The vibrant soundbridge (VSB) middle ear implant: hearing and quality of life (QOL) outcomes in patients with mixed and conductive hearing loss (CHL)

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Declaration

This is to certify that this thesis does not incorporate, without acknowledgement, any material previously submitted for a degree or diploma from any university and that, to the best of my knowledge and belief, does not contain any material previously published or written by another person except where due reference is made in the text.

Signed  ____________________________________________

Roberta Marino

Date:  ____________________
Abstract

Background and aims

The vibrant soundbridge (VSB) implant offers a solution for people who suffer hearing losses that cannot be corrected using conventional hearing aids (CHAs). Although the VSB implant can assist with perception of speech in quiet and noise, whether it delivers benefits that are comparable to those from CHAs was not known prior to this work.

The specific aims of this work were therefore:

- To determine if the round window application of the vibrant soundbridge (VSB-RW) provides comparable results to CHAs for speech perception in quiet and in noise.
- To determine if the VSB-RW application improves quality of life (QOL) outcomes and specifically tinnitus perception.
- To determine if stapes or incus vibroplasty is comparable to round window (RW) vibroplasty with regard to coupling and outcomes.
- To investigate the effect of different floating mass transducer (FMT) attachment points on hearing outcomes.

Methods

Speech in quiet and speech in noise performance was measured in 18 patients undergoing RW placement of the FMT for mixed or conductive hearing loss (CHL). Their performance was evaluated in comparison to the subjects wearing a CHA (Aim 1). QOL outcomes were measured using the tinnitus reaction questionnaire (TRQ) and the abbreviated profile of hearing aid benefit (APHAB) in 10 of these patients (Aim 2). The effect of different FMT attachment points was evaluated in 16 patients (Aims 3 and 4).

Results

Aim 1 (Chapter 3)
Subjects attained equivalent performance for speech in quiet with the VSB compared to their pre-operative performance with CHAs.

Subjects attained improved performance for speech in noise with the VSB compared to their pre-operative performance with hearing aids.

**Aim 2 (Chapter 4)**

- Subjects reported significant improvements in their QOL with improved hearing in background noise (BN) and in reverberant conditions, as well as in their overall ease of communication (EC).
- Subjects with tinnitus pre-implantation all experienced a reduction in tinnitus following implantation with the VSB.

**Aims 3 and 4 (Chapter 5)**

- Subjects with FMT placement on the stapes showed the best coupling efficiency, followed by placement at the incus, RW vibroplasty without interposed tissue, and lastly RW vibroplasty with interposed tissue.

Preliminary data suggested that different placement of the FMT was not associated with differences in outcomes.

**Conclusions**

In carefully selected patients, the VSB can provide significant hearing benefits including improved hearing in quiet and in BN. Performance in noise was superior to performance using CHAs. Patients experiencing tinnitus pre-implantation reported a reduction in tinnitus perception with VSB use. Our preliminary results suggest that ossicular placement, and in particular the stapes, provides the best coupling efficiency for patients with mixed and conductive losses. However, no differences in hearing outcomes between the different vibroplasty placement groups were apparent.
Acknowledgements

To Gunesh – thank you for believing in me (even when I didn’t!) and providing me with so many opportunities. Your support and feedback over many years have been invaluable! Not only do I consider you a great mentor but also a friend.

To Barry – thank you for your patience and kindness and pouring over my many drafts. You are always so welcoming - every time I left your office I felt inspired. Thank you!

Dayse – we did it! 😊 So lucky to have been able to share this journey with you.

Ai miei cari Nonni – grazie per tuo amore e per sempre essere li per me!

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To Mel, Amy and Ryan, thanks for putting up with all the late nights, times locked away in the study and my sleep deprived grumpiness. Unfortunately for you all, even post-thesis submission and hopefully acceptance, I still won’t be perfect! 😊

To Luciano and Ootam – the best brothers anyone could ever hope for! You are always there for me with such generous, good humoured hearts.

To Ana, for being the ultimate editor and one of the best people in my life – thank you!
Statement of candidate contribution

This thesis contains published work which has been co-authored. The bibliographical details of the work and where it appears in the thesis are outlined below.

Chapter 3

The study design was formulated by all authors. Data collection was undertaken by Roberta Marino and Elle Statham. Statistical analysis was conducted by Dr Robert Eikelboom. Writing of the manuscript was performed by Roberta Marino with editing conducted by all co-authors – please refer to Appendix 1.

Chapter 4

The study design was formulated by Roberta Marino, Dayse Távora-Vieira and Professor Gunesh Rajan. Roberta Marino performed data collection, analysis and interpretation with the assistance of a statistician (Edda Amann). Drafting of the manuscript was performed by Roberta Marino, Dayse Tavora-Vieira and Professor Gunesh Rajan – please refer to Appendix 2.

Chapter 5
The study design was formulated by Professor Gunesh Rajan, Peter Lampacher, Gregor Dittrich, Jafri Kuthubutheen and Dayse Távora-Vieira and Roberta Marino. Data collection and interpretation was executed by Roberta Marino, Professor Gunesh Rajan and Peter Lampacher. Writing of the manuscript was conducted by Roberta Marino with revision of the manuscript performed by all co-authors – please refer to Appendix 3.

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Professor Barry Iacopetta
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Abbreviations

ANSI  American National Standards Institute
APHAB  Abbreviated profile of hearing aid benefit
AV  Aversiveness
Baha  Bone anchored hearing aid
Baha®  Bone anchored hearing aid (Cochlear Ltd, Australia)
BAI  Bone anchored implant
BKB  Bench-Kowal-Bamford
BN  Background noise
CHA  Conventional hearing aids
CHL  Conductive hearing loss
COM  Chronic otitis media
COSI  Client oriented scale of improvement
CSOM  Chronic suppurative otitis media
dB  Decibel
dBHL  Decibels hearing level
dBSPL  Decibels at sound pressure level
DSL  Desired sensation level
EC  Ease of communication
ECog  Electrocochleography
ENT  Ear, nose and throat
FMT  Floating mass transducer
GBI  Glasgow benefit inventory
HL  Hearing level
Hz  Hertz
ILD  Interaural level differences
ITD  Interaural time differences
MRC  Modified radical cavities
OW  Oval window
PFW  Promontory fenestration window
QOL  Quality of life
RC  Radical cavities
RMS  Root mean square
RV  Reverberation
RW  Round window
RW-FMT  Round window floating mass transducer
<table>
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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>TM</td>
<td>Tympanic membrane</td>
</tr>
<tr>
<td>TRQ</td>
<td>Tinnitus reaction questionnaire</td>
</tr>
<tr>
<td>VSB</td>
<td>Vibrant sound bridge</td>
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<tr>
<td>VSB-OW</td>
<td>Oval window application of the vibrant sound bridge</td>
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<tr>
<td>VSB-RW</td>
<td>Round window application of the vibrant sound bridge</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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1. Introduction

1.1. Hearing loss: prevalence rates and effects

Hearing loss is one of the three most prevalent conditions affecting the world’s population (WHO, 2004). The World Health Organization (WHO) states that 5.3% of the world’s population has a hearing loss with levels greater than 40 decibels hearing level (dBHL) (WHO, 2012). It was estimated that in 2004, 361 million people worldwide had mild hearing loss (in the range of 26-40dB) and approximately 276 million had moderate or greater hearing loss (41dB or greater loss; WHO, 2004). In adults, hearing loss occurs in approximately 15%, 16.6% and 16.1% of people living in Nordic countries, Australia and the United Kingdom, respectively (Sorri et al., 2001; Wilson et al., 1999; Davis, 1989).

The work described in this thesis explores two types of hearing loss referred to as conductive or mixed hearing losses, and the implementation of a hearing implant – the vibrant soundbridge (VSB) (Med-EL, Innsbruck), for individuals experiencing these types of loss. The proportion of the Australian population with a conductive or mixed hearing loss is estimated to be 0.4% and 0.6%, respectively (Wilson et al., 1998). The exact proportion of this 1% of the total population who cannot wear hearing aids is unknown; however, the implications of hearing loss can significantly impair an individual’s QOL.

The worldwide prevalence of conductive and mixed hearing losses is unknown. There is limited information available on different types of hearing loss because standardised testing procedures that could help to differentiate between the different types have not been applied (ie. conductive, mixed or sensorineural). Also, much of the prevalence data relies on self-reporting, with many individuals not aware of the severity of their hearing loss or even if a loss is truly present. Self-reporting of hearing loss in adults has been
associated with a false-positive rate of 46% and a false negative rate of up to 17% (Wilson, 1999).

In adults, hearing loss causes difficulties with communication, personal relationships, employment opportunities (Listen Hear, 2006), increased risk of depression (Li & Hoffman, 2014), and increased incidence and accelerated rate of cognitive decline in older adults (Lin et al., 2013). There is also an increased risk of early retirement for younger and middle aged adults with low frequency hearing loss (Helvik et al., 2013).

In children, the effects of hearing loss are more devastating and widespread given they are still learning to communicate and have not established strong speech and language foundations. Hearing loss in children can lead to difficulty in perceiving speech, even when the loss is compensated with the use of hearing aids (Pittman et al., 2009). These difficulties are more pronounced when listening in BN (Crandell, 1993). Early intervention in the form of hearing aids and cochlear implants can improve outcomes for these children; however, they are still delayed in their expressive and receptive language, speech production, social and auditory skills and overall functional abilities (Ching et al., 2013). Hearing loss in children is also associated with increased behavioural problems (Stevensen et al., 2007). With diminished speech and language skills, the literacy and subsequent education of these children is affected, thus limiting their future employment opportunities.

Tinnitus can also be a by-product of hearing loss. Individuals with hearing loss have a 70-85% chance of experiencing tinnitus (Martines et al., 2010).

In summary, hearing loss can significantly impact an individual’s QOL. Treatment via medical intervention where possible, or via compensatory means in the form of hearing aids or medically implanted devices, can help to alleviate or neutralise these negative impacts.
1.2. **How does a normally functioning hearing system work?**

The three components to the hearing mechanism are:

- The outer ear – compromising of the pinna and ear canal.

- The middle ear – compromising of the tympanic membrane (TM) (eardrum), the middle ear space, and middle ear bones / ossicles (malleus, incus and stapes).

- The inner ear – compromising of the cochlea, labyrinth and auditory nerve.

See Figure 1.1 for a diagrammatic representation of the hearing mechanism.
Sound waves are transmitted via air through the ear canal.

Sounds waves cause vibration of the TM (eardrum) causing different motions depending on the frequency and intensity of the sounds. The TM has the first ossicle – the malleus, embedded in the membrane and movement of the TM, causes movement of the ossicular chain.

The ossicular chain works as an effective lever, transmitting air borne sound through the OW membrane to the fluid filled cochlea / inner ear. There is another membrane, the RW which moves in synchrony and at 180° out of phase with the OW in response to auditory stimuli. Fluid movement within the cochlea leads to movement of the cochlear hair cells.

Movement of the hair cells leads to mechanoelectric excitation which results in stimulation of the auditory (hearing) nerve which are then delivered to the brain and interpreted as sound.
1.2.1. Classification of hearing loss
The three different categories of hearing loss are:

- **CHL** (Conductive Hearing Loss) is caused by a blockage or malfunction of the outer or middle ear which can be present at birth or acquired. A congenital condition such as atresia, where the external and middle ear spaces are not properly developed, causes permanent CHL. Some conductive losses are caused by temporary, acute conditions such as otitis media (middle ear infection), discharging ears or a blockage in the outer ear canal such as ear wax or a foreign object. Permanent CHL can result from acute conditions such as long-term otitis media leading to a non-healing TM perforation or causing disintegration of one or more of the ossicles.

- **Sensorineural hearing loss** is caused by damage to the cochlea, the auditory part of the inner ear, the cochlear hearing hair cells or to the hearing nerve (auditory nerve), or to both. Conditions such as perinatal infections (Rubella, Measles, Cytomegalovirus, Toxoplasmosis etc…), Meniere’s, genetic mutations, immune conditions, exposure to ototoxic substances or noise exposure can cause sensorineural hearing loss.

- **Mixed hearing loss** is the combination of conductive and sensorineural hearing loss. An individual could have a CHL caused by an ear infection but also have an underlying sensorineural hearing loss caused by noise exposure. A condition such as otosclerosis which affects the middle ear can also affect the inner ear, causing the release of toxic substances that damage the hair cells over time. In these cases, mixed hearing loss is the result (Ealy and Smith, 2010).

1.3. Varying severity of hearing loss
Hearing levels (HLs) are described graphically on an audiogram which depicts the intensity (often described as volume) and is reflected on the vertical (y) axis. The
frequency/pitch is reflected in the horizontal (x) axis. The intensity of sound on an audiogram is described in dBHL with a normal hearing ear typically having the ability to hear sounds from –10dBHL to 20dBHL – see Figures 1.2, 1.3 and 1.4.

Figure 1.2. Basic anatomy of the hearing mechanism and the components involved in conductive and sensorineural hearing

Figure 1.3. Audiogram with pitch represented on the horizontal axis and intensity on the vertical axis. The degrees of hearing loss are also represented
In Figure 1.4, the air conduction results indicate hearing acuity when sound travels through the outer and middle ear systems before detection by the inner ear (cochlea). The bone conduction results reflect HLs when sound is delivered directly to the cochlear, bypassing the outer and middle ears. As can be seen, there is a mismatch between the air conduction thresholds in the left ear and the bone conduction thresholds in the left ear. Air conduction thresholds are on average around 55dBHL whereas bone conduction results in the left ear are on average 10dBHL. This difference is commonly referred to as the ‘air-bone gap’.

HLs of greater than 25dB are considered to represent hearing loss, as defined by WHO criteria. Hearing loss at this level or greater starts to impair an individual’s ability to communicate in daily life and hearing aids are normally required (WHO, 2014). There are varying degrees of hearing loss. Hearing loss and the effects on communication as per the WHO scale are listed in Table 1.1.
### Grades of hearing impairment

<table>
<thead>
<tr>
<th>Grade of impairment</th>
<th>Corresponding audiometric ISO value</th>
<th>Performance</th>
<th>Recommendations</th>
</tr>
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<tbody>
<tr>
<td>0 - No impairment</td>
<td>25 dB or better (better ear)</td>
<td>No or very slight hearing problems. Able to hear whispers.</td>
<td></td>
</tr>
<tr>
<td>1 - Slight impairment</td>
<td>26-40 dB (better ear)</td>
<td>Able to hear and repeat words spoken in normal voice at 1 metre.</td>
<td>Counseling. Hearing aids may be needed.</td>
</tr>
<tr>
<td>2 - Moderate impairment</td>
<td>41-60 dB (better ear)</td>
<td>Able to hear and repeat words spoken in raised voice at 1 metre.</td>
<td>Hearing aids usually recommended.</td>
</tr>
<tr>
<td>3 - Severe impairment</td>
<td>61-80 dB (better ear)</td>
<td>Able to hear some words when shouted into better ear.</td>
<td>Hearing aids needed. If no hearing aids available, lip-reading and signing should be taught.</td>
</tr>
<tr>
<td>4 - Profound impairment including deafness</td>
<td>81 dB or greater (better ear)</td>
<td>Unable to hear and understand even a shouted voice.</td>
<td>Hearing aids may help understanding words. Additional rehabilitation needed. Lip-reading and sometimes signing essential.</td>
</tr>
</tbody>
</table>

Grades 2, 3 and 4 are classified as disabling hearing impairment.

The audiometric ISO values are averages of values at 500, 1000, 2000, 4000 Hz.

Table courtesy of WHO, 2014

1.4. **Problematic cases of conductive and mixed hearing loss**

Some outer and middle ear conditions are not medically treatable, while some ear conditions such as chronic suppurative otitis media (CSOM) make the wearing of external ear moulds or aids impossible. The wearing of anything in the ears can aggravate the condition by limiting the air flow and increasing humidity (Snik et al., 2001). People with ear drum perforations are also at increased risk of infections. In some cases of chronic otitis media (COM), the ossicular chain has been damaged and middle ear
reconstructive surgeries (ossiculoplasty) have limited success rates. Often, if the initial surgery was effective, the underlying chronic middle ear condition returns and can affect long-term outcomes and necessitate further surgery (Colletti et al., 2006).

People with microtia (congenital malformations of the external ear), anotia (an absent external ear), atresia (absent ear canal) or stenosis (where the external auditory canal is very narrow), cannot wear CHAs (Dillon, 2012).

Some conductive and mixed hearing losses are so severe that amplification through conventional air conduction hearing aids is not sufficient and an individual derives greater benefits from devices that can stimulate the cochlea directly (Dillon, 2012).

1.5. **Conventional treatment for permanent hearing losses: hearing aids**

The first treatment option for people with hearing loss is the use of a hearing aid. However, some people with mixed and CHL are unable to benefit from CHAs or are not able to use CHAs due to malformations, trauma or repeated surgeries for chronic ear disease. Whether the hearing aid is an ‘in-the-ear’ model or a ‘behind-the-ear’ model, there is always a mould or aid that sits within the ear canal, especially when significant hearing loss is present as is typically the case with a conductive or mixed hearing loss. Figure 1.5 illustrates both in-the-ear and behind-the-ear styles of hearing aid.

While this is a satisfactory option for most people with hearing loss, for those suffering ongoing ear infections with discharging ears, or those who do not have a viable ear canal, hearing aids are not effective. There are also patients who have undergone outer ear surgery and their ear canal cannot tolerate a mould, or their ear canal is mis-shapen to the extent that a traditional hearing aid cannot be comfortably worn.
Images of an in-the-ear and a behind-the-ear hearing aid

When the ear drum or middle ear bones (ossicles) are affected and the cochlea is also damaged, there can be a substantial blockage in the transmission of sound and use of a hearing aid cannot overcome the hearing loss. People experiencing a blockage in their conductive hearing pathway require much greater amplification than individuals who have a pure sensorineural hearing loss (Dillon, 2012).

