

**AUDIOLOGICAL FUNCTION IN A GROUP OF ADULTS FOLLOWING  
MYRINGOPLASTY: AN EXPLORATORY STUDY IN A DEVELOPING COUNTRY**

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**Declaration**

I, Namita Ramdin, declare that this submission is my own original work and all the help and assistance I have received is mentioned in my acknowledgments. I declare that this report has not been submitted for any other degree or diploma at any other university. I am solely responsible for this study and all conclusions that were reached.

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Namita Ramdin

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Date

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**List of abbreviations**

ABG(s): air bone gap(s)

AC: air-conduction

BC: bone-conduction

C: butterfly cartilage inlay surgery

CSOM: chronic suppurative otitis media

dB: decibels

ECV: ear canal volume

ENT: Ear, Nose & Throat Specialist

Hz: Hertz

F: fascia underlay surgery

Freq: Frequency

HIV/AIDS: Human immunodeficiency virus infection / acquired immunodeficiency syndrome

PTA: pure tone average

Pre: pre operative

Po: post operative

SD: standard deviation

SRT(s): speech reception threshold(s)

TM: tympanic membrane

Tymp: tympanometry

WHO: World Health Organisation

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## **Definition of terms: Glossary**

**Butterfly cartilage inlay surgery:** The butterfly cartilage overlay or inlay technique is a type of myringoplasty surgery whereby the temporal fascia is harvested during surgery (ENT Surgeon, n.d.)

**Developing country:** also called a less-developed country is a nation with a lower living standard, underdeveloped industrial base, and low Human Development Index (HDI) relative to other countries. There is no universal, agreed-upon criterion for what makes a country developing versus developed and which countries fit these two categories, although there is general reference points such as a nation's GDP per capita compared to other nations.

**Fascia underlay surgery:** The fascia underlay technique is a type of myringoplasty surgery which involves use of the temporalis fascia which is grafted (ENT Surgeon, n.d.)

**Graft take rate:** the rate at which the graft adheres to the ear drum, also used to describe the success of the surgical grafting procedure.

**HIV/AIDS:** is a disease of the human immune system caused by infection with human immunodeficiency virus (HIV). During the initial infection, a person may experience a brief period of influenza-like illness. This is typically followed by a prolonged period without symptoms.

**Myringoplasty:** Myringoplasty is one of the surgical techniques for the management of chronic suppurative otitis media with permanent perforation of tympanic membrane. It is defined as simple surgical repair of tympanic membrane perforation without doing ossicular reconstruction. It is also referred to as a type 1 tympanoplasty (Baloch, Baloch & Rasheed, 2012).

**P-value:** Statistical significance is usually expressed as a P-value. The smaller the P-value, the less likely it is that the results are due to chance (and more likely that the results are true).

Researchers generally believe the results are probably true if the statistical significance is a P-value less than 0.05 ( $p < .05$ )

**Pre operative:** before surgery

**Post operative:** after surgery

**Statistical significance:** A mathematical technique to measure whether the results of a study are likely to be true. Statistical significance is calculated as the probability that an effect observed in a research study is occurring because of chance.

**Tympanoplasty:** entails grafting of the tympanic membrane with inspection of ossicular chain with/without reconstruction of the middle ear hearing mechanism; there are many types of tympanoplasty techniques (Baloch et al., 2012).

## Abstract

**Purpose:** Otitis media is a global middle ear disease with health and economic burden especially in Africa and other developing nations. Chronic suppurative otitis media is an important cause of preventable hearing loss which warrants attention; particularly in the developing world, as it may have important socio-economic implications over and above patients' quality of life. When presenting with an infected ear due to chronic suppurative otitis media, one may have impaired hearing and a perforated eardrum/s. Thus a type 1 tympanoplasty, i.e. myringoplasty operation is indicated to seal the eardrum. A review of literature demonstrates that extensive evidence exists on the success rate and efficacy of myringoplasty surgery in terms of audiological improvement worldwide; however there is paucity of evidence within the developing world context. Numerous studies published are from developed countries which are vastly different to developing countries. Thus this study aimed to explore audiological function in a group of adults following myringoplasty within a developing country context.

**Participants:** Participant files from the last six years were obtained from the Ear, Nose and Throat (ENT) and Audiology departments at two academic hospitals in Gauteng, Johannesburg. The total sample comprised of 52 participant files consisting of, 20 males (38%) and 32 females (62%), with ages ranging from 18-63years with a mean age of 39.9 years. All 52 participant files could not be included in all the analysis due to missing biographical and/or audiological information in some of the files.

**Design:** This study was conducted using a retrospective record review quantitative research design; where specific objectives of the study were explored. These included; a description and comparison of hearing function pre and post myringoplasty and an exploration of the possible influence of factors such as HIV/AIDS and type of surgical technique on hearing outcome post-surgery.

**Data analysis:** Data was analysed using both descriptive and inferential statistics. Inferential statistics in the form of Kolmogorov-Smirnov two sample test and two-tailed paired (dependent) t-test were used to establish statistical significance levels to determine where statistically significant changes occurred pre and post-operatively and to establish if these changes were dependent on specific variables (HIV status and type of surgical technique).

**Results:** Clinically overall hearing improved post-operatively in terms of tympanometry, pure tone audiometry (air-conduction and bone-conduction testing) and speech reception threshold testing. The predictors for improved hearing outcome post-operatively were; HIV negative status and

butterfly cartilage inlay surgery as a surgical technique adopted. Although clinically hearing outcomes improved post-operatively at all air-conduction frequencies; statistically the changes in air-conduction hearing function were only statistically significant at specific frequencies.

HIV/AIDS appeared to have an influence on hearing outcome post surgery when investigating clinically but these changes were only statistically significant mainly in HIV negative patients at three air-conduction frequencies. No statistically significant differences were found in mean change in hearing function in both HIV negative and positive patients at all bone-conduction thresholds. Although the type of surgical technique (specifically the butterfly cartilage inlay surgery) had an influence on hearing outcome post-surgery; these changes in air-conduction hearing function in patients who underwent this surgical technique were only statistically significant at specific frequencies. For patients who underwent fascia underlay, no statistically significant changes were found postoperatively.

**Conclusion:** Current findings offer valuable baseline evidence on hearing outcome pre and post myringoplasty within this developing country context. This evidence can serve as a baseline for future research in the South African population. The study yielded relevant information regarding variables affecting the outcome of myringoplasty surgery in a South African context which is essential in the management of patients from an audiological and surgical perspective.

**Key words:** audiological, developing, hearing, myringoplasty, otitis media, myringoplasty surgery

## Chapter Outlines

### **Chapter 1 - Introduction, Rationale, Literature review**

This chapter provides an introduction to the study highlighting some key factors that were considered when determining the research aims. South Africa, a developing nation and the influence of HIV/AIDS was discussed. Prevalence of hearing loss in South Africa and internationally was described. A background on otitis media; specifically definition, statistics and causes were provided. The management of otitis media internationally was compared to that in South Africa. Thereafter myringoplasty surgery and the two types of myringoplasty techniques were explored. A review of the literature pertaining to hearing outcomes post myringoplasty was conducted; and this culminated into the rationale for the current study and appropriate research aims.

### **Chapter 2 - Methodology**

This chapter includes the aims of the study (primary and specific aims) followed by the research questions. Thereafter the research design was explained and a description of participants and the participant selection criteria (inclusion and exclusion criteria) was provided. The sampling procedure was described and the importance of the sample size stated. The data collection process was initiated with the pilot study which was followed by the data collection procedure for the current study. The areas of data collections (biographical and audiological) were listed and explained. Data analysis and statistical procedures were then discussed; specifically the types of statistical measures adopted. Issues pertaining to reliability and validity were discussed followed by ethical considerations that the researcher observed.

### **Chapter 3 – Results**

This chapter presents the results of the study and these were presented according to the aims of the study. The results were described firstly in terms of the total sample size ( $N$ ) and then according to sub-sample sizes ( $n$ ) which described specific aims of the study that were investigated. A detailed description of the participants pertaining to each of these smaller sample groups was provided according to the research questions.

### **Chapter 4 – Discussion**

This chapter provides a discussion of key factors that were considered when interpreting the results yielded by the current study. The results were then discussed according to the research questions and findings were compared and correlated to published evidence from the literature reviewed. The researchers view on these similarities and differences were provided as well as why these findings exist. The implications of these findings were discussed in terms of influence of the findings on the research and clinical community.

### **Chapter 5 – Conclusion and Recommendations**

This chapter provides a summary of the key factors that were considered in the current study followed by a summary of the results and finally concluding comments. This chapter also highlights the benefits, limitations of the current study and implications (clinical and educational). Thereafter recommendations for future research are proposed.

### **References and appendices**

This section lists the references consulted for the current study and provides the appendices (raw data, approval letters etc).

## Chapter 1

### Introduction, Rationale, Literature review

**Hearing loss in South Africa and internationally.** Globally, hearing loss is the most common sensory deficit across the human race (World Health Organization [WHO], 2010). In 2008, approximately 278 million people presented with moderate to profound hearing loss worldwide (WHO, 2010). Eighty percent of deaf and hearing-impaired people live in low and middle-income countries. WHO (2010), further highlights that the major preventable causes of hearing impairment in low and middle-income countries are middle ear infections, excessive noise, inappropriate use of certain drugs, problems during childbirth and vaccine-preventable infections. The burden of otitis media occurs overwhelmingly in the developing world with almost nine times more cases reported compared to developed countries (Smith & Mathers, 2006). Hearing loss may be perpetuated in these poorer communities because of the exposure to more risks of hearing loss, such as unhygienic living conditions, disease outbreaks, lack of access to healthcare, and poorer knowledge about prevention (Swanepoel et al., 2010). Thus a cycle of hearing loss contributing to poverty and poverty contributing to hearing loss may be perpetuated in the developing world (Swanepoel et al., 2010).

Nowhere is the irony of global inequality more striking than in hearing health care, with more than 80% of people with hearing loss residing in developing countries where services are either totally absent or very limited (WHO, 2006; Fagan & Jacobs, 2009). Despite being the most prevalent disabling condition globally and one of the major contributors to the global burden of disease, hearing loss has historically been ignored on global health care agendas (Swanepoel et al., 2010). According to the WHO (2008), it is “easily overlooked and under underestimated” because it is not as “dramatic” as other health care conditions. It is therefore not surprising that hearing loss has been referred to as a silent epidemic (Swanepoel, 2008; WHO, 2008).

The World Health Organization estimates that less than one in every 40 people who could benefit from hearing aids actually receive this device (WHO, 2006). This means that a simple intervention option such as provision of hearing aids is available to less than 2.5% of individuals who can benefit from them. Hearing health care surveys confirm that the paucity of services is mainly due to the limited numbers of available hearing health care professionals globally (Goulios & Patuzzi, 2008; Fagan & Jacobs, 2009). The average ratio of audiologists to the general population in developing countries reportedly varies between one for every half a million people to as high as one for every 6.25 million people (Goulios & Patuzzi, 2008). A recent survey of countries in sub-Saharan Africa indicated that many of these countries do not have any audiology or otolaryngology services (Fagan & Jacobs, 2009).

In developed countries the average ratio for audiologists to people was one to every 20 000 (Goulios & Patuzzi, 2008). These shortages of hearing health care professionals are primarily due to a reported lack of government funding, professional and public awareness, and, most significantly, available training programs (Goulios & Patuzzi, 2008). Only two African countries, for example, indicated having any training programs in audiology and many countries also indicated that they had no otolaryngology training programs (Fagan & Jacobs, 2009). Emigration of trained staff, for economic reasons, to developed economies is another factor leading to acute shortages of hearing health care professionals (McPherson, 2008). In addition, there is an unequal distribution of existing hearing health care providers who are primarily situated in metropolitan areas which often leaves vast rural territories underserved.

**South Africa: a developing nation and the influence of HIV/AIDS.** Factors influencing health care in developing countries are numerous. South Africa has the largest number of people living with HIV/AIDS and carries a sixth of the global disease burden (Sloan, Dlamini & Dedicat, 2009; Garcia-Jardon, Bhat, Blanco–Blanco & Stepien, 2010). The total number of people living

with HIV in South Africa is 5.7 million (Gracia-Jardon et al., 2010). Statistics South Africa (Stats SA) (2013) stated that the total number of people living with HIV is estimated at approximately 5.26 million by mid 2013. For adults aged 15-49 years an estimated 15.9% are HIV positive (Stats SA, 2013).

Disorders of the auditory and vestibular system are often associated with human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) (Heinze, Swanepoel & Hofmeyer, 2010). Auditory pathology associated with HIV/AIDS involves structures including the outer and middle ear, cochlea, neural pathways, and central nervous system; the disease may involve one or many of these structures (Heinze et al., 2010). Opportunistic infections related to the outer and middle ear may include acute otitis externa and otitis media with effusion. Heinze et al. (2010) stated that highly active antiretroviral therapy combinations may be ototoxic, as may some treatments for opportunistic infections, resulting in hearing loss, tinnitus and hyperacusis. Opportunistic infections have been considered indirect causes of hearing loss by some researchers; even though they may be a direct consequence of the disease (Khoza-Shangase, 2010). Khoza-Shangase and Ross (2002) found higher prevalence of sensori-neural hearing loss in a sample of adults with HIV infection, where a definite increase in the number of occurrences of sensori-neural hearing loss from stage one (asymptomatic HIV infection) to stage three (clinical AIDS) was also established in adults who were not on antiretroviral therapy. Khoza-Shangase (2008) found that 47% of clinical hearing loss had a tendency for sloping (high frequency) configuration of hearing loss. Furthermore the sensori-neural high frequency nature of hearing loss is consistent with features typical of ototoxic hearing loss.

The reported prevalence and incidence of hearing loss in cases of HIV and AIDS varies considerably, but this inconsistency may be attributed to a variety of factors such as the vastly different samples, different research methodologies, as well as different participant inclusion criteria used in the diverse documented studies (Khoza-Shangase, 2010). HIV status has never been

investigated as a variable that may influence the outcome of hearing post myringoplasty surgery. Given the prevalence of HIV in South Africa; this variable was deemed important in the selected context and formed part of the objectives investigated in the current study.

**Background on Otitis media.** Otitis media is a global middle ear disease with health and economic burden especially in Africa and other developing nations, where the disease prevalence is expected to be as high as 11% in some African countries with severe economic implications (Ibekwe & Nwaorgu, 2011). In South Africa the high prevalence of otitis media has been attributed to overcrowding, inadequate housing, poor hygiene, not breastfeeding, poor nutrition, and high rates of nasopharyngeal colonisation with potentially pathogenic bacteria (Department of Health [DOH], 2012). Thus poverty is a major risk factor in South Africa. It is known that in developing countries factors like poverty, ignorance, dearth of specialists and limited access to medical care amongst others conspire to worsen the course of otitis media; thus hearing loss with risks of developing behavioural, speech, language and cognitive problems are not uncommon complications of otitis media in the developing countries (Ibekwe & Nwaorgu, 2011). Monasta et al. (2012) believe that because otitis media is a leading cause of health care visits and frequent drugs prescription; that its complications and consequences are important causes of preventable hearing loss, particularly in developing countries. Studies conducted in developed countries reveal that by their third birthday, 80% of children will have experienced at least one episode of acute otitis media and 40% will have six or more recurrences by the age of seven years (Monasta et al., 2012). Arguably, these numbers might be substantially higher in developing countries where presentation and management of health conditions is significantly influenced by a host of factors absent in the developed world.

Otitis media is a broad subject which could be classified according to (1) duration, either acute otitis media or chronic otitis media, (2) nature of fluid/discharge, either suppurative or non-suppurative otitis media, (3) otitis media with effusion and (4) causative organism, either bacterial otitis media (more common) or specific otitis media such as tubercular or syphilitic otitis media

(less common) (Ibekwe & Nwaorgu, 2011). Otitis media is an inflammation of the middle ear which may be acute, effusing or chronic (Nwokoye et al., 2012). Acute otitis media is the most common in children, otitis media with effusion occurs when the tympanic membrane integrity and duration of the disease is characterized by the otitis media (Nwokoye et al., 2012). While otitis media with effusion is characterized by asymptomatic middle ear effusion, “plugged ear feeling” and a translucent tympanic membrane with diminished mobility. Chronic suppurative otitis media is associated with hearing loss (Nwokoye et al., 2012) and is an important cause of preventable hearing loss particularly in the developing world (Monasta et al., 2012). Preventing hearing loss due to chronic suppurative otitis media becomes particularly important in children because of the well documented long term effects on early communication, language development, auditory processing, psychological and cognitive development, education progress and achievement (Acuin, 2004; Monasta et al., 2012).

As with most infectious diseases, the burden of acute otitis media varies substantially across countries (Monasta et al., 2012). Studies have shown that the main differences in the manifestation of the burden of acute otitis media resides in the frequency of suppurative complications such as mastoiditis and meningitis and in the consequences such as hearing loss due to chronic suppurative otitis media (Vergison, Dagan, Arguedas, Bonhoeffer & Cohen, 2010). Type and degree of hearing loss varies depending on the type of otitis media. Typically acute otitis media is associated with conductive hearing loss and discharge from ears in more than 90% of cases in some parts of the developing world, whereas only 10% in developed nations (Ibekwe & Nwaorgu, 2011). Otitis media with effusion is associated with conductive hearing loss which is mild-moderate in nature (less than or equal to 40dB) in children below 5 years of age; (Ibekwe & Nwaorgu, 2011) thus resulting in speech difficulties. Patients with chronic suppurative otitis media normally present with a history of recurrent foul smelling ear discharge which may result in a cholesteatoma if not treated (Vikram, Khaja, Udayashankar, Venketsha & Manjunath, 2008). In all developing countries the

incidence of chronic suppurative otitis media is very high because of poor socioeconomic standard, overcrowding, poor nutrition and lack of health education (Joshi, Jha, Rijal, Dhungana & Shrestha, 2013).

The presentation of chronic suppurative otitis media may be unilateral or bilateral (Ibekwe & Nwaorgu, 2011) and patients mainly present with conductive hearing loss or mixed hearing loss (conductive hearing loss and sensori-neural hearing loss) (Olusesi, 2008). Conductive hearing loss accompanying chronic suppurative otitis media results from blockage of the external auditory canal by discharge and perforation of the tympanic membrane (WHO, 2006). Hearing loss greater than 40dB may indicate fixation or discontinuity of the ossicular chain, sensorineural hearing loss is due to infiltration of infectious or inflammatory agents through the round window to produce a serous labyrinthitis (WHO, 2006). The ototoxic effects of some antibiotics used to treat the infection may add to these effects (WHO, 2006).

Acute otitis media is a very common bacterial infection in children worldwide, leading to excessive antibiotic consumption in children in most countries and to a substantial burden of deafness and suppurative complications in developing countries (Vergison et al., 2010). A study was conducted in which a group of international multidisciplinary experts met to propose to clinicians and public health officials their views on the actions needed to be taken to reduce the disease burden caused by acute otitis media and the microbial antibiotic resistance resulting from the use of antibiotics. The major unanimous concern amongst the experts were that there was an urgent need to reduce unnecessary prescribing of antibiotics to prevent further increases in antibiotic resistance (Vergison et al., 2010). Prevention of acute otitis media with existing and future viral and bacterial vaccines seemed the most promising approach discussed in this study to affect disease burden and consequences, both in developed and developing countries (Vergison et al., 2010). Management of otitis media has not received a pattern prescription because aetiologies vary depending on clinical presentation (Nwokoye et al., 2012).

**Management of otitis media.** Management for acute otitis media varies and commonly consists of ear swabs for the discharging ear that are taken for microscopy culturing and sensitivity testing prior to the commencement of oral and/or topical antibiotics (Ibekwe & Nwaorgu, 2011). It has been argued that antibiotic treatment for acute otitis media may not be effective; as most cases of acute otitis media are associated with viral infections (Hassmann-Poznanska, 2007; Thompson et al., 2008). In the developing world, most cases of acute otitis media are mixed (bacterial and viral) infections and thus daily aural toileting of the ear is necessary for the discharging ear (Ibekwe & Nwaorgu, 2011). Due to South Africa facing a number of challenges that complicate the progressive realization of access to health care (Meyer, 2010), it can be suggested that daily aural toileting for the discharging ear may not be possible for most patients within the South African population leading to untreated otitis media which can result in permanent hearing loss. Only in the developed countries and a few of the more advanced developing countries does greater than 95% of the population have regular access to essential drugs (WHO, 2006). Many of the poorer developing countries have regular access for less than 50% of the population; consequently often appropriate treatment is not available in places where the disease is commonest (WHO, 2006). In addition, there is no ear drop (antibiotic or antiseptic) listed in the WHO Essential Drugs List which means that in some developing countries these drugs are even less readily available than other types of drugs (WHO, 2006).

Management of otitis media with effusion involves treating the causative factors first via surgical repairs or manoeuvres to resolve the otitis media and prevent future occurrences, e.g. cleft lip/palate repairs, adenoidectomy and tonsillectomies (Hong et al., 2008). When effusion is viscid or massive, myringotomy (grommet insertion) is necessary (Ibekwe & Nwaorgu, 2011). Evidence has shown that better outcome and lesser complications in otitis media with effusion managed with tympanostomy tube placement; as compared to those managed conservatively (Diacova & McDonald, 2007).

**Management of otitis media in South Africa.** South Africa has the highest income inequality globally and the gap between public and private health care, with regards to affordability and quality of service remains a great concern (Meyer, 2010). As a result of this inequality; majority of South Africa's population can only afford access to government healthcare services. This places a huge demand on the government hospitals which has resulted in long waiting periods for surgical procedures due to a lack of adequate numbers of medical professionals and an increase in caseload (WHO, 2006). Waiting lists for tympanostomy surgery may be as long as six months in these hospitals and this delay in intervention could potentially exacerbate the otitis media with effusion disease into chronic suppurative otitis media which then results in long term hearing loss as a consequence.

