therefore AEP's may provide useful information when behavioral functional gain measurements are not readily available due to the subject's age or developmental incapacity. The next section will therefore focus on AEP's in the field of pediatric audiology.

2.3 CRITICAL EVALUATION OF AEP's IN PEDIATRIC AUDIOLOGY

There has always been a need for objective tests that assess auditory function in infants, young children and/or any patient whose developmental level precluded the use of behavioral audiometric techniques. Although several approaches have been tried, for the past 25 years, that need has been met primarily by the measurements of short-latency auditory-evoked potentials, primarily the auditory brainstem response (ABR) (Gorga & Neely, 2002:49). In recent years the Auditory Steady State Responses has become available as a different technique to measuring the brain's responses to sound (Picton et al., 2002:65). In pediatric audiological practice AEP's have proven to be indispensable for diagnostic purposes but they have also begun to demonstrate the potential to assist beyond the diagnostic process with the validation of amplification.

In the following section these two techniques will be discussed in terms of their application in the field of pediatric audiology, both diagnostic and in amplification validation.

2.3.1 Auditory Brainstem Response

The ABR is mostly used in the assessment of auditory function in infants, children and adults who cannot participate in voluntary audiometry and is by far the most widely used AEP in audiology (Arnold 2000:451; Hood, 1998:96). The popularity of the ABR stems from the fact that it is a robust response that varies very little between individuals (including infants), making the response fairly easy to identify under most circumstances (Hall, 1992:20). It is also highly stable – characteristics of the response do not vary between wakefulness and sleep and are not affected by most medications, which mean that children may be tested reliably during natural or sedation induced sleep (Arnold, 2000:455; Rance et al., 1995:499). These characteristics have made it the most commonly used electrophysiological tool to estimate hearing thresholds in difficult-to-test populations. The ABR will be discussed in terms of three applications in the field of pediatric audiology, namely: **detection, diagnosis** and **hearing aid fitting in infants.**

2.3.1.1 Detection of hearing loss

Screening, or early detection, of disorders has received increasing attention in health care over the last quarter century (Feightner, 1992:1). The general premise for screening, or early detection, clearly makes sense. Early detection offers the opportunity to recognize the condition before symptoms appear, and to prevent or diminish suffering (Feightner, 1992:2). Hearing loss is an invisible disability and is nearly impossible to detect during a routine clinical examination. Thus, if hearing loss is not detected through newborn hearing screening programs, it often goes undetected before 18 months of age (Diefendorf, 2002:469; Hayes & Northern, 1997:214).

Although the ABR is not a direct test of hearing sensitivity, it has earned a strong clinical reputation as a valuable tool to evaluate the integrity of the auditory pathways (Diefendorf, 2002:471; Stapells, 2000a:13). Click evoked ABR's can be recorded from infants as young as 27 weeks gestation age, although responses may be poorly formed (Hall, 1992:490). By 33 to 35 weeks of gestation, responses are more stable, and visual detection level is comparable to that of older infants. Traditional ABR screening depended on identification of wave V at 30-40 dBnHL (Northern & Downs, 2002:285).

Automated ABR (AABR) systems have been developed and used specifically for hearing screening purposes. The automated ABR systems use a rule-directed, statistical method to detect a response – thus eliminating subjective response recognition (Cone-Wesson, 2003:266). These automatic detection algorithms works by comparing the online responses from the infant with a 'normal' template response pattern obtained from a large sample population of newborns. If the test infant's responses correlate with the normative data, the automated instrument renders a 'pass' decision. If there is no correlation between the 'normal' template and the test infant's responses, a 'refer' response is obtained – suggesting the need for further testing (Northern & Downs, 2002:285). These AABR systems are entirely objective and are programmed to determine pass or refer criteria for infants younger than six months of age.

A click stimulus is used when eliciting an AABR. The click ABR accurately approximates behavioral pure tone thresholds in the middle to high frequency regions (Sininger & Cone-Wesson, 2002:303) – therefore limiting detection of hearing loss in different frequency ranges (Stapells, Gravel & Martin, 1995:361). Information from this single intensity screening test is insufficient to predict degree of hearing impairment or the site of dysfunction (Hayes & Northern, 1997:256). The advantages and limitations of the click evoked ABR will be discussed in detail in the following section.

2.3.1.2 Diagnosis of hearing loss

i. ABR threshold evaluations using clicks

The most widely used evoked potential method for evaluating auditory threshold is the ABR to non-masked broadband clicks (Stapells & Oates, 1997:258). The click-evoked ABR consists of a series of seven positive-to-negative waves, occurring within about 10 ms after stimulus onset (Arnold, 2000:451). It was not until the late 1960's that electrical potentials generated by the brainstem were identified in the laboratories of Jewett and colleagues in the USA and Sohmer and Feinmesser in Israel (Hall & Mueller, 1997:322; Hood, 1998:5). Jewett and colleagues demonstrated that neural responses could be recorded from the brainstem pathways – showing a response composed of a series of five to seven peaks (Burkard & Décor, 2002:233). It is generally agreed that the ABR is generated by the auditory nerve and subsequent fiber tracts and nuclei within the auditory brainstem pathways. A series of Roman numerals (from I to VII) were assigned to the peaks. These designators have been used since that time to identify the various components of the ABR (Hood, 1998:5). The most widely used ABR measure is the latency of a component peak (Don & Kwong, 2002:274).

The click-evoked ABR yields the clearest ABR response for threshold estimation as this robust response varies little between individuals and is easy to identify (Hall, 1992:20; Arnold, 2000:455). In assessing hearing sensitivity, wave V of the ABR is used because it is the most robust of the waves and the one best correlated with behavioral audiometric thresholds (Arnold, 2000:456). The lowest click level at which Wave V can be elicited provides information about the degree of hearing loss (Arnold, 2000:456).

However, the rapid onset of the click, and its broad frequency spectral content, results in activation of a wide area of the basilar membrane. Since a broad range of frequencies is stimulated, it is not possible to obtain accurate information about hearing sensitivity at different frequencies using a non-masked click alone (Stapells & Oates, 1997:248). When using frequency-specific stimuli, there is a trade-off between frequency specificity and neural synchrony (Hood, 1998:96; Hall 1992:123).

The acoustic principle underlying this trade-off, involves the relationship between the duration of the stimulus and its frequency content – the longer the duration, the more frequency specific it will be.

Another aspect influencing the frequency specificity of the click ABR is the transducer. A 100-microsecond electrical pulse, impressed on a standard earphone, generates a broadband signal (click) whose primary frequency emphasis is determined by the resonant frequency of the transducer (Hood, 1998:96; Hall, 1992:123). Thus a click, though a broadband stimulus, is nonetheless somewhat frequency specific, based primarily on the frequency response of the earphones (Gorga, 1999:31; Hood, 1998:96). A click therefore, with its abrupt onset and brief duration, is better to elicit a synchronous neural response, but is not very frequency specific (Hood, 1998:97). The maximum energy peaks are in the frequency region between 1000 and 4000 Hz (Hood, 1998:96; Hall, 1992:107). The greatest agreement with pure-tone thresholds is in the 2000 to 4000 Hz frequency range. Click ABR's do; however, provide a gross estimate of hearing sensitivity and an assessment of VIIIth nerve and auditory brainstem pathway integrity – allowing the clinician to rule out possible neurological involvement (Arnold, 2000:454; Gorga, 1999:31; Stapells & Oates, 1997:248).

Stapells & Oates (1997:258) cautions that this may be true, on average and across a large group of patients with hearing loss. It does not translate into one being able to use the click ABR threshold as a reliable estimate of 2000-4000 Hz threshold for *individual* patients. These researchers have demonstrated that any particular click ABR threshold may represent a wide range of pure-tone thresholds, making accurate determination of degree of hearing loss impossible. This seems especially true in the case of sloping hearing losses.

The major explanation for the problems with the click ABR for threshold estimation lies with the broad-band nature of clicks, and the resulting frequency contributions to the click-evoked ABR (Stapells & Oates, 1997:261). A normal click ABR threshold does not necessarily imply normal hearing. It may only imply an area of normal sensitivity between 1000 and 4000 Hz (Perez-Abalo et al., 2001:200; Rickards et al., 1994:327). When a hearing impairment is restricted to a particular frequency region, click-evoked ABR will often miss the loss or substantially underestimate the degree of the loss (Stapells, 2000a:15; Stapells, Gravel & Martin, 1995:361). This situation can occur with high frequency losses, low-frequency losses or impairments confined to the mid-frequency regions (e.g. 'cookie-bite' losses) (Stapells & Oates, 1997:261). As in behavioral audiometry in older children, narrower band stimuli must be used in order to obtain ABR threshold estimated for specific frequency regions. In contrast to thresholds to clicks, ABR thresholds to brief tonal stimuli provide more frequency specific results.

ii. ABR threshold evaluation using brief tones

The click-evoked ABR may be useful and clinically practical for estimation of auditory function in the 1000 – 4000 Hz region. This might be adequate for hearing screening, but information on auditory sensitivity across the audiometric range, especially the speech frequency region (500 – 4000 Hz) is essential for audiological management, such as for the fitting of hearing aids (Gorga & Neely, 2002:50; Hall, 1992:107). The ABR to clicks alone can therefore not provide information concerning hearing sensitivity for specific frequencies (Gorga, 1999:31; Stapells, Gravel & Martin, 1995:361). Stapells, Gravel and Martin (1995:361) also state that hearing loss restricted to particular frequency regions may be underestimated or missed entirely by the click-ABR threshold. It is therefore not possible to characterize the shape of the hearing loss from click-evoked ABR alone even with consideration of the latency/intensity function (Sininger & Cone-Wesson, 2002:303). An estimation of low frequency hearing status is especially desirable in order to estimate auditory function across the audiometric range (Hall, 1992:107). Several types of stimuli and recording methods have therefore been proposed to provide information for narrower frequency regions, such as tone bursts, filtered clicks, tone bursts and clicks mixed with various types of noise, and high-pass masking of clicks (Hood, 1998:98). These techniques all have advantages and limitations. Tone burst stimuli are now widely available on commercial ABR instrumentation, and are therefore the most commonly used type of frequency specific stimuli in ABR testing (Hood, 1998:98; Stapells & Oates, 1997:258).

In attempting to approximate the behavioral pure tone audiogram, it has become fairly common to include brief-duration tonal stimuli as part of the test protocol in order to estimate the audiogram of young infants (Sininger & Cone-Wesson, 2002:303; Stapells, 2002:11; Hood, 1998:96; Hall & Mueller, 1997:360). This type of stimulus is the result of an attempt to find the "best compromise" that would maximize frequency specificity and neural synchrony (Hood, 1998:98). These stimuli have narrower frequency spectra than clicks but are substantially broader than the pure tone stimuli used for conventional audiometry, because of the brief rise/fall time (Hall, 1992:108).

Brief tone bursts have their concentration of energy at a nominal frequency of the tone (predominant energy peak) and sidebands of energy at lower and higher frequencies (Arnold, 2000:459; Oates & Stapells, 1998:62). The spread of stimulus energy to frequencies other than the nominal frequency is known as spectral splatter. Because the sidebands are less intense than the peak of energy, the frequency spread is more of a problem at high levels of stimulation (Arnold, 2000:459). The degree of spectral splatter is also influenced by several parameters of the stimuli, including rise time, duration, temporal shaping and type of transducer used (Oates & Stapells, 1998:62).

Various ramping or envelope shaping techniques such as Blackman ramping have been implemented as a way to improve frequency specificity of toneburst stimuli. At high stimulus intensities, stimulation can however still spread to adjacent frequency areas in persons with better hearing, due to basilar membrane mechanics (Arnold, 2000:459). An alternative way to ensure frequency specificity is to combine different masking methods with the stimuli (Gorga, 1999:29). The n*otched noise* is currently the most clinically used masking technique (Arnold, 2000:459). Notched noise is similar to wide band noise, containing energy across the frequency spectrum, except within a certain narrow range of frequencies (the notch). The frequency, at which the notch occurs, corresponds to the frequency of the tone burst. Thus, the side bands of energy present in the tone burst are masked out, restricting the area of stimulation to the nominal frequency of the tone burst. This ensures that the ABR is generated by neurons sensitive only to the test frequency (Arnold, 2000:459; Gorga, 1999:36; Oates & Stapells, 1998:62).

Gorga (1999:40) concluded in his research, that accurate estimates of thresholds are possible for a wide range of frequencies, using tone burst stimuli. Reasonably accurate estimates of the pure tone behavioral audiogram from 500 Hz – 4000 Hz can be provided. Although a recent meta-analysis of the tone burst ABR literature by Stapells (2000b:74) has shown that across studies, tone-ABR thresholds have been found to be between 10 and 20 dBnHL in normal hearing individuals and are generally within 15 dB of behavioral threshold for hearing impaired individuals, some studies have questioned the frequency specificity and reliability of threshold estimation with low frequency tone- evoked ABR (Vander Werff et al., 2002:228; Dimitrijevic et al., 2002:206). The credence is that the ABR to 500 Hz tonal stimuli is *primarily* generated from the basal end of the cochlea, especially to higher-intensity stimuli, and thus these thresholds are poor predictors of low-frequency behavioral thresholds (Stapells & Oates, 1997:261).

Furthermore, ABR to both click and tone burst stimuli does not appear to be able to distinguish severe-to-profound hearing losses in the range of 85 to 95 dB HL from those in the more profound ranges of 100 to 120 dB HL (Stapells, 2000a:24). The possibility of residual hearing at these profound levels can therefore not be investigated through the use of ABR (Arnold, 2000:454; Rance, 1998:506). Another limitation of the ABR is the subjective nature of interpreting the results (Oates & Stapells, 1998:67; Bachmann & Hall, 1998:42). Interpreting ABR waves – especially to low frequency tone burst stimuli - is problematic. Interpretation of these results requires experience and expertise (Stapells, 2000a:13). These techniques may also be time consuming (Dimitrijevic et al., 2002:206).

In carrying out clinical ABR tests on infants and young children, clinicians usually proceed with an expectation that the patient will wake up at any moment (Stapells, 2002:26). The aim in pediatric audiology is therefore to gain as much information as possible in the time available. ABR test protocols, therefore aim to gather frequency-specific threshold information in the shortest possible time (Stapells, 2000a:26; Arnold, 2000:460). The duration of an ABR test session for infants and young children is determined by the amount of time they will remain asleep (Stapells, 2002:16). It is therefore essential to use a test protocol that is fast, efficient, and one that provides the greatest increase in clinical information with each successive step (Stapells, 2002:14). Although the click ABR provides important information about auditory function, it does not provide sufficient information to understand auditory function across the frequency range (Gorga, 1999:40). With low frequency information, provided through tone burst ABR, auditory function can be defined with greater precision. Acquisition of the high frequency information provided by the click ABR or 2000 Hz tone burst, in combination with low frequency information provided by the tone burst ABR, is necessary to define the configuration of the hearing loss (Arnold, 2000:461). This information is essential in the development of a habilitative program, including the use of personal amplification (Gorga, 1999:40).

2.3.1.3 The ABR in pediatric hearing aid fittings

Without the information from behavioral evaluations, it is difficult to assess the performance of hearing aids – even when the theoretical amplification specifications are known (Garnham, Cope, Durst, McCormick & Mason, 2000:267). Using electrophysiological measures to assist in the hearing aid fitting in infants is not a new idea. According to

Mahoney (1985:351) altered auditory evoked potentials were measured by Rapin and Graziani in 1967 under amplification. This procedure involved the adjustment of the hearing aid until the latency of wave V of the ABR decreased to within normal limits (Picton et al., 1998:315).

Some studies have used the *ABR threshold method*. According to Mahoney (1985:357), Mokotoff and Krebs (1976) obtained unaided and aided ABR thresholds, audiometric thresholds and electroacoustic measures on cooperative adult hearing aid users and found favorable correlations between these procedures. Other studies (Cox & Metz, 1980; Hecox, 1983) mentioned in Mahoney (1985:359), suggested the use of *ABR wave V absolute latency* and/or L-I slope to predict appropriate hearing aid specifications. The basic premises were that normal wave V latencies require an intact auditory system up to the neural generator, that normal L-I slope suggests normal dynamic loudness function and that speech intelligibility and ABR latency are correlated. It followed that if a hearing aid can be adjusted in gain, output, and compression characteristics to generate as normal an ABR as possible in a pathological ear, the procedure had merit as a tool for the evaluation of amplification. Another ABR Hearing Aid Evaluation method was employed by Kiessling (1982) (Mahoney, 1985:361). An unaided ABR projection system based on normal and *pathological amplitude growth*, to prescribe appropriate hearing aid gain, compression ratio and compression onset was used.

More recently Garnham et al. (2000:267) used the ABR as an objective measure to verify the aided hearing thresholds in a group of children. Objective data were collected from the ABR and behavioral thresholds were measured by use of age appropriate tests. When comparing the unaided ABR click thresholds to behavioral thresholds, the ABR threshold was on average 9 dB lower. Using the same comparison for aided responses, a difference of <5 dB was observed. This group of researchers concluded that aided ABR thresholds are valuable in the management of young children. However, when performing these measurements, it is essential to be aware of the limitations of the hearing aid and the stimulus.

Although Mahoney (1985:356) illustrated the feasibility of using ABR for functional gain measurements, the widespread use of this technique did not occur. This procedure is technically challenging due to four main concerns. First, the click stimulus is very brief and can be significantly distorted both in the sound field speaker and in the hearing aid. The resultant stimulus artifacts may obscure interpretation of the responses (Garnham et al., 2000:268). Second, the most significant limitation concerning this technique stems from the fact that hearing aids react differently to rapidly changing stimuli than to more continuous stimuli which leads to distortion of the stimulus (Mahoney, 1985:368). Third, the click ABR is mainly related to high frequency gain and correlation between wave V latency and loudness is low, particularly when there is a sloping hearing loss (Picton et al., 1998:316). Fourth, the brief stimuli that are optimal for ABR recordings may not activate the hearing instrument's compression circuitry in the same way as longer-duration speech sounds (Brown, Klein & Snydee, 1999:196) and may be treated as 'noise' by hearing instruments with speech detection algorithms (Alcantra, Moore, Kuhnel & Launer, 2003:40). For these reasons attempts to use the ABR to evaluate hearing instruments have largely been abandoned (Purdy, Katsch, Dillon, Storey, Sharma & Agung, 2005:116).

2.3.1.4 *Summary of the ABR application in pediatric audiology*

As a conclusion to this critical evaluation of the ABR, Table 2.2 summarizes the advantages and limitations of the ABR.

Table 2.2 Advantages and limitations of the ABR

Advantages	Limitations
Diagnosis	
• A noninvasive, safe approach • Stable response – resistant to state of consciousness • Characteristics similar between people – easy to identify response – even in infants • Recordable – close to behavioral thresholds • Tone burst stimuli can be used to provide more frequency-specific information	• Click ABR provides general assessment of high frequencies • No distinction between severe and profound losses • Stimuli contain energy over range of frequencies and may evoke a response at any of these • Time-consuming • Subjective interpretation of results
Validation Process	
• Potential to provide objective information concerning hearing aid functional benefit	• Click stimuli is very brief and distorts in speaker and/or hearing aid • Hearing aids react differently to rapidly changing stimuli • Click ABR is mainly related to high frequency gain and correlation between wave V latency and loudness is low • Compression circuitry activated differently from speech stimuli

One technique that has demonstrated promise in addressing the limitations of the ABR in validating hearing aid fittings in infants is the Auditory Steady State Response (ASSR). This procedure also demonstrates promise in addressing some of the ABR limitations in assessing hearing abilities in the difficult-to-test population (Swanepoel, Hugo & Roode, 2004:531).

2.3.2 Perspectives on the Auditory Steady State Response

In the past two decades, an evoked potential particularly suited to frequency-specific measurement, commonly referred to as the Auditory Steady State Response (ASSR) or Steady State Evoked Potential (SSEP), has been under close scrutiny for clinical application (Perez-Abalo et al., 2001:200).

2.3.2.1 Definition and Development of Auditory Steady State Response

The ASSR are periodic scalp potentials that arise in response to regularly varying stimuli such as sinusoidal amplitude and/or frequency modulated tone (Rance, Dowell, Rickards, Beer & Clark, 1998:49). It yields a waveform closely following the time course of the stimulus modulation and a response specific to the frequency of the carrier. By varying the intensity of the eliciting stimulus a threshold response can be measured (Jerger, 1998: editorial).

The principle underlying the ASSR is based on the following cochlear mechanics as outlined by Lins, Picton, Boucher, Durieux-Smith, Champagne, Moran, Perez-Abalo, Martin and Savio (1996:84) and illustrated by Figure 2.1: Sound waves produce an effect of polarization and depolarization of the inner hair cells. Only the depolarization of inner hair cells causes auditory nerve fibers to transmit action potentials. The electrical action potential output of the cochlea therefore contains a rectified version of the acoustic stimuli. This rectification causes the output of the cochlea to have a spectral component at the frequency at which the carrier was modulated. This component, which is not present in the spectrum of the stimuli, can be used to assess the response of the cochlea to the frequency of the carrier tone.

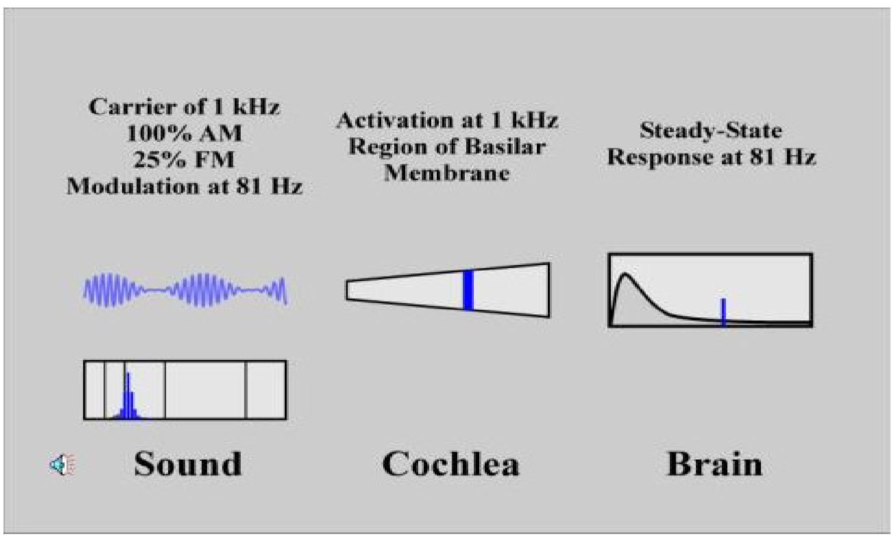

Figure 2.1 Principles underlying the ASSR (from Picton, 2005: conference presentation)

The stimuli used to evoke the ASSR are a modulated tone in the standard audiometric range (Cone-Wesson, 2003:267). The tone can be amplitude (AM) or frequency (FM) modulated; or both amplitude and frequency modulated. The stimuli consists of a carrier frequency (CF) (test frequency), modulated over time in the amplitude domain at a frequency of modulation (MF) (Perez-Abalo, et al., 2001:201). Figure 2.2 demonstrates the modulation of a pure tone.

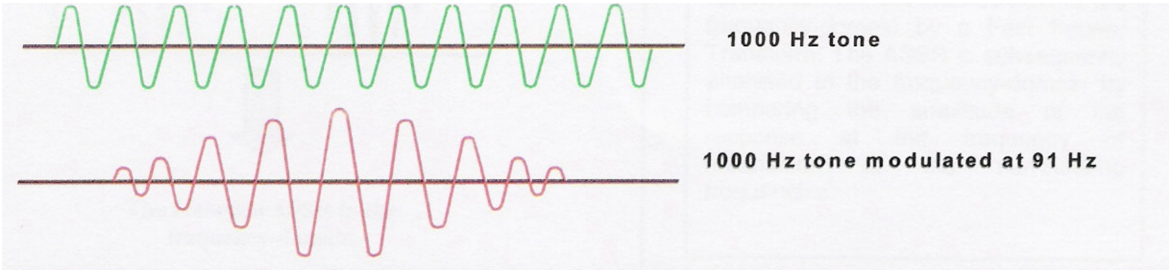

Figure 2.2 A single tone and a modulated tone (from Swanepoel, Schmulian & Hugo, 2002:51).

According to Dimitrijevic et al. (2002:206), ASSR's were first suggested as an objective means to assess hearing by Galambos and colleagues in 1981. These researchers used modulation frequencies between 35 and 55 Hz to assess hearing threshold. They subsequently showed that the 40-Hz steady-state response was easy to identify at intensities just above behavioral thresholds. However, some limitations for objective audiometry are present with the 40-Hz steady-state response such as: (1) The response is unreliable in estimating thresholds in infants and young children (Herdman & Stapells, 2001:41); (2) The response diminishes when subjects are asleep or sedated (Dimitrijevic, 2002:206 & Rance, 1995:500); (3) Response amplitude diminishes when several stimuli are presented simultaneously (John, 1998:59).

Recent work has therefore focused on alternative rates of stimulation for audiometric purposes. Some researchers have found that responses are recorded consistently – during sleep, and at low sound pressure levels - in all subjects (including infants) when a modulation rate of above 70 Hz is used (Stapells & Herdmann 2001:41; Lins et al., 1996:82; Rance et al., 1995:500; Rickards et al., 1994:327). Therefore the ASSR elicited by carrier frequencies with higher modulation rates have been proposed as an alternative to objective frequency specific audiometry (Perez-Abalo et al., 2001:200). The carrier sine wave is the frequency being tested and can be presented at any low or high frequency tone as in pure tone testing (Swanepoel, Schmulian & Hugo, 2002:51). These modulated tones are as frequency specific as pure tones because spectral energy is contained only at the frequency of the carrier tone and the frequency of modulation (Cone-Wesson & Sininger, 2002:311; Hood, 1998:117).

Studies investigating the neural sources of the ASSR indicate they originate primarily from brainstem structures (Stapells, 2005:44; Kuwada et al., 2002:202) but this depends on the rate of modulation and subject state (Cone-Wesson, 2003:267). Although not yet confirmed, it is possible that the ASSR are ABR wave V to rapidly presented stimuli (Stapells, 2005:44). The ASSR is generated when the carrier frequency (test frequency) is presented at a rate (modulation frequency) that is sufficient to cause an overlapping of transient responses, thus being a sustained response (Swanepoel, Schmulian & Hugo, 2002:51). A carrier frequency stimulus triggers a specific region of the basilar membrane, activating hair cells in the cochlea in the region that corresponds primarily to the tone frequency. As the resulting neural activity travels along the auditory pathway, EEG activity ‘synchronizes with’ or ‘follows’ the amplitude modulation frequency (Lins et al., 1996:85). This means that the carrier frequency stimulates the cochlea with pockets of energy at the rate of the modulation frequency (Swanepoel, Schmulian & Hugo, 2002:51). The energy in the resultant response is at the frequency of modulation and its harmonics, allowing analysis of the response in the frequency domain (Herdman & Stapells, 2001:41).

The ASSR is recorded in a time-domain and must be converted to a frequency-domain by a Fast Fourier Transform (FFT) for analysis (Lins, 1996:85). In the frequency domain, the response to the carrier frequency can be assessed by the amplitude and phase of the FFT component corresponding to the frequency of modulation of the carrier (Swanepoel, Schmulian & Hugo, 2002:51). Combining responses whilst maintaining both phase and amplitude information obtain an average response (Perez-Abalo et al., 2001:201). Figure 2.3 illustrates this procedure.

