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Monitoring longitudinal behaviour of impedance and Neural Response Telemetry measurements in a group of young cochlear implant users

by

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"*Be the change that you wish to see in the world.*"

- Mahatma Gandhi -

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LIST OF ABBREVIATIONS

Auto-NRT™	-	Automatic Neural Response Telemetry
BTE	-	Behind-the-ear (instrument)
CI	-	Cochlear Implant
C- level	-	Comfortable loudness level
ECAP	-	Electrically evoked compound action potential
EHDI	-	Early Hearing Detection and Intervention
FDA	-	United States Food and Drug Administration
JCIH	-	Joint Committee on Infant Hearing
NRT™	-	Neural Response Telemetry
T- level	-	Threshold hearing level
TNRT™	-	Threshold Neural Response Telemetry
QOL	-	Quality of life

ABSTRACT

TITLE: Monitoring longitudinal behaviour of impedance and Neural Response Telemetry measurements in a group of young cochlear implant users

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Electrophysiological measures such as impedance telemetry and Neural Response Telemetry (NRT™) were developed by Cochlear™ in 1992 as clinical tools allowing the objective setting of stimulus levels for cochlear implant users. Extensive research proved the usefulness of NRT™'s as an aid in the programming process of audible and comfortable stimulus levels for children younger than six years. The Nucleus® Freedom™, launched in 2005, introduced new developments in cochlear implantation. Approval from the FDA for this system was obtained in March 2005 and for the first time included children from age 12 months with profound hearing loss. The Joint Committee on Infant Hearing suggested that children be diagnosed and that treatment commenced by the age of six months. The new features of the Nucleus Freedom™ give clinicians the necessary tools to treat this challenging population. An urgent need exists to ascertain the stability and accuracy of the new features introduced by this system, especially the Auto-NRT™ software, to validate its use within the paediatric population.

A longitudinal descriptive design was utilized implementing quantitative research methods to critically describe the behaviour of impedance telemetry and NRT™'s in a group of young cochlear implant users. The quantitative method included the application of the Custom Sound™ software and the Auto-NRT™ feature for this group at implantation, device activation, and then at determined follow-up visits.

Nine young children between nine months and five years and eleven months were used as participants during the twelve months of research. Impedance telemetry was described in terms of the mean Common Ground (CG) and Monopolar 1+2 (MP1+2) values calculated from measurement data collected on the basal, medial, and apical electrodes of the electrode array. The electrodes identified for statistical procedures for both measurement types were E3, E6, E8, E11, E13, E16, E19 and E21. Friedman's ANOVA was used as a statistical measure to determine the level of significance in changes among the measurement modes and conditions. The Wilcoxon signed-rank test was indicated in the presence of significant changes identified by Friedman's ANOVA to calculate the level of significance in a pair-wise comparison.

Results indicate that impedance telemetry remained consistent over the electrode array and over time in both measurement modes. A slight increase in mean values was observed during the first three months, followed by a gradual decrease at the six months interval. These changes were statistically non-significant. No specific trends were evident in impedance telemetry over time. NRT™-measurements remained consistent across the electrode array over time. Significant changes were present between the intra-operative to device activation measurement intervals. This trend is also described in studies of adult cochlear implant users. NRT™-measurements were stable during the first year post-implantation within the paediatric population. A comparison between the mean impedance telemetry and NRT™'s disclosed an inverse trend during the first six months post-implantation. Most changes were non-significant, indicating that these measures can be used effectively in the new semi-automated fitting software. The implementation of these measurements can lead to streamlined and accountable service delivery to young cochlear implant users.

Keywords: *audiological services, Auto-NRT™, cochlear implants, electrode array, impedance telemetry, neural response telemetry, Nucleus® Freedom™ cochlear implant system, paediatric population, stimulation levels, South Africa.*

OPSOMMING

TITEL:	Monitering van die longitudinale beweging van impedans- en Neurale Respons Telemetriemetings in ‘n groep jong gebruikers van kogleêre inplantings.
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In 1992 is elektrofisiologiese metings soos impedanstelemetrie en Neurale Respons Telemetrie (NRT™) deur Cochlear™ ontwikkel as kliniese hulpmiddels om objektiewe instelling van stimulasievlakke vir kogleêre gebruikers moontlik te maak. Navorsing het bewys dat NRT™’s ‘n effektiewe hulpmiddel is tydens programmering van hoorbare en gemaklike stimulasievlakke by kinders jonger as ses jaar. Die Nucleus® Freedom™ met nuwe ontwikkelings ten opsigte van kogleêre inplantings is in 2005 bekendgestel. Die FDA het in Maart 2005 hierdie sisteem goedgekeur vir gebruik by kinders selfs so jonk as 12 maande met uitermatige gehoorverlies. Die *Joint Committee on Infant Hearing* het voorgestel dat diagnose en aanvang van rehabilitasie teen ses maande ouderdom moet plaasvind. Die nuwe funksies van die Nucleus® Freedom™ stel oudioloë in staat om hierdie uitdagende bevolking te hanteer. ‘n Dringende behoefte bestaan om te bepaal of hierdie sagteware, veral Auto-NRT™ wat saam met hierdie sisteem bekendgestel is, oor voldoende akkuraatheid en stabiliteit beskik om in die hantering van die pediatriese bevolking te gebruik.

‘n Longitudinale, beskrywende ontwerp, wat kwantitatiewe metodes implementeer, is aangewend om die beweging van impedanstelemetrie en NRT™’s by ‘n groep jong gebruikers van kogleêre inplantings krities te beskryf. Dit het die gebruik van die Custom Sound™ sagteware en die ingeslote Auto-NRT™ funksie behels. Dit is tydens inplantering, by aktivering van die toestel,

en bepaalde opvolgsessies uitgevoer. Nege jong kinders tussen die ouderdomme van nege maande en vyf jaar en 11 maande is tydens die 12 maande navorsingsperiode as proefpersone benut. Die impedansmetings is beskryf in terme van die *Common Ground* (CG) en *Monopolar 1+2* (MP1+2) stimulasiemodaliteite. Data is verkry vanaf geselekteerde elektrodes op die basale, mediale en apikale gedeeltes van die elektrode. Vir statistiese ontledings van impedans en NRT™ is hierdie elektrodes geselekteer: E3, E6, E8, E11, E13 E16, E19 en E21. As statistiese ontledingsmetode, is Friedman se ANOVA toegepas om die vlakke van beduidenheid van beweging tussen die verskillende toetsmodaliteite en -omstandighede te bepaal. Die *Wilcoxon signed-rank* toets is aangedui in die teenwoordigheid van statisties beduidende veranderinge. Die doel van hierdie toets was om die vlak van beduidenheid paarsgewys te verifieer.

Resultate dui op konstante impedansmetings oor die elektrode asook oor tyd in beide toetsmodaliteite. ‘n Geringe, statisties nie-beduidende, verhoging in gemiddelde waardes is waargeneem tydens die eerste drie maande na inplantering, waarna die waardes weer geleidelik afgeneem het tot en met die ses maande opvolginterval. Geen spesifieke neiging kon vir impedanstelemetrie bepaal word nie. NRT™-metings het konstant gebly oor die elektrode en met tyd. Statisties beduidende veranderinge is gemeet tussen die intra-operatiewe en aktiveringsintervalle. Hierdie neiging is ook beskryf in studies van volwasse gebruikers van kogleêre inplantings. NRT™-metings, binne die pediatriese populasie, het dus stabiel gebly oor die 12 maande periode post-inplantering. ‘n Vergelyking tussen die gemiddelde impedans- en NRT™-metings het ‘n inverse neiging geïdentifiseer gedurende die eerste ses maande na inplantering. Veranderinge was oor die algemeen statisties nie-beduidend, wat daarop dui dat hierdie metings effektief gebruik kan word. Die implementering van hierdie metings kan meer doeltreffende dienslewering aan die jong gebruikers van kogleêre inplantings tot gevolg hê.

Sleutelwoorde: *kogleêre inplantings, pediatriese bevolking, neurale responstelemetrie, impedanstelemtrie, stimulasievlakke, Joint Committee on Infant Hearing, Nucleus® Freedom™ kogleêre inplantingsisteem, Auto-NRT™, oudiologiese dienste, Suid-Afrika.*

CHAPTER 1

INTRODUCTION AND ORIENTATION

Aim: To introduce the problem addressed by this study, to provide the rationale thereof, to describe the terminology used, and to present an overview of the content and organization of the study.

"And the deaf hear"

Luke 7 verse 22

1.1 INTRODUCTION

The cochlear implant has been referred to as a "*modern miracle"* (Müller & Wagenfeld, 2003:57). Its fundamental value in the treatment of profoundly deaf adults and children in whom conventional hearing aid fitting could not improve or initiate oral communication, has been firmly established (Brown, Abbas, Fryauf-Bertschy, Kelsay & Gantz, 1994:168; Haensel, Engelke, Ottenjann & Westhofen, 2005: 456-458; Nikolopoulos, Dyar, & Gibbin, 2004:128; Nourski, Abbas, Miller, Robinson & Jeng, 2005:141 and Parisier, Elexiades, Hoffman & Madell, 2004:256). Cochlear implantation resulted from research in many disciplines, including Audiology, a dynamic profession, characterised by continued and rapid growth in which traditional practices are constantly reviewed in a quest to improve efficacy and accountability (Clark, 2003: x and Northern & Downs, 2002:259). Research has caused cochlear implantation to develop from a small number of isolated, experimental studies done by a few, to a diverse discipline explored by many (Clark, 2003:x). The somewhat imperceptible nature of hearing loss in young children and an innate aspiration amongst audiologists to intervene as early as possible (Northern & Downs, 2002:259), has provided the momentum for continued research in implanting children at younger ages (Zwolan, 2002: 755). Implanting young children as soon as possible after the onset and diagnosis of profound hearing loss leads to enhanced achievements in

hearing and speech and language development (Sanderson & Nash, 2001:1). Cochlear implantation has hence been established as an inherent component of the audiological practice, and a crucial step toward providing effective audiological services to the paediatric population.

1.2 DEVELOPMENT OF PAEDIATRIC COCHLEAR IMPLANTATION

The advent of universal neonatal hearing screening has changed the way audiologists perceive, diagnose and manage the [1]child with a hearing loss (Anderson, Weichbold, D'Haese, Szuchnik, Quevedo, Martin, Dieler and Phillips, 2004:425). The rapid technological development and the first cochlear implants on children in the 1990's, brought questions regarding the suitability of the cochlear implant as a means of management to the centre of scientific research specifically in the case of children with severe to profound hearing loss (Anderson et al, 2004: 425 and Sanderson & Nash, 2001:1). With the rapid advancement of technology and the first cochlear implantations on children in the 1990's, a possible new management of a child with a severe to profound hearing loss was introduced and studied ever since.

The cochlear implant device has improved dramatically since the initial ventures of cochlear stimulation, especially over the last two decades. The first published report of electrical stimulation of the auditory system in an adult with a hearing loss was made by Djourno and Eyries in 1957 (in Clark, 2003:9 & Zwolan, 2002:740). Ten years later the first single-channel cochlear implant operation in the United States was performed in 1961 by William House, where a hardwire

[1] This population can broadly be described as deaf, hard-of-hearing or children with hearing loss. The National Deaf Children's Society (NDCS) uses the term deaf to mean the full range of deafness that is mild, fluctuating, sudden, progressive, late onset, or unilateral deafness and also auditory neuropathy, resulting in central auditory processing disorders. For the purpose of this study the term children (nought to five years) with hearing loss will be used and is defined as permanent bilateral or unilateral, sensory or conductive hearing loss of 20 dB or more in the frequency region important for speech recognition (approximately 500 Hz through 4000 Hz) (The Pediatric Working Group of the Conference on Amplification for Children with Auditory Deficits, 1996: 54).

gold electrode was placed in the scala tympani via the ear canal and round window (Zwolan, 2002:740). These pioneer devices were succeeded by multi-channel devices, more complex single-channel devices and multi-channel extra-cochlear devices (Beynon, 2005:17-18). Multi-channel intra-cochlear devices were introduced in the early 1990's and were also the first devices to be implanted in children (Beynon, 2005:17-18). Recently, body-worn speech processors have been replaced by ear-level models that are much more compact and more comfortable to wear (Cochlear, 2005a: 3, 29).

The introduction of new cochlear implant devices and the approved minimum age for cochlear implantation are strictly controlled by the Food and Drug Administration (FDA) (Brown et al.,1994:168; Clark, 1998:73; Hughes, Brown, Abbas, Wolaver & Gervais, 2000:164; Luxford, Eisenberg, Johnson & Mahnke, 2004:376-377; Seyle & Brown, 2002:72S and Zwolan, 2002:740). In recent years, the FDA has decreased the age boundary to 12 months, based on published reports on improvements in oral communication abilities of young children identified with hearing loss and receiving intervention by the age of six months (Nikolopoulos, Archbold & Gregory, 2005:184-186; Sinninger, 2002:187-188; Spivak & Sokol, 2005:104 -112 and Zwolan, 2002:740).

Cochlear implantation is steadily burgeoning in the South African context. Since the first cochlear implant was performed in November 1986 at the Tygerberg Hospital in Cape Town, nearly 550 cochlear implants have been performed country wide (Annual Report of the Cochlear Implant Unit, Tygerberg Hospital, University of Stellenbosch, 2006; Pretoria Cochlear Implant Programme – Annual Report 2006). Of the nearly 550 cochlear implants performed, 67% of the recipients were children. To date, six established cochlear implant units in Tygerberg Hospital, Pretoria, Johannesburg, Bloemfontein, One Military Hospital and Port Elizabeth are performing cochlear implant surgery in South Africa (Kaltenbrünn, Louw & Hugo, 2005:15).

The Pretoria Cochlear Implant Programme was established in 1991 and a total of 274 patients have been implanted. The Programme follows the guidelines set by the FDA regarding candidacy and age of implantation (Annual Report of the

Pretoria Cochlear Implant Programme for the year 2007). A total of 156 adults and 118 children have been implanted up to the end of the year 2007. The number of children being implanted increased gradually between 1991 and 2001, and then suddenly escalated from 2002 when proven performance of early implantation became evident (Annual Report of the Pretoria Cochlear Implant Programme for the year 2007, 2007). This escalation in the number of implants among children is not just true for the Pretoria Cochlear Implant Programme at present, more and more children between the age of 12 and 36 months are also being implanted with cochlear implant devices in South Africa as a whole (Müller, HPCSA Licensing Course in Cochlear Implantation, September 2005). This escalation in the number of children with hearing loss may be contributed to the implementation of newborn hearing screening programmes in the South African health system (Swanepoel, Delport & Swart, 2004:634-635).

The implementation of Universal Newborn Hearing Screening (UNHS) programmes is changing the face of cochlear implantation worldwide (Drinkwater, 2004:1). The Joint Committee on Infant Hearing (JCIH) (2000) suggests that children with hearing loss should be identified within the first few months after birth and intervention started by the age of six months. The JCIH Year 2000 position statement on neonatal hearing screening was accepted by the Professional Board for Speech, Language and Hearing Professions of the Health Professions Council of South Africa (HPCSA). The HPCSA developed a South African position statement, the Hearing Screening Position Statement Year 2002 (published by the HPCSA) and then the Early Hearing Detection and Intervention Programmes in South Africa Position Statement Year 2007 (published by the HPCSA). This position statement embraces the main aim of the position JCIH counterpart, namely: "*EHDI programmes, as proposed in this position statement, are recommended to identify, diagnose and treat newborns and infants with disabling hearing loss as early as possible to ensure optimum, cost effective solutions that enable persons to communicate effectively, allowing them to develop to their maximum potential, and thereby to secure their full participation in, and contribution to, society and the country's economy* (HPCSA, 2007:2). The audiologist's paediatric case load will thus be growing steadily as this position

statement is applied in the South African context and as more and more infants with hearing loss are identified at a very young age.

The ultimate objective of early implantation in South Africa, as globally, is to offer young children the auditory abilities to achieve optimal speech and language development that will ultimately affect academic outcomes in the educational environment (Kileny & Zwolan, 2004:S16). A variety of studies have confirmed superior speech perception outcomes in children receiving cochlear implants at very young ages (younger than twelve months), in comparison to children implanted at older ages (Clark, 1998:73-74; Clark, 2003:381,409; Drinkwater, 2004:1; Gordon, Papsin, & Harrison, 2004:S28; Haensel, et al., 2005:456-458; Flynn, 2003:15-17 and Zwolan, 2002:755). This has established a trend towards implantation of children with profound hearing losses, younger than one year of age, thus creating a new and more challenging population within the field of cochlear implantation. In 2004, over five hundred children younger than twelve months were implanted worldwide (Luxford et al., 2004:376-377). These early implanted children present new challenges to the audiologists due to their inexperience with auditory sensations, limited behavioural skills and cognitive limitation (Brown et al., 1994:168-169,175; Luxford et al., 2004:377-379 and Parisier et al., 2004:256-258). Children are not able to make reliable assessments of subjective loudness, while such judgements are needed to set the optimal stimulation level of the cochlear implant speech processor (Van Wermeskerken, Van Olpen & Van Zanten, 2006:589).

Optimal stimulation levels are set within the individual dynamic range. The dynamic range is determined by setting the Threshold-levels (T-levels) and Comfortable-levels (C-levels) for all active electrodes (Thai-Van, Truy, Charasse, Boutitie, Chanal, Cochard, Piron, Ribas, Deguine, Fraysse, Moudain, Uziel & Collet, 2004:153). According to Luxford et al. (2004:378), behavioural responses to sound will remain the “gold standard” for post-implant programming. However, objective measures offer more reliable results for device activation and the first few months of device programming for these children implanted at young ages due to their inexperience to sound and limited behavioural responses. Cochlear implant teams worldwide are currently using subjective methods for device

programming, based on behavioural methods applied when programming devices of the adult and the older child cochlear implant users (Clark, 2003:207). Play audiometry and visual response audiometry observation are used during evaluation procedures for young children (age zero to five years). With very young children, observation of changes in the child's behaviour is used during device programming. Very young children have inexperience with auditory sensations, limited language skills and behavioural and cognitive limitations due to their young age. This implies that very young children with severe-to-profound hearing loss often provide questionable behavioural responses based on the limitations of their age (Brown et al., 1994:168-169,175, Luxford et al., 2004:377-379 and Parisier et al., 2004:256-258). These immature, often questionable responses could result in unreliable T- levels and C-levels with little or no value when setting the dynamic range of the speech processor (Mėnard, Gallego, Truy, Berger-Vachon, Durrant & Collet 2004:S39). Inaccurate T- and C-levels may result in stimulation levels either being too high, causing discomfort to the cochlear implant user by sounds being experienced as too loud, or stimulation levels being too low, where auditory input is experienced as being too soft. Accordingly, the call for objective measurements has become increasingly important in the field of paediatric cochlear implantation (Hoppe, Rosanowski, Iro & Eysholdt 2001:119-120; Mason, Cope, Garnham, O'Donoghue & Gibbin, 2001 and Mason, 2004:226). These measurements may assist in attaining optimal stimulation levels for audible and comfortable auditory input. Gordon et al. (2004:S28) emphasised the importance of these objective measurements by stating that prospective advantages of early implantation in this population could be hindered unless clinicians are able to provide optimal stimulation levels which offer audible and comfortable auditory input upon device activation.

Mason (2004:S33) remarked that "…*Electrophysiological and objective measures have a valuable role to play in the management of patients receiving cochlear implants, in particular young children, complex cases and difficult-to-test patients. The number of young implanted children is increasing worldwide as the benefits of early implantation become apparent*." A wide range of electrophysiological and objective measures is available to aid in the intra-operative and post-operative stages of cochlear implantation (Mason, 2004:S33). These electrophysiological

measurements are based on the intracochlear measurements of electrically evoked compound action potentials (ECAP). Intracochlear measurements include impedance telemetry and Neural Response Telemetry (NRT™) (Gordon, et al., 2004: S28-S29; Lorens, Skarzinsky, Piotrowska, Walkowaik, Sliwa & Kochanek, 2003: 379-380; Mason, et al., 2001:225-226 and Polak, Hodges, King & Balkany, 2004: 104-105).

One such intra-cochlear measurement is performed by means of the reverse telemetry technique and is referred to as Electrical impedance measurements, also commonly known as impedance telemetry (French, 1999:61). Electrical impedance encompasses resistance, capacitance and inductance measured in voltage within a given circuit. Electrical impedance measurements within the cochlea can give valuable data regarding the status of individual electrodes of a cochlear implant (French, 1999:61-62). Impedance telemetry is a straightforward and speedy procedure for checking the internal component of the cochlear implant device and for recording the impedance of the electrode-tissue interface inside the cochlea (Mason, 2004:S34). Longterm research proved that impedance telemetry results stabilises one month after surgery when neural tissue has stabilised around the electrode array (Henkin, Kaplan-Neeman, Muchnik, Kronenberg & Hildesheimer, 2003: 874, 878, 879). Electrodes can be identified as potentially faulty if impedances are either very high, termed open circuit, or when impedance values are very low, termed short circuit (French, 1999:62 & Mason, 2004:S34).

According to Clark (2003:167), impedance measurements of the stimulating electrodes should be regularly monitored as they reflect changes at the electrode-tissue interface due to the degree of fibrous tissue and bone formation or an increase in the surface area of the electrode as a result of platinum dissolution. New bone formation, starting 4 to 6 weeks post-implantation, causes an increase in impedance values of the tissues surrounding the electrode array, thus resulting in higher current levels (Clark, 2003:108). These higher current levels have an influence on the T- and C-levels and the dynamic range of the

MAP[2]. A comparison of electrode impedance values and cochlear histology indicated that the most obvious association between electrode impedance and fibrous tissue was the density and continuity of the fibrous tissue capsule surrounding the electrode array (Clark, 2003:168). Histology of the cochlea indicates that a dense fibrous tissue capsule is generally present by 27 months post-implantation, and therefore, impedance telemetry values should stabilise at this point in time (Clark, 2003:108).

An additional objective measure is the Neural Response Telemetry measurement. In 1992, Neural Response Telemetry (NRT™) was developed by Cochlear™ as a clinical tool allowing the objective setting of stimulus levels in their Nucleus CI24M device (Dillier, Lai, Almqvist, Frohne, Müller-Deile, Stecker & Von Wallenberg, 2002:407; Petrick, Seligman & Clark, 1997:142 and Lai & Dillier, 2000:333). Research has proven the NRT™ technique to be safe and consistent in measuring the auditory nerve's responsiveness during surgery, as well as post-operatively. A success rate of 95% in measuring responses has been obtained during the application of NRT™'s in adults and children (Abbas, Brown, Shallop, Firzst, Hughes, Hong & Staller, 1999:46; Brown, Hughes, Luk, Abbas, Wolaver, & Gervais, 2000:151-152; Briaire & Frijns, 2005:143-144; Lai & Dillier, 2000:334 and Lai, Aksit, Akdas & Dillier, 2004:252,262). Research has also proven the benefits of NRT™ measurements in the establishment of audible T-levels to aid in the initial fitting process (Di Nardo, Ippolito, Quaranta, Cadoni, & Galli, 2003:352,354-355; Mason, 2004:S37; McKay, Fewster, & Dawson, 2004:66; Ramos Macias, Maggs, Hanvey, John, Castillo, Goenaga, Cuyás, & Caferelli Dees, 2004:380-383, Seyle & Brown, 2002:72S and Thai-Van, Chanal, Coudert, Veuillet, Truy, E & Collet, 2001:153).

Over the last five years extensive research has been performed to investigate the usefulness of NRT™'s as an aid in the device activation and programming process to select audible and comfortable stimulus levels (Cochlear, 2005b). Over 250 clinics globally have applied the Nucleus NRT™ in more than two thousand cases to confirm that the NRT™- threshold lies between T- levels and

[2] MAP is general term that refers to individual stimulation parameters. Please refer to section 1.6, page 16 for an explanation of the term MAP.

C-levels and that T-levels are audible. (Cochlear, 2005b, Luxford et al., 2004:377 and Thai-Van et al., 2004:2822). It has also been demonstrated that the correlations between NRT-thresholds and the behavioural T- and C-levels improve over time in children (Cochlear Report, 2000:8 and Thai-Van et al., 2001:154). These studies confirmed the value of the application of the NRT-threshold levels at device activation, proving that stimulation levels set using objective measurements closely relates to behavioural responses. The clinical application of the NRT™ is especially helpful to the audiologist to ensure the programming of audible stimulation levels during device activation and the first few weeks post-implant of children under the age of 6 years (Battmer, Dillier, Lai, Weber, Brown, Gantz, Thomas Roland, Cohen, Shapiro, Pesch, Killian, & Lenarz, 2004:S10, S14; Cochlear, 2005b; Polak et al., 2004:105; Thai-Van et al., 2001:154 and Thai-Van et al., 2004:2811).

NRT™ data is thus clinically applied in the selection of initial stimulation levels of speech processors, especially in the paediatric population where subjective fitting procedures are often unreliable and risk providing either inadequate stimulation for audition due to a limited dynamic range of stimulation or uncomfortably loud stimulation levels (Gordon et al., 2004) This may prolong the process of establishing audible electrical stimulation through the cochlear implant (Ramos Macias et al., 2004:381). Research performed by Ramos Macias et al. (2004:383) proved that applying intra-operative NRT-threshold data in initial device activation of young children provide them immediately with audible electrical stimulation levels. Clinical application of objective measurements in initial fitting procedures of young children are thus time-saving and cost-effective since device programming sessions are now less frequent and of shorter duration (Ramos Macias et al., 2004:383). The latest software editions utilises NRT-threshold measurements to create a series of progressive stimulation levels or MAPs. This provides the opportunity for extended periods between follow-up sessions in the first few weeks and months post device activation. By streamlining the service delivery process of the young cochlear implant user, the audiologist is able to deliver accountable services to a steadily growing population (Luxford et al., 2004:377).

In the search of streamlining the service delivery process, long term research on NRT™ has identified changes in the amplitude growth function and NRT-threshold levels (Cochlear Report, 2000:6 and Lai et al., 2004:258). The most significant changes between measurements were observed between intra-operative and the first post-operative measurements. Research performed by Lai et al. (2004:252) exhibited little changes in NRT™-levels over a 4 year period post-implantation. The largest changes observed in this study, occurred within the first 15 months post-operatively, and then diminished over time (Lai et al, 2004:253). These variations are due to changes in and around the auditory neural periphery as a result of the implant surgery, for example tissue reactions, the growth of a new fibrous tissue capsule around the electrode array and changes to the electrode surface due to electrical stimulation (Lai et al., 2004:252). Less significant long term changes in amplitude growth function and NRT-threshold measurements were evident over the subsequent post-operative time intervals (Cochlear Report, 2000:6 and Lai et al., 2004:253). These studies verified that intra-operative NRT™-data were generally stable enough to be used for assisting in the initial speech processor fitting sessions (Lai et al, 2004: 253). The question of how applicable intra-operative NRT™-data is at a later stage has become more pertinent with the increasing number of semi-automated methods for using NRT™-data to assist in speech processor fittings that have been proposed (Brown et al, 1994: 170; Brown et al, 2000: 151). Long term monitoring of NRT™ data provides an idea of how stable this data is over time. Stability of NRT™ data over a 4 year period was exhibited in the study performed by Lai et al. (2004:152) for the Nucleus™ CI24M Cochlear Implant System, confirming its use in the semi-automated fitting methods proposed by Brown et al. (2000: 151). Semi-automated fitting methods are especially helpful in the speech processor fitting of very young cochlear implant users, who are unable to provide reliable subjective loudness judgements for setting the MAP T- and C-levels.

These semi-automated fitting methods ensure optimal stimulation levels for audible and comfortable auditory input. Inaccurate T- and C-levels may result in stimulation levels either being too high, causing discomfort to the cochlear implant user by sounds being experienced as too loud, or stimulation levels being too low, where auditory input is experienced as being too soft. Semi-automated

fittings based on NRT™-data are considered as an objective procedure and has become increasingly important in the field of paediatric cochlear implantation (Hoppe, et al., 2001:119-120; Mason *et al.,* 2001:225 and Mason, 2004:226).

1.3 STATEMENT OF PROBLEM AND RATIONALE

The most recent cochlear implant device released by Cochlear® in 2005, the Nucleus Freedom™, contains the latest software release of NRT™, namely version 3.0. This version brings new features to NRT™ measurements namely, integrated telemetry systems and automatic NRT™-measurements (Cochlear, 2005b and Cochlear, 2005c). However, the clinical changes in performance of the Nucleus NRT™ 3.0 and later software editions are still under evaluation at this moment (Cochlear, 2005b). Long term monitoring (over a four year period) of NRT™-data was performed for previous Nucleus™ Cochlear Implant Systems (Nucleus™ CI24M), to establish its stability over time and its application in semi-automated fitting methods (Lai et al, 2004:152). Since the Nucleus Freedom™ is a new cochlear implant system, it is still necessary to confirm the stability of NRT™-data over an extended period of time, before it can be successfully applied in semi-automated fitting methods.

The Nucleus Freedom™ was introduced in South Africa in May 2005 (Annual Report of the Pretoria Cochlear Implant Program for the year 2005, 2005). In Pretoria, the first child receiving the Nucleus Freedom™ cochlear implant was in June 2005, and since then most children implanted have received this speech processor (Personal interview, Ronèl Chester-Brown, Co-ordinator of Pretoria Cochlear Implant Team, 30 January 2006). Thus, the investigation into the long term changes in impedance telemetry and NRT™-measurements is a priority for the clinicians managing very young children with cochlear implants worldwide as well as in South Africa.

As mentioned previously, research investigated changes in the amplitude growth function and NRT-threshold levels intra-operatively and post-operatively proving

stability and very little changes across measurements in older software verions (Lai et al., 2004:259). The latest software editions utilises NRT-threshold measurements to create a series of progressive stimulation levels or MAPs. This provides the opportunity for extended periods between follow-up sessions in the first few weeks and months post device activation. By streamlining the service delivery process of the young cochlear implant user, enables the audiologist to deliver accountable services to a steadily growing population (Luxford et al., 2004:377). The delivery of accountable services is a key concern within the South African Health Sector (Kaltenbrünn, et al., 2005:15-16). South Africa is a country faced with limited financial resources within the public sector (Swanepoel, et al., 2004:634). The implementation of the EHDI and consequentially more cochlear implantations among very young children with severe to profound hearing losses, will make it essential that cost-effective devices and techniques such as impedance telemetry and NRT™ be employed when managing this population. For the Nucleus Freedom™ cochlear implant using the Custom Sound version 3.0 and later software editions, these measurements are still variables in the clinical setting. The question that arises is:

Are any changes present in impedence telemetry and NRT™-measurements during the first twelve months post-implantation within the paediatric population?

1.4 ADDRESSING THE PROBLEM

In an attempt to address the question about the presence of any changes in impedance telemetry and NRT™-measurement during the first twelve months post-implantation within the paediatric population, this study will conduct both a theoretical and an empirical investigation.

The problem statement will be addressed in two sections. The first section will be of a theoretical nature, while the second section will be an empirical study. The theoretical section will evaluate scientific data relevant to the research question presented, providing an overview of the latest literature indicating the current trends in paediatric cochlear implant service delivery and the use of impedance

telemetry and NRT™-measurements as part of the service delivery process, offering insight into the areas requiring further study, and discussing the future use of the measurements in the clinical setting.

The theoretical background will be followed by an empirical investigation based on a longitudinal assessment of impedance telemetry and NRT™-measurement data up to twelve months post-implantation of paediatric cochlear implant users. A theoretical as well as an empirical approach will be used, so as to make contextually relevant recommendations.

1.5 ORGANISATION OF THE STUDY

A brief outline and description of the organisation of the sections included in this study is provided in Table 1.1.

TABLE 1.1 Outline and description of the sections comprising this study

CHAPTER 1:	The first chapter provides the background, rationale and statement of the problem identified in this study; the organisation of the content outlining the chapter contents; a clarification of terminology; and a list of abbreviations used.
CHAPTER 2:	Chapter 2 discusses the most relevant theoretical perspectives about the new developments in the field of paediatric cochlear implantation and objective measurements. It will specify concepts and constructs as they are defined in the literature and how this is applicable to the research project at hand.
CHAPTER 3:	Chapter 3 provides a thorough description of the design, criteria, apparatus, collection procedures and analysis techniques implemented in the research methodology to acquire the data according to the objectives of this study, with the purpose of addressing the main aim of the study.
CHAPTER 4:	This chapter is a presentation of the empirical results obtained for each objective specified for the study.
CHAPTER 5:	Chapter 5 then discusses the empirical results presented in Chapter 4. Data is interpreted and discussed in terms of the new meaning or levels contributed by the research project and the implications thereof, integrating information from the known theoretical perspectives. It also evaluates the validity of the results obtained.
CHAPTER 6:	Chapter 6 presents conclusions from the theoretical and empirical sections of the study. The researcher provides a critical evaluation of the complete research approach, design, the conduction of the research and the suitability of the results found. The most important conclusions and implications of the study are then discussed and finally making recommendations regarding further research.

1.6 TERMINOLOGY

The following terms are described and motivated according to their application and meaning as used in this study:

- **Auto-NRT™:**

  The term Auto-NRT™ is a term denoting a new feature in the Nucleus NRT™ version 3.0 software and later, allowing automatic measurement of NRT-thresholds and impedance telemetry (Cochlear, 2005b). This new feature can be used intra-operatively as well as post-operatively. It is used during surgery to confirm the auditory nerve's responsiveness as well as integrity of the internal electrode. Post-operative measurements aid in the initial stimulation of very young children and difficult to test individuals as well as aid in follow-up MAPping procedures (Cochlear, 2005b).

- **C-level:**

  This general term refers to the electrical currents on each electrode producing the maximum comfortable loudness level. This is determined on each individual electrode as part of the MAPping process (Brown et al., 2000: 156). The electrical current is determined by pathological changes at the electrode-tissue interface (Clark, 2003: 665).

- **Cochlear Implant**

  This general term refers to a surgically implanted electronic device that restores useful hearing in severely hearing impaired adults and children when the organ of hearing situated in the inner ear has not developed or is destroyed by disease or injury. It bypasses the inner ear and provides information to the auditory centres through direct stimulation of the acoustic nerve (Clark, 2003: xxxi and Zwolan, 2002: 740). The device has several common components that work together to provide the hearing impaired individual with sound. These components include the surgically implanted internal device consisting of the receiver coil or internal processor and the electrode array; and an externally worn speech processor (Clark, 2003: xxxi,

Wilson: 2002:109 and Zwolan, 2002: 740). The term is used throughout the current study referring to the multi- channel cochlear implant systems currently in use by all manufacturers since the early 1980's (Beynon, 2005:17-18 and Zwolan, 2002: 741).

- **Electrically evoked compound action potential (ECAP):**

  This general term refers to a measure of synchronous VIIIth nerve fibre activity elicited by electrical stimulation (Franck & Norton, 2001:289). The intra-cochlear electrodes are used for both stimulation and recording of the ECAP. The cochlea is stimulated in one area, while the response is measured from a neighbouring are within the cochlea (Abbas et al., 1999: 45). The ECAP is typically recorded as a negative peak, called N1, followed by a positive peak, called P2 (Abbas et al., 1999: 45). The main purpose of this measurement is thus to measure the responsiveness of auditory neurons (Rubenstein, 2005:S4). The first system with the capability of recording the ECAP of the auditory nerve was introduced by Cochlear™ when the Nucleus 24 Cochlear Implant was released in 1996. This system used Neural Response Telemetry to record the ECAP (Lai, 1999: 4 and Clark, 2003: 683). Figure 1.2 is a graphic representation of a typical ECAP response, showing the negative peak N1 followed by the positive peak P2.

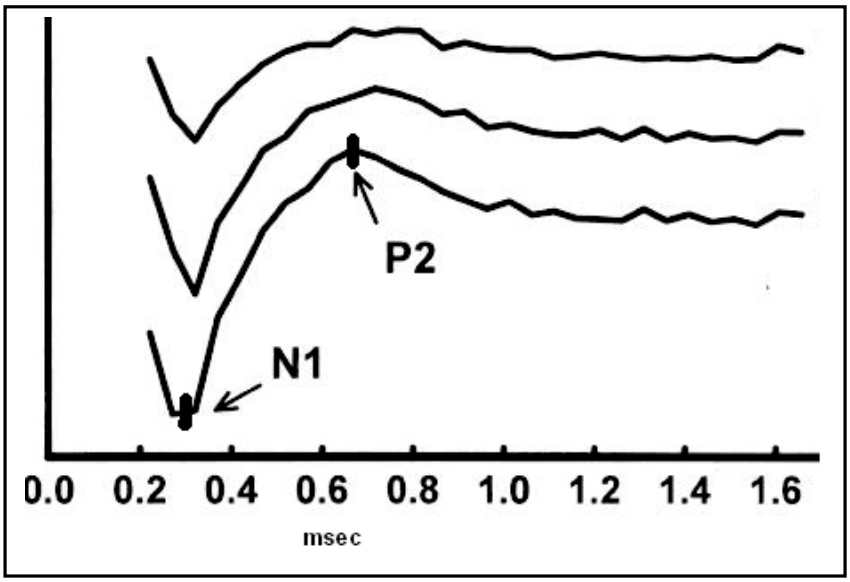

Figure 1.1 Graphic representation of the ECAP recording

- **Impedance telemetry:**

  This is a general term referring to an objective measure used to examine the functioning of the cochlear implant by measuring the electrical component of the biphasic stimulus pulse via computer software (French, 1999:61). Electrical impedance encompasses resistance, capacitance and inductance measured in voltage within a given circuit. It is the physical quantity that relates voltage to current within a given circuit. With some of the implant systems it is possible to generate current either between two electrodes within close proximity inside the cochlea, known as bipolar stimulation, or between one electrode within the cochlea and one close to, but outside the cochlea, known as monopolar stimulation. A further possibility is to use one intra-cochlear as the active electrode and all the others inside the cochlea as a reference. This mode of stimulation is known as common ground. Electrical impedance measurements within the cochlea can give valuable data regarding the status of individual electrodes of a cochlear implant (French, 1999:61-62). Impedance telemetry is a straightforward and speedy procedure for checking the internal part of the cochlear implant device and for recording the impedance of the electrode-tissue interface inside the cochlea (Mason, 2005).

- **MAP:**

  This general term refers to information of individual stimulation parameters (eg. Threshold - and Comfortable-levels) programmed and stored in a cochlear implant speech processor (Clark, 1998: 147).

