Factors Influencing Post-Implantation Hearing Ability of Adult Cochlear Implant Candidates with Pre-Operative Acoustic Hearing

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Abstract

It is becoming increasingly common for adults with significant residual acoustic hearing in one or both ears to attend cochlear implant centres for candidature assessment. The clinical decision-making and provision of recommendations regarding this candidate population is complex, because there are only limited clinical data currently available to assist with counselling of candidates regarding expected outcomes. Pre- and post-implantation (3, 6 and 12-month) measures were obtained for 65 subjects who were implanted unilaterally in the poorer ear, and who had significant pre-operative acoustic hearing in one or both ears.

This research first investigated outcomes in relation to the potential risks associated with implantation of such candidates; (1) the risk to loss of acoustic hearing in the implanted ear for candidates with pre-operative bilateral acoustic hearing, (2) the potential for less post-implantation benefit in candidates with better contralateral hearing, and (3) the unknown influence of predictive factors in this expanded population. In (3) were included the influence of demographic and hearing configuration, as well as an aspect of post-operative device fitting relating to the degree of match between the assigned acoustic input frequency in the sound processor and the electrical pitch percept. Finally, the factors that influenced the electrical pitch percept were examined.

Significant group mean post-implantation improvement was observed on a sentence-in-coincident babble test and for spatial release from masking advantage when the noise location favoured the implanted side. Self-reported group ratings of functional benefit were improved post-implantation for all questionnaires administered. Objective assessment revealed poorer group mean localisation ability post-operatively for subjects with pre-operative bilateral acoustic hearing, however subjective ratings in real-world environments were more variable. Degree of post-implantation SRT benefit on the coincident babble test and on self-reported ratings of perception of soft speech and sounds in the environment was greater for subjects with less contralateral hearing.

Factors that predicted better unilateral word scores in quiet (and accounted for 34.1% of the variance) were a shorter duration of severe-to-profound hearing loss in the implanted ear and poorer pure-tone-averaged thresholds in the contralateral ear. A shorter duration
of severe-to-profound hearing loss in the implanted ear, a lower age at the time of implantation, and better contralateral hearing thresholds were associated with higher bilateral word recognition in quiet and SRT in noise (and accounted for 36.0% and 30.9% of the variance respectively). Degree of match between the initial (pre-activation) pitch percept elicited from stimulation on the most apical channel and the assigned frequency affected rate of post-operative improvement in the unilateral but not bimodal device configuration. Post-experience measures revealed higher unilateral word in quiet and sentence in babble scores for those subjects with closer match between the assigned acoustic input frequency and electrical pitch percept. No significant correlation was observed between degree of match and bilateral speech recognition ability. Subjects with poorer hearing in the implanted ear tended to have a lower pitch and a shallow electrical pitch function than predicted by the spiral ganglion frequency-position model. There was no significant group effect of listening experience.

Declaration

This is to certify that:

- The thesis comprises only my original work towards the PhD except where indicated in the Preface
- Due acknowledgement has been made in the text to all other material used
- The thesis is fewer than 100 000 words in length, exclusive of tables, maps, bibliographies and appendices
Preface

I certify that I developed the research idea and have taken leadership to conduct all parts of this research work, including writing the content of the thesis. My supervisors (Professor Robert Cowan, Professor Hugh McDermott and Dr Richard van Hoesel) and members of the Steering Committee (Professor Richard Dowell and Dr Pamela Dawson) assisted with analyses and interpretation of the data, as well as the quality of the written publications. Statistical support was obtained from Dr Sue Finch at the University of Melbourne Statistical Consulting Centre when required.

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Appendix 7: Publication Reprint – Factors Influencing Electrical Place Pitch Perception in Bimodal Listeners
1 Introduction

1.1 Preamble

Ongoing advances in development of technology and improved surgical techniques have resulted in continual improvement in post-operative outcomes for cochlear implant recipients. This has led to a subsequent expansion over the years in the indications for candidature of cochlear implants. An increasing number of hearing aid users with relatively good pre-operative hearing, in one or both ears, are now approaching cochlear implant centres for candidacy assessment. Expansion in the range of candidates being assessed for cochlear implantation introduces added complexity in the clinical setting, in that there is increased degree of uncertainty regarding expected outcomes. Such uncertainty can make it difficult for a clinician to provide recommendations and to be confident when setting post-operative expectations with an individual candidate.

Evidence of the progressive change in candidacy has been obtained through data analysis in the adult clinical outcome database from the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne, Australia. Pre-operative open-set monosyllabic word scores were reviewed for the 1194 adult cochlear implant recipients in the clinic’s database, and showed a progressive increase in the percentage of recipients implanted with hearing in one or both ears. Until the year 2000, only 3.1% of the implanted recipients had a pre-operative monosyllabic word score in the implanted ear of greater than or equal to 5%. Between 2001 and 2009 the percentage increased to 15.6%, and in the three years 2010-2012 increased again to 24.5%. Similarly, the percentage of recipients with word scores greater than or equal to 5% in the contralateral ear has increased significantly. Between the years 1979 and 2000 only 8.6% of recipients met this criterion, and this increased to 15% between 2001 and 2009. More recent analysis for the 550 recipients implanted between the years 2010 and 2014 revealed that the percentage of recipients with word scores of greater than or equal to 5% in the contralateral ear was 62%.

There are a number of challenges in the clinical setting regarding counselling and management of candidates with pre-operative acoustic hearing. First, it is important to establish and continually monitor the candidacy guidance criteria, or to revise indication criteria, to ensure that candidates likely to benefit from implantation are able to access
the technology. Second, it is important to identify the factors that contribute to post-operative outcomes (both positive and negative) so that clinicians can provide more reliable predictions of post-operative benefit for individual candidates. This is particularly important for candidates with pre-operative acoustic hearing, where there may be less certainty regarding the expected benefit, or where there is risk to post-operative loss of acoustic hearing. Finally, consideration as to the optimal post-operative fitting approach is important to ensure that maximum benefit is obtained from the technology. Each of these factors has been investigated within the current thesis, with an aim to provide practical clinical guidance to clinicians to assist with the decision-making and provision of recommendations to candidates considering cochlear implantation as an intervention option. Following is a summary of the current state of knowledge in areas deemed most relevant to the current research, and from which the research questions and methodology have been developed.

1.2 Definition of Substantial Acoustic Hearing

The term ‘substantial’ acoustic hearing has been used throughout the thesis, and so requires definition. There are a number of challenges to defining what constitutes substantial hearing. First, the candidacy criteria for cochlear implantation vary worldwide according to the regulatory regimes governing different regions and countries and their respective cochlear implant clinics. Criteria vary in terms of whether the implanted ear thresholds, implanted ear speech perception scores or best-aided speech perception scores (or a combination of measures) are used to define candidacy. For example, in the United States of America, Food and Drug Administration (FDA) approved indications specify audiometric guidelines in addition to both implanted ear speech perception and best-aided speech perception scores, whereas approved indications in the European Union and in Australia describe audiometric criteria in the ear to be considered for implantation that are based on pure-tone-average guidelines. Although not described in the approved indications for use in Europe and Australia, a number of clinics have developed their own speech perception guidance criteria, and those vary as to whether they refer to the unilateral (ear to be implanted) and best-aided configuration. Indications also vary according to the specific electrode type selected. For example, the Hybrid-L24 electrode array (Cochlear Limited) which was specifically developed for
electro-acoustic applications has more restricted candidature indications as compared to the Contour Advance electrode array.

A second challenge in defining what constitutes substantial acoustic hearing is that there is variability in speech perception tests used globally, and no basis to compare findings directly across centres. Test materials differ in terms of structural design, the language used, the speech presentation level and characteristics of each individual speaker, all of which may contribute to varying levels of difficulty. There is currently no published data that compares the materials across multiple sites. This variability in approach used for defining candidacy, and in use of different speech perception test materials, means that the findings presented in research publications at one centre cannot often be directly applied for use at a local implanting centre, particularly in a different country.

An overview of the current indications by device type and region is described below. Note that at the time of commencement of the research presented in this thesis, the indication criteria in Europe and Australia were not as broad as outlined below. Specifically, the implantation of candidates with substantial hearing in the contralateral ear was not indicated. During the course of the research, the implantation of candidates with single-sided hearing loss has been a focus of much research, as has broadening of the indications for candidates presenting for candidacy assessment with bilateral acoustic hearing.

**USA Food and Drug Administration (FDA) Approved Indications**

The current FDA-approved audiometric indications for the Nucleus Contour Advance electrode (since 2005) specify that candidates have profound hearing loss in both ears in the mid to high frequencies and a moderate to profound loss in the low frequencies. Speech recognition criteria specify maximum scores on a recorded, open-set aided sentence test in both the ear to be implanted (with intelligibility less than or equal to 50%) and in the best aided condition (with intelligibility no more than 60%). Similarly, the indications for the Nucleus Hybrid L24 cochlear implant system specify both a speech perception score criterion for the implanted ear and best-aided condition. That device is intended to provide electric stimulation to the mid to high-frequency region of the cochlea and acoustic amplification to the low frequency regions (for candidates with residual low-frequency hearing sensitivity). Typical pre-operative hearing of candidates ranges from
normal to moderate hearing loss in the low frequencies (thresholds no poorer than 60 dB HL up to and including 500 Hz), with severe to profound mid-to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 75 dB HL) in the ear to be implanted, and moderately severe-to-profound mid-to-high-frequency hearing loss (threshold average of 2000, 3000 and 4000 Hz ≥ 60 dB HL) in the contralateral ear. The CNC word recognition score criterion is between 10% and 60%, inclusively, in the ear to be implanted in the pre-operative aided condition and equal to or better than that of the ear to be implanted but not more than 80% correct in the contralateral ear.

European Union and Australian Therapeutic Administrative Agency Approved Indications

Both the Slim Straight (CI422) and the Contour Advance electrode have been approved in the European Union by the European Commission (Medical Devices) and in Australia by the Therapeutic Goods Administration (TGA) for the following groups of candidates:

- Individuals aged 12 months to 17 years who have clinically established bilateral sensorineural hearing loss and who have compromised functional hearing with hearing aids or would receive no benefit with hearing aids. Typical pre-operative threshold levels in the impaired ears demonstrate a pure-tone average loss of moderately severe to profound degree. Pure-tone average loss can be defined as the average threshold calculated for 4 frequencies at 500, 1000, 2000 and 3000 or 4000 Hz as available.

- Individuals aged 18 years and older who have clinically established post-linguistic bilateral or unilateral sensorineural hearing loss and who have compromised functional hearing with hearing aids, or would receive no benefit with hearing aids. Typical pre-operative threshold levels in the impaired ears demonstrate a pure-tone average loss of moderately severe to profound degree. Pure-tone average loss can be defined as the average threshold calculated for 4 frequencies at 500, 1000, 2000 and 3000 or 4000 Hz as available.

- Pre-linguistically or peri-linguistically deafened individuals aged 18 years and older who have profound bilateral sensorineural hearing loss and who have compromised hearing with hearing aids.
**European and Australian Speech Perception Guidance Criteria**

At the level of individual countries or clinics, guidelines relating to pre-operative speech recognition ability have been developed that inform candidacy decisions. Prior to the recent change in indication to include adult candidates with unilateral hearing impairment in Europe and Australia (in 2013), there were specific guidelines published. In Germany (Aschendorff et al., 2007), it was recommended that candidates should obtain less than 30% correct for Freiburg monosyllables at a presentation level of 70 dB SPL in the best aided condition. In France adult candidates should obtain less than 50% correct on the Fournier bi-syllabic word test presented in quiet at 60 dB SPL (James et al., 2005; Fraysse et al., 2006). In the United Kingdom (UKCochlearImplantStudyGroup, 2004) the BKB sentences are used for assessment, with a target of less than 50% correct in the best-aided condition used as the basis for candidacy decisions. Change in speech perception-based candidacy criteria is ongoing, particularly as increasing experience is gained with the implantation of candidates with unilateral hearing impairment.

**Melbourne Cochlear Implant Clinic**

In addition to the Australian criteria, individual clinics may vary this, in particular if they are involved in research studies relating to candidature such as is the case with the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne. The current selection criteria in the Melbourne Cochlear Implant Clinic are based on retrospective data analysis conducted with 210 post-lingual adults. Analysis involved a statistical approach based on post-operative outcomes (Dowell et al., 2004) obtained after three months of cochlear implant experience. Guidelines are primarily based on the assumption of likely monosyllabic phoneme score improvement in the implanted ear relative to that ear pre-operatively. A secondary consideration assesses the expectation that the unilateral implanted ear score will exceed the score in the better hearing (contralateral) ear. The speech perception criterion of \( \leq 46\% \) phoneme score for the ear to be implanted provides a 75% chance of speech recognition improvement with that ear after implantation based on the mean clinical outcome with the implant alone. The contralateral ear speech perception criterion of \( \leq 67\% \) phoneme score similarly affords a 50% chance that implanted ear performance is better than that of the contralateral ear. Given the complexity in determining what constitutes substantial acoustic hearing based on global
data, the research in the current thesis has been developed based upon those local candidacy guidelines of the Royal Victorian Eye and Ear Hospital.

1.3 Types of Candidates with Pre-Operative Acoustic Hearing

There are two relatively distinct groups of candidates who would be considered to have substantial pre-operative acoustic hearing in the context of the guidelines described above. These candidate groups comprise those who either:

(a) Have more hearing in the ear to be implanted than recommended by the candidacy guidelines. These candidates are typically implanted in the poorer ear and so have potential access to low-frequency, fine-timing binaural cues provided by bilateral acoustic hearing.

(b) Meet the guidance criteria in the ear to be implanted but have more substantial hearing in the contralateral ear (up to normal hearing) than would be typically recommended.

For the group as outlined in (a) above, the expansion in candidacy criteria globally has in part occurred as a result of the development of specialist hearing preservation devices that increase the likelihood of maintaining hearing in the implanted ear post-operatively (Fraysse et al., 2006; Gantz et al., 2009; Lenarz, 2009; Skarzynski et al., 2010). Previous research has shown that hearing aids are often ineffective in providing high frequency speech information to adults with severe-to-profound high frequency hearing loss (Ching et al., 1998). In contrast, the provision of such high frequency information through a cochlear implant, for use in combination with low frequency information provided through acoustic hearing, has been shown to be beneficial.

More recently, there has been interest in examining outcomes for the type of candidate outlined in (b) above, who have asymmetric or even unilateral hearing impairment. While initial research was conducted to examine the potential use of electrical stimulation to alleviate tinnitus (Van de Heyning et al., 2008; Buechner et al., 2010; Punte et al., 2011; Ramos et al., 2012), there is increasing evidence in support of functional performance benefits following implantation for this recipient group. Hearing-impaired individuals with this type of hearing loss can report difficulties in speech understanding in their everyday listening environments, along with significant communication handicaps that
interfere with their quality of life (Wie et al., 2010). These reports of hearing difficulty in some listening situations are not surprising given the known benefits of bilateral hearing for understanding speech in the presence of background noise (Bronkhorst and Plomp, 1988) and for localising sound sources, as well as the significant impact of loss of bilateral hearing on socioeconomic and quality of life outcomes (Noble et al., 2008; Wie et al., 2010).

1.4 Risk-Benefit Considerations for Candidates with Pre-Operative Acoustic Hearing

There are a number of important considerations during the pre-operative counselling and post-operative management of candidates with pre-operative acoustic hearing. These include: 1) the risk of post-operative hearing loss in the implanted ear for candidates with pre-operative bilateral acoustic hearing; 2) potential for less post-implantation benefit for candidates with more salient contralateral hearing; and 3) lack of knowledge as to the factors that contribute to unilateral and bilateral speech recognition in the ‘expanded’ candidate population.

Each of these considerations will be discussed in the following sections, with reference as to the key issues, supporting research and gaps in current knowledge.

1.4.1 Risk to Post-Operative Loss for Candidates with Pre-operative Bilateral Hearing

Loss of acoustic hearing may arise during the surgical procedure as a result of damage to cochlear structures. Electrode designs and surgical techniques have therefore focussed on reducing trauma, through the design of relatively short electrode arrays and soft-surgery techniques (Gantz and Turner, 2003; Adunka et al., 2004; Gantz et al., 2004; Gstoettner et al., 2004; Gantz et al., 2005; Fraysse et al., 2006; Gantz et al., 2006; Skarzynski et al., 2006; Baumgartner et al., 2007; Gstoettner et al., 2009; Lenarz, 2009; Skarzynski et al., 2010; Skarzynski et al., 2012). Despite these initiatives, the preservation of acoustic hearing remains a possibility in all cases, not a probability that can be guaranteed.

Immediate post-operative acoustic hearing preservation has been reported to generally range from 50-100% (Fraysse et al., 2006; Baumgartner et al., 2007; Gantz et al., 2009;
Lenarz, 2009; Skarzynski et al., 2012), although the reported rates vary according to differences in study methodologies. Additional to the immediate risk to hearing that occurs as a result of electrode insertion, there is also evidence of delayed loss in the implanted ear (Baumgartner et al., 2007; Gantz et al., 2009). Given the risk to post-operative hearing loss in the implanted ear in some cases, it is important for cochlear implant candidates to understand the potential implication of loss on functional outcomes post-implantation.

There is considerable published evidence of post-implantation speech perception benefit in candidates with pre-operative implanted ear acoustic hearing, or with pre-operative bilateral best-aided scores that exceed the FDA criteria, using traditional measures of speech in quiet and speech in coincident noise. Evidence has been obtained either through assessing pre- and post-operative unilateral outcomes (Cullen et al., 2004; Gantz et al., 2009; Lenarz, 2009; Lenarz et al., 2013), or pre- and post-operative bilateral best-aided outcomes obtained with the combined electrical stimulation and contralateral hearing aid (Gantz et al., 2006; Gantz et al., 2009; Gifford et al., 2010; Amoodi et al., 2012; Skarzynski et al., 2014). However the majority of studies have been conducted in subject groups where hearing was preserved to varying degrees after implantation, and there is more limited published information describing pre- and post-implantation performance when hearing is lost in the implanted ear.

Unilateral benefit using the cochlear implant alone for recipients who lost all hearing in the implanted ear has been reported by Cullen et al. (2004). Those 12 subjects had pre-operative speech perception in quiet in the implanted ear that was outside of the FDA candidacy criteria for the Contour Advance electrode. Specifically, subjects met one of the following criteria for speech recognition in quiet: a CUNY sentence test score of greater than 60%, a HINT sentence score of > 50%, or a monosyllabic CNC word score of greater than 20%. In that study the pre-operative monosyllabic CNC word score in the ear selected for implantation ranged from 4% to 36%. All subjects improved post-implantation in the unilateral implant-alone condition, with group mean improvement of 15, 47 and 33 percentage points on the CUNY, HINT in quiet and CNC word scores respectively after six months of cochlear implant experience. The smaller improvement observed for the CUNY sentence test was likely influenced by ceiling effects. Similar benefit was reported in 27 subjects implanted with devices from three manufacturers, and
who had pre-operative word scores ranging from 8% to 48% (Amoodi et al., 2012). All subjects improved post-implantation in the unilateral implant-alone condition, with group mean improvement of 26.2 and 37.1 percentage points on the HINT in quiet and CNC word tests respectively. Although the majority of subjects in that study were reported to have lost hearing in the implanted ear post-implantation, there were six subjects for whom hearing was partially preserved. Average post-operative hearing thresholds in the implanted ear at frequencies of 250 Hz and 500 Hz for those subjects were 70 dB HL and 89 dB HL, however it is not mentioned in the manuscript whether that hearing was amplified and so likely to have contributed to the post-operative speech perception scores. Although it is possible that the group mean improvement reported by Amoodi et al. (2012) has been impacted by the contribution of acoustic hearing for those 6 subjects with residual acoustic hearing, it is clear that there were benefits observed for the 21 subjects for whom acoustic hearing was not preserved.

Arguably of more relevance for the candidate group with pre-operative bilateral acoustic hearing is the best-aided function. That assessment demonstrates the post-implantation change that occurs when using combined acoustic and electric stimulation, in comparison to that obtained using pre-operative bilateral acoustic hearing. Evidence of bilateral benefit on the traditional measures of speech recognition performance used clinically (speech in quiet or speech in coincident noise) has been demonstrated in two different populations; those implanted with the Contour Advance electrode who had best-aided hearing that exceeded the candidacy criterion of the FDA (Gifford et al., 2010; Amoodi et al., 2012), and those with steeply-sloping bilateral hearing loss implanted with electrode arrays specifically designed to minimise insertion trauma and so preserve residual acoustic function (Gantz et al., 2006; Gantz et al., 2009; Lenarz, 2009; Lenarz et al., 2013; Skarzynski et al., 2014).

Specific research describing the impact of loss of acoustic hearing in the implanted ear in those populations is limited. In the former-mentioned case, bilateral benefit has been reported in candidates who exceeded the best-aided candidacy criterion of the FDA, i.e. those with greater than 60% on the HINT sentence in noise test (Amoodi et al., 2012) or with greater than 30% word score on the monosyllabic word in quiet test. However, since enrolment was based on the best-aided rather than single-ear criterion for those studies, not all subjects had useable hearing in the ear selected for implantation. Although
subjects with pre-operative word scores of up to 44% in the ear selected for implantation were included in the study by Amoodi et al. (2012), twelve of the 27 subjects had scores that were below 10% and nine had no measurable word recognition in that ear. Single-ear word scores were not reported by Gifford et al. (2010), however 16 of the 22 subjects had unaided audiometric thresholds of less than or equal to 80 dB HL at 250 Hz and 500 Hz and aidable hearing within that audiometric threshold to 1 kHz and 4 kHz for five and three subjects respectively. Given the unaided hearing thresholds it is assumed that the hearing in the implanted ear contributed to the pre-operative best-aided score for at least some of the subjects in that study. As previously discussed in reference to the unilateral test condition, the grouped mean post-implantation improvement of 37.1 percentage points reported by Amoodi et al. (2012) might be affected by the hearing preservation in 6 of the 27 subjects, and so not truly indicative of the best-aided post-operative outcome if hearing were lost after implantation. In the group of 22 subjects examined by Gifford et al. (2010) the grouped mean best-aided pre- and post-operative monosyllabic word scores (after 6-months of implant use) were 41% and 82% respectively. In that study hearing in the implanted ear was reported to be lost for all subjects, however there was no separate ear information provided in the publication to determine the extent to which subjects had access to bilateral acoustic hearing. Therefore, the direct relevance of those findings to the candidate group with bilateral acoustic hearing cannot be determined.

Contrary to the research conducted with the Contour Advance electrode, the indication criteria for enrolment into the hearing preservation studies specified a degree of pre-operative bilateral acoustic hearing which would warrant attempts at preservation. As a result, the findings in those studies are more directly relevant when considering the pre-to post-operative change in bilateral function. Where acoustic hearing is preserved in the implanted ear, those recipients are able to utilise the bilateral acoustic hearing in combination with unilateral electrical stimulation (commonly termed the ‘combined’ mode) and, when hearing is lost in the implanted ear, use the cochlear implant in combination with the contralateral ear acoustic hearing. Significant post-implantation benefit in the combined mode for such candidates has been reported in a number of studies with the Hybrid S12 (Gantz et al., 2006; Gantz et al., 2009), Hybrid L24 (Lenarz, 2009; Lenarz et al., 2013) and Slim Straight (CI422) arrays (Skarzynski et al., 2014). Group mean improvement post-implantation on a word test in quiet ranged from 26.6% to 40% in those studies, whereas in noise the reported benefit was 20% or 6.5 dB.
Preliminary findings from the Hybrid S12 clinical trial conducted with 87 subjects (Gantz et al., 2009) indicated best-aided post-operative improvement in either word in quiet scores or SRT in noise for 74% of the subjects. Earlier published data (Gantz et al., 2006) in the first 11 subjects to have reached the 12-month post-activation time point indicated that the mean pre- and post-operative monosyllabic word in quiet scores were 32% and 72% respectively. A group median increase of approximately 6.5 dB was observed on an adaptive sentence test in noise in a study of 66 subjects implanted with the Hybrid-L24 electrode (Lenarz et al., 2013). More recently, Skarzynski et al. (2014) published the results of a clinical trial of the Nucleus® Slim Straight electrode array in 35 subjects. In subjects with a pre-operative 500 Hz threshold of less than or equal to 50 dB HL, the percentage increase for a test administered in noise was greater than 20%. Those studies provide confidence in implanting candidates with pre-operative acoustic hearing, however they do not provide information regarding expected performance when hearing is lost in the implanted ear. Gantz et al. (2009) reported that post-operative change in bilateral speech perception on tests in quiet and noise was not correlated with degree of hearing loss in the implanted ear, and that the post-operative contribution of electric hearing provided by the device more than compensated for any observed reduction in acoustic hearing thresholds. However further investigation is warranted in candidates with a wider bandwidth of pre-operative hearing thresholds than examined in the Hybrid-S12 study which was limited to candidates with bilateral steeply-sloping hearing loss.

Candidates with pre-operative bilateral acoustic hearing may present with a range of unaided threshold configurations, which is important to consider in the context of the risk to loss of acoustic hearing. Figure 1 shows example audiograms for two types of candidates, both of which scored greater than or equal to 46% on the monosyllabic word test in quiet in the ear selected for implantation. The upper and lower broken lines shown on each of the graphs indicate the unaided audiometric threshold inclusion criteria range for the hearing preservation devices. Example audiograms for three typical candidates for those devices are shown in the left panel, with the thresholds falling within the recommended range. In the right panel, implanted ear unaided audiometric thresholds are shown for three candidates with speech perception ability outside of the local candidacy guidance criterion but who also have poorer low frequency audiometric thresholds than would be recommended for implantation with the shorter hearing preservation electrode types. Although those candidates have poorer low frequency
hearing than the hearing preservation guidelines, they have better high frequency thresholds than the range recommended by that criterion. The impact of loss of acoustic hearing for this candidate group has not been examined to date.

![Figure 1: Illustrative examples of unaided audiometric thresholds for the implanted ear for candidates with bilateral acoustic hearing. Broken lines indicate the minimum and maximum unaided audiometric threshold range for the selection of the Hybrid-L24 electrode as indicated by FDA criteria. The different symbols on each of the graphs are indicative of individual subject thresholds, and are shown as examples only.](image)

An additional and perhaps more important consideration for this candidate group relates to the relative lack of published information describing bilateral spatial hearing outcomes. In particular, it is relevant to establish whether the binaural cues provided by use of two hearing aids would also be available through use of combined acoustic and electric stimulation. For normal-hearing listeners, spatial separation of the two ears results in timing and intensity differences that influence the ability to hear a target signal in the presence of noise (Bronkhorst and Plomp, 1988). Detection of the target can be facilitated through bilateral unmasking that is particularly effective for low frequencies when target and noise contain different interaural time delays. The ability to hear sources as originating from different locations also helps to reduce the deleterious effect of
informational masking, through allowing the listener to correctly group the various components in the total signal that belong to the target talker as opposed to interferers (Kidd et al., 2008). In addition to those binaural cues, when speech and noise are spatially separated the physical head shadow differs at the two ears, which allows a listener with access to both ears to attend the shadowed ear that has the more favourable signal-to-noise ratio (SNR). The SNR advantage at the shadowed ear is dependent on the specific locations of target and interferers, and on the frequency content of the sounds, because high frequencies are more affected by the head (Shaw, 1974). The ability to benefit from the head shadow will be smaller for listeners with less high-frequency hearing in the shadowed ear. The effects of bilateral unmasking, spatial release from informational masking, and SNR advantage at the shadowed ear can all contribute to spatial release from masking (SRM).

When considering the likely effect on localisation of replacing acoustic with electric hearing in one ear, it is important to consider the degree of access to interaural level differences (ILDs) and ITD (interaural timing difference) cues in the pre- and post-operative conditions. A signal originating from one side of a listener's head will arrive earlier and be greater in intensity at the ear closer to the sound source. As a result, the listener will potentially have access to ITD and ILD cues as well as unilateral level and spectral cues to facilitate localisation ability. According to the duplex theory (Rayleigh, 1907), the cues used for localisation in the horizontal plane arise from predominately ILDs in the high frequencies and from ITDs in the low frequencies. Fine timing ITDs at the two ears may be perceived pre-operatively with bilateral amplification to localise sound sources or to facilitate communication in complex noisy listening environments. However, those cues will not be available post-operatively due to the lack of fine-timing information perceived by implant users (van Hoesel, 2012; Francart and McDermott, 2013). Distortion of envelope timing and ILDs with bimodal devices, as compared to bilateral hearing aids, may also be problematic due to the substantially different signals in the two ears.

The majority of studies that have investigated localisation ability with cochlear implant recipients have reported modest bimodal benefit as compared to the unilateral cochlear implant alone or hearing aid alone test conditions (Ching et al., 2004; Firszt, 2008; Potts et al., 2009). Assessment of pre- to post-implantation localisation ability in the group
of candidates with substantial bilateral acoustic hearing has not been examined to date. Although not a direct measure of pre- and post-implantation localisation ability, Dunn et al. (2010) compared post-operative localisation ability using a within-subject design and with a range of device combinations that included bilateral hearing aids and bimodal devices. Subjects were all implanted with the Hybrid S12 device with preserved acoustic hearing in the implanted ear, and had bilateral steeply-sloping hearing loss. On a localisation test using a range of everyday sounds all subjects could localise at better than chance levels using bilateral hearing aids. However, only four of the eleven subjects could achieve that outcome using the bimodal device configuration. Those data suggest that localisation ability would be reduced with use of bimodal devices compared to bilateral acoustic aided hearing. More direct comparison of pre- and post-implantation localisation ability is warranted, and particularly when considering the candidate with the broader bandwidth of acoustic hearing as described in Figure 1.

Candidates with relatively symmetrical acoustic hearing loss and an unaided audiometric threshold configuration in the implanted ear as shown in the left panel of Figure 1 might be able to utilise low-frequency fine-timing ITD cues for localisation and hearing in noise, whereas those in the right panel might have more limited access to the low-frequency cues but more access to bilateral high-frequency ILD cues with use of hearing aids. Although clear benefit of implantation has been demonstrated for candidates with steeply-sloping hearing loss on speech perception and self-report subjective rating measures (Gantz and Turner, 2003; Gantz et al., 2004; Gstoettner et al., 2008; Lenarz, 2009; Skarzynski et al., 2009; Podskarbi-Fayette et al., 2010), there has been only limited research investigating the effect of loss of acoustic hearing on spatial hearing abilities. Even with a successful hearing outcome using electrical-only stimulation, it is well established that fine temporal cues are not presented via the cochlear implant sound processor and this may impact specific spatial hearing abilities such as localisation of sounds in the horizontal plane or reduction of hearing ability in noisy situations. Impact of loss of acoustic hearing may be more significant for those subjects with a wider frequency bandwidth of pre-operative bilateral hearing because they may have access to ILDs in addition to ITDs which facilitate localisation. Wider bandwidth also increases the likelihood of being able to attend to the ear with better SNR due to head shadow effects.
In summary, there are a number of research questions relating to the potential impact of loss of acoustic hearing on bilateral function after cochlear implantation. Although positive speech perception outcomes have been reported for candidates with best-aided hearing scores outside of the criteria of the FDA, not all subjects had hearing in the ear selected for implantation to enable investigation as to the impact of loss of hearing on post-implantation performance. Additionally, outcomes have been measured in subjects with varying degrees of hearing preservation, rather than specifically focusing on the ‘worst-case’ situation which is likely to be of interest to candidates. Impact of loss of acoustic hearing in the implanted ear on post-implantation spatial hearing abilities is an important consideration, particularly for those candidates with access to ITD cues pre-operatively since low-frequency fine-timing cues are not perceived by bimodal listeners. Examining a broad range of outcomes for a candidate group with substantial pre-operative bilateral acoustic hearing of varying configurations would be expected to provide improved guidance to candidates when considering the risks and likely benefits of implantation.

1.4.2 Potential for Less Benefit for Candidates with More Salient Contralateral Hearing

Candidates with substantial pre-operative acoustic hearing in the contralateral ear and with an asymmetric or unilateral configuration of hearing impairment seek evidence-based guidance from clinicians with respect to the expected benefits of implantation. A key consideration in the clinical setting is the extent to which expected benefit might be impacted by the degree of contralateral hearing.

There is published evidence of reduced speech perception benefit for a candidate group with contralateral acoustic hearing, as compared to more traditional recipients. Gifford et al. (2010) compared best-aided outcomes for 22 subjects with substantial pre-operative hearing (defined as greater than 30% on a monosyllabic word test in quiet), with a group of more traditional cochlear implant candidates and found no difference between the groups in average bilateral post-operative word scores. Since the subjects with pre-operative hearing had higher pre-operative levels of performance than those without, they obtained less post-operative improvement following implantation than the more traditional cochlear implant candidates. Mok et al. (2006) examined the benefit of using electrical stimulation in combination with a contralateral hearing aid in 14 adult recipients.
and reported that recipients with mid to high frequency aided thresholds in the ear contralateral to the cochlear implant demonstrated less bimodal benefit than those recipients with poorer mid to high frequency thresholds.

A number of studies have also been conducted in the asymmetric or unilateral hearing impaired populations, either through comparison of pre- and post-implantation test scores or through assessing the benefit provided by use of the cochlear implant in combination with normal or near-normal contralateral hearing. Firszt et al. (2012) examined pre- and post-operative outcomes for a group of ten subjects with asymmetric hearing loss, using a range of speech perception measures in noise that included the R-SPACE laboratory sound system (Compton-Conley et al., 2004). All subjects scored at least 50% in the contralateral ear on a monosyllabic word or sentence test in quiet pre-operatively, and had little or no hearing in the ear selected for implantation. Contralateral ear hearing thresholds varied substantially across the group, with the PTA (using frequencies 0.5, 1.0 and 2.0 kHz) ranging from 27 to 88 dB HL and a mean of 56 dB HL. After six months of cochlear implant use, significantly higher grouped mean scores using the combined devices after implantation for the seven subjects with post-lingual hearing loss were observed for all tests (using metrics of HINT sentences in noise, TIMIT sentences in noise, and TIMIT sentences presented in quiet).

Contrary to that finding in asymmetric listeners, there has been a lack of reported benefit using coincident presentation of speech and noise in a number of studies conducted in listeners with normal or near-normal hearing thresholds on the better hearing (non-implanted) ear. In a group of subjects with a PTA threshold in the better ear of between 7 and 30 dB HL (Arndt et al., 2011a; Arndt et al., 2011b), direct comparison of pre- and post-operative outcomes were examined in up to 22 post-lingual adults with relatively short duration of single-sided hearing impairment. No significant post-operative improvement was observed after 6 months of cochlear implant experience. Lack of benefit from addition of the cochlear implant to information provided by acoustic hearing in the contralateral ear alone when listening to coincident speech in noise has also been reported by Vermeire and Van de Heyning (2009) in a subject group with contralateral pure-tone-averaged thresholds of better than or equal to 39 dB HL, and in five subjects with unilateral hearing loss (Buechner et al., 2010).
An important consideration with respect to access to bilateral cues is the ability of an individual to understand speech when the target and noise are spatially separated. As previously discussed, the physical head shadow differs at the two ears and allows a listener with access to both ears post-operatively to potentially attend to the shadowed ear that has the more favourable SNR. Significant speech in noise improvement in spatially separated speech and noise test configurations has been observed in unilateral hearing impaired individuals. As expected, the benefit reported in those published studies has been due primarily to the head shadow effect, with increased benefit when the implanted ear receives a better signal-to-noise ratio than the non-implanted ear (Vermeire and Van de Heyning, 2009; Buechner et al., 2010; Arndt et al., 2011a). Due to the different test set-ups and experimental design across the published studies, it is difficult to accurately extract information relating to the degree of post-implantation spatial hearing benefit as a function of contralateral hearing.

Although not a direct examination of pre- and post-implantation outcomes, the bimodal benefit provided by the cochlear implant (relative to the contralateral acoustic ear alone) has been examined in two separate subject groups using the same experimental design (Vermeire and Van de Heyning, 2009). In that study subjects were grouped according to whether they had normal contralateral hearing (defined as having a PTA threshold of better than 38 dB HL) or had compromised but aided hearing in the contralateral ear (with PTA of between 38 and 79 dB HL). Significant bimodal benefit was observed for a test configuration with speech in front of the listener and noise at 90 degrees on the side of the cochlear implant for the subject group who had aided hearing on the contralateral side, but not for those with normal hearing. Similarly, subjective ratings from the speech hearing and quality sub-scales of the SSQ questionnaire indicated qualitative improvement for the group only with the more compromised contralateral acoustic hearing.

Further research is warranted to investigate the clinical outcomes for candidates who present with varying degrees of contralateral acoustic hearing, and who seek guidance as to expected benefits. Comparison of findings across published research suggests that the degree of post-implantation benefit on traditional coincident speech in noise tests is less for those candidates with better contralateral hearing. However, to date, the impact of contralateral hearing on bimodal benefit has not been explicitly studied. Additionally,
although there is strong evidence of speech intelligibility improvement when SNR advantage is provided to the shadowed implanted ear, the only study to have assessed outcomes as a function of the contralateral hearing level (Vermeire and Van de Heyning, 2009) has not utilised a longitudinal design of pre- and post-operative assessment, and has categorised candidates based on the pure-tone-average thresholds rather than use of a continuous variable. An additional clinical consideration for this candidate group, and one which has not been researched to date, is the question as to whether those candidates with more substantial contralateral hearing might take longer to acclimate to the device in the post-operative period.

1.4.3 Inability to Predict Post-Implantation Outcomes

Inability to reliably predict post-operative unilateral and/or bilateral outcomes is problematic for both clinicians and candidates during the pre-operative counselling and guidance process. Clinicians need to provide evidence-based guidance regarding candidacy recommendations, and to set expectations regarding the likelihood of post-operative improvement. The uncertainty regarding prediction of implant performance is arguably of more significance for a candidate with pre-operative acoustic hearing than for a more traditional cochlear implant candidate. For a candidate without pre-operative hearing there will typically be an overall benefit to communication and speech perception, regardless of the variability in potential outcomes. However, as pre-operative performance increases, the variability in post-operative performance means that in addition to the mean benefit being reduced (Gifford et al., 2010), the proportion of candidates who are likely to benefit decreases. For pre-operative performance that matches the mean cochlear implant performance there is an equal chance of increase or decrease in performance.

The majority of past research that has investigated factors predicting degree of post-operative benefit has focussed on prediction of unilateral (cochlear implant alone) outcomes. For traditional candidates presenting with bilateral severe-to-profound hearing loss this was of most relevance, since there is little or no contribution of the contralateral ear to the hearing outcome. However, for candidates with more substantial pre-operative acoustic hearing, factors important to prediction of bilateral (bimodal) rather than unilateral outcomes are not well understood, yet are likely of most relevance when
considering the likely benefit of implantation on real-world function. Additionally, the majority of studies conducted to date have aimed to predict outcomes on a word test in quiet. For the candidates with more substantial pre-operative hearing, word tests are subject to potential limitations such as ceiling effects, and therefore a more sensitive measure would be sentence in noise tests.

*Demographic and Hearing Configuration Factors Predicting Unilateral (Cochlear Implant Alone) Word in Quiet Speech Recognition*

Prediction of unilateral outcomes following implantation is difficult in the cochlear implant population due to a high degree of variability. In only a few studies have substantial amounts of variance been accounted for by predictive factors (Shipp and Nedzelski, 1995; Rubinstein *et al*., 1999). More typically however, studies of this nature have reported that the known factors tend to account for only a relatively small percentage of the variance in post-operative speech perception scores (Fritze and Eisenwort, 1989; Shea *et al*., 1990; Summerfield and Marshall, 1995; Waltzman *et al*., 1995; Blamey *et al*., 1996a; Dowell *et al*., 2004; Roditi *et al*., 2009; Lazard *et al*., 2012; Blamey *et al*., 2013). Based on the findings from those studies, the most robust predictors of post-implantation word recognition in quiet were the duration of profound deafness and pre-operative speech recognition (Rubinstein *et al*., 1999; Friedland *et al*., 2003; Gomaa *et al*., 2003; Dowell *et al*., 2004; Roditi *et al*., 2009).

The most comprehensive and recent study to investigate factors that affect unilateral auditory performance in cochlear implant recipients has involved analysis of data from 2251 post-lingual adults implanted in 15 centres (Blamey *et al*., 2013). The 3-stage model of auditory performance over time, that was identified based on an earlier analysis of data from 808 post-lingual adults (Blamey *et al*., 1996a) was applied to the population of recipients implanted after 2002. The model incorporated two stages relevant to pre-operative auditory experience; the period of normal hearing, and the duration of time between the onset of profound hearing loss and the date of implantation. A variable effect of aetiology was also incorporated into the model, taking into account the prior observation that recipients with bacterial labyrinthitis tended to obtain poorer than average outcomes, and that those with Meniere’s disease obtained better outcomes post-implantation. The third stage of the model related to post-operative experience, which
may have encompassed such factors as device use, surgical trauma, electrode positioning, access to rehabilitation and cerebral reorganisation and plasticity.

A diagram of the 3-stage model is shown below.

![Diagram of 3-stage model](image)

Figure 2: The 3-stage model of auditory performance indicating the predictive factors as described by Blamey et al 2013.

Percentile ranking of scores for each subject within each centre was required to compensate for variation in the type of test materials, language and presentation level. Independent factors of duration of severe-to-profound hearing loss, age at onset of severe-to-profound hearing loss, duration of implant experience and age at implantation were partitioned into ranges for analysis. Aetiology was included as a categorical factor. The dependent variable was the percentile ranked speech recognition score. Four factors were identified which accounted for between 9.5% and 10.5% of the variance; 1) duration of implant experience, 2) age at onset of severe-to-profound hearing loss or age at implantation, 3) duration of severe-to-profound hearing loss and 4) aetiology. A longer period of post-operative experience with the implant, later age at onset of severe-to-profound hearing loss or younger age at implantation, shorter duration of severe-to-profound hearing loss, and aetiology of genetic or Meniere’s disease were all significant predictors of higher post-operative speech recognition ability.
An expanded analysis based on the same dataset (Lazard et al., 2012) was conducted using fifteen pre-, peri- and post-operative factors that included those identified in the Blamey publication. Additional pre-operative factors were 1) gender, 2) education level, 3) duration of moderate hearing loss, 4) pre-operative hearing aid use, 5) pure-tone-average of the ear selected for implantation, 6) pure-tone-average of the better hearing ear, 7) hearing threshold at 500 Hz in the ear selected for implantation, 8) hearing threshold at 500 Hz in the better hearing ear, 9) ranked aided speech perception, 10) date of implantation, and 11) identification of whether the implanted ear was the better or worse ear. Surgical approach (classified as either insertion via the cochleostomy or round window) was assessed as a potential peri-operative factor that might affect post-operative speech recognition. Additional post-operative factors examined were brand of cochlear implant, angle of insertion of the electrode array and percentage of active electrodes.

Analysis was conducted by entering each of the additional factors under investigation to the four-factor model previously developed (Blamey et al., 2013), and highly significant factors (with p<0.001) then entered into a final General Linear Model. Factors identified as significant contributors to the four-factor model were 1) duration of moderate hearing loss, 2) hearing aid use, 3) pure-tone-average of the better ear, 4) hearing level at 500 Hz of the better ear, 5) ranked pre-operative aided speech perception, 6) brand of cochlear implant and 7) percentage of active electrodes. The majority of those identified factors were then analysed in combination with the previous four-factors. A stronger history of hearing aid use, a shorter duration of moderate hearing loss, and better pure-tone-average thresholds in the better ear were all significant predictors of higher post-operative speech recognition ability. However, it is important to note that the effect of pure-tone-average in the contralateral ear was marginal and likely impacted by the small number of subjects with pure-tone-average thresholds better than 70 dB HL. Subjects with a higher percentage of active electrodes also obtained better outcomes. This would likely depend on the underlying reason for deactivating the electrodes, however those data were not presented in the publication.

Importantly, the identified predictive factors from the Blamey et al. (2013) and Lazard et al. (2012) accounted for only 22% of the outcome variance. Reliance on only the identified pre-operative demographic factors would further reduce the ability to account for outcome variance, since each of the proposed models incorporate a number of post-
operative factors in addition to those which would be available during candidate assessment in the clinical setting.

Figure 3: The 3-stage model of mean expected auditory performance ranking over time, as described by Lazard et al, 2012.

Another recent study (Holden et al., 2013) examined factors predicting word recognition scores in quiet in a group of 114 post-lingually deafened adults. Subjects were arbitrarily categorised using the post-operative score obtained after two years of cochlear implant experience, with rank order percentages of <10%, 10-24%, 25-49%, 50-74%, 75-89% and 90-100%. MANOVA analysis revealed similar findings to those observed in the larger studies, in that a younger age at implantation and shorter duration of hearing loss were correlated with higher speech recognition scores. Duration of hearing loss was a principal component composite variable comprising duration of any hearing loss, duration of hearing aid use and duration of severe-to-profound hearing loss. An effect of post-operative listening experience was also observed but not included in the model, since the focus was on understanding the pre- and peri-operative factors impacting post-operative speech recognition. Other factors shown to be significant predictors of better post-operative speech recognition additional to those identified in the Blamey et al. (2013) and Lazard et al. (2012) studies were better pre-operative aided sentence scores,
higher cognitive function, lower percentage of electrodes in scala vestibuli, more medial as compared to lateral position of the electrode, and deeper insertion angle of the basal electrode.

Although duration of hearing loss has been the most robust predictor of unilateral speech recognition outcomes in the studies conducted to date, the relevance of that knowledge to the candidate population with more substantial acoustic hearing is not known. There is increasing evidence that the period of bilateral as compared to unilateral (implanted ear) auditory deprivation prior to implantation is likely of most importance in influencing unilateral speech recognition outcomes (Friedland et al., 2003; Francis et al., 2004; Matterson et al., 2007; Boisvert et al., 2011; Boisvert et al., 2012b). Those studies support the assertion that the maintenance of auditory input in only one ear preoperatively might be sufficient to maintain the ability of the central auditory pathway to respond to electrical stimulation in the longer-term hearing-impaired ear. Histological analysis in the animal model lends support to the hypothesis that central auditory stimulation is important to maintaining potential for optimal post-operative clinical performance. Auditory cortex re-organisation in response to high frequency hearing loss in which the high frequency region adapts to be responsive to lower frequencies has been shown to occur in response to high frequency hearing loss animal models (Irvine et al., 2003; Fallon et al., 2009b). Improved frequency discrimination (McDermott et al., 1998; Thai-Van et al., 2003), improved amplitude modulation detection (Moore and Vinay, 2009), and improvement in low frequency speech perception (Moore and Vinay, 2009) have been reported to occur in high-frequency hearing impaired adult subjects, and have been hypothesised to be attributed to cortical reorganisation.

A challenge in reviewing the literature relating to impact of duration of hearing loss on post-implantation outcomes in cochlear implant recipients is the lack of specific reference in some studies to the criteria applied. Duration of hearing loss and duration of severe-to-profound hearing loss in the publications by Blamey et al. (2013), Lazard et al. (2012) and Dowell et al. (2004) were clearly stated to be the time from which auditory input was compromised at both ears. However it is not clear from other studies (Gomaa et al., 2003; Holden et al., 2013) whether values assigned to duration of hearing loss were for the implanted ear alone or for the duration of bilateral deprivation. Although much of the earlier research in this area reported that the duration of hearing loss in the implanted ear
impacted outcomes, the findings likely apply to the candidates with bilateral auditory deprivation, since those studies were conducted in bilaterally hearing-impaired subjects at a time when the candidacy criteria were more conservative. The other issue is that often the onset of hearing loss is not clearly identified and is based on subjective subject recollections.

Understanding the impact of auditory deprivation in both the ear to be implanted and bilateral conditions is likely important to consider in the population with more acoustic hearing. The presence of contralateral hearing might better maintain the functional integrity of the central auditory pathway, and diminish any negative effect that might be expected as a result of implanted ear auditory deprivation. In that case, the duration of hearing loss would not likely be a significant predictor of outcomes in the population with pre-operative acoustic hearing; rather, other factors might be more relevant. Better hearing in the contralateral ear might, for example, be an important predictor in the expanded population. There is some evidence for that hypothesis in the published literature. Lazard et al. (2012) reported that better pure-tone-average thresholds in the contralateral ear (with a 3-frequency pure-tone-average within the range 40-49 dB HL) was correlated with higher unilateral post-operative word scores. However, that finding should be interpreted with caution due to the relatively small number of only 14 subjects in that group. Further investigation is warranted as to the potential impact of that factor on unilateral outcomes, and to assess whether the factors that predict outcomes differ from those previously examined in more traditional cochlear implant candidates.

Demographic and Hearing Configuration Factors Predicting Bilateral (Bimodal) Speech Recognition

Due to the majority of early implantations occurring in a single ear, and in candidates with relatively limited acoustic hearing in the contralateral ear, there is substantially less research conducted to understand the factors that influence bilateral (bimodal) outcomes, as compared to unilateral speech recognition outcomes. However, this is arguably of most interest to the new range of candidates with more acoustic hearing. For these candidates, when considering expected post-implantation outcomes, daily function would typically involve bilateral hearing through use of the hearing and cochlear implant sound processor in combination. Although there might be more complexity in examining
outcomes over time in the bilateral as compared to the unilateral condition, e.g. due to the extra variance that might be introduced through variation in hearing aid function, the likely practical application to a candidate means that this is an important area of clinical research.

There are currently only two published studies that report on factors influencing post-implantation bilateral speech recognition. In the most comprehensive study, Gantz et al. (2009) examined influence of a range of factors on bilateral word scores for 61 subjects implanted within the FDA clinical trial of the Hybrid S12 electrode. Factors in the model included pre-operative word score, age at onset of hearing loss, age at implantation, duration of hearing loss in the high frequencies, and whether there was post-surgical acoustic hearing loss of greater than 30 dB HL. Pre-operative word score and duration of hearing loss in the high frequencies explained 29% of the variance in post-operative word score.

Amoodi et al. (2012) applied the Iowa and Johns Hopkins formulae to a group of 27 subjects who scored greater than 60% pre-operatively on the HINT sentence test and were assessed bilaterally on a test of word recognition in quiet. The formulae comprised predictive factors of pre-operative sentence score and duration of hearing loss. Pre-operative bilateral word score ranged from 8% to 48%, with a mean 28.5%. Statistical correlation was reported between predicted post-operative word score and actual performance for both models. The authors concluded that pre-operative speech recognition and duration of hearing loss are important in predicting outcomes for the population with acoustic hearing. However the contribution of the factors were not analysed within a predictive model. Also it is not clear from the publication whether the duration of hearing loss data included in the analysis related to the single implanted ear or for the bilateral condition.

Device Fitting: Influence of Frequency-Pitch Match in Bimodal Listeners

Although there are a number of potential fitting considerations for combined acoustic and electric stimulation, only one aspect will be examined within the current thesis. Of interest is the extent to which the acoustic input frequency mapped to an intracochlear electrode is aligned with the pitch percept that arises from electrical stimulation on that electrode. In Nucleus® sound processors (Cochlear Limited) the extraction of frequency
information from the incoming signal is achieved through use of a Fast Fourier Transform (FFT), with bin spacing of 125 Hz. The single output from each of the bins in the low frequencies is presented to apical channels, and multiple bins are combined to create wider filter bands at higher frequencies. Bins are combined to give an approximation to the critical band spacing of human hearing as determined by Zwicker in 1972, with linear spacing at the apex and logarithmic spacing towards the basal end of the cochlea.

Conventional allocation of frequencies to electrodes assigns a range of acoustic analysis frequencies from 188 Hz to 7938 Hz between the most apical and most basal electrode. In Figure 4 a screen capture from the Nucleus Custom Sound clinical programming software is shown, which indicates the way in which acoustic frequency bands are assigned to electrodes. For each of the 22 electrodes or channels of stimulation (shown along the top of the screen), an acoustic analysis frequency range defined by the information ‘LF’ (for low-frequency) and ‘UF’ (for upper-frequency) in the bottom of the screen is assigned to each of the channels. The bandwidth of the FFT bin (‘BW’) is also shown in the data grid at the bottom of the screen. Although customisable with Nucleus devices using the Custom Sound programming software, the recommendation for electric only stimulation is to use the default frequency allocation table (FAT) for mapping cochlear implant recipients. In part, that recommendation arises from an inability to reliably customise the assignment of analysis frequency to an individual’s insertion angle and cochlear characteristics.
Figure 4: Mapping screen from the Nucleus Custom Sound clinical programming software, which indicates the way in which acoustic analysis frequencies are assigned to electrodes in the sound processor during the mapping procedure. For each of the channels (numbered 22 to 1) the lower (LF) and upper (UF) frequency boundary of the acoustic filter is shown. Also shown is the bandwidth of the acoustic filter (BW).

Insertion angle of the most apical electrode varies according to a number of factors, including cochlear size, medial location within the scala tympani, and electrode design. In prior studies that have assessed the electrical pitch percept obtained with stimulation on intracochlear electrodes, the most typical insertion angle has been reported as approximately 450 degrees (Blamey et al., 1996b; Boex et al., 2006; McDermott et al., 2009), although pitch perception for deeper insertion angles of up to 680 degrees has also been examined (Baumann and Nobbe, 2006; Boex et al., 2006). Expected pitch percept for an electrode with an insertion angle of 450 degrees would be 550 Hz, based on the Kawano et al. (1996) adaptation of Greenwood’s model of the frequency along the organ of Corti (Greenwood, 1990). Stimulation of a more basally located electrode with insertion angle of 360 degrees would be expected to result in a higher pitch percept of 979 Hz. Use of the default acoustic analysis frequency range, without compensating for insertion angle, would typically result in an increasingly compressive effect with more shallow insertion. Substantial inter-subject variability has also been reported as to
whether the pitch percept aligns with that expected based on the organ of Corti and spiral ganglion frequency-place models (Blamey et al., 1996b; Baumann and Nobbe, 2006; Boex et al., 2006; Reiss et al., 2007; Vermeire et al., 2008; McDermott et al., 2009; Carlyon et al., 2010)

The effect of mismatch between the allocated input acoustic frequency and the electrical pitch percept (in this thesis referred to for simplicity as the ‘frequency-pitch match’) has been shown to negatively impact unilateral speech recognition and music perception in a number of published studies, most of which have been conducted using vocoder simulations in normal hearing listeners (Dorman et al., 1997; Shannon et al., 1998; Fu and Shannon, 1999; Baskent and Shannon, 2003). A similar finding has been reported by Baskent and Shannon (2004) in cochlear implant listeners in an acute experiment with Med-El Combi 40+ users, in which varying six-electrode configurations were used to examine a range of compression and expansion conditions. Di Nardo et al. (2010) reported a significant positive correlation between sentence recognition scores in both quiet and noise and the degree of frequency-pitch match in seven subjects. Testing was conducted using a relatively simple technique, which involved presentation of an acoustic tone in one ear and selection of the best-matched electrode to that tone during a sweep across electrodes using the Nucleus® Custom Sound clinical programming software. Such an approach may not have sufficiently controlled for non-sensory bias as has been described by Carlyon et al. (2010).

There are a number of reasons why it is of interest to further evaluate the effect of frequency-pitch match on speech recognition performance. First, there is limited published information describing the impact of such a match on post-implantation outcomes in cochlear implant recipients after an extended period of device use. The majority of research conducted to date has involved acute experiments, which may introduce bias for the frequency assignment which is used clinically. Second, it is important to examine the influence of frequency-pitch match in a larger number of subjects and with a tightly-controlled experimental design, to confirm the findings as reported by Di Nardo et al. (2010). Finally, the impact of frequency-pitch match in the implanted ear, when used in combination with acoustic hearing on the contralateral side, has not been investigated to date. This is an important concern for implant users with
more acoustic residual hearing when considering how to best benefit from the combined use of the cochlear implant sound processor and hearing aid in combination.

1.5 Factors Influencing Electrical Pitch Percept in Bimodal Listeners

Understanding the factors that influence the electrical pitch percept would be important in the clinical setting if individualised fitting approaches were to be used to optimise the fitting of either unilateral or bilateral (bimodal) devices. It is known that obtaining clinical measures of the electrical pitch percept is a complex and time-consuming task, and one which is prone to non-sensory bias (Carlyon et al., 2010). If radiological scans were available, it might be possible to reliably calculate the intracochlear electrode positions and assign the appropriate acoustic input frequency to the correct electrode based on the cochlear frequency-place models. However, there is evidence from review of the published literature that the electrical pitch percept can deviate from the expected spiral ganglion and organ of Corti characteristic frequency functions.

To investigate the relationship between insertion angle and electrical pitch percept, the published data from four studies (Baumann and Nobbe, 2006; Boex et al., 2006; Vermeire et al., 2008; McDermott et al., 2009) have been collated and plotted in Figure 5. The likelihood of the electrical pitch being higher than expected appears to be greater for insertion angles beyond approximately 530 degrees. Lack of differentiation in pitch percept for more deeply inserted electrodes, compared to those situated more basally, may have contributed to that finding (Baumann and Nobbe, 2006). For insertion angles up to approximately 450 degrees, there appear approximately 50% of subjects where the electrical pitch estimate was lower than predicted by the frequency-place models, consistent with the majority of published data. Apparent in the plotted data is the variability in outcomes across individual subjects, some of which may be accounted for by the different experimental methodology across studies, e.g. the difference in measurement technique and subject demographics, as well as the fact that estimates were obtained from graphs in some of the publications rather than accurate data contained within tables in the manuscript. Understanding the source of variability would be
clinically relevant if applying individualised mapping approaches to recipients.

Figure 5: Compilation of published electrical pitch estimates obtained from four published studies. Shown is the pitch percept elicited by stimulation on electrodes at varying intra-cochlear insertion angles. The solid grey line indicates the mean spiral ganglion frequency according to Stakhovskaya et al. (2007) and the dashed lines the upper and lower range of the spiral ganglion frequency-position function. The dotted grey line indicates the Greenwood function of organ of Corti characteristic frequency.

In addition to the difference in electrical pitch estimates obtained due to varying electrode insertion angle, there are a number of additional factors that may also be expected to impact the electrical pitch percept. Degree of deviation from the models has been hypothesised to be related to factors such as the degree of hearing in the contralateral ear (Vermeire et al., 2008; Carlyon et al., 2010; Reiss et al., 2015) and the effect of listening experience (Reiss et al., 2007; McDermott et al., 2009; Reiss et al., 2014). Although such effects have been reported in the literature, there remains a degree of variability and uncertainty regarding the influence of each of those factors. Further research is warranted.
to understand the impact of demographic and hearing threshold factors on electrical pitch perception, with an aim to provide information as to the potential practical application of pitch matching in the clinical setting.

1.6 Literature Review Summary

This literature review summarises a wide range of studies reporting outcomes for cochlear implant recipients with different degrees and configurations of acoustic hearing, and discusses the rationale under which expanded candidature has arisen. It is evident from these studies that there is a lack of a systematic analysis, which is made difficult by the various devices, test materials, protocols and the inherent variability in outcomes common amongst cochlear implant recipients. Improving our understanding regarding the clinical outcomes for such candidates is important in the clinical setting, in that there are a number of important considerations when providing guidance and discussing expectations during the candidacy assessment phase of an individual’s clinical management. Further, it is important to more fully understand the factors that impact outcomes resulting from clinical device programming, and to endeavour to investigate potential future approaches to optimising bimodal devices.
2 Research Questions and Justification

In the previous section, the clinical challenges and considerations in guiding candidates who have pre-operative acoustic hearing as to expected outcomes after implantation were outlined. This section outlines the specific research questions addressed in this thesis, and why they are considered important in guiding management of cochlear implantation in future.

Study A

a) To quantify the change in clinical performance after cochlear implantation for adults with pre-operative bilateral acoustic hearing who lose hearing in the implanted ear after surgery; and

b) To examine whether pre-operative spatial hearing abilities are predictive of clinical outcomes when one ear is fitted with a cochlear implant and hearing is lost in the implanted ear post-surgery

Relevance: Risk of loss of hearing post-operatively is an important consideration and in particular for those cochlear implant candidates with pre-operative bilateral acoustic hearing. Binaural cues available with bilateral hearing aids pre-operatively may not be available post-operatively due to either loss of hearing acuity post-operatively, or to lack of fine-timing information and potential distortion of envelope timing and interaural level cues provided through the input from bimodal devices. Given that preservation of residual acoustic hearing cannot be guaranteed within the limits of current surgical technique and available technology, it is important to examine the effect of loss of acoustic hearing on spatial hearing and real-world experience after implantation, in order to provide guidance as to the worst-case scenario for candidates during pre-operative counselling discussions.
**Study B**

- **c)** To examine post-implantation bilateral benefit for candidates with more hearing in the contralateral non-implanted ear than has been previously considered within local candidacy guidelines
- **d)** To examine the effect of degree of hearing in the contralateral ear on rate of acclimation to the cochlear implant in the post-operative period
- **e)** To examine whether degree of post-implantation benefit varies as a function of the degree of contralateral hearing

**Relevance:** In candidates with substantial acoustic hearing in the contralateral ear it is important to consider the degree of benefit expected after implantation, and the ability of a candidate to effectively combine the perceptually different signals arising through acoustic hearing and electrical stimulation. In contrast to the candidate group with pre-operative bilateral acoustic hearing, the candidates with asymmetric or unilateral hearing impairment would not need to consider the risk to loss of acoustic hearing in the implanted ear. However, the decision for an individual as to whether to proceed with implantation remains complex, given factors such as surgical considerations, cost, and post-operative device management. Individuals seek reassurance that the implant is likely to provide substantial benefit in daily life, and that the expected benefit outweighs the perceived risks. For clinicians, there remains limited information to assist with setting expectations for this candidate group, particularly with respect to the expected benefit as a function of the degree of contralateral hearing.

**Studies C and D**

- **f)** To examine the pre-operative demographic and hearing configuration factors that predict unilateral and bilateral speech perception outcomes in candidates with more acoustic hearing than previously examined
- **g)** To examine the rate of post-operative improvement as a function of the match between the initial (pre-activation) place-pitch percept on the most apical electrode and the frequency assignment to that channel in both the unilateral and bilateral listening condition; and
h) To examine the effect of match in perceptual pitch to the acoustic frequency assignment after 12-months of cochlear implant use on speech recognition in both the unilateral and bilateral listening condition

Relevance: Prediction of outcomes in the clinical setting is difficult, with known factors accounting for only approximately 10-20% of the variance in post-operative unilateral monosyllabic word scores after implantation. This inability to reliably predict outcomes is of particular significance for the candidate group with pre-operative acoustic hearing. Depending on the pre-operative hearing configuration, there may be a higher perceived risk and impact of loss of auditory function after implantation or questions as to the bilateral (bimodal) advantage likely to be provided by combining electric with relatively salient contralateral ear acoustic cues. The relevance of the previously identified predictive factor of duration of severe-to-profound hearing loss has not been evaluated in the expanded candidacy population. Additionally, it is possible that additional factors are of more importance in this population.