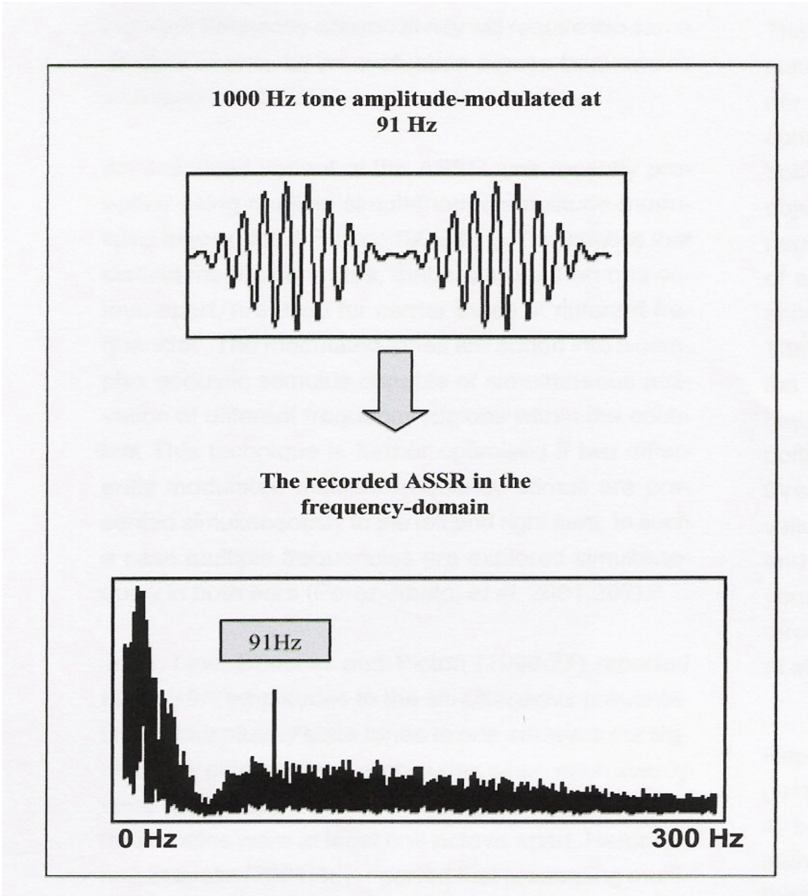

Figure 2.3 Recording the ASSR (from Swanepoel, Schmulian & Hugo, 2002:52).

i. Single stimuli vs. multiple stimuli ASSR

The ASSR can be evoked using a single frequency stimulus (Rance et al., 1995:501) or the ASSR can be evoked using multiple-frequency stimuli presented simultaneously (Lins et al., 1996:81). With the latter technique, it is possible to present multiple amplitude-modulated CF's simultaneously and perform a separate analysis for each MF used in the complex stimulus

(Sininger & Cone-Wesson, 2002:313). Lins and Picton (1995:420) showed that it is possible to present up to four CF's in ears, using 500, 1000, 2000 and 4000 Hz with eight different MF's. The MF's vary for each ear and CF. When suprathreshold level (60 dB SPL) stimuli were used, there were no difference in response amplitude for the single-tone-alone condition, four stimuli combined in one ear, or four stimuli combined in two ears (Cone-Wesson, 2003:271; Sininger & Cone-Wesson, 2002:313). On average, an 18 dB difference between behavioral thresholds for the single tones and the ASSR thresholds was found when two CF's were presented simultaneously. The major advantage of this technique is that by simultaneously presenting multiple stimuli, (e.g. four stimuli in each ear for a total of eight), multiple responses can be recorded during the time normally required to record one (John et al., 2002:247; Dimitrijevic et al., 2000:207). Figure 2.4 illustrates the multi frequency ASSR.

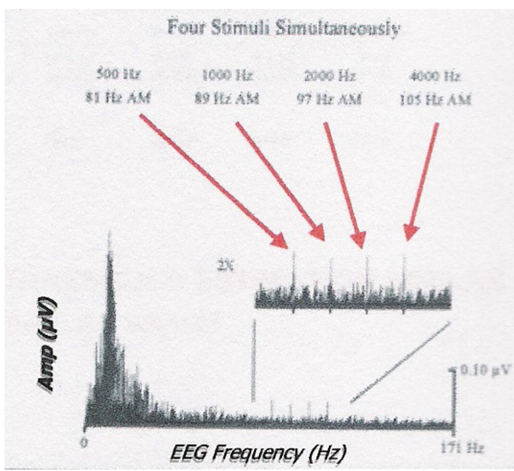

Figure 2.4 Multiple ASSR (From Stapells, 2004: conference presentation).

2.3.2.2 Threshold determination

The presence or absence of a response is determined automatically and objectively, using detection protocols that compare the response to the background EEG activity (Picton, 2002:65; Rance, 1995:501). Automatic response detection protocols rely on computer algorithms which are applied to the recorded EEG signal to analyze the magnitude and phase of EEG activity corresponding to the modulation frequency of the tone and to determine the presence or absence of an ASSR (Cone-Wesson & Sininger, 2002:317).

Samples of EEG activity are recorded and analyzed as the continuous modulated tone is presented. In each EEG sample, the magnitude and phase of the EEG activity corresponding to the tone modulation frequency is quantified (Cone-Wesson & Sininger, 2002:317). The peaks in the resulting spectrum, and the amplitude and phase of the spectral peak, can be measured for phase coherence (PC). The phase of the major peak can be plotted on polar coordinates. The sine and cosine of the angles formed by each phase vector are calculated. PC values vary from 0.0 to 1.0 (Cone-Wesson & Sininger, 2002:317). When the sample phases are in phase with one another, there is a high coherence, and the value will be closer to 1.0. When the sample phases are random, there is low coherence and values are closer to 0. Usually when a significant level of $p < 0, 05$ is obtained, the nil hypothesis is rejected, the samples can be considered phase locked or coherent, and an evoked response is determined to be present. Figure 2.5 shows a polar plot of phase coherence.

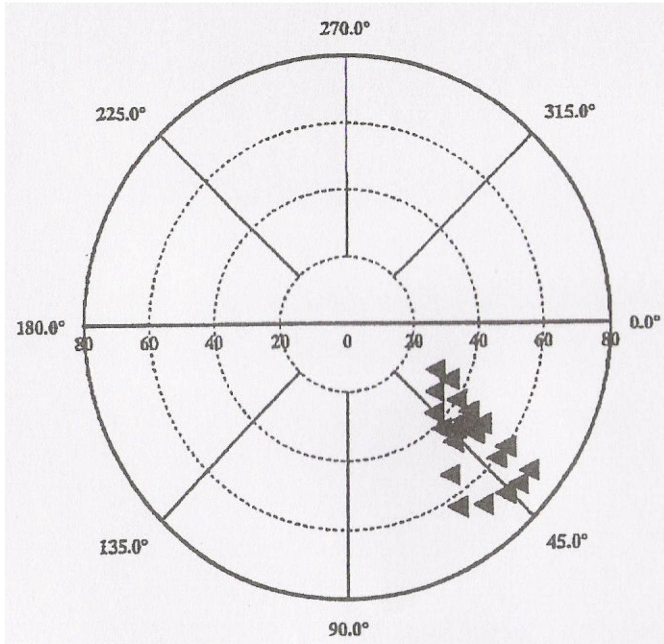

Figure 2.5 Polar Plot to Phase Coherence (from Sininger & Cone-Wesson, 2002)

By recording responses at descending intensities, a threshold or minimum response level can be obtained at the lowest intensity eliciting a response (Swanepoel et al, 2002:51).

2.3.2.3 Current Clinical Application of the ASSR in Infants

The major goal of evoked potential audiometry in infants is to predict or to estimate an infant's behavioral audiogram from evoked potential data – without any response from the patient or subjective interpretations of the results by a clinician (Dimitrijev et al., 2002:206; Goldstein & Aldrich, 1999:109). Furthermore it is important to seek a procedure that may give the most information with regard to frequency range, signal magnitude range, response reliability, clear criteria for establishing threshold and validity in terms of the patient's actual auditory sensitivity. In the past two decades, ASSR techniques have become available as an option for objective hearing testing (Rance et al., 1998:499). Several researchers found the ASSR to be a reliable method to obtain frequency specific estimates of behavioral pure tone thresholds in adults and older children (Dimitrijevic et al., 2002:205; Herdman & Stapells, 2001:41; Lins et al.; 1996:81 and Rance et al., 1995:499). Rickards et al. (1994:327) did research on the application of ASSR on well babies and other researchers did retrospective studies on the application of ASSR on infants (Vander Werff et al., 2002:227; Cone-Wesson et al., 2002:173) – comparing the ABR results with ASSR results. The clinical application of the ASSR will now be discussed – looking at three aspects, namely **detection**, **diagnosis** and **hearing aid fitting in infants**.

i. Detection

'*It is almost axiomatic in the field of audiology that early detection and early intervention will yield a better functioning hearing impaired child*' (Luterman, 1999:35). Over the past thirty years, several different procedures for screening newborns, including cardiac response, respiration audiometry, or alteration of sucking and startle responses have been used, investigated and found wanting (Luterman, 1999:37). Several methods of implementation of the high risk register approach have been used in the USA. It seems to identify about half of newborns with hearing loss (Northern & Hayes, 1997:21). Recently the ABR has been automated and the EOAE has been developed. Both these procedures can be rapidly administered, thus making universal screening for hearing impairment feasible (Luterman, 1999:39).

ASSR's may have an advantage over the ABR and EOAE's in newborn screening (Sininger & Cone-Wesson, 2002:318). EOAE's are thought to have an advantage over the click-evoked ABR, because it is more “frequency-specific”. EOAE’s appear to indicate cochlear integrity for at least the 1000 – 4000 Hz hearing range (Sininger & Cone-Wesson, 2002:318), however, EOAE’s do not test neural function and cannot predict hearing threshold (Hall, 2000:26). The AABR on the other hand, only uses click stimuli, limiting estimation of hearing loss in different frequency ranges (Stapells, Gravel & Martin, 1995:361).

ASSR tests optimized for screening may overcome both the frequency limitations of click AABR and the site-of–lesion limitations of EOAE. Since ASSR tests use tonal stimuli, the evoked potential can be efficiently detected with well-documented algorithms, and accurate threshold estimates can be obtained (Sininger & Cone-Wesson, 2002:318; Rickards, 1994:327). The Rickards group recorded ASSR’s from 337 normal full-term sleeping newborns to combined amplitude and frequency modulated tones. Responses were found most easily and consistently, recorded at carrier frequencies of 500 Hz, 1500 Hz and 4000 Hz with modulation frequencies between 60 Hz and 100 Hz. In this modulation frequency range, the response latencies were between 11 ms and 15 ms and the mean response threshold for the three carrier frequencies were found to be 41.36 dB HL, 24.41 dB HL and 34.51 db HL respectively. These researchers suggested that the ASSR may be useful for frequency-specific automated screening in newborns when modulation rates exceeded 60 Hz. Cone-Wesson et al. (2002:276) used established tools (AABR and EOAE’s) as the gold standard against which an ASSR screening protocol was compared. It was found that a three-frequency screening test (1000, 2000 and 4000 Hz) protocol could be completed within two minutes for each ear. Although the ASSR would seem to be an ideal screening tool, appropriate screening performance data (i.e., sensitivity and specificity) in appropriate clinical samples will be needed before possible implementation (Stapells, 2005:56).

Audiogram estimation is clearly the most important clinical application of the ASSR at this time. The following section will focus on the diagnosis of hearing loss in infants

ii. Diagnosis

Various experiments have demonstrated that the ASSR can be reliably recorded at intensities near behavioral thresholds in sedated and sleeping adults (Dimitrijevic et al., 2002:205; Herdman & Stapells, 2001:41; Lins et al., 1996:81). Lins et al. (1996:81) used a test time of 3.2 to 12.8 minutes for each recording and found evoked response thresholds that were approximately 11 to 14 dB above behavioral thresholds in the frequency range of 500 – 4000 Hz. ASSR thresholds appear to approach behavioral thresholds more closely with hearing losses of approximately 60 dB HL or higher. Rance et al. (1995:500) recorded ASSR thresholds within 11 to 20 dB of the behavioral thresholds in a range 1 to 4 kHz and approximately 11 to 40 dB at 500 Hz in subjects with a hearing loss of 60 dB or more. In subjects with hearing losses below 60 dB HL, ASSR thresholds were found over a wider range.

Several investigators obtained ASSR thresholds from infants who were not at risk for hearing loss. There were some differences in age of the infants between the studies – Rickards et al. (1994:327) tested infants younger than 7 days. This group of investigators found ASSR thresholds from 32 dB SPL (1500 Hz) to 53 dB SPL (500 Hz). Lins et al. (1996:81) tested the age range of 1 to 10 months and found thresholds from 26 dB SPL (2000 Hz) to

58 dB SPL (500 Hz). Cone-Wesson et al. (2002:260) tested at a mean age of 11.5 months and had similar results: thresholds varied from 29 dB SPL (2000 Hz) to 45 dB SPL (500 Hz). The ASSR evoked responses offers definite advantages over techniques that require short duration stimuli (Rance et al., 1998:49). The ASSR is evoked by frequency-specific stimuli (Cone-Wesson, 2003:267 & Hood, 1998:117). This is because the steady state stimuli are continuous tones that do not suffer the spectral distortion problems associated with brief tone bursts and clicks (Rance et al., 1998:49). This specificity allows testing across the audiometric range and the generation of evoked potential audiograms, which in subjects with hearing loss, can reflect the configuration of the loss accurately (Rance et al., 1995:500).

Rance et al. (2005:297) and Rance et al. (1998:506) demonstrated the advantages of using the ASSR to determine residual hearing thresholds for those infants and children from whom a click ABR could not be evoked (at 100 dBnHL). In the 1998 study, completed by Rance et al., ASSR's were obtained using CF's of 250-4000 Hz with MF's of 90 Hz. The average discrepancy between ASSR and behavioral threshold ranged only 3 to 6 dB with larger discrepancies found at 250 and 500 Hz. ASSR thresholds were within 20 dB of pure tone thresholds for 99% of the comparisons and 10 dB or less for 82% of the comparisons. Rance et al. (2005:297) demonstrated results consistent with the previous study. Overall, the findings showed a strong correlation between ASSR threshold and behavioral hearing threshold levels. Pearson *r* correlation coefficient values ranged from 0.96 to 0.98 across the test frequencies in subjects with hearing loss. These findings demonstrated the efficacy of ASSR's for estimating the audiogram in infants and children who can benefit from amplification of their residual hearing (Sininger & Cone-Wesson, 2002:316).

The determination of air-conduction (AC) and bone-conduction (BC) thresholds is a mainstay of clinical audiology (Cone-Wesson, Rickards, Poulis, Parker, Tan & Pollard, 2002:271). It is therefore important to determine the conductive component to an infant's hearing loss (Jeng, Brown, Johnson & Vander Werff, 2004:68), particular in infants and young children, who have a high incidence of middle ear disorders, causing conductive hearing loss (Cone-Wesson et al., 2002:271). The ASSR can be presented using both AC and BC transducers (Picton & John, 2004:542). Jeng et al. (2004;68) and Cone-Wesson et al. (2002:271) have shown a strong correlation between that of the ASSR bone conduction gap and audiometric estimates of air bone gap. Using the ASSR in this manner provides additional information about the nature of the hearing loss.

A further advantage of the ASSR, important for the application in infants, as cited by Rance (1995:506), is the speed in which a response can be detected. Responses could be detected within 20 – 90s after onset of the stimulus. Van der Reijden, Mens & Snik (2005:300) concluded in their summary of test time in the infant population that it approximately took between 3.2 to 12.8 minutes per ear, if four carrier frequencies were tested. This fast test time reduces the need to have the infant asleep or under sedation for long periods of time. As a result, the clinician is more likely to obtain all the information that is required before the subject awakens, and within one testing period (John et al., 2004:551; Rance et al., 1995:506).

A distinguishing and advantageous feature of the ASSR technique is that objective detection algorithms rather than visual detection methods are always used to determine presence or absence of a response (Sininger & Cone-Wesson, 2002:316; Lins et al., 1996:82). This is a particular advantage for techniques claiming to be "objective" in nature as accurate information with regards to the configuration of the hearing loss is necessary to develop a habilitation program, such as the use of amplification.

iii. The ASSR in pediatric hearing aid fittings

Another application of the ASSR is when rehabilitation has started and hearing aids have been fitted according to the electrophysiologic targets. Picton (1998:315) and Glockner in Cone-Wesson (2003:272) showed that ASSR's could be recorded when stimuli were presented simultaneously through a sound-field speaker and amplified using a hearing aid. Picton et al. (1998:315) recorded responses at carrier frequencies of 500, 1000, 2000 and 4000 Hz in a group of 35 hearing-impaired children using hearing aids. The physiologic responses were recorded at intensities close to the behavioral thresholds for sounds in the aided condition, with average differences between the physiologic and behavioral thresholds of respectively 17, 13, 13, and 16 dB for carrier frequencies 500, 1000, 2000 and 4000 Hz. While there were discrepancies between behavioral (aided) threshold and ASSR (aided) threshold, it appeared to be no greater than those found when stimuli were transduced by earphones (Sininger & Cone-Wesson, 2002:319). Their findings suggest that it would be possible to measure functional gain of hearing aids on the basis of ASSR threshold predictions. The Picton group (1998) used a multiple-simultaneous stimulus technique and for some subjects, responses were only found at high suprathreshold levels or were absent. Retest with single AM tones in these cases, showed better correspondence between pure tone and ASSR threshold. This technique shows great promise as a way to assess aided thresholds objectively in subjects who cannot reliably respond to behavioral testing.

Although hearing loss is commonly assessed using pure tone thresholds, the most debilitating aspect of a hearing loss is difficulty in speech perception (Dimitrijevic, John & Picton, 2004:68). A necessary first step in the perception of a word is to discriminate changes in the frequency and amplitude of a sound. The ability of the brain to detect changes in frequency and amplitude may be assessed by recording ASSR's to modulations in the frequency and amplitude of supra-threshold tones (Dimitrijevic, John & Picton, 2004:68). In this particular study independent amplitude and frequency (IAFM) modulation of tones stimulus parameters were adjusted to resemble the acoustic properties of everyday speech to determine how well responses to these speech-modulated stimuli were related to word recognition scores (WRS). The correlations between WRS and the number of IAFM responses recognized as significantly different from the background were between 0.70 and 0.81 for the 40 Hz stimuli, between 0.73 and 0.82 for the 80 Hz stimuli, and between 0.76 and 0.85 for the combined assessment of 40 Hz and 80 Hz responses. They concluded their research, stating that IAFM responses are significantly correlated with WRS and that it may provide an objective tool for examining the brain's ability to process the auditory information needed to perceive speech.

2.3.2.4 Critical evaluation of the ASSR

The ASSR shows promise in addressing some of the limitations of the ABR; however it still needs to be validated in the clinical field – especially in the pediatric field, before it can be recommended for clinical use.

The limited database for infants with hearing loss is a matter of great concern. According to Stapells (2004: conference presentation), relatively few studies are available. Of these studies the total sample size is not large – especially for the multiple ASSR. Of these studies comparisons were made with the click ABR, which is inappropriate as this measure do not give frequency specific information. Only two studies compared infant ASSR to tone evoked ABR, but only for 500 Hz. Only a few studies included a comparison between the ASSR and behavioral threshold. All of above studies included only Air Conduction (AC) ASSR. No information is available on Bone Conduction (BC) in infants with hearing loss or infants with conductive and/or mixed hearing losses (Stapells, 2004: conference presentation). Limited information is available about infants with mild or moderate hearing loss.

Some recent studies showed the possibility of spurious/artificial ASSR's at high intensity stimuli (Small & Stapells, 2004:611; Gorga et al., 2004:302; Jeng et al, 2004:67; Picton & John, 2004:541). ASSR thresholds were measured in subjects who had no behavioral responses to sound at the limits of pure-tone audiometers. It may thus appear that some responses in infants with profound SNHL may not be auditory. Some of these spurious responses may be due to aliasing, thus a signal processing issue and other spurious responses are likely physiologic and may be a vestibular response (Stapells, 2004: conference presentation). Clinically this may be of little consequence, as these patients will in all likelihood receive cochlear implants (Gorga et al., 2004:302). The manufacturer was made aware of this problem and correction was made to the software (Personal correspondence: Biologic systems).

Although Jeng et al. (2004:67) and Cone-Wesson et al. (2002:271), recorded ASSR using BC, with their results demonstrating a good correlation between estimated air-bone gap (ABG) using pure tone audiometry and ASSR, the subjects used in these studies were adults and therefore no information on BC ASSR are available for infants. Data from subjects with profound hearing loss also demonstrated that the levels where stimulus artifacts become problematic, were relatively low (Jeng et al., 2004:67; Small & Stapells, 2004:611). Small & Stapells (2004:622) concluded their study that although ASSR's appear to be promising, bone-conduction ASSR's will not be ready for clinical use until there are normative threshold data for infants of different ages.

Optimal stimuli and analysis is not yet determined. According to Stapells (2004: conference presentation), this, in itself, is not a problem. However, the small clinical database available has used different protocols, e.g. single vs. multiple ASSR's, F-test analysis, noise criteria, stopping rules, to name a few. Another concern is the duration of the stimulus when assessing the profound SNHL as the duration of high-intensity stimulation could result in acoustic trauma (Stapells, 2004: conference presentation).

Research studies (Rance et al., 2005:297; Cone-Wesson, 2002:185; Dimitrijevic et al., 2002:205; Vander Werff, 2002:227) show that the ASSR perform in the clinical pediatric setting and the results to the data from these research studies are very promising. The concerns mentioned above are surmountable and used in conjunction with the ABR, the ASSR can provide additional information about the configuration and degree of any existing hearing loss. Some questions still remain:

The neural generators of the response are still in dispute, particularly as a function of MF. Cone-Wesson (2002:281) feels that this should not limit adoption of the ASSR in the clinic as the precise sites and structures involved in the ABR have not been fully defined either. The effect of neuro-development and neuro-maturation insult on the ASSR is a critical issue for investigation. A related issue is the definition of normal "threshold" for the ASSR as a function of age – as this is expected to vary with both maturation of the auditory system periphery and the central auditory nervous system.

ASSR's have not yet been exploited for neuro-otologic diagnosis. It is likely that measures of phase coherence and also of latency could be used to indicate retrocochlear abnormalities for suprathreshold stimuli (Sininger & Cone-Wesson, 2002:319).

Lins & Picton (1995:420) investigated the physiology underlying the ASSR – using modulation rates between 150-190 Hz. Equal contributions between the brainstem and cortical areas were noted at these higher modulation rates. These researchers hypothesize that some insight may be gained into pathology of the auditory system up to cortical level.

Research is still required to establish whether single modulated tones offer higher frequency specificity at high stimulation intensities. Gorga, Neely, Hoover, Dierking, Beauchaine and Manning (2004:306) cautions the interpretation of high-level ASSR threshold measurements – using the multi-frequency system, as it may not provide information about peripheral hearing. Clinically this may be of little consequence, as these patients with "responses" observed at such high levels will in all likelihood receive cochlear implants. Research is also required to establish whether aided thresholds can be obtained from cochlear implant users, using an adapter cable, to maximize usage of electrode configurations in the maps (Marais, 2003:37).

2.3.2.5 *Summary of the ASSR application in pediatric audiology*

As a conclusion to this critical evaluation of the ASSR, Table 2.3 indicates the advantages as well as the limitations of the ASSR.

Table 2.3 Advantages and limitations of the ASSR

Advantages	Limitations
Diagnosis	
• Frequency specific – approximate pure tones • Stable – resistant to state of consciousness • Objective automatic detection of response • Distinguish between severe and profound losses • Relatively fast procedure	• Requires clinical validation – especially in the pediatric field: ➢ Bone-conduction ➢ Duration of high-intensity stimuli ➢ New equipment ➢ Spurious/artificial ASSR • Cannot differentiate between hearing loss of peripheral origin and those with neural transmission or retrocochlear origin
Validation Process	
• Provides ability to evaluate hearing aids	• Requires clinical validation ➢ Very limited research reports on applicability of this unconventional application of the ASSR

It is evident that the ASSR shows great promise for the clinical field of pediatric audiology as various researchers have demonstrated the advantages of the ASSR, over other AEP techniques, such as the ABR to use as an objective procedure to identify the nature, degree, symmetry and configuration of the hearing loss in infants as well as validation of hearing aids. It is imperative however that more research validate this procedure against the ABR – the current gold standard in clinical practice for pediatric audiology.

2.4 CONCLUSION

The need for a technique to estimate frequency-specific hearing thresholds in a clinically time-efficient manner in the difficult-to-test populations has long been a priority in the field of pediatric audiology (Hayes & Northern, 1997:234). Auditory Evoked Potentials have been used in diagnostic audiology for the past three decades and it is clear that in the field of objective audiology, large strides have been made in addressing this important need.

The most widely used AEP technique currently used to determine hearing thresholds in infants is the ABR. This technique – using a click stimulus, can provide a general evaluation of hearing sensitivity in the high frequency region (2 – 4 kHz). By using tone burst stimuli, more frequency specific information will be provided. Although the ABR is a valuable tool, it presents with important limitations.

The ASSR have been used in audiology research centers around the world for two decades and has demonstrated promise in addressing some of the limitations of the ABR (Cone-Wesson et al., 2002:273). The results from clinical studies have shown that ASSR thresholds can be used to predict pure-tone threshold in sleeping infants and young children (John et al., 2004; Rance et al., 2002; Rance et al., 1998; Rance et al., 1995). ASSR should therefore have an increasing role in the follow-up and diagnostic evaluation of infants who have failed newborn hearing screening. Used in conjunction with ABR (AC and BC tone-evoked ABR), ASSR's provide additional information about the contour and degree of any existing hearing loss (Stapells, 2004: conference presentation; Cone-Wesson et al., 2002:281). The ASSR also shows great promise as a way to validate hearing aid fittings objectively in subjects who cannot reliably respond to behavioral testing, but research data is still limited.

2.5 SUMMARY

This chapter aimed to orientate the reader on the topics of relevance and to provide a critical evaluation and interpretation of the relevant literature. In order to achieve this, the most widely used AER technique for estimating auditory thresholds in infants, namely the ABR was described, evaluated and discussed. Subsequently the importance of the hearing aid fitting process was discussed – describing the different, but equally important aspects of verification and validation. The role of each aspect in the hearing aid fitting process was clarified. Lastly the ASSR was discussed as an AEP promising to address the current limitations of the ABR. Finally the general ideas of the chapter were summarized in the conclusion.

Chapter 3

RESEARCH METHODOLOGY

This chapter aims to explain the method used to conduct the research component of this study. This will be discussed in terms of aims set for this research, the research design, ethical considerations, subjects, material apparatus and procedures used.

3.1 INTRODUCTION

"*Research has one end: the ultimate discovery of truth*" (Leedy & Omrod, 2001: xviii). Its purpose is to learn what has never been known before; to ask a significant question for which no conclusive answer has previously been found; and, through the medium of relevant data and their interpretation, to find an answer to that question (Leedy & Omrod, 2001:xviii).

Chapter one introduced the problem surrounding this research endeavor. It also provided a rationale for the study and explained the research question. Chapter two provided a theoretical framework, as support for the empirical research component, concepts and constructs were then specified. Chapter two also provided an interpretation of the current and relevant literature available.

This chapter aims to explain the methodological approach implemented in conducting the empirical component of the current study.

3.2 AIMS OF RESEARCH

Significant correlations between ASSR thresholds and behavioral audiometric thresholds as well as correlations between the ASSR and ABR as a threshold prediction technique have been found by several researchers (Dimitrijevic, 2002:205; Cone-Wesson et al., 2002:173; Vander Werff et al., 2002:227; Herdman & Stapells, 2001:41; Lins et al., 1996:81; Rance et al., 1995:499). Although these results indicate the ASSR to be a promising technique in determining the auditory ability of adults, the need arises to validate this procedure for the infant population.

Stapells (2002:14 & 2004:conference presentation) cautioned audiologists about the use of the ASSR in the clinical setting in the infant population, as only a few studies had been done in this regard. This present study focused on the use of ASSR in the diagnosis of hearing loss and validation of hearing aid fitting in infants. The importance of this technique, should it prove to have valid clinical application, is evident for the difficult-to-test populations. Therefore the aims of the current study are as follows:

3.2.1 Main aim

The main aim of the study is to investigate the clinical value of the ASSR for early diagnosis and for early hearing instrument fitting of hearing loss in infants.

3.2.2 Sub aims

The following sub-aims were formulated in order to realize the main aim of the study:

- To investigate the potential clinical value of the ASSR for early diagnosis of a hearing loss in a group of infants by determining and comparing the:
    - Unaided ABR thresholds (click and toneburst) at the age of 3 – 6 months
    - Unaided ASSR thresholds at the age of 3 – 6 months
    - Unaided behavioral thresholds at the age of 8 – 12 months (after a time lapse of 2 – 6 months following diagnosis)

- To investigate the potential clinical value of the ASSR for early hearing aid fitting in a group of infants by:
    - Determining aided ASSR at the time of hearing aid fitting
    - Comparing unaided and aided ASSR at the time of hearing instrument fitting
    - Determining aided behavioral thresholds at the age of 8 – 12 months and comparing these results with aided ASSR's.

3.3 RESEARCH DESIGN

Babbie and Mouton (2002:72) said science is an enterprise dedicated to "finding out". Research design addresses the planning of scientific enquiry, designing a strategy for finding out something specific. The *design* is the complete strategy of tackling the central problem. It provides the structure within which the selected variables are controlled, manipulated and measured (Hegde, 1987:135). The *method* of research is defined by Leedy and Ormrod (2001:100) as the framework to extract the meaning from the data collected.

In this section the research plan is described in terms of the goal set, the approach followed and the specific research design utilized. An exploratory, correlative-descriptive study (Bellis, 2003:433) with a quasi-experimental design (Leedy & Ormrod, 2005:231), implementing a quantitative research approach, was selected to achieve the aims of this study.

The goal or purpose of this study was to explore, describe and correlate (Bellis, 2003:433). **Exploratory** research is typically used when a researcher is examining a new interest or when the subject of study is itself relatively new and unstudied (Babbie, 1992:90). The ASSR is a relatively new adjunct to the field of Audiology and specifically needs validation in the pediatric field. The goal of **descriptive** research is to describe the characteristics of a selected phenomenon (Bellis, 2003:436). In this study information was collected with regards to different test methods in a group of subjects. The results from this group's performance was recorded and described. The goal of the study as reflected in the main- and sub-aims was therefore to explore, correlate and describe the clinical value of the ASSR as compared with the ABR for diagnosis of hearing loss. The role of the ASSR and validation processes of hearing instrument in infants are also explored and described. A **correlative** study examines the extent to which differences in one characteristic or variable are related to differences in one or more other characteristics or variables (Leedy & Ormrod, 2001:191). In this study a correlation was made between the two different methods utilized to estimate infants' hearing abilities. A further correlation was drawn between the aided and unaided predicted thresholds done through ASSR technology and the gold standard of behavioral threshold measures – looking at both the aided and unaided behavioral thresholds.