1.6. Hearing devices for conductive and mixed hearing loss
At the commencement of this research study in 2012, the options available to individuals unable to wear CHAs and who suffer from conductive or mixed hearing loss were:

- Bone conductor hearing aids.
• Bone anchored implants (BAIs) (Baha®, Cochlear Ltd, Australia and Oticon Medical, Denmark).

• Vibrant Soundbridge (VSB).

1.6.1. Bone conductor hearing aids
Bone conductor hearing aids are a non-surgical option for people with conductive or mild mixed hearing losses with relatively good cochlear functioning. They consist of a powerful behind-the-ear hearing aid which is connected via a cable to a transducer. The transducer must be pushed tightly against the head for the system to be effective and is typically fitted to a cloth or steel string headband or included in the frame of glasses (Figure 1.6). Another option is to include the transducer, behind-the-ear hearing aid and cables into a hat or cap. The bone conduction transducer delivers sound through bone conduction directly to the cochlea and potentially to both cochleae if there is good cochlea / sensorineural hearing.

Disadvantages of the bone conductor hearing aid system are described by Dillon (2012) and include:

- The device can be uncomfortable because of the need to apply pressure against the head for it to be worn effectively. Depressions in the skin and pain can result.

- The device is not aesthetically appealing.

- Sounds cannot be sent independently to both cochleas so the wearer finds it more difficult to localise the direction of incoming sounds.

- Sound is attenuated by the skin, making it difficult to attain sufficient low and high frequency amplification.
Figure 1.6. Bone conduction hearing aids

a) Image of a bone conduction hearing aid
b) Image of a bone conductor aid fitted to a pair of glasses

Images courtesy of CICADA (Cochlear Implant Club and Advisory Association)

1.6.2. Bone anchored implants (BAIs)

The two main manufacturers of BAIs in 2010 were Cochlear Ltd (Australia) and Oticon Medical (Denmark). The Cochlear Ltd device is commonly referred to as a bone anchored hearing aid (Baha®). This device obtained FDA (Food and Drug Administration) approval in 1996 for mixed and CHL, although it has been available since 1977.

BAI consists of a titanium implant, an external abutment and a sound processor. The sound processor can be a ‘head-level’ device or a more powerful body-worn version.

A titanium conductor screw is implanted into the temporal bone of the skull (Figure 1.7) and after a period of approximately 4-6 weeks in adults the sound processor can be loaded onto the abutment as the process of the titanium screw and bone bonding (osseointegration) has occurred (Snik et al., 2005). The sound processor transmits sound through vibrations to the external abutment and titanium screw which transmits the vibrations onto the bone, resulting in vibrations of the cochlea. (Figure 1.8).
Transmission of sound through the skin and skull (percutaneous coupling) through a device such as the Baha can provide good results for those with CHL such as in cases of atresia (Yellon, 2010), or for mild mixed hearing losses (Snik et al., 2004).

BAIs, unlike bone conduction hearing aids, do not suffer the problems of pressure or slippage of the transducer. The transmission of sound is also more efficient because this is not attenuated by the skin or subcutaneous soft tissues (Hakansson et al., 1985). Baha provide 10-15dB greater amplification than BCHA (Hakansson et al., 1984; Tjellstrom et al., 2005).

Figure 1.7. The titanium screw in position

![Image of titanium screw in position](Photo courtesy of Oticon Medical)

Figure 1.8. Images of the titanium abutment and the Cochlear Ltd and Oticon Medical’s processor

![Images of titanium abutment and processor](Images courtesy of Cochlear Ltd and Oticon Medical)
While BAI s are the most commonly used implant to treat conductive and mixed hearing loss, complications with the percutaneous coupling can occur and range between 6.7% (Hakanson et al., 1990) to 38% of patients experiencing severe skin reactions (Gluth et al., 2010). Badran et al. (2009) reported that 34% of 177 Baha implants required revision surgery due to loss of osseo-integration, pain, severe skin reactions, thickening or overgrowth of skin, primary bleeding, hair growth around the abutment, intolerable pain and recurrent infections. Serious complications are rare and the surgery does not involve the structures of the middle ear or mastoid, making revision relatively straightforward. Regular cleaning and hygiene is required by patients to decrease the risk of skin infections, skin thickening and graft site ulceration (Davids et al., 2007). Another problem of BAI, especially in children, is traumatic damage to the sound processor due to it being external and thus exposed (Zeitoun et al., 2002).

1.6.3. Vibrant soundbridge (VSB)

The VSB has been in use since 1996 as a middle ear implant to treat sensorineural hearing loss in patients unable to wear hearing aids. As described earlier, sensorineural loss is a term used to describe hearing loss at the level of the inner ear (cochlea) or auditory nerve or higher structures. In the initial application of the VSB, the transducer of the device (the FMT) was crimped onto one of the bones of the ossicular chain called the incus (Figure 1.9a).

As a middle ear implant, the VSB does not require any device or mould to be worn within the ear canal and thus overcomes many of the problems described previously. The middle ear implant consists of an external audio processor, an internal implant with a conductor cable and a FMT. The FMT is a tiny magnet which vibrates on electrical stimulation (Figure 1.9b). The external audio processor detects sounds and transmits this as electrical energy waves through to the internal implant. The electrical energy then travels through the conductor cable to the FMT, which translates the signal to a mechanical movement
either to the incus or to the RW membrane (Figure 1.10). In both the incus and RW application of the implant, the movement transmits sound directly to the cochlea which in turn transmits sounds to the auditory nerve and then ultimately to the brain which interprets the signal as sound.

Since 2005, the VSB FMT has been placed further along the auditory pathway in the RW niche (Colletti, 2006; Figure 1.10). This application is useful for patients with CHL where transmission of sound is affected by challenges in the outer ear or middle ear. It is also useful for patients affected by mixed hearing loss where there is a combination of sensorineural hearing loss and CHL. By placing the FMT on the RW niche, the diseased or malformed outer and/or middle ear is bypassed. Positioning the FMT directly onto the RW also allows vibrational sound energy to be sent directly to the cochlea to compensate for the sensorineural component of the hearing loss.

Normal sound transmission involves movement of the stapes vibrating the oval window (OW). This movement of the OW leads to movement of the perilymph which is present in the scala vestibuli and tympani and vibrates the RW in a complementary rhythm. This movement leads to movement of the scala media which is caught between the two perilymph filled spaces (Figure 1.11a).

Whereas stimulation at the RW employs the process of sono-inversion, the RW membrane movement mirrors the input created by the stapes movement in regard to frequency, phase and amplitude, but in reverse (Edfelt and Rask-Andersen, 2013; Figure 1.11b).
Figure 1.9. Diagrammatic representation of incus and round window vibroplasty

a) The classic incus vibroplasty application of the VSB where the FMT is clipped onto the incus.

b) Round window vibroplasty where the FMT is in contact with the round window.

Images courtesy of Med-EL, Innsbruck
Figure 1.10. Vibroplasty with the FMT coupled to the RW

![Vibroplasty with the FMT coupled to the RW](image)

Images courtesy of Med-EL, Innsbruck

Figure 1.11. Oval window stimulation and sono-inversion

a)

![Diagram of oval window stimulation](image)

b)

![Diagram of sono-inversion](image)

a) Normal sound transmission pathway commencing with stimulation at the OW.
b) Sono-inversion where stimulation commences at the RW via movement of the FMT.
In theories developed in the 1950s (Wever and Lawrence, 1954) and revisited by Colletti et al. (2006), it was postulated that acoustic stimulation of the RW can result in equivalent cochlear potentials to those elicited via OW stimulation. This theory supports the application of devices such as the VSB, which can be used to stimulate the RW directly in cases where the normal middle ear pathway is compromised. However, the relationship is not always so simple and can be affected by the severity of the air conduction and bone conduction loss, distortion in the transducer, transducer (in this case the FMT) placement, and ‘third window’ anomalies (Soli, 2008).

In the first ever application of RW vibroplasty, Colletti et al. (2006) included seven patients with ossicular chain defects and a history of unsuccessful ossiculoplasty (repair of the ossicles) in their initial study. Kiefer et al. (2006) extended the RW application of the VSB to a patient with bilateral microtia and described excellent post-operative air conduction hearing thresholds within 30dB. Wollenberg et al. (2007) applied the VSB to three patients with atretic ears where the ear canal was not present. All three patients demonstrated excellent post-operative open-set speech recognition results when tested in a quiet listening situation. The RW application was further extended with good results in patients requiring a subtotal petrosectomy and complete fat obliteration of the middle ear and mastoid cavities for end-stage chronic ear disease (Linder et al., 2008).

Frenzel et al. (2009) reported good outcomes from the RW application in patients with unilateral osseous atresia. Colletti et al. (2009) used the VSB RW application in 19 patients with bilateral moderate to severe mixed hearing losses. Their performance was found to be better than an unaided group of matched subjects who had undergone ossiculoplasty using a total ossicular replacement prosthesis to overcome the conductive component of their mixed hearing loss. Dumon et al. (2009) demonstrated the effectiveness of the VSB on either the ossicular chain or the RW membrane, whether
implanted alone or as part of another middle ear procedure. The improvement in speech perception and access to sound with RW vibroplasty has also been demonstrated by others (Ambett et al., 2010; Baumgartner et al., 2010).

Previous studies have compared patients’ performance using the VSB in the classic incus application with a hearing aid that used the same audio processing technology as in the VSB (Uziel et al., 2003). However, no published studies have compared the performance of patients using CHAs to their performance when using the VSB-RW application in the treatment of mixed or CHL.

The only study to date that has examined QOL improvement with VSB use for patients with conductive or mixed hearing loss was by Baumgartner et al. (2010). These workers compared pre- versus post-operative results using the APHAB. For 12 subjects who underwent RW vibroplasty, a statistically significant improvement was noted for the EC, the reverberation (RV) and the BN subscales. There was no significant change in the aversiveness (AV) subscale. Significant improvements were also reported on the hearing device satisfaction scale, with a mean improvement from 43% pre-operatively to 74% post-operatively. Results obtained with the Glasgow benefit inventory (GBI) showed an average positive improvement of 17 and 24 on the overall benefit and general benefit subscales.

No study to date has examined the effectiveness of the VSB as a treatment option for patients with mixed or CHL who suffer from tinnitus. This is an important area of investigation given that approximately 33% of the general population experience tinnitus (McFerran et al., 2007) and that 10-20% of this sub-set experience debilitating or crippling tinnitus (Henry et al., 2005). It is estimated that 70-85% of the hearing impaired population experience some form of tinnitus (Martines et al., 2012) and that prevalence rates are higher with increased hearing loss (Nondahl et al., 2002). For people affected by
CHL, 35% have been found to have tinnitus (Holgers and Hakansson, 2002). Therefore, the hearing impaired population is at much greater risk of experiencing tinnitus, regardless of whether they have sensorineural or CHL. Tinnitus varies in disturbance level from non-bothersome to a disabling condition. It can negatively affect a person’s emotional wellbeing, their social life, relaxation and work performance. Tinnitus may also contribute to psychological problems such as depression, stress, anxiety, anger and suicidal thoughts (Kochkin and Tyler, 2008).

The FMT can be placed on viable parts of the ossicular chain including the incus and stapes, or on the RW where it is termed vibroplasty. As mentioned above, RW vibroplasty has been used since 2005 (Colletti et al., 2006) for mixed and CHL. To date, however, the optimal positioning and coupling of the FMT in cases of mixed and conductive losses has not been comprehensively investigated. It is still not clear whether better results would be achieved by placing the FMT in direct contact with the RW membrane, or by using an interposed material such as fascia or tutoplast (processed allograft pericardium) that sits between the FMT and RW, as shown in Figure 1.12. It is also not clear whether stapes or incus vibroplasty is comparable to RW vibroplasty with regard to the coupling and outcomes, especially in cases such as atresia or chronic ear disease where both vibroplasty options could be implemented.
Figure 1.12. Diagrammatic representation of FMT positioning to be evaluated in this study

a) Incus placement  
b) Stapes placement  
c) RW-FMT with interposed fascia  
d) RW-FMT with no interposed fascia

1.7. Aims of the study

This research was conducted to determine the efficacy of the VSB middle ear implant in patients with mixed or CHL. At the commencement of the study there were no published reports that compared the effectiveness of the VSB with that of hearing aids in patients with mixed or CHL. In addition, there were no studies of VSB outcomes that examined the benefits of device use on tinnitus perception. This was despite reports in the literature that 35% of people affected by some form of conductive loss also have tinnitus (Holgers et al., 2002). In this research, results from speech in quiet and in noise, as well as results from QOL questionnaires (including a tinnitus questionnaire) will be compared to pre-operative data attained with CHAs. In this way, each subject serves as their own control in a single test protocol.

The optimal positioning of the VBT internal FMT is still debatable in the case of mixed and CHL and is likely to have a critical effect on hearing outputs. There is much debate
between different surgical groups and experimental studies to date on placement in cadavers and on ‘living subjects’ have not proven definitive. This study will attempt to provide greater clarity on the optimal placement of the FMT. The impact on hearing outputs and coupling efficiency will be evaluated by comparing various vibroplasty types in the middle ear, including the RW, both with and without interposed fascia, incus or stapes placement.

1.7.1. Aim 1
Background: VSB application is proven in sensorineural hearing loss to be an effective treatment option, however, no studies have examined the benefits of VSB-RW application compared to performance with air conduction hearing aids.

Aim 1: Does the VSB-RW application provide comparable results as CHAs for speech perception in quiet and in noise?

This aim was addressed in Chapter 3.

1.7.2. Aim 2
Background: QOL outcomes are critical for ensuring the success of any hearing intervention or management. No study to date has examined tinnitus perception in patients with mixed or CHL and how this may be affected with use of the VSB device.

Aim 2: Does the VSB-RW application improve QOL outcomes, specifically tinnitus perception?

This aim was addressed in Chapter 4.

1.7.3. Aim 3
Background: The VSB-RW is a rehabilitation option for people with conductive, mixed and sensorineural hearing losses. The positioning of the FMT in vibroplasty could have a significant effect on hearing outputs.
Aim 3.1: Is stapes or incus vibroplasty comparable to RW vibroplasty with regard to coupling and outcomes?

Aim 3.2: Are different FMT attachment points critical in hearing outcomes and do they provide equivalent hearing outcomes?

These aims were addressed in Chapter 5.
2. **Methods**

2.1. **Study populations**
Potential recipients of the VSB-RW application were identified by ear, nose and throat (ENT) specialists and audiologists at the Fremantle and Sir Charles Gairdner Hospitals. Approval from the human research ethics committees was obtained from these institutions. Subjects had to fall within the manufacturer’s audiological inclusion criteria, namely:

- Bone conduction thresholds have to be better than or equal to 45dBHL at 500Hz, 50dBHL at 1000Hz and 65dBHL at 2000 and 4000Hz.
- Speech perception in quiet in the ear to be implanted had to be 50% or better.
- The hearing loss had to be stable.
- Subjects 18 years of age or older, and
- Subjects must have realistic expectations on post-operative performance with the VSB.

There was also one additional criteria for this study. Subjects had to be fitted with an appropriate hearing aid within the past 2 years, either through daily use or in a hearing aid trial. Surgery was undertaken by two ENT surgeons experienced in implantable devices. Patients were audiologically assessed pre-operatively and then again at 3, 6, 12 and 24 months post-implantation surgery. A total of 26 patients were involved in the study. Information on patient demographics (age, pathology, HLs) are shown in Tables 2.1, 2.2 and 2.3.

2.2. **Standard audiological evaluation**
Pure tone audiometry, tympanometry and unaided speech perception testing under headphones was conducted as per standard audiological evaluation. The sound booth,
audiometer and free-field speakers were calibrated to relevant American National Standards Institute (ANSI) standard.

2.3. **Aided threshold testing**

Aided thresholds were determined from 250 to 8000Hz in the free field using warble tones whilst the subjects wore the VSB processor. Figure 2.1 below shows a diagrammatic representation of the test set-up. The contralateral ear was plugged with a foam plug and then with headphones to ensure it did not assist during the test procedure. This was especially important given the contra-lateral ear was typically the better hearing ear and in some subjects had normal hearing thresholds.

Figure 2.1. Aided thresholds were compared to unaided thresholds to determine the functional gain of the VSB

2.4. **Speech recognition in quiet testing**

Speech testing was conducted using pre-recorded speech material and presented in a sound booth. The sound booth, audiometer and free-field speakers were calibrated to the relevant ANSI standard. Monosyllabic word test at 65dBSPL (decibels at sound pressure level) was conducted in the following conditions: a) implanted ear unaided, b) implanted ear aided with CHAs used pre-operatively and c) implanted ear wearing the VSB. In all three conditions, the contralateral ear was masked (Figures 2.2a-c).
2.4.1. Speech in noise testing

Each subject served as their own control in a single test protocol that compared the effects of VSB to results obtained in unaided and in conventionally aided hearing conditions. Results were obtained for all patients, including those who could not tolerate the consistent use of a hearing aid. For the purpose of this study, speech in noise measures were collected either with the subject’s own digital hearing aid(s), or with a fully digital six channel behind-the-ear hearing aid. The subjects’ personal hearing aids ranged in technology from fully digital six channel power behind-the-ear hearing aids, to 20 channel receiver-in-the-canal hearing aids. If a subject had bilateral hearing loss then both ears were fitted pre-operatively with CHAs. Aids were fitted or adjusted to best meet targets according to the NAL-NL1 prescription (Dillon, 2001) taking into account the conductive component. The VSB processors used were the standard Audio Processor 404 (AP404) or the low output version of the AP404. Neither version of the AP404 has a directional microphone. Speech testing was conducted using pre-recorded speech material and presented in a sound booth. The sound booth, audiometer and free-field speakers were calibrated to the relevant ANSI standard.

