Effects of Middle Ear Surgery on Extended High Frequency Hearing

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Abstract

It is well documented that middle ear surgery leads to a deterioration in hearing acuity in the extended high frequency range (EHF). However, it is yet to be determined whether this deterioration is due to a disruption in sound transmission through the middle ear system or damage to the inner ear. Gaining this information remains a challenge due to limitations in the output of EHF stimuli. The current study aimed to build on two small pilot studies which used a system capable of measuring air conduction (AC) and bone conduction (BC) EHF pure tone thresholds with some degree of masking. Using a modified TEAC HP-F100 BC transducer and a custom laptop audiometer, AC and BC thresholds across the entire audiometric frequency range were monitored up to 1 month (N =20) and 3 months (N =11) post middle ear surgery.

Results from this study demonstrate post-operative deterioration in AC thresholds immediately post-op followed by some recovery. Despite encountering constraints in EHF masking output, we report clear evidence of a deterioration in in EHF BC thresholds that persists up to 3 months post-op mainly at 9 to 11.2 kHz. The current study builds a foundation for future studies to examine post-operative outcomes in the range of hearing.

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Table Contents

List of Tables

List of Figures

List of Abbreviations

AAO-HNS	American Academy of Otolaryngology–Head and Neck Surgery
ABG	Air bone gap
AC	Air conduction
SHA	American Speech-Language Hearing Association
BC	Bone Conduction
BBN	Broadband Noise
CF	Conventional Frequency
CHL	Conductive Hearing loss
COM	Chronic Otitis Media
dB	decibel
dB HL	decibel Hearing Level
dB SPL	decibel Sound Pressure level
EAC	External Auditory Canal
EAM	External Auditory Meatus
EHF	Extended High Frequency
Hz	Hertz
IA	Interaural Attenuation

IHC	Inner hair cell
ISO	International standards organisation
MET	Mechano-electrical transduction
NBN	Narrowband noise
NIHL	Noise induced hearing loss
NTE	Non-test ear
NSAIDs	Non-steroidal anti-inflammatory drugs
OHC	Outer hair cells
PORP	Partial ossicular replacement prosthesis
PTA	Pure tone audiometry
PTS	Permanent threshold shift
SNHL	Sensorineural hearing loss
SPL	Sound pressure level
TE	Test ear
TM	Tympanic membrane
TORP	Total ossicular replacement prosthesis
TTS	Temporary threshold shift

Chapter 1: Introduction

Disease of the middle ear can drastically affect the quality of life of an individual. Though hearing loss is typically the primary complaint of these patients; balance issues, facial numbness or facial paralysis and risk of the spread of infection can also result from middle ear pathologies. Surgical intervention is the typical mode of treatment for such cases. The primary goal of middle ear surgery is to eradicate disease, shared with the secondary aim of restoring the air conduction pathway through the middle ear system to improve hearing.

The parameters used to measure outcomes following middle ear surgery varies greatly throughout the literature. Nevertheless, there is an overall consensus that surgical intervention leads to an improvement in hearing. It is important to consider that these studies typically report hearing improvement in the conventional frequency range (250 – 8000 Hz) which is the focus of clinical audiometric testing. However, there is increasing evidence that suggests middle ear surgery has a negative effect hearing threshold beyond 4000 Hz. Indeed, patients are warned of a small risk of post-surgical hearing loss and generally refer to a 0.5 % risk of total loss, and 5% risk of partial loss (Dawes & Curry, 1974). Bergin, Bird, Vlajkovic, and Thorne (2015) proposed these rates are greatly underestimated, reporting up to 25% of patients undergoing middle ear surgery walk away with a sensorineural hearing loss at 4 kHz post-surgery. Moreover, the human range of hearing spans up to 20,000 Hz in a healthy young individual. However, the effect of middle ear surgery beyond the conventional frequency range, namely the extended high frequency range (EHF) (9 – 20 kHz) is not well characterised. A study focusing on patients undergoing stapedectomy by Babbage (2015) demonstrated a deterioration in air conduction thresholds in the EHF range.

Audibility beyond 4000 Hz contributes to speech understanding, sound localisation and the ability to hear in background noise. Therefore, it is important to gain an understanding on how this range of hearing is affected by middle ear surgery. Gaining insight into the mechanism(s) of insult will contribute towards work in refining surgical techniques in such a way to prevent injury.

A number of limitations arise when conducting audiometric testing in this range. The predominant limitation is the high energy output required to present stimuli in this range, which cannot be met by current clinical diagnostic equipment. This renders the task of testing individuals with conductive hearing loss problematic as they require even higher presentation levels for both stimuli and makers during audiometric testing.

A modified TEAC bone conduction transducer offers the ability to measure bone-conduction stimuli in the EHF. Previous pilot studies demonstrate this transducer to be a feasible option for audiometric testing in both pure tone audiometry (Howey, 2019) and measuring the auditory brain stem response (Salter, 2019). Obtaining bone conduction thresholds in the EHF range has been a limitation faced by numerous studies and solving this puzzle has the potential to offer invaluable information regarding the site of lesion attributed to surgical intervention.

By utilising this transducer, the current study aims to monitor changes in EHF hearing over a 3-month period following middle ear surgery. The following chapter will provide the necessary foundation in the structure and function of the auditory system and the relevant techniques in assessing auditory function.

Chapter 2: The auditory system and assessing auditory function

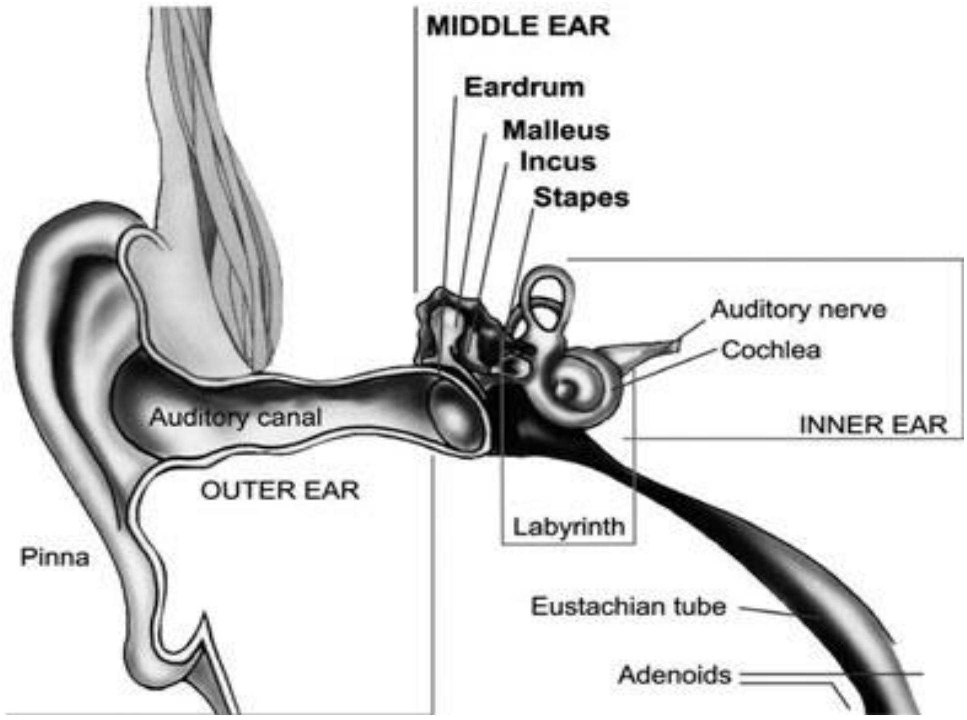

Figure 1 -Peripheral auditory system - divided into outer ear, middle ear and inner ear components. Figure by US Department of Health and Human Services Retrieved from: http://www.nidcd.nih.gov/health/hearing/pages/otosclerosis.aspx

2.0 Structure and function of the auditory system

The auditory system allows the perception of sound stimuli. Sound travelling through the external auditory canal causes movement of the tympanic membrane, which then transmits this energy through the middle ear ossicles to the fluid within the inner ear, causing stimulation of the sensory organ of Corti (Figure 1). This activity results in neural outputs that travel via the auditory nerve and several brainstem nuclei to the central auditory centres where sound is perceived (Holley, 2005). This chapter will discuss the structure and function of each component of the auditory system in further detail.

2.1 The outer ear

The outer ear consists of the pinna and the external auditory canal. The pinna is a structure composed of elastic cartilage covered by skin supported by ligaments to protrude from the lateral aspect of the temporal bone. The surface of the pinna comprises depression and ridges described as an acoustical antenna with resonators and reflectors (Kahana & Nelson, 2006). Spatial characteristics of external sound stimuli, particularly above the 5 kHz range are coded into temporal and spectral cues (Kahana & Nelson, 2006). The external auditory canal (EAC) is an s-shaped tunnel closed medially by the tympanic membrane (TM) and a lateral opening (external auditory meatus [EAM]). The EAC acts as a channel for sound waves to travel medially towards the TM which marks the lateral boundary of the middle ear (Canalis & Lambert, 2000). Because of the closed pipe configuration, it generates a resonance between the 3 and 4 kHz range, providing a 10-15 decibel (dB) boost in a typical adult (Dallos, 1973). The lateral one third of the EAC comprises cartilaginous tissue lined with epidermal epithelium containing hair follicles and sebaceous and ceruminous glands. The medial two thirds is embedded in the osseous tissue of the temporal bone, lined by epithelium that lacks hair follicles and glands (Canalis & Lambert, 2000).

2.2 The middle ear

The middle ear space is an air-filled chamber. It is lined with a mucous membrane containing ciliated and non-ciliated columnar epithelium, secretory granules and goblet cells (Luers & Hüttenbrink, 2016). The lateral ‘wall’ of the middle ear space is mainly occupied by the TM. The TM is composed of three layers. The lateral layer is composed of stratified squamous epithelium, continuous with the lining of the EAC (Anthwal & Thompson, 2016). Epidermal cells at the centre of the ear drum divide and migrate towards the periphery and laterally towards the opening of the EAC, acting as a self-cleaning mechanism of the outer ear (Litton, 1963). The intermediate layer of the TM is composed of loose connective tissue, and the inner medial layer is composed of simple mucosal epithelium continuous with the lining of the middle ear cavity. The TM holds a conical shape pointing medially. It can also be divided into two portions based on changes in collagen composition in the intermediate layer. The pars tensa spans the inferior region of the TM and contains type I and II collagen fibres that radially from the centre of TM and concentrically especially towards of the periphery, respectively (Møller & Moore, 2001; Zemlin, 1998). In addition, the lamina propria of the pars tensa contains collagen fibres running horizontally. The pars flaccida spans a smaller area on the superior aspect of the TM consisting of fewer collagen fibres that do not run in a regular manner (Liu, Agrawal, Ladak, & Wan, 2016).

The vibration of the TM transfers energy to the attached ossicles. The three ossicles of the middle ear space are the malleus, the incus, and the stapes, all of which are suspended in position by several ligaments. The lateral most ossicle is the malleus. It can weigh from around 23-37 mg and is approximately 9 mm in length (Musiek & Baran, 2020). It is supported by three ligaments: the superior malleal ligament, and the anterior and lateral malleal ligaments (Gelfand, 2016). It is composed of the manubrium, embedded in the umbo of the TM, a lateral process, a neck and a head which is the site of articulation to the incus through the double-saddle malleoincudal joint (Canalis & Lambert, 2000). The incus is the largest of the three ossicles, weighing around 30 mg and is approximately 7 mm in length. The incus comprises a body, a short process and a long process which runs parallel to the manubrium of the malleus. It is suspended by the superior and inferior incudal ligaments. Extending from the long process is the lenticular process, which articulates with the head of the stapes through the incudostapedial joint (Seikel, Drumright, & King, 2016). The stapes is the smallest of the ossicles, weighing 2 – 4 mg. Extending from the neck of the stapes are two processes (the anterior and posterior crura) connected by a footplate, forming the obturator foramen. The stapes footplate is embedded into the oval window of the cochlea supported by the annular ligament.

Structures within this chamber collect the acoustic signal from the outer ear. The signal is then converted to a mechanical signal and is passed to the inner ear fluids (Dong, Tian, Gao, & Jung, 2017). The acoustic impedance of the inner ear fluids is much greater than that of air. If the detection of sound stimuli relied on sound waves travelling through air to directly vibrate the oval window, much of the sound would be reflected. This would limit the sensitivity of the auditory system. One role of the middle ear is to compensate for the impedance mismatch between air and the fluids and tissues of the inner ear. This is achieved by the following three mechanisms.

The first is the difference in the surface area between the tympanic membrane and the considerably smaller stapes footplate. It is estimated that two-thirds of the total area of the tympanic membrane makes close contact with the manubrium of the malleus, on average 55 mm^2. Vibratory force travels through the ossicular chain and is transmitted to the oval window through the stapes footplate which has an area of about 3.2 mm^2. Therefore, the force perunit area is greater at the stapes footplate at a magnitude 17 times greater (about 25 dB) (Yost, 2007).

Secondly, the conical shape and arrangement of the radial fibres of the tympanic membrane results in more effective driving of the manubrium, generating about twice the force (Funnell, 1996).

Finally, a greater length of the manubrium and neck of the malleus compared to that of the long process of the incus results in a lever system. The lever action provides a small increase in the force at the tympanic membrane 1.3 times greater (about 2.3 dB) (Yost, 2007).

Overall, the middle ear transformer system provides a significant increase in pressure exerted to the oval window to effectively stimulate the inner ear.

2.3 The inner ear

The inner ear is membranous structure encapsulated by the bony otic capsule, embedded in the petrous portion of the temporal bone. The supero-posterior aspect is the vestibular portion, while the cochlear portion lies infero-posteriorly (Canalis & Lambert, 2000). The vestibular portion includes five peripheral vestibular sensory organs: three semicircular canals and two otolith organs (Bogle, 2018).

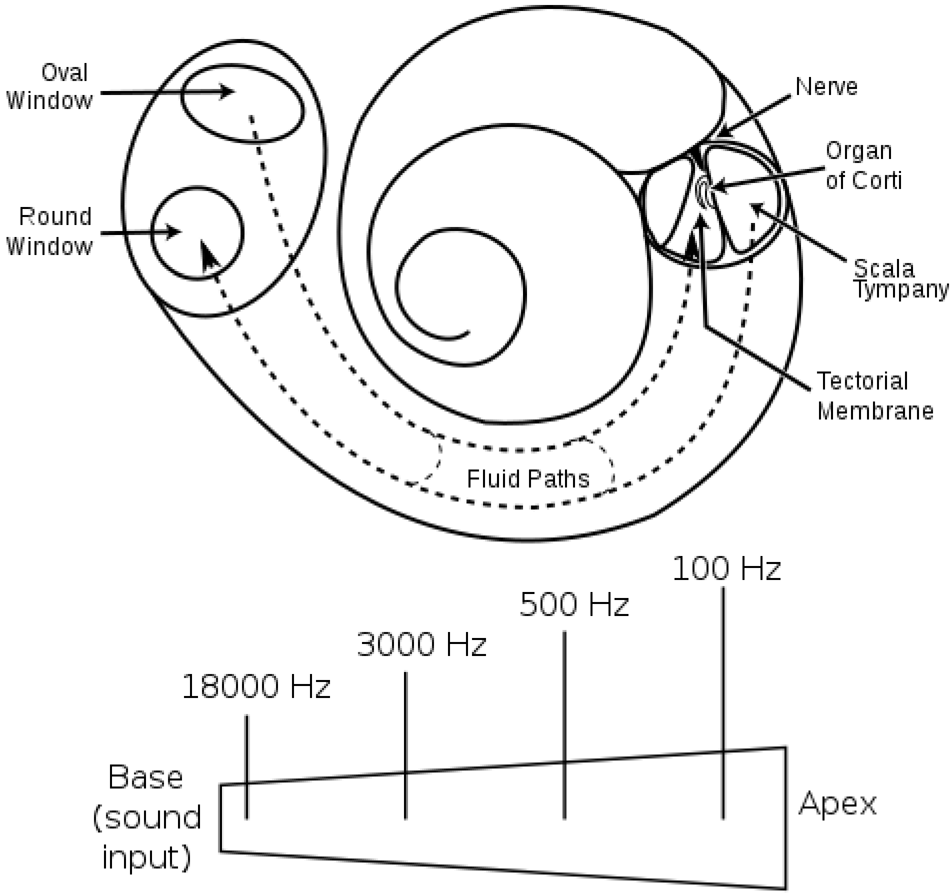

Figure 2: Schematic of the auditory division of the inner ear organ (Above) and the basilar membrane, depicting high frequency stimuli encoded at the base of the cochlea, and low frequency stimuli encoded at the apex (below) Figure by Dick Lyon, retrieved from: https://commons.wikimedia.org/wiki/File:Cochlea.svg and Dave Dunford retrieved from: https://commons.wikimedia.org/wiki/File:Basilarmembrane2_topath.svg

The auditory division of the inner ear is the cochlea. The role of the cochlea is to convert the vibratory energy at the oval window into neural output via the auditory nerve. The cochlea is approximately 31-33 mm in length rolled into a snail-like shape consisting of about 2.5-2.75 turns around a central modiolus (Figure 2). A thin plate of bone called the osseous spiral lamina projects from the modiolus like threads of a screw (Yost, 2007). The spiral lamina broadly divides the cochlea into two compartments, the scala vestibuli sitting superiorly and scala tympani in the inferior compartment. The scala vestibuli is closed by oval window whereas scala tympani is closed by the round window. The two compartments are continuous through the helicotrema at the apex of the cochlea containing perilymph, a fluid of similar composition to that of extracellular fluid. Separating these two compartments is a third triangular shaped cavity filled with endolymph named the scala media. The external wall of the scala media is the spiral ligament which is covered by the stria vascularis, a highly metabolic, three layered secretory membrane. Reissner's membrane, a two cell layered membrane located superiorly separates the scala media and the scala vestibuli superiorly (Canalis & Lambert, 2000). The basilar membrane separates the scala media and scala tympani inferiorly. The basilar membrane is 0.1 mm wide at the base, gradually widening to 0.5 mm in width while getting thinner towards the apex, resulting in a gradation of mass and stiffness (Figure 2) (Canalis & Lambert, 2000). The functional consequence of this is a variation of the amplitude of vibration as a pressure wave travels along the basilar membrane, with peak amplitude of vibration corresponding to the stimulus frequency (Von Békésy, 1960).

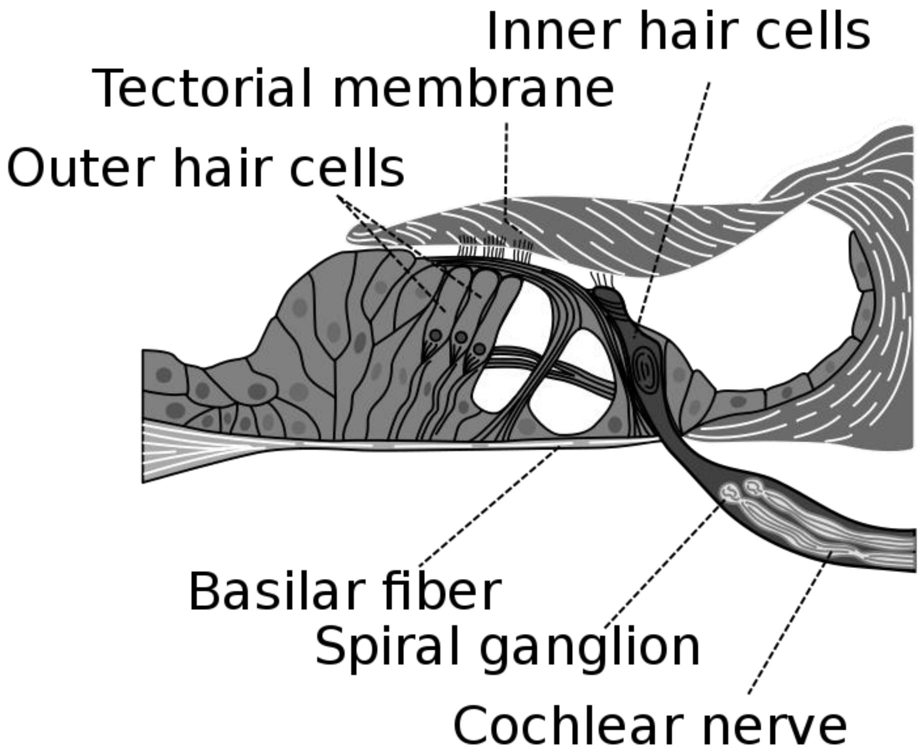

Figure 3: Schematic cross section of the organ of Corti within the cochlea. Figure by K.H. Maen, retrieved from https://commons.wikimedia.org/wiki/File:Organ_of_corti.svg

The end organ of hearing, named the organ of Corti lies on the basilar membrane and forms boundary between scala tympani and scala media. It is responsible for the mechano-electrical signal transduction in response to auditory stimuli. The organ of Corti contains two types of hair cells – the outer hair cells (OHCs) and inner hair cells (IHCs) – as well as a range of supporting cells (Figure 3) (Canalis & Lambert, 2000). OHCs are more numerous, arranged in rows of three in a 'W' formation; while IHCs are arranged in a single, linear row. Stereocilia extend from the apical aspect of both OHCs and IHCs. The tips of the stereocilia extending from the apical surface of the three rows of OHCs are embedded in the gelatinous tectorial membrane overlying the organ of Corti. Conversely, those extending from the apical surface of the IHCs do not make contact with the tectorial membrane (Yost, 2007). The hair cell stereocilia contain the mechano-electrical transducer (MET) channels essential to hair cell function. MET channels open when the hair bundles are deflected towards stria vascularis and close with deflection towards the modiolus. The opening and closing of the MET channels in the OHCs are therefore directly coupled with the vibrations of the basilar membrane, while in the IHCs, they are coupled with the velocity of the surrounding endolymph. The opening and closing of the MET channels allows the flow of cations (mainly K^+) from the endolymph into both types of hair cells, resulting in cyclical fluctuations of membrane potential (LeMasurier & Gillespie, 2005). The flow of cations into hair cells is driven by an electrochemical gradient, the +95 mV endocochlear potential maintained by the highly metabolically active stria vascularis (Tasaki & Spyropoulos, 1959). In the OHCs, the change in membrane potential results in the contraction and elongation of Prestin, a contractile protein embedded in the lateral membrane of the cell (Dallos, Zheng, & Cheatham, 2006). This cycle-by-cycle contraction returns energy into the basilar membrane vibration, producing a positive feedback mechanism (the "active process") that cancels damping. The magnitude of the basilar membrane vibration is amplified, increasing the frequency specificity or sharpness of its' tuning (Dallos et al., 2000). In contrast, cyclic depolarisation of the IHC membrane potential leads to the synaptic release of neurotransmitters, namely glutamate onto the primary afferent dendrites of the auditory nerve (Jia, Dallos, & He, 2007). Each afferent neuron corresponds to a specific place along the basilar membrane and firing will only occur if that point of the basilar membrane is vibrating. This frequency-specific information encoded based on the place of activation is known as 'tonotopic organisation' which is conserved throughout the central auditory pathways (LeMasurier & Gillespie, 2005).

2.3.1 Vulnerability of hair cells to damage

Structures within the organ of Corti are susceptible to damage over an individual's lifetime. However, the inner and outer hair cells lack the ability to regenerate, resulting in permanent hearing impairment. Models of hearing loss demonstrate outer hair cells to be more susceptible to damage compared to inner hair cells (Wagner & Shin, 2019). Furthermore, hair cells at the basal end of the cochlea, responsive to high frequency stimulation, are more vulnerable to damage than those at the apical end. This pattern is injury is true for all types of damage: overstimulation, direct mechanical manipulation of the ossicles or ototoxicity.

2.3.1.1 Mechanisms of damage resulting from overstimulation

Hair cell overstimulation due to excessive noise exposure (noise-induced hearing loss) is the most common form of sensorineural hearing loss (described further in section 2.6.2). Over stimulation occurs after exposure to a low intensity noise over a long period of time or a high intensity noise over a brief period. Depending on the intensity and duration of noise exposure, the result is either a temporary hearing threshold shift that recovers within 24 to 48 hours, termed temporary thresholds shift (TTS) or a permanent threshold shift (PTS). Nordmann, Bohne, and Harding (2000) demonstrates adequate stimulation can transiently uncouple outer hair cell stereocilia from the tectorial membrane. PTS is characterised by the permanent trauma to not only the outer hair cells, but other structures within the organ of Corti as a consequence of noise exposure exceeding 130 dB SPL (Henderson & Hamernik, 1986). Damage to the system can be a result of mechanical and metabolic processes. Mechanical damage describes the permanent uncoupling of the organ of Corti to the basilar membrane, cell junction disruption in the stria vascularis and the mixing of cochlear fluids resulting in the reduction of the endocochlear potential (Le, Straatman, Lea, &

Westerberg, 2017). Metabolic damage results from the formation of reactive oxygen species, glutamate excitotoxicity and the activation of apoptotic (cell death) signalling pathways.

Reactive oxygen species cause direct damage to DNA and cell membranes in addition to the activating signalling pathways leading to cell apoptosis. They appear in the stria vascularis within a week following noise exposure, forming from the basal end of the cochlea and spreading apically (Yamane et al., 1995).

Glutamate excitotoxicity is the swelling of post-synaptic dendrites and cell bodies as a result of high levels of hair cell glutamate release following excessive noise exposure (Robertson, 1983).

Finally, overstimulation of the cochlea leads to the immediate increase of free calcium ions in outer hair cells. High intracellular calcium ion concentrations can trigger cell pathways leading to apoptotic and necrotic cell death (Fridberger, Flock, Ulfendahl, & Flock, 1998).

As aforementioned, the tonotopic organisation of the basilar membrane is such that high frequencies are encoded at the basal end of the cochlea, and low frequencies stimulate the apical end of the cochlea. Due to the travelling wave phenomenon, the basal end of the basilar membrane will always be stimulated even in response to high frequency stimuli. Consequently, the basal turn is subject to most shear stress over a life time.

2.3.1.2 Mechanisms of damage resulting from ossicular chain manipulation

While the underlying mechanisms are not yet understood, ossicular chain manipulation during middle ear surgery elevated summating potential and compound action potential thresholds in guinea pigs (Bergin et al., 2015). This suggests damage occurs at the level of the hair cells and possibly the afferent nerve fibres. Notably, this damage was more pronounced at the basal end of the cochlea (Bergin et al., 2015).

