CHAPTER 5

RESEARCH METHODS

AIM

This chapter's aim is to describe and justify the methodology followed in the empirical research of the study. The end goal is to answer the research question: What is the clinical value of ASSRs in the audiological evaluation of pseudohypacusic mine workers with noise-induced hearing loss?

5.1 INTRODUCTION

The research question put forward in Chapter 1 centres around the clinical value of auditory steady state response methods in audiological assessments of pseudohypacusic mine workers with noise-induced hearing loss.

In the South African mining industry a large number of workers (between 68 and 80 per cent) are exposed at equivalent levels of noise exceeding 85 dB (Franz & Phillips, 2001). The high incidence of noise-induced hearing loss, combined with workers' awareness of noise-induced hearing loss compensation, creates a situation in which workers commonly exaggerate symptoms of their hearing loss for compensation purposes. Conventional assessment methods available to audiologists currently fail to provide accurate and reliable hearing thresholds in such cases, delaying the conclusion of some claims and, in all likelihood, resulting in overcompensation of others.

Promising alternative methods to address the current situation include auditory tests utilizing evoked potentials (AEPs: Chapter 3) and more specifically auditory steady state response testing (ASSRs: Chapter 4). The need to be met is for a once-off test, capable of concluding diagnostic procedures, for pseudohypacusic

workers by estimating accurate hearing thresholds for compensation claims and "fitness-for-duty" assessments. According to most of the literature reviewed, ASSR testing provides an accurate means of predicting pure-tone hearing thresholds without any need for the patient to respond to the sound - thus providing a possible solution to the research question.

In a survey of the literature it has become clear that primarily two modulation frequencies have been used in research with ASSRs, that is 40 Hz (Stapells *et al.,* 1984) and 80 to 110 Hz (Lins & Picton, 1995). There are also currently two stimulation methods namely monotic (Rickards *et al*., 1994) and dichotic (Perez-Abalo *et al.,* 2001). These presentation variations need to be taken into consideration when planning empirical research in this field. The fact that auditory evoked potentials are affected by the state of consciousness of the patient (Dobie & Wilson, 1998) is another important aspect to incorporate in the research design especially in situations were the co-operation or lack of co-operation of the patient is a factor that can influence the assessment outcome. It is thus clear that empirical research designed to answer the stated research question will of necessity be complex and involved.

5.2 AIMS OF THE RESEARCH

The aims of the present research are detailed in the sections below:

5.2.1 PRINCIPAL AIM

The principal aim of the study was to determine the clinical value of ASSR methods in the hearing assessment of pseudohypacusic mine workers presenting with noise-induced hearing loss.

Roeser *et al*. (2000b) drew attention to the fact that the effectiveness of an audiological test needs to be evaluated. The same authors stated that tests

could be evaluated to decide on validity, reliability, sensitivity and specificity. An audiological test's value lies in its ability to perform as intended. In order to determine the value of ASSR tests the norm for "clinical value" was the threshold estimation ability of this procedure. Could ASSR tests accurately estimate pure-tone thresholds in a pseudohypacusic population in order to conclude diagnostic procedures and thus facilitate in correct and meaningful recommendations regarding rehabilitation?

Apart from the clinical efficiency in estimating thresholds, the cost- and time efficiency of ASSR methods will also aid in decisions related to the ultimate value of the specific method.

5.2.2 SUB AIMS

The principal aim of the study, to decide on the threshold estimation ability of ASSRs in a pseudohypacusic population, can only be attempted if ASSRs have been validated in an adult mine worker population with noise-induced hearing loss. Since this procedure has not been validated in this population the sub-aims are:

5.2.2.1 To compare ASSR and pure-tone thresholds in a co-operative population of adult mine workers with sensory neural hearing loss

The clinical value of ASSR techniques, in other words the ability to estimate pure-tone thresholds, has to be investigated for co-operative noise-exposed mine workers and specifically those with identified noise-induced hearing loss. The pure-tone and ASSR threshold estimates of all the subjects need to be compared in order to evaluate the effectiveness of ASSRs in estimating pure-tone thresholds. All the frequencies specified in legislation for the mining industry should be tested, namely, 500, 1 000, 2 000, 3 000 and 4 000 Hz (RMA guidelines, 2003) and in both ears.

5.2.2.2 To compare the accuracy of multiple-frequency (dichotic) and single frequency (monotic) ASSR stimulation methods in estimating pure-tone thresholds in a mine worker population

The effectiveness of multiple-frequency (MF) ASSR and single frequency ASSR methods for threshold estimates should be compared in order to make recommendations regarding the most effective method possible. The reason being that time saving is an important factor in an industry with large case loads. The ASSR threshold estimates for both these stimulation methods are compared to pure-tone thresholds. Comparing the testing time of both stimulation methods will also be an indication of the stimulation method of choice.

5.2.2.3 To compare different modulation frequencies' effectiveness in estimating pure-tone thresholds

Modulation frequencies of 40 and 80 to 110 Hz are usually used in ASSR testing. Threshold estimates obtained when using the different modulation frequencies are compared to pure-tone thresholds. A decision regarding the most accurate and time effective modulation frequency for carrier frequencies in ASSR testing of adults with impaired hearing is then possible.

5.2.2.4 To determine the effect of sedation on the ASSR test's ability to estimate pure-tone thresholds

In order to evaluate the effect of sedation on the threshold estimates obtained with ASSR tests, the threshold estimates' accuracy with and without sedation needs to be compared. The testing time with and without sedation will aid in the above decision.

The reason why a study of the effect of sedation is needed is that the 40 Hz response will be used in the experimental phase. There are contradictory research results with regard to the effect of sedation on the 40 Hz response. The dramatic effect of sleep and state of consciousness on the 40 Hz response has

been cited by Galambos *et al*. (1981). Dobie and Wilson (1998) in comparison could find no real negative influence of sedation on the 40 Hz response of adults. See Section 4.3.14.

5.2.2.5 To determine if pure-tone threshold estimates can be obtained in unco-operative mine workers

In a clinical situation pseudohypacusic patients do not co-operate and accurate hearing thresholds cannot be obtained. ASSR methods were used in a group of unco-operative mine workers to investigate if thresholds could be obtained. ASSR thresholds were compared to pseudohypacusic pure-tone thresholds and the information gained from the ASSR thresholds were analyzed in order to obtain clinical information.

5.3 RESEARCH PLAN

The discussion below focuses on the research design as the strategic framework for action that serves as a bridge between the research question and the execution of the research (Dane, 1990).

An empirical study was conducted. Mouton (2001) describes an empirical study as the use of primary and numerical data with high control. Sources of data used in this study were physical measurements: in this case auditory thresholds. An experimental research method was also selected for this study (Leedy, 1997). In experimental research, the researcher attempts to maintain control over all the factors that may affect the result of an experiment (Key, 1997). The strength of an experimental design lies in its ability to infer causality and test causal relationships. One limitation of an experimental design that needs to be addressed is the fact that small sample sizes make generalisability risky (Mouton, 2001).

The research was also quantitative. Berg (1998) explains that quantitative research has to provide rigorous, reliable and verifiably large aggregates of data,

and that quantitative research can be regarded as a formal and systematic process. In this study, the experimental research process was pursued by using a quasi-experimental design, as described by De Vos (2002). The main disadvantage of this method is the lack of a control group – the difficulty with including a control group in this study or doing different ASSR procedures on the same group was the lengthiness of these procedures. To prevent bias from creeping in, it was therefore important to ensure a random allocation of subjects to different sub-groups.

In order to answer the research question and to meet the research aims set out in Section 5.2 (the clinical value of ASSR testing in a population of pseudohypacusic mine workers with noise-induced hearing loss), a multi-group design was followed (De Vos, 2002): six experimental groups were organised and utilised in two research phases. Groups 1,1 to 1,5 were mine workers (co-operative) with proven noise-induced hearing loss and Group 2 were non-co-operative mine workers with suspected pseudohypacusis. The research plan is logically set out in Table 5.1.

TABLE 5.1: RESEARCH PLAN: PHASES, EXPERIMENTAL GROUPS AND EXPERIMENTAL PARAMETERS

Research phase	Experimental groups	Instrument	Modulation frequency (Hz)	Monotic/dichotic Stimulation	Sedation	Number of subjects	Type of hearing loss
Phase 1	1,1	Audera	80-110	Monotic	No	12 (subject 1-12)	NIHL
	1,2	Audera	40	Monotic	No	16 (subject 13-28)	NIHL
	1,3	MASTER Biologic	80-110	Dichotic	No	20 (subject 29-48)	NIHL
	1,4	Audera	40	Monotic	Yes	13 (subject 49-61)	NIHL
	1,5	MASTER Biologic	80-110	Dichotic	Yes	20 (subject 62-81)	NIHL
Phase 2	2	Audera	40	Monotic	No	29 (subject 82-119)	Pseudohy-pacusis

Different ASSR test procedures were used on the different groups in order to compare the different methods' ability to estimate pure-tone thresholds.

The selection and grouping of the 81 subjects for Phase 1 (co-operative subjects with noise-induced hearing loss) in the different groups listed (Table 5.1) enabled the following comparisons:

- All 81 subjects' pure-tone and ASSR thresholds (Groups 1.1, 1.2, 1.3, 1.4 and 1.5) could be compared to decide whether ASSR thresholds can estimate pure-tone thresholds accurately.
- ASSR-thresholds' accuracy, obtained with an 80 to 110 Hz stimulation rate (1.1, 1.3 and 1.5) (Rickards & Clark, 1984) could be compared to the

ASSR thresholds' accuracy obtained using a 40 Hz stimulation rate (Groups 1.2 and 1.4) (Rance *et al.*, 1995).