No standardised, pre-recorded adaptive speech in noise test with an Australian speaker was available. Therefore the Australian version Bench-Kowal-Bamford (BKB) sentence test with four speaker multi talk babble was used in an adaptive protocol. The patient sat at an equidistance of 1m from two speakers, one placed at 0º azimuth and the other at either 90º or 270º azimuth.
Figure 2.2a  Implanted ear unaided and contralateral ear plugged

Figure 2.2b  Implanted ear aided with the CHA used pre-operatively and contralateral ear plugged

Figure 2.2c  Implanted ear wearing the VSB and contralateral ear plugged

The target sentences were consistently presented at 0º azimuth at 65dBSPL. The four speaker multi talk babble was varied in 1dB steps until the subject achieved a score ranging between 48-52%, or as close as possible to this. The resulting signal-to-noise
ratio was recorded for all three listening conditions *i.e.* S0N0, S0N90, S0N270 (Figure 2.3). Percentage scores were then obtained post-operatively while employing the pre-operative signal-to-noise ratio, so that the percentage change in pre- and post-operative performance could be compared (Davis *et al.*, 2001; Eager, 2010). Although this procedure was initially devised for a paediatric hearing aid fitting study of non-linear hearing aids, it was appropriate given the sensitivity to performance of different amplification systems.

In the pre-operative condition, optimised CHAs were fitted either monaurally or binaurally depending on the hearing loss. In the post-operative condition, one ear was fitted with the VSB, and for subjects with bilateral hearing losses the contralateral ear was re-fitted with the same hearing aid as pre-operatively.

**Figure 2.3. Speech in noise test configurations**

![Speech in noise test configurations](image)

- a) Speech (S) and noise (N) presented at 1m directly in front of subject
- b) Speech presented in front and noise at 90° (normalised to VSB implanted side)
- c) Speech presented in front and noise at 90° (normalised to contra-lateral ear).

### 2.5. Coupling method and measurements of coupling efficiency of the FMT

#### 2.5.1. Coupling method

Coupling method was defined for each patient according to whether they had an intact ossicular chain or an ossicular chain remnant in which case the stapes or incus were used
as an attachment point. If the RW vibroplasty was employed there was either: 1) fascia interposed and fascial covering FMT, or 2) direct coupling with no fascia interposed but fascial covering. In cases of direct coupling, FMT contact was further delineated by either complete or partial contact.

2.5.2. Vibroplasty coupling measurements
Measurement of the vibroplasty thresholds was similar to pure-tone audiometry with the stimulus being presented via the FMT. Behavioural vibroplasty thresholds were determined by applying the modified Hughson-Westlake method (Carhart & Jerger, 1959). Results were reported on a decibel scale which was normalised to the maximum transducer excitation voltage of the FMT (dB re. 4.47 uV).

To investigate the relationship between vibroplasty thresholds and traditional bone conduction thresholds, the vibroplasty thresholds were entered into a scatter plot versus corresponding bone conduction thresholds. In addition, a linear trend was calculated for each test frequency. The difference between the trend line and data points of an individual subject, averaged across all test frequencies, was used to calculate the relative coupling efficiency. The underlying assumption was that data points below the regression line are indicative of ‘good’ coupling, meaning ‘better than the average within the study’.

2.6. Implant benefit questionnaires
These were administered pre-operatively and at 1, 3, 6 and 12 months post-operatively.

2.6.1. The APHAB
The APHAB Version A (Cox and Alexander, 1995) is a standardised 24-item self-assessment inventory in which the subject reports the degree of difficulty they have with communication and perception of environmental sounds. A copy of the questionnaire is show as Appendix 1. The questionnaire’s outcomes are divided into four subscales: EC, BN, RV and AV. The subscales EC, BN and RV are used to examine
speech understanding in everyday situations. The AV scale examines negative reactions to environmental sounds. The APHAB was administered pre-operatively and at 1, 3, 6 and 12 months post-operatively.

2.6.2. The TRQ
The TRQ (Wilson et al., 1991) was used to assess the degree that disturbance from tinnitus has impacted the subjects’ wellbeing, emotions and lifestyle. A copy of the TRQ is shown in Appendix 2. The TRQ was also completed before and after surgery in order to compare post-operative outcomes. The range of scores with TRQ is a maximum of 104 and a minimum of 0. All post-operative testing was conducted at 1, 3, 6 and 12 months, with the most recent result being the post-operative score. The latter was compared to pre-operative results.

2.7. Statistical analysis

2.7.1. Statistical methods used in Chapter 3
All participants were entered in a custom-written Microsoft Access database. Data were plotted using Microsoft Excel and analysed using SPSS v19. Pre- and post-operative air- and bone conduction thresholds were examined for differences using the paired sample T-test. Speech recognition in quiet test data were analysed using Wilcoxon signed rank test to determine if there was a significant change in results. Speech recognition in noise scores were analysed using the paired-sample T-test and univariate analysis of variance test. The Shapiro-Wilk W test was used to determine if the data was normally distributed.

2.7.2. Statistical methods used in Chapter 4
The data distribution of the APHAB global scale and its four subscales of the individual subjects are shown in graph format. The subjective benefit was measured using the APHAB at different test intervals after implantation and compared to the pre-operative acoustic hearing condition. To detect differences between the pre-operative test results
and the most recent post-operative testing, the non-parametric Wilcoxon signed rank test was applied. The Kolmogorov Smirnov test was used before to check the data distribution. To determine also the clinical relevance, a benefit score of the APHAB was assessed, according to the method of Cox and Alexander (1995). The benefit score was calculated by subtracting the aided average (most recent post-operative score) from the unaided average (e.g. pre-operative score). If the difference in benefit scores on the three subscales EC, RV and BN were at least 10% (difference in mean) greater for the respective test strategy, it can be concluded from a clinical perspective that this difference reflects a true benefit with a 95% probability.

To detect differences in the TRQ between the pre-operative test results and the most recent post-operative testing, the non-parametric Wilcoxon signed rank test was applied. The Kolmogorov Smirnov test was used as before to check the data distribution.

2.7.3. Statistical methods used in Chapter 5
The Mann-Whitney $U$ test was used to compare coupling efficiency of the FMT in various placements: a) Fascia between FMT and RW, b) Direct FMT contact, c) FMT crimped to incus, (long process) and d) FMT crimped to stapes (on the posterior crus). The Wilcoxon signed rank test was used to determine if there was a significant change in results of speech recognition in quiet.

The non-parametric Wilcoxon signed-rank test was applied to analyse APHAB scores. The Kolmogorov-Smirnov test was used to check the data distribution. A benefit score of the APHAB was assessed as per the method of Cox and Alexander (1995) to determine the clinical relevance. The benefit score was calculated by subtracting the aided average (most recent post-operative score) from the unaided average (pre-operative score). If the difference in benefit scores on the three subscales EC, RV and BN was at least 10%
(difference in mean) greater for the respective test strategy, it can be concluded from a clinical perspective that this difference reflects a true benefit with a 95% probability.

To detect differences between the pre-operative TRQ test results, a difference of 40% was deemed to be significant as per the recommended analysis (Wilson et al., 1991). A non-parametric Wilcoxon signed-rank test was also applied.
3. **Comparison of hearing aids and RW application of the VSB**

The work described in this chapter was published in:


3.1. **Abstract**

The purpose of this chapter is to determine the efficacy of the RW application of the VSB in patients with mixed or CHL. Speech in quiet and in noise were compared to pre-operative data obtained with CHAs so that each subject served as his or her own control in a single test protocol. Eighteen adults were implanted monaurally with the VSB in the poorer hearing ear and experience with the VSB ranged from 9 to 25 months. Sixteen of the 18 subjects were successful VSB users and wore their device during all waking hours. There was no significant deterioration in the average pre-operative bone conduction results versus post-operatively (p<0.05). Speech recognition in quiet results were not significantly different to those attained whilst wearing hearing aids (p<0.05). Speech recognition in noise performance was substantially improved with use of the VSB in most test conditions. For the majority of subjects, the VSB was an effective method of hearing restoration for mixed and CHL.

3.2. **Introduction**

The proportion of the population with a conductive or mixed hearing loss is estimated to be 0.4% and 0.6%, respectively (Wilson *et al.*, 1998). Amongst these, a subset cannot make use of CHAs for various medical, physiological or technical reasons. Limitations in hearing aid functionality arise when hearing aids cannot provide sufficient
amplification in the case of CHL, or when medical problems preclude the use of conventional amplification. Medical contraindications to the fitting of hearing aids include several conditions affecting the outer or middle ear.

Such conditions may directly affect the coupling of hearing aids or moulds with the ear canal, for example in the case of chronic otitis externa, aural atresia, or permanent alteration of the ear canal due to reconstruction (Frenzel et al., 2009). Conditions affecting the middle ear or integrity of the ossicular chain may require greater amplification than a hearing aid can provide, for example in cases of COM with extensive destruction of the ossicular chain or severe otosclerosis (Colletti et al., 2009).

With the development of open-fit hearing aids, sufferers of various outer or middle ear pathologies can be fitted with hearing aids which occlude the ear canal to a significantly lesser degree than traditional hearing aid fittings using moulds. This allows many more people to become successful hearing aid users without initiation or exacerbation of outer- and middle ear infections. However, a true open ear canal fitting cannot accommodate all types of hearing losses, particularly those with a significant degree of impairment in the lower frequencies, or conductive losses where greater gain is required, typically in the order of half the sensorineural component and half again of the conductive component (Dillon, 2001). If patients with outer ear conditions (such as chronic otitis externa or permanent alteration of the ear canal) and a conductive or mixed hearing loss (where the sensorineural component was minimal) could wear a more closed hearing aid, they would most likely benefit from conventional amplification. This is with the understanding that patients with conductive losses usually have good sound tolerance and excellent speech recognition scores (Dillon, 2001). Furthermore, with bone conduction thresholds better than 65dBHL, dead cochlear regions which can adversely affect speech perception functioning are highly
unlikely. Middle ear implants provide a possible solution to this dilemma because they do not occlude the ear canal and are therefore also suitable for patients suffering from outer ear conditions or who lack a viable ear canal. One of these is the VSB which was initially coupled to the incus, but has also recently been placed directly onto the round window (VSB-RW), allowing it to overcome the conductive component of hearing losses by bypassing the middle ear. Furthermore, in patients with mixed hearing loss it can overcome the sensorineural component of the loss via amplification provided by the VSB system (Beltrame et al., 2008).

Other available implantable devices that target this group of patients are the Baha® (Cochlear Ltd, Australia) and the Carina MET (Otologics, USA). Such devices work by applying vibrational energy to the entire skull (Baha®) or to individual cochlea (Carina MET). The Baha® can provide good results for patients with CHL or mild mixed hearing losses (Snik et al., 2004) and was the first commercially available device. The fitting range of the Baha Intenso (ear level) is claimed to be narrower than that proposed by the manufacturer. Bosman et al. (2009) report the fitting range is limited to 42, 44, 58, and 48dBHL for bone conduction thresholds at 500, 1000, 2000, and 4000Hz, respectively.

Complications with the percutaneous coupling can also occur, with reported complication rates ranging from 6.7% (Hakanson et al., 1990), to 38% (Gluth et al., 2010) of patients experiencing severe skin reactions. Surgery revision rates can vary from 12.1% in 602 Baha implantations (Hobson et al., 2009) to 34% of 177 Baha implantations requiring revision surgery due to loss of osseointegration, pain, severe skin reactions, thickening or overgrowth of skin, primary bleeding, hair growth around the abutment, intolerable pain, and recurrent infections (Badran et al. (2009). Serious
complications were rare and the surgery did not involve the structures of the middle ear or mastoid.

The Carina MET (Otologics) middle ear implant consists of a fully implantable prosthesis that can be coupled to the stapes footplate or to the RW (Tringali et al., 2007). The battery has a limited number of charging cycles and a limited lifetime, meaning that additional surgery is required to change components of the implant and for any updates that are not software driven. This is a significant disadvantage when compared to semi-implantable devices. A study of 11 patients with mixed hearing loss implanted with the Carina MET reported two cases of infection (one requiring explantation) and one of reduced initial benefit and eventually a non-functioning device (Martin et al., 2009). Results in the remaining eight patients showed improved speech recognition, but were inconsistent in terms of the benefit as assessed by the ABPHAB questionnaire.

Another study implanted eight patients: seven with sensorineural hearing loss and one with a mixed hearing loss (Bruschini et al., 2010). Two patients required surgical revision at least once after initial implantation, and one device was removed for reasons unrelated to the performance of the device. Post-operative free field thresholds improved, as did speech perception.

The VSB has been in use since 1996 as a middle ear device to treat sensorineural hearing loss. Since 2005 the VSB transducer (the FMT) is placed in the RW niche where it bypasses the disordered outer and/or middle ear. This delivers vibrational sound energy directly to the cochlea to compensate for the sensorineural component of the hearing loss. The initial study included seven patients with ossicular chain defects and a history of unsuccessful ossiculoplasty (Colletti et al., 2006). Kiefer et al. (2006) extended the RW application to a patient with bilateral microtia and reported excellent
post-operative air conduction hearing thresholds within 30dB. Wollenberg et al. (2007) applied the VSB to three patients with atretic ears and all demonstrated excellent post-operative open-set speech recognition results when tested in a quiet listening situation. The RW application was extended with good results for subtotal petrosectomy and complete fat obliteration of the middle ear and mastoid cavities (Linder et al., 2008). Frenzel et al. (2009) performed the RW application in patients with unilateral osseous atresia and reported good outcomes. Colletti et al. (2009) used the VSB-RW application in 19 patients with bilateral moderate to severe mixed hearing losses. They reported better performance compared to an unaided group of matched subjects who had undergone ossiculoplasty using a total ossicular replacement prosthesis to overcome the conductive component of their mixed hearing loss. Dumon et al. (2009) demonstrated the effectiveness of the VSB on either the ossicular chain or the RW membrane, and whether implanted alone or as part of another middle ear procedure.

Previous studies have compared patient performance using the VSB in the classic application with a hearing aid that used the same audio processing technology as in the VSB (Uziel et al., 2003). However, no published studies have compared patient performance using conventional air conduction hearing aids to that of the VSB-RW application for the treatment of mixed or CHL.

The aims of this study were therefore to (1), determine the effects of VSB-RW surgery, (2) establish the effect on hearing of the VSB-RW application in individuals with a mixed hearing loss or CHL, and (3) compare these results with hearing outcomes obtained with traditional hearing aids in the same test settings, specifically in speech perception in quiet and in noise test situations.
3.3. Methods
The patient cohort studied in this chapter, together with the audiological evaluations and statistical techniques are described in Chapter 2.

3.4. Results

3.4.1. Post-operative surgical findings and experiences
While there were no complications reported during surgery, device positioning of the FMT was challenging for subject 17 who had congenital external and middle ear abnormalities. Typical waiting periods between device implantation and activation were 4-6 weeks. No subjects in this study reported post-operative fullness, taste disturbance, or vertigo. The majority described tenderness over the implant site and slept on the contralateral side for the first 2-6 weeks post-operatively. Two subjects (2 and 7) required the low output audio processor to be fitted as they were able to detect the internal noise of the external audio processor immediately following activation. Both had essentially normal cochlear hearing. While awaiting replacement with the low output device, an aluminium foil was placed on the underside of the processor to reduce the audibility of the internal noise (Table 3.1).

Of the 18 subjects, 11 reported immediate hearing benefit following activation of the external audio processor. At the final follow up time (range 9-25 months post-implantation), their devices were still working well. VSB surgery was deemed to be ‘successful’ for the purposes of this study if the patient achieved monosyllabic word speech perception scores of 80% or above in the implanted ear alone at a normal conversation level (65dBSPL). Subject 13 unfortunately died from causes unrelated to the VSB surgery or device usage. Prior to his death, he had worn the VSB and attained good results for 12 months.
Five subjects (3, 6, 16, 17, and 18) required revision surgery due to intermittent or no sound percept through the device. The onset of problems ranged from immediately post-surgery to 12 months of successful device usage. CT scans were performed prior to revision surgery to check the FMT position in the RW niche. In four of the five subjects, scan results confirmed migration of the FMT. Device failure was confirmed for the remaining subject (subject number 18), thought to be caused by a bony spur rubbing against the lead wiring.

Revision surgery consisted of repositioning the FMT and reinforcing the position with cartilage to create a rigid structure and prevent device migration. In three of the five subjects (3, 6, and 16) revision surgery was successful and these patients continued to do well after 17, 11, and 12 months respectively. Of the remaining two who underwent revision surgery, one (subject 18) experienced intermittent sound while the other (subject 17) continued to have a non-functioning device for no known reason. The hearing thresholds for both of these subjects remained within the recommended indication criteria and there was no change in unaided speech perception results. Successive CT scans showed no FMT dislocation from the RW.

