Chapter-3

Methodology

METHODOLOGY

The aim of the current study was to compare the neural encoding of speech sounds in three different age groups, namely- Younger Age **(YA)** group, Middle Age **(MA)** group and Older Age **(OA)** group. Further, as an attempt at addressing the clinical implication as a component of the study, assessment of the neural encoding of speech sounds in first time hearing aid users was also initiated. This chapter focuses on outlining and detailing the **study design (3.1), study center (3.2)** and **data sampling (3.3).**Further, it includes description of the **equipment (3.4), stimuli (3.5)** used, procedure of **data collection (3.6)** and overview of the **analysis (3.7).**

3.1. Design

Study Design: It was an observational study design to evaluate and compare the speech sound encoding at the level of brainstem in YA, MA and OA. The reason for choosing this design was to emphasize the effect of age on speech sound encoding, traceable at one point of time for all the three groups. Further, this study assessed the potential clinical applications by performing the SEABR on first time hearing aid users at a given point of time. Thus, an observational study by virtue of its merits with relevance to the aim of the study was used.

3.2. Study center

The present study was carried out in the Audiology and Electrophysiology lab of the Department of Speech and Hearing, Kasturba Hospital, Manipal University, India and the final phase in the Audiology Unit, University Hospital, Sharjah, UAE. Besides being the work places of the researcher, the centers were chosen for their proximity to the medical college hospital with state of the art lab for SEABR data collection with the latest evoked potential

technology systems. Being attached to the Medical College hospital the study center allowed the researcher to carry out the clinical implications of the current study in clinical population of first time hearing aid users, who visited the hospital with their hearing related issues.The study was carried out from June 2011- July 2015, a period of 4 years.

3.3. Data

3.3.1. Sample size

Appropriate statistical methods were employed to derive the required sample size, i.e the required number of participants in the current study. The mathematical formula used to calculate the sample size depended on the objectives of the study. The primary objective of this study was to compare the mean values of the SEABR responses elicited for the stop consonant /da/ for the three groups. With the need to conduct a pilot study for sample size calculation, feasible only after the approval of the Institutional Ethical Committee (IEC), sample size was recalculated subsequent to the recommendation of IEC. Based on the recommendations, the sample size was calculated by using the following formula.

$$n = 2(Z\alpha + Z\beta)^2 . \sigma^2 / \delta^2$$

- $Z\alpha$ = 1.96 ((Significance Level) . $Z\beta$ = .84 (Power)σ = 5.5 (Standard deviation).

- δ = 2.85(Clinical difference).

- Sample size (n) = 2 $(Z_a + Z_B)^2$ x $(\sigma)^2/(d)^2$=15.2*30.25/7.84 = 56.6 $\cong$ 57

- 57 participants in each group worked out to **57 x 3 = 171 as the total sample size.**

In order to assess the clinical implication of the current study, a sample of 29 participants (50% of the sample size in OA group) was recruited in first time hearing aid user group.

On completion of data collection, the Doctoral Advisory Committee (DAC) for the candidate recommended recalculation of the sample size to ensure adequate data for statistical analysis. Recalculation endorsed the data from 171 participants as adequate for the data analysis.

3.3.2. Study group description

With a focus on the aim of the study, the participants were carefully divided into three normal hearing groups as follows. *(Petry, 2002).*

3.3.2.1. Younger Adults (YA): participants were defined as individuals in the age range of 18-35 years and inclusive of both genders.

3.3.2.2. Middle aged Adults (MA): participants were defined as individuals in the age range of 36 to 53years, both genders inclusive.

3.3.2.3. Older Adults (OA): participants were defined as those   in the age range of 54 years and above, both genders inclusive.

The first time hearing aid users' group participants were defined as follows;

3.3.2.4. First time hearing aid (HA) users groups: Participants using hearing aid for the first time in any one ear and who were 54 years old or above. The group comprised of both genders.

3.3.3. Selection criteria

All the participants were recruited for the current study by using a convenient sampling method. Their recruitment was either during their visit to the centers or by virtue of their residences being close to the study centers. Each participant for the current study was

accommodated into one of the three groups based on the pre defined age criteria. **YA** were defined as individuals between the ages of 18-35 years and included both the genders. **MA** participants were defined as individuals between the ages of 36 to 53years and included both genders and **OA** participants were defined as those in the age group of 54 years and above with both genders. These participants were recruited based on the outlined inclusion criteria in order to maximize the effectiveness of the current study. The inclusion criterion for the normal hearing groups is outlined as follows;

✓   Hearing thresholds within normal limits (<25dBHL)

✓   Age range for younger adults-18-35 years

✓   Age range for middle aged adults-36-53years

✓   Age range for older adults-55 years & above

If the participants met all the above stated criteria, then, he/she was recruited for the research study for recording of their SEABRs in a carefully controlled sound treated room .Further; the following parameters were also considered in participant selection to exclude them from the study so as to minimize wrong sample inclusion in the study. They are as follows;

✓   No history of ear infection

✓   No otologic history

✓   No neurological problems

Following the normal hearing group sampling, a first time hearing aid user group was also recruited for the study in order to assess the clinical implications of the study, presumed to strengthen the overall aim of the study. For this purpose, a group of first time hearing aid users was targeted and recruited for the recordings based on convenient sampling method. To

maximize the effectiveness in recording and minimize the recording errors, following inclusion criteria were set before enrolment for the SEABR recording.

✓   Bilateral senosri-neural hearing loss

✓   Moderate degree of loss

✓   Hearing aid fitting: Monaural

✓   Type of hearing aid: Digital

✓   First time hearing aid user

✓   No neurological problems

✓   No history of congenital hearing loss

If any known factors other than the above mentioned were noticed, the participant was excluded from the SEABR recording. Even though the hearing aid group was not the primary focus of the research, utmost care was taken in recruiting the hearing aid users, as the study implications were expected to create a wide range of clinical applications in hearing aid selection, mainly in hearing aid programming and fine tuning.
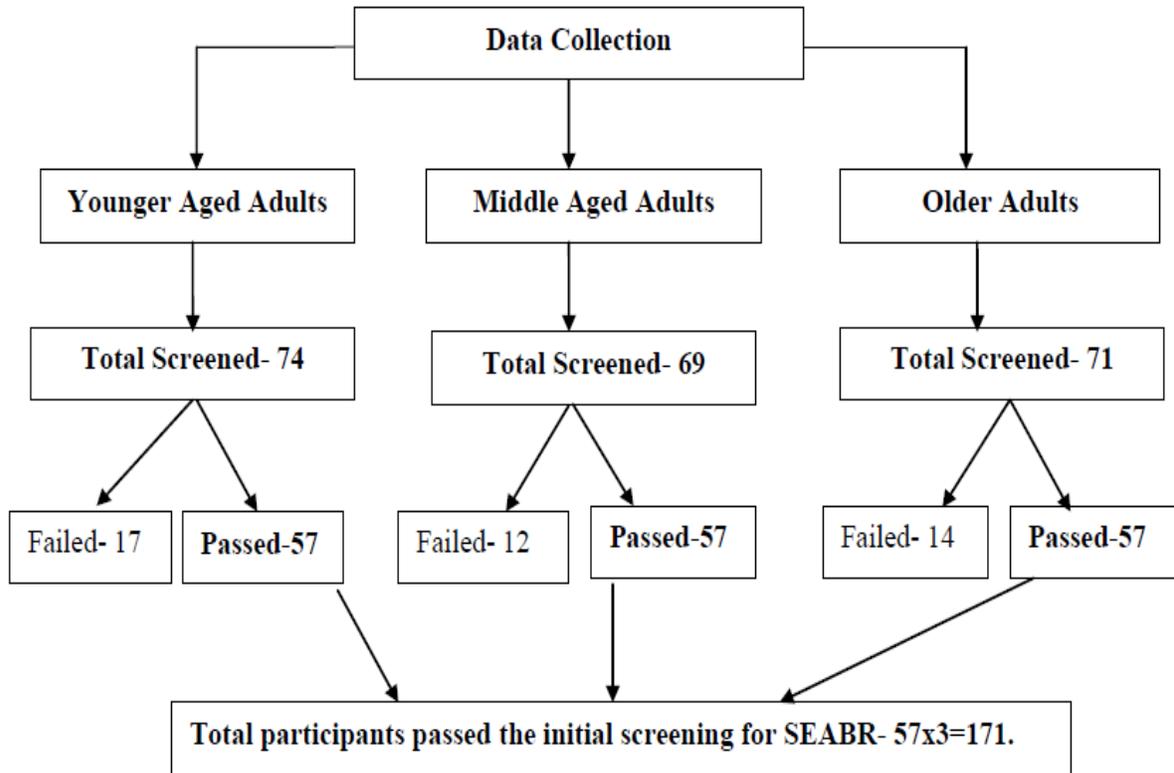
Flow chart 3.1: *Depicting the participants' recruitment for the SEABR recording in normal hearing groups*
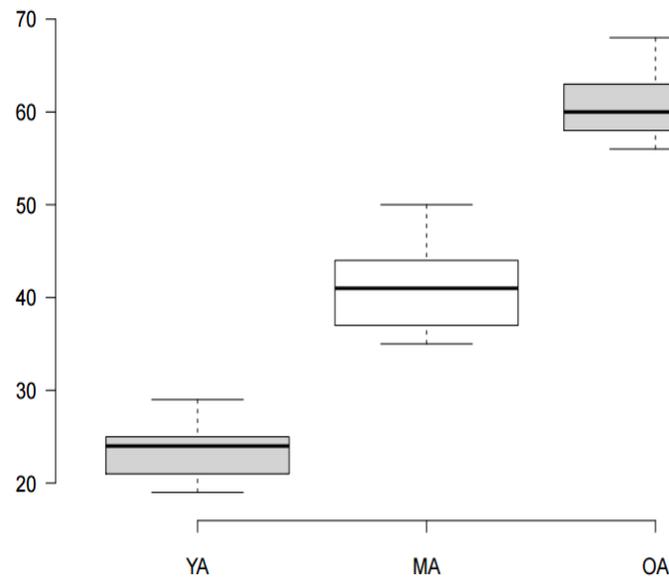

Graph: 3.1: *Age distribution of participants' recruitment for the SEABR recording in normal hearing groups*
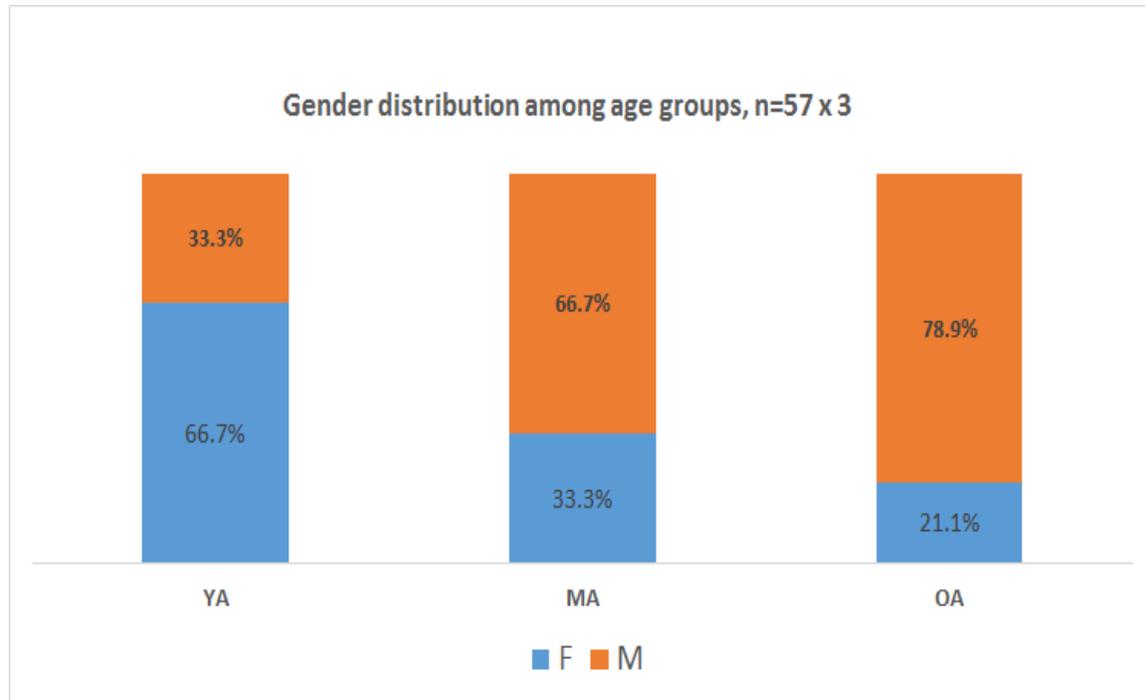
Graph 3.2: *Gender distribution of the participants' recruitment for the SEABR recording in normal hearing groups*

For the initial screening measures, 74 participants in the **YA** group were considered of whom 17 didn't turn up for the SEABR recording due to personal reasons. All these participants had passed the initial screening tests required for their inclusion in the study. In the **MA** group, a total of 69 participants were screened, of whom 12 were excluded due to their failure in OAE and PTA measures. Out of these 12 participants, 4 had hard wax in both the ear canals resulting in absent TEOAE measures. Remaining 8 were excluded due to a large air-bone gap in their PTAs, further confirmed with absence of TEOAEs. For the **OA** groups, a total of 71 participants were screened, out of which 14 were excluded from the SEABR recording due to the set exclusion criteria. 2 participants had history of middle ear surgery done in less than five years period with Otoscopic examination revealing congested tympanic membranes. 7 had border line or mild sloping sensorineural hearing loss and 3,

border line PTA with absent TEOAEs binaurally. Thus, overall, 57 participants were recruited

for the SEABR recording in all the three groups.
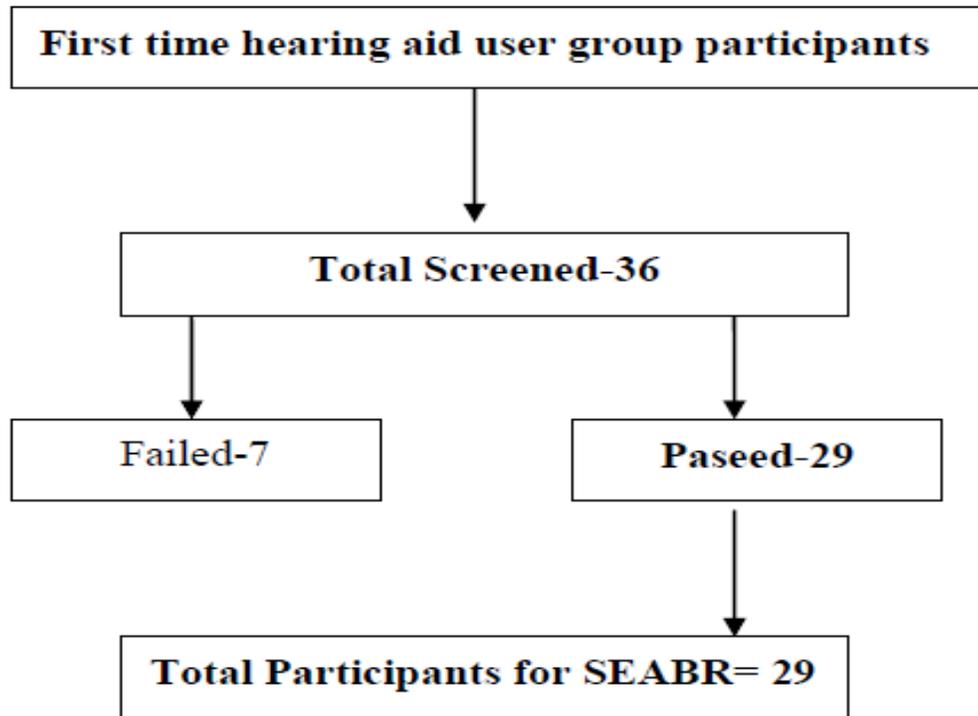
Flow chart3.2: *Depicting the recruitment for the SEABR recording in first time hearing aid users*

In first time hearing aid users group, a total of 36 participants were screened based on

the inclusion criteria. 3 participants were excluded due to lack of cooperation during the

SEBR recording. 2 participants had issues with the hearing aid and ear mould. These

participants had requested to be relieved from the SEABR recording at that point of time with

assurance of return after rectification of their ear mould issues: however, they didn't turn up

for the recording. Another 2 participants, a couple had initially agreed to participate in the

SEABR research; subsequently, they too had requested to be relieved due to the distance they

had to travel from their residence to the study center. Hence, a total of 29 participants were recruited in the first time hearing aid user group.

3.4. Instruments used

The following instruments were used for data collection from the participants in the study.

   3.4.1. Pure tone Audiometer: A duly calibrated pseudo 2 channel clinical audiometer - *GSI-61 clinical audiometer (SI No: IN205102257, Model No: 1761-9700-XXE)* was used for pure tone audiometry for all the participants

Figure: 3.1- GSI Clinical Audiometer

3.4.2. Otoacoustic Emission Instrument: Transient Evoked Otoacoustic Emissions (TEOAEs) were obtained in both the ears separately using a duly calibrated *ILO-V6-* OAE instrument *(Otodynamics Ltd).*

Figure: 3.2: ILO OAE instrument

3.4.3. Evoked potentials:

During the initial plan of the study, SEABR recordings were to be with **Neuroscan-Stim 2 Compudmedics Ltd**. However, due to the technical glitches with the equipment and the delay in its installation process, SEABR recordings were done with Intelligent **Hearing Systems (IHS)- SMART-evoked potentials***(IHS Smart-EP V.5,No: M010010)* instrument. Care was taken to notify the effect of change in the equipment in SEABR recordings and the outcome. It was believed that SEABR are mainly recorded from the brainstem level in an order of 40 ms using the stop consonants. These brainstem responses are presumed to remain

intact, when elicited from IHS- SMART EP , Biologic Navigator Pro or Neuroscan equipments barring the temporal resolution of the waveform obtained from the later. Thus, to hasten the data collection within the stipulated period of the study, SEABR was recorded from the IHS – Smart EP equipment for the current study.

A duly calibrated I**ntelligent Hearing Systems- SMART-Evoked Potentials** *(IHS Smart-EP V.5,No: M010010)* instrument with insert earphones (ER-3 Etyomotic Research) with foam tip was used to obtain the SEABR in a sound treated room for the normal hearing group. Duly calibrated JBL-loudspeaker was used for the stimulus delivery to record the SEABR in first time hearing aid users.

Figure: 3.3- IHS-EP instrument

*3.4.4. Test environment***:**

All the tests were carried out in a sound treated air-conditioned room with adequate lighting and with the participants seated in a reclining chair for comfort during the test procedure.

Figure: 3.4: EP Lab

3.5. Stimuli used

Description of the test stimulus -/da/: For the current study, a stop consonant stimulus /da/ was used for the SEABR recording. The stimulus has been developed in the auditory neuroscience laboratory, North Western University USA by Dr. Nina Kraus (2002) and her team and widely used in clinical research studies. The acoustical features of the stop

consonant /da/ stimulus are as follows: The 40 ms phoneme was generated with a digital speech synthesizer (SenSyn) at a sampling rate of 10 kHz. The stimuli were composed of five formants that transitioned from the consonant /d/ to the vowel/a/. The fundamental frequency ($F0$) and the first three formants ($F1$, $F2$, $F3$) changed linearly over the duration of the stimulus: $F0$ changed from 103 to 125 (0–35 ms) to 121.2 Hz (35–40 ms), $F1$ from 220 to 720 Hz, $F2$ from 1700 to 1240 Hz and $F3$ from 2580 to 2500 Hz. $F4$ and $F5$ remained constant at 3600 and 4500 Hz, respectively *(King et al 2002, Russo et al 2004).* The initial 10 ms of the stimulus contained an onset burst in $F3$, $F4$ and $F5$ as described by *Klatt (1980).* The vowel /a/ was abbreviated to allow increased presentation rate, in order to better stress the system and thus allowed the stimulus duration to be precise in eliciting the intended response. Synthesized speech was used as these stimuli were used for various perceptual measures, thus facilitating comparison of physiological and behavioural measures.
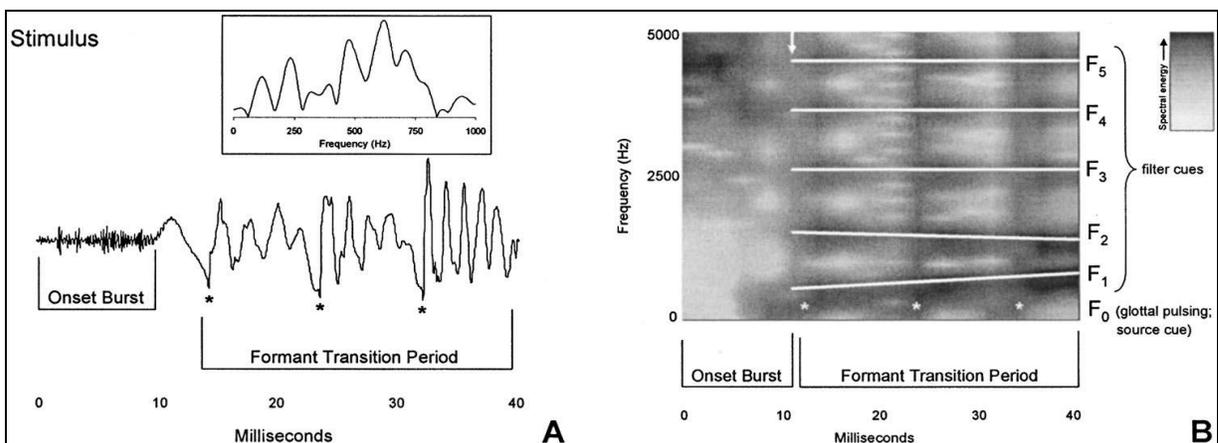

Figure. 3.5. Stimulus characteristics of the Stop consonant- /da/ stimulus. Johnson et al 2005

3.6. Procedure

3.6.1. Ethical approval

Prior to the commencement of the study, due permission and approval were obtained from the departmental and institutional research committees as well as from the institutional research board and ethics committees of Manipal University. *(Appendix-1- IEC approval letter)*

3.6.2. Consent form

Once the participants fulfilled the selection criteria, the aim, objectives and the need for the study were explained to them. Consent forms*(Appendix-2)* were filled up and duly signed by the participants before participation. All the participants were given the consent form in their mother tongue to be filled and signed by them.

3.6.3. Preliminary tests

Prior to the SEABR recording, all the participants underwent basic preliminary hearing evaluation and hearing tests to ascertain their hearing status and also to decide on the candidacy criteria. The basic evaluations performed were as follows

3.6.3.1. Otoscopic examination

A visual examination of the ear canal of both ears using a hand held Otoscope was done to rule out any infections or abnormalities in the ear canal

3.6.3.2. Pure tone Audiometry
Hearing thresholds were obtained for frequencies from 500Hz, 1000Hz, 2000Hz, and 4000Hz for air conduction and 500Hz, 1000Hz, 2000Hz for bone conduction in a sound treated room using GSI-61 clinical audiometer.

3.6.3.3. Otoacoustic emissions

Transient Evoked Otoacoustic emissions were obtained in all the participants in both the ears separately using a duly calibrated ILO-instrument in order to assess the integrity of the outer hair cell function.

3.6.4. Participant preparation

Once the preliminary procedures were over, the participants were guided to the EP lab for the SEABR procedure. Participants were instructed to lie down comfortably, relax and to close their eyes on a reclining chair in an electrically shielded room. Instructions were given in the mother tongue of the participant. Before placing the electrodes, the electrode sites were cleaned using skin preparation and conduction gel was applied to increase the conductivity. All the recordings were done with silver–silver chloride electrodes with the impedance matching maintained at less than 5kOhms; placement was Cz-to-Ipsilateral earlobe, with forehead as ground. An Etyomotic Research -3A(ER-3A) insert receiver was placed in the right ear of the participant by using a soft tear tip and a duly calibrated JBL loud speaker was placed at an angle of 45 degree azimuth of the hearing aid fitted ear.

3.6.5. Data recording

Stimuli were presented at the conversational level ie, 60dBnHL to all the participants via ER-3A insert receivers. The responses were band pass filtered from 100 Hz to 3000 Hz and digitized at 20,000 Hz with an analysis time window of pre stimulus 10ms to post stimulus 60ms. This time window allows examination of the onset response, occurring within the first 10 ms, the frequency following response (FFR) that continues for the duration of the stimulus, and the offset response occurring within 40 ms of stimulus cessation. Artifact

criteria of ±35 V was applied to reject epochs that contained myogenic artifacts. For each stimulus, the processed epochs were separately averaged (according to polarity) and then added together in order to isolate the neural response from the cochlear microphonics .The final average waveform for each stimulus was 2000 sweeps per participant.. The test took approximately 30 to 45 minutes to be completed for each participant.Table 3.1 explains the stimulus and recording parameters used for recording the SEABR in the three normal hearing groups.

Table-3.1

Stimulus and recording parameters used for SEABR recording in three normal hearing groups

SEABR- Stimulus parameters	
Intensity	60dBnHL
Rate	7.1/seconds
Polarity	Alternating(Condensation & Rarefaction)
Stimulus	/da/
Duration	40ms
Presentation mode	Monaurally
Transducer	Inert ear phones
SEABR- Recording parameters	
Electrode montage	Cz-Fz-A1
Filter setting	100-3000Hz
Time window	60msec
Number of sweeps	2000
Artefact rejection	35 microvolt
Amplification	1,00000 times

For the clinical utility and application of the current research study, SEABR recordings were done for first time hearing aid users. Hearing aid trial and fitting were done in the hearing aid clinic, following which they were recruited for the SEABR recording in the Audiology lab. All the hearing aid users fulfilled the above mentioned inclusion criteria. The stop consonant speech stimulus was presented through the loudspeaker placed at an azimuth of 45 degrees to the participant's ear. Before each recording, the Sound Pressure Level (SPL) output from the speaker was calibrated using a Sound Level Meter (SLM) in order to obtain accurate results. Table 3.2 represents the stimulus and recording parameters used to record the response in the first time hearing aid users.

Table-3.2

SEABR- Stimulus and Recording parameters used for the first time hearing aid users

SEABR- Stimulus parameters	
Intensity	60dBnHL
Rate	7.1/seconds
Polarity	Alternating(Condensation & Rarefaction)
Stimulus	/da/
Duration	40ms
Presentation mode	Monaurally
Transducer	JBL Loud speaker
SEABR- Recording parameters	
Electrode montage	Cz-Fz-A1
Filter setting	100-3000Hz
Time window	60msec
Number of sweeps	2000
Artefact rejection	35 microvolt
Amplification	1,00000 times

3.7. Data Analysis

3.7.1. SEABR outcome analysis

The SEBAR responses were offline band pass filtered from 100–3000 Hz at 12 dB roll-off per octave .The analysis time window was averaged over a period of 70-ms with 10-ms pre stimulus and 60-ms post stimulus onset. Separate averages were created for each stimulus. A total of 7 peaks were identified viz. V, A, C, D, E, F, O. They were divided into **Onset Response (OR)** and the **Sustained Response (SR) -FFR** were analyzed separately. For the OR, peaks V and A, C, O were considered and for the FFR, peaks D, E, F were analyzed for both latencies and amplitudes. The latencies were measured in msec (time) and the amplitude in μV in both normal hearing groups as well as in first time hearing aid users.

3.7.2. Statistical Analysis

The obtained data was subjected to statistical analysis using Statistical Package for Social Sciences (SPSS) version 16.0 for windows. *Mean* and *Standard Deviation* of the latencies and amplitudes were calculated for all the participants in the normal hearing groups as well as for first time hearing aid users group. Analysis of variance (ANOVA) was administered to compare the variance between the responses obtained within the three normal hearing groups. Additionally, post analysis of each parameter was done using Bonferroni Post hoc test. Independent sample t test was used to compare the results obtained from the first time hearing aid user group with that of the older aged group. The significance level was kept at .05 levels. The analysed data is presented as results and discussed in the subsequent chapters.