2.3.1.3 Mechanisms of damage resulting from ototoxicity

Several classes of drugs are known to cause cochlear damage including platinum-based chemotherapeutic drugs, aminoglycoside antibiotics, and salicylates (Wright, 1973). These compounds gain access to the organ of Corti through the blood stream, the cerebrospinal fluid, or diffusion through the middle ear and target cell membrane structures and internal metabolic processes. It has also been established that the basal end of the cochlea is more susceptible to ototoxic affects (Forge, Forge, & Richardson, 1993).

2.4 Central auditory pathways

2.4.1 Afferent transmission

The central auditory pathway relays the neural output of the two cochleae through the brainstem up to the primary auditory cortex within the temporal lobe. As previously mentioned, cochlear afferents are encoded with frequency specific information depending on where they innervate the basilar membrane. This frequency map is conserved throughout the auditory pathway right up to the auditory cortex in the brain. Neural tracts ascend to both the ipsilateral cortex and decussate at several sites to ascend to the contralateral side suggesting auditory processing relies on binaural inputs (Yost, 2007). Indeed, the central auditory process relies on timing and intensity differences between the left and right inputs for sound localisation (Pannese, Grandjean, & Frühholz, 2015).

The auditory nerve (the 8th cranial nerve) is the relay from the cochlear spiral ganglion to the cochlear nucleus. From the cochlear nucleus outputs ascend towards the ipsilateral and contralateral olivary complex. The superior olive relays towards the inferior colliculus and/or around the lateral lemniscus towards the medial geniculate body. From the medial geniculate body, tracts ascend to the auditory cortex within the temporal lobe (Yost, 2007).

Overall, the perception of sounds is achieved by the complex structures within the peripheral and central auditory system. Numerous techniques have been developed to assess the integrity of the many components of this system.

2.5 Audiological assessment

Audiometry is a means of identifying and quantifying hearing disorders. The aim is to determine the type, degree and configuration of a hearing impairment. Because the auditory system and signal processing is multifaceted, diagnostic assessment of hearing relies on numerous subjective and objective functional tests (Hoth & Baljić, 2017).

2.5.1 Objective measures

2.5.1.1 Immitance

Immitance audiometry is an objective measure of the acoustical impedance of the middle ear system, or its reciprocal, admittance (Hoth & Baljić, 2017). It serves as a detection tool for middle ear disorders, the differentiation between cochlear and retrocochlear disorders (via measurement of the middle-ear reflex), and serves as a cross check for pure-tone audiometry (Stach & Jerger, 1987). The primary tool for measuring admittance is the tympanometer, which presents a pure tone (usually at 226 Hz) into the sealed ear canal and uses a microphone in the probe to measure the sound pressure level (SPL) that results in the ear canal – the higher the sound pressure level measured for a particular volume velocity, the lower the admittance. The static air pressure in the ear canal can also be varied to displace the tympanic membrane and map the change in admittance across this range of pressures. In a healthy middle ear system, when the air pressure deviates from the air pressure of that which produces peak admittance, the recorded SPL will increase sharply as less sound is transmitted through the system. This results in the typical peaked tympanogram. In the presence of middle ear pathology, this peak may be shallow, absent or shifted (Hoth & Baljić, 2017; Stach & Jerger, 1987).

Immitance audiometry is also used to measure a middle ear muscle reflex known as the stapedial reflex, or acoustic reflex (Stach & Jerger, 1987). The reflex is a contraction of the stapedial muscle in response to high level intensity 0.5, 1, 2 or 4 kHz pure tones or broadband noise. This contraction leads to the stiffening of the ossicular chain, thus decreasing the admittance of the middle-ear system. Like tympanometry, this can be detected by changes in the level of the reflected sound in the EAC by the probe microphone (Schairer, Feeney, & Sanford, 2013). This reflex relies on a functional neural pathway involving CN8 and the facial nerve. Thus the presence or absence of the reflex can assist in the differentiation between cochlear and retrocochlear pathology (Stach & Jerger, 1987).

2.5.1.2 Distortion product otoacoustic emissions

Low intensity sound waves generated by OHC's can travel the reverse pathway through the ossicles and out the EAC, which can be detected by a microphone (Gelfand, 2016). These are termed otoacoustic emissions. One way to evoke otoacoustic emissions are by presenting two tones simultaneously to the ear, usually at 65 dB (Hoth & Baljić, 2017). Because of the non-linearity of the active process, passing two tones results in intermodulation distortion. This leads to the generation of distortion products, the most robust to measure being the frequency 2f1-f2. These emissions give the term distortion product otoacoustic emissions.

As the generation of emissions are reliant on outer hair cell function and not affected by retrocochlear pathology, this test is a useful differential diagnostic tool (Hoth & Baljić, 2017). One drawback of this test is that the ability to record emissions relies on a functioning middle ear system to relay the stimulus to the ear canal where the recording microphone lies (Robinette & Glattke, 2007). Therefore cochlear function cannot be confirmed by this test in the presence of a significant conductive loss.

2.5.2 Subjective measures

Pure tone audiometry (PTA) is described as the gold standard for testing hearing thresholds and classifying hearing loss. In conjunction with the rest of the audiological test battery, it provides the basis for diagnostic and management decisions surrounding auditory dysfunction. It is a subjective measure of an individual's threshold to perceive low intensity pure tones through the performance of psychophysical experiments. In the clinical setting, diagnostic PTA measures hearing thresholds in the conventional frequency (CF) spanning from 0.25 – 8 kHz. The CF range is believed to contain the most important spectral information to understand speech (Fulop, 2011). Hearing thresholds are expressed in decibel hearing level (dB HL) which is a scale based on normal hearing in which 0 dB HL is the median threshold for each tested frequency in otologically normal hearing adults (Margolis et al., 2015).

In the clinical setting, pure tone hearing thresholds are obtained manually using the Modified Hughson and Westlake method, an adaptive psychophysical procedure (Raymond Carhart & Jerger, 1959). This involves presenting the tone at an audible intensity and attenuating the level in 10 dB steps until the tone is no longer audible, and then increasing the intensity in 5 dB steps until the tone is audible again and repeating this procedure until the same threshold is obtained two out of three ascending runs. Thresholds are recorded on an audiogram, which is a plot of frequency (Hz) on the y-axis against intensity (dB HL) on the x-axis to demonstrate the degree of deviation from normal hearing.

Hearing thresholds are measured through the air conduction (AC) pathway and the bone conduction (BC) pathway. Comparing AC and BC hearing thresholds provides a means of determining presence of pathology and approximating the site of lesion (Hoth & Baljić, 2017). AC audiometry is typically performed up to 8 kHz however extended high-frequency (EHF) audiometry, discussed in detail later, extends this upper AC frequency from 8 kHz to 16 kHz. AC audiometry is achieved by presenting the airborne stimulus either through headphones placed sitting directly over, or surrounding the pinna (supra-aural headphones and circumaural headphones, respectively), through foam tipped insert earphones placed within the EAC or through speakers in a sound field (Zwislocki et al., 1988). Stimuli must travel through the external auditory canal, middle ear and inner systems to be audible. Therefore, any pathology along this pathway will result in elevated thresholds to air conduction stimuli.

BC audiometry can be performed up to 4 kHz by placement of an electromagnetic bone vibrator (Radioear B-71 or B-81) against the skull, but its inherent mass limitations prevent reliable testing above this frequency

(Reinfeldt et al., 2013). Like air conduction stimuli, bone conduction stimuli result in pressure changes in the cochlear fluids resulting in the movement of the basilar membrane. The propagation of the wave along the basilar membrane is identical for AC and BC modalities. BC stimuli bypass the outer and middle ear system, testing the inner ear directly through several pathways discussed in the following section (Khanna et al., 1976).

2.5.2.1 Mechanical distortion components of bone conduction stimulation

Bone vibrators cause sufficient skull vibration to deform the lining of the external auditory ear canal. This in turn causes airborne vibrations within the ear canal which are them transmitted through the auditory system identically to an air conduction stimulus (Dauman, 2013). Von Békésy (1932) and Tonndorf (1968) describe a similar pathway in which bone conduction stimuli result in compression and relaxation of the otic capsule, producing fluid movement within the cochlea. Tonndorf (1968) suggests that the resulting pressure gradient and corresponding basilar membrane vibration is a consequence of the differences in volume of the scala vestibuli and scala tympani and impedances of the oval and round windows.

2.5.2.2 Inertial components of bone conduction stimulation

This mechanism refers to the vibration of the ossicles as a result of skull vibrations. Together, the ossicles and supporting connective tissue act as a mechanical spring and mass system (Yost, 2007). Namely the tympanic membrane and annular ligament act as springs attached to a mass of bone (the ossicles). At low frequencies, the system moves in phase with the surrounding skull vibrations. However, the phase of vibration is decoupled from the surrounding skull at higher frequencies resulting in a relative motion between the round window and bony capsule; which in turn sends transmissions through the cochlear fluids (Dauman, 2013).

Similarly, vibrations of the skull in response to a bone conduction stimulus subject cochlear fluids to inertial forces. Fluid movement on either side of the basilar membrane is possible due to the compliance of the oval and round windows. These forces generate a pressure gradient across the basilar membrane resulting in a travelling wave (Yost, 2007).

As mentioned, the comparison of AC and BC pure tone thresholds is a tool used to approximate site of lesion. It aids in the separation of pathology affecting sound transmission through the external or middle ear systems from cochlear or retrocochlear pathology. It is important to note that several pathways of bone conduction stimuli involve the external and middle ear systems suggesting BC thresholds does not exclusively depend on cochlear and retrocochlear integrity. However, the relative contribution of these pathways is yet to be determined and BC pure tone audiometry remains the most reliable way of testing cochlear function in a clinical setting.

2.6 Hearing loss

Hearing loss can be described by degree, configuration and type. The degree of hearing loss is dictated by hearing thresholds measured through pure tone audiometry and the degree to which they deviate from normal hearing. There are two main classifications used internationally (Cahart, 1945; Goodman, 1965). Used in this study was Cahart's classification of hearing loss, which ranges from normal hearing to a profound hearing loss. Hearing loss can also be described by the configuration corresponding on the audiogram. Common configurations include a flat hearing loss; a falling or sloping loss, in which thresholds in the higher frequencies are greater (poorer) than thresholds in the low frequency range; conversely a rising configuration displays poorer thresholds in the low frequency range with recovery in the higher frequencies; and a notched audiogram displays a significant loss at one frequency compared to adjacent octave frequencies (Katz, 2015). Audiogram configuration is helpful in the clinical setting in the diagnosis process and when describing a hearing loss to patients or other professionals. Finally, the type of hearing loss falls into three main categories: conductive, sensorineural and mixed hearing loss (Figure 4).

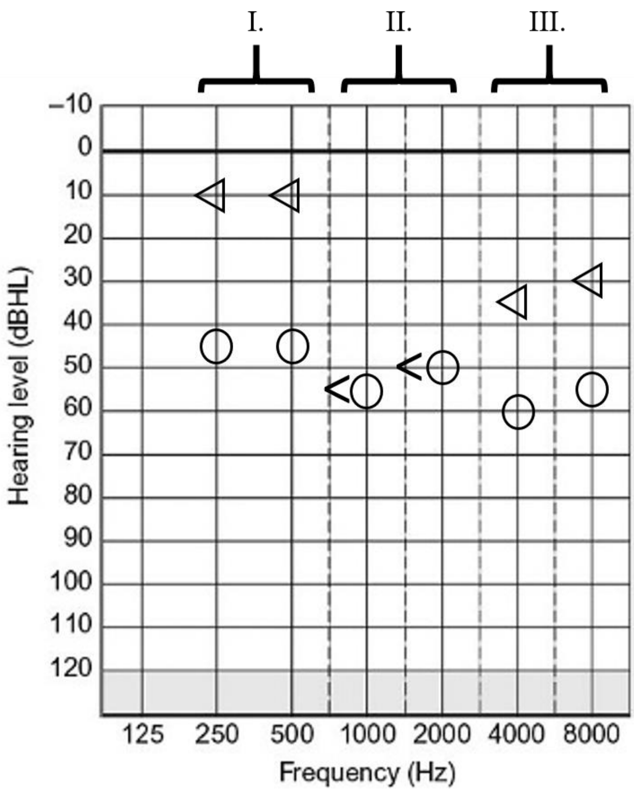

Figure 4: Pure tone audiogram depicting the 3 types of hearing loss. I. – Conductive hearing loss; II. – Sensorineural hearing loss and III. – Mixed hearing loss

2.6.1 Conductive hearing loss

Any disturbance in the transmission of sound travelling from the EAC towards the inner ear in otherwise normal inner ear and auditory pathway function is classified as a conductive hearing loss (Zahnert et al., 2016). Therefore, a conductive hearing loss will manifest as elevated AC thresholds compared to measured BC thresholds within normal limits on a pure tone audiogram (Figure 4). The magnitude of the conductive loss is expressed as the difference between AC and BC thresholds and is termed the air-bone gap (ABG). For an air-bone gap to be considered significant, it must be greater than 10 dB due to test-retest reliability. A conductive loss has a maximum ABG value of about 65 dB (Schlauch & Nelson, 2015). Conductive hearing loss has many aetiologies resulting in either transient or permanent hearing losses. The most common cause of transient conductive hearing loss is the presence of middle ear fluid (otitis media) while other causes include occlusion of the EAC by cerumen or foreign bodies and Eustachian tube dysfunction. Permanent conductive losses (i.e. those unlikely to improve without surgical intervention) include atresia of the EAC, but more commonly, pathologies interfering with the function of the ossicular chain (Zahnert et al., 2016). These pathologies will be discussed further in section 3.1.

2.6.2 Sensorineural hearing loss

Sensorineural hearing loss (SNHL) is defined by hearing loss due to dysfunction in the cochlea or the cochlear nerve (Moser, Predoehl, & Starr, 2013). Therefore, in the absence of a conductive hearing loss, a sensorineural hearing loss will be indicated on a pure tone audiogram by AC and BC thresholds measured outside the normal range and within 10 dB of each other (Figure 4) (Schlauch & Nelson, 2015). Because of the structural complexity of the cochlea, organ of Corti, and proximity to the auditory nerve there are many pathologies that can lead to SNHL. SNHL can be genetic or acquired through excess noise exposure, toxin exposure etc. The most common SNHL, in fact the most common hearing loss overall, is age related hearing loss, or presbycusis (Tu & Friedman, 2018).

2.6.3 Mixed hearing loss

A mixed hearing loss is a combination of a conductive hearing loss overlying a sensorineural loss. This is seen on the audiogram as BC thresholds outside the normal range, and an ABG greater than 10 dB (Figure 4) (Schlauch & Nelson, 2015). Masking the non-test ear to obtain ear specific hearing thresholds poses a challenge in patients with a mixed hearing loss; particularly when hearing thresholds are asymmetric. Masking and the challenges it presents in patients undergoing middle ear surgery will be discussed in the following section.

2.7 Clinical masking

It is critical to obtain ear specific information when conducting any form of audiologic evaluation to gain accurate information relating to auditory function and appropriately determine the site of lesion (if a hearing loss is identified) (Hannley, 1986). Under certain conditions there is the potential for the non-test ear to contribute to test ear responses during air conduction and bone conduction testing. This phenomenon is termed *cross over* (Studebaker, 1967).

2.7.1 Cross over

Cross over is commonly encountered when performing audiologic testing on patients with asymmetric hearing thresholds. It may manifest on a pure tone audiogram as a *shadow curve* (Yacullo, 2015). An example of a shadow curve is shown in Figure 5 which demonstrates thresholds obtained in the ear with greater hearing loss which mimic the pattern of that from the better hearing ear. The difference between the better ear thresholds and the shadow curve is typically around the value of the interaural attenuation of the transducer used for testing (IAA discussed further below). In this example, thresholds measured from presenting the stimuli to the poorer ear may reflect the detection of the stimulus by the non-test ear (better ear) due to crossover rather than from the poorer ear itself. This carries the risk of underestimating the degree of hearing loss in the poorer hearing ear.

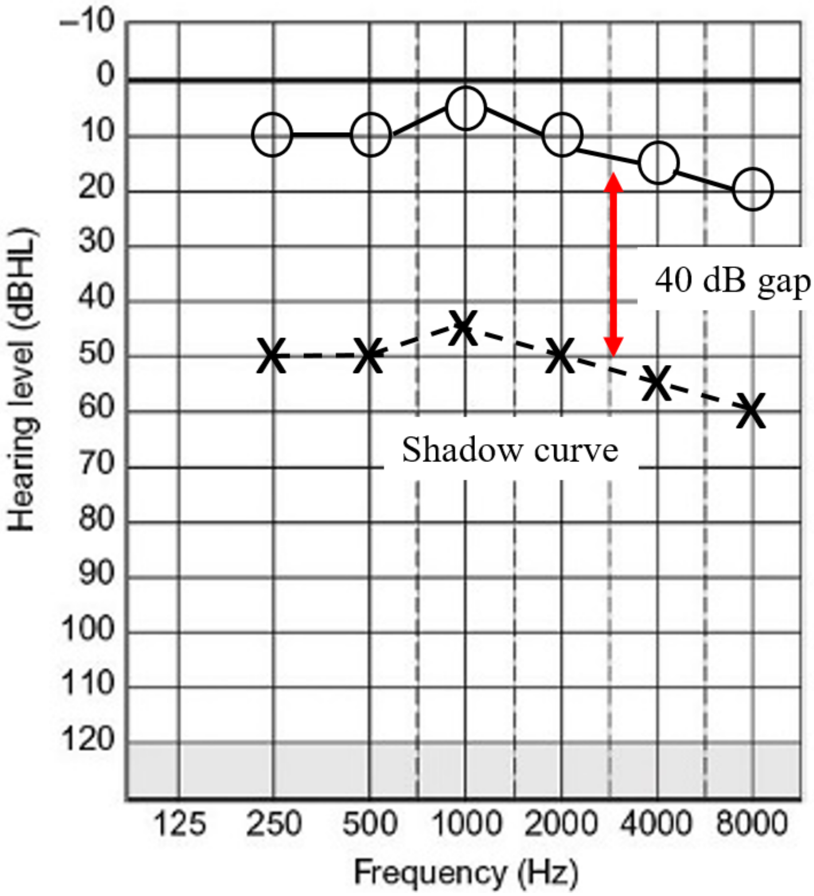

Figure 5: Pure tone audiogram demonstrating a shadow curve as a result of cross-over. The configuration of left ear thresholds (crosses) match that of right ear thresholds (circles) with a 40 dB deficit, equal to the IA of the supraaural transducer

Crossover in bone conduction audiometry is almost unavoidable due to the negligible interaural attenuation of bone oscillating transducers. In the absence of masking, the clinician or researcher cannot assume the threshold value obtained to be a response from the side at which the transducer is placed on the mastoid (Studebaker, 1967). This issue is commonly encountered in patients with asymmetric hearing and is important to consider when differentiating between conductive, sensorineural or mixed hearing loss (Naunton, 1960). Take for example Figure 6 (left). The patient shows normal air and bone conduction thresholds in the right ear. The left ear shows a flat moderate hearing loss indicated by the air conduction thresholds. In the unmasked condition, bone conduction thresholds obtained from the right mastoid are identical to those measured from the left ear. Without masking, these results suggest a unilateral conductive hearing loss. However, as shown in Figure 6 (right), when eliminating contributions of the left cochlea through masking, right bone conduction thresholds more closely match air conduction thresholds suggesting a sensorineural hearing loss.

The errors mentioned above can drastically affect clinical decision making regarding medical or surgical treatment and/or amplification. Therefore, a masking stimulus should be presented to the non-test ear to eliminate any contribution of the non-test ear as a consequence of cross over, avoiding erroneous results (Roeser & Clark, 2007).

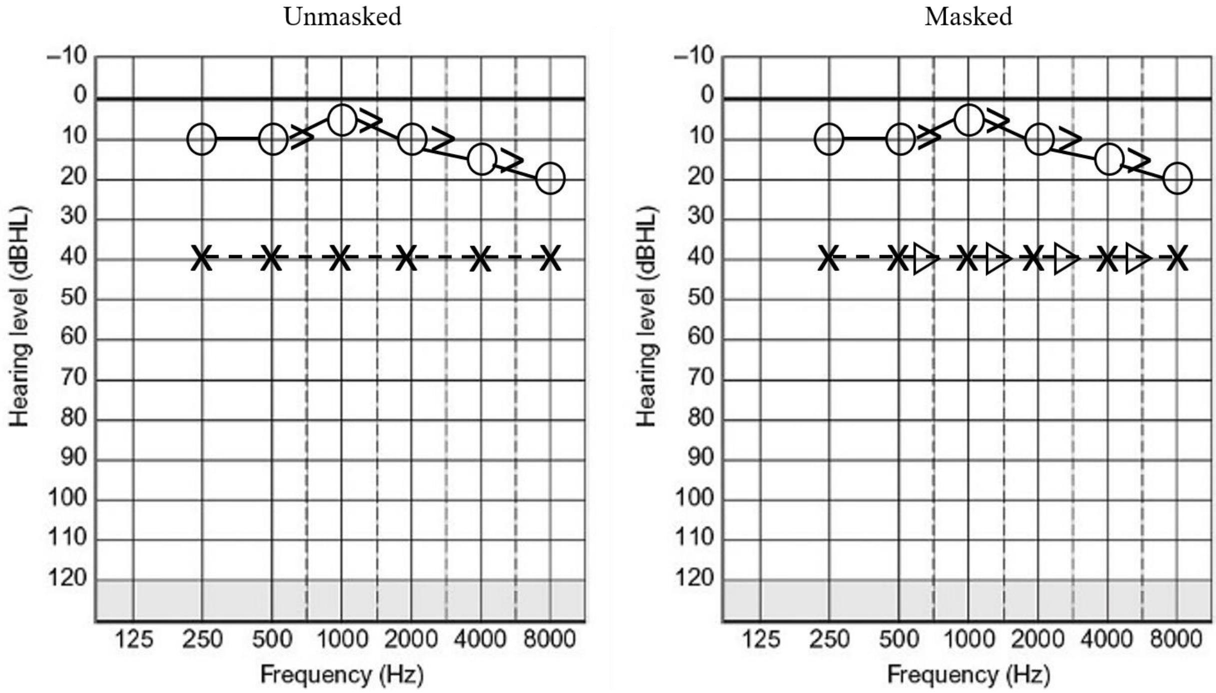

Figure 6: Pure tone audiograms demonstrating differences in unmasked and masked BC results in a patient with unilateral hearing loss in the left ear. Left - Unmasked BC thresholds suggesting a CHL . Right – Pure tone audiogram of same patient marked with masked BC thresholds revealing a unilateral SNHL in the left ear.

2.7.1.1 Mechanisms of cross over

Sound stimuli travel from the test ear to the non-test ear through two concurrent pathways (Yacullo, 2015).

Bone conduction pathway of cross over

If the transducer vibrates with sufficient force, it will cause deformations of the entire skull. Because both cochlea are enclosed in the skull, these vibrations will stimulate both the test ear and non-test ear cochlea (Yacullo, 2015). The mechanisms of bone conduction stimulation described in detail in sections 2.5.2.1 and 2.5.1.2., is believed to be the primary mechanism of crossover.

Air conduction pathway of cross over

The stimulus presented to the test ear also travels around the head and stimulates the non-test ear through the air conduction pathway. This pathway is considered to be the secondary contributor to crossover as the non-test ear is also covered by a headphone providing some attenuation (Roeser & Clark, 2007). Furthermore, the presence of a conductive hearing loss in the non-test ear will greatly reduce the contribution of this pathway (Yacullo, 2015).

2.7.2 Interaural attenuation

The amount of cross over that reaches the non-test ear is inherent to the type of transducer used to deliver the stimulus, the stimulus frequency content and individual variability. It is quantified as the interaural attenuation (IA), which is the reduction of the signal intensity crossing over from one ear to the other (Studebaker, 1967). Therefore, the greater the IA, the less cross over occurs. Because the bone conduction pathway is the primary pathway of crossover, a greater IA is achieved by decreasing transducer contact with the skull. As mentioned in section 2.5.2, the standard transducers used to deliver air conduction stimuli for audiometry are as follows with reducing skull contact respectively. Circumaural headphones place the transducer close to the external auditory meatus with cushioning surrounding the pinna, whereas supra-aural headphones place the transducer close to the EAM with the cushioning directly pressed onto the pinna. Insert tip earphones are inserted into the ear canal (Zwislocki et al., 1988). Therefore circumaural headphones have a smaller IA thus greater risk of crossover, while insert earphones have the greatest IA and carry less risk of crossover. Bone conduction oscillators vibrate the entire skull in which both cochlea are housed. Therefore the IA of these transducers is significantly less compared to air conduction transducers. The IA value for air conduction transducers have been established in the past by investigating patients with single sided deafness (Park, Park, Jun, Oh, & Lee, 2011). In this population, you can present stimuli in the ear with profound deafness with confidence that the deaf cochlea will not contribute to any responses. Therefore once adequate intensity is reached, cross over occurs and the subject will respond due to stimulation of the contralateral cochlea. This value can range considerably between subjects due to variations in physical skull features and skull thickness; therefore values are based on the most conservative IA values measured (Studebaker, 1967). One drawback to using the most conservative value is the risk of unnecessary masking that expends precious appointment time (Yacullo, 2015). Table 1 presents the current IA values used in clinical practice (Yacullo, 2015).

Table 1: Current IA values for Standard AC Transducers used in clinical practice.

Transducer	*Frequency (Hz)*						
	125	*250*	*500*	*1000*	*2000*	*4000*	*8000*
Supra-aural	35 dB	40 dB	40 dB	40 dB	40 dB	40 dB	40 dB
Insert (deeply inserted)	60 dB	60 dB	60 dB	60 dB	50 dB	50 dB	50 dB

2.7.3 Mechanism of masking

Masking is a phenomenon defined as the interference in the ability to detect one signal in the presence of second sound (Gelfand, 2016). The masker's ability to shift the hearing threshold of the signal of interest is determined by the masker intensity and frequency spectrum. As mentioned in section 2.3, the structure of the basilar membrane and the resulting pattern of mechanical vibration lends to the ability of the cochlea to detect auditory stimuli and frequency selectivity (Von Békésy, 1960). Early works by Fletcher (1940) describe the basilar membrane as a series of overlapping auditory filters in which there will be a maximum point of vibration at one point of the membrane in response to a pure tone stimulus. Introduction of a masking stimulus that occupies the same auditory filter as the signal of interest will shift the detection threshold for that signal. A masker is therefore effective when the masker stimulates the same frequency region or auditory filter as the signal. (Fletcher, 1940) estimated the bandwidth of these filters through masking experiments in which a pure tone stimulus and narrow band noise with a similar centre frequency to the pure tone are presented simultaneously. His experiments showed that by increasing the bandwidth of the narrow band noise causes shifts in pure tone thresholds. However once the bandwidth exceeded the filter bandwidth, widening the narrow band noise filter no longer shifted the pure tone thresholds. This point was termed the critical bandwidth.

