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Short-term test-retest reliability of aided late latency auditory evoked potentials in adult cochlear implant recipients

by

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LIST OF ABBREVIATIONS

ACE	advanced combination encoder
eCAEPs	electrical cortical auditory evoked potentials
CI	cochlear implant
CV	coefficient of variance
dB	decibel
JCIC	Johannesburg Cochlear Implant Centre
HL	hearing level
Hz	hertz
ICC	intraclass correlation coefficient
LLAEP	late latency auditory evoked potentials
msec	milliseconds
PCIU	Pretoria Cochlear Implant Unit
PTA	pure tone average
µV	microvolts

DEFINITIONS

Aided P300s: The aided P300 is a LLAEP response that follows the CAEP with a latency that ranges from 270 to 400 ms. This response is related to the rate at which an individual organises auditory signals, allocates attention and updates memory**.**

Cochlear implant: An implantable, electronic device that directly stimulates the auditory nerve through various electrodes that are placed in the cochlear, which is located in the inner ear.

Decibel: This is a unit of measurement that is responsible for measuring the intensity of a sound by comparing the results obtained with a given level on a logarithmic scale.

Electrical cortical auditory evoked potentials: An evoked potential that is created when a stimulus bypasses the speech processor of a CI and this stimulus is then directly transmitted to the implanted device, therefore eradicating any pre-processing effects created by the CI.

Hearing aids: Small electronic devices that fit on the ear and are responsible for the amplification of sound. These devices are worn by individuals who are hard of hearing.

Late Latency Auditory Evoked Potentials: LLAEPs are a specific objective measurement that is used to determine the neurophysiological changes that occur in the cortical regions of the auditory pathway with respect to specific skills that include attention, memory, auditory discrimination, integration and memory.

ABSTRACT

Background

Late latency auditory evoked potentials (LLAEPs) provide objective evidence of an individual's central auditory processing abilities. Electrically evoked cortical auditory evoked potentials (eCAEPs) and aided P300s are LLAEPs that are capable of providing an objective measure of aided speech perception and auditory processing abilities in cochlear implant (CI) recipients.

Aim

To determine the short-term test-retest reliability of aided LLAEPs in adult CI recipients.

Design

An explorative, within-subject repeated measures research design was employed.

Study sample

The study sample included twelve postlingually deafened, unilaterally implanted adult CI recipients with at least nine months of CI experience.

Method

eCAEPs representing basal, medial and apical cochlear regions and aided P300s were recorded in the implanted ears of each participant. Measurements were repeated seven days after the initial assessment.

Results

Lower coefficient of variation values were found for measures of latency compared to amplitude for both aided LLAEP measurements. Intraclass correlation coefficient (ICC) values for eCAEP latencies and amplitudes ranged from moderate to excellent when averaged across cochlear regions in terms of consistency and agreement. Moderate and poor consistency and agreement was seen for the aided P300 absolute peak latency and amplitudes respectively.

Conclusion

There were no significant differences between test and retest for all aided P300 and eCAEP latencies and amplitudes when eCAEP responses were averaged across electrodes. However, confidence intervals indicated very broad measures of consistency and agreement ranging from moderate to excellent for eCAEPs and moderate for aided P300 latencies. Aided P300 amplitudes demonstrated poor test-retest reliability.

CHAPTER 1

Introduction

Late latency auditory evoked potentials (LLAEPs) are used to determine the neurophysiological changes that occur in the cortical regions of the auditory pathway with respect to specific skills that include attention, memory, auditory discrimination, integration and memory (Perez, Ziliotto, & Pereira, 2016). These auditory evoked potentials therefore provide objective evidence of an individuals' central auditory processing abilities (Kelly, Purdy, & Thorne, 2005). It is believed that a cochlear implant (CI) recipient's speech perception and auditory processing abilities with a CI is strongly linked to the integrity of that individual's central auditory pathways, from the auditory nerve to the cortex (Kraus et al., 1993). LLAEPs, which include cortical auditory evoked potentials (CAEPs) as well as P300 auditory evoked potentials are capable of providing an objective measure of aided speech perception and auditory processing abilities in CI recipients (Kelly et al., 2005). Over the past few years, literature has drawn more attention to the possibility of using aided CAEPs and P300s as a method of assessing central auditory function in CI recipients (Kelly et al., 2005; Kim, Brown, Abbas, Etler, & Brien, 2009).

CAEPs are voltage potentials which originate from various auditory structures in the brain in response to sound (Katz, 2009). These areas include the primary auditory cortex and the thalamic and auditory association areas (Katz, 2009), more specifically the superior temporal gyrus, medial temporal gyrus, inferior frontal gyrus, frontal gyrus, and insula (Sharma, Glick, & Campbell, 2016). CAEP latency values indicate the neural travel time in response to auditory stimulation and this provides

information with regards to the integrity and maturation of the central auditory pathways from the auditory nerve to the cortex (Ponton, Don, Eggermont, Waring, & Masuda, 1996; Sharma, Dorman, Spahr, & Todd, 2002).

In addition to threshold estimation, CAEPs are used in the clinical setting in order to provide an estimate of an individual's supra-threshold processing abilities (Hyde, 1997) as well as to examine plasticity-related changes that occur in the brain (Katz, 2015). CAEPs may also provide important information with regards to speech processing at the level of the auditory cortex (Czarniak, 2011). CAEPs have been used for the assessment of individuals with communication disorders as well as the monitoring of variations following different types of auditory rehabilitation such as cochlear implantation (Tremblay et al., 2003). These variation include the neural detection of time-varying cues in individuals over time (Tremblay, Friesen, Martin, & Wright, 2003).

Aided CAEPs can be defined as an auditory evoked potential response that is elicited from a hearing aid user or CI recipient using stimuli that is processed by the individual's hearing aid or CI (Billings, 2013). The main purposes of recording aided CAEPs in hearing aid users is to verify that the amplified signal created by the hearing aid is being successfully processed by the brain and to examine any changes that occur in the brain as a result of plasticity (Billings, 2013; Katz, 2015).

A very early study compared CAEPs and aided CAEPs in infants less than two years of age with severe to profound sensorineural hearing loss and fitted with conventional hearing aids (Rapin & Graziani, 1967). Responses were elicited

through click and tonal stimuli and results indicated that aided CAEPs were at least 20dB better when compared to unaided results (Rapin & Graziani, 1967). Glista et al. (2012) compared the aided CAEP response in hearing aid users and age matched normal hearing individuals. Results indicated that aided CAEPs were larger in amplitude when recorded in hearing aid users compared to normal hearing individuals, Furthermore, there was a strong association between the presence of repeatable aided CAEPs in hearing aid users and the degree of audibility during the recording of this electroacoustic verification (Glista, Easwar, Purcell, & Scollie, 2012). The presence of repeatable aided CAEP responses at a suprathreshold intensity in hearing aid users therefore provides physiological evidence that the stimuli presented is being detected at the level of the auditory cortex in these individuals (Glista et al., 2012). However, research has found that the amplification effect provided by the hearing aid is not always present in hearing aid users (Billings, Tremblay, & Miller, 2011; Billings, Tremblay, Souza, & Binns, 2007; Jenstad, Marynewich, & Stapells, 2012; Marynewich, Jenstad, & Stapells, 2012). A number of studies confirmed no statistically significant difference between aided and unaided CAEPs for hearing aid users, despite the additional gain that is provided by the hearing aid (Billings, Tremblay, & Miller, 2011; Billings, Tremblay, Souza, & Binns, 2007; Jenstad, Marynewich, & Stapells, 2012; Marynewich, Jenstad, & Stapells, 2012). A probable explanation for this could relate to participants' hearing aids not being optimally fitted and verified to the degree of hearing loss or that participants' hearing aids were not functioning properly at the time of testing (Korczak et al., 2005). Other possible reasons could include differences in methodologies used across studies such as the differences with regards to the calibration of the stimuli

that was used as well as differences in the way participants' hearing aids were adjusted at the time of testing (Korczak et al., 2005).

Measuring CAEPs in CI recipients is an objective way of understanding how electrical stimuli are registered by these CI recipients' central auditory system (Firszt, Chambers, Kraus, & Reeder, 2002). In order to record CAEPs in CI recipients, either aided CAEPs or electrical CAEPs (eCAEPs) can be measured. However, in contrast to aided CAEPs, the stimulus bypasses the speech processor when measuring eCAEPs and this stimulus is directly transmitted to the implanted device, therefore eradicating any pre-processing effects created by the CI (Czarniak, 2011; Firszt et al., 2002). For CI recipients specifically, aided CAEPs have been used to not only assess auditory functioning, record developmental changes that occur post implantation but also to assist in device programming (Brown et al., 2008; Groenen et al., 1996; Kileny, Boerst, Zwolan, & Arbor, 1997). The aided CAEP response is modified by the CI settings and therefore can also be used to determine the effects of various signal processing strategies on evoked neural activity (Katz, 2015). In order for this LLAEP to be successfully recorded in CI recipients, aided CAEPs or eCAEPs are recorded through the use of a passive listening paradigm, nevertheless, a mental alerting task is recommended in order to measure this response (Kim et al., 2009).

Groenen et al. (1996) compared aided CAEP latencies between adult CI recipients whose aided speech perception performance, two years post-implantation, was rated to be either 'moderate' or 'good' based on several speech perception tests. Results demonstrated that adult CI recipients with 'good' speech perception outcomes

obtained aided CAEP latencies and amplitudes that correlated with age-matched, normal hearing adults (Groenen et al., 1996). However, adult CI recipients with 'moderate' speech perception outcomes presented with reduced P2 amplitudes compared to CI recipients with 'good' speech perception outcomes, suggesting that the cochleotopical organization of the auditory cortex is less distinct in these CI recipients with 'moderate' speech perception outcomes (Groenen et al., 1996).

Kelly et al. (2005) also found similar latencies and amplitudes for CAEPs with well-defined morphology indicated by prominent N1 and P1 responses, in normal hearing adults and aided CAEPs in postlingually deafened adult CI recipients with over a year of CI experience. However, results indicated that those CI recipients who were good performers with his/her CI, presented with a decreased P1 amplitude and an increased N1 amplitude when compared to poorer performing CI recipients (Kelly et al., 2005). Performance with an individual's CI was determined based on several speech perceptions tests (Kelly et al., 2005). Aided CAEPs may be used to predict an individual's performance with a CI (Groenen et al., 1996) as speech perception outcomes correlate with aided CAEP amplitudes in adult CI recipients (Groenen et al., 1996; Katz, 2015; Kelly et al., 2005). Further understanding of CAEPs may offer a better understanding with regards to the variability that exists in CI recipients' performance (Czarniak, 2011).