Influence of device fitting is also an important factor to consider, and likely to impact post-implantation outcomes. One such area that warrants further investigation is the impact of mismatch between frequency assignment to electrodes in clinical devices and the electrical pitch percept that arises from electrical stimulation. The impact of frequency-place mismatch on unilateral outcomes has been shown to negatively impact speech recognition and music perception in a number of published studies, but most studies have been conducted using vocoder simulations in normal hearing listeners. Although there is some evidence of place-pitch mismatch resulting in poorer unilateral speech recognition in noise in cochlear implant listeners, there is no published data describing the impact of such a mismatch on bilateral (bimodal) outcomes. Additionally, there has been no assessment to date as to whether such a place-pitch mismatch results in a longer period of adaptation to the cochlear implant signal in the post-operative period.
**Study E**

i) To examine factors that affect perceptual pitch match between acoustic and electric stimulation

**Relevance:** There are variable findings in the literature regarding the degree of perceptual match typically obtained between acoustic and electric stimulation, and the factors that impact the electrical pitch percept. Understanding factors that influence the degree of match in pitch is important for clinical management if attempting to match the percept across ears and to optimise the assignment of acoustic analysis frequencies to electrodes for individual cochlear implant recipients. Although factors such as the degree of hearing in the contralateral ear and the effect of listening experience have been reported to influence the electrical pitch estimate, there remains a degree of variability and uncertainty regarding the influence of each of those factors.
3 General Methodology

In this section is outlined the general methodology underpinning the five studies described within the thesis.

3.1 Human Research Ethics Committee Approval

The overall study “Evaluating Clinical Outcomes for Adult Subjects with Significant Residual Hearing” was approved and conducted under the ethical oversight of the Human Research Ethics Committee of the Royal Victorian Eye and Ear Hospital (Project Number 09/872H) and the Royal Prince Alfred Hospital (Project Number 09/RPAH/427).

The overall study was undertaken under the auspices of the clinical investigations of the HEARing Cooperative Research Centre, which provided clinical trial insurance for all of the five studies included in this thesis.

All subjects provided written consent both clinically for their cochlear implant procedure, and individually for participation in the research studies undertaken and presented in this thesis.

3.2 List of Clinical Studies

An outline of the clinical studies conducted is provided below:

A. Clinical Outcomes for Recipients Experiencing Loss of Useable Acoustic Hearing in the Implanted Ear;
B. Influence of Contralateral Acoustic Hearing on Adult Bimodal Outcomes After Cochlear Implantation;
C. Factors Predicting Post-Implantation Speech Recognition in Candidates with Acoustic Hearing;
D. Influence on Speech Recognition of Match between Frequency assignment to Electrodes in the Sound Processor and Electrical Place-Pitch Percept; and
E. Factors Influencing Electrical Place Pitch Perception in Bimodal Listeners
3.3 Subject Overview

A total of sixty-five post-lingually hearing-impaired adults participated in the project. To address each of the identified research objectives, sub-projects were undertaken with differing numbers of subjects. Subjects were recruited from the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne and from the Sydney Cochlear Implant Centre in Sydney. Implantation dates for recruited subjects ranged from 4 June 2009 to 14 August 2012. Subjects were invited to participate by clinical case managers in the implanting clinics and the majority of candidates who met the inclusion and exclusion criteria and were deemed suitable were approached as to their interest in participating. Approximately 70% of eligible candidates were enrolled into the study. The main reasons for eligible candidates not participating in the study included inability to attend the required study appointments due to either limited time or them living too far from the research centre.

All subjects in all sub-projects were implanted with Nucleus cochlear implants (with Contour Advance or Slim Straight electrode arrays) and all used the CP810 sound processor. A summary of group demographic characteristics of the subjects is shown in Table 1. The age of the subjects at the time of enrolment into the study ranged from 27 years to 81 years, with a mean age of 62.6 years. Twenty-five subjects were female and forty were male. Monosyllabic word as compared to phoneme scores have been listed in the table since that is more commonly referenced in past published data, even though phoneme scores were used as the basis for subject recruitment.

All recruited subjects had a pre-operative phoneme score on the monosyllabic Consonant-Vowel-Consonant (CVC) word test of greater than 46% in at least one ear. That criterion was used based on the rationale that candidates with more than that degree of pre-operative hearing would fall outside the typical candidature guidelines used within the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic (Dowell et al., 2004). In cases in which there was no response on an audiometric measure at maximum output levels, the value of 125 dB HL was entered into the datasheet.
Table 1: Group demographic information for all subjects (S1-65) including age at the time of implantation, duration of bilateral hearing loss, duration of severe-to-profound hearing loss (SPHL), pre-operative pre-tone average (PTA) thresholds in the implanted and contralateral ear, and pre-implantation monosyllabic word score in the implanted and contralateral ear. PTA was calculated by averaging unaided audiometric hearing thresholds at frequencies of 500, 1000 and 2000 Hz.

<table>
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<th>Demographic Factor</th>
<th>Mean</th>
<th>Range</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Implantation</td>
<td>62.6 Years</td>
<td>27-81 Years</td>
<td>11.6 Years</td>
</tr>
<tr>
<td>Duration Bilateral Hearing Loss</td>
<td>20.5 Years</td>
<td>0-58 Years</td>
<td>15.3 Years</td>
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<tr>
<td>Duration Bilateral SPHL</td>
<td>5.1 Years</td>
<td>0-40 Years</td>
<td>7.9 Years</td>
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<tr>
<td>Pre-Operative PTA Implanted Ear</td>
<td>92.8 dB HL</td>
<td>57.5-125 dB HL</td>
<td>19.7 dB HL</td>
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<tr>
<td>Pre-Operative PTA Contralateral Ear</td>
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<td>0-113 dB HL</td>
<td>23.7 dB HL</td>
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<tr>
<td>Pre-Operative Monosyllabic Word Score in Implanted Ear</td>
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<td>0-62%</td>
<td>11.7%</td>
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<tr>
<td>Pre-Operative Monosyllabic Word Score in Contralateral Ear</td>
<td>49.9%</td>
<td>10-99%</td>
<td>26.9%</td>
</tr>
</tbody>
</table>
3.4 Individual Subject Demographic, Device & Pre-Operative Hearing Level Data

An overview of the demographic, device, pre-operative monosyllabic word and phoneme scores and pre-operative audiometic threshold data for each of the subjects is shown in Appendices 1, 2 and 3.

Appendix 1 includes information regarding gender, age at the time of implantation, aetiology of hearing impairment, the duration since onset of hearing loss in the implanted ear, the duration of severe-to-profound hearing loss in the implanted ear, and the duration of bilateral severe-to-profound hearing loss. Duration of hearing loss was examined for two degrees of loss; initially for the degree of severe-to-profound loss, and subsequently for the duration of any hearing loss. Duration of any hearing loss was estimated based on hearing history and subjective reports as to the time from which hearing loss was first noticed and was deemed to have first impacted hearing ability.

Duration of severe-to-profound hearing loss was estimated based on the period of time for which the subject could not use the aided hearing alone to communicate without lip-reading. Combined with the information obtained via hearing history, severe-to-profound hearing loss was defined as having a three-frequency PTA exceeding 70 dB HL (using frequencies 0.5, 1 and 2 kHz). For data pertaining to bilateral severe-to-profound hearing loss, subjects were required to have a PTA unaided threshold of greater than 70 dB HL in both ears; for duration of loss associated with the implanted ear the criterion was applied to the single ear pre-operatively. For over 50% of the subjects enrolled in the study (35 of the 65 subjects), the contralateral ear median unaided threshold was better than 70 dB HL, so the duration of severe-to-profound bilateral hearing loss for those subjects was zero.

An overview of the devices used during the clinical study for each of the subjects is shown in Appendix 2. The table provides information regarding electrode type, the hearing aid used in the ear selected for implantation pre-operatively, the contralateral hearing aid type, sound processor type, whether the acoustic hearing in the implanted ear was amplified using an acoustic component, and the acoustic input frequency assignment range to electrodes in the sound processor. Pre-operative hearing aid fitting was conducted by the hospital clinics as part of the routine clinical assessment program. Suitability of fitting was evaluated by experienced audiologists and hearing aid fitting
either confirmed as appropriate, modified within the clinical setting, or candidates were referred back to initial clinical providers for device optimisation as required.

Pre-operative monosyllabic phoneme and word scores in each of the ear selected for implantation and the contralateral ear are shown in Appendix 3. Pre-operative unaided audiometric threshold data are shown in Figure 6. As shown, there was marked variability across the subject pool in both the degree and configuration of hearing loss in both the implanted and contralateral ear, and in the degree of asymmetry shown between the two ears.

This section has outlined the general methodology under which this series of studies was undertaken, and the demographic information on the subjects involved in the studies. The following five sections describe the specific studies undertaken to address each of the research questions.
**Figure 6:** Pre-operative unaided audiometric thresholds for each subject. Implanted ear thresholds are indicated by unfilled square markers, and contralateral thresholds as filled circles. Absence of symbols at a particular frequency indicates no response at the limits of the audiometer.
4 Clinical Outcomes for Adult Cochlear Implant Recipients Experiencing Loss of Usable Acoustic Hearing in the Implanted Ear

The information contained within this section comprises only the content of the publication, with the reprint provided in Appendix 4.

4.1 Abstract

**Objectives:** The first aim of the study was to quantify the change in clinical performance after cochlear implantation for adults who had pre-operative levels of acoustic hearing in each ear of greater than or equal to 46% phoneme score on an open-set monosyllabic word test, and who subsequently experienced loss of useable acoustic hearing in the implanted ear. Pre- and post-operative spatial hearing abilities were assessed, since a clinical consideration for candidates with bilateral acoustic hearing is the potential for post-operative reduction in spatial hearing ability. Secondly, it was of interest to examine whether pre-operative localisation ability, as an indicator of access to interaural timing and level cues pre-operatively, might be correlated with post-operative change in spatial hearing abilities.

**Design:** Clinical performance measures in the bilateral condition were obtained pre-operatively and at twelve months post-operatively in nineteen postlinguistically hearing-impaired adult subjects. Pre-operative localisation ability was investigated as a potential correlate with post-operative change in spatial hearing abilities.

**Results:** Significant post-operative group mean improvement in speech perception was observed on measures of open-set monosyllabic word perception in quiet and on an adaptive sentence test presented in coincident 4-talker babble. Observed benefit was greater for a lower presentation level of 55 dB SPL as compared to a conversational speech level of 65 dB SPL. Self-reported ratings of benefit also improved for all questionnaires administered. Objective assessment of localisation ability revealed poorer localisation post-operatively, although subjective ratings of post-operative change in localisation ability in real-world environments were more variable. Post-operative spatial release from masking was not different to that measured pre-operatively for the configuration where the side of the head with the hearing aid was advantaged, but improved post-operatively for the configuration that advantaged the implanted side. Pre-
operative bilateral localisation ability was not correlated with post-operative spatial hearing abilities.

Conclusions: The findings from this study support cochlear implantation for candidates with pre-operative levels of bilateral acoustic hearing within the range examined within the current study. This includes subjects with pre-operative open-set monosyllabic word scores ranging from 11% to 62% in the implanted ear, and from 16% to 75% on the contralateral side. Post-operative improvement would be expected for those subjects on a range of clinical measures, even when acoustic hearing was lost in the implanted ear following implantation.

4.2 Introduction

Cochlear implantation is a well-established clinical intervention for restoring hearing function in recipients with severe-to-profound sensorineural hearing loss. Significant advancements in implantable and external technology design and in surgical techniques have led to progressive improvements in post-operative speech recognition, and contributed to an expansion in candidacy criteria for implantation over time. Candidates now often present at clinical centres with substantial levels of pre-operative acoustic hearing in one or both ears. The development of evidence based recommendations and guidance for these candidates is important during the pre-operative counselling process, and in setting post-operative expectations.

Although hearing preservation in the implanted ear after cochlear implantation has been demonstrated with a range of devices (Gantz and Turner, 2003; Adunka et al., 2004; Gantz et al., 2004; Gstoettner et al., 2004; Gantz et al., 2005; Fraysse et al., 2006; Gantz et al., 2006; Skarzynski et al., 2006; Baumgartner et al., 2007; Gstoettner et al., 2009; Lenarz, 2009; Skarzynski et al., 2010; Skarzynski et al., 2012), it is not yet possible to guarantee that hearing will be preserved. Immediate post-operative acoustic hearing preservation has been generally reported to range from 50% to 100% (Fraysse et al., 2006; Baumgartner et al., 2007; Gantz et al., 2009; Lenarz, 2009; Skarzynski et al., 2012), although the reported rates vary according to differences in study methodologies, e.g. the criteria used to define preservation, and the use of different subject inclusion and exclusion criteria. Additional to the immediate risk to hearing that occurs as a result of electrode insertion, there is evidence of delayed loss in the implanted ear (Baumgartner
et al., 2007; Gantz et al., 2009). Risk to post-operative hearing loss in the implanted ear is an important consideration for cochlear implant candidates and it is important to understand the potential implication of loss on functional outcomes post-implantation. Binaural cues may be salient with bilateral hearing aids pre-operatively but not available post-operatively with bimodal devices due to the lack of fine-timing information perceived by implant users (Francart et al., 2009). Distortion of envelope timing and interaural level differences with bimodal devices may also be problematic due to the substantially different signals in the two ears (Francart et al., 2008).

The expected effect of transitioning from bilateral pre-operative aided acoustic hearing to use of bimodal devices post-operatively can be partly understood in the context of reviewing the literature describing 1) unilateral post-operative outcomes for candidates with pre-operative acoustic hearing in the ear selected for implantation, 2) the benefit of bimodal device use compared to the cochlear implant alone, and 3) within-subject examination of pre- and post-operative bilateral outcomes for candidates with pre-operative acoustic hearing.

Examination of unilateral outcomes for candidates with pre-operative acoustic hearing in the implanted ear has revealed significant benefit from implantation. In those studies, conducted with the FLEX$^{\text{soft}}$ EAS electrode (Gstoettner et al., 2004; Helbig et al., 2011) and the Nucleus® Contour Advance® electrode (James et al., 2006), post-operative speech recognition was assessed using electrical stimulation alone, and compared to pre-operative scores obtained using the hearing aid in the implanted ear. Pre-operatively, subjects in those studies had pure-tone average thresholds of less than 65 dB HL in the low frequencies (up to 500 Hz) and greater than 50 dB HL or 60 dB HL thresholds at frequencies greater than 1 kHz. Group mean pre- and post-operative scores were 9% and 48% (Gstoettner et al., 2004), 21% and 52% (Helbig et al., 2011) and 22% and 56% (James et al., 2006). Similar findings have been reported by Gifford et al. (2010) in nine subjects with pre-operative speech perception scores that ranged from 0% to 40% and pre-operative 500 Hz unaided audiometric thresholds that ranged from 40 dB HL to 115 dB HL. Pre- and post-operative group mean scores were 31% and 67% respectively. Similar benefit has been reported for speech perception improvement in noise (Gstoettner et al., 2004; James et al., 2006; Helbig et al., 2011). Together those data show the benefit of implantation in improving hearing in the treated ear. However it is likely of most
relevance clinically to consider the bilateral rather than unilateral outcomes for candidates with substantial pre-operative acoustic hearing.

Enhancement in speech intelligibility in quiet and for coincident presentation of speech in noise has been demonstrated in numerous studies that have assessed the benefit provided by contralateral acoustic amplification to cochlear implant recipients (Waltzman et al., 1992; Armstrong et al., 1997; Ching et al., 2001; Tyler et al., 2002; Dunn et al., 2005; Kong et al., 2005; Firszt, 2008; Potts et al., 2009). Many recipients have reported preference for the sound quality of the devices used in combination as compared to electrical stimulation alone, as well as improvement in recognition and quality of music (Kong et al., 2005; Gfeller et al., 2008; Sucher and McDermott, 2009; McDermott, 2011). The benefit of adding a hearing aid in the non-implanted ear has largely been attributed to the additional spectral-temporal information provided by the acoustic hearing that is complementary to the spectral information provided by electrical stimulation.

Review of the published literature (Ching et al., 2007; Sammeth and Bundy, 2011) has revealed modest improvement in localization ability using bimodal devices compared to use of unilateral hearing in either ear. Results from studies that have assessed speech perception of spatially separated speech and noise in bimodal listeners (Armstrong et al., 1997; Ching et al., 2004; Dunn et al., 2005; Luntz et al., 2005; Morera et al., 2005; Mok et al., 2006; Dorman et al., 2008; Potts et al., 2009; Berrettini et al., 2010) have shown little or no benefit attributable to the head shadow effect when the hearing-aid ear had the more favourable signal to noise ratio. This is likely due to the limitation or absence of high-frequency hearing in the shadowed ear for the subjects evaluated in those studies. As expected, there was no evidence of bilateral unmasking or spatial release from informational masking in those clinical assessments, likely as a result of the difficulties of matching of level and timing cues and the absence of perceptible fine-timing in the electrical signal (Francart and McDermott, 2013).

Of particular relevance for candidates considering cochlear implantation is a direct within-subject assessment of pre-operative and post-operative outcomes. The majority of studies conducted in candidates with pre-operative bilateral acoustic hearing have involved subjects with steeply sloping hearing loss implanted with hearing preservation devices. Post-operative speech perception benefit in the combined condition (using
acoustic hearing in one or both ears combined with electric hearing) as compared to scores obtained in the best-aided bilateral condition pre-operatively has been reported in those studies (Gantz et al., 2009; Lenarz, 2009; Helbig et al., 2011; Skarzynski et al., 2014). Although benefit of hearing preservation has been demonstrated, Gantz et al. (2009) reported that post-operative change in bilateral speech perception, using test materials presented in quiet or with coincident presentation of speech in noise, was not correlated with the degree of hearing loss in the implanted ear. Post-operative contribution of electric hearing provided by the Hybrid S12 device was reported to have more than compensated for any reduction in acoustic hearing thresholds.

Gifford et al. (2010) and Amoodi et al. (2012) also examined outcomes for subjects with bilateral speech perception scores that were outside the traditional candidacy guidelines in the United States and Canada. Gifford et al. (2010) described post-operative improvement for a group of 22 subjects with pre-operative bilateral scores on the monosyllabic CNC word test in quiet that ranged from 30 to 60%. In that study the grouped mean bilateral pre- and post-operative monosyllabic CNC word scores in quiet were 41% and 82% respectively. Individual subject analysis demonstrated that 59% of the patients achieved a significantly higher post-operative score in the implant only unilateral condition compared to the pre-operative bilateral aided condition, and 91% demonstrated a statistically significant benefit in a bilateral pre- to post-operative comparison. Similarly, Amoodi et al. (2012) examined speech perception in a group of 27 adult subjects with a pre-implantation bilateral Hearing in Noise Test (HINT) score of greater than 60%. Pre-operative implanted ear monosyllabic word scores ranged from 0% to 44%, and contralateral scores from 0% to 68%. All subjects showed a statistically significant benefit of implantation after 12 months of experience, with grouped mean word scores at the pre- and post-operative assessment of 28.5% and 65.6% respectively. No subjects experienced post-operative reduction in speech recognition ability. Those positive findings provide evidence that cochlear implantation is a viable treatment option for candidates with substantial levels of pre-operative hearing.

Findings from two studies that have assessed localisation ability have shown varied results; one with subjects having bilateral acoustic hearing implanted with the 10mm Hybrid electrode (Dunn et al., 2010), and the other with subjects having single-sided hearing impairment (Arndt et al., 2011a). Although not a direct measure of pre- and post-
operative performance, Dunn et al. (2010) compared localisation ability using a within-subject design and with a range of device combinations that included bilateral hearing aids and bimodal devices. On a localisation test using a range of everyday sounds all subjects could localise at better than chance levels using bilateral hearing aids. However, only four of the eleven subjects could achieve that outcome using the bimodal device configuration. These data suggest that localisation ability is reduced with use of bimodal devices compared to bilateral acoustic aided hearing for subjects with steeply sloping hearing loss. Arndt et al. (2011a) examined localisation ability in 11 adult subjects implanted with pre-operative asymmetric hearing loss, to compare performance using the acoustic hearing alone prior to implantation and with the bimodal devices post-operatively. The study utilised a 7 loudspeaker arc in a 180 degree horizontal plane, using sentences from the Oldenburg Sentence Test (OLSA) as stimuli. Median absolute localisation error was 33.9 and 15 degrees in the pre- and post-operative conditions respectively, although the post-operative error is likely underestimated due to the measured error being less than the loudspeaker spacing and the likely introduction of quantisation effects (Hartmann et al., 1998). Both studies provide evidence that, for some listeners, the use of bimodal devices can provide information to assist with sound source localisation. The study by Dunn et al. (2010) also provides a direct indication that bimodal localisation ability post-operatively may be poorer than would be obtained with bilateral hearing aids pre-operatively.

Although positive post-operative outcomes have been reported in subjects with pre-operative bilateral acoustic hearing, it is of interest to further explore this area of research for a number of reasons. Firstly, it is important to examine the post-operative experience of subjects with a wider frequency bandwidth of usable acoustic hearing in one or both ears pre-operatively than has been reported in literature so far. Analysis of pre-operative acoustic thresholds in the population studied by Gifford et al. (2010) revealed that 86% of the 22 subjects had median low frequency thresholds (across the range 0.125 to 1 kHz) in the better ear of less than or equal to 90 dB HL. However, only 41% had high frequency thresholds (in the range 1-4 kHz) meeting that criterion. Further outcome data for subjects with high frequency hearing would provide important information for new candidates considering implantation, and would supplement the data reported by Gifford et al. (2010) regarding expected outcomes.
Secondly, it is important to further examine post-operative change in spatial hearing abilities, given the potential for degraded bilateral cues in the bimodal as compared to bilateral hearing aid configuration. There is limited published information regarding the spatial hearing outcomes associated with implantation of candidates with pre-operative, bilateral acoustic hearing, and specifically for those recipients where hearing is lost in the implanted ear during or after implantation. Findings from the study would contribute to the published literature, through providing information relating to outcomes for such candidates. Comprehensive assessment of localisation ability and speech perception in spatially separated speech in noise, as well as administration of questionnaires to assess real-world performance, would be beneficial in providing pre-operative guidance to candidates. Since pre-operative localisation may be reflective of a candidate’s ability to utilise interaural timing and levels cues with bilateral hearing aids, this may also be predictive of the impact of post-operative loss of acoustic hearing in the implanted ear on general bilateral function. Those subjects with better localisation ability pre-operatively might be more likely impacted by potential disruption of interaural timing and interaural level cues after implantation.

4.3 Materials and Methods

Subjects

Nineteen postlinguistically hearing-impaired adults participated in the study. All were implanted with Nucleus cochlear implants (the Nucleus® Contour Advance®, the Nucleus CI422 cochlear implant with Slim Straight electrode, or the Modiolar Research Array) and used the Freedom™ or CP810 sound processors. Subjects were recruited from the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne, and from the Sydney Cochlear Implant Centre. The decision to proceed with implantation and the provision of clinical devices was managed through the routine clinical procedures in each cochlear implant clinic. No external source of funding for devices was provided during the conduct of the clinical investigation. All recruited subjects had a phoneme score on the monosyllabic Consonant-Nucleus-Consonant (CNC) word test of greater than 46% in each ear measured individually pre-operatively. Those scores were obtained using a presentation level of 65 dB SPL RMS, and were an average of scores across two lists of recorded words presented in quiet from a frontal loudspeaker at zero degrees
azimuth. Selection criteria were an extension of those used in the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic, with enrolment of subjects having greater speech perception in the ear to be implanted than would be recommended by current local candidacy guidelines. The current selection criteria in the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne are based on a retrospective data analysis conducted with 210 post-lingual hearing-impaired adults. Analysis involved a statistical approach based on post-operative outcomes (Dowell et al., 2004) obtained after three months of cochlear implant experience. The analysis revealed that the first quartile phoneme score in the implanted ear was 46%, and so indicated that there would be a 75% chance of improvement for an individual candidate with a pre-operative phoneme score that was less than or equal to this value. All subjects who met the pre-operative selection criteria were sequentially enrolled into the study based on date of surgery.

Post-linguistic hearing loss was defined as having an onset of deafness later than two years of age. Demographic information for each of the subjects is shown in Table 2. The age of the subjects at the time of enrolment into the study ranged from 54 years to 76 years, with a mean age of 64.7 years. Table 5 also provides information regarding gender, aetiology of hearing impairment, the duration since onset of hearing loss, the type of electrode, the type of sound processor, the electrical stimulation frequency allocation table, and the hearing aid model used during the study. All subjects used bilateral hearing aids at the time of enrolment in the study.

All except subject S18 used the frequency allocation table in the sound processor that mapped acoustic input frequencies to filters across the range 188-7938 Hz. Subject S18 was implanted with the Hybrid™ L24 electrode, and input frequencies were mapped to electrodes using the range 688-7938 Hz. The use of the higher frequency range of 688-813 Hz on the most apical channel for that subject was consistent with the perceived pitch percept obtained prior to initial clinical activation of the device. The Slim Straight electrode was inserted to 20 mm via the round window membrane, which would be expected to be within the range of insertion angle 300 to 360 degrees (Skarzynski et al., 2012). The Contour Advance and Modiolar Research Array electrodes were fully inserted for all subjects. Comparative insertion angles for cochleostomy insertion of the Contour Advance electrode have been reported to range from 270 to 400 degrees (Adunka and
Kiefer, 2006), when excluding cases with a malformed cochlea, or from 230 to 290 degrees (Briggs et al., 2006).
**Table 2.** Subjects’ demographic information; including gender, age at the time of implantation (in years), aetiology of hearing impairment, duration of hearing loss in the implanted ear (in years), type of electrode, type of sound processor used, input frequency allocation range to electrodes, and hearing aid used during the clinical study.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age at Implantation (years)</th>
<th>Aetiology</th>
<th>Duration hearing loss implanted ear (years)</th>
<th>Electrode Type</th>
<th>Sound Processor Type</th>
<th>Input Frequency Allocation Range (Hz)</th>
<th>Implanted Ear/Contralateral Ear Hearing Aid</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>F</td>
<td>58</td>
<td>Familial/autoimmune</td>
<td>20</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Audeo (Rx in canal)</td>
</tr>
<tr>
<td>S2</td>
<td>M</td>
<td>61</td>
<td>Unknown</td>
<td>58</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Perseo daz</td>
</tr>
<tr>
<td>S3</td>
<td>F</td>
<td>54</td>
<td>Unknown</td>
<td>9</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Perseo 211 dAZ</td>
</tr>
<tr>
<td>S4</td>
<td>F</td>
<td>65</td>
<td>Familial</td>
<td>20</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Savia/Naida</td>
</tr>
<tr>
<td>S5</td>
<td>F</td>
<td>62</td>
<td>Unknown</td>
<td>30</td>
<td>MRA</td>
<td>Freedom</td>
<td>188-7938</td>
<td>Phonak Microsavia</td>
</tr>
<tr>
<td>S6</td>
<td>F</td>
<td>57</td>
<td>Unknown</td>
<td>10</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Savia 211 dSZ</td>
</tr>
<tr>
<td>S7</td>
<td>M</td>
<td>68</td>
<td>Familial</td>
<td>38</td>
<td>Slim Straight</td>
<td>CP810</td>
<td>188-7938</td>
<td>Siemens Artis P</td>
</tr>
<tr>
<td>S8</td>
<td>M</td>
<td>71</td>
<td>Noise/familial</td>
<td>50</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Excelia M</td>
</tr>
<tr>
<td>S9</td>
<td>F</td>
<td>64</td>
<td>Otosclerosis</td>
<td>40</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Excelia Art P</td>
</tr>
<tr>
<td>S10</td>
<td>F</td>
<td>74</td>
<td>Unknown</td>
<td>30</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Siemens Motion 100</td>
</tr>
<tr>
<td>S11</td>
<td>M</td>
<td>66</td>
<td>Unknown</td>
<td>31</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Siemens Intuis SP</td>
</tr>
<tr>
<td>S12</td>
<td>M</td>
<td>68</td>
<td>Unknown</td>
<td>20</td>
<td>Contour Adv.</td>
<td>Freedom</td>
<td>188-7938</td>
<td>Siemens Prisma/Senso Diva</td>
</tr>
<tr>
<td>S13</td>
<td>M</td>
<td>58</td>
<td>RH Incompatibility</td>
<td>58</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Audeo (Rx in canal)</td>
</tr>
<tr>
<td>S15</td>
<td>M</td>
<td>76</td>
<td>Unknown</td>
<td>16</td>
<td>Slim Straight</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Naida III dAZ</td>
</tr>
<tr>
<td>Subject (continued)</td>
<td>Gender</td>
<td>Age at Implantation (years)</td>
<td>Aetiology</td>
<td>Duration hearing loss implanted ear (years)</td>
<td>Electrode Type</td>
<td>Sound Processor Type</td>
<td>Input Frequency Allocation Range (Hz)</td>
<td>Implanted Ear/Contralateral Ear Hearing Aid</td>
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<td>---------------------</td>
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</tr>
<tr>
<td>S16</td>
<td>F</td>
<td>63</td>
<td>Unknown</td>
<td>44</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Extra 311 AZ</td>
</tr>
<tr>
<td>S17</td>
<td>M</td>
<td>64</td>
<td>Meniere’s Disease</td>
<td>30</td>
<td>Slim Straight</td>
<td>CP810</td>
<td>188-7938</td>
<td>Phonak Naida V</td>
</tr>
<tr>
<td>S18</td>
<td>F</td>
<td>68</td>
<td>Ototoxicity</td>
<td>4</td>
<td>Hybrid-L24</td>
<td>CP810</td>
<td>688-7938</td>
<td>Phonak Audio</td>
</tr>
<tr>
<td>S19</td>
<td>F</td>
<td>64</td>
<td>Meniere’s Disease</td>
<td>10</td>
<td>Contour Adv.</td>
<td>CP810</td>
<td>188-7938</td>
<td>Widex Flash SL19</td>
</tr>
</tbody>
</table>
Mean pre-operative percentage correct scores on the monosyllabic word test are shown in Table 3, for each of the single ear and the bilateral condition. Although phoneme scores were used as enrolment criteria, consistent with that used by the Melbourne Cochlear Implant Clinic, monosyllabic whole word scores were used for pre- and post-operative measurements to minimise the effect of ceiling effects on tests administered post-operatively. Pre-operative, bilateral phoneme scores ranged from 46% to 92%. Approximately 75% of subjects already scored greater than or equal to 70% pre-operatively, resulting in limited ability to quantify the degree of post-operative improvement. Subjects are listed in the table in order of lowest to highest bilateral pre-operative word score. The mean word score in the ear to be implanted ear was 22.4%, and ranged from 11% to 62%. The mean word score in the contralateral (non-implanted) ear was 39.6%, and ranged from 16% to 75%. The mean bilateral score for the group of subjects was 44.3%, and ranged from 12% to 81%.

Also shown in Table 3 are the median unaided hearing thresholds for the frequency ranges of 0.125 - 1 kHz (‘LF’; low frequency), and for 1 - 4 kHz (‘HF’; high frequency). These values were calculated with a value of 125 dB for the frequencies where there was no measurable response (NR). For subjects S7, S15 and S18 post-operative thresholds were measurable in the implanted ear. All median post-operative thresholds were greater than or equal to 95 dB HL for those subjects. For all other subjects post-operative hearing tests revealed no hearing in the implanted ear.
Table 3. Mean pre-operative speech perception scores on open-set monosyllabic words, scored as percent correct for both phonemes and whole words for each of the unilateral (implanted: I and contralateral: C), and bilateral listening conditions. Implanted (I) and contralateral (C) median pre- and post-operative unaided audiometric thresholds for the low (LF, 0.125-1 kHz) and the high frequency (HF, 1-4 kHz) ranges (in dB HL). NR indicates no response obtained at the limits of the audiometer (125 dB HL). Implanted ear post-operative unaided audiometric thresholds by acoustic frequency.

| Subject | CVC Word Test – Phon. Score (%) | CVC Word Test - Word Score (%) | Pre-Operative Median Unaided Audiometric Thresholds (dB HL) Implanted | Contralateral | Implanted Ear Post-Operative Median Unaided Audiometric Thresholds (dB HL) | Implanted Ear Post-Operative Frequency & Unaided Audiometric Threshold | Frequency | Threshold (Hz | dB HL) |
|---------|---------------------------------|---------------------------------|-------------------------------------------------|----------------|----------------------------------------------------------------------------|-----------------------------------------------------------------|-----------|----------|
|         |                                 |                                 | Implanted | Contralateral                                  | 0.125-1 kHz | 1-4 kHz                         | 0.125-1 kHz | 1-4 kHz |
| I       | C                               | Bilateral                       | I         | C                                           | 1-4 kHz      |                                 |                                 |
| S1      | 46                              | 47                              | 46        | 15  | 18  | 12                              | 30 | 30 | 115 | 115 | NR | NR | NR |
| S2      | 47                              | 53                              | 59        | 11  | 24  | 23                              | 75 | 80 | 90 | 100 | NR | NR | NR |
| S3      | 49                              | 47                              | 57        | 18  | 16  | 25                              | 85 | 80 | 75 | 70  | NR | NR | NR |
| S4      | 46                              | 54                              | 50        | 16  | 23  | 25                              | 45 | 50 | 85 | 85  | NR | NR | NR |
| S5      | 47                              | 54                              | 55        | 17  | 24  | 27                              | 35 | 25 | 125 | 125 | NR | NR | NR |
| S6      | 46                              | 47                              | 60        | 16  | 19  | 29                              | 60 | 55 | 125 | 90  | NR | NR | NR |
| S7      | 52                              | 63                              | 67        | 23  | 33  | 30                              | 55 | 60 | 80 | 75  | 95 | 95 | 250 | 100; 500 | 95; 1000 | 90; 2000 | 90; 4000 | 90 |
| S8      | 52                              | 64                              | 70        | 19  | 36  | 39                              | 50 | 55 | 110 | 90  | NR | NR | NR |
| S9      | 49                              | 71                              | 68        | 22  | 41  | 40                              | 85 | 80 | 75 | 80  | NR | NR | NR |
| S10     | 55                              | 77                              | 74        | 16  | 51  | 42                              | 55 | 60 | 70 | 70  | NR | NR | NR |
| Subject (cont.) | CVC Word Test – Phon. Score (%) | CVC Word Test - Word Score (%) | Pre-Operative Median Unaided Audiometric Thresholds (dB HL) Implanted | Contralateral | Implanted Ear Post-Operative Median Unaided Audiometric Thresholds (dB HL) | Implanted Ear Post-Operative Frequency & Unaided Audiometric Threshold Frequency | Threshold (Hz | dB HL) |
|----------------|---------------------------------|---------------------------------|---------------------------|---------------|---------------------------|--------------------------------|---------------------------------|
|                | I C Bilateral                   | I C Bilateral                   | 0.125-1 kHz         | 1-4 kHz       | 0.125-1 kHz         | 1-4 kHz       | Frequency | Threshold |
| S11            | 64 67 74                        | 31 50 42                        | 70 | 65             | 95 | 85             | NR             | NR                  | NR |
| S12            | 51 77 79                        | 16 51 53                        | 55 | 65             | 125 | 65            | NR             | NR                  | NR |
| S13            | 51 76 76                        | 18 48 54                        | 55 | 55             | 90 | 85            | NR             | NR                  | NR |
| S14            | 47 61 79                        | 18 37 57                        | 80 | 65             | 70 | 85            | NR             | NR                  | NR |
| S15            | 65 80 82                        | 34 58 61                        | 65 | 65             | 75 | 70            | 100            | 100                 | 250 | 110; 500 | 100; 1000 | 95; 2000 | 100; 4000 | 105 |
| S16            | 72 73 81                        | 43 41 62                        | 70 | 70             | 90 | 90            | NR             | NR                  | NR |
| S17            | 46 64 80                        | 14 38 64                        | 70 | 65             | 70 | 55            | NR             | NR                  | NR |
| S18            | 78 82 90                        | 62 69 75                        | 55 | 55             | 85 | 80            | 105            | 95                  | 500 | 110; 1000 | 115; 2000 | 120; 4000 | 105 |
| S19            | 46 90 92                        | 16 75 81                        | 85 | 65             | 65 | 90            | NR             | NR                  | NR |
Pre-operative unaided audiometric thresholds for each subject are shown in Figure 7. Implanted ear thresholds are indicated by unfilled square markers, and contralateral markers as filled circles. Absence of thresholds indicates no response at the limits of the audiometer for the specific frequency. Data was not collected for S19 at the frequency of 125 Hz.

Figure 7. Pre-operative unaided audiometric thresholds for each subject. Implanted ear thresholds are indicated by unfilled square markers, and contralateral thresholds as filled circles. Absence of symbols at a particular frequency indicates no response at the limits of the audiometer.
Study Design

The study used a prospective, longitudinal within-subject experimental design in which each subject served as his or her own control. Clinical performance measures were obtained pre-operatively and twelve months post-operatively. All testing was conducted at each time point in the bilateral aided condition, i.e. bilateral hearing aids pre-operatively and the cochlear implant in combination with the contralateral hearing aid post-operatively. A comprehensive test battery was administered at each time point and included measures of speech perception in both coincident and spatially separated noise, self-reported real-world ratings of benefit via questionnaires, and sound source localisation in the horizontal plane.

Speech Perception Test Materials and Procedures

A range of different speech perception test materials were administered pre- and post-operatively. All materials were digitally recorded, and presented in a sound-attenuated booth. The sound field was calibrated at the position of the listener using one-third octave noise centred at a frequency of 1 kHz, and with an RMS sound pressure level equivalent to that of the speech. The subject was seated at a distance of 1.2 metres from each of three loudspeakers; one directly in front and one on each side at an azimuth of 90 degrees. All test items were presented once and no feedback was given to the subjects regarding the correctness of the responses.

Two lists of open-set monosyllabic words were presented in quiet at a level of 65 dB SPL RMS from directly in front of the subject. These words were based on the original CNC words developed by (Peterson and Lehiste, 1962), with fifty words per list and a consonant-nucleus-consonant structure. Open-set, Australian CUNY sentences were presented in 4-talker babble, with both signal and noise coincident at the frontal loudspeaker. Two lists of sentences were presented at each of two fixed signal-to-noise ratios (+10 and +5 dB SNRs), to minimise the influence of floor and ceiling effects on test scores. The most appropriate SNR for each listener was selected in the presentation of results. Testing was also conducted using an adaptive sentence in noise test (AuSTIN) (Dawson et al., 2013). This adaptive sentence test was included to ensure performance measures were obtained in the most sensitive region of the performance-intensity function, avoiding issues associated with floor and ceiling effects that would influence
the test scores (Mackie and Dermody, 1986; Nilsson et al., 1994; Brand and Kollmeier, 2002). This was important due to the relatively large changes expected from pre- to post-operative performance for some subjects, and the resultant difficulty in using a single SNR that provided a sensitive measure at each time point. The adaptive test used BKB-like sentences and provided the SNR for 50% intelligibility at the pre- and post-operative assessment for each of the speaker configurations and presentation levels. The sentences were developed for Australian use by the Cooperative Research Centre for Cochlear Implant and Hearing Aid Innovation in accordance with the guidelines used in the development of the original BKB sentences (Bench et al., 1979). Each SRT test run comprised 32 sentences, which were a combination of two 16-sentence lists. Sentence presentation level was fixed at either 65 or 55 dB SPL RMS. The target sentence was presented from directly in front of the subject for all configurations, and the noise was either presented coincident with the speech (S0N0) or from 90 degrees on the side of the subject (S0N90). For this latter condition with spatially separated speech and noise there were two separate configurations: one with noise from the left and one with noise from the right of the subject. The competing babble for both the fixed-level and adaptive tests in noise consisted of two male and two female interferers. The babble was shaped according to the International Long Term Average Speech Spectrum (Byrne et al., 1994).

The noise level was adapted during test administration using the HINT scoring method (Nilsson et al., 1994). This method used a step size of 4 dB for the initial four sentences, and a 2 dB step size for the remaining 28 sentences. The SNR of the fifth sentence was calculated to be the mean of the first four SNRs and the SNR which would have been used for the fifth sentence. The starting SNR was selected to ensure that the first four sentences were presented within a sensitive range for each subject. The level of the competing noise was adjusted by a software program, according to the subject’s responses. The noise level increased when the subject responded with more than 50% of morphemes correct, and decreased when the subject failed to repeat 50% of morphemes correctly in the sentence. This provided an SRT measure, indicating the signal-to-noise ratio at which the subject scored 50% of morphemes correct.

All competing noise was presented continuously. A beep was presented prior to each sentence within the adaptive test to alert the subject to the onset of the presentation interval. The open-set word test used a male talker whereas both fixed-level and adaptive
sentences were spoken by a female talker. For the sentence presentation the target talker varied across the two different types of measures.

**Sound Source Direction Identification**

Localisation ability was measured pre- and post-operatively using software developed at the HEARing CRC. The stimuli were pink noise bursts of 500 millisecond duration, and were presented randomly from one of eight loudspeakers spanning a 180-degree arc in the frontal horizontal plane. Each token had a 50 ms rise and fall time. All testing was conducted bilaterally (in the best-aided condition) at each time point. The maximum presentation level was 68 dB SPL, and level was roved down by up to 8 dB in steps of 1 dB. Two localisation tests were conducted at each interval, each with ten random presentations from each loudspeaker, i.e. a total of 80 stimuli presented per test. Training was conducted prior to assessment.

**Questionnaire Test Procedures and Administration**

Self-reported outcome measures were obtained using a range of questionnaires. The Speech, Spatial and Qualities of Hearing Scale (SSQ) questionnaire was administered pre-operatively and at the 12-month post-operative time points. This questionnaire comprises fifty questions, separated across the three different domains of speech understanding, spatial hearing, and sound quality (Gatehouse and Noble, 2004) and uses a rating scale from zero to ten. The questionnaire was taken home for completion by each subject at each of the assessment times. Responses were checked when the questionnaire was returned, and questions asked directly of the subject where clarification was needed. The administration of the questionnaire was modified from its original design by using an anchored format, in which subjects were allowed to view the ratings they had made previously.

The International Outcome Inventory for Cochlear Implantation was based on that developed for hearing aid assessment (Cox and Alexander, 2002). The seven-item questionnaire comprises a range of questions designed to be generally applicable in evaluating the effectiveness of hearing aid or cochlear implant treatments. The questions covered areas such as hours of use of the device, the benefit provided by the device, the
level of difficulty experienced when using the device, whether implantation was worth the trouble, and how much the implantation changed enjoyment of life.

A Device Use questionnaire was developed by the author to specifically assess usage patterns of the hearing aid and sound processor in the post-operative period, as well as to obtain specific feedback regarding overall perceived benefits and limitations of cochlear implantation.

**Hearing Aid Fitting and Management**

All subjects were experienced bilateral hearing aid users prior to enrolment in the study. Hearing aids were provided by each subject’s clinical audiologist and the fitting was reviewed pre-operatively using real-ear measurement. The NAL-RP or NAL-NL1 prescription was used as the basis for initial hearing aid fitting. Frequency transposition was not used by any subjects, although was trialled pre-operatively for S14 and S15.

To monitor the stability of hearing in the non-implanted ear both aided and unaided thresholds were monitored over the course of the study. Aided thresholds for frequencies of 250, 500, 750, 1000, 1500, 2000, 3000 and 4000 Hz were measured using a Madsen Itera audiometer with calibrated output to a loudspeaker, and used as a measure of stable hearing aid function. Unaided thresholds were obtained under headphones to monitor stability of hearing in the non-implanted ear.

Post-operative review of the hearing aid and the sound processor fitting was conducted in a sound treated room to evaluate the degree of loudness balance between the devices. The subject was seated in front of a loudspeaker and provided with a 10-point loudness rating scale for use during the evaluation. The loudness rating scale had a numerical scale from 1 to 10 with labels on numbers 1 (no difference), 4 (slightly louder), 7 (moderately louder) and 10 (much louder). Initially 20-talker babble was presented at a level of 65 dB SPL and the subject was asked to indicate in which ear, if either, the sound was louder. If there was no difference in loudness between ears the subject indicated that the number was 1. If one ear was louder than the other the subject advised which ear, and the extent on the numerical scale to which the loudness differed. Where differences of greater than 4 were reported, the volume controls on the hearing aid and sound processor were adjusted until the sounds at the two ears were rated as similar as possible. The volume
control which provided the closest match across devices for the 65 dB SPL presentation level was used for clinical testing.

Device Parameters

All speech perception and localisation measures were obtained with each subject’s preferred program and volume settings on the hearing aids (adjusted for closest match in loudness at 65 dB SPL where necessary). The preferred input processing programs in the sound processor were also used, with the exception of the Beam algorithm which is available in the cochlear implant sound processor. The beamformer was not used for testing due to the significant effect on microphone directivity and likely degradation of bilateral cues. All subjects used the Everyday or Noise programs in the majority of real-world listening situations.

Sample Size Requirement

Prospective sample size estimations for a paired t-test were conducted, given that the study used a repeated-measures design to investigate its hypotheses. Sample size estimation was based on both monosyllabic word perception in quiet and adaptive sentence perception. Retrospective data was used to determine the standard deviation of change, based on a dataset collected with a larger group of subjects having acoustic hearing in one or both ears. Based on that analysis the standard deviation of change was 8.6% for monosyllabic words and 2.2 dB SRT (SD) – the variability measured in the scores obtained in the same test configuration as would be used within the current study. In order to detect clinical meaningful target differences of 10% on monosyllabic word tests and 1.5 dB on the adaptive SRT test, the required sample size would be 10 and 19 respectively. Sample size in the current study was based on the required sample size calculation for the adaptive SRT measurement.

Statistical Analysis

Speech Perception

Speech perception data used in statistical analyses was the average of the two scores obtained in a single test session at each of the pre- and post-operative time points. Grouped mean data was analysed using a 2-tailed paired t-test to compare the pre-
operative and six month post-operative scores. Where data was not normally distributed the Wilcoxon Signed Rank Test was used.

Although insufficient data was collected for a more comprehensive analysis of individual subject data, the critical difference was calculated for the subject group by examining each test’s reliability. This provides an indication of the inherent variability of each test measure, and provides a guide to interpreting the degree of post-operative change in test score at an individual subject level. At each of the two time points (pre- and post-operative) the difference between the two successive administrations of each test measure was calculated. The standard deviation of the difference values for the group of subjects at each time point was divided by the square root of 2 (since two lists were administered at each time), and multiplied by 1.96 to obtain the two-sided critical difference at the 95% confidence level. The critical difference value provided on each graph was the root-mean-squared average of the pre- and post-operative calculations. Based on this analysis, the critical difference for monosyllabic word testing was 12.0 percentage points, and for CUNY sentences in noise was 17.5 percentage points. For the adaptive SRT testing the calculated critical difference was 2.3 and 3.7 dB for the S0N0 test conditions at 65 and 55 dB SPL presentation level respectively. The critical difference calculated for SRM measures for the subject group was 3.8 dB for the test condition that favoured the implanted ear, and was 2.6 dB for the condition that advantaged the hearing aid.

**Sound Source Direction Identification**

Raw data from each of the two localisation tests administered at each of the pre- and post-operative points was independently analysed by calculating the root-mean-squared (RMS) error. This was the root mean squared deviation of the responses from the target speaker locations. Grouped mean data was analysed using a paired t-test. As for the speech perception data analysis for individual subjects, the critical difference was calculated by examining the test reliability for the group. The two-sided critical difference at the 95% confidence level (based on the RMS average of the pre- and post-operative calculations) was 11.0 degrees. As mentioned previously, the critical difference value is provided as a guide to the reader as to the test-retest reliability of the measure, rather than an absolute statement regarding significance for an individual.
SSQ Questionnaire Subscales

Group analysis of questionnaire responses on each of the speech, spatial and quality subscales used the non-parametric Signed Rank Test to compare the pre- and post-operative ratings. The mean rating was obtained for each of the subscales at each interval for each subject. Where the subject rated a listening situation as being ‘not applicable’ or there were inconsistencies in the data at a particular interval, the corresponding data at the comparative interval was also removed from the analysis.

A measure of test reliability was obtained through repeat administration of the SSQ questionnaire in a group of 26 adult recipients with a minimum of six months of cochlear implant experience. The questionnaire was administered twice for each subject, on occasions separated by two weeks. Between the two administrations of the SSQ questionnaire a different questionnaire was administered as a foil. The two-sided critical difference at the 95% confidence interval level was 1.1, 1.0 and 2.0 for the Speech, Spatial and Quality sub-scales of the questionnaire respectively. This information is provided as a reference for the reader regarding the critical difference of the test measure.

Correlation Analysis

Bland-Altman analysis was conducted to examine whether there was a significant relationship between pre- and post-operative localisation abilities. Pearson Product Moment correlation analysis was conducted to assess whether there was a correlation between pre-operative localisation ability and post-operative change in other spatial hearing abilities (spatial release from masking, spatial ratings on the SSQ subscale).

4.4 Results

4.4.1 Contralateral Ear Hearing Stability

Group median pre- and post-operative median unaided hearing thresholds (across frequencies 0.125 to 4 kHz) were 75 dB HL for both time points. Post-operative median thresholds were within 10 dB HL for all except subjects S6 and S8. For those subjects the post-operative median thresholds were poorer than those obtained pre-operatively by 17.5 dB HL.
4.4.2 Implanted Ear Aided Thresholds

Median aided thresholds were calculated in both the low frequency (0.250-1 kHz) and the high frequency (1-4kHz) at each of the pre- and post-operative time points. Analysis of grouped median low frequency data using the Wilcoxon Signed Rank Test revealed a significant effect of time point [Z=-2.845, p=0.003], with median values at the pre-operative and post-operative assessment being 33 and 26 dB HL respectively. In the high frequency region, the degree of improvement post-operatively was more marked. Grouped data analysis using the Wilcoxon Signed Rank Test revealed significant post-operative improvement in thresholds, with median pre- and post-operative thresholds of 48 and 23 dB HL respectively [Z=-3.784, p<0.001].

4.4.3 Speech Perception

*Monosyllabic Words in Quiet (S0)*

Mean percentage correct scores for perception of monosyllabic words are shown in Figure 8 for individual subjects (S1-19) and for grouped data. The black bars show the pre-operative score using bilateral hearing aids, and the white shaded bars indicate the post-operative bilateral, bimodal scores after twelve months of cochlear implant experience. Analysis of grouped mean data using a two-tailed paired t-test revealed a significant effect of time point [t(18)=-6.018, p<0.001], with mean scores at the pre-operative and six month post-operative assessment being 44.3% and 75.3% respectively. Eighteen of the nineteen subjects showed an improvement in test scores post-operatively, and for fifteen subjects the degree of improvement exceeded the critical difference of the test. No subjects showed a reduction in monosyllabic word perception post-operatively that was greater than the calculated critical difference. Post-operative scores may have been impacted by ceiling effects on the test measure, since ten of the nineteen subjects obtained post-operative scores of greater than 80%, and five obtained scores of greater than 90%.
Figure 8. Mean percentage correct scores for intelligibility of open-set monosyllabic words in quiet for individual subjects (1-19) and for grouped data. Pre-operative scores are shown as filled black columns and post-operative as white shaded columns. Error bars indicate the standard error of the difference scores. Critical difference markers show the two-sided critical difference at the 95% confidence interval across the subject group. Significant group mean difference between pre- and post-operative mean scores is indicated by asterisks (*** significance at the 0.001 level).

Speech Perception in Noise (S0N0)

Adaptive speech in noise testing at the target presentation level of 65 dB SPL was collected for 17 of the 19 subjects, and for the lower presentation level of 55 dB SPL was collected for 16 subjects. Pre- and post-operative individual and grouped mean scores are shown in Figures 9 and 10 for sentence presentation levels of 65 dB SPL and 55 dB SPL respectively. For subjects 4 and 5 the adaptive test data was not collected, so scores for fixed level CUNY sentence presentation (using + 5 dB SNR) are provided as an alternative measure in noise for the speech presentation level of 65 dB SPL. No testing at the lower input level was conducted for those subjects in noise. Data are presented so that more negative SRT scores (i.e. better performance) are shown in the figure to be higher on the y-axis.
Data for the 65 dB SPL presentation level violated the normality test and this was not resolved with arcsine square root transformation. Analysis using the Wilcoxon Signed Rank test revealed a significant post-operative improvement \( [Z=-3.575, p<0.001] \), with grouped median scores being 6.5 dB and 2.7 dB for the pre- and post-operative time points respectively. Twelve of the 17 subjects showed improvement in SRT post-operatively that exceeded the 2.3 dB critical difference value. Of the two subjects tested using the CUNY sentence in noise test one subject (S4) exceeded the critical difference of 17.5% on that test. Overall, 13 of the 19 subjects experienced post-operative improvement beyond the critical difference of the test measure. No subjects experienced a reduction after implantation that exceeded the critical difference of the test measure.

![Figure 9](image)

**Figure 9.** Mean pre- and post-operative bilateral SRT scores in babble, for the speech presentation level of 65 dB SPL. More negative SRT scores indicate better performance (shown as higher on the y-axis). Inset is the mean percentage correct CUNY sentence scores for subjects 4 and 5, since SRT data was not obtained. Pre-operative scores are shown as filled black columns and post-operative as white shaded columns. Error bars indicate the standard error of the difference scores. Critical difference markers show the two-sided critical difference at the 95% confidence interval across the subject group. Significant group mean difference between pre- and post-operative mean scores is indicated by asterisks (** significance at the 0.01 level).
For the lower presentation level of 55 dB SPL there were two subjects where it was not possible to measure an SRT pre-operatively due to an inability to perceive a minimum of 50% of the morphemes correct in noise. For those subjects a value of 31 dB was used, since this was the point at which the SRT software reported that the measurement could not be obtained. At this level the test was effectively being conducted in quiet, due to the low level presentation of noise, and so there was an inability to obtain the speech reception threshold. Analysis using the paired t-test revealed a significant post-operative improvement \([t(15)=5.211, p<0.001]\), with grouped mean scores being 15.0 dB and 3.8 dB for the pre- and post-operative time points respectively. Data analysis was also conducted after removal of the subject data for the two subjects where a pre-operative SRT could not be reliably obtained. Analysis using the paired t-test revealed a significant group mean post-operative improvement \((t(13)=5.249, p<0.001)\). Group mean pre- and post-operative scores were 12.7 and 3.8 dB respectively. Fourteen of the 17 subjects had a post-operative score that exceeded the 3.7 dB critical difference of the test.

**Figure 10.** Mean pre- and post-operative bilateral SRT scores in babble, for the speech presentation level of 55 dB SPL. More negative SRT scores indicate better performance (shown as higher on the y-axis). Pre-operative scores are shown as filled black columns and post-operative as white shaded columns. Error bars indicate the standard error of the difference scores. Critical difference markers show the two-sided critical difference at the 95% confidence interval across the subject group. Significant group mean difference
between pre- and post-operative mean scores is indicated by asterisks (***) significance at the 0.001 level).

Spatial Release from Masking (SRM)

Pre- and post-operative spatial release from masking (SRM) measures for noise presented at ninety degrees to the left and right, were calculated by subtracting the mean S0N0 from the mean S0N90 SRT at each of the time points. This calculation resulted in a positive value when there was advantage through separating the speech and the noise, as compared to coincident presentation. Data are shown for both the listening configuration with noise presented at ninety degrees to the side of the implanted ear (Figure 11) and for the configuration with noise to the side of the hearing aid contralateral to the cochlear implant (Figure 12). In those figures is shown the pre- and post-operative S0N0 and S0N90 SRT data for both individual and grouped mean data. Grouped mean data are shown as a shaded box on the bottom right side of the figure. Pre-operative data are indicated by black shaded bars and post-operative as shaded white bars. The calculated SRM for each time point is shown in text above each of the pre- and post-operative data sets.
Figure 11. Individual subject and group mean SRT scores for the S0N0 and S0N90 pre- and post-operative measures. S0N90 measures were obtained with noise presented on the side of the ear which was implanted. Pre-operative measures are shown in black for each subject, and post-operative with white shaded bars. SRM, defined as the benefit obtained through movement of the noise from coincident presentation with the speech signal (S0N0) to 90 degrees on the implanted side of the subject, is shown above each of the pre- and post-operative points for each subject. A more positive SRM indicates a higher level of performance obtained through spatial separation of the signal and noise.
Figure 12. Individual subject and group mean SRT scores for the S0N0 and S0N90 pre- and post-operative measures. S0N90 measures were obtained with noise on the side of the hearing aid contralateral to the ear which was implanted. Pre-operative measures are shown in black for each subject, and post-operative with white shaded bars. SRM, defined as the benefit obtained through movement of the noise from coincident presentation with the speech signal (S0N0) to 90 degrees on the non-implanted side of the subject, is shown above each of the pre- and post-operative points for each subject. A more positive SRM indicates a higher level of performance obtained through spatial separation of the signal and noise. Significant group mean difference in SRM between
pre- and post-operative mean scores is indicated by asterisks (* significance at the 0.05 level).

Pre-operative group mean SRM using bilateral hearing aids was relatively symmetric across the different spatial listening configurations, being on average 2.4 dB when the noise was presented to the side selected for implantation, and 1.7 dB for the condition where the noise was presented on the contralateral side. When the spatial separation advantaged the hearing aid, i.e. the noise was presented to the side of the cochlear implant, post-operative SRM was not significantly different to that measured pre-operatively. The 95% two-tailed confidence interval for the difference of means was -1.980 to 1.474 dB. When the spatial configuration advantaged the implanted side, i.e. the noise was presented from the side of the hearing aid, there was a significant increase in SRM \[ t(16) = -2.501, p=0.024 \]. Group mean post-operative SRM was 4.4 dB, which was an increase in SRM from pre-operative levels of 1.7 dB.

**Sound Source Direction Identification**

Pre- and post-operative measures of localisation performance were collected for fourteen of the nineteen subjects. Data for individual subjects and for the subject group is shown in Figure 13. In this figure, the root-mean-squared (RMS) error on the localisation test is shown on the y-axis, with a greater degree of error shown as a higher value. Chance performance using the eight loudspeaker configuration with a 180 degree span would be expected to be approximately 86 degrees if responses were uniformly distributed across the speaker array or 59 degrees if responses were at a fixed location directly in front of the subject (van Hoesel and Litovsky, 2011). Chance performance for each response strategy is shown as dashed lines on the chart above the grouped mean localisation values.

The grouped mean pre-operative localisation RMS error was 20.7 degrees, which was slightly below the spacing of the speakers used for the evaluation. Post-operative grouped mean RMS error was 41.3 degrees. Grouped mean analysis using a paired t-test showed a significant post-operative increase in error \[ t(14) = -5.190, p<0.001 \]. Individual subject analysis showed that eight of the fourteen subjects experienced a post-operative reduction in localisation ability that exceeded the critical difference of 11 degrees. For pre-operative localisation all subjects performed at better than chance performance on the test. Post-operatively, all subjects performed at better than chance performance for the
response strategy based on uniform response distribution, however three performed close to chance level based on responses to a fixed frontal location.

Figure 13. Individual subject and group mean localisation ability for 14 subjects. Pre-operative localisation RMS error values are shown as filled black columns and post-operative as white shaded columns. Significant group mean difference between pre- and post-operative mean scores is indicated by asterisks (*** for significance at the 0.001 level).

Self-Reported Ratings of Benefit

SSQ Speech, Spatial and Quality Subscales

Figures 14, 15 and 16 show individual and grouped mean pre and post-operative self-reported ratings on the speech, spatial and quality subscales of the SSQ questionnaire respectively. Analysis of grouped data using the non-parametric Signed Rank Test revealed a significant post-operative improvement on each of the speech ($Z=3.783$, $p<0.001$), spatial ($Z=3.3$, $p<0.001$) and quality ($Z=3.763$, $p<0.001$) sub-scales. The median pre-operative rating on the speech subscale was 2.5, which increased to 6.1 post-operatively. Eighteen of the nineteen individual subjects rated the post-operative
performance on the speech subscale as higher than pre-operative ratings, and seventeen exceeded the critical difference of 1.1 on this measure. On the quality sub-scale, the grouped median ratings obtained pre- and post-operatively were 4.1 and 6.5 respectively. Twelve of the individual subjects reported post-operative improvement in quality ratings that were equal to or exceeded the critical difference of 2.0. No subjects reported a post-operative reduction on the speech or quality subscales that exceeded the critical difference of the measure.

On the spatial subscale, the pre- and post-operative group median ratings were 2.5 and 5.9 respectively. Fifteen subjects indicated positive improvement post-operatively on this measure and for fourteen subjects the post-operative change was greater than the critical difference. Three subjects (S7, S13 and S16) indicated a post-operative reduction in spatial hearing ability however the difference was less than the critical difference for two of the subjects. Subject S13 indicated poorer spatial hearing ability of 1.6 on the rating scale, which was greater than the critical difference of the test measure.

![Figure 14](image)

**Figure 14.** Individual subject and group mean ratings on the Speech subscale of the SSQ questionnaire. Pre-operative scores are shown as filled black columns and post-operative as white shaded columns. Significant group median difference between pre- and post-operative mean scores is indicated by asterisks (*** for significance at the 0.001 level). Error bars indicate the standard error of the difference scores. Critical difference markers
show the two-sided critical difference at the 95% confidence interval across the subject group.

**Figure 15.** Individual subject and group median ratings on the Spatial subscale of the SSQ questionnaire. Pre-operative scores are shown as filled black columns and post-operative as white shaded columns. Significant group median difference between pre- and post-operative mean scores is indicated by asterisks (***) significance at the 0.001 level). Error bars indicate the standard error of the difference scores. Critical difference markers show the two-sided critical difference at the 95% confidence interval across the subject group.
**Figure 16.** Individual subject and group median ratings on the Quality subscale of the SSQ questionnaire. Pre-operative scores are shown as filled black columns and post-operative as white shaded columns. Significant group mean difference between pre- and post-operative mean scores is indicated by asterisks (*** significance at the 0.001 level). Error bars indicate the standard error of the difference scores. Critical difference markers show the two-sided critical difference at the 95% confidence interval across the subject group.

**International Outcome Inventory**

The International Outcome Inventory for Cochlear Implants (IOI) was completed by seventeen of the nineteen subjects. Histograms indicating the number of subjects selecting each of the responses to the seven questions are shown in Figure 17. It can be seen that all subjects used the cochlear implant for a minimum of four hours each day, and all except one of the subjects selected the highest category of use (more than 8 hours per day). Most subjects indicated that the implant ‘helped very much’ in hearing in a situation where they most wanted to improve hearing prior to implantation, that the implant was ‘very much worth’ the trouble, and that implantation had resulted in improved enjoyment of life.
Figure 17. Histograms indicating the number of subjects selecting each option provided on the International Outcome Inventory.
Device Use Questionnaire

Sixteen of the nineteen subjects completed the Device Use Questionnaire. Subjects were asked to indicate which device, i.e. the hearing aid or the cochlear implant, provided best overall hearing and understanding. Nine subjects reported best hearing via the cochlear implant, six indicated that the best device differed according to different listening situations, and one reported that the hearing aid provided best hearing. All except subject S1 used both devices together in everyday listening environments. Subject S1 elected to use the cochlear implant sound processor alone since there was no reported benefit through use of the hearing aid and sound processor in combination.

Most subjects indicated that hearing had improved post-operatively when listening in quiet, listening in noise, listening to the television or radio, and for detecting and hearing soft sounds. In quiet situations, fifteen of the sixteen subjects reported improvement, and twelve subjects reported post-operative improvement in noise. Twelve subjects indicated benefit when listening to the television or radio, and thirteen reported improvement in the ability to detect soft sounds and speech. No subjects experienced worsening of ability in those situations. Specific examination of the reported change in localisation showed that experience varied across subjects. Three subjects (S2, S12 and S19) indicated improvement in localisation whereas four subjects (S1, S6, S13 and S15) reported worsening of localisation ability.