A quantitative research approach was implemented. **Quantitative** research is used to answer questions about relationships among measured variables with the purpose of explaining, predicting, and controlling phenomena (Leedy & Ormrod, 2001:101). Quantitative researchers seek explanations and predictions that will generalize to other persons and places (Leedy & Ormrod, 2001:102). Quantitative data collection methods were selected for this study due to the nature of the data to be collected, namely threshold estimation values, behavioral thresholds, functional gain estimations and functional gain behavioral thresholds. Quantitative research is also used to answer questions about relationships among measured variables, with the purpose of explaining, predicting and controlling phenomena (Leedy & Ormrod, 2005:231). This study aimed to look at the relationship between different methods used to predict thresholds in infants and functional gain measurements. During quantitative research, standardized procedures are used to collect numerical data (Leedy & Ormrod, 2001:191). The variables to be studied are usually isolated and extraneous variables are controlled. This type of data collection allows for the use of statistical procedures to analyze and interpret the data.

This study lends itself to a quasi-experimental design (Drummond, 2003:32). When conducting a **quasi-experimental** study, all confounding variables cannot be controlled. Variables and explanations that have not been controlled for need to be taken into consideration when data is interpreted (Leedy & Ormrod, 2005:227). According to Mouton (2001:160), a quasi-experimental design is usually quantitative in nature, aims to provide a causal study of a small number of cases under controlled conditions as in this study. Subsequently this study lacks the ingredient of randomization techniques of a true experimental design.

A controlled test environment, with uniformity in test equipment and test protocol, was selected to control environmental conditions. The validity of the exploratory study was enhanced by the inclusion of six subjects.

3.4 ETHICAL CONSIDERATIONS

Scientists consider research to be an ethical activity. Researchers seek knowledge, solve problems, and design new methods of treating diseases and disorders, but they have the responsibility of doing all of this in an honest, responsible, open and **ethically** justifiable manner (Hegde, 1987:414). The basic tenet of ethical research is to preserve and protect the human dignity and rights of all subjects involved in a research project (Jenkins, Price & Straker, 2003:46).

The basic ethical principles of autonomy, beneficence and justice (Hyde, 2005:297; Louw, 2004:1) were incorporated in this study.

3.4.1 Autonomy

Autonomy refers to the freedom of will, the right to self-government and personal freedom (Concise Oxford Dictionary, 1984:59). In research, autonomy refers to strictly voluntary participation (Leedy & Ormrod, 2001:107), to choose whether or not to be recipients of specific actions (Hyde, 2005:297). The person involved must have the legal capacity to give consent (Jenkins, Price & Straker, 2003:47). The infant is a minor and therefore the parent or caregiver became the advocate for the infant. In this study, the parent or caregiver had the responsibility to act in the best interest of the infant.

- ***Informed consent***

Each subject's parent or caregiver was requested to give written permission for participation in this study. A letter of informed consent was drawn up (Appendix B). This letter explained the purpose and nature of this study (Leedy & Ormrod, 2001:107). The letter informed the parents or caregivers of the infants of what was expected of them and about their and their infant's rights. Subjects' rights included the following:

Withdrawal of participants

The parents/caregivers were given the assurance that they had the right to withdraw their baby as a subject from this study at any time.

Privacy, confidentiality, anonymity

Parents'/caregivers' permission was requested to use information in personal client records of a private practice, for research purposes. All information used was confidential. The privacy of all subjects was upheld. A letter stating the latter was given to each subject (Appendix B).

Disclosure of information

The parents/caregivers of subjects were informed of the fact that the results from this study may in future be used in the publishing of a scientific article or conference or seminar presentation. Information might be discussed at academic gatherings.

Debriefing of respondents

All information gathered from this research was made available to the parents or caregivers. Research findings were summarized in a letter and sent to each participant. Since these letters contained personal information, no copies are included in the appendix of this research report.

- ***Ethical Clearance***

This study had ethical clearance from the Research Proposal and Ethics Committee of the Faculty of Humanities, University of Pretoria. A letter of confirmation to this effect is included in Appendix A. Since the subjects were clients of the researcher's own private practice, no ethical clearance or letter of informed consent to another institution was required.

3.4.2 BENEFICENCE

Beneficence refers to acting in kindness (Concise Oxford Dictionary, 1984:83) or to the conferral of benefits (Hyde, 2005:297). Researchers should not expose research participants to undue physical or psychological harm (Leedy & Ormrod, 2001:107; Babbie, 1992:465). The risk involved in participating in a study should not be appreciably greater than the normal risks of day-to-day living. This aspect was dealt with in the following manner:

- **Competency**

The researcher was competent to carry out the research due to her professional qualification, as well as years of experience in the field of Audiology. Two supervisors were involved in this process – ensuring a suitable research design and giving guidance in the process of research. The researcher (STA 011037) and the supervisors were registered with the Health Professions Council of South Africa.

- **Relevance**

The topic of research was highly relevant at the time of development in the Audiologic field as is indicated in the rationale for the study.

- **Risks**

Potential medical risks involved in this study were considered and addressed. The usual procedures and care maintained in the clinical practice applied. In cases where subjects needed sedation, chloral hydrate was prescribed by a pediatrician and administered orally by a qualified and experienced pediatric nurse. The pediatric nurse monitored subjects for oxygen saturation, respiratory rate and heart rate.

- **Discrimination**

There was no discrimination between subjects on the grounds of race, economic status or gender. Parents/caregivers were given the assurance that their baby's status as client of the researcher's private practice would not be influenced by their consent or refusal to participate in the study.

3.4.3 JUSTICE

In research '*justice*' refers to honesty with professional colleagues (Leedy & Ormrod, 2001:108). It also relates to fairness in the distribution or allocation of benefits among members of society (Hyde, 2005:297). Researchers must report their findings in a complete and honest fashion. 'Justice' was addressed in the following manner:

- **Dissemination of results**

Research results were made available to all participants. The results were made available to the professionals in the field of Audiology in order to gain knowledge of new developments in the field as well as improve service delivery. Research findings were published in the form of a research article, which may be used and distributed by the public.

3.5 SUBJECTS

Six infants with hearing loss were identified as subjects for this study.

3.5.1 Sampling

The subjects included in this study were selected, based on a non-probability convenience sampling approach (Babbie, 1992:230). The subjects were selected from the clinical caseload of the researcher's private practice in Cape Town. These were infants referred for follow-up evaluations after failing a screening evaluation.

3.5.2 Selection criteria

The subjects were selected according to the following criteria:

3.5.2.1 Client status and record

Subjects were clients of the researcher's private practice of whom information is available and whose parent/caregivers had given their consent for the baby to be included in the study (Appendix B).

3.5.2.2 Hearing ability

Subjects were those who were referred for electrophysiologic assessment after failing a click-evoked ABR screening and OAE's screening assessment.

3.5.2.3 Normal Middle Ear Functioning

Subjects were included only if they showed no evidence of middle ear pathology in order to rule out any other factors influencing tests results. The middle ear status was determined by otoscopic examination and high frequency tympanometry – using a 1000 Hz probe tone and an examination by an Ear-Nose-and Throat surgeon. A single-peaked high frequency (1000 Hz) tympanogram was indicative of normal middle ear function (Kei et al., 2003:27).

3.5.2.4 Age at time of identification

Infants[2] were selected for this study, through referral, failing a hearing screening protocol. At the time of identification, these infants were too young to measure hearing abilities through traditional behavioral methods and it was therefore appropriate to use electrophysiologic measures. Once an infant achieved a developmental age of approximately six to eight months, audiometric information could be obtained efficiently using a behavioral technique, based on principles of conditioning (Diefendorf & Weber, 1994:57). When the subjects reached this age, behavioral methods were used to determine unaided and aided thresholds.

3.5.2.5 Neurological status

In order to rule out the presence of auditory neuropathy (neural transmission disorder), both an ABR and OAE evaluation was conducted. In the case of an auditory neuropathy, the OAE or cochlear response would still be present with an abnormal or absent ABR. Subjects were included when the ABR assessment showed no evidence of a neural transmission disorder (Rance & Rickards, 2002:237). This aspect was further addressed by measuring OAE's – the absence of these OAE's confirmed the absence of auditory neuropathy.

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[2] Infant as defined by Concise Oxford Dictionary (1984:513): child during earliest period of life – before age 1.

3.5.3 Subject Selection Apparatus

The following apparatus were used in the selection procedures of the subjects:

3.5.3.1 Hearing Screening Apparatus

Screening for hearing loss through Automated Auditory Brainstem Response techniques (AABR) and Otoacoustic Emissions (OAE) methods were done on the ABAER from *Biologic Audiometric Systems*, (calibrated June 2004). The sound was transduced into the ear canal by the probe microphone.

The ABR is a physiological measure of the auditory system to stimuli presented to the ear. Short-duration 'click-stimuli' was presented to each ear via the probe microphone at 35 dBnHL. Recording was done using a three-electrode montage of high forehead and the mastoid bone of each ear. A maximum impedance of 8 kOhm was allowed with a minimum difference of 4 kOhm.

Otoacoustic Emission measurements were performed on each subject. Distortion Product Otoacoustic Emissions using a 65/55 dB probe tone was performed on each subject (Hall & Mueller, 1997:247). A 2 – 5 kHz screening protocol with ¾ pass rate was used. The absence of a response with these parameters was indicative of the presence of a hearing loss greater than 30 dB.

3.5.3.2 Otoscopic Examination

The otoscopic examination of the external meatus and tympanic membrane were performed with a *Heine mini 2000* otoscope.

3.5.3.3 Middle Ear Assessment

High frequency tympanometry and acoustic reflex measurements – using a 1000 Hz probe tone were performed with the *GSI Tympstar middle ear analyzer* (calibrated June 2004).

Fowler & Shanks (2002:201) noted that tympanometry – using a high frequency probe tone give more useful information with regards to the middle ear system of infants. A single-peaked high frequency (1000 Hz) tympanogram was indicative of normal middle ear function (Kei et al., 2003:27). Further, the presence of an acoustic reflex helped to confirm a normal middle ear system. The absence of the acoustic reflex in the presence of normal tympanometry supported the possible presence of a hearing loss.

3.5.4 Subject Selection Procedures

The six subjects (2 male and 4 female) included in this study were referred to the practice of the researcher for diagnostic electrophysiological assessment following failure on a click-evoked ABR screening assessment and a subsequent failure on the OAE screen. Results of these screening procedures ruled out the possibility of a subject presenting with a neural transmission disorder (auditory neuropathy). These assessments were administered by the researcher herself.

All subjects had normal middle ear function as determined by an otoscopic examination and high frequency tympanometry – using a 1000 Hz probe tone. The otoscopic examination was performed to inspect whether any visible obstruction was present that could affect the conduction of sound to the tympanic membrane (Stach, 1998:174). Both the otoscopic examination and high frequency tympanometry were conducted on each of the test occasions (ABR screening and OAE previously and the day of diagnostic assessment).

The test sequence started with the performance of the OAE measurement. Failure on this evaluation was followed with high frequency tympanometry in order to exclude middle ear pathology. After showing normal immittance measurements, an AABR assessment followed. The infant was considered a subject for this study, after failing the AABR.

3.6 DESCRIPTION OF SUBJECTS

The subjects included six infants with different degrees of hearing loss. Two male and four female subjects with a hearing loss and an average age of five months (ages ranged from three to six months of age) were identified. These were babies of whom hearing screening data since birth was available to the researcher. Table 3.1 includes information regarding the age of identification, gender and the degree of hearing loss. Additional information regarding the individual subjects accompanies the description of individual results in Chapter 4.

Table 3.1 Description of subjects

Subject number	Gender	Age at time of hearing loss identification	Degree of hearing loss
1	Male	3 months	Moderately Severe
2	Female	5 months	Moderately Severe in right ear Moderate in left ear
3	Female	6 months	Severe in right ear Profound in left ear
4	Female	6 months	Severe
5	Female	4 months	Profound
6	Male	6 months	Profound

3.7 MATERIAL AND APPARATUS

The following data collection apparatus, materials and procedures were used for the collection of data:

3.7.1 Hearing threshold estimation apparatus

The *GSI Audera* from GSI (a division of VIASYS), (calibrated November 2003), was used to predict hearing thresholds – using both click evoked and tone burst Auditory Brainstem Response (ABR) and Auditory Steady State Response techniques (ASSR). The ABR and ASSR were recorded using both ipsilateral and contralateral electrode montages with high forehead positive, the mastoids negative and the ground electrode positioned on the low forehead (Vander Werff et al., 2002:229). The stimuli were presented via TIP 50 Insert HA-2 Tubephones with foam earplugs. Electrode impedance values were $\leq$ 5 kOhms and were within 1.5 kOhms of each other.

The protocol followed for click ABR is represented in Table 3.2. Table 3.3 represents the protocol followed for tone burst ABR and Table 3.4 represents the protocol for the ASSR measurements.

Table 3.2 Protocol for click ABR

Settings	*Parameters*	
Stimulus	Click	Hall & Mueller, 1997:334;
Duration	0.1 ms	Hall & Mueller, 1997:334; Hood, 1998:54
Transducer	Tip 50 insert earphones	GSI-equipment
Polarity	Rarefaction	Hall & Mueller, 1997:334; Hood, 1998:52
Rate	33.1/sec.	Hood, 1998:51
Electrode placement	Ipsilateral and contralateral electrode montages with: • High forehead - positive • Mastoids – negative • Low forehead – ground.	
Impedance	≤ 5 kOhms with difference between electrodes no greater than 1.5 kOhms.	

Table 3.3 Protocol for tone burst ABR

Settings	*Parameters*	
Stimulus	500 Hz, Blackman ramping 2-1-2 cycles	Purdy & Abbas (2002:359); Stapells (2000a:17); Gorga (1999:37
Filter choice	30 – 1500 Hz	GSI-protocol
Transducer	Tip 50 insert earphones	GSI-equipment
Polarity	Alternating	Minimizes a frequency following type of response (Stapells, 2000a:17)
Rate	39.1/sec	Stapells (2000a:17)
Electrode placement	Ipsilateral and contralateral electrode montages with: • High forehead - positive • Mastoids – negative • Low forehead – ground.	
Impedance	≤ 5 kOhms with difference between electrodes no greater than 1.5 kOhms.	

Table 3.4 Protocol for the ASSR

Settings	*Parameters*	
Carrier frequencies	500, 1000, 2000, 4000 Hz	
Modulation frequencies	500 | 1000 | 2000 | 4000 74 | 81 | 88 | 95	Cone-Wesson et al. (2002:178); Vander Werff et al. (2002:230).
AM percentage	100%	GSI *Audera* protocol. Cone-Wesson et al. (2002:178); Vander Werff et al. (2002:230).
FM percentage	10%	
Transducer	Tip 50 insert earphones	
Number of sweeps	16 (minimum) – 64 (maximum)	
Impedance	≤ 5 kOhms with difference between electrodes no greater than 1.5 kOhms.	
Electrode placement	Ipsilateral and contralateral electrode montages with: • High forehead - positive • Mastoids – negative • Low forehead – ground.	

The stimuli used to evoke the ASSR consisted of carrier frequencies of 500, 1000, 2000 and 4000 Hz that were 100 percent amplitude modulated and 10 percent frequency modulated at modulation frequencies of 74, 81, 88 and 95 Hz respectively (Cone-Wesson et al., 2002:178; Vander Werff et al., 2002:230). The *Audera* device averaged the ongoing EEG activity and computed the phase coherence of the spectral component of the response at the modulation frequency. Statistical analysis was used to determine the probability that the observed response was due to chance. Between 16 and 64 sweeps were analyzed during each recording. The test was terminated when the phase coherence reached statistical significance or at 64 sweeps if significance was not reached. The significant level was set at 0.03 (GSI, 2001:3). The ASSR thresholds are used to estimate the pure-tone audiogram. This estimation utilizes an algorithm based on published research from the University of Melbourne in which ASSR thresholds measured for patients with various amounts of hearing loss were correlated with their behavioral audiograms (GSI, 2001:6).

3.7.2 Functional Gain Estimation Apparatus

The *GSI Audera* from GSI (calibrated November 2003), was used to predict functional gain. Stimuli were transduced through a RCA PRO-X33AV loudspeaker in the free field. The loudspeaker was calibrated to present stimuli at 0º, 30 cm from the forehead.

3.7.3 Clinical audiometer

Pure tone thresholds were obtained using a *GSI 61 Clinical Audiometer* (calibrated June 2004). Acoustic stimuli were presented through sound field presentation. Ear specific information was recorded using insert earphones (Scollie & Seewald, 2002:689). Narrow bands of noise were used as test stimuli, as these infants were younger than 14 months of age (Gravel, 2002:40).

Functional gain was determined through sound field presentation. Narrow bands of noise were once again used as test stimuli.

3.7.4 Test environment

Behavioral testing was conducted in a double-walled, sound-attenuating room. Electrophysiological testing was conducted in a quiet side room of the private practice.

3.7.5 Data collection sheet

The collected data was tabulated on a summative data collection sheet (Appendix C).

3.8 PROCEDURE

The following procedures were followed in order to obtain the necessary data.

3.8.1 Data Collection Procedures

The aim was to collect at least five sets of data on each infant. The five sets of data from each subject included the following:

- Unaided ABR to click and 500 Hz tone burst stimuli
- Unaided ASSR to 4 frequencies per ear

- Aided ASSR to 4 frequencies per ear
- Unaided pure tone behavioral thresholds
- Aided behavioral thresholds

Data collection was done by a qualified audiologist, registered with the Health Professions Council of South Africa, with 14 years of experience in the field of pediatric audiology. The data collection procedures concerning the different types of data will be discussed according to the synopsis presented in Figure 3.1.

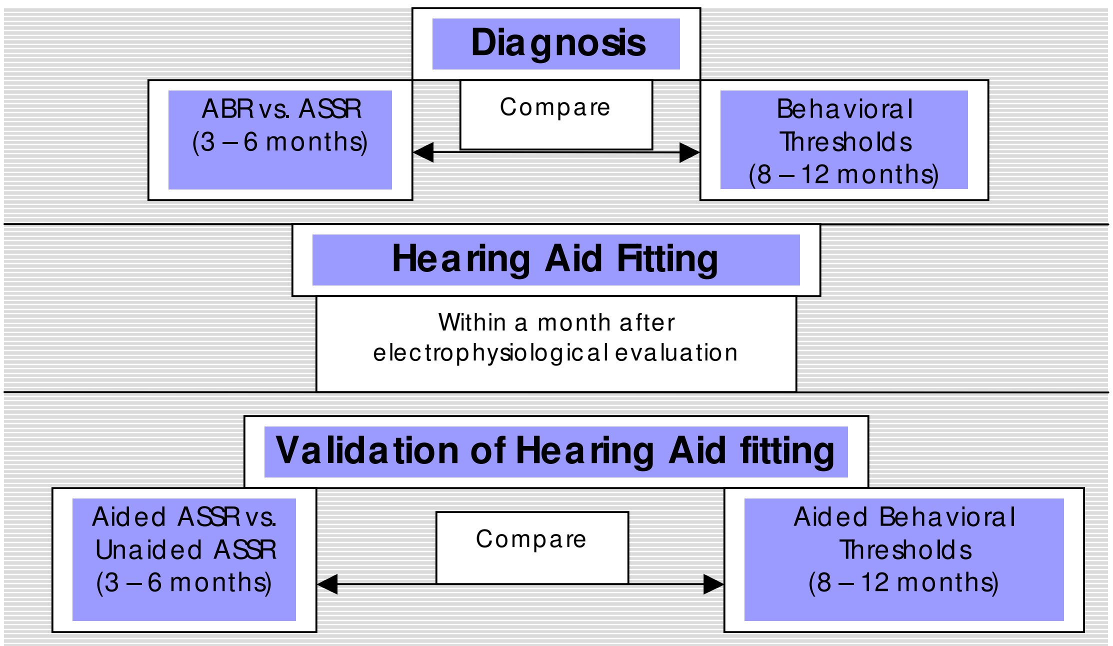

Figure 3.1 Schematic representations of the data collection procedures

Subjects under the age of six months of age were nursed by a parent and were tested whilst in a natural sleep. If sedation was needed, subjects were sedated with chloral hydrate – prescribed by a pediatrician (50mg/kg, administered orally) and were monitored for oxygen saturation, respiratory rate, and heart rate throughout the procedure by a pediatric nurse.

3.8.1.1 Auditory Brainstem Response (ABR)

ABR testing was completed at referral, as shown in Figure 3.1. Initially, click-evoked ABR thresholds were recorded bilaterally (Gorga 1999:36). ABR thresholds were then recorded using 500Hz, 1000Hz and 2000Hz toneburst stimuli (Vander Werff et al., 2002:230). At each presentation level, a minimum of 1200 sweeps were averaged. Increments of 10 dB were used for suprathreshold presentations. Increments were reduced to 5 dB near threshold, and a minimum of two replications were recorded at stimulation levels near threshold (Rance & Rickards, 2002:238). The threshold was defined as the lowest level that resulted in a replicable ABR wave V (Vander Werff et al., 2002: 230; Cone-Wesson et al., 2002:177).

3.8.1.2 Auditory Steady State Response (ASSR)

The same electrodes used for the ABR testing were used for ASSR testing. ASSR testing began after the ABR testing was completed (see Figure 3.1). ASSR testing was conducted at 2000 Hz and 500 Hz in both ears. If time permitted and the infant was still asleep, ASSR testing at 1000 Hz and 4000 Hz followed (Vander Werff et al., 2002:228). Thresholds were obtained using a 10 dB down and 5 dB up search procedure with a starting level of 50 dB. Threshold was defined as the minimum level at which the phase coherence was statistically significant (Rance & Rickards, 2002:238; Cone-Wesson et al., 2002:178). When no ASSR could be identified at maximum presentation levels, the run was repeated (Vander Werff et al., 2002:231).

The ASSR measured thresholds were then used to estimate the pure-tone audiogram. This estimation utilized an algorithm based on published research from the University of Melbourne in which ASSR thresholds measured for patients with various amounts of hearing loss were correlated with their behavioral audiograms (Rance et al., 1995:499). This present study refers to these estimations as '*ASSR predicted thresholds*'.

3.8.1.3 Aided ASSR thresholds

These tests commenced approximately a month after hearing aid fitting (Figure 3.1). Hearing aids were programmed according to each infant's hearing loss – using prescriptive methods. Responses were measured at frequencies of 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz through the free field speaker (Picton et al., 2002:69). A 10 dB down, 5 dB up search procedure was again utilized. Starting levels were commenced at 50 dB. Threshold for functional gain prediction was defined as the minimum level at which the phase coherence was statistical significant (Rance & Rickards, 2002:238). Depending on the technology of the hearing aids, certain features of the hearing aids needed to be deactivated, such as noise reduction systems and feedback management systems (Kuk, 2004:1).

'*ASSR measured threshold'* for each frequency was defined as the lowest HL at which a trial was judged to be a 'response'. '*ASSR predicted threshold'* for each frequency referred to the estimated behavioral audiogram – using the University of Melbourne algorithm (Rance et al., 1995:499). Both these measurements were used during the comparison between aided ASSR's and aided behavioral thresholds as the normative data from which predicted thresholds were calculated were compiled by data not derived for aided ASSR's.

3.8.1.4 Unaided behavioral pure tone thresholds (BT)

This evaluation was conducted at the age at which the infants were mature enough to complete the audiometric testing. There was a time delay of four to six months between the times of the evoked potential and audiometric testing (see Figure 3.1). Infants who were 3 – 6 months of age at the time of electrophysiological testing were at least 7 – 9 months old at the time of the behavioral testing and were therefore mature enough to complete the behavioral assessment.

The following *Visual Response Audiometry Protocol* was followed (Gravel, 2000:39):

Narrow bands of noise were used as test stimuli. Assessment began with sound field presentations of the stimulus (500 Hz) at 30 dB HL. If the subject oriented toward the loudspeaker, the head turn response was reinforced and another stimulus at the same level was presented. A head turn was again reinforced and the threshold search (descending) was initiated. If no response occurred, after two presentations at 30 dB HL, signal level was increased in 20 dB step sizes until an orientation towards the loudspeaker occurred. Two responses at the same level was the starting level for threshold search. The initial descent step size for threshold search was 10 dB and remained 10 dB for the up-down threshold search procedure. Sound field thresholds were obtained across the frequency range from 500 Hz through 4000 Hz. Test order was 500 Hz, followed by 2000 Hz, 4000 Hz, and then 1000 Hz. Threshold was calculated from the levels of the three response reversals following the first miss on the initial descent.

In cases where there was no response to sound field stimuli at 80 dB HL, a bone-conducted signal(narrow band noise at 250 or 500 Hz that was intense enough to be felt) was used to teach the subject the head-turn response.

Insert earphones were used to determine ear specific thresholds – using the same order of test frequencies as used in sound field presentations. Insert earphones were preferred as they are lightweight, do not inhibit the head-turn response and provide good interaural attenuation in the cases of asymmetrical hearing loss. For threshold search under these conditions, the step size was reduced to 5 dB. Threshold search was identical to that described for sound field assessment.

3.8.1.5 Aided behavioral thresholds

Testing was conducted with each subject's own hearing aids. Frequencies of 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz were tested – using broad band signals with the speakers positioned at 0º. Assessment of aided responses followed the same procedure as described above with sound field presentations as discussed in 3.8.1.4. (Also see Figure 3.1).

3.8.2 Procedures for data recording, processing and analysis

The following procedures were followed to record, process and analyze the data.

3.8.2.1 Recording of data

The following information was recorded for each subject on a data sheet (Appendix C).

Data yielded from each subject included:

- Unaided ABR click threshold (determined at time of diagnosis)
- Unaided ABR 500 Hz tone burst threshold (determined at time of diagnosis)

- Unaided ASSR threshold for at least 2000 Hz and 500 Hz (determined at time of diagnosis)
- Aided ASSR thresholds (determined within a month after diagnosis)
- Unaided Behavioral Thresholds (determined 4 – 6 months after diagnosis)
- Aided Behavioral Thresholds (determined 4 – 6 months after diagnosis)

3.8.2.2 Procedures for processing and analysis of data

"Statistics are among the most powerful tools in the researcher's toolbox", (Leedy & Ormrod, 2001:252). These tools include descriptive and inferential statistics. **Descriptive statistics** entails ordering and summarizing the data by means of tabulation and graphic representation and the calculation of descriptive measures. In this way the inherent trends and properties of the observed data emerge clearly (Steyn, Smit, Du Toit & Strasheim, 2003:5). **Inferential statistics** on the other hand serve a different purpose. It draws conclusions about the population from which the sample was drawn by comparing descriptive measures that have been calculated. (Leedy & Ormrod, 2005:252). In this study the options available for reliable and valid analysis was to a certain extent limited by the relatively small sample. A statistician at the Department of Statistics and Actuarial Science of the University of Stellenbosch was consulted in his private capacity during the planning of this study.

In order to determine the clinical value of the ASSR method in infants, each subject's individual performance was described on each procedure. The results obtained during the unaided ASSR evaluation were compared with the unaided ABR results at the time of diagnosis and subsequently with the results obtained during the unaided behavioral assessment. The same procedure was followed with the aided ASSR and aided behavioral assessment results. Thereafter the collective results for all subjects were analyzed. The focus was not on comparing the data of different subjects as such, but to compare the data for the different ears as it was recorded through the use of three different measuring techniques based on a particular stimulus. In this way the data collected through the use of the ASSR could be compared to the data collected through the use of other measuring techniques. The collected data were tabulated in raw data tables and graphically compared in figures resembling an audiogram.

In order to get a broader perspective on the research findings, the data for all subjects collectively was further analyzed using **descriptive statistics.** In these analyses three aspects were taken into account, namely: points of central tendency (mean); extent of dispersion (range/standard deviation); and the extent to which different variables were related to one another (correlation) (Leedy & Ormrod, 2005:257; Drummond, 2003:112). Data processing and analysis of the collective data entailed the following:

- Calculating the **range of threshold values** for the 12 ears per stimulus frequency as recorded by each measuring technique.
- Calculating the **standard deviation (SD)** for the measured thresholds for each stimulus frequency in addition to the range. However, the decision to include the SD was taken with full knowledge that the limited number of data points increases the possibility that the SD may be unduly influenced by a single data

point. With this in mind, the SD data for responses to a single stimulus frequency was considered with extreme care.