The P300 is another LLAEP response that follows the CAEP with a latency that ranges from 270 to 400 ms (Reis et al., 2014). This response is related to the rate at which an individual organises auditory signals, allocates attention and updates memory (Picton, 1992). The exact location of the origin of the P300 auditory evoked

potential is still unknown, however, it is believed that this response is generated by the hippocampal, sensory-specific cortex, centroparietal cortex and frontal cortex (Micco, Kraus, Dawn, et al., 1995; Picton, 1992). In order to elicit the P300 response, an ‘odd ball’ paradigm is mostly used where two different stimuli, a predictable, continuous stimulus and an infrequent, unpredictable stimulus (oddball) are presented (Perez et al., 2016). In contrast to CAEPs, active attention is required for the recording of the P300 measurement and is therefore known as an endogenous response due to the fact that the response is elicited through the performance of a specific task (Duarte et al., 2009; Reis et al., 2014). It is important to keep the brain active during the recording of the P300 response so that the neural mechanisms, that contribute to the discrimination task taking place can be determined (Katz, 2015; Micco, Kraus, Koch, et al., 1995).

The amplitude of the P300 is largely affected by individual characteristics whereas the P300 latency provides an indication of the time it takes for neural activity to travel along the auditory pathway, as well as the amount of time that occurs in synaptic transmission and neural conduction (Eggermont, 2006). A variety of factors have been shown to influence the latency and amplitude of the P300 wave, resulting in inter-participant variations. The most prominent of these factors being attention, where poorer attention to the infrequent stimuli results in a decreased amplitude and an increased latency (Covington & Polich, 1996). Other factors may include lack of motivation as well as the level of anxiety and fatigue at the time of testing (Kilney & Kripal, 1987; Perez et al., 2016; Reis et al., 2014). Intra-participant variations have found to occur due to the fact that advancing age may lead to an increased P300 latency response as well as a decreased amplitude (Covington & Polich, 1996;

Verleger, Neukater, Kompf, & Vieregge, 1991). Gender differences have also been noted with regards to the amplitude of the P300 response, again affecting intra-participant reliability (Mata, Hataiama, & Goncalves, 2011). Several pathologic factors have shown to influence the P300 response such as dementia, dyslexia and depression (Polich & Criado, 2006).

In order to record P300s in CI recipients, aided P300s are performed. During the recording of this measurement, stimuli are processed by the speech processor of the CI so that it best reflects the natural signal processing of the stimuli (Czarniak, 2011). When measured in CI recipients, the aided P300 measurement is a way to identify the central neurophysiological aspects underlying speech perception (Micco, Kraus, Dawn, et al., 1995). This is determined by evaluating the central auditory processes that contribute to the perception of speech, as success following cochlear implantation is often measured by the CI recipient's speech perception abilities (Micco, Kraus, Dawn, et al., 1995). These speech perception abilities include a CI recipients ability to comprehend speech and language and to communicate effectively (Micco, Kraus, Dawn, et al., 1995). Speech perception abilities as measured by several speech perception tests, vary greatly between CI recipients and this cannot completely be explained by the differences in the functioning of a CI recipient's peripheral auditory system or the difference between each recipients' CI device (Micco, Kraus, Koch, et al., 1995; Tyler, 1990; Tyler et al., 1988). A possible explanation for the differences in CI recipients' speech perception abilities can partly be due to the variations in the capability of the central auditory system to adapt to the electrical stimulation created by the CI as well as the difference between cognitive

abilities to use the limited information provided by the CI (Micco, Kraus, Dawn, et al., 1995).

Groenen et al. (1996) successfully recorded the aided P300 response in CI recipients and results indicated that the latencies of these responses correlated to a CI recipient's speech perception performance with a CI. Adult CI recipients with 'moderate' speech perception outcomes presented with longer P300 latencies, when compared to CI recipients with 'good' speech perception outcomes (Groenen et al., 1996). Longer P300 latencies are therefore indicative of greater discrimination difficulties than shorter P300 latencies (Groenen et al., 1996).

The test-retest reliability of the aided CAEP and P300 response needs to be determined in CI recipients before this response can be successfully utilised in the rehabilitation process of this population. Tremblay et al. (2003) determined the short term test-retest reliability of a specific CAEP, namely the acoustic change complex in seven normal hearing individuals between 23 to 31 years of age by using naturally produced speech stimuli, presented through a speaker. These individuals were tested over two sessions with the second session falling within eight days of the first session (Tremblay et al., 2003). The intra-class correlation (ICC) statistic of the grand mean responses indicated high short term test-retest reliability when CAEPs were recorded from the same individual (Tremblay et al., 2003; ICC = moderate to good across individuals). This could indicate that any variations that occur in the morphology of the CAEP responses measured in a particular individual over a short period of time could possibly reflect changes in neural activation to speech. Therefore this LLAEP could be used to determine changes in neural activity over

time following various types of rehabilitation such as cochlear implantation (Tremblay et al., 2003). Czarniak (2011) also determined the test-retest reliability of aided CAEPs in CI recipients and found aided CAEPs, through the use of speech stimuli, to be repeatable across test sessions when elicited through a sound field. The test-retest reliability was determined through a repeated measures analysis and various scatter plots (Czarniak, 2011). However, to the author's knowledge, there is no published literature addressing the test-retest reliability of eCAEPs in CI recipients specifically.

Several studies have indicated that the P300 amplitude and latency values obtained in normal hearing adults, are replicable and reliable with no significant short term (Kilney & Kripal, 1987; Mata et al., 2011; Nakamura, Kinoshita, Eisuke, & Morita, 1995; Perez et al., 2016) or long term (Segalowitz & Barnes, 1993) test-retest variations. Nakamura et al. (1995) and Perez et al. (2016) determined the test-retest reliability of the P300 response in normal hearing adults which was determined by ICC values which were found to be either moderate or good (0.57 to 0.84). In contrast, Reis et al. (2014) found a significant difference in the short term test-retest latency when measured in normal hearing females, which was determined by linear regression models. However, no significant amplitude difference of the P300 response was found when testing this specific population who presented with normal hearing (Reis et al., 2014). This difference in latency found between sessions in the female population is however not consistent with previous literature (Kilney & Kripal, 1987; Mata et al., 2011; Nakamura et al., 1995; Perez et al., 2016; Segalowitz & Barnes, 1993). Reis et al. (2014) stated that a possible explanation for this difference in P300 latency between test and retest in the female population could be due to the

menstrual cycle as all other factors that could possibly influence the results, were controlled. However, to the author's knowledge, there is no published literature addressing the short-term test-retest reliability of P300s in CI recipients specifically.

The increased reliance on objective measures to evaluate CI performance is becoming more evident in literature (Brown et al., 2008; Friesen & Tremblay, 2006; Groenen et al., 1996; Micco, Kraus, Dawn, et al., 1995; Reis et al., 2014). This is seen in the way that aided CAEPs and P300s are utilised in the rehabilitation process following cochlear implantation by regularly recording these aided LLAEP measurements in the same individual and comparing results (Brown et al., 2008; Groenen et al., 1996; Tyler, 1990). These results are then utilised in order to assess auditory functioning, document developmental changes that occur post implantation and assist in device programming (Brown et al., 2008; Groenen et al., 1996; Tyler, 1990). Thus, if a modified neural response could be created by modifications to a CI MAP, this could possibly improve the potential for speech perception in CI recipients (Tremblay et al., 2003).

The increased need to utilize objective measures in CIs can be linked to the fact that children are being implanted at earlier ages and require more objective programming options (Firszt et al., 2002). Furthermore, objective measures can provide important information that will add to the understanding of the variability of CI outcomes (Firszt et al., 2002). Aided LLAEPs are relatively easy to record in the clinical setting and there are vast applications of these measures. It has been concluded that LLAEPs can be recorded reliably and appear to be stable over short intervals when measured in normal hearing individuals (Groenen et al., 1996; Kilney & Kripal, 1987; Nakamura et al., 1995; Perez et al., 2016; Reis et al., 2014; Segalowitz & Barnes, 1993;

Tremblay et al., 2003). Although the validity of aided CAEPs and P300s in the clinical setting has been proved, there is a lack of published literature specifically addressing the test-retest reliability of eCAEPs and aided P300 measurements in CI recipients. It is important to determine the test-retest reliability of aided LLAEP results in CI recipients in order to improve confidence in these measurements and to draw rational conclusions based on these measurements (Koo & Li, 2016). If aided LLAEP results do not vary in CI recipients, then eCAEPs and aided P300 measurements may be interpreted in a similar way as in normal hearing individuals. The present study therefore aimed to determine the short-term test-retest reliability of aided LLAEPs in CI recipients.

CHAPTER 2

Methodology

2.1 Research aim

The aim of this study was to determine the short-term test-retest reliability of aided LLAEPs in adult CI recipients.

2.2 Research design

An explorative, within-subject repeated measures research design was employed in order to evaluate the short-term test retest reliability of aided LLAEPs in adult CI recipients. This research design employed a within-subject approach in order to minimise the chance that outside effects might bring about any changes observed (Leedy & Ormrod, 2014). LLAEP measurements were recorded in the implanted ears of the participants and these measurements were then repeated one week after the initial assessment. A seven day interval was selected as this is the time period that was utilised in previous short term test-retest literature (Reis et al., 2014). Quantitative data was collected, including latencies and amplitudes of eCAEPs and aided P300s. eCAEPs and aided P300s were selected as these are the LLAEPs performed post-operatively in the researchers' clinic and it is also the protocol advocated by Cochlear© (N. Robertson, personal communication).

2.3 Ethical considerations

Ethical considerations were addressed in order to protect the rights and welfare of the participants involved in the study (Leedy & Ormrod, 2014). Ethical clearance was obtained through the Research Ethics Committee of the Department of Speech-

Language Pathology and Audiology, followed by that of the Faculty of Humanities, University of Pretoria, prior to data collection (Appendix A).

Written consent was obtained from the CI team coordinators of the two participating CI programs, namely the Pretoria Cochlear Implant Unit (Appendix B) and the Johannesburg Cochlear Implant Centre (Appendix C) in order to obtain permission to access patient data as well as to contact CI recipients for the purpose of this study. Participants were informed of the nature of the study as well as their level of involvement in this study (Leedy & Ormrod, 2014). Informed consent was obtained from all participants that took part in this study, after providing them with a written information letter and oral information regarding the aims and methods of this research project as well as what would be expected of them (Appendix D).

Understanding of the information letter was ensured and participants were encouraged to ask any questions they may have had regarding the study, or with regards to their rights as participants in the study. This ethical aspect ensured adherence to the ethical principle of autonomy, or allowing the participant to make their decisions freely and independently (South African Speech-Language-Hearing Association, 2010). Potential participants were required to be competent in either English or Afrikaans in order to ensure understanding of the instructions given for data collection. The researcher is competent in both languages and participants were given the opportunity to ask questions if there was any aspect about the study that was unclear. Each potential participant had the right to refuse to participate or to withdraw consent at any time without reprisal. Data collection only took place once

participants understood the information letter provided and signed the consent slip attached to the end of the information letter (Appendix D).