- **Neural Response Telemetry (NRT™):**

  This term denotes a specific measurement using a bidirectional telemetry feature to record electrically evoked compound action potentials (ECAP) of the auditory nerve using specifically designed software and the cochlear implant device. It is the neural response resulting from a stimulus presented at one location within the cochlea and then recorded from a neighbouring location also within the cochlea (Dillier et al., 2002:407). This NRT™ software system was produced by Lai and Dillier at the University of Zurich in

collaboration with Cochlear™ (Clark: 2003: 683, Lai, 1999: 4 and Lai & Dillier: 2000:333). Similar software applications have been introduced by other manufacturers as well (Zwolan, 2002:740). In this study, the term NRT™ will refer to the NRT™ measurement used by the Nucleus devices of Cochlear™.

The typical neural action potential to be measured is small, of the order of 100μV in amplitude. The stimulus used, however, produces an artefact several orders of magnitude larger in amplitude close to the evoked neural response, resulting that the recording will be obscured by the artefact. The Forward-Masking paradigm was developed by Lai & Dillier (Lai, 1999:3) which subtracts the artefact from the recording and separate out the neural response. The Forward-Masking paradigm involves three stimulation levels, namely:

A. A probe stimulus alone is presented, resulting in a recording consisting of both the neural response and the Probe Stimulus artefact.

B. A Masker stimulus is presented first, followed by a a short inter-stimulus interval (referred to as the Masker Advance). This produces a recording which contains the stimulus artefact and the associated neural activity due to the Masker, plus the stimulus artefact of the Probe.

C. In this interval, the Masker and Probe sequence is repeated but with the Probe stimulus set to a minimal level. The corresponding recording contains only artefact from the Masker and associated neural activity.

Subtracting the recording obtained at Interval 3 from the recording obtained at Interval 2, yields the neural response to the Probe. A further artefact, known as the Baseline measurement, is produced every time the measurement amplifier is switched on. This is then measured in a fourth interval D, known as the Subtraction Paradigm, where both the Masker and Probe is presented at minimal amplitude and thereby contributing no stimulus artefacts. The Baseling measurement is then subtracted from the recordings. The Subtraction Paradigm is implemented in the NRT™ software processes to yield the neural response (Lai, 1999:3). The resultant trace is referred to as

the Baseline Corrected display, as illustrated in Figure 1.1. To summarize the complete Subtraction Paradigm:

A-(B-(C-D)) = Baseline Corrected display

There are currently four applications of the Nucleus NRT™ and especially in children:

1) to confirm the integrity of the implant and the status of the peripheral auditory nerve (French, 1999:61)
2) to assist with the programming of initial MAPs, especially in young children and recipients who are difficult to test (Clark, 2003:683 and Mason, 2005 website accessed 29 January 2005)
3) to supplement behavioural testing and monitor peripheral responsiveness over time (Clark, 2003:683 and Ramos Macias et al., 2004: 380)
4) to create an entire MAP based on two behavioural measurements (Clark, 2003:683 and Ramos Macias et al., 2004: 380).

- **T-level:**

  This general term refers to the electrical current level on each electrode producing the softest detectable stimulation level. This is determined on each individual electrode as part of the MAPping process (Brown et al., 2000: 156). The electrical current is determined by pathological changes at the electrode-tissue interface (Clark, 2003: 665). The current levels between the T- level and C-level are known as the dynamic range (Brown et al., 2000: 156 and Clark, 2003: 665).

- **Neural Response Telemetry™ Threshold (**NRT-threshold**):**

  This general term refers to the ECAP threshold as measured using NRT™ software (Cochlear, 2000:1). This procedure involves the reduction of the amount of supplied to the auditory nerve via an electrode until no ECAP can be elicited from the auditory nerve (Ramos Macias et al., 2004:381). Clinical studies have reported a relationship between the NRT-threshold and

behavioral Comfortable levels during the MAPping procedure (Brown et al., 2000:152).

1.7 CONCLUSION

Rapid advances in the field of cochlear implantation have taken place in which the benefits of implantation have exceeded expectations. There is no doubt that cochlear implants, and the application of electrophysiological strategies, will further advance over the next few years to promote the benefit of cochlear implants in adults and children. NRT™'s furnish the audiologist or clinician with objective NRT-threshold levels that can be used in the setting of stimulation levels, ensuring audible stimulation levels from the start. The value of impedance and NRT™ measurements are thus significant within the South African context. A steadily budding population of very young children receiving cochlear implants, a multi-cultural nation with eleven official languages, a high level of illiteracy, resource-poor and strain on financial resources (Swanepoel et al., 2004:634) call on the need of effective service delivery. As mentioned previously, research investigated changes in the amplitude growth function and NRT-threshold levels intra-operatively and post-operatively proving stability and very little changes across measurements in older software versions (Lai et al., 2004:259). The latest software editions utilise NRT-threshold measurements to create a series of progressive stimulation levels or MAPs. This provides the opportunity for extended periods between follow-up sessions in the first few weeks and months post device activation. By streamlining the service delivery process of the young cochlear implant user, enables the audiologist to deliver accountable services to a steadily growing population (Luxford et al., 2004:377). For the Nucleus Freedom™ cochlear implant using the NRT™ version 3.0 and later software editions, these measurements are still variables in the clinical setting. The aim of this study is therefore to provide much needed empirical evidence regarding the longitudinal behaviour[3] of impedance telemetry and NRT™ measurements,

[3] The term behaviour is used in current literature to descirbe the changes or variations in impedance telemery and NRT™-measurements.

measured via the latest Auto- NRT™ software for the Nucleus Freedom™ cochlear implant system.

1.8 SUMMARY

This chapter provided an argument to support the importance of conducting clinical research regarding the application of the latest of electrophysiological strategies in cochlear implant systems within the burgeoning paediatric population being implanted at young ages, in order to assure effective service delivery. Finally, a research question was formulated for the investigation of impedance telemetry and NRT™ measurements for a period of twelve months post-implantation. A description was given of how the study poses to address the question followed by a list of the terminology used in the study. Finally, a conclusion to the chapter was supplied.

CHAPTER 2

DEVELOPMENT AND CURRENT PRACTICE OF COCHLEAR IMPLANTATION IN THE PAEDIATRIC POPULATION

Aim: This chapter investigates the development of cochlear implantation for the paediatric population and evaluates current cochlear implantation practice

2.1 INTRODUCTION

In the three decades after the first cochlear implant operation in the Melbourne Hospital, Australia, in 1978, more than one hundred thousand individuals with hearing loss received cochlear implants. Prior to the 18th century, deafness was a severe sensory disability with the ear trumpet as the only aid to facilitate communication. Children in particular were disadvantaged – they led sheltered, restricted lives in institutions and were referred to as being deaf and dumb. The first efforts to help children with hearing loss were made by l`Abbè de l`Eppé at the Paris Deaf School and Heineke in Germany in 1794 (Clark, 2003:1).

Over the past two decades cochlear implantation has proven its fundamental value in the treatment of profoundly deaf adults and children for whom conventional hearing aid fitting could not improve or initiate oral communication (Brown, Abbas, Fryauf-Bertschy, Kelsay & Gantz, 1994:168; Haensel, Engelke, Ottenjann & Westhofen, 2005: 456-458; Nikolopoulos, Dyar, & Gibbin, 2004:128;

Nourski, Abbas, Miller, Robinson & Jeng, 2005:141; Parisier, Elexiades, Hoffman & Madell, 2004:256). Safety and efficacy of cochlear implant devices have been well documented (Sauberman, 2000:122; Zwolan, 2002:740). Clark (2003:1) defines the modern cochlear implant as "…*a bionic ear, which restores useful hearing in severely to profoundly deaf people when the organ of hearing situated in the inner ear (cochlea) has not, developed or is destroyed by disease or injury. This device bypasses the inner ear and provides information to the hearing centres through direct stimulation of the hearing nerve*".

2.2 DEVELOPMENT OF THE COCHLEAR IMPLANT

The discovery that electrical stimulation to the auditory system can create a perception of sound occurred around 1790 when an Italian physics professor, count Alessandro Volta, placed metal rods in his own ears and connected them to a 50 Volt circuit (Niparko & Wilson, 2002:103). He presented his results at the Royal Society in London and reported a "*…kind of jerky crackling or bubbling, as though some…matter was boiling"* (Clark, 2003:3). Due to the unpleasant nature of these sensations, this phenomenon was only further investigated 50 years later. In 1868, Brenner performed an extensive investigation on the effects of altering the polarity, rate, and intensity of the stimulus, and the placement of electrodes, on the hearing sensation produced. He elicited sensations resembling buzzing, hissing, whistling, and ringing sounds at various pitches (Clark, 2003:3).

Further experimentation occurred sporadically until the first direct stimulation of an acoustic nerve with an electrode was performed by Andre Djourno and Charles Eyries in 1957 (Niparko & Wilson, 2002:105; Clark, 1997:9; Zwolan, 2002:740). Six years later, in 1961, the first single-channel cochlear implant operation in the United States was performed by William House, where a hardwire gold electrode was placed in the scala tympani via the ear canal and round window (Zwolan, 2002:740). Later on in 1969 the first wearable cochlear implant, consisting of a single electrode, was developed with the help of Jack Urban to aid lip-reading (Clark, 2003:8; Niparko & Wilson, 2002:106). Dr Graeme Clark continued with research throughout the 1970's. He developed cochlear

implants, known today as a multi-channel cochlear implant, which stimulated the cochlea at multiple points. On 1 August 1978 the first recipient of the intra-cochlear multi-channel cochlear implant was implanted in Melbourne, Australia (Clark, 2003: 24).

These pioneer devices were succeeded by multi-channel devices, more complex single-channel devices, and multi-channel extra-cochlear devices (Beynon, 2005). Multi-channel intra-cochlear devices were introduced in the early 1990's (Beynon, 2005:17-18). In December 1984, the Nucleus™ cochlear implant was approved by the United States Food and Drug Administration (FDA), to be implanted in adults. Since this study will focus on the Nucleus™ cochlear implant system, a brief description of the development of this system will now be provided.

2.2.1 The Nucleus ™ 22 Implant system

The first Nucleus™ electrode to be approved by the US FDA for use in adults in 1985 and in children in 1990 was the Nucleus™ 22 electrode array (Zwolan, 2002: 743). This electrode array consisted of 22 active intra-cochlear electrodes on a straight Silastic array (Clark, 2003: 521). The Nucleus 22™ system included the CI-22M and Mini-20+2 receiver stimulator implants and the Spectra-22 speech processor (Clark, 1997:128). The Spectra-22 speech processor made use of the SPEAK speech coding strategy. More than eight thousand children and ten thousand adults have been implanted with this array (Zwolan, 2002: 743). This system provided the basis for a sequence of improvements in speech processing.

2.2.2 The Nucleus ™ 24 Implant system

The successor of the Nucleus™ 22, the Nucleus ™ 24 multi-channel cochlear implant, was introduced in 1997 and received FDA approval for use in adults and children in 1998 (Zwolan, 2002: 743). The internal components of this system consists of an electrode array consisting of 22 banded intra-cochlear electrodes, with an additional 2 extra-cochlear ground electrodes, resulting in a total of 24

electrodes (Zwolan, 2002: 743; Clark, 2003: 527). These 2 additional electrodes introduced the use of bipolar and monopolar stimulation modes (Zwolan, 2002: 743; Clark, 2003: 527).

A perimodular array or precurved electrode array was also introduced with this system to minimize surgical impact on the cochlea during implantation surgery (Zwolan, 2002: 744; Clark, 2003: 526). Instead of using positioners during surgery, a malleable platinum stylet is placed at the tip of the electrode array to allow the array to curve during insertion (Clark, 2003: 533). Once the array is inserted in the cochlea and the stylet is removed, the electrode curls close to the inner wall of the cochlea (Zwolan, 2002:744). The rationale behind this design is having the electrode array lying close to the centre of the modiolus which in turn will provide improved sound quality, speech recognition, and power efficiency. This electrode array was named the Nucleus™24 Contour (Zwolan, 2002:744). Another aspect in which the Nucleus™24 differs from the Nucleus™22 is that the Contour electrode is attached to a smaller receiver-stimulator, which allows for implantation in younger children (Cochlear Corporation, 2000). The Nucleus™ Contour electrode was introduced in 2000 and received FDA approval for use in adults and children in the same year (Zwolan, 2002: 743).

The Nucleus™24 offers two different speech processors, the SPrint and the ESPrit. The SPrint is a body-worn unit with four programme options as well as 2 battery options. A Liquid Crystal Display (LCD) communicates information regarding the programme in use, the volume and sensitivity settings as well as icons for troubleshooting, to the patient. The SPrint headset consists of a microphone worn behind the ear and a transmitter coil that is held in place with a magnet (Zwolan, 2002: 744). The ESPrit processor was the first ear-level speech processor commercially available. The ESPrit microphone is worn behind the ear and is similar in size and weight to a conventional behind-the-ear (BTE) hearing aid. The microphone is also connected to a transmitter coil and magnet. This speech processor can store 2 different programmes and can be connected to assistive listening devices (Zwolan, 2002: 744). Both the SPrint and the ESPrit can use any of the speech coding strategies, namely ACE, CIS, and SPEAK (Zwolan, 2002: 744).

The ESPrit 3G speech processor, a third generation BTE speech processor, was introduced for the Nucleus™24 electrode array in 2002. This speech processor provides an inbuilt telecoil for wireless use of telephones and assistive listening devices. It also has a Whisper setting that enhances soft sounds not normally heard with standard speech processors. The ESPrit 3G speech processor became available for Nucleus™22 implant users in 2004 (Cochlear™. 2005b).

2.2.3 The Nucleus ™ 24 Implant System and Neural Response Telemetry

An additional feature of the Nucleus™24 implant system allowing implantation in younger children is Neural Response Telemetry (NRT™). In 1992, Neural Response Telemetry (NRT™) was developed by Cochlear™ as a clinical tool allowing the objective setting of stimulus levels in their Nucleus™24 implant system (Dillier, Lai, Almqvist, Frohne, Müller-Deile, Stecker & Von Wallenberg, 2002:407; Petrick, Seligman & Clark, 1997:142; Lai & Dillier, 2000:333). The software was developed by Lai and Dillier from the University Hospital in Zurich, Switzerland. The NRT™ system was conceived to make intra-cochlear measurements of the electrically evoked compound action potential (ECAP) of the cochlear nerve (Lai, 1999: ii). NRT™ software allows measurement of the ECAP via a bidirectional telemetry system where one electrode within the cochlea is stimulated, while a different intra-cochlear electrode measures the ECAP (Zwolan, 2002: 744; Lai, 1999: ii). The recorded ECAP is then amplified and subsequently encoded for transmission via the radio-frequency (RF) link back to the speech processor to capture, process, store, and display the measurement data on a computer. The NRT™ software also controls the parameters of the stimulus used to evoke the response being measured as well as the parameters used to perform the recording (Dillier *et al*., 2002: 407). Also implemented by the software is the masker-probe paradigm or forward-masking paradigm to cancel large stimulus masker artifacts, in order to extract the relatively small neural response (Dillier *et al*., 2002: 407). In the end, the ECAP recordings consist of a single negative peak called N1 that is followed by a less

prominent positive potential called P2. The average latency of N1 is between 0,2 and 0,4 milliseconds after the onset of the stimulus (Brown *et al*., 2000: 151). One of the most important potential applications of the NRT™, the possibility that an NRT™ can be used in the programming of the cochlear implant speech processor, could benefit audiologists working with very young children where programming the speech processor could be very challenging (Brown *et al*., 2000: 151)

Multi-centre clinical trials and research has proven the NRT™ technique to be safe and consistent in measuring the auditory nerve's responsiveness during surgery, as well as post-operatively. A success rate of 95% in measuring responses has been obtained during the application of NRT™'s in adults and children (Abbas, Brown, Shallop, Firzst, Hughes, Hong & Staller, 1999:46; Brown, Hughes, Luk, Abbas, Wolaver & Gervais, 2000:151-152; Briaire & Frijns, 2005:143-144; Lai & Dillier, 2000:334; Lai, Aksit, Akdas & Dillier, 2004:252,262). Research has also proven the benefits of NRT™ measurements in establishing audible T-levels to aid in the initial fitting process (Di Nardo, Ippolito, Quaranta, Cadoni, & Galli, 2003:352,354-355; Mason, 2004:S37; McKay, Fewster & Dawson, 2004:66; Ramos Macias, Maggs, Hanvey, John, Castillo, Goenaga, Cuyás, & Caferelli Dees, 2004:380-383; Seyle & Brown, 2002:72S; Thai-Van, Chanal, Coudert, Veuillet, Truy, E & Collet, 2001:153).

Over the past five years extensive research has been undertaken to investigate the usefulness of NRT™'s as an aid in the device activation and programming process to select audible and comfortable stimulus levels (Caferelli-Dees, Lai, Dillier, Von Wallenburg, Van Dijk, Akdas, Aksit, Beynon, Burdo, Chanal, Collet, Conway, Courdet, Craddock, Cullington, Deggouj, Fraysse, Grabel, Kiefer, Kiss, Lenarz, Mair, Maune, Müller-Deile, Piron, Razza, Tasche, Thai-Van, Toth, Truy, Uziel & Smoorenberg, 2005: 105). Over 250 clinics globally have applied the Nucleus NRT™ in more than two thousand cases to confirm that the NRT™-threshold lies between T-levels and C-levels and that T-levels are audible (Cochlear, 2005b; Luxford *et al*., 2004:377; Thai-Van *et al*., 2004:2822). It has also been proven that the correlations between NRT-threshold and the behavioural T- and C-levels improve over time in children (Cochlear Report, 2000:8; Thai-Van *et al*., 2001:154). These studies confirmed the value of the

application of the NRT-threshold levels at device activation, proving that stimulation levels set using objective measurements closely relate to behavioural responses. The clinical application of the NRT™ is especially helpful to the audiologist to ensure the programming of audible stimulation levels during device activation and the first few weeks post-implant in children under the age of 6 years (Battmer *et al*, 2004:S10, S14; Cochlear, 2005b; Polak *et al*., 2004:105; Thai-Van *et al*., 2001:154; Thai-Van *et al*., 2004:2811).

NRT™ data is clinically applied, therefore, in the selection of initial stimulation levels of speech processors, especially in the paediatric population where subjective fitting procedures are often unreliable and consequently risk providing either inadequate stimulation for audition due to a limited dynamic range of stimulation or uncomfortably loud stimulation levels (Gordon *et al*., 2004). This may prolong the process of establishing audible electrical stimulation through the cochlear implant (Ramos Macias *et al*., 2004:381). Research performed by Ramos Macias *et al*. (2004:383) proved that applying intra-operative NRT-threshold data in initial device activation of young children provides them immediately with audible electrical stimulation levels. Clinical application of objective measurements in initial fitting procedures of young children are thus time-saving and cost-effective, since device programming sessions are now less frequent and of shorter duration (Ramos Macias *et al*., 2004:383). The latest software editions utilise NRT-threshold measurements to create a series of progressive stimulation levels or MAPs. This provides the opportunity for extended periods between follow-up sessions in the first few weeks and months after device activation. Streamlining the service delivery process to the young cochlear implant user enables the audiologist to deliver accountable services to a steadily growing population (Luxford *et al*., 2004:377).

2.2.4 The Nucleus ™ Freedom Cochlear Implant System

The Nucleus ™ Freedom cochlear implant system is the 4th generation cochlear implant system from Cochlear™. This system was launched in 2005 for use in both adults and children after FDA approval in March 2005 (Nucleus®

Introductory CI Course, February 2007, Mechelen, Belgium). This implant system has been approved for use in severe-to-profoundly deaf adults and children as young as two years of age, while children between the ages of 12 months and two years must present with a profound hearing loss (Healthy Hearing, 2007. Date of access: 1 June 2007; The University Hospital, 2007. Date of access: 1 June 2007). The Nucleus® Freedom features both an internal component and an external speech processor.

The Nucleus® Freedom implant utilises the Contour Advance™ electrode. This is a self-curling array that allows the electrodes to be inserted close to the centre of the modiolus of the cochlea for targeted stimulation and increased power efficiency, while applying minimal pressure on the cochlear structures (Healthy Hearing, 2007. Date of access: 1 June 2007). The Contour Advance™ electrode was designed with a Softip™ to protect the cochlear structures during surgery, which is vital in the preservation of residual hearing (The University Hospital, 2007. Date of access: 1 June 2007). The dimensions of the implant have also been adjusted to allow the implant to be suitable for infants as well as adults, and enables shorter surgery as well as shorter recovery times (Healthy Hearing, 2007. Date of access: 1 June 2007; The University Hospital, 2007. Date of access: 1 June 2007). The implant contains a SmartSound™ digital microchip, designed to handle a range of future upgrades and enhancements. This will allow users to take advantage of new speech processing technologies without further need for future surgery (Healthy Hearing, 2007. Date of access: 1 June 2007; The University Hospital, 2007. Date of access: 1 June 2007).

The Nucleus® Freedom sound processor contains SmartSound™ digital technology allowing the programming of different strategies for different listening environments. An LCD with a built-in help function communicates settings to the user (Healthy Hearing, 2007. Date of access: 1 June 2007; The University Hospital, 2007. Date of access: 1 June 2007). The ear-level sound processor is splash resistant. The sound processor is available in different wearing options, making it more accessible for adults and infants (Healthy Hearing, 2007. Date of access: 1 June 2007; The University Hospital, 2007. Date of access: 1 June 2007).

The Custom Sound™ software used to programme the Nucleus® Freedom also contains a new version of NRT™, entitled Auto-NRT™. With Auto-NRT™, the software performs the procedure automatically, searching for a NRT-threshold without any input from the clinician. These measurements can be performed intra- and post-operatively and can be used to attain objective and streamlined programming of stimulation levels of the sound processor. Progressive MAPs can be created based on NRT-threshold levels, streamlining the fitting process and ensuring audible stimulation levels for even very young children (Healthy Hearing, 2007. Date of access: 1 June 2007; The University Hospital, 2007. Date of access: 1 June 2007). The Auto-NRT™ measurements will be the focus of this study.

2.2.5 Speech Coding Strategies

A focal point of research in cochlear implantation has been speech coding strategies (Nucleus Report, 2005; Wilson, 2000:129). At present, cochlear implant systems offer various ways to process a speech signal. Each coding strategy has particular variables, for example rate of stimulation, the number of intra-cochlear sites stimulated simultaneously or periodically, and the successive sequences of electrode activations (Beynon, Snik & Van der Broek, 2003: 392-394). The following strategies are widely used: SPEAK, CIS, ACE and ACE-RE (Cochlear website, accessed 14 October 2005; Wilson, 2000; Zwolan, 2002:745-746).

In general, speech coding strategies can be regarded as the pattern of electrical stimulation that a cochlear implant applies to supply information regarding pitch, loudness, and temporal aspects of the acoustical signal. Speech coding strategies extract and encode specific information from the electrical reproduction of the acoustical signal gathered by the microphone of the speech processor (Moore, 2003: 243). The encoded signal is used to deliver specific stimulus characteristics to the relevant electrode pairs. Preference for speech coding strategies is unique to each person, but research does show advantages and

preferences in the choice of certain speech coding strategies (Beynon, Snik & Van den Broek, 2003: 392; Arndt, Staller, Arcaroli, Hines & Ebinger, 1999: 1).

SPEAK or Spectral Peak is a dynamic, roving, pulsitile and interleaved speech coding strategy with an average speed of stimulation. With SPEAK, the most optimal peaks of the acoustical signal are selected for stimulation (Parkinson, Parkinson, Tyler, Lowder & Gantz, 1998: 1075). The loudest frequencies or spectral maxima of the incoming signal are collected and then delivered to the different electrodes according to their frequency range. This particular speech coding strategy is clearly based on the processing of spectral information (Clark, 2003: 735). The speech processor analyses the incoming wave pattern in the frequency domain and activates the tonotopic relevant electrodes with a pulse (Beynon *et al*., 2003: 393). Research has shown that the spectral, formant, amplitude, and temporal information supplied to the electrode array enhances the recognition of vowels and consonants, which in turn leads to better speech recognition (Clark, 2003:356).

Continuous Interleaved Sampling or CIS is a high speed strategy which only stimulates a limited set of electrodes or channels based on the incoming acoustic signal (Arndt *et al*., 1999: 3; Clark, 2003: 736). A high speed stimulating strategy provides information regarding the temporal aspects of speech. The acoustic waveform is sampled and then divided into different frequency bands by the speech processor. The speech processor then generates pulses that are delivered sequentially to the electrodes according to their frequency range. No specific speech information is selected from the speech signal (Arndt *et al*., 1999:4). The CIS is available in the Nucleus ™ 24 and Nucleus ™ Freedom cochlear implant systems (Skinner, Holden, Whitford, Plant, Psarros & Holden, 2002: 228).

The Advanced Combination Encoders (ACE) strategy is a combination of the most prominent features of the SPEAK and the CIS speech coding strategies. Like SPEAK, ACE is a dynamic and roving strategy where up to 22 channels can be stimulated at once. The high speed properties of CIS are also incorporated in ACE. Therefore, ACE delivers important information regarding spectral and

temporal information of the speech signal to the electrode array (Arndt *et al*., 1999: 4; Clark, 2003: 737). The higher speed of stimulation emphasizes the spectral information of speech, improving speech perception in quiet and noise (Beynon *et al*., 2003: 394). Electrodes are stimulated sequentially, from the basal to the apical area (Skinner *et al*., 2002: 229).

ACE-RE is a newer version of the ACE strategy, which is unique to the Nucleus ™ Freedom cochlear implant system. The strategy is based on ACE, with the only difference being that ACE-RE is able to apply even higher stimulation rates (Nucleus ™ Custom Sound Help version 3.1).

The appropriate speech coding strategy to be applied can be selected by assessing speech perception skills in quiet and noise, and the user's every day performance (Beynon *et al*., 2002: 394). In numerous studies a great amount of cochlear implant users preferred ACE above SPEAK and CIS (Beynon *et al*., 2002: 394; Arndt *et al*., 1999:6; Clark, 2003: 743; Skinner *et al*., 2002: 222). Because clinicians now have the option to choose a specific speech coding strategy, the best strategy can be selected for each individual cochlear implant user in order to ensure optimal functioning. Optimalization of the coding and processing of speech information remains a focus area within the research field, the main goal being to bridge the gap between electrical and acoustical hearing.

Table 2.1 is a brief summary of the main differences between the stimulus parameters of SPEAK, CIS and ACE speech coding strategies (Nucleus ™ Custom Sound Help version 3.1).

TABLE 2.1 Main differences between the different speech coding strategies

Strategy	No. of stimulation sites	Stimulation rates per channel (Hz)	No. of maxima or channels stimulated per frame
SPEAK	20	250	6 to 10
CIS	4, 6, 8 or 12	900, 1200, 1800 or 2400	4, 6, 8 or 12

ACE	22	250, 500, 720, 900, Up to 20 1200 or 2400

2.3 DEVELOPMENT OF COCHLEAR IMPLANTATION IN YOUNG CHILDREN

While the impact of hearing loss in an adult varies significantly with the degree of the hearing loss and lifestyle choices made by the adult, the impact of an advanced level of hearing loss in infancy and early childhood is invariably profound. Since virtually every aspect of verbal communication development and language learning is sub-served by early access to the phonology of speech, the effects of a failure to access phonologic inputs are pervasive (Niparko & Blankenhorn, 2003: 265). For example, a normal-hearing five-year-old child should present with a vocabulary that ranges between five thousand and twenty six thousand words. In comparison a deaf child of the same age usually has access to a vocabulary of about two hundred words, and limited ability to structure a sentence (Berliner & Eisenberg, 1985:S10; Moog & Geers, 1999: 1127). Even children presenting with progressive hearing loss fall significantly behind their normal-hearing peers in their mastery of the surrounding oral language in its written, read, spoken and signed forms (Svirksy, Robbins, Kirk, Pisoni & Miyamato, 2000:153). Since the developmental effects of a profound hearing loss are multiple, cochlear implants have been applied to ever younger children in an attempt to promote a more normal level of developmental learning through audition (Niparko & Blankenhorn, 2003:267).

The advancement of the cochlear implant for children with severe to profound hearing loss is noteworthy for numerous reasons. The cochlear implant represents one of the many innovative technologies that enable the rapid transfer of processed information. The cochlear implant can encode speech sounds with precision and in this manner provide opportunities for developmental and oral language learning in young children. For the past two decades, cochlear implants have been successfully applied to hearing impaired children. Auditory thresholds

of children implanted with cochlear implants allow access to auditory information beyond that available to the thresholds supplied by conventional amplification or hearing aids, offering a critical foundation for auditory therapy (Niparko & Blankenhorn: 2003: 267). In order to investigate the development and application of the cochlear implant for young children, the following aspects will be addressed: changing candidacy selection criteria for a cochlear implant; post-implantation performance and quality of life, and cost-effectiveness.

2.3.1 Changing selection criteria for a cochlear implant in children

For nearly two decades, cochlear implantation has been an accepted procedure to restore sound to profoundly deaf children (Müller & Wagenfeld, 2003: 57). Procedures to determine candidacy for an implant have been strict, to ensure that children who are selected are likely to benefit from this type of intervention. The main selection criteria have included a profound sensory neural hearing loss in both ears; little or no benefit from conventional hearing aid use; no medical contra-indications; and a chronological age of two years or more. Some other prerequisites included realistic expectations of the parents, access to an educational programme that stresses auditory and verbal skills, and a high degree of motivation on the part of the parents (Rizer & Burkey, 1999: 1117). Children who receive a multi-channel cochlear implant are expected to perform better than they had with conventional hearing aids.

During the early stages of cochlear implantation in children, a minimum age of 2 years was established by the FDA in the United States in 1990 (Müller, 2005). Some of the reasons for this age requirement included concerns about being able to diagnose a child's profound hearing loss correctly before the age of two years, and concerns about having time to judge the benefit of conventional amplification. No objective measures were available to confirm the audiological benefit obtained by a child from the hearing aids and its settings. Uncertainties existed regarding the effect of small skull size and level of physical development on surgery, as well as whether future growth might cause electrode extrusion or device migration (Rizer & Burkey, 1999: 1117; Clark, 2003: 560).

It is generally agreed that there is greater potential to learn speech and language when cochlear implantation is performed early, before or during the critical period usually associated with language development. A simpler argument for early cochlear implantation is that it will minimize or prevent a growing gap between the child's chronological age and his language use. Nikolopoulus *et al*. (2004a:629) reported that the expressive language age of profoundly deaf children using hearing aids only, progresses at about half the rate of their chronological age, in contrast with the rate of language development following cochlear implantation which begins to match changes in chronological age.

The special problems associated with meningitis served as the initial factor leading to children being implanted prior to the age of two years. The ossification of the cochlea following meningitis can prohibit complete insertion of the electrode array and result in poorer implanted performance. Performing surgery as quickly as possible following meningitis can preclude this complication and the associated degradation in implant performance. The successful implantation of these children demonstrated that being two years of age does not constitute an impassable barrier to cochlear implantation. Results from these children also suggested that implantation prior to two years of age should be possible for children deafened by other causes (Rizer & Burkey, 1999: 1119).

Anatomical and physiological studies addressed initial concerns regarding the small skull size and level of physical development and their effect on surgery, and the question whether future growth might cause electrode extrusion or device migration. These studies proved that the electrode is inserted into a labyrinth that is adult size at birth and thus poses no special problem in very young children (Rizer & Burkey, 1999: 1120). Studies of the long term effects of cochlear implants in children show no significant incidence of device or electrode migration or extrusion over time (Burton, Shephard & Xu, 1994: 167; Waltzman, Cohen, Green & Roland, 2002: 505). Surgical procedures for mastoidectomy, cochleostomy, as well as electrode insertion and closure of the wound in children are similar to procedures followed for an adult (Niparko & Blankenhorn, 2003: 270).

Cochlear implantation entails risks inherent in extended mastoid surgery. Two of the major potential complications are facial nerve paralysis and device failure. Longitudinal studies of facial nerve paralysis showed an incidence of 0,39% in children in the year 2002 (Clark, 2003: 624). In order to reduce this incidence figure, implantation should only be undertaken in centres with considerable otological experience, pre-operative x-rays should be taken, overheating of the nerve when drilling in the vicinity needs to be prevented by constant irrigation, and a facial nerve monitor should be used (Clark, 2003: 624). Failure of the implant may be due to malfunction of the electronics, lack of auditory nerve function, damage to the electrodes or extra-cochlear placement of the electrode array in a hypo-tympanic cell, or a blow to the skull. The latest statistics released by Cochlear™ (2007) regarding device failures showed cumulative failure percentages over the last 2 years on their Nucleus ® Freedom™ implant of 0,26% for adults and 0,24% for children. On other Nucleus® devices, the cumulative failure percentages for children per device are as follows: the Nucleus® 24 implant after 7 years 1,5%, and the Nucleus® 22 implant after 19 years 9%.These results confirm overall good reliability of the devices (Cochlear™, 2007).

Another risk associated with cochlear implantation is meningitis. Meningitis following middle ear infection can occur either in the early post-operative period when the round window seal has not yet fully formed or at a later stage from a superimposed infection (Clark, 2003: 627). In July 2002 the FDA reviewed data of 18 patients with Nucleus ® devices who presented with meningitis. The FDA found that 17 of these patients did not have device-related meningitis (Clark, 2003: 627). To minimize the risk of meningitis, all cochlear implant candidates receive an immunization against *H. Influenza* B and *S. pneumoniae* (Clark, 2003: 627). In South Africa, cochlear implant candidates routinely receive Prevenar® and Pneumovax® one month prior to cochlear implant surgery. This is in accordance to the FDA regulations (Müller, 2005).

During the early stages of cochlear implantation, the FDA was also concerned about being able to diagnose a child's profound hearing loss correctly before the

age of two years and about having time to judge the benefit of conventional amplification. No objective measures were available to confirm the audiological benefit obtained by a child from hearing aids and their settings (Rizer & Burkey, 1999: 1117). Preliminary consideration for cochlear implant candidacy is based on an individual's baseline hearing and, when feasible, experience with amplification. Children considered as cochlear implant candidates at ages of 2 years or younger, present with inexperience regarding auditory sensations, limited behavioural skills, and cognitive limitations, making this population more challenging to assess thoroughly (Brown *et al*., 1994:168-169,175; Luxford *et al*., 2004:377-379; Parisier *et al*., 2004:256-258).

The evolvement of electrophysiological testing in audiology has made the assessment and verification of the type and severity of any hearing loss possible. An audiological evaluation typically includes unaided air and bone conduction thresholds, unaided speech detection thresholds, speech discrimination testing, and immittance measurements. In young children, behavioural visual reinforcement audiometric results can be verified with the use of the auditory brainstem response test (ABR), the frequency specific auditory steady state response test (ASSR), and oto-acoustic emission testing (OAE's). These electrophysiological tests are objective and can confirm behavioural responses from the young child (Clark, 2003: 560; Luxford *et al*., 2004:377; Mẻnard *et al*., 2004: S39; Zwolan, 2002: 748).

The pre-operative hearing aid evaluation is used to evaluate the patient's performance with appropriate amplification and usually includes the evaluation of aided detection and speech perception skills. In adults, free field audiometric testing is performed to assess individual aided benefit. Insertion gain testing is also performed to measure aided benefit from conventional amplification objectively (Zwolan, 2002: 748). Benefit from amplification is not as easy to define in children as in adults. In young children, little or no benefit from appropriate binaural hearing aids is defined as lack of progress in developing simple auditory skills with appropriate amplification and intensive aural habilitation over a 3 to 6 month period (Zwolan, 2002: 748). Thus, young children should be enrolled in an intensive aural habilitation programme that focuses on

the development of auditory-based skills prior to receiving a cochlear implant. This is important, since the child's teacher will be able to provide valuable information regarding how the child communicates on a daily basis and also to provide input regarding the amount of progress the child is making with auditory skill development (Clark, 2003: 654).

Aided benefit can also be measured via speech perception testing. Simplified tests, such as the "Early Speech Perception Test" (ESP) from Moog and Geers (1990), have been developed for young children (Zwolan, 2003: 749). Since very young children may not be able to perform speech perception tests, benefit from amplification is also based on parental responses to questionnaires such as the "Meaningful Auditory Integration Scale" (MAIS) developed by Robbins in 1998, or its infant-toddler version the IT-MAIS developed by Zimmerman-Phillips *et al*. in 1998 (Niparko & Blankenhorn, 2003: 268; Zwolan, 2003: 749). Most cochlear implant programmes also include a 3 to 6 month hearing aid trial, before speech perception tests are performed (Zwolan, 2002: 748). The development of these evaluation procedures solved the troubling issues regarding the very young child as a cochlear implant candidate. Precise documentation of pre-operative speech perception skills is also important as such data will influence future expansion of cochlear implant candidacy requirements.

The face of cochlear implantation in young children was also changed worldwide with the advent of Universal Newborn Hearing Screening (UNHS) programmes (Dettman, Pinder, Briggs, Dowell & Leigh, 2007: 11S; Drinkwater, 2004:1). The programme has facilitated earlier referral, diagnosis, and intervention for infants with hearing loss. The Joint Committee on Infant Hearing (JCIH) (2000) suggests that children with hearing loss should be identified within the first few months after birth and intervention started by the age of six months. The ultimate objective of early intervention is to offer young children the auditory abilities to achieve optimal speech and language development, and in due course exhibit age-appropriate progress in the educational environment (Kileny & Zwolan, 2004:S16). A variety of studies have confirmed superior speech perception outcomes in children receiving cochlear implants at very young ages (younger than twelve months), in comparison to children implanted at older ages (Clark,

1997:16-17; Clark, 1998:73-74; Clark, 2003:381,409; Drinkwater, 2004:1; Gordon, Papsin, & Harrison, 2004: S28, Haensel *et al*., 2005:456-458; Flynn, 2003:15-17; Zwolan, 2002:755). This has established a trend towards implantation of children younger than one year of age who have profound hearing losses, thus creating a new and more challenging population within the field of cochlear implantation. In 2004, over five hundred children younger than 12 months were implanted worldwide (Luxford *et al*., 2004:376-377).

Improvements in device technology, two decades of paediatric clinical experience, and a growing recognition of the efficacy of cochlear implants for young children have collectively led to the recent changes in the FDA's age criteria (Dettman *et al*., 2007: 11S). In 1998 with the launch of the Nucleus® 24 implant, children of 18 months or older with a profound sensory-neural hearing loss were included by the FDA (Zwolan, 2002: 743). A further expansion of selection criteria by the FDA in the year 2000 included children as young as 12 months of age. Children younger than 2 years should present with a profound sensory-neural hearing loss, while children of 2 years and older should present with a severe to profound sensory neural hearing loss in order to be considered for a cochlear implant (Dettman *et al*., 2007: 11S).