The Department of Health (DOH) South Africa has devised a hearing guide for the prevention of hearing impairment due to otitis media at clinic level located within the primary health care level. The goal of this protocol is to provide a rational, as well as cost-effective and user-friendly set of treatment guidelines for otitis media in order to prevent acquired hearing impairment owing to chronic otitis media that may result in; brain abscess, destruction or fixation of the middle ear structures responsible for conduction of sound into the inner ear, spread of infection into mastoid and inner ear and language developmental delay (DOH, 2012). These guidelines are to be implemented at primary health care clinics, mobile clinics, community health care centres and district hospitals. According to these guidelines, the management of chronic suppurative otitis media involves adoption of non-drug treatment and prescription of antibiotic treatment. Non-drug treatment entails performance of a procedure called dry mopping which is of paramount importance (if the ear is discharging pus) in the management of chronic otitis media. The guidelines emphasize the importance of keeping the ear dry once the infection has resolved. The technique for dry mopping is deemed cost effective within the South African context and must be demonstrated to the

patient or to the escort so that they can perform the procedure at home thus reducing the number of times they need to visit the clinic or hospital (DOH, 2012).

The guidelines further stipulate that it must be explained to the parents/escorts that pus in the ear canal must be removed to make it relatively dry. Evidence suggests that although mopping takes a long time; not doing it could cause the child/patients to go deaf, and that repeated antibiotics and injections alone do not help (DOH, 2012). The guidelines further emphasised that the following information must be conveyed to the patient/escort: wash hands before undertaking mopping exercise, mop the ear at least three times a day at home, use this treatment for as many days as it takes until the wick used during mopping no longer gets wet when put in the ear canal and no pus drains from the ear (usually 1 - 2 weeks), and that the ear canal must not be blocked with anything between treatments (DOH, 2012).

According to the DOH (2012) guidelines for prevention of hearing impairment due to otitis media at clinic level should the non-drug treatment inadequately treat the chronic suppurative otitis media; then antibiotic treatment is recommended. Prior to this treatment, a pus swab for culture and sensitivity testing is done to get an indication of what drug to use (Ibekwe & Nwaorgu, 2011). Radiological imaging (X-rays and CT Scans) (Trojanowska, Trojanowski, Olszonski, Klatka & Drop, 2007) is deemed essential for the grading of the degree of the disease. Audiological investigations (pure tone audiogram and speech testing) to assess degree and type of hearing loss are reported as essential in guiding the mode of rehabilitation and the management of choice (Ibekwe & Nwaorgu, 2011).

Chronic suppurative otitis media can further be managed medically or surgically or via a combination of both (Ibekwe & Nwaorgu, 2011). Active mucosal chronic suppurative otitis media is managed via aural toileting and appropriate antibiotics (topical and systemic), nasal decongestants and vitamin (C and A) supplements to enhance healing (Jones & Smith, 2007). Once total disease eradication and dryness is achieved the level of function loss is evaluated in order to

decide the need for further surgical intervention in the form of myringoplasty surgery (Ibekwe & Nwaorgu, 2011).

**Myringoplasty surgery.** The classification of tympanoplasty related to ideal and theoretical postoperative hearing outcomes, based on middle-ear mechanics, consists of five types, each of which is based on the most lateral intact structure that remains connected to the inner ear:

- Type I: Tympanoplasty (or myringoplasty) when all three ossicles are normal, which should result in normal hearing.
- Type II: Tympanoplastic graft (or tympanic membrane) is in contact with the incus and the stapes is present, both of which are connected and mobile, which ideally should result in a minimal hearing loss of only 2.5 dB.
- Type III: Tympanoplastic graft (or tympanic membrane) is in direct contact with the suprastructure of the stapes (columella effect), which should result in a hearing loss of only 2.5 dB; also known as myringostapediopexy.
- Type IV: Ossicular chain is absent and the tympanic membrane is in contact with a mobile stapes footplate, which theoretically should result in a 27.5 dB hearing loss; also known as a cavum minor.
- Type V: A window is surgically made in the horizontal semicircular canal, which should result in hearing similar to a Type IV; also known as a fenestration.

(Bluestone, 1999)

For the purpose of the current study type I tympanoplasty, i.e. myringoplasty was investigated. When presenting with an infected ear or impaired hearing due to a perforated eardrum; one receives a type I tympanoplasty surgical procedure, i.e. myringoplasty operation to seal the eardrum. Perforation of the tympanic membrane primarily results from middle ear infection, trauma or iatrogenic causes (Sarker, Ahmed, Patwary, Islam & Joarder, 2011). The goal of myringoplasty surgery is to achieve a dry, self-cleansing ear while preserving or restoring hearing (Harris &

Linder, 2012). Myringoplasty refers to the grafting of the tympanic membrane without inspection of the ossicular chain (Harris & Linder, 2012). Myringoplasty surgery has been reported to be highly successful when performed by a qualified ear nose and throat (ENT) surgeon using the correct equipment. Literature suggests that up to 80% of the size of the perforation undergoes spontaneous closure (Albera, Vittorio, Michelayelo & Andrea, 2006; Sarker et al., 2011). Where spontaneous closure has not occurred, three principal indications for myringoplasty have been documented (1) recurrent otorrhea, (2) desire to swim without wearing water proof in the ear and (3) need to improve the conductive hearing loss resulting from a non-healing perforation of the tympanic membrane (Sarker et al., 2011). The primary goal in myringoplasty is the restoration of the integrity of the tympanic membrane; and this result can be obtained by means of surgical techniques based on the positioning of the connective tissue at the site of the ear drum perforation. Thus, the main purpose of surgery is to stimulate skin and mucosal regeneration, leading to permanent closure of the defect (Albera et al., 2006).

Ear surgery may have a role in both the primary and secondary prevention of chronic suppurative otitis media and it plays an essential part in the prevention of further hearing impairment and sometimes in the improvement of hearing (WHO, 2006). Thus, human resources and appropriate facilities and equipment should be provided for an essential range of surgical services at the primary, secondary and tertiary levels of health care for proper management of chronic suppurative otitis media (WHO, 2006). In many developing countries, there is a lack of ear specialists as well as overburdened hospital facilities (Meyer, 2010).

At the secondary (intermediate) level of health care, usually based at district hospitals, ear nose and throat surgeons (ENTs) are generally not available, and a programme of additional training in otology for the medical assistant/clinical officer grade, (or for general hospital/clinic doctors in some health systems) may need to be set up to achieve this goal. At the tertiary referral level, the number of ear specialists may need to be increased by a programme of regional training

with a defined career structure with government commitment (Meyer, 2010). This type of surgery within a developing country context may not always be feasible due to the expensive equipment needed to perform a myringoplasty, difficulty in getting patients to return for follow up and the high level of training required by the ear nose and throat (ENT) specialist (WHO, 2006). In some developing countries, there are advocates of a simple, quick myringoplasty using a plug for the perforation from ear lobe fat or a small piece of fascia which could be done by the clinical officer or medical assistant grade (WHO, 2006). Even though the take-rate of this procedure is lower; it is argued that it would still substantially reduce the numbers who remain hearing-impaired. However, in other countries it has been found that at least medically qualified ear nose and throat (ENT) specialists are needed to perform myringoplasty surgery and training medical assistants or clinical officers to do them was not satisfactory (WHO, 2006).

One of the major controversies surrounding myringoplasty surgery is whether or not total dryness should be achieved before reconstructive surgery is embarked upon (Mustafa, et al., 2008). However published evidence has indicated that dry ears prior to reconstruction may be better favoured in the South African context, i.e. a developing country. Specifically when considering limiting environmental factors such as limited manpower and resources as well as severe cost of failures in such reconstructions (Ibekwe & Nwaorgu, 2011). Healed chronic suppurative otitis media; a dry ear with a central perforation needs no further active intervention, other than a regular review of the patient (Ibekwe & Nwaorgu, 2011). Myringoplasty is an operation that can improve hearing in many cases independent of age, gender and the size or site of the perforation (Karela, Berry, Watkins & Phillipps, 2008). Although a 90% success rate of surgery is frequently quoted for myringoplasty, the routine nature of the procedure, as well as the effect of many influencing factors on the success or failure of this procedure remains unresolved (Sarker et al., 2011). It has been suggested that factors such as the age of the patient; site of the perforation, size of the perforation, length of time that the ear has been dry for prior to surgery, the presence of infection at the time of

surgery, as well as the status of the opposite ear may all be influencing factors affecting outcome of myringoplasty surgery (Sarker et al., 2011).

**Types of myringoplasty techniques.** The concept of surgical repair of tympanic membrane was first introduced by Berthold in 1878, whereby a thick skin graft by overlay technique was used. Wullstein and Zollner used the split skin grafts. In the 1960s and 1970s, homograft (cadaveric) materials, including tympanic membrane, dura, and pericardium, among others, were used with varying success (Joshi et al., 2013). Since then, over the period of many decades, different grafts and techniques evolved and myringoplasty has gone through many changes in technique and materials (Baloch et al., 2012; Joshi et al., 2013). None of these materials gained universal acceptance and today pose a problem because of the potential for transmitting diseases such as Jakob-Creutzfeldt disease and HIV infection (Joshi et al., 2013). Temporalis fascia continues to be the material of choice for reconstruction of the tympanic membrane (Manolidis, 2003 as cited in Joshi et al., 2013). There is still no consensus about the optimal technique, which is often employed on the basis of the surgeon's preference and skills, and not on the type of the tympanic membrane perforation (Sergi et al., 2011; Baloch et al., 2012). The ideal reconstructive technique however should obtain a thin, conically shaped, vibrating membrane replacing the original ear drum in order to prevent infection and restore or improve hearing (Sergi et al., 2011).

Two types of myringoplasty techniques were investigated in this study. These techniques were found to be the most common types of techniques performed at tertiary hospitals in Gauteng. The types investigated were the fascia underlay technique and the butterfly cartilage inlay technique. The fascia underlay technique involves use of the temporalis fascia which is grafted (ENT Surgeon, n. d.). The surgery is performed where an incision is made along the edge of the perforation and a ring of epithelium is removed and a strip of mucosal layer is removed from the inner side of the perforation (ENT Surgeon, n. d.). The middle ear is packed with gel foam soaked with an antibiotic and the edges of the graft should extend under the margins of the perforation and

a small part should also extend over the posterior canal wall; the tympanomeatal flap is then replaced (ENT Surgeon, n. d.). The butterfly cartilage overlay or inlay technique is where the temporal fascia is harvested (ENT Surgeon, n. d.). An incision is made to raise medial meatal skin with tympanic membrane epithelium and the graft is placed on the outer surface of the tympanic membrane and a slit is made to tuck it under the handle of malleus (ENT Surgeon, n. d.). The ear is packed with gel foam and antibiotics and the incision is closed and finally mastoid dressing is performed (ENT Surgeon, n. d.).

The advantages of both types of ear surgeries are to restore the hearing function and in some cases, alleviate tinnitus; to check the re-infection from external auditory canal and eustachian tube and to monitor if aeroallergens reaching the exposed middle ear mucosa, leading to persistent ear discharge (ENT Surgeon, n. d.). Myringoplasty surgery is thus contraindicated in cases where there is active discharge from the middle ear, nasal allergy, which should be controlled before surgery; and when the other ear is dead or not suitable for hearing aids, where there is recurrent otitis externa; and in children below three years of age (ENT Surgeon, n. d.). Sergi et al. (2011) and Joshi et al. (2013) concluded that myringoplasty is a safe and effective surgical procedure in achieving intact tympanic membrane and to improve the hearing loss. Sergi et al. (2011), found that 88.6% of participants showed anatomical success post-surgery (closure of perforations) and functional success (improved hearing) was obtained in 73.5% of the participants post-surgery which was comparable to the literature. Similarly Joshi et al. (2013) found that the graft take rate in case of posterior and anterior perforation were 88.89% and 84.21% respectively. In terms of hearing function, an improvement in the mean air-conduction post-operatively was observed as well as improved air-bone gap post-operatively (Joshi et al., 2013).

**Hearing outcome post myringoplasty.** Several studies have reported that the most popular techniques for closure of a tympanic membrane perforation include either the temporalis fascia

underlay approach or the butterfly cartilage inlay approach (Mauri, Neto, & Fuchs, 2001; Becker & Lubbe 2011 & Demirpehlivan et al., 2011; Chhapola & Matta, 2012). Due to the ease of the accessibility of the temporalis fascia grafts at the surgical site and the successful closure of the tympanic membrane in 90% of normal ventilated middle ears by insertion of membranous materials, temporalis fascia grafts have been used for many years for reconstruction of the tympanic membrane (Demirpehlivan et al., 2011). However, healing has been reported to have a much poorer prognosis in cases of tubal dysfunction, adhesive processes, tympanic fibrosis, smoking, bilateral disease, and where defects of the entire tympanic membrane exist (Demirpehlivan et al., 2011). In these cases, cartilage tympanoplasty has been hailed to promise a better prognosis than fascia or perichondrium; with the effect argued to probably be due to its higher mechanical stability under negative pressure changes in the middle ear (Demirpehlivan et al., 2011).

Clinical studies comparing outcomes of tympanic membrane reconstruction with fascia and cartilage show contradictory results (Kazikdas, Onal, Boyraz, and Karabulut, 2007). However, it is postulated that the clinical results might be misleading because of confounding variables such as revision surgery, variances in size and location of the perforation, a draining ear at the time of surgery, bilateral disease, ossicular discontinuity or cholesteatoma in the study group (Demirpehlivan et al., 2011). Hearing outcomes also vary considerably in the literature. Gerber, Mason and Lambert (2000) compared temporalis fascia and cartilage tympanoplasty in patients undergoing primary surgery and found no significant difference in hearing outcome post operatively. Chhapola and Matta (2012) found that tragal cartilage perichondrium seems to be an ideal graft material for tympanic membrane in terms of postoperative healing and acoustic properties as it can easily withstand negative middle ear pressure; which may have contributed to the development of otitis media and significantly affects healing outcomes in postoperative period. Furthermore tragal cartilage; being composed of collagen type II; is also physiologically similar to the nature of the tympanic membrane (Chhapola & Matta, 2012). Mauri et al. (2001) found that the

audiometric results following inlay cartilage tympanoplasty or underlay tympanoplasty were similar. Inlay butterfly cartilage tympanoplasty did not require general anaesthesia, was less expensive, and more comfortable for the patient (Mauri et al., 2001).

Numerous studies have reported outcomes of myringoplasty performed in district hospitals and by surgical outreach teams in developing countries and remote indigenous communities. A few however have demonstrated promising results (Makaya 2006; Homoe, Slim & Bretlau 2008; Horlbeck, Boston & Baloug, 2009; Snidvongs, Vatanasapt, Thanaviratananich, 2009). However, some of these studies have not included audiological outcomes (Horlbeck et al., 2009) or were limited by small sample sizes (Snidvongs et al., 2009), while others have reported disappointing outcomes that are significantly poorer than those achieved at tertiary institutes in developed nations (Mak, MacKendrick & Bulsara, 2004). The reasons why outcomes of surgery for chronic otitis media remain poor in some developing countries and remote indigenous settings are not well understood (Triolo & O'Leary, 2010). Factors such as the nature of the disease, the availability of peri-operative care, the general health of the patient and the level of surgical expertise have all been considered as potentially relevant (Triolo & O'Leary, 2010).

Shrestha and Sinha (2006) investigated hearing improvement after myringoplasty within ten weeks following surgery in a developing country. Results indicated that air-bone gaps improved significantly postoperatively as only 22% of patients presented with an air-bone gap after surgery. In that study; 78% of patients had their hearing gain exceeding 15dB after surgery (Shrestha & Sinha, 2006). Therefore this study concluded that myringoplasty is a beneficial procedure for hearing improvement. Another study was conducted by Shaikh, Onali, Shaikh and Rafi (2009) in a developing country, where factors influencing the success of myringoplasty by underlay technique; such as age, gender, cause, site and size of tympanic membrane perforation and pre and postoperative audiogram results were investigated. Results suggested that there was no significant

effect of age, gender and size of perforation on closure. Furthermore all patients with traumatic perforation, in that study, had successful closure and the mean air-conduction thresholds improved postoperatively, while the mean bone-conduction thresholds remained the same pre & postoperatively (Shaikh et al., 2009). This study therefore concluded that the underlay technique for myringoplasty is an effective method for closure of uncomplicated tympanic membrane perforations and patients with a traumatic perforation have a high success rate as post-operatively these patients have recorded improvement in hearing on pure tone audiogram (Shaikh et al., 2009).

One published study by Becker and Lubbe (2011), within the South African context at the Groote Schuur Hospital in Cape Town; which investigated the success rate of myringoplasty surgery and presumed prognostic factors was found. In this study, a record review of patients' medical information was conducted from January 2005 to December 2009. Prognostic factors such as the rank of the surgeon, size and location of the perforation, graft used (cartilage or temporalis fascia) and whether it was a revision procedure, were evaluated. Where possible in this study, the audiometric gain following surgery was also calculated. Patients were followed up at six weeks, three months and six months post-surgery. The operation was considered to have failed if a perforation was still present at 3 months. The size and location of the perforation was determined via microscopic evaluation, and the pure tone average was calculated before and after surgery. The overall success rate found in that study was 71%; and this was seen to compare well with figures quoted in the literature (Becker & Lubbe, 2011). The average improvement in pure tone average was reported as 12.4 dB, with 64% of patients achieving socially acceptable hearing levels postoperatively. The success rate in patients who had revision surgery was 72.4%. In that study, none of the prognostic factors assessed were statistically significant ( $p > 0.05$ ). Even though multiple studies have been conducted evaluating the influencing factors to myringoplasty, many of these remain unresolved (Becker & Lubbe, 2011).

**Summary and rationale.** Literature reviewed has demonstrated that enough research has been done on the success rate and efficacy of myringoplasty surgery in terms of audiological improvement worldwide; more so in developed countries than in developing countries. Outcome of surgery is dependent on many factors which vary substantially in developing and developed countries as discussed. Although it has been demonstrated that hearing does improve postoperatively in developing countries, the exact factors determining the outcome of surgery and predictors of hearing improvement in the current context remain unknown. Thus the current study aimed to describe hearing function pre and post-operatively in a group of patients aged 18-63 who had undergone Type 1 tympanoplasty surgery: myringoplasty at the Chris Hani Baragwanath and Charlotte Maxele Academic Hospitals in Gauteng within the last six years; with some focus on the possible influencing factors.

## Chapter 2

### Methodology

#### Aims of the study

*Primary aim.* The primary aim of the study was to describe hearing function pre and post-operatively in a group of adults who had undergone type 1 tympanoplasty surgery, i.e. myringoplasty at academic hospitals in Gauteng.

#### *Specific aims*

- To compare pre and post-operative hearing function.
- To explore the possible influence of HIV/AIDS on hearing outcome post- surgery.
- To assess if the type of surgical technique has an influence on hearing outcome post-surgery.

#### Research objectives

- a) What are the changes in hearing function post type 1 tympanoplasty, i.e. myringoplasty?  
And are these changes in hearing statistically significant?
- b) Does HIV/AIDS have an influence on hearing outcome post-surgery? And are these changes statistically significant?
- c) Does the type of surgical technique have an influence on hearing outcome post-surgery?  
And are these changes statistically significant?

**Research design.** A quantitative approach retrospective record review design was used as quantitative studies are primarily involved in predicting causal relationships and describing characteristics of a sample (Neill, 2007). Data were collected through a retrospective record review, with no manipulation of variables whereby the researcher used existing documents to analyse variables across time or condition (Devlin, 2006). The reasons for conducting a retrospective record review is that it is relatively inexpensive as it is less resource intensive than prospective research designs (Panacek, 2007). Furthermore retrospective review studies can generally be conducted at times of convenience to the researcher; and they allow for possible association to be quickly evaluated (Panacek, 2007). Doing research based on available data is said to have higher authenticity, greater ecological validity and can be useful in exploring data focused on establishing trends for future more formal empirical investigation (Panacek, 2007).

There are however also limitations and potential errors of retrospective reviews (Panacek, 2007), which have been acknowledged as limitations of the current study. Firstly in retrospective record review designs; data may be difficult to locate, may not be complete or accurate and there may be challenges in codifying data in a systematic fashion (Panacek, 2007). The current researcher experienced difficulty in locating surgical data at one of the chosen hospitals. Once this surgical data was obtained; locating pre and post-surgical audiological data was a tedious procedure due to inadequate filing systems. Several audiograms were incomplete and it was found that at times standard audiological diagnostic testing protocols were not routinely implemented. This in turn affected the sample size as many of the participants needed to be excluded from the study due to missing audiological information.

### **Description of participants**

**Sample.** The total sample comprised of fifty-two participant files, twenty males (38%) and thirty-two females (62%), with ages ranging from 18-63years with a mean age of 39.9 years. Four

of the participants' ages were unknown and therefore excluded in the age range and mean calculations – although they were known to have been adults. Right, left or bilateral surgery was also documented as this affected the sample size per aim ( $n$ ) in the data analysis. For participants who had bilateral surgery each ear was considered separately. All participants of the selected files had undergone type 1 tympanoplasty, i.e. myringoplasty surgery in the last six years; however the type of myringoplasty was not known for all participants.

***Participant selection criteria.*** Participants in the files selected had to meet the following criteria in order to be included in the study:

- Participants needed to have undergone type 1 tympanoplasty surgery, myringoplasty in the last six years at one of the two chosen tertiary hospitals.

The reason for selecting participant files only from the last six years was that after conducting the pilot study the most available data was from the past six years. Prior to this there were considerable amounts of missing audiological and surgical data.

- Participants needed to be between 18-63 years of age.

Although it is known that the normal decline in hearing sensitivity begins in the sixth decade (prebycusis); the data yielded consisted of a few patients between the ages of 60-63 years. The researcher thus decided to include participants until age 63 to increase the sample size for more statistically significant results.

- HIV status of the participants needed to be known; although this was not a strict exclusionary criterion.

For some participants the HIV status was unknown due to missing biographical information. These participants were included in certain aspects of the data analysis as HIV status was not the only variable considered in this study. However when investigating whether HIV status has

an influence on hearing outcome post myringoplasty surgery these participant files with missing known HIV status were excluded.

- Both pre and post-surgery audiograms had to be available on each participant.
- Information on the type of surgery needed to be recorded in the files. Two types of surgical techniques were included in the study i.e. butterfly cartilage inlay technique and fascia underlay technique.

The following criteria were used when excluding participants from certain sections of the inferential data analysis of the study:

- Patients not between the ages 18-63 years.
- Unknown surgical technique
- Unknown HIV status
- Missing audiological information – the minimum information that was required was air and bone-conduction thresholds at 500Hz, 1000Hz, 2000Hz and 4000Hz in the ear/s operated on pre and post surgery.