According to Leedy and Omrod (2014), the risk involved in participating in a study should not be greater than the normal risks of day to day living. The study incorporated two non-invasive, objective LLAEP assessments which did not benefit nor harm the participants in any way. An explanation was given to each participant as to what was expected of him/her. If the participant experienced any discomfort at any time during the LLAEP assessments in this study, testing was stopped. These provisions ensured that the ethical principle of non-maleficence was adhered to (South African Speech-Language-Hearing Association, 2010).

The confidentiality of patient records were maintained as each participant was assigned a unique alphanumeric research code, adhering to the ethical principle of confidentiality (World Medical Association, 2013). Therefore, no results or identifying information were made known in the data analysis or reporting process in such a way that others may have become aware of a participant's identity. This was clearly stated in the information letter (Appendix D). The participants' data was stored and reported anonymously, although the identity of the participants was known to the researcher. On completion of the study, data will be stored in both digital and hard copy at the Department of Speech-Language Pathology and Audiology, University of Pretoria for a period of at least 15 years, in accordance with the University of Pretoria's requirements on data storage (Appendix E). The results obtained from this research study were recorded anonymously, reported honestly and as accurately as possible and every attempt was made to avoid plagiarism when reporting the results

of this study. This adhered to the ethical principle of truth-telling (South African Speech-Language-Hearing Association, 2010).

This study was the researchers own original work and all secondary material cited was carefully acknowledged and referenced according to APA sixth edition referencing guidelines. This research study adhered to the University of Pretoria policy on plagiarism. A declaration against plagiarism and originality was signed by the researcher (Appendix F).

2.4 Validity and reliability

Validity determines whether the means of measurement are accurate and whether they are measuring what they are intending to measure (Golafshani, 2003). To ensure validity, test procedures (eCAEP and aided P300 testing), were performed on the same day and both of these test procedures were repeated seven days later. All equipment utilised was also calibrated according to regulations before any testing began. Reliability refers to the degree that a specific measurement remains unchanging over a period of time, how stable this measurement is and how similar the measurements are within a specific time period (Kirk & Miller, 1986). To ensure reliability, the testing protocol, stimulus parameters, settings, equipment and testing environment were kept precisely the same for each participant where possible and also between testing sessions. Participants' programming parameters and settings of their speech processors remained unchanged between testing sessions and it was ensured that each participant's speech processor was in a proper working condition before testing was initiated. In an attempt to enhance the reliability of test results, comfort breaks were provided to each participant between LLAEP assessments to

ensure that participants did not tire. A minimum of three waveforms were averaged for each aided P300 and eCAEP response from each session for increased reliability. Two objective evaluators confirmed the latencies and amplitudes of the measured data by independently analysing the eCAEP and aided P300 responses. Both evaluators were experienced in the field of electrophysiology, but the second evaluator had extensive experience in the field of CAEP's specifically. Independent analyses were then compared and discussed amongst the evaluators until both evaluators were in agreement. A third option was not required for any of the analyses. Due to considerable inter-participant variability, a within-subjects approach was employed, where LLAEP results obtained in a participants' implanted ear, were compared to results obtained from that same ear, seven days later. As a result, the influence of external factors on the obtained results, were minimised.

2.5 Research participants

2.5.1 Participant selection

Permission was obtained from the CI team coordinators of the two participating CI programs to access clinical patient data and contact details of participants (Appendix B & C). Patient registers were reviewed at the two CI programs in order to locate adult CI recipients who complied with the inclusion criteria for this study. Eligible CI recipients were then contacted by the researcher in order to provide them with the purpose and procedures of the study and to invite them to participate (Appendix D).

Data collection took place at the Department of Speech-Language Pathology and Audiology at the University of Pretoria (Pretoria) and at the Johannesburg Cochlear Implant Centre (Johannesburg). A nonprobability purposive sampling method was used in order to obtain participants for this study in order to focus on particular

characteristics of this specific population (Leedy & Ormrod, 2014). All the participants in this study received device programming and rehabilitation services at either the Pretoria Cochlear Implant Unit or the Johannesburg Cochlear Implant Centre and met the following requirements:

- Participants had to be ≥ 18 years old.
- Participants had to be unilateral CI users who were postlingually deafened.
- Participants had to be implanted for a minimum of six months and present with stable speech processor settings and MAPs. Speech processor program settings (including threshold and comfort levels) and impedance telemetry are known to stabilise six months after implant use (Henkin, Kaplan-Neeman, & Muchnik, 2003).
- Participants were expected to be unilaterally implanted with either a Cochlear Nucleus CI24RE (CA) or CI512 device and presented with at least a severe sensorineural hearing loss in the contralateral, non-implanted ear. A severe sensorineural hearing loss is defined as a pure tone average (PTA) of 71-90 dB HL (Swanepoel & Laurent, 2012). A PTA is based an individual's behavioural pure tone audiometric thresholds obtained at 500, 1000 and 2000 Hz (Swanepoel & Laurent, 2012).
- Participants had to have had an uneventful CI surgery, with full electrode insertions, a minimum of 20 active electrodes and made use of the *advanced combination encoder* (ACE) speech processing strategy.
- Participants had to be oral communicators, competent in either English or Afrikaans, with the receptive language abilities to understand and question the instructions given for testing.

Etiologies such as meningitis, auditory neuropathy spectrum disorder and tuberculosis were not considered in order to exclude the possible influence of a central auditory component.

2.5.2 Equipment and procedure required for participant selection

Equipment

Otoscopy, immittance and pure tone air conduction testing were performed only on the initial day of testing, prior to the aided LLAEP assessments, with the exception of immittance testing which was performed on the initial day of testing and then again at retest seven days later. The equipment that was used is presented in **Table 2.1**.

Procedure

Potential participants' clinical files were accessed at the two participating CI programs in order to obtain data with regards to each participants age, aetiological risk factors for permanent hearing loss, onset of severe-profound hearing loss, duration of deafness prior to CI, duration of CI use, type of CI device and speech processor and lastly the number of active electrodes. This information allowed the researcher to determine potential participants for this study. Once consent was obtained from prospective participants, a behaviour pure tone audiological assessment was performed to determine each participant's hearing status in the non-implanted ear. The procedure that was followed to determine each participant's residual hearing abilities is presented in **Table 2.1.**

Table 2.1. Equipment and procedure required for participant selection

Test	Equipment	Procedure
Otoscopy	• **Otoscope:** a hand-held instrument with a light and a cone-shaped attachment (speculum) which is used to examine the outer ear canal.	An otoscope was used to visualise the ear canal and tympanic membrane of each potential participant in order to determine the status of the outer ear canal and the tympanic

	• **Speculum:** cone shaped attachment. • **Alcohol swabs:** used to disinfect speculum after use.	membrane.
Immittance testing	• **Comprehensive middle ear GSI 38 Auto Tympanometer:** a device used to test middle ear functioning. A probe is inserted into the outer ear canal and automatic measurements are taken by the equipment. • **Probe tips:** available in various sizes and inserted into the participants ear in order to measure middle ear functioning. • **Alcohol swabs:** used to disinfect probe tips after use.	A 226 Hz probe tone was presented in each participant's ear in order to elicit tympanometry. Once a proper seal was obtained, the test began. This test indicated the functioning of the participant's middle ear. Once the results were obtained from the one ear, the same procedure was completed in the opposite ear.
Behavioural pure tone air conduction testing	• **Grason Stadler GSI 61 clinical audiometer:** a diagnostic two channel audiometer for air, bone, speech and masking tests. • **TDH-30 supra-aural headphones** calibrated in accordance with SANS 10154-1 (2012) are placed onto the ears (air-conduction testing). • **Double-walled soundproof booth compliant with the standards required by SANS 10182 (2012):** in order to eliminate background noise so that accurate results could be obtained.	Air conduction thresholds were obtained from 125 Hz to 8000 Hz using headphones. The Hughson-Westlake technique was used in order to obtain air conduction thresholds. A threshold is considered as the softest intensity at which a pure tone can just be heard 50% of the time (Katz, 2015). The Hughson-Westlake technique requires the audiologist to present a pure tone at a reasonable intensity and if the participant responds, the intensity is reduced by 10 dB HL until there is no response whereby the tone is increased by 5 dB HL until there is a response.

All study participants were tested at the University of Pretoria, Department of Speech Language Therapy and Audiology, or at the Johannesburg Cochlear Implant Centre. Once participants gave written consent to participate in this research study (Appendix D) they underwent basic audiological pure tone air conduction testing to determine the degree of hearing loss in the non-implanted ear. Testing started with otoscopy and immittance testing. Once completed, unaided air-conduction hearing thresholds were determined for the non-implanted ear only as participants had to have presented with at least a severe sensorineural hearing loss in this ear. All

potential participants who then, after testing, adhered to the inclusion criteria, were invited for further participation in the research study.

2.5.3 Study sample

The study sample consisted of twelve postlingually deafened, adult CI recipients (five males, seven females) aged 27 to 67 years (mean = 50.3 years, SD = 12.9 years). Characteristics of the participant sample are presented in **Table 2.2.**

Participants were unilaterally implanted with either a Nucleus CI24RE (CA) or CI512 device from Cochlear © and presented with at least a severe sensorineural hearing loss in the non-implanted ear. For all participants surgery was uneventful and a full electrode insertion was achieved. Duration of deafness prior to cochlear implantation ranged from 1.1 years to 45.8 years (mean = 20.1 years, SD = 18 years) and duration of CI use at the time of data collection ranged from 0.8 years to 9 years (mean = 4.7 years, SD = 3.6). All participants had at least 20 active electrodes and made use of the ACE speech processing strategy. Participants were oral communicators and had the receptive language abilities to understand and question the instructions given for testing.