- A comparison of the prediction value of ASSR thresholds was possible when multiple frequency and single frequency ASSR procedures were followed (Groups 1.1, 1.2, 1.4 vs 1.3 and 1.5) (Perez-Abalo *et al.*, 2001 and Rance *et al.*, 1995).
- Lastly, a comparison between the ASSR and pure-tone thresholds was possible between sedated and non-sedated subjects (Groups 1.1, 1.2 and 1.3 *versus* Groups 1.4 and 1.5).

The testing of subjects in Phase 1 was used to determine the most effective test equipment, stimulation rate and stimulation method (multiple- or single frequency), as well as the effect of sedation, thereby establishing a protocol of choice for a population with noise-induced hearing loss.

- The last experimental group was a group of mine workers (29) with known noise-exposure but who were not co-operating and for whom thus no pure-tone thresholds were available (Phase 2). The goal was to determine whether ASSR thresholds can be obtained for unco-operative subjects. The questions to be answered were whether thresholds can be obtained at all the needed frequencies for unco-operative patients and in what space of time this can be done.

A total of 110 subjects participated in the study.

5.4 ETHICAL CONSIDERATIONS

Ethical concerns need to be taken into account in order for research to be conducted in a manner which is fair to all the participants and employers. Furthermore research ethics, according to Neuman (1997), define what is legitimate and moral during research. For the purposes of this study, the

following ethical aspects were taken into account: willing participation, informed consent, permission for the use of sedation, employers' permission and ethical clearance. These aspects are discussed in more detail below.

5.4.1 WILLING PARTICIPATION

Subjects were assured that if they chose not to participate in the study, they would not be disadvantaged in any way. Workers who did not wish to participate were routed back for a continuation of standard medical surveillance procedures. Subjects were not coerced or manipulated into volunteering, in line with the principles set out by Berg (1998). Subjects were also able to withdraw from the research whenever they chose to do so, in accordance with the ideas of Strydom (1998).

5.4.2 INFORMED CONSENT

Informed consent was obtained in writing from each subject (see Appendix A for the form used). Obtaining such consent implies that the worker was informed about the goal of the investigation and the procedures followed. The presentation of accurate and complete information was emphasised, so that subjects fully comprehended the investigation, in accordance with suggestions by De Vos (2002). The subjects' comprehension of the procedure was aided by providing a trained African languages translator. Voluntary participation was the goal and subjects were assured of anonymous participation.

5.4.3 CONSENT TO SEDATION

Apart from the informed consent obtained as stated in Section 5.4.2 (above), subjects who would be sedated were supplied with a patient information sheet on the effect of the medication (see Appendix B). Additional consent (see Appendix B) for this participation was also obtained in writing with the help of a translator. The subjects who gave consent were then referred to an Ear-, Nose- and Throat

specialist or occupational medical practitioner (OMP) who perused the subjects' medical history and prescribed the sedation. The sedation of the subjects took place at Occupational Health Centres (OHCs) where an OMP was on duty. After their participation, the subjects were transported back to their hostels. They only returned to work the following day.

5.4.4 EMPLOYERS' PERMISSION

Permission to involve their employees was obtained from the mining companies whose workers participated (Gold Fields - see Appendix C, and Harmony - see Appendix D).

5.4.5 ETHICAL CLEARANCE

Ethical clearance was obtained from the University of Pretoria's Ethics Committee (Faculty of Humanities) and the Research Committee of the Department of Communication Pathology (see Appendix E).

5.5 SUBJECTS

5.5.1 POPULATION

The population of this study, in other words, all the individuals who possessed the specific characteristics that represent the measurements of interest in the study as described by De Vos (2002) were South African mine workers with noise-induced hearing loss (Phase 1) and pseudohypacusic South African mine workers (Phase 2). A population of mine workers was selected from workers undergoing their annual Certificate of Fitness assessments at their mines' Occupational Health Centres in the Randfontein and Carletonville areas. All the subjects worked underground and, hence, had been exposed to hazardous noise (Franz & Phillips, 2001).

5.5.2 SAMPLING

Results from a study can only be generalised if the sample tested is seen to be representative of the population. A sample is, in other words, a small portion of the total set of persons that comprise the subject of the study (De Vos, 2002). The reason for sampling is feasibility, since it is impossible to include all the possible members of a population of this nature.

Non-probability quota sampling (Neuman, 1997; De Vos, 2002) was used in this study, in other words, in the selection of an underground mine worker in the predetermined group. Any subjects who happened to undergo medical surveillance at the OHC and who had noise-induced hearing loss and worked underground were included in the sample. All potential subjects complying with the selection criteria were selected, within the time constraints imposed by the length of a working day and the lengthy test procedures. A three-month period was allowed for the experimental research, from September to November 2002.

The objective was to conduct experimental testing on the same day as medical surveillance procedures, to prevent interference with normal production at the mines. It was not always possible to achieve this, particularly with subjects who had been sedated, since the occupational medical practitioner had to peruse the worker's medical history and prescribe the sedation.

A total of 81 male subjects (162 ears) between the ages of 23 and 60 were selected for the first phase of the research and 29 (58 ears) were selected for the pseudohypacusic group. The sample size was verified by a statistician of the Medical Research Council (Pretoria).

5.5.3 CHARACTERISTICS OF SUBJECTS AND THE PROCEDURES FOLLOWED IN THE SELECTION OF THESE SUBJECTS

5.5.3.1 Occupation

Subjects had to be mine workers (in a gold mine) allocated to underground duties and therefore exposed to hazardous noise. Noise exposure was important since the study aimed to evaluate the effectiveness of ASSR techniques in subjects with noise-induced hearing loss. Occupational Health Centre staff verified that these workers did indeed work underground.

5.5.3.2 Abnormal hearing with and without a functional overlay

As mentioned previously, the population under scrutiny was one of mine workers with proven noise-induced hearing loss. The subjects had to have sensory neural hearing loss (no persons with mixed and conductive hearing losses were selected) and proven noise exposure of more than five years (Begley, 2003). In order to confirm exposure to hazardous noise and exclude other possible causes of sensory-neural hearing loss (for example, ototoxic drugs, ear infection and head injury), a case history (see Appendix G) was compiled and recorded by a trained African languages translator.

Based on the aims of the study, it is clear that the subjects in the study had to have hearing loss. Subjects (without a functional overlay) were required to have a pure-tone average exceeding 25 dB (500, 1 000, 2 000, 3 000 Hz) thereby qualifying them for consideration for noise-induced hearing loss compensation. This criterion was derived from the legislation implemented in the South African mining industry at the time when the experimental research was done, namely the Workmen's Compensation Commissioner's (WCC) internal instruction 168, 1995. Hearing loss is also commonly defined in the literature as hearing thresholds worse than 25 dB (Northern & Downs, 1991). The initial selection was done on the basis of the results of the screening hearing test done during medical surveillance. Pure-tone air- and bone conduction audiograms performed

by audiologists in a controlled environment on the same subjects served as a confirmation of the screening thresholds.

A group of pseudohypacusic workers (functional overlay) was also evaluated. By definition their true hearing status was unknown since they exaggerate their true hearing thresholds (Martin, 2000). Two pure-tone audiograms were performed at 500, 1 000, 2 000, 3 000 and 4 000 Hz, to enable threshold comparisons for the purpose of identifying pseudohypacusis. A difference of 15 dB or more (Rintelmann *et al.*, 1991) at all the frequencies and in both ears was regarded as an indication of pseudohypacusis. The two audiograms recorded used different threshold determining techniques, namely the ascending (first procedure) and descending methods (Rintelmann *et al.,* 1991). The two audiograms were performed by the same audiologist in the same environment during two consecutive test sessions. This group of workers also had to have normal middle ear function to exclude conductive hearing loss and proven noise exposure to fit into the category of mine workers with sensory neural hearing loss.

5.5.3.3 Normal middle ear function

Normal middle ear function was a prerequisite for subject selection. The findings of Hood (1995) and Hall and Mueller (1997) have indicated that middle ear pathology affects ASSR amplitude. To exclude cases of middle ear pathology and conductive impairment, subjects had to have normal middle ear function. Furthermore, normal middle ear function was also included as a criterion since a population of people with noise-induced hearing loss was the focus of the study.

Middle ear function was assessed by means of tympanometry. The following selection criteria (indicating normal middle ear functioning) were applied to the tympanometry results:

- ear canal volume: 0,5-1,5 cc;
- compliance: 0,3-1,6 cc (Stach, 1998);
- Type A tympanograms – Northern and Downs (1991) define Type A tympanograms as adequate compliance and normal middle ear pressure at the point of maximal compliance. Normal middle ear pressure was taken as –50 mm to +50 mm H2O.

Normal middle ear function was further verified by otoscopy. Otoscopic examinations were performed on both ears for each subject, to identify any middle ear/tympanic membrane pathology or obstruction of the external auditory meatus that could affect the conduction of sound, as proposed by Stach (1998).

Finally, an air-bone gap of 10 dB indicating possible middle ear abnormalities excluded some subjects (Roeser *et al*., 2000b).

5.5.3.4 Age and gender

All the subjects were male. This was not a prerequisite of the study but arose from the fact that the vast majority of mine workers in South Africa are traditionally male. Stapells *et al.* (1984) have proven that there is an absence of gender bias with ASSR testing and thus the results will be applicable to both sexes. Because Hood (1998) has shown that electrophysiological tests show no age effects between 10 and 60 years, it was required that the age of all subjects be within this range. This requirement was easily met, since the working age of mine workers is between 18 and 60 years. The age information was obtained from patient files and the case history information (see Appendix G).