**Sampling procedure.** The sampling procedure that was adopted was purposive sampling technique. According to Halloway and Wheeler (2010), purposive sampling is criterion based and non-probalistic. This means that the researcher can adopt certain criteria to choose a specific group and setting to be studied (Halloway & Wheeler, 2010); appropriate for the current study. Data gathering is crucial in research, as the data is meant to contribute to a better understanding of a theoretical framework (Bernard 2002). It then becomes imperative that selecting the manner of obtaining data and from whom the data will be acquired be done with sound judgement, especially since no amount of analysis can make up for improperly collected

data (Bernard 20002). Thus, the purposive sampling technique adopted in the current study, was a deliberate choice due to the qualities it possesses (Tongco, 2008); and due to the fact that in its non-random nature; it does not require underlying theories or a set number of participants; thus the researcher decides what needs to be known and sets out to find people who can and are willing to provide the information by virtue of knowledge or experience (Bernard 2002; Lewis & Sheppard 2006); and in the current study – patients’ surgical and audiological records.

**Sample size.** The researcher aimed for a large sample size, greater than 60 participants so that the data could allow for statistically significant calculations to be conducted; in order to be able to draw conclusive conclusions (Halloway & Wheeler, 2010). Large sample sizes also ensure that the results obtained can be generalized across the population. The power of analysis has been considered with regards to the sample size of the current study. The power of analysis suggests that the larger the sample size the greater the power of analysis (Smith, 2004). Due to the limitations of a retrospective record review the anticipated sample size was not obtained due to unforeseen situations during the data collection process; nonetheless a large enough sample size was secured.

The total sample size ( $N$ ) comprised of 52 participant files, of these 10 participants had undergone bilateral surgery with each ear being considered separately; thus a total of 62 ears were investigated. However not all participants could be included in the inferential analysis of the research questions due to some presenting with missing audiological data in the participant files; thus the sample size per research question ( $n$ ) varied.

## **Data collection**

### ***Pilot study***

*Rationale for pilot study.* A pilot study is a pre-study conducted on a smaller scale that aims to assess the logistics of the main study and gathers information prior to a larger study; in order to

improve the latter's quality and efficiency (Teijlingen, Rennie, Hundley, Graham, 2001). A pilot study can reveal deficiencies in the design of a proposed experiment or procedure and these can then be addressed before time and resources are expended on large scale studies (Teijlingen et al., 2001). One of the advantages of conducting a pilot study is that it might give advance warning about where the main research project could fail, where research protocols may not be followed, or whether proposed methods or instruments are inappropriate or too complicated (Teijlingen et al., 2001).

For the purposes of the current study the researcher conducted a pilot study to achieve the following objectives:

- Develop and test the adequacy of the data collection tool
- Assess the feasibility of a (full-scale) study
- Design a research protocol
- Assess whether the research protocol is realistic and workable
- Establish whether the sampling frame and technique were effective
- Assess the likely success of proposed recruitment approaches
- Identify logistical problems which might occur using proposed methods
- Estimate variability in outcomes to help determine sample size
- Collect preliminary data
- Determine what resources were needed for the planned study
- Assess the proposed data analysis techniques to uncover potential problems

- Develop research questions and research plan

*Methodology for pilot study.* The prospective hospitals' audiology and ear nose and throat (ENT) departments were contacted telephonically and the availability of audiological and surgical records was established. Thereafter a list of 137 patients was obtained from one of the hospitals. The list consisted of all patients who underwent myringoplasty surgery between 2009 and 2012 and this was obtained from an ENT specialist at the hospital. A total of 73 (42%) of the patients were older than 18 years and thus extracted from the available list as part of the study. Thus 12 participant files (16%) of this group was randomly selected for a pilot study ( $Np=12$ )

#### *Results of the pilot study*

Table 1

*Demographic information of pilot study participants ( $Np=12$ )*

<b>Gender</b>	Male	5 (42%)	
	Female	7 (58%)	
<b>Age</b>	Range	20-50 years	
	Mean	35years	
<b>Ear in which surgery was performed</b>	<b>Right</b>	<b>Left</b>	<b>Bilateral</b>
	4	3	2
<b>HIV Status</b>	<b>Positive (%)</b>	<b>Negative (%)</b>	
	2 (17%)	10 (83%)	
<b>Type of surgical technique</b>	F (fascia underlay)	1 (8.33%)	
	C (butterfly cartilage inlay)	10 (83.33%)	
	U (unknown surgical technique)	1(8.33%)	

**KEY:**  $Np$  = number of participants for pilot study

An interview was conducted with the ear nose and throat (ENT) specialist to determine if the chosen information that the researcher wished to review would answer the proposed research questions and be of research value.

a. Biographical data

*Age of the patient:* All participant ages were known. The ear nose and throat (ENT) specialist stated older patients have poorer prognosis for hearing improvement especially when a pre-morbid hearing loss exists; this correlates with the known natural effects of the aging hearing system and presbycusis.

*Gender of the patient:* Gender was known for all participants. The ear nose and throat (ENT) specialist stated that this had no effect on outcome however may be used for statistical purposes.

*HIV status:* HIV status was known for all participants. The ear nose and throat (ENT) specialist explained that all patients that were on anti-retroviral treatments (ARVs) and that “look healthy” were operated on. He further stated that this variable may potentially affect outcome of hearing post-operatively due to the effects of the HIV virus on the auditory system. Across the literature reviewed HIV status has never been investigated as a possible variable that may influence hearing outcome post myringoplasty. Thus the results of the current study yielded valuable information regarding the changes in hearing post-surgery and the possible effect of HIV status and type of surgical technique on hearing outcome. Therefore the findings of the current study are of particular relevance to audiologists and ear nose and throat (ENT) specialists in South Africa in terms of predicting and monitoring hearing outcome post-surgery as well as in the overall management of participants requiring myringoplasty.

*Cause of middle ear pathology:* The ear nose and throat (ENT) specialist stated that cause of middle ear pathology would potentially have no influence on hearing outcome as patients are ordinarily not operated on unless the cause of the middle ear pathology has been resolved. Literature has shown that the cause of the middle ear pathology has no influence on the success rate of myringoplasty in terms of anatomical and functional outcome (Westerberg, Harder, Magnuson, Westerberg & Hyden, 2011).

*Ear which was operated on:* Right, left or bilateral surgery was known for each participant however unilateral or bilateral surgery would not affect the outcome of hearing changes post-operatively. This did however affect the sample size particularly for the descriptive clinical analysis as each ear of the participants with bilateral surgery were considered separately thus increasing the sample size ( $n$ ) for this analysis.

The ear nose and throat (ENT) specialist suggested considering the type of myringoplasty technique; as this may have an influence on hearing outcome based on unpublished evidence from the hospital's clinic. Thus a comparison of type 1 myringoplasty, i.e. fascia underlay and butterfly cartilage inlay was conducted. For the purpose of this study butterfly cartilage surgery was referred to as overlay or inlay technique is where the temporal fascia is harvested (ENT Surgeon, n.d.) and fascia underlay surgery was described as the technique which involves use of the temporalis fascia which is grafted (ENT Surgeon, n.d.)

#### b. Audiological data

##### *Tympanometry results*

Table 2

*Availability of tympanometry results (Np =12)*

Pre		Post	
Did not test due to perforation	6	DNT – reasons not noted	4
No records	4	Complete records	3
Only type (no pressure, compliance and ECV)	1	No records	5
Only info for one ear	1		

**KEY:**  $Np$ = number of participants for pilot study, **Pre**= pre-operatively, **Post**= post-operatively, **DNT**= did not test,

**ECV**= ear canal volume

As seen from Table 2, the availability of tympanometry results was limited. Understandably; there were no complete tympanometry results obtained pre-operatively and only three complete

tympanometry results available post-operatively due to the fact that participants would generally have perforated tympanic membranes pre-operatively. This suggested that potential sample size for tympanometry results would be relatively small.

*Air-conduction (AC) testing results*

Table 3

*Availability of air-conduction results (Np=12)*

Pre		Post	
Complete audiogram	8	Complete audiogram	7
No records	4	No records	5

**KEY:** *Np*= number of participants for pilot study, **Pre**= pre-operatively, **Post**= post-operatively

As seen in Table 3, most of the participants (8 out of 12) had complete air-conduction audiograms pre operatively and most participants (7 out of 12) had complete air-conduction audiograms post operatively. This suggested that for the main study; a relatively large sample of participants with both pre and post air-conduction thresholds would be expected.

*Bone-conduction (BC) testing results*

Table 4

*Availability of bone-conduction results (Np=12)*

Pre		Post	
Complete audiograms	8	Complete audiograms	6
No records	4	No records	5

**KEY:** *Np*= number of participants for pilot study, **Pre**= pre-operatively, **Post**= post-operatively

As seen in Table 4, most of the participants (8 out of 12) had complete bone-conduction thresholds pre operatively and half of the participants (6 out of 12) had complete bone-conduction

thresholds post operatively. This suggested that pre operative bone-conduction results were more readily variable than post operative bone-conduction results.

*Speech Reception thresholds (SRT) testing results*

Table 5

*Availability of speech reception threshold results (Np=12)*

Pre		Post	
Complete SRT	7	Complete SRT	7
No records	5	No records	5

**KEY:** *Np*= number of participants for pilot study, **Pre**= pre-operatively, **Post**= post-operatively, **SRT**= speech reception threshold

As seen in Table 5, most of the participants (7 out of 12) had complete speech reception thresholds pre operatively and a similar number (7 out of 12) had complete speech reception thresholds post operatively. This was a good indicator of available speech reception threshold results in the larger sample size.

*Discussion and conclusion of pilot study results.* Findings from the pilot study guided the researcher to make amendments to the data collection tool such as variables to excluded (cause of middle ear pathology) and include (type of surgical technique). The adequacy of the data collection tool was established and necessary adaptations were made. The feasibility of a (full-scale) study was confirmed and the research protocol proved to be realistic and workable. The sampling frame and technique was fairly effective. Logistical problems were identified and problem solved. Variability in outcomes was established which assisted in determining and predicting a sample size. Some preliminary data was collected and resources that were needed for the planned study were identified. The proposed data analysis techniques to uncover potential problems were assessed. The research questions were then amended and a research plan finalized.

***Data collection for current study.*** The method of data collection was a retrospective data review. The researcher documented via tabulation (see APPENDIX A) the following biographical information and pre-post medical and audiological findings:

a. Biographical and medical information

*Age and gender of participant:* This assisted the researcher with pertinent biographical information and was used for descriptive statistics (mean and age range) purposes. Gender was also considered when comparing the mean change in hearing function (dB) at six air-conduction and four bone-conduction thresholds in male and female participants respectively.

*Ear in which surgery was performed:* Right, left or bilateral surgery was known for each participant however unilateral or bilateral surgery would not affect the outcome of hearing changes post-operatively. This did however affect the sample size particularly for the descriptive clinical analysis as each ear of participants with bilateral surgery were considered separately thus increasing the sample size ( $n$ ) for this analysis.

*Technique of surgery:* This provided important information regarding whether or not the type of surgical technique had an impact on outcome of surgery; specifically relating to hearing outcomes.

*HIV status:* Known HIV status allowed the researcher to document, compare and finally draw conclusions regarding the possible effect of HIV/AIDS on hearing changes post-surgery.

b. Audiological information

*Tympanometry results:* It was important to determine the middle-ear status, as middle ear pathology or abnormalities of the middle ear produce conductive losses, thereby affecting the bone-conduction thresholds and, in turn, the testing results (Martin, 1997). Tympanometry in isolation is limited and should not be used to make assumptions regarding hearing sensitivity. Thus, the

tympanogram was analysed in conjunction with the severity and configuration of the hearing loss (obtained through pure-tone audiometry) (Shanks & Shohet, 2009). Tympanometry results were classified according to the existing Jerger system for classification of types A-As, Ad, B, C and D with the type A regarded as normal middle ear functioning and all other types as abnormal (Katz, 1994; Campbell, 2002). The Jerger system was implemented in the current study because it is the most commonly used classification for tympanograms.

The following range of norms was used; ear canal volume ( $0.2\text{cm}^3$  to  $2.0\text{cm}^3$ ), compliance peak ( $0.28\text{cm}^3$  to  $1.8\text{cm}^3$ ) and pressure peak ( $-150\text{daPa}$  to  $50\text{daPa}$ ) (Valente, 2009).

*Air-conduction and bone-conduction thresholds:* The primary purpose of air-conduction (AC) and bone-conduction (BC) audiometry is to describe the degree and type of hearing loss (Harrell, 2002). The various degrees of hearing loss are reported in terms of average thresholds at three frequencies, 500Hz, 1000Hz and 2000Hz; which represent the most important frequencies for understanding speech and therefore holds the most promise for estimation of the degree of communication difficulty that particular hearing loss is likely to cause (Harrell, 2002). Khoza-Shangase (2010) reported that findings have indicated that the audiometric data trends imply worsening hearing loss in high frequencies in patients with HIV/AIDS. Khoza and Ross (2002) assert that the configuration of the hearing loss in HIV disease may not be frequency-range-specific, but may rather involve all frequencies either unilaterally or bilaterally; thus the researcher thus included air-conduction thresholds at 4000Hz and 8000Hz.

Pure tone threshold measurement provides a convenient, reliable way to quantify auditory sensitivity (Harrell, 2002). Pure-tone audiometry is the foundation for a comprehensive audiological assessment (Valente, 2009). Sounds are also heard through bone-conduction, when vibrations elicit compressions in the skull bones and cause disturbances in the ossicular chain and inner ear; thus bone conduction testing is vital to comprehensive diagnostic evaluation (Valente, 2009). Air-bone

gaps (ABGs) at 500Hz, 1000Hz, 2000Hz and 4000Hz were calculated. According to Valente (2009), normal hearing thresholds for adults are recorded at 25dB or less. Air-bone gaps are considered to be significant when greater than or equal to 10dB (Valente, 2009).

*Speech reception threshold (SRT):* The purpose of speech reception threshold testing is threefold. It is a check of the pure tone air-conduction threshold result, it provides an index of hearing sensitivity for speech; and lastly it serves as the baseline for determining the presentation levels for supra-threshold speech recognition tests (Brandy, 2002). Pure tone averages should correlate within 10dB of the speech reception threshold for each ear (Valente, 2009). Speech reception threshold results for each ear were documented pre and post operatively. This audiological test of hearing function was selected as many studies used speech reception threshold results to assess and measure the hearing outcome post-operatively (Gerber et al., 2000). To ensure reliability of the results obtained; adherence to the cross-check principle was done where all tests (air-conduction, bone-conduction and speech reception threshold results) were correlated to draw a final conclusion was done. This ensured greater reliability of the data collected. Test-retest variability was further employed to ensure repeatability. Repeatability or test–retest reliability is the variation in measurements taken by a single person or instrument on the same item and under the same conditions (Trochim, 2006). A less-than-perfect test–retest reliability causes test–retest variability. A measurement may be said to be repeatable when this variation is smaller than some agreed limit (Trochim, 2006). The researcher ensured the following conditions were fulfilled in the establishment of repeatability; the same measurement procedure, the same observer, the same measuring instrument, used under the same conditions, the same location and repetition over a short period of time.

**Data analysis and statistical procedures.** Due to the fact that the current study was exploratory in nature, there were no prior hypotheses, and data were analysed using both descriptive

and inferential statistics. Descriptive statistics aims to describe what is or what the data shows whereas inferential statistics attempts to reach conclusions that extend beyond the immediate data alone (Trochim, 2006). The data collected indicated to the researcher which statistical tests to employ in order to answer the specific research questions of the study.

***Descriptive statistics.*** This entailed a description of the demographical and medical presentation of the participants. A series of tables were created depicting the distribution of participants by the following variables (age, HIV status, type of surgical technique and ear surgery was performed on); in order to determine the number of participants ( $n$ ) for each variable.

Audiological data were described using descriptive statistics thus changes in tympanometry post-operatively was analysed and the influence of HIV status as well as type of surgical technique was described from a clinical point of view. Tympanometry results were classified into three categories, i.e. improved, deteriorated and no change using the Jerger classification system. Data were analysed descriptively by describing trends in tympanometry changes in relation to HIV status and type of surgical technique and inferentially using the Kolmogorov-Smirnov two sample test to inferentially determine if the changes in tympanometry results were dependent on a) HIV status and b) type of surgical technique.

Air-conduction threshold and bone-conduction threshold results were described using descriptive statistics in terms of degree of hearing loss, type of hearing loss, mean hearing gain per frequency and a pre and post-operative comparison of the air-bone gap. Thereafter inferential statistics was utilised adopting a two-tailed paired (dependent) t-test to assess the changes in hearing function pre and post operatively. Thereafter the influence of HIV status and type of surgical technique on hearing outcome was investigated. The mean comparison test of hypothesis for paired data was used to assess the influence of HIV status and type of surgical technique on hearing threshold outcomes.

Speech reception thresholds were recorded in decibels (dB) and a descriptive analysis was conducted to determine pre and post-operative differences in speech reception thresholds.

**Reliability and validity.** The reliability of an instrument refers to the stability of the measurement (Vos, Strydom, Fouche & Deloport, 2005). Furthermore reliability refers to whether data collected was measured under the same circumstances (O’Leary, 2004). Ensuring reliability in the current study allowed the researcher to capture and interpret meaningful data (Creswell, 2003). Reliability for the current study was ensured by examining inconsistencies that cause error. In the current study the two common sources of error; observer error and environmental error (Gravetter & Forzano, 2006) were carefully monitored. Observer error may develop from simple human error when collecting data. The researcher thus re-checked all data collected; and also had an independent verification of the data by the research supervisor and statistician. Environmental changes are common during data collection; and may affect the data collection process (Gravetter & Forzano, 2006). The goal of the study was to collect all the data within consecutive days in the same environmental conditions thus reducing environmental error.

Validity of an instrument refers to the ability of the instrument to measure what it was intended to measure accurately (Vos et al., 2005). The researcher employed principles of predictive and construct validity to ensure that the data collection procedure measured what it claimed to measure. Most theories make predictions about the constructs they contain; specifically theories predict how different values of a construct affect behaviour (Gravetter & Forzano, 2006). For the current study the researcher used predictive measures to ensure that the data collection process is valid by comparing data collected to norms. For most variables that the researcher was likely to encounter; numerous studies have already examined similar variables. Previous research has thus demonstrated how specific variables behave; the researcher thus attempted to demonstrate

that those variables behave in a similar manner in the current study in order to establish construct validity and thus increasing generalisability of the findings.

Due to the nature of the current study, a retrospective record review, performing audiological testing, controlling for patient variables and ensuring equipment calibration was not possible to control; but was assured by the research site. It was confirmed that the above mentioned procedures and variables were monitored and performed thoroughly as part of best practice standards by qualified audiologists.

**Ethical considerations.** “Researchers have two basic categories of ethical responsibility; (1) responsibility to ensure the welfare and dignity of individuals, both human and non-human, who participate in research studies and (2) responsibility to ensure that public reports of their research are accurate and honest” (Gravetter & Forzano, 2006, pp 90).

Approval from the Medical Research Ethics Committee at the University of the Witwatersrand was obtained prior to commencing the data collection (Protocol number M121012). See APPENDIX B for ethical clearance certificate.

The researcher ensured ethical standards were met by;

**Obtaining informed consent.** The principle of informed consent requires the researcher to provide all available information about a study so that the individual can make a rational, informed decision to participate in the study (Gravetter & Forzano, 2006). Due to the nature of the current study informed consent was obtained from the Chief Executive Officers (CEOs) of the hospitals as well as Heads of Departments (HODs) of the relevant departments to review surgical and audiological data; and not from participants themselves. Thus before the study commenced permission letters were given to the CEOs of the hospitals in order to obtain formal written or verbal permission to use data from the hospital (APPENDIX C) and written permission was

obtained (APPENDIX D) from the CEO of one hospital and verbal permission from the second hospital. Thereafter a letter was sent to the head of Department (HOD) of Speech Therapy and Audiology at the respective hospitals (APPENDIX E) and to the HOD of ENT theatre at the respective hospitals (APPENDIX F) in order for written consent to be secured to access audiological information and surgical information from the departments respectively. Verbal permission was obtained from both the Speech Therapy and Audiology departments from both hospitals and one ENT theatre department also provided verbal permission only. The second ENT theatre department provided written consent (APPENDIX G).

***Ensuring confidentiality and anonymity.*** Confidentiality ensures that the information obtained from a research participant is kept secret and private (Gravetter & Forzano, 2006). Furthermore the enforcement of confidentiality benefits both the participants and the researcher. Anonymity is the practice of ensuring individual names is not directly associated with information or measurements obtained from that individual (Gravetter & Forzano, 2006). Confidentiality and anonymity of the participants in the current study were maintained by implementing a research coding system instead of using participant names and hospital numbers.

## Chapter 3

### Results

The results of the study are presented according to the aims and objectives of the study. The results are described firstly in terms of the total sample size ( $N$ ) and then according to sub-samples ( $n$ ) which describe specific aims of the study that were investigated. A detailed description of the participants pertaining to each of these smaller sample groups was provided.

#### **Results of the total sample ( $N$ )**

*Description of the participants.* The total sample comprised of 52 participant files which consisted of 20 males (38%) and 32 females (62%), with ages ranging from 18-63years with a mean age of 39.9 years. Four of the participants' ages were unknown and therefore excluded in the age range and mean calculations. Right, left or bilateral surgery was also documented as this affected the sample size per aim ( $n$ ) in the data analysis. For participants undergoing bilateral surgery each ear was considered separately. Although the sample size for the current study was deemed appropriate; it was relatively small in comparison to studies of a similar nature (Gerber et al., 2000; Becker & Lubbe 2011; Sarker et al., 2011; Joshi et al., 2013). Large sample sizes allow for results to be generalized across the population; an acknowledged limitation of the current study. Due to the limitations of a retrospective record review the anticipated sample size was not obtained due to unforeseen circumstances during the data collection process; such as missing data. The sample size per research question and sub-aim was different as there was a variety of different missing data per participant in different areas and stages of the data collection process. Regardless of the sample size limitations; a study of this nature has never been conducted in the selected context and thus this research may serve as a baseline for future research pertaining to this area of audiology in this context.