**Correlation Analysis: Pre-operative Localisation & Post-Operative Spatial Hearing Abilities**

Pearson Product Moment correlation analysis revealed no significant correlation between pre-operative localisation ability and the change in spatial hearing ability post-operatively for each of the measures examined: SRM with noise on the side of the hearing aid (r=0.52, p=0.07), SRM with noise on the side of the cochlear implant (r=0.40, p=0.18) and spatial ratings from the SSQ questionnaire (r=-0.02, p=0.95). No significant correlation was observed between the pre-operative localisation ability and the change in localisation post-operatively. The latter analysis was conducted through examining the relationship between 1) the average of the pre- and post-operative localisation and 2) the difference in post- and pre-operative localisation ability, due to the inter-relationship between the examined variables.
4.5 Discussion

Results show functional improvement on a range of measures for this group of recipients who presented for cochlear implantation and subsequently lost acoustic hearing in the implanted ear post-operatively. Grouped mean monosyllabic word perception increased from 44.3% to 75.3% for the group of subjects, consistent with the findings by Gifford et al. (2010), where the grouped mean pre- and post-operative word scores were 41% and 82% respectively. Post-operative scores in the current study may have been impacted by ceiling effects, since ten of the 19 subjects obtained scores of greater than 80%. Individual analyses of the speech perception data revealed that 79% of the subject group experienced post-operative change in scores on the monosyllabic word test that exceeded the critical difference, and 68% and 82% exceeded the critical difference on the adaptive SRT test at the 65 and 55 dB SPL presentation levels respectively. No subjects experienced a reduction in speech perception scores post-operatively or on the speech and quality subscales of the SSQ questionnaire. The findings from the current study provide further evidence from that observed by Gifford et al. (2010) in support of positive post-operative outcomes for candidates with substantial pre-operative hearing. Furthermore, the current study has demonstrated positive clinical outcomes for candidates with more high frequency hearing than has been previously examined. All subjects in the current study had median low frequency hearing thresholds of less than or equal to 90 dB HL in both ears, whereas in the Gifford et al. (2010) study there were 77% and 86% of subjects with that level of hearing in the implanted and contralateral ear respectively. Similarly, 68% of subjects enrolled in the current study had median HF unaided hearing thresholds of less than or equal to 90 dB HL in the implanted ear, as compared to 41% of subjects evaluated by Gifford et al. In the contralateral ear there were 84% of subjects in the current study and 68% in the Gifford et al study with that level of high frequency hearing. The extension in this study to assessing outcomes for candidates with better pre-operative hearing levels than previously examined should increase confidence in recommending implantation as a treatment option for this candidate group. This is particularly the case given that these findings represent the ‘worst-case’ situation, where hearing is lost in the implanted ear, and that most subjects would be expected to have hearing preserved after implantation.
A further finding from the current study relates to the examination of speech perception performance at lower speech presentation levels than typically examined in the clinical setting. Speech reception thresholds in noise for the presentation level of 55 dB SPL were 15.0 dB and 3.8 dB at the pre- and post-operative assessments respectively, representing a significant post-operative improvement of 11.2 dB. This compared to a post-operative improvement of 3.2 dB for the signal presentation level of 65 dB SPL. The larger benefit for the lower presentation level would be expected as a result of the improved audibility across the hearing frequency range obtained with the cochlear implant as compared to the hearing aid. Median high frequency aided thresholds were on average 40 dB HL better post-operatively than were obtained on pre-operative measures, and all subjects achieved high frequency hearing within the aided range of 15-35 dB HL after implantation. The improvement in speech perception at the lower input signal level was consistent with the information obtained from the Device Use Questionnaire, where thirteen of the sixteen subjects who completed the questionnaire reported post-operative improvement in the ability to detect soft sounds and speech in the real-world environment. Improved audibility and perception of soft sounds is important in providing reliable access to the softer components of speech and in situations such as where the speaker or signal originates at a distance from the listener (Alkaf and Firszt, 2007).

Pre-operative spatial hearing performance is likely an important consideration for the population of candidates presenting at cochlear implant centres with pre-operative bilateral acoustic hearing. Loss of acoustic hearing in the implanted ear may negatively impact on a recipient’s ability to utilise interaural time and level cues post-operatively. Pre-operative SRM was relatively symmetric across the different spatial listening configurations, i.e. with noise on the side of the ear selected for implantation and the contralateral side, being 2.4 dB and 1.8 dB respectively. Post-operatively there was an improvement in SRM when the spatial configuration advantaged the implanted side, with group mean SRM of 4.1 dB. This post-operative improvement is likely explained by the improved access to the unilateral head-shadow effect due to provision of high-frequency hearing via electrical stimulation. The observed effect is close to the approximate 5 dB advantage based on review of previous studies (van Hoesel, 2012).

For the spatial configuration which advantaged the hearing aid side a decrease in SRM might have been expected if subjects had access to bilateral unmasking pre-operatively.
The lack of significant change in SRM in that configuration was expected if bilateral unmasking was not a contributing factor, since the unilateral head shadow effect would have been somewhat constant across the pre- and post-operative time points due to relative stability in aided and unaided hearing thresholds over the course of the investigation.

Assessment of real world benefit via the range of administered questionnaires showed positive acceptance and reported benefit for the majority of subjects. Two subjects indicated a small reduction in spatial hearing abilities after implantation. The negative report from one of those subjects (S7) was also obtained on other measures, including the International Outcome Inventory. On that measure subject S7 indicated that the cochlear implant was only ‘moderately worth the trouble’ and that enjoyment of life had not changed after implantation. The responses were not consistent with the monosyllabic word scores in quiet or the speech subscale ratings on the SSQ for that subject which showed post-operative improvement. However the lack of perceived benefit with the cochlear implant was consistent with the speech in noise measure, and with the small reduction in localisation ability that was observed in the post-operative period. Pre-operative assessment for that subject revealed poorer than expected speech perception scores given the hearing thresholds, which provided aidable hearing to 8000 Hz in the better hearing ear. This factor may explain the reduced benefit for this subject as compared to other subjects enrolled in the study.

The observed post-operative reduction in objective assessment of localisation ability is consistent with findings from Dunn et al. (2010), where use of bimodal devices was shown to result in poorer localisation ability compared to that obtained using bilateral hearing aids. Post-operative localisation RMS errors for each subject in the current study were better than chance performance, and ranged from 24.6 degrees to 58.6 degrees, with a mean of 41.3 degrees. Results were comparable with RMS errors of 33, 39, and 64 degrees in studies by Firszt et al. (2012), Potts et al. (2009) and Ching et al. (2004) respectively. Direct comparison of localisation error between the current study and those by Firszt and Potts is not possible as a result of different test methodology. The lower errors reported for those studies is likely to be attributed to the smaller loudspeaker arc of 140 degrees which would have reduced ambiguity in ITD and ILD cues, as well as the allowance of head turns during the assessment procedure. Although different test
methodology was also used between the current study and that of Arndt et al. (2011a), the post-operative median MAE of 15 degrees in that study may at least in part be attributed to the better high frequency hearing thresholds in the ear contralateral to the cochlear implant.

The mean RMS error was more than twice as large post-operatively, which may have been expected to be a significant down-side to implanting subjects, particularly in everyday, dynamic listening conditions where talker location varies frequently. However, the objective assessment of localisation ability was not clearly correlated with subjects’ experience in real-world situations. Responses from the Device Use Questionnaire indicated that three subjects reported improvement and four a noticeable reduction in localisation ability after implantation. Controlled measurement was obtained in only one of the three subjects who reported improved post-operative localisation ability, and that subject showed no measurable change. Of the four subjects who reported poorer post-operative localisation ability on the Device Use Questionnaire three were evaluated objectively. For those subjects the controlled measures were consistent with the subjective ratings. However, self-reported ratings on the spatial subscale of the SSQ showed more variable results. On that measure two subjects indicated post-operative improvement, one post-operative reduction and one reported little change in spatial hearing function. An additional five subjects showed reduction in localisation using objective measures but reported no change in localisation ability in real-world environments. The Device Use Questionnaire specifically asked for subjects to report on post-operative change in localisation ability, as compared to the spatial subscale of the SSQ which assessed a broader range of spatial ability. This may have explained the difference between objective measures and subjective ratings on that measure. Also, the self-report questionnaires administered during the study may have assessed different aspects of localisation than the static laboratory evaluation, and this may also have contributed to the differences observed between objective and subjective performance.

Based on the localisation findings, it would be important in the clinical setting to discuss the potential for post-operative reduction in localisation ability with cochlear implant candidates. This information should be presented to candidates with consideration as to the expected substantial benefits of cochlear implantation but include discussion of this aspect of performance where hearing may be lost in the implanted ear. Although there
would be expected a high likelihood of retaining hearing in the implanted ear after implantation it would be beneficial to set expectations in the event that hearing is not able to be preserved initially, or is subsequently lost during the post-operative period.

Post-operative change in spatial hearing abilities, as measured through spatial release from masking and through ratings of real-world performance using the spatial component of the SSQ questionnaire, were not correlated with pre-operative localisation ability. It was hypothesised that pre-operative localisation ability may be reflective of a subject’s ability to utilise interaural timing and level cues with bilateral hearing aids, and be predictive of the impact of post-operative loss of acoustic hearing in the implanted ear on bilateral function. Use of different outcome measures that were more sensitive to assessment of bilateral hearing function may have resulted in a different finding, however there is currently no evidence of association between localisation ability and post-operative spatial hearing ability.

When considering the overall subjective benefit of implantation for the subject group assessed within the clinical study it is important to consider the ratings on the self-report questionnaires. Key findings from the International Outcome Inventory were that all subjects regularly used the cochlear implant in daily life, that all reported benefit from the implant in a situation deemed particularly important, that all indicated that the cochlear implant was worth the trouble and that all except one subject reported that the implant had significantly improved enjoyment of life. Those findings, in addition to the positive results observed for other subjective and objective measures, provides confidence in considering cochlear implantation as an intervention option for such candidates. Although risk to loss of acoustic hearing should be considered and discussed with candidates, the findings from this study suggest that the benefit of implantation typically outweighs the potential risk of loss of implanted ear acoustic hearing.

4.6 Conclusions

The findings from this study report the expected benefits and limitations of cochlear implantation for candidates transitioning from bilateral hearing aids in the pre-operative period to post-operative use of a cochlear implant in combination with a contralateral hearing aid. Although the ability to reliably preserve acoustic hearing after implantation has been demonstrated in a number of previous studies, it is important to consider the
potential impact of loss of acoustic hearing in the implanted ear on post-operative performance. Significant improvement in speech recognition and in real-world ratings of benefit after implantation provides further evidence of positive findings for those candidates presenting to clinics with pre-operative bilateral acoustic hearing. No correlation between pre-operative localisation ability and post-operative change in spatial hearing abilities (using measures of SRM and spatial ratings on the subscale of the SSQ questionnaire) was observed. Reduction in the ability to localise sound direction after implantation is an important issue for consideration and discussion during the pre-operative counselling phase with candidates, even though there was not a clear relationship between controlled measures and subjective ratings of localisation ability.
5 Influence of Contralateral Acoustic Hearing on Adult Bimodal Outcomes after Cochlear Implantation

The information contained within this section comprises only the content of the accepted publication, with the reprint provided in Appendix 5.

5.1 Abstract

Objective: To examine post-implantation benefit and time taken to acclimate to the cochlear implant for adult candidates with more hearing in the contralateral non-implanted ear than has been previously considered within local candidacy guidelines.

Design: Prospective, within-subject experimental design.

Study Sample: Forty post-linguistically hearing-impaired subjects with a contralateral ear word score in quiet ranging from 27% to 100% (median 67%).

Results: Post-implantation improvement of 2.4 dB and 4.0 dB was observed on a sentence in coincident babble test at presentation levels of 65 and 55 dB SPL respectively, and a 2.1 dB benefit in spatial release from masking (SRM) advantage observed when the noise location favoured the implanted side. Significant post-operative group mean change of between 2.1 and 3.0 was observed on the sub-scales of the Speech, Spatial and Qualities (SSQ) questionnaire. Degree of post-implantation SRT benefit on the coincident babble test and on perception of soft speech and sounds in the environment was greater for subjects with less contralateral hearing. The degree of contralateral acoustic hearing did not affect time taken to acclimate to the device.

Conclusions: The findings from this study support implantation for candidates with substantial acoustic hearing in the contralateral ear, and provide guidance regarding post-implantation expectations.

5.2 Introduction

With progressive expansion in criteria for cochlear implantation candidacy, it is increasingly common for candidates to have substantial acoustic hearing in the better hearing ear. Provision of evidence-based recommendations is important during the
clinical assessment and counselling process for anyone considering a cochlear implant. However, there is less information available to assist with clinical recommendations for candidates with greater levels of pre-operative acoustic hearing than for more traditional candidates. To address this, it is important to carefully assess outcomes for this new cochlear implant candidate population, with an aim to improve the evidence-base for clinical guidance as relates to predicted outcomes for individuals.

Measures of post-implantation speech recognition improvement have typically employed either tests of perception of speech in quiet, or of speech presented coincident with background noise from directly in front of the listener. There is published evidence of reduced speech perception benefit for candidates with contralateral acoustic hearing, as compared to more traditional candidates, on such measures. Gifford et al. (2010) compared best-aided outcomes for 22 subjects with substantial pre-operative hearing (defined as greater than 30% on a monosyllabic word test in quiet), with a group of more traditional cochlear implant candidates and found no difference between the groups in average bilateral post-operative word scores. Since the subjects with pre-operative hearing had higher pre-operative levels of performance than those without, they obtained less post-operative improvement.

Review of findings across a number of other published studies also suggest reduced benefit as a function of the degree of contralateral hearing in the coincident speech in noise test configuration. Firszt et al. (2012) examined pre- and post-operative outcomes for a group of ten subjects with asymmetric hearing loss, using a range of speech perception measures in noise. All subjects scored at least 50% on a word or sentence test in quiet pre-operatively, and had little or no hearing in the ear selected for implantation. Contralateral ear pure-tone averaged (PTA) thresholds ranged from 27 to 88 dB HL, with a mean of 56 dB HL. Best-aided scores on a TIMIIT sentence in quiet and noise test for the seven postlingual subjects improved by approximately 40% and 20% respectively. Vermeire and Van de Heyning (2009) specifically examined the change in speech recognition ability in two subject groups categorised according to whether or not they used a hearing aid on the contralateral ear. Mean PTA thresholds for frequencies 0.5, 1, 2 and 4 kHz for the group of nine hearing-aid users was 60.1 dB HL (with a range from 38 to 79 dB HL). Although not statistically significant, the average SRT was 3.3 dB lower for the bilateral as compared to unilateral test condition for the group of hearing
aid users, whereas was 0.3 dB lower in the unaided group who had better contralateral hearing thresholds. Lack of benefit on a coincident speech in noise test has also been reported for subjects with unilateral hearing impairment (Buechner et al., 2010; Arndt et al., 2011a).

Although there is evidence of less benefit of cochlear implantation in subjects with better contralateral hearing on traditional speech perception measures, it is important to assess spatial hearing ability and real-world functional outcomes (Tyler et al., 2006), which are likely more indicative of an individual’s ability to function effectively in real-world listening environments. Significant advantage provided by the cochlear implant in spatially separated speech and noise test configurations is thought to have been primarily due to improved access to favourable SNRs imparted by the head shadow, with benefit reported when the implanted ear received a better signal-to-noise ratio than the non-implanted ear (Buechner et al., 2010; Arndt et al., 2011a). Additionally, positive findings have been observed on tests of localisation ability (Arndt et al., 2011a; Firszt et al., 2012). Those findings are in line with earlier research in subjects with less contralateral hearing (Tyler et al., 2002). Vermeire and Van de Heyning (2009) examined the change in speech recognition ability with spatially separated signal and noise in the two groups of subjects who differed as to whether they used a hearing aid or had better hearing that was unaided. Significant improvement from adding the cochlear implant was observed for both groups using a test condition in which noise was presented from directly in front of the listener and speech from the side of the cochlear implant at an angle of 90 degrees. In that test condition the advantage provided by the bimodal devices, as compared to the use of the hearing aid alone, was the combined result of improved signal-to-noise ratio and potential access to binaural cues.

In a test configuration with speech presented from the front and noise from 90 degrees on the implanted side, Vermeire and Van de Heyning (2009) reported a significant 3.8 dB SNR improvement from adding the cochlear implant for the hearing-aid users but not the subjects with better contralateral hearing. The difference between groups is likely attributed to the relative performance between ears; for hearing aid users the addition of the cochlear implant, even when at a poorer SNR, still offers improvement because the hearing aid alone does not provide a high level of performance. However, for subjects with good performance in the contralateral, non-implanted ear, the addition of the
cochlear implant at a poorer SNR does not result in significant improvement as compared to the single ear condition. For those subjects the performance of the contralateral ear with a more favourable SNR would likely perform better than the cochlear implant side.

Another metric used to assess benefit of cochlear implantation is subjective qualitative questionnaires such as the SSQ questionnaire (Gatehouse and Noble, 2004). Significant post-implantation improvement on the speech sub-scale has been reported for both the asymmetric (Vermeire and Van de Heyning, 2009; Firszt et al., 2012) and unilateral (Vermeire and Van de Heyning, 2009; Arndt et al., 2011a) hearing-impaired subject groups. Similar findings have been reported on the spatial sub-scale for the majority of studies (Arndt et al., 2011a; Firszt et al., 2012), although not for the subject group in the study by Vermeire and Van de Heyning (2009) who used a hearing aid in the contralateral ear. It was hypothesised by those authors that spatial hearing ability in that group may have been compromised by the use of two independent devices with different signal compression characteristics, as compared to use of a single device in combination with normal hearing. However, in contrast, the benefit reported by Firszt et al. (2012) was observed for subjects using the hearing aid in combination with the cochlear implant sound processor.

On the quality sub-scale, there were more varied results. Significant benefit was reported in the asymmetric hearing impaired subject group examined by Firszt et al. (2012) although less benefit was observed on the quality sub-scale than on the speech and spatial scales in that study. Similarly, significant improvement in quality ratings was observed in the hearing aid users examined by Vermeire and Van de Heyning (2009). No group mean change in quality ratings was observed in the single-sided hearing impaired group examined by Vermeire and Van de Heyning (2009) or in the Arndt et al. (2011a) study. Although there is some variability in the reported findings on the SSQ questionnaires, there does appear to be an effect of degree of contralateral hearing on expected post-implantation outcomes.

In addition to the SSQ questionnaire, a number of additional self-reported rating measures have been used to assess post-operative benefit in the asymmetric and single-sided hearing impaired population. Arndt et al. (2011a) administered the Health Utilities Index 3 (HUI-3) (Furlong et al., 2001) and reported a significant improvement after
implantation as compared to CROS and BAHA devices used pre-operatively. Benefit in that study was also observed on the seven domains of the International Outcome Inventory (IOI) (Cox and Alexander, 2002).

Another consideration is that recipients with contralateral hearing may have difficulty in combining the different perceptual signals provided by the two ears. A larger perceptual difference between electric and acoustic hearing may result in a longer period of adaptation to the cochlear implant in the post-operative period. Additionally, the presence of more salient contralateral ear acoustic cues might result in less attention being directed to the implanted ear. There is some evidence for this potential effect in the published literature. Some recipients with substantial pre-operative hearing experienced decreases in bilateral hearing performance after 1, 3 and 6 months post-activation, but benefit was observed after 12 months of experience (Adunka et al., 2008). Slower post-operative progress using the cochlear implant alone was reported for a group of subjects with pre-operative hearing compared to a similar group without hearing (Cullen et al., 2004). Although performance was not assessed in that study using bimodal devices, it does suggest potential for slower progress. Mok et al (2006) examined bimodal hearing performance in 14 adult recipients and reported that recipients with mid to high frequency aided thresholds in the ear contralateral to the cochlear implant demonstrated less bimodal benefit than those recipients with poorer mid to high frequency thresholds. There are suggestions in the literature that cochlear implant recipients adapt over time to initial pitch mismatch associated with the way in which frequencies are allocated to electrodes in the sound processor (Rosen et al., 1999; Fu et al., 2002; Reiss et al., 2007; McDermott et al., 2009), however it is not clear whether that would impact the time taken to obtain maximal benefit from the electric stimulation in the post-operative period.

The aim of the current study was to further explore the clinical outcomes for subjects with contralateral hearing. Variability in findings reported to date is likely influenced by the characteristics of the different subject groups evaluated, the range of test configurations used for assessment of benefit, and the different time points of measurement; i.e. whether data has been obtained using a pre- to post-operative design, or using measures of bimodal versus better-ear performance. Vermeire and Van de Heyning (2009) suggest that degree of contralateral hearing affects outcomes on some measures. However, this warrants further investigation with a longitudinal study design incorporating direct measures of
pre- and post-operative performance. Furthermore, it is of interest to examine the time taken to obtain benefit after implantation, to investigate whether those subjects with more contralateral hearing might take longer to benefit from the electrical stimulation. The findings from the study will be used to better inform candidates of expected benefit and to assist clinicians in pre-operative counselling discussions.

5.3 Materials and Methods

Subjects

Forty postlingual hearing-impaired adults participated in the study. Subjects were recruited from the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne and from the Sydney Cochlear Implant Centre. The study was approved by the Human Research Ethics Committee at the Royal Victorian Eye and Ear Hospital (Project Number 09/872H) and the Royal Prince Alfred Hospital (Project Number 09/RPAH/427). All subjects had a phoneme score on the monosyllabic Consonant-Vowel-Consonant (CVC) word test of 67% or greater in the contralateral (better hearing) ear. In the implanted ear the pre-operative phoneme score ranged from 0% to 78%. The word score for the same test ranged from 27% to 100% with a median of 67% in the contralateral ear, and from 0% to 62% with a median of 1.5% in the implanted ear.

Pre-operative speech perception scores were obtained as an average of two lists presented in quiet at 65 dB SPL from a frontal loudspeaker at zero degrees azimuth. Selection criteria were an extension of those used in the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic, with enrolment of subjects having greater speech perception in the contralateral ear than would be recommended by the current local candidacy guidelines. The median PTA unaided audiometric thresholds in the contralateral ear (averaged across frequencies 0.5, 1.0 and 2.0 kHz) was 63 dB HL with a range of 0 to 113 dB HL.

Demographic information for each of the subjects is shown in Table 4. The age of the subjects at the time of enrolment into the study ranged from 27 years to 76 years, with a mean age of 60.7 years. Table 4 also provides information regarding aetiology of hearing impairment, the duration of severe-to-profound loss in the implanted ear, the pre- and post-operative PTA in the implanted ear, the PTA in the contralateral ear, and the pre-
operative word scores in each ear. PTA was calculated by averaging the thresholds obtained at frequencies 0.5, 1.0 and 2.0 kHz. Where there was no measurable response, or the PTA was greater than 120 dB HL, the text in the table indicates NR (for ‘no response’). Three subjects had mixed hearing loss in the contralateral ear (S2, S4 and S27) of greater than 10 dB HL when averaged across frequencies 250, 500 and 1000 Hz. The average air-bone gap for those subjects were 20 dB HL, 61 dB HL and 40 dB HL respectively.
Table 4. Subjects’ demographic information; including age at the time of implantation (in years), aetiology of hearing impairment, duration of hearing loss (in years) in the implanted ear and contralateral ear, pre-operative implanted, post-operative implanted, and contralateral pure-tone averaged thresholds (across frequencies 0.5, 1 and 2 kHz), pre-operative phoneme and word scores in the implanted and contralateral ear. NR indicates ‘no response’ on audiometric unaided threshold measures.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age at Implant (years)</th>
<th>Aetiology</th>
<th>Duration implanted ear severe-profound hearing loss (years)</th>
<th>Pre-operative implanted ear PTA (dB HL)</th>
<th>Post-operative implanted ear PTA (dB HL)</th>
<th>Contralateral PTA (dB HL)</th>
<th>Pre-operative implanted ear word score (%)</th>
<th>Contralateral word score (%)</th>
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<tr>
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<td>Aetiology</td>
<td>Duration implanted ear severe-profound hearing loss (years)</td>
<td>Pre-operative implanted ear PTA (dB HL)</td>
<td>Post-operative implanted ear PTA (dB HL)</td>
<td>Contralateral PTA (dB HL)</td>
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<td>Contralateral word score (%)</td>
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<td>125</td>
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<td>NR</td>
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<td>Subject (cont.)</td>
<td>Age at Implant (years)</td>
<td>Aetiology</td>
<td>Duration implanted ear severe-profound hearing loss (years)</td>
<td>Pre-operative implanted ear PTA (dB HL)</td>
<td>Post-operative implanted ear PTA (dB HL)</td>
<td>Contralateral PTA (dB HL)</td>
<td>Pre-operative implanted ear word score (%)</td>
<td>Contralateral word score (%)</td>
</tr>
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<td>Meniere's</td>
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<td>90</td>
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<td>Viral</td>
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<td>68</td>
<td>85</td>
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</table>
Study Design

The study used a prospective, longitudinal, within-subject experimental design in which each subject served as his or her own control. Clinical performance measures were obtained pre-operatively and at 12 months post-operatively in the best aided condition. Additional measures were obtained at three and six months after activation to enable analysis of the rate of improvement after activation of the device. Pre-operatively, subjects used either bilateral hearing aids or, for subjects with single-sided hearing impairment, the preferred option of either a Baha sound processor mounted on a head band or a CROS hearing aid. Post-operatively, all subjects used the cochlear implant sound processor in combination with either the contralateral hearing aid or natural acoustic hearing.

Speech Perception Test Materials & Procedure

Adaptive sentence in noise testing was conducted at each of the pre- and post-operative time points, with the signal presented at both 65 and 55 dB SPL at the centre of the subject’s head position and at the level of the sound-processor microphone. The subject was seated at a distance of 1.2 metres from each of three loudspeakers; one directly in front and one on each side at an azimuth of 90 degrees. Testing was conducted in three spatial configurations: 1) with coincident presentation of speech and noise from directly in front of the listener (S0N0) at both signal presentation levels; 2) with speech from the front and noise at ninety degrees on the side of the hearing aid/natural hearing (S0N90 HA) at a level of 65 dB SPL; and 3) with speech from the front and noise from ninety degrees on the side of the cochlear implant (S0N90 CI) at a level of 65 dB SPL.

The adaptive test used BKB-like sentences and estimated the SNR for 50% intelligibility at the pre- and post-operative assessment for each of the speaker configurations and presentation levels. Each SRT test run comprised 32 sentences, which were a combination of two 16-sentence lists. The noise level was adapted during test administration using the HINT scoring method (Nilsson et al., 1994). A step size of 4 dB was used for the initial four sentences, and then a 2 dB step size for the remaining 28 sentences. The level of the competing noise was adjusted by a software program according to the subject’s responses. The noise level increased when the subject responded with more than 50% of morphemes correct, and decreased when the subject
failed to repeat at least 50% of morphemes correctly in the sentence. The SRT indicated the signal-to-noise ratio at which the subject scored 50% of morphemes correct, and was calculated by averaging the signal-to-noise ratios of the final 28 sentences. All competing noise was presented continuously. The pre-operative SRT value was limited to +15 dB SNR since the adaptive procedure was deemed not to be working correctly beyond that point (Kaandorp et al., 2015). A beep was presented prior to each sentence within the adaptive test to alert the subject to the onset of the presentation interval. All test items were presented once and no feedback was given to the subjects regarding the correctness of the responses. Speech perception data used in statistical analyses was the average of the two values obtained in a single test session at each of the pre- and post-operative time points. Testing was not conducted in quiet due to pre-operative ceiling effects on the test measure for the majority of subjects.

Questionnaire Test Procedures and Administration

Self-reported outcome measures were obtained using the following questionnaires: the SSQ questionnaire (Gatehouse and Noble, 2004), the IOI (Cox and Alexander, 2002) modified from its original form for use with cochlear implants, and a general Device Use questionnaire to obtain specific feedback regarding overall perceived benefits and limitations of cochlear implantation. The Device Use questionnaire required subjects to indicate whether hearing had improved, remained unchanged, or worsened after implantation, across a range of real-world listening scenarios. Those scenarios were listening in quiet situations, in noisy situations, on the telephone, to the television or radio, localising the direction of sounds, and detecting soft sounds and speech. The SSQ was administered in an anchored format, with subjects able to view pre-operative ratings when completing their ratings after implantation.

Device Settings

All speech perception measures were obtained with each subject’s preferred program and volume settings on the hearing aids. The hearing aid volume control was adjusted by the subject while listening to a free-field frontal presentation of 20-talker babble at a signal level of 65 dB SPL, with the subject instructed to create the most balanced percept between ears.
Subjects were either experienced hearing aid users at the time of study enrolment or, for eight subjects who presented with unilateral hearing impairment, were fitted with the Baha Intenso mounted on a headband, or with the Phonak Una M CROS aid. Hearing aids were provided by each subject’s clinical audiologist and the fitting was reviewed pre-operatively using real-ear measurement. Prescribed amplification characteristics were not modified during the research study; rather than clinically applied parameters were utilised. The hearing aid response and sound processor frequency response were verified in an acoustic test box prior to post-operative testing with each subject to ensure appropriate function relative to the baseline pre-operative function. The preferred input processing programs in the sound processor were used. All subjects used their preferred Everyday or Noise programs in the majority of real-world listening situations.

Data Analysis

Pre- and post-implantation grouped mean data for each of the clinical measures was analysed using a 2-tailed, paired t-test. Analyses for each of the speech perception measures were based on the data averaged across two test lists for each subject. For the SSQ the analysis used the mean rating on each of the sub-scales. Where the subject rated a listening situation as being ‘not applicable’ on that questionnaire, the corresponding datum at the comparative interval was not included.

Investigation as to the influence of degree of contralateral hearing on change in scores post-implantation was conducted using multiple linear regression analyses or, for responses on the Device Use questionnaire, binary or ordinal logistic regression. Binary logistic regression was used when only two of the three categories were selected, being a) improved after implantation and b) unchanged after implantation. When all three categories were selected, i.e. the category stating that performance worsened after implantation was selected by some subjects, the analysis was conducted used ordinal logistical regression. Explanatory variables examined in addition to the contralateral word scores were; 1) age at implantation, 2) duration of severe-to-profound hearing loss in the implanted ear and 3) pre-operative word scores in the implanted ear. The change in performance post-implantation was calculated based on the 12-month as compared to the pre-operative scores on each of the outcome measures.
Time taken to reach 90% of the maximum speech in coincident noise SRT value was calculated for the speech in noise test administered at a presentation level of 65 dB SPL. Subjects were categorized according to whether they obtained that level of performance within six or within 12 months post-activation. The most conservative estimate of time taken to reach the maximum score was used in the analysis, in that where the specified level of performance was reached by six months but not maintained to 12 months, the latter time point was used in the analysis. Only subjects with post-operative improvement of greater than the critical difference of the test measure at the 12-month time point were included in the analysis. The two-sided critical difference at the 95% confidence interval was calculated by dividing the standard deviation of the difference values for the group of subjects by the square root of 2 (since two successive lists were administered for each subject), and multiplied by 1.96. Based on that calculation the critical difference of the test measure was 1.4 dB. Binary logistic regression analysis was used to examine whether the time taken to reach the specified level of performance was associated with contralateral word score.

5.4 Results

5.4.1 Pre- and Post-Implantation Performance

*Speech Perception in Noise (S0N0)*

Adaptive speech in coincident noise testing was collected for 38 subjects at a presentation level of 65 dB SPL and for 37 subjects at the lower level of 55 dB SPL. For three subjects (S25, S33 and S34) testing was not conducted after 12 months of device experience; for those subjects the data collected at the six month time point was used in the analysis. Pre- and post-operative grouped mean SRT in noise values are shown in Figure 18. Lower SRT values indicate better performance and are shown as higher on the y-axis. Pre- and post-operative grouped mean SRT values obtained at the level of 65 dB SPL were 3.5 dB and 1.1 dB respectively \([t(37)=6.7, \ p<0.001]\). The observed mean benefit was 2.4 dB and the 95% two-tailed confidence interval for difference in mean values ranged from 1.7 to 3.1 dB. Pre- and post-operative grouped mean SRT values for the presentation level of 55 dB SPL were 6.0 dB and 2.0 dB respectively \([t(36)=6.1, \ p<0.001]\). At that presentation level the mean benefit was 4.0 dB, with the 95% two-tailed confidence interval for difference in mean values ranging from 2.6 to 5.4 dB.
**Figure 18:** Mean pre- and post-operative bilateral SRT scores in babble, for the S0N0 configuration. More negative SRT scores indicate better performance (shown as higher on the y-axis). Pre-operative scores are shown as filled black columns and post-operative as white shaded columns. Error bars indicate the standard error of the difference scores. Significant group mean difference between pre- and post-operative mean scores is indicated by asterisks (*** significance at the 0.001 level, * significance at the 0.05 level), and the mean degree of difference is shown in text above the asterisks.

Analysis of individual subject data revealed better post-operative as compared to pre-operative SRT in babble noise values were obtained for 94.8% and 83.8% of subjects for the presentation levels of 65 and 55 dB SPL respectively. At the presentation level of 65 dB SPL, 68.4% of subjects obtained post-operative SRT improvement that exceeded the critical difference of the test measure (1.4 dB). At the lower level there were 64.9% of subjects who improved beyond the critical difference on that test of 3.7 dB SRT. Most importantly, only one subject (S23) obtained a poorer SRT in noise post-operatively that exceeded the critical difference.
Spatial Release from Masking (SRM)

Pre- and post-operative SRM measures for noise presented at ninety degrees on the cochlear implant or hearing aid side were calculated by subtracting the mean S0N90 from the mean S0N0 SRT at each of the time points. This calculation resulted in a positive value when there was advantage through separating the speech and the noise, as compared to coincident presentation. SRM measures potentially incorporate the combined effects of monaural changes in SNR at the two ears due to the head shadow, as well as any release from masking on the basis of binaural cues. Data are shown in Figure 19 for both the listening configuration with noise presented at ninety degrees to the side of the hearing aid (left panel) and for the configuration with noise to the implanted side (right panel). With noise location moved from the front to the side of the hearing aid (i.e., when providing an SNR advantage to the implanted side) there was a significant post-operative improvement of 2.1 dB in the degree of SRM [t(37)=4.0, p<0.001]. The 95% two-tailed confidence interval for difference in SRM was 1.0 to 3.1 dB. With noise moved from the front to the implanted side (i.e., providing spatial advantage to the contralateral ear) there was no significant difference between pre- and post-operative SRM [t(37)=0.18, p=0.860).
Figure 19: Mean spatial release from masking SRT scores, for noise presented on the side contralateral to the implanted ear (in the left panel), and for noise presented on the implanted side (in the right panel). SRM is the measure of the advantage provided by the spatial separation of the speech and noise (i.e., comparison of performance in the S0N0 and S0N90 conditions). Pre-operative measures are shown in black for each subject, and post-operative with white shaded bars. A more positive SRM indicates a higher level of performance obtained through spatial separation of the signal and noise.

Self-Reported Ratings of Benefit: SSQ

Pre- and post-operative grouped mean ratings for each of the SSQ sub-scales is shown in Figure 20, with data for the speech, spatial, and quality sub-scales in the left, mid and right panels respectively. Analysis using the paired t-test revealed significantly higher post-operative as compared to pre-operative ratings on each of the speech hearing \([t(38)=-10.6, p<0.001]\), spatial \([t(38)=-7.8, p<0.001]\) and qualities \([t(38)=-7.4, p<0.001]\) sub-scales. For the speech hearing sub-scale the pre- and post-operative grouped mean ratings were 2.8 and 5.8 respectively. The 95% two-tailed confidence interval for difference of means was 2.4 to 3.6. Pre- and post-operative grouped mean ratings for the spatial hearing sub-scale were 2.7 and 4.9, and for the qualities sub-scale were 4.6 and 6.6
respectively. The 95% two-tailed confidence interval for difference of means on each of the spatial and qualities sub-scales was 1.7 to 2.8.

**Figure 20:** Grouped mean ratings on the Speech, Spatial and Quality subscales of the SSQ questionnaire. Pre-operative scores are shown as filled black columns and post-operative as white shaded columns. Significant group mean difference between pre- and post-operative mean scores is indicated by asterisks (*** for significance at the 0.001 level). Error bars indicate the standard error of the difference scores.

Analysis of individual subject post-operative ratings on the subscales of the SSQ questionnaire revealed that the majority of subjects provided post-operative ratings that were equal to or better than those obtained pre-operatively. Only subjects S7 and S10 indicated poorer post-operative function on the spatial sub-scale, and S40 on the quality sub-scale. The degree of reduction in spatial performance was 1.1 and 1.5 respectively on the 10-point rating scale for the two subjects.

**International Outcome Inventory**

The IOI was completed by 36 of the 40 subjects enrolled in the study. Histograms indicating the number of subjects selecting each of the responses to the seven questions are shown in Figure 21. It can be seen that all except one subject used the cochlear implant for a minimum of four hours each day, and 72% selected the highest category of use (more than 8 hours per day). Most subjects indicated that the implant ‘helped very
much’ in hearing in a situation where they most wanted to improve hearing prior to implantation, that it was ‘very much worth’ the trouble, and that implantation had resulted in improved enjoyment of life.

Figure 21: Histograms indicating the number of subjects selecting each option provided on the International Outcome Inventory.
Figure 22 shows the percentage of subjects who reported improvement, no change, or worsening from pre-operative performance after 12 months of device use. Data are shown for a range of real-world clinical measures. Most subjects indicated that hearing had improved post-operatively when listening in quiet, listening in noise, listening to the television or radio, and for detecting and hearing soft sounds. Only one subject reported poorer hearing in noise after implantation. That subject had pre-operative unilateral hearing impairment. On ratings related to use of the telephone, 21% reported post-implantation improvement. All except one subject reported use of the telephone in everyday life. The majority (73.8%) used the hearing aid or natural acoustic hearing for communication on the telephone, 5.2% used the cochlear implant alone, and 18.4% were able to utilise two ears on the phone through use of the telecoil, speakerphone, or Bluetooth streaming to both devices. One subject reported worsening of performance on the telephone post-implantation, as a result of background noise being more audible when listening with the hearing aid. Post-implantation improvement in localisation was reported for 34% of subjects. Post-operative worsening of localisation was reported by 13% of the group (S5, S7, S10, S16 and S20). Those had bilateral pre-operative acoustic hearing, with the implanted ear pure-tone-averaged thresholds ranging from 70-87 dB HL across the subject group.
5.4.2 Influence of Contralateral Hearing on Post-Implantation Benefit

Best-subset regression analysis revealed that a lower contralateral word score was significantly correlated with more post-implantation SRT (S0N0) benefit at both presentation levels of 65 dB SPL and 55 dB SPL. Scatterplots indicating the post-implantation change on each of the speech in noise measures as a function of the contralateral word scores is shown in Figure 23. There was not a significant correlation between the contralateral word score and the clinical measures of spatial release from masking or assessment using the subscales of the SSQ questionnaire. Explanatory variables of age at implantation, duration of severe-to-profound hearing loss and pre-operative implanted ear word score were not correlated with change in clinical performance in noise.
Figure 23: Scatterplots indicating the post-implantation change on each of the speech in noise measures (at 65 dB SPL and 55 dB SPL presentation level in the left and right panels respectively) as a function of the contralateral word scores.

Contralateral word score accounted for 25.1% and 34.9% of the variance in SRT benefit at 65 and 55 dB SPL respectively. An increase of 1% in the contralateral word score is associated with a reduction in post-operative SRT benefit of 0.06 dB and 0.12 dB for the presentation levels of 65 and 55 dB SPL respectively. Results of the linear regression analysis are outlined in Table 5. The relatively small Mallows Cp value of 2.0 indicated that the model was precise in estimating the true regression coefficients and predicting future responses.
Table 5. Model statistics and regression coefficients describing the relationship between contralateral word score and post-operative change in bilateral SRT in babble

### 65 dB SPL Presentation Level

**Overall Model:** $F=13.1, \ p=0.001, \ R^2=0.272, \ Adjusted \ R^2=0.198, \ Mallows \ Cp=2.0$

**Regression Coefficients**

<table>
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<th>Variable</th>
<th>Coefficient</th>
<th>SE Coefficient</th>
<th>95% CI</th>
<th>t</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>Constant (Intercept)</td>
<td>-6.33</td>
<td>1.10</td>
<td>-8.57, -4.09</td>
<td>-5.74</td>
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<td>Contralateral Word Score (%)</td>
<td>0.056</td>
<td>0.016</td>
<td>0.03, 0.09</td>
<td>-3.62</td>
<td>0.001</td>
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### 55 dB SPL Presentation Level

**Overall Model:** $F=19.7, \ p<0.001, \ R^2=0.367, \ Adjusted \ R^2=0.349, \ Mallows \ Cp \ 2.0$

**Regression Coefficients**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient</th>
<th>SE Coefficient</th>
<th>95% CI</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant (Intercept)</td>
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<td>1.98</td>
<td>-16.55, -8.51</td>
<td>-6.33</td>
<td>&lt;0.001</td>
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<tr>
<td>Contralateral Word Score (%)</td>
<td>0.124</td>
<td>0.028</td>
<td>0.067, 0.180</td>
<td>4.44</td>
<td>&lt;0.001</td>
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Binary or ordinal logistic regression analyses for each of the categories listed in the Device Use Questionnaire revealed no significant relationship between each of the explanatory variables and post-operative rating for the categories of listening in quiet situations, in noisy situations, on the telephone and localizing the direction of sounds. There was a weak but significant negative association between the contralateral word score and the reported change in listening to the television and radio after implantation ($p=0.042$). However that factor accounted for only 2.5% of the variance in post-operative rating of benefit. A stronger association was observed between the contralateral word score and the ratings that described detection of soft sounds and speech ($p=0.002$), and that factor accounted for 12.1% of the variance in reported post-operative benefit. For each 1% increase in contralateral word score there was an observed reduction of 6.7% in the odds of reporting real-world benefit in detecting soft sounds and speech. The 95% confidence interval for the odds ratio was 0.91 to 0.99.

5.4.3 Time Taken to Reach 90% of Final SRT

Analysis of time taken to reach 90% of the final SRT at 12-months post-implantation was conducted for 23 subjects. Excluded from the analysis were subjects who did not obtain greater than or equal to 1.4 dB SRT post-operative improvement, which was the critical difference of the test measure for the subject group. Those subjects were excluded because of the research objective to assess time to benefit from the cochlear implant. Nine subjects reached the 90% of final SRT performance within six months of device use and 17 obtained that performance level at 12-months. Binary logistic regression analysis revealed that each of the explanatory variables of contralateral word score ($p=0.133$), pre-operative implanted ear word score ($p=0.590$), age at the time of implantation ($p=0.7$) and duration of severe-to-profound hearing loss in the implanted ear ($p=0.594$) were not correlated with the time taken to reach 90% of the final SRT value.

5.5 Discussion

Results show functional improvement on a range of clinical measures for the candidate group with more hearing in the contralateral ear than would have been recommended based on local candidacy guidelines. Significant group mean post-operative improvement was observed on measures of speech recognition for spatially coincident speech and noise, for spatial release from masking measures where head shadow
advantage was provided to the implanted ear, and on a range of real-world, self-reported functional outcome measures. Overall, the findings of the current study support clinics providing a positive recommendation on implantation for cochlear implant candidates with relatively good contralateral hearing.

The 2.4 dB significant post-operative benefit at conversational speech levels for subjects in the current study was similar to the grouped mean benefit of 3.3 dB shown for subjects in the hearing aid group examined by Vermeire and Van de Heyning (2009) (although noting that the difference reported in that study was not statistically significant). Additionally the findings were similar to those reported in prior research that has examined benefit obtained through bimodal as compared to unilateral cochlear implant performance (McDermott and Henshall, 2010). Observed benefit was greater for a lower presentation level of 55 dB SPL as compared to a conversational speech level of 65 dB SPL. The improvement in speech perception at the lower input signal level was consistent with the information obtained from the Device Use Questionnaire, where 71% of the subjects who completed the questionnaire reported post-operative improvement in the ability to detect soft sounds and speech in the real-world environment. Considering that the subject group examined had median word scores in the contralateral ear of 67%, the finding of improved perception of soft speech and detection of soft environmental sounds with real-world use indicates the importance of testing low level audibility in the clinical setting. Improved audibility and perception of soft sounds is important in providing reliable access to the softer components of speech and in situations such as where the speaker or signal originates at a distance from the listener (Alkaf and Firszt, 2007).

Of particular interest in the clinical setting is the guidance regarding expected outcomes for subjects with varying levels of contralateral hearing. It might be expected that those candidates with better functional contralateral hearing would expect to obtain less post-operative benefit. Similar to the findings of Vermeire and Van de Heyning (2009) sentence in noise benefit was less for subjects with better contralateral hearing. The expected benefit of the post-implantation bilateral as compared to pre-operative monaural listening in the test configuration for spatially coincident speech and noise is largely the result of the complementary nature of the signals in the two ears. For those candidates with an already relatively high level of pre-operative function due to normal or near-normal contralateral hearing sensitivity, the addition of the input from the second ear
might provide less relative performance improvement than for those candidates with more compromised contralateral hearing. Additionally, the presence of more salient acoustic hearing pre-operatively may result in less attention being provided to the signal from the implanted side.

The observed association between extent of benefit in noise and contralateral hearing was not observed on the majority of other clinical measures. There was no significant correlation between the degree of benefit obtained on spatial release from masking measures, the sub-scales of the SSQ, and the majority of categories from the Device Use questionnaire. The weak but significant negative association between the contralateral word score and the reported change after implantation when listening to the television or radio is unlikely to be clinically significant since the influence of contralateral word score accounted for only 2.5% of the variance in reported benefit. The report of there being less benefit in detecting soft sounds and speech in subjects with more contralateral hearing would be expected due to there being less reliance on the hearing provided by the cochlear implant in those recipients.

The SRM results can largely be interpreted in terms of the effect of the headshadow at the ear that benefits from it. With the noise moved opposite to the implanted ear, the post-operative increase in SRM compared to the pre-operative outcome is likely attributable to the greater effect of the head shadow at higher frequencies that are likely to be more readily available with the cochlear implant than with the hearing aid or non-amplified ear. The advantage related to head-shadow benefit that was observed in the current study is consistent with that reported in prior studies (Vermeire and Van de Heyning, 2009; Buechner et al., 2010; Arndt et al., 2011a). In contrast, when the noise is moved to the side of the implanted ear, the effect of the head shadow at the ear with improved SNR is the same for pre- and post-operative measures. The absence of any significant decreases in SRM following implantation for that noise location also indicates that binaural cues were equally effective or ineffective before and after implantation. The modest SRM values obtained compared to listeners with normal hearing (Hawley et al., 2004) indicate binaural cues probably did not play a significant role in either case.

In addition to considering the group mean findings, it is important to understand the individual variability in the data. The better post-operative as compared to pre-operative
SRT in noise for 94.8% and 83.8% of subjects at conversational speech and softer presentation levels respectively is an important finding with respect to providing reassurance to candidates. Using the more conservative calculation based on the critical difference of the test measures there were 64.9% and 68.4% of subjects for whom post-implantation benefit was observed. Most importantly, only one subject obtained a poorer SRT in noise post-operatively that exceeded the critical difference. That subject reported a positive outcome based on questionnaire data, in that post-operative subjective ratings of benefit were higher on the speech and quality sub-scales of the SSQ questionnaire than those obtained pre-operatively. The ratings from the International Outcome Inventory also indicated that the implant helped this recipient ‘quite a lot’ in difficult listening situations and that enjoyment of life was ‘quite a lot’ better after implantation. Those functional performance ratings suggest that the poorer speech recognition obtained on the objective measure of speech recognition is likely not a significant finding.

Similarly, analysis of individual subject post-operative ratings on the subscales of the SSQ questionnaire revealed that the majority of subjects provided post-operative ratings that were equal to or better than those obtained pre-operatively. Of the two subjects who reported poorer post-operative function on the spatial sub-scale of between 1.1 and 1.5, it is hypothesised that the reduction in spatial hearing for those subjects may have been related to the loss of acoustic hearing sensitivity in the implanted ear post-implantation. Both subjects had pre-operative PTA thresholds in the implanted ear of better than 77 dB HL, which may have been utilised in combination with the contralateral ear acoustic hearing to provide access to binaural cues. Post-operatively there was no measurable acoustic hearing in those subjects. Although there was a small reduction in reported spatial hearing ability in those subjects, both rated their overall experience after implantation as positive, with both stating on the International Outcome Inventory that the cochlear implant was ‘very much’ worthwhile, and that enjoyment of life was ‘very much better’. The poorer quality rating for S40 was consistent with less-favourable post-operative experience. That subject had normal acoustic hearing thresholds in the contralateral ear, and rated experience with the implant as ‘moderately worth it’ and enjoyment of life as only ‘slightly better’.

The post-operative reduction in localisation ability for 13% of subjects as reported on the Device Use Questionnaire was not expected, however is likely related to the extent to
which pre-operative bilateral acoustic cues were available and the loss of acoustic hearing in the implanted ear that occurred during the surgical procedure. All five subjects who reported post-operative worsening of localisation ability had pre-operative hearing in the implanted ear, with pure-tone average thresholds of between 70 dB HL and 87 dB HL. There is likely a degree of individual variability with respect to whether loss of acoustic hearing in the implanted ear results in poorer spatial hearing abilities post-operatively; however this is an important consideration in the clinical setting (Plant et al., 2014b).

Another clinical question investigated in the current study relates to the time taken to benefit from the cochlear implant in the post-operative period. This analysis focussed on the time taken to obtain close to maximum 12-month performance on ability to understand speech in coincident noise. Based on that analysis, there is no evidence that subjects with more contralateral hearing take longer to obtain benefit from the cochlear implantation. This information is likely of assistance to clinicians when discussing post-operative expectations with candidates, although it is important to consider that different results may have been obtained using different clinical measures of performance. However further research is warranted to examine this in further detail. The current study was limited in terms of the time points in which post-operative assessment was conducted. To more fully examine the influence of contralateral hearing on acclimitization to the cochlear implant, an experimental design which incorporated closer monitoring of the trajectory of change would likely be beneficial.

5.6 Conclusions

This study examined the expected benefits and limitations of cochlear implantation for candidates with substantial hearing in the non-implanted ear. Significant improvement in speech recognition and in real-world ratings of benefit after implantation occurred for the examined subject group. These findings provide confidence in recommending implantation as an intervention option for candidates with substantial functional contralateral hearing. Although less benefit on adaptive SRT in noise and on perception of soft sounds and speech in the environment was observed for subjects with better contralateral hearing, the majority of subjects obtained and reported substantial benefit on those clinical metrics. Rate of adaptation to the cochlear implant in the post-operative period did not appear to be affected by the degree of contralateral hearing.
6 Factors Predicting Post-Operative Unilateral and Bilateral Speech Recognition in Adult Cochlear Implant Recipients with Acoustic Hearing

The information contained within this section comprises only the content of the publication with the reprint provided in Appendix 6.

6.1 Abstract

Objectives: The first objective was to examine factors that could be predictive of post-operative unilateral (cochlear implant alone) speech recognition ability in a group of subjects with greater degrees of pre-operative acoustic hearing than has been previously examined. Secondly, the study aimed to identify factors predictive of speech recognition in the best-aided, bilateral listening condition.

Design: Participants were 65 postlinguistically hearing-impaired adults with pre-operative phoneme in quiet scores of greater than or equal to 46% in one or both ears. Pre-operative demographic and audiometric factors were assessed as predictors of 12-month post-operative unilateral and bilateral monosyllabic word scores in quiet and of bilateral SRT in babble.

Results: The predictive regression model accounted for 34.1% of the variance in unilateral word recognition scores in quiet. Factors that predicted better scores included: a shorter duration of severe-to-profound hearing loss in the implanted ear; and poorer pure-tone-averaged thresholds in the contralateral ear. Predictive regression models of post-implantation bilateral function accounted for 36.0% of the variance for word scores in quiet, and 30.9% of the variance for SRT in noise. A shorter duration of severe-to-profound hearing loss in the implanted ear, a lower age at the time of implantation, and better contralateral hearing thresholds were associated with higher bilateral word recognition in quiet and SRT in noise.

Conclusions: In this group of cochlear implant recipients with pre-operative acoustic hearing, a shorter duration of severe-to-profound hearing loss in the implanted ear was shown to be predictive of better unilateral and bilateral outcomes. However, further research is warranted to better understand the impact of that factor in a larger number of
subjects with long-term hearing impairment of greater than 30 years. Better contralateral hearing was associated with poorer unilateral word scores with the implanted ear alone, but better absolute bilateral speech recognition. As a result, it is clear that different models would need to be developed to predict unilateral and bilateral post-implantation scores.

6.2 Introduction

With candidates for cochlear implantation now including those with greater degrees of pre-operative acoustic hearing than severe-to-profound bilateral deafness, the need for better prediction of potential post-implantation outcomes is increasingly important to assess the degree of risk to their pre-operative communication ability. However, prediction of an individual’s unilateral (cochlear implant alone) outcome after implantation has proven difficult due to a high degree of inter-subject variability across the cochlear implant population. Most research has reported that known predictive factors typically account for less than 60% of the variance in post-operative, unilateral speech recognition scores in post-linguistically hearing-impaired adults (Shea et al., 1990; Summerfield and Marshall, 1995; Waltzman et al., 1995; Blamey et al., 1996a; Dowell et al., 2004; Roditi et al., 2009; Lazard et al., 2012; Blamey et al., 2013). In a relatively recent analysis of data for 2251 post-lingually deafened adults from fifteen cochlear implant centres (Lazard et al., 2012; Blamey et al., 2013), a combination of pre- and post-operative predictive factors were reported to account for only 22% of the variance in post-operative open-set monosyllabic word scores in quiet. Inability to reliably predict outcomes for candidates results in a degree of uncertainty and introduces complexity in providing guidance and setting clinical expectations.

A range of factors have been identified in past studies as being correlated with post-operative, unilateral speech recognition outcomes. Blamey et al. (2013) identified pre-operative factors of age at onset of severe-profound hearing loss, duration of severe-profound hearing loss and aetiology as accounting for 10% of the variance in post-operative monosyllabic word scores. An expanded model based on the same dataset (Lazard et al., 2012), but with inclusion of additional factors, accounted for a total 22% of the variance in post-operative word scores. Additional predictive factors identified were a shorter duration of moderate hearing loss, hearing aid use, and higher speech
recognition ability in the implanted ear. Significant post-operative factors were brand of cochlear implant, the number of active electrodes expressed as a percentage of the total available electrodes on the electrode array, and cochlear implant experience. Holden et al. (2013) reported similar findings for 114 post-lingual subjects, with significant pre-operative predictive factors being identified as a shorter duration of severe-to-profound hearing loss, a shorter duration of hearing loss, lower age at the time of implantation, and higher pre-implant sentence recognition. Post-operative predictive factors identified were implanted ear aided sound field thresholds and electrode position within the cochlea.

A number of studies have identified duration of hearing loss prior to implantation as the most robust predictor of post-operative unilateral speech recognition scores. Detailed investigation of the specific effect of duration and degree of hearing loss on speech recognition is difficult to assess, due to varying criteria used for definition of those factors in the literature. However, there is an indication that a longer duration of profound or severe-to-profound (Gantz et al., 1988; Kileny et al., 1991; Blamey et al., 1992; Waltzman et al., 1995; Blamey et al., 1996a; Rubinstein et al., 1999; Gomaa et al., 2003; Dowell et al., 2004; Leung et al., 2005; Green et al., 2007; Blamey et al., 2013; Holden et al., 2013), a longer duration of moderate hearing impairment (Lazard et al., 2012), and a longer duration of any degree of hearing impairment (Roditi et al., 2009) have each corresponded with worse post-operative unilateral word recognition.

As candidature criteria for cochlear implantation has expanded over time, and increasingly includes candidates with aidable residual acoustic hearing in one or both ears, it has become apparent that bilateral deprivation of auditory stimulation to the central auditory system, rather than unilateral deprivation, is likely to be of greater significance in prediction of post-operative performance. There is now considerable published evidence that positive outcomes can be achieved after implantation of a long-term hearing-impaired ear. In candidates with profound loss caused by otosclerosis, implantation in the long-term hearing-impaired as compared to the better ear did not result in long-term disadvantage (Matterson et al., 2007). Boisvert et al. (2011) examined the effect of duration of hearing impairment in a group of 16 subjects who were implanted in an ear with greater than 15 years duration of deafness. In that study it was observed that a longer history of bilateral auditory deprivation resulted in lower unilateral word scores, but that there was no influence of the duration of unilateral deprivation. Francis et al.
(2004) compared post-operative speech recognition scores across three groups of subjects: those with bilateral severe loss; those with severe loss in one ear and profound loss in the other; and those with bilateral profound hearing impairment. The presence of pre-operative acoustic hearing in at least one ear was associated with higher post-operative scores, but there was no difference in outcome in relation to whether the implanted ear had a profound or a severe degree of hearing loss. Comparable post-operative speech recognition scores were obtained in each ear of a group of 10 subjects who received bilateral implants but had unilateral long-term auditory deprivation of greater than 15 years (Boisvert et al., 2012b). Friedland et al. (2003) conducted a retrospective data analysis in which the University of Iowa predictive model, which incorporates factors of duration of severe-to-profound hearing loss and pre-operative speech recognition ability, was applied to 58 subjects examined at The Johns Hopkins University. The subject group differed from that initially examined in Iowa, in that the policy was to implant the poorer rather than better hearing ear. The model predicted similar outcomes across groups, and the authors concluded that the findings supported the assertion that an individual’s overall auditory experience, rather than ear-specific history, was likely of most relevance in predicting post-operative outcomes.

The association of higher pre-operative speech recognition scores in the ear selected for implantation with better monosyllabic word scores has been reported in a number of studies (Rubinstein et al., 1999; Friedland et al., 2003; Gomaa et al., 2003; Dowell et al., 2004; Gantz et al., 2009; Holden et al., 2013). Positive influence of pre-operative audiometric thresholds has been observed in some (Gantz et al., 1988; Gantz et al., 1993) but not all studies (Blamey et al., 1992; Green et al., 2007; Gifford et al., 2010; Holden et al., 2013). Varied findings have been reported in the literature as to the effect of age at implantation on post-operative unilateral speech recognition. The independent effect of age at implantation is often difficult to assess due to the relationship between that factor and the duration of hearing loss, however the majority of studies have reported poorer word scores in older subjects (Gantz et al., 1988; Blamey et al., 1992; Waltzman et al., 1995; Blamey et al., 1996a; Green et al., 2007; Blamey et al., 2013; Holden et al., 2013).

Despite considerable research to date in outcome prediction for adult cochlear implant recipients, a number of important questions remain unanswered. First, the relevance of the factors predicting unilateral outcomes in the general cochlear implant population to a
population with better pre-operative hearing than previously implanted unknown. Second, it is important to examine and identify factors that are predictive of bilateral performance obtained using the combination of contralateral acoustic and electric stimulation (the ‘bimodal’ condition). The majority of past research has focussed on prediction of unilateral outcomes using only the cochlear implant. However, this is unlikely to be predictive of the real-world benefit to communication for cochlear implant candidates using their implant in combination with acoustic amplification.

Information pertaining to each of those areas will be discussed in the following sections.

6.2.1 Predicting unilateral outcomes in candidates with acoustic hearing

Previous studies have in general included subjects with bilateral severe-to-profound hearing loss. More recently, an increasing number of candidates are being assessed in the clinical setting who have asymmetric or single-sided hearing impairment (Firszt, 2008; Van de Heyning et al., 2008; Vermeire and Van de Heyning, 2009; Buechner et al., 2010; Arndt et al., 2011a; Punte et al., 2011; Ramos et al., 2012), or who have substantial levels of pre-operative hearing in ear to be implanted (Fraysse et al., 2006; Gantz et al., 2009; Lenarz, 2009; Skarzynski and Podskarbi-Fayette, 2010).

As such, the influence of duration of hearing loss may be less significant in the candidate population with more contralateral hearing due to there being a relatively short or no period of bilateral auditory deprivation. The level of hearing in the contralateral ear might be expected to be a significant prognostic factor, since more salient acoustic input might be expected to maintain the central function to a greater extent than would be obtained with a more compromised input. Influence of pre-operative pure tone averaged thresholds in the contralateral ear on post-operative unilateral speech recognition scores has been examined by Lazard et al. (2012), with marginally higher scores obtained for the fourteen of 2251 subjects who had a pure tone average of better than 50 dB HL. Although a significant finding, the authors cautioned that the variance of the group was large as a result of the small subject numbers. Examination of the effect of contralateral hearing on clinical outcomes is of interest to further investigate the findings reported by Lazard et al. (2012), and to extend the subject group to include those with more hearing than previously examined.
6.2.2 Predicting bilateral outcomes

The ability to predict bilateral outcomes for candidates is likely more important in the clinical setting than prediction of unilateral performance, because of the direct applicability to real-world function. Gantz et al. (2009) examined the influence of a range of factors on bilateral word scores for 68 subjects implanted within the FDA clinical trial of the Hybrid S8 (10 mm) electrode. Factors in the model included pre-operative bilateral word score, age at onset of hearing loss, age at implantation, duration of hearing loss from onset to implantation, and whether there was post-surgical acoustic hearing loss of greater than 30 dB HL. Whether the demographic factors of age at onset of hearing loss and duration of hearing loss reflected unilateral or bilateral deafness is not specified in the manuscript. Pre-operative word score and duration of hearing loss explained 29% of the variance in post-operative word score. With an intercept of 55.1%, the model indicated that approximately every 2% increase in pre-operative word score resulted in a 1% increase in post-operative score, and for every two years duration of hearing loss the model predicted a post-operative score reduction of 1%. In another study, bilateral outcomes were examined for two groups of 15 subjects who were implanted in either the long-term sound-deprived ear or the ear aided prior to implantation (Boisvert et al., 2012a). There was no significant difference in post-operative bilateral speech recognition between the groups, which supports the assertion that the period of bilateral as contrasted to unilateral deprivation is likely to be more important in predicting post-operative outcomes.

The aim of the current study was to examine the factors that contribute to post-operative speech recognition outcomes in quiet and in noise, for both the unilateral and bilateral listening conditions, in a group of candidates with pre-operative acoustic hearing in one or both ears prior to implantation. Findings from the study would be beneficial in assisting clinicians in counselling candidates pre-operatively, and in setting post-operative expectations.

6.3 Materials and Methods

Subjects
Sixty-five post-lingually hearing-impaired adults participated in the study. All were implanted with Nucleus cochlear implants (with Contour Advance or Slim Straight electrode arrays) and used the CP810 sound processor. Subjects were recruited from the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne and from the Sydney Cochlear Implant Centre. Implantation dates for recruited subjects ranged from 4 June 2009 to 14 August 2012. Subjects were invited to participate by clinical case managers in the implanting clinics and the majority of candidates who met the inclusion and exclusion criteria and were deemed suitable were approached as to their interest in participating. Approximately 70% of eligible candidates were enrolled into the study. The main reasons for eligible candidates not participating in the study included inability to attend the required study appointments due to either limited time or them living too far from the research centre. The study was approved by the Human Research Ethics Committee at the Royal Victorian Eye and Ear Hospital (Project Number 09/872H) and the Royal Prince Alfred Hospital (Project Number 09/RPAH/427).

All recruited subjects had a pre-operative phoneme score on the monosyllabic Consonant-Vowel-Consonant (CVC) word test of greater than 46% in at least one ear. That criterion was used based on the rationale that candidates with more than that degree of pre-operative hearing would fall outside the typical candidature guidelines used within the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic (Dowell et al., 2004). A summary of group demographic characteristics of the subjects is shown in Table 6. Where there was no response on audiometric measures the value 125 dB HL was entered into the datasheet. The age of the subjects at the time of enrolment into the study ranged from 27 years to 81 years, with a mean age of 62.6 years. Monosyllabic word as compared to phoneme scores have been listed in the table since that is more commonly referenced in past published data, even though phoneme scores were used as the basis for subject recruitment.
Table 6: Group demographic information including age at the time of implantation, duration of bilateral hearing loss, duration of severe-to-profound hearing loss (SPHL), pre-operative pre-tone average (PTA) thresholds in the implanted and contralateral ear, and pre-implantation monosyllabic word score in the implanted and contralateral ear. PTA was calculated by averaging unaided audiometric hearing thresholds at frequencies of 500, 1000 and 2000 Hz.