Initial testing indicated excellent results for subject 10. Although the skin over the receiver coil was thin, it was intact and there was no indication of infection. After a period of 4 months, the patient experienced a severe flare of rheumatoid arthritis, for which she was prescribed a high dosage of steroids. This led to wound breakdown over the already thin skin on the receiver coil and resulted in infection in the surrounding area. Treatment, including use of a hyperbaric chamber, was unsuccessful and the implant required explantation.
Table 3.1. Subjects’ pathology, VSB experience and audiological characteristics including implanted ear pathology, surgical history pre-VSB, VSB surgical technique employed; (1) Facial recess approach to RW (Facial Rec); (2) RW placement in MRC; and (3) Subtotal petrosectomy, blind sac closure and cavity obliteration (Sub Pet.), Age (years), Audio processor used; standard 404 or low output (LO) device, experience with VSB (months), experience with VSB post-revision surgery, four frequency average (4FAHL) of implanted ear; bone and air conduction

<table>
<thead>
<tr>
<th>Subject</th>
<th>Pathology</th>
<th>Surgeries pre-VSB</th>
<th>VSB surgical technique</th>
<th>Processor type</th>
<th>VSB experience (mths)</th>
<th>Experience post-revision (mths)</th>
<th>Bone conduction (dBHL)</th>
<th>Air conduction (dBHL)</th>
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</table>

CSOM (chronic suppuratives otitis media) # required revision surgery with successful outcomes, ~ required device explantation, ^ now deceased, * No sound through VSB even after revision surgery, @ intermittent device functioning even after revision surgery.
3.4.2. Pre-operative versus post-operative bilateral pure-tone bone conduction thresholds

This data allows identification of possible cases of noise-induced hearing loss sustained while drilling out the RW, or hearing loss caused by physical damage to the RW. As shown in Figure 3.1, there was no significant deterioration in the four frequency averaged bone conduction results at 500, 1000, 2000, and 4000Hz. Average thresholds were 26.5dB (+/-11.4dB) pre-operatively compared to 26.9dB (+/-13.1dB) post-operatively (p<0.05).

Figure 3.1. Pre-operative and post-operative four-frequency average bone conduction thresholds (n=18)

A more specific examination of pre- versus post-operative unaided bone conduction thresholds demonstrated improvement in thresholds greater than 10dB for some subjects. Improvements ranged from 15-30dB at specific frequencies for subjects 2, 3, 5, 9, 10, 11, 14, and 17. Subjects 9 and 10 in particular showed improvements in thresholds, with their 4FAHL improving from 27.5-11.3dB and from 53.8-37.5dB, respectively. Conversely, subjects 4, 5, 7, 10, 11, 16, 17, and 18 experienced deteriorations in hearing thresholds at specific frequencies greater than 10dB. Subjects
15 demonstrated a deterioration of 25dB at 500Hz and subject 18 had a deterioration of 35dB at 2000Hz. Interestingly, many of the subjects who experienced improvement in thresholds at certain frequencies also showed deterioration in thresholds at other frequencies (subjects 5, 10, and 16).

3.4.3. VSB-aided thresholds versus pre-operative unaided thresholds
Overall, subjects with successful outcomes with the VSB experienced aided thresholds in the free field (with contralateral ear masked) of 40dBHL or better from 500-3000Hz (Figure 3.2).

Figure 3.2. Aided thresholds attained whilst wearing the VSB versus unaided thresholds (n=16)

Aided thresholds were not measured for subjects 17 and 18 as they did not benefit from the VSB. Although gain levels could have been increased in the processor fitting software to give even better aided thresholds, client preference played a major part in determining the gain and compression characteristics of each individual’s audio processor.
3.4.4. Pre- versus post-operative speech recognition in quiet
A significant improvement (p<0.05) in performance was found when comparing the unaided condition to the conventionally aided condition, and again when comparing the unaided condition to the VSB condition. The average unaided score was 7.6% (SD±15.2%). This compared to 85.3% (SD±11.8%) with a hearing aid and 83.8% (SD±24.5%) with the VSB (Figure 3.3).

Figure 3.3. Unaided speech perception in implanted ear versus aided speech perception whilst wearing hearing aid, and speech perception results while wearing the activated VSB. A monosyllabic word test in quiet was used at 65dB SPL presentation level

As speech perception data did not show normal distribution (p<0.05), the Wilcoxon signed rank test was used. This revealed significant differences (p<0.05) between unaided speech test results and assistance with either a hearing aid or a VSB. There was no significant difference (p=0.81) between the hearing aid and the VSB aided speech test results in quiet.
3.4.5. Pre- versus post-operative speech recognition in noise

Post-operative data for subjects 17 and 18 were not available for this test and hence these were not included in the analysis. Statistical analysis using paired-sample T-tests showed a significant difference between pre-operative and post-operative scores for each of the three speech recognition in noise tests: (1) for the S0N0 condition where noise and speech emanate from the same speaker in front of the subjects (p<0.002); (2) for the S0N90 condition where the noise is presented to the implanted ear and the speech from the front (p<0.05); and (3) for the S0N270 where the noise is presented to the non-implanted (contralateral) ear and the speech from the front (p<0.016).

Unilateral analysis of variance, with the speech in noise score as the dependent variable, and the test condition (S0N0, S0N90, or S0N270), and pre- or post-operative test as the factors, revealed a significant improvement in scores (F=20.25, p<0.001, β=0.994), but no significant effect due to the test condition. A plot of the percent change between the pre-operative score (with optimally fitted hearing aids) and post-operative score (with a VSB and an optimally fitted contralateral hearing aid, where appropriate) allowed investigation of the individual outcomes (Figure 3.4).

For test condition S0N0, only subject 15 showed deterioration of scores. For test condition S0N90, most subjects showed unchanged or improved scores, with subjects 2, 8, and 11 experiencing approximately 40% improvement. For test condition S0N270, all but three subjects improved their scores in post-operative testing.
Figure 3.4. Percent change in speech in noise scores from scores attained while wearing hearing aid versus scores attained with VSB (n=16)

a) Percent score change in S0N0 listening condition
b) Percent score change in the S0N90 listening condition. Results are normalised so that noise was presented to the implanted ear. (c) Percent score change in S0N270 listening condition. Results are normalised so that noise was presented to the non-implanted ear.
3.5. Discussion
The results of this study indicate that VSB proved to be a successful method for the rehabilitation of conductive or mixed hearing loss in 16 of 18 study subjects. No post-operative symptoms such as fullness, taste disturbance or vertigo were experienced, in contrast to previous studies (Sterkers et al., 2003; Schmuziger et al., 2006).

When averaged across all participants, no significant change in post-surgical bone conduction threshold was found. This is consistent with other studies of the VSB-RW application, with the exception of Linder et al. (2008) who noted a deterioration in bone conduction results at 2000Hz. This was postulated to be related to loss of the middle ear component close to the resonant frequency of the ossicular chain. A comparison of changes in bone conduction thresholds for individual subjects indicated substantial variability, with improvement of up to 30dB and deterioration of up to 35dB at some frequencies. Individual variation in bone conduction results pre- and post-operatively are not generally reported in the literature for the VSB-RW application and hence it cannot be determined whether this is consistent with other similar studies. While there are no clearly defined criteria for what constitutes a significant change in hearing thresholds, a change of more than 5dB is generally accepted to be significant. Some authors have suggested that variability in bone conductor positioning can lead to test re-test variability of up to 8dB (Robinson & Shipton, 1982), which would explain only a small component of the variation found in this study. The bone conductor placement may have contributed to the variability, since the post-operative placement may have differed significantly from pre-operative placement due to the in situ implant. While less efficient than mastoid placement, frontal bone placement of the transducer could possibly have been used in both pre- and post-operative measurements in order to ensure greater retest reliability.
A further cause of variability could be discomfort caused by pressure from the bone conduction headband over or close to the implant site. Significant deterioration in bone conduction thresholds could indicate possible cases of noise-induced hearing loss sustained while drilling out the RW, or hearing loss caused by physical damage to the RW, and can thus be readily explained. Significant improvements in bone conduction thresholds are more difficult to explain, but may indicate that measured sensorineural hearing thresholds are dependent on middle ear mechanics in addition to cochlear mechanics. It is well known that bone conduction thresholds can be depressed around 2000Hz when changes in ossicular function and middle ear resonance are caused by otosclerosis (Pickles, 2008). This can be reversed after surgery, indicating that middle ear surgery can cause measurable improvement in sensorineural hearing thresholds. Similarly, individual variation in bone conduction thresholds could be due to changes in the acoustics and resonance of the middle ear and cochlea. This may be caused by the additional mass of the FMT on the RW, reduced middle ear volume after insertion of the FMT and securing tissue, together with interaction of the remaining middle ear components after surgery.

Aided thresholds for most subjects were 40dBHL or better from 500-3000Hz. At 4000Hz the average post-operative threshold was 46.9dBHL, but this had improved from an average pre-operative threshold of 80.0dBHL. This means the entire speech spectrum was made audible at conversational level. Speech recognition in quiet results with the VSB were greatly improved compared to unaided performance and were equal to pre-operative performance whilst wearing conventional amplification. No significant difference was found when comparing performance of the CHA with the VSB, probably due to ceiling effects. An adaptive speech test in quiet may have been more sensitive to changes between the two aided conditions. Schmuziger et al. (2006) found that speech performance in quiet was better with CHAs than with the VSB, although this was in the
classic VSB application with coupling of the FMT onto the incus in sensorineural hearing loss. In contrast, other studies have demonstrated better performance with the VSB (Todt et al., 2002; Truy et al., 2008; Sterkers et al., 2003), while Leutje et al. (2002) showed equivalent performance between CHAs and the VSB in quiet.

The present study demonstrated better speech recognition in noise with the RW application of the VSB than with a CHA. Other comparative studies of hearing aids versus VSB with standard incus coupling found equivalent (Schmuziger et al., 2006, Luetje et al., 2002) or better speech in noise performance with the VSB (Todt 2002; Uziel et al., 2003; Truy et al., 2008). Five of the subjects were fitted pre-operatively with sophisticated 20-channel hearing aids with adaptive directionality and noise suppression features. No directional microphone was available in the VSB audio processor (AP404) used for subjects in this study.

Nevertheless, performance with hearing aids was for the most part overshadowed by results attained with the VSB. This can be attributed to the distortion in sound quality that occurs when CHAs provide the substantial gain required to meet the amplification needs of patients with significant mixed hearing. Maier (2009) reports that in some severe mixed hearing losses, a pressure change of 2% must be generated in the small space of the average adult ear canal (approximately $2\text{ cm}^3$) by a small loudspeaker before sufficient amplification can be delivered to the auditory system. The hearing aid user then faces the additional challenge of integrating the resulting distorted signal with a very different signal received in the contralateral ear. Since the conductive component of the hearing loss is bypassed when the FMT is positioned on the RW, less gain is required, distortion is reduced, and potential difficulties from blending the signal with that received from the contralateral ear are diminished.
Another possible contributor to the better results in noise with the VSB in comparison to CHAs could be the increased acclimatisation time with the VSB processor. All subjects could not wear their CHA pre-operatively for any length of time without exacerbation of otitis externa, pain, or distortion of the sound, whereas there were no contraindications to constant VSB use.

Three of the 18 subjects experienced less than optimal results. One subject required device explantation due to infection at the implant site after 4 months of successful use. The causes of intermittent device functioning in one subject (subject 18) and no sound percept through the VSB for another subject (17) remain unclear. In the case of intermittent sound in subject 18, the FMT may have moved in and out of position in the round niche, although three post-operative CT scans confirmed correct device positioning. Device testing indicated the implant was working well and the subject’s hearing had not changed significantly and was still within the VSB fitting criteria. Another possibility is that a damaged lead wire caused the FMT to inconsistently receive sufficient current for vibration. Previously this subject had required revision surgery because of lead wire damage which was confirmed by the manufacturer.

In the case of the subject with no sound percept (subject 17), device testing and CT scans confirmed the internal implant was working well and the FMT was in the correct position. Audiological testing confirmed cochlear functioning was still in the VSB fitting range. This subject presented with congenital abnormality of the external and middle ear. Possible explanations for the poor outcomes include immobility of a damaged or stiffened OW an abnormally functioning RW, or middle ear instability. Dumon et al. (2009) reported that stability of the middle ear is essential for long-term tolerance and stability of the implant. This subject was offered a Baha pre-operatively and then post-operatively trialled a Baha on a test band for a period of 1 month.
However, the subject declined to pursue this option, opting instead for an open-fit hearing aid for his contralateral ear which has a mild to moderate high frequency sensorineural hearing loss.

In our study, we did not account for the possible interaction between the input received at the OW and that received at the RW. Theories developed in the 1950s (Wever & Lawrence, 1954) and highlighted by Colletti et al. (2006) propose that acoustic stimulation of the RW can result in equivalent cochlear potentials to those elicited via OW stimulation. This theory supports the application of devices such as the VSB, which can be used to stimulate the RW directly in cases where the normal middle ear pathway is compromised. It also suggests that cochlear potentials will be the vector sum of the two inputs received at the OW and RW. This could have implications for subjects in the present cohort with milder forms of conductive and sensorineural loss who still had an intact ossicular chain and normal OW function. These subjects could in theory be experiencing some phase cancellation and subsequent degradation of incoming sounds when they receive equivalent signals from the OW and RW, an effect we did not measure. In considering candidates for the VSB-RW application, the greater the degree of CHL (decreasing the relative input of the OW) and the greater the degree of sensorineural hearing loss (increasing the relative input of the RW), the more effective the RW application of the FMT (Colletti et al., 2006).

With results compromised for two of the 18 subjects following VSB surgery, particularly for subject 17 where blind sac closure was conducted to ensure stability of the FMT, the question arises as to how better outcomes may have been obtained. Recently, conscious sedation for eight patients undergoing vibroplasty was conducted (Canale et al., 2009). All eight patients responded and could give feedback to ensure correct device positioning. This technique was employed for subjects in the present
study who required revision surgery and could perhaps also be performed routinely for selected cases.

The large number of subjects in our study who required revision surgery or showed sub-optimal results raises another question. Should VSB candidates with a pure conductive or milder mixed hearing loss be offered the Baha as a trial hearing solution prior to VSB implantation? Dumon *et al.* (2009) suggest the Baha may be a better option for subjects who, while fulfilling audiological criteria, do not have stable middle ears. Five of the 18 subjects (including subject 17 who received no sound percept) were offered the Baha but were reluctant to explore this option due to device aesthetics.

Linder *et al.* (2008) reported in their study that all subjects were able to choose between a VSB and Baha and all declined the Baha because of the hollow sound quality and fear of skin infection. It is still our view that where appropriate a bone conductor aid trial should be extended to all patients who are considering the VSB for mixed or CHL.

It was a prerequisite of this study that VSB subjects had excellent speech recognition results in the implanted ear. In cases of bilateral mixed hearing loss it can be difficult to determine a patient’s true speech perception abilities due to difficulty in providing sufficient amplification. Care should therefore be taken to ensure that results truly reflect the patient’s speech perception abilities in the ear considered for implantation. Given the VSB provides stimulation to the implanted ear alone, it is vital this ear has good speech perception as per the manufacturer’s guidelines of 50% or better speech recognition results on a monosyllabic word test. This highlights the importance of thorough pre-operative assessment for all potential VSB cases.

In conclusion, CHAs do not cater for a proportion of the population with mixed/CHL for reasons including insufficient amplification or pathologies of the outer or middle ear. This study shows the VSB-RW application to be an effective alternative, with the
majority of our subjects having equivalent speech performance in quiet outcomes with the VSB as they did pre-operatively with CHAs. The majority of subjects were able to substantially improve their speech recognition in noise. Prior to consideration of VSB, it is recommended that a thorough pre-operative assessment be conducted. In indicated cases a bone conduction aid on a test-band trial should also be offered.
4. **Tinnitus and QOL outcomes after VSB**

The work described in this chapter was published in:


4.1. **Abstract**

In Chapter 3 it was demonstrated that the VSB-RW application could improve patients’ speech perception performance both in quiet and in noise. In the latter condition, the improvements were greater than those observed with CHAs. The aim of work presented in this chapter was to measure the QOL outcomes and impact on tinnitus perception in patients following VSB-RW treatment for mixed or CHL.

A single-subject, repeated measures design was employed. All VSB fittings were based on hearing threshold results and were not set to mask tinnitus. Ten VSB-RW patients were assessed with the APHAB and the TRQ. Subjects reported less hearing difficulties in three of the four APHAB subscales. Tinnitus perception was decreased in all subjects with pre-operative tinnitus.

VSB-RW in our cohort of patients with mixed or conductive hearing improved their QOL outcomes. There was significant improvement of APHAB scores and a significant decrease in tinnitus perception in subjects who experienced tinnitus prior to implantation.

4.2. **Introduction**

The FMT (MedEL, Innsbruck, Austria) was initially coupled to the Incus to treat patients who were unable to wear a CHA or who were dissatisfied with their hearing aid(s) because of issues such as poor sound quality, feedback and/or occlusion effect.
Vibration of the FMT results in movement and sound transmission to the cochlea via the ossicular chain. Incoming sounds are transmitted to the FMT via an externally worn sound processor. After the initial VSB-RW described by Colletti et al. (2006), various types of FMT coupling modalities have been developed and are generally referred to as vibroplasty.

In VSB-RW, the FMT is placed onto the RW membrane in patients with conductive or mixed hearing loss who cannot wear CHAs. By bypassing the pathologic outer and/or middle ear, vibrational sound energy is transmitted directly to the cochlea to compensate for the conductive and/or sensorineural component of the hearing loss.

The improvement in speech perception and access to sound with VSB-RW has been demonstrated in many studies (Colletti et al., 2006; Ambett et al., 2010; Baumgartner et al., 2010; Dumon et al., 2009; Wollenberg et al., 2007). However, only one study to date has examined QOL improvement with VSB use in patients with conductive of mixed hearing loss (Baumgartner et al., 2010).

It is estimated that approximately 33% of people experience tinnitus (McFerran and Phillips, 2007) and that 10-20% of these experience debilitating or crippling tinnitus (Henry et al., 2005). Approximately 70-85% of the hearing impaired population experience some form of tinnitus (Martines et al., 2010) and prevalence rates are higher with increased hearing loss (Nondahl et al., 2002). In people affected by CHL, 35% have been found to have tinnitus (Holgers and Hakansson, 2002). Tinnitus varies in disturbance level from non-bothersome to a disabling condition.

The aim of this study was to measure QOL outcomes in patients following VSB-RW treatment for mixed and CHL. This was achieved using the APHAB and the TRQ. To date, there have not been any reports on VSB outcomes that evaluated the benefits of this device on tinnitus perception.
4.3. Methods
All methods used here were described in Chapter 2.

4.4. Results
A total of 10 patients (seven females and three males) were included in the study. Individual patient details are given in Table 4.1. The average age at surgery was 55.4 years (SD±15.8; range 26.0-78.6), with the average for male patients being 49.7 years and for females 57.9 years. Four subjects had a pure CHL whereas six had a mixed hearing loss in the ear considered for implantation. Subjects were unable to derive benefit from CHAs because of chronic otitis externa (subjects 1, 5-10), blind sac closure (2), pain associated with hearing aid mould use (3), and severe to profound mixed hearing loss (4). Nine subjects had the RW placement in modified radical cavities (MRCs) and one subject (4) was implanted using the facial recess approach. Fascia or perichondrium was used to stabilise the implant in the RW niche and the cable was fixed into a groove in the mastoid with bone pate and soft tissue flaps for cavity obliteration and coverage of the conductor link.

The mean hearing loss in the implanted ear using the four frequency average of air conduction thresholds was 68.25dB (SD±18.12dB). The average bone conduction threshold was 22.75dB (SD: ± 10.26) in the implanted ear.
Table 4.1  Subjects’ pathology, surgical and audiological characteristics

<table>
<thead>
<tr>
<th>Subj No</th>
<th>Age (yrs)</th>
<th>Pathology</th>
<th>Surgeries (no.) Pre-VSB</th>
<th>VSB Surgical Technique</th>
<th>VSB Experience (mths)</th>
<th>VSB experience post-revision (mths)</th>
<th>4 FAHL (dBHL)</th>
<th>Bone Conduction</th>
<th>Air Conduction</th>
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<tr>
<td>1</td>
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<td></td>
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<tr>
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<td>59</td>
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<td>RW in MRC</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
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<td>RW in MRC</td>
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<td>17</td>
<td>9</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>4</td>
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<td>1</td>
<td>Facial Rec</td>
<td>24</td>
<td>38</td>
<td>101</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>25 *</td>
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<td>RW in MRC</td>
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<td>70</td>
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<td>RW in MRC</td>
<td>4</td>
<td>21</td>
<td>68</td>
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<td>4</td>
<td>RW in MRC</td>
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<td></td>
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<tr>
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<td>RW in MRC</td>
<td>9</td>
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<tr>
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<td>RW in MRC</td>
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<tr>
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<td>78 §</td>
<td>CSOM</td>
<td>3</td>
<td>RW in MRC</td>
<td>1</td>
<td>12</td>
<td>40</td>
<td>91</td>
<td></td>
</tr>
</tbody>
</table>

Otoscl: Otosclerosis; VSB: surgical technique employed: Facial rec: Facial recess approach to RW; RW in MRC: RW placement in Modified Radical Cavities; Experience with VSB (months); Experience with VSB post-revision surgery; four frequency average (4FAHL) of implanted ear; Bone and air conduction. * required revision surgery with successful outcomes; + required device explantation; § intermittent device functioning pre- and post-revision surgery.

Three of the 10 patients (subjects 3, 5 and 10) required revision surgery either because of FMT displacement or device failure in one subject (subject 10). In both cases with progressive loss of hearing related to FMT migration, this occurred between 3-6 months after surgery. Following revision surgery, subjects 3 and 5 had success with the device, whereas subject 10 experienced intermittent sound with the VSB.

Initial testing indicated excellent results for subject 6. The skin over the receiver coil was thin but intact and there was no indication of infection. After a period of 4 months, the patient experienced a severe flare of rheumatoid arthritis for which she was prescribed a high dose of steroids. This led to the wound breaking down over the already thin skin on the receiver coil, resulting in infection of the surrounding area. Treatment (including use of a hyperbaric chamber) was unsuccessful and the implant required explantation.
Subject 1 reported a “static-like” noise when in close proximity to the telecommunications centre at his work and when walking through department store security doors.

There was no significant deterioration ($P<0.05$) in the four frequency averaged bone conduction results at 500, 1000, 2000 and 4000Hz pre-operatively compared to post-operatively (pre- versus post-operative bone conduction results). Overall, subjects having successful outcomes with the VSB achieved aided thresholds in the free field (masked contralateral ear) of 40dBHL or better from 500-4000Hz.

Speech perception in quiet showed a significant difference ($P<0.05$) between unaided speech test results and being aided with either a hearing aid or a VSB. There was no significant difference ($P=0.979$) between speech test results when aided with a hearing aid or the VSB. Averaged scores varied from 25.5% (unaided), 91% (conventionally aided with hearing aid) to 93% (VSB aided). Speech perception in noise results indicated a trend for subjects to have better scores when using their VSB compared to CHAs in the following listening conditions: (1) speech and noise from front, (2) speech present in front (noise to implanted ear), and (3) speech present in front (noise to contralateral ear).

Individual mean APHAB percentage scores for the global score and for the EC, RV, BN, and AV subscales are shown in Figure 4.1 for the pre-operative testing and for the most recent post-operative testing. Improvements between the pre-operative test condition and the most recent post-operative test condition for the global score and for the subscales were all statistically significant, except for a trend for BN (global score, $P=0.043$; EC, $P=0.018$; RV, $P=0.043$; BN, $P=0.06$). However, no significant improvement was observed for the AV subscale ($P=0.31$).

The method of Cox and Alexander (1995) was used to evaluate the clinical relevance of the VSB. The mean differences in benefit scores on the three subscales EC, RV and BN
between pre-operative testing and the most recent post-operative test results were all >10% at 30%, 25% and 22%, respectively. This reflects a benefit of the VSB with 95% probability. According to the method of Cox and Alexander, the AV subscale did not show significant benefit from a clinical perspective.

All four subjects (3, 4, 5, 6) who experienced tinnitus pre-surgery reported a decrease in their perceived tinnitus levels post-surgery (Figure 4.2). Subjects 3, 4 and 5 demonstrated clinically significant pre-operative tinnitus levels (scores >17). A score of 17 is the threshold value for tinnitus to be considered clinically significant. No subjects reported an increase in their tinnitus disturbance.

The overall decrease in perceived tinnitus between the pre-operative test condition and the most recent post-operative test condition was statistically significant (Wilcoxon signed-rank test: \( P=0.018 \)).
Figure 4.1. APHAB results pre- versus post-operative

APHAB - Average Scores (n = 10)

Figure 4.2. TRQ results pre- versus post-VSB. A lower score represents lower tinnitus perception.

TRQ - Pre-op and Post-op (n=10)
4.5. Discussion

Baumgartner et al. (2010) compared pre- and post-operative results using the APHAB for 12 subjects who underwent VSB-RW. These researchers found statistically significant improvement for the EC, RV and BN subscales, but no significant change in the average AV subscale. Significant improvements were also reported on the hearing device satisfaction scale, with mean scores of 43% pre-operatively and 74% post-operatively.

Our results are broadly in line with those of Baumgartner et al. and indicate that VSB improved QOL outcomes for the majority of subjects (Table 4.2). Significant improvements were seen for the EC, BN and RV subscales of APHAB. Agreement with results from the Baumgartner et al. study were also observed for the AV subscale.

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Ease of communication</th>
<th>Background noise</th>
<th>Reverberation</th>
<th>Aversiveness</th>
</tr>
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<tbody>
<tr>
<td>% score pre-op</td>
<td>66</td>
<td>42</td>
<td>73</td>
<td>52</td>
</tr>
<tr>
<td>% score post-op</td>
<td>28</td>
<td>14</td>
<td>40</td>
<td>34</td>
</tr>
<tr>
<td>% change</td>
<td>-38</td>
<td>-28</td>
<td>-33</td>
<td>-18</td>
</tr>
</tbody>
</table>

In our study, scores on the AV subscale did not increase but instead showed a slight decrease (Table 4.2). With greater access to sound it is expected that tolerance to louder sounds either decreases or remains unchanged. Baumgartner et al. (2010) reported that AV scores remained relatively unchanged and postulated this was due to ceiling effects because their subjects did not report pre-operative problems with sound tolerance.

In contrast to other studies (Sterkers et al., 2003; Schmuziger et al., 2006), no post-operative symptoms such as fullness, taste disturbance or vertigo were reported in our study. One subject experienced interference when in close proximity to a telecommunications centre at his workplace and when traveling through security doors.
No other study has reported this occurrence. This client may have been particularly sensitive to small changes in FMT positioning caused by changes in external electromagnetic fields.

Three of the 10 patients in our study required revision surgery due to FMT migration and in one subject (10) this was because of device failure. Baumgartner et al. (2010) also reported migration of the FMT in VSB-RW in one of 12 subjects, which was rectified by device re-positioning. However, the results from their study extended only to 3 months post-surgery, whereas in the current study the results extended to 25 months post-surgery. Each of the three subjects in our study requiring revision surgery had undergone at least two mastoid surgeries prior to the VSB surgery and had an underlying Eustachian tube dysfunction. According to Dumon et al. (2009), middle ear function can help to gauge the potential for FMT migration. In order to eliminate future migration, we now routinely reinforce the fascial packing of the FMT with cartilage in patients with middle ears that have poor Eustachian tube function. This has so far proven effective and has avoided the need for further revision in our cohort.

Current research indicates that use of amplification devices such as hearing aids can help to diminish tinnitus disturbance (Searchfield et al., 2010). Therefore, it was hypothesised that use of the VSB could reduce tinnitus disturbance because of increased amplification of external noise. With less effort required to hear, it was expected there would also be less associated stress which could assist in tinnitus perception.

Scores on the TRQ improved for all three subjects who experienced clinically significant pre-operative tinnitus (scores >17 on TRQ). This benefit is a new observation in vibroplasty. The proposed mechanism for reduced tinnitus is the increased level and frequency range of background sounds received by the cochlea (Jastreboff and Jastreboff, 2003). Hearing aids improve the understanding of speech and thereby decrease the ‘strain
to hear’ phenomenon and decrease the attention given to the hearing problems and tinnitus (Jastreboff and Jastreboff, 2003).

Stimulation via hearing aids and the VSB could also be effective in reducing tinnitus because of functional changes in parts of the auditory system due to decreased auditory stimulation. Auditory deprivation is thought to induce cortical reorganisation (Park et al., 2010) and a dysfunctional process of adaptation might be involved in tinnitus generation (Langguth, 2005). Amplification devices can stimulate cerebral plasticity and partly re-establish the proper functioning of auditory nerve pathways, thus limiting one of the likely causes of tinnitus (Searchfield et al., 2010).

Subject 4 had a pre-operative tinnitus score of 87 which decreased to 68 post-operatively. This subject had the greatest air conduction loss amongst the subjects presenting with tinnitus and also had a history of otosclerosis. Hearing loss and otosclerosis are known risk factors for tinnitus (Nondahl et al., 2002). Folmer and Caroll (2006) found significant tinnitus reduction in a group of 50 subjects who used hearing aids for an average of 18 months. However, this was not the case for subject 4 in our study, who had used the device for 24 months. While a reduction in tinnitus was observed for this subject, the change was deemed not to be significant.

Future patients undergoing VSB surgery for mixed or CHL are recommended to undergo tinnitus counselling prior to surgery. No subjects in the present study or in any other known study underwent VSB-RW for debilitating tinnitus. However, it would be worthwhile giving patients an understanding of the possible impact on their tinnitus as soon as possible. This subset of the hearing impaired population is unable to wear CHAs, which may be able to give some tinnitus relief through acoustic stimulation. They are also not good candidates for tinnitus treatments such as the Neuromonics program (Davis et al., 2007) due to the severity of their hearing loss.
In this study, two of the three subjects (66%) who reported pre-operative tinnitus experienced a reduction of their tinnitus perception after VSB implantation. In comparison, Surr et al. (1985) found that approximately 50% of new hearing aid users reported relief from tinnitus. The VSB-RW application may be more effective for tinnitus reduction than CHAs; however, studies with a larger sample size are required to confirm this. Holgers and Håkansson (2002) reported that use of a Baha for people with CHL was useful in reducing tinnitus. This may be related to absence of the occlusion effect, which is also achieved with VSB. Occluding hearing devices can increase the perception of tinnitus in some tinnitus sufferers, particularly in people with good low frequency hearing (Parazzini et al., 2011; Del Bo and Ambrosetti, 2007).

In conclusion, VSB-RW can improve QOL measured by various parameters in patients with mixed or CHL who are not suitable for CHAs. In addition, it can provide significant benefits in terms of reducing tinnitus. These features, together with the established benefits in hearing performance, means VSB-RW can offer this group of challenging patients an effective hearing rehabilitation.
5. Does coupling and positioning in vibroplasty matter?

The work described in this chapter was published in:


5.1. Abstract

Vibroplasty offers a new modality of hearing rehabilitation in patients with mixed, conductive and sensorineural hearing loss who cannot wear hearing aids. The positioning of the FMT during vibroplasty surgery can have a potentially critical effect on hearing outputs. There are currently no clearly established guidelines on the best positioning of the FMT with the VSB middle ear implant. In this chapter, the impact of various vibroplasty applications in the middle ear on hearing outputs and coupling efficiency will be evaluated. So far, there have been no reports that examined the coupling efficiency of a RW versus an ossicular vibroplasty application.

This chapter describes a prospective cohort study of 16 patients with underlying ear pathologies who were not able to wear hearing aids. All patients underwent a standard audiological test battery. Direct drive transfer function analysis results were correlated with bone conduction thresholds to assess the efficiency of FMT coupling. Speech perception in quiet, and QOL measure questionnaires were used to assess outcomes. Nine patients had RW vibroplasty, six patients had stapes vibroplasty, and one patient had traditional incus vibroplasty.

Patients with a soft tissue coupler between the FMT and the RW had significantly reduced coupling efficiency, whereas patients who had direct RW contact experienced
significantly improved coupling efficiency. Patients who underwent stapes or incus vibroplasty had the greatest coupling efficiency.

This study demonstrates that attachment to the stapes or incus provides better coupling compared to VSB-RW. When suitable, stapes or incus coupling should be the first choice when implementing vibroplasty.

5.2. Introduction

As described in Chapter 3, conventional hearing amplification is sometimes not an available option for hearing loss due to medical contraindications or amplification limitations. Medical contraindications include conditions that affect the wearing of hearing aids or moulds within the ear canal. These include chronic otitis externa, aural atresia, or patients who have had multiple ear surgeries for chronic ear disease. A hearing aid is often unable to provide sufficient amplification for cases with significant mixed hearing loss.

The use of middle ear implants such as the VSB with FMT may provide a solution to the limitations of CHAs. The FMT can be placed on different elements of the middle ear (termed vibroplasty) such as the incus and stapes, or on the RW.

Transmission of sound through the skin and skull (percutaneous coupling) through a device such as the Baha can provide good results for patients with CHL or mild mixed hearing losses (Snik et al., 2001), or with atresia (Yellon, 2011). At the start of this study, the Baha 3 Power BP110 (Cochlear Ltd, Australia) head-level processor had sufficient gain for cochlear losses up to and including 55dBHL, whereas the VSB (Med-EL, Innsbruck) provides gain for cochlear losses of up to 65dB at 2-4KHz. Furthermore, infection rates with percutaneous devices can range from 6.7% (Hakansson et al., 1990) to 38% (Gluth et al., 2010), with patients experiencing severe skin reactions. The VSB
can provide ear-specific information which can be advantageous for patients with asymmetrical cochlear hearing loss.

VSB-RW has been used since 2005 (Colletti et al., 2005) for mixed and conductive losses. However, the optimal positioning and coupling of the FMT in vibroplasty is the subject of ongoing debate. Different variables such as the type of vibroplasty, the level of RW-FMT contact and the use of soft tissue or titanium couplers all affect the efficiency and outcomes. It is unclear whether better results could be achieved by placing the FMT in direct contact with the RW membrane or by using an interposed material such as fascia or tutooplast. It is also unknown whether stapes or incus vibroplasty is comparable to VSB-RW with regard to coupling and outcomes, especially in cases such as atresia or chronic ear disease where both vibroplasty options can often be implemented. The present study aims to provide more insight into these aspects.

VSB-RW poses surgical challenges relating to the anatomy of the RW. There is a clear mismatch between the size of the RW membrane with a mean diameter of 0.92mm (Roland et al., 2007) and the size of the FMT with a diameter of 1.8mm and a length of 2.3mm. Furthermore, the shape of the RW niche and the actual location of the RW membrane present additional challenges. The RW niche is frequently funnel-shaped with the RW membrane sitting at the deep and narrow end and away from the rim of the niche. This makes direct placement impossible, even with the available couplers. Pennings et al. (2010) noted that the RW niche size, angle and exposure of the RW membrane were highly variable in 10 cadaveric temporal bones. In addition, many patients that could benefit from the RW application of the VSB had already undergone multiple middle ear surgeries, making placement of the FMT challenging due to fibrosis of the middle ear or fibrous obliteration of the RW niche. Rajan et al. (2011) demonstrated that the FMT needed to be in contact with the RW to attain good coupling efficiency, but the extent of
contact was not a factor in patient outcomes. Therefore, good hearing outcomes could be attained even in cases with partial contact. This is potentially in contrast to patients with a mixed hearing loss who rely on the best possible coupling in order to maximise the amplifying gain and to minimise the loss of sound transfer energy.

The role of couplers and of soft tissue interposition is controversial. The literature includes both cadaveric and in vivo patient studies. The latter is more pertinent for clinical decision making given we are dealing with ‘living tissue’ involving healing processes and scar tissue formation.

Human temporal bone studies demonstrate improved coupling efficiency with the use of interposed fascia between the FMT and the RW membrane (Pennings et al., 2010; Nakajima et al., 2010; Arnold et al., 2010; Koka et al., 2009). In addition, some clinicians recommend the additional use of a cartilage or soft tissue cap behind the FMT to create some pre-tension on the FMT and thus improve coupling to the RW membrane (Pennings et al., 2010; Nakajima et al., 2010; Arnold et al., 2010).

Colletti et al. (2012) recommend the use of interposed fascia with ECog (electrocochleography) measurements to guide optimal placement of the FMT intra-operatively. Conversely, Skarzynski et al. (2014) report better coupling with direct FMT to RW contact. Mandalà et al. (2011) examined positioning of the FMT in 14 children with congenital aural atresia and conductive or mixed hearing loss and reported that fascia overlying the FMT and cartilage packing gave the best ECog recordings.

Rajan et al. (2011) investigated the coupling efficiency in seven patients with mixed hearing loss and one with CHL. All patients showed significantly improved scores for speech in quiet and in noise post-operatively compared with pre-operative. Coupling efficiency was also higher with partial or total direct contact of the FMT with the RWM, but reduced when soft tissue coupling was used. This was one of the first studies that
conducted objective coupling efficiency measurements to investigate whether partial or full contact with the RW was essential and whether use of interposed fascia gave better coupling in the RW-FMT application.

This study expands the earlier work of Rajan et al. (2011) by examining the coupling efficiency when the FMT is in contact with the RW directly or with fascial underlay, or crimped to the stapes or the incus.

5.3. Methods
All methods used in this study were described in Chapter 2.

5.4. Results
The patient characteristics, ear pathology, coupling technique used and hearing thresholds are shown in Table 5.1.

5.4.1. Surgical outcomes
Of the 16 patients, three required FMT re-positioning within the first 6 months following implantation. None of the subjects who underwent incus or stapes vibroplasty experienced any post-operative complications.

5.4.2. Coupling measurements
The association between vibroplasty thresholds and bone conduction thresholds is shown in Figure 5.1. Patients with a soft tissue coupler between the FMT and the RW had significantly reduced coupling efficiency (p<0.05) compared to all other coupling configurations. The coupling efficiency for the RW direct placement was significantly worse (p=0.01) compared to the RW fascia group (Figure 5.2a). The coupling efficiency for the combined RW application groups (direct contact and fascia interposed) was significantly worse (p=0.02) than for the stapes vibroplasty patients (Figure 5.2b).
Although not reaching significance (p=0.08), the stapes group demonstrated a trend for better coupling efficiency compared to the RW direct group (Figure 5.2c).

**Figure 5.1. Summary of coupling efficiency for individual patients**

Smaller values are consistent with better coupling efficiency.
Table 5.1. Subject characteristics, implanted ear pathology, surgical history pre-VSB surgery, VSB surgical technique employed.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Pathology</th>
<th>Surgeries pre-VSB</th>
<th>VSB surgical Technique</th>
<th>FMT coupling</th>
<th>Age (yrs)</th>
<th>Bone 4FAHL</th>
<th>Air 4FAHL</th>
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<td>RW in MRC</td>
<td>Direct partial</td>
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<td>10</td>
<td>41</td>
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<td>RW in MRC</td>
<td>Direct complete</td>
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<td>Fascia</td>
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<td>45</td>
<td>60</td>
</tr>
<tr>
<td>16</td>
<td>CSOM</td>
<td>1</td>
<td>RW in MRC</td>
<td>Partial</td>
<td>63</td>
<td>36.3</td>
<td>70</td>
</tr>
</tbody>
</table>

Facial Rec: Facial recess approach to RW; RW in MRC: RW placement in Modified Radical Cavity; Age (years); Four frequency average (4FAHL) of implanted ear; bone and air conduction. CSOM = Chronic Suppurative Otitis Media.
Figure 5.2a  Coupling efficiency of the RW direct (no fascia) group (n=5) compared to the RW Fascia (n=4) group (p=0.01)

Figure 5.2b  Coupling efficiency of RW combined (n=9, fascia and direct contact groups) compared to that of stapes vibroplasty (n=6; p=0.02)

Figure 5.2c  Coupling efficiency of the RW direct group (n=5) and stapes placement of the FMT group (n=6; p=0.08).

Figure 5.3 shows the relative coupling efficiency across frequencies. The fascia coupling group had a lower coupling efficiency across the frequencies as reflected in the thresholds being to the left of the ‘best fit’ line.
5.4.3. Audiologic testing: outcomes for speech in quiet
The improvement in Monosyllable speech perception from pre-operative to post-operative testing was significant (p<0.001). An average unaided score of 32.7% (SD±35.35%) was attained, compared to 90.8% (SD±5.53%) with the VSB (Figure 5.4).

5.4.4. QOL outcomes
The mean differences in benefit scores on the three subscales EC, BN and RV between pre-operative testing and the most recent post-operative test results were all >10% (35%, 33.8% and 36.9% respectively), thus reflecting with 95% probability a true benefit of the VSB (Figure 5.5). The AV subscale was not significant from a clinical perspective. The difference between pre- and post-operative testing was significant for the global scale and for all subscales (p<0.001) except AV (p=0.906).
Patients with stapes and incus coupling as well as those with direct coupling show below average functions, reflecting better coupling efficiency. The underlying assumption is that data points below the regression line are indicative of ‘good’ coupling.
Figure 5.4  Monosyllabic word scores: pre- versus post-operative

Words were presented in the free-field at 65dBSPL. Scores are indicated by percent correct answers.
Note: Mean values are depicted as black quadrants; median values as horizontal lines. Circles and asterisks represent outliers.

Figure 5.5  APHAB score: pre- versus post-VSB use

The lower the score the less the perceived difficulty.

Tinnitus levels decreased for three subjects (2, 4 and 11) who experienced tinnitus pre-surgery (Figure 5.6). Subjects 4 and 11 experienced a decrease in their tinnitus perception with VSB use to a non-significant level according to clinical criteria (TRQ
≤17; Wilson et al., 1991) and their percentage score was reduced by >40%. The difference in TRQ score between pre- and post-operative testing was significant (p=0.027).

Figure 5.6. Tinnitus perception scores as measured by the TRQ

5.5. Discussion

The findings from this study indicate that patients attain hearing benefits post-VSB surgery, regardless of the coupling technique employed. The most efficient coupling was achieved with the FMT coupled to the stapes. The next most efficient vibroplasty modality was the incus, followed by RW contact (either partial or complete). The least efficient modality was RW with interposed fascia. These findings held true across the complete frequency range. Therefore, coupling the FMT to the ossicular chain or to remnants of the chain wherever possible is the preferred option for sensorineural, mixed or CHL. Other studies also support the use of the stapes as the first choice of coupling site when there is a viable attachment point and the RW reflex is present (Verhaegen et al., 2010; Tsang et al., 2012; Tsang et al., 2013). Tsang et al. (2013) also report that stapes coupling provides natural stimulation to the inner ear and results in a better perceived
sound quality than the RW vibroplasty technique, as well as being less challenging surgically. In two paediatric cases with congenital aural atresia where the stapes was present and mobile, positioning of the FMT to the stapes head gave better ECog results than direct contact with the RW (Mandalà et al., 2011). Even in cases with a rudimentary ossicular chain, good results can be attained as reported by Lesinskas et al. (2012) who used rudimental stapes as the attachment point for three patients with Treacher Collins Syndrome.

Another benefit is that no drilling of the RW niche is required when using the ossicular chain as an attachment point, thus reducing the risk of iatrogenic sensorineural hearing loss. This also removes the surgical complexity associated with the high degree of variability evidenced in RW anatomy across individual patients. From the patients’ perspective, coupling to the ossicular chain allows immediate post-operative VSB activation.

Ossicular chain attachment reduces the risk of FMT-migration encountered in RW vibroplasty. None of the subjects in this study with stapes or incus placement experienced FMT migration. This is in line with other publications reporting no FMT displacements with the classic incus application, with the exception of one patient who underwent magnetic resonance imaging and required revision surgery to re-attach the FMT to the incus (Schmuziger et al., 2006). In contrast, revision surgery because of FMT displacement in RW vibroplasty has been reported by Skarzynski et al. (2013) for two of 21 subjects, by Baumgartner et al. (2010) for one of 12 subjects, and by our group for four of 18 subjects (Chapter 3).

Patients who require an implantable hearing solution such as the VSB typically have an underlying chronic middle ear pathology which could potentially persist after device implantation (Boheim et al., 2012). With a more ‘secure’ attachment point such as the
stapes or incus, the risk of a recurring active middle ear condition that affects FMT placement may be reduced compared to RW.

In cases of RW vibroplasty, some groups prefer the use of interposed fascia or Tutoplast as an interface between the FMT and RW (Pennings et al., 2010; Nakajima et al., 2010; Arnold et al., 2010; Colletti et al., 2012; Baumgartner et al., 2010; Edfelt and Andersen, 2013). However, the possibility of scar tissue formation in the interposed fascia and a reduction in the long term coupling efficiency has been raised (Pennings et al., 2010). Edfelt and Rask-Andersen (2013) also suggest it could be difficult to control the position of the FMT following the application of fascia, perichondrium and cartilage. More recently it has been proposed that interposed fascia may be resorbed after a period of time, thereby reducing coupling (Schwabe, 2014). These authors also suggest that perichondrium is superior for interposition as it is more robust and consistent. However, it is uncertain how this interposed tissue will respond in the long term.

Rajan et al. (2011) found that direct and if possible complete direct FMT placement on the RW provides better efficiency than a soft tissue interface. However, the size mismatch between FMT and RW as well as the diameter variations observed for the RW niche remain ongoing challenges that make it extremely difficult to achieve direct contact. In these cases, a soft tissue coupler or commercially available clip coupler is necessary. Though the coupling efficiency is not as effective, the FMT properties and programming of the external processor can compensate for any coupling inefficiencies, especially in patients with a CHL. It is important, however, to consider that patients with significant mixed hearing losses require significant gain which can only be achieved through optimal coupling.
One of the limitations of this study is clearly the small sample size, with outliers having the potential to skew results. Further investigations are being undertaken in a larger group of patients to confirm these initial findings.
6. **General discussion**

6.1. **Background**

Hearing loss is the second most prevalent disease in Australia, with 3.55 million Australians affected by this condition (Listen Hearing, 2006). Of these, 1.3% are reported to have a mixed or CHL and a small proportion of this subgroup have hearing losses that are not amenable to corrective surgery or the use of CHAs (Wilson et al., 1998).

For such individuals, bone conductor hearing implants have traditionally been the implant of choice. However, with the advent of middle ear implantable devices such as the VSB, surgeons and patients now have the option of a transcutaneous device without the inherent risk of infection associated with percutaneous devices. The VSB is the most commonly used active middle ear implantable device in the world today.

At the commencement of this study, there was no published data on the benefits of VSB for mixed and conductive losses in comparison to conventional hearing aid amplification. There was also very limited data on QOL outcomes for this subset of patients, particularly with regards to tinnitus perception, and on the optimal positioning of the FMT.

6.2. **Aim 1: Does the VSB-RW application provide comparable results to CHAs for speech perception in quiet and in noise?**

6.2.1. **Speech in quiet performance**

The results detailed in Chapter 3 and published in Marino et al. (2013) demonstrate significant improvement in a patient’s speech perception with the VSB when compared to unaided performance. This concurs with many other studies published on the VSB application for mixed and CHL (Colletti et al., 2006; Streitberger et al., 2009; Colletti et al., 2009; Linder et al., 2011; Beltrame et al., 2009; Beleites et al., 2011; Kontorinis et
al., 2011; Rajan et al., 2011; Bernadeschi et al., 2011; Verhaert et al., 2011; Boheim et al., 2012; Schwab et al., 2012; Yu et al., 2012; Gunduz et al., 2012; Edfelt & Rask-Andersen, 2013; Colletti et al., 2013; Schwab et al., 2013; Vysokil et al., 2013; Canale et al., 2014; Bernadeschi et al., 2014).

However, published data that compares the performance of VSB against CHAs is sparse. It is important therefore to consider whether VSB shows a performance comparable to conventional treatment options for hearing loss. Comparison of the performance of middle ear implants to CHAs was also investigated by Tysome et al. (2010). The results presented in Chapter 3 demonstrate that performance with the VSB is at least as good as, if not better, than results obtained with conventional amplification in quiet and in noise. Luers et al. (2014), in their review of the VSB application for mixed and CHL, state:

....Unfortunately, attempts to compare the hearing results of the VSB at conductive or mixed hearing loss with ‘best fitting’ CHA in a convincing manner are rare……. A fairly good attempt to compare VSB with CHA has been recently made by Marino and colleagues, 2013 who also used the NAL-NL1 prescription to optimize the CHA fitting before VSB implantation. Here, comparable speech test results were achieved with VSB and CHA in quiet, but VSB performance was substantially better in most speech-in-noise test conditions.

Results presented in Chapter 3 show that the performance with the VSB was similar to that of a CHA when speech was presented in quiet. This is in line with several other recent reports published during the course of this work (Atas et al., 2014; Gunduz et al., 2012; Edfelt Rask-Andersen, 2013). Table 6.1 lists the publications that provide speech perception results. In contrast, Kontorinis et al. (2011) demonstrated better performance in quiet using CHAs as compared to the VSB in two subjects. The patients both presented with osteogenesis imperfecta and severe to profound mixed hearing loss. This type of
hearing loss is particularly difficult to overcome adequately with CHAs due to the power requirements and the potential distortion. This may explain the discrepant results of the Kontorinis study compared to other studies. In summary, the current literature and our own results suggest the performance of the VSB in quiet, is comparable to that of CHAs.

6.2.2. **Speech in noise performance**

Published data that compares speech in noise performance between VSB and CHAs is very limited. The only studies so far that have compared this are by Gunduz et al. (2012), Marino et al. (2013; Chapter 3) and Rajan et al. (2011), with the latter comprising a subset of subjects from the study by Marino et al. (2013). Table 6.1 provides a summary of findings from these studies. Gunduz and colleagues examined the performance of their patients with a CHA at a set signal to noise ratio of +5dB. They reported equivalent performance with the VSB when tested under identical conditions.

The results in Chapter 3 (Marino et al., 2013) demonstrate better performance in noise with the VSB device. All patients in this study were tested using the older model AP404 processor, whereas approximately 50% of patients in the study by Gunduz et al. (2012) used this older processor and the remainder used the newer model Amadé processor with enhanced noise suppression strategies.
<table>
<thead>
<tr>
<th>Authors</th>
<th>No. cases</th>
<th>VSB coupling Method</th>
<th>Processor used</th>
<th>Controls</th>
<th>Functional gain</th>
<th>Speech in quiet (hearing aid versus VSB)</th>
<th>Speech in noise (hearing aid versus VSB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marino et al., 2013 (Chapter 3 of this thesis)</td>
<td>18</td>
<td>VSB-RW 15 – fascia 3 – direct contact</td>
<td>AP404</td>
<td>Own hearing aid</td>
<td>++ compared to unaided (average of 34dB)</td>
<td>= to CHA ++ to unaided (from 7.6% to 85.3% &amp; 83.8% With CHA &amp; VSB)</td>
<td>++ to CHA Adaptive speech in noise Tests in 0;0, 0;90 &amp; 0;270 conditions</td>
</tr>
<tr>
<td>Edfelt &amp; Rask-Andersen, 2013</td>
<td>7</td>
<td>VSB-RW</td>
<td>NS</td>
<td>Own hearing aid</td>
<td>++ in higher frequencies compared to CHA gain</td>
<td>= to CHA (though presentation levels varied from 65 to 80dB? (HL or SPL)</td>
<td>NS</td>
</tr>
<tr>
<td>Atas et al., 2013 &amp; Gunduz et al., 2012 (same subset of patients)</td>
<td>19</td>
<td>14 – VSB-OW 5 – VSB-RW Direct coupling – no fascia but supporting cartilage Vibrant D 404 (n=11) Amadé (n=10)</td>
<td>Own hearing aid</td>
<td>+ mid frequencies (1 &amp; 2KHz) ++ in higher frequencies (for both OW/RW &gt; CHA)</td>
<td>= to CHA ++ to unaided</td>
<td>+5dBSNR test = CHA ++ to unaided</td>
<td></td>
</tr>
<tr>
<td>Bernadeschi et al., 2014</td>
<td>25 pts 29 ears (4 bilat cases)</td>
<td>VSB-incus = 16 VSB-RW = 10 Stapes = 3</td>
<td>NS</td>
<td>Comparison of different coupling sites and to unaided condition</td>
<td>+ 39dB compared to unaided (63dB unaided, minus 24dB aided)</td>
<td>French Fourier Word test ++ compared to unaided for all coupling sites</td>
<td>NS</td>
</tr>
<tr>
<td>Canale et al., 2014</td>
<td>18</td>
<td>8 VSB-OW 10 VSB-RW RW group had interposed fascia? OW group – not stated</td>
<td>NS</td>
<td>Unaided &amp; comparison of OW to RW group</td>
<td>++ versus. unaided ++ at 500Hz RW &gt; OW ++ at 4000Hz OW &gt; RW</td>
<td>++ to unaided</td>
<td>NS</td>
</tr>
<tr>
<td>Colletti et al., 2013</td>
<td>50</td>
<td>VSB-RW</td>
<td>NS</td>
<td>Unaided to aided speech perception</td>
<td>Gain on average of 51dB (adults) 56dB (child) ++ gain to unaided especially at 1 &amp; 2KHz</td>
<td>Unaided compared to aided at 65dBHL ++ to unaided of 8.5% COM = 73.8% RC = 68.9% CAA = 91%</td>
<td>NS</td>
</tr>
<tr>
<td>Authors</td>
<td>No. cases</td>
<td>VSB coupling Method</td>
<td>Processor used</td>
<td>Controls</td>
<td>Functional gain</td>
<td>Speech in quiet (hearing aid versus VSB)</td>
<td>Speech in noise (hearing aid versus VSB)</td>
</tr>
<tr>
<td>------------------</td>
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<td>----------------</td>
<td>--------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>---------------------------------------</td>
</tr>
<tr>
<td>Schwab et al., 2013</td>
<td>49</td>
<td>VSB-RW = 37 VSB-RW with coupler = 22</td>
<td></td>
<td>Comparison of RW no coupler and RW coupler group</td>
<td>+ Gain slightly increased with RW coupler</td>
<td>= between no coupler &amp; coupler group (80% + at 65dBHL)</td>
<td>NS</td>
</tr>
<tr>
<td>Vyskocil et al., 2013</td>
<td>9</td>
<td>5 stapes / OW 2 RW (interposed neuro-patch and fibrin glue) 2 PFW</td>
<td>NS</td>
<td>Compared to 9 patients with incus VSB (data not in study, just averages)</td>
<td>+39dB gain overall OW; 40dB RW; 45dB PFW; 30 or 35dB ? 9 incus pts; 25dB gain</td>
<td>Freiburg word test at 65 &amp; 80dB 51% in 9 pts studied versus incus comparison group had 21% increase</td>
<td>NS</td>
</tr>
<tr>
<td>Yu et al., 2012</td>
<td>8</td>
<td>VSB-RW = 6 Stapes = 2</td>
<td>Amadé</td>
<td>Unaided for audiological data CHA for QOL</td>
<td>+ approx 11dB from 0.5 to 2KHz</td>
<td>++ to unaided with S0, S-ipsi &amp; S-contra 10-14dB increase</td>
<td>++ to unaided at 0.0, 0.90 and 0;270</td>
</tr>
<tr>
<td>Boheim et al., 2012</td>
<td>12</td>
<td>VSB-RW</td>
<td>NS</td>
<td>Single subject compared to unaided</td>
<td>15-43dBHL (max gain at 1.5-4kHz)</td>
<td>Freiburger word test ++ unaided 6% to 67% SRT: Pre-op; 66dB 3 months; 51dB 6 months: 45dB</td>
<td>++ to unaided Pre-op: +10dB/9SNR 3mths: +3dB 6mths: +5dB</td>
</tr>
</tbody>
</table>