Table 6

*Demographic information of participants (N=52)*

Variable	Factor	Results	
Gender	Male	38%	
	Female	62%	
Age	Range	18-63years	
	Mean	39.9years	
Ear in which surgery was performed	Right	Left	Bilateral
	26	16	10

KEY: N= total number of participants for current study

The sample was then divided according to variables that would potentially affect hearing outcomes such as HIV status and type of surgical technique. Out of the 52 participant files it was found that 37 (71%) of the participants were HIV negative, 11 (21%) were HIV positive and four (8%) participants had an unknown HIV status. Two types of surgical techniques were investigated. Out of the 52 participant files it was determined that seven (14%) of the participants underwent the fascia underlay technique (F), 34 (65%) underwent the butterfly cartilage inlay technique (C) and for 11 (21%) of the participants the type of surgical technique was unknown.

Table 7

*Number of participants (n) per variable investigated*

Variable	Factor	%	n
HIV status	Positive	21%	11
	Negative	71%	37
	Unknown	8%	4
Type of surgical technique	F (fascia underlay)	14%	7
	C (butterfly cartilage inlay)	65%	34
	U (unknown surgical technique)	21%	11

KEY: N= number of participants for current study

As seen in Table 7 the majority of the participants were HIV negative (71%) and 65% of the participants underwent butterfly cartilage inlay surgical technique.

### **Research objective A**

#### ***What are the changes in hearing function pre and post type 1 tympanoplasty:***

***myringoplasty?*** The changes in hearing function were described using descriptive statistics and inferential measures. Assumption of normality was tested for in order to determine which summary measure (mean or median) would be appropriate to the data. Testing for the validity of this assumption was performed graphically; by means of a histogram and the Skewness-Kurtosis test for normality under the null hypothesis that the observations of the mean differences were normally distributed at 5% level of significance. Results showed that mean differences at all frequencies were normally distributed hence no evidence of significant deviation was observed. Descriptive analysis was carried out using means to summarise age and frequency and percentage for categorical variables (gender, HIV and surgical technique). Separate testing was also implemented using the paired t-test at sub-group level in order to identify and compare change in hearing function between groups. All statistical significance was reported at 5% alpha level. A mean comparison test for paired data was used to test for significant difference between group mean changes (for example: HIV positive versus HIV negative participants).

All analyses were carried out in Stata version 12.1

### **Tympanometry**

***Description of the participants.*** Given the total number of participant files ( $N=52$ ), 16 of the participants files had missing middle ear results due to missing pre and/or post tympanometry results and therefore 36 tympanometry results (including four bilateral surgeries) could be included in the analysis. For the four bilateral surgeries each ear was considered and analysed separately. Ten

(28%) of the results showed an improvement in middle ear functioning. Six (17%) showed a deterioration in middle ear functioning and 20 (55%) showed no change in middle ear functioning. These results are depicted in Figure 1.

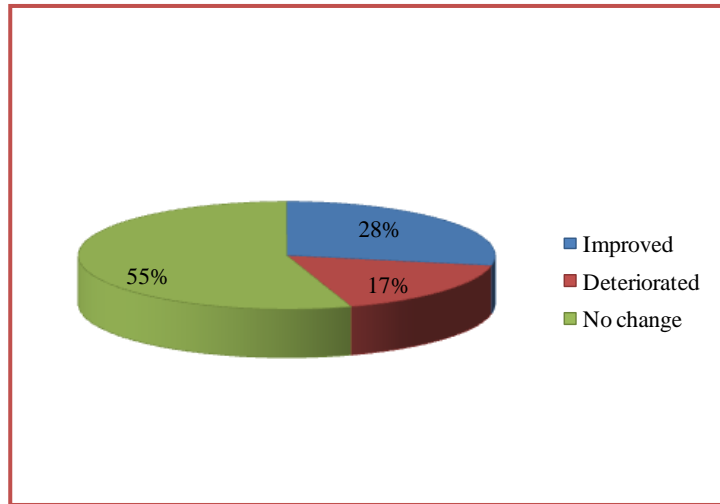


Figure 1. Tympanometry results post-operatively ( $n=36$ ).

Of the 10 ears that showed an improvement in middle ear functioning; two were of participants who were HIV positive, seven were HIV negative and one had an unknown HIV status. The majority of these participants underwent butterfly cartilage inlay technique of surgery (70%); which suggests that given the current sample size this type of surgical technique yielded the best middle ear functioning in HIV negative participants post surgery.

Using inferential statistics the influence of two variables (HIV status and type of surgical technique) were investigated to assess the outcome of tympanometry results post surgery using the Kolmogorov-Smirnov two sample test. This test was selected because the two groups are independent of each other. In practical research, there are needs to test hypothesis about the agreement between the underlying distribution of a sample and a hypothetical distribution (Dong, 2013). This type of test is frequently labelled as “goodness-of-fit” test, i.e. checking if data are normally distributed (Dong, 2013). Furthermore, there are two-sample tests about the hypothesis of the agreement of the underlying distributions of two samples. The K-S goodness-of-fit test was developed by the work from Smirnov (1939), Scheffe (1943), and Wolfowitz (1949).

### VARIABLE 1: HIV STATUS

Table 8

*HIV Status versus tympanometry result*

	Deteriorated functioning	No change in functioning	Improved functioning	<i>n</i>
<b>HIV +</b>	1	12	2	15
<b>HIV -</b>	5	7	7	19
<b>HIV U</b>	0	1	1	2

**KEY:** *n* = number of participants, **HIV+** = HIV positive, **HIV-** = HIV negative, **HIV U** = Unknown HIV status

HIV status unknown (*n*=2) was too small to be included in the analysis and therefore excluded. Using the Kolmogorov-Smirnov two sample test; results indicated that there are no statistically significant differences in the tympanometry results due to HIV status and therefore HIV does not influence outcome of tympanometry results post-surgery.

### VARIABLE 2: TYPE OF SURGICAL TECHNIQUE

Table 9

*Type of surgical technique versus tympanometry result*

	Deteriorated functioning	No change in functioning	Improved functioning	<i>n</i>
<b>OP1</b>	3	13	7	23
<b>OP2</b>	2	2	2	6
<b>OP3</b>	1	5	0	6

**KEY:** *n* = number of participants, **OP1**= C (butterfly cartilage inlay), **OP2**= F (fascia underlay), **OP3**= U (unknown surgical technique)

OP3 (*n*=6) was too small to be included in the analysis and therefore excluded. Using the Kolmogorov-Smirnov two sample test; results indicated that there are no statistically significant

differences in the tympanometry results due to type of surgical technique and therefore type of surgical technique does not influence outcome of tympanometry results post surgery.

Thus there were no statistically significant differences in the tympanometry results due to;

1. HIV status,
2. Type of surgical technique

as per the Kolmogorov-Smirnov two sample test.

### **Type of hearing loss**

*Description of the participants.* Out of the 52 participant files, 36 participant files had complete audiograms (both pre and post-operatively), 12 participant files had pre audiograms only and six participant files had post audiograms only. Pre and post hearing could therefore only be compared in 36 of the participant files.

Descriptively, the type of hearing loss was analysed pre and post operatively. Results revealed that the total number of ears with hearing loss (including conductive hearing loss and mixed hearing loss) pre operatively was 45 (56%) and this decreased post-operatively to 36 (44%).

Table 10

#### *Summary of the type of hearing loss pre and post-operatively*

	<b>Pre</b>	<b>Post</b>
<b>Conductive hearing loss (CHL)</b>	29	16
<b>Mixed hearing loss (MHL)</b>	16	13
<b>Sensorineural hearing loss (SNHL)</b>	0	0
<b>Total no of hearing loss</b>	45	36
<b>Percentage of hearing loss</b>	56%	44%

**KEY:** Pre= pre-operative, Post= post-operative

As seen in Table 10 the total number of hearing loss has decreased post-operatively suggesting that overall hearing (air-conduction and bone-conduction thresholds) improved post operatively. This was particularly noted in participants with purely conductive hearing loss (CHL); without any sensory (inner ear) involvement.

**Degree of hearing loss.** The degree of loss was classified according to a severity scale: normal, mild, mild-moderate, moderate, moderate-severe, severe-profound and profound which was designed by Silman and Silverman's (1991) classification of magnitude of hearing impairment. Table 11 represents the system of classification of hearing severity in terms of degree of hearing loss used in the current study.

Table 11

*Silman and Silverman's (1991) classification of magnitude of hearing impairment*

Average hearing level (dB)	Description
< 26dB	Normal range
26dB-40dB	Mild hearing loss
41dB-55dB	Moderate hearing loss
56dB-70dB	Moderately severe hearing loss
71dB-90dB	Severe hearing loss
>90dB	Profound hearing loss

The degree of hearing loss was analysed pre and post-operatively and then compared. Table 12 compares the number of participant's per degree of hearing loss pre and post-operatively as well as the total number of hearing loss pre and post-operatively.

Table 12

*Degree of hearing loss pre and post operatively*

	Normal	Mild	Moderate	Mod-sev	Severe	Profound	Total no of HL
Pre	2	5	19	16	2	6	50
Post	10	5	22	6	2	2	47

**KEY:** **Pre**= pre-operatively, **Post**= post-operatively, **Normal**= hearing within normal limits, **Mild**= mild hearing loss, **Moderate**= moderate hearing loss, **Mod-sev**= moderate to severe hearing loss, **Severe**= severe hearing loss, **Profound**= profound hearing loss, **Total no of HL**= total number of hearing loss

As depicted in Table 12, significant improvements in severity of hearing loss post-operatively were found. The most notable improvement was in the moderate-severe range; followed by the profound range. Post-operatively; at least 8 participants presented with hearing within normal limits; when they had not preoperatively.

The mean air-conduction (AC) and bone-conduction (BC) thresholds were calculated pre and post-operatively at each frequency for right and left ears respectively as depicted in the following figures.

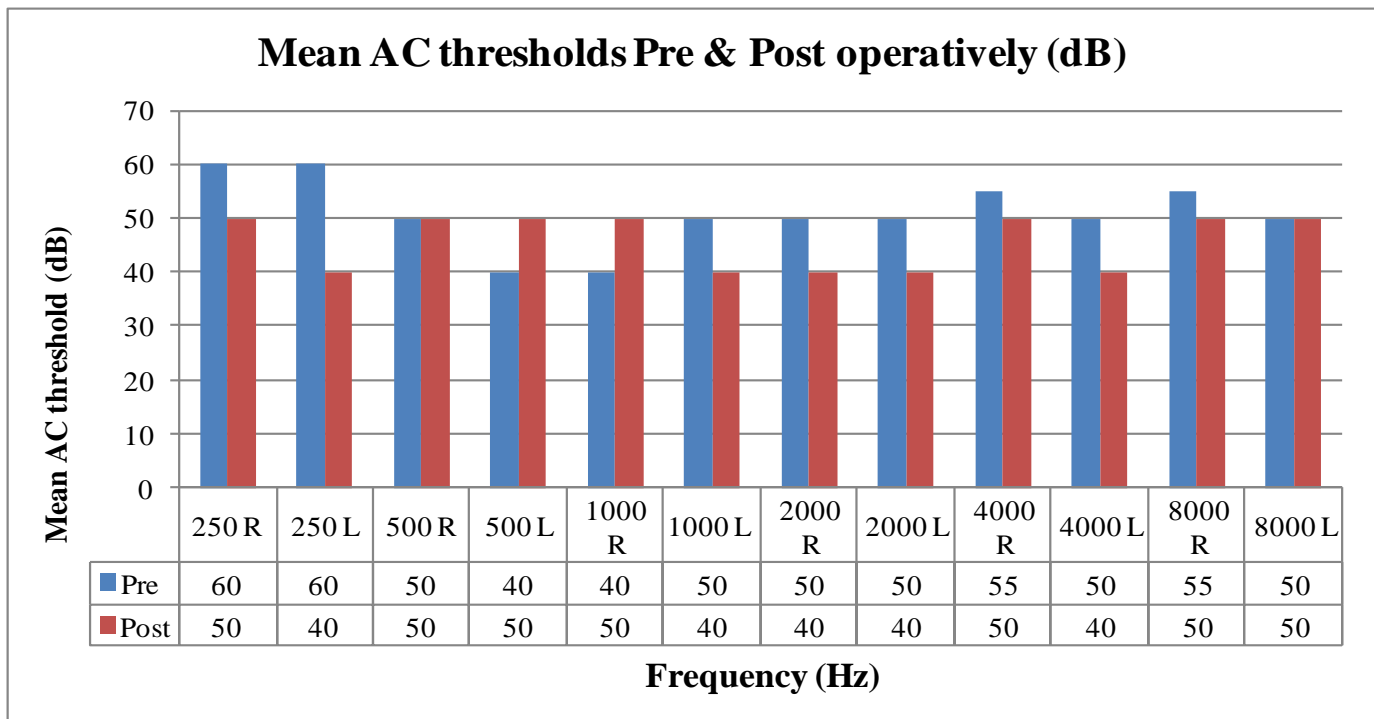
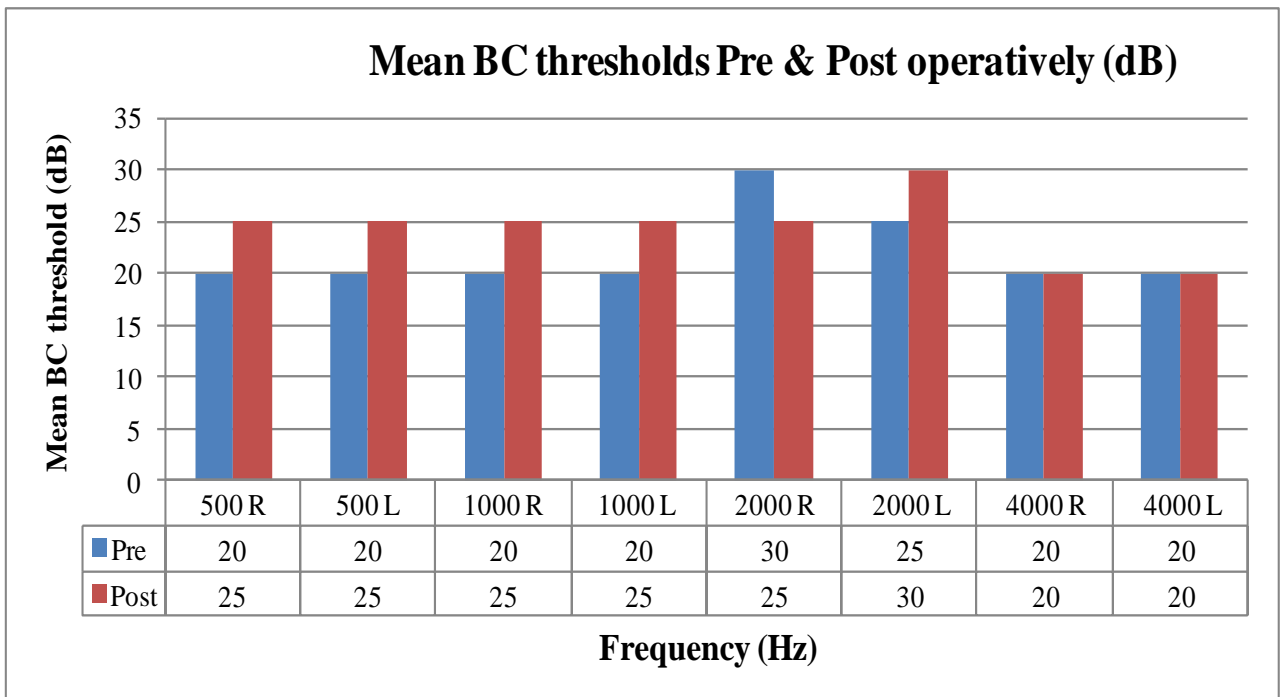


Figure 2. Mean air-conduction thresholds pre and post-operatively (dB).

**KEY:** **AC**= air-conduction, **Pr**= pre-operatively, **Post**= post-operatively, **R**= right ear, **L**= left ear, **dB**= decibels

As represented in Figure 2 the mean air-conduction thresholds were consistently higher pre operatively, except at 500Hz in the left and 1000Hz in the right ear. This suggests that mean air-conduction thresholds decreased post-operatively at most frequencies implying that hearing ability has improved overall post-operatively.



*Figure 3.* Mean bone-conduction thresholds pre and post-operatively (dB).

**KEY:** **BC**= bone-conduction, **Pre**= pre-operatively, **Post**= post-operatively, **R**= right, **L**= left, **dB**= decibels

Figure 3 represents the mean bone-conduction results pre and post operatively; the results indicate that the mean pre thresholds were consistently lower than the mean post thresholds, except at 2000Hz in the right ear. This suggests that bone-conduction thresholds have progressively worsened post-operatively.

Hearing gain per frequency was calculated by subtracting the post-operative threshold from the pre-operative threshold (pre-post) for each frequency for right and left ears separately (See APPENDIX H) and then analysed. If the difference between pre and post threshold is a positive

value this suggests an improvement in hearing post-operatively as the pre threshold would have been the larger value, for example;

Pre – 15dB

Post – 10dB

Hearing change = pre-post = 15dB-10dB = 5dB (positive value suggesting that hearing post-operatively has improved).

If the difference between pre and post is a negative value this suggests deterioration in hearing post-operatively as the pre threshold would have been the smaller value, for example:

Pre – 10dB

Post – 15dB

Hearing change = pre-post = 10dB-15dB = -5dB (negative value suggesting that hearing post-operatively has deteriorated).

Figure 4 represents the mean gain per frequency for both right and left ears that had a pre and post threshold in air-conduction and bone-conduction testing.

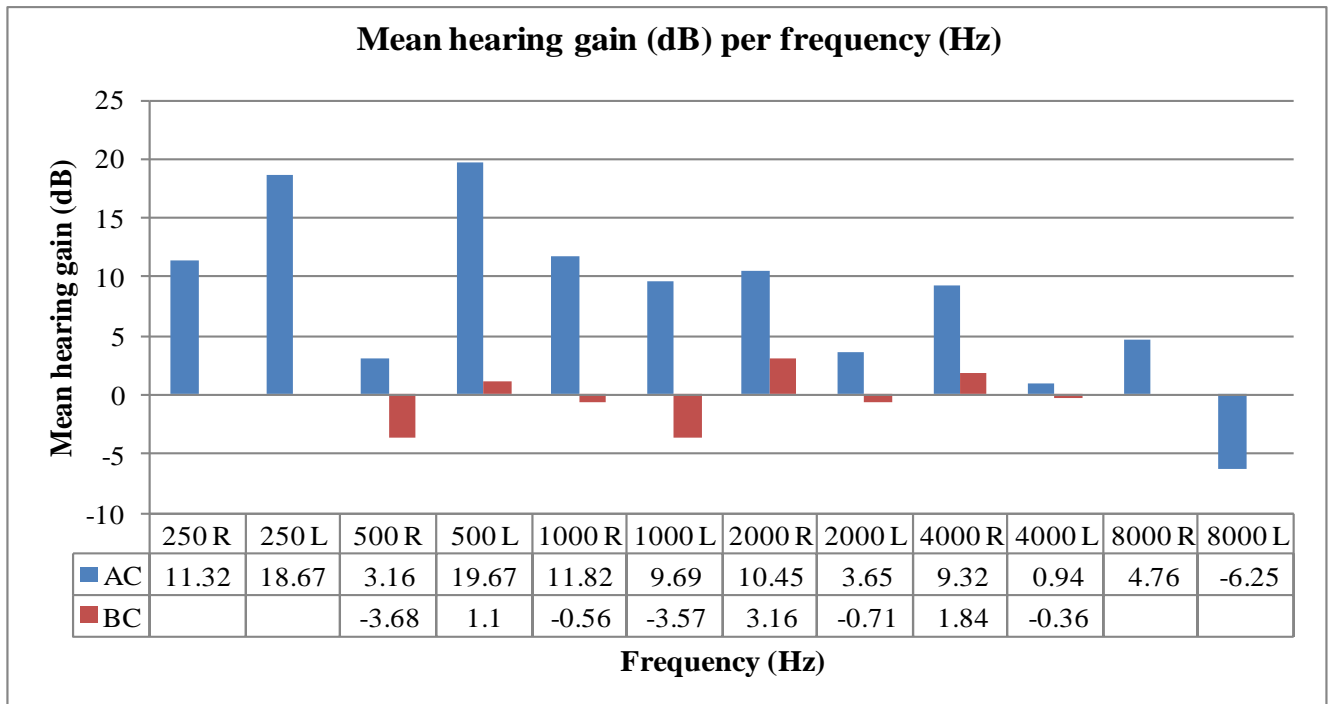


Figure 4. Mean hearing gain (dB) per frequency (Hz).

**KEY:** AC= air-conduction, BC= bone-conduction, R= right, L= left, dB= decibels

Figure 4 displays the mean hearing gain in air and bone-conduction thresholds. It can be seen that for air-conduction thresholds there was an improvement in hearing (positive values) at all frequencies in the right ear and all frequencies in the left ear except for 8000Hz in the left ear (-6.3dB). This suggests overall hearing has improved post-operatively for air-conduction thresholds in both ears. For bone-conduction the mean hearing gain showed deterioration in hearing (negative values) at 500Hz and 1000Hz in the right ear and at 1000Hz, 2000Hz and 4000Hz in the left ear. This suggests the overall hearing has deteriorated post-operatively for bone-conduction in both the right and left ears

**Air-bone gap (ABG).** Pre and post-operative air-bone gaps (ABGs) at 500Hz, 1000Hz and 2000Hz were calculated for 33 participants (See APPENDIX I). The air-bone gap is the difference between the air-conduction threshold and the bone-conduction threshold. If the difference is greater than 10dB the air-bone gap was considered to be indicative of a conductive component in the audiogram.