5.5.4 DESCRIPTION OF SUBJECTS

The subjects who eventually participated in this study and their characteristics are described in the following tables and figures.

5.5.4.1 Hearing thresholds - co-operative group

Table 5.2 supplies hearing thresholds in decibels at all the frequencies required for the subjects with noise-induced hearing loss without a functional overlay.

TABLE 5.2: HEARING THRESHOLDS (DECIBEL)(HL) FOR THE CO-OPERATIVE GROUP

PURE-TONE THRESHOLDS FOR LEFT EAR					PURE-TONE THRESHOLDS FOR RIGHT EAR					
500Hz	1000Hz	2000Hz	3000Hz	4000Hz	500Hz	1000Hz	2000Hz	3000Hz	4000Hz	Subject
60	80	60	55	65	40	70	60	55	70	1
20	45	55	50	50	20	45	40	40	45	2
35	45	50	35	30	30	40	40	35	30	3
10	50	55	55	60	10	45	50	60	50	4
15	25	45	55	65	20	20	25	50	60	5
5	5	40	65	80	5	10	35	70	70	6
15	40	50	75	75	25	30	30	50	55	7
15	25	30	35	35	15	30	35	30	30	8
30	45	45	50	50	25	40	40	45	50	9
20	20	20	30	35	15	25	20	30	30	10
30	45	35	40	45	30	40	45	35	45	11
35	40	35	35	40	30	30	20	40	45	12
10	15	50	55	55	10	15	50	65	50	13
40	45	40	70	75	30	45	35	45	55	14
20	45	70	80	70	10	35	60	60	55	15
25	35	45	50	50	20	40	45	50	55	16
15	35	40	45	40	5	25	40	45	45	17
25	40	35	30	40	25	40	25	35	35	18
10	30	45	35	35	5	35	45	35	35	19
15	35	45	45	40	10	20	35	40	40	20
15	45	35	25	40	20	50	55	55	50	21
40	50	55	65	70	25	50	50	60	65	22

PURE-TONE THRESHOLDS FOR LEFT EAR					PURE-TONE THRESHOLDS FOR RIGHT EAR					
500Hz	1000Hz	2000Hz	3000Hz	4000Hz	500Hz	1000Hz	2000Hz	3000Hz	4000Hz	Subject
10	30	45	50	50	30	25	40	45	65	23
50	50	40	15	25	50	50	40	20	15	24
20	25	45	35	40	5	15	25	25	30	25
30	45	50	55	55	30	50	50	60	60	26
20	35	35	40	45	20	35	45	40	45	27
35	40	35	35	40	30	30	20	40	45	28
45	55	55	50	50	35	60	55	55	60	29
10	30	40	50	40	15	15	35	45	30	30
40	40	35	25	25	45	55	50	50	50	31
20	30	35	35	25	15	30	40	20	25	32
10	30	50	55	65	10	20	50	50	65	33
5	15	50	45	45	5	20	35	40	55	34
30	40	35	30	25	30	25	35	30	40	35
10	45	60	45	50	5	45	60	55	60	36
15	25	55	60	80	5	5	35	50	80	37
30	40	60	65	65	20	25	30	45	55	38
20	25	30	55	65	15	25	35	60	90	39
30	40	50	50	55	25	30	50	50	50	40
30	45	40	50	35	30	35	30	30	45	41
15	25	45	45	50	20	30	45	55	55	42
15	20	50	45	45	10	25	30	60	65	43
45	65	65	70	75	45	55	55	65	75	44
0	30	50	60	55	0	20	30	65	50	45
10	45	45	50	50	10	35	45	55	40	46
25	20	35	55	60	20	50	50	45	55	47
30	45	40	50	40	30	45	40	35	35	48
5	10	30	40	45	10	15	40	40	45	49
30	55	60	60	60	35	50	50	60	65	50
15	20	35	40	40	15	30	35	45	50	51

PURE-TONE THRESHOLDS FOR LEFT EAR					PURE-TONE THRESHOLD FOR RIGHT EAR					
500Hz	1000Hz	2000Hz	3000Hz	4000Hz	500Hz	1000Hz	2000Hz	3000Hz	4000Hz	Subject
10	20	35	55	50	15	20	35	45	55	52
20	50	50	50	55	30	50	45	45	55	53
15	65	75	70	65	30	65	75	75	80	54
5	20	30	35	40	20	30	50	55	50	55
15	40	45	55	50	15	45	55	50	50	56
25	45	55	60	65	25	35	55	65	65	57
5	15	15	85	85	15	20	10	75	85	58
30	35	30	50	60	30	45	45	55	50	59
10	30	45	45	45	10	30	40	50	40	60
20	40	45	50	40	5	15	35	40	30	61
20	40	60	60	55	10	30	55	55	40	62
35	40	55	55	75	25	40	35	40	65	63
20	40	45	55	50	10	35	40	45	55	64
15	50	50	45	50	20	45	50	45	55	65
15	25	75	75	75	10	25	55	45	45	66
20	55	50	60	60	25	50	55	60	60	67
15	40	45	40	40	25	40	45	45	50	68
25	45	45	50	35	30	45	45	50	45	69
0	25	40	50	60	5	20	35	50	65	70
15	20	40	30	25	15	25	45	40	40	71
30	40	40	40	50	25	35	55	65	60	72
25	40	35	35	40	30	40	40	35	40	73
30	40	50	50	60	25	30	50	55	65	74
20	45	55	50	50	20	45	45	45	55	75
15	40	50	50	50	20	40	45	40	50	76
30	30	35	55	50	20	50	60	55	65	77
20	40	45	30	30	20	45	35	35	20	78
30	40	45	40	45	30	40	45	40	45	79
10	35	55	45	35	10	25	40	40	45	80
30	60	50	50	45	35	60	55	50	50	81

To summarise the information in the above table: it can be seen that the subjects had hearing thresholds representing different degrees of hearing loss, ranging from mild (26-40dB), moderate (41-65dB) to severe (66-95dB). The numbers of hearing thresholds per frequency in the different severity ranges were the following:

- Mild hearing thresholds – 251.
- Thresholds indicating moderate hearing loss – 346.
- Thresholds indicating severe hearing loss – 32.
- Due to the sloping nature of sensory-neural hearing loss, 181 normal thresholds (0-25dB) were also obtained, mainly in the 500 Hz area.

5.5.4.2 Age of co-operative group

The subjects were 81 male mine workers with noise-induced hearing loss between the ages of 23 and 60 years. Figures 5.1 to 5.5 represent the age distributions of mine workers with noise-induced hearing loss across five-year age intervals. The subjects were randomly assigned to different groups to study the influence of different ASSR-equipment and techniques on the comparison of the ASSR and pure-tone thresholds. The structure for this was already indicated in Table 5.1.

In addition, in Figures 5.7 to 5.12, the participants' years of noise exposure in the mining industry and their age is indicated for the different research groups and the different experimental phases.