2.3.2 Post-implantation performance and results in young children

The first three years of a child's life are critical for acquiring information about the world, communicating with family, and developing a cognitive and linguistic foundation from which all further development unfolds. If a child is able to develop age-appropriate spoken language skills, he or she will be more likely to be prepared to enter a preschool setting ready to participate fully in all activities and to engage in meaningful social interactions with teachers and peers (Nicholas & Geers, 2006: 287).

Auditory perception, that is, learning to listen, in hearing children as well as children with hearing loss, is associated with the regular occurrence of speech events coupled with the features of attention, memory, and meaning. If listening

is not developed during the critical language learning years, a child's potential to use speech input is likely to deteriorate. The key feature of the developing auditory system is plasticity, which is present at birth and decreases with age. Evidence suggests that myelination occurs early on in life and facilitates stable neural connections so that memory and learning can develop (Niparko *et al*., 2000: 55). Studies regarding the human foetus's capability to detect sound, neonates' preferences for their native language, and restrained perceptual discrimination skills toward the end of the first 12 months, have led researchers to propose a phonological critical period from the 6th month of foetal life to 12 months chronological age (Dettman *et al*., 2007:12S). The earlier a child receives a cochlear implant, the greater the child's potential to benefit from thise critical period of neural development. A younger age at implantation is also related to optimum communication outcomes for children with cochlear implants (Dettman, 2007:12S; Geers, Nicholas & Sedey, 2003: 46S).

Cochlear implants are provided to children with severe to profound hearing loss on the hypothesis that short-term outcomes in auditory receptive skills will translate via a cascade of medium-term outcomes into a greater social independence and quality of life (QOL) in adulthood. It is believed that all the benefits for a child will continue to emerge over the 20 years following implantation (Sanderson & Nash, 2001:2). Figure 2.1 is a graphic representation of the outcomes associated with cochlear implantation for children.

The following section will investigate the post-implantation outcomes of young children in terms of receptive and expressive language skills, speech perception, and educational outcomes.

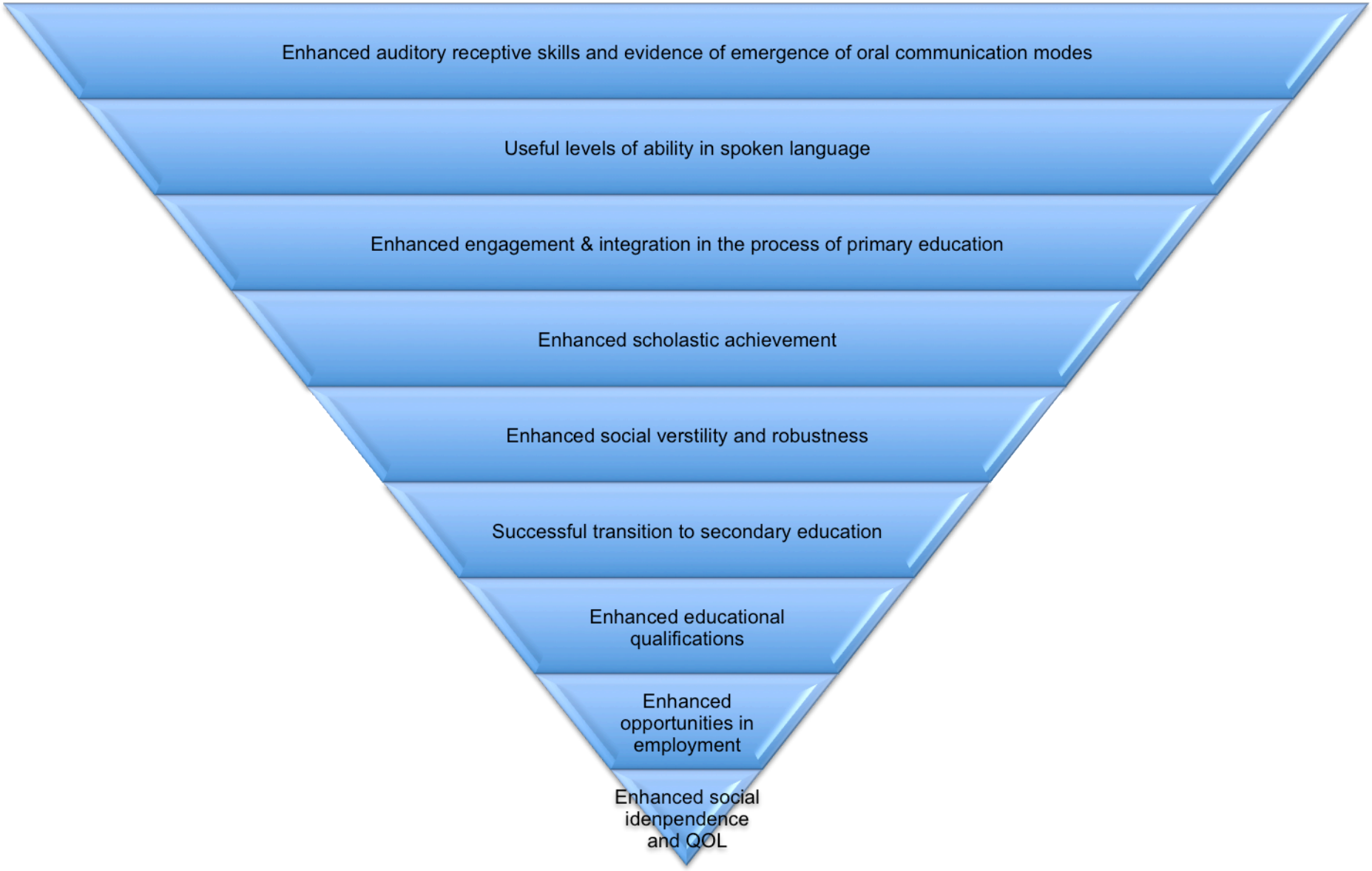

Figure 2.1 Cascade of outcomes following cochlear implantation in young children

2.3.2.1 Receptive and expressive language skills

Children with profound sensory-neural hearing loss are at considerable risk for acute speech and language delays that can impact their communication, academic, and social development (Connor, Craig, Raudenbush, Heavner & Zwolan, 2006: 628). The principal goal of implantation in children is to facilitate comprehension and expression through the use of spoken language. Language can be considered a medium for shaping and relating abstractions for communication (Niparko & Blankenhorn, 2003: 272). Although challenging to characterize, effects on receptive language skills and language production after implantation should be considered vital measures of the effectiveness of implants provided to young children.

For children using hearing aids, many of the negative impacts of hearing loss on communication development can be avoided, or at least substantially minimized, if intervention and training are initiated early in life. Studies have shown that early diagnosis and apposite intervention for infants with hearings aids is associated with improvements in receptive and expressive language skills. Yoshinago-Itano and colleagues (1995) demonstrated that children who were identified and aided in the first 12 months of life had notably better language development than children aided after 12 months of age, despite significant hearing loss. For children with cochlear implants, a younger age at surgery is associated with optimum speech perception, speech intelligibility, and language outcomes (Tye-Murray, Spencer & Woodsworth, 1995: 327). Whereas deaf children without cochlear implants achieved language competence at half the rate of normal hearing peers, children using cochlear implants exhibited language-learning rates that matched, on average, those of their normal hearing peers (Niparko & Blankenhorn, 2003: 272; Rizer & Burkey, 1999:1118).

Many studies over the past twenty years of cochlear implantation in children have shown the significant benefit children gained from timely cochlear implantation. From 1984 onwards studies regarding expressive language skills, comparing pre- and post-operative phoneme production and mean length of utterances, reported

that phonemes were acquired post-implantation in an order similar to that displayed by normal hearing children . In addition, a steady growth in the mean length of utterances was present over a 4 year period post-implantation (Clark *et al*., 1997: 219). From 1995 onwards, studies of language skill development began to focus on the advantages of implantation before the age of two years. The findings of these initial studies were later on confirmed by dozens of other studies. Phoneme accuracy, speech production, and word intelligibility were shown to progress significantly post-implantation (Tye-Murray *et al*., 1995: 327). Language learning also requires the acquisition of communicative behaviour, including eye contact and turn-taking, which typically develops within the first six months post-implantation (Tait & Lutman, 1994:352). It has also been reported that verbal reasoning, narrative ability, and lexical diversity in spontaneous conversations of children using cochlear implants are on track when compare to that of normal hearing peers (Geers *et al*., 2003: 52S0.

A study by Anderson *et al*. (2004: 425) involving 73 children implanted before the age of 5 years showed that children implanted before the age of 3 years performed better in expressive and receptive language skills than their later-implanted peers. They were also found to have better voice control, auditory attention, and interaction with their parents (Anderson *et al*., 2004: 425; Baumgartner, Pok, Egelierler, Franz, Gstoettner & Hamvazi, 2002: 223). A rapid growth in consonant-production accuracy was also demonstrated immediately after implantation (Connor *et al*., 2006: 628). A study of speech physiology pre- and post-implantation reported a decrease in deviant speech phonology patterns after implantation, for example use of implosives, oral and nasal substitutions, high pitch, and strained voice quality (Higgins, Mc Cleary, Carney & Schulte, 2003: 49).

Recent studies of receptive language skills also show a noteworthy improvement among young children using cochlear implants. Connor *et al*. (2006:628) demonstrated receptive vocabulary growth curves that approximated those observed for children with normal hearing sensitivity, especially in children implanted before the age of 2 years.

All of the studies over the past two decades have proved the significant improvement in speech and language skills post-implantation. However, great variability among children can still be observed. These variations can be attributed to age of onset of hearing loss, age of implantation, previous experience with hearing aids, length of cochlear implant use, access to language rich habilitation programmes, mode of communication, and amount of residual hearing before implantation (Connor *et al*., 2006:629; Geers & Brenner, 2003: 2S; Müller & Wagenfeld, 2003: 61).

2.3.2.2 Speech perception skills

Speech perception in normal hearing listeners is a multi-sensory process that typically involves attending to and encoding not only the auditory properties of the speech signal, but also the visual articulatory attributes of the speaker. Multi-sensory integration of speech occurs naturally and automatically in normal hearing listeners of all ages. Many studies over the years have found that normal hearing children and even young infants are capable of multi-sensory perception. The primary sensory modality for speech perception in normal hearing children is audition, while the primary sensory modality for speech perception in children with hearing loss is vision, using lip-reading cues (Bergeson, Pisoni & Davis, 2005: 149). A great deal of research has investigated the changes in open-set and closed-set speech perception skills of children post-implantation, in order to evaluate the efficacy of cochlear implantation in children.

In 1986 a conference was held to assess children in a clinical trial for the FDA in order to obtain approval for cochlear implantation in children. The clinical trial for the FDA involved 142 children implanted with the Nucleus® 22 implant system (Clark, 1997:22). The results of this clinical trial were presented to the FDA in June 1990, and based on these results cochlear implantation was accepted as safe and effective for use in children of 2 years of age and older (Clark, Cowan & Dowell, 1997:22). The results that were presented showed that 51% of the children had significant open-set performance with their cochlear prosthesis compared to 6% pre-operatively. In addition, 68% of the children could perceive spectral cues for speech perception with the cochlear implant, compared to 23%

before surgery. Performance in open-set and closed-set speech perception also improved significantly up to 3 years post-operatively (Clark *et al*., 1997:22).

The following question arises: if children with hearing loss are primarily dependent on visual cues for speech perception, what happens to their lip-reading abilities once their auditory channel is restored via a cochlear implant? Studies have reported an improvement in lip-reading skills over time after implantation. As the children accumulated experience with the implant, their lip-reading skills in perceiving speech via vision alone also improved. The combination of lip-reading and audition, however, showed the greatest improvement. Thus, studies reported that pre-lingually deaf children who use cochlear implants show evidence of multi-sensory enhancement and benefit when speech is presented in combined auditory and visual channels (Bergeson *et al*., 2005: 153; Horn, Davis, Pisoni & Miyamato, 2005: 389).

2.3.2.3 Educational outcomes

The link between speech perception, speech production, and the development of language is a strong one. Furthermore, a solid foundation in language is an essential key to the development of literacy skills (Spencer, Barker & Tomblin, 2003: 236). Improved speech perception and production skills lay the foundation for closing the communication gap and are viewed as the principal benefits of cochlear implantation. Subsequently, secondary benefits regarding academic and social development can also be expected. One such domain that may benefit is that of literacy development. Literacy development will now be discussed in terms of reading proficiency and writing proficiency.

In 1979 Chall identified 5 stages of reading development that can be observed in children with normal hearing (Spencer *et al*., 2003: 237). **Figure 2.2** is a summary of the 5 stages of reading development (Spencer *et al*., 2003:237). There is a very close link between spoken language development and reading and writing development. It has been proved that children who enter school with poor spoken language are at risk for developing reading problems later on. Spencer *et al*. (2003:238) reported that normal hearing children with lower

language scores on standardized tests wrote shorter sentences, had less clausal density, and made more grammatical errors than their peers. The interdependence of spoken language and reading and writing skills is further illustrated in research involving children with hearing loss. Numerous studies of children and adults with hearing loss show that developing reading proficiency has been a longstanding challenge for this population. As a result, most of these children complete high school with reading levels no greater than that of hearing children performing at a grade 4 level and 30% of students with hearing loss can be classified as functionally illiterate upon graduation (Spencer *et al*., 2003: 238).

The writing proficiency of children with hearing loss has been studied in such depth that it would be beyond the scope of this study to review the literature in detail. Studies have focused on the development of writing mechanics, the development of sentence structures, and written language. Studies comparing writing skills of normal hearing children and children with hearing loss reported that children with hearing problems wrote texts composed of shorter sentences. By the age of 17 years, children with hearing loss were able to produce sentences that were comparable to those of normal hearing children of 8 years of age (Spencer *et al*., 2003: 240). Moog & Geers (1999:1127) stated that "*it seems apparent that many deaf children neither read nor write the English language even adequately, and this is reflected in low educational performance in general.*" Given the relative importance of developing solid literacy skills, it is essential to investigate the effect of cochlear implants on the literacy development of children.

Spoken language serves as one of the critical contributors to reading and writing development. When a child with a hearing loss uses an imperfect speech perception-coding-production scheme, therefore, literacy proficiency is ultimately retarded. If use of a cochlear implant improves this scheme, it would also be expected that advancements in literacy proficiency of paediatric cochlear implant users be evident (Spencer *et al*., 2003:246). Studies found that increased literacy skills were indeed associated with improved language skills, as reflected in the increased spoken language skills and reading performance of children using cochlear implants (Tomblin, Spencer & Gantz, 2000: 301. This will in turn elevate the academic performance of these children in the long run.

Figure 2.2 is a brief summary fo the 5 stages of reading proficiency development (Spencer *et al*., 2003:237).

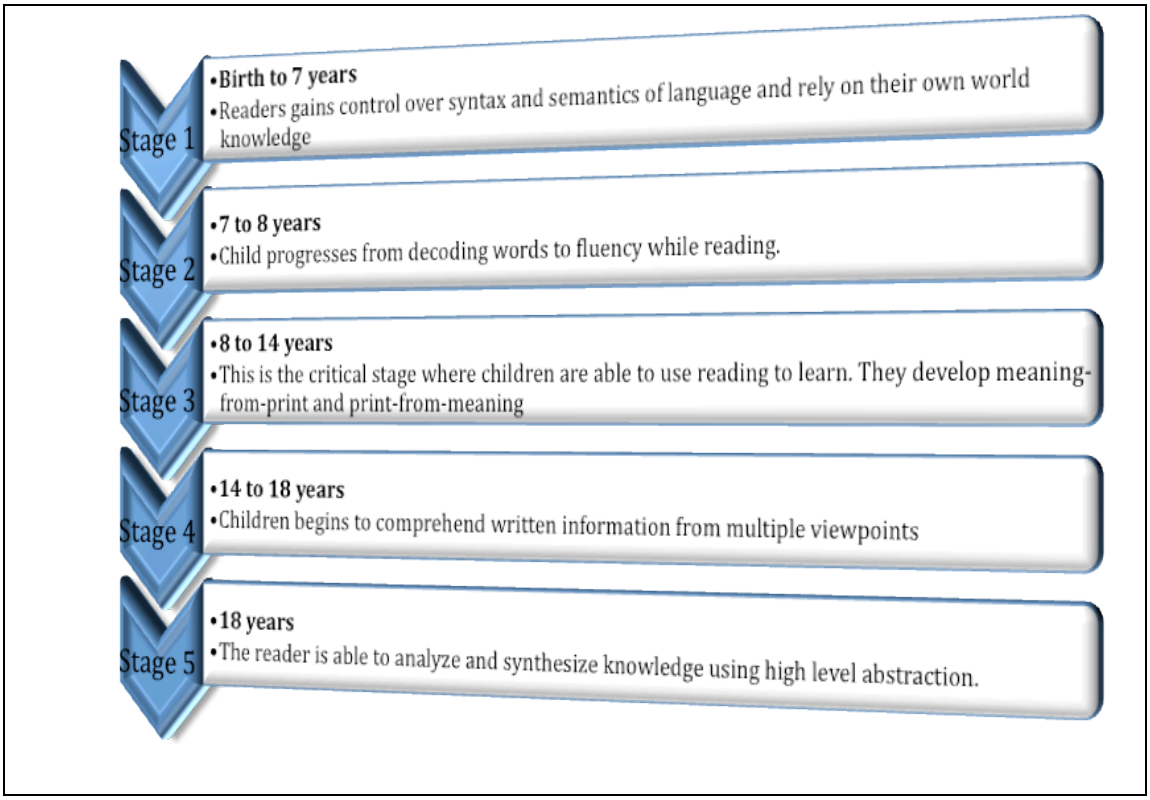

Figure 2.2 Stages of reading proficiency (adapted from Spencer *et al*., 2003:237).

Sanderson & Nash (2001:6) studied the integration process of children with cochlear implants in primary education. They reported that cochlear implantation accompanied by aural habilitation enhances the verbal and educational independence of children with profound pre-lingual hearing impairment. Children with more than two years of implant experience were placed in a mainstream school at twice the rate or more of age-matched children with profound hearing loss who did not have implants (Niparko & Blankenhorn, 2003: 273; Sanderson & Nash, 2001: 7).

In general, children with cochlear implants have increased educational opportunities since they are progressively able to participate in mainstream placement. It is anticipated that in future, a growing number of cochlear implant

recipients will be graduating from mainstream secondary education, with the opportunity to pursue further qualifications.

2.3.3 Quality of life and cost-effectiveness of cochlear implantation in young children

Hearing loss is not generally a life-threatening disability, and the cochlear implant procedure itself has little direct impact on life expectancy. However, cochlear implantation does improve the patient's quality of life, through restoring or allowing acquisition of auditory skills and improving articulation, and enhancing the development of language comprehension, including reading and writing skills, in children (Clark, 2003: 771). The impact of cochlear implants on speech and language, as well as their biological safety, are crucial in assessing the socio-economic benefits of cochlear implantation (Clark, 2003:767; Niparko *et al*., 2000:115 ; Sanderson & Nash, 2001:1; Wyatt, Niparko, Rothman & De Lissovoy, 1996: 816). Health economics are based on the objective of optimising social well-being when there are limited resources available to produce the goods and services that society values (Sanderson & Nash, 2001:1). Health economics assess the outcomes that a society and an individual values and also assess the relating cost of a particular medical procedure to determine cost-effectiveness of that procedure (Sanderson & Nash, 2001:10).

To communicate effectively in the hearing community, adequate hearing and the development of aural or oral speech and language in children are vital (Clark, 2003:768). A severe to profound hearing loss in young children limits appropriate development of oral and written language, impacting educational and vocational opportunities. This type of hearing loss in an adult affects his vocational and social abilities (Clark, 2003:768). For these reasons, it is of great importance to restore the ability to hear in both adults and children. Studies of the social benefit of cochlear implants confirmed an increase in quality of life due to increased social interaction (Clark, 2003: 771; Mo *et al*., 2005:186; Müller & Wagenfeld, 2003:61; Niparko *et al*., 2000:270; Sanderson & Nash, 2001:9). Positive impacts on family interaction have been reported for both adults and children (Clark,

2003:768; Sanderson & Nash, 2001:9). The development of oral language skills in children have meant that these children can be educated in a mainstream school, they have access to enhanced educational qualifications, and are given the opportunity to become a productive part of the workforce and earn their own income. These children are no longer a burden for the state or the community because no special intervention is needed (Clark, 2003:769; Sanderson & Nash, 2001:10).

In summary, cochlear implants positively benefit auditory receptive skills, the development of oral communication, useful levels of spoken language, communication skills, speech intelligibility, integration in primary education, enhanced scholastic achievement, social interaction, transition to tertiary education and employment opportunities, and social independence as adults (Clark, 2003:770; Sanderson & Nash, 2001:10).

2.4 CURRENT PRACTICE OF COCHLEAR IMPLANTATION IN THE PAEDIATRIC POPULATION

Widespread universal hearing screening programmes and increased general awareness of cochlear implants have resulted in increasing numbers of children younger than 12 months of age being diagnosed and referred to implantation centres. The “earlier the better” argument, as it relates to cochlear implants receives support from physiological studies and from studies of children using hearing aids. Physiological studies have proved that a human foetus can detect sound. The key feature to the developing auditory system is plasticity, which is present at birth and decreases with age (Dettman *et al*., 2007: 11S). The younger the age at implantation, the greater the child’s potential to benefit from the critical period of neural development. Studies of hearing aid fittings have reported that early diagnosis and appropriate intervention for infants with hearing aids are related to improvements in receptive and expressive language skills (Miyamato, Houston, Kirk, Perdew & Svirsky, 2003: 241). Apuzzo and Yoshinago-Itano (1995: 124) demonstrated that infants who were identified and aided in the first 2 months of life had notably better language development than children identified

between 3 and 12 months of age, in spite of significant hearing loss. A variety of other studies have confirmed superior speech perception outcomes in children receiving cochlear implants at ages younger than twelve months, in comparison to children implanted at older ages (Clark, 1997:16-17; Clark, 1998:73-74; Clark, 2003:381,409; Drinkwater, 2004:1; Gordon, Papsin, & Harrison, 2004; S28, Haensel, et al., 2005:456-458, Flynn, 2003:15-17; Zwolan, 2002:755). Thus, a younger age at implantation is associated with optimum communication results for children with cochlear implants (Dettman *et al*., 2007: 12S).

The implementation and execution of newborn hearing screening programmes across the continent has had a significant influence on cochlear implantation (Drinkwater, 2004:1). Identification and the initiation of intervention programmes within the first six months of age, is advocated by the JCIH (2000). The ultimate effect of this policy is that the paediatric population is gradually increasing globally. The definitive aim of early implantation is age-appropriate speech and language development and age-appropriate progress in the educational setting (Kileny & Zwolan, 2004:S16). A new trend of implanting children before the age of one year has been developing the last couple of years. Service delivery to this population is more demanding since they have had limited exposure to auditory sensations, and they have limited behavioural and cognitive skills (Brown *et al*., 1994:168-169,175; Luxford *et al*., 2004:377-379; Parisier *et al*., 2004:256-258). Luxford *et al*. (2004: 376) estimated that over five hundred children younger than twelve months were implanted by the year 2004.

The management of the very young cochlear implant user is thus a reality in the field of cochlear implantation. As mentioned above, due to their young age, inexperience with sound and limited behavioural and cognitive skills, it is the responsibility of the audiologist to ensure that this population receives optimal stimulation levels, which offer audible and comfortable auditory input upon device activation and future stimulation. Should optimal stimulation levels not be in place, the prospective advantages of early implantation cannot be fully attained in the paediatric population (Gordon *et al.*, 2004: S28).

Stimulation levels are usually set within the individual dynamic range, which lies between the hearing threshold level (T-level) and most comfortable loudness level (C-level) for all active electrodes (Thai-Van, Truy, Charasse, Boutitie, Chanal, Cochard, Piron, Ribas, Deguine, Fraysse, Moudain, Uziel & Collet, 2004:153). According to Luxford *et al*. (2004:378), behavioural responses to sound will remain the "gold standard" for post-implant programming. However, objective measures offer more reliable results for device activation and the first few months of device programming for these children implanted at young ages. To date, cochlear implant teams worldwide are currently using subjective methods for device programming, based on behavioural methods applied when programming devices of the adult and the older child cochlear implant users (Clark *et al*., 1997:207). Visual Response Audiometry and play audiometry observation are used during evaluation procedures for young children, while with very young children observation of changes in the child's behaviour is used during device programming. Very young children with severe-to-profound hearing loss often provide less-than-reliable behavioural responses because they have not yet developed language, behaviour, and cognitive skills and in addition have no experience with auditory sensations (Brown *et al*., 1994:168-169;175, Luxford *et al*., 2004:377-379; Parisier *et al*., 2004:256-258). The result is unreliable T-levels and C-levels with little or no value when setting the dynamic range of the speech processor (Mėnard, Gallego, Truy, Berger-Vachon, Durrant & Collet, 2004:S39).

These limitations restrict clinicians when they are determining optimal stimulation levels for audible and comfortable auditory input. Accordingly, the call for objective measurements has become increasingly important in the field of paediatric cochlear implantation (Hoppe *et al*., 2001:119-120; Mason, Cope, Garnham, O'Donoghue & Gibbin, 2001; Mason, 2004:226). These measurements will ensure optimal stimulation levels for audible and comfortable auditory input.

Since the introduction of NRT™ in 1996, a wide range of electrophysiological measurements, based on the intra-cochlear measurement of the ECAP, has become available for use in cochlear implantation. These measurements can be used in the intra- and post-operative stages of cochlear implantation. These

electrophysiological measurements serve as objective measurements and can be applied in the management of the very young cochlear implant user, to ensure the setting of optimal stimulation levels, despite the challenges brought forward by this unique population (Mason, 2004:S33). Mason (website, date of access: 29 January 2005) remarked that "…*Electrophysiological and objective measures have a valuable role to play in the management of patients receiving cochlear implants, in particular young children, complex cases and difficult-to-test patients*." These objective, intra-cochlear measurements include impedance telemetry and Neural Response Telemetry (NRT™) (Gordon *et al*., 2004: S28-S29; Lorens, Skarzinsky, Piotrowska, Walkowaik, Sliwa & Kochanek, 2003: 379-380; Mason *et al*., 2001:225-226; Polak, Hodges, King & Balkany, 2004: 104-105).

2.4.1 The application of NRT™-measurements in the paediatric population

The development of the NRT™-measurement was described in detail in section 2.2.3 of this chapter. It was pointed out that one of the most important applications of this measurement is its use in the objective programming of optimal stimulation levels when managing the very young cochlear implant user due to its high success rate when measuring and its stability over time (Brown *et al*., 2000: 151).

As the age of implantation in congenitally deaf children is lowered, the challenge to create a reliable and audible first MAP in these young children, as quickly as possible, is greater than ever. A method for using the intra-operative ECAP-thresholds recorded via NRT™ in the initial programming of congenitally deaf children was introduced and successfully applied since 1998 by the Bengt Almqvist/Lund cochlear implant programme (Ramos Macias *et al*., 2004:380). According to this method, an initial MAP is created based on the NRT-threshold using a predetermined offset prior to the first fitting session. After sweeping the stimulation levels across all active electrodes, this initial MAP is checked in "Live mode" for sound awareness and comfort. The T- and C-levels are then modified

globally if necessary (Ramos Macias *et al*., 2004:380). The Nucleus® Freedom™ speech processor enables the audiologist to load four progressive MAPs on the four different programmes of the speech processor. Each of these four MAPs is programmed with the C-level set 10 current levels higher than the subsequent MAPs. The child the progresses through each MAPS during a selected period of time (Ramos Macias *et al*., 2004:380).

This new approach to the initial fitting of very young cochlear implant users based on NRT-threshold measurements was compared to the traditional behavioural fitting method with regard to the time spent in testing and programming, as well as the difference in performance between groups and within subjects. The research results revealed that the average time spent during the initial fitting of the four progressive MAPs based on the intra-operative NRT-threshold measurements was 20 minutes compared to an average of 40 minutes spent on the first MAPS solely based on behavioural methods. The performance between the groups and within subjects was measured via aided sound field thresholds at one, three, and 6 months after the initial fitting session. The aided sound field thresholds obtained at one month after the initial fitting confirmed the audibility of the NRT™-based MAPs, although they were more conservative than the behavioural MAPs. At six months after device activation, matched paired performance was obtained for speech perception measurements for children with both NRT™-based and behavioural MAPs (Ramos Macias *et al*., 2004:383).

The research discussed above confirmed the valuable applications of NRT™-measurements when managing the paediatric cochlear implant users:

- NRT™-measurements were performed intra-operatively during the closure of the skin flap to ensure that the measurements did not extend surgery time.
- Fitting time for the initial fitting was significantly reduced from an average time of 40 minutes to an average time of 20 minutes.
- Sound field thresholds at one month after device activation confirmed the audibility of NRT™-based MAPs.

- No statistical significant differences in performance were observed between NRT™-based and behavioural MAPs.

The results suggested that this objective method of using intra-operative NRT-thresholds in the initial fitting is a significantly faster process to achieve audible MAPs in very young congenitally deaf children, as young as five months, with comparable outcomes to those achieved with behavioural programming methods.

NRT™ data is thus clinically applied in the selection of initial stimulation levels of speech processors, especially in the paediatric population where subjective fitting procedures are often unreliable and risk providing either inadequate stimulation for audition due to a limited dynamic range of stimulation or uncomfortably loud stimulation levels (Gordon *et al*., 2004). This may prolong the process of establishing audible electrical stimulation through the cochlear implant (Ramos Macias *et al*., 2004:381). Clinical application of objective measurements in initial fitting procedures of young children are thus time-saving and cost-effective since device programming sessions are now less frequent and of shorter duration (Ramos Macias *et al*., 2004:383).

The most recent software edition of the Nucleus® Freedom™ speech processor utilises NRT-threshold measurements to create a series of progressive stimulation levels or MAPs. This provides the opportunity for extended periods between follow-up sessions in the first few weeks and months after device activation, streamlining the service delivery process for the young cochlear implant users (Luxford *et al*., 2004:377).

2.4.2 The application of impedance telemetry in the Paediatric population

Young cochlear implant users may present with restricted speech and language skills attributable to their age and inexperience with auditory input (Henkin *et al*., 2003: 878). Accordingly, when a young child does not initially respond to sound via stimulation of the implant, it is vital to rule out malfunctioning of the device

prior to spending time on rehabilitation (Garnham, Marsden & Mason, 2001:31-32).

External hardware failures are moderately simple to rule out by checking and replacing external components of the speech processor (Garnham *et al*., 2001:32). Conversely, internal device malfunction or failure is more difficult to detect using only behavioural methods. Consequently, for these young children it is desirable to apply an objective test such as impedance telemetry that can verify device functioning without the child's participation (French, 1999:65; Garnham *et al*., 2001:31; Henkin *et al*., 2003:874; Mason, 2004:S33).

Impedance telemetry is an intra-cochlear measurement and is performed by means of reverse telemetry (French, 1999:61). Electrical impedance encompasses resistance, capacitance, and inductance measured in voltage within a given circuit. Electrical impedance measurements within the cochlea can give valuable data regarding the status of individual electrodes of a cochlear implant (French, 1999:61-62). Impedance telemetry is a straightforward and speedy procedure for checking the internal part of the cochlear implant device and for recording the impedance of the electrode-tissue interface inside the cochlea (Mason, 2004). Long-term research proved that impedance telemetry results stabilise one month after surgery when neural tissue has stabilised around the electrode array (Henkin, Kaplan-Neeman, Muchnik, Kronenberg & Hildesheimer, 2003: 874, 878, 879). Electrodes can be identified as potentially faulty if impedances are either very high, termed open circuit, or when impedance values are very low, termed short circuit (French, 1999:62; Mason, 2004:S34).
The electrode is the all-important interface between the electrical stimulus and the auditory nerve fibres that must be stimulated. A vital feature of the electrode`s design is the electrical impedance which depends on electrode surface area, morphological processes, and electro-chemical processes initiated by the electrical stimulation (Van Wermeskerken, Van Olpen & Smoorenburg, 2006:537). Impedance telemetry is an objective measure to identify malfunctions in the electrode array, diagnose complete device failure, or confirm the normal functioning of the cochlear implant device (Garnham *et al*., 2001:32). In the Nucleus® 24 and Freedom™ devices, software communicating with the intra-

cochlear parts is used to perform impedance telemetry, ensuring a non-invasive and comfortable procedure that can be performed intra-operatively and post-operatively to evaluate device functioning in an objective manner (Cochlear website, 2005; Garnham *et al*., 2001:31-32; Henkin *et al*., 2003:874, 879).

In addition to the valuable information impedance telemetry delivers regarding electrode integrity, it also provides an indication of the status of the electrode-tissue interface (Van Wermeskerken *et al*., 2006:537). In the early stages after implantation, before the device activation, initial changes in electrode impedance may be expected due to morphological changes at the electrode-tissue interface (Hughes, Van der Werff, Abbas, Brown Kelsay *et al*., 2001: 472). It has been shown that the changes in impedance are due to the encapsulation of the electrode array by a fibrous tissue layer (Kawano, Seldon, Clark, Ramsden & Raine, 1998:323). High impedances observed after implantationare therefore due to the presence of tissue and/or bone growth near the electrode array (Van Wermeskerken *et al*., 2006:538). Electrical stimulation may also affect electrode impedance. Research on chronically implanted kittens indicated a short-term elevation and subsequent decrease in impedance threshold during the first few months after implantation. This was then followed by a period of threshold stability. The observed steady increase in impedance threshold correlated with the degree of tissue and bone growth observed within the scala tympani (Hughes *et al*., 2001: 473). It seems as though electrode impedance is primarily related to the restrictive characteristics of the fluid and tissue surrounding the electrodes (Tykocinski, Duan, Tabor & Cowan, 2001: 66). The initial increase in impedance thresholds after implantation is followed by a decrease in thresholds the first month after device activation (Henkin *et al*., 2003: 873). Longitudinal studies of impedance proved that impedance values also stabilise within the first month of electrical stimulation (Henkin *et al*., 2003: 877).

The combination of NRT™-measurements and impedance telemetry measurements provide the clinician working with the very young cochlear implant user with objective techniques to ensure a device functioning satisfactorily, and also with a way of providing audible stimulation levels from device activation. These objective measurements thus play an important role in the management of

the paediatric cochlear implant population to ensure the delivery of accountable services and to ensure that all the prospective advantages of early implantation can be fully attained (Gordon *et al*., 2004: S28).

2.5 CURRENT PRACTICE OF COCHLEAR IMPLANTATION IN THE PAEDIATRIC POPULATION: THE SOUTH AFRICAN CONTEXT

Early detection of and intervention for hearing impairment has become an increasingly important aspect of neonatal care in developed countries with the implementation of Universal Newborn Hearing Screening programmes. South Africa has taken the first step towards Universal Newborn Hearing Screening in the form of a Hearing Screening Position Statement (Swanepoel, Delport & Swart, 2004:634-635) published by the Professional Board for Speech, Language and Hearing Professions of the Health Professions Council of South Africa (HPCSA). The HPCSA developed a South African position statement, the Hearing Screening Position Statement Year 2002. This embraces the main aim of the position statement of the Year 2000 Joint Committee on Infant Hearing Screening (JCIH), namely: "*The Early Hearing Detection and Intervention Programme (EHDI) for individuals identified with hearing loss is to ensure optimum, cost effective solutions to enable persons to communicate effectively, thereby allowing maximum habilitation or rehabilitation of the individual's capabilities and potential, to ensure their full participation in, and contribution to, society and the country's economy*" (HPCSA, 2002:1). The paediatric population with hearing loss will be growing steadily as this position statement is applied in the developing South African context, and as more and more infants and neonates with hearing loss are identified at a very young age.

Cochlear implantation is steadily increasing in the South African context. Since the first cochlear implant was performed in November 1986 at the Tygerberg Hospital in Cape Town, nearly 680 cochlear implants have been performed country wide. Of the recipients of these nearly 680 cochlear implants, 67% were children. To date, seven established cochlear implant units in Tygerberg Hospital,

Pretoria, Johannesburg, Bloemfontein, One Military Hospital, Chris Hani Baragwanath Hospital and Port Elizabeth are performing cochlear implant surgery in South Africa (Annual Report of the Cochlear Implant Unit, Tygerberg Hospital, University of Stellenbosch, 2007; Pretoria Cochlear Implant Programme – Annual Report 2007; Chris Hani Baragwanath Cochlear Implant Programme – Annual Report 2007; Johannesburg Cochlear Implant Programme – Annual Report 2007; Durban Cochlear Implant Programme – Annual Report 2007; 1 Military Hospital Cochlear Implant Programme – Annual Report 2007; Bloemfontein Cochlear Implant Programme – Annual Report 2007; Port Elizabeth Cochlear Implant Programme – Annual Report 2007).

The Pretoria Cochlear Implant Programme was established in 1991 and a total of 250 patients have been implanted. The Programme follows the guidelines set by the FDA regarding candidacy and age of implantation. A total of 173 adults and 111 children have been implanted up to the end of the year 2006 (Annual Report of the Pretoria Cochlear Implant Programme for the year 2007). The number of children being implanted was gradually increasing between 1991 and 2001, and then suddenly escalated from 2002 when proven performance of early implantation became evident (Annual Report of the Pretoria Cochlear Implant Programme for the year 2006, 2006). This escalation in the number of implants in children is not just true for the Pretoria Cochlear Implant Programme. At present, more and more children between the age of 12 and 36 months are also being implanted with cochlear implant devices in South Africa as a whole (Müller, HPCSA Licensing Course in Cochlear Implantation, September 2005). The escalation in the number of children identified with hearing loss may be contributed to the implementation of newborn hearing screening programmes and the consequent phenomenon that the early identification of hearing loss in infants is slowly expanding in the South African health system (Swanepoel, Delport & Swart, 2004:634-635).

Large-scale transformation in the South African socio-political arena has been witnessed over the past decade. These changes have not only been political in nature, but have also brought about changes in national health, education, and

welfare policy (Kritzinger, 2000:86). The national changes in South Africa have also not only been politically driven, but have also been inspired by international tendencies and developments in healthcare, education for learners with special needs, and views on people with disability (Kritzinger, 2000:85). The ultimate objective of early implantation in South Africa, as globally, is to offer young children the auditory abilities to achieve optimal speech and language development, and in due course to exhibit age-appropriate progress in the educational environment. Unfortunately, a developing country like South Africa presents with certain unique challenges that can interfere with accountable service delivery.