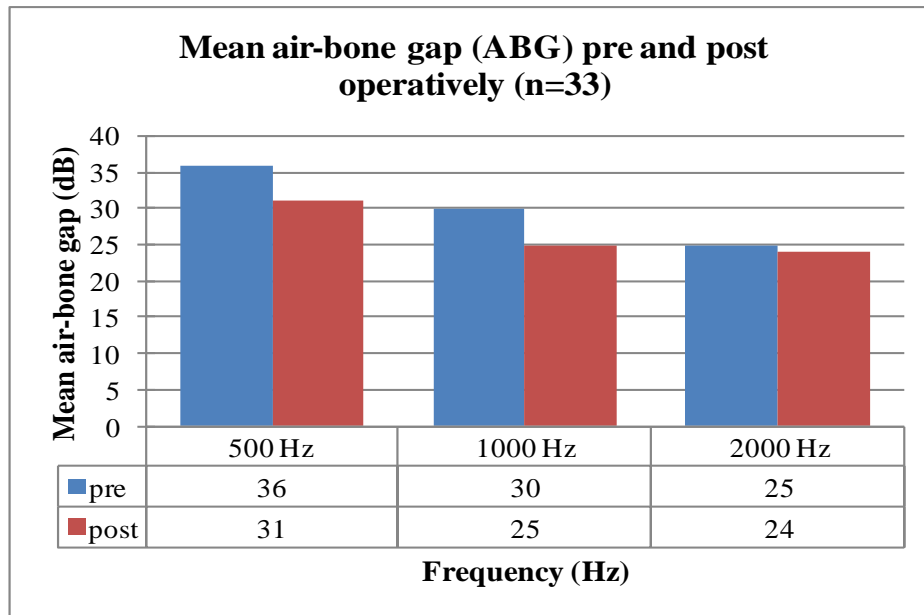


Figure 5. Mean air-bone gap (ABG) (dB) pre and post-operatively ( $n=33$ ).

**KEY:** ABG= air-bone gap, Pre= pre-operatively, Post= post-operatively, dB= decibels

Figure 5 shows that the mean air-bone gap decreased post-operatively; although not as significantly as anticipated; but did suggest that the conductive component has improved post-operatively overall. This correlated well with the earlier analysis on degree of hearing loss comparison pre and post-operatively.

**Speech reception thresholds (SRTs).** Out of 52 participant files only 19 files (37%) had complete speech reception thresholds (SRTs) both pre and post-operatively. SRTs were recorded pre and post-operatively and then compared. See APPENDIX J for detailed results.

Table 13

*Summary of SRTs pre and post-operatively ( $n=19$ )*

	Pre operative SRT (dB)	Post operative SRT (dB)
Mean (dB)	44	32

**KEY:** SRT= speech reception threshold, dB= decibels

Table 13 indicates that there was an overall decrease in speech reception threshold (SRT) means post-surgery which suggests that mean speech reception threshold improved post-operatively. Sixteen (84%) of the participants were HIV negative and three (16%) were HIV

positive. Five (26%) of the participants underwent fascia underlay (F) surgery 13 (68%) underwent butterfly cartilage inlay (C) surgery and one (6%) had an unknown surgical technique. Thus it can be suggested that in the current sample ( $n=19$ ) predictors for improved speech reception threshold results are HIV negative status and having undergone butterfly cartilage inlay surgery.

**Inferential statistical analysis findings.** The statistical results are presented according to the research questions. The analysis of air-conduction thresholds and bone-conduction thresholds was done separately and then the results were correlated and compared. The sample size for air-conduction and bone-conduction differs as there was missing audiological information that resulted in some participants needing to be excluded from the analysis.

A total of 33 participants were considered in this analysis for the air-conduction thresholds and 30 participants were considered for the bone-conduction thresholds. For participants with both right and left records, the researcher excluded either the left or the right ear records in order to avoid the problem of intra-individual correlation (a situation whereby measured observations on the same individual overestimate the true estimates due to higher degree of similarity of observations within each participant). Exclusion was done in a random way. Participants with incomplete records (with either no pre or no post) were also excluded from both analyses.

Table 14

*Description of participants for air-conduction thresholds (n=33)*

Variable	n=33	Mean (SD)
<b>Age</b>	30	39 (12)
	<b>n</b>	<b>%</b>
<b>Gender</b>		
Male	10	30
Female	23	70
<b>HIV status</b>		
Negative	20	65
Positive	11	35
<b>Surgical technique</b>		
Cartilage	21	78
Fascia underlay	5	19
Unknown surgical technique	1	4

**KEY:** *n*= number of participants, **SD**= standard deviation

As depicted in Table 14; for air-conduction the mean age of patients was 39 years, standard deviation was 12 with an age range of 18 to 63 years. Females constituted 70% (*n*=23) of the study population. In addition, 65% (*n*=20) of the patients were HIV positive and more than two third underwent butterfly cartilage surgery. The only one participant with an unknown surgical technique was excluded from this air-conduction analysis as the sample size (*n*=1) was too small to included.

Research objective A: What are the changes in hearing function pre and post type 1 tympanoplasty, i.e. myringoplasty? And are these changes in hearing statistically significant at specific air-conduction and bone-conduction frequencies?

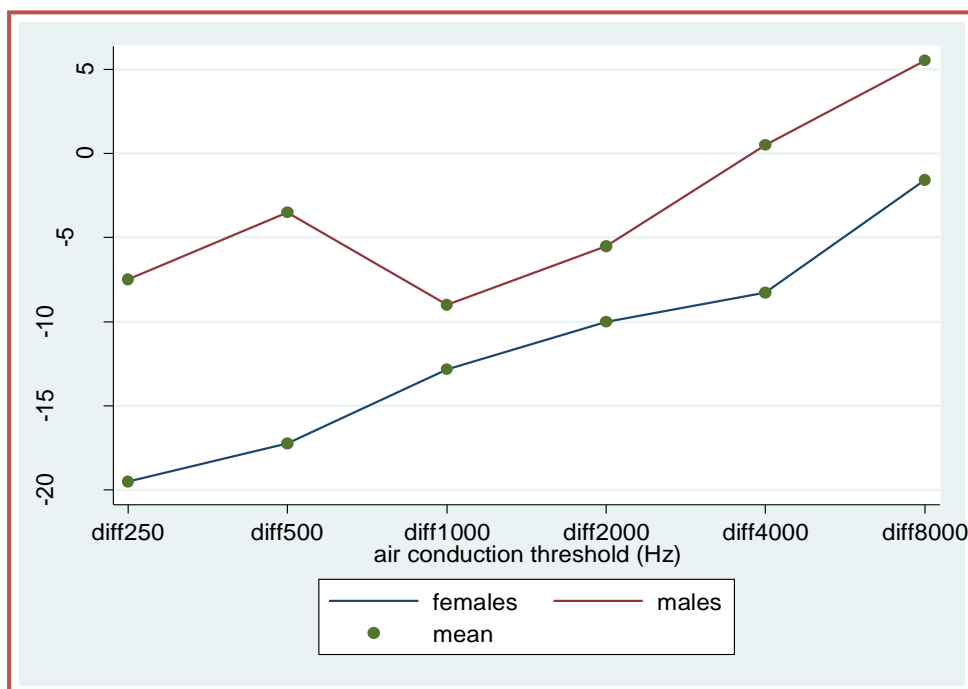
Table 15

*Overall mean paired differences in hearing capacity in air-conduction pre and post-operatively at six air-conduction frequencies*

Frequency (n) in Hz	Mean Diff (SD) in dB	SE	P-value
250 (30)	15.5 (20.82)	3.67	<0.001*
500 (30)	12.67 (26.22)	4.79	0.013*
1000 (33)	11.67 (19.95)	3.47	0.002*
2000 (33)	8.64 (21.11)	3.68	0.025*
4000 (33)	5.61 (24.93)	4.34	0.206
8000 (32)	-0.63 (26.17)	4.63	0.893

**KEY:** n= sample size within each frequency, SD= standard deviation, SE= standard error; \*P-value<0.05

Results in Table 15 showed that the mean paired difference (changes in hearing function) in dB at different air-conduction frequencies was statistically significant after surgery at 250, 500, 1000 and 2000Hz; frequencies most typically affected by conductive pathology.



*Figure 6.* A graphical comparison of mean change in hearing function (dB) at six AC frequencies in male and female participants.

As depicted in Figure 6, overall, males had higher mean change in hearing function at all air-conduction thresholds while a consistent rise in mean air-conduction threshold was observed among females.

Table 16

*Description of participants for bone-conduction thresholds (n=30)*

<b>Variable</b>	<b>n=30</b>	<b>Mean (SD)</b>
<b><u>Age</u></b>	27	41 (12)
<b><u>Gender</u></b>	<b>N</b>	<b>%</b>
Male	10	33
Female	20	67
<b><u>HIV status</u></b>		
Negative	17	61
Positive	11	39
<b><u>Surgical technique</u></b>		
Cartilage	18	75
Fascia underlay	5	21
Unknown surgical technique	1	4

**KEY:** *n*= number of participants, **SD**= standard deviation

As depicted in Table 16, a total of 30 participants were considered in this analysis of which 67% (*n*=20) were female. In addition, 61% (*n*=17) of the participants were HIV negative and more than two thirds underwent butterfly cartilage surgery. The only one participant who had an unknown surgical technique was excluded from this bone-conduction analysis as the sample size (*n*=1) was too small to be included.

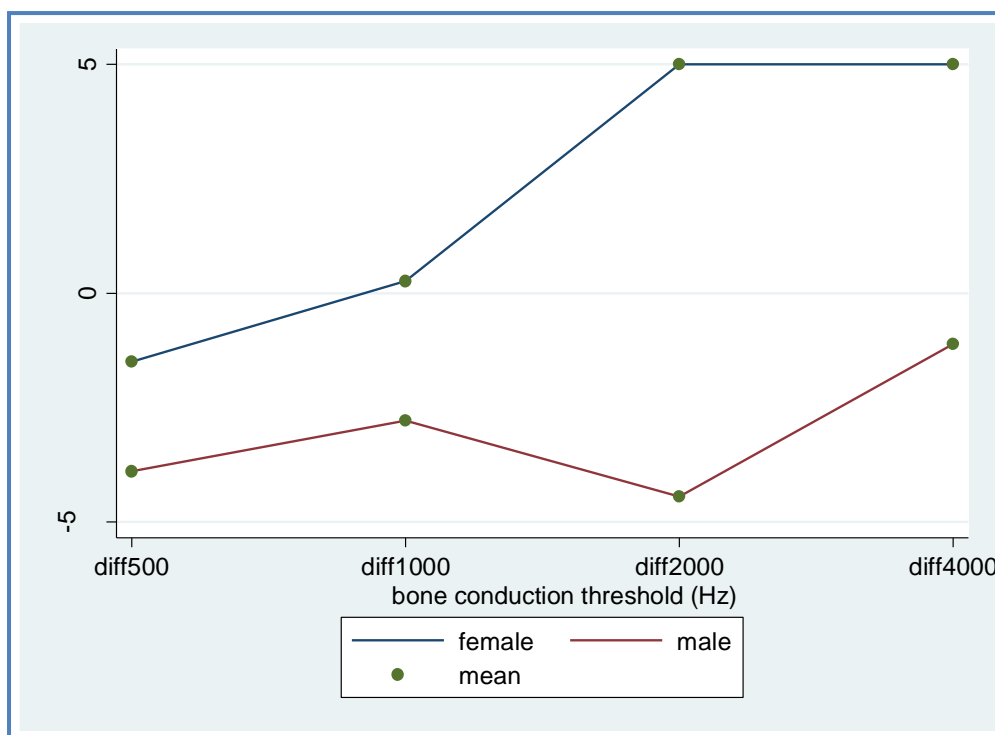
Table 17

*Overall mean paired differences in hearing capacity in bone-conduction thresholds pre and post-operatively at four bone-conduction frequencies*

Frequency (n) in Hz	Mean Diff (SD)	SE	P-value (<0.05)
500 (29)	-2.24 (25.2)	4.68	0.636
1000 (32)	-0.71 (19.85)	3.75	0.850
2000 (33)	2.06 (21.61)	4.01	0.610
4000 (33)	3.10 (24.18)	4.49	0.495

**KEY:** n= sample size within each frequency, SD= standard deviation= standard error; \*P-value<0.05

Table 17 indicates that overall, no evidence of statistically significant differences in mean paired change was observed at all bone-conduction frequencies.



*Figure 7. A graphical comparison of mean change in hearing function (in dB) at four bone-conduction (BC) frequencies in male and female participants.*

As depicted in Figure 7, on average, females had higher mean change in hearing function compared the males at all bone-conduction frequencies.

Research objective B: Does HIV/AIDS have an influence on hearing outcomes post-surgery? And is there a statistically significant difference in hearing function outcome between HIV positive and HIV negative patients?

Table 18

*Mean differences (pre-post) in hearing function pre and post-operatively by HIV status at six air-conduction frequencies*

HIV Negative Patients			HIV Positive Patients				
AC frequency (n) in Hz	Mean diff in hearing function (SD)	P-value	AC frequency (n) in Hz	Mean diff in hearing function (SD)	P-value	Diff of Diff	P-value
250 (19)	15.53 (23.15)	0.009*	250 (9)	13.9 (17.64)	0.046*	1.63	0.854
500 (19)	17.37 (23.06)	0.004*	500 (9)	7.78 (18.22)	0.236	9.59	0.285
1000 (20)	11.00 (19.24)	0.019*	1000 (11)	9.55 (17.81)	0.106	1.45	0.838
2000 (20)	9.25 (20.21)	0.055	2000 (11)	5.00 (21.10)	0.450	4.25	0.585
4000 (20)	0 (23.00)	1.000	4000 (11)	7.67 (24.98)	0.255	-7.67	0.396
8000 (20)	-6.25 (24.43)	0.267	8000 (10)	0 (6.32)	1.000	-6.25	0.437

**KEY:** n= sample size within each frequency, SD= standard deviation= standard error; \*P-value<0.05

Results in Table 18 showed statistically significant differences at 250, 500 and 1000Hz at air-conduction frequencies in HIV negative participants but only at 250Hz in HIV positive participants. A comparison of mean paired differences in air-conduction outcome in HIV positive participants to HIV negative participants showed no evidence of statistically significant difference across all air-conduction thresholds as shown in Table 18 (the last column).

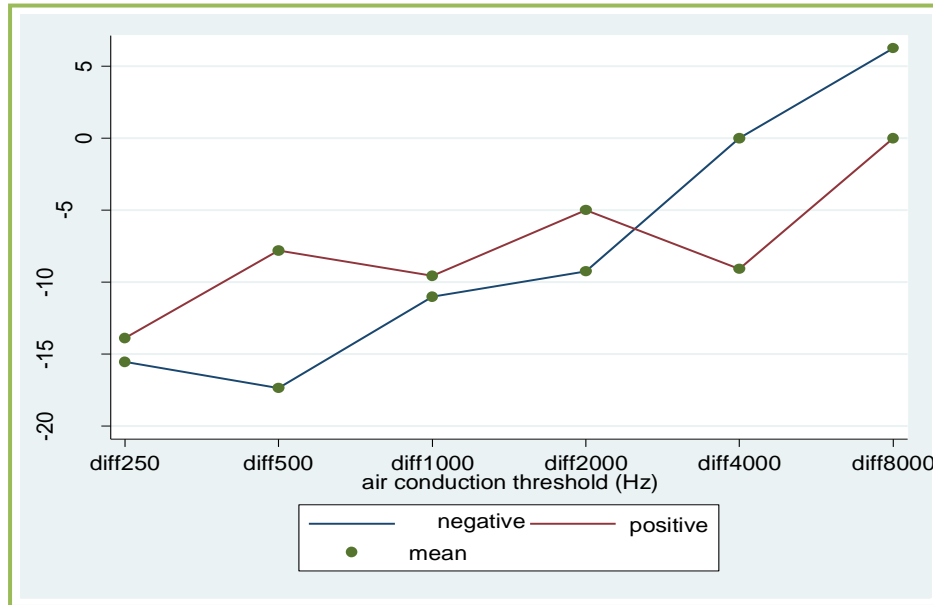


Figure 8. A graphical comparison of the mean change in hearing function (dB) at six air-conduction (AC) frequencies in HIV positive and HIV negative participants.

Figure 8 depicts that the mean change in air-conduction hearing threshold was consistently lower in HIV negative participants at 250, 500, 1000 and 2000Hz. From 2000-8000Hz the mean change in hearing was higher in HIV negative participants.

Table 19

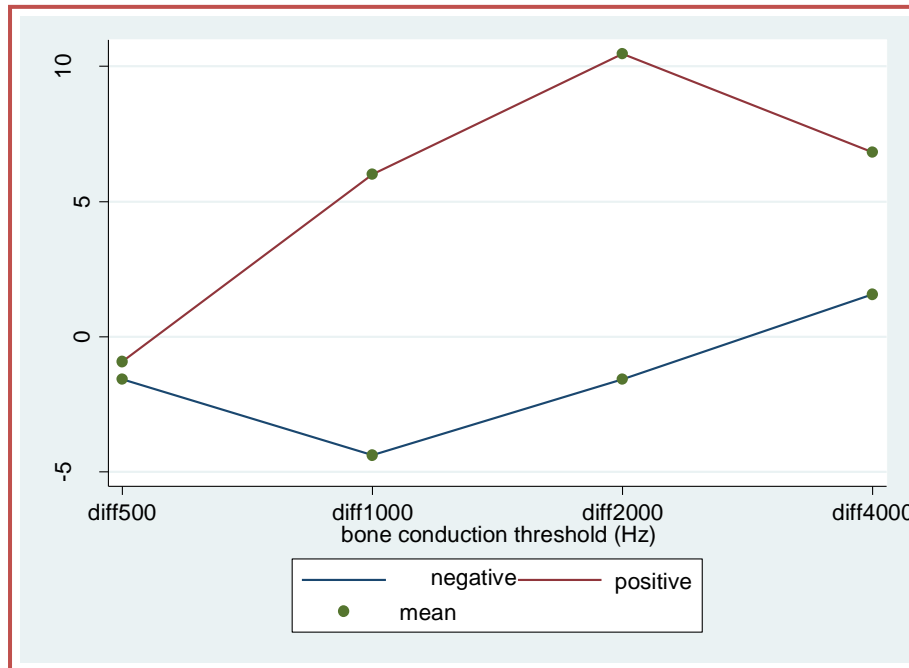
Mean differences (pre-post) in hearing function (dB) pre and post-operatively by HIV status at four bone-conduction frequencies

HIV Negative Patients			HIV Positive Patients				
Frequency (n) in Hz	Mean diff (SD)	P-value	Frequency (n) in Hz	Mean diff (SD)	P-value	Diff of Diff	P-value
500 (16)	-2.1 (20.4)	0.683	500 (11)	-0.9 (32.8)	0.929	-1.2	0.907
1000 (16)	-4.4 (18.2)	0.353	1000 (10)	6.0 (23.3)	0.437	-10.4	0.215
2000 (16)	-1.6 (17.3)	0.723	2000 (11)	10.5 (26.1)	0.214	-12.1	0.159
4000 (16)	1.6 (23.4)	0.793	4000 (11)	6.8 (27.6)	0.432	-5.2	0.602

**KEY:** n= sample size within each frequency, SD= standard deviation= standard error; \*P-value<0.05

Results presented in Table 19 showed no statistically significant differences in mean change in hearing function in both HIV negative and positive participants at all bone-conduction frequencies. Similarly, a comparison of mean paired differences in bone-conduction outcome in

HIV positive participants to HIV negative participants showed no evidence of statistically significant difference across all frequencies as shown in Table 19 (the last column).



*Figure 9.* A graphical comparison of mean change in hearing function (dB) at four bone-conduction (BC) frequencies in HIV positives and HIV negative participants.

As shown in Figure 9 a complementary relationship was observed between HIV positive and HIV negative participants. While the former had an overall substantial higher increase in bone-conduction mean change a sharp drop was observed between 2000 and 4000Hz. On the other hand, HIV negative participants had an initial drop between 500 and 1000Hz, a subsequent rise was observed.

Research objective C: Does the type of surgical technique have an influence on hearing outcome post-surgery? And are these changes statistically significant?

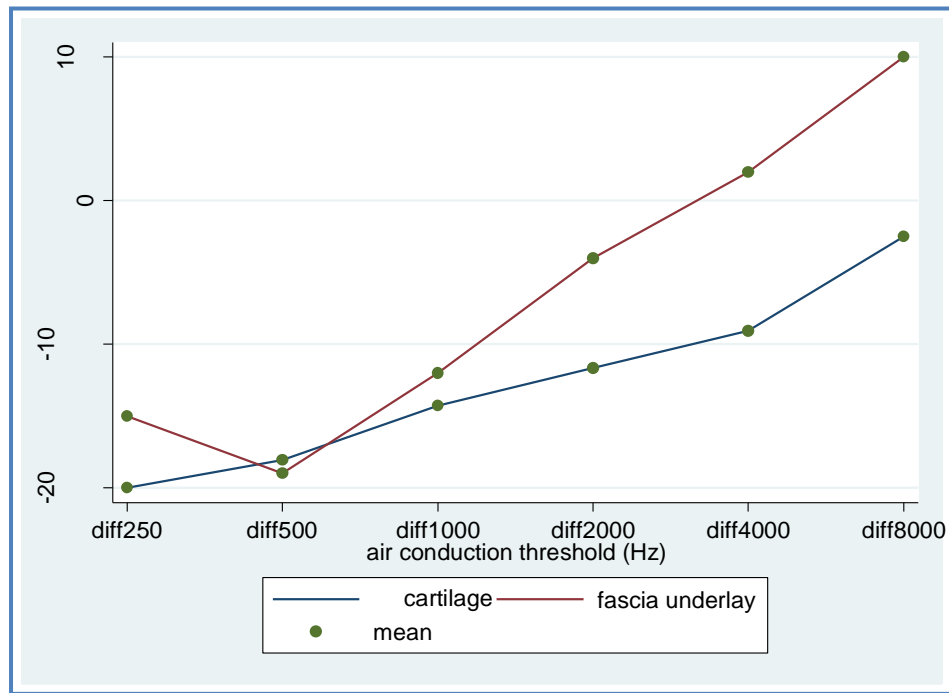
Table 20

*Mean differences (pre-post) in hearing function (dB) pre and post-operatively by type of surgical technique at six air-conduction frequencies*

Cartilage			Fascia underlay				
AC frequency (n) in Hz	Mean diff in hearing function (SD)	P-value	AC frequency (n) in Hz	Mean diff in hearing function (SD)	P-value	Diff of Diff	P-value
250 (18)	20.0 (22.8)	0.002*	250 (5)	15.0 (20.0)	0.169	5.0	0.662
500 (18)	18.1 (22.8)	0.004*	500 (5)	19.0 (29.0)	0.217	-0.90	0.942
1000 (21)	14.3 (21.3)	0.006*	1000 (5)	12.0 (25.6)	0.354	2.3	0.836
2000 (21)	11.7 (20.9)	0.019*	2000 (5)	4.0 (32.9)	0.799	7.7	0.514
4000 (21)	9.0 (25.4)	0.118	4000 (5)	-2.0 (27.5)	0.879	11	0.399
8000 (21)	2.5 (28.2)	0.696	8000 (5)	-10.0 (11.7)	0.129	12.5	0.347

**KEY:** n= sample size within each frequency, SD= standard deviation= standard error; \*P-value<0.05

Results in Table 20 showed statistically significant differences with regard to air-conduction mean change in hearing function in participants who had butterfly cartilage inlay surgery at 250, 500, 1000 and 2000Hz. On the other hand, no evidence of statistically significant difference in air-conduction mean change in hearing function was found in the five participants who underwent fascia underlay surgical technique at all frequencies (Table 20).



*Figure 10.* A graphical comparison of mean change in hearing function (in dB) at six air-conduction (AC) frequencies in participants who had butterfly cartilage inlay surgery and participants who had fascia underlay surgery.

As depicted in Figure 10 after an initial drop (between 250 and 500 Hz) in the mean change in hearing capacity in participants who had fascia underlay surgery showed a subsequent steeper rise in the mean change. In comparison for participants who underwent butterfly cartilage inlay surgery a consistent increase in hearing function at all frequencies was observed.

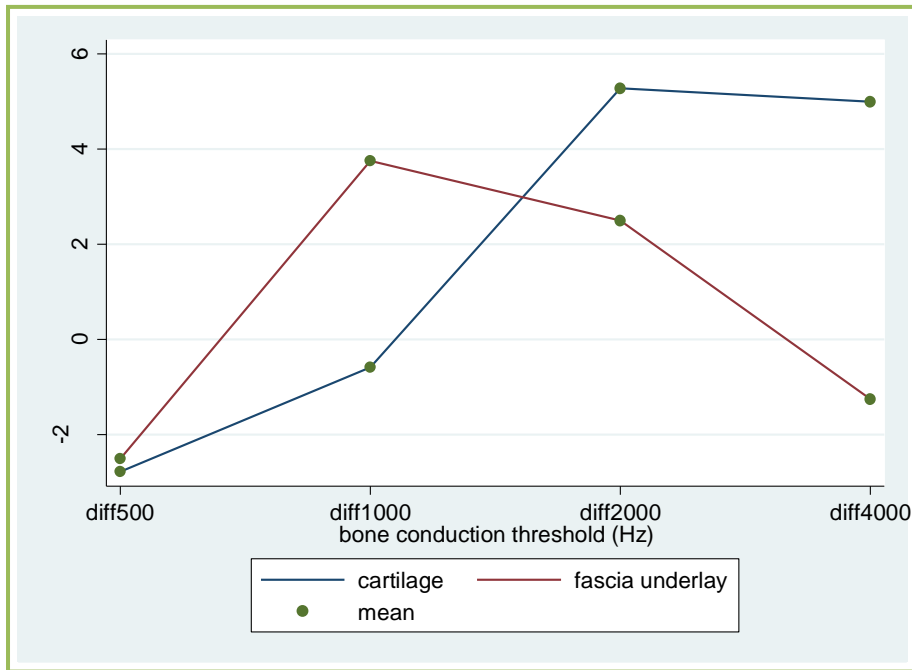
Table 21

*Mean differences (pre-post) in hearing function pre and post-operatively by type of surgical technique at four bone-conduction frequencies*

Cartilage			Fascia underlay				
BC frequency (n) in Hz	Mean diff in hearing function (SD)	P-value	BC frequency (n) in Hz	Mean diff in hearing function (SD)	P-value	Diff of Diff	P-value
500 (18)	-2.8 (28.1)	0.681	500 (4)	-2.5 (30.1)	0.879	-0.3	0.985
1000 (18)	-0.6 (24.8)	0.923	1000 (4)	3.8 (11.1)	0.547	-4.4	0.736
2000 (18)	5.3 (22.6)	0.335	2000 (4)	2.5 (30.7)	0.881	2.8	0.835
4000 (18)	5.0 (24.3)	0.395	4000 (4)	-1.3 (39.2)	0.953	6.3	0.678

**KEY:** *n*= sample size within each frequency, **SD**= standard deviation= standard error; \***P-value**<0.05

Results in Table 21 showed no statistically significant differences with respect to mean change in hearing function in participants who had butterfly cartilage inlay and fascia underlay surgeries at all frequencies.



*Figure 11.* A comparison of mean change in hearing function (in dB) at four bone-conduction (BC) frequencies in participants who had butterfly cartilage inlay surgery and participants who had fascia underlay surgery.

Figure 11 displays that participants who had fascia underlay surgery had an initial higher increase in bone-conduction mean change in hearing function between 500 and 1000Hz after which a cross over effect occurred with a consequent higher increase observed in patient who had butterfly cartilage inlay surgery at the higher frequencies.

## Chapter 4

### Discussion

This chapter provides a discussion of the results in accordance to the research aims and objectives of the study. The discussion relates and compares findings from earlier and recent studies which allowed for relevant conclusions to be made. Findings from the current study are discussed in this chapter in accordance with the research objectives as presented in earlier chapters.

**Demographic information of participants.** The demographic profile consisted of age and gender. The age range of the total population ( $N=52$ ) was 18-63 years with a mean age of 39 years; with only a few participants over the age of 60 years. This age range eliminated the possibility of the aging process (presbycusis) influencing hearing outcome post-surgery. Presbycusis is the normal aging process which will produce a characteristic sensorineural hearing loss which usually begins in the sixth decade of life (Rappaport & Provençal, 2002). Sixty-two percent of the total population ( $N=52$ ) were female and while only 38% were male. The fact that the sample consisted of majority females was not an indication of skewness of results (data) as gender has not been documented in the literature to affect hearing outcome post-surgery. However when gender was investigated when comparing the mean change in hearing function (dB) at air-conduction and bone-conduction thresholds in male and female participants respectively; significant changes were noted which are of particular interest, as findings of this nature has not been documented in similar studies in the literature.

The medical profile consisted of HIV status and type of surgical technique. Majority of the participants (71%) were HIV negative and most participants (65%) underwent butterfly cartilage inlay technique. This sample with regards to HIV status is thus a true representation of the current South African context as a recent survey conducted by statistics South Africa stated that for adults aged 15-49years living in South Africa an estimated 15.9% are HIV positive. This suggests that

84% are HIV negative which correlates well with the chosen samples' medical profile. Butterfly cartilage inlay surgery was reported as a more common surgical technique by ear nose and throat (ENT) surgeons and specialists within the two chosen tertiary hospitals. Due to that fact that the two chosen tertiary hospitals are the largest in Gauteng, this suggests that the sample with regards to type of surgical technique is thus a true representation of the current South African context.

**The effects of gender on hearing outcome post myringoplasty.** Findings of the current study indicated that males had higher mean change in hearing function at all air-conduction thresholds with an initial rise and fall between 250 and 1000Hz and a subsequent increase between 1000 and 8000Hz post-operatively. On the other hand, a consistent rise in mean air-conduction threshold was observed among females. This suggests that females have a consistently lower mean change in hearing threshold at all air-conduction frequencies relative to the males. With regards to bone-conduction females had higher mean change in hearing function compared to males at all frequencies. However, an increase in mean change was observed in females from 500 to 2000Hz after which it levelled off. Although the mean change in hearing was lower in the males; there was a gradual increase with a subsequent decrease between 1000 and 2000Hz. These findings are in agreement with a study conducted by Hodges and McBride (2012); similarly in their study it was found that females have significantly lower air-conduction thresholds but only at 8000 Hz. The bone-conduction hearing analysis indicated that females had significantly better hearing thresholds at 6000Hz and 8000Hz (Hodges & McBride, 2012). In addition it was concluded that the location of the bone-conduction transducer may also impact the threshold differences; in their study for instance, females had significantly better hearing thresholds for the 8000Hz signal at the mastoid location only. In the current study the exact location of the bone-conduction transducer (either on forehead or mastoid) is unknown due to the retrospective nature of the study and thus such conclusion cannot be made as to the possible reasons for the results obtained.

The results obtained in the current study are thus of particular interest to ear nose and throat (ENT) specialists as well as audiologists; as male and females changes in hearing outcome post myringoplasty surgery has never been investigated in the current context. These findings highlight the importance of demographic information that may potentially affect the results of a study and indicate that one should consider gender when comparing hearing outcome post myringoplasty surgery. Knowing the location of the bone-conduction transducer may also be of relevance to audiologists as may affect the threshold differences in male and females; as shown by Hodges and McBride (2012) in their study. It is of importance to note that majority of the participants in the current sample were female and thus a repeated study of a more even distribution of male and female patients may have yielded different results. These findings further highlight the importance of gender being a possible variable that may influence hearing outcome post-operatively. They indicate that males and females have different changes in hearing when looking at air-conduction and bone-conduction testing. Thus these findings alert the research and clinical community to a new possible variable that needs to be explored and investigated further within the current context, so that these baseline findings can be compared and correlated to other research.

**Research objective A: The changes in hearing function pre and post myringoplasty.** In terms of the primary aim of the study; investigating the changes in hearing outcome post myringoplasty some of the findings were comparable and other findings not comparable to that of similar studies. It was determined that there was a lack of literature comparing tympanometry results and middle ear functioning post myringoplasty surgery. These findings highlight the importance of assessing and comparing middle ear functioning post surgery as changes in middle ear status clearly exist. Although assessing the status of the middle ear is a crucial aspect of the diagnostic audiological test protocol; many participants had missing tympanometry results. It is important to determine the middle-ear status, as middle ear pathology or abnormalities of the middle ear produce conductive losses, thereby affecting the bone-conduction thresholds and, in

turn, the audiological testing results (Martin, 1997). Tympanometry results thus improve and validate audiological findings (Shanks & Shoet, 2009). Not testing (pre and post-operatively) due to a perforated tympanic membrane, blood and/or wax in the ears was to be expected which further reduces the sample size. The clinical findings indicated that middle ear status does improve post-operatively, which is an indicator of success of ear surgery.

To further validate the tympanometry findings, as they cannot be compared to other results in the literature; statistical measures were employed. These were used to specifically determine the influence of HIV status and type of surgical technique on tympanometry results post-surgery. Using the Kolmogorov-Smirnov two sample test results showed there were no statistical significant differences in the tympanometry results due to; HIV status and type of surgical technique. These findings may have been influenced by medical profile as majority of the participants were HIV negative (71%) and 65% of the total sample underwent butterfly cartilage inlay surgery. These findings highlight that although statistically changes in middle ear functioning are not dependent on HIV status and type of surgical technique; clinically dependency on the aforementioned variables do exist. This is of importance in predicting middle ear outcome of surgery using HIV status and type of surgical technique as a predictive variable.

There has been debate in the literature as to whether tympanometry testing should be done post myringoplasty surgery. According to Syms (2003), the answer is dependent on the technique and the nomenclature. If temporalis fascia is used to repair the perforation, particularly if the ear canal is packed, then there is no danger to the graft, but the test will not give any information of value (Syms, 2003). This is similar to a tympanogram on a patient with an ear canal with complete cerumen impaction. It will yield a type B tympanogram with low volume, but will not reflect any information on the status of the tympanic membrane or middle ear (Syms, 2003).

Audiologically air-conduction and bone-conduction results were described and discussed clinically; in terms of type of hearing loss, degree of hearing loss, mean gain per frequency, mean changes in air-bone gap and speech reception threshold findings. Findings overall suggested an improvement in hearing outcome post-surgery from a clinical audiological perspective. There was a decrease in total number of hearing loss (from 56% to 44%) post operatively; this correlates with results found in the literature (Gerber et al., 2000; Shresta & Sinah, 2006; Shaikh et al., 2009; Becker & Lubbe, 2011; Sarker et al., 2011 & Joshi et al., 2013). A significant decrease in the total number of conductive hearing loss was found post-operatively. Thirteen less participants presented with a conductive hearing loss post-operatively. It is known that diseases of the middle ear such as acute otitis media, otitis media with effusion and chronic suppurative otitis media are associated with a conductive hearing loss (Vikram et al., 2008 & Ibekwe & Nwaorgu, 2011;). It is known that conductive hearing loss generally improves post ear surgery in most cases (Vikram et al., 2008). Majority of the participants of the current study presented with one of the aforementioned diseases which affects the middle ear functioning. Conductive hearing loss accompanying chronic suppurative otitis media results from blockage of the external auditory canal by discharge and perforation of the tympanic membrane (WHO, 2006), thus myringoplasty surgery is indicated.

Significant improvements in severity of hearing loss post-operatively were found. The most notable improvement was in the moderate-severe range; followed by the profound range. Post-operatively; at least eight participants presented with hearing within normal limits; when they had not pre-operatively. Overall these findings suggest that hearing has improved post-operatively and is found to be consistent with studies in the literature (Shresta & Sinah, 2006; Shaik et al., 2009) but differ from the current study in terms of the criteria that they used to assess hearing outcome. Shresta and Sinah (2006) used air-bone gaps and found that 78% of patients had their hearing gain exceeding 15dB after surgery whereas Shaikh et al. (2009) assert that the mean air-conduction thresholds improved postoperatively, while the mean bone-conduction thresholds remained the

same pre & postoperatively. Joshi et al. (2013) however used similar criteria to assess changes in pure-tone thresholds (air and bone-conduction thresholds). They found that the mean pre and post-operative air conduction threshold in the successful cases were 38.69dB and 30.35 dB respectively with a mean audiological improvement of around 8dB. These findings have a direct correlation with that of the current study as mean air-conduction thresholds showed a consistent improvement across all frequencies post-operatively. The reason for this improvement maybe due to restoration of the hearing mechanism post-operatively that improves air-conduction thresholds (Sarker et al., 2011).

The mean hearing gain for air-conduction and bone-conduction thresholds showed that air-conduction thresholds improved overall and bone-conduction thresholds deteriorated overall. These results are comparable (but not similar) to that of Shaikh et al. (2009) whereby they assert that the mean air-conduction thresholds improved postoperatively, however they found that the mean bone-conduction thresholds remained the same pre & postoperatively which differs from that of the current study. A possible reason for this difference may be due to the type of surgical technique, as majority of the participants for the current study had butterfly cartilage inlay surgery whilst all the participants in Shaikh et al. (2009) study underwent temporalis fascia underlay surgery. With regards to the current study although overall hearing outcome has improved post-operatively when mean bone-conduction thresholds are viewed per frequency in isolation there is a distinctive decrease in mean hearing gain overall. It must be noted that bone-conduction thresholds are never looked at in isolation and form part of the diagnostic test battery for a comprehensive hearing assessment (Harrell, 2002). Bone-conduction thresholds are also highly sensitive to bone conductor placement and calibration of the audiometer (Harrell, 2002). These factors could not be controlled due to nature of the data collection process being a retrospective record view. Although the bone conduction thresholds are frequently elevated in chronic otitis media, in pre-operative period, it may not be due to direct inner ear involvement in all the cases (Vijayendra & Parikh, 2011). In most of the cases it may be due to mechanical factors (so called Carhart effect or pseudoperceptive

deafness) and thus successful results can be achieved in most of these patients regardless of the deteriorated bone conduction thresholds (Vijayendra & Parikh, 2011).

Statistically however, when looking at the mean paired difference (changes in hearing function) in dB at different air-conduction thresholds; it was found that there were statistically significant changes before and after surgery at 250Hz ( $p < .001$ ), 500Hz ( $p = .013$ ), 1000Hz ( $p = .002$ ) and 2000Hz ( $p = .025$ ). This suggests that there was a consistent improvement in hearing function at the above mentioned air-conduction frequencies from pre to post-operative threshold. These frequencies are the most important frequencies when evaluating hearing function. The various degrees of hearing loss are reported in terms of average thresholds at three frequencies, 500Hz, 1000Hz and 2000Hz; which represent the most important frequencies for understanding speech and therefore holds the most promise for estimation of the degree of communication difficulty that particular hearing loss is likely to cause (Harrell, 2002). Overall no evidence of statistically significant differences in mean paired change was observed at all bone-conduction thresholds. These findings have a close correlation with results from the study conducted by Shaikh et al. (2009), where the mean air-conduction threshold improved post operatively, while the mean bone-conduction threshold remained the same pre & post-operatively (Shaikh et al., 2009). These findings alert the research community that analysing data audiological (clinically) and statistically may potentially result in different findings within the same sample set of data. This highlights the importance of analysing data using different methods and correlating and comparing the results.

The mean air-bone gap was calculated at 500, 1000 and 2000Hz ( $n=33$ ) and results indicated a decrease in air-bone gap overall post-operatively. Although the air-bone gap decreased post-operatively the mean air-bone gap at all frequencies post-operatively were above 10dB which suggests that even though there has been an improvement in air-bone gap a conductive component remains post-operatively. At all frequencies the air-bone gap improved within 10dB suggesting that

there was closure of the air-bone gap. For the air-bone gap analysis majority of the participants (74%) underwent butterfly cartilage inlay surgery and were HIV negative (55%). Shrestha and Sinah (2006) concluded that it is common to expect an air-bone gap post-operatively depending on the size of the perforation. They reported that for large central perforations the likelihood of a remaining air-bone gap (of within 20dB) is expected (Shrestha and Sinah, 2006). The size of the perforation was not considered for the current study; however it can be expected that for some of the participants a large central perforation may have been present. It is reasonable to expect that replacing a large portion of the tympanic membrane with cartilage would add stiffness and/or mass that would affect individual frequencies, but not significantly impact averaged audiometric data such as air-bone gap (Gerber et al., 2000). However, a tendency for better air-bone gap closure at 2000Hz was noted. It is possible that a larger population would detect small differences in hearing that was missed in the relatively small sample size for air-bone gap ( $n=33$ ) of the current study.

There was an overall decrease in speech reception threshold means post-operatively which suggests that speech reception thresholds have improved post-operatively for the majority of the participants which correlates with Gerber et al. (2000). Of all the participants that has speech reception threshold results 84% were HIV negative and 68% underwent butterfly cartilage inlay surgical technique; thus it can be suggested than in the current sample ( $n=19$ ) predictors for improved speech reception threshold results are HIV negative status and having undergone butterfly cartilage inlay surgery. Geber et al. (2000) found that participants who underwent butterfly cartilage inlay surgery had better speech reception thresholds compared to participants who underwent fascia underlay surgery which correlates with the results in the current study. The demographics of the participants in Gerber et al. (2000) are similar to the demographics of the participants of the current study in terms of age and gender.

These findings highlight the importance considering speech reception thresholds changes when evaluating hearing outcome post myringoplasty. They indicate that the chosen variables had an influence on hearing outcome post-operatively when clinically evaluating the speech reception threshold results. These findings alert the clinical community to conduct thorough diagnostic assessments. According to Valente (2009) comprehensive audiological assessment should include speech reception threshold testing as this assesses one's ability to discriminate speech in noise. The importance of speech reception thresholds are that it is a check of the pure tone air-conduction threshold result (must correlate within 10dB), it provides an index of hearing sensitivity for speech and it serves as the baseline for determining the presentation levels for supra-threshold speech recognition tests (Brandy, 2002). The availability of speech reception threshold data was scarce (37%) in the current sample. The implications of not completing speech reception threshold testing may result in misinterpretation of audiological findings and inability to deduce holistic conclusions regarding hearing function. These results further alert the research and clinical community to always include speech reception thresholds as a measure for assessing hearing changes post myringoplasty.

Another variable to consider may the time post operatively hearing was evaluated. It was noted that the protocols at the two tertiary hospitals were different and time frame post operatively hearing was evaluated differed. This may result in variability of results obtained as healing of the eardrum and restoration of hearing at different time intervals changes. According to most studies reviewed the time post operatively hearing should be evaluated is six weeks, three months and six months. Standardizing this time frame of testing post operatively is vital in monitoring the changes in hearing sensitivity and should be a variable to investigate in future studies,

**Research objective B: The influence of HIV/AIDS on hearing outcome post myringoplasty.** HIV status was found to be a possible variable that may have an influence on

hearing outcome post myringoplasty. These findings are of particular interest to the research and clinical community; as South Africa has the largest number of people living with HIV/AIDS and carries a sixth of the global disease burden (Sloan et al., 2009 & Garcia-Jardon et al., 2010). Stats SA (2013) stated that the total number of people living with HIV is estimated at approximately 5.26 million by mid-2013. For adults aged 15-49 years an estimated 15.9% are HIV positive (Stats SA, 2013). Findings highlighted statistically significant differences at 250Hz ( $p = .009$ ), 500Hz ( $p = .004$ ) and 1000Hz ( $p = .019$ ) at air-conduction thresholds in HIV negative participants but only at 250Hz ( $p = .046$ ) in HIV positive patients. The mean change in air-conduction hearing was consistently lower in HIV negative participants at 250, 500, 1000 and 2000Hz. From 2000-8000Hz the mean change in hearing was higher in HIV negative participants and a subsequent decrease in mean hearing threshold was noted in HIV positive participants from 2000Hz. This correlates with trends of hearing loss in HIV positive participants found in the literature; Khoza-Shangase (2008) found that 47% of HIV positive participants with clinical hearing loss had a tendency for sloping (high frequency) configuration of hearing loss. Furthermore the sensori-neural high frequency nature of hearing loss is consistent with features typical of ototoxic hearing loss in participants with HIV. Khoza-Shangase (2010) reported that the audiometric data trends imply worsening hearing loss in high frequencies in participants with HIV/AIDS. This correlates with the audiological results of the current study, whereby being HIV negative was an indicator for improved hearing post operatively; in terms of mean gain per frequency, mean changes in air-bone gap and speech reception threshold results. In contrast to this a comparison of mean paired differences in air-conduction outcome in HIV positive participants to HIV negative participants showed no evidence of statistically significant difference across all air-conduction thresholds. These results highlight the importance of using both clinical (audiological) and statistically measures to assess the influence of HIV status on hearing outcome post myringoplasty.