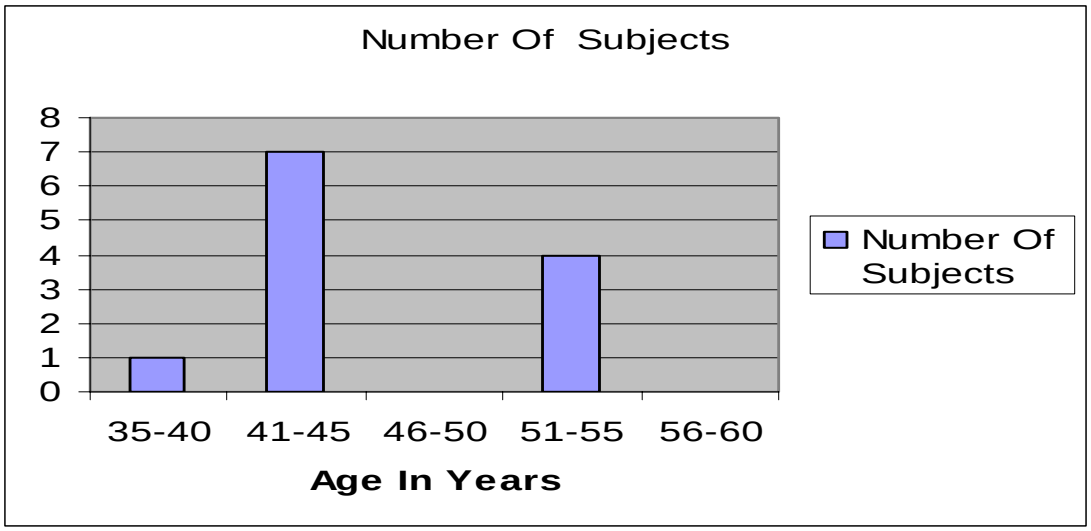

FIGURE 5.1: AGE DISTRIBUTION OF THE SF/80 HZ/NON-SEDATED GROUP (n=12): MEAN AGE 45,8 YEARS

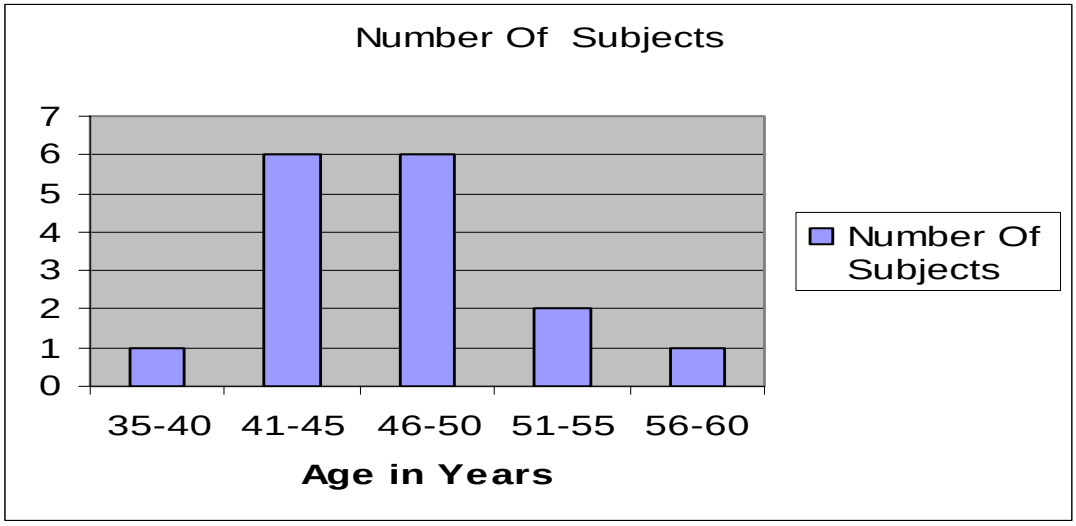

FIGURE 5.2: AGE DISTRIBUTION OF THE SF/40 HZ/NON-SEDATED GROUP (n=16): MEAN AGE 47,5 YEARS

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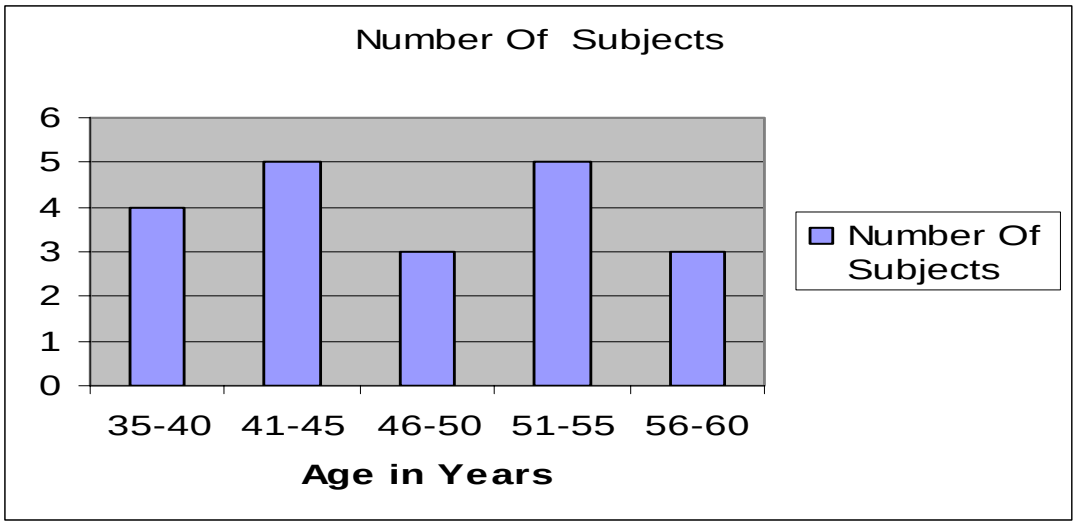

FIGURE 5.3: AGE DISTRIBUTION OF THE MF/80 HZ/NON-SEDATED GROUP (n=20): MEAN AGE 46,38 YEARS

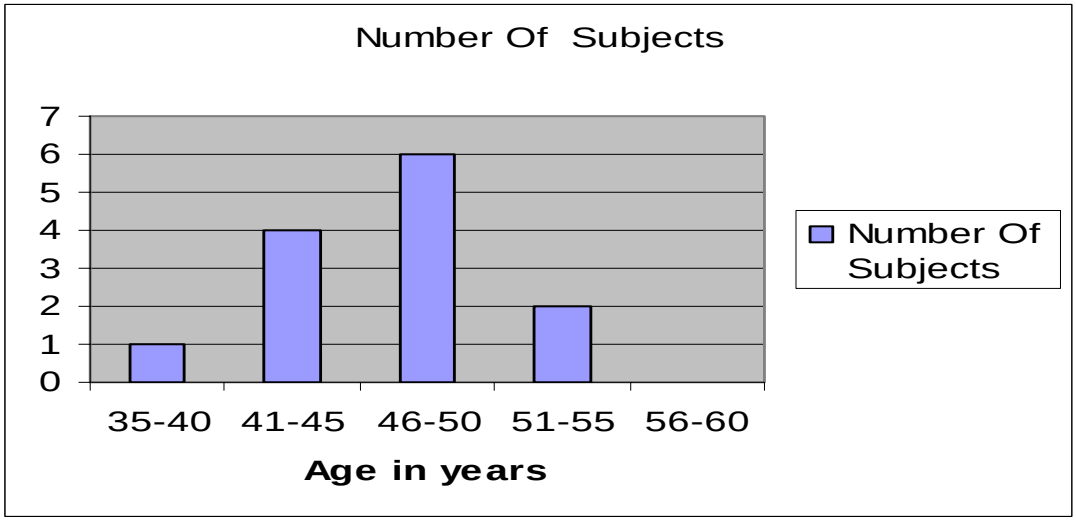

FIGURE 5.4: AGE DISTRIBUTION OF THE SF/40 HZ/SEDATED GROUP (n=13): MEAN AGE 47,3 YEARS

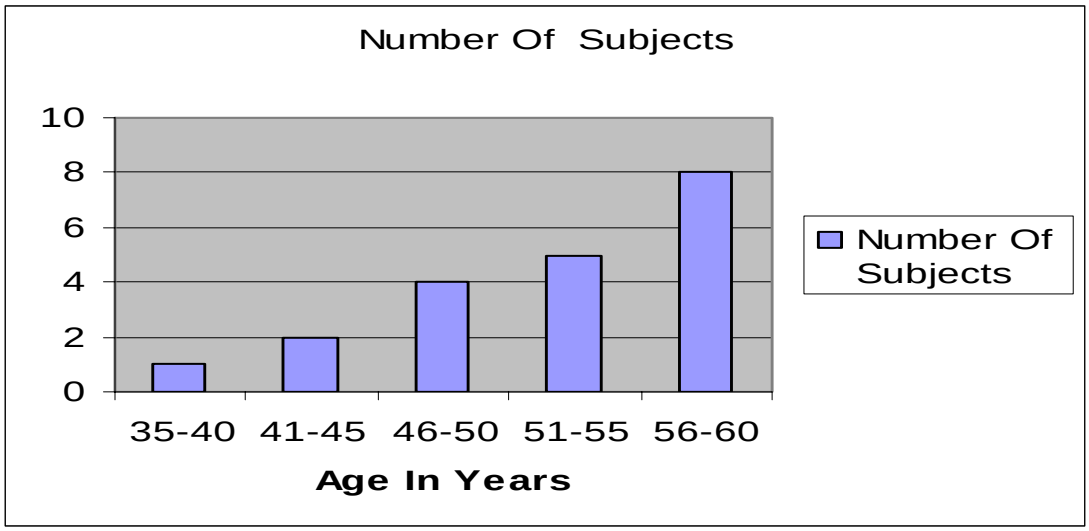

FIGURE 5.5: AGE DISTRIBUTION OF THE MF/80 HZ/SEDATED GROUP (n=20): MEAN AGE 52 YEARS

5.5.4.3 Age distribution of pseudohypacusic group

The group of mine workers with pseudohypacusis consisted of 29 subjects. In Figure 5.6, the age distribution of this group is shown.

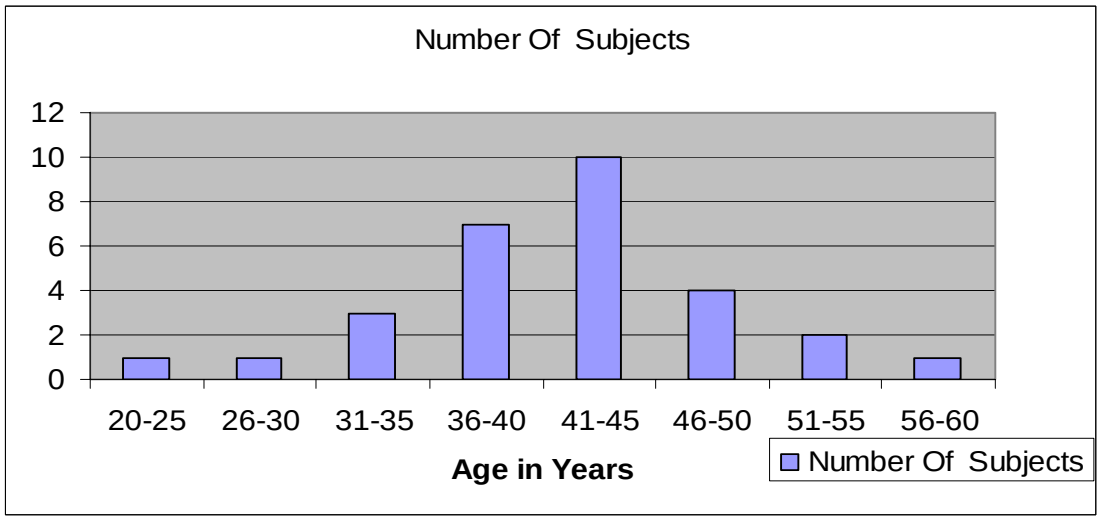

FIGURE 5.6: AGE DISTRIBUTION OF PSEUDOHYPACUSIC GROUP (n=29): MEAN AGE 41,86

5.5.4.4 Years of experience/exposure

Figures 5.7 to 5.11 represent the experience and hence period of exposure for various sub-groups within the experimental groups.