To this point, masking has been discussed in the presence of two sounds presented to the same ear (simultaneous monaural masking). However, the ability to detect a sound stimulus in one ear can be affected by the presence of a masker in the contralateral ear, a phenomenon termed *central masking* (Gelfand, 2016). Furthermore, *temporal masking* refers to a masking a stimulus by presenting the masker prior to (*forward masking*) or following the signal (*backward masking*) (Yost, 2007). The mechanisms of these forms of masking occur centrally, rather than at the level of the cochlea.

2.7.4 Masking stimuli

There are two types of masking noises typically used. Broadband noise (BBN) and narrowband noise (NBN). BBN or white noise carries a wide frequency response at equal intensities, ranging from 100 to 10,000 Hz. NBN is a BBN passed through a band-pass filter within a defined frequency range. The centre frequency of the NBN masker is matched with the frequency of the test signal (Roeser & Clark, 2007). BBN is used clinically in both pure tone and speech audiometry. It can efficiently mask most stimuli as it can interfere with a wide range of auditory filters. However, energy is distributed across the entire frequency range of the masker which can lead to a number of issues. As mentioned above, increasing the bandwidth of the masker beyond the filter critical bandwidth will not cause further shifts in threshold. When using a BBN masker, energy in the stimulus outside the critical band of the stimulus you are attempting to mask is wasted energy that does not contribute to masking said stimulus. Therefore presenting a BBN masker at a high level can result in loudness discomfort to the listener. In addition, there is a higher risk of crossover, leading to over masking (discussed in further detail below) (Hannley, 1986). Alternatively, NBN is considered to be a more efficient masker, as the energy content is restricted within a defined band. As a result, less energy is required to mask the non-test ear. In turn this reduces the risk of loudness discomfort to the listener and reduces the chance of over masking (Roeser & Clark, 2007).

2.7.5 When masking is necessary

Masking is required in any case of potential crossover producing erroneous results. Simple calculations can be used to identify the need for masking in air conduction and bone conduction audiometry. These calculations consider unmasked thresholds and the IA of the transducer used for testing. Similar principles apply for speech audiometry, however will not be discussed in this document. AC masking is indicated when the difference between AC thresholds in the NTE and the TE is greater than the most conservative IA designated to the transducer used for testing (Yacullo, 2015).

$$AC_{Test\ Ear} - BC_{Non-test\ ear} \geq IA$$

A bone conduction threshold must be masked if the resulting air-bone gap is deemed clinically significant (equal to or greater than 15 dB) (Yacullo, 2015).

$$Air\ Bone\ Gap_{Test\ ear} \geq 15\ dB$$

Where: $Air\ Bone\ Gap = AC_{Test\ Ear} - Unmasked\ BC$

2.7.6 Plateau method of masking

The plateau method, first described by Hood (1960) is the most accepted masking procedure used once the need for masking is identified. There are three stages of masking when using this procedure indicated in Figure 7.

The first stage is undermasking. Undermasking occurs at any masking intensity at which cross over from the test ear stimulus still evokes a response in the non-test ear. During under masking the stimulus threshold will increase as the masker level is increased in a one-for-one manner.

Once the masker has reached the minimum effective masking level (discussed below), the masking plateau begins. The minimum effective masking level is the masker level at which the non-test ear is effectively masked and the perception of the test stimulus is from the test ear. Increasing the masker intensity at this stage will not affect the test ear threshold until the point of maximum permissible masking (Roeser & Clark, 2007). The plateau width is defined as the difference between the maximum permissible masking level and the minimum effective masking level. In a clinical setting, audiologists will accept a masked threshold to be valid by demonstrating a plateau width of 20 dB (Gelfand, 2016).

The third stage of masking, termed overmasking is reached when the masker level exceeds the maximum permissible masking level. At intensities beyond this level, the masker noise level is sufficient to cross over from the non-test ear to the test ear. This results in a shift in stimulus threshold of the test ear beyond the true threshold in a one-for-one manner similar to the undermasking stage. Overmasking is likely to occur when the masker level is equal to or greater than the IA plus the BC threshold of the test ear (Roeser & Clark, 2007).

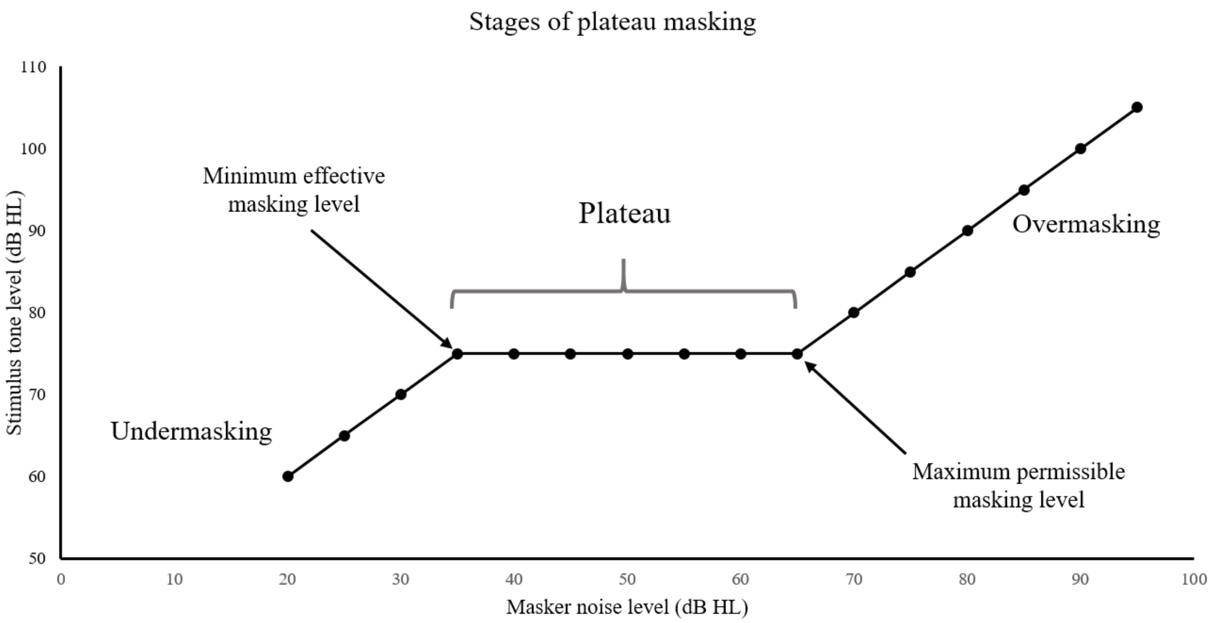

Figure 7: Three stages of plateau masking as described in section 2.7.6, showing changes in threshold response (Y-axis) with increasing masker noise level (X-axis).

2.7.7 Plateau masking procedure

The first step of plateau masking is establishing the initial masking level to present to the non-test ear. It is important to distinguish the initial masking level from the minimum effective masking level. As described, the minimum effective masking level is the masker level at which the non-test ear is adequately masked. The initial masking level is the initial masking presentation level and may not provide adequate masking. For air conduction masking, Martin (1974) suggests the addition of a 10 dB safety factor to account for intersubject variability. For bone conduction masking, Martin (1974) suggests the addition of further safety factor to account for the *occlusion effect*. The occlusion effect refers to the erroneous increase in bone conduction threshold values as a consequence of occluding the ear canal. The occlusion effect safety factor varies depending on the transducer selection and the frequency being tested, values are summarised on Table 2. Therefore the calculations for minimum effective masking level is as follows:

$$Initial\ masking\ presentation\ level = AC_{NTE} + 10\ dB$$

Table 2: Summary of safety factors added to initial masking presentation level

Transducer	*Frequency (Hz)*		
	250	*500*	*1000*
Supra-aural	30 dB	20 dB	10 dB
Insert (deeply inserted)	10 dB	10 dB	0 dB

Once the initial masking presentation level is established, the following protocol is identical for air conduction and bone conduction masking. The masker is continuously presented in the listener's ear while the unmasked threshold is presented. The threshold will either remain the same, or the listener will no longer respond. In the former result, the tester increases the masker level by 10 dB increments while the test signal level remains at the constant. If the listener continues to respond at each 5 dB increment for a span of a 20 dB plateau, the test signal level is taken as the true threshold. For the second result where the listener does not respond to the test signal in the presence of the masker, the tester increases the test signal by 5 dB increments until the listener provides a response again and attempts to gain a 20 dB plateau.

2.7.8 Masking dilemma

The masking dilemma describes the scenario in which it is impossible to sufficiently mask the non-test ear without exceeding the maximum permissible masking level (Naunton, 1960). This problem is typically encountered when attempting to gain ear specific thresholds in patients with bilateral conductive or mixed hearing loss. Take for example, a patient with bilateral moderately severe conductive loss (audiogram pictured in Figure 8).

$$Initial\ masking\ presentation\ level = AC_{NTE} + 10\ dB$$

$= 60 + 10 = 70$ dB HL

Level of cross over in NTE = presentation level to TE - IA

$= 60 – 60 = 0$ dB HL

BC threshold in NTE = -5 dB HL

Therefore crossover is audible to NTE

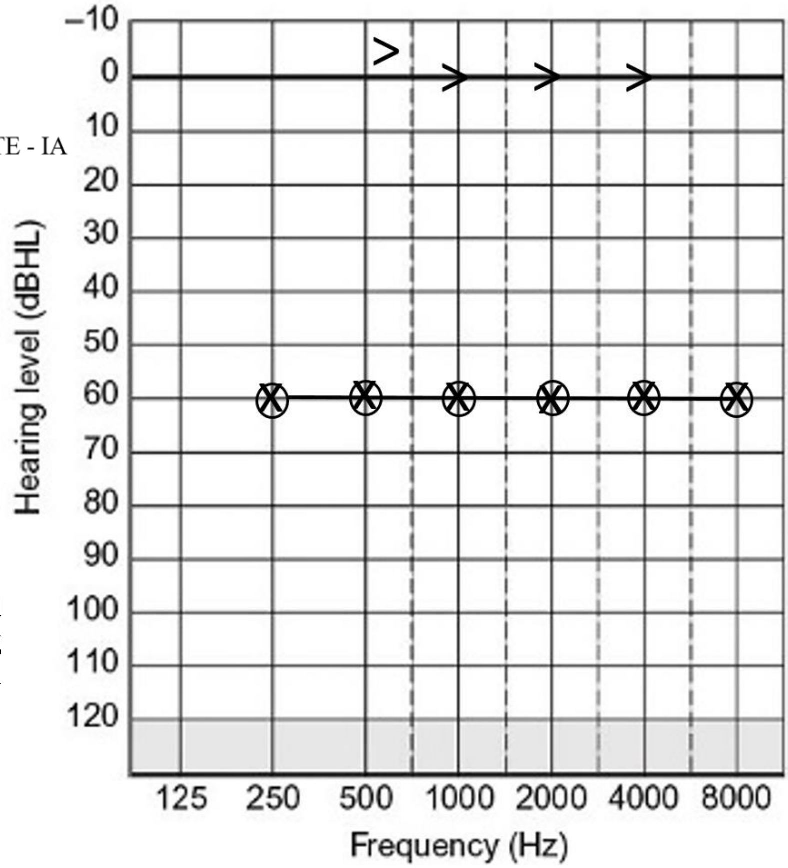

Figure 8: Masking dilemma
Pure tone audiogram for a patient with bilateral moderately severe conductive loss. Initial masking level to the NTE would be beyond the maximum permissible masking level. Therefore masked BC thresholds cannot be attained.

When obtaining a masked BC threshold in the TE, the initial masking presentation level must be 70 dB to overcome the conductive overlay and audible to the NTE. The clinician then runs into an issue of *over masking* in which the masker intensity is sufficient to cross-over back to the TE, likely causing a shift in the perceived threshold (Gelfand, 2016). When using the plateau method, the next step would be to increase the tone stimulus level to be audible by the TE. This is followed by increasing the masker level which will again affect the TE threshold. This pattern of overmasking is demonstrated on Figure 7. This was first described in Naunton's masking dilemma in 1960. The result leads to inconclusive AC and BC audiometric thresholds which can compromise clinical decision making.

The focus of the current study is on patients undergoing middle ear surgery. While middle ear surgery is commonly performed unilaterally, patients typically present with a bilateral conductive loss. The masking dilemma is the basis of a majority of limitations encountered and steps to minimise it are discussed throughout this paper.

Chapter 3: High frequency hearing loss following middle ear surgery

A number of pathologies causing conductive hearing losses can be treated surgically. While the priority of these surgeries is to eradicate disease, one of the aims is to close the air-bone gap and improve AC hearing thresholds (Luers & Hüttenbrink, 2016). With refinements in techniques and improved technology, we generally see successful hearing outcomes in the conventional frequency range. However, there is growing evidence suggesting that middle ear surgeries result in hearing loss in the extended high frequency range (Babbage, O'Beirne, Bergin, & Bird, 2017; Bergin et al., 2015; Domenech & Carulla, 1988)). This chapter will first provide background on middle ear pathology, middle ear surgeries and the current literature reporting the resulting deterioration extended high frequency hearing. It will then describe the current study investigating the effect of middle ear surgery on extended high frequency bone conduction thresholds.

3.1 Middle ear pathology and surgical intervention

This section will examine common pathologies managed by middle ear surgery and the classification of middle surgeries.

3.1.1 Classification of middle ear pathologies

3.1.1.1 Inflammatory pathologies

Otitis media (OM) is spectrum of disorders involving infection of the middle ear space (Rovers, Schilder, Zielhuis, & Rosenfeld, 2004). The pathogenesis of OM can be attributed to Eustachian tube dysfunction, bacterial and viral infections, environmental factors such as smoking in the household and genetic factors (Reddy, 2014; Wiertsema et al., 2011; Zhang et al., 2014). Chronis otitis media (COM) is the long-standing inflammation of the middle ear space. COM can be categorised as mucosal COM or squamous COM and either active or inactive. Mucosal COM is inflammation in the middle ear space due to a chronic perforation in the pars tensa of the TM (Wallis, Atkinson, & Coatesworth, 2015). This can be a result of chronic Eustachian tube dysfunction, but is also a complication of ventilation tube insertion (Kay, Nelson, & Rosenfeld, 2001). Active mucosal COM is defined as the presence of a perforation and active infection which may involve discharge from the middle ear space and complicated by tissue granulation, ulceration and polyp formation. Inactive mucosal COM is the presence of a TM perforation in the absence of infection, known as a dry ear. Squamous COM is the result of long-standing negative resulting in retraction of the ear drum into the middle ear space forming a retraction pocket. Inactive squamous COM is the presence of a retracted ear drum with no keratin build up. A chronic retraction can lead to the adherence of the TM to the ossicles, atelectasis or breakdown of TM layers (Wallis et al., 2015). Active squamous COM is defined as the collection of keratinising epithelium in a retraction pocket, otherwise known as cholesteatoma. Cholesteatomas evoke cytokine release, initiating inflammatory processes that erode surround structures such as the ossicles, temporal bone or bony labyrinth (Pusalkar, 2015). Overall, COM can affect the transmission of sound through the middle ear structures, resulting in a CHL of up to 60 dB (Merchant, Ravicz, Voss, Peake, & Rosowski, 1998).

3.1.1.2 Middle ear pathologies fixating the ossicular chain: otosclerosis and tympanosclerosis

Otosclerosis is commonly characterised as a progressive conductive hearing loss. It is a result of increased bone deposition in relation to bone absorption in the otic capsule. Increased bone deposition can lead to the fixation of the stapes footplate to the oval window, decreasing the efficiency of sound transmission into the cochlear fluids (Chole & McKenna, 2001). Histological otosclerosis is the presence of otosclerosis in the absence of clinical symptoms, usually identified post-mortem. Clinical otosclerosis implies the presence of a hearing loss (Van Den Bogaert, Smith, Govaerts, & Van Camp, 2003). The prevalence of clinical otosclerosis ranges from 0.1% to 2.5% in the literature but is one of the most common causes of CHL present in adults (Thys & Camp, 2009). The age of onset for clinical otosclerosis is most commonly between the ages of 30 and 40. Females are almost twice as likely to develop otosclerosis, and there is a strong correlation of prevalence with certain ethnicities (eg. European and Japanese). Autoimmune disorders and genetic factors have also been implicated in the development of otosclerosis (Chole & McKenna, 2001). The typical audiogram in an individual with clinical otosclerosis will show an elevation of AC thresholds, primarily at the low frequency range and eventually extending to the entire audiometrtic range (McKenzie, 1948). A common diagnostic indicator of otosclerosis is the presence of a dip of the 2 kHz BC threshold, first described by Cahart (1950) which has been postulated to be a shift in otic capsule resonance the higher frequencies rather than a cochlear injury.

Tympanosclerosis can be defined as calciferous deposits on the TM, tympanic cavity or mastoid rendering the middle ear stiff (Weilinga & Kerr, 1993). The pathogenesis remains unclear, but current theories include calcium deposition in response to post-inflammatory factors, immunecomplex mediated reactions, and exposure to hydrolytic enzymes following otitis media (Lesser et al., 1988; Møller & Jannetta, 1984; Schiff, Schiff, Yoo, & Yoo, 1985; Wielinga et al., 1988). A history of COM is the biggest risk factor for tympanosclerosis, with a prevalence ranging from 11-36% in COM patients (Asiri, Hasham, Anazy, Zakzouk, & Banjar, 1999). Tympanosclerosis is often aymptomatic, but cases that cause significant hearing loss are surgically treated (Gurr, Hildmann, Stark, & Dazert, 2008).

3.1.1.3 Ossicular discontinuity

Ossicular discontinuity is the separation of the ossicles at the site of one or multiple ossicular joints or within a bone due to a fracture (Farahmand et al., 2016). Disarticulation of the malleoincudal or incudostapedial joints is much more common than fractures. Ossicular discontinuity can be a result of head trauma or chronic otitis media (Delrue et al., 2016; Jeng, Tsai, & Brown, 2003). A separation with no contact between the disarticulated ends prevents any transmission of sound to the inner ear and is classified as a complete ossicular discontinuity, resulting in a flat 60 dB CHL across all frequencies (Sim et al., 2013). Whereas, partial ossicular discontinuity is a case of separation bridged by soft tissue, or opposing bones (Farahmand et al., 2016). Soft tissue transmits low frequency sound more efficiently than high frequency sounds; therefore a predominately high frequency conductive hearing loss is often seen in a partial ossicular discontinuity with a presentation of fluctuating hearing loss (Sim et al., 2013). Unique to other bones, the ossicles do not have the capacity to regenerate, therefore a discontinuity is often treated with ossicular reconstruction (Luers & Hüttenbrink, 2016).

3.1.2 Classifications of middle ear surgeries

A range of middle ear surgeries have been developed to address the pathologies described above. Factors dictating the type of surgery include the site of lesion, the conductive mechanism affected, the severity of the pathology and the preference of the surgeon. Because of the complexity of the middle ear system and the vast variety of pathologies, each middle ear surgery will be unique in the way it is performed, however they can be broadly classified into the following procedures.

3.1.2.1 Tympanoplasty

Tympanoplasty is the surgical closure of a TM perforation of the TM to improve hearing (Chavan, Ingole, & Birajdar, 2017). The earliest record of tympanoplasty was in 1878 by Berthold, who grafted the TM using a combination of plaster and remnants of de-epithelialised TM (Sarkar, 2013).

Since then, a wide array of grafts and surgical techniques have been developed.

Auto grafts, which is a tissue graft retrieved from a different part of the individual's body are most commonly used in tympanoplasty. Grafts used include skin from the EAC (Zöllner, 1955) and vein grafts (Shea, 1960), but most commonly used are temporalis muscle fascia (Trakimas et al., 2018) and pinna cartilage (Zahnert et al., 2016). These grafts tend to show 80 to 98% graft acceptance (Chavan et al., 2017).

A vast range of surgical techniques exist for tympanoplasty which depend on the size and location of the perforation. Likewise, surgical outcomes will largely depend on size and location of the perforation and which surgical technique and graft was used. A review of 789 patients who underwent tympanoplasty report 85% of cases show a closure of the ABG (with a mean closure of about 12 dB) (Indorewala, Adedeji, Indorewala, & Nemade, 2015). A review by (Chavan et al., 2017) showed improvements ranging between 9 to 26 dB in AC thresholds post-surgery. Tympanoplasty procedures will often be performed in conjunction with ossicular chain repairs (Wullstein, 1956). The current study will classify such procedures as ossiculoplasties.

3.1.2.2 Ossiculoplasty

Ossiculoplasty is the reconstruction of the ossicular chain to treat a stiffened middle ear system or discontinuity (Mudhol et al., 2013). It usually involves the placement of an interposition graft with the aim of improving middle each mechanics to allow efficient transmission of sound towards the inner ear.

Like tympanoplasty, a wide range of both autograft and alloplastic (any artificial material) grafts can be used in ossiculoplasty. The most commonly used autograft material is the incus body, but other options include cortical bone and cartilage (Iurato, Marioni, & Onofri, 2001). Alloplastic materials used include metals such as titanium and gold (A. D. Martin & Harner, 2004; Naragund, Mudhol, Harugop, & Patil, 2011) and biomaterials such as hydroxylapatite (Moretz Jr, 1998). The advantage of autograft material is the reduced risk of extrusion. However, autograft material may not be available in the presence of disease, there is a risk of fixation to the middle ear wall and operative time can significantly increase when obtaining and reshaping the material (Mudhol et al., 2013). Alloplastic materials have the advantage of reduced operative time, easy manipulation during surgery and show promising results in ABG closure Martin & Harner (2004). Despite these considerations, autograft incus ossiculoplasty remains the gold standard (Luers & Hüttenbrink, 2016; Mudhol et al., 2013).

Two main modes of ossiculoplasty are available to the surgeon, and technique selection depends on the state of the disease middle ear. The two modes are a total ossicular replacement prosthesis (TORP) and partial ossicular replacement prosthesis (PORP) (Yu et al., 2013). In the case of a defect of the malleus and/or incus, a PORP will be placed, connecting the TM or handle of the malleus to the stapes. However, in the case of a stapes defect, a TORP will be placed connected the TM to the stapes footplate (Luers & Hüttenbrink, 2016). In the circumstance where middle ear surgery reduces the middle ear space volume, TORP or PORP may not be feasible (Wood, O'Connell, Lowery, Bennett, & Wanna, 2019). In such case, a type 3 tympanoplasty, or stapes columella may be performed where the placement of a TM graft is extended medially and placed directly on the head of the stapes (Mehta, Ravicz, Rosowski, & Merchant, 2003). Finally, a type IV tympanoplasty where transmission of sound to the inner ear occurs directly at a mobile stapes footplate while a TM graft is placed over the round window (Merchant et al., 1998).

3.1.2.3 Stapedectomy/stapedotomy

Surgeries discussed to this point rely on a mobile stapes footplate to transfer mechanical vibrations to the cochlear fluids through the oval window. In the case of a fixed stapes such as otosclerosis where vibrations can no longer be transmitted to the oval window, a stapedectomy or stapedotomy may be performed (Luers & Hüttenbrink, 2016).

A stapedectomy is the partial, or total removal of the stapes footplate followed by placement of a tissue graft over the oval window or prosthesis (Fisch, 2009).

A stapedotomy is the creation of a small perforation, usually 0.6 mm in diameter at the centre of the fixated footplate where a prosthesis is placed and hooked to the incus (De La Cruz & Chandrasekhar, 1998). The advantages of stapedotomy over stapedectomy include a reduced risk of damage to the cochlear duct and vestibular organs, reduced risk of prosthesis fixation or prosthesis migration (Fisch, 2009). Stapedotomy surgeries can vary by the means of producing the fenestra in the stapes footplate and/or by the material of prosthesis used. Prostheses include Teflon, gold, platinum, titanium and alloys (Bansal, 2016).

Traditionally, cold sharp instrumentation such as a Shea's pick was used to bore a hole in the stapes footplate, however technological advances have been made in microdrills and lasers which are being increasingly employed in stapes surgeries (Parida, Kalaiarasi, & Gopalakrishnan, 2016; Young, Mitchell-Innes, & Jindal, 2015). The use of microdrills can expose the ear to up to 100 dB SPL, and therefore has been argued to have an effect on inner ear function in both the surgical ear and the contralateral ear (Baradaranfar et al., 2015). Lasers offer a means of perforation without making direct contact, however also pose a risk to inner ear injury due to damaging effects of thermal energy on surrounding structures (Kamalski et al., 2014). Despite these downfalls, a comparison of perforation techniques show no significant difference in hearing outcomes (Pauli, Strömbäck, Lundman, & Dahlin-Redfors, 2019).

3.1.2.4 Mastoidectomy

Mastoidectomy encompasses a range of procedures that involve either partial or complete removal segments of the temporal bone in order to remove disease and/or increase visualisation of the middle ear cavity. It is the main surgical treatment of cholesteatoma and mastoiditis (Bento & De Oliveira Fonseca, 2013; Pusalkar, 2015). In addition, it is the initial step of cochlear implantation (Kronenberg & Migirov, 2003) and tumour removal surgeries that require access to the skull base (Schick & Dlugaiczyk, 2013).

Mastoidectomy can be broadly categorised into canal wall up procedures, canal wall down procedures, radical and modified radical mastoidectomy (Placanica, Griffin, Mahanta, & Jumeau, 2018).

3.2 Audiometric outcomes following middle ear surgery

While not always the primary goal of middle ear surgery, improving hearing acuity is one of the main drivers for individuals to proceed with surgical intervention (Bergin et al., 2015). The American Academy of Otolaryngology – Head Surgery (AAO-HNS) produced a document in 1995 which provides guidelines for the reporting of hearing results following surgery to correct conductive hearing loss ("Committee on Hearing and Equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss. American Academy of Otolaryngology-Head and Neck Surgery Foundation, Inc," 1995). That said, there is significant variability in outcome measures reported. Changes in hearing acuity following middle ear surgery has been quantified by improvement of AC thresholds, comparing mean AC thresholds pre and post. Air-bone gap closure has been reported by either comparing the mean air-bone gap pre-operatively to mean post-operative values; or the rate of closure to a specified value. Analyses of results vary further by which frequencies are tested or the definition of a successful air-bone gap closure, which can range from a closure within 10 dB (Nicola Quaranta, Besozzi, Fallacara, & Quaranta, 2005; N. Quaranta, Taliente, Coppola, & Salonna, 2015) to 25 dB (Al Anazy, Alobaid, & Alshiha, 2016). Some studies do not specify a magnitude or rate of closure, rather report on the overall improvement of the air-bone gap (Vartiainen & Seppä, 1997). Furthermore, there is no uniformity in the reported follow up periods when obtaining thresholds post operatively. However, this may be unavoidable in some cases when working around participant schedules and especially in retrospective studies working off case files. Typically, studies that investigate air-bone gap closure and changes in AC and BC thresholds in the low frequency range report high success rates and low incidence of post-operative hearing loss. Conversely, studies that focus on AC and BC threshold changes in the high frequency range at 4 kHz and beyond identify a much higher incidence of post-operative hearing loss.

3.2.1 Air bone gap closure in the conventional frequencies

Countless studies report successful outcomes following middle ear surgery in the conventional frequency range. Such studies either report the closure of the ABG (Al Anazy et al., 2016; Ginsberg et al., 1978; House & Teufert, 2001; Nicola Quaranta et al., 2005; Ramsay, Kdrkkdinen, & Palva, 1997; Sehra et al., 2019; Wiatr, Wiatr, Składzień, & Stręk, 2015) or restoration of AC values similar to BC thresholds operatively (Harder, Jerlvall, Kylen, & Ekvall, 1982; House & Teufert, 2001; Persson, And, & Magnuson, 1997; Salmon, Barriat, Demanez, Magis, & Lefebvre, 2015).

3.2.2 Post-operative hearing loss

Post-operative sensorineural hearing loss is well documented risk of middle ear surgery. A risk of dead ear, or total loss has been reported to be 0.5% (Prinsley, 2013), where rates of sensorineural loss range from 4.6 to 60% (Al Anazy et al., 2016; Babighian & Albu, 2009; Bergin et al., 2015; Desai, Aiyer, Pandya, & Nair, 2004; Schick & Dlugaiczyk, 2013; Tos et al., 1984). Hearing loss following middle ear surgery has also been documented frequencies beyond 8 kHz. This will be discussed in detail in the following section.

3.3 Extended high frequency hearing

While typical audiometric testing assesses the CF range, the frequency range of the human ear extends to 20,000 Hz (Sakamoto, Sugasawa, Kaga, & Kamio, 1998). The 9 – 20 kHz frequency range is termed *extended high frequencies* (EHF) (Valiente, Trinidad, García-Berrocal, Gil, & ramirez camacho, 2014). The EHF range has been proposed to contribute to sound localisation, sound quality and speech audibility and recognition.

3.3.1 Clinical significance of EHF hearing

Several studies have demonstrated that spectral cues in the EHF range are important in sound localisation, including the localisation of speech signals. In a study comparing localisation of ‘virtual’ sound sources against ‘real’ sound sources, participants showed reduced localisation performance when presented with virtual sound sources which showed distorted signals in the high frequency (7 kHz and above) range (Bronkhorst & Bronkhorst, 1995). Adding to this, when comparing localisation performance between high pass and low pass filtered white noise, it was found that stimuli spectrally restricted above 2 kHz low pass filtered white noise resulted in a greater number of cone of confusion errors (Carlile, Delaney, & Corderoy, 1999). In a similar experiment using filtered speech signals (monosyllabic words), there was an increase in the number of cone of confusion associated errors in low pass filtered (at 8 kHz) signals (Best, Carlile, Jin, & Van Schaik, 2005). In addition to speech localisation, Best et al. (2005) suggest EHF spectral cues have a role in speech understanding. While it has been argued that important speech signals lie only between 0.25 – 8 kHz, Monson, Lotto, and Story (2012) report important spectral cues in speech and singing above 8 kHz, and that detecting such cues are potentially valuable when distinguishing between and identifying human vocalisations. In support of this, Badri, Siegel, and Wright (2011) studied individuals who showed poor performance in speech perception in noise tests, despite have clinically normal hearing in the CF range audiogram. The difference between this population and controls was broader psychophysical tuning curves and elevated EHF hearing thresholds.

Moore, Stone, Füllgrabe, Glasberg, and Puria (2008) indicate a role of EHF spectral cues in speech understanding and suggest amplification in this region has the potential to assist a proportion of those with age related EHF hearing loss.

3.3.2 EHF audiometry as useful diagnostic tool

Age-related reference curves for EHF pure tone audiometry have been established by (Dreschler, v.d. Hulst, Tange, & Urbanus, 1985). While not routinely tested in a clinical setting, testing hearing in the EHF range can be a useful diagnostic tool for early detection of hearing loss as a result ototoxic drug administration, noise induced cochlear damage, presbycusis and post-operative hearing loss.

It has been well documented that several classes of drugs have ototoxic effects including cisplatin, aminoglycoside antibiotics, loop diuretics and non-steroidal anti-inflammatories (NSAIDs) (Hoshino, Tabuchi, & Hara, 2010; Sergi et al., 2004). Immunohistological studies of spiral ganglion neurons (Ruan et al., 2014) and electron microscope studies of inner hair cell integrity (Sone, Schachern, & Paparella, 1998; Tange & Hodde, 1985; Tange & Vuzevski, 1984) in animal cochleae have demonstrated that these ototoxic effects are initiated at the basal end of the cochlea and progress towards the apex. Indeed, this pattern of hearing loss is seen in human patients administered with such drugs, proving EHF audiometry a valuable diagnostic tool (Dreschler et al., 1985; Stephen A. Fausti et al., 1992; S. A. Fausti et al., 1979).

Noise induced hearing loss (NIHL) is second to presbycusis as the most common form of acquired hearing loss. It is most commonly a result of occupational noise exposure, including heavy machinery and high intensity impulse sounds but can also result from recreational noise exposure such as shooting and attending concerts. Currently, NIHL is identified using conventional audiometry. It presents on the audiogram as an elevated threshold or ‘notch’ at 4 kHz, showing recovery at 6 and 8 kHz. Like presbycusis, EHF audiometry has been shown to be a more sensitive test for the detection of hearing loss in individuals with occupational NIHL (Mehrparvar et al., 2014). A study of young adults with significant leisure noise exposure (eg. night clubs and instrument playing) demonstrated a higher association of elevated thresholds in the EHF range compared to the conventional ‘noise notch’ to level of exposure (Wei et al., 2017).

3.4 Post-operative hearing loss in the extended high frequencies

The current literature provides a limited number of studies reporting audiometric data in the EHF range following middle ear surgery. Mair and Laukli (1986) is one of the earliest reports of audiometric changes in the EHF range following middle ear surgery. In this study, AC hearing thresholds in the CF and EHF ranges were compared pre and post myringoplasty or stapes surgery, with no fixed interval for follow up time. Audiometric thresholds in the CF range up to 4 kHz showed a marked threshold improvement follwoing both types of surgeries, whereas the EHF range showed poorer threshold post-surgery, particularly in the 12-16 kHz range. Furthermore, this EHF deterioration was greater in stapes surgery patients. In line with this data, Verbist, Debruyne, Rector, and Feenstra (1993) demonstrate an increase in 10 kHz and 14 kHz AC thresholds following mastoidectomy in twenty participants. A larger, more recent study by Babbage et al. (2017) looked at AC thresholds in the CF and EHF range in 39 patients undergoing stapes surgery, follow up to 12 months post-surgery. Improvements were seen in AC thresholds within the CF range, whereas hearing loss was demonstrated in the 9 – 11.2 kHz range. Notably, this study reports 77% of patients experienced a decrease in the highest frequency they could hear 1 week following surgery. This value decreased to around half the patients at 3 months and stayed stable up to 12 months follow up. Likewise, Bagger-Sjöbäck et al. (2015) report worsening 10, 12 and 14 kHz thresholds following stapes surgery in 144 patients. This study also reports a drop in the highest recordable frequency, where 80% of patients had a detectable threshold at 10 kHz pre-operatively, dropping to 74% post-operatively. This pattern was similar at 12 kHz changing from 65% to 57%, and at 14 kHz from 36% to 33% (Bagger-Sjöbäck et al., 2015). From these studies, a lack of EHF BC thresholds makes it unclear whether the deterioration in EHF thresholds is conductive or sensorineural in nature.

Studies reporting EHF BC thresholds are sparse. Doménech, Carulla, and Traserra (1989) report EHF audiometric changes in 20 patients undergoing stapedectomy. The study reports changes in AC thresholds as well as EHF cochlear function data using transcutaneous electrical stimulation. A deterioration in threshold in response to EHF transcutaneous electrical stimulation is demonstrated in 83% of patients. In addition, there was a decrease in the upper most frequency heard in 67% of patients. Deterioration was most prominent between 11 and 14 kHz, and at 18 kHz. This study is largely limited by the absence of masking noise to isolate ear specific information.

A study by Hegewald et al. (1989) also used electrostimulation to examine changes in cochlear function in the EHF range but in 25 patients undergoing mastoidectomy. Post-operative thresholds were measured 1 day and 1 month following surgery. Temporary threshold shifts were noted 1 day post-surgery, most notably at 3 to 4 kHz. However, 1 month post-operative testing showed no significant deterioration compared to pre-operative values, indicating that post-damage was not permanent.

Both Doménech et al. (1989) and Hegewald et al. (1989) studies have been criticised as transcutaneous electrical stimulation does not mimic the natural BC hearing and may not be a true reflection of BC thresholds.

A more recent study by Mair and Hallmo (1994) utilise the Pracitronic KH70 bone vibrator rather than transcutaneous electrical stimulation to test cochlear function in the EHF range. Both AC and BC thresholds were monitored following myringoplasty in 22 subjects and demonstrate a deterioration in AC thresholds. In agreement with the Hegewald et al. (1989) study, the EHF BC thresholds remained stable up to 11 months post-surgery.

Preliminary longitudinal studies by Babbage (2015) and Howey (2019) used a system in which EHF BC thresholds were monitored following middle ear surgery using a modified magnetostrictive TEAC HP-F100 transducer. This transducer has been shown to be a reliable means of measuring EHF BC thresholds (Popelka, Telukuntla, & Puria, 2010). Babbage (2015) conducted a small study monitoring both AC and BC EHF thresholds in 4 participants undergoing middle ear surgery. Two participants show a deterioration in both AC and BC thresholds immediately following surgery. Assessments 3 months post-operatively in these participants showed a recovery in AC thresholds, while the BC thresholds remained elevated. The remaining participants show no significant effect of middle ear surgery on EHF AC and BC thresholds. The Howey (2019) study follows 4 cases, including two stapedotomies, one ossiculoplasty and one tympanoplasty. This small case study reported two different outcomes. Two stapes surgeries showed an overall increase in BC thresholds from 8 to 16 kHz 1 month following surgery. There was a slight recovery at the 3 month follow up, however thresholds were all at least 5 dB greater than pre-operative values. The remaining surgery types resulted in a large conductive component 1 month following surgery.

While there is a clear consensus that middle ear surgery leads to a deterioration of AC thresholds in the EHF range, caution must be taken when making comparison between studies investigating changes in BC thresholds in the range. First, the methods in which EHF cochlear function is measured varies greatly between studies. Earlier studies relied on electrostimulation of the cochlea, rather than traditional bone conduction transducers. Furthermore, every study focuses on different surgery types, each of which may impact middle and inner ear functions in a unique way. Another important consideration is the lack of masking in earlier studies. This is a fundamental challenge faced when testing hearing thresholds in the EHF range, and will be discussed in detail in the following section.

3.5 Limitations faced when testing EHFs

Currently, there are no bone conductors used in clinics or commercially available that are capable of reliably testing bone conduction threshold above 6 kHz. High frequency output of the current B-71 or B81 electromagnetic vibrators is limited by the inherent mass of the rod (Reinfeldt et al., 2013).

As mentioned in previous sections, the external and middle ear contribute to mechanisms involved in the perception of bone conduction stimuli. Økstad, Laukli, and Mair (1988) suggest that BC thresholds above 6 kHz need to be interpreted with caution, particularly in conductive hearing losses or following middle ear surgery. BC thresholds may not reflect true changes in cochlear function, rather changes in the sound transmission through the external and middle ear.

Limitations in output affecting both BC stimuli and masking remains the principal challenge in this field. The study by Hegewald et al. (1989) was limited to 60 dB SPL. It is difficult to detect significant changes in thresholds if pre-operative thresholds are beyond the limits of the audiometer. Furthermore, the ability to produce sufficient masking is largely limited, particularly in studies focusing on outcomes following middle ear surgery as this population typically present with a bilateral conductive hearing loss.

Chapter 4: Methods – EHF audiometry following middle ear surgery

4.1 Study rationale and aims

The goals of this study were:

1. To evaluate if and how hearing is differentially affected across the entire audiometric test frequency range (0.25 – 16 kHz).
2. To distinguish whether EHF hearing loss post-middle ear surgery was conductive or sensorineural in origin
3. To describe the extent and time course of any recovery in hearing in the 3 months' postoperative period.

4.2 Study hypotheses

To address these aims, the following hypotheses were posed for pooled results including all surgery types, it was predicted that:

- Air conduction thresholds in the CF range would improve over successive assessment periods
- Air conduction thresholds in the EHF range would deteriorate immediately following surgery with some recovery at later assessments

- A significant population would show a loss in the highest measureable frequency immediately post-op, and this number will decrease at later assessments.
- Bone conduction thresholds following surgery would show deterioration in the 4 kHz to 16 kHz frequency range.
- Air bone gaps would be greater immediately following surgery
- Air bone gaps would be smaller than pre-op values at later (1 month and 3 month) assessment periods
- Extended high frequency hearing loss would recover over by the 3 months assessment in a majority of cases, with a small population who retain this loss.

4.3 Participants

Participants for this study were recruited from the Department of Otolaryngology Head and Neck Surgery, Christchurch Hospital or patients seeing one otologist working in the private sector in Christchurch. It includes patients with conductive hearing loss scheduled to undergo middle ear surgery. To be eligible to participate in the study

1. At or above the age of 16 years

2. Scheduled to undergo either primary or revision stapedectomy/stapedotomy, tympanoplasty or ossiculoplasty.
3. Measurable pre-operative bilateral AC thresholds beyond 8 kHz
4. Average pre-operative BC thresholds at 0.5, 1 and 2 kHz no more than 50 dB HL
5. No other significant disorders that may have resulted in an auditory or vestibular impairment.
6. Availability for pre-operative and post-operative testing.

In accordance with ethical approval obtained from the University of Canterbury Ethics Committee, an information sheet (Appendix A) was provided to patients who met eligibility criteria at the time of their preadmission appointment and invited to participate in the study by the surgeon or primary researcher. Written consent (Appendix B) was obtained from all patients who agreed to participate in the study.

4.4 Equipment

Testing was conducted in a double walled sound treated booth at Christchurch Public Hospital or in the University of Canterbury Department of Audiology Speech and Hearing clinic and Audiology research lab. Sound treated rooms met International Organization for Standardization [ISO] 8253-1 (2010). Tympanometry was conducted using a calibrated Grason-Stadler GSI Tympstar Tympanometer (Grason-Stadler, Eden Prarie, MN). Conventional frequency audiometry was performed using a calibrated calibrated diagnostic GSI 61 audiometer (Grason-Stadler, Eden Prarie, MN). EHF audiometric testing was performed using a similar system to Babbage (2015) and Howey (2018) with some alterations made. The current set up was calibrated to match the output of the previous system, outlined in Appendix C. Air conduction stimuli in the CF range were delivered through ER-3A insert ear phones (Etymotic Research Inc., Elk Grove Village, IL), or through TDH-39 supra-aura headphones (Telephonics Corporation, Farminingdale, NY) if otoscopy showed discharge. Air conduction stimuli in the EHF range were delivered through Synthesiser HDA2000 circumaural headphones (Sennheiser electronic GmbH & Co., Wennebostel, Germany). Bone conduction stimuli in the CF range were presented through the Radioear B-71 (Radioear Corporation, New Eagle, PA) bone conduction oscillator placed on the test ear mastoid process. The EHF bone conduction stimuli were delivered through the modified TEAC HPF100 bone conductor for BC stimuli placed on the participant’s forehead as close to the midline of the head as possible.

4.5 General procedure

We aimed to repeat full audiological assessment including otoscopy, tympanometry, bilateral air and bone conduction pure tone audiometry in the CF and EHF ranges at four time points. The first, no more than one month before their scheduled surgery, followed by 1-2 weeks, 1 month, and 3 months postoperatively. Tympanometry in the surgical ear was not performed within the first three months following middle ear surgery as it is contraindicated during this period. The assessments were best matched to post-surgical follow-up appointments with the otolaryngologist for patient convenience.

4.5.1 Conventional frequency pure-tone audiometry

Audiometric thresholds were measured in 5 dB HL steps using the modified Hughson-Westlake technique (Cahart & Jerger, 1959) . Air conduction thresholds of both ears were measured at octave frequencies from 0.25 to 8 kHz in addition to 3 and 6 kHz. Bone conduction thresholds were measured with the transducer positioned on the ipsilateral mastoid process at 0.5, 1, 2 and 4 kHz. Narrow-band masking noise was presented to the contralateral ear using the selected transducer when the difference between air conduction thresholds in the test ear and non-test ear exceeded the interaural attenuation values; or if the air bone gap was greater of equal to 15 dB as outlined by (Yacullo, 2015). Air and bone conduction masking were performed using a step masking method (Turner, 2004) if appropriate, otherwise the plateau method was performed (Hood, 1960). The result was recorded as “no response” on the audiogram when the participant did not respond after two consecutive presentations of a tone set at the intensity limits of the audiometer for the frequency and ear being tested.

Bone conduction thresholds in the CF range were obtained as per American Speech-Language-Hearing Association (ASHA) (2005). Bone conduction thresholds were only obtained if air conduction thresholds showed a clinically significant hearing loss (> 20 dB HL). Furthermore, 6 and 8 kHz bone conduction thresholds were not tested. This maintained external validity as testing these frequencies are not included in best practice guidelines which are followed in a clinical setting (American Speech-Language-Hearing Association (ASHA), 2005). In addition, the focus of previous literature investigating changes in bone conduction following middle ear surgery is at 0.5, 1, 2 and 4 kHz range. While these missing data pose a threat to the internal validity of the study, the testing protocol was based around testing in a time efficient manner, addressing the challenge of testing in an under-resourced public hospital setting with overflowing wait-lists and immense time-pressures.

4.5.2 Extended high frequency pure-tone audiometry

Both air and bone conduction thresholds were measured at 1/6th octave frequencies from 8 - 16 kHz in both ears using the modified Hughson-Westlake technique (Raymond Carhart & Jerger, 1959). Air and bone conduction masking were performed using a step masking method (Turner, 2004). A conservative IAA value of 40 dB HL for the HDA200 was used as outlined by Brännström et al. (2010). In cases where adequate masking exceeded the output limits of the audiometer, an asterisk was marked on the audiogram to indicate insufficient masking.

4.6 Data Analysis

4.6.1 Changes in AC/BC pure tone thresholds and ABG

The current study aimed to assess changes in AC and BC thresholds and air bone gaps across assessments up to 3 months post-surgery. Mean threshold values at each time point were calculated for each frequency and analysed using a repeated measures ANOVA using SPSS version 25 (2017, IBM Corp., Armonk, NY). Mauchly's Sphericity test was performed to assess the variances of the differences between all possible pairs of within-subject conditions. If this was non-significant, the null hypothesis is accepted and the variances are equal. Therefore, the *F* ratio is valid and interpreted. In the case that Mauchly's test is significant, a Greenhouse-Geisser correction was made. If test of within subject effects showed significance with a p value <.05, pairwise comparisons were assessed and deemed statistically significant with a value of $p < 0.05$.

4.6.2 Rates of loss in the highest measurable frequency

When a participant's thresholds were beyond the limits of the audiometer, the threshold was recorded as 5 dB above the limit. The highest measurable frequency at each time point was recorded for each participant. The proportion of participants who showed in loss, gain or no change in the highest measurable frequency, relative to pre-op was calculated for each post-op assessment period.

4.6.3 Rates of SNHL at 4 kHz and the EHF range

Post-op bone conduction thresholds for 4 kHz and the EHF range were subtracted from pre-op thresholds for each time point. A positive value indicates improvement, a negative value indicates deterioration. A change in threshold ≥15 dB was deemed a significant change. The proportion of participants who showed in loss, gain or no change (0 or <15 dB change) in bone conduction threshold, relative to pre-op was calculated for each post-op assessment period.

Chapter 5: Results

Of a total 28 patients invited to partake in the study, 20 participants returned for at least the 1 month follow up test and were included in data analysis. Of the 20 participants, there were 10 males and 10 females. Participant age ranged from 27 to 79 years with a mean age of 49 years. 7 participants were recruited from the Christchurch Public Hospital waiting list and 13 were recruited from the surgical list of one otologist working in the private sector. One patient was lost to follow up at 1 month time point. From the remaining 19 participants, one participant was excluded due to a dislodged prosthesis and eight were lost to follow up and. Surgery was performed on eleven left ears and nine right ears. Three patients underwent ossiculoplasty, seven underwent mastoidectomy and ten stapedotomies were performed.

Due to the numbers of participants measured, statistical analyses were performed on the pooled data from all surgery types (mastoidectomy, ossiculoplasty and stapedotomy). Data showing results separated by type of surgery are presented in section 5.8.

Three month assessments were still in process at the time of submission of this thesis. Because of the small sample size at this time point (N = 11) a decision was made to exclude this set of data from statistical analyses due to the inability to draw meaningful conclusions from those data. Three month data was included in some figures and tables in the following sections, but was not included in the statistical analysis.

5.1 Post-operative changes in air conduction thresholds – pooled data

As summarised on Table 3, there was a significant effect of time on AC thresholds when comparing pre op up to 1 month assessment points at all frequencies with the exception of 16,000 Hz. The direction of these changes is visible in the mean thresholds presented in Table 4 and 5. Mean threshold shifts at 1 week, 1 month and 3 months in relation to pre-op values are summarised in Figure 9.

Table 3: Results of test of within subject effects when comparing AC thresholds across assessment periods. Note *p* <.05 = a significant effect of time for that frequency

Frequency	*F ratio*	*df*	*p value*	*ηp2*
250	1.37	1.37,36	<.05	.323
500	10.28	1.34,24.18	<.05	.364
1000	11.145	1.5,36	<.05	.382
2000	7.52	2,36	<.05	.295
3000	9.22	2,36	<.05	.339
4000	6.94	1.49,26.73	<.05	.278
6000	4.52	1.51,27.22	<.05	.201
8000	5.389	1.49,26.85	<.05	.230
9000	7.367	2,36	<.05	.290
10,000	10.47	2,36	<.05	.368
11,200	8.15	1.4,25.37	<.05	.312
12,500	4.29	1.23,22.18	<.05	.192
14,000	9.38	1.42,36	<.05	.343
16,000	3.17	2,34	.055	.157

Table 4: Mean CF range AC thresholds across 3 assessment periods

*Mean [dB HL] ± SD [dB]) * - significant relative to pre op; † - significant relative to 1 week*

Frequency (Hz)	**Pre op**	**1 week post op**	**1 month post op**
250	54.2 ± 20.0	42.11 ± 20.6*	35.0 ± 19.1*†
500	55.5 ± 22.2	41.32 ± 23.0*	33.42 ± 20.9*†
1000	53.9 ± 22.5	46.06 ± 22.9	34.47 ± 20.9*†
2000	50.8 ± 23.4	53.95 ± 26.9	35.79 ± 19.9*†
3000	52.9 ± 25.7	57.11 ± 30.6	36.58 ± 22.9*†
4000	60.3 ± 26.1	62.11 ± 28.4	44.74 ± 21.9 *†
6000	63.4 ± 24.6	71.84 ± 27.5	56.32 ± 21.9†

Table 5: Mean EHF range AC thresholds across 3 assessment periods

*Mean [dB HL] ± SD [dB]) * - significant relative to pre op; † - significant relative to 1 week*

Frequency (Hz)	**Pre op**	**1 week post op**	**1 month post op**
8000	67.6 ± 25.9	80.5 ± 23.5*	70.5 ± 24.9†
9000	66.1 ± 24.4	77.9 ± 24.8*	66.3 ± 26.2†
10,000	67.4 ± 24.7	81.3 ± 20.8*	69.2 ± 22.9†
11,200	72.1 ± 23.3	86.3 ± 19.8*	79.7 ± 19.8†
12,500	75.5 ± 20.7	83.9 ± 19.8*	81.1 ± 19.3†
14,000	77.1 ± 12.2	83.7 ± 8.8	83.9 ± 8.4
16,000	60.6 ± 9.2	64.2 ± 6.5*	63.1 ± 3.9*

5.1.1 Improved AC thresholds in the low to mid frequency range

Pairwise comparisons of mean AC thresholds across time points for each frequency in the conventional range are summarised in Table 4. Repeated measures ANOVA yielded the following significant changes:

250 and 500 Hz

When compared to pre-op thresholds, a significant improvement was seen at both 1 week and 1 month time points. Furthermore, an improvement was observed at the 1 month time point compared to the 1 week period.

1000 to 4000 Hz

Thresholds at 1000, 2000, 3000 and 4000 Hz show significant improvements at the 1 month assessment period when compared to both pre-operative values and 1 week post-op thresholds. No significant change was seen 1 week following surgery.

6000 Hz

There was no significant change in thresholds observed immediately post-surgery. However, there is a significant improvement in thresholds from 1 week post-op to 1 month post-op.

Mean shift in CF range AC thresholds

Box plots in Figure 9 show AC thresholds between 250 Hz to 1 kHz improve immediately post-op and successive periods. Post-operative deterioration is seen at 2 – 8 kHz followed up improvements in later assessment points.

5.2 Post-operative changes in AC thresholds in the high frequency range – pooled data

Repeated measures ANOVA showed the following significant changes, mean thresholds and standard deviations are reported on Table 5

8000 to 12,500 Hz

At frequencies between 8000 and 12,500 Hz, there was a significant deterioration in AC thresholds 1 week post-op. This was followed by a significant improvement 1 month following surgery. There was no significant difference between pre-op and 1 month thresholds.

16,000 Hz

When comparing 16,000 Hz AC thresholds across the three time points, both 1 week and 1 month thresholds were significantly poorer than pre-op thresholds.