As South Africa is a Third World country, funding and cost are two of the principal limitations in the field of cochlear implantation. With an estimated population of 43 million people, a huge discrepancy exists in the health care industry between the private (16%) and public (84%) sectors (Müller & Wagenfeld, 2003). Five sources of funding are used in South Africa, namely provincial departments of health, 100% funding from medical aids, funding from medical aids supplemented by fundraising, fundraising alone, and donations (Müller & Wagenfeld, 2003:61). When considering candidacy for a child in South Africa, it is important to consider future expenses, for example batteries, device maintenance, and other therapies. The parents of the child should have ample support from family and at least one of the parents must earn an income. The parents must be able to access appropriate educational and audiological facilities (Müller, 2005). The first state driven cochlear implant programme was officially opened on 28 September 2006 at the Chris Hani Baragwanath Hospital in Soweto, Johannesburg, and on 29 September 2006 the first fully government funded cochlear implant surgery was performed. To date, there have been three successful unilateral surgeries on adult patients with the Nucleus® Cochlear™ Implant System. Due to the lack of sufficient educational facilities in this area, children are not considered for cochlear implantation at this stage. The focus of this programme is to demonstrate the value of cochlear implantation as a means of financial cost efficacy for government healthcare institutions in developing countries (Annual

Report of the Chris Hani Baragwanath Hospital Cochlear Implant Programme 2007).

The number of Cochlear Implant Programmes in South Africa has increased from 2 to 7 over the last two years, broadening the service delivery possibilities in South Africa. Still, patients need to travel great distances to access these centres as well as appropriate educational facilities. Travelling also places a burden on finances. Should patients not be able to receive appropriate intervention, outcomes may be influenced negatively (Müller, 2005). The lack of services may be attributed to manpower shortages. Formal full-time training for audiologists and speech language therapists is lacking in most tertiary institutions in developing countries, contributing to too few available early interventionists who are appropriately trained to provide suitable intervention services (Louw & Avenant, 2002: 146-147).

South Africa is a culturally diverse country. In some cultures, little or no attention is often paid to persons with disabilities. Special provision for disabled persons is not common in public facilities and the social stigma associated with hearing loss often results in a tendency to withdraw from people (Louw & Avenant, 2002: 146-147). Different cultures have different family structures and dynamics. Certain cultures do not support parent-child interaction as required by the cochlear implant programme. South Africa also presents with a high rate of illiteracy amongst adults, which has a negative influence on the execution of habilitation programmes compiled for parents of children with hearing loss (Kaltenbrünn *et al*., 2005:15-16). Due to the financial impact of the cochlear implant, one or both of the parents may have to work away from home, which influences family dynamics and also may cause unnecessary conflict about unequal distribution of funds and attention (Müller, 2005). Being a diverse nation, South Africa boasts 11 official languages. Cochlear implant programmes often are not able to render services in the patient's mother tongue, and the resultant multilingual communication environment may cause additional language confusion or delays (Kaltenbrünn *et al*., 2005:15-16).

In a developing country like South Africa, where health policies are aimed at saving lives rather than at improving quality of life, the motivation for addressing an invisible non-life-threatening condition such as hearing loss is very limited. A significant issue to be addressed within the South African context is the HIV/AIDS epidemic. Due to the multifaceted symptoms and presentation of the disease, it may influence the surgical procedure and it is difficult to predict outcomes. This is a contra-indication to the value of cochlear implantation as a means of financial cost efficacy for government healthcare institutions (Kaltenbrünn *et al*., 2005:15-16; Müller & Wagenfeld, 2003: 61).

Despite all the challenges brought forward by the South African context, it is still evident from the annual reports of the different cochlear implant programmes in South Africa that the very young cochlear implant population is steadily growing. The lack of manpower and of access to facilities providing cochlear implant related services, however, place a large burden on the audiologists managing the current programmes to deliver cost-effective but accountable services. The need for objective measurements to handle this population is therefore of great concern to these clinicians, as such measurements will enable them to ensure time efficient service delivery, audible stimulation levels from the start, progressive MAPs to reduce the amount of follow-up sessions, and an objective manner to ensure optimal device functioning.

2.6 CONCLUSION

The biologic utilization of electricity has driven the development of a wide range of medical treatments using electricity. Although interest in the biological application of electricity is centuries old, the level of preoccupation has often surpassed the level of understanding of the mechanics of action, and historical descriptions often communicate a mix of fear and mystique (Clark, 2003:3). Today, the cochlear implant is best characterised as *a device that provides access to the sound environment for adults and children with severe to profound sensory neural hearing loss* (Niparko & Blankenhorn, 2003:267).

The development of cochlear implants over the decades has led to progress from a single channel intra-cochlear device with 22 intra-cochlear electrodes to a multi-channel extra-cochlear device with 22 intra-cochlear electrodes and 2 extra-cochlear electrodes (Beynon, 2005:17-18). Speech processors progressed from heavy body worn units to lightweight ear level processors with multi-programme options and the choice of different speech coding strategies (Zwolan, 2002: 743). The Freedom™ processor from Nucleus® has an LCD-screen which communicates important device settings and malfunctions to the user (Healthy Hearing, 2007: Date of access: 1 June 2007; The University Hospital, 2007: Date of access: 1 June 2007).

A major development in the field of cochlear implantation was the discovery of the measurement of the intra-cochlear ECAP of the Cochlear Nerve (Zwolan, 2002: 743). This opened the door to many electro-physiological measurements that can be applied objectively to the programming of the speech processor. One such measurement, the NRT™, developed by Cochlear™, allows measurement of the ECAP via a bidirectional telemetry system where one electrode within the cochlea is stimulated, while a different intra-cochlear electrode measures the ECAP. Studies reported that NRT™ is a stable measurement over time and NRT™ data is thus suitable to be clinically applied in the selection of initial stimulation levels of speech processors, especially in the paediatric population where subjective fitting procedures are often unreliable and risk providing inadequate stimulation for audition (Zwolan, 2002: 744; Lai, 1999: ii).

Based on the NRT™-measurement, new fitting techniques have been developed especially for the management of the very young cochlear implant user. MAPs at device activation are based on intra-operative NRT-threshold measurements. Research conducted on this new fitting procedure reported that the time in programming the device is significantly reduced, while the MAPs is audible and comparable to those based on behavioural fitting methods.

Impedance telemetry is performed by means of reverse telemetry. Impedance telemetry is a straightforward and speedy procedure for checking the internal part

of the cochlear implant device and for recording the impedance of the electrode-tissue interface inside the cochlea (Mason, 2004:S33). Impedance measurements within the cochlea can give valuable data regarding the status of individual electrodes of a cochlear implant (French, 1999:61-62).

The electro-physiological measurements described above provide the audiologist working with the paediatric cochlear implant user with objective techniques to ensure a device functioning effectively, and a way of providing audible stimulation levels from device activation. These objective measurements thus play an important role in the management of the paediatric cochlear implant population to ensure the delivery of accountable services and to ensure that all the prospective advantages of early implantation can be fully attained (Gordon *et al*., 2004: S28).

The advances made in the field of cochlear implantation has made it an attractive treatment option for young children with severe to profound sensory neural hearing loss where amplification with conventional hearing aids no longer deliver the desired audiological outcomes (Niparko & Blankenhorn, 2003:267).. Many studies have reported on the prospective advantages of early implantation. These studies promote the implantation of children younger than the age of 12 months. This has set in motion the expansion of the current selection procedure and the service delivery process for this unique population (Luxford *et al*., 2004:376-377; Miyamato *et al*., 2003: 241; Niparko & Blankenhorn, 2003: 272).

Despite contextual challenges in South Africa, cochlear implantation in young children is also on the increase. Due to limited finances, resources, and manpower, it is of the utmost importance for clinicians in South Africa to deliver time-efficient, cost-effective, and accountable services to this population (Kaltenbrünn *et al*., 2005:15-16). The advances in the field of cochlear implantation in terms of the application of electro-physiological measurements make improved service delivery in the South African context a possibility.

The significance of the development of the cochlear implant for young children has been proven repeatedly. The cochlear implant represents one of many innovative technologies that enable the rapid transfer of processed information. A

unique feature of implant technology, however, is that it represents an alliance of processing strategies that utilize both manufactured and natural neural circuits. To the extent that a cochlear implant can encode the sounds of speech with precision, the device can provide opportunities for age-appropriate developmental and oral language learning in young children.

2.7 SUMMARY

This chapter provided an investigation into the development of cochlear implantation for the paediatric population and evaluated the current practice. The development of the cochlear implant system was discussed. The development of the Nucleus® cochlear implants was explored in detail and focused on the Nucleus® 22, 24 and Freedom™ implant systems. An in-depth exploration of the NRT™-measurement was then conducted. The focal area of this study was the application of the cochlear implant for the paediatric population. The growth of this application was evaluated in terms of changing selection criteria, post-implantation performance in young children, and the effect of cochlear implantation on quality of life. A critical evaluation of the current practices in paediatric cochlear implantation was then conducted. This section evaluated the effect of Universal Newborn Hearing Screening on cochlear implantation and then focused on the application of NRT™ and impedance telemetry measurements when managing this challenging population. The challenges posed by the South African context and their influence on the current practice of cochlear implantation in the paediatric population were summarised. The chapter was rounded off with an appropriate conclusion.

CHAPTER 3

RESEARCH DESIGN AND METHOD

Aim: To present the research design and methodological approach implemented in conducting the empirical component of this study

3.1 INTRODUCTION

Science, in the broadest sense, refers to any system of knowledge which attempts to model objective reality. In a more restricted sense, science refers to a system of acquiring knowledge based on the scientific method, as well as to the organised body of knowledge gained through such research (Cambridge Dictionaries Online, 2007). It is this scientific or organised method that unites different sciences (Leedy and Ormrod, 2005:2)

Research into the field of cochlear implantation in many disciplines, including bio-engineering and Audiology, have characterised the continued and rapid growth in which traditional practices are constantly reviewed in a quest to improve efficacy and accountability (Clark, 2003: x and Northern and Downs, 2002:259). As a result of research, cochlear implantation has developed from a small number of isolated, experimental studies done by a few, to a diverse discipline explored by many (Clark, 2003:x). The inconspicuous nature of hearing loss in young children and an innate aspiration amongst audiologists to intervene as early as possible (Cohen, Labadie & Hayr: 2005: 11 and Northern and Downs, 2002:259), has provided the momentum for continued research in the trend to implant children at younger ages (Zwolan, 2002: 755). Implanting young children as soon as possible after the onset and diagnosis of profound hearing loss leads to enhanced achievements in hearing and speech and language development (Sanderson and Nash, 2001:1). Thus, making this process of early implantation

an inherent component of audiological practice and serves as one of the crucial steps toward providing effective audiological services to the paediatric population.

Despite the fact that the South African Department of Health highlights Essential National Health Research (Health Research Policy in South Africa, 2001), there are at this time no published records of research projects, performed on the use of electrohysiological measures when implanting children at a young age, available from the South African Medical Research Council (South African Medical Research Council: 2007). This lack of evidence based research, the importance of early implantation in order to aid the development of hearing abilities and speech and language and the need to provide effective audiological services to the paediatric population, provide the rationale for the current study. The monitoring of the longitudinal behaviour of impedance and Neural Response Telemetry measurements in a group of young cochlear implant users required the selection of a fitting research design and method to obtain apposite empirical data to address the research problem.

The research design and research method selected for this study provided the plan and process to answer the following research question: ***What changes in impedence telemetry and NRT™-measurements are present during the first 12 months post-implantation?***

This chapter discusses the selected research design as the general plan for addressing the research question at hand and also sets out the methodological approach to acquiring, recording and analysing the empirical data.

3.2 AIMS and OBJECTIVES

This section will focus on the main aim and objectives of this particular study.

3.2.1 Main aim:

The main of this study was to monitor the longitudinal changes in impedance and Neural Response Telemetry measurements in a group of young cochlear implant users.

3.2.2 Objectives of this study:

The following objectives were formulated to realise the aim of the study:

1. To describe impedance telemetry measurements obtained intra- operatively and up to twelve months post-cochlear implantation.
2. To describe Neural Response Telemetry measurements obtained intra-operatively and up to twelve months post–cochlear implantation.
3. To compare trends in the measurements of impedance and Neural Response Telemetry at implantation and post-implantation over a period of twelve months.

3.3 RESEARCH APPROACH

The research approach is defined by the specific research method that will be followed by the study. Leedy and Ormrod (2005:93) describes the research method as "...*an operational framework within which data are placed so that their meaning may be seen more easily*." The research project at hand was guided by a quantitative research approach or method. The research approach determined the research methodology that was implemented to extract meaning from data. Thus, the nature of the data that was collected in the resolution of the aim and objectives of the study, determined the research approach (Leedy and Ormrod, 2005:94).

Generally, quantitative research is implemented to address questions regarding relationships among measured variables, intending to explain, predict, and control phenomena (Leedy and Ormrod, 2005:94). It entails either discovering the characteristics of an observed phenomenon or investigating probable correlations among two or more phenomena (Leedy and Ormrod, 2005: 179). The goal of this study was to investigate and describe changes in NRT™- and impedance telemetry measurements measured intra-operatively and post-operatively over a twelve-month period in a group of young cochlear implant users, using objective ways, thus meeting the general principles of the quantitative research approach.

Carefully structured guidelines exist for using a quantitative research method. The researcher chooses methods that permit him to objectively measure the variables of interest, remaining detached from the research participants in order to draw unbaised conclusions (Leedy and Ormrod, 2005: 95). The specific methods chosen to measure the specific phenomena are identified, developed and standardized with consideration to the validity and reliability of the measurement instruments (Leedy and Ormrod, 2005: 95,96). The chosen measurement procedures, NRT™ and impedance telemetry, has been proven to be stable measurement tools during a 4 year study by Lai et al. (2004:152) and studies by Clark (2003:108).

Data analysis relies on deductive reasoning, using preset objective, statistical procedures and objective criteria to assess the outcomes of those procedures (Leedy and Ormrod, 2005:96). Quantitative research data is usually processed to means, medians, correlations and statistics. Individual scores are not taken into account, the power of interpretation rests in the large number of scores that depict the norm or average of the group's performance (Leedy and Ormrod, 2005:96). The quantative data collected during the field study, was investigated with both descriptive statistics, and inferential statistics (Leedy and Ormrod, 2005: 252,253). The statistical procedures used for these purposes were Friedman's ANOVA test and the Wilcoxon matched-pair signed rank test. These procedures will be discussed in detail in section 3.13.

3.4 TYPE OF RESEARCH

This type of research project is characterised as applied research, aiming to describe specific details around the changes in NRT™ and impedance telemetry measurements over a longitudinal period. Leedy and Ormrod (2005:43) states that applied research aims at addressing issues that have immediate relevance to current practices, procedures and policies. Within the context of applied research, explorative research techniques were utilised to describe the changes in the abovementioned measurements over a longitudinal period.

3.5 RESEARCH DESIGN

The research design is like a route planner providing a set of guidelines and instructions on how to reach the goal that has been set by the researcher (Leedy and Ormrod, 2005: 3). The research design is a purposeful plan to acquire relevant empirical data in order to answer the research question at hand (Leedy and Ormrod, 2005: 3). Descriptive research assesses a situation as it is. It involves either identifying the characteristics of an observed phenomenon or exploring possible correlations among two or more phenomena (Leedy and Ormrod, 2005: 179). In order to investigate the changes in phenomena over time, a developmental design is necessary. The research design, within the context of applied research, was thus of a single group, descriptive and longitudinal nature. The implementation of a descriptive approach to quantitative research involved the description of the changes and trends in and between NRT™ and impedance telemetry measurements, in view of the fact that specific characteristics of the above mentioned phenomena was explored in depth, without adapting the situation under investigation and not establishing cause-and-effect relationships (Leedy and Ormrod, 2005:179 and Fouchè, 2002:109).

The research project was also of a longitudinal nature, where the electrophysiological measurements of a single group of children were monitored over several months and data of the characteristics investigated were correlated at different intervals (Leedy and Ormrod, 2005:183).

The collection of data was performed in six consecutive phases as depicted on the data collection worksheet (Appendices F & G). The quantitative data collection phases that were applied are described in Table 3.1.

Table 3.1: Quantitative Data Collection Procedures

Phases	Description
Phase 1:	Intra-operative measurement of impedance telemetry and NRT™ measurements at *implantation*
Phase 2:	Impedendance telemetry and NRT™ measurements performed post-operatively at *device activation*
Phase 3:	Impedendance telemetry and NRT™ measurements performed post-operatively at *1 month after device activation*
Phase 4:	Impedendance telemetry and NRT™ measurements performed post-operatively at *3 months post- device activation*
Phase 5:	Impedendance telemetry and NRT™ measurements performed post-operatively at *6 months post-device activation*
Phase 6:	Impedendance telemetry and NRT™ measurements performed post-operatively at *12 months post- device activation*

The table above is an outline of the sequential phases of procedures the researcher applied in order to obtain the data for this research project.

3.6 ETHICAL ISSUES

Ethics in the field of social or humanitarian sciences define research procedures as valid or invalid as well as moral or immoral (Neuman, 2004:443). Ethical aspects are of importance where the focus of a research study is human beings and it is the responsibility of the researcher to vigilantly consider the ethical implications of what is proposed in the study (Strydom, 2002:63 and Leedy and Ormrod, 2005:101). Strydom (2002:63) defines ethics as “a set of moral principles that are suggested by an individual or group, are subsequently widely accepted, and offer rules and behavioural expectations about the most correct conduct towards experimental subjects and participants, employers, sponsors, assistants and students.” Ethics are therefore a set of guidelines and important standards from which a researcher must assess his/her own behaviour to protect the participants involved in a research study.

The following pertinent ethical issues (Strydom, 2002:64 and Leedy and Ormord, 2005:101) were considered in the planning, design and implementation of this study:

- **Avoidance of harm to experimental participants**

  When conducting research, the ethical obligation rests with the researcher to protect participants from any undue physical or emotional discomfort (Strydom, 2002:62 and Leedy and Ormrod, 2005:101-105). As a universal rule, the risk involved in participating in a research study, should not be noticeably greater than the normal risks of everyday living (Leedy and Ormrod, 2005:101). To ensure no physical discomfort, data collection procedures utilised in this study were non-invasive. The NRT™ measurements and impedance telemetry measurements are standard and routine procedures in the MAPping and evaluation of a cochlear implant device. According to the Global White Paper published by Cochlear™ (2000: 1) "…*NRT™ is… a quick and non-invasive way for clinicians …. recording the ECAP…"*. The frequency of these measurements was also in alignment with the routine post-operative cochlear implant follow-up consultations. Participants were thoroughly informed beforehand verbally and in a written format regarding the measurement procedures with the purpose of acquainting them with the procedures and environment in which the research was conducted. As a result of the age of the research population, the abovementioned aspects were discussed with the parents or legal guardians of the children involved (see Appendices B & C).

- **Obtaining informed consent**

  Informed consent is an essential requirement of any study in the human service professions. This gives the participant the opportunity to entirely grasp the scope of the investigation and accordingly be able to make a voluntary and rational decision about their participation in the study (Strydom, 2002:65-66). It is paramount that comprehensive and precise information be translated during informed consent. Research subjects must be informed about the nature of the study to be conducted, be given a choice of either participating or not participating and they must be aware of the fact that they may withdraw at any stage (Leedy and Ormrod, 2005:101-102). Confidentiality will also be guaranteed as part of informed consent.

This issue was addressed through a verbal explanation to all possible participants of the scope of the research and the required involvement of the participants. The verbal explanations were provided in English and Afrikaans. An informed consent form was compiled to supplement the verbal explanation. This was presented before commencing with the study to the parents or legal guardians of the participants. This informed consent form was available in English and Afrikaans (see Appendices B & C). The consent form had to be signed either by the parents or guardians indicating agreement to participate in the study. Informed assent was also verbally obtained from the child. Since most children with severe to profound hearing loss presents with a communication delay, a colouring book was designed by the researcher to help explain the content of an informed consent letter in a comprehensible manner for a child (see Appendix D). The researcher made time available for any questions before the data collection procedure commenced, during the data collection procedures and after the data collection procedure was finalised. These actions served as tools to ensure that participants comprehended the study and were thus able to make an informed decision on the participation of their child in this study (Strydom, 2002:65-66).

- **Ensuring privacy, anonymity and confidentiality**

  Any social or humanitarian research study conducted should respect a participant's right to privacy (Leedy and Ormrod, 2005:102). It is the researcher's duty and obligation to safeguard any information regarding participants, whether it was requested by the participant or not (Strydom, 2002:64). During the investigation, participants were informed verbally and in written format that all data would be confidential and participants would remain anonymous in the dissemination of findings (Ingham, 2003:326-327). Every participant was supplied with a unique number, which was used to refer to his/her data. The participants' confidentiality was guaranteed in the informed consent form.

- **Ensuring the accountability of the actions and competency of the researcher**

  Researchers are under an ethical obligation to ensure that they are competent and adequately skilled to undertake a specific research project (Strydom, 2002:69-70). Every step of the research project must be conducted in ethically correct manner and the researcher should constantly be aware of his/her ethical responsibility. Research is a search of the truth (Ingham, 2003:335) and implies that the researcher has an obligation towards other professionals and colleagues in the scientific community to conduct research in an accountable manner (Strydom, 2002:69-70).

  To address this issue, the researcher constantly reminded herself of her ethical responsibility throughout the gathering of the research population, the implementation of the method, processing of the data, up to writing the research report (Strydom, 2003:69-70). Thorough training in the field of cochlear implantation will ensure competent and accountable data collection. The researcher has attended a three-week post-gradual licensing course in the field of cochlear implantation at the University of Stellenbosch (training students in all aspects of cochlear implantation) as well as several practical workshops presented by Cochlear™. This ensured adequate knowledge and experience in the research apparatus that were used in the study. Ethical clearance for conducting the study was obtained from the Research Proposal and Ethics Committee, Faculty Humanities, University of Pretoria (Appendix H).

- **Responsibility of the researcher to release and/or publish findings**

  The results of the study should be introduced to the public in a written form, otherwise the meaning of the scientific investigation will be lost and not viewed as research (Strydom, 2002:71-72). An ethical obligation rested on the researcher to ensure that information be formulated and delivered in an accurate and unambiguous manner. Results were also made available to participants who participated in the investigation on request (Leedy and Ormrod, 2005:102). It remained an ethical obligation of the researcher to maintain confidentiality of all participants in publication. No names were

published, all participants were referred to according to the number assigned to him/her. Should future publications be made of the study, the researcher will then also maintain confidentiality of all participants by referencing to the assigned numbers of the participants.

3.7 RESEARCH SAMPLE

The research participants of the research project consisted of a group of 10 children who was selected as cochlear implant candidates by the Pretoria Cochlear Implant Programme and then implanted with the Nucleus Freedom™ cochlear implant system from Cochlear™. Permission was obtained from the head of the Pretoria Cochlear Implant Programme, namely Prof. J.G. Swart, to use their patient contact list as a resource for research participants (Appendix E). The following guidelines were used while selecting the research participants:

3.7.1 Selection Criteria

The selection criteria of the Pretoria Cochlear Implant Programme (PCIP) were used as guidelines for the study's selection criteria and are available in Appendix A. The selection criteria that were followed during the study has been described in Table 3.2.

TABLE 3.2: Selection Criteria of Research Population

Criteria	Description	Justification
Age	6 months to 83 months.	➢ The researcher was specifically interested in young children who are still at an age where it is usually difficult to obtain reliable MAPs during MAPping sessions and thus objective measures are needed to increase reliability. According to the co-ordinator of the Pretoria Cochlear Implant Programme, this is the population where objective measures are most needed. (Personal interview, Ronel Chester-Brown, Audiologist of the Pretoria Cochlear Implant Programme, 30 January 2006).
Approved as a cochlear implant candidate by Pretoria Cochlear Implant Programme	Candidacy is determined by: ➢ Degree of hearing loss ➢ Benefit derived from hearing aids ➢ Duration of deafness ➢ Radiological and medical considerations ➢ Family expectations and support ➢ Educational setting and support Please see Appendix A for a description of the candidacy criteria followed by the Pretoria Cochlear Implant Programme.	➢ Criteria applied by Pretoria Cochlear Implant Programme for children (Personal interview, Ronel Chester-Brown, Audiologist of the Pretoria Cochlear Implant Programme, 30 January 2006). ➢ Candidacy criteria were stipulated to ensure that the investigative measurements would be performed on a homogenous group and to restrict potential variables in the study. The candidacy criteria ensures that a representative sample of the paediatric cochlear implant population is selected. This sample will then be used to draw conclusions about the paediatric cochlear implant population as a whole. Thus, the external validity of the study is increased by using a homogenous sample (Leedy and Ormrod, 2005:99).
Device Implanted	Nucleus Freedom™ of Cochlear ©	The Auto-NRT™ feature is exclusive to this cochlear implant system (Cochlear™, 2005. Nucleus Freedom™ information brochures). The software developed for this implant type allows the researcher to do Auto-NRT™ measurements, which no other implant type up to date has been able to do.
Language	English or Afrikaans speaking participants	The researcher is proficient in these two languages only and will be used for conveying of information. This will ensure that information conveyed and instructions provided are fully understood by the participants.

3.7.2 Selection procedure

The selection procedure applied in this study was non-probability convenience sampling. According to Leedy and Ormrod (2005:206), when using non-probabiltiy sampling, the researcher has no way of predicting or guaranteeing that each characteristic of the population being investigated, will be represented in the sample. Convenience sampling or accidental sampling, makes no pretense of identifying a representative subset of a specific population. Participants are selected from a readily available pool (Leedy and Ormrod, 2005: 206). This selection procedure was applicable to this research project, since research participants were selected from the awaiting cochlear implantation list of the Pretoria Cochlear Implant Programme. Thus, an already existing pool, the approved paediatric candidates for cochlear implants, containing the research population was accessed to select the participants.

In order to obtain informed assent from the child, a colouring book was designed by the researcher to help clarify issues regarding confidentiality, the nature of the research and the option of terminating participation in the study (see Appendix D). The child was only included in the research sample when both the parent/s and child (where possible) had provided informed consent (see Appendices B & C).

3.7.3 Description of research participants

Ten children between the age of 6 months and 83 months (6 years;11 months) were selected form the awaiting cochlear implant candidacy list of the PCIP. A description of the research participants are summarised in Table 3.3.

TABLE 3.3: Description of Research Participants

Participant number	Gender	Chronological age at implantation	Aetiology of hearing loss	Extent of hearing loss	Period of hearing aid use	Type of sound amplification used
1	Female	12 months	Congenital unknown	12 months	7 months	Widex Senso P37 (power digital)
2	Male	23 months	Progressive unknown	4 months	4 months	Phonak Superfront PPCL4+ (power analogue)
3	Female	36 months	Progressive unknown	18 months	18 months	Phonak Supero 411 (power digital)
4	Female	9 months	Progressive unknown	5 months	5 months	Phonak PowerMAXX 411 (power digital)
5	Male	62 months	Congenital unknown	62 months	55 months	Phonak Supero 411 (power digital)
6	Female	71 months	Premature birth	36 months	35 months	Phonak Supero 412 (power digital)
7	Male	77 months	Congenital unknown	59 months	56 months	Phonak Supero 412 (power digital)
8	Male	32 months	Congenital unknown	28 months	27 months	Phonak PowerMAXX 412 (power digital)
9	Male	50 months	Progressive unknown	38 months	37 months	Phonak Supero 412 (power digital)
10	Male	22 months	Congenital unknown	22 months	5 months	Phonak PowerMAXX 411 (power digital)

This table supply a description and summary of the characteristics of the participants who participated in this study. The table outlined characteristics such as gender, chronological age, ethiology of hearing loss, duration of hearing loss, period of hearing aid use and the type of amplifcation used by the participant.

The participants consisted of six males and 4 females. In Figure 3.1 a graphical presentation is available for the reader of the distribution of gender among the research participants.

Figure 3.1 Graphical representation of the gender of the participants

This figure is visual summary of the gender distribution of the research participants.

The chronological age at implantation varied across the participants with the youngest participant 9 months old, and the oldest 77 months old. The mean age of the participants was 39,4 months. In figure 3.2, a graphical representation of the chronological age of the participants at implantation, is available.

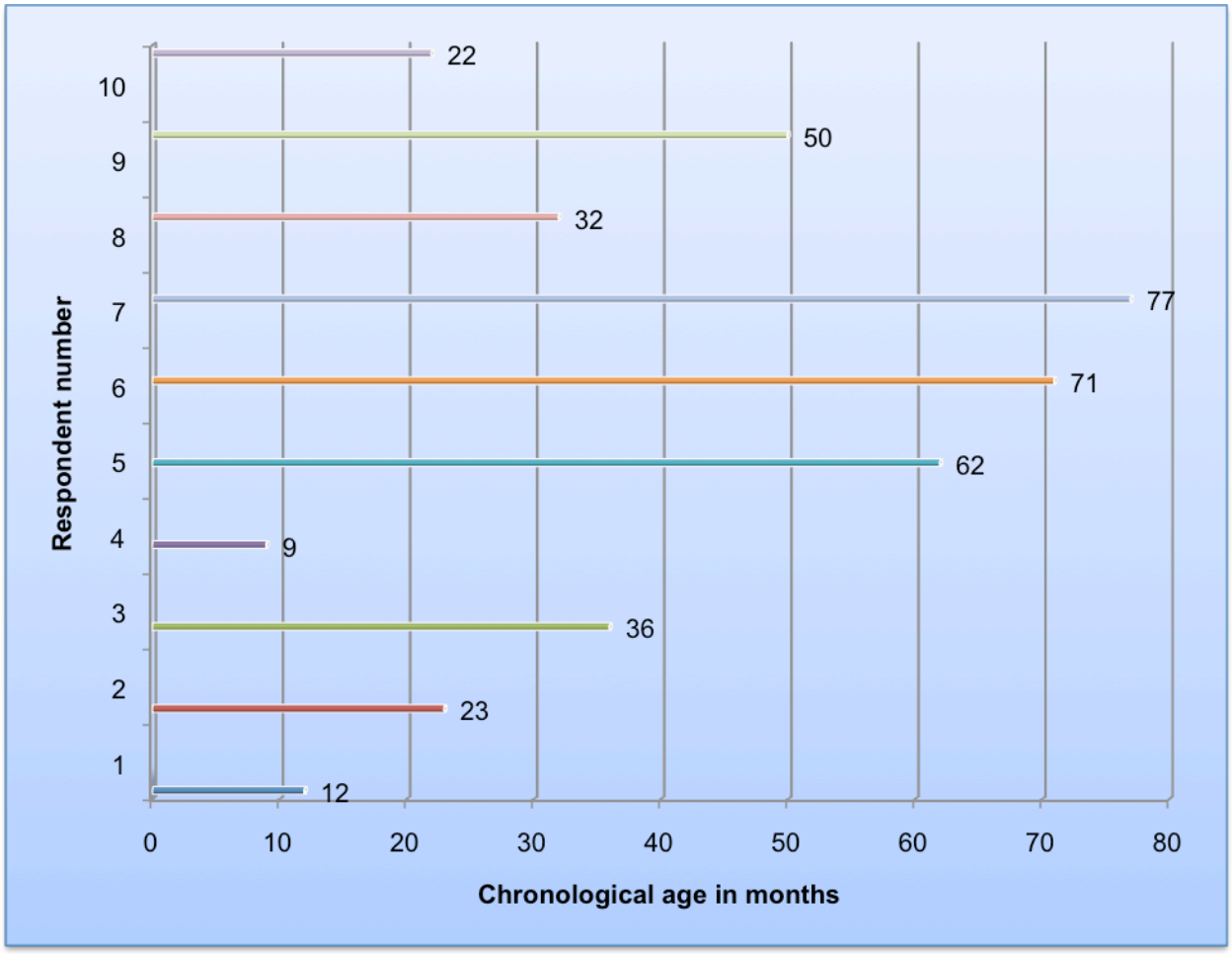

Figure 3.2 Chronological age at implantation

This figure provides a summary of the chronological age at implantation of the participants.

The extent of the hearing loss before implantation varied between 4 and 62 months. Five of the research participants, presented with a progressive unknown hearing loss, which influenced the extent of the hearing loss due to the age of diagnosis being later in months, than those participants who presented with congenital hearing loss. The period of the hearing aid use before cochlear implantation varied between 4 and 56 months, with the mean time of hearing aid use at 24,9 months. Figure 3.3

supplies a graphical comparison between the chronological age at implantation, extent of the hearing loss and the period of hearing aid use of each participant.

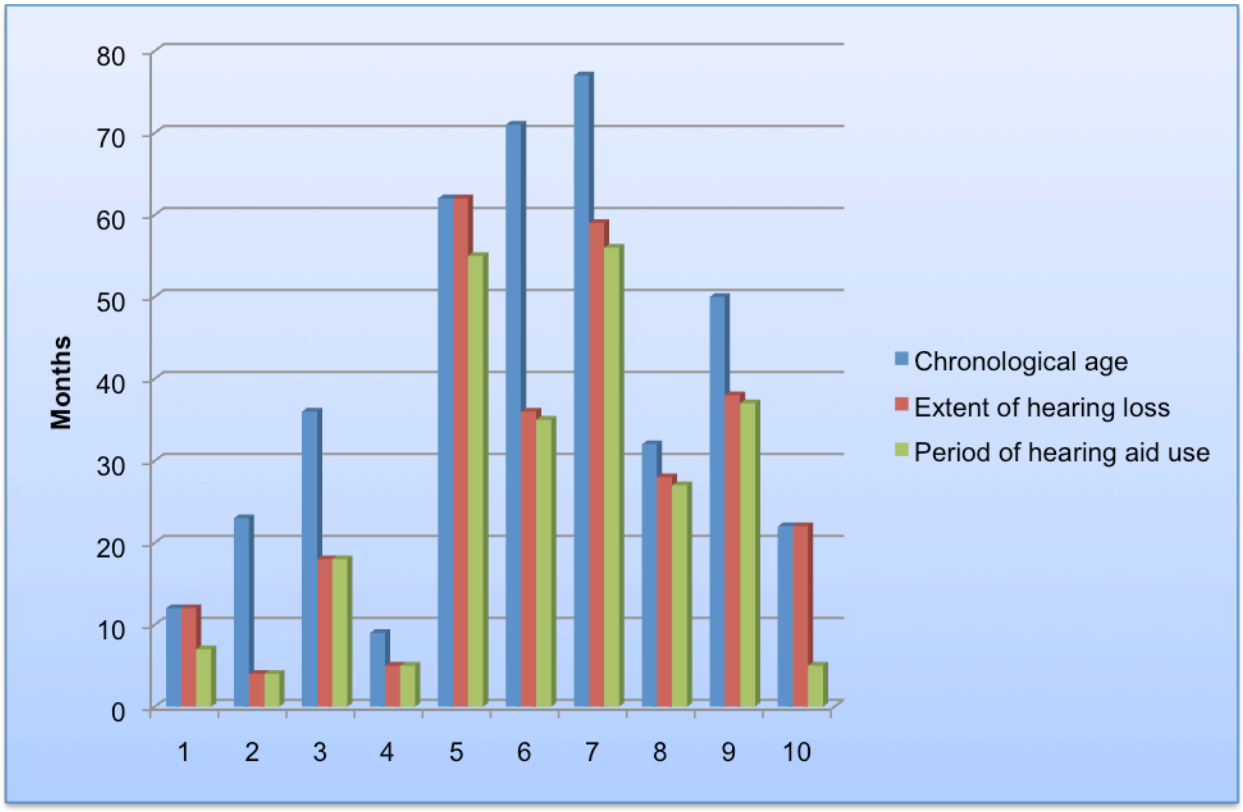

Figure 3.3 Graphical comparison of the chronological age at implantation, the extent of the hearing loss and the period of hearing aid use of each participant.

This figure clearly demonstrates the difference between the participants' chronological age, the extent of their hearing loss and the period of hearing aid use before cochlear implantation was performed.

Sound amplification used by the participants was of a power digital nature, with only one participant fitted with power analogue hearing aids. All the participants were implanted with the Nucleus Freedom Contour Advance™ electrode array and were fitted with the Nucleus Freedom™ speech processor at device activation. The research participants' speech processors were programmed with the ACE processing strategy.

3.8 DATA COLLECTION APPARATUS

The collection of data for the current study included the following material and apparatus:

- a laptop computer running Windows™ XP Professional
- Nucleus™ software Custom Sound EP™ was used to perform impedance and NRT™ measurements intra-operatively
- Impedance measurements and NRT™ measurements post-operatively was conducted using the Custom Sound Suite software from Nucleus™
- The Nucleus Freedom cochlear implant external device consisting of speech processor and magnetic coil.
- The Programming Pod and connecting cable that connects the cochlear implant system with the laptop computer.
- Various types of toys, eg magnetic play board, building blocks and a peg board, were used post-operatively to occupy the participants during the data collection procedure.

All apparatus included in intra-operative measurements complied with hospital regulations regarding sterility in theatre. The Nucleus™ Freedom cochlear implant external device consisting of speech processor and magnetic coil is wrapped in sterile plastic provided by the theatre nurse scrubbing for the implanting surgeon (Personal interview, Ronel Chester-Brown, Pretoria Cochlear Implant Programme, 30 January 2006).

3.9 DATA COLLECTION MATERIAL

Data collection material consisted of the following:

- An NRT™ recording sheet for 22 electrode measurements was designed by the researcher to record the NRT™-levels for each electrode. Basic participant

information was also recorded on this recording sheet. The data collection worksheet sheet is available in Appendix G.

- An impedance telemetry worksheet was designed by the researcher to record impedance values. This worksheet provided for impedance values measured in different polarity modes, namely common ground (CG), Mono-polar 1 (MP1), Mono-polar 2 (MP2) and Mono-polar 1+2 (MP 1+2). Basic participant information was also recorded on this sheet. This recording sheet is available in the data collection worksheet in Appendix F.

3.10 PILOT STUDY

According to Leedy and Ormrod (2005:110) a pilot study is a small study conducted prior to a larger set of research to evaluate whether the methodology, sampling, instruments and analysis are sufficient and appropriate (Leedy and Ormrod, 2005:110). The pilot study is described below.

3.10.1 Aim of the Pilot Study

The aim of the pilot study was to evaluate the data collection apparatus and data collection procedure in terms of feasibility and practicality. The researcher aimed at answering the following questions:

1. Data collection apparatus and material:
    - Is the apparatus sufficient and effective in obtaining impedance telemetry and NRT™ measurements?
    - Is the recording material sufficient and effective to record data measured?
    - Is the apparatus portable and easy to use in the intra-operative and post-operative environments?
2. Data collection procedure:
    - Does the performance of both procedures influence the length of the surgery during intra-operative measurements?
    - Does the performance of the data collection procedures influence the of the device activation session?