Table 2.2. Characteristics of participants (n=12)

Participant	Age (years)	Gender	Aetiological/ risk factors for permanent hearing loss	Onset of severe-profound hearing loss	Duration of deafness prior to CI (years)	CI device	Duration of CI use (years)	Number of active electrodes	Implanted ear	Type of speech processor
1	64.3	Female	Inner ear autoimmune condition	Sudden	1.1	CI512	2.6	20	Right	CP810
2	67.0	Male	Unknown	Progressive	39.3	CI24RE(CA)	5.1	22	Right	CP910
3	67.7	Male	Unknown	Progressive	8.1	CI24RE(CA)	2.3	22	Right	CP810
4	27.1	Female	Usher's Syndrome	Progressive	13.2	CI24RE(CA)	11.5	22	Right	CP910
5	37.0	Male	Waardenburg Syndrome	Progressive	2.2	CI512	1.4	21	Left	CP910
6	64.2	Female	Chronic Otitis Media	Progressive	43.9	CI24RE(CA)	11.4	22	Right	CP810
7	43.8	Female	Chronic Otitis Media	Progressive	31.9	CI24RE(CA)	3.8	22	Right	CP910
8	39.3	Male	Ototoxic medication	Progressive	1.5	CI24RE(CA)	0.8	22	Left	CP810
9	44.3	Female	Ototoxic medication	Progressive	5.8	CI24RE(CA)	3.9	22	Right	CP920
10	42.4	Female	Ototoxic medication	Progressive	5,7	CI512	2	22	Left	CP920
11	58.4	Female	Rubella	Sudden	43.2	CI512	2.6	20	Left	CP920
12	50.8	Male	Unknown	Sudden	45.8	CI24RE(CA)	9	22	Right	CP910

2.6 Data collection

2.6.1 Equipment required for data collection

Equipment and materials that were used during the testing of eCAEPs and aided P300s is summarised in **Table 2.3.**

Table 2.3. Equipment and materials used for data collection

Equipment	Description
Interacoustics Eclipse EP25 Auditory Evoked Response System V1.3 software (Interacoustic A/S, Assens Denmark), calibrated in accordance with ISO 389-9 (2014), using NuPrep abrasive paste, Ten20 neurodiagnositc electrode paste and silver chloride cup electrodes.	The Interacoustics Eclipse EP25 Auditory Evoked Response System V1.3 software was used to record the eCAEPs and aided P300 responses in the CI recipients.
Custom Sound EP 5.0 (Cochlear©) software	The stimulus was presented through the Custom Sound EP 5.0 software in order to record the eCAEP response.
Citronic ST5 MKII Active Studio Monitor Speaker	During recording of aided P300s, the stimulus was presented at a comfortable, suprathreshold intensity through this speaker. The output of the speaker was set so that a dial setting of 90dB delivered a tone burst of 90 dB (A) (impulse) as measured at ear level using a level one sound level meter.

Calibration of the Interacoustics Eclipse EP25 Auditory Evoked Response System V1.3 software (Interacoustic A/S, Assens Denmark) included peak equivalent sound pressure level (peSPL) and normal hearing level (nHL) calibration. With regards to peSPL dB value, the maximum acoustical or vibration level was calibrated to match the dBSPL level of continuous tones obtained on a sound level meter. However, the acoustical or vibration value given in dB peSPL does not correspond well with nHL. Therefore a correction factor was used, which compensates for the difference in perceived loudness of very brief stimuli like clicks and tone bursts. ISO 389-6-2007 specifies that these brief tone burst correction values from peSPL to nHL are based

on a 2-1-2 manual burst. This correction is done by the software and the resulting dB value nHL then displayed. Longer duration tone bursts as are used for LLAEPs make use of peak-to-peak equivalent reference equivalent threshold sound pressure levels values as described in ISO 389-1 (Interacoustics, 2018).

2.6.2 Data collection procedure

Aided LLAEP measurements were recorded in the implanted ears of each participant and these measurements were repeated seven days after the initial assessment. Each participant was seated on a slightly reclined, comfortable chair. The sites of electrode placement were cleaned with Nuprep abrasive paste. Each silver chloride cup electrode was filled with Ten20 Neurodiagnostic Electrode Paste and the electrodes were attached to the skin with tape. For recording of the P300 responses, electrodes were placed on the mastoid (Mi-inverting electrode), the high forehead (Cz-non inverting electrode) and on the low forehead (Fpz- ground electrode) of each participant in order to record the aided P300 responses (Wall, Davidson, & Dalebout, 1991). In order to record the CAEP response, the inverting electrode was placed on the contralateral mastoid (Mi-inverting electrode) in order to minimise CI stimulus artefacts (Kelly et al., 2005). Impedances were required to be below 3 kΩ prior to commencement of testing (Kelly et al., 2005).

2.6.2.1 eCAEPs

eCAEP testing was the first LLAEP test performed and recording took place in a sound treated room. Whilst recording the eCAEP response, the electrical stimulus was presented through the CI, via the Custom Sound EP 5.0 (Cochlear©) software. This software was linked to the Interacoustics Eclipse EP25 Auditory Evoked

Response System V1.3 software (Interacoustic A/S, Assens Denmark), calibrated in accordance with ISO 389-9 (2014), via a trigger cable. The current level of the stimulus was slowly increased until the participant indicated that the stimulus being presented was set at a comfortable intensity. Once this comfortable intensity was determined, recording began and each participant was asked to open his/her eyes and to mentally count backwards from 400 in intervals of three to ensure he/she was mentally alert during the test procedure, whilst reclining in a comfortable chair. eCAEPs were measured on three different electrodes along the electrode array, representing apical, medial and basal cochlear regions. Each recording was repeated four times on each electrode in order to determine an average between recordings.

The protocol and parameters that were used in order to record the eCAEP response are presented in **Table 2.4.**

Table 2.4. Protocol and parameters used to measure eCAEPs

eCAEPs	
	• **Interacoustics Eclipse EP25 Auditory Evoked Response System V1.3 software** • **Custom Sound EP 5.0™ software (Cochlear©)**
Setting	Sound treated room.
Participant state	Awake, quiet with eyes open whilst mentally counting backwards from 400 in intervals of three.
Instructions to participant	You can make yourself comfortable while I place two electrodes on your forehead and one behind your ear. I will connect your CI to my computer and you will hear a sound being presented. The sound will gradually increase in volume. Please indicate when the sound is being presented at a comfortable intensity. Once a comfortable intensity has been obtained, please remain still during this test procedure, with your eyes open and mentally count backwards from 400 in intervals of three. If you have any questions or discomfort, please let me know.
Transducer	• CI (the trigger cable will connect the CI to the Interacoustics Eclipse EP25 Auditory Evoked Response System V1.3 software)
Stimulus	Pulse width: 25 µs

	Inter Phase Gap: 7 μs Number of pulses per burst: 450 Stimulation rate: 900 Hz Duration: 498945 μs Repetition rate: 0.9 Hz
Intensity	The electrical stimulus was presented at a suprathreshold current level that was comfortable for each CI recipient via the Custom Sound EP 5.0 (Cochlear©) software.
Acquisition Parameters	
Amplification	50000
Analysis time	500 ms
Prestimulus time	200 ms
Sweeps	3 x sweeps of 20-40 stimuli averaged
Artifact rejection	Disabled artifact rejection
Band pass filters	Low pass: 100 Hz High pass: 1.0 Hz 6/oct
Electrode type	Silver chloride cup electrodes
Electrode placement	2 channel electrode montage • Inverting: Mi (contralateral mastoid) • Noninverting: Cz (high forehead) • Ground: Fpz (low forehead)
Recording eCAEPs	
Measurements	• N1, P2 latency • N1 amplitude (baseline to trough) • P2 amplitude (base-line to peak) • P2- N1 amplitude

Once the eCAEP responses were recorded, two objective evaluators confirmed the latencies and amplitudes of the measured data by independently analysing the eCAEP responses. Both evaluators were required to be in agreement with regards to the analysis of the amplitude and latencies of the waveforms measured.

2.6.2.2 Aided P300

Aided P300s, as opposed to electrically evoked P300s were recorded, as aided P300s best reflected the natural signal processing of the stimuli and the effect that

the processor had on the incoming acoustic signal was not eliminated (Czarniak, 2011). Aided P300 testing was the second LLAEP test performed, in a quiet room, with each participant sitting comfortably and facing a Citronic ST5 MKll Active Studio Monitor Speaker. Participants were positioned one meter away from the speaker at 0˚ azimuth and participants' CI speech processors were positioned on the implanted ear and switched on during the test procedure. Participants were well informed beforehand as to what was expected of them during the recording of the aided P300 responses. The stimulus was presented at a comfortable, suprathreshold intensity of 100dB HL for both the frequent and infrequent stimulus through this speaker, which was linked to the Interacoustics Eclipse EP25 Auditory Evoked Response System V1.3 software (Interacoustic A/S, Assens Denmark). The output of the speaker was set so that a dial setting of 90dB delivered a tone burst equal to that of a 90dB (A) impulse as measured at ear level using a level one sound level meter. Each participant was required to be awake and alert in order to attend to any changes in tonal stimuli and then indicate awareness by making a note on a piece of paper every time the infrequent (oddball) stimulus was heard. The protocol and parameters that were used in order to record the aided P300 response are presented in **Table 2.5.**

Table 2.5. Protocol and parameters used to measure aided P300s

Aided P300	
	• **Interacoustics Eclipse EP25 Auditory Evoked Response System V1.3 software** • **Custom Sound EP 5.0™ software (Cochlear©)**
Setting	Sound treated room.
Participant state	Awake and alert in order to attend to any changes in tonal stimuli and required to indicate awareness to change by making a note on a piece of paper every time the infrequent stimulus is heard
Instructions to participant	You can make yourself comfortable while I place two electrodes on your forehead and one behind your ear. You will hear a specific tone being presented

	through the speaker in front of you. You will then hear, at random, a tone that is lower in pitch. Please indicate every time you hear the tone that is lower in pitch. If you have any questions or discomfort, please let me know.
Stimulus Parameters	
Transducer	CI (via a calibrated speaker)
Stimulus type	Tone burst Frequent stimulus: 1 kHz Rare stimulus: 750 Hz
Duration	Rise/fall: 26.7 ms
	Plateau: 80 ms
	Rate: 0.6/sec
Intensity	Frequent stimulus: 100 dB HL Rare stimulus: 100 dB HL The output of the speaker was set so that a dial setting of 90dB delivered a tone burst equal to that of a 90 dB (A) impulse as measured at ear level using a level one sound level meter.
Presentation	Oddball paradigm 20% of rare stimuli 80% of frequent stimuli
Probability of occurrence of oddball stimulus	20% with the presentation of the oddball stimulus being pseudorandom.
Acquisition Parameters	
Amplification	50000
Analysis time	500-1000 ms
Prestimulus time	400 ms
Sweeps	50-300
Artifact rejection	Disabled artifact rejection
Band pass filters	Low pass: 100 Hz High pass: 1.0 Hz 6/oct
Electrode type	Silver chloride cup electrodes
Electrode placement	2 channel electrode montage • Inverting: Mi (mastoid) • Noninverting: Cz (high forehead) • Ground: Fpz (low forehead)
Recording P300	
Measurements	• Peak latency • Peak to proceeding trough amplitude

Once the aided P300 response was recorded, two independent and experienced evaluators evaluated the waveforms. Both evaluators were required to be in

agreement with regards to analysis of the amplitude and latencies of the waveform measured.

The above mentioned procedure was then repeated seven days later and compared to the initial results obtained in order to determine the short-term test-retest reliability of aided LLAEPs in adult CI recipients. All CI settings remained the same at the retest session and the exact same testing protocol and stimulus parameters were utilised with regards to the recording of the aided LLAEP responses seven days later.