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Range</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Implantation</td>
<td>62.6 Years</td>
<td>27-81 Years</td>
<td>11.6 Years</td>
</tr>
<tr>
<td>Duration Bilateral Hearing Loss</td>
<td>20.5 Years</td>
<td>0-58 Years</td>
<td>15.3 Years</td>
</tr>
<tr>
<td>Duration Bilateral SPHL</td>
<td>5.1 Years</td>
<td>0-40 Years</td>
<td>7.9 Years</td>
</tr>
<tr>
<td>Pre-Operative PTA Implanted Ear</td>
<td>92.8 dB HL</td>
<td>57.5-125 dB HL</td>
<td>19.7 dB HL</td>
</tr>
<tr>
<td>Pre-Operative PTA Contralateral Ear</td>
<td>65.4 dB HL</td>
<td>0-113 dB HL</td>
<td>23.7 dB HL</td>
</tr>
<tr>
<td>Pre-Operative Unaided Threshold (4000 Hz) Implanted Ear</td>
<td>105.8 dB HL</td>
<td>60-125 dB HL</td>
<td>20.8 dB HL</td>
</tr>
<tr>
<td>Pre-Operative Unaided Threshold (4000 Hz) Contralateral Ear</td>
<td>78.9 dB HL</td>
<td>5-125 dB HL</td>
<td>29.3 dB HL</td>
</tr>
<tr>
<td>Pre-Operative Monosyllabic Word Score Implanted Ear</td>
<td>9.4%</td>
<td>0-62%</td>
<td>11.7%</td>
</tr>
<tr>
<td>Pre-Operative Monosyllabic Word Score Contralateral Ear</td>
<td>49.9%</td>
<td>10-99%</td>
<td>26.9%</td>
</tr>
</tbody>
</table>
As a group, the enrolled subjects had higher levels of pre-operative acoustic hearing than subjects in prior studies that have examined factors predicting post-implantation speech recognition. Twenty percent of subjects in the current study had a pure-tone average (PTA) threshold of better than 50 dB HL in the ear contralateral to that selected for implantation, as compared to less than 1% in the subject group reported by Blamey et al. (2013) and Lazard et al. (2012). In the current study, 52% of subjects had pure-tone-average thresholds of better than 70 dB HL in the contralateral ear as compared to 15% for the subjects of Blamey et al (2013). Comparison of pre-operative PTA hearing thresholds for the current study group as compared to subjects of Holden et al. (2013) revealed similar mean and range pertaining to the implanted ear, but differences in terms of the degree of residual acoustic hearing in the contralateral ear. In the current study the mean PTA threshold in the contralateral ear was 65.4 dB HL (with a range 0-113 dB HL) as compared to 97.6 dB HL (with a range 60-120 dB HL) in the subject sample that was examined by Holden et al. (2013).

**Hearing Aid Fitting and Management**

Subjects were either experienced hearing aid users at the time of study enrolment or, for eight subjects who presented with unilateral hearing impairment, were fitted with the Baha Intenso mounted on a headband, or with the Phonak Una M CROS aid. Hearing aids were provided by each subject’s clinical audiologist and the fitting was reviewed pre-operatively using real-ear measurement. Prescribed amplification characteristics were not modified during the research study; rather the clinically applied parameters were utilised. For subjects with unilateral hearing impairment who were provided with the Baha Intenso or CROS aid, a period of at least two weeks of take-home experience was provided for all except one subject prior to speech perception assessment. Testing was conducted with the CROS aid for seven subjects and with the Baha device for one subject, based on preference after listening with each of the devices.

**Study Design and Test Materials**

The study used a prospective, longitudinal experimental design. Pre-operative data relating to each subject’s unilateral and bilateral speech perception ability, unaided audiometric thresholds, detailed hearing history and demographics were obtained from review of hospital medical files, direct questions to subjects and through clinical
measurement. Post-operative assessment was conducted after 12 months of cochlear implant use, both for unilateral (cochlear implant alone) speech recognition in quiet, and for bilateral speech recognition in quiet and for SRT measures in noise. All bilateral speech recognition data were obtained in the best-aided condition at each of the pre- and post-operative time points. The pre-operative best-aided condition comprised bilateral amplification where that was possible and able to be utilised by an individual participant. For 75% of the subject group, the best-aided pre-operative testing was conducted with bilateral hearing aids. Post-operative assessment was conducted using bimodal devices or, where applicable, the cochlear implant sound processor in combination with natural hearing.

For the unilateral testing the contralateral ear was masked using continuous speech weighted noise presented at 65 dB SPL RMS. The noise was presented via an insert earphone connected to a portable audio device. For unilateral testing the aided responses in subjects who were using CROS aids or the Baha soft-band device for bilateral testing, were obtained using the unilateral, implanted ear alone condition.

*Speech Perception Test Materials and Procedures*

All test materials were digitally recorded and sound files were presented in a sound booth via speakers in the free-field. Open-set monosyllabic words were presented in quiet in both the unilateral (ear to be implanted or cochlear implant alone) and bilateral listening conditions. Words were presented free-field at a level of 65 dB SPL RMS, and were based on the original CNC words developed by Peterson and Lehiste (1962). Two lists of words were presented via a loudspeaker located directly in front of the listener at each of the pre- and post-operative time points for each subject. Adaptive SRT in noise was also measured in the bilateral condition using the AuSTIN test (Dawson *et al.*, 2011). Two lists of sentences were administered after a training list was presented to each subject. The adaptive test used BKB-like open-set sentences and provided the SNR for 50% intelligibility at the pre- and post-operative time points. The eighty lists of sentences, each comprising 16 sentences, were constructed in accordance with guidelines used in the development of the original BKB sentences (Bench *et al.*, 1979). The sentence presentation level was fixed at 65 dB SPL RMS. Both the target sentence and the noise were presented from directly in front of the listener. The words were spoken by a male
and the sentences by a female. The competing babble consisted of two male and two female interferers speaking meaningful continuous discourse.

The noise level was adapted during test administration using the HINT scoring method (Nilsson et al., 1994). The method used a step size of 4 dB for the initial four sentences, and a 2 dB step size for the remaining 28 sentences. The fifth sentence was presented at the mean of the SNRs of the first four sentences and the SNR at which the fifth sentence would have been presented on the basis of the response to the fourth sentence. The level of the competing noise was adjusted by a software program, according to the subject’s responses. The noise level increased when the subject responded with greater than or equal to 50% of morphemes correct, and decreased when the subject failed to repeat 50% of morphemes correctly in the sentence. The SRT was calculated as the average of the signal-to-noise ratios for sentences 5 to 32 and also the signal-to-noise ratio at which sentence 33 would have been presented on the basis of the subject’s response to sentence 32. All competing noise was presented continuously. A beep was presented prior to each sentence within the adaptive test to alert the subject to the onset of the presentation interval.

Explanatory Variables

The demographic variables examined as correlates with each of the post-operative measures were: 1) age at implantation; 2) duration of bilateral hearing loss; 3) duration of implanted ear hearing loss; 4) PTA unaided thresholds in the implanted ear; and 5) PTA unaided thresholds in the contralateral ear. Correlation coefficients and p-values computed for each of the pairs of explanatory variables are shown in Table 7.
Table 7: Correlation coefficients (r) and p-value for pairs of explanatory variables included in the analysis. Significant correlations between explanatory variables (p<0.05) are indicated in bold font.

<table>
<thead>
<tr>
<th>Explanatory Variable Pairs</th>
<th>r</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age – Duration Bilateral SPHL</td>
<td>0.193</td>
<td>0.124</td>
</tr>
<tr>
<td>Age – Duration Implanted Ear SPHL</td>
<td>0.121</td>
<td>0.338</td>
</tr>
<tr>
<td>Age – PTA Implanted Ear</td>
<td>-0.193</td>
<td>0.124</td>
</tr>
<tr>
<td>Age – PTA Contralateral Ear</td>
<td>0.210</td>
<td>0.093</td>
</tr>
<tr>
<td>Duration Bilateral SPHL – Duration Implanted Ear SPHL</td>
<td>0.353</td>
<td><strong>0.004</strong></td>
</tr>
<tr>
<td>Duration Bilateral SPHL – PTA Implanted Ear</td>
<td>0.032</td>
<td>0.802</td>
</tr>
<tr>
<td>Duration Bilateral SPHL – PTA Contralateral Ear</td>
<td>0.457</td>
<td><strong>&lt; 0.001</strong></td>
</tr>
<tr>
<td>Duration Implanted Ear SPHL – PTA Implanted Ear</td>
<td>0.312</td>
<td><strong>0.011</strong></td>
</tr>
<tr>
<td>Duration Implanted Ear SPHL – PTA Contralateral Ear</td>
<td>0.118</td>
<td>0.349</td>
</tr>
<tr>
<td>PTA Implanted Ear – PTA Contralateral Ear</td>
<td>0.014</td>
<td>0.915</td>
</tr>
</tbody>
</table>

The explanatory variables representing the degree of pre-operative functional hearing in each of the implanted ear and contralateral ear were the PTA unaided thresholds, rather than pre-operative speech perception measures. The rationale for use of PTA thresholds was that the measure is a globally standardised audiometric technique and so not impacted by factors such as varying difficulty of speech perception test materials. Pre-operative word score and PTA in the ear selected for implantation were correlated (r= -0.548, p<0.001), as were those variables pertaining to the contralateral ear (r= -0.733, p<0.001). As a result, it was not possible to include both factors in the multiple regression analyses. Although the data for the model that included PTA as explanatory variables is presented in detail throughout the manuscript, reference is made to the effect on the model where the pre-operative implanted and contralateral word scores were used rather than the PTA values.

Duration of hearing loss was examined for two degrees of loss; initially for the degree of severe-to-profound loss, and subsequently for the duration of any hearing loss. Duration of any hearing loss was estimated based on hearing history and subjective reports as to the time from which hearing loss was first noticed and was deemed to have first impacted hearing ability. Duration of severe-to-profound hearing loss was estimated based on the
period of time for which the subject could not use the aided hearing alone to communicate without lip-reading. Combined with the information obtained via hearing history, severe-to-profound hearing loss was defined as having a three-frequency PTA exceeding 70 dB HL (using frequencies 0.5, 1 and 2 kHz). For data pertaining to bilateral severe-to-profound hearing loss, subjects were required to have a PTA unaided threshold of greater than 70 dB HL in both ears; for duration of loss associated with the implanted ear the criterion was applied to the single ear pre-operatively. For over 50% of the subjects enrolled in the study (35 of the 65 subjects), the contralateral ear median unaided threshold was better than 70 dB HL, so the duration of severe-to-profound bilateral hearing loss for those subjects was zero.

6.4 Results

6.4.1 Factors Predicting Unilateral (Implanted Ear Alone) Speech Recognition

Best-subsets regression analysis was used to determine which of the explanatory variables should be included in a multiple linear regression model. The post-operative unilateral word recognition scores were not normally distributed, so results were transformed using arcsine square root transformation. Transformation resulted in data being normally distributed. Analysis was performed using Minitab version 16. The first analysis was conducted with duration of severe-to-profound loss as the ‘duration’ factor, as compared to the duration of any clinically noticeable hearing loss. Evaluation of residuals revealed normality, linearity and homoscedasticity. The best-fit model included two factors which were the duration of severe-to-profound hearing loss in the implanted ear and the PTA thresholds in the contralateral ear. Those factors together accounted for 34.1% of the variance in post-operative unilateral scores. Results of the multiple linear regression analysis for those factors are outlined in Table 8. The model was selected based on determination of balance between the variance accounted for by inclusion of each of the explanatory variables and the smallest Mallows Cp value. The relatively small Mallows Cp value (4.5) indicated that the model was precise in estimating the true regression coefficients and predicting future responses. The Variance Inflation Factor was also examined to ensure that there was not an issue within the model of multi-collinearity between predictor variables.
Table 8: Predictive model statistics and regression coefficients for the dependent variable unilateral word scores in quiet

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient</th>
<th>SE Coefficient</th>
<th>95% CI</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>0.587</td>
<td>0.098</td>
<td>0.390, 0.784</td>
<td>5.97</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Duration SPHL Implanted Ear (Yrs)</td>
<td>-0.012</td>
<td>0.003</td>
<td>-0.018, -0.007</td>
<td>-4.49</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PTA Contralateral Ear (dB HL)</td>
<td>0.006</td>
<td>0.001</td>
<td>0.003, 0.009</td>
<td>4.37</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Overall Model**: F Statistic 17.6, p<0.001, R^2 0.36, Adjusted R^2 0.341, Mallows Cp 4.5
Scatterplots indicating the relationship between the explanatory variables and unilateral word scores are shown in Figure 27. Higher post-operative unilateral word scores were obtained for subjects with a shorter duration of severe-to-profound hearing loss in the implanted ear and poorer PTA contralateral unaided audiometric thresholds. In the regression analysis pertaining to the duration of severe-to-profound hearing loss in the implanted ear, the removal of the data for three subjects with greater than or equal to 30 years of severe-to-profound hearing loss resulted in a lack of correlation between the explanatory and dependent variable. Those data points are shown as open circles in the left panel of Figure 1, and the regression line is dashed to indicate the reliance on those data points for the significant finding.

Additional analyses were conducted to investigate whether there was an influence of explanatory variables not examined within the initial model. Repeat of the best subset regression analysis with duration of clinically noticeable hearing loss rather than duration of severe-to-profound hearing loss revealed that duration of both bilateral and implanted ear alone hearing loss (not specifically of severe-to-profound degree) were not significant factors in predicting outcomes. Analysis using the speech perception rather than the PTA-based explanatory variables revealed that 27% of the variance was explained by the same factors as for the PTA-based model.
Figure 24: Scatterplots showing correlation between each of duration of severe-to-profound hearing loss in the implanted ear (left panel) and contralateral PTA unaided audiometric threshold (right panel), with the arcsine transformed unilateral word recognition scores obtained in quiet. Analysis that excluded the data points shown as open circles in the left panel (subjects with longer than 30 years duration of severe-to-profound hearing impairment in the implanted ear) resulted in lack of correlation between the explanatory and dependent variable. The dashed regression line has been used to indicate that the reported correlation was dependent on inclusion of those three data points.
6.4.2 Factors Predicting Bilateral Speech Recognition

As for the analysis of unilateral data, best-subsets regression analysis was used to determine the best fit model for the bilateral word in quiet and sentence in noise data. The bilateral word in quiet score was arcsine transformed to achieve a normal distribution. Data was obtained for 58 subjects on the SRT in noise test. SRT data was not quite normally distributed due to values obtained for the two poorest performing subjects. Removal of data for those subjects did not change the influence of explanatory variables nor significantly the degree of variance accounted for by the model. As a result, the full dataset was included in the analysis.

The explanatory variables of duration of severe-to-profound hearing loss in the implanted ear, PTA unaided thresholds in the contralateral ear, and age at implantation were identified as predictive factors in the bilateral data analysis. Those factors together accounted for 36.0% and 30.9% of the variance in bilateral post-operative word in quiet scores and SRT values in noise respectively. Examination of residuals revealed normality, linearity and homoscedasticity between the predicted dependent variable scores and errors of prediction.

Results of the multiple linear regression analysis relating to dependent variables of word in quiet scores and SRT values in noise are shown in Table 9. Figure 28 shows scatterplots revealing the significant correlation between the explanatory variables and the bilateral word score. It can be seen that higher post-operative bilateral word scores were obtained in subjects with a shorter duration of severe-to-profound hearing loss in the implanted ear, a better unaided audiometric PTA threshold in the contralateral ear, and a lower age at implantation. Contrary to the observation that removing the data for the three subjects with greater than 30 years of severe-to-profound hearing loss resulted in lack of correlation between the explanatory and dependent variable for the unilateral analysis, removal of those subjects for the bilateral data analysis strengthened the correlation between the variables. The correlation coefficients were -0.386 (p=0.002) and -0.473 (p<0.001) for the complete and reduced datasets respectively.

Figure 29 shows results for the sentence in noise dependent variable. A more negative signal-to-noise ratio (shown as higher on the graph) indicates better performance. The adaptive test provides an ability to examine the performance level without influence of
ceiling effects which were observed on the word in quiet test. For the bilateral sentence in noise evaluation, removal of the data points for subjects with more than 30 years duration of severe-to-profound hearing loss in the implanted ear resulted in lack of correlation between the examined variables. As for the bilateral monosyllabic word in quiet scores, better post-operative bilateral SRT values were obtained for subjects with a lower age at implantation, better unaided audiometric PTA threshold in the contralateral ear, and a shorter duration of severe-to-profound hearing loss in the implanted ear. Analysis using the speech perception rather than the PTA-based explanatory variables revealed that the best-fit model comprised the same factors, which together accounted for 47% and 37.5% of the variance in bilateral word score in quiet and SRT in noise respectively.
Table 9: Predictive model statistics and regression coefficients for the dependent variables bilateral word scores obtained in quiet and SRT in babble

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient</th>
<th>SE Coefficient</th>
<th>95% CI</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>1.17</td>
<td>0.1370</td>
<td>1.437, 1.986</td>
<td>12.47</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Duration SPHL Implanted Ear (Yrs)</td>
<td>-0.007</td>
<td>0.002</td>
<td>-0.011, -0.003</td>
<td>-3.51</td>
<td>0.001</td>
</tr>
<tr>
<td>PTA Contralateral Ear (dB HL)</td>
<td>-0.004</td>
<td>0.001</td>
<td>-0.006, -0.002</td>
<td>-3.46</td>
<td>0.001</td>
</tr>
<tr>
<td>Age at Implantation (Yrs)</td>
<td>-0.004</td>
<td>0.002</td>
<td>-0.009, 0.00005</td>
<td>-2.23</td>
<td>0.029</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient</th>
<th>SE Coefficient</th>
<th>95% CI</th>
<th>t</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>-2.173</td>
<td>2.210</td>
<td>-6.603, 2.258</td>
<td>-0.98</td>
<td>0.330</td>
</tr>
<tr>
<td>Duration SPHL Implanted Ear (Yrs)</td>
<td>0.056</td>
<td>0.028</td>
<td>0.001, 0.111</td>
<td>2.04</td>
<td>0.046</td>
</tr>
<tr>
<td>Word Score Contralateral Ear (%)</td>
<td>-0.041</td>
<td>0.012</td>
<td>-0.066, -0.015</td>
<td>03.21</td>
<td>0.002</td>
</tr>
<tr>
<td>Age at Implantation (Yrs)</td>
<td>0.091</td>
<td>0.030</td>
<td>0.032, 0.151</td>
<td>3.07</td>
<td>0.003</td>
</tr>
</tbody>
</table>
Figure 25: Scatterplots showing correlation between contralateral PTA unaided audiometric threshold (top left panel), duration of severe-to-profound hearing loss in the implanted ear (top right panel) and age at implantation (bottom left panel) with bilateral word recognition scores obtained in quiet.
Figure 26: Scatterplots showing correlation between age at implantation (top left panel), contralateral PTA unaided audiometric threshold (top right panel) and duration of severe-to-profound hearing loss in the implanted ear (bottom left panel) with bilateral SRT in noise values.
A range of pre-operative factors were examined as predictors of clinical outcomes in the current study. Key differences from prior studies were: 1) the enrollment of a subject population with more substantial levels of pre-operative acoustic hearing in one or both ears than has been previously examined; and 2) the examination of factors that predicted both unilateral and bilateral post-implantation performance and benefit. Understanding the factors of greatest importance to predicting post-implantation experience would be beneficial in the clinical setting, since there is currently limited information on which to provide guidance to candidates with greater levels of residual hearing regarding expectations and risks.

Examination of explanatory variables predictive of unilateral speech recognition scores factors revealed some key differences compared to prior studies. First, in contrast to a number of prior studies (Gantz et al., 1988; Blamey et al., 1992; Battmer et al., 1995; Waltzman et al., 1995; Dowell et al., 2004; Green et al., 2007; Roditi et al., 2009; Blamey et al., 2013; Holden et al., 2013), age at implantation was not found to be significantly correlated with post-operative unilateral word recognition. It was hypothesised that the lack of correlation between age at implantation and post-implantation unilateral word scores might have been due to an inter-relationship between that factor and the duration of severe-to-profound hearing loss in the implanted ear, which was identified as a significant predictor in the current defined model. However, there was no correlation between age at implantation and duration of severe-to-profound implanted-ear hearing loss in the population examined in the current study. Another potential explanation for the lack of correlation of age at implantation as a predictive factor in this group may be the more limited age range of the examined subjects as compared to prior studies. In the current study, the age at implantation ranged from 27 to 81 years, with a mean of 62.6 years and a standard deviation of 11.6 years. The subject groups examined within the most recent prior research (Roditi et al., 2009; Lazard et al., 2012; Holden et al., 2013) had a similar age range but slightly larger standard deviation (range 15.3 to 17.3 years).

A second key observation from the current study was the lack of correlation between duration of bilateral hearing loss and post-implantation speech recognition. That factor has been identified as a significant predictor of unilateral word recognition in prior studies.
(Roditi et al., 2009; Lazard et al., 2012). Similarly, duration of bilateral severe-to-profound hearing loss was not a significant predictor in the current study, in contrast to previously reported research (Gantz et al., 1988; Kileny et al., 1991; Blamey et al., 1992; Waltzman et al., 1995; Blamey et al., 1996b; Rubinstein et al., 1999; Gomaa et al., 2003; Dowell et al., 2004; Leung et al., 2005; Green et al., 2007; Blamey et al., 2013; Holden et al., 2013). This is not surprising however, given that most subjects in the current study had hearing in at least one ear pre-operatively.

The finding that a shorter duration of severe-to-profound hearing impairment in the implanted ear was correlated with higher post-operative unilateral word scores is somewhat contrary to the hypothesis that unilateral auditory deprivation is not important when input to the central system is maintained through contralateral hearing (Francis et al., 2004; Roditi et al., 2009; Boisvert et al., 2011; Boisvert et al., 2012a; Boisvert et al., 2012b). Since the three data points for subjects with greater than 30 years duration of severe-to-profound hearing loss in the implanted ear drive the slope of the correlation, data were analysed with those three subjects’ data removed. In the analysis for the unilateral word scores and bilateral SRT the removal of the data points for those subjects resulted in a lack of correlation between the explanatory and dependent variables. However, for the bilateral word score analysis the removal of those data points strengthened the correlation between duration of severe-to-profound hearing loss and word scores in quiet. Each of those three subjects did not have any measurable pre-operative hearing thresholds in the implanted ear, and so may have had poor spiral ganglion cell survival that could have resulted in compromised outcomes with electrical stimulation in the unilateral listening condition. Further investigation as to the influence of long-term auditory deprivation in the implanted ear on unilateral speech recognition outcomes would be warranted based on that observation. With an increasing number of candidates being implanted who have substantial acoustic hearing in the contralateral ear, it is likely that the influence of duration of loss on the implanted side will be better understood in time.

Similar to the majority of recent published data (Green et al., 2007; Gifford et al., 2010; Lazard et al., 2012), there was no significant correlation in the current study between implanted ear pre-operative hearing thresholds and unilateral post-operative speech recognition. However, poorer scores were obtained for subjects with better contralateral
PTA hearing thresholds. This finding differs from that reported by Lazard et al. (2012), where higher post-operative word scores were obtained for subjects with better contralateral ear hearing thresholds, although the authors cautioned that subject numbers in that analysis were too low to be conclusive. Poorer unilateral word scores with the implanted ear for subjects with better contralateral hearing is not consistent with the hypothesis that maintenance of central auditory pathways as a result of auditory input would result in improved speech recognition after implantation (Boisvert et al., 2011; Boisvert et al., 2012b). A possible reason for the lower unilateral word scores using the cochlear implant alone could be due to recipients with greater levels of contralateral acoustic hearing relying more on that information as the primary salient signal. Such reliance on acoustic contralateral hearing may result in less attention being given to the electrical signal and so affect the unilateral speech perception outcomes. The finding has an important implication in the clinical setting, in that assessment of performance in the unilateral condition may underestimate the actual benefit provided by the combination of acoustic and electric stimulation. Additionally, further research is warranted to examine whether specific cochlear implant alone rehabilitation or auditory training might be beneficial during the post-operative period.

Another important consideration in the clinical setting is that performance with one ear is unlikely to accurately predict outcomes with two ears. If the contralateral ear performs much better than the implanted ear, for example, outcomes with the cochlear implant may be largely irrelevant. In addition, if the implant signal and contralateral acoustic signal provide complementary information, then even measuring both ears separately cannot accurately predict outcomes for bilateral (bimodal) device use. It is also possible that binaural benefits might arise in the combined case. It is likely most important when setting candidate expectations to consider the factors predictive of bilateral as compared to unilateral speech recognition. Such discussion of expected bilateral outcomes would be more relevant to a candidate’s real-world functional performance. Also, the development of a bilateral outcome prediction model would enable clinicians to track an individual’s progress over time and examine whether performance is meeting expectations, without potential influence of lack of familiarity in the unilateral listening condition on outcome measures.
Factors that best predicted bilateral speech recognition were the same for the outcome measures administered in quiet or noise. As expected, subjects with better contralateral-ear unaided audiometric thresholds tended to obtain better results on both metrics. The higher speech recognition scores in those situations would be expected as a result of the more substantial contribution provided to the bilateral listening condition by the acoustic contralateral hearing. Although the word in quiet measure is likely impacted by the influence of ceiling effects, the SRT in noise metric is adaptive in nature and so more robust to that potential issue. Although there is only limited published data describing factors important in predicting bilateral outcomes, pre-operative bilateral word score has been reported to be predictive of post-operative outcomes (Gantz et al., 2009; Amoodi et al., 2012). That factor, combined with duration of hearing loss, accounted for 29% of the variance in outcome for 68 Hybrid recipients. However, it is not clear from the published manuscript whether the demographic factor of duration of hearing loss reflected unilateral or bilateral deafness. In the current study there was a significant correlation between the implanted and contralateral ear pure-tone-average thresholds and the corresponding word scores, and so the threshold values were used in the analysis. Use of threshold values as compared to pre-operative word scores would be expected to provide benefit in a global clinical setting, in that the findings could be applied without complexity associated with regional variability in speech perception test materials. Although not explicitly identified as a predictive factor in the best-fit model of Gantz et al. (2009), a lower age at implantation was also reported to be a positive predictor of speech recognition with the Hybrid implant. That finding is also consistent with that observed in the current study.

There are a number of important considerations related to potential application of an outcome prediction model in the clinical setting. First, it is of interest to consider the potential advantages and disadvantages of each of the unilateral and bilateral model approaches. A model that predicted unilateral outcomes would likely be more easily applied clinically, in that outcomes could be predicted for the cochlear implant alone without consideration of the influence of the contralateral acoustic device as a potential source of additional variability. However, it is likely of most relevance to a candidate to discuss the expected outcome in the bilateral condition. In applying a model that predicts an absolute measure of bilateral outcome, it would be important to discuss with a candidate their current pre-operative bilateral performance on any particular measure, and
the expected change post-implantation. Without consideration as to the pre-operative bilateral auditory function in this type of candidate with substantial degrees of pre-operative residual hearing, the predicted post-implantation score would not be clinically meaningful. A second important consideration, in line with prior published research, is that there remains a significant proportion of the variance in outcomes that cannot be accounted for by the factors examined within the current study. Further research would be warranted to understand the factors predictive of post-operative bilateral outcomes, given the limited information currently available to provide guidance and set post-operative expectations for candidates.

In addition to improving the quality of the information provided to candidates during pre-operative discussion, there would also be other advantages arising from improving the ability to predict post-operative outcomes. Monitoring outcomes against those ‘expected’ may in the future provide an opportunity to better allocate limited clinical resources, and identify those recipients who require more extensive post-operative support. Identification of the factors that may contribute to poorer performance may also lead to opportunities to better address those factors through modification to technology or to more individualised approaches to device fitting and rehabilitation.

6.6 Conclusions

Factors most important in predicting unilateral and bilateral outcomes have been identified for candidates with substantial levels of acoustic hearing in one or both ears presenting at cochlear implant centres. The predictive models identified within the current study accounted for 34.1% and 36.0% of the variance in unilateral and bilateral post-implantation word recognition scores obtained in quiet and 30.9% of the variance for bilateral SRT in babble. A shorter duration of severe-to-profound hearing loss in the implanted ear was shown to be predictive of better unilateral and bilateral outcomes. However, further research is warranted to better understand the impact of that factor in a larger number of subjects with long-term hearing impairment of greater than 30 years. Listeners with better contralateral hearing were shown to obtain better bilateral outcomes, however they also benefited less from implantation. The poorer unilateral outcomes in the listeners with better contralateral performance may have contributed to the reduced benefit in those listeners compared to listeners with poorer contralateral hearing.
The findings from the study indicate that different models apply to predicting unilateral and bilateral post-implantation speech recognition scores. Although a unilateral model may be more easily applied clinically, such a model may underestimate the post-implantation benefit that is provided through integration of the acoustic and electric modalities. Use of a bilateral outcome prediction model would likely be more clinically relevant. However, when applying such a model in the clinical setting, it would be important to present expected post-implantation performance with reference to pre-operative scores to indicate the likely degree of improvement post-implantation.
7 Influence on Speech Recognition of Match Between Frequency Assignment to Electrodes in the Sound Processor and the Electrical Place-Pitch Percept

7.1 Abstract

Examined was the effect on clinical performance of alignment between the centre frequency of the acoustic analysis input frequency assigned to the most apical channel in the sound processor, and the frequency corresponding to the electrical pitch percept on that electrode (referred to as the ‘frequency-pitch match’ in this manuscript). Electrical pitch estimates were obtained using magnitude estimation of five pure tones and five 900 Hz electrical pulse trains. Degree of match between the initial (pre-activation) pitch percept and the assigned acoustic input frequency affected rate of post-operative improvement in the unilateral (cochlear implant alone) but not bimodal device configuration in 25 subjects. Post-experience measures of electrical pitch perception in 37 subjects revealed higher unilateral speech recognition scores in both quiet and noise for those subjects with closer match between acoustic input frequency and electrical pitch percept. No significant correlation was observed between degree of match and bilateral speech recognition ability.

7.2 Introduction

Mapping of acoustic input frequency to electrodes in multi-channel cochlear implants is configured via clinical programming software, and not typically adjusted from the clinically recommended default settings. In Nucleus® cochlear implant sound processors the Fast Fourier Transform (FFT) bins are combined to give an approximation to the critical band spacing of human hearing as determined by Zwicker in 1972, with linear spacing at the apex and logarithmic spacing towards the basal end of the cochlear. Acoustic analysis frequencies ranging from 188 Hz to 7938 Hz are assigned to the 22 intracochlear electrodes, with the frequency range 188 Hz to 313 Hz assigned to the most apically located electrode.

Insertion angle of the most apical electrode varies according to a number of factors, including cochlear size, medial location within the scale tympani, and electrode design. In prior studies that have assessed the electrical pitch percept obtained with stimulation
on intracochlear electrodes, the most typical insertion angle has been reported as approximately 450 degrees (Blamey et al., 1996b; Boex et al., 2006; McDermott et al., 2009), although pitch perception for deeper insertion angles of up to 680 degrees has also been reported (Baumann and Nobbe, 2006; Boex et al., 2006). The expected pitch percept for an electrode with an insertion angle of 450 degrees would be 550 Hz, based on the Kawano et al. (1996) adaptation of Greenwood’s model of the frequency along the organ of Corti (Greenwood, 1990). Stimulation of a more basally located electrode with insertion angle of 360 degrees would be expected to result in a higher pitch percept of 979 Hz. Use of the default acoustic analysis frequency range, without compensation based on insertion angle, would typically result in an increasingly compressive effect with more shallow insertion.

Although it might be expected that the electrical pitch percept could be predicted from the insertion angle of the electrode (Greenwood, 1990; Stakhovskaya et al., 2007), and such information could be used to customise an individual’s optimal frequency allocation, there are a number of reasons why that is not typically possible. First, high quality radiology and resources to calculate the insertion angle are not often available within implanting clinics to enable such a customised mapping approach. The second and likely more important reason is that electrical pitch percepts have been reported to vary from the model-based predictions, with deviation attributed to factors such as the degree of hearing in the contralateral ear (Vermeire et al., 2008; Carlyon et al., 2010), the degree of hearing in the implanted ear (Plant et al., 2014a) and the effect of listening experience (Reiss et al., 2007; McDermott et al., 2009; Reiss et al., 2014).

There are varied findings in the literature as to whether the electrical pitch percept adapts over time to converge to the assigned acoustic input frequency range, with substantial individual variability (Reiss et al, 2007, Reiss et al, 2014) and lack of evidence of convergence in some studies (Carlyon et al., 2010; Plant et al., 2014a; Reiss et al., 2015). Simulations in normal hearing listeners (Rosen et al 1999; Fu et al, 2002) have also shown that only partial adaptation to substantial spectral shifts might occur. Adaptation towards the assigned frequency range has been reported to occur in hybrid (Reiss et al., 2007) but not bimodal listeners (Reiss et al., 2015). It has been hypothesised by Reiss et al. (2015) that adaptation might be more likely to occur in listeners with better contralateral
thresholds since there is more likely to be perceptual mismatch between acoustic and electrical stimulation in those listeners.

Given the range of variables likely to impact the electrical pitch percept that arises from intracochlear stimulation, and the variation in insertion angle that occurs across individuals and electrode types (Wanna et al., 2015), it would be expected that there would be instances where there is a degree of mismatch between the frequency that is assigned to a given electrode and the electrical place-pitch percept that arises from stimulation.

Considerable research has been conducted to understand the impact of distortion in the frequency-to-place mapping on speech recognition. In vocoder simulations with normal hearing listeners, significant reduction in speech recognition has been reported in response to acoustic input frequencies being compressed toward high frequencies (Baskent, 2003), expanded (Baskent and Shannon, 2003), shifted (Dorman et al., 1997; Fu and Shannon, 1999) or warped using a logarithmic or exponential transformation (Shannon et al., 1998). Similar findings have been observed in acute experiments with experienced cochlear implant recipients, with up to 4mm compression and expansion applied across six electrodes in six users of the Med-El Combi 40+ (Baskent and Shannon, 2004).

However, there is more limited published information describing the impact of frequency-place mismatch on post-implantation outcomes after an extended period of device use, which would avoid the potential confounding factor in acute experiments of bias towards the assignment used in the clinical setting. Di Nardo et al. (2010) reported significant correlation between sentence recognition scores in both quiet and noise and the degree of offset between the frequency assigned to an electrode and the best-matched electrode. Data in that study were collected in seven subjects with a minimum of six months of cochlear implant experience. Reiss et al. (2015) categorised 19 subjects according to the pattern of change that occurred in the first 12 months of cochlear implant use, with categories of pitch-adapting, pitch-dropping and pitch-unchanging. There was a tendency, albeit not significant, for subjects with a pitch-adapting or pitch-unchanging profile to exhibit the expected increase in unilateral word recognition scores in quiet,
whereas those subjects with a pitch-dropping pattern tended to exhibit a drop in scores over time.

The current study aimed to examine a number of research questions relating to the impact of frequency-pitch match on clinical performance, in a larger cohort of subjects than has been previously examined, and including both the unilateral and bilateral (bimodal) listening configurations. First, it was of interest to examine whether the initial (pre-experience) degree of frequency-pitch match influenced the rate of adaptation to the cochlear implant in the post-operative period. It was hypothesised that closer frequency-pitch match would improve an individual’s ability to integrate acoustic and electric signals and result in a more rapid post-operative improvement. Second, the effect of frequency-pitch match after a minimum of 12 months of cochlear implant experience would be examined, to assess whether the degree of mismatch negatively affected speech recognition. Although the impact of frequency-pitch mismatch has been demonstrated in a number of studies using acute, vocoder-based experiments in normal hearing listeners, there has been relatively little published information related to impact of mismatch in cochlear implant recipients. Additionally, research to date has involved assessment of the unilateral, cochlear-implant alone performance, without examination of the effect of frequency-pitch match on bimodal function. Consideration of the effect of frequency-pitch on speech recognition in the bimodal condition is relevant in that it more accurately reflects real-world function and may be more sensitive to mismatch due to potential for conflicting cues being presented across the two ears.

7.3 Materials and Methods

Subjects

Thirty-seven postlinguistic hearing-impaired adults participated in the study. All were implanted with Nucleus cochlear implants (Contour Advance, Slim Straight or Hybrid-L24). The age of the subjects at the time of enrolment ranged from 42 years to 81 years, with a mean age of 64.6 years. Twenty-five subjects were evaluated using a longitudinal study design from the time just prior to initial activation of the cochlear implant to 12 months post-activation. Demographic information for those subjects is shown in Table 10. Shown in the table is information relating to each subjects’ gender, age at the time of implantation, aetiology of hearing impairment, duration of severe-to-profound hearing
impairment, median low (0.125 to 1 kHz) and high (1-4 kHz) frequency unaided audiometric hearing thresholds and electrode type. An additional twelve subjects were evaluated at a single time point after a minimum of 12 months experience with the cochlear implant. Demographic information for the twelve additional subjects is shown in Table 11.

**Study Design**

Electrical pitch perception for the twenty-five subjects was measured using a magnitude estimation procedure just prior to initial cochlear implant activation, before any adaptation might have occurred as a result of the mapping of acoustic analysis bands to electrodes in the sound processor. The acoustic frequency corresponding to the pitch percept obtained with stimulation on the most apical electrode was calculated, and compared to the acoustic analysis frequency assigned to that electrode within the sound processor. Those data were used for the analysis of the effect of the initial (pre-activation) degree of frequency-pitch match on the post-activation rate of change in monosyllabic word recognition scores in quiet. Data from the additional twelve experienced subjects was collected using the same magnitude estimation procedure after a minimum of 12-months of cochlear implant experience. The combined dataset from the 37 subjects was used to examine the extent to which the degree of post-experience frequency-pitch match was correlated with speech recognition scores.

**Pitch Estimation Procedure**

Pitch estimation measures were obtained using a magnitude estimation procedure. Stimuli consisting of five acoustic pure tones and five single-electrode pulse trains were delivered via custom software and a custom interface box. All tones were of 500 msec duration and had 30 msec linear amplitude tapers applied at the onset and offset. Acoustic tones were presented via a tube-phone to ear contralateral to the implanted side, and were either one-third or two-third octave pure tones spanning the frequencies at which each subject had acoustic hearing thresholds of better than 80 dB HL. Electric stimuli consisted of 900 Hz pulse trains of 500 msec duration, presented to single electrodes at the mid to apical end of the array. Stimulus pulse parameters used a stimulation mode of MP1+2, a pulse width of 25 µsec and an interphase gap of 8.4 µsec, consistent with default parameters used within the clinical Custom Sound programming software.
provided by Cochlear Limited. Typically the electrodes used for the pitch estimation task were 22 (most apical), 19, 16, 13 and 10.

All stimuli were initially loudness balanced using the highest frequency pure tone acoustic stimulus as the reference signal. The reference tone was set to an initial comfortable listening level. Repeated pairs of tones were then presented sequentially, and subjects were asked to adjust the loudness of the second tone to match that of the first presented tone. Adjustment was made using a toggle switch on the custom interface box. During the loudness balancing procedure the starting level of the test stimulus was randomly set to a high or soft level at each of the repeated balancing tasks to ensure accurate bracketing of the equal loudness level. This repeated loudness balancing was conducted until the level of the test stimulus was within acceptable criteria for two repeated loudness balancing tasks. Acceptable criteria were 2 dB SPL or 2 Current Levels for the acoustic and electric stimuli respectively.

Pitch of the loudness balanced signals was measured using a magnitude estimation psychophysical task. The reference tone was the highest frequency pure tone stimulus, and subjects were asked to assign the numerical value of 50 to that tone. Subjects were advised that each subsequent tone would need to be allocated a number, and that the numerical value assigned to describe the pitch of the stimulus would be relative to the reference signal. A stimulus with a pitch deemed twice as high as the reference signal would be allocated a number that was twice as high as the reference, i.e. 100 as compared to 50. A stimulus with a pitch perceived as being half the pitch of the reference would be allocated a number that was half that of the reference signal, i.e. 25. Subjects were encouraged to use a wide number range if appropriate, and advised not to limit at the upper end based on an arbitrary range, i.e. not to limit the numerical estimate to 100 unless this provided a true indication of the pitch of the stimulus. The range of ten stimuli was presented sequentially 2-3 times prior to commencement of the pitch estimation task, to enable familiarisation with the range of sounds to be included in the pitch estimation procedure. During the pitch estimation task a single-interval procedure was used, with each stimulus presented individually ten times in random order. Loudness jitter of +/- 2 dB was applied to the acoustic signal and of +/- 2 Current Level was applied to the electrical signal, to reduce any influence of loudness differences impacting the data.
Mean pitch estimates of the five acoustic and five electric pitch estimates were calculated and plotted as points on a scatterplot with frequency or electrode on the x-axis, and pitch estimates on the y-axes for the acoustic and electrical stimuli respectively. A linear regression line was fitted to the acoustic pitch measures, and the pitch estimate from the most apical electrode was obtained from reading from the acoustic regression line. More detailed information relating to the pitch estimation procedure is outlined in Plant et al. (2014a). The procedure has been shown to provide good test-retest reliability, to be seemingly unaffected by non-sensory bias and to be sensitive to measurement of electrical place-pitch percept.

Speech Recognition Measures

Test materials used for speech perception assessment were open-set monosyllabic words presented in quiet and open-set sentences presented in 4-talker babble. The monosyllabic words were based on the original CNC words developed by Peterson and Lehiste (1962), with fifty words per list and a consonant-nucleus-consonant structure. The sentences were based on those developed by the City University of New York (CUNY), with each list consisting of 12 sentences containing 102 words that are scored as percent correct (Boothroyd et al 1985). Two lists of words and two lists of sentences were presented at each of the pre-operative, 3, 6 and 12 month post-activation time points, with novel lists used for each test session. Testing in noise used a +10 dB signal-to-noise ratio. The evaluations were conducted in a sound-attenuated booth using recorded materials presented at a level of 65 dB SPL at the behind-the-ear microphone. All materials were presented from a loudspeaker located directly in front of the listener. Test measures were administered in both the unilateral (cochlear implant sound processor alone) and bilateral (cochlear implant sound processor in combination with the contralateral hearing aid) conditions.

Demographic Factors

A number of demographic factors were also assessed as potential correlates with each of the speech recognition outcome measures. Those were; a) the age at implantation, b) the duration of severe-to-profound hearing loss in the implanted ear, c) the pure-tone-averaged thresholds in the implanted ear, and d) the pure-tone-averaged (PTA) thresholds in the contralateral ear. Duration of severe-to-profound bilateral hearing loss was not
included as an explanatory variable in the analysis because the majority of subjects did not have that degree of hearing loss in the contralateral ear.

**Data Analysis:**

1) **Effect of Initial (Pre-Activation) Frequency-Pitch Match on Rate of Post-Implantation Improvement**

The time taken to reach 90% of the 12-month post-operative unilateral and bilateral word score was calculated for each of the 25 subjects. Subjects with a pre-operative bilateral word score of greater than 80% were excluded from that analysis since it was not possible to reliably measure post-operative improvement due to ceiling effects on the test measure. Those were subjects S39, S41, S42, S44, S45, S46, and S47, leaving a total of 18 subjects for whom data was analysed for the bilateral listening condition. Data for all subjects were analysed for the unilateral test condition, since there were no pre-operative scores within the range impacted by ceiling effects.

Subjects were categorised according to the time taken to reach the level of specified performance, with initial categorisation into one of two categories. The first category represented those subjects who reached the specified performance level within 3-6 months of initial device activation. The second represented those who took longer to reach the specified performance level, and had either reached that level by the 12-month post-activation time point or had not demonstrated significant improvement from pre-operative measures at that time. The acoustic frequency corresponding to the electrical pitch estimate obtained on the most apical electrode (electrode 22) was calculated for each individual subject, and the ratio between that pitch estimate and the centre frequency of the assigned acoustic analysis frequency used to define the degree of match.

**Effect of Post-Experience Pitch Match on Speech Recognition**

Pearson Product Moment correlation coefficients were computed to assess the relationship between the electrical pitch match and the unilateral and bilateral speech recognition measures in quiet and in noise.
Table 10: Subjects’ demographic information for those evaluated using the longitudinal study design. Included are age at the time of implantation (in years), gender, aetiology of hearing impairment, duration of severe-to-profound hearing loss (in years), median unaided low (0.125-1 kHz) and high (1-4 kHz) frequency audiometric thresholds (in dB HL), and type of electrode array.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age at Implant (yrs)</th>
<th>Aetiology</th>
<th>Duration severe-profound loss (yrs)</th>
<th>Median LF Unaided Threshold (dB HL)</th>
<th>Median HF Unaided Threshold (dB HL)</th>
<th>Electrode Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2</td>
<td>M</td>
<td>61</td>
<td>Unknown</td>
<td>Implanted 10, Contra 10</td>
<td>80 75</td>
<td>100 90</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S9</td>
<td>F</td>
<td>64</td>
<td>Otosclerosis</td>
<td>Implanted 15, Contra 0</td>
<td>85 80</td>
<td>75 80</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S13</td>
<td>M</td>
<td>58</td>
<td>RH incompatibility</td>
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<td>60 55</td>
<td>90 85</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S14</td>
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<td>Accident(I), Unknown (C)</td>
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<td>80 65</td>
<td>70 85</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S16</td>
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<td>63</td>
<td>Unknown</td>
<td>Implanted 15, Contra 16</td>
<td>70 70</td>
<td>90 90</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S25</td>
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<td>71</td>
<td>Unknown</td>
<td>Implanted 3, Contra 0</td>
<td>80 50</td>
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<td>Contour Advance</td>
</tr>
<tr>
<td>S27</td>
<td>F</td>
<td>52</td>
<td>Otosclerosis</td>
<td>Implanted 10, Contra 10</td>
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<td>125 95</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S28</td>
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<td>74</td>
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<td>125 75</td>
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</tr>
<tr>
<td>S32</td>
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<td>125 65</td>
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</tr>
<tr>
<td>S34</td>
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<td>125 70</td>
<td>Contour Advance</td>
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<td>S39</td>
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<tr>
<td>S41</td>
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<td>110 63</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S42</td>
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<td>75</td>
<td>Meniere’s disease</td>
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<td>65 70</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S44</td>
<td>M</td>
<td>64</td>
<td>Meniere’s disease</td>
<td>Implanted 4, Contra 0</td>
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<td>125 40</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S45</td>
<td>M</td>
<td>68</td>
<td>Trauma</td>
<td>Implanted 50, Contra 0</td>
<td>125 25</td>
<td>125 25</td>
<td>Contour Advance</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Subject (Cont.)</th>
<th>Gender</th>
<th>Age at Implant (yrs)</th>
<th>Aetiology</th>
<th>Duration severe-profound loss (yrs)</th>
<th>Median LF Unaided Threshold (dB HL)</th>
<th>Median HF Unaided Threshold (dB HL)</th>
<th>Electrode Type</th>
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<tbody>
<tr>
<td>S46</td>
<td>M</td>
<td>51</td>
<td>Meniere’s disease</td>
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<td>125/20</td>
<td>Contour Advance</td>
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<td>56</td>
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<td>125/0</td>
<td>Contour Advance</td>
</tr>
<tr>
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<td>110/110</td>
<td>Slim Straight</td>
</tr>
<tr>
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<td>35/35</td>
<td>110/115</td>
<td>Slim Straight</td>
</tr>
<tr>
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<td>74</td>
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<td>90/65</td>
<td>80/90</td>
<td>Contour Advance</td>
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<td>66</td>
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<td>0/0</td>
<td>75/55</td>
<td>120/115</td>
<td>Slim Straight</td>
</tr>
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<td>81</td>
<td>Noise Exposure</td>
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<td>85/65</td>
<td>125/90</td>
<td>Contour Advance</td>
</tr>
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<td>Hybrid-L24</td>
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<td>S64</td>
<td>M</td>
<td>72</td>
<td>Accident</td>
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<td>110/65</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S65</td>
<td>M</td>
<td>65</td>
<td>Meniere’s disease</td>
<td>10/15</td>
<td>100/65</td>
<td>90/70</td>
<td>Contour Advance</td>
</tr>
</tbody>
</table>
Table 11: Subjects’ demographic information for additional subjects evaluated after cochlear implant experience. Included are age at the time of implantation (in years), gender, aetiology of hearing impairment, duration of severe-to-profound hearing loss (in years), median unaided low (0.125-1 kHz) and high (1-4 kHz) frequency audiometric thresholds (in dB HL), and type of electrode array.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age at Implant (yrs)</th>
<th>Aetiology</th>
<th>Duration severe-profound loss (yrs)</th>
<th>Median LF Unaided Threshold (dB HL)</th>
<th>Median HF Unaided Threshold (dB HL)</th>
<th>Electrode Type</th>
</tr>
</thead>
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<tr>
<td>S3</td>
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<td>75</td>
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<td>S4</td>
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</tr>
<tr>
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<td>60</td>
<td>90</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S11</td>
<td>F</td>
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<td>70</td>
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</tr>
<tr>
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</tr>
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<td>64</td>
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<td>1</td>
<td>85</td>
<td>65</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S20</td>
<td>M</td>
<td>75</td>
<td>Ossicular Fixation</td>
<td>40</td>
<td>125</td>
<td>125</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S24</td>
<td>M</td>
<td>72</td>
<td>Unknown</td>
<td>10</td>
<td>55</td>
<td>125</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S31</td>
<td>F</td>
<td>76</td>
<td>Unknown</td>
<td>10</td>
<td>90</td>
<td>85</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S33</td>
<td>F</td>
<td>46</td>
<td>Unknown</td>
<td>5</td>
<td>125</td>
<td>115</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S58</td>
<td>F</td>
<td>72</td>
<td>Unknown</td>
<td>0</td>
<td>107.5</td>
<td>100</td>
<td>Contour Advance</td>
</tr>
<tr>
<td>S63</td>
<td>F</td>
<td>45</td>
<td>Measles/Mumps</td>
<td>15</td>
<td>65</td>
<td>105</td>
<td>Contour Advance</td>
</tr>
</tbody>
</table>
7.4 Results

7.4.1 Effect of Initial (Pre-Activation) Frequency-Pitch Match on Rate of Post-Implantation Improvement

In Figure 27 is shown group median data indicating the effect of the degree of frequency-pitch match on time taken to reach 90% of the 12-month post-activation bilateral and unilateral monosyllabic word score. In the left panel is shown the data for the bilateral scores, and in the right panel are the scores obtained when testing in the unilateral condition. Nine subjects reached the specified post-activation performance level within 3-6 months of device activation, and nine reached the 90% performance level at the 12-month time point or did not show significant improvement beyond the critical difference of the test measure. Analysis using the Mann-Whitney Rank Sum test indicated no significant effect of the degree of frequency-pitch mismatch on the time taken to obtain the specified level of post-operative performance in the bilateral listening condition (T=85, p=1.0). The group median pitch ratio was 1.8 for subjects reaching the post-operative performance level within 3-6 months, and was 1.9 for those subjects taking longer to reach the performance level or failing to benefit on the test measure after implantation.

In the right panel is shown the data for the unilateral scores. Analysis using the Mann-Whitney Rank Sum test indicated a significant effect of the degree of frequency-pitch match on the time taken to obtain the specified level of post-operative performance (T=192, p<0.001). The group of subjects reaching 90% of the monosyllabic word score within 3-6 months post-activation had a closer electrical pitch match ratio (with a median ratio of 1.3) as compared to those taking longer or failing to obtain post-operative benefit (with a median ratio of 2.5).
Figure 27: Boxplots showing time taken to reach 90% of the final (12-month+) word score in the bilateral (left panel) and unilateral (right panel) listening configurations. The ratio between the frequency corresponding to the electrical pitch percept on the most apical electrode and the allocated acoustic analysis frequency to that electrode in the sound processor is shown on the y-axis, and time represented on the x-axis. The dotted line shows the point at which the ratio between the measured pitch percept and allocated frequency were matched.

The same analysis was conducted for unilateral and bilateral sentence in noise scores, and is shown in Figure 28. Data were available for 24 subjects in the unilateral condition, with one subject not assessed at the 12-month time point on the sentence in noise measure. Data were available for 22 subjects in the bilateral condition after excluding subjects with a pre-operative score of greater than or equal to 80% and so in the region at which ceiling effects would be expected to impact the calculation. Group median analysis using the Mann-Whitney Rank Sum test indicated no significant effect of frequency-pitch match on the time taken to reach the 90% performance level in the bilateral condition (T=100, p=0.086). As for the unilateral testing in quiet, subjects reaching the specified level of performance more quickly on the sentence in noise test had significantly less frequency-pitch mismatch (T=111, p=0.026). The median ratio between the frequency corresponding to the electrical pitch percept and the assigned acoustic frequency was 1.5.
and 2.2 for the group reaching a high level of performance within 3-6 months as compared to the slower group respectively.

A number of pre-operative demographic factors that might have been expected to have impacted the rate of adaptation in the unilateral condition were examined as potential correlates with each of the outcome measures. Factors examined were age at implantation, duration of severe-to-profound hearing impairment in each ear, and median unaided audiometric low (0.125-1 kHz) and high (1-4 kHz) frequency thresholds in each ear. Mann-Whitney Rank-Sum analysis revealed no significant difference between the groups in the demographic factors of age at implantation, duration of severe-to-profound hearing loss in each ear and median unaided audiometric low and high frequency thresholds in each ear.

![Boxplots showing time taken to reach 90% of the final (12-month+) sentence in noise score in the bilateral (left panel) and unilateral (right panel) listening configurations. Ratio between the frequency corresponding to the electrical pitch percept on the most apical electrode and the allocated acoustic analysis frequency to that electrode in the sound processor is shown on the y-axis, and time on the x-axis. The dotted line shows the point at which the ratio between the measured pitch percept and allocated frequency were matched.](image)

**Figure 28:** Boxplots showing time taken to reach 90% of the final (12-month+) sentence in noise score in the bilateral (left panel) and unilateral (right panel) listening configurations. Ratio between the frequency corresponding to the electrical pitch percept on the most apical electrode and the allocated acoustic analysis frequency to that electrode in the sound processor is shown on the y-axis, and time on the x-axis. The dotted line shows the point at which the ratio between the measured pitch percept and allocated frequency were matched.
7.4.2 Effect of Post-Experience Frequency-Pitch Match on Speech Recognition

Bilateral Speech Recognition

No correlation was observed between the frequency-pitch match and bilateral speech recognition scores on each of the tests administered in quiet and in noise.

Unilateral (Cochlear Implant Alone) Speech Recognition

In the left panel of Figure 29 is shown the unilateral monosyllabic word score plotted as a function of the frequency-pitch match. In the right panel is shown the same plot but for the sentence in noise scores. Pearson Product Moment Correlation analyses revealed a significant correlation between the frequency-pitch match and monosyllabic word recognition ($r = -0.449$, $p=0.005$). Best subset regression analysis that included other explanatory variables revealed that both a poorer pure-tone-average threshold in the contralateral ear and a closer frequency-pitch match were significant predictors of a higher arcsine transformed unilateral word score. Those factors were shown to account for 44.8% of the adjusted variance in monosyllabic word score in quiet. Results of the multiple linear regression analysis are shown in Table 12. The relatively small Mallows Cp value indicated that the model was precise in estimating the true regression coefficients and predicting future responses.

A weak correlation was observed between the degree of frequency-pitch match and sentence in noise scores ($r = -0.336$, $p=0.049$). Subjects with a better frequency-pitch match tended to obtain a higher score on each of the speech perception test measures. However, when the effect of frequency-pitch match was examined within a multiple linear regression model the factor was not shown to be a significant predictor of sentence recognition score in babble; rather the influence of the contralateral ear hearing sensitivity and age at implantation were shown to be the most significant independent predictors on that measure. Results of the regression model are shown in Table 13 for the sentence in babble predictors.
Table 12: Predictive model statistics and regression coefficients for the dependent variable unilateral word scores in quiet

<table>
<thead>
<tr>
<th>Overall Model: F Statistic 10.8, p&lt;0.001, R² 0.478, Adjusted R² 0.448, Mallows Cp 3.2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regression Coefficients</strong></td>
</tr>
<tr>
<td>Variable</td>
</tr>
<tr>
<td>Constant</td>
</tr>
<tr>
<td>PTA Contralateral Ear (dB HL)</td>
</tr>
<tr>
<td>Frequency-Pitch Match Ratio</td>
</tr>
</tbody>
</table>

Table 13: Predictive model statistics and regression coefficients for the dependent variable unilateral sentence scores in babble

<table>
<thead>
<tr>
<th>Overall Model: F Statistic 6.16, p=0.006, R² 0.359, Adjusted R² 0.301, Mallows Cp 4.9</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regression Coefficients</strong></td>
</tr>
<tr>
<td>Variable</td>
</tr>
<tr>
<td>Constant</td>
</tr>
<tr>
<td>Age at Implantation</td>
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<tr>
<td>PTA Contralateral Ear (dB HL)</td>
</tr>
<tr>
<td>PTA Ipsilateral Ear (dB HL)</td>
</tr>
</tbody>
</table>
Figure 29: Scatterplots showing correlation between the frequency-pitch match on the apical electrode (number 22) and the post-experience monosyllabic word score (in the left panel) and the sentence in babble score (in the right panel) for the unilateral (cochlear implant alone) test condition.
7.5 Discussion

In this study the measure of electrical frequency-pitch match was first examined using a longitudinal experimental design in a group of newly implanted cochlear implant recipients. Of interest in that group was the effect of frequency-pitch match on the rate of post-implantation improvement during the first 12-months of cochlear implant use. In this study, the group of subjects who obtained 90% of the 12-month unilateral word and sentence score within the first six months of device use had a better frequency-pitch match than those subjects who took longer to improve or who did not show improvement from pre-operative measures. However there was no observed influence in the current study of frequency-pitch match influencing bilateral speech recognition when using the combined acoustic and electric stimulation.

The impact of frequency-pitch match on post-experience speech recognition scores in quiet and noise was also examined in 37 subjects. Different to the majority of published studies that have examined the effect of shifting the degree or pattern of offset in frequency to place mapping, the current study involved cochlear implant recipients rather than vocoder simulations in normal hearing listeners. Additionally, the study adopted a design that avoided the potential confounding factor of bias toward a familiar allocation of frequency to electrodes. Similar to the finding of Di Nardo et al. (2010), less offset between the assigned acoustic frequency and the electrical pitch percept was correlated with better speech recognition in both quiet and noise when listeners were evaluated using the implanted ear alone. The finding is also consistent with the majority of studies that have assessed the impact of modifying the acoustic input frequency in both vocoder simulations with normal hearing listeners (Dorman et al., 1997; Shannon et al., 1998; Fu and Shannon, 1999; Baskent and Shannon, 2003), and in acute experiments with cochlear implant listeners (Baskent and Shannon, 2004).

Contrary to the findings in the unilateral listening condition, there was no evidence in the current study that the frequency-pitch match impacted speech recognition when listening in the bilateral condition using both acoustic and electric modalities. Further research is warranted to investigate whether the impact of frequency-pitch match in such listeners might vary as a function of the relative contribution of each modality to the combined speech perception performance. It is possible that those listeners less reliant on acoustic
contralateral hearing might be more dependent on having a close frequency-pitch match. Furthermore, it would be of interest to examine whether the degree of frequency-pitch match impacts bilateral function on spatial hearing abilities, such as ability to localise sounds in the horizontal plane, since binaural interaural timing and/or level cues may be more dependent on matched pitch percepts across ears (Francart and Wouters, 2007; Francart et al., 2009; Kan et al., 2015).

It is important to consider that the analysis conducted within the current study was limited to measurement of the electrical pitch percept on the most apical electrode. The impact of electrical frequency-pitch match on the more medial and basally located electrodes would be of interest to examine in future studies. Although a small number of subjects had high frequency hearing thresholds within the examined cohort, there were insufficient numbers to consider the impact of frequency-pitch match that occurred with stimulation on more basally located electrodes.

7.6 Conclusions

A closer match between the custom frequency assignment to an apical electrode and the pitch percept elicited through electrical stimulation on that channel would appear to provide a more rapid speech perception improvement within the first 12 months of device use. However, the impact of such a frequency-pitch match would be expected only when testing involved the cochlear implant alone, and not when electrical stimulation was combined with acoustic hearing in the contralateral ear. Similarly, a closer degree of match after 12-months of cochlear implant experience appears to be positively correlated with the absolute scores on the speech recognition test materials when using the cochlear implant alone, but not with use of combined acoustic and electric stimulation. The potential application of pitch estimation in the clinical setting requires further investigation, but may be warranted to maximise clinical benefit and rate of adaptation to the electrical signal post-implantation.
8 Factors Influencing Electrical Place Pitch Perception in Bimodal Listeners

The information contained within this section comprises only the content of the publication, with the reprint provided in Appendix 7.

8.1 Abstract

Factors that might affect perceptual pitch match between acoustic and electric stimulation were examined in 25 bimodal listeners using magnitude estimation. Pre-operative acoustic thresholds in both ears, and duration of severe-profound loss, were firstly examined as correlates with degree of match between the measured pitch and that predicted by the spiral ganglion frequency-position model. The degree of match was examined with respect to 1) the ratio between the measured and predicted pitch percept on the most apical electrode, and 2) the ratio between the slope of the measured and predicted pitch function. Secondly, effect of listening experience was examined to assess whether adaptation occurred over time to match the frequency assignment to electrodes. Pre-experience pitch estimates on the apical electrode were within the predicted range in only 28% of subjects, and the slope of the electrical pitch function was lower than predicted in all except one subject. Subjects with poorer hearing tended to have a lower pitch and a shallower electrical pitch function than predicted by the model. Pre-operative hearing thresholds in the contralateral ear and hearing loss duration were not correlated with the degree of pitch match, and there was no significant group effect of listening experience.

8.2 Introduction

Implantation of multi-channel cochlear implants in recipients with acoustic hearing provides an opportunity to compare the pitch percept that is obtained through electrical stimulation, at different place positions within the cochlea, to that provided by acoustic stimulation. Understanding the relationship between acoustic and electric percepts may provide clinically relevant information to assist with optimisation of outcomes for listeners using bimodal devices, i.e. when combining the signal from the cochlear implant sound processor with that obtained through acoustic amplification. Approaches to optimising bimodal performance are becoming increasingly important in the clinical
setting due to expansion in candidacy indications for cochlear implantation (Fraysse et al., 2006; Gantz et al., 2009; Lenarz, 2009; Skarzynski et al., 2009; Vermeire and Van de Heyning, 2009; Buechner et al., 2010; Arndt et al., 2011a).

Pitch information can be conveyed by cochlear implants by means of encoding temporal and spectral cues (Townshend et al., 1987; McDermott, 2004), with place of stimulation being the predominant cue. Although amplitude modulation of pulsatile stimulation, or pulse rate itself, at rates below approximately 300 Hz can be effective as a means of delivering temporal pitch, this efficacy is variable across listeners and typically saturates at rates beyond approximately 300 Hz (Shannon, 1983; Tong and Clark, 1985). Electrical stimulation of intracochlear electrodes within the scala tympani typically results in progressively higher pitch as the site of stimulation changes from an apical to basal location. This is consistent with the tonotopic organisation of the cochlea as described by von Bekesy (1960), with different areas of maximum basilar membrane oscillation arising in response to acoustic sounds of different frequency. The variation in place-pitch sensation that occurs as a result of stimulating electrodes at different positions in the cochlea is important to convey information relating to spectral shape, which is critical to accurate speech perception. A number of studies conducted to date have suggested that a particular allocation of frequencies to electrodes, based on electrode position within the cochlea, may be important for speech recognition and music perception (Dorman et al., 1997; Shannon et al., 1998; Fu and Shannon, 1999; Faulkner et al., 2003). Matched place-pitch across ears has also been shown to improve interaural level perception in bimodal listeners (Francart and Wouters, 2007) and perception of interaural timing (Long et al., 2003; Kan et al., 2015) and level differences (Kan et al., 2015) with use of bilateral cochlear implants.