- Was the child comfortable while performing NRT™-measurements post-operatively?

3.10.2 Participants in the Pilot Study

One child, fitting the selection criteria as set out in Table 3.2, was chosen randomly from the Pretoria Cochlear Implant Programme candidacy list as a participant for the Pilot study.

3.10.3 Material and apparatus of the Pilot Study

The material and apparatus utilized in the pilot study were identical to the material and apparatus stipulated and described in sections 3.8 and 3.9.

3.10.4 Data Collection Procedure of the Pilot Study

The following data collection procedure was followed in the pilot study:

- Intra-operative measurement of impedance telemetry as part of the routine cochlear implant surgery procedure was performed during the closure of the skin flap in four electrode polarity modes, namely common ground, mono-polar 1, mono-polar 2 and mono-polar 1+2. The recording time was approximately 1 minute.
- Intra-operative measurement of NRT to measure NRT-thresolds on all electrodes as part of the cochlear implant surgery procedure was performed during the closure of the skin flap, using the Auto-NRT™ functionality of the software. This measurement was performed within approximately 5 minutes.
- Measurements were repeated 4 weeks post-operatively at device activation.
- Measurements were then performed at intervals of 1 month and 3 months post-device activation during routine consultations.

3.10.5 Results of the Pilot Study

The results are provided according to the aim of the pilot study.

- **Material and apparatus of the Pilot Study:**
  It was determined that the material and apparatus that were used were sufficient and effective in obtaining the impedance telemetry and NRT™ measurements. The NRT and impedance telemetry recording sheets did not specify whether the measurements were made intra- or post-operatively. In the case of post-operative measurements, the need to specify the interval post-device activation became apparent.

  The apparatus are portable and easy to maneuver and set up in the different environments, namely in operation theatre during intra-operative measurements and then in consulting rooms for measurements performed post-operatively.

- **Procedure of the Pilot Study:**
  - The most important aspect that was assessed when considering the procedure was the time taken to perform both the measurements. The intra-operative measurements are part of the general protocol of the surgical process, but should not unnecessarily lengthen the surgery time. The impedance telemetry measurement was performed within the one minute time frame described in the software guidelines of the software. The NRT™-measurements were performed during the closure of the skin flap. This took approximately five minutes and the procedure was finished before the surgeons had completely closed the skin flap. The procedures thus did not lengthen the surgery time in any way.
  - Measurements at switch-on were part of the protocol and did not take up unnecessary time from the audiologist or patient's family. The child was not bothered by the potentially loud stimulation levels of the NRT™-measurements and measurements were successfully completed on all 22 electrodes.

3.10.6 Implications of Pilot Study

The pilot study resulted in the refinement of the NRT™ and impedance telemetry recording sheets to include information regarding the nature of the measurement, i.e. intra- or post-operative, and then in the case of post-operative measurements a space to indicate the time interval post-device activation had to be included on the recording sheet.

In general, the procedures were effective and adequate for obtaining the impedance and NRT™ measurements at different time intervals, confirming its feasibility and practicality for this study.

3.11 DATA COLLECTION PROCEDURES

All intra-operative data was collected during cochlear implant surgeries performed at a private hospital. Post-operative measurements were conducted in different settings due to the different environments in which the researcher functioned. This was mainly controlled by the participant's particular needs. The post-operative measurements of six of the participants were conducted at a hearing centre in Pretoria, which they regularly visit for follow-up visits. Four participants' post-operative measurements were conducted at a private nursery school for children with hearing loss in Pretoria where follow-up visits are performed in combination with auditory training sessions. The research was conducted over period of 19 months.

3.11.1 Data Collection Procedures:

Changes in NRT™ and impedance telemetry measurements performed intra-operatively and post-operatively over a period of twelve months were investigated and described. The research process consisted of the following data-collection procedures:

1) Potential participants were selected from the PCIP's awaiting cochlear implant surgery list.
2) The potential participants' parents or legal guardians were contacted by telephone in order to invite them to take part in the study. The aim of the study, as well as a short description of the data collection procedures, were explained to them.
3) An informed consent form as well as a colouring book was faxed, mailed or mailed electronically in order to complete it.
4) The informed consent form was returned to the researcher on the date of the implantation surgery.
5) Intra-operative measurement of impedance telemetry was performed as part of the routine cochlear implant surgery procedure, was performed during the closure of the skin flap in four electrode polarity modes, namely common ground, mono-polar 1, mono-polar 2 and mono-polar 1+2. Recording time was approximately 1 minute. Values were recorded on the impedance telemetry worksheet.
6) Intra-operative measurement of NRT™ was conducted to measure NRT-thresholds on all 22 electrodes as part of the routine cochlear implant surgery procedure during the closure of the skin flap, using the Auto-NRT™ functionality of the software. This measurement was performed within a approximately 5 minutes. Values were then recorded on the NRT™ worksheet.
7) Impedance telemetry and NRT™ measurements were repeated 4 weeks post-operatively at device activation.
8) Impedance telemetry and NRT™ measurements were then performed at intervals of 1 month, 3 months, 6 months and 12 months post-device activation during routine consultations.

Since the post-operative procedures are part of routine cochlear implant device MAPping sessions, the participant did not spend more time with the researcher than during routine sessions. All procedures performed have been developed by Cochlear™ to be generally comfortable to the cochlear implant user.

3.11.2 Stimulus Parameters used during impedance telemetry and NRT™ measurements:

The following stimulus parameters were used during the impedance telemetry and NRT™ measurments:

3.11.2.1 Impedance Telemetry Stimulus Parameters

During impedance telemetry measurements, the cochlear implant device was activated using the Windows-based CustomSound™ and CustomSound EP software, version 2.0, provided by the manufacturer (Cochlear Corp., Lane Cove, Australia). Impedance were measured on all 24 electrodes on the electrode array of the implant. The stimuli consisted of bi-phasic current pulses presented at a level of 100 clinical units. Each pulse was presented for 25 µs/phase at a rate of 250 pulses per second (Van Wermeskerken, Van Olpen & Smoorenburg, 2006: 538).

In the present study, electrode impedance was measured in common ground (CG) mode, Monopolar +1 (MP+1) mode, Monopolar+2 (MP2) mode and Bipolar (BP) mode. In CG mode, the impedance is measured between an intracochlear electrode and all other intracochlear electrodes coupled in parallel (Van Wermeskerken et al., 2006: 538). In MP1 mode the impedance is measured between the active intracochlear electrode and the reference ball electrode implanted underneath the temporal muscle (Van Wermeskerken et al., 2004:538). Measurements performed in the MP2 mode, measured current flow between the active intracochlear electrode and the plate electrode situated on the body of the implant. The MP1+2 mode measured current flow between the active intracochlear electrode and both extracochlear electrodes, namely the ball and plate electrodes. In BP stimulation, both the active and the indifferent electrodes are inside the cochlea (French, 1999:61-62). Table 3.4 indicates the stimulus parameters that were applied during the performance of impedance telemetry (Custom Sound™ Software).

TABLE 3.4 Impedance telemetry Stimulus Parameters

Impedance telemetry Stimulus Parameters	
Stimulation mode:	Common ground, Monopolar +1, Monopolar +2 and Bipolar
Recording electrodes:	1-22
Pulse type:	Bi-phasic
Pulse duration (µs/phase):	25
Number of pulses per second:	250
Current level:	100 clinical units

3.11.2.2 AutoNRT™ Stimulus and Recording Parameters

AutoNRT™ measurements were performed to measure NRT-thresholds on all 22 active electrodes of the electrode array. According to the stimulus parameters, the recording site was to be two electrodes apically removed from the stimulation site, for example if a measurement was performed on electrode 10, the recording site was electrode 12. The Auto-NRT™ software automatically selected stimulation active/indifferent electrode pairs to be different from recording active/indifferent electrode pairs in order to minimize the effect of the stimulus artefact on the recorded signal (Lai et al., 2004: 253). For example, if stimuli were presented on electrode 11 in MP1 mode (monopolar mode, between electrode 11 and the external ball electrode), the neural response would be recorded from electrode 13 in MP2 mode (monopolar mode, between electrode 13 and the external plate electrode).

The neural responses at each stimulation site were characterised by an amplitude growth function, indicating how the neural response amplitude varied with the stimulation level. Each amplitude growht function involved a series of at least 3 recordings with clear neural responses at different stimulation levels, and the amplitude growth function was approximated as a straight-line function using linear regression (Lai et al., 2004: 253).

The AutoNRT™ software implements a forward-masking paradigm as designed by Lai and Dillier (Abbas et al., 1999:50 and Lai, 1999:5). This involves a masker stimulus followed by a probe stimulus to seperate the neural response from the accompanying stimulus artefacts. The probe and the masker were presented at the same stimulation site, namely MP1. Biphasic stimuli of 25 µs/phase were implement for both probe and masker stimuli, with the masker preceding the probe by 400 µs. A probe stimulation rate of 80Hz was used (Lai et al., 2004:253). A set recording delay of 122 µs and gain of 50dB were applied during all AutoNRT™ measurements (Lai et al., 2004:253).

The basic parameters used during the AutoNRT™ measurements on all electrodes are indicated in Table 3.5 (Nucleus™ Technical Bulletin, 2006:2).

TABLE 3.5 AutoNRT™Stimulus Parameters

AutoNRT™ Stimulus Parameters	
Pulse active electrode:	Series
Probe indifferent electrode:	MP1
Probe current level:	170
Probe pulse width (µs):	25
Probe rate (Hz):	80
Masker active electrode:	Probe Active electrode+ 0 Offset
Masker Indifferent electrode:	MP1+ 0 Offset
Masker current level:	11 + 10 Offset
Masker Pulse width (µs):	25 + 0 Offset
Number of maskers:	1
Masker rate (Hz):	100
Masker probe interval (µs):	400

The recording parameters that were used during the AutoNRT™ measurements are shown in Table 3.6 (Nucleus™ Technical Bulletin, 2006:2).

TABLE 3.6 AutoNRT™ Recording Parameters

AutoNRT™ Recording Parameters	
Recording active electrode:	Probe Active electrode +2 Offset
Recording indifferent electrode:	MP2
Gain (dB):	50
Delay (μs):	122
Artefact cancellation technique:	Forward Masking
Artefact reduction:	Off
Averaging: number of sweeps	50
Averaging: measurement window (μs):	1600
Averaging: effective sampling rate (kHz):	20

It is important to note that the aim of this study was to investigate NRT-threshold measurements measured by the AutoNRT™ software. No parameter optimisation was performed by the researcher in order to obtain NRT-threshold measurements in instances where no recordings could be made on an electrode.

3.12 DATA RECORDING PROCEDURES

The quantitave data was recorded onto a data collection worksheet (Appendix G) which consisted primarily of numerical data. The data was in a raw format on the data collection worksheet (Appendix G). This data was coded by the researcher and checked a second time to ensure that all data was correctly coded. This coding is done to organise data into a suitable format for data capturing on digital format, allowing analysis of the data (Neuman, 1997:295). The coded data on the data collection worksheets was entered into the Statistical Package for the Social Sciences (SPSS) computer programme to allow for statistical alysis of the data.

3.13 DATA ANALYSIS PROCEDURES

Data analysis, according to Neuman (1997:422), implies the search for patterns in data. This entails organising, examining, categorising, assessing, comparing, synthesising, contemplating and reviewing the data (Neuman, 1997: 422). The data analysis procedure applied in the current study is presented according to each objective in Table 3.7.

Table 3.7 Statistical analyses implemented for each objective

Objective	Statistical procedure
1. To describe impedance telemetry measurements obtained intra-operatively and up to twelve months post-cochlear implantation.	▪ Friedman's test ▪ Wilcoxon matched-pair signed rank test
2. To describe Neural Response Telemetry measurements obtained intra-operatively and up to twelve months post–cochlear implantation.	▪ Friedman's test ▪ Wilcoxon matched-pair signed rank test
3. To compare trends in the measurements of impedance and Neural Response Telemetry for each child pre-implantation and post-implantation over a period of twelve months.	Wilcoxon matched-pair signed rank test

The analysis of the quantitative data relied primarily on statistical analysis procedures. After the data had been prepared for digital format, as well as captured

in this format, statistical analyses were performed on the data set. The coded data represented on spreadsheets, was analysed statistically using the SPSS software package. Both descriptive statistics, which describes what the data looks like, and inferential statistics, which allow for making inferences about large populations by collecting data on relatively small samples, were used to investigate the quantitative data (Leedy and Ormrod, 2005: 252; Maxwell & Satake, 2006:10; Struwig & Stead, 2001:3).

The study at hand investigated the changes in impedance and Neural Response Telemetry from implantation up to twelve months post-implantation, meaning that these two measurements were repeated over time on the same group of research participants. For statistic purposes, this implied that inferential tests had to be selected that can test for the difference between several related groups of data where the same data collection procedure was repeated. Nonparametric statistical procedures are used to determine whether two samples with ordinal data differ from each other when a relationship exists between the samples. In simpler terms – when each data point in one sample is paired with a data point in the other sample (Leedy & Ormrod, 2005: 274). The Student's t-test is usually applied on the data to determine whether a statistically significant difference exists between two means exists (Leedy & Ormrod, 2005: 274). Friedman's ANOVA test was selected since the Student's t-test could not be performed on the data that was available due to the small amount of participants.

Friedman's ANOVA is a non-parametric test procedure used for testing variations between experimental conditions, when there a more than two conditions and the same participants have been used in all conditions. Friedman's ANOVA is based on the ranks of the SPSS dataset for each condition and not the actual scores. The mean ranks of conditions are important for the interpreting of any effects, indicating the test statistic's degree of freedom and its significance value. The SPSS Output indicates the test statistic as a Chi-Square distribution (Field, 2009: 562; Struwig & Stead, 2001:155) . In order to evaluate the effects of the data over time, it is

compared with the level of significance (p-value) which is 5% or 0.05. Should the significance value be greater than the p-value, it is indicated that no significant changes over time have been measured (Field, 2009: 562; Struwig & Stead, 2001:155). The opposite is true when the significance value is smaller than the p-value, thus confirming significant changes in measurements over time. Friedman's ANOVA test was performed on the mean ranks (calculated by the SPSS Output) of each of the selected electrodes' impedance telemetry and NRT™ measurement conditions. Once it has been established that significant changes in the mean ranks between the conditions are evident, post-hoc tests for Friedman's ANOVA are performed in order to investigate the level of significance between each condition.

The Wilcoxon matched-pair signed rank test was selected as the post-hoc procedure. This test corrects for the number of tests performed by applying the Bonferroni correction. In the social sciences, this usually means 0.05/number of comparisons (Field, 2009: 563; Struwig & Stead, 2001:156). For this study, the level of significance had to be determined across five conditions. Thus, the level of significance was determined by the calculation: 0.05/5 = 0.01 (Field, 2009: 563). The Wilcoxon paired signed-rank test was performed on each of the five pairs of test conditions of the selected electrodes where significant changes had been indicated by the Friedman's ANOVA test.

3.14 VALIDITY AND RELIABILITY ISSUES

This study implemented a quantative research method and require the application of quality criteria (e.g. validity, reliability, trustworthiness). The quality criteria is applied to ensure tha the study generated accurate and valid findings (Neuman, 1997:145). The steps taken to apply these quality criteria are discussed as follows.

- **Ensuring Validity**

  Validity refers to whether an instrument measures the concept in question and whether the concept is measured accurately (Delport, 2002:167). To answer questions regarding the accuracy, meaningfulness and credibility of the proposed

study, issues regarding both external and internal validity were considered in the following ways.

External validity of a study is the extent to which the results relate to situations beyond the study, in other words, the generalisability of the data (Leedy and Ormrod, 2005: 99). When research is conducted that has implications that extend far beyond the specific situation actually studied, more is contributed to humanities knowledge about the world (Leedy and Ormrod, 2005: 99). Accordingly, this study aimed to increase its external validity according to two main criteria specified by Leedy and Ormrod (2005:99-100) namely: selecting a *real life setting* and allowing for a *representative sample* .

- The Pretoria Cochlear Implant Programme is a *real life setting* in use by the professionals involved in the Programme.
- A *representative sample* was acquired since research participants were selected from the Pretoria Cochlear Implant Programme's cochlear implant candidate list.
- The validity of the software measurements of impedance telemetry and NRT™ via the Nucleus™ software Custom Sound EP and Custom Sound Suite has been firmly established (Cochlear, 2005c).
- The data collected during the study was derived from electrophysiological measurements, which are objective since the measurements are not reliant on the co-operation of the participant. Thus, the data in not bias and this contributes to the validity of the study(Leedy & Ormrod, 2005:93).

➢ **Ensuring Reliability**

According to Leedy and Ormrod (2005:93) reliability of a measurement instrument refers to "*the extent to which it yields consistent results when characteristic being measured hasn't changed."* Reliablity issues that were

considered were *internal consistency reliability* and *test-retest reliability.* Reliability issues were considered in the folllowing ways:

- The measurements used in monitoring impedance telemetry and NRT™ are two measurements used standard with all cochlear implant users.
- Stimulus and recording parameters applied were standardised by the manufacturing companies.
- The researcher also ensured that all data recorded on the data collection worksheets was correct, by checking it twice.
- The researcher underwent training to perform theses procedures as part of the prescribed licensing course by the HPCSA for practicing in the field of cochlear implantation.

3.15 CONCLUSION

In the light of the recommendations from the The South African Department of Health to place emphasis on Essential National Health Research (Health Research Policy in South Africa, 2001) and the fact that no published records of research projects performed on cochlear implant related issues are available from the South African Medical Research Council (South African Medical Research Council: 2007), the empirical research of this study was designed to investigate the use of electrophysiological measurements within the paediatric cochlear implant population. The study aimed at investigating electrophysiological measurements in order to provide effective audiological services to the paediatric population. In due course, this will aid in the realization of the ultimate objective of early identification and implantation namely, the development of age appropriate hearing abilities and speech and language within this population.

3.16 SUMMARY

This chapter provided a description of the procedures implemented in the research method to acquire the data according to the sub-aims, in order to adrress the main

aim of the study. Monitoring longitudinal variations in impedance telemetry and NRT™ measurements in young cochlear implant users was the driving force behind this project. The research approach was described and followed by a discussion of ethical issues involved in the current study. A discussion of the selection criteria and description of subjects used in this study followed. The apparatus used, the collection of data and analysis thereof was discussed subsequently, followed by the data collection procedures according to the different techniques. The chapter was concluded by an overview of the data recording and analysis procedures implemented as well as a discussion regarding issues of validity and reliability in the current study.

CHAPTER 4

RESULTS AND DISCUSSION

Aim: To present the results of the empirical research, and to elucidate the meaning and significance of the findings

4.1 INTRODUCTION

The South African Department of Health endorses Essential National Health Research (Health Research Policy of South Africa, 2001), but at present no published records of research projects involving the use of electrophysiological measures when implanting children at a young age, are available from the South African Medical Research Council (South African Medical Research Council: 2007). This lack of evidence based research, the importance of early implantation in order to aid the development of hearing abilities as well as speech and language, and the need to provide effective audiological services to the paediatric population, provided the rationale for the current study. This type of research is essential to provide much needed empirical evidence regarding the longitudinal behaviour of impedance telemetry and NRT™ measurements, measured via the latest Auto- NRT™ software for the Nucleus Freedom™ cochlear implant system. By streamlining the process of service delivery to young cochlear implant users, professionals can ensure accountable and effective service delivery to a steadily increasing population in the South African context.

A theoretical underpinning of the implementation of electrophysiological measurements in the paediatric cochlear implant population, including the justification, current practice, and challenges in the developing context of South Africa, was provided in Chapter 2. Chapter 3 described the methodological approach that supplied the operational structure for extracting the data required in order to

address the main aim of this study. **The aim of this chapter is to describe the changes in longitudinal measurements of impedance and Neural Response Telemetry measurements in young cochlear implant users, and to discuss these changes in terms of relevant and comparable literature.** Figure 4.1 provides an illustration of the sub-aims that were proposed to attain the main goal of the study.

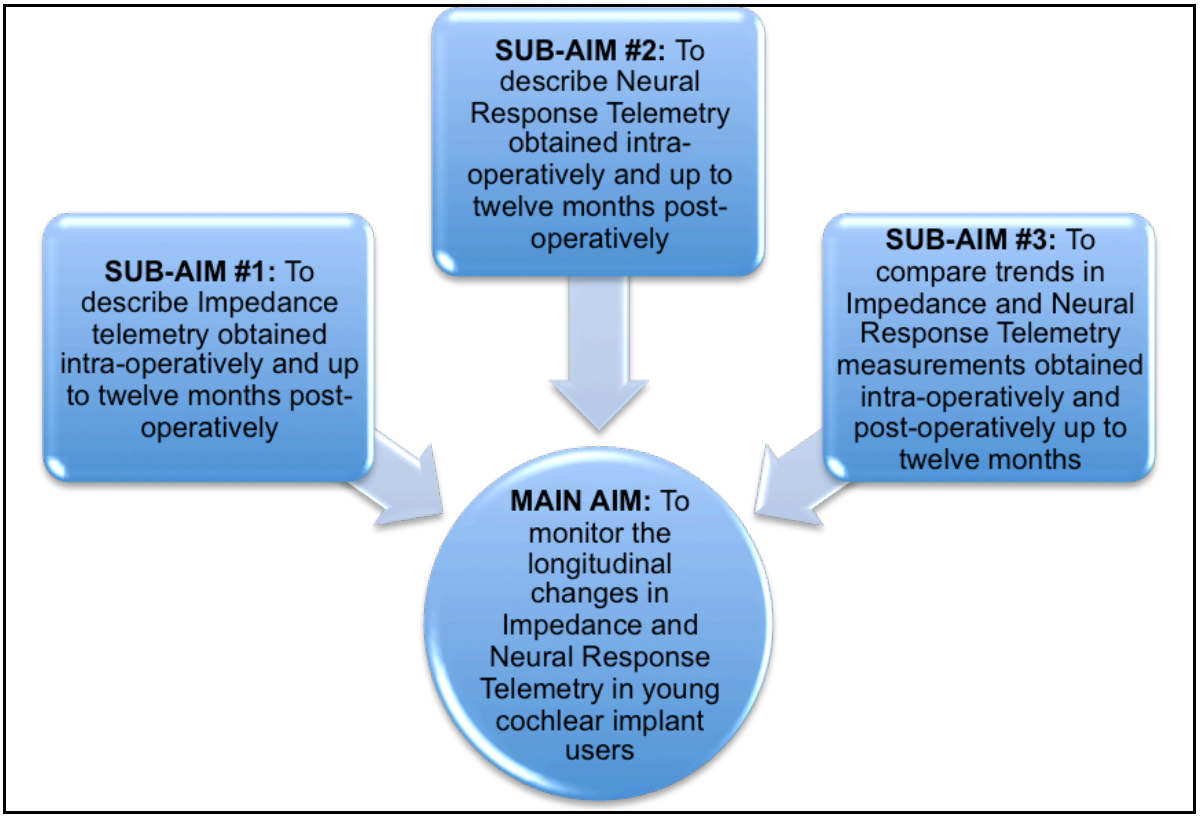

FIGURE 4.1 Sub-aims contributing to the main aim of this study

The research question of this study will be addressed by the description of the results of the sub-aims. Neuman (1997:367) stated that comparison is the key to all research. The meaning and significance of results depend upon appropriate interpretation, relevant conclusions, and generalisations, based on the analysed data (Leedy and Ormrod, 2005:226). The results of the current study are presented and discussed according to the sub-aims as indicated in Figure 4.1.

In the upcoming section data collected on specific electrodes during the field study will be presented and then discussed according to the placement of the electrodes in the cochlea. The electrodes selected for analysis cover the entire electrode array, so that there are apical (Electrodes 16, 19 and 22), medial (Electrodes 8, 11 and 13), and basal Electrodes (3 and 6) in the sample (Henkin *et al*., 2003:875).

4.2 RESULTS AND DISCUSSION OF SUB-AIM #1: IMPEDANCE TELEMETRY – INTRA-OPERATIVELY AND TWELVE MONTHS POST-OPERATIVELY

The first sub-aim of the study was to describe the changes in impedance telemetry obtained intra-operatively and up to twelve months post-operatively in young children. Data collected with the specified software and noted on the impedance telemetry-recording sheet (Appendix F) was recorded and analysed. Impedance telemetry data for all electrodes was obtained from eight respondents for all measurement intervals. Respondent 5 failed to complete the study due to rescheduling of follow-up appointments and therefore these results were excluded from statistical computations. The statistical procedures were only performed on the Common Ground (CG) and MP1+2 data measurements, since these two test modalities are most commonly used in the clinical setting to monitor changes in impedance values and integrity of the electrode array over time (Rance & Dowell, 1997:157). This section will be divided into 2 sub-sections. The first sub-section will analyse the impedance results according to basal, medial and apical electrodes. The second sub-section will be a discussion of the impedance results on all electrodes.

4.2.1 Results of impedance telemetry

In the current sub-section impedance telemetry data collected on Electrode 3, 6, 8, 11, 13, 16, 19 and 22 will be presented and analysed.

4.2.1.1 Impedance telemetry results collected on basal electrodes

This subdivision will concentrate on the presentation of the data sets collected during the six measurement intervals for Electrodes 3 and 6. Table 4.1 is an overview of the Common Ground (CG) impedance values measured on Electrodes 3 and 6, while Table 4.2 is a presentation of the data collected during MP1+2 measurements.

Table 4.1 Common Ground impedance values measured on basal Electrodes 3 & 6

Electrode number	Sample	Mean (kΩ):	Minimum (kΩ):	Maximum (kΩ):	Standard Deviation (kΩ):
Electrode 3	Intra-Operative	6.70	2.92	13.47	3.68
	Device Activation	7.72	3.89	10.78	1.94
	3 Months follow-up	7.74	4.47	9.66	1.70
	6 Months follow-up	6.67	4.56	10.36	1.96
	9 Months follow-up	6.36	4.17	8.47	1.78
	12 Months follow-up	6.10	3.73	8.35	1.88
Electrode 6	Intra-Operative	5.72	2.97	12.31	2.91
	Device Activation	7.54	5.77	10.25	1.47
	3 Months follow-up	7.55	5.24	10.29	1.69
	6 Months follow-up	6.86	4.21	9.47	2.09
	9 Months follow-up	6.81	3.83	10.08	2.40
	12 Months follow-up	6.42	3.37	10.02	2.29

= Lowest impedance value **= Highest impedance value**

Table 4.2 MP1+2 impedance values measured on basal Electrodes 3 & 6

Electrode number	Sample	Mean (kΩ):	Minimum (kΩ):	Maximum (kΩ):	Standard Deviation (kΩ):
Electrode 3	Intra-Operative	7.18	3.75	13.37	3.41
	Device Activation	8.48	4.56	11.41	1.97
	3 Months follow-up	8.14	5.22	10.35	1.69
	6 Months follow-up	7.50	5.34	11.14	1.91
	9 Months follow-up	7.21	4.95	9.31	1.72
	12 Months follow-up	7.10	4.64	9.46	1.90
Electrode 6	Intra-Operative	6.42	3.94	12.65	2.73
	Device Activation	8.38	6.84	11.03	1.41
	3 Months follow-up	8.46	6.36	11.21	1.64
	6 Months follow-up	7.89	5.40	10.45	2.01
	9 Months follow-up	7.85	5.06	11.01	2.29
	12 Months follow-up	7.68	4.56	10.98	2.30

= Lowest impedance value **= Highest impedance value**

For purposes of statistical analysis, the Friedman's ANOVA test was selected. The mean ranks (calculated by the SPSS Output) of Electrode 3 and 6's impedance telemetry measurement modes and conditions were used to determine the level of significance in the changes between them. Should significant changes in the mean ranks between the conditions be marked, post-hoc tests for Friedman's ANOVA would be executed to examine the level of significance across the measurement conditions. The SPSS Output specifies the test statistic as a Chi-Square distribution. In order to assess the effects of the data longitudinally, a level of significance (p-value), which is 5% or 0.05, is used for comparison. If the significance value is greater than the calculated p-value, it is indicative of significant changes between the measurement intervals (Field, 2009:562).

Table 4.3 is a summary of the results of Friedman's ANOVA performed on the dataset of Electrode 3 and 6 regarding impedance telemetry measurements for CG and MP1+2 testing modes.

Table 4.3 Level of significance on impedance telemetry on basal electrodes

Electrode Number	Test Mode	Test Statistic (Chi-squared)	p-value	Significant (*p-value* ≤ *0.05*)
3	Common ground	9.07	0.11	No
3	MP1+2	8.50	0.13	No
6	Common ground	10.00	0.75	No
6	MP1+2	10.36	0.66	No

Friedman's ANOVA test on the impedance telemetry data of both the basal electrodes indicated that no significant changes were present in CG and MP1+2 modes from the intra-operative measurement to the 12 months follow-up interval as reflected in Table 4.3 above.

In view of the fact that no significant changes were specified by Friedman's ANOVA test, the ad-hoc Wilcoxon signed-rank test was not indicated (Field, 2009:566). It was the intent of the researcher, however, to do a comprehensive analysis of changes between each measurement interval. Based on this reasoning, the Wilcoxon signed-rank test was performed on each measurement interval. Table 4.4 is a summary of the outcomes of this statistical procedure on the impedance telemetry data of the basal electrodes.

Table 4.4 Level of significance for the 5 measurement phases for impedance telemetry on the basal electrodes : Wilcoxon Signed-Rank test

Electrode number	Pair-wise comparison	p-value CG	Significant (*p-value*≤ 0.01)	p-value MP1+2	Significant (*p-value*≤ 0.01)
Electrode 3	Intra-operative to Device activation	0.52	No	0.44	No
	Device activation to 3 month follow-up	0.67	No	0.67	No
	3 to 6 month follow-up	0.33	No	0.33	No
	6 to 9 month follow-up	0.21	No	0.18	No
	9 to 12 month follow-up	0.12	No	0.33	No
Electrode 6	Intra-operative to Device activation	0.11	No	0.09	No
	Device activation to 3 month follow-up	1.00	No	0.89	No
	3 to 6 month follow-up	0.21	No	0.21	No
	6 to 9 month follow-up	0.67	No	0.78	No
	9 to 12 month follow-up	0.40	No	0.67	No

The purpose of the Wilcoxon signed-rank test procedure is to also calculate the significance of changes, but to do it in a pair-wise manner. A *Bonferonni-correction* is also applied by dividing the critical level of significance (0.05) by the amount of measurement pairs, namely 5 for this study, resulting in a new critical level of

significance of 0.01 (Field, 2009:563). The p-value of each measurement pair was weighed against this new level.

According to Table 4.4 no significant changes for either Electrode 3 or 6 were indicated by the Wilcoxon paired-sign test during the longitudinal measurement of impedance telemetry in the CG and MP1+2.

The analysis of the impedance telemetry results collected on the basal electrodes consisted firstly of a description of the data collected on Electrodes 3 and 6. Secondly, the outcome of Friedman's ANOVA and the Wilcoxon signed-pair test was analysed in terms of their significance. In section 4.1.2.4 these results will be discussed in detail.

4.2.1.2 Impedance telemetry results on medial electrodes

In the following subdivision, impedance telemetry data collected on Electrodes 8, 11 and 13 was analysed. A description of the data collected on Electrode 8, 11 and 13 in the CG test mode is represented in Table 4.5, while the MP1+2 test mode data is depicted in Table 4.6.

Table 4.5 Common Ground impedance values measured on medial Electrodes 8, 11 and 13

Electrode number	Sample	Mean (kΩ):	Minimum (kΩ):	Maximum (kΩ):	Standard Deviation (kΩ):
Electrode 8	Intra-Operative	5.86	2.92	10.25	2.41
	Device Activation	7.44	5.70	9.30	1.48
	3 Months follow-up	7.46	5.01	12.54	2.50
	6 Months follow-up	6.84	4.32	10.23	2.04
	9 Months follow-up	6.99	3.94	9.38	2.17
	12 Months follow-up	6.31	3.48	8.71	1.93
Electrode 11	Intra-Operative	5.94	3.12	10.40	2.95
	Device Activation	6.68	4.85	9.50	1.55
	3 Months follow-up	7.05	4.62	13.08	2.59
	6 Months follow-up	6.04	4.21	8.23	1.38
	9 Months follow-up	6.42	3.59	10.91	2.29
	12 Months follow-up	5.91	3.27	8.65	1.88
Electrode 13	Intra-Operative	6.63	3.39	10.70	2.70
	Device Activation	7.43	4.96	9.84	1.46
	3 Months follow-up	7.89	5.74	11.71	2.13
	6 Months follow-up	6.19	3.21	8.58	1.99
	9 Months follow-up	7.14	4.28	10.94	2.23
	12 Months follow-up	6.54	3.50	9.63	2.31

= Lowest impedance value **= Highest impedance value**

Table 4.6 MP1+2 impedance values measured on medial Electrodes 8, 11 and 13

Electrode number	Sample	Mean (kΩ):	Minimum (kΩ):	Maximum (kΩ):	Standard Deviation (kΩ):
Electrode 8	Intra-Operative	6.65	3.94	10.73	2.23
	Device Activation	8.39	6.90	10.27	1.44
	3 Months follow-up	8.46	6.30	13.54	2.48
	6 Months follow-up	7.94	5.60	11.35	1.99
	9 Months follow-up	8.09	5.19	10.44	2.07
	12 Months follow-up	7.47	4.71	9.71	1.84
Electrode 11	Intra-Operative	6.80	3.94	10.95	2.81
	Device Activation	7.69	5.91	10.48	1.50
	3 Months follow-up	8.08	5.59	13.87	2.49
	6 Months follow-up	7.22	5.39	9.52	1.36
	9 Months follow-up	7.55	4.88	11.93	2.20
	12 Months follow-up	7.13	4.64	9.78	1.78
Electrode 13	Intra-Operative	7.52	4.52	11.21	2.51
	Device Activation	8.46	5.77	10.73	1.46
	3 Months follow-up	8.99	7.06	12.66	2.09
	6 Months follow-up	7.70	5.86	10.02	1.65
	9 Months follow-up	8.37	5.57	12.03	2.19
	12 Months follow-up	7.66	4.88	10.73	2.17

= Lowest impedance value **= Highest impedance value**

As reflected in Table 4.5 and Table 4.6, the standard deviation remained stable over time. This is demonstrated by the low levels of fluctuation between the highest and lowest mean values recorded in the CG and MP1+2 test modes. Mean values in the CG mode varied from 5.86 to 7.89 kΩ, while values in the MP1+2 test mode varied between 6.65 and 8.99 kΩ. An analysis of the specific kΩ-values indicated that the lowest impedance values for Electrodes 8 (2.92 kΩ) and 11 (3.12 kΩ) in the CG test mode, and also for Electrodes 8 (3.92 kΩ), 11 (3.92 kΩ) and 13 (4.52 kΩ) in the MP1+2 test mode, were measured during the intra-operative measurement interval. Only Electrode 13 in the CG mode deviated from the other medial electrodes with the lowest kΩ-value (3.21 kΩ) measured in the 6 months post-operative measurement interval. Maximum kΩ-values peaked for all medial electrodes in both test modalities during the 3 months post-operative measurement intervals (see Table 4.5 and Table 4.6 for values highlighted in green).

Friedman's ANOVA test was selected for statistical analysis and used the mean ranks (calculated by the SPSS Output) of Electrode 8, 11 and 13's impedance telemetry data collected in the CG and MP1+2 modes and six different test conditions to determine the level of significance in the changes between them. In the case of significant changes being indicated in the mean ranks between the conditions, post-hoc tests for Friedman's ANOVA are needed to study the level of significance across the measurement conditions. The SPSS Output specifies the test statistic as a p-value.

Table 4.7 supplies an outline of the results of Friedman's ANOVA performed on the dataset of Electrode 8, 11 and 13's impedance telemetry measurements for CG and MP1+2 testing modes.

Table 4.7 Level of significance on impedance telemetry on medial electrodes

Electrode Number	Test Mode	Test Statistic (Chi-squared)	p-value	Significant (*p-value ≤ 0.05*)
8	Common ground	7.22	0.21	No
8	MP1+2	7.71	0.17	No
11	Common ground	4.00	0.55	No
11	MP1+2	4.43	0.49	No
13	Common ground	6.93	0.23	No
13	MP1+2	7.64	0.18	No

Table 4.7 provides the results of Friedman's ANOVA test on the impedance telemetry data of all medial electrodes in both test modalities. The p-value value is compared with a level of significance, which is 5% or 0.05. Significant changes between the measurement conditions are indicated if the Chi-square distribution is greater than the calculated p-value. It is clearly indicated that no significant changes were present in CG and MP1+2 modes from the intra-operative to the 12 months follow-up interval.

Since no significant changes were indicated by the Friedman's ANOVA test, the ad-hoc Wilcoxon signed-rank test was not required. The rationale of the Wilcoxon signed-rank test procedure is to also calculate the significance of changes, but do it in a pair-wise manner. The Friedman's ANOVA is not a pair-wise comparison and in view of the fact that it was the aim of the researcher to do a comprehensive analysis of changes between each measurement interval, thus pair-wise, the Wilcoxon signed-rank test was performed for this specific purpose. Based on this reasoning, the Wilcoxon signed-rank test was performed on the five measurement phases. The *Bonferonni-correction* was also applied, resulting in a new critical level of significance of 0.01 (please see explanation of this in section 3.13. The p-value of each measurement pair was measured against the 0.01 level of significance. An

overview of the outcomes of the Wilcoxon signed-rank test procedure on the impedance telemetry data of the medial electrodes is available in Table 4.8.

Table 4.8 Level of significance for the 5 measurement phases for impedance telemetry on medial electrodes : Wilcoxon Signed-Rank test

Electrode number	Pair-wise comparison	p-value CG	Significant (*p-value*≤ 0.01)	p-value MP1+2	Significant (*p-value*≤ 0.01)
Electrode 8	Intra-operative to Device activation	0.86	No	0.09	No
	Device activation to 3 month follow-up	0.67	No	0.67	No
	3 to 6 month follow-up	0.23	No	0.33	No
	6 to 9 month follow-up	0.78	No	0.83	No
	9 to 12 month follow-up	0.05	No	0.07	No
Electrode 11	Intra-operative to Device activation	0.26	No	0.17	No
	Device activation to 3 month follow-up	0.61	No	0.48	No
	3 to 6 month follow-up	0.09	No	0.12	No
	6 to 9 month follow-up	0.40	No	0.48	No
	9 to 12 month follow-up	0.03	No	0.12	No
Electrode 13	Intra-operative to Device activation	0.77	No	0.59	No
	Device activation to 3 month follow-up	0.67	No	0.58	No
	3 to 6 month follow-up	0.09	No	0.12	No
	6 to 9 month follow-up	0.26	No	0.21	No
	9 to 12 month follow-up	0.04	No	0.11	No

Table 4.8 clearly indicates that no significant changes for Electrodes 8, 11 and 13 were indicated by the Wilcoxon sign-rank test during the longitudinal measurement of impedance telemetry in the CG and MP1+2.

In this subdivision, the impedance telemetry results collected on the medial electrodes (Electrodes 8, 11 and 13) were analysed. A description of the data collected on these electrodes was supplied followed by an analysis of the outcome of Friedman's ANOVA and the Wilcoxon signed-pair test in terms of their significance. The discussion of these results will follow section 4.1.2.4.

4.2.1.3 Impedance telemetry results on apical electrodes

The subsequent subdivision will supply an analysis of the impedance telemetry data collected in the CG and MP1+2 test modes for the apical electrodes. The apical electrodes consisted of Electrodes 16, 19 and 21. A description of the data collected on these electrodes in the CG test mode will be presented in Table 4.9, and for the MP1+2 test mode in Table 4.10.

Table 4.9 Common Ground impedance values measured on apical Electrodes 16, 19 and 21

Electrode number	Sample	Mean (kΩ):	Minimum (kΩ):	Maximum (kΩ):	Standard Deviation (kΩ):
Electrode 16	Intra-Operative	5.63	4.28	10.73	2.79
	Device Activation	7.09	4.75	10.27	2.03
	3 Months follow-up	6.92	5.19	13.54	1.40
	6 Months follow-up	6.20	4.35	11.35	1.04
	9 Months follow-up	6.04	3.37	10.44	1.36
	12 Months follow-up	5.67	3.06	9.71	1.41
Electrode 19	Intra-Operative	5.93	3.19	10.95	1.89
	Device Activation	6.63	4.96	10.48	1.43
	3 Months follow-up	6.41	4.73	13.87	1.51
	6 Months follow-up	5.51	4.33	9.52	1.39
	9 Months follow-up	5.52	3.66	11.93	1.35
	12 Months follow-up	5.44	3.18	9.78	1.54
Electrode 21	Intra-Operative	5.89	3.20	11.21	3.32
	Device Activation	9.17	5.91	10.73	6.34
	3 Months follow-up	9.72	5.43	12.66	6.78
	6 Months follow-up	6.70	4.75	10.02	1.19
	9 Months follow-up	6.18	4.57	12.03	1.25
	12 Months follow-up	5.88	3.95	10.73	1.59

= Lowest impedance value **= Highest impedance value**

Table 4.10 MP1+2 impedance values measured on apical Electrodes 16, 19 and 21

Electrode number	Sample	Mean (kΩ):	Minimum (kΩ):	Maximum (kΩ):	Standard Deviation (kΩ):
Electrode 16	Intra-Operative	6.49	4.48	12.08	2.55
	Device Activation	8.08	5.99	11.33	1.94
	3 Months follow-up	8.04	6.29	9.51	1.16
	6 Months follow-up	7.35	5.50	8.58	1.04
	9 Months follow-up	7.21	4.56	8.75	1.34
	12 Months follow-up	6.89	4.33	8.37	1.42
Electrode 19	Intra-Operative	6.19	4.34	9.41	1.67
	Device Activation	7.55	5.82	9.71	1.42
	3 Months follow-up	7.36	5.76	8.88	1.11
	6 Months follow-up	6.60	5.15	8.96	1.41
	9 Months follow-up	6.23	4.96	8.77	1.28
	12 Months follow-up	6.58	4.62	8.93	1.48
Electrode 21	Intra-Operative	6.54	5.25	10.62	3.34
	Device Activation	10.10	6.71	26.01	6.48
	3 Months follow-up	10.65	6.37	27.29	6.85
	6 Months follow-up	7.78	5.80	9.50	1.27
	9 Months follow-up	7.24	5.57	8.47	1.17
	12 Months follow-up	7.04	5.04	8.96	1.45

= Lowest impedance value

= Highest impedance value

Standard deviation levels, summarised in Tables 4.9 and 4.10, were consistent over the measurement intervals of Electrodes 16 and 19 for CG and MP1+2 test modes. Electrode 21 showed a slight increase in the standard deviation levels during the Device activation and 3 months post-operative measurement intervals, after which they returned to values in line with those measured on Electrodes 16 and 19. This phenomenon is also observed in the mean kΩ-values measured. Mean kΩ-values for Electrode 16 fluctuated between 5.63 and 7.90 kΩ in the CG test mode and then between 6.49 and 8.09 kΩ in the MP1+2 test mode. Electrode 19 showed variation during the CG mode from 5.44 to 6.63 kΩ and in the MP1+2 test mode from 6.19 to 7.75 kΩ. On average, the mean kΩ-values for Electrodes 16 and 19 differed with 1.66 kΩ. Electrode 21 showed greater variation in the mean kΩ-values across the measurement intervals of both test modes. For the CG test mode, the mean kΩ-values fluctuated between 5.88 kΩ and 9.72 kΩ, a difference of 3.84 kΩ. The mean kΩ-values for the MP1+2 test mode fluctuated between 6.54 kΩ and 10.54 kΩ, a difference of 4.11 kΩ. Not only were the differences much greater than the 1.66 kΩ calculated for Electrodes 16 and 19, but the mean kΩ-values were also higher in Electrode 21. The maximum kΩ-values measured for Electrode 21 were 21.67 kΩ (CG mode) and 27.29 kΩ (MP1+2 mode). In comparison to Electrode 21, the maximum values for Electrode 16 were lower: 11.73 kΩ (CG mode) and 12.08 kΩ (MP1+2 mode). Maximum values for Electrode 19 were measured at 9.03 kΩ (CG mode) and at 9.71 kΩ and at 9.71 kΩ (MP1+2 mode), also lower than the maximum values for Electrode 21. The maximum values for Electrodes 16 and 19 for CG and MP1+2 test modes were measured during the intra-operative measurement interval. The maximum values for Electrode 21 were measured in the 3 months post-operative measurement interval. Minimum values across the apical electrodes were constant, although they were not measured in the same measurement intervals.

As mentioned in subdivisions 4.2.1.1 and 4.2.1.2, Friedman's ANOVA test was selected for statistical analysis. The mean ranks of Electrode 16, 19 and 21's impedance telemetry data were collected in two test modes and across six different test conditions to establish the level of significance of the changes between them.

Should significant changes be indicated, the post-hoc Wilcoxon signed-rank test was needed to calculate the level of significance across the measurement intervals. The SPSS Output specifies the test statistic as a p-value. This value is compared with a level of significance which is 5% or 0.05. Significant changes between the measurement conditions are indicated if the calculated p-value is greater than the level of significance. In Table 4.11 an outline of the results of Friedman's ANOVA performed on the dataset of the apical electrodes' impedance telemetry measurements for CG and MP1+2 testing modes is supplied.

Table 4.11 Level of significance on impedance telemetry on apical electrodes

Electrode Number	Test Mode	Test Statistic (Chi-squared)	p-value	Significant (*p-value ≤ 0.05*)
16	Common ground	9.56	0.09	No
16	MP1+2	8.50	0.13	No
19	Common ground	8.42	0.13	No
19	MP1+2	8.79	0.12	No
21	Common ground	7.14	0.21	No
21	MP1+2	5.07	0.41	No

No significant difference in the impedance values of the apical electrodes is indicated over time according to Friedman's ANOVA, as indicated in Table 4.11.

In the absence of significant changes calculated by Friedman's ANOVA, no ad-hoc statistical procedures are indicated. The researcher had particular interest in the changes between each measurement interval. It was thus decided to continue with the Wilcoxon signed-rank test which is a statistical measure to determine the significance of changes over time between pairs of tests – a pair-wise comparison. The Wilcoxon signed-rank test applies a Bonferroni-correction to the level of significance (5% or 0.05) by dividing it by the number of pairs being compared. In this case, 5 test pairs were being used, calculating a new value of significance of 1%

or 0.01 (a detailed description of this procedure appears in section 3.13). Table 4.12 is a summary of the results of the Wilcoxon signed-rank test as performed on impedance telemetry values of the apical electrode.

Table 4.12 Level of significance for the 5 measurement phases for impedance telemetry on the apical electrodes : Wilcoxon Signed-Rank test

Electrode number	Pair-wise comparison	p-value CG	Significant (*p-value*≤ 0.01)	p-value MP1+2	Significant (*p-value*≤ 0.01)
Electrode 16	Intra-operative to Device activation	0.26	No	0.14	No
	Device activation to 3 month follow-up	0.67	No	0.89	No
	3 to 6 month follow-up	0.09	No	0.07	No
	6 to 9 month follow-up	0.58	No	0.57	No
	9 to 12 month follow-up	0.03	No	0.09	No
Electrode 19	Intra-operative to Device activation	0.07	No	0.05	No
	Device activation to 3 month follow-up	0.58	No	0.58	No
	3 to 6 month follow-up	0.12	No	0.16	No
	6 to 9 month follow-up	0.48	No	0.58	No
	9 to 12 month follow-up	0.48	No	0.58	No
Electrode 21	Intra-operative to Device activation	0.59	No	0.44	No
	Device activation to 3 month follow-up	0.33	No	0.33	No
	3 to 6 month follow-up	0.12	No	0.16	No
	6 to 9 month follow-up	0.21	No	0.21	No
	9 to 12 month follow-up	0.16	No	0.48	No

Analysis of Table 4.12 indicated that no significant changes were present over time when comparing the impedance telemetry values for the measurement phases, in the CG and MP1+2 test modes.

The analysis of the impedance telemetry data measured on the apical electrodes consisted firstly of a description of the data collected on electrodes 16, 19 and 21. Secondly, the outcomes of Friedman's ANOVA and the Wilcoxon signed-pair test were explained in terms of their significance. In section 4.1.2.4 these results will be discussed in detail in relation to the results of the medial and apical electrodes.

4.2.1.4 Discussion of impedance telemetry results on basal, medial and apical electrodes

The results presented in sections 4.2.1.1 to 4.2.1.3 will now be discussed according to the first sub-aim of this study, namely to describe the changes in impedance telemetry measurements from intra-operative up to twelve months post implantation.

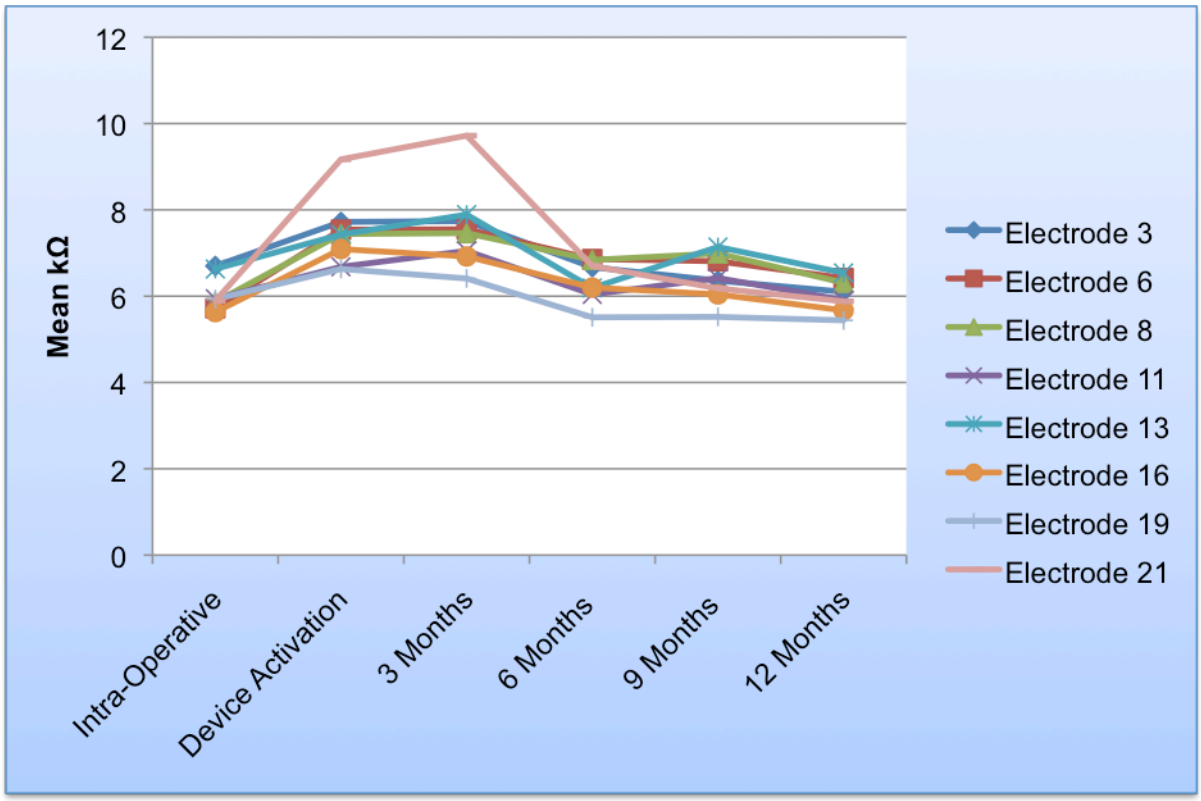

Figure 4.2 Graphical representations of the mean impedance values (CG) measured on the selected basal, medial and apical electrodes.

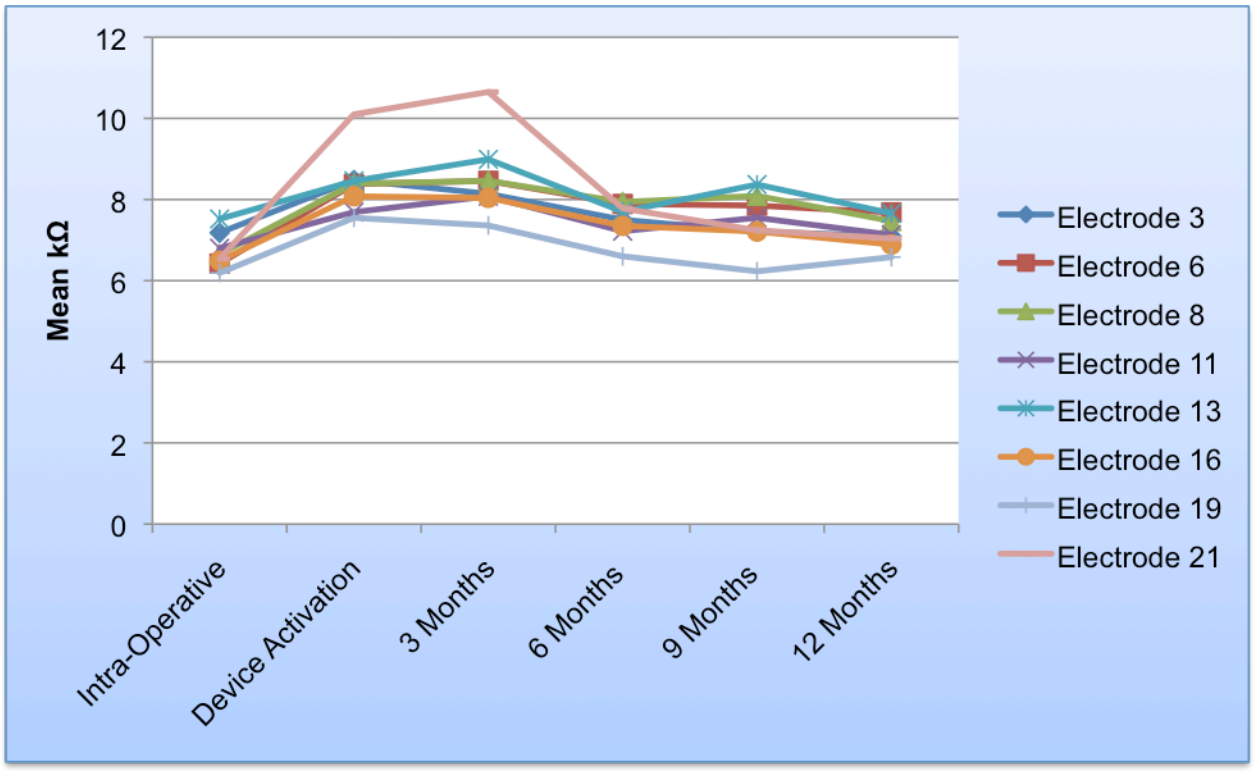

Figure 4.3 Graphical representations of the mean impedance values (MP1+2) measured on the selected basal, medial and apical electrodes.

Figures 4.2 and 4.3 show a similar graph configuration for the majority of the electrodes. Only electrode 21 deviated from the norm. Also to be observed in Figure 4.1 is that the majority of the mean kΩ- values were roughly distributed between 6 and 8 kΩ. Values are thus consistent across the electrode array and remain consistent over time. It was also observed that the electrodes showed similar characteristics across the electrode array and also over time. The only exception to this statement was observed on electrode 21. Mean kΩ- values were higher than those of the surrounding electrodes. This is also reflected in Tables 4.1, 4.5 and 4.9. Visual inspection of the graphical comparisons shows a gradual increase in impedance values between the intra-operative up to the 3 months follow-up measurement intervals. From the 6 months follow-up interval, impedance levels decrease slightly and remained consistent over time, but these changes were not significant as calculated by the inferential statistical procedures. Again, Electrode 21 demonstrated a greater fluctuation in mean kΩ- values at the device activation

measurement interval up to the 3 months follow-up measurement interval. Mean kΩ-values returned to levels comparable with the other selected electrodes across the electrode array over the long term.

Impedance telemetry provides information concerning the electrode integrity from implantation and over the long term. Information such as the prevalence of open and short circuits is provided, but an essential indication of the electrode-tissue interface is also reflected by the impedance telemetry (Van Wermeskerken *et al*., 2006:537). An additional advantage of impedance telemetry is that it indicates the level of use by the cochlear implant user, i.e. whether or not the electrode array was stimulated or not. Initial changes in impedance telemetry, before electrical stimulation, may be expected due to the morphological changes at the electrode-tissue interface (Hughes *et a*l., 2001: 480). Kawano *et al.* (1998: 313) and Li, Parkins and Webster, (1999:27) reported that the electrode array becomes encapsulated in fibrous tissue after implantation. An increase in bone growth was also observed near the electrode array within the scala tympani in implanted guinea pigs even in the absence of electrical stimulation (Van Wermeskerken *et al*., 2006:537).

In the current study, a slight increase was observed between the intra-operative and device activation measurements of the mean impedance values of all the selected electrodes. It is of primary importance for clinicians to know what impedance can routinely be expected. Determining these values, like in the present investigation, may aid in determining what can be seen as typical trends and when values should be regarded as a-typical. In such cases, integrity tests or magnetic imaging can be conducted to investigate possible device failures.

As discussed, this phenomenon of a slight increase in the mean impedance values may be attributed to the morphological changes at the electrode-tissue interface caused by new bone growth around the electrode and the formation of fibrous tissue in the scala tympani (Van Wermeskerken *et al*., 2006:537). An initial increase in impedance values between the intra-operative and the device activation

measurement intervals was also reported by Hughes *et al*. (2001: 472) in a comparable study on the Nucleus 24M electrode array in adult cochlear implant users. They reported an increase in impedance levels from the first week post-implantation up to two months post-implantation, after which the levels decreased (Hughes *et al*., 2001: 472). The impedance values then remained consistent from two months post-implantation up to two years post-implantation (Hughes *et al*., 2001: 471). This was confirmed by the research performed by Van Wermeskerken *et al*. (2006:543) on adult users. They also observed an initial increase in impedance values up to one month after the initial stimulation. A decrease in impedance values was then observed, followed by stable values up to two years post-implantation (Van Wermeskerken *et al*., 2006:543). A study performed by Henkin *et al*. (2003:873), also on the Nucleus 24M electrode array, focused on electrophysiological measurements in children. They observed a significant decrease in impedance values one month after device activation. After this period impedance values increased gradually, but these changes were not statistically significant (Henkin *et al*., 2003:876). According to their report, impedance values stabilized after one month (Henkin *et al*., 2003:877).

Previous research on adult cochlear implant users illustrated a decrease in impedance values about one month after initial stimulation (Hughes *et al*., 2001: 471; Van Wermeskerken *et al*., 2006:543). In the current study on the Nucleus Freedom Contour Advance array, the minor increases in impedance values were followed by a slight decrease in mean impedance values from the 3 months follow-up measurement interval, but yet again the nature of the changes were not statistically significant. These findings correlate with the outcomes of the studies by Hughes *et al.* (2001:471) and Van Wermeskerken *et al.* (2006:543). Agreement between the results of the present study and that of Henkin *et al*. (2003:877) was observed in the stability of impedance values after one to three months post device activation in children. The outcomes of the present study, as well as those of past research, indicated the prevalence of changes in impedance telemetry after initial stimulation

for periods up to six months. It is thus clear that long term electrical stimulation also affects impedance values.

The long term effect of electrical stimulation of the cochlea has been a much researched topic since the 1970's. Issues regarding safety and the regeneration of spiral ganglion cells have been studied widely (Kawano *et al*., 1998:313; Li *et al*., 1999:28; Tykocinski *et al.,* 2001:54). One communal finding of these studies was the intra-cochlear changes that were observed following electrical stimulation. The study by Kawano *et al.* (1998:314) attributed the changes found in electrical impedances after initial stimulation to the following factors: the volume of Rosenthal's canal, the density of fibrous tissue, new bone growth, and the density of residual spiral ganglion cells. Since impedance telemetry is a reflection of the electrode-tissue interface, they concluded that osteoneogenesis and the formation of fibrous tissue around the electrode array were two of the major implications of long term electrical stimulation, directly influencing the electrical impedance values (Kawano *et al*., 1998:324).

The effect of electrical stimulation on the electrode-tissue interface was also researched from another angle. A different stream of researchers attributed the decrease in impedance values after electrical stimulation to the formation of a hydride layer across the surface of the electrode array. This occurrence was demonstrated by Pfingst (1990:225), who studied the effect of long term electrical stimulation on electrical impedance in adult macaques. Later on, this was also demonstrated in implanted kittens (Ni, Shepard, Seldon, Xu & Clark, 1992: 63). These researchers attributed the decrease of impedance values after a period of electrical stimulation, i.e. a few months post device activation, to the formation of a hydride layer on the surface of the electrodes. This layer forms bumps and grooves on the surface of the electrodes, which increases the surface area of the electrode array, causing the reduction in the impedance values (Henkin *et al*., 2003: 877; Hughes *et al*., 2001:480; Ni *et al*., 1992:63; Van Wermeskerken *et al*., 2006:544).

The minor decrease in impedance values in the study in hand, as well as in the studies of Hughes *et al*. (2001:471) and Van Wermeskerken *et al*. (2006:543), may thus be attributed to the formation of a hydride layer across the surface of the electrode array due to electrical stimulation. The only noteworthy difference between the current study and the similar studies of Hughes *et al*. (2001:471) and Van Wermeskerken *et al*. (2006:543) is that no statistically significant changes in measurements were observed in the current study on the Nucleus Freedom Contour Advance electrode array.

In this study, as well as the research performed by Hughes *et al*. (2001:480) and Henkin *et al.* (2003:877), a decrease in impedance values were observed after one to three months post device activation. Van Wermeskerken *et al*. (2006: 538) compared changes in impedance telemetry over the long term between the Nucleus 24M (straight array) and the Nucleus Contour array. They illustrated that the changes in impedance values were greater on the straight electrode array than on the contour array (Van Wermeskerken *et al*., 2006: 538). The Nucleus Freedom Contour Advance array was used for this study and although changes were reported over time, these changes were not as significant in nature as those in previous studies involving the predecessor of the Freedom implant. The technical design of this implant, which is thinner than the Nucleus 24 Contour array, might be a reason for the non-significant changes reported in this study.

The even spread of impedance values over time in this study was also confirmed by the inferential statistical procedures performed on the data sets of Electrodes 3, 6, 8, 11, 13, 16, 19 and 21. Friedman's ANOVA test indicted no significant level of change over time (see Tables 4.3, 4.7, and 4.11). Although not indicated, the researcher analyzed the results further by applying the Wilcoxon signed-pair rank test to the different measurement phases to determine if significant levels of change were present between them. Tables 4.4, 4.8, and 4.12 indicated that no significant levels of change were present between the measurement phases.

Past research not only provided evidence that there was a significant difference in the overall impedance values at specific time intervals, but they also observed differences in the degree of change in impedance values with electrode number, thus from basal to apical (Hughes *et al*., 2001:482). Impedance levels were reported to be higher overall and changes more significant in the apical electrodes. The researchers attributed this difference between the two electrode arrays to the physical design specifications (Van Wermeskerken *et al*., 2006:541). The Nucleus 24M electrode array has a surface area of 0.58mm² basally and then reduces to 0.38mm² apically. On the other hand, the surface area of the Nucleus Contour array changes very little with a surface area of 0.31mm² basally and 0.28mm² apically. The design specifications of the Nucleus Freedom Contour Advance array are alike to the Nucleus Contour array used in Van Wermeskerken *et al*.'s (2006) study. Although changes were observed in impedance telemetry levels in the current study, the mean impedance values of the basal versus the medial versus the apical electrodes are consistent, as illustrated in Figures 4.1 and 4.2. This occurrence might be attributed to the physical design of the Nucleus Freedom Contour Advance array, as illustrated by Van Wermeskerken *et al*. (2006:541) in their study on the Nucleus 24 contour array.

In this subsection, the impedance telemetry results of the basal, medial, and apical electrodes were discussed in terms of recent findings and literature on studies similar to this study. The findings in this study revealed a slight, statistically non-significant increase in impedance telemetry from the intra-operative to device activation measurement interval up to the 3 months follow-up measurement interval. Impedance telemetry decreased minimally from the 6 months follow-up measurement interval and remained consistent afterward. These results correlate with previous research involving the predecessors of the Nucleus Freedom Contour array. Impedance results on the Nucleus 24M and contour arrays also showed an initial increase in impedance values up to 3 months post-implantation. Impedance values remained consistent over time for up to two years thereafter. The only difference between the study in hand and past research is that their changes over

time were significant, while changes in the current study showed no significance. Changes in impedance telemetry values were most probably attributable to the formation of a hydride layer across the electrode array after the first electrical stimulation as well as to bone and tissue growth. The electrode surface areas of the different electrode arrays seem to have affected the impedance values.

4.2.2 Summary of results and discussion for sub-aim#1

A summary of the results and discussion for sub-aim #1 is provided in Table 4.13.

TABLE 4.13 Summary of results and discussion for sub-aim #1

• Impedance values were consistent across electrode array and over time.
• A gradual increase in impedance values, but not statistical significant increase, was observed from the intra-operative up to the 3 months follow-up measurement intervals.
• From the 6 months follow-up interval, impedance values decreased slightly and remained consistent over time. Changes were not significant.
The results documented for this study corresponded with previous research on predecessors of the Nucleus Freedom Contour array. The slight changes in impedance values were ascribed to the development of a hydride layer across the electrode array after initial electrical stimulation as well as to bone and tissue growth.

4.3 RESULTS AND DISCUSSION OF SUB-AIM #2: NEURAL RESPONSE TELEMETRY – INTRA-OPERATIVELY AND TWELVE MONTHS POST-OPERATIVELY

The second sub-aim of the study was to describe the changes in Neural Response Telemetry measured intra-operatively and up to twelve months post-operatively in young children. Data collected with the specified software and noted on the Neural Response Telemetry recording sheet (Appendix F) was recorded and analysed. NRT™- data for all electrodes was obtained from eight respondents for all measurement intervals. Respondent 5 failed to complete the study due to rescheduling of follow-up appointments and results were excluded from statistical computations.

Descriptive and inferential statistical procedures were performed on the following electrodes along the electrode array: Electrodes 3, 6, 8, 11, 13, 16, 19 and 21. The selected electrodes cover the complete electrode array, with basal (Electrodes 22, 19 and 16), medial (Electrodes 13, 11 and 8), and apical Electrodes (6 and 3) in the sample (Henkin *et al*., 2003:875). Friedman's ANOVA test was performed on the SPSS data sets of all the selected electrodes in order to determine whether or not significant changes in the NRT-threshold levels were indicated over time. Wilcoxon paired- sign tests were used ad-hoc to follow up on the findings of Friedman's ANOVA test.

This section will be divided into two sub-sections. The first sub-section will analyse the NRT™-results according to apical, medial and basal electrodes. The second sub-section will be a discussion of the NRT™- results on all electrodes.

4.3.1 Results of Neural Response Telemetry (NRT™) measurements

In the current sub-section NRT™-data collected on Electrodes 3, 6, 8, 11, 13, 16, 19 and 22 will be presented and analysed.

4.3.1.1 NRT™ results collected on basal electrodes

This section will focus on the presentation of the data sets obtained during the six measurement intervals for NRT™ measurements for Electrodes 3 and 6. The following data sets, comprising of the mean current levels (CL)-values of each measurement interval, were compared: Intra-Operative measurements versus Device Activation, Device activation vs. 3 months follow-up, 3 months follow-up vs. 6 months follow-up, 6 months follow-up versus 9 months follow-up, and finally 9 months versus 12 months follow-up. Table 4.14 is a description of the data set collected on Electrodes 3 and 6.

Table 4.14 NRT™ measurements on basal electrodes

Electrode Number	Sample	Mean (CL):	Minimum (CL):	Maximum (CL):	Standard Deviation (CL):
Electrode 3	Intra-Operative	168.75	142	211	21.37
	Device Activation	158.37	137	197	21.88
	3 Months follow-up	157.63	135	200	23,54
	6 Months follow-up	161.25	135	197	23,63
	9 Months follow-up	163.88	137	200	23,89
	12 Months follow-up	169.75	137	195	22,74
Electrode 6	Intra-Operative	165.00	133	186	16.45
	Device Activation	158.63	139	182	15.54
	3 Months follow-up	158.50	138	176	12.84
	6 Months follow-up	162.38	146	180	11.12
	9 Months follow-up	162.75	138	185	14.35
	12 Months follow-up	167.63	150	186	11.67

= Lowest NRT-threshold level measured

= Highest NRT-threshold level measured

Table 4.14 clearly reveals that the standard deviation was constant across the different data sets for Electrodes 3 and 6. The standard deviation is a standard measure of variability between datasets (Leedy & Ormrod, 2000:262).

When considering data collected on Electrode 3, as represented in Table 4.14, it is clear that the mean Current Level (CL) for Electrode 3 varied between 168.75 CL and 157.63 CL, a difference of 11.21 CL. The maximum CL measured for Electrode 3 across time was 211 CL (measured in the intra-operative phase), while the lowest NRT-threshold level was 135 CL (measured in both the 3 and 6 months follow-up phases).

Also represented in Table 4.14 is the data collected for Electrode 6. Its mean Current Level fluctuates between 167.63 CL and 158.50 CL. A difference of 9.13 CL exists between the highest and lowest NRT-threshold levels. During the Intra-operative and the 12 month follow-up phases, the highest NRT-threshold level of 186CL was measured over time. 133 CL was the lowest NRT-threshold level measured for Electrode 6 over time, also in the Intra-operative phase.

Friedman's ANOVA test was selected for the purpose of statistical analysis. It was performed on the mean ranks (calculated by the SPSS Output) of Electrodes 3 and 6's NRT™ measurement conditions to establish the level of significance in the changes in the NRT-threshold measurements over time. Once it was established that significant changes in the mean ranks between the conditions were evident, post-hoc tests for Friedman's ANOVA were performed to investigate the level of significance between each condition. The SPSS Output indicated the test statistic as a Chi-Square distribution, which in turn was used to determine a p-value for each electrode. To evaluate the effects of the data over time, this p-value was compared to the level of significance which is 5% or 0.05 (Field, 2009: 563). Should the significance value be greater than the p-value, it was indicated that significant changes over time had been measured. Table 4.15 is a summary of the results of

Friedman's ANOVA performed on the dataset of Electrode 3 and 6's NRT-threshold measurements.

Table 4.15 Level of significance of NRT™ measurements based on Friedman's ANOVA

Electrode Number	Test Statistic (Chi-squared)	p-value	Significant (*p-value ≤ 0.05*)
3	15.39	0.01	Yes
6	12.18	0.03	Yes

It is evident from Table 4.15 that the NRT™- measurements performed on Electrodes 3 and 6 did show significant changes over time. Due to the presence of significant changes, ad-hoc testing was indicated. For this purpose, the Wilcoxon signed-rank test was applied on the NRT™-data of the basal electrodes. The extent of the change between the five measurement phases was determined by performing the Wilcoxon signed-rank test. This test determines whether two samples with ordinal data differ from each other when a relationship exists between the samples (Leedy & Ormrod, 2000:274). A *Bonferonni-correction* is applied in this test by dividing the critical level of significance (0.05) by the number of measurement pairs, namely 5 for this study, consequential to a new critical level of significance of 0.01. The p-value of each measurement pair was evaluated against the 0.01 (Field, 2009: 563). Table 4.16 is a summary of the outcomes of this statistical procedure on the Neural Response Telemetry data of the basal electrodes.

Table 4.16 Level of significance for the 5 measurement phases: Wilcoxon Signed Rank test

Electrode number	Pair-wise comparison	p-value	Significant (*p-value*≤ 0.01)
Electrode 3	Intra-operative to Device activation	0.01	Yes
	Device activation to 3 month follow-up	0.79	No
	3 to 6 month follow-up	0.93	No
	6 to 9 month follow-up	0.16	No
	9 to 12 month follow-up	0.13	No
Electrode 6	Intra-operative to Device activation	0.04	No
	Device activation to 3 month follow-up	0.75	No
	3 to 6 month follow-up	0.12	No
	6 to 9 month follow-up	0.87	No
	9 to 12 month follow-up	0.18	No

According to Table 4.16, the only significant change in NRT-threshold levels was measured during the intra-operative to device activation measurement phase on Electrode 3. No other significant changes were indicated for Electrode 3 or 6.

In this subdivision, the NRT™ results collected on the basal electrodes (Electrodes 3 and 6) were analysed. A description of the data was supplied followed by an analysis of the outcome of Friedman's ANOVA and the Wilcoxon signed-rank test in terms of the significance in changes in NRT™-values across the measurement phases. The discussion of these results will follow in section 4.3.1.4.

4.3.1.2 NRT™ results collected on the medial electrodes

The following sub-section will present an analysis of the NRT™-measurement results of the medial Electrodes 8, 11 and 13 (Henkin *et al*., 2003:875).

NRT™-measurements were performed at six intervals on Electrodes 8, 11 and 13 in order to achieve the second sub-aim of this study. NRT™-measurements was

performed at implantation, device activation approximately four weeks post-implantation, and then at the 3, 6, 9 and 12 months follow-up sessions. The measurements were performed on eight children implanted by the Pretoria Cochlear Implant Programme. Table 4.17 is a summary of the data obtained on the electrodes specified above.

Table 4.17 NRT™ data obtained on medial electrodes

Electrode Number	Sample	Mean (CL):	Minimum (CL):	Maximum (CL):	Standard Deviation (CL):
Electrode 8	Intra-Operative	169.13	110	191	25.45
	Device Activation	160.88	113	185	21.66
	3 Months follow-up	162.13	116	187	21.56
	6 Months follow-up	164.75	115	186	22.68
	9 Months follow-up	168.88	140	186	20.02
	12 Months follow-up	171.38	137	192	20.62
Electrode 11	Intra-Operative	176.25	119	200	25.02
	Device Activation	165.38	116	187	22.54
	3 Months follow-up	161.88	101	182	26.60
	6 Months follow-up	168.13	134	191	20.73
	9 Months follow-up	175.75	158	194	22.89
	12 Months follow-up	177.00	149	196	20.57
Electrode 13	Intra-Operative	176.13	147	197	16.41
	Device Activation	161.50	125	193	24.72
	3 Months follow-up	146.38	0	188	62.35
	6 Months follow-up	165.25	128	195	26.39
	9 Months follow-up	165.88	110	194	27.99
	12 Months follow-up	173.88	131	198	23.62

= Lowest NRT-threshold level measured

= Highest NRT-threshold level measured

Table 4.17 clearly indicates that the standard deviation for Electrodes 8 and 11 remained consistent over time. Some variation was seen on Electrode 13 over time due to the fact that no NRT-threshold could be measured on this electrode during the 3 months follow-up interval for respondent 4. This had a significant impact on the mean NRT-threshold levels measured for this interval, on which the calculation of the standard deviation is based.

Electrode 8 showed a variation of 9.13 CL between the highest and lowest mean NRT-threshold levels. The lowest NRT-threshold level measured for Electrode 8 was 133 CL, while the highest level was 186 CL, both measured in the intra-operative phase. Mean NRT-threshold levels for Electrode 11 showed a variation of 10.5 CL. NRT-threshold levels for Electrode 9 fluctuated from 110CL (in the intra-operative phase) to 192 CL (at the 12 months follow-up phase). Due to the no-response measured on Electrode 13 during the 3 months follow-up interval, the mean levels and specifically the lowest NRT-threshold level differ significantly from the data of the other two Electrodes. The mean vlevels varied with 29.75 CL, in comparison with the 9.13 CL and 10.5 CL differences of Electrodes 8 and 11. The highest NRT-threshold level corresponds well with the other two medial electrodes, with a level of 198 CL.

Friedman's ANOVA and the ad-hoc Wilcoxon signed-pair test were also applied to the data sets of the medial electrodes to determine whether or not significant differences in the NRT™ measurements were present over time. Friedman's ANOVA uses a p-value of 5% or 0.05 as its level of significance. Should the calculated p-value be greater than the level of significance, it is indicated that significant changes over time were measured (Field, 2009:563). Table 4.18 is an outline of the results of Friedman's ANOVA performed on the data set of Electrode 8, 11 and 13's NRT™ measurements.

Table 4.18 Level of significance of NRT™ measurements based on Friedman's ANOVA for medial electrodes

Electrode Number	Test Statistic (Chi-squared)	p-value	Significant (*p-value ≤ 0.05*)
8	17.86	0.003	Yes
11	17.18	0.004	Yes
13	17.68	0.003	Yes

It is clear from Table 4.18 that significant differences in the NRT-threshold levels were measured over time for all the medial electrodes. Since Friedman's ANOVA highlighted significant changes between the NRT-threshold levels over time, the ad-hoc Wilcoxon signed- rank test was indicated. The Wilcoxon signed-rank test uses a *Bonferroni correction* in order to determine the critical value of significance (see section 3.13 for an in-depth explanation). The critical value of significance calculated for this study is 0.01 against which the p-values of the different time intervals were weighed. Table 4.19 is a summary of the *p-values* for each of the 5 measurement phases and their comparison to the level of significance for the three medial electrodes.