- Determining the **extent of the difference** between thresholds recorded for a particular stimulus frequency by considering the number of thresholds that falls within 10 dB, 15 dB, 20 dB and more than 20 dB from each other. This can be seen as a categorical comparison of differences.
- Determining the **mean** of the threshold values for the 12 ears per stimulus frequency, recorded by each measurement technique.
- Calculating the **difference** between the mean of thresholds (of 12 ears per stimulus frequency) recorded by two specific measuring techniques.
- Establishing the **statistical significance** of the differences between the mean of thresholds for 12 ears per stimulus frequency by using inferential statistics. Two-sample comparisons between the unaided ASSR results vs. the unaided ABR results; the unaided ASSR results vs. the unaided behavioral results; and the aided ASSR results vs. the aided behavioral results were done by applying the Wilcoxon Signed-Rank Test (Steyn et al., 1991:594). This test is valid with the assumption that the samples were drawn independently from two sets of data with distributions of similar shape (Steyn et al., 1994:594). This test is powerful because it uses the *size* (magnitude) of differences as well as the *direction* (positive or negative). The size of the differences is indicated by ranking the differences for the combined scores (Drummond, 1998:128). The Wilcoxon Signed-Rank test determines a p-value, determining the statistical significance of the difference between two data sets. For two sets of data to have a statistical significant difference, the p-value

should be smaller than 0.05. The data concerning this specific analysis are represented in the form of tables showing the p-value.

- In an effort to broaden the scope of the statistical description of results, the mean and the SD for thresholds for all measurements (including measurements for all stimulus frequencies and all ears), evaluated with a particular procedure, were calculated. The motivation for doing so was to include a larger number of data points and subsequently minimizing the effect that one single data point may have on the SD value. This approach however is also not without its problems, since one procedure may prove to be more sensitive to higher or lower stimulus frequencies and intensities than another, resulting in a canceling effect. These SD values were therefore also interpreted with extreme caution.
- In the final instance, determining the **correlation coefficient** of threshold values (per ear, per stimulus frequency) provided by two specific measuring techniques. The correlation values were interpreted according to categorical guidelines provided by Koenker (in Leedy, 1981:115).

3.8.3 Validity and Reliability

The **validity** of a measurement is the extent to which the instrument measures what it is supposed to measure (Leedy & Ormrod, 2005:31). Research literature reveals many validation procedures (Bailey, 1982:69; Babbie, 1992:132):

- Internal validity asks whether a difference exists at all in any given comparison (Bailey, 1982:72). In this present study it would ask whether or not an apparent difference between results can be explained as measurement artifacts. It was therefore important to use the same test protocol with the equipment set up in the prescribed manner with each individual subject.

- External validity is the problem of interpretation (Bailey, 1982:73). In this present study this aspect would refer to the interpretation of the different test results as obtained through different measurements. This aspect was addressed by the fact that the researcher was competent to carry out the different procedures due to her qualification and years of experience.

Reliability of a measure is simply its consistency (Babbie, 1992:135; Drummond, 2003:79). The researcher used different techniques to measure the same concept – in this case unaided and aided thresholds measures. These techniques were administered to the same subjects, using the same test protocol and test environment in each individual case.

3.9 SUMMARY

This chapter provided a comprehensive description of the procedures implemented in the research methodology to obtain the data according to the sub-aims of this study. This was done in order to achieve the main aim of the study. The need for clinical validation of the ASSR in the pediatric population was the motivation for this study. The experimental design was described, followed by the discussion of the subjects in terms of selection criteria, procedures involved in selection and apparatus used for selecting subjects. Subsequently a description was provided of the subjects. The material and apparatus used for the collection of data and the analysis thereof as well as the procedures for data analysis were discussed, followed by a description of the procedures for data processing and analysis. The chapter concluded with a review of validity and reliability as it relate to the current study.

Chapter 4

RESULTS AND DISCUSSION

This chapter aims to present the results of the empirical research and elucidates the meaning and significance thereof within the current body of knowledge

4.1 INTRODUCTION

The dawn of an era of early identification of hearing loss in newborns and infants poses new challenges and offers new opportunities to audiologists. With the advent of universal newborn hearing screening, it is common for an audiologist to see infants less than two to three months of age who, during the newborn period, have been identified as being at risk for hearing loss. It is therefore essential to find evidence in order to establish a protocol that would yield the most information with regard to residual hearing abilities in this population. Research, as initiated in this study, is essential to the implementation of appropriate diagnostic protocols in this specific population.

The methodological approach, specified in chapter 3 has provided the operational framework for extracting the necessary data for addressing the main aim of this study. The main aim of this study, to establish the clinical value of the ASSR for early diagnosis and amplification of infants with hearing loss, was addressed through the realization of two sub-aims. These aims are schematically summarized in Figure 4.1.

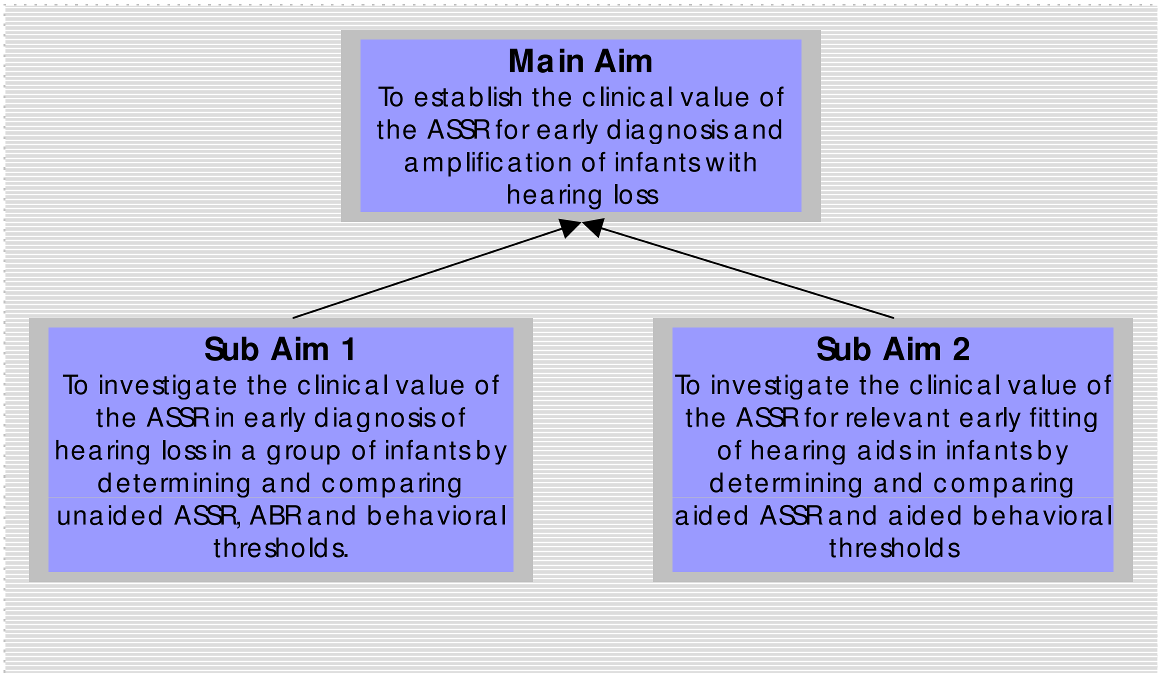

Figure 4.1 Main-aim and sub-aims of study

Analyzed results for the current study are grouped, reported, interpreted and subsequently discussed in relation to relevant and comparable literature. The first sub-aim was achieved by determining and comparing the unaided ASSR and ABR thresholds at the time of diagnosis at a young age (3-6 months of age). These ASSR and ABR thresholds were then compared with unaided behavioral thresholds obtained at a later developmental age, when subjects were able to provide reliable behavioral responses (8 – 14 months of age).

The second sub-aim was addressed by determining aided ASSR thresholds within a month after diagnosis of hearing loss and after each subject was fitted with hearing aids. The aided ASSR thresholds were then compared with aided behavioral thresholds when the subjects reached a developmental age allowing reliable behavioral responses to be elicited. The results are presented and described according to each of the sub-aims. The results from each individual subject are initially considered, followed by a collective analysis of the results for the six subjects. In the second part of this chapter, a discussion of results alongside current literature will follow. In the final section of this chapter, general conclusions from the study are drawn and the main research question is answered.

In order to determine the **clinical value of the ASSR method in early diagnosis of a hearing loss in infants**, each subject's individual performance will be described on each evaluation procedure. The results obtained during the unaided ASSR evaluation will be compared with the unaided ABR results at the time of diagnosis and subsequently both these procedures will be compared with the unaided behavioral assessment results obtained. Following presentations of each individual case, the results for the six subjects collectively will be considered. In the collective analysis of the data, the focus will be on a comparison of the threshold data for all 12 ears (of the six subjects) as it was recorded through the use of three different measuring techniques. The descriptive and inferential statistics from the group will be reported.

In order to determine the **clinical value of the ASSR in the validation of hearing aid fitting,** the second part of the results will present each subject's individual performance on the aided ASSR – comparing unaided ASSR values with the aided ASSR values and subsequently with results obtained during aided behavioral assessment. Thereafter the results of all six subjects will be analyzed collectively, as it was recorded through the use of these two measuring techniques. The descriptive and inferential statistics from this group of six subjects will be presented.

4.2. RESULTS FOR SUB-AIM 1: TO INVESTIGATE THE POTENTIAL CLINICAL VALUE OF THE ASSR IN EARLY DIAGNOSIS OF HEARING LOSS IN A GROUP OF INFANTS BY DETERMINING AND COMPARING UNAIDED ASSR, ABR AND BEHAVIORAL THRESHOLDS.

Bilaterally click-evoked ABR responses were recorded first. Thereafter the tone burst ABR assessment was carried out, followed by the ASSR assessment. Behavioral thresholds were obtained from each subject at the developmental age when they could render reliable behavioral responses. The results for each individual subject are described in the following section.

4.2.1 Individual subject results for sub-aim 1

In order to aid the interpretation of the individual results, a short summary of each subject's background information is added to the unaided ABR, ASSR and behavioral assessment results summarized in table format (see Tables 4.1 – 4.6).

4.2.1.1 Subject 1: Results for sub-aim 1

The background information and test results for subject 1 are presented in Table 4.1 and Figure 4.2.

Table 4.1 Background information and test results for subject 1

Sex	**Male**			
Risk factors	Born at 34 weeks gestation age. Diagnosed with cytomegalovirus			
Age at time of hearing loss identification	3 months			
Degree of hearing loss	Moderately severe sensory neural hearing loss in the right ear. No response could be measured at maximum intensities of equipment in the left ear.			
Age at time of hearing aid fitting	4 months			
Type of hearing aid	Digital hearing aid on right ear			
Age at time of behavioral assessment	10 months			
ABR results	**Tone burst** R = 50 dBnHL L = NR		**Click** R = 65 dBnHL L = NR	
ASSR predicted results	**500 Hz** R = 55 dB L = NR	**1000 Hz** R = 55 dB L = NR	**2000 Hz** R = 65 dB L = NR	**4000 Hz** R = 70 dB L = NR
Behavioral assessment results	**500 Hz** R = 50 dB L = NR	**1000 Hz** R = 55 dB L = NR	**2000 Hz** R = 65 dB L = NR	**4000 Hz** R = 75 dB L = NR

NR = No Response

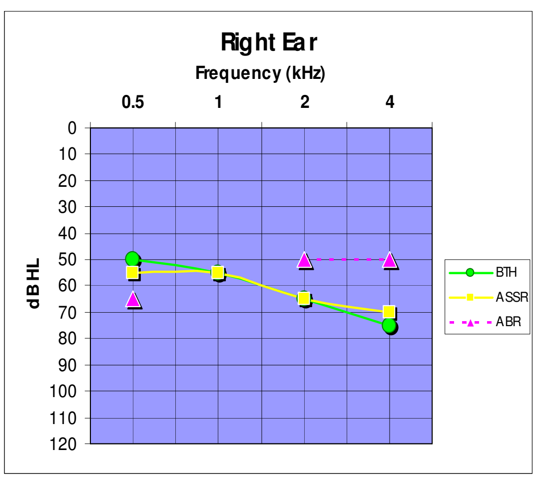

Figure 4.2 Schematic representations of the ABR, ASSR predictions and BT results for subject 1

For this individual case the tone burst ABR was 5 dB lower than the 500Hz ASSR predicted threshold. The click ABR yielded the same threshold as the 2000 Hz ASSR predicted threshold and there was only a 5 dB difference compared to the 4000 Hz ASSR predicted threshold, with the ABR having the lower value. In comparison with the behavioral thresholds measured at a later stage, the ASSR prediction thresholds closely followed the configuration of the behavioral thresholds – a difference of only 5 dB at 500 Hz and 4000 Hz was noted. Thresholds corresponded at 1000 Hz and 2000 Hz on these two procedures. When comparing the results from the ABR with the behavioral thresholds, identical thresholds were measured with the tone burst ABR and at 500 Hz. The click ABR and 2000 Hz behavioral response yielded the same thresholds and at 4000 Hz the behavioral response was 10 dB lower than the click ABR.

No response could be measured on any of the three measuring techniques in the left ear at maximum intensity of the equipment.

4.2.1.2 Subject 2: Results for sub-aim 1

The background information and test results for subject 2 are presented in Table 4.2 and Figure 4.3.

Table 4.2 Background information and test results for subject 2

Sex	**Female**
Risk factors	Born at 36 weeks gestational age through

	emergency caesarian; Low birth weight; Admitted to NICU.			
Age at time of hearing loss identification	Five months			
Degree of hearing loss	Moderately severe sensory neural loss in right ear; Moderate sensory neural hearing loss in left ear			
Age at time of hearing aid fitting	Five months			
Type of hearing aid	Digital hearing aids binaurally			
Age at time of behavioral assessment	14 months			
ABR results	**Tone burst** R = 60 dBnHL L = 70 dBnHL		**Click** R = 75 dBnHL L = 60 dBnHL	
ASSR predicted results	**500 Hz** R = 60 dB L = 40 dB	**1000 Hz** R = 50 dB L = 50 dB	**2000 Hz** R = 65 dB L = 55 dB	**4000 Hz** R = NR L = 50 dB
Behavioral assessment results	**500 Hz** R = 70 dB L = 50 dB	**1000 Hz** R = 65 dB L = 60 dB	**2000 Hz** R = 80 dB L = 75 dB	**4000 Hz** R = 95 dB L = 95 dB

NR = No Response

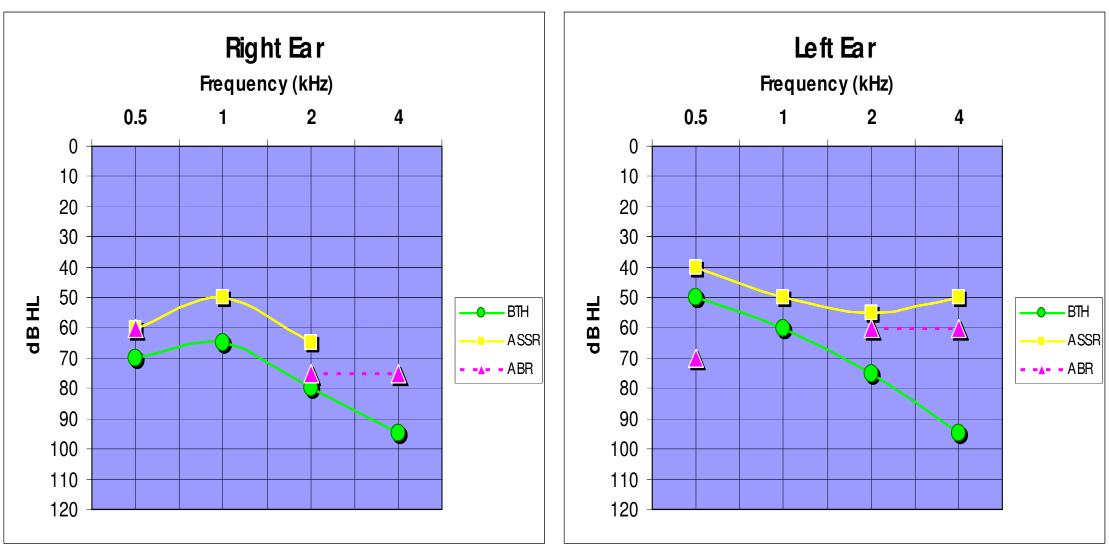

Figure 4.3 Schematic representations of the ABR, ASSR predictions and BT results for subject 2

The ABR and ASSR indicated comparable results in the right ear. On both the tone burst ABR and 500 Hz ASSR prediction, a threshold estimation of 60 dB was measured. A difference of only 10 dB with the click ABR threshold and 2000 Hz ASSR predicted threshold was noted. This subject woke up before completing the 4000 Hz ASSR in the right ear and therefore no result is available on that specific measurement. Behavioral responses were measured at 14 months of age. These thresholds were elevated by 10 to 15 dB at the respective frequencies for both the ASSR and ABR measurements.

In the left ear the tone burst ABR threshold was 30 dB higher than the 500 Hz ASSR predicted threshold. A difference of 5 to 10 dB was present between the ASSR predicted thresholds for 2000 and 4000 Hz in comparison with the click evoked ABR threshold. The ASSR had the lower value. The behavioral thresholds yielded responses with a difference of 10 dB at 500 Hz and 1000 Hz in comparison with the ASSR predicted thresholds at the same frequencies (the ASSR again had the lower values). The high frequencies (2000 and 4000 Hz) showed big discrepancies between the ASSR predicted thresholds and behavioral thresholds (± 20 to 45 dB) with the ASSR having the lower values. The tone burst ABR thresholds were 20 dB higher than the 500 Hz behavioral threshold, but the high frequencies of 2000 Hz and 4000 Hz behavioral thresholds were 15 to 35 dB higher than the click ABR thresholds.

4.2.1.3 Subject 3: Results for sub-aim 1

The background information and test results for subject 3 are presented in Table 4.3 and Figure 4.4.

Table 4.3 Background information and test results for subject 3

Sex	**Female**			
Risk factors	One of a twin, born at 32 weeks gestational age with a family history of congenital deafness.			
Age at time of hearing loss identification	Six months			
Degree of hearing loss	Severe sensory neural hearing loss in right ear; Profound sensory neural hearing loss in left ear.			
Age at time of hearing aid fitting	Six months			
Type of hearing aid	Digitally programmable analogue hearing aids binaurally			
Age at time of behavioral assessment	12 months			
ABR results	**Tone burst** R = 90 dBnHL L = 90 dBnHL		**Click** R = 70 dBnHL L = 95 dBnHL	
ASSR predicted results	**500 Hz** R = 90 dB L = 95 dB	**1000 Hz** R=105 dB L = 95 dB	**2000 Hz** R = 95 dB L = 85 dB	**4000 Hz** R = 80 dB L = 80 dB
Behavioral assessment results	**500 Hz** R = 80 dB L = 80 dB	**1000 Hz** R = 70 dB L = 75 dB	**2000 Hz** R = 70 dB L = 90 dB	**4000 Hz** R = 80 dB L = 80 dB

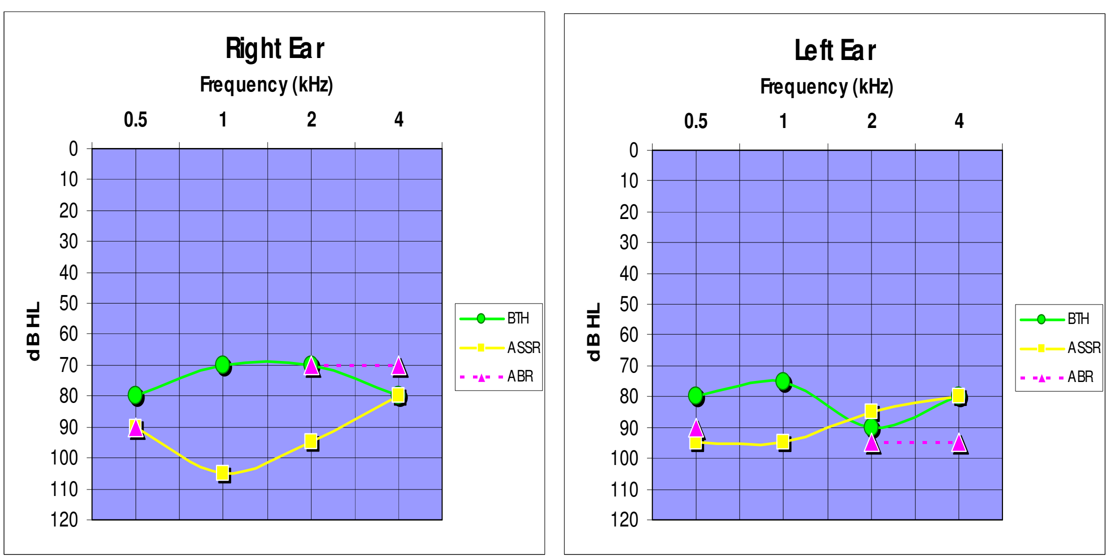

Figure 4.4 Schematic representations of the ABR, ASSR predictions and BT results for subject 3

The right ear's responses can be described as follows: responses in the right ear for the tone burst ABR and 500 Hz ASSR predicted thresholds yielded the same threshold. The click ABR threshold was 25 dB lower than the 2000 Hz ASSR predicted threshold. The difference between the click ABR threshold and 4000 Hz ASSR predicted threshold was 10 dB, with the click ABR having the lower value. When comparing the ASSR predicted thresholds and behavioral thresholds, a difference of 10 dB was noted at 500 Hz and a difference of 35 dB at 1000 Hz. The 2000 Hz comparison between these two measurements showed a 25 dB difference. In all of these instances the ASSR predicted thresholds had the higher value. At 4000 Hz the thresholds between these two measurements corresponded well. A 10 dB difference was noted between the tone burst ABR and 500 Hz behavioral thresholds, with the tone burst ABR having the higher value. The click ABR yielded the same threshold as the 2000 Hz behavioral threshold. A 10 dB difference was present between the click ABR and 4000 Hz behavioral threshold with the behavioral response being the lower value.

The thresholds from the left ear corresponded better between the different measurements. A difference of 5 dB was noted between the tone burst ABR and 500 Hz ASSR predicted thresholds with the ASSR having the higher value. A similar result was obtained in the high frequencies – with a difference of 10 dB between the click ABR and 2000 Hz ASSR predicted thresholds, and 15 dB difference between the click ABR and 4000 Hz ASSR predicted thresholds. In this instance the click ABR had the higher value. When comparing the ASSR predicted thresholds and behavioral thresholds in the low frequencies (500 Hz and 1000 Hz), behavioral thresholds were 15 to 20 dB lower than the ASSR thresholds. The

ASSR predicted thresholds yielded 5 to 10 dB lower thresholds in the high frequencies of 2000 Hz and 4000 Hz. When comparing the tone burst ABR threshold with the behavioral threshold, a 10 dB difference is noted between these two measurement techniques – the tone burst ABR being the higher value. The comparison between the click ABR threshold and behavioral threshold shows a 5 dB difference with the 2000 Hz comparison and a 15 dB difference with the 4000 Hz comparison – in both cases the ABR having the higher value.

4.2.1.4 Subject 4: Results for sub-aim 1

The background information and test results for subject 4 are presented in Table 4.4 and Figure 4.5.

Table 4.4 Background information and test results for subject 4

Sex	**Female**			
Risk factors	Twin of subject 3, born at 32 weeks gestational age with a family history of congenital deafness.			
Age at time of hearing loss identification	Six months			
Degree of hearing loss	Severe sensory neural hearing loss bilaterally			
Age at time of hearing aid fitting	Six months			
Type of hearing aid	Digitally programmable analogue hearing aids binaurally			
Age at time of behavioral assessment	12 months			
ABR results	**Tone burst** R = 75 dBnHL L = 75 dBnHL		**Click** R = 75 dBnHL L = 75 dBnHL	
ASSR predicted results	**500 Hz** R = 90 dB L = 80 dB	**1000 Hz** R = 85 dB L = 85 dB	**2000 Hz** R = 85 dB L = 85 dB	**4000 Hz** R = 80 dB L = 70 dB
Behavioral assessment results	**500 Hz** R = 80 dB L = 85 dB	**1000 Hz** R = 80 dB L = 75 dB	**2000 Hz** R = 75 dB L = 80 dB	**4000 Hz** R = 90 dB L = 80 dB

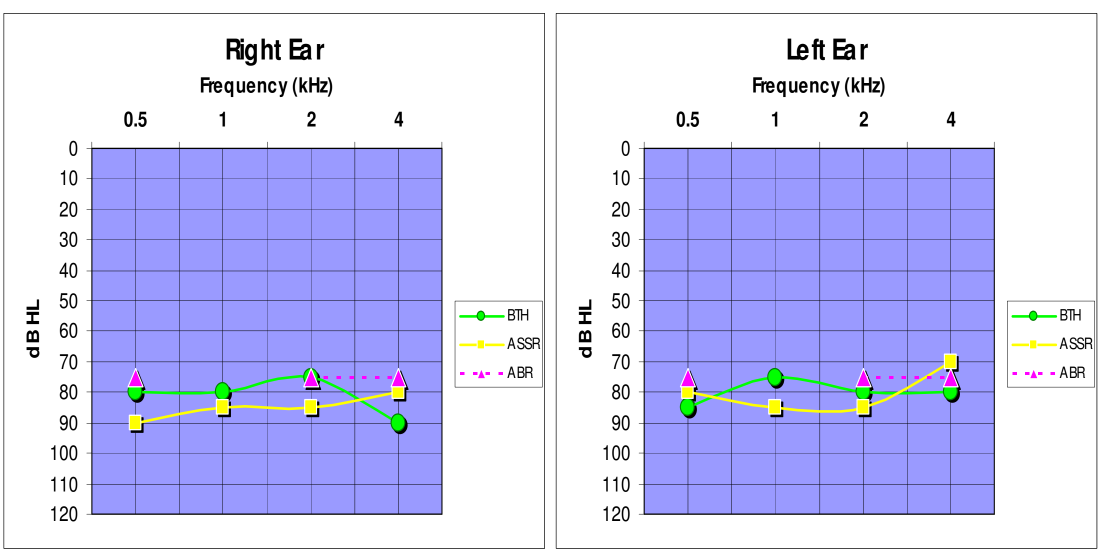

Figure 4.5 Schematic representations of the ABR, ASSR predictions and BT results for subject 4

The results from this subject showed a good comparison between the different procedures. The right ear showed a difference of 15 dB when comparing the tone burst ABR threshold with the 500 Hz ASSR predicted threshold. In this case the ABR had the lower threshold. The click ABR threshold was 10 dB lower than the threshold for the 2000 Hz ASSR predicted threshold and 5 dB lower than the threshold for 4000 Hz ASSR prediction. The comparison between the ASSR predicted thresholds and behavioral thresholds showed an average difference of 5 to 10 dB with the ASSR having the lower threshold at all frequencies except at 4000 Hz. The tone burst ABR threshold was 5 dB lower than the 500 Hz behavioral threshold. The click ABR threshold had the same value as the 2000 Hz behavioral threshold and was 5 dB lower than the 4000 Hz behavioral threshold.

Similar results were found in the left ear. The tone burst ABR threshold was 5 dB lower than threshold for the 500 Hz ASSR prediction. The threshold for the click ABR was 10 dB lower than the threshold at 2000 Hz on the ASSR prediction and 5 dB lower than the 4000 Hz threshold on the ASSR prediction. The ASSR predicted thresholds differed with 5 to 10 dB from those of the behavioral assessment across the frequency range. A 10 dB difference was present between thresholds of the tone burst ABR and the 500 Hz behavioral - with the tone burst ABR having the lower value. The click ABR threshold was 5 dB lower than the 2000 Hz and 4000 Hz behavioral thresholds.

4.2.1.5 Subject 5: Results for sub-aim 1

The background information and test results for subject 5 are presented in Table 4.5 and Figure 4.6.