2.7 Data analysis

An Excel spreadsheet was used in order to organise and capture the data obtained from the patient files and the eCAEP and aided P300 recordings. The latencies for the eCAEP and aided P300 waves were defined as the time in msec from stimulus onset to peak amplitude value (Czarniak, 2011; Picton et al., 2000). The N1 and P2 amplitudes were measured from the baseline-to-trough (McClaskey, Dias, Dubno, & Harris, 2018) and baseline-to-peak of the N1 and P2 response respectively (Czarniak, 2011) whilst the P300 amplitude was measured from the peak of the P300 response to the proceeding trough (Wall et al., 1991).

Descriptive and inferential statistics were used to determine the difference in the aided LLAEP results obtained seven days apart. The latencies (msec) and amplitudes (μV) of the aided P300 and eCAEP waves were compared between sessions. Descriptive statistics included the mean, standard deviation (SD) and the coefficient of variation (CV). The CV is a measure of relative variability. It is the ratio of the standard deviation to the mean. This result is generally expressed as a

percentage (Howell, 1997). The lower the CV percentage, the less response variability and the data therefore is seen as more accurate (Polich & Herbst, 2000).

In order to evaluate the normality of distribution of latency and amplitude measures, the Shapiro-Wilks test with histograms and normal Q-Q plots was used. The Shapiro-Wilk test was not significant ($p>0.05$) for 22 out of the 30 eCAEP variables and one out of four of the aided P300 variables. However, by visual inspection of the histograms and normal Q-Q plots, and due to the small sample size (viz. 12 participants), non-parametric statistics were used, namely the Wilcoxon signed rank test to statically compare the average of the results obtained for the latencies and amplitudes of aided P300s and eCAEPs in test and retest to assess for significant differences. The ICC was employed to determine the reliability of the results and to reflect both the degree of correlation and agreement between measures. It is recommended that the reliability of a measure not only be evaluated by looking at difference at test and retest, as was achieved using Wilcoxon signed rank test, but also in terms of both consistency and agreement (Koo & Li, 2016). Therefore ICC measures of both consistency and agreement were determined. ICC estimates and their 95% confident intervals were therefore calculated based on a single-rater, consistency, 2-way random-effects model, as well as a single-rater, agreement, 2-way random-effects model. The 2-way random effects model was used as the raters were randomly selected from a larger population of raters with similar characteristics (Koo & Li, 2016). ICC coefficients ranged from 0, for dissimilar latencies and amplitudes, to 1 for identical latencies and amplitudes. ICC estimate values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and more than 0.90 indicated poor, moderate, good, and excellent reliability, respectively, based on the 95% confident interval (Koo & Li, 2016). Statistics were calculated using SPSS statistical

package version 24 (SPSS Inc, Chicago, IL). For ICC measures of agreement and consistency and for Wilcoxon signed rank test, a significance level of $p<0.05$ was adopted.

CHAPTER 3

Results

The mean, standard deviation and co-efficient of variance for eCAEPs at test and retest are presented in **Table 3.1.**

Table 3.1. Mean, standard deviation and co-efficient of variance of eCAEP latencies and amplitudes at test and retest (n=12)

		Electrode	Mean		SD		CV	
			Test	Retest	Test	Retest	Mean	SD
Latency (msec)	N1	Basal	83.17	75.83	28.26	12.04	13%	0.12
		Medial	80.33	81.00	18.80	13.52	8%	0.15
		Apical	80.83	75.00	15.15	13.90	9%	0.10
		Average	81.44	77.28	16.03	10.07	14%	0.09
	P2	Basal	164.83	172.83	46.24	37.54	10%	0.10
		Medial	177.50	174.33	49.71	32.43	13%	0.14
		Apical	180.70	172.50	42.70	40.70	11%	0.09
		Average	174.33	173.22	34.39	30.65	17%	0.06
Amplitude (µV)	N1 baseline-to-trough	Basal	4.79	5.44	3.94	3.87	41%	0.37
		Medial	5.74	5.38	3.94	3.79	32%	0.31
		Apical	5.70	5.20	3.64	3.75	21%	0.19
		Average	5.34	5.41	3.30	3.66	37%	0.20
	P2 baseline-to-peak	Basal	4.63	3.87	3.14	4.23	46%	0.34
		Medial	3.79	4.76	2.87	3.41	45%	0.36
		Apical	3.28	5.62	1.81	3.26	48%	0.37
		Average	4.75	3.90	2.99	1.71	56%	0.16
	N1-P2	Basal	9.37	8.97	4.55	5.08	18%	0.17
		Medial	9.55	10.15	4.79	3.86	25%	0.26
		Apical	8.69	10.83	4.29	4.67	23%	0.21
		Average	9.20	9.98	3.50	3.37	35%	0.15

CV: coefficient of variation;
SD: standard deviation;
msec: milliseconds;
µV: microvolts

Lower CV values (ranging from 8-13%) were noted for eCAEP latencies in comparison to eCAEP amplitudes (ranging from 21-48%). Overall, larger SDs were noted for amplitudes compared to latencies where the largest SD (SD = 49.71 msec) was noted on the medial electrode, in the initial test session of the P2 latency and

the smallest SD (SD = 1.81 msec) was noted on the apical electrode in the initial test session of the P2 baseline to peak amplitude. Wilcoxon signed-rank test indicated no significant differences between median latencies and amplitudes between the test and retest sessions ($p>0.05$), except for the P2 amplitude on the apical electrode ($z = 2.045$, $p = 0.041$). When results for apical, medial and basal electrodes were averaged together, no significant differences between median latencies and amplitudes between the test and retest sessions ($p>0.05$) were found.

The mean, standard deviation and co-efficient of variance of aided P300s at test and retest are presented in **Table 3.2.**

Table 3.2 Mean, standard deviation and co-efficient of variance of aided P300 latencies and amplitudes at test and retest (n=12)

		Mean		SD		CV	
		Test	Retest	Test	Retest	Mean	SD
Latency (msec)	Peak	366.42	374.58	47.16	43.83	6%	0.05
Amplitude (µV)	Peak to proceeding trough	21.27	28.38	11.64	20.27	45%	0.33

CV: coefficient of variation;
SD: standard deviation;
msec: milliseconds;
µV: microvolts

A lower CV (6%) was noted for the latencies of the P300 response, in comparison to the aided P300 amplitudes (45%). The mean absolute latency of the aided P300 response in the initial session (366.42 msec) was similar to that obtained seven days later (374.58 msec). The aided P300 amplitude presented with mean values of 21.27 and 28.38 µV in the test and retest respectively. The Wilcoxon signed-rank test indicated no significant differences in median latencies and amplitudes between test and retest sessions ($p>0.05$). Intra-participant agreement and consistency was

determined by the ICC. **Table 3.3** indicates the ICC values and corresponding confidence intervals of the eCAEP responses.

Table 3.3 eCAEP intra-participant test-retest ICC reflecting agreement and consistency with 95% confidence intervals (n=12)

		Electrode	Consistency		Agreement	
			ICC	95% confidence interval	ICC	95% confidence interval
Latency	N1	Basal	0.53	-0.64 – 0.86	0.53	-0.58 – 0.86
		Medial	0.66*	-0.17 – 0.90	0.68*	-0.68 – 0.91
		Apical	0.74*	0.10 – 0.83	0.72*	0.12 – 0.92
		Average	0.74*	0.08 – 0.92	0.73*	0.12 – 0.92
	P2	Basal	0.84*	0.46 – 1.00	0.85*	0.48 – 1.00
		Medial	0.13	-2.02 – 0.75	0.14	-2.66 – 0.77
		Apical	0.78*	0.24 – 0.94	0.79*	0.27 – 0.94
		Average	0.75*	0.12 – 0.93	0.76*	0.13 – 0.93
Amplitude	N1 baseline-to-trough	Basal	0.88**	0.59 – 0.97	0.88**	0.57 – 0.97
		Medial	0.89**	0.61 – 0.97	0.89**	0.63 – 0.97
		Apical	0.95**	0.81 – 0.99	0.95**	0.82 – 0.98
		Average	0.93**	0.77 – 0.98	0.94**	0.78 – 0.98
	P2 baseline-to-peak	Basal	0.72*	0.04 – 0.92	0.73*	0.07 – 0.92
		Medial	0.28	-1.51 – 0.79	0.28	-1.58 – 0.80
		Apical	-0.19	-3.12 – 0.66	-0.14	-1.53 – 0.61
		Average	0.67*	-0.15 – 0.91	0.66*	-0.10 – 0.90
	N1-P2	Basal	0.92**	0.73 – 0.98	0.93**	0.74 – 0.98
		Medial	0.55	-0.57 – 0.87	0.57	-0.62 – 0.88
		Apical	0.82*	-0.38 – 0.95	0.78*	0.25 – 0.94
		Average	0.85*	0.49 – 0.96	0.85*	0.51 – 0.96

** significant (p<0.05);*
*** highly significant (p<0.01)*

Excellent consistency and agreement (ICC>0.9) was seen for the N1 amplitude (apical cochlear regions) and the N1-P2 amplitude (basal cochlear region). Good consistency and agreement (ICC = 0.75-0.9) was obtained for the P2 latency (basal and apical cochlear regions), the N1 amplitude (basal and medial cochlear regions)

as well as the N1-P2 amplitude (apical cochlear region). Poor consistency and agreement (ICC<0.5) was obtained for P2 latency (medial cochlear region) and P2 amplitude (medial and apical cochlear regions). Confidence intervals indicated very broad measures of consistency and agreement ranging from poor to excellent. Averaged results for basal, medial and apical cochlear regions indicated that consistency and agreement ranged from moderate to excellent (ICC = 0.66–0.94).

Statistically significant ICC ($p<0.05$) were evident between test and retest for all amplitudes and latencies, except for N1 latency (basal cochlear regions), P2 latency (medial cochlear regions), P2 amplitude (medial and apical cochlear regions) and N1-P2 amplitude (medial cochlear regions). ICC values were highly significant for the N1 amplitude (all electrodes) and N1-P2 amplitude measured with basal electrode stimulation. Averaged results for basal, medial and apical cochlear regions indicated statistically significant and highly significant ICC values between test and retest for all amplitudes and latencies. **Table 3.4** contains the ICC values and corresponding confidence intervals of the latencies and amplitudes for the aided P300.

Table 3.4 Aided P300 intra-participant test-retest ICC reflecting agreement and consistency with 95% confidence intervals (n=12)

		Consistency		**Agreement**	
		ICC	**95% confidence interval**	**ICC**	**95% confidence interval**
Latency	**Peak**	0.62	-0.31 – 0.89	0.64	-0.30 – 0.90
Amplitude	**Peak to proceeding trough**	-1.78	-13.28 – 0.27	-0.54	-4.88 – 0.57

Moderate ICC consistency (ICC = 0.62) and agreement scores (ICC = 0.64) were measured for aided P300 latencies. Poor ICC consistency and agreement scores (ICC = -1.78 - -0.54) were measured for aided P300 peak to proceeding trough amplitudes with large confidence intervals noted for aided P300 latencies and amplitudes. No significant ICC scores were found between test and retest sessions for P300 measures.

CHAPTER 4

Discussion

The aim of the current study was to determine the short-term test-retest reliability of eCAEPs and aided P300s in adult CI recipients. eCAEPs and aided P300s were performed on twelve postlingually deafened, unilaterally implanted adult CI recipients and repeated seven days later.

Electrically evoked cortical auditory evoked potentials

eCAEP latencies and amplitudes were reported as measured from basal, medial and apical electrodes. The P2 amplitude as measured on the apical electrode was the only variable which was significantly different at test and retest ($p=0.041$). Averaged across the three electrodes, no significant difference was found between test and retest for N1 and P2 latencies and amplitudes ($p>0.05$). The mean N1(75.00 to 83.17 msec) and P2 (164.83 to 180.70 msec) latencies of the eCAEP response measured at basal, medial and apical electrodes for both test and retest fell within the standard range for normal hearing adults ranging from 75 to 150 msec for N1 latency and 150 to 250 msec for P2 latency. These results indicated that central auditory processing up to the level of the auditory cortex was relatively intact in the current sample of postlingually deafened adult CI recipients (Crowley & Colrain, 2004; Kelly et al., 2005; Kilney & Kripal, 1987). eCAEP latencies measured in the current study were also in agreement with aided N1 and P2 latencies obtained for CI recipients in previous studies (Groenen et al., 1996; Micco, Kraus, Koch, et al., 1995). The lower CV values that were revealed for the N1 and P2 latencies compared to the CV values of the amplitudes indicated that the eCAEP latencies were less variable when

compared to the amplitudes (Perez et al., 2016). Previous literature that recorded aided LLAEPs in normal hearing individuals also found latencies to be more variable in comparison to amplitudes (Perez et al., 2016; Polich & Herbst, 2000).

All P1 and N2 amplitudes and latencies showed moderate to excellent test-retest reliability when averaged across electrodes (ICC = 0.66 to 0.93 msec). The present study's findings are consistent with previous literature that determined the reliability of CAEPs in response to tones in normal hearing individuals (Pekkonen, Rinne, & Näätänen, 1995; Virtanen, Ahveninen, Ilmoniemi, Näätänen, & Pekkonen, 1998). Study results are also in agreement with previous literature that found aided CAEPs to be reliably recorded in the sound field for individuals with and without a digital hearing aid (Billings, 2013; Martin, Tremblay, & Korczak, 2008; Tremblay et al., 2003).

P1 and N2 amplitude and latency ICC scores averaged across electrodes ranged from moderate to excellent and therefore supports the findings of Tremblay et al (2003) who obtained ICC scores ranging from moderate to good consistency and agreement when recorded over short intervals in normal hearing individuals. In the current study, poorer ICC scores were found for amplitudes compared to latencies. It is well established that attention has an influence on both the latency and amplitude of the N1-P2 response (Crowley & Colrain, 2004; Martin, Tremblay, & Stapells, 2007). This could possibly explain why amplitudes decreased/increased between sessions as participants may have experienced different levels of attentiveness in the retest session compared to the initial testing session. Attentiveness can be controlled to some degree by determining participants emotional state at the time of testing, determining whether they are tired or worried and also by controlling their

physical activity prior to testing (Reis et al., 2014). Czarniak, (2011) determined the effects of speech stimulus level on aided CAEPs presented through the speech processor of adult CI recipients. Results indicated that aided CAEPs latencies are found to be more variable at higher intensities as compared to lower intensities as the compression characteristics of a CI that were present, may have influenced the results obtained at these higher intensities (Czarniak, 2011). By using eCAEPs in the current study the number of variables that could potentially influence test-retest reliability was therefore reduced as compared to aided CAEP, which is also influenced by the CI speech processor (Czarniak, 2011).

Aided P300s

The mean latencies of the aided P300 waves for test and retest in the current study (i.e. 366.42 and 374.58 msec respectively) fell within the normal range for normal hearing adults which range from 270 to 400 msec (Reis et al., 2014). This finding correlates with previous literature that found no difference in aided P300 latencies between 'good' CI performers, as determined by speech perception scores and normal hearing individuals (Groenen et al., 1996). The latency of the aided P300 response in this study is indicative of cognitive efficiency and auditory processing speed and provides a measure of the relative timing of the stimulus recognition, discrimination and classification (Coles, Smid, Scheffers, & Otten, 1995; John Polich & Criado, 2006).

The P300 amplitude is related to the amount of attention paid to the change in stimulus being presented (listening effort) and the clarity with which the stimulus is perceived (Picton, 1992; Sommer & Matt, 1990). The large mean amplitude values (i.e. 21.27 μV and 28.38 μV at test and retest) obtained for the aided P300 response

in this study fell slightly above the normal ranges of between 5μV and 20μV for normal hearing adults when measured in the sound field with speech and tonal stimuli (Perez et al., 2016). Literature suggests that the amplitude of the aided P300 response is related to task difficulty and that greater amplitudes will be found when discriminating easier tasks (Polich, 1987). This could be a possible explanation for the slightly elevated P300 peak amplitudes in this study as participants could possibly have perceived the discrimination task to be rather easy. However, another possible explanation for the large aided P300 amplitudes could be that the electrical artifacts caused by the speech processor could have impacted the amplitude of the aided P300 response (Czarniak, 2011). However, no significant difference was measured between test and retest.

The slight increase in the mean latency and mean amplitude of the aided P300 response from test to retest session could possibly suggest that the discrimination task did not get easier for the CI recipients between sessions and that there was no learning effect with the retest session (Perez et al., 2016). In order to elicit the P300 response, an active behavioural response is needed (Micco, Kraus, Koch, et al., 1995). Therefore, non-auditory factors such as lack of motivation or attention may have contributed to this slight increase in the mean latency and mean amplitude of the aided P300 response in the retest session of the current study (Perez et al., 2016; Reis et al., 2014).

In the current study, the mean difference between the aided P300 latencies for test and retest (8.16 msec), is in agreement with the findings of Reis et al. (2014) who indicated that the aided P300 latency may vary up to 15 to 20 msec between testing

sessions when repeated at relatively short intervals for individuals with normal hearing.

No significant differences ($p>0.05$) were noted between test and retest sessions for the aided P300 latencies and amplitudes. This is consistent with previous literature when P300s were repeated over a short interval in normal hearing individuals (Kilney & Kripal, 1987; Nakamura et al., 1995; Perez et al., 2016). Despite this, in terms of consistency and agreement, poor ICC scores were obtained for the amplitudes of the aided P300 response for the test and retest sessions (ICC= -1.78-0.64). To the authors knowledge there are no published reports specifically addressing the short term test-retest reliability of aided P300s in CI recipients. Nevertheless, to some extent participants' attentive state could have accounted for the variability of the aided P300 amplitudes recorded between sessions in this study as active attention of the infrequent stimulus is required when measuring the P300 response (Duarte et al., 2009). Other possible influencing factors, such as the time of day that testing took place as well as the temperature, were controlled where possible (Covington & Polich, 1996). Variability of the P300 response is evident when this response is measured in normal hearing individuals (Perez et al., 2016; Polich & Herbst, 2000; Reis et al., 2014). A greater amount of variability may therefore be expected in CI recipients as they are likely to present with poorer attentional abilities (Quittner, Smith, Osberger, Mitchell, & Katz, 1994; Smith, Quittner, Osberger, & Miyamoto, 1998) and require increased listening effort when compared to normal hearing individuals (Noble, Tyler, Dunn, & Bhullar, 2008). The lower CV values that were revealed for the aided P300 latencies compared to P300 amplitudes indicated that the aided P300 latencies and therefore processing speed, was less variable when

compared to the aided P300 amplitudes which is in agreement with previous literature (Perez et al., 2016; Polich & Herbst, 2000).

Electrically evoked cortical auditory evoked potentials versus aided P300s

Although exceptions do occur, most CI recipients present with superior attention skills when compared to profoundly deafened individuals who are fitted with hearing aids or vibrotactile devices (Quittner et al., 1994). Nevertheless, compared to normal hearing individuals, these CI recipients are still found to present with poorer attentional abilities when compared to normal hearing individuals (Quittner et al., 1994; Smith et al., 1998). CI recipients require increased listening effort when compared to normal hearing individuals and more so for unilaterally implanted recipients as opposed to bilaterally implanted individuals (Noble et al., 2008). This increased expenditure of listening effort can result in lower levels of attention (Damen, van den Oever-Goltstein, Langereis, Chute, & Mylanus, 2006). Thus, the effects of attention on cognitive processing could therefore influence the recording of aided LLAEPs (Fritz, Elhilali, David, & Shamma, 2007). Whilst recording the aided P300 responses, active attention of the infrequent stimulus is required (Duarte et al., 2009) whereas passive attention is required during the recording of the eCAEP response (Lightfoot & Kennedy, 2006). The increased variability for the aided P300 compared to the eCAEP response, as evidenced by the poorer test-retest correlation and broader confidence intervals was foreseen.

An advantage of performing aided P300s where the stimuli is processed by the speech processor of the CI, as opposed to directly stimulating the CI, is that it best reflects the natural signal processing of the stimuli and the effect that the processor has on the incoming acoustic signal will not be eliminated (Czarniak, 2011).

However, noise and extraneous artifacts, including electrical noise in the recording environment, artifacts caused by participant movement and eye blinking are common to all electrophysiological recordings (Czarniak, 2011). When performing electrophysiological measurements in CI recipients, implant associated artifacts created by the speech processor itself are also present and therefore additional limitations can be expected when recording aided P300s in CI recipients as opposed to recording P300s in normal hearing individuals or electrically evoked P300s in CI recipients (Katz, 2015). These specific artifacts change the acoustic/electric aspects of the incoming signal, especially when the incoming signal is presented in the sound field as with the aided P300 response (Katz, 2015). Therefore, when interpreting the study results, the additional variables that are introduced when measuring aided P300s in CI recipients, should be taken into consideration (Czarniak, 2011). These variables could therefore have contributed to the greater variability, poorer correlation scores and larger confidence intervals obtained for aided P300 responses compared to eCAEP responses in the present study (Czarniak, 2011).

In the current study, the removal of residual noise was attempted by placing the reference electrode on the contralateral mastoid, through signal and trace averaging and the use of an artifact rejection algorithm. However, residual noise levels at test and retest may not have been comparable between sessions as this factor was not controlled. Therefore, residual noise may have played a role in the variability of results (Gilley et al., 2006). It is recommended that future studies that measure test-retest reliability for eCAEPs and aided P300s control for residual noise levels between test sessions (British Society of Audiology, 2016).

CHAPTER 5

Clinical implications and conclusion

The aim of the current study was to determine the short-term test-retest reliability of aided late latency auditory evoked potentials in adult CI recipients. The increased reliance on objective measures to evaluate CI performance is becoming more evident in literature (Brown et al., 2008; Friesen & Tremblay, 2006; Groenen et al., 1996; Micco, Kraus, Dawn, et al., 1995; Reis et al., 2014). Objective measures can provide important information that will add to the understanding of the variability of CI outcomes (Firszt et al., 2002). Therefore, aided eCAEPs representing basal, medial and apical cochlear regions and aided P300s were recorded in the implanted ears of each participant. Measurements were repeated seven days after the initial assessment.

There was no significant difference ($p>0.05$) between test and retest in terms of N1 and P2 latencies and amplitudes of eCAEPs (when averaged across electrodes) or between P300 latencies and amplitudes. Moderate to excellent ICC scores were obtained for averaged N1 and P2 latencies and amplitudes of eCAEPs in terms of consistency and agreement. Moderate ICC scores were obtained for aided P300 latencies while ICC scores for amplitude were poor in terms of both consistency and agreement.

5.1 Clinical implications

- In the current study, there were no significant differences between short term test and retest for aided P300 and eCAEP latencies and amplitudes when eCAEP responses were averaged across electrodes. These results provide

improved confidence in these aided LLAEP measurements in CI recipients (Koo & Li, 2016). Due to the test-retest reliability found with regards to aided LLAEPs in the current study, these objective tests may therefore be used in the rehabilitation process following cochlear implantation by providing important information with regards to speech processing at the level of the auditory cortex (Czarniak, 2011).

- An assessment and follow up protocol for eCAEPs and aided P300s is essential for these measurements to be successfully utilised in the clinical setting. As eCAEP and P300 amplitudes and latencies were reliably recorded in adult CI recipients, the assessment protocol and parameters used to obtain the data in the current study can be used as a guideline for future studies in order to create a standardised assessment protocol that can be used in the management of adult CI recipients. As a result, eCAEPs and aided P300s can be utilised more regularly in the clinical setting to provide information with regards to the integrity and maturation of the central auditory pathway, assess auditory functioning and record developmental changes that may occur post implantation (Brown et al., 2008; Czarniak, 2011; Groenen et al., 1996; Kileny et al., 1997; Ponton et al., 1996; Sharma et al., 2002). Aided P300 latencies and amplitudes using different MAPs may be compared to guide CI device programming (Brown et al., 2008). Both eCAEPs and aided P300s can determine the central neurophysiological aspects underlying speech perception by evaluating the central auditory processes that contribute to the perception of speech (Brown et al., 2008; Czarniak, 2011; Groenen et al., 1996; Kileny et al., 1997; Ponton et al., 1996; Sharma et al., 2002).

- Poor ICC scores were obtained for the aided P300 amplitude. The amplitude of the aided P300 response is related to attention and working memory which are factors that are known to be variable (Covington & Polich, 1996; Perez et al., 2016; Reis et al., 2014). CI recipients are found to present with poorer attentional abilities when compared to normal hearing individuals and as a result, auditory attention and working memory for the active listening task is likely to be more difficult for these individuals (Quittner et al., 1994; Smith et al., 1998). Therefore, clinicians need to be cautious when interpreting changes in P300 amplitudes from baseline measurements.
- Despite the lack of significant differences in test-retest reliability, the ICC scores in terms of consistency and agreement demonstrated broad CIs. This implies that there was much variation between test-retest of both LLAEPs, however more so with aided P300s than eCAEPs within the target population. Clinicians therefore need to be aware hereof and exercise caution with regard to interpretation of these aided LLAEPs performed post-operatively. It is therefore essential that clinicians make use of a test protocol that includes both objective and subjective outcome measures.
- An individual's attentive state has found to influence the amplitudes and latencies of CAEPs and particularly P300s, therefore creating variability between results (Covington & Polich, 1996). This was evident in the variability of the current study's results, especially with regards to the amplitude of the P300 responses. The current study therefore highlights the significant influence of attention on eCAEP and aided P300 recordings, which is a factor that clinicians need to take into consideration during the recording of aided LLAEPs in order to accurately record these measurements. This can be

controlled in future to some extent by regularly reminding participants to pay attention during the recording of the aided P300 and aided eCAEP response as well as providing more regular breaks during the testing session to ensure patients do not tire and as a result present with a decreased attentive state.

5.2 Study strengths and limitations

A critical evaluation of this research project was conducted to evaluate its strengths and weaknesses.

5.2.1 Study strengths

- To the researcher's knowledge, the current study was the first of its kind to address the test-retest reliability of eCAEPs and aided P300s in CI recipients. Previous literature has found aided CAEPs and P300s to be reliably recorded in normal hearing individuals (Groenen et al., 1996; Kilney & Kripal, 1987; Nakamura et al., 1995; Perez et al., 2016; Reis et al., 2014; Segalowitz & Barnes, 1993; Tremblay et al., 2003). Aided CAEPs and P300s have also been recorded in CI recipients (Brown et al., 2008; Friesen & Tremblay, 2006; Groenen et al., 1996; Kelly et al., 2005; Kraus et al., 1993; Micco, Kraus, Koch, et al., 1995), however these research studies do not provide data pertaining to the test-retest reliability of these aided LLAEPs recorded in CI recipients. Therefore the current study provided valuable information, such as the test-retest reliability of eCAEPs and aided P300s that can be used in the clinical setting for CI recipients and in future research studies.
- Previous studies that explored test-retest reliability provided gross measures of reliability (Friesen & Tremblay, 2006; Tremblay et al., 2003). The current study made use of a strict measure of test-retest reliability by analysing

individual aspects of response amplitude and latency at test and retest for aided P300s and eCAEPs in CI recipients. Moreover, both measures of ICC consistency and agreement were utilised to determine the reliability of the results. It is recommended that the reliability of a measure not only be evaluated by looking at difference at test and retest, as was achieved using Wilcoxon signed rank test, but also in terms of both consistency and agreement (Koo & Li, 2016).

- The current study measured eCAEPs as opposed to other research studies which measured aided CAEPs (Czarniak, 2011; Groenen et al., 1996; Kelly et al., 2005). An advantage of measuring eCAEPs in the current study is that during recording, the stimulus bypasses the speech processor and is directly transmitted to the implanted device, therefore eradicating any pre-processing effects created by the CI and thereby creating less CI associated noise (Czarniak, 2011; Firszt et al., 2002; Gilley et al., 2006). These specific artifacts change the acoustic/electric aspects of the incoming signal, especially when the incoming signal is presented in the sound field (Katz, 2015). These added artifacts therefore created more difficulty with regards to the accurate analysis of the measured response (Katz, 2015).

5.2.2 Limitations of study

- Due to the small sample size of the current study, the statistical power of the data was decreased (Wilson Van Voorhis & Morgan, 2007). As a result, the data obtained from measuring the eCAEPs and aided P300s do not represent the characteristics of the adult CI population as accurately as with a larger sample size (Wilson Van Voorhis & Morgan, 2007).

- A very narrow selection criteria was employed in the current study and therefore the results obtained are only representative of a small and very specific population of post-lingual, unilaterally implanted CI recipients. Therefore these results cannot necessarily be generalised to all CI recipients (Czarniak, 2011).
- Noise and extraneous artifacts, including electrical noise in the recording environment, artifacts caused by participant movement and eye blinking are common to all electrophysiological recordings (Czarniak, 2011). In the current study, implant associated artifacts were also present whilst recording aided P300s and eCAEPs in CI recipients (Katz, 2015). These specific artifacts change the acoustic/electric aspects of the incoming signal, especially when the incoming signal is presented in the sound field as was done in this study with the aided P300 response (Katz, 2015). Therefore, due to the high electrical artifacts created by the CI, there was some difficulty with the analysis of the aided P300 and eCAEP responses in this study. There was greater difficulty to accurately analyse the aided P300 responses as the CI speech processor was bypassed during the recording of eCAEPs (Firszt et al., 2002). In the current study, the removal of residual noise was attempted by placing the reference electrode on the contralateral mastoid, through signal and trace averaging and the use of an artifact rejection algorithm. However, residual noise levels at test and retest may not have been comparable as this factor was not controlled between sessions. Therefore, residual noise may have played a role in the variability of results (Gilley et al., 2006).

5.3 Recommendations for future research

The following recommendations for future research were made:

- It is recommend that future research makes use of the *British Society of Audiology* recommendations in order to measure the residual noise level during testing so that eCAEP and aided P300 traces with equal residual noise can be compared during test and retest sessions (British Society of Audiology, 2016).
- Although artifacts were controlled for as far as possible through the use of an artifact rejection algorithm and signal averaging, a successful method to completely eradicate artifacts associated with a CI still needs to be determined (Czarniak, 2011).
- Incorporating a larger sample size when determining the test-retest reliability of aided LLAEPs in future will increase the power of statistical analyses as well as more accurately represent the characteristics of adult CI recipients (Czarniak, 2011; Wilson Van Voorhis & Morgan, 2007).
- Future studies may incorporate an alternative mental task in the retest session whilst recording aided P300s in order to determine if better motivation and/or attention can be elicited from participants.
- Further research that determines the correlation between subjective and objective measures of working memory and attention in CI recipients may provide further elucidation on how the variability of the P300 amplitude affects the listening skills of CI recipients on a daily basis.
- Future studies can include a broader selection criteria by including not only postlingually deafened CI recipients as was done in the current study, but also

pre/ perilingually deafened CI recipients. Due to the fact that postlingually deafened CI recipients present with normal auditory system development before hearing loss occurs, eCAEPs and aided P300 responses may differ between these two groups (Czarniak, 2011). The current study only included CI recipients implanted with Cochlear© CI devices. Future research can expand to include CI recipients with different CI devices to better understand the effects of various processing strategies as this will allow generalisation of results to a larger population size (Czarniak, 2011).

5.4 Conclusion

There were no significant differences between short term test and retest for all aided P300 and eCAEP latencies and amplitudes when eCAEP responses were averaged across electrodes. The ICC scores of consistency indicated moderate to excellent test-retest reliability for eCAEPs latencies and amplitudes when averaged across electrodes and poor to moderate test-retest reliability for aided P300s latencies and amplitudes. However, confidence intervals indicated very broad measures of test-retest agreement ranging from moderate to excellent for eCAEPs and moderate for aided P300 latencies. Aided P300 amplitudes demonstrated poor test-retest agreement however. Therefore eCAEPs can be utilised in the clinical setting for adult CI recipients for the monitoring of variations in the neural detection of time-varying cues in individuals over time while the P300 latency can provide insight into the time it takes for the speech processor to process stimuli and travel along the auditory pathway. Given the reliability of aided LLAEPs, these auditory evoked potentials can be applied to study and monitor neural processing in CI recipients. Caution should be exercised however, when interpreting changes in P300 amplitude, as this may

rather be variability of attention and working memory as opposed to neural processing or the consequence of the programming of the speech processor.