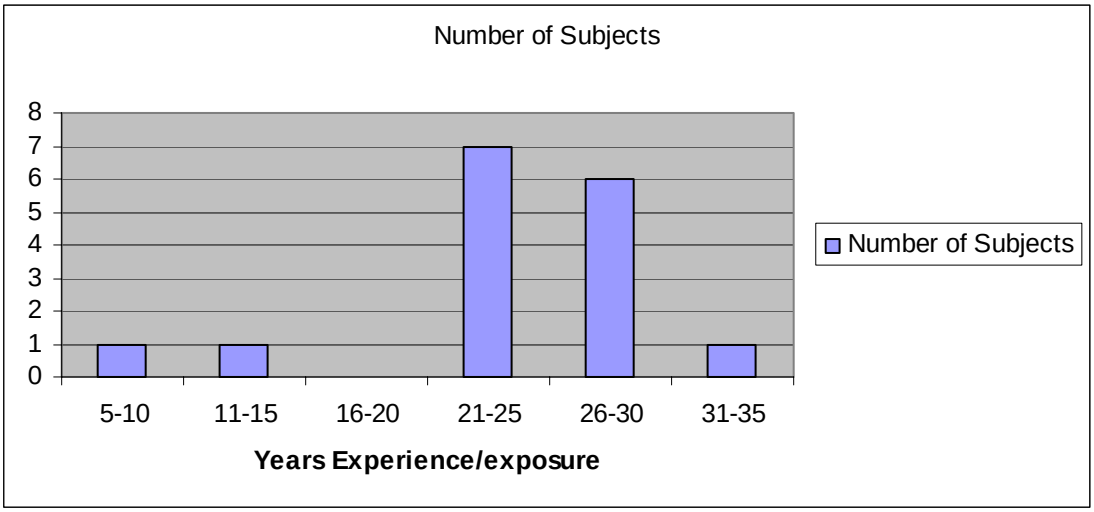

FIGURE 5.7: EXPERIENCE/EXPOSURE: SF/80 HZ/NON-SEDATED GROUP

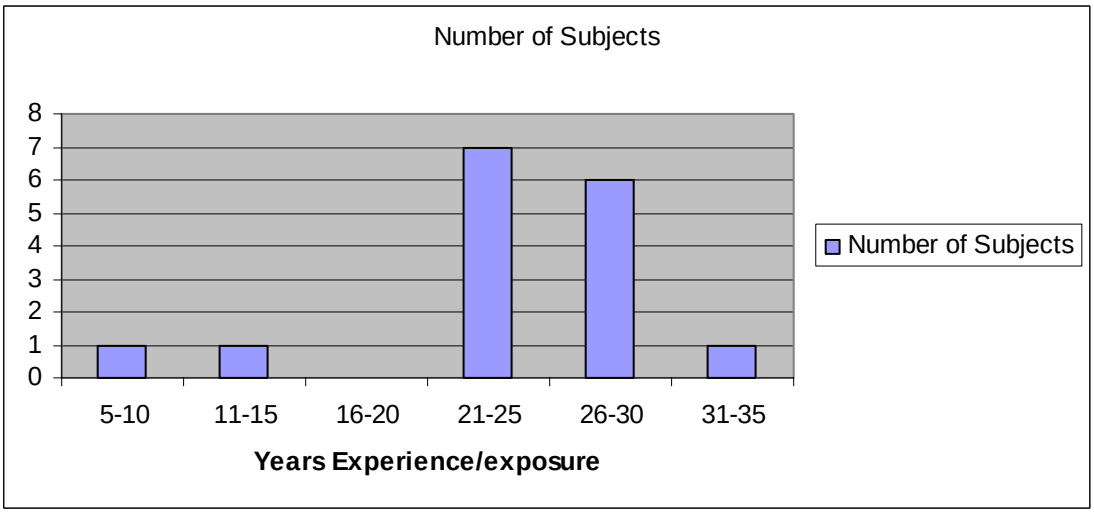

FIGURE 5.8: EXPERIENCE/EXPOSURE: SF/40 HZ/NON-SEDATED GROUP

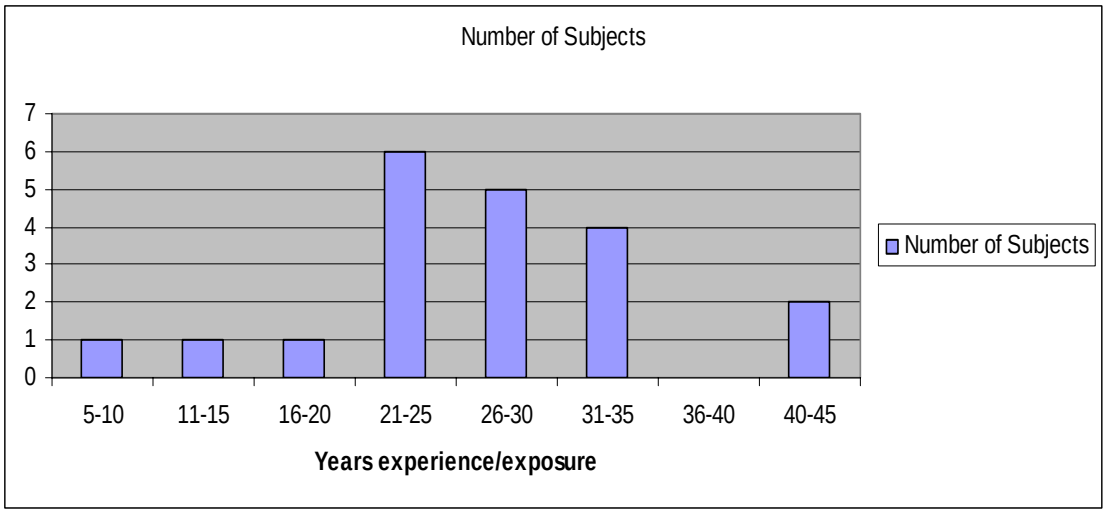

FIGURE 5.9: EXPERIENCE/EXPOSURE: MF/80 HZ/NON-SEDATED GROUP

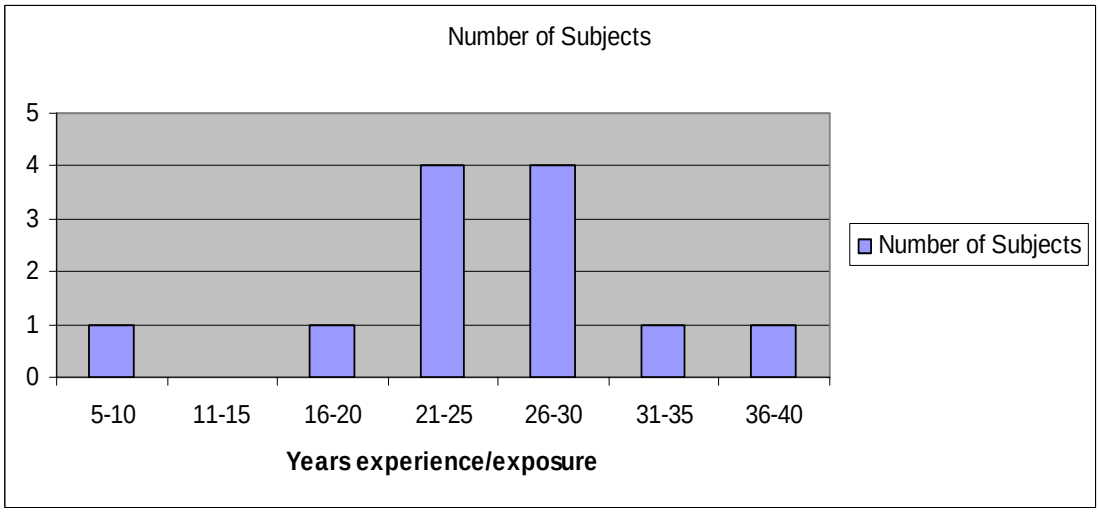

FIGURE 5.10: EXPERIENCE/EXPOSURE: SF/40 HZ/SEDATED GROUP

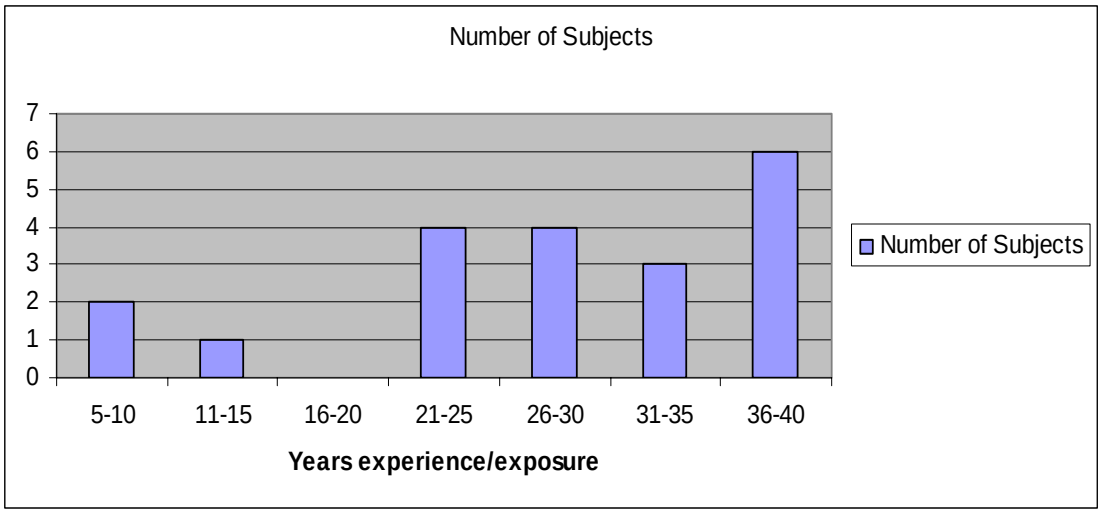

FIGURE 5.11: EXPERIENCE/EXPOSURE: MF/80 HZ/SEDATED GROUP

5.5.4.5 Experience of pseudohypacusic group

The group of mine workers with pseudohypacusis consisted of 29 subjects, distributed by experience, as can be seen in Figure 5.12 below.