Table 4.5 Background information and test results for subject 5

Sex	**Female**	
Risk factors	Born at 26 weeks gestational age; Admitted to NICU for 2 months.	
Age at time of hearing loss identification	Four months	
Degree of hearing loss	Profound sensory neural hearing loss bilaterally	
Age at time of hearing aid fitting	Five months	
Type of hearing aid	High power digitally programmable analogue hearing aids binaurally	
Age at time of behavioral assessment	12 months	
ABR results	**Tone burst**	**Click**

	R = NR L = NR		R = NR L = NR	
ASSR predicted results	**<u>500 Hz</u>** R=105 dB L=105 dB	**<u>1000 Hz</u>** R=115 dB L=105 dB	**<u>2000 Hz</u>** R=105 dB L=105 dB	**<u>4000 Hz</u>** R=100 dB L=110 dB
Behavioral assessment results	**<u>500 Hz</u>** R = 95 dB L = 95 dB	**<u>1000 Hz</u>** R=105 dB L=105 dB	**<u>2000 Hz</u>** R=100 dB L=110 dB	**<u>4000 Hz</u>** R=100 dB L=110 dB

NR = No Response

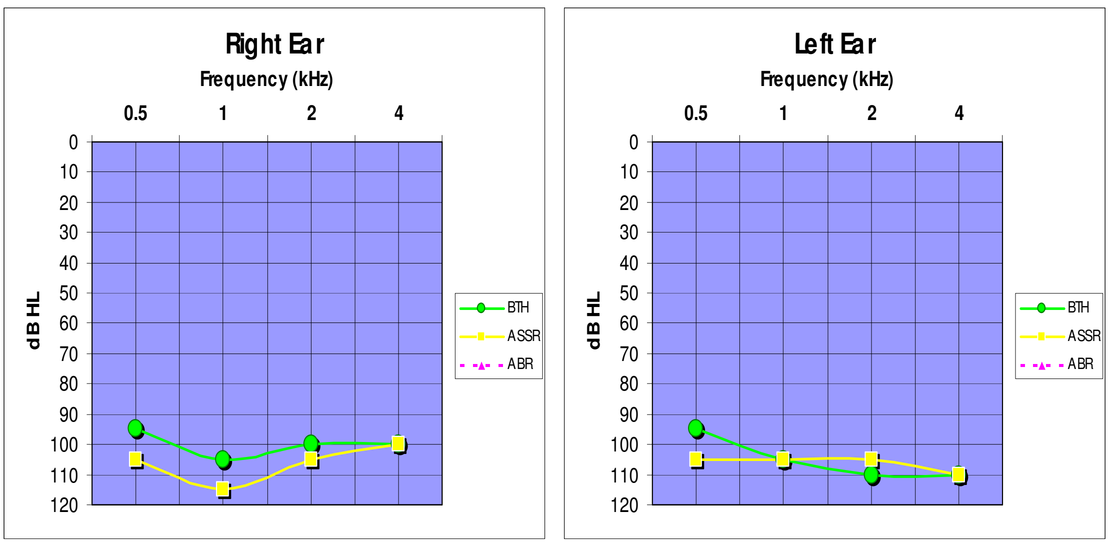

Figure 4.6 Schematic representations of the ABR, ASSR predictions and BT results for subject 5

No response could be measured on the ABR at maximum output (90 dBnHL) of the equipment on both the tone burst ABR and the click ABR. The ASSR showed responses across the frequency range of 500 Hz to 4000 Hz. Behavioral responses were also measured at all the frequencies.

When comparing the results of the right ear between the ASSR predicted thresholds and behavioral assessment, a 5 to 10 dB difference was noted at 500, 1000 and 2000 Hz, with the behavioral thresholds being lower. The thresholds at 4000 Hz corresponded on these two procedures.

The left ear had similar results. A difference of 10 dB was noted at 500 Hz between the ASSR predicted thresholds and behavioral thresholds - with the behavioral threshold being lower. A difference of 5 dB was present at 2000 Hz with the ASSR predicted thresholds being the lower value in this instance. The frequencies of 1000 Hz and 4000 Hz yielded the same results on these two measurements.

4.2.1.6 Subject 6: Results for sub-aim 1

The background information and test results for subject 6 are presented in Table 4.6 and Figure 4.7.

Table 4.6 Background information and test results for subject 6

Sex	**Male**			
Risk factors	None			
Age at time of hearing loss identification	Six months			
Degree of hearing loss	Profound sensory neural hearing loss bilaterally			
Age at time of hearing aid fitting	Six months			
Type of hearing aid	High power digital hearing aids binaurally			
Age at time of behavioral assessment	8 months			
ABR results	**Tone burst** R = NR L = NR		**Click** R = NR L = NR	
ASSR predicted results	**500 Hz** R=105 dB L=105 dB	**1000 Hz** R=105 dB L=115 dB	**2000 Hz** R=105 dB L=115 dB	**4000 Hz** R = NR L = NR
Behavioral assessment results	**500 Hz** R=105 dB	**1000 Hz** R=110 dB	**2000 Hz** R=105 dB	**4000 Hz** R = NR

	L=105 dB	L=110 dB	L=110 dB	L = NR

NR = No Response

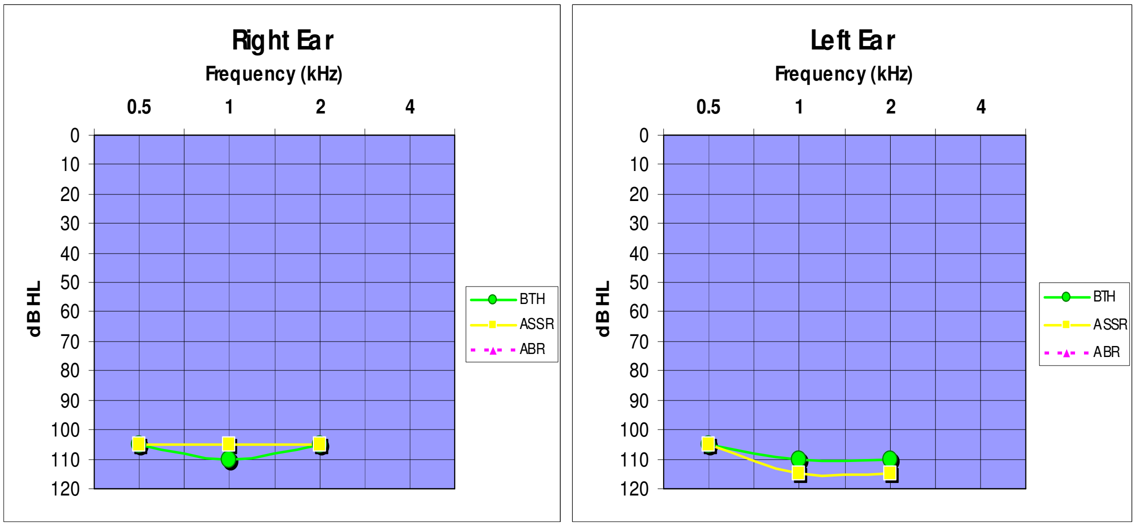

Figure 4.7 Schematic representations of the ABR, ASSR predictions and BT results for subject 6

No responses for subject 6 could be measured on either the tone burst ABR or the click ABR at the maximum output of the equipment (90 dBnHL). Both the ASSR and behavioral measures yielded no response at 4000 Hz.

The threshold prediction on the ASSR and the measured behavioral thresholds in the right ear differed with only 5 dB at 1000 Hz - with the ASSR having the lower value. Results at the other frequencies yielded the same threshold values.

Similar results were obtained in the left ear, with a 5 dB difference at 1000 Hz and 2000 Hz between the ASSR predicted thresholds and behavioral thresholds. In this case the behavioral thresholds were the lower levels.

In conclusion, when considering the results of the individuals, indications are that the ASSR may prove to be a very useful addition to the pediatric audiology test battery – 80.5 % of the frequencies predicted by the ASSR, estimated behavioral thresholds within 10 dB as oppose to the 57% of the ABR. Yet, it is only when considering the results for a number of individuals that a particular trend may be identified. In the following section the results that concern the early diagnosis as it is based on measurements for all six subjects (12 ears), are described, compared and discussed.

4.2.2 Collective results for all six subjects concerning sub-aim 1

The collective results for all six the subjects concerning sub-aim 1 are summarized in Table 4.7. Focusing on the collective results for all ears measured, a further comparison of the three evaluation procedures were done taking into account the dispersion, the central tendency and the relation of the collective data provided by the different evaluation procedures. The absolute threshold measurements of each ear measured and the arithmetic mean values for the number of ears measured, per stimulus frequency, determined by each of the three procedures, are also included in Table 4.7, as well as the calculated range and the standard deviation of the absolute threshold values and the number of ears measured for a particular stimulus frequency. Table 4.8 summarizes the mean of the responses to all stimulus frequencies presented per ear, as recorded by the three different procedures, as well as the standard deviation, and the number of data points used for this calculation.

Table 4.7 Summary of unaided thresholds for the six subjects as determined by the ABR, ASSR and BT.

	ABR		ASSR				Behavioral thresholds			
	Tone Burst	**Click**	**500 Hz**	**1000 Hz**	**2000 Hz**	**4000 Hz**	**500 Hz**	**1000 Hz**	**2000 Hz**	**4000 Hz**
Subject 1	R=65dBnHL L =NR	R=50dBnHL L=NR	R=55dB L=NR	R=55dB L=NR	R=65dB L=NR	R=70dB L=NR	R=50dB L=NR	R=55dB L=NR	R=65dB L=NR	R=75dB L=NR
Subject 2	R=60dBnHL L=70dBnHL	R=75dBnHL L=60dBnHL	R=60dB L=40dB	R=50dB L=50dB	R=65dB L=55dB	R=NR L=50dB	R=70dB L=50dB	R=65dB L=60dB	R=80dB L=75dB	R=95dB L=95dB
Subject 3	R=90dBnHl L=90dBnHL	R=70dBnHL L=95dBnHL	R=90dB L=95dB	R=105dB L=95dB	R=95dB L=85dB	R=80dB L=80dB	R=80dB L=80dB	R=70dB L=75dB	R=70dB L=90dB	R=80dB L=80dB
Subject 4	R=75dBnHL L=75dBnHL	R=75dBnHL L=75dBnHL	R=90dB L=80dB	R=85dB L=85dB	R=85dB L=85dB	R=80dB L=70dB	R=80dB L=85dB	R=80dB L=75dB	R=75dB L=80dB	R=90dB L=80dB
Subject 5	R=NR L=NR	R=NR L=NR	R=105dB L=105dB	R=115dB L=105dB	R=105dB L=105dB	R=100db L=110dB	R=95dB L=95dB	R=105dB L=105dB	R=100dB L=110dB	R=100dB L=110dB
Subject 6	R=NR L=NR	R=NR L=NR	R=105dB L=105dB	R=110dB L=115dB	R=105dB L=115dB	R=NR L=NR	R=105dB L=105dB	R=110dB L=110dB	R=105dB L=110dB	R=NR L=NR
Mean	**75dBnHL**	**71.4dBnHL**	**84.6dB**	**87.3dB**	**87.7dB**	**87.5dB**	**81.4dB**	**82.7dB**	**87.3dB**	**87.8dB**
Range	**30**	**45**	**65**	**65**	**60**	**40**	**55**	**55**	**45**	**35**
SD	**11.5**	**14.06**	**23.07**	**24.73**	**19.54**	**16.69**	**18.99**	**20.90**	**16.49**	**11.76**
Number of ears measured	**7**	**7**	**11**	**11**	**11**	**8**	**11**	**11**	**11**	**9**

NR = No Response

ASSR = ASSR predictions

SD = Standard Deviation

Table 4.8 Average of all frequencies tested on the three procedures

	ABR	ASSR predictions	BT
Mean	73.2	86.71	82.74
SD	12.5	20.78	18.75
Number of data points	21	41	42

Click ABR results were completed on 12 ears (six subjects). Of those 12 ears, five had no response to clicks at the maximum intensity limit (90 dBnHL) of the equipment. Toneburst ABR to 500 Hz was completed on all 12 ears to which five had no response at the limits of the equipment (90 dBnHL).

ASSR's measurements were completed on all 12 ears. Only one ear had no response at any frequency of the ASSR except 4000 Hz, where another three ears had no response at the maximum intensity of the equipment.

The behavioral assessment showed one ear with no response at all frequencies on the behavioral testing. Another two ears had no response at 4000 Hz. The results from all the subjects are shown in Table 4.7.

4.2.2.1 Comparing the unaided ABR *and unaided ASSR*

As indicated in Table 4.7, the **range** of the absolute measurements values for the 500 Hz ASSR's is 35 dB broader than the range for the tone burst ABR. The range for the 2000 Hz ASSR predictions is 20 dB broader than the range for the click ABR. The range of the 4000 Hz ASSR predictions is however 5 dB smaller than that of the click ABR. The number of ears taken into account is again seven on the ABR, 11 on the 2000 Hz ASSR, but eight on the 4000 Hz ASSR prediction. Although the range of the threshold that was determined with the ASSR seems in most cases broader than the range of measurements determined with the ABR, it would also seem as if the difference between the range may be influenced by the number of ears measured (See Table 4.7). It is therefore difficult to draw any conclusions based on the range of the threshold measured with the ASSR and ABR. The **SD** values seem to confirm the range values. It is however risky to draw any conclusions from the SD data since the number of data points for the ABR measurements were limited to seven and considering the inevitable individual differences, variation in responses can be expected to be high and would inevitably have an affect on the SD values for such a small sample.

Comparing the ABR results for both tone bursts and clicks with the 500 Hz, 2000 Hz and 4000 Hz ASSR, it was noted that the majority of comparable thresholds - 14 of the 21 (67%) – showed a difference of 10 dB or less. These results are summarized in Figure 4.8.

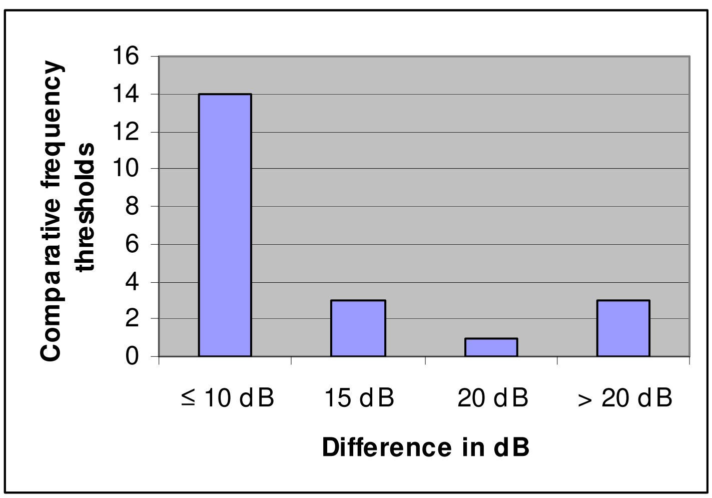

Figure 4.8 Representation of comparative frequency thresholds between the ABR and ASSR

Further insight was gained by calculating the **mean** and considering the difference between the mean of the absolute values for each of the evaluation procedures. The mean of the unaided click ABR's ranged from 71.4 dBnHL for the click ABR and 75 dBnHL for the unaided tone burst ABR. The mean ASSR predicted thresholds levels ranged from 84.6 dB HL to 87.7 dB HL. The mean of all the tone burst ABR thresholds were 10 dB lower than the mean of all the 500 Hz ASSR predicted thresholds (see Table 4.7). When comparing the click ABR with the 2000 Hz ASSR and 4000 Hz ASSR, the mean results indicate that the ABR measurements again had the lower response level, with a difference of approximately 17 dB. It is relevant though, to take into account the number of ears tested with each procedure (Table 4.7). Only seven ears represent the results on the ABR, where 11 are represented on the ASSR average. The five ears not represented on the ABR results are the ones that had no response on this procedure and therefore fall in a category more severe than could be measured by the ABR, thus inflating the calculated mean of the ASSR measurements.

Additional analyses provided a collective view of thresholds to all stimulus frequencies as determined by a specific procedure. As indicated in Table 4.8, the **mean** of all frequencies tested on the ABR was 73.2 dBnHL in comparison with a mean of the 86.71 dB on the ASSR. The standard deviation on these two measuring techniques differed - with the SD 12.5 dB on the ABR and 20.78 dB on the ASSR, indicating a wider dispersion of ASSR measurements. Due to the output limitations of equipment, the ABR could not render responses on all subjects resulting in a smaller number of available ABR measurements (21), as opposed to available ASSR measurements (41). Although a higher number of data points were available the SD values for all measurements per procedure should again be interpreted with caution.

Statistical analyses of the mean data – using the Exact Wilcoxon Rank Sum Test - indicated that no statistically significant difference exist between the mean thresholds measured with the ABR and the ASSR. Table 4.9 summarizes the results of the inferential statistical analysis of average for all the ears measured with the tone burst ABR vs. 500 Hz ASSR and the click ABR vs. 2000 Hz and 4000 Hz ASSR.

Table 4.9 Statistical analysis of ABR and ASSR predicted results

Stimulus	P value
• **Click ABR vs. 2000 Hz ASSR**	P = 0.4074
• **Click ABR vs. 4000 Hz ASSR**	P = 1.0000
• **500 Hz tone burst vs. 500 Hz ASSR**	P = 0.4991

For a difference to be significant the p-value should be smaller than 0.05 (Steyn, Smit, Du Toit & Strasheim, 2003:596). In this case none of the p-values were smaller than 0.05 and therefore no significant statistical difference was noted between thresholds determined by the unaided ABR and by the unaided ASSR.

The results provided by the ABR and ASSR were also compared with regard to its relation. Figure 4.9 shows the relationship or correlation coefficient between the 500 Hz toneburst ABR (TB) and the ASSR predicted threshold, using a 500 Hz carrier frequency. It is important to note that a large proportion of ears (5 of 12) had no response to the 500

Hz tone burst ABR at 90 dBnHL; therefore, only 7 ears are represented in the equation. The data indicate that there is a moderate to marked positive correlation between ASSR thresholds at 500 Hz and the 500 Hz tone burst ABR thresholds (r = .77).

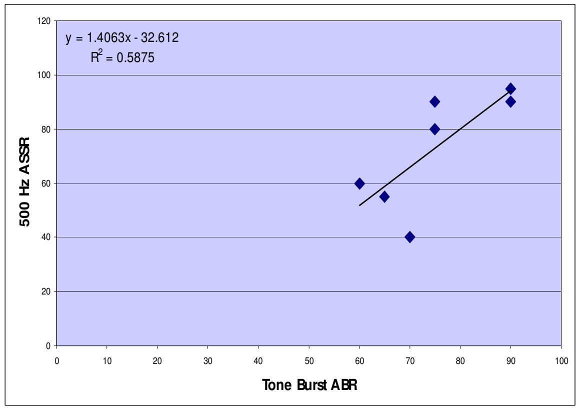

Figure 4.9 Relationship between 500 Hz tone burst ABR and ASSR prediction based on the measurement for seven ears

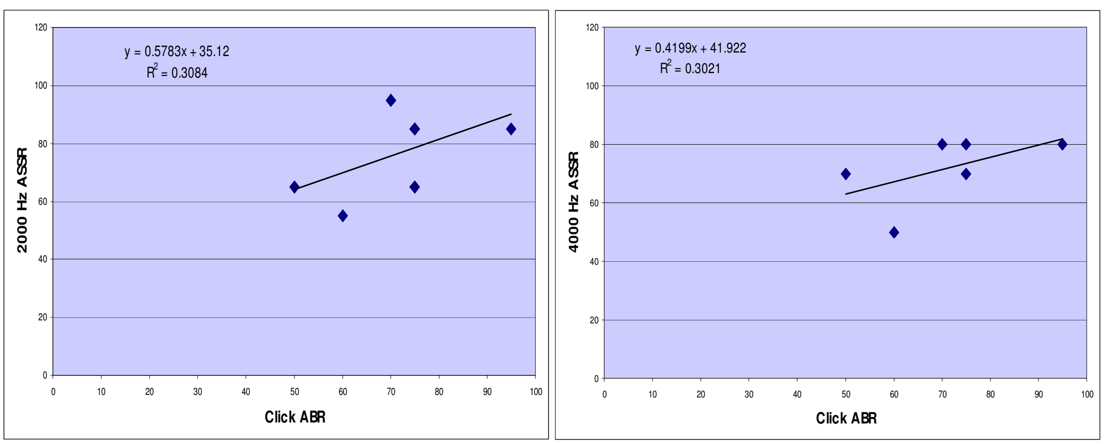

Figure 4.10 Relationship between the click ABR and 2000 and 4000 Hz ASSR prediction based on the measurement of seven ears

Figure 4.10 shows a comparison matrix between the thresholds for seven ears as obtained with the click ABR to the 2000 Hz and 4000 Hz ASSR. It is important to note that 5 of the ears tested, had no response to clicks at 90 dBnHL; therefore only 7 ears are represented in figure 4.8. The data indicate that there is a fair degree of positive correlation between the click ABR and the 2000 Hz ASSR threshold ($r = .56$). A similar degree of positive correlation is found between the 4000 Hz ASSR threshold and the click-evoked ABR threshold ($r = .57$). The correlation results are therefore a confirmation of what was indicated by the inferential statistics.

To summarize:

- Results indicate that it was in more instances possible to determine thresholds with the ASSR than with the ABR
- In 67% of the frequencies tested the thresholds between the ABR and ASSR corresponded within 10 dB of each other.
- ASSR thresholds for the six subjects show a bigger variation than the ABR thresholds, but it is impossible to come to a clear conclusion as to what this may indicate.
- Differences between mean thresholds measured with the ASSR and the ABR exist, but it shows no statistical significance
- Results confirm that there is a moderate to fair positive correlation between the thresholds determined by the ASSR and ABR respectively (Leedy & Ormrod, 2005:306).

4.2.2.2 Unaided ASSR vs. unaided behavioral thresholds

The number of ears tested was similar on these two approaches. When analyzing the **range** information on these two measurements, the range of the results also seems similar (see Table 4.7). A difference of 5 dB in the range of the 4000 Hz comparison is present, with a difference of 15 dB at 2000 Hz, 10 dB at 1000 Hz and 10 dB at 500 Hz. The SD values seem to confirm the range values – the SD values on the ASSR varied from 16.69 to 24.73. The SD values on the behavioral thresholds varied from 11.76 to 20.90. Interpretation of the SD values on such a small sample however is risky.

Figure 4.11 illustrates the **mean** unaided ASSR predicted thresholds and unaided behavioral thresholds obtained at each frequency for all the ears tested (n=12). The mean unaided ASSR predicted threshold levels ranged from 84.6 dB HL to 87.7 dB HL. The mean behavioral threshold levels ranged from 81.4 dB HL to 87.8 dB HL (Table 4.7). One ear showed no response on either of the two procedures at all frequencies. Another three ears had no response at 4000 Hz on the ASSR and two of these ears had no response at 4000 Hz on the behavioral evaluation.

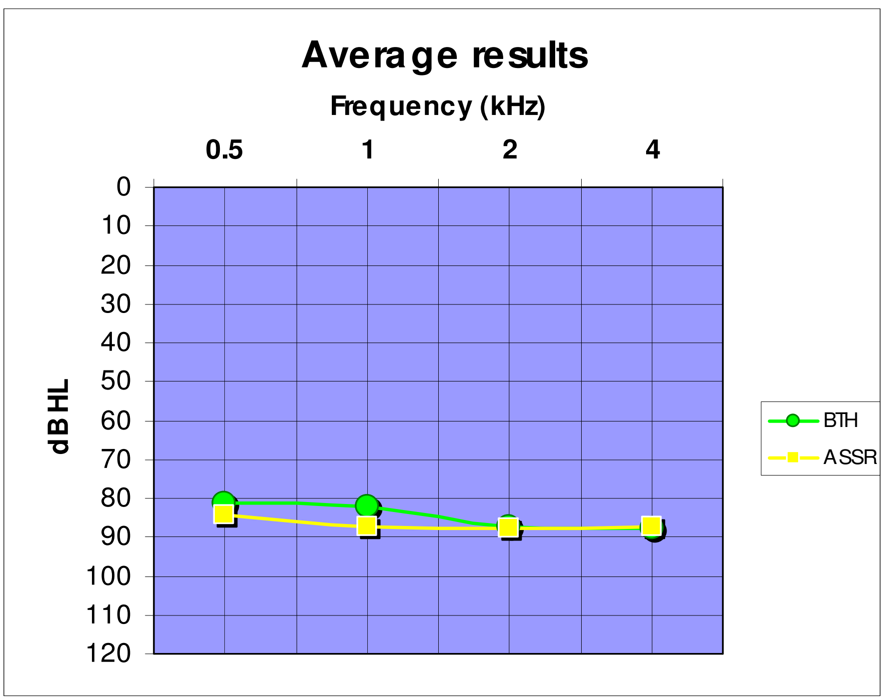

Figure 4.11 Mean unaided ASSR thresholds and unaided behavioral thresholds obtained at each frequency for all the ears tested (n=12).

A difference of 5 dB was noted at 500 Hz and 1000 Hz and 10 dB at 4000 Hz between the **mean** of the thresholds determined by the ASSR prediction and behavioral measurements. In the low frequencies the behavioral thresholds were slightly lower and at 4000 Hz the ASSR predicted thresholds were minimally lower. Results show that the averages of thresholds for all the ears, determined with the ASSR and behavioral assessments, were very similar (see Table 4.8).

Comparing the ASSR predicted thresholds with behavioral thresholds for all frequencies tested, it was noted that the majority of comparable thresholds - 33 of the 41 (80.5%) – showed a difference of 10 dB or less. These results are summarized in Figure 4.12.

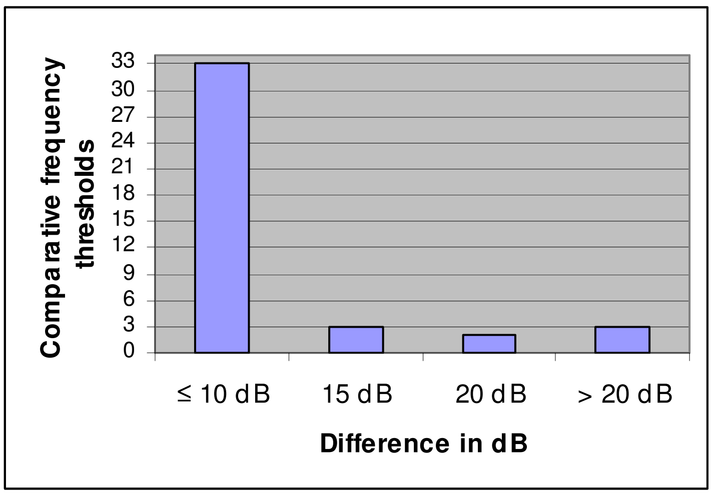

Figure 4.12 Representation of comparative frequency thresholds between the ASSR predicted thresholds and behavioral thresholds

Statistical analyses (Exact Wilcoxon Rank Sum Test) of the mean data are summarized in Table 4.10. No statistical difference between the thresholds determined by the unaided ASSR and unaided behavioral assessment was found, as all p-values were more than 0.05.

Table 4.10 Statistical analysis of ASSR predictions and behavioral measures

Stimulus	P - value
• 500 Hz ASSR vs. behavioural threshold	P = 0.8128
• 1000 Hz ASSR vs. behavioural threshold	P = 0.7475
• 2000 Hz ASSR vs. behavioural threshold	P = 0.7440
• 4000 Hz ASSR vs. behavioural threshold	P = 0.5039

The results provided by the ASSR and behavioral assessment were also compared with regard to its relation. The following scatter plots in Figure 4.13 represent the relationship or correlation coefficient between each frequency tested during the ASSR evaluation and the subsequent behavioral measurement. A highly dependable to moderate positive correlation is identified for three of the test frequencies, namely r = .93 at 500 Hz; r = .82 at 1000 Hz; r = .79 at 2000 Hz, determined with the ASSR and behavioral assessments. Thresholds determined with the two procedures indicates a moderate to fair degree of positive correlation at 4000 Hz (r = .59).

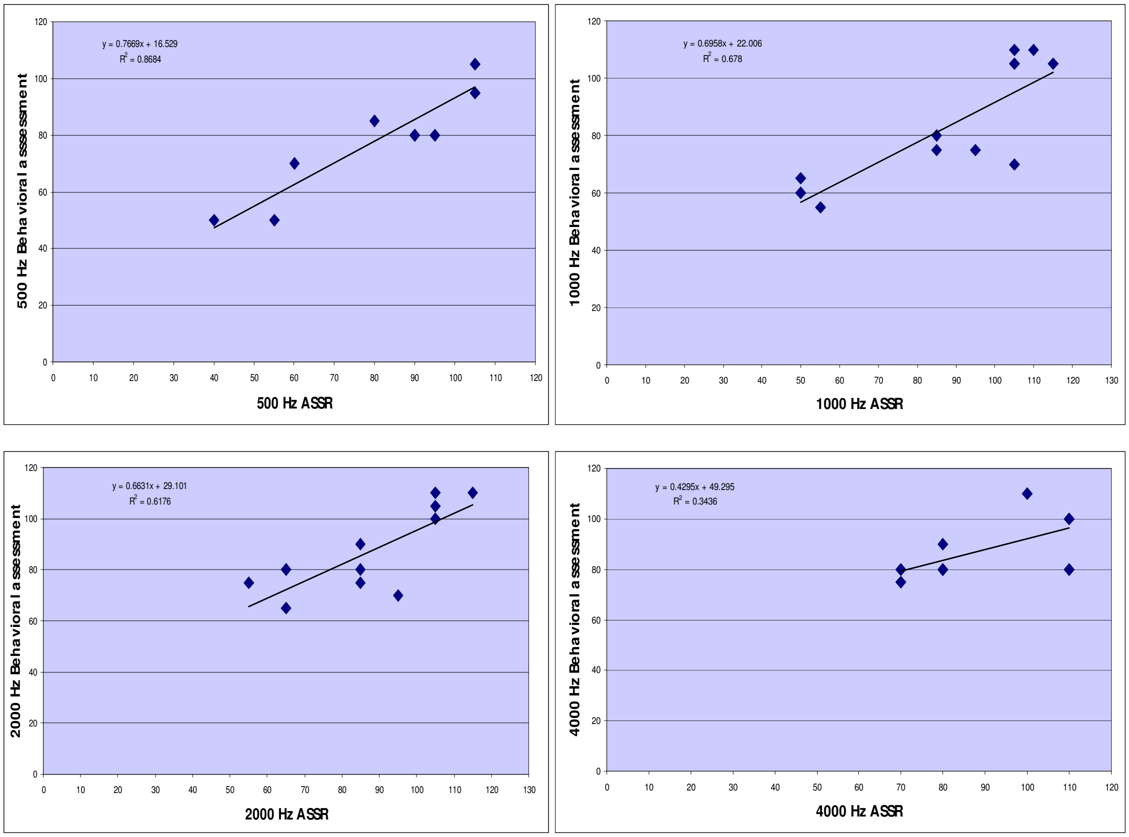

Figure 4.13 Relationship between thresholds determined with ASSR predictions and behavioral responses for a specific number of ears.

