# 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.

[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<br>Moderate in left ear |
| ***3*** | Female | 6 months | Severe in right ear<br>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:<br>• High forehead - positive<br>• Mastoids – negative<br>• 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,<br>Blackman ramping 2-1-2 cycles | Purdy & Abbas (2002:359);<br>Stapells (2000a:17);<br>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:<br>• High forehead - positive<br>• Mastoids – negative<br>• 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 | Cone-Wesson et al. (2002:178); Vander Werff et al. (2002:230). |
| | 74 | 81 | 88 | 95 | |
| **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:<br>• High forehead - positive<br>• Mastoids – negative<br>• 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.

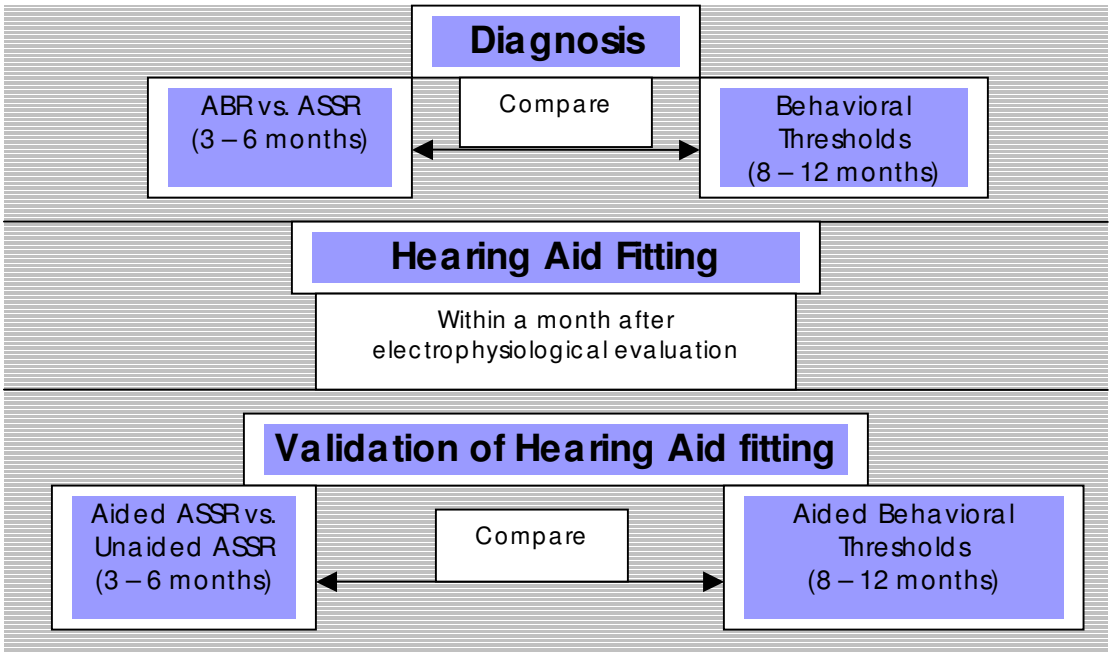


**Figure 3.1 Schematic representations of the data collection procedures**

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.