CHAPTER 6

References

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APPENDICES

Appendix A

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

21 April 2017

Dear Ms Pike

Project:	**Short-term test-retest reliability of aided late latency auditory evoked potentials in adult cochlear implant recipients**
Researcher:	**M Pike**
Supervisor:	**Drs L Biagio and T le Roux**
Department:	**Speech-Language Pathology and Archaeology**
Reference number:	**13156846 (GW20170307HS)**

Thank you for the response to the Committee's correspondence of 10 April 2017.

I have pleasure in informing you that the Research Ethics Committee formally **approved** the above study at an *ad hoc* meeting held on 20 April 2017. Data collection may therefore commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should your actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

We wish you success with the project.

Sincerely

Prof Maxi Schoeman
Deputy Dean: Postgraduate and Research Ethics
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: tracey.andrew@up.ac.za

cc: Prof B Vinck (HoD)

Research Ethics Committee Members: Prof MME Schoeman (Deputy Dean); Prof KL Harris; Dr L Blokland; Ms A dos Santos; Dr R Fasselt; Ms KT Govinder; Dr E Johnson; Dr C Panebianco; Dr C Puttergill; Dr D Reyburn; Dr M Taute; Prof GM Spies; Prof E Taljard; Ms B Tsebe; Dr E van der Klashorst; Dr G Wolmarans; Ms D Mokalapa

Appendix B

PCIU
PRETORIA COCHLEAR IMPLANT UNIT

20 April 2017

To whom it may concern

PERMISSION FOR THE USE OF INFORMATION OF
COCHLEAR IMPLANT RECIPIENT OF PCIU

Herewith I, Mrs Nicolize Cass, give permission that the information of adult CI recipients from the Pretoria Cochlear Implant Unit (PCIU) may be used for the research project titled: *Short-term test-retest reliability of aided late latency auditory evoked potentials in adult cochlear implant recipients.*

I have received the necessary information about this study and I have had the opportunity to ask questions regarding this project.

Kind regards

NICOLIZE CASS
COORDINATOR: PRETORIA COCHLEAR IMPLANT UNIT

Communication Pathology, Building, Room 3-33, Lynnwood Road, Pretoria, 0002
Phone: 012 420 3684 | Fax: 012 420 3617 | Email: ptacoch@up.ac.za |

Appendix C

JCIC

Johannesburg Cochlear Implant Centre
Lower Level
18 Eton Rd
Parktown
Johannesburg, South Africa

011 482 6141
011 356 6198

admin@jcic.co.za

13 October 2017

To whom it may concern

RE: PERMISSION FOR THE USE OF INFORMATION OF COCHLEAR IMPLANT RECIPIENTS OF THE JCIC

Herewith I, Mrs Leone Nauta, state that I gave Meghan Pike permission to test and go through adult Cochlear Implant participant files at JCIC for information to be used for her research project titled: Short-term test-retest reliability of aided late latency auditory evoked potentials in adult cochlear implant recipients.

I have received the necessary information about this study before started and I have had the opportunity to ask questions regarding this project.

Kind regards

L Nauta.

Leone Nauta
Coordinator / Audiologist: Johannesburg Cochlear Implant Centre
+27(0)83 631 0367 / +27(0)11 482 6141
leone@jcic.co.za

Appendix D

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Department of Speech-Language Pathology and Audiology

September 2016

Dear cochlear implant recipient

INVITATION TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: *Short-term test-retest reliability of aided late latency auditory evoked potentials in adult cochlear implant recipients*

PRIMARY RESEARCHER: Meghan Pike

INSTITUITION: Department of Speech-Language Pathology and Audiology
University of Pretoria

CONTACT NUMBER: 0794855500

We would like to invite you to participate in a research project from the Department of Speech-Language Pathology and Audiology. The purpose of this research project is to describe the short-term test-retest reliability of aided late latency auditory evoked potentials in adult cochlear implant recipients. Information about the study, as well as what you can expect to happen during the study, is detailed in this letter. Please read the information and complete the consent form should you choose to participate in the research.

PURPOSE OF THIS STUDY:

The human ear is divided into three parts, the outer ear, the middle ear and the inner ear. Sound travels from the outer, middle and inner ear and then travels to specific auditory areas in the brain. In order to describe the length of time that it takes

specific sounds to reach various areas along the hearing pathway as it travels up to the brain, two objective tests can be performed. It has been determined that these objective measures give an indication of an adult's central auditory processing abilities in the brain, as well as their ability to perceive and discriminate speech and sounds. Therefore we want to perform these objective measures in adult CI recipients at two different intervals (one week apart) in order to determine the short-term test-retest reliability of these objective tests.

WHERE WILL TEST PROCEDURES FOR THIS STUDY TAKE PLACE AND HOW LONG WILL THE TEST PROCEDURES TAKE?

This research project will take place at the Department of Speech-Language Pathology and Audiology at the University of Pretoria or the Johannesburg Cochlear Implant Centre. The procedures that will be included in this research project are visual inspection of the ear with a light, assessment of the middle ear functioning, an assessment to determine the degree of residual in each ear and lastly two objective assessments that indicate the length of time that it takes specific sounds to reach various areas along the hearing pathway as it travels up to the brain. Duration of this assessment will be approximately 90 minutes and will be performed twice with an interval of one week.

Test procedures:

1. Otoscopy: A light will be used to look into both of your ears, to determine the status of the ear canal and eardrum.
2. Immittance measures: This enables us to evaluate the functioning of your middle ear. A probe will be inserted into each ear and you will feel a slight build-up of pressure followed by a number of sounds. This is an objective test procedure and therefore you are not required to give any response. During this assessment it is important that you do not talk, chew or swallow so that we can accurately determine your middle ear functioning.
3. Pure tone audiometry: This is the standard hearing assessment you are already familiar with. You will be placed in a sound proof booth and sounds will be presented to each ear, via headphones that will be placed in your ear.

You will be required to remove your CI during this test procedure. The sounds that will be presented will differ in loudness and pitch. You will be required to press a button every time you hear a sound, no matter how soft the sound becomes.

4. Late Latency Auditory Evoked Potentials (LLAEPs): Electrodes will be placed on the top of your forehead, the bottom of your forehead and on the bone behind your ear. Sounds will be produced through your cochlear implant. You will be reclining in a comfortable chair and you will first be required to be quiet and still, whilst counting backwards from 400 in intervals of three. You will then be asked to listen closely to the sounds being presented in your ear and indicate every time you hear the non-frequent sound.

In addition to LLAEP measurement data, clinical data (demographics, case history and CI data) will be captured from clinical patient files.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This research study's ethical proposal was submitted to the Faculty of Humanities Research Ethics Committee, University of Pretoria and written approval has been granted by both committees.

WHAT ARE YOUR RIGHTS IF YOU TAKE PART?

You only have to take part in this study if you want to. You can decide not to participate without having to give a reason. You can also decide to stop taking part at any time without giving a reason.

WILL ANY OF THESE PROCEDURES BE PAINFUL OR UNCOMFORTABLE?

This study will incorporate visual inspection of the ear with a light, a test procedure to determine middle ear functioning, a test procedure to confirm the degree of hearing loss in each ear and lastly two non-invasive objective test procedures which will not harm you in any way. Should you experience any discomfort at any time during the test procedures in this study, testing will be stopped.

CONFIDENTIALITY

Identifying data of all participants will not be disclosed and data obtained from clinical patient files will be handled with strict confidentiality. Although the researcher will know the identity of all participants, each participant will be assigned an identifying code which will be used for data processing. Data will be securely stored at the Department of Speech-Language Pathology and Audiology as well as in an electronic format for a minimum of 15 years.

Should you require any further information regarding the study, please do not hesitate to contact the researcher.

If you agree to participate in this study, please complete the written consent section below.

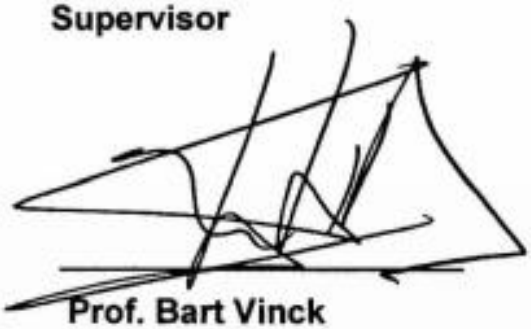
Thank you for showing interest in this research project.

Yours sincerely,

Meghan Pike
Primary researcher

Dr Leigh Biagio de Jager
Supervisor

Mrs Talita Le Roux
Supervisor



Prof. Bart Vinck
Head of Department

INFORMED CONSENT:

PARTICIPATION IN THE STUDY: Late latency auditory evoked potentials in individuals with single sided deafness and cochlear implants

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Please complete the following:

I_____, hereby confirm that I have read and understood the above stated information on this research study. I have also had the opportunity to ask questions about the study.

I hereby consent to participation in this study. I understand that I do so voluntarily and that I may withdraw from the study at any time.

I give permission to the researcher to have access to my clinical records and that this information may be used for the purpose of this research study and for publication in scientific literature. I understand that patient confidentiality will be maintained at all time and that the data will be securely stored at the Department of Speech-Language Pathology and Audiology as well as in an electronic format for a minimum of 15 years. Should the data obtained for this study be used for future studies, written consent will again be obtained from me.

_____

Signature

_____

Date

_____

Contact number(s)

Appendix E

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

FACULTY OF HUMANITIES
RESEARCH ETHICS COMMITTEE

Declaration for the storage of research data and/or documents

I/ We, the principal researcher(s) Meghan Pike

and supervisor(s) Dr Leigh Biagio-de Jager & Mrs Talita Le Roux

of the following study, titled Short-term test-retest reliability of aided late latency auditory evoked potentials in adult cochlear implant recipients

will be storing all the research data and/or documents referring to the above-mentioned study in the following department: Speech-Language Pathology and Audiology

We understand that the storage of the mentioned data and/or documents must be maintained for a minimum of 15 years from the commencement of this study.

Start date of study: 09/01/2016

Anticipated end date of study: 30/11/2016

Year until which data will be stored: 2032

Name of Principal Researcher(s)	Signature	Date
Meghan Pike		08/02/2016

Name of Supervisor(s)	Signature	Date
Dr Leigh Biagio-de Jager		08/02/2016
Mrs Talita Le Roux		08/02/2016

Name of Head of Department	Signature	Date
Prof. Bart Vinck		08/02/2016

Appendix F

UNIVERSITY OF PRETORIA
FACULTY OF HUMANITIES
DEPARTMENT SPEECH-LANGUAGE PATHOLOGY AND AUDIOLOGY

DECLARATION

Full Name: Meghan Pike

Student Number: 13156846

Degree: BA Audiology

I declare that this research report is my own original work. Where secondary material is used, this has been carefully acknowledged and referenced in accordance with university requirements.

I understand what plagiarism is and am aware of the University of Pretoria's policy in this regard.

SIGNATURE

07/09/2016

DATE