In summary:

- The number of frequencies where thresholds could be determined with ASSR compares favorable with that of the behavioral assessments.
- In 80.5% of the frequencies tested, the thresholds between the ASSR and behavioral assessment corresponded within 10 dB of each other.
- The range of the measurements determined with the two procedures compares well.

- There is no statistical difference between averages determined with the ASSR predictions and behavioral thresholds
- Results indicate a highly dependable to fairly positive correlation between thresholds determined by ASSR and behavioral assessments.

4.2.2.3 Unaided ABR vs. unaided behavioral thresholds

As indicated in Table 4.7, the **range** of the absolute measurements values for the 500 Hz behavioral threshold is 25 dB broader than the range for the tone burst ABR. The range for the click ABR and 2000 Hz behavioral response are both 45 dB. The range for the click ABR was 10 dB broader than the range for the 4000 Hz behavioral thresholds. The number of ears taken into account is seven on the ABR and 11 on the 2000 Hz behavioral thresholds assessment, but nine on the 4000 Hz behavioral assessment. It would seem as if the range of the threshold that were determined with the 500 Hz behavioral threshold assessment is broader than the range of the tone burst ABR. This is not the case however with the range of threshold determination between the click ABR and 2000 Hz behavioral threshold assessment. It is therefore difficult to draw any conclusions based on the range of the thresholds measured with the ABR and behavioral threshold assessments. It is again risky to draw conclusion from the SD values. These values seem to confirm the range values. The number of data points for the ABR measurements were limited to seven and considering the inevitable individual differences, variation in responses can be expected to be high and would have an affect on SD values for such a small sample.

Comparing the tone burst and click evoked ABR thresholds with the behavioral thresholds, it was noted that only 12 of the 21 (57%) of the comparable thresholds, showed a difference of 10 dB or less. These results are summarized in Figure 4.14.

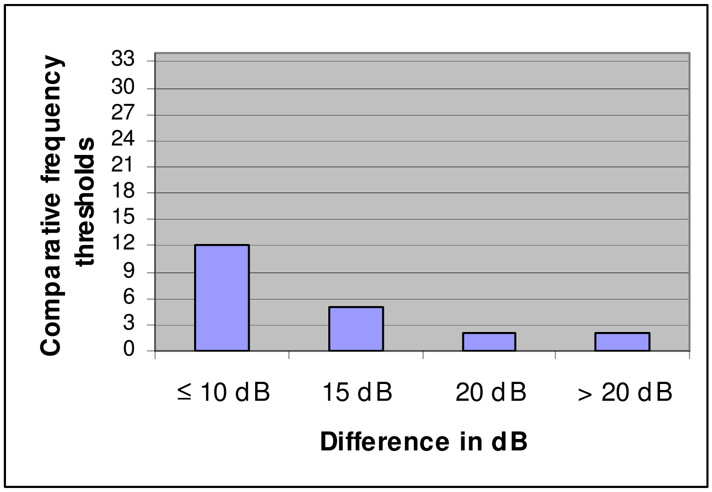

Figure 4.14 Representation of comparative frequency thresholds between the ABR and behavioral thresholds

Further insight was gained by again calculating the **mean** and considering the difference between the mean of the absolute values for each of the evaluation procedures. The mean of the ABR ranged from 71.4 dBnHL for the click ABR to 75 dBnHL for the tone burst ABR. The mean of the behavioral thresholds ranged from 81.4 dB HL to 87.8 dB HL. The mean of the tone burst ABR thresholds differed with 6.4 dB from the 500 Hz behavioral thresholds (see Table 4.7). The tone burst ABR had the lower value. When comparing the click ABR with the 2000 Hz and 4000 Hz behavioral thresholds, the average results indicate that the ABR again had the lower response level – with a difference of approximately 16.3 dB. It is relevant though, to consider again the number of ears tested on each procedure (Table 4.7). Only seven ears represent the results on the ABR, where 11 are represented on the 500 Hz and 2000 Hz behavioral threshold measurement and nine ears are represented on the 4000 Hz behavioral threshold measurement. The five ears not represented on the ABR results are the ones that had no response on this procedure and therefore fall in a category more severe than could be measured by the ABR.

Additional analyses provided a collective view of thresholds to all stimulus frequencies as determined by a specific procedure. As indicated in Table 4.8, the mean of all frequencies tested on the ABR was 73.2 dBnHL in comparison with the mean of 82.74 dB on the behavioral assessment. The SD on these two measuring techniques differed – with the SD 12.5 dB on the ABR and 18.75 on the behavioral assessment, indicating a wider dispersion of behavioral thresholds. Due to the output limitations of equipment, the ABR could not render response on all subjects resulting in a smaller number of available ABR thresholds (21) as opposed to available behavioral thresholds (42). Although a higher number of data points were available, the SD values for all measurements per procedure should again be interpreted with caution.

Statistical analysis of the mean data – using the Exact Wilcoxon Rank Sum Test – indicated that no statistical significant difference exists between the mean thresholds measured with the ABR and behavioral threshold assessments. Table 4.11 summarizes the results of the inferential statistical analysis of the average for all the ears measured with the tone burst ABR vs. 500 Hz behavioral assessment and the click ABR vs. 2000 Hz and 4000 Hz behavioral threshold assessment.

Table 4.11 Statistical analysis of ABR and behavioral measures

Stimulus	P - value
• 500 Hz behavioural threshold vs. tone burst ABR	P = 0.1563
• 2000 Hz behavioural threshold vs. click ABR	P = 0.5000
• 4000 Hz behavioural threshold vs. click ABR	P = 0.2188

The results provided by the ABR and behavioral assessment were also compared with regard to its relation. Figure 4.15 shows the relationship or correlation coefficient between the tone burst ABR and the 500 Hz behavioral threshold assessment. It is important to note that a large proportion of the ears (5 of 12) had no response to the tone burst ABR at 90 dBnHL; therefore, only seven ears are represented in this equation. The data indicate that there is a moderate to marked positive correlation between behavioral threshold assessment at 500 Hz and the tone burst ABR (r = .77).

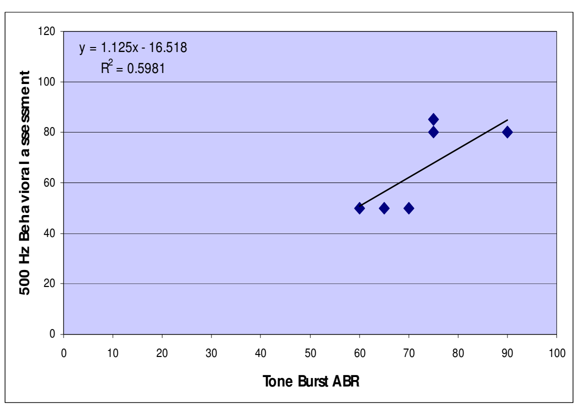

Figure 4.15 Relationship between tone burst ABR and 500 Hz behavioral threshold assessment based on the measurement for seven ears

Figure 4.16 shows a correlation matrix between the thresholds for seven ears as obtained with the click ABR to the 2000 Hz and 4000 Hz behavioral threshold assessment. Again it should be noted that only seven ears are represented in the equation as five ears had no response to the ABR at 90 dBnHL. The data indicate that there is a dependable positive correlation between the click ABR threshold and 2000 Hz behavioral threshold assessment (r = .89). A fair degree of positive correlation is also found between the 4000 Hz behavioral threshold and the click ABR (r = .40). The correlation results are therefore a confirmation of what was indicated by the inferential statistics.

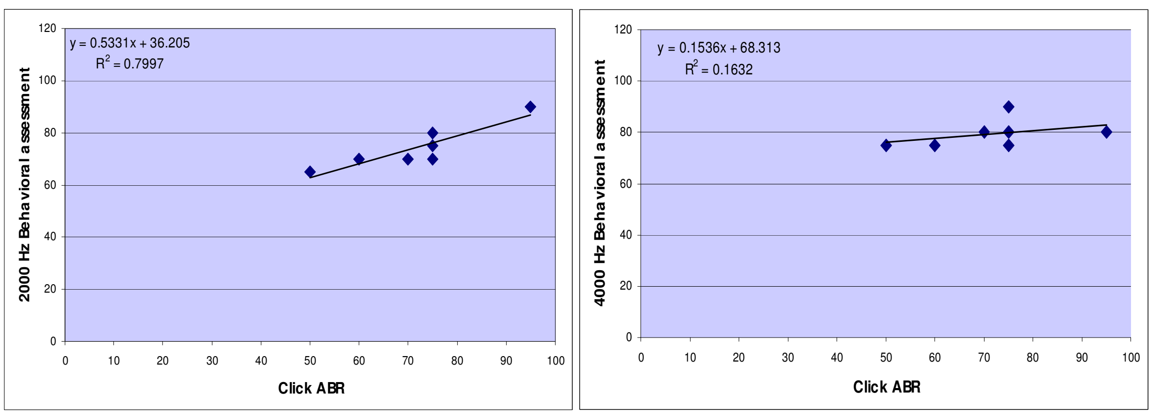

Figure 4.16 Relationship between click ABR and 2000 Hz and 4000 Hz behavioral threshold assessment based on the measurement for seven ears respectively

To summarize:

- Results indicate that it was not possible to determine thresholds with the ABR in all the cases.
- In only 57% of the frequencies tested the thresholds between the ABR and behavioral assessment corresponded within 10 dB of each other.

- Differences between averages of thresholds measured with the ABR and behavioral threshold assessments exist, but it shows no statistical significant difference.
- Results confirm that there is a fair to dependable positive correlation between the thresholds determined by the ABR and behavioral threshold assessment respectively.

Considering the comparative results described in *4.2.2.1, 4.2.2.2* and *4.2.2.3,* it seems that the ASSR measurement compare well to the measurements done with the other two procedures, although there seems to be a slightly higher correlation between the ASSR and the behavioral assessments than what exist between the ABR and the behavioral assessments. 80.5% of the frequencies tested through the use of ASSR corresponded within 10 dB with the behavioral thresholds. Only 57% of the frequencies tested through the use of the ABR corresponded within 10 dB of the behavioral thresholds – even though no corrections were made for the ABR thresholds.

4.3 RESULTS FOR SUB-AIM 2: TO INVESTIGATE THE CLINICAL VALUE OF THE ASSR FOR RELEVANT EARLY FITTING OF HEARING AIDS IN INFANTS BY DETERMINING AND COMPARING AIDED ASSR AND AIDED BEHAVIORAL THRESHOLDS.

Except in the case of subject 1, responses were recorded while the subject was wearing binaural hearing aids. The thresholds recorded are therefore an indication of the aided thresholds of the best response at each frequency of the best ear.

Responses for the ASSR were recorded at carrier frequencies of 500, 1000, 2000 and 4000 Hz in this group of six hearing impaired infants using hearing aids. The same frequencies were evaluated during the behavioral assessment. The results from the individual subjects will be discussed first, followed by the collective results.

4.3.1 Individual subject results for sub-aim 2

Each individual subject's aided results will now be reported on. In the individual tables (See Tables 4.12 to 4.17) an indication is given of both the unaided ASSR results – the measured thresholds and the predicted thresholds. Both these threshold values will be taken into account as the normative data from which predicted thresholds are calculated, were not compiled for aided ASSR's. Therefore a true comparison can be made between the unaided and aided ASSR results. The behavioral results will be compared with both values on the aided ASSR.

4.3.1.1 Subject 1: Results for sub-aim 2

The aided test results for subject 1 are presented in Table 4.12 and Figure 4.17.

Table 4.12 Unaided ASSR, aided ASSR and aided behavioral thresholds measurements for subject 1

Unaided ASSR results	500 Hz **70 dB**	1000 Hz **65 dB**	2000 Hz **75 dB**	4000 Hz **80 dB**
Unaided ASSR predicted results	**500 Hz** 55 dB	**1000 Hz** 55 dB	**2000 Hz** 65 dB	**4000 Hz** 70 dB
Aided ASSR results	**500 Hz** NR	**1000 Hz** 50 dB	**2000 Hz** 30 dB	**4000 Hz** 45 dB
Aided ASSR predicted results	**500 Hz** NR	**1000 Hz** 30 dB	**2000 Hz** 20 dB	**4000 Hz** 15 dB
Aided Behavioral assessment results	**500 Hz** 25 dB	**1000 Hz** 20 dB	**2000 Hz** 25 dB	**4000 Hz** 30 dB

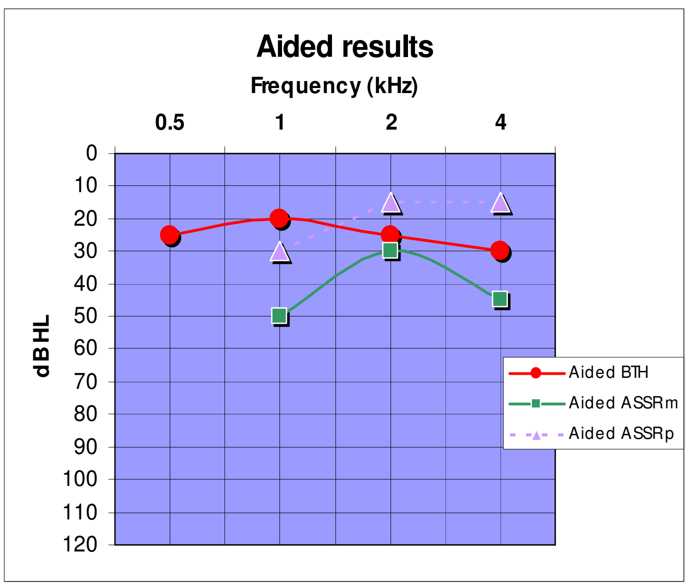

Figure 4.17 Aided results for subject 1 including behavioral thresholds and ASSR thresholds – measured and predicted

A recognizable difference was noted between the unaided and aided ASSR responses (see Table 4.12). When comparing the *measured* thresholds, a difference of between 15 to 45 dB across the frequency range was noted. When considering the difference in the aided and unaided *predicted* ASSR thresholds, the difference is approximately 10 dB more. No aided response could be measured at the maximum outset of the equipment at 500 Hz.

When comparing the aided ASSR with the aided behavioral thresholds, a difference of 30 dB was noted between the *measured* aided ASSR and the behavioral threshold at 1000 Hz. A difference of 5 dB was present for the same comparison at 2000 Hz and a 15 dB difference was present for the 4000 Hz comparison. On all of these comparisons, the aided behavioral thresholds had the lower value.

When comparing the aided ASSR – using the *predicted* thresholds with the aided behavioral thresholds, a difference of 10 dB was noted at 1000 Hz, 5 dB at 2000 Hz and 15 dB at 4000 Hz. In this case the ASSR had the lower values for the 2000 Hz and 4000 Hz comparison.

4.3.1.2 Subject 2: Results for sub-aim 2

The aided test results for subject 2 are presented in Table 4.13 and Figure 4.18.

Table 4.13 Unaided ASSR, aided ASSR and aided behavioral thresholds

measurements for subject 2

Unaided ASSR results	500 Hz **60 dB**	1000 Hz **60 dB**	2000 Hz **60 dB**	4000 Hz **65 dB**
Unaided ASSR predicted results	**500 Hz** 40 dB	**1000 Hz** 50 dB	**2000 Hz** 55 dB	**4000 Hz** 50 dB
Aided ASSR results	**500 Hz** 50 dB	**1000 Hz** 35 dB	**2000 Hz** 35 dB	**4000 Hz** 30 dB
Aided ASSR predicted results	**500 Hz** 25 dB	**1000 Hz** 20 dB	**2000 Hz** 20 dB	**4000 Hz** 5 dB
Aided Behavioral assessment results	**500 Hz** 30 dB	**1000 Hz** 35 dB	**2000 Hz** 35 dB	**4000 Hz** 40 dB

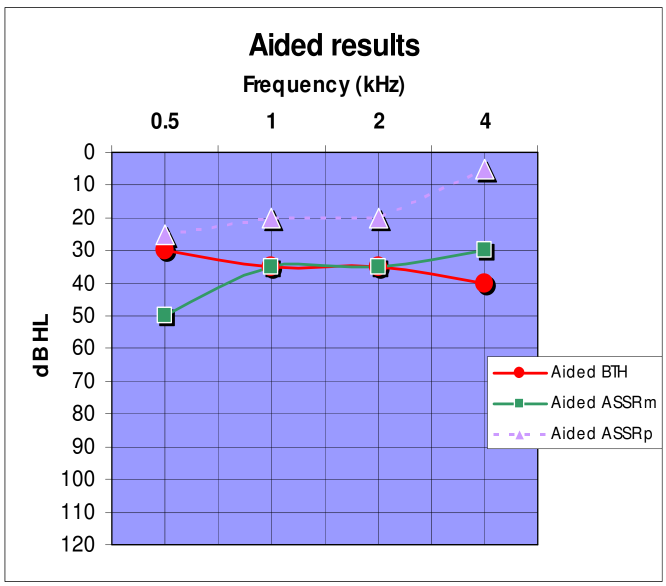

Figure 4.18 Aided results from subject 2 including behavioral thresholds and ASSR thresholds – measured and predicted

A recognizable difference was noted between the unaided and aided ASSR thresholds (see Table 4.13). When comparing the *measured* thresholds, a difference of between 10 to 35 dB across the frequency range was noted. When considering the difference in the aided and unaided *predicted* ASSR thresholds, the difference between the values were 15 to 45 dB.

When comparing the aided ASSR threshold with the aided behavioral thresholds, a difference of 20 dB was noted between the *measured* aided ASSR threshold and the behavioral threshold at 500 Hz. No difference was present at 1000 Hz and 2000 Hz. At 4000 Hz a 10 dB difference was noted. For the 500 Hz comparison, the aided behavioral thresholds had the lower value. For 4000 Hz comparison, the ASSR value had the lower value.

When comparing the aided ASSR – using the *predicted* thresholds with the aided behavioral thresholds, a difference of 5 dB was noted at 500 Hz, 15 dB at 1000 Hz, 15 dB at 2000 Hz and 35 dB at 4000 Hz. In this case the ASSR had the lower values across the frequency range.

4.3.1.3 Subject 3: Results for sub-aim 2

The aided test results for subject 3 are presented in Table 4.14 and Figure 4.19.

Table 4.14 Unaided ASSR, aided ASSR and aided behavioral thresholds measurements for subject 3

Unaided ASSR results	500 Hz	1000 Hz	2000 Hz	4000 Hz
	100 dB	**100 dB**	**90 dB**	**90 dB**
Unaided predicted ASSR results	**500 Hz**	**1000 Hz**	**2000 Hz**	**4000 Hz**
	90 dB	95 dB	85 dB	80 dB
Aided ASSR results	**500 Hz**	**1000 Hz**	**2000 Hz**	**4000 Hz**
	NR	50 dB	60 dB	50 dB
Aided predicted ASSR results	**500 Hz**	**1000 Hz**	**2000 Hz**	**4000 Hz**
	NR	35 dB	45 dB	35 dB
Aided Behavioral assessment results	**500 Hz**	**1000 Hz**	**2000 Hz**	**4000 Hz**
	35 dB	35 dB	40 dB	40 dB

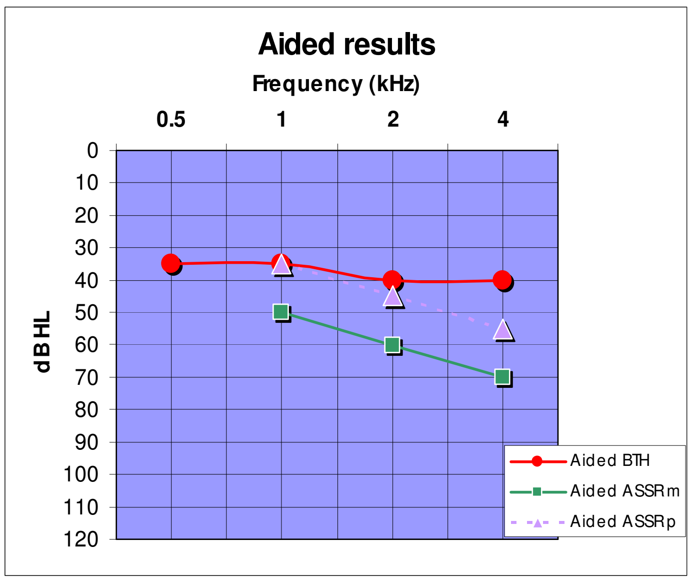

Figure 4.19 Aided results from subject 3 including behavioral thresholds and ASSR thresholds – measured and predicted

Again a recognizable difference was noted between the unaided and aided ASSR thresholds (see Table 4.14). When comparing the *measured* ASSR threshold, a difference of between 40 to 50 dB across the frequency range was noted. When considering the difference in the aided and unaided *predicted* ASSR thresholds, the difference between the values were 25 to 60 dB. No aided ASSR response at 500 Hz could be measured on this subject.

When comparing the aided ASSR threshold with the aided behavioral thresholds, a difference of 15 dB was noted between the *measured* aided ASSR threshold and the behavioral threshold at 1000 Hz. A difference of 20 dB was noted at 2000 Hz and a 30 dB difference at 4000 Hz. In this comparison the aided behavioral thresholds had the lower value.

When comparing the aided ASSR – using the *predicted* thresholds with the aided behavioral thresholds, no difference was noted at 1000 Hz, 5 dB at 2000 Hz and 15 dB at 4000 Hz. In this case the ASSR had the higher value for 2000 Hz and the lower value for 4000 Hz.

4.3.1.4 Subject 4: Results for sub-aim 2

The aided test results for subject 4 are presented in Table 4.15 and Figure 4.20.

Table 4.15 Unaided ASSR, aided ASSR and aided behavioral thresholds measurements for subject 4

Unaided ASSR results	500 Hz	1000 Hz	2000 Hz	4000 Hz

	90 dB	90 dB	90 dB	80 dB
Unaided predicted ASSR results	**500 Hz** 80 dB	**1000 Hz** 85 dB	**2000 Hz** 85 dB	**4000 Hz** 70 dB
Aided ASSR results	**500 Hz** NR	**1000 Hz** 50 dB	**2000 Hz** 60 dB	**4000 Hz** 50 dB
Aided predicted ASSR results	**500 Hz** NR	**1000 Hz** 35 dB	**2000 Hz** 45 dB	**4000 Hz** 35 dB
Aided Behavioral assessment results	**500 Hz** 30 dB	**1000 Hz** 35 dB	**2000 Hz** 25 dB	**4000 Hz** 25 dB

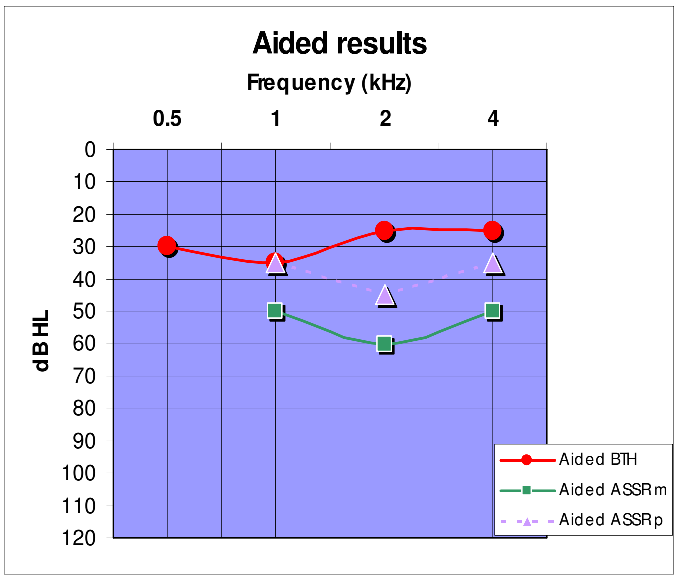

Figure 4.20 Aided results from subject 4 including behavioral thresholds and ASSR thresholds – measured and predicted

Again a recognizable difference was noted between the unaided and aided ASSR responses (see Table 4.15). When comparing the *measured* thresholds, a difference of between 30 to 40 dB across the frequency range was noted. When considering the difference in the aided and unaided *predicted* ASSR thresholds, the difference between the values were 35 to 50 dB. No aided ASSR response at 500 Hz could again be measured on this subject.

When comparing the aided ASSR with the aided behavioral thresholds, a difference of 15 dB was noted between the *measured* aided ASSR and the behavioral threshold at 1000 Hz. A difference of 35 dB was noted at 2000 Hz and a 25 dB difference at 4000 Hz. In this comparison the aided behavioral thresholds had the lower value.

When comparing the aided ASSR – using the *predicted* thresholds with the aided behavioral thresholds, no difference was noted at 1000 Hz, 20 dB at 2000 Hz and 10 dB at 4000 Hz. In this case the ASSR had the higher value for 2000 Hz and 4000 Hz.

4.3.1.5 Subject 5: Results for sub-aim 2

The aided test results for subject 4 are presented in Table 4.16 and Figure 4.21.

Table 4.16 Unaided ASSR, aided ASSR and aided behavioral thresholds measurements for subject 5

	500 Hz	1000 Hz	2000 Hz	4000 Hz
Unaided ASSR results	110 dB	110 dB	110 dB	105 dB
Unaided predicted ASSR results	105 dB	105 dB	105 dB	100 dB
Aided ASSR results	NR	60 dB	70 dB	80 dB
Aided predicted ASSR results	NR	45 dB	60 dB	65 dB
Aided Behavioral assessment results	45 dB	50 dB	55 dB	60 dB

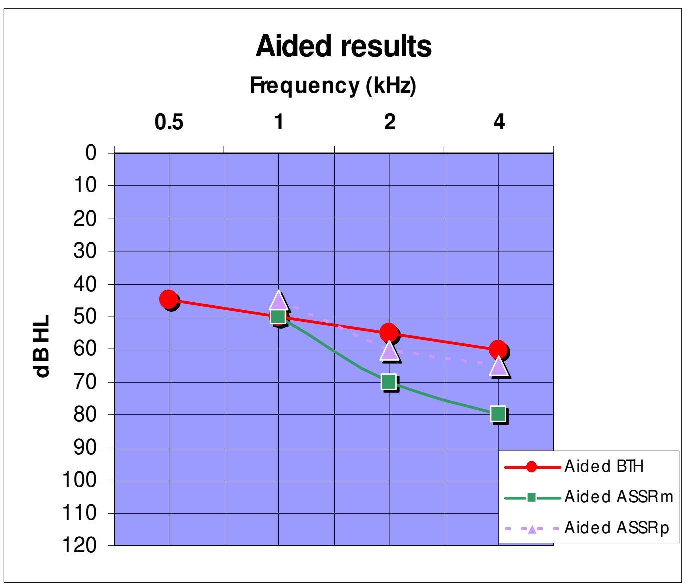

Figure 4.21 Aided results from subject 5 including behavioral thresholds and ASSR thresholds – measured and predicted

Again a recognizable difference was noted between the unaided and aided ASSR responses (see Table 4.16). When comparing the *measured* thresholds, a difference of between 30 to 50 dB across the frequency range was noted. When considering the difference in the aided and unaided *predicted* ASSR thresholds, the difference between the values were 35 to 60 dB. No aided ASSR response at 500 Hz could again be measured on this subject.

When comparing the aided ASSR with the aided behavioral thresholds, a difference of 10 dB was noted between the *measured* aided ASSR and the behavioral threshold at 1000 Hz. A difference of 15 dB was noted at 2000 Hz and a 20 dB difference at 4000 Hz. In this comparison the aided behavioral thresholds had the lower value.

When comparing the aided ASSR – using the *predicted* thresholds with the aided behavioral thresholds, a 5 dB difference was noted at all the frequencies measured (1000 Hz – 4000 Hz). In this case the ASSR had the higher value for 2000 Hz and 4000 Hz.

4.3.1.6 Subject 6: Results for sub-aim 2

The aided test results for subject 4 are presented in Table 4.17 and Figure 4.22.