When assessing the influence of HIV status on bone-conduction thresholds; findings showed no statistically significant differences in mean change in hearing function in both HIV negative and positive participants at all bone-conduction frequencies. Similarly, a comparison of mean paired differences in bone-conduction outcome in HIV positive participants to HIV negative participants showed no evidence of statistically significant difference across all frequencies. These findings are consistent with Shaikh et al. (2009) whereby the mean bone-conduction thresholds remained the same pre & postoperatively, however HIV status was not considered as a variable in their study and thus the bone-conduction results of the current study are not completely comparable to that of Shaikh et al. (2009). Graphically a complementary relationship was observed between HIV positive and HIV negative participants; while the former had an overall substantial higher increase in bone-conduction mean change a sharp drop was observed between 2000 and 4000Hz. On the other hand, HIV negative participants had an initial drop between 500 and 1000Hz, a subsequent rise was observed. This correlates with general trends of hearing patterns in patients with HIV/AIDS (Khoza-Shangase (2010)). These findings serve as a baseline of how HIV status influences hearing outcome post myringoplasty in the selected context. These findings are not completely comparable to that of other studies due to methodological and population differences. Conducting further research in this area within the current context is needed to obtain more consistent and comparable conclusions.

**Research objective C: The influence of type of surgical technique on hearing outcome post myringoplasty.** When assessing the influence of butterfly cartilage inlay surgery on hearing outcome post-operatively; statistically significant differences with regard to air-conduction mean change in hearing function were observed at 250Hz ( $p = .002$ ), 500Hz ( $p = .004$ ), 1000Hz ( $p = .006$ ) and 2000Hz ( $p = .019$ ). Therefore suggesting that butterfly cartilage inlay surgery had an influence on air-conduction thresholds at specific frequencies. This correlates well with a study conducted by Chhapola and Matta (2012) where they assert that cartilage perichondrium seems be an ideal graft

material for tympanic membrane in terms of postoperative healing and improved acoustic properties as it can easily withstand negative middle ear pressure. Furthermore they found statistical significant differences in all air-conduction thresholds (Chhapola & Matta (2012).

On the other hand, no evidence of statistically significant difference in air-conduction mean change in hearing function was found in the five participants who underwent fascia underlay surgery at all air-conduction thresholds; suggesting that this type of surgical technique has no influence on hearing outcome post-operatively. This correlates with the clinical findings whereby a predictor of improved middle ear functioning, improved air-bone gap and improved speech reception thresholds was having undergone butterfly cartilage inlay surgery. In contrast when statistically comparing the mean paired differences in hearing function outcome in participants who had butterfly cartilage inlay surgery to participants who had fascia underlay surgery showed no evidence of statistically significant difference at all air-conduction thresholds. This suggests that statistically the type of surgical technique has no influence on the hearing outcome post-operatively. These findings highlight the importance of clinical evaluation and indicate that more detailed clinical conclusions may be drawn from a descriptive clinical evaluation compared to a statistical analysis.

When graphically assessing the influence of type of surgery on hearing outcome post-surgery it was determined that after an initial drop (between 250 and 500 Hz) in the mean change in hearing capacity in participants who had fascia underlay surgery showed a subsequent steeper rise in the mean change. In comparison for participants who underwent butterfly cartilage inlay surgery a consistent increase in hearing function at all air-conduction frequencies was observed. In comparison when looking at bone-conduction analysis; no statistically significant differences with respect to mean change in hearing function in participants who had butterfly cartilage inlay and fascia underlay surgeries at all bone-conduction thresholds. These findings highlight the importance

of determining air-conduction and bone-conduction thresholds separately when investigating the influence of type of surgical technique on hearing outcome as differences in hearing outcome between the two pure-tone measures clearly exists.

Gerber et al. (2000) compared hearing outcome in participants who underwent fascia underlay and butterfly cartilage inlay and found no significant difference in air and bone-conduction thresholds. Similarly in the current study a comparison of mean paired differences in hearing function in participants who had butterfly cartilage inlay surgery to participants who had fascia underlay also showed no evidence of statistically significant difference at all bone-conduction thresholds in the current study. Hearing outcomes post butterfly cartilage inlay surgery and fascia underlay surgery varies considerably in the literature. Mauri et al. (2001) found that the audiometric results following inlay cartilage tympanoplasty or underlay tympanoplasty were similar. A single study conducted within the South African context by Becker and Lubbe (2011) looked at the type of graft used (cartilage or temporalis fascia) as one of the prognostic factors that may influence outcome of surgery and found that none of the prognostic factors assessed were statistically significant ( $p>0.05$ ).

It must be noted that many of the studies reviewed did not use the same criteria to assess hearing outcome compared to that of the current study. There are several different kinds of myringoplasty techniques which are often adapted by surgeons according to their resources and clinical presentation of the patients; which differ from country to country. Thus making the results yielded in the current study not fully comparable to that of other similar studies. There are various techniques of myringoplasty with their own corresponding results (Sergi et al., 2011). However, still there is no consensus about the optimal technique, which is often employed on the basis of surgeon's preference and skills (Sergi et al., 2011).

## Chapter 5

### Conclusion and Recommendations

The current study which aimed to explore the changes in hearing outcome post myringoplasty and investigate the possible influence HIV status and type of surgical technique on hearing outcome post-operatively has implications for audiologists and ear nose and throat (ENT) specialists working in South Africa. The findings of the current study can be summarized as follows:

- The total sample ( $N=52$ ) comprised of more females (62%) compared to males (38%) with a mean age was 39.9 years which suggests that few patients were over the age of 60 years which eliminates the effects of presbycusis on the findings obtained in the current study.
- Of the total sample ( $N=52$ ) majority of the participants were HIV negative (71%) and 65% of the participants underwent butterfly cartilage inlay technique.
- When investigating tympanometry results clinically in the current study; being HIV negative and having undergone butterfly cartilage inlay surgery was the best predictor for improved tympanometry results post-operatively
- Statistically there were no statistical significant differences in the tympanometry results due to HIV status and type of surgical technique as per the Kolmogorov-Smirnov two sample test.
- When evaluating type and degree of hearing loss clinically in the current study; the total number of hearing loss has decreased post-operatively and the degree of hearing loss for the normal range increased post-operatively suggesting that overall hearing (air-conduction and

bone-conduction thresholds) improved post-operatively which correlates with results from other studies in the literature.

- Hearing gain per frequency indicated an overall improvement in air-conduction hearing thresholds post-operatively and an overall deterioration in bone-conduction hearing thresholds; these results are contradictory to the air-bone gap analysis in which it was found that the overall air-bone gap improved post operatively. Although a conductive component remained post surgery and this may be a consequence of the deterioration of the mean hearing gain per frequency for bone-conduction thresholds.
- Clinically the mean speech reception threshold improved post operatively; which correlates with results found in the literature.
- The changes in hearing function were statistically significant before and after surgery at 250Hz, 500Hz, 1000Hz and 2000Hz for air-conduction thresholds.
- Statistically significant differences were found at 250, 500 and 1000Hz at air-conduction thresholds in HIV negative participants but only at 250Hz in HIV positive participants.
- No statistically significant differences were found in mean change in hearing function in both HIV negative and positive participants at all frequencies for bone-conduction thresholds.
- Statistically significant differences with regard to air-conduction mean change in hearing function were found in participants who had butterfly cartilage inlay surgery at 250, 500, 1000 and 2000Hz. On the other hand, no evidence of statistically significant difference in air-conduction mean change in hearing function was found in the five participants who underwent fascia underlay surgical technique at all frequencies for air-conduction thresholds.

- No statistically significant differences with respect to mean change in hearing function in participants who had butterfly cartilage inlay and fascia underlay surgeries at all frequencies for bone-conduction thresholds.

**Benefits.** These findings can be used to guide audiologists in the management of patient's pre and post myringoplasty surgery in terms of monitoring hearing function post surgery and providing audiologists with possible variables that influence hearing outcome so that they can anticipate management protocols. The findings of the study can also assist ear nose and throat specialists (ENTs) in anticipating hearing outcome post myringoplasty surgery which affects their decision making process in terms of type surgical to be conducted.

A study of this nature specifically investigating HIV status as a variable and its influence on hearing outcome post myringoplasty surgery has never been conducted in the current context. Therefore the results may serve as a baseline of findings which can be expanded upon in future research.

The researcher chose the two largest tertiary hospitals in Gauteng to collect data from in order to obtain data that can be generalised to the region. Furthermore a detailed audiological comparison including tympanometry and comprehensive pure tone analysis was conducted. This type of in-depth audiological analysis was not conducted in most of the literature reviewed as some did not include tympanometry results and looked at pure-tone average (PTA) and/or air-bone gap (ABG) and/or speech reception threshold (SRT) results only. Although different studies used different criteria to assess hearing outcome post-operatively; only some of the findings of the current were comparable to that of other studies.

The findings of the current study serve as a baseline that can be used for future research in this area within the South African context.

**Limitations.** One of the major limitations in the current study is the chosen research design, i.e. retrospective record review. This was a limitation in itself as it brought about potential challenges such as incomplete audiograms, inaccurate audiograms and reliance on Audiologist skills and knowledge. A small percentage of the audiograms presented with poor correlation of among various audiological tests performed. This warrants attention in terms of validity of the audiological test protocols conducted within the two tertiary hospitals used in the current study.

The research design thus resulted in a small sample size; as many of the participants needed to be excluded from the inferential statistics due to missing information. Small sample sizes affect the power of analysis; which in turn affects the generalisability of the study.

Due to the fact that a study of this nature was never conducted within the chosen context; findings obtained could not be fully compared to other studies due to population difference and treatment differences. Most studies used different criteria to assess hearing outcome and thus the chosen criteria was not all comparable to that of other studies due to methodological differences and demographical differences.

## **Implications**

***Clinical implications.*** It was hoped that other pertinent variables raised in the literature review of the current study such as lack of resources resulting in long waiting periods for surgery and hearing tests was identified to assist the Department of Health with allocating appropriate funding to these departments to improve service delivery.

Alerting the clinical community specifically audiologists to follow complete test protocols as complete audiograms are of crucial importance to ear nose and throat (ENTs) specialists in their decision making pre and post-operatively.

The developments of standardized clinical protocols are to be adhered to for patients who require myringoplasty as implications of incomplete audiograms have been highlighted in the current study.

***Educational implications.*** Increase of awareness of the importance of conducting all relevant audiological tests for patients who require surgical intervention such as myringoplasty.

**Recommendations for future research.** In view of the paucity of research on the effects of middle ear pathologies on hearing and the varied outcomes of hearing after myringoplasty surgery, it was hoped that the current study added value to the audiological and surgical (ear nose and throat) research domain. In light of the lack of research in this area in South Africa the following are recommendations for future research:

- A replication of this study on a larger sample size; thus yielding more statistically significant information. Many of the participants needed to be excluded from the current study due to missing biographical and audiological data.
- As otitis media is more prevalent in children; including the paediatric population may be of particular relevance and interest. Hearing outcome post surgery may take a different course and the variables affecting their hearing outcome post surgery may be different. Being able to better predict their outcome post surgery may impact the progression of the speech-language and behavioural development.
- Considering the time period for which hearing assessments pre and post surgery was evaluated may be variable to consider for future research as research has shown that hearing sensitivity at different time intervals (six weeks, three months and six months) post-surgery does change.

- Conducting the current study using a different research design instead of retrospective record review may eliminate some of the limitations and barriers the researcher encountered such as incomplete audiograms. By the researcher conducting the relevant audiological tests one may have more control of the reliability of the tests and yield more data to draw more accurate conclusions.

The current study yielded pertinent information regarding the changes in hearing post myringoplasty and the influence of HIV status and type of surgical technique on hearing outcome post operatively. The current study has shown that the changes in hearing function post two types of myringoplasty are not comparable to all studies of similar nature; due to the fact that not all studies looked at the exact measures of hearing which the current study investigated. Some of these changes in hearing have been found to be statistically significant. The study also found that clinically HIV/AIDS does have an influence on hearing outcome post-surgery and when specifically looking at air-conduction thresholds some of these changes was statistically significant. Predictors of improved audiological outcome also indicated trends in HIV status and its effect on different aspects of audiological testing. The type of surgical technique clinically does have an influence on hearing outcome post-surgery and specifically when looking at air-conduction thresholds in which some changes were found to be statistically significant.

In conclusion, the results from the current study suggested that clinically hearing post-operatively improves in HIV negative patients who underwent butterfly cartilage inlay surgery; although these changes are not statistically significant. However, this study highlights the importance of performing all relevant audiological tests in patients who require surgical intervention such as myringoplasty. There is a lack of research in South Africa regarding hearing outcome post myringoplasty and the effects of variables like HIV status and type of surgery on

hearing outcome. Thus, the findings of the current study served as a baseline which can be expanded upon in future research.

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Appendices

**Appendix A.** Raw biographical and audiological data

PT	AGE	GEN	HIV	EAR	TECH	ECV R	ECV L	Compl R	Compl L	Press R	Press L	AC R 250	AC L 250	AC R 500	AC L 500	AC R 1000	AC L 1000	AC R 2000	AC L 2000	AC R 4000	AC L 4000	AC R 8000	AC L 8000	BC R 500	BC L 500	BC R 1000	BC L 1000	BC R 2000	BC L 2000	BC R 4000	BC L 4000	SRT R	SRT L				
*1A	27	M	N	R	F	7		NR		NR		20		20		15		20		20		10		DNT		DNT		DNT		DNT		10		50			
*1B						0.5		0.1		-35		15		15		5		25		30		20		0		0		20		10		20					
*2A	48	M	N	L	F		PER		PER		PER		45		45		30		25		30		35		20		15		20		20		20		35		
*2B							1.3		0.1		120		20		15		15		15		35		35		10		5		15		20		20		20		
*3A	48	F	N	R	C	1.9		0.2		-125		25		20		30		15		35		50		15		5		0		0		30					
*3B						2.2		NP		NP		30		25		25		5		25		40		25		10		5		10		5		5			
*4A	46	F	N	L	C		PER		PER		PER		60		65		60		45		55		50		25		20		30		45		50		50		
*4B							TY C		TY C		TY C		25		20		25		40		50		80		10		10		20		25		25		25		
*5A	23	F	N	B	F	PER	2	PER	0.1	PER	-385	45	60	70	75	45	55	40	30	50	30	30	40	10	-10	5	-5	20	20	0	0	55	55	55	55		
*5B						PER	PER	PER	PER	PER	PER	55	35	55	35	40	20	45	15	50	20	45	45	10	0	5	5	20	10	10	5	50	25	25	25		
*6A	47	M	N	L	F		0.8		NR		NR		35		50		55		60		45		65		-5		-5		10		10		50		50		
*6B																																					
*7A	50	F	N	L	C		PER		PER		PER		75		65		45		40		50		40		10		15		15		0		45		45		
*7B							0.6		NR		NR		15		10		10		10		40		50		NO BC		NO BC		NO BC		10		15		15		
*8A	59	F	N	R	U	PER		PER		PER		55		60		55		35		55		30		20		25		40		15		50		50		50	
*8B																																					
*9A	30	M	N	R	C	PER		PER		PER		50		60		60		40		40		45		-5		15		5		0		50		50		50	
*9B						PER		PER		PER		90		90		85		50		110		95		35		10		25		60		80		80		80	
*10A	42	F	N	B	C	PER	PER	PER	PER	PER	PER	25	35	25	20	30	5	25	15	30	35	40	65	20	15	10	5	15	10	10	10	35	20	20	20	20	

PT	AGE	GEN	HIV	EAR	TECH	ECVR	ECVL	ComplR	ComplL	Press R	Press L	AC R 250	AC L 250	AC R 500	AC L 500	AC R 1000	AC L 1000	AC R 2000	AC L 2000	AC R 4000	AC L 4000	AC R 8000	AC L 8000	BC R 500	BC L 500	BC R 1000	BC L 1000	BC R 2000	BC L 2000	BC R 4000	BC L 4000	SRT R	SRT L				
*10B						NO PO																															
*11A	40	F	N	L	U		PER		PER		PER		70		70		65		55		55		60		20		20		25		25		60				
*11B							1		0.7		-30		45		50		50		35		65		90		10		15		25		20		50				
*12A	33	F	P	B	F	1.5	1.5	0.7	NR	NR	NR	50	80	40	75	40	70	40	65	25	65	40	50	15	30	30	30	25	25	25	15	DNT	DNT				
*12B						0.8	PER	NR	PER	NR	PER	75	95	80	100	60	100	40	110	45	105	70	80	60	60	40	75	60	80	70	40	50	DNT				
*13A	27	F	N	L	F	NO PR																															
*13B							PER		PER		PER		35		35		20		25		30		35		5		5		10		5		40				
*14A	38	F	N	R	C	NO PR																															
*14B						2.7		0.1		165		60		65		60		60		110		85		10		25		35		30		60					
*15A	48	F	P	R	C	PER		PER		PER		40		35		30		40		40		45		15		10		20		20		DNT					
*15B						PER		PER		PER		10		0		0		20		30		25		-5		-10		10		20		20					
*16A	45	M	N	B	C	PER	PER	PER	PER	PER	PER	60	60	45	65	50	55	75	45	80	40	60	40	5	25	0	20	35	30	40	25	50	55				
*16B						NO PO																															
*17A	49	F	P	B	C	1.1	PER	NR	PER	NR	PER	55	60	45	65	45	55	25	45	40	40	30	40	5	25	15	20	20	30	15	25	40	55				
*17B						1.7	1.5	NR	NR	NR	NR	70	35	60	45	55	50	55	50	40	40	40	35	20	25	30	35	30	25	20	20	DNT	DNT				
*18A	36	F	N	R	C	4.5		NR		NR		40		25		15		25		55		65		15		5		20		10		40					
*18B						5		NR		NR		40		25		15		35		50		80		0		0		30		20		30					
*19A	40	M	N	L	C	PER		PER		PER		60		55		50		45		40		45		20		10		40		20		50					
*19B						1.4		0.3		-15		50		30		50		40		50		60		20		15		30		10		40					
*20A	58	M	N	B	C	NO PR																															
*20B						PER	1.8	PER	2.5	PER	-15	30	30	40	40	55	50	55	50	NR	100	NR	100	NO BC	20	NO BC	40	NO BC	45	NO BC	65	55	55				
*21A	55	F	N	R	C	NO PR																															
*21B						1.5		NR		NR		10		10		20		20		15		40		-5		0		10		-10		25					
*22A	25	F	N	B	C	PER	NO PR	PER	NO PR	PER	NO PR	35	NO PR	30	NO PR	30	NO PR	25	NO PR	30	NO PR	20	NO PR	15	NO PR	10	NO PR	15	NO PR	5	NO PR	25	NO PR				

PT	AGE	GEN	HIV	EAR	TECH	ECVR	ECVL	Compl R	Compl L	Press R	Press L	AC R 250	ACL 250	AC R 500	ACL 500	AC R 1000	ACL 1000	AC R 2000	ACL 2000	AC R 4000	ACL 4000	AC R 8000	ACL 8000	BC R 500	BC L 500	BC R 1000	BC L 1000	BC R 2000	BC L 2000	BC R 4000	BC L 4000	SRT R	SRT L
*22B						NO PO	PER	NO PO	PER	NO PO	PER	NO PO	30	NO PO	25	NO PO	20	NO PO	15	NO PO	20	NO PO	45	NO PO	5	NO PO	5	NO PO	0	NO PO	0	NO PO	20
*23A	51	F	N	L	C		1.5		NR		NR		70		60		40		45		45		60		30		10		25		20		40
*23B							PER		PER		PER		50		35		55		40		40		35		30		25		50		40		55
*24A	46	M	N	R	F	TY C		TY C		TY C		55		70		60		60		65		35		35		25		55		55		55	
*24B						1		0.1		255		20		25		30		15		30		40		10		10		15		5		30	
*25A	40	M	N	L	C		PER		PER		PER		60		45		35		25		25		35		10		5		20		10		30
*25B							0.5		0.4		-15		50		50		40		55		30		75		20		30		40		5		45
*26A	44	M	N	R	C	PER		PER		PER		40		20		15		30		25		30		5		10		15		10		30	
*26B						NO PO																											
*27A	23	F	P	R	C	PER		PER		PER		DNT		DNT		55		60		60		40		55		35		25		20		20	
*27B						1.3		0.2		-365		DNT		DNT		30		30		20		10		25		70		0		-5		0	
*28A	40	M	N	L	C		PER		PER		PER		30		25		20		30		55		70		5		0		15		5		DNT
*28B						NO PO																											
*29A	20	F	N	L	C		PER		PER		PER		45		35		20		15		15		20		5		15		10		5		20
*29B							PER		PER		PER		25		20		15		15		25		30		NO BC		NO BC		NO BC		NO BC		25
*30A	49	F	N	R	C	TY C		TY C		TY C		95		100		100		110		100		120		20		20		20		20		60	
*30B							PER		PER		PER		DNT		DNT		65		55		55		55		70		80		10		15		15
*31A	44	M	N	R	U	PER		PER		PER		DNT		DNT		25		20		25		30		20		20		25		10		10	
*31B						NO PO																											
*32A	36	M	N	R	C	NO PR																											
*32B						1.5		NR		NR		20		30		25		20		20		45		15		15		10		15		30	
*33A	37	F	P	B	C	PER	1.5	PER	NR	PER	60	DNT	DNT	DNT	DNT	55	55	65	60	65	60	75	55	55	40	55	45	25	15	20	20	55	35
*33B						PER	1	PER	NR	PER	65	DNT	DNT	DNT	DNT	40	50	55	55	65	55	65	50	45	50	35	45	25	10	15	10	45	35
34A	U	F	N	L	U		1.7		NR		NR		60		75		60		65		60		75		20		10		20		5		DNT