Table 4.19 Level of significance for the 5 measurement phases for NRT™ measurements on medial electrodes: Wilcoxon Signed-Rank test

Electrode number	Pair-wise comparison	p-value	Significant (*p-value*≤ 0.01)
Electrode 8	Intra-operative to Device activation	0.01	Yes
	Device activation to 3 month follow-up	0.36	No
	3 to 6 month follow-up	0.94	No
	6 to 9 month follow-up	0.36	No
	9 to 12 month follow-up	0.26	No
Electrode 11	Intra-operative to Device activation	0.01	Yes
	Device activation to 3 month follow-up	0.04	No
	3 to 6 month follow-up	0.29	No
	6 to 9 month follow-up	0.12	No
	9 to 12 month follow-up	0.75	No
Electrode 13	Intra-operative to Device activation	0.01	Yes
	Device activation to 3 month follow-up	0.89	No
	3 to 6 month follow-up	0.21	No
	6 to 9 month follow-up	0.78	No
	9 to 12 month follow-up	0.03	No

The Wilcoxon signed-rank test did highlight some significant changes as illustrated in Table 4.19. All the medial electrodes had significant changes in the measured NRT-threshold levels in the intra-operative to device activation measurement phase.

In this subdivision, the NRT™ results collected on the medial electrodes (Electrodes 8, 11 and 13) were analysed. An account of the data collected was supplied. This was followed by an investigation of the outcome of Friedman's ANOVA and the Wilcoxon signed-rank test in terms of the significance in changes in NRT™-levels

across the measurement phases. The discussion of these results will follow in section 4.3.1.4.

4.3.1.3 NRT™ results collected on apical electrodes

This subdivision will comprise of a report of the NRT™-measurement results of the apical electrodes. The apical electrodes that were used in this study were Electrodes 16, 19 and 21. NRT™-measurements on the apical electrodes were performed at implantation, device activation, and then up to 12 months afterwards on eight participants. The data collected during the field study on the basal electrodes is summarised in Table 4.20.

Table 4.20 NRT™ results of the apical electrodes

Electrode Number	Sample	Mean (CL):	Minimum (CL):	Maximum (CL):	Standard Deviation (CL):
Electrode 16	Intra-Operative	174.13	139	198	18.62
	Device Activation	161.13	116	187	25.82
	3 Months follow-up	161.00	119	185	24.81
	6 Months follow-up	162.75	104	187	30.56
	9 Months follow-up	170.00	115	188	24.39
	12 Months follow-up	172.13	119	194	23.34
Electrode 19	Intra-Operative	168.38	130	188	21.60
	Device Activation	159.25	116	182	22.39
	3 Months follow-up	159.13	114	179	24.15
	6 Months follow-up	160.75	116	188	26.94
	9 Months follow-up	168.13	127	194	20.56
	12 Months follow-up	169.63	134	192	18.56
Electrode 21	Intra-Operative	167.88	140	187	15.49
	Device Activation	159.50	128	181	17.45
	3 Months follow-up	159.13	134	182	20.14
	6 Months follow-up	157.50	133	181	20.67
	9 Months follow-up	165.13	140	189	19.82
	12 Months follow-up	171.75	146	191	20.00

= Lowest NRT-threshold level measured

= Highest NRT-threshold level measured

As indicated by Table 4.20, the standard deviation for the apical electrodes remained consistent over time. This is indicative of mean NRT-threshold levels that remained consistent over the time period of the study. The mean NRT-threshold levels fluctuated minimally, with the divergence between the highest and lowest mean NRT-threshold levels of Electrode 16, 19 and 21 correspondingly at 13.13 CL, 10.5 CL and 14.25 CL. On Electrode 16, the lowest NRT-threshold level was measured at the 6 months measurement interval with a level of 104 CL, whereas the maximum CL was measured at 198 CL during the intra-operative interval. Similarly, for Electrode 19, the minimum NRT-threshold level (114 CL) was measured during the 3 months follow-up interval and the maximum level (194 CL) measured at the 9 months follow-up interval. On the other hand, NRT™-measurements on Electrode 21 oscillated between a maximum NRT-threshold level of 191 CL (12 months follow-up) and a minimum level of 128 CL (device activation). Although NRT-threshold levels among the electrodes are similar, no similarities between the measurement intervals are indicated.

Friedman's ANOVA and the ad-hoc Wilcoxon signed-pair test were selected as inferential statistical procedures to be applied to the data sets of the apical electrodes. The aim of the inferential statistical procedures was to determine whether or not significant differences in the NRT™-measurements were present over time. Friedman's ANOVA uses a value of 5% or 0.05 as its level of significance. Should the calculated significance value be equal or smaller than the p-value, it is indicated that significant changes over time have been measured (Field, 2009:563). Table 4.21 is a summary of the results of Friedman's ANOVA performed on the data set of Electrode 16, 19 and 22's NRT™ measurements.

Table 4.21 Level of significance of NRT™ measurements based on Friedman's ANOVA for apical electrodes

Electrode Number	Test Statistic (Chi-squared)	p-value	Significant (*p-value* ≤ *0.05*)
16	17.68	0.003	Yes
19	11.22	0.047	Yes
22	16.49	0.006	Yes

Table 4.21 demonstrates that according to Friedman's ANOVA, significant changes were present on all the apical electrodes. Indication of significant changes by Friedman's ANOVA implies the application of ad-hoc statistical procedures. The procedure selected for this study was the Wilcoxon sign-rank test. The Wilcoxon paired sign test uses a *Bonferroni correction* in order to determine the critical value of significance. For this study the critical value of significance was calculated as 0.01 and then compared to the p-values of the different time intervals. A summary of these results is supplied in Table 4.22.

Table 4.22 Level of significance for the 5 measurement phases for NRT™ measurements on the apical electrodes: Wilcoxon Signed-Rank test

Electrode number	Pair-wise comparison	p-value	Significant (*p-value*≤ 0.01)
Electrode 16	Intra-operative to Device activation	0.01	Yes
	Device activation to 3 month follow-up	0.79	No
	3 to 6 month follow-up	0.93	No
	6 to 9 month follow-up	0.16	No
	9 to 12 month follow-up	0.13	No
Electrode 19	Intra-operative to Device activation	0.01	Yes
	Device activation to 3 month follow-up	0.93	No
	3 to 6 month follow-up	0.58	No
	6 to 9 month follow-up	0.12	No
	9 to 12 month follow-up	0.46	No
Electrode 21	Intra-operative to Device activation	0.01	Yes
	Device activation to 3 month follow-up	0.36	No
	3 to 6 month follow-up	0.94	No
	6 to 9 month follow-up	0.36	No
	9 to 12 month follow-up	0.26	No

Table 4.22 is a summary of the *p-values* for each of the 5 measurement phases and their comparison to the level of significance for the three apical electrodes. The results indicate that statistically significant changes were present on all three apical electrodes at the Intra-operative to device activation interval. No further significant changes were indicated across the time period for all the apical electrodes.

The analysis of the NRT data measured NRT™-data collected on the apical electrodes consisted firstly of a description of the data collected on electrodes 16, 19 and 21. Secondly, the results of Friedman's ANOVA and the Wilcoxon signed-rank test were presented in terms of their significance. In section 4.3.1.4 these results will be discussed in detail in relation to the results of the medial and apical electrodes.

4.3.1.4 Discussion of NRT™ results on basal, medial, and apical electrodes

The results presented in sections 4.3.1.1 to 4.3.1.3 will now be discussed according to the second sub-aim of this study, that is, to describe the changes in neural response telemetry measurements from intra-operative up to twelve months post-implantation in a group of young children.

At the outset, the analytic sub-sections examined the diversity in the mean CL-levels measured on the selected electrodes across time. The stable standard deviation levels are indicative of very little change over the different measurement intervals. One exception was the fluctuation in the standard deviation of Electrode 13, which was due to the fact that no responses could be measured in the 3 months follow-up measurement interval of one of the respondents. Figure 4.4 is a graphical comparison of the mean CL, on which the standard deviations were based, measured over time.

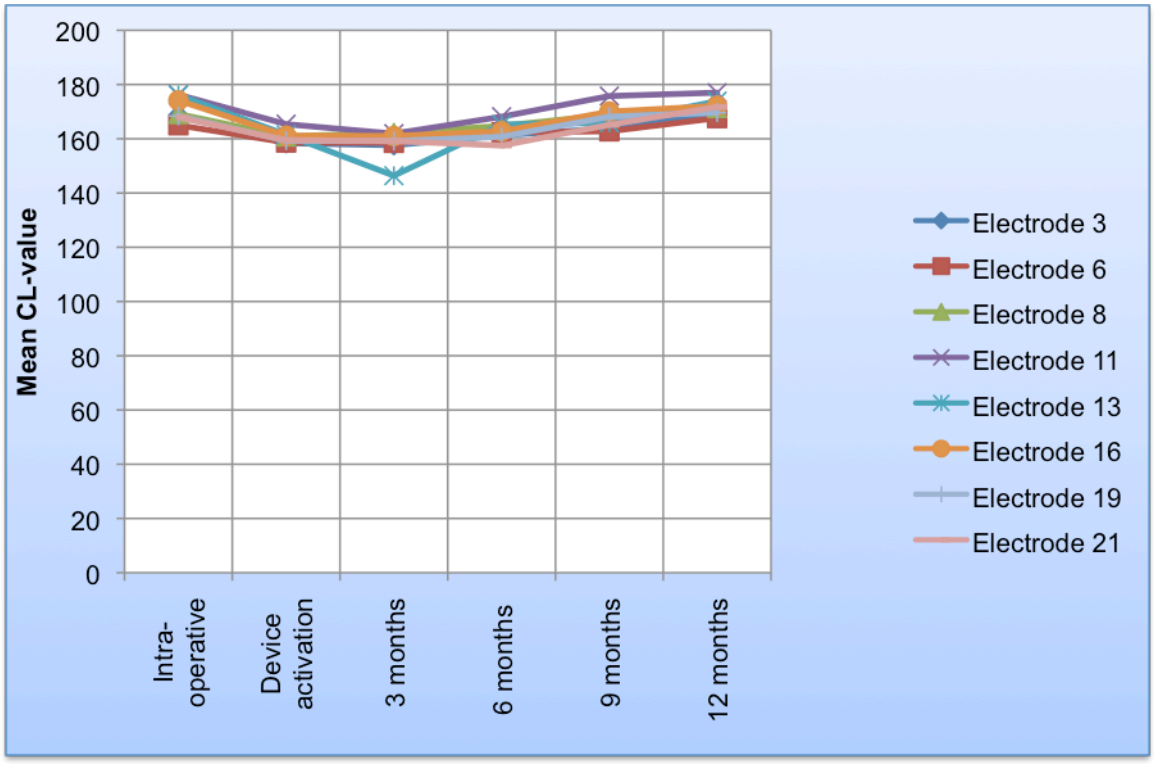

Figure 4.4 Comparison of NRT™ measurements over time

Visual inspection of Figure 4.4 reveals that the majority of the electrodes follow the same configuration over time. The only electrode deviating from the rest is Electrode 13 with a much greater decrease in NRT-threshold levels, but that can be attributed to a decrease in the mean CL due to the no-response measured during the 3 months follow-up measurement of one of the respondents. Following the configuration, it is clear that all the electrodes showed a decrease in mean CL between the intra-operative and device activation measurement intervals. The NRT™-measurements remained stable for another three months up to the 6 months follow-up measurement interval, after which a slight increase in mean NRT-threshold levels can be observed.

This visual observation was confirmed by the differential statistical procedures selected and performed. Friedman's ANOVA calculations applied the mean CL across all the measurement intervals (for all electrodes) to determine the significance of changes across the measurements. Significant changes were present in all basal, medial, and apical electrodes. The presence of significant changes highlighted by Friedman's ANOVA called for the application of the ad-hoc Wilcoxon signed-rank test, which is a pair-wise comparison over time to determine whether or not significant changes are present between two similar test measurements. The following figure is a representation of the results obtained.

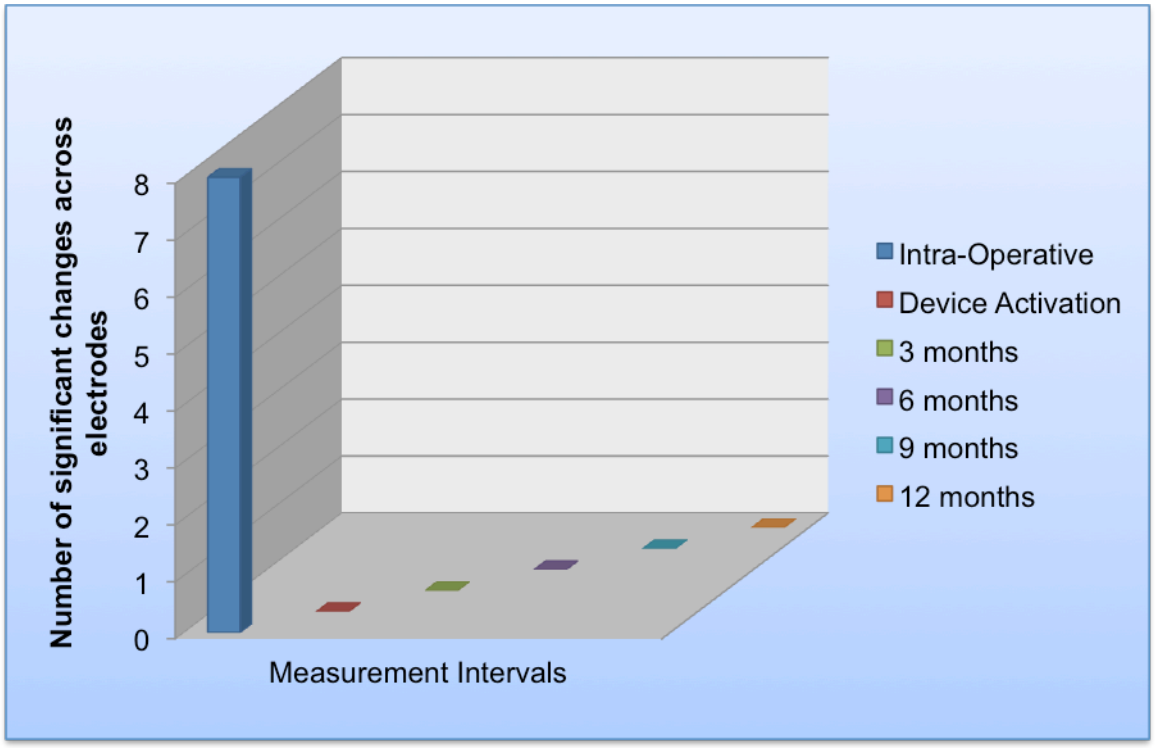

Figure 4.5 Comparisons of significant changes present over time across all electrodes

Figure 4.5 clearly illustrates that there was a significant change in NRT-threshold levels from the intra-operative to the device activation measurement intervals. From the device activation onwards, no significant changes were indicated in any of the measurement intervals. In a similar study performed by Hughes *et al*. (2001:483) it was noted that NRT-threshold levels decreased significantly between implantation and device activation. NRT-threshold levels showed a minimal increase in NRT-threshold levels over the long term, although no significant changes occurred. This phenomenon was also observed in a study by Van Wermeskerken *et al*. (2006:591) on the Nucleus® 24M and Nucleus® 24 Straight array. In general, no significant changes in the mean NRT-threshold levels were present between intra-operative and after device activation (Van Wermeskerken *et al*., 2006:592). However, when they examined specific electrodes, significant changes were present between the intra-operative and device activation mean NRT-threshold levels (Van Wermeskerken *et al*., 2006:592). In a study on the Nucleus Freedom implant, similar to the study in hand, Lai *et al*. (2004:259) also indicated a significant level of change between NRT-threshold measurements from intra-operative to device activation, after

which NRT-threshold levels stabilised. In Lai *et al*.'s study (2004), the device activation mean NRT-threshold levels were significantly lower than intra-operatively. In 2007 the first research on the AutoNRT™ recording system of the Nucleus Freedom Contour Advance electrode was performed by Van Dijk, Botros, Battmer, Begall *et al*. (2007:558). The researchers investigated the differences between the intra- and post-operative NRT-threshold levels. They noted that post-operative NRT-threshold levels were significantly lower than intra-operative levels (Van Dijk *et al.,* 2007:569). The results of the present study correspond with the past research on the predecessors of the Nucleus Freedom array, as well as with research on the Freedom array itself.

A similar study on the predecessor of the Nucleus® Freedom™ electrode array, the Nucleus® 24M, was conducted by Lai and his partners in 2004. They calculated that on average, the mean NRT-threshold levels per electrode fluctuated with 6-8 CL from the minimum to maximum level measured (Lai *et al*., 2004:261). In the present study, the mean CL was calculated as 13.48 CL. This is much higher than the levels calculated by Lai *et al*. (2004:261). The main difference between the study by Lai *et al*. (2004:261) and the current study is its population. The current study was performed on the paediatric population, while Lai *et al*.'s study (2004:261) was performed on a group of adult cochlear implant users. In the study performed by Hughes *et al*. (2001:483) on the Nucleus 24M, NRT-threshold levels in adults and children were compared. It was observed that children showed much more variation in their mean NRT-threshold levels and that changes over time were much greater in children than in adults (Hughes *et al*., 2001:483). They attributed this fluctuation in the NRT-threshold levels of children to changes in the path of current flow or changes in the neural responsiveness (Hughes *et al*., 2001:483). This mean CL of fluctuation observed in the current study, much higher than that of the study of Lai *et al*. (2004), may also be explained by these changes.

Hughes *et al.* (2001:483) attributed the more noticeable fluctuation in the NRT-threshold levels of children to current flow changes and neural responsiveness. This is further explained by them as changes in the electrode-tissue interface due to formation of new bone (osteogenesis) around the electrode as well as the

formation of new fibrous tissue. The researchers also ascribed the changes in the electrode-tissue interface to the formation of a hydride layer across the surface of the electrode. This hydride layer creates a rougher, uneven surface, resulting in increased surface area (Hughes *et al*., 2001: 482). But, since the NRT-threshold levels were relatively stable over time and did not show any further significant changes, it can be argued that only initial changes in the electrode-tissue interface has an effect on NRT-threshold levels. In general, the effects of changes to the auditory neural periphery are not noticeable in the NRT-threshold level (Van Wermeskerken *et al*., 2006:593).

Osteogenesis and the formation of new fibrous tissue around the electrode array alter the current path from the electrode, thus causing changes in the neural responsiveness (Hughes *et al*., 2001: 483). This implies that a larger population of neurons or a different, more responsive population of neurons are stimulated. It may also be that the current path changes from stimulating the neuron more peripherally to more central, axonal stimulation (Hughes *et al*., 2001: 483). Osteogenesis or new tissue growth may also cause the electrode to be pushed away from the neural population that can be stimulated. If this should be the case, the expectation is that the NRT-threshold level will increase ((Hughes *et al*., 2001: 483). Studies concerning the effect of long term electrical stimulation on the cochlea have indicated that the majority of the osteogenesis along the electrode array was found on the walls of the scala tympani in the lower basal turn of the cochlea (Kawano *et al*., 1998:317; De Sauvage *et al*., 1997:132). Gordon *et al.* (2004: S30) described found a significantly higher NRT-threshold levels in children in the basal electrodes in a study on the Nucleus 24M (straight) electrode array. Research on the Nucleus 24 Contour array, on the other hand, revealed no significant differences in NRT-threshold levels along the electrode array (Lai *et al*., 2004:252). This difference might be attributed to the technical specifications of the two different array types. The electrodes on the Contour array are half-rings, which are approximately only half the geometric size of the full ring electrodes of the standard array (Saunders, Cohen, Aschendorff, Shapiro *et al*., 2002:28S). NRT-threshold levels might be lower in the Nucleus 24 Contour than in the straight array due to their positioning close to the modiolus, while the straight array is closer to the outer wall of the scala tympani (Saunders *et al*.,

2002:39S). In this study, no significant differences could be observed between NRT-threshold levels measured on the different measurement sites along the electrode array (see Figure 4.3). This finding can be attributed to the modiolus-hugging contour array. Since there is no difference between NRT-threshold levels of the basal, medial and apical electrodes, the assumption can be made that there was an even spread of bone growth along the electrode array.

Sub-aim 2 was to describe the changes in NRT™™-measurements from intra-operative up to twelve months post-implantation. Figure 4.4 is a graphical representation of the changes that were significant over time across the electrode array. It is clearly indicated that significant changes were present in all electrodes in the intra-operative to device activation measurement interval. From the 3 months up to the 12 months follow-up measurement intervals, significant changes between intervals were absent. Only two other significant changes could be measured.

To encapsulate, NRT™-measurements over time showed significant changes across the electrode array only in the intra-operative to device activation measurement interval. This phenomenon is supported by research on the Nucleus® 24 electrode array by Lai *et al*. (2004:261) and Van Wermeskerken (2006:591) who also reported significant changes on NRT™-measurements only from intra-operative to device activation (Van Dijk *et al*., 2007: 559; Lai *et al*., 2004: 261 and Van Wermeskerken *et al*., 2006:591).

4.3.2 Summary of results and discussion of sub-aim #2

A summary of the results and discussion for sub-aim #2 is provided in Table 4.23

TABLE 4.23 Summary of the results and discussion for sub-aim #2

• NRT™-levels showed very little change over the different measurement intervals.
• A similar pattern of change was observed across the electrode array: a slight decrease in mean CL between the intra-operative and the device activation measurement intervals, stable mean CL for six months up to the 6 months follow-up interval, then a slight increase in mean NRT-threshold levels.
• Significant changes in NRT-threshold levels were present in all electrodes, but only between the intra-operative to the device activation measurement intervals.
• NRT-threshold levels fluctuated with 13.48CL and is much higher than those levels documented in previous research, indicating a difference between the adult and paediatric populations due to greater changes in neural responsiveness and faster bone and tissue growth.
• No significant changes in NRT-threshold levels could be measured on the different measurement sites of the electrode array.
The results documented for this study corresponded with previous research on predecessors of the Nucleus Freedom Contour array. Previous research also revealed significant changes in NRT™- measurements between implantation and device activation. It also seems as though these changes are more pronounced in children than in adults, due to differences in neural responsiveness.

4.4 RESULTS AND DISCUSSION OF SUB-AIM #3: COMPARISON OF TRENDS IN IMPEDANCE AND NEURAL RESPONSE TELEMETRY FROM INTRA-OPERATIVE AND UP TO TWELVE MONTHS POST-OPERATIVELY

The third and final sub-aim of this study was to compare trends in impedance telemetry and Neural Response Telemetry measurements intra-operatively and then post-operatively for 12 months. No specific measurements were performed during the field study in order to investigate this specific sub-aim. The data collected during the impedance telemetry and Neural Response Telemetry measurements were used to investigate and discuss the question raised by the third sub-aim. The data collected for these two measurements have been analysed and discussed in sections 4.2 and 4.3 of this chapter. Of essential value to this section are the results of the statistical measurements performed on the data sets collected for sub-aim 1 and 2.

The manner, in which trends were determined in impedance telemetry and NRT™measurements, was to use the outcomes of the statistical procedures to identify the measurement intervals where changes occurred in both impedance telemetry and NRT measurements.

The Friedman's ANOVA test was selected for statistical purposes. The mean ranks (calculated by the SPSS Output) of all the selected electrode's impedance telemetry measurement modes and conditions as well as the mean ranks of the NRT™, were used to establish the level of significance in the changes among them. The presence of significant changes in mean impedance values called for further testing to evaluate the level of significance across the measurement conditions. Table 4.22 is a summary of the outcomes of Friedman's ANOVA on the impedance telemetry and NRT™ measurements of the selected electrodes. The data used in Table 4.24 is based on the data outlined and discussed in Tables 4.3, 4.7, 4.11, 4.15, 4.18 and 4.21.

Table 4.24 Outcomes of Friedman's ANOVA on impedance telemetry and NRT™-measurements

Electrode number	Outcomes of Friedman's ANOVA: Significant or not (p-value ≤ 0.05)		
	Impedance Telemetry: Common Ground	Impedance Telemetry: MP1+2	NRT™
3	No	No	Yes
6	No	No	Yes
8	No	No	Yes
11	No	No	Yes
13	No	No	Yes
16	No	No	Yes
19	No	No	Yes
21	No	No	Yes

According to Table 4.24 there were no significant levels of changes in impedance telemetry measurements in both the Common Ground and MP1+2 modalities, while the results on the NRT™ measurements indicated significant change in all electrodes. There is no obvious trend that links impedance telemetry and NRT™ measurements.

The presence of significant level of change in the NRT™ measurements according to Friedman's ANOVA, called for ad-hoc testing. The Wilcoxon signed-rank test was used to determine where specifically the change in the measurements occurred in the longitudinal study. This test used a pair-wise comparison to determine the level of significance in changes between the different measurement intervals. The Wilcoxon signed-rank test was not indicated for the impedance telemetry measurements since no significant changes over the electrodes were present, but since it was the researcher's intent to do an in-depth analysis of changes across time, the test was also applied on the data sets of the impedance telemetry measurements. Tables 4.25, 4.26, and 4.27 restate the results of this test on both the impedance telemetry and NRT™ measurements for the basal, medial and apical electrodes.

Table 4.25 Level of significance for the 5 measurement phases for both impedance telemetry and NRT™ measurements on the basal electrodes: Wilcoxon Signed Rank test

		Type of measurement and significant difference (*p-value*≤ 0.01)		
Electrode number	Pair wise comparison	Impedance Telemetry: Common Ground	Impedance Telemetry: MP1+2	NRT™
Electrode 3	Intra-operative to Device activation	No	No	Yes
	Device activation to 3 month follow-up	No	No	No
	3 month to 6 month follow-up	No	No	No
	6 month to 9 month follow-up	No	No	No
	9 month to 12 month follow-up	No	No	No
Electrode 6	Intra-operative to Device activation	No	No	No
	Device activation to 3 month follow-up	No	No	No
	3 month to 6 month follow-up	No	No	No
	6 month to 9 month follow-up	No	No	No
	9 month to 12 month follow-up	No	No	No

Table 4.26 Level of significance for the 5 measurement phases for both impedance telemetry and NRT™ measurements on the medial electrodes: Wilcoxon Signed-Rank test

		Type of measurement and significant difference (*p-value*≤ 0.01)		
Electrode number	Pair wise comparison	Impedance Telemetry: Common Ground	Impedance Telemetry: MP1+2	NRT™
Electrode 8	Intra-operative to Device activation	No	No	Yes
	Device activation to 3 month follow-up	No	No	No
	3 month to 6 month follow-up	No	No	No
	6 month to 9 month follow-up	No	No	No
	9 month to 12 month follow-up	No	No	No
Electrode 11	Intra-operative to Device activation	No	No	Yes
	Device activation to 3 month follow-up	No	No	No
	3 month to 6 month follow-up	No	No	No
	6 month to 9 month follow-up	No	No	No
	9 month to 12 month follow-up	No	No	No
Electrode 13	Intra-operative to Device activation	No	No	Yes
	Device activation to 3 month follow-up	No	No	No
	3 month to 6 month follow-up	No	No	No
	6 month to 9 month follow-up	No	No	No
	9 month to 12 month follow-up	No	No	No

Table 4.27 Level of significance for the 5 measurement phases for both impedance telemetry and NRT™ measurements on the apical electrodes: Wilcoxon Signed Rank test

		Type of measurement and significant difference (*p-value*≤ 0.01)		
Electrode number	Pair wise comparison	Impedance Telemetry: Common Ground	Impedance Telemetry: MP1+2	NRT™
Electrode 16	Intra-operative to Device activation	No	No	Yes
	Device activation to 3 month follow-up	No	No	No
	3 month to 6 month follow-up	No	No	No
	6 month to 9 month follow-up	No	No	No
	9 month to 12 month follow-up	No	No	No
Electrode 19	Intra-operative to Device activation	No	No	Yes
	Device activation to 3 month follow-up	No	No	No
	3 month to 6 month follow-up	No	No	No
	6 month to 9 month follow-up	No	No	No
	9 month to 12 month follow-up	No	No	No
Electrode 21	Intra-operative to Device activation	No	No	Yes
	Device activation to 3 month follow-up	No	No	No
	3 month to 6 month follow-up	No	No	No
	6 month to 9 month follow-up	No	No	No
	9 month to 12 month follow-up	No	No	No

According to Tables 4.25, 4.26, and 4.27, there were no significant changes in impedance telemetry measurements from Intra-operative measurements up to the 12 months follow-up measurement interval. These results were discussed and compared to literature in section 4.2.1.4. The trend is thus that impedance measurements remain consistent over time and that no significant changes can be expected.

With regard to NRT™-measurements over time, Tables 4.25, 4.26, and 4.27 highlight significant changes during the Intra-operative to Device activation measurement phase across the electrode array and across time. No other significant changes were indicated otherwise. The trend in NRT™-measurements over the long term is that significant changes can be expected between the Intra-operative and Device activation measurement intervals. This trend is verified by research on the Nucleus® 24 electrode array by Lai *et al*. (2004:261), Van Wermeskerken (2006:591), and other researchers who also reported significant changes on NRT™-measurements only from intra-operative to device activation (Roland *et al*., 2007: 559).

The main purpose of Tables 4.25, 4.26, and 4.27 was to compare significant changes among impedance telemetry measurements in the Common ground and MP1+2 test modes and NRT™ measurements over time. As discussed previously, the only significant changes were those present in the NRT™ measurements during the Intra-operative to Device activation measurement phase. No trend of correspondence between NRT™ measurements and impedance telemetry measurements could be identified over the long term.

In a longitudinal study on impedance telemetry and NRT™-measurements in adults and children by Hughes *et al*. (2001:483), on the other hand, an inverse relationship was identified between impedance telemetry and NRT™-measurements between the Intra-operative and Device activation measurement phase in children. During this measurement phase, impedance values increased while NRT-threshold levels decreased (Hughes *et al*., 2001:483). The researchers suggested a common underlying mechanism that affects both of

these measurements, but in a different manner. They assumed that these changes were reflecting physical changes taking place in the cochlea during this time period. After implantation, a fibrous tissue encapsulates the electrode array causing a change in the path of current flow. This will affect the ECAP-measurements, causing the NRT-threshold levels to decrease. The presence of tissue growth will also affect electrode impedance. At Device activation, the electrode array is stimulated and impedance values increase. They also argued that it is unlikely that an increase in impedance values would cause a decrease in NRT-threshold levels. The more likely possibility is that tissue or bone growth would continue after Device activation and that the additional tissue or bone could alter the current paths in the cochlea, resulting in the increase in impedance values and the decrease in the NRT-threshold levels (Hughes *et al*., 2001:483).

In section 4.2.1.4 the researcher demonstrated that visual inspection of the mean impedance values revealed a slight increase in these measurement values from the Intra-operative to the Device activation measurement intervals (see Figures 4.1 and 4.2). These values remained higher up to the 3 months follow-up measurement interval, where after the values decreased again and remained unchanged up to the 12 months follow-up interval. The inverse pattern was observed in section 4.3.1.4, where visual inspection of the mean NRT-threshold levels illustrated a decrease in NRT-threshold levels from the Intra-operative to Device activation measurement intervals (see Figure 4.3). These levels remained lower up to the 3 months follow-up measurement interval, whereafter they increased slightly. The initial decrease in the NRT-threshold levels was significant, as indicated in Tables 4.25, 4.26, and 4.27. According to these findings, it is clear that an inverse relationship exists between impedance telemetry measurements and NRT™ measurements. This correlates with the findings of Hughes *et al*. (2001:483), although in the current study the changes in impedance telemetry measurements were not significant over time. Thus, an inverse trend exists between impedance telemetry and NRT™ measurements from the Intra-operative to the 6 months follow-up interval. As suggested by Hughes *et al.* (2001:483), this is most probably due to physical changes in the

cochlea as a result of the formation of fibrous tissue and new bone growth around the electrode array, which alters the flow of current in the cochlea.

In this section, the researcher compared the outcomes of the statistical measures in order to determine whether any trends were present between impedance telemetry and NRT™ measurements over time. No trend was evident in impedance telemetry over time since no significant changes were present. NRT™ measurements showed a trend towards a decrease in NRT-threshold levels during the Intra-operative to Device activation measurement phase. When the mean impedance values and mean NRT-threshold levels were compared, an inverse relationship between these two types of measurements was identified. Thus, an inverse trend between impedance telemetry and NRT™ measurements is present during the first 6 months from Device activation. It was also indicated that this trend is probably due to physical changes in the cochlea affecting the flow.

4.4.1 Summary of results and discussion for sub-aim #3

A summary of the results and discussion for sub-aim #3 is provided in Table 4.28.

TABLE 4.28 Summary of results and discussion of sub-aim #3

• The trend observed in impedance telemetry measurements is that values remain consistent over time.
• The trend in NRT™ measurements over time is that significant changes are present between implantation and device activation.
• No trend of correspondence could be identified between impedance telemetry and NRT™ measurements over the long term.
• An inverse trend was observed between impedance telemetry and NRT™ measurements from implantation up to six months after device activation.
The results documented for this study corresponded with previous research on predecessors of the Nucleus Freedom Contour array. No trends were documented, except for the inverse trend between the two types of measurements between implantation and six months after device activation. This inverse trend is most likely due to the changes in the cochlea to new bone growth affecting current flow.

4.5 CONCLUSION

The current study described specific details around the changes in impedance telemetry and NRT™ measurements over a longitudinal period. The researcher explored each of these measurement types in order to address the main aim of this study.

The results obtained in this study revealed that impedance telemetry measurements as well as NRT™ measurements remained consistent over time. Impedance telemetry measurements revealed slight, insignificant, changes between implantation and up to the first three months after device activation. Similarly, NRT™ measurements showed changes in NRT-threshold levels from implantation up to device activation, then a stable period of six months, after which a slight increase in levels were observed. Changes were however significant in nature between implantation and the device activation. These findings have indicated that although changes do occur in impedance telemetry and NRT™ measurements, they are in general not significant. Clinicians can thus expect changes in both types of measurements during the initial follow-up sessions, stabilising within three months after device activation. This confirms these two measurement types as effective and reliable objective measurements to be applied in the service delivery process of young cochlear implant users, ensuring accountable service delivery even in the South African context.

4.6 SUMMARY

This chapter provided a presentation and discussion of the results obtained in the empirical study. The results were presented and discussed according to the three sub-aims specified for this study aiming to address the main aim of the study. The discussion integrated the findings with the current body of knowledge to demonstrate the relevance thereof. The chapter was concluded with a summary and conclusion.

CHAPTER 5

CONCLUSIONS AND IMPLICATIONS

Aim: To draw general conclusions and derive implications from the research findings, critically evaluate the research, and make recommendations for future research

5.1 INTRODUCTION

A reciprocal relationship exists between informed clinical practice and clinical research. Informed clinical practice is guided by applied research activities and clinical practice in turn stimulates these research endeavours (Fouché, 2002a:109). This relationship is required to steer evidence-based practice, and in areas where there is a dearth of clinical practice appropriate procedures should only be established on the foundation of applied contextual research activities.

The number of cochlear implants in young children with hearing loss has been escalating since 2002. The increase can be attributed to the implementation of newborn hearing screening programmes in the South African Health system (Swanepoel, Delport & Swart, 2004:634-635). This implies that the audiologist's paediatric case load will steadily expand as these programmes are implemented more widely in South Africa and more and more infants with hearing loss are identified at a very young age. The definitive aim of early cochlear implantation, in South Africa and internationally, is to offer young children the auditory abilities to attain optimal speech and language development that will ultimately affect academic outcomes in the educational environment (Kileny & Zwolan, 2004:S16). Developing audiological services for this specific case load is, however, dependent on research that meets the unique local demands of the South African population and context in a socially and economically justifiable manner (Hugo, 1998:12).

The current study, in which the longitudinal behaviour of impedance and Neural Response Telemetry measurements in a group of young cochlear implant users was monitored, aspires to address this responsibility by providing research-based recommendations for clinical practice. This investigation can therefore serve to initiate further research and guide future implementation of these two measurements in the audiological service delivery process when dealing with this population, ensuring that hearing healthcare for South African children with hearing loss is both cost-effective and accountable.

The aim of this chapter therefore, is to draw general conclusions and implications from the results of the empirical study, to critically evaluate the research, and to make specific recommendations from the empirical research conducted during this study.

5.2 CONCLUSIONS

This study focused on monitoring the longitudinal behaviour of impedance and Neural Response Telemetry measurements in a group of young cochlear implant users of the Pretoria Cochlear Implant Programme in order to answer the research question: ***Are any changes present in impedance telemetry and NRT™-measurements during the first twelve months post-implantation within the paediatric population?*** The empirical research was conducted according to three objectives or sub-aims, which resulted in the following summarised conclusions.

Objective #1: To describe impedance telemetry measurements obtained intra-operatively and up to twelve months post-cochlear implantation

Impedance telemetry was described in terms of the mean Common Ground (CG) and Monopolar 1+2 (MP1+2) values. Mean values for both measurement modalities remained consistent over the electrode array and over time. A gradual increase in mean values were observed from the intra-operative to the 3 months follow-up interval, followed by a gradual decrease at the 6 months follow-up interval, with mean values remaining consistent thereafter. The gradual increase and decrease of values were, however, not statistically significant. This finding

differed from the findings of previous research involving the adult population, where significant changes were found in impedance values during the first three months post-implantation.

Objective #2: To describe Neural Response Telemetry measurements obtained intra- operatively and up to twelve months post–cochlear implantation

NRT™-measurements across the electrode array remained consistent over time. The only significant changes in mean NRT-threshold levels were observed from intra-operative to device activation where levels decreased; no other significant changes were present up to the twelve months follow-up stage. This finding is supported by research findings from the adult population and other electrode arrays.

Objective #3: To compare trends in the measurements of impedance and Neural Response Telemetry at implantation and post-implantation over a period of twelve months

Changes in impedance telemetry and NRT™-measurements were compared from implantation to twelve months post-implantation. No trend was evident in impedance telemetry over time since no significant changes were present. NRT™-measurements showed a trend towards a decrease in NRT-threshold levels during the Intra-operative to Device activation measurement phase. By comparing the mean impedance and NRT™-measurements levels, an inverse trend between these two types of measurements was identified during the first 6 months post-implantation.