Table 4.17 Unaided ASSR, aided ASSR and aided behavioral thresholds measurements for subject 6

Unaided ASSR results	500 Hz **110 dB**	1000 Hz **110 dB**	2000 Hz **110 dB**	4000 Hz **NR**
Unaided predicted ASSR results	**500 Hz** 105 dB	**1000 Hz** 105 dB	**2000 Hz** 105 dB	**4000 Hz** NR
Aided ASSR results	**500 Hz** 50 dB	**1000 Hz** 40 dB	**2000 Hz** 70 dB	**4000 Hz** NR
Aided predicted ASSR results	**500 Hz** 25 dB	**1000 Hz** 25 dB	**2000 Hz** 60 dB	**4000 Hz** NR
Aided Behavioral assessment results	**500 Hz** 40 dB	**1000 Hz** 50 dB	**2000 Hz** 65 dB	**4000 Hz** NR

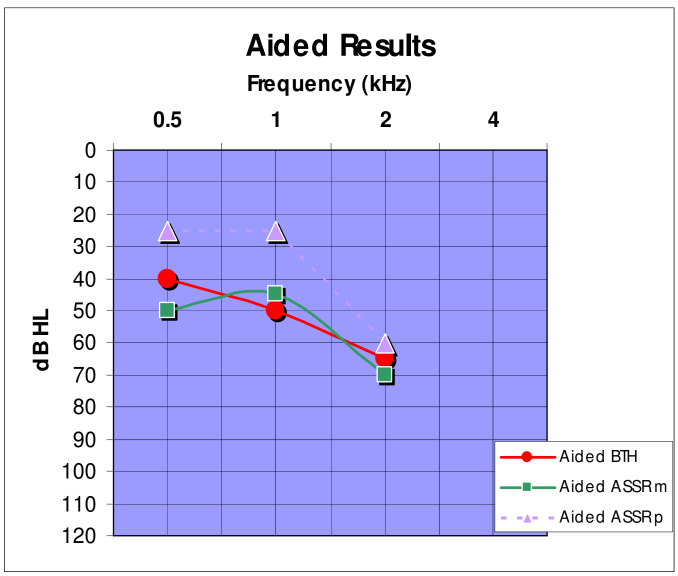

Figure 4.22 Aided results from subject 6 including behavioral thresholds and ASSR thresholds – measured and predicted

A recognizable difference was noted between the unaided and aided ASSR responses (see Table 4.17). When comparing the *measured* thresholds, a difference of between 40 to 70 dB across the frequency range was noted. When considering the difference in the aided and unaided *predicted* ASSR thresholds, the difference between the thresholds were 45 to 80 dB. No aided ASSR response at 4000 Hz could be measured on this subject.

When comparing the aided ASSR with the aided behavioral thresholds, a difference of 10 dB was noted between the *measured* aided ASSR threshold and the behavioral threshold at 500 Hz. A difference of 10 dB was noted at 1000 Hz and 2000 Hz. In this comparison the aided behavioral thresholds had the lower value for 500 and 2000 Hz.

When comparing the aided ASSR – using the *predicted* thresholds with the aided behavioral thresholds, a 15 dB difference was noted at 500 Hz, 25 dB at 1000 Hz and 5 dB at 2000 Hz. In this case the ASSR had the lower thresholds for the frequencies tested.

Looking at these aided results of the individual subjects, it would seem that the ASSR may proof a valuable contribution to the process of pediatric hearing aid fittings. In the following section, the results that concern validation of hearing aid fittings in infants as it is based on the measurements for all six subjects are described, compared and discussed.

4.3.2 Collective results for all six subjects concerning sub-aim 2

All of the subjects showed recognizable aided ASSR responses above their unaided ASSR thresholds. In Table 4.18 the results of the aided ASSR – the measured threshold and the predicted ASSR threshold (using the prediction formulae devised by Melbourne University: Rance et al., 1995) as well as the aided behavioral thresholds are provided. Four subjects showed no response on the ASSR at 500 Hz aided response at the maximum output of the speaker (77,7dB). Only one subject had no response to 4000 Hz aided ASSR (94,9dB). Responses were recorded at carrier frequencies of 500, 1000, 2000 and 4000 Hz in this group of six hearing impaired infants using hearing aids. The same frequencies were tested during the behavioral assessment, namely 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

Table 4.18 Summary of aided thresholds for the six subjects as determined by ASSR and behavioral assessments respectively.

	Aided ASSR (measured)				Aided ASSR (predicted)				Aided BT			
	500 Hz	**1000 Hz**	**2000 Hz**	**4000 Hz**	**500 Hz**	**1000 Hz**	**2000 Hz**	**4000 Hz**	**500 Hz**	**1000 Hz**	**2000 Hz**	**4000 Hz**
Subject 1	NR	50 dB	30 dB	45 dB	NR	30 dB	15 dB	15 dB	25 dB	20 dB	25 dB	30 dB
Subject 2	50 dB	35 dB	35 dB	30 dB	25 dB	20 dB	20 dB	5 dB	30 dB	35 dB	35 dB	40 dB
Subject 3	NR	50 dB	60 dB	70 dB	NR	35 dB	45 db	55 dB	35 dB	35 dB	40 dB	40 dB
Subject 4	NR	50 dB	60 dB	50 dB	NR	35 dB	45 dB	35 dB	30 dB	35 dB	25 dB	25 dB
Subject 5	NR	50 dB	70 dB	80 dB	NR	45 dB	60 dB	65 dB	45 dB	50 dB	55 dB	60 dB
Subject 6	50 dB	45 dB	70 dB	NR	25 dB	25 dB	60 dB	NR	40 dB	50 dB	65 dB	NR
Mean	**50 dB**	**46.7 dB**	**54.2 dB**	**55 dB**	**25 dB**	**31.7 dB**	**40.8 dB**	**35.5 dB**	**34.2 dB**	**37.5 dB**	**40.8 dB**	**39 dB**
Range	**O**	**15**	**40**	**50**	**0**	**25**	**45**	**60**	**20**	**30**	**40**	**35**
Number	**2**	**6**	**6**	**5**	**2**	**6**	**6**	**5**	**6**	**6**	**6**	**5**

NR = No Response

P = prediction

The **range** of response determined with the ASSR (measured and predicted) and behavioral measurements was similar between different measurements. At 500 Hz the range was the same between the two different ASSR results, as only two ears had responses and the response level was the same for the ears. The range was 20dB on the behavioral measurement, but six values are calculated as opposed to two. The range at 1000 Hz was 15dB on the measured ASSR, 25dB on the predicted ASSR and 30dB on the behavioral assessment. At 2000 Hz the same range was noted for the measured ASSR and behavioral assessment. The predicted ASSR was 5 higher than these measures. At 4000 Hz the measured ASSR had a range of 50dB, the predicted ASSR 60dB and the behavioral assessment 35dB.

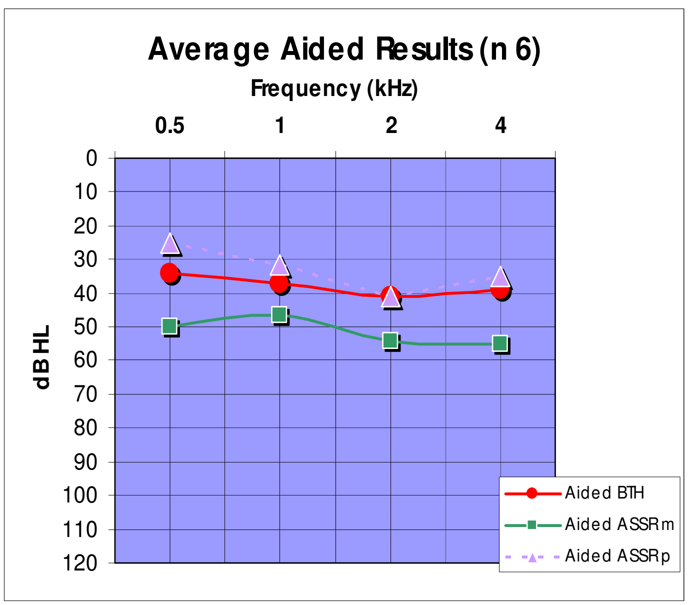

Figure 4.23 Comparison of average aided results for all measured ears based on aided behavioral assessment, measured and ASSR predicted values

Figure 4.23 represents the average aided results. The **mean** aided ASSR measured thresholds ranged from 0 to 55 dB HL. The mean aided ASSR predicted thresholds ranged from 25 to 40.8 dB HL and the mean aided behavioral thresholds ranged from 34.2 to 40.8 dB HL. A recognizable difference was noted between the mean unaided and mean aided ASSR thresholds. When using the *measured* values, an average difference of between 20 to 40 dB across the frequency range was noted. When looking at the difference in the *predicted* values, the differences between the aided and unaided values were 45 to 60 dB.

When comparing the **mean** aided ASSR *measured* thresholds with the aided behavioral thresholds, a difference of 15.8 dB was noted between the aided ASSR measured thresholds and the behavioral threshold at 500 Hz. A difference of 9.2 dB was noted at 1000 Hz, 13.4 dB at 2000 Hz and 16 dB at 4000 Hz. In this comparison the aided behavioral thresholds had the lower value.

When comparing the **mean** aided ASSR – using the *prediction* values with the average aided behavioral thresholds, a 9.2 dB difference was noted at 500 Hz, 5.8 dB at 1000 Hz, no difference at 2000 Hz and 4 dB differences at 4000 Hz. In this case the ASSR had the lower values for the frequencies tested.

Comparing the aided ASSR measured thresholds with aided behavioral thresholds for all the frequencies tested, it was noted that only 8 out of 19 comparable aided thresholds corresponded within 10 dB of each other. These results are represented in Figure 4.24.

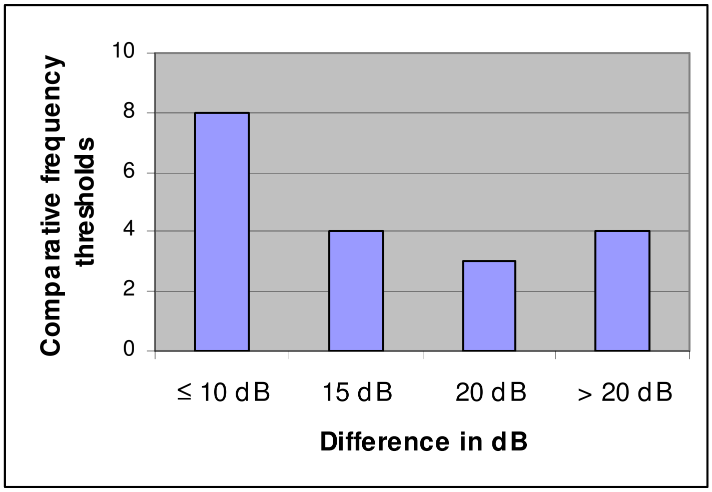

Figure 4.24 Representation of comparative frequencies on aided ASSR measured thresholds and aided behavioral thresholds

Comparing the aided ASSR predicted thresholds with aided behavioral thresholds for all the frequencies tested, it was noted that 11 of 19 comparable aided thresholds corresponded within 10 dB of each other. Figure 4.25 represents these results.

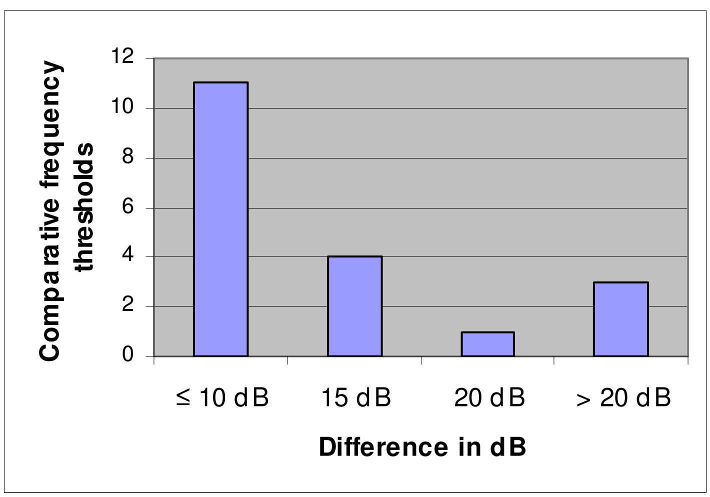

Figure 4.25 Representation of comparative frequencies on aided ASSR predicted thresholds and aided behavioral thresholds

Statistical analyses (Exact Wilcoxon Rank Sum Test) of the results for differences in average thresholds as determined by the Aided ASSR *measured* thresholds and behavioral thresholds are summarized in Table 4.19. No statistical difference between any of the aided results determined with these two procedures was found, as all p-values were more than 0.05. However the p-value on the 2000 Hz showed a smaller value than the other frequency values. It would seem that although the p-value still indicates no statistically significant difference, there seems to be a tendency towards a difference being present on this specific measurement. No analyses could be made at 500 Hz as responses on the aided ASSR could be measured only on two subjects.

Table 4.19 Aided ASSR measured responses vs. aided behavioral responses

Stimulus	P - value
• **Aided 500 Hz ASSR vs. aided behavioural threshold**	N.A. (only 2 values)
• **Aided 1000 Hz ASSR vs. aided behavioural threshold**	P = 0.1875
• **Aided 2000 Hz ASSR vs. aided behavioural threshold**	P = 0.0625 **
• **Aided 4000 Hz ASSR vs. aided behavioural threshold**	P = 0.1250

N.A. not applicable

**** Tendency toward difference**

The results provided by the aided ASSR measured thresholds and aided behavioral thresholds were also compared with regard to its relation. The following scatter plots in Figure 4.26 represent the relationship or correlation coefficient between each frequency tested during the aided ASSR *measured* evaluation and the subsequent aided behavioral measurement. A positive correlation was noted on each individual frequency tested. A moderate to marked correlation was noted at 2000 Hz (r = .70) and at 4000 Hz (r = .63). A change relationship between the results of the procedures is indicated at 1000 Hz (r = .07).

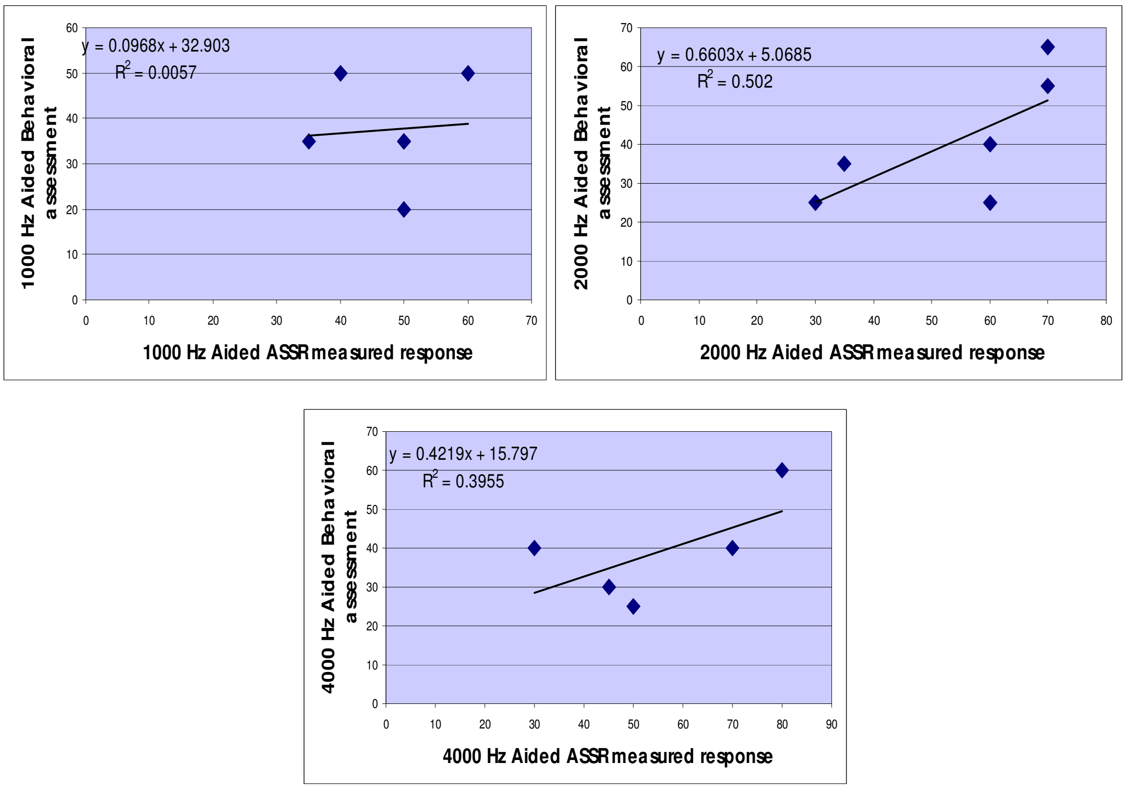

Figure 4.26 Relationship between aided behavioral thresholds and aided ASSR measured responses based on the measurements for six subjects

Statistical analyses (Exact Wilcoxon Rank Sum Test) of the results for differences in average thresholds as determined by the Aided ASSR *predicted* values and behavioral thresholds are summarized in Table 4.20. No statistical difference between any of the aided results determined with these two procedures was found, as all p-values were more than 0.05. No analyses could be made at 500 Hz as responses on the aided ASSR could be measured only with two subjects.

Table 4.20 Aided ASSR predicted responses vs. aided behavioral responses

Stimulus	P - value
• **Aided 500 Hz ASSR vs. aided behavioural threshold**	N.A. (only 2 values)
• **Aided 1000 Hz ASSR vs. aided behavioural threshold**	P = 0.1249
• **Aided 2000 Hz ASSR vs. aided behavioural threshold**	P = 0.2438
• **Aided 4000 Hz ASSR vs. aided behavioural threshold**	P = 0.2504

N.A. not applicable

The comparison with regard to the relation between the aided ASSR predicted thresholds and aided behavioral thresholds are represented in the following scatter plots. Figure 4.27 represent the relationship or correlation coefficient between each frequency tested during the aided ASSR *predicted* evaluation and the subsequent aided behavioral measurement. A positive correlation was noted on each individual frequency tested. A marked correlation was noted at 2000 Hz (r = .76) and at 4000 Hz (r = .61). A slight relationship between the results of the procedures in indicated at 1000 Hz (r = .28).

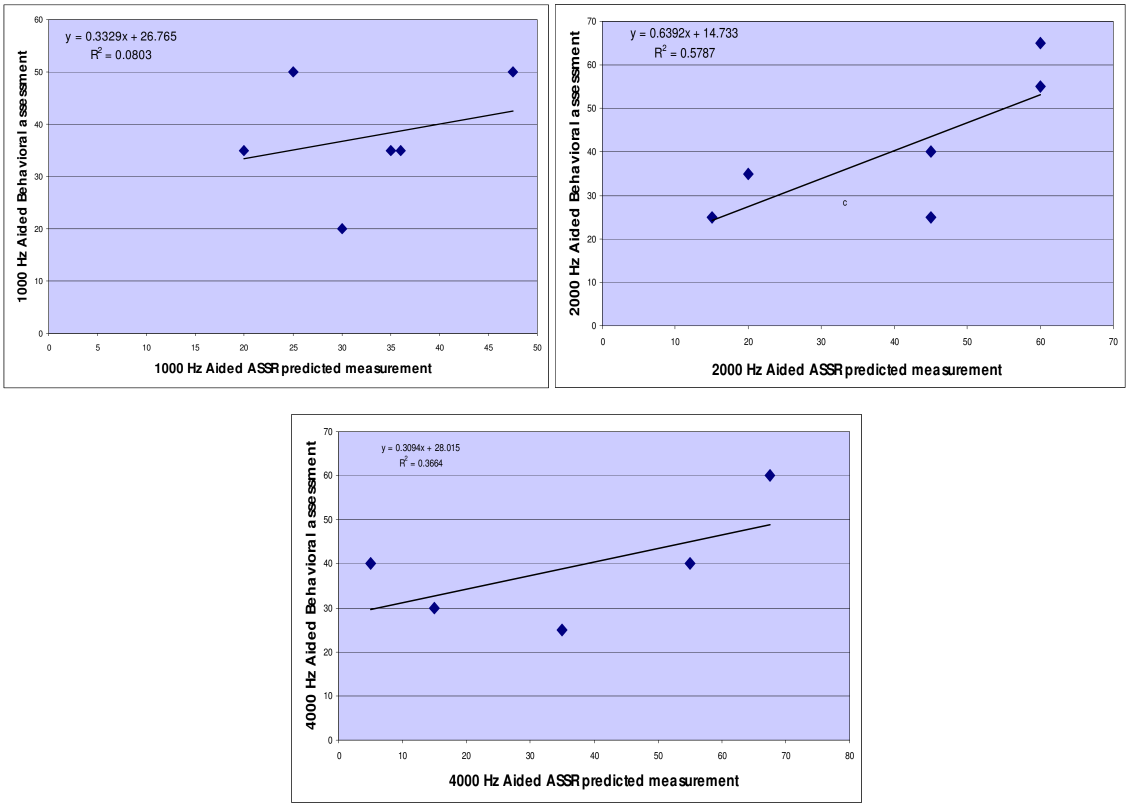

Figure 4.27 Relationship between aided behavioral thresholds and aided ASSR predicted responses based on the measurements for six subjects

To summarize:

- The same amount of frequencies tested, demonstrated results with aided ASSR *measured* and the aided ASSR *predicted* thresholds.
- In only 42% of the aided frequencies tested, the aided ASSR *measured* thresholds and aided behavioral thresholds corresponded within 10 dB of each other.
- In 58% of the aided frequencies tested, the aided ASSR *predicted* thresholds and aided behavioral thresholds corresponded within 10 dB of each other.

- No statistically significant differences were evident between aided averages of ASSR *measured* thresholds and aided behavioral thresholds.
- No statistical significant differences were evident between aided averages of ASSR *predicted* thresholds and aided behavioral thresholds.
- Results confirm that there is a moderate to change correlation between the aided ASSR *measured* response and aided behavioral assessment.
- Results confirm that there is a fair to moderate positive correlation between the aided thresholds determined by the behavioral assessment and the ASSR *predicted* response.

Analysis of the data led to comparative results which indicated that both the aided ASSR (measured and predicted) results compare favorably to that of aided behavioral assessments, although there is a higher correlation between the aided ASSR predictions and the aided behavioral assessments.

4.4 DISCUSSION

The purpose of this study was to determine the clinical value of the ASSR for early diagnosis and amplification of infants with hearing loss. This was done by using both ABR and ASSR measurements to predict hearing thresholds and to compare these results obtained in infants with hearing loss. Aided ASSR thresholds were measured in order to validate the hearing aid fitting. These results were compared with behavioral measurements. In the following sections the results of this study will be discussed according to the sub-aims.

4.4.1 Sub-aim 1: To investigate the potential clinical value of the ASSR in early diagnosis of hearing loss in a group of infants by determining and comparing unaided ASSR, ABR and behavioral thresholds.

Sub-aim 1 will be discussed in the following section.

4.4.1.1 ABR vs. ASSR

Although some discrepancies were noted between these two measuring techniques in the individual subjects (subject 2 and subject 4: tone burst ABR vs. 500 Hz ASSR and subject 3: click ABR and 2000 Hz ASSR), the results from this study show that the tone burst ABR and 500 Hz ASSR have a strong positive correlation (r = .77). Similar results were obtained with the click ABR and 2000 Hz ASSR comparison (r = .62). Johnson and Brown (in Vander Werff et al., 2002:233), tested a small group of hearing impaired adults with a range of hearing losses and compared toneburst ABR thresholds with ASSR thresholds. These researchers found a strong positive correlation of r = .91 between ABR and ASSR thresholds. The study by Vander Werff et al. (2002:233) agrees well with the previous study mentioned. The study conducted by Cone-Wesson et al. (2002:184) concluded that tone-ABR and ASSR could both be used to estimate hearing thresholds as positive correlations were found between these two measurements. This is confirmed by the results of the current study. In this current study however, no correction were made for the ABR results.

The population for whom ASSR threshold estimation procedures may prove particularly beneficial is children with severe to profound hearing losses. The continuous tones used to elicit the ASSR resemble the stimuli used in behavioral testing and can therefore presented at higher levels than the ABR. The ASSR is therefore well suited to quantify hearing loss in the severe to profound range (Rance et al., 2005:298). This present study reported on five ears for which no click ABR or 500 Hz tone burst ABR was recorded at the maximum stimulation levels. Four of these ears had measurable ASSR thresholds at 500 and 2000 Hz. Two ears also had responses at 4000 Hz on the ASSR. Only one ear had no response on either of the measurements. These findings of potential advantages of ASSR over ABR for severe to profound losses are consistent with results of previously reported studies (Rance et al., 2005:294; Swanepoel et al., 2004:534; Vander Werff, 2002:233; Rance et al., 1998:57; Rance et al., 1995:505). These studies have shown that error in prediction of hearing loss decreases with increasing degree of hearing loss. The evidence from this study further indicates that absent ASSR implies no usable hearing at that frequency. That is not true of ABR, for which evidence has shown that absent ABR does not rule out useful residual hearing (Rance et al., 1998:48).

Both the ASSR and tone burst ABR have demonstrated clinical value for estimating the pure-tone audiogram in infants with hearing loss (Cone-Wesson et al., 2002:185). The data from this present study and those of other studies (Stueve & O'Rourke, 2003; Vander Werff, 2002) suggest that there are no significant differences in threshold determination between the two techniques.

4.4.1.2 ASSR vs. Behavioral measures

The results from this study show that the ASSR procedure can accurately identify and quantify hearing loss in infancy. For these subjects there was a strong relationship between the ASSR thresholds obtained during infancy and their subsequently established behavioral audiograms. The difference between the average ASSR threshold prediction and the average behavioral threshold was 0 – 10 dB (Figure 4.11), with correlation values of .93 at 500 Hz; .82 at 1000 Hz; .79 at 2000 Hz and .59 at 4000 Hz. In studies that have compared the ASSR with behavioral thresholds, very strong positive correlations were also found between these two measures (Rance et al., 2005:295).

In a study to determine the effect of audiometric configuration on thresholds and suprathreshold ASSR, a highly significant correlation between pure-tone behavioral and ASSR thresholds for individuals with either sloping or flat audiometric configurations was revealed (Vander Werff & Brown: 2005:319). In the present study of 12 ears, it was found that the ASSR results were accurate in determining the configuration of the loss. As with the study by Rance et al. (1998:58) and Rance et al. (2005:295), the findings for individual frequencies translated into accurate descriptions of the subjects' hearing losses. The difference in thresholds differed between 0 – 20 dB, with the ASSR in most of the cases being slightly higher than the behavioral threshold – especially in the low frequencies (excluding subject 2 & 3). Rance et al. (1998:58) found a similar pattern in their subjects with the ASSR thresholds slightly overestimating the behavioral levels and mirroring the audiogram configuration. These findings are similar to the findings of Lins et al. (1996:95) when they found a significant difference in mean threshold at 500 Hz in a group of adult subjects. These researchers also showed a general tendency across frequency for ASSR thresholds in infants to be higher than for adults.

In this present study, the results from subject 2 showed inaccurate thresholds predictions. The ABR thresholds and ASSR prediction thresholds correlated well at time of diagnosis, but subsequent behavioral thresholds were 10 dB to 35 dB lower at different frequencies than previous electrophysiological results. There is evidence of deterioration in hearing level in this subject. This aspect is being evaluated further. The results from the behavioral assessment impact negatively on the results of this study. The electrophysiological assessment in subject 3 indicated to a greater hearing loss than what was subsequently determined with behavioral audiometry. No apparent reason for these discrepancies could be found. A possible influence may be the presence of abnormal tuning curves in the cochlea, caused by impairment. Picton et al. (1998:329) found that the presence of abnormal tuning curves in the cochlea caused the impaired system to have place and frequency specificity discrepancies. This mechanism might not lead to well synchronized steady state responses and the physiologic thresholds may be elevated relative to the behavioral thresholds (Picton et al., 1998:329).

The audiograms shown of each individual subject also reflects one of the particular advantages of the ASSR assessment in subjects with minimal amounts of residual hearing (subject 5 & 6). The continuous tones used to elicit the ASSR resemble the stimuli used to elicit behavioral responses and can be presented at higher levels than is possible for brief stimuli. The ASSR is therefore especially well suited for quantifying hearing loss of a severe to profound nature (Rance et al., 2005:298). Of the five hundred and fifty-six subjects with either normal hearing or sensorineural hearing loss, only four showed ASSR thresholds at levels > 10 dB lower than their subsequently established behavioral thresholds.

In a recent study Picton, Dimitrijevic, Perez-Abalo and Van Roon (2005:154) concluded their report by stating that the accuracy of threshold estimation depends on the variability of threshold estimation rather than on any mean difference between physiological and behavioral thresholds. The results from their experiments demonstrated several ways to improve the accuracy of estimating behavioral thresholds from the ASSR – the main factor being to reduce background noise. With time limitation in the clinical setting, the results will typically be thresholds that have a standard deviation of 10 dB – which is similar to the variability obtained using tone burst ABR (Stapells, 2000b:74).

This present study supports the findings of the previous studies. The ASSR assessment demonstrates the clinical value for estimating the pure-tone audiogram in infants with hearing loss. It can thus be seen as a very useful step in the evaluation process for these early-identified infants – allowing the behavioral audiogram to be predicted and intervention processes to be implemented.

4.4.1.3 ABR vs. Behavioral measures

This study also shows that reasonably accurate estimates of 500 Hz and 2000 and 4000 Hz pure tone behavioral thresholds can be obtained by recording tone burst ABR and click ABR. A marked correlation (r = .77) was found between the 500 Hz behavioral assessment and tone burst ABR. Similar findings are well reported on in several studies (Stapells, Gravel & Martin, 1995:361; Stapells, 2000a:20; Gorga, 1999:29). The click ABR showed a dependable correlation with the 2000 Hz behavioral assessment and only a fair degree of positive correlation with 4000 Hz behavioral assessment. This finding agrees with the notion that the click ABR threshold represents hearing in the 2000 to 4000 Hz frequency region.