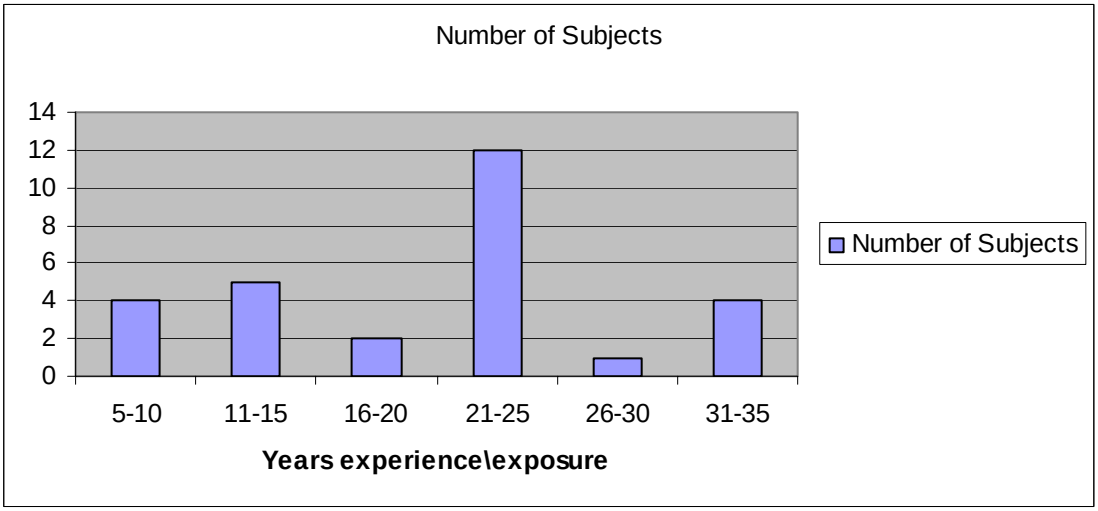

FIGURE 5.12: EXPERIENCE/EXPOSURE: PSEUDOHYPACUSIC GROUP

5.6 MATERIAL AND APPARATUS

The apparatus used in this study to obtain the research questions was the following:

5.6.1 THE MATERIAL AND APPARATUS USED FOR SUBJECT SELECTION

- Otoscopic examinations were performed using a **Heine Mini 2000** otoscope.
- Tympanometry was performed with a **GSI 33 middle ear analyser** and a **Beltone 2000 immittance tester**, both of which were calibrated (certificates in Appendices H and I) according to IEC 1027 regulations.
- Pure-tone audiometry (air- and bone-conduction) was performed by audiologists using a **Madsen OB 822** and **GSI 60 diagnostic audiometers.** This equipment was calibrated in accordance with SABS 0154-1 & 2 for pure-tone audiometers (the calibration certificates are appended as Appendices J and K).
- Diagnostic audiometry was performed in acoustically-treated test enclosures, calibrated in accordance with SABS 0182-1998 (the background noise certificates are appended as Appendices L and M).
- The patient files of the mine workers were perused at the Occupational Health Centres. The files were used to verify the participants' number of years of exposure and the use of ototoxic drugs and to obtain previous screening audiograms.
- A Case History questionnaire (see Appendix G) was used to exclude all other possible causes of sensory neural hearing loss and record all experimental procedures.

5.6.2 THE MATERIAL AND APPARATUS USED FOR DATA COLLECTION

5.6.2.1 Pure-tone testing

Pure-tone thresholds were obtained using the same calibrated audiometers and acoustic enclosures as detailed in the preceding section, that is a **Madsen OB 822** and a **GSI 60.** The calibration certificates are appended as Appendices J and K.

5.6.2.2 MF-ASSR testing

MF-ASSR responses were recorded using a multiple auditory steady state response system (MASTER), a Windows-based test and a data acquisition system developed by the Bio-logic Systems Corporation (2002). The MASTER system includes both software and hardware and is run using a personal computer. Bio-Logic's Navigator Pro TM unit performed the necessary analogue-to-digital and digital-to-analogue conversions, including the production of the stimulus output to earphone inserts and the gathering of the electroencephalogram input from the electrodes. The Navigator Pro was connected to the computer's serial port in order for the RS-232 communication protocol to be used. The computer hardware specifications were the following:

COMPUTER SYSTEM:

- an IBM-compatible 166 MHz Pentium computer
- 64 MB of RAM
- a 150 MB hard disk
- a Windows-compatible mouse
- a Windows 98 Operating system
- a 1.44 Mb 3,5" floppy disk drive

The installation and operation of the MASTER system requires a minimum of 20 MB free space on the hard drive (Bio-logic Systems Corporation, 2002).

PRINTING DEVICE:

- a Windows 98-compatible printer (Hewlett Packard DeskJet 840C).

OTHER HARDWARE:

- a Navigator Pro TM EP unit and accessories.

Disposable ear probe tips were supplied by Bio-logic Systems Corporation. The electrodes were latex-free and made of hypoallergenic material.

ASSR measurements were obtained in a calibrated environment, for which calibration certificates are supplied in Appendices L and M.

5.6.2.3 Single frequency ASSR testing

SF-ASSR data were collected using a GSI Audera system, manufactured by Grason-Stadler. The Audera system comprises:

- a notebook computer system with a Pentium II 200 MHz processor, 256 MB of RAM, a 5 GB hard disk, a 1,4 MB 3,5" diskette drive and pointing device (mouse/touch pad), running Windows XP;
- a USB connector;
- Audera software;
- an Audera unit;
- an Audera amplifier;
- electrodes; and
- GSI tip-50 inserts earphones with disposable ear tips.

Two Audera systems were used, a Beta prototype and a commercial production unit, because Grason-Stadler's South African agent (HASS) lent the equipment to the researcher and it was not possible to keep it on loan for the entire three-

month experimentation period. The Beta unit was a single channel instrument, requiring the researcher to switch channels after testing each ear.

5.6.2.4 Data preparation

Data preparation was performed using Excel for Windows 1998 (Levin, 2003).

5.7 DATA COLLECTION PROCEDURES

Three sets of data were collected from each subject in the co-operative noise-induced hearing loss group (Phase 1), namely a pure-tone air-conduction test (500, 1 000, 2 000, 3 000, 4 000 Hz), ASSR threshold estimates at the same frequencies and the test duration for each ASSR procedure. Data from each subject were collected on the same day, whenever possible starting with pure-tone testing (which also served as a subject selection procedure). Audiologists performed data collection procedures either at the Phumlani Occupational Health Centre in Randfontein, or at the Driefontein Occupational Health Centre in Carletonville. Recording was done in calibrated sound environments.

For the pseudohypacusic group of 29 subjects (Phase 2), four sets of data were obtained. These included two pure-tone air-conduction threshold tests at 500, 1 000, 2 000, 3 000, 4 000 Hz (ascending technique) followed by thresholds obtained at the same frequency, but using a descending method, SF-ASSR threshold estimates at the same frequencies, using a 40 Hz modulation rate and, lastly, the time required for testing.

5.7.1 PURE-TONE AUDIOMETRY

Pure-tone audiometry was performed during subject selection and data collection procedures, at 500, 1 000, 2 000, 3 000, 4 000 Hz, in line with Instructions 168 and 171 (Workmens' Compensation Commissioner, 1995 and 2000). These frequencies were selected since they are used for evaluations of fitness and

compensability. These thresholds were also used as a basis for comparison with ASSR thresholds. The pure-tone average from the audiogram was required to be in excess of 25 dB, to confirm potentially compensable abnormal hearing. In the pseudohypacusic group, the two pure-tone tests confirmed pseudohypacusis when they demonstrated a discrepancy of 15 dB or more between the two tests.

Pure-tone audiometry was performed using descending steps of 10 dB and ascending steps of 5 dB, with a 50 per cent positive response at the same level taken as the threshold, in accordance with the criteria of Stach (1998). Thresholds were determined first for the left and then for the right ear and were recorded on audiograms attached to the Case History questionnaire form (see Appendix G).

5.7.2 MF-ASSR DATA COLLECTION

Two groups of subjects were tested using a dichotic MF-ASSR technique, one without sedation and the other with sedation, to obtain threshold estimates at 500, 1 000, 2 000, 3 000, 4 000 Hz. Multiple amplitude moduated tones were selected with the carrier frequencies modulated between 80 and 110 Hz. It is important to note that a 40 Hz modulation is not available in multiple frequency test systems. Carrier frequencies were spaced at least one octave apart in line with suggestions by Perez-Abalo *et al.* (2001), and four frequencies were evaluated (dichotic) for each ear. Previous studies have indicated that a modulation rate of 80 to 110 Hz is appropriate for adults and that there are no significant differences between results using single- and multiple-frequency techniques (Lins & Picton, 1995). Time efficiency could also be evaluated in this way, since the design of the experiment left options for comparing the time required for using single- and multiple-frequency techniques. The carrier frequency, starting intensity and the size of the decrements (5 or 10 dB steps) were selected by the researcher, after which the computer directed the test procedure.

In the sedated group, 10 mg of Valium was administered after informed consent and medical clearance had been obtained. A medical doctor was present on the same premises to supply medical back-up or assistance if it were to be needed, and testing commenced one hour after the medication had been administered, to allow time for the medication to be absorbed. Subjects were transported back to their hostels and only reported for work the following day.

An electrode skin-preparation swab coated with Nuprep (an abrasive paste) was used to clean the areas where electrodes were to be affixed. Once the electrode sites had been cleaned, the skin was dried with a gauze pad to remove any residue, and disposable self-adhesive snap electrodes supplied by Biologic were affixed to the skin. Electrode impedance was immediately confirmed to be below five kilo-ohms, with no differences greater than two kilo-ohm between electrodes (Bio-logic Systems Corporation, 2002).

The electrodes were placed as followed:

- on the mastoid process – test ear
- on the mastoid process – (reference) contra-lateral to the test ear
- high on the forehead as recommended by Bio-logic Systems Corporation (2002)

Earphone probes were then inserted, using an appropriately sized disposable ear tip in accordance with the size of the subject's ear canal. The ear tip was securely coupled to the probe and fully inserted into the ear canal, to ensure proper stimulus delivery. In addition, correct cable connections were confirmed to prevent any juxtaposition of results for the right and left ears.

The test parameters used during this multiple frequency ASSR procedure were the default values as determined by the software supplied by Bio-logic System Corporation (2002).

The subject was asked to lie still, to relax or sleep and to keep his eyes closed. A pillow was provided for support to prevent any myogenic noise from impacting on the data collection when modulation frequencies between 80 and 100 Hz were used (Bio-logic Systems Corporation, 2002). Testing was performed in a sound-proof booth and the air conditioning in adjacent rooms was switched off, as were all telephones and cell phones. In addition, the door to the adjacent test room was closed, and visual distractions were minimised by switching off lights in the booth and the adjacent room. Before testing commenced, electrode impedance was re-confirmed. The audiologist was positioned in an adjacent room and had visual contact with the subject through a window in the test booth.

To ensure safety, power to the system was never switched on or off while a subject was connected to the system. Threshold determination occurred within a hearing level range of -20 to 120 dB, and the software warned the researcher when very high intensities were selected.

The software recorded the test data, providing for an exact measurement of the time taken for each subject. Electrophysiological thresholds were eventually determined from the responses obtained, based on a requirement for a less than 5 per cent chance that the subject's response might be attributable to chance (f-ratio statistics at a 0,05 level of confidence). The electrophysiological thresholds were eventually converted to pure-tone thresholds by subtracting 10 dB to predict a conventional audiogram, Guidelines on estimating a pure-tone thresholds were requested by the researcher in a personal communication with Bio-logic (Bio-logic, Systems Corporation, 2002).

- **Carrier frequencies**

  The default protocols were selected in order to obtain thresholds (four per ear) at 500, 1 000, 2 000, 3 000, 4 000 Hz. Default protocols prevented

testing at all the frequencies required in a single stimulation sequence, thereby requiring more than one set of stimulus presentations.

- **Modulation frequencies**

The modulation frequencies used were as indicated in Table 5.3

Table 5.3: MODULATION FREQUENCIES USED BY MASTER

CF	500 Hz	1 000Hz	2 000Hz	3 000Hz	4 000Hz
Modulation frequency	86.914Hz	89.844Hz	91.797Hz	83.008Hz	94.727Hz

The amplitude modulation percentage of the carrier frequency was set at 100 per cent and the frequency modulation percentage was set at 10 per cent (per side).

- **Number of sweeps**

The number of sweeps the MASTER runs per subject and per test threshold was set to 32 sweeps per test in accordance with the recommended protocol (Bio-logic Systems Corporation, 2002).

- **Epochs per sweep**

The number of epochs collected per sweep before the fast fourier transform (FFT) was performed was set at 16. Data transmitted to the FFT represented an averaged response from the subject, obtained from a running sum of all the sweeps that were recorded, divided by the number of sweeps collected.

5.7.3 SINGLE FREQUENCY DATA COLLECTION

Single frequency data collection procedures using the GSI Audera (Grason-Stadler) were applied to a group of sedated mine workers with noise-induced

hearing loss, as well as to two groups of subjects with noise-induced hearing loss who were not sedated. This allowed comparisons to be made to determine the most advantageous "state of consciousness" during ASSR testing. The two non-sedated groups were compared by using different stimulation rates (40Hz and 80Hz). Both of these rates had previously been found to provide reliable estimates of pure-tone thresholds during previous research.

Thresholds were required for 500, 1 000, 2 000, 3 000, 4 000 Hz, to allow comparisons of the single frequency ASSR, multiple frequency-ASSR and pure-tone thresholds. ASSR thresholds were obtained using both ascending and descending threshold-seeking procedures, starting at a hearing level of 40 dB, as with behavioural testing, and increments and decrements of 10 dB were used to limit the testing time. Single frequency ASSR tests were performed immediately after pure-tone testing, to ensure that all the procedures were completed on the same day. For sedated subjects, one hour was allowed for the absorption of the 10 mg of Valium, with the same provisions for consent and medical support met as for multiple frequency testing (again same-day testing was not always possible).

Electrodes were placed according to Grason-Stadler's specifications, as follows:

- the Audera Beta version: on the left and right ear lobes and high on forehead
- the Audera Commercial version: on the left and right ear lobes, high on forehead and low on forehead (the extra electrode allows clinicians to perform ABR testing as well).

Figure 5.13 illustrates the electrode placement for the Audera system.

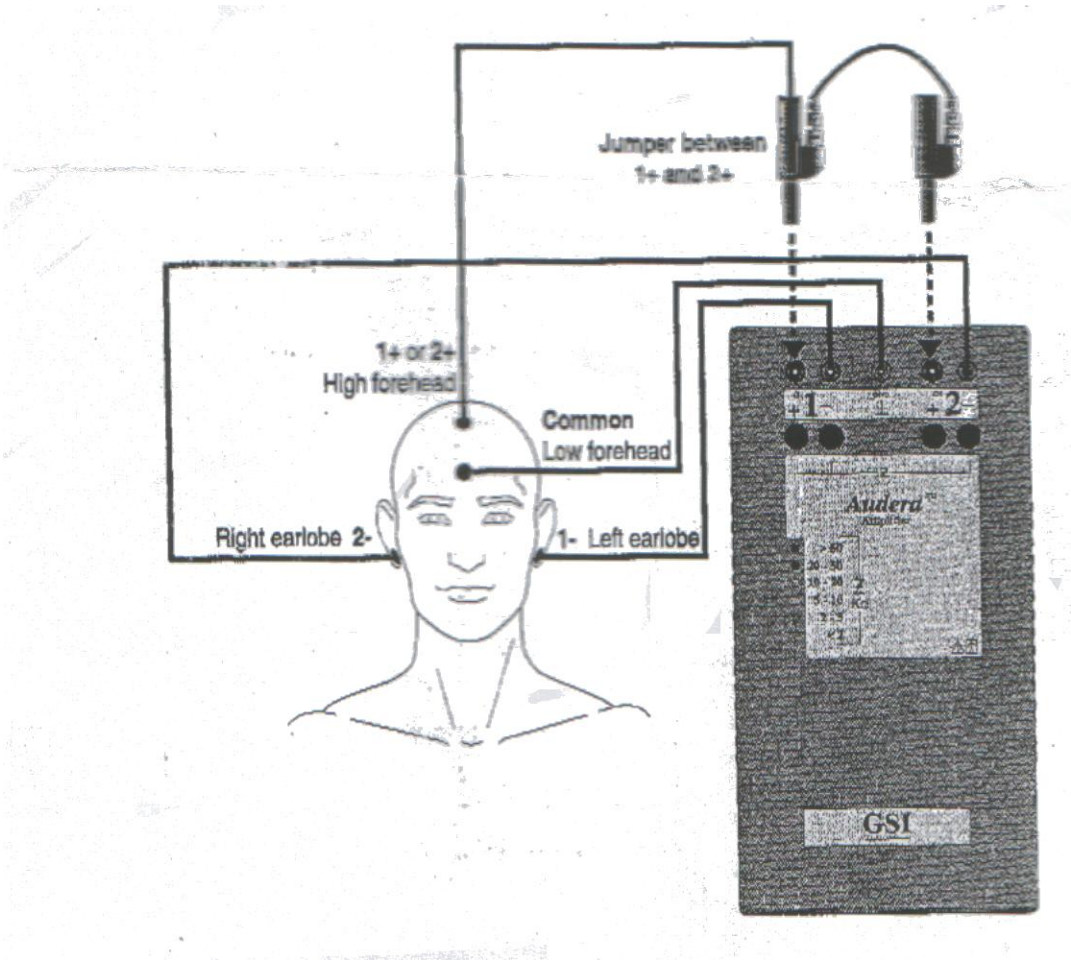

FIGURE 5.13: AUDERA ELECTRODE PLACEMENT (HASS: SOUTHERN AFRICA)

The same skin preparation procedures were used as for MF-ASSR tests before affixing re-usable electrodes (supplied by Grason-Stadler) with conductive gel (Elefix) and electrode tape. An electrode impedance of five kilo-ohms or lower was confirmed, and earphone inserts of an appropriate size were selected and fitted snugly into the external auditory meatus. After each test, the electrodes were removed and thoroughly cleaned in soapy water with a soft brush.

Instructions to the subjects and management of the test environment were similar to those for multiple frequency testing, in that subjects were asked to lie down, relax or sleep and to keep their eyes closed. Electrode impedance was re-

confirmed once the subject was lying down, and the audiologist was positioned in an adjacent room. Environmental noise was controlled in the same way as for multiple frequency tests.