No changes were present in impedance telemetry measurements during the first twelve months post-implantation, while NRT™-measurements showed changes only from Implantation to the device activation measurement intervals, remaining stable thereafter.

5.3 CLINICAL IMPLICATIONS OF RESEARCH FINDINGS FOR THE FIELD OF COCHLEAR IMPLANTATION

The most prominent clinical implications that can be derived from the empirical results obtained in this study are presented in the following paragraphs according to the objectives of the research.

Objective #1: To describe impedance telemetry measurements obtained intra- operatively and up to twelve months post-cochlear implantation

- Impedance telemetry within the cochlea can supply the audiologist with valuable data regarding the status of individual electrodes of the electrode array (French, 1999:61-62). Electrodes can be identified as potentially faulty if impedances are either very high, termed open circuit, or when impedance values are very low, termed short circuit (French, 1999:62; Mason, 2004:S34). Impedance values for CG and MP1+2 test modalities remained consistent over the long term. These findings imply that the impedance telemetry measurements of the Nucleus Freedom implant system can provide the audiologist with accurate data regarding the status of the individual electrodes of the electrode array. The current study revealed that values might increase gradually over the first three months post-implantation due to the formation of new bone and tissue growth around the electrode array. Major changes in impedance values during the first three months and thereafter should thus be considered non-typical and further investigation into the integrity of the electrode should be advised. This is of essential value for the audiologist working with members of the paediatric population, who have limited speech and language to communicate as well as limited auditory experience and consequently are not able to communicate malfunctions to their parents or audiologist.
- New bone and tissue formation during the first three months post-implantation causes an increase in impedance values due to an increase of the tissues surrounding the electrode array, resulting in higher current

levels. These higher current levels have an influence on the T- and C-levels and the dynamic range of the MAP (Clark, 2003:108). This study indicated that impedance values show no significant changes over time. A gradual increase during the first three months post-implantations may result in higher T- and C-levels during this period. The clinical audiologist can expect that T- and C-levels will decrease slightly after this period and then remain stable.

Objective #2: To describe Neural Response Telemetry measurements obtained intra- operatively and up to twelve months post–cochlear implantation

- The NRT™- technique has been considered safe and consistent in measuring the auditory nerve's responsiveness during surgery, as well as post-operatively. A success rate of 95% in measuring responses on previous Nucleus® cochlear implant systems has been obtained during the application of NRT™'s in adults and children (Abbas *et al*.,1999:46; Brown *et al*., 2000:151-152; Briaire & Frijns, 2005:143-144; Lai & Dillier, 2000:334). During this study, a total of 384 NRT™-measurements were used for analytical purposes. In only one measurement no NRT-threshold could be measured. This finding indicates a high success rate when utilising the AutoNRT™ software application of the Custom Sound software implemented with the new Nucleus® Freedom™ implant system in young children.

- Long term studies on NRT™-measurements verified that intra-operative NRT™-data was generally stable enough to be used for assisting in the initial speech processor fitting sessions (Lai *et al*., 2004: 253). Long term monitoring of NRT™- data provides an indication of how stable this data is over time. The current study, monitoring NRT™-data collected with the new Custom Sound software and Nucleus® Freedom™ implant system over a twelve month period, indicated NRT™-levels that remained stable from device activation. Significant changes in NRT™-levels were identified when measurements taken at implantation were compared to those taken at device activation. Lai *et al*. (2004:252) also observed the most

significant changes between measurement between intra-operative and the first post-operative measurements and attributed these findings to new bone growth and tissue formation around the electrode after implantation. This finding implies that intra-operative NRT™-levels measured with the AutoNRT™ software can be applied post-operatively since these intra-operative measurements correspond well with the NRT-threshold levels measured 12 months post-operatively.

- The potential applicability of intra-operative NRT™-data at a later stage has become a more pertinent issue with the increasing number of semi-automated methods that have been proposed for using NRT™-data to assist in speech processor fittings (Brown *et al*., 1994: 170; Brown *et al*., 2000: 151). Stability of NRT™- data over a 4 year period was demonstrated by Lai *et al*. (2004:152) for the Nucleus® CI24M Cochlear Implant System, confirming its serviceability in the semi-automated fitting methods proposed by Brown *et al*. (2000: 151). Results from the present study confirmed the stability of NRT™-measurements in young cochlear implant users with the Nucleus® Freedom™ system over a twelve month period. The new objective device programming methods developed specifically for the paediatric population, based on the intra-operative NRT™-levels, are thus based on stable measurements. This implies that the clinician can deliver effective and accountable services to this challenging population.

- The delivery of accountable services is a key concern within the South African Health Sector (Kaltenbrünn *et al*., 2005:15-16). South Africa is a country faced with limited financial resources within the public sector (Swanepoel *et al*., 2004:634). The implementation of the EHDI and consequently more cochlear implantations among very young children with severe to profound hearing losses make it essential that cost-effective devices and techniques be employed when managing this population. The stability of NRT™-measurements in young cochlear implant users implanted with the Nucleus® Freedom™ cochlear implant was proven by the current study. The stability of NRT™-measurements implies that the

use of new semi-automated fitting procedures, based on NRT™-measurements, will enable audiologists to provide accountable and cost-effective services to this population in South Africa. Audiologists and clinicians are thus able to apply intra-operative NRT™-levels from device activation, without having to spend time on repeating AutoNRT™-measurements at every follow-up visit. The semi-automated fitting procedures ensure that audiologists will be providing audible electrical stimulation levels from the onset of device programming.

Objective #3: To compare trends in the measurements of impedance and Neural Response Telemetry at implantation and post-implantation over a period of twelve months

- An inverse trend between impedance telemetry and NRT™-measurements was identified during the first 6 months post-implantation of this study. The changes in impedance telemetry and NRT™-measurements can be attributed to new bone growth and tissue formation around the electrode during the first few weeks after implantation (Clark, 2003:108; Lai *et al*., 2004:252). Stabilization of the impedance and NRT™-levels will indicate to the audiologist that changes in the electrode-tissue interface are decreasing and that MAP T- and C-levels should start stabilizing. This implies that programming sessions are needed less frequently, which will aid in streamlining the service delivery process and increase its cost-effectiveness.

The empirical results of this study suggest priorities for prospective research in impedance telemetry and NRT™-measurements.

5.4 RESEARCH IMPLICATIONS

When a research question is answered, a multitude of new questions typically rear up to be answered and in this aspect the current study was no exception. The results obtained and the conclusions drawn from the current study revealed several significant facets that require additional investigation. These are

presented in this section to offer guidelines and suggestions for future research endeavours.

- Results indicated that changes in impedance telemetry and NRT™-measurements could be attributed to new bone growth and new tissue formation around the electrode array especially during the first six months post-implantation. These anatomical changes influence the amount of current flow, thus also influencing the T- and C-levels and dynamic range of the MAP. Clinicians should be aware of the relationship between the changes in impedance telemetry and NRT™-levels and MAP changes, especially in young children where semi-automated fitting methods are implemented.

- Measurement techniques such as impedance telemetry and NRT™ serve a useful purpose in that they streamline the service delivery process and influence the cost-effectiveness of the service delivery process. Clinicians in the South African context should be aware of the advantages of implementing such techniques in comparison to previous service delivery methods. Clinicians should consider aspects such as the number of programming sessions needed to reach optimum programming parameters, the length of programming sessions, and the cost-effectiveness of such a service delivery process.

- The main aim of early implantation is the development of age-appropriate speech and language abilities. Clinicians should know that implementing techniques such as impedance telemetry and NRT™-measurements allows them to provide young children with the necessary sound input to attain this. Outcomes in terms of speech and language development of children programmed with the implementation of impedance telemetry and NRT™-measurements in semi-automated programming software, should be compared to past results where these procedures were not available.

The clinical results of the empirical research conducted in this study have provided direction for future research priorities aimed at providing accountable audiological services by implementing impedance telemetry and NRT™-measurements in clinical practice when working with young children with cochlear implants in South Africa.

5.5 CRITICAL EVALUATION OF THE STUDY

A critical evaluation of an empirical research project is essential to ensure the appropriate interpretation of results within the framework of the strengths and limitations of the research (Mouton, 2001:125). Table 5.1 provides a critical evaluation of the empirical study based on the strengths and limitations of the data collection method and procedures, as well as of the selection of research participants.

Table 5.1 Critical evaluation of the empirical study

DATA COLLECTION
Strengths: ▪ A quantitative research method was selected to process means, medians and correlations of the data collected. Individual scores were not taken into account. The power of interpretation rested in the large number of scores that depicted the norm or average of the group's performance. ▪ The data collection procedure that was followed was performed at specific time intervals in order to enhance the validity of the study. Those research participants' results, who could not meet these scheduled intervals, were excluded from the data sample. **Limitations:** ▪ The data collected in the current study consisted of values measured from the implantation of the electrode array up to twelve months post-device activation. The majority of similar studies were however performed over a twenty four to thirty six months time lapse from the device activation.
RESEARCH PARTICIPANTS
Strengths: ▪ The research participants consisted of eight children. The ages of the participants varied from 9 months of age at implantation up to 77 months at implantation. The spread of age covers the range specified by the selection criteria of the Pretoria Cochlear implant Programme for the paediatric population, namely 6 months to 84 months. **Limitations:** ▪ A relatively small number of research participants were used for the study, namely eight, making it difficult to generalise findings and conclusions of the results of the study. Although the research sample was used it has to be taken into consideration that the Pretoria Cochlear Implant Programme currently has 364 cochlear implant users, of which half is children. An average of 16 children is implanted yearly making the research sample 50% of the paediatric population implanted in 2006 (Personal interview, Mrs Janet Wiegman, Manager of Southern ENT, January 2010).

The study in hand succeeded in investigating important and appropriate clinical measurements used in the process of service delivery to young children with cochlear implants in a manner that can guide contextually relevant clinical implementation and future research.

5.6 FINAL COMMENTS

The basic rationale behind early detection and intervention of hearing impairment is that it maximises the benefits not only for the child, but also for the family and society (Diefendorf, 2002:469; HPCSA, 2002:1). It remains the responsibility of the audiologist to meet the challenge of delivering accountable services to the paediatric population with hearing loss, in such a way as to ensure that they may develop to their maximum potential (Swanepoel, 2004:11). Cochlear implants have become an essential part of the service delivery process to very young children with severe to profound hearing loss (Niparko & Blakenhorn, 2003:267). Objective, electrophysiological measurements, for example impedance telemetry and NRT™, have developed over time to ensure that the audiologist can set optimal electrical stimulation levels even for this population, whose members pose a challenge due to their inexperience with auditory sensations, limited behavioural skills, and cognitive limitation (Brown *et al*., 1994:168-169). Due to the implementation of the Hearing Screening Position Statement (HPCSA, 2002) and the Early Hearing Detection and Intervention Programmes (published by the HPCSA, 2007) in South Africa, the audiologist's paediatric case load has been growing steadily as more and more infants with hearing loss are identified at a very young age. The central objective of early implantation in South Africa, as globally, is to present young children with the auditory abilities to attain the best possible speech and language development that will ultimately affect academic outcomes in the educational environment (Kileny & Zwolan, 2004:S16). As a result of limited finances, resources, and manpower, it is of the utmost importance for clinicians in South Africa to deliver time-efficient, cost-effective, and accountable services to this population (Kaltenbrünn *et al*., 2005:15-16). The

application of electro-physiological measurements makes improved service delivery in the South African context a possibility.

With the introduction of the Nucleus Freedom® cochlear implant system in 2005, new software releases introduced semi-automated fitting methods. These new semi-automated fitting methods were based on the impedance and NRT™-values measured with the Custom Sound software version 3.0. Research investigated changes in the amplitude growth function and NRT-threshold levels intra-operatively and post-operatively, proving stability and very little changes across measurements in older software versions (Lai *et al*., 2004:259). The question that arose was: ***Are any changes present in impedance telemetry and NRT™-measurements during the first twelve months post-implantation within the paediatric population?***

The current research succeeded in answering this question by indicating that impedance telemetry and NRT™-measurements remained stable during the first twelve months post-implantation within the paediatric population. These measures can therefore be used effectively in the new semi-automated fitting software. The implementation of these measurements can thus lead to a streamlined service delivery process to young cochlear implant users. Audiologists can deliver accountable services by providing optimal electrical stimulation levels from device activation, addressing one of the key concerns in the South African Health Sector. Children with severe to profound hearing loss are as much part of the future of South Africa as those with normal hearing. An optimally programmed cochlear implant can give these children access to auditory skills that will impact positively on their oral communication, communication skills, speech intelligibility, incorporation into primary education, scholastic achievement, social interaction, the opportunity for tertiary education, and employment opportunities, giving them social independence as adults. These children will have an opportunity equivalent to that of children with normal hearing to transform, inspire, and guide the development of South Africa.

> *"Hearing is the soul of knowledge and information of a high order. To be cut off from hearing is to be isolated indeed."*
>
> Helen Keller (Keller, 1910)

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APPENDICES

APPENDIX A

CANDIDACY SELECTION CRITERIA FOR CHILDREN APPLIED BY THE PRETORIA COCHLEAR IMPLANT PROGRAMME

Criteria	Description
Degree of hearing loss:	• Severe to profound sensory-neural hearing loss or moderate to profound hearing loss (Müller & Wagenfeld, 2003: 58-59, Osberger, 1997:145-148, Zwolan, 2000: 63-71 and Zwolan, 2002:746-748).
Minimum age:	• No minimum age for referral for cochlear implantation candidacy assessment (Müller & Wagenfeld, 2003: 58-59). • Minimum age of 12 months for cochlear implantation as approved by the US FDA (Nikolopoulos, et al., 2005:184-186, Sinninger, 2002:187-188, Spivak & Sokol, 2005:104 - 112 and Zwolan, 2002:740).
Benefit with conventional amplification:	• Little or no benefit from optimally fitted hearing aids in terms of access to speech sounds. Aided hearing thresholds are outside the speech spectrum, especially in the high frequency speech spectrum – 2kHz and above. This is especially important in the age group birth to 24 months (Müller & Wagenfeld, 2003: 58-59, Zwolan, 2000: 63-71 and Zwolan, 2002:746-748). • In the age group 2-5 years, failure to develop an acceptable or age appropriate level of auditory skills with optimally fitted hearing aids and participation in an intensive auditory habilitation programme. This can also be demonstrated by parental response to client-administrated questionnaires (Müller & Wagenfeld, 2003: 58-59, Osberger, 1997:145-148, Zwolan, 2000: 63-71 and Zwolan, 2002:746-748).

Benefit with conventional amplification:	• In children above the age of 5 years, minimal benefit from amplification is demonstrated by minimal scores (50% or less) on open-set speech recognition measurements (Müller & Wagenfeld, 2003: 58-59, Osberger, 1997:145-148, Zwolan, 2000: 63-71 and Zwolan, 2002:746-748). • A three to six month hearing aid trail, with optimally fitted hearing instruments, is required for children with no previous hearing instrument experience (Zwolan, 2000: 63-71 and Zwolan, 2002:746-748).
Duration of hearing loss:	• The onset of the loss can be congenital or progressive (Müller & Wagenfeld, 2003: 58-59, Osberger, 1997:145-148, Zwolan, 2000: 63-71 and Zwolan, 2002:746-748).
Radiological and medical considerations:	• No medical or radiological contra-indications to surgery should be present (Zwolan, 2000: 63-71 and Zwolan, 2002:746-748). • A complete medical and ear-, nose- and throat evaluation should be performed to attempt to identify the aetiology of the hearing loss, and to determine whether any other medical factors are present which may influence the child's suitability to undergo surgery and rehabilitation (Müller & Wagenfeld, 2003: 58-59).
Family expectations and emotional support:	• Motivated family and consent from the child where possible (Zwolan, 2000: 63-71 and Zwolan, 2002:746-748). • Children must have adequate family support and parents should be gainfully employed in order to maintain the device (Müller & Wagenfeld, 2003: 58-59).

Educational setting:	• Placement in an educational setting that is able and willing to provide a concentrated auditory skill development programme (Zwolan, 2000: 63-71 and Zwolan, 2002:746-748). • An accessible, compulsory and appropriate educational setting should be available (Müller & Wagenfeld, 2003: 58-59).

APPENDIX B

LETTER OF INFORMED CONSENT TO PARENTS - ENGLISH

Date:

Dear Parent:

A study on the AutoNRT™ of the Nucleus Freedom™ Cochlear Implant

I am doing a research project on the new Auto-NRT™ functionality of the latest cochlear implant device from Cochlear™, the Nucleus Freedom. This feature is performed during surgery, at discharge as well as routinely in all follow-up sessions during the first twelve months. The data from this measurement aids in monitoring device integrity and helps the audiologist with the initial setting of stimulation levels of the cochlear implant device.

This research project aims to use the collected data to test the predictability of stimulation levels based on the Auto-NRT™ measurement, to aid in the cochlear implant fitting process of children. As mentioned previously, the measurement is performed as part of routine fitting session during the first 12 months of implantation. No extra time or consultations from your part will be necessary to perform the measurement. The test is fairly quick to perform (a few minutes) and uses the Auto-NRT™ software designed by Cochlear™ and the cochlear implant device. This type of measurement has been performed for routinely in the past and is completely safe. It does not depend on participation from your child and can even be performed while sleeping. We ensure that all data collected will be treated as confidential and all particulars of participants will stay confidential. The research findings will be made available to you at the conclusion of this project.

If you are willing to participate in this research project, please complete the consent form below. Should you wish to withdraw from the study, you can do so at any stage with no consequences.

Should you have any further questions, please contact us at the Communication Pathology Department, University of Pretoria, Tel.(012) 420 2357.

Thank you,

Mrs. Nicolize Cass
M. Communication Pathology student

Dr. Catherine van Dijk
Research Supervisor

Prof. B. Louw
HOD: Dept. of Communication Pathology

Dr. De Wet Swanepoel
Co-supervisor

University of Pretoria
Department of Communication Pathology

Surname: _____ **Name:** _____

Child's name: _____ **Child's date of birth:** _____

I/We hereby consent that ……., may participate as a research subject in the research project on Auto-NRT™'s . I acknowledge that I may withdraw from the study at any stage without any consequences.

Signature: _____ **Date:** _____

APPENDIX C

LETTER OF INFORMED CONSENT TO PARENTS - AFRIKAANS

Datum:

Geagte ouer

Navorsingsprojek oor die AutoNRT™ van die Nucleus Freedom™ kogleêre inplanting

Die Departement Kommunikasiepatologie by die Universiteit van Pretoria is besig met ‘n navorsingsprojek oor die nuwe Auto-NRT™-meting van die nuwe kogleêre inplanting van Cochlear™, die Nucleus Freedom. Hierdie meting word uitgevoer tydens chirurgie, voor ontslag uit die hospital en roetinegewys as deel van elke opvolgsessie. Hierdie data word gebruik om die funksionering van die inplanting te monitor, maar assisteer ook met die eerste aanskakeling deur stimulasievlakke voor te stel.

Die studie beoog om die data van die Auto-NRT™-metings te gebruik om stimulasievlakke te voorspel om te help met die passing van kogleêre inplantings by jong kinders. Soos reeds genoem, is hierdie metings deel van die standaard opvolgsessies gedurende die eerste 12 maande. U deelname aan die studie sal dus nie aanspraak maak op enige ekstra tyd of afsprake nie. Die meting word redelik vinnig gedoen (‘n paar minute) en is nie afhanklik van u kind se samewerking nie. Dit kan selfs uitgevoer word as hy/sy slaap. Die meting word gedoen deur spesifiek-ontwerpte sagteware van Cochlear™ en die kogleêre inplanting. Hierdie prosedure vorm deel van die standaard-opvolgsessies na inplantering en is baie veilig. Ons verseker u dat alle inligting vertroulik behandel sal word en dat alle deelnemers konfidensieel sal bly. Data oor die navorsingsprojek sal gestoor word in ‘n konfidensiële wyse vir verdere navorsingsdoeleindes.

Indien u bereid is om deel te neem aan hierdie navorsingsprojek, voltooi asb. die toestemmingsbrief hieronder. Sou u ter enige tyd besluit om te onttrek van die studie kan dit gedoen word sonder enige gevolge. Indien u enige verder inligting verlang, kontak asb. die Departement Kommunikasiepatologie van die Universiteit van Pretoria, Tel: (012) 420 2357.

Baie dankie

Mev. Nicolize Cass M.Kommunikasiepatologie student	Dr. C. van Dijk Navorsingsleier
Prof. B. Louw Hoof: Dept. Kommunikasiepatologie	Dr. D. Swanepoel Mede-navorsingsleier

Universiteit van Pretoria
Departement Kommunikasiepatologie

Van: _____ **Naam:** _____

Kind se naam: _____ **Kind se geboortedatum:** _____

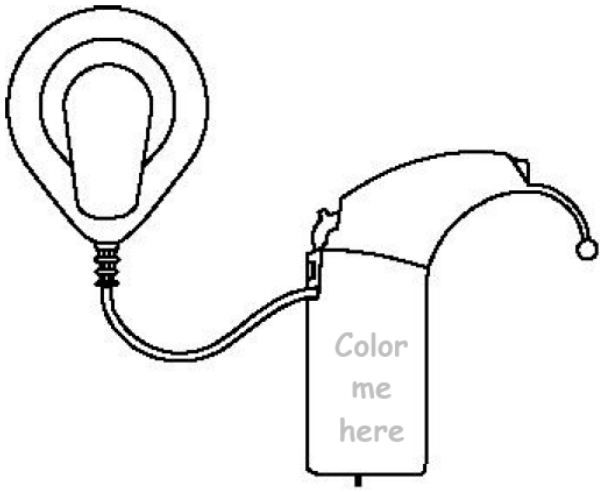
Ek/Ons gee hiermee toestemming dat ……., mag deelneem aan die bogenoemde navorsingsprojek. Ek verneem dat ons ter enige tyd van die studie kan onttrek sonder enige gevolge.

Handtekening: _____ **Datum:** _____

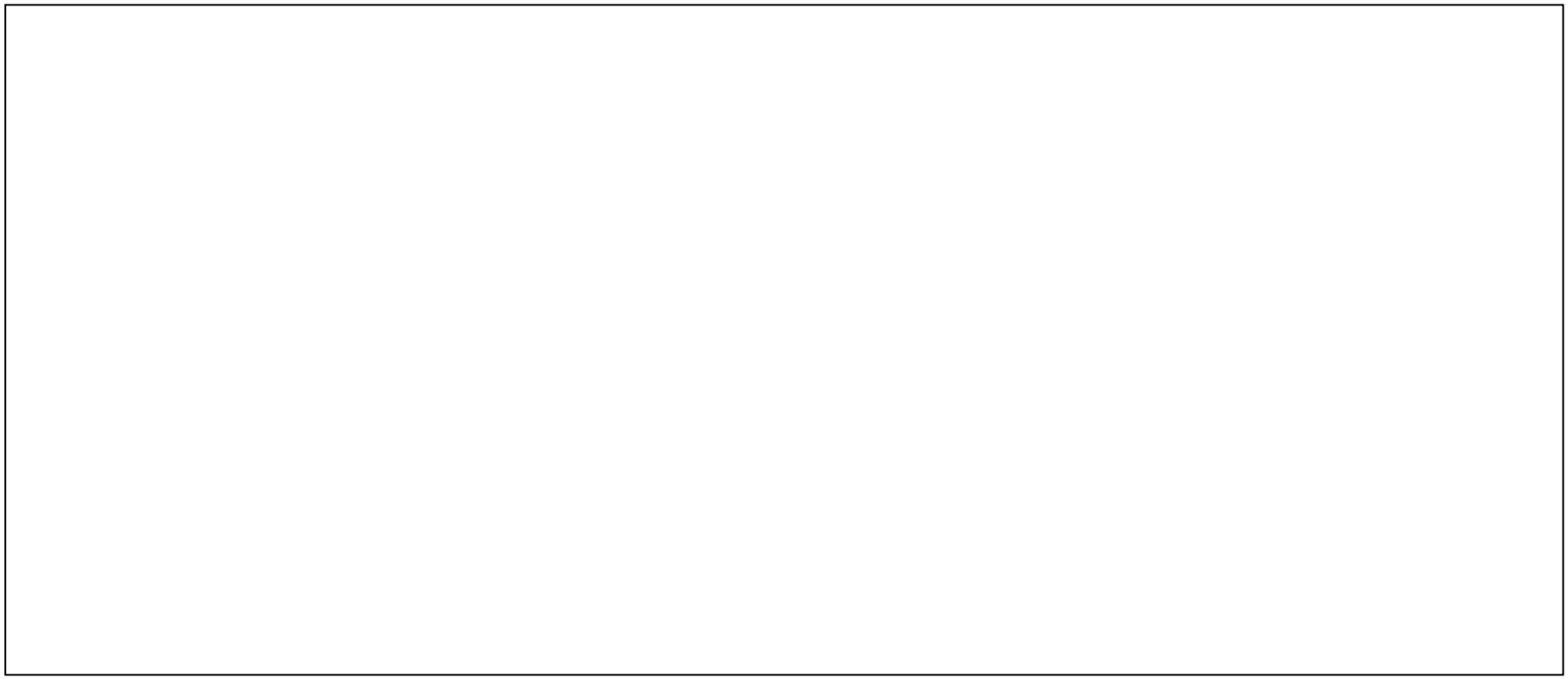
APPENDIX D

COLOURING BOOK FOR INFORMED CONSENT FROM CHILDREN

I am helping Nicolize to learn more about Cochlear Implants…

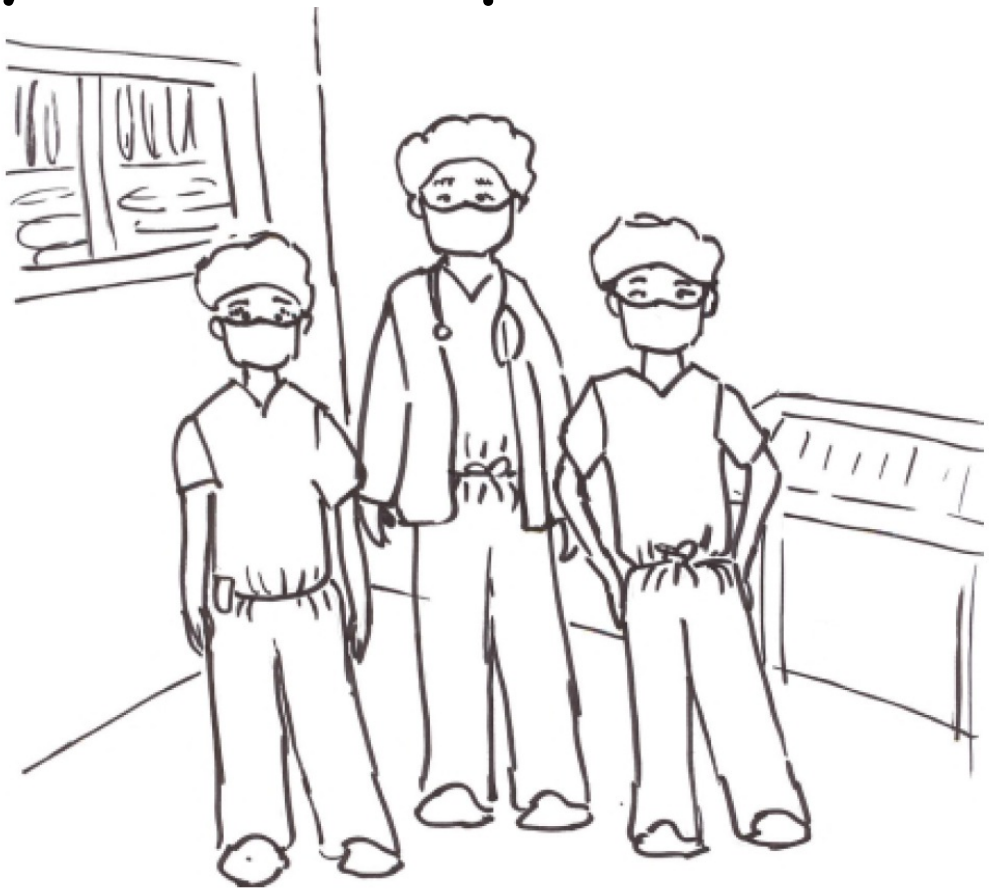


I am getting a cochlear Implant!



Draw or paste a picture of me

In the hospital, Nicolize will come to make sure that my cochlear implant is working fine.



Later, when we switch my cochlear implant on for the first time, Nicolize will check the implant again.

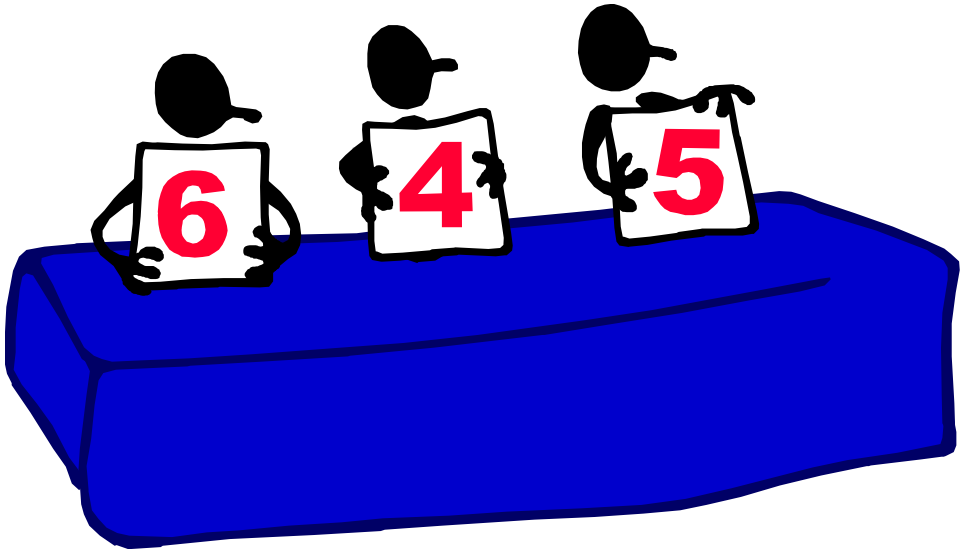
I will have to listen very carefully!

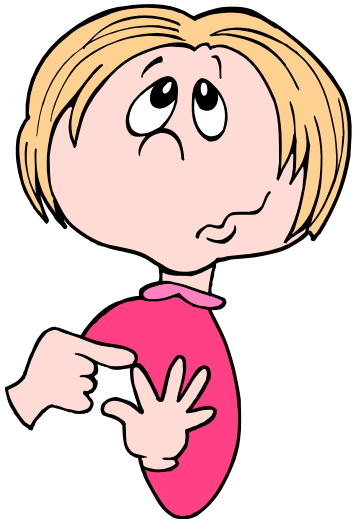
I can hear my friend talking!

Every time we visit Nicolize, she will check my cochlear implant.

The sounds I will hear will be very loud! I will not get hurt at any time!

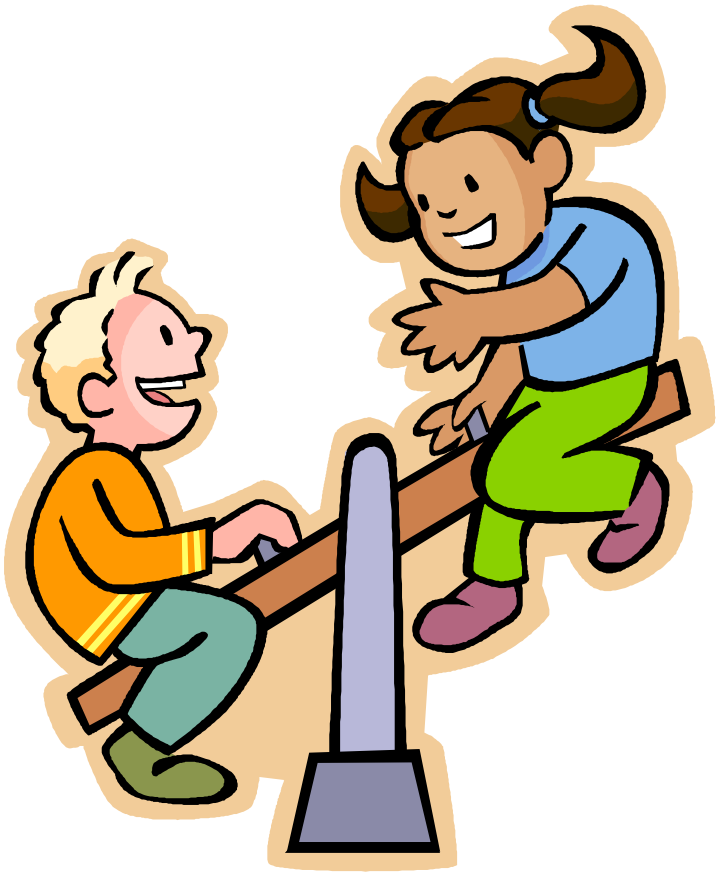
Nicolize will also check other kids' cochlear implants. Every one of us will have our own number so nobody else will know my name.





Nicolize will write a story about all the Kids' cochlear implants.

This book will help Audiologists to help other kids with cochlear implants.



If I don't want Nicolize to check my cochlear implant, I can ask her to stop.

She will not be angry. Mommy and Daddy won't mind either.

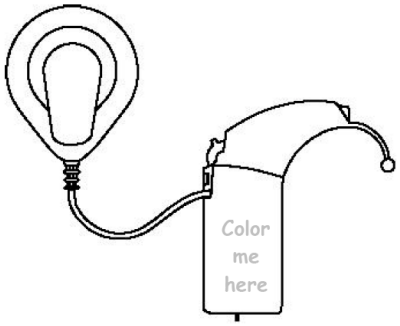
I will help Nicolize to write a story about cochlear implants.

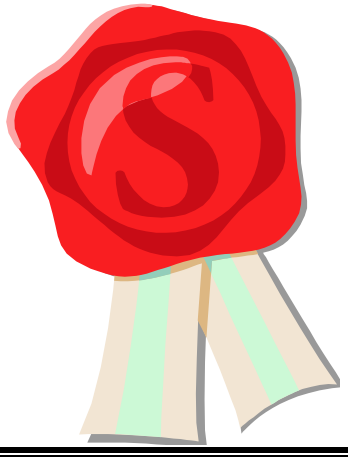
Write your own name here or draw a picture of yourself.

This certificate is presented to

_____

for helping Nicolize to learn more about cochlear implants.





APPENDIX E

LETTER OF INFORMED CONSENT: PROF JG SWART

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

31 Maart 2006

Geagte Prof. Swart

Toestemming: Langtermynstudie oor Nucleus Freedom™ se NRT- en Impedansmetings

Ek is tans besig met die beplanning van 'n navorsingsprojek oor die nuwe Auto-NRT™-meting van die Nucleus Freedom, ten voldoening aan die vereistes vir die M.Kommunikasiepatologie Graad. Die Auto-NRT sal uitgevoer word tydens chirurgie en roetinegewys as deel van elke opvolgsessie. Hierdie data word gebruik om die funksionering van die inplanting te monitor, maar assisteer ook met die eerste aanskakeling deur stimulasievlakke voor te stel. Die pediatriese populasie sal spesifiek aandag geniet.

Die doel van die studie is om die stabiliteit van T-NRT metings en Impedansmetings soos gemeet deur die nuwe Auto-NRT, te ondersoek oor ,n periode van 12 maande binne die pediatriese populasie (0 – 6 jaar). Soos reeds genoem, is hierdie metings deel van die standaard opvolgsessies gedurende die eerste 12 maande. Die deelname aan die studie sal dus nie aanspraak maak op enige ekstra tyd of afsprake van die respondente nie. Ons verseker u dat alle inligting vertroulik behandel sal word en dat alle respondene anoniem sal bly.

Graag vra ek u toestemming vir die uitvoer van die projek en gebruik van toerusting en pasiente van die Pretoria Kogleere Inplantingsprogram.

Ek bedank u en u span vir die geleentheid om hierdie projek te mag aanpak en sien uit daarna om die resultate met u te deel.

Indien u enige verder inligting verlang, kontak as. die Departement Kommunikasiepatologie van die Universiteit van Pretoria, Tel: (012) 420 2357.

Baie dankie

Nicolize Cass
M.Kommunikasiepatologie student

Dr. Catherine van Dijk
Navorsingsleier

Prof. B. Louw
Hoof: Dept. Kommunikasiepatologie

Dr. De Wet Swanepoel
Mede-navorsingsleier

Ek,…….gee hiermee toestemming dat Nicolize Cass, mag voortgaan met die bogenoemde navorsingsprojek.

Handtekening: _____ **Datum:** _____

APPENDIX F

IMPEDANCE TELEMETRY DATA COLLECTION SHEET

IMPEDANCE TELEMETRY DATA COLLECTION SHEET	
Respondent nr:	
Intra-Operative:	
Device Activation:	
3 months follow up:	
6 months follow-up:	
9 months follow-up:	
12 months follow-up:	

Electrode nr:	CG	MP1	MP2	MP1+2
22				
21				
20				
19				
18				
17				
16				
15				
14				
13				
12				
11				
10				
9				
8				
7				
6				
5				
4				
3				
2				
1				

APPENDIX G

NRT COLLECTION SHEET

NRT DATA COLLECTION SHEET	
Respondent nr:	
Intra-Operative:	
Device Activation:	
3 months follow up:	
6 months follow-up:	
9 months follow-up:	
12 months follow-up:	
Electrode nr:	Current level:
22	
21	
20	
19	
18	
17	
16	
15	
14	
13	
12	
11	
10	
9	
8	
7	
6	
5	
4	
3	
2	
1	

APPENDIX H

LETTER OF ETHICAL CLEARANCE: ETHICS COMMITTEE FACULTY OF HUMANITIES UNIVERSITY OF PRETORIA

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

University of Pretoria

Research Proposal and Ethics Committee
Faculty of Humanities

16 April 2007

Dear Dr van Dijk

Project: ***Monitoring longitudinal behaviour of Impedance and Neural Response Telemetry measurements in a group of young cochlear implant users***

Researcher: **N Cass**
Supervisor: **Dr C van Dijk**
Department: **Communication Pathology**
Reference number: **97029182**

Thank you for your response to the Committee's letter of 8 December 2006.

I have pleasure in informing you that the Research Proposal and Ethics Committee formally approved the above study at an *ad hoc* meeting held on 16 April 2007. The approval is subject to the candidate abiding by the principles and parameters set out in her application and research proposal in the actual execution of the research.

The Committee requests you to convey this approval to Ms Cass.

We wish you success with the project.

Sincerely

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