PT	AGE	GEN	HIV	EAR	TECH	ECVR	ECVL	Compl R	Compl L	Press R	Press L	AC R 250	AC L 250	AC R 500	AC L 500	AC R 1000	AC L 1000	AC R 2000	AC L 2000	AC R 4000	AC L 4000	AC R 8000	AC L 8000	BC R 500	BC L 500	BC R 1000	BC L 1000	BC R 2000	BC L 2000	BC R 4000	BC L 4000	SRT R	SRT L	
34B						PER		PER		PER		65	70	70	65	75	85	10	15	10	25													DNT
35A	23	M	N	L	U	PER		PER		PER		60	60	55	50	40	55	20	25	20	0													DNT
35B																																		
NO PO																																		
36A	42	M	P	R	U	PER		PER		PER		40	30	35	30	30	60	20	5	15	0													DNT
36B						PER		PER		PER		45	35	30	30	35	85	-5	10	25	0													DNT
37A	U	F	P	R	C	PER		PER		PER		65	45	70	100	120	NR	20	40	70	65	60												
37B						PER		PER		PER		25	25	35	70	65	95	95	NR	15	35													DNT
38A	32	F	U	R	C	PER		PER		PER		65	60	60	55	60	55	0	15	20	10													DNT
38B																																		
NO PO																																		
39A	18	M	U	R	C	PER		PER		PER		100	100	110	100	70	75	10	25	30	10													DNT
39B						0.9		1.3		-195		65	55	50	50	35	25	20	25	35	5													DNT
40A	26	M	U	R	U	PER		PER		PER		50	30	25	25	95	95	0	5	5	0													DNT
40B						PER		PER		PER		40	95	25	30	45	40	20	15	30	15													DNT
41A	31	F	P	L	C		PER		PER		PER	50	50	50	45	75	95	30	30	30	35													55
41B							PER		PER		PER	30	30	35	35	50	110	25	25	30	40													DNT
42A	42	F	U	B	U	PER	3.1	PER	0.2	PER	15	75	55	50	35	45	35	60	45	70	50	75	65	20	30	0	0	30	40	30	35	60	55	
42B																																		
NO PO																																		
43A	52	F	N	R	C	PER		PER		PER		85	70	60	55	50	60	50	40	35	65	25	30	30	5								DNT	
43B						PER		PER		PER		65	55	55	40	35	65	25	30	30	5													DNT
44A	58	F	N	R	U	PER		PER		PER		105	105	95	100	100	105	50	40	60	65													DNT
44B						PER		PER		PER		95	100	90	105	100	95	40	40	50	50													DNT
45A	26	M	N	R	U	PER		PER		PER		50	50	70	75	60	55	5	15	35	30													DNT
45B						PER		PER		PER		60	60	70	80	80	70	20	25	50	35													DNT
46A	U	M	N	R	C																													
NO PR																																		

PT	AGE	GEN	HIV	EAR	TECH	ECV R	ECV L	Compl R	Compl L	Press R	Press L	AC R 250	AC L 250	AC R 500	AC L 500	AC R 1000	AC L 1000	AC R 2000	AC L 2000	AC R 4000	AC L 4000	AC R 8000	AC L 8000	BC R 500	BC L 500	BC R 1000	BC L 1000	BC R 2000	BC L 2000	BC R 4000	BC L 4000	SRT R	SRT L
46B						PER		PER		PER		80		55		50		45		45		100		45		95		35		40		DNT	
47A	49	F	N	R	C	2		0.1		-185		80		70		70		55		50		45		20		10		20		0		DNT	
47B						1.2		0.3		20		25		20		25		20		35		35		NO BC		NO BC		NO BC		NO BC		DNT	
48A	18	F	N	B	C	PER	PER	PER	PER	PER	PER	50	45	45	30	15	20	20	25	15	15	30	10	0	5	0	5	5	10	0	0	DNT	DNT
48B	NO PO																																
49A	60	M	N	L	C		PER		PER		PER		100		105		110		110		110		100		55		60		65		80		DNT
49B	NO PO																																
50A	63	F	P	B	C	PER	PER	PER	PER	PER	PER	95	80	90	85	80	80	85	85	90	100	110	110	60	70	65	65	75	75	85	80	DNT	DNT
50B						PER	PER	PER	PER	PER	PER	90	60	95	55	70	40	80	55	95	65	90	90	35	55	25	30	40	35	45	30	95	55
51A	33	F	P	R	C	PER		PER		PER		50		25		20		30		35		30		0		0		10		0		25	
51B						PER		PER		PER		30		25		25		40		25		30		NO BC		NO BC		NO BC		NO BC		DNT	
52A	U	F	P	L	U		PER		PER		PER		55		50		45		50		45		60		30		30		30		0		DNT
52B							PER		PER		PER		50		40		35		35		40		70		35		25		25		20		DNT

**KEY:** \* participants from hospital A, **A** pre operative results, **B** post operative results, **PT** Patient, **GEN** gender, **M** male, **F** female, **TECH** technique of surgery, **C** butterfly cartilage inlay surgery, **F** fascia underlay surgery, **U** unknown surgical technique, **P** HIV positive status, **N** HIV negative status **ECV** ear canal volume, **R** right ear, **L** left ear, **COMP** static compliance (cm<sup>3</sup>), **PRESS** pressure (daPa), **AC** air-conduction, **BC** bone-conduction, **PER** perforation in eardrum, **TY** type, **NR** no response, **PO** post-operative, **PR** pre-operative, **DNT** did not test, **SRT** speech reception threshold

**Appendix B. Ethical clearance certificate**



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

**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)**  
R14/49 Ms Namita Ramdin

**CLEARANCE CERTIFICATE**

**M121012**

**PROJECT**

Audiological Function in a Group of Adults following Myringoplasty: An Exploratory Study in a Developing Country Context

**INVESTIGATORS**

Ms Namita Ramdin.

**DEPARTMENT**

Speech Pathology & Audiology

**DATE CONSIDERED**

26/10/2012

**DECISION OF THE COMMITTEE\***

Approved unconditionally

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

**DATE**

26/10/2012

**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

**Appendix C.** Letter to Chief Executive Officer (CEO) of Chris Hani Baragwanath Academic Hospital/ Charlotte Maxele Academic Hospital



***SPEECH PATHOLOGY AND AUDIOLOGY***

***School of Human & Community Development***

**Faculty of Humanities**

**University of the Witwatersrand**

**Private Bag 3, WITS, 2050**

**Tel: (011) 717 4577 Fax: (011) 717 4572**



**RE: Request to review patient files at Chris Hani Baragwanath Academic Hospital/Charlotte Maxele Academic Hospital**

***To the Chief Executive Officer at Chris Hani Baragwanath Academic Hospital/ Charlotte Maxele Academic Hospital***

My name is Namita Ramdin. I am a Speech Therapist and Audiologist.

I am a postgraduate student at the University of the Witwatersrand conducting a Masters study in Audiology focusing on hearing outcome post myringoplasty surgery. I am requesting to review surgical and audiological records from your hospital from the last 6 years of all patients who have undergone this surgery aged 18-63 years.

**What the study entails:** Once permission from the CEO has been granted; I will send letters to the HOD's of the Speech Therapy and Audiology Department as well as the ENT department to get written permission to access the data. I will arrange with the departments which days and times will be convenient for them as well as myself to review the necessary data and collect the information I require. I will need a space in which to review the data within the department and will thus not remove any documents from the department. I will be as discreet as possible and not disturb the staff or patients during my data collection process.

**What information will I be recording and why:** I will require biographical information such as age of patient, gender of patient, HIV Status and type of surgical technique performed. This biographical information will be used for statistical purposes and provide essential information that will be used to answer the research questions such as "does the presence of HIV/AIDS affect hearing outcome post-surgery?" And "does the type of surgical technique have an influence on hearing outcome post surgery?"

I will require audiological information (pre and post myringoplasty operation) such as type of tympanogram, air-conduction thresholds at 250Hz, 500Hz, 1000Hz, 2000Hz, 4000Hz and 8000Hz,

air bone gaps at 500Hz, 1000Hz, 2000Hz and 4000Hz and speech reception thresholds. The above audiological information is essential in determining the audiological changes pre and post surgery which is the primary aim of the study.

**Benefit of the study:** The study is of paramount importance as such an investigation has never been conducted in the selected population. Thus the study will yield relevant information regarding variables affecting the outcome of myringoplasty surgery in a South African context which is essential in the management of patients from an audiological and surgical perspective when undergoing myringoplasty surgery.

**Ethical considerations:** I will ensure confidentiality and anonymity by not allowing anyone else to review the data other than myself and my supervisor. Efforts will be made to keep personal information confidential by creating a numeric/alphabetic coding system (assign number and alphabets) to the patient's names so not to reveal their identities.

I trust you will consider my request favourably, looking forward to your positive response. Please feel free to contact me or my supervisor with any questions/concerns.

Thank you,

---

Namita Ramdin

Researcher

(Cell: 079 881 0386)

Email: [namita1437@yahoo.com](mailto:namita1437@yahoo.com)

---

Professor Katijah Khoza-Shangase

Research Supervisor

(Tell: 011 717 4565)

Email: [katijah.khoza-shangase@wits.ac.za](mailto:katijah.khoza-shangase@wits.ac.za)

**Should you consent for me to conduct my study at your hospital please complete the section below:**

I \_\_\_\_\_ give Namita Ramdin permission to conduct her research at \_\_\_\_\_. I fully understand what the study entails and the benefit thereof.

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Witness details**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Appendix D. Permission letter from the CEO of Charlotte Maxeke Academic Hospital**



**GAUTENG PROVINCE**  
HEALTH  
REPUBLIC OF SOUTH AFRICA

**CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL**

Enquiries:  
Office of the Chief Executive Officer  
Charlotte Maxeke Johannesburg Academic Hospital  
Tell: 011 488 3792  
Fax: 011 488 3753  
Email: [ljindiwe.mngomezulu@gauteng.gov.za](mailto:ljindiwe.mngomezulu@gauteng.gov.za)  
Date: 06 February 2013

Ms. Namita Ramdin  
Speech and Audiology  
CMJAH

**RE: "Audiological Function in a Group of Adults following Myringoplasty: An Exploratory Study in a Developing Country Context"**

Permission is granted for you to conduct the above research as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in any way incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.

Please liaise with the Head of Department and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Yours sincerely,



.....  
Dr. M. Mofokeng  
Acting Chief Executive Officer

**Appendix E.** Letter to Head of Department (HOD) Speech Therapy and Audiology at Chris Hani Baragwanath Academic Hospital/ Charlotte Maxele Academic Hospital



***SPEECH PATHOLOGY AND AUDIOLOGY***

***School of Human & Community Development***

**Faculty of Humanities**

**University of the Witwatersrand**

**Private Bag 3, WITS, 2050**

**Tel: (011) 717 4577 Fax: (011) 717 4572**



**RE: Request to review patient files at Chris Hani Baragwanath Academic Hospital/Charlotte Maxele Academic Hospital**

***To the Head of Department (HOD) Speech Therapy and Audiology at Chris Hani Baragwanath Academic Hospital/ Charlotte Maxele Academic Hospital***

My name is Namita Ramdin. I am a Speech Therapist and Audiologist.

I am a postgraduate student at the University of the Witwatersrand conducting a Masters study in Audiology focusing on hearing outcome post myringoplasty surgery. I am requesting to review surgical and audiological records from your hospital from the last 6 years of all patients who have undergone this surgery aged 18-63 years.

**What the study entails:** Once permission from the CEO has been granted; I will send letters to the HOD's of the Speech Therapy and Audiology Department as well as the ENT department to get written permission to access the data. I will arrange with the departments which days and times will be convenient for them as well as myself to review the necessary data and collect the information I require. I will need a space in which to review the data within the department and will thus not remove any documents from the department. I will be as discreet as possible and not disturb the staff or patients during my data collection process.

**What information will I be recording and why:** I will require biographical information such as age of patient, gender of patient, HIV Status and type of surgical technique performed. This biographical information will be used for statistical purposes and provide essential information that will be used to answer the research questions such as "does the presence of HIV/AIDS affect hearing outcome post-surgery?" And "does the type of surgical technique have an influence on hearing outcome post surgery?"

I will require audiological information (pre and post myringoplasty operation) such as type of tympanogram, air-conduction thresholds at 250Hz, 500Hz, 1000Hz, 2000Hz, 4000Hz and 8000Hz, air bone gaps at 500Hz, 1000Hz, 2000Hz and 4000Hz and speech reception thresholds. The above

audiological information is essential in determining the audiological changes pre and post surgery which is the primary aim of the study.

**Benefit of the study:** The study is of paramount importance as such an investigation has never been conducted in the selected population. Thus the study will yield relevant information regarding variables affecting the outcome of myringoplasty surgery in a South African context which is essential in the management of patients from an audiological and surgical perspective when undergoing myringoplasty surgery.

**Ethical considerations:** I will ensure confidentiality and anonymity by not allowing anyone else to review the data other than myself and my supervisor. Efforts will be made to keep personal information confidential by creating a numeric/alphabetic coding system (assign number and alphabets) to the patient's names so not to reveal their identities.

I trust you will consider my request favourably, looking forward to your positive response. Please feel free to contact me or my supervisor with any questions/concerns.

Thank you,

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Namita Ramdin

Researcher

(Cell: 079 881 0386)

Email: [namita1437@yahoo.com](mailto:namita1437@yahoo.com)

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Professor Katijah Khoza-Shangase

Research Supervisor

(Tell: 011 717 4565)

Email: [katijah.khoza-shangase@wits.ac.za](mailto:katijah.khoza-shangase@wits.ac.za)

**Should you consent for me to conduct my study at your hospital please complete the section below:**

I \_\_\_\_\_ give Namita Ramdin permission to conduct her research at \_\_\_\_\_. I fully understand what the study entails and the benefit thereof.

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Witness details**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Appendix F.** Letter to Head of Department (HOD) Otolaryngology at Chris Hani Baragwanath Academic Hospital/ Charlotte Maxele Academic Hospital

***SPEECH PATHOLOGY AND AUDIOLOGY***

***School of Human & Community Development***

**Faculty of Humanities**

**University of the Witwatersrand**

**Private Bag 3, WITS, 2050**

**Tel: (011) 717 4577 Fax: (011) 717 4572**



**RE: Request to review patient files at Chris Hani Baragwanath Academic Hospital/Charlotte Maxele Academic Hospital**

***Head of Department (HOD) Otolaryngology at Chris Hani Baragwanath Academic Hospital/ Charlotte Maxele Academic Hospital***

My name is Namita Ramdin. I am a Speech Therapist and Audiologist.

I am a postgraduate student at the University of the Witwatersrand conducting a Masters study in Audiology focusing on hearing outcome post myringoplasty surgery. I am requesting to review surgical and audiological records from your hospital from the last 6 years of all patients who have undergone this surgery aged 18-63 years.

**What the study entails:** Once permission from the CEO has been granted; I will send letters to the HOD's of the Speech Therapy and Audiology Department as well as the ENT department to get written permission to access the data. I will arrange with the departments which days and times will be convenient for them as well as myself to review the necessary data and collect the information I require. I will need a space in which to review the data within the department and will thus not remove any documents from the department. I will be as discreet as possible and not disturb the staff or patients during my data collection process.

**What information will I be recording and why:** I will require biographical information such as age of patient, gender of patient, HIV Status and type of surgical technique performed. This biographical information will be used for statistical purposes and provide essential information that will be used to answer the research questions such as "does the presence of HIV/AIDS affect hearing outcome post-surgery?" And "does the type of surgical technique have an influence on hearing outcome post surgery?"

I will require audiological information (pre and post myringoplasty operation) such as type of tympanogram, air-conduction thresholds at 250Hz, 500Hz, 1000Hz, 2000Hz, 4000Hz and 8000Hz, air bone gaps at 500Hz, 1000Hz, 2000Hz and 4000Hz and speech reception thresholds. The above audiological information is essential in determining the audiological changes pre and post surgery which is the primary aim of the study.

**Benefit of the study:** The study is of paramount importance as such an investigation has never been conducted in the selected population. Thus the study will yield relevant information regarding variables affecting the outcome of myringoplasty surgery in a South African context which is essential in the management of patients from an audiological and surgical perspective when undergoing myringoplasty surgery.

**Ethical considerations:** I will ensure confidentiality and anonymity by not allowing anyone else to review the data other than myself and my supervisor. Efforts will be made to keep personal information confidential by creating a numeric/alphabetic coding system (assign number and alphabets) to the patient's names so not to reveal their identities.

I trust you will consider my request favourably, looking forward to your positive response. Please feel free to contact me or my supervisor with any questions/concerns.

Thank you,

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Namita Ramdin

Researcher

(Cell: 079 881 0386)

Email: [namita1437@yahoo.com](mailto:namita1437@yahoo.com)

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Professor Katijah Khoza-Shangase

Research Supervisor

(Tell: 011 717 4565)

Email: [katijah.khoza-shangase@wits.ac.za](mailto:katijah.khoza-shangase@wits.ac.za)

**Should you consent for me to conduct my study at your hospital please complete the section below:**

I \_\_\_\_\_ give Namita Ramdin permission to conduct her research at \_\_\_\_\_. I fully understand what the study entails and the benefit thereof.

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Witness details**

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Appendix G. Permission letter from the HOD Otolaryngology at of Charlotte Maxeke Academic Hospital**



**GAUTENG PROVINCE**  
HEALTH  
REPUBLIC OF SOUTH AFRICA

**CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL  
OTORHINOLARYNGOLOGY - HEAD NECK SURGERY**

To whom it concerns:

This is to confirm that Ms Namita Ramdin (Cell: 079 881 0386), Audiologist & Speech Therapist, at the University of the Witwatersrand, has been granted permission to access information related to her Masters Study on Audiological results of Myringoplasty procedures performed in the ENT department at CMJA Hospital. The permission for the study & to access hospital records has already been granted by the Office of the CEO – CMJA Hospital.

Further permission from the ENT Department is now granted for Ms N Ramdin to access records from the Operating Theatre Records; Ward Records & Out-patient Records. This will be at no costs incurred to the ENT department. Assistance will be required from Nursing, Administrative and Medical Staff.

The Information she requires includes:

1. Permission to access and review ENT records over the past 3 years from the wards, OPD, and Operating Theatre Room Registers.
2. Names of patients (to be kept confidential by using codes),
3. Hospital no's (requires confidentiality by using codes),
4. Gender,
5. Age,
6. HIV status and
7. Type of Graft material used in the Myringoplasty procedure performed (ie free Temporalis Fascia; free Cartilage; free Perichondrium)
8. Clinical follow up and Clinical & Audiological results.

Sincerely

Prof PC Modi  
Clinical Head – ENT  
February 14<sup>th</sup> 2013

Cc:	Dr S Motakef.	Senior Specialist.	ENT
Cc:	Dr M Torres-Holmes.	Specialist.	ENT
Cc:	Dr R K Maringa.	Specialist.	ENT



PT	AC R 250	ACL 250	AC R 500	ACL 500	AC R 1000	ACL 1000	AC R 2000	ACL 2000	AC R 4000	ACL 4000	AC R 8000	ACL 8000	BC R 500	BCL 500	BC R 1000	BCL 1000	BC R 2000	BCL 2000	BC R 4000	BCL 4000
50	5	20	-5	30	10	40	5	30	5	35	20	20	25	15	40	35	35	40	40	50
51	20		0		-5		-10		10		0									
52		5		10		10		15		5		-10		-5		5		5		-20

**KEY:** PT Patient, R right ear, L left ear, AC air-conduction, BC bone-conduction

**NB:** blank spaces in the table indicate missing thresholds

**Appendix I. Air-bone gap pre and post-operatively (dB)**

PT	HIV	TECH	Pr ABG 500Hz	Pr ABG 1000Hz	Pr ABG 2000Hz	Po ABG 500Hz	Po ABG 1000Hz	Po ABG 2000Hz
2	N	F	25	15	5	5	10	10
3	N	C	5	25	15	0	15	0
4	N	C	40	40	15	10	15	20
5 (R)	N	F	60	40	20	45	35	25
5 (L)	N	F	85	60	10	35	15	5
9	N	C	65	45	35	55	80	90
11	N	U	50	35	30	40	35	10
12 (R)	P	F	25	10	15	20	20	20
12 (L)	P	F	45	40	40	40	25	30
15	P	C	20	20	45	5	10	10
17 (R)	P	C	40	30	5	65	65	30
17 (L)	P	C	30	35	15	20	15	25
18	N	C	10	10	5	25	15	20
19	N	C	35	40	5	10	35	10
23	N	C	30	30	20	5	30	20
24	N	F	35	35	5	15	20	0
25	N	C	35	30	5	30	10	15
27	P	C		20	40		40	30
30	N	C	80	80	90		15	45
33 (R)	P	C		0	40		5	30
33 (L)	P	C		10	45		5	45
34	N	U	65	45	55	50	45	45
36	P	U	10	30	15	40	20	5
37	P	C	25	30	30	70		55
39	U	C	90	85	70	35	25	0
40	U	U	30	20	20	75	10	15
41	P	C	20	20	15	5	10	5
43	N	C	20	20	20	30	25	10
44	N	U	0	5	10	60	50	55
45	N	U	45	55	40	40	45	30

50 (R)	P	C	30	15	10	55	45	40
50 (L)	P	C	15	15	10	0	10	20
52	P	U	20	15	20	5	10	10

**KEY:** **PT** Patient, **HIV** HIV status, **N** negative HIV status, **P** positive HIV status, **TECH** type of surgical technique, **C** butterfly cartilage inlay, **F** fascia underlay, **U** unknown surgical technique, **Pr** pre operatively, **Po** post operatively, **ABG** air-bone gap

**NB:** blank spaces in the table indicate missing thresholds

**Appendix J.** Speech reception thresholds pre and post-operatively (dB)

<b>PARTICIPAN T</b>	<b>PRE</b>	<b>PARTICIPAN T</b>	<b>POST</b>	<b>HIV</b>	<b>TYPE OF SURGERY</b>
1A	50	1B	20	N	F
2A	35	2B	20	N	F
3A	30	3B	5	N	C
4A	50	4B	25	N	C
5A R	55	5B R	50	N	F
5A L	55	5B L	25	N	F
7A	45	7B	15	N	C
9A	50	9B	80	N	C
11A	60	11B	50	N	U
18A	40	18B	30	N	C
19A	50	19B	40	N	C
23A	40	23B	55	N	C
24A	55	24B	30	N	F
25A	30	25B	45	N	C
27A	20	27B	0	P	C
29A	20	29B	25	N	C
30A	60	30B	15	N	C
33A R	55	33B R	45	P	C
33A L	35	33B L	35	P	C

**KEY:** **A** pre, **B** post, **R** right, **L** left, **PRE** pre SRT (dB), **POST** post SRT (dB), **HIV** HIV status, **N** negative HIV status, **P** positive HIV status, **TECH** type of surgical technique, **C** butterfly cartilage inlay, **F** fascia underlay, **U** unknown surgical technique