Greenwood’s characterisation (Greenwood, 1990) of the frequency to position function along the organ of Corti has largely provided the basis for comparison of the electrical pitch percept with that which would be predicted according to the intracochlear electrode position. Previous research with bimodal listeners has involved measurement of the pitch obtained through electrical stimulation compared to that obtained using contralateral acoustic hearing. Electrical pitch percepts have generally been reported to be 1-2 octaves lower than would be predicted by Greenwood’s function (Blamey et al., 1996b; Boex et al., 2006; Reiss et al., 2007; McDermott et al., 2009). However, alternative findings have
also been reported in the literature. Evidence of close match to the Greenwood cochlear place prediction has been observed in two independent publications (Vermeire et al., 2008; Carlyon et al., 2010). Higher pitch than predicted by Greenwood’s function on the most apical electrodes was observed in six users of the Med-El Combi 40+ device (Baumann and Nobbe, 2006) and in one of six subjects assessed by Boex et al. (2006) using the HiRes™ 90K device. In understanding both the reasons for variability across studies, and potential reasons for lower than predicted pitch estimates reported in the literature, it is of interest to examine a range of potential factors that may have influenced the findings. Those factors include: 1) the test procedure used to obtain the pitch estimates, 2) direct stimulation of spiral ganglion cells and cochlear anatomy, 3) neural survival in the implanted ear, 4) the degree of hearing in the reference (contralateral) ear, and 5) the effect of listening experience. A summary of the published data relating to each of these areas is provided below.

Test Procedure

Pitch matching between ears with different perceptual qualities has been shown to be highly susceptible to non-sensory bias (Carlyon et al., 2010). Multiple techniques have been used in past publications to obtain electrical pitch estimates. These include the method of constant stimuli, pitch matching by adjustment, interleaved adaptive adjustment and magnitude estimation. Variability in the reported findings across studies may, at least in part, have arisen as a result of the measurement technique used.

Direct stimulation of spiral ganglion cells & cochlear anatomy

One proposed contributor to the lower than predicted pitch percept is that the intracochlear electrode array, when positioned facing the modiolus and close to the spiral ganglion, stimulates the spiral ganglion cells within Rosenthal’s canal directly, rather than stimulating the more rapidly degenerating radial nerve fibres that lie close to the organ of Corti (Blamey et al., 1996b). Stakhovskaya et al. (2007) developed a frequency-place map of the spiral ganglion cells relative to the organ of Corti through an analysis of nine human temporal bones, and reported a compressive effect in the apical region of the cochlea beyond 1000 Hz. This effect has been reported to arise as a result of the different length of the cochlear structures, and the fact that the radial nerve fibres from the organ of Corti take an increasingly tangential path into the spiral ganglion in that region. That
observation may account in part for the discrepancy observed between the pitch estimates and the prediction based on Greenwood’s function; however, there is only a relatively small difference between the two modelling approaches up to an insertion angle of 720 degrees. As a result, there are likely other contributing factors.

Variation in the degree of match to the models as a function of insertion angle may be expected due to the fact that the frequency-place function becomes shallower as insertion angle is increased. In line with those functions, more deeply inserted electrodes would be expected to have a smaller relative change in pitch as insertion angle is increased. Lack of differentiation in pitch percept for more deeply inserted electrodes has been reported by (Baumann and Nobbe, 2006), and may explain the higher pitch than predicted by Greenwood’s model in that study and in one of six subjects assessed by Boex et al. (2006). There is also suggestion that cross-turn stimulation may occur in the apical region based on cochlear modelling (Frijns et al., 2001) as a result of arrangement of the auditory nerve endings being different in the apical as compared to the basal region of the cochlea, and which may result in lower pitch percepts than expected at high stimulation levels.

*Neural survival in the implanted ear*

Another potential factor affecting the degree of match between the measured and predicted pitch may be the changes that occur as a result of impairment in cochlear function as a result of different patterns of neural survival within the cochlea (McDermott et al., 2009). Given that the most typical pattern of hearing loss involves a greater reduction in high- as compared to low-frequency sensitivity, there may be shifts in the electrical pitch percept that occur as a result of poor neural survival in the stimulated region. Stimulation in a region of the cochlea that would typically be tuned to high frequencies, but has poor neural survival, may result in stimulation of the more-apical neural population. Support for this hypothesis would be expected to manifest as an effect of insertion angle on the goodness of match in electrical pitch percept to the frequency-place models, since neural survival might be expected to be greater for more deeply inserted electrodes. Although there appears to be considerable variability in the data, the incidence of the pitch being more closely matched or higher than predicted would appear greater for insertion angles beyond approximately 600 degrees, and this is in line with the general finding reported by Baumann and Nobbe (2006) and for one of the
subjects assessed by Boex et al. (2006). For insertion angles below approximately 450 degrees, the majority of findings in published literature suggest lower electrical pitch percepts than would be predicted from the cochlear or spiral ganglion models (Blamey et al., 1996b; Boex et al., 2006; McDermott et al., 2009). Shallower slope of electric as compared to acoustic hearing, as has been reported by Blamey et al. (1996b), may also be a contributing factor to the lower than predicted pitch for shallower insertion angles.

*Degree of hearing in the reference (contralateral) ear*

Vermeire et al. (2008) and Carlyon et al. (2010) hypothesised that the close match to Greenwood’s function in their data was the result of subjects in those studies having normal or near-normal hearing thresholds in the ear contralateral to the implant. It was hypothesised that the pitch percept in an impaired acoustic hearing ear, used as the reference for pitch matching, might have been lower due to the presence of dead regions and the resultant spread in the travelling wave toward the apex of the cochlea. At the peripheral level, presentation of acoustic stimuli to a cochlea with a severe sensorineural impairment may result in a shift in the position of the peak of the travelling wave which could lead to lower than normal pitch match for a given input frequency (Liberman CM, 1986). Frequency selectivity may also affect the ability to obtain reliable pitch data (Green et al., 2012).

The degree of hearing in the contralateral ear may also influence the tonotopic structure of the auditory cortex. Auditory cortex re-organisation in response to high frequency hearing loss has been shown to occur in animal models (Irvine et al., 2003; Fallon et al., 2009a), with the region of the cortex typically responsive to high frequency stimuli adapting to be responsive to lower frequencies. Improved frequency discrimination (McDermott et al., 1998; Thai-Van et al., 2003) have been attributed to this cortical reorganisation. Such cortical reorganisation in the ear used as the acoustic reference for pitch assessment may have influenced the findings.

*Effect of listening experience*

The effect of listening experience on electrical pitch is an important consideration, both in terms of understanding the potential contribution of this factor to published data, but also for potential clinical application of matching acoustic and electric percepts for
bimodal devices. In one study, the effect of cochlear implant listening experience on electric and acoustic pitch estimates was assessed in fourteen adult subjects (McDermott et al., 2009). Higher electric pitch percepts on the apical electrode were observed for five subjects having no implant experience, as compared to nine tested after experience (of between seven months and four years). The group mean pure tone frequency that elicited the same pitch as the most apical electrode for the subjects with and without cochlear implant experience were 382 and 667 Hz respectively. In that study it was postulated that the pitch associated with electrode position might be close to that predicted by the spiral ganglion frequency map prior to implant experience, and then change post-operatively in response to the way in which acoustic input frequencies are assigned to electrodes in the sound-processor program.

To date, there has been only limited examination of longitudinal pitch estimates in the electrically stimulated ear. There is evidence of convergence in pitch estimates toward the assigned frequency range in some studies (Reiss et al., 2007; Green et al., 2012; Reiss et al., 2014), however there is also reported high degree of variability across listeners. Carlyon et al. (2010) reported that the degree of match between electric and acoustic pitch was not strongly influenced by experience in two subjects with normal contralateral acoustic hearing. However, in that study the data were collected as a secondary objective, within a study primarily examining the effect of implantation on alleviation of tinnitus, and there was only limited ability to examine the effect of listening experience on electrical pitch perception. Further evaluation of the effect of experience on electrical pitch estimates is warranted, given the limited data and the importance of this factor when considering potential clinical application of matching acoustic and electrical stimulation with bimodal devices.

The current study firstly aimed to examine a number of factors that may influence the degree of initial match (i.e., that obtained prior to listening experience being provided with the cochlear implant) in perceived electrical pitch to that predicted by the spiral ganglion map. Specifically it was of interest to assess whether implanted ear characteristics of pre-operative hearing thresholds and duration of severe-profound hearing impairment, as potential measures of neural survival, were correlated with the degree of initial (pre-experience) match. Additionally, the effect of the degree of contralateral hearing on initial pitch estimates was examined to investigate further the
finding of Vermeire et al. (2008) and Carlyon et al. (2010) that contralateral hearing sensitivity may have explained the improved pitch match for those subjects having normal or near-normal thresholds in the contralateral ear. Use of a standardised procedure across a range of subjects, with differing levels of contralateral hearing, was used to provide further information relating to the findings from those studies. Finally, detailed assessment of electrical pitch changes over time investigated the hypothesis proposed by McDermott et al. (2009) that subjects without cochlear implant listening experience may have a closer alignment between the measured and predicted pitch percept, and that the lower than predicted pitch percept observed in previous studies may be a result of adaptation to the way in which frequencies are assigned to electrodes in the sound processor program. Examination of the effect of listening experience using a within-subject design was conducted in a group of subjects implanted with longer electrode arrays than previously examined by Reiss et al. (2007) and provided information regarding adaptation in a larger number of subjects than has been previously examined. Findings from the study may lead to improved programming techniques for users of bimodal and hybrid devices, through providing information to assist in matching of acoustic and electrical signals.

8.3 Materials and Methods

Subjects

Twenty five postlinguistically hearing-impaired adults participated in the study. All were implanted with Nucleus cochlear implants (Contour Advance, Slim Straight or Hybrid-L24). Demographic information for each of the subjects is shown in Table 14. The age of the subjects at the time of enrolment ranged from 42 years to 81 years, with a mean age of 64 years. Table 1 also provides information regarding gender, aetiology of hearing impairment, duration of severe-to-profound hearing loss, median unaided low (0.25-1 kHz) and high frequency (1-4 kHz) audiometric thresholds and type of electrode array.
Table 14: Subjects’ demographic information; including age at the time of implantation (in years), gender, aetiology of hearing impairment, duration of severe-to-profound hearing loss (in years), median unaided low (0.25-1 kHz) and high frequency (1-4 kHz) audiometric thresholds (in dB HL), and type of electrode array.

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<th>Aetiology C: Contralateral</th>
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Study Design

The study employed a prospective, longitudinal within-subject experimental design, in which each subject served as his or her own control. Numerical estimates of pitch were obtained using a magnitude estimation technique at four time points with each subject: just prior to clinical mapping, and at approximately 3, 6, and 12 months post-activation. Testing conducted prior to clinical mapping involved psychophysical stimulation on the electrodes, but subjects were not provided with any electrical stimulation that included mapping of input frequencies to electrodes via the clinical program in the sound processor. Stimuli consisted of five acoustic pure tones and five single-electrode pulse trains, and were delivered via custom software and a custom interface box. The five acoustic pure tones spanned the range of acoustic hearing available in the ear contralateral to the cochlear implant. All tones were of 500 ms duration and had 30 ms linear amplitude tapers applied at the onset and offset. Acoustic tones were presented via a tube-phone to the ear contralateral to the implanted side.

To minimise the likelihood of data being affected by non-sensory bias (Carlyon et al., 2010) two different acoustic frequency ranges were selected and evaluated for each subject where possible. For an individual subject, this involved either testing using one-third octave spacing for one test condition and two-third octave frequency spacing for the alternative range, or with two different ranges that used one-third octave spacing. Selection of each of those options was dependent on the degree of acoustic hearing impairment, i.e. whether there was sufficient acoustic hearing to span a frequency range that used two-third octave frequency spacing. Collection of pitch estimates using two acoustic frequency ranges aimed to overcome the possible bias of subjects selecting pitch estimates near the centre of the acoustic frequency range. Electric stimuli consisted of 900 Hz pulse trains of 500 ms duration, presented to single electrodes at the mid to apical end of the array. Stimulus pulse parameters used a monopolar electrode configuration (MP1+2), a pulse width of 25 µs and an interphase gap of 8.4 µs, consistent with default parameters used within the clinical Custom Sound programming software provided by Cochlear Limited. Typically the electrodes used for the pitch estimation task were 22 (the most apically located electrode), 19, 16, 13, and 10. Variation in the selected electrodes across the multiple administrations of the test procedure was used when time permitted, through selection of electrodes 22, 20, 18, 16, and 14. As for the acoustic
stimuli, this technique aimed to minimise any potential for the range of stimuli used in the assessment to introduce non-sensory bias and so potentially influence the findings. Frequency and electrode selection did not likely affect the outcome of the study, however was used to minimise potential confounding factors.

To examine the reliability of the experimental procedure, test-retest repeatability was examined for test administrations that used the same frequency spacing. Those data were obtained for the majority of subjects and test sessions. In addition, the potential influence of non-sensory bias on the findings was examined through comparing the pitch estimates obtained using the two different acoustic frequency ranges, to examine whether the pitch estimates were influenced by the range of acoustic signals used during the test procedure. Salience of the electrical pitch percept was assessed by examination of variation in electrical pitch rating as a function of electrode.

All stimuli were initially loudness-balanced using the highest frequency pure tone acoustic stimulus as the reference signal. The reference tone was set to a comfortable listening level. Repeated pairs of stimuli were then presented sequentially, and subjects were asked to adjust the loudness of the second tone to match that of the first presented tone. Adjustment was made using a toggle switch on a custom interface box, with step size of 2 dB SPL or 2 current level steps for the acoustic and electric stimuli respectively. During the loudness-balancing procedure the starting level of the test stimulus was randomly set to a loud or soft level at each of the repeated balancing tasks to ensure accurate bracketing of the equal loudness level. This repeated loudness balancing was conducted until the level of the test stimulus was within acceptance criteria (of 2 dB SPL or 2 current level steps) for two repeated loudness balancing tasks for the acoustic and electric stimuli respectively.

Subsequently, the pitch of the loudness-balanced signals was measured using a psychophysical magnitude estimation task. The reference tone formed one of the ten stimuli, and so was presented multiple times throughout the procedure. The reference tone was the highest frequency pure-tone stimulus, and subjects were asked to assign the numerical value of 50 to that tone. The purpose of the reference tone was to reduce the likelihood of subjects compressing responses at either end of the scale. Subjects were advised that each subsequent stimulus should be allocated a number, and that the
numerical value assigned to describe the pitch of the stimulus should be relative to the reference signal. For example, a stimulus with a pitch deemed twice as high as the reference signal would be allocated a number that was twice as high as the reference, i.e. 100 as compared to 50. A stimulus with a pitch perceived as half that of the reference would be allocated 25, and so on. Subjects were encouraged to use a wide number range if appropriate, and advised not to limit estimates at the upper end based on an arbitrary range; i.e., not to limit the estimates to 100 unless this provided a true indication of the pitch of the stimulus. The full set of ten stimuli was presented sequentially 2-3 times prior to commencement of the pitch estimation task, to enable familiarisation with the range of sounds to be included in the pitch estimation procedure. During the pitch estimation task a single-interval procedure was used, with each stimulus presented ten times in random order. To reduce any influence of residual loudness differences on the pitch estimations, random level variations of +/- 2 dB were applied to the acoustic signals and +/- 2 Current Levels to the electrical signals.

For each subject at each of the evaluation time points, there were 3-4 repeat procedures conducted. Up to two repeat measurements were obtained for each of two different stimulus ranges. Pitch estimates obtained from repeat measurements of the same stimulus range were averaged using geometric means. Where two different acoustic frequency ranges were used, the final electrical pitch value used for subsequent data analysis was the geometric mean obtained across the entire data set. Post-operative x-rays were obtained for each subject using a modification of the technique described by Tykocinski et al. (2000), and insertion depth angle estimates were calculated. Acoustic frequency correlates to insertion angle for the most apical electrode were calculated using data provided by (Stakhovskaya et al., 2007).

The magnitude estimation procedure was selected over a pitch matching approach for a number of reasons. Firstly, this technique was likely less prone to bias for the objectives of the current study, where it was of interest to examine pitch changes across multiple electrode positions. With use of a direct pitch matching procedure, where subjects compare the electric stimulus with an adjustable acoustic stimulus, it is likely that an acoustic frequency would be deemed to match regardless of whether there was a true pitch match. In the example provided in Figure 1, it would have been expected that direct pitch matching would have been possible for electrodes 22, 19, and 16, since there is a
corresponding acoustic pitch estimate within the range used for those electric stimuli. However for the more-basal electrodes (13 and 10), a pitch match would not have been accurately obtained using a direct matching technique because the pitch estimates on those electrodes were greater than those obtained with the highest frequency acoustic stimulus that could be made comfortably loud. Secondly, magnitude estimation provides the ability to obtain all pitch estimates at one time, rather than obtaining each comparison in sequence. Finally, it is practically impossible to fix the acoustic stimulus and ask the subject to vary the electrode position, so it is not possible to reduce the bias associated with the adjustment of only one parameter while the other one is fixed. This problem does not occur with use of the magnitude estimation procedure.

Mean pitch estimates for the five acoustic and five electric stimuli were calculated and plotted as points on a scatterplot with frequency or electrode on the x-axis, and pitch estimates on the y-axes for the acoustic and electrical stimuli respectively. Data relating to two aspects of electrical pitch percept were obtained: 1) the electrical pitch percept obtained on the most apical electrode, and 2) the ratio in slope between the electrical pitch function and that of the spiral ganglion map. Both aspects of pitch perception were included in the analysis to provide an understanding of the impact of the examined factors on the degree of match both at a fixed and variable electrode location within the cochlea. Understanding how pitch changes as a function of place in both a relative and absolute sense was also of interest in considering potential clinical application of the study findings.

For calculation of the electrical pitch percept obtained on the most apical electrode, a linear regression line was fitted to the acoustic pitch measures, and the pitch estimate from the most apical electrode (electrode 22) was obtained by reading from the acoustic regression line. An example of the data obtained from a single experimental run is shown in Figure 30. In this example the acoustic pitch that corresponded to that obtained on the most-apical electrode was 481 Hz. For simplicity in describing the findings of the current study, use of the term ‘pitch’ (when referring to the electrical pitch estimate) throughout the paper will describe the frequency that was matched in pitch to the acoustic tone.
Figure 30: Example of data obtained from a single pitch estimation experimental run. The left panel shows pitch estimates (on the y-axis) as a function of acoustic pure tone stimuli. The right panel shows pitch estimates for electrical stimulation (y-axis) for each of five electrodes tested (x-axis). The frequency corresponding to acoustic pitch was calculated for the electrical stimuli, either on the apical electrode or on a series of electrodes evaluated to determine the slope of the measured function relative to the spiral ganglion frequency-place model.

For calculation of the ratio in slope between the measured electrical pitch function and that predicted by the spiral ganglion map, a linear regression line was first fitted to both the electric and acoustic data. For all electrodes with a pitch estimate that corresponded to the pitch range using pure tones (i.e. in the area of overlap between the acoustic and electric data), the corresponding acoustic frequency was obtained. In Figure 31 is plotted data to provide an example of the procedure used for calculation of the slope of the electrical and spiral ganglion pitch function. The graph indicates the acoustic frequency corresponding to insertion angle. The solid grey line indicates the mean frequency according to Stakhovskaya et al. (2007), and the dashed lines the upper and lower range of the spiral ganglion frequency-position function. The dotted grey line indicates the Greenwood function of Organ of Corti characteristic frequency, as adapted by Kawano et al. (1996) for insertion angle. The black squares indicate the frequency corresponding to electrical stimulation on electrodes 22 and 19 for subject S21 to demonstrate the procedure used. In this example, the predicted frequency based on the spiral ganglion map was 785 Hz and 1420 Hz for electrodes 22 and 19 respectively and those points are
visible on the figure along the spiral ganglion frequency-place function as open triangle symbols. For this subject, the acoustic frequency corresponding to the pitch estimate on electrodes 22 and 19 was 725 Hz and 1053 Hz respectively. The slope of each of the predicted and measured functions was calculated, and the relative slope of the measured and predicted spiral ganglion cell frequency function was expressed in Hz per degree. For the selected example the ratio between the measured slope and the spiral ganglion map slope was 0.52.

A number of variables were investigated as potential correlates with the two aspects of electrical pitch perception: 1) the electrical pitch percept obtained on the most apical electrode, and 2) the slope in the electrical pitch function. Examined variables were pre-operative hearing levels and duration of severe-to-profound hearing impairment in both the implanted and contralateral ear.

**Figure 31:** Frequency corresponding to electrical pitch estimates across multiple electrodes, providing visualisation of the slope of the electrical pitch function. The solid grey line indicates the mean spiral ganglion frequency according to Stakhovskaya et al (2007), and the dashed lines the upper and lower range of the spiral ganglion frequency-position function.

The dotted grey line indicates the Greenwood function of Organ of Corti characteristic frequency. Filled black squares represent the data for S21 as an example to explain the procedure used for calculation of the measured electrical slope function relative to the slope of the spiral ganglion model (corresponding points for the spiral ganglion model are shown as open triangles).
8.4 Results

8.4.1 Validation of pitch estimation methodology

Test-retest reliability

Test-retest reliability measures were obtained through repeat administration of the pitch estimation task for the same acoustic and electric frequency range with the same subject. The acoustic frequency corresponding to stimulation on the most apical channel was determined for each of the experimental runs. Data were collected for 112 test-retest pairs, with repeat testing conducted with all subjects enrolled in the study at a minimum of one of the post-operative time points evaluated. In the left panel of Figure 32 (a) is shown a correlation plot of the log of first and second acoustic frequency calculated across experimental runs. Pearson product moment correlation coefficients were computed between first and second administration of the pitch estimation task, and revealed a highly significant correlation (r=0.9, p<0.001).

Figure 32: (a) Left Panel: Test-retest pitch estimates from repeat administration of the pitch estimation task for the same acoustic and electric frequency range with each subject. (b) Right Panel: Median pitch ratings as a function of electrode. Higher pitch estimates were obtained with more basally located electrodes.
Assessment for non-sensory bias

To determine whether the pitch estimates were likely to have been affected by non-sensory bias (Carlyon et al., 2010), i.e. whether subjects were influenced by the ranges or midpoints of the selected acoustic signals, the relationship between the pitch estimates between two different frequency ranges was analysed. It would be expected that the presence of non-sensory bias would have resulted in the pitch estimate for the higher midpoint having a higher pitch percept than that obtained for the lower midpoint. Analysis using a paired t-test indicated no significant difference between the pitch estimates obtained using the different frequency ranges \([t(54)=-0.456, p=0.7]\). Mean estimates for the range with the lower and higher midpoints were 494 Hz and 502 Hz respectively. The 95% two-tailed confidence interval for the difference of means included zero (-44.5 to 27.9), suggesting no evidence of influence of non-sensory bias, related to acoustic frequency range, on the pitch estimation data collected.

Salience of electrical pitch percept

To investigate the salience of the electrical pitch percept, mean pitch ratings across electrodes (and across multiple time points) were calculated for each individual subject. Electrode measurement refers to the electrode numbers from the apical to basal location, and constituted one of two electrode combination; either electrodes 22, 20, 18, 16, and 14, or electrodes 22, 19, 16, 13 and 10. Analysis of group data using Friedman repeated-measures analysis on ranks revealed a significant difference of electrode on electrical pitch estimates \([\text{Chi-square}(4)=96.064, p<0.001]\). As expected, median pitch estimates were higher for electrodes positioned more basal in the cochlea. Data are shown in the right panel of Figure 32 (b).

8.4.2 Pre-experience pitch comparison to spiral ganglion frequency-position function

In the left panel of Figure 33 is shown the acoustic frequency that corresponds to the pitch percept obtained when stimulating on the most apical electrode, plotted as a function of insertion angle of that electrode. The solid grey line indicates the mean frequency according to Stakhovskaya et al. (2007), and the dashed lines the upper and lower range of the spiral ganglion frequency-position function. The dotted grey line indicates the Greenwood function of Organ of Corti characteristic frequency, as adapted by Kawano
et al. (1996) for insertion angle. The right panel shows the pitch across multiple electrodes, and so provides a visualisation of the slope of the electrical pitch function for individual subjects, across the range of frequencies at which the slope could be obtained, i.e. where there was sufficient overlap between multiple electrodes with the acoustic frequency range. Apical electrode pitch estimates were within or above the spiral ganglion model range in only 28% of subjects. Slope of the electrical pitch function was lower than that for the spiral ganglion model for all except one subject.

**Figure 33:** Left panel: Acoustic frequency corresponding to the pitch percept obtained when stimulating on the most apical electrode, plotted as a function of insertion angle of the electrode. Right panel: Frequency corresponding to electrical pitch estimates across multiple electrodes, providing visualisation of the slope of the electrical pitch function. The solid grey line indicates the mean spiral ganglion frequency according to Stakhovskaya et al (2007), and the dashed lines the upper and lower range of the spiral ganglion frequency-position function. The dotted grey line indicates the Greenwood function of Organ of Corti characteristic frequency.
8.4.3 Examination of variables as correlates with pre-experience degree of pitch match to spiral ganglion frequency on apical electrode

Pearson Product Moment correlation coefficients were calculated for each of the variables examined as potential correlates with the degree of match between measured and predicted frequency. Variables examined were 1) the pre-operative implanted ear unaided audiometric hearing threshold at the frequency corresponding to the spiral ganglion mean frequency for insertion angle of the most apical electrode 2) the pre-operative contralateral unaided audiometric hearing threshold at the frequency corresponding to the spiral ganglion mean frequency for insertion angle of the most apical electrode, 3) the duration of severe-to-profound hearing loss in the implanted ear, and 4) the duration of severe-to-profound hearing loss in the contralateral ear.

Pre-operative hearing thresholds in implanted ear

In Figure 34 is shown the ratio between the measured and predicted pitch elicited at the most apical electrode, plotted against the pre-operative unaided acoustic hearing level in the implanted ear. On the x-axis is shown the pre-operative unaided hearing threshold (in dB HL) that was obtained at the corresponding frequency in the cochlea, based on insertion angle using Stakhovskaya et al. (2007), at which the apical electrode was located. On the y-axis is shown the ratio between measured and predicted pitch percept obtained prior to listening experience with the cochlear implant. An exact match between the measured and predicted pitch would be indicated as a ratio of 1. Results from two correlation analyses are shown. The solid line indicates the fit to the entire dataset, and the dotted line for an analysis conducted without inclusion of those subjects for whom no audiometric response (shown as 130 dB HL) was measurable.

Pearson Product Moment Correlation analysis for the entire set of data revealed a significant correlation between the pre-operative acoustic hearing threshold and the degree of pitch match ($r = -0.445, p = 0.026$). Subjects with poorer acoustic hearing (shown as a higher unaided threshold value) tended to show a lower than predicted pitch percept. However the significant relationship between the examined variables was not observed with exclusion of the subject with the best unaided hearing threshold (of 35 dB HL) and the ratio of 2.48 between measured and predicted pitch. Analysis of the data with exclusion of the 130 dB HL values improved the degree of observed correlation ($r=$-
.642, p=0.003. As for the case for the entire dataset, the removal of the data-point for the subject with the best unaided hearing threshold removed the significant correlation observed.

![Graph](image)

**Figure 34**: Ratio between measured and predicted electrical pitch (on the y-axis) plotted against the pre-operative unaided acoustic hearing threshold (in dB HL) at the frequency in the implanted ear corresponding to insertion angle of the most apical electrode. The dotted reference line indicates point at which there was exact match between the measured and predicted pitch. Points above the reference line reflect the measured pitch being higher than predicted by electrode location; those below the line reflect the measured pitch being lower than predicted. Shown is a plot (solid line) of data for the entire dataset, and a plot (dashed line) for the dataset without inclusion of subjects without measurable hearing in the implanted ear.

*Pre-operative hearing thresholds in contralateral ear*

Pearson Product Moment Correlation analysis revealed no significant correlation between the pre-operative acoustic hearing threshold in the contralateral ear and the degree of pitch match from that predicted by the spiral ganglion frequency-position model ($r = -0.206$, p = 0.324).
Duration of severe-to-profound hearing impairment

Pearson Product Moment Correlation analysis revealed no significant correlation between the duration of severe-to-profound hearing impairment in the implanted ear and the degree of match between measured and predicted pitch (r = -0.327, p = 0.11). A similar finding of non-significance was observed for duration of hearing impairment in the contralateral ear and the degree of pitch match (r = -0.207, p = 0.32).

8.4.4 Examination of variables as correlates with pre-experience degree of electrical pitch match to the spiral ganglion frequency slope

Pre-operative hearing thresholds in the implanted ear

On the y-axis of Figure 35 is shown the ratio between the measured slope in pitch across multiple electrodes and the slope of the spiral ganglion frequency function (‘slope-match’). This figure differs from Figure 34 in that the degree of match in slope to the spiral ganglion function has been calculated rather than the degree of match on the single apical electrode. On the x-axis is shown the median pre-operative implanted ear unaided low-frequency acoustic hearing (across the frequency range 0.25 – 1 kHz). Pearson Product Moment Correlation analysis revealed a significant negative correlation between these variables (r = -0.84, p < 0.001). Subjects with better hearing, i.e. lower unaided audiometric thresholds, showed a closer match in electrical slope to the slope of the spiral ganglion frequency-position function. Subjects with median low frequency hearing thresholds of greater than 80 dB HL showed little or no match in slope, and shallower electrical slope functions relative to those subjects with lower thresholds.

Pre-operative hearing thresholds in the contralateral ear

No correlation was observed between the slope match and the degree of low frequency (0.25–1 kHz) hearing in the contralateral ear.

Duration of severe-to-profound hearing impairment

No correlation was observed between the degree of slope match and the duration of severe-to-profound hearing impairment in either ear. When examining this effect with
use of median high frequency unaided hearing thresholds in the contralateral ear (from 1-4 kHz) there was again no significant slope match.

Figure 35: Ratio between measured slope of the electrical pitch function (across multiple electrodes) and the slope of the spiral ganglion frequency function. On the x-axis is shown the low frequency unaided hearing threshold in dB HL in the implanted ear (across the frequency range from 0.25 to 1.0 kHz) plotted against the electrical slope relative to the slope of the spiral ganglion frequency.
8.4.5 Effect of listening experience on electrical pitch

*Pitch percept on most apical electrode*

In the left panel of Figure 36 is shown the acoustic pure-tone frequency that corresponds to the pitch percept obtained when stimulating on the most apical electrode (on the y-axis) plotted as a function of insertion angle of that electrode. Pitch estimation data are shown for each subject at two different time points; those obtained just prior to initial activation are indicated by open circles, and those at the 12-month post-activation time point are indicated by black filled triangles. The solid line shows the spiral ganglion mean characteristic frequency corresponding to the insertion angle, and the lower and upper dashed lines indicate the approximate range of associated characteristic frequencies (as reported by (Stakhovskaya et al., 2007)). In the right panel of the figure is shown the group median acoustic frequency corresponding to stimulation on the most apical electrode at each of the time points.

Analysis using the Wilcoxon Signed Rank test revealed no significant group mean difference between the pitch estimates obtained between the initial and 12-month time points ($Z=-1.41, p=0.16$). Median initial and 12-month pitch estimates were 445 Hz and 369 Hz respectively. Similarly, no significant difference was observed between the initial and each of the 3- and 6-month time points.
Figure 36: Left panel: Acoustic frequency corresponding to the pitch on the most apical electrode (y-axis) plotted as a function of insertion angle of that electrode. Open circles show pitch estimates for individual subjects prior to electrical stimulation, and closed triangles the pitch estimates after 12-months of experience with the cochlear implant. The solid grey line indicates the mean spiral ganglion frequency according to Stakhovskaya et al (2007), and the dashed lines the upper and lower range of the spiral ganglion frequency-position function. The dotted grey line indicates the Greenwood function of Organ of Corti characteristic frequency. Right panel: Group median acoustic frequency corresponding to apical electrode stimulation at the two time points; prior to stimulation (initial) and after 12-months of experience.

Individual subject data showing the effect of listening experience is plotted in Figure 37. Plotted for each individual is the degree of offset between the electrical pitch percept on the most apical electrode and the centre point of the input frequency range assigned to that channel (on the y-axis), across the different time points (on the x-axis). Default frequency allocation on electrode 22 for subjects 1-24 was from 188 Hz to 313 Hz, whereas for subject 25 the allocated frequency range was 813 Hz to 938 Hz, due to use of the Hybrid-L24 electrode and the non-overlapping acoustic and electrical stimulation. Filter frequency bandwidth used in the sound processor is 125 Hz in the linear range of
the frequency allocation table (FAT) below approximately 1 kHz. As a result, an offset of ‘1’ for subjects 1-24 indicates that the pitch percept was within the range of the adjacent frequency band (upper and lower boundaries of 314 Hz and 438 Hz respectively), and -1 indicates a pitch percept within the range 63-187 Hz. For those subjects an offset of ‘2’ the pitch estimate was between 439 Hz and 563 Hz. The dotted lines signify the -1 to +1 range, i.e. the range in which the pitch estimate would fall within the allocated frequency range. The dashed line signifies the reference point of zero.

Pitch estimates for S1-S13 largely fell within the allocated filter boundaries at the time point just prior to initial activation, and remain relatively stable over the time course of the study. S14 showed an initial electrical pitch within the filter boundary but this increased progressively to the six month assessment point, and then showed a reduction towards the allocated boundary after 12 months of experience. Five subjects (S15, S16, S18, S20 and S25) obtained an initial high pitch percept which then decreased over time to within or near the allocated frequency range. The remaining six subjects showed an initial high pitch percept that remained high after experience. These were S17, S19, S21, S22, S23 and S24. Three of those subjects (S21, S23 and S24) were assessed after two years of experience, and the electrical pitch estimate was shown to have remained high at that time.
**Figure 37:** Individual subject data showing effect of listening experience on the pitch percept obtained from stimulation of the most apical electrode. Plotted is the degree of offset between the electrical pitch percept and the input frequency assigned to electrode (on the y-axis) plotted against the different time points (x-axis) of 0 (pre-activation) and 3, 6 and 12 months post-activation. The dashed line reflects the reference point of 0, and the dotted lines of +1 and -1 filter bandwidth. Data points within the dotted lines indicate that the pitch percept was within the range of allocated frequency to electrode.
Slope of electrical pitch function relative to Frequency Allocation Table

Slope in the electrical pitch function was shallower than the slope used for frequency allocation to electrodes used in the sound processor program. Analysis using the Wilcoxon Signed Rank test revealed no significant group mean difference between the electrical slope values at each time point. Median slope was 0.37 and 0.46 for the initial and 3-month time points respectively (Z=0.847, p=0.43). Median slope was 0.42 and 0.55 for the 6-month time points respectively (Z=-0.259, p=0.82). At the initial and 12-month time points, the median electrical slope was 0.37 and 0.40 respectively (Z=-0.622, p=0.82). A high degree of individual variability was observed. Subjects S5, S7 and S19 showed an initial shallow slope which adapted over time to more closely match the allocated frequency range. Subjects S17 and S24 showed initial match to allocated slope at the time prior to experience and this reduced over time. Most subjects showed little change in slope over time.

8.5 Discussion

Consistent with the majority of previous studies, initial pitch estimates obtained within the current study were lower than would be predicted by the spiral ganglion frequency-position map or from Greenwood’s function (Greenwood, 1990; Kawano et al., 1996). Only 28% of initial pitch estimates on the most apical electrode were within or above the range predicted by Stakhovskaya et al. (2007). The slope of the electrical pitch function was shallower than that predicted by Stakhovskaya et al. (2007), consistent with prior studies by Blamey et al. (1996b), Baumann and Nobbe (2006) and Boex et al. (2006). The initial slope in electrical pitch in the current study (prior to listening experience with the cochlear implant) was 0.37 of the slope of the spiral ganglion frequency-position function.

Influence of pre-operative implanted ear hearing thresholds on pitch estimates

The finding that subjects with better pre-operative unaided acoustic thresholds in the implanted ear had closer match to the predicted pitch, both for the most apical electrode and for the slope of the electrical pitch function, is consistent with the hypothesis proposed by McDermott et al. (2009) that a contributor to the lower than predicted pitch percept may be poor neural survival within the stimulated region of the cochlea.
However it is important to consider that the significant correlations observed between the variables for the apical electrode were not robust, since this was affected by removal of the apparent outlier from the data. Including more subjects with better hearing thresholds, as in the case of the subject removed from the dataset, would be important to examine further the data collected for the apical electrode. A stronger correlation was observed between the pre-operative threshold and the degree of slope match, as compared to the single apical electrode measure. Such data describing the effect of implanted ear thresholds on the degree of pitch match is not available from the majority of prior publications, since the focus has been on reporting the degree of hearing in the ear contralateral to that implanted, i.e. that which was typically used as the reference acoustic test condition. Only the publication by McDermott et al. (2009) reported inclusion of two subjects with hearing in the implanted ear, since the hearing was maintained post-operatively and used as the acoustic reference. Given that there is evidence that unaided audiometric threshold measures are not particularly sensitive to detecting loss of cochlear afferent synapses and cochlear nerve degeneration (Kujawa and Liberman, 2009; Lopez-Poveda and Barrios, 2013), it is possible that use of different measures may have resulted in a closer match in electrical pitch percept to that predicted by the spiral ganglion model.

Influence of contralateral hearing thresholds on pitch estimates

Contrary to the findings of Vermeire et al. (2008) and Carlyon et al. (2010), the subjects with normal or near normal hearing in the ear contralateral to the implant did not necessarily show a close match in the electrical pitch percept to the spiral ganglion function. Although the three subjects with normal hearing across the frequency range did show close match to the predicted function, another subject with only a mild hearing impairment in both the low and high frequency region experienced an initial low frequency percept. Three additional subjects with mild hearing impairment in the cochlear frequency corresponding to the apical electrode location, showed varied pitch estimates. There was no significant correlation between the degree of hearing impairment in the contralateral ear and the degree of initial pitch match in the current study.

Influence of duration severe-profound hearing loss on pitch estimates

Another clinical indicator of neural survival may be the duration of hearing impairment, either through an effect of peripheral function or to the potential for cortical re-
organisation in response to auditory deprivation. Although no significant effect of
duration of severe-profound hearing impairment on the degree of initial pitch match was
observed in the subject group examined within the current study, it is possible that this
may have been affected by the reliance on subject-reported audiological history for
collection of the information. Assessment of duration of hearing impairment is often
difficult in the clinical setting, because the majority of subjects do not have prior
audiograms available for reference, and it is often difficult to obtain frequency specific
and ear specific information. Further investigation as to the potential relationship
between duration of hearing loss and initial pitch estimates may be warranted in a larger
number of subjects, in which the variability associated with potential for inaccurate
hearing history information would be reduced.

There is no evidence in the current study of high frequency hearing loss affecting the
electrical pitch percept. It would be hypothesised that auditory cortex re-organisation that
occurs in response to high frequency hearing loss might result in lower than predicted
pitch perception in the basal region of the cochlea (Irvine et al., 2003; Fallon et al.,
2009b). No correlation was observed between the degree of high frequency hearing in
the better hearing, contralateral ear, and the degree of match in apical electrode pitch or
slope of the electrical pitch function to that predicted by the models.

Effect of listening experience on pitch estimates relative to assigned frequencies

The absence of clear evidence of longitudinal change in the group mean pitch estimates
in this study is consistent with the study findings by Carlyon et al. (2010), where it was
suggested that the degree of match between acoustic and electric pitch was not affected
by experience in the small group of subjects evaluated. The current study findings do not
support the hypothesis that listening experience explains the lower than predicted
electrical pitch percept that has been observed in some prior studies, including that by
McDermott and Varsavsky (2009), in which electrical pitch estimates were lower for a
group of subjects post-experience as compared to a separate group assessed prior to
device activation.

Similar to the results of Reiss et al. (2007) and Reiss et al. (2014), the longitudinal pitch
estimates from the current study showed a degree of variability. Eight subjects showed
a post-experience reduction in pitch percept on the most apical electrode, eight showed a
slight increase, and nine subjects showed no change in pitch percept between the pre- and post-experience time points. For subjects with an initial apical electrode pitch percept that was close to the input frequency allocation to that electrode in the sound processor (typically ranging from 188 to 313 Hz), there appeared to be little or no change in the pitch percept associated with listening experience. For subjects with an initial pitch percept that fell within one filter boundary of the allocation to electrode, i.e. less than the lower filter cut-off of 188 Hz, or between 313 and 563 Hz, the pitch percept tended to increase slightly, or remain unchanged, between the pre-activation and 12 month post-experience time points. Seven of nine subjects with a pitch percept that fell within 2-3 filter boundaries higher than the frequency allocation showed a reduction in the pitch percept with experience. All subjects with a pitch higher than an offset of three filter boundaries did not show a substantial change in pitch over time. This finding cannot be understood in terms of the predictive factors examined within the study. The lack of adaptation for subjects with a high initial pitch percept is consistent with that reported by Reiss et al. (2014), where three of eleven subjects experienced a high pitch percept which did not adapt over time. Although the findings for two of those subjects may be explained by the lack of interaction between electric and the contralateral acoustic hearing, the lack of adaptation for the third subject was unexplained.

It may be hypothesised that a longer time of device experience may be required for change in electric pitch percept, i.e. longer than the 12 month period of evaluation assessed within the study. Reiss et al. (2007) reported individual variability across all subjects tested, however suggested that those subjects tested over a time scale of less than one year showed more variable changes in pitch than those assessed with up to 60 months of experience post-activation. Ongoing assessment of electrical pitch over time with the current subject group would be beneficial in monitoring whether change occurs after more extended listening experience with the cochlear implant. However, testing of three subjects at two years post-activation showed sustained high pitch percepts, so listening experience may not account for this effect. Of the three subjects with very high pitch percepts at the 12-month evaluation point, two subjects (S23 and S24) were within the group assessed at 2 years post-implantation.

Even if more time would be required for adaptation of the electrical pitch percept to the allocated acoustic frequency range, the inability of some subjects to adapt over a 12 month
period suggests that optimisation of the sound processor parameters may be beneficial. Adjustment of the frequency allocation to electrodes may result in improvement in measures of clinical performance, such as speech perception and subjective ratings of sound quality. Investigation of potential correlation between the measures of electric pitch perception and aspects of clinical performance may provide important information regarding the potential application of optimising the sound processor program to best match the acoustic hearing in the contralateral ear.

8.6 Conclusions

Closer match in electrical pitch to the spiral ganglion frequency-position function was observed for subjects with better pre-operative unaided hearing thresholds in the ear to be implanted, both for the measures obtained on the apical electrode and for the slope of the electrical pitch function. However, the correlation data for the apical electrode was not robust since it was affected by removal of the subject with best low frequency hearing. Contralateral acoustic hearing measures, and duration of severe-profound hearing impairment in the contralateral or implanted ear, were not correlated with the degree of initial pitch match. No adaptation of the electrical pitch percepts over time was observed for this group of subjects, although there was evidence of adaptation for some subjects.
9 General Discussion

9.1 Risk-Benefit Considerations for Candidates with Pre-Operative Acoustic Hearing

In this thesis a number of clinical questions relevant to the cochlear implant candidate population with substantial pre-operative acoustic hearing were examined. As discussed, the provision of clinical guidance regarding expectations is important to candidates during the pre-operative discussions. For such candidates the decision-making process regarding whether to proceed with implantation would involve consideration as to risk of loss of acoustic hearing, and the likely benefit obtained from combining electrical stimulation from the cochlear implant with the acoustic residual hearing on the contralateral ear. As outlined in the introduction of the thesis, there are a number of particular considerations for this candidate group with regards to risk and benefit. These will each be discussed in the context of the findings from the current research.

9.1.1 Risk to Post-Operative Loss for Candidates with Pre-Operative Bilateral Hearing

In Study A (Chapter 4) the clinical impact of loss of usable acoustic hearing in the implanted ear was evaluated for a group of 19 subjects who presented at the cochlear implant clinic with substantial bilateral acoustic hearing. The findings from the research are particularly relevant for such candidates, due to the risk of loss of acoustic hearing in the implanted ear that may occur either during or after the surgical procedure. Given that a positive outcome with the cochlear implant cannot be reliably guaranteed, candidates must make an informed decision from the information provided by health care professionals about the potential risks and benefits of proceeding with implantation as the intervention of choice. Based on the findings from the current research, it would be expected that most subjects with the degree of pre-operative hearing at the level of the examined cohort (i.e. with greater or equal to 46% phoneme score in both ears, and up to 78% in the ear selected for implantation) would benefit after implantation.

On traditional measures of benefit, which involved assessment of monosyllabic words presented in quiet at 65 dB SPL and sentences presented in coincident 4-talker babble (S0N0) there was a significant group mean post-operative improvement of 31 percentage points and 3.8 dB SRT respectively. The improvement of 31 percentage points on the
word test was likely impacted by ceiling effects with high post-operative scores observed, and so likely underestimates the benefit obtained on that measure. A more substantial group mean SRT improvement of 11.2 dB was observed for the lower presentation level of 55 dB SPL, which is likely to have real world benefit in providing improved perception of soft speech and sounds in the listener’s environment (Alkaf and Firszt, 2007). The larger benefit for the lower presentation level would be expected due to improved audibility across the frequency range obtained with the cochlear implant as compared to the hearing aid.

Of particular importance for this candidate group is the risk to loss or compromise to spatial hearing abilities, since low-frequency interaural timing cues may be accessible through bilateral acoustic hearing but not typically perceived with bimodal devices. For spatial speech in noise configurations that advantaged the hearing aid side, it was possible that a reduction in SRM would arise after implantation if subjects were able to utilise binaural unmasking pre-operatively. The finding that group mean SRM was not reduced after implantation in that test condition (Figure 12), and improved by 2.7 dB when the spatial configuration advantaged the implanted ear (Figure 11), provides confidence in implanting such recipients.

The grouped mean RMS error on the in-booth localisation assessment increased from 20.7 degrees to 41.3 degrees, consistent with findings from Dunn et al. (2010), where use of bimodal devices was shown to result in poorer localisation ability compared to that obtained using bilateral hearing aids. Although the subjective ratings describing real-world localisation ability did not consistently support the objective observation, there were four of the 19 subjects who did report worsening of localisation ability after implantation. Counselling such candidates about the possibility of poorer localisation ability after implantation would be important to ensure that this is considered when deciding whether to proceed with implantation, and that realistic post-implantation expectations are set.

Of interest was the extent to which post-operative spatial hearing ability might be correlated with pre-operative function as measured objectively on an in-booth localisation test. No significant correlation was observed in the current study between an individual’s pre-operative localisation ability and any of the spatial measures of spatial release from
masking, spatial ratings from the SSQ questionnaire and change in localisation ability after implantation. However, further investigation is warranted to explore whether an individual’s pre-operative utilisation of low-frequency fine-timing ITDs with bilateral acoustic hearing impacts post-implantation spatial hearing experience. It is well established that fine-timing ITDs are neither preserved in clinical devices nor well perceived with electrical stimulation in bimodal listeners (Kong et al., 2012; Francart and McDermott, 2013). Although envelope ITDs are retained in clinical sound processors, the ability to utilise those cues may be problematic due to the substantially different signals in the two ears (Francart et al., 2008), and also likely dependent on having acoustic hearing thresholds in the non-implanted ear that allow the use of frequencies higher than about 1-2 kHz (Francart et al., 2009).

The findings from the research should be considered in the context that the ability to preserve hearing during cochlear implantation has been demonstrated (Gantz et al., 2009; Lenarz, 2009; Lenarz et al., 2013; Skarzynski et al., 2014). Although risk to loss of acoustic hearing should be considered and discussed with candidates, the findings from this study suggest that the benefit of implantation typically outweighs the potential risk of loss of implanted ear acoustic hearing in the examined cohort who exceeded the current clinical guidance criteria of the local implanting centre (with more hearing in the implanted ear than recommended by the candidacy guidelines of the Royal Victorian Eye and Ear Hospital).

9.1.2 Potential for Less Benefit in Candidates with Contralateral Acoustic Hearing

In Study B (Chapter 5) the bilateral clinical outcomes were examined for a group of candidates with more hearing in the contralateral (better hearing) ear than would have been recommended for implantation based on local candidacy guidance criteria. Those candidates had pre-operative phoneme scores in the contralateral ear that ranged from 67% to 100% (and when scored as word rather than phoneme scores ranged from 27% to 100% with a median of 67%). Significant group mean post-implantation benefit of 2.4 dB and 4.0 dB were obtained on the SRT in babble test at presentation levels of 65 dB SPL and 55 dB SPL respectively (Figure 18). A 2.1 dB spatial release from masking benefit was also observed when the noise location was at 90 degrees ipsilateral to the hearing aid and speech was presented from directly in front of the listener, i.e. when the
implanted ear was advantaged by the head shadow (Figure 19). Self-reported rating of benefit was also observed for responses on the SSQ questionnaires, with group mean advantage of 3.0, 2.2 and 2.1 on the speech, spatial and quality sub-scales respectively (Figure 20).

Of particular interest within the current study was the influence of contralateral hearing on post-implantation benefit on each of the clinical metrics. A lower contralateral word score was significantly correlated with more post-implantation SRT benefit at both presentation levels of 65 and 55 dB SPL, and with the self-rated ability to detect soft sounds and speech. However there was no significant correlation between the contralateral word score and other clinical measures of spatial release from masking, functional real-world ratings on the SSQ questionnaire and the majority of other questions as listed on the Device Use questionnaire (listening in quiet situations, in noisy situations, on the telephone and localising the direction of sounds). The more substantial benefit provided for candidates with less contralateral hearing is generally consistent with that reported by Vermeire and Van de Heyning (2009), however differences were observed between studies. In the study by Vermeire and Van de Heyning (2009) outcomes were compared for two groups of subjects; those with aided contralateral hearing and a PTA of between 38-79 dB HL, and those with unaided thresholds of better than 38 dB HL. Significant benefit was reported for the group with more compromised contralateral hearing on a spatially separated test in noise and on the subjective ratings obtained on the speech hearing and quality sub-scales of the SSQ. In the current study there was no significant correlation between the degree of contralateral hearing and the degree of benefit obtained after implantation. The difference between studies may be attributed to the classification approach used by Vermeire and Van de Heyning (2009), however additional research would be required to further understand the observed differences.

The current study investigated whether candidates with better contralateral hearing might take longer to acclimate to the device in the post-operative period. It utilised an approach that quantified the time taken to reach 90% of the 12-month final SRT. Although there was no significant correlation between the examined explanatory variables (contralateral word score, pre-operative implanted word score, age at the time of implantation and duration of severe-to-profound hearing loss) and the time taken to reach 90% of the final SRT value, further research is warranted. There is no prior published information as to
the potential impact of contralateral hearing on rate of progress after implantation. It is possible that a different approach to quantifying rate of post-implantation benefit may have yielded different findings. For example, more regular monitoring of progress after implantation than used in the current study might indicate a different pattern of learning that was not evidenced by the measurements obtained only at 3, 6 and 12-months post-activation.

9.1.3 Inability to Predict Post-Implantation Outcomes

Improving the ability to predict outcomes after implantation would provide increased confidence to both candidates and clinicians during the pre-operative counselling process, and would also potentially enable more individualised management of implanted recipients. Post-implantation it may be possible to track a recipient’s progress against expectations and determine the need for additional intervention, however the utility of such an approach depends on the reliability of the outcome prediction.

In Study C (Chapter 6) a range of explanatory variables were investigated as predictors of unilateral word recognition scores in quiet, which is the approach that has been taken to date in a number of outcome prediction studies in the published literature. Also investigated were the factors that predicted bilateral word recognition, which has not been considered in the majority of published research. For a candidate with hearing in the non-implanted ear, it is of most real world relevance to predict the level of bilateral performance, particularly when considering the extent to which the acoustic and electric stimulation are likely to be synergistic. The current study examined the factors correlated with bilateral word in quiet scores and SRT values obtained in noise.

In this group of cochlear implant recipients with pre-operative acoustic hearing in one or both ears, a shorter duration of severe-to-profound hearing loss in the implanted ear was shown to be predictive of better unilateral and bilateral outcomes. Duration of hearing loss in both ears was not found to be a significant predictor in the examined group. Although it has been established in past research that the duration of bilateral as compared to unilateral (implanted ear) hearing loss is likely of most importance in predicting unilateral outcomes, the subjects examined in the current study did not have bilateral pre-operative hearing loss due to hearing in one or both ears at the time of enrolment. Although it was hypothesised that the impact of auditory deprivation in the implanted ear
might not be a significant predictor in the candidate population with pre-operative acoustic hearing, that was not supported by the current findings. However, further research is warranted to better understand the impact of unilateral duration of severe-to-profound hearing impairment in a larger number of subjects with long-term hearing impairment of greater than 30 years.

Better contralateral hearing with the hearing aid alone was associated with poorer unilateral word scores with the cochlear implant, but better absolute bilateral speech recognition. As a result, it is clear that different models would need to be developed to predict unilateral and bilateral post-implantation scores. The apparent negative influence of better hearing in the contralateral ear on implant-alone outcomes is contrary to the observation of Lazard et al. (2012). It is possible that the relatively small number of subjects in the cohort examined by Lazard et al. (2012) and the classification approach used in that study might explain the differences observed between the studies, however this warrants further research. Although bilateral outcome prediction models would likely be the preferred approach in the clinical setting, there are practical advantages of implementing a unilateral model. Such a model would be easier to implement through, for example, direct streaming of audio signals to a well controlled and standardised device, and avoid additional variance attributed to contralateral hearing aid function. Future research would also be beneficial in understanding the extent to which the poorer unilateral cochlear implant word scores in recipients with higher contralateral word scores can be explained by lack of attention provided to the cochlear implant during everyday listening. Understanding whether implant alone performance can be improved by unilateral cochlear implant training during the early post-activation period would be of interest for such recipients.

Further research should also be conducted to examine additional demographic factors that might predict post-implantation outcomes, since the known factors identified in this and past research have not been shown to reliably predict speech recognition scores. Inclusion of a broader range of explanatory variables is warranted. These might include measurement of cognitive ability (Heydebrand et al., 2007; Akeroyd, 2008; Besser et al., 2012; Holden et al., 2013), level of social support and engagement in the community, technical competence, and motivation. Additionally, it would be of interest to examine further the extent to which peripheral measures of pre-operative acoustic function, such
as gap detection (Sagi et al., 2009) and spectral discrimination (Won et al., 2007) are correlated with post-operative cochlear implant performance, through providing pre-operative information relating to the integrity of the acoustic neural pathway.

Additional to the influence of demographic and pre-operative hearing configuration factors, it is important to consider the potential impact of device fitting on bimodal outcomes. In Study D (Chapter 7), it was observed that the subject group who showed more rapid benefit in speech recognition after implantation had a closer match between the frequency assigned to the most apical electrode and the frequency corresponding to the pitch percept elicited from stimulation on that channel. However, that significant finding was only observed when testing was conducted in the cochlear implant alone condition. With use of bilateral devices, there was no significant difference across the groups. Similar to that finding was the observation that the extent to which the frequency assignment matched the electrical pitch percept impacted unilateral but not bilateral word recognition scores in quiet. That finding was robust to inclusion in a multiple linear regression model, which revealed that a closer pitch match and poorer contralateral ear hearing sensitivity together accounted for 44.8% of the variance in word score.

The absence of a significant effect of the degree of pitch match and clinical function in the bilateral condition may be largely due to the substantial reliance on the contralateral acoustic hearing. It is further possible that use of the word test presented in quiet was not a sensitive measure, since subjects would not have been required to utilise binaural cues which might have been negatively impacted by frequency mismatch (Francart and Wouters, 2007; Francart and McDermott, 2013). It is possible that a more difficult test in noise might force listeners to make better use of both ears.

9.2 Factors Influencing Electrical Pitch Percept in Bimodal Listeners

Given the research finding in the current study of the apparent importance of mapping input frequencies to the elicited pitch percept for optimal speech recognition, it may be beneficial to consider using such an approach in the clinical setting. However, there is considerable complexity in obtaining reliable pitch estimates, and each of the recommended procedures are time-consuming when the required controls are in place to adequately control for non-sensory bias (Carlyon et al., 2010). Additionally, the task of comparing two perceptually different acoustic and electric signals is difficult for many
listeners. Although post-operative imaging techniques might provide information regarding intracoehlear electrode position, there is considerable variability across subjects with respect to which the pitch percept that is elicited in response to electrical stimulation and the extent to which the pitch percept differs from that expected based on the organ of Corti (Greenwood, 1990; Kawano et al., 1996) and spiral ganglion (Stakhovskaya et al., 2007) models.

Research findings from Study D, outlined in Chapter 8, describe the results of a comprehensive investigation as to the factors correlated with match in electrical pitch percept to the spiral ganglion model. Contrary to the findings of Carlyon et al. (2010) and Vermeire et al. (2008), the degree of hearing in the contralateral ear was not correlated with the extent to which pitch percept was matched to the model. Rather, a better pre-operative unaided audiometric threshold that corresponded to the expected frequency based on insertion angle was shown to be correlated with both a better apical electrode pitch match and closer match in slope to the electrical pitch function. That finding is consistent with the hypothesis of McDermott et al. (2009) that a contributor to the lower than expected pitch percept reported in a number of prior studies may be poor neural survival within the stimulated region of the cochlea. However, given that the significant correlation found in the present study was not robust to removal of an outlier in the data relating to the apical electrode pitch percept, it is important to verify this finding in a larger subject group. On the other hand, it is possible that different measures than unaided thresholds, which are more sensitive to detecting loss of cochlear afferent synapses and cochlear nerve degeneration might have led to a stronger correlation.

Further research is warranted to understand the contributors to variability in electrical pitch perception and, in future, may lead to improved approaches to individualise the mapping and potentially improve clinical outcomes for implanted recipients. Such work should also investigate the impact of place-pitch mismatch on spatial hearing ability, since that may be an important consideration for bimodal listeners. Mismatch in place of stimulation has been reported to adversely affect ILD discrimination in normal-hearing listeners (Francart and Wouters, 2007; Francart and McDermott, 2013). However, additional differences in signal processing characteristics, and perceptual consequences associated with use of differing stimulation modalities, are likely to impact the ability to
utilise both ITD and ILD cues with bimodal devices. A review of those factors is provided by Francart and McDermott (2013).

It might be hypothesised that the degree of pitch mismatch could explain in part the observation by Blamey et al. (2013) and Lazard et al. (2012) of post-implantation improvement with cochlear implant device experience. However, based on the analysis in Study E, outlined in Section 9, there was no evidence of a systematic change in the electrical pitch percept to match the assigned frequency range over the 12-month period for the 25 bimodal listeners assessed in that longitudinal study design. That finding is also consistent with a recent study (Reiss et al., 2015) in which variability and lack of consistent pitch adaptation was reported in bimodal listeners, and hypothesised to be different to that observed in listeners utilising the hybrid device with acoustic and electric stimulation in the same ear (Reiss et al., 2007; Reiss et al., 2012; Reiss et al., 2014). Carlyon et al. (2010) also reported lack of change in perceptual pitch over time in a small group of bimodal listeners. It would be beneficial in future research to understand the reasons for the apparent lack of systematic pitch adaptation in bimodal listeners, since lack of adaptation would further strengthen the clinical need to optimise the device fitting to achieve maximum post-implantation outcomes. An important consideration is that some listeners did not appear to experience adaptation even after 1-2 years of use. Further research might investigate the extent to which modification to the frequency allocation to best match the perceived pitch provides benefit in bimodal listeners.

Although the benefit of matching acoustic frequency to the correct acoustic place in the cochlea has been demonstrated using vocoder simulations in normal hearing listeners (Dorman et al., 1997; Shannon et al., 1998; Fu and Shannon, 1999; Baskent and Shannon, 2003), and in acute experiments with cochlear implant recipients (Baskent and Shannon, 2004), research to date has focused on testing electrical stimulation in the implanted ear alone. In that listening condition degradation in unilateral speech recognition has been reported in simulations of insertion depth of less than approximately 19mm (Faulkner et al., 2003; Baskent and Shannon, 2005) when the acoustic input frequency range assigned to electrodes was truncated to provide only place-matched information. Those experiments suggest that assignment of an analysis frequency of greater than 1000 Hz to the apical electrode, i.e. removing lower-frequency acoustic information from the electrical signal, would result in poorer unilateral speech recognition. Such a condition
would be expected to arise for an electrode insertion angle of approximately 360 degrees, since the acoustic analysis frequency range that would be assigned to the most apical electrode would range from 938 Hz to 1063 Hz in the Nucleus device.

Provision of low-frequency information via a hearing aid may reduce the negative impact of reduction in the acoustic analysis bandwidth. In listeners with acoustic hearing there may be benefit in better matching the acoustic analysis signal to the correct cochlear place, and more ready acceptance of such an approach due to complementary low frequency information being provided by the hearing aid. Although there is some evidence of place-pitch mismatch resulting in poorer unilateral speech recognition in noise in cochlear implant listeners (Dorman et al., 1997; Shannon et al., 1998; Fu and Shannon, 1999; Baskent and Shannon, 2003; 2004), there is no published data describing the impact of such a mismatch on bilateral (bimodal) outcomes. This is an area that warrants further investigation.