Mean shift in EHF AC thresholds

Box plots on Figure 9 show deterioration in AC thresholds immediately post-op across all EHF. Some recovery is seen at 9, 10 and 12.5 kHz, but the remaining frequencies stay relatively stable.

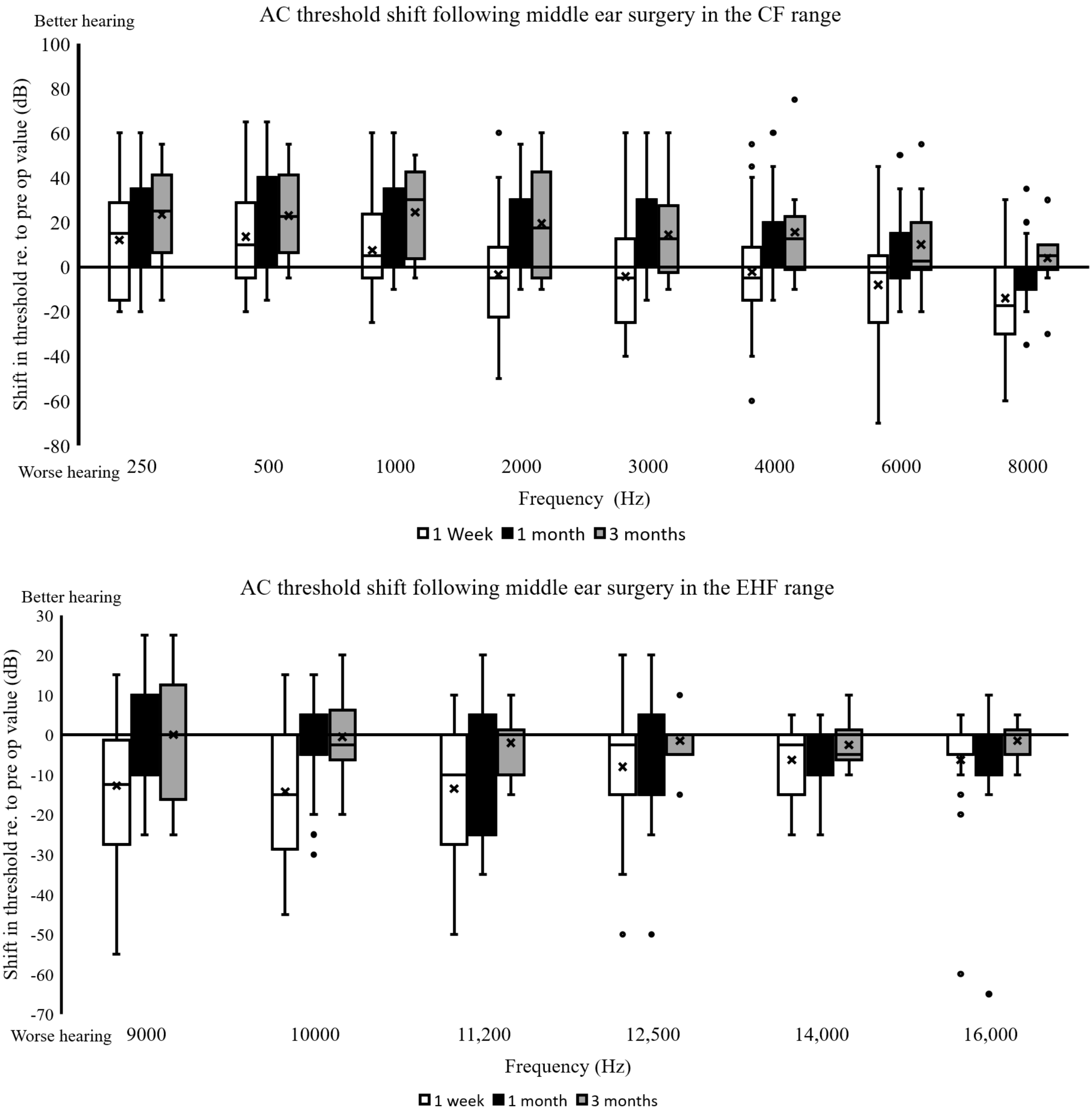

Figure 9: Box plots depicting mean shift in AC thresholds in the conventional range (above) and EHF range (below) relative to pre-op thresholds at 1 week (white boxes), 1 month (black boxes) and 3 months (grey boxes).

5.3 Changes in the highest measurable frequency

Table 6 summarises the change in highest measurable frequency at each time point, relative to pre-op measurements. To note, 70% of participants had a loss in the highest measureable frequency 1 week post-op, 50% at 1 month post-op and 73% at 3 months post-op.

Table 6: Rate of loss of highest measurable frequency at each post-op assessment point

Time point	*Loss*	*Gain*	*No change*
1 week post op	70%	10%	20%
1 month post op	50%	20%	30%
3 months post op	73%	9%	18%

5.4 Post-operative changes in BC thresholds – pooled data

As summarised on Table 7, there was a significant effect of time on BC thresholds at 1000, 2000, 4000, 9000 and 10,000 Hz when comparing across the three assessment periods. The direction of these changes is visible in the mean thresholds presented in Table 7. Mean BC thresholds shifts relative to pre-op values is summarised on Figure 10. Table 8 displays the mean BC thresholds across the three time points, repeated measures ANOVA showed the following significant changes indicated by a p value <0.5.

Table 7: Results of test of within subject effects when comparing BC thresholds across assessment periods. Note p <.05 = a significant effect of time for that frequency

Frequency (Hz)	*F ratio*	*df*	*p value*	η_p^2
500	2.56	2,36	.091	.124
1000	8.06	2,36	<.05	.309
2000	4.78	2,36	<.05	.21
4000	3.54	1.9,34.27	<.05	.164
9000	4.55	2,36	<.05	.202
10,000	7.5	2,36	<.05	.294
11,200	2.99	2,36	.063	.142
12,500	1.26	2,36	.297	.065
14,000	.867	1.4,25.27	.397	.046
16,000	.468	2,36	.630	.025

Table 8: Mean BC thresholds across 3 assessment periods

*Mean [dB HL] ± SD [dB]) * - significant relative to pre op; † - significant relative to 1 week*

Frequency (Hz)	Pre op	1 week post op	1 month post op
500	22.9 ± 14.7	23.7 ± 14.0	17.4 ± 11.7
1000	22.4 ± 13.9	21.1 ± 14.0	13.4 ± 12.8*†
2000	34.7 ± 18.3	35.3 ± 16.8	30.3 ± 15.9*†
4000	23.4 ± 18.6	26.1 ± 20.1	20.5 ± 17.9†
9000	28.7 ± 20.7	35.5 ± 15.9*	33.9 ± 15.5*
10,000	28.9 ± 22.1	39.7 ± 16.9*	35.8 ± 15.3*
11,200	38.7 ± 21.2	43.9 ± 18.2	43.9 ± 16.6
12,500	34.5 ± 17.8	40.00 ± 16.7	41.6 ± 16.1
14,000	45.3 ± 14.8	46.3 ± 11.5	47.4 ± 11.9
16,000	46.1 ± 8.1	45.3 ± 6.1	46.3 ± 7.2

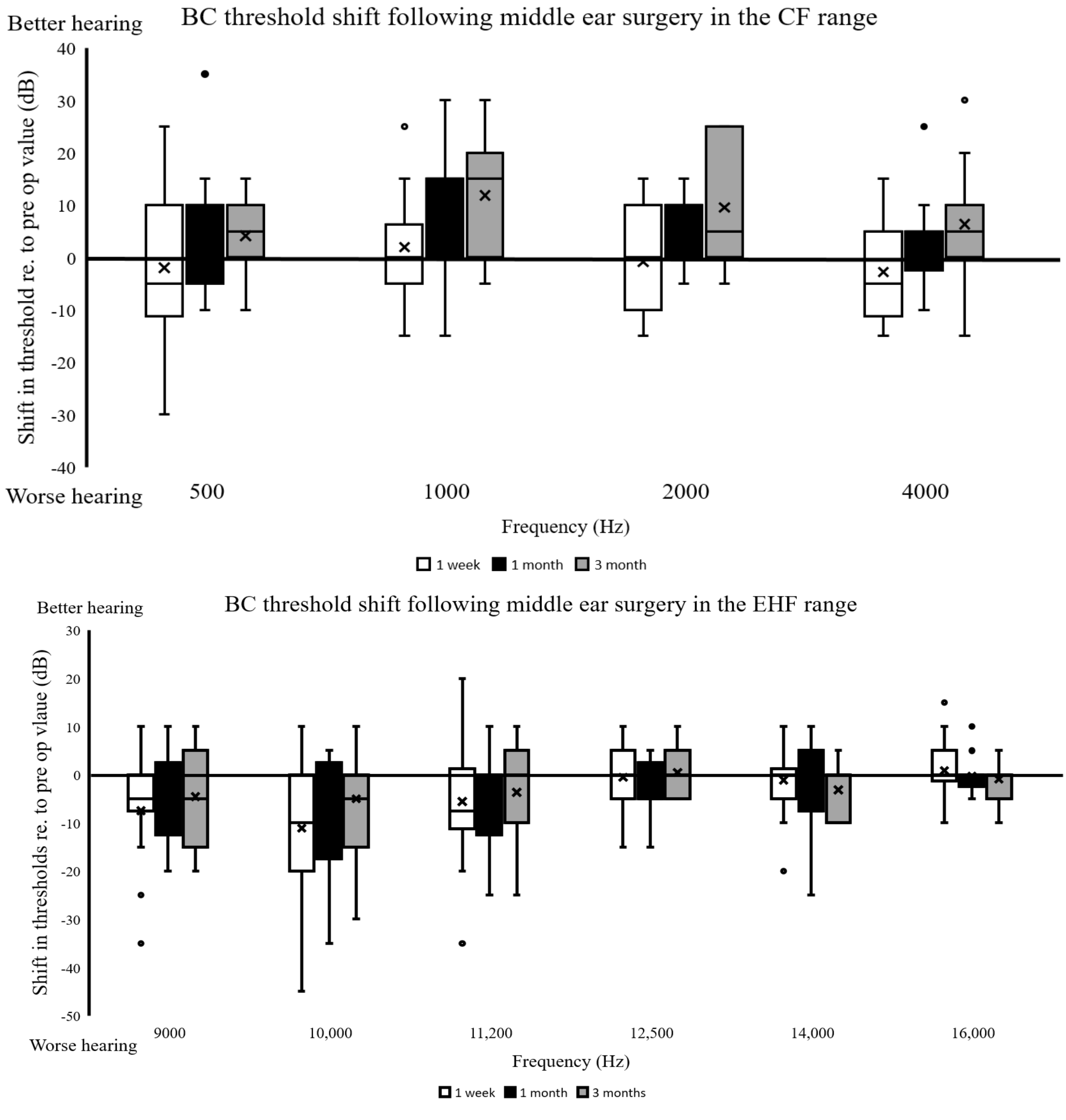

Figure 10: Box plots depicting mean shift in BC thresholds in the conventional range (above) and EHF range (below) relative to pre-op thresholds at 1 week (white boxes), 1 month (black boxes) and 3 months (grey boxes).

5.4.1 Improved BC thresholds

BC Thresholds at 1000 and 2000 Hz showed significant improvement at 1 month when compared to both pre-op and 1 week post-op values. Likewise, 1 month thresholds at 4000 Hz showed significant improvements compared to 1 week thresholds.

5.4.2 Deterioration in BC thresholds

BC thresholds at 9000 and 10,000 Hz were significantly poorer 1 week and 1 month assessment points when compared to pre-op thresholds.

Mean shift in BC thresholds

Displayed in Figure 10, BC thresholds in the conventional frequency range remain relatively stable, with some improvement in later assessments. In the EHF range, there is an overall deterioration in BC thresholds, most notably at 9 to 11.2 kHz.

5.5 Post-operative changes in ABG – pooled data

As summarised on Table 9, there was a significant effect of time on ABG magnitude at all frequencies tested when comparing across the three assessment periods, with the exception of 10,000, 14,000 and 16,000 Hz. The direction of these changes is visible in the mean thresholds presented in Table 10. Figure 11 displays the changes in mean ABG measured across the three time points. Repeated measures ANOVA showed the following significant changes.

Table 9: Results of test of within subject effects when comparing air bone gaps across assessment periods.Note p <.05 = a significant effect of time for that frequency

Frequency (Hz)	*F ratio*	*df*	*p value*	η_p^2
500	9.62	1.34,36	<.05	.348
1000	4.11	2,36	<.05	.186
2000	5.47	2,36	<.05	.133
4000	4.27	2,36	<.05	.192
9000	3.55	2,36	<.05	.165
10,000	2.87	2,36	.07	.137
11,200	3.32	2,36	<.05	.156
12,500	3.99	1.304,23.48	<.05	.181
14,000	3.26	1.43,25.81	.05	.153
16,000	2.94	1.35,24.31	.066	.140

Table 10: Mean ABG across 3 assessment periods

*Mean [dB HL] ± SD [dB]) * - significant relative to pre op; † - significant relative to 1 week*

Frequency (Hz)	Pre op	1 week post op	1 month post op
500	32.6 ± 18.6	17.6 ± 15.6[a]	16.1 ± 14.7*
1000	31.6 ± 15.3	25.0 ± 18.9	21.1 ± 13.9*
2000	16.1 ± 15.5	18.7 ± 16.2	5.5 ± 10.1*†
4000	36.8 ± 20.8	36.1 ± 19.1	24.2 ± 13.4*†
9000	37.4 ± 12.6	42.4 ± 16.5	32.4 ± 17.1†
10,000	38.4 ± 11.4	41.6 ± 12.7	33.4 ± 12.7
11,200	33.4 ± 14.4	42.4 ± 12.3*	35.8 ± 11.6†
12,500	36.1 ± 11.0	43.9 ± 10.2*	39.5 ± 10.1†
14,000	31.8 ± 11.1	37.4 ± 8.2	36.6 ± 10.2
16,000	11.3 ± 16.6	18.7 ± 6.2	16.8 ± 4.8

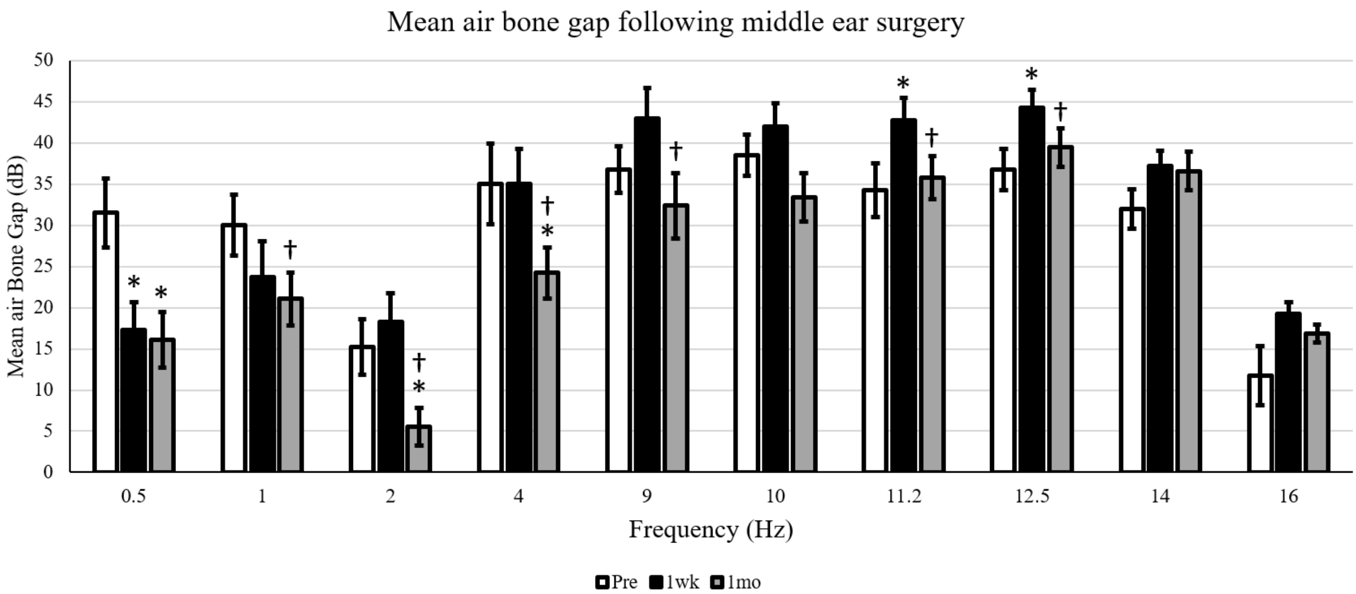

Figure 11: Mean air bone gaps following middle ear surgery : pre-op (white bars), 1 week (black bars) and 1 month (grey bars) post-op. Error bars = SEM, Repeated measures ANOVA results indicated by * - *p* <.05 relative to pre-op, † - *p* <.05 relative to 1 week post op

5.5.1 Air bone gap closure in the conventional frequency range

The air bone gap at 500 Hz was significantly reduced 1 week post-op. A significant reduction in the air bone gap was achieved in all the conventional frequencies by 1 month post-op when compared to pre-op values. Furthermore, 1 month post-op values were significantly reduced when compared to 1 week-post op air bone gaps.

5.5.2 Air bone gap changes in the extended high frequency range

The mean air bone gap was significantly elevated 1 week post-op compared to pre-op values at both 11,200 Hz and 12,500 Hz. This was followed by a significant decreased in air bone gap at 1 month follow up for both frequencies. However, mean 1 month air bone gaps were not significantly different compared to pre-op values.

5.6 Rates of post-operative SNHL – pooled data

Rates of post-operative SNHL were calculated by measuring the proportion of those who showed a 15 dB or greater deterioration in BC threshold at 4 kHz and beyond. Tables 11-17 display the rate of those of showed a significant loss, those who showed no change in threshold, and those who showed significant improvement.

Table 11: Rate of post-operative SNHL at 4 kHz for each assessment point

Time point	*> 15 dB Loss*	*> 15 dB gain*	*No change*
1 week post op	20%	15%	65%
1 month post op	0%	10%	90%
3 months post op	9%	18%	73%

Table 12: Rate of post-operative SNHL at 9 kHz for each assessment point

Time point	*> 15 dB Loss*	*> 15 dB gain*	*No change*
1 week post op	20%	0%	80%
1 month post op	20%	0%	80%
3 months post op	27%	0%	73%

Table 13: Rate of post-operative SNHL at 10 kHz for each assessment point

Time point	*> 15 dB Loss*	*> 15 dB gain*	*No change*
1 week post op	40%	0%	60%
1 month post op	40%	0%	60%
3 months post op	27%	0%	73%

Table 14: Rate of post-operative SNHL at 11.2 kHz for each assessment point

Time point	*> 15 dB Loss*	*> 15 dB gain*	*No change*
1 week post op	20%	10%	70%
1 month post op	20%	0%	80%
3 months post op	18%	0%	82%

Table 15: Rate of post-operative SNHL at 12.5 kHz for each assessment point

Time point	*> 15 dB Loss*	*> 15 dB gain*	*No change*
1 week post op	10%	0%	90%
1 month post op	5%	0%	95%
3 months post op	0%	0%	100%

Table 16: Rate of post-operative SNHL at 14 kHz for each assessment point

Time point	*> 15 dB Loss*	*> 15 dB gain*	*No change*
1 week post op	5%	0%	95%
1 month post op	10%	0%	90%
3 months post op	0%	0%	10%

Table 17: Rate of post-operative SNHL at 16 kHz for each assessment point

Time point	*> 15 dB Loss*	*> 15 dB gain*	*No change*
1 week post op	0%	5%	95%
1 month post op	0%	0%	10%
3 months post op	0%	0%	10%

5.7 Participants with ear specific information

Sufficient masking to the non-test ear in the EHF range up to 12.5 kHz was only achieved in 5 of the 11 participants.

2 showed EHF BC thresholds within normal limits prior to surgery and showed no changes as a result to surgery. Both individuals maintained a stable conductive loss up to the 3 month point.

The remaining 3 showed a significant deterioration in 9 and 10 kHz BC thresholds immediately post-surgery with a conductive overlay. The shift in BC thresholds remained stable to the 3 month assessment period while the conductive overlay closed from 9-11.2 kHz and remained at higher frequencies.

5.8 Results based on surgery type

Of the 20 participants, 10 underwent stapedotomy, 7 underwent mastoidectomy and 3 underwent ossiculoplasty. Table 18 summarises the number of participants at each assessment point broken down by surgery.

Interpretation of ossiculoplasty outcomes is limited due to a small pool of participants (*N* =3). Threshold shifts relative to pre-operative values are summarised from 1 week, 1 month and 3 months below in Table 19-24, where a positive value indicates an improvement in hearing and a negative value indicates hearing deterioration.

Table 18: Number of participants at each assessment point divided by surgery

Surgery type	**Pre**	**1 week**	**1 month**	**3 months**
Stapedotomy	**10**	**10**	**10**	**5**
Mastoidectomy	**7**	**7**	**6**	**5**
Ossiculoplasty	**3**	**3**	**3**	**1**

Table 19: AC Threshold shift (dB) at each frequency 1 wk post-ossiculoplasty surgery

	Frequency (Hz)													
Participant	*250*	*500*	*1000*	*2000*	*3000*	*4000*	*6000*	*8000*	*9000*	*10000*	*11200*	*12500*	*14000*	*16000*
1	-20	-20	-25	-50	-25	-30	-30	-40	-30	-25	-30	0	0	0
2	-15	-5	0	-10	-10	-5	-5	15	0	0	0	0	-5	-5
3	-15	-5	10	5	15	10	0	-20	5	5	0	-10	-20	5

Table 20: AC thresholds shift (dB) at each frequency 1 mo post-ossiculoplasty surgery

Participant	*250*	*500*	*1000*	*2000*	*3000*	*4000*	*6000*	*8000*	*9000*	*10000*	*11200*	*12500*	*14000*	*16000*
1	-15	-10	0	-10	5	-10	-10	-10	5	-5	-25	0	-5	5
2	-15	-5	-5	-10	-10	5	-5	10	0	0	-5	-5	-10	-15
3	-10	-5	5	0	5	10	-20	-20	-5	5	0	5	-5	0

Table 21: AC thresholds shift (dB) at each frequency 3 mo post-ossiculoplasty surgery

Participant	*250*	*500*	*1000*	*2000*	*3000*	*4000*	*6000*	*8000*	*9000*	*10000*	*11200*	*12500*	*14000*	*16000*
1						LOST	TO	F/U						
2	-15	-5	-5	-10	-10	5	0	10	-5	0	0	0	-5	-5
3						LOST	TO	F/U						

Table 22: BC threshold shift (dB) at each frequency 1 wk post-ossiculoplasty

	Frequency (Hz)									
Participant	500	1000	2000	4000	9000	10000	11200	12500	14000	16000
1	-5	0	-15	-5	5	10	20	10	0	0
2	-5	0	-10	5	-5	0	5	0	0	-10
3	5	5	10	0	-5	-20	-5	0	-20	-5

Table 23: BC thresholds shift (dB) at each frequency 1 mo post-ossiculoplasty surgery

	Frequency (Hz)									
Participant	500	1000	2000	4000	9000	10000	11200	12500	14000	16000
1	-5	0	-15	-5	5	10	20	10	0	0
2	-5	0	-10	5	-5	0	5	0	0	-10
3	5	5	10	0	-5	-20	-5	0	-20	-5

Table 24: BC thresholds shift (dB) at each frequency 3 mo post-ossiculoplasty surgery

	Frequency (Hz)									
Participant	*500*	*1000*	*2000*	*4000*	*9000*	*10000*	*11200*	*12500*	*14000*	*16000*
1				LOST	TO	F/U				
2	0	20	-5	10	-5	-5	-10	0	-10	5
3				LOST	TO	F/U				

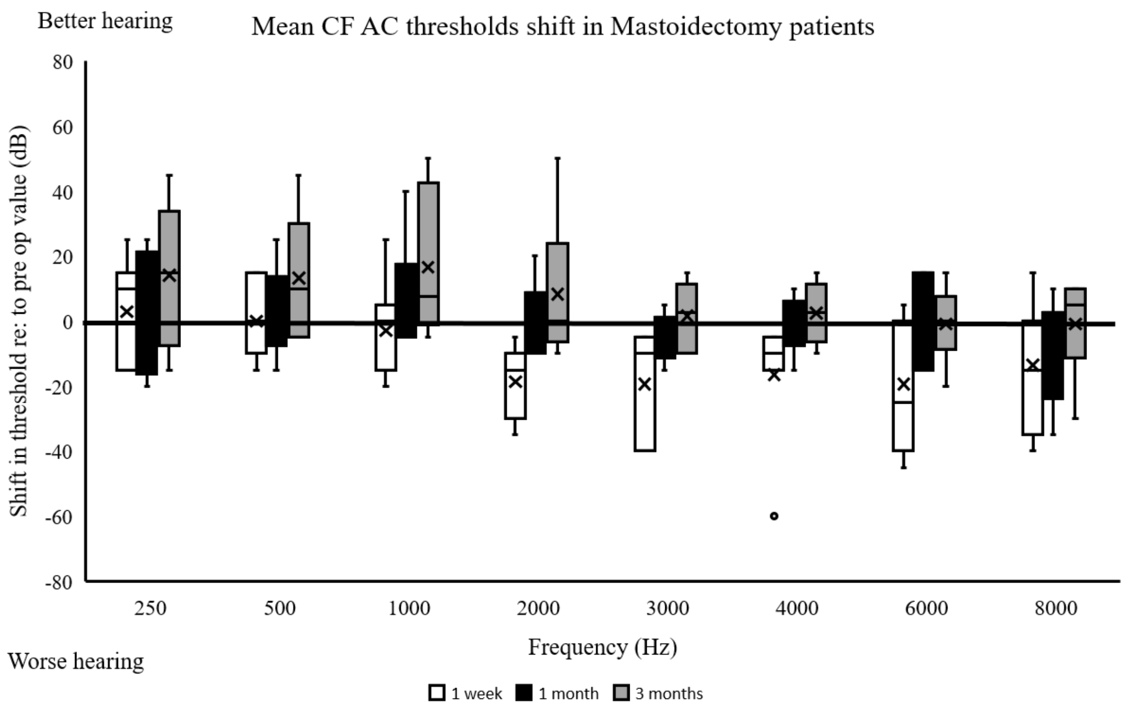

Figure 12: Box plots demonstrating mean shift in CF AC thresholds in Mastoidectomy patients1 week post-op *N* = 7, 1 month *N* = 6; 3 months *N* = 5

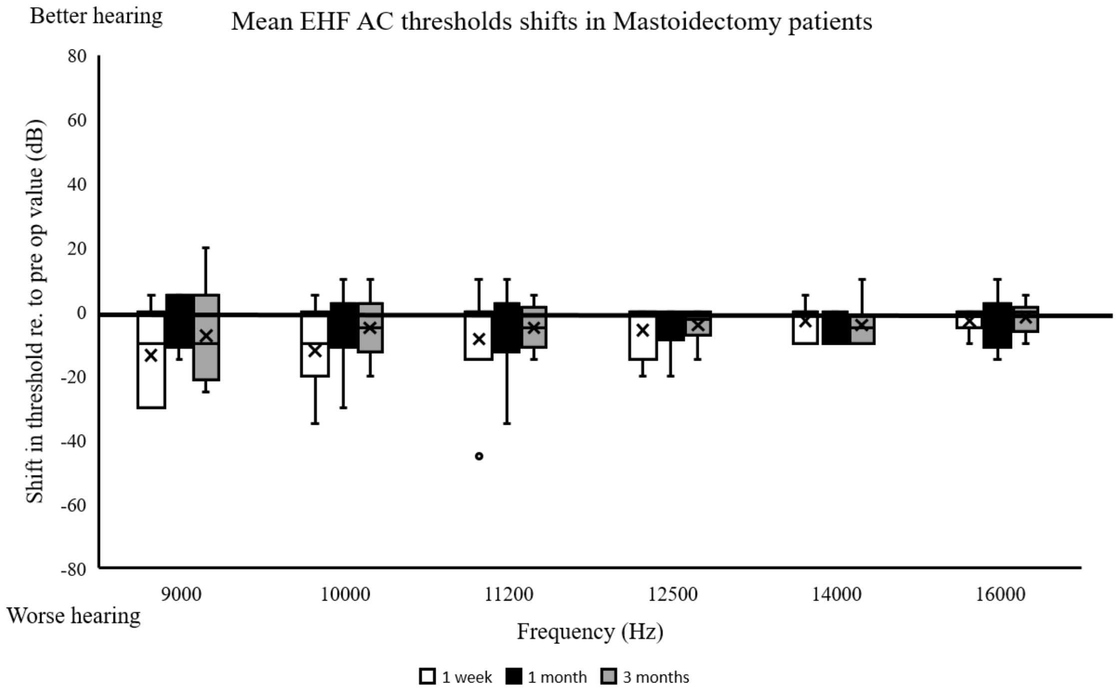

Figure 13: Box plots demonstrating mean shift in EHF AC thresholds in Mastoidectomy patients *N* = 7, 1 month *N* = 6; 3 months *N* = 5

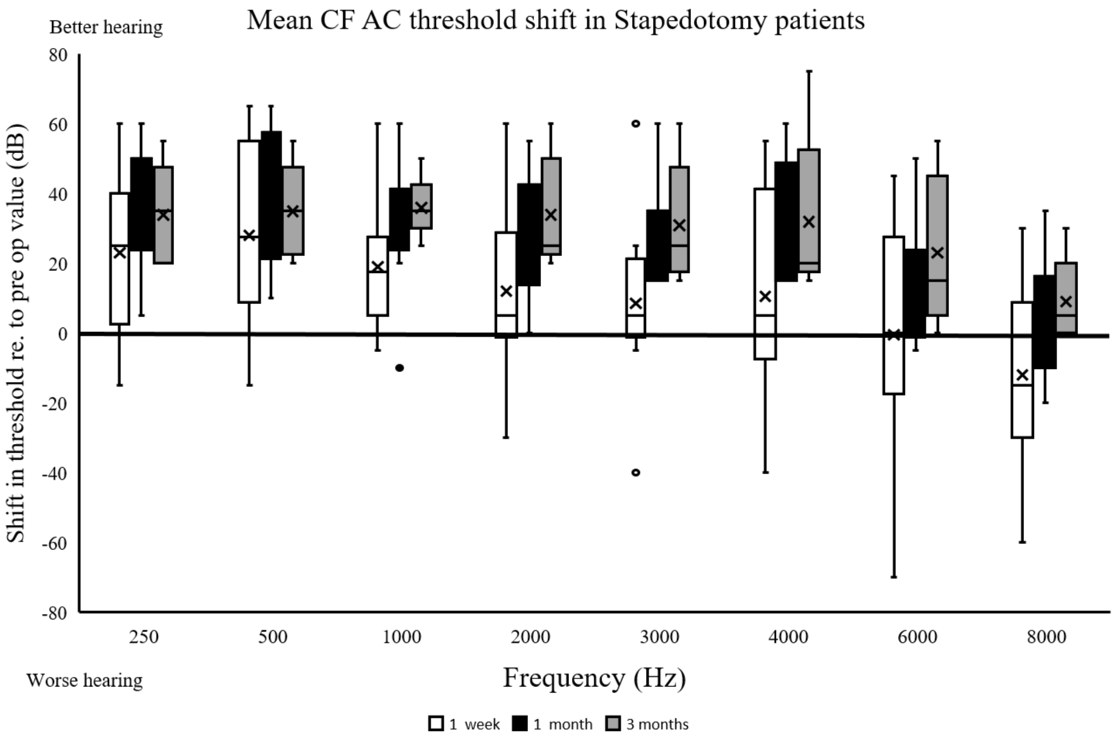

Figure 14 Box plots displaying mean shift in CF AC thresholds in Stapedotomy patients *N* = 10 at al time points

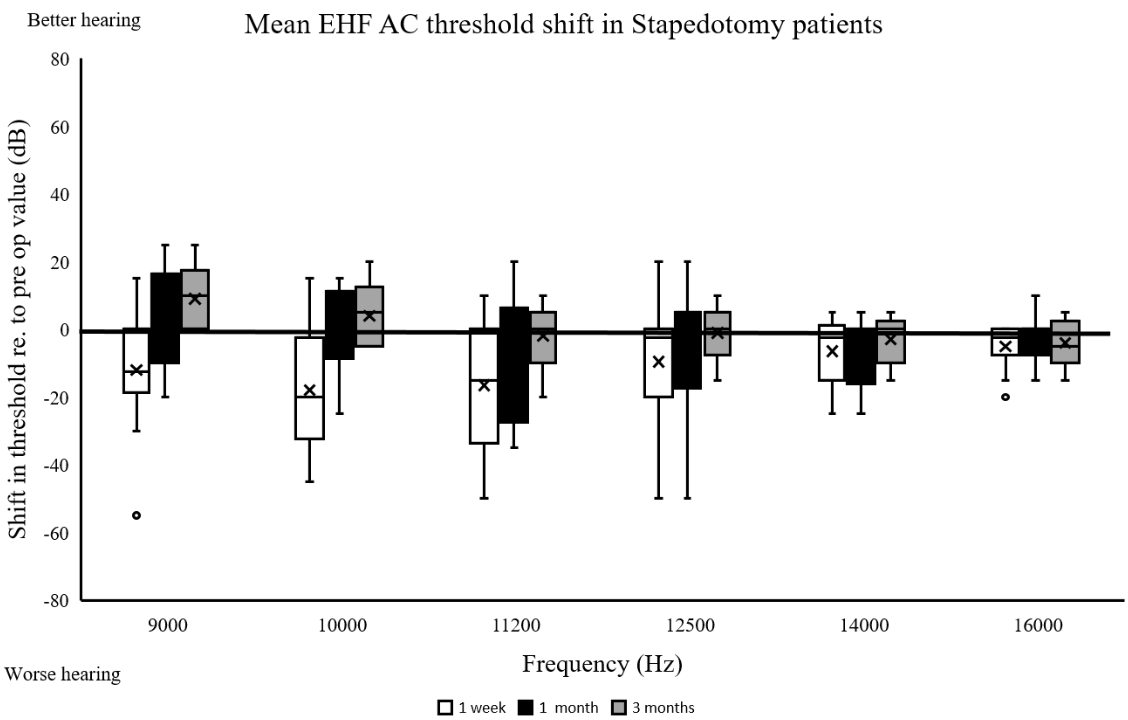

Figure 15 Box plots displaying mean shift in EHF AC thresholds in Stapedotomy patients. *N* = 10 at all time points

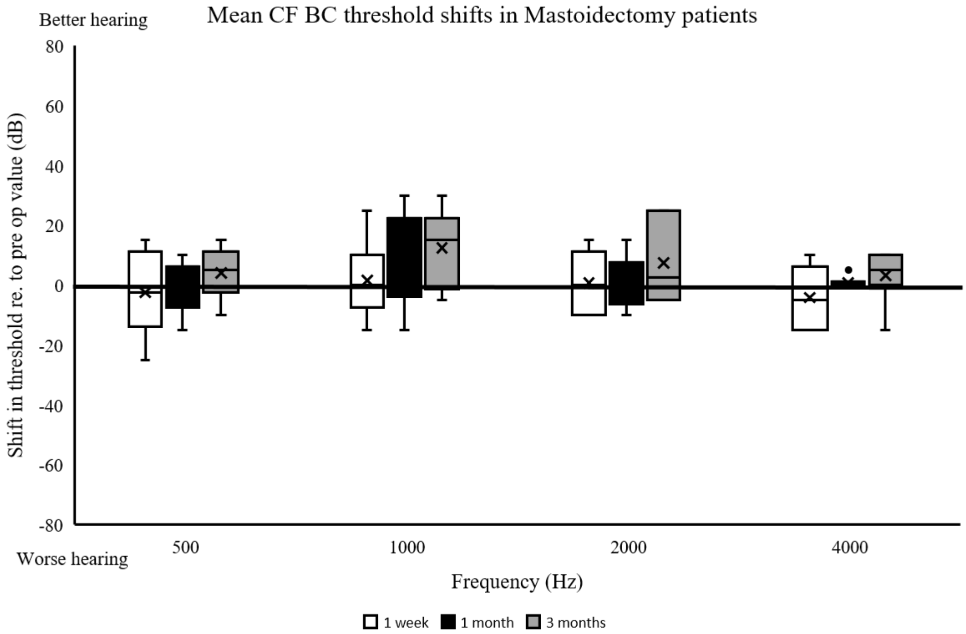

Figure 16: Box plots displaying mean shift in CF BC thresholds in mastoidectomy patients1 week *N* = 7; 1 month *N* = 6 and 3 months *N* = 5

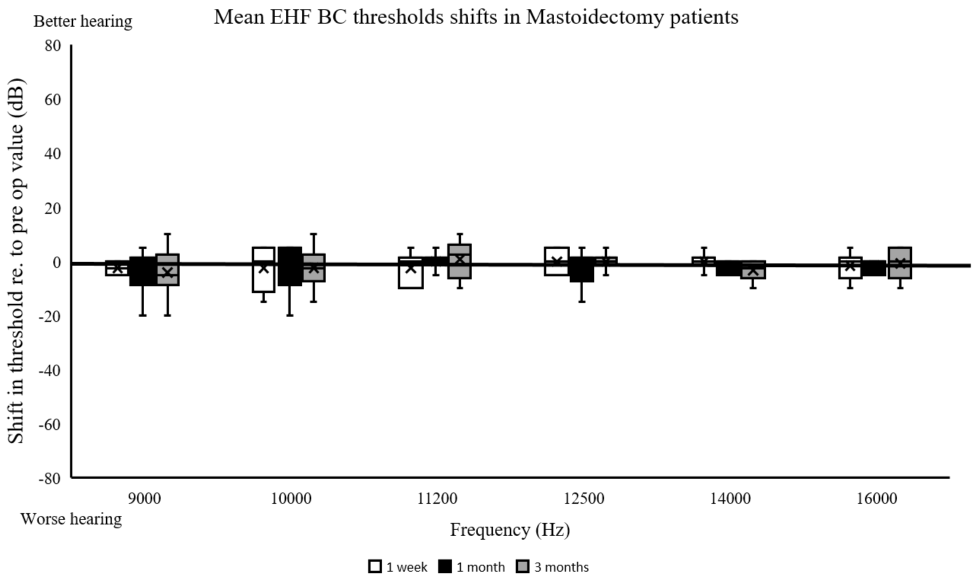

Figure 17: Box plots displaying mean shift in EHF BC thresholds in mastoidectomy patients *N* = 7; 1 month *N* = 6 and 3 months *N* = 5

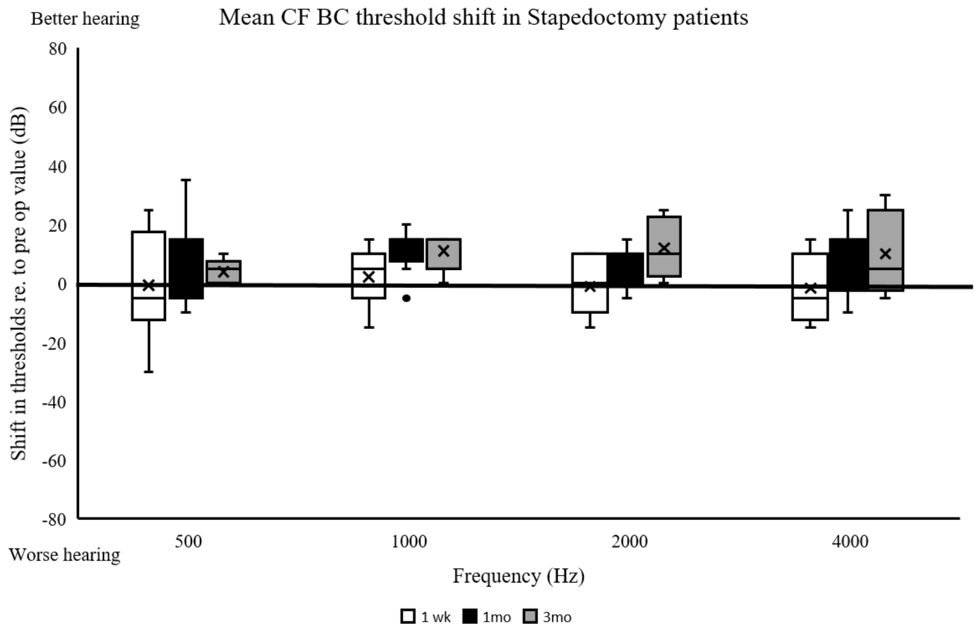

Figure 18: Box plots displaying mean shift in CF BC threshold in stapedotomy patients *N* = 10 at all time points

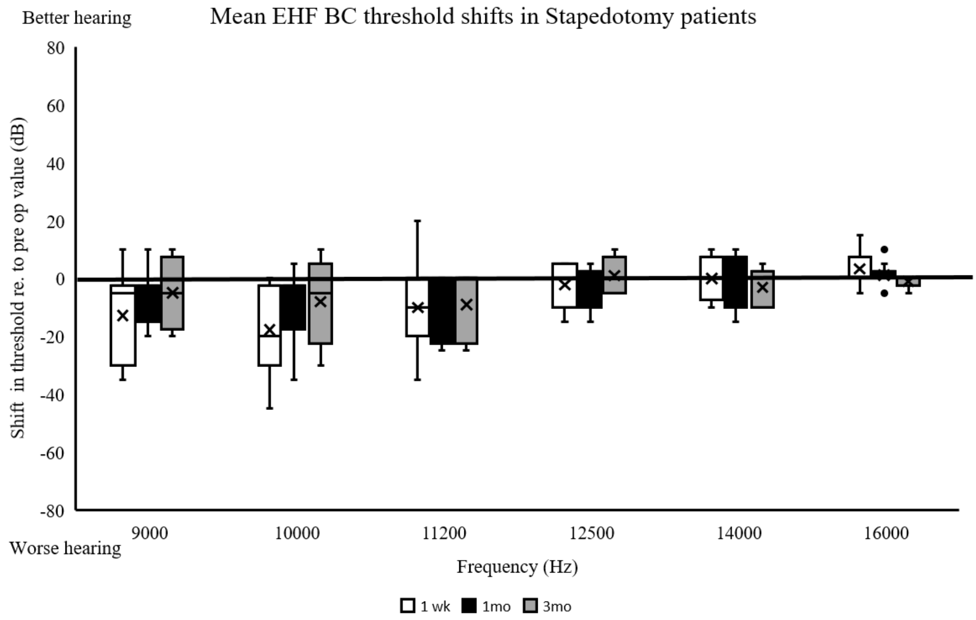

Figure 19: Box plots displaying mean shift in EHF BC threshold in stapedotomy patients *N* = 10 at all time points.

5.8.1 Shifts in air conduction thresholds

In both stapedotomy and mastoidectomy patients, AC threshold deteriorations are observed in the EHF range, especially following stapes surgery (Figures 13 and 15). The main difference between the two procedures are AC thresholds outcomes is in the CF range, where stapedotomy patients show a marked positive threshold shift (Figure 14) compared to mastoidectomy patients who show positive shifts up to 2 kHz but some deterioration beyond 3 kHz (Figure 12).

5.8.2 Shifts in bone conduction thresholds

When looking at BC shifts following stapedotomy and mastoidectomy, there is a small proportion of participants that result in a negative shift in CF thresholds immediately post-op. Almost all participants show an improvement in BC thresholds at later assessment points, remaining stable up to 3 months (Figures 16 and 18).

In the EHF, stapedotomy patients show a prominent negative shift particularly at 9 to 11.2 kHz (Figure 19). Whereas, BC thresholds shifts in the EHF are largely centred around 0 (no change) in mastoidectomy patients (Figure 17).

5.8.3 ABG changes

Stapedotomy patients show clear air bone gap closures in the conventional frequency range immediately post-op that remain stable up to 3 months (Figure 20). There are trends showing reduced air bone gap in the EHF range up to 11.2 kHz, however no changes are seen at higher frequencies. Mean air bone gaps show little change pre and post-surgery in patients undergoing mastoidectomy (Figure 20).

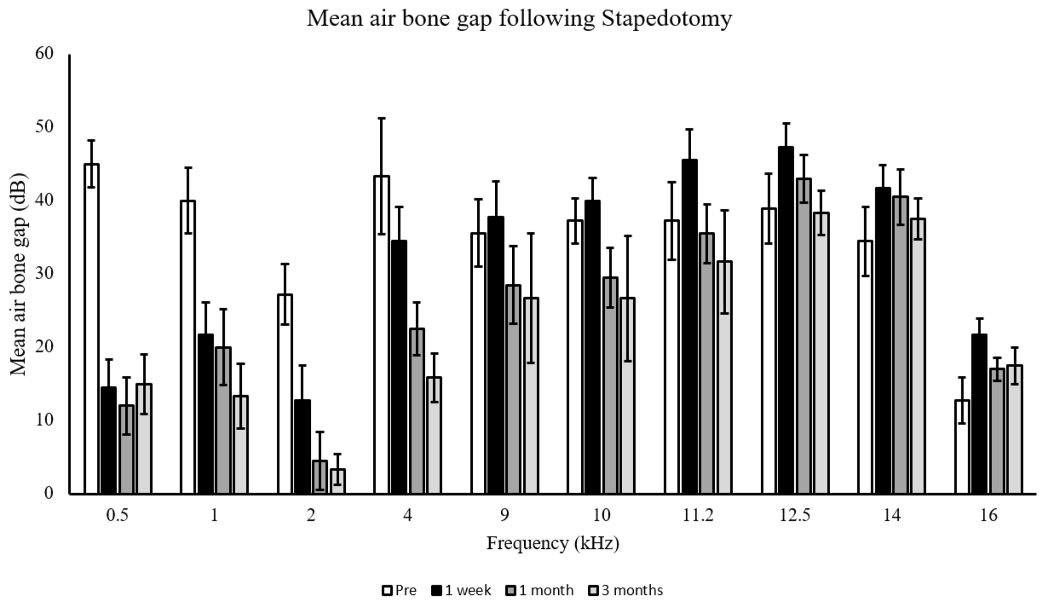

Figure 20: Bar graph displaying mean air bone gap across 4 assessment periods in stapedotomy patients *N* = 10 at all time points

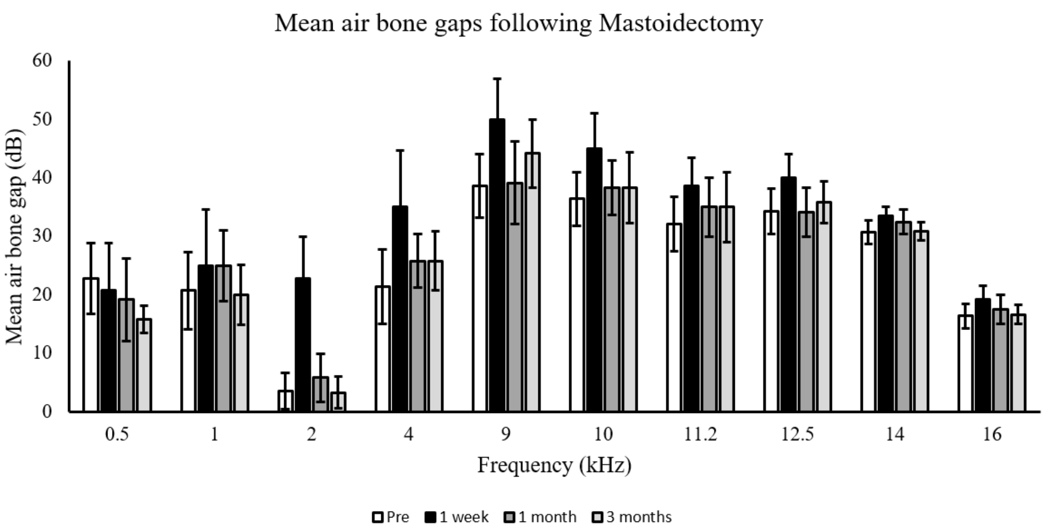

Figure 21: Bar graph displaying mean air bone gap across 4 assessment periods in masoidectomy patients Pre op *N* = 7, 1 week post-op *N* = 7, 1 month *N* = 6 and 3 months *N* = 5

5.9 Summary of results

Overall, there was an improvement seen in AC thresholds in the 250-1000 Hz range immediately post-surgery, and a general improvement in AC thresholds across the CF range at 1 month. These finding are in line with the first hypothesis that predicted air conduction thresholds in the CF range would improve over successive assessment periods.

AC thresholds in this range generally showed a deterioration after 1 week, which recovers at the 1 month post-op period. These results are in line with our second hypothesis: air conduction thresholds in the EHF range would deteriorate immediately following surgery with some recovery at later assessments.

When observing changes in the highest measurable frequency, a large proportion demonstrated a loss 1 week post-op. This number decreased at the 1 month stage. This was in line with our third hypothesis, however the proportion of loss increased again at the 3 month assessment period.

Bone conduction thresholds in the high frequency range showed deterioration, particularly at 9 and 10 kHz. Which was predicted by our fourth hypothesis.

The fifth hypothesis predicted air bone gaps would be greater immediately following surgery. This was demonstrated in the EHF range, particularly at 11.2 and 12.5 kHz. This did not hold true in the conventional frequency range.

1 month data shows that air bone gaps were significantly reduced in the conventional frequency range when compared to pre-op values. This matches our sixth hypothesis. However, these effects were not seen in the EHF range.

Statistical analysis was not performed in surgery specific data due to limited numbers, especially in ossiculoplasty patients (N = 3). Positive AC CF outcomes were seen in both stapedotomy and mastoidectomy patients. Both of these procedures showed EHF AC deterioration in line with pooled data. Stapedotomy showed notable deteriorations in EHF BC thresholds particularly at 9 to 11.2 kHz.

Chapter 6: Discussion

Hearing loss in the EHF range following middle ear surgery has been documented since the 1980s (Domenech & Carulla, 1988; Mair & Laukli, 1986) . Studies have successfully observed long term changes in AC thresholds in patients undergoing middle ear surgery; although this information alone is not sufficient to characterise the nature of insult. Early studies used a variety of tools to measure cochlear function in the EHF range and report transient sensorineural loss (Doménech et al., 1989; Økstad et al., 1988). But these studies are largely limited by a lack of ear-specific information regarding cochlear function. Pilot studies by Babbage (2015) and Howey (2019) used a system that could deliver sufficient BC output in the EHF range and some degree of EHF NBN masking to the NTE to characterise changes in EHF BC thresholds following surgery. Both studies were limited to 4 participants, and report a mix of post-operative conductive and SNHL.

The current study aimed to validate these findings in a larger number of participants. It was hypothesised that conventional frequency AC thresholds will improve over successive assessment periods. In addition, it was predicted that AC and BC EHF thresholds will deteriorate immediately post-surgery with some participants showing recovery at later stages.

Audiometric testing was performed using a similar system to Babbage (2015) and Howey (2010) with some alterations made. These alterations described in Appendix C streamlined the system so that EHF bone conduction audiometry was conducted only from the custom laptop, rather than a combination of BC stimuli presented through custom audiometer and AC stimuli presented through the GSI61 diagnostic audiometer. Furthermore, the aging MOTU multi-channel external soundcard used in previous studies was replaced with an X-FI soundcard to future proof the system. Two trials measuring EHF BC thresholds using the new X-FI sound card set-up matched those measured by the Howey (2019) study, ensuring the current set up was calibrated to match the output of the previously calibrated system.

The study initially aimed to monitor changes over a 3 month assessment period. 20 participants were assessed up to 1 month post-op. However, data for the 3 month time point was still under collection during the submission of this thesis. At that stage there was a small 3 month sample size (N = 11) and a decision was made to exclude these data from statistical analyses due to the inability to draw meaningful conclusions from those data. Therefore, mean AC and BC thresholds and ABG are only reported up to 1 month. 3 month data was included for some tables and figures and should be regarded as preliminary findings.

Results were grouped in several ways. The main set of results pooled all surgery types together to provide adequate numbers for statistical analysis. Outcomes in five participants who were sufficiently masked in the EHF were also reported. Finally, results were split into the three main surgery types encountered during the study: ossiculoplasty, stapedotomy and mastoidectomy. Albeit, with a small sample size, no statistical analysis could be conducted when split into surgical groups.

6.1 Patterns of hearing threshold changes following middle ear surgery – pooled data

6.1.1 AC conventional frequencies

In line with the first hypothesis, changes in the conventional frequency range show an overall improvement in hearing (Figure 9), demonstrating a similar pattern of change compared to previous works (Harder et al., 1982; Persson et al., 1997; Salmon et al., 2015). It is typically reported that AC thresholds are generally poorer in the immediate time frame following middle ear surgery (Sergi et al., 2004; Sperling, Sury, Gordon, & Cox, 2013). This is likely due to the presence of packing, blood and residual inflammation (Cho et al., 2007). However, about a 10 dB improvement was evident at the 1 week post-op period at 250 and 500 Hz. Mean thresholds for the remaining frequencies in the conventional range showed no clinically significant change 1 week post-op compared to pre-op values. Following this, 15-20 dB improvements were seen at all frequencies up to 4 kHz at the 1 month post-op period when compared to pre-op values. Mean thresholds showed no significant change at 6 kHz after 1 month post-op. Despite the positive mean shift immediately post-op, box plots in Figure 9, are more in-line with findings by Sergi et al. (2004) and Sperling et al. (2013). This was evident at frequencies beyond 2 kHz where a sizeable a proportion of participants showed a deterioration immediately post-surgery, particularly at 8 kHz. Furthermore, the proportions of those with a loss in the CF range greatly reduce over time to the 3 month point (Figure 9), likely due to the resolution of inflammation.

6.1.2 AC extended high frequencies

Few studies have investigated changes in AC thresholds in the EHF range following middle ear surgery. Deterioration in EHF AC thresholds has been demonstrated following myringoplasty and stapedectomy particularly in the 12-16 kHz region (Mair et al., 1986) and in mastoidectomy patients at 10 and 14 kHz (Verbist et al., 1993). These studies do not report the time point at which these changes were measured and were limited by small sample size (N= 36 and 20 respectively). A more recent study by Babbage et al. (2017) focused on 39 stapedectomy patients, reporting a high frequency hearing loss from 9 to 11.2 kHz.

Results from the current study show a 10-15 dB deterioration in AC thresholds at 9 to 12.5 kHz 1 week following middle ear surgery. 16 kHz showed a statistically significant deterioration of about 4 dB, however this is within test-retest reliability and would not be deemed clinically significant. Each of these frequencies showed recovery at the 1 month post-op assessment as they were not statistically or clinically different to pre-op threshold values.

6.2 Changes in highest measurable frequency – pooled data

The highest measurable frequency is the highest frequency at which the participant's thresholds was within the limits of the audiometer. Changes in the highest measurable frequency is an outcome measure reported by Babbage et al. (2017) who both report loss in the highest measurable frequency in more than of 70% participants in early post-op assessments. This proportion decreases to 50% at later assessment points (3-12 months). The current study is in agreement with these figures as summarised on Table 6. However the 3 month point shows an increase back up to 73%, however this data is limited by a small sample size (N = 11).

6.3 BC threshold changes in the conventional frequency range – pooled data

Bergin (2015) reported post-operative SNHL at 4 kHz can occur in up to 25% of patients undergoing middle ear surgery. A significant SNHL has been defined as a deterioration anywhere between 15 to 30 dB. The current study showed no significant change in mean 4 kHz bone conduction thresholds when compared to pre-op values. Though when looking at rates of significant SNHL (15 dB or greater loss), 20% had a loss immediately post-op, with numbers reducing at later assessment points (Table 11). Interestingly, there was an improvement in 1 and 2 kHz BC thresholds observed at the 1 month time point. However the improvements were <10 dB which would not be deemed clinically significant. BC thresholds at the remaining conventional frequencies stayed stable through the 1 month time course.

6.3.1 EHF BC changes

The ability to measure BC thresholds in the EHF range remains problematic, particularly in a population with bilateral conductive hearing loss. The primary reason being limitations in the output of both BC and NBN masking stimuli in the EHF range (discussed in detail in section 3.5).

Sufficient masking to the non-test ear in the EHF range up to 12.5 kHz was only achieved in 5 of the 11 participants. Of these participants, 2 showed EHF BC thresholds within normal limits prior to surgery and showed no changes as a result to surgery. However they both maintained a stable conductive loss up to the 3 month point. The remaining 3 showed a significant deterioration in 9 and 10 kHz BC thresholds immediately post-surgery with a conductive overlay. The shift in BC thresholds remained stable to the 3 month assessment period while the conductive overlay closed from 9-11.2 kHz and remained at higher frequencies. These findings are in line with the pilot study by Babbage (2015), who found the 9 to 11.2 kHz range showed the greatest deterioration in BC thresholds.

When looking at the pooled data analysed to 1 month post-op, a large proportion lack ear specific information. This limitation leads to a number of considerations when interpreting this data. One possibility is that for some individuals, the interaural attenuation is greater due to skull variability and sufficient masking was actually achieved. However, it is also likely that some thresholds obtained are contributions from the non-test ear. Nevertheless, deteriorations are seen in mean BC thresholds at 9 and 10 kHz at both 1 week and 1 month post-op points. However the only clinically significant change (>10 dB) was an 11 dB increase at 1 week for 10 kHz. Despite this, when looking at mean shifts (Figure 10), a sizeable proportion of participants (75th percentile) show up to a 30 dB deterioration in BC thresholds at 10 kHz, and this persists to the 3 month assessment point. Similar trends are seen at 9 kHz, with a maximum loss of about 20 dB. When looking at the rate of significant SNHL at each frequency, 10 kHz showed the highest rate of loss with 40% immediately post-op and 1 month with 27% remaining at 3 months. Both 9 and 11.2 kHz showed rates of about 20% across all time points.

With insufficient masking we cannot confidently report the true degree of loss and site of lesion. One could suspect that a greater deterioration was seen in a proportion of these participants however the loss was underestimated due to contributions of the non-test ear. There may be a chance that these deteriorations are actually bilateral. Until a greater masker output can be achieved to sufficiently mask, these conclusions cannot be made.

6.4 Changes in the air bone gap - pooled data

Air bone gap closure is another outcome measure commonly reported for middle ear surgeries. In the conventional frequency range (500 Hz, 1, 2 and 4 kHz), the air bone gap at 500 Hz shows significant improvement 1 week post-op, and remained stable at 1 month. Air-bone gaps at 1,2 and 4 kHz showed no change 1 week post op. In line with our hypothesis, conventional range ABG significant improvement 1 month post-op, all showing closures of about 10-15 dB.

When looking at ABG changes in the EHF range, there was a significant increase in the air-bone gap at 11.2 and 12.5 kHz, 1 week following surgery of just less than 10 dB. Mean air-bone gap at following time points showed a significant improvement in air-bone gap but were not significantly different to pre-operative values.

Again, caution must be taken when interpreting these results as not all bone conduction thresholds were adequately masked and many air conduction thresholds were beyond the limits of the audiometer. Therefore, it is possible that BC thresholds may be poorer than recorded, and changes in AC thresholds beyond the limits of the audiometer are not detected. Both of these possibilities can largely affect the air-bone gap.

6.5 Surgery specific information

Although small sample sizes limits statistical analysis, some interesting trends are seen when breaking up results by surgery type. Only 3 ossiculoplasty patients were included in the study, limiting any conclusions made. However when comparing stapedotomy and mastoidectomy surgeries, both procedures showed positive outcomes in mean post-op AC threshold shifts (Figure 12 and 14). As seen in pooled data, when looking at these surgeries in isolation, improved BC thresholds shifts were seen in the CF range (Figure 16 and 18). Conversely, both procedures lead to a negative shift in EHF BC thresholds, consistent with pooled data. However, Figure 19 demonstrates that this is more pronounced in stapedotomy procedures compared to mastoidectomy (Figure 18). It is unknown why stapes surgeries cause more EHF loss, but it does involve opening into the middle ear. This may initiate inflammation or may cause overstimulation of the cochlear compared to other surgeries: tympanoplasty, ossiculoplasty or mastoidectomy. Grafting the TM would seem very low risk. Ossicular manipulation poses potential risk but the inner ear is very tolerant to low frequency stimulation, which is usually the case with ossicular surgery. Mastoidectomy showed poorer results compared to stapes surgery and one must consider that it introduces drill noise and the possibility of direct contact with the ossicles if the chain is intact. Again, these data are limited by sample size and suggestions to build on this are discussed in following sections.

6.6 Clinical implications

Described in section 2.2, the peripheral auditory system, especially the middle ear, amplifies incoming sound signals in order to match the impedance of the air and the inner ear fluids. While middle ear surgery is adequate to restore this conductive mechanism for sounds in the CF range, it is unclear how surgery affects the transmission of EHF sound stimuli. In addition, the contributions of a healthy middle ear system towards the perception of bone conduction stimuli in the EHF range, let alone those of a middle ear system altered by surgery, are not well understood (section 2.5.2.1). BC thresholds are typically seen as reflection of cochlear function. However, as seen in pathologies such as third window disorders, BC thresholds can be altered by other factors not related organ of Corti function. It may be that alterations in the middle ear space as a result of middle ear surgery results in a positive effect on BC thresholds in the CF range, and a negative effect on BC thresholds in the EHF range; without affecting the integrity of the organ of Corti. It is also possible that these procedures do cause EHF inner ear trauma. Determining this will help clinicians, particularly surgeons, make decisions regarding surgical techniques. This is important as a wide range of surgical techniques (described in section 3.1.2) are available, and their effects on the EHF range are not well researched. The current system has the potential to provide insight into these areas if some limitations are addressed.

6.7 Study limitations

It is important to note that many of the AC thresholds measured were noted at the limits of the audiometer. The output is especially limited in the 11.2 to 16 kHz range. Therefore, the degree of loss is likely to be underestimated in many cases. Furthermore, any changes in threshold beyond these limits will be undetectable. Indeed, minimal changes were detected at 16 kHz. One possibility is that these surgeries do not impact the highest frequencies as greatly as the 9-11.2 kHz range. However, the anatomical location of these frequency regions are more prone to damage. It is more likely that threshold changes as a result of surgical trauma were not detected due to output limitations. Until a greater output is achieved, this will remain the primary challenge for EHF pure tone audiometry. To attempt to address this, changes in the highest measurable frequency were recorded. While this is not a true reflection of threshold changes; it provides clinicians with a useful outcome measure to detect and changes resulting from surgery and has been used in previous literature (Babbage et al., 2017; Bagger-Sjöbäck et al., 2015; Domenech & Carulla, 1988; Hegewald et al., 1989).

The current study used a system described in Appendix C which had the ability to produce NBN masking noise in the EHF range. The limits of the masking output are summarised below in Table 18.

Table 25: Maximum masker output capability of current custom audiometer at each EHF frequency

Frequency (kHz)	*9*	*10*	*11.2*	*12.5*	*14*	*16*
Maximum masker output (dB HL)	65	65	65	60	60	35

These output limits underlie the fundamental challenge faced when attempting to measure ear specific bone conduction thresholds in this frequency range. To achieve a 20 dB plateau during masking protocol (as described in section 2.7.7), the non-test ear would require a maximum of a 45 dB HL threshold from 9-11.2 kHz, a 40 dB HL threshold at 12.5 and 14 kHz and a mere 15 dB HL threshold at 16 kHz; assuming that there will be no shift in test ear threshold while gaining a plateau. This is problematic when testing patients undergoing middle ear surgery for a number of reasons. The first is that a majority of the conductive hearing losses treated by middle ear surgery (section 3.1.1) are bilateral. Therefore the non-test ear typically has elevated thresholds. Moreover, high frequencies are first affected by age-related hearing loss and other environmental factors. Valiente et al. (2014) reports evidence of decreasing EHF thresholds beginning from the age of 20.

So it is important to consider that the participants in the current study had a mean age of 49 and are likely to have age related elevated thresholds as well as a conductive overlay. Indeed, when we retrospectively examined the pre-operative audiograms of 88 participants in the Babbage (2015) study, we calculated that the current system would not provide sufficient masking in the entire EHF in 35% of participants. This figure varied between surgery types, where 66% of mastoidectomy patients would be unmaskable, followed by 40% of ossiculoplasty patients, and 28% of stapes surgery and tympanoplasty patients.

While the current study expands on the number of participants tested in the Babbage (2017) and Howey (2019) studies, it lacks in numbers compared to other similar studies. Statistical analysis was not conducted on 3 month data as a consequence of a small sample size. The pool of potential participants was limited to the surgical list of only one otolaryngologist. As with any clinical research, loss to follow-up was a major issue. This was in part due to the large geographical area which the hospital covered, requiring some patient's significant travel to reach appointments. In addition, many candidates undergoing middle ear surgery did not have measurable thresholds in the EHF range and were therefore unsuitable candidates for the study.

6.7 Future considerations

Despite the limitations described, this study provides novel information regarding post-operative hearing loss affecting EHF BC thresholds, mostly affecting 9 and 10 kHz. This was seen when looking at i) individuals with ear specific information, and ii) the entire participant group, some of whom were not masked sufficiently.

To consolidate these findings, a larger pool of participants is required. A larger sample size will provide the opportunity to statistically analyse changes in thresholds based on specific surgery types. This is important as there is limited understanding on how various middle ear surgeries uniquely affect middle ear transmission and inner ear function. A larger sample size can be achieved in a number of ways. The first would be to recruit more participants who have appropriate NTE thresholds that will allow EHF BC thresholds. A multi-centre study may achieve higher numbers at a reasonable rate. A more effective solution to increase the number of participants who are able to give ear specific bone conduction thresholds is to increase the output of the high frequency bone conductor and the NBN masking noise. This would allow clinicians and researchers to obtain ear-specific BC thresholds in more patients with significant bilateral conductive hearing loss. Solving this would also open up opportunities for use outside pure tone audiometry such as the monitoring of EHF auditory function using electrophysiological techniques.

Conclusions

In line with previous works, this study demonstrates a deterioration in EHF hearing following middle ear surgery. We present novel and convincing evidence of a negative shift in EHF BC thresholds that remains stable up to 3 months, particularly at 9 to 11.2 kHz. We also report that almost all patients who underwent middle ear surgery resulted in either a CHL or mixed hearing loss in the EHF range. This suggests that cochlear insult occurs as a result of surgery, as well as a lasting disruption in middle ear sound transmission. As suggested by earlier studies, stapes surgeries were demonstrated to result in the greatest EHG loss. These preliminary findings can be consolidated by improving the dynamic range of EHF audiometers and transducers. By doing so, EHF has the potential to be used as a sensitive measure of cochlear function following medical and surgical interventions regarding middle and inner ear pathologies.

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Appendix

Appendix A Participant Information Sheet

School of Psychology, Speech and Hearing
Email: david.timajo@pg.canterbury.ac.nz
16.05.19

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

Changes in Extended High Frequency Hearing Impairment Following Middle Ear Surgery

Information Sheet

My name is David Timajo and I am the primary researcher in a study designed to assess the effect of middle ear surgery on hearing levels in the high-frequency range. Your participation in this study is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part you will receive the standard treatment/care available.

Ear surgery is performed for different reasons but a common reason is to improve hearing. Hearing often improves at the hearing frequencies (pitches) that are tested during a standard hearing test. However, there may be decreases in hearing in the higher frequencies that are not usually tested. This can be due to very subtle trauma to the inner ear during surgery. The inner ear (cochlea) is a very delicate hearing organ and it is possible that it is affected by some surgical trauma, such as vibration from equipment and inflammation during the healing process. When the cochlea is damaged, hearing is generally more easily affected in the higher frequencies. These frequencies are above the frequency levels that we usually test, but the audiology department is able to test these frequencies with special equipment.

Our department is very interested in studying the effect of middle ear surgery on all frequencies of hearing (those that are typically measured and the high frequencies that are not commonly measured). This will give us good information into whether the cochlea is affected after middle ear surgery and also help us plan future treatment to minimize the effect of surgery on the ear.

If you choose to take part in this study, your participation in this project will involve having an extra hearing test (ten minutes) in addition to the standard hearing test that you will be having anyway. This extra hearing test will involve pressing a button in response to ultra-high pitch tones that you hear first through headphones that are placed on your ears, and then through a special device that sits on your forehead and gently vibrates the bone. Data will be recorded by the researcher onto an audiogram sheet, and it is anticipated that testing will take one hour in total.

As a follow-up to this investigation, you will be asked to repeat these hearing tests at your post-operative visits, when you would be having a hearing test anyway. The study will not impact your surgery success in any way, nor will it affect healing.

In the performance of the tasks and application of the procedures there is a risk that a change in your hearing may be detected, in which case these results will be discussed with you and you will be invited to make an appointment at the University of Canterbury Speech and Hearing Clinic for a free diagnostic hearing assessment and consultation at your convenience.

Participation is voluntary and you have the right to withdraw at any stage without penalty or effect on your care after surgery. You may ask for your raw data to be returned to you or destroyed at any point. If you withdraw, I will remove information relating to you. However, once analysis of raw data starts within one month after testing commences, it will become increasingly difficult to remove the influence of your data on the results.

The results of the project may be published, but you may be assured of the complete confidentiality of data gathered in this investigation: your identity will not be made public without your prior consent. To ensure anonymity and confidentiality, no identifiable information will be used in any reports throughout this study, and only the research team will have access to the information you provide. All data collected will be kept in locked and secure facilities and in password protected electronic form, and will be destroyed after five years. A thesis is a public document and will be available through the UC Library.

Please indicate to the researcher on the consent form if you would like to receive a copy of the summary of results of the project.

The project is being carried out as a requirement for a Master of Audiology degree by David Timajo under the supervision of Professor Greg O'Beirne, Dr Melissa Babbage and Mr Philip Bird, who can be contacted at gregory.obeirne@canterbury.ac.nz, melissa.b@dilworth.co.nz and phil.bird@chchorl.co.nz, respectively. They will be pleased to discuss any concerns you may have about participation in the project.

If you have any questions or would like anything to be explained to you in further detail, please do not hesitate to contact the research team. If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate: Free phone: 0800 555 050

Free fax: 0800 2 SUPPORT (0800 2787 7678) Email: advocacy@hdc.org.nz

This project has been reviewed and approved by the University of Canterbury Human Ethics Committee, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

If you agree to participate in the study, you are asked to please complete the consent form and return it to the researcher, either in person or by sending the consent form to david.timajo@pg.canterbury.ac.nz.

With thanks,

David Timajo 2nd year MAud Student

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Email: david.timajo@pg.canterbury.ac.nz
Phone: 027 634 0637

Greg O'Beirne, PhD

Primary research supervisor & Professor in Audiology
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Phone: +6433694313

Appendix B Consent Form

School of Psychology, Speech and Hearing
Email:
david.timajo@pg.canterbury.ac.nz
16/05/19

UC UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

Changes in Extended High Frequency Hearing Impairment Following Middle Ear Surgery

Consent Form

- ☐ I have been given a full explanation of this project and have had the opportunity to ask questions.
- ☐ I understand what is required of me if I agree to take part in the research.
- ☐ I understand that participation is voluntary and I may withdraw at any time without penalty. Withdrawal of participation will also include the withdrawal of any information I have provided should this remain practically achievable.
- ☐ I understand that any information or opinions I provide will be kept confidential to the researcher and that any published or reported results will not identify the participants. I understand that a thesis is a public document and will be available through the UC Library.
- ☐ I understand that all data collected for the study will be kept in locked and secure facilities and/or in password protected electronic form and will be destroyed after ten years.
- ☐ I understand the risks associated with taking part and how they will be managed.
- ☐ I understand that I can contact the researcher David Timajo by sending an email to david.timajo@pg.canterbury.ac.nz or supervisors Associate Professor Gregory O'Beirne, Dr Melissa Babbage and Mr Philip Bird by emailing gregory.obeirne@canterbury.ac.nz, melissa.b@dilworth.co.nz or phil.bird@chchorl.co.nz for further information. If I have any complaints, I can contact the Chair of the University of Canterbury Human Ethics Committee, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz)
- ☐ I would like a summary of the results of the project.
- ☐ By signing below, I agree to participate in this research project.

Name:________________________________Signed:______________________________
Date:_________________________________Email address:________________________

Please return the completed consent form back to David Timajo, either in person or by sending it to the researcher at david.timajo@pg.canterbury.ac.nz.

Thank you for your assistance

Appendix C - Custom laptop set up

This section describes steps taken to streamline the EHF PTA set up used by the Babbage (2015) and Howey (2019) studies in order to minimise the limitations mentioned in section 3.5.

Testing was performed in a sound treated booth meeting International Organization for Standardization [ISO] 8253-1 (2010) in the University of Canterbury School of Psychology, Speech and Hearing research lab.

Modified TEAC HPF100 bone conductor

TEAC HP-F100 Filltune HiFi bone conducting headphones are a previously commercially available product designed for consumers to listen to music, providing stimulation bilaterally. These headphones produce adequate vibratory output for testing in the EHF range (Popelka et al., 2010). The headphones consist of two magnetostrictive bone conduction transducers separated by a plastic headband. As outlined in (Babbage, 2015), the large convex shape of each transducer poses a number of challenged. First, it cannot be calibrated using a standard artificial mastoid due to differences in the contact surface area (4.15cm^3 [TEAC] vs. 1.75cm^3 [Radioear B-71]) and convex shape of the TEAC HP-F100 versus the flat shape of the Radioear B-71. Second, the convex shape of the TEAC transducer may result in increased difficulty in accurate placing of the transducer in the correct position, leading to unreliable threshold measurements during testing. Third, the coupling force controlled by the plastic headband differs to that of the B-71 headband.

With these constraints in mind, TEAC HP-F100 was modified to ensure it is suitable for reliable audiometric threshold measurements. As outlined in (Popelka et al., 2010), the TEAC transducer was connected to a Radioear P-3333 headband, which is a chrome plated sprung steel used with the B-71 transducer, designed to ensure stimulation is delivered at a force of approximately 5.4 N. To mount the TEAC transducer to the P-3333 headband, the steel yoke was removed and a 6 cm long steel bracket originally attached to the TEAC transducer was attached directly to the curved steel of the P-3333 headband. This was attached using three brass screws. To ensure the angle at which the contact surface of the transducer met the skull, a 12 mm brass screw was inserted through the plastic casing at the top of the transducer resting against the steel bracket.

Changing soundcard

Pilot studies by Babbage (2015) and Howey (2019) that were conducted using the modified TEAC bone vibrator transducer presented stimuli using a computer based custom audiometer software, written by the supervisor using LabVIEW (National Instruments, Austin, TX). The stimuli were presented through a MOTU UltraLite mk3 multi-channel external sound card (MOTU, Cambridge, MA) that was connected to a laptop via USB. The same study presented masking noise simultaneously through a G61 diagnostic audiometer (Grason-Stadler, Eden Prairie, MN). The primary researcher and supervisor of the current study decided to change sound card for two reasons. First, the MOTU soundcard was old, providing a potential point of vulnerability for the study. Second, it required driver software not readily compatible with computers the researchers had access to for testing. The goals were to achieve a set up that would allow for masking noise to be delivered through the custom audiometer software using a reliable sound card for timing and ergonomic convenience.

Matching output of X-FI sound card to calibrated MOTU output:

To ensure the X-FI sound card would deliver the same output as the previously calibrated MOTU output, the voltage output of the MOTU sound card was compared to the X-FI sound card when both soundcards were loaded by the input impedance of the TEAC HFBC. Measurements were conducted at audiometric frequencies between 250 Hz and 20 kHz using a pure-tone stimulus delivered at 40 dB attenuation (i.e. 40 dB below the maximum output level of the soundcard). The output level of the X-Fi soundcard was found to be 9.9 ± 0.1 dB lower than that of the MOTU across the frequency range. This conveniently flat offset value was then used to adjust the calibration value embedded in the custom software.

In order to use the HFBC calibration values derived by Howey (2019) with the X-Fi soundcard, we first needed to verify that we were calibrating against the same MOTU-soundcard/TEAC-transducer combination used in that study. This was done by comparing the author's HFBC thresholds measured with our MOTU-soundcard/TEAC-transducer combination against his thresholds as measured during the Howey study. The results, shown in Figure 12 demonstrated that they were within test-retest limits, thereby confirming the equivalence of the equipment. This gave us confidence that any further comparisons made were valid against the correction factors derived by the Howey study.

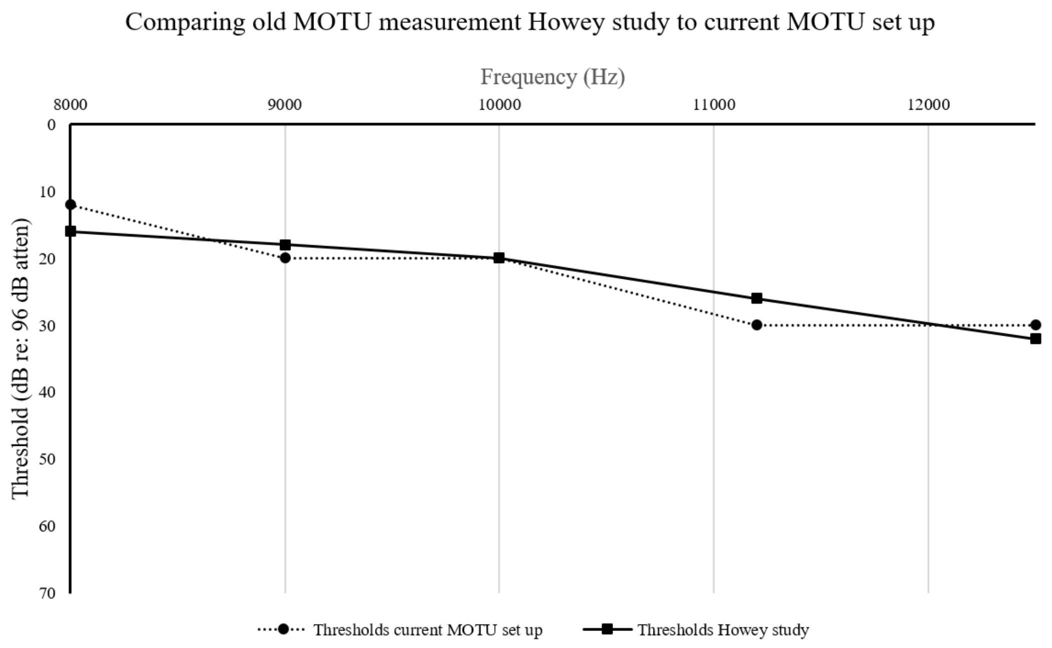


Figure 22: EHF BC thresholds measured by the current MOTU set up versus thresholds measured in the Howey (2019) study

To validate the correction factors applied when using the new X-Fi soundcard, EHF bone conduction thresholds to the closest 2 dB were measured and compared using the MOTU-soundcard/TEAC-transducer combination against two trials using the new X-Fi-soundcard/TEAC-transducer combination. Results shown in Figure 13 show thresholds were within test-retest variability confirming that the new set up delivers the same output to that of the Howey study. Because the thresholds from the MOTU lie between the two trials measured using the X-Fi, it is clear that the transducer itself (and its placement) is the dominant source of variability rather than the soundcard.

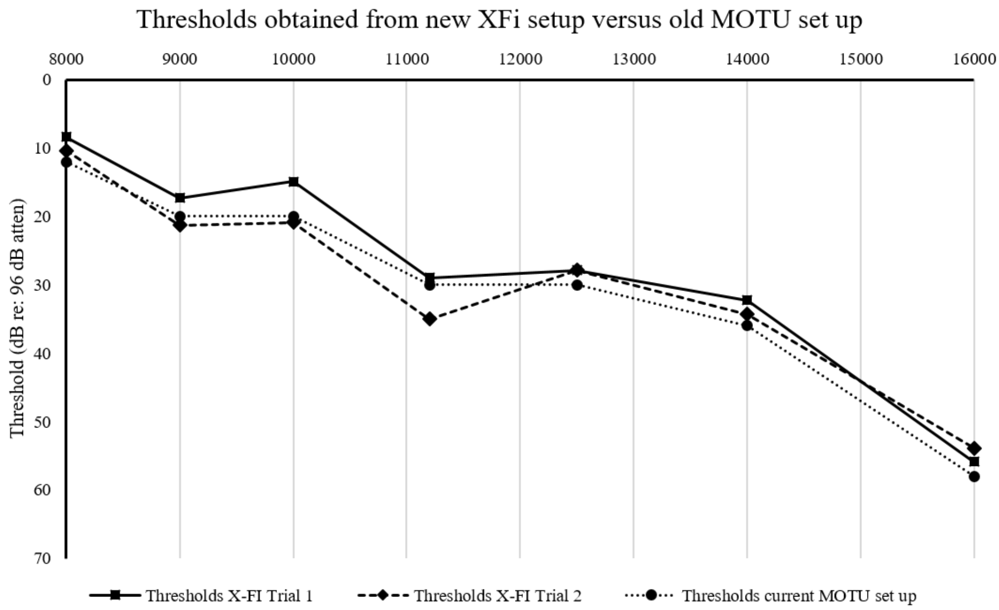


Figure 23: Two trials of EHF BC thresholds measured by the XFI setup versus the current MOTU set up

As a final measure to validate the new set up, EHF BC thresholds were compared against EHF AC thresholds. Using the author as a participant, tympanometry showed no evidence of CHL. Furthermore, CF audiometry show no signed of CHL demonstrated by no ABG. Therefore assuming that this remains true for the EHF, we would expect that the EHF BC thresholds measured using the XFi-TEAC combination would match the EHF AC thresholds measured by the calibrated GSI 61. Indeed, two trials of EHF BC thresholds showed no significant difference when compared to the AC thresholds measured by the GSI 61 as shown in Figure 14.

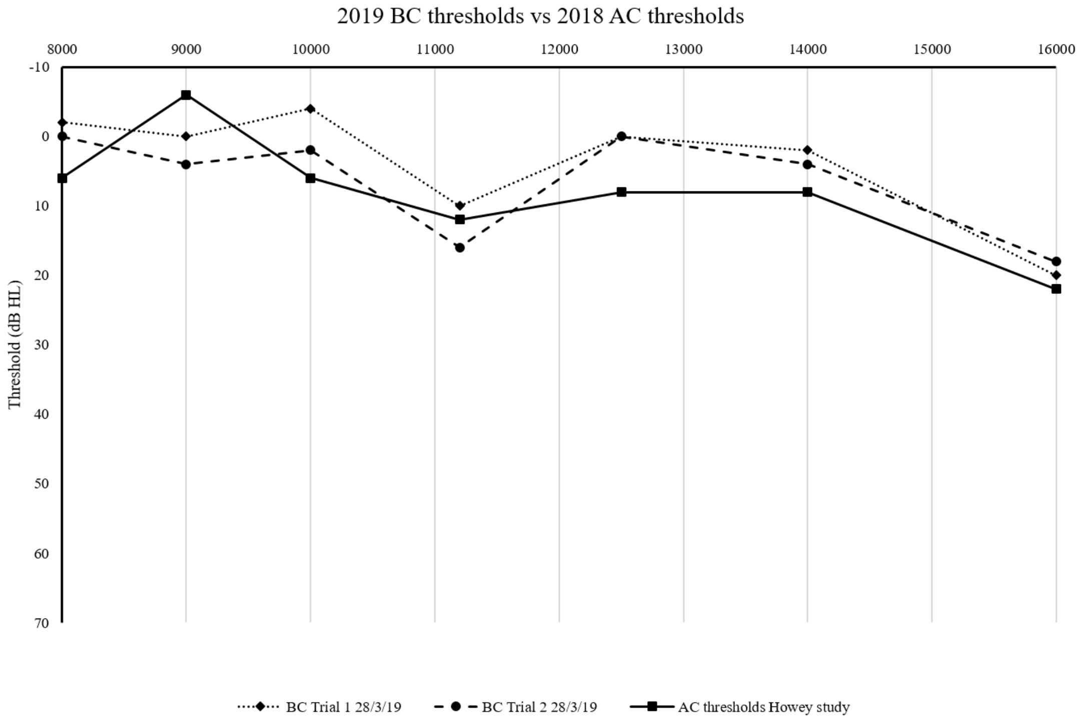


Figure 24: Two trials of EHF BC thresholds measured by the current set up versus AC thresholds measured by the Howey (2018) study.

Set up to present air conduction masking via HDA200 circumaural headphones using custom computer

To generate NBN masking noise, 2nd order Butterworth filters (slope: -12 dB/octave) geometrically centred at the frequency of the test tone were applied to white noise. Corner frequencies were based on ANSI standards 3.43-1992 and ISO 7566. To ensure AC narrow band noise (NBN) masking delivered through the custom laptop was the appropriate level in dB HL and spectrum; output levels and power spectrum of the electrical output were compared between the X-FI soundcard versus the GSI 61. Electrical output levels were measured using custom software written in LabVIEW 2016 (National Instruments, Austin, TX) that measured voltage output of the HDA200 headphones using a National Instruments NI USB-6009 data acquisition card (National Instruments, Austin, TX). Averaged spectra were measured (n=100 per masker centre frequency) using a sampling rate of 192 kHz. An iterative process was used to adjust the output voltage of the software audiometer/X-Fi combination to that of the GSI61 at 30 dB HL. The spectra were overlaid for comparison and are shown in Figures 15 and 16.

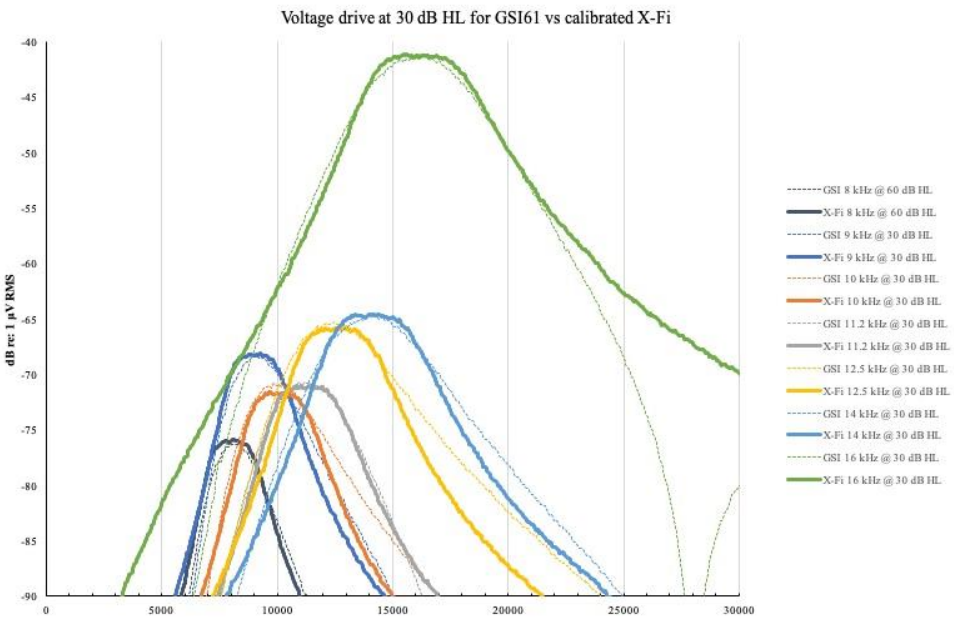


Figure 25: Comparison of GSI61 and custom software voltage spectra of NBN centred around EHF audiometric test frequencies.

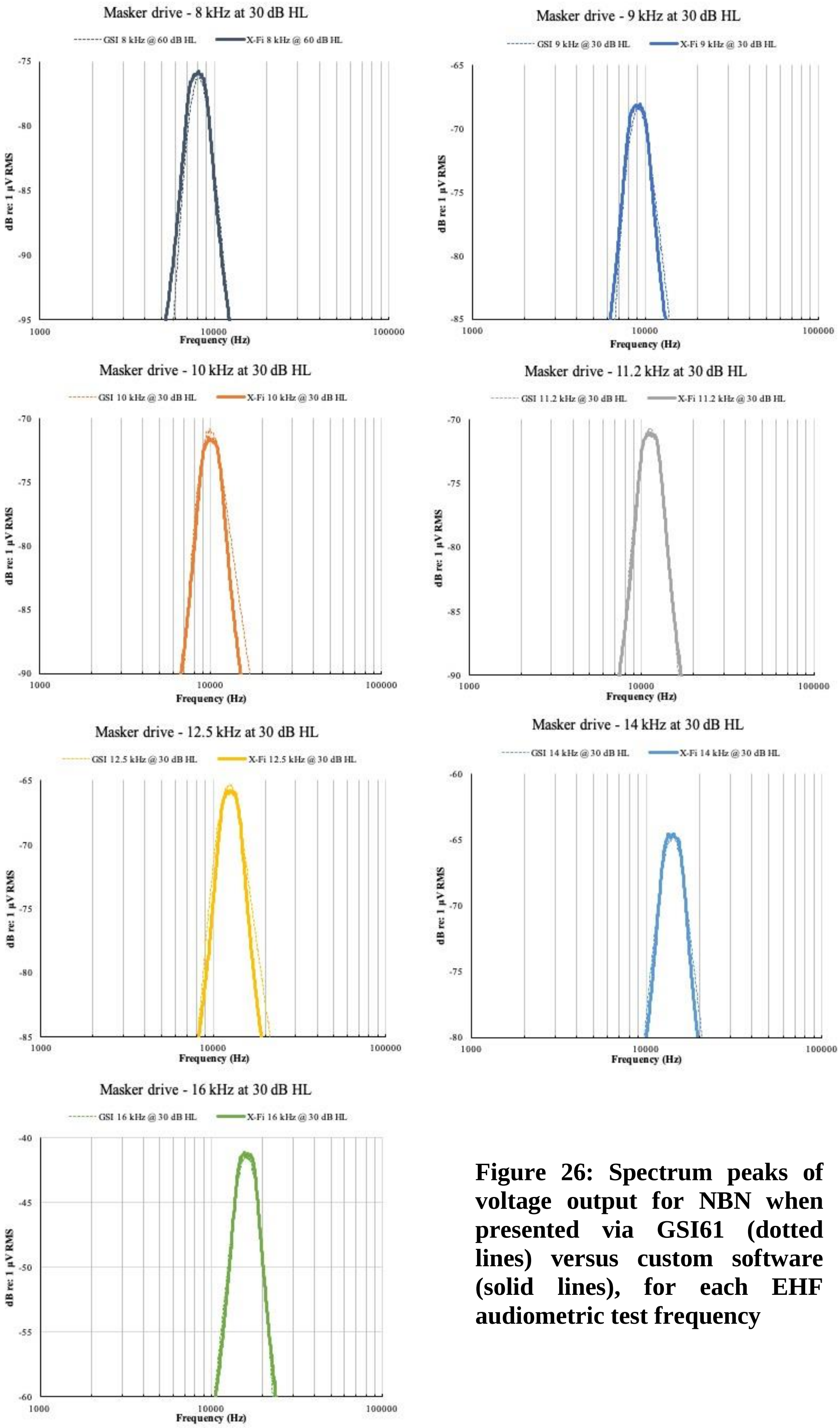


Figure 26: Spectrum peaks of voltage output for NBN when presented via GSI61 (dotted lines) versus custom software (solid lines), for each EHF audiometric test frequency

To determine whether masking noise is best presented via the calibrated GSI-61 audiometer or the custom software audiometer, we established the maximum intensity of masking noise free of distortion was established in both systems. Spectra were recorded at 8, 9, 11.2, 12.5, 14 and 16 kHz increasing intensity by 5 dB steps. The maximum intensity without distortion was one step below the intensity which led to a subjectively audible distortion through the HDA200 transducer. Spectra showed no change in shape between the two 5 dB steps (introduction of harmonic peaks) suggesting that the audible distortion is a result of mechanical clipping of the transducer rather than the voltage output. The maximum levels did not differ between the X-FI and GSI 61 (Figure 17).

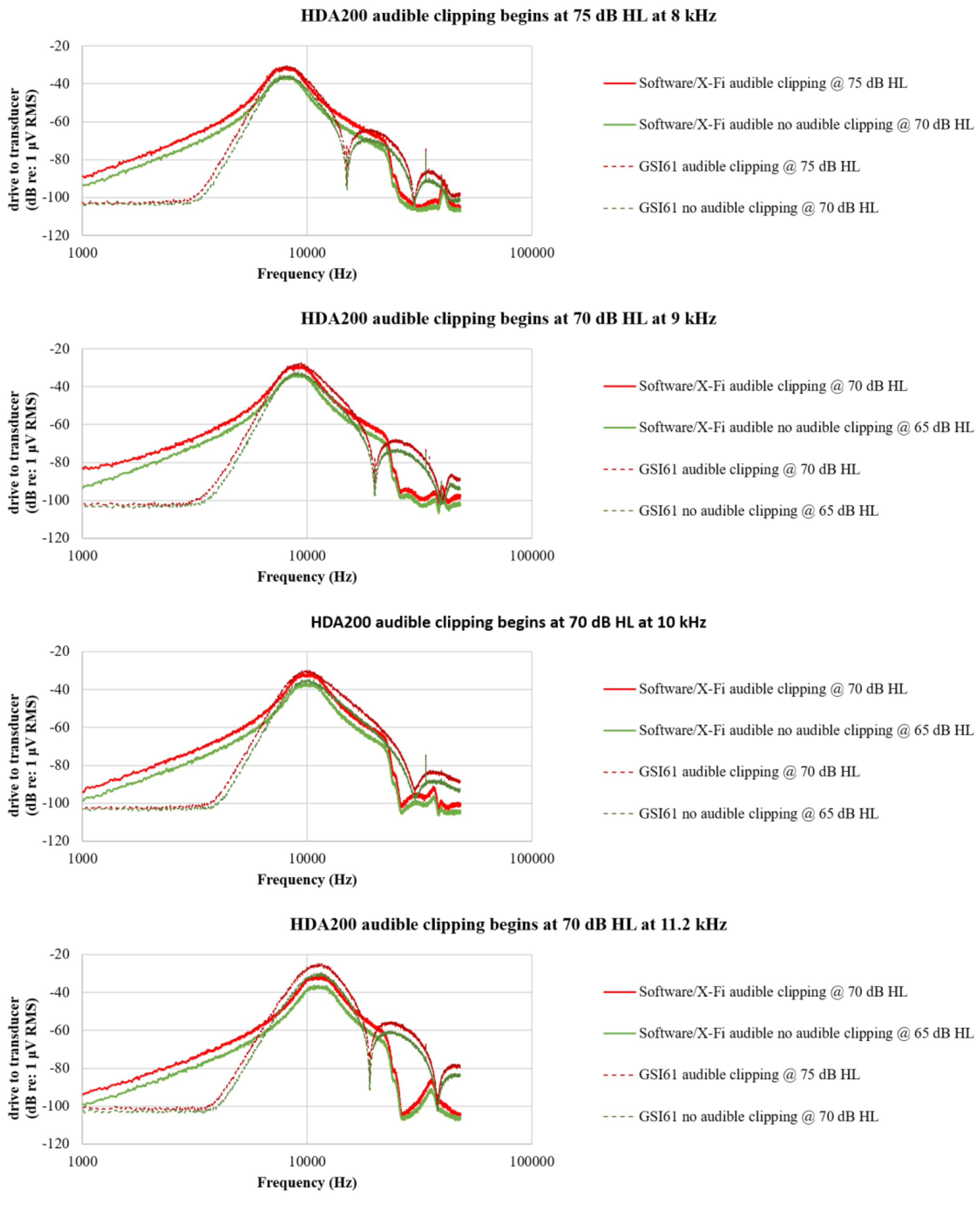


Figure 27: Power spectra of HDA200 when presenting NBN centred from 8 – 11.2 kHz from GSI 61(dotted lines) versus custom software (solid lines). Green lines represent spectra with no audible clipping. Red lines represent spectra with audible clipping, clearly demonstrating additional harmonic peaks.

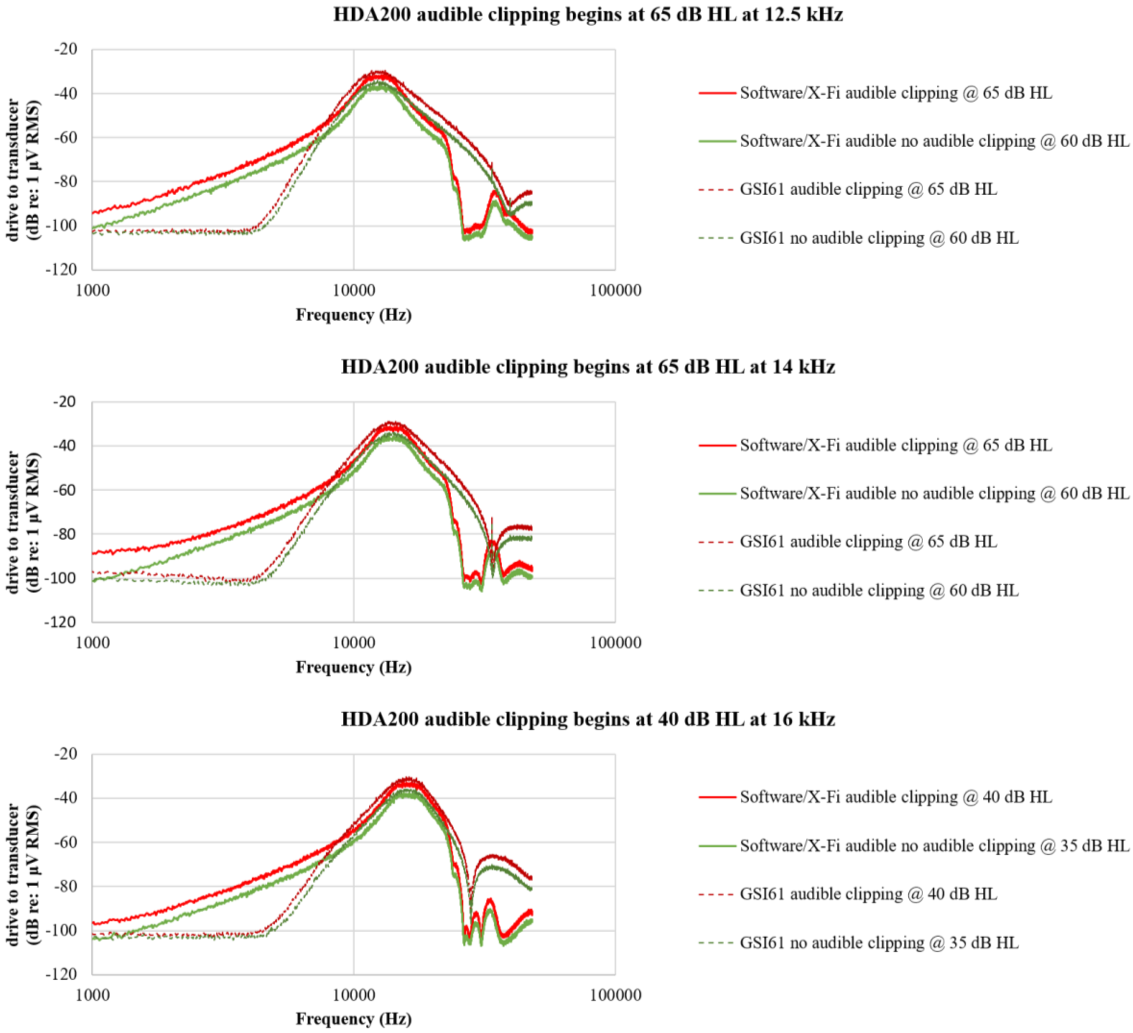
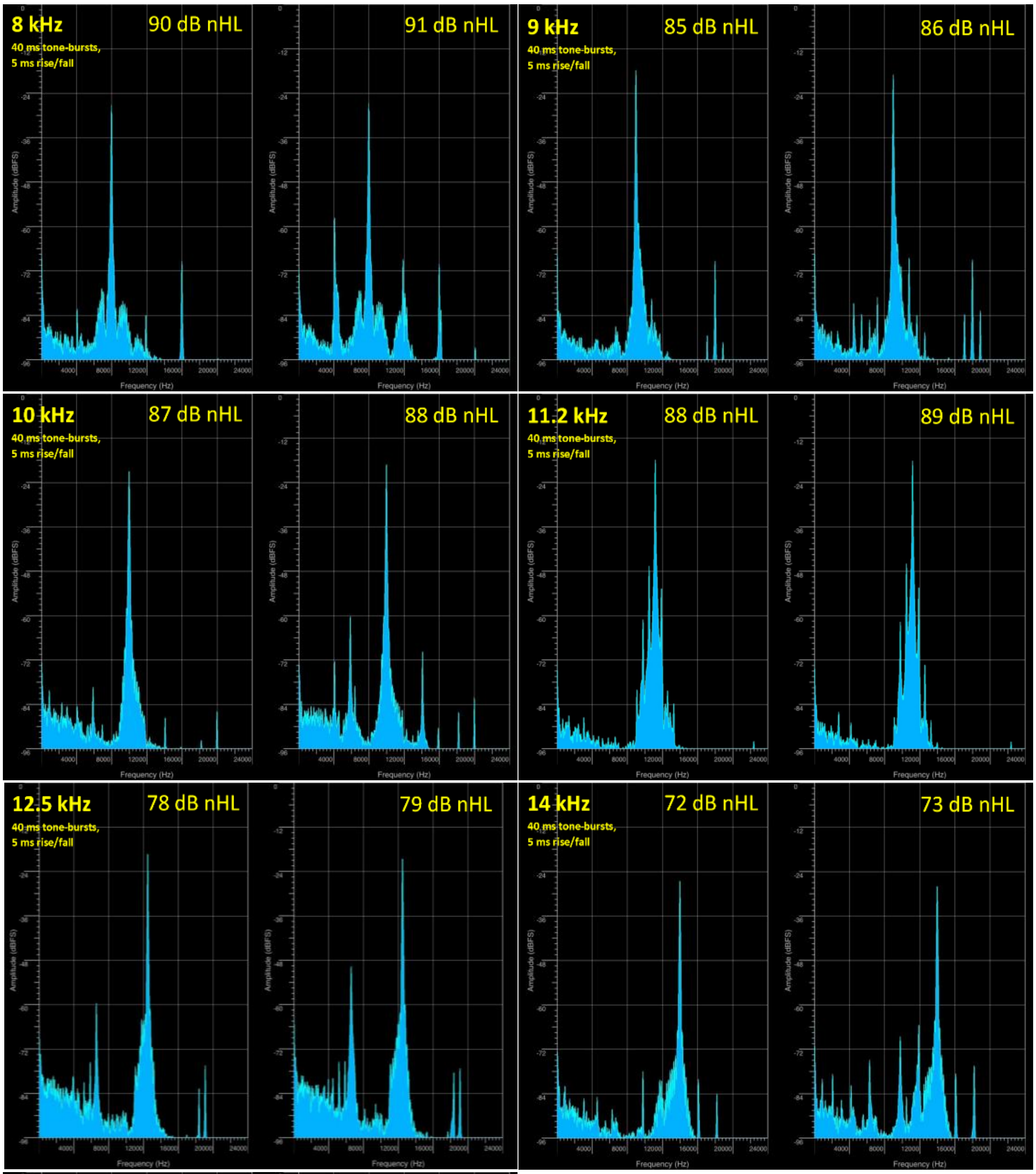


Figure 28: Power spectra of HDA200 when presenting NBN centred from 12.5 – 14 kHz from GSI 61 (dotted lines) versus custom software (solid lines). Green lines represent spectra with no audible clipping. Red lines represent spectra with audible clipping, clearly demonstrating additional harmonic peaks.

Overall, by applying correction factors, the spectrum and electrical output of the NBN masking noise played through the circumaural HDA200 transducer was matched when driven through the GSI61 audiometer or X-FI soundcard. Furthermore, the X-FI provides adequate dynamic range when compared to the GSI 61. This allowed for masked EHF BC audiometry to be performed solely from the custom audiometer, as opposed to BC thresholds measured from the custom software and the NBN AC masking noise delivered by the G61 audiometer.

Determining the maximum output of the TEAC bone conductor

During preliminary testing, mechanical distortion was encountered when presenting pure tones in the EHF range using the TEAC bone condutor. We set out to determine the maximum presentation level allowable free of distortion. Popelka et al. (2010) use specialised equipment to measure the vibratory output of the TEAC transducer. This technology was not available to the authors, therefore output was measured using the Spectrum View 2.3 spectrum analyser app on an iPhone 7, with the transducer located over the microphone input, in physical contact with the rubber phone case. The maximum output of the transducer was determined to be 1 dB below the point at which addition spectral peaks were introduced, indicating mechanical distortion (Figure 19).



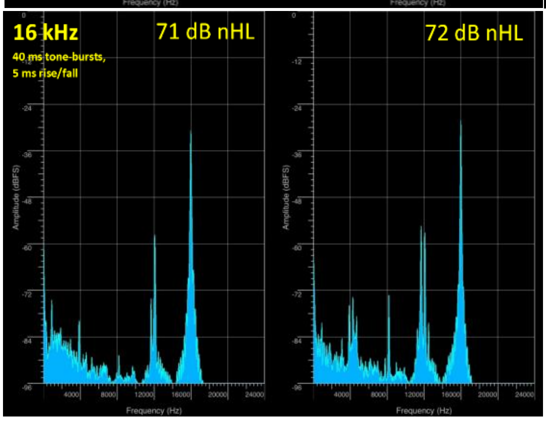


Figure 29: Spectra of maximum output of Modified TEAC bone conductor in the EHF range

Each panel shows the maximum level free of distortion to the left, followed by a 1 dB increase demonstrating additional spectral peaks due to mechanical distortion.