The testing and data collection parameters were the following:

- **Carrier frequencies**

Carrier frequencies of 500, 1 000, 2 000, 3 000 and 4 000 Hz were used to allow comparisons between single frequency and multiple frequency estimated thresholds. With the Audera commercial version, it was possible to test all the above frequencies whereas with the Beta version the test software made no provision for the testing of 3000 Hz.

- **Modulation frequencies**

Two modulation frequencies were compared, namely, 40 Hz (awake) and 80 Hz (asleep).

- **FM and AM modulation**

The modulation rates used were the default values of 10 per cent for frequency modulation and 100 per cent for amplitude modulation.

- **Number of samples**

A total of 64 samples were taken per carrier frequency and hearing level set, for example, 1 000 Hz at 30 dB. The number of samples was specified by algorithms provided by the manufacturer.

- **Statistical measures**

For each electroencephalogram sample, the magnitude and phase of the electrical activity corresponding with the frequency of the tone modulation were quantified. Magnitude and phase information was shown as a vector in a polar plot, with the vector length corresponding with the magnitude and vector angle reflecting the phase or time delay between the tone modulation and the brain's response. Figure 5.14 illustrates a polar plot for a case where both the ear and the brain responded to a tone. The vectors in the plot are clustered, indicating a "phase-locked" brain response.

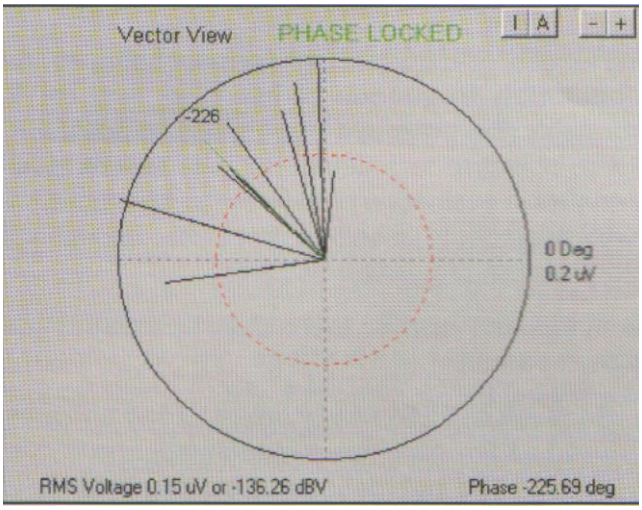

FIGURE 5.14: PHASE-LOCKED RESPONSE

Figure 5.15 shows the vectors obtained when the tone was presented at an inaudible level. Vector length varies and, most importantly, vectors are randomly distributed around the plot, indicating that there is no phase relationship between the electrical response and the tone modulation, in other words, no response.

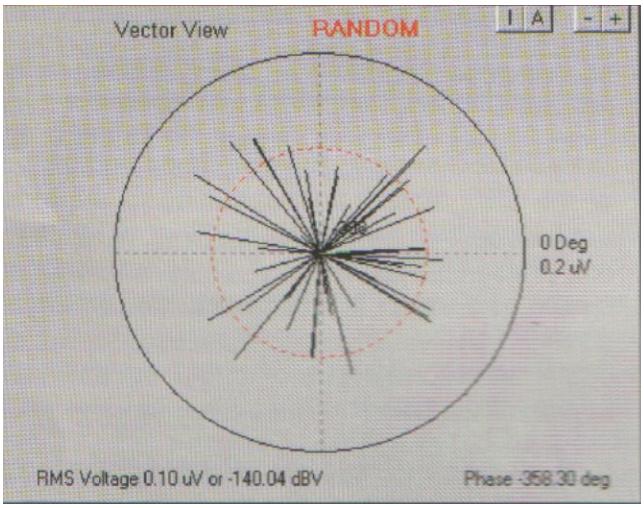

FIGURE 5.15: RANDOM RESPONSE

The identification of responses such as those illustrated in the preceding two figures as phase-locked or random was based on statistical analyses performed in real-time while samples were being recorded, and not on subjective visual assessments. A probability value of $p<0,03$ set the false-positive threshold for the single frequency technique at 3 per cent, and any trial contaminated with excessive noise was automatically terminated and labelled accordingly, as shown in Figure 5.16.

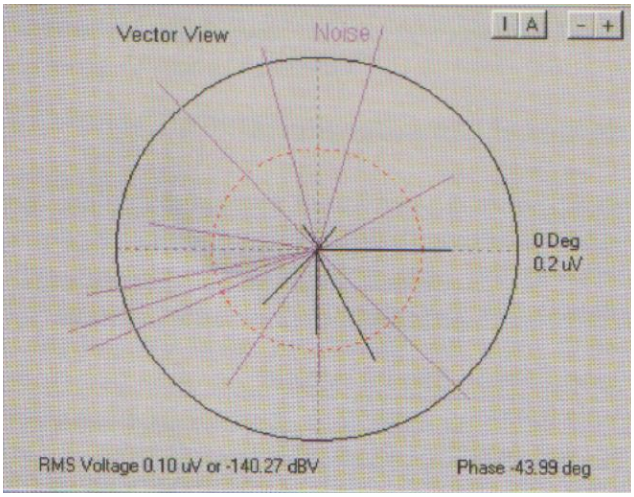

FIGURE 5.16: EXAMPLE OF RESULTS REJECTED DUE TO EXCESS NOISE

The results of all trials were plotted on a graph (Figure 5.17) with phase-locked results marked by an upward arrow to indicate that the ASSR threshold was better than the corresponding pure-tone threshold. Conversely, “random” or no-response results were marked with a downward arrow to indicate a lack of response. Thresholds were taken as the lowest level at which a “phase-locked” response was obtained for a given frequency.

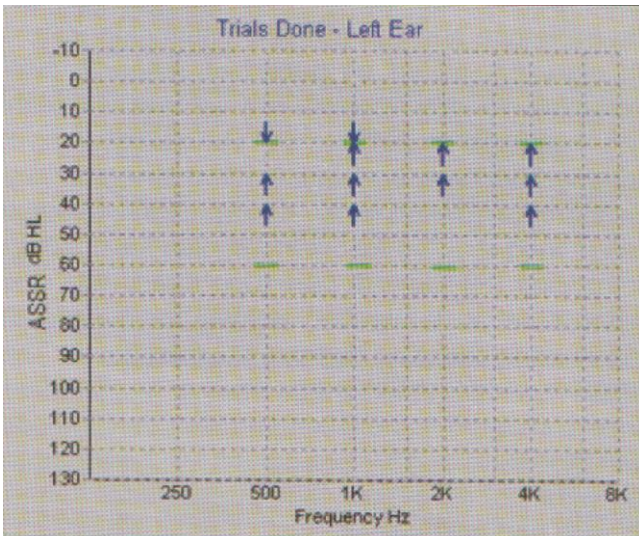

FIGURE 5.17: PLOTTED RESULTS OF TRIALS DURING AN ASSR TEST

Pure-tone thresholds were estimated on the basis of an algorithm developed from the research findings of Rance *et al.* (1995), as illustrated in the example in Figure 5.18, where the estimated pure-tone thresholds are presented objectively and without the clinician's input.

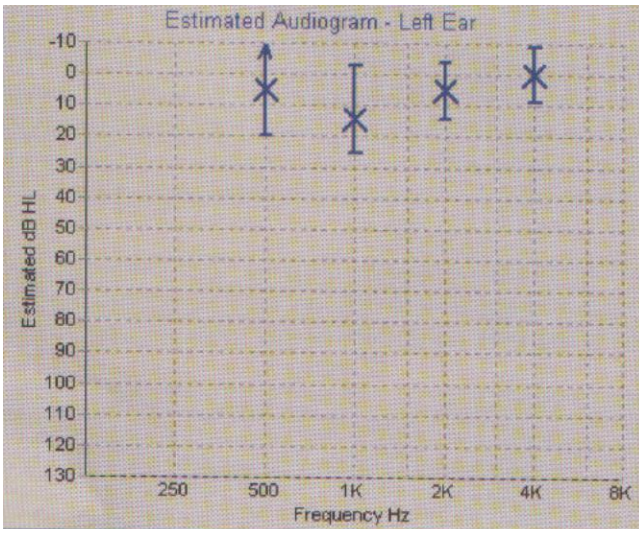

FIGURE 5.18: ESTIMATED AUDIOGRAM BASED ON THE ASSR RESULTS

Estimated pure-tone audiograms such as that shown in the preceding figure were compared with multiple frequency ASSR and conventional pure-tone thresholds.

5.8 DATA ANALYSIS PROCEDURES

A Microsoft Excel (2000) spreadsheet was used to collate data, which were then analysed using statistical measures developed by the Medical Research Council (Levin, 2002). Data analysis seeks to identify patterns in the data, in accordance with criteria determined by the test protocol used. This involves examining, sorting, categorising, evaluating, comparing, synthesising, contemplating and reviewing the data (Neuman, 1997). The following statistical procedures were applied:

- the sample t-test is a test that is used to compare different populations' means; and
- the two way analysis of variance is used for the analysis for experiments involving several independent variables (Wackerly, Mendenhall & Schaeffer, 1996).

5.9 SUMMARY

This chapter has described the research methods used in the acquisition of data in this study to determine the clinical value of ASSR methods in the audiological assessment of mine workers with sensory neural hearing loss and pseudohypacusis. The experimental design was discussed, after which the criteria and procedures for subject selection were detailed. The equipment used in the subject selection, data collection and data analysis were subsequently considered, after which data collection and analysis procedures were listed.

The next chapter presents the data obtained from the use of these methods.