SRT: Speech reception thresholds; CAA: congenital aural atresia; NS: not studied
The equivalent results obtained by Gunduz and colleagues may reflect ceiling effects as they used a fixed signal to noise ratio. In contrast, the present study used an adaptive speech in noise test which is more sensitive to differences between the hearing aid and VSB aided conditions.

As discussed in Chapter 3, the superior performance of the VSB in noise can be attributed to the distortion in sound quality likely to occur when CHAs provide the substantial gain needed for patients with significant mixed hearing. The CHA user then faces the additional challenge of integrating the resulting distorted signal with a very different signal received in the contralateral ear. The conductive component of the hearing loss is bypassed when the FMT is positioned on the RW. This means less gain is required, distortion is reduced, and potential difficulties in blending the signal with that received from the contralateral ear are reduced.

Another possible contributor to the better results in noise with the VSB compared to CHA could be the increased acclimatisation time with the VSB processor. None of the subjects could wear their CHA pre-operatively for any length of time without exacerbation of otitis externa, pain, or distortion of the sound, whereas there were no contraindications to continuous VSB use.

Our results indicate the VSB provides equivalent if not better results in noise compared to CHA. The mechanisms underlying this are not fully understood and more studies are required to evaluate the benefits of VSB for speech in noise.

6.3. **Aim 2: Does the VSB-RW application improve QOL outcomes and specifically tinnitus perception?**

The QOL questionnaires used by various research groups are different, although generally it would appear that QOL is significantly improved with VSB use (Atas et al., 2014; Edfelt and Rask Andersen, 2013; Marino et al., 2013; Yu et al., 2012; Boheim et
al., 2012). The most consistently used questionnaire is the APHAB (Cox & Alexander, 1995). Similar to Marino et al. (2012; Chapter 4), Boheim et al. (2012) and Baumgartner et al. (2010) reporting on the same group of patients found significant improvement for all subscales of the APHAB, except for the AV subscale which examines a person’s tolerance to louder sounds. Yu et al. (2012) also used the APHAB in their group of six VSB-RW and two stapes vibroplasty patients but found that reported outcomes were comparable to those attained while wearing CHAs.

Table 6.2 summarises the QOL outcomes for various studies using the VSB. The present study (Chapter 4; Marino et al., 2012) is the only one to have examined the impact of the VSB on tinnitus perception using the TRQ (Wilson et al., 1991). QOL is often affected to a greater extent in individuals suffering from hearing loss and tinnitus compared to those suffering from hearing loss alone. Therefore, it is paramount to look at options that can treat both conditions either in isolation or simultaneously.
Table 6.2. QOL studies using VSB

<table>
<thead>
<tr>
<th>Study</th>
<th>No.</th>
<th>Coupling method</th>
<th>Processor</th>
<th>APHAB</th>
<th>IOI-HA</th>
<th>GBI</th>
<th>HDSS</th>
<th>COSI</th>
<th>TRQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marino et al., 2012</td>
<td>10</td>
<td>VSB-RW</td>
<td>AP404 = 16 AP404 Lo = 2</td>
<td>++ EC, ++ BN, ++ RV, = AV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>++</td>
</tr>
<tr>
<td>Yu et al., 2012</td>
<td>8</td>
<td>VSB-RW (6) Stapes (2)</td>
<td>Amadé</td>
<td>= to CHA</td>
<td>= to CHA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boheim et al., 2012 (same subjects as Baumgartner et al., 2010)</td>
<td>12</td>
<td>VSB-RW</td>
<td>NS</td>
<td>++ EC, ++ BN, ++ RV, = AV</td>
<td>= to unaided</td>
<td>= to unaided at 3 months &amp; ++ at 6 mths</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atas et al., 2014</td>
<td>19</td>
<td>VSB-OW (14) VSB-RW (5)</td>
<td>Vibrant D 404 (10) Amadé (10)</td>
<td>+ total score + benefit &amp; residual participation restrictions compared to CHA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edfelt &amp; Rask-Andersen, 2013</td>
<td>7</td>
<td>VSB-RW</td>
<td>With fascia</td>
<td></td>
<td>++</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monini et al., 2013</td>
<td>7</td>
<td>?? VSB-RW</td>
<td></td>
<td></td>
<td>++</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

++ indicates significant positive outcome; -- significant negative outcomes; = no difference; + positive outcomes (not significant or no significance reported); - negative outcome (not significant or no significance reported; if no entry – then test not performed

IOI-HA: international outcome inventory for hearing aids; HDSS: hearing device satisfaction scale; NS: not stated
The impact of VSB on tinnitus perception is an important factor considering the extent to which tinnitus can be debilitating and intrusive for some individuals. The results presented in Chapter 4 (Marino et al., 2012) were the first published data on tinnitus perception and the VSB-RW application. In their review of middle ear implantation devices for tinnitus treatment, Biesinger and Mazzoli (2011) discussed the impact of VSB in the classic incus application for patients with high frequency hearing loss. For one patient with tinnitus in the worse hearing ear, they reported that implantation with the VSB caused the tinnitus to be perceived in his better hearing ear. This better hearing ear was then implanted with a VSB 3 months later and the tinnitus perception diminished significantly, although to date these results have not been published. These workers also described another unpublished case study initiated by Med-EL® in 2008 of a patient whose tinnitus disappeared completely after VSB activation for their sensorineural hearing loss.

In contrast to our findings and the two above mentioned cases, Skarzynski et al. (2014) reported that in their cohort of 21 patients, four experienced tinnitus but this resolved 3 months post-operatively. In our cohort, three patients with significant pre-operative levels of tinnitus reported reduced severity of tinnitus perception as measured by the TRQ. Given our initial positive results and the fact that hearing aids (Trotter and Donaldson, 2008; Folmer and Carroll, 2006), Bahas (Holgers & Håkansson, 2002) and cochlear implants (Baguley and Atlas, 2007) can all help to reduce tinnitus perception, it is likely that patients with tinnitus and mixed or CHL can hope to gain some reduction of this debilitating condition.

Counselling is the cornerstone of many tinnitus treatments including tinnitus retraining therapy (Jastebroff and Jastebroff, 2003), cognitive behavioural therapy (Hiller and
Haerkötter, 2005), as well as being an important factor in neuromonics tinnitus treatment (Davis et al., 2008).

None of the patients in the present study (Chapter 4; Marino et al., 2012) received counselling on the potential benefits of implantation on their tinnitus percept, and yet very positive results were obtained. Some authors have suggested that tinnitus reduction is more effective when amplification is provided, compared to counselling alone (Searchfield et al., 2010). The percentage improvement in the total tinnitus handicap questionnaire score for subjects’ in the present study fitted with hearing aids (37%) was approximately twice that of patients who received counselling alone (13%).

6.3.1. Pre-operative tinnitus assessment
Conducting test procedures that are normally used for routine tinnitus assessments tinnitus could be useful for counselling prior to implantation. In particular, the tinnitus pitch-match assessment where patients listen to different frequency tones as a paired comparison and match this to the pitch of their tinnitus. McNeil et al. (2012) found that if the pitch of the tinnitus falls within the amplification range of a hearing aid, the patient is more likely to attain tinnitus masking when aided. Schaette et al. (2010) reported the likelihood of achieving a reduction in perceived tinnitus loudness was higher when the tinnitus pitch was located within the frequency range of the treatment device. In their study of 15 patients, those whose tinnitus was matched to frequencies less than 6000Hz attained significantly more tinnitus reduction post-hearing aid or masking device use. In contrast, patients whose tinnitus was matched at higher than 6000Kz did not experience any tinnitus reduction.

The FMT transducer has the potential to deliver gain for frequencies up to 15,000Hz; however, output is limited by the external processor (currently the Amadé processor) which can only deliver gain up to 8000Hz (Figure 6.1). In Chapter 3 (Marino et al., 2013)
where the VSB was used for conductive or mixed losses, aided thresholds were attained up to and including 8000Hz. Though limited, this frequency range is still higher than the frequency response of many hearing aids which can only deliver effective amplification up to 5000-6000Hz (Moore, 2007).

The VSB fitting strategy used in our study – desired sensation level (DSL) (Seewald, 1997) was the default strategy employed by the manufacturers. DSL places greater emphasis on low and high frequency amplification compared to other fitting strategies and may be preferred by tinnitus sufferers (Wise, 2003; McNeill et al., 2012).

Figure 6.1. The VSB FMT (left) has a frequency response up to 15,000Hz, while the external processor (Amadé processor, right) has a frequency range of 250-8000Hz

Most studies of tinnitus have evaluated patients with high frequency hearing loss, whereas in patients with mixed and CHL, thresholds are affected more evenly across the frequency range. Given that tinnitus pitch often correlates to the area of greatest hearing loss, patients with typical high frequency sensorineural loss requiring classic application of the VSB could benefit more from the extended frequency range of the VSB than patients affected by conductive or mixed hearing loss.

6.3.2. Tailored tinnitus programs
Research suggests that use of a tailored ‘tinnitus’ program and certain fitting strategies with hearing aids and cochlear implants can help with tinnitus suppression. Wise (2003) found the DSL [i/o] prescription with a low compression knee-point resulted in the
greatest reduction in tinnitus awareness. This is the default prescription in the VSB processor programming software and prescribes more low frequency gain than other programming prescriptions.

Searchfield (2005) suggests that increasing the amount of ambient and environmental sounds via hearing aids can help to diminish tinnitus perception. A program with the directional microphone disabled and which uses low compression knee points could be useful. Although this would not provide optimal speech perception, it could be added as an extra program for patients with persistent tinnitus. This would be easy to implement in the newer Amadé processor as patients can access up to three separate listening programs, whereas only one program is available with the older model AP404 processor. The newly released ‘Samba’ (MedEL, Innsbruck) audio processor has the facility for users to access five different listening programs.

QOL is often more severely impacted in individuals suffering from hearing loss and tinnitus than in those suffering from hearing loss alone. Therefore, it is important to examine options that can treat both conditions, either in isolation or simultaneously. For patients with mixed or CHL, the VSB can assist in the treatment of both conditions.

6.4. **Aim 3: Is stapes or incus vibroplasty comparable to RW vibroplasty with regard to coupling and outcomes?**
Active middle ear devices such as the VSB were developed for a healthy middle ear and intact ossicular chain, not for diseased middle ear systems where the mechanical functioning of the system is compromised (Beleites et al., 2014). Therefore, in cases of mixed and CHL there are no clear guidelines for optimal placement of the FMT and the preferred attachment points in different clinical presentations and aetiologies. At the beginning of this study, RW vibroplasty was considered by most surgeons to be the recommended attachment point for patients with mixed or CHL. However, our results
(Chapter 5; Marino et al., 2015) indicate the RW is no longer the attachment site of choice for such patients.

We found the stapes provides better coupling efficiency compared to the incus or RW vibroplasty. However, these results should be interpreted with caution given that results from only one incus placement patient were available. Use of the stapes head or footplate as the preferred coupling site are also supported by ear simulation models (Bornitz et al., 2010). ‘Living’ patient studies also support use of the stapes when there is a viable attachment point and the RW reflex is present (Verhaegen et al., 2010; Tsang et al., 2012; Tsang et al., 2013).

Verhaegen et al. (2010) used auditory steady state response (ASSR) thresholds intra-operatively while manipulating the FMT to different positions to find the optimal coupling position. Their study was conducted using four patients with severe mixed hearing losses and they reported FMT attachment to the stapes resulted in more efficient coupling compared to RW placement. Vibration of the FMT in parallel with the natural direction of the stapes seemed to give better results.

Mandalà et al. (2011) investigated positioning of the FMT in 14 children with congenital aural atresia and conductive or mixed hearing loss. They found that overlying the FMT with fascia and cartilage packing gave the best ECog recordings. However, in two subjects where the stapes was present and mobile, positioning of the FMT to the stapes head gave better CAP threshold results than direct contact with the RW. These findings are in agreement with our results.

As discussed in Chapter 5, stapes is the preferred option because of the enhanced coupling efficiency, but also because it reduces the risk of FMT displacement. Use of the stapes also negates the need for drilling in the RW niche, which in RW vibroplasty carries
the risk of permanent hearing loss. For patients who do not have a viable stapes, use of the RW should be considered.

6.4.1. RW vibroplasty: interpose tissue or not?
The results presented in Chapter 5 indicate that no interposed tissue between the FMT and RW membrane achieves the best coupling efficiency. However, most cadaver temporal bone studies and the few ‘in situ living patient’ studies published to date indicate that use of interposed tissue is a better option. The use of a soft tissue material placed between the FMT and RWM is recommended for two reasons. Firstly, to minimise the risk of perforating the RW membrane, and secondly to avoid the FMT coming into contact with bone (Beltrame et al., 2014). Colletti et al. (2009) and Wollenberg et al. (2007) recommend covering the FMT with a soft tissue material to avoid contact with the surrounding bone, thereby reducing vibration of the FMT.

Beleites et al. (2014) have commented that the results of Rajan et al. (2011), which laid the foundation for the work presented in Chapter 5 (Marino et al., 2015), are in contrast to most other published studies. They propose that patients with interposed fascia have reduced coupling efficiency because the FMT was likely to be in contact with bone in the RW niche, even when interposed tissue was used. Beleites et al. (2014) state:

This deviation from other temporal bone investigations may have been caused by their (Rajan et al., 2011) selection of patients because the soft tissue between the FMT and RWM, used in cases with mismatch between RWM and FMT diameter, should increase the coupling. However, in these patients, RW bony barrier problems may also have existed.

These authors go on to diagrammatically represent the proposed mechanism causing the ‘one-off’ results of Rajan et al. (2011), as shown in Figure 6.2.
Several studies on human temporal bone have demonstrated improved coupling efficiency with the use of interposed fascia between the FMT and the RW membrane (Salcher et al., 2014; Pennings et al., 2010; Nakajima et al., 2010; Arnold et al., 2010; Koka et al., 2009). Some clinicians also recommend the additional use of cartilage, soft tissue cap or fibrin glue behind the FMT to create pre-tension on the FMT, thereby improving coupling to the RW membrane (Salcher et al., 2014; Edfelt & Rask-Andersen, 2013; Pennings et al., 2010; Nakajima et al., 2010; Arnold et al., 2010).

Based on in situ studies with living subjects, Colletti et al. (2011) also recommended the use of interposed fascia in cases of RW vibroplasty. These authors recommended using electrophysiological measures specifically ECog to determine the optimal positioning for patients with mixed and conductive losses. In their study, 13 of 26 patients underwent ECog testing during FMT positioning within the RW niche. The efficiency of coupling was measured with respect to threshold, latency and amplitude of the ECog response. They also demonstrated that better coupling was attained if the FMT was placed perpendicularly to the RW by drilling the bony floor.
In their consensus statement on RW vibroplasty, Beltrame et al. (2014) state that the best interposed tissue is perichondrium or artificial fascia, as these materials appear to provide the best results over time. Tutopatch is well-defined in terms of thickness and is also a good option; however, it is expensive and is not available in some countries because it is made from bovine tissue. Beltrame and colleagues note that during revision surgery where the FMT required re-positioning, no interposed tissue or material was present in five patients in which their own fascia had been used. In contrast, interposed tissue or material was present when perichondrium or artificial fascia had been used. The patients’ fascia was thought to be resorbed, whereas this was not the case with artificial interposed material or tissue. These findings are supported by Schwabe (2014).