However it was evident that the severe to profound sensory neural hearing loss will not be identified and evaluated with the ABR. This was evident as only seven of the 12 ears could be evaluated using the ABR. These findings are consistent with previously reported studies (Rance et al., 2005; Vander Werff et al., 2002; Rance et al., 1998; Rance et al., 1995).

Summary:

- This study concludes that both the ABR and ASSR can both be used to estimate hearing thresholds – as positive correlations were found between these two measurements. However the ASSR proved to be more beneficial in the severe to profound hearing loss population to quantify their hearing losses.
- This study indicates that the ASSR procedure can accurately identify and quantify hearing loss in infants as a strong relationship was noted between the ASSR thresholds obtained during infancy and their subsequently obtained behavioral audiograms.
- Although the tone burst ABR and click evoked ABR indicated to provide reasonably accurate estimates of the 500 Hz, 2000 Hz and 4000 Hz behavioral audiogram, it was evident that the severe to profound sensory neural hearing losses will not be identified and evaluated through the use of the ABR.

4.4.2 Sub-aim 2: To investigate the clinical value of the ASSR for relevant early fitting of hearing aids in infants by determining and comparing aided ASSR and aided behavioral thresholds.

Sub-aim 2 will be discussed in the following section.

4.4.2.1 *Unaided ASSR vs. aided ASSR responses*

All of the subjects showed recognizable aided ASSR responses above their unaided ASSR thresholds. In this study both the measured ASSR and the ASSR using the prediction formulae devised by Melbourne University (Rance et al., 1995) was used. On the measured ASSR, the responses were within 20 - 40 dB above the unaided measured ASSR. Using the prediction formulae, the average difference between the unaided ASSR and aided ASSR was 45 – 60 dB. In only two subjects however could an aided ASSR response be measured at 500 Hz at the maximum output of the speaker (77,7 dB).

The inability in this present study to determine more aided ASSR thresholds at 500 Hz might be explained by hearing aid characteristics and the output of the calibrated speaker. Aided hearing thresholds are limited by the output of the hearing aid (Garnham et al., 2000:277). Saturation and distortion of the output signal when using a high-intensity stimuli in conjunction with moderate to high gains were reported in the study by Garnham and his colleagues. Distortion introduces additional sideband frequencies to those in the input stimuli, thus decreasing the frequency specificity of the response – influencing the response measurement of the ASSR.

An aspect that might have played a further role in the inability to obtain more aided ASSR thresholds at 500 Hz might be the test environment. These measurements were obtained in a quiet room in the practice of the researcher. Results from previously reported studies (Perez-Abalo et al., 2001:210; Swanepoel, 2001:120; Lins et al., 1996:95) indicated that acoustic ambient background noise exerts a significant influence on the ASSR results. Noise levels within this specific test room may not have been sufficiently quiet to establish thresholds in the sound field at 500 Hz (Harrell, 2002:75).

Another possible influence may be the presence of abnormal tuning curves in the cochlea, caused by impairment. Picton et al. (1998:329) found that the presence of abnormal tuning curves in the cochlea caused the impaired system to have place and frequency specificity discrepancies. Despite amplification, the sounds - in this instance 500 Hz - may be processed through areas of the cochlea that are not place specific for 500 Hz. This mechanism might not lead to well synchronized steady state responses and the physiologic thresholds may be elevated relative to the behavioral thresholds (Picton et al., 1998:329).

4.4.2.2 Aided ASSR responses vs. aided behavioral responses

In the group of six subjects, the aided ASSR *measured* responses were on average between 9.2 dB and 16 dB higher than the aided behavioral thresholds. These results are similar to the differences reported by Picton et al. (1998:327), where the aided ASSR responses were on average between 13 and 17 dB higher than the behavioral thresholds. The Picton group of researchers investigated the possible use of the MASTER (multiple auditory steady-state response) technique in the assessment of aided thresholds in the sound field on 38 children (ages 11 – 17 years) with hearing impairment. Most children in their study showed recognizable responses within 10 and 30 dB above their behavioral thresholds with their hearing aids. The physiologic thresholds were quite closely related to the behavioral thresholds except at 4000 Hz where there was a significantly greater variability in the relation between the behavioral and physiological thresholds. In several of the aided subjects, no responses were found at 4000 Hz even when stimuli were significantly above behavioral thresholds. Picton et al. (1998:322) obtained better thresholds – using the same stimuli – presented singly. The relations between the physiologic and behavioral thresholds became closer. There were no significant differences in the physiologic-behavioral differences among the different audiometric frequencies. The conclusion for their findings was that the physiologic-behavioral difference was probably related to recruitment – the response reaches a level where it is recognizable at intensity closer to threshold.

In the current group of six subjects, the aided ASSR *predicted* thresholds were on average between 4 dB and 9.2 dB lower than the aided behavioral thresholds. These results differ from the Picton group results (1998:327); however, Picton et al. (1998:327) did not use prediction formulae to determine aided ASSR threshold levels. The aided ASSR thresholds in their report were the actual measured thresholds – using the MASTER.

Comparing the mean aided ASSR *measured* and *predicted* thresholds in comparison with the aided behavioral thresholds, it would seem as if the correlation between the aided ASSR *predicted* values and aided behavioral threshold values are more positive by a small margin – especially at 1000 and 2000 Hz. However in the individual cases variations are noted: the aided ASSR *predicted* values for subject 1, 3, 4 and 5 closely approximated the aided behavioral threshold values more so than the aided ASSR *measured* values. The results from subject 2 and 6 indicated to the ASSR *measured* values to approximate the aided behavioral thresholds more closely than the ASSR *predicted* values.

The differences between ASSR (measured thresholds) and behavioral thresholds varied between 0 and 20 dB. The differences between ASSR (predicted values) and behavioral thresholds varied between 5 and 25 dB. The variance might be explainable by inter-subject differences. Subject 1, 2 and 6 showed lower responses on the aided ASSR *predicted* values as on the aided behavioral measurement. These were the subjects who were fitted with digital hearing aids. Subject 3, 4 and 5 were fitted with digitally programmable hearing aids. Their aided ASSR *predicted* responses were between 0 and 20 dB higher than the aided behavioral thresholds. This range is far from optimal; however where there is no other information about aided thresholds, this degree of accuracy is acceptable (Picton et al., 1998:327). It is clear however, that the results from this study indicate to the aided ASSR *measured* responses to be not specific enough and that the aided ASSR *predicted* thresholds overestimate thresholds. New correction figures may be needed for the ASSR to be used for the purpose of estimating functional gain and larger scale studies are needed to validate this approach.

This study has shown that aided ASSR are valuable in the validation of the aided performance in some subjects and can provide valuable functional information. In this group of six subjects, it was the first clear response recorded on these infants. It also clearly indicated possible cochlear implantation candidacy for subject 5 and 6 and confirmed that the unaided thresholds were not based solely on spurious/artificial AASR's at high intensity stimuli (Small & Stapells, 2004:611; Gorga et al., 2004:302; Jeng et al, 2004:67; Picton & John, 2004:541; Dillon, 2001:419). However, some limitations to aided ASSR were found:

- Only the linear operation of the aid can be tested (Garnham et al., 2000:277). Advanced processing features, such as feedback managing systems and noise reduction systems, were deactivated on the digital hearing aids.
- Aided thresholds are not uninformative – clearly if thresholds are below the speech intensities, the aid cannot improve speech perception. Picton et al. (2002:68) cautions that the assessment of aided thresholds is occurring at levels that are not relevant to the perception of amplified speech. Objective assessment of hearing aid measurements at comfort levels may be a more efficient approach to fitting of hearing aids than determining aided thresholds (Picton et al., 1998:328).

Although these limitations are present, aided ASSR's were found to be valuable – especially in the cases of subject 5 and 6 where cochlear implant candidacy was determined at such a young age. Aided ASSR measures may become more valuable as the need arise to determine cochlear implantation candidacy at earlier ages and to manage infants with hearing loss more effectively. However, when performing aided hearing aid threshold measurements it is essential to be aware of limitations in both the hearing aids and the stimuli used to evoke a response.

Summary:

- All subjects showed recognizable aided ASSR responses above their unaided ASSR thresholds. There was an inability to determine aided ASSR's at 500 Hz in four subjects.

- In the group of six subjects, the aided ASSR *measured* thresholds were on average between 9.2 dB and 16 dB higher than the aided behavioral thresholds. The aided ASSR *predicted* were on average between 4 dB and 9.2 dB lower than the aided behavioral thresholds – indicating to the aided *measured* thresholds to underestimate behavioral thresholds and the aided *predicted* thresholds to overestimate the aided behavioral thresholds.

4.5 CONCLUSION

The results from the current study indicate good correlation between the ABR and ASSR as method to predict hearing thresholds in this group of infants. The ASSR however does have the advantage over the ABR in individuals with a severe to profound hearing loss. Responses could be measured in these cases through the use of ASSR in the absence of any ABR responses. Furthermore, the absence of ASSR responses at maximum levels was a reliable indicator of profound or total hearing loss. The ASSR thus allowed for greater degrees of hearing impairment to be evaluated. The frequency specificity of the stimulus tones allowed assessment of residual hearing across the audiometric frequency range.

The ASSR findings for individual frequencies translated into accurate descriptions of the subjects' hearing losses in comparison with behavioral thresholds. The configuration of the hearing loss could be predicted through the use of ASSR. Results such as these can provide the basis for early intervention such as fitting of hearing aids or determining candidacy for cochlear implantation.

Hearing aid fitting in the infant population remains a challenge and aided ASSR have the potential to provide objective information with regards to hearing aid functional benefit in the validation process. Aided ASSR threshold information is valuable and important in the management of challenging children. In this study aided ASSR thresholds provided additional information.

It would therefore seem as if the ASSR has got clinical value in the early diagnosis of hearing loss in infants as the unaided ASSR values correlated well with the ABR at the time of diagnosis and subsequently with the unaided behavioral thresholds.

Furthermore it would seem as if the ASSR has an additional clinical value in the validation of hearing aid fittings for infants as the aided ASSR *measured* and *predicted* values correlated well with the aided behavioral thresholds.

4.6 SUMMARY

This chapter reported and discussed the results obtained in this study according to the two sub-aims. These sub-aims were selected in an attempt to answer the main aim of this study. The results pertaining to each sub-aim were discussed and integrated with literature to ensure the validity thereof. Conclusions were drawn from the results in each sub-aim and summarized at the end of the chapter in order to answer the main aim of the study.

Chapter 5

CONCLUSIONS AND IMPLICATIONS

This chapter aims to draw general conclusions and implications from the research, critically evaluate findings, and make recommendations for future research

5.1 INTRODUCTION

Within a relatively short period of time, there has been remarkable and revolutionary changes in the field of pediatric audiology that demand professionals to rethink diagnostic and intervention paradigms (Kurtzer-White & Luterman, 2001: introduction). 'Evidence Based Practice' (EBP) is therefore an approach to clinical service delivery that has become increasingly advocated (Gravel, 2005:17). EBP refers to '*conscientious, explicit, and judicious use of current best evidence in making decisions about the care of patients*' (Oxford-Centre for Evidence Based Medicine, 2004: online). The primary element of EBP is the major role of *scientific* evidence in *clinical* decision-making (Gravel, 2005:17). This sentiment has been the underlying driving force behind the research endeavor of this study.

There has always been a need for objective tests that assess auditory function in infants, young children, and/or any patient whose developmental level precluded the use of behavioral audiometric techniques (Gorga & Neely, 2002:49). The ASSR have therefore gained considerable attention and is seen as a promising addition to the AEP 'family'. This study proposed to gather evidence with regards to the clinical value of the ASSR in infants. It is thus logical to evaluate 'best evidence' through *critical appraisal* of this research endeavor (Hill & Spittlehouse, 2005:1). *Critical appraisal* is an essential part of evidence-based clinical practice that includes the process of systematically finding, appraising and acting on evidence of effectiveness. *Critical appraisal* is a systematic process, examining research evidence to assess its validity, results and relevance. This process allows making sense of research evidence and thus begins to close the gap between research and practice (Hill & Spittlehouse, 2005:1).

The purpose of this chapter is therefore to draw relevant conclusions from the results reported and discussed in chapter 4. A critical evaluation of the study is subsequently provided to identify the inherent and methodological limitations of this study, followed by recommendations for future research. Finally a conclusion and summary of the chapter is provided.

5.2 CONCLUSIONS

The need for research to provide evidence to justify clinical practices is acknowledged by most clinicians (Jenkins, Price & Straker, 2003:4). This exploratory study was conducted according to two sub-aims, which resulted in the summarized conclusions that follow below.

5.2.1 Sub-aim 1: To investigate the potential clinical value of the ASSR in early diagnosis of hearing loss in a group of infants by determining and comparing unaided ASSR, ABR and behavioral thresholds

- This study concluded that both the ABR and ASSR could both be used to estimate hearing thresholds – as positive correlations were found between these two measurements. However the ASSR proved to be more beneficial in the severe to profound hearing loss population to quantify their hearing losses.
- This study indicated that the ASSR procedure can accurately identify and quantify hearing loss in infants as a strong relationship was noted between the ASSR thresholds obtained during infancy and their subsequently obtained behavioral audiograms.
- Although the tone burst ABR and click evoked ABR indicated to provide reasonably accurate estimates of the 500 Hz, 2000 Hz and 4000 Hz behavioral audiogram, it was evident that the severe to profound sensory neural hearing losses will not be identified and evaluated through the use of the ABR.

The ASSR has the potential to provide accurate predictions of the behavioral audiogram and be used successfully with populations with severe to profound losses.

5.2.2 Sub-aim 2: To investigate the clinical value of the ASSR for relevant early fitting of hearing aids in infants by determining and comparing aided ASSR and aided behavioral thresholds

- All subjects showed recognizable aided ASSR responses above their unaided ASSR thresholds. There was an inability to determine aided ASSR's at 500 Hz in four subjects.
- In the group of six subjects, the aided ASSR *measured* thresholds were on average between 9.2 dB and 16 dB higher than the aided behavioral thresholds. The aided ASSR *predicted* were on average between 4 dB and 9.2 dB lower than the aided behavioral thresholds – indicating to the aided *measured* thresholds to underestimate behavioral thresholds and the aided *predicted* thresholds to overestimate the aided behavioral thresholds.

The ASSR has the potential to determine aided ASSR thresholds. This procedure can therefore be used to determine functional gain and thus play a role in the ongoing process of validating hearing aid fittings in infants.

The ASSR, despite some limitations identified, demonstrated great promise for early diagnosis and amplification of infants with hearing loss. The discussions according to the specified sub-aims, revealed valuable theoretical and clinical implications and made recommendations for protocols to serve as a guide for future use of the ASSR in the clinical setting.

5.3 THEORETICAL AND CLINICAL IMPLICATIONS

A major justification for electrophysiologic audiometry is that reasonable measures of hearing thresholds in a frequency specific manner can be obtained in order to construct an audiogram (Goldstein & Aldrich (1999:3). Neonates provide the prime example. At present the tone-evoked ABR is the only technique that can provide both the air- and bone- conduction results required for early intervention for children with conductive or sensorineural hearing loss. The tone-evoked ABR has sufficient research, clinical database, and clinical history to recommend it as the **primary technique** for threshold estimation in infants (Stapells, 2005:55).

This present study has proved however that both the ASSR and ABR demonstrated efficacy for estimating the pure-tone audiogram in infants with hearing loss. No significant difference in threshold determination was found between these two techniques. The ASSR did however have the advantage over the ABR in determining residual hearing in the severe to profound group.

It is therefore evident that both techniques have its own advantages and its disadvantages. As indicated by the review of the current literature, the evidence is lacking and not yet sufficient to recommend the ASSR as the **primary** electrophysiologic measure of hearing in infants (Stapells, 2005:56). These two techniques should probably be used in conjunction with each other (Hall, 2005: conference presentation). Jerger & Hayes (1976) in Diefendorf (2002:473) promoted the concept of a test battery approach so that no single test will be interpreted in isolation, but various tests act as a cross-check on the final outcome. Inappropriate or incomplete diagnostic conclusions will lead to inappropriate management and the consequences thereof will be with the child forever (Seewald, 2001:70). By using these techniques in combination, a more solid foundation for intervention will be provided.

When considering two of the most important 'truths' in EBP (Oxford-Centre for Evidence Based Medicine: online), namely:

- *Practice must always be considered in view of the needs, culture and preferences of the individual;*
- *There is the real probability that some of the evidence-base supporting current practice will change or, indeed, be entirely refuted by evidence that will emerge in the future,*

there is a need to continually re-examine the current approach to evaluate hearing abilities in infants.

The ASSR and ABR present with unique qualities that can be combined to provide complementary results, which will serve to verify results obtained with each procedure (Swanepoel, 2001:114). Time is limited when working with infants. It is therefore essential to use a test protocol that is fast, efficient, and one that provides the greatest amount of clinical information with each successive step taken (Stapells, 2002a:14) for each individual infant (Oxford-Centre for Evidence Based Medicine: online).

Although Stapells (2004: conference) has called for the click ABR to be abolished, the click ABR has proven itself over the last three decades as a reliable predictor of auditory sensitivity in the high frequency region despite its lack of frequency-specificity (Swanepoel, 2001:115). It has remained the most commonly used electrophysiologic measure because of the clear response, the high reproducibility and stability of the response (Arnold, 2000:455). The click ABR is also the only technique at present to assess the presence of auditory neuropathy (AN) – also known as auditory dys-synchrony (Tharpe & Haynes, 2005:271). Both procedures approximated the behavioral thresholds well in this study – however the ASSR approximated behavioral thresholds closer than the ABR (group results). This aspect was influenced by the fact that fewer ears could be tested with the ABR than with the ASSR. Although additional research on ASSR testing in infants with hearing loss is needed (Stapells, 2005:55), by using the ASSR in addition to the ABR, useful information may already be provided to help distinguish between infants with severe and profound losses (Roush, 2005:105).

These results suggest a test-battery approach to objective audiometry. These two techniques are independent measures of auditory sensitivity that are able to provide different, though complementary information. The *needs* and *preference* of each infant will be accommodated by using this test-battery approach. Not only will a cross-check principle be advantageous to each individual infant, but the specific advantages of each procedure will give the most comprehensive assessment necessary to ensure that a true reflection of each infant's auditory status is available from which rehabilitative decisions can be made (Roush, 2005:105).

After hearing loss is diagnosed, fitting of hearing instruments can occur when infants are as young as five weeks old (Yoshinago-Itano, 2004:451). Objective measures such as AEP's offer the possibility of evaluating the effectiveness of hearing instruments in infants. This present study did not evaluate the ABR's ability to determine hearing instrument effectiveness as the literature has shown that the brief stimuli that are optimal for ABR recordings may be contaminated by stimulus artifacts. This specific procedure was also seen as complicated and attempts to use the ABR to evaluate hearing instruments have largely been abandoned (Purdy, 2005:116). This study indicated to the ASSR being a reliable method to determine aided thresholds to ensure audibility of speech sounds. The results from the aided ASSR may suggest the need to consider alternative management – such as in the case of two subjects in this study who both had profound sensory neural hearing losses and were fitted with high-powered hearing aids. The decision to proceed with cochlear implantation was expedited. The idea that the ASSR can be used to validate hearing instrument fittings is reasonable, but is yet to be validated as a procedure.

5.4 CRITICAL EVALUATION OF THE CURRENT STUDY

Critical appraisal of an empirical research endeavor is essential to determine the value of the results obtained and is an essential part of evidence-based clinical practice. Reliability and validity of the results as well as the influence of identified limitations, inherent to the study, is required to ensure the appropriate interpretation thereof. Several aspects deserving critical appraisal will be discussed in the following paragraphs.

The first aspect to be considered is the sampling size of the current study. The basic rule is, *the larger the sample, the better* (Leedy & Ormrod, 2005:207). The sampling size necessary for a study depends on the type of study and is required to provide a representative population from which inferences can be drawn regarding a specific phenomenon in a specific population. Although the sample in the current study was representative of both sexes and covered a range of ages in infants, the sample size was not significantly representative of hearing impaired infants. This was however an exploratory study – only the second reporting on aided ASSR's and the first of its nature on infants.

The second aspect that needs to be taken into consideration is the test environment. All behavioral thresholds (aided and unaided) were obtained in a double walled, sound-attenuated booth, while the electrophysiological assessments were completed in a quiet room without any sound attenuation. The acoustical ambient background noise levels were not measured and therefore did not allow for comparison between acoustic noise levels between the double-walled, sound-attenuated booth and the quiet room. The possible difference was not considered when interpreting the results. This noise factor might have played a role – especially in obtaining aided ASSR results. Higher levels of ambient acoustic noise in the quiet room might have caused elevated thresholds and the absence of the reported aided 500 Hz ASSR thresholds. Thus the threshold differences could be inflated on account of the variability in the test environments (Perez-Abalo et al., 2001:210; Swanepoel, 2001:120; Lins et al., 1996:95).

A third aspect identified in the critical appraisal of the current study is the lack of test-retest reliability measures. According to Stapells (2000a:13), one of the limitations with the ABR is the inappropriate interpretation of waveforms. A way to improve reliability of a test is to have two administrators correlating the results of the same procedure. This may be of value in both the interpretation of ABR and behavioral threshold assessment. The responses measured during this study, was interpreted by the researcher alone.

A fourth aspect that needs to be taken into consideration, is the fact that a click-evoked ABR and only a 500 Hz tone burst were used to compare with the ASSR. Narrow frequency regions (ASSR) were therefore compared with those from broad and uncertain frequency regions (click ABR). Ideally a comparison should be made between the infants' ASSR thresholds to their tone-evoked ABR – the current 'gold standard' infant threshold measure (Hyde, 2005:287; Stapells, 2002:14).

The critical evaluation of the literature, current study and consideration of significance of the results obtained has revealed future research implications that are discussed in the following paragraph.

5.5 RECOMMENDATION FOR FUTURE RESEARCH

Clearly, there is an important role for the ASSR in estimating hearing thresholds and validating hearing aid fittings of infants. However, a research question answered raises new questions to be answered. The results obtained in and conclusions drawn from this present research endeavor, revealed aspects that require further investigation. These are presented to provide suggestions for future research endeavors.

In order to validate the ASSR procedure in the infant population, it will be of value to compare the ASSR obtained at all frequencies, with tone burst ABR – using different frequency tone bursts. This data will not only provide comparative data to the accuracy of threshold determination, but also reliability and time-efficiency of each procedure.

In order to further validate the ASSR procedure in the infant population, it will be of value to determine bone conduction ASSR. By determining the

BC ASSR, possible middle ear involvement will be ruled out during the assessment and a true picture of the hearing loss will emerge.

Although the vast majority of research has focused on threshold determination and optimal detection strategies, this present study and a study from Picton (1998) explored the use of ASSR and hearing aid performance. The results from this study are very promising, but the procedures need to be validated on a larger group of infants as well as on children of other ages – as this procedure will probably be of use to the difficult-to-test population, including older children with developmental delays. Different prediction formulae might also be necessary to be developed for the application of the ASSR for this purpose.

An aided threshold supplies certain information about audibility of sounds, but no information about perception of sounds is given. Studies by Dimitrijevic et al. (2004:68) used the ASSR to predict suprathreshold auditory abilities such as word discrimination. Multiple carriers of independently modulated frequency and amplitude ('IAFM') stimuli have been modeled to have similar acoustic spectra to speech. Using these speech-modeled stimuli, significant correlations between word discrimination and detection of IAFM were found in normal-hearing and hearing-impaired subjects (Dimitrijevic et al., 2004:84). Although ASSR's represent a relatively low level of auditory processing, IAFM may be used to determine whether or not the auditory system has sufficiently processed the necessary input required for speech perception at a later and higher level of processing (Stapells, 2005:56).

5.6 CONCLUSION

AEP's are an ideal tool for investigating auditory function in young infants, as they provide an objective measure of the brain's response to sound (Purdy et al., 2005:115). Recent technological and research advancements have aided the development of this field, ensuring the continuation of endeavors generating techniques that approximate the accuracy, reliability, frequency-specificity and time efficiency of behavioral pure tone audiometry (Swanepoel, 2001:121) – both unaided and aided.

This investigation of the clinical value of the ASSR in infants has demonstrated the ASSR's ability to estimate behavioral pure tone thresholds reasonably well. It has also shown that the ASSR has the potential to play a role in the ongoing process of hearing instrument fitting in infants as aided ASSR thresholds compared reasonably well with aided behavioral thresholds. However, while additional research on ASSR testing in infants with hearing loss is needed, it is important to critically consider currently available procedures alongside the new. In his closing address of *A Sound Foundation through Early Amplification* conference in 1998 Bess challenged the clinicians to become more evidence based with the following words: *'Effective clinicians produce improved techniques and constantly question and evaluate evidence, methods, and procedures, discarding the unproductive, and developing and testing the new' (*Bess, 2000:250).

This becomes essential in order to implement techniques in accordance to the advantages and disadvantages of each procedure. Evidence from the current study indicated that the ASSR presented with unique characteristics that should be incorporated in a test-battery approach and therefore has clinical value for early diagnosis and amplification of infants with hearing loss.

> *'if we truly desire to afford the best possible services to children and their families, we must be willing to continually modify our clinical protocols as new evidence emerges'* (Bess, 2000:250)

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Appendix A

University of Pretoria

Research Proposal and Ethics Committee
Faculty of Humanities

6 September 2004

Dear Mr Swanepoel

Project:	***The clinical value of the Auditory Steady State Response (ASSR) for early diagnosis and amplification for infants (0-8 months) with hearing loss***
Researcher:	**D Stroebel**
Supervisor:	**DCD Swanepoel**
Department:	**Communication Pathology**
Reference number:	**85243435**

Thank you for the application you submitted to the Research Proposal and Ethics Committee, Faculty of Humanities.

I have pleasure in informing you that the Research Proposal and Ethics Committee formally approved the above study on 26 August 2004.

The committee requests you to convey this approval to Mrs Stroebel.

We wish you success with the project.

Sincerely

Prof Brenda Louw.
Chair: Research Proposal and Ethics Committee
Faculty of Humanities
UNIVERSITY OF PRETORIA

Appendix B

Researcher: Deidré Stroebel
Tel: 021 930 3136

21 July 2004

To Whom It May Concern:

Proposed research project:
The clinical Application of ASSR in the Diagnosis and fitting of Hearing Aids in Infants (0 – 8 months)

Thank you for considering for your child to be part of this research project. The positive results of early identification of hearing loss in infants on different aspects of their development are well known. Different methods are used to obtain information about infants' hearing status. These methods differ from the techniques used on adults. As technology improves, new methods become available that shows a lot of promise in the field of pediatric audiology.

I am currently planning a research study in this regard as part of the requirements for a master's degree at the University of Pretoria. The proposed project involves determining the clinical value of Auditory Steady State Responses (ASSR) as a way to predict hearing thresholds, and to evaluate hearing aids in young infants. The results from the hearing assessments will be monitored and compared with the results of two clinically proven procedures, frequently used to determine hearing thresholds, namely the Auditory Brainstem Response (ABR) and Pure tone Audiometry, for a period of time. The study will be conducted under the supervision of personnel at the Department of Communication Pathology.
Procedures currently included in the standard test protocol used to assess infants in my private practice, involve the following:

- The diagnostic session – including ABR and ASSR.
- Measuring the gain from hearing aids through ASSR
- Behavioral testing after the age of 6 months.

As a client of this practice these procedures will also be used to evaluate and monitor your baby's hearing. All of the above procedures are non-invasive, no pain is involved and the ABR and ASSR procedures are normally done while the baby is sleeping. If sedation should be needed, this will be done in consultation with a pediatrician and with the necessary medical supervision. No additional costs will be charged for the Auditory Steady State Response test, as the value of this test is still being researched.

I would like to request your consent for your baby's participation; permission to use the results of your baby's routine hearing tests; as well as permission to use information from your baby's records for this research project. You have my assurance that no unnecessary tests will be done. You may also withdraw your child from the study at any time.

Myself, my supervisor, Mr. De Wet Swanepoel, or Prof. B. Louw, head of the Department of Communication Pathology at the University of Pretoria may be contacted, should you need any further information.

Thank you for your assistance.

Deidré Stroebel
Researcher

Mr. De Wet Swanepoel
Supervisor

Prof. B. Louw
HEAD: Department of Communication Pathology

Surname: ____________________________ Name: ______________________________

I have read the letter of information regarding Mrs. D. Stroebel's proposed research study.

I understand what is involved and give permission that the test results of my child ____________________________________ may be used.

______________________________   _____________________________________

Signature   Date

Appendix C

DATA RECORDING SHEET

Subject: ___________________________

ABR	
Tone Burst	Click

Date: Age at time of assessment:

ASSR				
	500 Hz	1000 Hz	2000 Hz	4000 Hz
Unaided Measured				
Unaided Predicted				
Aided Measured				
Unaided Predicted				

Date (unaided): Age at time of assessment:
Date (aided): Age at time of assessment:

Behavioral thresholds				
	500 Hz	1000 Hz	2000 Hz	4000 Hz
Unaided BT				
Aided BT				

Date (unaided): Age at time of assessment:
Date (aided): Age at time of assessment: