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Gautschi, Katherine

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Preservation of Residual Hearing after Cochlear Implant Surgery: An Exploration of Residual Hearing Function in a Group of Recipients at South African Cochlear Implant Units

Katherine Gautschi

A Research Dissertation submitted for
The Degree of Master of Audiology
Faculty of Humanities
University of the Witwatersrand

June 2014

Acknowledgements

This Masters dissertation is dedicated to my beloved brother Rob. His intelligence, love and compassion for others was an inspiration to me. Rob touched many lives and will always be remembered.

I would like to express my sincere appreciation and gratitude to the following people, without whom this dissertation would not have been possible:

Professor Katijah Khoza-Shangase, my supervisor, for her valuable input and encouragement during the supervision of my dissertation.

Dhanashree Pillay, my co-supervisor, for her support throughout this process.

To the surgeons and audiologists who participated in this study – thank you for your valuable contribution.

To the cochlear implant participants – thank you for making this study possible.

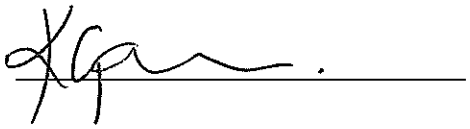
To my parents, Jenny and Johann, for their endless support, love, guidance and encouragement.

To my husband, Richard, for his unfailing love, endless support, advice, reassurance and patience throughout this process.

Author's Declaration

I, Katherine Jeanne Gautschi, declare that the dissertation entitled "Preservation of Residual Hearing following Cochlear Implant Surgery: An Exploration of Residual Hearing Function in a Group of Recipients at South African Cochlear Implant Units" is my original work. Authors have been acknowledged and referenced throughout. This dissertation has been submitted for the Degree of Master of Arts in Audiology at the University of the Witwatersrand and has not been submitted to any other university for examination.

Katherine Gautschi



Date: 30/06/2014

Abstract

The preservation of residual hearing is becoming increasingly important in cochlear implant surgery. Surgical and technological advancements have resulted in this preservation, which have in turn led to the expansion of the inclusion criteria. Conserving residual hearing is a positive prognostic indicator for improved hearing abilities. ***Objective:*** The primary aim of the current study was to explore the preservation of residual hearing following cochlear implantation in a group of recipients at two major cochlear implant centres in South Africa. Secondary objectives included investigating whether a relationship existed between the hearing findings and certain factors, namely aetiology, age, gender, the duration of pre-operative hearing loss, degree of pre-operative hearing, duration between surgery and unaided post-operative hearing testing, model and manufacturer of implant, surgical technique employed and surgical complications relating to intracochlear structures. ***Design:*** A quantitative paradigm was adopted and exploratory research conducted, with a retrospective data review being the design followed. ***Study sample:*** The sample consisted of audiological records from 60 observations - i.e. 53 patients, seven of whom were fitted bilaterally. Additionally, the sample consisted of 50 surgical records. The audiological and surgical records were selected using purposive sampling and consisted of records from post-lingually hearing-impaired participants (ranging from six to 59 years), and pre-lingually hearing-impaired children (from six years). ***Data analysis:*** The researcher conducted a comparative analysis of unaided audiological test results pre- and post-operatively. Factors documented to have a possible influence on cochlear implant surgery outcomes were examined in an attempt to establish relationships that may exist. Findings were analysed by means of both inferential and descriptive statistics. ***Results:*** Results indicated a high success rate of 92% preservation of residual hearing – 42% partial and 50% complete - in cochlear implant recipients across all frequencies post-operatively. A total post-operative hearing loss was found in only 8% of cochlear implantees across all frequencies. There was a direct correlation between the surgical techniques as well as cochlear implant type and the successful hearing findings, in the absence of surgical complications. Preservation was achieved with the majority of implantees receiving the Contour Advance electrode from Cochlear with complete insertion via the scala tympani and the Advance Off-Stylet surgical technique being used. Surgical complications had significant negative effects on the post-operative hearing outcomes and resulted in hearing loss. Other factors explored, namely the duration and degree of pre-operative hearing loss and duration between surgery and unaided post-operative hearing testing did not have any negative effect on the hearing findings and positive outcomes were achieved, regardless of age, gender and aetiology of hearing loss. ***Conclusions:*** Findings suggest

that cochlear implant surgery is successful in terms of preservation of residual hearing and that factors such as age, gender, aetiology of hearing loss and degree of pre-operative hearing loss did not have an impact on the hearing findings post-operatively. It is apparent that where there were no surgical complications, the surgical techniques and implant type used by the surgeons in this study resulted in positive outcomes and successful preservation of post-operative residual hearing - this was evidenced by a 92% hearing preservation rate. This is a positive prognostic indicator for individuals with pre-operative residual hearing as the preserved residual hearing allows for the potential of electro-acoustic stimulation (EAS), which in turn has its own hearing benefits. These findings will add to the limited body of knowledge on the topic in South Africa. Furthermore, these findings have implications not only for audiologists, but for Ear, Nose and Throat surgeons and other professionals working in the field as well as for future cochlear implant candidates with residual hearing, medical aids and the Department of Health in South Africa.

Keywords: cochlear implant, cochlear implantees, preservation, residual hearing, cochlear implant surgery

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i. Definition of terms

The following definitions are either frequently-used terms or terms that may require clarification:

Advance off-stylet (AOS): a non-invasive surgical technique involving inserting the electrode and stylet through the cochleostomy until a marker on the body of the electrode array is reached at the opening; the electrode array is advanced off the stylet until full insertion is achieved and the stylet is then removed

Cochleostomy: an opening of the perilymphatic spaces of the cochlea

Contour Advance electrode: an electrode designed for atraumatic scala tympani insertion of the electrode array during cochlear implantation

Electro-acoustic stimulation (EAS): involves using a combination of cochlear implant and hearing aid in the same ear and is used for implantees whose low to mid-frequency residual hearing has been preserved post-operatively

Endosteum: the layer of vascular connective tissue lining the medullary cavities of bone

Mastoidectomy: type of surgery that removes a portion of the mastoid bone for insertion of the cochlear implant into the inner ear at the correct angle, achieving good visualization

Scala Tympani: the lower most channel and terminates basally at the round window

Scala Vestibuli: the uppermost of the two perilymph-filled channels of the cochlear duct and terminates basally at the oval window

"Soft surgery" technique: a surgical technique designed to minimize trauma to the inner ear, thereby preserving residual hearing by avoiding intracochlear suctioning and preventing entry of bone dust and blood

Posterior tympanotomy: a surgical approach to the middle ear designed to expose the round window

ii. Abbreviations

AC: air conduction

AOS: Advance off-stylet

BC: bone conduction

dB: decibel

CH: change (in residual hearing)

COMPLIC: surgical complications

DUR: duration of hearing loss prior to surgery (in years)

EAS: electro-acoustic stimulation

EA_DEPTH: electrode array depth

EA_INS: electrode array insertion

EA_TYPE: electrode array type

GLM: General Linear Model

HL: hearing loss

HTL: hearing threshold level (s)

Hz: hertz

IM_MANU: implant manufacturer

IM_TYPE: type of implant

LAT: coding for unilateral or bilateral

MAR: Missing at Random

n: number of observations of sub-sample

N: number of observations of total sample

NF: Nucleus Freedom

NR: no response

Overall: Unit A and Unit B combined

POST: post-operative

PRE: pre-operative

PTA: pure tone average

RWM: round window membrane

s.d.: standard deviation

SNHL: sensori-neural hearing loss

SPL: sound pressure level

SURG_TECH: surgical technique

T_POST: time between surgery and first post-operative hearing test, in months

T_PRE: time between last pre-operative hearing test and surgery, in months

UNIT (S): cochlear implant centre(s) – Unit A, B and C

iii. Chapter outlines

Chapters 1 and 2 offer an introduction to the current study, incorporating its rationale, stressing the importance and relevance of the current study, as well as a literature review to provide evidentiary support for the conceptual framework.

Chapter 3 presents the methodology adopted in the current study. This commences with a presentation of the research aims and design adopted. Participant description, selection and sampling strategy are also set out, allowing the researcher the opportunity to discuss in depth the processes followed to allow for replicability of the study. Methods of data collection and data analysis are discussed. Reliability and validity as well as ethical considerations are then addressed in this chapter.

Chapter 4 is an integrated presentation of the results and a discussion of the findings. The results are presented with reference to the objectives of the study and the findings critically analysed and discussed. Comparisons are drawn between current findings and existing evidence. Reference is made to published evidence where the findings of the current study are supported. In this chapter, the researcher aims to use the research in order to make clinical sense of the findings so as to arrive at conclusions and implications for policy formulation, future research and clinical management.

Chapter 5 summarizes the main findings and sets out the conclusions and recommendations of the current study. A description of the strengths and limitations of the study, as well as recommendations and implications for the field of cochlear implantation concludes this chapter.

CHAPTER 1: INTRODUCTION

Chapter 1: Introduction

1.1. Overview

"The preservation of residual hearing is becoming a high priority in cochlear implant surgery" (Berrettini, Forli & Passetti, 2008, p.246). Internationally, cochlear implants are believed to have become the main form of management for severe-profound bilateral hearing loss (Di Nardo, Cantore, Melillo, Ciafrone, Scorpecci & Paludetti, 2007). Gstoettner, Helbig, Settevendemie, Baumann, Wagenblast and Arnoldner (2009) and Lenarz, Stöver, Buechner, Lesinski-Schiedat, Patrick and Pesch (2009). Lenarz et al. (2009) observe that this development has emerged over the last two decades.

According to the World Health Organisation, in 2012 there were 360 million individuals with a disabling hearing loss world-wide, representing 5.3% of the world's population (WHO, 2012). In 2001, 20% of the South African population presented with hearing disability (Stats SA, 2001). Currently, there are more than 120 000 cochlear implantees worldwide (Steve Biko Academic Hospital Board, Robert Kerr Trust Health Programme, 2011). In South Africa, more than 1 000 individuals benefit from having cochlear implants (Steve Biko Academic Hospital Board, Robert Kerr Trust Health Programme, 2011). From the abovementioned statistics, it can be deduced that the majority of hearing-impaired individuals in South Africa do not have access to cochlear implants.

In the past, only profoundly hearing-impaired individuals (i.e. those with no residual hearing) were implanted (Verhaegen, Snik, Beynon, Leeuw & Mylanus, 2010) due to the risks involved intra-operatively (Gstoettner et al., 2009) and trauma to intracochlear structures from electrode insertion (Balkany, Connell, Hodges, Payne, Telischi, Eshraghi et al., 2006), resulting in loss of residual hearing. The inclusion criteria for recipients have, however, recently expanded (Verhaegen et al., 2010). Within the last decade individuals with some residual hearing became eligible for implantation (Verhaegen et al., 2010; Gstoettner et al., 2009) due to technological advancements (Skarzynski, Lorens, Piotrowska, & Podskarbi-Fayette, 2009), improvements in surgical techniques (Gstoettner et al., 2009; Lenarz et al., 2009), less traumatic electrode array insertion (Lenarz et al., 2009), and because pre-operative residual hearing has become a good prognostic indicator for cochlear implantation (Kiefer, Gstoettner, Baumgartner, Pok, Tillein, Ye et al., 2004). With increased numbers of people receiving cochlear implants, the seemingly

expanding criteria for implantation (Briggs, Tykocinski, Stidham & Roberson, 2005), the continuous increased success rate of cochlear implants over the last two decades (Kiefer et al., 2004) and the positive performance indicators of pre-operative residual hearing (Verhaegen et al., 2010), preservation of residual hearing has taken centre stage; hence the importance of the current study.

Over the past 20 years, technological advances in cochlear implantation and improvements in surgical techniques have increasingly progressed at a precipitous rate (Balkany et al., 2006). These advances played an important role in limiting intracochlear damage caused by insertion of electrode arrays (Skarzynski & Podskarbi-Fayette, 2010). The developments resulted in improved speech perception, which in turn led to an expansion of the inclusion criteria (Balkany et al., 2006). Hitherto, many patients were frequently excluded from being implanted as a result of having residual hearing in the low frequencies. This was the case even though these patients experienced poor speech discrimination when fitted with high quality digital hearing aids (Skarzynski & Podskarbi-Fayette, 2010). Prospective implantees with greater degrees of residual hearing are now candidates for the procedure (Balkany et al., 2006). The expansion in the inclusion criteria has led to better outcomes, as recipients with residual hearing can now experience improved performance post-surgery (Balkany et al., 2006). Recent developments in surgical techniques and electrode arrays have resulted in limited trauma to intracochlear structures (Balkany et al., 2006) and subsequent preservation of residual hearing.

In the past it was believed that residual hearing was lost during cochlear implantation as a result of trauma caused by the insertion of the electrode array (Balkany et al., 2006). The said recent advances have led to more positive outcomes post-operatively for implantees with pre-operative residual hearing. A further and most significant advance has been the introduction of bimodal electric-acoustic stimulation (EAS), which involves using a combination of cochlear implant and hearing aid in the same ear (Balkany et al., 2006). This is used for implantees whose low to mid-frequency residual hearing has been preserved post-operatively (Balkany et al., 2006) and has considerable benefits for hearing. As more hearing-impaired patients with low frequency residual hearing are being implanted and as EAS becomes a reality, so the preservation of residual hearing has achieved a level of clinical significance (Balkany et al., 2006).

1.2. Definition of cochlear implants

A cochlear implant is an electronic device, which is implanted surgically into the cochlea in patients with bilateral severe-to-profound sensori-neural hearing loss, who derive limited or no benefit from hearing aids (Clark, 2003; House & Berliner, 1991; Kirtane, Mankekar, Mohandas, & Patadia, 2010). A cochlear implant has internal components which consist of a receiver-stimulator and an electrode array, and external components which consist of a microphone, speech processor and transmitter coil (Kirtane et al., 2010). A directional microphone picks up environmental sounds and transmits them to a speech processor, where sound is processed. These are then converted into electrical signals which are transmitted through the skin to a receiver-stimulator implanted in the mastoid bone via a transmitter coil (Clark, 2003; Kirtane et al., 2010). The signals are decoded by the receiver-stimulator. Electrode arrays placed around the first turn of the cochlea elicit currents which electrically stimulate the spiral ganglion cells in the scala tympani (Clark, 2003). Impulses are then sent to the brain via hearing nerve fibres (Clark, 2003; Kirtane et al., 2010) for the sound to be heard and interpreted. In this way, cochlear implants afford hearing to those with hearing impairment who are candidates for the procedure.

Advancements in cochlear implant technology have enabled individuals who receive little or no benefit from hearing aids to be implanted (Skarzynski et al., 2009; Briggs et al., 2005 & Koike, 2006). Hearing aids provide amplification to increase the intensity of the signal, but may not be sufficient for individuals with severe hearing impairment who have poor auditory discrimination (Koike, 2006). A cochlear implant bypasses the non-functional inner ear, directly stimulating the auditory nerve through an electro-physiological process (Koike, 2006) and thus offers more benefit to these individuals with poor auditory discrimination.

1.3. Historical background

The history of cochlear implants can be traced back to 1790, when Volta, an Italian physicist, tried to stimulate the hearing nerve by placing two metal rods, connected to batteries, into his ear (Clark, Tong & Martin, 1981). In 1957, Djourno and Eyres performed the first cochlear implant surgery in Paris. The patient was able to hear sounds and a few words and could distinguish some distinctive frequency changes, but speech perception was not achieved (Mangus, Rivas, Tsai, Haynes & Roland, 2012). Dr. William House introduced the single-

electrode cochlear implant (Moller, 2006). In approximately 1960, William F. House implanted 2 patients – one with a multi-electrode implant. Both patients had to be have their implants removed due to infection and rejection. Prior to rejection of the implants, there was some auditory input (Niparko, 2000). In the 1960s, F. Blair Simmons and Robin Michelson experimented with and implanted single-electrode cochlear implant devices (Niparko, 2000). Further developments culminated in Graeme Clark and his multi-disciplinary team successfully performing the first multi-channel cochlear implantation in 1978 in Melbourne, Australia (Clark et al., 1981).

In South Africa, the first cochlear implant was performed at the University of Stellenbosch Tygerberg Cochlear Implant Unit (US-TBH CIU) in 1988 (Müller & Wagenfeld, 2003). Subsequent cochlear implant centres in South Africa include those in Pretoria, Johannesburg, Bloemfontein, Durban, Port Elizabeth and East London (D. Schlesinger, personal communication, February 17, 2011; L. Müller, personal communication, March 5, 2011). Through the 1980s and 1990s, there were developments in speech processing strategies and a reduction in the size of the external device (Kirtane et al., 2010) Additional features were introduced to ensure the safety of cochlear implants. These developments made cochlear implants significantly valuable for profoundly hearing-impaired individuals (Kirtane et al., 2010). Recent developments have led to severe-to-profound hearing-impaired individuals with low frequency residual hearing being implanted as a result of refined surgical techniques and improved electrode designs (Gstoettner et al., 2009 & Lenarz et al., 2009).

1.4. Context of study

- **Relevance in South Africa in relation to financial constraints**

According to the American Speech-Language Hearing Association (ASHA), "the overall cost of cochlear implants ranges from $45, 000 to $105 000" (cited in Moctezuma & Tu, 2011, p. 3), and some of the cost is covered by health insurance. This fee covers the pre-surgery evaluation, surgery, the device package, hospitalization, programming, and rehabilitation. The procedure involves the expertise from a team comprised of an audiologist, an otologist/neurosurgeon, a counsellor/psychologist, and a speech pathologist (Moctezuma & Tu, 2011). By 2008, there were over 120 000 cochlear implantees globally (Mangus et al., 2012). According to the American Speech-Language Hearing Association (2011), cochlear implants,

on average, cost in excess of $40 000 for the procedure and post-operative aural rehabilitation (American Speech-Language Hearing Association, 2011). Research in Stellenbosch, South Africa, has shown that the initial purchase of the implant system is the most substantial cost involved in cochlear implantation and amounts to a total of R221 000. The research also indicated that cost of the procedure, including the follow-up costs, over the next 10 years would amount to R379 626 and R455 225 for adults and children respectively (Kerr, G, 2010; University of Stellenbosch).

Cochlear implants are unaffordable and unattainable for the majority of candidates in developing countries such as South Africa, where there are significant financial constraints (Statistics South Africa, 2011). In September 2010, Statistics South Africa found that the total number of paid workers was 12.9 million and the median monthly earnings amounted to R2 812 (Statistics South Africa, 2010). These statistics illustrate the financial constraints endured by many South Africans and the lack of funds available for what could be deemed an expensive procedure, such as cochlear implantation, which would compete with basic needs such as food and shelter for the average South African. Wagenfeld, Loock, Müller, Perold, Kerr and Kaltenbrünn (2004) highlight that there are minimal resources and limited allocation of funds for cochlear implantation in South Africa. Müller and Wagenfeld (2003) further hold that resources are considerably limited in South African society and that there is major competition for funds.

At the US-TBH CIU, between 1985 and 2003, roughly 241 of 439 cochlear implant candidates could not undergo cochlear implant surgery due to socio-economic status (Wagenfeld et al., 2004). In South Africa, for those individuals who can afford privately funded healthcare, some but not all medical aids, in recognition of the value of cochlear implants, partially contribute towards the cost of cochlear implantation (Profmed Schedule of Benefits, 2011; Discovery Schedule of Benefits, 2011). However, medical aid is only available to a select few individuals in this developing country. Of a total population of 49.869 million South Africans in 2010, the total number of South Africans with medical aid coverage amounted to 8.742 million people (Statistics SA, 2010). There is therefore a major discrepancy in the funding available to those in the private and public health sectors in South Africa (Wagenfeld et al., 2004); and consequently there is also a major discrepancy in availability and access to services in these sectors.

Due to the significant costs involved in cochlear implantation and because of the limited financial resources in relation to all factors including burden of disease, the researcher of the current study holds that there are factors that may influence government policies and medical aids in South Africa to provide more funding towards this procedure. Gstoettner et al. (2009) assert that the attendant risks of implantation are being demonstrably minimized and that there are considerable advancements in the preservation of residual hearing. The current researcher is in support of Gstoettner et al. (2009) and believes that these assertions are factors which could influence both government policies in South Africa with regard to the funding of cochlear implantation and could also provide motivation for medical aids to provide more funding for the procedure - hence one of the motivations for the current study.

1.5. Rationale

The literature provides abundant evidence that the preservation of low frequency residual hearing is an achievable outcome. However, despite all attempts to preserve their residual hearing, some implantees continue to lose their hearing post-cochlear implantation (Gstoettner et al., 2009). In the light of this, it was relevant that the researcher explored whether the implantees in this study preserved their residual hearing post-operatively - this being a rationale for the current study.

Although some implantees continue to lose their residual hearing post-surgery despite all efforts to preserve it, the rate at which implantees are preserving their residual hearing is increasing at a steady pace. The reason for this is because of expanding knowledge and experience of advancements in electrode designs and surgical techniques, resulting in minimal trauma (Gstoettner et al., 2009, p. 372). Therefore, the researcher considered that it was pertinent to establish whether the refinements in surgical techniques and improved electrode designs resulted in better outcomes in terms of hearing preservation post-operatively. This was another motivating factor for the current study.

The researcher's rationale for determining the relevance of whether residual hearing could be preserved post-operatively, was to establish whether the implantees with successfully preserved hearing could be candidates for EAS - which provides considerable benefits for hearing. The advantages of utilising EAS highlight the importance of the current study. EAS can only be

used if residual hearing is preserved (Balkany et al., 2006) and therefore this is an additional motivation for this study.

In the study of Adunka, Pillsbury and Buchman (2010), they found that the majority of cochlear implant recipients retained their residual hearing post-operatively. However, 90% achieved only partial preservation, leading them to conclude that "further work is clearly needed to optimize surgical protocols in an attempt to achieve total hearing preservation in all cases." This is a motivating factor for the current study. In this study, the researcher wished not only to determine the preservation of residual hearing in a group of cochlear implant recipients at two centres in South Africa, but also to determine the extent of preservation – i.e. partial versus complete hearing preservation.

In the current study, the researcher aimed to contribute to the literature internationally and to address the current paucity of research into the preservation of residual hearing following cochlear implantation in South Africa.

The researcher in this study hopes to have produced research that "should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature" (Nuremberg Code, 1949, p.182).

CHAPTER 2: LITERATURE REVIEW

Chapter 2: Literature Review

2.1. Introduction

Cochlear implants have revolutionized the way we approach rehabilitation of patients with severe to profound hearing impairment in restoring speech understanding (Skarzynski & Podskarbi-Fayette, 2010). Success in conservation of residual hearing after cochlear implantation has benefited patients with high levels of residual low frequency hearing who were not previously considered for conventional cochlear implantation (Skarzynski & Podskarbi-Fayette, 2010).

Since the inception of cochlear implantation, profoundly hearing impaired individuals have had access to a device which enables them to hear speech sounds hitherto denied them. Verhaegen et al. (2010) have discussed how the advent of cochlear implantation has enabled individuals with bilateral profound sensori-neural hearing impairment (who obtain minimal or no benefit from hearing aids) to be effectively rehabilitated. Gstoettner et al. (2009) have observed that over the last two decades, cochlear implants have become the standard mode of intervention for individuals with profound sensori-neural hearing loss. In their study in 2009, Lenarz et al. (2009) held that cochlear implantation is the "current treatment of choice in patients with profound sensori-neural hearing loss" (p. 22).

As early as 1997 it was reported in a study conducted by Hodges, Schloffman and Balkany (1997) that there was preservation of residual hearing in about 50% of implantees (Balkany et al., 2006). However, early reports in the literature on the efficacy of cochlear implantation indicated that there were significant decreases in residual hearing following surgery, with most implantees losing their residual hearing following implantation (Di Nardo et al., 2007). As a result, only profoundly hearing-impaired individuals were implanted (Di Nardo et al., 2007). Briggs et al. (2005) have referred to the fact that initially candidates who were selected for implantation had little residual hearing. Moreover, the fact that there was a significant reduction in residual hearing post-operatively was a source of concern for both recipients and professionals in the field (Di Nardo et al., 2007). Di Nardo et al.'s (2007) study lead these researchers to conclude that loss or reduction of residual hearing had implications and resulted in limited efficacy because optimal benefits could not be obtained.

James, Albeger, Battmer, Burdo, Deggouj, Deguine, et al. (2005), on the other hand, have reported that some researchers had documented a partial retention of residual hearing following cochlear implant surgery. Di Nardo et al. (2007) found evidence in the literature that it was possible to have minimal trauma to structures in the cochlea following electrode array insertion during cochlear implant surgery. Furthermore, Skarzynski et al. (2009) observed that recent research demonstrated the preservation of residual hearing following surgery.

Regardless of these contradictory reports, researchers have shown there to be increased benefits for cochlear implant recipients and technological advancements in cochlear implantation (Briggs et al., 2005). Therefore, there has been an expansion of the criteria for candidacy for cochlear implants (Briggs et al., 2005) and the inclusion criteria have broadened to include patients with severe-profound sensori-neural hearing loss (Koike, 2006).

Approximately ten years ago, hearing-impaired individuals with some residual hearing became suitable for implantation (Verhaegen et al., 2010; Gstoettner et al., 2009). This enabled individuals who were previously denied cochlear implantation the opportunity to undergo the procedure. Gstoettner et al. (2009) stated that "the rate of hearing preservation has steadily increased as a result of our growing experience of more refined and less traumatic surgical techniques and improved electrode designs" (p. 372). Lenarz et al. (2009) have postulated that increased surgical experience along with less traumatic electrode insertion have resulted in a dramatic increase in hearing preservation following implantation.

2.2. Preservation of residual hearing

Several authors have argued for the importance of hearing preservation with cochlear implantation, although Verhaegen et al. (2010) have noted that not all researchers believe that residual hearing is a positive predictor for cochlear implantation. Nonetheless, according to Verhaegen et al. (2010) and Kiefer et al. (2004), residual hearing is a positive prognostic indicator for good performance with cochlear implants. The researcher in the current study reviewed the studies of Kiefer et al. (2004) and Berrettini et al. (2008) amongst others and found a common link between these two studies, in that they both demonstrated that residual hearing following cochlear implant surgery allowed for long-lasting and stable performance related to speech understanding. Berrettini et al. (2008) observed that cochlear implantation resulted in improved speech perception. Researchers in South Africa, Müller and Wagenfeld

(2003), also believe that the amount of pre-operative residual hearing affects the outcomes and performance of speech perception in cochlear implantees post-operatively. It is for these reasons that the researcher in the current study aimed to explore residual hearing conservation following cochlear implantation in the chosen population.

Skarzynski, Lorens, D'Haese, Walkowiak, Piotrowska, Sliwa et al. (2002) investigated the preservation of residual hearing with the use of the "soft surgery" technique and atraumatic electrode insertion. In their study, 62% of implantees retained their residual hearing and 19% experienced a total loss of functional hearing. Skarzynski et al. (2002) found that age, gender, aetiology and implant type did not have an influence on the hearing findings. The current researcher investigated possible influencing factors and their effects on the preservation of residual hearing.

Cosetti et al. (2013) also examined the effects of certain factors on the conservation of post-operative residual hearing. They found that whilst age had an effect on the hearing findings, gender, aetiology, degree and duration of pre-operative hearing loss and implant type did not negatively impact the preservation of residual hearing.

Although "the mechanisms of hearing loss that occur after cochlear implant surgery are not well known" (Derinsu, Serin, Akdas, & Batman, 2011, p. 522), researchers have investigated surgical techniques to ascertain which techniques minimize the loss of residual hearing. The researcher in the current study discusses different surgical techniques, such as the "soft surgery" and Advance off-stylet (AOS) techniques, which may have positive outcomes relating to the preservation of residual hearing.

2.2.1. Technological and surgical advancements

There have been significant surgical and technological advancements in recent years resulting in trauma to the cochlea being minimized. Patients with low frequency residual hearing were not considered in the past for cochlear implantation, due to the risk of trauma to intracochlear structures during surgery which could result in residual hearing being destroyed. This was in spite of their having poor speech perception even with acoustic amplification. Research has found that patients with hearing thresholds beyond 55-60 dB HL derive little benefit from hearing aids (Skarzynski & Podskarbi-Fayette, 2010). Since 2002, many patients suffering from

high-frequency hearing loss above 500-750 Hz could be treated according to the protocol for cochlear implantation for partial deafness. Moreover, technological and surgical advancements have made it possible for residual hearing to be preserved in patients with some degree of low frequency hearing with total high frequency hearing loss (termed "ski-slope" or "cliff" hearing loss). In order to achieve this conservation, new electrodes were developed and successful preservation occurred with the use of short and medium length electrodes and both straight and perimodiolar electrode arrays (Skarzynski & Podskarbi-Fayette, 2010).

2.2.2. Surgical procedures

The aim of developing improved surgical procedures is to provide atraumatic surgical techniques, thereby minimizing intracochlear damage (Adunka et al., 2010). The researcher in this study holds that this should in turn result in the preservation of residual hearing – either partial or complete.

The surgical procedure for cochlear implants is described by Kirtane et al. (2010). An incision is made behind the ear and a well is created for the receiver-stimulator by drilling the cortical skull bone, after which a cortical mastoidectomy and a posterior tympanotomy is performed. The round window membrane is located and the cochleostomy is made just anterior and inferior to the round window. The receiver-stimulator in the well is secured by sutures to fix it in place. The electrode array is positioned into the cochleostomy, which is filled with connective tissue to avoid the cerebrospinal fluid from leaking or the cochlear implant from migrating (Kirtane et al., 2010).

2.2.3. Scala tympani vs. scala vestibuli

Adunka et al. (2010) suggest that the cochleostomy site should be located slightly anterior and inferior to the round window membrane, allowing an opening to be made into the scala tympani, thereby limiting damage to the cochlea (Adunka et al., 2010). According to them, due to refinements of the electrode arrays, less damage is caused during insertion (Adunka et al., 2010).

In a study conducted by Adunka, Kiefer, Unkelbach, Radeloff and Gstoettner (2005), the researchers investigated intracochlear trauma after implantation of different cochlear implant electrodes via the scala vestibuli. Findings indicated that electrode array insertions via the scala vestibuli did not cause severe osseous or neural structure trauma, thereby preserving the basis for EAS. However, damage to Reissner's membrane and to the Organ of Corti would impact negatively on residual hearing and result in the loss thereof (Adunka et al., 2005).

Recent studies suggest that the location of the electrode arrays should be within the scala tympani and it has been suggested that dislocation or placement into the scala vestibuli may lead to worse outcomes (Skinner et al., 2007; Aschendorff et al., 2007 as cited in Adunka et al., 2005).

2.2.4. Surgical approaches

According to Briggs, Tykocinski, Xu, Risi, Svehla, Cowan et al. (2006), the round window and cochleostomy approaches have both proven to be effective in preserving residual hearing in cochlear implantees.

James et al. (2005) observed that it is of paramount importance to reduce basal trauma. In order to achieve this, therefore, the method of opening the cochlea, either by a cochleostomy or round window approach, should be geared to avoid such trauma, whichever length of electrode is used (James et al., 2005). Mangus et al. (2012) concurred with James et al. (2005) and emphasized the importance of surgical techniques minimizing trauma to improve the patients' post-operative outcomes.

Moreover, to avoid damage to the intracochlear structures, surgeons should ensure that the cochleostomy site is slightly anterior and inferior to the round window, resulting in an opening into the scala tympani (Adunka et al., 2010). Adunka et al. (2010) recognised that a further precaution to limit intracochlear damage is to develop and fine-tune the electrode arrays. They found that these techniques resulted in hearing being partially preserved in almost 90% of cases (Adunka et al., 2010). The current researcher holds that this statistic indicates that the combination of these techniques resulted in a successful outcome.

Derinsu et al. (2011) support the round window approach and mention that this approach offers many benefits over the standard cochleostomy approach in terms of the electrode insertion. They assert that the round window approach results in a reduction in the amount of drilling, minimizing acoustic trauma by limiting the entry of bone dust into the scala tympani and reducing loss of perilymph. The round window approach has the further advantage of minimizing the risk of infection, as this technique facilitates the more effective sealing of the tissues around the electrodes, with the concomitant advantage of the promotion of accelerated healing (Derinsu et al., 2011). Round-window membrane insertion enables entry into the basal region of the cochlea in order for the neuronal elements located in the base of the cochlea to be stimulated for combined EAS (Derinsu et al., 2011). Derinsu et al. (2011) stressed the importance of minimizing trauma during surgery and of hearing preservation through the implementation of the round-window approach. These researchers mentioned that hearing preservation enabled EAS (Derinsu et al., 2011).

Derinsu et al. (2011) discussed how the goal of successful cochlear implantation is to ensure the least traumatic insertion of the electrode array in order to prevent damage to intracochlear structures, thereby ensuring the preservation of residual hearing. Derinsu et al. (2011) also hold the view that the insertion of the electrodes via the round window membrane minimizes damage to the cochlea during implantation more successfully than the traditional cochleostomy (Derinsu et al., 2011).

Derinsu et al. (2011) performed a retrospective study over approximately two years to evaluate the round window approach. They evaluated 31 patients who had been implanted via the round window membrane with full insertion of a standard array (Derinsu et al., 2011). They compared pre- to post-operative hearing thresholds from the range of 250 Hz to 4000 Hz. From their results, it became evident that low-frequency (250 Hz and 500 Hz) hearing preservation was accomplished in 87% (27 of 31 patients). Complete hearing preservation (all frequencies) was achieved in 35.48% (11 patients). Loss of post-operative hearing occurred in 12.9% (four patients). However, it must be noted that these four patients had a 120 dB pre-operative loss at 250, 500 and 1000 Hz (Derinsu et al., 2011). As a result, the current researcher observed that the change in residual hearing could not be calculated at these frequencies for these four patients. Derinsu et al. (2011) observed that the extensive use of the round-window approach has resulted in conserving residual hearing post-operatively (Derinsu et al., 2011).

Addams-Williams, Munaweera, Coleman, Sheperd and Backhouse (2011) found that the insertion of the electrode array via the round window was generally more successful in conserving residual hearing. These researchers assert that insertion of the electrode via a cochleostomy route could lead to intracochlear trauma (Addams-Williams et al., 2011), which could result in loss of hearing function post-operatively.

Mangus et al. (2012) have described the traditional cochleostomy and round window membrane approaches in their study and discussed the benefits of each technique with regard to the reduction in damage to intracochlear structures, thereby preserving residual hearing.

2.2.4.1. Traditional cochleostomy technique

According to Mangus et al. (2012), improved speech perception in noise and heightened listening ability can be achieved in patients with residual low-frequency hearing through improved surgical techniques, such as utilizing a short/hybrid electrode when the cochleostomy is performed. The traditional approach for performing a cochleostomy can potentially cause damage to basal turn structures. However, according to Mangus et al. (2012), many surgeons believe that this approach is the preferred method to achieve the optimal angle for insertion via the scala tympani and around the basal turn of the cochlea. This approach has the added advantage of bypassing the hook region of the cochlea (Mangus et al., 2012).

The size of the electrodes ranges from 1.0 – 1.4 mm and dictates the size of the cochleostomy (Mangus et al., 2012). The site for drilling the cochleostomy is at the promontory anterior and inferior to the round window membrane, below the stapes tendon (Mangus et al., 2012). Drilling is performed with a 1 mm to 1.5 mm diamond burr until the lining of the endosteum, which lies level and is continuous with the round window membrane (RWM), is exposed. If the RWM is obscured, the round window niche is removed (Mangus et al., 2012). Considerable acoustic damage to the inner ear can result from penetration of the endosteum so caution must be taken to avoid this (Mangus et al., 2012).

In order to prevent bone dust and blood from entering the scala tympani, surgeons have to exercise caution (Mangus et al., 2012). Insertion of the electrode array takes place once the endosteum has been opened (Mangus et al., 2012). In order to preserve residual hearing and prevent infection, intra-tympanic steroids are administered (Mangus et al., 2012).

2.2.4.2. Round window approach

Several studies have shown that the round window approach has several advantages over the standard cochleostomy approach, the most important being the fact that damage to the cochlear is limited and therefore the potential for preservation of residual hearing is improved (Mangus et al., 2012).

In the round window approach the insertion of the electrode is inserted at an acute angle to avoid going directly into the wall of the scala tympani (Mangus et al., 2012). The surgical incision is sealed by both the muscle and the electrode (Mangus et al., 2012). In order to expose the round window, thereby achieving a clear view, both the round window niche is removed and a facial recess is created by drilling away the bone over the stapedius muscle (Mangus et al., 2012).

The round window approach has advantages, the most important of which is the preservation of residual hearing, thereby enabling the use of EAS, which has significant benefits (Mangus et al., 2012). The traditional cochleostomy may cause trauma to the inner ear produced from the drilling process (Mangus et al., 2012).

Briggs et al. (2006) have emphasized the importance of conserving residual hearing, as this enables the implantee to have EAS. To this end, they aimed to develop a technique which would cause minimal damage to the cochlea. In their study their subjects were fitted with 16-mm multichannel electrode arrays which allowed more accurate placement of the electrode and consequently minimized trauma to the cochlea. They studied the use of both a cochleostomy approach, inserting the electrode array via the scala tympani, and also explored the effect on other patients by inserting the array inferior to the round window membrane in order to protect the basilar membrane and spiral ligament from trauma and subsequent damage. Both the scala tympani approach and the round window method successfully avoided trauma during surgery, thereby achieving the conservation of residual hearing (Briggs et al., 2006). It can be seen that they therefore found that both approaches were equally advantageous in minimizing intracochlear trauma, thereby resulting in the preservation of residual hearing.

Mangus et al. (2012) concluded that postoperative performance would depend on minimizing invasive procedures in order to conserve intracochlear structures.

2.2.5. Surgical techniques

Di Nardo et al. (2007) asserted that the preservation of residual hearing should be a desired result of cochlear implant surgery. In their study, Di Nardo et al. (2007) conducted a retrospective case study on the preservation of residual hearing after cochlear implant surgery, investigating comparative pre- and post-operative data for 37 cochlear implant recipients with measurable pre-operative hearing thresholds. The recipients had been implanted with various devices: four Med-El, seven Advanced Bionics, 24 Cochlear and two MXM (Di Nardo et al., 2007). This contrasted with Lenarz et al.'s (2009) and Gstoettner et al.'s (2009) studies, which only investigated one device, making Di Nardo et al.'s (2007) data more representative. Di Nardo et al. (2007) evaluated two different types of electrode arrays, namely the stylet and non-stylet. Unaided pure-tone testing was conducted 3-12 months post-operatively and compared to the pre-operative data. An atraumatic surgical approach was used, resulting in the majority retaining their residual hearing. However, 22% experienced a total loss of residual hearing (Di Nardo et al., 2007), which the current researcher believes indicates a need for further refinement in surgical protocol, unless other unmentioned factors were implicated in the loss. Di Nardo et al. (2007) deduced that residual hearing can be retained following cochlear implant surgery and that the cochlea is not that sensitive to the effects of trauma during implantation. Di Nardo et al.'s (2007) view regarding the importance of hearing preservation in cochlear implantation is also held by Berrettini et al. (2008), who concluded that it is a priority for surgeons to preserve residual hearing during implant surgery, a postulation which the current researcher hopes to validate further.

2.2.5.1. "Soft surgery" technique

Verhaegen et al. (2010) noted that many researchers found that "soft surgery" resulted in the retention of residual hearing in more than 70% of cochlear implant recipients. Lehnhardt introduced the "soft surgery" technique, which involves a 1.2mm cochleostomy, positioned anteriorly and inferiorly to the round window (Di Nardo et al., 2007). Verhaegen et al. (2010) described the major characteristics of "soft surgery" as follows: dispensing corticosteroids, drilling until the cochlear endosteum is detected, opening the endosteum with a sharp needle, avoiding intracochlear suctioning and preventing entry of bone dust and blood. Both Di Nardo et al. (2007) and Verhaegen et al. (2010) agreed that the aim of "soft surgery" is to minimize damage to the inner ear and Di Nardo et al. (2007) asserted that this would result in better

hearing. In view of the aforementioned, the current researcher observes that the "soft surgery" technique is beneficial for preserving residual hearing.

In their research, Verhaegen et al. (2010) evaluated retrospectively the retention of residual hearing by using the "soft surgery" and classic surgery techniques in 58 patients after cochlear implantation. For participants with a significant level of residual hearing pre-operatively, the "soft surgery" technique was implemented. The classic surgery technique was utilised for participants with less residual hearing. "Soft surgery" was used to minimize any trauma to the inner ear, thereby preserving residual hearing. The focus on only two techniques, although somewhat limiting, is advantageous because an in-depth investigation was done (Verhaegen et al., 2010). Verhaegen et al. (2010) included participants that had pre-operative residual hearing threshold levels better than the "level of vibrotactility", i.e. 90 dB or better and 110 dB or better at 250 Hz and 500 Hz respectively. This is significant in that it ensured more accurate results by avoiding recording thresholds that are vibrotactile instead of heard. However, the strict inclusion criteria limited the number of participants that could be included in their study. Nonetheless, a statistically significant sample size of 58 patients was investigated. In contrast to previous studies, Verhaegen et al.'s (2010) study focused on individuals with residual hearing in the low frequencies to avoid potential ceiling effects caused by immeasurable high frequency hearing threshold levels. The researcher of the current study believes this to be limited because the lack of measurement of higher frequencies may result in post-operative residual hearing at these levels being overlooked. Verhaegen et al.'s (2010) research differed from other studies in that they corrected for potential non-implant-related threshold level changes. They achieved this by using the non-implanted ear as a reference and thereafter alluded to the threshold difference in the implanted ear as the "corrected threshold difference." These researchers felt this approach was advantageous in that this would avoid over-estimation of the true difference between the pre- and post-operative hearing threshold levels. Verhaegen et al. (2010) drew comparisons between their data and those of other studies and found the "soft surgery" technique to be beneficial in preserving residual hearing.

2.2.5.2. "Advance off-stylet" technique

Research has found that there are advantages to the "Advance off-stylet" (AOS) technique for the preservation of residual hearing (Roland, 2005). Roland (2005) discussed the benefit of combining the AOS technique with Contour Advance electrodes, which involved less invasive

insertion, thereby minimizing trauma (Roland, 2005). According to James et al. (2005), the AOS technique has been developed in such a way that it prevents major contact with the cochlea's lateral wall and the electrode array is designed to fit the cochlea. Roland (2005) asserted that AOS has proved to be more reliable than the standard insertion technique.

Contrastingly, Verhaegen et al. (2010) found that the AOS technique and the Softip of the electrode array made no appreciable contribution to the preservation of residual hearing. However, the limitations of Verhaegen et al.'s (2010) study make their findings less representative. Given the evidence in the literature and the properties of the AOS technique, the current researcher considers this technique to be valuable for preserving residual hearing.

Stover et al. (2005) investigated three different insertion techniques, namely conventional insertion, AOS insertion performed manually and AOS performed with an insertion tool. These researchers evaluated these insertion techniques to determine whether they caused damage to microstructures of the cochlea and they utilised 25 temporal bones to realise their aim (Stover et al, 2005). Stover et al. (2005) concluded that, particularly when using the conventional technique with a Softip electrode array, the insertions resulted in perforations of the basilar membrane. When using the prototype insertion tool, there was good placement of the array, but two basilar membrane perforations were observed in their study (Stover et al., 2005). The AOS insertion technique (with Softip), on the other hand, did not result in basilar membrane perforations and enabled perimodiolar placement of the electrode arrays (Stover et al., 2005). Thus, it was concluded that the AOS technique (with Softip) was able to provide more atraumatic insertions (Stover et al., 2005). The researcher of the current study believes that this is important for the preservation of residual hearing and hence the relevance to the current study.

2.2.6. Cochlear implant manufacturers and electrode arrays

2.2.6.1. Cochlear implant manufacturers

Locally and worldwide, cochlear implant manufacturers include: Cochlear Corporation or Nucleus (Australia) (see 2.2.6.4. for types of electrode arrays produced by this manufacturer and types which are relevant to the current study); Med-El Corporation (Austria); and Advanced Bionics Corporation or Clarion (United States) (Zeng, Popper & Fay, 2004).

2.2.6.2. Insertion depth of electrode arrays

Di Nardo et al. (2007) demonstrated that insertion depth also seems significant in preserving residual hearing. Their study used electrode arrays designed to be inserted to a depth exceeding 360°, or one full turn of the cochlea. It was found that residual hearing could be preserved up to 500Hz with an insertion angle of 400°. They mentioned that insertion angles greater than 400° seem to result in hearing impairment at frequencies of 250-500 Hz (Di Nardo et al., 2007).

According to Bruce, Bates, Melling, Mawman and Green's (2011) study, the insertion depth is critical to the preservation of residual hearing. This has reportedly resulted in the development of shorter electrodes being used to reduce the risk of trauma to the intracochlear structures (Bruce et al., 2011).

2.2.6.3. Length of electrode arrays

Technological advances are aimed at reducing loss of hearing and a short electrode, 10mm in length, was developed. This was the Iowa/Nucleus Hybrid device and was successfully used by Gantz et al. (2006), who examined 49 patients implanted with this device. Forty-seven patients retained their residual low-frequency hearing post-operatively, whilst two patients lost their hearing some months later (Gantz et al., 2006).

Turner, Reiss and Gantz (2008) observed that short electrode devices were less invasive than long electrode arrays and therefore caused less damage to intracochlear structures.

2.2.6.4. Types of electrode arrays

The following electrode arrays are illustrated below as they are relevant to the current study and are manufactured by the Cochlear Corporation or Nucleus (Australia):

- Nucleus CI24RE Series implants with Contour Advance or Straight electrodes
- Nucleus 5 implant (CI512)
- Nucleus CI24R with Contour Advance® electrode



Figure 1. Nucleus CI24RE Series implants with Contour Advance or Straight electrodes
According to the cochlear.com website, "The CI24RE was developed in 2005 and has 50% greater impact resistance than the CI24R" (www.cochlear.com).



Figure 2. Nucleus 5 implant (CI512)
According to the cochlear.com website, "the CI512 was developed in 2009 and is 40% thinner than the CI24RE and measures 3.9mm deep" (www.cochlear.com).

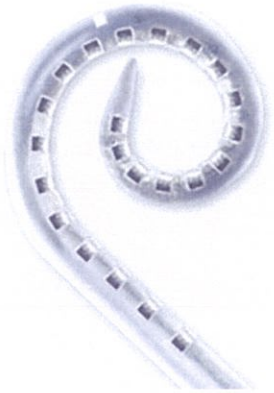


Figure 3. Nucleus CI24R with Contour Advance® electrode

According to the cochlear.com website, "the CI24R was developed in 2002 and has a Softip, which is designed to protect delicate structures of the cochlea and simplify surgery with the Advance Off-Stylet® (AOS) technique" (www.cochlear.com).

- **Contour Advance electrode**

Roland, Shelva, Gibson and Treaba (2005) conducted a clinical trial where they investigated the Nucleus 24 Contour Advance electrode.

The Nucleus 24 Contour electrode was FDA approved and first released in 2000. It enables perimodiolar positioning of the electrode array (compared with a standard straight array) (Richter et al., 2001; Tykocinski et al., 2000, as cited in Roland et al., 2005). In order to improve safety of insertion of the electrode array, the Nucleus 24 Contour Advance was developed. It differed from the original Contour in that it allows perimodiolar positioning and has a modified Softip. The Softip results in reduction of outer or lateral wall of the cochlear forces when utilised with the AOS technique. The Softip enables smooth insertion by enhancing the initiation of the array and preventing rollover of the tip of the array, thus guiding the electrode via the scala tympani, which is likely to reduce intracochlear trauma (Roland et al., 2005).

According to Roland et al. (2005), the best results are seen with Nucleus 24 Contour Advance electrode when the AOS technique is performed with this array. This is because the AOS technique is specifically designed to minimize the outer wall forces of the cochlea during

electrode insertion and to assist with the perimodiolar positioning. The AOS technique involves inserting the electrode and stylet through the cochleostomy until a marker on the body of the electrode array is reached at the opening. The stylet is then held in place and the array is advanced off the stylet until full insertion is achieved. Thereafter, the stylet is removed (Roland et al., 2005).

In their study, Roland et al. (2005) found that there was a marked decrease in the forces during insertion on the intracochlear structures when using the AOS technique in contrast to using the standard technique for insertion. This is significant for minimizing trauma (Roland et al., 2005). The current researcher holds that this in turn is a good prognostic indicator for the preservation of residual hearing.

- **Straight vs. perimodiolar electrode arrays**

Kirtane et al. (2010) compared straight/standard and perimodiolar electrodes. They found that straight electrodes are deeply inserted into the cochlea and result in the widest contact spacing. Retention of residual hearing with the concomitant improvement in speech perception is achieved by the insertion of the perimodiolar electrodes closer to the cochlea's modiolar wall (where the spiral ganglion cells are positioned) (Kirtane et al., 2010). Due to the proximity of the perimodiolar electrodes, there is selective stimulation of spiral ganglion cells and less current is required for each stimulation (Kirtane et al., 2010). James et al. (2005) consider that the perimodiolar array is appropriate for cochlear implant candidates and it has been demonstrated that the performance is as good as or superior to the straight electrode arrays (James et al., 2005). Conversely, Gstoettner et al. (2009) believe that perimodiolar arrays, when forcefully inserted, result in more damage to intracochlear structures than standard electrodes that are atraumatically inserted. Due to the contradictory findings from different researchers, the current researcher considers that further research is needed into the use of straight and perimodiolar electrodes.

It is evident from the research documented above that the advancements in surgical techniques and refined electrode arrays have led to hearing conservation. This preservation of residual hearing has positive outcomes - the most significant of which is that it enables the utilisation of EAS for prospective candidates.

2.3. Electro-acoustic stimulation (EAS)

2.3.1. Overview of EAS

The conservation of low frequency residual hearing in patients with high-frequency hearing loss is a prerequisite for electro-acoustic stimulation (EAS) (Verhaegen et al., 2010). EAS involves the preserved low frequencies being amplified by means of acoustic stimulation (i.e. a hearing aid) whilst the high-frequency hearing loss is being addressed with a cochlear implant, – i.e. electrical stimulation – in the same ear (Verhaegen et al., 2010).

Bimodal EAS was introduced in 1999 by von Ilberg et al. as a new treatment modality for patients with preserved low frequency residual hearing (Gstoettner et al., 2009). Since 1999, many researchers have demonstrated the significant advantages of EAS over utilising either modality on its own (Gstoettner et al., 2009) – i.e. hearing aid alone or cochlear implant alone.

2.3.2. Shortcomings of hearing aids

Hearing loss is addressed by cochlear implants, which attempt to replace the damaged receptor hair cells by stimulating the auditory nerve. There are very few functioning hair cells in patients with profound hearing loss, severely limiting the acoustic input to the cochlea and therefore compromising hearing ability. Hearing aids are not sufficient to address this degree of hearing loss, as there is very limited speech information being conducted by the damaged hair cells. A cochlear implant thus becomes the desired strategy for coping with this type of hearing loss, as the implant effectively replaces function of the damaged hair cells by the insertion of the electrode arrays, thereby enabling speech processing and hearing (Turner et al., 2008).

On the whole, patients retain some degree of residual hearing as hair cells are damaged in varying degrees with the most severe loss occurring along the basilar membrane. Where there is partial retention of hearing, the patient can receive some speech cues through acoustic stimulation. These speech cues vary according to the severity of the hearing loss (Turner et al., 2008).

Hogan and Turner (1998), Ching et al. (1998) and Turner and Brus (2001) (as cited in Turner et al., 2008) also found in their studies that speech recognition in patients with severe to

profound high-frequency hearing loss was compromised. Turner et al. (2008) reported that Vickers et al. (2001) made similar findings and referred to these areas of inner hair cell loss as "dead regions". These researchers all concluded that amplification alone could not adequately address severe to profound hearing loss (Turner et al., 2008).

2.3.3. Limitations of electrical stimulation alone

Gantz et al. (2005) postulated that electric stimulation with cochlear implants alone does not achieve as successful an outcome as using EAS, which would require a degree of residual hearing. The cochlear implantees in their study achieved poor pitch resolution which, whilst not problematical for speech perception in quiet, resulted in poor speech understanding in background noise (Gantz et al., 2005). Musical appreciation was also compromised (Gantz et al., 2005).

Gantz et al. (2005) reported that at best the cochlear implants provided only six to eight channels of distinct place-frequency information across the entire spectral range, thus limiting spectral resolution. This adversely impacted on the patient's understanding of speech in the presence of background noise. Whilst cochlear implants successfully restore speech understanding in quiet in the majority of implantees, speech perception in noise is considerably compromised, even with the best cochlear implants (Gantz et al., 2005). Thus, it is evident that EAS significantly improves the patient's ability to understand speech in background noise. Gantz et al. (2005) reported that results from their clinic demonstrated that the retention of residual hearing therefore produced positive outcomes for improved speech in noise.

Researchers have found that the electrical stimulation devices were inadequate for the patients' ability to differentiate musical sounds. For example, Turner et al. (2008) commented that in Gfeller et al.'s (2002) study, cochlear implant users had difficulty when listening to music in discriminating pitches, sometimes needing as much as two octaves difference between notes before being able to identify differences. As a result, the patients were unable to identify melodies (Gfeller et al., 2002 as cited in Turner et al., 2008).

These studies demonstrate that poor frequency resolution is a major drawback suffered by cochlear implant users. The implant users are subjected to many situations which affect their ability to perceive speech in everyday life. In contrast, even when patients have a severe hearing

loss, acoustic hearing provides better frequency resolution. Thus, the preservation of residual hearing in cochlear implant patients becomes important (Turner et al., 2008).

2.3.4. Advantages of electro-acoustic stimulation (EAS)

The benefits of EAS predominately include improved speech perception in noise and musical acuity (Gstoettner et al., 2009). Moreover, Adunka, Pillsbury and Kiefer (2006) reported that EAS resulted in improved speech perception in noise. According to Adunka et al. (2006), this additional advantage is dependent on the amount of post-operative preserved residual acoustic hearing and thus on atraumatic electrode array insertion (Adunka et al., 2006).

According to Mangus et al. (2012), there are considerable advantages to the combining of acoustic (hearing aid alone) with electric stimulation (i.e. cochlear implant alone) over using either modality alone. These researchers commented that there is improved hearing in quiet and noise, and musical sounds are received better, while melodies can be more accurately identified (Mangus et al., 2012).

The importance of EAS has engendered research into ways of reducing trauma during the insertion of the electrode array in order to achieve conservation of low-frequency hearing (Mangus et al., 2012).

Adunka et al. (2006) asserted that candidates for EAS should have preserved low frequency hearing loss. This allows the electrode array to be inserted into the basal region of the cochlea (i.e. high frequency region), avoiding the apex (or low frequency region) of the cochlea. Therefore, the aim of EAS is to stimulate the high frequencies to approximately 1000 Hz via electric stimulation (Adunka et al., 2006).

Figure 4 clearly illustrates the tonotopic organization of the cochlea – where the high frequencies are situated at the base of the cochlea and the low frequencies at the apex of the cochlea (Martin & Clark, 2006).

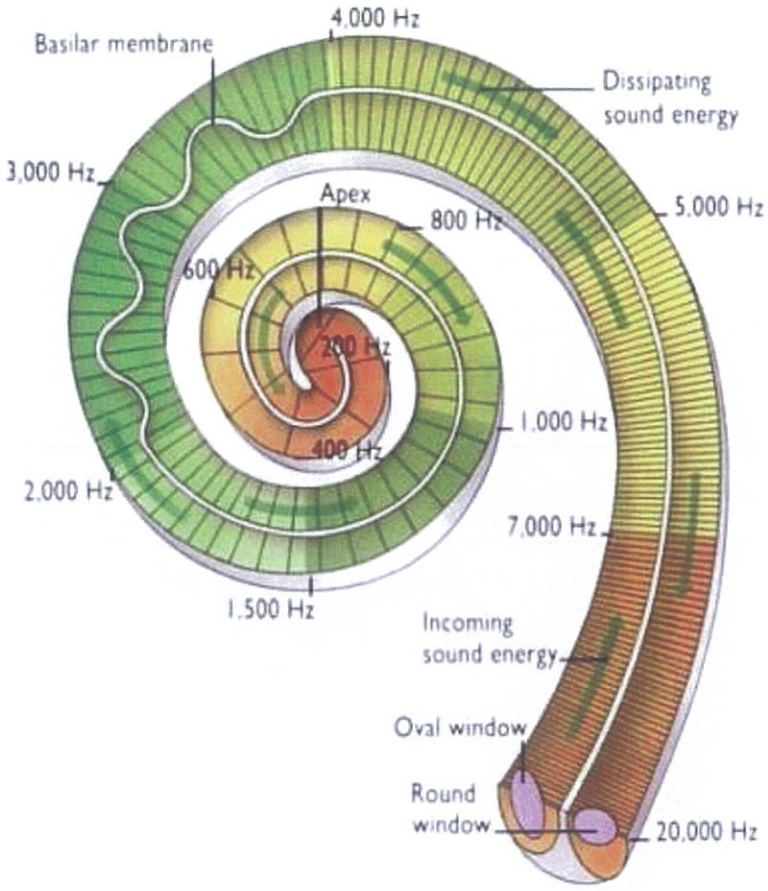


Figure 4. Tonotopic organization of the cochlea. From SACIG Presentation, Sunnybrook Presentation: University of Toronto (M.C., Lin, Nedzelski, Chen, Shipp, Symons, et al., 2010)

Mangus et al. (2012) have commented that EAS is made possible by the brain being able to process the high-frequency information provided by the cochlear implant and integrating this with the improved acoustic hearing achieved in the lower frequencies by a hearing aid.

Since the inclusion criteria for cochlear implantation has broadened to include patients with more residual hearing, Gantz et al. (2005) have highlighted the relevance of hearing preservation at the low frequencies during cochlear implantation. Their study investigated surgical techniques using a short hybrid cochlear implant in an attempt to preserve low-frequency residual hearing. Gantz et al. (2005) discussed the advantages of using EAS, including improved speech perception in noise and clearer discernment of musical sounds.

Derinsu et al. (2011) have also discussed the benefits of using a hearing aid with a cochlear implant - i.e. EAS. According to Derinsu et al. (2011), these advantages include better speech perception and improved hearing abilities. These researchers mentioned that since surgeons have been implanting patients with residual hearing, they have concentrated on the preservation of this residual hearing. The aim is to restore the high frequency speech perception with electrical stimulation from the cochlear implant and improve speech understanding by preserving the low frequencies (Derinsu et al., 2011), which are then amplified by a hearing aid. According to Derinsu et al. (2011), "the combination of electric and acoustic stimulation would provide a more complete representation of speech frequencies" (p. 522).

Lenarz et al. (2009) indicated that residual hearing enables EAS, which offers benefits for speech perception in noise and sound localization. Turner and Gantz (2004) also recognised that with EAS there are improvements in speech in competing background noise as well as improvements in sound quality. Lenarz et al.'s (2009) findings confirmed the findings from Turner, Gantz, Vidal, Behrens and Henry's (2004) study, which demonstrated that residual acoustic hearing also allows for the possibility of having an ipsilateral hearing aid to stimulate low frequencies in addition to a cochlear implant for high frequencies, also serving to improve speech recognition. Turner et al. (2004) have provided strong support for preservation of residual low-frequency acoustic hearing in implantees. They demonstrated that the benefits of short-electrode cochlear implants and EAS involve better speech perception in noise (Turner et al., 2004). Given this evidence in the literature, the current researcher recognizes the importance of preserving residual hearing for EAS; hence another motivation for the current study.

Gstoettner et al. (2009) conducted a clinical trial with the Med-El Flex EAS array, investigating this new electrode array for retention of residual acoustic hearing in cochlear implantation. These researchers made use of only nine participants and included those with bilateral sensori-neural hearing loss with pure-tone thresholds < 60 dB HL at at least two frequencies 125, 250, and 500 Hz and > 60 dB HL at frequencies >1000 Hz. They compared pre- and post-operative hearing threshold levels by measuring residual hearing at defined intervals post-operatively to ascertain if and when residual hearing had been lost or retained post-operatively. The current researcher holds that this clinical trial had unprecedented success in that Gstoettner et al. (2009) found that all implantees retained their residual hearing, either partially or completely. The recipients were implanted by the same surgeon, an important variable which might have

contributed to the positive influence on the findings. The surgeons' expertise and experience may therefore have been a factor in the success of the results. Gstoettner et al. (2009) found the results of EAS to be more beneficial than those obtained with a cochlear implant alone, which became evident in the speech perception in noise testing results. They noted that the encouraging results reflected improvements in the mechanical properties of the electrode arrays and the sophisticated advances in surgical techniques. As a result of their positive findings, Gstoettner et al. (2009) aimed to continue using the Med-El Flex EAS electrode on a broader population. The current researcher has observed that this study had very strict inclusion criteria, included a small sample size and investigated only one type of electrode and hence presented with limited generalizability.

Lenarz et al. (2009) conducted a similar clinical trial for another electrode, the Hybrid-L. The study consisted of one group of 24 recipients with residual hearing who were fitted with the Hybrid-L electrode combined with an ipsilateral hearing aid (i.e. EAS). A second group of eight recipients with less residual hearing were fitted with a cochlear implant alone, allowing a comparison between the two groups (Lenarz et al., 2009). The Freiburger Monosyllabic Word Test was administered to all 32 recipients and the results indicated remarkable progress in the recipients with EAS. The Oldenberg Sentence Test in noise demonstrated a significant improvement on average in these recipients compared to the pre-operative condition where a hearing aid alone was used (Lenarz et al., 2009). The researchers found that adding a contralateral hearing aid provided a further advantage. One of the main advantages of the Hybrid-L electrode is that it is atraumatic, which the current researcher believes is a good prognostic indicator for the preservation of residual hearing. Unlike most other studies, Lenarz et al.'s (2009) study examined the effect of the duration of pre-operative hearing loss on residual hearing. They found that those with a shorter duration of pre-operative high frequency hearing impairment demonstrated better outcomes post-operatively than those individuals with a longer duration of pre-operative hearing loss (Lenarz et al., 2009). It is noteworthy that auditory deprivation appears to have an influence on the post-operative outcomes. Their findings indicated that the majority of participants retained residual hearing post-operatively and there were specific advantages, particularly for speech perception in noise and sound localization, validating the success of the Hybrid-L electrode (Lenarz et al., 2009). The current researcher postulates that although their study was limited in that it was a clinical trial only investigating one electrode array, it was an in-depth investigation which has contributed significantly to the understanding of the benefits of residual hearing and of EAS. Lenarz et al.

(2009) emphasized the added benefit of EAS, which the current researcher believes makes their research significant in the development of cochlear implantation.

In summary, preserving low frequency hearing allows for acoustic amplification of these low frequencies, whilst stimulating the high frequencies via electrical stimulation – i.e. EAS. This has its advantages for hearing. Thus, preservation of residual hearing post-operatively is an important goal of cochlear implant surgery and therefore the researcher in this study aimed to investigate this preservation pre- and post-operatively at two major cochlear implant centres in South Africa.

The current researcher endorses Roland et al.'s (2005) view that "in light of the recent work in minimally invasive surgery and preservation of residual hearing, electrodes and insertion techniques that reduce insertion forces are becoming recognized as important factors that ultimately affect clinical results" (p. 6).

2.4. Surgical complications

In addition to examining the refined electrodes, surgical approaches and techniques as well as the benefits of residual hearing after surgery, it is important to attempt to identify the reasons for any loss of hearing that may have occurred. An examination of the surgical complications will enhance the understanding of the reasons for this loss.

Di Nardo et al. (2007) have demonstrated that loss of residual hearing during cochlear implant surgery is predominantly as a result of traumatic effects due to the insertion of the electrode. On the other hand, Kiefer et al. (2004) have cautioned that damage to the cochlea could be a result of acoustic trauma from bone drilling during surgery which is required for the cochleostomy. Di Nardo et al. (2007) mention that the researchers Clark et al. (1988) and Balkany et al. (1999) considered that intracochlear structures could be damaged during cochlear implantation due to surgical complications, such as damage to the spiral ligament and osseous spiral lamina fracture. The transductional function could be impaired with damage to the intracochlear fluid compartments and a sheath may develop around the electrode array (Di Nardo et al., 2007).

Derinsu et al. (2011) have speculated that the reasons for loss of hearing may include inflammatory processes within the cochlea and loss of perilymph. Hearing loss may also result from drilling on the cochlea, tissue disruption, mechanical vibration damping effects of the electrode and electrical stimulation (Derinsu et al., 2011).

Despite these surgical complications being documented, Derinsu et al. (2011) have highlighted the fact that there is limited knowledge about the mechanisms of hearing impairment as a result of implant surgery. It is evident that opinions vary as to the cause of residual hearing loss following surgery. It is for these reasons that the current researcher believes that further research in this area is required.

2.5. Summary

The review of the literature underscores the need for the current research, as studies have shown a variance in opinions regarding the most efficacious way of preserving residual hearing after cochlear implant surgery. As one of the specific objectives of the current study, the researcher explored whether there was a relationship between the surgical techniques and the preservation of residual hearing.

According to Di Nardo et al. (2007), it is "surprising" that conservation of residual hearing is possible given the invasive nature of cochlear implant surgery. Hence they suggested that further studies should be conducted to establish explanations for these results obtained. Gstoettner et al. (2009) observed that it had become abundantly evident in the literature that although some implantees lost their residual hearing post-operatively, nevertheless, conservation of functional hearing was achieved for the majority. The researcher in the current study concurs with Di Nardo et al. (2007) that there is a necessity for additional studies given the "surprising" results, the fact that some recipients continue to lose their residual hearing despite all efforts to conserve it and due to the fact that, to date, research on this topic is limited in South Africa. Therefore, the current study, which aims to investigate preservation of residual hearing following cochlear implant surgery in a group of recipients at the two South African cochlear implant centres has particular relevance.

CHAPTER 3: METHODOLOGY

Chapter 3: Methodology

3.1. Introduction

The methodology chapter describes the aims, research design, participant selection and methods of data collection. Data analysis will then be explained. The researcher will later explore reliability and validity as well as ethical considerations with regard to the current research.

3.2. Research aims

3.2.1. Main aim

The primary objective of the study was to explore the preservation of residual hearing function in a group of cochlear implant recipients at Unit B and Unit A in South Africa.

- The null hypothesis is that there is NO change in hearing function from pre-implantation to post-implantation (i.e. there is preservation of residual hearing post-operatively).
- The alternate hypothesis is that there IS a change in hearing function from pre-implantation to post-implantation (i.e. there is loss of residual hearing post-operatively).

3.2.2. Sub-aims

The secondary objectives included the following:

- Describing hearing function before and after cochlear implant surgery.
- Performing a comparative analysis of hearing function pre- versus post-cochlear implant surgery.
- Determining to what extent residual hearing has been preserved or lost.

- Establishing whether a relationship exists between the hearing findings and the following:
    - age
    - gender
    - aetiology of hearing loss
    - duration of pre-operative hearing loss
    - degree of pre-operative hearing
    - duration between surgery and unaided post-operative hearing testing
    - model and manufacturer of implant
    - surgical technique employed
    - complications relating to intracochlear structures

3.3. Research questions

3.3.1. Main research question

Has residual hearing been preserved following cochlear implant surgery in a group of cochlear implant recipients at Unit B and Unit A in South Africa?

3.3.2. Secondary research questions

- What are the hearing functions before and after cochlear implant surgery?
- What is the calculated change between hearing function pre- versus post-cochlear implant surgery?
- To what extent has residual hearing been preserved or lost?
- Does a relationship exist between the hearing findings and the following?
    - Duration of pre-operative hearing loss
    - Degree of pre-operative hearing
    - Duration between surgery and unaided post-operative hearing testing
    - Model and manufacturer of implant
    - Surgical technique employed

- Complications relating to intracochlear structures

3.4. Research design

A retrospective data review was used for the current study. Retrospective research is designed to investigate already recorded data before a research problem has been devised (Schiavetti & Metz, 2002). The researcher retrospectively examined existing pre- and post-operative unaided audiological testing results to determine whether residual hearing had been preserved. Further, the researcher retrospectively explored existing surgical records to establish whether there was a relationship between the hearing findings and surgical techniques employed. The data was collected after the participants had undergone surgery and had had pre- and post-operative audiological testing and after they had signed consent forms to release their data for research purposes. Unit B already had a form in place which their patients signed prior to surgery to release their data for research purposes. Consent had to be obtained from individual participants at Unit A.

It must be taken into consideration that there may be some shortcomings of retrospective research which may affect the reliability and validity of the findings. For example, the audiological equipment may have been out of calibration on the day of testing, the audiograms may have been obtained by audiologists who followed different protocols or by audiologists who may have taken shortcuts in the measurement methods due to time constraints (Schiavetti & Metz, 2002). However, it was felt that such possible shortcomings were unlikely to have occurred as the researcher relied on the professionalism and the integrity of the audiologists conducting the testing. Other limitations of retrospective research during data collection of medical records include possible variations in the interpretation of data, selection bias, availability of records and erroneous recording of data (Taylor, 1999). Purposive sampling used in the current study eliminated the possibility of selection bias and the quantitative research design minimised any misinterpretation of data. Additionally, although there were a few missing records, this only had a minimal effect on the sample size which was adequate for the current study. Great care was taken by the researcher in recording data, thereby minimising errors in transcription.

A quantitative paradigm was used in the current study in order to determine whether there had been any change by comparing the numerical data obtained from pre-operative and post-

operative unaided pure-tone testing. "Quantitative research is explaining phenomena by collecting numerical data that are analysed using mathematically based methods (in particular statistics)" (Muijs, 2010, p.1).

The researcher made use of an adequate sample size of 53 participants (and 60 observations – i.e. including bilateral implantees), consistent with the quantitative paradigm. Stability is an important component of the research process (Welman, Kruger & Mitchell, 2005) and to this end the researcher made use of a large number of cases and numerical data, making a quantitative paradigm a suitable research design for the current study. Structured methods were used in order to confirm or disprove hypotheses, which is elemental in quantitative research. It is beneficial to use a quantitative paradigm as such an approach focuses on reliability and ensures that results may be replicated. Furthermore, quantitative research aims to keep an objective view, free from bias (Welman et al., 2005).

However, there may be some disadvantages to adopting a quantitative approach. In order to prevent any form of bias, a quantitative approach is limited in terms of flexibility (Welman et al., 2005). Qualitative research, on the other hand, is defined by flexible, explorative methods, which enable the researcher to adjust to the data progressively in order to gain an in-depth understanding (Welman et al., 2005). Whereas quantitative research deals with objective data, qualitative research involves subjective data (Welman et al., 2005). In certain studies subjective data may have more clinical relevance.

Nonetheless, the researcher made use of a quantitative instead of a qualitative paradigm as it was felt that in the current study the benefits of using such a paradigm outweighed the limitations.

3.5. Participant selection

3.5.1. Sampling strategy

Purposive sampling, which is the most significant form of non-probability sampling, was used (Welman et al., 2005). In purposive sampling, the participants' characteristics are already known, making them suitable candidates for selection (May, 1997). The researcher drew on experience, previous research findings and ingenuity to purposively obtain data so that the

sample could be regarded as representative of the relevant population (Welman et al., 2005). The sample and records were obtained from the audiologists working at Unit B and Unit A.

3.5.2. Participant description

The records of participants in this research included audiological testing data and surgical records from cochlear implantees with pre-operative residual hearing. Participants consisted of male and female, unilateral and bilateral cochlear implant recipients from Unit B and Unit A. The children had to be at least six years old at pre-operative hearing testing and the adults not more than 59 years old at post-operative testing.

Despite the fact that Valente (2009) holds that four- to five-year olds may be evaluated via conventional techniques, the researcher in the study included records only from those children who were six or older in order to ensure reliability of pure-tone testing. In addition, persons 60 years and older were also excluded from the study due to the prevalence of presbycusis at this age. Presbycusis or hearing loss as a result of aging is characterized by a gently sloping, high-frequency sensory-neural hearing loss, which is slightly more prevalent in men than in women (Schlauch & Nelson, 2009). Presbycusis occurs in men and women in their early and late 60s respectively, although there is no clear evidence in the literature as to exactly when it begins (Martin & Clark, 2006). Therefore, the researcher excluded participants 60 years and older. The ceiling for the inclusion criteria was 59 years of age.

A pre-requisite of this study was that the participants had to have some pre-operative residual hearing at any or all of the following frequencies: 125 Hz, 250 Hz, 500 Hz, 750 Hz, 1000 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz and 8000 Hz. In other words, they would have had to have had some pre-operative residual hearing up to the maximum output of the audiometer (i.e. up to 120 dB). This was a requirement for the current study, as this study compared pre-operative and post-operative residual hearing. Normal hearing is considered to range between -10 dB and 15 dB (Koike, 2006). Slight or borderline hearing is considered to range between 16 dB and 25 dB (Koike, 2006). Classifications of hearing losses for this study included: moderate sloping to profound, severe to profound, and profound sensori-neural hearing loss (SNHL). Patients with these classifications pre-operatively were included as even those with pre-operative moderate sloping to profound SNHL are currently being implanted.

Those with corner-audiograms (i.e. no residual hearing) pre-operatively were excluded from this study.

Some researchers have stricter inclusion criteria and only include participants who have some pre-operative residual hearing at specific frequencies. Di Nardo et al. (2007), for example, required pre-operative residual hearing to be at at least two detectable frequencies (Di Nardo et al., 2007). In Gstoettner et al.'s (2009) study, the participants had to have had some residual hearing pre-operatively (i.e. a sensori-neural hearing loss with pure-tone thresholds < 60 dB HL) at at least two detectable frequencies (125 Hz, 250 Hz and 500 Hz and at > 60 dB at frequencies > 1000 Hz). However, in order to broaden the sample size in this study to ensure statistical significance, the inclusion criteria were expanded to include those with any residual hearing at any frequency.

3.5.3. Participant sample size

The sample comprised 53 audiological records of participants (32 from Unit B and 21 from Unit A) and 50 surgical records of participants (32 from Unit B and 18 from Unit A). The sample size of 53 audiological and 50 surgical records of participants allowed the researcher to detect patterns or general trends from the findings. Although there were 53 participants, seven of these individuals were bilaterally implanted, yielding a sample size of 60 observations.

The sample size is determined by the key research question, which in turn determines the key statistical technique to be used. This, together with other assumptions, is used to determine an adequate sample size for the current study. In this case, the key research question was to determine whether residual hearing function was preserved, at each particular frequency, between pre and post (i.e. before and after cochlear implant surgery). This required the use of a General Linear Model (GLM) with the CH (change in residual hearing) as the dependent variable and four parameters to be estimated: one each for PRE (pre-operative hearing), T_PRE (time (months) between last pre-operative hearing test and surgery), T_POST (time (months) between surgery and first post-operative hearing test) and UNIT (Unit A/Unit B). According to Hair et al. (2009), at least 5 observations are required per parameter to be estimated, preferably 10-15. This means that the researcher required at least 4*5=20 and preferably 10*4=40 to 15*4=60 observations. Thus, the 60 observations available for the current study are adequate to answer the key research question.

3.5.4. Selection criteria

3.5.4.1. Participant inclusion criteria

- *Cochlear implants:* The participants must have been fitted with a cochlear implant unilaterally or bilaterally at least one month prior to post-operative pure-tone testing. When the researcher initially set out to do this study, it was planned that unaided post-operative testing be done at least six months after surgery, as this was becoming the protocol for surgery in South Africa (L. Nauta, personal communication, February 23, 2012). However, during the data collection phase of this study, a study was being conducted by Med-El Cochlear Implant Company, which required unaided post-operative testing to be conducted as early as one month after surgery (i.e. at switch-on) and again one year post-operatively (J. Perold, May 2012, personal communication). This data was more readily available and was therefore collected for the current study. Thus, the researcher changed the criteria and included post-operative testing from one month after surgery onwards.
- *Hearing status:* The participants were required to have had a moderate sloping to profound, a severe to profound or a profound SNHL (i.e. some residual hearing at any of the frequencies - not a corner audiogram) in both ears and must have had some degree of benefit, even if only minimal, from hearing aids. According to Kirtane et al. (2010), these recent criteria for cochlear implantation ensured that only participants who had some residual hearing pre-implantation were included in the study.
- *Speech discrimination:* Due to the fact that the participants underwent cochlear implantation, it was assumed that pre-operatively, the participants scored $\leq$50% for sentence recognition in the ear to be implanted and $\leq$60% in the non-implanted or contralateral ear or bilaterally for speech discrimination, as this is a criterion for cochlear implantation (Wagenfeld et al., 2004).
- *Auditory nerve functioning:* Given the fact that the participants had cochlear implants, the researcher could make the assumption that the participants' auditory nerve fibres were intact so that they could receive electrical stimuli inside the cochlea (Moctezuma & Tu, 2011, p. 3).
- *Medical condition:* It was assumed that the participants' medical conditions and inner ear structures met the requirements for implantation, as these are criteria for candidacy (Moctezuma & Tu, 2011).

- *Age:* One of the inclusion criteria was that the participants' ages had to range between 6 and 59 years to ensure reliability of results.
- *Onset of deafness:* Adult participants should have been post-lingually hearing-impaired, whereas child participants could be pre- or post-lingually hearing-impaired. This is because the inclusion criteria for candidacy were: post-lingually hearing-impaired adults, pre-lingually hearing-impaired children, and post-lingually hearing impaired children. Pre-lingual deafness formed part of the inclusion criteria for the study provided that the participant had acquired enough language to follow simple instructions and participate reliably in the pre- and post-operative unaided audiological testing.
- *Cochlear implant manufacturer and model:* Participants in the study could have had any model of cochlear implant from any cochlear implant manufacturer. This aided the researcher in determining whether patterns or general trends appeared within and between different cochlear implant models and manufacturers.

3.5.4.2. Participant exclusion criteria

The following factors resulted in a participant being excluded from the study:

- *Hearing status:* If participants had not undergone cochlear implantation.
- *Lack of residual hearing:* Participants without residual hearing pre-operatively were excluded from the study as the researcher investigated the preservation of residual hearing.
- *Age:* Infants and children below the age of six years were excluded, as there is evidence that unreliable results may arise when conventional pure-tone testing is conducted on this population (Valente, 2009). Adults over 59 years were excluded, as presbycusis is prevalent in this population (Martin & Clark, 2006). Should presbycusis be present, testing results would be affected and the cause of the hearing loss would be unclear.
- *Records:* Files of participants who did not have both pre- and post-operative audiological assessment results were excluded. In order to meet the inclusion criteria, the participants in this study were required to have pre-operative and post-operative audiological records for analysis. If there were pre-operative and post-operative audiological records but no post-operative surgical records, the participants would still be candidates as the audiological data is the primary analysis in this study. However, should there have been post-operative surgical records but no pre- and post-operative audiological records available in the files, the

participants could not be candidates as the audiological data was required for primary analysis and the surgical data only necessary for secondary analysis.

- *Reliability:* Should any participants have affected the reliability of testing, those participants would have been excluded from the study – i.e. those who were specifically mentioned by the audiologists who conducted the testing as unreliable or who had questionable reliability (see 'Reliability and Validity').

3.6. Data collection

Data collection was carried out at Unit B over a period of one week. Retrospective audiological (pre- and post-operative pure-tone testing results) as well as surgical data was recorded by the researcher at this centre. The audiological and surgical data was provided to the researcher by the head of department at Unit B.

At Unit A, audiological data, namely pre-operative and some post-operative pure-tone testing results, was collected over a two-week period. Further, some post-operative testing was performed specifically for the current study over the course of the subsequent ten months and the researcher collected this data at random intervals – i.e. as it became available. The audiological data was provided to the researcher by the head of Unit A. Surgical data for Unit A was collected from two surgeons at this centre on two separate occasions.

All the data (audiological and surgical) was collected by the current researcher alone. The surgeons and audiologists at Unit A and Unit B as well as the researcher had access to the data. Both units had stored the data in a paper-based format. Audiology records were stored at Unit A audiology offices and the surgical records for Unit A were stored at the Ear, Nose and Throat surgeons' offices. All records for Unit B were stored at Unit B.

3.6.1. Methods of data collection

3.6.1.1. Audiological data review

The researcher collected audiological data on 53 patients who underwent cochlear implant surgery at two South African cochlear implant units (namely, Unit A and Unit B). The following data was collected:

- UNIT: Cochlear implant unit (Unit A / Unit B)
- EAR: (left/ right)
- LAT: Bilateral (B) / Unilateral (U) implant
- T_PRE: Time (months) between last pre-operative hearing test and surgery
- T_POST: Time (months) between surgery and first post-operative hearing test
- The hearing thresholds (in dB) of the pure-tone air-conduction testing conducted pre-operatively (PRE) and post-operatively (POST) at the following frequencies: 125 Hz; **250 Hz; 500 Hz;** 750 Hz; **1000 Hz;** 1500 Hz; **2000 Hz;** 3000 Hz; **4000 Hz;** 6000 Hz and **8000 Hz.**
- The change (CHANGE), i.e. the post-pre difference between the hearing thresholds (in dB) of the pure-tone testing results, at the above frequencies where these frequencies could be measured.

The frequencies marked in bold were those forming part of the standard test protocol and were expected to have been carried out for each patient. Tests at other frequencies were only carried out as needed. The researcher reviewed unaided pre- and post-operative air-conduction testing results at the above frequencies, namely: 125 Hz, 250 Hz, 500 Hz, 750 Hz, 1000 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz. These frequencies were chosen as these are in line with the protocol for diagnostic audiometry. This protocol involves measuring thresholds at the octaves between 250 Hz and 8000 Hz, in addition to 3000 Hz and 6000 Hz (Schlauch & Nelson, 2009). When a 20 dB difference between the adjacent octaves exists intra-octave thresholds are measured as a standard protocol (Schlauch & Nelson, 2009). Although 125 Hz is not typically recorded by audiologists during air-conduction testing, the researcher recorded 125 Hz, as it was assumed that the participants presented with low-frequency hearing losses and this frequently is the protocol for this type of loss (Valente, 2009).

These tests were carried out by different audiologists within the different centres. Additionally, it is probable that different instruments (i.e. audiometers) may have been used. The reason for this is due to the fact that the testing recorded in the current study spanned a considerable time span.

Where data was available for more than one PRE or POST test, the data for the test closest to the date of surgery was used by the researcher. This was in order to eliminate extraneous variables which could have caused hearing from deteriorating further from affecting the testing results. These extraneous variables may have been implicated in hearing loss, as opposed to other factors which the research was investigating such as surgical complications, electrode array insertion and surgical technique. Extraneous variables may have included aetiologies, such as ototoxicity, meningitis and noise-induced hearing loss, which were unrelated to the causes mentioned in the current study.

The same frequencies were not necessarily tested in the PRE and POST test for a given participant. Thus, data for CHANGE could not be calculated where data for a given frequency was not present for both PRE and POST for a particular participant. The researcher assumed that such data was "Missing At Random" (MAR).

- The researcher collected additional data, which included the following:
    - AGE
    - GENDER
    - ETIOLOGY
    - DUR: Duration of hearing loss prior to implantation (in years)
    - IM_TYPE: Implant type
    - IM_MANUF: Implant manufacturer
    - EL_TYPE: Electrode type
    - EA_INS: Electrode array insertion
    - EA_DEPTH: Electrode array depth
    - SURG_TECH: Surgical technique
    - COMPLIC: Intra-operative complications

At Unit A not all participants had received post-operative testing when the study was conducted. Where post-operative testing was not completed at Unit A, but pre-operative testing

had taken place, the audiologists at this centre performed the post-operative testing after the study had commenced. This meant that post-operative testing was conducted at random intervals – ranging from "switch-on" - i.e. approximately one month post-surgery - to various stages after surgery (see the Results section).

3.6.1.2. Surgical form

The researcher set out to explore different surgical techniques used by different surgeons at Unit B and Unit A to detect patterns in order to determine whether there was a relationship between the techniques used and the preservation of residual hearing.

From the samples provided to the researcher by the audiologists at Unit B and Unit A, it appeared that the cochlear implant patients who were implanted many years ago could not be included in the sample for the current study. This was due to the fact that these patients did not fit the criteria for this study as they had no pre-operative residual hearing. These patients did not have any residual hearing, as only those patients with profound hearing losses were being implanted at the time due to the surgical risks involved and the less refined electrodes being implanted causing intra-operative damage. As a result of this, the researcher could not compare older surgical techniques (i.e. those techniques used many years ago when the focus was not on the preservation of residual hearing) to the latest technique(s), such as AOS.

For the majority of Unit A participants, the surgeons' notes (with permission from the surgeons) were used to obtain information regarding cochlear implantation and an adapted surgical form (Appendix A), originally devised by Unit B, was filled in, using these surgical notes. When adapting the original surgical form, the researcher only extracted information that was pertinent to the current study and addressed the research questions and the researcher omitted any information that would not have had a bearing on the findings (see Appendix A). For two participants, a meeting was held with one of the surgeons at Unit A and notes on the relevant participants were taken by the researcher. Thereafter, the researcher filled in the surgical form using this information.

At Unit B, the original surgical form (Appendix B) was filled in by the surgeons at the time of surgery and this was used by the researcher to collect surgical data. The adapted surgical form was then completed by the researcher.

The researcher accessed the same information from the surgeons' notes for each participant to eliminate bias. The information from the surgical form included data relevant to this study. The following data was collected for each participant:

- ***Cochlear implant centre:*** This was important for statistical purposes. The researcher aimed to obtain statistics on the cochlear implant sites individually as well as collectively to obtain an adequate sample size for the current study.
- ***Biographical data of the participant, including age and gender:*** This was important for statistical purposes. The participants remained anonymous and a coding system was used as a form of identification.
- ***Hearing loss:*** The duration of loss prior to implantation was important to determine whether this had an effect on the preservation of residual hearing. The onset of hearing loss and aetiology were important for statistical purposes.
- ***Ear implanted (i.e. right, left or bilateral):*** This added to the statistical data and aided in the analysis of the findings.
- ***Date of implantation:*** This added to the statistical data in that it addressed two of the research questions for this study:
  - Does a relationship exist between the hearing findings and the duration of pre-operative hearing loss (i.e. date of onset of hearing loss until date of surgery)?
  - Does a relationship exist between the hearing findings and the duration between surgery/ implantation and unaided post-operative hearing testing?
- ***Model and manufacturer of cochlear implant:*** This allowed for a comparison between the hearing findings and the model and manufacturer of the implant.
- ***Surgical technique:*** Recording the surgical technique was significant to establish whether the technique had an impact on the findings.
- ***Electrode array type:*** This was relevant as the electrode array type can affect the preservation of residual hearing depending on the type of array.
- ***Electrode array insertion:*** According to Kiefer et al. (2004), it is important to have atraumatic insertion of the array to prevent surgical complications and damage to intracochlear structures.
- ***Electrode array depth:*** The electrode array insertion depth may an influence on the preservation of residual hearing (Di Nardo et al., 2007). Thus, it is important to include this data, as it has a relevance with regard to residual hearing.

- ***Intra-operative complications:*** Intra-operative complications during cochlear implantation may occur (Clark, 2003). Intra-operative complications may include injury to nerves (chorda tympani, facial nerve), bleeding, and misplacement of the electrode (E. Burden presentation, August 2012). Furthermore, intra-operative complications may lead to damage to the intracochlear structures and loss or reduction of residual hearing.

3.7. Data analysis

3.7.1. General

The researcher analysed the data to draw inferences from the research findings (Schiavetti & Metz, 2002). By doing so, the researcher was able to answer the research questions using statistical analysis within the context of the research design (Myers, Well, & Lorch, 2010).

The research questions of the current study were addressed by analysing the data collected. In recording pre- and post-operative differences, the researcher incorporated the data from all participants' records, as was done in James et al.'s study (2005). The researcher measured the thresholds at each frequency post-operatively and then compared them to the thresholds at the same frequencies pre-operatively for each participant.

During data analysis, vibrotactile responses were not regarded as hearing responses and were excluded from the calculations (as in Kiefer et al.'s (2004) study) as they could cause unreliable results. According to Schlauch & Nelson (2009), "In persons with significant hearing losses, sound vibrations produced by earphones and bone vibrators may be perceived through the sense of touch. Such thresholds are known as vibrotactile thresholds" (p. 42).

3.7.2. Data preparation

The researcher performed the following data preparation prior to data analysis.

Data preparation involved the following steps:

- LAT (unilateral or bilateral cochlear implant) was coded.

- Age at surgery was calculated from date of birth (DOB) and date of surgery.
- The hearing change classifications were coded.
- For analysis of PRE and POST variables, NR was replaced by 125 dB.
- For analysis of CHANGE variables as continuous variables,
    - a POST value of NR was replaced by 125 dB so that the CHANGE variable could be calculated.
    - a PRE value of NR was regarded as missing data.

3.7.3. Rationale

The researcher adopted James et al.'s (2005) approach by including all participants who fitted the selection criteria (i.e. in the current study this involved those who had some pre-operative residual hearing at any of the above frequencies) and chose not to omit those whose thresholds could not be measured (i.e. NR) after cochlear implant surgery. This avoided the possibility of bias. James et al. (2005) mention that by omitting the data for the participants the greatest increases in hearing threshold levels, the results will be left out of the calculation thereby resulting in favourable bias.
The current researcher holds that an added benefit of not omitting this data is that the sample size was not reduced, yielding an adequate sample size for this study.

The researcher chose to adopt James et al.'s (2005) approach whereby an artificial value is used to represent the total loss of residual hearing. James et al. (2005) suggested that this could occur at the maximum output of the audiometer. As suggested by James et al. (2005), the researcher in this study chose to use an artificial value to represent the total loss of residual hearing at the maximum output of the audiometer. As mentioned above, the researcher felt that this approach was more beneficial than leaving out data points as it avoids favourable bias and has the added benefit of preventing the researcher from having to reduce the sample size. However, as mentioned by Di Nardo et al. (2007), James et al. (2005) also stated that this approach can result in underestimated group statistics.

Verhaegen et al. (2010), Kiefer et al. (2004) and Balkany et al. (2006) defined the auditory thresholds beyond the upper limit of the audiometer as the upper limit plus 5 dB HL. This level

was chosen in order "to represent a data point that will be poorer than the maximum threshold that could be tested" (Verhaegen et al., 2010, p. 127).

In James et al.'s (2005) study, thresholds that postoperatively exceeded the limit of the audiometer output were recorded as "not measurable" (NM). NM values were recorded when thresholds exceeded maximum audiometer output limits of 83 dB HL at 125 Hz, 96 dB HL at 250 Hz and 120 dB HL for the remaining frequencies 500 - 4000 Hz (James et al., 2005).

Stach (2010) chose to replace the "no responses" or the "not measurable" values with numerical values, namely: 75 dB at 125 Hz; 90 dB at 250, 6000 and 8000 Hz and 110 dB from 500 through 4000 Hz. According to Stach (2010), these are the typical maximum output levels of earphones (Stach, 2010, p. 195). Martin and Clark's (2006) statement supports this: " ...each tone is amplified to a maximum of about 110 dB HL in the frequency range of 500 to 4000 Hz, with less output above and below those frequencies" (p. 52).

The researcher chose to assign an artificial or numerical value to represent the total loss of residual hearing at the maximum output of the audiometer plus 5 dB. The researcher also elected to represent the maximum output of the audiometer as 120 dB. The researcher adopted levels for the maximum output of the audiometer as 120 dB HL, as advocated by Schlauch & Nelson (2009): "Maximum output levels for AC testing are as high as 120 dB HL for frequencies where hearing thresholds are most sensitive" (p. 42). The reason for choosing the same value for every calculation was that the maximum output of the audiometer was not always recorded by the audiologists at the two cochlear implant centres. Further, maximum outputs of audiometers varied, as the testing was conducted on different audiometers at the two cochlear implant centres.

In calculating the pre-operative hearing thresholds alone, when the hearing threshold level was "no response", the researcher assigned a value of 125 dB to NR. This value of 125 dB was assigned to replace NR in order to determine the residual hearing or lack thereof pre-operatively.

Similarly, when the researcher calculated the post-operative hearing threshold levels alone and the value was "no response", again 125 dB was assigned to NR. The replacement of NR with 125 dB was used to determine the residual hearing or lack thereof post-operatively.

The reason for the above method was that a value needed to be assigned in order for the researcher to be able to calculate the change in residual hearing (i.e. the difference between the pre-operative and post-operative hearing threshold levels – or POST values minus PRE values).

However, when using PRE values to calculate CHANGE in residual hearing and when the pre-operative hearing threshold level was NR, the researcher did not assign a value of 125 dB to NR. The reason for this was because the researcher would not have been able to calculate or measure the change because there was no pre-operative residual hearing to begin with.

In Verhaegen et al.'s (2010) study the researchers predominately focused on hearing deterioration of the lower frequencies, i.e. 125 Hz, 250 Hz and 500 Hz, due to the possible ceiling effects as a result of immeasurable hearing thresholds for higher frequencies (Verhaegen et al., 2010). The current study included the higher frequencies (even if these levels reached the upper limit(s) of the audiometer(s) and thus may have been deemed immeasurable) in addition to the low frequencies for the purposes of representative calculation. Additionally, the researcher felt that by omitting the higher frequencies, it would have created favourable bias and an inaccurate depiction of the participants' hearing. Thus, by including thresholds across the entire frequency range (i.e. by incorporating all the frequencies, namely 125 Hz through to 8000 Hz), the researcher felt an accurate picture would be achieved and, moreover, any bias would be avoided.

3.7.4. Statistical procedures

Data analysis was carried out in STATISTICA (version 10).

The results for the current study were analysed using descriptive and inferential statistics.

Descriptive statistics were used to address the objectives of the current study and the following steps were implemented:

- The hearing function, namely pre-operative unaided pure-tone thresholds, was examined using descriptive statistics (i.e. mean and median).

Pre- and post-operative unaided pure-tone thresholds were presented in order to compare them (Kiefer et al., 2004). The researcher used the mean to better determine the indicative threshold shift (Di Nardo et al., 2007) in addition to calculating the median. Further, the mean or average of both pre- and post-operative unaided hearing threshold levels was calculated in order to examine the comparison more clearly (Kiefer et al., 2004).

- The hearing function, namely post-operative unaided pure-tone thresholds, was examined using descriptive statistics.

The researcher calculated and compared the thresholds at individual frequencies, as in Verhaegen et al.'s (2010) study, to achieve a more in-depth and accurate overview.

- Descriptive statistics were used to establish whether the duration of pre-operative hearing loss had an effect on post-operative performance or benefits.

- A comparative analysis of hearing function was performed pre-operatively versus post-operatively. This was achieved by comparing the pre- and post-operative unaided hearing threshold levels at each frequency in order to determine whether the hearing level had remained the same or decreased since surgery.

- General patterns or trends were examined in order to determine whether certain relationships existed between the post-operative hearing findings and the following:
  - degree of pre-operative hearing
  - duration between surgery and unaided post-operative hearing testing
  - model and manufacturer of implant

Univariate descriptive statistics were used to explore the central tendency and spread of each of the variables used in the study. Continuous variables were analysed using the mean, standard deviation, median and interquartile range. Histograms were used to assess the distributions of the variables. Categorical variables were analysed by frequency tabulation.

Inferential statistics are concerned with inferences that are made about the population (Welman, Kruger & Mitchell, 2005). By using inferential statistics, the researcher attempted to reach conclusions that extended beyond the immediate data alone. Inferential statistics were thus used in the current study in order to make judgments of the probability of whether an observed difference between the two groups was a dependable one or if it may have happened by chance. Thus, inferential statistics were used to make inferences from the data to more general conditions (Trochim, 2006).

Inferential statistics in the current study involved the following tests: Pearson's X^2 test, Fisher's exact test, t-test, Wilcoxon's test and one-way analysis of variance (ANOVA). The 95% confidence level was used throughout, unless specified otherwise.

The X^2 test was used to assess the relationships between categorical variables. Fisher's exact test was used for 2 x 2 tables or where the requirements for the X^2 test could not be met. The relationship between continuous and categorical variables was assessed by the t-test (or ANOVA for more than two categories). Where the data did not meet the assumptions of these tests, a non-parametric alternative, the Wilcoxon rank sum test (or the Kruskal-Wallis test for more than two categories) was used.

Within-group tests for paired continuous data were carried out using the paired t-test. Where the data did not meet the assumptions of this test, a non-parametric alternative, the Wilcoxon matched pairs test was used. Where multiple comparisons were carried out, alpha values were adjusted accordingly.

The tables and figures in the results section further illustrate these results. The breakdown of the sample - consisting of 60 cases, with 27 (45%) from Unit A and 33 (55%) from Unit B – in terms of key variables is presented in the results section (see Tables 1, 17, 18, 20, 22 & 24-30). Each of these variables was tested for significant differences between units: categorical variables were tested by Pearson's X^2 test (or Fisher's exact test in the case of 2x2 tables), while continuous variables were tested by the t-test for independent groups. Significant differences at the 95% confidence level have been marked in red.

3.8. Reliability and validity

The researcher attempted to produce results that were reliable and valid. Thus, the researcher endeavoured to ensure that the findings were credible as well as an accurate representation of the situation (Welman et al., 2005) in order to be considered valid. Reliability of the findings involves the degree to which the findings are credible (Welman et al., 2005). Whereas validity relates to making sure the researcher is measuring what she is intended to measure, reliability ensures that results are consistent from test session to test session by reducing error (Valente, 2009).

As already mentioned, a quantitative paradigm was adopted to ensure that results could be replicated and were reliable (Welman et al., 2005).

It is important to take into consideration that certain variables, such as researcher, participant and stimulus variables could result in artefacts being introduced into the test session (Valente, 2009). The researcher attempted to overcome such artefacts as follows: to minimize participant variables from impacting on the reliability and validity of results, the researcher excluded any records where participants were reported to have been "unreliable" during testing or where there was "questionable reliability". Further, as in Kiefer et al.'s (2004) study, any "vibrotactile" responses reported by the participants were excluded from calculations for statistical purposes. The researcher worked on the assumption that the specialist audiologists would have reported any unreliable responses.

The nature of the current study – i.e. a retrospective data review – meant that test reliability was compromised as patient variables could not be controlled (Frank, 2000 in Kanji, 2010). However, in the current study, the researcher worked on the assumption that certain variables (such as calibration of equipment) were controlled for, as qualified audiologists would have conducted the testing in line with the standard protocols.

The audiometer must measure the chosen construct, that is, decibels at chosen frequencies. The measuring instrument measured what it was intended to measure, thereby adhering to the process of construct validity (Welman et al., 2005). Therefore, the audiometer needed to be calibrated at the time of testing in order to ensure valid results (Shanks & Shohet, 2009). As the testing was done on different occasions by different audiologists at two different cochlear

implant centres, it was difficult to determine whether or not the equipment had in fact been calibrated. It was not possible for the researcher to obtain calibration certificates for each test over time as the audiometers had changed and often no record was kept as to which audiometer was used. While recognizing the limitations of this, the researcher relied on the audiologists who conducted the testing on the participants to have checked the date of calibration of the equipment prior to use. The date of calibration of the equipment should be checked in accordance with the SANS standards (SANS 0154-1). Accurate calibration is paramount in audiological testing, since it ensures that the intensity levels delivered are the same as indicated on the intensity dial readings. It also allows for standardization of results and thus comparison within and between patients (Valente, 2009).

Should background noise levels be sufficiently high during testing, this may interfere with accurate measurement by causing masking (Martin, 1997). The researcher worked on the assumption that the audiologists tested the participants in a mildly echoic testing booth with acceptably low ambient noise levels, as this is standard practice.

3.9. Ethical considerations

Prior to the commencement of the study, the researcher obtained ethical clearance from the Human Research Ethics Committee (Medical) at the University of the Witwatersrand (Appendix C). Thereafter, the researcher obtained permission from the relevant authorities at the two chosen research sites from Unit A and B (Appendix D and E respectively). Initially, permission to conduct research was granted at Unit C. A consent form was signed on the 31 January 2012 by one of the audiologists working at Unit C, granting permission to access their patients' pre-operative and post-operative audiological records (Appendix F), pending ethical clearance. Unit C also signed a form stating that their patients have given permission to access their data for research purposes (Appendix F continued). Consent was then obtained from Unit C to access patients' audiological records (Appendix G). Further, permission from two of Unit C's surgeons to access their surgical data for their patients was given on 25 January and 2 February 2012 respectively (Appendix H & I). However, Unit C withdrew from participating in this study on 22 May 2012 due to the fact that they are a "cochlear implant research institution" and "to avoid over-investigating their clients". Attrition thus took place in this instance. Attrition occurs when research participants, or in this case an institution or cochlear implant site, withdraws from a study prior to its completion.

During the study, the researcher followed the regulations and ethical guidelines of the Nuremberg Code, where applicable, and also incorporated the following ethical principles as laid out by Fontana and Frey (1994):

3.9.1. Informed consent

The researcher obtained the necessary permission from the Head of Audiology Department at Unit B to access the audiological records of cochlear implant recipients that met the criteria outlined above. The surgeons at Unit B gave written permission for their surgical records to be used in the current study.

At Unit A, the participants were contacted individually to participate in this study as they had not signed a consent form prior to surgery for their data to be used for research purposes. The surgeons at Unit A were then contacted in order to gain permission to access their surgical data pertaining to the selected participants (who had given consent). The head of the audiology department at Unit A also gave permission to the researcher to access the audiological records at Unit A.

The audiologists and surgeons at Unit A and the head of department at Unit B were informed about the purpose of the research (Fontana & Frey, 1994). They were given an information sheet providing details of the study. This included the researcher's name, institution, a brief description of the study and the purpose and aims of the research. Letters of consent were signed by the heads of the audiology departments at Unit A and Unit B (Appendix D & E) and surgeons (Appendix J, K, L, M & N) at Unit A. Consent was obtained prior to conducting the study.

Initially, the researcher obtained verbal permission, pending ethical clearance, from one of Unit A's surgeons and head of the audiology department at Unit B to conduct the research at the cochlear implant sites. Unit B received written permission from all their patients to access their records for research purposes (Appendix O). The surgeons at Unit B also provided permission for the researcher to access their surgical data (Appendices P, Q, R & S). Unit A recently introduced a form for their patients to give Unit A permission to share their data (audiological and surgical) for research purposes. However, the participants in the study had not signed this

form and therefore consent had to be obtained from these patients individually. Therefore, written permission from each participant or caregiver (if the participant was under 18 years of age) was obtained (Appendix T & U respectively). Letters were also given to the participants and caregivers at Unit A, explaining the study (Appendices V & W). If the participant was under the age of 18 years, a letter explaining the study was given (Appendix X) and an assent form was also signed by these individuals (Appendix Y). For this study, data was collected from February 2012 until September 2012 at Unit A (due to the need for post-operative testing to be conducted on some of the participants at Unit A) and May 2012 at Unit B. Consent from all Unit A's participants was obtained in advance, before data collection.

Permission to conduct this study at Unit B was obtained from the Manager of Medical Services (Western Cape Government - Ethics) for Tygerberg Hospital (Appendix Z).

Additionally, written permission from the chief executive officer at Wits Donald Gordon Medical Centre (for Unit A) (Appendix A.1) was obtained prior to conducting the study.

3.9.2. Right to privacy

Anonymity of the participants' records and surgeons was ensured and a coding system was used by the researcher as a form of identification (Schiavetti & Metz, 2002).

3.9.3. Involvement of the researcher

The researcher has abided by the strict code of ethics set out by the Nuremberg Code. Moreover, the interpretation of the audiograms for the participants was free from manipulation (Fontana & Frey, 1994). The researcher also honoured all agreements and commitments made to the surgeons and audiologists at Unit B and Unit A (Schiavetti & Metz, 2002) in that the researcher used a coding system and ensured anonymity.

3.10. Summary

This chapter discussed the methodology of the research. The methodology chapter involved discussion of the research aims and a description of the research design. Participant description

and participant selection criteria were presented. Lastly, the researcher discussed data collection, reliability, validity, ethical considerations and data analysis.

CHAPTER 4: RESULTS AND DISCUSSION

Chapter 4: Results and Discussion

4.1. Introduction

The primary objective of the current study was to explore preservation of residual hearing in a group of cochlear implant recipients at Unit A and Unit B following cochlear implant surgery.

In this chapter, the results obtained from the study are presented, analysed and discussed in relation to the secondary objectives, namely to describe hearing function before and after cochlear implant surgery and to determine the change in hearing function.

Additional sub-aims that supported the main aim of the current study are presented and discussed as these form a significant part of the study. These sub-aims were to establish whether a relationship existed between the hearing findings and the following factors: the duration of pre-operative hearing loss, the degree of pre-operative hearing, the duration between surgery and unaided post-operative hearing testing, model and manufacturer of cochlear implant, the surgical technique employed and, lastly, surgical complications relating to intracochlear structures. The researcher has chosen to present these secondary aims first, as these are all factors which may influence the hearing findings.

Results are presented in the form of tables and figures, and descriptive and inferential statistics performed, interpreted and analysed to reach conclusions, which are discussed in this chapter. Literature demonstrating relevant studies is discussed in order to provide both contrasting opinions and evidentiary support.

4.2. Demographic profile

Table 1 represents the demographic profile of the sample in the current study at Unit A and Unit B individually and at both centres combined.

Table 1

Demographic profile of observations (N=60)

Variable	**Overall**	**Unit A**	**Unit B**	**p-value for Ho: no significant difference between units**
Number of participants	53	21	32	-
Number of bilateral implants	7	6	1	0.0062 (Fisher's exact test)
Ears (% of total ears)	60	27 (45%)	33 (55%)	-
Ears (% of L ears)	40%	48%	33%	0.30 (Fisher's exact test)
Age at surgery (mean ± 95% confidence interval)	30.8 ± 3.6	23.9 ± 5.4	36.4 ± 4.1	0.0003 (t-test)
Gender: % male	36%	48%	27%	0.17 (Fisher's exact test)

4.2.1. Number of participants

A total of 60 observations formed the basis of the current study. Out of these 60 observations, 45% (n=27) were from Unit A and 55% (n=33) from Unit B. These observations or participants' ears totalled 60, due to the number of bilateral implantees. In total, there were seven bilateral implantees – six at Unit A and only one at Unit B. Thus, data was collected on a total number of 53 implantees or patients at the two South African cochlear implant centres. These 53 participants consisted of 21 and 32 implantees from Unit A and Unit B respectively.

In the researcher's opinion, this study has achieved a particular significance due to the fact that the sample size was adequate for the current study and had a greater number of observations than some other studies reported in the literature. Gstoettner et al. (2009), for instance,

conducted a highly successful clinical trial using the Med-El Flex EAS array, wherein the residual hearing of all the recipients was preserved post-operatively; however, there were only nine recipients, limiting the generalizability of their study. Lenarz et al. (2009) conducted a clinical trial where 24 patients were fitted with the Hybrid-L electrode together with an ipsilateral hearing aid, with eight recipients being fitted with a cochlear implant only. Lenarz et al.'s (2009) study made use of a greater number of participants, namely 32 in total, thereby making their findings more representative.

During data collection, the researcher established that there were no participants recorded by the audiologists who conducted the testing as having questionable reliability. As a result, there were no exclusions of records for this reason.

The researcher holds that the sample size in the current study was large enough to be adequate for the statistical analysis employed, making the findings particularly relevant.

4.2.2. Bilateral implantees

The researcher investigated the number of bilateral implantees overall and at each centre individually. There were seven patients fitted bilaterally overall. These consisted of six bilateral implantees at Unit A and one at Unit B.

From Table 1 it can be seen that the difference between the number of bilateral implantees at Unit A and Unit B was statistically significant – there being a higher number of those implanted bilaterally at Unit A. This became evident during the implementation of the Fisher's exact test, where the p-value was 0.0062 (indicating this statistical significance). The above discrepancy between bilateral implantees at the two centres may be explained by the fact that Unit B is a government subsidised institution and Unit A a private institution. Given the fact that cochlear implantation is an expensive procedure and that there are limited funds available in South Africa, the government provides only one implant for each candidate (bilateral implantation is not considered due to this limited availability of funds). Affordability for the procedure in the private sector, on the other hand, is possible and thus bilateral implantation is a more realistic goal for implantees. The researcher thus believes that this might explain why the proportion of bilateral implantees was greater at Unit A than at Unit B.

4.2.3. Ear implanted

Table 1 illustrates that 60% of implantees in the sample were fitted in the right ear while 40% were fitted in the left ear - 48% of whom were from Unit A and 33% from Unit B. However, according to the Fisher's exact test, the difference between the two centres was not statistically significant. Thus, this was not a significant finding.

4.2.4. Mean age at surgery

Overall, out of a total sample of 60 observations (N=60), the mean age at surgery was 30.8 years (s.d. ± 3.6 years).

4.2.5. Gender

Data was collected from a sample of 36% males and 64% females overall at the two units.

4.3. Hearing function before and after cochlear implant surgery

The researcher investigated the hearing threshold levels (in decibels) pre-operatively and post-operatively and calculated the change (i.e. the difference between pre- and post-operative hearing levels at each frequency) at both centres combined and at each centre individually. In this way the preservation of residual hearing could be determined at each frequency at Unit B and Unit A and overall.

4.3.1. Hearing function before surgery (PRE)

One of the secondary aims of this study was to determine the pre-operative hearing threshold levels prior to surgery (PRE). The researcher first investigated the time between the last pre-operative hearing test and surgery in months (T_PRE) at both centres and each centre individually, as this could impact the results obtained. T_PRE was used as a covariate in the analysis of the results in order to prevent the results being affected by extraneous variables.

Pre-operative hearing threshold levels at individual frequencies for the sample at Unit A, Unit B and at both centres combined were examined and are presented in the figures below (Figure

5 - 7). Figures 6 and 7 illustrate the pure-tone thresholds prior to surgery at both centres at frequencies ranging from 125 Hz to 8000 Hz.

From the raw data, the researcher observed that there was no data at 125 Hz for Unit B (and only 11 data points at Unit A i.e. n=11). Consequently, no comparative analysis could be performed between the two centres at this frequency. Although according to Franks, Stephenson and Merry (1996), criteria for testing protocol must include 125 Hz for clinical testing, there was no data at this particular frequency for Unit B and minimal data at Unit A.

The researcher also noted that there were limited data points at other frequencies. There were only four data points at 750 Hz; two data points at 1500 Hz; nine at 3000 Hz and nine at 6000 Hz - all at Unit A. The researcher in this study considered that the reason for this may have been due to the fact that these particular frequencies are half-octaves and according to Franks et al. (1996), when conducting hearing testing for clinical purposes, half-octaves are only "sometimes" tested.

During data collection, the researcher also noted that there were limited data points at other frequencies. This is depicted in Figure 9 where there were only four data points at 750 Hz, two data points at 1500 Hz, nine at 3000 Hz and nine at 6000 Hz - all at Unit A. The researcher believes that the reason for this may be due to the fact that these particular frequencies are half-octaves and thus are not standard protocol for testing.

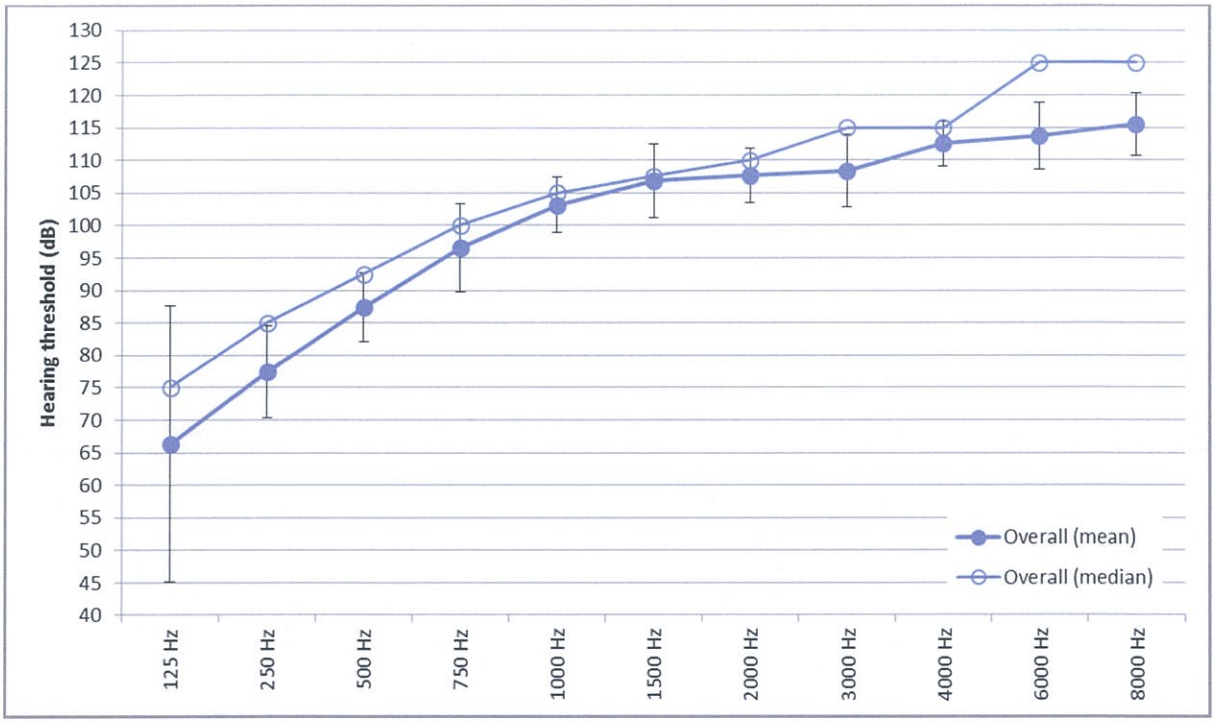


Figure 5. Pre-operative hearing threshold level(s) overall (PRE HTL_Overall)

The mean and median values of the hearing thresholds for each frequency are plotted in Figures 5 - 8. The 95% confidence interval for the means are shown as error bars.

Significant differences between frequencies (paired *t*-test) have been listed below each graph. Alpha values were adjusted to account for multiple comparisons, and the Wilcoxon matched pairs test was used as a non-parametric alternative to the paired *t*-test where the assumptions of the *t*-test were not met.

Figure 5 depicts the pre-operative hearing threshold levels at both Unit A and Unit B combined at individual frequencies from 125 Hz to 8000 Hz for all the participants. Results indicated that pre-operatively, participants in the overall sample presented with some degree of low frequency residual hearing with poorer hearing in the high frequencies. As the frequencies increased (i.e. from 250 Hz to 8000 Hz), so the hearing loss increased (i.e. poorer hearing and less residual hearing). This was expected and can be explained by the tonotopicity of the cochlea (Martin & Clark, 2006). "Tonotopicity is the spatial representation of the frequency layout of the cochlea in the retrocochlear structures" (Martin & Clark, 2006, p326).

Table 2

Significant differences between the frequencies (overall)

125 Hz vs. 500, 1000, 2000, 4000 and 8000 Hz
250 Hz vs. 500 Hz and greater
500 Hz vs. 750 Hz and greater
750 Hz vs. 1000 Hz and greater
1000 Hz vs. 1500, 2000, 4000, 6000 and 8000 Hz
1500 Hz vs. 6000 and 8000 Hz
2000 Hz vs. 4000, 6000 and 8000 Hz
3000 Hz vs. 4000 and 8000 Hz

There were significant differences between the above frequencies in terms of the hearing threshold levels (in decibels).

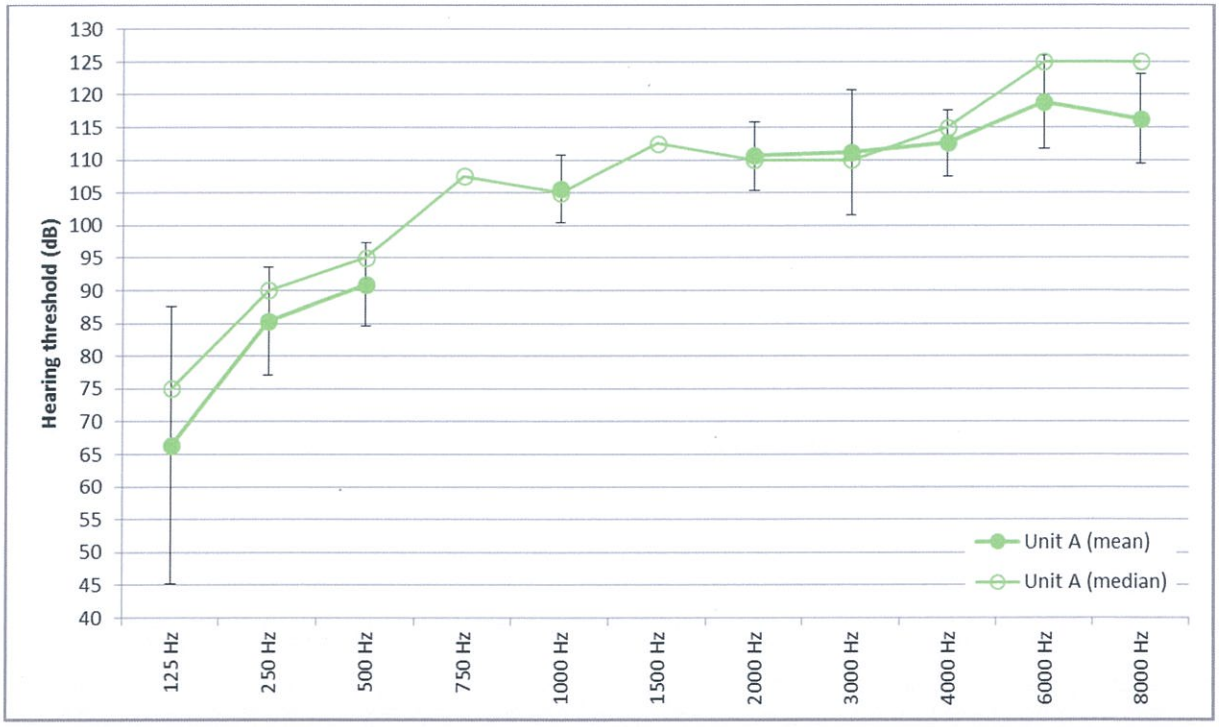


Figure 6. Pre-operative hearing threshold levels at Unit A (PRE HTL_Unit A)

Table 3

Significant differences between the frequencies (at Unit A)

125 Hz vs. 500, 1000, 2000, 4000 and 8000 Hz
250 Hz vs. 1000, 2000 Hz and greater
500 Hz vs. 1000, 2000 Hz and greater
1000 Hz vs.2000, 4000 Hz and greater

There were significant differences between the above frequencies in terms of the hearing threshold levels (in decibels).

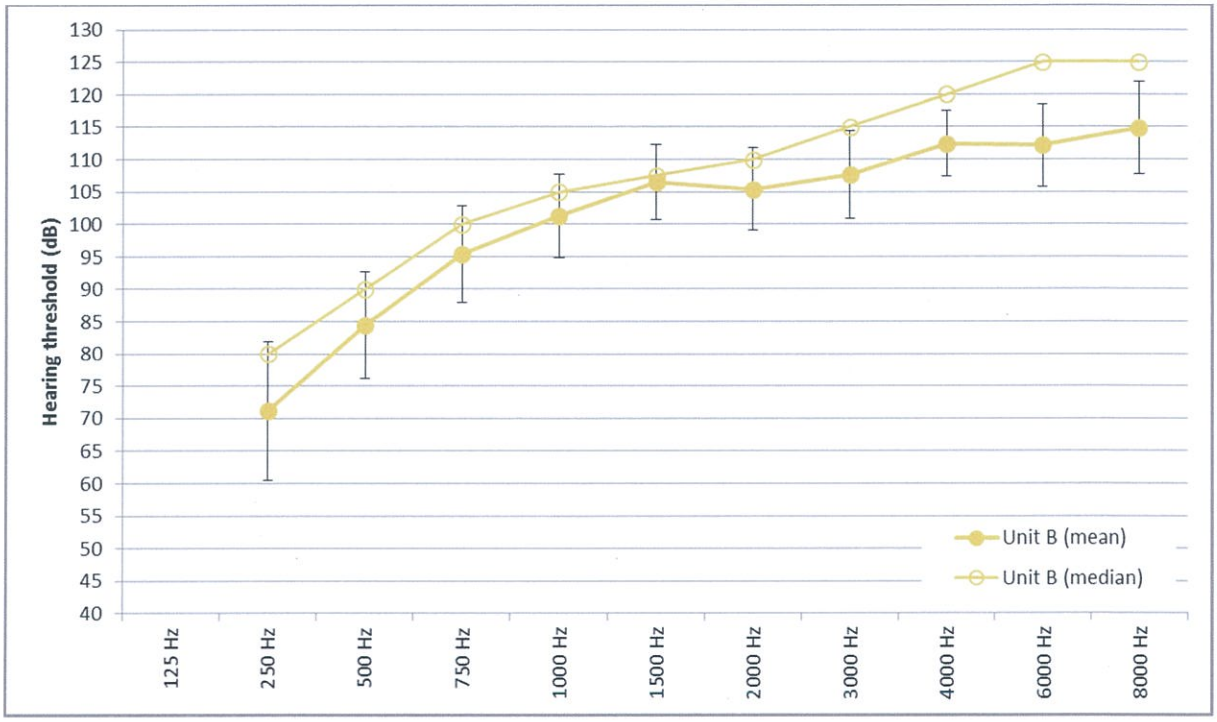


Figure 7. Pre-operative hearing threshold levels at Unit B (PRE_HTL Unit B)

Figure 7 represents the mean sample with a high frequency hearing loss pre-operatively at Unit B. The graph further indicates that the sample has some low frequency residual hearing pre-operatively. It can be seen that there was more residual hearing in the low- and mid-frequencies than in the high frequencies pre-operatively. Very little or no residual hearing was present in the high frequencies pre-operatively.

It should be noted that similar patterns were observed in all the above results, illustrated in the figures above – overall and for Unit A and Unit B. It can therefore be concluded that the general pattern appeared to be that prior to surgery the participants in this study had high frequency hearing losses and some low frequency residual hearing pre-operatively. Findings of post-operative residual hearing will be discussed later in order to determine whether surgery had an impact on the low frequency residual hearing and to determine whether there has been any preservation of the hearing thresholds – low, mid or high frequencies.

The above reduction in residual hearing in the high frequencies pre-operatively may be explained by the fact that high frequencies are more susceptible to damage as a result of the tonotopic organization of the cochlea and thus high frequency hearing loss is more common (Martin & Clark, 2006).

Table 4

Significant differences between the frequencies (at Unit B)

250 Hz vs. 500 Hz and greater
500 Hz vs. 750 Hz and greater
750 Hz vs. 1000 Hz and greater
1000 Hz vs. 1500, 4000 Hz and greater
1500 Hz vs. 6000 and 8000 Hz
2000 Hz vs. 4000 Hz and greater
3000 Hz vs. 4000 and 8000 Hz

There were significant differences between the above frequencies in terms of the hearing threshold levels.

The bar graphs in Figures A, B and C in the appendices illustrate the pre-operative hearing threshold levels at each frequency, overall and for each centre (PRE-freq distrib). These bar graphs or frequency distributions provide more detailed information than Figures 6 and 7 with regard to the pre-operative hearing threshold levels as they depict the pure-tone hearing thresholds at each individual frequency – ranging from 125 Hz to 8000 Hz – overall (Figure

A.1 – A.11), Unit A (Figure B.1 – B.11) and Unit B (Figure C.1 – C.10). Figures 8 – 9 are relevant for interpretation and discussion of the results, as they assisted the researcher in detecting general patterns or trends. Figures A-C in the appendices, on the other hand, assisted the researcher with analysing specific information to further add to the interpretation of the results and discussion of the findings.

These frequency distributions in Figures A, B and C in the appendices well illustrate the number of observations found at each hearing threshold level for each frequency - overall (Figure A), at Unit A (Figure B) and at Unit B (Figure C). Overall, results indicated that the hearing thresholds levels were better at the low frequencies and decreased as the frequencies increased. A similar pattern between the two units – Unit A and Unit B – appeared in the frequency distributions. A general linear model (GLM) was used in order to provide evidence for this. This pattern or trend showed more residual hearing in the low frequencies and as the frequencies increased, so the hearing thresholds decreased pre-operatively.

The GLM was used to determine whether there were any significant differences between the units (refer to Table A.1 in appendices for calculations of the GLM).

Results of the GLM are tabulated in Table A.2 in the appendices and significant parameters are marked in red.

As expected, in all cases the hearing threshold levels at each frequency were significantly different to zero.

From Table A.1 and A.2, the researcher noted the following:

- The coefficient for UNIT (α_1) was significantly different to zero for PRE 250 Hz. The predicted value for PRE 250 Hz for Unit A was 9.2 dB higher than that for Unit B, controlling for T_PRE. This indicated that the hearing threshold level was slightly poorer at 250 Hz for the average participants at Unit A (increased decibel level at that particular frequency).

- The coefficient for UNIT (α_1) was not significantly different to zero for any of the other frequencies. This is indicative that the mean hearing thresholds for the two units were not

significantly different at any of the frequencies, while controlling for T_PRE. In other words, the hearing threshold levels across the frequencies were similar at both the units (i.e. not statistically significant). Taking these results together, the difference at 250 Hz was unlikely to be of any practical consequence. The statistical results correlate with the audiological findings – i.e. from the audiological interpretation of the graph or frequency distributions it became evident that the hearing threshold levels were similar between the two centres across the frequencies.

From the above results, the researcher deduced that the pre-operative hearing threshold results that were obtained at both centres and overall were expected. Of the current sample, findings indicated that the majority of the participants presented with severe sloping to profound sensori-neural pre-operative hearing loss (with some residual hearing in the low- and mid-frequencies and very little or no residual hearing in the high frequencies pre-operatively). According to these findings, there was more residual hearing in the low frequencies and as the frequencies increased, so the hearing thresholds decreased pre-operatively. This pattern or trend occurred at Unit A and at Unit B and at both centres combined. These findings were expected due to high frequencies being more susceptible to damage as a result of the tonotopicity of the cochlea. The researcher then examined the post-operative hearing threshold levels at each frequency at the individual centres and overall in order to later calculate the change in these levels to determine whether residual hearing had been preserved post-surgery.

4.3.2. Hearing function after surgery (POST)

Another secondary aim of the current study was to determine the post-operative hearing threshold levels (POST).

From the findings, the researcher noted that there was no data for 125 Hz for Unit B (and only n=5 for Unit A at 125 Hz, all had "no response"/NR). The lack of data points at Unit B and the limited data points at Unit A for 125 Hz could be explained by the fact that 125 Hz does not form part of the audiological testing protocol and is generally only tested when there is a low frequency hearing loss. However, this is not a standard protocol according to some.

Through further analysis, the researcher found that at Unit A there was only one data point for 750 Hz and there were four data points for 1500 Hz, 19 for 3000 Hz and 16 for 6000 Hz. The

reason for the few data points at these particular frequencies at this centre could be due to the fact that 750 Hz, 1500 Hz, 3000 Hz and 6000 Hz are all half octaves and are not frequencies which are frequently tested. Half octaves do not form part of the audiological testing protocol, but are tested when there is a 20 dB difference between the decibels between the octaves. The frequencies 3000 Hz and 6000 Hz are also tested if the patient is a hearing aid candidate and is being tested prior to hearing aid programming. This does not form part of the basic test battery during an audiological evaluation or hearing test.

The mean and median values of the hearing thresholds for each frequency are plotted in Figures 8 - 10. The 95% confidence interval for the means are shown as error bars.

Significant differences between frequencies (paired *t*-test) are listed below each graph. Alpha values were adjusted to account for multiple comparisons, and the Wilcoxon matched pairs test was used as a non-parametric alternative to the paired *t*-test where the assumptions of the *t*-test were not met.

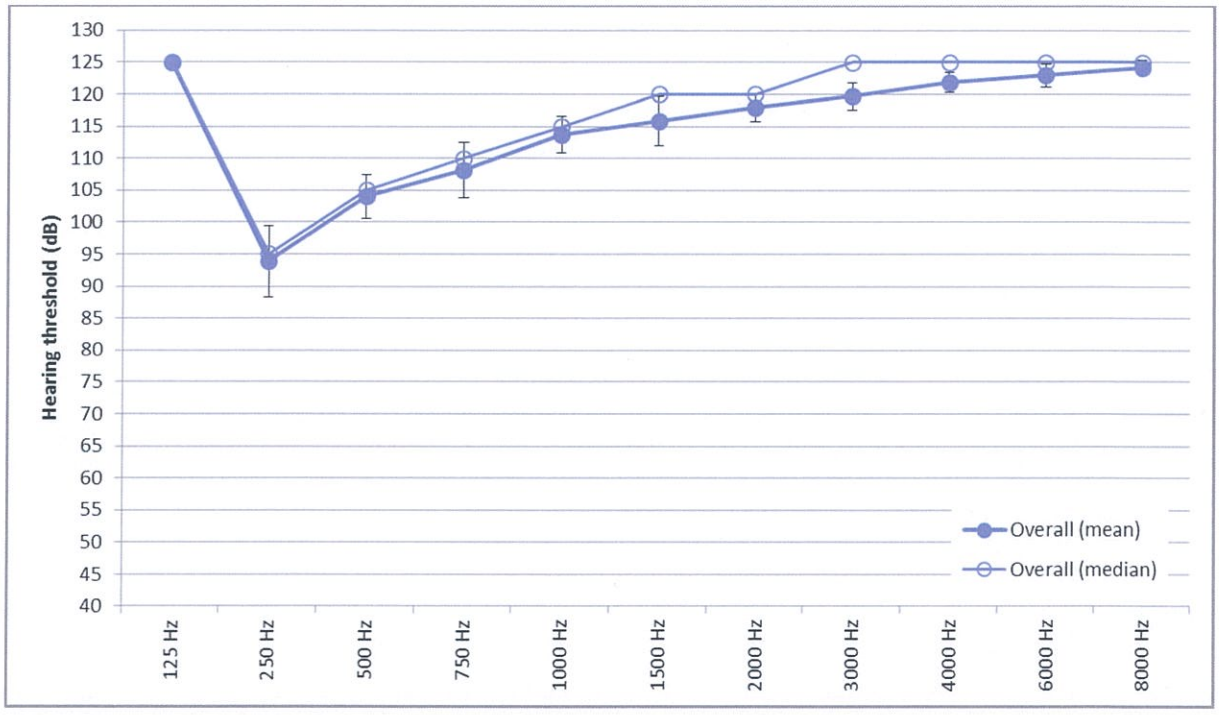


Figure 8. Post-operative hearing threshold levels overall (POST HTL_Overall)

Table 5

Significant differences between the frequencies (Overall)

250 Hz vs. 500 Hz and greater
500 Hz vs. 750 Hz and greater
750 Hz vs. 1000 Hz and greater
1000 Hz vs. 2000 Hz and greater
1500 Hz vs. 6000 Hz and greater
2000 Hz vs. 4000 Hz and greater
3000 Hz vs. 8000 Hz

There were significant differences between the above frequencies in terms of the hearing threshold levels for the average participant at both centres combined.

The results obtained indicated a high frequency loss, with some preservation of the low frequencies and slight preservation of the mid-frequencies post-operatively.

When analysing the findings in detail, the researcher observed that the results indicated total loss of residual hearing at 125 Hz overall. From Figure 8, the researcher speculated that the data point at 125 Hz was an outlier. Thus, this data point was not considered in the interpretation of the results. The outlier at 125 Hz overall was a result of the findings at 125 Hz at Unit A being an outlier (Figure 9). There were no data points at 125 Hz at Unit B (Figure 10) and thus this could not have affected the overall findings.

There was some preservation of residual hearing at the low frequencies and as the frequencies increased, so the hearing threshold levels decreased – i.e. there was a high frequency loss. At 8000 Hz, there was a total loss of hearing, while at 250 Hz, the hearing threshold level was 95dB. Although, the results indicated some preservation of low frequency and mid frequency hearing (the latter to a lesser degree), it became evident from the results and the figures above that there was some loss in residual hearing – i.e. the hearing threshold levels dropped from before surgery to after surgery. This can be seen when comparing the pre-operative and post-

operative data/ hearing threshold levels – refer to CH/ change in residual hearing below (POST-PRE=CH)

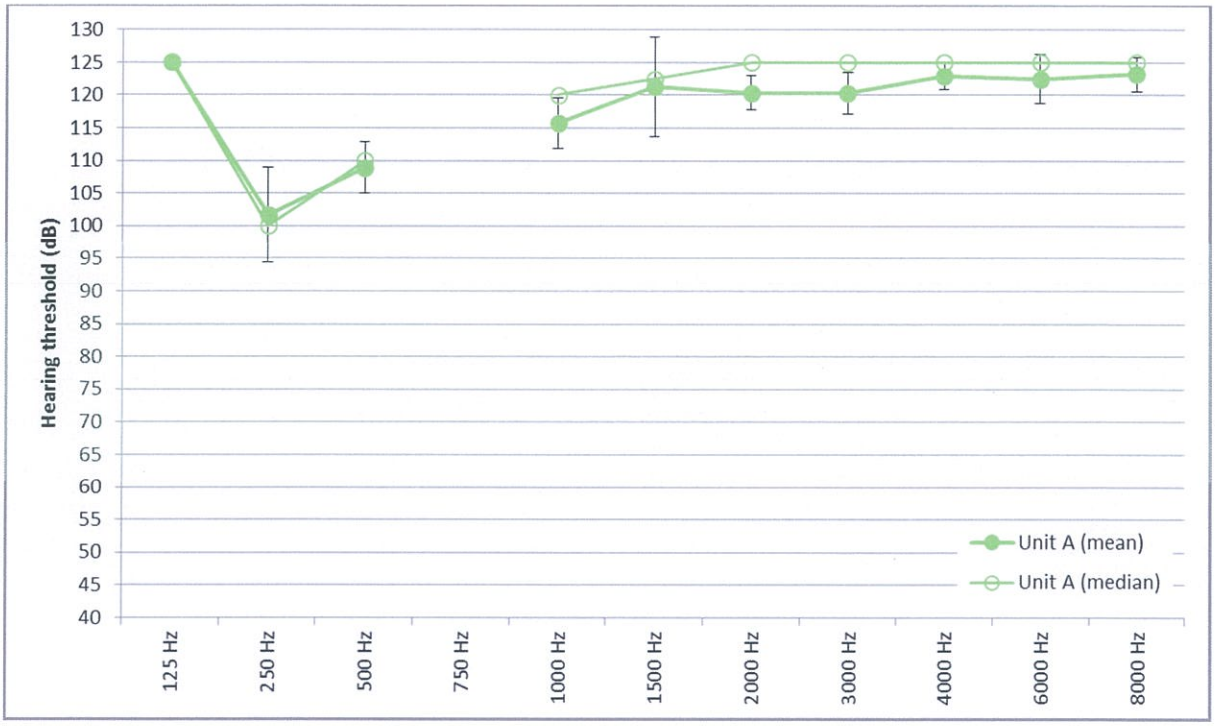


Figure 9. Post-operative hearing threshold levels at Unit A (POST HTL_Unit A)

Table 6

Significant differences between the frequencies (at Unit A)

250 Hz vs. 1000, 2000 Hz and greater
500 Hz vs. 1000 Hz and greater
1000 Hz vs. 2000 Hz and greater

There were significant differences between the above frequencies in terms of the hearing threshold levels for the average participant at Unit A.

With the exception of 125 Hz (which was an outlier), there was preservation of low frequency hearing among the average individuals at Unit A. The hearing threshold levels suffered less deterioration at the low frequencies than at the high frequencies. As with the findings overall above, Figure 9 illustrates a mean high frequency hearing loss. No data existed for 750 Hz. It

is possible that this was because this is a half octave and only tested if there is a 20 dB difference between the two adjacent frequencies.

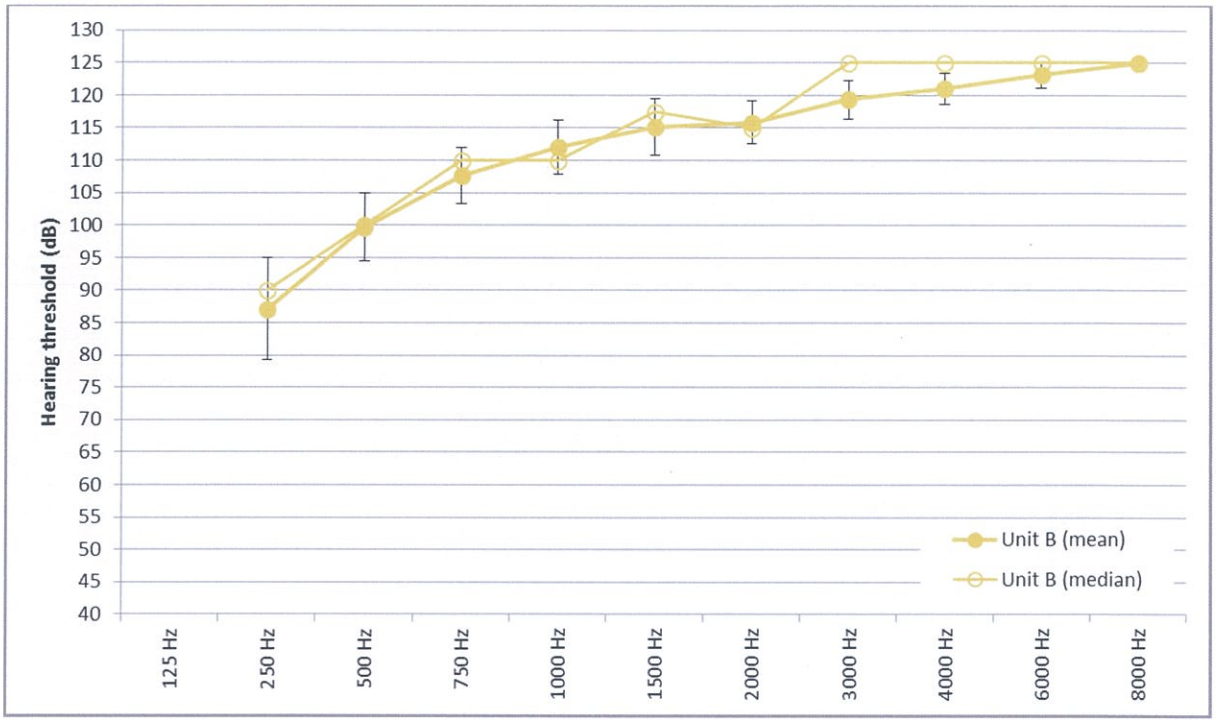


Figure 10. Post-operative hearing threshold levels at Unit B (POST HTL_Unit B)

Table 7

Significant differences between the frequencies (at the UNIT B)

250 Hz vs. 500 Hz and greater
500 Hz vs. 750 Hz and greater
750 Hz vs. 1000 Hz and greater
1000 Hz vs. 3000 Hz and greater
1500 Hz vs. 3000 Hz and greater
2000 Hz vs. 3000 Hz and greater
3000 Hz vs. 8000 Hz
4000 Hz vs. 8000 Hz

There were significant differences between the above frequencies in terms of the hearing threshold levels for the average participant at Unit B.

The researcher observed that, compared to Unit A, there was less low frequency hearing loss at Unit B – i.e. the mean hearing thresholds were better in the low frequencies at Unit B than at Unit A. Additionally, the mean threshold levels were better in the mid- and high-frequencies at Unit B than at Unit A.

Figures D (overall post-operative data for 250 Hz to 8000 Hz), E (Unit A post-operative data for 250 Hz to 8000 Hz) and F (Unit B post-operative data for 250 Hz to 8000 Hz) in the appendices represent the post-operative hearing threshold levels at each frequency for each centre separately and both units combined.

These frequency distributions provide more specific and detailed information than Figures 8 – 10 with regard to the post-operative hearing thresholds, as they illustrate the hearing thresholds levels at each individual frequency – ranging from 125 Hz to 8000 Hz – overall (Figure D.1 – D.9 - 250 Hz to 8000 Hz), Unit A (Figure E.1 – E.10 – 125 Hz to 8000 Hz) and Unit B (Figure F.1 – F.10 250 Hz to 8000 Hz). Figures 8 - 10 were significant for interpretation and discussion of the findings in discovering trends that may exist in relation to the post-operative hearing threshold levels. The researcher then examined the individual frequencies in order to obtain a more in-depth analysis of the post-operative hearing threshold levels for the mean participants at each centre and at individual units. Figures D - F in the appendices further assisted the researcher obtain a holistic view and aided in the interpretation of the results and discussion of the findings.

The researcher examined Figures D – F and found that the post-operative results indicated that, overall, the hearing thresholds levels were better at the low frequencies and decreased as the frequencies increased. Similarly, the findings at Unit A and Unit B reflected a high frequency hearing loss, with better hearing in the low and mid frequencies (particularly the former). In other words, there was a sloping high frequency hearing loss. This pattern or configuration of hearing loss seen overall and at each unit individually was observed by the researcher pre-operatively too – the difference being the level of hearing loss (i.e. poorer post-operative hearing compared to pre-operative hearing). Even though the researcher found that the low and mid frequencies were not affected to the same extent as the high frequencies, all frequencies

decreased to some degree post-operatively. This was to be expected, given the number of factors that could affect hearing during cochlear implantation.

A GLM was used to determine whether there were any significant differences between the units (refer to Table B.1 in the appendices for calculations of the GLM).

The results of the GLM are tabulated in Table B.2 in the appendices and the significant parameters have been marked in red.

The researcher used the GLM (refer to Table B.1 and B.2 in the appendices) to compare the results between Unit A and Unit B. This statistical model was used to determine whether there had been any difference in terms of the post-operative hearing threshold levels for the mean cochlear implantee at each frequency between the two centres.

From the GLM, the researcher observed the following:

- The intercept (α_0) was the predicted value of POST_freq at T_POST=0 and for Unit=Unit B. In all cases, as expected, this was significantly different to zero.
- The coefficient for UNIT (α_1) was not significantly different to zero for any of the frequencies. This meant that the mean thresholds for the two units were not significantly different at any of the frequencies, while controlling for T_POST.
- The effect of T_POST was also not significant at any of the frequencies. This suggested that the post-operative hearing threshold levels (POST values) were not affected by the time between the surgery date and the post-operative testing date (T_POST). However, it should be noted that the researcher was not comparing repeated measurements for individuals, but measurements for different individuals made at different T_POST times.

The reason for this was because of the inconsistency in terms of testing dates and lack of or limited data at set intervals. Should there have been a set protocol in place for the post-operative testing - e.g. post-operative testing at one month, six months and one year – and if there had been sufficient data at these intervals - then the researcher could have collected data at set intervals, thereby comparing repeated measurements. However, in the current study, given the abovementioned reasons, this was not possible and as a result measurements for different individuals at different post-operative testing times were recorded, analysed and interpreted.

4.3.3. Change in hearing function (CH)

One of the main secondary objectives was to determine the difference between pre- and post-cochlear implant surgery – i.e. to determine the change ("CH") in hearing function.

By determining the change in hearing function, the researcher was able to determine the preservation of residual hearing, thereby addressing the primary research question.

Key univariate statistics for each of the CH variables were analysed – overall, and by UNIT. The frequency distributions of each of the variables are provided in the appendices (Figures I, J and K).

During analysis of the findings, the researcher observed that there was no data for 125 Hz for Unit B (and only n=1 for Unit A). Thus, this frequency was not considered for the analysis.

The researcher also noted that at Unit A there were no data points for 750 Hz, and at 1500 Hz there were five data points at 3000 Hz; there was only one data point at 6000 Hz; and four data points at 8000 Hz. At Unit B, there were 12 data points at 6000 Hz and seven at 8000 Hz.

The mean and median values of the change in hearing thresholds for each frequency have been plotted below – overall (Figure 11), at Unit A (Figure 12) and at Unit B (Figure 13). The 95% confidence interval for the means are shown as error bars.

Significant differences between frequencies (paired *t*-test) are listed below each graph. Alpha values were adjusted to account for multiple comparisons and the Wilcoxon matched pairs test was used as a non-parametric alternative to the paired *t*-test where the assumptions of the *t*-test were not met.

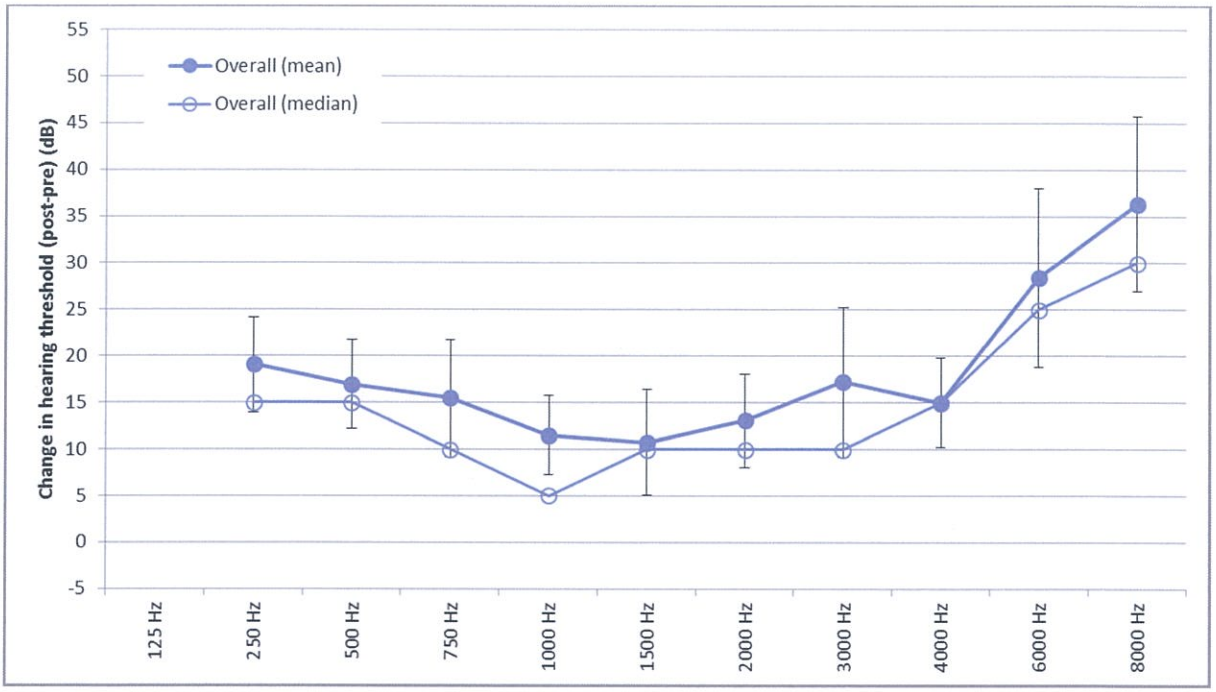


Figure 11. Change in hearing threshold level(s) overall (CH HTL_Overall)

Table 8

Significant differences between the frequencies (Overall)

250 Hz vs. 1000, 1500, 2000, 8000 Hz
500 Hz vs. 1000, 8000 Hz
750 Hz vs. 1000 Hz
1000 Hz vs. 8000 Hz
2000 Hz vs. 8000 Hz
4000 Hz vs. 8000 Hz

There were significant differences between the above frequencies in terms of the hearing threshold levels (in decibels).

Overall, as depicted in Figure 11, there had been a mean loss in residual hearing, particularly in the high frequencies. There was also a loss in the low and mid frequencies, but to a lesser degree than the high frequencies. In the low and mid frequencies, there was more preservation of residual hearing than in the high frequencies. Even though there was some loss of residual

hearing, it became evident from Figure 11 that there was some preservation of residual hearing in the low and mid frequencies.

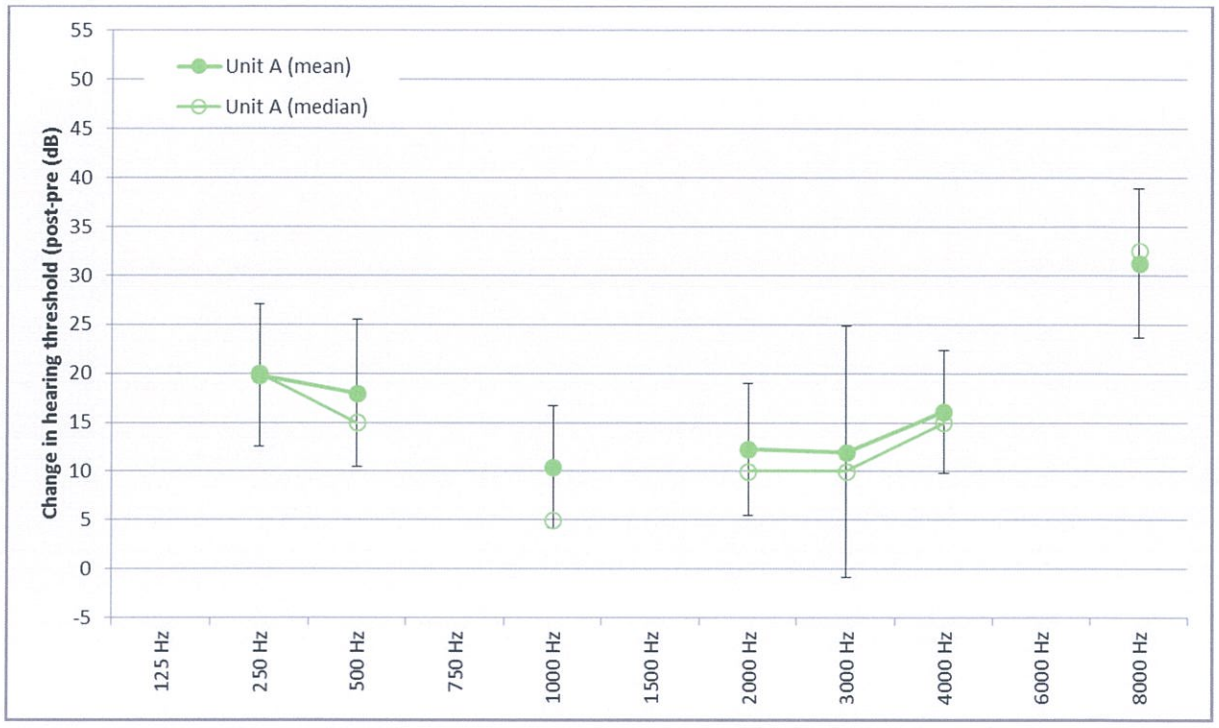


Figure 12. Change in hearing threshold at Unit A (CH HTL_Unit A)

Table 9

Significant differences between the frequencies (at Unit A)

250 Hz vs. 1000 Hz
500 Hz vs. 1000 Hz

There were significant differences between the above frequencies in terms of the hearing threshold levels (in decibels).

Although there was missing data at some frequencies where change in residual hearing could not be calculated for Unit A, a trend became apparent. From Figure 12, the researcher observed that there was a greater mean loss of residual hearing in the high frequencies (with slight hearing preservation) than in the low and mid frequencies. Thus, there was the greatest change in hearing threshold levels in the high frequencies and some hearing preservation in the low and mid frequencies.

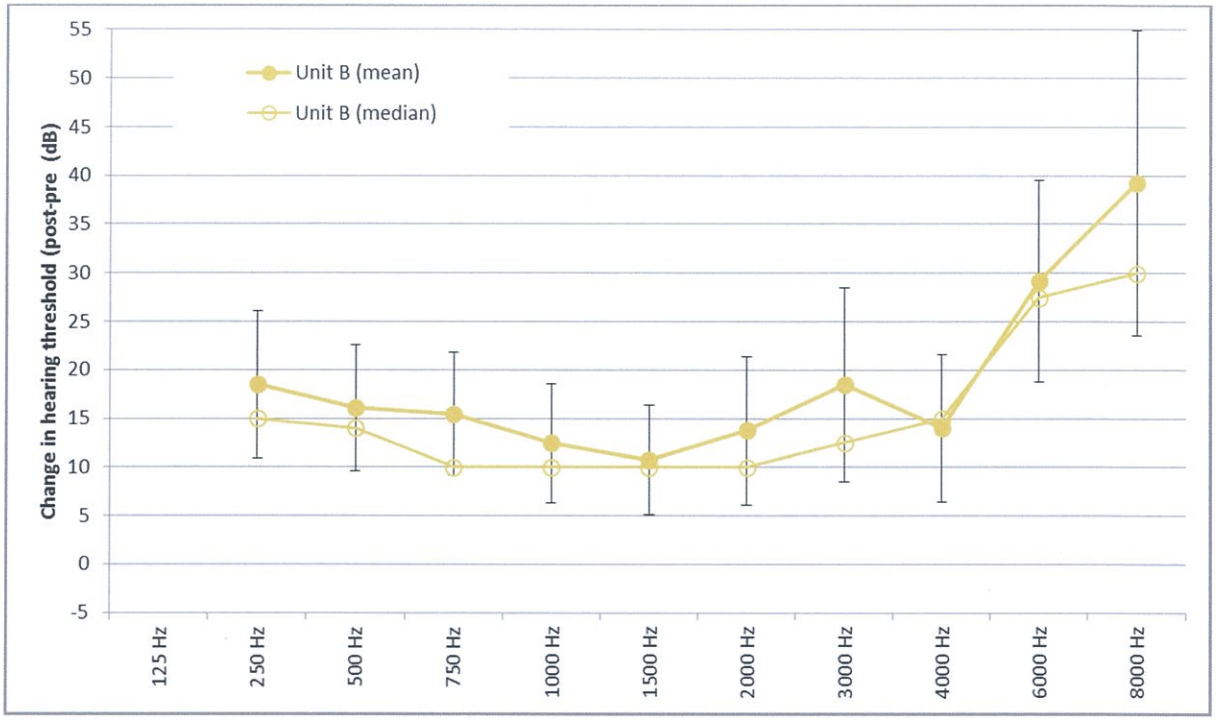


Figure 13. Change in hearing threshold levels at UNIT B (CH HTL_Unit B)

Table 10

Significant differences between the frequencies (at Unit B)

250 Hz vs. 1500 Hz
750 Hz vs. 1000 Hz

There were significant differences between the above frequencies in terms of the hearing threshold levels (in decibels).

From Figure 13, it can be seen that there was preservation of residual hearing in the low and mid frequencies (slightly more than at Unit A) and less preservation in the high frequencies – i.e. the change or decrease in residual hearing was greater in the high frequencies than in the low and mid frequencies.

The change in residual hearing (i.e. loss of hearing) was less in the mid and low frequencies. This is clinically significant in that the preserved mid frequencies could assist with speech perception in noise and allow for the consideration of acoustic amplification (along with the preservation of the low frequencies) with a hearing aid – and a cochlear implant for the high frequencies, i.e. EAS.

It was expected that there would be a change in hearing threshold levels in the high frequencies (i.e. a decrease in hearing at the high frequencies) due to the placement and the insertion of the electrode in the cochlea and due to the tonotopicity of the cochlea (the outer hair cells stimulate the high frequencies at the base of the cochlea where the electrode is inserted, thereby causing possible damage to these hair cells). Additionally, the high frequencies are more susceptible to damage, given their placement in the cochlea. Given the placement and insertion of the electrodes and tonotopicity, the researcher expected the low and mid frequencies, which are situated at the apex of the cochlea to be preserved to a greater extent in terms of residual hearing than the high frequencies.

When investigating the change in residual hearing at each frequency for Unit A, Unit B and both units combined, the researcher examined Figure 11, 12 and 13.

All the error bars in Figure 11 – 13 did not include zero (with the exception of Unit A at 3000 Hz where n=5). This was indicative of change in threshold at each frequency being significantly different to zero. This was the identical result to performing a simple paired t-test on the PRE and POST values. The means were all positive, indicating a loss in mean hearing function at each frequency. In other words, there had been a change in hearing, namely a reduction in hearing threshold levels.

To establish whether the change in hearing function was significantly different to zero, the researcher included T_PRE and T_POST as covariates, as well as the value of PRE itself since this may have influenced the magnitude of change (CH). Thus, the GLM was used. Table C.1 in the appendices provides the GLM calculations. The results are tabulated in Table C.2 (see appendices (CH_GLM)). Significant parameters are marked in red.

From the findings the researcher observed the following:

- The intercept (α_0) and the effect of PRE ($\alpha 1$) were significantly different to zero for all the frequencies. This coefficient for PRE was negative in all cases, which meant that the magnitude of CH decreased as PRE increased. In other words, as the pre-operative hearing threshold levels increased, so the change in residual hearing decreased – i.e. less change in residual hearing or less loss of hearing.

- The effect of PRE on CH at each frequency is illustrated in the profile plot below (at mean values for T_PRE, T_POST). Thus, the researcher is unable to state that there was a significant increase in hearing loss at a particular frequency. This was dependent on the value of PRE: the higher PRE, the lower the CH. In other words, increased pre-operative hearing thresholds (or greater hearing loss pre-operatively) resulted in less change in residual hearing – i.e. less decrease in hearing threshold levels or more preservation of residual hearing post-operatively. Figure 14, 15 and 16 below reflect this pattern overall, at Unit A and Unit B respectively. From these figures it can be seen that the aforementioned general trend exists for each centre and both units combined.

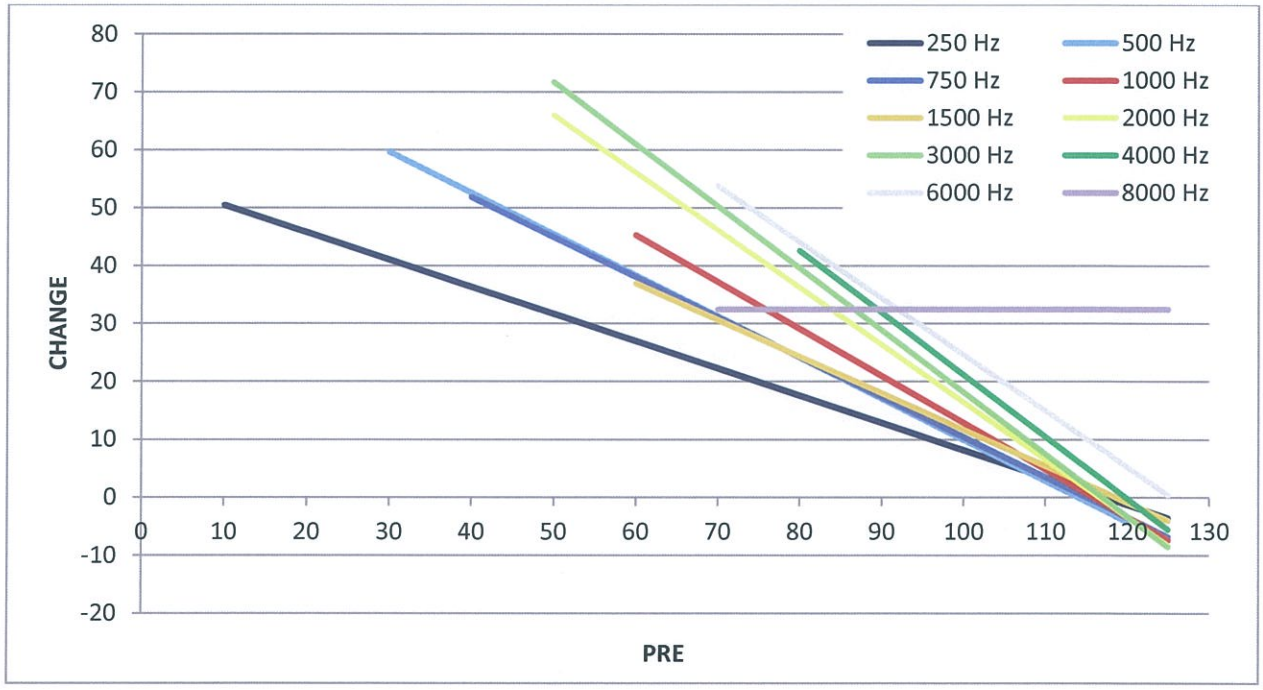


Figure 14. Change in general linear model overall (CH_GLM Overall)

The coefficients for T_PRE (α_2), T_POST(α_3) and UNIT (α_4) were not significantly different to zero for any of the frequencies, which meant that these variables did not have a significant effect on CH.

Figure 15 (GLM_CH Unit A) below illustrates the effect of pre-operative hearing threshold levels (PRE) on change (CH). A pattern arose whereby the change variables were dependant on the pre-operative hearing threshold levels and the latter influenced the former. The PRE values affected the CH variables in that, as the pre-operative hearing decreased (i.e. greater

degree of hearing loss), so there was a lesser change in hearing threshold levels post-operatively (i.e. more preservation in residual hearing post-operatively).

There was missing data at certain frequencies at Unit A. However, this did not affect the interpretation of the results as a trend could still be seen by the researcher. Furthermore, data was obtained from the low, mid and high frequencies so a comprehensive, holistic view could be obtained for interpretation. It did, however, result in not all the results being comparable at certain frequencies to the findings obtained from Unit B (where the data was not missing – refer to Figure 16).

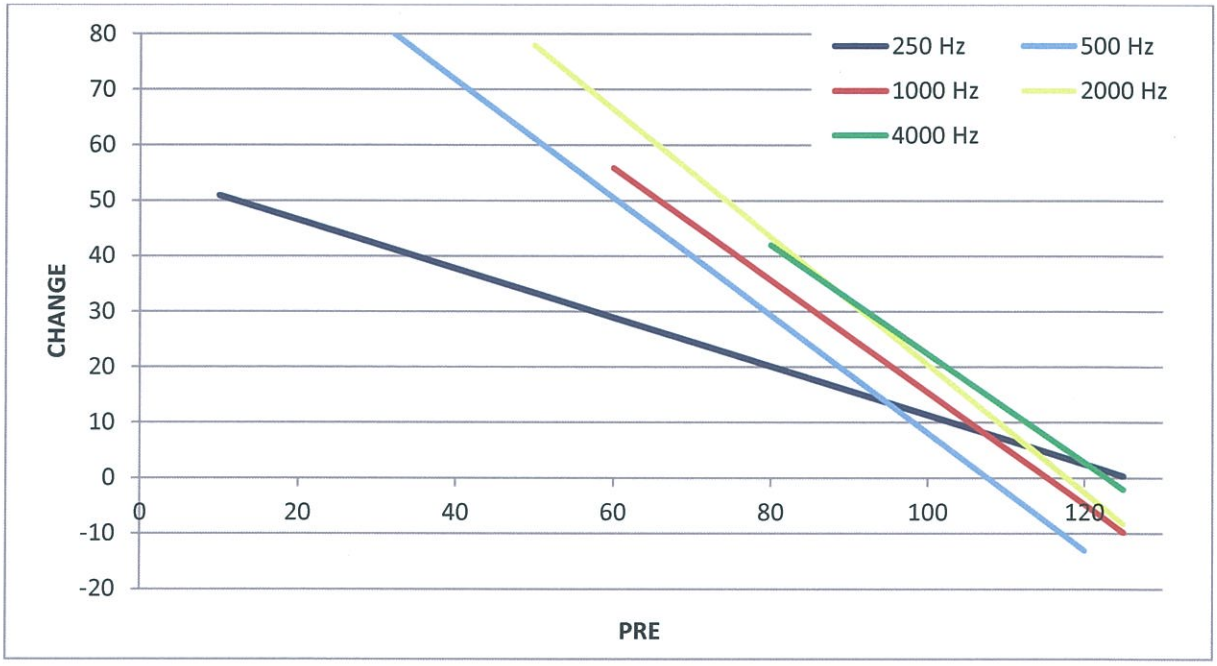


Figure 15. Change in general linear model (Unit A) (CH_GLM Unit A)

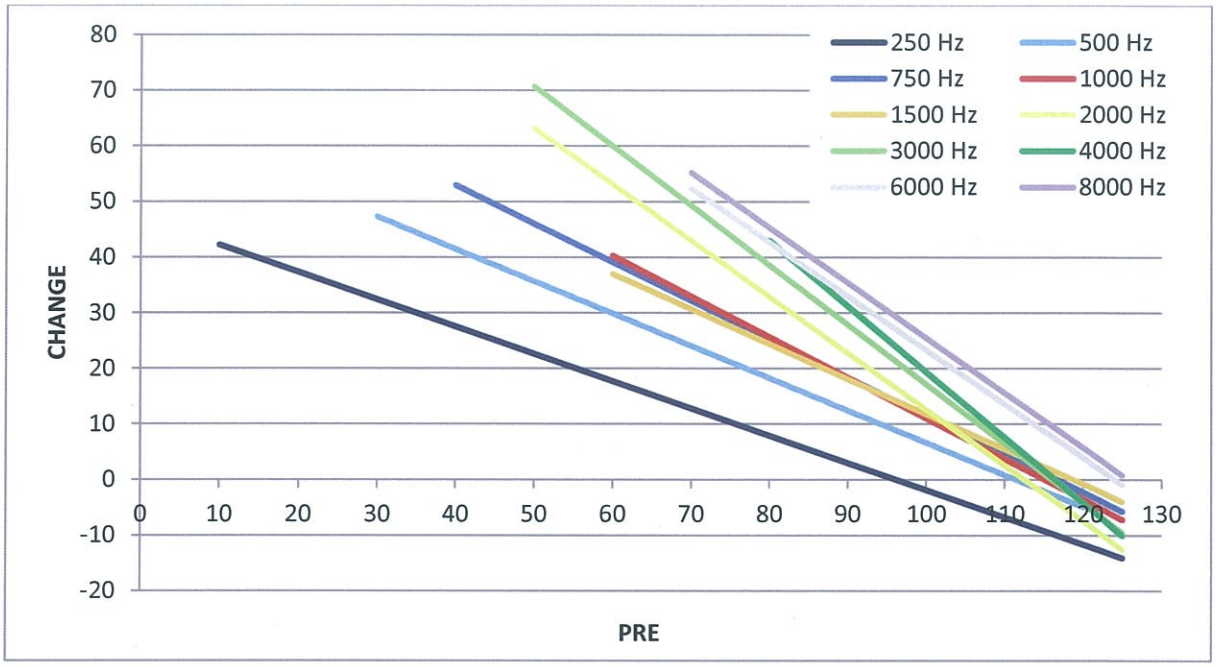


Figure 16. Change in general linear model (Unit B) (CH_GLM Unit B)

The same model, but excluding the term for UNIT, was estimated for each centre separately. The results are illustrated in the figures above – Figure 15 (CH_GLM Unit A) and Figure 16 (CH_GLM Unit B).

It should be noted that for Unit A, the term T_PRE was also significant at 250 Hz: an increase in T_PRE was associated with a decrease in the change in hearing threshold levels (CH).

The researcher plotted the pre-operative and the post-operative hearing threshold levels on the same graph in order to better depict the change in residual hearing (i.e. loss of hearing, preservation of residual hearing or increase in hearing threshold levels). Thus, the POST versus the PRE intensity thresholds for each of the main frequencies – overall, and by UNIT - were plotted on unity lines below. From the figures below it is apparent that the majority of cases lie above the unity line. This is indicative of hearing loss having taken place.

Figures 17-22 represent the PRE versus POST intensity thresholds overall at specific frequencies, ranging from 250 Hz to 8000 Hz. Figures A, B and C in the appendices illustrate the pre-operative overall and at Unit A and Unit B respectively.

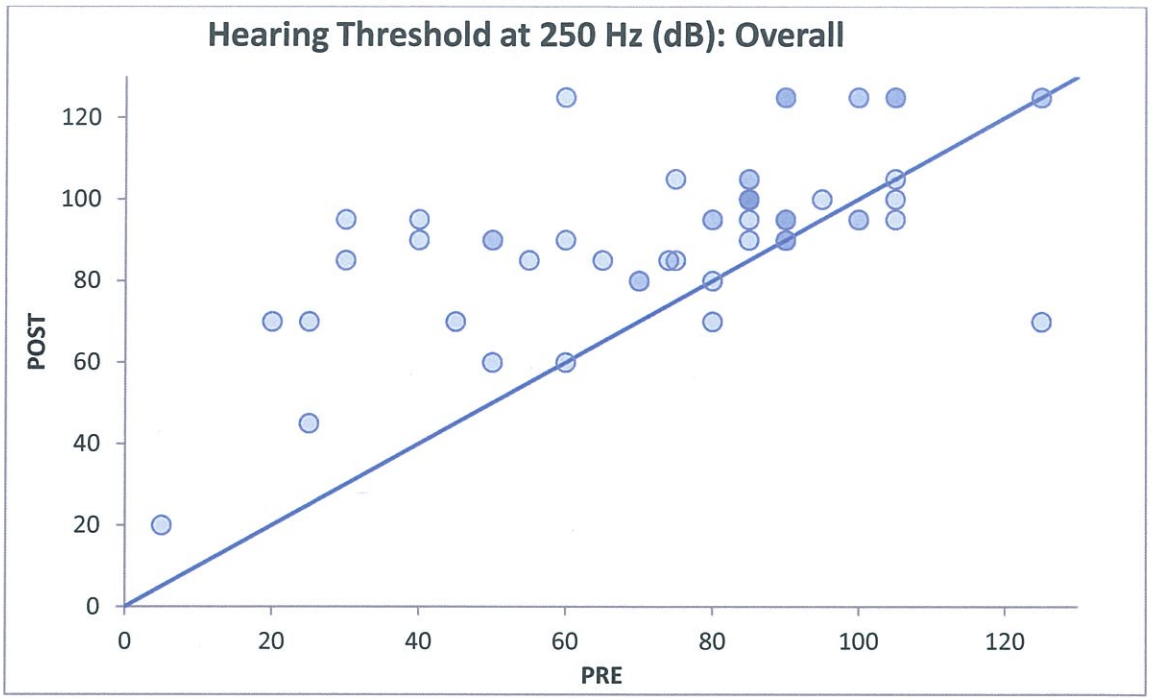


Figure 17. Pre- and post-operative hearing threshold levels at 250 Hz (PRE-POST HLT 250 Hz_Overall)

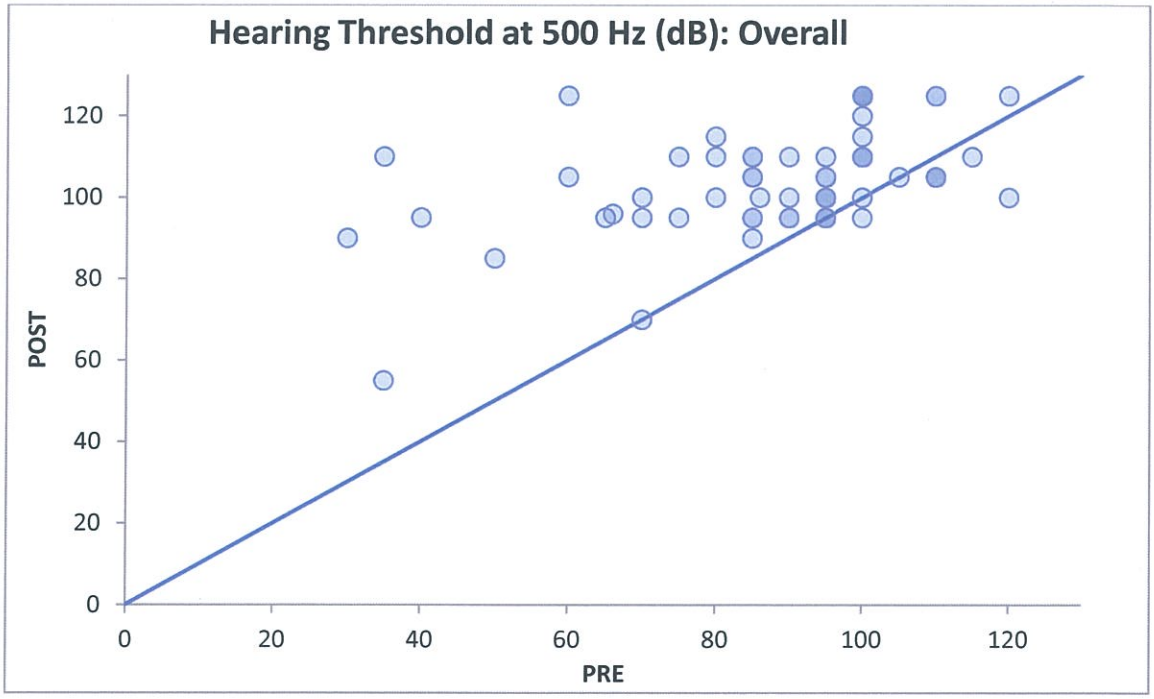


Figure 18. Pre- and post-operative hearing threshold levels at 500 Hz (PRE-POST HLT 500 Hz_Overall)

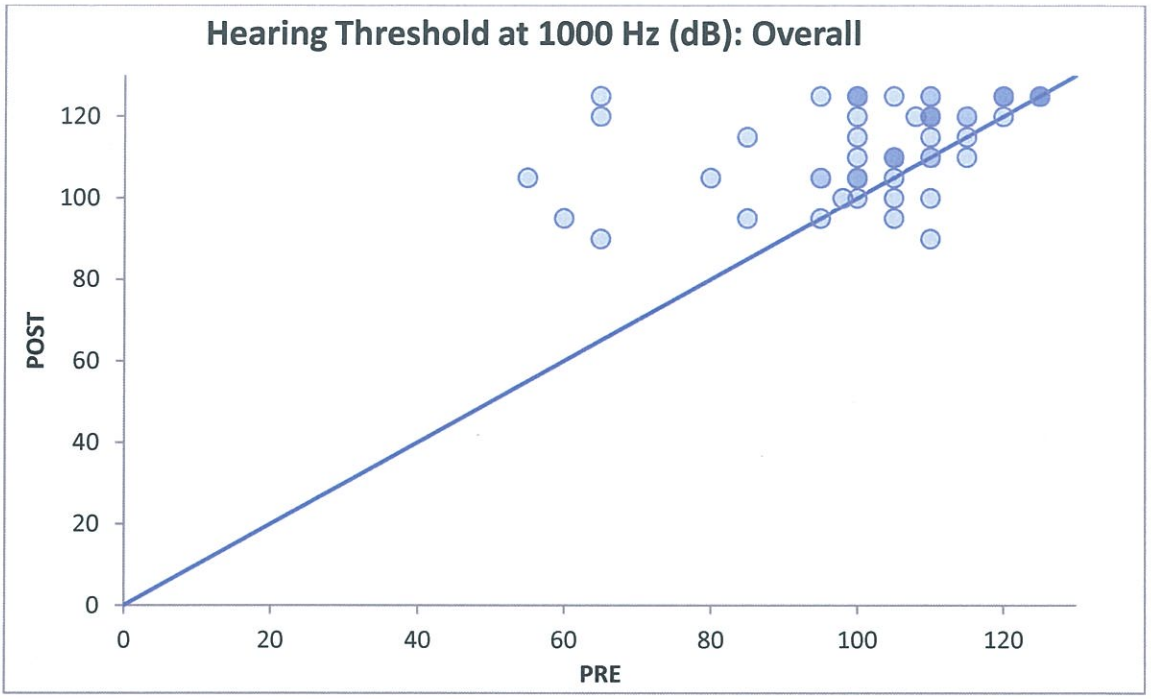


Figure 19. Pre- and post-operative hearing threshold levels at 1000 Hz (PRE-POST HLT 1000 Hz_Overall)

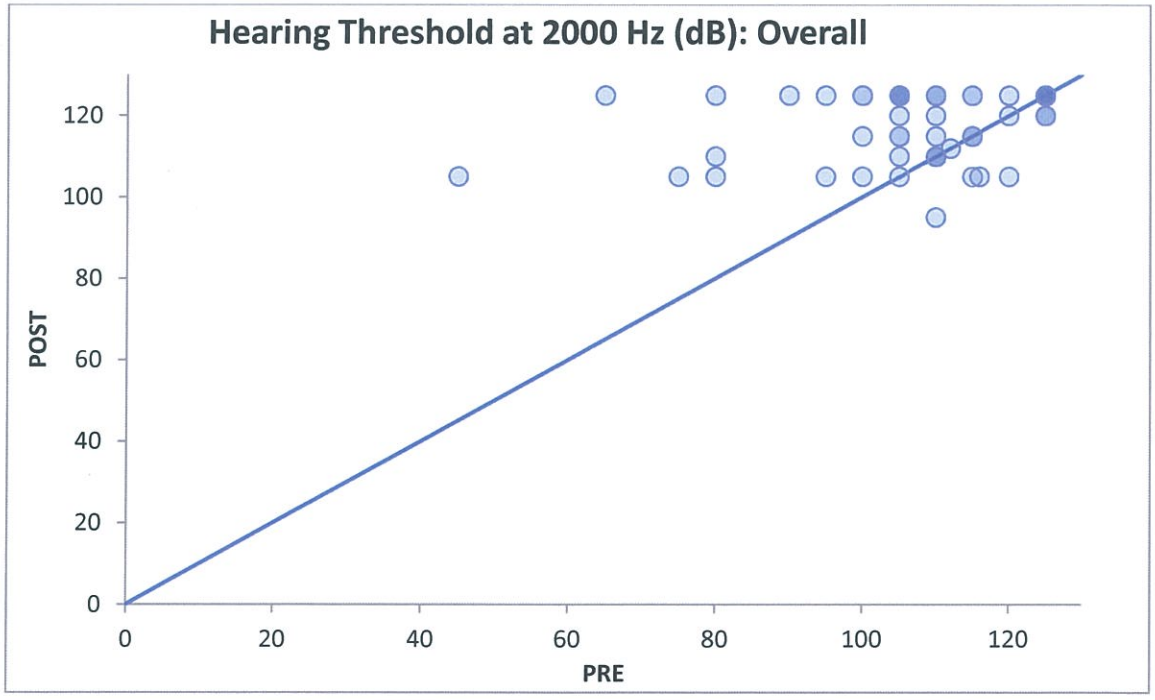


Figure 20. Pre- and post-operative hearing threshold levels at 2000 Hz (PRE-POST HLT 2000 Hz_Overall)

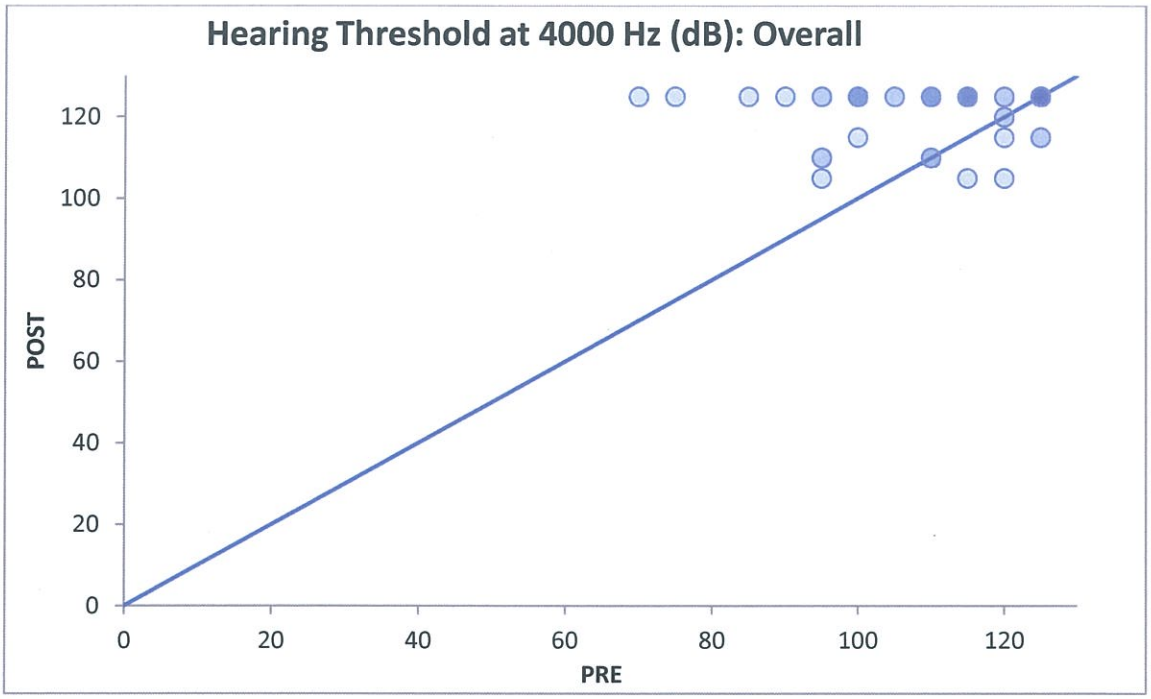


Figure 21. Pre- and post-operative hearing threshold levels at 4000 Hz (PRE-POST HLT 4000 Hz_Overall)

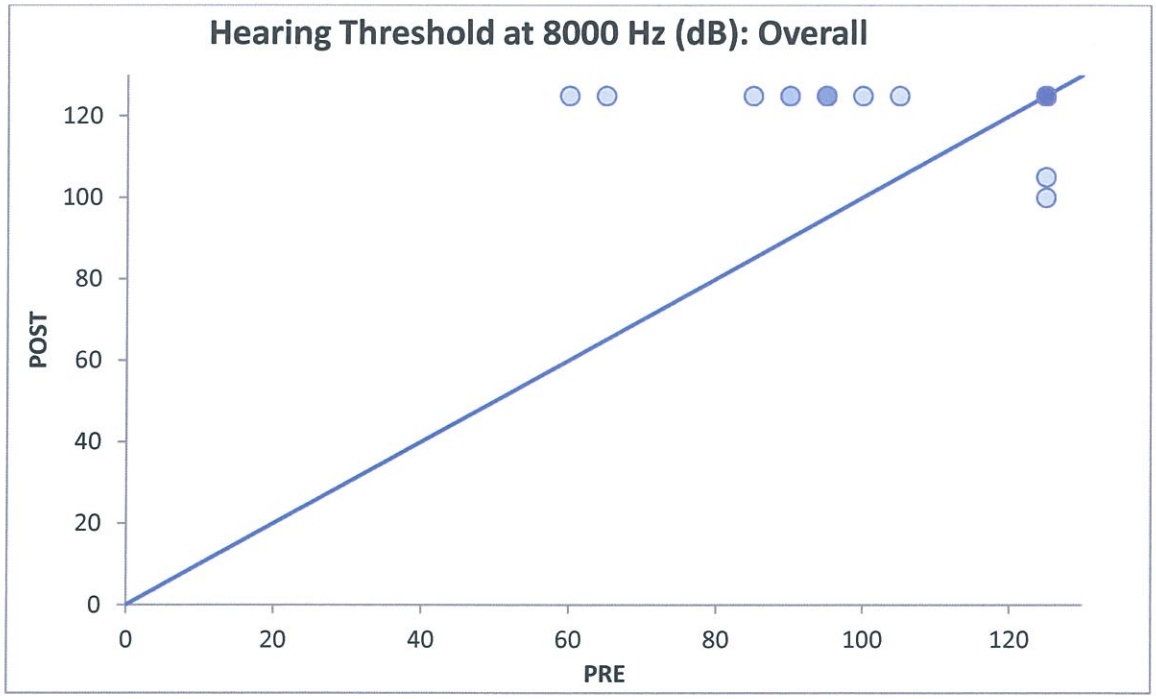


Figure 22. Pre- and post-operative hearing threshold levels at 8000 Hz (PRE-POST HLT 8000 Hz_Overall)

The figures representing the unity lines indicate that change in residual hearing loss had taken place above the unity line. For example, in Figure 22 at 8000 Hz, overall, there was an average

of 60 dB pre-operative hearing, and post-operatively there was a mean hearing threshold level of 120 dB at this same frequency. This means that the average participant lost 60 dB hearing post-operatively at this frequency (i.e. change or decrease in hearing threshold levels). In this case, hearing loss had occurred and there was no preservation of residual hearing at this frequency. However, where the results appeared above the unity line, but did not have a 120dB (i.e. "no response") post-operative hearing threshold, partial retention of residual hearing had been achieved (see classification in section 4.4. below). Where results appeared on the line, this was indicative of no change in hearing threshold levels post-operatively – i.e. there was complete preservation of residual hearing. Where the data points are positioned below the unity line, this is suggestive of improvement in residual hearing. The post-operative improvement in residual hearing was rare at both centres at all frequencies, as depicted in the unity line graphs above.

From the above findings, the following trend can also be detected from the unity line (at Unit A, at Unit B and at both centres combined):

- For the pre-operative hearing test results, the hearing threshold levels decreased as the frequencies increased.
- For the post-operative hearing test results, the hearing threshold levels decreased as the frequencies increased.

4.4. Hearing preservation

4.4.1. Classification of change in hearing function

The change in hearing function (CH) from pre-operative to post-operative hearing threshold levels (PRE to POST) was classified for each participant according to the following scheme:

Table 11

Classification of change in hearing function

Complete preservation of residual hearing:	0-10 dB
Partial preservation of residual hearing:	>10dB
Complete loss of residual hearing:	VALUE (PRE) TO NR (POST)

The rationale for the adoption of the above scheme has already been provided by the current researcher in the methodology section of this study. In addition to adopting the above scheme for the classification (in terms of intensity/decibel levels) of change in hearing function, provided in Table 10, the researcher adopted the classifications of the researchers Gstoettner et al. (2009) and Balkany et al. (2006) when selecting the frequencies at which the change in hearing function would be calculated. Additionally, the researcher chose to include all frequencies in this study so as to obtain more detailed information with regard to the change in residual hearing – i.e. by investigating low, mid and high frequencies.

The researcher planned to exclude cases for which both PRE and POST values were "no responses" (NR) at particular frequencies. Should the participant have had NR at a particular frequency pre-operatively, then this frequency would have been excluded due to the fact that there was no residual hearing at that particular frequency initially and thus as a consequence change would not have been able to be calculated. However, after data collection, it became apparent that there were in fact no such cases.

Three different combinations of frequencies were used as inputs for the above classification:

(i) Gstoettner (GS_CLASS): Average of 125-750 Hz

(ii) Balkany (BAL_CLASS): Average of 250, 500 and 1000 Hz

(iii) All (ALL_CLASS): Average across all frequencies

NRs were replaced by 125 dB for these calculations, except where the thresholds for a patient were NR across all the frequencies for a particular calculation, in which case NR was retained.

The change in hearing function, according to the three classifications, for both the overall sample and the two units separately, are provided in the tables below (Table 12-14).

Table 12

Gstoettner et al.'s (2009) classification (GS_CLASS)

GS_CLASS	UNIT - Unit A	UNIT - Unit B	Overall
Hearing preserved	23	30	53
	85%	94%	90%
Complete preservation	10	13	23
	37%	41%	39%
Partial preservation	13	17	30
	48%	53%	51%
Complete loss	4	2	6
	15%	6%	10%
Totals	27	32	59

Table 13

Balkany et al.'s (2006) classification (BAL_CLASS)

BAL_CLASS	UNIT - Unit A	UNIT - Unit B	Overall
Hearing preserved	24	31	55
	89%	94%	92%
Complete preservation	10	14	24
	37%	42%	40%
Partial preservation	14	17	31
	52%	52%	52%
Complete loss	3	2	5
	11%	6%	8%
Totals	27	33	60

Table 14

The researcher's classifications (ALL_CLASS)

ALL_CLASS	**UNIT - Unit A**	**UNIT - Unit B**	**Overall**
Hearing preserved	24	31	55
	89%	94%	92%
Complete preservation	13	17	30
	48%	52%	50%
Partial preservation	11	14	25
	41%	42%	42%
Complete loss	3	2	5
	11%	6%	8%
Totals	27	33	60

Table 15 represents the amount of hearing preservation (%) according to the above three classifications, namely Balkany et al. (2006), Gstoettner et al. (2009) and the researcher's classification.

The tables above illustrate hearing preservation, partial hearing preservation and complete loss of hearing at the two units and overall, according to the three classifications – i.e. average of low frequencies, namely average of 125-750 Hz (Gstoettner et al., 2009); pure tone average (PTA), namely average of 250, 500 and 1000 Hz (Balkany et al., 2006); and the average across all frequencies (the current researcher).

There was no significant association between any of the classifications and the units at the 95% confidence level (according to Pearson's X^2 test).

From Table 12 - 14 it is evident that the vast majority of the recipients - at each centre and at both units combined - preserved their hearing either partially or completely. There was no significant difference between the three classifications. Thus, the researcher chose to analyse and comment on Balkany et al.'s (2006) classification (BAL_CLASS). According to Balkany et al.'s (2006) classification, overall (i.e. at Unit A and Unit B combined) 92% of the implantees experienced hearing preservation post-operatively – either partial or complete hearing

preservation. When analysed further, the statistics showed 50% experienced complete hearing preservation (0-10 dB change in hearing threshold levels) and 42% partial hearing preservation (>10 dB change in hearing thresholds). The minority, namely 8% of the cochlear implantees, experienced a total loss of residual hearing post-operatively (i.e. no responses at any frequencies post-operatively).

In summary, the findings indicate that the vast majority of the cochlear implantees – at Unit A and Unit B and overall - experienced preservation of residual hearing – either partial or complete hearing preservation. The researcher considers these results to be significant.

4.4.2. Hearing loss versus preservation of residual hearing

The researcher compared the mean PREs (at key frequencies) and T_POST for patients with and without preservation of hearing.

Table 15

Hearing preservation overall: Unit A, Unit B

Variable	Overall			Unit A			Unit B		
	Patients without HP	**Patients with HP**	**P**	**Patients without HP**	**Patients with HP**	**p**	**Patients without HP**	**Patients with HP**	**p**
n	5	54-55		3	23-24		2	31	
PRE 250 Hz	97.0 ± 30.0	75.6 ± 7.3	0.092	90.0 ± 64.5	84.8 ± 8.7	0.68	107.5 ± 222.4	68.8 ± 10.8	0.079
PRE 500 Hz	96.0 ± 27.2	86.6 ± 5.5	0.33	86.7 ± 57.4	91.5 ± 6.6	0.64	110.0 ± 127.1	82.8 ± 8.4	0.11
PRE 1000 Hz	102.0 ± 29.6	103.2 ± 4.2	0.87	93.3 ± 68.4	107.2 ± 4.2	0.078	115.0 ± 127.1	100.4 ± 6.7	0.28
T_POST (months)*	12.8 (9.3-83.4)	7.3 (3.8-29.5)	0.063	83.4 (12.8-93.6)	39.7 (7.1-67.1)	0.23	8.4 (7.6-9.3)	6.6 (1.5-7.5)	0.12

Note. * Medians (interquartile ranges) are presented. P-values are for Wilcoxon rank sum test.

From the classifications above, three new variables were created: GS_HP, BAL_HP and ALL_HP.

For each of these variables, the classifications were as follows:

1 = complete or partial hearing preservation

0 = complete loss of hearing

These variables were almost identical with only the following differences:

- GS_HP (and GS_CLASS) had one missing value (P08: no POST data for required frequency range).
- GS_HP and BAL_HP were identical except for one case (P31) which was affected by the POST 1000 Hz value (in BAL, not in GS).
- BAL_HP and ALL_HP were identical.

The researcher found it was not necessary to carry out these analyses on all three classifications, but chose BAL_HP (which was identical to ALL_HP) since it did not have the missing data point.

The means for the two groups were compared by the implementation of a t-test (the Wilcoxon rank sum test was used for T_POST as the assumption of normality of the data for the t-test was not met). The results are presented for the overall sample and the two units separately (Table 15). There were no significant differences - the very small HP=0 group makes the confidence intervals for the means very wide.

The researcher repeated the above exercise, but did not combine the complete and partial hearing preservation groups. The means of the three groups were compared by means of an ANOVA (the Kruskal-Wallis test was used for T_POST as the assumption of normality of the data for the ANOVA was not met). The results are presented for the overall sample and the two units separately (see Table D in the appendices).

It must be noted from the findings above that the sample size for the "no HP" group was very small, which resulted in large confidence intervals for estimates for this group.

From the findings, the researcher could conclude the following from the three classifications:

Gstoettner classification:

- Overall, there were significant differences between the partial HP and complete HP for PRE 250 Hz and PRE 500 Hz. In both cases, the hearing threshold for the partial HP group was lower than that for the complete HP group.
- For Unit B unit alone, there were significant differences between the partial HP and complete HP for PRE 250 Hz, PRE 500 Hz as well as PRE 1000 Hz. In all three cases the hearing threshold for the partial HP group was lower than that for the complete HP group.
- There were no significant differences for Unit A unit.

Balkany classification:

- The conclusions were identical to those for the Gstoettner classification.

All frequencies classification:

- Overall, there were significant differences between the partial HP and complete HP for PRE 500 Hz and PRE 1000 Hz. In both cases the hearing threshold for the partial HP group was lower than that for the complete HP group.
- For Unit B unit alone, there was a significant difference between the partial HP and complete HP for PRE 1000 Hz. The hearing threshold for the partial HP group was lower than that for the complete HP group.
- There were no significant differences for Unit A unit.

On examination of the literature, the researcher observed that Balkany et al.'s (2006) research was one of many hearing preservation studies published over a 17-year period. According to Balkany et al. (2006), the first of these studies indicated preservation of pure-tone threshold levels in approximately 33% of implantees post-operatively (this was conducted in the 1980s). Thereafter, the second study conducted in the 1990s showed conservation of residual hearing in approximately half their patients post-surgery. Balkany et al. (2006) reported in their 2006 study that there was a preservation rate of 89% post-operatively - 32% achieved complete preservation (0-10 dB loss) and 57% partial preservation (>11 dB) post-surgery. According to Balkany et al. (2006), this improvement over the last two decades can be attributed to a combination of advancements in surgical techniques and cochlear implant technology. The

findings in the current research achieved a higher rate of partial and complete hearing preservation according to the similar classification (and thus results were more comparable) – i.e. 50% and 42% for complete and partial preservation respectively. The findings in the current study were found to have a more successful hearing conservation outcome overall than that of Balkany et al. (2006) – i.e. 92% as opposed to 89% when combining partial and complete hearing preservation statistics.

According to Gstoeottner et al. (2009), Gantz et al. (2005) achieved partial and complete hearing preservation in 96% of patients post-operatively with a short electrode and shallow insertion depth. Gstoettner commented that this preservation of residual hearing was rare and in their study, Gstoettner et al. (2009) achieved post-operative hearing preservation in 70% of their patients. The current study found similar results to Gantz et al. (2005) – i.e. 92% when combining partial and complete hearing preservation. The rate of conservation of residual hearing in the current study was considerably higher than that achieved by Gstoettner et al. (2009). As mentioned above, according to Gstoettner et al. (2009), the high rate of 96% of hearing preservation achieved by Gantz et al. (2005) is rare. The similar high rate achieved in the current study further validates the high success rate of the current study.

In Gstoettner et al.'s (2009) study, the researchers found complete hearing conservation in 44% of their implantees and 55.6% partial preservation up to approximately 15 months post-surgery. These researchers achieved this successful result by means of insertion into the scala tympani (entered anterior and inferior to the round window membrane) and utilisation of the MedEl Flex EAS array (Gstoettner et al., 2009). They reported that none of the recipients lost hearing post-operatively (Gstoettner et al., 2009). The current researcher considers this outcome to be an unprecedented success.

The findings in the current study are comparable to those of Gstoettner et al. (2009) in that their classification for hearing preservation was adapted for this study. Gstoettner et al.'s (2009) study achieved a slightly higher rate of hearing preservation than the current study – 44% versus 50% for complete and 54.6% versus 42% for partial preservation. However, there was no total loss of residual hearing in Gstoettner al.'s (2009) study, while there was minimal loss in the current study. The slight loss could be attributed to the surgical complications, as evidenced above, where there was a direct correlation between the hearing findings and intracochlear trauma. In summary, both Gstoettner et al. (2009) and the current researcher

demonstrated in their studies that marked success was achieved in the conservation of residual hearing.

4.5. The relationship the hearing findings and various factors

4.5.1. Mean age at surgery

The researcher calculated the mean age at surgery in order to establish whether there was any significant relationship between age and the hearing findings post-operatively.

Table 16

Age of participants at surgery (years) (N=60)

UNIT	Valid N	Mean Age	Median Age	Std.Dev.
Overall	60	30.8	30.6	13.9
Unit A	27	23.9	22.4	13.6
Unit B	33	36.4	37.0	11.6

The mean age the participants is tabulated in Tables 1 and 2. Overall, out of a total sample of 60 observations (N=60), the mean age at surgery was 30.8 years (s.d. ± 3.6 years). This is illustrated in Figure 23.

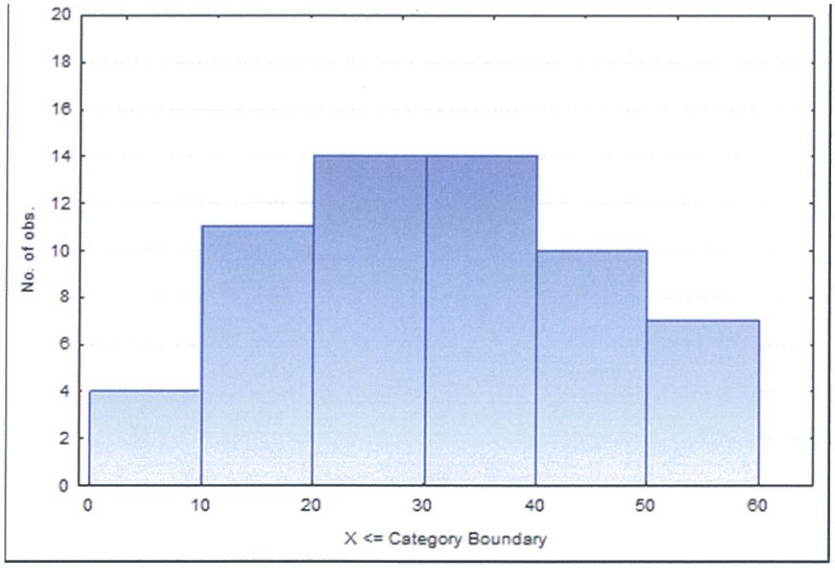


Figure 23. Frequency distribution for Age_Overall (N=60)

At Unit A, the mean age of participants was 23.9 years (s.d. ± 5.4) out of a total of 27 implantees (n=27) at this centre. This is depicted in the frequency distribution shown in Figure 24.

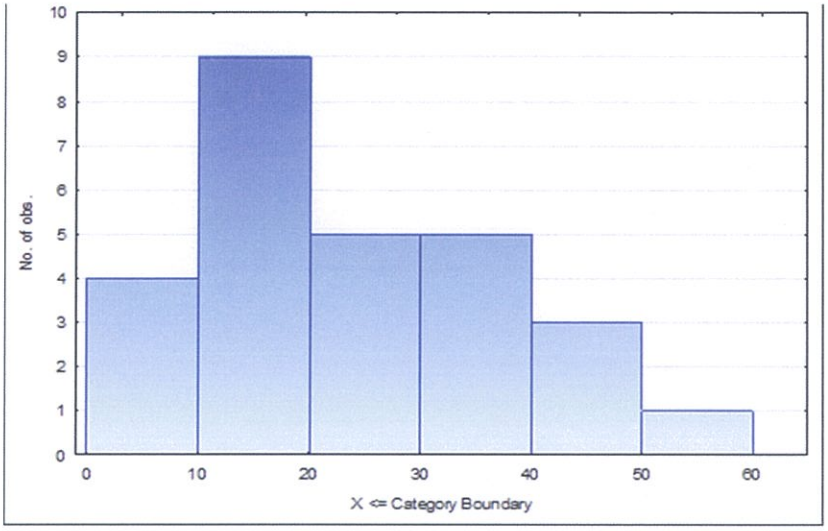


Figure 24. Frequency distribution for Age_Unit A (n=27)

From a sample of 33 participants (n=33) at Unit B, the mean age was 36.4 years (s.d. ± 4.1). Figure 7 below illustrates the frequency distribution of the mean ages of the participants at the UNIT B.

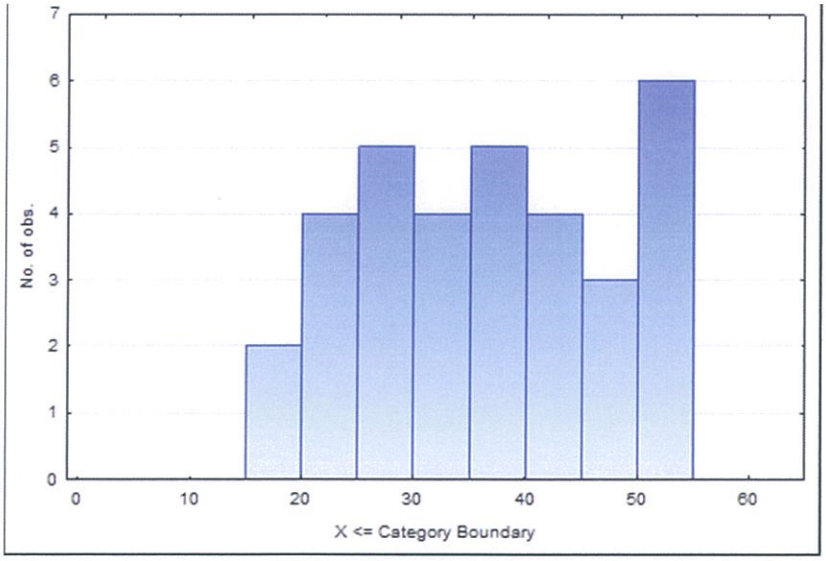


Figure 25. Frequency distribution for Age_Unit B (n=33)

According to the t-test, the differences in terms of the mean age between the two units were statistically significant. The mean age at surgery was significantly lower at Unit A due to the fact that all 10 children under the age of 16 in the data set were treated at this unit. Due to the fact that 10 implantees were under the age of 16, this skewed the results and led to the overall sample at Unit A being significantly lower in terms of age. The age group for the sample made available to the researcher at Unit B was considerably older than that in the sample at Unit A. Whereas records for adult patients, but not children, were provided to the researcher at Unit B, records of both children and adults were made available at Unit A. The skewed results could thus be attributed to these factors.

- **Relationship between hearing findings and age**

An analysis for the relationship between the hearing findings and age was performed in order to establish whether or not age had an impact on the results.

The effect of AGE on CH was not significant for any of the frequencies. This means that the age of the cochlear implant recipient did not affect the hearing findings – i.e. the post-operative hearing threshold levels or change in residual hearing.

These findings are not consistent with the findings of Cosetti et al. (2013) where they discovered that there was a direct correlation between the younger age at implantation and the preservation of residual hearing (Cosetti et al., 2013). On the other hand, Skarzynski et al. (2002) found that age did not have any effect on the post-operative hearing threshold levels - as found in the current study.

4.5.2. Gender

Data was collected from a sample of 36% males and 64% females overall at the two units. Fisher's exact test revealed that there was no statistical significance between the two units for gender; thus the findings with regard to the difference between the two units are unremarkable.

- **Relationship between hearing findings and gender**

An analysis for the relationship between the hearing findings and gender was carried out to determine whether gender had an impact on the results.

The effect of GENDER on CH was not significant for any of the frequencies. In other words, the gender of the implantees did not affect the post-operative outcome in terms of hearing threshold levels or change in residual hearing.

These findings are consistent with those of Cosetti et al. (2013) where they discovered that there was no relationship between gender and hearing preservation. Similarly, Skarzynski et al. (2002) found that gender had no effect on the post-operative hearing findings. Thus, gender appears to have had no influence on the post-operative hearing results.

4.6. Data deemed crucial for supporting secondary objectives in the study

The following data was considered to be critical in support of the secondary aims of the current study:

- Degree of pre-operative hearing loss
- Data on hearing loss, i.e. aetiology, duration of hearing loss prior to surgery
- Time between last pre-operative test and surgery
- Cochlear implants, i.e. implant type, implant manufacturer, electrode type
- Surgical data, i.e. electrode array insertion, insertion depth, surgical technique, intra-operative complications

4.6.1. Degree of pre-operative hearing loss

- **Relationship between the hearing findings and degree of pre-operative hearing loss**

Findings indicated that the degree of pre-operative hearing had no effect on the post-operative hearing findings. In other words, the degree of pre-operative hearing loss did not determine the outcome of the post-operative hearing threshold levels.

Similarly, in Cosetti et al.'s (2013) study, they found there was no significant relationship between the low-frequency pure-tone-average and the post-operative hearing findings (Cosetti et al., 2013).

The findings in the current study contrast with those of Balkany et al. (2006) where these researchers found there was a relationship between the degree of pre-operative hearing loss and the hearing findings, in that those patients who had a greater degree of pre-operative hearing loss tended to experience a complete loss of residual hearing post-operatively. The findings of Balkany et al. (2006) differed from the results found in the current study in that the current study demonstrated that there was no significant correlation between the pre-operative hearing threshold levels and the preservation of post-operative residual hearing ($p = 0.174$).

Despite the fact that there was a correlation between the degree of pre-operative hearing threshold levels and post-operative hearing in Balkany et al.'s (2006) study, this was limited to patients who experienced a complete loss of residual hearing post-operatively. In general, there was no significant relationship between the degree of pre-operative hearing loss and the unaided post-operative hearing findings.

4.6.2. Aetiologies of hearing loss

Table 17

Aetiologies of hearing loss

Variable	Overall	Unit A	Unit B	p-value for H_0: no significant difference between units
Number of participants	53	21	32	-
Aetiology				
Genetic/congenital	38%	48%	30%	0.036 (X^2 test)
Disease/virus	37%	19%	15%	
Progressive	10%	0%	18%	
Damage to ear	5%	0%	9%	
Other	3%	0%	6%	
Missing	27%	33%	21%	

As depicted in Table 17 and Figure 26 the main categories for aetiologies of hearing loss were made up of the following:

- 38% genetic/congenital overall (48% at Unit A; 30% at Unit B)
- 37% disease/virus overall (19% at Unit A; 15% at Unit B)
- 10% progressive overall (5 at Unit A; 18% at Unit B)
- 5% damage to the ear overall (0% at Unit A; 9% at Unit B)
- 3% other overall (0% at Unit A; 6% at Unit B)
- 27% missing overall (33% at Unit A; 21% at Unit B)

Other aetiologies from single isolated cases included:

- pachymeningitis
- severe post-natal jaundice – kernicterus, athetoid cerebral palsy

From the data obtained, the researcher observed that the aetiology of hearing loss for the majority of cases was comprised of genetic/congenital factors (38%) as well as disease/virus (37%). Similarly, in Derinsu et al.'s (2011) study the aetiologies of hearing loss in their sample

indicated a predominance of congenital factors. However, these researchers' sample also comprised a high prevalence of progressive aetiologies (Derinsu et al., 2011) which was not the case in the current study.

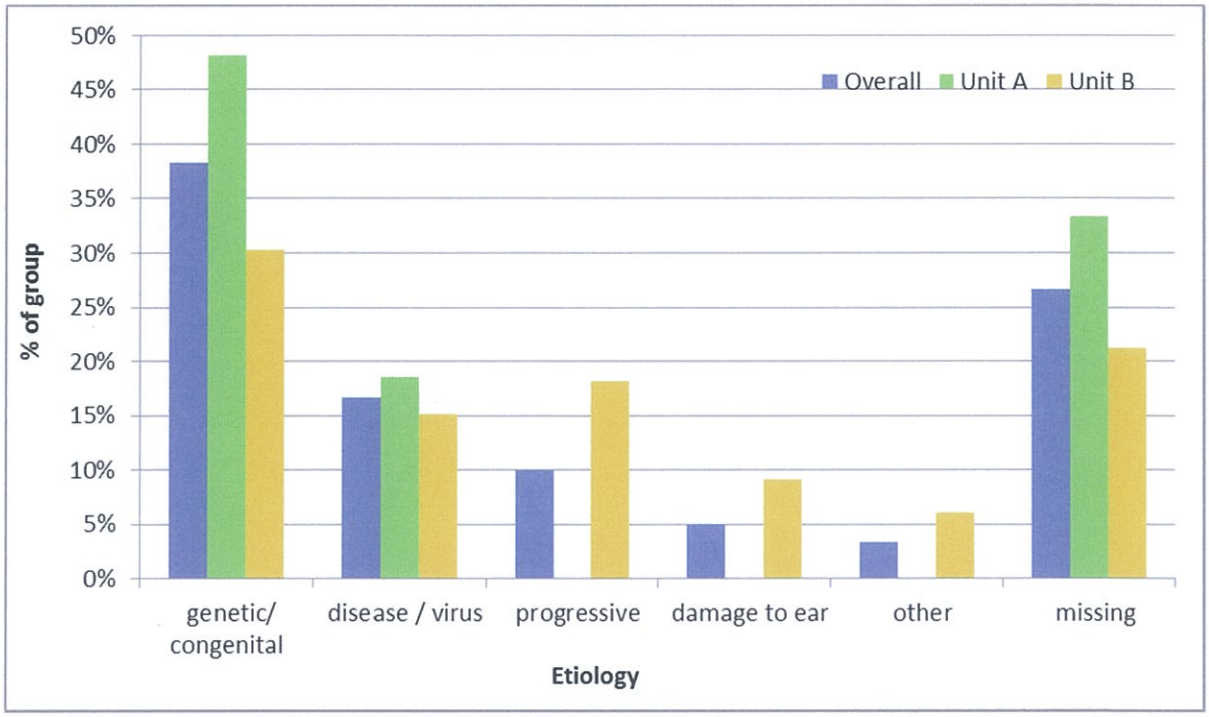


Figure 26. Aetiology of hearing loss in the sample (N=60)

- **Relationship between hearing findings and aetiology of hearing loss**

An analysis for the relationship between the hearing findings and aetiology of hearing loss was carried out in order to determine whether aetiology of hearing loss had any effect on the results.

The effect of AETIOLOGY on CH was not significant for any of the frequencies, except for Unit A at 500 Hz: the mean CH was 7.4 units lower for genetic/congenital vs. disease/virus. Given that there was no trend with respect to the other frequencies, this could have been a spurious result.

The fact that aetiologies in the present study did not have any effect on the hearing findings is consistent with the findings of Cosetti et al. (2013). These findings are also consistent with those of Skarzynski et al. (2002), who found that aetiologies had no influence on the post-

operative hearing findings. This implies that there is no relationship between the cause of hearing loss prior to implantation and the post-operative residual hearing outcomes.

4.6.3. Duration of hearing loss prior to surgery

The mean duration of hearing loss prior to surgery was established to determine the relationship between the duration of the hearing loss before surgery and the post-operative hearing findings.

Table 18

Duration of hearing loss in the sample (N=60)

Variable	**Overall**	**Unit A**	**Unit B**	**p-value for H_0: no significant difference between units**
Number of participants	53	21	32	-
Duration of hearing loss prior to surgery (yrs.) (mean ± 95% confidence interval) (DUR)	22.9 ± 3.1	20.3 ± 5.0	25.0 ± 4.0	0.14 (t-test)

Table 19

Duration of hearing loss in the sample (N=60)

UNIT	**Valid N**	**Mean**	**Median**	**Std.Dev.**
Overall	60	22.9	24.9	12.1
Unit A	27	20.3	17.8	12.7
Unit B	33	25.0	25.9	11.3

Note. Valid N: number of observations; Std. Dev.: standard deviation

The findings in Tables 18 indicate that, out of a sample of 60 observations (N=60), the mean duration of hearing loss prior to surgery (DUR) was 22.9 years (s.d. = ± 3.1) overall. Out of 27 participants at Unit A, the mean duration of hearing loss prior to surgery was 20.3 years (s.d. = ± 5.0). The mean duration of hearing loss prior to surgery from a sample of 33 participants

at Unit B was 25.0 years (s.d. = ± 4.0). Refer to appendices 11.1-11.3 for bar graphs depicting DUR.

From Table 18 it is evident that the mean duration of hearing loss prior to surgery was similar between the two units – a mean difference of 4.7 years between the two centres. According to the t-test, a p-value of 0.14 indicated that there was no statistical significant difference between the two centres in terms of the duration of hearing loss prior to surgery.

- **Relationship between the hearing findings and duration of pre-operative hearing loss**

An analysis of the relationship between hearing findings and the duration of the pre-operative hearing loss was performed.

Findings indicated that the effect of DUR on CH was not significant for any of the frequencies. In other words, the duration of pre-operative hearing loss did not have an effect on the hearing findings (i.e. did not result in any change of residual hearing – there was no loss or gain in hearing threshold levels at any of the frequencies). Thus, there was no significant difference in terms of post-operative hearing threshold levels between those implantees who had a longer duration of pre-operative hearing loss and for those implantees who experienced hearing loss for a shorter period of time.

Lenarz et al. (2009) found that patients with a shorter duration of pre-operative hearing loss had better hearing preservation post-operatively than those with a longer duration of loss pre-operatively.

The findings of the current study are consistent with those of Cosetti et al. (2013), who found that there was no correlation between the duration of hearing loss and the unaided post-operative hearing findings. This implies that, as in the current study, the length of hearing loss has no effect on hearing threshold levels after cochlear implant surgery.

4.6.4. Time between last pre-operative hearing test and surgery

Statistical analysis on the mean time between the last pre-operative hearing test and surgery (T_PRE) was performed in order to determine whether this had had an effect on the post-operative hearing findings.

Table 20

Time between last pre-operative hearing test and surgery

Variable	Overall	Unit A	Unit B	p-value for H_0: no significant difference between units
Number of patients	53	21	32	-
Time between last pre-operative hearing test and surgery (mean ± 95% confidence interval) (T_PRE) (mnths)	7.0 ± 1.8	5.7 ± 2.5	8.1 ± 2.6	0.17 (t-test)

Table 21

Time between last pre-operative hearing test and surgery

UNIT	Valid N	Mean	Median	Std.Dev
Overall	60	7.0	4.6	6.86
Unit A	27	5.7	3.9	6.28
Unit B	33	8.1	5.4	7.20

Note. T_PRE = time between last pre-operative hearing test and surgery (in months); Valid N = number of observations; Std. Dev. = standard deviation

As depicted in Table 20, the mean time between surgery and the first pre-operative hearing test overall was seven months (s.d. = ± 1.8). Furthermore, from Table 5 it is apparent that the mean time between surgery and the first pre-operative hearing test was longer at Unit B – i.e. the mean time was 8.1 months (s.d. = ± 2.6) at Unit B as opposed to a mean of 5.7 months (s.d. = ± 2.5) at Unit A. However, a p-value of 0.17 on the t-test indicated that there was no statistical

significance between the two centres. It was important to ascertain this information in the current study to ensure that pre-operative results were reasonably close to the time of surgery to control for possible impact of progression of hearing loss prior to surgery.

Figures 12.1-12.3 in the appendices depict the time between the last pre-operative hearing test and surgery in months (T_PRE) overall (Figure 12.1), at Unit A (Figure 12.2) and at Unit B (Figure 12.3). The frequency distributions illustrate the number of observations when hearing testing was conducted prior to the surgery date at each time interval at the cochlear implant centres.

On examination of the frequency distributions (see Figures 12.1-12.3 in the appendices), the researcher found that the time between the pre-operative testing and the surgery date (T_PRE) varied significantly between Unit B and Unit A. The range overall was 0.1 – 26 months. This meant that whereas some patients had pre-operative testing conducted close to the surgery date, other patients were tested as long as 26 months before the surgery date.

It became apparent that the distribution was positively skewed (see Figures 12.1-12.3 in the appendices). This indicates that although the majority of implantees had their pre-operative hearing tests performed relatively close to the surgery date, some cochlear implant recipients did not. Hence, their hearing could have deteriorated further before surgery due to extraneous variables, thus affecting the change in residual hearing (i.e. "CH" data). Therefore, the researcher used T_PRE as a covariate in the analyses of the results in order to overcome this.

- **Relationship between hearing findings and the time between the last pre-operative hearing test and surgery**

From the results, it became evident that the time between the last pre-operative hearing test and surgery (T_PRE) affected the change in residual hearing post-operatively.

4.6.5. Time between surgery and first post-operative hearing test

The researcher examined the mean time between surgery and first post-operative hearing test (T_POST) to ascertain whether T_POST had had any influence on the post-operative hearing

threshold levels. T_POST was used as a covariate in the analysis of the results in order to prevent the findings being affected by any extraneous variables.

Table 22

Time between surgery and first post-operative hearing test (N=60)

Variable	Overall	Unit A	Unit B	p-value for H_0: no significant difference between units
Number of participants	53	21	32	-
Time between surgery and first post-operative hearing test, in months (mean ± 95% confidence interval) (T_POST)	24.7 ± 9.0	46.2 ± 16.9	7.2 ± 2.9	<0.0001 (t-test)

Table 23

Time between surgery and first post-operative hearing test (N=60)

UNIT	Valid N	Mean	Median	Std.Dev.
Overall	60	24.7	7.6	35.0
Unit A	27	46.2	50.0	42.7
Unit B	33	7.2	6.7	8.2

Note. T_POST = time between surgery and first post-operative hearing test (in months)

As depicted in Table 22, the mean time in months between the last post-operative hearing test and surgery was considerably longer at Unit A than at Unit B – i.e. a mean of 46.2 months (s.d. = ± 16.9) at Unit A and 7.2 months (s.d. = ± 2.9) at Unit B. From these descriptive statistics it can be seen that the time between surgery and the first post-operative date for the average implantee was much longer at Unit A than at Unit B. According to the t-test, there was a statistically significant difference between the two units in terms of the mean time between surgery and the first post-operative hearing test (p-value < 0.0001). This could be attributed to the fact that Unit A performed post-operative testing specifically for the current study at the

request of the researcher. Therefore, the mean time between the last pre-operative hearing test and surgery would have been longer at Unit A. In general, Unit B performed the unaided post-operative hearing testing as part of their audiological protocol. Overall, the mean time between surgery and first post-operative hearing test was 24.7 months (s.d. = ± 9.0).

Figures 13.1 – 13.3 in the appendices illustrate the time between surgery and the first post-operative hearing test in months (T_POST) overall (Figure 13.1), at Unit A (Figure 13.2) and at Unit B (Figure 13.3). These frequency distributions depict the number of observations (n) when hearing testing was conducted after surgery, at each time interval at the centres. Figures 13.1, 13.2 and 13.3 illustrate the mean and median of T_POST overall, at Unit A, and at Unit B respectively. The key univariate statistics for each of the POST variables as well as T_POST, overall, and by unit, are tabulated in the appendices (Table B).

From analysis of the figures, the researcher noted that the time between surgery and the first post-operative hearing test (T_POST) varied significantly: the range was 0.5 – 159 months (13 years 4 months). The distribution was positively skewed, which means that although most implantees had their post-operative hearing testing done relatively close to the date of surgery, some recipients did not. These implantees had their post-operative testing done long after the surgery date. Hence, their hearing could have deteriorated further after surgery, thus affecting the change in residual hearing (i.e. CH data). Therefore, the researcher used T_POST as a covariate in the analyses.

The researcher also observed that there was a significant difference between the mean T_POST for the two units. At Unit B all but one patient was tested within 18 months of surgery, while T_POST was much longer for many patients at Unit A. The reason for this could have been that the audiologists at Unit A performed post-operative testing on many of their cochlear implantees specifically for this study at the request of the current researcher. As a result, the tests were conducted at random intervals and many of the tests were conducted long after the surgery date at this centre.

- **Relationship between hearing findings and duration between surgery and unaided post-operative hearing testing**

The relationship between the hearing findings and the duration between surgery and unaided post-operative hearing testing has already been addressed since T_POST was included as a covariate in the earlier models for CH.

Results indicated that T_POST was not significant. This meant that the duration between surgery and unaided post-operative hearing testing did not affect the preservation of residual hearing post-operatively.

4.6.6. Cochlear implant type

Table 24

Type of cochlear implants for participants (N=60)

Variable	Overall	Unit A	Unit B	p-value for H_0: no significant difference between units
Number of participants	53	21	32	-
Implant Type				
NF – CI24RE	50%	44%	55%	0.29 (X2 test)
CN – CI 512	25%	19%	30%	
Other	17%	19%	15%	
Missing	8%	19%	0%	

Note. NF - CI24RE = Nucleus Freedom cochlear implant with Contour Advance or Straight electrodes; CN - CI 512 = Cochlear Nucleus 5 cochlear implant

The findings for the type of cochlear implant used by the participants at the two units are summarized in Table 24 and Figure 27.

The findings revealed that the cochlear implant types predominantly used at Unit A and Unit B were the Nucleus Freedom cochlear implant (CI24RE) and the Nucleus 5 cochlear implant (CI512). Overall, 50% of implantees were given the CI24RE implant and 25% the CI512.

The category "Other" (17%) included inter alia the cochlear implant type - Nucleus CI24R with Contour Advance electrode (n=5). In this study, the type of implant that was used most after the two categories mentioned above (namely, the CI512 and the CI24RE), was the CI24R. However, there were only five observations for the CI24R. There were even fewer observations for other implant types which included CI24M, Nucleus CI24(ST), and Nucleus CI422. Statistics could not be performed on these implant types as there was not sufficient data (i.e. the number of observations was too small).

There were more CI24RE and CI512 implants at Unit B than at Unit A, and at Unit A there were more "other" implants (19%) than at Unit B. At Unit B, 44% of patients were implanted with the CI24RE and 30% with the CI512. At Unit A, 44% of patients were implanted with the CI24RE and 19% with the CI512.

The results were not statistically significant between the two centres for neither the CI24RE nor the CI512 (as evidenced by the X^2 test where p-value = 0.29).

At Unit A, the "other" category also included two implant types from another cochlear implant manufacturer, namely MED-EL. These two cochlear implant types were the Med-El Pulsar (n=6) and the Med-El Sonata (n=1).

Derinsu et al. (2011) also made use of Mel-El Pulsar and Nucleus Freedom devices in their study. The researcher noted that the proportion of participants who were implanted with the Med-El Pulsar were fewer in the current study compared to that in Derinsu et al.'s (2011) study. In both the current study and that of Derinsu et al. (2011), the cochlear implant type Nucleus Freedom was implanted more frequently than the Med-El Pulsar.

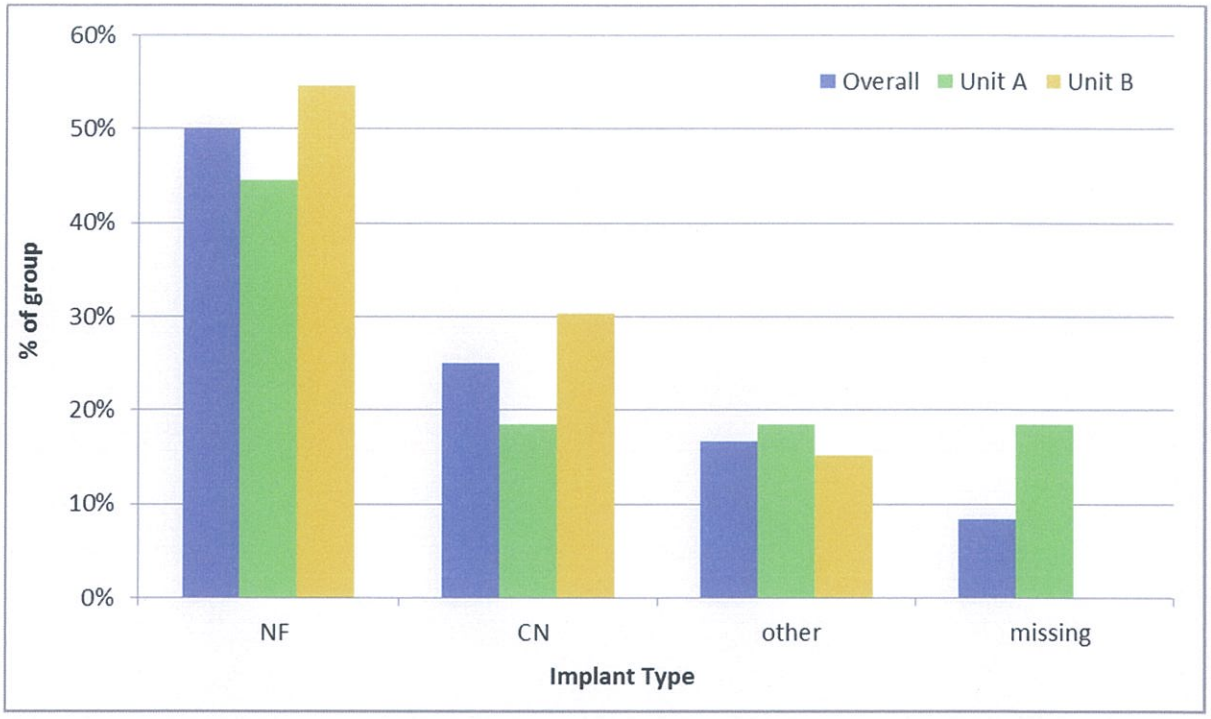


Figure 27. Implant types in the sample (N=60). NF = Nucleus Freedom CI24RE; CN = Cochlear Nucleus CI512; Other = alternate/other classification; Missing = missing data

- **Relationship between hearing findings and type of cochlear implant**

An analysis for the relationship between the hearing findings and the type of implant was carried out.

The effect of IM_TYPE on CH was not significant for any of the frequencies, with the exception of 2000 Hz: the mean CH was 5.9 units higher for Other vs. NF. In other words, the type of implant did not have a negative effect on the post-operative hearing threshold levels (or the change in residual hearing), with the exception of that at 2000 Hz. Given that there was no trend with respect to the other frequencies, this could have been a spurious result.

Although the discrepancy of 5.9 units between the Nucleus Freedom and Other was only at one frequency, namely 2000 Hz, and the difference was minimal, this was clinically relevant for speech understanding. This is because 2000 Hz is considered a major speech frequency and is important for speech perception (Stach, 2010).

Given the above results, it became evident that the type of implant (NF/Cochlear/Other) used for cochlear implantation did not have a negative influence on the post-operative hearing findings, namely the post-operative hearing threshold levels – i.e. there was no change (loss/decrease or gain/increase in hearing).

These research findings are consistent with those of Cosetti et al. (2013) who found that implant type did not have any effect on the hearing findings.

From the aforementioned results, the researcher concluded that by implication the types of implants utilised by the surgeons in the present study resulted in positive outcomes – i.e. preservation of residual hearing.

4.6.7. Cochlear implant manufacturer

Table 25

Cochlear implant manufacturers used at the two units

Variable	Overall	Unit A	Unit B	p-value for H_0: no significant difference between units
Number of participants	53	21	32	-
Implant manufacturer				
Cochlear	90%	78%	100%	0.40 (Fisher's exact test)
MED-EL	2%	4%	0%	
Missing	8%	19%	0%	

The findings for the cochlear implant manufacturers used by the participants at the two units and overall are depicted in Table 25 and are illustrated in Figure 28.

Two main cochlear implant manufacturers were used at the two centres, namely Cochlear and MED-EL.

Unit B only made use of one cochlear implant manufacturer – i.e. Cochlear – for their patients, whereas Unit A made use of two cochlear implant manufacturers, i.e. MED-EL and Cochlear. A small minority of patients used the MED-EL as the cochlear implant manufacturer at Unit A.

Although there were noticeable differences in terms of percentages with regard to the cochlear implant manufacturers at the two units, Fisher's exact test with a p-value of 0.40 indicated that the difference was not statistically significant between the two centres.

Figure 28 depicts the percentages of the cochlear implant manufacturers used by the implantees at Unit A and Unit B and at both centres combined.

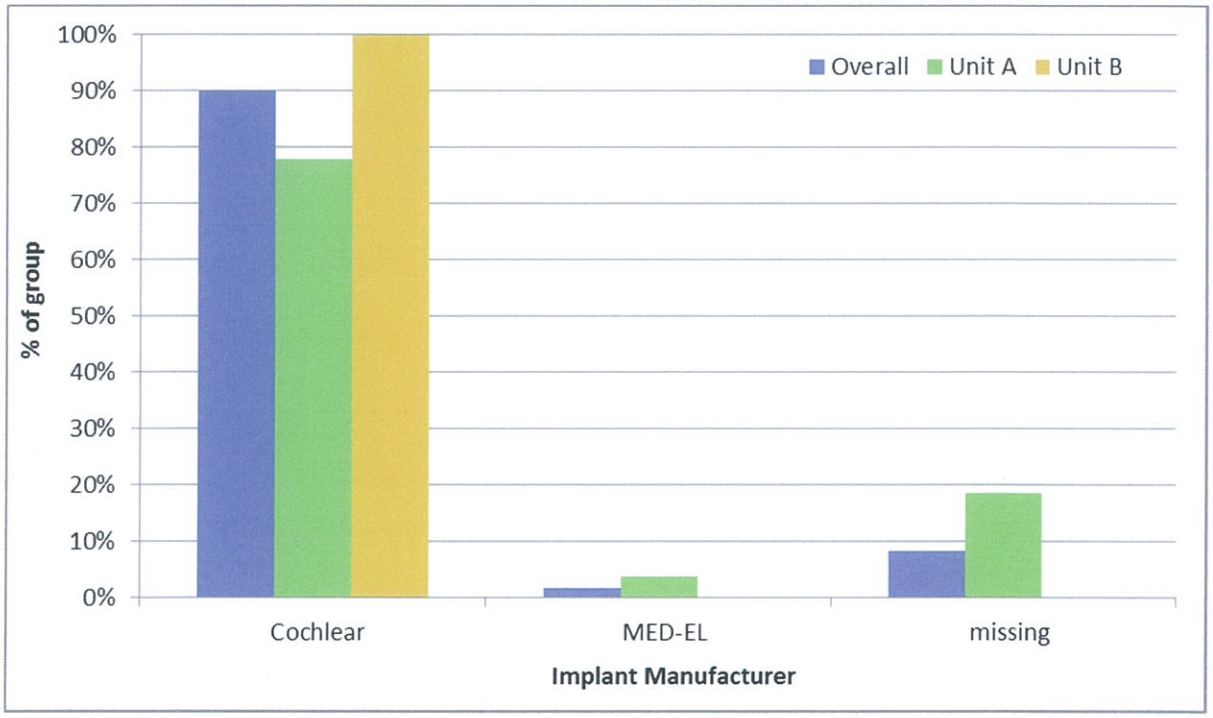


Figure 28. Implant manufacturer in the sample (N=60)

Derinsu et al. (2011) found that both manufacturers - Cochlear and MED-EL – were used, but that more use was made of Cochlear. In both the current study and that of Derinsu et al. (2011), it was found that Cochlear implants were used more frequently than MED-EL implants.

- **Relationship between hearing findings and manufacturer**

Statistics were not performed to determine the relationship between hearing findings and manufacturer as all the participants utilised the same manufacturer (namely Cochlear) and only one participant used Med-El. Thus, the results were not comparable and therefore not useful.

4.6.8. Electrode array type

Table 26

Electrode array type in the current sample (N=60)

Variable	Overall	Unit A	Unit B	p-value for H_0: no significant difference between units
Number of participants	53	21	32	-
Electrode Type				
Contour Advanced	83%	70%	94%	0.38 (Fisher's exact test)
Other	8%	11%	6%	
Missing	8%	19%	0%	

The type of electrodes utilised by the surgeons for the participants during cochlear implantation at each centre and overall are tabulated in Table 9. The large majority (see Table 26 and Figure 29) of the participants (i.e. 83% overall; 70% at Unit A; 94% at Unit B) had the contour advanced electrode array implanted. Other classifications included "other" electrode types (8% overall; 11% at Unit A; 6% at Unit B).

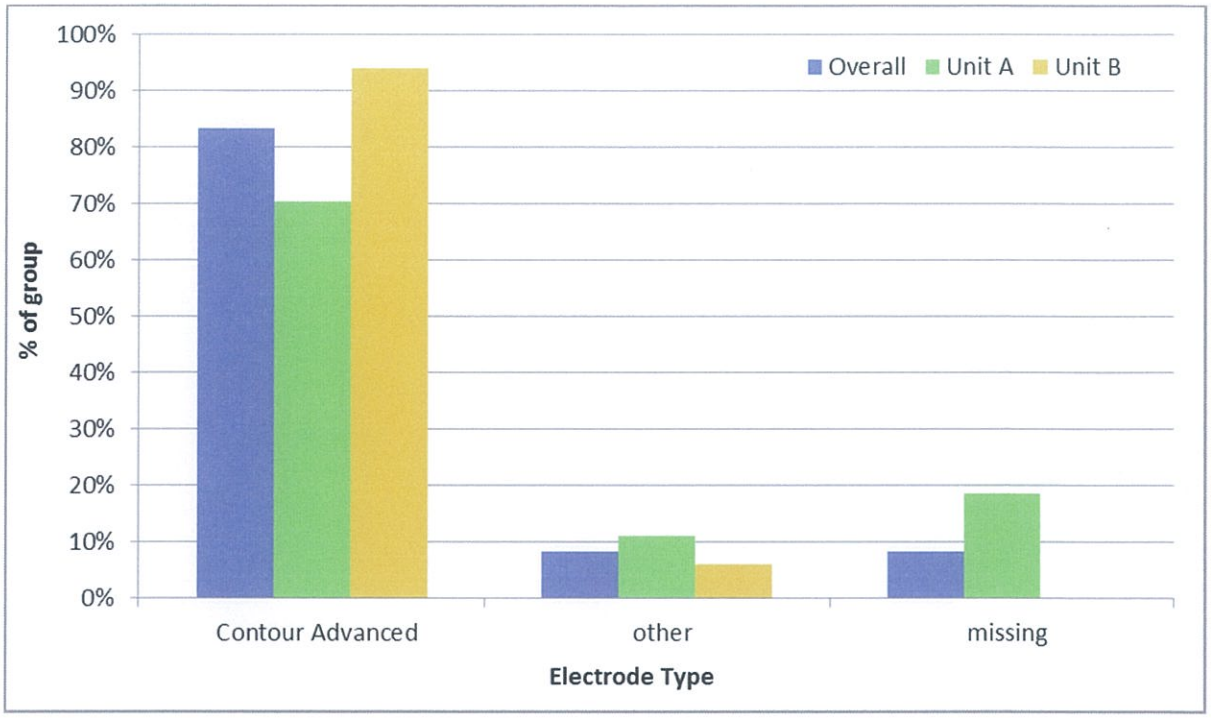


Figure 29. Electrode array type in the current sample (N=60)

- **Relationship between hearing findings and electrode array type**

There were only five cases with non-Contour Advance EA_TYPE and these five cases were categorized as "Other". The common electrode type used by all surgeons at both centres was the Contour Advance Electrode.

The Contour Advance electrode is the only perimodiolor array in the industry and is pre-curved for complete insertion, with Softip which enables atraumatic insertion (Roland et al., 2005).

As only five non-Contour Advance Electrodes were implanted, it would not have been possible to compare the results and thus the researcher found it to be impractical to perform this analysis which looked at the relationship between the hearing findings and the electrode array type. Therefore, the researcher did not perform this analysis as the data obtained would have no relevance to the findings.

In Skarzynski et al.'s (2002) study, it was found that the electrode type did not have any effect on the hearing findings post-operatively.

4.6.9. Electrode array insertion

Table 27

Electrode array insertion in the current sample (N=60)

Variable	Overall	Unit A	Unit B	p-value for H_0: no significant difference between units
Number of participants	53	21	32	-
Electrode array insertion				
Scala tympani	82%	70%	91%	0.29 (Fisher's exact test)
Other	5%	0%	9%	
Missing	13%	30%	0%	

The findings with regard to the percentages for electrode array insertion at the two centres and overall are tabulated in Table 27 and Figure 30 illustrates these findings.

From the statistics, it is evident that the majority of participants – both at Unit A (70%) and Unit B (91%) – had their electrode arrays inserted via the scala tympani during surgery (i.e. 82% overall). The category for the insertion of the electrode array for 9% of the patients was "Other." From the available data at Unit A, electrode array insertion did not involve any region other than the scala tympani. However, 30% of the data with regard to electrode array insertion was missing at Unit A. There was no missing data at Unit B.

The category "Other" included inter alia one case at Unit B involving electrode array insertion via the scala vestibuli and another via the round window. However, given the fact that there was only one patient in each case, a meaningful statistical analysis could not be performed on the results.

Although meaningful statistics could not be performed on these two cases at Unit B, it is interesting to note that there were no surgical complications in either of these patients.

From the Fisher's exact test, it became evident with a p-value of 0.29 that there was no statistical significance between the two centres with regard to the electrode array insertion.

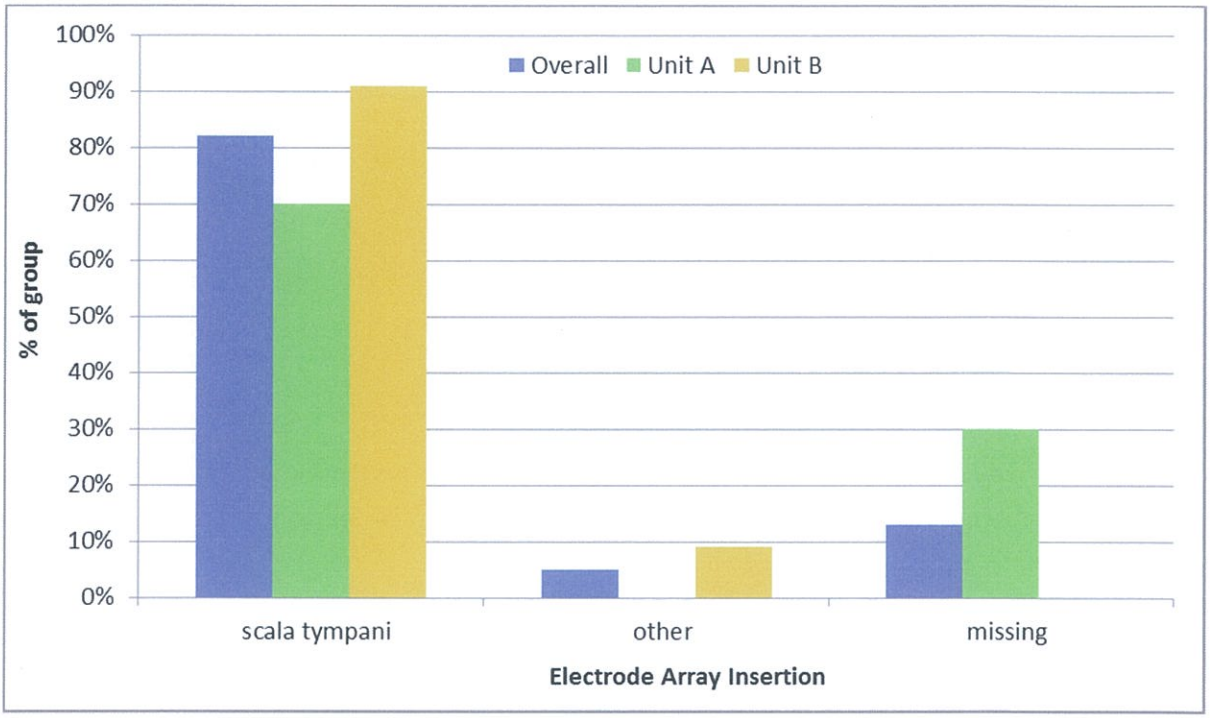


Figure 30. Electrode array insertion in the current sample (N=60)

- **Relationship between hearing findings and electrode array insertion**

There were only three cases with non-scala tympani EA_INS and these three cases were categorized as "Other." The researcher did not perform an analysis due to the small number of observations which would have made the findings meaningless.

The technique used by the surgeons at Unit A and Unit B is upheld by Adunka et al. (2010). They have advocated that the cochleostomy site should be slightly anterior and inferior to the round window, thereby opening the scala tympani, thus avoiding damage to the cochlea. In their study, 90% of recipients retained their residual hearing (Adunka et al., 2010).

In the current study, there was one case where the electrode was inserted via the scala vestibuli. However, this did not result in surgical complications. This was surprising as in previous studies it has been discovered and reported in the literature that insertion via the scala vestibuli can result in intracochlear damage (Adunka, Marc, Unkelbach, Martin, Markus, Gstoettner et al., 2004).

91% of patients were implanted via the scala tympani and there was a 92% success rate in the preservation of residual hearing (partial and complete) at both centres combined, so it can be inferred that this technique did not negatively influence the hearing findings – indeed the technique by implication must have enabled the successful conservation of hearing.

4.6.10. Electrode array insertion depth

Table 28

Electrode insertion depth in the current sample (N=60)

Variable	Overall	Unit A	Unit B	p-value for H_0: no significant difference between units
Number of participants	53	21	32	-
Insertion depth				
Complete	93%	93%	94%	1.00 (Fisher's exact test)
Partial	2%	0%	3%	
Missing	5%	7%	3%	

In the current study, the researcher found that the majority of the participants (i.e. 94% overall – 93% at Unit A and 94% at Unit B) underwent complete insertion of the electrode array during surgery. Very few patients – 3% at Unit B and 0% at Unit A (i.e. a mean of 2% overall) - underwent partial insertion of the electrode array during implantation. Five per cent of the records on insertion depth overall were classified as missing data; 7% was considered missing at Unit A, and 3% at Unit B. The results obtained for the electrode array insertion depth were not statistically significant between the two centres (according to the Fisher's exact test where p-value = 1.00). Figure 31 illustrates these findings.

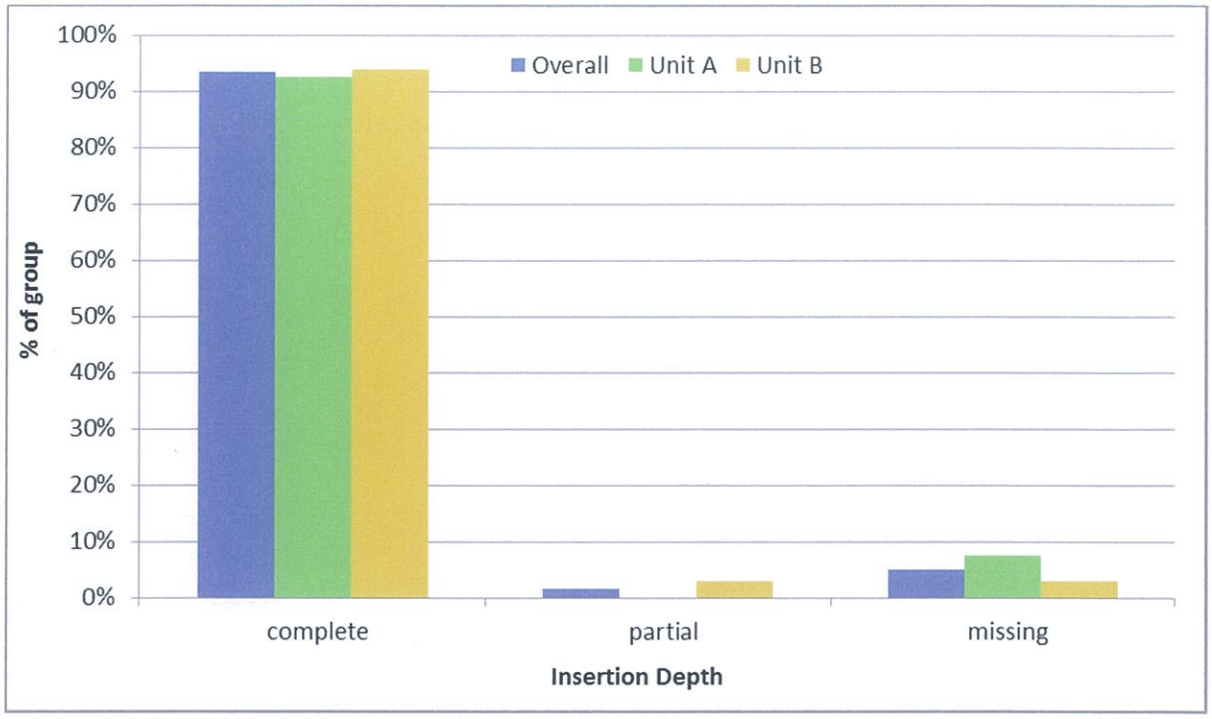


Figure 31. Electrode insertion depth in the current sample (N=60)

- **Relationship between hearing findings and electrode array insertion depth**

There was only one case of EA_DEPTH with partial insertion. The remainder of the data consisted of the electrode array depth being complete insertion. As a result of this, the results were not comparable. Thus, the researcher did not perform this analysis as it would not have added any meaning to the findings.

In the study of Bruce et al. (2011), it was emphasized that the insertion depth was critical to the successful conservation of residual hearing. Shorter electrodes were used in order to avoid contact with the apex in the cochlea, with the result that trauma to intracochlear structures was minimized. In the current study, complete insertion depth was achieved in the majority of the recipients. Partial insertion was achieved in one participant in this study. There is evidence in the literature to suggest that shorter electrodes reduce the loss of residual hearing by avoiding damage to intracochlear structures (Gantz et al., 2006). Nonetheless, in this study preservation of residual hearing (either partial or complete) was achieved in the majority of cases even though all but one participant were implanted via complete not partial insertion.

Turner et al. (2004) have also reported that less damage was caused to intracochlear structures by using short electrode devices rather than the more invasive long electrode arrays. James et al. (2005) studied 12 patients who had received a long electrode and they reported that there was preservation of post-operative residual hearing in 10 out of 37 patients, and after a few months it was found that three more patients suffered a total loss. In the current study, however, the findings indicated that even though there was complete insertion with standard length electrodes, this did not have an effect on the hearing findings. In other words, contrary to the findings of earlier studies, the post-operative unaided hearing threshold levels were not affected by the insertion depth in this study. This is significant in that even though there was complete insertion of the electrode arrays, successful conservation of residual hearing (92%) was able to be achieved.

4.6.11. Surgical techniques

Table 29

Surgical technique in the current sample (N=60)

Variable	Overall	Unit A	Unit B	p-value for H_0: no significant difference between units
Number of participants	53	21	32	-
Surgical Technique				
Contour on stylet	8%	11%	6%	0.0001 (X2 test)
AOS (advance off-stylet)	67%	33%	94%	
Other	20%	44%	0%	
Missing	5%	11%	0%	

The findings for the surgical techniques are summarized in Table 29 and in Figure 32. Two main surgical techniques were used at the two centres. These were the contour on stylet and the AOS (advance off-stylet) technique. The majority of surgeons at both centres used the AOS technique – i.e. 67 % overall; 33% at Unit A; 94% at Unit B. Eleven per cent of the surgeons at Unit A and 6% at Unit B used the contour on stylet technique (8% overall). Other surgical techniques used at Unit A made up 44% of the participants. No other surgical techniques were

used at Unit B, apart from the AOS and the contour on stylet. The X^2 test indicated that there was a statistically significant difference between the two units for the data obtained on surgical techniques. This was evidenced by the p-value, which was 0.0001.

At Unit A, 11% of the data for the surgical techniques was missing. There was no missing data at Unit B.

The majority of surgeons at both units utilised a cochleostomy approach, with the exception of four cases where the round window approach was used.

Mangus et al. (2012) asserts that the round window approach has advantages for the conserving residual hearing over the cochleostomy approach which may result in intracochlear trauma. However, the positive findings in the current study have demonstrated that cochleostomy approach has achieved success in preserving residual hearing post-operatively.

Briggs et al. (2006) observed in their study that both approaches successfully avoided trauma to the cochlea during surgery, thus conserving post-operative residual hearing.

In their study, Derinsu at al. (2011) evaluated the round window approach and found that complete preservation of residual hearing was achieved in 35.48% of patients. Using the cochleostomy approach in the majority of cases, the current study found a more positive outcome as complete preservation was achieved in 43% of patients.

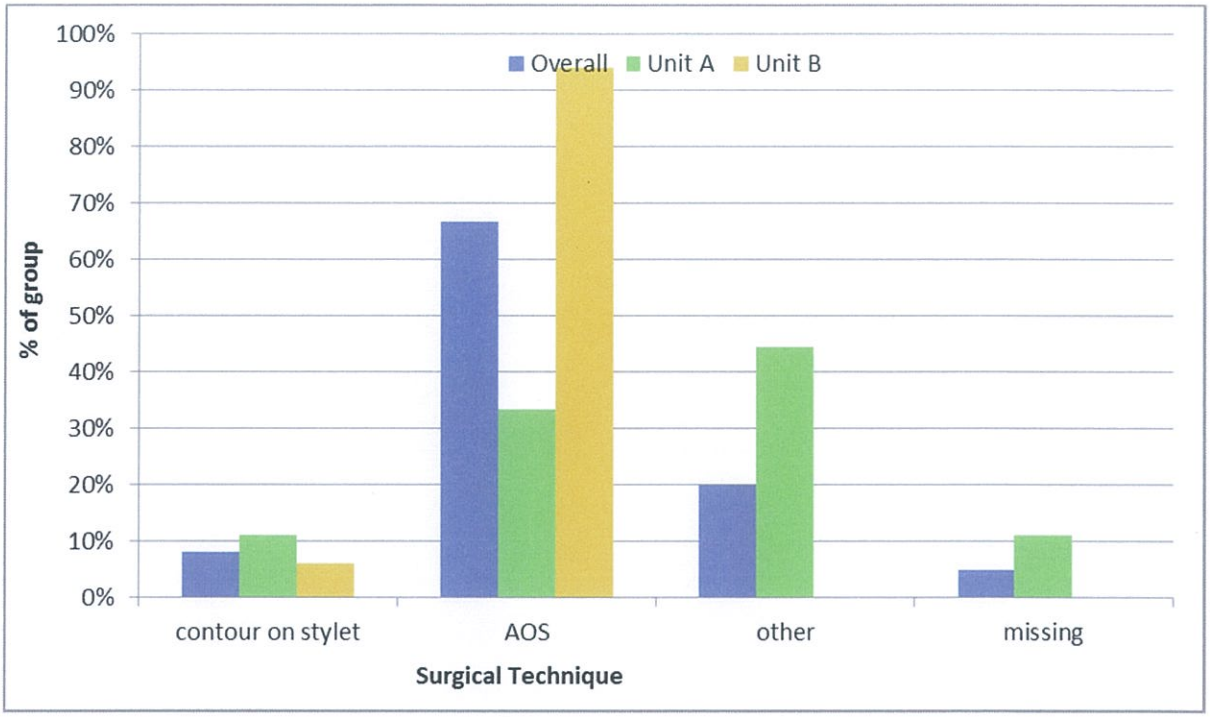


Figure 32. Surgical techniques in the current sample (N=60)

- **Relationship between hearing findings and surgical techniques**

The examination of the surgical techniques was considered to be relevant in terms of establishing the possible effect or lack of effect on the preservation of residual hearing. By investigating their effects of the hearing findings, the researcher was interested in determining whether or not certain surgical techniques were more favourable than others for preserving residual hearing. Thus an analysis was carried out to establish whether a relationship existed between the hearing findings and the surgical technique employed.

The effect of SURG_TECH on CH was not significant for any of the frequencies, except for Overall (and Unit A) for 2000 Hz, where the mean CH was 10.1 (10.3) units lower for Contour on stylet (Contour) vs. AOS, and the mean CH was 7.9 (6.8) units higher for Other vs. AOS.

The analysis for Unit B was limited since the AOS technique was used almost exclusively.

As the above discrepancy was limited to one frequency (i.e. 2000 Hz), overall and at Unit A, and as the change in hearing threshold levels was minimal, this was unremarkable statistically. However, the slight change in hearing threshold levels at 2000 Hz has clinical significance in

that this frequency is a speech frequency and is important for speech perception and thus even a slight decrease in hearing at this particular frequency could affect discrimination of speech – particularly in the presence of background noise.

Thus, it can be concluded that at both centres combined the surgical technique used did not have a negative effect on the post-operative hearing threshold levels (i.e. change in residual hearing), with the exception of 2000 Hz at Unit A. In other words, by using the AOS or a Contour or "Other" technique, it did not change the post-operative outcome in terms of preservation of residual hearing, except at one relevant speech frequency at one of the cochlear implant centres, namely Unit A. In other words, conservation was achieved, using these techniques. The fact that there was no change demonstrates the significance of the present study, as these techniques used, successfully preserved residual hearing.

From the findings the researcher established that there were common links between that of Roland et al. (2005) and that of the two units under study with regard to the surgical techniques, electrode insertion and the electrode arrays used. In the study of Roland et al. (2005) they examined the use of Contour Advance electrodes with the AOS technique. Atraumatic insertion was achieved by precise perimodiolar positioning in the scala tympani, thereby affording protection to intracochlear structures (Roland et al., 2005). This is consistent with the findings of the current study, where the findings show that residual hearing was also successfully preserved.

4.6.12. Intra-operative complications

The researcher investigated surgical complications to determine the possible influence on residual hearing and whether they affected the conservation of functional hearing post-surgery.

Table 30

Surgical complications in the current sample (N=60)

Variable	Overall	Unit A	Unit B	p-value for H_0: no significant difference between units
Number of participants	53	21	32	-
Intra-operative complications				
Adhesions	3%	7%	0%	0.049 (X2 test)
Drill out of basal turn	3%	0%	6%	
Gusher	5%	7%	3%	
Trauma	10%	0%	18%	
Other	3%	0%	6%	
None reported	68%	70%	67%	
Missing	7%	15%	0%	

The main categories for intra-operative complications at Unit A, Unit B and at both centres combined included (refer to Table 30): adhesions (3% overall; 7% at Unit A; none at Unit B); drill out of basal turn (3% overall; none at Unit A ; 6% at Unit B); Gusher (5% overall; 7% and 3% at Unit A and Unit B respectively); trauma (10% overall; none at Unit A; 18% at Unit B); other (3% overall; none at Unit A; 6% at Unit B); none reported (68% overall; 70% and 67% at Unit A and Unit B respectively) and missing (7% overall; 15% at Unit A; none at Unit B). These results are illustrated in Figure 33. From the X^2 test, it became evident that there was a statistically significant difference between the two centres for these results (p-value=0.049).

From the findings, it became apparent that the majority of cases at both centres did not have any intra-operative complications reported. This is a positive prognostic indicator for the preservation of residual hearing. Intra-operative complications could result in intracochlear damage, which in turn may lead to loss of residual hearing thereby affecting the preservation of residual hearing.

From the statistics in Table 30 and illustrated in Figure 33, the researcher found that trauma and gusher were more prevalent than other surgical complications.

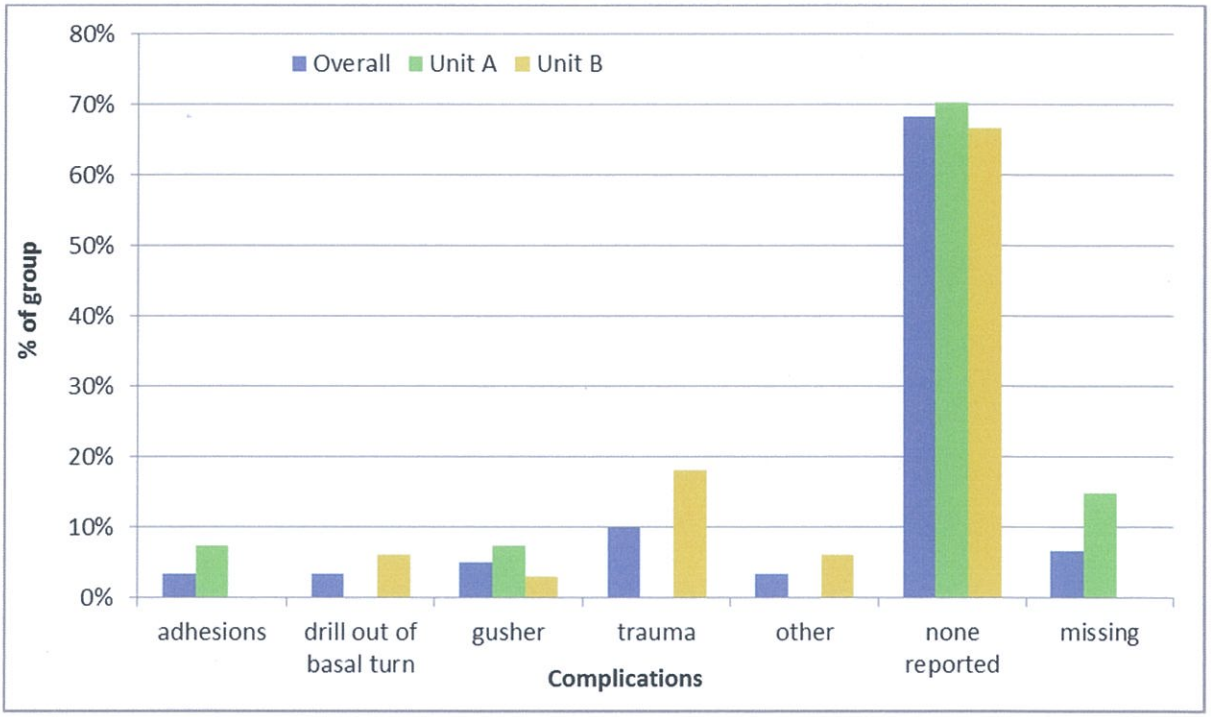


Figure 33. Surgical complications in the current sample (N=60)

- **Relationship between hearing findings and surgical complications**

On analysing the relationship between hearing findings and surgical complications, several significant effects were found.

Overall data:

- There was a significant effect of gusher on CH at 750 and 1000 Hz: In both cases the effect of a gusher complication (vs. no complication) was to lower CH by 14 -19 dB (depending on the frequency).
- There was a significant effect of trauma on CH at 250, 500 and 8000 Hz: In all three cases the effect of a trauma complication (vs. no complication) was to increase CH by ~9-24 dB (depending on the frequency).

Unit A data:

- There were no significant effects for any of the complication types on the hearing findings. This means that at Unit A surgical complications did not affect the post-operative hearing threshold levels or the change in residual hearing.

Unit B data:

- At Unit B there was a significant effect of gusher on CH at 750 Hz: The effect of a gusher complication (vs. no complication) was to lower CH by 19 dB. In other words, the surgical complication, namely gusher, affected the change in residual hearing or affected the post-operative hearing threshold levels by 19 dBs. Hearing decreased by 19 dBs (i.e. 19 dB loss in residual hearing) as a result of the surgical complication gusher. There was thus a direct correlation.

According to Clark et al. (1988) and Balkany et al. (1999) (as cited in Di Nardo et al., 2007), surgical complications affect anatomical structures following implantation. A relationship between the surgical complications and hearing threshold levels became apparent in the current study where the researcher found a direct correlation between the surgical complications and the hearing findings at Unit B.

Kiefer et al. (2004) have cautioned that damage to the cochlea could be a result of acoustic trauma from bone drilling during surgery which is required for the cochleostomy. According to Clark et al. (1988) and Balkany et al. (1999) as cited in Di Nardo et al. (2007), anatomical structures which could be damaged during implantation due to surgical complications include osseous spiral lamina fracture, damage to the spiral ligament, stria and the Organ of Corti, changes in the ionic equilibrium within the cochlea and the development of a fibrous sheath encompassing the electrode array (Di Nardo et al., 2007). The researcher in the current study found that the surgical complications in this study included inter alia adhesions, gusher, trauma and drill out of basal turn.

From the findings above, it was observed that trauma and gusher affected the hearing findings at Unit B – i.e. led to a loss or reduction in residual hearing post-operatively at this centre. This relationship has also been observed by other researchers in the literature, albeit due to other surgical complications. Derinsu et al. (2011) hold that hearing loss may also result from drilling

on the cochlea, tissue disruption, mechanical vibration damping effects of the electrode, and electrical stimulation.

In Di Nardo et al.'s (2007) study it was found that the cochlea was not that sensitive to trauma caused by surgery. The current researcher holds that this should result in positive outcomes with regard to preservation of residual hearing. However, 22% of implantees experienced a total loss of hearing post-operatively.

Although the researcher found that trauma had an effect on the hearing findings, the post-operative outcomes were more positive in the current study than in that of Di Nardo et al. (2007) – i.e. 8% as opposed to 22% complete loss of residual hearing.

When summarizing the relationship between the hearing findings and the various factors listed above, it became evident that the variables investigated had little or no negative effect in general on the preservation of residual hearing, with the exception of surgical complications. It was found that complications during cochlear implant surgery had a direct influence on the change in residual hearing in that the surgical complications resulted in loss of residual hearing. Although the overall results indicated this finding, it must be noted that surgical complications had no effect on the hearing findings at Unit A, but had a direct impact on post-operative residual hearing at Unit B.

The above results also indicated relationships between certain variables at certain frequencies and the hearing findings – i.e. these factors affected the hearing threshold levels at these particular frequencies. Although the decrease in hearing threshold levels in decibels was slight and thus not statistically significant, it had some clinical significance in that it affected those frequencies used for speech perception.

CHAPTER 5: CONCLUSION

Chapter 5: Conclusion

5.1. Summary of the findings

The preservation of residual hearing was successfully achieved at the two centres examined in the current study. Preservation of post-operative residual hearing was achieved in 92% of participants, with 42% partial and 50% complete hearing conservation. A minimal overall complete loss was experienced by 8% of the recipients post-operatively.

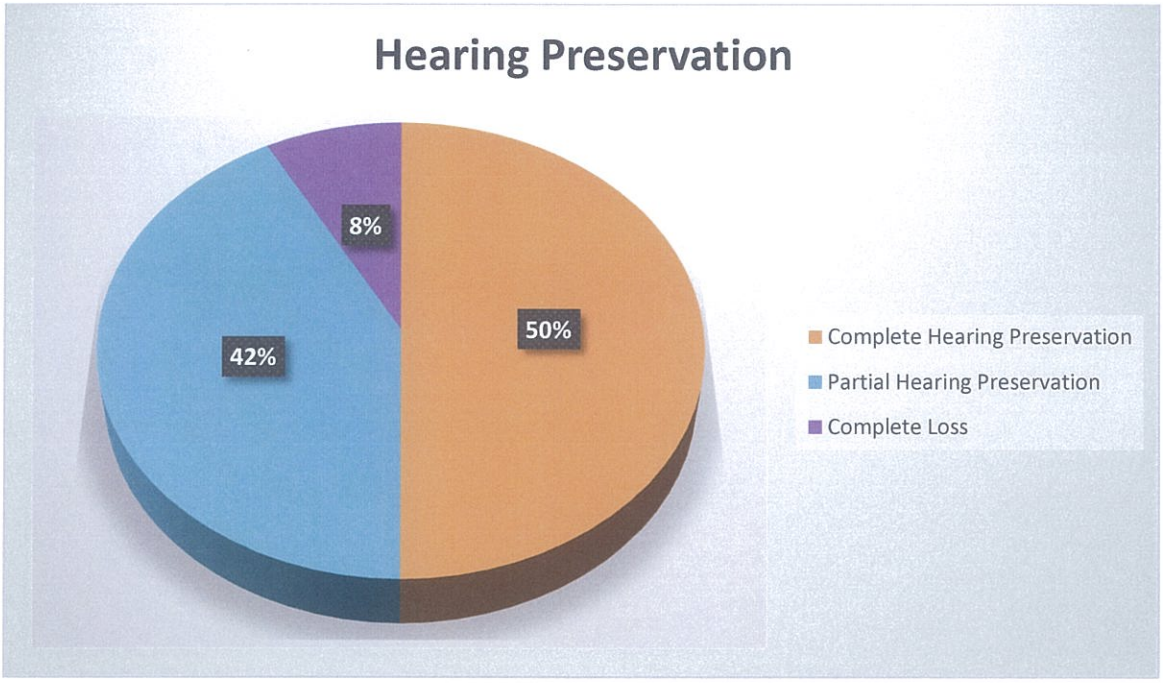


Figure 34. Percentage of hearing preservation in current sample (N=60)

Significant success was achieved in the preservation of residual hearing in the current study compared with earlier studies, such as that of Hodges et al.'s study in 1997 where hearing was only preserved in 50% of implantees (Balkany et al., 2006). In Di Nardo et al.'s (2007) study, despite an atraumatic surgical approach being used and the majority of implantees retaining their residual hearing, 22% experienced a total loss of hearing following surgery.

In their study in 2006, Gantz et al. observed successful conservation in 47 out of 49 implantees using the Nucleus Hybrid device with short electrode arrays (Gantz et al., 2006). These positive outcomes are consistent with those found in the current study. According to Gstoettner et al. (2009), this high rate of 96% of preservation of residual hearing is rare.

As recently as 2010, Verhaegen et al. (2010) observed retention of residual hearing post-operatively in 70% of implantees. Although these findings indicate an improvement over earlier studies, the successful overall preservation rate of 92% found in the current study was considerably higher.

A more recent study conducted by Derinsu et al. (2011) demonstrated positive results of 87% overall hearing preservation – similar to the successful findings of 92% found by the current researcher. However, in Derinsu et al.'s (2011) study a total loss of 12.9% was experienced compared with 8% loss in the current study.

The researcher found that the following variables investigated did not affect the post-operative hearing findings in the current study: age, gender, degree of pre-operative hearing loss, aetiology, along with the duration of pre-operative hearing loss, the time between the last pre-operative hearing test and surgery, and the duration between surgery and the unaided post-operative hearing testing. The current study has shown that the preservation of residual hearing is possible regardless of these variables. In Skarzynski et al.'s (2002) study, hearing preservation was achieved in 62% (as opposed to 92% in the current study) and they also found that the following variables did not influence the results: age, gender, aetiology and implant type.

In general, the surgeons at both units used the same electrode array, insertion method, insertion depth and implant manufacturer. Therefore, comparative statistics were not performed. From the positive findings of 92% preservation of residual hearing, it could be inferred that optimal results for conservation could be achieved by using the Contour Advance electrode from the manufacturer Cochlear, the AOS technique and complete insertion of the electrode into the cochlea via the scala tympani – as was done in the majority of cases in the current study.

From the data, it became evident that there was a direct correlation between the surgical complications and a deterioration of post-operative hearing threshold levels. An 8% complete loss of hearing was experienced by the implantees at both units combined. Findings indicated that in the absence of surgical complications, there was no deterioration of post-operative hearing findings in relation to implant type and surgical technique employed – i.e. there was

successful preservation of residual hearing of 92% (partial and complete) at both units combined.

5.2. Strengths

It can be observed that the use of the Contour Advance electrode with AOS by the surgeons at the two centres in the current study, resulted in a high success rate in the preservation of post-operative residual hearing in the candidates implanted.

The positive outcomes of the current study have clinical significance, including making EAS a reality.

In addition, significance can be attached to the model of implant together the type of electrode array, as this combination together with the surgical techniques employed in the current study, have resulted in highly successful outcomes.

The large sample size of 60 observations is an adequate sample size for the current study.

The findings of the current study may make a significant contribution towards future knowledge in the field of the conservation of residual hearing.

5.3. Limitations

The study measured post-operative data at approximately one month or more following cochlear implantation. The measurements were not taken at defined time intervals as in Gstoettner et al.'s (2009) study. This was limiting in that the testing dates occurred at random intervals. To overcome these limitations, the researcher in this study looked at general trends to determine whether there was a pattern as to when the participants lost or retained their residual hearing.

There was some missing data, which lead to the exclusion of some participants. However, this had a minimal impact on the sample size, which remained adequate for the current study.

Another limitation was that there was no consistent audiological follow-up of patients post-implantation to establish whether the hearing thresholds remained stable.

A further limitation was that meaningful statistics could not be performed on all the data as the same electrode array, insertion method, insertion depth and implant manufacturer were used in the majority of implantees, thus the results were not comparable.

5.4. Recommendations

When this study was planned, there were only three participants in South Africa with Electro-acoustic Stimulation (EAS) (L. Naute, personal communication, February 17, 2011), thus this was beyond the scope of the study. However, in the future, when there is a statistically significant sample of EAS recipients, it is recommended that this be studied and the results generalized to the population.

This study focused on the preservation of residual hearing at Unit A and Unit B and obtained an adequate sample size for this study in South Africa. It is recommended that this study be conducted on a broader population – i.e. at a number of different cochlear implant centres across South Africa – in order to obtain data that could be generalized to an even broader population in South Africa.

5.5. Implications

The findings of the study may be beneficial for cochlear implant surgeons, as they may be able to examine the extent to which residual hearing can been preserved. General patterns regarding the relationship between residual hearing function and surgical technique together with the choice of atraumatic electrode arrays may emerge. In addition, the use of the Contour Advance electrode with AOS could become protocol for cochlear implant surgery given the highly successful rate of conservation achieved in the current study.

The findings may also offer advantages to audiologists and other professionals working in the field, as they may be able to utilise the findings to inform cochlear implant candidates with residual hearing about the possible benefits and risks involved.

Future cochlear implant candidates with residual hearing and those candidates for EAS may also benefit, as the findings may assist them in the decision-making process. Moreover, the findings may be of use to medical aids in South Africa who may as a result provide more funding for cochlear implantation.

The researcher hopes that government policies in South Africa may be influenced along with the Department of Health. This research study has provided evidence that there are minimal risks involved with regard to the loss of residual hearing in cochlear implant surgery and therefore this may have an influence on government providing unilateral cochlear implantation to hearing-impaired individuals who fit the criteria.

5.6. Conclusion

Based on the findings of this study, the researcher is of the opinion that successful conservation of residual hearing is possible post-surgery with the AOS technique using Contour Advance electrodes with complete insertion into the cochlea. It is evident from the findings depicted in this study that surgical complications have a direct negative influence on the hearing findings and the conservation of functional hearing post-surgery. Conversely, the hearing findings demonstrate that successful preservation of hearing was achieved in the absence of such complications and with the use of the advanced surgical techniques and the refinements in both the cochlear implant types and electrode arrays.

The researcher believes that the success achieved in the preservation of residual hearing in this study and other recent studies is attributable to technological advancements and refinements in surgical techniques, which have resulted in minimizing surgical complications, thereby avoiding intracochlear damage and in turn leading to the positive outcomes.

The current researcher concurs with Lenarz et al. (2009) who believes that the dramatic increase in post-operative hearing retention can be attributed to increased surgical experience along with less traumatic electrode insertion.

It is important that surgical techniques continue to be improved and electrodes refined so as to limit intracochlear trauma, thereby optimizing the preservation of residual hearing post-operatively.

The conservation of residual hearing post-surgery has many advantages for future cochlear implant candidates with pre-operative residual hearing and for those implantees with preserved post-operative residual hearing. These cochlear implant candidates and recipients could then become candidates for EAS, which in turn has many hearing benefits, such as improved speech perception in noise and musical acuity.

From the successful findings demonstrated by the high rate of preservation of residual hearing in the current study, it can be concluded that the benefits outweigh the attendant risks. With further advancements in cochlear implant technology and surgical techniques, and with continued research into this area, more prospective candidates with residual hearing will hopefully be encouraged to undergo the procedure – recognizing that the advantages supercede the risks. Additionally, it is hoped that the benefits will be recognized by the Department of Health and medical aids to provide more funding for cochlear implantation for those candidates who would otherwise not be able to afford the procedure.

This study demonstrates the success of the preservation of residual hearing following cochlear implant surgery. These findings will add to the current paucity of research on the topic in South Africa. Moreover, these findings may have implications not only for audiologists, but also for Ear, Nose and Throat surgeons and other professionals working in the field.

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Appendix A: Surgical Form (adapted)

Patient: .....

Date of birth: ..... CA: ..... Male ☐ Female ☐

Aetiology of hearing loss: .....

Duration of hearing loss prior to implantation: .....

Surgeon: .....

Date of implantation: ..... Ear: ☐ Right ☐ Left

Implant type: .....

Implant model: .....

Implant manufacturer: .....

Implant serial number: .....

Surgery protocol or surgical technique:

.....

.....

.....

.....

.....

Electrode type: .....

Electrode array insertion: .....

Electrode array depth: .....

Intra-operative complications:

.....

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.....

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Appendix B

COCHLEAR IMPLANTOPERATION CHECKLIST

Name of patient:.....

Date of birth:.....CA: .....Male ☐ Female ☐

Name of surgeon:..... Hospital.....

Date of implantation:..... Ear ☐ right ☐ left

Implant type:..... Serial number:.....

Special preparations:.....

.....

Skin incision:

.....

Posterior tympanotomy:

Access:.....

- incus..... - Chorda .....

- VII..... - Annulus.....

Cochleostomy site: .....

☐scala tympani ☐scalavestibuli Trauma to Basilar Membrane ☐ Yes ☐ No

Ossification: yes ☐ no ☐

Drill out of basal turn: ☐ yes ☐ no Length: .....mm

Comments:.....

Local drugs used:.....

Electrode array:

Electrode inserted through: cochleostomy☐ round window ☐

☐ complete insertion; insertion depth:.....mm

☐ partial insertion; no. of electrodes ..... / rings ..... outside cochlea

Insertion technique:.....

Fixation of the electrode array .....

Suction .....

Placement of the ground electrode:.....

Position of Receiver/Stimulator.....

Fixation of Receiver/Stimulator.....

Remarks .....

.....

.....

Stapedius reflex test: ☐ **yes** ☐ **no**

Channel: ....

Threshold: ....

Implant test: function verified ☐ **yes** ☐ **no**

Intra-operative Complications: ☐ yes ☐ no If yes, please specify:

Anaesthetic: ☐ yes ☐ no .....

Trauma to:

External Auditory Canal: Bony: ☐ yes ☐ no Skin: ☐ yes ☐ no

Annulus: ☐ yes ☐ no Chorda: ☐ yes ☐ no

Tympanic membrane: ☐ yes ☐ no Facial nerve: ☐ yes ☐ no

Basilar Membrane: ☐ yes ☐ no

Gusher :☐ yes ☐ no Other: .....

....

.....

Duration of surgery:

Patient on table ..... Surgical starting time: .....

Surgical finishing time: ..... Patient leaves theatre: .....

Post operative X-Ray: ☐ yes ☐ no

Signature of the surgeon:..... Date.....

Appendix C: Human Research Ethics Committee (Medical) from the University of the Witwatersrand

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ms Katherine J Gautschi

CLEARANCE CERTIFICATE	M111037
PROJECT	Preservation of Residule Hearing after Cochlear Implant Surgery: An Exlporation of Residule Hearing Function in a Grou[of Recipients at South African Cochlear Implants
INVESTIGATORS	Ms Katherine J Gautschi.
DEPARTMENT	Department of Speech Pathology & Audiology
DATE CONSIDERED	28/10/2011
M1110370DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 11/11/2011 CHAIRPERSON .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Prof K Shangase-Khoza

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report.
PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Appendix D: Consent letter and form to access data from head of audiology department at Unit A

Private Bag X26

Benmore

2010

Phone No. (011) 783 4903

Fax No. 086 670 8611

Dear Sir/Madam

RE: PERMISSION TO CONDUCT RESEARCH ON A GROUP OF COCHLEAR IMPLANT RECIPIENTS AT SOUTH AFRICAN COCHLEAR IMPLANT UNITS

I am a Speech Therapist and Audiologist, currently registered as a Postgraduate Master's student in the Discipline of Audiology at the University of the Witwatersrand, Johannesburg. To fulfil my degree requirements, I am required to complete a dissertation. The title for my dissertation is: *Preservation of residual hearing after cochlear implant surgery: an exploration of residual hearing function in a group of recipients at South African Cochlear Implant Units.*

I would appreciate it if I could obtain your permission to conduct my research at the Johannesburg Cochlear Implant Centre. I also aim to conduct my research at the University of Stellenbosch – Tygerberg Hospital Cochlear Implant Centre and the University of Pretoria Cochlear Implant Unit.

For the purposes of my research, I shall conduct a retrospective data review, comparing a minimum of 30 existing pre-operative and post-operative unaided audiological testing results to determine whether residual hearing has been preserved and, if so, to what degree. Factors documented to have a possible influence on cochlear implant surgery outcome will be examined in an attempt to establish relationships that may exist.

Involvement from your centre would include allowing me access to existing pre-operative and post-operative unaided audiological testing results for participants with residual hearing. I would require permission from the surgeons to access their surgical records on cochlear implant recipients with residual hearing, in order for me to fill in a surgical form for each recipient (please see attached). Confidentiality and anonymity will be ensured.

It is hoped that my research findings will be useful to cochlear implant candidates with residual hearing, Audiologists and other professionals working in the field, Ear, Nose and Throat surgeons, Medical Aids and the Department of Health.

Please do not hesitate to contact me should you have any queries.

Katherine Gautschi

MA (Audiology) Student, University of the Witwatersrand

Tel: (011) 783 4903 Cell: (082) 468 3072 Email: kathgaut@iafrica.com

I, Leone' Nauta, at the Johannesburg Cochlear Implant Centre, hereby grant permission for Katherine Gautschi to access the existing pre-operative and post-operative unaided audiological testing results of cochlear implant recipients with residual hearing.

Sign: L Nauta Date: 30 / 11 / 2011

Appendix E: Consent letter and form to access data from head of audiology department at Unit B

Private Bag X26

Benmore

2010

Phone No. (011) 783 4903

Fax No. 086 670 8611

Dear Sir/Madam

RE: PERMISSION TO CONDUCT RESEARCH ON A GROUP OF COCHLEAR IMPLANT RECIPIENTS AT SOUTH AFRICAN COCHLEAR IMPLANT UNITS

I am a Speech Therapist and Audiologist, currently registered as a Postgraduate Master's student in the Discipline of Audiology at the University of the Witwatersrand, Johannesburg. To fulfil my degree requirements, I am required to complete a dissertation. The title for my dissertation is: *Preservation of residual hearing after cochlear implant surgery: an exploration of residual hearing function in a group of recipients at South African Cochlear Implant Units.*

I would appreciate it if I could obtain your permission to conduct my research at the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit. I also aim to conduct my research at the Johannesburg Cochlear Implant Centre and the University of Pretoria Cochlear Implant Unit.

For the purposes of my research, I shall conduct a retrospective data review, comparing a minimum of 30 existing pre-operative and post-operative unaided audiological testing results to determine whether residual hearing has been preserved and, if so, to what degree. Factors documented to have a possible influence on cochlear implant surgery outcome will be examined in an attempt to establish relationships that may exist.

Involvement from your centre would include allowing me access to existing pre-operative and post-operative unaided audiological testing results for participants with residual hearing. I would require permission from the surgeons to access their surgical records on cochlear implant recipients with residual hearing, in order for me to fill in a surgical form for each recipient (please see attached). Confidentiality and anonymity will be ensured.

It is hoped that my research findings will be useful to cochlear implant candidates with residual hearing, Audiologists and other professionals working in the field, Ear, Nose and Throat surgeons, Medical Aids and the Department of Health.

Please do not hesitate to contact me should you have any queries.

Katherine Gautschi

MA (Audiology) Student, University of the Witwatersrand

Tel: (011) 783 4903 Cell: (082) 468 3072 Email: kathgaut@iafrica.com

I, A. M.U. Müller, at the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit, hereby grant permission for Katherine Gautschi to access the existing pre-operative and post-operative unaided audiological testing results of cochlear implant recipients with residual hearing.

Sign: A Müller Date: 25 / 1 / 2012

Appendix F: Consent permission forms for records at Unit C pending ethical clearance

I, Prof Vinck, at the University of Pretoria-Cochlear Implant Unit, hereby confirm that our cochlear implant patients (prospective participants for the proposed study) have given written permission to our Cochlear Implant Centre to share their audiological and surgical records for research purposes.

Sign: _____ Date: 19 / 10 / 2011

Appendix F continued: Consent permission forms for records at Unit C pending ethical clearance

I, Natje Cass, at the University of Pretoria-Cochlear Implant Unit, hereby confirm that our cochlear implant patients (prospective participants for the proposed study) have given written permission to our Cochlear Implant Centre to share their audiological and surgical records for research purposes.

Sign: [signature] Date: 19 / 10 / 2011

Appendix G: Consent letter and form for audiological records at Unit C

Private Bag X26

Benmore

2010

Phone No. (011) 783 4903

Fax No. 086 670 8611

Dear Sir/Madam

RE: PERMISSION TO CONDUCT RESEARCH ON A GROUP OF COCHLEAR IMPLANT RECIPIENTS AT SOUTH AFRICAN COCHLEAR IMPLANT UNITS

I am a Speech Therapist and Audiologist, currently registered as a Postgraduate Master's student in the Discipline of Audiology at the University of the Witwatersrand, Johannesburg. To fulfil my degree requirements, I am required to complete a dissertation. The title for my dissertation is: *Preservation of residual hearing after cochlear implant surgery: an exploration of residual hearing function in a group of recipients at South African Cochlear Implant Units.*

I would appreciate it if I could obtain your permission to conduct my research at the University of Pretoria Cochlear Implant Unit. I also aim to conduct my research at the Johannesburg Cochlear Implant Centre and the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit.

For the purposes of my research, I shall conduct a retrospective data review, comparing a minimum of 30 existing pre-operative and post-operative unaided audiological testing results to determine whether residual hearing has been preserved and, if so, to what degree. Factors

documented to have a possible influence on cochlear implant surgery outcome will be examined in an attempt to establish relationships that may exist.

Involvement from your centre would include allowing me access to existing pre-operative and post-operative unaided audiological testing results for participants with residual hearing. I would require permission from the surgeons to access their surgical records on cochlear implant recipients with residual hearing, in order for me to fill in a surgical form for each recipient (please see attached). Confidentiality and anonymity will be ensured.

It is hoped that my research findings will be useful to cochlear implant candidates with residual hearing, Audiologists and other professionals working in the field, Ear, Nose and Throat surgeons, Medical Aids and the Department of Health.

Please do not hesitate to contact me should you have any queries.

Katherine Gautschi

MA (Audiology) Student, University of the Witwatersrand

Tel: (011) 783 4903 Cell: (082) 468 3072 Email: kathgaut@iafrica.com

I, Nicolize Cass, at the University of Pretoria Cochlear Implant Unit, hereby grant permission for Katherine Gautschi to access the existing pre-operative and post-operative unaided audiological testing results of cochlear implant recipients with residual hearing.

Sign: _____ Date: 31 / 01 / 2012

Appendix H: Consent letter and form from a surgeon from Unit C

Private Bag X26

Benmore

2010

Phone No. (011) 783 4903

Fax No. 086 670 8611

Sir

RE: PERMISSION TO CONDUCT RESEARCH ON A GROUP OF COCHLEAR IMPLANT RECIPIENTS AT SOUTH AFRICAN COCHLEAR IMPLANT UNITS

I am a Speech Therapist and Audiologist, currently registered as a Postgraduate Master's student in the Discipline of Audiology at the University of the Witwatersrand, Johannesburg. To fulfil my degree requirements, I need to complete a dissertation. The title for my dissertation is: *Preservation of residual hearing after cochlear implant surgery: an exploration of residual hearing function in a group of recipients at South African Cochlear Implant Units.*

I aim to conduct my research at the Johannesburg Cochlear Implant Centre, the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit and the University of Pretoria Cochlear Implant Unit.

For the purposes of my research, I shall conduct a retrospective data review, comparing a minimum of 30 existing pre-operative and post-operative unaided audiological testing results to determine whether residual hearing has been preserved and, if so, to what degree. Factors

documented to have a possible influence on cochlear implant surgery outcome will be examined in an attempt to establish relationships that may exist.

Should permission from your cochlear implant centre be granted, existing pre-operative and post-operative unaided audiological testing data will be accessed for each cochlear implant recipient with residual hearing.

I would like to invite you to participate in my study. Should you choose to partake, your involvement would be to allow me to access your surgical records, in order for me to fill in a surgical form on the cochlear implant recipients with residual hearing (please see attached). Confidentiality and anonymity will be ensured.

It is hoped that my research findings will be useful to cochlear implant candidates with residual hearing, Audiologists and other professionals working in the field, Ear, Nose and Throat Surgeons, Medical Aids and the Department of Health.

Please do not hesitate to contact me should you have any queries.

Katherine Gautschi

MA (Audiology) Student, University of the Witwatersrand

Tel: (011) 783 4903 Cell: (082) 468 3072 Email: kathgaut@iafrica.com

I, E. Burden, an Ear, Nose and Throat Surgeon at the University of Pretoria Cochlear Implant Unit, hereby agree to participate in Katherine Gautschi's study. This participation will involve her accessing my surgical records on cochlear implant recipients with residual hearing.

Sign: E Burden Date: 25 / 1 / 2012

Appendix I: Consent form from a surgeon from Unit C

I, Louis Murray Hitmey, an Ear, Nose and Throat Surgeon at the University of Pretoria Cochlear Implant Unit, hereby agree to participate in Katherine Gautschi's study. This participation will involve her accessing my surgical recordson cochlear implant recipients with residual hearing.

Sign: _____ Date: 2 / 2 / 2012

Appendix J: Consent letter and form from a surgeon at Unit A

Private Bag X26

Benmore

2010

Phone No. (011) 783 4903

Fax No. 086 670 8611

Dear Sir/Madam

RE: PERMISSION TO CONDUCT RESEARCH ON A GROUP OF COCHLEAR IMPLANT RECIPIENTS AT SOUTH AFRICAN COCHLEAR IMPLANT UNITS

I am a Speech Therapist and Audiologist, currently registered as a Postgraduate Master's student in the Discipline of Audiology at the University of the Witwatersrand, Johannesburg. To fulfil my degree requirements, I need to complete a dissertation. The title for my dissertation is: *Preservation of residual hearing after cochlear implant surgery: an exploration of residual hearing function in a group of recipients at South African Cochlear Implant Units.*

I aim to conduct my research at the Johannesburg Cochlear Implant Centre, the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit and the University of Pretoria Cochlear Implant Unit.

For the purposes of my research, I shall conduct a retrospective data review, comparing a minimum of 30 existing pre-operative and post-operative unaided audiological testing results to determine whether residual hearing has been preserved and, if so, to what degree. Factors

documented to have a possible influence on cochlear implant surgery outcome will be examined in an attempt to establish relationships that may exist.

Should permission from your cochlear implant centre be granted, existing pre-operative and post-operative unaided audiological testing data will be accessed for each cochlear implant recipient with residual hearing.

I would like to invite you to participate in my study. Should you choose to partake, your involvement would be to allow me to access your surgical records, in order for me to fill in a surgical form on the cochlear implant recipients with residual hearing (please see attached). Confidentiality and anonymity will be ensured.

It is hoped that my research findings will be useful to cochlear implant candidates with residual hearing, Audiologists and other professionals working in the field, Ear, Nose and Throat Surgeons, Medical Aids and the Department of Health.

Please do not hesitate to contact me should you have any queries.

Katherine Gautschi

MA (Audiology) Student, University of the Witwatersrand

Tel: (011) 783 4903 Cell: (082) 468 3072 Email: kathgaut@iafrica.com

I, _____, an Ear, Nose and Throat Surgeon at the Johannesburg Cochlear Implant Centre, hereby agree to participate in Katherine Gautschi's study. This participation will involve her accessing my surgical records on cochlear implant recipients with residual hearing.

Sign: _____ Date: 17/ 1 /2012

Appendix K: Consent form from a surgeon at Unit A

I, _____, an Ear, Nose and Throat Surgeon at the Johannesburg Cochlear Implant Centre, hereby agree to participate in Katherine Gautschi's study. This participation will involve her accessing my surgical records on cochlear implant recipients with residual hearing.

Sign: _____ Date: _____/ _____ / 2011

Appendix L: Consent form from a surgeon at Unit A

I, Duane Nel, an Ear, Nose and Throat Surgeon at the Johannesburg Cochlear Implant Centre, hereby agree to participate in Katherine Gautschi's study. This participation will involve her accessing my surgical records on cochlear implant recipients with residual hearing.

Sign: _____ Date: 17 / 01 / 2012

Appendix M: Consent form from surgeon at Unit A

I, KEITH DAVIDGE-PITTS, an Ear, Nose and Throat Surgeon at the Johannesburg Cochlear Implant Centre, hereby agree to participate in Katherine Gautschi's study. This participation will involve her accessing my surgical records on cochlear implant recipients with residual hearing.

Sign: _____ Date: 17 / 1 / 2012

Appendix N: Consent form from surgeon at Unit A

I, ASHEN NAMAN, an Ear, Nose and Throat Surgeon at the Johannesburg Cochlear Implant Centre, hereby agree to participate in Katherine Gautschi's study. This participation will involve her accessing my surgical records on cochlear implant recipients with residual hearing.

Sign: _____ Date: 17 / 01 / 2012

Appendix O: Consent permission letter from head of audiology department at Unit B

I, A.M.H. Muller, at the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit, hereby confirm that our cochlear implant patients (prospective participants for the proposed study) have given written permission to our Cochlear Implant Centre to share their audiological and surgical records for research purposes.

Sign: Amuller Date: 6 / 10 / 2011

Appendix P: Consent letter and form from a surgeon at Unit B

Private Bag X26

Benmore

2010

Phone No. (011) 783 4903

Fax No. 086 670 8611

Dear Sir/Madam

RE: PERMISSION TO CONDUCT RESEARCH ON A GROUP OF COCHLEAR IMPLANT RECIPIENTS AT SOUTH AFRICAN COCHLEAR IMPLANT UNITS

I am a Speech Therapist and Audiologist, currently registered as a Postgraduate Master's student in the Discipline of Audiology at the University of the Witwatersrand, Johannesburg. To fulfil my degree requirements, I need to complete a dissertation. The title for my dissertation is: *Preservation of residual hearing after cochlear implant surgery: an exploration of residual hearing function in a group of recipients at South African Cochlear Implant Units.*

I aim to conduct my research at the Johannesburg Cochlear Implant Centre, the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit and the University of Pretoria Cochlear Implant Unit.

For the purposes of my research, I shall conduct a retrospective data review, comparing a minimum of 30 existing pre-operative and post-operative unaided audiological testing results to determine whether residual hearing has been preserved and, if so, to what degree. Factors

documented to have a possible influence on cochlear implant surgery outcome will be examined in an attempt to establish relationships that may exist.

Should permission from your cochlear implant centre be granted, existing pre-operative and post-operative unaided audiological testing data will be accessed for each cochlear implant recipient with residual hearing.

I would like to invite you to participate in my study. Should you choose to partake, your involvement would be to allow me to access your surgical records, in order for me to fill in a surgical form on the cochlear implant recipients with residual hearing (please see attached). Confidentiality and anonymity will be ensured.

It is hoped that my research findings will be useful to cochlear implant candidates with residual hearing, Audiologists and other professionals working in the field, Ear, Nose and Throat Surgeons, Medical Aids and the Department of Health.

Please do not hesitate to contact me should you have any queries.

Katherine Gautschi

MA (Audiology) Student, University of the Witwatersrand

Tel: (011) 783 4903 Cell: (082) 468 3072 Email: kathgaut@iafrica.com

I, GARY KROUKAMP, an Ear, Nose and Throat Surgeon at the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit, hereby agree to participate in Katherine Gautschi's study. This participation will involve her accessing my surgical records on cochlear implant recipients with residual hearing.

Sign: _____ Date: 25 / 01 / 2012

Appendix Q: Consent form from a surgeon at Unit B

Should permission from your cochlear implant centre be granted, existing pre-operative and post-operative unaided audiological testing data will be accessed for each cochlear implant recipient with residual hearing.

I would like to invite you to participate in my study. Should you choose to partake, your involvement would be to allow me to access your surgical records, in order for me to fill in a surgical form on the cochlear implant recipients with residual hearing (please see attached). Confidentiality and anonymity will be ensured.

It is hoped that my research findings will be useful to cochlear implant candidates with residual hearing, Audiologists and other professionals working in the field, Ear, Nose and Throat Surgeons, Medical Aids and the Department of Health.

Please do not hesitate to contact me should you have any queries.

Katherine Gautschi

MA (Audiology) Student, University of the Witwatersrand

Tel: (011) 783 4903 Cell: (082) 468 3072 Email: kathgaut@intrica.com

I, Derrick Wagenfeld, an Ear, Nose and Throat Surgeon at the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit, hereby agree to participate in Katherine Gautschi's study. This participation will involve her accessing my surgical records on cochlear implant recipients with residual hearing.

Sign: _____ Date: 26 / 1 / 2012

Appendix R: Consent form from a surgeon at Unit B

I, Neil Heine Nel, at the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit, hereby grant permission for Katherine Gautschi to access the existing pre-operative and post-operative unaided audiological testing results of cochlear implant recipients with residual hearing.

Sign: _____ Date: 14 / 3 / 2012

Appendix S: Consent form from a surgeon at Unit B

I, Prof Loock, an Ear, Nose and Throat Surgeon at the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit, hereby agree to participate in Katherine Gautschi's study. This participation will involve her accessing my surgical records on cochlear implant recipients with residual hearing.

Sign: _____ Date: 23 / 5 / 2012

Appendix T: Example of consent form given to participants (18 years and older) at Unit A to access their audiological and surgical records for research purposes

I, _____, hereby grant permission for Katherine Gautschi to access my existing hearing test results (before and after surgery) and surgical records for her proposed study.

Sign: _____ Date: _____/ _____ / 2012

Appendix U: Example of consent form given to caregivers of participants younger than 18 years at Unit A to access their audiological and surgical records for research purposes

I, _____, hereby grant permission for Katherine Gautschi to access my child's existing hearing test results (before and after surgery) and surgical records for her proposed study.

Sign: _____ Date: _____/ _____ / 2012

Appendix V: Example of letter given to participants (18 years and older) at Unit A to explain study

Private Bag X26

Benmore

2010

Phone No. (011) 783 4903

Fax No. 086 670 8611

Dear Prospective Participant

My name is Katherine Gautschi. I am a Speech Therapist and Audiologist, currently registered as a Postgraduate Master's student in the Discipline of Audiology at the University of the Witwatersrand, Johannesburg. To fulfil my degree requirements, I am required to conduct research. The title for my study is: *Preservation of residual hearing after cochlear implant surgery: an exploration of residual hearing function in a group of recipients at South African Cochlear Implant Units.*

I aim to conduct my research at the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit, the Johannesburg Cochlear Implant Centre and the University of Pretoria Cochlear Implant Unit. For the purposes of my research, I shall compare a minimum of 30 existing hearing test results before and after surgery to determine whether residual hearing has been preserved and, if so, to what degree. Factors documented to have a possible influence on cochlear implant surgery outcome will be examined in an attempt to establish relationships that may exist.

I would like to invite you to participate in my study. Your involvement will include allowing me to access your hearing test results (before and after surgery) and surgical records. Data collected will be confidential and anonymous. Participation in this study is entirely voluntary.

Should you choose to participate in my study, please sign the consent letter below and email (kathgaut@iafrica.com) or fax (086 670 8611) it back to me.

It is hoped that the current research findings will be useful to cochlear implant candidates with residual hearing, Audiologists and other professionals working in the field, Ear, Nose and Throat Surgeons, Medical Aids and the Department of Health.

Please do not hesitate to contact me should you have any queries.

Katherine Gautschi

MA (Audiology) Student, University of the Witwatersrand

Tel: (011) 783 4903

Cell: (082) 468 3072

Email: kathgaut@iafrica.com

Appendix W: Example of letter given to caregivers of participants younger than 18 years at Unit A to explain study

Private Bag X26

Benmore

2010

Phone No. (011) 783 4903

Fax No. 086 670 8611

Dear Parent/ Caregiver

My name is Katherine Gautschi. I am a Speech Therapist and Audiologist, currently registered as a Postgraduate Master's student in the Discipline of Audiology at the University of the Witwatersrand, Johannesburg. To fulfil my degree requirements, I am required to conduct research. The title for my study is: *Preservation of residual hearing after cochlear implant surgery: an exploration of residual hearing function in a group of recipients at South African Cochlear Implant Units.*

I aim to conduct my research at the University of Stellenbosch-Tygerberg Hospital Cochlear Implant Unit, the Johannesburg Cochlear Implant Centre and the University of Pretoria Cochlear Implant Unit. For the purposes of my research, I shall compare a minimum of 30 existing hearing test results before and after surgery to determine whether residual hearing has been preserved and, if so, to what degree. Factors documented to have a possible influence on cochlear implant surgery outcome will be examined in an attempt to establish relationships that may exist.

I would like to invite your child to participate in my study. Involvement will include allowing me to access the hearing test results (before and after surgery) and surgical records of your child. Data collected will be confidential and anonymous. Participation in this study is entirely voluntary.

Should you choose to allow your child to participate in my study, please sign the form below and email (kathgaut@iafrica.com) or fax (086 670 8611) it back to me.

It is hoped that the current research findings will be useful to cochlear implant candidates with residual hearing, Audiologists and other professionals working in the field, Ear, Nose and Throat Surgeons, Medical Aids and the Department of Health.

Please do not hesitate to contact me should you have any queries.

Katherine Gautschi

MA (Audiology) Student, University of the Witwatersrand

Tel: (011) 783 4903

Cell: (082) 468 3072

Email: kathgaut@iafrica.com

Appendix X: Example of assent form for participants younger than 18 years of age at Unit A to access their audiological and surgical records for research purposes

I, _____(Name), will share my hearing test information and my Doctor's/ Surgeon's notes with Katherine Gautschi for her study on cochlear implants.

Sign: _____ Date: _____/ _____ / 2012

Appendix Y: Example of assent form for participants younger than 18 years of age at Unit A explaining study

Private Bag X26

Benmore

2010

Phone No. (011) 783 4903

Fax No. 086 670 8611

Preservation of residual hearing after cochlear implant surgery: an exploration of residual hearing function in a group of recipients at South African Cochlear Implant Units.

Hello

My name is Katherine Gautschi. I am doing a study on cochlear implants because I would like to know if some hearing before the cochlear implant operation stays the same after the operation. If you would like, you can be in my study.

If you decide you want to be in my study, I will look at your hearing test information before and after you cochlear implant operation to see if your hearing has stayed the same or not. If your hearing has not stayed the same since your operation, I would like to see what may have changed your hearing.

Other people will not know you are in my study. When I tell other people about my study, I will not use your name, so no one can tell who I am taking about.

Your parents or guardians have to say it is okay for you to be in the study. After they decide, you get to choose if you want to do it too. If you do not want to be in the study, no one will be upset or angry with you. If you want to be in the study now and change your mind later, that is okay. You can stop at any time.

If you choose to be in my study, please sign the form below and email (kathgaut@iafrica.com) or fax (086 670 8611) it back to me.

I hope that the information of my study will help you, other people with some hearing who want to have a cochlear implant, Audiologists, Doctors and others.

My telephone number is 082 468 3072. You can call me if you have any questions about the study or if you decide you do not want to be in the study any more.

With many thanks,

Katherine Gautschi

MA (Audiology) Student, University of the Witwatersrand

Tel: (011) 783 4903 Cell: (082) 468 3072 Email: kathgaut@iafrica.com

Appendix Z: Written permission from the Manager of Medical Services (Western Cape Government - Ethics) for Tygerberg Hospital for conduction of the study for Unit B



Tygerberg Hospital and
Mitchells Plain & Tygerberg Oral Health Centres
REFERENCE: Researches
ENQUIRIES: Dr M A Mukosi
TELEPHONE: 021 938-5966

ETHICS NO: WITS1
Preservation of residual hearing after cochlear implant surgery: an exploration of residual hearing function in a group of recipients at South African Cochlear Implant Units.

Dear Ms Gautschi

PERMISSION TO USE DATA FROM COCHLEAR IMPLANT UNIT

Permission is granted to use data from the Cochlear Implant Unit on patient files for this research.
Yours sincerely

DR. M A MUKOSI
MANAGER: MEDICAL SERVICES

Administration Building, Francie van Zijl Avenue, Parow, 7500
tel: +27 21 938-5966 fax: +27 21938-6698
Private Bag X3, Tygerberg, 7505
www.capegateway.gov.za

Appendix A.1

I, Sue Tager, the Chief Executive Officer at the Wits Donald Gordon Medical Centre, hereby grant permission for Katherine Gautschi to conduct her proposed study at the Johannesburg Cochlear Implant Centre. This will involve her accessing existing pre-operative and post-operative unaided audiological testing results and surgical records of cochlear implant recipients with residual hearing.

Sign: _____ Date: 01 / 12 / 2011

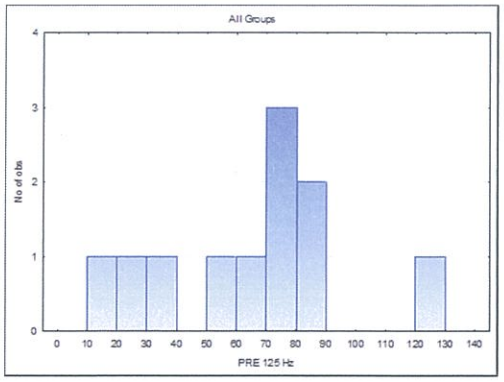


Figure A.1. Overall PRE 125Hz

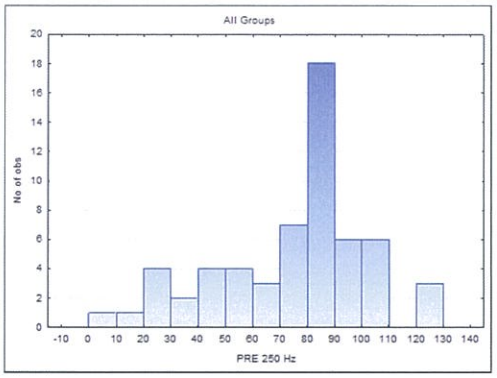


Figure A.2. Overall PRE 250Hz

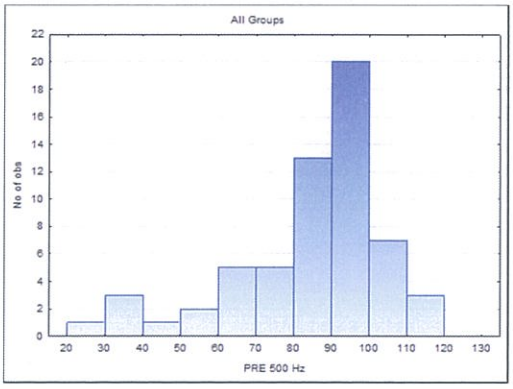


Figure A.3. Overall PRE 500Hz

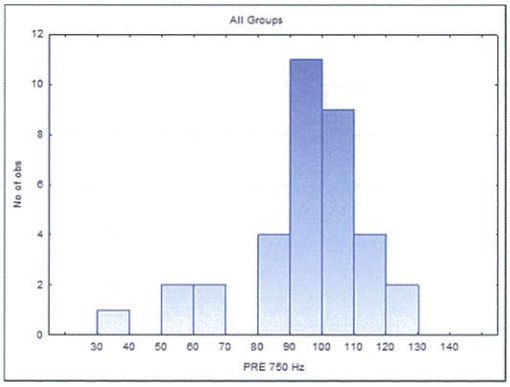


Figure A.4. Overall PRE 750Hz

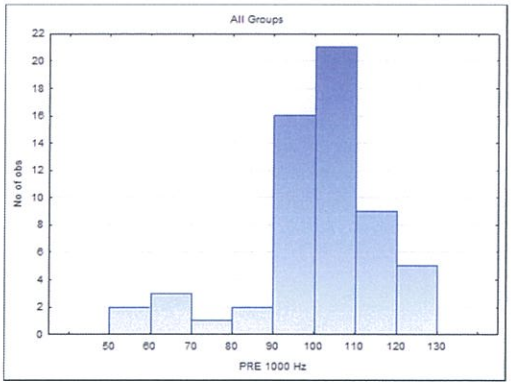


Figure A.5. Overall PRE 1000Hz

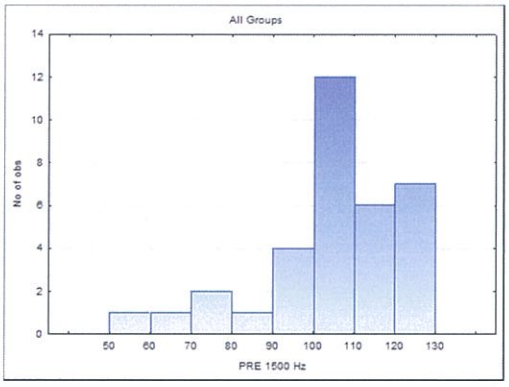


Figure A.6. Overall PRE 1500Hz

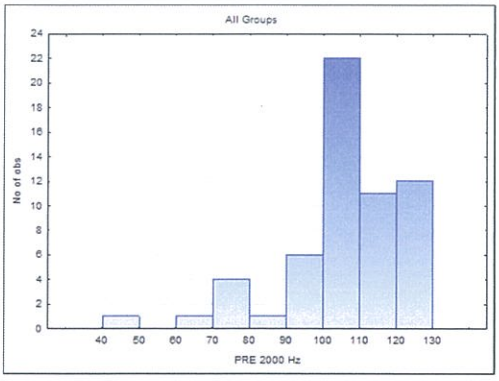


Figure A.7. Overall PRE 2000Hz

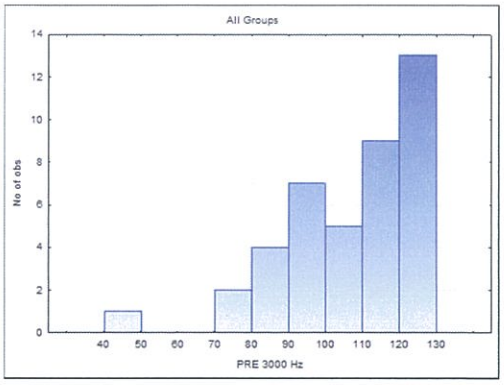


Figure A.8. Overall PRE 3000Hz

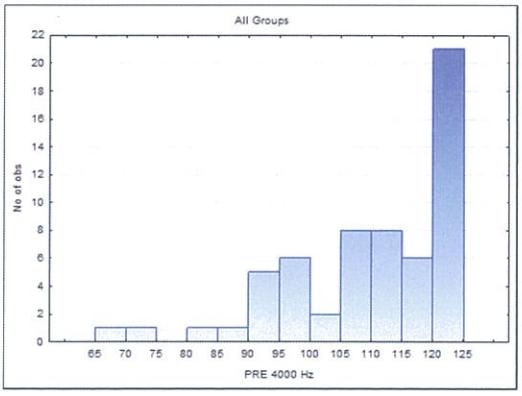


Figure A.9. Overall PRE 4000Hz

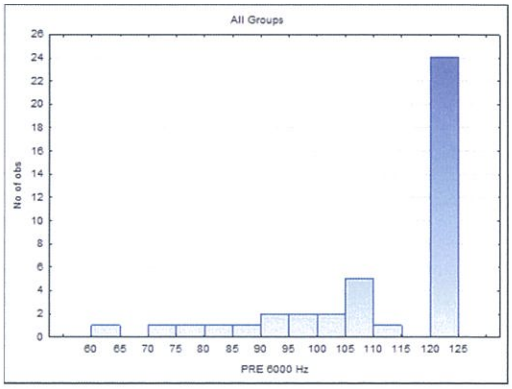


Figure A.10. Overall PRE 6000Hz

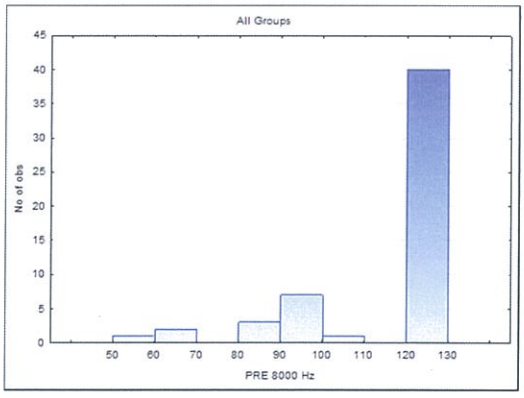


Figure A.11. Overall PRE 8000Hz

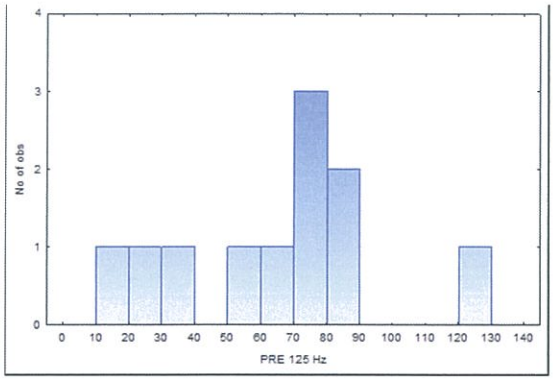


Figure B.1. UNIT A PRE 125Hz

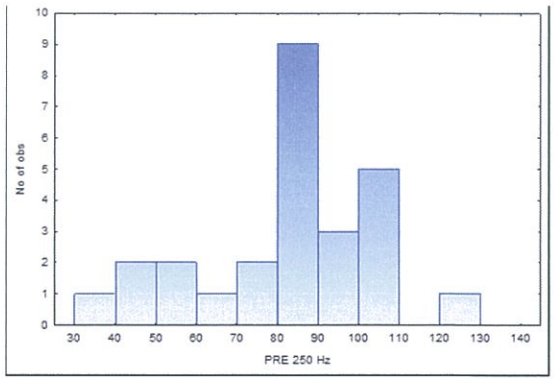


Figure B.2. UNIT A PRE 250Hz

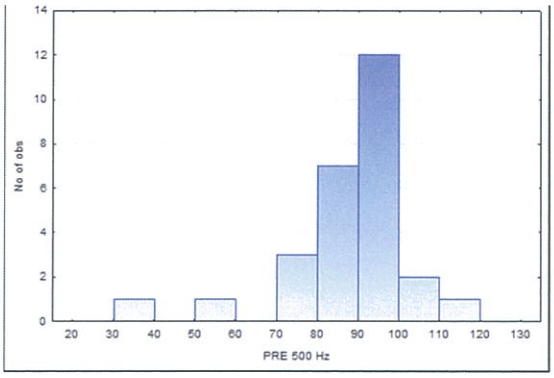


Figure B.3. UNIT A PRE 500Hz

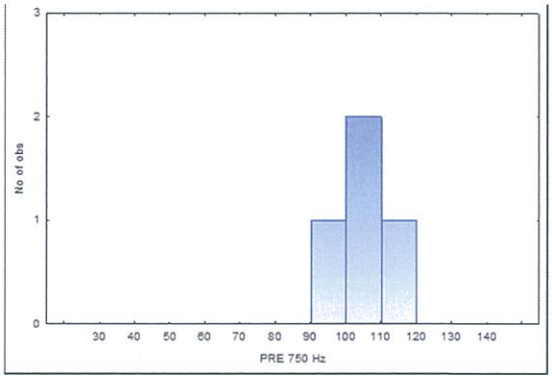


Figure B.4. UNIT A PRE 750Hz

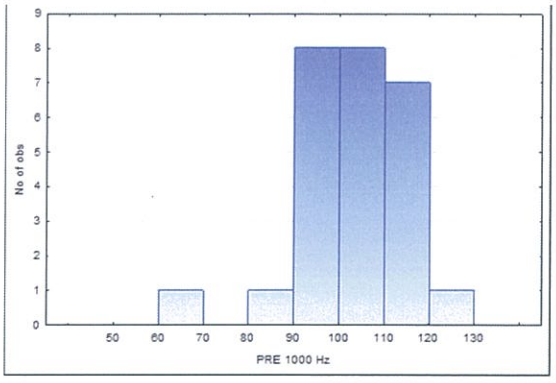


Figure B.5. UNIT A PRE 1000Hz

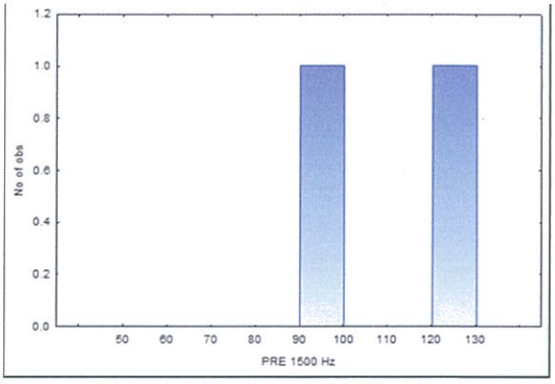


Figure B.6. UNIT A PRE 1500Hz

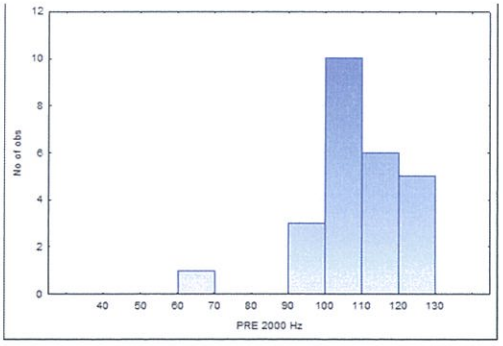


Figure B.7. UNIT A PRE 2000Hz

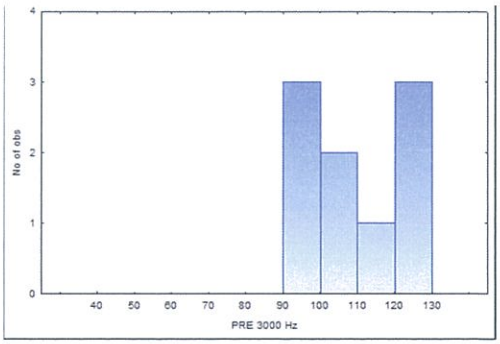


Figure B.8. UNIT A PRE 3000Hz

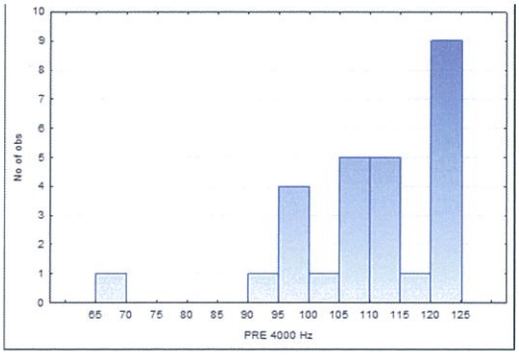


Figure B.9: UNIT A PRE 4000Hz

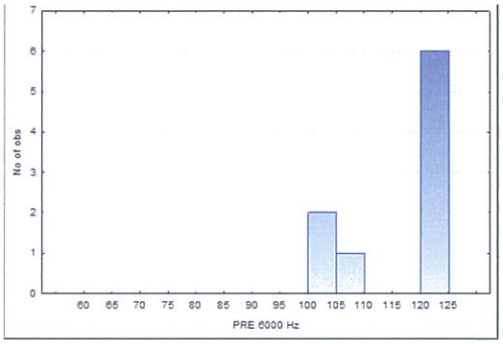


Figure B.10: UNIT A PRE 6000Hz

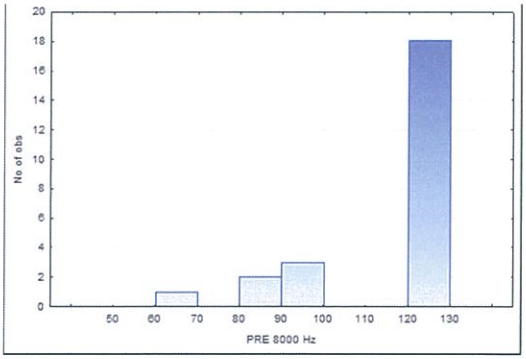


Figure B.11. UNIT A PRE 8000Hz

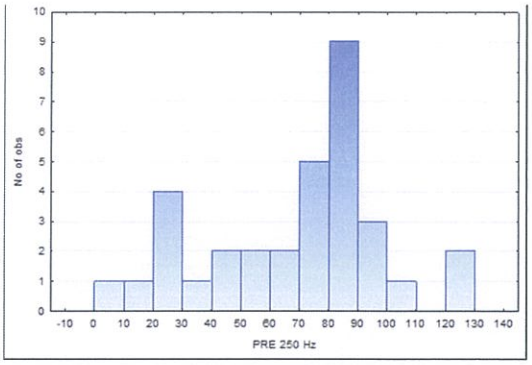


Figure C.1. UNIT B PRE 250Hz

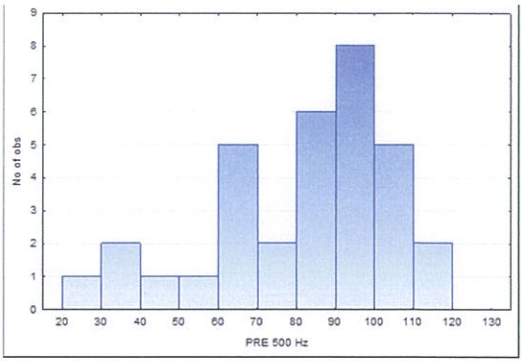


Figure C.2. UNIT B PRE 500Hz

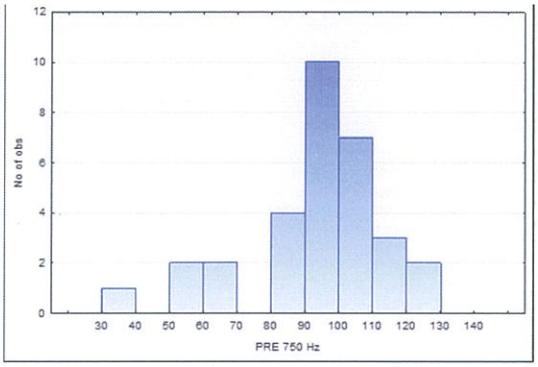


Figure C.3. UNIT B PRE 750Hz

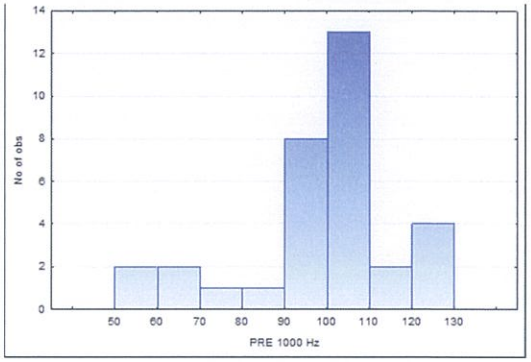


Figure C.4. UNIT B PRE 1000Hz

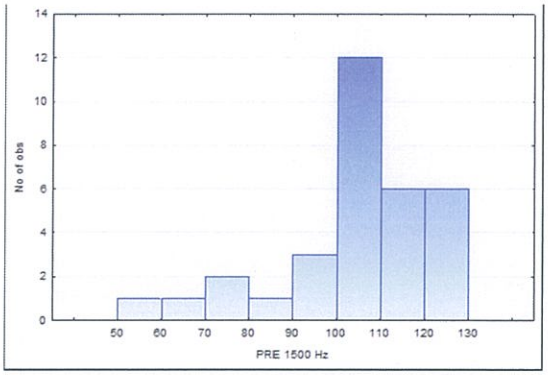


Figure C.5. UNIT B PRE 1500Hz

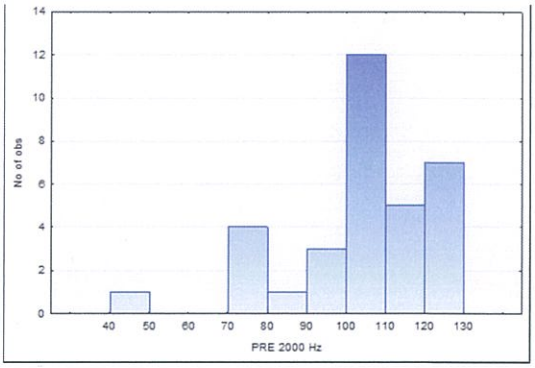


Figure C.6. UNIT B PRE 2000Hz

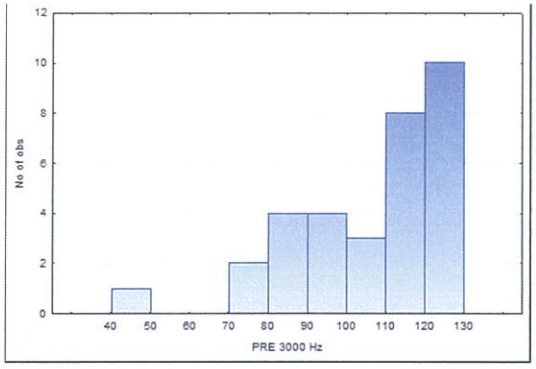


Figure C.7. UNIT B PRE 3000Hz

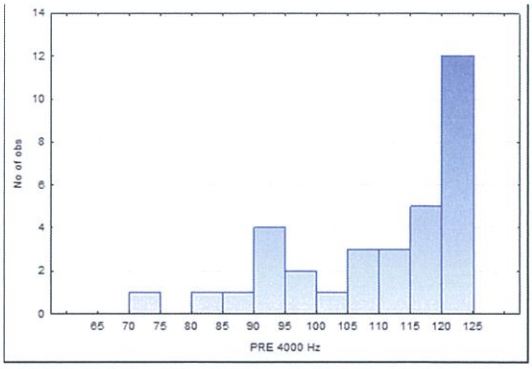


Figure C.8. UNIT B PRE 4000Hz

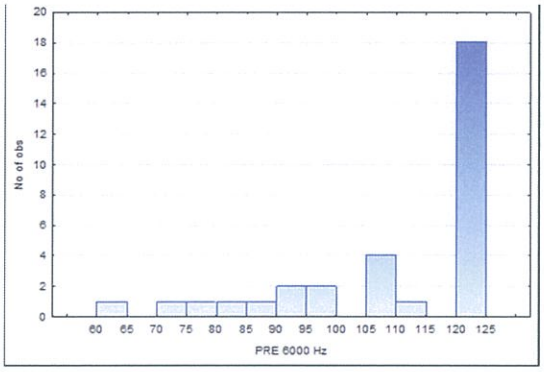


Figure C.9. UNIT B PRE 6000Hz

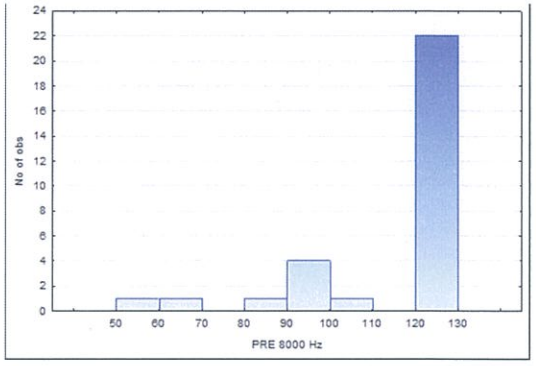


Figure C.10. UNIT B PRE 8000Hz

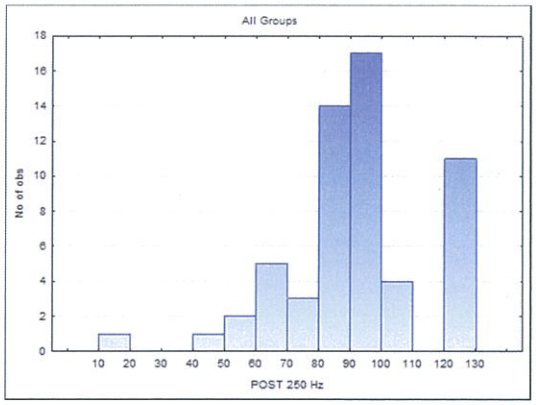


Figure D.1. OVERALL POST 250Hz

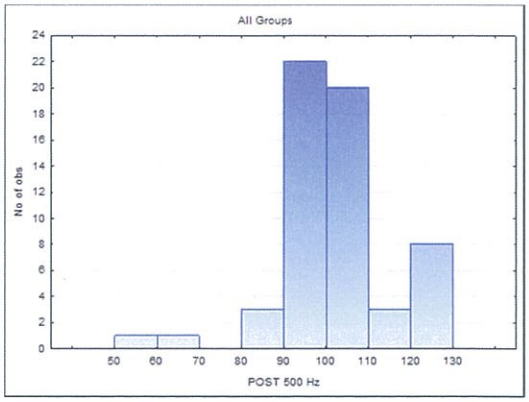


Figure D.2. OVERALL POST 500Hz

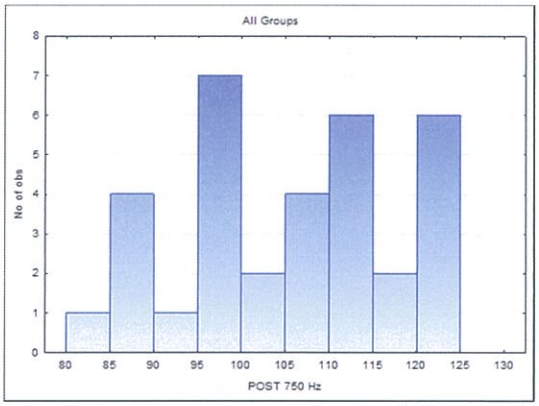


Figure D.3. OVERALL POST 750Hz

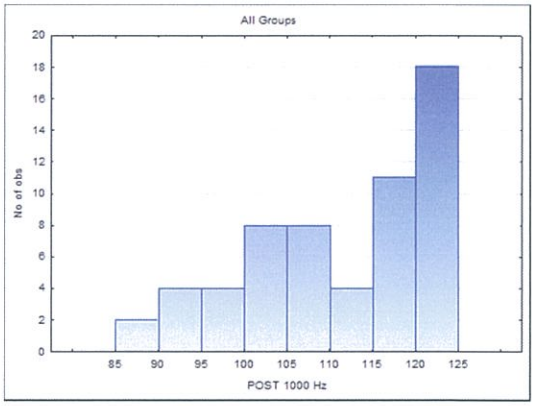


Figure D.4. OVERALL POST 1500Hz

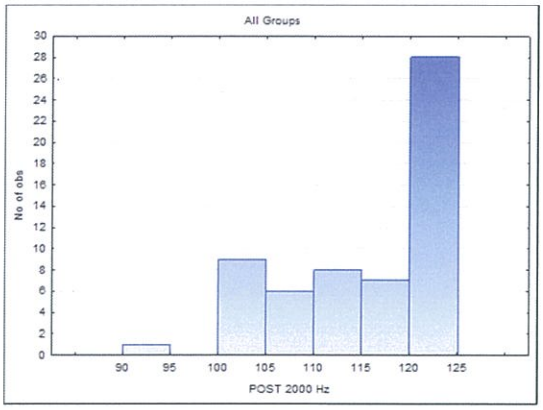


Figure D.5. OVERALL POST 2000Hz

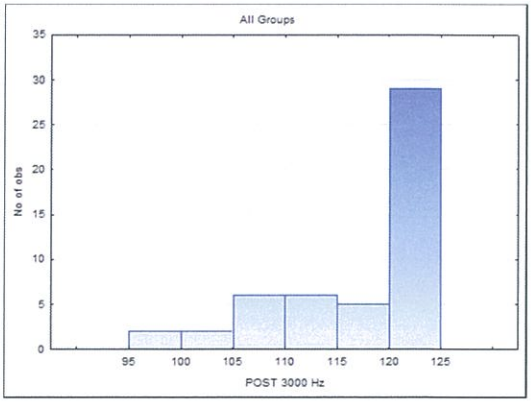


Figure D.6. OVERALL POST 3000Hz

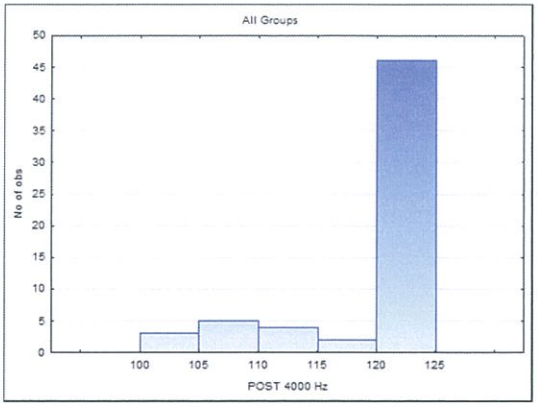


Figure D.7. OVERALL POST 4000Hz

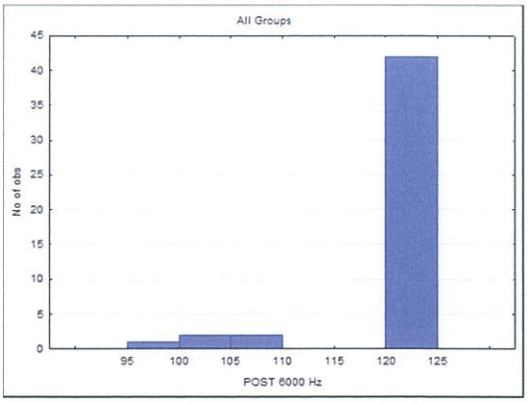


Figure D.8. OVERALL POST 6000Hz

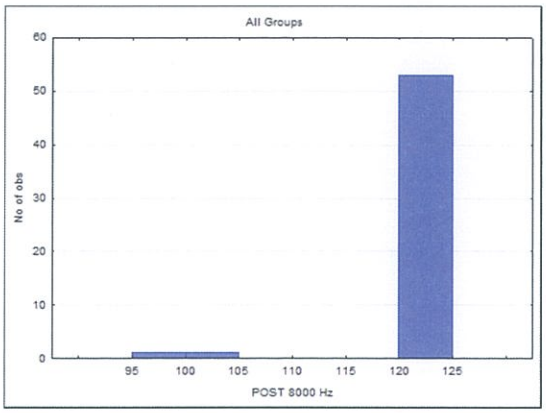


Figure D.9. OVERALL POST 8000Hz

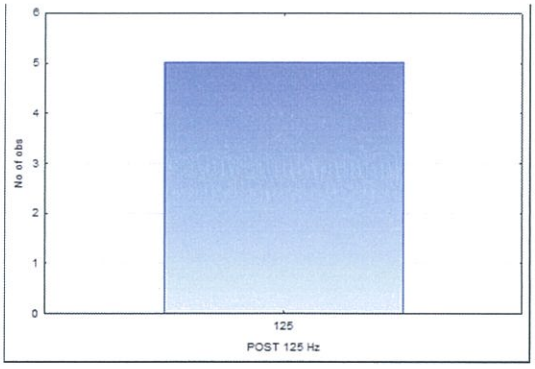


Figure E.1. UNIT A POST 125Hz

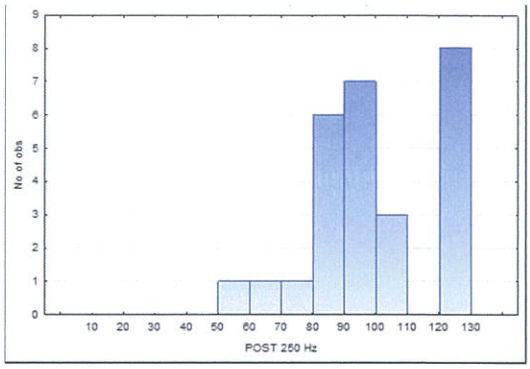


Figure E.2. UNIT A POST 250Hz

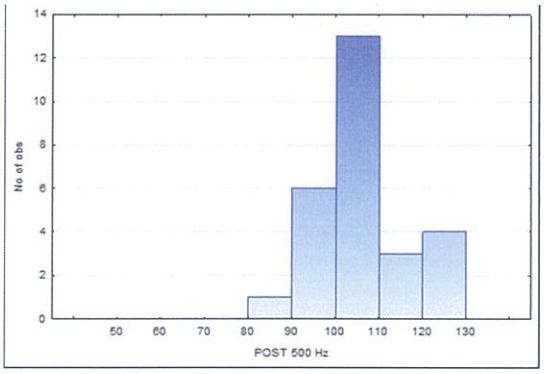


Figure E.3. UNIT A POST 500Hz

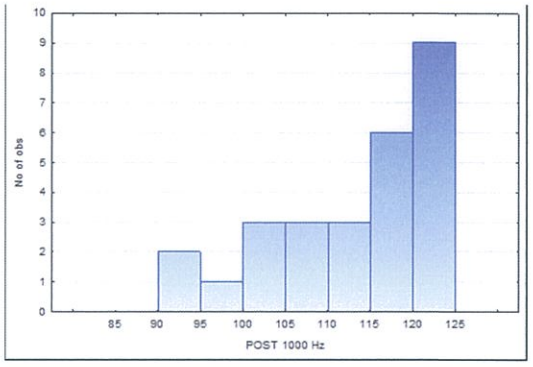


Figure E.4. UNIT A POST 1000Hz

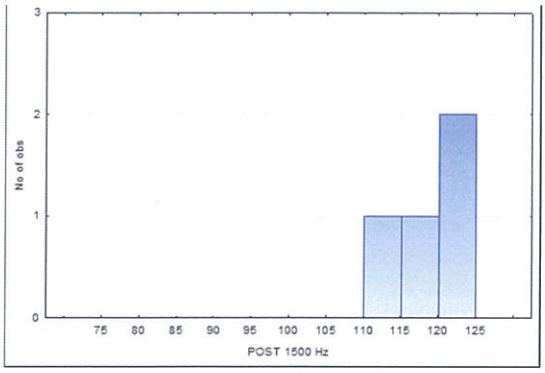


Figure E.5. UNIT A POST 1500Hz

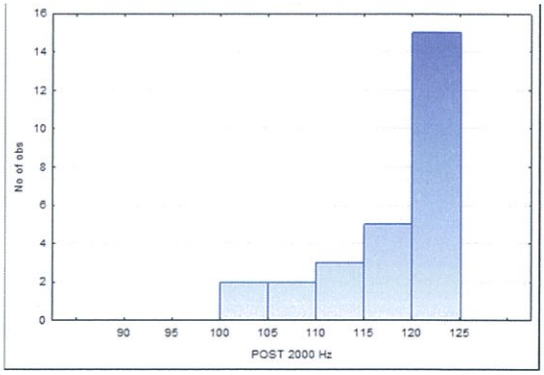


Figure E.6. UNIT A POST 2000Hz

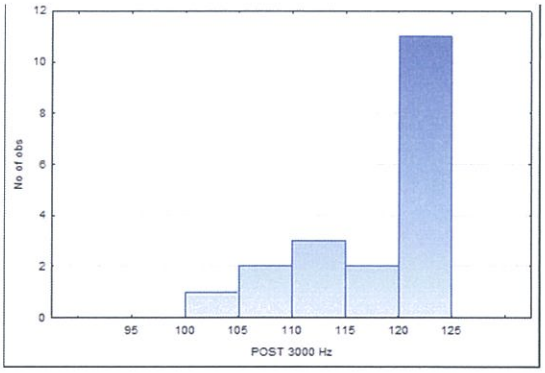


Figure E.7. UNIT A POST 3000Hz

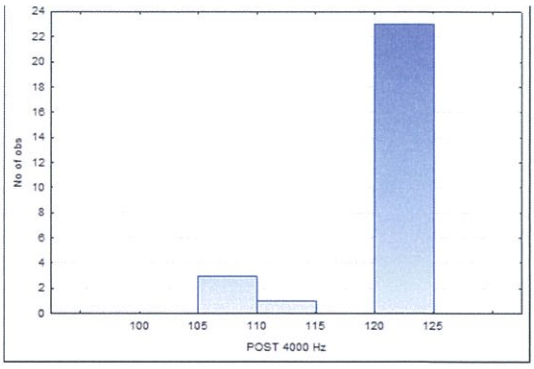


Figure E.8. UNIT A POST 4000Hz

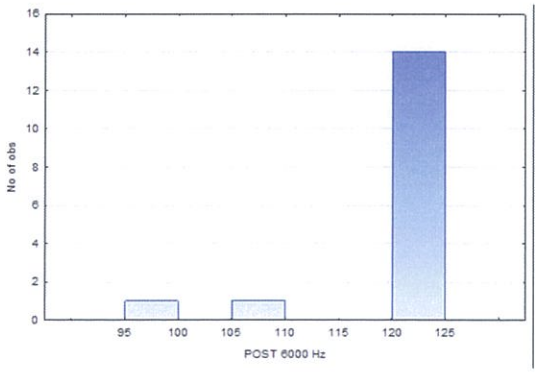


Figure E.9. UNIT A POST 6000Hz

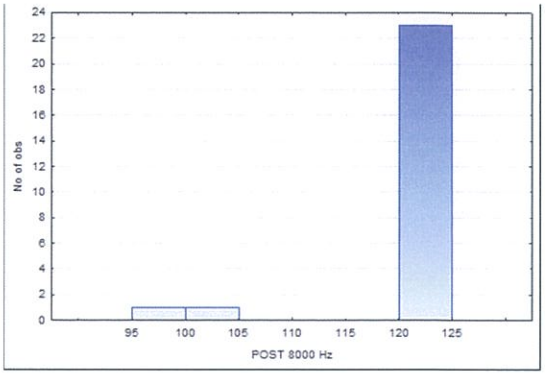


Figure E.10. UNIT A POST 8000Hz

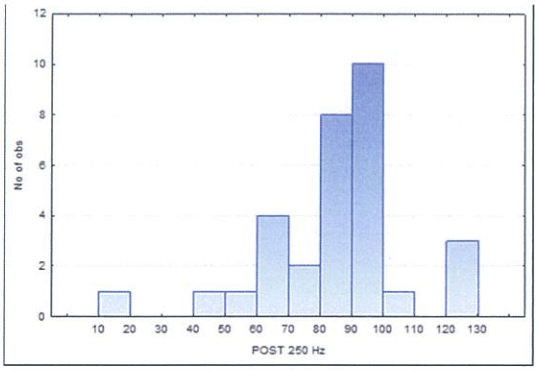


Figure F.1. UNIT B POST 250Hz

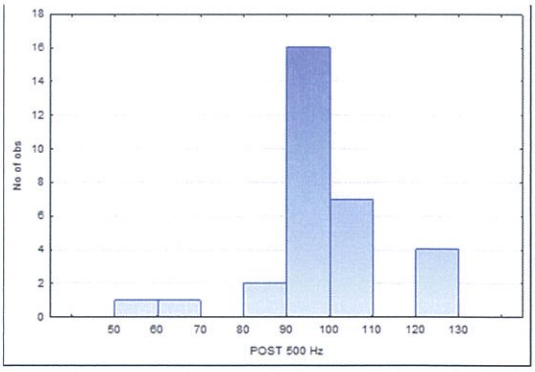


Figure F.2. UNIT B POST 500Hz

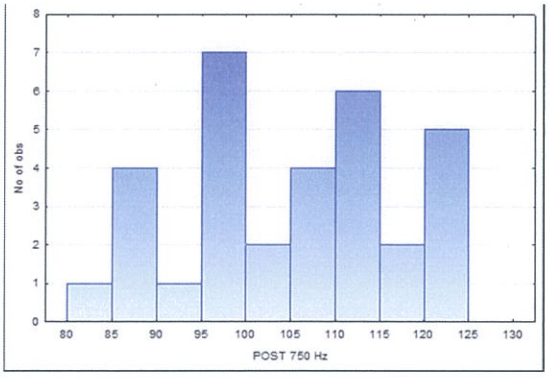


Figure F.3. UNIT B POST 750Hz

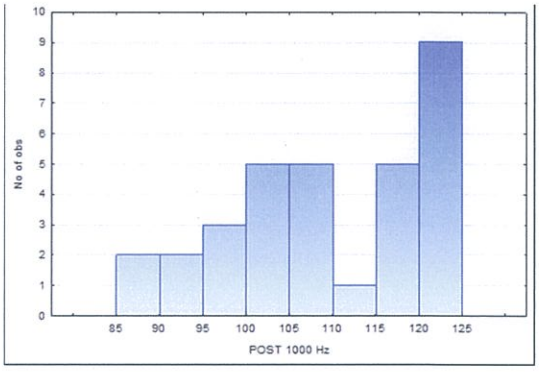


Figure F.4. UNIT B POST 1000Hz

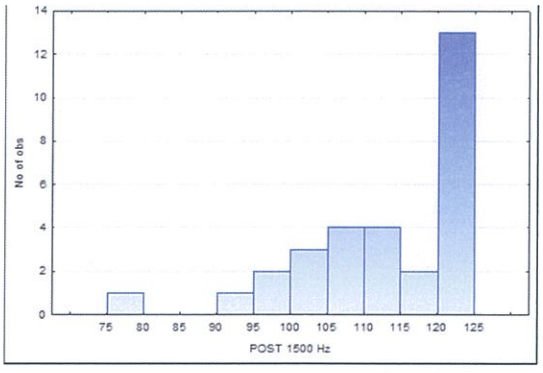


Figure F.5. UNIT B POST 1500Hz

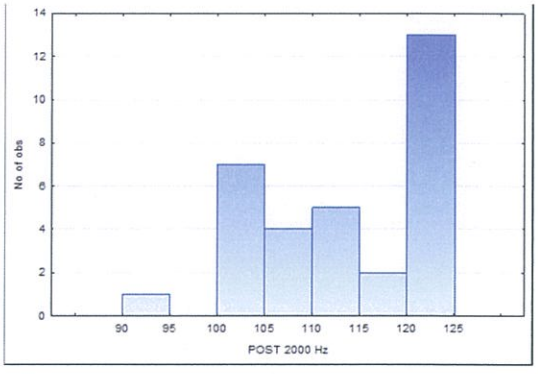


Figure F.6. UNIT B POST 2000Hz

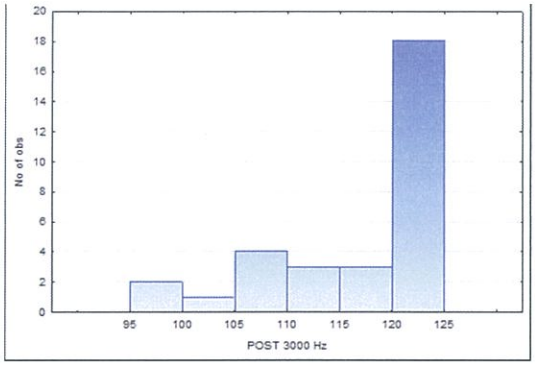


Figure F.7. UNIT B POST 3000Hz

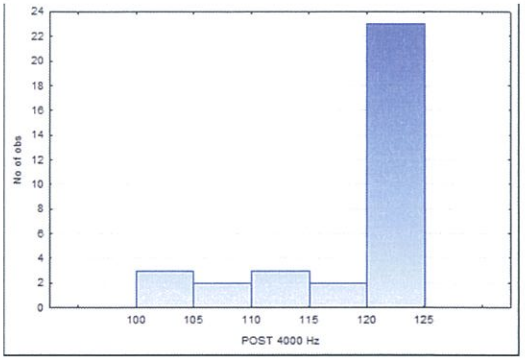


Figure F.8. UNIT B POST 4000Hz

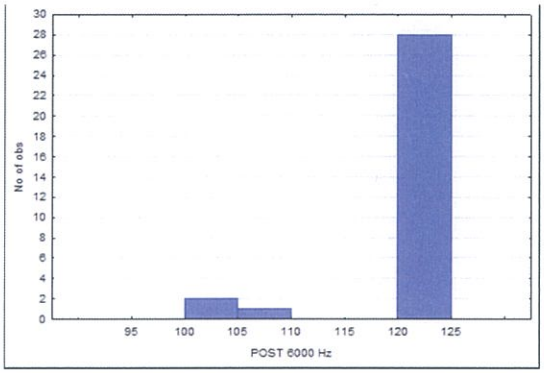


Figure F.9. UNIT B POST 6000Hz

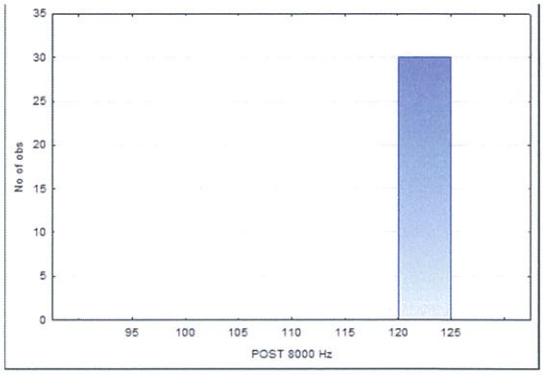


Figure F.10. UNIT B POST 8000Hz

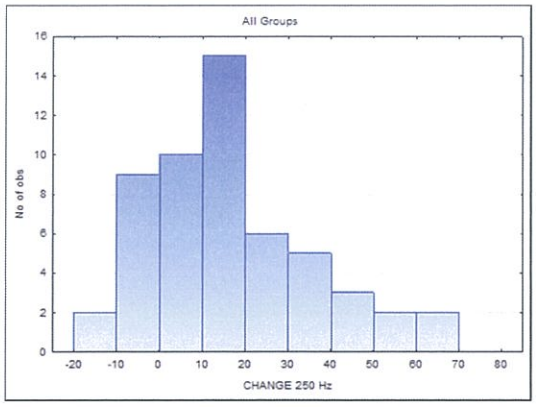


Figure G.1. OVERALL CH 250Hz

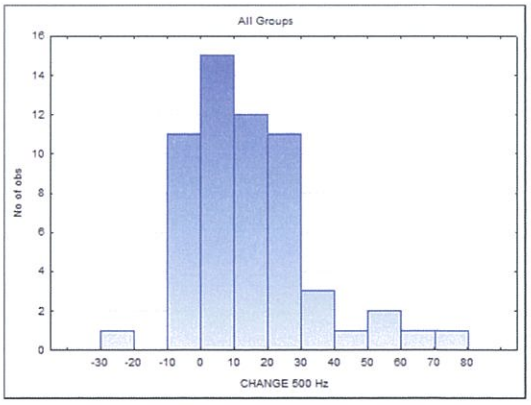


Figure G.2. OVERALL CH 500Hz

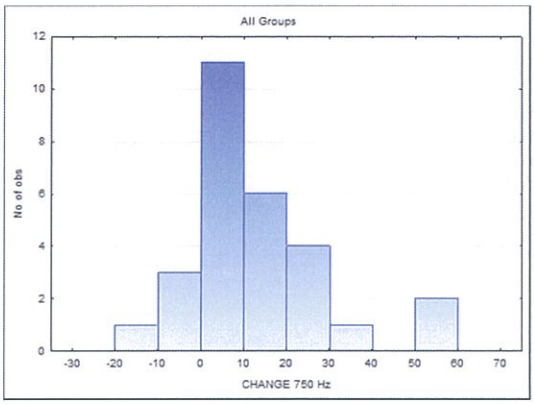


Figure G.3. OVERALL CH 750Hz

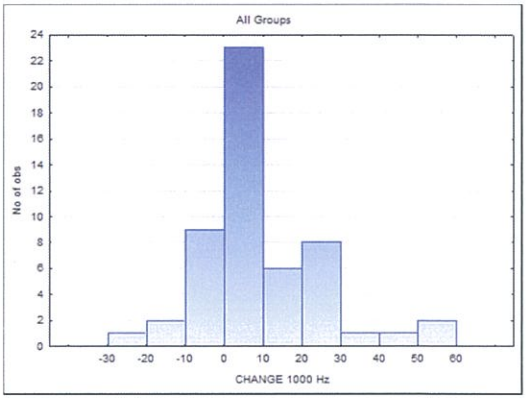


Figure G.4. OVERALL CH 1000Hz

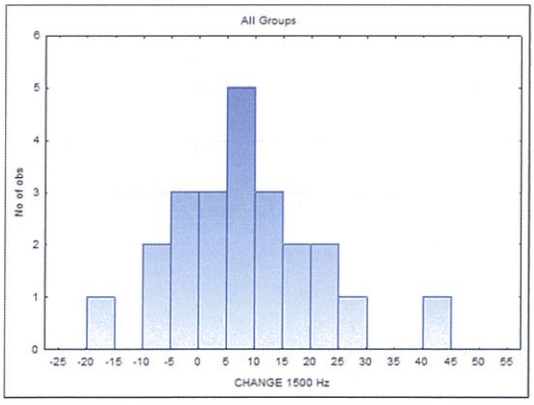


Figure G.5. OVERALL CH 1500Hz

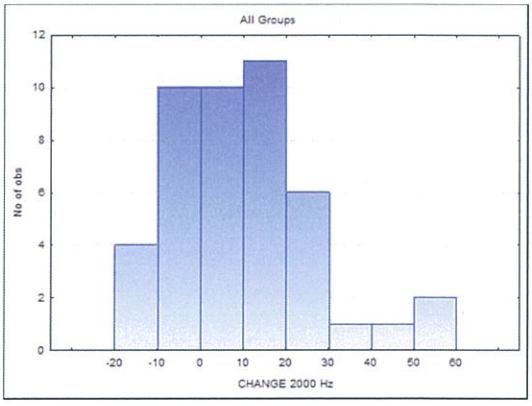


Figure G.6. OVERALL CH 2000Hz

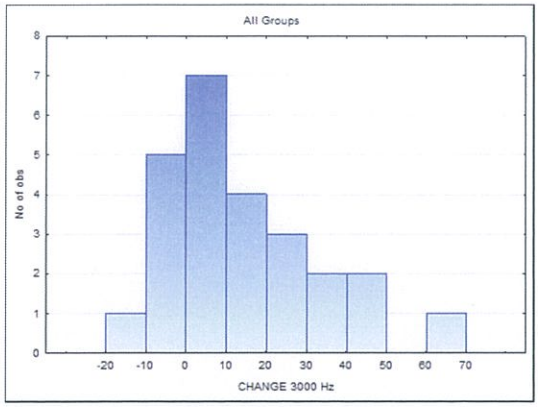


Figure G.7. OVERALL CH 3000Hz

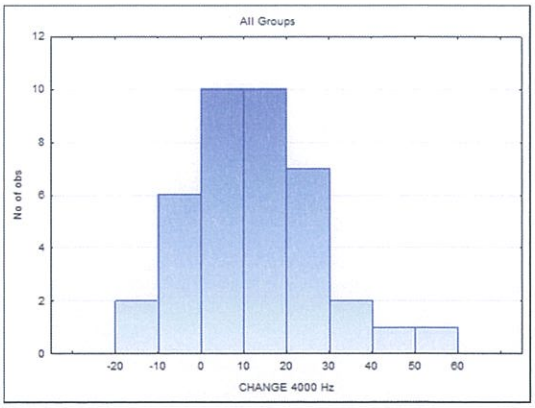


Figure G.8. OVERALL CH 4000Hz

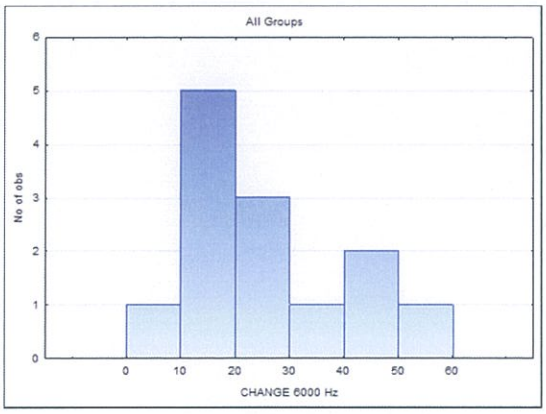


Figure G.9. OVERALL CH 6000Hz

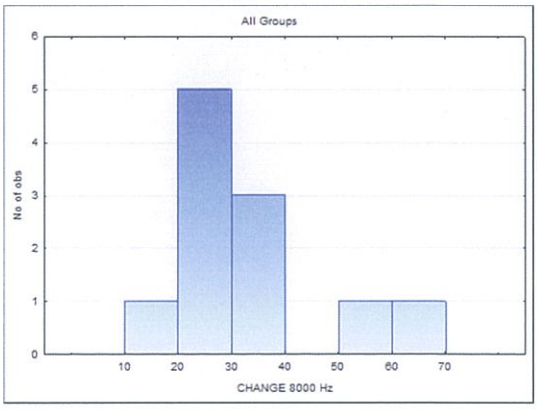


Figure G.10. OVERALL CH 8000Hz

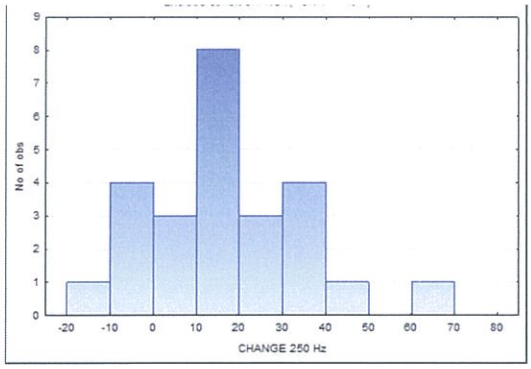


Figure H.1. UNIT A CH 250Hz

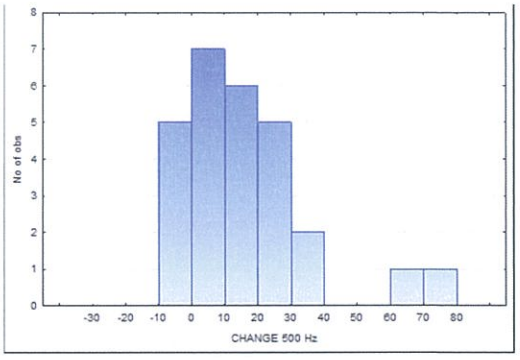


Figure H.2. UNIT A CH 500Hz

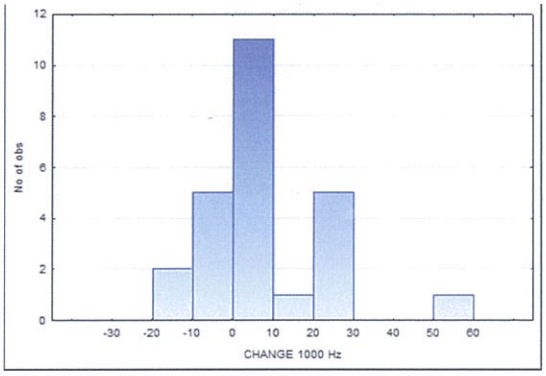


Figure H.3. UNIT A CH 1000Hz

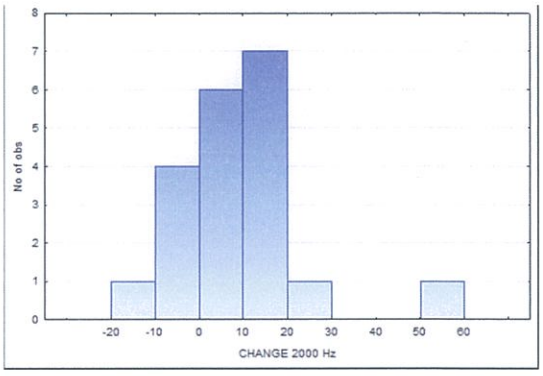


Figure H.4. UNIT A CH 2000Hz

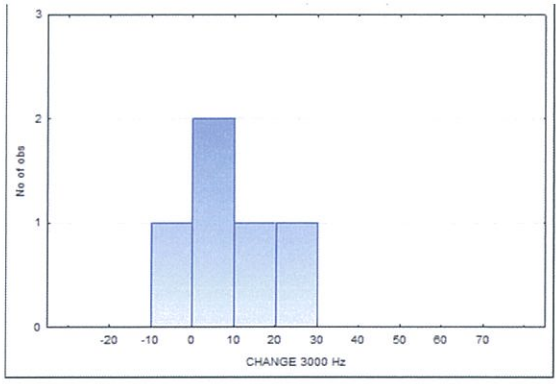


Figure H.5. UNIT A CH 3000Hz

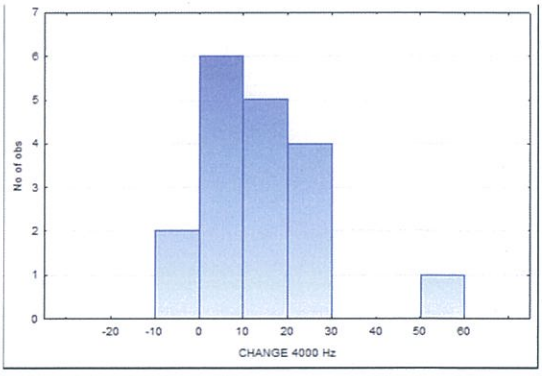


Figure H.6. UNIT A CH 4000Hz

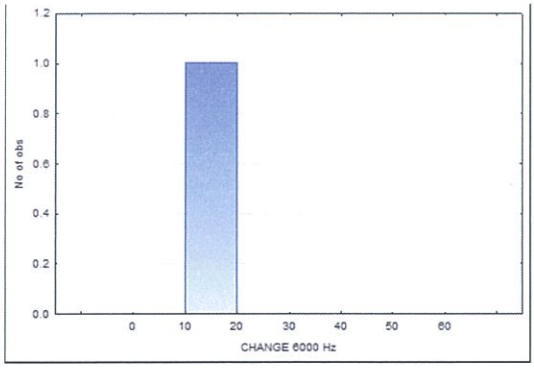


Figure H.7. UNIT A CH 6000Hz

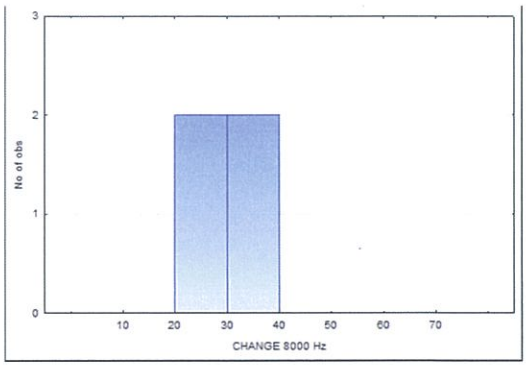


Figure H.8. UNIT A CH 8000Hz

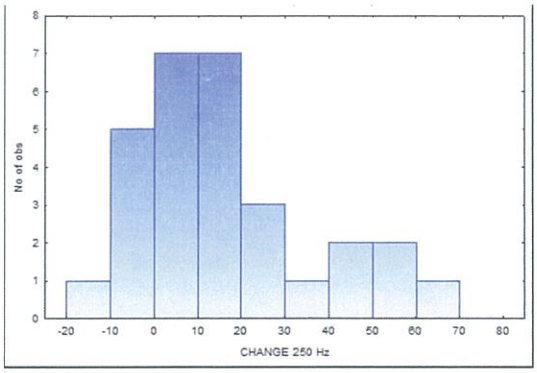


Figure I.1. UNIT B CH 250Hz

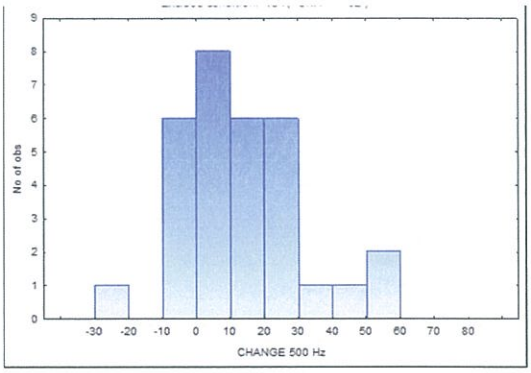


Figure I.2. UNIT B CH 500Hz

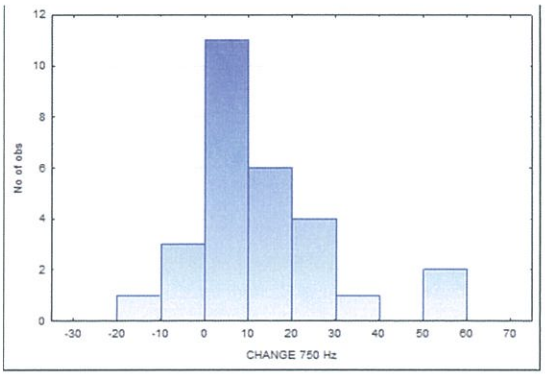


Figure I.3. UNIT B CH 750Hz

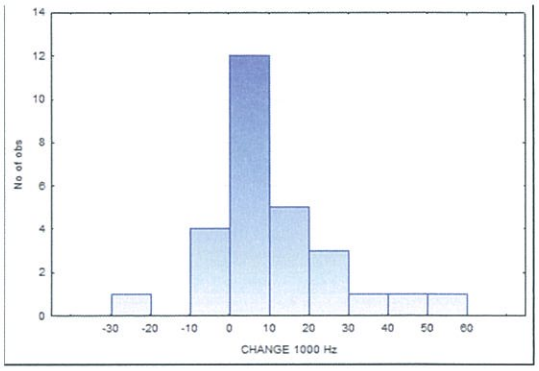


Figure I.4. UNIT B CH 1000Hz

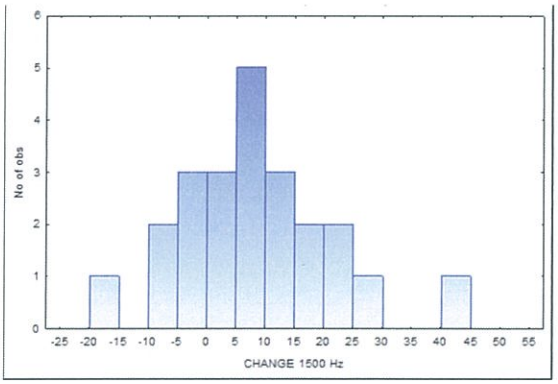


Figure I.5. UNIT B CH 1500Hz

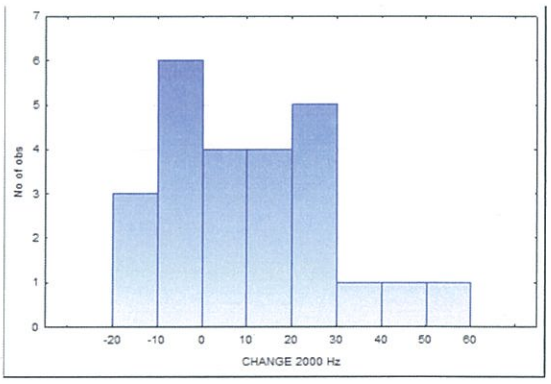


Figure I.6. UNIT B CH 2000Hz

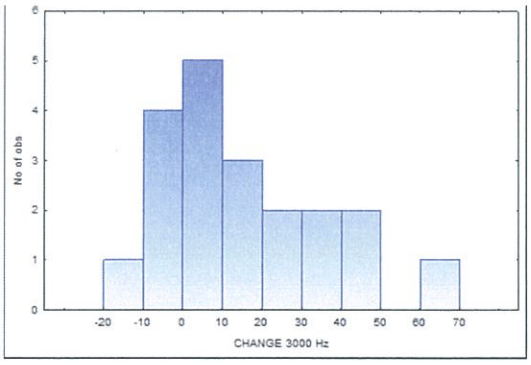


Figure I.7. UNIT B CH 3000Hz

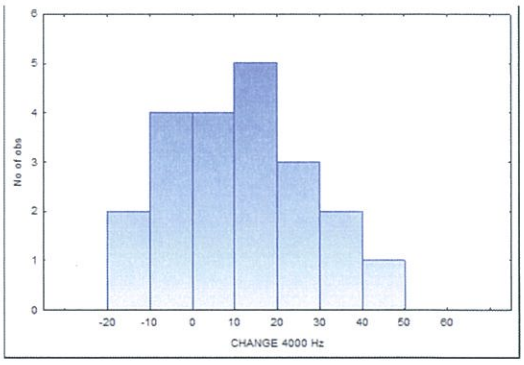


Figure I.8. UNIT B CH 4000Hz

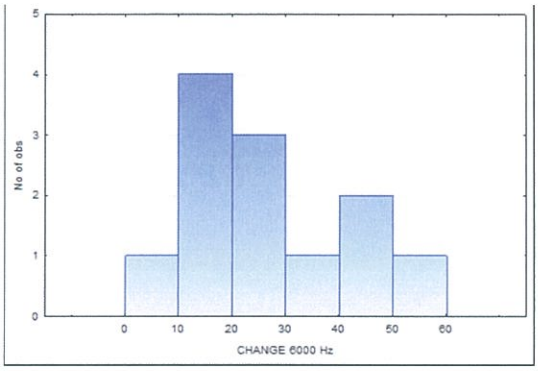


Figure I.9. UNIT B CH 6000Hz

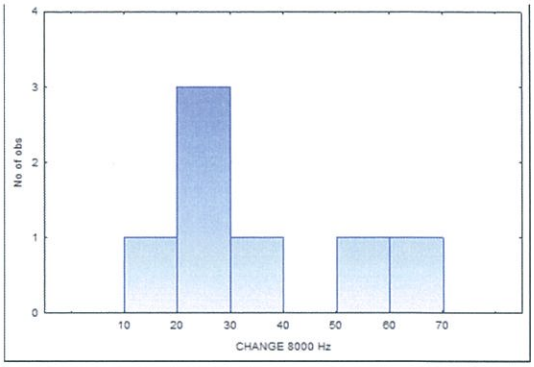


Figure I.10. UNIT B CH 8000Hz



Figure J.1. HTL 250 Hz at Unit A

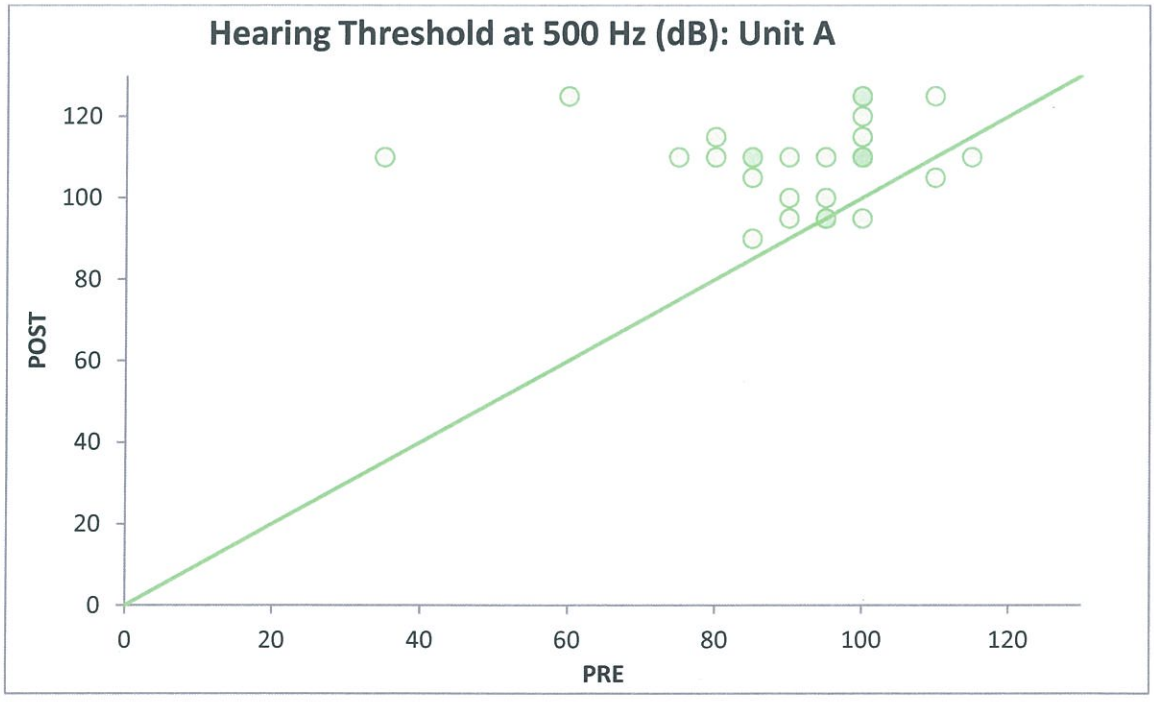


Figure J.2. HTL 500 Hz at Unit A



Figure J.3. HTL 1000 Hz at Unit A

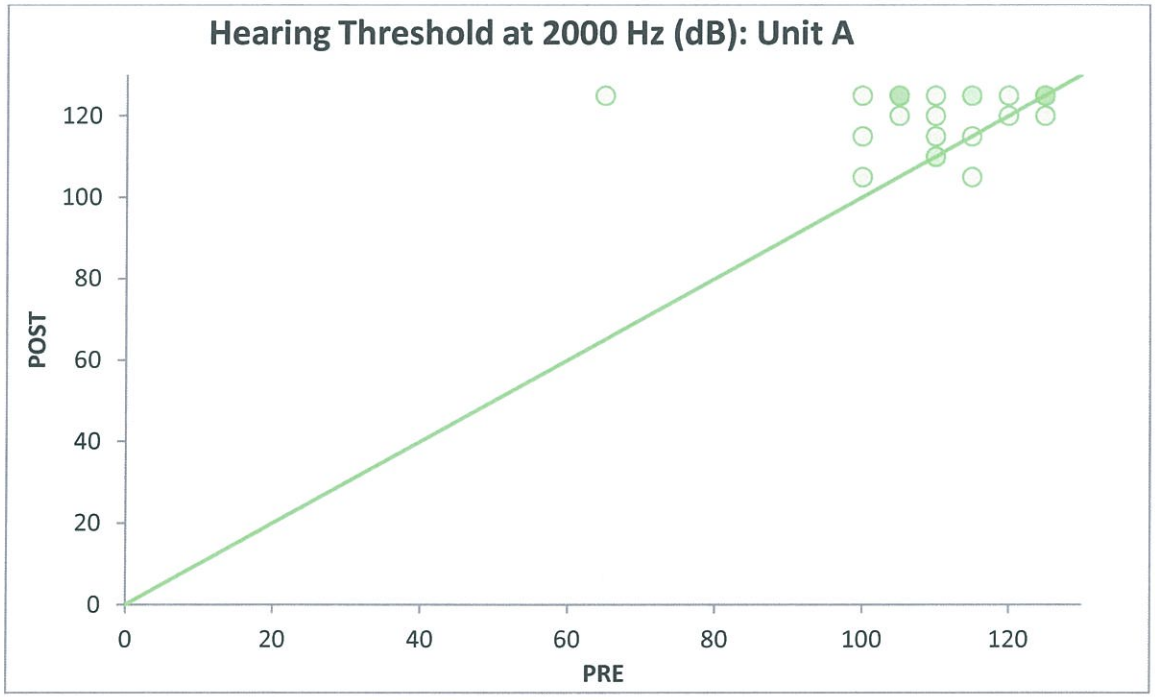


Figure J.4. HTL 2000 Hz at Unit A

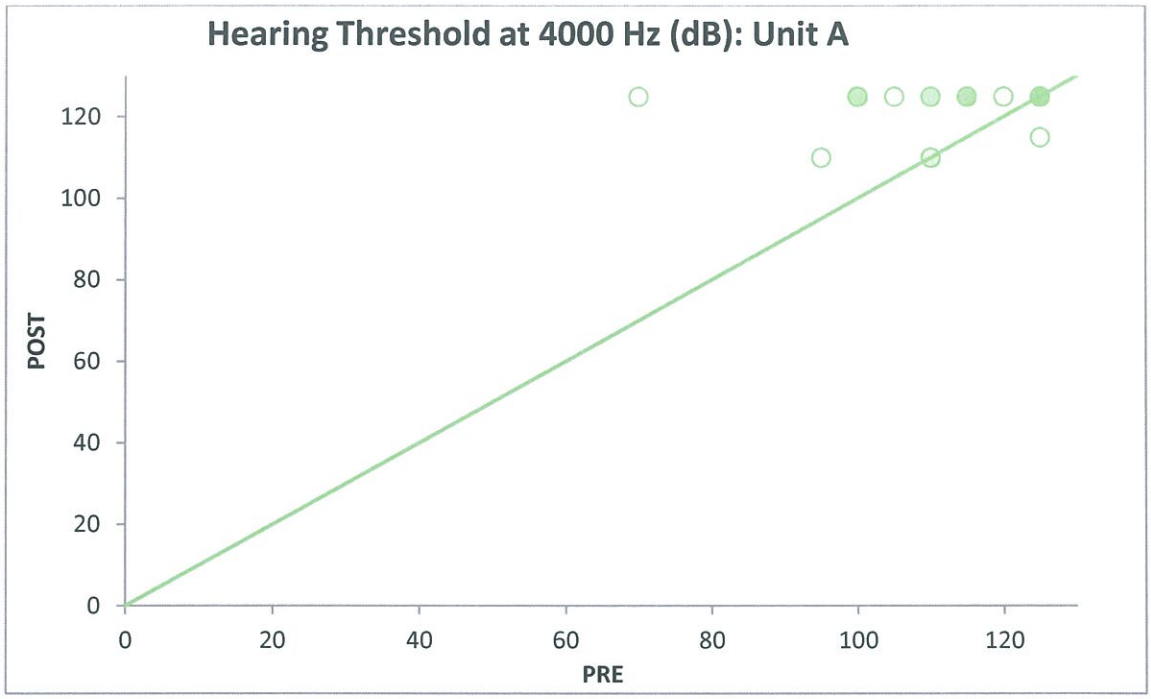


Figure J.5. HTL 4000 Hz at Unit A

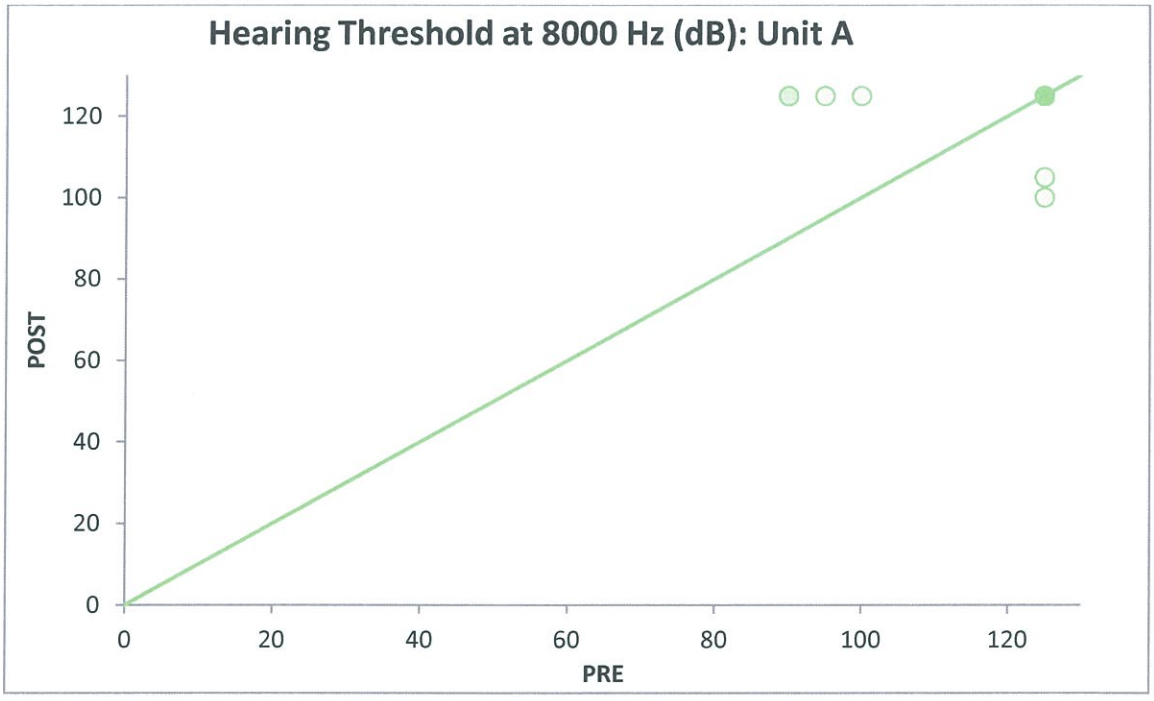


Figure J.6. HTL 8000 Hz at Unit A



Figure K.1. PRE_POST 250 Hz at Unit B

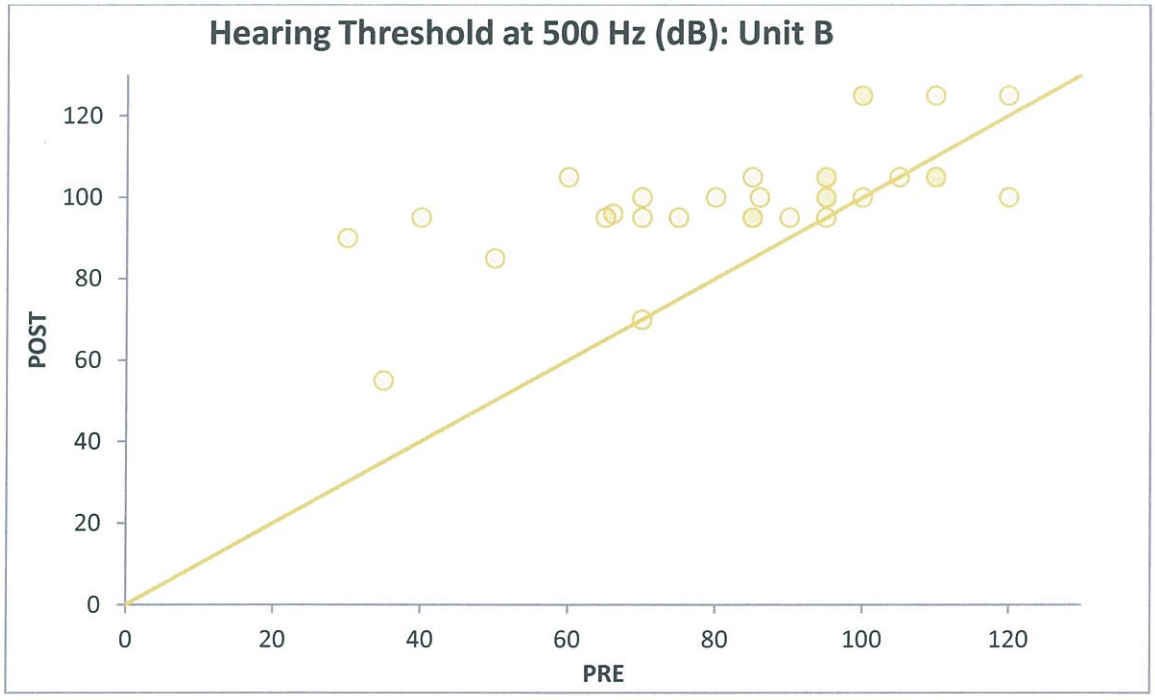


Figure K.2. PRE_POST 500 Hz at Unit B



Figure K.3. PRE_POST 750 Hz at Unit B

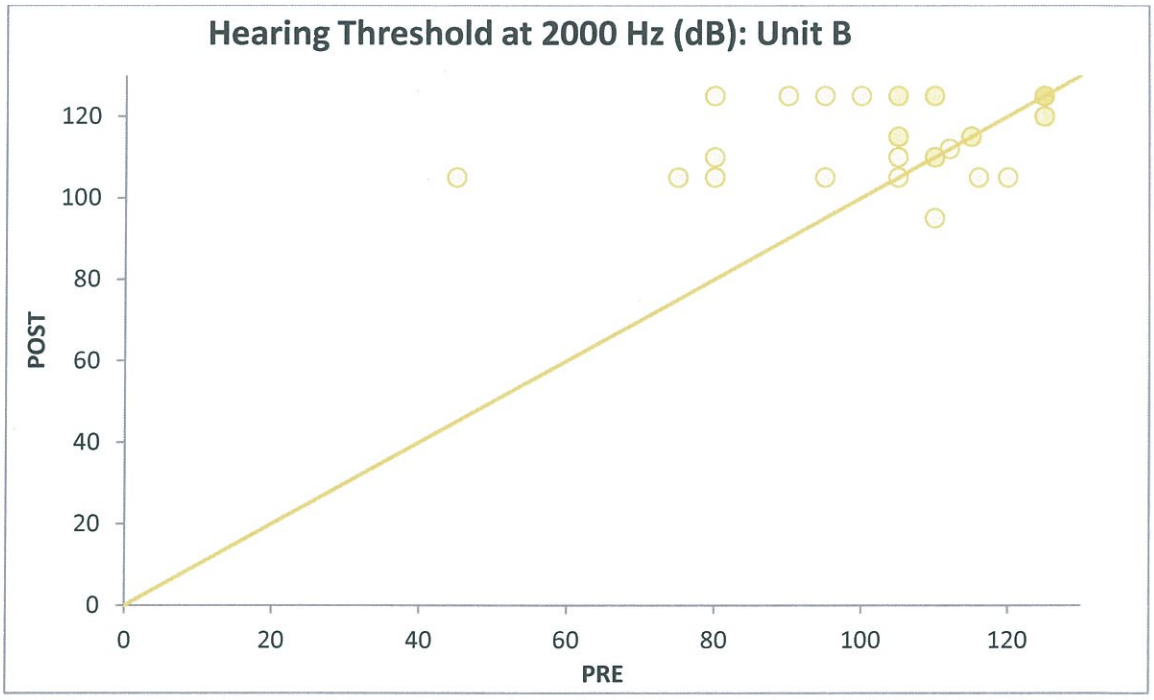


Figure K.4. PRE_POST 2000 Hz at Unit B

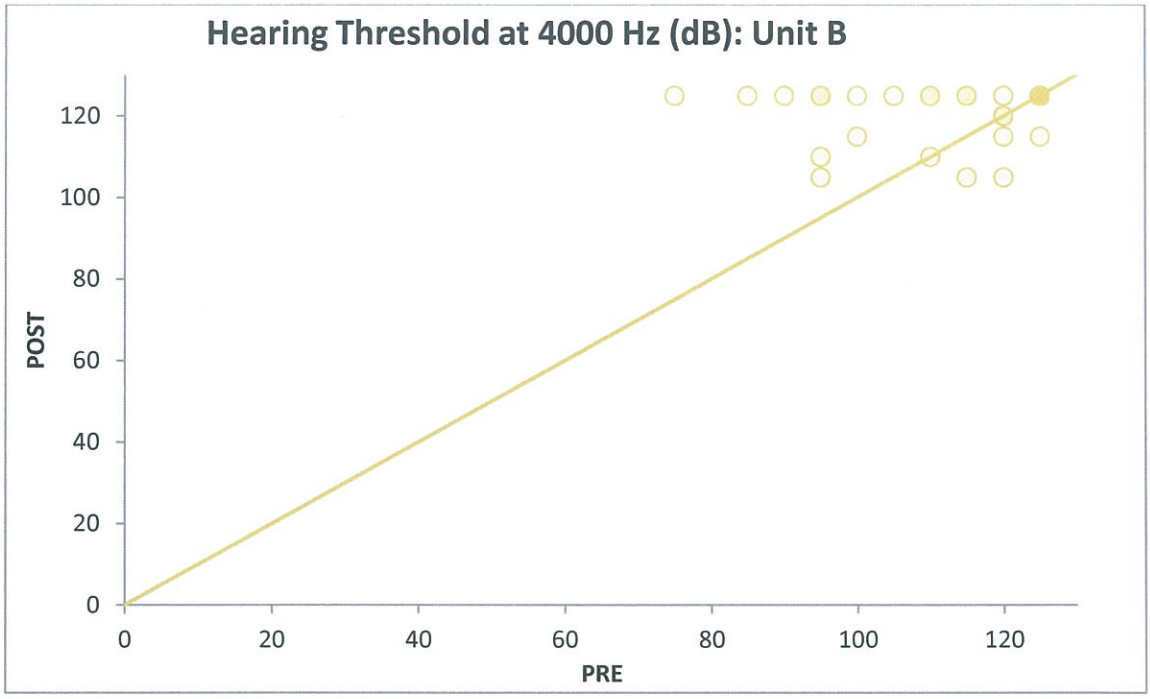


Figure K.5. PRE_POST 4000 Hz at Unit B

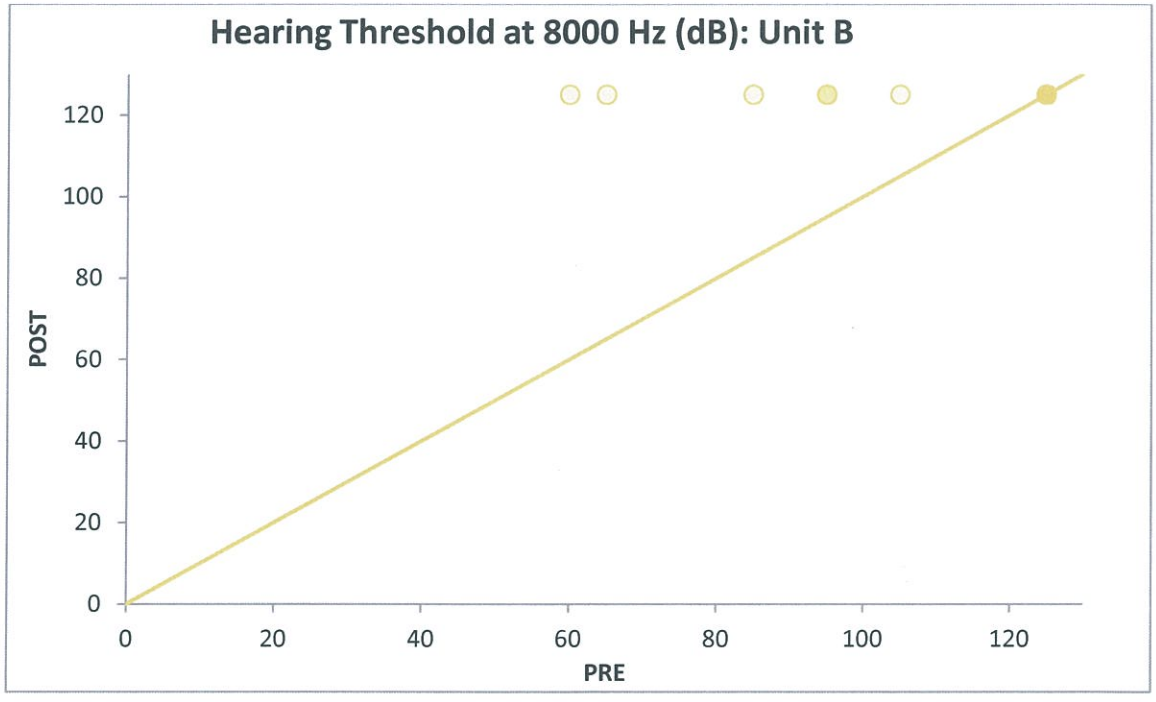


Figure K.6. PRE_POST 4000 Hz at Unit B

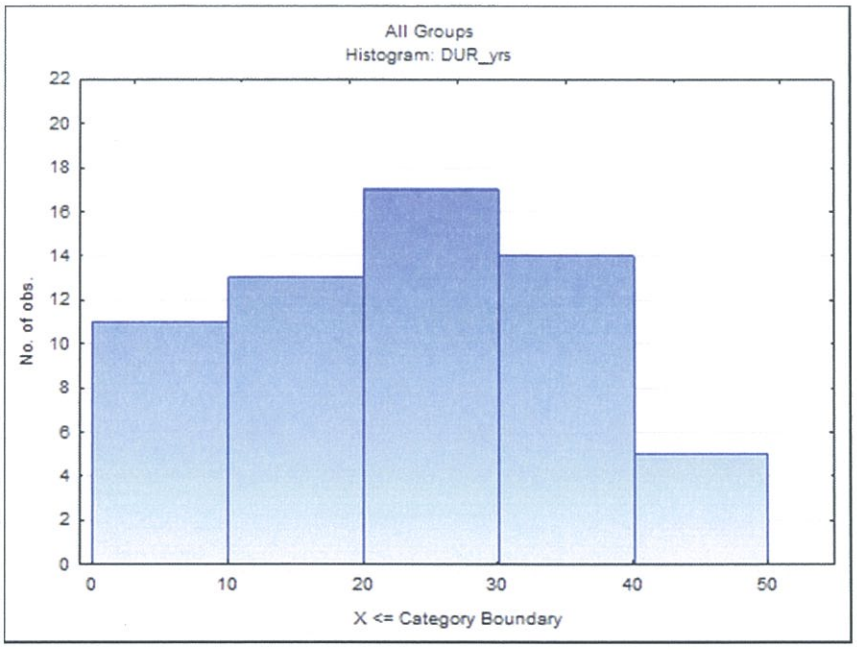


Figure L.1 Frequency distribution for DUR_Overall

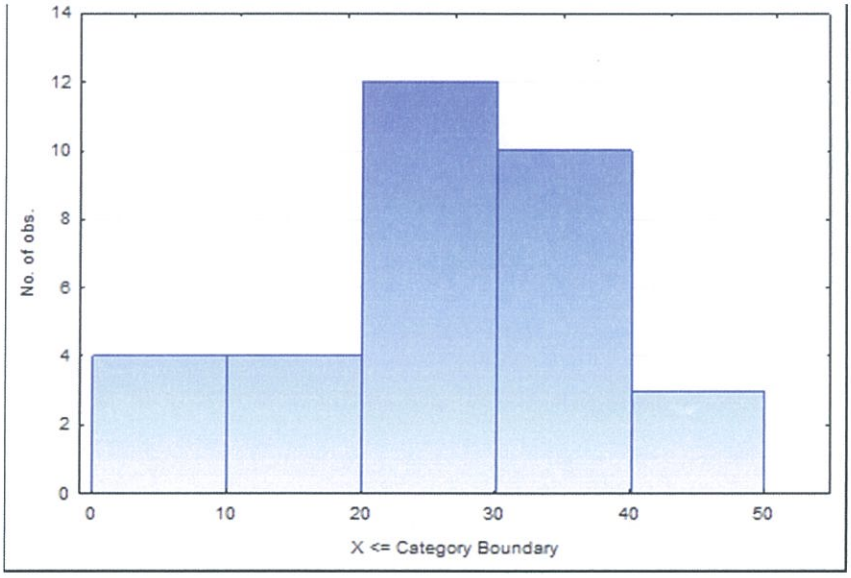


Figure L.2. Frequency distribution for DUR_Unit A

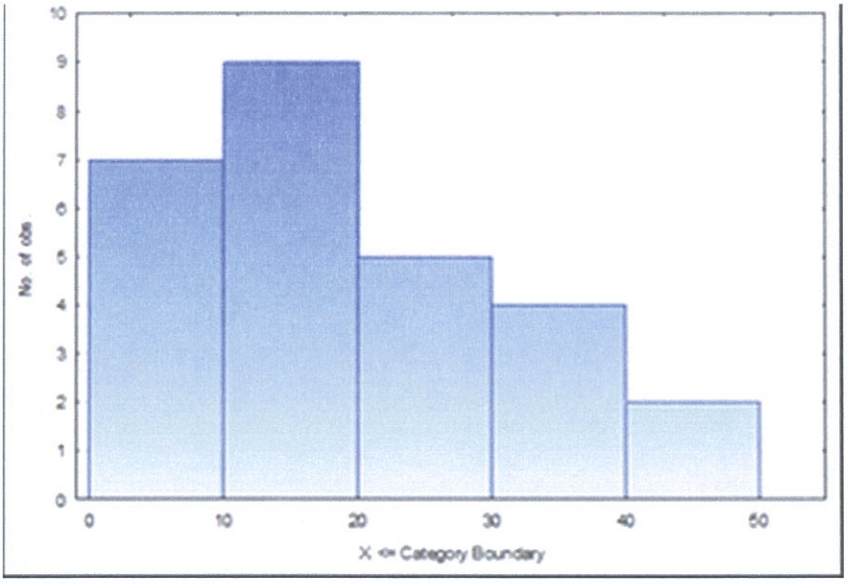


Figure L.3. Frequency distribution for DUR_Unit B

Note: DUR: duration of pre-operative hearing loss

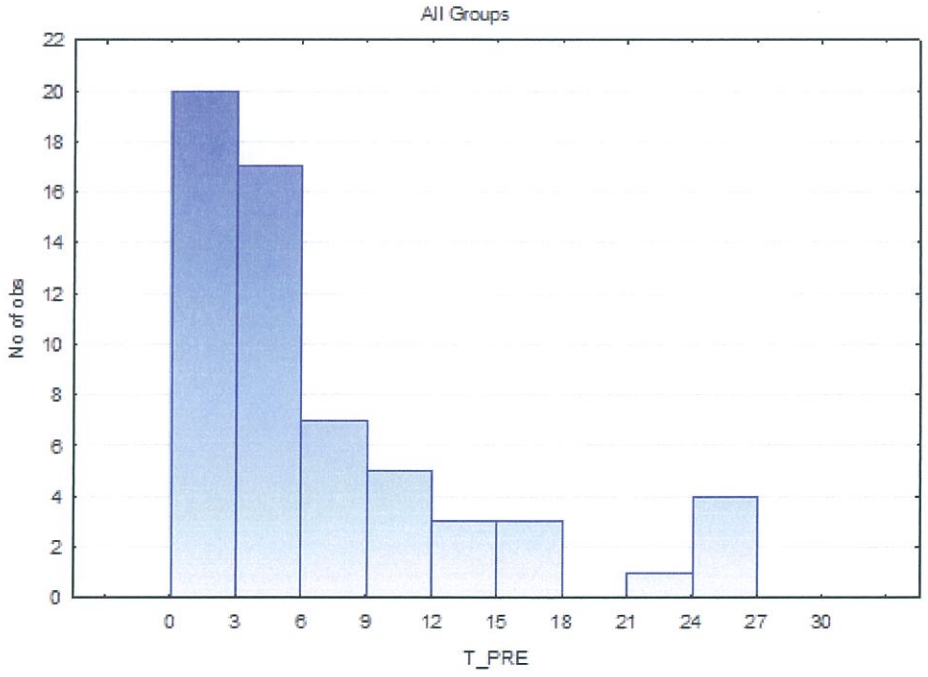


Figure M.1. Frequency distribution for T_PRE_Overall

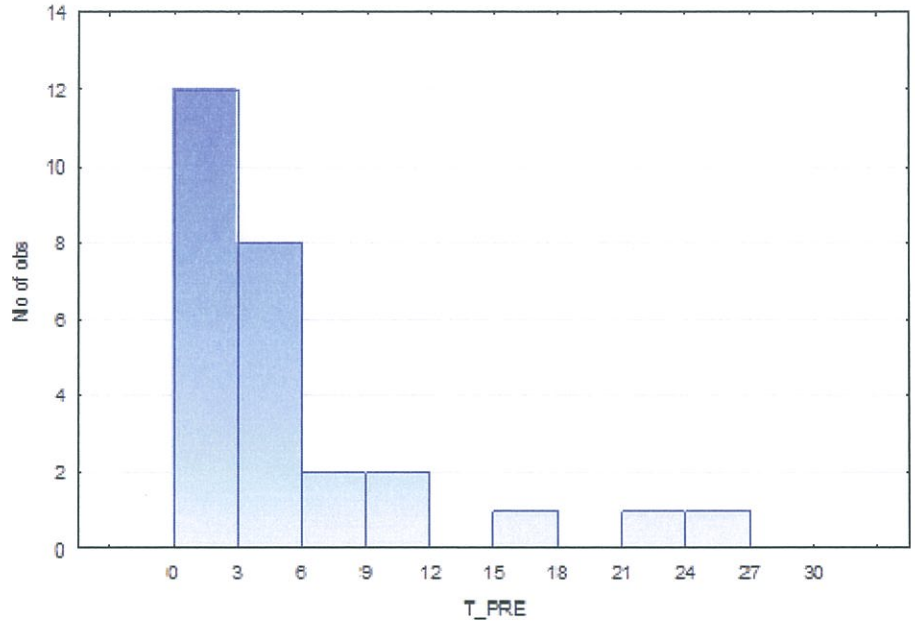


Figure M.2. Frequency distribution for T_PRE_Unit A

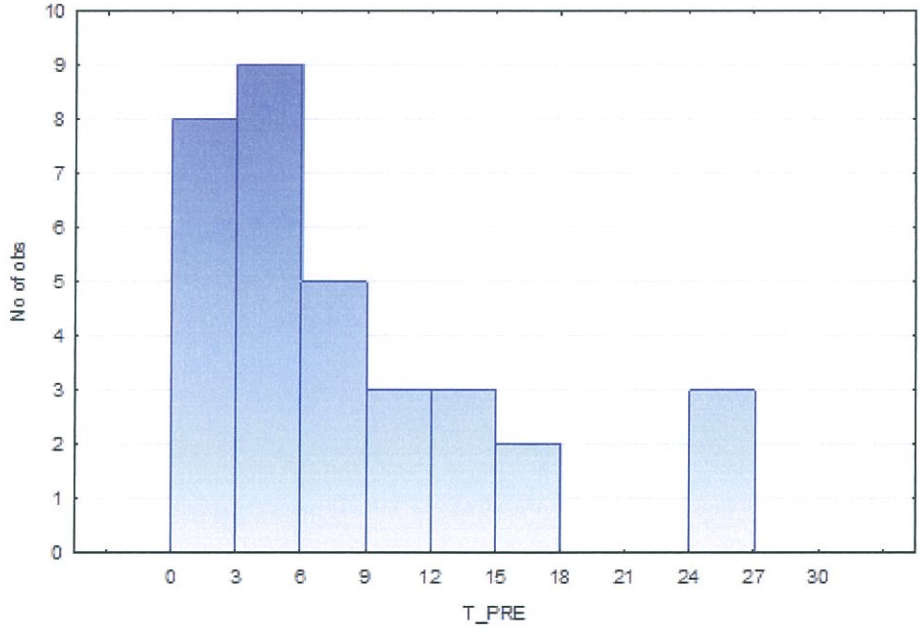


Figure M.3. Frequency distribution for T_PRE_Unit B

Note: T_PRE: time between last pre-operative hearing test and surgery, in months

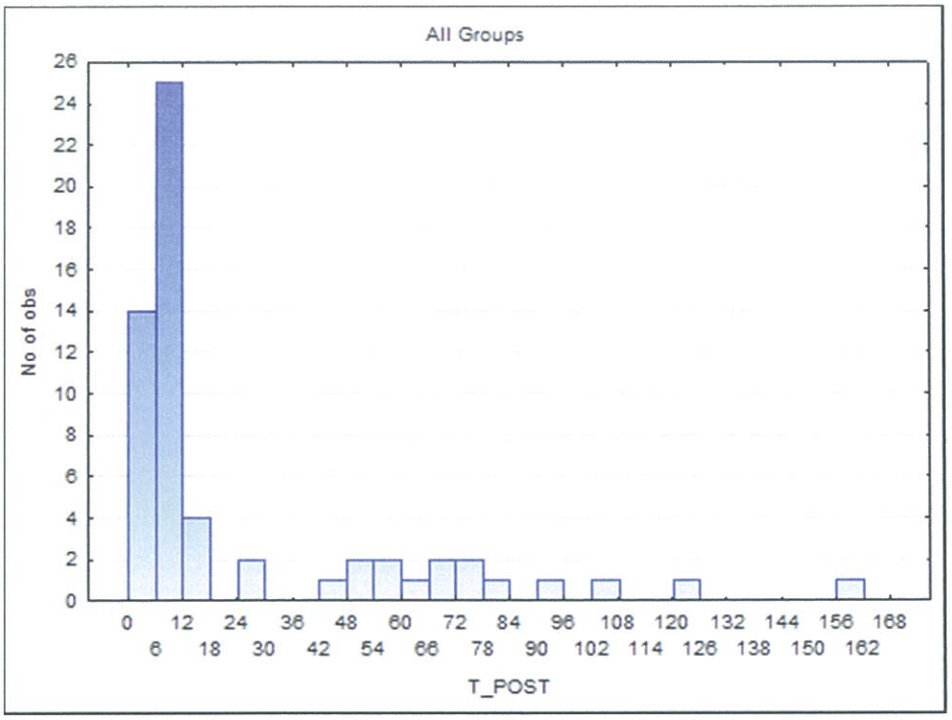


Figure N.1. Time between surgery and first post-operative hearing test (T_POST) - Overall

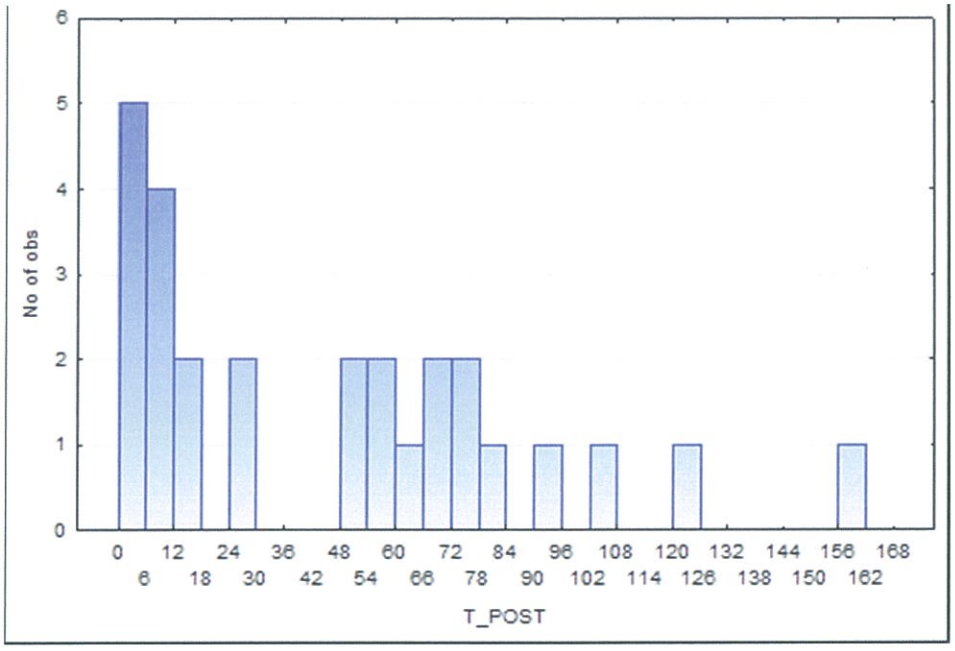


Figure N.2. Time between surgery and first post-operative hearing test (T_POST) - Unit A

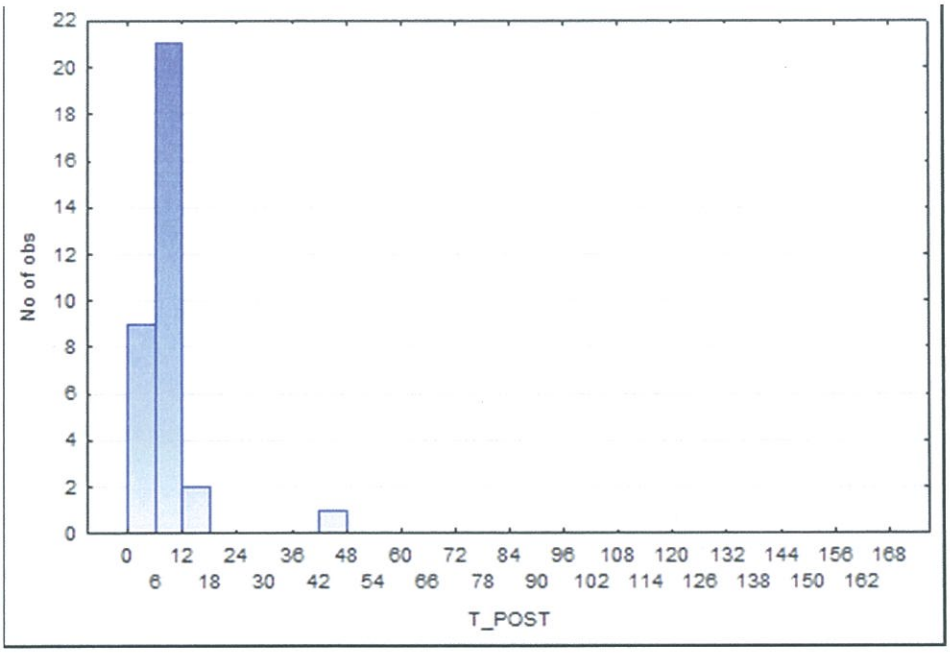


Figure N.3. Time between surgery and first post-operative hearing test (T_POST) - Unit B

Note:T_POST: time between surgery and first post-operative hearing test - in months

Table A.1. General Linear Model calculations (PRE):

$PRE_freq = \alpha_0 + \alpha_1(UNIT) + \alpha_2(T_PRE) + \varepsilon$
where:
PRE_freq = PRE intensity threshold at a particular frequency,
α_0, α_1 and α_2 are parameters to be estimated and
ε is the error term
UNIT B was used as the reference category for UNIT

Table A.2. General Linear Model (Pre-operative) - GLM_PRE

Frequency	N	a_0 (intercept)		a_1 (coefficient for UNIT) (UNIT A vs. UNIT B)		a_2 (coefficient for T_PRE)	
		parameter	p-value	Parameter	p-value	parameter	p-value
125 Hz	no data for UNIT A						
250 Hz	59	69.56	<0.0001	9.21	0.0090	1.33	0.014
500 Hz	60	82.41	<0.0001	4.17	0.12	0.76	0.051
750 Hz	35	94.84	<0.0001	8.26	0.11	1.09	0.023
1000 Hz	59	98.45	<0.0001	3.32	0.12	0.75	0.021
1500 Hz	34	106.35	<0.0001	4.90	0.41	0.61	0.13
2000 Hz	58	104.44	<0.0001	3.70	0.10	0.57	0.11
3000 Hz	41	105.80	<0.0001	2.64	0.44	0.54	0.18
4000 Hz	60	109.87	<0.0001	0.55	0.76	0.38	0.15
6000 Hz	41	114.17	<0.0001	3.82	0.24	0.22	0.57
8000 Hz	54	114.06	<0.0001	1.17	0.65	0.23	0.58

Note: PRE: Pre-operative; GLM: General Linear Model

Table B. Time between surgery and first post-operative hearing test (T_POST)

	UNIT	Valid N	Mean	95% confidence limit (upper)	95% confidence limit (lower)	Median
T_POST	Overall	60	24.7	15.7	33.8	7.6
T_POST	UNIT A	27	46.2	29.3	63.1	50.0
T_POST	UNIT B	33	7.2	4.3	10.1	6.7

Table C. GLM_POST: General Linear Model calculations (POST)

$POST_freq = \alpha_0 + \alpha_1(UNIT) + \alpha_2(T_POST) + \varepsilon$

where:

POST_freq = POST intensity threshold at a particular frequency,

α_0, α_1 and α_2 are parameters to be estimated and

ε is the error term.

UNIT B was used as the reference category for UNIT

Table C.2. General Linear Model (Post-operative) - GLM_POST

Frequency	n	a_0 (intercept)		a_1 (coefficient for UNIT) (UNIT A vs. UNIT B)		a_2 (coefficient for T_POST)	
		parameter	p-value	parameter	p-value	parameter	p-value
125 Hz	no data for UNIT A						
250 Hz	58	92.56	<0.0001	5.94	0.068	0.07	0.45
500 Hz	58	102.39	<0.0001	3.16	0.11	0.07	0.20
750 Hz	33	117.50	<0.0001	9.62	0.27	-0.04	0.87
1000 Hz	59	111.80	<0.0001	0.33	0.84	0.08	0.11
1500 Hz	34	117.86	<0.0001	2.75	0.69	0.01	0.96
2000 Hz	59	117.82	<0.0001	2.05	0.11	0.01	0.76
4000 Hz	60	121.43	<0.0001	0.53	0.58	0.02	0.43
6000 Hz	47	122.38	<0.0001	-0.72	0.55	0.02	0.62
8000 Hz	55	124.43	<0.0001	-0.66	0.36	-0.01	0.56

Table D.1. GLM_CH: General Linear Model calculations (CHANGE):

$CH_freq = \alpha_0 + \alpha_1(PRE) + \alpha_2(T_PRE) + \alpha_3(T_POST) + \alpha_4(UNIT) + \varepsilon$

where:

- CH_freq = change in intensity threshold at a particular frequency,
- α_0, α_1, α_2, α_3 and α_4 are parameters to be estimated and
- ε is the error term
- UNIT B was used as the reference category for UNIT

Table D.2. GLM_CH

Frequency	n	a_0 (intercept)		a_1 (coefficient for PRE)		a_2 (coefficient for T_PPRE)		a_3 (coefficient for T_POST)		a_4 (coefficient for UNIT) (JCIC vs. US)	
		parameter	p-value	parameter	p-value	parameter	p-value	parameter	p-value	parameter	p-value
125 Hz	1										
250 Hz	54	56.41	<0.0001	-0.47	<0.0001	-0.57	0.11	0.054	0.43	2.80	0.30
500 Hz	58	78.78	<0.0001	-0.71	<0.0001	-0.05	0.84	0.049	0.34	2.53	0.18
750 Hz	28	77.80	<0.0001	-0.69	<0.0001	0.37	0.28	-0.039	0.86	not included (no data for JCIC)	
1000 Hz	53	91.23	<0.0001	-0.81	<0.0001	0.10	0.72	0.064	0.19	0.80	0.64
1500 Hz	23	79.70	<0.0001	-0.63	0.0003	-0.57	0.22	-0.040	0.86	not included (no data for JCIC)	
2000 Hz	45	115.34	<0.0001	-0.99	<0.0001	-0.07	0.83	0.024	0.61	2.31	0.14
3000 Hz	25	125.93	<0.0001	-1.07	<0.0001	-0.21	0.58	0.029	0.78	0.38	0.87
4000 Hz	39	127.98	<0.0001	-1.07	<0.0001	-0.17	0.46	0.036	0.34	0.99	0.46
6000 Hz	13	121.96	0.0001	-0.97	0.0001	-0.14	0.76	0.015	0.94	0.65	0.88
8000 Hz	11	124.70	0.0001	-1.00	<0.0001	0.01	0.43	0.000	0.93	-0.03	0.67

Table E. Hearing Preservation

Variable	Overall				UNIT A				UNIT B			
	Patients without HP	Patients with partial HP	Patients with complete HP	p	Patients without HP	Patients with partial HP	Patients with complete HP	p	Patients without HP	Patients with partial HP	Patients with complete HP	p
Gstoettner												
n	6	30	23		4	13	10		2	17	13	
PRE 250 Hz	95.8 ± 22.9	64.8 ± 11.0	89.3± 6.9	0.0007	90.0 ± 33.8	77.3 ± 12.7	95.0 ± 11.8	0.11	107.5 ± 222.4	55.2 ± 16.3	85.4 ± 9.1	0.0030
PRE 500 Hz	98.3 ± 21.4	78.9 ± 7.4	95.4 ± 7.6	0.043	92.5 ± 35.3	90.4 ± 5.6	91.0 ± 15.5	0.98	110.0 ± 127.1	70.1 ± 11.1	98.8 ± 8.1	0.0003
PRE 1000 Hz	104.2 ± 23.1	99.2 ± 6.8	107.7 ± 4.2	0.17	98.8 ± 39.7	108.5 ± 6.2	10.4.4 ± 7.0	0.41	115.0 ± 127.1	92.1 ± 10.3	110.0 ± 5.7	0.011
T_POST (months)*	11.1 (7.6-83.4)	7.7 (6.6-58.0)	6.4 (0.9-10.9)	0.025 (no sig. differences in post-hoc tests)	48.1 (10.2-88.5)	60.3 (50.0-72.9)	8.8 (1.0-29.5)	0.07	8.4 (7.6-9.3)	6.7 (6.0-7.5)	6.2 (0.9-7.2)	0.14
Balkany												
n	5	31	24		3	14	10		2	17	14	
PRE 250 Hz	97.0 ± 30.0	67.1 ± 11.4	87.2 ± 5.7	0.0046	90.0 ± 64.5	81.1 ± 13.9	90.6 ± 8.3	0.52	107.5 ± 222.4	55.5 ± 16.5	85.0 ± 8.4	0.0028
PRE 500 Hz	96.0 ± 27.2	77.8 ± 7.9	97.9 ± 4.8	0.0004	86.7 ± 57.4	87.1 ± 10.4	97.5 ± 6.6	0.28	110.0 ± 127.1	70.1 ± 11.1	98.2 ± 7.6	0.0002
PRE 1000 Hz	102.0 ± 29.6	99.1 ± 6.5	108.9 ± 4.1	0.082	93.3 ± 68.4	107.9 ± 5.9	106.1 ± 7.4	0.21	115.0 ± 127.1	91.8 ± 10.1	110.7 ± 5.4	0.0054
T_POST (months)*	12.8 (9.3-83.4)	7.6 (6.6-50.9)	6.6 (0.9-13.2)	0.040 (no sig. differences in post-hoc tests)	83.4 (12.9-93.6)	54.4 (11.1-72.9)	17.9 (1.0-57.3)	0.19	8.4 (7.6-9.3)	6.8 (6.0-7.6)	6.3 (0.9-7.2)	0.15
All frequencies												
n	5	25	30		3	11	13		2	14	17	
PRE 250 Hz	97.0 ± 30.0	66.4 ± 12.7	83.6 ± 7.7	0.014 (no sig. differences in post-hoc tests)	90.0 ± 64.5	77.7 ± 17.0	91.3 ± 7.3	0.27	107.5 ± 222.4	57.5 ± 18.8	78.2 ± 12.0	0.030 (no sig. differences in post-hoc tests)
PRE 500 Hz	96.0 ± 27.2	79.0 ± 9.4	92.9 ± 5.9	0.023	86.7 ± 57.4	85.0 ± 13.2	96.9 ± 5.3	0.18	110.0 ± 127.1	74.3 ± 14.2	89.8 ± 10.0	0.044 (no sig. differences in post-hoc tests)
PRE 1000 Hz	102.0 ± 29.6	97.0 ± 7.5	108.7 ± 3.9	0.027	93.3 ± 68.4	105.5 ± 6.6	108.8 ± 6.2	0.18	115.0 ± 127.1	90.4 ± 12.0	108.6 ± 5.6	0.0078
T_POST (months)*	12.8 (9.3-83.4)	7.3 (6.0-48.0)	6.9 (3.8-24.9)	0.17	83.4 (12.9-93.6)	50.0 (7.6-72.9)	29.5 (3.8-67.1)	0.45	8.4 (7.6-9.3)	6.5 (0.8-7.3)	6.7 (6.2-7.5)	0.25

* Medians (interquartile ranges) are presented. P-values are for Wilcoxon rank sum test.

Table F.1. Calculations for relationship of hearing findings and duration of pre-operative hearing loss

$CH_freq = \alpha_0 + \alpha_1(PRE_freq) + \alpha_2(T_PRE) + \alpha_3(T_POST) + \alpha_4(UNIT) + \alpha_5(DUR) + \varepsilon$

where:

CH_freq = change in intensity threshold at a particular frequency,

α_0, α_1, α_2, α_3, α_4 and α_5 are parameters to be estimated and

ε is the error term

UNIT B was used as the reference category for UNIT

Table F.2. Calculation for relationship between hearing findings and type of implant

$CH_freq = \alpha_0 + \alpha_1(IM_TYPE) + \alpha_2(PRE_freq) + \alpha_3(T_PRE) + \alpha_4(T_POST) + \alpha_5(UNIT) + \varepsilon$

where:

CH_freq = change in intensity threshold at a particular frequency,

α_0, α_1, α_2, α_3, α_4 and α_5 are parameters to be estimated and

ε is the error term

Table F.3. Calculations for relationship between hearing findings and electrode array type

$CH_freq = \alpha_0 + \alpha_1(EA_TYPE) + \alpha_2(PRE_freq) + \alpha_3(T_PRE) + \alpha_4(T_POST) + \alpha_5(UNIT) + \varepsilon$

where:

CH_freq = change in intensity threshold at a particular frequency,

α_0, α_1, α_2, α_3, α_4 and α_5 are parameters to be estimated and

ε is the error term

Table F.4. Calculations for relationship between hearing findings and electrode array insertion

$CH_freq = \alpha_0 + \alpha_1(EA_INS) + \alpha_2(PRE_freq) + \alpha_3(T_PRE) + \alpha_4(T_POST) + \alpha_5(UNIT) + \varepsilon$

where:

CH_freq = change in intensity threshold at a particular frequency,

α_0, α_1, α_2, α_3, α_4 and α_5 are parameters to be estimated and

ε is the error term

Table F.5. Calculations for relationship between hearing findings and electrode array depth

$CH_freq = \alpha_0 + \alpha_1(EA_DEPTH) + \alpha_2(PRE_freq) + \alpha_3(T_PRE) + \alpha_4(T_POST) + \alpha_5(UNIT) + \varepsilon$

where:

CH_freq = change in intensity threshold at a particular frequency,

α_0, α_1, α_2, α_3, α_4 and α_5 are parameters to be estimated and

ε is the error term

Table F.6. Calculations for relationship between hearing findings and surgical techniques

$CH_freq = \alpha_0 + \alpha_1(SURG_TECH) + \alpha_2(PRE_freq) + \alpha_3(T_PRE) + \alpha_4(T_POST) + \alpha_5(UNIT) + \varepsilon$

where:

CH_freq = change in intensity threshold at a particular frequency,

α_0, α_1, α_2, α_3, α_4 and α_5 are parameters to be estimated and

ε is the error term

Table F.7. Calculations for relationship between hearing findings and surgical complications

$CH_freq = \alpha_0 + \alpha_1(COMPLIC) + \alpha_2(PRE_freq) + \alpha_3(T_PRE) + \alpha_4(T_POST) + \alpha_5(UNIT) + \varepsilon$

where:

CH_freq = change in intensity threshold at a particular frequency,

α_0, α_1, α_2, α_3, α_4 and α_5 are parameters to be estimated and

ε is the error term

The analysis was carried out for the overall sample and for each UNIT separately (omitting the UNIT term in the above model)