6.5. **Aim 4: Are different FMT attachment points critical in hearing outcomes and do they provide equivalent hearing outcomes?**

In cases of RW vibroplasty, the FMT must be in contact with the RW for good results to be achieved. Patients with inadequate coupling attained poor hearing outcomes with insufficient gain or no hearing sensation elicited (Bernadeschi *et al.*, 2014; Marino *et al.*, 2013; Monini *et al.*, 2013; Edfelt and Rask-Andersen, 2013; Skarzynski *et al.*, 2013; Yu *et al.*, 2012; Boheim *et al.*, 2012; Baumgartner *et al.*, 2010).

Ossicular chain attachment reduces the risk of FMT migration encountered in RW vibroplasty. None of the subjects in this study with stapes or incus placement experienced FMT migration (Chapter 5). This concurs with other published studies that reported no FMT displacement in the classic incus application. The one exception was a patient who underwent magnetic resonance imaging and required revision surgery to re-attach the FMT to the incus (Schmuziger *et al.*, 2006). The results presented in Chapter 5 indicate there was no difference in outcomes for patients with RW – direct contact compared to patients with interposed tissue or with stapes or incus placement.
Atas et al. (2013) reported on 14 patients with oval window application of the vibrant soundbridge (VSB-OW) and five patients with RW vibroplasty. Both groups demonstrated increased gain in the mid frequencies and even more gain in the high frequencies compared to the same patients with CHAs. No differences in gain or outcomes were apparent between the two vibroplasty groups. This contrasts with Canale et al. (2014) who demonstrated increased gain for RW vibroplasty compared to OW vibroplasty at 500Hz, but increased gain for OW vibroplasty at 4000Hz.

Vyskocil et al. (2013) demonstrated increased gain with OW, RW and promontory fenestration window (PFW) compared to patients with incus vibroplasty, as well as more improvement in speech perception (51% versus 21%, respectively). However, these patients suffered from a greater average hearing loss, meaning they had more scope for improvement. Their hearing loss was also mixed or conductive in nature, whereas incus vibroplasty patients have sensorineural hearing loss. Compared to patients with sensorineural losses, those with a conductive component often exhibit better speech perception results post-amplification, either through hearing aids or implantable devices. Schwab et al. (2013) demonstrated a slight improvement in gain using the RW coupler as compared to RW vibroplasty, although speech perception results were equivalent.

Currently, there are no clearly defined outcomes resulting from different coupling sites; however, the small number of cases, different aetiologies and varying degrees of loss make it difficult to interpret results.

### 6.5.1. Is further enhancement of coupling efficiency possible? RW couplers as an alternative?

The most important factor for energy transfer to the inner ear at the RW is the quality of contact between the RW membrane and the FMT. This contact can be improved with coupler elements. The RW coupler (Figure 6.3) was introduced in 2010 and has been used both in vivo (Schwab et al., 2013) and in cadaver studies (Salcher et al., 2014). It is useful
when a patient’s anatomy does not allow perpendicular placement of the FMT to the RW membrane.

In a study using eight fresh temporal bones, Salcher et al. (2014) reported an increased output of 11.9dB from 500-2000Hz when using interposed Tutopatch and RW coupler compared to direct FMT to RW contact. There was also less variability in output, with a standard deviation of 3.4dB versus 10.9dB, respectively. Some of the decreased output and increased variability with the ‘direct contact’ method, especially in the mid-frequencies, may be attributable to contact of the FMT with the bony rim of the RW. This bony contact can be prevented through the use of interposed material such as Tutopatch. The study by Salcher et al. (2014) study was not ‘in vivo’ and hence it was easy to maintain the static force. However, in the clinical situation involving a flexible lead wire, this may not be so easily achieved.
Figure 6.3. Round window coupling options

a) RW coupler. Designed for conductive or mixed hearing losses. The RW coupler has three ‘legs’ which are clipped onto the FMT. The legs are placed so that the conductor link exits above the shorter legs. The coupler is then placed onto the RW.

b) RW soft coupler. Also designed for use with conductive or mixed hearing losses. The coupler is anatomically optimised and has a height of 1mm and is placed onto the FMT by using an adhesive pad. The RW soft coupler is placed on the RW and normally is stabilised by inserting a piece of cartilage behind the FMT.

Images courtesy of Med-EL, Innsbruck

6.5.2. Other placement options and couplers
Some surgical groups have started to advocate use of the OW rather than the RW in cases where the stapes supra-structure is absent (Canale et al., 2014; Gunduz et al., 2012). The rationale for this is that drilling of the RW niche is not required for OW placement, thus reducing the risk of hearing loss.

6.5.3. Optimal placement via intraoperative measures
There are no routinely performed measures of coupling efficiency during surgery for patients with conductive or mixed hearing loss. The ability to conduct these measures
easily with a defined protocol would be very useful given there are still no definitive answers on optimal coupling configurations.

Reverse transfer function (RTF) measures developed by Med-EL, can be employed during surgery to confirm optimal FMT positioning in cases of an intact ossicular chain. However in most cases of conductive or mixed hearing loss, an intact middle ear system is not present making this type of coupling efficiency measure impossible (Radeloff et al., 2010).

Many researchers have used electrophysiological measures such as ECog (Electrocochleography) intra-operatively to determine optimal FMT positioning (Colletti et al., 2013; Yu et al., 2012; Mandalà et al., 2011). Compound action measures have also been utilised (Radeloff et al., 2010). In some cases of revision and re-implantation surgeries, surgeons have employed patient feedback while under local anaesthetic to attain optimal results (Canale et al., 2009; Mylinski & Ball, 2015).

At this point in time, while advancements in optimising coupling efficiency have occurred, formalised test procedures are not available. The development of coupling measurements that are integrated into the manufacturer’s programming software would be of significant benefits to surgeons intra-operatively and ensure optimal patient outcomes.

6.6. Future studies and applications

6.6.1. Proposed new trial for localisation with the VSB

Many of the subjects enrolled in the present study reported difficulty in localising the direction of incoming speech and sounds, causing them to constantly ‘scan’ their environment visually to determine the location of incoming sound sources. This led to problems such as knowing the direction of approaching cars, of partner’s voices when
they were not visible and of ambient sounds, as well as feeling ‘less connected’ with the world. One subject felt her localisation skills worsened following implantation of the VSB, although her ability to perceive speech in quiet and in noise both improved. This was a surprising result since it was thought that restoration of hearing through the VSB would lead to improvement of localisation skills. In fact, the VSB is often promoted above bone conduction implants because ‘cochlea’-specific stimulation is thought to be better for directional hearing (Kunst et al., 2008). In contrast, bone conduction implants can stimulate both the ipsi- and contralateral cochlea because of limited skull attenuation of the bone-conducted signal.

The ability to localise in the horizontal plane relies mainly on the processing of binaural acoustic differences in sound level, called interaural level differences (ILDs) for frequencies above 3KHz, and phase interaural time differences (ITDs) for frequencies below 1.5KHz (Agterberg et al., 2012). Humans are not born with the ability to specifically localise and the precision and accuracy of localisation ability improves until approximately the age of 5 years (Bellis, 2003). Grothe et al. (2010) have proposed there is a sensitive period for the adequate maturation of neuronal mechanisms that underlie processing of ITDs and ILDs. If this maturation does not occur, the individual may not be able to develop localisation skills. The inability to localise has so far not been investigated in people using the VSB. It has been reported, however, that people with unilateral or asymmetrical hearing loss have reduced ability to detect ILDs and ITDs and therefore to localise sounds (Keating and King, 2013; Agterberg et al., 2012).

People who have had diminished hearing, particularly in one ear, can undergo adaptive changes in the way spatial cues are processed. However, if the hearing loss is resolved either spontaneously or through clinical intervention with for example an implantable hearing device, these adaptive changes can become maladaptive (Keating and King,
Therefore, by introducing VSB to partially restore ‘normal hearing’, are we also making it more difficult for our patients to interpret spatial cues?

6.6.2. Localisation results to date

One of the goals of ongoing research in our group is to determine the localisation skills of patients implanted with the VSB. By performing pre-operative testing we hope to determine if this skill is further compromised with VSB use, or instead if it is enhanced. The localisation testing will be performed using the A§E localisation test software described by Távora-Vieira et al. (2014) and compared to the performance of normal hearing individuals. Briefly, the A§E software presents a narrow band noise of 1/3\(^{rd}\) octave centred around 4000Hz simultaneously through two loudspeakers that are placed at −60 and 60 degrees from the listener (Figure 6.4). The noise from the speakers is correlated with an ITD of zero. The presentation level differs from each speaker simulating an ILD, thus creating the illusion of a sound source localised somewhere on the azimuth between the two loudspeakers. The subjects are asked to identify the speaker they thought the sound was coming from and their response is entered into the software which calculates the degree of error. Subjects undergo testing in the unaided condition and with the VSB and hearing aid if fitted to the contra-lateral ear.
Figure 6.4. Position of the subject and the loudspeakers

The test person faces loudspeaker 0. The loudspeakers 6 and −6 (in black) are real functioning loudspeakers, while the other speakers (in grey) are sham loudspeakers. The two real loudspeakers are positioned at −60 and +60° in front of the test person, and the sham loudspeakers are at 10° angles between −60 to +60°.

Results obtained from the first seven patients tested in our cohort of VSB patients indicate they have improved access to speech in quiet and in noise; however, their localisation skills are often not improved. See Figure 6.5. When reporting on localisation ability, the term root mean square (RMS) error is used. The lower the degree of RMS, the better a person’s localisation ability. Whether this lack of improvement in localisation ability is related to inappropriate programming, a mismatch of device stimulation, or a casualty of asymmetrical stimulation during critical learning periods during childhood is currently unknown. We hope this work will address such issues and inform future efforts to improve spatial hearing skills.
Figure 6.5. The RMS error of patients in the unaided condition compared to their performance while wearing the VSB

The lower the RMS error, the better the subject’s accuracy in localising the direction of sounds. People with normal hearing, have a RMS error of 8 degrees (Tavora-Vieira et al., 2015).

Audiological data, aetiology and duration of hearing loss for subjects involved in this preliminary study are shown in Tables 6.3 and 6.4. There does not seem to be any clear pattern between the type of hearing loss, duration of hearing loss and localisation ability. Any results should, however, be interpreted with caution given the small sample size.
Table 6.3.  Subject details, type and duration of hearing loss

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yrs)</th>
<th>Type of loss</th>
<th>Duration of deafness</th>
<th>Aided in contralateral ear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>66</td>
<td>Symmetrical bilateral mixed</td>
<td>60 years</td>
<td>No. Unable due to ongoing discharge</td>
</tr>
<tr>
<td>Female</td>
<td>57</td>
<td>Unilateral loss</td>
<td>20 years</td>
<td>No. Unilateral loss</td>
</tr>
<tr>
<td>Female</td>
<td>79</td>
<td>Conductive in implanted ear Mild loss in contralateral ear</td>
<td>34 years</td>
<td>No. Unilateral loss</td>
</tr>
<tr>
<td>Male</td>
<td>58</td>
<td>Asymmetrical bilateral conductive</td>
<td>From childhood</td>
<td>Bilateral VSB</td>
</tr>
<tr>
<td>Male</td>
<td>79</td>
<td>Asymmetrical bilateral mixed loss</td>
<td>3 years</td>
<td>No. Has aid but only wears one device at time</td>
</tr>
<tr>
<td>Female</td>
<td>64</td>
<td>VSB ear: mixed loss Contra ear: sensorineural loss</td>
<td>4 years</td>
<td>Yes. With receiver in canal hearing aid</td>
</tr>
<tr>
<td>Female</td>
<td>34</td>
<td>Asymmetrical bilateral conductive</td>
<td>From childhood</td>
<td>No. Unable due to discharge</td>
</tr>
</tbody>
</table>

Table 6.4.  Audiological data for the seven subjects included to date

<table>
<thead>
<tr>
<th></th>
<th>Implant ear (4FAHL)</th>
<th>Contralateral ear (4FAHL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air conduction</td>
<td>60.6dB (SD: 15.1dB)</td>
<td>33.3dB (SD: 15.6dB)</td>
</tr>
<tr>
<td>Bone conduction</td>
<td>23.3dB (SD: 7.1dB)</td>
<td>18.75dB (SD: 7.9dB)</td>
</tr>
</tbody>
</table>

If the VSB is not effective in providing localisation abilities, is it still worth persisting with because of the benefits it may provide relative to bone conduction devices? The high rates of complications associated with VSB use (Chapter 3; Marino et al., 2013) must be considered, as well as the possibility of using percutaneous bone conduction devices such as the Bone Bridge (MedEL, Innsbruck) or the Baha Attract (Cochlear Ltd, Sydney).

Initial published results show that 4 patients implanted with a Baha bone conduction implant (Cochlear, Ltd) had equivalent localisation ability to a matched group of patients implanted with the VSB for unilateral aural atresia (Agterberg et al., 2013).
6.6.3. Changing clinical practice and pre-operative assessment

Monini et al. (2013) report that pre-operative trial by the patient of a bone conductor implant processor placed on a headband (Figure 6.6) provides good information on the likely satisfaction and performance from the VSB-RW application. Prior to the Monini study, this pre-operative trial condition was only used for patients who were to receive implantable Bahas such as the Baha®. The external processor used in the trial was identical to that used later for the implant. The functional gain derived via the ‘test’ situation was the same as the implant in situ and there were no significant differences in the unaided versus aided speech recognition scores in quiet and in noise. When the QOL questionnaire client oriented scale of improvement (COSI) was administered, patients were required to list the five hearing situations that were the most challenging and these were rated on a visual analogue scale. Patients using the VSB–FMT rated a slight improvement; however, this was not statistically significant.

Typically, if a patient experiences positive results with the bone conductor on a test headband for both speech perception and QOL, then outcomes with the FMT in situ will produce similar or better results.

Figure 6.6. Bone conductor processor worn on a headband

The Apollon bone conduction device frequently used for pre-operative trials.

Future studies should be more comprehensive and include the following measurements:
• **Pure tone threshold measurements**, including air and bone conduction pre-implantation compared to post-implantation.

• **Speech in quiet measurements**, comparing pre-operative unaided to pre-operative best conventionally aided condition. Test bone conductor on a headband to aided with the implanted VSB.

• **Speech in noise measurements** under the same test conditions as the speech in quiet measurements would be useful. Scores need to be expressed as a signal to noise ratio instead of as percent correct score so that results can be standardised and compared internationally. At the time this study commenced there were no adaptive speech in noise tests available in Australian English. One is now available for research purposes, but not yet commercially. Called the AuSTIN (Australian sentence test in noise), this was developed by the HEARing Cooperative Research Centre in Melbourne, Australia (Dawson et al., 2013).

• **Functional gain measurements** that evaluate unaided air conduction results of the implanted ear and compare this to aided sound field measurements when wearing:
  - CHA (pre-operatively).
  - Test bone conductor device on a headband (pre-operatively).
  - The VSB (post-operatively).

### 6.6.4. QOL measurements: implementation of new tests and methods

Pre-operative tinnitus evaluation should include administration of the TRQ as before, but also conduct tinnitus pitch and level matching and the evaluation of how soon tinnitus reduction was noted post-VSB implantation. Was this apparent immediately post-activation? Or is there a lag time before the reduction occurs? How long after non-use of the VSB processor before the tinnitus re-occurs or increases in severity?
By addressing these questions, useful information would be made available to assist with pre-operative counselling and for programming of the VSB processor post-implantation. Evaluation of any reduction in tinnitus perception using the pre-operative test bone conduction device would also be helpful for counselling. Administration of a more general QOL questionnaire such as the GBI developed by Robinson et al. (1996) would help to compare the benefit derived from VSB with that of other otological interventions.

6.7. Conclusions

6.7.1. Summary of the major findings from this work
- VSB use is associated with good speech in quiet and speech in noise outcomes.
- Coupling of the FMT to the stapes provides the best coupling efficiency and stability.
- Coupling position does not appear to affect hearing outcomes.
- QOL is improved for people using the VSB.
- Localisation skills do not appear to improve for all VSB users.

6.7.2. Future studies arising from this work
- Investigate the coupling efficiency in a larger group of patients and monitor the relationship between coupling sites and hearing outcomes.
- Investigate the use of manufactured couplers.
- Determine if specific tailored ‘tinnitus’ programs provide further tinnitus relief.
- Determine if counselling provided alongside VSB use provides further tinnitus relief.
- Measure the localisation ability of a larger patient cohort using a seven speaker localisation test set-up where patients can utilise both ILD and ITD cues.
- Measure patients’ perception of their localisation ability using a QOL questionnaire.
- Compare the localisation ability of patients using the VSB to those using bone conductor devices.

In conclusion, the VSB is an effective device for restoring hearing in individuals with conductive and mixed hearing losses whose hearing is not amenable to surgical restoration or compensation via CHAs. Benefits include improved hearing in quiet and in noise. Coupling the FMT to the stapes or incus gives the best results in terms of coupling efficiency and stability of the device. However, there does not appear to be any benefits in terms of hearing outputs. In cases where there is no viable ossicular attachment point, the present study found evidence to support the use of direct contact with the RW membrane. In contrast, most other published studies to date favour the use of interposed tissue. QOL is improved for patients using the VSB and in particular this work showed that tinnitus can be reduced using this device. Our preliminary data suggests that sound localisation does not improve through use of the VSB; however, a larger patient cohort is required to provide more definitive evidence.
7. Bibliography


8. Appendices

8.1. Appendix 1
8.2. **Appendix 2**
8.3. Appendix 3