9.3 Considerations Regarding Practical Development of Candidacy Guidance

Findings from research such as that described within the current thesis can assist in the development of a clinical candidacy guidance tool. There are a number of considerations as to the development of such a tool, and a range of different approaches that could be taken. Following is a discussion of key issues and considerations that are likely to be relevant.

a) Approaches to Classifying Pre-Operative Hearing Loss

i. Speech perception criterion

The initial classification approach taken within the current thesis involved use of pre-operative phoneme recognition score on a monosyllabic word test, in line with the local candidacy guidance criteria as applied within the Royal Victorian Eye and Ear Hospital clinic. Use of a speech perception criterion has validity in that it is likely more representative of functional hearing ability than a threshold-based criterion. However, a particular challenge with such an approach is that there are currently no globally agreed candidacy criteria, nor any standardised test material to control inter-regional and inter-clinic differences. Future development
of a candidacy guidance tool based on speech perception classification criteria would either require development of a globally standardised materials or normalisation applied to outcomes with different materials applied globally. An additional limitation with respect to classification based on pre-operative speech perception ability is the lack of frequency-specific information which can be obtained by such a measure, which might be particularly important when considering guidance relating to spatial hearing ability and the likely access to pre- and post-implantation binaural cues.

ii. Unaided threshold criterion
Classification based on pre-operative unaided or aided thresholds may be beneficial in that the measure is globally standardised and frequency-specific. Quantifying the degree of hearing loss across frequencies would be more beneficial than a speech perception-based criterion in assessing likely access to bilateral ITD and ILD cues in the pre- and post-implantation device combinations. There is evidence in the published literature of a relationship between unaided audiometric thresholds and functional spatial hearing ability. A greater degree of bilateral acoustic hearing impairment has been shown to result in poorer horizontal localisation ability in hearing aid users (Noble et al., 1994) and is particularly a factor at relatively low signal presentation levels where audibility is more likely to be compromised. Lower self-reported ratings of localization ability in real-world environments have also been reported for subjects with a 4-frequency pure-tone-average of > 50 dB HL as compared to listeners with lesser degree of hearing loss (Noble et al., 1995). However, there remains a degree of individual variability as to ability to utilise binaural cues, that cannot simply be explained by the audiometric thresholds.

iii. Functional access to ITD and ILD cues
Classification based on direct measurement of functional access to pre-operative binaural cues might be beneficial in the clinical setting in aiding prediction of post-implantation spatial hearing ability. However, in
applying such a pre-operative categorisation approach, it would be important to further understand the pre- and post-operative ability of bimodal listeners to utilise such cues in real-world environments. Although there was an observed group mean reduction in localisation ability in listeners who lost hearing in the implanted ear in Study A, the effect of loss of acoustic hearing was not reported as being as significant in real-world use. No correlation was observed between the pre-operative localisation ability and post-implantation change in localisation ability, benefit from spatial release from masking or subjective ratings of spatial hearing ability in the take-home real-world environment. It is possible that listeners who could localise well pre-operatively, but lost acoustic hearing in the implanted ear post-operatively, were able to retain access to spatial information using different methods post-operatively, e.g. by using ILDs or spectral cues. Further research is warranted to understand this further.

b) Application of Multiple Regression Outcome Prediction Models

i. Use of Both Bilateral & Unilateral Models

When discussing expected post-implantation outcomes it would likely be most meaningful to candidates to consider bilateral (bimodal) rather than unilateral outcomes. However, there are advantages of also considering use of a unilateral model. Use of a unilateral model would be simpler to apply clinically, through avoiding additional variability that may occur as a result of variable performance across listeners with the contralateral acoustic device and a need to control the device parameters and settings for the hearing aid in addition to the cochlear implant sound processor. It is clear from the current research that different models would need to be developed to predict unilateral and bilateral post-implantation scores. In the current study, better contralateral hearing was associated with poorer unilateral word scores with the cochlear implant alone, but better absolute bilateral speech recognition.
ii. **Explanatory Variables**

A multiple regression outcome prediction model would only be clinically meaningful if it could account for a substantial degree of variance in outcomes. Similar to past research with more traditional outcome prediction models, the variance accounted for by the current study was less than would be required to provide accurate guidance to candidates. The predictive regression model accounted for only 30.9% of the variance in bilateral SRT in noise, which was the most sensitive clinical measure examined since it was not impacted by ceiling effects. Better post-implantation bilateral SRT values in noise were obtained in subjects who were younger, had better contralateral ear unaided audiometric thresholds (or higher contralateral word scores) and who had a shorter duration of severe-to-profound hearing loss in the implanted ear. The inclusion of additional explanatory variables such as cognitive ability and social engagement might improve the predictive ability and make application of such a bilateral model more clinically meaningful.

iii. **Outcome Measure**

Although past research has involved prediction of speech recognition in quiet or spatially coincident noise, it would be important in the expanded population to consider a wider range of clinical metrics. Use of a more comprehensive battery that incorporates functional outcomes and spatial hearing abilities would be beneficial in providing accurate guidance. The utility of such measures was shown in the current study by the post-implantation benefit provided as a result of head shadow advantage provided to the shadowed ear in listeners with contralateral hearing, as well as the functional hearing outcomes obtained for recipients with normal or near-normal hearing in the contralateral ear. It was evident also that implantation for the bilateral listeners resulted in more substantial benefit when the signal was presented at a softer than conversational level of 55 dB SPL, which is likely to have real world benefit in providing improved perception of soft and distance speech and sounds in the listener’s environment.
iv. Patient-Centric Candidature
With the broad range of candidates being assessed for implantation there may be benefit in segmentation when considering application of outcome prediction models. Such segmentation would facilitate tailoring of the candidacy guidance to an individual’s key areas of concern with respect to expected post-operative outcome. A candidate with bilateral severe-to-profound hearing loss, for example, would likely be most interested in the likelihood of speech perception improving in quiet and noise, and be unable to localise pre- and post-operatively so would not require discussion in that area. A candidate with functional pre-operative bilateral acoustic hearing would likely be interested not only in expected speech perception in noise, but also localisation ability. Similarly, a candidate with asymmetric or unilateral hearing loss would not be concerned as to whether speech perception would improve in quiet, but would be particularly interested in expected spatial hearing improvements and also speech perception in noise. The potential benefit of a segmented approach for candidacy guidance can be clearly understood by considering the risks and benefits relating to expected change in localisation ability post-implantation. Although candidates with low frequency bilateral acoustic hearing have potential for a reduction in localisation ability, those with unilateral hearing loss do not risk loss of localisation ability; rather those candidates have capacity to gain localisation ability through access to bimodal cues not available pre-operatively.

9.4 Summary
In summary, the findings from the current research support cochlear implantation as a viable intervention to improve hearing of candidates who present with substantial pre-operative acoustic hearing in one or both ears. Additionally, the research has provided information related to risk-benefit considerations to assist clinicians when counselling candidates pre-operatively: 1) the risk to post-operative hearing loss in the implanted ear for candidates with pre-operative bilateral acoustic hearing; 2) potential for less post-
implantation benefit for candidates with more salient contralateral hearing; 3) lack of knowledge as to the factors that predict unilateral and bilateral speech recognition in the ‘expanded’ candidate population.

A summary of key outcomes or new knowledge attained from each study is outlined below:

**Study A: Outcomes for Recipients Experiencing Loss of Usable Acoustic Hearing in the Implanted Ear**

- Significant group mean post-operative benefit was observed on all clinical measures except for localisation ability.

- Benefit was particularly evident at soft levels (55 dB SPL target speech) with an 11.2 dB SRT post-operative improvement.

- Findings provide confidence in implanting recipients with bilateral acoustic hearing however risk to poorer post-operative localisation ability warrants discussion in the clinical setting.

- Although the objective assessment of localisation ability revealed a group mean increase in RMS of 20.7 degrees, subjective ratings of post-operative change in localisation in real-world environments were more variable.

- There was no correlation between change in spatial hearing ability and pre-operative utilisation of binaural cues as measured using an in-booth localisation test.

**Study B: Influence of Contralateral Acoustic Hearing on Bimodal Outcomes After Cochlear Implantation**

- Findings provide confidence in implanting candidates with contralateral acoustic hearing (as examined with a median monosyllabic word score of 67%, and range 27-100%).

- Degree of contralateral hearing did not have a substantial influence on real-world ratings of benefit as obtained through functional listening questionnaires.
- Although less benefit was observed for candidates with better contralateral hearing on measures of speech recognition in spatially coincident noise and ability to detect soft sounds, there was no significant correlation for the range of other outcome measures examined (spatial release from masking, self-reported ratings on the Device Use Questionnaire and each of the SSQ subscales).

- A group mean benefit of 2.1 dB was observed when the cochlear implant side was advantaged by the head shadow.

**Study C: Influence of Contralateral Acoustic Hearing on Bimodal Outcomes After Cochlear Implantation**

- Factors predicting unilateral cochlear implant alone word in quiet scores in the examined cohort differed from those identified in past research:
  
  - Age at implantation was not a significant predictor.
  
  - Better contralateral hearing was correlated with poorer unilateral cochlear implant alone scores, contrary to the findings of Lazard et al. (2012).
  
  - Poorer word scores in listeners with a longer duration of severe-to-profound hearing loss in the implanted ear is contrary to the hypothesis that unilateral auditory deprivation is not important when input to the central auditory system is maintained, however further investigation is warranted in a larger number of subjects with long-term loss of greater than 30 years.

- Better contralateral hearing was associated with poorer unilateral word scores but better bilateral (bimodal) speech recognition.

- Although a number of pre-operative factors were identified as predictors of unilateral and bilateral word recognition in quiet, and of bilateral SRT in babble, there remains a large degree of unexplained variance.
  
  - The predictive regression model accounted for 34.1% of the variance in unilateral word recognition scores in quiet. Factors that predicted better
scores were a shorter duration of severe-to-profound hearing loss in the implanted ear and poorer pure-tone-averaged thresholds in the contralateral ear.

- The predictive regression model of post-implantation bilateral function accounted for 36.0% of the variance for word scores in quiet, and 30.9% of the variance for SRT in noise. A shorter duration of severe-to-profound hearing loss in the implanted ear, a lower age at the time of implantation, and better contralateral hearing thresholds were associated with higher bilateral speech recognition outcomes.

**Study D: Influence on Speech Recognition of Match Between Frequency Assignment to Electrodes in the Sound Processor and Electrical Place-Pitch Percept**

- A closer match between the electrical place-pitch percept on the apical electrode and the assigned acoustic frequency in the sound processor was shown to be associated with both a more rapid improvement in unilateral cochlear implant alone improvement in speech recognition in quiet and noise, as well as a higher unilateral word score in quiet.

- No significant correlation was observed between degree of electrical place-pitch match and bilateral speech recognition ability.

**Study E: Factors Influencing Electrical Place-Pitch Perception in Bimodal Listeners**

- There was no evidence of a systematic change in the electrical pitch percept over time for the examined cohort, and observed residual mismatch after 12 months of cochlear implant use for some subjects.

- Recipients with better pre-operative thresholds, and potentially better neural survival, had an electrical pitch percept that more closely matched that expected from the cochlear and spiral ganglion models. That finding is consistent with the hypothesis of McDermott et al. (2009) that a contributor to the lower than predicted pitch percept as reported in past research may be poor neural survival within the stimulated region of the cochlea.
Lack of correlation between the electrical pitch match and degree of contralateral hearing is contrary to published findings (Vermeire et al., 2008; Carlyon et al., 2010; Reiss et al., 2015).
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## 11 Appendix 1 – Individual Subject Demographic Information

Individual subject demographic information including gender, age at the time of implantation, duration of hearing loss in the implanted ear, duration of severe-to-profound hearing loss (SPHL) in the implanted ear, and duration of bilateral SPHL.

<table>
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<th>Subject</th>
<th>Gender</th>
<th>Age at Implantation (years)</th>
<th>Aetiology</th>
<th>Duration hearing loss implanted ear (years)</th>
<th>Duration SPHL implanted ear (years)</th>
<th>Duration bilateral SPHL (years)</th>
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12 Appendix 2 – Individual Subject Device Information

Individual subject device information, including electrode type, the hearing aid used in the ear selected for implantation pre-operatively, the contralateral hearing aid type, sound processor type, whether the acoustic hearing in the implanted ear was amplified using an acoustic component, and the acoustic input frequency assignment range to electrodes in the sound processor.

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### Appendix 3 – Individual Subject Pre-Operative Phoneme and Word Scores

Individual subject pre-operative phoneme and word scores (in %) for each of the implanted and contralateral ears.

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Clinical Outcomes for Adult Cochlear Implant Recipients Experiencing Loss of Usable Acoustic Hearing in the Implanted Ear

Kerrie L. Plant, 1, 2 Richard J.M. van Hoesel, 1, 3 Hugh J. McDermott, 3, 4 Pamela W. Dawson, 1, 2 and Robert S. Cowan 1, 5

Objectives: The first aim of the study was to quantify the change in clinical performance after cochlear implantation for adults who had pre-operative levels of usable hearing in each ear of greater than or equal to 46% phoneme score on an open-set monosyllabic word test, and who subsequently experienced loss of usable acoustic hearing in the implanted ear. Pre- and post-operative spatial hearing abilities were assessed, because a clinical consideration for candidates with bilateral acoustic hearing is the potential for post-operative reduction in spatial hearing ability. Second, it was of interest to examine whether pre-operative localization ability, as an indicator of access to interaural timing and level cues preoperatively, might be correlated with post-operative change in spatial hearing abilities.

Design: Clinical performance measures in the binaural condition were obtained preoperatively and at 12 months postoperatively in 19 post-linguistically hearing-impaired adult subjects. Preoperative localization ability was investigated as a potential correlate with post-operative change in spatial hearing abilities.

Results: Significant postoperative group mean improvement in speech perception was observed on measures of open-set monosyllabic word perception in quiet and on an adaptive sentence test presented in coincident 4-talker babble. Observed benefit was greater for a lower presentation level of 55 dB SPL, as compared with a conversational speech level of 65 dB SPL. Self-reported ratings of benefit also improved for all questionnaires administered. Objective assessment of localization ability revealed poorer localization postoperatively, although subjective ratings of post-operative change in localization ability in real-world environments were more variable. Postoperative spatial release from masking was not different to that measured preoperatively for the configuration where the side of the head with the hearing aid was advantaged, but improved postoperatively for the configuration that advantaged the implanted side. Preoperative binaural localization ability was not correlated with postoperative spatial hearing abilities.

Conclusions: The findings from this study support cochlear implantation for candidates with pre-operative levels of binaural acoustic hearing within the range examined within the present study. This includes subjects with preoperative open-set monosyllabic word scores ranging from 11 to 62% in the implanted ear, and from 15 to 75% on the contralateral side. Post-operative improvement would be expected for those subjects on a range of clinical measures, even when acoustic hearing was lost in the implanted ear after implantation.

Key words: Acoustic hearing, Bimodal, Candidacy, Cochlear implant, Outcomes.

INTRODUCTION

Cochlear implantation is a well-established clinical intervention for restoring hearing function in recipients with severe-to-profound sensorineural hearing loss. Significant advancements in implantable and external technology design and in surgical techniques have led to progressive improvements in postoperative speech recognition and contributed to an expansion in candidacy criteria for implantation over time. Candidates now often present at clinical centers with substantial levels of preoperative acoustic hearing in one or both ears. The development of evidence-based recommendations and guidance for these candidates is important during the preoperative counseling process and in setting post-operative expectations.

Although hearing preservation in the implanted ear after cochlear implantation has been demonstrated with a range of devices (Gantz & Turner 2003; Adunka et al. 2004; Gantz et al. 2004, 2005, 2006; Gostetzner et al. 2004; Fraysee et al. 2006; James et al. 2006; Skarzynski et al. 2006; Baumgartner et al. 2007; Lenarz 2009; Simpson et al. 2009; Skarzynski & Lørens 2010), it is not yet possible to guarantee that hearing will be preserved. Immediate postoperative acoustic hearing preservation has been generally reported to range from 50 to 100% (Fraysee et al. 2006; Baumgartner et al. 2007; Gantz et al. 2009; Lenarz 2009; Skarzynski et al. 2012), although the reported rates vary according to differences in study methodologies, for example, the criteria used to define preservation, and the use of different subject inclusion and exclusion criteria. Additional to the immediate risk to hearing that occurs as a result of electrode insertion, there is evidence of delayed loss in the implanted ear (Baumgartner et al. 2007; Gantz et al. 2009). Risk to postoperative hearing loss in the implanted ear is an important consideration for cochlear implant candidates and it is important to understand the potential implication of loss on functional outcomes postimplantation. Binaural cues may be salient with bilateral hearing aids preoperatively but not available postoperatively with bimodal devices due to the lack of fine-timing information perceived by implant users (Francart et al. 2009). Distortion of envelope timing and interaural level differences with bimodal devices may also be problematic due to the substantially different signals in the two ears (Francart et al. 2008).

The expected effect of transitioning from bilateral preoperatively aided acoustic hearing to use of bimodal devices postoperatively can be partly understood in the context of reviewing...
the literature describing (1) monaural post-operative outcomes for candidates with preoperative acoustic hearing in the ear selected for implantation, (2) the benefit of bimodal device use compared with the cochlear implant alone, and (3) within-subject examination of pre- and postoperative binaural outcomes for candidates with preoperative acoustic hearing.

Examination of monaural outcomes for candidates with preoperative acoustic hearing in the implanted ear has revealed significant benefit from implantation. In those studies, conducted with the FLEX® EAS electrode (Gstoettner et al. 2004; Helbig et al. 2011) and the Nucleus® Contour Advance® electrode (James et al. 2006), postoperative speech recognition was assessed using electrical stimulation alone, and compared with preoperative scores obtained using the hearing aid in the implanted ear. Preoperatively, subjects in those studies had pure-tone average thresholds of less than 65 dB HL in the low frequencies (up to 500 Hz) and greater than 50 dB HL or 60 dB HL thresholds at frequencies greater than 1 kHz. Group mean pre- and postoperative scores were 9% and 48% (Gstoettner et al. 2004), 21% and 52% (Helbig et al. 2011), and 22% and 56% (James et al. 2006). Similar findings have been reported by Gifford et al. (2010) in nine subjects with preoperative speech perception scores that ranged from 0 to 40% and preoperative 500 Hz unaided audiometric thresholds that ranged from 40 to 115 dB HL. Pre- and postoperative group mean scores were 51% and 67%, respectively. Similar benefit has been reported for speech perception improvement in noise (Gstoettner et al. 2004; James et al. 2006; Helbig et al. 2011). Together, these data show the benefit of implantation in improving hearing in the treated ear. However, it is likely of most relevance clinically to consider the binaural outcomes for candidates with preoperative acoustic hearing.

Enhancement in speech intelligibility in quiet and for coincident presentation of speech in noise has been demonstrated in numerous studies that have assessed the benefit provided by contralateral acoustic amplification to cochlear implant recipients (Waltzman et al. 1992; Armstrong et al. 1997; Ching et al. 2001; Tyler et al. 2002; Dunn et al. 2005; Kong et al. 2005; Fisch et al. 2006; Potts et al. 2009). Many recipients have reported preference for the sound quality of the devices used in combination as compared with electrical stimulation alone, as well as improvement in recognition and quality of music (Kong et al. 2005; Giffler et al. 2008; Sucher & McDermott 2009; McDermott 2011). The benefit of adding a hearing aid in the non-implanted ear has largely been attributed to the additional spectral-temporal information provided by the acoustic hearing that is complementary to the spectral information provided by electrical stimulation.

Review of the published literature (Ching et al. 2007; Sammeth et al. 2011) has revealed modest improvement in localization ability using bimodal devices compared with the use of monaural hearing in either ear. Results from studies that have assessed speech perception of spatially separated speech and noise in bimodal listeners (Armstrong et al. 1997; Ching et al. 2004; Dunn et al. 2005; Luntz et al. 2005; Moreta et al. 2005; Mok et al. 2006; Dorman et al. 2008; Potts et al. 2009; Berrettini et al. 2010) have shown little or no benefit attributable to the head shadow effect when the hearing-aid ear had the more favorable signal to noise ratio (SNR). This is likely due to the limitation or absence of high-frequency hearing in the shadowed ear for the subjects evaluated in those studies. As expected, there was no evidence of binaural unmasking or spatial release from informational masking in those clinical assessments, likely as a result of the difficulties of matching of level and timing cues and the absence of perceptible fine-timing in the electrical signal (Francoart & McDermott 2013).

Of particular relevance for candidates considering cochlear implantation is a direct within-subject assessment of pre-operative and post-operative outcomes. The majority of studies conducted in candidates with preoperative bilateral acoustic hearing have involved subjects with steeply sloping hearing loss implanted with hearing preservation devices. Postoperative speech perception benefit in the combined condition (using acoustic hearing in one or both ears combined with electric hearing) as compared with scores obtained in the best-aided bilateral condition preoperatively has been reported in those studies (Gantz et al. 2009; Lenarz 2009; Helbig et al. 2011; Skarzynski et al. 2014). Although benefit of hearing preservation has been demonstrated, Gantz et al. (2009) reported that postoperative change in binaural speech perception, using test materials presented in quiet or with coincident presentation of speech in noise, was not correlated with the degree of hearing loss in the implanted ear. Postoperative contribution of electric hearing provided by the Hybrid 512 device was reported to have more than compensated for any reduction in acoustic hearing thresholds.

Gifford et al. (2010) and Amoodi et al. (2012) also examined outcomes for subjects with binaural speech perception scores that were outside the traditional candidacy guidelines in the United States and Canada. Gifford et al. (2010) described post-operative improvement for a group of 22 subjects with preoperative binaural scores on the monosyllabic consonant-nucleus-consonant (CNC) word test in quiet that ranged from 30 to 60%. In that study, the grouped mean binaural pre- and postoperative monosyllabic CNC word scores in quiet were 41% and 82%, respectively. Individual subject analysis demonstrated that 59% of the patients achieved a significantly higher post-operative score in the implant only monaural condition compared with the preoperative binaural aided condition, and 91% demonstrated a statistically significant benefit in a pre- to post-operative comparison. Similarly, Amoodi et al. (2012) examined speech perception in a group of 27 adult subjects with a preimplantation binaural Hearing in Noise Test (HINT) score of greater than 60%. Preoperative implanted ear monosyllabic word scores ranged from 0 to 44%, and contralateral scores from 0 to 68%. All subjects showed a statistically significant benefit of implantation after 12 months of experience, with grouped mean word scores at the pre- and post-operative assessment of 28.5% and 65.6%, respectively. No subjects experienced post-operative reduction in speech recognition ability. Those positive findings provide evidence that cochlear implantation is a viable treatment option for candidates with substantial levels of pre-operative hearing.

Findings from two studies that have assessed localization ability have shown varied results; one with subjects having bilateral acoustic hearing implanted with the 10 mm Hybrid electrode (Dunn et al. 2010), and the other with subjects having single-sided hearing impairment (Arndt et al. 2011). Although not a direct measure of pre- and post-operative performance, Dunn et al. (2010) compared localization ability using a within-subject design and with a range of device combinations that included binaural hearing aids and bimodal
devices. On a localization test using a range of everyday sounds, all subjects could localize at better than chance levels using bilateral hearing aids. However, only four of the 11 subjects could achieve that outcome using the bimodal device configuration. These data suggest that localization ability is reduced with use of bimodal devices compared with bilateral acoustic aided hearing for subjects with steeply sloping hearing loss. Arndt et al. (2011) examined localization ability in 11 adult subjects implanted with preoperatively asymmetric hearing loss, to compare performance using the acoustic hearing alone before implantation and with the bimodal devices postoperatively. The study utilized a 7 loudspeaker arc in a 180-degree horizontal plane, using sentences from the Oldenburg Sentence Test as stimuli. Median absolute localization error was 33.9 and 15 degrees in the pre- and post-operative conditions respectively, although the post-operative error is likely underestimated due to the measured error being less than the loudspeaker spacing and the likely introduction of quantization effects (Hartmann et al. 1998). Both studies provide evidence that, for some listeners, the use of bimodal devices can provide information to assist with sound source localization. The study by Dunn et al. (2010) also provides a direct indication that bimodal localization ability postoperatively may be poorer than would be obtained with binaural hearing aids preoperatively.

Although positive post-operative outcomes have been reported in subjects with preoperative binaural acoustic hearing, it is of interest to further explore this research for a number of reasons. First, it is important to examine the post-operative experience of subjects with a wider frequency bandwidth of usable acoustic hearing in one or both ears preoperatively than has been reported in literature so far. Analysis of preoperative acoustic thresholds in the population studied by Gifford et al. (2010) revealed that 80% of the 22 subjects had median low-frequency thresholds (across the range 0.125 to 1 kHz) in the better ear of less than or equal to 90 dB HL. However, only 41% had high-frequency thresholds (in the range 1 to 4 kHz) meeting that criterion. Further outcome data for subjects with high-frequency hearing would provide important information for new candidates considering implantation, and would supplement the data reported by Gifford et al. (2010) regarding expected outcomes.

Second, it is important to further examine post-operative change in spatial hearing abilities, given the potential for degraded binaural cues in the bimodal as compared with binaural hearing aid configuration. There is limited published information regarding the spatial hearing outcomes associated with implantation of candidates with preoperative, binaural acoustic hearing, and specifically for those recipients where hearing is lost in the implanted ear during or after implantation. Findings from the study would contribute to the published literature, through providing information relating to outcomes for such candidates. Comprehensive assessment of localization ability and speech perception in spatially separated speech in noise as well as administration of questionnaires to assess real-world performance would be beneficial in providing pre-operative guidance to candidates. Because pre-operative localization may be reflective of a candidate's ability to utilize interaural timing and levels cues with bilateral hearing aids, this may also be predictive of the impact of post-operative loss of acoustic hearing in the implanted ear on general binaural function. Those subjects with better localization ability preoperatively might be more likely impacted by potential disruption of interaural timing and interaural level cues after implantation.

MATERIALS AND METHODS

Subjects

Nineteen postlinguistically hearing-impaired adults participated in the study. All were implanted with Nucleus cochlear implants (the Nucleus Contour Advance®, the Nucleus CI422 cochlear implant with Slim Straight electrode, or the Medtronic Research Array) and used the Freedom™ or CP810 sound processors. Subjects were recruited from the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne, and from the Sydney Cochlear Implant Centre. The decision to proceed with implantation and the provision of clinical devices was managed through the routine clinical protocols in each cochlear implant clinic. No external source of funding for devices was provided during the conduct of the clinical investigation. All recruited subjects had a phoneme score on the monosyllabic CNC word test of greater than 46% in each ear measured individually preoperatively. Those scores were obtained using a presentation level of 65 dB SPL root-mean-squared (RMS), and were an average of scores across two lists of recorded words presented in quiet from a frontal loudspeaker at zero degrees azimuth. Selection criteria were an extension of those used in the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic, with enrollment of subjects having greater speech perception in the ear to be implanted than would be recommended by present local candidacy guidelines. The present selection criteria in the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne are based on a retrospective data analysis conducted with 210 postlingual hearing-impaired adults. Analysis involved a statistical approach based on post-operative outcomes (Dowell et al. 2004) obtained after 3 months of cochlear implant experience.

The analysis revealed that the first quartile phoneme score in the implanted ear was 46%, and so indicated that there would be a 75% chance of improvement for an individual candidate with a preoperative phoneme score that was less than or equal to this value. All subjects who met the preoperative selection criteria were sequentially enrolled into the study based on date of surgery.

Postlinguistic hearing loss was defined as having an onset of deafness later than 2 years of age. Demographic information for each of the subjects is shown in Table 1. The age of the subjects at the time of enrollment into the study ranged from 54 to 76 years, with a mean age of 64.7 years. Table 1 also provides information regarding gender, aetiology of hearing impairment, the duration since onset of hearing loss, the type of electrode, the type of sound processor, the electrical stimulation frequency allocation table, and the hearing aid model used during the study. All subjects used bilateral hearing aids at the time of enrollment in the study.

All except subject S18 used the frequency allocation table in the sound processor that mapped acoustic input frequencies to filters across the range 188 to 7937 Hz. Subject S18 was implanted with the Hybrid™ L24 electrode, and input frequencies were mapped to electrodes using the range 688 to 7937 Hz. The use of the higher frequency range of 688 to 813 Hz on the most apical channel for that subject was consistent with the perceived pitch percept obtained before initial clinical activation of the device.
TABLE 1. Subjects’ demographic information, including gender, age at the time of implantation (in years), etiology of hearing impairment, duration of hearing loss in the implanted ear (in years), type of electrode, type of sound processor used, input frequency allocation range to electrodes, and hearing aid used during the clinical study.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age at Implantation (Years)</th>
<th>Aetiology</th>
<th>Duration Hearing Loss Implanted Ear (Years)</th>
<th>Electrode Type</th>
<th>Sound Processor Type</th>
<th>Input Frequency Allocation Range (Hz)</th>
<th>Implanted Ear/ContraLateral Ear Hearing Aid</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>F</td>
<td>58</td>
<td>Familial/autoimmune</td>
<td>20</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Audeo (Rx in canal)</td>
</tr>
<tr>
<td>S2</td>
<td>M</td>
<td>61</td>
<td>Unknown</td>
<td>58</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Paradoz</td>
</tr>
<tr>
<td>S3</td>
<td>F</td>
<td>54</td>
<td>Unknown</td>
<td>9</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Paradoz 211 dAZ</td>
</tr>
<tr>
<td>S4</td>
<td>F</td>
<td>65</td>
<td>Familial</td>
<td>20</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Savia/Naida</td>
</tr>
<tr>
<td>S5</td>
<td>F</td>
<td>62</td>
<td>Unknown</td>
<td>30</td>
<td>Mita Freedom</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Microsavia</td>
</tr>
<tr>
<td>S6</td>
<td>F</td>
<td>57</td>
<td>Unknown</td>
<td>10</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Savia 211 dSZ</td>
</tr>
<tr>
<td>S7</td>
<td>M</td>
<td>68</td>
<td>Familial</td>
<td>38</td>
<td>Slim Straight</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Siemens Artsi P</td>
</tr>
<tr>
<td>S8</td>
<td>M</td>
<td>71</td>
<td>Noise/familial</td>
<td>50</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Excelia M</td>
</tr>
<tr>
<td>S9</td>
<td>F</td>
<td>64</td>
<td>Otitis externa</td>
<td>40</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Siemens Excelia Art P</td>
</tr>
<tr>
<td>S10</td>
<td>F</td>
<td>74</td>
<td>Unknown</td>
<td>30</td>
<td>Slim Straight</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Siemens Motion 100</td>
</tr>
<tr>
<td>S11</td>
<td>M</td>
<td>66</td>
<td>Unknown</td>
<td>31</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Siemens Intra SP</td>
</tr>
<tr>
<td>S12</td>
<td>M</td>
<td>68</td>
<td>Unknown</td>
<td>20</td>
<td>Freedom</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Siemens Prisma/Senso Diva</td>
</tr>
<tr>
<td>S13</td>
<td>M</td>
<td>58</td>
<td>RI incompatibility</td>
<td>58</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Audeo (Rx in canal)</td>
</tr>
<tr>
<td>S14</td>
<td>M</td>
<td>69</td>
<td>Accident</td>
<td>14</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Oticon Diogotique/Siemens Motion P</td>
</tr>
<tr>
<td>S15</td>
<td>M</td>
<td>76</td>
<td>Unknown</td>
<td>16</td>
<td>Slim Straight</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Naids III dAZ</td>
</tr>
<tr>
<td>S16</td>
<td>F</td>
<td>63</td>
<td>Unknown</td>
<td>44</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Extra 311 AZ</td>
</tr>
<tr>
<td>S17</td>
<td>M</td>
<td>64</td>
<td>Meniere's disease</td>
<td>30</td>
<td>Slim Straight</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Phonak Naids V</td>
</tr>
<tr>
<td>S18</td>
<td>F</td>
<td>68</td>
<td>Ototoxicity</td>
<td>4</td>
<td>Hybrid-L24</td>
<td>CPB10</td>
<td>688–7937</td>
<td>Phonak Audio</td>
</tr>
<tr>
<td>S19</td>
<td>F</td>
<td>64</td>
<td>Meniere's disease</td>
<td>10</td>
<td>Contour Advance</td>
<td>CPB10</td>
<td>188–7937</td>
<td>Widex Flash SL19</td>
</tr>
</tbody>
</table>

The Slim Straight electrode was inserted to 20 mm via the round window membrane, which would be expected to be within the range of insertion angle 300 to 300 degrees (Skarzynski et al. 2012). The Contour Advance and Modular Research Array electrodes were fully inserted for all subjects. Comparative insertion angles for cochleostomy insertion of the Contour Advance electrode have been reported to range from 270 to 400 degrees (Adunka & Kiefer 2006), when excluding cases with a malformed cochlea, or from 230 to 290 degrees (Briggs et al. 2006).

Mean preoperative percentage correct scores on the monosyllabic word test are shown in Table 2, for each of the single ear and the binaural condition. Although phoneme scores were used as enrollment criteria, consistent with that used by the Melbourne Cochlear Implant Clinic, monosyllabic whole word scores were used for pre- and post-operative measurements to minimize the effect of ceiling effects on tests administered postoperatively. Preoperative, binural phoneme scores ranged from 46 to 92%. Approximately 75% of subjects already scored greater than or equal to 70% preoperatively, resulting in limited ability to quantify the degree of post-operative improvement. Subjects are listed in the table in order of lowest to highest binaural preoperative word score. The mean word score in the ear to be implanted ear was 22.4%, and ranged from 11 to 62%. The mean word score in the contralateral (non-implanted) ear was 39.6%, and ranged from 16 to 75%. The mean binaural score for the group of subjects was 44.3%, and ranged from 12 to 81%.

Also shown in Table 2 are the median unaided hearing thresholds for the frequency ranges of 0.125 to 1 kHz ("LF", low frequency), and for 1 to 4 kHz ("HF", high frequency). These values were calculated with a value of 125 dB for the frequencies where there was no measurable response. For subjects S7, S15, and S18 post-operative thresholds were measurable in the implanted ear. All median postoperative thresholds were greater than or equal to 95 dB HL for these subjects. For all other subjects, postoperative hearing tests revealed no hearing in the implanted ear.

Preoperative unaided audiometric thresholds for each subject are shown in Figure 1. Implanted ear thresholds are indicated by unfilled square markers, and contralateral thresholds as filled circles. Absence of thresholds indicates no response at the limits of the audiometer for the specific frequency. Data were not collected for S19 at the frequency of 125 Hz.

Study Design

The study used a prospective, longitudinal, within-subject experimental design in which each subject served as his or her own control. Clinical performance measures were obtained preoperatively and 12 months postoperatively. All testing was conducted at each time point in the bilateral aided condition, that is, bilateral hearing aids preoperatively and the cochlear implant in combination with the contralateral hearing aid post-operatively. A comprehensive test battery was administered at each time point and included measures of speech perception in both coincident and spatially separated noise, self-reported real-world ratings of benefit via questionnaires, and sound source localization in the horizontal plane.

Speech Perception Test Materials and Procedures

A range of different speech perception test materials were administered pre- and postoperatively. All materials were digitally
TABLE 2. Mean pre-operative open-set monosyllabic phoneme and word speech perception scores (shown as percent correct) for each of the monaural and binaural listening conditions. Implanted and controlateral median pre- and postoperative unaided audiometric thresholds for the low (LF, 0.125 to 1 kHz) and the high frequency (HF, 1 to 4 kHz) ranges (in dB HL).

| Subject | C | Binaural | C | Binaural | Pre-operative Median Unaided Audiometric Thresholds (dB HL) | Implanted | Contralateral | Pre-operative Median Unaided Audiometric Thresholds (dB HL) | Implanted | Unaided Audiometric Thresholds Frequency 1 Threshold (Hz | Implanted | Post-operative | Ear | Frequency and Unaided | Ear | Frequency Threshold | dB HL) | dB HL) |
|---------|---|----------|---|----------|-----------------------------------------------------------|-----------|---------------|-----------------------------------------------------------|-----------|------------------------|-----------|-----------------------|-----------|-----------------------|--------|------------------------|
| S1      | 46 | 47       | 49 | 46       | 15 | 18 | 12 | 15 | 18 | 12 | 30 | 30 | 115 | 115 | NR | NR | NR | NR | NR | NR | NR | NR |
| S2      | 47 | 53       | 59 | 47       | 11 | 24 | 23 | 15 | 16 | 25 | 75 | 80 | 90 | 100 | NR | NR | NR | NR | NR | NR | NR | NR |
| S3      | 49 | 47       | 57 | 18 | 16 | 25 | 85 | 80 | 75 | 70 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S4      | 46 | 54       | 50 | 16 | 23 | 25 | 45 | 50 | 85 | 85 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S5      | 47 | 54       | 55 | 17 | 24 | 27 | 35 | 25 | 125 | 125 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S6      | 46 | 47       | 60 | 16 | 19 | 29 | 60 | 55 | 125 | 90 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S7      | 52 | 63       | 67 | 23 | 33 | 30 | 55 | 60 | 80 | 75 | 95 | 95 | 250 | 100; 500 | 195; | 1000 | 190; 2000 | 190; | 4000 | 190 |
| S8      | 52 | 64       | 70 | 19 | 36 | 39 | 50 | 55 | 110 | 90 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S9      | 49 | 71       | 69 | 22 | 41 | 40 | 85 | 80 | 75 | 80 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S10     | 55 | 77       | 74 | 18 | 51 | 42 | 55 | 60 | 70 | 70 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S11     | 64 | 67       | 74 | 31 | 50 | 42 | 70 | 65 | 95 | 85 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S12     | 51 | 77       | 79 | 16 | 51 | 53 | 55 | 65 | 125 | 65 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S13     | 51 | 76       | 79 | 18 | 48 | 54 | 55 | 65 | 125 | 85 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S14     | 47 | 61       | 79 | 18 | 37 | 57 | 80 | 65 | 70 | 85 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S15     | 65 | 80       | 82 | 34 | 58 | 61 | 65 | 65 | 75 | 70 | 100 | 100 | 250 | 110; 500 | 190; | 1000 | 190; 2000 | 190; | 4000 | 1105 |
| S16     | 72 | 73       | 81 | 43 | 41 | 62 | 70 | 70 | 90 | 90 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S17     | 46 | 64       | 80 | 14 | 38 | 64 | 70 | 65 | 70 | 55 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |
| S18     | 78 | 82       | 90 | 62 | 69 | 75 | 55 | 55 | 85 | 80 | 105 | 105 | 500 | 110; 1000 | 115; | 2000 | 1120; 4000 | 105 |
| S19     | 46 | 90       | 92 | 16 | 75 | 81 | 85 | 65 | 65 | 90 | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR | NR |

Implanted ear post-operative unaided audiometric thresholds by acoustic frequency. C, contralateral; I, implanted; NR, no response obtained at the limits of the audiometer (70-25 dB HL).

recorded and presented in a sound-attenuated booth. The sound field was calibrated at the position of the listener using one-third octave noise centered at a frequency of 1kHz, and with an RMS sound pressure level equivalent to that of the speech. The subject was seated at a distance of 1.2 m from each of three loudspeakers; one directly in front and one on each side at an azimuth of 90 degrees. All test items were presented once and no feedback was given to the subjects regarding the correctness of the responses.

Two lists of open-set monosyllabic words were presented in quiet at a level of 65 dB SPL RMS from directly in front of the subject. These words were based on the original CNC words developed by Peterson and Lehiste (1962), with 50 words per list and a CNC structure. Open-set, Australian CUNY sentences were presented in a talker babble, with both signal and noise coincident at the frontal loudspeaker. Two lists of sentences were presented at each of two fixed signal to noise ratios (-10 and +5 dB SNR), to minimize the influence of floor and ceiling effects on test scores. The most appropriate SNR for each listener was selected in the presentation of results. Testing was also conducted using an adaptive sentence in noise test (Austin) (Dawson et al. 2011). This adaptive sentence test was included to ensure performance measures were obtained in the most sensitive region of the performance-intensity function, avoiding issues associated with floor and ceiling effects that would influence the test scores (Mackie & Dermody 1986; Nilsson et al. 1994; Brand & Kollmeier 2002). This was important due to the relatively large changes expected from pre- to post-operative performance for some subjects, and the resultant difficulty in using a single SNR that provided a sensitive measure at each time point. The adaptive test used Bamford-Kowal-Bench (BKB) like sentences and provided the SNR for 50% intelligibility at the pre- and post-operative assessment for each of the speaker configurations and presentation levels. The sentences were developed for Australian use by the Cooperative Research Centre for Cochlear Implant and Hearing Aid Innovation in accordance with the guidelines used in the development of the original Bamford-Kowal-Bench (BKB) sentences (Bench et al. 1979). Each speech reception threshold (SRT) test run comprised 32 sentences, which were a combination of two 16-sentence lists. Sentence presentation level was fixed at either 65 or 55 dB SPL RMS. The target sentence was presented from directly in front of the subject for all configurations, and the noise was either presented coincident with the speech (SO0) or from 90 degrees to the side of the subject (SO90). For this latter condition with spatially separated speech and noise, there were two separate configurations: one with noise from the left and one with noise from the right of the subject. The competing babble for both the fixed-level and adaptive tests in noise
consisted of two male and two female interferers. The babble was shaped according to the International Long Term Average Speech Spectrum (Byrne et al. 1994).

The noise level was adapted during test administration using the HINT scoring method (Nilsson et al. 1994). This method used a step size of 4 dB for the initial four sentences, and a 2 dB step size for the remaining 28 sentences. The SNR of the fifth sentence was calculated to be the mean of the first four SNRs and the SNR which would have been used for the fifth sentence. The starting SNR was selected to ensure that the first four sentences were presented within a sensitive range for each subject. The level of the competing noise was adjusted by a software program, according to the subject’s responses. The noise level increased when the subject responded with more than 50% of morphemes correct, and decreased when the subject failed to repeat 50% of morphemes correctly in the sentence. This provided an SRT measure, indicating the SNR at which the subject scored 50% of morphemes correct.

All competing noise was presented continuously. A beep was presented before each sentence within the adaptive test to
alert the subject to the onset of the presentation interval. The open-set word test used a male talker, whereas both fixed-level and adaptive sentences were spoken by a female talker. For the sentence presentation, the target talker varied across the two different types of measures.

Sound Source Direction Identification

Localization ability was measured pre- and postoperatively using software developed at the HEARing CRC. The stimuli were pink noise bursts of 500 millisecond duration and were presented randomly from one of eight loudspeakers spanning a 180-degree arc in the frontal horizontal plane. Each talker had a 50 millisecond rise and fall time. All testing was conducted bilaterally (in the best-sided condition) at each time point. The maximum presentation level was 68 dB SPL, and level was varied down by up to 6 dB in steps of 1 dB. Two localization tests were conducted at each interval, each with 10 random presentations from each loudspeaker, that is, a total of 80 stimuli presented per test. Training was conducted before assessment.

Questionnaire Test Procedures and Administration

Self-reported outcome measures were obtained using a range of questionnaires. The Speech, Spatial and Qualities of Hearing Scale (SSQ) questionnaire was administered preoperatively and at the 12-month post-operative time points. This questionnaire comprises 50 questions, separated across the three different domains of speech understanding, spatial hearing, and sound quality (Gatehouse & Noble 2004), and uses a rating scale from 0 to 10. The questionnaire was taken home for completion by each subject at each of the assessment times. Responses were checked when the questionnaire was returned, and questions asked directly of the subject where clarification was needed. The administration of the questionnaire was modified from its original design by using an anchored format, in which subjects were allowed to view the ratings they had made previously.

The International Outcome Inventory for Cochlear Implantation was based on that developed for hearing aid assessment (Cox & Alexander 2002). The seven-item questionnaire comprises a range of questions designed to be generally applicable in evaluating the effectiveness of hearing aid or cochlear implant treatments. The questions covered areas such as hours of use of the device, the benefit provided by the device, the level of difficulty experienced when using the device, whether implantation was worth the trouble, and how much the implantation changed enjoyment of life.

A Device Use questionnaire was developed by the author to specifically assess usage patterns of the hearing aid and sound processor in the post-operative period as well as to obtain specific feedback regarding overall perceived benefits and limitations of cochlear implantation. Questions included within the questionnaire are shown in the Supplemental Appendix.

Hearing Aid Fitting and Management

All subjects were experienced bilateral hearing aid users before enrollment in the study. Hearing aids were provided by each subject’s clinical audiologist and the fitting was reviewed preoperatively using real-ear measurement. The NAL-RP or NAL-NL1 prescription was used as the basis for initial hearing aid fitting. Frequency transposition was not used by any subjects, although it was trialed preoperatively for S14 and S15.

To monitor the stability of hearing in the non-implanted ear, both aided and unaided thresholds were monitored over the course of the study. Aided thresholds for frequencies of 250, 500, 750, 1000, 1500, 2000, 3000, and 4000 Hz were measured using a Madsen Itea audiometer with calibrated output to a loudspeaker and used as a measure of stable hearing aid function. Unaided thresholds were obtained under headphones to monitor stability of hearing in the non-implanted ear.

Post-operative review of the hearing aid and the sound processor fitting was conducted in a sound treated room to evaluate the degree of loudness balance between the devices. The subject was seated in front of a loudspeaker and provided with a 10-point loudness rating scale for use during the evaluation. The loudness rating scale had a numerical scale from 1 to 10 with labels on numbers 1 (no difference), 4 (slightly louder), 7 (moderately louder), and 10 (much louder). Initially 20-talker babble was presented at a level of 65 dB SPL and the subject was asked to indicate in which ear, if either, the sound was louder. If there was no difference in loudness between ears the subject indicated that the number was 1. If one ear was louder than the other the subject advised which ear, and the extent on the numerical scale to which the loudness differed. Where differences of greater than 4 were reported, the volume controls on the hearing aid and sound processor were adjusted until the sounds at the two ears were rated as similar as possible. The volume control which provided the closest match across devices for the 65 dB SPL presentation level was used for clinical testing.

Device Parameters

All speech perception and localization measures were obtained with each subject’s preferred program and volume settings on the hearing aids (adjusted for closest match in loudness at 65 dB SPL, where necessary). The preferred input processing programs in the sound processor were also used, with the exception of the Beam algorithm which is available in the cochlear implant sound processor. The beamformer was not used for testing due to the significant effect on microphone directivity and likely degradation of binaural cues. All subjects used the Everyday or Noise programs in the majority of real-world listening situations.

Sample Size Requirement

Prospective sample size estimations for a paired t-test were conducted, given that the study used a repeated-measures design to investigate its hypotheses. Sample size estimation was based on monosyllabic word perception in quiet and adaptive sentence perception. Retrospective data were used to determine the standard deviation of change, based on a data set collected with a larger group of subjects having acoustics hearing in one or both ears. Based on that analysis, the standard deviation of change was 8.6% for monosyllabic words and 2.2 dB SRT (SD) — the variability measured in the scores obtained in the same test configuration as would be used within the present study. To detect clinical meaningful target differences of 10% on monosyllabic word tests and 1.5 dB on the adaptive SRT test, the required sample size would be 10 and 19 respectively. Sample size in the present study was based on the required sample size calculation for the adaptive SRT measurement.

Statistical Analysis

Speech Perception • Speech perception data used in statistical analyses were the average of the two scores obtained in a single
test session at each of the pre- and postoperative time points. Grouped mean data were analyzed using a 2-tailed paired t-test to compare the pre-operative and 6-month post-operative scores. Where data were not normally distributed, the Wilcoxon Signed Rank test was used.

Although insufficient data were collected for a more comprehensive analysis of individual subject data, the critical difference was calculated for the subject group by examining each test's reliability. This provides an indication of the inherent variability of each test measure, and provides a guide to interpreting the degree of post-operative change in test score at an individual subject level. At each of the two time points (pre- and postoperative), the difference between the two successive administrations of each test measure was calculated. The standard deviation of the difference scores for the group of subjects at each time point was divided by the square root of two (because two lists were administered at each time), and multiplied by 1.96 to obtain the two-sided critical difference at the 95% confidence level. The critical difference value provided on each graph was the root-mean-squared average of the pre- and post-operative calculations. Based on this analysis, the critical difference for monosyllabic word testing was 12.0 percentage points, and for CUNY sentences in noise was 17.5 percentage points. For the adaptive SRT testing, the calculated critical difference was 2.3 and 3.7 dB for the S/N0 and 65 and 55 dB SPL presentation level, respectively. The critical difference calculated for spatial release from masking (SRM) measures for the subject group was 3.8 dB for the test condition that favored the implanted ear and was 2.6 dB for the condition that advantaged the hearing aid.

Sound Source Direction Identification • Raw data from each of the two localization tests administered at each of the pre- and post-operative points was independently analyzed by calculating the RMS error. This was the root mean squared deviation of the responses from the target speaker locations. Grouped mean data were analyzed using a paired t-test. As for the speech perception data analysis for individual subjects, the critical difference was calculated by examining the test reliability for the group. The two-sided critical difference at the 95% confidence level (based on the RMS average of the pre- and post-operative calculations) was 11.0 degrees. As mentioned previously, the critical difference value is provided as a guide to the reader as to the test-retest reliability of the measure, rather than an absolute statement regarding significance for an individual.

SSQ Questionnaire Subscales • Group analysis of questionnaire responses on each of the speech, spatial, and quality subscales used the non-parametric Signed Rank test to compare the pre- and post-operative ratings. The mean rating was obtained for each of the subscales at each interval for each subject. Where the subject rated a listening situation as being "not applicable" or there were inconsistencies in the data at a particular interval, the corresponding data at the comparative interval were also removed from the analysis.

A measure of test reliability was obtained through repeat administration of the SSQ questionnaire in a group of 26 adult recipients with a minimum of 6 months of cochlear implant experience. The questionnaire was administered twice for each subject, on occasions separated by 2 weeks. Between the two administrations of the SSQ questionnaire, a different questionnaire was administered as a foil. The two-sided critical difference at the 95% confidence interval level was 1.1, 1.0, and 2.0 for the speech, spatial, and quality subscales of the questionnaire, respectively. This information is provided as a reference for the reader regarding the critical difference of the test measure.

Correlation Analysis • Blund-Altman analysis was conducted to examine whether there was a significant relationship between pre- and postoperative localization abilities. Pearson Product Moment correlation analysis was conducted to assess whether there was a correlation between preoperative localization ability and post-operative change in other spatial hearing abilities (SRM, spatial ratings on the SSQ subscale).

RESULTS

Contralateral Ear Hearing Stability

Group median pre- and postoperative median unaided hearing thresholds (across frequencies 0.125 to 4kHz) were 75 dB HL for both time points. Postoperative median thresholds were within 10 dB HL for all except subjects S6 and S8. For those subjects, the postoperative median thresholds were poorer than those obtained preoperatively by 17.5 dB HL.

Implanted Ear Aided Thresholds

Median aided thresholds were calculated in both the LF (0.250 to 1kHz) and the HF (1 to 4kHz) at each of the pre- and postoperative time points. Analysis of grouped median LF data using the Wilcoxon Signed Rank test revealed a significant effect of time point ($z = -2.845, p = 0.003$), with median values at the pre-operative and post-operative assessment being 33 and 26 dB HL, respectively. In the HF region, the degree of improvement postoperatively was more marked. Grouped data analysis using the Wilcoxon Signed Rank test revealed significant post-operative improvement in thresholds, with median pre- and post-operative thresholds of 48 and 23 dB HL, respectively ($z = -3.784, p < 0.001$).

Speech Perception

Monosyllabic Words in Quiet (SO) • Mean percentage correct scores for perception of monosyllabic words are shown in Figure 2 for individual subjects (SI to 19) and for grouped data. The black bars show the pre-operative score using bilateral hearing aids, and the white shaded bars indicate the post-operative binaural, bimodal scores after 12 months of cochlear implant experience. Analysis of grouped mean data using a two-tailed paired t-test revealed a significant effect of time point ($t(18) = -6.018, p < 0.001$), with mean scores at the pre-operative and 6-month post-operative assessment being 44.3% and 75.3%, respectively. Eighteen of the 19 subjects showed an improvement in test scores postoperatively, and for 15 subjects the degree of improvement exceeded the critical difference of the test. No subjects showed a reduction in monosyllabic word perception postoperatively that was greater than the calculated critical difference. Post-operative scores may have been impacted by ceiling effects on the test measure, because 10 of the 19 subjects obtained post-operative scores of greater than 80%, and 5 obtained scores of greater than 90%.

Speech Perception in Noise (S/N0) • Adaptive speech in noise testing at the target presentation level of 65 dB SPL was collected for 17 of the 19 subjects, and for the lower presentation
level of 55 dB SPL was collected for 16 subjects. Pre- and postoperative individual and grouped mean scores are shown in Figures 3 and 4 for sentence presentation levels of 65 dB SPL and 55 dB SPL, respectively. For subjects 4 and 5, the adaptive test data were not collected, so scores for fixed level CUNY sentence presentation (using + 5 dB SNR) are provided as an alternative measure in noise for the speech presentation level of 65 dB SPL. No testing at the lower input level was conducted for those subjects in noise. Data are presented so that more negative SRT scores (i.e., better performance) are shown in the figure to be higher on the y-axis.

Data for the 65 dB SPL presentation level violated the normality test and this was not resolved with arcsine square root transformation. Analysis using the Wilcoxon Signed Rank test revealed a significant post-operative improvement (z = −3.575, p < 0.001), with grouped median scores being 6.5 dB and 2.7 dB for the pre- and postoperative time points, respectively. Twelve of the 17 subjects showed improvement in SRT post-operatively that exceeded the 2.3 dB critical difference value. Of the two subjects tested using the CUNY sentence in noise test, one subject (S4) exceeded the critical difference of 17.5% on that test. Overall, 13 of the 19 subjects experienced post-operative improvement beyond the critical difference of the test measure. No subjects experienced a reduction after implantation that exceeded the critical difference of the test measure.

For the lower presentation level of 55 dB SPL, there were two subjects where it was not possible to measure an SRT preoperatively due to an inability to perceive a minimum of 50% of the morphemes correct in noise. For those subjects, a value of 31 dB was used, because this was the point at which the SRT software reported that the measurement could not be obtained. At this level, the test was effectively being conducted in quiet, due to the low level presentation of noise, and so there was an inability to obtain the SRT. Analysis using the paired t-test revealed a significant post-operative improvement (t(15) = 5.231, p < 0.001), with grouped mean scores being 15.0 dB and 3.8 dB for the pre- and postoperative time points, respectively. Data analysis was also conducted after removal of the subject data for the two subjects where a pre-operative SRT could not be reliably obtained. Analysis using the paired t-test revealed a significant group mean post-operative improvement (t(13) = 5.249, p < 0.001). Group mean pre- and post-operative scores were 12.7 and 3.8 dB, respectively. Fourteen of the 17 subjects had a post-operative score that exceeded the 3.7 dB critical difference of the test.

Spatial Release from Masking (SRM) • Pre- and postoperative SRM measures for noise presented at 90 degrees to the left and right, were calculated by subtracting the mean S/N0 from the mean S/N90 SRT at each of the time points. This calculation resulted in a positive value when there was advantage through separating the speech and the noise, as compared with coincident presentation. Data are shown for both the listening configuration with noise presented at 90 degrees to the side of the implanted ear (Fig. 5) and for the configuration with noise to the side of the hearing aid contralateral to the cochlear implant (Fig. 6). In those figures are shown the pre- and post-operative S/N0 and S/N90 SRT data for both individual and grouped mean data. Grouped mean data are shown as a shaded box on the bottom right side of the figure. Pre-operative data are indicated by black shaded bars and postoperative as shaded white bars. The calculated SRM for each time point is shown in text above each of the pre- and post-operative data sets.

Preoperative group mean SRM using bilateral hearing aids was relatively symmetric across the different spatial listening configurations, being on average 2.4 dB when the noise was presented to the side selected for implantation, and 1.7
dB for the condition where the noise was presented on the
contralateral side. When the spatial separation advantaged the
hearing aid, that is, the noise was presented to the side of the
cochlear implant, post-operative SRM was not significantly
different to that measured preoperatively. The 95% two-tailed
confidence interval for the difference of means was 1.980
to 1.474 dB. When the spatial configuration advantaged the
implanted side, that is, the noise was presented from the side
of the hearing aid, there was a significant increase in SRM
($t_{[16]} = -2.501, p = 0.024$). Group mean post-operative SRM
was 4.4 dB, which was an increase in SRM from pre-operative
levels of 1.7 dB.

Fig. 3. Mean pre- and postoperative binaural speech reception
threshold (SRT) scores in babble, for the speech presentation level of 65 dB SPL. More negative SRT scores indicate better
performance (shown as higher on the y axis). Inset is the mean percentage correct CLUNY sentence scores for subjects 4 and 5,
because SRT data were not obtained. Pre-operative scores are shown as filled black columns and post-operative as white
dashed columns. Error bars indicate the standard error of the
difference scores. Critical difference markers show the two-sided critical difference at the 95% confidence interval across the subject
group. Significant group mean difference between pre- and postoperative mean scores is indicated by asterisks (** significance at the 0.001 level).

Fig. 4. Mean pre- and postoperative binaural speech reception
threshold (SRT) scores in babble, for the speech presentation level of 55 dB SPL. More negative SRT scores indicate better
performance (shown as higher on the y axis). Pre-operative scores are shown as filled black columns and post-operative as
white dashed columns. Error bars indicate the standard error of the difference scores. Critical difference markers show the two-sided critical difference at the
95% confidence interval across the subject group. Significant group mean difference between pre- and postoperative mean scores is indicated by asterisks
(**** significance at the 0.001 level).
Fig. 5. Individual subject and group mean speech reception threshold (SRT) scores for the SI/D0 and SI/D0 pre- and post-operative measures. SI/D0 measures were obtained with noise presented on the side of the ear which was implanted. Pre-operative measures are shown in black for each subject and post-operative with white shaded bars, spatial release from masking (SRM), defined as the benefit obtained through movement of the noise from coincident presentation with the speech signal (SI/D0) to 90 degrees on the implanted side of the subject, is shown above each of the pre- and post-operative points for each subject. A more positive SRM indicates a higher level of performance obtained through spatial separation of the signal and noise.

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Fig. 6. Individual subject and group mean speech reception threshold (SRT) scores for the S0N0 and S0N90 pre- and post-operative measures. S0N90 measures were obtained with noise on the side of the hearing aid contralateral to the ear which was implanted. Pre-operative measures are shown in black for each subject and post-operative with white shaded bars. Spatial release from masking (SRM), defined as the benefit obtained through movement of the noise from coincident presentation with the speech signal (S0N0) to 90 degrees on the non-implanted side of the subject, is shown above each of the pre- and post-operative points for each subject. A more positive SRM indicates a higher level of performance obtained through spatial separation of the signal and noise. Significant group mean difference in SRM between pre- and post-operative mean scores is indicated by asterisks (* significance at the 0.05 level).

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Sound Source Direction Identification

Pre- and post-operative measures of localization performance were collected for 14 of the 19 subjects. Data for individual subjects and for the subject group are shown in Figure 7. In this figure, the RMS error on the localization test is shown on the y-axis, with a greater degree of error shown as a higher value. Chance performance using the eight loudspeaker configuration with a 180-degree span would be expected to be approximately 86 degrees if responses were uniformly distributed across the speaker array or 59 degrees if responses were at a fixed location directly in front of the subject (van Hoesel & Litovsky 2011). Chance performance for each response strategy is shown as dashed lines on the chart above the grouped mean localization values.

The grouped mean preoperative localization RMS error was 20.7 degrees, which was slightly below the spacing of the speakers used for the evaluation. Postoperative grouped mean RMS error was 41.3 degrees. Grouped mean analysis using a paired t-test showed a significant post-operative increase in error ($t(14) = -5.190, p < 0.001$). Individual subject analysis showed that eight of the 14 subjects experienced a post-operative decrease in localization ability that exceeded the critical difference of 11 degrees. For pre-operative localization, all subjects performed at better than chance performance on the test. Postoperatively, all subjects performed at better than chance performance for the response strategy based on uniform response distribution; however, three performed close to chance level based on responses to a frontal location.

Self-Reported Ratings of Benefit

SSQ Speech, Spatial, and Quality Subscales • Figures 8-10 show individual and grouped mean pre and postoperative self-reported ratings on the speech, spatial, and quality subscales of the SSQ questionnaire, respectively. Analysis of grouped data using the non-parametric Signed Rank test revealed a significant post-operative improvement on each of the speech ($z = 3.783, p < 0.001$), spatial ($z = 3.3, p < 0.001$), and quality ($z = 3.763, p < 0.001$) subscales. The median pre-operative rating on the speech subscale was 2.5, which increased to 6.1 postoperatively. Eighteen of the 19 individual subjects rated the post-operative performance on the speech subscale as higher than pre-operative ratings, and 17 exceeded the critical difference of 1.1 on this measure. On the quality subscale, the grouped median ratings obtained pre- and postoperatively were 4.1 and 6.5, respectively. Twelve of the individual subjects reported post-operative improvement in quality ratings that were equal to or exceeded the critical difference of 2.0. No subjects reported a post-operative reduction on the speech or quality subscales that exceeded the critical difference of the measure.

On the spatial subscale, the pre- and postoperative group median ratings were 2.5 and 5.9, respectively. Fifteen subjects indicated positive improvement postoperatively on this measure, and for 14 subjects the post-operative change was greater than the critical difference. Three subjects (S7, S13, and S16) indicated a post-operative reduction in spatial hearing ability; however, the difference was less than the critical difference for two of the subjects. Subject S13 indicated poorer spatial hearing ability of 1.6 on the rating scale, which was greater than the critical difference of the test measure.

International Outcome Inventory • The International Outcome Inventory (IOI) for Cochlear Implants was completed by 17 of the 19 subjects. Histograms indicating the number of subjects selecting each of the responses to the seven questions...
Fig. 8. Individual subject and group mean ratings on the speech subscale of the Speech, Spatial and Qualities of Hearing Scale (SSQ) questionnaire. Preoperative scores are shown as filled black columns and postoperative as white shaded columns. Significant group median difference between pre- and postoperative mean scores is indicated by asterisks (*** for significance at the 0.001 level). Error bars indicate the standard error of the difference scores. Critical difference markers show the two-sided critical difference at the 95% confidence interval across the subject group.

are shown in Figure 11. It can be seen that all subjects used the cochlear implant for a minimum of 4 hours each day, and all except one of the subjects selected the highest category of use (more than 8 hours per day). Most subjects indicated that the implant "helped very much" in hearing in a situation where they most wanted to improve hearing before implantation, that the implant was "very much worth" the trouble, and that implantation had resulted in improved enjoyment of life.

Device Use Questionnaire • Sixteen of the 19 subjects completed the Device Use questionnaire. Subjects were asked to

Fig. 9. Individual subject and group median ratings on the spatial subscale of the Speech, Spatial and Qualities of Hearing Scale (SSQ) questionnaire. Preoperative scores are shown as filled black columns and postoperative as white shaded columns. Significant group median difference between pre- and postoperative mean scores is indicated by asterisks (*** for significance at the 0.001 level). Error bars indicate the standard error of the difference scores. Critical difference markers show the two-sided critical difference at the 95% confidence interval across the subject group.
indicate which device, that is, the hearing aid or the cochlear implant, provided best overall hearing and understanding. Nine subjects reported best hearing via the cochlear implant, six indicated that the best device differed according to different listening situations, and one reported that the hearing aid provided best hearing. All except subject S1 used both devices together in everyday listening environments. Subject S1 elected to use the cochlear implant sound processor alone, because there was no reported benefit through use of the hearing aid and sound processor in combination.

Most subjects indicated that hearing had improved postoperatively when listening in quiet, listening in noise, listening to the television or radio, and for detecting and hearing soft sounds. In quiet situations, 15 of the 16 subjects reported improvement, and 12 subjects reported post-operative improvement in noise. Twelve subjects indicated benefit when listening to the television or radio, and 13 reported improvement in the ability to detect soft sounds and speech. No subjects experienced worsening of ability in those situations. Specific examination of the reported change in localization showed that experience varied across subjects. Three subjects (S2, S12, and S19) indicated improvement in localization, whereas four subjects (S1, S6, S13, and S15) reported worsening of localization ability.

Correlation Analysis: Pre-Operative Localization and Post-Operative Spatial Hearing Abilities

Pearson Product Moment correlation analysis revealed no significant correlation between preoperative localization ability and the change in spatial hearing ability postoperatively for each of the measures examined: SRM with noise on the side of the hearing aid \( r = 0.52, p = 0.07 \), SRM with noise on the side of the cochlear implant \( r = 0.40, p = 0.18 \), and spatial ratings from the SSQ questionnaire \( r = -0.02, p = 0.95 \). No significant correlation was observed between the preoperative localization ability and the change in localization postoperatively. The latter analysis was conducted through examining the relationship between (1) the average of the pre- and postoperative localization and (2) the difference in post- and preoperative localization ability, due to the inter-relationship between the examined variables.

DISCUSSION

Results show functional improvement on a range of measures for this group of recipients who presented for cochlear implantation and subsequently lost acoustic hearing in the implanted ear postoperatively. Grouped mean monosyllabic word perception increased from 44.3 to 75.3% for the group of subjects, consistent with the findings by Gifford et al. (2010), where the grouped mean pre- and postoperative word scores were 41% and 82%, respectively. Post-operative scores in the present study may have been impacted by ceiling effects, because 10 of the 19 subjects obtained scores of greater than 80%. Individual analyses of the speech perception data revealed that 79% of the subject group experienced post-operative change in scores on the monosyllabic word test that exceeded the critical difference, and 68% and 82% exceeded the critical difference on the adaptive SRT test at the 65 and 55 dB SPL presentation levels, respectively. No subjects experienced a reduction in speech perception scores postoperatively or on the speech and quality subscales of the SSQ questionnaire. The findings from the present study provide further evidence from that observed by Gifford et al. (2010) in support of positive post-operative outcomes for candidates with substantial pre-operative hearing. Furthermore, the present study has demonstrated positive clinical outcomes for candidates with...
more HF hearing than has been previously examined. All subjects in the present study had median LF hearing thresholds of less than or equal to 90 dB HL in both ears, whereas in the Gifford et al. (2010) study there were 77% and 86% of subjects with that level of hearing in the implanted and contralateral ear, respectively. Similarly, 68% of subjects enrolled in the present study had median HF unaided hearing thresholds of less than or equal to 90 dB HL in the implanted ear, as compared with 41% of subjects evaluated by Gifford et al. In the contralateral ear, there were 84% of subjects in the present study and 68% in the Gifford et al. study with that level of HF hearing. The extension in this study to assessing outcomes for candidates with better preoperative hearing levels than previously examined should increase confidence in recommending implantation as a treatment option for this candidate group. This is particularly the case given that these findings represent the “worst-case” situation, where hearing is lost in the implanted ear, and that most subjects would be expected to have hearing preserved after implantation.

A further finding from the present study relates to the examination of speech perception performance at lower speech presentation levels than typically examined in the clinical setting. SRTs in noise for the presentation level of 55 dB SPL were 15.0 dB and 3.8 dB at the pre- and post-operative assessments respectively, representing a significant post-operative improvement of 11.2 dB. This compared with a post-operative improvement of 3.2 dB for the signal presentation level of 65 dB SPL. The larger benefit for the lower presentation level would be expected as a result of the improved audibility across the hearing frequency range obtained with the cochlear implant as compared with the hearing aid. Medium HF aided thresholds were on average 40 dB HL better postoperatively than were obtained on pre-operative measures, and all subjects achieved HF hearing within the aided range of 15 to 35 dB HL after implantation. The improvement in speech perception at the lower input signal level was consistent with the information obtained from the Device Use Questionnaire, where 13 of the 16 subjects who completed
the questionnaire reported post-operative improvement in the ability to detect soft sounds and speech in the real-world environment. Improved audibility and perception of soft sounds is important in providing reliable access to the softer components of speech and in situations such as where the speaker or signal originates at a distance from the listener (Alkaf & First 2007).

Preoperative spatial hearing performance is likely an important consideration for the population of candidates presenting at cochlear implant centers with preoperative bilateral acoustic hearing. Loss of acoustic hearing in the implanted ear may negatively impact on a recipient’s ability to utilize interaural time and level cues postoperatively. Preoperative SRM was relatively symmetric across the different spatial listening configurations, that is, with noise on the side of the ear selected for implantation and the contralateral side, being 2.4 dB and 1.8 dB, respectively. Postoperatively, there was an improvement in SRM when the spatial configuration advantaged the implanted side, with group mean SRM of 4.1 dB. This post-operative improvement is likely explained by the improved access to the monaural head-shadow effect due to provision of HF hearing via electrical stimulation. The observed effect is close to the approximate 5 dB advantage based on review of previous studies (van Hoezel 2012). For the spatial configuration which advantaged the hearing aid side, a decrease in SRM might have been expected if subjects had access to binaural unmasking preoperatively. The lack of significant change in SRM in that configuration was expected if binaural unmasking was not a contributing factor, because the monaural head shadow effect would have been somewhat constant across the pre- and postoperative time points due to relative stability in aided and unaided hearing thresholds over the course of the investigation.

Assessment of real-world benefit via the range of administered questionnaires showed positive acceptance and reported benefit for the majority of subjects. Two subjects indicated a small reduction in spatial hearing abilities after implantation. The negative report from one of those (S7) was also obtained on other measures, including the I0H. On that measure, subject S7 indicated that the cochlear implant was only "moderately worth the trouble" and that enjoyment of life had not changed after implantation. The responses were not consistent with the monosyllabic word scores in quiet or the speech subscale ratings on the SSQ for that subject which showed postoperative improvement. However, the lack of perceived benefit with the cochlear implant was consistent with the speech in noise measure, and with the small reduction in localization ability that was observed in the postoperative period. Preoperative assessment for that subject revealed poorer than expected speech perception scores given the hearing thresholds, which provided audible hearing to 8000 Hz in the better hearing ear. This factor may explain the reduced benefit for this subject as compared with other subjects enrolled in the study.

The observed post-operative reduction in objective assessment of localization ability is consistent with findings from Dunn et al. (2010), where use of bimodal devices was shown to result in poorer localization ability compared with that obtained using bilateral hearing aids. Post-operative localization RMS errors for each subject in the present study were better than chance performance, and ranged from 24.6 to 58.6 degrees, with a mean of 41.3 degrees. Results were comparable with RMS errors of 33, 39, and 64 degrees in studies by First et al. (2012), Potts et al. (2009), and Ching et al. (2004), respectively.

Direct comparison of localization error between the present study and those by First and Potts is not possible as a result of different test methodology. The lower errors reported for those studies is likely to be attributed to the smaller loudspeaker arc of 140 degrees which would have reduced ambiguity in interaural timing (ITD) and interaural level (ILD) cues as well as the allowance of head turns during the assessment procedure. Although different test methodology was also used between the present study and that of Arndt et al. (2011), the postoperative median MAE of 15 degrees in that study may at least in part be attributed to the better HF hearing thresholds in the ear contralateral to the cochlear implant.

The mean RMS error was more than twice as large postoperatively, which may have been expected to be a significant downside to implanting subjects, particularly in everyday, dynamic listening conditions where talker location varies frequently. However, the objective assessment of localization ability was not clearly correlated with subjects’ experience in real-world situations. Responses from the Device Use Questionnaire indicated that three subjects reported improvement and four a noticeable reduction in localization ability after implantation. Controlled measurement was obtained in only one of the three subjects who reported improved postoperative localization ability, and that subject showed no measurable change. Of the four subjects who reported poorer postoperative localization ability on the Device Use Questionnaire, three were evaluated objectively. For those subjects, the controlled measures were consistent with the subjective ratings. However, self-reported ratings on the spatial subscale of the SSQ showed more variable results. On that measure, two subjects indicated post-operative improvement, one post-operative reduction, and one reported little change in spatial hearing function. An additional five subjects showed reduction in localization using objective measures but reported no change in localization ability in real-world environments. The Device Use Questionnaire specifically asked for subjects to report on post-operative change in localization ability, as compared with the spatial subscale of the SSQ which assessed a broader range of spatial ability. This may have explained the difference between objective measures and subjective ratings on that measure. Also, the self-report questionnaires administered during the study may have assessed different aspects of localization than the static laboratory evaluation, and this may also have contributed to the differences observed between objective and subjective performance.

On the basis of the localization findings, it would be important in the clinical setting to discuss the potential for post-operative reduction in localization ability with cochlear implant candidates. This information should be presented to candidates with consideration as to the expected substantial benefits of cochlear implantation but include discussion of this aspect of performance where hearing may be lost in the implanted ear. Although there would be expected a high likelihood of retaining hearing in the implanted ear after implantation, it would be beneficial to set expectations in the event that hearing is not able to be preserved initially, or is subsequently lost during the post-operative period.

Post-operative change in spatial hearing abilities, as measured through SRM and through ratings of real-world performance using the spatial component of the SSQ questionnaire, were not correlated with preoperative localization ability. It was hypothesized that preoperative localization ability may be reflective of a subject’s ability to utilize interaural timing and level
cases with bilateral hearing aids, and be predictive of the impact of post-operative loss of acoustic hearing in the implanted ear on binaural function. Use of different outcome measures that were more sensitive to assessment of binaural hearing function may have resulted in a different finding; however, there is currently no evidence of association between localization ability and post-operative spatial hearing ability.

When considering the overall subjective benefit of implantation for the subject group assessed within the clinical study, it is important to consider the ratings on the self-report questionnaire. Key findings from the IOI were that all subjects regularly used the cochlear implant in daily life, that all reported benefit from the implant in a situation deemed particularly important, that all indicated that the cochlear implant was worth the trouble, and that all except one subject reported that the implant had significantly improved enjoyment of life. Those findings, in addition to the positive results observed for other subjective and objective measures, provides confidence in considering cochlear implantation as an intervention option for such candidates. Although risk to loss of acoustic hearing should be considered and discussed with candidates, the findings from this study suggest that the benefit of implantation typically outweighs the potential risk of loss of implanted ear acoustic hearing.

CONCLUSIONS

The findings from this study report the expected benefits and limitations of cochlear implantation for candidates transitioning from bilateral hearing aids in the pre-operative period to post-operative use of a cochlear implant in combination with a contralateral hearing aid. Although the ability to reliably preserve acoustic hearing after implantation has been demonstrated in a number of previous studies, it is important to consider the potential impact of loss of acoustic hearing in the implanted ear on post-operative performance. Significant improvement in speech recognition and in real-world ratings of benefit after implantation provides further evidence of positive findings for those candidates presenting to clinics with preoperative binaural acoustic hearing. No correlation between preoperative localization ability and post-operative change in spatial hearing abilities (using measures of SRM and spatial ratings on the subscale of the SSQ questionnaire) was observed. Reduction in the ability to localize sound direction after implantation is an important issue for consideration and discussion during the preoperative counseling phase with candidates, even though there was not a clear relationship between controlled measures and subjective ratings of localization ability.

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REFERENCES


Appendix 5 – Reprint Study B

Influence of contralateral acoustic hearing on adult bimodal outcomes after cochlear implantation

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Abstract

Objective: To examine post-implantation benefits and time taken to acclimatise to the cochlear implant for adult candidates with more hearing in the contralateral non-implanted ear than has been previously considered within local candidacy guidelines. Design: Prospective, within-subject experimental design. Study sample: Forty postlingual hearing-impaired adult subjects with a contralateral ear word score in quiet ranging from 27% to 100% (median 67%). Results: Post-implantation improvement of 2.4 dB and 4.0 dB was observed on a sentence in coin.incident babble test at presentation levels of 65 and 55 dB SPL, respectively, and a 2.1 dB benefit in speech release from masking (SRM) advantage observed when the noise location favoured the implanted side. Significant post-operative group mean change of between 2.1 and 3.6 was observed on the sub-scales of the speech, spatial, and qualities (SSQ) questionnaire. Degree of post-implantation speech reception threshold (SRT) benefit on the incident babble test and on perception of left speech and sounds in the environment was greater for subjects with less contralateral hearing. The degree of contralateral acoustic hearing did not affect time taken to acclimatise to the device. Conclusions: The findings from this study support cochlear implantation for candidates with substantial acoustic hearing in the contralateral ear, and provide guidance regarding post-implantation expectations.

Key Words: Cochlear implant, bimodal, acoustic hearing, outcomes, candidacy

Introduction

With progressive expansion in criteria for cochlear implantation candidacy, it is increasingly common for candidates to have substantial acoustic hearing in the better hearing ear. Provision of evidence-based recommendations is important during the clinical assessment and counselling process for anyone considering a cochlear implant. However, there is less information available to assist with clinical recommendations for candidates with greater levels of pre-operative acoustic hearing than for more traditional candidates. To address this, it is important to carefully assess outcomes for this new cochlear implant candidate population, with an aim to improve the evidence-base for clinical guidance as relates to predicted outcomes for individuals.

Measures of post-implantation speech recognition improvement have typically employed either tests of perception of speech in quiet, or of speech presented coincident with background noise from directly in front of the listener. There is published evidence of reduced speech perception benefit for candidates with contralateral acoustic hearing, as compared to more traditional candidates, on such measures. Gifford et al (2010) compared best-aided outcomes for 22 subjects with substantial pre-operative hearing (defined as greater than 30% on a monosyllabic word test in quiet), with a group of more traditional cochlear implant candidates and found no difference between the groups in average bilateral post-operative word scores. Since the subjects with pre-operative hearing had higher pre-operative levels of performance than those without, they obtained less post-operative improvement.

Review of findings across a number of other published studies also suggest reduced benefit as a function of the degree of contralateral hearing in the coincident speech in noise test configuration. First et al (2012) examined pre- and post-operative outcomes for a group of ten subjects with asymmetric hearing loss, using a range of speech perception measures in noise. All subjects scored at least 50% on a word or sentence test in quiet pre-operatively, and had little or no hearing in the ear selected for implantation. Contralateral ear pure-tone averaged (PTA) thresholds ranged from 27 to 88 dB HL, with a mean of 56 dB HL. Best-aided scores on a TIMIT sentence in quiet and noise tests for the seven postlingual subjects improved by approximately 40% and 20% respectively. Vermeire and van de Heyning (2009) specifically...
examined the change in speech recognition ability in two subject groups categorized according to whether or not they used a hearing aid on the contralateral ear. Mean PTA thresholds for frequencies 0.5, 1, 2, and 4 kHz for the group of nine hearing-aid users was 60.1 dB HL (with a range from 38 to 79.9 dB HL), whereas for the unaided group of 11 subjects it was 17.7 dB HL (with a range from 10 to 39.0 dB HL). Although not statistically significant, the average SRT was 3.3 dB lower for the bilateral compared to unilateral test condition for the group of hearing-aid users, whereas it was 0.3 dB lower in the unaided group who had better contralateral hearing thresholds. Lack of benefit on a coincident speech in noise test has also been reported for subjects with unilateral hearing impairment (Arndt et al., 2011; Buechner et al., 2010).

Although there is evidence of less benefit of cochlear implantation in subjects with better contralateral hearing on traditional speech perception measures, it is important to assess spatial hearing ability and self-reported outcomes (Tyler et al., 2006), which are likely more indicative of an individual’s ability to function effectively in real-world listening environments. Significant advantage provided by the cochlear implant in spatially separated speech and noise test configurations is thought to have been primarily due to improved access to favorable SNRs imparted by the head shadow, with benefit reported when the implanted ear received a better signal-to-noise ratio than the non-implanted ear (Arndt et al., 2011; Buechner et al., 2010). Additionally, positive findings have been observed on tests of localization ability (Arndt et al., 2011; Firtz et al., 2012). Those findings are in line with earlier research in subjects with less contralateral hearing (Tyler et al., 2002). Vermeire and van de Heyning (2009) examined the change in speech recognition ability with spatially separated signal and noise in the two groups of subjects who differed as to whether they used a hearing aid or had better hearing that was unaided. Significant improvement from adding the cochlear implant was observed for both groups using a test condition in which noise was presented from directly in front of the listener and speech from the side of the cochlear implant at an angle of 90 degrees. In that test condition the advantage provided by the bimodal devices, as compared to the use of the hearing aid alone, was the combined result of improved signal-to-noise ratio and potential access to binaural cues.

In a test configuration with speech presented from the front and noise from 90 degrees on the implanted side, Vermeire and van de Heyning (2009) reported a significant 3.8 dB SNR improvement from adding the cochlear implant for the hearing-aid users but not the subjects with better contralateral hearing. The difference between groups is likely attributed to the relative performance between ears; for hearing-aid users the addition of the cochlear implant, even when at a poorer SNR, still offers improvement because the hearing aid alone does not provide a high level of performance. However, for subjects with good performance in the contralateral, non-implanted ear, the addition of the cochlear implant at a poorer SNR does not result in significant improvement as compared to the single ear condition. For those subjects the contralateral ear with a more favourable SNR would likely perform better than the cochlear implant side.

Another metric used to assess benefit of cochlear implantation is subjective qualitative questionnaires such as the SSQ questionnaire (Gatehouse & Noble, 2004). Significant post-implantation improvement on the speech sub-scale has been reported for both the asymmetric (Firtz et al., 2012; Vermeire & van de Heyning 2009) and unilateral (Arndt et al., 2011; Vermeire & van de Heyning 2009) hearing-impaired subject groups. Similar findings have been reported on the spatial sub-scale for the majority of studies (Arndt et al., 2011; Firtz et al., 2012), although not for the subject group in the study by Vermeire and van de Heyning (2009) who used a hearing aid in the contralateral ear. It was hypothesized by those authors that spatial hearing ability in that group may have been compromised by the use of two independent devices with different signal compression characteristics, as compared to use of a single device in combination with normal hearing. However, in contrast, the benefit reported by Firtz et al. (2012) was observed for subjects using the hearing aid in combination with the cochlear implant sound processor.

On the quality sub-scale, there were more varied results. Significant benefit was reported in the asymmetric hearing impaired subject group examined by Firtz et al. (2012), although less benefit was observed on the quality sub-scale than on the speech and spatial scales in that study. Similarly, significant improvement in quality ratings was observed in the hearing-aid users examined by Vermeire and van de Heyning (2009) or in the Arndt et al. (2011) study. Although there is some variability in the reported findings on the SSQ questionnaires, there does appear to be an effect of degree of contralateral hearing on expected post-implantation outcomes.

In addition to the SSQ questionnaire, a number of self-reported rating measures have been used to assess post-operative benefit in the asymmetric and unilateral hearing-impaired population. Arndt et al. (2011) administered the Health Utilities Index 3 (HUI-3) (Furlong et al., 2001) and reported a significant improvement after implantation as compared to CROS and BAHAs devices used pre-operatively. Benefit in that study was also observed on the seven domains of the international outcome inventory (IOI) (Cox & Alexander, 2002).

Another consideration is that recipients with contralateral hearing may have difficulty in combining the different perceptual signals provided by the two ears. A larger perceptual balance between electric and acoustic hearing may result in a longer period of adaptation to the cochlear implant in the post-operative period. Additionally, the presence of more salient contralateral ear acoustic cues might result in less attention being directed to the implanted ear. There is some evidence for this potential effect in the published literature. Some recipients with substantial pre-operative hearing experienced decreases in binaural hearing performance after one, three, and six months post-activation, but benefit was observed after 12 months of experience (Adunka et al., 2008). Slower post-operative progress using the cochlear implant alone was reported for a group of subjects with pre-operative hearing compared to a similar group without hearing (Cullen et al., 2004). Although performance was not assessed in that study using bimodal devices, it does suggest potential for slower progress. Mok et al. (2006) examined bimodal hearing performance in 14 adult recipients and reported that recipients with mild to high frequency aided thresholds in the ear contralateral to the cochlear implant demonstrated less bimodal benefit than those recipients with poorer mild to high frequency thresholds. There are suggestions in the literature that cochlear
implant recipients adapt over time to initial pitch mismatch associated with the way in which frequencies are allocated to electrodes in the sound processor (Fu et al., 2002; McDermott et al., 2009; Reiss et al., 2007; Rosen et al., 1999), however it is not clear whether that would impact the time taken to obtain maximal benefit from the electrical stimulation in the post-operative period.

The aim of the current study was to further explore the speech recognition and self-reported real-world ratings of benefit for subjects with contralateral hearing. Variability in findings reported to date is likely influenced by the characteristics of the different subject groups evaluated, the range of test configurations used for assessment of benefit, and the different time points of measurement; i.e. whether data have been obtained using a pre- to post-operative design, or using measures of brainstem versus better-ear performance. Vermeire and van de Heyning (2009) suggest that degree of contralateral hearing affects outcomes on some measures. However, this warrants further investigation with a longitudinal study design incorporating direct measures of pre- and post-operative performance. Furthermore, it is of interest to examine the time taken to obtain benefit after implantation, to investigate whether those subjects with more contralateral hearing might take longer to benefit from the electrical stimulation. The findings from the study would be integrated within current literature to better inform candidates of expected benefit and to assist clinicians in pre-operative counselling discussions.

Materials and Methods

Subjects

Forty postlingual hearing-impaired adults participated in the study. Subjects were recruited from the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne and from the Sydney Cochlear Implant Centre. The study was approved by the Human Research Ethics Committee at the Royal Victorian Eye and Ear Hospital (Project Number 09/8721) and the Royal Prince Alfred Hospital (Project Number 09/RPAH/427). All subjects had a phoneme score on the monosyllabic consonant-vowel-consonant (CVC) word test of 67% or greater in the contralateral (better hearing) ear. In the implanted ear the pre-operative phoneme score ranged from 0% to 78%. The word score for the same test ranged from 27% to 100% with a median of 67% in the contralateral ear, and from 0% to 62% with a median of 1.5% in the implanted ear.

Pre-operative speech perception scores were obtained as an average of two lists presented in quiet at 65 dB SPL from a frontal loudspeaker at zero degrees azimuth. Selection criteria were an extension of those used in the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic, with enrolment of subjects having greater speech perception in the contralateral ear than would be recommended by the current local candidacy guidelines. The median PTA unaided audiometric thresholds in the contralateral ear (averaged across frequencies 0.5, 1, and 2 kHz) was 63 dB HL with a range of 0 to 113 dB HL.

Demographic information for each of the subjects is shown in Table 1. The age of the subjects at the time of enrolment into the study ranged from 27 years to 76 years, with a mean age of 60.7 years. Table 1 also provides information regarding audiometry of the implanted ear, the pre- and post-operative PTA in the implanted ear, the PTA in the contralateral ear, and the pre-operative word scores in each ear. PTA was calculated by averaging the thresholds obtained at frequencies 0.5, 1, and 2 kHz. Where there was no measurable response, or the PTA was greater than 120 dB HL, the text in the table indicates NR (for ‘no response’). Three subjects had mixed hearing loss in the contralateral ear (S2, S4, and S27) of greater than 10 dB HL when averaged across frequencies 0.25, 0.5, and 1 kHz. The average air-bone gap for those subjects were 20, 61, and 40 dB HL, respectively.

Study design

The study used a prospective, longitudinal, within-subject experimental design in which each subject served as his or her own control. Clinical performance measures were obtained pre-operatively and at 12 months post-operatively in the best aided condition. Additional measures were obtained at three and six months after activation to enable analysis of the rate of improvement after activation of the device. Pre-operatively, subjects used either bilateral hearing aids or, for subjects with single-sided hearing impairment, the preferred option of either a Baha sound processor mounted on a head band or a CROS hearing aid. Post-operatively, all subjects used the cochlear implant sound processor in combination with either the contralateral hearing aid or natural acoustic hearing.

Speech perception test materials & procedure

Adaptive sentence in noise testing was conducted at each of the pre- and post-operative time points, with the speech signal presented at both 65 and 55 dB SPL at the centre of the subject’s head position and at the level of the sound-processor microphone. The subject was seated at a distance of 1.2 metres from each of three loudspeakers; one directly in front and one on each side at an azimuth of 90 degrees. Testing was conducted in three spatial configurations: (1) with coincident presentation of speech and noise from directly in front of the listener (SON0) at both signal presentation levels; (2) with speech from the front and noise at ninety degrees on the side of the hearing aid/natural hearing (SON0/09A) at a level of 65 dB SPL; and (3) with speech from the front and noise from ninety degrees on the side of the cochlear implant (SON0/91C) at a level of 65 dB SPL.

The adaptive test used BKB-like sentences and estimated the SNR for 50% intelligibility at the pre- and post-operative assessment for each of the speaker configurations and presentation levels. Each SRT test run comprised 32 sentences, which were a combination of two 16-sentence lists. The noise level was adapted during test administration using the HINT scoring method (Nilsson et al., 1994). A step size of 4 dB was used for the initial four sentences, and then a 2 dB step size for the remaining 28 sentences. The level of the competing noise was adjusted by a software program according to the subject’s responses. The noise level increased when the subject responded with more than 50% of morphemes correct, and decreased when the subject failed to repeat at least 50% of morphemes correctly in the sentence (Dawson et al., 2013). The SRT indicated the signal-to-noise ratio at which the subject scored 50% of morphemes correct, and was calculated by averaging the signal-to-noise ratios of the final 28 sentences. All competing noise was presented continuously. The pre-operative SRT value was limited to 115 dB SNR since the adaptive procedure was deemed not to be working correctly beyond that point (Kaandorp et al., 2015). A beep was presented prior to each sentence within the adaptive test to alert the subject to the onset of the presentation interval. All test items were presented once and no feedback was given to the subjects regarding the correctness of the
Table 1. Subjects’ demographic information; including age at the time of implantation (in years), etiology of hearing impairment, duration of hearing loss (in years) in the implanted ear and contralateral ear, pre-operative implanted, post-operative implanted and contralateral PTA thresholds (across frequencies 0.5, 1, and 2 kHz), pre-operative phoneme and word scores in the implanted and contralateral ear. NR indicates ‘no response’ on audiometric unaided threshold measures.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Race</th>
<th>Age at implant (years)</th>
<th>Duration implanted ear severe-profound hearing loss (years)</th>
<th>Pre-operative implanted ear PTA (dB HL)</th>
<th>Post-operative implanted ear PTA (dB HL)</th>
<th>Contralateral PTA (dB HL)</th>
<th>Pre-operative implanted ear word score (%)</th>
<th>Contralateral ear word score (%)</th>
</tr>
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<tbody>
<tr>
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<td>Unknown</td>
<td>20</td>
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<td>NR</td>
<td>80</td>
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<td>31</td>
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<td>72</td>
<td>Oscicular fixation</td>
<td>40</td>
<td>125</td>
<td>NR</td>
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<td>Oscicular fixation</td>
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<td>105</td>
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<td>4</td>
</tr>
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</tr>
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<td>100</td>
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<td>71</td>
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<td>3</td>
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<td>NR</td>
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<td>Otosclerosis</td>
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<td>118</td>
<td>NR</td>
<td>88</td>
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<td>4</td>
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<td>NR</td>
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<td>87</td>
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<td>75</td>
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<td>4</td>
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responses. Speech perception data used in statistical analyses was
the average of the two values obtained in a single test session at
each of the pre- and post-operative time points. Testing was not
conducted in quiet due to pre-operative ceiling effects on the test
measure for the majority of the subjects.

Questionnaire test procedures and administration

Self-reported outcome measures were obtained using the following
questionnaires: the SSQ questionnaire (Gatehouse & Noble, 2004),
the IOT (Cox & Alexander, 2002) modified from its original form
for use with cochlear implants, and a general device use question-
naire to obtain specific feedback regarding overall perceived
benefits and limitations of cochlear implantation. The device use
questionnaire required subjects to indicate whether hearing had
improved, remained unchanged, or worsened after implantation,
across a range of real-world listening scenarios. Those scenarios
were listening in quiet situations, in noisy situations, on the
telephone, to the television or radio, localizing the direction of
sounds, and detecting soft sounds and speech. The SSQ was
administered in an anchored format, with subjects able to view
pre-operative ratings when completing their ratings after implantation.

Device settings

All speech perception measures were obtained with each subject’s
preferred program and volume settings on the hearing aids.
The hearing-aid volume control was adjusted by the subject while
listening to a free-field frontal presentation of 20-talker babble at a
signal level of 65 dB SPL, with the subject instructed to create the
most balanced percept between ears.
Subjects were either experienced hearing-aid users at the time of study enrolment or, for eight subjects who presented with unilateral hearing impairment, were fitted with the Baha Intenso mounted on a headband, or with the Phonak Uno M CROS aid. Hearing aids were provided by each subject’s clinical audiologist and the fitting was reviewed pre-operatively using real-ear measurement. Prescribed amplification characteristics were not modified during the research study; rather than clinically applied parameters were utilized. The hearing-aid response and sound processor frequency response were verified in an acoustic test box prior to post-operative testing with each subject to ensure appropriate function relative to the baseline pre-operative function. The preferred input processing programs in the sound processor were used. All subjects used their preferred everyday or noise programs in the majority of real-world listening situations.

Data analysis
Pre- and post-implantation grouped mean data for each of the clinical measures was analysed using a two-tailed, paired t-test. Analyses for each of the speech perception measures were based on the data averaged across two test lists for each subject. For the SSQ the analysis used the mean rating on each of the sub-scales. Where the subject rated a listening situation as being ‘not applicable’ on that questionnaire, the corresponding datum at the comparative interval was not included. Investigation as to the influence of contralateral word score on change in bilateral scores post-implantation was examined with multiple linear regression analysis or, for responses on the device use questionnaire, binary or ordinal logistic regression. Binary logistic regression was used when only two of the three categories were selected, being (1) improved after implantation, and (2) unchanged after implantation. When all three categories were selected, i.e. the category stating that performance worsened after implantation was selected by some subjects, the analysis was conducted using ordinal logistic regression. Explanatory variables examined in addition to the contralateral word scores were: (1) age at implantation, (2) duration of severe-to-profound hearing loss in the implanteed ear, and (3) pre-operative word scores in the implanted ear. The change in performance post-implantation was calculated based on the 12-month as compared to the pre-operative scores on each of the outcome measures.

Time taken to reach 90% of the maximum speech in coincident noise SRT value was calculated for the speech in noise test administered at a presentation level of 65 dB SPL. Subjects were categorized according to whether they obtained that level of performance within six months or within 12 months post-activation. The most conservative estimate of time taken to reach the maximum score was used in the analysis, in that where the specified level of performance was reached by six months but not maintained to 12 months, the latter time point was used in the analysis. Only subjects with post-operative improvement of greater than the critical difference of the test measure at the 12-month time point were included in the analysis. The two-sided critical difference at the 95% confidence interval was calculated by dividing the standard deviation of the difference values for the group of subjects by the square root of 2 (since two successive lists were administered for each subject), and multiplied by 1.96. Based on that calculation the critical difference of the test measure was 1.4 dB. Binary logistic regression analysis was used to examine whether the time taken to reach the specified level of performance was associated with contralateral word score.

Results
Pre- and post-implantation performance
Speech perception in noise (S0N0)
Adaptive speech in coincident noise testing was collected for 38 subjects at a presentation level of 65 dB SPL, and for 37 subjects at the lower level of 55 dB SPL. For three subjects (S25, S33, and S34) testing was not conducted after 12 months of device experience; for those subjects the data collected at the six month time point was used in the analysis. Pre- and post-operative grouped mean SRT in noise values are shown in Figure 1. Lower SRT values indicate better performance and are shown as higher on the y-axis. Pre- and post-operative grouped mean SRT values obtained at the level of 65 dB SPL were 3.5 dB and 1.1 dB respectively (t(37) = 6.7, p<0.001). The observed mean benefit was 2.4 dB and the 95% two-tailed confidence interval for difference in mean values ranged from 1.7 to 3.1 dB. Pre- and post-operative grouped mean SRT values for the presentation level of 55 dB SPL were 6.0 dB and 2.0 dB respectively (t(36) = 6.1, p<0.001). At that presentation level the mean benefit was 4.0 dB, with the 95% two-tailed confidence interval for difference in mean values ranging from 2.6 to 5.4 dB.

Analysis of individual subject data revealed better post-operative as compared to pre-operative SRT in babble noise values were obtained for 94.8% and 83.8% of subjects for the presentation levels of 65 and 55 dB SPL respectively. At the presentation level of 65 dB SPL, 68.4% of subjects obtained post-operative SRT improvement that exceeded the critical difference of the test measure (1.4 dB). At the lower level there were 64.9% of subjects who improved beyond the critical difference on that test of 3.7 dB SRT. Most importantly, only one subject (S23) obtained a poorer SRT in noise post-operatively than the critical difference.

Figure 1. Grouped mean pre- and post-operative binaural SRT scores in babble for the S0N0 configuration at signal presentation levels of both 65 dB SPL and 55 dB SPL. More negative SRT scores indicate better performance (shown as higher on the y-axis). Pre-operative scores are shown as filled black columns, and post-operative as white shaded columns. Error bars indicate the standard error of the difference scores. Significant group mean difference between pre- and post-operative mean scores is indicated by asterisks (*** significance at the 0.001 level), and the mean degree of difference is shown in text above the asterisks.
Spatial release from masking (SRM)

Pre- and post-operative SRM measures for noise presented at ninety degrees on the cochlear implant or hearing aid side were calculated by subtracting the mean SNR00 from the mean SNR0 SRT at each of the time points. This calculation resulted in a positive value when there was advantage through separating the speech and the noise, as compared to coincident presentation. SRM measures potentially incorporate the combined effects of monaural changes in SNR at the two ears due to the head shadow, as well as any release from masking on the basis of binural cues. Data are shown in Figure 2 for both the listening configuration with noise presented at ninety degrees to the side of the hearing aid (left panel) and for the configuration with noise to the implanted side (right panel). With noise location moved from the front to the side of the hearing aid (i.e. when providing an SNR advantage to the implanted side) there was a significant post-operative improvement of 2.1 dB in the degree of SRM (t(37) = -4.0, p < 0.001). The 95% two-tailed confidence interval for difference in SRM was 1.0 to 3.1 dB. With noise moved from the front to the implanted side (i.e. providing spatial advantage to the contralateral ear) there was no significant difference between pre- and post-operative SRM (t(37) = 0.18, p = 0.860).

![Figure 2. Grouped mean spatial release from masking values for noise presented on the side of the hearing aid (in the left panel) and for noise presented on the implanted side (in the right panel). SRM is the measure of the advantage provided by the spatial separation of the speech and noise (i.e. comparison of performance in the SN00 and SNR00 conditions). Pre-operative measures are shown in black for each subject, and post-operative with white shaded bars. A more positive SRM indicates a higher level of performance obtained through spatial separation of the signal and noise. Significant group mean difference between pre- and post-operative SRM is indicated by asterisks (** for significance at the 0.001 level) and the mean degree of difference is shown in text above the asterisks.](http://example.com/figure2)

Self-reported ratings of benefit: SSQ

Pre- and post-operative grouped mean ratings for each of the speech, spatial, and quality sub-scales are shown in Figure 3, with data for the speech, spatial, and quality sub-scales in the left, mid, and right panels respectively. Analysis using the paired t-test revealed significantly higher post-operative as compared to pre-operative ratings on each of the speech hearing (t(38) = 10.6, p < 0.001), spatial (t(38) = 7.8, p < 0.001), and qualities (t(38) = 7.4, p < 0.001) sub-scales. For the speech hearing sub-scale the pre- and post-operative grouped mean ratings were 2.8 and 5.8 respectively. The 95% two-tailed confidence interval for difference of means was 2.4 to 3.6. Pre- and post-operative grouped mean ratings for the spatial hearing sub-scale were 2.7 and 4.9, and for the qualities sub-scale were 4.6 and 6.6 respectively. The 95% two-tailed confidence interval for difference of means on each of the spatial and qualities sub-scales was 1.7 to 2.8.

Analysis of individual subject post-operative ratings on the sub-scales of the SSQ questionnaire revealed that the majority of subjects provided post-operative ratings that were equal to or better than those obtained pre-operatively. Only subjects S7 and S10 indicated poorer post-operative function on the spatial sub-scale, and S40 on the quality sub-scale. The degree of reduction in spatial performance was 1.1 and 1.5 respectively on the 10-point rating scale for the two subjects.

![Figure 3. Grouped mean ratings on the speech, spatial, and quality subscales of the SSQ questionnaire. Pre-operative scores are shown as filled black columns and post-operative as white shaded columns. Significant group mean difference between pre- and post-operative mean scores is indicated by asterisks (** for significance at the 0.001 level). Error bars indicate the standard error of the difference scores.](http://example.com/figure3)
INTERNATIONAL OUTCOME INVENTORY

The IOI was completed by 36 of the 40 subjects enrolled in the study. Histograms indicating the number of subjects selecting each of the responses to the seven questions are shown in Figure 4. It can be seen that all except one subject used the cochlear implant for a minimum of four hours each day, and 72% selected the highest category of use (more than eight hours per day). Most subjects indicated that the implant helped very much in hearing in a situation where they most wanted to improve hearing prior to implantation, that it was ‘very much worth’ the trouble, and that implantation had resulted in improved enjoyment of life.

DEVICE USE QUESTIONNAIRE

Figure 5 shows the percentage of subjects who reported improvement, no change, or worsening from pre-operative performance after 12 months of device use. Data are shown for a range of real-world clinical measures. Most subjects indicated that hearing had improved post-operatively when listening in quiet, listening in noise, listening to the television or radio, and for detecting and hearing soft sounds. Only one subject reported poorer hearing in noise after implantation. That subject had pre-operative unilateral hearing impairment. On ratings related to use of the telephone, 21% reported post-implantation improvement. All except one subject reported use of the telephone in everyday life. The majority (73.8%) used the hearing aid or natural-acoustic hearing for communication on the telephone. 5.2% used the cochlear implant alone, and 18.4% were able to utilize two ears on the phone through use of the telecoil, speakerphone, or Bluetooth streaming to both devices. One subject reported worsening of performance on the telephone post-implantation, as a result of background noise being more audible when listening with the hearing aid in one ear.

Figure 4. Histograms indicating the number of subjects selecting each option provided on the international outcome inventory.
Figure 5. Percentage of subjects reporting post-operative better performance (in black), worse performance (in dark grey), and no change (in shaded white) for each of the categories of the device use questionnaire.

aid. Post-implantation improvement in localization was reported for 34% of subjects. Post-operative worsening of localization was reported by 13% of the group (S5, S7, S10, S16, and S20). Those had bilateral pre-operative acoustic hearing, with the implanted ear PTA thresholds ranging from 70-87 dB HL across the subject group.

Influence of contralateral hearing on post-implantation benefit

Best-subset regression analysis revealed that a lower contralateral word score was significantly correlated with more post-implantation SRT (SNO0) benefit at both presentation levels of 65-dB SPL ($r = 0.52$, $p < 0.001$) and 55-dB SPL ($r = 0.61$, $p < 0.001$). Scatterplots indicating the post-implantation change on each of the speech-in-noise measures as a function of the contralateral word scores are shown in Figure 6. There was not a significant correlation between the contralateral word score and the clinical measures of spatial release from masking or assessment using the subspaces of the SSQ questionnaire. Explanatory variables of age at implantation, duration of severe-to-profound hearing loss, and pre-operative implanted ear word score were not correlated with change in clinical performance in noise.

Contralateral word score accounted for 25.1% and 34.9% of the variance in SRT benefit at 65 and 55 dB SPL respectively. An increase of 1% in the contralateral word score was associated with a reduction in post-operative SRT benefit of 0.06 dB and 0.12 dB for the presentation levels of 65 and 55 dB SPL respectively. Results of the linear regression analysis are outlined in Table 2. The relatively small Mallows Cp value of 2.0 indicated that the model was precise in estimating the true regression coefficients and predicting future responses.

Binary or ordinal logistic regression analyses for each of the categories listed in the device use questionnaire revealed no significant relationship between each of the explanatory variables and post-operative rating for the categories of listening in quiet situations, in noisy situations, on the telephone, and localizing the direction of sounds. There was a weak but significant negative association between the contralateral word score and the reported change in listening to the television and radio after implantation ($p = 0.042$). However that factor accounted for only 2.5% of the variance in post-operative rating of benefit. A stronger association was observed between the contralateral word score and the ratings that described detection of soft sounds and speech ($p = 0.002$), and that factor accounted for 12.1% of the variance in reported post-operative benefit. For each 1% increase in contralateral word score there was an observed reduction of 6.7% in the odds of reporting real-world benefit in detecting soft sounds and speech. The 95% confidence interval for the odds ratio was 0.91 to 0.99.

Time taken to reach 90% of final SRT

Analysis of time taken to reach 90% of the final SRT at 12-months post-implantation was conducted for 23 subjects. Excluded from the analysis were subjects who did not obtain greater than or equal to 1.4 dB SRT post-operative improvement, which was the critical difference of the test measure for the subject group. Those subjects

Figure 6. Scatterplots showing correlation between contralateral word score (on the x-axis) and the difference in SRT between post- and pre-operative measures (on the y-axis) at the two presentation levels of 65 and 55-dB SPL. More post-operative benefit is indicated by a more negative SRT value, with a greater degree of change shown as higher on the y-axis.
Table 2. Model statistics and regression coefficients describing the relationship between contralateral word score and post-operative change in bilateral SRT in babble.

65 dB SPL presentation level
Overall model: F = 13.1, p = 0.001, R² = 0.272, Adjusted R² = 0.219, Mallows Cp = 2.0
Regression coefficients

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55 dB SPL presentation level
Overall model: F Statistic: 19.7, p < 0.001, R² = 0.367, Adjusted R² = 0.349, Mallows Cp = 2.0
Regression coefficients

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<td>Contralateral word score (%)</td>
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were excluded because of the research objective to assess time to benefit from the cochlear implant. Nine subjects reached the 90% of final SRT performance within six months of device use and 17 obtained that performance level at 12-months. Binary logistic regression analysis revealed that each of the explanatory variables of contralateral word score (p = 0.133), pre-operative implanted ear word score (p = 0.590), age at the time of implantation (p = 0.7), and duration of severe-to-profound hearing loss in the implanted ear (p = 0.594) were not correlated with the time taken to reach 90% of the final SRT value.

Discussion

Results show functional improvement on a range of clinical measures for the candidate group with more hearing in the contralateral ear than would have been recommended based on local candidacy guidelines. Significant group mean post-operative improvement was observed on measures of speech recognition for spatially coincident speech and noise, for spatial release from masking measures where head shadow advantage was provided to the implanted ear, and on a range of real-world, self-reported functional outcome measures. Overall, the findings of the current study support clinics providing a positive recommendation on implantation for cochlear implant candidates with relatively good contralateral hearing.

The 2.4 dB significant post-operative benefit at conversational speech levels for subjects in the current study was similar to the group mean benefit of 3.3 dB shown for subjects in the hearing aid group examined by Vermeire and van de Heyning (2009) (although noting that the difference reported in that study was not statistically significant). Additionally the findings were similar to those reported in prior research that has examined benefit obtained through bimodal as compared to unilateral cochlear implant performance (McDermott & Henshall, 2010). Observed benefit was greater for a lower presentation level of 55 dB SPL as compared to a conversational speech level of 65 dB SPL. The improvement in speech perception at the lower input signal level was consistent with the information obtained from the device use questionnaire, where 71% of the subjects who completed the questionnaire reported post-operative improvement in the ability to detect soft sounds and speech in the real-world environment. Considering that the subject group examined had median word scores in the contralateral ear of 67%, the finding of improved perception of soft speech and detection of soft environmental sounds with real-world use indicates the importance of testing low level audibility in the clinical setting. Improved audibility and perception of soft sounds is important in providing reliable access to the softer components of speech and in situations such as where the speaker or signal originates at a distance from the listener (Alkaf & Firor, 2007).

Of particular interest in the clinical setting is the guidance regarding expected outcomes for subjects with varying levels of contralateral hearing. It might be expected that those candidates with better functional contralateral hearing would expect to obtain less post-operative benefit. Similar to the findings of Vermeire and van de Heyning (2009) sentence in noise benefit was less for subjects with better contralateral hearing. The expected benefit of the post-implantation bilateral as compared to largely pre-operative monaural listening in the test configuration for spatially coincident speech and noise is largely the result of the complementary nature of the signals in the two ears. For those candidates with an already relatively high level of pre-operative function due to normal or near-normal contralateral hearing sensitivity, the addition of the input from the second ear might provide less relative performance improvement than for those candidates with more compromised contralateral hearing. Additionally, the presence of more salient acoustic hearing pre-operatively may result in less attention being provided to the signal from the implanted side.

The observed association between extent of benefit in noise and contralateral hearing was not observed on the majority of other clinical measures. There was no significant correlation between the degree of benefit obtained on spatial release from masking measures, the sub-scales of the SQQ, and the majority of categories from the device use questionnaire. The weak but significant negative association between the contralateral word score and the reported change after implantation when listening to the television or radio is unlikely to be clinically significant since the influence of contralateral word score accounted for only 2.5% of the variance in reported benefit. The report of there being less benefit in detecting soft sounds and speech in subjects with more contralateral hearing would be expected due to there being less reliance on the hearing provided by the cochlear implant in those recipients.

The SRM results can largely be interpreted in terms of the effect of the head shadow at the ear that benefits from it. With the noise moved opposite to the implanted ear, the post-operative increase in
SRM compared to the pre-operative outcome is likely attributable to the greater effect of the head shadow at higher frequencies that are likely to be more readily available with the cochlear implant than with the hearing aid or non-amplified ear. The advantage related to head-shadow benefit that was observed in the current study is consistent with that reported in prior studies (Arndt et al., 2011; Buchholzer et al., 2014; Vermeire & van de Heyning, 2009). In contrast, when the noise is moved to the side of the implanted ear, the effect of the head shadow at the ear with improved SNR is the same for pre- and post-operative measures. The absence of any significant decreases in SRM following implantation for that noise location also indicates that binaural cues were equally effective or ineffective before and after implantation. The modest SRM values obtained compared to listeners with normal hearing (Hawley et al., 2004) indicate binaural cues probably did not play a significant role in either case.

In addition to considering the group mean findings, it is important to understand the individual variability in the data. The better post-operative as compared to pre-operative SRT in noise for 94.8% and 83.5% of subjects at conversational speech and softer presentation levels respectively is an important finding with respect to providing reassurance to candidates. Using the more conservative calculation based on the critical difference of the test measures, there were 64.9% and 68.4% of subjects for whom post-implantation benefit was observed. Most importantly, only one subject obtained a poorer SRT in noise post-operatively that exceeded the critical difference. That subject reported a positive outcome based on questionnaire data, in that post-operative subjective ratings of benefit were higher on the speech and quality subscales of the SSQ questionnaire than those obtained pre-operatively. The ratings from the international outcome inventory also indicated that the implant helped this recipient ‘quite a lot’ in difficult listening situations and that enjoyment of life was ‘quite a lot’ better after implantation. Those functional performance ratings suggest that the poorer speech recognition obtained on the objective measure of speech recognition is likely not a significant finding.

Similarly, analysis of individual subject post-operative ratings on the subscales of the SSQ questionnaire revealed that the majority of subjects provided post-operative ratings that were equal to or better than those obtained pre-operatively. Of the two subjects who reported poorer post-operative function on the spatial sub-scale of between 1.1 and 1.5, it is hypothesized that the reduction in spatial hearing for those subjects may have been related to the loss of acoustic hearing sensitivity in the implanted ear post-implantation. Both subjects had pre-operative PTA in the implanted ear of better than 77 dB HL, which may have been utilized in combination with the contralateral ear acoustic hearing to provide access to binaural cues. Post-operatively there was no measurable acoustic hearing in those subjects. Although there was a small reduction in reported spatial hearing ability in those subjects, both rated their overall experience after implantation as positive, with both stating on the international outcome inventory that the cochlear implant was ‘very much’ worthwhile, and that enjoyment of life was ‘very much better’. The poorer quality rating for S40 was consistent with less-favourable post-operative experience. That subject had normal acoustic hearing thresholds in the contralateral ear, and rated experience with the implant as ‘moderately worth it’ and enjoyment of life as only ‘slightly better’.

The post-operative reduction in localization ability for 13% of subjects as reported on the device use questionnaire was not expected, however is likely related to the extent to which pre-operative bilateral acoustic cues were available and the loss of acoustic hearing in the implanted ear that occurred during the surgical procedure. All five subjects who reported post-operative worsening of localization ability had pre-operative hearing in the implanted ear, with PTA of between 70 dB HL and 87 dB HL. There is likely a degree of individual variability with respect to whether loss of acoustic hearing in the implanted ear results in poorer spatial hearing abilities post-operatively; however this is an important consideration in the clinical setting (Plant et al., 2014).

Another clinical question investigated in the current study relates to the time taken to benefit from the cochlear implant in the post-operative period. This analysis focused on the time taken to obtain close to maximum 12-month performance on ability to understand speech in coincident noise. Based on that analysis, there is no evidence that subjects with more contralateral hearing take longer to obtain benefit from the cochlear implant. This information is likely of assistance to clinicians when discussing post-operative expectations with candidates, although it is important to consider that different results may have been obtained using different clinical measures of performance. However further research is warranted to examine this in further detail. The current study was limited in terms of the time points in which post-operative assessment was conducted. To more fully examine the influence of contralateral hearing on acclimatization to the cochlear implant, an experimental design which incorporated closer monitoring of the trajectory of change would likely be beneficial.

Conclusions

This study examined the expected benefits and limitations of cochlear implantation for candidates with substantial hearing in the non-implanted ear. Significant improvement in speech recognition and in real-world ratings of benefit after implantation occurred for the examined subject group. These findings provide confidence in recommending implantation as an intervention option for candidates with substantial functional contralateral hearing. Although less benefit on adaptive SRT in noise and on perception of soft sounds and speech in the environment was observed for subjects with better contralateral hearing, the majority of subjects obtained and reported substantial benefit on those clinical metrics. Rate of adaptation to the cochlear implant in the post-operative period did not appear to be affected by the degree of contralateral hearing.

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Declaration of interest: The authors report no conflicts of interest.
Appendix 6 – Reprint Study C

Factors Predicting Postoperative Unilateral and Bilateral Speech Recognition in Adult Cochlear Implant Recipients with Acoustic Hearing

Kerrie Plant,1,2 Hugh McDermott,3,4 Richard van Hoezel,1,3 Pamela Dawson,1,2 and Robert Cowan1,3,5

Objectives: The first objective was to examine factors that could be predictive of postoperative unilateral (cochlear implant alone) speech recognition ability in a group of subjects with greater degrees of postoperative acoustic hearing than has been previously examined. Second, the study aimed to identify factors predictive of speech recognition in the best-aided, bilateral listening condition.

Design: Participants were 65 postlingually hearing-impaired adults with preoperative phoneme in quiet scores of greater than or equal to 46% in one or both ears. Preoperative demographic and audiometric factors were assessed as predictors of 12-month postoperative unilateral and bilateral monosyllabic word scores in quiet and of bilateral speech reception threshold (SRT) in babble.

Results: The predictive regression model accounted for 34.1% of the variance in unilateral word recognition scores in quiet. Factors that predicted better scores included: a shorter duration of severe to profound hearing loss in the implanted ear; and poorer pure-tone-averaged thresholds in the contra-ear. Predictive regression models of post-implantation bilateral function accounted for 36.0% of the variance for word scores in quiet, and 30.0% of the variance for SRT in noise. A shorter duration of severe to profound hearing loss in the implanted ear, a lower age at the time of implantation, and better contra-ear hearing thresholds were associated with higher bilateral word recognition in quiet and SRT in noise.

Conclusions: In this group of cochlear implant recipients with preoperative acoustic hearing, a shorter duration of severe to profound hearing loss in the implanted ear was shown to be predictive of better unilateral and bilateral outcomes. However, further research is warranted to better understand the impact of that factor in a larger number of subjects with long-term hearing impairment of greater than 30 years. Better contra-ear hearing was associated with poorer unilateral word scores with the implanted ear alone, but better absolute bilateral speech recognition. As a result, it is clear that different models would need to be developed to predict unilateral and bilateral postimplantation scores.

Key words: Acoustic Hearing, Bimodal, Cochlear Implant, Outcomes.

INTRODUCTION

With candidates for cochlear implantation now including those with greater degrees of postoperative acoustic hearing than severe to profound bilateral deafness, the need for better prediction of potential postimplantation outcomes is increasingly important to provide a clearer assessment of the degree of risk to their preoperative communication ability. However, prediction of an individual’s unilateral (cochlear implant alone) outcome after implantation has proven difficult due to a high degree of intersubject variability across the cochlear implant population. Most research has reported that known predictive factors typically account for less than 60% of the variance in postoperative, unilateral speech recognition scores in postlinguistically hearing-impaired adults (Shea et al. 1990; Summerfield & Marshall 1995; Waltzman et al. 1995; Blamey et al. 1996a, 1996b; Dowell et al. 2004; Bodda et al. 2009; Lazar et al. 2012). In a relatively recent analysis of data for 2251 postlingually deafened adults from 15 cochlear implant centers (Blamey et al. 2013; Lazar et al. 2012), a combination of pre- and post-operative predictive factors were reported to account for only 22% of the variance in postoperative open-set monosyllabic word scores in quiet, inability to reliably predict outcomes for candidates results in a degree of uncertainty and introduces complexity in providing guidance and setting clinical expectations.

A range of factors have been identified in past studies as being correlated with postoperative, unilateral speech recognition outcomes. Blamey et al. (2013) identified preoperative factors of age at onset of severe profound hearing loss, duration of severe profound hearing loss and etiology as accounting for 10% of the variance in postoperative monosyllabic word scores. An expanded model based on the same dataset (Lazar et al. 2012), but with inclusion of additional factors, accounted for a total 22% of the variance in postoperative word scores. Additional predictive factors identified were a shorter duration of moderate hearing loss, hearing aid use, and higher speech recognition ability in the implanted ear. Significant postoperative factors were brand of cochlear implant, the number of active electrodes expressed as a percentage of the total available electrodes on the electrode array, and cochlear implant experience. Holden et al. (2013) reported similar findings for 114 postlingually subjects, with significant preoperative predictive factors being identified as a shorter duration of severe to profound hearing loss, a shorter duration of hearing loss, lower age at the time of implantation, and higher preimplant sentence recognition. Postoperative predictive factors identified were implanted ear aided sound field thresholds and electrode position within the cochlea.

A number of studies have identified duration of hearing loss before implantation as the most robust predictor of postoperative unilateral speech recognition scores. Detailed investigation of the specific effect of duration and degree of hearing loss on speech recognition is difficult to assess, due to varying criteria used for definition of those factors in the literature. However, there is an indication that a longer duration of profound or severe to profound hearing impairment (Gantz et al. 1988;

As candidate criteria for cochlear implantation has expanded over time, and increasingly includes candidates with an identifiable residual acoustic hearing in one or both ears, it has become apparent that bilateral deprivation of auditory stimulation to the central auditory system, rather than unilateral deprivation, is likely to be of greater significance in prediction of postoperative performance. There is now considerable published evidence that positive outcomes can be achieved after implantation of a long-term hearing-impaired ear. In candidates with profound loss caused by otosclerosis, implantation in the long-term hearing impaired as compared with the better ear did not result in long-term disadvantage (Mattern et al. 2007). Boisvert et al. (2011) examined the effect of duration of hearing impairment in a group of 16 subjects who were implanted in an ear with greater than 15 years duration of deafness. In that study, it was observed that a longer history of bilateral auditory deprivation resulted in lower unilateral word scores, but that there was no influence of the duration of unilateral deprivation. Francis et al. (2004) compared postoperative speech recognition scores across three groups of subjects: those with bilateral severe loss; those with severe loss in one ear and profound loss in the other; and those with bilateral profound hearing impairment. The presence of preoperative acoustic hearing in at least one ear was associated with higher postoperative scores, but there was no difference in outcome in relation to whether the implanted ear had a profound or a severe degree of hearing loss. Comparable postoperative speech recognition scores were obtained in each ear of a group of 10 subjects who received bilateral implants but had unilateral long-term auditory deprivation of greater than 15 years (Boisvert et al. 2012b). Friedland et al. (2003) conducted a retrospective data analysis in which the University of Iowa predictive model, which incorporates factors of duration of severe to profound hearing loss and preoperative speech recognition ability, was applied to 38 subjects examined at The Johns Hopkins University. The subject group differed from that initially examined in Iowa, in that the policy was to implant the poorer rather than better hearing ear. The model predicted similar outcomes across groups, and the authors concluded that the findings supported the assertion that an individual’s overall auditory experience, rather than ear-specific history, was likely of most relevance in predicting postoperative outcomes.

The association of higher preoperative speech recognition scores in the ear selected for implantation with better monosyllabic word scores has been reported in a number of studies (Rubinstein et al. 1999; Friedland et al. 2003; Gornaa et al. 2003; Dowell et al. 2004; Gantz et al. 2009; Holden et al. 2013). Positive influence of preoperative audiometric thresholds has been observed in some (Gantz et al. 1988; Gantz et al. 1993) but not all studies (Blamey et al. 1992; Green et al. 2007; Gifford et al. 2010; Holden et al. 2013). Varied findings have been reported in the literature as to the effect of age at implantation on postoperative unilateral speech recognition. The independent effect of age at implantation is often difficult to assess due to the relationship between that factor and the duration of hearing loss; however, the majority of studies have reported poorer word scores in older subjects (Gantz et al. 1988; Blamey et al. 1992; Waltzman et al. 1995; Blamey et al. 1996a; Green et al. 2007; Blamey et al. 2013; Holden et al. 2013).

Despite considerable research to date in outcome prediction for adult cochlear implant recipients, a number of important questions remain unanswered. First, the relevance of the factors predictive of unilateral outcomes in the general cochlear implant population to outcomes for a population with greater degrees of preoperative hearing than previously implanted is unknown. Second, it is important to examine and identify factors that are predictive of bilateral performance obtained using the combination of contralateral acoustic and electric stimulation (the “bimodal” condition). The majority of past research has focused on prediction of unilateral outcomes using only the cochlear implant. However, this is unlikely to be predictive of the real-world benefit to communication for cochlear implant candidates using their implant in combination with acoustic amplification.

Information pertaining to each of those areas will be discussed in the following sections.

## PREDICTING UNILATERAL OUTCOMES IN CANDIDATES WITH ACOUSTIC HEARING

Previous studies have in general included subjects with bilateral severe to profound hearing loss. Recently, an increasing number of candidates are being assessed in the clinical setting who have asymmetric or single-sided hearing impairment (First et al. 2008; Van de Heyning et al. 2008; Vermeire & Van de Heyning 2009; Buzcluer et al. 2010; Arndt et al. 2011; Punte et al. 2011; Ramos et al. 2012), or who have substantial levels of preoperative hearing in the ear to be implanted (Frayse et al. 2006; Gantz et al. 2009; Lenear 2009; Szarzynski & Podskarbi-Fayette 2010).

As such, the influence of duration of hearing loss may be less significant in this candidate population with greater degrees of contralateral hearing, due to there being a relatively short or no period of bilateral auditory deprivation. The level of hearing in the contralateral ear might be expected to be a significant prognostic factor, since more salient acoustic input might be expected to maintain the central function to a greater extent than would be expected with a more compromised input. Influence of preoperative pure tone averaged thresholds in the contralateral ear on postoperative unilateral speech recognition scores has been examined by Lazard et al. (2012), with marginally higher scores obtained for the 14 of 2251 subjects who had a pure-tone average (PTA) of better than 50 dB HL. Although a significant finding, the authors cautioned that the variance of the group was large as a result of the small subject numbers. Examination of the effect of contralateral hearing on clinical outcomes is of interest to further investigate the findings reported by Lazard et al., and to extend the subject group to include those with more hearing than previously examined.

## PREDICTING BILATERAL OUTCOMES

The ability to predict bilateral outcomes for candidates is likely more directly relevant in the clinical setting than prediction of unilateral performance, due to its direct applicability to real world function. Gantz et al. (2009) examined the influence
of a range of factors on bilateral word scores for 68 subjects implanted within the FDA clinical trial of the Hybrid S8 (10mm) electrode. Factors in the model included preoperative bilateral word score, age at onset of hearing loss, age at implantation, duration of hearing loss from onset to implantation, and whether there was posturgical acoustic hearing loss of greater than 30 dB HL. Whether the demographic factors of age at onset of hearing loss and duration of hearing loss reflected unilateral or bilateral deafness is not specified in the article. Preoperative word score and duration of hearing loss explained 29% of the variance in postoperative word score. With an intercept of 55.1%, the model indicated that approximately every 2% increase in preoperative word score resulted in a 1% increase in postoperative score, and for every 2 years duration of hearing loss the model predicted a postoperative score reduction of 1%. In another study, bilateral outcomes were examined for two groups of 15 subjects who were implanted in either the long-term sound-deprived ear or the ear aided before implantation (Boskert et al. 2012a). There was no significant difference in postoperative bilateral speech recognition between the groups, which supports the assertion that the period of bilateral as contrasted to unilateral deprivation is likely to be more important in predicting postoperative outcomes.

The aim of the present study was to examine the factors that contribute to postoperative speech recognition outcomes in quiet and in noise, for both the unilateral and bilateral listening conditions, in a group of candidates with preoperative acoustic hearing in one or both ears before implantation. Findings from the study would be beneficial in assisting clinicians in counseling candidates preoperatively, and in setting postoperative expectations.

MATERIALS AND METHODS

Subjects

Sixty-five postlingually hearing-impaired adults participated in the study. All were implanted with Nucleus cochlear implants (with Contour Advance or Slim Straight electrode arrays) and used the CP910 sound processor. Subjects were recruited from the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic in Melbourne and from the Sydney Cochlear Implant Centre. Implantation dates for recruited subjects ranged from June 4, 2009, to August 14, 2012. Subjects were invited to participate by clinical case managers in the implanting clinics and the majority of candidates who met the inclusion and exclusion criteria and were deemed suitable were approached as to their interest in participating. Approximately 70% of eligible candidates were enrolled into the study. The main reasons for eligible candidates not participating in the study included inability to attend the required study appointments due to either limited time or them living too far from the research centre. The study was approved by the Human Research Ethics Committee at the Royal Victorian Eye and Ear Hospital (Project Number 09/672H) and the Royal Prince Alfred Hospital (Project Number 09/RPAH/427).

All recruited subjects had a preoperative phoneme score on the monosyllabic consonant–vowel–consonant word test of greater than 40% in at least one ear. That criterion was used based on the rationale that candidates with more than that degree of preoperative hearing would fall outside the typical candidacy guidelines used within the Royal Victorian Eye and Ear Hospital Cochlear Implant Clinic (Dowell et al. 2004). A summary of group demographic characteristics of the subjects is shown in Table 1. In the case of no response on audiometric measures, a value of 125 dB HL was entered into the data sheet. The age of the subjects at the time of enrolment into the study ranged from 27 years to 81 years, with a mean age of 62.6 years. Monosyllabic word as compared with phoneme scores have been listed in the table since that is more commonly referenced in past published data, even though phoneme scores were used as the basis for subject recruitment.

As a group, the enrolled subjects had higher levels of preoperative acoustic hearing than subjects in prior studies that have examined factors predicting postimplantation speech recognition. Twenty percentage of subjects in the present study had a PTA threshold of better than 50 dB HL in the ear contralateral to that selected for implantation, as compared with less than 1% in the subject group reported by Blamey et al. (2013) and Lazard et al. (2012). In the present study, 52% of subjects had PTA thresholds of better than 70 dB HL in the contralateral ear as compared with 15% for the subjects of Blamey et al. Comparison of preoperative PTA hearing thresholds for the present study group as compared with subjects of Holden et al. (2013) revealed similar mean and range pertaining to the implanted ear, but differences in terms of the degree of residual acoustic hearing in the contralateral ear. In the present study, the mean PTA threshold in the contralateral ear was 65.4 dB HL (with a range 0 to 113 dB HL) as compared with 97.6 dB HL (with a range 60 to 120 dB HL) for the subject sample that was examined by Holden et al. (2013).

Hearing Aid Fitting and Management

Subjects were either experienced hearing aid users at the time of study enrolment or, for 8 subjects who presented with unilateral hearing impairment, were fitted with the Baha Intenso mounted on a headband, or with the Phonak Una M CROS aid. Hearing aids were provided by each subject’s clinical audiologist and the fitting was reviewed preoperatively using real-ear measurement. Prescribed amplification characteristics were not modified during the research study; rather, the clinically applied parameters were utilized. For subjects with unilateral hearing impairment who were provided with the Baha Intenso or CROS aid, a period of at least 2 weeks of take-home experience was provided for all except one subject before speech perception assessment. Testing was conducted with the CROS aid for 7 subjects and with the Baha device for 1 subject, based on preference after listening with each of the devices.

Study Design and Test Materials

The study used a prospective, longitudinal experimental design. Preoperative data relating to each subject’s unilateral and bilateral speech perception ability, unaided audiometric thresholds, detailed hearing history and demographics were obtained from review of hospital medical files, direct questions to subjects and through clinical measurement. Postoperative assessment was conducted after 12 months of cochlear implant use, both for unilateral (cochlear implant alone) speech recognition in quiet, and for bilateral speech recognition in quiet and for SRT measures in noise. All bilateral speech recognition data were obtained in the best-aided condition at each of the pre- and post-operative time points. The preoperative best-aided
TABLE 1. Group demographic information including age at the time of implantation, duration of bilateral hearing loss, duration of SPHL, preoperative PTA thresholds in the implanted and contralateral ear, and preimplantation monosyllabic word score in the implanted and contralateral ear

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Range</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at implantation</td>
<td>62.6</td>
<td>27-81</td>
<td>11.6</td>
</tr>
<tr>
<td>Duration bilateral hearing loss</td>
<td>29.5</td>
<td>0-38</td>
<td>15.3</td>
</tr>
<tr>
<td>Duration bilateral SPHL</td>
<td>5.1</td>
<td>0-40</td>
<td>7.9</td>
</tr>
<tr>
<td>Preoperative PTA implanted ear</td>
<td>60.8</td>
<td>57.5-125</td>
<td>19.7</td>
</tr>
<tr>
<td>Preoperative PTA contralateral ear</td>
<td>66.4</td>
<td>0-113</td>
<td>23.7</td>
</tr>
<tr>
<td>Preoperative monosyllabic word score implanted ear</td>
<td>9.4%</td>
<td>0-62%</td>
<td>11.7</td>
</tr>
<tr>
<td>Preoperative monosyllabic word score contralateral ear</td>
<td>49.5%</td>
<td>10-99%</td>
<td>26.9</td>
</tr>
</tbody>
</table>

PTA was calculated by averaging unaided audiometric hearing thresholds at frequencies of 500, 1000, and 2000 Hz.
SPHL, severe to profound hearing loss; PTA, pure-tone average.

Speech Perception Test Materials and Procedures

All test materials were digitally recorded and sound files were presented in a sound booth via speakers in the free field. Open-set monosyllabic words were presented in quiet in both the unilateral (ear to be implanted or cochlear implant alone) and bilateral listening conditions. Words were presented free field at a level of 65 dB SPL, RMS, and were based on the original CNC words developed by Peterson & Lehiste (1962). Two lists of words were presented via a loudspeaker located directly in front of the listener at each of the pre- and post-operative time points for each subject. Adaptive SRT in noise was also measured in the bilateral condition using the AuSTIN test (Dawson et al., 2013). Two lists of sentences were administered after a training list was presented to each subject. The adaptive test used BKB-like open-set sentences and provided the SNR for 50% intelligibility at the pre- and post-operative time points. The 80 lists of sentences, each comprising 16 sentences, were constructed in accordance with guidelines used in the development of the original BKB sentences (Bench et al., 1979). The sentence presentation level was fixed at 65 dB SPL, RMS. Both the target sentence and the noise were presented from directly in front of the listener. The words were spoken by a male and the sentences by a female. The competing babble consisted of two male and two female interferers speaking meaningful continuous discourse.

The noise level was adapted during test administration using the HINT scoring method (Nilsson et al., 1994). The method used a step size of 4 dB for the initial four sentences, and a 2 dB step size for the remaining 28 sentences. The fifth sentence was presented at the mean of the SNRs of the first four sentences and the SNR at which the fifth sentence would have been presented on the basis of the response to the fourth sentence. The level of the competing noise was adjusted by a software program, according to the subject's responses. The noise level increased when the subject responded with greater than or equal to 50% of morphemes correct, and decreased when the subject failed to repeat 50% of morphemes correctly in the sentence. The SRT was calculated as the average of the signal to noise ratios for sentences 5 to 32 and also the signal to noise ratio at which sentence 33 would have been presented on the basis of the subject's response to sentence 32. All competing noise was presented continuously. A beep was presented before each sentence within the adaptive test to alert the subject to the onset of the presentation interval.

Explanatory Variables

The demographic variables examined as correlates with each of the postoperative measures were (1) age at implantation, (2) duration of bilateral hearing loss, (3) duration of implanted ear hearing loss, (4) PTA unaided thresholds in the implanted ear, and (5) PTA unaided thresholds in the contralateral ear. Correlation coefficients and p values computed for each of the pairs of explanatory variables are shown in Table 2.

The explanatory variables representing the degree of preoperative functional hearing in each of the implanted ear and contralateral ear.

TABLE 2. Correlation coefficients (r) and p values for pairs of explanatory variables included in the analysis

<table>
<thead>
<tr>
<th>Explanatory Variable Pairs</th>
<th>r</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age-duration bilateral SPHL</td>
<td>0.193</td>
<td>0.124</td>
</tr>
<tr>
<td>Age-duration implanted ear SPHL</td>
<td>0.121</td>
<td>0.338</td>
</tr>
<tr>
<td>Age-PTA implanted ear</td>
<td>-0.193</td>
<td>0.124</td>
</tr>
<tr>
<td>Age-PTA contralateral ear</td>
<td>0.210</td>
<td>0.093</td>
</tr>
<tr>
<td>Duration bilateral SPHL-duration implanted ear SPHL</td>
<td>0.330</td>
<td>0.004</td>
</tr>
<tr>
<td>Duration bilateral SPHL-PTA implanted ear</td>
<td>0.002</td>
<td>0.002</td>
</tr>
<tr>
<td>Duration bilateral SPHL-PTA contralateral ear</td>
<td>0.457</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Duration implanted ear SPHL-PTA implanted ear</td>
<td>0.312</td>
<td>0.011</td>
</tr>
<tr>
<td>Duration implanted ear SPHL-PTA contralateral ear</td>
<td>0.118</td>
<td>0.349</td>
</tr>
<tr>
<td>PTA implanted ear-PTA contralateral ear</td>
<td>0.014</td>
<td>0.915</td>
</tr>
</tbody>
</table>

Significant correlations between explanatory variables (p < 0.05) are indicated in bold font.
PTA, pure-tone average; SPHL, severe to profound hearing loss.
contralateral ear were the PTA unaided thresholds, rather than preoperative speech perception measures. The rationale for use of PTA thresholds was that the measure is a globally standardized audiometric technique and so not impacted by factors such as varying difficulty of speech perception test materials. Preoperative word score and PTA in the ear selected for implantation were correlated (r = -0.548, p = 0.001), as were those variables pertaining to the contralateral ear (r = -0.733, p < 0.001). As a result, it was not possible to include both factors in the multiple regression analyses. Although the data for the model that included PTA as explanatory variables is presented in detail throughout the manuscript, reference is made to the effect on the model where the preoperative implanted and contralateral ear word scores were used rather than the PTA values.

Duration of hearing loss was examined for two degrees of loss; initially for the degree of severe to profound loss, and subsequently for the duration of any hearing loss. Duration of any hearing loss was estimated based on hearing history and subjective reports as to the time from which hearing loss was first noticed and was deemed to have first impacted hearing ability. Duration of severe to profound hearing loss was estimated based on the period of time for which the subject could not use the aided hearing alone to communicate without lip reading. Combined with the information obtained via hearing history, severe to profound hearing loss was defined as having a threshold frequency PTA exceeding 70 dB HL (using frequencies 0.5, 1, and 2 kHz). For data pertaining to bilateral severe to profound hearing loss, subjects were required to have a PTA unaided threshold of greater than 70 dB HL in both ears; for duration of loss associated with the implanted ear the criterion was applied to the single ear preoperatively. For over 50% of the subjects enrolled in the study (35 of the 65 subjects), the contralateral ear median unaided threshold was better than 70 dB HL, so the duration of severe to profound bilateral hearing loss for those subjects was zero.

RESULTS
Factors Predicting Unilateral (Implanted Ear Alone) Speech Recognition
Best subsets regression analysis was used to determine which of the explanatory variables should be included in a multiple linear regression model. The postoperative unilateral word recognition scores were not normally distributed, so results were transformed using arcsine square root transformation. Transformation resulted in data being normally distributed. Analysis was performed using Minitab version 16. The first analysis was conducted with duration of severe to profound loss as the “duration” factor, as compared with the duration of any clinically noticeable hearing loss. Evaluation of residuals revealed normality, linearity, and homoscedasticity. The best-fit model included two factors which were the duration of severe to profound hearing loss in the implanted ear and the PTA thresholds in the contralateral ear. Those factors together accounted for 34.1% of the variance in postoperative unilateral scores. Results of the multiple linear regression analysis for those factors are outlined in Table 3. The model was selected based on determination of balance between the variance accounted for by inclusion of each of the explanatory variables and the smallest Mallows Cp value. The relatively small Mallows Cp value (4.5) indicated that the model was precise in estimating the true regression coefficients and predicting future responses. The variance inflation factor was also examined to ensure that there was not an issue within the model of multicollinearity between predictor variables.

Scatterplots indicating the relationship between the explanatory variables and unilateral word scores are shown in Figure 1. Higher postoperative unilateral word scores were obtained for subjects with a shorter duration of severe to profound hearing loss in the implanted ear and poorer PTA contralateral unaided audiometric thresholds. In the regression analysis pertaining to the duration of severe to profound hearing loss in the implanted ear, the removal of the data for three subjects with greater than 30 years of severe to profound hearing loss resulted in a lack of correlation between the explanatory and dependent variable. Those data points are shown as open circles in the left panel of Figure 1, and the regression line is dashed to indicate the reliance on those data points for the significant finding.

Additional analyses were conducted to investigate whether there was an influence of explanatory variables not examined within the initial model. Repeat of the best subset regression analysis with duration of clinically noticeable hearing loss rather than duration of severe to profound hearing loss revealed that duration of both bilateral and implanted ear alone hearing loss (not specifically of severe to profound degree) were not significant factors in predicting outcomes. Analysis using the speech perception rather than the PTA-based explanatory variables revealed that 27% of the variance was explained by the same factors as for the PTA-based model.

Factors Predicting Bilateral Speech Recognition
As for the analysis of unilateral data, best subsets regression analysis was used to determine the best fit model for the bilateral word in quiet and sentence in noise data. The bilateral word in quiet score was arcsine transformed to achieve a normal distribution. Data was obtained for 58 subjects on the SRT in noise test. SRT data was not normally distributed due to values obtained for the two poorest performing subjects. Removal of data for those subjects did not change the influence of explanatory variables nor significantly the degree of variance accounted for by the model. As a result, the full dataset was included in the analysis.

The explanatory variables of duration of severe to profound hearing loss in the implanted ear, PTA unaided thresholds in the contralateral ear, and age at implantation were identified as predictive factors in the bilateral data analysis. Those factors together accounted for 36.0 and 30.9% of the variance in bilateral postoperative word in quiet scores and SRT values in noise respectively. Examination of residuals revealed normality, linearity, and homoscedasticity between the predicted dependent variable scores and errors of prediction.

Results of the multiple linear regression analysis relating to dependent variables of word in quiet scores and SRT values in noise are shown in Table 4. Figure 2 shows scatterplots revealing the significant correlation between the explanatory variables and the bilateral word score. It can be seen that higher postoperative bilateral word scores were obtained in subjects with a shorter duration of severe to profound hearing loss in the implanted ear, a better unaided audiometric PTA threshold in the contralateral ear, and a lower age at implantation. Contrary to the observation that removing the data for the three subjects
with greater than 30 years of severe to profound hearing loss resulted in lack of correlation between the explanatory and dependent variable for the unilateral analysis, removal of those subjects for the bilateral data analysis strengthened the correlation between the variables. The correlation coefficients were $-0.386 (p = 0.002)$ and $-0.473 (p < 0.001)$ for the complete and reduced datasets, respectively.

Figure 3 shows results for the sentence in noise-dependent variable. A more negative signal to noise ratio (shown as higher on the graph) indicates better performance. The adaptive test provides an ability to examine the performance level without influence of ceiling effects which were observed on the word in quiet test. For the bilateral sentence in noise evaluation, removal of the data points for subjects with more than 30 years duration of severe to profound hearing loss in the implanted ear resulted in lack of correlation between the examined variables. As for the bilateral monosyllabic word in quiet scores, better postoperative bilateral SRT values were obtained for subjects with a lower age at implantation, better unaided audiometric PTA threshold on the contralateral ear, and a shorter duration of severe to profound hearing loss in the implanted ear. Analysis using the speech perception rather than the PTA-based explanatory variables revealed that the best-fit model comprised the same factors, which together accounted for 47% and 37.5% of the variance in bilateral word score in quiet and SRT in noise, respectively.

### DISCUSSION

A range of preoperative factors were examined as predictors of clinical outcomes in the present study. Key differences from prior studies were (1) the enrollment of a subject population with more substantial levels of preoperative acoustic hearing in one or both ears than has been previously examined, and (2) the examination of factors that predicted both unilateral and bilateral postimplantation performance. Understanding the factors of greatest importance to predicting postimplantation experience would be beneficial in the clinical setting, since there is currently limited information on which to provide guidance to candidates with greater levels of residual hearing regarding expectations and risks.

Examination of explanatory variables predictive of unilateral speech recognition scores factors revealed some key differences as compared with prior studies. First, in contrast to a number of prior studies (Gantz et al. 1998; Blamey et al. 1992; Battmer et al. 1995; Walliman et al. 1995; Dowell et al. 2004; Green et al. 2007; Roditi et al. 2009; Blamey et al. 2013; Holden et al. 2013), age at implantation was not found to be significantly correlated with postoperative unilateral word recognition. It was hypothesized that the lack of correlation between age at implantation and postimplantation unilateral word scores might have been due to an interrelationship between that factor and the duration of severe to profound hearing loss in the implanted ear, which was identified as a significant predictor.
in the current defined model. However, there was no correlation between age at implantation and duration of severe to profound implanted ear hearing loss in the population examined in the present study. Another potential explanation for the lack of correlation of age at implantation as a predictive factor in this group may be the more limited age range of the examined subjects as compared with prior studies. In the present study, the age at implantation ranged from 27 to 81 years, with a mean of 62.6 years and a standard deviation of 11.6 years. The subject groups examined within the most recent prior research (Roditi et al. 2009; Lazard et al. 2012; Holden et al. 2013) had a similar age range but slightly larger standard deviation (range 15.3 to 17.3 years).

A second key observation from the present study was the lack of correlation between duration of bilateral hearing loss and postimplantation speech recognition. That factor has been identified as a significant predictor of unilateral word recognition in prior studies (Roditi et al. 2009; Lazard et al. 2012). Similarly, duration of bilateral severe to profound hearing loss was not a significant predictor in the present study, in contrast to previously published research (Gantz et al. 1988; Kileng et al. 1991; Waltzman et al. 1995; Rubinstein et al. 1999; Gomaa et al. 2003; Dowell et al. 2004; Leung et al. 2005; Green et al. 2007; Blamey et al. 2013, 1996b, 1992; Holden et al. 2013). This is not surprising, however, given that most subjects in the present study had hearing in at least one ear preoperatively.

The finding that a shorter duration of severe to profound hearing impairment in the implanted ear was correlated with higher postoperative unilateral word scores is somewhat contrary to the hypothesis that unilateral auditory deprivation is not important when input to the central system is maintained through contralateral hearing (Francis et al. 2004; Roditi et al. 2009; Boisvert et al. 2012a, b, 2011). Since the three data points for subjects with greater than 30 years duration of severe to profound hearing loss in the implanted ear drive the slope of the correlation data were analyzed with those three subjects’ data removed. In the analysis for the unilateral word scores and bilateral SRT, the removal of the data points for those subjects resulted in a lack of correlation between the explanatory and dependent variables. However, for the bilateral word score analysis, the removal of those data points strengthened the correlation between duration of severe to profound hearing loss and word scores in quiet. Each of those three subjects did not have any measurable preoperative hearing thresholds in the implanted ear, and so may have had poor spiral ganglion cell survival that could have resulted in compromised outcomes with electrical stimulation in the unilateral listening condition. Further investigation as to the influence of long-term auditory deprivation in the implanted ear on unilateral speech recognition outcomes would be warranted based on that observation. With an increasing number of candidates being implanted who have substantial acoustic hearing in the contralateral ear, it is likely that the influence of duration of loss on the implanted side will be better understood in time.

Similar to the majority of recent published data (Green et al. 2007; Gifford et al. 2010; Lazard et al. 2012), there was no correlation in the present study between implanted ear preoperative hearing thresholds and unilateral postoperative speech recognition. However, poorer scores were obtained for subjects with better contralateral PTA hearing thresholds. This finding differs from that reported by Lazard et al. (2012), where higher postoperative word scores were obtained for subjects with better contralateral ear hearing thresholds, although the authors cautioned that subject numbers in that analysis were too low to be conclusive. Poorer unilateral word scores with the implanted ear for subjects with better contralateral hearing is not consistent with the hypothesis that maintenance of central auditory pathways as a result of auditory input would result in improved speech recognition after implantation (Boisvert et al. 2011, 2012b). A possible reason for the lower unilateral word scores using the cochlear implant alone could be due to recipients with greater levels of contralateral acoustic hearing relying more on that information as the primary salient signal. Such reliance on acoustic contralateral hearing may result in less attention being given to the electrical signal and so limit the extent to which adaptation occurs to the electrical signal alone. In that case,
specific cochlear implant alone rehabilitation or auditory training might be beneficial during the postoperative period.

Another important consideration in the clinical setting is that performance with one ear is unlikely to accurately predict outcomes with two ears. If the contralateral ear performs much better than the implanted ear, for example, outcomes with the cochlear implant may be largely irrelevant. In addition, if the implant signal and contralateral acoustic signal provide complementary information, then even measuring both ears separately cannot accurately predict outcomes for bilateral (bimodal) device use. It is also possible that binaural benefits might arise in the combined case. It is likely most important when setting candidate expectations to consider the factors predictive of bilateral as compared with unilateral speech recognition. Such discussion of expected bilateral outcomes would likely be more relevant to a candidate’s real-world functional performance. Also, the development of a bilateral outcome prediction model would enable clinicians to track an individual’s progress over time, and examine whether performance is meeting expectations, without potential influence of lack of familiarity in the unilateral listening condition on outcome measures.

Factors that best predicted bilateral speech recognition were the same for the outcome measures administered in quiet or noise. As expected, subjects with better contralateral ear unaided audiometric thresholds tended to obtain better results on both metrics. The higher speech recognition scores in those situations would be expected as a result of the more substantial contribution provided to the bilateral listening condition by the acoustic contralateral hearing. Although the word in quiet measure is likely impacted by the influence of ceiling effects, the SRT in noise metric is adaptive in nature and so more robust to that potential issue. Although there is only limited published data describing factors important in predicting bilateral outcomes, preoperative bilateral word score has been reported to be predictive of postoperative outcomes (Gantz et al. 2009, Amoozdar et al. 2012). That factor, combined with duration of hearing loss, accounted for 29% of the variance in outcome for 68 hybrid recipients. However, it is not clear from the published manuscript whether the demographic factor of duration of hearing loss reflected unilateral or bilateral deafness. In the present study, there was a significant correlation between the implanted and contralateral ear PTA thresholds and the corresponding
word scores, and so the threshold values were used in the analysis. Use of threshold values as compared with preoperative word scores would be expected to provide benefit in a global clinical setting, in that the findings could be applied without complexity associated with regional variability in speech perception test materials. Although not explicitly identified as a predictive factor in the best-fit model of Grant et al. (2009), a lower age at implantation was also reported to be a positive predictor of speech recognition with the hybrid implant. That finding is also consistent with that observed in the present study.

There are a number of important considerations related to potential application of an outcome prediction model in the clinical setting. First, it is of interest to consider the potential advantages and disadvantages of each of the unilateral and bilateral model approaches. A model that predicted unilateral outcomes would likely be more easily applied clinically, in that outcomes could be predicted for the cochlear implant alone without consideration of the influence of the contralateral acoustic device as a potential source of additional variability. However, it is likely of most relevance to a candidate to discuss the expected outcome in the bilateral condition. In applying a model that predicts an absolute measure of bilateral outcome, it would be important to discuss with a candidate their current preoperative bilateral performance on any particular measure, and the expected change postimplantation. Without consideration as to the preoperative bilateral auditory function in this type of candidate with substantial degrees of preoperative residual hearing, the predicted post-implantation score would not be clinically meaningful. A second important consideration, in line with prior published research, is that there remains a significant proportion of the variance in outcomes that cannot be accounted for by the factors examined within the present study. Further research would be warranted to understand the factors predictive of postoperative bilateral outcomes, given the limited information currently available to provide guidance and set postoperative expectations for candidates.

In addition to improving the quality of the information provided to candidates during preoperative discussion, there would also be other advantages arising from improving the ability to predict postoperative outcomes. Monitoring outcomes against those “expected” may in the future provide an opportunity to better allocate limited clinical resources, and identify those recipients who require more extensive postoperative support.
Identification of the factors that may contribute to poorer performance may also lead to opportunities to better address those factors through modification to technology or to more individualized approaches to device fitting and rehabilitation.

CONCLUSIONS

Factors most important in predicting unilateral and bilateral outcomes have been identified for candidates with substantial levels of acoustic hearing in one or both ears presenting at cochlear implant centers. The predictive models identified within the present study accounted for 34.1% and 36.0% of the variance in unilateral and bilateral postimplantation word recognition scores obtained in quiet and 30.9% of the variance for bilateral SRT in babble.

A shorter duration of severe to profound hearing loss in the implanted ear was shown to be predictive of better unilateral and bilateral outcomes. However, further research is warranted to better understand the impact of that factor in a larger number of subjects with long-term hearing impairment of greater than 30 years. Listeners with better contralateral hearing were shown to obtain better bilateral outcomes, however they also benefited less from implantation. The poorer unilateral outcomes in the listeners with better contralateral performance may have contributed to the reduced benefit in those listeners compared with listeners with poorer contralateral hearing.

The findings from the study indicate that different models apply to predicting unilateral and bilateral postimplantation speech recognition scores. Although a unilateral model may be more easily applied clinically, such a model may underestimate the postimplantation benefit that is provided through integration of the acoustic and electric modalities. Use of a bilateral outcome prediction model would likely be more clinically relevant. However, when applying such a model in the clinical setting, it would be important to present expected postimplantation performance with reference to preoperative scores to indicate the likely degree of improvement postimplantation.

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REFERENCES


Factors influencing electrical place pitch perception in bimodal listeners

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Factors that might affect perceptual pitch match between acoustic and electric stimulation were examined in 25 bimodal listeners using magnitude estimation. Pre-operative acoustic thresholds in both ears, and duration of severe-profound loss, were first examined as correlates with degree of match between the measured pitch and that predicted by the spiral ganglion frequency-position model. The degree of match was examined with respect to (1) the ratio between the measured and predicted pitch percept on the most apical electrode and (2) the ratio between the slope of the measured and predicted pitch function. Second, effect of listening experience was examined to assess whether adaptation occurred over time to match the frequency assignment to electrodes. Pre-experience pitch estimates on the apical electrode were within the predicted range in only 28% of subjects, and the slope of the electrical pitch function was lower than predicted in all except one subject. Subjects with poorer hearing tended to have a lower pitch and a shallower electrical pitch function than predicted by the model. Pre-operative hearing thresholds in the contralateral ear and hearing loss duration were not correlated with the degree of pitch match, and there was no significant group effect of listening experience. © 2014 Acoustical Society of America.  
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I. INTRODUCTION

Implantation of multi-channel cochlear implants in recipients with acoustic hearing provides an opportunity to compare the pitch percept that is obtained through electrical stimulation, at different place positions within the cochlea, to that provided by acoustic stimulation. Understanding the relationship between acoustic and electric percepts may provide clinically relevant information to assist with optimization of outcomes for listeners using bimodal devices, i.e., when combining the signal from the cochlear implant sound processor with that obtained through acoustic amplification. Approaches to optimizing bimodal performance are becoming increasingly important in the clinical setting due to expansion in candidacy indications for cochlear implantation (Frayse et al., 2006; Gantz et al., 2009; Lenarc et al., 2009; Skarzynski et al., 2009; Vermeire and Van de Heyning, 2009; Buchner et al., 2010; Arndt et al., 2011).

Pitch information can be conveyed by cochlear implants by means of encoding temporal and spectral cues (Townshend et al., 1987; McDermott, 2004) with place of stimulation being the predominant cue. Although amplitude modulation of pulsatile stimulation, or pulse rate itself, at rates below approximately 300Hz can be effective as a means of delivering temporal pitch, this efficacy is variable across listeners and typically saturates at rates beyond approximately 300Hz (Shannon, 1983; Tong and Clark, 1985). Electrical stimulation of intracochlear electrodes within the scala tympani typically results in progressively higher pitch as the site of stimulation changes from an apical to basal location. This is consistent with the tonotopic organization of the cochlea as described by von Bekesy (1960) with different areas of maximum basilar membrane oscillation arising in response to acoustic sounds of different frequency. The variation in place-pitch sensation that occurs as a result of stimulating electrodes at different positions in the cochlea is important to convey information relating to spectral shape, which is critical to accurate speech perception. A number of studies conducted to date have suggested that a particular allocation of frequencies to electrodes, based on electrode position within the cochlea, may be important for speech recognition and music perception (Dorman et al., 1997; Shannon et al., 1998; Fu and Shannon, 1999; Faulkner et al., 2003). Matched place pitch across ears has also been shown to improve interaural level perception in bimodal listeners (Francault and Wouters, 2007) and perception of interaural timing differences (Long et al., 2003) with use of bilateral cochlear implants.

Greenwood’s characterization (Greenwood, 1990) of the frequency to position function along the organ of Corti has
largely provided the basis for comparison of the electrical pitch percept with that which would be predicted according to the intracochlear electrode position. Previous research with bimodal listeners has involved measurement of the pitch obtained through electrical stimulation compared to that obtained using contralateral acoustic hearing. Electrical pitch percepts have generally been reported to be 1–2 octaves lower than would be predicted by Greenwood’s function (Blamey et al., 1996; Boex et al., 2006; Reiss et al., 2007; McDermott et al., 2009). However, alternative findings have also been reported in the literature. Evidence of close match to the Greenwood cochlear place prediction has been observed in two independent publications (Vermeire et al., 2008; Carlyon et al., 2010). Higher pitch than predicted by Greenwood’s function on the most apical electrodes was observed in six users of the Med-El Combi 40+ device (Baumann and Noble, 2006) and in one of six subjects assessed by Boex et al. (2006) using the HiRes™90K device. In understanding both the reasons for variability across studies and potential reasons for lower than predicted pitch estimates reported in the literature, it is of interest to examine a range of potential factors that may have influenced the findings. Those factors include: (1) the test procedure used to obtain the pitch estimates, (2) direct stimulation of spiral ganglion cells and cochlear anatomy, (3) neural survival in the implanted ear, (4) the degree of hearing in the reference (contralateral) ear, and (5) the effect of listening experience. A summary of the published data relating to each of these areas is provided in the following text.

A. Test procedure

Pitch matching between ears with different perceptual qualities has been shown to be highly susceptible to nonsensory bias (Carlyon et al., 2010). Multiple techniques have been used in past publications to obtain electrical pitch estimates. These include the method of constant stimuli, pitch matching by adjustment, interleaved adaptive adjustment, and magnitude estimation. Variability in the reported findings across studies may, at least in part, have arisen as a result of the measurement technique used.

B. Direct stimulation of spiral ganglion cells and cochlear anatomy

One proposed contributor to the lower than predicted pitch percept is that the intracochlear electrode array, when positioned facing the modiolus and close to the spiral ganglion, stimulates the spiral ganglion cells within Rosenthal’s canal directly rather than stimulating the more rapidly degenerating radial nerve fibers that lie close to the organ of Corti (Blamey et al., 1996). Stakhovskaya et al. (2007) developed a frequency-place map of the spiral ganglion cells relative to the organ of Corti through an analysis of nine human temporal bones and reported a compressive effect in the apical region of the cochlea beyond 1000 Hz. This effect has been reported to arise as a result of the different length of the cochlear structures and the fact that the radial nerve fibers from the organ of Corti take an increasingly tangential path into the spiral ganglion in that region. That observation may account in part for the discrepancy observed between the pitch estimates and the prediction based on Greenwood’s function; however, there is only a relatively small difference between the two modeling approaches up to an insertion angle of 72°. As a result, there are likely other contributing factors.

Variation in the degree of match to the models as a function of insertion angle may be expected due to the fact that the frequency-place function becomes shallower as insertion angle is increased. In line with those functions, more deeply inserted electrodes would be expected to have a smaller relative change in pitch as insertion angle is increased. Lack of differentiation in pitch percept for more deeply inserted electrodes has been reported by Baumann and Noble (2006), and may explain the higher pitch than predicted by Greenwood’s model in that study and in one of six subjects assessed by Boex et al. (2006). There is also suggestion that cross-turn stimulation may occur in the apical region based on cochlear modeling (Fijnheer et al., 2001) as a result of arrangement of the auditory nerve endings being different in the apical as compared to the basal region of the cochlea and that may result in lower pitch percepts than expected at high stimulation levels.

C. Neural survival in the implanted ear

Another potential factor affecting the degree of match between the measured and predicted pitch may be the changes that occur as a result of impairment in cochlear function as a result of different patterns of neural survival within the cochlea (McDermott et al., 2009). Given that the most typical pattern of hearing loss involves a greater reduction in high- as compared to low-frequency sensitivity, there may be shifts in the electrical pitch percept that occur as a result of poor neural survival in the stimulated region. Stimulation in a region of the cochlea that would typically be tuned to high frequencies, but has poor neural survival, may result in stimulation of the more-apical neural population. Support for this hypothesis would be expected to manifest as an effect of insertion angle on the goodness of match in electrical pitch percept to the frequency-place models because neural survival might be expected to be greater for more deeply inserted electrodes. Although there appears to be considerable variability in the data, the incidence of the pitch being more closely matched or higher than predicted would appear greater for insertion angles beyond approximately 60°, and this is in line with the general finding reported by Baumann and Noble (2006) and for one of subjects assessed by Boex et al. (2006). For insertion angles below approximately 45° the majority of findings in published literature suggest lower electrical pitch percepts than would be predicted from the cochlear or spiral ganglion models (Blamey et al., 1996; Boex et al., 2006; McDermott et al., 2009). Shallow slope of electric as compared to acoustic hearing, as has been reported by Blamey et al. (1996), may also be a contributing factor to the lower than predicted pitch for shallower insertion angles.

D. Degree of hearing in the reference (contralateral) ear

Vermeire et al. (2006) and Carlyon et al. (2010) hypothesized that the close match to Greenwood’s function
in their data was the result of subjects in those studies having normal or near-normal hearing thresholds in the ear contralateral to the implant. It was hypothesized that the pitch percept in an impaired acoustic hearing ear, used as the reference for pitch matching, might have been lower due to the presence of dead regions and the resultant spread in the traveling wave toward the apex of the cochlea. At the peripheral level, presentation of acoustic stimuli to a cochlea with a severe sensorineural impairment may result in a shift in the position of the peak of the traveling wave that could lead to a lower than normal pitch match for a given input frequency (Lebman et al., 1986). Frequency selectivity may also affect the ability to obtain reliable pitch data (Green et al., 2012).

The degree of hearing in the contralateral ear may also influence the tonotopic structure of the auditory cortex. Auditory cortex reorganization in response to high-frequency hearing loss has been shown to occur in animal models (Irvine et al., 2003; Fallon et al., 2009) with the region of the cortex typically responsive to high-frequency stimuli adapting to be responsive to lower frequencies. Improved frequency discrimination (McDermott et al., 1998; Thau-Van et al., 2003) and improvement in low-frequency speech perception (Moore and Vinay, 2009) have been attributed to this cortical reorganization. Such cortical reorganization in the ear used as the acoustic reference for pitch assessment may have influenced the findings.

E. Effect of listening experience

The effect of listening experience on electrical pitch is an important consideration, both in terms of understanding the potential contribution of this factor to published data and for potential clinical application of matching acoustic and electric percepts for bimodal devices. In one study, the effect of cochlear implant listening experience on electric and acoustic pitch estimates was assessed in 14 adult subjects (McDermott et al., 2009). Higher electric pitch percepts on the apical electrode were observed for five subjects having no implant experience as compared to nine tested after experience (of between 7 months and 4 years). The group mean pure tone frequency that elicited the same pitch as the most apical electrode for the subjects with and without cochlear implant experience were 382 and 667 Hz, respectively. In that study, it was postulated that the pitch associated with electrode position might be close to that predicted by the spiral ganglion frequency map prior to implant experience, and then change post-operatively in response to the way in which acoustic input frequencies are assigned to electrodes in the sound-processor program.

To date, there has been only limited examination of longitudinal pitch estimates in the electrically stimulated ear. There is evidence of convergence in pitch estimates toward the assigned frequency range in some studies (Reiss et al., 2007; Green et al., 2012; Reiss et al., 2014); however, there is also reported high degree of variability across listeners. Carlyon et al. (2010) reported that the degree of match between electric and acoustic pitch was not strongly influenced by experience in two subjects with normal contralateral acoustic hearing. However, in that study, the data were collected as a secondary objective within a study primarily examining the effect of implantation on alleviation of tinnitus, and there was only limited ability to examine the effect of listening experience on electrical pitch perception. Further evaluation of the effect of experience on electrical pitch estimates is warranted given the limited data and the importance of this factor when considering potential clinical application of matching acoustic and electrical stimulation with bimodal devices.

The current study first aimed to examine a number of factors that may influence the degree of initial match (i.e., that obtained prior to listening experience being provided with the cochlear implant) in perceived electrical pitch to that predicted by the spiral ganglion map. Specifically it was of interest to assess whether implanted ear characteristics of pre-operative hearing thresholds and duration of severe-profound hearing impairment, as potential measures of neural survival, were correlated with the degree of initial (pre-experience) match. Additionally, the effect of the degree of contralateral hearing on initial pitch estimates was examined to investigate further the findings of Vermeire et al. (2008) and Carlyon et al. (2010) that contralateral hearing sensitivity may have explained the improved pitch match for those subjects having normal or near-normal thresholds in the contralateral ear. Use of a standardized procedure across a range of subjects, with differing levels of contralateral hearing, was used to provide further information relating to the findings from those studies. Finally, detailed assessment of electrical pitch changes over time investigated the hypothesis proposed by McDermott et al. (2009) that subjects without cochlear implant listening experience may have a closer alignment between the measured and predicted pitch percept and that the lower than predicted pitch percept observed in previous studies may be a result of adaptation to the way in which frequencies are assigned to electrodes in the sound processor program. Examination of the effect of listening experience using a within-subject design was conducted in a group of subjects implanted with longer electrode arrays than previously examined by Reiss et al. (2007) and provided information regarding adaptation in a larger number of subjects than has been previously examined. Findings from the study may lead to improved programming techniques for users of bimodal and hybrid devices through providing information to assist in matching of acoustic and electrical signals.

II. MATERIALS AND METHODS

A. Subjects

Twenty-five postlinguistically hearing-impaired adults participated in the study. All were implanted with Nucleus cochlear implants (Contour Advance, Slim Straight or Hybrid-L24). Demographic information for each of the subjects is shown in Table I. The age of the subjects at the time of enrollment ranged from 42 to 81 years with a mean age of 64 years. Table I also provides information regarding gender, etiology of hearing impairment, duration of severe-to-profound hearing loss, median unaided low (0.25–1 kHz)
<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age at implant (yr)</th>
<th>Duration severe-to-profound loss (yr)</th>
<th>Median LF unaided threshold (dB HL)</th>
<th>Median HF unaided threshold (dB HL)</th>
<th>Electrode type</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>M</td>
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<td>125</td>
<td>Contour Advance</td>
</tr>
<tr>
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<td>15</td>
<td>85</td>
<td>125</td>
<td>Contour Advance</td>
</tr>
<tr>
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<td>64</td>
<td>15</td>
<td>85</td>
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</tr>
<tr>
<td>S4</td>
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<td>90</td>
<td>Contour Advance</td>
</tr>
<tr>
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<td>125</td>
<td>125</td>
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</tr>
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<td>95</td>
<td>90</td>
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<tr>
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</tr>
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</table>

and high frequency (1–4 kHz) audiometric thresholds, and type of electrode array.

### B. Study design

The study employed a prospective, longitudinal within-subject experimental design in which each subject served as his or her own control. Numerical estimates of pitch were obtained using a magnitude estimation technique at four time points with each subject: just prior to clinical mapping and at approximately 3, 6, and 12 months post-activation. Testing conducted prior to clinical mapping involved psycho-physical stimulation on the electrodes, but subjects were not provided with any electrical stimulation that included mapping of input frequencies to electrodes via the clinical program in the sound processor. Stimuli consisted of five acoustic pure tones and five single-electrode pulse trains and were delivered via custom software and a custom interface box. The five acoustic pure tones spanned the range of acoustic hearing available in the ear contralateral to the cochlear implant. All tones were of 500 ms duration and had 30 ms linear amplitude tapers applied at the onset and offset. Acoustic tones were presented via a tube-phantom to the ear contralateral to the implanted side.

To minimize the likelihood of data being affected by non-sensory bias (Carbyon et al., 2010), two different acoustic frequency ranges were selected and evaluated for each subject where possible. For an individual subject, this involved either testing using one-third octave spacing for one test condition and two-third octave frequency spacing for the alternative range or with two different ranges that used one-third octave spacing. Selection of each of those options was dependent on the degree of acoustic hearing impairment, i.e., whether there was sufficient acoustic hearing to span a frequency range that used two-third octave frequency spacing. Collection of pitch estimates using two acoustic frequency ranges aimed to overcome the possible bias of subjects selecting pitch estimates near the center of the acoustic frequency range. Electric stimuli consisted of 900 Hz pulse trains of 500 ms duration presented to single electrodes at the mid to apical end of the array. Stimulus pulse parameters used a monopolar electrode configuration (MP1 + 2), a pulse width of 25 μs and an interphase gap of 8.4 μs, consistent with default parameters used within the clinical custom sound programming software provided by Cochlear Limited. Typically the electrodes used for the pitch estimation task were 22 (the most apically located electrode), 19, 16, 13, and 10. Variation in the selected electrodes across the multiple administrations of the test procedure was used when time permitted, through selection of electrodes 22, 20, 18, 16, and 14. As for the acoustic stimuli, this technique aimed to minimize any potential for the range of stimuli used in the assessment to introduce non-sensory
bias and so potentially influence the findings. Frequency and
electrode selection did not affect the outcome of the
study; however, they were used to minimize potential con-
 founding factors.

To examine the reliability of the experimental proce-
dure, test-retest repeatability was examined for test admin-
istrations that used the same frequency spacing. Those data
were obtained for the majority of subjects and test sessions.
In addition, the potential influence of non-sensory bias on
the findings was examined through comparing the pitch esti-
mates obtained using the two different acoustic frequency
ranges to examine whether the pitch estimates were influ-
enced by the range of acoustic signals used during the test
procedure. Salience of the electrical pitch percept was
assessed by examination of variation in electrical pitch rating
as a function of electrode.

All stimuli were initially loudness-balanced using the
highest frequency pure tone acoustic stimulus as the reference
signal. The reference tone was set to a comfortable listening
level. Repeated pairs of stimuli were then presented sequen-
tially, and subjects were asked to adjust the loudness of the
second tone to match that of the first presented tone.
Adjustment was made using a toggle switch on a custom
interface box, with step size of 2 dB SPL or 2 Current Level
steps for the acoustic and electric stimuli, respectively.
During the loudness-balancing procedure, the starting level of the test
stimulus was randomly set to a loud or soft level at each of the
repeated balancing tasks to ensure accurate bracketing of
the equal loudness level. This repeated loudness balancing
was conducted until the level of the test stimulus was within
acceptance criteria (of 2 dB SPL or 2 Current Level steps) for
two repeated loudness balancing tasks for the acoustic and
electric stimuli, respectively.

Subsequently, the pitch of the loudness-balanced signals
was measured using a psycho-physical magnitude estimation
procedure. The reference tone was the highest frequency pure-tone stimulus,
and subjects were asked to assign the numerical value of 50 to
that tone. The purpose of the reference tone was to reduce the
likelihood of subjects compressing responses at either end of
the scale. Subjects were advised that each subsequent stimulus
should be allocated a number and that the numerical value
assigned to describe the pitch of the stimulus should be rela-
tive to the reference signal. For example, a stimulus with a
pitch deemed twice as high as the reference signal would be
allocated a number that was twice as high as the reference,
i.e., 100 as compared to 50. A stimulus with a pitch perceived
as half that of the reference would be allocated 25 and so on.
Subjects were encouraged to use a wide number range if
appropriate and advised not to limit estimates at the upper end
based on an arbitrary range; i.e., not to limit the estimates to
100 unless this provided a true indication of the pitch of the
stimulus. The full set of ten stimuli was presented sequentially
two to three times prior to commencement of the pitch estima-
tion task to enable familiarization with the range of sounds to
be included in the pitch estimation procedure. During the
pitch estimation task, a single-interval procedure was used
with each stimulus presented ten times in random order. To
reduce any influence of residual loudness differences on the
pitch estimations, random level variations of ±2 dB were
applied to the acoustic signals and ±2 Current Levels to the
electrical signals.

For each subject at each of the evaluation time points
there were three to four repeat procedures conducted. Up to
two repeat measurements were obtained for each of two dif-
ferent stimulus ranges. Pitch estimates obtained from repeat
measurements of the same stimulus range were averaged
using geometric means. Where two different acoustic fre-
cency ranges were used, the final electrical pitch value used
for subsequent data analysis was the geometric mean obtained
across the entire data set. Post-operative x-rays were obtained
for each subject using a modification of the technique
described by Tykocinski et al. (2000), and insertion depth
angle estimates were calculated. Acoustic frequency corre-
lates to insertion angle for the most apical electrodes were cal-
culated using data provided by Stukovskaya et al. (2007).

The magnitude estimation procedure was selected over
a pitch matching approach for a number of reasons. First,
this technique was likely less prone to bias for the objectives
of the current study where it was of interest to examine pitch
changes across multiple electrode positions. With use of a
direct pitch matching procedure, where subjects compare the
electric stimulus with an adjustable acoustic stimulus, it is
likely that an acoustic frequency would be deemed to match
regardless of whether there was a true pitch match. In the
example provided in Fig. 1, it would have been expected that
direct pitch matching would have been possible for electro-
des 22, 19, and 16 because there is a corresponding acoustic
pitch estimate within the range used for those electric stim-
uli. However, for the more basal electrodes (13 and 10), a
pitch match would not have been accurately obtained using a
direct matching technique because the pitch estimates on
those electrodes were greater than those obtained with the
highest frequency acoustic stimulus that could be made com-
fortably loud. Second, magnitude estimation provides the
ability to obtain all pitch estimates at one time rather than
obtaining each comparison in sequence. Finally, it is practi-
cially impossible to fix the acoustic stimulus and ask the sub-
ject to vary the electrode position, so it is not possible to
reduce the bias associated with the adjustment of only one
parameter while the other one is fixed. This problem does
not occur with use of the magnitude estimation procedure.

Mean pitch estimates for the five acoustic and five elec-
tric stimuli were calculated and plotted as points on a scatter-
plot with frequency or electrode on the x axis and pitch
estimates on the y-axis for the acoustic and electrical stim-
uli, respectively. Data relating to two aspects of electrical
pitch perception were obtained; (1) the electrical pitch percept
obtained on the most apical electrode and (2) the ratio in
slope between the electrical pitch function and that of the
spiral ganglion map. Both aspects of pitch perception were
included in the analysis to provide an understanding of the
impact of the examined factors on the degree of match both
at a fixed and variable electrode location within the cochlea.
Understanding how pitch changes as a function of place in
both a relative and absolute sense was also of interest in con-
sidering potential clinical application of the study findings.
For calculation of the electrical pitch percept obtained on the most apical electrode a linear regression line was fitted to the acoustic pitch measures, and the pitch estimate from the most apical electrode (electrode 22) was obtained by reading from the acoustic regression line. An example of the data obtained from a single experimental run is shown in Fig. 1. In this example, the acoustic pitch that corresponded to that obtained on the most-apical electrode was 481 Hz. For simplicity in describing the findings of the current study, use of the term “pitch” (when referring to the electrical pitch estimate) throughout the paper will describe the frequency that was matched in pitch to the acoustic tone.

In calculation of the ratio in slope between the measured electrical pitch function and that predicted by the spiral ganglion map a linear regression line was first fitted to both the electric and acoustic data. For all electrodes with a pitch estimate that corresponded to the pitch range using pure tones (i.e., in the area of overlap between the acoustic and electric data), the corresponding acoustic frequency was obtained. In Fig. 2 are plotted data to provide an example of the procedure used for calculation of the slope of the electrical and spiral ganglion pitch function. The graph indicates the acoustic frequency corresponding to insertion angle. The solid gray line indicates the mean frequency according to Kamara et al. (1996) for insertion angle. The black squares indicate the frequency corresponding to electrical stimulation on electrodes 22 and 19 for subject S21 to demonstrate the procedure used. In this example, the predicted frequency based on the spiral ganglion map was 785 and 1420 Hz for electrodes 22 and 19, respectively, and those points are visible on the figure along the spiral ganglion frequency-place function as open triangle symbols. For this subject, the acoustic frequency corresponding to the pitch estimate on electrodes 22 and 19 was 725 and 1053 Hz, respectively. The slope of each of the predicted and measured functions was calculated, and the relative slope of the measured and predicted spiral ganglion cell frequency function was expressed in Hertz per degree. For the selected example, the ratio between the measured slope and the spiral ganglion map slope was 0.52.

A number of variables were investigated as potential correlates with the two aspects of electrical pitch perception: (1) the electrical pitch percept obtained on the most apical electrode and (2) the slope in the electrical pitch function. Examined variables were pre-operative hearing levels and duration of severe-to-profound hearing impairment in both the implanted and contralateral ear.

III. RESULTS

A. Validity of pitch estimation methodology

1. Test-retest reliability

Test-retest reliability measures were obtained through repeat administration of the pitch estimation task for the same acoustic and electric frequency range with the same...
subject. The acoustic frequency corresponding to stimulation on the most apical channel was determined for each of the experimental runs. Data were collected for 112 test-retest pairs with repeat testing conducted with all subjects enrolled in the study at a minimum of one of the post-operative time points evaluated. In the left panel of Fig. 3(a) is shown a correlation plot of the log of first and second acoustic frequency calculated across experimental runs. Pearson product moment correlation coefficients were computed between first and second administration of the pitch estimation task and revealed a highly significant correlation ($r = 0.9, p < 0.001$).

2. Assessment for non-sensory bias

To determine whether the pitch estimates were likely to have been affected by non-sensory bias (Carlyon et al., 2010), i.e., whether subjects were influenced by the ranges or midpoints of the selected acoustic signals, the relationship between the pitch estimates between two different frequency ranges was analyzed. It would be expected that the presence of non-sensory bias would have resulted in the pitch estimate for the higher midpoint having a higher pitch percept than that obtained for the lower midpoint. Analysis using a paired t-test indicated no significant difference between the pitch estimates obtained using the different frequency ranges ($t(54) = -0.456, p = 0.7$). Mean estimates for the range with the lower and higher midpoints were 494 and 502 Hz, respectively. The 95% two-tailed confidence interval for the difference of means included zero (−44.5 to 27.9), suggesting no evidence of influence of non-sensory bias, related to acoustic frequency range, on the pitch estimation data collected.

3. Salience of electrical pitch percept

To investigate the salience of the electrical pitch percept, mean pitch ratings across electrodes (and across multiple time points) were calculated for each individual subject. Electrode measurement refers to the electrode numbers from the apical to basal location and constituted one of two electrode combinations: ‘E’ in ‘Electrodes’ 22, 20, 18, 16, and 14, or electrodes 22, 19, 16, 13, and 10. Analysis of group data using Friedman repeated-measures analysis on ranks revealed a significant difference of electrode on electrical pitch estimates [Chi-square(4) = 96.064, $p < 0.001$]. As expected, median pitch estimates were higher for electrodes positioned more basal in the cochlea. Data are shown in the right panel of Fig. 3(b).

B. Pre-experience pitch comparison to spiral ganglion frequency-position function

In the left panel of Fig. 4 is shown the acoustic frequency that corresponds to the pitch percept obtained when stimulating on the most apical electrode, plotted as a function of insertion angle of that electrode. The solid gray line indicates the mean frequency according to Stakheuskaya et al. (2007) and the dashed lines the upper and lower range of the spiral ganglion frequency-position function. The dotted gray line indicates the Greenwood function of organ of Corti characteristic frequency.
Corti characteristic frequency as adapted by Kawano et al. (1996) for insertion angle. The right panel shows the pitch across multiple electrodes and so provides a visualization of the slope of the electrical pitch function for individual subjects, across the range of frequencies at which the slope could be obtained, i.e., where there was sufficient overlap between multiple electrodes with the acoustic frequency range. Apical electrode pitch estimates were within or above the spiral ganglion model range in only 28% of subjects. Slope of the electrical pitch function was lower than that for the spiral ganglion model for all except one subject.

C. Examination of variables as correlates with pre-experience degree of pitch match to spiral ganglion frequency on apical electrode

Pearson product moment correlation coefficients were calculated for each of the variables examined as potential correlates with the degree of match between measured and predicted frequency. Variables examined were (1) the pre-operative implanted ear unaided audiometric hearing threshold at the frequency corresponding to the spiral ganglion mean frequency for insertion angle of the most apical electrode, (2) the pre-operative contralateral unaided audiometric hearing threshold at the frequency corresponding to the spiral ganglion mean frequency for insertion angle of the most apical electrode, (3) the duration of severe-to-profound hearing loss in the implanted ear, and (4) the duration of severe-to-profound hearing loss in the contralateral ear.

1. Pre-operative hearing thresholds in implanted ear

In Fig. 5 is shown the ratio between the measured and predicted pitch elicited at the most apical electrode, plotted against the pre-operative unaided acoustic hearing level in the implanted ear. On the x axis is shown the pre-operative unaided hearing threshold [in dB hearing level (HL)] that was obtained at the corresponding frequency in the cochlea, based on insertion angle using Stakhovskaya et al. (2007) at which the apical electrode was located. On the y axis is shown the ratio between measured and predicted pitch percept obtained prior to listening experience with the cochlear implant. An exact match between the measured and predicted pitch would be indicated as a ratio of 1. Results from two correlation analyses are shown. The solid line indicates the fit to the entire dataset, and the dotted line for an analysis conducted with exclusion of those subjects for whom no audiometric response (shown as 130 dB HL) was measurable.

Pearson product moment correlation analysis for the entire set of data revealed a significant correlation between the pre-operative acoustic hearing threshold and the degree of pitch match \( r = -0.445, p = 0.026 \). Subjects with poorer acoustic hearing (shown as a higher unaided threshold value) tended to show a lower than predicted pitch percept. However, the significant relationship between the examined variables was not observed with exclusion of the subject with the best unaided hearing threshold (of 35 dB HL) and the ratio of 2.48 between measured and predicted pitch. Analysis of the data with exclusion of the 130 dB HL values improved the degree of observed correlation \( r = -0.642, p = 0.003 \). As for the case for the entire dataset, the removal of the data point for the subject with the best unaided hearing threshold removed the significant correlation observed.

2. Pre-operative hearing thresholds in contralateral ear

Pearson product moment correlation analysis revealed no significant correlation between the pre-operative acoustic hearing threshold in the contralateral ear and the degree of pitch match from that predicted by the spiral ganglion frequency-position model \( r = -0.206, p = 0.324 \).

3. Duration of severe-to-profound hearing impairment

Pearson product moment correlation analysis revealed no significant correlation between the duration of severe-to-profound hearing impairment in the implanted ear and the degree of match between measured and predicted pitch \( r = -0.327, p = 0.111 \). A similar finding of non-significance was observed for duration of hearing impairment in the contralateral ear and the degree of pitch match \( r = -0.207, p = 0.32 \).

D. Examination of variables as correlates with pre-experience degree of electrical pitch match in slope to the spiral ganglion frequency slope

1. Pre-operative hearing thresholds in implanted ear

On the y axis of Fig. 6 is shown the ratio between the measured slope in pitch across multiple electrodes and the slope of the spiral ganglion frequency function ("slope-match"). This figure differs from Fig. 5 in that the degree of match in slope to the spiral ganglion function has been calculated rather than the degree of match on the single apical
2. Pre-operative hearing thresholds in contralateral ear

No correlation was observed between the slope match and the degree of low-frequency (0.25–1 kHz) hearing in the contralateral ear.

3. Duration of severe-to-profound hearing impairment

No correlation was observed between the degree of slope match and the duration of severe-to-profound hearing impairment in either ear. When examining this effect with use of median high-frequency unaided hearing thresholds in the contralateral ear (from 1 to 4 kHz), there was again no significant slope match.

E. Effect of listening experience on electrical pitch

1. Pitch percept on most apical electrode

In the left panel of Fig. 7 is shown the acoustic pure-tone frequency that corresponds to the pitch percept obtained when stimulating on the most apical electrode (on the y axis) plotted as a function of insertion angle of that electrode. Pitch estimation data are shown for each subject at two different time points; those obtained just prior to initial activation are indicated by open circles, and those at the 12-month post-activation time point are indicated by black filled triangles. The solid line shows the spiral ganglion mean characteristic frequency corresponding to the insertion angle, and the lower and upper dashed lines indicate the approximate range of associated characteristic frequencies [as reported by Stakhovskaya et al. (2007)]. In the right panel of the figure is shown the group median acoustic frequency corresponding to stimulation on the most apical electrode at each of the time points.

Analysis using the Wilcoxon signed rank test revealed no significant group median difference between the pitch estimates obtained at the initial and 12-month time points.
Individual subject data showing the effect of listening experience are plotted in Fig. 8. Plotted for each individual is the degree of offset between the electrical pitch percept on the most apical electrode and the center point of the input frequency range assigned to that channel (on the y axis) across the different time points (on the x axis). Default frequency allocation on electrode 22 for subjects 1–24 was from 188 to 313 Hz, whereas for subject 25 the allocated frequency range was 813 to 938 Hz due to use of the Hybrid-L24 electrode and the non-overlapping acoustic and electrical stimulation. Filter frequency bandwidth used in the sound processor is 125 Hz in the linear range of the frequency allocation table (PAT) below approximately 1 kHz. As a result, an offset of “1” for subjects 1–24 indicates that the pitch percept was within the range of the adjacent frequency band (upper and lower boundaries of 314 and 438 Hz, respectively), and “−1” indicates a pitch percept within the range 63–187 Hz. For those subjects with an offset of “2” the pitch estimate was between 439 and 563 Hz. The dotted lines signify the −1 to +1 range, i.e., the range in which the pitch estimate would fall within the allocated frequency range. The dashed line signifies the reference point of zero.

Pitch estimates for S1–S13 largely fell within the allocated filter boundaries at the time point just prior to initial activation, and remain relatively stable over the course of the study. S14 showed an initial electrical pitch within the filter boundary, but this increased progressively to the 6-month assessment point and then showed a reduction toward the allocated boundary after 12 months of experience. Five subjects (S15, S16, S18, S20, and S25) obtained an initial high pitch percept which then decreased over time to within or near the allocated frequency range. The remaining six subjects showed an initial high pitch percept that remained high after experience. These were S17, S19, S21, S22, S23, and S24. Three of those subjects (S21, S23, and S24) were assessed after 2 years of experience, and the electrical pitch estimate was shown to have remained high at that time.

2. **Slope of electrical pitch function relative to frequency allocation table**

Slope in the electrical pitch function was shallower than the slope used for frequency allocation to electrodes used in the sound processor program. Analysis using the Wilcoxon signed rank test revealed no significant group median difference between the electrical slope values at each time point. Median slope was 0.37 and 0.46 for the initial and 3-month time points, respectively (Z = 0.847, p = 0.40). Median slope was 0.42 and 0.55 for the 6-month time points, respectively (Z = −0.20, p = 0.82). At the initial and 12-month time points, the median electrical slope was 0.37 and 0.40, respectively (Z = −0.622, p = 0.82). A high degree of individual variability was observed. Subjects S5, S7, and S19 showed an initial shallow slope which adapted over time to more closely match the allocated frequency range. Subjects S17 and S24 showed initial match to allocated slope at the time prior to experience, and this reduced over time. Most subjects showed little change in slope over time.
IV. DISCUSSION

Consistent with the majority of previous studies, initial pitch estimates obtained within the current study were lower than would be predicted by the spiral ganglion frequency-position map or from Greenwood’s function (Greenwood, 1990; Kawano et al., 1996). Only 28% of initial pitch estimates on the most apical electrode were within or above the range predicted by Stakhovskaya et al. (2007). The slope of the electrical pitch function was shallower than that predicted by Stakhovskaya, consistent with prior studies by Blamey et al. (1996), Baumann and Nobbe (2006), and Boix et al. (2006). The initial slope in electrical pitch in the current study (prior to listening experience with the cochlear implant) was 0.37 of the slope of the spiral ganglion frequency-position function.

A. Influence of pre-operative implanted ear hearing thresholds on pitch estimates

The finding that subjects with better pre-operative unaided acoustic thresholds in the implanted ear had a closer match to the predicted pitch, both for the most apical electrode and for the slope of the electrical pitch function, is consistent with the hypothesis proposed by McDermott et al. (2009) that a contributor to the lower than predicted pitch percept may have poor neural survival within the stimulated region of the cochlea. However, it is important to consider that the significant correlations observed between the variables for the apical electrode were not robust because this was affected by removal of the apparent outlier from the data. Including more subjects with better hearing thresholds, as in the case of the subject removed from the dataset, would be important to examine further the data collected for the apical electrode. A stronger correlation was observed between the pre-operative threshold and the degree of slope match as compared to the single apical electrode measure. Such data describing the effect of implanted ear thresholds on the degree of pitch match are not available from the majority of prior publications because the focus has been on reporting the degree of hearing in the ear contralateral to that implanted, i.e., that which was typically used as the reference acoustic test condition. Only the publication by McDermott et al. (2009) reported inclusion of two subjects with hearing in the implanted ear because the hearing was maintained post-operatively and used as the acoustic reference. Given that there is evidence that unaided audiometric threshold measures are not particularly sensitive to detecting loss of cochlear afferent synapses and cochlear nerve degeneration (Kujawa and Liberman, 2009; Lopez-Poveda and Barrantes, 2013), it is possible that use of different measures may have resulted in a closer match in electrical pitch percept to that predicted by the spiral ganglion model.

B. Influence of contralateral hearing thresholds on pitch estimates

Contrary to the findings of Vermeire et al. (2008) and Carlyon et al. (2010), the subjects with normal or near normal hearing in the ear contralateral to the implant did not necessarily show a close match in the electrical pitch percept to the spiral ganglion function. Although the three subjects with normal hearing across the frequency range did show close match to the predicted function, another subject with only a mild hearing impairment in both the low- and high-frequency region experienced an initial low-frequency percept. Three additional subjects with mild hearing impairment in the cochlear frequency corresponding to the apical electrode location showed varied pitch estimates. There was no significant correlation between the degree of hearing impairment in the contralateral ear and the degree of initial pitch match in the current study.

C. Influence of duration severe-profound hearing loss on pitch estimates

Another clinical indicator of neural survival may be the duration of hearing impairment, either through the effect of peripheral function or to the potential for cortical reorganization in response to auditory deprivation. Although no significant effect of duration of severe-profound hearing impairment on the degree of initial pitch match was observed in the subject group examined within the current study, it is possible that this may have been affected by the reliance on subject-reported audiological history for collection of the information. Assessment of duration of hearing impairment is often difficult in the clinical setting because the majority of subjects do not have prior audiograms available for reference, and it is often difficult to obtain frequency specific and ear specific information. Further investigation as to the potential relationship between duration of hearing loss and initial pitch estimates may be warranted in a larger number of subjects in which the variability associated with potential for inaccurate hearing history information would be reduced.

There is no evidence in the current study of high-frequency hearing loss affecting the electrical pitch percept. It would be hypothesized that auditory cortex reorganization that occurs in response to high-frequency hearing loss might result in lower than predicted pitch perception in the basal region of the cochlea (Irvine et al., 2003; Fallon et al., 2009). No correlation was observed between the degree of high-frequency hearing in the better hearing, contralateral ear, and the degree of match in apical electrode pitch or slope of the electrical pitch function to that predicted by the models.

D. Effect of listening experience on pitch estimates relative to assigned frequencies

The absence of clear evidence of longitudinal change in the group mean pitch estimates in this study is consistent with the study findings by Carlyon et al. (2010) where it was suggested that the degree of match between acoustic and electric pitch was not affected by experience in the small group of subjects evaluated. The current study findings do not support the hypothesis that listening experience explains the lower than predicted electrical pitch percept that has been observed in some prior studies, including that by McDermott et al. (2009), in which electrical pitch estimates
were lower for a group of subjects post-experience as compared to a separate group assessed prior to device activation.

Similar to the results of Reiss et al. (2007) and Reiss et al. (2014), the longitudinal pitch estimates from the current study showed a degree of variability. Eighty subjects showed a post-experience reduction in pitch percept on the most apical electrode, eight showed a slight increase, and nine subjects showed no change in pitch percept between the pre- and post-experience time points. For subjects with an initial apical electrode pitch percept that was close to the input frequency allocation to that electrode in the sound processor (typically ranging from 188 to 313 Hz), there appeared to be little or no change in the pitch percept associated with listening experience. For subjects with an initial pitch percept that fell within one filter boundary of the allocation to electrode, i.e., less than the lower filter cut-off of 188 Hz, or between 313 and 563 Hz, the pitch percept tended to increase slightly, or remain unchanged, between the pre-activation and 12 months post-experience time points. Seven of nine subjects with a pitch percept that fell within two to three filter boundaries higher than the frequency allocation showed a reduction in the pitch percept with experience. All subjects with a pitch higher than an offset of three filter boundaries did not show a substantial change in pitch over time. This finding cannot be understood in terms of the predictive factors examined within the study. The lack of adaptation for subjects with a high initial pitch percept is consistent with that reported by Reiss et al. (2014), where 3 of 11 subjects experienced a high pitch percept that did not adapt over time. Although the findings for two of those subjects may be explained by the lack of interaction between electric and the contralateral acoustic hearing, the lack of adaptation for the third subject was unexplained.

It may be hypothesized that a longer time of device experience may be required for change in electric pitch percept, i.e., longer than the 12 month period of evaluation assessed within the study. Reiss et al. (2007) reported individual variability across all subjects tested; however, they suggested that those subjects tested over a time scale of less than 1 yr showed more variable changes in pitch than those assessed with up to 60 months of experience post-activation. Ongoing assessment of electrical pitch over time with the current subject group would be beneficial in monitoring whether change occurs after more extended listening experience with the cochlear implant. However, testing of these subjects at 2 yr post-activation showed sustained high pitch percepts, so listening experience may not account for this effect. Of the three subjects with very high pitch percepts at the 12-month evaluation point, two subjects (523 and 524) were within the group assessed at 2 yr post-implantation.

Even if more time would be required for adaptation of the electrical pitch percept to the allocated acoustic frequency range, the inability of some subjects to adapt over a 12 month period suggests that optimization of the sound processor parameters may be beneficial. Adjustment of the frequency allocation to electrodes may result in improvement in measures of clinical performance, such as speech perception and subjective ratings of sound quality. Investigation of potential correlation between the measures of electric pitch perception and aspects of clinical performance may provide important information regarding the potential application of optimizing the sound processor program to best match the acoustic hearing in the contralateral ear.

V. CONCLUSIONS

Closer match in electrical pitch to the spiral ganglion frequency-position function was observed for subjects with better pre-operative unaided hearing thresholds in the ear to be implanted, both for the measures obtained on the apical electrode and for the slope of the electrical pitch function. However, the correlation data for the apical electrode were not robust because it was affected by removal of the subject with best low-frequency hearing. Contralateral acoustic hearing measures, and duration of severe-profound hearing impairment in the contralateral or implanted ear, were not correlated with the degree of initial pitch match. No adaptation of the electrical pitch percepts over time was observed for this group of subjects although there was evidence of adaptation for some subjects.

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